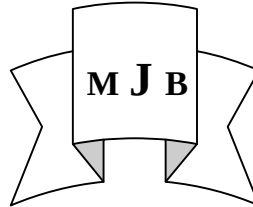


Outcome Of Conservative Management Of Incomplete 1st Trimester Miscarriage: Observational Study

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Abstract

Background: The principle of emptying the uterus as quickly and safely as possible remains the corner stone of management of incomplete miscarriage. In many countries surgical uterine evacuation is the standard treatment, expectant management has been advocated as an alternative in several observational studies.

Objectives: To evaluate the effectiveness of expectant management of incomplete 1st trimester miscarriage.

Study design and setting: Prospective observational study carried out at Babylon hospital for maternity and pediatrics between feb.2009-jan. 2010.

Materials and methods: The study involved 120 clinically stable patients with incomplete 1st trimester miscarriage (diagnosed by TVU), those patients subjected to conservative examination treatment (no intervention) and follow up for 2 weeks by clinical examination and transvaginal ultrasound.

The main outcome measures were complete miscarriage (absence of vaginal bleeding and endometrial thickness 15 mm by TVU), need for emergency curettage, infection and need for blood transfusion.

Result: Successful outcome without surgical intervention was seen in of 85% of cases infection reported in 1.6% of cases, emergency curettage needed for 5 % (1.6% for infection and 3.3% for excessive vaginal bleeding), 10% of cases required elective surgical evacuation (4.1% of them refused follow up >1 week and 5.8% to failed to have complete miscarriage after 2 weeks of observation) without reported complications.

Conclusion: Expectant management of clinically stable patients with retained product of conception after 1st trimester incomplete miscarriage is safe, effective and well tolerated.

فعالية العلاج التحفظي في علاج حالات الاجهاض الناقص في الثلاثة أشهر الأولى من الحمل

الخلاصة

المقدمة: تعد عملية إفراغ الرحم من محتوياته بالطرق الأسرع والأقل مضاعفات الحجر الأساس في معالجة حالات الإجهاض الناقص وغالبا ما تتم بواسطة الطرق الجراحية والتي لا تخلو من المضاعفات. وقد حاولت دراسات عديدة بيان فعالية العلاج التحفظي و إمكانية الاستعاضة به عن التدخل الجراحي.

الهدف من الدراسة: تقييم فعالية العلاج التحفظي في حالات الإجهاض الناقص في الثلاثة أشهر الأولى من الحمل

نوع ومكان الدراسة: دراسة تقديمية أجريت في مستشفى بابل للنسائية والأطفال خلال الفترة من شباط 2008 – كانون الثاني 2010.

طريقة العمل: شملت الدراسة 120 حالة اسقاط ناقص في الثلاثة أشهر الأولى من الحمل (شخصت بواسطة فحص الموجات فوق الصوتية) وكانت مستقرة سريريا وتمت مراقبة الحالات لمدة أسبوعين بدون تدخل وتمت ملاحظة الحالات التي تحولت إلى إجهاض كامل والمضاعفات من حيث الحاجة للتدخل الجراحي الطارئ والالتهابات والنزف الشديد والحاجة لنقل الدم.

النتائج: أظهر العلاج التحفظي نجاحا في 85% من الحالات حيث تحولت إلى إجهاض كامل كما أظهرت الدراسة أن 5% من الحالات احتاجت للتدخل الجراحي الطارئ (جرف الرحم الآلي) 1.6% بسبب الالتهابات و 3.3% بسبب النزف الشديد و 10% من الحالات لم تستجب للعلاج (4.1% رفضوا الملاحظة لأكثر من أسبوع واحد و 5.8% لم يستجيبوا بعد أسبوعين من الملاحظة) وتمت معالجة هذه الحالات جراحيا بدون مضاعفات.

الاستنتاج: العلاج التحفظي لحالات الإجهاض الناقص (المستقرة سريريا) طريقة فعالة وامينة ويمكن تحملها من قبل المرضى .

Introduction

Miscarriage is the most common complication of pregnancy and remains an important clinical problem [1].

Spontaneous miscarriage occur in approximately 15-20% of all pregnancies as recorded by hospital episode statistics, the actual figure from commonly based assessment may be up to 30% as many cases remain unreported to hospital[2].

The great majority of miscarriage occur early before 12 weeks of gestation while midtrimester loss between 12 and 24 weeks occur less frequently and constitute < 3% of pregnancy outcomes[3].

The management of miscarriage has changed little this century and conventional surgical evacuation of uterus has been recommended when there are retained products of conception [1]. This approach was based on an assumption that retained tissue increase risk of infection and hemorrhage, however surgical evacuation was introduced at a time when high rate of retained products and infections with ensuing morbidity and mortality were likely to be due to

high number of illegal termination of pregnancy and the absence of any antibiotics medications[3].

For most of the 20th century spontaneous miscarriage was managed by evacuation of retained products of conception, traditionally carried out with ovum forceps and curettage, this method changed to vacuumed aspiration after advances were made in the equipments to deal with surgical termination of pregnancy [4] as it is associated with fewer complications as uterine perforation, cervical tear, intrauterine adhesions and hemorrhage [3].

Over the past decade alternative management options (expectant and medical) have been developed and many women prefer the option of a treatment without the attendant risks associated with a surgical procedure [3].

In recent years the medical management of miscarriage which can achieve complete uterine evacuation in 95% of early miscarriage this method involve the combined use of antiprogesterone (mifepristone) and prostaglandin E1 analogue (misoprostol) and has been shown to

result in lower cost for patients compared with surgical treatment [5].

More recently it has been proposed that selected cases of spontaneous miscarriage can be managed using watch and wait or conservative management strategy [1].

Expectant management often result in absorption of retained tissue while little associated bleeding, for those women managed in general practice expectant management has long been the treatment of choice [3].

Factors affecting the success rate of expectant management were the type of miscarriage, duration of follow up and whether clinical or ultrasound features were used for review. The clinical dilemma is therefore which patient suitable for expectant management [3].

When ultrasound assessment of uterine cavity is suggestive of retained products of conception with an anterior-posterior diameter of endometrial 15 mm or less genuine retained products are less likely to be confirmed histological hence

Such cases are best managed expectantly and these women are said to have suffered a complete miscarriage. One study showed that 98% of women treated expectantly following a scan report a complete miscarriage had an uneventful recovery [3]

Early pregnancy assessment unite open to patients without the need for referral ,the use of TVU have enable the presence of the stage of early pregnancy failure to be determined from direct image. Preliminary data arising from these developments have shown that expectant management with serial monitoring may be used to

identify those patients who will not required surgery [6].

We report observational study designed to assess the uptake and effectiveness of expectant management of incomplete 1st trimester miscarriage.

Aim of the study

To asses the role of expectant (conservative) treatment in management of incomplete 1st trimester spontaneous miscarriage.

Materials and Methods

A prospective observational study carried out at Babylon teaching hospital for maternity and pediatrics throughout the period between feb.2009-jan.2010,

The study involved 120 clinically stable patients with incomplete spontaous 1st trimester miscarriage <13 weeks of gestation.

Retained product of conception diagnosed by transvaginal ultrasound with the presence of heterogeneous intrauterine mass or anterior-posterior diameter of the endometrium more than 15 mm. those patients either asymptomatic or had mild vaginal bleeding.

Exclusion criteria

- Patients with considerable vaginal bleeding and hemodynamically unstable.
- Patients with evidence of infection (those who had abdominal pain, fever, offensive vaginal discharge and elevated WBC count).
- Patients who refuse conservative treatment.

All patients in this study recruited from outpatient clinic and full history and clinical examination (medical and gynecological) done for them.

Demographic criteria of the patients were assessed including age, parity, number of previous miscarriages, gestational age and presence of vaginal bleeding.

Base line investigation was done for all patients including blood group and Rh status, Hb level. WBC count, plasma fibrinogen and high vaginal swab to exclude infection.

The patients in this study then subjected to conservative treatment

(Watch and wait) in which patients seen at weekly interval for two weeks. At

During the period of observation patients asked to report immediately any abdominal pain, vaginal bleeding, fever and offensive vaginal discharge.

Expectant management considered to be successful when there is absence of vaginal bleeding and no evidence of retained product of conception by TVU.

Patient who refused to continue the conservative treatment subjected to surgical evacuation of uterus.

Main outcome measures

* Complete miscarriage (absence of vaginal bleeding and endometrial thickness less than 15 mm on TVU.)

* Number of women completing their miscarriage within each week of management.

* Complications (excessive bleeding and clinical evidence of infection).

* The need for emergency and elective curettage.

Result

Description of the study group

A total of 120 patients with incomplete spontaneous 1st trimester miscarriage.

Demographic criteria of them were assessed, the mean age was 33.2+ 6.9 years and the mean gestational age was 10.5 +1.4 weeks.

58 patients (48.3%) were nullipara and 62(51.6%) were multipara.

Previous miscarriage reported in 28 (23.3%) of patients.

Mild vaginal bleeding was reported in 42(35%) of patients.

The mean Hb level of all patients was 13.7+ 1 gm/ dl and WBC count was 7.7+2.1 *10⁹/ l. table (1).

Outcome of the study

Of 120 patient with incomplete spontaneous 1st trimester miscarriage who subjected to conservative treatment, complete miscarriage which diagnosed by absence of vaginal bleeding and endometrial thickness by TVU less than 15 mm was achieved in 102(85%) of patients.

65(54%) of them achieved complete miscarriage at 1st week of observation and 37 (30.8%) after two weeks.

Emergency curettage was required for 6 patients (5%), 2 of them (1.6%) because of clinical evidence of infection that required admission and evacuation of the uterus under antibiotic cover.

Excessive bleeding that required emergency curettage reported in 4 patients (3.3%) and only one of they required blood transfusion.

Elective curettage done for 12 patients (10%), 5 of them refused to continue

conservative treatment beyond 1 week. The remaining 7 patients failed to achieve complete miscarriage after 2 weeks of observation and their retained

products of conception removed surgically without reported complications. Table (2).

Table 1 demographic criteria of the patients

Age years	G.A(wk s)	Parity 0	Parity > 1	Previous miscarriage	Vaginal bleeding	Hb level(gm/dl)	WBC count
33.2 +6.9	10.5 +1.4	58 %48.3	62 %51.6	28 23.3 %	42 35 %	13.7 +1	7.7 2.1+

Table 2 the outcome of the study

Outcomes	Result (no.)	Result (%)
Complete miscarriage	102	85
At 1 week	65	54
At 2 weeks	37	30.8
Emergency curettage	6	5
Due to infection	2	1.6
Due to bleeding	4	3.3
Elective curettage	12	10
Refusal of follow up	5	4.1
Failure of treatment	7	5.8
Blood transfusion	1	0.8
perforation	0	0
infection	2	1.6
Cervical damage	0	0

Discussion

In many countries, surgical evacuation of the uterus is the standard treatment for women with miscarriage, expectant management has been advocated as an alternative in several observational studies.[7]

Nielsen et al reported 1st randomized study describing the conservative management of women with retained products of conception, this study include women with residual intrauterine tissue represented on endometrial thickness between 15-50 mm in AP diameter, women in this study were managed expectantly for 3 days only, the success rate found to be 79% for expectant management and 89% for surgical management .and the infection reported in 3% of expectant group versus 10% of surgical group.[8]

Although this study has several methodological problems, its finding created a lot of interest among clinician to explore the role of conservative management further.

A randomized controlled trial was conducted to compare expectant management with surgical evacuation by Margreat et al (2002), in this study the success of conservative management found to be 37% after 7 days and 47% at 6 weeks follow up, while success rate for surgical treatment found to be 95%, no differences were found in number of emergency curettage and complications between expectant and surgical treatment [7].

Paulet et al (2009) in a prospective observational study evaluate the effectiveness and acceptability of expectant management of induced and spontaneous 1st trimester incomplete miscarriage , in this study patients with incomplete miscarriage divided into two groups , 1st group received

misoprostol and 2nd group assigned for conservative management .TVU performed weekly, the result of this study showed that the incidence of complete miscarriage was 86.4% for misoprostol group and 82.1% for conservative group [9] .

In our study we achieved success rate for conservative treatment in about 85% which is comparable to the above study.

Casikar et al (2010) in their observational prospective study assess the uptake and success of expectant management of 1st trimester miscarriage for a period of 14 days period in order to evaluate 2 weeks rule of management, they found that spontaneous resolution at 2 weeks was 81% for incomplete miscarriage , 53% for empty sac and 35% for missed miscarriage.[10]

In this study it has been shown that the incidence of unplanned emergency curettage due to gynecological infection or hemorrhage was 2.5 %.[10]

We depend on this study for determination of our period of observation (2 weeks) and our result was comparable, success rate was 85% and incidence of emergency curettage due to gynecological infection was 1.6% and due to hemorrhage was 3.3% while the incidence of elective curettage was 10% (4.1% refused follow up more than one week and 5.8% failed to had complete miscarriage after 2 weeks).

Many studies done to optimized the rule of expectant management and clarify the factors that affect the success rate of this treatment and compare its efficacy with both surgical and medical management.

Trinder J et al (2006) in their randomized trial comparing medical and expectant management with surgical management of 1st trimester miscarriage to ascertain whether a clinically important differences exist in the incidence of gynecological infection between these modalities of treatment , they conclude that there was no difference in the incidence of confirmed infection within 14 days between expectant, medical and surgical method 2-3% and no evidence exist of differences by the method of management ,however significantly more unplanned admissions and unplanned surgical curettage occurred after expectant and medical management than after surgical management.[11]

Luise et al (2002) report success rate of expectant management of 70% within 14 days and 81% after 4 weeks .complication occurred in 1% of conservatively treated group versus 2% of surgically treated group. [12]

Inspite of all those encouraging results, some studies showed a lower success rate of conservative treatment as what had been found by Sotiridis a et al, (2005) who found in their observational study a success rate of conservative management to be of 39% only [13]

In a trial to assess the long term impact of the method of management of miscarriage Smith et al perform a study to compare the fertility rate after the three modalities of management of early miscarriage. the conclusion of this study was that the method of managing miscarriage does not affect subsequent pregnancy rate and women could be reassured that long term fertility concern need not to affect their choice of management of miscarriage.[14]

Conclusion

Expectant management based on two weeks rule is safe and viable option for women with incomplete spontaneous 1st trimester miscarriage.

Recommendations

- Further studies required to compare conservative management with other modality of treatment (medical and surgical).

-Further studies to assess the efficacy of conservative management of other types of miscarriage.

- Further studies to assess the long term effect of conservative treatment on subsequent fertility.

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