Surgical treatment versus expectant care in the management of incomplete miscarriage: a randomised controlled trial

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(Index words: incomplete miscarriage, expectant care)

Abstract

Objectives To determine whether expectant care of incomplete miscarriages can significantly reduce the need for surgical evacuation of retained products of conception (ERPC) without increasing complications.

Methods A randomized controlled trial conducted at the University Unit, Teaching Hospital Mahamodara, Galle. Consecutive women with uncomplicated incomplete miscarriages at <14 weeks period of amenorrhoea (POA), admitted from 01 January to 15 July 2009 with retained products of conception (RPC) measuring 15-50 mm in the anteroposterior (AP) diameter on transvaginal sonography (TVS) were randomised to ERPC under general anaesthesia (n=80) and expectant care (n=80) groups. Both groups were reviewed after one week clinically and with TVS. The expectant care group was reviewed weekly up to four weeks unless complete expulsion of RPC was confirmed earlier.

Results Age, parity, POA, socio-economic status, distance of residence from the hospital and the AP diameter of RPC at recruitment were similar in both groups. In the expectant care group, complete expulsion of RPC occurred within one week in 69%, and three patients needed ERPC. One patient in the ERPC group required a repeat ERPC. The durations of abdominal pain and the days off normal work were similar in both groups. The expectant care group had a longer duration of vaginal bleeding ($p < 0.01$) than the ERPC group. Complications were rare and similar in both groups and not of clinical significance.

Conclusion Expectant care in the management of uncomplicated first trimester incomplete miscarriage is safe and effective with no significant short-term complications.

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Introduction

Incomplete miscarriage is diagnosed in the presence of abdominal pain, uterine bleeding with the passage of retained products of conception (RPC) after a period of amenorrhoea (POA) and with an open cervical internal OS on examination. It is confirmed by transvaginal sonography (TVS), which shows heterogeneous tissue measuring more than 15 mm in the anteroposterior (AP) diameter, with or without a gestational sac [1]. Traditionally incomplete miscarriage at <14 weeks POA has been treated by surgical evacuation of the retained products of conception (ERPC) due to the possible increased risk of infection and haemorrhage. ERPC may rarely be associated with serious complications like anaesthetic complications, infections, formation of uterine synechae, Ashermann's syndrome, cervical injuries, severe haemorrhage and uterine perforations which may even lead to bladder or bowel damage [1-3]. Manual Vacuum Aspiration and medical management are also effective in the management of incomplete miscarriage [6-9]. Considering the requirement of operation theater facilities, clinical expertise, hospital stay and costs, expectant management is more cost effective, and has gained popularity recently [1-4].

The risk of infection and haemorrhage is low with spontaneous miscarriage even if no treatment is given, and is a justification for expectant care which involves watchful waiting for spontaneous expulsion of RPC usually up to 4 to 6 weeks after onset of bleeding. The risk of upper genital tract infection is low if no uterine instrumentation is carried out, while uterine evacuation is associated with a significantly higher risk of infection [1, 5]. Therefore in areas where unsafe abortions are common and the risk of pelvic infection is high, expectant care cannot be recommended [5,6]. Over the last few decades expectant care has been advocated to minimise unnecessary surgical interventions while maintaining low morbidity and mortality and is considered suitable for women with no maternal anaemia and RPC which has an AP diameter of 15 mm-50 mm on TVS [1-4, 6-10]. The success rate of expectant care is reported to vary from 25 -100% [7].

Improved access to early pregnancy assessment units and greater awareness among women has led to an increasing demand for more conservative management of incomplete miscarriage, and up to 70% of women may prefer expectant care if given the choice [1,8,9]. Patient preferences for expectant or surgical management have also been found to be largely affected by the attending

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specialist's recommendation [1,4,6,8]. Encouraging women to choose the management modality according to their own preference could have the best health related quality of life [7,8]. Patient satisfaction rates of 90% with family physician care and 84.6% with hospital care have been reported [6,10]. Expectant care could be continued as long as the woman is willing and provided there is no infection and it has been associated with lower infection rates compared to ERPC [1,6,8,9,11]. ERPC would be indicated if the AP diameter of RPC is more than 50 mm on TVS, bleeding is excessive or infected tissue is present in the uterine cavity [1,4,11]. Due to lack of a clear superiority of either management, women's preference should play a key role in the decision making and further research is being continued on this topic [1,3,8,9,10].

In Sri Lanka, most women with incomplete miscarriage have a routine ERPC as most patients, doctors and other medical staff are not aware or have a poor knowledge of expectant care. In two recent studies carried out in the North Colombo Teaching Hospital and Sri Jayewardenepura Teaching Hospital, expectant care was found to be a safe and effective alternative to ERPC [12,13].

The current study was designed to determine whether expectant care is feasible and acceptable in women attending a Teaching Hospital in southern Sri Lanka, and whether it could significantly reduce the need for ERPC in women with uncomplicated spontaneous incomplete miscarriage without increasing any adverse effects.

Methods

Before commencing the study, information leaflets were distributed and all the staff in the unit were educated regarding expectant care. It was stressed that a patient in the expectant care group could have an ERPC at any time if she requested it and could come to the hospital at any time in an emergency. Approval was obtained from the Ethical Review Committee of the Faculty of Medicine, Galle. The trial was registered in the Clinical Trials Register, Sri Lanka (SLCTR/2008/011).

Currently, ERPC is routinely carried out in all women (100%) with incomplete miscarriage. The sample size required to detect a 30% reduction in the need for ERPC in the expectant care group with a power of 80% and precision of 0.1, was calculated to be 72 in each group, using the standard formula [14]. Expecting a dropout or cross over rate of 10 - 15%, it was decided to recruit 160 patients for the study.

Consecutive women with uncomplicated spontaneous incomplete miscarriage presenting within three days of bleeding and <14 weeks POA, admitted from 01 January to 15 July 2009 to the University Unit of Teaching Hospital, Mahamodara, Galle, were recruited for the study. Women who had RPC within an open cervical canal had the RPC removed digitally or with a sponge forceps under strict aseptic condition. A TVS was then carried out and patients who had RPC less than 15 mm in the AP diameter were considered to have complete miscarriages, and were reassured and discharged home. Patients who had RPC more than 50 mm in the AP diameter were offered ERPC due to the potential high risk of infection and haemorrhage if managed expectantly.

Women who refused randomisation because of strong preference for either form of management, those who had significant vaginal bleeding, pain or fever, those with evidence or suspicion of induced abortion, those who had any other medical conditions which necessitated early ERPC and those who had a history of cervical OS incompetence were excluded from the study.

Sequentially numbered sealed opaque envelopes with a card mentioning the study arm were prepared earlier by the second author. After TVS, uncomplicated patients (n=160) who fulfilled the criteria (RPC between 15-50 mm in AP diameter) were randomised to two groups by block randomisation.

Women allocated to the ERPC group had ERPC and blunt curettage of endometrial cavity under general anaesthesia within 24 hours of ultrasound evaluation and discharged home after an overnight stay following ERPC. Women allocated to the expectant care group were discharged home after an overnight stay. Prophylactic antibiotics were not given. Both groups were reviewed after one week clinically and with TVS. The expectant care group was re-assessed in the same manner as outpatients, weekly up to four weeks unless complete expulsion of RPC was confirmed earlier. If RPC with an AP diameter of more than 15 mm was detected at four weeks, they had an ERPC. If at any time a patient in the expectant care group required or requested an ERPC, it was carried out.

At the end of four weeks, the women were assessed for complications and their acceptance of the management modality that they received. Any complications developing in patients of either group were managed according to the routine clinical practice in the ward.

Data collected and stored in an ongoing computer software database included age, parity, POA, educational level, monthly family income, distance of residence from the hospital, amount and duration of bleeding, duration of abdominal pain, time off normal work, evidence of infection and patient satisfaction. Strict confidentiality was maintained.

Baseline characteristics of the two groups were compared using the means of these continuous variables and the student t test. The percentage reduction of requirement of ERPC rate in the expectant care group and the other secondary outcomes which were percentages or categorical data were analysed using the Chi square test. The continuous variables, eg. number of days with pain or bleeding and number of days off normal work between the two groups were found to be skewed, and therefore were compared using the Mann-Whitney U test.

Statistical analyses were carried out using the computer software SPSS 11 (SPSS Inc., Chicago, IL, USA). A p value of <0.05 was considered to be statistically significant. Success of treatment, complications and duration of symptoms were analyzed according to the intention to treat principle.

Results

There were no significant differences in age, POA, proportion of primigravidae, level of education, monthly family income, distance from hospital or the AP diameter of RPC between the two study groups (Table 1). The vast majority of the women were housewives, having a monthly family income of Rs. 10,000 - 25,000/=, and living more than 10 killometers away from the hospital.

Of the 160 participants, 62 (39%) had RPC of 15-25 mm in AP diameter and had a POA of 8-11 weeks. Only 7 (4%) had RPC of 36-50 mm in AP diameter (Table 2). Four patients in the expectant care group and six patients in the ERPC group did not come for review at the end of the first week. They were contacted via telephone and none of them had complications and all had stopped bleeding. Therefore it was assumed that all of them had had complete spontaneous expulsion of RPC.

In the expectant care group spontaneous expulsion of RPC occurred in 55 (69%) patients in one week, and 67 (84%) patients after two weeks, and one patient needed ERPC after four weeks. One patient underwent emergency ERPC due to significant haemorrhage and needed one unit of blood transfusion and another requested and had an ERPC soon after recruitment. Therefore the reduction in the need for an ERPC in the expectant care group was 96.6%. In the ERPC group one patient needed repeat ERPC after one week, due to an incomplete primary procedure (Table 3).

The rate of intrauterine infection was low and there were no significant differences between the two groups. Two women in the ERPC group had suspected uterine perforations and were managed conservatively with no serious adverse effects. Two others who underwent ERPC had headache and nausea related to anaesthesia and therefore were not satisfied with the treatment they received. Two patients in the expectant care group were also not satisfied with the treatment they received because of the increased time taken for their management (Table 3).

Table 1. Baseline characteristics of the study population (n=160)

	Expectant care (n=80)	*ERPC (n=80)*	*p*
Age – years:			
mean (95% CI)	29.0 (27.7 - 30.3)	28.9 (27.7 - 30.1)	NS
range	19 - 45	18 - 43	
Period of amenorrhoea – weeks:	9.2 (8.7 - 9.7)	8.9 (8.4 - 9.4)	NS
mean (95% CI)	5 - 13	6 - 13	
range			
Primigravidae (%)	52 (64.6)	49 (61.2)	NS
Level of education:			
primary (%)	9 (10.9)	8 (10.0)	
secondary (%)	66 (81.7)	67 (83.7)	NS
tertiary (%)	5 (6.3)	5 (6.3)	
Monthly family income – rupees:			
<10,000	10 (13.4)	9 (11.3)	
10,000 - 25,000	61 (77.5)	64 (80.0)	NS
>25,000	9 (10.9)	7 (8.8)	
Distance from hospital – km			
<10	17 (21.9)	15 (18.8)	
10 - 30	50 (62.2)	51 (63.7)	NS
>30	13 (15.9)	14 (17.5)	
Maximum AP diameter of RPC – mm			
mean (95% CI)	23.4 (22.2 - 24.6)	23.8 (22.5 - 25.1)	NS
range	16 - 44	16 - 43	

ERPC = evacuation of retained products of conception
95% CI = 95% confidence interval AP = antero-posterior NS = not significant

Table 2. Relationship of antero posterior diameter of retained products of conception to period of amenorrhoea (n=160)

POA in weeks / *AP diameter of RPC (mm)*	*5 - 7 (n=45)*	*8 -11 (n=91)*	*12 - 14 (n=24)*
15 - 25	31 (19.4%)	62 (38.8%)	19 (11.9%)
26 - 35	13 (8.1%)	25 (15.6%)	3 (1.9%)
36 - 50	1 (0.6%)	4 (2.5%)	2 (1.2%)

POA = period of amenorrhoea

RPC = retained products of conception

AP = antero-posterior

Table 3. Main outcomes (n=160)

	Expectant care (n=80)	*ERPC (n=80)*	*p*
RPC Expelled:			
≤ 1 week	55 (69%)	79 (98.8%)	<0.001
≤ 2 weeks	67 (84%)	80 (100%)	<0.001
≤ 4 weeks	77 (96.6%)	80 (100%)	NS
Required ERPC	3	1	NS
Infection	2	3	NS
Uterine perforation	0	2	NS
Needed blood transfusion	1	0	NS
Headache and nausea	0	2	NS
Satisfied with management	78 (97.5%)	78 (97.5%)	NS

RPC = retained products of conception

NS = not significant

ERPC = evacuation of RPC

The durations of abdominal pain and the time off normal duty were similar in both groups. The expectant care group had a longer duration of vaginal bleeding (p<0.01) than the ERPC group.

Discussion

The majority of patients were between 8 - 11 weeks of gestation and almost 40% of them had 15 - 25 mm AP diameter of RPC on TVS. Since only three women needed ERPC in the expectant care group, expectant care can be considered to be feasible and effective and with no major adverse sequelae. Duration of pain and days off work in the patients in the two groups were not significantly different. Even though the expectant care group had an increased duration of vaginal bleeding than the ERPC group, the bleeding was mild and did not significantly affect their normal life styles. However, in the Sri Jayewardenepura study, women in the ERPC group reported longer durations of days off from their day to day activities, and complained of greater intensity of pain which lasted longer [12]. These aspects were not reported in the North Colombo study [13].

In comparison with the current study, greater proportions of women had spontaneous expulsion of ERPC within two weeks in the North Colombo study. However, in the latter study there was a greater proportion of multigravidae and the mean quantity of RPC in the women also appeared to be less. These may be the reasons for this difference. Although ERPC was required in 16% of women who underwent expectant care in the Sri Jayewardenepura study the requirement of ERPC in the women who underwent expectant care was much less in the current study (3.8%) and the North Colombo study (5.6%) (Table 5).

In the current study, complications like infection and haemorrhage were rare and there were no significant differences between the groups. Although there were two suspected uterine perforations in the ERPC group, they had no serious adverse outcomes. Routine assessment of anaemia could not be carried out due to poor patient compliance. Only one patient who was in the expectant care group needed blood transfusion and no other patients in the study had clinical features of anaemia.

While 17% of women in the current study lived more than 30 killometers away from the Hospital, 76% of women of the Sri Jayewardenepura study lived within five kilometers of the hospital. Furthermore women in the Sri Jayewadenepura study were more educated and had a higher monthly family income compared to the women in the current study.

Since the current study and studies carried out in North Colombo and Sri Jayewardenepura have been carried out in three different regions of Sri Lanka, expectant care appears to be a good alternative for ERPC in the management of properly selected women with uncomplicated spontaneous incomplete miscarriage of <14 weeks POA in Sri Lanka. However, analyses of long term complications such as chronic pelvic pain, intrauterine adhesions or infertility need to be studied.

Table 4. Secondary outcomes (n=160)

	Expectant care (n=80)	*ERPC (n=80)*	*p*
Number of days with pain:			
median (IQR)	1 (1)	1 (1)	
range	0 - 8	0 - 6	NS
Number of days with bleeding:			
median (IQR)	3 (2)	1 (1)	<0.01
range	1 - 12	1 - 7	
Number of days off work:			
median (IQR)	1 (1)	2 (2)	
range	1 - 7	1 - 8	NS

ERPC = evacuation of retained products of conception
NS = not significant
IQR = inter quartile range

Table 5. Comparison of outcomes

	Current study		*North Colombo study*		*Sri Jayewardenepura study*	
	Expectant care (n=80)	*ERPC (n=80)*	*Expectant care (n=71)*	*ERPC (n=69)*	*Expectant care (n=85)*	*ERPC (n=99)*
Required ERPC	3	1	4	3	14	0
Satisfied with management	78 (97.5%)	78 (97.5%)	Not known	Not known	76 (89.4%)	78 (78.8%)

ERPC = evacuation of retained products of conception

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A qualitative study on patients' perceptions of expectant management of first trimester incomplete miscarriage

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(Index words: incomplete miscarriage, qualitative research, expectant management)

Abstract

Introduction Efficacy and safety of expectant management of first trimester miscarriage are well known, though the patients' perceptions and attitudes are less clear. This study was designed to understand the women's perception of symptoms, acceptability, fertility wishes and care received.

Methods A qualitative study among 25 women who were allocated to the expectant management arm of a randomised control trial, which compared expectant versus surgical management of incomplete miscarriage, was carried out. Interviews were recorded at the end of two weeks from the initial diagnosis based on five themes, which were transcribed and analysed.

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