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REGRET AROUND FERTILITY CHOICES IS DECREASED WITH PRE-TREATMENT COUNSELING IN GYNECOLOGIC CANCER PATIENTS

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Abstract

Purpose—Data have demonstrated an association between regret and lack of fertility counseling among patients undergoing treatment for non-gynecologic cancers. We sought to determine if fertility-related regret is reduced with pre-treatment counseling or fertility-sparing surgery (FSS) in patients with gynecologic cancers.

Methods—A cross-sectional survey was administered to 593 reproductive-age survivors (18-40 years old at diagnosis) of localized cervix, ovarian, or endometrial cancers that were eligible for FSS. A validated Decision Regret Score was used to evaluate regret in patients.

Results—470 women completed the survey. Forty-six percent received pre-treatment counseling about treatment's effects on fertility. Having received counseling (adjusted ß-coefficient of −1.24, 95% CI=−2.29-−0.18, p=0.02), satisfactory counseling (adjusted ß-coefficient of −2.71, 95% CI= −3.86–−1.57, p<0.001) and FSS (adjusted ß-coefficient of −1.26, 95% CI=−2.39-−0.14, p=0.03) were associated with lower regret post-treatment, after adjusting for age. Time since diagnosis, prior parity, socioeconomic status and cancer type were not associated with regret (p>0.05). While 50% of women reported desiring more children after diagnosis, desire for children after treatment was associated with increased regret (adjusted ß-coefficient of 3.97, 95% CI=2.92-5.02, p<0.001).

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COMPLIANCE WITH ETHICAL STANDARDS

The authors declare no conflict of interest. This research was supported by the National Institutes of Health (Grant Number T32 HD007440- Dr. Chan). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Conclusions—Though less than half of study participants received counseling about the effect of cancer treatment on future fertility, both fertility counseling and FSS were associated with decreased regret in reproductive-aged women with gynecologic cancers. Desire for more children after treatment was associated with increased regret.

Implications for Cancer Survivors—Inquiring about fertility desires and providing counseling regarding reproductive outcomes following cancer treatment should be implemented as part of the treatment process.

Keywords

regret; fertility; fertility preservation; counseling; survivorship; gynecologic oncology

INTRODUCTION

Of the over 1.5 million new cancers diagnosed, an estimated 98,280 will affect the gynecologic tract[1] and 15-20% of women diagnosed with these malignancies are under the age of forty[2]. Per the 2010 Surveillance, Epidemiology and End Results (SEER) statistics, 8% of endometrial cancer, 12% of ovarian cancer, and 40% of cervical cancers are diagnosed during childbearing years. Standard treatments of these cancers often involve surgical removal of the uterus, fallopian tubes and ovaries, pelvic radiation or chemotherapy that may render a patient sterile[3]. In young women who have not yet completed childbearing, these treatments may have negative consequences. Existing studies have indicated that the potential iatrogenic loss of the ability to produce and raise a healthy child is an important concern for young cancer patients[4], particularly female patients[5].

With early detection of cancer and improved treatment protocols, survival of cancer patients has improved. Thus, quality of life issues, such as the maintenance of fertility, are important and fertility-sparing treatment options are integral to the care of reproductive-aged women with cancer without compromising cancer outcomes[6]. Fertility-sparing surgery for localized gynecological cancers has been associated with a significant number of post-treatment pregnancies[7]. When faced with a diagnosis of cancer, patients face an onslaught of information and are tasked with making many decisions regarding the next steps of their care. A 2015 systematic review of studies that reported primary data regarding satisfaction and psychological outcomes among women who underwent fertility preservation counseling cites regret around fertility decisions as a key component of quality of life concerns for reproductive-age cancer survivors[8]. For reproductive-age patients in particular, how these decisions may impact future fertility and the regret and distress caused by the consideration of alternative treatments are significant.

While it is known that reproductive concerns are important to many young gynecologic cancer survivors[9], the effect that fertility counseling and undergoing fertility-sparing therapies have on regret after treatment is unknown. The aim of this study is to compare regret in gynecologic cancer survivors who did and did not recall pre-treatment fertility counseling. Women who are younger and have desire for more children are at highest risk of regret. We hypothesize that regret will be lower in those who received counseling. This study also aims to evaluate the effect of fertility-sparing surgery (FSS) on regret and to

characterize the patients at highest risk of regret. We hypothesize that those who undergo FSS have lower regret scores compared with those who did not.

MATERIALS AND METHODS

A cross-sectional survey study was performed using the California Cancer Registry (CCR), a statewide population-based cancer surveillance system that collects data obtained from cancer patients' medical records. The CCR is a searchable database that contains demographic, diagnostic, and treatment data that allows researchers to contact eligible participants for studies. The University of California, San Francisco (UCSF) Committee on Human Research approved all study procedures. Investigators obtained informed consent from each participant.

Patients

Patients with a history of localized cervical, ovarian, and endometrial cancers were included. Women were diagnosed between 1993 and 2007 and were between the ages of 18 and 40 at the time of diagnosis. All available cases in the time period were included for potential participation. Stage of cancer was determined by the Surveillance Epidemiology and End Results (SEER) staging index that stratifies advancement of disease as in-situ, localized, regional by direct extension, regional by lymph nodes, regional by direct extension and lymph nodes and metastatic disease. Patients with localized cervical, ovarian and endometrial cancers with a SEER stage of 1 ("confined to organ of origin") were included. We excluded patients with non-localized disease (SEER score > 1).

Recruitment

Women were contacted between January 2010 and June 2013. A contact letter was sent to potential participants explaining the purpose of the survey, the source of the individual's personal contact information and provided a link to the online survey. Participants could opt out of the survey and decline further contact. A second mailing was sent to participants who did not respond to the first. This included a printed survey, consent form, a postage-paid return envelope and a refusal postcard. Those who did not reply within one month received a reminder phone call.

Survey

The survey was created at UCSF and was assessed for content validity – the extent to which our survey accurately assessed reproductive health history, quality of life, and decisional satisfaction and regret – by two independent experts in survey methodology. Twenty patients from the UCSF Center for Reproductive Health piloted the survey for content and readability. The final survey included questions about demographic information, past obstetric and gynecologic history, cancer type and treatment, fertility preservation actions, and post-treatment quality of life (including regret).

Regret Assessment

The Decision Regret Scale (DRS) was used to estimate regret in participants following cancer treatment. The DRS is a validated scale that measures "distress or remorse after a

[health care] decision"[10] and includes five questions pertaining to feeling that one had chosen the wrong treatment, a wish to change the decision, or doubt about the value of any treatment. Each question was measured on a Likert scale with 5 possible responses ranging from "strongly agree" to "strongly disagree", with three questions assessing decisional satisfaction and two questions assessing decisional regret. High scores on regret indicate strong misgivings about one's choice of treatment and a counterfactual wish to change one's mind. This scale has been used in other studies to measure regret with decision-making in non-gynecologic cancer patient populations[11-13].

Fertility Counseling

We asked whether one's "oncologists or surgeons discussed how your health and treatment could affect [one's] reproductive function." Respondents answered: "No, not at all," "Yes, but not as much as you wanted," "Yes, almost as much as you wanted," or "Yes, and as much as you wanted." Those who answered "Yes, almost as much as you wanted" or "Yes, and as much as you wanted" were considered as having received satisfactory counseling about reproductive options.

Statistical Analysis

Survey data was merged with CCR data under unique, anonymous identifier codes. Statistical analyses were performed using STATA Version 11 (College Station, TX). Statistical significance was defined by two-sided p-values less than 0.05. Power analyses revealed that our sample size would permit detection of a difference of 1 or greater on the DRS between women who did and did not receive fertility counseling. Comparisons between survey responders and non-responders were performed two-sided Student's t-tests, Wilcoxon Rank-Sum tests, and logistic regression as appropriate. Linear regression was performed to determine the relationship between regret and multiple independent variables. Multivariable regression analysis was performed to determine risk factors for regret after adjusting for confounders as appropriate. An alpha of 0.05 was used for all statistical tests.

RESULTS

Patient Sample

470 completed the survey and 123 declined participation. Table 1 compares those who completed the survey with those who declined. The groups were similar with respect to age at the time of diagnosis, age at the time of survey, and socioeconomic status. There was a higher rate of decline amongst ovarian cancer survivors as compared with other cancers ($p<0.001$). Demographic characteristics of the 470 responders are shown in Table 2. The mean age of the total sample at the time of diagnosis was 33.7 years. The mean age at the time of survey completion was 45.2 years. Sixty-nine percent of women had children prior to their cancer diagnosis, and 50% desired more children after diagnosis.

Associations with Regret

Among the 470 respondents with localized disease who were eligible for FSS, 206 (46%) recalled pre-treatment counseling from their oncologist or surgeon about the treatment's potential effects on future fertility. In univariate analysis, counseling regarding the effect

cancer treatment would have on fertility was associated with lower regret scores (ß-coefficient of −1.76, 95% CI = −2.78 - −0.734, p=0.001) (Table 3). One hundred ninety of the 206 who recalled receiving counseling about their fertility responded to questions regarding satisfaction with such counseling. Forty-seven percent (90/190) of those who were counseled recalled a satisfactory counseling experience. Satisfaction with this counseling was associated with even lower regret scores (ß-coefficient of −3.37, 95% CI = −4.49 - −2.24, p<0.001).

One hundred and eighty-two women (39%) underwent FSS (where the uterus and at least one ovary were retained – i.e. cold knife cone, trachelectomy, unilateral salpingo-oophorectomy, ovarian cystectomy). Among all patients eligible for FSS, there was not an association between undergoing FSS and regret (ß-coefficient of −0.554, 95% CI = −1.63 - . 517, p = 0.31).

Desire for more children at the time of diagnosis was associated with higher regret scores (ß-coefficient of 3.83, 95% CI = 2.87 - 4.79, p <0.001). Age (at the time of diagnosis or completion of survey), time since diagnosis, prior parity, socioeconomic status, cancer type and race were not associated with regret in this population (p>0.05).

In multivariable regression analysis, after adjusting for age at the time of diagnosis and at the time of survey, having received counseling about cancer treatment effects on fertility (adjusted ß-coefficient of −1.24, 95% CI = −2.29 - −0.18, p=0.02), satisfaction with this counseling (adjusted ß-coefficient of −2.71, 95% CI = −3.86 – −1.57, p<0.001) and undergoing FSS (adjusted ß-coefficient of −1.26, 95% CI = −2.39 - −0.14, p=0.03) were all associated with lower regret scores. Desire for children at the time of cancer diagnosis was again associated with higher regret (adjusted ß-coefficient of 3.97, 95% CI = 2.92-5.02, p<0.001).

DISCUSSION

This is one of the first studies to evaluate decisional regret around fertility choices in reproductive-age survivors of localized gynecologic cancers. While less than half of participants (46%) received pre-treatment fertility counseling, women had lower regret scores around fertility choices when they received this counseling and if they were satisfied with this counseling. Undergoing FSS was also independently associated with decreased regret. While the majority of participants had children prior to their cancer diagnoses, half of participants desired more children at the time of diagnosis, and desire for more children was associated with higher regret scores.

Our findings are consistent with prior studies in other cancer populations. Pre-treatment fertility counseling has been demonstrated to be associated with an improvement in the quality of life of young survivors of nongynecologic cancer [12]. It has also been demonstrated that negative experiences surrounding fertility preservation consultation prior to gonadotoxic treatment in young women is correlated with decisional regret[14]. Among those who received counseling, our study demonstrated that those who received satisfactory counseling had lower regret scores than those who received unsatisfactory counseling

($p<0.001$). This highlights the importance of and need for quality counseling and education surrounding fertility choices prior to pursuing cancer treatment. As part of updated practice guidelines, American Society of Clinical Oncology recognized the importance of early discussions of the possibility of infertility associated with cancer treatments for reproductive-aged patients early in to allow for the consideration of fertility preservation options[15]. Education leads to less decisional remorse and likely improved satisfaction with one's choice of cancer treatment.

Approaches to pre-treatment fertility counseling that could reduce regret would improve the experience of newly diagnosed cancer patients who must make decisions regarding future fertility. This can be achieved through the use of fertility-related decision aids[16], increasing provider awareness of the importance of fertility counseling prior to treatment[17] and clearly determining the future childbearing desires of patients. In the current study, participants who received pre-treatment counseling experienced less regret, emphasizing the importance of counseling in reducing the risk of later regret. Age at the time of cancer diagnosis, prior parity, cancer type, socioeconomic status, race and ethnicity did not appear to be independently associated with regret.

Strengths and Limitations

To our knowledge, this is the first study of decisional regret in reproductive-age gynecologic cancer survivors surrounding issues of fertility preservation. A large proportion of our study population completed the survey and our response rate is similar to several other registry-based studies of young cancer survivors (range 26-51%)[18-21]. Our cohort was assembled through identification through a well-characterized state cancer registry. Cancer registries are considered by the National Cancer Institute to be important sources of information on survivorship issues[22]. Recall bias may play a role in any cross-sectional study, as we elicit self-report of regret surrounding a historical decision. However, given that decisional regret can only be measured after a decision has been made, any outcome will be influenced by some degree of recall bias. To address the issue of recall bias, time from diagnosis was evaluated as a categorical variable (<5 years, 5-10 years, >10 years) and regret scores were evaluated across time categories. DRS scores did not change as patients were further out from diagnosis. Furthermore, time from diagnosis was not independently associated with regret in univariate analysis. Hence, the time component would be less likely to contribute to regret over time. The women responding to the survey are on average 10 years out from their original diagnosis, and more likely free of disease. Values and perspectives towards the counseling they received at the time of cancer diagnosis, and recall of how much of a fertility preservation attempt may have been undertaken may be impacted by survivor status. Moreover, while a large percentage of participants received their counseling from cancer surgeons (46% amongst those who reported receiving counseling from a single provider), the subjects received counseling from a variety of other sources (e.g. gynecologists, medical oncologists, general practitioners, nurses) and from more than one provider. Given this, it may be difficult to determine which provider delivered the most effective counseling. However, a comparison of mean regret scores of patients receiving counseling from different providers revealed that there was no difference in scores based on who provided the counseling. Additionally, there was a higher rate of response amongst cervical and

endometrial cancer survivors as compared with ovarian cancer survivors. This could be attributed to decreased opportunity for fertility preservation in this population and lack of desire to participate in this research study. As such, there is concern for selection bias and may limit the generalizability of our findings to ovarian cancer survivors. Finally, as the CCR does not provide detailed information on practice patterns of gynecologic oncology surgeons during the time period sample, we were limited in making reasonable inferences regarding the determination of eligibility of patients for FSS, based on cancer type and standard of care. As such, only localized disease was included in the group eligible for FSS in this study. It is possible that some patients with more advanced, non-localized disease who were offered FSS by their surgeons were excluded from the analysis and may bias the results.

Conclusion

Pre-treatment fertility counseling and undergoing fertility-sparing surgery are associated with reduced regret around fertility choices in reproductive-aged survivors of localized cervical, ovarian and endometrial cancers. Those who desired more children after treatment experienced higher regret. Therefore, a thorough discussion about fertility desires is important to survivorship. Such discussions should be routinely incorporated into counseling for patients who are undergoing treatment for gynecological cancers.

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Table 1

Comparison of survey responders vs. declined/unable to contact

	Completed survey (n = 470)	Declined (n = 123)	p-value[a]
Age at diagnosis, years	34 (18-40)	35 (19-40)	0.30
Age at survey, years	42 (24-57)	45 (23-57)	0.40
Socioeconomic Index[b]	2 (1-5)	2 (1-5)	0.93
Time since diagnosis, years	11 (3-18)	11 (3-18)	0.48
Diagnosis	n (%)	n (%)	
- Cervical cancer	228 (87%)	33 (13%)	ref
- Ovarian cancer	125 (60%)	84 (40%)	<0.001
- Endometrial cancer	117 (95%)	6 (5%)	0.41

Data shown are median (range) unless otherwise stated

[a] p-values calculated Wilcoxon Rank-Sum Test† or logistic regression* as appropriate

[b] Calculated from median income and education for the census block group of residence at diagnosis

Table 2

Characteristics of survey respondents

	Total (n = 470)	Cervical (n = 228)	Ovarian (n = 125)	Endometrial (n = 117)
Age at diagnosis, years[a]	33.7 (5.4)	33 (4.9)	32 (6.4)	36.4 (3.9)
Age at survey, years[a]	45.2 (7.0)	45.0 (6.8)	43.3 (8.0)	47.7 (5.8)
Years since diagnosis[a]	11.6 (4.2)	12.0 (4.0)	11.4 (4.2)	11.2 (4.5)
Children before treatment	69%	74%	56%	72%
Desiring children after treatment	50%	51%	56%	45%

[a]Data shown are mean (standard deviation)

Table 3

Univariable linear regression for regret among women with localized gynecologic cancer

	Beta coefficient (95% CI)	p-value
Age at diagnosis	−0.0817 (−.178 −0.016)	0.10
Age at survey	−0.06 (−.133 −0.013)	0.11
Years since diagnosis	−0.39 (−.161 −0.083)	0.53
Socioeconomic status	0.928 (−.313 −2.17)	0.14
Cancer type		
Cervical		referent
Ovarian	−0.11 (−1.38 −1.16)	0.86
Uterine	0.68 (−.57 −1.93)	0.29
Race		
Caucasian		referent
African American	−1.09 (−9.09 −6.9)	0.79
Hispanic	0.539 (−1.44 −2.52)	0.59
Asian American	−6.09 (−17.3 −5.14)	0.29
Native American	−4.09 (−15.3 −7.14)	0.48
Prior parity	−0.19 (−1.31 −0.92)	0.74
Desired more children at diagnosis	3.83 (2.87 −4.79)	<0.001
Underwent FSS	−0.554 (−1.63 −.517)	0.31
Counseled regarding cancer treatment effect on fertility	−1.76 (−2.78 - −0.734)	0.001
Satisfied with counseling regarding treatment effect on fertility	−3.37 (−4.49 - −2.24)	<0.001

Abbreviations: FSS = Fertility-sparing surgery