OUTCOMES FOLLOWING SACROSPINOUS FIXATION FOR ADVANCED PELVIC ORGAN PROLAPSE - A FIVE-YEAR COHORT STUDY

REGISTRATION NUMBER: 221716404

A dissertation submitted to Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfilment of the rules and regulations for the degree M.S. in Obstetrics and Gynaecology, to be held in May 2020
DECLARATION CERTIFICATE

This is to certify that the dissertation titled “Outcomes following sacrospinous fixation for Advanced Pelvic organ Prolapse- a Five- year cohort study”, which is submitted by me in partial fulfilment towards the M.S Branch VI (Obstetrics and Gynaecology) Degree Examinations of The Tamil Nadu Dr. M.G.R Medical University, Chennai to be held in May 2020 comprises only my original work and due acknowledgment has been made in text to all the material used.

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This is to certify that the dissertation “Outcomes following sacrospinous fixation for Advanced Pelvic organ Prolapse- a Five- year cohort study”, is a bonafide work of Dr. Kruthika Benjamin, that was carried out under guidance and supervision for the M.S (Obstetrics and Gynaecology) examination of the Tamil Nadu DR. M.G.R Medical University, to be held in May 2020.

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Outcomes following sacrospinous fixation for advanced pelvic organ prolapse – A five year cohort study.
Dr. Kruthika Benjamin, (Emp. No. 29566), PG Registrar, Obstetrics and Gynecology;
Dr. Lilly Varghese (Emp. No. 20945), Obstetrics and Gynecology, Dr. Emily Divya Ebenzer (Emp. No. 28966), Obstetrics and Gynecology.


Dear Dr. Kruthika Benjamin,

I enclose the following documents:

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

CC: Dr. Lilly Varghese, OG - 2, CMC, Vellore.
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Dr. Kruthika Benjamin,
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Outcomes following sacrosinous fixation for advanced pelvic organ prolapse – A five year cohort study.
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Ref: IRB Min. No. 11649 [OBSERVE] dated 08.11.2018

Dear Dr. Kruthika Benjamin,

The Institutional Review Board (Blue, Research & Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled “Outcomes following sacrosinous fixation for advanced pelvic organ prolapse – A five year cohort study” on November 08th 2018.

The Committee reviewed the following documents:

1. IRB application form.
2. CVs of Drs. Emily, Lilly Varghese, Kruthika Benjamin.
3. Consent Form and Information Sheets
4. Questionnaire
5. No. of documents 1-4.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on November 08th 2018 in the New IRB Room, Bagayam, Christian Medical College, Vellore 632 004.
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We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Outcomes following sacrospinous fixation for advanced pelvic organ prolapse - A five year cohort study" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

**Fluid Grant Allocation:**

A sum of 37,950/- INR (Rupees Thirty Seven Thousand Nine Hundred and Fifty Only) will be granted for 24 Months.

Yours sincerely,

Dr. Biju George  
Secretary (Ethics Committee)  
Institutional Review Board

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ACKNOWLEDGEMENT

I am grateful to my Guide, Dr. Lilly Varghese, for giving me the opportunity to work on this subject, and for patiently ensuring and encouraging me towards the completion of this study. This study has been moulded and shaped, by the constant efforts put in by my guide, and the forbearance to work with me, a novice at research.

I would also like to thank my Co-guide, Dr. Emily, for all the support and calm reassurance that she has given me throughout my course.

I would like to thank my Statistician, Mrs. Mahasampath Gowri, for being so approachable and prompt with her responses, and appreciate her quick grasp over my study, enabling me to complete my analysis with ease.

I would like to thank my family and friends for bearing with me, and supporting me through thick and thin.

And last but not the least, The God Almighty for the divine intervention, without whom, this study would not have become a reality.
ABBREVIATIONS

POP : Pelvic organ Prolapse
PHVP : Post Hysterectomy vault prolapse
SSF/SSLF : Sacrospinous ligament fixation
PFDI : Pelvic Floor Distress Inventory
UDI-6 : Urinary Distress Inventory
CRADI-8 : Colorectal and Anal Distress Inventory
POPDI-6 : Pelvic Organ Prolapse Distress Inventory
PFIQ : Pelvic Floor Impact Questionnaire
VH : Vaginal Hysterectomy
PFR : Pelvic floor repair
SUI : Stress Urinary Incontinence
IUGA : International Urogynaecological Association
AUGS : American Urogynaecological Society
ICS : International Continence Society
Contents

INTRODUCTION .......................................................................................................................... 16
AIMS OF THE STUDY: ............................................................................................................. 18
OBJECTIVES: ............................................................................................................................ 19
HYPOTHESIS: ............................................................................................................................. 20
METHODOLOGY ...................................................................................................................... 21
  STUDY POPULATION: ............................................................................................................. 22
  SAMPLE SIZE: ......................................................................................................................... 24
  DATA COLLECTION: ................................................................................................................. 26
  STATISTICAL ANALYSIS: ...................................................................................................... 29
LITERATURE REVIEW ............................................................................................................ 30
  ANATOMY OF THE PELVIS WITH RELATION TO SACROSPINOUS LIGAMENT: .................. 31
    Clinical application of Anatomy of Sacrospinous ligament: .............................................. 33
POP-Q CLASSIFICATION: ........................................................................................................ 34
POP-Q SCORING .................................................................................................................... 35
EPIDEMIOLOGY: ..................................................................................................................... 38
HISTORY(19): ............................................................................................................................ 40
AETIOLOGY OF RECURRENT PELVIC ORGAN PROLAPSE: ................................................... 43
APICAL PROLAPSE SURGERY(26): ....................................................................................... 44
QUESTIONNAIRE: Pelvic floor distress inventory (PFDI) and the Pelvic floor Impact
questionnaire (PFIQ): .............................................................................................................. 47
POST HYSTERECTOMY VAULT PROLAPSE: ......................................................................... 49
SACROSPINOUS LIGAMENT FIXATION- SURGICAL DETAILS: ............................................. 51
  OPERATIVE TECHNIQUE: ...................................................................................................... 52
    Standard Precautions taken: ............................................................................................... 53
    Unilateral vs Bilateral sacrospinous fixation: ...................................................................... 53
    Suture material: .................................................................................................................... 54
  Complications following SSF: .............................................................................................. 55
LONG TERM COMPLICATIONS: ............................................................................................. 59
Recurrence following SSF: ................................................................. 59
Recurrence of cystocele: ............................................................... 61
RESULTS .............................................................................................. 62
I) DEMOGRAPHIC VARIABLES: .......................................................... 64
II- DETAILS OF THE SURGERY: ............................................................ 71
   1) TYPE OF SURGERY: ................................................................. 71
   2) INTRAOPERATIVE BLOOD LOSS: ............................................... 72
   3) OPERATING TIME: .................................................................... 73
   4) ADDITIONAL SURGICAL PROCEDURES: ..................................... 74
   6) POST-OPERATIVE COMPLICATIONS: ......................................... 75
      Immediate post-operative: ........................................................... 75
III) OUTCOMES: .................................................................................. 77
      A) Anatomic Recurrence: ............................................................. 79
      b) Functional Recurrence: ............................................................ 80
DISCUSSION: ....................................................................................... 86
STRENGTHS OF THE STUDY: ............................................................. 89
LIMITATIONS: ...................................................................................... 90
CONCLUSION: ..................................................................................... 91
ANNEXURE I ....................................................................................... 97
   PATIENT INFORMATION SHEET ................................................... 97
ANNEXURE II ..................................................................................... 98
   CONSENT FORM ............................................................................. 98
ANNEXURE III: ................................................................................ 100
   PROFORMA: .................................................................................. 100
ANNEXURE IV: ................................................................................ 105
   THESIS DATA ............................................................................... 105
INTRODUCTION
Pelvic organ prolapse [POP] is a common health problem affecting up to 50% of parous women over 50 years old. Pelvic organ prolapse may adversely affect physical, emotional and sexual health of an individual. With increasing vaginal descent, of pelvic organs into the vagina, various bladder, bowel and prolapse symptoms increase.

A significant number of women undergo surgery for pelvic organ prolapse by the age of 80 (1). Vaginal hysterectomy [VH] with a pelvic floor repair [PFR] surgery is the most common primary surgery done for POP. However, long term recurrence rates following a hysterectomy with a vault prolapse, have been noted to be a remarkable 17-30% (2,3).

Defects in the apical vaginal support are crucial to recognise and address when undertaking surgery for prolapse, and a failure to recognize or address apical prolapse is likely to lead to suboptimal treatment outcomes for prolapse procedures resulting in recurrence after primary surgery. (4)

Sacropinous ligament fixation is a procedure which seeks to restore the apical vaginal support, and is one of the site-specific approaches used, (4) to prevent a recurrence in apical compartment in advanced pelvic organ prolapse. It can be performed as a concomitant procedure with a primary POP repair surgery, and has
been practiced at our institution for the past 10 years for advanced pelvic organ prolapse.

This is a Historical cohort study, to evaluate the outcomes following Sacrospinous ligament fixation done in women with advanced pelvic organ prolapse in Christian Medical College, Vellore, under the Department of Obstetrics and Gynaecology - Unit II.

AIMS OF THE STUDY:

- To evaluate the anatomic outcome following Sacrospinous fixation in patients who underwent vaginal surgery with pelvic floor repair for advanced pelvic organ prolapse and post hysterectomy vault prolapse.
- To evaluate the post-operative functional outcome and quality of life following SSF by using validated standardised questionnaires.
OBJECTIVES:

Primary objective:

To estimate the anatomic outcome in terms of the recurrence rate of POP in various segments of the pelvis in patients who have undergone Sacrospinous fixation for advanced POP over the past 5 years in CMCH, using POP Q classification.

Secondary objective:

1. To evaluate the functional outcome following SSF in patients who have undergone surgery for POP using standardised questionnaires regarding genitourinary and defecatory and recurrent pelvic organ prolapse symptoms.

2. To assess the quality of life in the study population.
HYPOTHESIS:

Our hypothesis is that the recurrent genital prolapse in women with advanced pelvic organ prolapse who underwent surgical treatment with sacrospinous fixation with or without concomitant VH and PFR is low. This results in a significant improvement in the overall quality of life, and is beneficial in women who wish to preserve sexual function.
METHODOLOGY
A historical cohort study.

**STUDY POPULATION:**

Women with stage III and IV POP, who were treated surgically and underwent a concomitant SSF for a period of 5 years in the department of Obstetrics and gynaecology Unit II in Christian Medical College, were approached telephonically or by post for participation in the study, and were also able to review in OPD for follow-up.

Patients who had undergone a SSF as a concomitant procedure with a primary prolapse procedure between the period from January 2012 to December 2016, amounting to 162 surgeries were considered, with a follow-up period of 2 years, so as to ensure the long-term outcomes are appropriately estimated.

Patients were contacted by telephone or by mail and invited for follow-up in OPD with an incentive for a non-payable check-up and redressal of any problems related to surgery.

Inclusion and exclusion criteria were applied.
Patients included were divided into the immediate post-operative, medium term and long-term follow-up (definitions as described in the upcoming segment).

The immediate post-operative and medium-term evaluation was through a chart analysis and the long term were reviewed either in person in OPD, through a telephonic interview or outpatient chart analysis.

Inclusion criteria:

- Patients willing for review in OPD
- Patients with a verbal consent, willing to answer our queries over the telephone.
- Chart analysis of patients who had reviewed post-operatively.

Exclusion Criteria:

- Women who are unwilling to participate in the study- Namely one patient who refused to participate as she was suffering from depression.
- Women not contactable either through telephone or mail, and were considered lost to follow-up.
- For those with a chart analysis with no pre-operative POP-Q staging.
SAMPLE SIZE:

All the women who underwent SSF for grade III and IV POP between January 2012 till December 2016 [over a period of 5 years] in the department of Obstetrics and Gynaecology, Unit II in CMC, were considered eligible for inclusion.

The patients were followed up in the immediate post-operative period (within 3 months of the surgery), the medium term follow-up and long term follow-up (more than 12 months after the surgery)(6). The sub group reviewed in the long term included patients who were able to follow-up in OPD either as a chart analysis or reviewed in person, or those who could be contacted and were willing for telephonic participation.

There were 162 women who had undergone Sacrospinous ligament fixation [SSF] under the Department of Obstetrics and Gynaecology Unit II between the period of January 2012 to December 2016.

All the women who were contactable through mail or the telephone, and willing to participate, were recruited in the study.
The follow-up of the patients was as follows, where the total number of patients were 115:

<table>
<thead>
<tr>
<th>FOLLOW UP</th>
<th>NO. OF PATIENTS</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHORT TERM</td>
<td>60/115</td>
<td>52.17%</td>
</tr>
<tr>
<td>MEDIUM TERM</td>
<td>15/115</td>
<td>13.04%</td>
</tr>
<tr>
<td>LONG TERM</td>
<td>40/115</td>
<td>34.78%</td>
</tr>
</tbody>
</table>

*Table 1: Table showing period of follow-up*

Women who also had an OPD record of follow-up post-operatively were included in the chart analysis. The patients included in this study were as follows:
Figure 1: Flowchart showing recruitment of patients

**DATA COLLECTION:**

Women who underwent SSF between 2012-2016
N=162

- Women who passed away N=7
- Not willing to participate=1
- Women with no follow-up N=39

Immediate post-op review N=60

Medium term review N=15

Long term analysis N=40:
- Telephonic interview N=7
- Chart analysis N=15
- Patients reviewed in OPD N=18
Primary outcome:

For patients reviewed in OPD, a general clinical and pelvic examination was done by
an experienced consultant, to prevent incorrect documentation of findings. The POP-Q
was recorded for each of the patients. The stage was noted through the POP-Q and
was taken as the anatomic recurrence.

Brubaker et al described anatomic (objective) recurrence as(1):

Any descent of the vaginal segment (anterior, posterior or apical cuff scar ) below a
point which is 1 cm above or below the level of the hymen (POP-Q ≥ stage 2)

Secondary outcome:

The patients were administered the Pelvic floor Distress Inventory [PFDI-20] and
Pelvic Floor Impact Questionnaire [PFIQ-7], which are validated questionnaires used
as the instruments in this study, and scored.

The two questionnaires, The PFDI- 20 and the PFIQ- 7 have been described in detail in
the literature review.

The subjective recurrence was described as:

Significant beyond a score of 62 as per the PFDI- 20(7)
A score above 20 shall be taken as significant for the PFIQ-7(8)

Patients who were contactable over the telephone, and unable to review in OPD, were asked two questions, considered significant for assessment of a functional recurrence, as described by Barber et al(9)

a) if they had any bulge symptoms?

b) if they felt the need for a re-operation?

The answers were recorded after a verbal consent was taken.

A detailed chart analysis was done from the available databases on the CMC workstation and the functional and anatomic recurrence was estimated from the records available.
STATISTICAL ANALYSIS:

Quantitative variables were summarized mean + SD / Median (interquartile range) for continuous variable depending on normality. Categorical variable were expressed as frequency and percentages.

The anatomic and functional recurrence rate will be presented with 95% CI.

Functional recurrence was estimated in terms of:

- PFDI and PFIQ scores- compared and was presented with mean+ SD/Median
- Symptoms- frequency and percentages were calculated.

The demographic variables in the anatomically recurred and non-recurred were compared using independent t-test and chi-square test for the categorical variables.

The Kaplan- Meier survival curve was created for descriptive purposes using the censoring interval to estimate the probability of anatomic failure.

All the analyses were done using STATA IC/ 15.0 software and SPSS statistics/17.0.
LITERATURE REVIEW
De Lancey’s levels of Vaginal supports and defects:

The upper vagina, cervix and uterus are tubular structures, which are supported by condensations of endopelvic muscles and fascia all along their length. The vagina measures approximately 7-10 cm in length.

It is important to understand the supports of the uterus and vagina at each level to understand the various compartment defects and how, sacrospinous ligament fixation, and other concomitant procedures can be utilized to address each of the defects. De Lancey described the supports as described below:
<table>
<thead>
<tr>
<th>LEVEL</th>
<th>SUPPORT</th>
<th>DEFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>I: Proximal (upper)</td>
<td>Paracolpium ligaments</td>
<td>UV prolapse</td>
</tr>
<tr>
<td></td>
<td>Uterosacral and cardinal ligaments</td>
<td>Vault prolapse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enterocoele</td>
</tr>
<tr>
<td>II: Mid- vaginal</td>
<td>Lateral attachment to pelvic side wall to ATFP, ATLA</td>
<td>Anterior and posterior wall defect and SUI</td>
</tr>
<tr>
<td>III: Distal vaginal</td>
<td>Pubococcygeal fascial and RVS fusion to UGD, PB</td>
<td>Lax perineum, low rectocoele and anal incontinence</td>
</tr>
</tbody>
</table>

Sacrospinous ligament fixation addresses apical prolapse, that is, level I defects.

Table 1 De Lancy's levels of supports and defects at each level; *UV- uterovaginal; *ATFP-arcus tendinus fascia pelvis; *ATLA-Arcus tendinus levator ani; *SUI-Stress urinary incontinence; *RVS- Rectovaginal septum; *UGD- urogenital diaphragm; *PB- Perineal body.
Clinical application of Anatomy of Sacrospinous ligament:

The sacrospinous ligament extends medially from the ischial spine to the medial aspect of the sacrum and coccyx. Anteriorly, the surface is muscular and forms the coccygeus muscle. SSF should be done some distance medial to the ischial spine to avoid the neurovascular bundle, namely, the pudendal complex and the sciatic nerve.

It is advised that the sutures be taken through the substance of the ligament and 2 cm medial to the ischial spine.

Figure 3 Anatomy of sacrospinous ligament; Katke et al; International Journal of Research in Health Sciences. July - Sept 2016 Volume-4, Issue-3
**POP-Q CLASSIFICATION:**

It is a universally accepted quantification system for pelvic organ prolapse, as mentioned in the Standardised Terminology jointly amended by the two professional bodies, The International Urogynaecological Association (IUGA) and the International Continence Society (ICS) and recommended by the American Urogynaecological Society (10–12).

The POP-Q is used as the tool to evaluate the anatomic recurrence in this study.

It has been used as the standard for Quantification of POP, as recommended by the AUGS in 2017 (13), and is being used by almost 82.1% of the Urogynaecologists, as reported in 2010 (14). A notable interobserver and intra-observer reliability has been demonstrated with the use of POP-Q (15).
POP-Q SCORING:

Points and landmarks for POP-Q system examination. Aa, point A anterior; Ap, point A posterior; Ba, point B anterior; Bp, point B posterior; C, cervix or vaginal cuff; D, posterior fornix (if cervix is present); gh, genital hiatus; pb, perineal body; tvl, total vaginal length.

Figure 4: Bump et. al; The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction; AJOG 1996
The POP-Q is represented in a grid fashion, with all the above-mentioned points represented as follows:

![Diagram of POP-Q scoring system]

*Fig. 2. Three-by-three grid for recording quantitative description of pelvic organ support.*

*Figure 5 Bump et al; The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction; AJOG 1996*
The points are noted and the staging is done according to the POP-Q staging defined by the International Continence Society (ICS), as described in the following table:

<table>
<thead>
<tr>
<th>STAGE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No prolapse demonstrable</td>
</tr>
<tr>
<td>1</td>
<td>Most distal portion of the prolapse is &gt;1 cm above the level of the hymen</td>
</tr>
<tr>
<td>2</td>
<td>The most distal portion of the prolapse is between 1 cm above or below the level of the hymen (atleast one point is -1,0 or +1)</td>
</tr>
<tr>
<td>3</td>
<td>The most distal portion of the prolapse protrudes &gt;1 cm below hymen, but no further than 2 cm &gt; TVL</td>
</tr>
<tr>
<td>4</td>
<td>Complete vaginal eversion; most distal prolapse protrudes to atleast (TVL-2) cm</td>
</tr>
</tbody>
</table>
**EPIDEMIOLOGY:**

Pelvic organ prolapse is a common health problem affecting up to 40 % of parous women over 50 years old (1). The lifetime risk of needing surgery for prolapse by the age of 80 is around 11-19% (2).

Recurrence in prolapse occurs approximately in 25% within 5 years, with need for subsequent surgery in around 17%(5)

Risk of recurrence was seen to increase with each vaginal delivery and an 8-fold increase in women with more than 4 vaginal deliveries. It has also been noted that hysterectomized, aged 55 years or older, have substantially increased risk of prolapse surgery, and more in those who had undergone a POP repair surgery in the form of a vaginal hysterectomy(4)

Recurrence has been defined in terms of subjective and anatomic recurrence, where the rates have been noted to be significantly low when a concomitant, site-specific repair was performed with the primary POP surgery, especially for advanced prolapse.(6)

A retrospective study of 114 women who underwent surgery between 1998 and 2003 in Northern Ireland, by Costa et al estimating the recurrence of prolapse following traditional vaginal hysterectomy with or without colporrhaphy in an Irish population showed Objective recurrence rate through POP Q assessment
[recurrence of vault prolapse of stage II of more] of 16% and subjective recurrence [The IVIQ- VS questionnaire for quality of life; need for re-operation or bulge symptoms] of 33%. (16)

The anatomic recurrence rates following SSF were found to be between 2.4% to 19% (17); and was found to vary with the different compartments, with the maximum recurrence in the anterior compartment in the form of a cystocoele [40.1 % anterior, 11% apical and 18.2% posterior]. The subjective recurrence was found to be between 10.3% to 13%(18)

The frequency of use of SSF for POP surgery is variable, depending on the skill and knowledge of the operating surgeon, the surgical expertise and the handedness of the surgeon, the associated co-morbidities and the stage of POP.

The SSF success rates shall be described later in the section for recurrence following SSF.

There were 162 women who underwent SSF along with a primary POP surgery in the department of Obstetrics and gynaecology, between the years 2012 to 2016. However, the number per year were highly variable, ranging from 59 in the year 2013 to a mere 6 in 2016, owing to the factors described above.
Pelvic organ prolapse has been described in ancient literature dating back to 2,000 BC, as. From the early 1800s through the turn of the century, various surgical approaches have been described to correct pelvic organ prolapse, which has now evolved from the use of pomegranates as pessaries to robot-assisted laparoscopic sacrocolpopexy. (1)

Figure 6: Te Linde’s Operative gynaecology; depicting ancient methods to correct POP
The first successful surgical attempt at cure of uterine prolapse was self-performed by Faith Raworth, as described by Willouby in 1670. She was reported to have self-performed the surgery, where she pulled down on the cervix and resected the prolapse with a sharp knife. However, she suffered from haemorrhage and urinary incontinence. From the early 1800s through the turn of the century, various surgical approaches have been described to correct pelvic organ prolapse.

Abdominal procedures like Sacro colpopexy were introduced and popularised. (20) However, vaginal procedures with native tissue repair like Mc Call’s culdoplasty, uterosacral ligament fixation and sacrospinous ligament fixation were developed as site-specific repair surgeries to prevent vault prolapse, and were implicated to have better outcomes in terms of recovery and success rates.

Zweifel, in 1892, first described this vaginal reconstructive approach when he connected the vaginal vault to the Sacro-tuberous ligament using silk worm sutures. Seder first described the idea of fixing the uterine prolapse and vaginal vault to the sacrospinous ligament in 1958 and it gained in popularity (Richter 1968 in Europe; Richter and Albrich 1981; Randall and Nichols 1971 in USA). To date, more than 40 different techniques have been described to treat vaginal vault prolapse (Sze and Karram 1997).
Sacrospinous ligament fixation was first described in 1987 by Miyazaki and popularised by Sharp and Richer. The technique underwent several modifications, describing various methods of placing the sutures, for example, the Miya Hook ligature carrier and the Shutt suture punch system adopted by Sharp. (21)
AETIOLOGY OF RECURRENT PELVIC ORGAN PROLAPSE:

Recurrence of POP is multifactorial. The factors most frequently described are:

- Multiple normal deliveries: Weakening of the pelvic floor as a result of injury to levator ani muscles is widely accepted as a risk factor, where, the diminished muscle contractility and strength and a widened genital hiatus, contribute to the increased likelihood to develop recurrent POP following a primary procedure (22).

- Several other factors such as age, obesity, high parity and advanced stage of an initial prolapse have been reported to be associated with recurrent POP (8–10)

- It has been implicated that recurrence of POP may also be due to persistent unrecognised compartment defects, unaddressed at primary surgery. Alternatively, de novo defects may occur in a different compartment predisposed to recurrence due to the redistribution of forces following a primary operation (23–25).
As described previously, apical prolapse is due to level I defects. There are various procedures developed, addressing these defects. Few of them very popularly used are:

- **Abdominal sacrocolpopexy**- an abdominal procedure done, where the vault is fixed to the sacral promontory, either with the patient’s native tissue or with the help of grafts.

- **Mc Call’s culdoplasty**- A method of securing the vault apex using the uterosacral and cardinal ligaments and attaching them to the posterior peritoneum.

*Figure 9: Te Linde’s Operative Gynaecology 12th edition; Mc Call’s culdoplasty*
- Ileococcygeus fascia suspension - Method to augment apical support, where the vaginal vault is anchored to the iliococcygeal fascia over the levator plate.
- Vaginal mesh to augment apical suspension.
- Sacrospinous ligament fixation - detailed description of the method is given in a later segment.

*Figure 10: Te Linde's Operative Gynaecology 12th edition; Mesh repair augmentation procedures*
Upto the late 90s, an abdominal sacral colpopexy was commonly performed and was considered the gold standard. After the introduction of various vaginal procedures, the choice of surgery has been based on the skill and the handedness of the operating surgeon, the medical co-morbidities associated, sexual activity and the stage of POP.

The results following a sacrospinous ligament fixation have been comparable to the other site-specific apical methods. However, despite the low recurrence rates following SSF, the reported recurrence in the anterior compartment has been noted to be higher than with other apical procedures. This has been described in detail later, and was attributed to the posterior deflection of the vault with an SSF. It has been implied that this deflection apparently pulls the anterior vaginal wall posteriorly, hence exposing this aspect to heavy weight bearing.
**QUESTIONNAIRE:** Pelvic floor distress inventory (PFDI) and the Pelvic floor Impact questionnaire (PFIQ):

Although POP is not responsible for any significant morbidity or mortality, it has a notable impact on the quality of life, sexual function and self-esteem. Hence, it is important to evaluate the functional impact following a surgery and to quantify the improvement in the quality of life as well as the anatomic recurrence.

In this study, we have used pre-validated questionnaires as the instruments to study the subjective outcomes.

The PFDI- 20 and the PFIQ-7 cover urinary, colorectal and pelvic/vaginal symptoms related to pelvic floor dysfunction. A Psychometric evaluation showed good correlation between the PFDI/PFIQ scoring and the physical symptoms(27)

The PFDI- 20 is a symptom inventory and assesses the presence and quantifies the distress caused by 20 pelvic floor disorder related symptoms. It comprises of 6 items of Pelvic organ prolapse Distress Inventory (POPDI-6), 8 symptoms of the Colorectal Anal Distress inventory (CRADI-8) and the Urinary distress Inventory (UDI-6) which includes 6 symptoms. Patients’ scores were recorded based on the presence of
symptoms and how much it bothered them on a scale of 1-4, with a higher score suggesting greater distress.

A retrospective case review done by Letouzey et al,(7) to determine a syndrome score threshold of PFDI/PFIQ, for a significant post-operative functional improvement, concluded that a PFDI score of above 62 over 300 had a positive predictive value of 83.6% and a specificity of 62.1% for assessing a functional recurrence. However, no similar significant threshold was found for the PFIQ in any of the pertaining studies till date.

The PFIQ-7, a set of 6 questions, assesses the impact of these symptoms on the activities of daily living, and hence, the impact on the quality of life. A pilot study by Chauvin et al (8) done to evaluate the validity of questionnaires, as a measure to assess improvement in prolapse-related symptoms, quality of life and sexuality following prolapse surgery showed that a PFIQ score of less than 20/300 was suggestive of an overall improvement in quality of life.
POST HYSTERECTOMY VAULT PROLAPSE:

The recurrence rates were described in terms of anatomic and functional recurrence.

**Anatomic recurrence:**

The International Continence committee defined recurrence of prolapse following hysterectomy as any descent of the vaginal segment (anterior, posterior or apical cuff scar) below a point which is 1 cm above or below the level of the hymen (POP-Q ≥ stage 2) (1)

**Subjective recurrence:**

The functional recurrence was considered significant when –

a) For a patient interviewed telephonically, the reply was in the affirmative for bulge symptoms or a need for re-operation (28)  
   OR

b) For a patient who came for immediate or medium-term follow-up and with no long-term review, we assume that there was no functional recurrence, and hence they did not present with symptoms in OPD.

c) For a patient interviewed in person, The Pelvic Floor Distress Inventory- PFDI 20 and the Pelvic Floor Impact Questionnaire PFIQ-7 were administered and the cut-offs applied.
The cut-off for the total score of PFDI was taken as an arbitrary 62/300, and a score of more than 20/700 was taken as significant for the PFIQ tally, from studies as described previously(7,8)

It is a well-established fact that following a primary surgery for pelvic organ prolapse, the risk of recurrence, with a vault prolapse is high, with an incidence for repair being reported as 0.36 per 1000 women years, and a cumulative incidence of 0.5%(29). However, it is important to note that the subjective recurrence was always found to be lower as compared to the anatomic recurrence, that is, all women with a vault prolapse were not symptomatic, as seen by Diez-Itza et al(30). This was attributable to the fact that most of the mechanical symptoms were relieved after a primary surgery along with a pelvic floor reconstructive surgery. Olsen et al.(23) similarly reported that only 10-20% of women who have previously undergone a hysterectomy seek medical treatment for any symptoms, although an estimated 50% of parous women lose pelvic floor support resulting in POP. The Objective recurrence rate was 16% and subjective recurrence through POP-Q assessment was 33%(16). Re-operation rate in women was found to be within a range of 9.2 – 29.2% cases(23,31)
This proportion was seen to be lower in women who had undergone a concomitant procedure, along with primary surgery, especially an apical compartment repair.\(^{(32)}\) According to DeLancey et al and Lowder et al,\(^{(6,33)}\), an adequate anterior and apical compartment repair corrected 55.5\% cases of cystoceles and 30\% cases of rectoceles.

**SACROSPINOUS LIGAMENT FIXATION - SURGICAL DETAILS:**

It is a procedure which involves suture suspension of the vaginal apex/ vault to the Sacrospinous ligament, which can be done bilaterally or unilaterally. The commonly used and accepted method is unilaterally to the right.

It can be performed as a concomitant procedure along with other prolapse surgery, with minimal increase in morbidity.

The procedure seeks to restore the Level I vaginal support and is considered durable, and maintains the apical vault support, and is recommended by the RCOG in the Greentop Guidelines, July 2015\(^{(34)}\)

It also helps in maintenance of the vaginal length, hence preserving sexual function in women who are active.
OPERATIVE TECHNIQUE:

Dr. Christopher Maher, a renowned Urogynecologist, described the steps of SSF as below(35), and the same has been routinely practiced in CMC by the department of OG II.

It is mostly performed as a concomitant procedure, with a primary POP repair, that is a vaginal hysterectomy with a pelvic floor repair.

Patients are operated under general/spinal anaesthesia, after an informed consent is taken. Patient is positioned in dorsal lithotomy supported by stirrups. For sacrospinous fixation, a longitudinal incision is given in the posterior vaginal wall to expose the rectovaginal space. The epithelium is dissected laterally into the pararectal space. By blunt finger dissection, a window is created between the rectovaginal space and ischial spine. Using the ischial spine as a prominent landmark, the sacrospinous ligament is palpated and visualised. The upper border of the ligament is clearly visualised. The suture is placed through the sacrospinous ligament coccygeus muscle complex 2 cm medial to the ischial spine. The sacrospinous sutures are placed through the full thickness of vaginal muscularis at the point of new vaginal apex. Vaginal cuff is now sutured and closed. The sutures taken through the sacrospinous ligament are now tied.
Standard Precautions taken:

- Prophylactic broad-spectrum cover was given to all patients to decrease the risk of infection.
- Thromboprophylaxis was given according to the Modified Caprini scale recommendations.
- A vaginal pack was often placed for the immediate 24 hours post-operative period to decrease the risk of bleeding.

A catheter was placed for continuous bladder drainage for a period considered apt depending on the grade of cystocele.

Unilateral vs Bilateral sacrospinous fixation:

Sacrospinous fixation was first described as a bilateral procedure, and was considered to be more anatomical and to maintain a wider vaginal vault.(21) However, when performed unilaterally, it has been found to cause less pull displacing the vault posteriorly, as described previously, and hence, causing an anterior wall defect.(26)

The clinical outcomes following unilateral and bilateral SSF were similar, where, the anatomical cure rates at 85.5% and 90.2% were statistically comparable(36). The peri-operative morbidity, in terms of bleeding requiring transfusions, organ injuries, febrile morbidity and post-operative stay were similar(37). There was no significant difference in the two groups with respect to recurrence of cystocele or vault prolapse.
Suture material:

Studies done compared absorbable (polyglactin-910) and delayed absorbable (polydioxanone PDS II) sutures for sacrospinous fixation. Non- absorbable sutures like prolene are supposed to remain durable and reduce the chances of recurrence, however, they were associated with increased risk of suture erosion, granuloma formation, vaginal bleeding and re-operation, and therefore, are not commonly in use(38). Following a 2-year follow-up, there was no significant difference between absorbable and delayed absorbable sutures, in terms of short or long-term morbidity. Both groups showed a similar improvement of 95% in Quality of life. There was no significant difference in the recurrence rates of cystocele and the objective cure rates were comparable, at 91.25 and 92.68% respectively.
Complications following SSF:

Even though there were no major surgical complications with SSF, the notable ones reported, in comparison to other concomitant apical procedures were:

**Intra-operative:**

1. **Bleeding:**

   The incidence of intra-operative bleeding necessitating transfusion varied from 0.5 to 2.5% (5) and correlated with the extent of surgical dissection. The mean estimated blood loss was 547 ml (39).

   The inferior gluteal artery is the most commonly injured vessel during SSLF due to its location (40). However, injury to the pudendal artery, coccygeal branches of the inferior gluteal artery, the sacral veins, arterial anastomoses or anomalous vessels adjacent to the posterior aspect of the ligament can also cause intra-operative haemorrhage. Mortality due to haemorrhage during SSLF is very rare. However, it is important to be aware of and identify the pelvic vascular anatomy, and know the treatment options available. Bleeding due to venous plexus injury can be controlled with pressure and packing. Bleeding from inferior gluteal vessel should be addressed with packing, vascular clips or arterial embolization (41). Internal iliac artery ligation could be done in case of bleeding from the internal pudendal artery.
2. **Organ injuries:**

Injuries to the adjacent structures like bladder and rectum are rare, with an increased risk with a prior colporrhaphy. The incidence of rectal injury during SSF is low at 0.6–0.8% (42). Bladder injury is more likely to be secondary to anterior pelvic floor reconstructive surgery, rather than SSLF itself (5).

3. **Operative time:**

The median operative time was 93 minutes for a uterovaginal prolapse and 75 minutes for a vault prolapse (43). This was recorded when it was performed as a concomitant procedure, along with a Primary POP surgery.

The mean operating time for unilateral SSLF, when performed along with a vaginal hysterectomy was an additional 76 minutes; as compared to a bilateral SSLF which took 80.5 minutes (37).
Immediate post-operative complications:

Gluteal pain and temporary foot drop:

The incidence of temporary buttock and posterior thigh pain ranges from 6.1 to 13.7%. Gluteal and posterior thigh pain have been particularly described following SSF. (44) The pain spontaneously resolved in most cases within 3-6 months (39).

A temporary foot drop was also reported, where there is a loss of sensation over the posterior aspect of the thigh, which again, is recovered over 6 weeks reported (45). Injury to the nerves to the coccygeus and levator ani, found traversing over the centre of the Sacrospinous ligament, and the pudendal nerve which is in close proximity as described previously, has been implicated. (46).

Hence, to avoid these neurovascular bundles, the medial third of the ligament, described as 2 cm from the ischial spine has been described as the ideal site for placing the sutures. (47)

Urinary tract infections:

Incidence of post-operative UTIs were found to range between 8-10%. However, the urinary tract function cannot be completely attributed to SSF as concomitant procedures like an anterior colporrhaphy were performed, which affect the outcome following the surgery. (39)
**Wound infections:**

Wound complications, such as cuff cellulitis and rare complications such as ischiorectal abscess, were seen only up to a maximum of 3% of the overall complications. (39)

All such reported cases were managed conservatively with antibiotics and there were no reported cases requiring surgical intervention for the above, in most of the studies done till date.
LONG TERM COMPLICATIONS:

Dyspareunia:

In a study done by Aigmueller et al(48), studying the long term outcomes following sacrospinous fixation, one patient out of the 99 women(1.1%) complained of dyspareunia following sacrospinous fixation.

Recurrence following SSF:

Listed below are a few similar studies in comparison; with the subjective and objective recurrence rates which were incurred:

The recurrence rates or the success rates were described in each of the studies and they have been noted down in a tabular format.
<table>
<thead>
<tr>
<th>AUTHORS</th>
<th>YEAR; PUBLICATION</th>
<th>STUDY TYPE</th>
<th>SAMPLE SIZE</th>
<th>INSTRUMENT</th>
<th>OBJECTIVE OUTCOME</th>
<th>SUBJECTIVE OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cruikshank &amp; Muniz et al</td>
<td>2003</td>
<td>prospective observational</td>
<td>173 SSF</td>
<td>POP-Q</td>
<td>-</td>
<td>87.3% success rate</td>
</tr>
<tr>
<td>2. Wong et al</td>
<td>Hong Kong J. of obstetric midwifery 2013</td>
<td>Retrospective cohort study</td>
<td>28</td>
<td>POP-Q, PFDI-20, PFIQ-7</td>
<td>89.3% success rate</td>
<td>(Mean scores- 21 and 5/300)</td>
</tr>
<tr>
<td>3. Aigmuller et al</td>
<td>Int Urogynaecol 2008</td>
<td>Cohort study</td>
<td>55</td>
<td>POP-Q</td>
<td>71% success rate</td>
<td>84% success rate</td>
</tr>
<tr>
<td>4. Tsai-shu Lo et al</td>
<td>TJOG, 2017 Aug</td>
<td>Prospective cohort study</td>
<td>139</td>
<td>POP-Q</td>
<td>73.3% success rate</td>
<td>70% success rate</td>
</tr>
<tr>
<td>5. Niemenen et al</td>
<td>AOGS 2003</td>
<td>Cohort study (Follow-up)</td>
<td>138 over 14 years</td>
<td>POPQ</td>
<td>21% recurrence With 14% cystocele</td>
<td>10% recurrence</td>
</tr>
<tr>
<td>6. Morgan et al</td>
<td>ACOG 2007</td>
<td>Systematic review</td>
<td>10 studies</td>
<td>-</td>
<td>10.3% recurrence</td>
<td>13% recurrence</td>
</tr>
<tr>
<td>7. Maher et al</td>
<td>AJOG 2004</td>
<td>Prospective Randomised study</td>
<td>9 studies</td>
<td>Baden Walker IIQ and SUDI</td>
<td>69% success</td>
<td>91% success</td>
</tr>
<tr>
<td>8. Costa et al</td>
<td>UMJ 2014</td>
<td>Retrospective Cohort study</td>
<td>114</td>
<td>POP-Q, ICQI-VS</td>
<td>33% recurrence</td>
<td>16% recurrence</td>
</tr>
</tbody>
</table>

*Table 2: Table with the long term outcomes of various comparable studies*
Recurrence of cystocele:

As described before, the anterior compartment prolapse has been seen to occur more commonly following an SSF. A metanalysis done by Petri and Ashok in 2010, looking at the recurrence rates was as below:

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Follow-up</th>
<th>Subjects (n)</th>
<th>Anterior vaginal prolapse</th>
<th>Symptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toglia (2008) (4)</td>
<td>Retrospective cohort</td>
<td>2 years</td>
<td>64</td>
<td>17.18%</td>
<td>3%</td>
</tr>
<tr>
<td>Hefni (2006) (5)</td>
<td>Prospective observational</td>
<td>57 months</td>
<td>305</td>
<td>13%</td>
<td>5%</td>
</tr>
<tr>
<td>Lovatos (2002) (6)</td>
<td>Retrospective</td>
<td>1-5 years</td>
<td>293</td>
<td>5.8%</td>
<td></td>
</tr>
<tr>
<td>Zaniech (2001) (7)</td>
<td>Retrospective</td>
<td>6 months-9 years</td>
<td>123</td>
<td>8.1%</td>
<td></td>
</tr>
<tr>
<td>Maher (2004) (9)</td>
<td>RCT-SSF VS ASC</td>
<td>6 months-5 years</td>
<td>48</td>
<td>14%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Dietz (2008) (18)</td>
<td>Prospective cohort</td>
<td>12.7 months</td>
<td>72</td>
<td>13.9%</td>
<td></td>
</tr>
<tr>
<td>Morgan (2007) (11)</td>
<td>Meta-analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 11: Petri & Ashok, AOGS 2010: showing anterior vaginal vault prolapse
RESULTS
Women who underwent SSF between 2012-2016
N=162

Women who passed away N=7

Not willing to participate=1

Women with no follow-up N=39

Immediate post-op review N=60

Medium term review N=15

Long term analysis N=40:

Telephonic interview N=7

Chart analysis N=15

Patients reviewed in OPD N=18

Figure 12: CONSORT FIGURE SHOWING THE RECRUITMENT OF PATIENTS
I) DEMOGRAPHIC VARIABLES:

The baseline characteristics in the entire cohort are as described below:

<table>
<thead>
<tr>
<th>N=115</th>
<th>MEAN</th>
<th>STANDARD DEVIATION</th>
<th>MEDIAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE(YRS)</td>
<td>54.5</td>
<td>10.55</td>
<td>55</td>
</tr>
<tr>
<td>BMI(KG/M2)</td>
<td>24.3</td>
<td>4.36</td>
<td>24.15</td>
</tr>
<tr>
<td>PARITY</td>
<td>3.11</td>
<td>1.39</td>
<td>3.00</td>
</tr>
<tr>
<td>YEARS POSTMENOPAUSAL N=85</td>
<td>13.29</td>
<td>7.12</td>
<td>12.0</td>
</tr>
<tr>
<td>STUDY PROCEDURE DONE NO. OF YEARS BACK</td>
<td>5.69</td>
<td>1.43</td>
<td>6.00</td>
</tr>
</tbody>
</table>

| | | |
| MENOPAUSAL | 115 | |
| POSTMENOPAUSAL | 85 | 73.9 |
| NATURAL | 71 | 61.7 |
| SURGICAL | 14 | 12.1 |
| PREMENOPAUSAL | 30 | 26.08 |
| STAGE OF POP | 115 | |
| III | 51 | 44.34 |
| IV | 64 | 55.65 |
| DOMICILE | 115 | |
| VELLORE | 69 | 60.3 |
| REST OF INDIA | 45 | 29.13 |
| BANGLADESH | 1 | 0.8 |
| RISK FACTORS | 115 | |
| NIL | 112 | 97.3 |
| BRONCHIAL ASTHMA | 2 | 1.7 |
| CHRONIC STEROID USE | 1 | 0.08 |

*Table 3: Depicting the baseline characteristics in the cohort*
a) Age:

The mean age for women undergoing a surgery for advanced pelvic organ prolapse was 54.5 years, with most women falling between the age of 46-63 years. (25th to 75th percentile)

The oldest woman in the cohort was 79 years of age.

Figure 13 Depicting the ages of the study population, with the mean as 54.5 years
b) BMI:

The mean BMI for the women undergoing surgery was found to be 24.33kg/m².

Figure 14: Table depicting the BMI among the study population - in kg/m²

11 women were classified Obese, with a BMI of >30.0kg/m², with the maximum being 37.8kg/m².

However, there was no correlation in the BMI of the overall cohort and the incidence of pelvic organ prolapse.
c) **PARITY:**

Women with a parity of 2 or more, which is a known risk factor, present more often with advanced pelvic organ prolapse, and are likely to opt for surgical management. In our series, women with parity of 2 or more was 93.9%
d) DOMICILE:

Out of the 115 patients recruited in this study, 69 patients were from in and around the Vellore district. 13 patients were from the rest of Tamil Nadu, one patient from Bangladesh, and the remaining belonged to the Rest of India.

Hence there was no wide variation in the ethnicity in the cohort.

Figure 16: Depicting the domicile of the study population: AP- Andhra Pradesh; TN- Tamil Nadu; WB- West Bengal
e) Menopausal status:

Amongst the 115 women recruited, women who were menopausal were 85 and the remaining 30 were pre-menopausal.

<table>
<thead>
<tr>
<th>Menopausal status</th>
<th>No. of women</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes Natural</td>
<td>71</td>
<td>61.73%</td>
</tr>
<tr>
<td>Yes Surgical</td>
<td>14</td>
<td>12.17%</td>
</tr>
<tr>
<td>No</td>
<td>30</td>
<td>26.08%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>N=115</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*Table 4: Depicting the menopausal status in the cohort*

*Figure 17: The years following menopause in the cohort, at review*
The no. of years following natural menopause, where the women presented with POP was 13.29 years (25th -75th percentile- 9-18 years following natural menopause)

Most women who underwent surgery for POP were 12 years post- menopausal.

The maximum number of women recruited was from the year 2013, which also had the maximum no. of surgeries, that is 48, and only 4 surgeries were performed in the year 2016.

Hence, out of the 115 patients recruited, the most no. of women who reviewed were from the year 2013, which was 6 years from the previous pelvic reconstructive surgery.

Table 5: Graph depicting the years following SSF at review
Other medical risk factors:

Among the well-known risk factors for POP, Chronic respiratory disease, that is Bronchial asthma was seen only in 2 women, and there was one lady with history of chronic steroid use for Rheumatoid arthritis.

II- DETAILS OF THE SURGERY:

1) TYPE OF SURGERY:

30 women had a post- hysterectomy vault prolapse, out of which 14 had undergone a previous abdominal hysterectomy. Out of the 16 patients who had undergone a vaginal hysterectomy, 8 patients had undergone a pelvic floor repair surgery.

![Flowchart depicting the primary POP surgery](image-url)
2) INTRAOPERATIVE BLOOD LOSS:

The intra-operative blood loss was estimated between 50 ml to 1800ml, with an average of 416ml (SD- 259.93ml). Four patients had bleeding quantified above 1 litre, out of whom, two required blood transfusions.

Figure 19: graph depicting the estimated blood loss in millilitres
3) OPERATING TIME:

The median operating time was found to be 120 minutes and ranged between 50 minutes to 4 hours, with the longest surgery having been prolonged due to an inadvertent bladder injury, requiring repair by Urologists.
4) ADDITIONAL SURGICAL PROCEDURES:

Coexisting uterine or ovarian pathology was noted in 7 women, out of whom, 4 had fibroid uterus and one had adenomyosis. One patient had a Right ovarian cyst, which was reported benign and another had a benign endometrial polyp.

2 patients underwent an additional cystoscopy for evaluation for bladder calculi, and another cystoscopy was performed for an inadvertent bladder injury. In both cases, Urologists were called for Intra-operative assistance.

A right ovarian cystectomy for the simple ovarian cyst as mentioned previously was done. Another patient underwent a bilateral salpingoophorectomy, as she also had post-menopausal bleeding, the histopathology report for which was reported benign.

A laparoscopic retrieval of gauze was performed in a patient where a gauze had inadvertently slipped into the pelvis during vault closure.

5) Among the 115 surgeries, 56 were performed by a Consultant and 59 were performed by a PG registrar with the assistance of a Consultant.

<table>
<thead>
<tr>
<th></th>
<th>NO. OF SURGERIES</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PG REGISTRAR (with assistance)</td>
<td>59</td>
<td>51.3%</td>
</tr>
<tr>
<td>CONSULTANT</td>
<td>56</td>
<td>48.69%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>115</td>
<td>100</td>
</tr>
</tbody>
</table>
6) POST-OPERATIVE COMPLICATIONS:

Immediate post-operative:

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. of Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=115</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary retention (2 weeks)</td>
<td>7</td>
<td>6.1</td>
</tr>
<tr>
<td>Gluteal pain</td>
<td>3</td>
<td>2.6</td>
</tr>
<tr>
<td>UTI</td>
<td>7</td>
<td>6.1</td>
</tr>
<tr>
<td>Haematoma/Haemorrhage</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>19</strong></td>
<td><strong>16.52</strong></td>
</tr>
</tbody>
</table>

Table 1: Depicting the post-operative complications

19 patients out of the 115 had immediate post-operative complications, which were:
Urinary Retention: 7 patients (6.1%) had post-operative acute urinary retention, necessitating re-catheterisation for 48 hours- 2 weeks. All of these 7 patients had stage IV POP with large cystoceles.

Gluteal Pain: Three patients (2.6%) had right gluteal pain, which resolved within 3 months after the surgery.

UTI: 7 patients (6.1%) developed a urinary tract infection, requiring therapeutic oral antibiotics, and 2 of them, intravenous antibiotics.

Haematoma and Haemorrhage (1.8%): One patient was readmitted with a vault haematoma and another with secondary haemorrhage, of almost 1.2 litre estimated blood loss, and were both managed conservatively with Oral antibiotics, and patients were discharged symptom-free.
III) OUTCOMES:

The outcomes were defined in terms of anatomic and functional recurrence.

<table>
<thead>
<tr>
<th>ANATOMIC RECURRENCE (in the overall cohort N= 115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>NO</td>
</tr>
<tr>
<td>TOTAL</td>
</tr>
</tbody>
</table>

*Table 7: Depicting the functional and anatomical recurrence in the cohort*

Out of the 115 patients, 20 patients had an anatomic recurrence and 7 patients out of those had a functional recurrence also. The details are given in the following segments.

**Isolated functional recurrence was not seen, that is, functional recurrence occurred only when the patient had an anatomical recurrence.**

<table>
<thead>
<tr>
<th>ANATOMIC RECURRENCE AMONG THE LONG TERM(N=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>NO</td>
</tr>
<tr>
<td>TOTAL</td>
</tr>
</tbody>
</table>

*Table 8: Functional and anatomic recurrence in the long-term follow-up group*
Duration of follow-up:

Amongst the 40 patients who had a long-term follow-up, either in person (18), through chart analysis (15) and via a telephonic interview (7), the functional recurrence rates were estimated.

All the patients with the anatomic recurrence were those with long-term follow-up:

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>No. of patients</th>
<th>Anatomical recurrence only</th>
<th>Functional recurrence only</th>
<th>Anatomic AND Functional Recurrence</th>
<th>Recurrence Rates N=115</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate</td>
<td>60</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medium term</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Long term</td>
<td>40</td>
<td>13</td>
<td>0</td>
<td>7</td>
<td>17%</td>
</tr>
<tr>
<td>Total</td>
<td>115</td>
<td>13</td>
<td>0</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Depicting the recurrence in terms of duration of follow-up

There was a high dropout rate, estimated at 65% in this study, where 75 women out of 115 did not review for a long-term follow-up following the procedure.
A) Anatomic Recurrence:

Twenty patients were found to have an Anatomic recurrence on a post-operative POP-Q evaluation, that is more than or equal to a stage 2 prolapse. That accounted for 17% of the overall cohort (95% Confidence interval- 10.99-25.57%; Standard Error 3.53) However, it is important to note that this is a generalised estimate and, as there were only 40 patients who had a long-term follow-up, we cannot consider these as the absolute recurrence rates.

The anatomic recurrence in the group with the long-term follow-up was 50% (95% CI 31-63%; Standard error of 7.8)

Incidentally, it was noted that, out of the 20, 11(9.6%) patients had recurrence in multiple compartments and only 9(7.8%) had a single compartment, namely the anterior compartment(cystocele) recurrence.

<table>
<thead>
<tr>
<th>Compartment</th>
<th>No. of patients with recurrence N=40</th>
<th>Percentage</th>
<th>Cumulative percentage N=115</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>9</td>
<td>45%</td>
<td>9.6%</td>
</tr>
<tr>
<td>Posterior</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Multiple</td>
<td>11</td>
<td>55%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100%</td>
<td>17%</td>
</tr>
</tbody>
</table>

Table 10: Depicting the compartment-wise anatomic recurrence
The demographic variables in the group with anatomic recurrence were as follows:

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>MEAN</th>
<th>SD</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE(YRS)</td>
<td>53.21</td>
<td>12.28</td>
<td>0.7297</td>
</tr>
<tr>
<td>HEIGHT(CM)</td>
<td>153.42</td>
<td>5.31</td>
<td>0.2132</td>
</tr>
<tr>
<td>WEIGHT(KG)</td>
<td>60.63</td>
<td>12.58</td>
<td>0.0341</td>
</tr>
<tr>
<td>BMI</td>
<td>25.47</td>
<td>5.44</td>
<td>0.2644</td>
</tr>
<tr>
<td>PARITY</td>
<td>2.47</td>
<td>1.12</td>
<td>0.0290</td>
</tr>
<tr>
<td>YEARS</td>
<td>13</td>
<td>7.20</td>
<td>0.8909</td>
</tr>
</tbody>
</table>

Table 2: Depicting the demographic variables in the group with anatomic recurrence; N=20

The risk of developing a recurrence was statistically significant only with respect to obesity and parity of more than 2.

b) Functional Recurrence:

Among the 20 patients with anatomic recurrence, it was noted that only 7 patients had a functional recurrence, which accounts for only 6.09% (95% CI: 2.4-12.1%; SE: 0.022). Here again, it is important to note that these are the generalised estimates among the Cohort. Among the women who had a long-term follow-up, the recurrence rates
calculated were much higher, at 7 out of 40 patients, which accounts to 17.5% (95% CI 7.3-32.77%; Standard error-6.07)

This was taken as a PFDI- 20 score of more than or equal to 62 and a PFIQ-7 score of more than 20.

In the patients with anatomic recurrence, 12 patients presented with bulge symptoms. However, only 7 patients out of those felt the need for a re-operation to correct their symptoms.

<table>
<thead>
<tr>
<th>NEED FOR RE-OPERATION</th>
<th>YES</th>
<th>NO</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>BULGE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES</td>
<td>7</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>NO</td>
<td>0</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>7</td>
<td>13</td>
<td>20</td>
</tr>
</tbody>
</table>

*Table 11: Symptomatic recurrence in the overall cohort- N=115*

This shows that Bulge symptoms have 100% sensitivity to a functional recurrence, and a 61% specificity.

Hence, a query on whether all post-operative patients had bulge symptoms would enable us to pick up most, if not all the patients with a functional recurrence.
PFDI AND PFIQ scores among the women with anatomic recurrence (20 patients); 2 underwent re-operation and were part of a chart analysis, and hence, the PFDI and PFIQ could not be recorded, and the rest were interviewed in person.

The remaining were 11 out of the 18 women interviewed in person had PFDI and PFIQ scores of 0.

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>UDI-6</th>
<th>CRADI-8</th>
<th>POPDI-6</th>
<th>PFDI-20</th>
<th>PFIQ-7</th>
<th>Functional recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>41.6</td>
<td>28.15</td>
<td>0</td>
<td>69.125</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>2.</td>
<td>37.5</td>
<td>0</td>
<td>29.1</td>
<td>66.6</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>3.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>4.</td>
<td>33.3</td>
<td>31.35</td>
<td>33.3</td>
<td>97.5</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>5.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6.</td>
<td>0</td>
<td>0</td>
<td>29.16</td>
<td>29.16</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>7.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>8.</td>
<td>0</td>
<td>28.125</td>
<td>29.16</td>
<td>57.28</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>9.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>10.</td>
<td>41.66</td>
<td>0</td>
<td>33.33</td>
<td>75.00</td>
<td>200</td>
<td>Yes</td>
</tr>
<tr>
<td>11.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>12.</td>
<td>0</td>
<td>0</td>
<td>33.33</td>
<td>33.33</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>13.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>14.</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>No</td>
</tr>
</tbody>
</table>
Table 12: PFDI and PFIQ scores among women with anatomic recurrence

<table>
<thead>
<tr>
<th>SCORE</th>
<th>NO. OF WOMEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>0-62</td>
<td>3</td>
</tr>
<tr>
<td>&gt;62</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 13: Women with significant PFDI scores in the anatomically recurred

The total number of women with Significant PFDI scores of $\geq 62$ was 4. However, one woman with functional recurrence had borderline PFDI score, which was 57.28.

Table 14: Tabulation of PFDI and PFIQ scores

<table>
<thead>
<tr>
<th>SCORE</th>
<th>MEAN</th>
<th>SD</th>
<th>MEDIAN</th>
<th>MIN</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFDI</td>
<td>25.40</td>
<td>33.28</td>
<td>0</td>
<td>0</td>
<td>97.5</td>
</tr>
<tr>
<td>PFIQ</td>
<td>11.11</td>
<td>47.14</td>
<td>0</td>
<td>0</td>
<td>200</td>
</tr>
</tbody>
</table>
### Table 15 Table showing PFDI scores and their relation to the women with anatomic recurrence

<table>
<thead>
<tr>
<th>PFDI score</th>
<th>No. of women</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>11</td>
<td>55%</td>
</tr>
<tr>
<td>1-40</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>40-61</td>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>&gt;62</td>
<td>4</td>
<td>20%</td>
</tr>
</tbody>
</table>

In women with significant bulge symptoms, i.e., 12 women, 5 of them had a significant or near significant PFDI score (>57), and the same held good for the POPDI-6 score, which reflects the bulge symptoms in the questionnaire. Hence, it could be inferred that presence of bulge symptoms was indicative of a functional recurrence.
The mean time for follow-up and presentation in the OPD for a functional recurrence was calculated as 13.044 months following surgery (95% CI; 12.27-13.81%; SE 0.39).

Figure 21: Showing the months of follow-up at which patient presents with recurrence
DISCUSSION:

Sacrospinous fixation is a surgical procedure to reinforce and provide durable apical support in patients undergoing POP surgery, as recommended by the Greentop Guidelines by the RCOG in July 2015. This study was done to assess the outcomes in women with advanced POP following a vaginal hysterectomy with pelvic floor repair or a post hysterectomy Vault prolapse repair with a concomitant SSF.(34)

Among the 162 women who had undergone SSF in our study period, only 115 women whose follow-up could be ascertained by means of available hospital records, those who could be contacted by telephone and those who came in person were recruited. There was a very high dropout rate of 65%, thus only 40 patients were followed up in the long term. Hence, there results can only be interpreted with caution providing a general estimate.

Of the 40 with long-term follow-up, 20 had an anatomic recurrence, which amounted to 17% of the overall cohort (95% Confidence interval- 10.99-25.57%; Standard Error 0.0353) and functional recurrence was seen in 7 women, which accounts for only 6.09% (95% CI; 2.4-12.1%; SE: 0.022). These recurrence rates were similar to those in other studies.(16,48,49). None of the women from the cohort presented with functional
recurrence alone. Conversely it can be said that all patients who had a functional recurrence were also found to have an anatomic recurrence.

The subjective recurrence rate was found to be lower, at 6.09%. We also found that patients who had an anatomical recurrence, were often asymptomatic and 13 patients out of the 20, did not wish to have a re-operation, when it was offered. Hence, we conclude that, for a post-hysterectomy vault prolapse, it is important to analyse the patient’s symptoms and address them only if the recurrence is distressing to the patient.

It was also important to note, that in contrast to the other studies, (48,50) which stated the recurrence following SSF is predominantly in a single compartment, namely the anterior, our study showed recurrence in multiple compartments (9.6%), as opposed to an exclusive anterior compartment prolapse, which was seen in 9/20 patients with an anatomic recurrence (7.8%). This supports the concept of an inherently weakened pelvic supports in women with advanced POP requiring addition apical suspension procedures, results in a higher incidence of multicompartmental recurrence of POP. The recurrence of a cystocele in our study was 7.6%, which was lower as compared to studies by Nieminen et al, where a 14% cystocele was reported(50)
Among the women with a recurrence, majority of them had presented for outpatient consultation and were reviewed prior to being approached or promptly turned up for redressal of their symptoms. Women with no recurrence did not review in OPD and were mostly symptom-free, as seen in those interviewed by telephone. From this, we presume that women who had any bothersome symptoms, sought or reviewed in person for treatment.

Bulge symptoms are sensitive for a functional recurrence and a simple question as to whether the patient had bulge symptoms or not could be conclusive of a Functional recurrence.

In the cohort of women who were recruited in this study, the demographic variables in the subgroup with recurrence and those without were comparable, and showed a statistical significance with obesity and parity more than 2.

The operative time, intra-operative blood loss and the post-operative complications following an SSLF, were not markedly increased when compared to a solitary primary POP repair surgery, and hence, it is an effective and durable procedure that could be adapted by gynaecologists, to address apical prolapse.
STRENGTHS OF THE STUDY:

This is the only study done in South India, assessing the long-term outcomes following a sacrospinous fixation.

The patients were examined by only two experienced Consultants, eliminating bias.

The instruments used in this study were universally accepted and recommended, like the Standardised POP-Q system and validated questionnaires.
LIMITATIONS:

As this was a historical cohort, a lot of the patients were lost to follow-up, owing to either a change in the telephone numbers or their addresses.

We have to take into consideration, the fact that, few women who had bothersome symptoms could have sought treatment elsewhere, and that data is not available to us.

A lot of women were not able to follow-up in OPD due to distance or age hampering mobility.

The drop-out rate for a long-term follow-up was very high, at 65%. Hence, interpretation of the results in the overall cohort should be taken with caution.

As the sample size and recurrence in the cohort were small numbers, we cannot generalise the results.
CONCLUSION:

Sacrospinous fixation could be recommended as a durable procedure addressing apical prolapse, and can be used by gynaecologists as a concomitant procedure, with a primary prolapse repair to prevent a vault recurrence.

A long-term follow-up, of more than 12 months is required to adequately assess or evaluate patients for a recurrence following SSF.

More long-term studies are required to estimate recurrence rates following a Sacrospinous ligament fixation.
BIBLIOGRAPHY:


19. SSL paper.pdf.


43. Sacrospinous ligament fixation for massive genital prolapse in women aged over 80 years - Nieminen - 2001 - BJOG: An International Journal of Obstetrics &


ANNEXURE I
PATIENT INFORMATION SHEET

Title of Research Project: Outcomes following sacrospinous fixation for Advanced Pelvic organ Prolapse- a Five- year cohort study.

Patient Information Sheet:

‘Sacrospinous Fixation’ is a surgery to prevent the vagina or the operated vaginal vault from sagging down following surgery for Pelvic organ prolapse. You have undergone this procedure as part of the treatment provided here for your prior condition, that is pelvic organ prolapse.

As part of your gynaecological evaluation here, we would like to assess the improvement in your stools, urinary and sexual function, and any other problems that you have faced post-operatively. This will help us understand the improvement in quality of your life and assess the need and success of the procedure.

This study will include a physical examination and will require that you answer a set of questions provided to you. No monetary benefits or any other incentives will be provided for participating in the study. Your participation in this study will not affect either the type or quality of any further treatment that you avail here.

The assessment of your responses will help us evaluate the outcome of the procedure and help us implement the results to improve the quality of care provided to our patients with similar problems in the future.

For any further clarifications, please contact:

Kruthika Benjamin.
Primary Investigator.
P.G. Registrar.
Department of Obstetrics and Gynaecology,
CMC- Vellore.
ANNEXURE II
CONSENT FORM

Informed Consent form

Study Title: Outcomes following Sacrospinous fixation for Advanced Pelvic organ prolapse- a Five-year cohort study.
Primary Investigator: Kruthika Benjamin
P.G. Registrar.
Department of Obstetrics and Gynaecology- CMC- Vellore.

Study Number: ____________

Subject’s Initials: _________________ Subject’s Name: __________________________________________

Date of Birth / Age: ___________________________  (Subject)

(i) I confirm that I have read and understood the information sheet dated ____________ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]
I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/______

Signatory’s Name: _________________________________ Signature:

Or

Representative: __________________________

Date: _____/_____/______

Signatory’s Name: _________________________________

Signature of the Investigator: ________________________

Date: _____/_____/______
**ANNEXURE III:**

**PROFORMA:**

**QUESTIONNAIRE**

<table>
<thead>
<tr>
<th>Study number:</th>
<th>Hospital Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME:</td>
<td>PLACE:</td>
</tr>
<tr>
<td>AGE:</td>
<td>Height:</td>
</tr>
<tr>
<td>BMI:</td>
<td>Weight:</td>
</tr>
<tr>
<td>PARITY:</td>
<td></td>
</tr>
<tr>
<td>NO. OF YEARS POSTMENOPAUSAL:</td>
<td>SURGICAL/ NATURAL</td>
</tr>
<tr>
<td>TYPE OF HYSTERECTOMY- ABDOMINAL/ VAGINAL</td>
<td></td>
</tr>
<tr>
<td>If Vaginal, pelvic floor repair done? YES/NO</td>
<td></td>
</tr>
<tr>
<td>Underwent Pelvic Reconstructive surgery _____ years ago</td>
<td></td>
</tr>
<tr>
<td>For Stage _____ POP</td>
<td></td>
</tr>
<tr>
<td>Any co-existing uterine/ ovarian pathology? YES/ NO; If yes, condition: _____________________</td>
<td></td>
</tr>
<tr>
<td>Any additional pelvic surgery YES /NO</td>
<td></td>
</tr>
<tr>
<td>Any pelvic floor repair done: YES/ NO; If yes, details: _____________________________</td>
<td></td>
</tr>
<tr>
<td>Patient presented with predominantly ________________ symptoms (as documented in the OPD records).</td>
<td></td>
</tr>
<tr>
<td>MEDICAL HISTORY:</td>
<td></td>
</tr>
<tr>
<td>Tobacco use: YES/ NO</td>
<td>Chronic respiratory disease: YES/ NO</td>
</tr>
</tbody>
</table>
Connective tissue disorders: YES/NO  
Chronic steroid use: YES/NO  
Use of Hormonal therapy: YES/NO  

Patient interview in person/ telephonically/ Chart analysis  

PRE- OPERATIVE POP Q:  
STAGE:  
Aa  Ba  C  
GH  PB  TVL  
Ap  Bp  D  

SURGICAL DETAILS:  
Suture material used for SSF:  
Intra-operative blood loss:  
Operative time:  
Skill of the operating surgeon:  
First assistant:  

POST-OPERATIVE:  
Patient examined by:  
POP Q:  
STAGE:  
Aa  Ba  C  
Gh  PB  TVL  
Ap  Bp  D  

101
Any post-operative complications? ___________________

Post – operative pelvic floor exercises done? YES/NO

Symptom-free period, if applicable ________________

**URINARY DISTRESS INVENTORY- 6**

Do you experience any of the symptoms below? No=0; If yes,

<table>
<thead>
<tr>
<th>How much does it bother you?</th>
<th>Not at all=1</th>
<th>Somewhat=2</th>
<th>Moderately=3</th>
<th>Quite a bit=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent micturition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine leakage associated with feeling of urgency, that is, a strong sensation of going to the bathroom?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine leakage related to coughing, sneezing or laughing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small amounts of urine leakage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulty emptying your bladder?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain or discomfort in the lower abdomen or genital region</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Score: Total*25=

**COLORECTAL- ANAL DISTRESS INVENTORY- 8**

Do you experience any of the below symptoms? If Not- 0; if yes-

<table>
<thead>
<tr>
<th>How much does any of the below bother you?</th>
<th>Not at all=1</th>
<th>Somewhat=2</th>
<th>Moderately=3</th>
<th>Quite a bit=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need to strain too hard to have a bowel involvement?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have not completely emptied your bowel at the end of a bowel movement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lose stool beyond your control if your stool is well formed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lose stool beyond your control if your stool is loose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lose gas from the rectum beyond your control?

Usually have pain when you pass your stool

do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?

Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

Score: Total *25=

PELVIC ORGAN PROLAPSE DISTRESS INVENTORY- 6

Do you experience any of the symptoms mentioned below? If Not- 0; if yes-

<table>
<thead>
<tr>
<th>How much does it bother you?</th>
<th>Not at all=1</th>
<th>Somewhat=2</th>
<th>Moderately=3</th>
<th>Quite a bit=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any pressure in the lower abdomen?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heaviness or dullness in the pelvic area?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have a bulge or something falling out that you can see or feel in your vaginal area?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have to push on the vagina or around the rectum to have or complete a bowel movement?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have a feeling of incomplete bladder emptying?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have to push up on the bulge in the vaginal area with your fingers to start or complete urination?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Score: Total *25=

TOTAL PFDI-20 score =______/300

PELVIC FLOOR IMPACT QUESTIONNAIRE- 7

Do your symptoms affect your ability to do any of the below mentioned activities? Not at all=0

If yes- Somewhat =1; Moderately=2; Quite a bit=3
How do your symptoms affect the following?

<table>
<thead>
<tr>
<th></th>
<th>Bladder</th>
<th>Bowel</th>
<th>Vagina</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to do household chores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to do physical activities like swimming, walking?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entertainment such as to go for movies or concert?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to travel by car or bus for a distance greater that 30 minutes away from home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participating in social activities outside your home?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional health (nervousness, depression, etc)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling frustrated?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mean from each column * 100/3 summed up =

Do you feel the need to undergo a repeat procedure? YES/NO

Anatomic recurrence - YES/NO  Segment – Single / Multiple : _____________

Functional recurrence - YES/NO  Score:

FOR THOSE INTERVIEWED TELEPHONICALLY:

1. Do you experience any bulge symptoms? YES/NO

If yes, the now many years after the surgery did you develop the symptoms.

2. Do you feel the need for repeat surgery? YES/NO
<table>
<thead>
<tr>
<th>Name</th>
<th>Thesis Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample v. Vallyard</td>
<td>039</td>
</tr>
<tr>
<td>Sathya v. Vallyard</td>
<td>019</td>
</tr>
<tr>
<td>Ravi v. Vallyard</td>
<td>009</td>
</tr>
<tr>
<td>Ramakrishna v. Vallyard</td>
<td>099</td>
</tr>
<tr>
<td>Nathu v. Vallyard</td>
<td>079</td>
</tr>
<tr>
<td>Rohini v. Vallyard</td>
<td>059</td>
</tr>
<tr>
<td>Rakesh v. Vallyard</td>
<td>039</td>
</tr>
<tr>
<td>Rakesh v. Vallyard</td>
<td>019</td>
</tr>
<tr>
<td>Rakesh v. Vallyard</td>
<td>009</td>
</tr>
<tr>
<td>Rakesh v. Vallyard</td>
<td>099</td>
</tr>
<tr>
<td>Name</td>
<td>Gender</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
</tr>
<tr>
<td>Patient 1</td>
<td>Male</td>
</tr>
<tr>
<td>Patient 2</td>
<td>Female</td>
</tr>
<tr>
<td>Patient 3</td>
<td>Male</td>
</tr>
<tr>
<td>Patient 4</td>
<td>Female</td>
</tr>
<tr>
<td>Patient 5</td>
<td>Male</td>
</tr>
<tr>
<td>Patient 6</td>
<td>Female</td>
</tr>
<tr>
<td>Patient 7</td>
<td>Male</td>
</tr>
<tr>
<td>Patient 8</td>
<td>Female</td>
</tr>
<tr>
<td>Patient 9</td>
<td>Male</td>
</tr>
<tr>
<td>Patient 10</td>
<td>Female</td>
</tr>
</tbody>
</table>

*Notes:* BM1 represents Body Mass Index, Surgery refers to the type of surgery performed.