Safety and effectiveness of manual vacuum aspiration compared to conventional curettage in first trimester miscarriages in Sri Lanka: A randomized controlled trial

E Ethayarooban[a], G Senthilnathan[a], V J Meegoda[b]

Abstract

Introduction: First-trimester miscarriage is a leading cause of hospital admissions in the developing world. Blind surgical evacuation of the uterus for the management of first trimester miscarriage using either suction evacuation or conventional curettage is challenging as the surgeon has to decide the completeness of the procedure based on subjective perception. Manual vacuum aspiration has emerged as a better alternative, that is being increasingly used, but no direct comparison of outcome between the methods has been made.

Methods: A randomized control trial was conducted among 136 patients presented to gynaecology ward at De Soysa Maternity Hospital with a first trimester miscarriage. Previously prepared sequentially numbered opaque sealed envelopes technique was applied for randomization. Data were analysed by using SPSS software and T-test was used in statistical comparison.

Results: Total study sample consisted of 136 participants. Age of the participants ranged from 18 years to 43 years (Mean 28.8:SD5.9). When patients who underwent conventional curettage were compared with patients managed with manual vacuum aspiration, there was a significant reduction of mean time duration (t=12.305), mean volume of blood loss (t=3.91) and the duration of hospital stay (t=5.03) among the vacuum aspirated patients. When the post aspiration pain score was considered, a significantly higher pain score (t=11.95) was reported among vacuum aspirated participants.

Conclusions: Manual vacuum aspiration technique can be utilized in place of conventional curettage with adequate pain relief for first trimester miscarriage management.

Keywords: manual vacuum aspiration, conventional curettage, miscarriage

Introduction

It is estimated that approximately 10-20% of pregnancies end in miscarriage, with the majority occurring within the first trimester[1]. First-trimester miscarriage ranks as the second most frequent cause of hospital admissions across many developing nations[1,2,17]. Presenting symptoms of miscarriage often include abdominal pain and vaginal bleeding, sometimes

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[a] *De Soysa Hospital for Women, Colombo, Sri Lanka.*
[b] *Postgraduate Institute of Medicine, University of Colombo, Sri Lanka.*

Correspondence: EE, e-mail: roobanethayan@gmail.com

https://orcid.org/0009-0008-5858-6741

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accompanied by the passing of clots or tissue. However, some cases may be asymptomatic[3]. Diagnosis typically involves clinical examination and ultrasound imaging[4]. Effective management aims to enhance safety and efficacy and evacuation of retained products of conception representing the primary treatment approach[1,5]. Options for managing first-trimester miscarriage include expectant management, medical interventions, and surgical procedures[2,5,6]. Despite advancements in healthcare, the clinical management of miscarriages has seen little change over the years, with a notable proportion of women still undergoing surgical evacuation[7].

Numerous studies conducted in developed countries indicate that surgical intervention is employed in over 80% of cases to manage first-trimester miscarriages[2,8]. Surgical evacuation is often considered the gold standard method due to its high predictive accuracy and success rate, which approaches 100%[3]. In developing countries, conventional curettage serves as the traditional method for surgically evacuating retained products. However, this approach has become obsolete in developed nations. Conventional curettage entails the use of a rigid metal curette to gently scrape the products and endometrial lining in an operating theatre under general or spinal anaesthesia following adequate dilatation of the cervix[5,8]. It's commonly performed as a blind procedure due to lack of ultrasound facilities within the theatre. Performing this procedure requires well-trained personnel, and even with skilled intervention, complications such as haemorrhage, incomplete evacuation, and perforation can still occur[5,8,9].

Previous researchers in this field have recommended manual vacuum aspiration as the optimal surgical method for managing first-trimester miscarriage[6,7,8,9]. Manual vacuum aspiration can be performed using either a manual or an electric vacuum aspirator under local anaesthesia (para cervical block) or with analgesics[9]. Manual vacuum aspiration is safer and more cost-effective than other surgical methods, boasting a success rate of 95-100%. Studies have demonstrated that this technique minimizes the risk of uterine damage, the need for re-evacuation, blood transfusion requirements, cervical trauma, and pelvic infection. In contrast, these complications are more common with conventional curettage. On the other hand, manual vacuum aspiration can help reduce healthcare costs without compromising the quality of care provided to patients[10].

Despite being simple, inexpensive, and easy to handle, its use has been limited because many clinicians are not familiar with the procedure. In developing countries, including Sri Lanka, conventional curettage is the preferred method for managing first-trimester missed miscarriages and incomplete miscarriages.

The main goal of this study is to evaluate the ability of manual vacuum aspiration to prevent post-operative short-term complications and reduce the duration of hospital stays, particularly in settings with limited resources. The primary hypothesis is that manual vacuum aspiration will be a safer and more effective procedure than conventional curettage, making it suitable for resource-limited environments.

Methodology

This randomized controlled trial compared the safety and effectiveness of manual vacuum aspiration versus conventional curettage in managing first-trimester missed or incomplete miscarriages. The study was conducted at De Soysa Maternity Hospital, Colombo, among patients meeting specified criteria, confirmed via ultrasound by a consultant gynaecologist.

Expectant and medical management were offered to all patients with an explanation of their pros and cons prior to recruiting them to the two arms of the study. Those who agreed for either medical or expectant management were excluded from the study. A convenient sampling technique was used, once participants provided informed written consent, they were assigned to treatment groups via sequentially numbered, opaque, sealed envelopes. The patients were blinded to the type of treatment they were receiving (manual vacuum aspirations vs conventional curettage). The principal investigator was not involved in patient management, which was undertaken by a trained postgraduate obstetrics and gynaecology trainee.

Conventional curettage involved surgical evacuation with a metal curette under general anaesthesia, while suction evacuation was performed as an outpatient procedure using a manual vacuum aspirator under analgesia without anaesthesia. Procedural details, including duration, blood loss, and complications, were meticulously recorded. Histological confirmation of retained products of conception, post-procedural monitoring for vaginal bleeding, and six-hour follow-up assessments of haemoglobin levels and procedural

completeness via ultrasound were conducted for all participants. No cervical ripening agents were used.

The primary outcome was hospital stay duration, with secondary outcomes including estimated blood loss, need for blood transfusion or repeat evacuation, post-operative pain, cervical trauma, and procedure duration. Data were analysed using SPSS (version 23.0), employing student's t-test for means, Chi-square test for proportions, and a p-value threshold of <0.05 for significance. Ethical approval was obtained from the Faculty of Medicine, University of Colombo, and the trial was registered with the Sri Lanka Clinical Trials Registry.

Results

Study sample consisted of 136 study participants and 68 were allocated for each arm. Mean age of the population was 28.8 +/- 5.89 and ranged from 18-43 years. Demographic and pregnancy related data of the two groups are depicted in Table 1.

Mean hospital stay of the vacuum aspirated patients (14.56 h) was statistically significant in comparison to the conventional curettage group (33.0h) (t - 5.03, p<0.001). Prolonged hospitalization (>24h post procedure) was noted among 14% (n=19) of the patients, out of which 68.4% (n=13) belonged to the conventional curettage group. The three reasons for prolonged hospitalization in order includes, need for repeated evacuation (68.9%) followed by persistent per-vaginal bleeding (30.4%) and 2% due to suspected perforation. Both cases of perforations were seen in the conventional curettage patients.

There was a statistically significant reduction of estimated blood loss and reduced surgical duration with manual vacuum aspiration in comparison to conventional curettage, but the pain scores were relatively higher among the manual vacuum aspiration group. Three patients in the curettage group had estimated blood loss of more than 500 ml, with none in the manual vacuum aspiration group. Please refer Table 2 for details.

Table 1. Basic demographic data of the two groups

Variable	Manual vacuum aspiration group (n=68)	Conventional Curettage group (n=68)
Age (years)		
<18	4 (5.9%)	7 (10.3%)
18-35	51 (75.0%)	47 (69.1%)
>35	13 (19.1%)	11 (16.2%)
POA		
<10 weeks	22 (32.4%)	25 (36.8%)
10 weeks	14 (20.6%)	13 (19.1%)
11 weeks	18 (26.5%)	13 (19.1%)
12 weeks	14 (20.6%)	15 (22.1%)
>12 weeks	01 (1.4%)	02 (2.9%)
Educational level		
No schooling	02 (2.9%)	1 (1.4%)
Up to Ordinary Level	46 (67.6%)	43 (63.2%)
Up to Advanced Level	14 (20.6%)	19 (27.9%)
Graduated	6 (10.3%)	5 (7.4%)

(Continued)

Variable	Manual vacuum aspiration group (n=68)	Conventional Curettage group (n=68)
Gravidity		
1	17 (29.3%)	20 (29.4%)
2	23 (33.8%)	19 (27.9%)
3	16 (23.5%)	17 (25.0%)
4	8 (11.7%)	7 (10.3%)
5 or more	4 (57.1%)	4 (3.9%)
Pregnancy planning		
Planned	31 (45.6%)	34 (50.0%)
Unplanned	37 (54.4%)	34 (50.0%)
BMI		
<18	5 (7.4%)	2 (2.9%)
18.1-23.0	31 (45.6%)	23 (33.8%)
23.1	32 (47.1%)	43 (63.2%)

Table 2. Comparison of outcomes

Variable	Manual vacuum aspiration group (Mean)	Conventional curettage group (Mean)	SD	Range	t value	P value
Primary outcome						
Duration of Hospital stay	14.56	33.0	23.19	6-96 h	5.03	<0.001
Secondary outcomes						
Estimated Blood loss (ml)	32.5	85.7	83.4	10-700	3.91	<0.001
Surgical duration (min)	10.45	17.75	5.02	5-25	12.25	<0.001
Pain score	3.77	2.20	1.09	2-6	11.95	<0.001

Table 3. Correlation between study variables

	r value / Odd's ratio	p value
Duration of surgery and blood loss	0.273	0.001
Age and pain score	0.137	0.110
Duration of surgery and pain score	-0.440	0.014
BMI and blood loss	-0.026	0.766
BMI and pain	0.094	0.274

Completeness of the procedure was measured by the 6 week follow up ultrasound scan and subsequent need for repeated evacuation. 91.6% of patients who underwent manual vacuum aspiration had a complete evacuation in comparison to 82.4% of the conventional curettage group (Z-2.05 P<0.05), which was statistically significant. Cervical laceration with oozing a complication of uterine evacuation was higher among the conventional curettage group (n=8, 11.8%) in comparison to the manual vacuum aspiration group (n=4, 5.9%). A statistically significant positive correlation was noted between the duration of the evacuation procedure and blood loss (r=0.273, p=0.001) and a negative correlation between the duration of surgery and perceived pain (r=0.44, p=0.014). No significant correlation was found between age with perceived pain and body mass index (BMI) with blood loss or pain.

Discussion

This study aimed to assess the safety and efficacy of manual vacuum aspiration for evacuating retained products of conception following first-trimester miscarriages in comparison to the currently popular method of conventional curettage. While uterine curettage is commonly utilized for this purpose in many developing countries, it poses risks of medical and surgical complications, including infection and perioperative blood loss. This study stands as the first comparison of the two methods within the Sri Lankan context.

The post-procedure hospital stay, was significantly less (mean 14.56 vs 33.0 h, t=5.03, p<0.001) in the manual vacuum aspiration group. A study from Pakistan in 2011[5] revealed a much lesser mean post-operative stay of 3.5 hours and the differences could be attributed to the logistics and regulations of the Sri Lankan government hospitals. As direct comparison with the curettage patients who underwent general anaesthesia was done, manual vacuum aspiration patients were also kept in the ward until the curettage patients regained consciousness. This may have also contributed to the longer hospital stay. Another contribution for prolonged hospital stay was the need of repeated evacuation which was higher among the curettage group (17.5% vs 8.4%). Rohana et al[10] in 2016 reported a much lower need for repeated evacuation, which was only 1.4%. Manual vacuum aspiration is a surgeon dependent procedure and the fact that most of the procedures in this study were carried out by post-graduate trainees in comparison to Senior Obstetrician and Gynaecologists may have contributed to the higher repeat evacuation rate, which was still less than conventional curettage. Shorter hospital stay contributes to less health expenses, which is vital to Sri Lanka given the free healthcare service it provides despite the economic constraints. Manual vacuum aspiration is performed as an out-patient procedure in other countries, which may be hugely impactful from an economic perspective.

Perioperative blood loss was significantly less in manual vacuum aspiration (32.5ml vs 85.7ml, t =3.91, p<0.001), which was compatible with most studies done in western countries comparing the two methods[3,4,9]. Manual vacuum aspiration is recommended even for a patient having severe anaemia or

suffered significant bleeding due to incomplete miscarriage. This also reduced the use of post or peri operative blood transfusion, the costs and complications associated with it.

When comparing the duration of the procedures, vacuum aspiration requires much less time (10.45 vs 17.75 mins. t=12.25, p<0.001). This is directly contributed by the need of general anaesthesia for curettage, which amounts to a considerable time period. Spending less time on a procedure makes more economical sense and frees up operating theatres and personal to attend to other procedures and patients. Vacuum aspiration also mitigates the need of general anaesthesia, the complications and costs associated with it.

However, post-operative pain emerged as a noteworthy drawback specifically associated with manual vacuum aspiration. Mean pain score which was assessed using a Likert scale was significantly (t=11.95, p<0.001) higher among the manual vacuum aspiration patients who were given local anaesthesia and analgesics (3.77) in comparison to the conventional curettage group (2.20), who were under general anaesthesia. Suitable alternative for pain relief during manual vacuum aspiration include paracervical block as recommended by Sunil et al[32] in a 2014 Indian study, combined analgesia rather than a single agent as reported by Natalia et al in a 2015 Nigerian study[19] and the use of specially designed needles for paracervical block with cervical priming as suggested by Farooq et al in a 2011 Pakistani study[4].

Post-operative complications were higher among the curettage group in comparison to manual vacuum aspiration group, but none of these differences reached statistical significance. These include cervical laceration (11.7% vs 5.8%, Z-1.2, p=0.2284), need for post-procedure blood transfusions (4.4% vs none in the vacuum group) and uterine perforation (2.94 vs none in the vacuum group). Similar reduction in complication rate was noted in other studies conducted throughout the world[1,4,10].

As evident by above findings, manual vacuum aspiration is more suitable procedure in many aspects for first trimester miscarriages than conventional curettage which is currently common in Sri Lanka. The lower usage of manual vacuum aspiration can possibly be attributed to the unfamiliarity and lack of training of the procedure in comparison to curettage which is a widely used procedure for many years with less performer technical demand.

The study included patients only from a single unit and hospital, which is a leading tertiary care centre of the country. A larger sample with more heterogeneity within the sample would provide better external validity to the study. Randomization was the only factor used to minimize bias in the trial due to time, logistic and economic constraints. As general anaesthesia was used in the curettage group, all patients of both groups were kept in the ward for at least 6 hours, the minimum time needed to regain consciousness, and this hampered the analysis of the possibility of performing manual vacuum aspiration as an out-patient procedure. Long-term follow up was not arranged to assess the complications of the procedures, even though all patients were advised to reach hospital if there are any problems.

Conclusions

Manual vacuum aspiration presents itself as a viable alternative to conventional curettage due to its demonstrated superior outcomes, reduced complications, and shorter hospital stays. Nonetheless, optimizing pain relief remains imperative for its broader adoption. The lower usage of manual vacuum aspiration is possibly due to the unfamiliarity and lack of training of the procedure but proper training and guidance can replace curettage as a more patient-friendly alternative.

Author contributions

Ethayarooban E – Principal Investigator, Data collection and analysis, writing of manuscript

Senthilnathan G – Supervisor

Meegoda V– Data analysis, writing of manuscript

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Conflicts of interest

No conflicts of interest to be declared.

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