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ORIGINAL RESEARCH

Vaginal examination does not improve diagnostic accuracy in early pregnancy bleeding

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Abstract

Objective: The study aims to determine if a vaginal examination improves diagnostic accuracy when assessing women who present to the ED with vaginal bleeding in the first trimester of pregnancy.

Methods: One hundred and thirty-five women with first trimester bleeding were randomised to have a vaginal examination ($n = 61$) or not ($n = 74$). They were given a provisional diagnosis, and then a final diagnosis after ultrasound, beta-human chorionic gonadotropin and gynaecological follow up. The provisional diagnosis was considered accurate if it matched the final diagnosis.

Results: The provisional and final diagnoses matched in a little over half of the cases, and there was no statistical difference between the two groups ($\chi^2 = 0.005$, $P = 0.94$).

Conclusion: In a stable patient presenting to the ED with first trimester bleeding, clinical diagnosis is highly inaccurate and is not improved by vaginal examination. Routine vaginal examination is not necessary as part of the initial patient assessment.

Key words: *abortion, diagnosis, first trimester, vaginal examination.*

Introduction

Bleeding in early pregnancy is a common ED presentation, occurring in 20–30% of all pregnancies.[1] Vaginal examination (bimanual and speculum) is traditionally considered an essential part of the diagnostic assessment, thereby directing management and disposition.[2] The examination is however unpleasant and invasive for the patient, time consuming in the ED and its necessity has been called into question when ultrasound is readily available.[3] A review by Isoardi concluded that routine pelvic (vaginal) examination adds little diagnostic information when ultrasound is available, but acknowledged the lack of any controlled studies.[4] This is a prospective randomised controlled trial testing the hypothesis that vaginal examination does not improve diagnostic accuracy in the assessment of a stable patient with first trimester bleeding in the ED.

Methods

Study design and setting

Caboolture Hospital is an outer Metropolitan district facility servicing a lower socioeconomic population, with an annual ED census of 48 000 patients, of broad case mix and relatively high acuity. A sample size of 200 was calculated to detect a 10% difference between the case and control groups in diagnostic accuracy using a χ^2-test; however, because of time constraints, recruitment ceased

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after a convenience sample of 150 women were enrolled over a period of 2 years. Recruitment and examination were performed by junior medical staff, all of whom had been briefed on the trial methodology.

Participants

Women were included if they were aged ≥16 years, and presented to the ED with vaginal bleeding in the first trimester of pregnancy (≤13 weeks). Patients were excluded if they had severe pain (pain score ≥5/10, or administration of opiate analgesia), severe bleeding (bleeding more than her normal period, pulse >100, or systolic blood pressure <90 mmHg), or the cause of the bleeding had already been diagnosed.

Study procedure

Following a routine history and abdominal examination, the women were given a written information sheet, provided written consent and were then randomised to have a vaginal examination (speculum and digital) or not, via a numbered envelope. The treating doctor then filled in a data form including a provisional diagnosis selected from one of the following options:

- Threatened abortion
- Incomplete abortion
- Complete abortion
- Missed abortion
- Ectopic pregnancy
- Other cause of bleeding

All patients had a formal ultrasound examination and quantitative beta-human chorionic gonadotropin within the next 24 h, performed either at the hospital or in a private facility. Follow up was completed by the Hospital Obstetric and Gynaecology (O&G) Department either primarily or following initial general practitioner review. Patient files were later searched and all patients assigned to one of the above diagnostic groups as a final diagnosis, based on the ultrasound result and opinion of the O&G team. The provisional diagnosis was considered to be accurate if it matched the final diagnosis. The study design was approved by the Redcliffe-Caboolture Health Service District Ethics Committee.

Statistical methods

A χ^2-test was used to compare the proportions of accurate diagnoses between per vagina (PV) and non-PV groups. A one-way, χ^2-test was used to test whether the proportion of accurate diagnoses was 0.5 in each group which would be expected by chance alone. Sample size calculations and statistical tests were completed using online calculators (statpages.org).

Results

Out of the 150 women enrolled, 15 had incomplete data, leaving 135 for analysis. The average age was 28 in the vaginal examination group (PV, $n = 61$), and 27 in the group not examined (non-PV, $n = 74$). The average parity was 1.4 and 1.3, respectively. Four patients were admitted for semi-elective dilatation and curettage, the remainder were discharged home from the ED (97%). The distribution of the provisional and final diagnoses is presented in Tables 1 and 2, and the accuracy of the provisional diagnosis in Table 3. The provisional diagnosis was accurate in a little more than half the cases for both the PV and non-PV groups, and diagnostic accuracy was not significantly different between the two groups ($\chi^2 = 0.005$, $P = 0.94$). There were six provisional diagnoses of ectopic pregnancy, none of which was correct, and consequently the four women who did have

Table 1. Distribution of provisional and final diagnoses – PV ($n = 61$)

	Threatened	Incomplete	Complete	Missed	Ectopic	Other
Provisional diagnosis	49	8	1	1	2	0
Final diagnosis	41	2	14	2	2	0

PV, per vagina.

Table 2. Distribution of provisional and final diagnoses – non-PV ($n = 74$)

	Threatened	Incomplete	Complete	Missed	Ectopic	Other
Provisional diagnosis	57	5	6	1	4	1
Final diagnosis	39	13	11	9	2	0

PV, per vagina.

Table 3. Comparison of provisional and final diagnoses

	Diagnoses match	Diagnoses do not match	Total
PV examination	35 (57%)	26 (43%)	61
Non-PV examination	42 (57%)	32 (43%)	74

PV, per vagina.

an ectopic pregnancy (two each in the PV and non-PV groups) were misdiagnosed in the initial assessment.

Discussion

Theoretically, vaginal examination provides diagnostic information regarding inevitable miscarriage, ectopic pregnancy and non-pregnancy-related causes of bleeding, which would influence both the management and disposition of the patient. In this study, diagnostic accuracy was not significantly different to 50%, regardless of whether or not vaginal examination was performed ($\chi^2 = 1.328$ with $P = 0.25$, and $\chi^2 = 1.351$ with $P = 0.30$ for PV and non-PV groups, respectively). This is consistent with Isoardi's review of the literature, whereby physical findings are unreliable for distinguishing a viable pregnancy from an ectopic or non-viable pregnancy,[4] as they are subjective with poor inter-observer agreement. Causes of bleeding unrelated to the pregnancy are rare, and a short delay in the diagnosis of non-pregnancy-related bleeding (until follow up) is unlikely to be clinically significant. Despite the fact that the provisional diagnosis was inaccurate, decisions on the disposition and management were unaffected. Almost all women went home from the ED, and the remainder were safe to be discharged had they elected to have delayed treatment. Decisions on operative or conservative management were dependent on the ultrasound result, and it has been shown that this can be safely delayed until the next day.[5]

Limitations

The sample size is small, with opportunistic selection; however, the distribution of final diagnoses is consistent with estimates in previous studies,[4] suggesting that it is representative of the larger population. The study was not sufficiently powered to detect a statistical difference between the PV and non-PV groups of less than 20%, but an improvement in diagnostic accuracy of 20% or less is unlikely to be clinically relevant, when the baseline accuracy is so low. Physical examinations were performed by junior medical staff, which increases the risk of inaccuracy, but this reflects real-life ED practice in Australia. The natural history of a proportion of patients with a threatened miscarriage is progression to miscarriage over time, such that the provisional diagnosis of threatened miscarriage might have been correct in more cases had an ultrasound been performed at the same time as the clinical assessment in this study. As the majority of the patients had a final diagnosis of threatened miscarriage; however, this would not substantially affect the conclusion that vaginal examination is inaccurate, nor the primary outcome of this study that vaginal examination did not improve that accuracy.

Conclusion

In a stable patient presenting to the ED with first trimester bleeding, clinical diagnosis is highly inaccurate. Vaginal examination does not improve accuracy, and is therefore unlikely to influence the management or disposition of the patient. When ultrasound is readily available, vaginal examination is not necessary as a routine part of the patient assessment.

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Competing interests

None declared.

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