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ORIGINAL ARTICLE

Comparison of Safety and Efficacy of Intrauterine Foley's Catheter Balloon and Uterovaginal Packing in Patients with Excessive Vaginal Bleeding after Vaginal Delivery

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ABSTRACT

Objectives: To compare the safety and efficacy of uterovaginal packing and Foley's catheter balloon tamponade in patients with excessive vaginal bleeding following vaginal delivery.
Design : RCT (Randomized Controlled Trial).
Setting : Obstetrics & Gynaecology Deptt. , HFH (holy family hospital) , RWP.
Duration: Six Months.
Materials & Methodology: 94 females who presented with excessive vaginal bleeding (> 500 ml) following vaginal delivery, 18 to 40 years of age , gestational age (GA) ≥37 weeks were included. Patients with retained products of conception, PPH due to perineal, cervical or vaginal tear and coagulation disorders were excluded. The patients were distributed equally into 2 groups ; a and b based on the lottery method. Group a was managed with uterine packing and Group b was managed by the Foley's catheter balloon tamponade. Efficacy and safety in both groups was measured.
Results: In my study, efficacy was significantly high in uterine packing group (Group a) compared to Foley's catheter balloon tamponade (group b) (89.36% versus 68.09%; respectively) with p-value of 0.012. In my study, safety was significantly high in uterovaginal packing group (Group a) compared to Foley's catheter balloon tamponade (group b) (72.34% versus 31.91%; respectively) with p-value of 0.0001.
Conclusion: Uterovaginal packing is more secure, prompt and efficient procedure to manage excessive hemorrhage after delivery compared to Foley's catheter balloon tamponade.
Keywords: Hemorrhage, uterovaginal packing ,foley's balloon tamponade.

INTRODUCTION

Obstetric emergency due to unexpected excessive vaginal bleeding after delivery , has been a matter of great concern. It is arguably the most preventable but still a major contributor to the maternal suffering and death in developing world like Pakistan.[1,2] It causes more than one lac deaths per annum ; majority of these occur within first 24hrs postpartum . In Pakistan , according to WHO, 34% females suffer from excessive bleeding postpartum.[3] According to Pakistan demographic & health survey (PDHS 2006-07), PPH is contributing for 27.2% maternal deaths in Pakistan.[4] Various potential causes are responsible for PPH, among these the mostly encountered is atonic uterus. Retained products of conception (RPOC's), ruptured uterus, cervical/ vaginal tears , uterine inversion and coagulation disorders constituite the other causes.[5] Risk factors of excessive bleeding after delivery include RPOC's , sepsis , hematocrit < 30% and coagulopathy .[6,7] Various drugs and surgical (both conservative & definitive) methods have been used to combat the situation .[8] An easy and efficient measure is to stop the postpartum hemorrhage due to uterine atony , is with utero-vaginal packing as it is prompt & underlying mechanism is direct compression of site of hemorrhage. Moreover, it also helps in stabilizing the mother till theatre is arranged , though it might preclude any intended surgical procedure at all .[9,10]

In modern obstetrics , intrauterine balloon tamponade (IUBT) in management of postpartum hemorrhage, is an innovative technique. A Foley's cather is introduced into the cavity of uterus and inflated with normal saline to produce direct compression .[11] Among different types of balloons ; the Bakri , the Roush , the Sengstaken–Blakemore , and Foleys catheters have been used. It is easy to train providers about its use, and its prompt insertion can stop bleeding effectively .[12] Recently, Rezk M et al in their study found success of uterovaginal packing to be >90% while 69 % in the other group ($p < 0.05$).[13] In a study, Ashraf N and colleagues determined the efficacy of uterine packing for controlling PPH and they observed the success rate in 59.4% of patient while fever was noted in 92.5% of patient.[14] On the other hand, Ali MK et al found that Foley's catheter found effective in 88.2% of cases.[15]

Use of both uterine packing and balloon catheters for controlling PPH is common in obstetric practice. Previously, scarce data is available that compared the Foley's catheter with uterine packing. This research aims to compare the efficacy of both these two management options in terms of controlling PPH and associated complications like fever in our local population. This would help the obstetricians to determine which management option is better for controlling PPH , that will eventually aid in lessening the number of maternal deaths due to PPH.

MATERIALS AND METHODOLOGY

Design: Randomized controlled trial (RCT).
Setting: Obs & Gynae Deptt., Holy Family Hospital (HFH), Rawalpindi.
Duration of Study: Six Months.
Sample Size: The sample size is determined as follows:

Level of significance (α):	5%
Test power :	90%
Anticipated Population proportion I:	59.4%[14]
Anticipated Population proportion II:	88.2%[15]

Sample size was n = 94 total patients (47in both groups)
Sample technique: Non-probability, consecutive sampling.
Sample Selection:
a. Inclusion Criteria:
a. All those females b/w 18 – 40 yrs , who had excessive vaginal bleeding following vaginal delivery (> 500 ml)
b. GA ≥ 37 wks.
b. Exclusion Criteria:
a. Postpartum hemorrhage due to perineal, cervical /vaginal tear or retained placenta.
b. Patients with previous cesarean section and coagulation disorders.
Data collection procedure: Ethical clearance was obtained from hospital ethical committee before starting the study. Patients with postpartum hemorrhage following vaginal delivery and fulfilling study inclusion criteria were enrolled from the indoor gynecology department of Holy Family Hospital, Rawalpindi. After taking

informed consent , the demographic and baseline characteristics were recorded. A complete physical examination of the patient was done and laboratory investigations as well as ultrasound was performed. The patients were segregated into 2 groups A & B by lottery method. Group a was managed with uterine packing and Group b was managed by the Foley's catheter balloon tamponade. In Group a patients, uterine packing was opted. Additional packing of vagina was also done to give a firm compression. Aseptic technique was used . While in Group b patients, 2-way Foley's catheter balloon was inserted transvaginally and was inflated with sterile 100ml saline until the uterine fundus was firmly palpable or no bleeding occurred through the cervix . Antibiotics were given to prevent infection for at least 48 h after of either treatment. Pulse, B.P , any vaginal bleeding was assessed every 30 min. Temperature was measured every 2 hours. After 24 h, the Foley's catheter balloon was deflated slowly and uterine pack was removed. All the procedures were performed by the researcher to maintain accuracy and to avoid bias ,remaining compliant to set protocols. The relevant data was recorded on the predesigned proforma .

Statistical analysis: SPSS software version 17 , was used to analyze the data. Continuous numerical variables like maternal age, GA & Body Mass Index (BMI) were described as Mean ±SD. Categorical variables like labor pain , efficacy and onset of fever were presented as frequency and percentage in both groups. Efficacy and safety was compared by using Chi-square test. P-value of ≤ 0.05 was significant.

Effect modifiers like Maternal Age, BMI, gestational age & labor pain were stratified . After then, chi-square test was used and P- value of ≤0.05 was considered significant.

RESULTS

Age range was from 18 to 40 yrs with Mean of 30.03 ± 3.21 yrs. In group a, it was 30.53 ± 4.16 yrs while it was 29.51 ± 3.23 years in the other group.

Mean gestational age in Group a was 39.09 ± 2.35 wks and in Group b it was 38.98 ± 2.38 wks (Table II). Mean BMI in group a was 28.70 ± 2.58 kg/m^2 and in group b, it was 28.98 ± 1.99 kg/m^2 (Table III). Distribution of patients according to labor pain status is depicted in Table IV.

My research found a significantly high efficacy in uterine packing group (Group a) compared to Foley's catheter balloon tamponade (group b) (89.36% versus 68.09%; respectively) with p-value of 0.012 (Table V). In my study, safety was significantly high in uterine packing group (Group a) compared to Foley's catheter balloon tamponade (group b) (72.34% versus 31.91%; respectively) with p-value of 0.0001 (Table VI).

Stratification of efficacy with respect to age, GA, BMI & labour pain status is presented in Table VII. While safety with regards to Age, GA, BMI & labor pain status is stratified and is presented in Table VIII.

Table-I: Age distribution (94).

	group a (n=47)		group b (n=47)		(n=94)	
Age (yrs)	Number of pts	%	Number. of pts	%	No. of patients	%
19-30	20	42.55	27	57.45	47	50.0
31-40	27	57.45	20	42.55	47	50.0
Mean ± SD	30.53 ± 4.16		29.51 ± 4.23		30.03 ± 4.21	

Table-II: Allocation of pts acc to GA .

GA (weeks)	group a (47)		group b (47)		t= (94)	
	Number of pts	%	Number of pts	%	Number of pts	%
37-39	28	59.57	30	63.83	58	61.70
40-41	19	40.43	17	36.17	36	38.30
Mean ± SD	39.09 ± 1.35		38.98 ± 1.38		38.95 ± 1.31	

Table-III: Allocation of pts acc to BMI .

BMI (kg/m^2)	group a (47)		group b (47)		t= (94)	
	Number of pts	%	Number of pts	%	Number of pts	%
≤27	18	38.30	13	27.66	31	32.98
>27	31	61.70	34	72.34	65	67.02
Mean ± SD	28.70 ± 2.58		28.98 ± 1.99		28.92 ± 2.33	

Table-IV:Allocation of pts acc to labour pain status.

Labour pain status	group a (47)		Group b (47)		t (94)	
	Number of pts.	%	Number of pts.	%age	Number of pts.	%
Yes	24	51.06	20	42.55	44	46.81
No	23	58.94	27	57.45	50	53.19

Table V: Relationship of efficacy (94).

	group a (47)			group b (47)	
	Number of Pts		%	Number of Pts	%
EFFICACY	Yes	42	89.36	32	68.09
	No	05	10.64	15	31.91

➢ P value is 0.012

Table VI: Relationship of safety (94).

		group a (47)		group b (47)	
		Number of Pts.	%	Number of Pts.	%
SAFETY	Yes	34	72.34	15	31.91
	No	13	27.66	32	68.09

P value is 0.0001

Table VII: Efficacy stratified with respect to age, gestational age, BMI and labour pain status.

		group a (47)		group b (47)		P-value
		Efficacy		Efficacy		
		Yes	No	Yes	No	
Age (years)	18-30	18	02	17	10	0.036
	31-40	24	03	15	05	0.210
Gestational age (weeks)	37-39	25	03	19	11	0.021
	40-41	17	02	13	04	0.296
BMI (kg/m^2)	≤27	18	00	07	06	0.001
	>27	26	05	25	09	0.311
Labour pain	Yes	21	03	13	07	0.076
	No	21	02	19	08	0.065

Table VIII: Safety stratified with Age, GA, Body Mass Index and labour pains.

		group a (47)		group b (47)		P value
		Safety		Safety		
		Yes	No	Yes	No	
Age (years)	18-30	18	02	08	19	0.0001
	31-40	16	11	07	13	0.100
Gestational age (weeks)	37-39	23	05	10	20	0.0001
	40-41	11	08	05	12	0.086
BMI (kg/m^2)	≤27	12	06	02	11	0.005
	>27	24	07	13	21	0.001
Labour pain	Yes	18	06	05	15	0.001
	No	16	07	10	17	0.022

DISCUSSION

Hemorrhage is a leading cause of maternal death . Excessive bleeding in postpartum period is an obstetrical emergency, which requires early identification and prompt management.[16] A multidisciplinary approach involving a senior obstetrician, a senior anesthetist and a senior hematologist is pivotal .Priority is to save uterus if the family is not complete.[17]Recently alternatives to hysterectomy, have been devised if medical treatment seems ineffective.Options are; uterine packing , B LYNCH suture, and stepwise devascularisation .[18,19]

The main purpose of the current research was to compare the safety and efficacy of uterovaginal packing and intrauterine inflated Foley's catheter insertion in patients with postpartum hemorrhage following vaginal delivery. In my study, efficacy was significantly high in uterine packing group (Group A) compared to Foley's catheter balloon tamponade (group B) (89.36% versus 68.09%; respectively) with p-value of 0.012. In my study, safety was significantly high in uterine packing group (Group A) compared to Foley's catheter balloon tamponade (group B) (72.34% versus 31.91%; respectively) with p-value of 0.0001 while comparing effectiveness, hemorrhage was controlled in 93.3% of uterovaginal packing cases compared to only 68.1% in the other group ($p < 0.05$).[13] In a study, Ashraf N and colleagues determined the efficacy of uterine packing for controlling PPH and they observed the success rate in 59.4% of patient while fever was noted in 92.5% of patient.[14] On the other hand, Ali MK et al found that Foley's catheter found effective in 88.2% of cases for controlling PPH while fever was noted in 26.7% of cases.[15]

Ali et al in a research recruited 42 patients with PPH. Uuterovaginal packing was done in 36 (86%) patients .Procedure failed in 7 (14.2%) patients. Hysterectomy was sequel in 8 % patients, while there was 1 maternal death .[20] Roman and Rebarber et al, found it significantly successful . Fever was clinically non-significant.[21] Mobusher I. et al, found uterovaginal packing efficient in 87.5% while in 4 cases hysterectomy was required.[22]

Success of foley's in management of PPH has been depicted in many case reports and case series.[23] Diemert A et al[24] noticed that up to 60% of patients with PPH responded very well to uterovaginal packing by direct compression of bleeding site & it was quick and effective method of securing homeostasis in a large number of cases.[25]Makosso M et al[26] has shown its success up to 91.9% in postpartum hemorrhage management.

Past research has proposed that intrauterine balloon cathter insertion should be preferred in the managing postpartum hemorrhage.[21-26]. Doumouchtsis et al[27] found it effective in 85% of cases. Among recent research work , Laas et al[28] noted it efficient in 86% of patients . All these studies have shown very much comparable success rates of balloon inflation to our study.

Hsu et al[29] reported success in 9 patients,in 1 patient packing failed resulting in postpartum hysterectomy. No associated untoward ailing was noted.

A research work in Dow University Pakistan concluded that uterovaginal packing be practiced at tertiary hospitals to avoid hysterectomy .[30] A study[31] reflected that uterovaginal packing is a secure, prompt and efficient procedure in controlling excessive bleeding due to atonic uterus and obviate the need of hystrectomy. Success rate was 85%.This simple technique should be practiced in centres with limited operative obstetric facilities.[32]

My study has shown that uterine packing in primary postpartum hemorrhage control is more effective than foley's in younger age group. Similar findings were also found in many previous studies.[33-37] In other study, impact of mode of delivery, parity and underlying cause of PPH on the outcome was statistically not significant with p-values of 0.461, 0.128 & 0.165 .[38] Similar statistical non-significance has been stated in the study by Fatima N, et al in 2008[39] for the above mentioned variables, with p-value of 0.91, 0.49 and 0.91 respectively.

CONCLUSION

Uterovaginal packing is an easy , cost effective , prompt and efficient procedure to control excessive vaginal bleeding . It is more safe & secure than Foley's catheter balloon. It is, therefore , recommended that in patients who suffer from heavy vaginal bleeding after delivery due to atonic uterus, uterine packing as a preliminary step can save lives as well as fertility of mothers.

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