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ANALYSIS OF NON-SURGICAL MANAGEMENT OF EARLY PREGNANCY FAILURE IN PAKISTAN

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Abstract

Introduction: *Early pregnancy failure can be devastating for women and their partners. The diagnosis may be preceded by days or weeks of cramping, bleeding, and hoping. Once the diagnosis is made, women are most satisfied when they are given management options and can choose the one that best fits their needs.* ***Aims and objectives:*** *The basic aim of the study is to analyze the non-surgical management of Early Pregnancy Failure in Pakistan.* ***Methodology of the study:*** *This study was conducted at Nishtar hospital, Multan during 2017. This was done with the permission of ethical committee of hospital and with the permission of patients. Total number of participants was 100 pregnant females who belong to different parts of Punjab.*

Results: *The number of women recruited to the trial was lower than that needed to meet the original sample size calculation. Recruitment was slower than anticipated and despite an additional 33 months of recruitment, we recruited a total of 100 women. Two women recruited to the trial were subsequently found to have a viable pregnancy. No important baseline differences were evident between the three groups.*

Conclusion: *It is concluded that women are increasingly offered a choice of treatment for the management of miscarriage. This study provides important data to enable women to be informed about their treatment choice. The ability of a unit to offer all three choices will depend on its facilities.*

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INTRODUCTION:

Early pregnancy failure (EPF; that is, pregnancy failure in the first trimester) can be devastating for women and their partners. The diagnosis may be preceded by days or weeks of cramping, bleeding, and hoping. Once the diagnosis is made, women are most satisfied when they are given management options and can choose the one that best fits their needs. Medical management of EPF is a safe and desirable option for some women [1]. Epidemiology of EPF EPF is an inclusive term that comprises incomplete, complete, or inevitable spontaneous abortion; anembryonic gestation (blighted ovum); and embryonic demise (missed abortion) at less than 14 weeks. Approximately 15% to 20% of clinically recognized pregnancies end in EPF. Many EPFs occur before pregnancies have been clinically recognized. It is estimated that up to 60% of all conceptions end in early losses [2]. Chromosomal abnormalities, most commonly translocations and aneuploidy, are responsible for more than half of all spontaneous EPFs. Other genetic defects that are currently impossible to discern by simple karyotype may be the cause of many spontaneous losses. Diagnosis of EPF The diagnosis of EPF may be suspected on signs and symptoms (vaginal bleeding, lower abdominal cramping, dilation of cervix) but is usually made by trans vaginal ultrasound (U/S) and/or symptoms and serial beta human chorionic gonadotropin (BhCG) levels [3]. Women with EPF may also be asymptomatic. The term "spontaneous abortion" includes complete abortion, incomplete abortion, inevitable abortion, an embryonic pregnancy, and embryonic or fetal demise. In the case of a complete abortion, the patient has had a positive pregnancy test, has experienced vaginal bleeding with passage of tissue, and has a closed cervical. In the case of incomplete abortion, the patient has had a positive pregnancy test, vaginal bleeding, and may have a closed or open cervical [4]. An endometrial thickness measurement distinguishing incomplete from complete abortion has not been established. Other management options (expectant or medical) have been offered to women with a miscarriage. Expectant management allows spontaneous passage of retained products of conception, and medical management uses drugs to aid expulsion of retained products. The optimal management for two common types of miscarriage, incomplete miscarriage and early fetal demise (previously termed "missed" miscarriage), is uncertain [5].

Background of the study

Medical management has also been used as an alternative to surgical management. Treatment regimens include the use of the anti-progesterone, mifepristone, and a prostaglandin analogue, the most commonly used of which is misoprostol. Nine randomized controlled trials have compared medical and surgical management. Success rates as low as 13% and as high as 93% have been reported in small trials. As with the observational studies, the trials used differing drug regimens and different measures of success [6].

Aims and objectives

The basic aim of the study is to analyze the non-surgical management of Early Pregnancy Failure in Pakistan.

Methodology of the study

This study was conducted at Nishtar hospital, Multan during 2017. This was done with the permission of ethical committee of hospital and with the permission of patients. Total number of participants was 100 pregnant females who belong to different parts of Punjab.

Collection of data

The basic method utilized in order to attain the data, involved conducting an interview with the management team of the Nishtar Hospital that is based in South Punjab. Women with a pregnancy of less than 13 weeks' gestation who had been diagnosed as having either an incomplete miscarriage or early fetal/embryonic demise were eligible. Exclusion criteria were severe haemorrhage or pain, pyrexia above 37.5°C, severe asthma, haemolytic disease or blood dyscrasias, current anticoagulation or systemic corticosteroid treatment, twin or higher order pregnancy, smoker aged over 35.

Interventions

We gave all women a specific information sheet, 30 co-dydramol tablets, and an emergency telephone number. Women in the expectant management arm were allowed home with no intervention. In the medical management arm, women with an incomplete miscarriage were admitted to hospital and given a single vaginal dose of 800 µg misoprostol. Women with early fetal or embryonic demise were pre-treated with a single oral dose of 200 mg mifepristone, then admitted to hospital 24-48 hours later for a single vaginal dose of 800 µg misoprostol. A surgical evacuation of retained products of conception was offered if expulsion of retained products had not started within eight hours of insertion of misoprostol. Women in the surgical management arm were admitted for surgical suction

curettage under general anaesthesia. No centre used prophylactic antibiotics at the time of curettage.

Blood analysis

In all three groups, blood was taken for full blood count. Rhesus negative women were offered 250 IU of anti-D irrespective of their allocated management. A follow-up appointment was arranged 10-14 days after trial entry for a transvaginal ultrasound scan, full blood count, consultation with the study nurse, and examination by a gynaecologist if symptoms of infection were present. Retained products of conception were diagnosed if areas of mixed echogenicity within the uterine cavity were seen. A surgical curettage was offered if retained products of conception were present.

Statistical Analysis

Statistical analyses (Anova Test and Post Hoc) were performed using the SPSS software program (17.0). All results were expressed as the mean ± standard deviation (SD). P value below 0.05 was considered to be statistically significant.

RESULTS:

The number of women recruited to the trial was lower than that needed to meet the original sample size calculation. Recruitment was slower than anticipated and despite an additional 33 months of recruitment, we recruited a total of 100 women. Two women recruited to the trial were subsequently found to have a viable pregnancy. No important baseline differences were evident between the three groups

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Table 1: Characteristics of participants

Characteristic	Surgical (n=402)	Expectant (n=398)	Medical (n=398)
Mean (SD) age (years)	31.5 (5.8)	31.3 (5.8)	31.2 (5.9)
Gestational age (days):			
<56	25 (6)	26 (7)	18 (5)
56 to 76	173 (43)	168 (42)	168 (42)
77 or more	147 (37)	147 (37)	155 (39)
Not known	57 (14)	57 (14)	57 (14)
Parity:			
Nulliparous	175 (44)	170 (43)	172 (43)
Parous	227 (56)	228 (57)	226 (57)
Type of miscarriage:			
Missed	310 (77)	306 (77)	308 (77)
Incomplete	92 (23)	92 (23)	90 (23)
Bleeding at entry	335 (83)	340 (85)	331 (83)
Pain	205 (51)	213 (54)	206 (52)
Median (interquartile range) antenoposterior diameter on ultrasound scan	21.0 (14-29)	21.0 (14-30)	21.0 (14-30)

In all three groups the median time to return to usual daily activities was two days. Sick leave was also similar in all three groups, the median was nine days in the surgical group, eight days in the expectant group, and nine days in the medical group. No differences existed in anxiety or depression scores on the hospital anxiety and depression questionnaire six to eight weeks after miscarriage

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Table 2: Clinical outcomes of selected patients

Outcome	Surgical	Expectant	Surgical-expectant % risk difference (95% CI)	Medical	Surgical-medical risk difference (95% CI)
Infection specified by criteria:					
By 10-14 day follow-up	12 (3)	11 (3)	0.2 (−2.2 to 2.7)	9 (2)	0.7 (−1.6 to 3.1)
By 8 week follow-up	16 (4)	14 (4)	0.5 (−2.3 to 3.2)	12 (3)	1.0 (−1.7 to 3.7)
Infection specified by antibiotic use:					
By 10-14 day follow-up	34 (8)	17 (4)	4.2 (0.8 to 7.7)	31 (8)	0.7 (−3.2 to 4.5)
By 8 week follow-up	44 (11)	31 (8)	3.2 (−0.9 to 7.3)	43 (11)	0.1 (−4.2 to 4.5)
10-14 day follow-up ultrasound scan:					
Evidence of RPOC	41 (10)	145 (36)	−26.2 (−31.7 to −20.6)	78 (20)	−9.4 (−14.3 to −4.5)
Equivocal result	53 (13)	42 (11)	2.6 (−1.9 to 7.1)	52 (13)	0.1 (−4.6 to 4.8)
Empty uterus	271 (67)	185 (46)	20.9 (14.1 to 27.5)	240 (60)	7.1 (0.5 to 13.7)
No follow-up scan	37 (9)	26 (7)	2.7 (−1.1 to 6.5)	28 (7)	2.2 (−1.7 to 6.0)
Median (interquartile range) duration of bleeding (days)	8 (4-14)	12 (7-15)		11 (7-15)	
Blood transfusion	0	7 (2)	−1.8 (−3.6 to −0.4)	4 (1)	−1.0 (−2.6 to 0.4)
Extra analgesia taken	71 (18)	177 (44)	−26.8 (−32.8 to −20.5)	98 (25)	−7.0 (−12.6 to −1.3)

DISCUSSION:

Medical management does not seem to offer greater success than expectant management when used to treat incomplete miscarriage, but it may offer an alternative management in early fetal demise. Allowing a longer time for products of conception to pass may increase the success rate [7]. However, the increased time spent in hospital could be unattractive to women and care providers alike. Another option would be to use misoprostol in an outpatient setting. Randomized trials have shown that this is possible, with success rates of 72-93%. The optimum regimen for medical management is yet to be devised, and further research is needed to determine this, particularly in an outpatient setting. Surgical curettage still offers the greatest complete evacuation rate, the least risk of needing unplanned admission, and the shortest duration of bleeding. It should therefore continue to be offered as a management option, particularly to those women with early fetal demise [8].

Gynecologists have been taught that surgical curettage is necessary to prevent infection after miscarriage. In this trial, the infection rates after expectant, medical, and surgical management were not significantly different and were reassuringly low. This was in the absence of screening for infection and without the use of prophylactic antibiotics. Moreover, the incidence of presumed infection as measured by antibiotic prescription in the first 14 days was significantly lower in the expectant management group than in the surgical group [9]. These data should be reassuring to people who have raised concern about the lack of evidence available for non-surgical treatment of miscarriage.

The success rates in this trial were comparable to those in other trials of expectant management of incomplete miscarriage and early fetal demise. Observational studies, however, had suggested that higher success rates were achievable. Some of these differences could be explained by the lack of a universal definition of ultrasound scan findings of incomplete miscarriage or the presence of retained products at follow-up [9]. Current clinical practice is not to do an ultrasound scan to measure endometrial thickness after a surgical curettage. Therefore, more women than usual may have been diagnosed as having retained products of conception and advised to have subsequent surgical curettage. For medical management, the success of the treatment protocol was disappointing compared with the higher success rates in the observational studies on which we based the treatment protocol and other observational studies [10].

CONCLUSION:

It is concluded that women are increasingly offered a

choice of treatment for the management of miscarriage. This study provides important data to enable women to be informed about their treatment choice. The ability of a unit to offer all three choices will depend on its facilities.

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