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Miscarriage Treatment–Related Morbidities and Adverse Events in Hospitals, Ambulatory Surgery Centers, and Office-Based Settings



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# Miscarriage treatment-related morbidities and adverse events in hospitals, ambulatory surgery centers, and office-based settings

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## Abstract

**Objective:** To examine whether miscarriage treatment-related morbidities and adverse events vary across facility types.

**Methods:** A retrospective cohort study compared miscarriage treatment-related morbidities and adverse events across hospitals, ambulatory surgery centers (ASCs), and office-based settings. Data on women who had miscarriage treatment between 2011-2014 and were continuously enrolled in their insurance plan for at least one year prior to and at least six weeks after treatment were obtained from a large national private insurance claims database. The main outcome was miscarriage treatment-related morbidities and adverse events occurring within six-weeks of miscarriage treatment. Secondary outcomes were major events and infections.

**Results:** 97,374 miscarriage treatments met inclusion criteria. Most (75%) were provided in hospitals, 10% ASCs, and 15% office-based settings. 9.3% had miscarriage treatment-related events, 1.0% major events, and 1.5% infections. In adjusted analyses, there were fewer events in ASCs (6.5%) than office-based settings (9.4%) and hospitals (9.6%), but no significant difference between office-based settings and hospitals. There were no significant differences in major events between ASCs (0.7%) and office-based settings (0.8%), but more in hospitals (1.1%) than ASCs and office-based settings. There were fewer infections in ASCs (0.9%) than office-based settings (1.2%) and more in hospitals (1.6%) than ASCs and office-based settings. In analyses stratified by miscarriage treatment type, the difference

between ASCs and office-based settings was no longer significant for miscarriages treated with procedures.

**Conclusions:** While there appear to be slightly more events in hospitals than ASCs or office-based settings, findings do not support limiting miscarriage treatment to particular settings.

**Keywords:** miscarriage, patient safety

## Introduction

Over the past 30 years, the provision of many healthcare procedures has moved out of hospitals to non-hospital-based outpatient settings, including Ambulatory Surgery Centers (ASCs) and office-based settings.[1] Many obstetric and gynecologic procedures – including treatments for miscarriages – are still primarily performed in hospitals.[2,3] Some women prefer receiving miscarriage treatment outside hospitals, and such care may cost less.[4,5]

Typically, patient safety has been a foremost concern when considering whether procedures should be moved to outpatient settings.[6] Research that directly compares patient safety between hospitals and outpatient settings has found few differences;[5,7,8] for induced abortion, research finds safety typically better in outpatient settings.[9,10] A small body of research has compared safety of different procedures across ASCs and office-based settings and has not found consistent differences.[11,12]

Research on safety of miscarriage treatment across facility types has been done primarily with small samples[5] and has not directly compared safety in two outpatient settings – ASCs v. office-based settings. The ASC vs. office-based setting comparison is important, as some state laws require a particular gynecologic procedure – abortion – to be performed in ASCs.[13] As procedures and medications used to treat miscarriage are similar to procedures and medications for abortion, evidence from comparisons of miscarriage safety across facility types is also relevant to abortion policies.

This study examines whether miscarriage treatment-related morbidities and adverse events vary across three facility types: hospitals, ASCs, and office-based settings.

## Materials and Methods

*Study design*

This retrospective cohort study uses 2011-2014 data from the Truven Health MarketScan® Commercial Claims and Encounters database, a database of approximately 50 million privately-insured people across the U.S. each year, including about 10 million women of reproductive age, to compare miscarriage treatment-related morbidities and adverse events across three facilities types:, hospitals, ASCs, and office-based settings. This study was considered exempt by Institutional Review Boards at authors' institutions. The exposure is procedure facility type (hospital v. ASC v. office-based setting) and the outcome is miscarriage treatment-related morbidities and adverse events.

*Data source*

The Truven Health database is a commercially available health insurance claims database often used in studies examining complications and follow-up care after health care procedures, including other gynecologic procedures.[12,14,15] It includes claims data for a sample of privately-insured people in all U.S. states, including demographic characteristics, health care utilization, dates of service, diagnosis codes, procedure codes, and facility type. The data represent claims from providers 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 data contributors, Truven Health has an extensive quality control process to verify that the data meet criteria for quality and completeness.[16]

*Study population*

The study population includes all beneficiaries in this database who had a procedure or medical treatment for miscarriage between 2011 and 2014 in a hospital, ASC, or office-based setting; who were enrolled in their insurance plan for at least one year prior to the index miscarriage treatment and at least six weeks after the miscarriage treatment; and who were between 11 and 59 years old. We identified facility types based on the standardized place-of-service code variable, which indicates setting where treatment was provided. Facility type was classified as hospital when the standardized place-of-service code variable (stdplac) equaled 21, 22, or 23 ("Inpatient hospital", "On-campus outpatient hospital", or "Emergency Room-hospital"), classified as ASC when stdplac equaled 24 "(Ambulatory Surgery Center") and office-based setting when stdplac equaled 11 ("Office"), which includes most office-based settings.[17]

We identified miscarriage treatments with the following Current Procedural Terminology, 4th edition (CPT-4) codes: 59812 (procedure for incomplete miscarriage, trimester not specified) , 59820 (first trimester pregnancy loss), 59821 (second trimester pregnancy loss), 59830 (procedure

for septic miscarriage, trimester not specified), and J3490 (medication treatment for miscarriage). We only included code J3490 (for misoprostol) when it was accompanied by miscarriage, early pregnancy loss, or unspecified abortion diagnosis codes. We did not include miscarriages treated with expectant management, as there is no specific treatment provided that would plausibly be influenced by facility type. We excluded ectopic pregnancies diagnosed and/or treated within seven days of the miscarriage treatment, and molar pregnancies.

*Outcome*

Miscarriage treatment-related morbidities and adverse events were identified by examining and evaluating diagnoses and treatments at all health care encounters – including emergency departments (EDs), the original treatment facility, other health care sites, or pharmacy – that occurred on the day of or within six weeks of the index miscarriage treatment. Each index miscarriage treatment was coded as to whether a miscarriage treatment-related event occurred on the day of or within the six weeks subsequent to the initial treatment. Events were defined as any post-miscarriage treatment morbidity or adverse event. Potential events were identified through International Classification of Diseases, 9th Revision (ICD-9) codes in primary and secondary positions, Health Care Common Procedure Coding System (HCPCS) codes, CPT-4 codes, and medication codes for each health care encounter within six weeks of the miscarriage treatment. We used a modified version of the PAIRS Framework,[18] which was originally

developed for first trimester aspiration abortions, to classify miscarriage treatment-related events into one or more of 12 possible diagnoses: retained products of conception, failed abortion, hemorrhage, infection, uterine perforation, anesthesia reaction, symptomatic intrauterine material (SIM), post-abortal hematometra, cervical injury, disseminated intravascular coagulation (DIC), and other/undetermined. SIM, as defined in the PAIRS framework,[18] is distressing symptoms of extended bleeding or cramping when there is no evidence of conceptus tissue. SIM should be considered when post-abortal hematometra and retained products of conception are ruled out. Using the PAIRS framework is appropriate as procedures to treat miscarriage are similar to abortion procedures and events that might occur are similar. We added retained placenta to the definition of retained products of conception and added disseminated intravascular coagulation (DIC) to classify additional types of events that could occur after second-trimester procedures. We also used different criteria for considering a subsequent dose of misoprostol an indication of retained products of conception or a repeat treatment; specifically, we considered subsequent doses of misoprostol after seven days for procedures and after 14 days for medication treatment to be indications.

Events were classified as major if they required overnight hospital admission, additional surgery, or blood transfusion. All others were classified as minor.

Identifying miscarriage treatment-related events involved the following. First, each miscarriage treatment with a subsequent inpatient visit was individually coded by a clinically-trained reviewer who evaluated all available billing data for all encounters that occurred within six weeks subsequent to these miscarriage treatments. Second, the reviewer individually coded a subset of subsequent ED visits and other health care encounters with a diagnosis code indicating a miscarriage or abortion complication (ICD-9: 638.x, 634.00 – 634.82, 639.x, 635.00 – 635.82). We included subsequent diagnosis codes for abortion complications because they were unlikely to be separate pregnancies and, instead, were likely billing coding errors as ICD-9 codes for miscarriage complications and abortion complications only differ in one number. We selected the subset of subsequent ED visits and other health care encounters with miscarriage or abortion complication codes that had a treatment, medication, and/or diagnosis code we identified as possibly indicating an event. Third, we selected a five percent random sample of ED visits and health care encounters with a complications diagnosis code (that had not been included in the first selection) to ensure we had not missed relevant cases. The reviewer then coded these random samples. Through coding of the random samples, we identified additional relevant treatments. We then pulled additional cases with subsequent ED visits and encounters with miscarriage or abortion complications diagnosis codes that had these treatments and individually coded these cases. The reviewer, blinded to index miscarriage

treatment facility type, first classified each case as having a miscarriage treatment-related morbidity or adverse event or not and then classified each case with a miscarriage treatment-related event into one or more of the 12 possible event types.

Next, we searched all encounters within six weeks and classified ectopic pregnancies not diagnosed or treated within seven days after the index miscarriage treatment as missed ectopics. We then searched all encounters within six weeks to identify injection and intravenous antibiotics commonly used to treat abortion- and miscarriage-treatment related infections. We then searched all encounters within six weeks to identify repeat miscarriage-treatments (abortion, miscarriage, or dilation and curettage procedures, or additional doses of misoprostol). Repeat miscarriage-treatments were further classified as retained products of conception, failed abortion, or other/undetermined based on diagnosis codes. We then added the injection and IV antibiotics and repeat procedures to the individually-coded dataset.

*Control variables*

Control variables included: miscarriage treatment type (first-trimester procedure for pregnancy loss – 59820, second-trimester procedure for pregnancy loss - 59821, procedure for septic or incomplete miscarriage, trimester not specified – 59830 or 59812, and medication treatment – J3490 plus a relevant diagnosis code[19]), diabetes, hypertension, age, number of previous-year outpatient health care visits, one or more inpatient visits the

previous year (as indicators of underlying health conditions), U.S. census region, and year. The reason that only women insured for at least one year before their miscarriage treatment were included was to have more complete data on chronic health conditions and health care utilization.

*Statistical analysis*

Analysis was conducted in Stata 14.2. We used generalized estimating equations with exchangeable correlation structure, logit link, and robust standard errors to account for possible clustering by individuals who had more than one miscarriage that was treated during our study period and controlled for potential confounders. Office-based settings were the reference group. We used the post-estimation testparm command to compare odds of events in hospitals and ASCs. We used the post-estimation margins command to obtain adjusted incidence rates. Per *a-priori* study plans, we then performed these analyses for major events and infections, and then conducted subgroup analyses for any event stratified by miscarriage-treatment type. As a supplementary analysis, we conducted a series of regressions that examined the effect on the main relationship of interest of adding each covariate to the model.

Sensitivity analyses assessed the impact of changing what was considered a miscarriage treatment-related event as well as the impact of using a different set of covariates to adjust for patient health status. The decision to conduct the first three sensitivity analyses was made prior to conducting main analyses. First, due to difficulties in measuring whether an

ectopic was missed based on billing data, we changed the definition of missed ectopics as those not diagnosed or treated within seven days to fourteen days. Second, we added additional injection or IV antibiotics that are not commonly used to treat miscarriage treatment-related infections, but were present in our dataset. Third, due to the possibility that we may have under-detected retained products of conception or repeat treatments after medication treatment by using a 14 day timeframe for a second dose of misoprostol to indicate a repeat treatment, we reduced the timeframe for when we considered a subsequent dose of misoprostol to be an event, i.e. we considered a second dose of misoprostol after 7 days for a medication treatment to be an indication of retained products of conception or a repeat treatment. We conducted a fourth sensitivity analysis *post-hoc*. This sensitivity analysis used the Elixhauser Comorbidity Index[20] as a control variable for patient health status 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[20,21] and, in a separate analysis, used the Elixhauser Comorbidity Index Readmission Score.[22]

**Results**

The database included 164,227 miscarriage treatments during the study period. 64,350 miscarriage treatments were excluded for not meeting inclusion criteria. [See Figure 1] Those with a molar (n=1,341) and/or not missed ectopic (n=1,152) pregnancy were then excluded. An additional 11

cases were excluded after individual coding, as they were determined to be live deliveries. The study cohort included 97,374 miscarriage treatments among 91,767 beneficiaries.

The mean age was 33 years; 67% were first-trimester procedures for pregnancy loss, 2% second-trimester procedures for pregnancy loss, 16% procedures for septic or incomplete miscarriages, and 16% medication treatments. [See Table 1] 75% of miscarriage treatments were in hospitals, 10% in ASCs, and 15% in office-based settings. The study population differed across facility type, with first-trimester procedures for pregnancy loss under-represented in office-based settings vs hospitals or ASCs and procedures for septic or incomplete miscarriages over-represented in office-based settings vs hospitals or ASCs. Miscarriages treated in hospitals and ASCs were more common in the South and Midwest.

9.3% had a miscarriage treatment-related event; 1.04% had a major event. [See Figure 1; Table 2] 7.0% of first-trimester procedures, 9.1% of second-trimester procedures, 9.9% of procedures for septic or incomplete miscarriages, and 18.7% of medication treatments had a miscarriage treatment-related event. 6.58% had retained products of conception. Infection and hemorrhage occurred in 1.47% and 1.08%). SIM, other/undetermined event, or  missed ectopic pregnancy occurred in 0.96%, 0.59%, and 0.40%. The remaining event types occurred in fewer than 0.1% of cases or were not present. [See Table 2]

In adjusted analyses, there were fewer miscarriage treatment-related events in ASCs (6.5%) than office-based settings (9.4%) and than hospitals (9.6%) ($p<.001$ for both), but no statistically significant difference between office-based settings and hospitals. There was no statistically significant difference in major events between ASCs (0.7%) and office-based settings (0.8%), but there were more major events in hospitals (1.1%) than ASCs and office-based settings, ($p<.01$ for both). [See Table 3] Miscarriage treatment type was the only variable controlled for in the adjusted analyses that affected the main association of interest between facility type and any event or major events. [See Supplemental Tables 1 and 2].There were fewer infections in ASCs (0.9%) than office-based settings (1.2%), $p<.05$ and more infections in hospitals (1.6%) than in ASCs and office-based settings ($p<.001$ and $p<.01$). [See Table 3]

In adjusted analyses stratified by miscarriage type, there were no statistically significant differences in events across ASCs and office-based settings for first trimester procedures for pregnancy loss (5.0% and 5.6%), second trimester procedures for pregnancy loss (7.1% and 5.8%), or incomplete or septic procedures (5.9% and 6.6%). There were fewer events after medication treatments in ASCs v. office-based settings (12.1% and 20.2%), $p<.01$. There were more events after first trimester procedures for pregnancy loss in hospitals (7.5%) than both ASCs and office-based settings ($p<.01$ and $p<.001$), more events after septic or incomplete procedures in hospitals (10.6%) than ASCs and office-based settings ($p<.001$ for both), and

fewer events after medication treatment in hospitals (17.4%) than office-based settings (p<.001). There were no statistically significant differences in events after medication treatment in hospitals than ASCs or in events after second trimester procedures across hospitals (9.6%), ASCs (7.1%), and office-based settings (5.8%).

*Sensitivity analyses*

There were no substantive differences in sensitivity analyses that changed what was considered a miscarriage treatment-related event. One substantive diference emerged in analyses using the binary one or more comorbidities on the Elixhauser Index and the Elixhauser Comorbidity Index Readmission Score. The difference in infections between ASCs and office-based settings was no longer statistically significant at a p<.05 level in either of those sensitivity analyses [results in Supplemental Tables 3-8].

**Comment**

In this retrospective analysis of more than 90,000 miscarriages treated in the U.S. between 2011 and 2014, treatments for miscarriage were safe in all locations, although there were some small differences by facility type. In particular, we found that miscarriage treatment-related events were as or more likely to occur after miscarriages treated in hospitals than either outpatient setting. While statistcally significant, those differences are not clinically significant. In addition, the slightly higher rate of miscarriage treatment-related events for those who received the index treatment in

hospitals could be due to patients at higher risk of an event being more likely to receive treatment in a hospital.

Our finding that miscarriage treatment safety is similar to or better in outpatient settings v. hospitals is consistent with other research, which typically finds that office-based procedures are as safe as, if not safer than, hospital-based procedures.[5,7,9,10,23] That we did not observe consistent differences in safety across ASCs and office-based settings is consistent with the small literature that compares safety of outpatient procedures across ASCs and office-based settings.[11,12]

Our estimates of miscarriage treatment-related events, including the more than 6% retained products of conception, are in the range of other estimates.[24-31] The rates of miscarriage treatment-related events are notably higher than published rates of abortion-related events.[9,10,12,32,33] One explanation is that there have been both government sponsored and professional association sponsored clinical quality improvement initiatives for abortion for more than 40 years,[33-35] meaning that considerable attention has been brought to ensuring and improving the safety of abortion care. This is important to emphasize, as many state laws require abortion – but not miscarriages or other procedures performed in outpatient settings – be performed in ASCs.[13]

While we used a large dataset, there was a small sample of second-trimester procedures (2%). The lack of statistically significant findings for second-trimester procedures across facility types may be due to the small

sample. There were more events after medication treatment in office-based settings than hospitals and ASCs, although still within the range of published estimates.[24-31] As medication treatment does not involve procedures performed in facilities, these findings may reflect how other aspects of care, such as patient education, follow-up, and treatments provided at follow-up, may vary across facility types.

Our study has limitations. First, we used a framework developed to classify morbidities and adverse events after induced abortion[18] to guide coding of miscarriage treatment-related events. As procedures and medication treatments used for abortions and to treat miscarriages are similar, this seems reasonable as there is no published framework specific to miscarriage treatment-related events. However, it is possible that we classified diagnoses or treatments as events in this context that should not be considered events and missed other relevant diagnoses or treatments. We took steps to address some differences, in particular related to additional doses of misoprostol after miscarriage treatment. One strength is that this approach allows comparison of miscarriage treatment-related event rates to abortion-related event rates. Second, we were unable to know precise weeks' gestation treatment was provided. Third, we do not know whether our classification of missed ectopic pregnancies was accurate; we chose a conservative approach by classifing all ectopics diagnosed and/or treated after seven days as missed. Fourth, we were unable to control for some potentially relevant variables; BMI, race, and previous cesarean section were

unavailable in the dataset. We did not identify any anesthesia-related reactions; therefore the inability to control for anesthesia should not bias results. Fifth, the data come from a private insurance claims database. Findings may thus not generalize to miscarriage treatments not paid for by private insurance, such as miscarriage treatments paid for by Medicaid or miscarriage treatments for people without health insurance. In addition, there are other limitations inherent to using administrative claims databases, such as lack of detailed clinical information (e.g., medical record notes).

Our study has strengths. First, we used a national sample of claims data from a database often used to examine health care procedures safety.[12,14,15] Using this database allows a sufficiently large sample to detect differences, avoid biases associated with small samples, and control for potential confounders. Second, claims databases routinely capture health care visits and treatments that occur subsequent to the procedure,[10] which increases the likelihood that most events are captured and limits potential biases due to loss to follow-up.

## Conclusions

While rates of miscarriage treatment-related morbidities and adverse events vary slightly across settings, findings do not support limiting provision of miscarriage treatment to particular types of settings.

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