Original Article

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Efficacy of Amnitear vs. Conventional Method for Artificial Rupture of Membranes: A Prospective Study

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Amnitear is a newer device which is to be worn over gloved index finger for doing artificial rupture of membranes.

Aim: To evaluate the efficacy of Amnitear in doing Artificial Rupture of Membrane (ARM) and to compare the efficacy and safety of amnitear Vs the conventional method (kocher's clamp) in ARM.

Material & Methods: A prospective, single-blinded, randomized study was done to evaluate the efficacy of Amnitear Vs conventional method (kocher's clamp) for doing ARM. Patients with even Inpatient Department (IPD) number were grouped as 'A' (study group) in which ARM was done with amnitear & Group 'K' (control group) constituted the patients with odd IPD number in which ARM was done with conventional method (kocher's clamp). There were 60 patients in each group. Obstetrician comfort level was assessed by the experience felt by the concerned doctor; in terms of excellent, good and poor. Pain and discomfort felt by the patient during the procedure was assessed with the help of visual analogue scale scoring system.

Results: One hundered and twenty women in labour requiring ARM were randomized into 2 groups. The efficacy of Amnitear was assessed in terms of number of attempts required to successfully perform the procedure which showed a statistical significant difference (p=0.02) in the two groups. Obstetrician comfort level was significantly better in amnitear group. No statistically significant difference was seen in the pain and discomfort felt by the patient during both the procedure.

Conclusion: Amnitear appears to be an efficacious device to do the ARM.

Keywords: Amniotomy, Induction, Labour, Prostaglandin

INTRODUCTION

ARM is a common obstetric intervention to induce and augment labour [1]. ARM is also done when there is need to conduct internal monitoring of the foetus or to obtain amniotic fluid for visual inspection of blood or meconium. The mechanism of action behind amniotomy is the release of Prostaglandin E2 (PGE2) and rise in Oxytocin level [2,3]. Various methods which can be used for ARM are conventional methods like amniotomy forceps or kocher's clamp and newer instruments like amnihook or amnitear [4]. There is no head to head study comparing the conventional methods vs newer methods. The conventional methods are in use since decades but their usage is difficult in situations like, when membranes are flat or patient is in early labour. Latent Phase of labour starts from the onset of mild uterine contractions till 3 cm cervical dilatation and active phase of labour was defined as the interval after the latent phase to full cervical dilatation [5,6]. Amnihook or amnitear are the newer devices which may be used in such difficult situations where conventional methods are not much helpful. So, the availability of these user friendly newer devices may help in surgical induction in difficult conditions which may lead to decrease the caesarean section rate in the community. This led us to do a study with the aim to evaluate the efficacy of Amnitear in doing ARM and to compare the efficacy and safety of amnitear Vs the conventional method (kocher's clamp) in ARM.

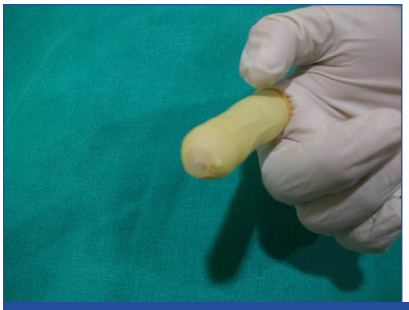
MATERIALS AND METHODS

It was a prospective, single-blinded, randomised study done in the labour room of Obstetrics and Gynaecology Department of Hamdard Institute of Medical Sciences & Research over a period of six months from Jan 2017 to July 2017. Purposive sampling was done. Informed written consent was taken from each patient in their own language. Ethical clearance was taken from the institutional ethical committee.

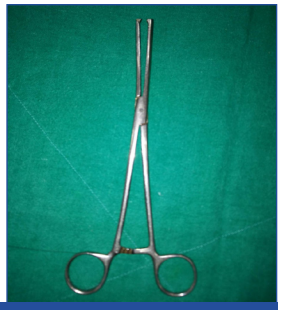
All the admitted term gestation patients in labour room requiring ARM for any indication whether in the latent or in the active phase were randomized in two groups using computer generated number. Patients with even IPD number were grouped as 'A' (study group) in which ARM was done with amnitear & Group 'K' (control group) constituted the patients with odd IPD number in which ARM was done with conventional method (kocher's clamp). Patients were managed according to the standard hospital protocols of the department and ARM was done according to obstetrical indication under all aseptic precautions. There were 60 patients in each group. Any patient in whom ARM was to be done for any indication with vertex presentation were included in the study. Routine precautions like fixing the head abdominally in cases of non-engaged head, slow drainage of liquor after procedure, foetal heart rate monitoring before and after the procedure were taken to prevent the complications like cord prolapse or abruption. Women who were having prior leaking or absent membranes and malpresentations like breech were excluded from the study.

In group A, after doing per-vaginum examination if the patient deemed fit for ARM, amnitear [Table/Fig-1] was worn over index finger. Index finger was slightly flexed so that direction of amnitear was away from vaginal walls. Once the middle finger was inside the cervix, index finger is straightened up to scratch the membranes. In group K, after doing per vaginum examination, kocher's forceps [Table/Fig-2] was introduced under the guidance of two fingers to prevent injury to the vaginal walls. On reaching into the cervical os, instrument was opened and membranes were scratched between the two jaws.

This study revealed the efficacy and safety of amnitear. Its outcome was compared in terms of patient's and doctor's comfort level in relation to kocher's clamp. Pain and discomfort during the



[Table/Fig-1]: Amnitear.



[Table/Fig-2]: Kocher's clamp.

procedure felt by the patient was assessed with the help of Visual Analogue Scale (VAS) scoring system [7]. Obstetrician comfort level was assessed by the experience felt by the concerned doctor in terms of excellent, good and poor.

STATISTICAL ANALYSIS

Data was entered on the Microsoft Excel sheet and SPSS version 20 was used to do the statistical analysis. Data was expressed as mean±SD, percentages and comparison was done using unpaired student t-test. Level of significance was taken as $p<0.05$.

RESULTS

This prospective randomized study included two groups (Group A & Group K) and both the groups were equally distributed in terms of baseline characteristics like age, religion, education, gravidity, parity & living issues to remove the bias. The demographic profile of the groups was comparable as shown in [Table/Fig-3].

	GROUP A (Study group) (60)	GROUP K (Control group) (60)	p-value
Mean age (years)	25.5±4.1	25.9±4.2	0.62
Religion			
Hindu	30 (50)	40 (66.7)	0.30
Muslim	30 (50)	20 (33.3)	
Education status			
Illiterate	6 (10)	8 (13.3)	1.00
Literate	54 (90)	52 (86.7)	
Gravida			
Primi	28 (46.7)	28 (46.7)	0.38
Two	16 (26.7)	26 (43.3)	
Three	8 (13.3)	2 (3.3)	
Four	6 (10.0)	4 (6.7)	
Five	2 (3.3)	0	
Parity			
Nulli	34 (56.7)	36 (60.0)	0.58
One	20 (33.3)	22 (36.7)	
≥Two	6 (10.0)	2 (3.3)	
Abortion			
0	38 (63.3)	48 (80.0)	0.32
1	16 (26.7)	10 (16.7)	
2	6 (10.0)	2 (3.3)	
Living issue			
0	34 (56.7)	38 (63.3)	0.57
1	20 (33.3)	20 (33.3)	
≥2	6 (10.0)	2 (3.3)	

[Table/Fig-3]: Baseline Characteristics of the control and the study group.

Number of attempts for ARM	GROUP A (60)	GROUP K (60)	p-value
1	56 (93.3)	38 (63.3)	0.02
2	2 (3.3)	10 (16.7)	
>2	2 (3.3)	12 (20.0)	
Doctors level of comfort (Subjective Perception)			
Good	10 (16.7)	48 (80.0)	<0.001
Excellent	50 (83.3)	2 (3.3)	
Poor	0	10 (16.7)	
VAS score			
Mean	3.3±1.8	5.0±2.0	0.69

[Table/Fig-4]: Comparison of different parameters in both the groups.

All the patients in group K (Kocher's clamp) were having contractions at the time of ARM whereas in group A, 8 (13.33%) were not having any contractions but this data was not statistically significant.

In Group A, 42 (70 %) patients were in latent phase and in group K, 26(43.3%) were in latent phase, rest of the patients were in the active phase. Forty (66.7%) were having bag of membranes in group A and in group B, 38 (63.3%) were having bag of membranes at the time when ARM was performed. But these differences were statistically insignificant. Among the women in which ARM was done in latent phase, none of the patients in group A and 20 women in group K required lithotomy position for the procedure.

A statistical significant difference was found in number of attempts in doing ARM and doctors level of comfort as shown in [Table/Fig-4]. The [Table/Fig-4] shows that the comfort level was significantly better in amnitear group as compare to kocher's group.

Patient pain perception was assessed with help of Visual Analogue scoring. Amnitear (Group A) group was having less mean VAS score in comparison of Kocher's group but this data was not statistically significant. Pain perception in women in which ARM was done in latent phase was also statistically insignificant in both the groups.

No complication like cord prolapse or abruption was noted in our study. But it requires careful introduction in the vagina so that it may not touch the vaginal walls as in one of the cases it caused vaginal bleeding while introduction and required stitching postpartum.

DISCUSSION

This is probably the first Indian study to assess the efficacy of amnitear. ARM is a common method used for inducing the labour and has been shown to be efficacious in reducing the duration of labour [1,8,9]. It has been shown to decrease the rate of dystocia and caesarean section. It is one of the most common obstetrical procedures performed in the labour room. It appears to be simple procedure but becomes tricky when it is to be done in early stages of labour and in uncooperative women even in best of the hands [10].

From the present study we can conclude that, among the options available for artificial rupture of membranes, Amnitear is having the following advantages over other conventional methods i.e., it can be used in cases of lesser cervical dilation, it causes less pain, discomfort and anxiety as compared with other more obtuse amniotic perforation instruments, increased accuracy as the clinician has greater tactile feedback and can more precisely apply the hook for membrane incision, eliminates the need for an assistant as the user's other hand is free to stabilize the presenting part, eliminates the need for patient to assume the lithotomy position when the cervix is posterior, sterile & disposable, low Cost (8 Rupees per

piece) and outer teardrop shape indicates orientation of hook. Although, no head to head analysis was done regarding the cost of the amnitear.

This is commonly used device in West but there are no studies to compare the efficacy on literature search. There is only one study by Harris M et al., where they have studied the effect in 100 women in established labour. They compared two devices currently used for amniotomy, the Amnihook, a long rigid instrument and the Amnicot, a finger stall with a plastic hook on the end. They found overall no difference in operator ease of use or maternal discomfort. There were significantly fewer babies with long scratches p=0.02, Odds ratio 0.19 (95% CI 0.05 to 0.68) and the mean scratch length was almost halved in the Amnicot group (p<0.05, 95% CI for difference between means 0.653 to 6.71) [11]. Women in labour are already in pain and as an obstetrician we should be having aim of decreasing the uncomfortable procedures. The introduction of this small device for doing the ARM can reduce this discomfort without increasing the cost and doesn't need any special expertise for performing the procedure. Amnihook is another device of similar efficacy but it is not available in India.

LIMITATION

The main limitation in our study was the small sample size. Doctor's level of comfort was assessed with a subjective scale. In our study we have remove this bias by doing all the number of cases in either group by a single doctor so interobserver bias was not present. However, when sample size will increase a scale will be needed for assessing doctors comfort level.

CONCLUSION

Amnitear is an efficacious device to do the ARM in labouring patient which reduces the women discomfort and has operator's ease as well.

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