Early pregnancy

The use of power Doppler colour scoring to predict successful expectant management in women with an incomplete miscarriage

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OBJECTIVE: To evaluate whether the use of power Doppler to confirm the presence or absence of blood flow within retained products of conception (RPC) in women with an incomplete miscarriage can predict subsequent successful expectant management.

METHODS: Prospective observational study in the Acute Gynaecology and Early Pregnancy Unit (AGEPU) at Nepean Hospital from November 2006 to February 2009. Incomplete miscarriage was defined by the presence of a measurable focus of hyperechoic material, in three planes, within the endometrial cavity using two-dimensional greyscale transvaginal ultrasound (TVS). Subjective qualitative power Doppler colour scoring (PDCS) of the RPC was performed. The vascularization of the RPC was scored using the colour scoring system of the International Ovarian Tumour Analysis (IOTA) group. PDCS 1 meant absence of vascularity, PDCS 2 represented minimal vascularity, PDCS 3 rather strong vascularity and PDCS 4 very strong vascularity. The correlation between the PDCS and successful expectant management of miscarriage was analysed. The volume of RPC was calculated using the ellipsoid formula and then compared with both the PDCS and the outcome of expectant management. Successful expectant management was defined as the resolution of symptoms and the absence of RPC on follow-up TVS.

RESULTS: A total of 1395 consecutive pregnant women underwent TVS. Of them, 198 women were diagnosed with an incomplete miscarriage; 172 were managed expectantly. Complete data were available on 158 cases. In total 84.8% (134/158) were managed successfully whilst 15.2% (24/158) failed expectant management. Of the total, 89% (121/136) of women with a PDCS 1 had successful expectant management compared with 57.1% (8/14) with PDCS 2 and 62.5% (5/8) with PDCS 3. Comparing absence of flow (PDCS 1) to presence of flow (PDCS 2 or more), the rate of success was significantly higher in the first group (89 versus 60.9%, Fisher’s exact test P = 0.00136). In the prediction of success, the absence of flow showed a sensitivity, specificity, positive predictive value, negative predictive value and positive likelihood ratio of 90.3, 37.5, 89, 40.9% and 1.445 (95% confidence interval: 1.055–1.979), respectively. There was no correlation between the volume of RPC and the PDCS; and there was no relationship between the volume of RPC and the success of expectant management.

CONCLUSIONS: PDCS can predict the likelihood of successful expectant management of incomplete miscarriage. The absence of flow on power Doppler is associated with a significant improvement in the rate of successful expectant management. This new approach may be helpful in quantifying the chances of successful expectant management in those women with an incomplete miscarriage at the primary scan.

Key words: power Doppler colour score / incomplete miscarriage / expectant management

Introduction

Miscarriage is the commonest serious pregnancy complication affecting ~30% of biochemical pregnancies and 11–20% of clinically recognized pregnancies. The diagnosis of miscarriage is made most commonly by transvaginal ultrasound (TVS) assessment. Diagnosis of miscarriage has traditionally been followed by surgical evacuation of retained products of conception (RPC), on the assumption that this reduces the risk of gynaecological infection. However, surgical management is not without its complications—for example, infection,
uterine perforation or bowel damage may arise from dilatation and evacuation (D&E) (Glenc, 1974; Chung et al., 1999). There is strong evidence supporting expectant management as a realistic alternative to surgical evacuation (Ankum et al., 2001). Results from the largest randomized controlled trial, the Miscarriage Treatment Trial (MIST), concluded that the rates of gynaecological infection, whatever the chosen management, were reassuringly low (2–3%) (Trinder et al., 2006).

Incomplete miscarriages seem to be particularly appropriate for expectant management (Ngai et al., 2001; Luise et al., 2002; Bagratee et al., 2004; Trinder et al., 2006). Luise et al. (2002) in their study of outcomes of incomplete miscarriage based on initial ultrasound criteria, concluded that neither the presence of a gestational sac nor the endometrial thickness (ET) were clinically useful indices for predicting the outcome of expectant management. While the majority of women with incomplete miscarriage achieved spontaneous resolution within 14 days, ~10% failed expectant management and needed curettage. More recently, our unit validated the ‘two-week’ rule for the expectant management of miscarriage (Casikar et al., 2010). In that study, women with an incomplete miscarriage were the most appropriate miscarriage group for expectant management with the highest rates of spontaneous resolution at 14 days. In our study, we hypothesize that in an incomplete miscarriage, if there is persistent communication between the residual trophoblast and maternal circulation, these women are more likely to fail expectant management. Power Doppler indirectly confirms the presence or absence of vascularity within the residual trophoblast. To date, there are no published data specifically looking at the association between subjective power Doppler colour scores (PDCS) of RPC and subsequent successful expectant management in women with an incomplete miscarriage. There are also no data evaluating the PDCS and volume of RPC. Therefore, the primary aim of this study was to evaluate whether the use of power Doppler to confirm the presence or absence of blood flow within RPC in women with an incomplete miscarriage can predict subsequent successful expectant management. The secondary aim was to determine whether there was a relationship between the PDCS and the volume of RPC in women with an incomplete miscarriage who choose expectant management.

Materials and Methods

We undertook a prospective observational study of all pregnant women attending the Acute Gynaecology and Early Pregnancy Unit (AGEPU) at Nepean Hospital, Sydney, from November 2006 to February 2009, inclusive. Ethics approval was obtained from the Human Research Ethics Committee (HREC). All women, irrespective of the presence or absence of symptoms, who presented to the AGEPU, underwent TVS of the pelvis using a 7.5 MHz transvaginal probe (LOGIQ-e-I, General Electric Healthcare, UK or Medison X8, Samsung Medison, Seoul, South Korea). The ultrasound scans were carried out by clinicians with experience of more than 3000 TVS scan examinations. The diagnosis of miscarriage was ultrasound based and defined according to the guidelines published by the Royal College of Obstetricians and Gynaecologists, UK (RCOG, 2006). Each woman’s miscarriage was classified as complete, incomplete, missed or an empty sac according to these guidelines. In particular, the diagnosis of incomplete miscarriage was defined by the presence of a measurable focus of hyperechoic material within the endometrial cavity using two-dimensional (2D) greyscale TVS (Figs 1–3). We did not use a specific endometrial cut-off to define this. In this study, we included only those women diagnosed with incomplete miscarriage as discussed above. All these women had previously confirmed intrauterine pregnancies. It was essential to not miss the diagnosis of pregnancy of unknown location. Women with missed miscarriage and empty sac miscarriage were excluded.

Expectant management meant that a ‘wait and watch’ approach was adopted. Those women who chose expectant management were scanned on a weekly basis for 2 weeks. Women who had persistent RPC on TVS at 14 days were deemed to have failed expectant management and advised to have surgery. Complete resolution of the miscarriage was defined as resolution of symptoms, i.e. vaginal bleeding, and the absence of RPC on follow-up TVS. We chose a finite 2-week period for expectant management based on our recent publication in which we validated the ‘2 week rule’ for the expectant management of miscarriage. This practical approach to the expectant management of miscarriage has been recently published (Casikar et al., 2010). Those women keen to continue expectant management, despite advice for surgical intervention at Day 14,
were again re-scanned at the end of the third week, i.e. Day 21. Those women who opted to continue expectant management for more than 2 weeks were excluded from the study. Women undergoing expectant management could change their mind at any time and opt for surgery. If they choose to discontinue expectant management at any stage, they were excluded from the study. If at any time during expectant management follow-up, the woman developed fever, chills, offensive vaginal loss, then expectant management was ceased and surgery was arranged that day. Surgery involved D&E under general anaesthesia.

Inclusion criteria for the study were three-fold—diagnosis of incomplete miscarriage, haemodynamic stability and absence of infection. The diagnosis of incomplete miscarriage as previously defined using TVS. Eligibility for expectant management required women to be clinically stable (without severe vaginal haemorrhage or haemodynamic instability) and with no signs of infection (temperature >38°C, tachycardia, offensive vaginal loss ± lower abdominal tenderness) at the primary scan. Women who satisfied the above criteria were given a choice of expectant or surgical management. Only those women who chose expectant management were included in this study. Women who declined expectant management or satisfied the exclusion criteria were placed on the emergency list for day surgery, and were treated in the standard way, i.e. (D&E) by experienced operators.

There were multiple sources of referral to the AGEPU—via the Emergency Department or from the local General Practitioners. The reasons for referral were therefore varied. These included the presence or absence of vaginal bleeding with or without clots and/or lower abdominal pain. Demographic, historical, clinical and ultrasonographic variables were recorded at the first visit. These included: maternal age, parity, number of previous deliveries, number of previous caesarean sections, number of previous miscarriages, number of previous termination of pregnancies, gestational age at presentation (determined by last menstrual period if known). The number of days to complete the miscarriage spontaneously was also recorded. The clinical variable included was the ‘Verbal Analogue Score’ (VAS), which was determined by asking the woman if she had abdominal pain to score it from 0 to 100.

Ultrasonographic variables included ET (measured in the mid-sagittal plane) and the three measurements of the RPC (antero-posterior (Radius 1), longitudinal (Radius 2) and transverse (Radius 3) measurements in millimetres (mm)). The volume of the RPC was calculated using the ellipsoid formula \( \frac{4}{3} \times \pi \times \text{Radius 1} \times \text{Radius 2} \times \text{Radius 3} \) and this was recorded in mm\(^3\). All eligible women with an incomplete miscarriage had the RPC evaluated using power Doppler ultrasound at their first presentation and ultrasound scan in the AGEPU. The average time between the onset of symptoms and assumed miscarriage and the first examination by ultrasound was <48 h. The power Doppler box included all the trophoblastic tissue within the endometrium. Magnification and settings were adjusted to ensure maximal sensitivity for blood flow (ultrasound frequency at least 5.0 MHz, pulse repetition frequency 0.3–0.9 kHz, wall filter 30–50 Hz); power Doppler gain was reduced until all colour artefacts disappeared. We assigned subjective vascularity scores of the retained tissue at the primary TVS. This power Doppler colour score (PDCS) ranged from 1 to 4. The PDCS is based on the colour Doppler scoring system adopted by the International Ovarian Tumour Analysis (IOTA) group. The IOTA scoring system is a subjective scoring system used in women with both benign and malignant ovarian masses (Timmerman et al., 2000). Whilst the IOTA study used this scoring system to describe the amount of blood flow within the solid components of the ovarian mass, we applied the same principle to the RPC within the endometrial cavity. A PDCS of 1 was given when no blood flow was found within the RPC (Fig. 1), a PDCS of 2 was given when only minimal flow could be detected (\( \times \) Fig. 2), a PDCS of 3 was given when rather strong flow was detected (Fig. 3) and a PDCS of 4 was given when the flow within the RPC appeared highly vascular with very strong blood flow. This PDCS (for the entire amount of RPC) was assigned only once at the time of the primary TVS. Doppler examination was not performed on subsequent TVS during the period of expectant management. This colour score only refers to the colour Doppler image and not to the Doppler shift spectrum. A subjective qualitative assessment of flow within the RPC was made.

The primary aim of this study was to evaluate the relationship between the PDCS and success rates for expectant management of incomplete miscarriage. Firstly, we compared the success of expectant management in all four PDCS groups individually, i.e. PDCS 1 versus PDCS 2 versus PDCS 3 versus PDCS 4. Secondly, we compared the success of expectant management to the absence of flow on power Doppler (PDCS 1) versus the presence of flow on power Doppler (PDCSs 2–4). The secondary aim of this study was to evaluate the relationship between the volume of RPC and both the PDCS as well as the outcome of expectant management.

Statistical analysis

Comparisons of descriptive statistics (for continuous variables) were made between those women who had successful expectant management and failure of expectant management. Comparisons of descriptive statistics (for continuous variables) were made between those women who had a PDCS equal to 1 and a PDCS ≥ 2. Comparisons of descriptive statistics (for continuous variables) were made between those women who were symptomatic and asymptomatic. ANOVA tests were used to determine if the differences between these groups were significant. \( P \)-values <0.05 were an indication of the presence of a significant association between the variables within the patient groups.

Comparisons of the discrete variables were made between those women who had successful expectant management and failure of expectant management. Comparisons of descriptive statistics (for continuous variables) were made between those women who had a PDCS equal to 1 and a PDCS ≥ 2. Comparisons of descriptive statistics (for continuous variables) were made between those women who were symptomatic and asymptomatic. ANOVA tests were used to determine if the differences between these groups were significant. \( P \)-values <0.05 were an indication of the presence of a significant association between the variables within the patient groups.

Comparisons of the discrete variables were made between those women who had successful expectant management and failure of expectant management. The rate of successful expectant management was expressed as a percentage. The \( P \)-values for the association between the binary feature variables and the rate of successful expectant management were calculated using the \( \chi^2 \) test. \( P \)-values <0.05 indicated a significant relationship between the binary feature variable and the expectant management success rate.

Box plots were generated to ascertain if there was a relationship between the three measurements of the RPC (antero-posterior, longitudinal and transverse measurements in mm) and the different PDCSs. Box plots were also generated to see if there was a relationship between the

**Figure 3** Incomplete miscarriage: power Doppler score 3 (rather strong flow).
volume of RPC and the different PDCSs. Spearman rank correlation tests were used to determine if the correlation between the RPC indices and PDCS were significant. P-values of < 0.05 represented statistical significance.

**Results**

A total of 1395 consecutive pregnant women presented to the AGEPU during the study period. These women were of < 13 weeks gestation based on last menstrual period. Of the total, 14.2% (198/1395) were diagnosed with an incomplete miscarriage at the first scan; 39.9% (79/198) of these women were nulliparous; 87% (172/198) of the women chose to be managed expectantly. We had complete data for analysis (PDCS and final outcome of expectant management) in 91.2% (158/172) of these women. Overall, 85 (134/158) achieved successful expectant management and 15% (24/158) failed expectant management after 2 weeks.

Table I shows the descriptive statistics for the women in the study. Table II compares the descriptive statistics between the groups of successful expectant management and failure of expectant management. The mean PDCS in women who had successful expectant management was significantly lower than in those women who failed expectant management (PDCS 1.13 versus 1.50, P = 0.0010) (Table II). There was no significant difference between the volumes of RPC in those women who had successful expectant management compared with those who failed expectant management (P = 0.0667) (Table II). There was also no significant difference between the ET in those women who had successful expectant management compared with those who failed expectant management (Table II). There were no significant differences in descriptive statistics between the women with absent blood flow within the RPC (PDCS = 1) and those where blood flow was present within the RPC (PDCS ≥ 2) (Supplementary data, Table SI) nor between symptomatic and asymptomatic women (Supplementary data, Table SI).

Table III compares the discrete variables between the groups of successful expectant management and failure of expectant management. The rate of successful expectant management in women who had vaginal bleeding (with or without clots) was significantly higher than in those women who did not have vaginal bleeding (87.3 versus 62.5%, P = 0.0241). The rate of successful expectant management in women who had PDCS ≥ 2 was significantly lower than in those women whose PDCS was ≤ 1 (59.1 versus 89.0%, P = 0.0010) (Table III).

Of the total, 86% (136/158) had a PDCS of 1, 8.9% (14/158) had a PDCS of 2 and 5.1% (8/158) had a PDCS of 3 (Table IV). We did not have any women with a PDCS of 4 during the study period. The rates of successful expectant management were 89% (121/136) in women with a PDCS 1, 57.1% (8/14) with a PDCS 2 and 62.5% (5/8) with a PDCS 3 (Table IV).

When comparing the pooled data for absence of blood flow on power Doppler (i.e. PDCS 1) with the presence of blood flow (i.e. PDCS 2 or more), the rate of successful expectant management was significantly higher in the first group (89 versus 60.9%, Fisher’s exact test P = 0.00136) (Table V).

In the prediction of successful expectant management, the absence of vascularity within the RPC demonstrated a sensitivity of 90.3, specificity of 37.5%, positive predictive value of 89%, negative predictive value of 40.9% and positive likelihood ratio of 1.445 (95% confidence interval: 1.055–1.979).

There was neither a relationship between the PDCSs and volume of RPC nor was there a relationship between the PDCSs and the three measurements of the RPC (anterio-posterior, longitudinal and transverse measurements in mm) (P = 0.39) (Fig. 4).

<table>
<thead>
<tr>
<th>Table I Descriptive statistics for continuous variables for the women in the study.</th>
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<tbody>
<tr>
<td>Minimum</td>
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</tr>
<tr>
<td>Age</td>
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<tr>
<td>Parity</td>
</tr>
<tr>
<td>NVD</td>
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<td>LSCS</td>
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<td>Miscarriages</td>
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<tr>
<td>TOPs</td>
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<tr>
<td>Gestation</td>
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<tr>
<td>VAS</td>
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<tr>
<td>ET_mm</td>
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<tr>
<td>RPC_vol (mm³)</td>
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<tr>
<td>log(RPC_vol)</td>
</tr>
<tr>
<td>RPC_mm1</td>
</tr>
<tr>
<td>RPC_mm2</td>
</tr>
<tr>
<td>RPC_mm3</td>
</tr>
<tr>
<td>ColourDoppler</td>
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<tr>
<td>Days_complete_misc</td>
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</tbody>
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NVD, normal vaginal delivery; LSCS, lower segment caesarean section; TOP, termination of pregnancy; VAS, visual analogue pain scale; ET, endometrial thickness; RPC, retained products of conception.
Discussion

This is the first study to prospectively confirm that PDCS can predict the likelihood of successful expectant management in women with an incomplete miscarriage. Our hypothesis was that in an incomplete miscarriage, if there is persistent communication between the residual trophoblast and maternal circulation, then those women are more likely to fail expectant management. We used power Doppler to confirm indirectly the presence or absence of vascularity within the residual trophoblast. Indeed, the absence of communication between the trophoblast and maternal circulation, as measured qualitatively by a PDCS 1, correlated with the highest rate of spontaneous resolution of incomplete miscarriage. Women diagnosed with an incomplete miscarriage using 2D greyscale alone are known to have high rates of spontaneous resolution. In our unit, using 2D greyscale imaging alone, 71% of women with an incomplete miscarriage who choose expectant management will complete their miscarriage within 2 weeks (Casikar et al., 2010). The addition of PDCS at the initial presentation, which can be easily ascertained at the primary TVS, enables appropriate selection of those incomplete miscarriages that are more likely to resolve spontaneously. In particular, the absence of vascularity (PDCS 1) equates to an
89% success rate at 2 weeks. Conversely, the presence of vascularity (PDCSs 2 and 3) equates to lower rates of success (60.9%). We believe that the use of PDCS enables the clinician to appropriately counsel women, at the primary TVS, with regard to their chances of success or failure with expectant management.

We have demonstrated that the PDCS is useful in selecting women with incomplete miscarriage that will be most likely to resolve spontaneously. We believe that this study enables the clinician to counsel women appropriately regarding their chances of success or failure if they choose expectant management. Clinically stable women will always have a choice of treatment irrespective of the PDCS scores at the initial scan. Conversely, women with PDCSs 2 and 3 have a cumulative failure rate of 40%. On the basis of the results of our study, we feel that it is appropriate to counsel these women with vascularized RPC so that they can make an informed decision whether to proceed with expectant management or go straight to D&E. Therefore, on the basis of our results, we would recommend that these women be discouraged from attempting expectant management.

We also have clearly demonstrated that there was no relationship between the PDCS and volume of RPC (Fig. 4). There was also no relationship between the volume of RPC and success and failure of expectant management (Table II). There was also no relationship between the volume of RPC and symptomatology (Supplementary data, Table SII). To the best of our knowledge, there have been no previously published studies specifically investigating the relationship between power Doppler and volume of RPC in women undergoing expectant management of incomplete miscarriage.

To date, whilst colour Doppler has been used to study inter-villous blood flow and its relationship to successful expectant management, no study has looked specifically at power Doppler and incomplete miscarriage rates. Other studies have used power Doppler to confirm the presence of RPC after miscarriage or delivery (Alcazar and Ortiz, 2002; Ben-Ami et al., 2005; Van den Bosch et al., 2008). Alcazar and Ortiz (2002) used colour Doppler to diagnose RPC in women who had spontaneous first-trimester miscarriage. They scanned clinically stable and asymptomatic women with spontaneous first-trimester miscarriage. Eighteen women suspected of having RPC on Doppler ultrasonography underwent curettage. Of these, 16 women were confirmed to have RPC on histopathology. The clinical significance of scanning, diagnosing RPC and curetting clinically asymptomatic women is not clear. They concluded that transvaginal colour Doppler ultrasonography is useful to detect or to rule out the presence of retained trophoblastic tissue after first-trimester spontaneous abortion and to select patients for expectant management.

### Table V Absence of flow versus presence of flow at PDCS assessment and the success of expectant management.

<table>
<thead>
<tr>
<th>PDCS</th>
<th>Expectant management success</th>
<th>Expectant management failure</th>
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<tbody>
<tr>
<td>1 (no flow)</td>
<td>121 (89.0)%</td>
<td>15 (11.0)%</td>
</tr>
<tr>
<td>2–4 (flow present)</td>
<td>13 (60.9)%</td>
<td>9 (39.1)%</td>
</tr>
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Number (%): women.

*Fisher’s exact test $P = 0.00136$.  

### Figure 4 Box and whisker plots to show the different measures of retained products of conception (RPC) at different values of the power Doppler colour score (PDCS). Spearman rank correlation tests show that there is no correlation between the PDCS and the retained products of conception (RPC) volume ($P = 0.39$).
Unlike in our study, they have not, however, used Doppler findings to predict successful expectant management of incomplete miscarriage.

Van den Bosch et al. (2008) have demonstrated that colour Doppler examination is clinically useful to confirm or exclude residual trophoblastic tissue. In most cases, they found retained tissue in clinically symptomatic women. In other words, they have used power Doppler to confirm what they would have suspected clinically. Although they have then managed their women with RPC expectantly, again, they have not correlated colour Doppler findings with the likelihood of successful expectant management (Van den Bosch et al., 2008).

Ben-Ami et al. (2005) demonstrated that the combination of both clinical and ultrasonographic evaluation is recommended before curettage to reduce the rate of unnecessary invasive procedures. While they reiterate the need for both physical and ultrasonographic evaluation to avoid unnecessary curettage, they have not used a power Doppler to qualitatively assess the RPC; nor have they correlated these findings to expectant management, which is the basis of our study (Ben-Ami et al., 2005).

A criticism of our PDCS colour scoring system is that it has not been validated in early pregnancy. Reproducibility data evaluating inter- and intra-observer variation of this subjective vascular scoring technique have not been published in either pregnant or non-pregnant populations. We acknowledge this fact and would suggest allocating PDCSs that reflect the absence or presence of vascularity in women with an incomplete miscarriage who are eligible for expectant management. In other words, rather than giving a specific PDCS from 1 to 4, we advocate a scoring system of PDCS 1 versus PDCSs 2–4. Qualitatively commenting on the absence or presence of blood flow using power Doppler (Table V) is a more simple scoring system that is more likely to be adopted clinically.

Conclusions

The absence of blood flow in residual trophoblastic tissue on power Doppler is associated with a significant improvement in successful expectant management of incomplete miscarriage. Using the subjective PDCS to qualitatively comment on the absence or presence of blood flow in RPC is a simple technique that can be adopted clinically. This new approach may be potentially helpful in quantifying the chances of successful expectant management in those women with an incomplete miscarriage at the primary scan who are eligible for expectant management. Ultimately, this information is useful while counselling patients regarding their success with different alternatives of management of incomplete miscarriage.

Supplementary data

Supplementary data are available at http://humrep.oxfordjournals.org/.

Authors’ roles

I.C. and G.C. were responsible for conception and design of the study, contributed towards the acquisition, analysis and interpretation of data, and participated in drafting and revising the article. C.L., J.O., T.B. and D.A. were responsible for the conception and design of the study, and contributed towards the acquisition, analysis and interpretation of data.

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Conflict of interest

None declared.

References


