International Journal of Emergency Medicine

RESEARCH

Open Access

Utility of pelvic examination in assessing women with bleeding in early pregnancy: a multicenter Canadian emergency department study

Steven Fisher[1], Stephanie Couperthwaite[1], Esther H. Yang[1,2], Nana Owusu Mensah Essel[1] and Brian H. Rowe[1,3*]

Abstract

Background Bleeding in early pregnancy is a common emergency department (ED) presentation. Although variability in approaches has been demonstrated, research is relatively uncommon on practices and outcomes. This study investigated the influence of clinical pattern of care, utility, and contribution of pelvic examination aimed at diagnosing and managing bleeding in early pregnancy at three Canadian EDs.

Methods After obtaining informed consent, data were collected from adult women who were pregnant and from treating ED physicians using a structured questionnaire. We defined the *change in management* based on the initial clinical plan at the time of the initial physician assessment in the ED and any subsequent changes made after the pelvic examination was performed. Patient telephone follow-up was supplemented by linking with provincial administrative data for births. Univariable and multivariable binary logistic regression analyses were performed to identify factors associated with a change in patient management following pelvic examination in the ED.

Results Overall, 200 women were enrolled. The mean age was 31 years, patients had been bleeding for a median of 1 day and stayed in the ED for a median of 5 h. Of these, 166 (83.0%) received a pelvic examination, including speculum examination *and/or* bimanual palpation. Pregnancy outcome data were available for 192 pregnancies; 107 (56%) experienced a miscarriage. Factors significantly associated with a change in management after pelvic examination in the univariate logistic regression analysis were brown/dark-red bleeding per vaginam (physician determined), tachycardia, right lower quadrant tenderness, and bimanual palpation. In the multivariate logistic regression analysis, brown/dark-red bleeding per vaginam was independently associated with a reduced likelihood of a change in management after pelvic examination (aOR = 0.37; 95% CI: 0.14–0.98).

Conclusion Among women presenting to the ED with bleeding in early pregnancy prior to 20 weeks gestation, only brown/dark-red vaginal bleeding, potentially indicative of bleeding resolution, significantly independently influenced the baseline odds of a change in management after pelvic examination. Until the debate on the utility of pelvic examination in the ED for this presentation is resolved, physician preferences and shared decision making

*Correspondence:
Brian H. Rowe
brian.rowe@ualberta.ca

Full list of author information is available at the end of the article

with patients should guide practice regarding speculum examination/bimanual palpation for the management of bleeding in early pregnancy.

Keywords Pelvic examination, Emergency department, Pregnancy, Management, Miscarriage, Bleeding in early pregnancy, Diagnostic utility

Background

Bleeding in early pregnancy is a common problem, and many women present for assessment at emergency departments (EDs) primarily due to timing, symptomatic urgency, and want of reassurance out of concern that they may have miscarried. It accounts for approximately 500,000 annual visits to the ED in the United States [1, 2], typically preceding the first prenatal visit [3]. In countries such as Canada and the United Kingdom, early pregnancy units have become commonplace for assessing and managing women with bleeding in early pregnancy; however, such units do not operate 24 h a day, not all pregnant women can access them, and they are not universally available [4]. Thus, the ED remains a common entry point for women experiencing bleeding in early pregnancy. In the ED, the management of bleeding in early pregnancy primarily focuses on excluding rare, albeit serious, conditions such as ectopic gestations, assessing fetal viability, and management of symptoms [5–7]. Previous authors have questioned whether abdominopelvic ultrasound can replace a formal pelvic examination, while studies conducted in non-ED settings have described the two diagnostic tools as complementary [8]. Nevertheless, in the ED, the pelvic examination is performed for a number of reasons: to document the vaginal and cervical appearance (e.g., presence/absence of tissue in the cervical os, cervical lesions that would explain the blood loss), the color and quantity of bleeding, and to rule out other serious causes of bleeding. Overall, the goal of the examination is to confirm the history and refine the diagnosis, at the same time as guiding future laboratory testing, imaging, and disposition (e.g., admit, discharge, refer) [9].

The utility of pelvic examination has been debated, with opponents citing the literature and proponents noting several methodological issues calling into question the reliability of the evidence [9, 10]. For example, using a composite calculation to compare 30-day morbidity outcomes in an underpowered equivalence study [11], and suggesting that the actual issue could be provider unease with the procedure, rather than one based on solid evidence [10]. Rosenberg also posits that to discard the pelvic examination, it should be proven to lead to more misleading outcomes than helpful ones [12].

Although the evidence remains inconclusive, preliminary studies reveal that omitting the pelvic examination in the ED has benefits without significant untoward outcomes, especially with the given improvements in diagnostic capacity within the ED setting. Thus, despite providing additional clinical information under specific circumstances, the existing practice of always including pelvic examinations while evaluating women presenting to the ED with bleeding in early pregnancy may no longer be appropriate. Due to conflicting information in the literature, this study aimed to investigate the clinical pattern of care, utility, and contribution of pelvic examination in the ED toward diagnosing and managing bleeding in early pregnancy. To achieve this, factors that determine a change in clinical management following pelvic examination in the ED were explored. Our primary hypothesis was that the findings on pelvic examinations (speculum and bimanual palpation) performed by ED physicians would not significantly alter the clinical decision-making process or the formulation of a care plan for women presenting with bleeding in early pregnancy.

Methods

Study setting and design

This prospective cohort study was conducted at three EDs located in Edmonton, Alberta, *Canada* (urban population ≈ 1 million) which are three of seven high-volume EDs within the region. The study participants were recruited between January 2014 and January 2018. The University of Alberta Hospital (UAH) is a major urban, academic, tertiary care center assessing approximately 67,000 adult patients per year with an admission proportion of 23% and access to ultrasound services; however, it has no obstetric in-patient capacity and no in-house obstetric services. The Royal Alexandra Hospital (RAH) is a mixed adult and pediatric urban hospital assessing approximately 72,000 adult patients per year with in-patient obstetric beds, an obstetric service, and access to ultrasound services. The Northeast Community Health Centre (NECHC) is a mixed adult and pediatric urban emergency department assessing approximately 41,000 patients per year with no in-patient beds, ultrasound services, or obstetric consultants. All sites are staffed with full-time emergency physicians, are teaching sites for emergency medicine and other academic programs, and operate 24 h per day.

Ethical considerations

The study complied with the Declaration of Helsinki (1964) and its later amendments. Written informed consent was obtained from all study participants before enrollment. The study protocol and materials were

approved by the Health Research Ethics Board (HREB; reference ID: Pro00047076) at the University of Alberta in Edmonton, Alberta, *Canada*. Operational and administrative approval was obtained from Alberta Health Services and a data sharing agreement was signed.

Study procedures and definitions

Pregnancy was primarily diagnosed through a combination of clinical assessment, patient history, and quantitative serum beta-human chorionic gonadotropin (β-HCG) levels. We defined *bleeding in early pregnancy* as the occurrence of vaginal bleeding in the first 20 weeks of pregnancy (calculated from the last normal menstrual period). When available, we also incorporated sonographic confirmation for pregnancy dating; specifically, if an ultrasound was performed during the ED visit or had been conducted recently, we used sonographic dating to refine the estimated gestational age (EGA).

For the purposes of this study, pelvic examination was defined as a composite of bimanual palpation and/or speculum examination. The primary outcome of our study was defined as a change in the management plan following the pelvic examination. We defined the change in management based on the ED physician's response to the question: "Did the findings on pelvic examination change your management plan?" comparing their initial assessment to their thoughts after the pelvic examination was performed. Emergency physicians were not asked to record their management approach before and after completing the pelvic examination. These subjective changes included, but were not limited to: a revised diagnosis and management plan (e.g., diagnosing an ectopic pregnancy or incomplete miscarriage that necessitated different clinical actions); decisions to request further diagnostic procedures such as additional imaging (e.g., transvaginal or pelvic ultrasound) or laboratory tests; a decision to refer the patient to an obstetrician for further evaluation and management; a decision to admit the patient to the hospital for observation, treatment, or surgical intervention; and a decision to extend the period of observation within the ED to monitor the patient's condition and response to initial management.

Sample size

No a priori sample size determination was performed. Rather, a convenience sample of women presenting to any of the three EDs with vaginal bleeding at an EGA < 20 weeks was utilized.

Physician/patient recruitment

Emergency physicians at each study site were invited to participate by completing a paper-based form to identify patients who presented with bleeding in early pregnancy. Patients were eligible if they were aged 17 years or older and presented to the ED with proven pregnancy and vaginal bleeding under 20 weeks gestation. We excluded patients who were hemodynamically unstable or experiencing excessive vaginal bleeding (passing large clots and/or soaking at least one pad per hour), non-English speaking women, and patients who did not consent to the study. In some cases, a research assistant identified potentially eligible patients using the Emergency Department Information System (EDIS), who then confirmed the patient's eligibility with the attending physician. A general patient survey was completed by ED physicians and/or a research assistant following written informed consent.

Data collection

Completed screening forms were retrieved by research assistants and the results were entered into REDCap (Vanderbilt University, Nashville, TN, USA), a secure web-based platform, licensed through the Women and Children's Health Research Institute (WCHRI) at the University of Alberta [13]. For each patient successfully enrolled, data were collected from the patient's paper chart and EDIS. Characteristics of interest are shown in Table 1 and included: (1) patients' demographics; (2) ED presentation (e.g., Canadian Triage and Acuity Scale [CTAS] score, mode of arrival, vital signs); (3) ED investigations (e.g., complete blood count, β-HCG levels, ultrasound, blood typing); (4) ED management (e.g., interventions, procedures, and drugs administered); (5) imaging findings; (6) ED length of stay (LOS) (triage to discharge) and time to assessment (triage to physician initial assessment [PIA]); (7) patient disposition and repeat visit to the ED within 30 days of discharge from the ED or discharge from hospital admission; and (8) consultations requested in the ED and post-hospital referrals. All participating EDs utilize CTAS, a five-level acuity assessment scoring system, as follows: CTAS 1 (resuscitation), CTAS 2 (emergent), CTAS 3 (urgent), CTAS 4 (semi-urgent), and CTAS 5 (non-urgent) [14, 15]. Duplicate data extraction was completed on the first 10 charts and reviewed by a clinical research nurse to identify potential disagreements and ensure a unified data collection methodology.

Linkage of administrative data

To validate the existing follow-up data and secure missing data, four population-based linked health administrative databases from Alberta Health Services (AHS) were obtained. All databases are hosted in the AHS Enterprise Data Warehouse. The EDIS dataset captured information on all ED visits in the Edmonton area. Each EDIS record represents a unique service and includes a unique identifier, start and end dates and times, presenting complaints, the number and type of consultation services, and

Table 1 Demographic and clinical characteristics and outcomes of 200 women presenting to three Canadian emergency departments with bleeding in early pregnancy

Variable	Value	Missing data
Age, years; mean (SD)	30.7 (5.7)	-
Age group, years; n (%)		-
≤25	26 (13.0)	
26–30	81 (40.5)	
31–35	50 (25.0)	
36–40	32 (16.0)	
>40	11 (5.5)	
Estimated gestational age, weeks; n (%)		6
4–6	72 (37.1)	
7–10	81 (41.8)	
11–14	29 (15.0)	
15–20	12 (6.2)	
Gravidity, n (%)		8
1–2	115 (59.9)	
3–4	51 (26.6)	
≥5	26 (13.5)	
Parity, n (%)		7
0	90 (46.6)	
1	60 (31.1)	
>1	43 (22.3)	
No. of abortions, median (IQR)	0 (0, 1)	37
History of ectopic gestation, n (%)	5 (2.5)	-
History of bleeding in early pregnancy, n (%)	61 (30.5)	-
History of spontaneous abortions, n (%)	55 (27.5)	-
Fertility treatment for index pregnancy, n (%)	13 (7.8)	34
Duration of vaginal bleeding, days; median (IQR)	1 (0.3, 2.0)	14
Bleeding in clots, n (%)	78 (42.4)	16
Self-reported pain score, median (IQR)	3 (0, 6)	35
Abdominal cramps present, n (%)	105 (52.5)	-
Abdominal discomfort present, n (%)	68 (34.0)	-
CTAS = 3, n (%)	152 (76.8)	2
Time of presentation (afterhours), n (%)	40 (20.9)	9
Hb, mg/mL; mean (SD)	130.7 (9.7)	29
β-HCG testing, n (%)	158 (82.3)	8
β-HCG level, mIU/mL; median (IQR)	10,406 (2576, 27228)	8
β-HCG category, n (%)		-
≤10,000 mIU/mL	75 (47.5)	-
>10,000 mIU/mL	83 (52.5)	-
Diastolic BP, mmHg; mean (SD)	76.1 (11.8)	10
Systolic BP, mmHg; mean (SD)	121.2 (20.9)	10
Hypertension, n (%)	35 (18.4)	10
Pulse, bpm; mean (SD)	87.4 (14.3)	9
Tachycardia, n (%)	37 (19.4)	9
Respiratory rate, cpm; mean (SD)	17.2 (2.1)	12
SpO_2, %; median (IQR)	99 (98, 100)	15
Temperature, °C; mean (SD)	36.6 (0.4)	13
Uterine size discrepancy, n (%)	0 (0.0)	-
Findings on abdominal exam, n (%)		-
Normal	81 (40.5)	
Abnormal	119 (59.5)	
Change in management after pelvic exam, n (%)	120 (72.3)	-
Concordant diagnosis before pelvic exam, n (%)	59 (76.6)	
Concordant diagnosis after pelvic exam, n (%)	65 (84.4)	
Bimanual palpation and/or speculum exam, n (%)	166 (83.0)	
Speculum exam findings, n (%)		-
Normal	17 (13.8)	
Abnormal	106 (86.2)	
Findings on bimanual palpation, n (%)		
Normal	38 (30.9)	-
Adnexal mass	1 (0.8)	-
Adnexal tenderness	9 (7.3)	-
Cervical motion tenderness	1 (0.8)	-
Uterine tenderness	8 (6.5)	-
Bulky uterus	5 (4.1)	-
ED LOS, h; median (IQR)	5 (3, 6)	8
Outcome of pregnancy		8
Live birth	85 (44.3)	
Pregnancy loss	107 (55.7)	

ED, emergency department; CI, confidence interval; LOS, length of stay; SD, standard deviation; IQR, interquartile range; CTAS, Canadian Triage Acuity Scale; Hb, hemoglobin; HCG, human chorionic gonadotropin; SpO2, oxygen saturation; BP, blood pressure; LLQ, left lower quadrant; RLQ, right lower quadrant

admitting services. These data were linked to the study cohort to secure any missing ED data on the factors mentioned above. The provincial laboratory data captured all general laboratory tests performed across the province and was used to identify women who underwent hemoglobin and β-HCG testing within the index early pregnancy visit to the ED for bleeding. The Alberta Perinatal Data captured information on maternal and perinatal data from the provincial delivery records for all deliveries occurring ≥ 20 weeks of gestation. Pregnancy-related outcomes (e.g., live birth, pregnancy loss, or stillbirth) that occurred within 9 months of the index ED visit were searched. Stillbirths were identified using both follow-up and administrative data. Finally, the Provincial Registry captured Alberta residents covered by the Alberta Health Care Insurance Plan. Alberta residents at the time of the ED visit were identified by records in this dataset during the fiscal year of the ED visit.

Statistical methods

The distributions of continuous and discrete data were tested using the Kolmogorov–Smirnov test. Normally distributed data are reported as means and standard deviations (SDs) while skewed variables are reported as medians and interquartile ranges (IQRs). Categorical

variables are reported as frequencies and percentages. To investigate factors associated with a change in management after pelvic examination, we performed univariable binary logistic regression (with the primary outcome being the physician's perceived change in management following pelvic examination) and reported odds ratios (ORs) and 95% confidence intervals (CIs). For β-HCG level, which had a right-skewed distribution, we selected an approximation of the median (10,404.5 mIU/mL) as the cut-off value. In the multivariable logistic regression analysis, we calculated adjusted ORs (aORs) for variables that showed marginal or significant associations (p-value < 0.1) in the univariable analyses. These included the color of bleeding (based on the physician's assessment), presence of abdominal cramping, tachycardia at presentation, right lower quadrant (RLQ) tenderness, and bimanual palpation within the ED. None of the variables included in the logistic regression analyses had more than 10% data missing for the 166 women included. All statistical computations were performed using R version 4.2.2 (The R Development Core Team, Vienna, Austria). Hypothesis tests were two-sided and considered statistically significant at p-value < 0.05.

Results

Patients' clinical and ED characteristics

Overall, 200 unique patients who presented to one of the study EDs with a complaint consistent with bleeding in early pregnancy were included in the study (Fig. 1). Selected patient demographic, clinical, and ED

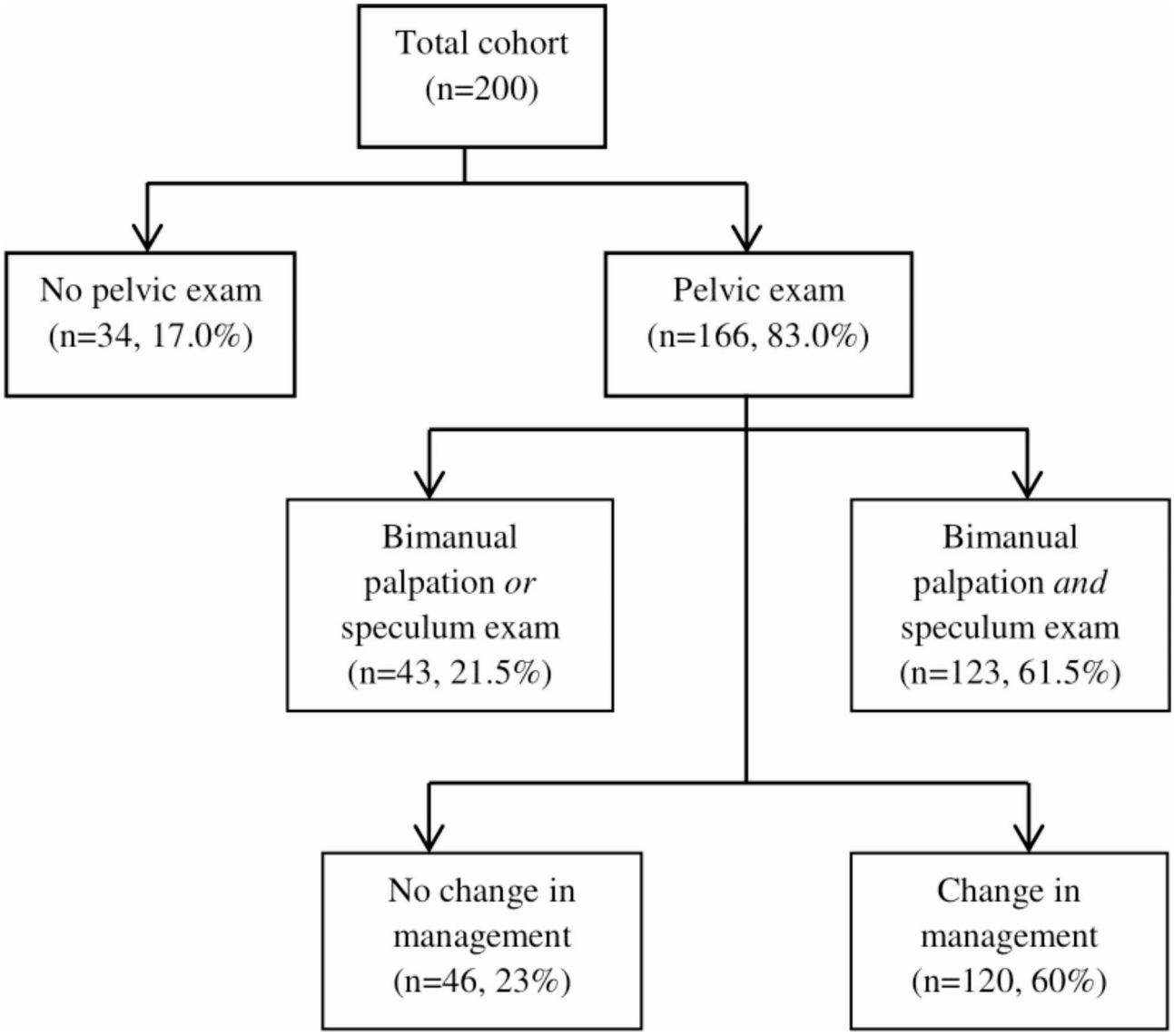

Fig. 1 Flow chart showing variations in the management of 200 women who presented to three Canadian emergency departments with bleeding in early pregnancy

characteristics are shown in Table 1. The mean age at presentation was 30.7 years (SD: 5.7), with a majority of women between 26 and 35 years of age. Most women (79%) presented with an EGA of ≤10 weeks, a median gravidity of 2 (IQR: 1, 3), and a median parity of 1 (IQR: 0, 1). Five (2.5%) women had a history of prior ectopic gestation, 61 (31%) had experienced bleeding in early pregnancy before the index pregnancy, and 55 (28%) had a history of spontaneous miscarriage. Thirteen women (7.8%) had undergone fertility treatment for their current pregnancy.

At presentation, the median duration of bleeding was 1 day (IQR: 0.3, 2.0), with a median pain score of 3 on a verbal analog scale of 0 to 10, and 53% had experienced abdominal cramping accompanying the bleeding episode. The median CTAS score was 3 and 21% presented after-hours. During their ED stay, 83% of women underwent at least one β-HCG measurement. On physical examination, 18% presented with either a systolic BP > 140 mmHg or a diastolic BP > 90 mmHg, and 19% were tachycardic (pulse > 100/min) (included in Table 1). Eighty-one women (41%) showed normal findings on abdominal examination; nearly equal proportions (~12%) showed diffuse tenderness, left lower quadrant tenderness, or RLQ tenderness; and 11 (6%) showed guarding.

Overall, 166 (83%) received a pelvic examination; 123 (62%) women received a speculum examination and 123 (62%) received a bimanual examination. 70% of women subjected to speculum examination in the ED showed bleeding at the cervical os and 14% showed normal findings. Similarly, bimanual palpation revealed normal findings among 31%, adnexal mass/tenderness in 8%, and cervical motion tenderness/uterine tenderness in 7%. At discharge, the median ED LOS was 5 h (IQR: 3, 6). Regarding outcomes, 107/192 (56%) patients with available pregnancy outcome data experienced a miscarriage.

Exploratory analysis of factors associated with a change in management after pelvic examination

The performance of pelvic exam did not significantly differ among facilities with and without ultrasound services (83.2% vs. 81.8%, chi-squared p-value = 0.88). On the other hand, the facility with in-house obstetric services (RAH) performed significantly more pelvic examinations than the other two facilities without (94.7% vs. 76.0%, chi-squared p-value < 0.001). There was no significant difference in the proportions of eventual miscarriage between patients who underwent vs. did not undergo pelvic examination (chi-squared p-value = 0.75). The results of univariate nominal logistic regression analysis seeking factors associated with a change in management after pelvic examination are shown in Table 2. In the multivariable logistic regression analysis, only brown/dark-red bleeding per vaginam (determined by the examining ED physician) was independently associated with a reduced likelihood of a change in management after pelvic examination in the ED (aOR = 0.37; 95% CI: 0.14–0.98). Controlling for other factors (that showed marginal to significant associations in the univariable analyses: presence of abdominal cramps, tachycardia, RLQ tenderness, bimanual palpation, and color of the blood) failed to identify other factors independently associated with a change in management based on pelvic examination findings.

Discussion

This prospective observational cohort study identified and characterized the management of 200 women with vaginal bleeding in early pregnancy at three Canadian EDs and further described factors associated with a change in management after pelvic examination. A large majority of included patients were young and had experienced a very short period of bleeding (~1 day) in their current pregnancy. Practice was variable among the treating clinicians; however, the majority (83%) performed a vaginal examination, 83% obtained serum β-HCG tests, and nearly all patients were referred for follow-up assessment. The decision to perform a bedside ultrasound was left to the discretion of the treating clinician and was documented in 63 (31.5%) women. These patients experienced prolonged ED stays, with some patients lingering for up to 15 h. Overall, their outcomes were poor (more than 50% experienced a miscarriage); however, it is important to recognize that this population is inherently at higher risk for adverse outcomes, given that a majority of spontaneous miscarriages in early pregnancy occur primarily due to chromosomal abnormalities in the embryo, for which no first trimester treatment exists.

Factors initially identified to be associated with a change in management after pelvic examination were: brown/dark-red bleeding per vaginam, tachycardia, RLQ tenderness, and the performance of bimanual examination in the ED. Among these, only brown/dark-red bleeding per vaginam, was independently associated with a change in management. There was no significant difference in the percentage of women receiving pelvic examinations between facilities with ultrasound services and those without; however, physicians practicing at the facility with in-house obstetric services tended to perform more pelvic examinations than those without. Both facility characteristics (the availability of ultrasound services and in-house obstetrics/gynecology services) were also not associated with a change in management following pelvic examination.

Among the 166 (83%) cases where a pelvic examination was completed, a significant majority of ED physicians reported that pelvic examination changed their approach to management (72.3% vs. 27.7%; difference, 44.6%; 95%

Table 2 Exploratory univariable and multivariable logistic regression analyses of factors associated with a change in management after pelvic exam among 166 women presenting to the ED with bleeding in early pregnancy

Variable	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Age, years (continuous)	0.97 (0.91 – 1.03)	0.313	-	-
Age group, years (categorical)				
≤25 (Ref.)	1.00	-	-	-
26–35	1.91 (0.78 – 4.70)	0.157	-	-
≥36	0.79 (0.28 – 2.19)	0.650	-	-
Estimated gestational age, weeks (categorical)				
4–6 (Ref.)	1.00	-	-	-
7–10	1.85 (0.83 – 4.14)	0.133	-	-
11–14	0.64 (0.24 – 1.68)	0.360	-	-
15–20	0.91 (0.21 – 4.01)	0.900	-	-
Gravidity (discrete)	0.89 (0.76 – 1.06)	0.195	-	-
Gravidity (categorical)				
1–2 (Ref.)	1.00	-	-	-
3–4	0.96 (0.43 – 2.15)	0.914	-	-
≥5	0.54 (0.21 – 1.41)	0.209	-	-
Parity (discrete)	0.82 (0.63 – 1.06)	0.133	-	-
No. of abortions (discrete)	1.11 (0.77 – 1.60)	0.574	-	-
Color of bleed				
Pink/bright-red	1.73 (0.89 – 3.47)	0.127		
Brown/dark-red	0.43 (0.22 – 0.87)	0.019	0.37 (0.14 – 0.98)	0.035
History of ectopic gestation	0.37 (0.05 – 2.73)	0.331	-	-
History of bleeding in early pregnancy	1.53 (0.72 – 3.25)	0.274	-	-
History of spontaneous abortions	1.67 (0.75 – 3.71)	0.209	-	-
Fertility treatment for index pregnancy	0.73 (0.21 – 2.57)	0.623	-	-
Duration of vaginal bleeding, days (continuous)	1.00 (0.91 – 1.09)	0.930	-	-
Self-reported pain score (discrete)	0.98 (0.86 – 1.12)	0.761	-	-
Abdominal cramps present	0.55 (0.27 – 1.10)	0.091	0.90 (0.34 – 2.38)	0.828
Abdominal discomfort present	1.94 (0.88 – 4.29)	0.103		
CTAS score (ordinal)				
2	0.28 (0.07 – 1.11)	0.070	-	-
3 (Ref.)	1.00	-	-	-
4	0.92 (0.37 – 2.28)	0.860	-	-
Hb, mg/mL (continuous)	1.02 (0.98 – 1.06)	0.313	-	-
β-HCG testing	1.22 (0.53 – 2.83)	0.642	-	-
β-HCG level, mIU/mL				
≤10,000 (Ref.)	1.00	-	-	-
>10,000	1.20 (0.55 – 2.62)	0.641	-	-
Diastolic BP, mmHg (continuous)	1.01 (0.97 – 1.04)	0.771	-	-
Systolic BP, mmHg (continuous)	1.00 (0.98 – 1.02)	0.711	-	-
Hypertension	0.61 (0.25 – 1.52)	0.291	-	-
Pulse, bpm (continuous)	0.99 (0.96 – 1.01)	0.223	-	-
Tachycardia	0.42 (0.18 – 0.99)	0.047	0.31 (0.09 – 1.14)	0.078
Respiratory rate, cpm (continuous)	1.01 (0.86 – 1.18)	0.922	-	-
SpO_2, % (continuous)	1.19 (0.97 – 1.47)	0.103	-	-
Temperature, °C (continuous)	1.06 (0.44 – 2.55)	0.898	-	-
Findings on abdominal exam, n (%)				
Normal	1.01 (0.51 – 1.99)	0.983	-	-
Rebound tenderness	0.38 (0.02 – 6.18)	0.495	-	-
Diffuse tenderness	0.95 (0.35 – 2.63)	0.925	-	-
LLQ tenderness	0.53 (0.20 – 1.39)	0.196	-	-
RLQ tenderness	0.36 (0.14 – 0.93)	0.034	0.39 (0.10 – 1.52)	0.176
Guarding	0.49 (0.11 – 2.30)	0.369	-	-

Table 2 (continued)

Variable	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Facility characteristics				
USG services available (vs. unavailable)	0.49 (0.13 – 1.77)	0.334	-	-
In-house OBGyn services available (vs. unavailable)	1.23 (0.62 – 2.46)	0.558	-	-
Speculum exam findings				
Normal	2.00 (0.60 – 6.67)	0.259	-	-
Cervical os bleeding	1.05 (0.45 – 2.47)	0.906	-	-
Bimanual palpation performed	0.36 (0.15 – 0.86)	0.022	0.55 (0.21 – 1.44)	0.222
Findings on bimanual palpation				
Normal	0.54 (0.24 – 1.21)	0.137	-	-
Adnexal tenderness	0.43 (0.09 – 2.03)	0.288	-	-
Uterine tenderness	0.80 (0.17 – 3.76)	0.778	-	-
Bulky uterus	0.39 (0.06 – 2.43)	0.311	-	-

ED, emergency department; CI, confidence interval; CTAS, Canadian Triage Acuity Scale; Hb, hemoglobin; HCG, human chorionic gonadotropin; SpO2, oxygen saturation; BP, blood pressure; LLQ, left lower quadrant; RLQ, right lower quadrant; Ref., reference category; OR, odds ratio; aOR, adjusted odds ratio

CI: 33.4–55.7). While cervical motion tenderness and the presence of adnexal masses are important findings on pelvic examination, they have low sensitivity (45% and 10%, respectively) and their subsequent positive likelihood ratios are unhelpful [16].

These findings agreed with a recent randomized controlled trial [17], which failed to meet its goals of enrolling patients with early pregnancy confirmed on ultrasound according to whether pelvic examination was performed during evaluation in the ED. Although the appropriateness of deriving practice-changing conclusions from an underpowered study has been called into question [11], it is worth noting that the researchers found no statistically significant difference in 30-day morbidity when 202 women underwent pelvic examination in the ED [17]. Upholding the aforementioned results would likely be based on the fact that ED ultrasound provides much more quantitative and qualitative information than the pelvic examination, particularly in ruling out ectopic gestation. Among such women, a meta-analysis showed that ultrasound performed by ED physicians led to a pooled sensitivity of 99.3%, a negative predictive value of 99.95%, and a negative likelihood ratio of 0.08, without substantial heterogeneity [18]. Similarly, upon detecting an adnexal mass and no intrauterine pregnancy, the positive likelihood ratio for ectopic gestation exceeded 1.00 while the negative likelihood ratio was 0.12 [16]. In the presence of ultrasound-confirmed intrauterine gestation, pelvic examination has neither been shown to add information to the management of patients with early pregnancy nor does it affect their disposition, even when the pelvic findings are unexpected [19, 20].

For a healthy, hemodynamically stable woman without clinical concern about bleeding in early pregnancy secondary to cervical neoplasia, vaginal trauma, vaginitis, or cervical polyps, some believe conducting a pelvic examination may be invasive, offers little diagnostic benefit, increases health care costs, decreases throughput, and increases the ED LOS [17, 19, 21]. Moreover, from a patient's perspective, women who did not undergo pelvic examination were half as likely to report a feeling of discomfort, compared to those who did, and when given a choice to participate, many (42%) eligible patients refused study enrollment because they preferred not to undergo pelvic examination [17]. Further, point-of-care ultrasonography is currently considered a crucial skill for emergency care providers and is recommended in the ED to improve diagnoses and outcomes [22, 23]. In another prospective cohort study, pelvic examination led to a change in management in only 6% of cases [20]. Determining the definitive impact and safety of omitting the ED pelvic examination when there is bedside ultrasound evidence of an intrauterine pregnancy needs to be assessed for equivalence with performing it to evaluate women with abdominal pain and/or bleeding per vaginam in early pregnancy.

Study limitations

Our study had some methodological limitations. First, this study relied on the support of participating ED physicians to identify patients with bleeding in early pregnancy; however, form completion was not universal and often incomplete. While some patients may have been misidentified as having bleeding in pregnancy, a majority of participating ED physicians had many years of clinical experience, so this risk was likely minimal.

We could not complete the analysis of some outcomes as planned due to poor reporting in the patient's charts or variability in the care provided by clinicians in these three ED settings. A standardized protocol for bleeding in early pregnancy was not in place at any site during this study. The proportion of patients lost to follow-up was high and would have invalidated these findings; however, the use of linked administrative data mitigated this problem (e.g., pregnancy outcomes could be ascertained for 192 of 200 included patients).

ED physicians were not asked to indicate their management approach before and after completing the pelvic examination. Instead, they were asked a general question as to whether the examination changed their management without specifying what changes might have occurred. We also did not record information about how any unexpected findings altered the treatment approach and thus could not ascertain how any such finding would correlate with a change in the management approach.

This study was conducted in Canada, where access to health care is assured by government funding and no copayments exist for ED care. As a result, ED management and disposition strategies used among such patients may not be representative of outcomes in studies conducted in other countries. Also, some social determinants of health (e.g., supports, race, income, housing, employment), behavioral factors (e.g., alcohol consumption, use of cigarettes/vaping, cannabis use, diet), and comorbidities (e.g., body mass index, diabetes mellitus) that may have affected pregnancy outcomes were also not recorded. Finally, the sample size limited the inclusion of molar pregnancy and other rare presentations.

Notwithstanding these limitations, we believe that our findings raise some important questions and contribute to the discourse regarding the routine performance of pelvic examinations in the ED among women with bleeding in early pregnancy. This is one of the first studies to comprehensively assess the management of patients with early pregnancy loss.

Conclusions

This pilot observational cohort study found that women presenting to the ED with bleeding in early pregnancy (EGA < 20 weeks) who were hemodynamically stable undergo variable assessment and approximately 56% suffer a miscarriage. These presentations appear to be an appropriate target for interventions to standardize care, as well as provide support for patients and their families. Moreover, only brown/dark-red bleeding per vaginam, potentially indicative of bleeding resolution, significantly independently influenced the baseline odds of a change in management after pelvic examination. Although our study primarily explores improving ED efficiency, until the debate regarding the utility of speculum/bimanual examination in the ED is resolved, physician preferences, availability of obstetric services, and shared decision making with patients should guide practice regarding speculum and bimanual pelvic examination for the management of bleeding in early pregnancy.

Abbreviations

AHS	Alberta Health Services
aOR	Adjusted Odds Ratio
CI	Confidence Interval
CTAS	Canadian Triage and Acuity Scale
ED	Emergency Department
EDIS	Emergency Department Information System
EGA	Estimated Gestational Age
HCG	Human Chorionic Gonadotropin
IQR	Interquartile Range
LLQ	Left Lower Quadrant
LOS	Length of Stay
NECHC	Northeast Community Health Centre
OR	Odds Ratio
RAH	Royal Alexandra Hospital
RLQ	Right Lower Quadrant
SD	Standard Deviation
UAH	University of Alberta Hospital
WCHRI	Women and Children's Health Research Institute

Acknowledgements

We would like to thank all of the emergency physicians who volunteered to participate in the study at the RAH, NECHC, and UAH Emergency Departments. We would also like to thank Ms. Natalie Runham for her support and assistance with the study.

Author contributions

Conceptualization: S.F. and B.H.R. Data collection: S.F., S.C., E.H.Y., and B.H.R. Data cleaning and formal analysis: N.O.M.E. and E.H.Y. Data interpretation: N.O.M.E., E.H.Y., and B.H.R. Writing-original draft: N.O.M.E., S.F., S.C., E.H.Y., and B.H.R. All the authors have reviewed and approved the manuscript in its current form.

Funding

Dr Rowe's research is supported by a Scientific Director's Grant (SOP 168483) from the Canadian Institutes of Health Research (CIHR) through the Government of Canada (Ottawa, ON). Dr Fisher's research was supported by the NECHC Emergency Medicine Special Purposes Fund. The funding organizations were not involved in any aspect of the conduct, analysis, and manuscript preparation of this study; the funders take no responsibility for the conduct or results of this study.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon request.

Declarations

Ethics approval and consent to participate

The study complied with the Declaration of Helsinki (1964) and its later amendments. Written informed consent was obtained from all study participants before enrollment. The study protocol and materials were approved by the Health Research Ethics Board (HREB; reference ID: Pro00047076) at the University of Alberta in Edmonton, Alberta, Canada. Operational and administrative approval was obtained from Alberta Health Services and a data sharing agreement was signed.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Notation of prior abstract publication/presentation

Partial results from this study were presented at the 2023 Annual Meeting of the Canadian Association of Emergency Physicians (CAEP), Toronto, ON, *Canada*, May 2023.

Author details

[1]Department of Emergency Medicine, Faculty of Medicine & Dentistry, College of Health Sciences, University of Alberta, 1G1.43 WMC, 8440-112 Street NW, Edmonton, AB T6G 2B7, Canada
[2]SPOR SUPPORT Unit, Alberta Health Services (AHS), Edmonton, AB, Canada
[3]School of Public Health, College of Health Sciences, University of Alberta, Edmonton, AB, Canada

Received: 16 May 2024 / Accepted: 22 August 2024
Published online: 03 September 2024

References

1. Evans CS. Early pregnancy loss in the Emergency Department: lessons learned as a spouse, New Father, and Emergency Medicine Resident. Ann Emerg Med. 2021;77(2):233–6.
2. Murtaza UI, Ortmann MJ, Mando-Vandrick J, Lee AS. Management of first-trimester complications in the emergency department. Am J Health Syst Pharm. 2013;70(2):99–111.
3. Miller CA, Roe AH, McAllister A, Meisel ZF, Koelper N, Schreiber CA. Patient experiences with Miscarriage Management in the emergency and ambulatory settings. Obstet Gynecol. 2019;134(6):1285–92.
4. VanArendonk SH, Rockhill K, Stickrath EH, Alston MJ. Evaluation of early pregnancy concerns in an early pregnancy unit compared with an Emergency Department. Obstet Gynecol. 2020;136:995–1000.
5. MacWilliams K, Hughes J, Aston M, Field S, Moffatt FW. Understanding the experience of miscarriage in the Emergency Department. J Emerg Nurs. 2016;42(6):504–12.
6. Hahn SA, Lavonas EJ, Mace SE, Napoli AM, Fesmire FM, American College of Emergency Physicians Clinical Policies Subcommittee on Early Pregnancy. Clinical policy: critical issues in the initial evaluation and management of patients presenting to the emergency department in early pregnancy. Ann Emerg Med. 2012;60(3):381–e9028.
7. Bacidore V, Warren N, Chaput C, Keough VA. A collaborative framework for managing pregnancy loss in the emergency department. J Obstet Gynecol Neonatal Nurs. 2009;38(6):730–8.
8. Hsu WP, Hsiao PC. Correspondence to pelvic examination is unnecessary in pregnant patients with a normal bedside ultrasound. Am J Emerg Med. 2010;28(4):532. author reply 532 – 3.
9. McLean ME, Santiago-Rosado L. Plight of the pelvic exam. Emerg Med J. 2019;36(6):383–4.
10. Radecki R. The End of the Emergency Pelvic Exam – Emergency Medicine Literature of Note. Available online: https://www.emlitofnote.com/?p=4022 (Accessed 26 Apr 2023).
11. Peyton K, Solnick R. What do we learn from an Equivalence Study without Statistical Power? Ann Emerg Med. 2018;72(2):223–4.
12. Rosenberg P. Medical myth: the usefulness of pelvic exam. CJEM. 2004;6(1):9–10.
13. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inf. 2009;42(2):377–81.
14. Ding Y, Park E, Nagarajan M, Grafstein E. Patient prioritization in Emergency Department Triage Systems: an empirical study of the Canadian triage and acuity scale (CTAS). Manuf Serv Oper Manag. 2019;21:723–41.
15. Murray JM. The Canadian triage and acuity scale: a Canadian perspective on emergency department triage. Emerg Med (Fremantle). 2003;15(1):6–10.
16. Crochet JR, Bastian LA, Chireau MV. Does this woman have an ectopic pregnancy? The rational clinical examination systematic review. JAMA. 2013;309(16):1722–9.
17. Linden JA, Grimmnitz B, Hagopian L, Breaud AH, Langlois BK, Nelson KP, et al. Is the pelvic examination still crucial in patients presenting to the Emergency Department with vaginal bleeding or Abdominal Pain when an intrauterine pregnancy is identified on Ultrasonography? A Randomized Controlled Trial. Ann Emerg Med. 2017;70(6):825–34.
18. Stein JC, Wang R, Adler N, Boscardin J, Jacoby VL, Won G, et al. Emergency physician ultrasonography for evaluating patients at risk for ectopic pregnancy: a meta-analysis. Ann Emerg Med. 2010;56(6):674–83.
19. Seymour A, Abebe H, Pavlik D, Sacchetti A. Pelvic examination is unnecessary in pregnant patients with a normal bedside ultrasound. Am J Emerg Med. 2010;28(2):213–6.
20. Brown J, Fleming R, Aristzabel J, Gishta R. Does pelvic exam in the emergency department add useful information? West J Emerg Med. 2011;12(2):208–12.
21. Aronu ME, Okafor CO, Mbachu II, Iloraah US, Ikeako L, Okafor CI. A review of the correlation between clinical diagnosis and ultrasound diagnosis in first trimester vaginal bleeding. Ann Med Health Sci Res. 2018;8:120–4.
22. Tucker P, Evans DD. Are pelvic exams necessary anymore? Adv Emerg Nurs J. 2019;41:282–9.
23. Ultrasound Guidelines. Emergency, point-of-care and clinical Ultrasound guidelines in Medicine. Ann Emerg Med. 2017;69(5):e27–54.

Publisher's note