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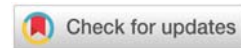
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Research Article

Comparison of blood loss between saline infiltration and no infiltration dissection during vaginal prolapse surgery -randomized controlled trial

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Abstract

Background: Pelvic organ prolapse is common among women above 50 years. The literature on intraoperative interventions to reduce blood loss during vaginal prolapse surgery is very limited. Vasopressin infiltration, shown to reduce blood loss during non-descent vaginal hysterectomy, has adverse effects.

Objectives: To compare blood loss between saline hydrodissection and no infiltration native tissue surgery for pelvic organ prolapse.

Methods and Materials: Settings and Design: Randomized controlled trial conducted in the Department of Obstetrics and Gynaecology of a tertiary care teaching hospital in South India. Women with stage 2 or higher prolapse involving at least two components, undergoing vaginal hysterectomy and reconstruction were included. Block randomization was used to study 22 women in each group. 60-80ml saline was instilled in sub-mucosa before vaginal wall dissection. The mean actual, average, and clinically estimated blood loss in the two groups during surgery was compared by Mann Whitney test.

Results: The mean age, stage of prolapse, and duration of surgery were comparable in the two groups. The Saline group had significantly higher parity, lower preoperative haemoglobin and a higher mean Ba point. Average blood loss was significantly lower in the saline dissection group 294.8 (+96.87) ml compared to 507.31(+348.37) ml in the no infiltration group ($z=-2.04$ $p=0.04$).

Conclusions: Saline dissection significantly reduces blood loss by approximately 200 ml in comparison to dissection with no infiltration without increasing any intra-operative and post-operative complications. We recommend its use during vaginal surgery for stage 2 or more uterovaginal prolapse involving more than one component

Key Messages: saline infiltration in vaginal submucosa before dissection significantly reduces blood loss (by 200ml) compared to no infiltration traditional dissection, during vaginal prolapse surgery with native tissue.

Clinical Trial Registry of India (CTRI) registration reference number: CTRI/2017/10/010193.

Introduction

The lifetime risk of surgery in POP is 11%–19% [1,2]. 16%–32% of hysterectomies in India were reported to be for pelvic organ prolapse [3,4]. Advanced stage Prolapse requires surgery. Vaginal hysterectomy and reconstruction with native tissue repair and McCall's culdoplasty for cases with apical prolapse

for vault fixation are considered a standard and preferred operation [5–10].

Most of these patients undergoing surgery are multiparous, belong to lower socioeconomic status and due to poor nutritional status are likely to be anaemic [11]. So, any strategy to prevent blood loss during surgery has an important long-term advantage.

Vasopressin infiltration has been studied in non-descent vaginal hysterectomy and found to reduce blood loss. Vasopressin is known to cause hemodynamic instability [12–14]. This becomes an increased concern if the women undergoing surgery are also hypertensive. In a survey conducted among the members of the Dutch urogynaecology society, 101 (76%) members were using hydrodissection for anterior colporrhaphy, and the majority use adrenaline along with either saline or local anaesthetic [15]. There are very few published studies on interventions to reduce blood loss during vaginal prolapse surgery. In a study on colpocleisis razor dermatome dissection was found to be faster and associated with lesser bleeding among women undergoing colpocleisis for prolapse [16].

Objectives

This trial aimed to compare the intra-operative blood loss with saline hydro dissection and no infiltration dissection during vaginal surgery for prolapse. We also studied the intraoperative or postoperative complications in the two groups.

Methods

Design and setting

This parallel arm randomized controlled trial was conducted from November 2017 to May 2019 in the Department of Obstetrics and Gynaecology at a tertiary care hospital and teaching institute of national importance, located in Pondicherry in the South of India. Institute Ethics Committee approval was obtained and prospective registration with Clinical Trial Registry of India (CTRI) was done. (Reference: CTRI/2017/10/010193).

Participants

The study population included women between 40 and 75 years of age with pelvic organ prolapse undergoing vaginal surgery that included a hysterectomy and at least one more compartment (anterior or posterior colporrhaphy) repair. We included only those operated by senior registrar or consultants. Cases of recurrent prolapse, non-descent vaginal hysterectomy intraoperative blood loss due to slippage of ligature, conservative surgery for prolapse, abdominal vaginal repair surgery for prolapse, additional procedures like Tension-free Vaginal Tape (TVT) or sacrospinous ligament fixation (SSLF), were excluded from the study.

Two groups were studied

Study group- vaginal hydro dissection with saline. (Saline group).

Control group- vaginal dissection without any infiltration. (No infiltration group).

Sample size calculation

Given that the blood loss with no infiltration dissection surgery is 500ml + 200ml as per estimate based on our hospital

records, and that saline hydro dissection can bring down the loss by 30% to 350 +150ml (Potter et al)(14) observed 330ml blood loss at vaginal hysterectomies with saline dissection. Data for prolapse surgery is not available in the literature), the sample size needed was 22 in each group for 80% power and 5% alpha error using open EPI version 3.

Randomization details

Block randomization was done using varying blocks generated via computer using randomization software. The allocation (1:1) was done by serially numbered opaque sealed envelopes generated by personnel from department of preventive and social medicine. The envelope was opened by the circulating staff in the operating room before the operation. There was no blinding but the blood loss was estimated by the principal investigator only for all cases.

Study procedure

The women who fulfilled the inclusion criteria were recruited. Written informed consent was given by all the participants included in the study. Demographic details like age, residence, socioeconomic status were collected. Medical comorbidities were noted. The preoperative prolapse staging (Pelvic Organ Prolapse Quantified {POP-Q}) was recorded as per proforma. Preoperative investigations including haemoglobin and haematocrit were done 24 hours before surgery. Vaginal packing for decubitus ulcer, and oestrogen cream for thin vagina, etc was individualized and carried out before recruitment. Preoperative preparation like enema, parts preparation by shaving just before surgery, and antibiotic prophylaxis was followed as per the departmental protocol. Vaginal hysterectomy and site-specific native tissue pelvic floor were done for all the cases. The Apical procedure of McCall's culdoplasty was carried out in all women after hysterectomy. If however, the suspension was not found to be satisfactory (vault less than 2 cm inside the introitus at the end of the surgery under the anaesthesia), then we proceeded with sacrospinous ligament fixation. Such cases were excluded from the study.

After cleaning and draping, the women randomized to the study group received 60– 80 ml of saline injection into the submucosa of the anterior and posterior vagina before incision and dissection. Saline was not injected into the parametrium or cervix. Vaginal hysterectomy and native tissue repair were done for all. An additional 60 ml was instilled for posterior vaginal wall dissection when the dissection was needed after hysterectomy. The saline infiltration was done by the chief surgeon with a 20 gauge needle. The usage of electrocautery was deliberately avoided in both arms.

Intraoperative anaesthesia details like type of anaesthesia, any hypotension, intravenous fluids, and blood transfusion were noted.

Clinically estimated blood loss was calculated by the weighing method (measuring the difference in the weight of the dry and the soaked gauzes, mops, soaked linen, and gowns). Besides, the floor spill was considered as 500, 1000, and 1500ml loss for 50, 75, 100cm floor spills. Kidney dish and Suction bottle collection were also measured.



The patients were followed up by post-operative haematocrit (hct) done 24 hours after surgery.

Actual blood loss was calculated by modified Gross formula [17]

Actual blood loss= blood volume [hct (i)-hct (f)]/ hct average]. hct (i) is the initial haematocrit 24 hours before surgery, hct (f) is the final haematocrit 24 hours after surgery. Blood volume = body weight in Kg x 70ml. Average blood loss was calculated by the mean of Actual blood loss and clinically estimated blood loss [18]. Patients were followed up till discharge for any complications like fever, infection, and reactionary or secondary haemorrhage.

Primary outcome measure

Comparison of intraoperative blood loss. The secondary measure was any intraoperative and postoperative complications. There was no change in the methods after trial commencement.

Statistical analysis

Categorical variables like parity, menopausal status, types, and stages of prolapse, etc. were expressed in terms of frequency and percentage, and the chi-square test was used as a statistical test. Continuous variables like age, blood loss during surgery, etc. were expressed in terms of mean with standard deviation or median with a range based on the distribution of data, and unpaired t-test /Mann Whitney test was used as a statistical test. All the statistical analysis was carried out at a 5% level of significance with a p-value < 0.05 considered as statistically significant.

Results

Sixty-six women were assessed for eligibility (Figure 1). Forty-Four women completed the study (Twenty-two in each arm) and the study was stopped. All forty-four women had symptoms of vaginal bulging. Thirteen (54.2%) participants of the saline and 11 (50%) of the no infiltration group had urinary symptoms. The commonest urinary problem was difficulty at initiation and need to manually reduce prolapse to void. There was no case of urinary retention or urinary incontinence. Only one of the study participants had a previous caesarean section. All women were multiparous.

Most of the parameters like age, weight, menopausal status, and comorbidities were comparable in the two groups. However, there was a significantly greater number of women with higher parity and lower mean haemoglobin in the saline hydro dissection group, though the difference in the mean haemoglobin between the two groups was only 0.8gm/dl (Table 1). All the participants had anterior, posterior, and apical compartment defects except one woman in the no infiltration group who had only apical and anterior compartment without posterior compartment prolapse. The prolapse stage and the mean descent of all points of POPQ classification were comparable in the two groups except the mean descent of point Ba alone was significantly higher in the saline compared to the no infiltration group (Table 2).

The blood loss (Table 3) was analysed under three headings of clinically estimated, actual and average blood loss based on the formulae explained in the material section. The blood loss did not follow a normal distribution, so the difference was analysed using the Mann-Whitney U test. We observed that the average blood loss was significantly lower in the saline 294.8(+196.87) ml compared with the no infiltration group 507.31(+348.37) ml (Z=-2.04 P=0.04). The mean operation time was comparable in the two groups.

Table 1: Summary of socio-demographic and clinical profile of the two groups.

Demographic details	Saline group (n=22)	No infiltration group (n=22)	P-value
Age (Mean ± SD *) (years)	61.4±9.32	54.68±11.92	0.052
Weight (mean ± SD*) (kg)	49.27±6.52	49.27±5.36	1.0
Occupation N (%)	Housewife	17(77.3)	0.18
	labourer	1(4.5)	
Socioeconomic class N (%)	Middle class	1(4.5)	0.345
	Lower class	18(81.8)	
Postmenopausal	19(88.4)	16(72.7)	p=0.2
Parity N (%)	P2	11(50)	x ² = 9.031 P = 0.02*
	>P2	17(77.3)	
Diabetes	5(22.7)	6(27.3)	
hypertension	5(22.7)	6(27.3)	
Pre-op Hemoglobin [‡] (gm/dl) (mean ± SD*)	10.74±1.35	11.5±1.19	t =-2.04,P=0.05*
History of prolonged labour N (%)	4(18.2)	3(13.6)	
Delivery of macrosomia baby. N (%)	3(13.6)	2(9.1)	

t= standard deviation, ‡= Hemoglobin, *- Significant

Table 2: Details of POP-Q classification of the study participants.

		Saline group (n=22)	No infiltration group (n=22)	P-value
Stage of prolapse n (%)	Stage 2	2 (9.1)	3(13.6)	0.173
	Stage 3	13(59.1)	17(77.3)	
	Stage 4	7(31.8)	2(9.1)	
Anterior compartment	Aa (mean±SD*) cm	2.045±1.21	1.86±1.037	0.399
	Ba (mean±SD*) cm	4.65±2.18	3.49±1.46	t=2.22 0.032*
Posterior compartment	Ap (mean±SD*) cm	0.36±2.08	0.136±1.67	0.728
	Bp (mean±SD*) cm	2.52±2.48	1.36±2.01	0.14
Apical compartment	C (mean±SD*) cm	5.38±2.72	4.27±2.2	0.144
	D (mean±SD*) cm	0.86	-0.14±1.00	0.318

† SD- Standard deviation.* t=student's t-test value, significant

Table 3: Blood loss and operative duration in the two groups.

Blood loss	Saline group (n=22)	No infiltration group (n=22)	P value
Clinically estimated (mean±ScD [†]), ml	158.62±118.72	310.71±228.85	Z=-2.58 P=0.01*
Actual (mean±SD [†]), ml	428.26±310.72	703.57±525.39	Z=-1.69 P= .091
Average (mean±SD [†]), ml	294.8±196.87	507.31±348.37	Z=-2.04 P=0.04*
Operating time (minutes)	137.4±45	145.8±51.6	z=-0.58 P=0.56

t= Standard deviation, *= significant

Spinal anaesthesia was the most common type of anaesthesia, it was used in 38 (86.4%) out of the 44 participants. Epidural anaesthesia was used in two (9.1%) participants of the hydro dissection group. Spinal along with general anaesthesia was used in one (4.5%) participant of the study and three (13.6%) participants of the control group. Intravenous fluid infused during surgery was comparable in the two groups.

There was one case of rectal mucosa injury in the no infiltration dissection group. It was managed by primary repair by the surgeons through the vaginal route. The patient recovered well.

There was no significant pyrexia, reactionary haemorrhage, vault infection, or vault hematoma formation in either group. Four participants in all (two in each group) received a blood transfusion. None of the women in either group required prolonged hospitalization. All were discharged home by day five or six of surgery.

Discussion

This randomized controlled trial was carried out in a tertiary care teaching hospital. Forty-four women (22 each in the two groups) were recruited and completed the study. All were multiparous women and delivered vaginally. Though the saline group had higher parity, higher mean descent of point Ba, a higher proportion of anaemic women, we found that saline dissection significantly reduces clinically estimated and average blood loss by approximately 200ml compared to no infiltration dissection.

Obesity is a known risk factor for POP. However, in our study, the mean weight of the study participants was 49.27 kg. In our study, nearly 90% of the women were from low socioeconomic status with poor nutrition and weight. Low nutritional status is likely to affect tone, elasticity, and collagen status of pelvic tissues [19] and could, therefore, aggravate prolapse in multiparous women. Anemia is a common problem above 50 years of age in our country especially in low socioeconomic status because of poor nutrition. 70% of study participants in our study had hemoglobin lower than 12gm%.

Our study was conducted in patients with stage 2 or more prolapse involving the apical compartment and at least one more compartment. All of them underwent vaginal hysterectomy with pelvic floor repair. We observed in our study that clinically estimated and average blood loss was significantly lower in the saline dissection group. Actual blood loss takes haematocrit as an important component of the calculation. The difference in the actual blood loss of 275ml is clinically significant though it did not reach statistical significance probably because the women in the saline group in our study were significantly more anaemic with lower haematocrit at recruitment compared to the women in the no infiltration group.

We searched PubMed, Google Scholar, and Cochrane databases. There are no randomized trials comparing saline dissection with no infiltration dissection. There are only two studies on hydro dissection for vaginal surgery for prolapse. A study compared no infiltration dissection and hydrodissection

with epinephrine [20]. The authors studied 22 women in each group. This study was published only as an abstract. These authors observed that the operative bleeding was significantly lower in the hydro dissection group with epinephrine 240.9(+111.9) ml compared with no infiltration 324.1(+104.9) ml. The study details, the method of estimation of blood loss, and randomization details are not available. The duration of surgery in their study was 135 and 139 minutes in the study and the control group respectively our study compares well with their study.

In a randomized controlled trial [21], the authors found that hydro dissection with vasoconstrictor ornipressin (n=40) significantly reduced median blood loss by 35ml compared to women subjected to saline hydro dissection (n=36). The above-mentioned study used only clinical estimation of blood loss by the weighing method. The mean operative duration in their study was 76.5 minutes in the intervention and 81.2 minutes in the control group. They had studied women undergoing vaginal surgery for any compartment prolapse. One-third of the participants in their study had prior prolapse surgery and one-fourth of the woman in both the groups had already had a hysterectomy prior and the population included stage 1 prolapse also. One-fourth of their study population had undergone single component prolapse surgery. This could explain the lower duration of surgery and the lower median blood loss in their study.

The use of vasoconstrictor for reducing blood loss at non-descent vaginal hysterectomy has been studied. The systematic review done in 2017 recommends injecting vasopressin intracervical at the start of non-descent vaginal hysterectomy to decrease blood loss [22]. Intra-cervical injection of vasopressin brings about vasoconstriction.

The maximum blood loss in vaginal prolapse surgery occurs while incising and dissecting the vagina from the urinary bladder in front and from the rectum behind during native tissue colporrhaphy. Injection of saline in the submucosa before incision of the vagina, as done in our study, forms a bleb that helps in separating and identifying the planes while dissecting the vagina. Saline in the submucosa reduces bleeding by pressure on small vessels. The systematic review on preoperative interventions before prolapse surgery [23], has reported the findings of the only RCT [21] published and even though the reduction in blood loss was not clinically significant, yet they recommend sub mucosal vaginal injection with ornipressin to have a cleaner surgical field during vaginal prolapse surgery but at the risk of causing hypertension.

In our study, we found that blood loss can be significantly reduced (up to 200ml) with the use of saline in comparison to that with no infiltration dissection. This is an especially important finding as saline is easily available and does not cause any cardiovascular compromise. Vaginal surgery for uterovaginal prolapse is a common surgery performed in the elderly age group, especially in our country. These women are likely to be anaemic. In the Dutch survey [15] whereas 70% used hydrodissection for anterior colporrhaphy, only 41 % used saline alone for hydro dissection. In a study from Japan, 98%

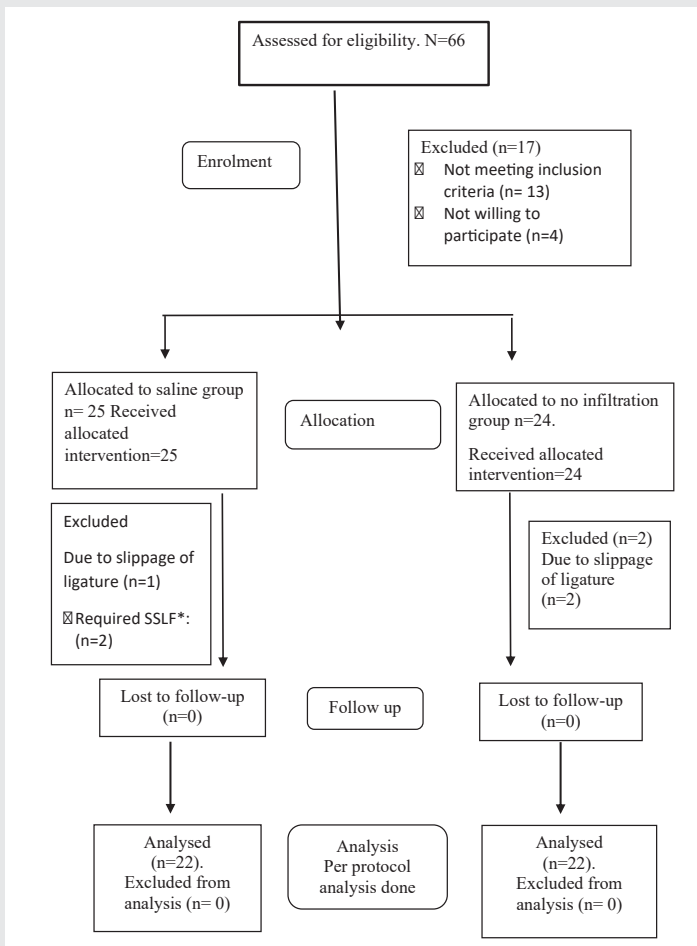


Figure 1: Consort diagram.

urologists and urogynecologists preferred hydrodissection for transvaginal mesh placement and 69% preferred full thickness scissors dissection [24]. In our centre saline dissection is not routine adopted for prolapse surgery. Our hospital is a tertiary care teaching institute. This might be because most are done by general gynecologists and there are limited published randomized trials on hydrodissection in prolapse surgery.

We recommend that saline dissection should be adopted to reduce blood loss in all women undergoing vaginal surgery for prolapse.

Strengths and limitations of the study

It was a randomized control trial. Minimal selection bias since all cases and controls had either stage 3 or stage 4 prolapse according to POP-Q. Complicated cases like recurrent prolapse, previously operated or combined incontinence procedures were not included in the study. So, a homogenous group of stage 2 or above prolapse was studied. Clinical blood loss was estimated for all cases by the principal investigator thereby minimizing the observer variation in measuring blood loss. Though the surgeon was not blinded the blood loss was calculated by the researcher, not the surgeon. The limitations of our study are that even though the surgeries were performed by qualified gynaecologists but the experience of the surgeons was variable from two to twenty years post-degree. This resulted in a wide variation of blood loss. The proportion of women with

anaemia was significantly higher in the hydro dissection group. This could have altered the haematocrit which would have influenced the calculation of actual blood loss. Hence, we didn't get a statistical difference in actual blood loss, even though clinically estimated blood loss and average blood loss were statistically lower in the saline dissection group.

Conclusion

Saline hydro dissection significantly reduces blood loss during vaginal surgery for stage 2 or more pelvic organ prolapse involving more than one component, by approximately 200 ml in comparison to no infiltration before dissection, and it does not add to any intra-operative or post-operative complications. We recommend that it should be universally practiced for vaginal prolapse surgery.

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