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Association of abortion facility type with procedural-related morbidities and adverse events among patients undergoing induced abortions

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Key points

Question: Is there an association between the type of facility in which an abortion is performed and abortion-related morbidities and adverse events?

Findings: In this retrospective cohort study of 50311 induced abortions among 49287 women with private health insurance, performance of the abortion in an ambulatory surgery center, compared with an office-based setting, was not associated with a significant difference in abortion-related morbidities and adverse events (adjusted odds ratio, 0.97).

Meaning: Rates of abortion-related morbidities and adverse events did not significantly differ by whether the abortion was performed in an ambulatory surgery center vs. an office-based setting.

Abstract

Importance

Multiple states have laws that require abortion facilities to meet standards of ambulatory surgery centers (ASCs). There is limited evidence regarding the occurrence of abortion-related morbidities and adverse events following abortions performed at ASCs compared with office-based settings.

Objective

To compare abortion-related morbidities and adverse events at ASCs versus office-based settings.

Design, Setting, and Participants

Retrospective cohort study of 49287 women continuously enrolled in US private health insurance who had 50311 induced abortions in an ASC or office-based setting January 1, 2011 - December 31, 2014. Outcomes were ascertained during the six weeks subsequent to the abortion using claims data from a large national private insurance claims database. The final follow-up date was February 11, 2015. Analyses were adjusted for age, abortion type, diabetes, hypertension, previous health care visits, year, and region.

Exposure

Facility type (ASCs vs. office-based settings, including facilities such as abortion clinics, non-specialized clinics, and physician offices) in which the abortion was performed. Facility type was based on the standardized place-of-service code variable used for health care billing purposes.

Main Outcomes and Measures

The primary outcome was any abortion-related morbidity or adverse event (such as retained products of conception, abortion-related infection, hemorrhage, and uterine perforation) that received an abortion-related diagnosis or treatment code from any source of health care within six weeks of the abortion. The two secondary outcomes, both subsets of the primary outcome, were major abortion-related morbidities and adverse events (such as hemorrhages treated with a transfusion, missed ectopic pregnancies treated with surgery, and abortion-related infections that resulted in an overnight hospital admission) and abortion-related infections.

Results

Among 49287 women (mean age 28 [SD 7.31]) who had 50311 induced abortions, (23891 [47%] first-trimester aspiration, 13480 [27%] first-trimester medication, and 12940 [26%] second-trimester or later), 5660 (11%) of abortions were performed in ambulatory surgery centers and 44651 (89%) were performed in office-based settings. Overall, 3.33% had an abortion-related morbidity or adverse event; 0.32% had a major abortion-related morbidity or adverse event; and 0.74% had an abortion-related infection. In adjusted analyses, there was no statistically significant difference between ASCs versus office-based settings, respectively, in the rates of abortion-related morbidities or adverse events [3.25% v. 3.34%, difference -0.8%, 95% CI -0.58% - 0.43%; aOR 0.97, 95% CI 0.81 – 1.17], major morbidities or adverse events [0.26% v. 0.33%, difference -0.06%,

95% CI -0.18% - 0.06%; aOR 0.78, 95% CI 0.45 – 1.37], or infections [0.58% v. 0.77%, difference -0.16%, 95% CI -0.35% - 0.03%; aOR 0.75, 95% CI 0.52 – 1.09].

Conclusions and Relevance

Among women with private health insurance who had an induced abortion, performance of the abortion in an ambulatory surgery center, compared with an office-based setting, was not associated with a significant difference in abortion-related morbidities and adverse events. These findings, in addition to individual patient and individual facility factors, may inform decisions about the type of facility in which induced abortions are performed.

Introduction

In June 2016, the U.S. Supreme Court ruled in *Whole Woman's Health vs. Hellerstedt* that Texas's law requiring abortion facilities to meet ambulatory surgery center (ASC) standards was unconstitutional.[1] ~~Despite this ruling,~~ Thirteen~~eight~~ states currently ~~enforce~~ have laws that require ~~licensing standards for~~ abortion~~s~~ ~~facilities that are comparable to the state's licensing standards for~~to be performed in ASCs.[2] These laws include such requirements as specified hall and door widths or separate procedure and recovery rooms.[2] Many of these apply only at a specific gestational week (or gestational duration), typically in the second-trimester.[2] Supporters of ASC laws have argued that ASC requirements make abortion safer.[1]

Limited published peer-reviewed research has directly compared abortion-related morbidities and adverse events across facility types. One

study found fewer abortion-related events in clinics than hospitals[3] and a recent review found similar rates of abortion-related events after first trimester abortion procedures across study populations in different facility types, including hospitals, ASCs, and office-based settings.[4]

More than 95% of induced abortions are provided in outpatient, non-hospital-based settings – in abortion clinics, non-specialized clinics, or physician offices.[5] Abortions have been performed in office-based settings, including abortion clinics, non-specialized clinics, and physician offices, for more than forty-five years.[6] ASCs developed in the 1980s to move some surgeries and procedures from hospitals to non-hospital-based outpatient settings.[7] In the 2000s, some states began passing laws that required abortions to be provided in ASCs, and some abortion clinics that had been office-based settings became licensed as ASCs to continue to perform abortions.[8] There are no published national estimates of the proportion of abortions performed in ASCs v. office-based settings; state-specific data indicate that the minority of outpatient abortion facilities are ASCs.[9,10] The present study used a private insurance claims database to compare abortion-related morbidities and adverse events at ASCs versus office-based settings.

Methods

Study design

This retrospective cohort study used 2011-2014 data from the Truven Health MarketScan® Commercial Claims and Encounters database to

compare abortion-related morbidities and adverse events across two facility types, ASCs and office-based settings. The University of California, San Francisco Institutional Review Board considered this study exempt and thus informed consent was not required. The Penn State Institutional Review Board considered this study not human subjects research.

Data source

The Truven Health MarketScan Commercial Claims and Encounters database is a commercially available health insurance claims database. It includes claims data for a sample of privately-insured people in all 50 U.S. states, including demographic characteristics (i.e., age and sex), health care utilization, dates of service, diagnosis codes, procedure codes, and facility type. The data represent claims from clinicians, hospitals, and pharmacies that have been adjudicated for payment and are obtained directly from a convenience sample of large employers and health plans that agree to participate in MarketScan. While no attempts are made to correct or change information received from the participating employers and health plans, Truven Health has a quality control process to verify that the data meet criteria for quality and completeness.[11] The database only includes data from fully paid and adjudicated claims and the diagnosis and procedure codes are compared to codes in effect when raw data were collected, and edited as necessary.[11] This database has been used in other studies examining complications and follow-up care after health care procedures.[12,13]

Study population

The study population included all beneficiaries in this database who were 11 years and older who had an induced abortion between January 1, 2011 and December 31, 2014 in an ASC or office-based setting and who were enrolled in their insurance plan for at least one year prior to the index abortion and at least six weeks after the abortion. Current Procedural Terminology (CPT) codes used to identify abortions are listed in eTable 1. Ectopic pregnancies diagnosed and/or treated within 7 days of the abortion and molar pregnancies were excluded, as ectopic pregnancies and molar pregnancies receive different treatments than abortions and have different expected potential morbidities and adverse events.

Exposure

Facility type was identified based on the standardized place-of-service code variable, which indicates the setting where the service occurred. Settings in the standardized place-of-service code variable are defined by the Centers for Medicare and Medicaid Services and used across health care billing.[14] There are 50 different possible settings that include settings such as schools, homeless shelters, inpatient hospital, skilled nursing facilities, and others.[15] Facility type was classified as ASC when the standardized place-of-service code variable (stdplac) equaled 24 (“Ambulatory Surgery Center”) and office-based setting when the place-of-service code variable equaled 11 (“Office”), which includes most office-based settings.[15] These settings included facilities such as abortion clinics, non-specialized clinics, and physician offices. Abortions performed in other settings were excluded.

Outcomes

The primary outcome was abortion-related morbidities and adverse events occurring within six weeks of the abortion. Secondary outcomes, which were both subsets of the primary outcome, were major abortion-related morbidities and adverse events and abortion-related infections.

Per methods published in a recent study of abortion-related events using billing data, abortion-related events were estimated by examining and evaluating all diagnoses and treatments at all health care encounters on the day of and within six weeks of the abortion.[3] Each index abortion was coded as to whether an abortion-related morbidity or adverse event occurred within the six weeks subsequent to the abortion. Events were defined as any abortion-related morbidity or adverse event that received an abortion-related diagnosis or treatment code at any care location, including emergency departments (EDs), the original abortion facility, other health care sites, or pharmacy within six weeks of an abortion. Events included those that occurred during, on the day of, or up to six weeks after the index abortion. Potential events were identified through an examination of International Classification of Diseases, 9th Revision (ICD-9) codes in either primary or secondary positions, Health Care Common Procedure Coding System (HCPCS) codes, CPT codes, and medication codes for each health care encounter within six weeks of the abortion. The PAIRS Framework [16] which was originally developed for first trimester aspiration abortions, was used to classify specific events into one or more specific diagnoses: retained

products of conception, failed abortion, hemorrhage, infection, uterine perforation, anesthesia reaction, symptomatic intrauterine material, post-abortal hematometra, cervical injury, disseminated intravascular coagulation, missed ectopic pregnancy, and other/undetermined. Retained placenta was added to the definition of retained products of conception and disseminated intravascular coagulation was added to account for additional types of events that could occur for second-trimester or later abortions. Events were classified as major if they required overnight hospital admission, additional surgery, or blood transfusion. All others were classified as minor.

Identifying abortion-related events involved the following steps. First, each abortion with a subsequent ED visit, a diagnosis code indicating an abortion or miscarriage complication on the day of the index abortion, a subsequent health care encounter with a diagnosis code indicating an abortion or miscarriage complication, or a subsequent inpatient visit was individually coded by a clinically-trained reviewer who evaluated all available billing data (ICD-9 and CPT codes, laboratory tests, and medications) for encounters that occurred within six weeks subsequent to these abortions, including on the day of the abortion. Diagnosis codes for miscarriage complications were included because they seemed unlikely to be separate pregnancies and, instead, were likely billing coding errors as the ICD-9 codes for miscarriage complications and abortion complications only differ in one number. The reviewer, blinded to abortion facility type, classified each index abortion with a subsequent ED visit, a complication diagnosis code, or a

subsequent inpatient visit as having an abortion-related event or not and then classified each case with an abortion-related event into one or more of the 12 possible types of diagnoses. Missed ectopic pregnancies were identified through searching all encounters within six weeks and ectopic pregnancies not diagnosed or treated within seven days after the index abortion were classified as missed ectopic pregnancies.

All encounters that were not individually coded within six weeks were searched to identify injection and IV antibiotics commonly used to treat abortion-related infections. All encounters within six weeks that were not individually coded were searched to identify repeat procedures (abortion, miscarriage, or dilation and curettage procedures, or additional doses of misoprostol). These repeat procedures were further classified as incomplete, failed, or other/undetermined based on diagnosis codes [See eTable 1]. Abortions that were incomplete, failed, or other/undetermined were coded as events. The injection and IV antibiotics and repeat procedures were added to the individually-coded dataset.

Control variables

Variables controlled for in the adjusted analyses included: abortion type (first-trimester aspiration abortion performed through 12 to 14 weeks, first-trimester medication abortion typically provided through nine weeks at the time abortions in this study were provided,[17] and second-trimester and later abortion performed after 12 to 14 weeks), diabetes, hypertension, age, number of previous-year outpatient health care visits, one or more inpatient

visits in the previous year (as proxies for underlying health conditions), U.S. census region, and year. In order to have more complete data on chronic health condition and health care utilization variables, only women insured for at least one year before their abortion were included.

Power analysis and sample size

When planning the study, 3530 induced abortions in ASCs and 15444 induced abortions in office-based settings in 2012 were identified in the Truven Marketscan dataset. Based on assumptions that there would be a similar number of abortions in each year from 2012-2014 and that about one half of the abortions would meet eligibility criteria, a sample size calculation for a difference in proportions indicated that there would be sufficient power to detect up to a .06/100 difference (assuming 0.80 power) between the 2.1/100 events expected based on prior published research[3] versus a possible 1.5/100 in ASCs. Based on Cohen's H, this would translate to a small effect size.[18] Even when controlling for potential confounders in logistic regression, this sample size would have 0.80 power to detect small effects, i.e. an Odds Ratio of 0.7 to 0.74 for ASCs v. office-based settings.[19] Upon extracting the data for 2012 through 2014 and identifying the abortions that met other eligibility criteria, the ratio of abortions in ASCs to office-based settings was closer to 1:7 than the 1:5 originally estimated. Prior to analyzing data, an updated sample size calculation was conducted and indicated that an additional year of data (2011) was needed to have sufficient power to

detect a 0.5% difference. The final dataset had 0.80 power to detect a 0.5% difference in events in ASCs v. offices, assuming 2.1/100 events in offices.

Statistical analysis

Analysis was conducted in Stata 14.2. In regression models, any abortion-related event was the main outcome and facility type the main exposure variable. The first model specified for each outcome included only facility type and the outcome. Then, adjusted models that simultaneously added all of the potential confounders were estimated. Analysis included generalized estimating equations with exchangeable correlation structure, logit link, binomial distribution, and robust standard errors to account for possible clustering by individuals who had more than one abortion during the study. The QIC program was used to select the correlation structure.[20] Per *a-priori* study plans, these analyses were repeated for major events and for infections (as infections could be an event type where there might be variation across procedure facility type). Then, per *a-priori* study plans, subgroup analyses were conducted for any event by abortion type using interaction terms, as rate of abortion-related morbidities and adverse events varies by abortion type[3] and some laws regarding ASC requirements apply specifically to second-trimester and later abortions.[2] Subgroup analyses were re-ran with first trimester medication abortions as the reference group and then with second trimester and later abortions as the reference group to get interpretable odds ratios for these abortion types. Analyses for the secondary outcomes and the subgroup analyses were exploratory. The post-

estimation margins command was used to obtain adjusted incidence rates and adjusted differences in incidence rates. As a supplementary analysis, a series of regressions that examined the effect on the main relationship of interest of adding each covariate to the model were also conducted. Additionally, the QIC program[20] was used to compare nested models for the primary outcome: those that included abortion type and those that did not. Although it is not possible to determine the extent to which data are missing, the analysis assumes that missing data are rare since these are adjudicated billing claims used to determine payments to clinicians, hospitals, and pharmacies.

Two prespecified sensitivity analyses that used different definitions of abortion-related morbidities and adverse events were conducted. First, there are considerable challenges of measuring whether an ectopic pregnancy was missed based only on billing data. In particular, there is no information available in billing data about whether the clinician suspected an ectopic pregnancy at the time of the abortion visit and the timing of follow-up could be influenced by when test results came back and when the patient was able to present at a facility that provides care for ectopic pregnancies. Because, the seven-day cut-off was somewhat arbitrary and could be overly restrictive, the definition of missed ectopics was changed to those not diagnosed or treated within 14 days. Second, additional injection or IV antibiotics that are not commonly used to treat abortion-related infections were present in the dataset and were added for a sensitivity analysis. A third

sensitivity analysis was conducted *post-hoc*. This sensitivity analysis used the Elixhauser Comorbidity Index[21] as a control variable instead of the pre-specified control variables of diabetes, hypertension, number of previous outpatient visits, and one or more previous inpatient visits. This analysis used a binary score of >=1 of the 30 comorbidities in the Elixhauser index[21,22] and, in a separate analysis, used the Elixhauser Comorbidity Index Readmission Score.[23] Statistical testing was 2-sided and used a p<.05 significance level.

Results

The database included 104,106 induced abortions during the study time period. 53795 abortions were excluded due to not being in an ASC or office-based setting, patients being enrolled in their insurance plan for less than one year prior or six weeks subsequent to the abortion, or patients having an age less than 11 years old; 216 abortions involved a molar pregnancy and 765 an ectopic pregnancy diagnosed and/or treated within seven days of the index abortion and were excluded. [See Figure 1] Most of the 17621 abortions in the database that were not performed in an ASC or office-based setting during the study time period were provided in inpatient, outpatient, or emergency department hospital-based settings (n=16909). The only other type of facility in which more than 1% of the 17621 abortions excluded due to facility type were performed was Federally Qualified Health Centers (n=297). The study cohort included 49287 patients who had 50311 abortions in an ASC or an office-based setting and who were continuously

enrolled in their insurance plan for at least one year prior and at least six weeks after the abortion.

Multiple abortions occurred in 798 patients (1822 abortions) during the study time period. Of the 1822 multiple abortions, 88% of them occurred in the same facility type for each abortion.

The mean age was 28 years [range 11 – 59 years, SD 7.3]. Of the 50311 included abortions, 23891 (47%) were first-trimester aspiration, 13480 (27%) first-trimester medication, and 12940 (26%) second-trimester or later abortions. [See Table 1] 5660 (11%) of abortions were performed in ASCs and 44651 (89%) performed in office-based settings. The study population differed by facility type: patients in ASCs were slightly older (28.6 v. 28.1 years, p<.001); more patients in ASCs had had a previous year inpatient encounter (9.8% v. 8.9%, p=.03); fewer medication abortions were in ASCs (2.6% of abortions in ASCs v. 29.9% of abortions in office-based settings, p<0.001 for comparison of abortion type by facility type); and abortions in ASCs were more common in the South and Midwest (25.1% of abortions in ASCs and 12.6% of abortions in office-based settings were in the South; 22.6% of abortions in ASCs and 11.5% of abortions in office-based settings were in the Midwest, p<0.001 for comparison of region by facility type).

Among the 50311 abortions, 3.33% (1674) had an abortion-related event; 0.32% (163) had a major event; 0.74% (374) had an abortion-related infection. [See Table 2] 2.52% (603/23891) of first-trimester aspiration

abortions, 5.42% (730/13480) of first-trimester medication abortions, and 2.64% (341/12940) of second-trimester or later abortions had an abortion-related event. At least 0.2% or more of abortions had one or more of the following types of events: retained products of conception, infection, other, symptomatic intrauterine material, hemorrhage, and missed ectopic pregnancy. The remaining types of events (failed abortion, disseminated intravascular coagulation, hematometra, uterine perforation, anesthesia-reaction, cervical injury) occurred in fewer than 0.05% of abortions or were not present in the dataset. [See Table 2]

In unadjusted analyses examining the primary outcome, abortion-related events were less common in ASCs than office-based settings (2.60%, 95% CI 2.21 – 3.05 in ASCs v. 3.42%, 95% CI 3.26 – 3.59 in office-based settings, p=0.001]. In unadjusted analyses examining secondary outcomes, there were not significant differences in major events (0.25%, 95% CI 0.15 – 0.42 in ASCs v. 0.33%, 95% CI 0.28 – 0.39 in office-based settings) or in abortion-related infections (0.58%, 95% CI 0.41 – 0.82 in ASCs v. 0.76%, 95% CI 0.69 – 0.85 in office-based settings) [See Table 2]. Unadjusted associations between variables controlled for in adjusted analyses and study outcomes are in eTable 2.

The QIC indicated that the exchangeable correlation structure was a better fit for the data than the independent correlation structure (QIC of 307274.59 for exchangeable v. 307277.23 for independent). In adjusted analyses, there were not significant differences in abortion-related events

(the primary outcome) [aOR 0.97, 95% CI 0.81 – 1.17, adjusted incidence rate 3.25% v. 3.33%, adjusted difference -0.08%, 95% CI -0.58% - 0.43%] between ASCs and office-based settings [See Table 3]. Full regression results including 95% CIs for adjusted incidence rates are in eTable 3. Abortion-type was the only variable controlled for in the adjusted analyses that affected the main association of interest between facility type and events. The model with only facility type had an OR of 0.75, p-value 0.001; models with all control variables other than abortion type had ORs of 0.74 or 0.75, p-value 0.001. The model that included abortion type had an OR of 0.97, p-value 0.77. [See eTable 4]. The QIC indicated that the model that included abortion type was a better fit for the data than the model that did not include abortion type (QIC of 307274.59 for model with versus 310114.09 for model without abortion type).

There were also not significant differences in the secondary outcomes of major abortion-related events [aOR 0.78, 95% CI 0.45 – 1.37, adjusted incidence rate 0.26% v. 0.33%, adjusted difference -0.06%, 95% CI -0.18% - 0.06%] or infections by facility type [aOR 0.75, 95% CI 0.52- 1.09, adjusted incidence rate 0.58% v. 0.77%, adjusted difference -0.16%, 95% CI -0.35% - 0.03%]. [See Table 3]

In unadjusted subgroup analyses by abortion type, there were not significant differences across facility type in abortion-related events among first-trimester aspiration abortions (events occurred in 78 out of 3630 or 2.15% [95% CI 1.72 – 2.68] of abortions performed in ASCs vs 525 of 20261

or 2.59% [95% CI 2.38 – 2.81] of abortions performed in office-based settings) or second-trimester abortions (events occurred in 53 of 1883 or 2.81% [95% CI 2.16 – 3.67] of abortions performed in ASCs vs 288 of 11057 or 2.60% [95% CI 2.32 – 2.92] of abortions performed in office-based settings). Among first-trimester medication abortions, the rate of abortion-related adverse events was significantly greater at ASCs, with events occurring in 16 of 147 or 10.88% [95% CI 6.74 – 17.12] of abortions performed in ASCs vs 714 of 13333 or 5.36% [95% CI 4.99 – 5.75] of abortions performed in office-based settings, p=0.003). [See Table 2]

In adjusted subgroup analyses, there were not significant differences between ASCs and offices in abortion-related events for first-trimester aspiration abortion [aOR 0.84, 95% CI 0.66 – 1.07, adjusted incidence rate 2.19% v. 2.59%, adjusted difference -0.38%, 95% CI -0.88% - 0.12%]. The interaction term for second-trimester and later abortion x facility type was not significant, indicating that there also was no statistical difference in events in ASCs v. offices for second trimester and later abortions, [aOR from model with second trimester and later as reference group, 1.01, 95% CI 0.75 – 1.37, adjusted incidence rate 2.62% v. 2.59%, adjusted difference 0.03%, 95% CI -0.70 – 0.76]. There were significant differences in odds of abortion-related events in ASCs versus office-based settings for medication abortions, p-value for interaction term was 0.001, [aOR from model with first-trimester medication abortion as reference group, 2.23, 95% CI 1.30 – 3.80, adjusted

incidence rate 11.22% v. 5.42%, adjusted difference 5.54%, 95% CI 5.12% - 10.56%]. [See Table 3]

There were no substantive differences in the sensitivity analyses using different definitions of abortion-related morbidities and adverse events and adjusting for comorbidities using the Elixhauser Comorbidity Index. [See eTables 5, 6, 7, 8 and 9]

Discussion

In this retrospective analysis of more than 50,000 induced abortions in the U.S. between 2011 and 2014, performance of abortions in ambulatory surgery centers, compared with office-based settings, was not associated with a significant difference in abortion-related morbidities and adverse-events. The lack of a significant association between abortions performed in ASCs vs office-based settings and the rates of abortion-related morbidities and adverse events is consistent with the small body of literature that compares the safety of other outpatient procedures across ASCs and office-based settings.[24]

This study reinforced that there are low rates of abortion-related morbidities and adverse events after abortion, with major events occurring in only one-third of one percent of cases. This study also confirmed that there are low rates of abortion-related morbidities and adverse events in both ASCs and office-based settings. Although the estimate of the overall abortion-related event rate was higher than a previous estimate using claims data, the estimate of major events was similar[3]. The estimates for events

after first-trimester aspiration abortions were higher than previous estimates using claims data, but were within the range of estimates in other published studies,[3,4] as were the estimates for second-trimester and later abortions.[25-27] The estimates for events after medication abortions are within the range of previous published estimates of events after medication abortions using claims data.[3]

The study was powered to detect a 0.5% difference in any abortion-related morbidities and adverse events. This difference is smaller than the predetermined acceptable risk difference of 2% used in a large noninferiority study comparing events after abortions performed by advance practice clinicians and physicians.[28] In that study, the acceptable risk difference was determined before the start of the study by a panel of researchers and clinicians.[28] The upper bound of the 95% CI around the 0.1% observed difference in this study was 0.6%, which is within the 2% specified as clinically insignificant in that previous study. The upper bound of the 95% CIs for observed differences for first-trimester aspiration and second trimester and later abortions were less than 1%, which is within the 2% threshold for any events. The upper bound of the 95% CI for the 0.1% observed difference in major events was 0.2%, which is slightly smaller than the 0.3% difference in major events defined as clinically important in a recent study.[29] The upper bound of the 95% CI for the 0.2% observed difference in infections was 0.4%, which is also not clinically important.

Abortion-related morbidities and adverse events appear more common among women having first-trimester medication abortions in ASCs than office-based settings. The upper bound of the difference (11%) may be clinically important. As medication abortions in ASCs were rare (only 2.6% of abortions in ASCs and 0.3% of all abortions in the sample), the significant association between facility type and abortion-related morbidities and adverse events for first trimester medication abortions should be interpreted with caution. It is possible, given that medication abortions are rarely performed in ASCs, that women who have medication abortions in ASCs may travel a long distance and may receive follow-up care at sites that may be more likely to provide an additional treatment.

Observational studies include the risk of unbalanced study groups, where differences are not adequately controlled in analyses. While there were some significant differences in the measured covariates across ASCs and office-based settings, the patient-level differences identified in this study were small (i.e., half a year of age, less than one percent difference in proportion with one or more inpatient encounters in the previous year). Only one of the observed covariates – abortion type – confounded the relationship between facility type and incidents [See eTable 4]. This confounding was due to first-trimester medication abortions being much more common in office-based settings and, similar to previous research,[3] having more incidents (more than 5%) than first-trimester aspiration and second trimester and later abortions (which had closer to 2.5%).

This study has strengths. First, the study used a national sample of claims data from a database that is often used to examine safety of health care procedures.[12,13] Using an insurance claims database that includes a national sample allows direct comparison of abortion-related morbidities and adverse events across ASCs vs. office-based settings and provides a sufficiently large sample to detect differences, avoid biases associated with focusing on a few facilities where practice could be unrepresentative, and control for potential confounders. Second, there was little loss to follow up because of the use of claims data. Claims databases are useful for examining morbidities and adverse events after health care procedures (including abortion) because they routinely capture health care visits and treatments that occur subsequent to the procedure,[3] thereby increasing chances that most post-procedure events will be captured in the dataset and limiting biases from loss to follow-up that have been noted in other studies examining abortion-related morbidities and adverse events.[28] Third, there was a large sample of second-trimester and later abortions, which allowed assessment of whether overall findings held among this subset of abortions.

Limitations

This study has several limitations. First, while the study differentiated between first and second-trimester abortions, it was not possible to know the weeks' gestation at which the abortion was provided, a potential limitation given that the risk of abortion-related events increases with each week gestation.[25,26] If there were differences in timing of abortions within the first

and second-trimesters across offices and ASCs, this could be an unmeasured confounder. Second, it is not known whether the ectopic pregnancies classified as missed were suspected at the index abortion visit. The approach of including all ectopics diagnosed and/or treated after seven days as missed was conservative. Third, by virtue of the data included in the Truven Marketscan database, the study only included abortions paid for by private insurance. Only about 15% of the almost one million abortions provided each year in the U.S. are paid for by private insurance.[5,30] Thus, findings may not be generalizable to all abortions in the U.S. Fourth, other potential confounders, including BMI, race, previous cesarean section, were not available in the database and thus could not be controlled. However, recent research has not indicated associations between obesity and abortion-related events, so this should partially address this concern.[25] Other indicators of health status, such as frequency of healthcare visits, were controlled for. As no anesthesia-related reactions were identified, it does not appear that not being able to control for anesthesia has biased the results. Fifth, the Truven Marketscan database did not include information on the specific type of facility (i.e. abortion clinics, non-specialized clinics, and physician offices) in which the aboritons were performed. This study thus was unable to assess whether abortion-related morbidities and adverse events vary by whether the abortion was performed in an abortion clinic, non-specialized clinic, or a physician office.

Conclusions

Among women with private health insurance who had an induced abortion, performance of the abortion in an ambulatory surgery center, compared with an office-based setting, was not associated with a significant difference in abortion-related morbidities and adverse events. These findings, in addition to individual patient and individual facility factors, may inform decisions about the type of facility in which induced abortions are performed.

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Dr. Sarah Roberts and Guodong Liu had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

The authors have completed and submitted ICMJE forms for Disclosure of Potential Conflicts of Interest and none were reported.

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Table 1. Sample description (n=50,311 abortions)				
	Total (n=50,311)	**Ambulatory surgery centers n=5,660**	**Office-based settings n=44,651**	**p-value**
Number of patients[a]	49,287	5,601	43,776	
Age in single years mean (sd), range	28.1(7.3), [11-59]	28.6(7.48), [11-59]	28.1(7.29), [11-58]	<0.001
Abortion type n(%)				<0.001
First trimester aspiration	23,891 (47.5%)	3,630 (64.1%)	20,261 (45.4%)	
First trimester medication	13,480 (26.8%)	147 (2.6%)	13,333 (29.9%)	
Second trimester and later	12,940 (25.7%)	1,883 (33.3%)	11,057 (24.8%)	
Diabetes n(%)	1,109 (2.2%)	133 (2.4%)	976 (2.2%)	0.43
Hypertension n(%)	1,960 (3.9%)	228 (4.0%)	1,732 (3.9%)	0.58
1 or more previous year Inpatient visits n(%)	4,532 (9.0%)	554(9.8%)	3978(8.9%)	0.03
Previous year outpatient visits n(%)				0.42
0-6	27,634 (54.9%)	3,085(54.5 %)	24,549 (55.0%)	
7-12	12,120 (24.1%)	1,383(24.4 %)	10,737(24.1%)	
13-23	6,923 (13.8%)	758(13.4%)	6,165(13.8%)	
>=24	3,634 (7.2%)	434(7.7%)	3,200(7.2%)	
Year of abortion n(%)				<0.001
2011	13,538 (26.9%)	1,639 (29.0%)	11,899 (26.7%)	
2012	13,808 (27.5%)	1,483(26.2 %)	12,325(27.6%)	
2013	11,119 (22.1%)	1,047 (18.5%)	10,072(22.6%)	
2014	11,846 (23.6%)	1,491(26.3 %)	10,355(23.2%)	
Region of the country n(%)				<0.001
Northeast	21,633 (43.0%)	2,081 (36.8%)	19,552 (43.8%)	
South	7,029 (14.0%)	1,418 (25.1%)	5,611 (12.6%)	
Midwest	6,390 (12.7%)	1,280 (22.6%)	5,110 (11.5%)	
West	14,290 (28.4%)	849 (15.0%)	13,441 (30.1%)	
Other	969 (1.9%)	32 (0.6%)	937 (2.1%)	

Note: p-value for table 1. is based on a chi-square test for categorical and binary variables and T test for continuous variable. Unit of analysis is abortions.

[a] The sum of patients in ambulatory surgery centers and office-based settings is greater than the total number of patients because, while most patients who had more than one

abortion had each abortion in the same facility type, a few had a subsequent abortion in a different facility type.

Table 2. Unadjusted rates of abortion-related morbidities and adverse events (n=50,311)

	Total (n=50,311)	Ambulatory surgery centers n=5660	Office-based settings n=44,651	p-value
Any abortion-related morbidity or adverse event (Primary outcome)	1674 (3.33%)	147 (2.60%)	1527 (3.42%)	0.001
Major abortion-related morbidity or adverse event[a] (Secondary outcome)	163 (0.32%)	14 (0.25%)	149 (0.33%)	0.28
Any abortion-related morbidity or adverse event				
First trimester aspiration	603/23,891 (2.52%)	78/3,630 (2.15%)	525/20,261 (2.59%)	0.12
First trimester medication	730/13,480 (5.42%)	16/147 (10.88%)	714/13,333 (5.36%)	0.003
Second trimester or later	341/12,940 (2.64%)	53/1,883 (2.81%)	288/11,057 (2.60%)	0.60
Specific types of abortion-related morbidities and adverse events				
	n, %	n, %	n, %	
retained products of conception	743 (1.48%)	46 (0.81%)	697 (1.56%)	
abortion-related infections[b] (secondary outcome)	374 (0.74%)	33 (0.58%)	341 (0.76%)	0.14
other or undetermined[c]	316 (0.63%)	49 (0.87%)	267 (0.60%)	
symptomatic intrauterine material	301 (0.60%)	28 (0.49%)	273 (0.61%)	
hemorrhage	201 (0.40%)	19 (0.34%)	182 (0.41%)	
missed ectopic pregnancy	106 (0.21%)	4 (0.07%)	102 (0.23%)	
failed abortion	15 (0.03%)	1 (0.02%)	14 (0.03%)	
disseminated intravascular coagulation	8 (0.02%)	1 (0.02%)	7 (0.02%)	
post-abortal hematometra	5 (0.01%)	0 (0.00%)	5 (0.01%)	
uterine perforation	2 (0.00%)	0 (0.00%)	2 (0.00%)	
anesthesia-reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	
cervical injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	

Note: an abortion could have more than one type of abortion-related morbidity or adverse event (e.g. abortion-related infection & retained products of conception). Of the 163 major events, 90 had only one specific type of morbidity or adverse event. The remaining 73 had two or more specific types of events. Unit of analysis is abortions.

[a] Events were classified as major if they required overnight hospital admission, additional surgery, or blood transfusion.

[b] Infections were a secondary outcome of interest.

[c] These are primarily repeat procedures where the diagnosis could not be determined

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Table 3. Multivariable logistic regressions of odds of events, adjusted incidence rate of events (aInc), and differences in adjusted incidence of events (aDiff) after abortion in ambulatory surgery centers vs. office-based settings among total sample and by abortion type (subgroup analyses)

Analyses among total sample						
	Adjusted Incidence		aDiff [95% CI of aDiff]		aOR [95% CI]	p-value
	Ambulatory Surgery Centers	Office-based settings				
Any abortion-related morbidity or adverse event (Primary outcome)	3.25%	3.33%	-0.08% [-0.58% - 0.43%]		0.97 [0.81 - 1.17]	0.77
Major abortion-related morbidity or adverse event (Secondary outcome)	0.26%	0.33%	-0.06% [-0.18% - 0.06%]		0.78 [0.45 - 1.37]	0.39
Abortion-related infection (Secondary outcome)	0.58%	0.77%	-0.16% [-0.35% - 0.03%]		0.75 [0.52 - 1.09]	0.13
Subgroup analyses						
	Adjusted Incidence		aDiff [95% CI of aDiff]	Variables	aOR [95% CI]	p-value
	Ambulatory Surgery Centers	Office-based settings		First trimester aspiration	ref	
Any abortion-related morbidity or adverse event among first trimester aspiration abortions	2.19%	2.59%	-0.38% [-0.88% - 0.12%]	First trimester aspiration X Ambulatory surgery centers	0.84 [0.66 - 1.07]	0.16
				First trimester medication	2.16 [1.93 - 2.43]	<0.001
Any abortion-related morbidity or adverse event among first trimester medication abortions	11.22%	5.42%	5.54% [5.12% - 10.56%]	First trimester medication X Ambulatory surgery centers	2.65 [1.47 - 4.76]	0.001
				Second trimester and later	1.00 [0.86 - 1.16]	0.99
Any abortion-related morbidity or adverse event among second trimester and later abortions	2.62%	2.59%	0.03% [-0.70% - 0.76%]	Second trimester and later X Ambulatory surgery centers	1.21 [0.82 - 1.77]	0.34
Interpretation of interactions is that main effect for abortion type is the aOR or adjusted probability for that abortion type in offices						

compared to first trimester procedures in offices, facility type main effect is for first trimester procedures in ambulatory surgery centers vs. in offices, and interaction terms are whether and to what extent that type of abortion in ambulatory surgery centers differs from that type of abortion in offices

Adjusted models for total sample control for age, abortion type, diabetes, hypertension, previous year outpatient health care visits, previous year inpatient health care visits, year, and region. Office-based settings are the reference group

Full regression results are available in eTable 3

Figure 1. Figure 1. Study flow diagram

Footnotes for Figure 1.

[1] abortions could be excluded for more than one reason

[2] There are 50 different possible settings that include settings such as schools, homeless shelters, inpatient hospital, skilled nursing facilities, and others. Facility type was classified as ASC when the place-of-service code variable (stdplac) equaled 24 ("Ambulatory Surgery Center") and office-based setting when the place-of-service code variable equaled 11 ("Office").

[3] events identified through individual review of cases with inpatient encounters, ED visits, and complication diagnosis codes were mutually exclusive.

[4] events identified through programming were not mutually exclusive; i.e. an abortion could have had one or more of the programmed events. These abortions were not individually reviewed by the clinician coder

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