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Is performing sacrospinous fixation with vaginal hysterectomy and McCall's culdoplasty for advanced uterovaginal prolapse preferable over McCall's culdoplasty alone?

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Abstract

Purpose of study Advanced uterovaginal prolapse can significantly affect the quality of life in women and usually requires surgical management. McCall's culdoplasty (M) or sacrospinous fixation (SSF) are done at the time of vaginal hysterectomy with pelvic floor repair (VHPFR) to reduce recurrence, but recurrence rates of 15% and 33% have been reported with these procedures respectively. We hypothesize that combining VH-PFR with both McCall's culdoplasty and sacrospinous fixation (VH-PFR-M-SSF) may decrease recurrence rates compared to VH-PFR-M without significantly affecting other perioperative outcomes.

Methods All patients with advanced uterovaginal prolapse and willing for VH-PFR at our institute from January 2015 to March 2018 were included after informed consent, except for medically unfit women and those preferring alternative management. We conducted a case control study comparing VH-PFR-M and VH-PFR-M-SSF with a follow-up period of 24 months. Qualitative and quantitative data were statistically analysed and Odds ratio and 95% Confidence interval was calculated. Kaplan Meier Curve was drawn and Log Rank test was used to compare recurrence.

Results Out of 174 patients who underwent surgery in the study period, 131 patients (75.28%) underwent VH-PFR-M and 43 patients (24.71%) underwent VH-PFR-M-SSF. Both groups were comparable for age, body mass index, parity, postmenopausal status, comorbidities and aggravating factors. Patients with higher stage of prolapse were more in group 2 ($p < 0.001$). There were no intraoperative complications or postoperative surgical interventions in either group. The duration of surgery was not significantly different. Change in haematocrit was more in group 2 but no patient required blood transfusion. There was no statistically significant difference in recurrence rates between the 2 groups.

Conclusion The procedure (VH PFR M-SSF) is safe and affordable with good results in Stage 3 with advanced bulge and stage 4 prolapse.

Keywords McCall's culdoplasty · Sacrospinous fixation · Uterovaginal prolapse · Vaginal hysterectomy · Recurrence

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Introduction

Pelvic organ prolapse (POP) is a common problem affecting the quality of life especially of perimenopausal and post-menopausal women. Advanced uterovaginal prolapse usually requires surgical management. Vaginal hysterectomy with pelvic floor repair (VH-PFR) is the most common surgical procedure performed for prolapse.

McCall's external and internal culdoplasty (M), where the vagina is transfixed to both the uterosacral ligaments and peritoneum, may be added to VH-PFR to reduce the recurrence rate (VH-PFR-M). Some centres perform sacrospinous fixation (SSF) with VH-PFR, where the vagina is transfixed to the sacrospinous ligament to reduce recurrence

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(VH-PFR-SSF). Thus, M or SSF is done independently with VH-PFR as a prophylactic measure to reduce the chances of recurrent prolapse. The literature suggests a high recurrence rate with VH-PFR-M (15%) and VH-PFR-SSF (33%) [1]. Owing to recent U.S. Food and Drug Administration warnings about mesh-related complications, it is important to explore other techniques that would reduce both recurrence rate and complication rate [2].

VH-PFR-M is done at our institute routinely for the management of advanced prolapse. We hypothesised that by combining unilateral SSF with McCall's culdoplasty while performing VH-PFR (VH-PFR-M-SSF), there will be further reduction in recurrence rates even in more advanced prolapse. Hence, unilateral SSF on the right side was added to the conventional procedure (VH-PFR-M) in patients with stage 3 prolapse having prominent bulge symptoms and stage 4 prolapse as prophylaxis to prevent recurrence.

Materials and Methods

We conducted a retrospective cohort study to compare the two groups (VH-PFR-M and VH-PFR-M-SSF) for recurrence and complications with a follow-up period of 2 years.

All the patients who presented to our institute with advanced uterovaginal prolapse and who were medically fit and willing for VH-PFR from January 2015 to March 2018 were included. A total of 174 patients were included in this study of which 131 patients underwent VH-PFR-M (Group 1) and 43 patients underwent VH-PFR-M-SSF (Group 2).

A patient was termed post-menopausal if they had a period of at least 12-month amenorrhoea from their last menses. Aggravating factors including parity, mode of delivery, difficult delivery, chronic cough or allergy, constipation, heavy work, obesity, comorbidities, family history and prior surgeries were considered. The duration of the presenting symptoms along with associated bowel and bladder complaints like incomplete voiding, difficulty in voiding or defecation, urgency, incontinence, etc., was noted.

Staging was done by simplified POP-Q system [3]. Four points Ba, Bp, C and D were considered, where Ba and Bp were the lowest points of anterior and posterior vaginal wall prolapse, C was the cervix and D was the pouch of Douglas. Patients were staged by doing a physical examination with maximum straining in the supine position. Stage 1 was defined as prolapse where the given point remains at least 1 cm above of the hymen, stage 2 when the given point descends to an area extending from 1 cm above to 1 cm below the hymen, stage 3 when the given point descends greater than 1 cm past the hymenal remnants but does not represent complete uterine procidentia, and stage 4 when there was complete vaginal vault eversion or complete uterine procidentia.

The cases with stage 2 and stage 3 prolapse with less bulge symptoms were included in Group 1, while those with stage 3 prolapse with severe bulge symptoms and stage 4 prolapse were included in Group 2 after informed consent. The patients were explained about their medical condition and the treatment options and were taken up for the surgical procedure after valid written informed consent. All patients were clinically and radiologically evaluated prior to the procedure. PAP screening was done for all cases, and endometrial biopsy was done in a few indicated patients.

All surgeries were performed under regional anaesthesia by a team of experienced gynaecologists. Three cases had to be converted to general anaesthesia. VH-PFR was done by the traditional method followed by McCall's culdoplasty in all the 174 patients. McCall's culdoplasty was done by suturing the vaginal wall to both the uterosacral ligaments and the posterior peritoneum with 1–0 polyglactin 910 suture. SSF was done in addition in a subset of 43 patients (Group 2). Unilateral SSF was done wherein the right sacrospinous ligament was exposed, and a double-needled 1–0 polypropylene suture was passed through it with a Miya hook and was transfixed once to the right lateral vaginal wall near the vault and once more to the centre of the newly formed vault. This was followed by colpoperineorrhaphy.

Intraoperative parameters like duration of surgery, change in haematocrit and intraoperative complications were analysed. Duration of hospital stay and immediate and late complications were also assessed. The patients were evaluated 6 weeks post-operatively and thereafter on a regular basis by history taking, physical examination and telephonic follow-up. Recurrence was defined objectively as any recurrence of prolapse (cystocele, vault prolapse, rectocele, enterocele). Recurrence was evaluated by physical examination. Vault prolapse was quantified by simplified POP-Q staging where point C is the vaginal cuff and point D is omitted.

The study was conducted with permission from the Institutional Ethical Committee of Believers Church Medical College Hospital.

Data analysis was done by a qualified biomedical statistician using SAS University Edition. To estimate the risk of developing recurrent prolapse for those who underwent VH-PFR-M-SSF compared to those who underwent VH-PFR-M, odds ratio and 95% confidence interval were calculated. Kaplan–Meier curve was drawn, and log-rank test was used to compare the rate of recurrence. Statistical significance was defined as $p < 0.05$.

Results

Out of the 174 patients who underwent vaginal hysterectomy for advanced prolapse, 25 patients presented with stage 2 prolapse, 140 with stage 3 prolapse, and 9 with stage 4 prolapse.

A total of 131 patients (75.28%) who underwent VH-PFR-M were included in Group 1, and 43 patients (24.71%) who underwent VH-PFR-M-SSF were included in Group 2. Both the groups were comparable for parameters like age, BMI, parity, post-menopausal status, comorbidities and aggravating factors (Table 1). Patients with more advanced stage of prolapse were significantly higher in Group 2 ($p < 0.001$). There were 25 patients with stage 2, 140 with stage 3 and 9 with stage 4 prolapse.

The intra- and post-operative complications and outcomes are shown in Table 2. There was no significant difference in the duration of surgery in both the groups ($p = 0.1$). The change in haematocrit was significantly more in Group 2 ($p = 0.02$), although no patient required blood transfusion. There were no intraoperative complications in either group.

Early complications (within 1 week) occurred in both groups but were not significantly different ($p = 0.52$). There was one case of secondary haemorrhage who presented on day 5 which was managed conservatively by vaginal packing and one patient with post-operative anaemia managed with parenteral iron in Group 2. There was one case of left ventricular failure who was managed conservatively in Group 1. Other early complications including vault infection (5), urinary tract infection (UTI) (21), urinary urgency (2), gastritis (2), spinal headache (4), right bundle branch block (1), respiratory infection (2), urinary incontinence (2), febrile morbidity (1), urinary retention (1), hypoglycaemia (1) occurred in both groups without any statistically significant difference. No patient required post-operative surgical intervention. The hospital stay was comparable in both the groups ($p = 1.0$).

Similarly, late post-operative complications were comparable in the two groups ($p = 0.28$). The late post-operative complications in Group 1 included urinary retention (1) managed by catheterisation, vault infection (10) and UTI (5) managed by antibiotics and urge incontinence (1), stress incontinence (2) and pain in abdomen (1) managed conservatively. In Group 2, late complications included UTI (2), vault infection (4) and minimal post-operative collection managed by oral antibiotics and stress urinary incontinence (SUI) (1) managed conservatively. One patient from Group 1 with vault infection and fever required readmission and was managed by intravenous antibiotics. There were no cases of ureteric kinking or

Table 1 Baseline characteristics of study subjects

	VH-PFR-M $n = 131$	VH-PFR-M-SSF $n = 43$	p value
Age (mean ± sd)	63.8 ± 11.1	65.3 ± 8.3	0.4
BMI (mean ± sd)	24.6 ± 3.8	25.5 ± 4.4	0.2
Parity (mean ± sd)	3.0 ± 1.3	3.1 ± 1.5	0.7
Aggravating factors n (%)	18 (13.7%)	11 (25.6%)	0.07
Post-menopausal n (%)	107 (81.7%)	40 (93%)	0.08
Co-morbid conditions n (%)	70 (53.4%)	22 (51.2%)	0.80
Stage 2 n (%)	25 (19.1%)	0 (0%)	< 0.001
Stage 3 n (%)	106 (80.9%)	34 (79.1%)	
Stage 4 n (%)	0 (0%)	9 (20.9%)	

Table 2 Outcome measures of study subjects

	VH-PFR-M $n = 131$	VH-PFR-M-SSF $n = 43$	p value
Recurrence n (%)	8 (6.1%)	5 (11.6%)	0.23
Intra-OP complications n (%)	0 (0%)	0 (0%)	1.00
Early (< 1 wk) complications n (%)	36 (27.5%)	14 (32.6%)	0.52
Late (> 1–6 wk) complications n (%)	21 (16.0%)	10 (23.3%)	0.28
Haematocrit change (mean ± sd)	0.8 ± 1.5	1.5 ± 1.6	0.02
Duration of surgery in hours (mean ± sd)	1.9 ± 0.7	2.2 ± 0.8	0.1
Duration of hospital in days (mean ± sd)	5.2 ± 0.6	5.2 ± 0.8	1.0
Duration of follow-up in months (mean ± sd)	20.7 ± 9.1	17.3 ± 7.7	0.03

significant shortening of vagina (total vaginal length > 4.5 cms) in our study.

The prevalence of recurrence in the VH-PFR-M group was 6.1%, and that of VH-PFR-M-SSF was 11.7%. However, there was no statistically significant difference in recurrence rates between the two groups. Seven patients (5.3%) had stage 1 and one patient (0.8%) had stage 2 recurrent prolapse in Group 1, and three patients (7.0%) had stage 1 and two patients (4.7%) had stage 2 recurrent prolapse in Group 2. The breakdown of the relapse as anterior compartment, posterior compartment and apical is shown in Fig. 1.

Since VH-PFR-M-SSF was not performed in any stage 2 prolapse and VH-PFR-M was not performed in any stage 4 prolapse, further statistical analysis for comparison of these two interventions was restricted to the patients with stage 3 prolapse. Table 3 shows baseline characteristics of stage 3 patients after dividing into the two groups.

On restriction the recurrence rate in the VH-PFR-M-SSF group dropped to 2.9% (Table 4). Those who underwent VH-PFR-M-SSF had 57% lower risk of developing a prolapse compared to those who underwent VH-PFR-M only, with odds ratio (95% confidence level) of 0.43 (0.05–3.61). However, the reduced risk was not statistically significant. The rate at which recurrence occurred did not differ for the two types of surgery up to 17 months post-surgery (Fig. 2). After 17 months, rate of recurrence increased for those who underwent VH-PFR-M. However, the difference was not statistically different ($p = 0.54$). Both groups had comparable ($p = 0.12$) follow-up period with an average of 20.7 ± 9.5 months for VH-PFR-M and 17.9 ± 7.2 months for VH-PFR-M-SSF.

Table 3 Baseline characteristics of stage 3 subjects

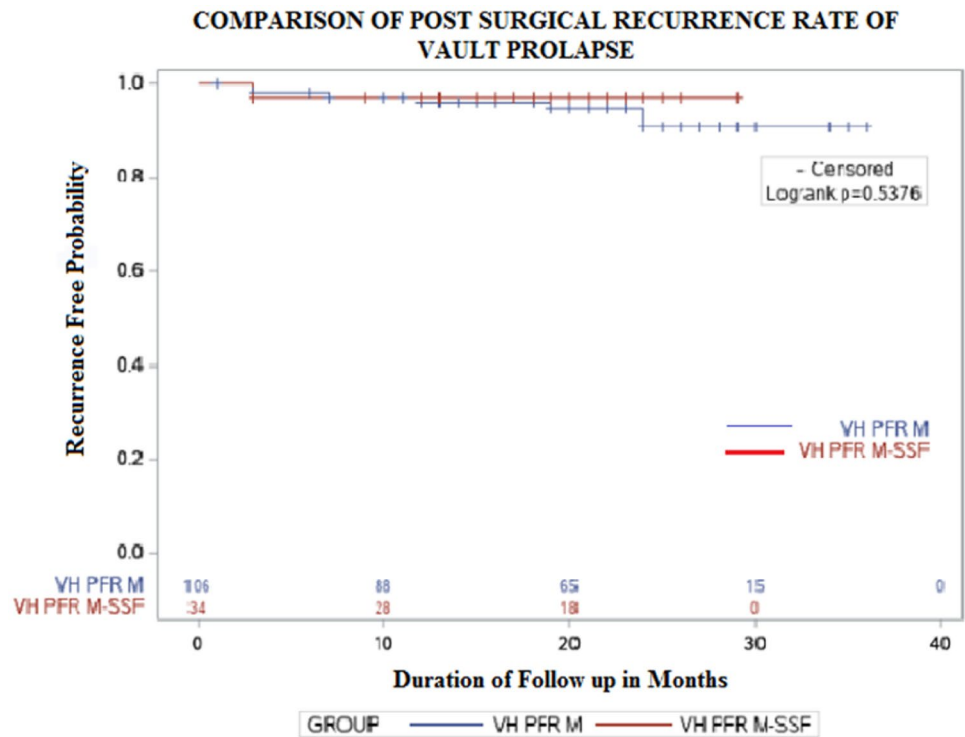|	VH-PFR-M $n = 106$	VH-PFR-M-SSF $n = 34$	p value
Age (mean ± sd)	64.9 ± 10.6	64.9 ± 7.9	1.00
BMI (mean ± sd)	24.7 ± 3.8	25.4 ± 3.7	0.35
Parity (mean ± sd)	3.1 ± 1.3	3.2 ± 1.4	0.70
Aggravating factors n (%)	14 (13.2%)	9 (26.5%)	0.07
Post-menopausal n (%)	88 (83.0%)	31 (91.2%)	0.25
Co-morbid conditions n (%)	53 (50.0%)	15 (44.1)%	0.55

Discussion

This study was conducted to compare the recurrence and complication rate of VH-PFR-M-SSF compared to VH-PFR-M surgical procedures. To the best of our knowledge, the complication rates and long-term effects of VH-PFR-M-SSF in patients with advanced prolapse have not been studied.

The recurrence rate within an average of about 20 months for VH-PFR-M-SSF is 11.6%, and that for VH-PFR-M was 6.1%. These rates are much lower than other similar studies. Pax et al. found anterior compartment recurrence rate of more than 50% and posterior compartment defects of more than 15% at 3 years when VH-PFR-M was done in patients with advanced prolapse [4]. The literature suggests high recurrence in patients with both VH-PFR-M and VH-PFR procedures [5, 6]. Alas et al. [7] found that there was a significant increase in anterior compartment defects at 1 year in patients with advanced prolapse who underwent VH-PFR-M. Prior studies have shown that VH-PFR-M has higher recurrence rates (15 to 50%) when performed in more advanced cases of uterovaginal prolapse (6) (5) (4).
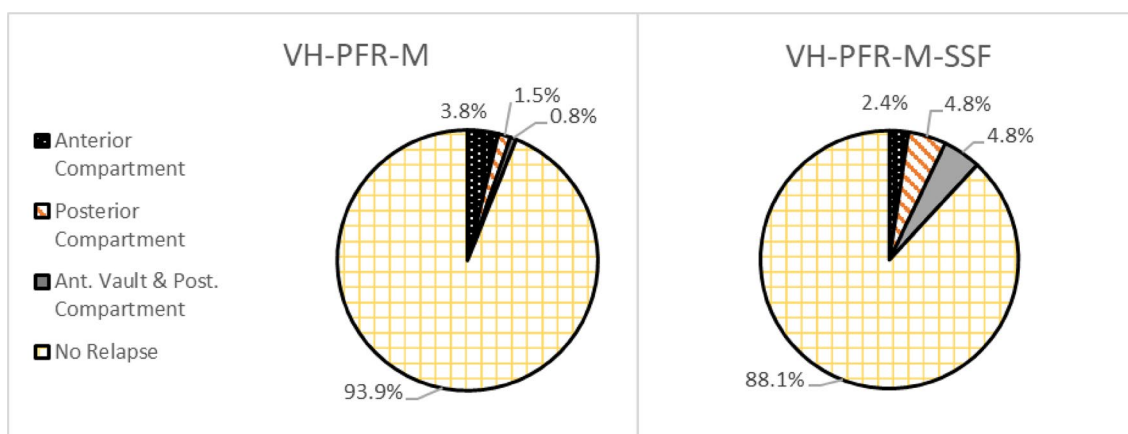
Fig.1 Types of relapse after VH-PFR-M and VH-PFR-M-SSF

Fig.2 Comparison of recurrence rates after VH-PFR-M and VH-PFR-M-SSF using Kaplan-Meier curves. There was no statistical difference between the two groups

Table 4 Outcome measures of stage 3 subjects

	VH-PFR-M n = 106	VH-PFR-M-SSF n = 34	p value
Recurrence stage 3 only n (%)	7 (6.6%)	1 (2.9%)	0.81
Intra-OP complications n (%)	0 (0%)	0 (0%)	1.00
Early (< 1 week) complications n (%)	26 (24.5%)	9 (26.5%)	0.81
Late (> 1–6 week) complications n (%)	17 (16.0%)	5 (14.7%)	0.86
Haematocrit change (mean ± sd)	0.8 ± 1.5	1.5 ± 1.6	0.02
Duration of surgery in hours (mean ± sd)	1.9 ± 0.7	2.1 ± 0.8	0.16
Duration of hospital stay in days (mean ± sd)	5.1 ± 0.5	5.2 ± 0.9	0.41
Duration of follow-up in months (mean ± sd)	20.7 ± 9.5	17.9 ± 7.2	0.12

The literature suggested higher rates of cystocele after VH-PFR-SSF. Colombo and Milani et al. reported a recurrence rate of 33% in patients who had undergone VH-PFR-SSF. (1) Similarly, Allahdin et al. found a recurrence of 28% at 12 months, Maher et al. found a recurrence of 33% at 19 months and Sze et al. found a recurrence of 18% at 24 months in patients who had undergone VH-PFR-SSF which is higher than our recurrence in VH-PFR-M-SSF though our group included only patients with more advanced prolapse. (1) Our study showed similar anterior compartment recurrence patterns in Group 1 and Group 2, 3.8% in VH-PFR-M and 2.4% in VH-PFR-M-SSF, which is lesser when compared to other studies. Posterior compartment and apex recurrence in the VH-PFR-M-SSF group are comparable to other studies.

Mesh surgery is an alternative choice in such patients, but it can add to the cost and lead to mesh-related complications resulting in pain and requiring re-operations [6, 8]. We added SSF to VH-PFR-M in patients with stage 3 prolapse with prominent bulge symptoms and stage 4 prolapse. The procedure is relatively cheap with the requirement of just one extra suture material and safe as patient's sacrospinous ligament is used for additional strength [9].

Prior studies have conflicting views on the role of SSF with regard to operating time, blood loss, complications and prolapse recurrence [1, 5, 10, 11]. Elif et al. found statistically significant increase in operating time, hospital stay and blood loss requiring blood transfusion in the SSF group [6]. Colombo and Milani et al. found SSF inferior to McCall's culdoplasty in terms of operative time, blood loss and recurrence. (1) But our study shows no statistically significant

difference in the operating time, intraoperative complications, immediate and late post-operative complications or hospital stay between both groups. Though there is a statistically significant difference in the blood loss, none of the patients in the VH-PFR-M-SSF group required blood transfusion. The patients in the VH-PFR-M-SSF group included patients with more advanced stage of prolapse which could also account for the relative increase in the blood loss.

Amongst the significant complications in the SSF group, Pasley et al., Hoffman et al. and Benson et al. found 2% bladder and bowel injuries in their studies independently. (1) Paraiso et al. found significant blood loss requiring blood transfusion in 8% of their patients. (1) Benson et al. found post-operative urinary retention to be as high as 75%, while Paraiso et al. and Hoffman et al. found it to be between 10 and 12%. Meschia et al. found cuff infections in about 14% patients, while Benson et al. found UTI amongst 21% patients of their study group. Maher et al. reported nerve injuries in 36% patients. (1) Elif et al. reported bladder injury in 5.8% patients in VH-PFR and rectal injury in 6.2% patients and vascular injury in 19% patients of VH-PFR-SSF, respectively. (6) Amongst the patients who underwent mesh procedures, Lopes et al. found mesh erosions to be as high as 50%, while Lo et al. reported 20% cases of mesh shortening. (1) In our study group, there were no bladder and bowel injuries and no nerve or vascular injuries, and none of the patients required blood transfusion. Urinary retention was found only in 0.5% of our entire study group, though vault infection and UTI were comparable with the literature.

The recurrence rate for the two groups was similar ($p = 0.23$) despite the fact that VH-PFR-M-SSF was done only for patients with stage 3 prolapse and having prominent bulge symptoms and stage 4 prolapse. All known risk factors, except stage of presenting prolapse, were equally distributed for the two types of surgeries. Stratification based on stage revealed that VH-PFR-M-SSF was not done on those with stage 2 prolapse and VH-PFR-M was not done on those with stage 4 prolapse. Therefore, on restricting to patients with stage 3 prolapse, those who underwent VH-PFR-M-SSF had 57% lower risk of developing a prolapse compared to those who underwent VH-PFR-M only. However, the reduced risk was not statistically significant.

The lack of significance could be due to inadequate sample size. Although we began with an adequate sample based on the assumption that recurrence amongst those who underwent VH-PFR-M would be 15% and for those who underwent VH-PFR-SSF would be 33%, based on prior studies (1), the reduced recurrence rate in the two groups rendered it inadequate. Further studies with larger sample size and longer follow-up are required to establish VH-PFR-M-SSF as a procedure of choice for advanced prolapse. However, the reduced recurrence rates and the comparable rates of complications, including intraoperative, early (< 1 week)

and late (< 6 weeks) and duration of hospital stay, suggest that this technique is worth pursuing and we intend to follow up these patients for a longer duration.

Conclusion

On the basis of this study, it may be concluded that this procedure (VH-PFR-M-SSF) could be recommended in more advanced stages of prolapse, without any significant increase in cost, procedure-specific complications, overall complications, hospital stay or recurrence rate.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical Approval This research involved human participants. The study has been conducted after approval from Ethical and Research committee of Believers Church Medical College, Thiruvalla, Kerala, India. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed consent Written Informed Valid consent was obtained from all patients prior to the procedure.

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