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IMPACT OF PERIOPERATIVE TEMPERATURE ON POSTOPERATIVE
SURGICAL SITE INFECTIONS: IMPROVING THE PREDICTABILITY OF
STANDARD RISK INDICES

by

Hanako Misao, RN, NM, PHN, MS

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

Nursing

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

William F. Atchison

Date

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**Impact of perioperative temperature on postoperative surgical site infections:
Improving the predictability of standard risk indices**

Hanako Misao

University of California, San Francisco, 2002

This retrospective cohort study was designed to examine the impact of perioperative temperature on prediction of postoperative surgical site infections (SSIs) among patients who underwent general abdominal surgery at San Francisco General Hospital. The current extant risk indices, Study on the Efficacy of Nosocomial Infection Control (SENIC) and National Nosocomial Infection Surveillance (NNIS) risk indices, and a modified risk index, in which a factor related to perioperative temperature was added to the extant risk indices, were compared in terms of predictability of SSIs.

Two hundred and thirty patients were followed by a total medical chart review within 30 days after surgery. SSIs were identified using the definitions of the Centers for Disease Control and Prevention. Of the final sample of 230 surgical patients, nearly 54% were trauma patients, yielding a cumulative SSI incidence of 22.6% for this high-risk group. Intraoperative core temperatures were measured at the following points: initial and final core temperatures, the lowest core temperature, and the minutes of the core temperature less than 35°C. Unlike the findings of previous studies, none of these perioperative temperature measurements were statistically significant at a p-value of less than 0.05. However, there were statistically significant differences between patients with and without SSIs in the change between the initial and final core temperatures ($p = .001$) as well as the change between the initial and lowest core temperatures ($p = .031$). Both the SENIC ($p < .01$) and NNIS ($p < .01$) risk indices were good predictors for postoperative SSIs. Logistic regression analysis showed that the change between the initial and final core temperatures, controlling for the influence

of the perioperative factors included each risk index, was an important predictor of SSIs: AOR = 2.923 for temperature change when added to SENIC factors; AOR = 2.101 for temperature change when added to NNIS factors.

The addition of temperature change during surgery to the extant risk indices for SSIs both improves the ability to predict this serious adverse event and provides nurses and other healthcare workers with a potentially modifiable factor to reduce risk.

Mary C. White

Mary C. White, RN, PhD, FAAN

Chairperson

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CHAPTER I

INTRODUCTION

Nosocomial infections, hospital-acquired infections, or recently called health-care related infections are estimated to involve more than 2 million patients annually in acute care facilities alone in the United States (Centers for Disease Control and Prevention [CDC], 1992). If other settings such as long-term care facilities or nursing homes were also considered, the total number of nosocomial and other institutional infections would exceed 4 million per year (Martone, Jarvis, Culver, & Haley, 1998). Furthermore, nosocomial infections directly cause at least 19,000 deaths nationwide per year and cost more than \$4.5 billion (Martone et al., 1998).

A surgical site infection (SSI), a complication that occurs when surgical wounds heal abnormally, is one of the most common and serious complications in patients who undergo surgery. Since the recognition of the role of bacteria in SSIs and the first advent of antisepsis and asepsis, effective strategies to reduce SSIs has progressed. Development of disinfection and sterilization, advanced techniques for skin preparations at the operative site, introduction of rubber gloves and ventilation system, and use of prophylactic antibiotics have significantly contributed to a reduction of the SSI rates. However, none of them brought us the conquest of the battle between bacteria and surgical patients.

Based on the National Nosocomial Infection Surveillance (NNIS) system, which was established in 1970 by CDC, it is estimated that SSIs develop in 2-5% of more than 46 million surgical procedures performed annually in the United States (Owings & Kozak, 1998; Wong, 1996). Also, SSIs comprise from 14% to 16% of all nosocomial infections, and are consistently ranked as either the second or third most common hospital-acquired infection (CDC, 1991; Emori, 1998; Emori & Gaynes, 1993; Haley, Culver, White, Morgan, & Emori, 1985) following urinary tract infections and/or blood

stream infections.

Despite the high quality and management of surgical operations, equipment, and postoperative patient care, among surgical patients, SSIs still continue to be a major source of morbidity and increased medical expense. The extra days of hospitalization has been estimated between 6.5 days and 20.75 days (Asensio & Torres, 1999; Kirkland, Briggs, Trivette, Wilkinson, & Sexton, 1999; Zoutman, McDonald, & Vethanayagan, 1998). Moreover, SSIs lead to direct medical costs estimated between \$868 and \$100,666 per occurrence (Calderone, Garland, Capen, & Oster, 1996; Haley, Schaberg, Von Allmen & McGowan, 1980; Kirkland et al. ; Zoutman et al.) and from \$1 to \$10 billion annually on a national basis including indirect costs (Sands, Vineyard, Livingston, Christiansen, & Platt, 1999). Although compared to the estimated mortalities related to nosocomial blood stream infections and pneumonia, the mortality rate of SSIs is low (Jarvis, 1996), the excess cost attributable to SSIs is the highest or the second highest among the common nosocomial infections (Gaynes 1998; Jarvis, 1996; Vegas, Jordan, & Garcia, 1993). After the prospective payment system (PPS) was introduced in the United States in 1985, hospitals are paid a fixed amount for each admission based on the patient's diagnosis-related group (DRG). Therefore, little additional reimbursement is provided for comorbid conditions, such as nosocomial infections (Haley, 1991a; Haley, White, Culver, & Hughes, 1987). SSIs have now become the major cause of considerable economic burden to hospitals in the United States.

In addition, current cost containment efforts by most hospitals in the United States have resulted in the reduction of nursing staff and infection control personnel (Jarvis, 1996). Several epidemiological studies identified that the relationships between understaffing or overcrowding in the units and transmission of nosocomial infections (Haley & Bregman, 1982; Haley et al., 1995; Harbath, Sudre, Dharan, Cadenas, & Pittet, 1999; Vicca, 1999). Saulnier et al. (2001) identified a reverse relationship, that is, excess nurse work load resulted from nosocomial infections due to multiresistant bacteria.

There is no available evidence of a relationship between understaffing and postoperative SSIs. However, it is easy to imagine that there is an undesirable circle among cost containment efforts by hospitals, the reduction of nursing and infection control personnel, and the occurrence of SSIs. To assure the better quality of care as well as the better patient's quality of life, we should interrupt this relationship, but how? As Calderone et al. (1996) pointed out, prevention of postoperative SSIs is the first line of defense in health care cost reduction. A reduction of the SSI rate to a minimum level could introduce marked benefits (Saywer & Pruett, 1994). This dissertation tries to propose one way to interrupt this undesirable circle, that is to give some answers to the following questions: Who is more likely to develop subsequent SSIs? How can we predict the more precisely the likelihood or the probability of the occurrence of a SSI in each surgical patient?

Purpose of the Study

The purpose of this dissertation research is to examine the impact of perioperative temperature on prediction of postoperative SSIs among general abdominal surgical patients at the regional trauma center. Perioperative temperature is used as an objective marker of patient's intrinsic risks of SSIs, and its effect or the joint effect with other markers on SSIs is measured. To examine the impact of perioperative temperature on prediction of SSIs, the current extant risk indices (Study on the Efficacy of Nosocomial Infection Control [SENIC] and NNIS) and a modified risk index, in which a factor related to perioperative temperature is added to the extant risk indices, are compared in terms of the predictability of SSIs.

Much of the extant research articles on SSIs have relied on traditional in-hospital SSI surveillance to capture the occurrence of SSIs. Due to the limitation of traditional in-hospital SSI surveillance, readmission, emergency room visits, and local clinic visits as well as antibiotics exposure within 30 days after surgery have also been

used as additional markers of the occurrence of SSIs in this study.

Significance of the Study

Routine in-hospital surveillance for SSIs has been recognized as a fundamental strategy for reducing the SSI rate, including feedback to surgeons on these SSI rates (Condon, Schulte, Malangoni, & Anderson-Teschendorf, 1983; Haley, Culver, White, Morgan, Emori, & Munn, 1985; Mead et al., 1986). However, the shorter length of hospitalization might be one of the major obstacles for accurate traditional in-hospital SSI surveillance data (Gaynes, 2001). The introduction of the PPS system in the United States resulted in decreasing hospital lengths of stay and increasing use of ambulatory surgery. It has led the increase in the percentage of postoperative SSIs that occur after patient's discharge from the hospital.

Considering that there are no accurate and efficient methods for outpatient SSI surveillance, some researchers have examined several variables, such as readmission (Kirkland et al., 1999) and utility of postoperative antibiotics (Yokoe, Shapiro, Simchen, & Richard, 1998) as indicators of SSIs in order to capture all occurrences of SSIs in-hospital as well as after patient's discharge from hospital. However, it is clear that post-discharge surveillance is resource- and work-intensive in order to get accurate data of SSIs among all surgical patients (Sands, Vineyard, & Platt, 1996). Therefore, it is urgent and necessary to develop a risk index for SSIs which can better quantify each patient's risk or probability for the occurrence of SSIs at the end of operation. This index can be used as an efficient screening tool for subsequent management or surveillance for high-risk or target populations for post-discharge follow-up.

Considerable epidemiological evidence is available to predict the occurrence of SSIs. This likelihood can be explained by complex interactions related to the patient's susceptibility to infection, environmental factors, and microorganism factors. Although various risk factors influence the incidence of SSIs, there are a few available research

results which examined this relationship among patients who underwent high-risk surgeries including trauma patients.

In this dissertation project, the impact of perioperative temperature (hypothermia) is examined with other several objective markers of the patient's susceptibility to SSIs. Due to the advanced, more complicated, and more invasive treatments, hospitalized surgical patients tend to have higher intrinsic risks. However, there are not enough studies that examined objective measurements as markers of a patient's intrinsic risks for SSIs. Also, to examine perioperative temperature or in combination with other markers would be a significant contribution to the controversy of the impact of hypothermia on the occurrence of SSIs. Many researchers examined the biological or physiological mechanisms between hypothermia and SSIs (Beilin et al., 1998; Forstot, 1995; Frank et al., 1992, 1997; Jonsson, Hunt, & Mathes, 1988; Hopf et al., 1997; Sessler, 1993), and found that perioperative unintentional hypothermia (approximately 2°C below the normal core body temperature) increases the patient's susceptibility to SSIs and risks for impaired wound healing by causing a decrease of oxygen in the susceptible tissues and impairment of immune function. However, due to limited evidence of the relationship between hypothermia and the occurrence of SSIs, hypothermia is the most controversial risk factor for SSIs (Barone, et al., 1999; Kurz, Sessler, Lenhardt, & The study of wound infection and temperature group, 1996). As Mortensen and Garrard (1996) pointed out, more studies on this subject are needed. Therefore, this dissertation can add data or information to the body of knowledge about this controversy.

Definition of terms

Colonization the multiplication of a microorganism at a body site or sites without evidence of infection (Hierfolzer, 1996).

Contamination the transient presence of microorganisms on body surface without any tissue invasion or physiologic reaction (Brachaman, 1998).

National Nosocomial Infection Surveillance (NNIS) system a voluntary, hospital-based reporting system in order to monitor and report trends in hospital-acquired infection in acute care hospitals and to guide the prevention efforts of infection control practitioners in the United States, which was established in 1970 by the Centers for Disease Control and Prevention (CDC, 2000).

NNIS risk index the following three variables that were modified from the SENIC risk index: 1) an American Society of Anesthesiologists (ASA) physical status classification greater than 3; 2) an operation classified as either contaminated or dirty-infected in the wound classification system; and 3) an operation with surgery duration more than T hours, where T is the 75 th percentile of the distributions of duration of each operation being performed (Culver et al., 1991).

Nosocomial Infection any infection which develops within a hospital or are produced by microorganisms acquired during hospitalization (Brachman, 1998). Infections considered to be hospital-acquired if they develop at least 48 hours after hospital admission, and 3 days after hospital discharge or within 30 days after an operative procedure (Eggimann & Pittet, 2001).

Risk factors for SSI any biological, social, behavioral, and environmental characteristics that are associated with an increased probability of occurrence of SSIs. Intrinsic risk factors for SSIs are the patient's underlying probability of infection or underlying conditions that reflect a patient's susceptibility to infection before undergoing any surgical procedures. Environmental risk factors are all that is external to the individual host, and limited to factors related to preoperative preparation, operative procedure, surgical techniques, operating room and personnel, and treatments administered during operations.

Risk index a combination of important and independent risk factors for occurrence of SSIs, based on the idea of stratifying surgical patients into strata according to each patient's risk for SSIs.

SENIC risk index the following four variables which were analyzed in the Study on the Efficacy of Nosocomial Infection Control (SENIC) project using logistic regression method, and developed into a simple risk index for SSIs in 1974: 1) having an operation which involves the abdomen; 2) having an operation which lasts more than two hours; 3) having an operation which is classified as either contaminated or dirty-infected in the wound classification system; and 4) having three or more underlying diagnoses at the time of discharge after the operation (Haley, Culver, Morgan, White, Emori, & Hooton, 1985).

Surgical site infection (SSI) "The product of the entrance, growth, metabolic activities, and resultant pathophysiologic effects of microorganisms in the tissues of the surgical patients" (Committee on Control of Surgical Infections of the Committee on Pre and Postoperative Care of the American College of Surgeons, 1976). Clinically, a surgical site is considered infected if purulent material drains from the incision site, even

though positive microbiologic results could not be obtained (Garner 1986; Wong 1996). Due to the disadvantages of this clinical definition, positive microbiological results, signs and symptoms of SSIs, and the diagnosis of SSI by the surgeon or attending physician are also considered when SSIs are diagnosed or evaluated (Garner, Jarvis, Emori, Horan, & Hughes, 1988). SSIs are divided into three anatomically distinct categories: superficial incisional, deep incisional, and organ/space SSIs.

Surveillance a means of monitoring the phenomena of SSIs. Hierholzer (1996) has defined surveillance as follows: “the systematic collection, analysis, and interpretation of data on specific events (cf. SSIs) and diseases and the feedback of the findings to those contributing data or to other interested groups.”

CHAPTER II

THEORETICAL BACKGROUD AND REVIEW OF LITERATURE

This chapter presents a theoretical framework for explaining the relationship among risk factors for SSIs, and reviews relevant literature concerning surveillance, major risk factors, and risk indices for SSIs. Based on this foundational background, the research questions will be posed.

Theoretical Framework

A symptomatic SSI is an imbalance between the patient's resistance to infections and the actions of the microorganisms. This imbalance results from the following five factors: a) patient's susceptibility to infection, b) presence of microorganisms, c) dose of organisms delivered, d) infectivity of the organisms, and e) microorganism's virulence.

Figure 1 is an epidemiological model (Gordis, 1996) for developing SSIs depicting the complex interaction among the patient's susceptibility, factors related to surgical operations, and microorganisms. Factors related to operations influence the probability and circumstances in which microorganisms gain access to the surgical site, and decrease the patient's resistance to microorganisms delivered to the surgical site. Whether or not a symptomatic SSI develops depends on the patient's susceptibility. Susceptibility comprises the person's specific and nonspecific defense mechanisms against microorganisms. A function of the nonspecific immune system is resistance to organisms: Whether or not a wound develops infection rests almost solely on the ability of phagocytic cells to leave the bloodstream, migrate to the site of infection, and ingest and kill such organisms. Thus, the nonspecific immune system plays an important role in natural resistance to infection at the surgical site.

"Patient's susceptibility to infection" is influenced by a person's genotype (e.g.,

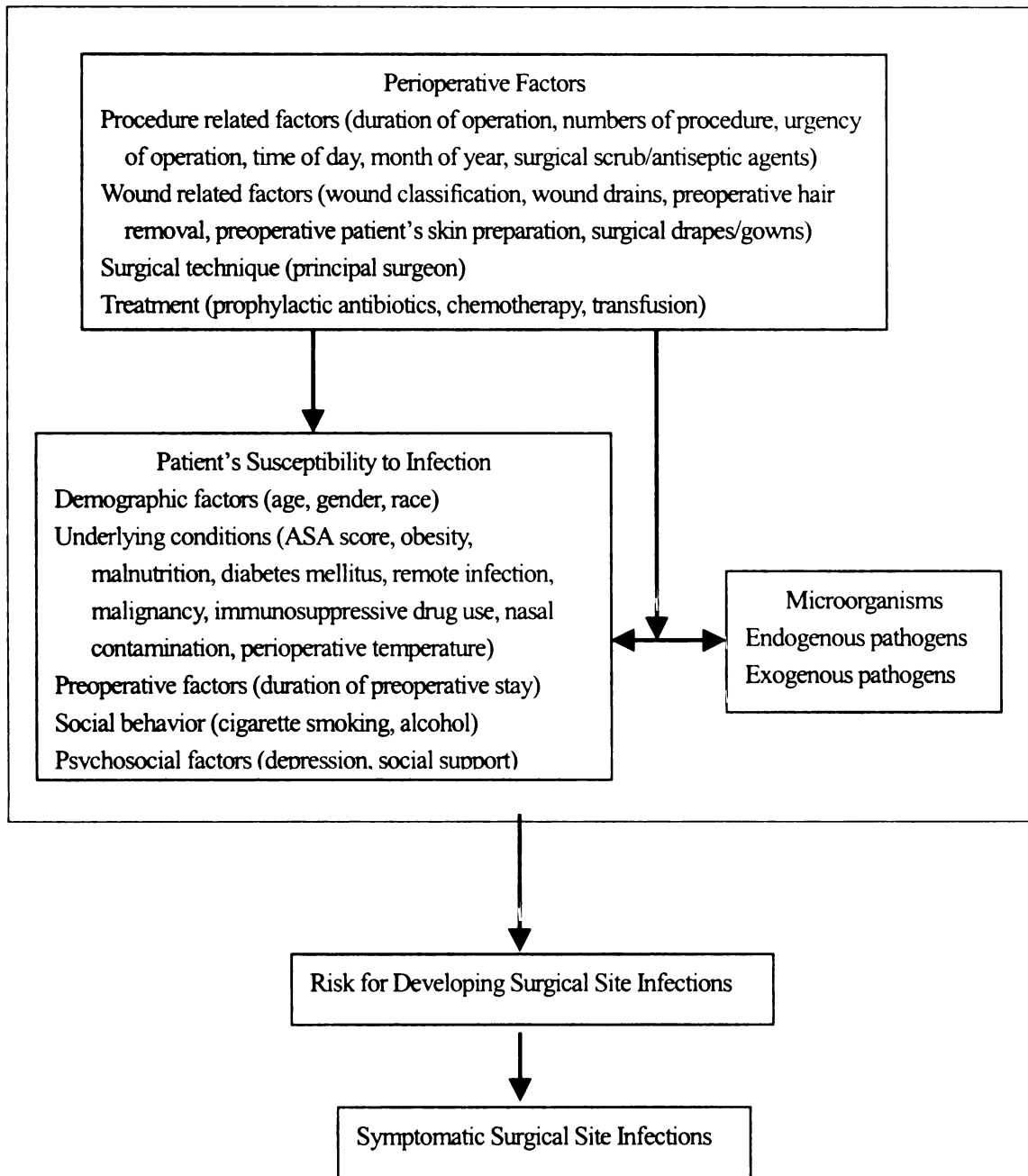


Figure 1. Epidemiological model for Surgical Site Infections.

demographic factors: age, gender, race), underlying conditions (e.g., the American Society of Anesthesiologists preoperative assessment score, malnutrition, obesity, diabetes mellitus, remote infection, malignancy, immunosuppressive drug use, nasal contamination, perioperative temperature), preoperative factors (e.g., duration of preoperative stay), social behavior (e.g., cigarette smoking, alcohol), and psychosocial factors (e.g., depression, social support). “Perioperative factors” are extrinsic factors that influence the likelihood of microorganisms reaching the surgical site, and consist of : 1) procedure related factors (e.g., duration of operation, numbers of procedures, urgency of operation, time of day, month of year, surgical scrub/ antiseptic agents); 2) wound related factors (e.g. wound classification system, wound drains, preoperative hair removal, preoperative patient’s skin preparation, surgical drapes/ gowns); 3) surgical technique (e.g., principle surgeon); and 4) treatment (e.g., prophylactic antibiotics, chemotherapy, transfusion). “Microorganisms” are endogenous pathogens and exogenous pathogens that cause SSIs. All characteristics or features related to the patient’s susceptibility to SSIs and perioperative factors are possible “risk factors for developing SSIs.” Epidemiological studies have shown that some are more strongly associated with an increased risk of the development of “symptomatic SSIs” than others. A symptomatic SSI is a clinical manifestation of localized signs and symptoms resulting from an infection.

Surveillance for Surgical Site Infections

Surveillance is a means of monitoring the phenomena of SSIs. The CDC (1988) has defined surveillance for nosocomial infections as follows: “the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know.” There are several purposes of conducting surveillance for nosocomial infections: 1) reducing

infection rates within a hospital, 2) establishing endemic baseline rates, 3) identifying outbreaks, 4) convincing medical personnel, 5) evaluating control measures, 6) satisfying regulators, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 7) defending malpractice claims, and 8) comparing infection rates between hospitals (Gaynes & Horan, 1996).

Historical Series of Surgical Site Infection Surveillance

Table 1 shows a historical series of epidemiological studies of SSIs. The collaborative study organized by the National Academy of Science, the National Research Council, and The Ad Hoc Committee on Trauma in 1964 may be historically the first systematic surveillance to identify SSI rates and factors contributing to the risk of SSIs (National Academy of Science, National Research Council, & Ad Hoc Committee on Trauma [NAS-NRC-AHCT], 1964). The NAS-NRC-AHCT study introduced a system for classifying surgical wounds or sites according to potential bacterial contamination, which is a wound classification system. This system ranks wounds as clean, clean-contaminated, contaminated, dirty, or multiple. The rationale for this classification is that the risk of developing a postoperative SSI is strongly affected by the degree of microbial contamination of the operative site at the end of the operation (Wong, 1996). This idea provided a basis for comparing the SSI rates among the various classifications and among different institutions. After the publication of the NAS-NRC-AHCT study results, the system of wound classification was modified and utilized in many epidemiological studies. Table 2 shows the modified form of the wound classification system. As Table 1 shows, there is a positive trend between the wound classification system and the subsequent postoperative SSI rates. Later studies have provided the evidence for intraoperative contamination and the increased risk for postoperative SSIs (Claesson, Filipsson, Holmlund, 1995; Claesson & Holmlund, 1988; Davidson, Clark, & Smith, 1971; Garibaldi et al., 1991).

Table 1
Historical Series of Epidemiological Studies of SSIs

	Years	# of wounds	# of infected wounds	Overall SSI rate (%)	Wound Classification ^a			
					C	C-CO	CO	D
National Academy of Science (1964)	1959 -1962	15,613	1,157	7.4	5.1	10.8	16.3	28.6
Edwards (1976)	1969 - 1972	40,923	1,966	4.8	^b	NA	6.0	10.1
Cruse & Foord (1980)	1967 - 1977	62,939	2,960	4.7	1.5	7.7	15.2	35.0
Haley et al. ^c (1985)	1975 - 1976	59,352		4.1	2.9	3.9	8.5	12.6
Olson & Lee (1990)	1977 - 1986	40,915	1,032	2.5	1.4	2.8	8.4	NA
Culver et al., (1991)	1987 - 1990	84,691	2,376	2.8	2.1	3.3	6.4	7.1

Note. ^a C: Clean, C-CO: Clean-contaminated, CO: Contaminated, D: Dirty and infected.

^b Refined clean (elective clean operations only) 4.2, Clean (other clean operations) 4.7.

^c From "Identifying patients at high risk of surgical wound infection" by Haley, Culver, Morgan, White, Emori, & Hooton, 1985, American Journal of Epidemiology, 121, 206-215.

Table 2

Modified Form of the Wound Classification System Introduced by NAS-NRC-AHCT Study (1964)

Class I /Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
Expected infection rate 1-5%.

Class II /Clean-Contaminated: An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
Expected infection rate 8-11%.

Class III/Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.
Expected infection rate 15-20%.

Class IV/Dirty-Infected: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.
Expected infection rate >25%, if skin is closed.

Note. From “CDC guideline for prevention of surgical wound infections, 1985: Supercedes guideline for prevention of surgical wound infections published in 1982” by J. S. Garner, 1986, Infection Control, 7, 195 and “APIC infection control and applied epidemiology: Principles and practice” by Association for Professionals in Infection Control and Epidemiology, 1996, Mosby.

The results of the SENIC project is the landmark project on surveillance for nosocomial infections in the United States, and showed that an adequately organized, routine, and hospital-wide surveillance program could be expected to reduce the overall nosocomial infection rates by 32% (Haley, Culver, White, Morgan, Emori, & Munn, 1985). The NNIS system is the only current source of national sentinel data on nosocomial infections in the United States. This system began in 1970 when selected hospitals in the United States started routinely reporting their nosocomial infection surveillance data to the CDC for aggregation into a national database (Gaynes & Horan, 1996). Three hundred and twelve hospitals have participated in this system as of February 2001 (Gerberding, 2001). All NNIS hospitals have greater than 100 beds and tend to be larger than other hospitals in the United States (median size: 360 beds in the NNIS hospitals versus 210 beds in US hospitals). The purpose of the NNIS system is to establish national risk-adjusted benchmarks for hospital-acquired infection rates and for device use ratios by using uniform case definitions as well as data collection methods and computerized data entry and analysis (CDC, 2000). The CDC has reported the SSI rates by operative procedure and the NNIS risk index category for SSIs (CDC NNIS system, 2000). The NNIS risk index was developed by Culver et al. in 1991 in order to stratify surgical patients into strata and to compare the SSI rates within strata. This was done because each patient has a different underlying medical condition before surgery and therefore his or her risks for SSIs are varied.

Definition of Surgical Site Infections

As Smyth and Emmerson (2000) pointed out, the use of the uniform and unchanged definition of SSIs is the most important component of SSI surveillance. The CDC definitions of SSIs, originally published in 1988 and modified in 1992 (Garner et al., 1988; Horan, Gaynes, Martone, Jarvis, & Emori, 1992) have been applied in the majority of studies. According to the CDC definitions, if at least one of the following is present, a superficial incisional SSI is diagnosed: 1) purulent drainage

from a superficial incision; 2) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; 3) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and if a superficial incision is deliberately opened by surgeon, unless the culture from the incision is negative; and 4) diagnosis of superficial incisional surgical site infection by the surgeon or attending physician (Horan et al., 1992) (Appendix 1). Although there are few studies to validate the CDC definitions (Bruce, Russell, Mollison, & Krukowski, 2001), the CDC has strongly recommended using the definitions of SSIs without modification in order to identify SSIs among inpatients (Mangram et al., 1999), because the use of uniform definition enables to compare infection rates between or among hospitals or with an aggregated database, such as the NNIS system.

Comparing the definitions to others, however, it is clear that the CDC definitions were modified or a part of the CDC definitions was used in some studies (Beitsch & Balch, 1992; Garibaldi et al., 1991; Mehta, Prakash, & Karmoker, 1988; Mishiriki, Law, & Jeffery, 1990; Simchen, Rozin, & Wax, 1990). Also, some studies used the definition of SSIs developed by researchers (Barone et al., 1999; Barry, Lucet, Kowmann, & Gehanno, 1999; Newman, Szozukowski, Bain, & Perlino, 1988). Bruce et al. (2001) identified that forty-one different definitions of SSIs have been used from their systematic literature review of published prospective studies over a seven-year period. Based on this result, they pointed out that theoretical validity and reliability of definitions for SSIs were different from those in terms of clinically important infections, which required medical interventions. Most of clinicians need practical and simple definitions for SSIs (eg., the presence of pus), and it is completely different from the definition used in epidemiological or evaluation research. The definition for SSIs influences the incidence of SSIs, which were reported in each study. Non-standardized criteria and definitions will cause misclassification of SSIs, with resulting intra- and inter-observer variation (Larson et al., 1991).

Case-Finding Methods

Gaynes and Horan (1996) proposed three issues related to case-finding methods: should SSIs be detected 1) by passive or active means, 2) on patient-based or laboratory-based data, and 3) prospectively or retrospectively. In a clinical randomized trial by Kurz et al. (1996), direct examination of surgical wounds by a physician, laboratory data of a culture of pus, and an instrument for scoring wound healing and SSIs were used. Their case-finding method of SSIs was active, patient and laboratory-based, and performed prospectively.

Active surveillance requires more professional skills and knowledge related to nosocomial infections than does passive surveillance in order to collect data from various data sources and to judge whether or not a nosocomial infection has occurred. Moreover, active surveillance can compensate for some limitations of the passive method, such as misclassification and underreporting. Laboratory-based surveillance solely depends on positive results of laboratory examinations of clinical specimens, therefore SSIs diagnosed based on signs and symptoms without any cultures would be missed (Gastmeier et al., 1999). Also, the positive microbiological result itself does not indicate the development of SSIs, because the presence of microorganisms in the surgical patients sometimes does not cause a specific immune response to infection (colonization or contamination). On the other hand, patient-based surveillance includes directly observing surgical sites, counting nosocomial infections, assessing risk factors, and monitoring patient care procedures and practices (Gaynes & Horan, 1996). Therefore, through patient-based surveillance, SSIs diagnosed based on purulent discharge and signs and symptoms of SSIs could be detected.

However, observing surgical wounds and deciding whether a SSI has occurred or not, depends on the subjectivity of researchers or observers, and even though they have been well trained, the decisions may be subjective. To increase the reliability of the data and to obtain more precise data, a standardized surveillance system or

technique has been recommended. Cardo, Falk, and Mayhall (1993b) conducted a study to determine the sensitivity and specificity of standard infection control surveillance techniques (medical chart review and discussion with staffs) for identifying SSIs, by evaluating the findings identified by infection control practitioners compared to hospital epidemiologists when they identified SSIs. They concluded that using a standard surveillance technique could lead to the high sensitivity and specificity in identifying SSIs without the direct examination of surgical wounds.

Pottinger, Herwaldt, and Perl (1997) examined several case-finding methods for identifying nosocomial infections. The sensitivity of total chart review was reported as 0.74 to 0.94, and the sensitivity of selected medical record review based on laboratory records ranged from 0.77 to 0.91, fever from 0.09 to 0.56, and antibiotic use was 0.57. One of the limitations of the chart review method is that it takes more time than other methods. Although each method has some advantages and limitations and there is no consensus about which method is best, Pottinger et al. concluded that total chart review was no more sensitive than other case-finding methods or combination of methods.

Discharge Surveillance for Surgical Site Infections

According to the consensus paper by the Surgical Wound Infection Task Force, a group composed of representatives of the Society for Hospital Epidemiology of America, the Association for Practitioners in Infection Control, the Surgical Infection Society, and the CDC, 98% of occurrence of SSIs could be detected within 28 days after surgery (Sherertz et al., 1992). However, due to shortened lengths of hospital stay, between 46% and 84% of SSIs do not become apparent until after a patient's discharge from hospital (Brown et al., 1987; Delgado-Rodriguez, Gomez-Ortega, Sillero-Arenas, & Llorca, 2001; Sands et al., 1996; Weigelt, Dryger, & Haley, 1992), and most incidents of SSIs occur within 21 days after an operation (Weigelt et al., 1992). Because the postoperative stay at hospitals continues to shorten, postdischarge

surveillance of SSIs is required to detect infections in the weeks that follow discharge. Also, when researchers decide to use the standard CDC definitions of SSIs as identification criteria, targeted surgical patients must be followed within 30 days postoperatively. However, some studies followed patients within 2 weeks (Garibaldi et al., 1991) after an operation. If postdischarge surveillance was not conducted, and data were collected only during hospitalization, the incidence of SSIs resulted in underestimates of the actual incidence of infections in the sample. Although there are several ways to conduct postdischarge surveillance of SSIs, a highly sensitive, specific, and practical method has not been developed. Among surgical patients who developed SSIs after their discharge from the hospital, Condon, Haley, Lee, and Meakins (1988) pointed out that most of them required readmission. Also, Kirkland et al. (1999) identified that the Relative Risk (RR) for readmission in infected patients was 5.5 (95% confidence interval [CI] = 4.0-7.7). In addition to readmission, utility of postoperative antibiotic exposure (Yokoe et al., 1998) has been used as an indicator of SSIs in order to capture all occurrences of in-hospital SSIs as well as SSIs after a patient's discharge from hospital. In order to obtain precise and accurate data by combining several methods to identify cases with SSIs and using a standard surveillance technique to determine SSIs can improve the reliability of data in future studies.

Risk Factors for Surgical Site Infections

In the following section, major risk factors that contribute to the development of SSIs are discussed. From the epidemiological point of view, the term "risk factor" has a certain meaning, strictly referring to a variable that has a statistically significant and independent association with the incidence of SSIs after a specific operation, which is identified by multivariate analyses in epidemiological studies (Mangram et al., 1999). However, as Mangram et al. pointed out, the term "risk factor" is often used

in a broad sense, and refers to patient or operation features in studies, in which authors used only univariate analysis. In this literature review, the term “risk factor” is used in a broad sense, and even those that need further studies or that have controversial findings are included. Even though a significant association between a risk factor and the incidence of SSIs was identified, the precise biological or physiological mechanism of this association is often not known. Therefore, plausible or possible explanations have often been provided based on logical reasoning but not on scientific evidence.

Literature Search and Data Extraction

A literature search using the MEDLINE and CINAHL database (1966-2001) was conducted with the keywords “surgical site infections,” “surgical wound infections,” and “risk factors.” In addition, a manual search was performed using reference lists from identified research articles. Available studies included in this literature review met the following criteria: (1) studies were published in English; (2) eligible participants were admitted to the hospital in order to undergo surgeries except surgical procedures for implants, which are required a one-year follow up by the CDC definitions of SSIs; (3) eligible participants were more than 18 years old; (4) the incidence of surgical site or wound infections occurred during hospitalization was reported; and (5) the magnitudes of association between each risk factor and SSIs were reported. Each study was reviewed with the data extraction form made by the author.

Magnitude of Association between Risk Factors and Surgical Site Infections

Researchers have reported possible associations with many risk factors using a variety of statistical analyses, for example univariate Odds Ratio (OR) or RR, multivariate OR, p-value based on comparison of two means, p-value from Chi-squared test for trend, and in some cases the specific method was unstated. Crude OR or RR based on univariate analysis and adjusted OR (AOR) based on multivariate analysis are used as the magnitude of risk factors on SSIs in this review. To examine the association between each risk factor and SSIs, the following criteria were used

(Bignardi, 1998):

1. Consistency; whether a statistically significant positive association was found in the majority of the studies using univariate analysis (at least three studies).
2. Independence; whether a statistically significant positive association was found even after using multivariate analysis.
3. Strength; an OR is well above 1 and statistically significant for risk factors investigated in the majority of the studies using univariate analysis (at least three studies). Or if the association was statistically significant both in univariate and multivariate analysis, and OR more than 5 was found in the latter in a single report, the risk factor was regarded as an independent risk factor for SSIs.
4. Biological plausibility; whether the precise biological or physiological mechanism of the association can be explained by scientific evidence or logical reasoning.

Association between Risk Factors and Surgical Site Infections

Patient's Susceptibility to Infection/ Intrinsic Risk Factors

Age. Twenty-seven studies examined an association between age and SSIs using either univariate or multivariate analysis (Table 3). The findings of 14 studies reached statistical significance (Beattie, Rings, Hunter, & Lake, 1994; Bertin, Crowe, & Gordon, 1998; Christou et al., 1987; Claesson et al., 1995; Claesson & Holmlund, 1988; Cronquist, Jakob, Lai, Latta, & Larson, 2001; Kluytmans et al., 1995; Lecuona, Torres-Lana, Delgado-Rodriguez, Llorca, & Sierra, 1998; Lizan-Garcia, Garcia-Caballero, & Asensio-Vegas, 1997; Medina-Cuadros et al., 1996; Mehta et al., 1988; Shapiro, Munoz, Tager, Schoenbaum, & Polk, 1982; Velasco, Thuler, Martins, Dias, & Gongalves, 1998; Vilar-Compte, Mohar, Sandoval, Rosa, Fordillo, & Volko, 2000). Except for the results of four studies, advanced age is an independent risk factor for SSIs (adjusted OR ranged from 1.02 to 1.6) (Beattie et al., 1994; Cronquist et al., 2001; Kluytmans et al., 1995; Shapiro et al., 1982). These findings provide substantive

Table 3

Results of the relationship between age and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI, p-value	AOR ^b	95%CI p-value
Beattie et al., 1994	Caesarean section	Prospective cohort	328	25.3%	NA	p= .03 younger		
Bertin et al., 1998	Breast surgery	Case-control ^c	18:37 ^d	4.0%	NA	p= .005 Older		
Christou et al., 1987	Elective surgery	Prospective Cohort	404	17.3%			1.02 (for every 10 years)	p = .003
Claesson et al., 1995	Colorectal surgery	Prospective	1079	5-48%	NA	p = .007	1.02 (for every one year)	p = .014
Claesson & Holmlund, 1988	Colorectal surgery	Prospective cohort	238	12.6%	NA	p < .01	1.05	p < .05
Cronquist et al., 2001	Craniotomy	Longitudinal	469	4.1%	NA	p < .05 younger	0.96	0.93-1.0
Kluytmans et al., 1995	Sternotomy	Case-control ^e	40: 120 ^d					
Lecuona et al., 1998	General surgery	Prospective cohort study	1,103	9.4% ^f	<=30 1 31-65 1.5 66-75 2.0 >75 3.7			
Lizan-Garcia, et al., 1997	General surgery	Prospective cohort	2237	11.4%	NA	p = .014 p = .000	1.2 (for every 10 years)	1.1-1.3 p = .000
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1483	10.5%	1.7 Over 65	1.2-2.4		
Mehta et al., 1988	Elective neurosurgery	Prospective cohort	536	8.2%	NA	p < .05	1.08 (age over 50)	
Shapiro et al., 1982	Elective Hysterectomy	Prospective Cohort	1125 323 ^g	18% 8% ^g	1.38 ^h Younger	1.04-1.85		p =.023

Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3%	1.4	1.05-1.83		
Vilar-Compte et al., 2000	All surgery	Case-control ⁱ	313:315 ^d	9.3%	1.6	1.12-2.27	1.35	0.87-2.11 p = .18
Barry et al., 1999	Head and neck oncologic surgery	Prospective cohort	208	35.3%	NA	p > .2		
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5% ^f	NA	p = .516		
He et al., 1994	Sternotomy	Prospective cohort	199	2.45%	NA			p = .3907
Lilienfeld et al., 1988	Coronary artery bypass grafting	Case-control ^j	18:72 ^d			Not sig.		
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1009	9.1%	<50 I	0.5-1.9		
					50-59	0.5-1.9		
					60-69	0.1-0.8		
					>70	p = .7532		
Ottino et al., 1987	Open-heart surgery	Prospective cohort	2,579	1.86% ^f				
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^f	1.56	0.86-2.82		
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	Over 65	0.8-2.8		
Simchen et al., 1990	Hernia surgery	Prospective cohort	1487	1.2-7.6%	1.61	p = .06	1.6	p = .07
					over 70			

Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Simchen et al., 1984	Orthopaedic surgery	Prospective cohort	376	4.8%	1.1	Not sig		
Slaughter et al., 1993	Coronary artery bypass operation	Prospective cohort ^k	125:125 ^d	5%		p = .72		
Trick et al., 2000	Coronary artery bypass grafting	Case-control ^l	30:90 ^d	1.7% ^f	NA	p = .87		
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective cohort	884	19.5%	NA	p = .479	NA	p = .781

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multivariate analysis. ^c Case: patients who had breast surgery with SSIs, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without SSIs. ^d The number of cases : the number of control. ^e Case: Patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: Patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^f Deep surgical site infections only. ^g Upper :Abdominal hysterectomy, lower: vaginal hysterectomy. ^h For a 20 years decrement. ⁱ Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections. ^j Case: patients who had cardiac surgery procedures with endocarditis (surgical wound infections), Control: cardiac surgery patients who were selected from the population of 1184 adults without infection, excluding those who died within 60 days of the procedure. Two control groups were used: (1) a random sample of the study population and (2) a sample matched by age, type of operation, and date of surgery. ^k All patients with SSIs were randomly matched with patients without SSIs for type of operation and month and year of the procedure. ^l Case: patients who underwent CABG with deep surgical site infections, Control: patients who had CABG during the study period without deep surgical site infections.

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evidence of advanced age as an independent risk factor for SSIs. Raymond et al. (2001) identified that mortality associated with intra-abdominal infections were significantly higher in the patients equal to or greater than 70 years old compared to those of patients under 70 years of age (23.2% vs. 6.3%, $p < .001$).

Four studies identified that younger age was significantly associated with the incidence of SSIs (Beattie et al., 1994; Cronquist et al., 2001; Kluytmans et al., 1995; Shanpiro et al., 1982). The majority of 13 studies that did not identify statistically significant associations between age and SSIs included patients who underwent cardiac surgery (Borger, Rao, Weisel, Ivanov, Cohen, Scully, & David, 1998; He et al., 1994; Lilienfeld, Vlahov, Tenney, & McLaughlin, 1988; Nagachinta et al., 1987; Ottio et al., 1987; The Parisian Mediastinitis Study Group, 1996; Slaughter, Olson, Lee, & Ward, 1993; Trick et al., 2000; Vuorisalo, Haukipuro, Pokela, & Syrjaja, 1998). When age is examined as a risk factor for SSIs, the relationship between age and some specific diseases that would require surgery, such as hysterectomy or coronary artery bypass grafting, or comorbid conditions should be considered.

Gender. Twenty-one studies examined an association between gender and SSIs (Table 4). Among them, four studies identified male as a risk factor for SSIs (Borger et al., 1998; The Parisian Mediastinitis Study Group, 1996; Tang et al., 2001; Velasco et al., 1998) and another three studies identified the opposite findings (Lilienfeld et al., 1988; Simchen et al., 1990; Vuorisalo et al., 1998). Although a few studies identified a statistically significant association between gender and SSIs using multivariate analysis, there is not enough evidence for gender as an important risk factor for SSIs.

Race/ ethnicity. In the previous study (NAS-NRC-AHCT, 1964), a small relationship between race/ ethnicity and SSIs was identified. Only three studies (Nagachinta et al., 1987; Simchen, Shapiro, Michel, & Sacks, 1981; Simchen, Stein, Sacks, Shapiro, & Michel, 1984) examined an association between race/ethnicity and

Table 4
Results of the Relationship between Gender and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI	AOR ^b	95%CI	p-value
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5% ^c	2.2 male	1.3-3.9			
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^c	2.55 male	p = .007 1.12-5.82			
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3%	1.3 male (1.1-1.8)	1.18-1.51	2.3	1.6-3.4	
Lilienfeld et al., 1988	Cardiac surgery	Case-control ^d	18:72 ^e	1.7%	female ^f	p < .05			
Simchen, et al., 1990	Hernia surgery	Prospective cohort	1,487	4.6%	2.1 female	p = .008	1.4		p = .4
Tang et al., 2001	Elective colorectal resection	Prospective cohort	2,809	4.7%			1.5 male	1.0-2.2	p < .05
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective cohort	884	19.5%	NA		1.59 female		p = .023
Barry et al., 1999	Head and neck oncologic surgery	Prospective cohort	208	35.3%	NA				Not sig
Claesson & Holmulund, 1988	Colorectal surgery	Prospective cohort	238	12.6%					Not sig
Claesson et al., 1995	Colorectal surgery	Prospective cohort	1,079	8.3%	1.4 male	0.9-2.0			Not sig
Garibaldi et al., 1991	skin incision greater than 6cm in length	Prospective cohort	1,852	6.5%	NA				Not sig
Kluytmans et al., 1995	Sternotomy	Case-control ^g	40: 120 ^e						Not sig

Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^c	NA		1.5 Male	0.9-2.5
Lizan-Garcia et al., 1997	General surgery	Prospective cohort	2,237	11.4%	1.18 male	0.9-1.55 Not sig		
Mehta et al., 1988	Neurosurgery	Prospective cohort	536	8.2%	NA		1.01 male	p > .05
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	1.3 female	0.8-2.2 Not sig		
Newman et al., 1988	Median sternotomy	Case-control ^h	68:136 ^c	0.7%	1.0 male	Not sig		
Ottino et al., 1987	Open-heart surgery	Prospective cohort	2,579	1.86% ^c		Not sig		
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	1.5 male	Not sig		
Simchen et al., 1984	Orthopaedic surgery	Prospective cohort	376	4.8%	1.2 male	Not sig	1.1	Not sig
Spelman et al., 2000	Coronary artery bypass grafting	Prospective cohort	693	9.38%	0.8 male	0.48-1.35 Not sig		

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Rate of deep surgical site infections. ^d Case: patients who had cardiac surgery procedures with endocarditis (SSIs), Control: cardiac surgery patients who were selected from the population of 1184 adults without infection, excluding those who died within 60 days of the procedure. Two control groups were used: (1) a random sample of the study population and (2) a sample matched by age, type of operation, and date of surgery. ^e The number of cases: the number of controls. ^f Female versus male. Crude Odds Ratio against population control is 3.5, and matched control 2.1. ^g Case: Patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: Patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^h Case: patients who had median sternotomy with postoperative mediastinitis, Control: patients who had median sternotomy without postoperative mediastinitis, and who were selected matching for sex, age, and date of surgery.

SSIs using either univariate or multivariate analysis (Table 5). Two studies compared Arabs to non-Arabs (Simchen et al., 1981; Simchen et al., 1984), and the findings were inconsistent. Because of a lack of the consistency, the strength, and the biological plausibility required to judge whether a variable is an important risk factor from the epidemiological point of view, race/ ethnicity is not an important risk factor for SSIs.

American Society of Anesthesiologists preoperative assessment score. An American Society of Anesthesiologists (ASA) preoperative assessment score has been used as an indicator for a patient's underlying severity of illness or the host susceptibility to infection (Culver et al., 1991; Mangram et al., 1999). This score was originally designed to standardize physical status categories for statistical studies and for hospital records so that uniform interpretation would be possible. It ranges from 1 for a normally healthy patient to 5 for a patient not expected to survive the next 24 hours (ASA, 1963).

Twelve studies examined an association between the ASA score and SSIs (Table 6). The findings of six studies reached statistical significance and four studies among them used multivariate analysis (AOR, 1.4-2.4) (Garibaldi et al., 1991; Lecuona et al., 1998; Medina-Cuardos et al., 1996; Rantala et al., 1997; Tang et al., 2001; Velasco et al., 1998). These results provide substantive evidence that general surgical patients with an ASA score of more than 2 or 3 points were identified to have significantly high risks for SSIs. However, the ASA score is not an important risk factor for patients who underwent a specific type of surgery, such as coronary artery bypass grafting (The Parisian Mediastinitis Study Group, 1996; Trick et al., 2000; Vuorisalo et al., 1998) and head and neck oncology surgery (Barry et al., 1999).

In addition, the accuracy of the rating of the ASA score is questionable. Several study results (Haynes & Lawler, 1995; Owens, Drkes, Gilvert, McPeek, & Ettling, 1975; Owens, Felts, & Spitznagel, 1978; Ranta, Hynynen, & Tammisto, 1997; Salemi, Anderson, & Flores, 1997) revealed enough evidence of the inconsistency or

Table 5

Results of the relationship between race/ethnicity and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95% CI	AOR ^b	95% CI	p-value
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	1.7 ^c	0.9-3.0			
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	4.8 ^d	1.8-12.2	6.1		
Simchen et al., 1984	Orthopaedic surgery	Prospective cohort	376	4.8%	0.7 ^d	0.1-5.1	0.4		Not sig

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Blacks versus non-Blacks. ^d Arabs versus non-Arabs.

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Table 6
Results of the Relationship between the American Society of Anesthesiologists Preoperative Assessment Score (ASA score) and SSIs

Source	Type of surgery	Design	N	SSI rate	Cut point	RR ^a	95%CI	AOR ^b	95%CI	p-value
Garibaldi et al., 1991	Operations with skin incision greater than 6cm in length	Prospective cohort	1,852	6.5%	≥3	4.2	2.8-6.4	2.4	1.8-4.0	p < .001
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^c	1	1		1.4	0.9-2.2	
					2	2.0	0.8-5.4			
					3	6.2	2.4-15.8			
					4-5	10.1	3.0-34.0			
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	≥3	2.7	p < .001			
							1.9-3.7			
Rantala et al., 1997	Abdominal, cardiothoracic and peripheral vascular, orthopedic, endocrine, plastic, and general surgery	Prospective cohort	772	6.6%	≥2	NA	P < .005			
Tang et al., 2001	Elective colorectal resection	Prospective cohort	2,809	4.7%	≥2			1.7	1.1-2.5	p < .01
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3%	≥3	1.7	1.3-2.14	1.8	1.2-2.8	
Barry et al., 1999	Head and neck oncologic surgery	Prospective cohort	208	35.3%	≥3	NA	P > .2			

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Table cont.

Source	Type of surgery	Design	N	SSI rate	Cut point	RR ^a	95%CI	AOR ^b	95%CI	p-value
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^c	>=3	1.47	0.66-3.29			p> .25
Trick et al., 2000	Coronary artery bypass grafting	Case-control ^d	30: 90 ^e	1.7% ^c	>3	1.8	0.7-4.6			p = .17
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective	884	19.5%		NA				p = .401
Vilar-Compte et al., 2000	All surgery	Case-control ^f	313:315 ^e	9.3%	1	1	0.53-2.7			p = .65
Wischniewski et al., 1998	Traumatology, abdominal surgery, and gynaecology and obstetrics	Prevalence	4,983	1.61%	>=3	NA	0.54-3.1			p = .07

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Deep surgical site infections. ^d Case: patients who had CABG with deep surgical site infections, Control: patients who had CABG without infections. ^e The number of case: the number of control. ^f Case: patient who had surgeries with postoperative surgical wound infection, Control: not mentioned.

the discrepancy of the ASA score as related to subjective determination by anesthesiologists. Salemi et al. found discrepancies in the ASA score by reviewing the medical charts of 250 patients after prosthetic-joint surgery. They pointed out that there was a 59% discrepancy rate between the class of ASA 2 and 3. Haynes and Lawler conducted a study of 113 anesthetists to evaluate the reproducibility of the grading system using 10 hypothetical patients who suffered from frequent problems. They concluded that there was an inconsistency regarding anesthetists in allocating the ASA score, and that the ASA score alone could not be considered to satisfactorily describe the preoperative physical status of a patient.

Obesity. Although the precise biological or physiological mechanism of the interaction between obesity and SSIs is still unclear, some studies of immunologic function in obese humans and experimental animals have indicated that excess adiposity is associated with impairments in the person's nonspecific defense mechanisms (Stallone, 1994).

Twenty-five published studies examined an association between obesity and SSIs. Table 7 shows the characteristics and the findings of these studies. The definitions of obesity were classified into the following three groups: 1) Body Mass Index (BMI), 2) patient's weight, and 3) thickness of the subcutaneous tissue. Soper, Bump, and Hurt (1995) used above three indicators to measure obesity. In two studies (Brown, Moor, Hummel, Marshall, & Collins, 1996; Slaughter et al., 1993), criteria or definitions of obesity were not mentioned.

Among 17 studies that used the BMI as an indicator of obesity, except for one study related to only deep SSIs (Moulton, Creswell, Mackey, Cox, & Rosenbloom, 1996) and three studies conducted by Chobau, Heckler, Burge, and Glancbaum (1995), Kluytmans et al. (1995), and Trick et al. (2000), obesity is positively related to the development of SSIs. In the study by Moulton et al., SSIs were divided into superficial and deep SSIs using the CDC definitions (Horan et al., 1992). They

Table 7
Results of the Relationship between Obesity and SSIs

Source	Type of surgery	Design	N	SSI rate	Definition of obesity	RR ^a	95% CI	AOR ^b	95% CI	p-value
Bertin et al., 1998	Breast surgery	Case-control ^c	18:37 ^d	4.0%	BMI: over 27	NA	p = .02			
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5%	BMI	NA	p = .001			
Chobau et al., 1995	General, urologic, gynecologic, or thoracic surgery	Retrospective cohort	881	0.8%	BMI: <27, 27-31, >31		Not sig			
Cronquist et al., 2001	Craniotomy	Longitudinal	469	4.1%	BMI: >27			2.9	1.1-7.9	
Garrow et al., 1988	Abdominal surgery	Prospective cohort	469	7.2%	BMI: >27 for men >30 for women	NA	p = .002			
He et al., 1994	Sternotomy	Prospective cohort	199	2.45%	BMI: >27.5					p = .0029
Kluytmans et al., 1995	Sternotomy	Case-control ^f	40: 120 ^d		BMI	NA	Not sig			
Lilienfeld et al., 1988	Coronary artery bypass grafting	Case-control ^g	18:72 ^d	1.7%	BMI	3.8	p < .05			
Medina et al., 1997	Hemiorrhaphy	Prospective cohort	497	8.0%	BMI: 33-37 >37	2.0 ^h		2.9	0.99-8.5	
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	BMI: <33.8 33.8-38.9 38.9+	1		7.2	1.92-26.6	
Moulton et al., 1996	Cardiopulmonary bypass	Prospective cohort	2,299	4.5%	BMI: >30	2.3	1.2-2.7	1.2	0.7-2.1	0.6-2.5
				0.7% ⁱ		0.8 ⁱ	0.2-2.4 ⁱ	3.4	1.4-4.9	1.4-8.1

Table cont.

Source	Type of surgery	Design	N	SSI rate	Definition of obesity	RR ^a	95% CI	AOR ^b	95% CI	p-value
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	BMI: under Overweight Obese	1 1.8 4.0	0.9-3.3 2.1-7.8	1.7 3.8	0.9-3.3 1.9-7.5	 p = .0001
Trick et al., 2000	Coronary artery bypass grafting	Case-control ^l	30: 90 ^d	1.7% ^c	BMI: over 30	1.8	p < .05 0.7-4.8			
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^c	BMI: over 30	2.79	p = .18 1.43-5.47 p = .003	2.67	1.27-6.0	p = .009
Roberts & Bates, 1992	Abdominal surgery	Two clinical trials	1) 658 2) 958	16% 10%	BMI		1)p < .05 2)p < .01			
Vilar-Compte et al., 2000	All surgery	Case-control ^k	313:315 ^d	9.3%	BMI: >27 for women, >27.7 for men	1.60	1.1-2.3 p = .01	1.76	1.14-2.7	p = .008
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective cohort	884	19.5%	BMI: over 30		p = .012	1.6		p = .015
Pelle et al., 1986	Cesarean sections	Prospective cohort	1,032	6.6%	Weight index	NA	p < .001			
Pitkin, 1976	Abdominal hysterectomy	Retrospective case-control ^l	300:300 ^d		Weight ≥ 200 pounds	NA	p < .001			
Spelman et al., 2000	Coronary artery bypass grafting	Prospective cohort	693	9.38%	1.5 times the patient's ideal weight	2.77	1.72-4.46 p < .001	2.82	1.58-5.0	p < .001
Nystrom et al., 1987	Elective colorectal	Prospective cohort	189	10.6%	Thickness of the subcutaneous fat layer	NA	p < .01			

Table cont.

Source	Type of surgery	Design	N	SSI rate	Definition of obesity	RR ^a	95% CI p-value	AOR ^b	95%CI p-value
Shapiro et al., 1982	Hysterectomy	Prospective cohort	1,125	18%	Skinfold thickness	1.25	0.93-1.69		
			323 ^m	8% ^m	>30				
Soper et al., 1995	Abdominal hysterectomy	Prospective cohort	150	11.3 %	Depth of subcutaneous tissue	NA	p = .0004	1.37	1.01-1.86
					BMI		p = .0032	1.02	0.93-1.11
					Weight		p = .0029	1.01	0.97-1.04
Brown et al., 1996	Cardiac surgery	Prospective cohort	1,717	1.1% ⁿ	No definition	3.25	1.29-8.22		
Slaughter et al., 1993	Coronary artery bypass grafting	Prospective cohort ^o	2,402	5%	No definition	NA	p = .79		

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Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Case: patients who had breast surgery with SSIs, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without SSIs. ^d The number of cases: the number of controls. ^e Deep surgical site infections. ^f Case: patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^g Case: patients who had cardiac surgery procedures with endocarditis (surgical wound infections), Control: cardiac surgery patients who were selected from the population of 1184 adults without infection, excluding those who died within 60 days of the procedure. Two control groups were used: (1) a random sample of the study population and (2) a sample matched by age, type of operation, and date of surgery. ^h Crude OR against a matched control: 2.0, against a population control: 3.8. ⁱ Upper: superficial surgical site infections, lower: deep surgical site infections. ^j Case: patients who underwent CABG with deep surgical site infections, Control: patients who had CABG during the study period without deep surgical site infections. ^k Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections. ^l Case: obese patients who were defined as weighing 200 pounds or more, and underwent abdominal total hysterectomy, Control: patients whose weights were less than 200 pounds, and underwent abdominal hysterectomy. ^m Upper: Abdominal hysterectomy, lower: vaginal hysterectomy. ⁿ Superficial surgical site infections. ^o All patients with SSIs (125) were randomly matched with patients without SSIs (125) for type of operation and month and year of the procedure.

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concluded that obesity was a significant risk factor for superficial SSIs but not for deep SSIs. Findings from the studies using the patient's weight and the thickness of the subcutaneous tissue as the definition of obesity did not provide enough evidence of obesity as a significant risk factor for SSIs (Brown et al., 1996; Nystrom, Jonstam, Hojer, & Ling, 1987; Pelle et al., 1986; Pitkin, 1976; Shapiro et al., 1982; Slaughter et al., 1993; Soper et al., 1995; Spelman et al., 2000). From these results, obesity increases the risk for developing SSIs, but the effect of obesity on SSIs is influenced by the definition or an indicator of obesity.

Malnutrition. Table 8 shows seven studies that examined an association between malnutrition and SSIs using serum albumin, hemoglobin, serum transferrin, total lymphocyte, or weight loss (Braga, Vignali, Radaelli, Gianotti, & Carlo, 1992; Casey et al., 1983; Christou et al., 1987; Medina-Cuadros et al., 1996; Nagachinta et al., 1987; Velasco et al., 1998). Besides various indicators used in each study, the definition of malnutrition was not clearly described in some previous studies (Cruse, 1981; Cruse & Foord, 1973, 1980; NAS-NAC-AHCT, 1964). Because of these issues, an epidemiological association between SSIs and malnutrition is difficult to demonstrate consistently.

Even though the effects of serum albumin levels on SSIs were not consistent, severe protein malnutrition seemed to be associated with the incidence of postoperative SSIs (Christou et al., 1987; Claesson et al., 1995; Medina-Cuadros et al., 1996; Nagachinta et al., 1987). Because of a lack of the association consistency and the strength as well as various indicators used to measure malnutrition, more studies would be needed to judge whether malnutrition is a significant risk factor for SSIs.

Diabetes mellitus. As hyperglycemia is well known to weaken the host defense mechanisms and resistance to infection (McMahon & Bruce, 1995), diabetes mellitus has been regarded as a possible risk factor for SSIs.

Sixteen studies examined an association between diabetes mellitus and SSIs

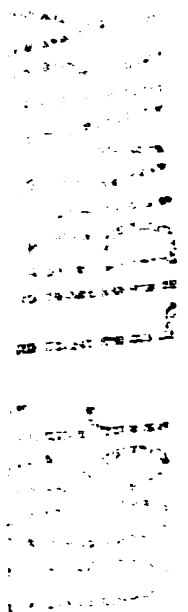
Table 8
Results of the Relationship between Malnutrition and SSIs

Source	Type of surgery	Design	N	SSI rate	Indicator	Cut off point	RR ^a	95% CI p-value	AOR ^b	95% CI p-value
Braga et al., 1992	Gastric, colorectal, or pancreatic cancer patients with surgical procedures	Prospective cohort	215	28%	Serum Albumin		NA	p = .50		
					Hemoglobin		NA	p = .76		
					Weight loss	>=10%	NA	p = .07		
Casey et al., 1983	Vascular surgery	Prospective cohort	75 ^c	47% ^d	Serum Albumin	3gm/dl	NA	p < .001		
					Serum transferrin	150mg/dl	NA	p < .01		
Christou et al., 1987	All surgery	Prospective cohort	404	17.3%	Serum Albumin	1g decrease			2.86	p < .0001
Claesson et al., 1995	Colorectal surgery	Prospective cohort	1079	8.3%	Serum Albumin		NA	p = .036		
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	Hemoglobin		NA	p > .30		
					Serum Albumin	<=37	4.1	2.3-7.3	0.8 ^e	0.7-0.9 ^e
						38-41	2.5	1.3-4.7		
						42-44	2.0	1.0-3.8		
						45-47	1.3	0.6-2.6		
						48+	1			
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	Serum Albumin	>4.5	1.0	-		
						4.4-4.5	1.9	0.9-4.3		
						3.9-4.3	3.0	1.5-6.0		
						<3.9	2.4	1.2-5.0		
								p = .004		

Table cont.

Source	Type of surgery	Design	N	SSI rate	Indicator	Cut off points	RR ^a	95% CI ^b	AOR ^b	95% CI ^b	p-value
Nagachinta et al., 1987 (cont.)	Elective cardiac surgery	Prospective cohort	1,009	9.1%	Total	>2271	2.4	1.2-5.0			p = .01
					lymphocyte	1827-	1.7	0.8-3.7			
						2271					
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3 %	Weight loss ^f	<1405	1.0	-			
							1.3	1.03- 1.71			

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c 75 High risk patients. Inclusion criteria of this study was as follows: patients aged 70 years or older, patients requiring repetitive vascular surgical procedures within a short period of time; and patients who already had wound problems due to ischemia or nonhealing minor amputation. ^d Wound complications included delayed healing and wound infections. ^e Adjusted OR, continuous as quintiles. ^f A recent 30-day weight loss greater than 10% of usual body weight.



(Table 9). The findings give substantial evidence that diabetes mellitus is an important risk factor for developing SSIs. Recent study conducted by Latham et al. (2001) identified the role of chronic hyperglycemia as a risk factor for the development of SSIs, and concluded that postoperative hyperglycemia and previously undiagnosed diabetes were associated with the risk of postoperative SSIs. Among 16 studies in the Table 9, the risk adjustment and the accuracy of data should be considered. Diabetes mellitus might be confounded by other factors, such as age and obesity. Also, the methods used in each study in order to collect the data about diabetes mellitus status were inconsistent. When the data were collected by self-report or medical chart review, the accuracy of the data might be influenced by observation bias.

Remote infections. Haley et al. (1981) identified that the presence of previous nosocomial or community-acquired infections at any site increased the risk of subsequent nosocomial SSIs fourfold, using the data of 169,526 medical and surgical patients selected from 338 hospitals in the United States. The mechanism between remote infections and SSIs might be presumed from the previous case report of sternal wound infections presenting 6 months after coronary artery bypass surgery (Stuesse, Robinson, & Durzinskey, 1995). Significant number of bacteria in any part of the body will gain access to the wound through the blood stream as well as the surgical procedure performed.

Table 10 shows six studies that examined an association between remote infections and subsequent SSIs (Garibaldi et al., 1991; Newman et al., 1988; Simchen et al., 1990; Valentine et al., 1986; Velasco et al., 1998; Vilar-Compte et al., 2000). As the findings were consistent and the association between remote infections and SSIs was strong, the presence of infections at any site of the body other than the surgical site at the time of operation increases the risk of SSIs.

Malignancy. Six studies examined an association between malignancy and SSIs (Table 11). All study findings reached statistical significance. Although

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5% ^c		p = .001	2.6	1.7-4.0
Brown et al., 1996	Cardiac operation	Prospective cohort	1,717	1.1% ^d			5.98	p < .01
Kluytmans et al., 1995	Sternotomy	Case-control ^e	40: 120 ^f					
Latham et al., 2001	Cardiothoracic surgery	Prospective cohort	74:970 ^f	7.1%	3.06 ^g	1.96-4.76 p < .001	2.76	1.64-4.66 p < .001
Medina-Cuadros et al., 1996	General surgery	Case-control Prospective cohort	1,483	10.5%	2.3	1.6-3.3		
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	3.0	1.6-5.4	2.6	1.4-4.8 p = .003
Richet et al., 1991	Vascular surgery	Prospective	561	4.1%	6.9	2.4-20	2.9	p = .03
Slaughter et al., 1993	Coronary artery bypass operation	Prospective cohort ^h	2,402	5%		p = .003		
Spelman et al., 2000	Coronary artery bypass grafting	Prospective cohort	693	9.38%	2.28	1.42-3.65 p < .001	2.09	1.20-3.63 p = .009
Trick et al., 2000	Coronary artery bypass grafting	Case-control ⁱ	30: 90 ^f	1.7% ^c	j		10.2 ^k	2.4-43 p = .008 ^k
Vilar-Compte et al., 2000	All surgery	Case-control ^l	313:315 ^f	9.3%	2.61	1.58-4.48 p = .0002	2.5	1.27-4.91 p = .008
Bertin et al., 1998	Breast surgery	Case-control ^m	18:37 ^f	4.0%	NA	p = .4		
Lilienfeld et al., 1988	Cardiac surgery	Case-control ⁿ	18:72 ^f	1.7%	1.29	0.39-4.26 0.41-4.46 p > .05		

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Source	Type of surgery	Design	N	SSI rate	RR ^a	95% CI	AOR ^b	95% CI	p-value
Newman et al., 1988	Median sternotomy	Case-control ^p	68:136 ^f	0.7%	2.2				Not sig
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^c	1.6	0.72-3.54			p = .25
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective	884	19.5%	NA				p = .083

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Rate of deep surgical site infections. ^d Rate of superficial incisional surgical site infection. ^e Case: patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^f The number of cases : the number of control. ^g Non-insulin dependent and Insulin dependent 2.7(95%CI = 0.9-8.0), Non-insulin dependent 1.0, Insulin dependent 21.0 (95%CI = 2.4-185.9). ^h All patients with SSIs (125) were randomly matched with patients without SSIs (125) for type of operation and month and year of the procedure. ⁱ Case: patients who had CABG with deep SSIs, Control: patients who had CABG without infections. ^j Crude OR of "Diabetes mellitus receiving insulin" 3.7(95%CI = 1.1-13, p = .01), OR of "Diabetes mellitus" 2.6(95%CI = 1.0-6.7, p = .02), and OR of "Preoperative glucose more than 200mg/dL 5.0(95%CI = 1.0-26, p = .02). ^k Preoperative glucose >=200mg/dL. ^l Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections. ^m Case: patients who had breast surgery with surgical wound infections, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without surgical site infections. ⁿ Case: patients who had cardiac surgery procedures with endocarditis (SSIs), Control: cardiac surgery patients who were selected from the population of 1184 adults without infection, excluding those who died within 60 days of the procedure. Two control groups were used: (1) a random sample of the study population and (2) a sample matched by age, type of operation, and date of surgery. ^o Crude OR against matched control: 1.29(95%CI = 0.39-4.26), against population control: 1.35 (95%CI = 0.41-4.46). ^p Case: patients who had median sternotomy with postoperative mediastinitis, Control: patients who had median sternotomy without postoperative mediastinitis and who were selected for each case, matching for sex, age, and date of surgery.

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Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Garibaldi et al., 1991	skin incision greater than 6cm in length	Prospective cohort study	1,852	6.5%	2.8	1.5-5.3		
Newman et al., 1988	Median sternotomy	Case-control study ^c	68:136 ^d	0.7%	^e	>2.6 ^e		
Simchen et al., 1990	Hernia surgery	Prospective cohort study	1487	4.6%	8.9	p < .001	9.5	p = .002
Valentine et al., 1986	Clean surgery	Prospective cohort study	2,349	7.6%		p < .001		
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort study	1,205	26.3%	1.6	1.25-2.13		
Vilar-Compte et al., 2000	All surgery	Case-control study ^f	313:315 ^d	9.3%	1.01	0.65-1.65		p = .81

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Case: patients who had median sternotomy with postoperative mediastinitis, Control: patients who had median sternotomy without postoperative mediastinitis, and who were selected matching for sex, age, and date of surgery. ^d The number of the cases: the number of the controls. ^e Pneumonia, broncoitis, pyuria, and skin infections. ^f Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections.

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Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Classen & Holmlund, 1988	Colorectal surgery	Prospective cohort	238	12.6%		p = .020		
Claesson et al., 1995	Colorectal surgery	Prospective cohort	1,079	8.3%		p < .001		
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^c	2.8	1.5-5.4		
Lizan-Garcia et al., 1997	General surgery	Prospective cohort	2,237	11.4%	1.76	1.22-2.54	1.69	1.07-2.67
Medina et al., 1997	Hemiorrhaphy	Prospective cohort	497	8.0%		p = .002	69.97	p = .0233
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	2.1	1.5-3.0	4.5	3.6-1376
								1.7-2.2
								p = .003

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c The rate of deep surgical site infections.

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Sawyer and Pruett (1994) asserted that malignancy could not be considered an independent risk factor for SSIs, it is an important risk factor for SSIs among patients who undergo specific surgical procedure from the results (Claesson et al., 1995; Claesson & Holmlund, 1988; Lecuona et al., 1998; Lizan-Garcia et al., 1997; Medina, Sillero, Martinez-Gallego, & Delgado-Rodriguez, 1997; Medina-Cuadros et al., 1996).

Malignancy might affect the patient's susceptibility to SSIs, because it leads to malnutrition or low albumin levels. The data about not only previous and current diagnoses of malignancy but also the phase or the stage of malignancy would be useful to examine the association between malignancy and SSIs. However, no study examined this association using data about severity of malignancy.

Immunosuppressive drug use. From the previous study findings, the effect of systematic steroid or other immunosuppressive drug use on SSIs is controversial (Cruse and Foord, 1973; Edwards, 1976; Haley et al., 1981; NAS-NRC-DCT, 1964; Post et al., 1991). Haley et al. reported that patients who took immunosuppressive medications were three times more likely to have developed SSIs than those without taking immunosuppressive drugs were. However, although steroid therapy is known to influence the patients' immune system, Spelman et al. (2000) and Morisolo et al. (1998) concluded that immunosuppressive therapy did not influence the SSI rate.

Table 12 shows six studies examined an association between systematic steroid or other immunosuppressive drug use and SSIs (Bertin et al., 1998; Kluytmans et al., 1995; Nagachinta et al., 1987; Slaughter et al., 1993; Spelman et al., 2000; Morisalo et al., 1998). There was not enough evidence for the independence and the strength of this association.

Nasal contamination. Staphylococcus aureus is most frequently isolated from the cultures of infected wounds. This pathogen is carried in the nares of 20% to 50% of healthy people (Perl & Golub, 1998, cited in Mangram et al., 1999).

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Bertin et al., 1998	Breast surgery	Case-control ^c	18:37 ^d	4.0%		Not sig		
Kluytmans et al., 1995	Sternotomy	Case-control ^c	40: 120 ^d		1.9	0.7-5.3		
Nagachinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	2.1 ^f	1.1-4.2		
Slaughter et al., 1993	Coronary artery bypass operation	Prospective cohort ^g	2,402	5%		p = .005 ^h		
Spelman et al., 2000	Coronary artery bypass grafting	Prospective cohort	693	9.38%		p = .59		
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective study	884	19.5%		p = .806 ⁱ		

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Case: patients who had breast surgery with surgical wound infections, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without surgical site infections. ^d The number of cases : the number of controls. ^e Case: patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^f Hormones use. ^g All patients with SSIs (125) were randomly matched with patients without SSIs (125) for type of operation and month and year of the procedure. ^h Steroid use. ⁱ Corticosteroid use.

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However, the association between skin contamination before surgery and postoperative SSIs is controversial. Three studies examined an association between preoperative nasal colonization with Staphylococcus aureus or Staphylococcus pyogenes and SSIs (Table 13). Kluytmans et al. (1995) identified that nasal carriage of Staphylococcus aureus significantly increased the incidence of SSIs with this organism after cardiac surgery, Davidson and his colleagues (Davidson, Clark, et al., 1971; Davidson, Smith, & Smylie, 1971), however, concluded that nasal and skin carriage of Staphylococcus pyogenes was not significantly associated with increases in Staphylococcal SSIs.

Therefore, the development of SSIs caused by S. aureus might be associated with preoperative nasal carriage with this organism, but more studies would be needed.

Perioperative temperature (hypothermia). Accidental hypothermia is defined as a spontaneous decrease in the core temperature, usually in a cold environment and associated with an acute problem without primary pathology of the temperature regulatory system. According to Dennison (1995), more than 90% of patients undergoing surgery experience some degree of postoperative accidental or unintentional hypothermia.

Many researchers examined the biological or physiological mechanisms between hypothermia and SSIs (Beilin et al., 1998; Forstot, 1995; Frank et al., 1992, 1997; Johsson et al., 1988; Hopf et al., 1997; Sessler, 1993), and perioperative unintentional hypothermia may increase the patient's susceptibility to SSIs and risks impaired wound healing by causing a decrease of oxygen in tissues and impairment immune function. Based on this knowledge, several researchers have tested the hypothesis that hypothermia increases the patient's susceptibility to SSIs and have established evidence to support their hypothesis (Hopf et al., 1997; Kurz et al., 1996; Hefffield, Sessler, & Hunt, 1994). A prospective randomized clinical trial by Kurz et al. (1996) identified that hypothermia was an independent risk factor for SSIs and hypothermic patients were five times more likely to develop SSIs than normothermic

Results of the Relationship between Nasal Contamination and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Davidson, Clark, & Smith, 1971	General surgery	Prospective cohort	1000	14.5%	Not sig ^c			
Khuytmans et al., 1995	Sternotomy	Case-control ^d	40: 120 ^e		9.6	3.9-23.7		
Mehta et al., 1988	Neurosurgery	Prospective cohort	536	8.2%			1.05	Not sig

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Nasal and skin carriage of *Staphylococcus pyogenes* was not significantly associated with increase in *Staphylococcus* wound infections. ^d Case: patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^e The number of cases : the number of controls.

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patients (AOR = 4.9, 95%CI = 1.7-14.5). However, three out of five studies (Barone et al., 1999; Munn et al., 1998; Trick et al., 2000), which examined the relationship between the intraoperative core temperature and SSIs, failed to identify that hypothermia was an important risk factor for SSIs (Table 14). Although the biological or physiological mechanisms between hypothermia and SSIs have been examined and explained by scientific evidence, the association between the perioperative core temperature and the occurrence of SSIs is controversial and more studies are needed.

Abdominal surgery. Abdominal surgery is more likely to be contaminated or dirty because most of them enter the gastrointestinal tract or involve open trauma injuries. Haley, Culver, Morgan et al. (1985) conducted a retrospective study using a nationwide sample of 58,498 surgical patients, and identified that the abdominal site of operation was the strongest predictor or risk factor for SSIs. Garibaldi et al. (1991) also showed an association between the lower abdominal sites and the high rates of SSIs by univariate analysis (RR = 2.0, 95%CI = 1.2-3.1). Recently, Nguyen et al. (2001) identified that abdominal surgery was a significant predictor for SSIs (AOR = 16, 95%CI = 1.5- 13.28) among surgical patients at two acute-hospitals in Vietnam. Despite of the limited number of research articles, due to the consistent findings and fairly strong association, abdominal surgery increases the risk of SSIs.

Duration of preoperative stay. Although the prolonged preoperative hospital stay has been regarded as an independent risk factor for SSIs, not all researchers identified a statistically significant association between the length of preoperative hospital stay and SSIs (Borger et al., 1998; Slaughter et al., 1993; Trick et al., 2000; Wisalo et al., 1998). Fourteen studies examined an association between the duration of preoperative stay and SSIs (Table 15). Even though arbitrary cut points of duration of hospital stay of each study were inconsistent, the findings of eight studies reached statistical significance. Therefore, the prolonged preoperative

Table 14

Results of the Relationship between Perioperative Temperature (Hypothermia) and SSIs

Source	Type of surgery	Design	N	SSI rate	Definition of Hypothermia	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Barone et al., 1999	Colorectomy	Retrospective cohort	150	12%	Intraoperative T < 95.5 °F (34.3 °C)	NA	p = .839		
Flores-Maldonado et al., 2001	Cholecystectomy	Prospective cohort	261	7.6%	Core temperature < 36 °C	6.0	p = .004	6.3	p = .01
Kurz et al., 1996	Colorectal surgery	Clinical random trial	200	6% ^e	2 °C below the normal core body T.		p = .009	4.9	1.7-14.5
Munn et al., 1998	Cesarean delivery	Retrospective case-control ^d	18:18 ^e	18% ^c		NA	p = .80		
Trick et al., 2000	Coronary artery bypass grafting	Case-control study ^g	30:90 ^e	1.7%	T < 35 °C	NA	p = .34		

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c SSI rate in hypothermia group was 18% and that in normothermia group was 6%. ^d Case: patients with wound infections, Control: patients without wound infections who were selected matching for age, weight, presence of gestational hypertension, and surgery length. All patients were selected from a cohort of 900 women who underwent cesarean delivery. ^e The number of cases : the number of controls. ^f Case: patients who had median sternotomy with postoperative mediastinitis, Control: patients who had median sternotomy without postoperative mediastinitis, and who were selected matching for sex, age, and date of surgery. ^g Case: Patients who had CABG with deep surgical site infections, Control: Patients who had CABG without infections.

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Table cont.

Source	Type of surgery	Design	N	SSI rate	Cut point	RR ^a	95%CI	AOR ^b	95%CI	p-value
Vilar-Compte et al., 2000	All surgery	Case-control ^j	313:315 ⁱ	9.3%	0	1	0.95-1.92			
					1-2	1.35	p = .09			
					3+ days	2.1	1.27-3.46			
						NA	p = .004			
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective cohort	884	19.5%		NA	p = .69			

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^bAdjusted Odds Ratio in multiple logistic regression analysis. ^cRate of deep surgical site infections. ^dRR: 0-1 days 2.2 (95%CI = 1.5-3.1), 2-6 days 1, >=7 days 2.3(955CI = 1.4-3.8). ^eIn only an-contaminated operations. ^f165 surgical procedures were performed among 160 patients. ^gAll patients with SSIs (125) were randomly matched with patients without SSIs (125) for type of operation and month and year of the procedure. ^hCase: patients who had CABG with deep surgical site infections, Control: patients who had CABG without infections. ⁱThe number of cases : the number of controls. ^jCase: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections.

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hospital stay is positively related to the development of SSIs.

Cigarette smoking. Nicotine from cigarette smoking results in the reduction of peripheral blood flow, and poor blood perfusion and oxygenation impair the oxidative killing system of the nonspecific immune system (Benhaim & Hunt, 1992). Also poor oxygenation in the tissues at the surgical wound site has been known to delay the normal wound healing process. Although the physiological mechanism remains conjectural, an association between cigarette smoking and SSIs might be strong.

Table 16 shows six studies examined an association between cigarette smoking and SSIs (Beitsch & Balch, 1992; Borger et al., 1998; Kurz et al., 1996; Nagachinta et al., 1987; Spelman et al., 2000; Vuorisalo et al., 1998). Kurz et al. identified that an adjusted OR of SSIs for cigarette smoking was 10.5 (95% CI = 3.2-34.1). Because of the consistency, the strength, and the biological mechanism of this association, cigarette smoking increases the risk of SSIs. In future studies, as Mangram et al. (1999) pointed out, the definition of current cigarette smoking or smoking history should be considered.

Alcohol use. Alcohol has been known to affect several physiological systems including the cardiovascular, central nervous, and immune systems. Therefore, alcohol use might increase the risk of postoperative SSIs. By using multiple logistic regression analysis in a prospective cohort study conducted by Rantala et al. (1997), alcohol abuse was strongly associated with the incidence of SSIs (Table 17). However, the finding of the study conducted by Newman et al. (1988) was opposite. Also, Weigelt et al. (1992) identified that nonalcoholic patients were more likely to have the risk of SSIs after discharge from hospitals in their prospective cohort study of 16,453 consecutive patients who underwent general surgery in trauma, thoracic, and transplant services. From these results, the effect of alcohol on SSIs is controversial. Therefore, more studies are needed to examine the relationship

Table 16
Results of the Relationship between Smoking and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Beitsch & Balch, 1992	Inguinal lymph node dissections	Retrospective cohort	168	29%		p < .05		
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5% ^c		p = .017 ^d		
Kurz et al., 1996	Colorectal surgery	Clinical random trial	200	6% 18% ^e		p = .004	10.5	3.2-34.1
Nagacinta et al., 1987	Elective cardiac surgery	Prospective cohort	1,009	9.1%	N: 1 E: 1.3 L: 2.0 M: 1.9 H: 2.0 ^f		1.8	1.1-3.1 p < .05
Spelman et al., 2000	Coronary artery bypass grafting	Prospective cohort	693	9.38%	1.25	0.7-2.5 0.6-7 0.9-4 0.9-4.4 p = .03 ^g 0.74-2.09		
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective cohort	884	19.5%		p = .4 p = .752		

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Rate of deep surgical site infections only. ^d Smoking status including "Never", "Former", and "Active" Result in Chi-square test. ^e Normothermia group 6%, Hypothermia group 18%. ^f Never smoker, ex-smoker, light smoker, medium smokers, heavy smokers (no definition). ^g Test for trend.

Table 17
Results of the Relationship between Alcohol and SSIs

Source	Type of surgery	Design	N	SSI rate	OR ^a	95%CI p-value	AOR ^b	95%CI p-value
Newman et al., 1988	Median sternotomy	Case-control ^c	68:136 ^d	0.7% ^e	1.0	Not sig		
Rantala et al., 1997	Abdominal, cardiothoracic and peripheral vascular, orthopedic, endocrine, plastic, and general surgery	Prospective cohort	772	6.6%		p < .05		p = .0001

Note. ^a Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Case: patients who had median sternotomy during the study period with postoperative mediastinitis, Control: patients had median sternotomy without postoperative mediastinitis, matched for sex, age, and date of surgery. ^d The number of case: the number of control. ^e Rate of deep surgical site infections.

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between alcohol use and SSIs.

Psychosocial factors. Few studies examined the relationship between psychosocial factors, such as depression and social support, and SSIs. Whitehouse, Friedman, Kirkland, Richardson, and Sexton (2002) conducted a pairwise-matched case-control study to examine the impact of orthopedic SSIs on the patient's quality of life, length of hospitalization, and cost. They identified that patients with SSIs had substantial reductions in their quality-of-life measures one year after their initial surgery, compared with those without SSIs. A meta-analysis paper by Herbert and Cohen (1993) identified that although the effects of all immune parameters were not consistent, in general stressful life experiences were associated with changes in immune parameters in human, including decrements in percentage of CD4 and CD8 T cells, decreases in the number and function of natural killer cells, and lower lymphocyte proliferation in response to specific mitogens. For patients, admission to hospitals and undergoing surgeries would be stressful life experiences, and those experiences might influence the patient's susceptibility to SSIs.

Perioperative Factors

Duration of operation. The mechanism of duration of operation is still unclear. Cruse and Foord (1980) proposed the following four explanations: 1) an increase in the contamination of the wound with longer operations; 2) an increase in tissue damage from drying, prolonged retraction, and manipulations; 3) an increase in the amount of suture and electrocoagulation, which may reduce the local resistance of the wound; and 4) greater suppression of the host defenses from blood loss and shock. Also, Dellinger, and Ehrenkranz (1998) have mentioned that prolonged operations result in the potential for hypothermia in patients, because multiple organs are exposed to unexpected cold ambient operating temperatures for a longer time period.

Twenty-eight studies examined an association between duration of operation and SSIs (Table 18). Although a few epidemiological studies failed to identify

Table 18
Results of the Relationship between Duration of Operation and SSIs

Source	Type of surgery	Design	N	SSI rate	Cut point	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Barry et al., 1999	Head and neck oncologic surgery	Prospective cohort	208	35.3%	<4	1			
					4-6	1.87	p = .07		
					6-8	0.86	p > .2		
					8+ hrs	2.24	p = .02		
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5% ^c		NA	p = .005		
Braga et al., 1992	Gastric, colorectal, or pancreatic cancer patients with surgical procedures	Prospective cohort	215	28%		NA	p < .01	1.01	p < .05
Brown et al., 1996	Cardiac operation	Prospective cohort	1,717	1.1%	>300 mins	Superficial		4.66	p = .01
						Deep		55.14	p = .00
						NA		1.12 ^e	p = .0988
Christou et al., 1987	All surgery	Prospective cohort	404	17.3%		NA			
Claesson et al., 1995	Colorectal surgery	Prospective cohort	1,079	8.3%		NA	p < .001		
Cronquist et al., 2001	Craniotomy	Longitudinal	469	4.1%				1.004	1.001-1.008
Garibaldi et al., 1991	skin incision greater than 6cm in length	Prospective cohort	1,852	6.5%	>2 hrs	4.6	3.1-6.8	3.0	1.6-3.6 p < .0001
Killian et al., 2001	Cesarean section	Prospective cohort	765	7.7%				1.01	1.00-1.02 p = .04

Table cont.

Source	Type of surgery	Design	N	SSI rate	Cut point	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^c	<=60 61-120 121-180 >180 mins Every 1 hr	1 2.8 6.5 9.8	1.3 1.2-6.6 2.7-15.7 3.2-29.9 p < .001 p = .000	1.3	0.9-1.7 p = .0000 1.0-1.03 p < .02 1.12-4
Lizan-Garcia et al., 1997	General surgery	Prospective cohort	2,237	11.4%				1.51	1.34-1.73
Mah et al., 2001	Cesarean section	Prospective cohort	785	2.8% ^f				1.01	p = .0000 1.0-1.03
Medina et al., 1997	Herniorrhaphy	Prospective cohort	497	8.0%				2.11 (hours)	p < .02 1.12-4
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	<60 60-119 120-179 180+ mins >3hrs	1 1.6 2.2 3.5	1.1-2.3 1.4-3.4 2.0-6.0	1.13	p < .01
Mehta et al., 1988	Neurosurgery	Prospective cohort	536	8.2%					
Newman et al., 1988	Median sternotomy	Case-control ^g	68:136 ^h	0.7% ^c		NA	22.4-68		
Rantala et al., 1997	Abdominal, cardiothoracic and peripheral vascular, orthopedic, plastic, endocrine, and general surgery	Prospective cohort	772	6.6%	>2hrs	NA	p < .05 p < .05		p = .028

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Table cont.

Source	Type of surgery	Design	N	SSI rate	Cut point	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Shapiro et al., 1982	Elective hysterectomy	Prospective Cohort	1,125 323 ⁱ	18% 8% ⁱ		1.63 ^j	1.32-2.0		Not sig
Simchen et al., 1990	Hernia surgery	Prospective cohort	1,487	4.6%	>=91 mins	2.6	p < .002	1.4	p = .3
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	>1hr	3.9	p < .05	7.3	
Simchen et al., 1984	Orthopaedic surgery	Prospective cohort	376	4.8%	>=5 hrs	3.0	p = .06	1.8	0.4-3.2
Velasco et al., 1998	Cancer patients with surgery	Prospective cohort	1205	26.3%	>=280 mins	1.6	1.69-2.74	2.7	1.9-3.9
Vilar-Compte et al., 2000	All surgery	Case-control ^k	313:315 ^h	9.3%	<60+ >=60 and<120 >=120	1 1.3 1.86	0.9-1.89 p = .158 1.35-2.55 p < .0001	1.44	0.77-2.69 p = .24
Bertin et al., 1998	Breast surgery	Case-control ^l	18:37 ^h	4.0%		NA	p = .6		
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ³⁾	>=200mins	1.71	0.92-3.16 p = .09		
Slaughter et al., 1993	Coronary artery bypass operation	Prospective cohort ^m	2,402	5%	>5hrs		p = .37		
Trick et al., 2000	Coronary artery bypass grafting	Case-control ⁿ	30: 90 ^h	1.7%		NA	p = .95		
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective cohort	884	19.5%	>245 mins	NA	p = .099		

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Rate of deep surgical site infections. ^d Upper: superficial surgical site infections, lower: deep surgical site infections. ^e One-hour increase. ^f Rate of incisional SSIs. ^g Case: patients who had median sternotomy with postoperative mediastinitis, Control: patients who had median sternotomy without postoperative mediastinitis, and who were selected matching for sex, age, and date of surgery. ^h The number of cases : the number of controls. ⁱ Upper: Abdominal hysterectomy, lower: vaginal hysterectomy. ^j 60-minutes increment. ^k Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections. ^l Case: patients who had breast surgery with surgical wound infections, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without surgical site infections. ^m All patients with SSIs (125) were randomly matched with patients without SSIs (125) for type of operation and month and year of the procedure. ⁿ Case: Patients who had CABG with deep surgical site infections, Control: Patients who had CABG without infections.

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duration of operation as an independent risk factor for SSIs (Bertin et al., 1998; Christou et al., 1987; The Parisian Mediastinitis Study Group, 1996; Slaughter et al., 1993; Trick et al., 2000; Vuorisalo et al., 1998), the majority of research findings have supported the strong association between duration of operation and SSIs. The researchers set arbitrary duration cut points for comparing the SSI rates. In spite of inconsistent cut points, there is a direct or linear relationship between duration of operation and the incidence of SSIs.

Number of operations. More than one operation during one hospitalization results in more opportunities for microorganisms to reach the surgical sites. Simchen et al. (1981) identified that patients who underwent more than one operation during an admission were more likely to develop SSIs than those with only one operation (AOR = 7.3, $p < .05$). Especially, there was a higher infection rate after the second operation, if it was performed within one week after the first operation. Numbers of operations might be an important risk factor for SSIs, however, due to little evidence, more studies are needed to examine this relationship.

Urgency of operation. Operations carried out under emergency conditions or circumstances have been considered a risk factor for postoperative SSIs. Fifteen studies examined an association between urgency of operation and SSIs (Table 19). Urgency of operation was defined as the mode of surgical intervention, an emergency or an elective operation (Ottino et al., 1987; Vuorisalo et al., 1998). Although urgency of operation might increase the risk of SSIs, more studies are needed because of a lack of the independence and the strength of this association.

Surgical scrub/ antiseptic agents. The basic aims of the use of preoperative hand and forearm antiseptic and surgical scrub are to remove dirt, skin oil and microbes from the healthcare personnel's skin, to reduce the microbial count as much as possible in the shortest period of time with the least amount of skin irritation, and to leave an antimicrobial residual residue on the skin as long as possible to prevent

Table 19

Results of the Relationship between Urgency of Operation and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Gil-Egea et al., 1987	Clean surgery	Prospective study	4,468	3.2%		p < .0005		
Lizan-Garcia et al., 1997	General surgery	Prospective cohort study	2,237	11.4%			1.99	1.35-2.92 p = .0019
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	2.2	1.6-3.1		
Beattie et al., 1994	Caesarean section	Prospective cohort	328	25.3%		Not sig		
Borger et al., 1998	Cardiac surgery	Retrospective cohort	12,267	2.5% ^c		p = .820		
Brown et al., 1996	Cardiac operation	Prospective cohort	1,717	1.1% ^d		p > .10		
Garibaldi et al., 1991	skin incision greater than 6cm in length	Prospective cohort	1,852	6.5%		Not sig		
He et al., 1994	Sternotomy	Prospective cohort	199	2.45%		Not sig		p = .716
Kluytmans et al., 1995	Sternotomy	Case-control ^e	40: 120 _f			p > .05		
Ottino et al., 1987	Open-heart surgery	Prospective cohort	2,579	1.86% ^c		P=0.3190		
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^c	1.45	0.62-3.40 p > .25		

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Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Rantala et al., 1997	Abdominal, cardiothoracic and peripheral vascular, orthopedic, plastic, endocrine, and general surgery	Prospective cohort	772	6.6%		Not sig		
Sellick et al., 1991	Cardiac surgery	Retrospective cohort	2,017 1,850 ^g	^h		p = .890 ⁱ		
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3%	1.4	0.93-2.10		
Vuorisalo et al., 1998	Coronary artery bypass grafting	Prospective study	884	19.5%		p = .245		

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Rate of deep surgical site infections. ^d Rate of superficial incisional surgical site infections. ^e Case: patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: patients who had CABG without sternotomy wound infections and were matched to cases by proximity of operation date. ^f The number of cases : the number of controls. ^g Sternotomy 2017, venectomy 1850. ^h Infection rates were as follows: 1988 sternotomy 3.4%; 1989 sternotomy 2.6%; 1988 venectomy 3.8%; 1989 venectomy 3.2%. In 1988, hair removal was performed with disposable razors and with electric clippers in 1989. ⁱ 1988 all sternotomy only.

1988 all sternotomy only.

microbial growth throughout an operation (Galle, Homesley, & Rhyne, 1978). The **choice** of appropriate antiseptic agents and the effective protocol of surgical scrub are **examined** in terms of prevention of SSIs. Issues such as scrubbing technique, **duration** of scrubbing, condition of the healthcare personnel's skin, complications of **scrubbing**, and techniques of drying and gloving should be considered.

Although Cruse and Foord (1973, 1980) reported that no relationship to SSIs **was** shown when different hand-scrub preparations were used, effective and **appropriate** methods and protocols for surgical scrubbing have been examined in **intervention** studies (Doebbeling et al., 1992; Galle et al., 1978). Alcohol is **considered** the gold standard for surgical hand preparation, but Doebbeling et al. (1992) identified that a hand-disinfection system using an antimicrobial agent (**chlorhexidine**) reduced the rate of nosocomial infections at the Intensive Care Unit **more** effectively than using alcohol and soap. Although Nichols, Smith, Garcia, **Waterman**, and Homes (1997) reported that providone-iodine and chlorhexidine **gluconate** are most frequently used in U.S. hospitals, alcoholic chlorhexidine was **found** to have greater residual antimicrobial activity than 7.5% povidone-iodine or 4% **chlorhexidine gluconate** (Wade & Casewell, 1991). More studies are needed to **determine** which methods of surgical scrub and antiseptic agents are appropriate for the **healthcare** personnel in the operating room. However, almost 150 years ago, since **Lister** introduced disinfection of hands and sterilization of operative instruments for a **reduction** of the SSI rates (Vandenbroucke-Grauls & Kluytmans, 2001), it is clear that **nonuse** of disinfectants or antiseptic agents as well as non-compliance with surgical **scrub** definitely increases the risk of SSIs.

Time of day. Cruse and Foord (1973) conducted a five-year prospective **study** of 23,649 surgical wounds and showed an association between time of day and **the occurrence** of SSIs. The SSI rate of the clean surgeries which were performed **between** midnight and 8 AM was more than tripled (8 AM- 4PM 2.0% vs. Midnight- 8

AM 6.8%), and the clean-contaminated infection rate during the same time period was doubled (8 AM- 4PM 9.9% vs. Midnight- 8 AM 18.3%). As authors explained, a loss of perfect operating techniques due to weariness and urgency of operation might cause the rise of the SSI rates. Also, Gil-Egea et al. (1987) showed the lower clean wound infection rates in the operations scheduled last compared to first or second ($p < .001$). Due to the limited results, it is difficult to interpret the association between time of day and the occurrence of SSIs.

Month of year. From the previous epidemiological studies, researchers found a peak of the infection rates in July (Condon et al., 1983; Cruse and Foord, 1980; Mead et al., 1986) or in hot and humid season (Mehta et al., 1988). However, Simchen et al. (1990) could not identify the same result in their prospective cohort study of 1,487 patents undergoing hernia surgery. Because of a lack of the consistency and the logical reasoning of this association, month or season of year might not be an important risk factor for SSIs.

Wound classification system. The classification system of wounds according to potential endogenous bacterial contamination was introduced in the NAS-NRC-AHCT study (1964). This classification system includes the following four categories of wounds: clean, clean-contaminated, contaminated, and dirty-infected.

Many subsequent epidemiological studies have utilized this classification system to compare the postoperative SSI rates according to all categories. Ten studies examined an association between this classification system and SSIs (Table 20) and all findings reached statistical significance. Therefore, there is substantial evidence to identify that the wound classification system is an important or independent risk factor for the development of SSIs.

Cardo, Falk, and Mayhall (1993a) examined the accuracy of surgical wound classification by circulating nurses compared to the results of physicians. They concluded that surgical wounds were classified with a high degree of the accuracy, and

Table 20
Results of the Relationship between the Wound Classification System and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Christou et al., 1987	All surgery	Prospective cohort	404	17.3 %		p < .05	0.76	p = .0633
Davidson, Clark, & Smith, 1971	General surgery	Prospective cohort	1,000	14.5 %		p < .001		
Garibaldi et al., 1991	skin incision greater than 6cm in length	Prospective cohort	1,852	6.5 %	C-CO /C 3.2 CO+D /C 22.6 ^c	2.0-5.2 11.3-45.2	2.7	1.9-4.6 p < .0001
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^d	C 1 C-CO 6.6 CO 8.7 D 9.8	1.5-29.2 2.0-38.5 2.2-44.4		
Lizan-Garcia et al., 1997	General surgery	Prospective cohort	2,237	11.4 %		p < .001 ^e p < .0000	C-CO/C 6.41 CO/C 3.65 D/C 9.33	3.47-11.84 1.79-7.43 5.25-16.58 p < .0000
Medina-Cuadros et al., 1996	General surgery	Prospective cohort study	1,483	10.5 %	C 1 C-CO 1.4 CO +D 4.6	1.0-2.1 3.0-6.9		
Rantala et al., 1997	Abdominal, cardiothoracic and peripheral vascular, orthopedic, endocrine, plastic, and general surgery	Prospective cohort	772	6.6 %	CO or D	p < .05		p = .011

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Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Tang et al., 2001	Elective colorectal resection	Prospective cohort	2,809	4.7%			C/C-CO 2.8	1.3-5.7
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort study	1,205	26.3 %	CO or D 3.2	2.33-4.35	3.4	p<.01 2.2-3.5
Wischniewski et al., 1998	Traumatology, abdominal surgery, and gynaecology & obstetrics surgery	Prevalence study	4,983	1.61 %	CO & D vs C-CO & C	p = .01		

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c C: Clean, C-CO: Clean-Contaminated, CO: Contaminated, and D: Dirty. ^d Rate of deep surgical site infections only. ^e Test for trend.

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that classification was more difficult in trauma than in general surgery by circulating nurses.

Wound drains. Wound drainage systems may give microorganisms that are **part** of the surgical patient's normal skin flora an opportunity to migrate along the **surface** of the drain, or exogenous pathogens might enter through abdominal drains if **an open** drainage system is used. Previous studies identified the possible relationship **between** wound drainage systems and the incidence of SSIs (Cruse, 1981; Cruse & **Foord**, 1973, 1980; NAS-NRC-ADCT, 1964). Eleven studies examined an **association** between wound drainage systems and SSIs (Table 21). Although three **studies** did not identify statistically significant results (Bertin et al., 1998; Garibaldi et al., 1991; Simchen et al., 1981), wound drains or drainage systems increase the risks of **postoperative** SSIs (Claesson et al., 1995; Gil-Egea et al., 1997; Lecuona et al., 1998; **Simchen** et al., 1990; Simchen et al., 1984; Tang et al., 2001; Velasco et al., 1998; **Vilar-Compte** et al., 2000), because of the consistent and independent findings as well **as the** biological plausibility.

Preoperative hair removal. The increased risk of SSIs associated with **shaving** has been attributed to microscopic cuts in the patients' skin that later serve as **foci** for bacterial multiplication (Mangram et al., 1999). Table 22 shows four studies **examined** an association between preoperative shaving and SSIs (Alexander, Fischer, **Boyajian**, Palmquist, & Morris, 1983; Mehta et al., 1988; The Parisian Mediastinitis **Study Group**, 1996; Sellick, Stelmach, & Mylotte, 1991). Preoperative shaving, **especially** shaving with a razor at the night before an operation, has been associated **with** significantly higher SSI rates than any other methods including the use of shaver, **clipping**, or depilatory in the morning of an operation (Alexander et al., 1983; Sellick et al., 1991; Seropian & Reynolds, 1971). Currently, if hair removal is necessary, the **use** of depilatory or clipper just before operation is the recommended and common **method**.

Table 21
Results of the Relationship between Postoperative Drains and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Claesson et al., 1995	Colorectal surgery	Prospective	1,079	8.3%		p < .001		
Gil-Egea et al., 1987	Clean surgery	Prospective cohort	4,468	3.2%		p < .0005		
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^c	4.7	2.3-10.0		
Simchen et al., 1990	Hernia surgery	Prospective cohort	1,487	4.6%	5.3	p < .001	4.1	p = .001
Simchen et al., 1984	Orthopaedic surgery	Prospective cohort	376	4.8%	Present: 3.1 Open: 11.7 Closed: 2.0	p = .04 p = .0001 p = .1	Open: 4.6	3.8-6.5 p < .05
Tang et al., 2001	Elective colorectal resection	Prospective cohort	2,809	4.7%			1.6	1.0-2.5 p < .05
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3%	1.6	1.19-2.06		
Vilar-Compte et al., 2000	All surgery	Case-control ^d	313:315 ^e	9.3%	2.24	1.62-3.2 p = .00025	1.5	0.9-2.42 p = .11
Bertin et al., 1998	Breast surgery	Case-control ^f	18:37 ^e	4.0%		p = .30		
Garibaldi et al., 1991	skin incision > 6cm in length	Prospective cohort	1,852	6.5%		Not sig		
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	2.1	0.92-4.5		

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Rate of deep surgical site infections. ^d Case: patients who had breast surgery with surgical wound infections, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without surgical site infections. ^e Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections. ^f The number of cases : the number of controls.

Table 22
Results of the Relationship between Preoperative Hair Removal and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI	AOR ^b	95%CI	p-value
Alexander et al., 1983	Major surgical procedures	Prospective randomized	1013	4.4%		p < .027			
Mehta et al., 1988	Neurosurgery	Prospective cohort	536	7.6% ^c 8.2%		p < .006 ^d	1.23 ^e		p < .01
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830	2.3% ^f	2.82	1.25-6.38			
Sellick et al., 1991	Cardiac surgery	Retrospective cohort	2017 1850 ^g	^h		p = .01 p = .010 p = .015 p = .837 p = .0534 ⁱ			

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Overall infection rates at discharge and 30-day follow up. ^d Four hair-removal methods: 1) routine shaving of the operative area the night before operation (PM razor); 2) routine shaving the morning of operation (AM razor); 3) clipping of hair from the operative area the evening before operation (PM clipping); and 4) clipping the morning of operation (AM clipping). Infection rates were lower in the AM clipping group (at discharge p < .027, at 30 days p < .006). ^e Time of shaving > 12 hours before operation versus time of shaving < 2 hours before operation. ^f Rate of deep surgical site infections. ^g Sternotomy 2017, venectomy 1850. ^h Infection rates were as follows: 1988 sternotomy 3.4%; 1989 sternotomy 2.6%; 1988 venectomy 3.8%; 1989 venectomy 3.2%. In 1988, hair removal was performed with disposable razors and with electric clippers in 1989. ⁱ Deep sternotomy, deep venectomy, incisional sternotomy, incisional venectomy.

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Preoperative patient's skin preparation. Preoperative bathing is a routine procedure for surgical patients in order to prevent postoperative SSIs, but the value of **this** practice in terms of the postoperative SSI rates is controversial. Kaiser, Kernodle, **Barg**, and Petracek (1988) identified that the number of Staphylococcal colony counts **increased** at both the subclavian and inguinal sites after washing with a non-medicated **soap** lotion, but that the use of chlorhexidine (Hibicleans) was shown to reduce the **number** of Staphylococcal colony counts at both sites. Shower or total body bathing **with** hexachlorophene or chlorhexidine resulted in significant reductions in skin **colonization** (Paulson, 1993). Also, from the finding of the study conducted by Leigh, **Stronge**, Marriner, and Sedgwick (1983), patients who were colonized with Staphylococcus aureus might benefit from preoperative total bathing with antiseptics. **Because** the incidence of colonization of the skin is not a very common phenomenon (**skin** colonization 2% versus nasal colonization 17.3%), complications by the use of **antiseptics** as well as benefits from preoperative shower or bathing with antiseptics **should** be examined and considered. Also, except for the studies conducted by Cruse **and** Foord (Cruse, 1981; Cruse & Foord, 1973, 1980), the effectiveness of preoperative **total** bathing or shower has not been shown to reduce the postoperative SSI rates. **Therefore**, more studies about preoperative patients' skin preparation in terms of **reducing** the incidence of SSIs are needed.

Surgical drapes/ gowns. The aim of the use of sterile surgical drapes and **gowns** is to create a barrier between the surgical field and potential sources of bacteria. **Sterile** surgical gowns are worn by all scrubbed operational personnel and sterile **drapes** are used to place over the patients. Although Garibaldi, Maglio, Lerer, Becker, **and** Lyons (1986) conducted a controlled clinical trial and identified that nonwoven **and** disposable gowns and drapes were no better barrier for intraoperative **contamination** or postoperative SSIs than reusable cotton gowns and drapes, the **opposite** results were reported by Moylan, Fitzpatrick, and Davenport (1987).

Recently, Tammelin, Harbraus, and Stahle (2001) compared conventional scrub suits to tightly woven special scrub suits, both of which were made of cotton and polyester, and identified that use of special scrub suits reduced the dispersal of bacteria including Staphylococcus aureus from staff in the operating room. Now several fabric types or characteristics of drapes and gowns are available (Smith & Nichols, 1991). For example, reusable and disposable gowns and drapes are used in the operating room, and also there are several kinds of fabric characteristics of disposable gowns and drapes. Because of this variety of available sterile surgical drapes and gowns, one consistent conclusion cannot be derived from the previous study results.

Principle surgeon. Surgical technique or skill has been believed to be an important risk factor for the development of postoperative SSIs, but it has been difficult for researchers to identify the relationship between the surgeon's technique and the rate of SSIs. Effective hemostasis, maintenance of an adequate blood supply, removal of all devitalized tissue, obliteration of dead space, use of fine nonabsorbed suture material, and wound closure without tension are held as basic to the practice of modern surgery and to the prevention of postoperative SSIs (Mayhall, 1993). Some researchers have tried to examine this relationship by comparing the postoperative SSI rates according to principle surgeons. Table 23 shows six studies examined this relationship (Conklin et al., 1988; Lecuona et al., 1998; Medina et al., 1997; Medina-Cuadros et al., 1996; Simchen et al., 1981; Simchen et al., 1990; Tang et al., 2001; Vilar-Compte et al., 2000). From these results, the principle surgeon is an important risk factor for SSIs.

Prophylactic antibiotics. Since antibiotics were introduced in 1950s (Dellinger, 2001), subsequent clinical trials and laboratory studies have demonstrated the usefulness of prophylactic antibiotics. The aim of the use of prophylactic antibiotics is to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm the host defenses (Mangram et al., 1999). The non-specific

Table 23

Results of the Relationship between Principle Surgeon and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Conklin et al., 1988	Coronary artery bypass grafting	Prospective randomized	100	16%	Dr. A	p = .0138	2.39	1.07-5.33 p = .065
Lecuona et al., 1998	General surgery	Prospective cohort	1,103	9.4% ^d	Dr.B ^c Low: 1 ^e Medium: 2.2 High: 2.7	p = .1017	2.23	0.98-5.07 p = .063
Medina et al., 1997	Herniorrhaphy	Prospective cohort	497	8.0%			L 0.16 M:1 H: 1.83	0.03-0.81 0.84-3.96
Medina-Cuadros et al., 1996	General surgery	Prospective cohort	1,483	10.5%	Low:1 ^e Medium: 1.9 High:2.6	1.0-3.5 1.6-4.4		
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	1.5 ^g	0.4-4.9		
Simchen et al., 1990	Hernia surgery	Prospective cohort	1,487	4.6%	1.2 ^h	p = .06	1.8	p = .34
Tang et al., 2001	Elective colorectal resection	Prospective cohort	2,809	4.7%			1.1-3.7	p < .01
Vilar-Corrupte et al., 2000	All surgery	Case-control ⁱ	313:315 j	9.3%	1.55	1.12-2.20 p = .007	1.25	0.76-2.04 p = .90

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Upper: Surgeon A, lower: Surgeon B. ^d Rate of deep surgical site infections. ^e Surgeons were classified into three groups according to their infection rates: low risk (<6%), medium risk (6-10%), and high risk (>10%). Low risk group is a reference group. ^f Test for trend. ^g Team of surgeons. Mixed team versus Seniors only team. ^h Junior residents group and junior and senior residents group versus only senior residents group. ⁱ Case: patients who had surgery with SSIs, Control: patients who had surgery without SSIs. ^j The number of cases : the number of controls.

host defense is critical to prevent SSIs immediately after an organism gains access to the surgical site. As within hours (“the decisive period”), the ultimate size of infectious lesion has been recognized to be determined, reduction or block of the host defense systems during this critical period leads to increase the risk for SSIs.

Therefore, prophylactic antibiotics have to be performed before tissue contamination with organisms in order to increase the host defense systems and to prevent SSIs (Ronald, 1983). It is now accepted as a routine part of surgical procedures in clean-contaminated surgeries and some type of clean surgeries (de Lalla, 2002). In the case of contaminated or dirty operations, bacterial contamination and/or infection has already been occurred before surgeries, therefore not the use of prophylactic antibiotics but the perioperative administration of antibiotics is necessary to treat SSIs.

Nineteen studies examined an association between antibiotic administration including prophylactic antibiotics and SSIs (Table 24). Some studies compared the SSI rates according to presence or absence of prophylactic antibiotics, and others compared the SSI rates according to the efficient protocol of the use of prophylactic antibiotics, such as timing of prophylactic antibiotics (Classen et al., 1992; Lizan-garcia et al., 1997; Trick et al., 2001). From these results, the use of antibiotics non-effectively, excessively, and inappropriately increases the risk for postoperative SSIs. Based on the wound classification of each surgery, the timing of antibiotics administration relative to the time of incision is the most crucial factor in preventing SSIs (Akalin, 2002).

Chemotherapy. Preoperative chemotherapy has been regarded as a possible risk factor for the development of SSIs. Table 25 shows three studies examined an association between chemotherapy and SSIs (Bertin et al., 1998; Penel et al., 2001; Velasco et al., 1998), but only one finding reached statistical significance. Chemotherapy influences on the patient’s immune system. Therefore chemotherapy itself may increase the risks of SSIs, but more studies are needed.

Table 24

Results of the Relationship between Antibiotic Administration and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Classen et al., 1992	Elective clean or clean- contaminated surgery	Prospective cohort	2,847	1.5%	Pre:1		Post: 5.8	2.4-13.8
				0.59%	Peri: 2.4	0.9-7.9	p = .0001	
				1.4%	Post: 5.8	2.6-12.3	1.8-10.4	
Claesson et al., 1995	Colorectal surgery	Prospective cohort	1,079	3.3%	Early: 6.7	2.9-14.7		p = .001
				3.8% ^c				
Killian et al., 2001	Cesarean section	Prospective cohort	765	8.3%		p < .001 ^d		
				7.7%			2.63	1.5-4.6
Kluytmans et al., 1995	Sternotomy	Case-control ^e	40: 120 ^f		0.4 ^g	0.1-0.6		
				9.4% ^h			0.6	
Lecuona et al., 1998	General surgery	Prospective cohort	1,103					
				11.4%				
Lizan-Garcia et al., 1997	General surgery	Prospective cohort	2,237					
				2.8% ^k	4.76	p < .0000 ⁱ	5.28	1.56-17.93
Mah et al., 2001	Cesarean section	Prospective cohort	785		3.0	p = .008 ^j		p = .0076
				8.2%		1.2-7.8	3.09	1.1-9.11
Mehta et al., 1988	Neurosurgery	Prospective cohort	536			p = .02		p < .04
				8.2%			1.01	p > .05
Newman et al., 1988	Median sternotomy	Case-control ^l	68:136 _f	0.7% ^h		Not sig ^m		
				2.3% ^h	0.92 ⁿ	0.33-2.56		
The Parisian Mediastinitis Study Group, 1996	Coronary artery bypass grafting	Prospective cohort	1,830			p > .25		

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Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Richet et al., 1991	Vascular surgery	Prospective cohort	561	4.1%			1.6 ^o	p = .03
Sharpino et al., 1982	Elective hysterectomy	Prospective Cohort	1,125 323 ^p	18% 8% ^o	1.88	1.32-2.6		p < .001
Simchen et al., 1981	Colon surgery	Prospective cohort	261	24.9%	2.2 ^q	1.1-4.3	2.4	
Simchen et al., 1984	Orthopedic surgery	Prospective cohort	376	4.8%	2.2	p = .1		
Simchen et al., 1990	Hernia surgery	Prospective cohort	1,487	4.6%			1.6	p = .4
Slaughter, Olson, Lee, & Ward, 1993	Coronary artery bypass operation	Prospective cohort ^r	2,402	5%		p = .56		
Trick et al., 2000	Coronary artery bypass grafting	Case-control ^s	30: 90 _f	1.7%	3.0 ^t	1.0-8.7 ^t p = .02	5.0 ^v	1.4-17 ^v p = .02
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort	1,205	26.3%	1.3			
Vilar-Compte et al., 2000	All surgery	Case-control ^w	313:315 _f	9.3%	1.62	1-2.64	1.4	0.77-2.65 p = .25

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Overall surgical site infection (SSI) rate- 1.5%, SSI rate of patients who were given antibiotics 0 to 2 hours before initial surgical incision (pre)- 0.59%, SSI rate of patients who were given antibiotics within 3 hours incision (peri)- 1.4%, SSI rate of patients who were given antibiotics more than 3 hours after incision (post)- 3.3%, SSI rate of patients who were given antibiotics 2 to 24 hours before the incision (early)- 3.8%. ^d Not giving Cefuroxime postoperatively versus giving Cefuroxime postoperatively. ^e Case: Patients who had CABG with sternotomy wound infections from which *S.aureus* was cultured, Control: Patients who had CABG without sternotomy wound infections and were matched to cases by proximity of

operation date. ¹ The number of cases : the number of controls. ⁸ Not giving Clindamycin as prophylaxis versus giving Clindamycin as prophylaxis.
^h Rate of deep surgical site infections. ¹ Giving prophylaxis correctly, giving prophylaxis incorrectly, not giving prophylaxis although indicated, and no recommendation. ¹ Giving prophylaxis \geq 2 hours. ^k rate of incisional SSIs. ¹ Case: patients who had median sternotomy with postoperative mediastinitis, Control: patients who had median sternotomy without postoperative mediastinitis and who were selected for each case, matching for sex, age, and date of surgery. ^m None, oral only, parenteral only, and oral and parenteral. ⁿ Not giving antimicrobial therapy within 10 days of operation versus giving antimicrobial therapy within 10 days of operation. ^o Short antimicrobial prophylaxis (three doses of Cefamandole) versus long antimicrobial prophylaxis (8 doses of Cefamandole). ^p Upper: Abdominal hysterectomy, lower: vaginal hysterectomy. ^q Not giving prophylaxis as protocol versus giving prophylaxis as protocol. ^r All patients with SSIs (125) were randomly matched with patients without SSIs (125) for type of operation and month and year of the procedure. ^s Case: Patients who had CABG with deep surgical site infections, Control: Patients who had CABG without infections. ^t Cefuroxime receipt \geq 2 hours before incision or after operation. ^u Cefuroxime receipt \geq 2 hours before incision. ^v Cefuroxime \geq 2 hours before incision vs. Cefuroxime $<$ 2 hours before incision. ^w Case: patients who had surgery with surgical site infections, Control: patients who had surgery without surgical site infections.

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Table 25
Results of the Relationship between Chemotherapy and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value
Bertin et al., 1998	Breast surgery	Case-control ^c	18:37 ^d	4.0%		Not sig		
Penel et al., 2001	Head and neck cancer surgery	Prospective cohort	165 ^e	41.8%	1.83	1.3-2.58 p = .008		
Velasco et al., 1998	Cancer patients with operative procedure	Prospective cohort study	1,205	26.3%	1.2	0.66-2.05		

Note. ^aRelative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Case: patients who had breast surgery with surgical wound infections, Control: patients who were selected randomly from a list of consecutive patients who had breast surgery without surgical site infections. ^d The number of cases : the number of controls. ^e 165 consecutive procedures were performed on 160 patients.

Transfusion. Perioperative blood transfusions have been recognized as an independent risk factor for postoperative SSIs (Houbiers et al., 1997; Tartter, 1989; Triulzi, Vanek, Rayn & Blumberg, 1992; Wobbes, Bemelmans, Kuypers, Beerthuizen, & Theeuwes, 1990), because it alters the host immune system. However, despite of the results that the use of homologous whole bloods was a significant predictor of postoperative SSI (Fernandez, Gottlieb, & Menitove, 1992), Ford, VanMoorleghem, and Menlove (1993) found that postoperative administration of packed red cells was an independent predictor of SSIs. From the results of the previous studies (Table 26), perioperative blood transfusion itself increases the risk of postoperative SSIs. However, because of the inconsistent findings due to different kinds of transfusion products, more studies are needed to examine what kinds of blood products increase the risk for postoperative SSIs.

Microorganism Factors/ Agent Factors

Pathogens that cause SSIs are acquired either endogenously from the patient's own flora or exogenously from contact with the surgical personnel or environment. According to the distribution of pathogens isolated from SSIs from 1986 to 1996, reported by the CDC (Mangram et al., 1999), Staphylococcus aureus, coagulase-negative staphylococci, Enterococcus spp. and Esherichia coli are the most frequently isolated pathogens. From 1990 to 1996, the percentage of isolated Staphylococcus aureus was 20%, coagulase-negative staphylococci 14%, Enterococcus spp. 12% and Esherichia coli 8%. These are endogenous pathogens, which are the microorganisms in the patients' normal flora, and are the primary etiologic agent for SSIs (Emori & Gaynes, 1993). The Surgical Wound Infection Task Force, a group composed of members of experts of the area of SSIs, published a consensus paper about issues around SSIs in 1992 (Sherertz, et al., 1992). In the consensus paper, endogenous contamination of wounds is the most important source of intraoperative microbial contamination. The endogenous sources consist essentially of the indigenous

Table 26

Results of the Relationship between Transfusion and SSIs

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value	Blood product
Braga et al., 1992	Gastric, colorectal, or pancreatic cancer patients with surgical procedures	Prospective cohort	215	28%	0:1 <500 : 1.94 500-1000: 2.39 >1000ml : 4.69	p = .55 p = .3 p < .05	2.32 2.34 6.49	p < .05	PRBC ; Plasma
Classson et al., 1995	Colorectal surgery	Prospective cohort	1,079	8.3%		p < .001			# of units
Conklin et al., 1988	Coronary artery bypass operation	Prospective randomized	100	16%		p = .0641	2.14	0.83-5.48	# of units
El Oakley et al., 1997	Median sternotomy	Prospective cohort	4,043	0.4% ^d			2.48 ^e	1.82-3.39	# of units
Fernandez et al., 1992	Orthopedic surgery	Retrospective cohort	376	6.1%		p = .023 ^f			^g
Ford et al., 1993	Colon cancer surgery	Retrospective cohort	N/M	N/M		PR: .0065 WB: .0088	PR: 3.4		PRBC, whole blood Yes/No
He et al., 1994	Sternotomy	Prospective cohort	199	2.45%				p = .5941	
Ottino et al., 1987	Open-heart surgery	Prospective cohort	2,579	1.86% ^h		p = .0001		p = .031	# of units
Simchen et al., 1990	Hernia surgery	Prospective cohort	1,487	4.6%	9.1	p < .001			Yes/No

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Table cont.

Source	Type of surgery	Design	N	SSI rate	RR ^a	95%CI p-value	AOR ^b	95%CI p-value	Blood product
Tang et al., 2001	Elective colorectal resection	Prospective cohort	2,809	4.7%		0:1 1-3unit: 2	1.1-3.3 p < .05		PRBC or whole blood
Vuorisalo et al., 1998	Coronary artery bypass grafting	Randomized clinical	884	19.5%		>=4 unit : 6.2	4.2-10.2 p < .001	p = .825	# of units

Note. ^a Relative Risk or Crude Odds Ratio in univariate analysis. ^b Adjusted Odds Ratio in multiple logistic regression analysis. ^c Packed red blood cells. ^d Rate of mediastinitis. ^e Administration of 3 or more units of blood transfusion. ^f Units of blood between infected and non-infected groups. ^g # of units, the source(autologous or homologous) and whether whole blood or packed red cells. ^h Rate of mediastinitis and osteomyelitis (deep surgical site infections).

bacterial flora of the alimentary, genitourinary, and respiratory tracts and the skin (Altemeier, Culbertson, & Hummel, 1968).

Exogenous sources of SSIs include surgical personnel, especially members of the surgical team, and the operating room including the ventilation system, all instruments and materials brought to the sterile operation field during a surgery (Wong, 1996). According to the consensus paper by the experts (Sherertz et al., 1992), factors associated with exogenous contamination during an operation were as follows: emergency nature of some procedures, type of skin preparation, razor shavings, bacterial flora of the operation room, use of drains, and the occurrence of glove punctures. Cruse and Foord (1973, 1980) reported that glove punctures during an operation were not associated with the rate of SSIs. Surgical glove perforation during an operation occurred in 34.5% of operations, but did not influence bacterial counts on the surgeons' hands or on the outside of their gloves. Also, there was no evidence that perforation increased wound sepsis (Dodds et al., 1988). The issues of surgical glove punctures should be considered in terms of the prevention of occupational infections among the healthcare personnel as well as SSIs.

Six studies examined an association between intraoperative wound contamination and SSIs collecting bacteriological samples from the surgical incisions at the end of an operation (Claesson & Holmlund, 1988; Claesson et al., 1995; Davidson, Clark et al., 1971; Garibaldi et al., 1991; Mehta et al., 1988; NAS-NRC-ADCT, 1964). From these results, an intraoperative culture was significantly associated with the incidence of SSIs. From the data about isolated pathogens in these studies, endogenous pathogens were a majority of those findings. Opposed to these findings, however, a longitudinal study conducted by Cronquist et al. (2001) identified that neither pre- nor postoperative total colony-forming unit (cfu) counts of endogenous pathogens at the operative sites were associated with subsequent SSIs.

Synthesis

Table 27 presents a summary of the associations between each risk factor and SSIs, which were discussed in this section. Considerable epidemiological evidence has shown that the development of SSIs can be explained by complex interactions among the patient's susceptibility to infection, perioperative, and microbiological factors. However, some risk factors are intercorrelated and confounded by other factors. Therefore, most risk factors interact and it is difficult to determine the true underlying structure for developing SSIs, which researchers are eager to identify in their studies. The amount that each risk factor contributes uniquely to that underlying structure would likely decrease because of this overlap among risk factors. For example, the ASA score, which indicates a patient's severity of illness, is an independent risk factor for SSIs. This risk factor also would be an alternative marker for underlying diseases such as malignancy, diabetes mellitus, malnutrition, or alcohol abuse. This indicates that a significant intercorrelation between the ASA score and each of those factors might be identified. However, in the majority of the research articles reviewed in this section, crude RR or OR, not adjusted OR, were used to examine the effect of each risk factor on SSIs. This is one of the limitations of this literature review.

On the other hand, contrary to multicollinearity among risk factors, there might be some unrelated and uncorrelated risk factors that could uniquely contribute to the underlying structure for the development of SSIs after the specific type of surgical procedures. For example, chronic obstructive pulmonary disease (COPD), reoperation, and tracheostomy have been identified as statistically significant risk factors for SSIs among patients undergoing cardiac surgery (Borger et al., 1998; Curtis et al., 2001; Vuorisalo et al., 1998). The number of prenatal care visits, the hours of ruptured membranes, and pregnancy body mass index ($PBMI = [\text{weight} - 51] / \text{height}$, in kg/ m²) were identified to increase significantly the risk of SSIs following cesarean

Table 27
 Summary of Associations between Risk Factors and SSIs

Risk factor	Consistency	Independence	Strength	Biological Plausibility	Level of association
Age (older)	○	○	△	△	○
Gender	○	△	△	×	△
Race	×	△	○	×	△
ASA score	○	○	○	△	○
Obesity	○	○	○	○	○
Malnutrition (serum albumin)	○	△	△	△	△
Diabetes mellitus	○	○	○	○	○
Remote infections	○	△	○	○	○
Malignancy	○	△	△	△	△
Immunosuppressive drug use	○	×	△	△	△
Nasal contamination	×	×	×	×	×
Perioperative temperature	△	△	○	○	○
Abdominal surgery	○	△	○	○	○
Duration of preoperative stay	○	○	△	△	○
Smoking	○	△	○	○	○
Alcohol	×	×	△	△	△
Psychosocial factors	×	×	×	△	×
Duration of operation	○	○	○	△	○
Number of operations	△	△	○	△	△
Urgency of operation	○	△	△	△	△
Month of year	△	△	△	×	△
Time of day	△	△	×	×	×
Wound classification system	○	○	○	○	○

Table 27 cont.

Risk factor	Consistency	Independence	Strength	Biological plausibility	Level of association
Wound drains	○	○	○	○	○
Preoperative shaving	○	△	△	○	○
Preoperative patient's skin preparation	△	△	△	△	△
Surgeons	○	○	○	△	○
Prophylactic antibiotics	○	○	○	○	○
Chemotherapy	△	×	×	△	×
Transfusion	○	○	△	○	○

Note. Consistency: statistically significant positive associations between risk factors and SSIs using univariate analysis,

○ more than three studies, △ one or two studies, × no study.

Independence: statistically significant positive associations between risk factors and SSIs using multivariate analysis,

○ more than three studies, △ one or two studies, × no study.

Strength: a crude RR or OR well above 1 in each study, or AOR above 5 in one study

○ AOR above 5 in one study, OR or RR well above 1 in more than 3 studies, △ crude RR or OR above 1 in one or two studies, × no study

Level of association: ○=1, △=0.5, ×=0

○ Total score ≥ 3 (definitely important risk factor for SSIs), △ Total score 1.5-2.5 (likely important risk factor for SSIs)

× Total score 0-1 (possible important risk factor for SSIs)

section (Horan, Culver, Gaynes, & National Nosocomial Infections Surveillance system, 1996; Killian et al., 2001).

Although various risk factors influence the incidence of SSIs, it is impossible to assess all risk factors preoperatively. Therefore, several combinations of the important and independent risk factors for the development of SSIs (“risk index” or “risk model”) have been identified and examined to predict the probability of SSIs or to quantify surgical patients’ risks for SSIs.

Risk Index for Surgical Site Infections

The nosocomial infection rate as well as the mortality rate or the length of hospitalization is an indicator of healthcare quality (Larson, Oram, & Hedrick, 1988). The JCAHO requires hospitals in the United States to participate in a performance measurement system as part of the accreditation process. Currently the JCAHO evaluates 45 performance areas including operative and other invasive procedures and complications from these procedures (JCAHO, 2001). A SSI is one of the complications of surgical procedures. The inter- or intra-hospital comparison of SSI rates cannot be done meaningfully without adjusting for the patient’s susceptibility to infections and the case mix of patients. Therefore, several risk indices have been developed to enable adequate comparisons of the SSI rates by controlling a patient’s underlying conditions or intrinsic risk factors (Culver et al., 1991; Haley, Culver, Morgan et al, 1985; Velasco et al., 1998). According to Haley (1991b), to measure a patient’s intrinsic risk and to account for a patient’s underlying physical condition gives the ability to show the residual variation in the SSI rates reflected by other risk factors. The JCAHO uses one of these risk indices to stratify or classify complicated patients into strata so that they can interpret the SSI rates as an indicator of the quality of care. In addition to the first purpose, the risk indices have been used to distinguish patients who have high risks for the development of SSIs from those with low risks

(Ehrenkranz, 1981; Haley, Culver, Morgan et al., 1985; Hooton, Haley, & Culver, 1980; Hooton et al., 1981; Richet et al., 1991). Infection control practitioners can conduct effective surveillance and focus on preventive measures for these high-risk patients. In this section, two standardized, two empirical risk indices, and seven models for predicting the risk of postoperative SSIs were reviewed.

Characteristics of Risk Index

To accomplish the above purposes, a satisfactory risk index would have certain characteristics (Haley, 1991b; Roy & Perl, 1997). First, a risk index represents all of the important underlying risk constructs or dimensions. Researchers should start with a pool of various risk factors for developing SSIs. Using adequate univariate analysis techniques, the impact of each risk factor on the incidence of SSIs and the interaction between risk factors would be examined. Second, a risk index is simple and practical. By using multivariate analysis techniques, independent and important risk factors for a risk index can be determined, and the set of risk factors for a risk index can be reduced. The information about the set of risk factors included in a risk index should be obtained at the end of an operation because of its predictability of postoperative SSIs. Third, a risk index has a weighting scheme. Each risk factor of a risk index weighted and a total score of a risk index for an individual patient can be calculated at the end of an operation. The total scores of a risk index are used to discriminate between patients with high and low risks for SSIs. Finally, the validity of a risk index should be verified using another sample. In this dissertation, the term “model” or “equation” is only used when researchers identified the set of the independent risk factors for SSIs using multivariate analysis. The major difference between a risk index and a risk model in the literature is whether or not it has a weighting scheme.

Standardized Risk Indices

Table 28 presents the two standardized risk indices, the SENIC and the NNIS

Table 28

Standardized Risk Indices for SSIs

	Sample size	Components	β	p	Predictive power
SENIC risk index (1985)	58,498	1) abdominal operation	1.12	< .0001	$\gamma = .70$ (the first sample),
	59,352 (patients)	2) operation lasting more than 2 hours	1.04	< .0001	.67 (the second sample)
		3) contaminated or dirty-infected operation	1.04	< .0001	(Wound classification system: $\gamma = .36$)
		4) having more than 3 diagnoses at patient's discharge	0.86	< .0001	
NNIS risk index (1991)	84,691 (operations)	1) ASA score of 3, 4, or 5	NA	NA	$\gamma = .44$
		2) Contaminated or dirty-infected operation			(Wound classification system: $\gamma = .30$)
		3) an operation lasting over T hours, where T depends on the operative procedure being performed			ASA physical status score: $\gamma = .34$)

Note. SENIC = Study on the Efficacy of Nosocomial Infection Control ; NNIS = National Nosocomial Infection Surveillance.

risk indices for SSIs.

SENIC Risk Index

In 1974, the CDC initiated the 10-year SENIC project, and one of the purposes of this project was to establish a simple risk index for SSIs, using a nationwide sample of 58,498 surgical patients (Haley, Culver, Morgan et al., 1985). The following four factors were identified as important components: 1) having an operation which involves the abdomen, 2) having an operation which lasts more than 2 hours, 3) having an operation which is classified as either contaminated or dirty-infected in the wound classification system, and 4) having three or more underlying diagnoses at the time of discharge after the operation. Considering the values of beta-coefficient, each of these is equally weighted and contributes a point when present. The range of this risk index is from 0 to 4. The validity of the SENIC risk index was verified in a prospective study using another sample of 59,352 surgical patients (Haley, Culver, Morgan et al., 1985). The predictability of the SENIC risk index was examined by calculating the Goodman-Kruskal G nonparametric coefficient. This statistic indicates the power of the risk index to predict postoperative SSIs. The Goodman-Kruskal G statistics were .70 in the first sample and .67 in the second sample, indicating high predictive power (Goodman & Kruskal, 1954; Haley, 1993). After the development of the SENIC risk index, few studies examined its reproducibility. Valle et al. (1999) conducted a prospective cohort study of 1,019 surgical patients to evaluate the reproducibility of the SENIC risk index at a university hospital in Spain. The results of this study (Table 29) showed a good reproducibility of the SENIC risk index. The researchers confirmed that by calculating the predictive power, the Goodman-Kruskal G statistic, the SENIC risk index showed a greater predictability than the wound classification system.

NNIS Risk Index

One of the NNIS projects was the study conducted by Culver et al. (1991),

Table 29

Reproducibility of the SENIC Risk Index

Design	Sample	Variables	β	SE	AOR (95%CI)	p	Predictive power
1-year prospective cohort	*1,019	1) Abdominal operation	1.44	.45	4.22 (1.76-10.10)	<.001	γ for the SENIC risk index =.81
		2) Operation lasting more than 2 hours	1.28	.24	3.61 (2.24-5.81)	<.001	γ for wound classification system = .74
		3) Contaminated or dirty- infected operation	1.54	.25	6.97 (4.32-11.26)	<.001	
		4) having more than 3 diagnoses at patient's discharge	1.37	.38	3.95 (1.86-8.40)	<.001	
		Constant	-4.45	.43		<.001	

Note. AOR = Adjusted Odds Ratio in multivariate analysis. ^a Patients underwent surgical procedures with hospitalization longer than 48 hours. From "Evaluation of the SENIC risk index in a Spanish university hospital," by V. Valls et al., 1999, *Infection Control and Hospital Epidemiology*, 20, 198.

which modified the SENIC risk index (Haley, Culver, Morgan et al., 1985) and developed the NNIS index, using the 84,691 operations which took place in the 44 hospitals where the nosocomial infection rates were reported to the CDC. The range of values in the NNIS risk index is from 0 to 3, and it consists of the following equally weighted three factors: 1) an ASA score greater than 3, 2) an operation classified as either contaminated or dirty-infected in the wound classification system, and 3) an operation with surgery duration more than T hours, where T is the 75th percentile of the distributions of duration of each operation being performed. The Goodman – Kruskal G statistic for the NNIS risk index was .44. Unfortunately, the validity of the NNIS risk index was not evaluated prospectively using another sample.

Besides the SENIC risk index, few studies have examined the reproducibility of the NNIS risk index. Roy, Herwaldt, Embrey, Kuhns, and Wenzel (2000) conducted a case-control study using 201 case and 398 control patients. A case was defined as any patient who underwent cardiothoracic surgery during the study period, and whose wound met the definitions of SSIs. The cases and controls were matched by age, gender, type of procedure, date of procedure, and past history of myocardial infarction.

Table 30 presents the result of the distribution of the NNIS risk index scores. Patients with a NNIS risk index score greater or equal to 2 were 1.8 times more likely to develop SSIs than those with a NNIS risk index score less than 2 (OR = 1.83; 95%CI = 1.14-2.94, $p = .01$). From the result presented in Table 31, however, Roy and his colleagues concluded that the NNIS risk index could stratify the risk of SSIs in cardiothoracic surgical patients by only one factor, that is an operation with surgery duration of more than T hours. In “Guideline for Prevention of Surgical Site Infection,” Mangram et al. (1999) pointed out the weakness of the NNIS risk index, that is the limited ability to discriminate the SSI risk of all types of operations. Some researchers have tried to develop risk indices for the population undergoing the

specific operative procedures, such as patients who were undergoing cesarean sections (Horan et al., 1996), patients with abdominal trauma (Nichols et al., 1984), or cancer patients with general surgery (Velasco et al. 1998).

Table 30

Distribution of the NNIS Risk Index Scores among Cardiothoracic Surgical Patients

NNIS risk index score	Case	Control
0	5 (3%)	15 (4%)
1	148 (74%)	320 (80%)
2	48 (24%)	63 (16%)
3	0	0
	201 (100%)	398 (100%)

Note. From “Does the Centers for Disease Control’s NNIS system risk index stratify patients undergoing cardiothoracic operations by their risk of surgical-site infection?” by M-C, Roy et al., 2000, Infection Control and Hospital Epidemiology, 21, 187.

Table 31

Characteristics of Cases and Controls

	Cases	Controls	p-value
Procedure duration (median)			
Total duration (min)	245	228	.008
Time on cardiopulmonary bypass (min)	117	108	.029
Components of NNIS risk index			
Wound class clean (%)	201 (100%)	398 (100%)	Not sig
ASA score >=3	196 (98%)	382 (98%)	Not sig
“T” > 75th percentile	48 (24%)	69 (16%)	.026

Note. From “Does the Centers for Disease Control’s NNIS system risk index stratify patients undergoing cardiothoracic operations by their risk of surgical-site infection?” by M-C, Roy et al., 2000, Infection Control and Hospital Epidemiology, 21, 187.

Comparison between the SENIC and the NNIS Risk Indices

Table 32 presents the results of comparison between the SENIC and NNIS risk indices. The Surgical Wound Infection Task Force, a group composed of representatives of the Society for Hospital Epidemiology of America, the Association for Practitioners in Infection Control, the Surgical Infection Society, and the CDC,

reviewed and evaluated the NNIS system including the NNIS and the SENIC risk indices, and a consensus paper was published (Sherertz et al., 1992). Through this consensus of experts, the content validity of the risk indices was examined. They concluded that the NNIS risk index was the best way to stratify SSI data, and that a second valid approach to the stratification of SSI data was the SENIC risk index. The use of discharge diagnoses makes the SENIC risk index less practical than the NNIS risk index.

Table 32

Comparison between the SENIC and the NNIS Risk Indices

	SENIC risk index	NNIS risk index
Sample	58,498 patients	84,691 operations
SSI rate	4.1%	2.8%
A pool of risk factors	Yes	No
Simplicity	Yes	Yes
Availability	The number of diagnoses at the discharge: No	Yes
Multivariate analysis	Yes	No
Weighting scheme	Yes	Yes
Verification of the validity of the index	Yes	No
Predictability	59,352 patients $\gamma = .70$ (the first sample), .67 (the second sample) Wound classification system $\gamma = .36$	$\gamma = .44$ Wound classification system $\gamma = .30$
Reproducibility	Good	Not good

Both risk indices have been identified as good predictors for postoperative mortality (Delgado-Rodriguez, et al., 1999), nosocomial sepsis (Farinas-Alvarez, Farinas, Peieto, & Delgado-Rodriguez, 2000), and SSIs (Delgado-Rodriguez et al., 1997) in surgical patients. Delgado-Rodriguez, Sillero-Arenas, Medina-Cuadros, and Martinex-Gallego (1997) conducted a prospective cohort study of 1,483 patients who

underwent general surgery (80% patients underwent abdominal surgery), and concluded that the NNIS risk index had a better discriminate power for the risk of SSIs than the SENIC risk index. However, Haley (1993) found that the predictive power for SSIs of the NNIS risk index was substantially less than that of the SENIC risk index, when both indices were compared using the original databases. The sample size and the characteristics of the sample of the study conducted by Delgado-Rodriguez et al. (1997) were completely different from the original samples with which the NNIS and the SENIC risk index were developed (Culver et al., 1991; Haley, Culver, Morgan et al., 1985). Therefore, because of the limited studies on comparing the discriminative powers for the risk of SSIs by the SENIC and the NNIS risk indices, it can not be concluded that the one risk index has a better predictive power than the other.

Empirical Models for Surgical Site Infections

In addition to the standardized risk indices, some researchers have identified models of risk factors or developed empirical risk indices for SSIs among specific patient populations using multivariate analysis. Lidwell (1961) was the first researcher who used multiple logistic regression analysis to identify risk factors for postoperative sepsis among 3,000 surgical patients in England. Logistic regression describes the relationship of several independent variables to a single dichotomous dependent variable, and yields a predictive equation or model (Kleinbaum, 1994). The statistics of the goodness-of-fit for the final model were statistically satisfactory ($\chi^2 = 49.9$, $p = 0.01$). Twelve factors were included in the model. Except for age, the rest of factors were related to an operation or a procedure performed.

The study conducted by Davidson, Clark et al. (1971), with a sample of 1000 patients undergoing general surgery, identified a model of risk factors for SSIs. The final predictors for the logistic regression model were bacteria in the wound, dirty surgery, old environment (a large multi-bed Nightingale unit), age of patient, and the

duration of operation. The results of the Wald test, a testing for the significance of the model, were presented (Hosmer & Lemeshow, 1989). They also tested the goodness-of-fit for the model using a classification table (Hosmer & Lemeshow, 1989; Polit, 1996). The overall rate of correct classification, 78.2%, was estimated as a predictive probability, with 71.7% of the infected cases and 79.3% of the uninfected cases being correctly classified. Although the overall model was statistically significant and the classification rates of this model were relatively high, the environmental component of this model was not appropriate for the well-controlled modern hospital environment.

Shapiro et al. (1982) prospectively studied the risk factors for SSIs among 1,448 patients who underwent vaginal or abdominal hysterectomy. They identified a logistic regression model for the risk for SSIs, and the final model was evaluated by the Wald test. Duration of operation as one of the components of the final model was not statistically significant after the interaction between duration of operation and prophylaxis was entered into the model, however, the researchers retained it in the model. Although the appropriateness of the model was evaluated by using the idea of the Hosmer-Lemeshow test (Hosmer & Lemeshow, 1989) and the researchers concluded that the final model fitted their data well, the result of this test and the corresponding p-value were not presented.

Bibby, Collins, and Ayliffe (1986) developed a mathematical model for calculating the probability of postoperative SSIs by performing second analysis of a prevalence study of 1,980 patients and an incidence study of 1,331 patients who underwent all types of surgery. At the same time, Pelle et al. (1986) conducted a prospective multi-center study among 1,032 patients who underwent cesarean sections to identify a logistic regression equation for the probability of postoperative SSIs. In both studies, statistical results of the tests of the logistic regression equations and the goodness-of-fit for the overall models were not presented.

Christou et al., (1987) conducted a prospective cohort study of 404 surgical patients to evaluate the contribution of altered host defense to the risk for developing a SSI and to identify a logistic regression model for the probability of a SSI for each patient. The model was comprised of the following factors: serum albumin level, age, duration of operation, delayed hypersensitivity test score (DHT), and intrinsic wound contamination level. Patient age, serum albumin level, and DHT were included as objective measurements of the patient's defense capability against infection in this study. Multiple indicators can measure the patient's susceptibility to infection more precisely than a single indicator. Using another matched same-size sample of surgical patients, the validity of this model was examined. Although the results of the goodness-of-fit for this model were statistically satisfactory ($\chi^2 = 66.6$, $p < .001$), one component of this equation, DHT, was not a practical indicator for the clinical settings.

To identify several independent risk factors for stratifying patients, Garibaldi et al. (1991) conducted a prospective cohort study of 1,852 surgical patients with skin incision greater than 6 cm in length. The wound classification introduced by the NAS-NRC-AHCT study (1964), duration of operation longer than 120 minutes, intraoperative contamination, and the ASA score greater than 3 were entered into a logistic regression model. Except for intraoperative contamination, the rest of the factors included in the model were the same components as those of the NNIS risk index. As the researchers pointed out, because there was a significant association between the positive intraoperative culture and the wound classification, it was better to compare the final model to the reduced model without the factor of intraoperative contamination in terms of the ability to predict the probability of postoperative SSIs. In addition, in terms of the availability, intraoperative culture might not be a routine procedure at most hospitals in the United States. Therefore, the value of intraoperative culture would be limited.

The following two studies developed the risk indices for the specific patient population in order to identify patients with high risk of postoperative SSIs. Richet et al. (1991) conducted a prospective study of 561 vascular surgery patients. Five variables were identified as independent risk factors for SSIs by using logistic regression analysis: surgery on lower extremities, delayed surgery, diabetes mellitus, past history of vascular surgery, and short antimicrobial prophylaxis. According to the p-values of the Wald test, all variables in this model were significantly associated with the probability of postoperative SSIs. Using the results of logistic regression analysis, each variable was equally weighted and the total score of the risk index for an individual patient was determined by adding the number of these variables when present. The range of this risk index was from 0 to 5. There was a statistically significant association between the scores of the risk index and the probability of postoperative SSIs ($p = .00002$). A few points, however, have to be pointed out. First, it is about a weighting scheme. Considering the various values of beta-coefficient, it is not appropriate to weight surgery on lower extremities ($AOR = 231, \beta = 5.44$) and short antimicrobial prophylaxis ($AOR = 1.6, \beta = 0.47$) equally. Second, short antimicrobial prophylaxis was entered into the final model, because one of the aims of this study was to compare two regimens of antimicrobial prophylaxis (short versus long). Therefore, this factor is not practical or realistic at the clinical settings because the usage of antimicrobial prophylaxis is usually controlled by a strict protocol or standard at each hospital.

The aims of a prospective cohort study conducted by Velasco et al. (1998) were to develop a risk index for the prediction of SSIs in cancer patients with operative procedures and to identify those with high risk of postoperative SSIs. Logistic regression analysis identified the following six independent risk factors for the final model: contaminated and infected in the wound classification introduced by the NAS-NRC-AHCT study (1964), duration of operation greater than 280 minutes, male sex,

prior radiotherapy, the ASA score greater than 3, and prophylaxis not as protocol. The statistical results of the significance of the overall model and the goodness-of-fit were not presented. To develop a risk index, each factor in the model weighted according to the values of beta-coefficient, and the total scores ranged from 0 to 17. There was a statistically significant positive correlation between the total scores of the risk index and the SSI rates ($r = .92$, $p = .001$). Moreover, the sensitivity and specificity of this risk index were calculated. The best prediction of SSIs by this risk index was reached at the total score greater than 9, with a sensitivity of 60.8% and a specificity of 74.8%.

Table 33 shows the findings of the studies on the empirical risk models or indices for postoperative SSIs that have been discussed in this section. Except for two studies conducted by Richet et al. (1991) and Velasco et al. (1998), the aims of each study were not to develop an ideal risk index, but to identify the risk factors that uniquely contributed to the development of SSIs among the specific type of operations. The reason why epidemiological researchers, in particular infection control epidemiologists, have been eager to identify the independent risk factors for SSIs is to quantify their risks and to identify patients with high risk of SSIs in order to compare the SSI rates at intra- and inter-hospitals. Only Christou et al. (1987), however, verified the validity of the risk model for SSIs using another sample. Some researchers did not present the statistical results of the significance of the model itself and the goodness-of-fit of the final model. Due to the limited applicability, none of the results has been widely used in SSI surveillance data analysis or epidemiological research.

Synthesis

In this section, two standardized, two empirical risk indices, and seven models for predicting the risks for postoperative SSIs were reviewed in terms of the criteria that an ideal risk index has to satisfy. How to measure the patient's susceptibility to

Table 33

Summary of the Studies of Empirical Risk Model or Index for SSIs

Author	A pool of risk factors (#)	# of factors	Indicator for susceptibility to infection	Usefulness	Evaluation of the final model	Weighting scheme	Validity
Lidwell, 1961	NP	12	Age	○	χ^2 test $p = .01$	NA	NA
Davidson et al., 1971	○ (15)	5	Age	× environmental factor △ intraoperative culture	Wald test Classification table	NA	NA
Shapiro et al., 1982	○ (12)	6	Age	○	Wald test	NA	NA
Bibby et al., 1986	○ (36)	5	Age, Sex, Special risk	○	NP	NA	NA
Pelle et al., 1986	○ (26)	3	Weight	○	NP	NA	NA
Christou et al., 1987	○ (8)	5	Serum albumin DHT score, Age	× DHT score	Wald test	NA	○
Garibaldi et al., 1991	○ (25)	4	ASA score	△ intraoperative culture	χ^2 test $p < .001$ Wald test	NA	NA
Richet et al., 1991	○ (24)	5	DM Past history of vascular surgery	× regimens of prophylaxis (long vs short)	Wald test	△	NA
Velasco et al., 1998	○ (13)	6	Sex ASA score Prior radiotherapy	○	NP	○	NA

Note. ○: satisfactory, △: satisfactory with some limitations, ×: not satisfactory. NP= not presented. NA= not applicable.

SSIs validly and precisely is an essential component of the ideal risk index. Various variables were identified as a marker for the patient's susceptibility to infection, including the ASA score and the number of discharge diagnoses. Some of them, such as serum albumin and DHT score, are objective measurements of the patient's defense capability to infection (Christou et al., 1987), however, most of the variables that were identified as a marker of the patient's susceptibility to infection by logistic regression analysis could not measure precisely the patient's resistance to SSIs. Consequently, a more precise indicator or multiple indicators for the patient's susceptibility to SSIs should be examined in future studies.

An ideal or tenable risk index can stratify surgical patients according to their risks for postoperative SSIs at the end of the operation, and help health care professionals identify the high risk population to whom they have to give their attention and provide some effective control measures to reduce SSIs. In reality, however, the risk indices or models for SSIs introduced in this section have been used to measure predictors or risks and to compare the SSI rates among inter- or intrahospitals retrospectively after the SSIs have occurred, and not used as a clinical tool for targeting high-risk patients for SSIs before patient's discharge from hospitals. As one of the purposes of the risk index is to discriminate between patients with and without risks of postoperative SSIs, there is a great possibility that the practical risk index with more discriminate power can be used by infection control personnel as well as clinical nursing staff in order to assess each patient's risk for postoperative SSIs at the end of the operation or before their discharge from the hospitals.

Hopf et al. (1997) conducted a prospective observational study of 130 patients who underwent general surgery and identified the subcutaneous wound oxygen tension as a more powerful predictor for SSIs than the SENIC risk index. Intraoperative hypothermia causes a decrease of the availability of tissue oxygen at the surgical sites. Therefore, hypothermia or in combination with other markers, may predict the

patient's susceptibility more precisely and objectively than the currently used markers, such as a high ASA score of the NNIS risk index, or the number of discharge diagnoses of the SENIC risk index.

Research Questions

By conducting a total medical chart review of patients who underwent general abdominal surgery at the regional trauma center, the investigator proposes to determine the impact of perioperative temperature on prediction of postoperative SSIs. The current extant risk indices, the SENIC and the NNIS risk indices, and a modified risk index, in which a factor related to perioperative temperature is added to the extant risk indices, are compared in terms of predictability of SSIs.

Research question 1. What is the SSI rate among patients who underwent general abdominal surgery?

Research question 2. Are there any significant differences in perioperative temperatures between patients with and without SSIs?

Ho1: There are no differences in the initial, final, and lowest intraoperative core temperatures between surgical patients with and without SSIs.

Ho2: There are no differences in duration of the intraoperative core temperatures less than 35°C between surgical patients with and without SSIs.

Ho3: There are no differences in the changes between the initial and final core temperatures during an operation between surgical patients with and without SSIs.

Ho4: There are no differences in the changes between the initial and lowest intraoperative core temperatures between surgical patients with and without SSIs.

Research question 3. Are there any significant differences in discriminative powers for SSIs among the SENIC risk index, the NNIS risk index, and a modified risk index, in which a factor related to perioperative temperature adds to the SENIC and NNIS risk indices?

H_{o5}: There are no differences in discriminative powers for SSIs between the SENIC risk index and a modified risk index.

H_{o6}: There are no differences in discriminative powers for SSIs between the NNIS risk index and a modified risk index.

CHAPTER III

RESEACH METHODOLOGY

This chapter describes the design of the study, the setting, the sample, the data collection methods, the data analyses used, and potential biases. Definitions of the variables for this dissertation are also described.

Study Design

Using a retrospective cohort study design, abdominal surgical patients aged older than 18 years old, who underwent exploratory laparotomy, large and small bowel surgeries at San Francisco General Hospital (SFGH) between January 1, 2000 and June 30, 2001 were followed by a total medical chart review. According to the operating room database of 1999 at SFGH, these three operations were major general surgeries involving the abdomen, which were performed at SFGH. From 1988, a laparoscope has used with increasing frequency to perform a variety of procedures including cholecystectomy (66%), appendectomy (19%), and colectomy (3%) (CDC NNIS system, 2000). At SFGH, a laparoscopic approach was used in the following general surgery in 1999: cholecystectomy 75, colectomy 7, gastrotomy 3, and bowel surgery 1. Laparoscopic general surgeries were excluded from this study, because it is reported that the use of a laparoscope reduced substantial risks of postoperative SSIs (Gaynes et al., 2001), and that the magnitude of patients' physical stress and the effect on postoperative immunological responses by a laparoscopic approach are different from those of laparotomy (Sietses et al., 1999).

Cohort Study Design

Cummings, Newman, & Hulley (2001) explained that "cohort" was the Roman term for a group of soldiers that marched together, and that in clinical research, it means a group of subjects followed over time. A cohort study design is a study in which

subjects who are initially free from the disease or outcome of interest and are followed over a certain time of period for the occurrence of the disease or outcome. This study design has two purposes: to describe the incidence of certain outcomes over time and to analyze associations between predictors or risk factors and those outcomes (Cummings et al., 2001).

There are two variations: prospective and retrospective. One study of the SENIC project examined the sensitivity and specificity of retrospective chart review to identify nosocomial infections compared to prospective surveillance method (Haley, Schaberg, McClish et al., 1980). From the epidemiological point of view, in a prospective design, researchers define the sample and measure predictor variables or risk factors before nosocomial infections have occurred, and follow the sample for the specific time period in order to judge whether or not nosocomial infections occur. In the retrospective method, researchers define the sample and collect all data related to predictor variables as well as the incidence of nosocomial infections after nosocomial infections have already occurred (Cummings et al., 2001). Haley, Schaberg, McClish et al. identified that the sensitivity of retrospective chart review was 0.74, whereas the sensitivity of prospective surveillance method was 0.76. The specificity of retrospective chart review was 0.967.

Even in a retrospective cohort study design, predictor variables or risk factors precede the outcome, and it ensures the time sequence between risk factors and the outcome. Therefore, a cohort study design is the appropriate research method to study the effects of a predictor of interest (Elwood, 1998). Moreover, this method enables to observe or collect the data of multiple effects of predictors on a single outcome. In this dissertation project, the incidence of SSIs is the outcome of interest, and the comparison between patients with and without SSIs is conducted to examine the impact of perioperative temperature on the incidence of SSIs. Because of the time relationship, the data of risk factors for SSIs cannot be biased by knowledge of which patients have

developed SSIs. In a retrospective cohort design, this is strengthened by care in identifying the sample and gathering risk factor data without knowledge of the outcome, even though the outcome has already occurred. A major disadvantage of a prospective cohort study is related to the time required and cost. However, a retrospective cohort design can overcome these disadvantages, because the sample of subjects are already assembled, the data of risk factors can be available, and the follow-up period has already taken place (Cummings et al., 2001).

Research Setting and Sample

SFGH is one of the affiliated hospitals with University of California at San Francisco (UCSF), and one of four main sites of patient care services offered by UCSF. SFGH is the city's municipal hospital and only level-1 trauma center situated in southeastern San Francisco. SFGH has a long history of serving the population of San Francisco regardless of the ability to pay for care and is nationally recognized for its research programs in HIV disease, lung biology, and tuberculosis (UCSF, 2002). The sample recruitment was conducted by using the computerized registry database of the operating room department of SFGH during the time period 01/01/2000-06/30/2001.

Inclusion and Exclusion Criteria (Definition of the Study Sample)

The inclusion criteria for this study were: 1) the first time undergoing general abdominal surgery during the study period, 2) age equal to or more than 18 years old at the time of surgery, and 3) patients who could be followed up for 30 days after surgery. Patients would be excluded from the study for the following reasons: 1) use of only laparoscopic approach during surgery, 2) reoperation not for treatment of SSIs during a single hospitalization, 3) any history of remote infections before surgery, and 4) patients who could not followed up within 30 days after surgery (e.g., death or transfer to another healthcare institution). However, if patients were diagnosed or developed SSIs before their death or transfer, those cases were included in the sample for this study. Approval

from the committee on Human Subjects was obtained for this dissertation project on September 19, 2001 (UCSF CHR Approval Number H7085-19487-01).

Sample Size Determination

Power analyses were conducted using nQuery Advisor software (Elashoff, 2000). The third research question of this study was to compare discriminative powers between the standard risk index (the SENIC or NNIS risk index) and a modified risk index, in which a factor related to perioperative temperature (hypothermia) would add to the standard risk index as an indicator of the patient's susceptibility to SSIs using logistic regression analysis. To calculate the sample size for this study adequately testing the hypothesis that there are no differences in discriminative powers for SSIs between the current extant risk index and a modified risk index among the population of abdominal surgical patients, some assumptions were made in order to estimate the sample size for this study that would give adequate power for statistical significance. As a value of squared correlation of perioperative temperature with included covariates, that is two or three components of the standard risk index, could not be calculated from the available previous research articles, therefore the value of a medium effect size (0.13) was used as a squared correlation or partial squared correlation (Cohen, 1988). Also, because of a limitation of this software, although the reported OR of hypothermia (perioperative temperature) on the incidence of postoperative SSIs was 4.9 (Kurz et al., 1996), 2.5 was the highest value that could be put in this software. Therefore, the SSI rates were underestimated in this power analysis. Assuming that a perioperative temperature factor was being added to the model after adjustment for prior covariates, the components of the standard risk index, that its multiple correlation with covariates already in the model was 0.13, and that the proportion of SSIs at the mean was 6%, with an alpha level = 0.05 and power of 0.80, it was determined that 226 abdominal surgical patients would be needed to detect statistical significance.

Data Collection Process

A total medical chart review of the patients who were eligible for this study was conducted. Primarily the following medical records of each patient were reviewed electronically and manually: administration record, discharge or transfer summary, discharge diagnosis and procedure record, inpatient progress record, nurse's progress record, nurse's admission record, operative record, operating room record, anesthesia record, preoperative evaluation sheet, physician's order sheet, antibiotics use record, outpatient clinic record, physician's emergency room record, nurse's emergency room record, and laboratory data. The following variables (see Table 34) were collected using data collection sheets made by the author.

Outcome Variable

SSIs were determined according to the CDC definitions within 30 days after the operation (Appendix 1). Infections were considered nosocomial in origin if they were not documented or suspected at the time of admission (Garner et al., 1988). The data related to whether a SSI developed or not (yes or no), the category of SSIs (superficial incisional, deep incisional, or organ/space SSIs), and the criteria for defining a SSI were collected. In order to evaluate criteria for SSIs, sufficient evidence of SSIs were also extracted, such as physicians' descriptions of signs and symptoms of SSIs in the inpatient progress record or diagnosis and treatment for SSIs. However, because of a lack of evidence, among some patients, it was difficult to categorize SSIs into superficial or deep incisional. In these cases, all infections were classified as superficial incisional SSIs.

The suspected cases of SSIs during hospitalization and after discharge from the hospital were identified using the following data: 1) discharge diagnoses, 2) outpatient clinic visits, 3) readmission, 4) emergency room visits, and 5) antibiotics exposure (except the operative day) within 30 days after surgery. All patients were followed at least one time within 30 days after the operation at general surgery clinic, trauma surgery clinic, or wound care clinic. To confirm whether the subjects developed postoperative

Table 34

Variables Included in this Study

Variable	Indicators
Outcome variables	
Surgical site infections	1) Yes/ No 2) Superficial incisional, deep incisional, or organ/space
Main predictor variables	
Perioperative temperature (hypothermia)	a) Initial core temperature b) Lowest intraoperative core temperature c) Duration of core temperature less than 35C° d) Final core temperature
Covariate variables	
Wound classification	a) Clean, b) Clean-contaminated, c) Contaminated, or d) Dirty-infected
Duration of operation	a) Time of skin incision b) Time of skin closure
Patient's severity of illness	ASA score: 0-5 Number of discharge diagnoses
Descriptive variables	
Age	Date of birth
Gender	Male or female
Ethnicity	a) White, b) Black, c) Hispanic, Mexican, Latino, d) Asian, e) Native American, f) Other
Living condition	a) Having a stable residence, b) homeless, c) Other
Underlying conditions	Number of past medical conditions/ diagnoses (including DM, cancer)
Obesity	Body mass index (preoperative weight and height)
Duration of preoperative stay	a) Date of admission – b) Date of surgery
Duration of hospitalization	a) Date of discharge – b) date of admission
Duration of anesthesia	a) Time of starting anesthesia b) Time of ending anesthesia
History of cigarette smoking	Yes/ No
History of alcohol use	Yes/ No
History of drug use	Yes/ No
Number of procedures	Number of procedures performed
Estimated blood loss	Amount of estimated blood loss
Type of trauma	a) Stab wound, b) Gunshot wound, c) Motor vehicle or cycle accident, d) Other, e) No
Urgency of operation	Elective / emergency
Oxygen therapy	Yes/ No
Transfusion	Yes/ No

SSIs or not after their discharge from the hospital, evidence of SSIs was obtained manually from patient's progress records, discharge summaries, or microbiological data. When data regarding follow-up clinic or emergency room visits were missing in patient's progress records, the suspected case was classified as non-infected. If the suspected case with several clinic or emergency room visits had a history of prescribed antibiotics without a specific reason or medical diagnosis, a detailed inquiry was conducted using results of culture of fluid or tissue from the surgical site incision or in the organ or space within 30 days after the operation in order to identify whether a postoperative SSI had developed.

Main Predictor Variable

In this study, a main predictor variable was a factor related to perioperative temperature (hypothermia). Hypothermia has been defined in several ways. The first is to define hypothermia using an arbitrary cut point of the core temperature, such as 34.5°C (Bush et al., 1995), 35°C (Reuler, 1978), 95.5°F (35.3°C) (Barone et al., 1999), or 97°F (36.1°C) (Slotman, Jed, & Burchard, 1985). The second way is to set the hypothermic range of the core temperature (Schmied, Kurz, Sessler, Kozek, & Reiter, 1996). In the third way, hypothermia is defined in terms of how many degrees of the core temperature decreases compared to the normal core temperature, for example 1-1.5°C or 2°C below the normal core temperature (Bellin et al, 1998; Kurz et al., 1996). Since usually, the body maintains its core temperature near 37°C, within $\pm 0.6^\circ\text{C}$ (Guyton & Hall, 1996), the core temperature itself has a deviation of the range, and each surgical patient has a range of the core temperature. Also, considering the normal thermoregulatory interthreshold range of 0.2°C, which is highly influenced by anesthesia, and the normal range of the core temperature is influenced by circadian rhythm, gender, age, and underlying disease, there may be a deviation of the range of the core temperature for triggering thermoregulatory responses. Therefore, hypothermia is defined as a difference of the core temperatures between the patient's initial core

temperature (before starting surgery) and the lowest intraoperative core temperature in this dissertation project. The data related to the perioperative core temperatures were collected at the following points: at the time of starting the operation (initial core temperature) and ending the operation (final core temperature), the lowest intraoperative core temperature, and duration of the core temperature less than 35°C. The intraoperative core temperature of patients with general abdominal surgery was monitored by temperature probes, which were a part of endotracheal tubes placed down the throat, through the vocal cords and into the main bronchus.

Covariate Variables

The SENIC risk index includes the following four components: 1) having an operation which involves the abdomen, 2) having an operation which lasts more than 2 hours, 3) having an operation which is classified as either contaminated or dirty-infected in the wound classification system, and 4) having three or more underlying diagnoses at the time of discharge after the operation. Each of these components is equally weighted and contributes a point when present. The range of values of the SENIC risk index is from 0 to 4. The range of values of the NNIS risk index is from 0 to 3, and consists of the following equally weighted three components: 1) an ASA score greater than 3, 2) an operation classified as either contaminated or dirty-infected in the wound classification system, and 3) an operation with surgery duration more than T hours, where T is the 75th percentile of the distributions of duration of each operation being performed. Therefore, the following components of the SENIC and NNIS risk indices were included as covariate variables in this study: duration of the operation, the wound classification system, the ASA score, and number of discharge diagnoses.

After reading the operative record written by a primary surgeon, the wound class (highest category of any of wounds) was determined using the definitions of the wound classification system published by the CDC and APIC (Table 2). The ASA score could be collected from several records: preoperative evaluation sheet, operating

room record, and anesthesia record. In case the ASA score of the same patient were not congruent among these three records, the score written on anesthesia record was used for this study. The number of discharge diagnoses was primarily extracted from discharge or transfer summary, but discharge diagnoses were not recorded in the same way among physicians. Some physicians included all surgical procedures performed in the list of discharge diagnoses, and others did not. Therefore, in this study, surgical procedures were not included in the list of discharge diagnoses.

Duration of the operation was calculated using the time from skin incision to skin closure. Because most of this sample underwent more than two operations, T hours of the NNIS risk index were determined using the major procedure performed. For example, in case a patient who underwent exploratory laparotomy, repair of small bowel enterotomy, repair of mesenteric laceration, and irrigation of abdomen, the T hours of exploratory laparotomy, which is 2 hours, were taken in account.

Descriptive Variables

Based on the literature review in the previous chapter, factors related to the patient's susceptibility and perioperative factors were included to describe characteristics of the sample of this study. The following were included as descriptive variables: age, gender, race/ethnicity, living situation, BMI, cigarette smoking, alcohol use, drug use, number of previous medical conditions/ diagnoses, duration of preoperative stay, duration of hospitalization, number of procedures performed, urgency of surgery, estimated blood loss, transfusion, oxygen therapy, and type of trauma. As one of exclusion criteria of this study was any recent history of remote infections before surgery, information related to preoperative antibiotic use, infections, and fever were used to determine whether each patient was eligible for this study. The BMI was defined as the weight in kilograms divided by the height in meters squared. A BMI of more than 30 has been defined as obese, corresponding to 1 standard deviation above the mean BMI (Moulton et al., 1996).

Potential Biases in this Study

Hulley, Newman, & Cummings (2001) defined bias as sources of variation that would distort the study findings in one direction, and it causes systematic error. In this section, two major problems of a cohort study design, which are selection bias and information bias, will be discussed as they relate to this dissertation project.

Selection Bias

Selection bias refers to “a distortion in the estimate of effect resulting from the manner in which subjects are selected for the study population” (Kleinbaum, Kupper, & Morgenstern, 1982). There are several sources of selection bias, and the main concern was the effect of losses to follow-up in this study. Although the definition of the sample and the manner of the sampling were clearly addressed, losses to follow-up occurred because some medical charts of eligible patients were not available for the author and charts or parts of charts were missing or incomplete. Therefore, this would be a potential bias in this study. However, consistent attempts were made to obtain data from multiple sources, and these attempts were made regardless of the main predictor variable or the outcome of interest.

Information Bias

Information bias refers to “a distortion in the estimate of effect due to measurement error or misclassification of subjects on one or more variables” (Kleinbaum et al., 1982). The major sources of information bias are invalid measurement, incorrect diagnostic criteria (diagnostic bias, ascertainment bias), losses to follow-up, imprecisions (recall bias or interview bias), or an incomplete or erroneous data source. As Cummings et al. (2001) pointed out, to assess the outcome of interest, that is the status of SSIs, the standardized or specific criteria should be used in order to avoid misclassification of the outcome of interest. Misclassification of the outcome would bias the results of the study towards the null hypothesis (Elwood, 1998). In this study, the CDC definitions of SSIs were used (Appendix 1). Even though there are few

studies to validate these definitions, CDC has strongly recommended using the definitions of SSIs without any modifications. In reality, the CDC definitions are most common and widely used in the clinical and epidemiological studies. Therefore, the problem of misclassification of SSIs status might be small.

As described above, the suspected cases without any data regarding follow-up clinic or emergency room visits within 30 days after the operation, were classified as non-infected. Each surgical patient was instructed that if he or she had the specific symptoms related to SSIs, such as fever, more pain, redness, more drainage, or pus from the wounds by either physicians or nurses at SFGH before their discharge, they should return to the hospital to get appropriate care and treatment at SFGH. Therefore, there was one assumption about patient's seeking professional medical care: If they had suffered from some specific symptoms related to their surgical wounds, they would return to the hospital. However, this decision might lead to underestimate of true infection rates of this sample. There was some possibility that infected patients after discharge from the hospital might go and ask medical care at another healthcare institution. Because infected patients were included in denominator, but not numerator, the infection rate would be underestimate. Moreover, it could not be denied that the medical records of infected patients would be more likely to be complete, then these charts were more likely to be available for the author. In this situation, if the charts of non-infected patients were not included in denominator, the infection rate would tend to be higher.

The accuracy of measurements of predictor variables is also important in order to avoid information bias. In a cohort study design, predictor variables or risk factors precede the outcome, and it ensures the time sequence between risk factors and the outcome. Because of this time relationship, the data of risk factors for SSIs cannot be biased by knowledge of which patients have developed SSIs. Besides this, the measurements of main predictor variables for this study were clearly defined and the data

collection sheet was made by the author before the data collection started. Therefore, the same or similar method of data collection for each patient of the study sample was performed.

The most serious concern of this study was incomplete or erroneous recorded data as a source of information bias, because the study design was a retrospective cohort study using a total medical chart review. Although there is one assumption that all medical records should be written precisely and correctly, inconsistent or incomplete descriptions sometimes occur. Therefore, in this study, a total medical chart review using more than fifteen records, including administration record, discharge or transfer summary, discharge diagnosis and procedure record, inpatient progress record, and others, was applied. Also, to reduce the problem of this bias, the data were collected from the following three sources: patient's medical record, operating room computerized database, and SFGH online database (named "invision"). In spite of the efforts to avoid this bias, it might be a potential bias in this study.

Data Analysis Procedure

All data were entered in SPSS statistical software (version 10). After the data were entered and cleaned, appropriate descriptive statistics were calculated. For all tests, a p-value of less than 0.05 was considered significant.

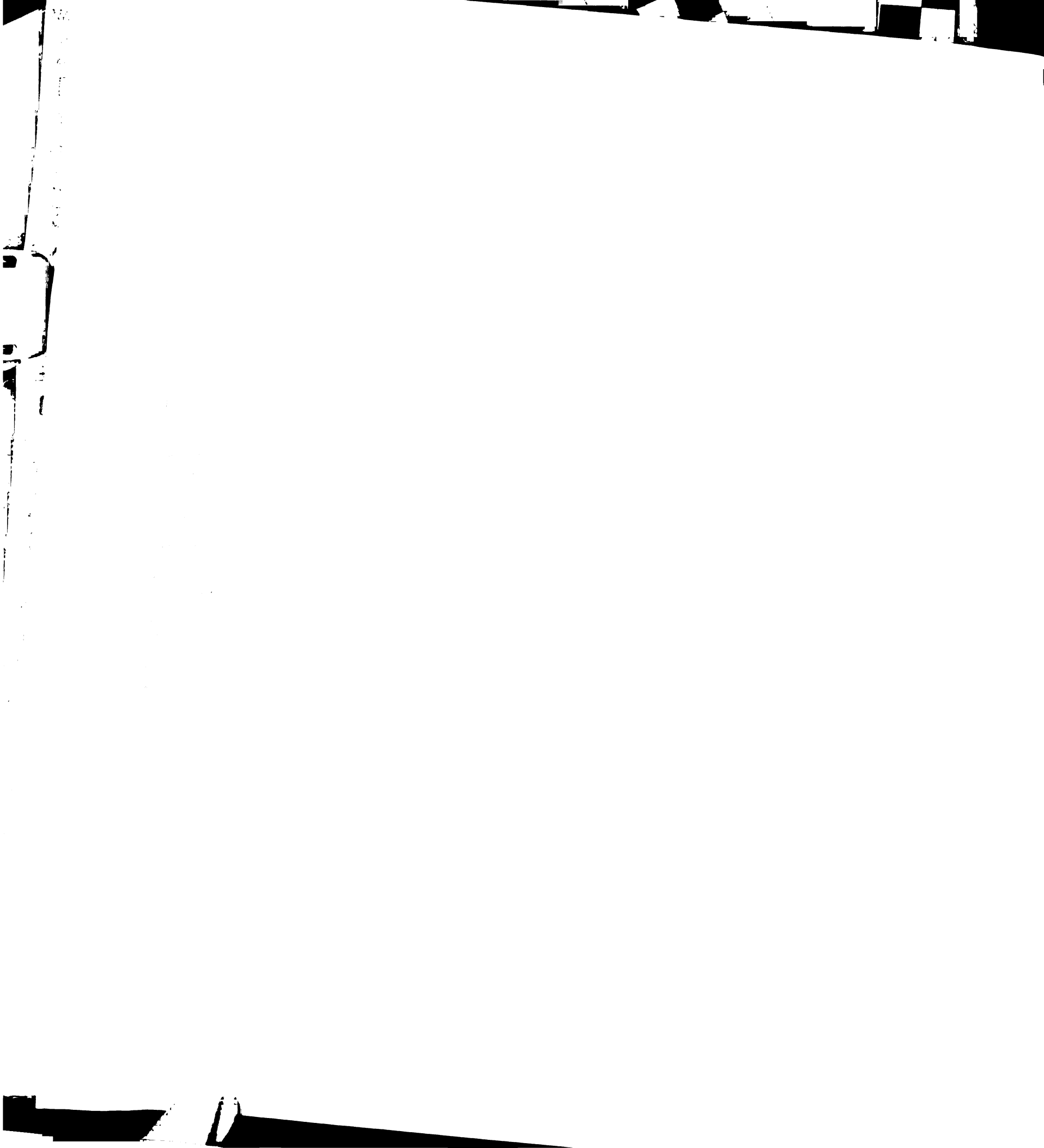
Research question 1. To answer this question, the SSI rate of the sample was calculated by the total number of surgical patients with SSIs (numerator) divided by the total number of surgical patients at the risk of SSIs (denominator).

Research question 2. To answer this question, the mean values of the initial core temperature, the lowest intraoperative core temperature, the final core temperature, and the duration of the core temperature less than 35C° between patients with and without SSIs were examined by unpaired, two-tailed t-tests. Also, the changes between the initial and lowest intraoperative core temperatures as well as the changes between the

initial and final core temperatures was calculated, and the mean differences between two groups were evaluated by unpaired, two-tailed t-tests.

Research question 3. The risk indices were examined in terms of the predictability of postoperative SSIs by Kendall's tau. The Kendall's tau statistic is a nonparametric measure of association for ordinal or ranked variables that take ties into account (SPSS, 1999). The values of correlation coefficient indicated the direction and the strength of the relationship, which was the power of the risk index to predict postoperative SSIs.

Estimates of RRs of SSIs for each component of the standard risk indices (NNIS and SENIC risk indices), as well as 95% CI of these estimates, were computed by fitting each variable with a logistic regression model. Logistic regression analysis describes the relationship of several independent variables to a single dichotomous dependent variable, and yields a predictive equation or model (Kleinbaum, 1994). Also, logistic regression analysis enables to analyze the relationship between multiple independent variables and a single dependent variable, in different combinations in order to find the best fitting model. A well fitting model will include the variables that have AOR within 95% CI that do not include one in the interval. In addition to AOR, the Wald statistic is used to test the significance of individual predictor variables in the model, and this statistic is distributed as a chi-square. Several other statistics have been used to assess the best fitting model, such as the likelihood index, the Hosmer-Lemeshow goodness-of-fit test, and the classification table. The likelihood index is the probability of the observed results, given the parameters estimated from the analysis (Polit, 1996). -2 Log likelihood is a transformed index of the likelihood index, indicates that small value of this index means the better model fitting (Polit, 1996). The Hosmer-Lemeshow goodness-of-fit statistic divides the data into deciles of risk and compares observed to expected frequencies of computed chi-square (Hosmer & Lemeshow, 1989). The overall rate of correct classification is estimated as a predictive probability, with the observed frequencies of the infected and non-infected surgical patients being correctly



classified.

After univariate analysis, the predictability of the modified risk index, in which a factor related to perioperative temperature added to the standard risk index as an indicator for the patient's susceptibility to SSIs, was examined by the same procedures. To examine whether the modified risk index added explanatory information to the standard risk index, the standard risk index was used as a primary explanatory variable, and examined a unique contribution of the modified risk index by regressing the standard risk index on the modified one.

CHAPTER IV

RESULTS

This chapter presents a description of the sample and the impact of perioperative temperature on prediction of SSIs examining by univariate analysis as well as multiple logistic analysis.

Using the computerized registry database of the operating room department of SFGH during Jan 1, 2000 and Jun 30, 2001, 341 surgical patients were eligible for this study. From them, 93 patients were eliminated from the original sample because of the following reasons: 1) patients who could not be followed up within 30 days after the operation due to death or transfer to another healthcare institution; 2) patients whose ages were under 18 years old; 3) patients with multiple operations during one hospitalization; 4) patients with non-abdominal general surgery; and 5) patients with only laparoscopic approach. Out of the remaining 248 surgical patients who underwent general abdominal surgery, the medical records of 18 patients were not available for the author. Therefore, 230 surgical patients were included in the final sample for analysis of this dissertation project (see Figure 2).

Description of the Sample

Incidence of Surgical Site Infections

Of the final sample of 230 surgical patients, 52 patients had the occurrence of a SSI, yielding a cumulative incidence of 22.6%. A case fatality rate of this sample was 7.7% ($n=4$). These SSIs included 30 superficial incisional SSIs (57.7%), 3 deep incisional SSIs (5.8%), 12 organ/ space SSIs (23.1%), and 7 both of incisional and organ/space SSIs (13.5%). If incisional SSIs could not been judged superficial or deep due to a lack of description in the medical records, all incisional SSIs were categorized as superficial SSIs. Table 35 shows how each SSI was diagnosed using the definitions of

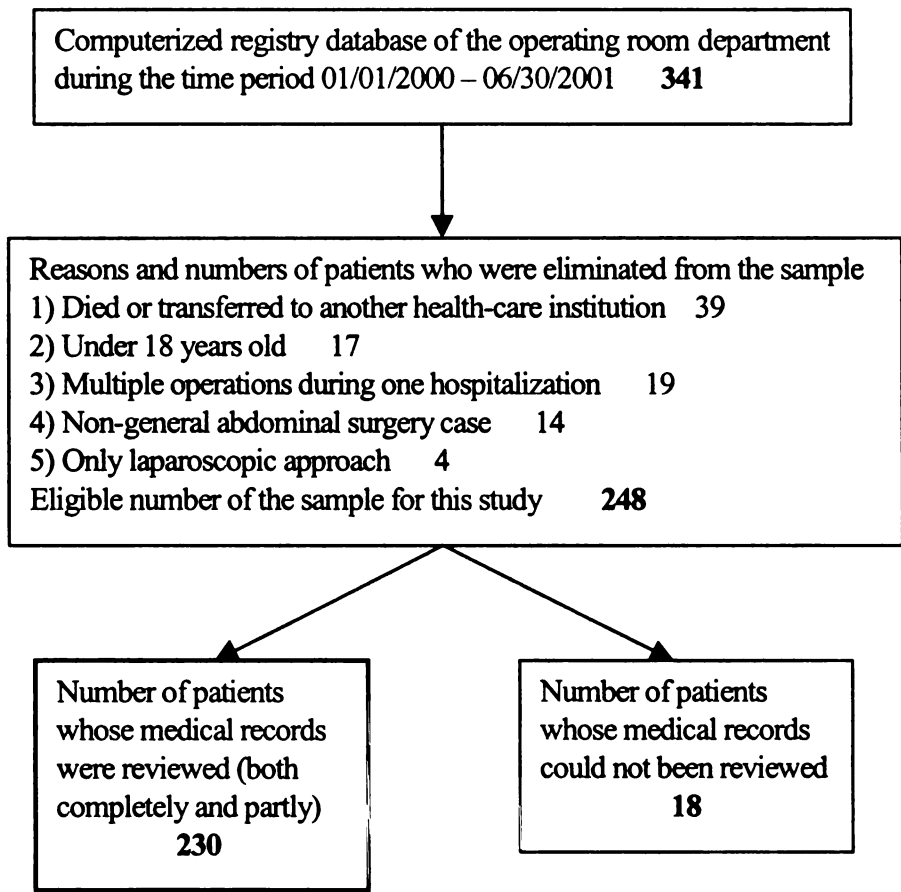


Figure 2. Record Review Process. (Numbers of medical records are shown).

Table 35

Types and Criteria of SSIs identified among Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SFGH

Criteria ^a	Surgical site infections			
	Superficial incisional	Deep incisional	Organ /Space	Both
1. Purulent drainage	11 (36.7%)	2 (66.7%)		
2. Organisms isolated	1 (3.3%)	N/A		
3. Signs and symptoms Debridement	7 (23.3%)		N/A	
4. Abscess and direct evidence of infection	N/A		12 (100%)	
5. Diagnosis	11 (36.7%)	1 (33.3%)		
1. and 4.				3 (42.9%)
3. and 4.				3 (42.9%)
5. and 4.				1 (14.2%)
Total	30^b (100%)	3 (100%)	12 (100%)	7 (100%)

Note. ^a Criteria were summarized and cited from "CDC definitions of nosocomial surgical site infections, 1992: A modification of CDC definitions of surgical wound infections" by T. Horan, R. P. Gaynes, W. J. Matone, W. R. Jarvis, & T. G. Emori, 1992, Infection Control and Hospital Epidemiology, 13, 606-608. ^b Six incisional SSIs which could not be categorized as either superficial or deep due to a lack of information, were included.



SSIs published by the CDC (CDC, 1992). The numbers (with percentages in parentheses) of SSIs diagnosed using this criteria among patients who developed a single SSI (n= 45) were as follows: purulent drainage 13 (28.8%); physician's diagnosis 12 (26.7%); abscess and direct evidence of infection 12 (26.7%); signs and symptoms, and debridement 7 (15.6%); and organisms isolated 1(2.2%). All organ/space SSIs in this sample were diagnosed by the fourth criterion, abscess and direct evidence of infection. Some patients with an organ/space SSI were needed a radiographic intervention and intra-abdominal surgical drains were placed for treatment. After this intervention, the patients were draining pus through the drains. These cases, however, were categorized into the fourth criterion, because the diagnosis had already been made based on the results of the abdominal CT scans. The criterion of a physician's diagnosis of a SSI did not always appear in a list of discharge diagnoses in discharge summary or transfer summary reviewed by the author. From inpatient's progress records, the description of assessment of the surgical wounds, treatment, and diagnosis were extracted. The availability of wound cultures was rare, therefore only one SSI was found using this criterion.

Follow-up data of 196 patients (85.2%) were available for the author. The rest of the sample had follow-up appointments at general surgery clinic, trauma surgery clinic, or wound care clinic at the time of their discharge from the hospital, but they missed the appointments. Among 52 patients with SSIs, 29 patients (55.8%) were detected SSIs during their hospitalization and 21 patients (40.4%) were detected SSIs after their discharge from the hospital. Two patients (3.8%) were detected SSIs both during their hospitalization and after their discharge from the hospital (see Table 36).

Characteristics of the Sample

Socio-Demographic Characteristics

Table 37 summarized socio-demographic characteristics of this sample by the occurrence of SSIs. The mean age of the sample was 42.8 years and the range of age

Table 36

Types of SSIs Identified during Hospitalization and after Discharge from the Hospital among Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SEGH

Timing	Surgical site infections				Total
	Superficial incisional	Deep incisional	Organ /Space	Both	
In-hospital	14 (46.7%)	2 (66.7%)	9 (75.0%)	4 (57.1%)	29 (55.8%)
After discharge	16 (53.3%)	1 (33.3%)	3 (25.0%)	1 (14.3%)	21 (40.4%)
Both				2 (28.6%)	2 (3.8%)
Total	30 ^a (100%)	3 (100%)	12 (100%)	7 (100%)	52 (100%)

Note. ^aSix incisional surgical site infections which could not be categorized into superficial or deep due to lack of information, were included.

Table 37

Socio-Demographic Characteristics of Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SFGH, by the Occurrence of Surgical Site Infections

Variables	Patients with SSIs (n = 52)	Patients without SSIs (n = 178)
Age		
M (SD)	47.3 (17.95)	41.4 (16.18)
Mdn	47.2	39.4
Gender		
Male	34 (65.4%)	135 (75.8%)
Female	18 (34.6%)	43 (24.2%)
Race/ Ethnicity		
White	14 (26.9%)	49 (27.5%)
Black	15 (28.8%)	54 (30.3%)
Hispanic	12 (23.1%)	30 (16.9%)
Native American	0	0
Asian	10 (19.2%)	36 (20.2%)
Other	0	3 (1.7%)
Unknown	1 (1.9%)	6 (3.4%)
Living condition		
Stable residence	44 (84.6%)	141 (79.2%)
Homeless	8 (15.4%)	29 (16.3%)
Others (Jail)	0	8 (4.5%)

was from 18 to 83. The mean age (with standard deviations in parentheses) of patients with SSIs was 47.3 ($SD = 17.95$) years and the median was 47.2 years. Nearly 65 % ($n = 34$) of them were male. The mean and median age of patients without SSIs were 41.4 ($SD = 16.18$) and 39.4 years. Nearly 75% ($n = 135$) of patients without SSIs were male. The sample was ethnically diverse, being composed of 30.0 % ($n = 69$) black, 27.4% ($n = 63$) white, 20.0% ($n = 46$) Asian, 18.3% ($n = 42$) Hispanic, and 1.3% ($n = 3$) others: Blacks, whites, and Hispanics represented nearly 80.0%. In both groups of patients with and without SSIs, living condition was similar: Nearly 80% of each group had a stable residence and 16.1% were homeless.

Health-Related Characteristics

Table 38 summarized health-related characteristics, indicating the patient's susceptibility to infections, by the occurrence of SSIs. Comparing the mean and median numbers of past medical condition or diagnoses, for example cancer, diabetes mellitus, or hypertension, patients with SSIs tended to be diagnosed with more conditions than those without SSIs. The mean and median values of BMI between groups of patients with and without SSIs were similar. The percentage of BMI more than 30 among patients with SSIs was 17.8%, and 16.2 % among those without SSIs.

Both patients groups with and without SSIs, nearly a half proportion of patients did not smoke. Comparing to the proportion of alcohol users of patients without SSIs, less surgical patients with SSIs drank alcohol. Thirteen (25.0%) patients with SSIs and 60 (33.7%) patients without SSIs used any kinds of drug including IV drugs.

Operative Characteristics

Table 39 summarized operative characteristics of this sample by the occurrence of SSIs. Because most operations in both groups were emergency (patients with SSIs 82.7%, patients without SSIs 80.9%), the numbers of days of preoperative stay were short. The mean duration of preoperative stay among patients with SSIs was 2.1 days ($SD = 4.22$) and 0.9 days ($SD = 2.98$) among patients without SSIs.

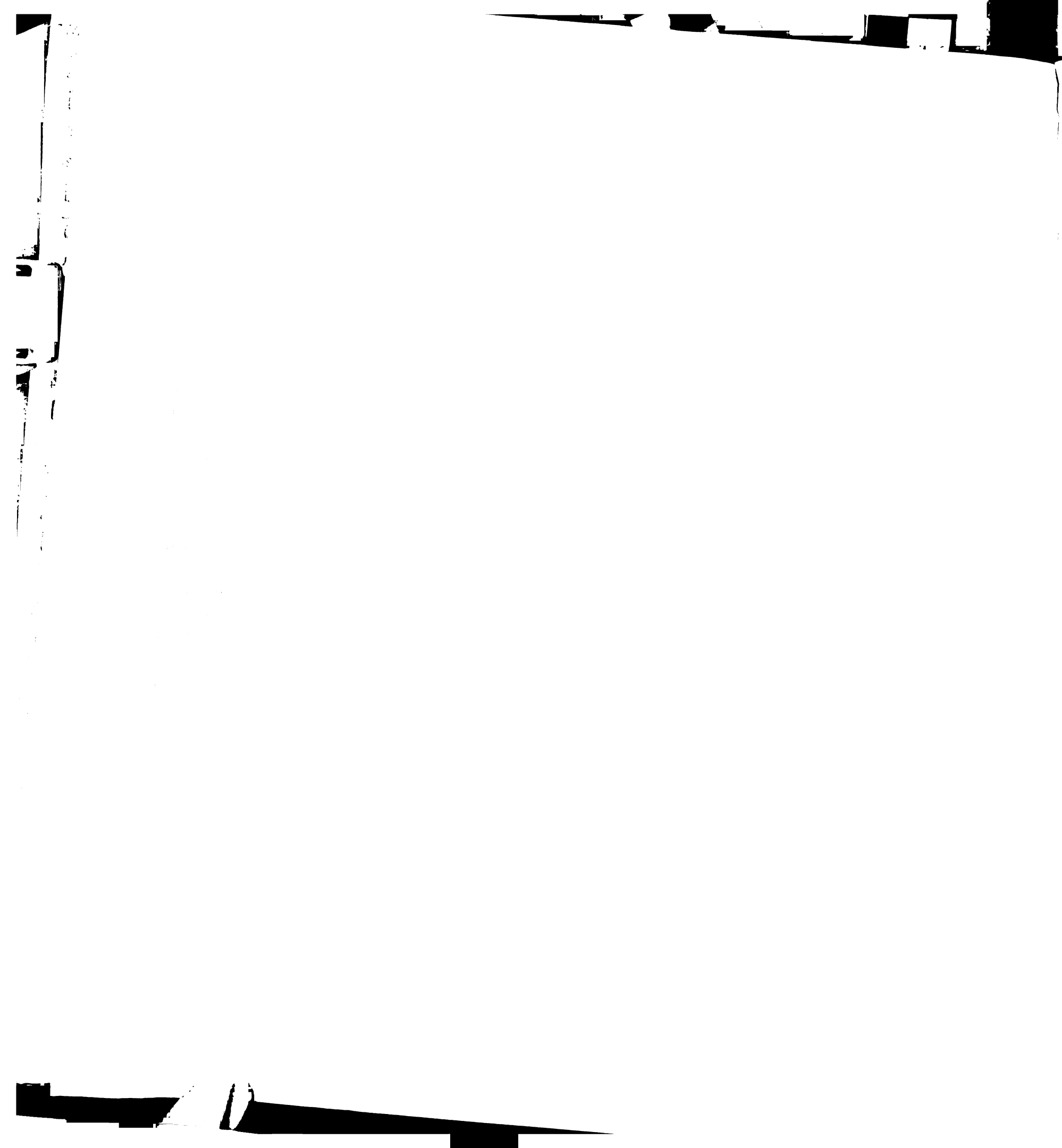


Table 38

Health-Related Characteristics of Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SFGH, by the Occurrence of Surgical Site Infections

Variables	Patients with SSIs (n = 52)	Patients without SSIs (n = 178)
# of past medical conditions/ diagnoses		
M (SD)	2.6 (2.81)	1.6 (1.95)
Mdn	1.0	1.0
Range	0 - 9	0 - 8
BMI		
M (SD)	26.4 (8.04) ^a	25.2 (5.17) ^b
Mdn	25.9	24.8
Range	13.0 - 49.7	16.5 - 50.8
Cigarette smoking		
Yes	25 (48.1%)	77 (43.3%)
No	26 (50.0%)	92 (51.7%)
Unknown	1 (1.9%)	9 (5.0%)
Alcohol		
Yes	18 (34.6%)	101 (56.7%)
No	32 (61.5%)	74 (41.6%)
Unknown	2 (3.9%)	3 (1.7%)
Drug use		
Yes	13 (25.0%)	60 (33.7%)
No	38 (73.1%)	112 (62.9%)
Unknown	1 (1.9%)	6 (3.4%)

Note. ^an = 45. ^bn = 154.

Table 39

Operative Characteristics of Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SFGH, by the Occurrence of Surgical Site Infections

Variables	Patients with SSIs (n = 52)	Patients without SSIs (n = 178)
Duration of preoperative stay		
M (SD)	2.1 (4.22)	0.9 (2.98)
Mdn	0.0	0.0
Duration of hospitalization		
M (SD)	18.4 (17.30)	8.9 (7.92)
Mdn	12.0	7.0
# of procedures performed		
M (SD)	3.6 (2.29)	3.0 (1.43)
Mdn	3.0	3.0
Duration of operation		
M (SD)	185.2 (128.19)	138.0 (77.34)
Mdn	149.5	125.0
Duration of anesthesia		
M (SD)	240.8 (136.83)	201.8 (98.08)
Mdn	206.0	180.0
Estimated blood loss		
M (SD)	629.4 (1371.3) ^a	541.2 (1014.7) ^b
Mdn	200	200
# of discharge diagnoses		
M (SD)	3.2 (1.97) ^c	2.4 (1.75)
Mdn	3.0	2.0
Wound class		
Clean	3 (5.9%) ^d	23 (12.9%)
Clean-contaminated	17 (33.3%)	102 (57.3%)
Contaminated	23 (45.1%)	45 (25.3%)
Dirty-infected	8 (15.7%)	8 (4.5%)
ASA score		
1	2 (4.0%) ^c	17 (9.6%)
2	23 (46.0%)	92 (51.7%)
3	13 (26.0%)	52 (29.2%)
4	12 (24.0%)	17 (9.6%)
Type of urgency		
Elective	9 (17.3%)	34 (19.1%)
Emergency	43 (82.7%)	144 (80.9%)

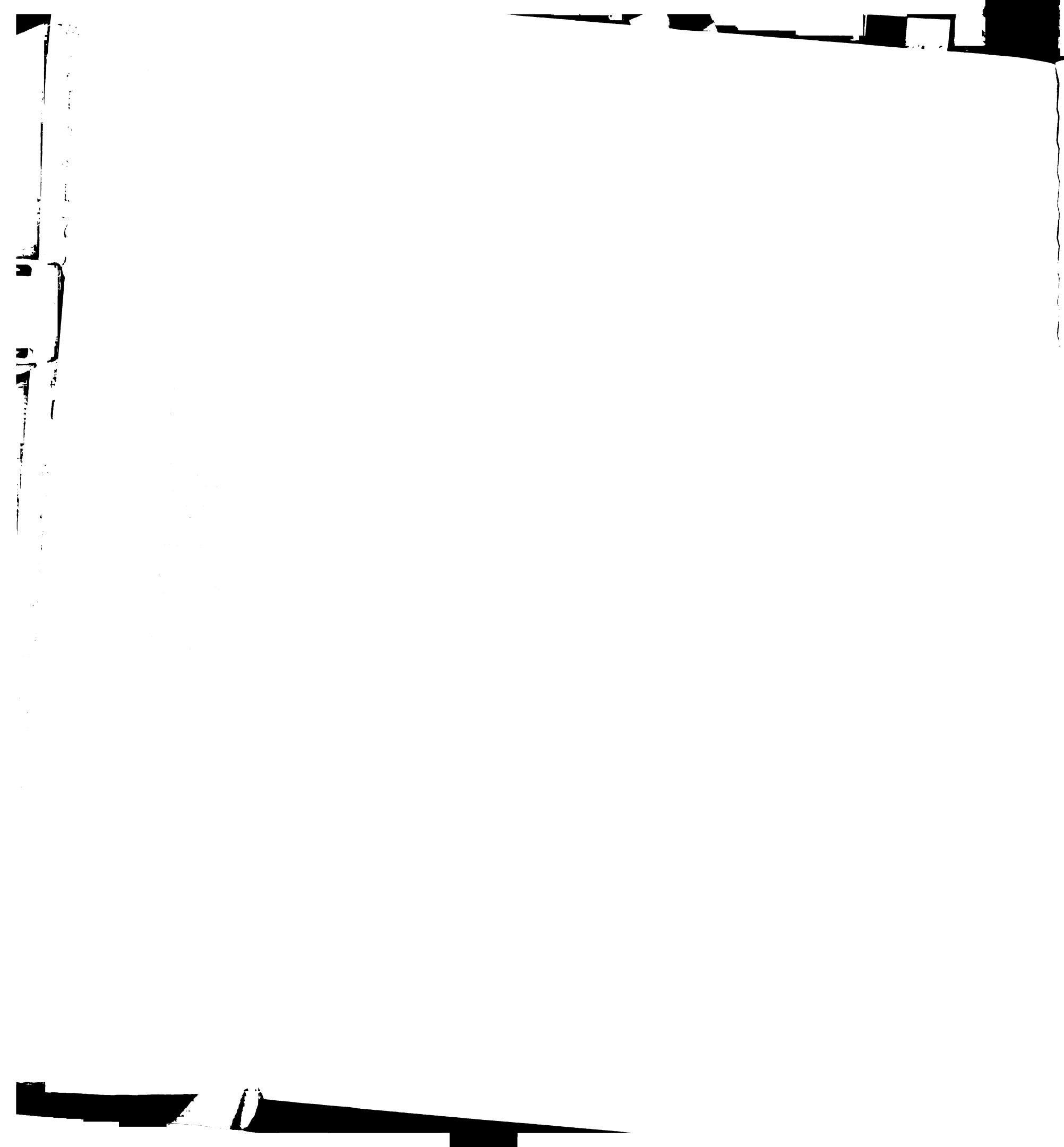


Table 39 cont.

Variable	Patients with SSIs (n = 52)	Patients without SSIs (n = 178)
Type of trauma		
Stab wound	8 (15.4%)	49 (27.5%)
Gunshot wound	7 (13.5%)	21 (11.8%)
MVA/MCA ^e	4 (7.7%)	26 (14.6%)
Others ^f	2 (3.8%)	6 (3.4%)
Not trauma	31 (59.6%)	76 (42.7%)
Transfusion		
Yes	20 (39.2%) ^d	56 (31.5%)
No	31 (60.8%)	122 (68.5%)
Oxygen therapy		
Yes	50 (96.2%)	163 (91.6%)
No	2 (3.8%)	15 (8.4%)

Note. ^a n = 35. ^b n = 107. ^c n = 50. ^d n = 51. ^e MVA= motor vehicle accident, MCA= motor cycle accident. ^f "Others" included fall and foreign body inserted.

The mean and median days of the hospitalization among patients with SSIs were 18.4 ($SD = 17.30$) and 12 days. Although in this study, the extra days attributable to SSIs were not examined, comparing to those days among patients without SSIs ($M = 8.9$, $SD = 7.92$, $Mdn = 7.0$), the duration of the hospitalization among patients with SSIs was definitely longer.

Duration of the operation was calculated using the time from skin incision to skin closure. Although the mean and median numbers of the procedures performed between patients with and without SSIs were similar, the mean and median minutes of duration of the operation as well as anesthesia among patients with SSIs were longer than those of patients without. The distribution of the major surgeries performed was as follows: exploratory laparotomy 145 (63.0%), hemicolectomy 16 (7.0%), colectomy (right, transverse, left, or sigmoid) 14 (6.1%), small bowel resection 13 (5.7%), colostomy/ileostomy takedown 9 (3.9%), diverting colostomy/ ileostomy 7 (3.0%), splenectomy 7 (3.0%), and others (cholecystectomy, appendectomy, jejunojejunostomy, splenorrhaphy, and others) 19 (8.3%).

According to the wound classification system published by the CDC (1986), the distribution of the wound class among patients with SSIs were as follows: clean wound 5.9% ($n = 3$), clean-contaminated wound 33.3% ($n = 17$), contaminated wound 45.1% ($n = 23$), and dirty-infected wound 15.7% ($n = 8$). Among patients without SSIs, the proportion of clean wound was 12.9% ($n = 23$), clean-contaminated wound 57.3% ($n = 102$), contaminated wound 25.3% ($n = 45$), and dirty-infected wounds 4.5% ($n = 8$). Comparing the distributions between both groups, the proportion of contaminated and infected-dirty wounds among patients with SSIs was higher, indicating that the wounds of patients with SSIs were more contaminated at the time of operation. Therefore patients with SSIs were at higher risk for developing postoperative SSIs.

The ASA score and the numbers of discharge diagnoses have been used as indicators for the patient's susceptibility to SSIs. In the both groups, none of patients

were categorized as class 5, which indicates patients are not expected to survive 24 hours with or without operation (American Society of Anesthesiologists, 1963). Among 50 patients with SSIs, the distribution of the ASA scores was as follows: class 1, 4.0% ($n = 2$), which indicates a normal healthy patient; class 2, 46.0% ($n = 23$), which indicates a patient with a mild systemic disease; class 3, 26.0% ($n = 13$), which indicates a patient with a severe systemic disease that limits activity, but is not incapacitating; and class 4, 24.0% ($n = 12$), which indicates a patient with an incapacitating systemic disease that is a constant threat to life (American Society of Anesthesiologists, 1963). The distribution of the ASA scores among 178 patients without SSIs was similar to that of the group of patients with SSIs. The mean and median numbers of discharge diagnoses among patients with SSIs were 3.2 ($SD = 1.97$) and 3.0, and 2.4 ($SD = 1.75$) and 2.0 among patients without SSIs. Comparing these results of severity of illness between both groups, patients with SSIs were in more severe condition.

One hundred and seven (46.5%) patients of the sample were not trauma patients. Fifty-seven patients (24.8%) had stab wounds, 28 (12.2%) patients had gunshot wounds, 30 (13.0%) patients had motor vehicle or cycle accidents, and 8 patients (3.5%) had other accidents, including fall and inserting a foreign body into the rectum. There was a statistically significant difference in the SSI rates between trauma patients and those without trauma, $F(1, 230) = 4.63$, $p = .04$. The distributions of transfusion and oxygen therapy during the operations were almost identical between patients with and without SSIs.

Impact of Perioperative Temperature on the Occurrence of Surgical Site Infections

The data on perioperative temperature were extracted at several points from anesthesia records, including the initial and final core temperatures, the lowest intraoperative core temperature, and the minutes of the intraoperative core temperature less than 35 °C. Also, the change between the initial and final core temperatures, and

the change between the initial and lowest intraoperative core temperatures were calculated. Table 40 shows the results of bivariate analysis examining the impact of perioperative temperature on the occurrence of SSIs.

The mean initial core temperature among patients with SSIs was 36.48 (SD = 1.23) °C, and among patients without SSIs was 36.18 (SD = 0.92) °C. The decrease of the intraoperative core temperature occurred in 72.2% of patients with and without SSIs (n = 166), ranged from 0.1°C to 1.9°C. The mean lowest intraoperative core temperature among patients with SSIs was 35.99 (SD = 1.14) °C, and 35.84 (SD = 0.93) °C among patients without SSIs. Also, the mean final core temperature among patients with SSIs was 36.52 (SD = 1.06) °C, and 36.58 (SD = 0.92) °C among patients without SSIs. From these results, patients with SSIs seemed to have higher temperatures than those without SSIs. The mean and median duration of intraoperative core temperature under 35°C among patients with SSIs were 88.13 (SD = 66.81) and 66.81 minutes. At the less than 0.05 significance p-value level, none of the four perioperative temperature measurements did not show statistically significant differences between patients groups with and without SSIs (t = 1.577, p = .120; t = .931, p = .353; t = -.402, p = .688; and t = .978, p = .334 respectively).

However, there were statistically significant differences between patients with and without SSIs in the change between the initial and final core temperatures (t = -3.231, p = .001) and the change between the initial and lowest intraoperative core temperatures (t = 2.176, p = .031). The mean and median values of the change between the initial and final core temperatures among patients with SSIs were 0.05 (SD = 0.79) °C and 0.1°C, and -0.43 (SD = 0.69) °C and -0.35°C among those without SSIs, indicating the final core temperature among patients without SSIs was higher than the initial core temperature. The mean and median values of the change between the initial and lowest intraoperative core temperatures among patients with SSIs were 0.48 (SD = 0.49) °C and 0.3°C, and 0.33 (SD = 0.40) °C and 0.2°C among patients without SSIs.

Table 40

Perioperative temperatures of Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SFGH, by the Occurrence of Surgical Site Infections

Indicators	Patients with SSIs (n = 52)	Patients without SSIs (n = 178)	p
Initial core temperature			
M (SD)	36.48 (1.23) ^a	36.18 (0.92) ^b	.120
Mdn	36.50	36.2	
Lowest intraoperative core temperature			
M (SD)	35.99 (1.14) ^a	35.84 (0.93) ^c	.353
Mdn	35.90	35.9	
Final core temperature			
M (SD)	36.52 (1.06) ^d	36.58 (0.92) ^e	.688
Mdn	36.45	36.6	
Duration of core temperature less than 35 °C			
M (SD)	88.13 (66.81) ^f	69.67 (41.81) ^g	.334
Mdn	66.81	60.0	
Difference between the initial and final core temperatures ^h			
M (SD)	0.05 (0.79) ^a	- 0.43 (0.69) ^b	.001
Mdn	0.1	- 0.35	
Difference between the initial and lowest core temperatures ⁱ			
M (SD)	0.48 (0.49) ^a	0.33 (0.40) ^b	.031
Mdn	0.3	0.2	

Notes. ^an = 49. ^bn = 172. ^cn = 174. ^dn = 50. ^en = 176. ^fn = 8. ^gn = 31. ^h(initial core temperature) – (final core temperature). ⁱ(initial core temperature) – (the lowest intraoperative temperature).

As stated in the methodology chapter, the predictor thought to be most useful in this analysis was the difference or change in the intraoperative core temperatures. This measure took into account variations within patients, and measured the change as a result of the operative procedure. Therefore, the change between the initial and final core temperatures as well as the change between the initial and lowest core temperatures was included in multivariate analysis.

Association between the Extant Risk Indices and the Occurrence of Surgical Site Infections

Table 41 presents the results of the distribution of each score of the SENIC and NNIS risk indices by the occurrence of SSIs. The distributions of the SENIC and NNIS scores in both groups of patients with and without SSIs were similar. At the less than 0.05 significance level, there were statistically significant relationships between the SENIC or the NNIS risk index and the occurrence of SSIs ($\underline{W} = .258, p < .01$ and $\underline{W} = .259, p < .01$ respectively) (see Table 42). The values of correlation coefficient of the SENIC and the NNIS risk indices indicated that there were moderate and positive relationships between the increase of the score of the SENIC or NNIS risk index and the occurrence of postoperative SSIs.

Logistic Regression Modeling of the Extant Risk Indices and Perioperative Temperature Factors on the Occurrence of Surgical Site Infections

Logistic regression analysis was performed to examine whether a modified risk index, in which a factor related to perioperative temperature was added to the standard risk index as an indicator of the patient's susceptibility of SSIs, added explanatory information to the standard risk index. Based on the results of bivariate analysis of the associations between perioperative temperature factors and the occurrence of SSIs (see Table 40), the two following perioperative temperature factors were included in this step

Table 41

SENIC and NNIS Risk Index Scores of Patients Undergoing General Abdominal Surgery from Jan 1, 2000 to Jun 30, 2001, SFGH, by the Occurrence of SSIs

Risk indices	Patients with SSIs (n = 50)	Patients without SSIs (n = 178)
SENIC risk index		
0	0	0
1	6 (12.0%)	56 (31.5%)
2	17 (34.0%)	76 (42.7%)
3	17 (34.0%)	39 (21.9%)
4	10 (20.0%)	7 (3.9%)
NNIS risk index		
0	7 (14.0%)	50 (28.1%)
1	11 (22.0%)	78 (43.8%)
2	22 (44.0%)	38 (21.3%)
3	10 (20.0%)	12 (6.7%)

Table 42

Nonparametric Correlation for the SENIC and NNIS Risk Index Scores and the Occurrence of SSIs (Kendall's tau-b analysis)(N = 228)

Scores of risk indices	SSI rates	<u>W</u>	<u>p</u>
SENIC risk index total score			
0	N/A	.258	< .01
1	9.7%		
2	18.3%		
3	30.4%		
4	58.8%		
NNIS risk index total score			
0	12.3%	.259	< .01
1	12.4%		
2	36.7%		
3	45.5%		

of analysis: 1) the change between the initial and final core temperatures and 2) the change between the initial and lowest core temperatures.

Table 43, 44, and 45 present correlation matrixes and variance inflation factors among the perioperative temperature factors and the SENIC risk index, in order to detect and evaluate multicollinearity. Because the surgical patients who underwent general abdominal surgery were included in this dissertation project, all patients got one point for this component. Therefore, in this step of the analysis, this variable was not included. When there are only two predictor variables, it is enough to examine the values of the correlation coefficient between two variables (Glantz & Slinker, 1990). However, when there are more than two predictor variables, the another diagnostic statistics, that is variance inflation factors, would be appropriate (Glantz & Slinker, 1990). As shown in Table 43 and 44, there were no values of the correlation coefficients above 0.8 (Glantz & Slinker, 1990) or 0.85 (Munro, 1997). The amounts of the variance of each variable that was shared with the other predictor variables were small (see Table 45). Therefore, multicollinearity was not a problem in these analyses. Using the same procedures, multicollinearity among the perioperative temperature factors and the NNIS risk index was examined, and was not a problem in these analyses (see Table 43,46,and 47).

As the purpose of this analysis was to examine whether the components of the extant risk index with a perioperative temperature factor had more predictive power for postoperative SSIs, the components of the SENIC or NNIS risk index were put into logistic regression analysis without any removal, even though any statistical significance could not be achieved. The following four models of each perioperative temperature factor were examined: 1) each component of the extant risk index (model 1), 2) each component of the extant risk index and a perioperative temperature variable (model 2), 3) total score of the extant risk index (model 3), and 4) total score of the extant risk index and a perioperative temperature variable (model 4). In the model 1 and 2, each component of the SENIC and NNIS risk indices were binomial variables.

Table 43

Correlation Matrix of Perioperative Temperature Factors and the Total Scores of the SENIC and NNIS Risk Indices

	SENIC risk index	NNIS risk index	Temperature (initial-final) ^a	Temperature (initial-lowest) ^b
SENIC risk index	1.000	N/A	-.250**	.023
NNIS risk index		.110	-.122	.084
Temperature (initial-final) ^a			1.000	N/A
Temperature (initial-lowest) ^b				1.000

** $p < .01$

Note. ^a Core temperature difference between at starting and ending points of the operation. ^b

Core temperature difference between at starting and the lowest temperature points of the operation.

Table 44

Correlation Matrix of Associations of Perioperative Temperatures and the Components of the SENIC Risk Index

	> 2 hours duration of operation	Wound class ^a	> 3 discharge diagnosis	Temperature (initial-final) ^b	Temperature (initial-lowest) ^c
> 2 hours duration of operation	1.000	.191**	.034	-.362**	-.069
Wound class ^a		1.000	.110	-.030	.050
> 3 discharge diagnosis			1.000	-.074	.076
Temperature (initial-final) ^b				1.000	.478**
Temperature (initial-lowest) ^c					1.000

** $p < 0.01$

Note. The components of the SENIC risk index were binomial variables.

^a Contaminated or dirty-infected wounds. ^b Core temperature difference between at starting and ending points of the operation. ^c Core temperature difference between at starting and the lowest temperature points of the operation.

Table 45

Variance Inflation Factor among Predictor Variables (Perioperative Temperature Factors and the Components of the SENIC Risk Index)

	Tolerance	VIF
> 2 hours duration of operation	.832	1.201
Wound class ^a	.947	1.056
> 3 discharge diagnosis	.984	1.016
Temperature (initial-final) ^b	.863	1.158
> 2 hours duration of operation	.952	1.050
Wound class ^a	.947	1.056
> 3 discharge diagnosis	.983	1.017
Temperature (initial-lowest) ^c	.986	1.014

Note. The components of the SENIC risk index were binomial variables.

^a Contaminated or dirty-infected wounds. ^b Core temperature difference between at starting and ending points of the operation. ^c Core temperature difference between at starting and the lowest temperature points of the operation.

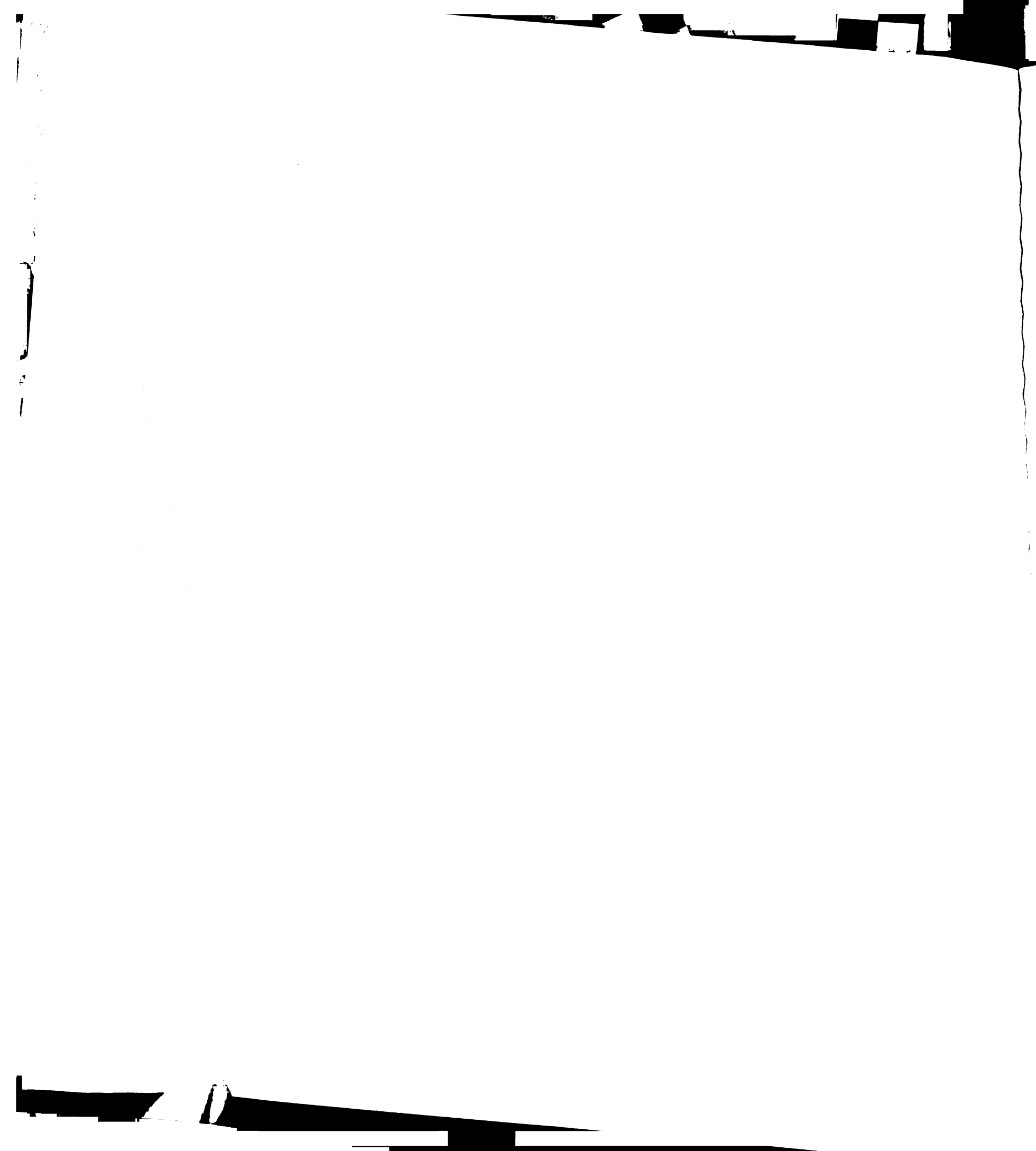


Table 46

Correlation Matrix of Associations of Perioperative Temperatures and the Components of the NNIS Risk Index

	ASA score ≥ 3	Wound class ^a	Duration of operation > T hours	Temperature (initial-final) ^b	Temperature (initial-lowest) ^c
ASA score ≥ 3	1.000	.044	.018	.108	.144*
Wound class ^a		1.000	.226**	-.030	.050
Duration of operation > T hours			1.000	-.306**	-.034
Temperature (initial-final) ^b				1.000	.478**
Temperature (initial-lowest) ^c					1.000

* p < 0.05

** p < 0.01

Note. The components of the NNIS risk index were binomial variables.

^a Contaminated or dirty-infected wounds. ^b Core temperature difference between at starting and ending points of the operation. ^c Core temperature difference between at starting and the lowest temperature points of the operation.

Table 47

Variance Inflation Factor among Predictor Variables (Perioperative Temperatures and the Components of the NNIS Risk Index)

	Tolerance	VIF
ASA score ≥ 3	.985	1.015
Wound class ^a	.943	1.061
Duration of operation > T hours	.854	1.171
Temperature (initial-final) ^b	.892	1.121
ASA score ≥ 3	.978	1.026
Wound class ^a	.942	1.022
Duration of operation > T hours	.943	1.062
Temperature (initial-final) ^c	.975	1.061

Note. The components of the NNIS risk index were binomial variables.

^a Contaminated or dirty-infected wounds. ^b Core temperature difference between at starting and ending points of the operation. ^c Core temperature difference between at starting and the lowest temperature points of the operation.

SENIC Risk Index and Perioperative Temperature Factors

Change between the Initial and Final Core Temperatures

Table 48 presents the final models of logistic regression analysis of the perioperative temperature factor, the change between the initial and final core temperatures, and the SENIC risk index. In the model 1 and 2, two components of the SENIC risk index, wound class (AOR of the model 1 = 3.531, 95% CI = 1.786, 6.979; AOR of the model 2 = 3.479, 95% CI = 1.696, 7.137) and more than three discharge diagnoses (AOR of the model 1 = 2.761, 95 % CI = 1.338, 5.698; AOR of the model 2 = 3.077, 95 % CI = 1.403, 6.751) were statistically significant. The test of significance of operative duration more than 2 hours did not show any statistical significance in both models (AOR of the model 1 = 0.662, 95 % CI = 0.585, 2.328; AOR of the model 2 = 1.935, 95 % CI = 0.894, 4.188). The perioperative temperature factor in the model 2 had a significant p-value of the Wald test and could increase the odds of developing SSIs (Wald = 14.190, $p = .000$, AOR = 2.759, 95% CI = 1.627, 4.678,).

In the model 3 and 4, the total scores of the SENIC risk index, ranging from 1 to 4, were put into the analysis, and were statistically significant (AOR of the model 3 = 2.248, 95%CI = 1.545, 3.269; AOR of the model 4 = 2.762, 95% CI = 1.816, 4.200). The interpretation of the model 4 of Table 48 is that every increase in the score of the SENIC risk index increases the odds of developing SSIs by 2.762, and that every 1°C of the decrease of the core temperature at the ending point of the operation comparing to the temperature at the starting point increases the odds of developing SSIs by 2.923.

Change between the Initial and Lowest Core Temperatures

Table 49 presents the final models of logistic regression analysis of the perioperative temperature factor, the change between the initial and lowest intraoperative core temperatures, and the SENIC risk index. In the model 1 and 2, two components of the SENIC risk index, wound class (AOR of the model 1 = 3.531, 95% CI = 1.786, 6.979; AOR of the model 2 = 3.313, 95% CI = 1.659, 6.619) and more than three

Table 48

Final Models of Logistic Regression Analysis of the SENIC Risk Index and a Perioperative Temperature Factor : Change between the Initial and the Final Core Temperatures

Model 2: Components of SENIC risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
Duration > 2 hours	0.660	.394	2.809	.094	1.935	0.894, 4.188
Wound class	1.247	.367	11.560	.001	3.479	1.696, 7.137
Diagnoses > 3	1.124	.401	7.863	.005	3.077	1.403, 6.751
Temperature	1.015	.269	14.190	.000	2.759	1.627, 4.678
Intercept	-2.238	.341	42.956	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 10.121$, $df = 8$, $p = .257$.

-2 Log likelihood = 195.864. Overall percentage of classification table = 77.8%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

Model 4: Total score of SENIC risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
Total score	1.016	.214	22.576	.000	2.762	1.816, 4.200
Temperature	1.073	.264	16.483	.000	2.923	1.742, 4.907
Intercept	-3.310	.532	38.721	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 9.288$, $df = 8$, $p = .319$.

-2 Log likelihood = 197.002. Overall percentage of classification table = 78.3%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

Table 49

Final Models of Logistic Regression Analysis of the SENIC Risk Index and a Perioperative Temperature Factor: Change between the Initial and lowest core temperatures

Model 2: Components of SENIC risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
Duration > 2 hours	0.195	.361	0.292	.589	1.215	0.599, 2.467
Wound class	1.198	.353	11.516	.001	3.313	1.659, 6.619
Diagnoses > 3	0.915	.381	5.766	.016	2.496	1.183, 5.266
Temperature	0.683	.375	3.318	.069	1.981	0.949, 4.133
Intercept	-2.418	.368	43.117	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 4.504$, $df = 8$, $p = .809$.

-2 Log likelihood = 208.683. Overall percentage of classification table = 79.2%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

Model 4: Total score of SENIC risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
Total score	.769	.193	15.815	.000	2.158	1.477, 3.152
Temperature	.743	.371	4.002	.045	2.101	1.015, 4.349
Intercept	-3.313	.529	39.232	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 4.340$, $df = 8$, $p = .825$.

-2 Log likelihood = 212.236. Overall percentage of classification table = 79.2%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

discharge diagnoses (AOR of the model 1 = 2.761, 95 % CI = 1.338, 5.698; AOR of the model 2 = 2.469, 95 % CI = 1.183, 5.266) were statistically significant. Operative duration more than 2 hours did not reach statistical significance (AOR of the model 1 = 0.662, 95 % CI = 0.585, 2.328; AOR of the model 2 = 1.215, 95 % CI = 0.599, 2.467). Although the test for significance of the perioperative temperature factor in the model 2 was not statistically significant (Wald = 3.318, $p = .069$), this factor could increase the odds of developing SSIs (AOR = 1.981, 95% CI = 0.949, 4.133).

In the model 3 and 4, the total scores of the SENIC risk index were put into the analysis, and were statistically significant (AOR of the model 3 = 2.248, 95%CI = 1.545, 3.269; AOR of the model 4 = 2.158, 95% CI = 1.477, 3.152). The interpretation of the model 4 of Table 49 is that every increase in the score of the SENIC risk index increases the odds of developing SSIs by 2.158, and that every 1°C of the decrease of the intraoperative core temperature comparing to the core temperature at the starting point of the operation increases the odds of developing SSIs by 2.101.

One of the components of the SENIC risk index, having an operation which lasts more than 2 hours, was a dichotomous variable, and the raw data of the duration of the operation categorized into “less than” or “more than” 2 hours. Table 39 showed that both of the mean and median minutes of the duration of the operation among patients with and without SSIs exceeded 120 minutes, that is 2 hours. Therefore, Table 50 presents the results of post-hoc logistic regression analysis, using the data of the duration of the operation as a continuous variable. Although the tests for significance of operative duration more than 2 hours did not show any statistical significance in Table 48 and 49, operative duration was statistically significant in the both models in Table 50 (model A: AOR = 1.006, 95% CI = 1.002, 1.009; model B: AOR = 1.004, 95% CI = 1.000, 1.007). The interpretation of the model A of Table 50 was that a surgical patient would have the greatest likelihood of developing postoperative SSIs, if the duration of the operation is 30 minutes longer (AOR = 1.184, $p = .002$), if the wound was

Table 50

Post-Hoc Logistic Regression Analysis of the SENIC Risk Index and a Perioperative Temperature Factor : Duration of the Operation as a Continuous Variable

A. Change between the initial and the final intraoperative temperatures

Variable	Wald	p	AOR ^a	95% CI ^b
Duration of operation	9.357	.002	1.006	1.002, 1.009
Wound class	10.514	.001	3.344	1.612, 6.938
Diagnoses > 3	7.747	.005	3.110	1.399, 6.915
Temperature	15.323	.000	2.846	1.686, 4.805
Intercept	46.840	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 11.517$, $df = 8$, $p = .174$.

-2 Log likelihood = 189.002. Overall percentage of classification table = 80.5%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

B. Change between the initial and the lowest intraoperative temperatures

Variable	Wald	p	AOR ^a	95% CI ^b
Duration of operation	4.869	.027	1.004	1.000, 1.007
Wound class	9.690	.002	3.008	1.504, 6.018
Diagnoses > 3	5.459	.019	2.473	1.157, 5.287
Temperature	2.611	.106	1.842	0.878, 3.865
Intercept	48.119	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 6.977$, $df = 8$, $p = .539$.

-2 Log likelihood = 204.255. Overall percentage of classification table = 80.5%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

categorized contaminated or dirty (AOR = 3.344, $p = .001$), if a patient had more than three discharge diagnoses (AOR = 3.11, $p = .005$), and if the core temperature at the time of ending the operation decreased 1 °C comparing to the core temperature at the starting point of the operation (AOR = 2.846, $p = .000$).

NNIS Risk Index and Perioperative Temperature Factors

Change between the Initial and Final Core Temperatures

The same procedures in logistic regression analysis were repeated for the NNIS risk index. Table 51 presents the final models of logistic regression analysis of the perioperative temperature factor, the change between the initial and final core temperatures, and the NNIS risk index. In the model 1, only one component of the NNIS risk index, wound class, was statistically significant (AOR of the model 1 = 3.402, 95% CI = 1.737, 6.666). In the model 2, wound class (AOR of the model 2 = 3.362, 95% CI = 1.653, 6.839) and operative duration more than T hours (AOR of the model 2 = 2.902, 95% CI = 1.368, 6.155) were statistically significant. The perioperative temperature factor in the model 2 had a significant p-value of the Wald test and could increase the odds of developing SSIs by 2.769 (Wald = 14.159, $p = .000$, AOR = 2.769, 95% CI = 1.627, 4.707).

In the model 3 and 4, the total scores of the NNIS risk index were put into the analysis, and were statistically significant (AOR of the model 3 = 2.131, 95%CI = 1.483, 3.062; AOR of the model 4 = 2.352, 95% CI = 1.589, 3.482). The interpretation of the model 4 of Table 50 is that every increase in the score of the NNIS risk index increases the odds of developing SSIs by 2.352, and that every 1°C of the decrease of the final core temperature comparing to the temperature at the starting point increases the odds of developing SSIs by 2.422.

Change between the Initial and Lowest Core Temperatures

Table 52 presents the final models of logistic regression analysis of the perioperative temperature factor, the change between the initial and lowest core

Table 51

Final Models of Logistic Regression Analysis of the NNIS Risk Index and a Perioperative Temperature Factor : Change between the Initial and Final Core Temperatures

Model 2: Components of NNIS risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
ASA score ≥ 3	0.231	.362	0.406	.524	1.259	0.620, 2.560
Wound class	1.213	.362	11.208	.001	3.362	1.653, 6.839
Duration > T hours	1.065	.384	7.711	.005	2.902	1.368, 6.155
Temperature	1.018	.271	14.159	.000	2.769	1.629, 4.707
Intercept	-2.175	.347	39.278	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 6.661$, $df=8$, $p = .574$.

-2 Log likelihood = 198.121. Overall percentage of classification table = 79.6%.

^aAOR = Adjusted Odds Ratio, ^b95% CI = 95% Confidence Interval

Model 4: Total score of NNIS risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
Total score	0.855	.200	18.280	.000	2.352	1.589, 3.482
Temperature	0.885	.251	12.466	.000	2.422	1.482, 3.958
Intercept	-2.210	.344	41.294	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 11.487$, $df=8$, $p = .176$.

-2 Log likelihood = 202.734. Overall percentage of classification table = 80.5%.

^aAOR = Adjusted Odds Ratio, ^b95% CI = 95% Confidence Interval

Table 52

Final Models of Logistic Regression Analysis of the NNIS Risk Index and a Perioperative Temperature Factor : Change between the Initial and Lowest Core Temperatures

Model 2: Components of NNIS risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
ASA score \geq 3	0.318	.349	0.803	.362	1.374	0.693, 2.723
Wound class	1.155	.350	10.889	.001	3.175	1.599, 6.306
Duration > T hours	0.619	.352	3.095	.079	1.857	0.932, 3.699
Temperature	0.722	.377	3.663	.056	2.058	0.983, 4.308
Intercept	-2.508	.369	46.220	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 10.714$, $df=8$, $p = .218$.

-2 Log likelihood = 210.667. Overall percentage of classification table = 78.3%.

^aAOR = Adjusted Odds Ratio ^b95% CI = 95% Confidence Interval

Model 4: Total score of NNIS risk index + a temperature factor

Variable	B	SE	Wald	p	AOR ^a	95% CI ^b
Total score	0.721	.188	14.691	.000	2.058	1.423, 2.976
Temperature	0.654	.365	3.209	.073	1.923	0.940, 3.931
Intercept	-2.509	.365	47.236	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 14.402$, $df=8$, $p = .072$.

-2 Log likelihood = 213.645. Overall percentage of classification table = 79.2%.

^aAOR = Adjusted Odds Ratio ^b95% CI = 95% Confidence Interval

temperatures, and the NNIS risk index. In the model 1 and 2, wound class showed statistically significant results (AOR of the model 1 = 3.402, 95% CI = 1.737, 6.666; AOR of the model 2 = 3.175, 95% CI = 1.599, 6.306). Other components, the ASA score of more than 3 and operative duration more than T hours were not statistically significant. Although the Wald test of the perioperative temperature factor in the model 2 did not show a significance p-value (Wald = 3.663, $p = .056$), this factor could increase the odds of developing SSIs (AOR = 2.058, 95% CI = 0.983, 4.308).

In the model 3 and 4, the total scores of the NNIS risk index were put into the analysis, and were statistically significant (AOR of the model 3 = 2.131, 95%CI = 1.483, 3.062; AOR of the model 4 = 2.058, 95% CI = 1.423, 2.976). The interpretation of the model 4 of Table 51 is that every increase in the score of the NNIS risk index increases the odds of developing SSIs by 2.058, and that every 1°C of the decrease of the intraoperative core temperature comparing to the core temperature at the starting point of the operation increases the odds of developing SSIs by 1.923.

Although the range of the numbers of procedures performed was from one to thirteen, as described in Chapter III, T hours were determined using the major procedure performed. One of the components of the NNIS risk index, the duration of the operation more than T hours, was a dichotomous variable, and the raw data were categorized into “less than” or “more than” T hours. Therefore, Table 53 presents the results of post hoc logistic regression analysis using the data of the operative duration as a continuous variable. In the both models presented in Table 53, operative duration were statistically significant (model A: AOR = 1.006, 95% CI = 1.002, 1.009; model B: AOR = 1.004, 95% CI = 1.000, 1.007). The interpretation of the model A of Table 53 was that a surgical patient would have the greatest likelihood of developing postoperative SSIs, if the duration of the operation is 30 minutes longer (AOR = 1.184, $p = .003$), if the wound was categorized contaminated or dirty (AOR = 3.535, $p = .001$), and if the core temperature at the time of ending the operation decreased 1 °C comparing to the core

Table 53

Post-hoc Logistic Regression Analysis of the NNIS Risk Index and a Perioperative Temperature Factor : Duration of the Operation as a Continuous Variable

A. Change between the initial and the final intraoperative temperatures

Variable	Wald	p	AOR ^a	95% CI ^b
ASA score ≥ 3	0.249	.618	1.200	0.583, 2.456
Wound class	12.015	.001	3.535	1.731, 7.218
Duration of operation	9.115	.003	1.006	1.002, 1.009
Temperature	13.416	.000	2.642	1.571, 4.444
Intercept	39.919	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 11.445$, $df=8$, $p = .178$.

-2 Log likelihood = 211.712. Overall percentage of classification table = 78.7%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

B. Change between the initial and the lowest intraoperative temperatures

Variable	Wald	p	AOR ^a	95% CI ^b
ASA score ≥ 3	0.611	.434	1.316	0.661, 2.623
Wound class	11.131	.001	3.201	1.616, 6.339
Duration of operation	4.957	.026	1.004	1.000, 1.007
Temperature	2.826	.093	1.885	0.900, 3.946
Intercept	44.638	.000		

Note. Hosmer – Lemeshow goodness-of-fit test $\chi^2 = 10.714$, $df=8$, $p = .218$.

-2 Log likelihood = 210.667. Overall percentage of classification table = 78.3%.

^a AOR = Adjusted Odds Ratio, ^b 95% CI = 95% Confidence Interval

temperature at the starting point of the operation (AOR = 2.642, $p = .000$).

Comparison of the Final Models of Logistic Regression Analysis.

Table 54 presents the values of test statistics of the goodness-of-fit of each model. The upper table is the results of comparisons between the extant risk indices and the modified risk index, in which the change between the initial and final core temperatures was added to the standard risk indices. The lower one is the results of comparisons between the standard risk indices and the modified risk index, which included the change between the initial and lowest core temperatures.

Change between the Initial and Final Core Temperatures

The likelihood ratio (LR) statistic is given by the difference of the values of the transformed index (-2 LL) between at the beginning step and after adding all predictor variables in the model. In SENIC model 1, the value of LR was 21.906 and the corresponding p-value reached statistical significance. Comparing -2LL statistics of the SENIC and NNIS risk indices, the values of model 2 and 4 were smaller than those of model 1 and 3, indicating the perioperative temperature factor could add extra explanatory information to the extant risk index for predicting SSIs (Munro, 1997).

The Hosmer-Lemeshow test is another test of the goodness-of-fit, based on the idea of comparing the observed number of individuals with each outcome with the number expected based on the yield logistic regression model (Glantz & Slinker, 1990). All values of the Hosmer-Lemeshow test were small and corresponding p-values were non-significant, indicating the models fitted the data well. However, comparing the values of the Hosmer-Lemeshow goodness-of-fit statistics of SENIC model 1 and 3 to the values of SENIC model 2 and 4, the former models fitted the data well.

Change between the Initial and Lowest Core Temperatures

Comparing -2LL statistics of the SENIC and NNIS risk indices, the values of model 2 and 4 were smaller than those of model 1 and 3, indicating the perioperative temperature factor could add extra explanatory information to the extant risk index for

Table 54

Comparisons of the Goodness-of-fit of the Final Logistic Regression Models

Perioperative temperature factor : Change between the initial and final core temperatures

	-2 LL ^a	LR	p	H-L test ^b	p
SENIC					
Model1	211.946	21.906	.000	0.597	.963
Model2	195.864	16.082	.000	10.121	.257
Model3	216.169	17.683	.000	0.772	.680
Model4	197.002	19.167	.000	9.288	.319
NNIS					
Model1	214.286	19.565	.000	4.567	.600
Model2	198.121	16.166	.000	6.661	.574
Model3	216.806	17.045	.000	3.458	.177
Model4	202.734	14.072	.000	11.487	.176

Perioperative temperature factor : Change between the initial and lowest core temperatures

	-2 LL ^a	LR	p	H-L test ^b	p
SENIC					
Model1	211.946	21.906	.000	0.597	.963
Model2	208.683	3.262	.071	4.504	.809
Model3	216.169	17.683	.000	0.772	.680
Model4	212.236	3.933	.059	4.340	.825
NNIS					
Model1	214.286	19.565	.000	4.567	.600
Model2	210.667	3.619	.057	10.714	.218
Model3	216.806	17.045	.000	3.458	.177
Model4	213.645	3.161	.075	14.402	.072

Note. ^a -2LL = transformed index of the likelihood index, ^b H-L test = the Hosmer-Lemeshow test

predicting postoperative SSIs (Munro, 1997). Moreover, the change between the initial and final core temperatures could add more explanatory power to the extant risk index for predicting SSIs than the change between the initial and lowest core temperatures.

Comparing the values of the Hosmer-Lemeshow goodness-of-fit statistics of all models of the SENIC risk index, those fitted the data quite well. The Hosmer-Lemeshow tests of the model 4 of the NNIS risk index had a probability value of a little over 0.05, indicating the models fitted the data not so well.

CHAPTER V

DISCUSSION

During the last two decades, it is clear that many researchers have been interested in the risk factors that increase the probability for SSIs following various kinds of procedures including elective and/or emergency operations (Haley, Culver, Morgan et al., 1985; Lizan-Garcia et al., 1997; Medina-Cuadros et al., 1996; The Parisian Mediastinitis Study Group, 1996). Considerable epidemiological evidence has shown that the development of SSIs results from the complex interactions among the patient's susceptibility to infection, perioperative, and microbiological factors. Among these factors, how to measure the patient's susceptibility to SSIs validly and precisely is a key issue to predict the probability of postoperative SSIs (Haley, 1991b). In this dissertation project, factors related to perioperative temperature were focused on, and their impact on prediction of postoperative SSIs was examined.

Sawyer et al. (2001) conducted three and half year nosocomial infection surveillance among general and trauma surgical patients, using the CDC definitions of SSIs. A total of 322 (31%) surgical wound infections and 185 (18%) intra-abdominal infections were identified among 1,053 all nosocomial infections, and the researchers concluded that patients with an infection clearly associated with surgery. In particular, an abdominal approach has been identified to increase the risk of SSIs significantly (Garibaldi et al., 1991; Haley, Culver, Morgan et al., 1985; Nguyen et al., 2001). Nearly 54% (n = 123) of the sample of this dissertation project were trauma patients, yielding 22.6% of the SSI rate. The SSI rates among abdominal surgical patients reported in previous studies were 16.3% (Roberts & Bates, 1992), 13% (Shukla, Roy, Kumar, & Vaidya, 1985), and 7.2% (Garrow et al., 1988). Comparing to these reported rates of SSIs, the SSI rate of this study was high. Not only abdominal surgery but also traumatic injury can increase the risk for nosocomial infections, and SSIs are the most

common site-specific nosocomial infections among patients with traumatic injuries (Jamulitrat, Na Narong, & Thongpiyapoom, 2002). Several clinical researchers have identified that surgical patients with penetrating abdominal trauma are at high risk for the development of SSIs (Nichols et al., 1984; Rush & Nichols, 1986). The findings of this dissertation project also supported that traumatic injuries increased the risk for postoperative SSIs. Therefore, the higher percentage of trauma patients included in the sample of this study might cause the higher rate of SSIs (54% in this dissertation vs. 28.5% in the research conducted by Sawyer et al.).

In addition to this high percentage of trauma patients, 81% ($n = 178$) of this sample underwent emergency surgery. This was another unique feature of this study sample. Out of 123 trauma patients of this sample, 85 patients (69.1%) underwent an emergency operation due to penetrating abdominal trauma. In previous studies, the percentage of emergency surgery included was from 11.5% (The Parisian Mediastinitis Study Group, 1996) to 41.6% (Borger et al., 1998). Urgency of operation itself has not been identified as a significant risk factor for SSIs, however, the mode of surgical intervention seems to be associated with the surgeon's performance and the preoperative preparation. Most of patients undergoing emergency surgery could not get any treatment for preoperative bowel preparation. As shown in Table 39, among patients with SSIs, 33.3% ($n = 17$) were clean-contaminated wounds and 45.1% ($n = 23$) were contaminated wounds. There was a reverse result in the distribution of the wound classification among patients without SSIs (clean-contaminated 57.3%, contaminated 25.3%). Inadequate preoperative bowel preparation makes wounds more contaminated. Once the amount of potential endogenous bacterial contamination increases, the risk of postoperative SSIs also increases.

The second research question of this study was whether there were any significant differences in perioperative temperatures between patients with and without SSIs. Beilin et al. (1998) have pointed out that mild hypothermia occurs in 50-70% of

patients undergoing surgery, because of anesthetic-induced impairment of thermoregulation and unintentional heat loss during operations due to exposure to a cold environment. All patients in this sample underwent general abdominal surgery under general anesthesia, and the intraoperative core temperature decreased at least 0.1°C in 72.2% of patients. General anesthesia produces dose-dependent thermoregulatory inhibition (Sessler, 1993) and impairs the normal control mechanism of body temperature, which includes thermoregulatory vasoconstriction, nonshivering thermogenesis (only in infants), and shivering. Those thermoregulatory responses have their own threshold (triggering core temperature) (Forstot, 1995). Although unanesthetized individuals tightly control their central temperature in a narrow interthreshold range of 0.2°C, general anesthesia increases this interthreshold range to approximately 4°C, and temperatures within this range simply do not trigger thermoregulatory responses (Sessler, 1997). Sessler (1993) mentioned that during general anesthesia, the threshold for thermoregulatory vasoconstriction, the first thermoregulatory response of the human body to cold stimulus, and shivering, are decreased approximately 3°C, shifted down from 37°C to 34.5°C. This means that thermoregulatory vasoconstriction does not occur during typical doses of anesthesia until the core temperature reaches approximately 34°C.

Heat loss in surgical patients is due to several of the following operation-related factors: 1) ambient cold operating room temperature, 2) open body cavities, and 3) temperature of intravenous fluid and blood administration (Frank et al., 1992, 1997). When surgical patients are exposed to a cold operating environment, temperatures of the peripheral tissue of skin, fat, and muscle decrease. To maintain the body's internal temperature to be constant at about 37°C, thermoregulatory responses to cold stimuli usually occur. In surgical patients during anesthesia, the normal thermoregulatory responses are impaired and thermoregulatory vasoconstriction and shivering do not occur. Consequently, internal body heat is redistributed from the warm core to the cooler

peripheral tissues (Sessler, 1993, 1997). Therefore, the core temperature in most surgical patients during anesthesia becomes hypothermic because of the combination of anesthetic-induced thermoregulatory impairment and redistribution of body heat caused by unintentional exposure to a cold operating environment.

The biological or physiological mechanisms between hypothermia and SSIs have been examined, and hypothermia may facilitate the development of SSIs by the following two reasons. First, thermoregulatory vasoconstriction decreases the partial pressure of oxygen in tissues, and this has been shown to lower resistance to SSIs in a study conducted with mongrel dogs (Jonsson et al., 1988). Hopf et al. (1997) identified that subcutaneous tissue oxygen tension (P_{sqO_2}) baseline and max values were significantly lower in infected patients than in uninfected patients who underwent general surgery. Second, intraoperative hypothermia directly impairs immune function (Beilin et al., 1998), including oxidative bacterial killing by neutrophils, by decreasing the availability of tissue oxygen (Sessler, 1995; Wenisch et al, 1996). Consequently, perioperative unintentional hypothermia may increase the patient's susceptibility to SSIs and the risk for impaired wound healing, by causing a decrease of oxygen in tissues and impairment of immune function.

Based on the knowledge of the association between the perioperative core temperature and postoperative SSIs, Kurz et al. (1996) conducted a prospective, double-blind, and randomly assigned clinical trial of 200 patients with colorectal surgery and demonstrated that the SSI rate of the normothermia group (mean intraoperative temperature 36.6 ± 0.5 °C) was 6%, compared to 19 % of the hypothermia group (mean intraoperative temperature 34.7 ± 0.6 °C), concluding that hypothermic patients were five times more likely to develop SSIs than normothermic patients ($p = .009$). The mean lowest core temperature of infected patients was 35.1 ($SD = 1.0$) °C and 35.8 ($SD = 1.1$) °C in those without infections ($p < .001$) (Sessler & Kurz, 1996). Similar results were reported in a prospective cohort study of 290 patients with clean-contaminated

surgery (Flores-Maldonado, Medina-Escobedo, Rios-Rodriguez, & Fernandez-Dominguez, 2001). Contrary to these reports, Baker et al. (1995), Munn et al. (1998), Barone et al. (1999), and Trick et al. (2000) identified that there were no differences in the SSI rates between normothermic and hypothermic patients.

In this study, the data related to perioperative temperature were collected in several ways: the core temperature at the time of starting the operation, the core temperature at the time of ending the operation, the lowest intraoperative core temperature, and duration of the intraoperative core temperature less than 35°C. The number of surgical patients whose core temperature dropped to less than 35°C was 40 (17.4%), and the mean lowest intraoperative core temperatures in both patient groups exceeded this arbitrary cut-off point. Unlike the findings of the study conducted by Kurz et al. (1996), no significant differences between patients with and without SSIs were found on these four perioperative temperature measurements. Recently, Crandall, Vongpatanasin, and Victor (2002) conducted a randomized, double-blind, placebo-controlled trial using seven healthy cocaine-naïve volunteers and concluded that impaired heat dissipation by cocaine caused elevation of body temperature. In this study, nearly 32% ($n = 73$) patients used any kinds of illicit drugs, including cocaine, heroin, ecstasy, amphetamine, and marijuana. Because of a retrospective cohort study design, the detailed data, such as frequency, dose, or preoperative last date of drug use, could not be obtained. Because no previous studies on intraoperative hypothermia reported the data regarding illicit drug users, cocaine users in particular, whether it is the average percentage of illicit drug users in the population or not is unknown. However, as among the healthy persons with passive heating, the small dose of intranasal cocaine impairs thermoregulatory responses to heat stimulus, it cannot be denied that surgical patients who were cocaine users in this study might affect the changes of the intraoperative core temperatures.

Barone and Lowenfels (1999) pointed out that the difference of one-point

measurement in the core temperature between infected and uninfected patients was not clinically significant, whereas the results were statistically significant. As mentioned in Chapter III, because the core temperature itself has a deviation of the range, and the normal range of the core temperature is influenced by age (Kurz, Plattner et al., 1993), gender (Dymond & Fewell, 1999), use of cocaine (Crandall et al., 2002) as well as circadian rhythm and underlying disease, there may be a deviation of the range of the core temperature for triggering thermoregulatory responses. Therefore, in this study, the lowest and final intraoperative core temperatures were compared to the initial intraoperative core temperature in order to measure how many degrees of the intraoperative core temperature decreased, compared to the individual's initial baseline core temperature. This intra-person difference of the intraoperative core temperature could take account for each patient's deviation of the range of the core temperature. Expectedly, there were statistically significant differences in the change between the initial and final core temperatures and the change between the initial and lowest core temperatures at a p-value of less than 0.05 in this study. The differences between two-point measurements of the perioperative core temperatures might give us more information about each patient's susceptibility to SSIs than one-point measurement, such as the lowest core temperature during the operation.

The rates of SSIs cannot be compared without adjustment for the patient's susceptibility to infections and the case mix of patients. The SENIC risk index and NNIS risk index are two simple systems for predicting postoperative SSIs, allowing adjustment for differences in the patient's susceptibility to SSIs among different hospitals or services. Two previous studies compared these two risk indices, and the findings were not consistent (Delgado-Rodriguez et al., 1997; Haley 1993). It cannot be concluded that the one risk index is better than the other for predicting the risk of SSIs. Although this comparison is beyond the purposes of this dissertation project, the values of Kendall's tau-b statistics were almost same and indicated that both indices were good

predictors for postoperative SSIs. Because only surgical patients who underwent abdominal surgery were included in this study sample, all patients got one point for the first variable of the SENIC risk index (having an operation which involves the abdomen). Therefore, this variable did not behave as a risk factor for SSIs among the sample of this dissertation, and this may explain the finding of this comparison in this study.

Although the experts pointed out that the limited ability to discriminate the SSI risk of all types of operations was weakness of the NNIS risk index (Mangram et al., 1999), the NNIS risk index has been recognized as the best way to stratify the risk for SSIs (Sherertz et al., 1992). Recently, examining a nationwide data of 738,398 operative procedures, investigators of the CDC concluded that the NNIS risk index was useful for risk adjustment for a wide variety of procedures and has encouraged to apply the index within a broad range of operative procedures including laparoscope use (Gaynes et al., 2001). At the same time, necessity of improvement in the risk indices for specific operative procedures has been appreciated (Horan et al., 1996; Nichols et al., 1984; Velasco et al., 1998).

The findings of this dissertation project suggest that the changes or the differences of two-point measurements of the perioperative core temperatures can improve the risk index among general abdominal surgical patients. The change between the initial and final core temperatures as well as the change between the initial and lowest core temperatures could add more explanatory power to both the SENIC and the NNIS risk indices, even though three odds and the corresponding p-values of the final models of the NNIS risk index were not statistically significant. The modified risk index with the change between the initial and final core temperatures fitted the data fairly well (see Table 54). However, the results of the goodness-of-fit tests of the extant risk index with the change between the initial and lowest core temperatures, were not consistent. Therefore, these results suggest that the change between the initial and final core temperatures added more explanatory power to the extant risk index than the change

between the initial and lowest core temperatures. It means that how well the final core temperature returns to the initial baseline core temperature gives healthcare professionals more information for predicting postoperative SSIs than how many degrees of the intraoperative core temperature decreases or the value of the lowest intraoperative core temperature itself. In another words, no matter what degrees of the initial core temperatures are, even less than 35 °C or nearly 38 °C, the minimum difference between the initial and final core temperatures or an excess of the final core temperature over the initial core temperature can reduce the chance or the probability of postoperative SSIs.

In spite of the additional information on postoperative SSIs, as Dellinger and Ehrenkranz (1998) pointed out, it is clear that there is intercorrelation between the perioperative core temperature and a prolonged operation. A prolonged operation results in a longer period of anesthesia and unintentional exposure to a cold operative environment. One of the components of both extant risk indices, duration of the operation, was a dichotomous variable, that is “less than” or “more than” 2 hours (SENIC risk index) or T hours (NNIS risk index). Comparing the modified risk indices, in which the perioperative temperature factor was added to the SENIC risk index, between using a dichotomous variable and a continuous variable of operative duration, the only results of logistic regression analysis using the latter showed that duration of the operation was statistically significant (see Table 48, 49, and 50). The categorization of duration of the operation reduces variability of the raw data, and it may mask the effect of the change of the intraoperative core temperatures on SSIs, because the mean and median minutes of the procedures performed among both patients with and without SSIs exceeded 2 hours. However, the change of the intraoperative core temperatures depends on not only duration of the operation but also several factors related to the patient’s susceptibility, such as age, gender, and severity of illness. Therefore, in spite of the overlapped information between the perioperative core temperatures and one of the components of the extant risk index, the change between the initial and final core

temperatures gives useful information which cannot be captured by the components of the extant risk index to the healthcare professionals.

As mentioned before, animal and human studies have identified the biological or physiological mechanisms between hypothermia and SSIs, and intraoperative hypothermia has been recognized to increase the risk of postoperative SSIs. Comparing the lowest intraoperative core temperatures between the groups with and without SSIs, several researchers have tested the hypothesis that intraoperative unintentional hypothermia increases the patient's susceptibility to SSIs and established evidence to support the hypothesis (Flores-Maldonado et al., 2001; Kurz et al., 1996; McAnally, Cutter, Rutternber, Clarke, & Todd, 2001). However, the findings of this dissertation study could not support this hypothesis. Not the lowest intraoperative core temperature (hypothermia) but the change of the perioperative core temperatures gave us additional information on the predictability of postoperative SSIs.

Significance

This is the first cohort study to examine the relationship between postoperative SSIs and intraoperative hypothermia using two-point measurements of the perioperative core temperature among general abdominal surgical patients. Most of the previous studies regarding SSIs have been focused on clean or clean-contaminated surgeries, such as cardiac surgery, hernia surgery, caesarean section, breast surgery, or elective colorectal surgery. In this study, regardless of their wound classification, all patients who underwent general abdominal surgeries were included. Considering complexity and high volume of the operations performed every day, whether an operation involved the abdomen or not is the first clue for healthcare professionals to assess the risk of postoperative SSIs in the clinical practice. Moreover, using the findings of this dissertation, healthcare personnel who care for patients perioperatively can get more specific information on prediction of SSIs. Also, the importance of the findings of this

dissertation study may lie in the use of two-point measurements of the perioperative core temperatures. Most of preeminent researchers who were interested in intraoperative hypothermia have been used the specific value of the intraoperative core temperature in their definitions of hypothermia. However, the findings of this study suggested that the two-point measurements of the perioperative core temperatures would be a more useful and practical information for the healthcare professionals.

Limitations

Several limitations related to selection bias and information bias, which were already discussed in Chapter III, will be discussed in this section.

The first limitation related to the fact that all medical records of eligible patients for this study were not available for the author. As mentioned in Chapter IV, 18 patients were eliminated from the study sample because their medical records could not be obtained or some of them were missing. All surgical patients in this study had follow-up appointments at SFGH, and the author could get the data of the majority of them (85.2%). However, the rest of the patients ($n = 34$) were classified as non-infected, because their data regarding follow-up clinic visits, emergency room visits, or readmission were not available. Therefore, these issues might distort the estimation of the occurrence of SSIs in this study.

The data extracted and analyzed in this study relied on previously existing data, which was not collected originally for this study. In an editorial letter written by Sessler, Kurz, and Lenhardt (1999), in which they defended the validity and reliability of their study conducted in 1996 against the critique by Barone et al. (1999), how to measure the perioperative core temperature is a key issue in an uncontrolled and retrospective study on intraoperative hypothermia. In this study, the intraoperative core temperature was monitored by temperature probes, which were a part of endotracheal tubes. As Sessler et al. pointed out, it is unlikely that the probes in these retrospectively studied patients

are properly positioned. As this dissertation was a retrospective cohort study, this point is also a limitation.

In addition to the data on perioperative temperature, the ASA score and the number of discharge diagnoses, which are components of the extant risk indices, were not congruent among the several records in each patient or between patients. The ASA score of each patient could be found in several records: preoperative evaluation sheet, operating room record, and anesthesia record. In some patients, the ASA score was not congruent among these records. Also, the number of discharge diagnoses was primarily extracted from discharge or transfer summary, which was written by a primary surgeon. The way to list up discharge diagnoses was not congruent among physicians. These issues related to the accuracy of the data collected for this study.

There was a limitation related to the use of the initial core temperature as the baseline temperature of each patient. Because of a retrospective study design, the author could not get the normal baseline temperature of each patient preoperatively. The initial core temperature of some trauma patients were less than 34 °C due to a longer period of exposure to a cold environment or impairment of the thermoregulatory mechanisms. Therefore, the value of the initial core temperature used in this study does not always simply take account for each patient's deviation of the range of the core temperature.

The final limitation of this dissertation was that only general abdominal surgical patients were included in this study. There are many other surgeries with and without an abdominal approach, which were not included in this study. Therefore, the findings of this study could not be generalized or applied directly to other patient populations.

Clinical Implications for Nursing

Although the estimated mortality rate related to SSIs is relatively low compared to those of other nosocomial infections, the excess cost attributable to SSIs has been

identified as the highest or the second highest among the common nosocomial infections. Therefore, SSIs are now recognized as a major cause of economic burden to hospitals in the United States, and prevention of postoperative SSIs is the first line of defense in health care cost reduction (Calderone et al., 1996). As the investigators of the CDC provided the strongest scientific evidence (Cruse & Foord, 1980; Haley, Culver, White, Morgan, Emori, & Munn, 1985), it is crucial for a reduction of nosocomial infection rates to develop an adequately organized, routine, and hospital-wide surveillance system and to monitor the incidence of SSIs precisely. This study can remind healthcare personnel of the importance of systematic SSI surveillance and suggest that perioperative assessment of the several risk factors for SSIs would be useful to identify high-risk or target population whom they have to prioritize in monitor or management during the postoperative period. The primary clinical implication of this dissertation is that not only infection control practitioners but also clinical nurses can use the change of the intraoperative core temperatures as an efficient screening tool for predicting the risk of subsequent postoperative SSIs.

Intraoperative protective methods or rewarming techniques are common in operating rooms in order to minimize hypothermia-related complications (Sessler, 1995). Several studies have examined the efficacy of these techniques: warming of intravenous fluid (Muth, Mainzer, & Peters, 1996; Smith et al., 1998), warming blankets (Camus, Delva, Bossard, Chandon & Lienhart, 1997; Camus, Delva, Just, & Lienhart, 1993; Chandon, Paugam, Cohen, & Lienhart, 1995; Sessler & Schroeder, 1993), circulating water mattress (Hynson & Sessler, 1992), and forced air warming (Clough, Kurz, Sessler, Christensen, 1996; Kurz, Kurz et al., 1993). Among them, forced air warming has been recognized as the most effective noninvasive warming method for surgical patients (Sessler, 1995). When any kinds of the warming techniques are applied to surgical patients, the arbitrary cut-off point of the intraoperative core temperature, for example when the intraoperative core temperature decreases less than 35 °C, would be used.

However, the findings of this study suggest that two-point measurements of the core temperatures, that is how many degrees of the core temperature decreases regardless of the initial core temperature, could provide more effective and practical cut-off points for applying and taking off rewarming devices.

Implications for Future Research

Due to the limited number of the available research articles on the association between intraoperative hypothermia and SSIs and the inconsistent study findings, this study would be a contribution to the controversy of the impact of hypothermia on the occurrence of SSIs. However, it is clear that more studies should be conducted on this subject. Considering a deviation of the range of each patient's core temperature, it is ideal to measure and set the normal baseline temperature of each patient preoperatively, and to compare the intraoperative temperature to the baseline temperature. In this dissertation, the data on perioperative temperature were collected at three points during the operation: the initial, lowest, and final core temperatures. These data could not show how the intraoperative core temperatures changed over the time. It is necessary to identify how the change of the intraoperative core temperature correlates with the duration of operation performed in the future studies. Also, to minimize information bias, the data should be collected by a team of some well-trained and experienced people in this area. Therefore, a prospective cohort study would be an appropriate research design for the future research.

In this study, patients who underwent the following three high volume procedures at SFGH were included: exploratory laparotomy, large and small bowel surgeries. Besides them, there are many other surgeries with an abdominal approach, which were not included in this study, such as gynecological surgery, cesarean section, and gastrectomy. Therefore, replication studies among the same population as this study as well as the different patient population within a broad range of operative

procedures are needed.

A final goal of this research program is to establish a simple and more practical risk index for predicting the probability of postoperative SSIs among surgical patients with various kinds of procedures. Evaluation study is needed to examine the validity of the modified risk index, in which a factor related to the perioperative core temperature was added to the extant risk index, and the range of applicability of this modified risk index. Also, whether the use of the modified risk index can contribute to a reduction of the SSI rates as well as whether the intervention for preventing a decrease of the intraoperative core temperature can reduce the risk for developing SSIs should be studied.

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APPENDIX

Criteria for Defining a Surgical Site Infection (SSI)

Superficial Incisional SSI

Infection occurs within 30 days after the operative procedure *and* involves only skin or subcutaneous tissue of the incision, *and* at least *one* of the following is present:

1. Purulent drainage from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat - *and* superficial incision is deliberately opened by surgeon, *unless* culture of incision is negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do *not* report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

Deep incisional SSI

Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure *and* infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision, *and* at least *one* of the following is present:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever(>38°C), localized pain, or tenderness, unless culture of the incision is negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Notes:

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.

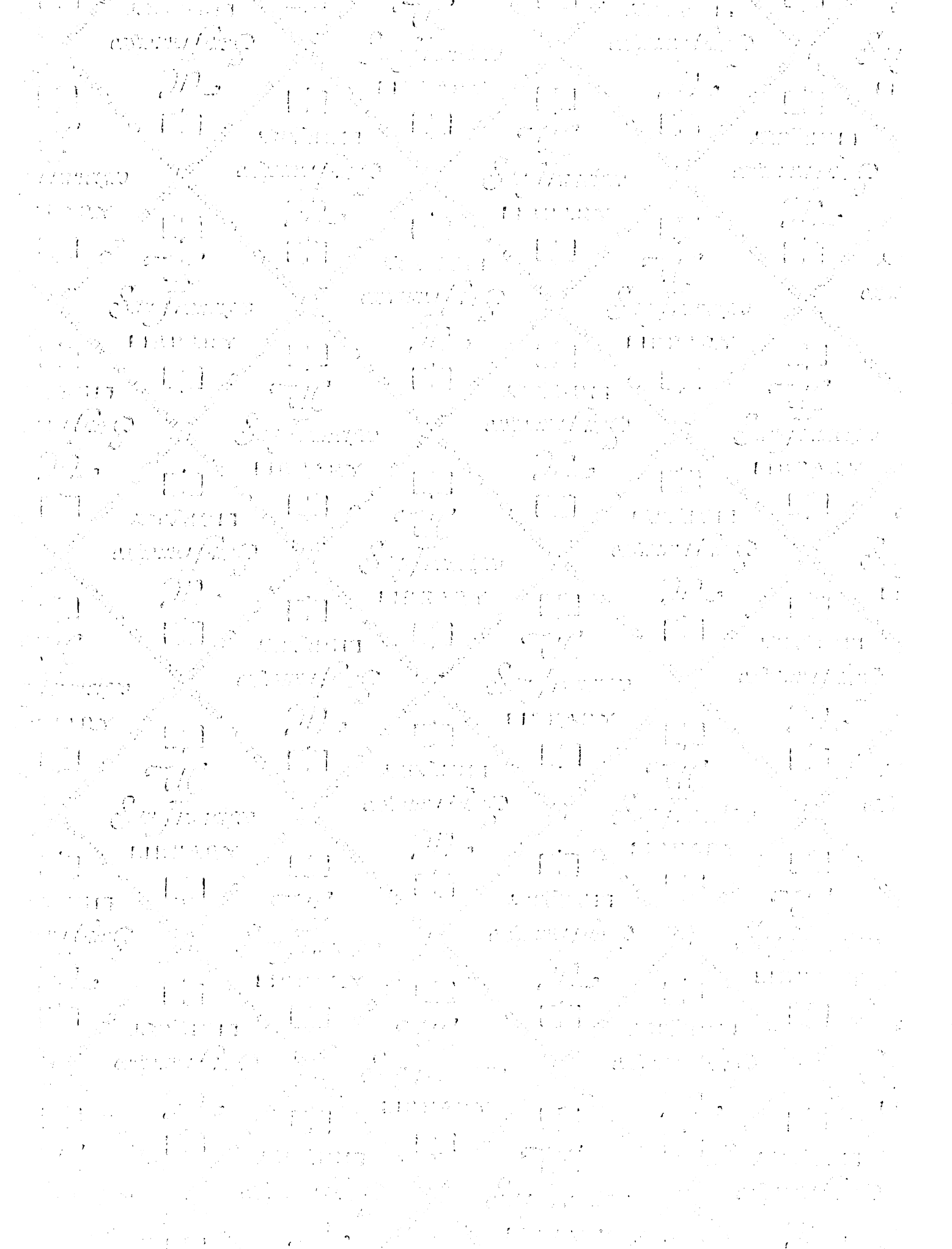
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Organ/space SSI

Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure *and* infection involves any part of the anatomy (e.g., organs or spaces), other than the incision opened or manipulated during an operative procedure, *and* at least *one* of the following is present:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

Note. From "CDC definitions of nosocomial surgical site infections, 1992: A modification of CDC definitions of surgical wound infections" by T. C. Horan, R. P. Gaynes, W. J. Matone, W. R. Jarvis, & T. G. Emori, 1992, Infection Control and Hospital Epidemiology, 13, 606-608.



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