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MISSED ABORTION;
MISOPROSTOL VERSUS CERVICAL CATHETER AS CERVICAL PRIMING AGENT

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ABSTRACT... Objective: To compare the effectiveness of extra-amniotic cervical catheter and vaginal misoprostol as a cervical priming agent prior to surgical evacuation in first trimester missed abortions. **Design:** Randomized clinical trial. **Setting:** At lady Willingdon hospital gynecology unit 1 from 1st March 2008 to 28th February 2009. **Methods:** 100 patients with diagnosis of missed abortions of up to 12 weeks + 6 days were studied. The primigravida were included. They were divided in two groups. In group. A (50) patients 400 microgram (2 tablet) misoprostol were placed high up in posterior vaginal fornix while in group B (50) patients extra-amniotic. Foleys catheter was placed aseptically 6 hour before surgical intervention as priming agent. **Exclusion criteria:** All multigravida, patients sensitive to prostaglandin, and with disturbed coagulation were excluded. **Main Outcome Measures:** The main out comes are 1, cervical dilatation and effacement 2, complications like fever, pain lower abdomen, headache and vomiting 3, amount of bleeding in ml after application of agent. **Results:** Cervical catheter proved to be good cervical priming agent comparable to misoprostol. Cervical dilatation was significantly better in misoprostol (> 10 mm 44%, > 8mm 30%, > 5mm 20%) as compared to Foleys group (>10 mm 24%, > 8mm 38%, > 5mm 20%) while in 3 (6%) dose of misoprostol was repeated and in 10 (20%) patient in Foleys group has no effect. The side effects occurred in both groups but systemic effects were more in misoprostol, pain lower abdomen 42% VS 46%, backache 18% VS 26%, fever 10% VS nil, headache 16% VS nil and no side effect 14% VS28%) as compared to Foleys catheter. Systemic effects were absent in Foleys catheter due to inert nature. Bleeding occurred in all patients with misoprostol while it was absent in 48% cases in Foleys group (>60ml 42% VS 8%, <40ml 32% VS 14% < 20ml 26% VS 30%). 48% cases had no bleeding in Foleys group. **Conclusion:** Cervical catheter proved to be good priming agent due to lesser systemic side effects as compared to misoprostol.

Key words: Misoprostol, Cervical Priming. Extra-amniotic Foleys catheter, missed abortions.

INTRODUCTION

Missed abortion refers to term early fetal demise or blighted ovum with retention of products of conception[1]. Surgical management has been the standard treatment (suction aspiration/ conventional curettage) for many years. Medical management is not widely used[2].

Surgical evacuation without prior cervical ripening is associated with many complications like cervical injury, uterine perforation, excessive hemorrhage and incomplete uterine evacuation[3] especially in primigravida or if patient age is less than 18years[4]. The commonly used methods for cervical ripening include

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osmotic dilator (laminaria tents in the USA). prostaglandin analogues (gemeprost in U.K) and misoprostol.

Misoprostol can be administered orally or vaginally, the vaginal route has been shown to be more effective in dose of 400 micro gram for termination of pregnancy in comparative studies[5]. The optimal interval for vaginal administration of misoprostol for cervical priming prior to surgical abortion is 3 hour[6]. Inflated Foley's catheters have gained popularity as a mechanical device for ripening of the cervix in patients with unfavorable cervix in term pregnancies[7]. It has been suggested that the use of an extra-amniotic catheter balloon has the advantages of simplicity, low cost, reversibility and lack of systemic or serious side effects. Many other studies have proved efficacy of the extra-amniotic. Foleys balloon in priming the cervix before induction of labor at term due to its mechanical as well as indigenous production of prostaglandins[8]. This aim of the study was conducted to assess the effectiveness of Foleys balloon as priming agent before surgical evacuation in 1st trimester missed abortions and it was compared with the effect of vaginal misoprostol over period of 6 hours.

PATIENTS & METHODS

This study was conducted at lady willingdon hospital Lahore affiliated with king Edward Medical University. All primigravida with confirmed diagnosis of missed abortion up to 12 weeks + 6 days were divided equally in two groups. Written consent was taken. History relevant to prostaglandins sensitivity was taken. All basic investigations were performed. 50 patients were selected for cervical catheter and 50 opted for misoprostol tablets vaginally. Two tablets of cytotec (400mcg) were placed simply high up in the posterior vaginal fornix while the patient was lying in the dorsal position six-hour preoperatively. (The tablets were not wet in water prior to insertion).

Foleys catheter was passed into the cervix by either using the lithotomy position to a depth of 3 cm so that the balloon of the Foley's catheter lay just over the internal OS. The balloon was then filled with 30-40 ml of distilled water. Study time was six hours. This extra-time of 2 hours was basically to allow some more time to the Foleys balloon to be effective. All these women were kept under observation before surgical procedure. For assessment of side effects the women were asked to complete a questionnaire with the help of junior doctor. Data was analyzed using SPSS. Chi-square was calculated and statistical significance was defined using P values.

RESULTS

A total of 100 patients were included in the study, the maternal age range was 18-29 years (mean 23 yrs). The gestational age in the study group ranged from 6-13 weeks (mean gestational age being – 64 days (9 weeks and 1 day).

Side effect experienced by patients is shown in Table-II.

Table-I. Side effects experienced

Symptoms	Foleys group A (N=50)	Misoprostol group B (N=50)	P-value
Abdominal pain	23 (46%)	21 (42%)	0.687
Backache	13 (26%)	09 (18%)	0.344
Fever	-	05 (10%)	0.022
Headache	-	08 (16%)	0.003
No symptoms	14 (28%)	07 (14%)	0.09

Lower abdominal pain and backache started almost immediately after insertion of the Foleys balloon in 36 women (72%) while 30 women (60%) in misoprostol group In misoprostol pain started immediately. The other systemic side effect like fever in 5 (10%) and headache in 8 (16%) were seen in misoprostol group but these were absent in Foleys group. The difference in proportions are statistically significant as p-values < 0.05. No side effects were seen in 14 (26%) in Foleys as compared to 7 (14%) in misoprostol group.

Table-II. Cervical dilatation in MM after 6 hours m					
Dilatation mm	**Misoprostol A (N=50)**	**%**	**Foleys group B (N=50)**	**%**	**P-value**
>10mm	22	44%	12	24%	0.035
>8mm	15	30%	18	36%	0.523
>5mm	10	20%	10	20%	-
No effect	03	6%	10	20%	0.04
	50	100%	50		

Cervical dilatation occurred in both groups more than 10 mm so that it does not required further force 22(40%) in misoprostol VS 12(24%) in Foleys group (p = 0.035). More than 8mm dilatation occurred comparable in both group 15 (30%) VS 18 (36 %) (p = 0.523). Minimal dilatation occurred in 10 (20%) VS 10 (20%) while 10 patients in Foleys group have no dilatation. The same was true in 3 (6%) in misoprostol required repeated dose.

Table-III. Blood loss in ml before the procedure				
Bleeding in ml	**Misoprostol A (N=50)**	**%**	**Foleys group B (N=50)**	**%**
> than 60ml	21	42%	04	08%
< than 40ml	16	32%	07	14%
< than 20ml	13	26%	15	30%
No bleeding	-	-	24	48%

In respect of bleeding. Foleys catheter was found to be good as compared to misoprostol (p < 0.001).

Bleeding started with in half hour in 21 (42%) with misoprostol and in 4 (8%) in Foleys group but it remained more than five pads (60ml). The bleeding was mild below 50 ml in both agents 16(32%) in misoprostol VS 7 (14%) in Foleys group. The bleeding was slight (20 ml) at insertion of agent in both group 26% VS 30%

DISCUSSION

The cervical priming has shown to facilitate transcervical procedure and to reduce the side effect in pregnant patients before surgical evacuation of products conception in missed abortion .In the past various agents have been used as priming agents by mechanical or medical means.These agents have confirmed role in induction of labor at term pregnancy[9]. Cervical priming in missed abortion reduces the operative time, reduces blood loss, and promotes easier mechanical dilatation. This leads to reduction in complication during operative procedure. These include perforation, micro fracture of cervix and false passage[10]. Studies have shown that misoprostol is an effective cervical priming agent before surgical evacuation. The role of misoprostol had been established as good cervical priming agent in large number of studies. It was as effective as gemeprost prior to suction aspiration[11].

Our study compared the results of effective cervical priming caused by the vaginal misoprostol to that of a Foleys balloon passed into the cervix and pressing over the internal os by its mechanical effect. Foleys catheter improves the cervical state probably by causing release of enzymes from the cervical tissue and uterine decidual cells, which act on the phospholipids to form arachidonic acid and prostaglandins. This view is supported by the demonstration of elevated levels of prostaglandins

metabolite when the cervix is disturbed as during a cervical encerclage[12].

Our results showed that in respect of cervical dilatation Foley's catheter was comparable to vaginal misoprostol. The dilatation occurred in both with no effect in 3 (6%) in misoprostol and 10 (20%) in Foleys group. Our results in total time and ease to perform the surgical procedure in both group are comparable to other studies conducted with vaginal misoprostol[11]. Studies have been conducted on the positive role of Foleys catheter in induction of labor at term[13] but no systematic review is available in the literature on its role in first trimester abortions although it is being used for the same purpose in many centers.

In terms of other parameters of the study i.e. the amount of blood loss and for side effects Foleys catheter proved the most effective and superior to vaginal misoprostol as can be seen in table-II. However, initial insertion of the Foleys catheter in the cervix may cause some discomfort to the patients, which might not be acceptable to some women. Other side effects like abdominal pain and backache are almost the same in both groups. The misoprostol had systemic side effect due to its absorption in to systemic circulation. The documented incidence of chills and fever with misoprostol is 32 % to 57 %, when it is used in dose of 600 micrograms in the postpartum hemorrhage[14]. Chills are a common side effect of misoprostol but are transient. In our study 10 % of patient had fever, probably due to lesser dose of misoprostol was used. Bleeding before surgery occurred in all patients with misoprostol while it was almost absent in Foleys catheter due to its inert nature. As the cervix is properly prepared and primed by both agents, the surgical evacuation of the uterus was smooth and uneventful. The blood loss was minimal during the procedure. The same was true in our study. Misoprostol can be used by orally and vaginal route. Vaginal route is more effective as compared to oral route. Wetting the tablet with water or an acid material does not appear to increase the efficacy[15]. This study also proves that cervical priming should be routine before surgical evacuation in case of missed abortion in whatever available way.

CONCLUSION

It is recommend that Foleys catheter is effective cervical priming agent and it has the advantages of simplicity, low cost and no systemic or serious side effects. The cervical priming prior to surgical procedure should be a routine process.

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