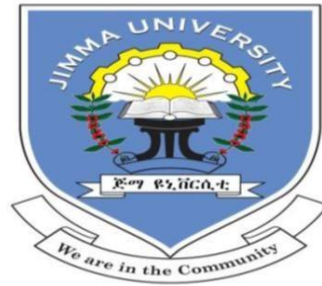


JIMMA UNIVERSITY
INSTITUTE OF HEALTH
SCHOOL OF MEDICINE
DEPARTMENT OF GYNECOLOGY AND OBSTETRICS



Assessment treatment outcome of sacrospinous ligament fixation for pelvic organ prolapse patients at Jimma Medical Center and Shenan Gibe hospital, Jimma, Southwest Ethiopia; A prospective cohort study design.

By: Ahmed Siraj (MD, Gynecologist and Obstetrician)

A research report to be submitted to Jimma University, Institute of health, School of medicine, Department of Gynecology and Obstetrics in partial fulfillment for the requirements for sub-specialty in Uro-gynecology and pelvic reconstructive surgery.

January, 2021

Jimma, Oromia, Ethiopia

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ABSTRACT

Background: Pelvic organ prolapse (POP) is one of the sub-component of pelvic floor dysfunction (PFD) which is a major health issue affecting approximately 50% of parous women over 50 years of age, 20% of adult women, with a lifetime prevalence risk of 30 –50% and the risk increases as age advances. POP is the descent of one or more of the pelvic organs due to the weakness of supportive structures and resulting in a herniation into the vaginal canal. It is primarily a common gynecological condition that also considered as a medical, mental and social problem, deeply rooted with poor health services and socio-cultural beliefs affecting women of both child bearing age and post-menopausal age. Worldwide, POP occurs in about 316 million women (9.3% of all females) and estimated to be diagnosed among one in four women. Despite, sacrospinous ligament fixation (SSLF) is one of the most frequently practiced and an appropriate surgical interventions for POP patients to maintain normal vaginal length and pelvic floor repair, some complications are still inevitable postoperatively which needs to be explored and managed accordingly.

Objective: The present study aimed to assess possible complications and the recurrence of vaginal vault prolapse, and associated factors after surgical interventions of SSLF among POP patients in Jimma medical center and Shenen Gibe hospital.

Materials and methods: Institutional based prospective cohort study design was employed among 55 POP patients for whom surgical intervention (SSLF) was done in 2018 and 2019 to assess possible short term and long term complications including recurrence rate after follow-up for 12 months. A structured questionnaire was used to collect patient profiles that obtained by history, physical examination and laboratory investigations. Complication/s of surgery was assessed by objective POP quantitation system (POP-Q) and a subjective satisfaction rate was assessed by a validated pelvic quality of life questionnaire (P-QoL/D) at different end points during the follow-up process. A successful surgical outcome was considered when women had “optimal” or “satisfactory” (POP-Q stage 0 or 1 and subjectively respond better than before surgery). The data was entered in to Epidata version 4.3.1 and finally exported to SPSS version 22 for further analysis. Descriptive and analytical statistical analysis was applied to express the finding and was reported by using tables, figures and narrations. A p-value of <0.05 was declared as statistically significant.

Results: About 55 POP patients were surgically intervened successfully at intraoperative period under different anesthesia techniques (spinal anesthesia (96.4%) and general anesthesia (3.6%) with the mean duration of surgery of 121 ± 43 minutes, mean blood loss of 469 ± 281 ml. The mean age of POP mothers for whom SSLF surgery done was 49.62 ± 13.79 years that ranges from 35-65 years where majority of them [32(58.2%)] were belong to menopausal age. The magnitude of complications were 7.3%, 43.6% and 30.9% at discharge, 3 months and 12 months respectively while the burden of overall recurrence rate of vaginal vault prolapse was 1.8%, 3.6%, 9.1% at discharge, 3 months and 12 months respectively. Finally, three variables [age (*menopausal*), marital status (*married*) and occupation (*house wife*)] were determined as the independent predictors for presence of complications/recurrence with AOR 3.3(1.01-14.6), P-v = 0.048); 3.6(1.01-14.6, P-v = 0.045 and 3.6(1.1-19.3), P-v = 0.031) respectively.

Conclusion and recommendation: Sacrospinous ligament fixation is a good and effective surgical intervention to restores vaginal size and prevent/minimize complications and recurrence rate. Hence, it is highly recommended to perform the procedure routinely.

Key words: Pelvic organ prolapse; Post-surgical intervention follow-up; Sacrospinous ligament fixation; Complications; Recurrence rate; Cohort study; Jimma; Ethiopia

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ABBREVIATION AND ACRONYMS

ICS: International Continence Society

IUGA: International Urogynecological Association

JMC: Jimma Medical Center

PFD: Pelvic Floor Dysfunction

POP: Pelvic Organ Prolapse

POP-Q: Pelvic Organ Prolapse Quantitation System

P-QoLQ: Pelvic Organ Prolapse Quality of Life Questionnaire

SSLF: Sacro Spinous Ligament Fixation

UVP: Utero Vaginal Prolapse

CHAPTER ONE: INTRODUCTION

1.1 Background

Pelvic organ prolapse (POP) is one of the sub-component of pelvic floor dysfunction (PFD) which is a major health issue affecting approximately 50% of parous women over 50 years of age, 20% of adult women, with a lifetime prevalence risk of 30 –50% and the risk increases with advanced age (1).

POP is the descent of one or more of the pelvic organs (anterior vaginal wall, posterior vaginal wall, the uterus /cervix, or the apex of the vagina/vaginal vault) due to the weakness/loss/lesion of supportive structures (uterosacral ligaments, the cardinal ligaments, complex and connective tissue of the urogenital membrane)and resulting in a herniation into the vaginal cannal (2). It is primarily a common gynecological condition that considered as a medical and social problem, deeply rooted with poor health services and socio-cultural beliefs affecting women in both age groups (child bearing age and post-menopausal) (3). The study also revealed that women with POP were vulnerable to different of mental health dysfunctions (4).

POP is not always manifested or complaint by mothers unless advanced in degree/severity. The presented symptom departure from normal sensation, structure, or function experienced by the woman in reference to the position of her pelvic organs that generally worse after long periods of standing or exercise (5,6). Thus, it needs due emphasis in early screening and surgical interventions to relieve its impacts and to improve quality of life. Different surgical approaches like abdominal (open or laparoscopic hysterectomy) and vaginal procedures (anterior and posterior corporrhaphy) have been applied as intervention among POP patients for ultimate goal of restoration of normal anatomy and pelvic organ function. But, they always accompanied by different short term and long term complications including surgical failure or recurrence of vaginal vault (7,8).

Currently, sacrospinous ligament fixation (SSLF) of vault/colpo-suspension (placement of suture(s) to the sacrospinous ligament, which is then attached to the vaginal vault) is preferred and frequently practiced for POP patients to maintain normal vaginal length and pelvic floor repair than other approaches of surgical interventions (abdominal hysterectomy). It is an appropriate technique for the treatment of vault prolapse allowing simultaneous easy repair of

coexistent cystocele, enterocele and rectocele for its effectiveness and efficiency (a shorter hospital stay, decreased blood loss, less risk of recurrence and preservation of coital function) (9–12). It can also use as prophylaxis in patients with severe uterovaginal prolapse, being associated with good anatomic results and low intraoperative morbidity (13). The SSLF that especially performed by new reusable suturing device (SeraPro and Veronikis ligature carrier) is a feasible and safe (no significant or less long-term morbidity/complications following vaginal pelvic floor reconstruction (14,15). Some scholars also recommend to perform SSLF as adjuvant to laparoscopic hysterectomy (16). It is an acceptable surgical means to care for symptomatic uterovaginal prolapse in women desiring uterine preservation or future child bearing as study reported successful pregnancies and vaginal deliveries post-surgical intervention (17,18). But, still different epidemiological studies are reporting complications of this surgery as some complications are inevitable (possibility of vaginal vault recurrence) following surgery, most commonly in the anterior segment (19).

Recurrent vaginal vault prolapse is defined as prolapse/ herniation of mass through vagina after at least one previous reconstructive surgery for POP. Vaginal vault (cuff scar after hysterectomy) prolapse occurs when the top of the vagina descends below a point that is 2 cm less than the total vaginal length above the plane of the hymen (20,21).

The systematic review reported the pooled successful outcome rates of SSLF in anterior, apical and posterior compartments of 81.2% (95% CI, 67.5–94.5%), 98.3% (95% CI, 95.7–100%), and 87.4% (95% CI, 67.5–94.5%) respectively among POP patients with different stages and it also varies across stages (22).

In nutshell, SSLF is an effective and safe surgical procedure with a low recurrence and complication rate (23). It is reported to be appropriate and safe surgical intervention for POP patients for long period of time (with success rates of 96% and 94.28% at 1 year and 7 years respectively) and also subjectively witnessed by victims for better satisfaction and improved quality of life after surgery (10,24).

1. 2 Statements of problems

POP is considered as one of the serious public health problems that may manifested by procidentia rectovaginal/ vesicovaginal fistula, urinary incontinence(stress/urge), bleeding, discharge from sore and ulceration, pain (back ache, chronic abdominal pain) and all-together restrict walking, sitting, carrying daily activities and general body gesture, discomfort and pain during sexual relations, profuse periods, irregular bleeding (25–27).

POP directly affects the genital organs as it interferes with sexual intercourse and can negatively impact sexual function (desire, arousal, and orgasm) and is dependent on various factors, including emotional well-being, intimacy, good general health, and quality of life (28). The presence of prolapse/herniation/mass per vagina may lead to pain during penetration or may be associated with fear of some form of lesion during intercourse, sensation of genital disfigurement and a diminished sense of attractiveness or femininity, and may result in isolation or avoidance of sexual contact (29–33).

POP creates substantial physical and emotional distress, bothers quality of life and generates a large financial burden that not only confined to affected individual women, but also affects their families, caregivers and society in large (27). It seriously compromises the quality of life of the women affected and accompanied with winkled consequences not only for their physical health, but also for their sexual lives, and their ability to work and earn a livelihood (34,35).

The disease impairs health seeking behavior of mothers (36) due to series of barriers (embarrassment or fear that it might be a cancer, women's reluctance, lack of familial support, cost and socio-cultural effect) (37).

Despite the effect of female pelvic floor disorders on women's quality of life, the significant financial cost of its management and treatment, and the increased occurrence of these conditions; pelvic floor disorders remain underreported and undertreated, and challenges its assessment. Underreporting has been attributed to women being too embarrassed to discuss the issues with their physicians, and the belief that incontinence is a normal part of aging. Most of the estimates for pelvic floor disorders are derived from the incidence of surgery for these disorders, or from clinic-based samples, which may overestimate the prevalence of these conditions (38).

But, there have been limited epidemiologic studies of POP in community-based populations due to the requirement of a pelvic examination in order to assess the presence or absence of genital prolapse which is not feasible in terms of time, human resources and costs (39,40). The potential

embarrassment and discomfort during genital examination also limit the participants to take part in the study. Thus, several studies have revealed prevalence of POP based on presence of prolapse related symptoms (41).

Globally, the prevalence of POP varies based on a means of assessment tools employed (physical examination and symptom questionnaires) in the community having their own pros and cons in estimating the burden of disease. The true prevalence of POP is not known because many of the cases are asymptomatic and many women feel shy to complain POP.

Worldwide POP occurs in about 316 million women (9.3% of all females) (42). Globally, some degree of POP seen in 1/2 to 2/3 of parous women and at least 30%- 50% of women develop a mild form of genital prolapse after pregnancy and child birth. Global prevalence is quoted as 2 – 20% under the age of 25 years. There is one in four women who complained and diagnosed with POP (43–50).

Majority of POP cases are asymptomatic and only 10-20% of these causing symptoms (41,51). The prevalence of symptomatic POP (vaginal protrusion past the introitus with straining) was 29–39% in general population and up to 50% when based upon vaginal examination in the global community and expected to double by the year 2030 (1).

Despite, SSLF is one of the most frequently practiced and an effective surgical interventions for POP patients to maintain normal vaginal length and pelvic floor repair, it also associated with short term and long term complications and recurrence of vaginal vault postoperatively (52–54). The recurrence rate of vault prolapse after SSLF varies in different points in time and based on different factors.

The systematic review study reported the overall recurrence rates of vaginal vault (apex 5.3% (0-14%), anterior 18.3% (0-42%) and posterior 2.4%(0-1%)) among POP patients following SSLF (55). The recurrence of stress incontinence after vault suspension (SSLF) was also reported among intervened POP patients (56).

The other reported complications following SSLF among POP patients were haemorrhage from pudendal/inferior gluteal vessels (57), damage/irritation of sciatic, pudendal and inferior gluteal nerve (58), urinary tract infections (59), urethral blockage (60), urinary incontinency (61), hematoma (62,63), injury to the rectum and bladder (64,65), buttock pain (66), sexual dysfunction and dyspareunia (67,68).

Study also revealed there is not statistically significant association observed among different factors (age, body mass index, parity, previous hysterectomy not for prolapse, vaginal versus abdominal approach, severity of prolapse, ethnicity, lung disease, smoking, previous corticosteroid use, and estrogen status) with occurred complications(53).

Even though, an International Uro-gynecological Association (IUGA)/International Continence Society (ICS) joint report on the outcomes of surgical procedures for POP strongly recommend conducting further epidemiological studies to assess the outcomes of surgery among POP patients, studies are limited in Africa including Ethiopia. Thus, the present study aimed to assess possible complications and the recurrence of vaginal vault and its associated factors after surgical interventions among POP patients.

1.3 Significance of the study

The findings of the present study will provide as input in gynecology and obstetrics for setting guideline for effective management modalities for patients with POP. It might serve for policymakers to design appropriate policy, programs and strategies in handling the POP patients. The study also contributes scientific evidence to available literatures and help as a baseline data for further studies.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction to POP

The burden of POP varies across countries as it has multi-factorial origin including genetics and ethnic influence (69–71).

The study conducted in America among elder mothers revealed that nearly half of them were diagnosed with mild or moderate POP and this number will increase by 46% (from 3.3 million in 2010 to 4.9 million in 2050). The highest projections estimate that 9.2 million women will have POP in America in 2050 (72,73).

A community based epidemiologic research study investigated high prevalence (67.7%) of stage II POP in southeastern Michigan among African- American and white women (74).

Another study conducted in America also reported that POP is a prevalent condition that affects 31-41% of women and results in 200,000 surgical procedures annually (75).

A population-based survey found the prevalence of POP to be over 30% in Swedish women (76).

A study in a European population (Sweden, France, German and England) found a prevalence of 8.3% for symptomatic POP which was relatively considered low annual rates per 1000 women of hospital admissions for POP if compared with the reported United States rate of 1.5 per 1000 women (77,78).

The prevalence of POP in elderly Thai women was 70% (79) and the prevalence of any degree of prolapse was approximately 31.7% in Korea (80).

The prevalence of symptomatic POP was 7.6% in a community of Indian women (81). The study showed the prevalence of POP of 9-35% in Nepal and over one fifth of women are reported the onset of POP before the age of 20 years (82). Another a community based population study in India reported 22.6% of POP (83).

A cross-sectional descriptive study conducted in the rural Nepalese community among 2849 women reported that POP was diagnosed in 207/2070 giving the incidence of 10% being commoner in the plains (8:1) than mountains (84).

The study conducted in a village of East Lebanon five hundred four ever-married women, aged 15 to 60 years showed Two hundred fifty-one (49.8%) women had clinically significant POP (85).

Despite the limitation of studies, some study revealed high burden of POP in less developed countries especially in sub-Saharan Africa and southern Asia that even occur at a younger age (86).

A systematic review and meta-analysis revealed the overall pooled prevalence of POP of 15% (95% CI of 10% –20%) among women in low and middle-income countries (87). Another study also reported the mean prevalence of POP in low and middle-income countries as about 19.7% (range 3.4%–56.4%) (88).

A smaller community based reproductive health survey found a high rate of POP in a rural Egyptian community (89).

The prevalence of POP was 3.4% in Nigeria where 66% of them were postmenopausal (90). A 5-year cross-sectional study conducted in Nnamdi Azikiwe University Teaching Hospital, Nnewi, southeast Nigeria shows the incidence of POP of 6.5% and the leading determinants were multiparity, menopause, chronic increase in intra-abdominal pressure and advanced age (91).

The annual incidence for hospital admission with a diagnosis of uterine prolapse was 2.1% in Nigeria being more prevalent among women >40 years (92).

A cross-sectional study conducted among women living in a rural Ghanaian community reported that 12.07% had POP where 81% of them were symptomatic but, only about one-third of women with symptomatic prolapse sought treatment because the cost of medical care outweighed the impact of the condition on their lives (93).

POP has a high overall prevalence of 46% population of rural Gambian. Only 13% of women with moderate or severe prolapse reported symptoms on direct questioning (94).

A population based study conducted in Kilimanjaro, Tanzanian rural community showed that about 64.6% of women had an anatomical POP stage II–IV that was associated with being aged 35+ years, being a farmer, doing petty trading and having delivered ≥ 3 times at home (95).

A community based study conducted in rural Ethiopia (East Harraghe, South Gondar and West Gojjam) among women of reproductive age (15–49 years) reported high prevalence of symptomatic POP (100:10,000 (95 % CI 86–114) and recommended urgent treatment (96).

Explorative qualitative study conducted in rural parts of the Amhara region in Ethiopia among women with POP reported that the disease is very common and affect women's lives, health and health seeking behavior in a resource-constrained setting, and how a complex web of barriers

(knowledge about the condition matters due to embarrassing and shamefulness of the diseases (97).

A community based cross-sectional study conducted among women in Dabat district, northwest Ethiopia reported the prevalence of 6.3 % for symptomatic POP (98).

A community-based study conducted in Kersa district Eastern Ethiopia revealed one in five women suffer from pelvic floor where POP accounts for (9.5%; 95% CI: 8.5-10.4) and they do not disclose their problems due to associated social stigma or lack of access to services that forced them to low health seeking and finally the authors call for urgent action to improve prevention, diagnosis and treatment services to mitigate the suffering of women from pelvic floor disorders (99).

An explorative qualitative study conducted among women with symptomatic POP at mixed setup (hospital and community) in the Amhara region of northwest, Ethiopia reported that physical strain on their body, such as childbirth, food scarcity or hard physical work, particularly during pregnancy and shortly after delivery, severe difficulties and pain while carrying out daily chores were common among the women that result them not to disclose their status due to embarrassment and fear of discrimination from people living close to them (100).

An unmatched case–control study conducted among gynecologic patients in Bahir Dar city hospitals determined as sphincter damage, family history of POP, being uneducated, having >4 vaginal deliveries, carrying heavy objects, BMI <18.5 kg/m², age >40 years and un assisted delivery were the independent determinants of POP (101).

A hospital based cross-sectional study was conducted in Gondar University hospital, Northwest Ethiopia among obstetric fistula and POP patients reported that 80.9% had POP and 19.1% obstetric fistula and high proportion of women who delayed treatment for POP (82.9%) due to fear of disclosing illness for social stigma (AOR = 2; 1.03, 3.9) and lack of money (AOR = 1.97; 1.01, 3.86) (102).

A qualitative study carried out in rural and semi-urban communities of north-west Ethiopia revealed that women who had not self-reported POP in the pilot but were diagnosed with severe prolapse after pelvic examination due to shame and fear of social exclusion, lack of trust in the study and data collectors, and lack of hope for cure prevented them from disclosing (103).

Cross-sectional study employed among pedestrian back-loading women in bench Maji Zone revealed 13.3% of POP and associated with age, duration of carrying heavy materials at back and

less BMI and finally, the author recommend urgent attention needed from concerned bodies (104).

A one-year review of POP at St. Paul's Hospital Millennium Medical College, Addis Ababa Ethiopia reported that there is ethnic difference among women with the disease who operated at the setup where it was more common among Guraghe ethnicity (105).

The study conducted in Jimma Medical Center reported high prevalence (40.7%) POP among mother admitted to the hospital from the catchment area for gynecologic operations (106).

The development of POP is multi-factorial (combinations of anatomical, physiological, genetic, lifestyle, and reproductive factors) where they vary from patient to patient (107). For instance (multiparity, prolonged labour, large baby, unsupervised deliveries/home delivery, domestic violence, aging, pelvic surgery or trauma, pregnancy, early marriage, vaginal birth, unsafe abortions, sexual intercourse immediately after delivery, tightening of stomach/wrap around the stomach with a piece of cloth after delivery, life style, exercise/heavy work, less rest period in postpartum, body mass index, poor nutrition, anemia, medical illness, substance abuse, smoking, constipation, illiteracy and genetics/ethnicity) (69,108,109).

Multiparity/repeated pregnancy was a significant determinant as 74% of them were grand multiparous with an adjusted relative risk of 10.85 (4.65-33.81) (48) due to frequent stretching and tearing of the endopelvic fascia, levator ani muscles and perineal body (110). Pregnancy itself without vaginal birth has been cited as a risk factor as well, vaginal mode of delivery is commonly associated with POP while caesarean section is controversy (69,110–114).

Aging related biological tissue modification, hormone changes/hypoestrogenism and genital atrophy also play important contributory roles in the pathogenesis of POP among post-menopause mothers (42,90).

Aging, pelvic trauma and surgery also evoke tissue denervation and devascularization, anatomic alterations, and increased degradation of collagen; lead to a decrease in mechanical strength and predispose an individual to prolapse. A reduction in protein content and estrogens impairs supportive structures to cause the herniation of pelvic organs through vagina (115).

Studies show a 5-fold increased risk of prolapse among siblings of women with severe prolapse as compared with the general population and a high concordance of prolapse in twins, as well as, in nulliparous and parous sister pairs (116–118). An association with POP was seen in individual studies for estrogen receptor alpha (ER- α) rs2228480 GA, COL3A1 exon 31, chromosome 9q21

(heterogeneity logarithm of the odds score 3.41) as well as 6 single nucleotide polymorphisms identified by a genome-wide association study (119–123).

Compared with controls, POP cases had greater body mass index and parity. Strenuous activity during teenage years may confer higher odds of POP (124,125). Presence of medical illness (hypertension (126), chronic lung disease (3) and diabetes (43,50). Body mass index higher than 24 kg/m² were found to be significant risk factors for POP, with relative risks of 1.09 ($P < 0.001$), 2.31 ($P < 0.0001$), and 1.62 ($P = 0.048$) respectively (3,85).

Moderate or severe anaemia and abnormal body mass may pre-dispose to prolapse at either end of the scale significant risk factor for pelvic organ prolapse in non-pregnant women. Low body mass index and anaemia were common (16% and 52%, respectively) (94). POP formed 2.8% of adolescent due to early marriage < 15 years in (50%) and unsupported delivery by skilled birth attendant (SBA) out of health facilities (99.2%). Resumption of manual labor after delivery less than a month and parity was responsible to some extent of POP (84).

In nutshell, studies also revealed important contributing factors that associated with POP (heavy work, illiteracy, early marriage and child birth, inadequate food during pregnancy and postpartum period, multi parity, home delivery/inaccessibility to quality maternal health care (Skilled Birth Attendant and Emergency Obstetric Care), vaginal delivery, less rest period in post partum/inadequate post natal care, no kegal exercise, smoking, poor nutrition/poverty and domestic violence (83,88). Prolonged labor, birth of big babies, unsafe abortions, sexual intercourse immediately after delivery, tightening of stomach using patuka (a piece of cloth used to wrap around the stomach) after delivery, hypertension and diabetes are supposed to be other causal factors of POP(50,127).

Compared with African-American women, Latina and white women had 4-5 times higher risk of symptomatic prolapse, and white women had 1.4 fold higher risk of objective prolapse with leading edge of prolapse at or beyond the hymen (128,129).

The likelihood of POP was higher in women of the Wolof tribe and genetically determined high risk among Caucasian due to joint hypermobility as a sign of ligament laxity (130,131). Under-nutrition as cause of poor tissue tensile strength may be a possible co-factor in the pathogenesis of POP (86).

2.2 Surgical intervention for POP patients

Different surgical approaches like abdominal (open or laparoscopic hysterectomy) and vaginal procedures (anterior and posterior corprohaphy) have been applied as intervention among POP patients for ultimate goal of restoration of normal anatomy and pelvic organ function. But, they always accompanied by different short term and long term complications including surgical failure or recurrence of vaginal vault (7,8).

Currently, SSLF is preferred and frequently practiced for POP patients to maintain normal vaginal length and pelvic floor repair than other approaches of surgery. But, still different epidemiological studies are reporting complications of this surgery as some complications are inevitable and possibility of vaginal vault recurrence following surgery (19).

Retrospective longitudinal study conducted in Paris, France reported acceptable post-operative complication rates and improved quality-of-life and sexuality and bowel function with the overall complication rate of 17.3% (rectal injury in pararectal hematoma and anterior vaginal vault recurrence) (64).

The study conducted in India among 95 POP patients who underwent SSLF to evaluate the outcome of surgery concluded that the surgery was safe, but, some complications also recorded (pain over right buttock, vaginal cuff infection, stress incontinence and recurrence rate) during follow-up periods (132).

CHAPTER THREE: OBJECTIVES OF THE STUDY

3.1. General Objective

- ✚ To assess the outcome of SSLF surgery and its associated factors among POP patients at Jimma medical center (JMC) and Shenen Gibe hospital.

3.2. Specific objectives

- ✚ To determine the recurrence rate of vaginal vault prolapse following surgical interventions among POP patients at JMC and Shenen Gibe hospital.
- ✚ To assess the possible complications (short term and long term) after surgical interventions among POP patients at JMC and Shenen Gibe hospital.
- ✚ To identify factors associated with complications and recurrence rate of POP following surgical interventions among POP patients at JMC and Shenen Gibe hospital.

CHAPTER FOUR: MATERIALS AND METHODS

4.1. Study area

The study was conducted at JMC and Shenen Gibe hospital located in Jimma town, Oromia regional state at about 350km distance to southwest from the capital of the country, Addis Ababa. JMC is one of the pioneer teaching referral hospitals in the country providing health service for millions of the catchment populations dwelling in the southwest of the country owned by Jimma University. Gynecology and Obstetrics is one of the health services rendered by different health professionals in the hospital.

4.2 Study period

The POP patients whom surgical intervention (SSLF) done in 2018 and 2019 were followed for 12 months.

4.3. Study design

Institutional based prospective cohort study design was employed.

4.4. Population

4.4.1. Source population

All mothers who diagnosed with POP and underwent surgical intervention.

4.4.2. Study population

A total of 55 POP patients for whom SSLF was done at JMC and Shenen Gibe hospital.

4.5. Data collection tools and Analysis method

Special log book was created to register and record POP patients' profile. A structured questionnaire was used to collect data obtained by history, physical examination and laboratory investigation results. Complication/s of surgery will be assessed by objective POP quantitation system (POP-Q)(133,134) and subjective satisfaction rates was assessed by a validated pelvic quality of life questionnaire (PFDI-20 and PFIQ-7)(135) at different end points during the follow-up process (at discharge, 3 months and 12 months) which was already validated in Ethiopia (136). A successful surgical outcome was considered when women had "optimal" or "satisfactory" (POP-Q stage 0 or 1 and subjectively respond better than before surgery). Prolapse recurrence was defined as stage II or greater descent according to the ICS POP quantification system for its objective anatomic assessment (137–141).

The data was entered into Epidata version 4.3.1 and finally exported to SPSS version 22 for further analysis. Descriptive statistical analysis was applied to express the finding and reported by using tables, figures and narrations. Cross-tabulations and logistic regression analysis was applied to determine factors associated with the observed complications and recurrence of POP. The changes in POP-Q stages and pelvic floor questionnaire scores between baseline, first follow-up and second follow-up were assessed by the paired Wilcoxon rank test as these variables were considered ordinal respectively were not normally distributed (142). A p-value of <0.05 was declared as statistically significant.

4.6. Data Quality control

All patients were operated by uro-gynecology fellows and supervisors and patient's profiles were registered and/or recorded on daily basis. The collected data was checked for completeness and cleaned for outliers and missed values.

4.7. Ethical Considerations

The study was approved and letter of ethical clearance was obtained by ethical review board committee of Jimma University, institute of health. Letter of support was also collected from JMC, Shenen Gibe hospital and Jimma University, department of gynecology and obstetrics prior to data collection. Oral and written consent was obtained from participants and their information was handled confidentially. The surgical intervention for POP patients was performed by maintaining all protocols of antiseptic techniques and all cares for Covid-19 also maintained as per the standards.

4. 8. Dissemination plan

The finding of the study will be reported to Jimma University, institute of health, department of gynecology and obstetrics and it will also present on different conferences. Finally, the study will be endeavored to be published on reputable journal.

CHAPTER FIVE: RESULTS

5.1: Baseline characteristics of participants

About 55 POP patients were surgically intervened by SSLF technique and observed for 12 months for possible complications. The mean age was 49.62 ± 13.79 years that ranges from 35-65 years where majority of them [32(58.2%)] were belong to menopausal age (Table 1).

Table 1: Socio-demographic status of study participants

Variables	Statistics
Age in years, Mean \pm SD; Ranges	49.62 \pm 13.79; 35-65
Parity in number, Mean \pm SD; Ranges	5.95 \pm 2.4; 1-11
Educational status (No formal education; Read and write only; Primary school; Secondary school and above), Number (%)	38(69.1);10(18.2);6(10.9);1(1.8)
Marital status (Married; Single; Divorced; Widowed), Number (%)	38(69.1); 1(1.8); 3(5.5);13(23.6)
Religious (Muslims; Orthodox; Protestant), Number (%)	36(65.5);14(25.5);5(9.1)
Occupation (Daily laborer; Government employee; House workers; Merchants), Number (%)	4(7.3);2(3.6);41(74.5);8(14.5)

5.2: Baseline characteristics of SSLF surgery intervened

SSLF surgery was intervened for all patients under different anesthesia techniques (spinal anesthesia (96.4%) and general anesthesia (3.6%).The mean duration of surgery was 121 ± 43 minutes that ranged from 105-220 minutes with mean blood loss of 469 ± 281 ml. All surgeries were successful intraoperatively. The mean duration of postoperative catheterization was 111 ± 55 hours.

Table 2: Baseline characteristics of SSLF surgery intervened

Variables	Statistics
Duration of surgery in minutes, Mean \pm SD; Ranges	121 \pm 43; 105-220
Total amount of blood loss in ml, Mean \pm SD; Ranges	469 \pm 281; 280-665
Duration of postoperative catheterization in hours, Mean \pm SD; Ranges	111 \pm 55; 45-295
Type of anesthesia (Spinal anesthesia; General anesthesia), Number (%)	53(96.4); 2(3.6)

5.3: Complications of SSLF surgery at different follow-ups period

Different complications were recorded at different follow-up intervals as detailed in Table 3. The overall success rate of SSLF was 98.2%, 96.4% and 90.9% at discharge, 3 months and 12 months respectively.

Table 3: Complications of SSLF surgery at different follow-ups period

Complications	Follow-up intervals, Frequency (%)		
	At discharge	At 3 months	At 12 months
Buttock pain	1(1.8)	9(16.4)	9(16.4)
Urinary retention	3(5.5)	5(9.1)	1(1.8)
Vault infection	2(3.6)	0(0)	1(1.8)
Stress incontinence	0(0)	2(3.6)	2(3.6)
Short vaginal length	2(3.6)	9(16.4)	15(27.3)
Overall recurrence rate	1(1.8)	2(3.6)	5(9.1)
POP-Q stage:			
Stage 0	10(18.2)	4(7.3)	19(34.5)
Stage 1	42(76.4)	49(89.1)	29(52.7)
≥ Stage 2	1(1.8)	2(3.6)	5(9.1)

5.3: Comparisons of complications and recurrence rates after surgical interventions of SSLF surgery at different follow-ups

The magnitude of complications were 7.3%, 43.6% and 30.9% at discharge, 3 months and 12 months respectively while the burden of overall recurrence rate of vaginal vault prolapse was 1.8%, 3.6%, 9.1% at discharge, 3 months and 12 months respectively (Table 4).

Table 4: Comparisons of complications and recurrence rates after surgical interventions of SSLF surgery at different follow-ups

Surgery outcomes	Categories	Follow-up intervals, Frequency (%)		
		At discharge	At 3 months	At 12 months
Complications	Yes	4(7.3)	24(43.6)	17(30.9)
	No	51(92.7)	31(56.4)	38(69.1)

Recurrence rate	Yes	1(1.8)	2(3.6)	5(9.1)
	No	54(98.2)	53(96.4)	50(90.9)
Both complications and recurrence	Yes	0(0)	2(3.6)	5(9.1)
	No	55(100.0)	53(96.4)	50(90.9)
Either recurrence or complications (any)	Yes	7(12.7)	24(43.6)	19(34.5)
	No	48(87.3)	31(56.4)	36(65.5)

5.4: Factors associated with either recurrence rate or complications of SSLF surgery at one year follow-up

The presence of any complications or recurrence rate of vaginal vault prolapse at 12 months follow-up was selected to evaluate for its possible predictors among intervened 55 POP patients. In bivariate logistic regression, about five variables [age (*menopausal*), educational status (*no formal education*), religious (*Muslim*), marital status (*married*) and occupation (*house wife*)] were selected (P-value < 0.25) as the candidate predictors to cause complications at 12 months post SSLF surgery. Finally, three variables [age (*menopausal*), marital status (*married*) and occupation (*house wife*)] were determined as the independent predictors for presence of complications.

Mothers of menopausal age were about three fold more likely to develop complications in comparison to child bearing age mothers (AOR 3.3(1.01-14.6), P-v = 0.048) probably due to the decrements of immunity upon aging. Married mothers had also three times likely hood of developing complications than other marital status may be triggered by active sexual intercourse with their couples (AOR 3.6(1.01-14.6, P-v = 0.045). Being house wife was also revealed as the independent risk factor for complications in relative to mothers who engaged in other occupations due to gender factors where carryout heavy works at home (AOR 3.6(1.1-19.3), P-v = 0.031) as showed in table 5.

Table 4: Factors associated with either recurrence rate or complications of SSLF surgery at one year follow-up

Variable	Category	Presence of either complications or recurrence of POP, Number (%)					
		Yes	No	COR(CI)	P-value	AOR(CI)	P-value
Age	Child	10(18.2)	13(23.6)	1		1	

	bearing age						
	Menopausal age	9(16.4)	23(41.8)	1.96(0.6-6.1)	0.240*	3.3(1.01-14.6)	0.048*
Educational status	No formal educations	10(18.2)	28(50.9)	3.1(0.95-10.4)	0.060*	1.6(0.2-9.4)	0.594
	Other education level	9(16.4)	8(14.5)	1		1	
Religious status	Muslim	9(16.4)	27(49.1)	3.3(1.1-10.8)	0.045*	1.1(0.2-6.1)	0.898
	Others	10(18.2)	9(16.4)	1		1	
Occupationa status	House workers	9(16.4)	31(56.4)	5.5(1.5-1.6)	0.010*	3.6(1.1-19.3)	0.031*
	Others	34(16.0)	5(9.1)	1		-	
Marital status	Married	10(18.2)	28(50.9)	3.1(0.95-10.4)	0.060*	3.6(1.01-14.6)	0.045*
	Others	9(16.4)	8(14.5)	1		1	
Previous mode of delivery/ies	SVD	17(30.9)	33(60.0)	1.3(0.2-8.5)	0.788	-	-
	Others (instrumental /C/S)	2(3.6)	3(5.5)	1		-	-
Parity	≤5	9(16.4)	12(21.8)	1		-	-
	>5	10(18.2)	24(43.6)	1.8(0.6-5.6)	0.311	-	-

*- statistically significant

CHAPTER SIX: DISCUSSION

Among observed 55 POP patients, the mean age was 49.62 ± 13.79 years that ranges from 35-65 years where majority of them [32(58.2%)] were belong to menopausal age. These baseline characteristics of POP patients were also in harmony with other studies (143–145).

All performed surgeries were successful intraoperatively with the mean duration of surgery of 121 ± 43 minutes and mean blood loss of 469 ± 281 ml. But, this figure was against other studies that happened within brief duration of surgery and minimal blood loss (143,146–149). But, studies of Ramesh Kumer et al reported comparable mean duration of surgery (120 minutes) (150).

The success rate of the intervened SSLF surgery was 90.9% at 12 months follow-up based on objective measurement of POP-Q system with recurrence rate of 9.1% which is within range of reported success rates of 67-93% among performed SSLF surgeries so far (151). The present figure of failure rate of SSLF surgery was also within the reported range of 3-17% of review study of Beer and Kuhn (152).

In line with the present finding of 9.1% recurrence rate of POP at 12 months, a lot of studies reported almost comparable figures [WONG et al (10.7%) (149); Mohamed Elnasharty et al (11.8%) (153); Amin MOA et al (15%) (154); Chin-Jui Wu et al (17.5%) (147); (Hefni and EL-Toukhy (18%) (155); Meschia et al (5-15%) (156)].

But, this figure was inconsistently less in comparison with studies of Randall and Nicols (25%) (157); Aigmueller (29%) (158) and Halaska et al (39.4%) (137). The recorded recurrence rate in the present study (9.1%) was also contrary higher if compared to studies of Malinowski et al (0%) (159); Ren C et al (2%) (148); Aksakal et al (4%) (145); Elbiaa et al (4.5%) (146) and Monthes et al (5.5%) (138). The difference might happen due to variation in population, operation facility and durations of follow-up.

The present study revealed that surgical failure rates gradually increased throughout the study period (3.6% at 3 months and 9.1% at 12 months) that was also in harmony with the study of Jelovsek et al (160).

The present study recorded overall complications (30.9%) at 12 months that was also supported by study of Elbiaa et al who reported the overall complication rate of (35.1%) at Kuwait Hospital. The extent of observed complications (buttock pain, infection and urinary symptoms)

in the present study were also supported by studies of Valecha and Dhingra (143), Dangal et al (161), KW Wong et al (149), Elnasharty et al (153), Gupta (162).

There were significantly difference distribution of POP mothers who had shorter vaginal length (at 3 months (16.4%) and 12 months (27.3%) when compared to baseline (at discharge 3.6%)) that also supported by study of Kavvadias et al (142) who reported shorter total vaginal length at first and second follow-up when compared to baseline.

Finally, three variables [age (*menopausal*), marital status (*married*) and occupation (*house wife*)] were determined as the independent predictors for presence of complications/recurrence rate with AOR 3.3(1.01-14.6), P-v = 0.048); 3.6(1.01-14.6, P-v = 0.045 and 3.6(1.1-19.3), P-v = 0.031) respectively. Those determined risk factors were also supported with studies of Wu et al (147) and Nieminen et al (163) who revealed that advanced age was a risk factor for recurrence of POP. But, in opposite with the present finding, Linder et al (164) reported that younger age was associated with the risk of prolapse recurrence (adjusted hazard ratio (aHR) 1.55, 95% confidence interval (CI) 1.12–2.13; p = 0.008) which needs further studies to establish this discrepancy. The other predictors determined in the present study (being married and house wife) were not supported in other literatures so far that offers future studies. But, the present finding justifies the role of married marital status to be active sexual acts and house wife mothers were engaged in heavy home works for gender bases and vulnerable to recurrent rate of vaginal vault prolapse at the setting.

CHAPTER SEVEN: CONCLUSSION AND RECOMMENDATION

Sacrospinous ligament fixation is a good and effective surgical intervention to restores vaginal size and minimizes complications and recurrence rate (with success rate of 90.9%). Hence, it is highly recommended and suggested to perform this procedure routinely in preference to old technique for POP by all uro-gynecologic physicians. Further studies are also encouraged to determine the risk factors of prolapse recurrence and overall complications.

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ANNEX

Introduction and Consent form

Hello! My name is Dr. Ahmed Siraj, gynecologist and obstetrician at Jimma University, Institute of health, and inspired to conduct study entitled “Follow-up outcome of sacrospinous ligament fixation for pelvic organ prolapse patients and its associated in Jimma Medical Center and Shenen Gibe hospital, Jimma, Southwest Ethiopia; A prospective cohort study design”.

Therefore, you are kindly requested to participate in the study voluntarily by considering your participation is incredible for further treatment modality and it entirely based on your willingness and your refusal doesn't affect the service you get from us. You have the right to participate and/or refuse and you can interrupt at any point to ask questions.

Any information obtained from you and your medical records will remain confidential and needed only for study purpose. If you agree to participate in the study, please proceed with interview after signing below. Thank you!

Name of Participant

Signature of Participant _____ Date _____

Questionnaires

PART I: Questions on Socio- demographic characteristics of the Respondents.

Sr. No	Question	Response	Remark
101	Identification Number	1. ID NO _____ 2. MRN _____	
102	Age	_____years	
103	Educational status	1. Don't read and write 2. Primary (1-8) 3. Secondary 4. Tertiary/ college and above	
104	Marital status	1. Single 2. Married 3. Widowed 4. Divorced 5. Separated	
105	Occupation of husband/partner	1. Farmer 2. Merchant 3. Daily laborer 4. Governmental employee 5. Private/NGO employee 6. Other specify(_____)	
106	Average monthly income	_____ETB	
107	Place of residency	1. Urban 2. Rural	
108	Duration of disease	-----years	

Complications

	complications		immediate	At discharge	3 month	At 12 months
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1	Buttock pain					
2	Urinary retention					
3	Vault infection					
4	Stress					
5	incontinence					
6	Short vaginal length					
7	Recurrence	cystocelle				
		rectocele				
		vault				
8	Anemia					

Outcomes

Outcomes	
Infection	Present Absent
Stage of POP after surgery	Stage 0 Stage 1 Stage 2 Stage 3 Stage 4
Stage of POP at 3 month follow up	Stage 0 Stage 1 Stage 2 Stage 3 Stage 4
Stage of POP at 12 months	1.Stage 0 2.stage 1 3. stage 2 4. stage 3 5. stage 4