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The effectiveness of the abdominal sacrocolpopexy / sacrohysteropexy with synthetic mesh for repair of apical prolapse

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ABSTRACT

Background: Pelvic organ prolapse is a common condition among parous women, badly affecting their life. They need a safe and consistent procedure that does anatomical correction and also improves their overall quality of life. Abdominal sacrocolpopexy and sacrohysteropexy are promising procedures for apical prolapse repair. Aim was to determine the effectiveness of the abdominal sacrocolpopexy /sacrohysteropexy with synthetic mesh for repair of vault and nulliparous prolapse respectively. The objectives were to describe the outcomes in the form of anatomical correction, symptomatic improvement and the complications in peri-operative and in follow up periods.

Materials and Methods: This prospective observational study was carried out in the department of Obstetric and Gynaecology, at a tertiary care center. The present study included 22 women with vault prolapse (n=18) and nulliparous prolapse (n=4), underwent abdominal sacrocolpopexy /sacrohysteropexy respectively for 2 years from 1st February 2021 to 31st January 2023 and follow up for 12 months.

Results: Most of the women had preoperative apical prolapse in stages-3 (59%), mean age in abdominal sacrocolpopexy/ sacrohysteropexy group was 53.6 years and 26.5 years respectively. Perioperative complications were bladder injury (n=1), paralytic ileus (n=1), wound dehiscence (n=1) and UTI (n=1). In post-operative reassessment of pelvic organ prolapse, vault/uterus was well supported (100%), 100% symptomatic relief. During follow up dyspareunia (n=1), lower backache (n=1) were present, no mesh erosion and no recurrence of Pelvic organ prolapse observed.

Conclusions: Abdominal sacrocolpopexy/ sacrohysteropexy with synthetic mesh are safe and durable procedures for vault and nulliparous prolapse repair respectively.

1. Introduction

Pelvic organ Prolapse (POP) is relatively a common condition among parous women. Uterine prolapse is defined as downward displacement of the uterus from its normal anatomical position usually associated with prolapse of the vaginal wall. Post-hysterectomy, vaginal vault slips down from anatomical position into or beyond vaginal introitus called vault prolapse. Uterine prolapse not associated with vaginal wall prolapse usually seen in nulliparous women is called nulliparous prolapse.

With increasing life span of women, POP incidence increases and it adversely affects the quality of life of the women. The lifetime risk of undergoing primary surgery for prolapse is 12.6%.[1] The incidence of vault prolapse after abdominal hysterectomy is estimated to be 0.2-1% and 11.6% following vaginal hysterectomy. The most important cause of vault prolapse is failure to identify and repair an enterocele during hysterectomy. The management of vault prolapse depends upon age, parity, associated comorbidities,

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duration of anesthesia; desire to preserve sexual function and expertise of the surgeon.[2] Conservative managements like vaginal ring pessary, pelvic floor exercise have limited role in management of vault prolapse. Many surgical procedures both vaginal and abdominal have been described over the years however abdominal sacrocolpopexy has better anatomical outcome.[3] It has been shown to be a reliable and durable procedure with a success rate of 78-100%.[4,5] In this procedure, the vaginal apex is fixed to the anterior ligament of the sacrum with a synthetic mesh. It restores the vaginal apex close to the normal anatomical position.[3] There are many retrospective studies on sacrocolpopexy and sacrohysteropexy where objective anatomical and surgical outcomes have been dealt with.[6] The functional components (vaginal symptoms, sexual life) of the procedure have been neglected. In the present study short term (12 months) anatomical and subjective (vaginal symptoms, sexual well-being and impact on quality of life of the patients) outcomes has been studied.

Aim of the present study was to determine the effectiveness of the abdominal sacrocolpopexy / sacrohysteropexy with synthetic mesh for repair of vault prolapse and nulliparous prolapse respectively. The primary objectives were to describe the outcomes in the form of anatomical correction, symptomatic improvement and women's satisfaction and the secondary objective was to describe the complications of the procedure in peri-operative and in follow-up period.

2. Material and Methods

This prospective observational study was carried out in the department of Obstetric and Gynaecology, ANMMCH, Gaya, a tertiary care center. Permission from the institute ethical committee was taken. The present study included 22 women who had vault prolapse (n=18) and nulliparous prolapse (n=4) and underwent abdominal sacrocolpopexy and sacrohysteropexy respectively for 2 years from 1^{st} February 2021 to 31st January 2023 and follow up for 12 months.

2.1. Inclusion criteria

1. All patients having symptomatic vault or uterine prolapse visiting the outpatient clinic of Obstetric and Gynaecology.
2. Patients given consent for post-operative follow up.

2.2. Exclusion criteria

1. Patients who were unfit for surgery.
2. Patients who were lost post surgeries for follow up.

A detailed history, general examination, gynecological examination including -pelvic organ prolapse (POP) quantitative evaluation by POP-Q system done. Patient's subjective evaluation for vaginal symptoms, sexual well-being and quality of life was carried out in pre-operative and post- operative periods by using International Consultation on Incontinence Questionnaire for Vaginal Symptoms (ICIQ-VS). After pre-operative work up and written consent, following standard preoperative protocol, abdominal sacrocolpopexy (ASCP) (n=18) and abdominal sacrohysteropexy (ASHP) (n=4) done where "point C" (vault or cervix) was fixed to the anterior longitudinal ligament of sacrum S1-S2 with non-absorbable, synthetic, mono-filament polypropylene mesh under regional anesthesia.

For abdominal sacrocolpopexy, the abdomen was opened with infra umbilical midline vertical or pfannenstiel incision. Vaginal vault was identified and held with two Babcock forceps. Bladder and rectum were dissected down from the vaginal vault anteriorly and posteriorly respectively and the 2 inches area of the vaginal vault made bare. Polypropylene mesh, 1 inch wide (length as per requirement) with 2 arms (each arm 2 inches long) in Y shape was made; arms were fixed anterior and posterior of the vault with three sutures on each side using prolene no.1. Then opening of the posterior peritoneum (starting from the sacral promontory, medial to the sigmoid colon up to the pouch of Douglas) was done. Posterior end of the mesh was fixed with anterior longitudinal ligaments of sacrum by using prolene no.1 with three sutures at S1- S2 level. After that the posterior peritoneum was closed over the mesh. In abdominal Sacrohysteropexy (ASHP), uterus was fixed to sacral ligaments (as above) by fixing anterior end of the mesh at posterior cervical isthmus between the attachments of uterosacral ligaments by three sutures using non absorbable suture (prolene no.1), rest steps of the procedure were same. Vagina was examined for remaining defects. Posterior perineorrhaphy was done as per need. Intraoperative complications, blood loss, duration of the procedure were noted. Postoperative protocol was followed. All stitches were removed on 8^{th} to 10^{th} postoperative day. Before the discharge, POP reassessment was done. Post-operative complications (fever, paralytic ileus, wound dehiscence, need of blood transfusion, burning micturition) were noted. Post-operative advice given- avoid strenuous work, lifting heavy weights, avoid constipation, cough and abstinence for 4 weeks post operatively.

Patients were followed for up to 12 months. Visits were done at 1, 3, 6 and finally at 12 months post procedure. In each visit, anatomical correction was assessed clinically by per speculum examination and patients' satisfaction for vaginal symptoms, sexual life and impact on quality of life was assessed based upon the International Consultation on Incontinence Questionnaire for Vaginal Symptoms (ICIQ-VS questionnaire).

The success rate was defined as apical prolapse - stage 0 or 1 in post procedure follow up at 12 months. In the ICIQ-

VS questionnaire, a set of 14 questions with answers scored from 0-10 (for how does a symptom bother them) was used. It included questions related to dragging abdominal pain, vaginal soreness, reduced sensation around vagina, vagina too loose/lax, lump coming down in vagina, lump coming out of vagina, dry vagina, vaginal digitation for bowel symptom, tight vagina, current sex life, worry about vagina affects sex life, relationship with partner, sex life spoilt, overall impact on everyday life and the outcomes were scored from 0-53 for vaginal symptoms, 0-58 for sexual matters associated with vaginal symptoms and 0-10 for impact on quality of life associated with vaginal symptoms.[7]

3. Results

All data collected and analyzed by using statistical tools-MS office Excel and Graphpad prism 8. Total 22 patients were enrolled for the study (sample size was according to reporting of vault prolapse in gynae.opd in our institute). Out of 22 patients, ASCP was done in 18 and ASHP in 4 patients. Most patients had pre-operative apical prolapse in stages-3 (59%). In the ASCP group mean age was 53.6 years, mean BMI was 30 Kg/m2 and mean parity was 4.5 (range 3-5). In the ASHP group the mean age was 26.5 years and mean BMI was 22.45 kg/m2. In this group only 1 patient had parity 2, 1 patient was unmarried and the rest 2 were nullipara. Posterior perineorrhaphy was done as per indication.

The mean operative time was 70.68min (60-90 min), average blood loss was 200ml (120-350ml).

In the intraoperative complications only one patient (4.54%) had bladder injury (cystostomy) that was repaired simultaneously. In the postoperative complication 1 patient (4.54%) developed paralytic ileus which was managed conservatively, wound dehiscence seen in 1 patient managed by secondary re-suturing along with appropriate antibiotics, urinary tract infection was found in 1 patient(4.54%) (Table 1).

There was no need for blood transfusion in any patients. Total duration of stay in the hospital (post procedure) was 8-10 days in 19 patients, only 3 patients had to stay longer (15-21 days) due to perioperative complications (cystostomy, paralytic ileus and wound dehiscence).

During follow-up at 1, 3, 6 and 12 months, all patients were evaluated for anatomical correction by per speculum examination and symptomatic relieves and last recorded values were used for analysis.

In the follow up period 1 patient had dyspareunia and 1 patient had lower backache around 6 months that gradually subsided and not present at 12 months, none of the patients had recurrence of pelvic organ prolapse in any compartment and mesh erosion (Table 2).

Pre-operative and post-operative quantitative measurements of POP (Table 3) and ICIQ-VS Scores were compared (Table 4). The POP-Q staging for apical prolapse in all patients was stage- 0/1 in post-operative follow-up at 12 months. Apical correction was 100% in all patients (mean point C= -7cm), 2 tailed p value was <0.0001 (t=35.41, df = 21, 95% confidence interval=10.70 to 12.03, R squared= 0.9835) which shows present study is highly significant (Table 3).

In the ASHP group- none of the patients got pregnant during the follow up period. They were advised for planned pregnancy; early ANC booking and proper follow up. Paired t test for subjective outcomes by ICIQ-VS scores (Pre-operative and post-operative ICIQ-VS Scores comparison) (Table 4), p value was < 0.0001 which showed study is highly significant (Figures 1 and 2).

Table 1: Perioperative complications of the procedures (n=22)

Intra operative complications	**n**	**%**
Cystostomy	1	4.54
Bowel injury	0	0
Hemorrhage (>500ml)	0	0
Post operative complications	**n**	**%**
Fever	0	0
Paralytic ileus	1	4.54
Wound dehiscence	1	4.54
Need of blood transfusion	0	0
Urinary Tract Infection	1	4.54

Table 2: Complications found during follow-up periods at 6 months and 12 months (n=22)

Complications	**6 Months**	**12 Months**
POP-Q staging	Stage 0/1	Stage 0/1
Recurrence of POP	None	None
Dyspareunia	1 (4.54%)	0
Backache	1 (4.54%)	0
Mesh erosion related symptoms	None	None

POP – Pelvic organ prolapse
POP– Q staging – Pelvic Organ Prolapse Quantification system

4. Discussion

There are various surgical options available for apical prolapse management. Vaginal sacrospinous colpopexy, abdominal sacrocolpopexy (reconstructive procedures) and colpocleisis (obliterative surgery) are surgical options for vault prolapse. For young and nulliparous women with uterine descent where uterus preservation is required, operative procedures are abdominal wall cervicopexy (uterus is fixed to under surface of abdominal wall), transvaginal sacrospinous fixation with uterine preservation, Shirodkar's procedure, various sling operations using autologous or synthetic graph material, sacrohysteropexy by open laparotomy or laparoscopy.

Table 3: Pre and postoperative quantitative measurements (in cm) of pelvic organ prolapse (n=22) and paired t test

	Aa		Ba		C		Ap		Bp	
	Pre-Op.	**Post-Op.**	**Pre-Op.**	**Post-Op.**	**Pre-Op.**	**Post-Op.**	**Pre-Op.**	**Post-Op.**	**Pre-Op.**	**Post-Op.**
Mean	1.86	-3	+2.3	-2.95	+4.31	-7	-0.22	-2.4	+1.22	-1.77
Range	-3 to +3	-	-3 to +4	-3 to - 2	+2 to +7	-9 to - 6	-3 to +1	-3 to - 1	-3 to +4	-3 to - 1
Paired t test (pre-op. versus post-op. quantitative measurements of POP										
	Aa		**Ba**		**C**		**Ap**		**Bp**	
p value	<0.0001		<0.0001		<0.0001		<0.0001		<0.0001	
p value summary	****		****		****		****		****	
Significantly different	Yes		Yes		Yes		Yes		Yes	
t, df	t=9.563, df=21		t=9.241, df=21		t=35.41, df=21		t=6.821, df=21		t=7.345, df=21	
R squared (partial eta squared)	0.8133		0.8026		0.9835		0.689		0.7198	
95% Confidence Interval	3.770 to 5.866		4.016 to 6.348		10.70 to 12.03		1.517 to 2.847		2.216 to 3.966	

Table 4: Subjective outcome by ICIQ-VS questionnaire

	VS Score (VS max=53)		SM Score (SM max=58)		QoL Score (QoL max=10)	
	Pre-Op.	**Post-Op.**	**Pre-Op.**	**Post-Op.**	**Pre-Op.**	**Post-Op.**
Mean	40.13	2.81	20.72	1.22	7.9	0.31
Range	13 to 52	0 to 6	0 to 58	0 to 27	5 to 10	0 to 2
Paired t test (comparing Pre & Post-Op. ICIQ –VS Score)						
	VS Score (VS max=53)		**SM Score (SM max=58)**		**QoL Score (QoL max=10)**	
p value	<0.0001		<0.0001		<0.0001	
Significantly different	Yes		Yes		Yes	
t, df	t=15.21, df=21		t=9.563, df=21		t=26.25, df=21	
R squared (partial eta squared)	0.9146		0.9003		0.9704	

ICIQ-VS: International Consultation on Incontinence Questionnaire – Vaginal Symptoms
SM: Sexual Matters QoL: Quality of Life
Pre- op.: Pre operative
Post- op: Post operative

The management of apical prolapse depends upon age, parity, associated comorbidities, duration of anesthesia; desire to preserve reproductive, sexual function and expertise of the surgeon.[2]

Abdominal sacrocolpopexy (ASCP) and vaginal sacrospinous colpopexy has been done commonly for vaginal vault prolapse. In ASCP, the vault is suspended with anterior longitudinal ligaments using non absorbable synthetic mesh by open laparotomy or laparoscopy. In a Cochrane database of systematic reviews conducted by Christopher Maher et al. where safety and efficacy of any surgical intervention was compared to another intervention for the management of apical vaginal prolapse. They concluded that sacral colpopexy is associated with lower risk of awareness of prolapse, recurrent prolapse on examination, repeat surgery for prolapse and post-operative SUI than a variety of vaginal interventions.[8]

Many novel techniques such as laparoscopic and robotic sacrocolpopexy have evolved. Though laparoscopic sacrocolpopexy can be equally effective as ASCP in selected women, inherent problems such as technical expertise and cost are disadvantages.[9]

The success rate ranges from 78-100% reported by Nygaard et al. in a comprehensive review for abdominal sacrocolpopexy.[10] In the present study the success rate was 100% in both objective and subjective point of view in all patients (n=22) as no recurrence of POP found in postoperative and follow-up periods as well as overall improvement of quality of life of the women. Similar comparable success rate was also found by Monika Anant et al. in their prospective observational study including 41 patients where success rate was 100% for both ASCP and ASHP procedures.[11] Also similar success rate found in Shika et al., Aparna et al. and Sapna Puri et al. in their prospective studies for effectiveness of ASCP/ ASHP for

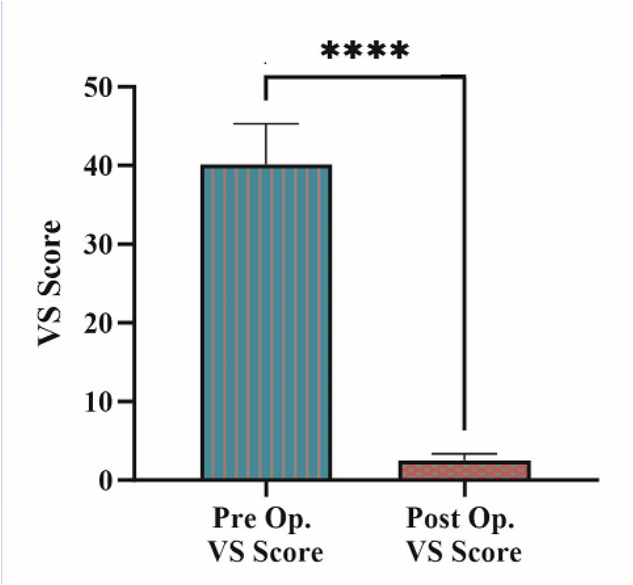

Figure 1: Showing preoperative and postoperative vs scores

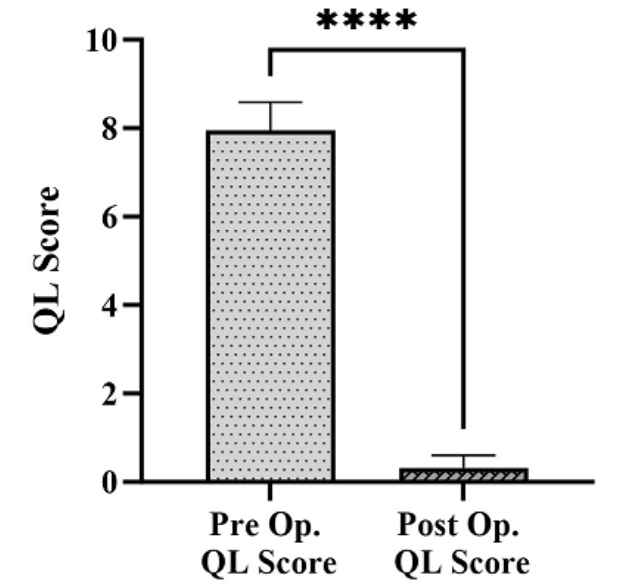

Figure 2: Showing preoperative and postoperative QoL scores

apical prolapse.[12–14]

ASCP/ASHP procedures are associated with minimal complications. In the present study 4.54% (n=1) patients had cystostomy intraoperatively, 4.54% patients developed paralytic ileus, 4.54% patients had wound dehiscence and 1 patient had urinary tract infection in the postoperative period. 4.54% (n=1) patients had dyspareunia and 1 patient had lower backache during follow up periods. Sapna Puri et al in their study found that there was no major intraoperative and post-operative complications except 1 patient had hemorrhage, 1 patient had paralytic ileus and 1 patient had dyspareunia that settled down in few months in long term follow up.[14] Similar finding also seen in Monika Anant et al., Dhama et al. in their respective studies.[11,15] Nygaard et al. concluded that sacrocolpopexy is a reliable procedure that effectively and consistently resolves vaginal vault prolapse. Patients should be counseled about the low, but present risk, of reopening for prolapse, stress incontinence, and complications.[4]

In the present study no blood transfusion was needed, no enterotomy or proctotomy happened, no SUI, no mesh erosion and mesh exposure seen. As it was a short term follow up study, so patients were counseled regarding the complications related to mesh erosion or exposure. If they develop vaginal discharge, vaginal bleeding, chronic abdominal pain, vomiting or having painful voiding, haematuria, recurrent urinary tract infection or dribbling of urine immediately report to our team. Nygaard et al. concluded in their comprehensive review for abdominal sacrocolpopexy that mesh erosion is uncommon and can occur with the use of any type of synthetic graft material. The overall mesh erosion rate was 3.4%. Abdominal sacrocolpopexy effectiveness should be balanced with long-term risks of mesh or suture erosion.[10] So to assess mesh related complications we need long term follow up to assess the success of ASCP/ASHP procedures.

Abdominal sacrohysteropexy is modifications of sacrocolpopexy that permit preservation of the uterus.[16,17] ASHP success rate reported 98.6% to 100%.[11,18]

In the present study all patients undergoing abdominal sacrohysteropexy had an objective and subjective 100% success rate. None of the patients conceived during the follow up period however they were counseled for planned conception and early ANC booking and also informed us. Monika Anant et al. reported in their study that ASHP group (n=9) concomitant tubal sterilization done in 7 patients, 1 patient conceived during follow up and delivered at 36 weeks of gestation and 1 patient was advised for follow-up in future pregnancy, the success rate was 100%.[11] Similar success rate was also seen in Sapna Puri et al. prospective study, but they had not commented on pregnancy out-come in nulliparous patients. The subject satisfaction rate was 100%.[14]

In my study all patients had marked improvement in vaginal symptoms and sexual life. They had a significant positive impact on their quality of life assessed by ICIQ-VS score. To sum, abdominal sacrocolpopexy has high and consistent success rate, no life threatening complications, improved subjective satisfaction and VS-score, abdominal sacrohysteropexy is also an effective procedure where uterus preservation is needed. Though the laparoscopic route can be equally effective as laparotomy, it has not replaced the traditional open laparotomy approach for sacrocolpopexy/sacrohysteropexy due to its inherent

problems.

5. Conclusion

Abdominal sacrocolpopexy for vault prolapse and sacrohysteropexy for nulliparous uterine prolapse have high and consistent success rate with minimal peri-operative complications. Along with this, these procedures are highly significant for patients satisfaction for vaginal symptoms and overall impact on their quality of life.

6. Limitation of the present study

As this is a short term follow up study, to assess complications especially mesh related and pregnancy outcomes in the sacrohysteropexy group need long term follow up with more sample size.

7. Source of Funding

The authors declare that this study received no financial support.

8. Conflict of Interest

The authors declare that they have no conflict of interest.

9. Ethical Approval

Ethical approval taken from the institute ethical committee.

10. Informed Consent

Informed consent was obtained from all individual participants included in the study before the procedures.

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