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Treatment Patterns for Early Pregnancy Failure in Michigan

Vanessa K. Dalton M.D., M.P.H.,[1] Lisa H. Harris, M.D., Ph.D.,[1] Sarah J. Clark, M.P.H.,[2] Lisa Cohn, M.S.,[2] Ken Guire, M.S.,[4] and A. Mark Fendrick, M.D.[3]

Abstract

Aims: We describe current treatment patterns for early pregnancy failure (EPF) among women enrolled in two Michigan health plans.

Methods: We conducted a retrospective review of EPF treatment among Michigan Medicaid enrollees between January 1, 2001, and December 31, 2004, and enrollees of a university-affiliated health plan between January 1, 2001, and December 31, 2005. Episodes were identified by the presence of a diagnostic code for EPF. Surgical treatment was distinguished from nonsurgical management using procedure codes. Facility charges, procedure, and place of service codes were used to determine whether a procedure was done in an office as opposed to an operating room. Cases without a claim for surgical uterine evacuation were examined for a misoprostol pharmacy claim and, if present, were classified as medical management. Cases without a procedure or pharmacy claim were classified as expectant management.

Results: Respectively, we identified 21,311 and 1,493 episodes of EPF in the Medicaid and university-affiliated health plan databases, respectively. Women enrolled in Medicaid were more likely to be treated with surgery than were enrollees of the university-affiliated health plan (35.3 vs. 18.0%, respectively, $p < 0.000$). Among Medicaid enrollees, only 0.5% of surgical evacuations occurred in the office, but office procedures were common among enrollees of the university-affiliated health plan (30.5%, $p < 0.000$). The proportion of cases managed with misoprostol was <1% in both groups. Caucasian race and age were both associated with having a surgical uterine evacuation ($p < 0.001$).

Conclusions: EPF is primarily being treated with expectant management or surgical evacuation in an operating room and may not reflect evidence-based practices or patient preferences.

Introduction

Nearly 25% of women will have an early pregnancy failure (EPF) at least once in their lifetime.[1] Numerous trials demonstrate that EPF can be safely treated with expectant management, medical treatment with misoprostol, and surgical uterine evacuation in either an operating room or an office setting.[2–14] Therefore, EFP care is an area in which patient preferences can be safely used to determine treatment in most instances.

There are no population-based studies characterizing usual treatment patterns in the United States for EPF. European and Canadian studies show that most women undergo either spontaneous passage of products or surgical management in an operative suite.[15,16] However, we and others have found that some patients prefer other treatment options, such as medical completion and office uterine evacuation.[14,17–19] A better understanding of current treatment practices can be used to monitor quality of care and to encourage patient-centered care models.

The purpose of this study was to describe current treatment patterns among members of two health insurance systems in Michigan: one with statewide enrollment and one with enrollment in Southeastern Michigan where treatment options were known to include office uterine evacuations and medication completion. We hypothesized that medical treatment with misoprostol and office uterine evacuations would be uncommon statewide. Our secondary objective was to use this sample to validate our classification methods that could be applied to other populations.

[1]Department of Obstetrics and Gynecology, [2]Department of Pediatrics, and [3]Department of Internal Medicine, University of Michigan Medical School, Ann Arbor, Michigan.
[4]Department of Biostatistics, University of Michigan School of Public Health, Ann Arbor, Michigan.

Materials and Methods

This study was approved by the Institutional Review Board at the University of Michigan (IRB No. HUM00001495) Claims data were used to identify patients with diagnostic codes for EPF between January 1, 2001, and December 31, 2005, among beneficiaries of two health plans. There was no patient contact during this study.

We used two administrative datasets to determine treatment patterns. A statewide Medicaid dataset was used to examine overall treatment patterns across the state. Because we knew that local treatment patterns included office uterine evacuations as well as medical management with misoprostol, we also examined treatment patterns in a local university-affiliated health plan. We used this university-affiliated plan to examine how the introduction of office evacuations and misoprostol therapy might affect overall treatment patterns. Furthermore, as we had access to medical records in this system, we used this data source to validate our classification scheme. At the time of our data collection, the university-affiliated health plan's service area covered Southeastern Michigan and included both teaching and community hospitals.

There were several differences in the types of data that were available through these two sources. For instance, we were able to obtain data on race only in the statewide plan and plan type only in the university-affiliated plan. Further, the statewide data included years 2001–2004, but the university-affiliated plan provided 2005 data as well.

First, we identified EPF cases using the presence of diagnosis codes for early pregnancy failure (*International Classification of Diseases*, 9th revision, codes 632, 634 and 637). All diagnostic and procedural codes submitted to each health plan were queried for the 42 days before and after the initial EPF diagnosis. A repeat episode of EPF was based on a second diagnosis code for EPF at least 180 days after the initial diagnosis.

Cases with a procedure code corresponding to a uterine evacuation were classified as surgical (CPT codes 59812, 59820 or 59830). Surgical cases were further classified as either operating room cases or office procedures using a combination of facility codes, location codes, and the presence of a departmental anesthesia charge. If there was a departmental anesthesia revenue code or an operating room revenue code, we classified the procedure as occurring in an operating room. Otherwise, if the facility type or place of service was a hospital, inpatient facility, or ambulatory surgical center and the place of service was not an office, the procedure was also classified as occurring in an operating room. Alternatively, if the place of service was an office or if the facility type and place of service were not hospitals and there were no inpatient procedure or revenue codes, the procedure was classified as occurring in an office. All other cases were coded as other/unknown treatment location because of missing or conflicting information.

Cases without procedure codes corresponding to a surgical uterine evacuation were classified as either medical or expectant management. To distinguish the two, we searched for pharmacy claims for misoprostol at any time during the 30 days prior to or after diagnosis. Cases with a pharmacy claim for misoprostol were classified as medical management. Cases with no pharmacy claim or CPT codes corresponding to a surgical evacuation were classified as expectant management. Additional information, such as patient demographics, was collected when available.

Procedural and diagnostic codes for 6 weeks surrounding the initial EPF episode were reviewed to identify evidence of miscoding. For instance, if we identified claims for cesarean section or vaginal delivery during that period, the accuracy of the EPF-associated codes was questioned, and such cases were excluded. If suspected or confirmed ectopic pregnancy was evident in the submitted claims, these subjects were also excluded.

We estimated we would obtain at least 300 cases per year in each health plan. With these numbers, we would have the power of 0.81 to detect a difference in proportions of 0.07 (i.e., 0.10 vs. 0.17) when comparing 2 years within each health plan. Descriptive statistics were used to describe treatment patterns in each dataset, and differences between subgroups were examined using Pearson's chi-square test. Categorical variables were also compared using Pearson's chi-square test.

Classification validation

We validated our classification methods by conducting chart reviews on a random sample of 200 women treated in the university-affiliated health plan. Because all treatment options were readily available in this system, this sample was expected to provide the diversity needed to estimate our misclassification in the statewide health plan. The charts were reviewed by a trained abstractor to verify diagnosis and treatment modality. The validation process found 25 of 200 (12.5%) randomly selected charts did not have evidence of an EPF despite having been assigned such a diagnosis code. In 80% of these cases, it appeared that the patient actually was being seen for complaints or complications after undergoing an induced abortion elsewhere, which may share a diagnosis code with an "incomplete miscarriage." Treatment of these cases was correctly classified by our scheme as expectant management, and none required additional treatment. When examining the whole validation sample, we found the classification scheme accurately identified treatment type. Of the cases we classified as surgery, 26 of 26 were actually treated with surgery, and our scheme correctly identified the procedure location in 76.9% cases. Only 1 case in the sample was classified as medication treatment, which was correct. Of the remaining 171 cases classified as expectant management, only 1 instance of misclassification was identified (0.6%). Overall, we concluded our classification methods accurately differentiated among surgery, medical management, and expectant management and reasonably identified treatment location.

Results

A total of 25,087 cases of EPF were initially identified in the state Medicaid database during the years of interest. Of these, 3,498 were found to have additional procedure or diagnosis codes suggesting a coding error, and 278 had invalid diagnosis codes. Once these cases were excluded, 21,311 episodes were analyzed. Using the same process, 1,493 cases were included from the university-affiliated plan database.

Information on the demographic characteristics of our two study groups was limited by the type of patient information available (Table 1). Medicaid eligibility for pregnant women in Michigan includes income <150% of the federal poverty level. There was no income information for individual

Table 1. Characteristics of Study Population

Patient characteristics	*Statewide Medicaid enrollees* n *(%)*	*Local health plan* n *(%)*
Age (years)*		
≤19	4063 (19.1)	39 (2.6)
20–24	7477 (35.1)	120 (8.0)
25–29	4727 (22.2)	336 (22.5)
30–34	2739 (12.9)	475 (31.8)
35–39	1538 (7.2)	354 (23.7)
40+	767 (3.5)	169 (11.4)
Race (Medicaid only)		
African American	6970 (32.7)	NA
Caucasian	12260 (57.5)	NA
Hispanic	1520 (7.1)	NA
Other/unknown	561 (2.6)	NA
Diagnosis*		
Missed/incomplete	17378 (81.5)	1102 (73.8)
Complete	3933 (18.5)	391 (26.2)
Plan type (local health plan only)		
GradCare	NA	60 (4.0)
HMO	NA	1212 (81.2)
POS	NA	149 (10.0)
PPO	NA	12 (0.8)
Medicaid	NA	61 (4.0)

*$p < 0.001$.

members of the university-affiliated health plan; however, only 80 of 1,493 episodes were Medicaid enrollees serviced under the university-affiliated health plan. Seventy-five percent of the Medicaid group were under the age of 30, as compared with 33% of participants enrolled in the university-affiliated health plan ($p < 0.0001$). Additionally, participants in the university-affiliated health plan group were more likely than women in the Medicaid group to be given the diagnosis of complete abortion at presentation ($p < 0.0001$).

Treatment patterns for the Medicaid enrollees and the university-affiliated health plan groups are presented in Figure 1. Statewide, patients were more likely to be treated with a surgical uterine evacuation than patients in the university-affiliated system (35.3 vs. 18.0%, $p < 0.000$). This trend persisted when we examined diagnostic subgroups. For instance, having a complete abortion as opposed to an incomplete abortion did not explain this difference. Medical treatment with misoprostol was uncommon in both groups. The proportion of surgical cases completed in an office setting was 0.5% in the statewide sample and 30.5% in the university-affiliated plan sample ($p < 0.000$) (Fig. 2).

Because enrollee race was available only in the statewide Medicaid dataset, we examined patient factors associated with surgical treatment in this group only (Table 2). Both race and age were associated with treatment type. Whites were more likely to be treated with surgery than either African Americans or Hispanics ($p < 0.001$). Further, African Americans and Hispanics were more likely than whites to be diagnosed with a completed spontaneous abortion at presentation (20.9 and 19.2% vs. 17.1%, respectively, $p < 0.05$). We were unable to determine if this difference explained the difference in treatment patterns, as the Medicaid data could only be provided in aggregate. Further, women <20 years old were less likely to be treated surgically than were 20–39-year-olds ($p < 0.025$).

We examined both datasets for changes over time. In the Medicaid group, misoprostol use was uncommon but increased over the study period from 0.3% to 1.2% ($p < 0.001$). In the university-affiliated health plan, the proportion of cases treated with surgery increased significantly from 16.5% to 32.6% ($p < 0.000$) over the study period. This did not occur in the statewide Medicaid group. The proportion of surgical cases that appeared to be completed in an office setting did not change over time in either group.

Discussion

Treatment options for EPF include expectant management, medical completion with misoprostol, and surgical evacuation in either an office or operative suite. Treatment patterns in Michigan do not appear to reflect either evidence-based practices[2–13] or patient preferences.[14,17–19] Rather, this study suggests that women in Michigan are typically managed either expectantly or with surgical uterine evacuation in an operating room. Our findings also suggest patient factors, such as age and race, may be associated with treatment type, which has important implications for improving clinical care. The main factor determining treatment patterns, however, is most likely having access to providers offering a range of treatment options.

Few studies have examined treatment preferences among patients seen for EPF. Graziosi et al.[18] interviewed women diagnosed with EPF about their views on medical treatment with misoprostol as compared to suction curettage. About 50% of women interviewed would choose medical management if

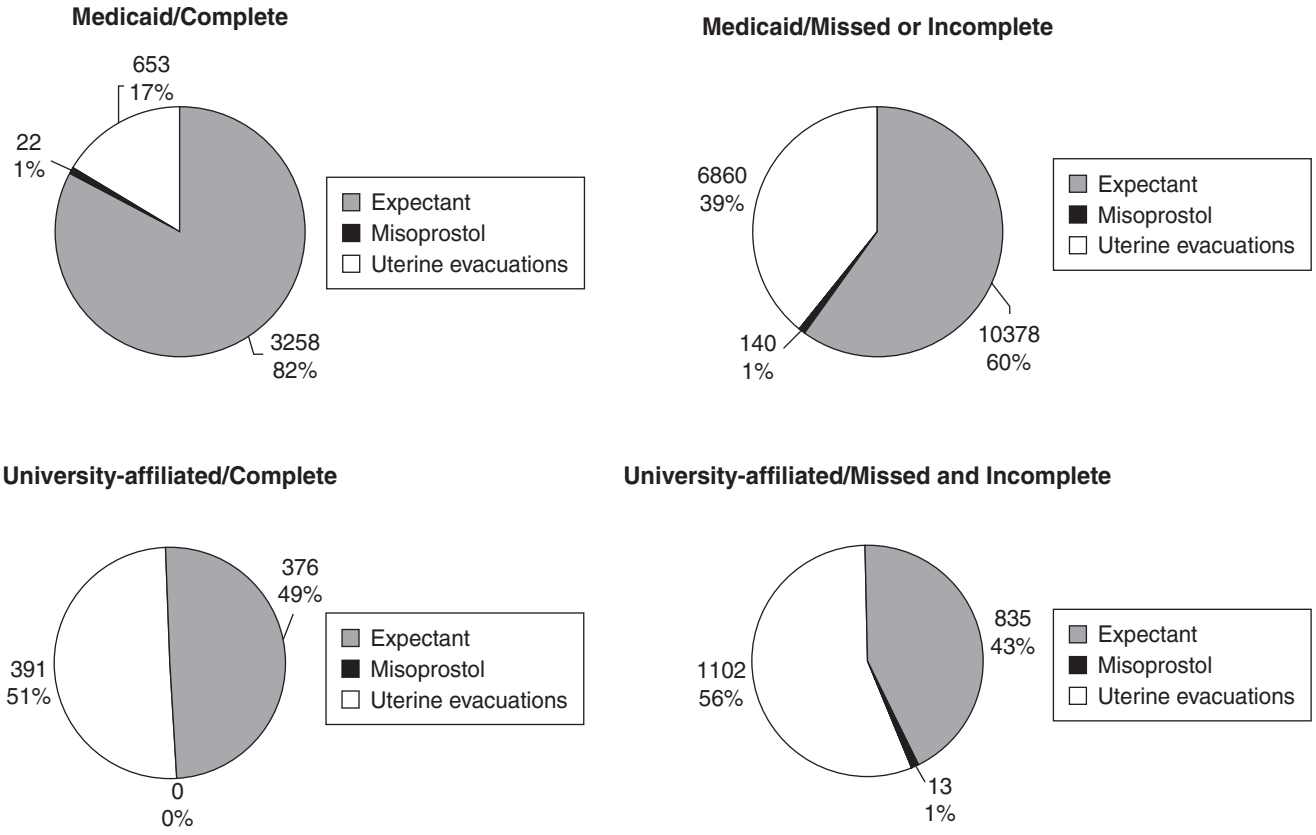

FIG. 1. Treatment patterns in Michigan by diagnosis and health plan.

its success rate exceeded 65%. Other studies have indicated that many women prefer to avoid general anesthesia for uterine evacuations.[20,21] Our previous work suggests almost half of women will choose to have their uterine evacuation completed in an office setting.[14] Based on these few studies, one would expect a greater proportion of cases than was identified in our study population to be managed with misoprostol or office uterine evacuation.

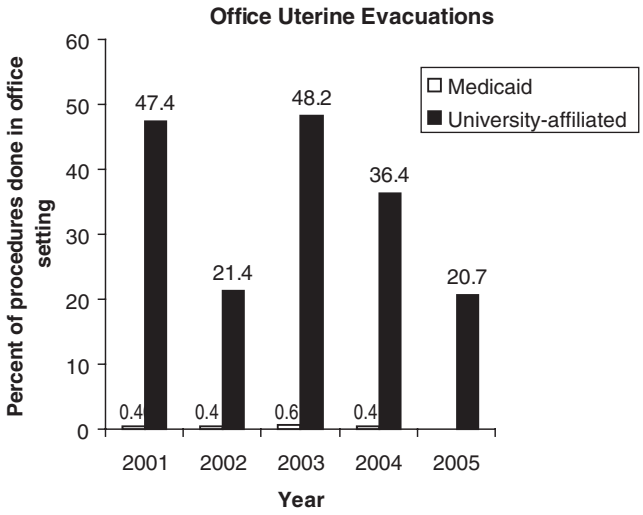

FIG. 2. Proportion of uterine evacuations performed in an office setting by study year and health plan.

Although this study was primarily designed to examine overall treatment patterns, we found that women in the local university-affiliated health plan are much more likely to have an office uterine evacuation than women enrolled in Medicaid. We believe that the main explanation for this treatment difference is that members of the university-affiliated health plan have access to a network of providers offering this service, whereas women in other parts of the state do not. It is also possible that particular populations, such as low-income or minority women, do not accept office procedures to the same degree as women in the university-affiliated system, but our study cannot assess such differences.

Although we were not surprised to find that office uterine evacuations were uncommonly used, our previous work with women experiencing EPF concluded that office procedures are acceptable and sometimes preferable over the same procedure in an operating room.[14,19] After office uterine evacuations were introduced into our health system, there was a surge of referrals indicating a high level of enthusiasm. Over time, use decreased slightly as patients and providers became familiar with the benefits and limitations of office procedures. Clearly, moving even some procedures out of an

Table 2. Proportion of Cases Treated with Surgery by Patient Race and Age

Patient characteristics	Number (%) treated with surgery	
	Incomplete/missed	*Complete*
Race/ethnicity		
White ($n = 12,260$)[a]	4,186/10,166 (41.2)	385/2,094 (18.4)
African American ($n = 6,970$)	2,046/5,511 (37.1)*	202/1,459 (13.8)*
Hispanic ($n = 1,520$)	441/1,228 (35.9)*	50/292 (17.1)
Age (years)		
≤19 ($n = 4,063$)	1,136/3,305 (34.3)*	73/758 (9.6)*
20–39 ($n = 16,481$)[b]	5,464/13,446 (40.6)	556/3035 (18.3)
≥40 ($n = 767$)	260/627 (41.5)	24/140 (17.1)

[a]Reference group.
[b]Reference group.
*$p < 0.001$.

operating suite offers substantial cost savings.[1,14,22] Still, a wide range of obstacles or disincentives probably limit the availability of office uterine evacuations, including discomfort with office procedures in general or a lack of perceived demand for such service. It is also possible that office uterine evacuations for EPF are uncomfortably similar to induced abortions, and some providers are reluctant to add the service to their practice.[23]

Two identified trends could reflect the recent adoption of newer treatment options by providers. First, the rate of surgical treatment increased significantly over the study period among the members of the university-affiliated health plan. This trend occurred immediately after office uterine evacuations were made widely available in this system. Because the service is convenient to patient and providers, we anticipated that it would move some patients out of the operating room into the clinic for their procedure. However, its addition may have effectively increased access to surgical treatment generally, resulting in more patients undergoing surgical completion as opposed to expectant or medical treatment. Increasing the rate of surgical intervention may not improve the quality of EPF care. Second, although misoprostol use was rare, its use appeared to be increasing over the study period, which may reflect early adoption of this treatment option. How the addition of misoprostol treatment will change overall treatment patterns is uncertain.

Patient race and age were associated with being treated with a surgical procedure among our study sample, which has not been described previously. Although African American women and Hispanic women were more likely to have a complete abortion based on ICD-9 coding, this study could not assess how much of the disparity was explained by this difference. It may be that these groups had a harder time accessing care and, therefore, sought care after spontaneous passage of products had already occurred. Alternatively, there may be community-based influences causing treatment preference differences between these groups. Our study could not explain these findings, but these treatment differences warrant further study.

After EPF, women express strong treatment preferences,[24] yet providers still influence ultimate treatment choice.[14,17] Although we found no study comparing treatment preference or acceptance among women presented with all options, several studies provide evidence that women will accept the range of options addressed in this study.[14,17–19,24,25] It is unlikely that treatment patterns in Michigan only reflect patient preference. Expanding treatment options to reflect patient preferences and evidence-based practices could both improve patient-centered care and possibly decrease healthcare resource use. However, changing clinical practices is a complex challenge. Previous work consistently shows that adherence to evidence-based practices is suboptimal.[26–29] A number of identified barriers to practice change might have particular significance in EPF care, such as a lack of confidence that one can actually perform the behavior or a belief that patients will not accept the change.[27] A better understanding of the existing barriers to changing clinical practices is needed to effectively encourage providers to broaden treatment choices for women experiencing EPF.

Our study methodology has several limitations. First, this methodology cannot explain the reasons underlying the identified treatment patterns, including associations with patient race or socioeconomic status. We also could not distinguish between patients who began with expectant management but went on to have a surgical uterine evacuation and those who primarily elected to have surgery. Further, administrative codes are often difficult to interpret, misclassification is common, and we would likely misclassify those who went outside their insurance plan for treatment. For instance, we doubted that the distinction between cases that were coded as complete vs. incomplete abortions was very accurate; therefore, we do not comment on the appropriateness of the relatively high number of surgical interventions done in the complete group. We also found that >10% of women identified as having an EPF by diagnosis code had no evidence of it upon chart review. Still, our classification scheme was able to determine treatment type with a high degree of accuracy, which was our primary objective. We opted not to attempt to correct for this bias in the larger database for two reasons. First, it is possible that the university-affiliated system is more likely to see these cases because of referral patterns. Second, we were primarily interested in validating our methods of treatment classification, which was not affected by these cases. Still, some degree of similar misclassification would probably

be present in other data sources as well. Based on our findings, this bias would likely increase the apparent proportion of cases managed expectantly.

We anticipated some difficulty in determining procedure location, which was somewhat confirmed during our validation process. Our validation process indicated that we overestimated the proportion of cases done in an office, at least among enrollees of the university-affiliated health plan. We also could not assess why a patient was prescribed misoprostol, and it is possible that it was used for another indication, such as hemorrhage. Again, this misclassification would overestimate the proportion of cases managed medically. Given the rarity of both office uterine evacuations and misoprostol use among Medicaid enrollees, it is unlikely that the presence of these biases changes our study's fundamental conclusions. Alternatively, it is possible that some providers dispense misoprostol in their office, which would not have been identified by our methods. We know that misoprostol is not being dispensed from offices in the university-affiliated health plan and suspect that this practice is uncommon elsewhere in the state.

Conclusions

Women experiencing EPF in these Michigan health plans appear predominantly to be treated expectantly or with surgical uterine evacuation in an operating room. Use of misoprostol or office uterine evacuations is very uncommon despite evidence supporting their safety and effectiveness. As several studies have consistently demonstrated high acceptance of both office evacuations and treatment with misoptrostol, the treatment pattern in Michigan is likely not driven by patient preference. Because providers influence this care pattern, a better understanding of provider attitudes toward these newer treatment options is needed to encourage the adoption of models of care that have proven safety, efficacy, and patient acceptance.

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Disclosure Statement

No competing financial interests exist.

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Address reprint requests to:
Vanessa K. Dalton, M.D. M.P.H.
Department of Obstetrics and Gynecology
University of Michigan
1500 E. Medical Center Drive, L4000
Women's Hospital
Ann Arbor, MI 48109

E-mail: daltonvk@med.umich.edu