Comprehensive Early Pregnancy Loss Management in the Emergency Department

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Abstract

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The goal of this study was to compare the outcomes of patients who present to the emergency department (ED) for early pregnancy loss (EPL) who receive comprehensive management in the ED versus referral for outpatient follow-up. We performed a retrospective cohort study of patients who presented to two EDs in our hospital system with EPL between 2014 and 2019. Patients received ED management (EDM; all counseling and/or management performed in ED) or outpatient management (OPM; discharged from ED and managed as an outpatient). We compared patients who received EDM and OPM on the proportion with complete EPL within one week, EPL-related complications, and time spent in the ED. We identified patients presenting to the ED with EPL using ICD-9 and 10 codes and abstracted relevant clinical information from their electronic health records. We tested for differences between EDM and OPM groups in the proportion with complete EPL within one week using multivariable logistic regression adjusted for age, race/ethnicity, insurance status, and specific EPL diagnosis to obtain odds ratios (ORs) and 95% confidence intervals (CIs). We identified 126 patients who received EDM and 37 who received OPM, and 78.6% and 54.1%, respectively, had complete EPL within one week. After adjustment, the odds of complete EPL within one week was 4.5 times higher among the EDM cohort than OPM (OR 4.55, 95%CI 1.78-11.67). The mean time spent in the ED was two hours longer among patients who received EDM (6.6 vs. 4.7 hours, $p<0.001$), but more patients who received OPM had EPL-related

return ED visits (37.8% vs 11.9%, $p<0.001$). In conclusion, comprehensive EPL management has a positive impact on patient outcomes and on factors unique to the ED setting. Comprehensive care should be widely implemented to improve patient-centered care for patients seen in the ED with EPL.

Introduction

Early pregnancy loss (EPL), or miscarriage, is a common complication, affecting twenty percent of clinically recognized pregnancies.[1] Patients commonly first seek care for EPL in the emergency department (ED) over other settings for ease of access, perceived sense of urgency of their symptoms, or due to lack of an established provider. The ED is a major point of access for EPL-related services, as vaginal bleeding in pregnancy is responsible for 500,000 emergency room visits each year.[2]

For patients with EPL, comprehensive care entails counseling the patient regarding their diagnosis and providing their selected option for management; expectant, medication, or surgical management.[1] Expectant management allows the patient to wait for pregnancy expulsion to occur without intervention. Medication management involves the use of misoprostol with or without the addition of mifepristone which induces the expulsion of pregnancy within 24-48 hours. The last option, surgical management, involves a uterine aspiration procedure, which can occur in a variety of settings. For the majority of patients, all three management options are appropriate, and patient satisfaction is highly correlated with the ability to choose their preferred option.

The provision of comprehensive EPL care in the ED is safe and cost-effective, and limited evidence demonstrates high acceptability among patients.[3-7] While individual ED sites have successfully integrated EPL management within their settings, ED staff concerns remain regarding throughput, logistics, and staffing involved in providing comprehensive EPL care, particularly surgical management.[8-10] Furthermore, poor communication, inadequate delivery of information, and lack of support in the ED can perpetuate negative feelings and sense of trauma for those experiencing EPL, particularly for those desiring expedited resolution of EPL.[11-13]

Patients seen in the ED for EPL typically have resolution of EPL within 11 days,[14] and providing comprehensive EPL care in the ED could potentially shorten this time, but it is unknown if time to resolution among those receiving comprehensive care in the ED is shorter than those referred directly for outpatient follow-up. We sought to compare outcomes of patients who receive comprehensive care for EPL in the ED versus those who are referred for outpatient management, specifically the timing of EPL resolution, prevalence of complications, and time spent in the ED.

Methods

Study Design and Setting

We conducted a retrospective cohort study of patients who were seen in the ED for EPL between January 1, 2014 and December 31, 2019 at the University of Washington Medical Center (UWMC) and Harborview Medical Center (HMC) in Seattle, WA. UWMC and HMC are two of the major hospitals within the University of Washington (UW) Medicine health system and the only ones in the system that offer surgical management in the ED for EPL. UWMC is the major referral medical center in Washington State. HMC is the largest safety-net hospital in Seattle and the only Level-1 trauma center in Washington State. The University of Washington Institutional Review Board approved all study activities.

Using the International Classification of Diseases, ninth and tenth revision (ICD-9 and ICD-10), diagnostic codes in the electronic medical record, we identified potential subjects who received a diagnosis of EPL in the ED in the study timeframe. Appendix A displays the ICD codes used to identify potential subjects. One of the authors (AO) manually reviewed electronic charts of potential subjects to confirm eligibility and collect demographic and clinical information. A second author (SG) reviewed a subset of charts to confirm interrater reliability. Appendix B and C show the list of variables collected and criteria for obtaining those variables. We collected and managed data using a structured RedCap database (RedCap version 9.3.2) hosted at the University of Washington.[15]

We excluded patients who received a diagnosis of complete EPL (EPL already resolved at the time of ED visit), pregnancy of unknown location, molar pregnancy, pregnancy after the first trimester, or septic abortion at the index ED visit, as counseling and management required for these patients differed from those with stable EPL. Patients who were clinically unstable requiring urgent intervention were also excluded because outpatient management would not have been a viable treatment option for these individuals. Some exclusions occurred at the time of chart review due to incorrect diagnosis coding. Lastly, we excluded patients if they did not have documentation of EPL being completed at or after the initial ED visit.

EPL Management

We classified patients into two cohorts: those who received comprehensive EPL care in the ED and those who were referred for outpatient management. We defined those in the ED management

(EDM) cohort as those who received comprehensive EPL counseling and/or management in the ED. After receiving an EPL diagnosis, a GYN provider or family medicine provider that specializes in EPL management was consulted to evaluate the patient, as these are currently the only providers in the UW Medicine hospital system that provide comprehensive EPL care. These providers reviewed the diagnosis with the patient and discussed their options for management. At that time, patients could opt to be expectantly managed, receive medication management in the ED, or proceed with uterine aspiration. Patients in the outpatient management (OPM) cohort were seen only by an ED provider and not offered medication or surgical management. These patients were instructed to follow up with a provider as outpatient after discharge.

Outcomes

Our primary outcome was complete EPL within 1 week. Complete EPL was defined as completion of a uterine aspiration procedure, confirmatory ultrasound showing absence of a gestational sac, negative pregnancy test, or other documentation within the medical record confirming the patient passed the pregnancy. Our secondary outcomes included time to resolution of EPL (in days), complications, and ED throughput. We defined time to resolution of EPL as the number of days between the date of the initial ED visit and the date of documented EPL completion. We identified complications via chart review. We abstracted the need for blood transfusion, inpatient hospital admission, development of infection, or additional ED visits related to continued EPL symptoms. We defined ED throughput from "ED Arrival Time" to "ED Departure Time". These time points are routinely documented for all patients seen in the ED. "ED Arrival Time" is when the patient is first registered in the ED. "ED Departure Time" is when the patient physically leaves the ED.

Sample size

We performed an *a priori* sample size calculation assuming that about 90% of patients will have successful completion of EPL by one week based on previous studies.[16,17] A prior randomized control trial found that 85 percent of patients who received immediate medication management in the ED had completed their miscarriage with one week.[16] Given that among patients with EPL, two-thirds choose surgical management and one-third choose medication management, with a very small percentage of patients choosing expectant management,[17] we extrapolated that 90% of patients who received EDM and

only 70 percent who received OPM would have complete EPL within 1 week. Using an alpha=0.05 with 80% power, we require 62 patients per cohort to detect a 20% difference in the proportion of patients with completed EPL at 1 week. Considering the potential burden of waiting for EPL completion has on patients' physical and emotional well-being,[11] we felt a 20% difference would be clinically significant.

Data analysis

We determined differences in baseline characteristics and clinical findings (including complications and ED throughput) between EDM and OPM cohorts using Student's t test for continuous variables and chi-square or Fisher exact tests for categorical variables. To examine differences in time to EPL completion, we plotted Kaplan-Meier survival curves for the EDM and OPM cohorts and used the log rank test to compare differences in time to EPL completion between the two groups. We examined outliers in time to EPL completion, and excluded one from these analyses with a very long time to EPL completion, attributable to use of beta-hCG measurements for determination, whereas ultrasound was the method employed in almost all other patients. Missing time to completion of EPL was more prevalent in the OPM cohort, raising concerns that the prevalence of complications would be inflated in this group relative to the truth. Complications in the setting of EPL are rare, occurring in less than one percent of cases.[4] We performed sensitivity analyses, assuming the complication rates of those without documentation of complete EPL were zero percent, to assess if any differences in complications between the two cohorts persist.

We used a multivariable logistic regression to determine association of EPL management with complete EPL within one week using odds ratios (ORs) and corresponding 95% confidence intervals (CIs) and a Cox proportional hazards model to compare time to resolution of EPL between the two management groups using hazard ratios (HRs) and 95% CIs. Variables in the model thought to have a clinically significant impact on outcomes were chosen *a priori* and included age, race/ethnicity, insurance status, and type of EPL diagnosis. All analyses were conducted using Stata/SE Version 16.1.

Results

The flow diagram for study inclusion is shown in Figure 1. Diagnostic codes identified 593 potentially eligible subjects, 16 of whom were excluded because they were not seen in the ED. After chart

review of 577 subjects, 360 were excluded for having ineligible diagnoses. Of the 233 subjects that had an eligible miscarriage diagnosis, 20% (N=47) were excluded for lacking documentation of complete EPL (N=19 subjects who received EDM and N=28 who received OPM). The final sample included 163 patients with data available on time to EPL completion: 126 in the EDM cohort and 37 in the OPM cohort. Demographic and clinical information for patients excluded due to missing time to complete EPL are presented in Appendix D. Within the OPM cohort, 60% of the excluded patients had public insurance compared to only 30% of the patients analyzed in the study but groups were otherwise similar. Table 1 shows the baseline demographic and clinical characteristics of the N=163 eligible patients stratified by cohort. More patients in the EDM cohort had public insurance (56.4% versus 29.7%, p=0.009) but patients in the two groups were otherwise similar. Roughly half of patients (49%) who received EDM elected for surgical management. Among those who elected for surgical management, 71% received it in the ED, 13% underwent an outpatient clinic procedure, and 8% had their procedure performed in the operating room.

Among EDM patients, 78.7% (N=99) had complete EPL within 1 week of the index ED visit compared to 54.1% (N=20) of patients who received OPM (p=0.003). The median number of days to complete EPL was 2 (range 0-39) and 7 (range 0-21) among the EDM and OPM cohorts, respectively (Figure 2), which was not found to be significantly different (log rank test: p=0.13). After adjusting for age, race, insurance status, and type of EPL diagnosis, the odds of complete EPL within 1 week was 4.6 times higher among those who received EDM compared to OPM (OR 4.56, 95% CI 1.78, 11.67, p=0.002). In adjusted Cox proportional hazards models, the odds of complete EPL on any given day after the index ED visit was 1.6 times higher for those who received EDM compared to OPM (HR 1.59, 95% CI 1.05-2.40, p=0.03).

The number of blood transfusions, hospital admissions, or development of infection did not differ significantly between the two groups in unadjusted analyses (Table 3). In a sensitivity analysis where we assumed that all subjects with missing information on complications did *not* have a complication and recalculated chi-square tests, findings remained unchanged. Regarding ED throughput, those who received EDM, on average, were in the ED two hours longer than those who received OPM (6.6 hours vs.

4.7 hours, p<0.001), but 37.8% of patients in the OPM cohort had additional ED visits related to EPL compared to 11.9% of patients who received EDM (p<0.001).

Discussion

Compared to patients seen in the ED for EPL and then managed in the outpatient setting, patients who received comprehensive EPL care in the ED were more likely to have complete EPL within 1 week of presentation and an overall greater likelihood of completion on any given day, with no difference in complications. ED throughput was longer among patients who received EDM; however, more patients in the OPM cohort returned to the ED for continued EPL symptoms when compared to those in EDM.

Comprehensive EPL care in the ED is feasible and may lead to faster resolution of EPL. With the ability to perform uterine aspiration in the ED, complete EPL can be expedited if a patient desires it. A large proportion of patients in our study elected for uterine aspiration in the ED, showing that rapid resolution is a common desire for patients, and that receiving this care in the ED at the time of EPL diagnosis is acceptable to patients. Reasons for quick resolution can vary and are influenced by social and emotional factors.[14,17] Patients who present to the ED for symptomatic EPL tend to be young, underinsured and of non-white race,[14,18] and prolonged management course may not be ideal or desired, especially given the potential for being treated differently due to implicit bias.[20-22] It is notable that our study showed that patients who were referred for outpatient follow-up returned to the ED for persistent EPL symptoms more commonly than those who received comprehensive care. Prior studies have shown that access to timely follow-up and continued uncertainty about condition are patients' primary motivators for returning to the ED.[23] Comprehensive EPL care could reduce the number of short-term, unscheduled return ED visits, which is often used as a quality-of-care measures for EDs.[24]

It is important to note the limitations of our study. Our population arises from two hospitals affiliated with a major academic medical center, which may not be generalizable to other hospital systems, particularly those that do not offer uterine aspiration in the ED setting. The sample analyzed is small with roughly 15 percent who received EDM and 43 percent who received OPM excluded for lacking documentation of a complete EPL date. It is possible the differences found related to time to completion could potentially be exaggerated within our sample. Patients who received OPM missing time to

completion data may have never needed to see a provider for follow-up because their EPL resolved on its own without intervention. Patients in the same group with a documented complete EPL date may be biased in the direction of having longer time to completion. When we examined the characteristics of patients excluded due to missing time to completion, about 70% of those who received OPM were publicly or not insured compared to 40% of those who received EDM. These underinsured patients may not have had adequate access to care or may have followed up in health systems that were not included in our study. It is unclear the impact the exclusion of these patients would have on time to completion of EPL, however our sensitivity analyses provided confidence in our findings regarding differences in the proportion of return ED visits. Lastly, it is important to acknowledge that while rapid resolution of EPL is important to many patients, some may prioritize other factors when making the decision regarding their management options, such as avoiding a procedure.

Our study is the first to look at the impact of comprehensive EPL care in the ED on patient outcomes and on important factors unique to the ED setting such as return visits and ED throughput. Larger prospective studies could allow for obtaining more complete data on time to complete EPL by including patients' self-report of completion. Ultimately, decisions regarding management should be patient-centered. Comprehensive EPL care can facilitate more patient-centered care, but time to completion of EPL is not necessarily correlated with patient satisfaction. Future studies should examine patient experiences and satisfaction with receiving comprehensive EPL care in the ED.

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Figure 1. Selection of study population

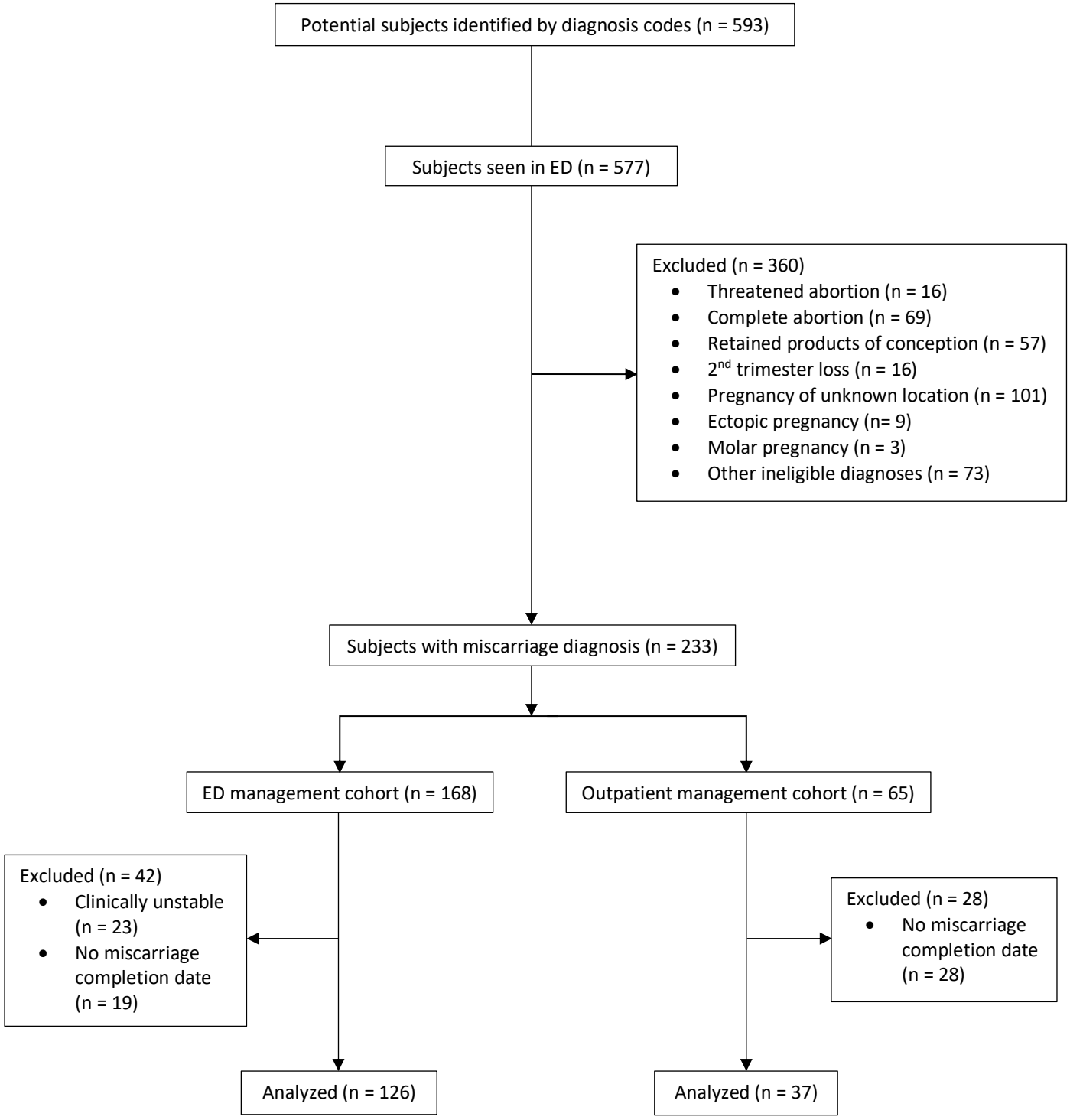
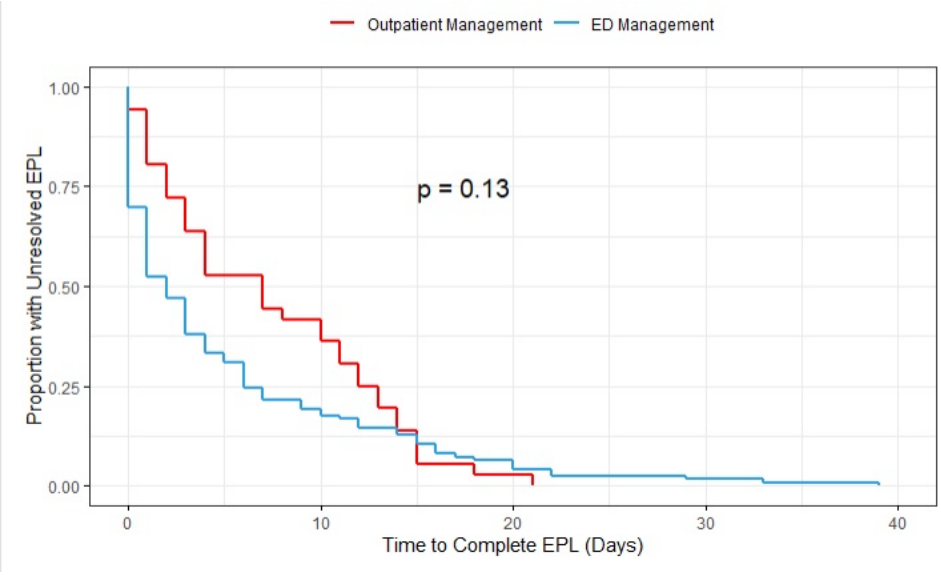


Figure 2. Kaplan-Meier survival curves of time to complete early pregnancy loss (EPL) for those who received comprehensive emergency department (ED) management or outpatient management



At risk for EPL (n)					
Outpatient Management	36	15	1	0	0
ED Management	126	24	8	2	0

Table 1. Characteristics of study population by management cohort

	ED Management (n = 126)	**Outpatient Management** (n = 37)	**p-value**
Age (years)	33.37 (±6.0)	32.11 (±5.0)	0.24
Parity			0.12
Nulliparous	44 (34.9)	17 (46.0)	
Multiparous	81 (64.3)	17 (46.0)	
Unknown	1 (0.8)	3 (8.1)	
Gestational Age by LMP (days)	72 (±16.1)	68.125 (±20.7)	0.62
Race/Ethnicity			0.43
Asian	13 (10.3)	6 (16.2)	
Black	49 (38.9)	10 (27.0)	
Hispanic/Latino	14 (11.1)	7 (18.9)	
White, Non-Hispanic/Latino	39 (31.0)	12 (32.4)	
Other or Unknown	11 (8.7)	2 (5.4)	
Insurance			0.009
Private	45 (35.7)	23 (62.2)	
Public	71 (56.4)	11 (29.7)	
Self-Pay	8 (6.4)	2 (5.4)	
Other	1 (0.8)	1 (2.7)	
History of 1st trimester loss			0.88
No	85 (67.5)	24 (64.9)	
Yes	40 (31.8)	12 (32.4)	
Unknown	1 (0.8)	1 (2.7)	
History of Infertility/Recurrent Pregnancy Loss			0.60
No	116 (92.1)	35 (94.6)	
Yes	10 (7.9)	2 (5.4)	
Pregnancy Result of ART			0.65
No	124 (98.4)	36 (97.3)	
Yes	2 (1.6)	1 (2.7)	
NEDOCS score[1]	90.74 (±51.3)	92.68 (±50.2)	0.84
Diagnosis Type			0.28
Anembryonic pregnancy	8 (6.4)	4 (10.8)	
Missed abortion	62 (49.2)	13 (35.1)	
Incomplete abortion	56 (44.4)	20 (54.1)	

ED: emergency department
LMP: last menstrual period
ART: assisted reproductive technology
[1] NEDOCS: National ED Overcrowding Study.[25] A validated scale that quantifies overcrowding in the emergency department. Maximum score is 200, and scores greater than or equal to 100 suggests the ED is overcrowded.

Data are reported as n (%) or mean (±SD). Student's t, Fischer exact, and chi-square tests were used as appropriate. Percentages may not add to 100% due to rounding.

Table 2. Patient outcomes by management cohort

	ED Management (n = 126)	**Outpatient Management** (n = 37)	**p-value**
Time Spent in the ED (hours)	6.61 (±2.52)	4.71 (±1.42)	<0.001
Complications			
Blood transfusion	2 (1.59)	3 (8.11)	0.07
Additional ED visits	15 (11.90)	14 (37.84)	<0.001
Hospital Admission	6 (4.76)	5 (13.51)	0.13
Developed Infection	5 (3.97)	2 (5.41)	0.66

ED: emergency department

Data are reported as n (%) or mean (±SD). Student's t, Fischer exact, and chi-square tests were used as appropriate. Percentages may not add to 100% due to rounding.

Appendix B. List of Covariates

- Age
- Gravidity
- Parity
- Living children
- Prior miscarriage
- Pregnancy result of ART
- Hx of infertility
- Race
- Ethnicity
- Insurance status
- Gestational age by LMP (days)
- Clinical diagnosis
- Date of ED encounter
- Day of the week seen in the ED
- ED arrival time
- Provider contact time
- ED departure time
- NEDOCS score
- Vaginal bleeding present in HPI
- Abdominal pain present in HPI
- Temperature (unit: degrees Celsius)
- Systolic BP (unit: mmHg)
- Diastolic BP (unit mmHg)
- Heart rate (bpm)
- Pain score
- Hemoglobin value (unit: g/dL)
- Cohort
- GYN consult
- Management choice (ED management cohort only)
- Number of subsequent ED visits before completion of miscarriage
- Number of subsequent clinic visits before completion of miscarriage
- Number of telephone calls before completion of miscarriage
- Hospital admission after ED visit
- Subsequent blood transfusion
- Uterotonics given
- Development of subsequent pelvic infection
- Need for additional procedures
- Date of miscarriage completion

Appendix D. Characteristics of population by cohort and presence of documentation of complete EPL

	ED Management – complete EPL documented (n = 126)	**ED Management – complete EPL not documented** (n = 19)	**Outpatient Management – complete EPL documented** (n = 37)	**Outpatient Management – complete EPL not documented** (n = 28)
Age (years)	33.37 (±6.0)	30.89 (±8.1)	32.11 (±5.0)	32.96 (±6.3)
Parity				
Nulliparous	44 (34.9)	7 (36.8)	17 (46.0)	10 (35.7)
Multiparous	81 (64.3)	12 (63.2)	17 (46.0)	16 (57.1)
Unknown	1 (0.8)	0 (0)	3 (8.1)	2 (7.1)
Gestational Age by LMP (days)	72 (±16.09)	58.25 (±11.7)	68.125 (±20.7)	76.57 (±16.8)
Race/Ethnicity				
Asian	13 (10.3)	1 (5.3)	6 (16.2)	0 (0)
Black	49 (38.9)	6 (31.6)	10 (27.0)	7 (25)
Hispanic/Latino	14 (11.1)	4 (21.1)	7 (18.9)	8 (28.6)
White, Non-Hispanic/Latino	39 (31.0)	7 (36.8)	12 (32.4)	11 (39.3)
Other or Unknown	11 (8.7)	1 (5.3)	2 (5.4)	2 (7.1)
Insurance				
Private	45 (35.7)	8 (42.1)	23 (62.2)	8 (28.6)
Public	71 (56.4)	8 (42.1)	11 (29.7)	17 (60.7)
Self-Pay	8 (6.4)	3 (15.8)	2 (5.4)	3 (10.7)
Other	1 (0.8)	0 (0)	1 (2.7)	0 (0)
Hx of 1st trimester loss				
No	85 (67.5)	14 (73.7)	24 (64.9)	20 (71.4)
Yes	40 (31.8)	5 (26.3)	12 (32.4)	7 (25)
Unknown	1 (0.8)	0 (0)	1 (2.7)	1 (3.6)
Hx of Infertility/Recurrent Pregnancy Loss				
No	116 (92.1)	19 (100)	35 (94.6)	24 (85.7)
Yes	10 (7.9)	0 (0)	2 (5.4)	3 (10.7)
Unknown	0 (0)	0 (0)	0 (0)	1 (3.6)
Pregnancy Result of ART				
No	124 (98.4)	19 (100)	36 (97.3)	27 (96.4)
Yes	2 (1.6)	0 (0)	1 (2.7)	0 (0)
Unknown	0 (0)	0 (0)	0 (0)	1 (3.6)
NEDOCS score[1]	90.74 (±51.4)	111.44 (±51.63)	92.68 (±50.2)	92.52 (±44.9)

ED: emergency department
LMP: last menstrual period
ART: assisted reproductive technology

[1] NEDOCS: National ED Overcrowding Study.[25] A validated scale that quantifies overcrowding in the emergency department. Maximum score is 200, and scores greater than or equal to 100 suggests the ED is overcrowded.
Data are reported as n (%) or mean (±SD). Percentages may not add to 100% due to rounding.