Patient Preferences, Satisfaction, and Resource Use in Office Evacuation of Early Pregnancy Failure

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OBJECTIVE: To examine patient treatment preferences and satisfaction with an office-based procedure for early pregnancy failure and to compare resource use and cost between office and operating room management of early pregnancy failure.

METHODS: This study was a prospective observational study of 165 women presenting for surgical management of early pregnancy failure. Participants completed a preoperative questionnaire addressing treatment preferences and expectations and a postoperative questionnaire measuring level of pain experienced and satisfaction with care. Resource use was determined by measuring the time patients spent at the health care facility and the actual procedure time. Cost was estimated using an institutional database.

RESULTS: One hundred fifteen women from the office and 50 from the operating room were enrolled. Patients selecting outpatient management scored "privacy," "avoiding going to sleep," and "previous experience" higher than the operating room group ($P < .05$). Patients who perceived that their physicians preferred one procedure over the other were more likely to select that procedure ($P < .001$). Satisfaction was high in both groups, and underestimating the procedure's discomfort was negatively associated with satisfaction ($P < .002$). Costs were greater than two-fold higher in the operating room group compared with the office group ($P < .01$). Complications were uncommon, but hemorrhage-related complications were four times more common in the operating room group than in the office group ($P < .01$).

CONCLUSION: Office-based surgical management of early pregnancy failure is an acceptable option for many women and offers substantial resource and cost savings. *(Obstet Gynecol 2006;108:103–10)*

LEVEL OF EVIDENCE: II-2

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Early pregnancy failure occurs in 14–19% of recognized pregnancies.[1] Treatment options include expectant management, surgical evacuation, and medical completion. Traditionally, first-line management has been dilation and curettage (D&C) in an operating room. This practice largely developed when women frequently presented in acute distress from hemorrhage, infection, or complications after attempted illegal abortions.[2,3] In this scenario, stabilization and management in an operative suite was the safest approach.[3] Currently, because ultrasonography and highly sensitive pregnancy tests now enable pregnancy failures to be diagnosed at increasingly earlier gestational ages, most patients present before the onset of heavy bleeding or infection.

Many other procedures have moved from the operating room into an ambulatory setting, but it appears that management of early pregnancy failure has not. Although there is no population-based study describing usual care in the United States, data from South Africa, Europe, and Canada indicate that most patients are still being managed in an operative suite,

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often under general anesthesia.[4–6] These studies also indicate that sharp curettage and general anesthesia are still common, despite evidence implicating their association with higher complication rates than suction curettage without general anesthesia.[7–9]

The objectives of this study were to examine patient treatment preferences and satisfaction with an office-based procedure for early pregnancy failure. Our hypothesis was that many patients prefer an office-based procedure because it would satisfy their treatment priorities, which would be different from those of women choosing an operative room procedure. We also predicted that those who were offered and selected an office procedure would be satisfied with their care. We also sought to compare resource use and cost between the office procedure and the operating room procedure. Finally, as a secondary objective we examined the efficacy and complications of the office-based procedure. Our hypothesis was that, among women meeting the medical criteria for an office-based procedure, those selecting an office procedure would have efficacy and complication rates similar to those choosing to have their procedure in the operating room.

MATERIALS AND METHODS

Approval for this study was granted by the University of Michigan Institutional Review Board. A prospective observational design was used. From July 2002 until July 2004, women 18 years of age and older presenting to the University of Michigan Department of Obstetrics and Gynecology for surgical management of a first-trimester early pregnancy failure were identified for possible enrollment. Diagnosis of early pregnancy failure was confirmed by either a combination of ultrasound diagnosis and abnormally progressing β-hCG levels or by serial ultrasound examinations alone. Gestational age was estimated by using fetal pole and mean gestational sac diameter. These measurements were documented within 72 hours of the procedure.

Patients opting for surgical management were considered for enrollment. Each study participant selected between an office or an operating room uterine evacuation after being counseled by her primary physician or midwife about both surgical options. Counseling was not formally standardized across physician or midwives, but hands-on training sessions were conducted, and each department was given written descriptions and preoperative checklists to aid in presenting the options to patients.

Participants in both groups had to be medically able to undergo either an office-based or an operating room–based procedure. Exclusion criteria were bleeding disorders, hemoglobin less than 8.0, severe cardiopulmonary disease, uncontrolled seizures, severe anxiety or inability to tolerate pelvic exams, molar pregnancies greater than 10 weeks, uncontrolled type 1 diabetes, and untreated mucopurulent cervicitis. Patients with pregnancies of more than 12 weeks 6 days of gestation by ultrasound examination were not considered for enrollment. Patients were also excluded if they were not offered both the office and operating room–based surgical options by their primary physicians or midwives.

Patients opting to have their uterine evacuations performed in the office were referred by their primary physicians or midwives to the obstetrics and gynecology clinic, where one of two physicians either performed the procedure themselves or supervised house officers. Anesthesia consisted of oral lorazepam (1 mg), ibuprofen (800 mg), and/or propoxyphene napsylate (100 mg/acetaminophen 650 mg), with paracervical block (10 mL of 1% lidocaine). Uterine evacuations were completed using manual vacuum aspiration without sharp curettage. Methylergonovine or oxytocin was administered for uterine atony as indicated. Uterine contents were examined for completeness after the procedure and sent to pathology for confirmation. For patients opting for the operating room, procedures were typically performed by the patient's primary gynecologist. Anesthesia options included intravenous sedation, regional anesthesia ,or general anesthesia according to the patient's request and/or the anesthesiologist's recommendation. Uterine evacuations were completed by using electric suction with or without sharp curettage. Postoperatively, the uterine contents were grossly examined for products of conception and sent to pathology for microscopic confirmation.

Data were collected using a combination of self-administered questionnaires, observation, and chart review. Questionnaire items were developed using expert opinion, consensus, and adaptation of previously published questions.[10,11] Pretesting was done in 3 office and 2 operating room patients, and subsequent changes were made to improve clarity. Additional items were added to the preference section based on answers to open-ended questions.

Participants completed a preprocedure self-administered questionnaire at the time of enrollment. This questionnaire addressed prior pregnancy losses, previous suction dilation and curettage, history of induced abortions, and experiences with office and/or awake procedures. The questionnaire measured patient perceptions of provider procedure preference

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with the question "Did you feel that your doctor wanted you to have one treatment more than the other?" Patient treatment priorities were measured using patient-reported level of importance ("not important" to "extremely important") of a series of items, such as "privacy" and "I wanted to be asleep." Each patient was asked to rate her level of preference and expectations about pain during the procedure using a 10-point scale. "Strong" preference was defined as a score of 7 or higher.

Immediately before discharge, participants completed a second questionnaire addressing pain, bleeding, and satisfaction with care. Using a 10-point scale, each participant recorded the pain level she experienced during and after the procedure. Satisfaction was measured using two items: "How satisfied are you with the communication that occurred between you and your care providers during this experience?" and "Overall, how satisfied were you with your experience?" Responses were measured using a 10-point scale. A total satisfaction score was obtained by summing these two scores. Other items addressed the likelihood of selecting the same procedure again and recommending the procedure to a friend faced with a pregnancy loss.

Resource use was estimated from patient time at the health care facility and procedure length expressed in minutes. Cost was estimated by using a database maintained by the University of Michigan Data Warehouse (TSI, Transition System Incorporated, Boston, MA); TSI is a cost accounting system that incorporates all direct and indirect costs in dollars, both variable and fixed, for a specific procedure.

A study investigator or a research assistant collected data for each procedure, including estimated blood loss, anesthesia type, use of a sharp curette, and the administration of oxytocin, carboprost, or methylergonovine. The investigators estimated blood loss from the total amount of blood collected in the suction canister plus an estimate of the amount lost on the surgical field. Complications, including retained uterine injury, unplanned admission, and need for immediate resuction, were documented. Two weeks postoperatively, an electronic chart review was conducted to identify any additional complications, including emergency room visits, endometritis, retained products, hospital admissions, or return to the operating room.

Our primary outcomes of interest were patient treatment preferences, satisfaction with care, resource use, and cost. Generally, acceptability rates and satisfaction with a particular procedure is high among women undergoing surgery for early pregnancy failure (> 80%),[11,12] but the scales and measures are inconsistent between studies. We anticipated that we would be least likely to detect a difference in satisfaction and lacked a good source for an expected standard deviation from a similar population. Therefore, in the absence of pilot data, we powered the study to detect a moderate effect size by using a two-sample t test comparison. The sample size was calculated to detect a 15% difference in overall satisfaction with a power of 90% with an α of 0.05; this required enrollment of 54 women into each group.

The mean cost and time spent between the two groups were compared by using unpaired t tests. Analysis of patient treatment preferences was done by creating dichotomous variables from the scale and comparing the two groups with either Pearson χ^2 or Fisher exact test. Satisfaction was compared with Mann-Whitney U and Pearson χ^2 after creating a dichotomous variable. Differences between expected and experienced level of pain were compared by using Mann-Whitney U, and logistic regression was used to examine the relationship between satisfaction and the difference between the expected level of pain and the experienced level of pain. Statistical analysis was performed with SPSS 12.0.1 software (SPSS Inc, Chicago, IL).

RESULTS

A total of 172 of 328 women undergoing surgical uterine evacuation for early pregnancy failure during the study period were asked to participate, and 165 women enrolled in the study: 115 in the office group and 50 in the operating room group (Fig. 1). Participation was high in both groups, with only 3 women declining to participate. Four women did not meet study criteria: two had intrauterine contents consistent with greater than 12 weeks, one had no documented intrauterine pregnancy, and one reported that she was only offered the office treatment option. Although we did not enroll the estimated 54 women needed to detect a lower satisfaction rate in the office group, even if these additional patients were enrolled, we would not been able to detect a difference in satisfaction scores between the two groups.

Table 1 presents the socioeconomic data and relevant medical histories of the two study groups. Overall, these groups were very similar. The operating room group has a slightly larger mean uterine size, although we did not consider this a clinically important difference. No difference was detected between the groups with regard to the type of provider, although patients with obstetrician-gynecologists appeared to be more likely to have their procedure in

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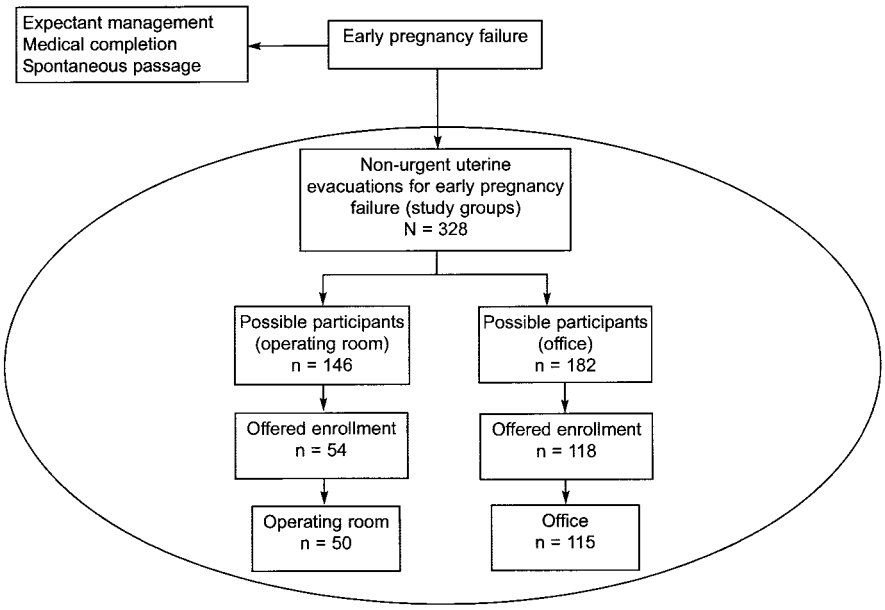

Fig. 1. Study enrollment.
Dalton. Office Evacuation of Early Pregnancy Failure. Obstet Gynecol 2006.

Table 1. Demographic Data of Participants by Treatment Type

	Procedure Type		
Characteristic	**Office (n = 115)**	**OR (n = 50)**	***P***
Discrete variables*			
Race			
White	91 (79)	45 (90)	.32
Asian	9 (8)	4 (8)	
African American	3 (3)	1 (2)	
Education			
High school or less	14 (12)	8 (16)	.5
College or greater	99 (86)	41 (82)	
Provider type†			
Obstetrician-gynecologist	90 (79)	45 (90)	.16
Family practice	15 (14)	4 (8)	
Certified nurse midwifery	10 (7)	1 (2)	
Suspected molar pregnancy	16 (14)	10 (20)	.36
Continuous variables‡			
Mean age (y)	31.7	30.2	.1
Mean gestational age by ultrasonography (wk)	7.8	8.4	.06
Mean uterine size (wk)	8.18	8.86	.03
Mean total number of pregnancies	2.4	2.6	.07
Mean total number of early pregnancy failures	1.36	1.53	.34
Mean number of previous D&Cs	0.51	0.45	.63
Mean number of induced abortions, surgical	0.25	0.14	.11
Mean days waiting for procedure	8	7.4	.64
Mean number of vaginal deliveries	0.54	0.84	.04
Mean preoperative hematocrit	38.4	38.2	.56

OR, operating room; D&C, dilation and curettage.
Data are expressed as n (%) unless otherwise indicated.
* Discrete variables were compared using the Pearson χ^2 or Fisher exact test.
† Although these differences were not significant, if obstetric provider was compared with others, there was a trend towards significance.
‡ Means were compared using *t* tests.

the operating room than those with other provider types, and this difference approached significance ($P = .05$).

All patients reported that the safety of the procedure was an important consideration when choosing between available procedures. Table 2 summarizes

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Table 2. Number and Percentage of Women Who Scored Each Item Highly Important by Treatment Type*

Treatment Priority	Office (n = 112)	OR (n = 49)	*P*
Safety of procedure	103 (90)	43 (86)	.28
Wanted to avoid going to sleep	23 (20)	2 (4)	< .001
Privacy	51 (44)	14 (28)	.03
Previous experience	90 (78)	31 (62)	.02
Wanted to avoid drugs	35 (30)	8 (16)	.04
Wanted to be asleep	10 (9)	31 (62)	< .001
Did not want to feel anything	44 (38)	34 (68)	< .001
Treated by own doctor	32 (28)	24 (48)	.02
Wanted to get home quickly	53 (46)	20 (40)	.23
Did not want to see blood	25 (22)	12 (24)	.83
Friend recommended procedure type	5 (4)	4 (8)	.31

OR, operating room.
* Scoring item 4 or 5 on a 5-point scale.

treatment preferences by group. Sixty percent of all participants reported a "strong" preference for their chosen procedures. Neither mean preference scores nor the proportion reporting a strong preference was different between the groups (data not shown).

Patient treatment choice appeared to be strongly influenced by physician or midwife preferences. Among patients who reported that they did not perceive a preference on the part of their health care provider, 68% selected the office-based manual vacuum aspiration. However, a perception of physician or midwife preference was associated with patient treatment (Fig. 2). Although the group was small (n = 13), patients who reported that their providers preferred them to have their procedure in the operating room were more likely to ultimately choose the operating room procedure ($P < .001$).

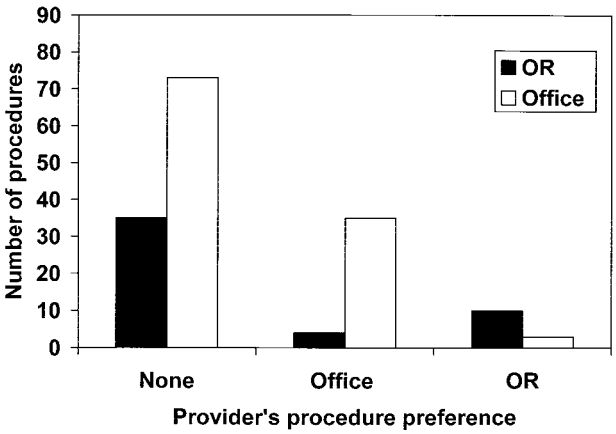

Fig. 2. Provider's influence on patient choice of procedure. The relationship between provider's preference and patient procedure choice between office and operating room (OR) management was tested with the Pearson χ^2 test ($P < .001$).
Dalton. Office Evacuation of Early Pregnancy Failure. Obstet Gynecol 2006.

Patients opting to have the office procedure reported expecting higher levels of pain than those going to the operating room, and as anticipated, they reported higher pain scores. Further, the difference between expected pain level and experienced pain level was greater in the office group than in the operating room group ($P < .001$; data not shown).

Neither the mean total satisfaction score nor the percentage of women who rated their total level of satisfaction high (18, 19, or 20) was different between the groups. There was no difference between groups with regard to whether they would choose the same procedure again for themselves, yet patients in the office were more likely to report that they would *not* recommend a similar procedure to a friend ($P = .02$) (Table 3). We also found that the difference between pain expectation and pain actually experienced was negatively associated with satisfaction ($P < .002$).

Table 3. Patient Satisfaction by Treatment Type

	Office (n = 110)	OR (n = 46)	*P*
Total satisfaction score (median)*	19	20	.32
Highly satisfied on total satisfaction†	81 (73)	36 (78)	.55
Maximum total satisfaction‡	51 (46)	26 (56)	.15
Would choose the same procedure again	93 (89)§	45 (98)	.11
Would recommend same procedure to a friend	94 (90)§	43 (100)‖	.02

OR, operating room.
Data are expressed as n (%) unless otherwise indicated.
* Total satisfaction = overall satisfaction with care + satisfaction with communication. This item was compared using Mann-Whitney *U*.
† Highly satisfied defined as a score of 18, 19, or 20.
‡ Maximum score given on both items.
§ n = 105.
‖ Only 43 answers were available for this item.

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Operating room management of early pregnancy failure incurred greater costs and used more resources based on all surrogate measures. The procedure itself was 80% longer and TSI estimated costs were more than two-fold higher in the operating room than in the office. However, physician reimbursement did not differ between the two groups (Table 4).

There were no major complications in either group. Further, no office procedure was moved to the operating room or converted to general anesthesia for patient discomfort. One patient in the office group was transferred to the operating room for hemorrhage but required no further treatment because bleeding spontaneously resolved. Another patient from the operating room group was admitted overnight for observation after hemorrhage. Hemorrhage-related complications were 4 times more common in the operating room group as shown in Table 5.

DISCUSSION

Overall, we found a high level of satisfaction among participants undergoing surgical uterine evacuation for early pregnancy failure in both the office and the operating room. Women differed in their treatment preferences and reported a strong preference for their chosen procedure. As expected, office-based treatment resulted in substantial resource savings, and women choosing office manual vacuum aspiration did not have higher complication rates than did patients who underwent the traditional procedure in the operating room. For both groups, complication rates were consistent with published rates.[13]

Although both groups were highly satisfied with their care, pain appeared to negatively affect satisfaction. Specifically, a greater difference between pain experienced and pain expected was negatively associated with satisfaction. This finding has obvious clinical implications. First, we need to realistically council patients regarding the discomfort they may experience during the office procedure. Alternatively, adding an option for intravenous sedation may improve the experience for women desiring to avoid the operating room but wanting more pain management than can be achieved with oral medications and a paracervical block. Similarly, adding more anesthesia options to the clinic setting may also influence how women would counsel friends in similar circumstances.

Table 4. Comparison of Resource Utilization by Treatment

	Office MVA		OR	
	Mean	SD	Mean	SD
Total patient time (min)	97	42	290	85*
Procedure time (min)	10	4.1	19	9.6*
TSI†	968	426	1,965	926*

MVA, manual vacuum aspiration; OR, operating room; SD, standard deviation; TSI, Transition System Incorporated cost accounting system.

* $P < .01$.

† Cost of the procedure was estimated using TSI data. Means were compared using *t* tests.

Our study findings and those of others dispute the notion that current practices are based on patient preferences.[14,15] Overall, our institution's experience has been that about half of women choose to have their procedures completed in the office. In the study group, only 25% of study participants reported that being asleep for the procedure was highly important. Instead many participants opted for an office procedure that better meets other needs such as privacy and efficiency. We suspect that some of clinical practice is driven by provider preference. Others have described provider influence on patients' treatment choices in early pregnancy failure.[16] Indeed, we also found that when patients perceived their providers' preferences, they were more likely to choose that option than if they did not know what their provider wanted.

As expected, we found that moving early pregnancy failures to an office setting resulted in an almost $1,000 savings in direct and indirect costs per case. Others have also reported on the substantial savings offered by manual vacuum aspiration in an ambulatory setting.[17–19] More recently, a cost-effectiveness model examining different care strategies estimated that using manual vacuum aspiration could save $779 million per year over traditional D&C.[20] Although all of these protocols use manual vacuum aspiration, it is really the shift from the operating room to an ambulatory setting that results in the greatest savings. Our study builds on these previous studies by examining an ambulatory, asymptomatic population.

Because our primary objective was to examine patient treatment preferences and satisfaction with care, we did not use an experimental design. Observational studies are more appropriate for examining patient preferences and satisfaction than experimental designs. Recently, Wieringa-De Waard et al[21] examined women's preferences in early pregnancy failure management and the effects of treatment on health-related quality of life. In their study population, over 70% refused randomization because of a strong treatment preference. In response, they included a group allocated to their treatment preference and found that

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Table 5. Complications by Treatment Type

	Office (n = 115)	OR (n = 50)	*P*
Any complication	9 (8)	20 (40)*	< .01
Molar pregnancy confirmed by histology	14 (12)	9 (18)	.22
Postprocedure infection	2 (2)	1 (2)	.99
Need for re-evacuation	4 (3)	1 (2)	.68
blood loss (mean mL ± SD)	70 ± 106	311 ± 344*	< .001
Median blood loss (mL)	50	200*	
Received uterotonic agent	10 (9)	11 (22)*	.02
Unplanned hospital admissions	1 (< 1)	2 (4)	.22
Emergency room visits within 2 weeks	3 (3)	3 (6)	.37

OR, operating room; SD, standard deviation.
Data are expressed as n (%) unless otherwise indicated.
Pearson χ^2 was used for categorical variables, and *t* test was used for continuous variables.
* $P < .05$.

women who chose their own treatment had the best health-related quality of life over time.

We have not demonstrated that an office-based management scheme is safer than traditional operating room management. However, we were concerned about the four-fold increase in bleeding-related complications in the operating room group. The most likely explanation for this finding was that all but one of the operating room procedures were done under general anesthesia, which may contribute to increased blood loss, particularly with the use of some halogenated gases.[22–24] Although the type of suction used in the two groups was different, we did not consider this difference a likely cause for these differences based on numerous studies comparing the two techniques.[7,15,25–28]

This study had notable weaknesses. First, our sample is not representative of all women experiencing early pregnancy failure, so the acceptability of office treatment should be examined in groups with better representation of minorities and low-income women. Second, although we attempted to offer enrollment to all women presenting for surgical management of early pregnancy failure, it was easier to enroll women opting for the office procedure. This could have resulted in unintentional enrollment bias. We also recognize that our sample size was insufficient to detect potentially relevant differences in satisfaction levels and complication rates. Nevertheless, examining the scores descriptively demonstrates that satisfaction levels were high in both groups. Finally, because we did not initially offer intravenous sedation in the clinic, we may have underestimated the acceptability of office-based management.

Office treatment of early pregnancy failure is preferred by many women. When women with early pregnancy failure present with hemorrhage or infection, urgent surgical intervention in an operating room is still indicated. However, when diagnosed in advance of infection or bleeding, office-based treatment is an excellent alternative because it conforms to the preferences and treatment priorities of many women, is effective, and significantly reduces resource use.

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