

SURGICAL EFFICIENCY, COMPLICATIONS AND PATIENT SATISFACTION OF SACROSPINOUS HYSTEROPEXY AND VAGINAL HYSTERECTOMY WITH VAULT SUSPENSION PROCEDURE, FOR THE TREATMENT OF UTERINE PROLAPSE

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Abstract

Background: With the enormous growth of the world population in the last decades, the higher life expectancy, and increasingly better health care facilities, older women remain more active in daily life. Thereby, pelvic organ prolapse has become a worldwide health problem. **Objective:** To study the surgical efficiency, complications and patient satisfaction of Sacrospinous Hysteropexy and Vaginal Hysterectomy with vault suspension procedure, for the treatment of uterine prolapsed. **Materials and Methods:** This was a prospective randomized controlled comparative study, conducted in the Department of Obstetrics and Gynaecology, VMMC & Safdurjung Hospital, New Delhi. A total number of 40 subjects, meeting all inclusion criteria, were selected and divided randomly, using Randomized table, into two subgroups. **Result:** The age groups were comparable. None of the patients in either of the groups had history of difficult delivery, prolonged labour or instrumental delivery. Percentage of post-menopausal women in control group was 50%. The menstrual status of the patients in both the groups was comparable (p=0.69). 70% of patients in the study had normal BMI. Most of the patients in both the groups had involvement of all the three compartments. 70% of the patients in study group and 75% of patients in control group had stage 3-4 cervical descent. None of the patients in the study or the control group had any immediate complication during surgery such as primary hemorrhage or injury to bladder / rectum. **Conclusion:** Sacrospinous Hysteropexy was associated with significantly lesser blood loss (p=0.000) as well as shorter mean intra-operative time (p=0.002) as compared to VH. No immediate complications were encountered with either SSH or VH. Delayed complications of SSH included temporary sensory skin loss over right thigh in two (10%) patients and mild to moderate buttock pain in three (15%) of the SSH patients, which got relieved within 2-3 weeks after surgery. Those undergoing VH with suspension had lower urinary tract infection in four (25%) patients and vault infection in one (5%) patient at one-month follow up.

INTRODUCTION

From population-based studies, it was estimated that one in ten women will have had pelvic surgery by the age of 80 years and 29% will require a second operation because of recurrences.^[1]

The goal of surgical treatment of POP is to relieve symptoms, achieve pelvic floor support, restore organ function, and treat and/or prevent sexual, bowel, or bladder dysfunction. It is often difficult for traditional surgery to satisfy all of these goals, and failure can result in patient dissatisfaction. With

increasing medical advances, multiple surgical options are becoming available, and surgeons who perform pelvic floor reconstruction can tailor treatment in response to specific patient needs.

Vaginal hysterectomy with suspension procedure is a traditional and time-tested treatment of uterine prolapse with good functional and anatomical outcomes and low complication rates.^[2] However there are many women who want to preserve their uterus for various reasons, an important one being the woman's emotional health that may also be affected by hysterectomy and the uterus has great psychological significance for some women, more so in certain cultures. Hysterectomy may be followed by problems such as depression, anxiety, and sexual dysfunction. Some women feel that by losing their uterus they have lost their womanhood. Finally, many women are strongly opposed, in principle, to the removal of any organ, genital or otherwise, unless absolutely necessary.

The sacrospinous ligament fixation can be performed as primary treatment for a uterine descent, a technique that can be referred to as 'sacrospinous hysteropexy'.^[3] The procedure is performed vaginally and can be combined with other prolapse surgery as anterior/posterior colporrhaphy and stress incontinence surgery. It restores normal vaginal length and axis, without leading to dyspareunia and with obliteration of the space for potential enterocele formation.^[4] The technique has been shown to be associated with low morbidity.^[4,5]

Although several studies have shown sacrospinous hysteropexy to be anatomically efficient and safe procedure, with which most women are highly satisfied,^[6,7] it is still unclear whether removing the uterus leads to better results and is necessary for primary treatment of uterine prolapse.^[8] No study has been reported till date from India.

The present study was planned as a prospective randomized controlled comparison of the sacrospinous hysteropexy with the more common vaginal hysterectomy for uterine prolapse, regarding the complications, recovery time, anatomical and functional outcome and the quality of life before and after the procedure.

MATERIALS AND METHODS

A prospective randomized controlled comparative study conducted in the Department of Obstetrics and Gynaecology, VMMC & Safdurjung Hospital, New Delhi. A total number of 40 subjects, meeting all inclusion criteria, were selected and divided randomly, using randomized tables, into two subgroups:

Study Group: This group contained a total of 20 females, who underwent Sacrospinous Hysteropexy with preservation of uterus.

Control Group: This group contained a total of 20 females, who underwent Vaginal Hysterectomy with McCall vault suspension procedure.

In both the groups, concomitant surgery for the correction of anterior/posterior defect & SUI was carried out, whenever indicated.

Inclusion Criteria

Women attending gynecology OPD with symptomatic pelvic organ prolapse

Adult females of age ≥ 35 years, who have completed family.

Examination reveals \geq stage 2 uterine descent with or without prolapse of anterior/posterior compartment

Ambulatory and willing to comply with return visits.

Exclusion Criteria

Women having abnormal uterine bleeding.

Women who have uterine/ovarian pathology on clinical examination/ultrasound

Women having abnormal cervical cytology/pathology

Women having history of surgery for prolapse.

Women not willing to come for return visits.

Methodology

All subjects included in the study were counseled and an informed consent (Appendix I) was taken in a language understood by the patient. All subjects underwent the detailed evaluations, the findings of which were noted in a Proforma.

Investigation: Ultrasound was done to rule out any uterine pathology

Endometrial Aspiration was done to rule out pathology

Pap smear was done for cervical cytology

Routine pre-operative investigations: Complete hemogram, RBS, LFT, KFT, SE, Urine-R/M, Chest X-ray, ABO group, HIV and HBsAG were done for all patients

Following the pre-anaesthetic check up, blood was arranged, and the surgeries were performed after obtaining an informed consent.

Surgery

The Sacrospinous Hysteropexy was performed unilaterally to the right ligament. All surgeries were performed by the same team of surgeons.

Vaginal Hysterectomy was performed by Heayne's 9 technique and combined with McCall's vault suspension procedure.

All women received perioperative thrombosis prophylaxis intravenous prophylactic antibiotics. Postoperatively, an indwelling bladder catheter was placed in all women and removed 24 hour after surgery.

Follow-UP

Follow-up was done at 1-month, 3-months and 6-months following surgery.

Outcome Measures

Anatomical cure: Anatomical cure was assessed by Clinical POP-Q at maximum straining, in conformation with the recommended standards of

the ICS, defining points Aa, Ba, C, D, Ap, Bp, GH, PB, TVL.

Surgical Efficiency: Following parameters were used to assess surgical efficiency

Blood-loss during surgery which was assessed by mop counting.^[10]

Medium size fully soaked mops were considered equivalent to 25 - 30 ml

Large size mops were considered equivalent to 45-50 ml blood loss

Operative time - was taken from the time of making the incision till the completion of surgery including the anterior and posterior compartment repairs. Time was also noted separately for procedures of sacrospinous hysteropexy and vaginal hysterectomy per-se.

Complications Immediate and delayed complications of surgery were recorded

Immediate 1. Bladder injury 2.Rectal injury 3.Primary haemorrhage

Delayed 1.Wound infection 2. Lower urinary tract infection 3.Vault infection or haematoma

4.Sensory skin loss 5.Buttock pain

Patient Satisfaction

Patient satisfaction was assessed with the validated QOL questionnaire and scored.

Functional Outcomes/ Quality-Of-Life

The effect of pelvic organ prolapse, gastrointestinal (GI) and lower urinary tract symptoms were measured using condition specific quality-of-life questionnaires, PFDI-20 and PFIQ-7. Both the questionnaires were scored.

Statistical Analysis

Descriptive statistics were used for the whole population. To compare differences between groups, a Student t-test was used for continuous data and the chi-square-test for nominal or ordinal data. The significance level was set at $p < 0.05$. Statistical analysis was performed with SPSS 12.0 for Windows.

RESULTS

The mean age of patients in the study group was 51.9 ± 8.01 years and the range was 35-60 years. In the control group, the mean age was 53.95 ± 12.42 years ranging between 35-77 years. The age groups were comparable ($p=0.22$).

The parity in study group ranged from 1 to 6 & in the control group from 1 to 8. The mean parity in both the groups was comparable ($p=0.67$). None of the patients in either of the groups had history of difficult delivery, prolonged labour or instrumental delivery.

55 % of the patients in the study group were post-menopausal; rest of the patients had normal menstrual cycle with no complaints regarding the regularity, flow or duration of cycles. [Table 1]

Percentage of post-menopausal women in control group was 50%. The menstrual status of the patients in both the groups was comparable ($p=0.69$)

70% of patients in the study had normal BMI. The number of patients with BMI below normal was 5 % and above was 25 %. In the control group 90% patients had normal BMI and in 10% BMI was below normal. Both groups were comparable ($p=0.66$)

In both the groups, the most common presenting complaint was the sensation of vaginal bulge or protrusion. Some patients also complained of difficulty in walking, low back pain, difficulty in performing daily activities and fear of carcinoma due to the bulge.

Urinary complaints such as burning or painful micturition, urine leak with urgency and urine leak with cough, sneeze or laugh were present in 35 % of patients in study group and in 40 % of women in the control group. Bowel complaints such as constipation were present in 15 % of patients in the study group and 5% in control group. Many patients had more than one associated complaint. Both the groups were comparable ($p > 0.5$). [Table 2]

7/16 (43.7%) women in SSH group and 8 /15 (53.3%) had sexual dysfunction. The sexual dysfunction in both groups was due to protruding parts outside vagina &/or vaginal dryness during intercourse. [Table 3]

The patients who were not sexually active, were not considered for the evaluation of sexual satisfaction (4:SSH, 7:VH). [Table 4]

Clinical Evaluation

Most of the patients in both the groups had involvement of all the three compartments. Only two patients (10%) in SSH did not have posterior compartment defect.



PLATE 1: Stage II Cervical Descent



Plate 2: Stage III Cervical Descent (with cystocele)

70% of the patients in study group and 75% of patients in control group had stage 3-4 cervical descent. Stage 2 cervical descent was seen in 30% of patients in study group and 25% in control group. Most of the patients in both the groups (60% in study group and 50% in control group) had anterior compartment descent of stage 3, while stage 2 descent was present in 40% of study group and 50% of control group. Regarding the posterior compartment, 70% of patients in the study group and 80% in control group had stage 2 descent). Stage 3 descent was present in 15% of study group and 10% of control group. Both the groups were comparable with respect to descent in all the three compartments

Surgical Efficiency

Surgical efficiency of the procedures was assessed by estimating the blood loss and the time taken during surgery.

The mean operative time for performing the complete operative procedures including the anterior and posterior compartment repairs in study group

(93.2 ± 28.1 minutes) was 30% less than that taken for the control group (134.75 ± 46.4 minutes) (p=0.001). Time taken for performing the sacrospinous hysteropexy (SSH) part alone was 10.50 ± 2.65 minutes and for VH (removal of uterus with suspension procedure) was 35 ± 10.62 minutes (p=0.00)

Blood Loss During Surgery: Most of the patients in SSH group (90%) had blood loss < 300ml, whereas in VH group 65% patients had blood loss of more than 300 ml. The mean blood loss in SSH (209 ml ± 79.96) was 39% less than that in VH group (346.5 ± 120.88 ml).

SSH was found to have significantly lesser blood loss (p=0.000) as well as shorter mean intra-operative time than VH (p=0.002).

Immediate Complications

None of the patients in the study or the control group had any immediate complication during surgery such as primary hemorrhage or injury to bladder / rectum.

Delayed Complications

Out of the patients who underwent SSH, two (10%) patients complained of sensory skin loss over right thigh after the surgery and were relieved two weeks post-surgery. During this period, patients were kept under observation. Three (15%) of the SSH patients had buttock pain starting a day after surgery that required analgesics. The pain was alleviated within 3-weeks of surgery.

Four VH patients developed lower urinary tract infection (LUTI) one month after surgery which was treated and patients were symptom free at the next follow up. One VH patient reported vaginal vault infection two weeks after the surgery for which she was re-admitted for local treatment and was discharged after 3 days.

Table 1: Distribution of Patients According to Age

AGE(years)	Study(SSH)N=20		Control(VH)n=20	
	No.	%	No.	%
35-45	4	20	3	15
46-55	9	45	7	35
56-65	5	25	7	35
66-75	2	10	2	10
76-85	0	0	1	5

Table 2: Distribution of Patients According to Menstrual Status

Menstrual Status	Study (SSH) N=20		Control (VH) n=20	
	No.	%	No.	%
Premenopausal	9	45	10	50
Postmenopausal	11	55	10	50

Table 3: Distribution of Patients According to Chief Complaint

Complaint	Study (SSH) N=20		Control (VH) n=20		P Value
	No.	%	No.	%	
Feeling of vaginal bulge or protrusion	20	100	20	100	0.96
Bladder complaints	7	35	8	40	0.64
Sexual complaints	7	35	8	40	0.64
Bowel complaints	3	15	1	5	0.56

Table 4: Distribution of sexual complaints before surgery

Complaint	Study (SSH) n=16		Control (VH) n=13		P Value
	No.	%	No.	%	
Problem with size of vagina	4	25.0	3	23.1	0.644
Vaginal dryness	3	18.7	5	38.4	0.678
Total	7	56.1	8	38.8	

Table 5: Distribution According to the Pelvic Compartment Involved in Descent

Compartment Involved	Study (SSH) N=20		Control (VH) n=20	
	No.	%	No.	%
Central + Anterior	2	10	0	0
Central + Anterior + Posterior	18	90	20	100

Table 6 Surgical Efficiency

Parameters for assessing Surgical Efficiency (Group Statistics)						
	Group	N	Mean	Sd. Deviation	S Error Mean	p value
Blood Loss (ml)	VH	20	346.50	120.886	27.031	0.000
	SSH	20	209.50	79.965	17.881	0.000
Operative Time (minutes)	VH	20	134.75	46.410	10.378	0.001
	SSH	20	93.25	28.017	6.265	0.002

Table 7: Patient Satisfaction following Surgery

Level of Satisfaction	Study (SSH) n=20		Control 2 (VH) n=20	
	No.	%	No.	%
Very dis-satisfied	1	5	0	0
Dissatisfied	2	10	2	10
Moderately Satisfied	4	20	2	10
Satisfied	11	55	16	80
Very satisfied	2	10	0	0

No significant difference was found in patient satisfaction in both the groups. Overall 17 (85%) women were satisfied in SSH compared to 18 (90%) in VH group. (p=0.66) The reason for dissatisfaction was recurrence of cervical descent and post operative buttock pain in SSH and recurrent cystocele and post operative infection in VH group.

DISCUSSION

The mean age of patients in the study group (51.9 ± 8.01 years) and the control groups (53.95 ± 12.41 years) was comparable. The mean age was lower than in other studies.^[12,13] The difference could be due to early age of childbearing in India as well as overall higher life expectancy in the developed world.

Parity range in the study group (1-6) & in the control group (1-8) was comparable. Previous studies have also found correlation between high parity and prolapse. It appears likely that the childbirth plays an important role in the pathogenesis of prolapse.^[13,14]

A large percentage of patients in the study group (55%) as well as the control group (70%) were postmenopausal. It has been seen that most cases of prolapse become evident after the age of menopause. Virtually all the tissues of the pelvis possess oestrogen receptors, and the atrophic changes that occur in the absence of oestrogen are a contributing cause of prolapse, however, in WHI trial no association was found between the estrogens status and prolapse.^[13]

Maximum patients in the study group (70%) as well as the control group (90%) had a normal BMI; 25% in study group had a BMI of 25 or more. It has been postulated that obesity directly increases the load on the pelvic floor and decreases mobility as well as the ability to do muscle strengthening exercises, leading to increased incidence of prolapse in women with higher BMI. Hendrix and Clark,^[13] associated increased body mass index with pelvic organ prolapse. Although other studies have failed to find an association between increased BMI and pelvic organ prolapse.^[14,15] In the present study also BMI did not correlate with prolapse

Quantification of Uterine Descent Before Surgery: All the subjects were examined using POPQ staging which is considered to have a high inter- and intra-observer validity.^[16] The preoperative POP staging of both groups was comparable. In earlier retrospective studies pre-operative prolapse staging was not available.^[3,17] Only Dietz et al,^[12] collected data by POPQ before and after surgery. Availability of preoperative data makes anatomical outcomes after surgery more defined and comparisons more precise.

At 6-month follow-up, there was marked improvement in all the domains of POPQ in both the groups. However, the results were better with SSH with respect to TVL. There are very few studies which have measured anatomical cure with respect to all points of POPQ. Similar results have been reported by the only other such study by Dietz et al.^[12] The explanation for a longer TVL in SSH could be that When SSH procedure is performed it is necessary to keep adequate vagina, otherwise the

cervix cannot be approximated to sacrospinous ligament, while during VH surgeon has no such constrain, therefore, while striving to achieve good anatomical cure more vagina is cut than required. Previous studies have also reported an average vaginal length of 8 cm after SSH.^[18,19]

Anatomical Outcomes

In the present study recurrence rate for the apical compartment after the sacrospinous hysteropexy at 6-month follow-up was 30%, whereas no patient after vaginal hysterectomy had apical recurrence. The recurrence rate of apical compartment in this study are comparable to the only other randomized prospective study comparing anatomical outcome of VH & SSH by Dietz et al,^[12] where the incidence of apical prolapse was found to be 27% in SSH compared to 3% in VH group. However, earlier studies have reported 0%-15% recurrences of the apical compartment after a sacrospinous hysteropexy,^[6,5,7,11] and 0% to 12% after a vaginal hysterectomy for uterine descent.^[3,6,17]

The higher rates of recurrence in our study and that of the Dietz et al,^[12] in comparison to earlier studies could be due to the heterogeneity of data collection. Most of earlier studies were retrospective, based on medical files, and not on gynecological examinations performed and regardless of symptoms. Besides the study of Dietz et al, only three other studies^{3,6} have been published in which the sacrospinous hysteropexy was compared with a vaginal hysterectomy in terms of anatomical outcomes, and in two of these studies the vaginal hysterectomy was combined with a prophylactic sacrospinous ligament fixation of the vault. Brummen et al,^[20] collected anatomical outcomes retrospectively from medical files that most likely underestimated the recurrence rates. Hefni et al,^[21] formed a prospective cohort study of women with a mean age of 74 years in which anatomical outcomes were not collected by an independent assessor.

Most recurrences of SSH occur between 4-6 months, as the women expands her activity, the prolene sutures are probably torn from cervix. In the present study also the cervical descent was noted in third month follow up in all the patients who had recurrence in SSH group. May be a longer follow-up data is required to find out recurrences after VH as apical prolapse after a vaginal hysterectomy is probably based on stretching of the tissue (sacrouterine ligaments) over time, and as a consequence, develop over time.

The recurrence of anterior vaginal wall prolapse after sacrospinous ligament suspension has been noted in many series.^[3,22] It was postulated in a study that, after a sacrospinous hysteropexy is performed, the vaginal axis would become more horizontal with a higher risk of developing a cystocele.^[7] Smilen et al could not confirm this hypothesis.^[23] In prospective randomized study of Dietz¹² in which both preoperative and postoperative data was collected by POPQ system, the recurrence rate of cystocele following vaginal

hysterectomy and SSH were similar. Present study also did not find more cystoceles after a sacrospinous hysteropexy compared with a vaginal hysterectomy.

Surgical efficiency: The study and control group were comparable with respect to concomitant surgery for anterior and posterior compartment along with VH or SSH. Therefore assessment of surgical efficiency was done by comparing the blood loss and time taken for surgery from incision to completion.

Average blood loss and the time taken for surgery was less in SSH as compared to VH due to avoidance of dissection for uterine removal. Previous studies^{4,5,6}, have also shown similar results. Therefore SSH can be an especially useful procedure for elderly and infirm patients.

Complications: After sacrospinous hysteropexy, postoperative complications were seen in some cases, but most of them were self limiting and none of them was life threatening. Sensory loss over right thigh that resolved within two weeks of surgery was seen in 10% and buttock pain in 15% patients of SSH which subsided after taking analgesics within 3 weeks. Numbness over the posterolateral aspect of the thigh has been seen following sacrospinous colpopexy with an incidence varying between 1-30%, while buttock pain is estimated at 10 - 15%.^[7,12] These complications, which are unique to SSH, can be explained by injury to the perforating cutaneous nerve or the posterior femoral cutaneous nerve respectively.

In an anatomical study, the relationship of the pudendal nerve to the sacrospinous ligament was found to be variable; one branch of the pudendal nerve piercing through the ligament was found in 11%²⁴. Barksdale et al²⁵ also showed that nerve tissue is widely distributed within the sacrospinous ligament. The occurrence of this complication can be minimized, without reducing the overall success rate of the procedure, by placement of the suture not too deep into the sacrospinous ligament. It is prudent to inform patients of this potential side effect before surgery to avoid unnecessary anxiety associated with this transient complication.^[24]

Patient Satisfaction and Recommendation to Other Patients:

Most of the women in each group were highly satisfied about the outcome of the procedure and would recommend the surgery (SSH & VH) to other patients. The patients who had recurrences in SSH group did not want to recommend the SSH surgery. In the study by Meher⁷ satisfaction rate was comparable for SSH & VH (86% vs 85%).

The strength of this study was the randomization that made the groups of women comparable. Availability of preoperative and postoperative data in a standardized format made the comparisons more precise. So far, only one other prospective randomized study has been published, using POPQ and validated quality of life questionnaires for comparing anatomical outcomes and functional

outcome of these two surgical procedures (Dietz 2010).^[12]

CONCLUSION

Sacrospinous Hysteropexy was associated with significantly lesser blood loss ($p=0.000$) as well as shorter mean intra-operative time ($p=0.002$) as compared to VH. No immediate complications were encountered with either SSH or VH.

Delayed complications of SSH included temporary sensory skin loss over right thigh in two (10%) patients and mild to moderate buttock pain in three (15%) of the SSH patients, which got relieved within 2-3 weeks after surgery. Those undergoing VH with suspension had lower urinary tract infection in four (25%) patients and vault infection in one (5%) patient at one-month follow up.

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