

# Expectant Versus Surgical Management of First Trimester Miscarriage regarding to Change in Packed Cell Volume and White Blood Cell Count

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**Abstract:** ***Introduction:** The aim of this study is to compare the efficacy and safety of expectant management with surgical management of first trimester miscarriage. **Methods:** This randomized prospective study was conducted in the gynecology department at Prince Ali Bin Al-Hussein hospital, Jordan between February 2016 and April 2017. A total of 234 women were recruited following diagnosis of first trimester incomplete or missed miscarriage and randomised into two groups: 109 women were randomised to expectant management (group I), and 125 women to surgical management (group II). All women were examined clinically and sonographically during the follow-up appointments at weekly intervals for up to four weeks as appropriate. The outcome measures were: efficacy, short term complications and duration of vaginal bleeding and pain. **Results:** Of 234 eligible women, 17 were lost to follow-up, and the remaining 217 women were analysed. The base line characteristics were similar in both groups. The total success rate at four weeks was lower for expectant than for surgical management (81.4% vs 95.7%;  $P=0.0029$ ). The type of miscarriage was a significant factor affecting the success rate. For missed miscarriage, the success rates for expectant versus surgical management were (75%) and (93.8%) respectively. For women with incomplete miscarriage, the rates were (90.5%) and (98%). No differences were found in the number of emergency curettages between the two study groups. The duration of bleeding was significantly more in the expectant than the surgical management (mean 11 days vs 7 days;  $P<0.0001$ ). The duration of pain was also more in the expectant than the surgical group (mean 8.1 days vs 5.5 days;  $P<0.0001$ ). The total complication rates were similar in both groups (expectant 5.9% vs surgical group 6.1%;  $P=0.2479$ ). However, the pelvic infection was significantly lower in the expectant than the surgical group (1.9% vs 3.5% respectively;  $P=0.0146$ ). **Conclusion:** Expectant management of clinically stable women with first trimester miscarriage is safe and effective and avoids the need for surgery and the subsequent risk of anaesthesia in about 81.4% of cases, and has lower pelvic infection rate than surgical curettage.*

**Keywords:** Expectant management, miscarriage, surgical curettage.

## 1. Introduction

Spontaneous miscarriage is the most common complication of early pregnancy. It occurs in 10-20% of clinically recognized pregnancies, with 80% of these occurring within the first trimester, and about 25% of women will have at least one miscarriage during their reproductive life (1, 2).

Uterine curettage was traditionally and still commonly performed unless evidence of complete miscarriage is present. Surgical evacuation of the retained products of conception (ERPC) is occasionally associated with many side effects like: anaesthetic complications, infection, uterine perforation, bowel injury and Asherman's syndrome. The re-evacuation rate of the uterus following surgical management of incomplete miscarriage varies between 1.1% and 2.1% (3), and the complication rate of the surgical method is about 6.6% (4). It also constitutes a large proportion of gynecological surgical workload.

With the advent of transvaginal scanning, alternative lines of management have been introduced. Prostaglandins and other medical treatment, as well as expectant management aim to avoid surgical evacuation of the uterus. Expectant management usually results in complete evacuation of the products of conception as spontaneous resolution after miscarriage occurs in 79% of cases (5). It is easy, effective, safe, cost effective and preferred by many treated women.

The aim of this study is to compare the short term outcome of expectant with surgical management of first trimester miscarriage.

## 2. Methods

This was a prospective randomised controlled study conducted at Prince Ali Bin Al-Hussein hospital, Jordan. The study was approved by the Ethical Committee of the Royal Medical Services in Jordan.

Between February 2016 and April 2017, a total of 329 women were referred to the gynecology clinics for assessment because of first trimester vaginal bleeding. In the consultation, a gynecologist and a nurse were present. After detailed history and clinical examination, a transvaginal ultrasound was performed by an experienced gynecologist. The uterus was examined to detect the presence or absence of a gestational sac and other retained products of conception. The endometrial thickness was measured in the sagittal plain across the widest part of the cavity. The miscarriages were classified as complete, incomplete, missed or anembryonic (blighted ovum) according to the Royal College of Obstetrician and Gynecologists guidelines (6). The last two classifications were confirmed by a repeat scan a few days later. Anembryonic miscarriage (blighted ovum) defined as an intact gestational sac of greater than 20 mm without internal structures; missed miscarriage defined as a fetus with a crown-rump length of more than 6 mm with no heart activity on transvaginal scan. Incomplete miscarriage defined

as areas of mixed echogenicity within the uterine cavity with or without a disordered gestational sac (6).

The entry criteria for the study were: women with missed miscarriage including blighted ovum and women with incomplete miscarriage, who were in good health aged 16 years or older, gestational age of  $\leq 13$  weeks, with anterior-posterior diameter of retained products ranging between 15-50 mm, bleeding not excessive with normal packed cell volume, haemodynamically stable and not febrile.

Women with complete miscarriage were excluded from the study and were asked to return to clinic or emergency department if they developed any worrying signs or symptoms.

The eligible women who fulfilled the entry criteria and consented to the study were assigned randomly to one of the two management methods: Group I (n=109) expectant management and group II (n=125) surgical management. Randomisation was done by a computer generated list of random numbers.

Women in the surgical management group were scheduled for surgical uterine evacuation under general anaesthesia within a week after inclusion in the study. Retained products of conception were sent for histopathology in all cases.

Expectant management group were informed that they might have some bleeding and pain and they were recommended to use Paracetamol tablets (Non-proprietary) for the pain. If the woman experienced heavy bleeding, or severe pain or developed an offensive smelling vaginal discharge, she was advised to return to the hospital for surgical uterine evacuation.

In both groups, blood samples were taken for complete blood count at inclusion and after four weeks.

Prophylactic antibiotics were not given, and Anti-D immunoglobulin was given to rhesus-negative women according to the hospital protocol. The women were given contact telephone numbers to obtain advice if they need it.

All women were examined clinically and sonographically during the follow-up appointments at weekly intervals for up to four weeks as appropriate. If retained products of conception with anterior-posterior diameter above 15mm were present, surgical uterine evacuation was done.

The outcome measures were the efficacy, short term complications and duration of vaginal bleeding and pain.

Successful expectant management was considered if spontaneous complete evacuation of the uterus (complete miscarriage) had occurred within four weeks of inclusion. Surgical method was successful if the curettage was performed without the need for further repeat curettage within four weeks. Emergency curettage is the need to do an unscheduled curettage due to severe vaginal bleeding or pain. Short term complications were: pelvic infection, excessive vaginal bleeding and uterine perforation. Pelvic infection defined as two or more of pyrexia  $>38^{\circ}\text{C}$ , purulent

vaginal discharge, uterine tenderness and white blood cell count  $> (15 \times 10^9 / \text{L})$  (7).

The two study groups were statistically compared using Student's t-test or Fisher's exact test.  $P < 0.05$  was considered to be statistically significant.

STATISTICA version 9 (StatSoft. Inc, Tulsa, USA) was used for the statistical analysis.

### 3. Results

Among 234 participants in the study, seventeen women were lost to follow-up: seven women from the expectant group and ten women from the surgical group, and the remaining 217 women were analysed.

Expectant management (n=102), of whom 42(41.2%) incomplete miscarriage and 60(58.8%) missed miscarriage and blighted ovum.

And a surgical group (n=115), of whom 51(44.3%) incomplete and 64(55.7%) missed and blighted ovum.

The patients' characteristics are shown in table I. There were no significant differences between the two randomised groups. Of the 102 women allocated to expectant management, 83 (81.4%) women had a spontaneous loss of the uterine contents within 4 weeks. The other 19(18.6%) had surgical uterine evacuation (ERPC): 8 due to retained products of conception with a diameter of more than 15 mm four weeks after inclusion, 5(4.9%) women had emergency ERPC due to severe vaginal bleeding and/or pain (two of them had blood transfusion), and 6 women had the procedure upon their own request due to mild persistent vaginal bleeding.

In the surgical evacuation group 110 women (95.7%) had a successful evacuation of the uterus. 6(5.2%) women had emergency ERPC before the time of scheduled surgery due to severe vaginal bleeding and/or pain (one of them required blood transfusion). 5 (4.3%) women had a second curettage due to incomplete evacuation of the products of conception during the first procedure.

The success rate was lower in group I than group II (81.4% vs 95.7%;  $P=0.0029$ ), and it was more in incomplete miscarriage (90.5% vs 98% for group I and group II respectively) than missed miscarriage and blighted ovum (75% vs 93.8%), as shown in table III.

No differences were found in the rate of emergency curettage (4.9% vs 5.2% for group I and group II respectively;  $P=0.1744$ ), as well as the rate of second curettage (3.9% vs 4.3% respectively;  $P=0.0975$ ). (Table II)

There were significant differences between the two groups with respect to the mean duration of bleeding, which was more in the expectant group ( 11 and 7 days for group I and group II, respectively;  $P<0.0001$  ) but this did not affect the packed cell volume (PCV) ( -1.65 and -1.52, respectively;  $P=0.7899$ ).

The mean duration of pain was more in the expectant group (8.1 and 5.5 days, respectively;  $P < 0.0001$ ) and they received more analgesia (25% and 14% respectively;  $P = 0.6711$ ).

The total complications rate was similar in both groups (5.9% and 6.1%, respectively;  $P = 0.2479$ ), but the incidence of pelvic infection was significantly lower in women managed expectantly; 2(1.9%) women in group I and 4(3.5%) women in group II were diagnosed and treated for pelvic infection ( $P = 0.0146$ ).

One (0.9%) case of uterine perforation occurred in the surgical group.

#### 4. Discussion

The results of this study showed that expectant management is an effective way for the management of women following a first trimester miscarriage, and it is a practical alternative to surgical uterine evacuation. However, many women prefer the surgical method than to wait for an unspecified period for a miscarriage to be completed.

In this study the success rate of expectant management was lower than surgical management (81.4% vs 95.7%) which is similar to other previously reported randomised trials by Louise et al (8) and Nielsen et al (5), but less than a study by Jurkovic et al (9) which showed a success rate of 99% for both expectant and surgical management. And also significantly higher than other randomised study by Ngai et al (10) which showed a success rate of only 48%.

Many studies compared expectant with surgical management of first trimester miscarriage also showed wide variation in efficacy (25-100%) (11, 12).

This variation in the success rate might be due to many factors like the type of miscarriage, duration of follow up and whether ultrasound or clinical examination was used for assessment of women during their follow-up appointments. A meta-analysis by Graziosi et al (11) showed that the type of miscarriage was a significant factor affecting the success rate with an expectant management. For missed miscarriage, the success rates for expectant versus surgical were 28% and 81% respectively. For incomplete miscarriage the rates were 94% and 99%. In the present study the success rates were more for incomplete miscarriage than missed miscarriage and blighted ovum, as have been found also in other studies (11).

The rate of emergency curettage as well as the rate of second curettage was similar between the two study groups, and like other studies (13).

The expectant management group was characterised by a longer duration of bleeding and pain than the surgical group, as has been found in other studies (11). However, the average duration of bleeding and pain in the present study was longer than that reported by Nielsen et al (5). This might be explained by the selection of patients (low number of incomplete miscarriages) and the longer period of expectant management in the present study.

For a long period the argument of safety was in favor of surgical management of miscarriage, and concerns have been raised about the infective risks of expectant management based on the belief that retained tissue increases the risk of infection. However, many studies showed that complications like laparotomy for uterine perforation may result from surgical management (13), and many published data also showed a reduction in the incidence of pelvic infection in women managed expectantly as compared to women managed by surgical evacuation (12,14,15). Graziosi et al reported infection rates of expectant management and curettage of 2.2% and 5.6% respectively (11).

The complication rate in the present study was similar in both groups. However the rate of pelvic infection was significantly lower in women randomised to expectant management than the surgical group. These results are consistent with other studies (11, 15).

Due to the maternal risks associated with ectopic pregnancy and molar pregnancy, it is recommended that tissues obtained at the time of uterine evacuation should be sent for histological examination to confirm pregnancy and to exclude ectopic pregnancy or gestational trophoblastic disease (16). Women who miscarry at home should be advised to take any tissue passed to the hospital for histological examination.

The cost-benefit analysis was not performed in this study; however, the reduction in in-patient care episodes, acute bed occupancy as well as the reduction in the theater and anaesthetic use in the expectant management group, suggests that the expectant management of miscarriage is more cost effective than the surgical method.

In conclusion expectant management is safe and effective way of managing first trimester miscarriage, resulting in spontaneous evacuation of the uterus in 81.4% of cases and reducing the need for surgery.

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**Table III:** Success rate according to type of miscarriage

Type of miscarriage	Expectant		Surgical	
	Total	Success rate	Total	Success rate
Incomplete	42 (41.2%)	38 (90.5%)	51 (44.3%)	50 (98%)
Missed/ blighted ovum	60 (58.8%)	45 (75%)	64 (55.7%)	60 (93.8%)
Total	102 (100%)	83 (81.4%)	115 (100%)	110 (95.7%)

Values are n (%).

**Table I:** Patient characteristics

	Expectant management (n=102)	Surgical management (n=115)	P
Age (years)	32.5(17-47)	33.4(16-48)	NS
Parity	3.7(0-12)	4.2(0-11)	NS
Gestational age (days)	62.5 (42-90)	63.9(40-92)	NS
Previous miscarriage	2.1(0-6)	2.0(0-7)	NS
Anterior-posterior diameter	21( 14-29)	21(14-30)	NS
Packed cell volume	38.1(2.0)	37.8(2.1)	NS

Values are mean (range) or mean (SD). NS= not significant

**Table II:** Outcome measures

Outcome	Expectant (n=102)	Surgical (n = 115)	P value
Success rate at four weeks	83 (81.4 % )	110 (95.7%)	0.0029
Emergency curettage	5 (4.9 % )	6 (5.2%)	0.1744
Second curettage	4 (3.9%)	5 (4.3%)	0.0975
Duration of bleeding (days )	11 (2.3)	7 (2.1)	< 0.0001
Change in PCV at four weeks	-1.60 (3.3)	-1.51 (1.4)	0.7899
Duration of pain ( days )	8.1 (2.7)	5.5 (1.7)	< 0.0001
Requirement of analgesia	25 (24.5 % )	16 (13.9%)	0.6711
Complications ( total )	6 (5.9 % )	7 (6.1 % )	0.2479
Pelvic infection	2 (1.9 % )	4 (3.5 % )	0.0146
Bleeding	4 (3.9 % )	2 (1.7 % )	0.0199
Uterine perforation	0	1 (0.9 % )	NS

Values are n (%) or mean (SD). NS= not significant