"Laparoscopic Hysterectomy for Benign Conditions-A Hospital Based Cross Sectional Study"

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ABBREVIATIONS

AH	Abdominal Hysterectomy
BMI	Body Mass Index
cm	CentiMeter
g	gram
IP ligament	InfundibuloPelvic ligament
LH	Laparoscopic Hysterectomy
MC	Chi square test with Monte Carlo simulation
min	Minute
ml	MilliLiter
MW	Mann Whitney U test
NBM	Nil By Mouth
No.	Number
t	Two sample t test
TAH	Total Abdominal Hysterectomy
TLH	Total Laparoscopic Hysterectomy
VH	Vaginal Hysterectomy

ABSTRACT

"Laparoscopic Hysterectomy for Benign Conditions - A Hospital Based Cross Sectional Study"

Background & Objectives: Laparoscopic gynaecologic surgery is frequently performed and provides a number of advantages. Hysterectomy is a widely done procedure for benign uterine conditions, however the route of hysterectomy is always a point of contention. Many studies have criticised laparoscopic hysterectomy for its complications and length of procedure. However, the advent of modern machines and processes has lately increased its popularity. The aim of the study is to find out the prevalence and type of complications in this surgery, indications for laparoscopic hysterectomy and the risk factors associated with the complications of laparoscopic hysterectomy performed by single surgeon.

Methods: This is a hospital based descriptive cross-sectional study that was conducted for a period of 1 year 9 months from January 2020 to September 2021, at the teaching hospital attached to KAHER's J.N Medical College, Belagavi, Karnataka. Patients who underwent laparoscopic hysterectomy, for benign indications, were enrolled as the subjects of the study. Demographic information, pre-operative findings, surgical indication, intra-operative and post-operative complications, estimated blood loss, operation time, and hospital stay were all documented and analysed. The patients were followed up until their discharge, after one week, and then after one month.

Results: The study included a total of 104 subjects. Mean age of the patients was 46.28 ± 7.38 years. The most common indication for surgery was fibroid uterus which accounted for 56.73 percent of all cases, followed by adenomyosis (25.96%). Mean

operating time was 78.7 ± 20.97 min. and average blood loss is 110.72 ± 64.69ml. The overall prevalence of complications was 11.54%. 0.96% cases had major complications while 10.58% cases had minor complications. Conversion to laparotomy was not needed in any of the patients. Iatrogenic complications were bladder injury (n=1), which was managed laparoscopically and vaginal tears (n=5). Mean duration of post operative hospital stay was 1.6 ± 1.52 days.

Conclusion: With surgical expertise, TLH is a safe and acceptable alternative to open hysterectomy for the majority of benign pelvic conditions, with benefits such as less blood loss, smaller incisions with less post operative discomfort, fewer wound infection, shorter inpatient stay, and faster recovery.

Key words: Complications, laparoscopy, hysterectomy, laparoscopic hysterectomy, benign conditions

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INTRODUCTION

The most common non-obstetric surgical treatment performed on women is hysterectomy. Each of the three main methods for removal of uterus (vaginal, abdominal, and laparoscopic) has its individual benefits and risks. Open gynecological surgeries are slowly getting replaced by minimally invasive surgeries like laparoscopy and hysteroscopy. In open surgery, we cut the structures which we are not intended to, for example, abdominal wall for hysterectomy. But laparoscopic surgery helps us to prevent this, as we need to make small incisions. The surgeon analyses specific indications for surgery, factors such as size of the uterus, previous history of surgical procedures, and the patient's preferences while discussing various routes of hysterectomy with a patient. The goal is to arrive at a decision that gives a procedural benefit while minimizing its risks.[1]

Laparoscopic hysterectomy has numerous advantages to abdominal hysterectomy. It is appropriately described as game changer. Now-a-days trend is changing towards this approach because of less postoperative morbidity, shorter inpatient stay, and quicker return to duty post-surgery.[2]

But there is only limited data available about this surgery in this part of the country. Hence there is a need for more studies to be done in this area. Some studies reported complications with laparoscopic approach such as vascular injury, bladder injury, bowel injury etc. Hence, current study was conducted to determine the safety of laparoscopic hysterectomy for benign conditions.

So, in this study, we want to find out the prevalence and type of complications in this surgery, benign indications for laparoscopic hysterectomy and the risk factors associated with the complications of laparoscopic hysterectomy.

Majority of the previous studies done in this field look into indications, complications and outcomes of hysterectomies done by multiple surgeons. Factors such learning curve, technique and expertise with the technique will all influence the results. But in this study these factors will be assessed in surgeries performed by a single senior surgeon, with more than 20 years of experience.

AIMS & OBJECTIVES

PRIMARY OBJECTIVE:

To find out the prevalence of complications and the type of complications associated with laparoscopic hysterectomy.

SECONDARY OBJECTIVE:

To find out the risk factors associated with the complications of laparoscopic hysterectomy.

To find out the indications for laparoscopic hysterectomy.

REVIEW OF LITERATURE

The hysterectomy is one of the most commonly performed major gynaecological procedures. Historically, the uterus was removed either abdominally or vaginally. When there are no contraindications, a vaginal procedure is recommended due to decreased morbidity and faster recovery. Laparoscopic hysterectomy has recently received a lot of interest on a global scale. The use of minimally invasive surgery to address pelvic issues is increasing.[3]

According to several research, laparoscopic hysterectomy is progressively replacing open hysterectomy. Laparoscopic hysterectomies achieve every pelvic surgeon's objective of offering a safe and simple surgery that gives great patient satisfaction. The advantages include less blood loss, a lower chance of surgical damage, less post operative discomfort, and earlier mobilisation.[3]

Many gynaecological surgeries can now be performed laparoscopically, because to advancements in electrical and optical technology during the last 50 years.[4,5]

HISTORY: (Table 1)

YEAR OF DISCOVERY	SCIENTIST	DISCOVERY
1879	Max Nirze	• utilised a lens to enlarge an illuminated area • forerunner of contemporary endoscopy's optical system • “The Father of Modern Endoscopy ”.
1887	Max Nirze	• Adapted Edison's light bulb for use in urological treatments, resulting in the first electrical light bulb
1901	George Kelling	• performed the first experimental laparoscopy • insufflated air into a dog's abdomen and

		utilised pneumoperitoneum and a cyctoscope on the dog
1910	Jacobaeus, Sweden	• introduced the pneumoperitoneum and use of the Trendelenburg posture, trocar, and cannula
1920	Zollikofer, Switzerland	• found the advantage of using CO2 gas for insufflation instead of filtered ambient air or nitrogen
1929	Kalk, Germany	• introduced forward oblique (135 degree) vision lens systems • proposed for a distinct pneumoperitoneum puncture site.
1934	Ruddock	• created a single-puncture operational laparoscope and its supporting tools for biopsies
1936	Boesch, Switzerland	• did the first laparoscopic tubal sterilization
1938	Janos Veress, Hungary	• designed Veress needle.
1947	Roaul Palmer	• reported his first 250 instances in which he employed the lithotomy Trendelenburg posture to induce gaseous distention. • explained how the uterine cannula was used to elevate uterus
1953	Professor Hopkins.	• discovered rigid rod lens system
1953	Dr Cameron Nehzat	• Performed the first videoscopic surgery using video camera
1965	Kurt Semm German Engineer and Gynaecologist	• developed an automated insufflation device capable of measuring intraabdominal pressures
1966	Kurt Semm German Engineer and Gynaecologist	• used thermocoagulation, loop knots, an irrigation device, and an endoscopic appendectomy as part of a gynaecologic operation
1968	Fragenheim	• noticed ovulation through laparoscope

1972	H.Coutnay Clarke	• demonstrated for the first time the technique of laparoscopic suturing
1978	Hasson	• pioneered a new trocar positioning technique. • suggested a blunt mini-laparotomy that allows for direct sight of trocar entry into the peritoneal cavity
1978	Steptoe and Edwards	• Laparoscopy was used for ovum retrieval, which led in embryo transfer and the delivery of a normal healthy kid
1988	Harry Reich	• conducted laparoscopic lymphadenectomy for ovarian cancer therapy
1989	Harry Reich	• first reported laparoscopic hysterectomy utilising bipolar desiccation, then staples, and eventually sutures for laparoscopic hysterectomy

Since the first laparoscopic hysterectomy reported in 1989, by Harry Reich in Pennsylvania, several changes have evolved and newer techniques have developed with the advances in the technology. The requirement to implant needles, trocars and cannulas for first abdominal entry distinguishes laparoscopic surgery from open surgery. This might cause vascular or bowel damage. Hence, risk is more from the commencement of surgery until visibility into peritoneal cavity is accomplished. As a result, after this phase is completed, the remainder of the procedure is linked with a low risk of problems.[4,5]

Laparoscopic hysterectomy has several subtypes:

- **Total laparoscopic hysterectomy (TLH):** Removal of the uterus and cervix. The whole surgery, including vaginal vault suturing, is done laparoscopically. Some surgeons may decide to stitch the vaginal cuff through the vaginal opening. Typically, the uterine specimen is removed through the vaginal vault, either whole or after morcellation.
- **Laparoscopic subtotal (supracervical) hysterectomy (LSH):** The uterus is removed, but the cervix is left intact. Specimen is removed through abdominal incisions or ports.
- **Laparoscopic-assisted vaginal hysterectomy (LAVH):** A complete hysterectomy is carried out. The laparoscopic method is often used to perform any necessary adnexal surgery and to manage the adnexal blood supply (utero-ovarian ligament if ovaries are conserved or infundibulopelvic ligament blood supply if ovaries are removed). The remainder of the treatment is carried out vaginally, including peritoneal cavity entrance and uterine vascular ligation from below.
- American Association of Gynaecologic Laparoscopist Classification System of laparoscopic hysterectomy, 2000[6]

Table 2 :- Types of laparoscopic hysterectomy

Type 0	"Preparation for vaginal hysterectomy through laparoscopy"
Type I	"Dissection up to but not including uterine arteries Type IA ovarian artery pedicle(s) only Type IB + I A + anterior structures Type IC I A + posterior culdotomy Type ID + I A + anterior structures and posterior culdotomy"
Type II	"Type I + uterine artery occlusion and division, unilateral or bilateral Type IIA Ovarian artery(ies) and uterine artery(ies) occlusion and division only Type IIB II A + anterior structures Type IIC II A + posterior culdotomy Type lID II A + anterior structures and posterior culdotomy"
Type III	"Type II + portion of cardinal-uterosacral ligament complex only, unilateral or bilateral Type IIIA Uterine and ovarian artery pedicles with portion of the cardinal-uterosacral complex only, unilateral or bilateral Type IIIB III A + anterior structures Type IIIC III A + posterior culdotomy Type IIID III A + anterior structures and posterior culdotomy"
Type IV	"Type II + total cardinal-uterosacral ligament complex, unilateral or bilateral Type IVA Uterine and ovarian artery pedicles with complete detachment of the total cardinal uterosacral ligament complex only, unilateral or bilateral Type IVB IV A + anterior structures Type IVC IV A + posterior culdotomy Type IVD IV A + anterior structures and posterior culdotomy Type IVE Laparoscopically directed removal of entire uterus"

Indications for laparoscopic hysterectomy:

Common benign indications include the following:

1)Fibroid uterus

2)Adenomyosis

3)Chronic pelvic pain

4)Endometriosis

5)Endometrial hyperplasia

6)Cervical intra-epithelial neoplasia

7)Abnormal uterine bleeding

8)Ovarian borderline lesion

9) Post-menopausal bleeding

Various case studies in the gynaecologic oncologic literature imply that laparoscopic hysterectomy may be indicated in both malignant and premalignant uterine pathology.

The American College of Obstetricians and Gynaecologists (ACOG) opined that there are certain conditions when either total laparoscopic route or laparoscopic assistance in vaginal hysterectomy may prove more advantageous over vaginal route. The conditions include presence of dense adhesions, endometriosis, leiomyomas hindering vaginal access, removal of difficult ovaries requiring infundibulopelvic ligament ligation, narrow sub-pubic angle, nulliparous pelvis and need for inspection of the abdominopelvic cavity.[6]

Laparoscopic approach, compared to abdominal or vaginal hysterectomy, has the best inspection capability due to clear, unrestricted and magnified view. Laparoscopy has better detection rate of unexpected pathological findings during surgery like leiomyomas, endometriosis and adhesions, for obvious reasons.

Moreover, laparotomy in obese patients has increased association with sepsis as compared to laparoscopic route, hence, the latter being the preferred approach.[6]

Contra-indications for laparoscopic hysterectomy:

With increasing expertise and advances in laparoscopic skills and technology, there is actually no absolute contraindication to a total laparoscopic hysterectomy for benign gynaecologic conditions. According to Sokol and Green, contraindications for laparoscopic hysterectomy include medical problems that prevent pneumoperitoneum, surgeon inexperience, malignancy necessitating removal of intact specimen, unavailability of equipment, and patient refusal.[6]

Advantages/Disadvantages over Abdominal Hysterectomy:

Total laparoscopic hysterectomy provides numerous demonstrated advantages to abdominal hysterectomy, such as greater pelvic anatomy vision and less blood loss. Many places, such as uterine arteries, vagina, and the rectum, can be accessed and manipulated from various angles. Advent of uterine manipulator in 1995, has added to this effect. Other major advantages of TLH over abdominal hysterectomy are reduced morbidity, wound sepsis, postoperative pain, shorter hospital stay, and early resumption of routine activities. The disadvantages of laparoscopic hysterectomy are longer operating time, cost constraints, maintenance of sophisticated instruments and training of surgeons.[6]

Advantages/Disadvantages over Vaginal Hysterectomy:

Laparoscopic surgery has an advantage over vaginal surgery in that it allows for simultaneous treatments (appendectomy, adnexal surgery, endometriosis excision) and a better inspection of the peritoneal cavity. Some surgeons find it feasible to perform laparoscopic hysterectomy in cases with large uteri. But, there are studies which refute this and have reported that if the surgeon is experienced in vaginal

surgery, equivocal outcomes are seen.[20] Rather than size, the key selection criterion for the method of choice to perform hysterectomy should be vaginal accessibility and mobility of uterus.[6]

Table 3 : Complications of laparoscopic hysterectomy

A. Anaesthetic complications	-Patient position: • Deep vein thrombosis • Nerve injuries -Pneumoperitoneum: • Respiratory acidosis(hypercarbia) • Subcutaneous emphysema • Pneumomediastinum • Pneumothorax • Pneumopericardium • Preperitoneal insufflation
B. Entry complications	• Injury to vessels • Abdominal wall haematoma • Wound infection • Injury to small bowel/ large bowel • Injury to retroperitoneal organ • Injury to liver/spleen
C. Intra-operative complications	• Bladder injury • Intestinal injury • Vascular injury • Ureter injury • Haemorrhage • Electrosurgical injury • Conversion to laparotomy
D. Post-operative complications	• Port site infection • Port site hernia • Vaginal cuff infection/abscess/haematoma/dehiscence • Vaginal bleeding • Fever • Urinary tract infection • Urinary retention • Genitourinary fistula • Rectovaginal fistula

Risk factors for complications were described as the higher BMI, higher incidence in postmenopausal women, number of vaginal deliveries, previous history of vaginal delivery, previous history of laparotomy, previous history of adhesion causing abdominopelvic surgeries.[7]

Review of articles

- The following has been observed in the previous studies on laparoscopic hysterectomy:
- The prevalence of major complications varied from 0.44% to 4.54% in about 10 studies with sample size ranging from 286 to 3190. The prevalence of bladder injury varied from 0 % to 2%in about 10 studies with sample size ranging from 100 to 175. The prevalence of ureter injury varied from 0%to 1.16% in about 8 studies with sample size ranging from 86 to 175. The prevalence of bowel injury varied from 0%to 0.9% in about 7 studies with sample size ranging from 100 to 435. The prevalence of minor complications (like fever, urinary tract infection, vault abscess, vaginal cuff bleeding) varied from 0%to 14.68% in about 7 studies with sample size ranging from 100 to 286. Most common benign indication for laparoscopic hysterectomy in majority of the previous studies was fibroid uterus followed by AUB, adenomyosis and recurrent post menopausal bleeding. The rate of conversion to laparotomy ranged from 0% to 9.6 %in about 8 studies with sample size ranging from 125 to 361.The amount of blood loss was in the range of 44±79ml to 313 ml in about 7 studies with sample size ranging from 361 to 435. The mean operating time was in the range of 95.6 min to 148±40 min in about 8 studies with sample size ranging from 100 to 125. The mean length of hospital stay ranged from1.2±0.4 days to3.85±1.97days in about 8 studies with sample size

ranging from 125 to 175. The risk factors associated with the complications were found to be history of previous abdominal or pelvic surgeries, severe adhesions, large uterus and low or high BMI. [11-20]

- Cheung VY et al. analysed the surgical outcome of total laparoscopic hysterectomy over a five-year period in research. There was no harm to the colon or urinary system in any of the individuals. Serious and moderate problems occurred at a rate of 4 percent and 2.9 percent, respectively. The average duration of procedure was 108.2 min., with a standard deviation (SD) of 29.6 minutes ranging from 60 to 199 minutes, and the average period of hospital stay was 1.2 days, with a standard deviation (SD) of 0.4 days. The biggest specimen weighed 1126 g, while the mean uterine weight was 292.9 g with a standard deviation of 206.3 g. The operating times and lengths of hospital stay in the study presented here were found to be comparable to reports published previously. TLH is an acceptable and safe alternative to standard hysterectomy.[18]
- In a retrospective study by O'Hanlan K et al., to examine the method and problems associated with TLH. A total of 5 (0.6%) of 830 consecutive patients had conversion to laparotomy. Patients had an average age of 50 ±11 years, 1.3 ±1.3 pregnancies, and a BMI of 27.6±6.8 kg/m^2. The average procedure lasted 132 ±55 min., with 130 ±189 mL of blood lost and a hospital stay of 1.4 ±0.9 days. The length of the surgery, blood loss, and hospital stay decreased as the surgeon's experience increased. Re-operative complications occurred in 38 people (4.7%). Urologic injuries were discovered in 23 patients (2.6%), with 9 (1.1%) requiring reoperation. They found that TLH provided the benefit of minimally invasive surgery for patients requiring hysterectomy, even if the uterus prolapsed.[19]

- Christopher CM et al. conducted a retrospective research to evaluate surgical technique in relation to the success of total laparoscopic hysterectomy. In all, 435 women decided to get a TLH. With three mini-laparotomies and five laparotomies, 427 cases (98.2%) had a successful surgery (1.8 percent failure rate). Among the injuries were one haemorrhage at base of the bladder, four bowel injuries, four vaginal lacerations, one uterine perforation, and one uterovaginal fistula. Major complications (defined as laparotomy conversion, excessive bleeding requiring blood transfusion, haemorrhage >or=1000 mL, ureteric injury, bowel injury, and pulmonary embolus) occurred in 21 women (4.8 percent), which compares favourably to previous reports of laparoscopic hysterectomy (4.0-11.0 percent). The average surgery duration, expected blood loss, length of hospital stay, and readmission rate are all comparable. The success rate of TLH is high, the morbidity rate is low, and there are minimal problems.[17]
- In a study by Donnez O et al., (2008) to assess the complication rate following laparoscopic total hysterectomy and LASH in cases of benign disease. Minor problems (temperature >38.5 ℃ after 48 hrs, 20 mm bladder incision, iatrogenic adenomyosis) and major complications (ureteral injury, vesicoperitoneal fistula, haemorrhage, rectal perforation / fistula) were observed both during and after surgery. In LASH group (n = 1613), mild complication rate was 0.99 % (n = 16), while significant complication rate was 0.37% (n = 6). In the total laparoscopic hysterectomy (LAVH/TLH) group (n = 1577), rate of minor complication (n = 18) and major complication (n = 8) were 1.14% (n = 18) and 0.51% (n = 8), respectively. In the vaginal hysterectomy group (n = 906), rates of minor and serious complications were 0.77% (n = 7) and 0.33% (n = 3), respectively. In the abdominal hysterectomy group (n = 409), rates of serious and minor

complications were 0.49 % (n = 2) and 0.73% (n = 3) respectively. There is no evidence that laparoscopic hysterectomy causes a rise in rates of serious complication.[14]

- A retrospective study was done by Silva CN et al., (2014) to assess the complication rate of TLH. The patients' mean age was 48.9 9.0 years, and 49.2 percent had prior abdomino-pelvic surgery. The average BMI was 26.5 4.5 kg/m2, with 42% of women being obese or overweight. The average operating time was 77.7 27.5 min., however it decreased considerably as training increased. Mean inpatient stay of 1.49± 0.9 days. Average uterine weight was 241.0168.4 g. The average postoperative haemoglobin fluctuation was -1.5 0.8 g/dL. Moderate and serious problems occurred at rates of 11.5 (n = 30) and 1.5 (n = 4) and respectively.[20]
- Begum M et al., (2016) conducted a retrospective research to evaluate the surgical outcome of complete laparoscopic hysterectomy. The rates of mild and major complications were 0% and 2% (bladder injury-2 occurrences) respectively. The mean surgical duration was 148± 40 minutes, and the average inpatient stay was 3±1 days. Ten and four weeks was the average uterine size. Due to fewer procedural complications, the operating time and hospital stay in our instances were generally similar. From the perspective of the patients, TLH is an acceptable and safe alternative operation to traditional hysterectomy.[11]
- Agarwal P et al., (2016) conducted a four-year prospective randomised research to investigate the risks and benefits of TLH vs complete abdominal hysterectomy. Since March 2010, 250 patients have been operated on either laparoscopically or openly. Significant problems occurred in 1.6 percent of TLH patients and 4 percent of TAH patients. After the first year after surgery, this incidence reduced

to 0% in the TLH group in subsequent years. In the third year of the study, the proportion of minor difficulties dropped from 14 to 4.5 percent. The overall conversion rate to laparotomy was 9.7%, with a significant drop after the first year. Furthermore, in terms of decreased blood loss, early ambulance postoperatively, and shorter hospitalisation, TLH dramatically beat TAH.[12]

- Pattanaik T et al. conducted a research to analyse the result of complete laparoscopic hysterectomy in terms of discomfort. The most common indication for surgery was leiomyoma (40.20 %), followed by abnormal uterine bleeding (28.32%). The average duration of operation in TLH is 2.340.67 hours, with a blood loss of 150.9±58.8ml. Major intraoperative problems occurred in 4.54% of patients, whereas mild postoperative complications occurred in 14.68% of cases. The laparotomy conversion rate was 1.39%, with urinary tract damage occurring in 0.68 percent of patients. The average length of inpatient stay was 2.58 ±1.98 days. It was concluded that TLH is a safe surgery with low blood loss and a shorter inpatient stay when performed by a surgeon with surgical skill.[22]
- In a cross-sectional study by Zafar SM et al., (2017) to investigate the complications associated with laparoscopic hysterectomy. TLH was done on 86 people. Only two people had problems, which were ureter ligation and vulvovaginal fistula. Cause was a history of previous surgery and multiple adhesions. Laparoscopic hysterectomy is becoming more common. The total complication rate in their research was 2.4 percent. These positive results show that when performed by skilled surgeons, it is a safe surgical approach.[13]
- In a retrospective cohort study by Ingole S et al., (2018) to examine the method and surgical outcome of complete laparoscopic hysterectomy. A total of 2307 hysterectomies were done over the course of five years. TLH was responsible for

270 of these (11.70 percent). Individuals receiving TLH had an average age of 45.84 years. The most common reason for surgery was fibroid uterus (38.14 percent), followed by dysfunctional uterine bleeding (28.88 percent), and adenomyosis (28.88 percent) (15.1 percent). On average, blood loss was calculated to be 1064.34 ml. Bladder injury (n = 4) and haemorrhage (n = 2) were the most common complications. TLH is a safe and effective operation for the vast majority of benign pelvic illnesses. With sufficient training, TLH may be used more generally in tertiary care hospitals and educational institutes.[16]

- Mereu L et al. (2018) conducted a retrospective analysis to evaluate the surgical outcome of complete laparoscopic hysterectomy for benign illness. C0mplications requiring surgical intervention under general anaesthesia occurred in 3 patients (0.8%): 1 (0.3%) hydroureteronephrosis, 1 (0.3%) bowel adhesions, and 1 (0.3%) port side hernia; complications necessitating surgical intervention without general anaesthesia occurred in 6 patients (1.6%): 1 (0.3%) hydroureteronephrosis, 1 (0.3%) bowel adhesions, and 1 (0.3%) port side hernia. There were two (0.6%) cases of hydroureteronephrosis, one (0.3%) case of vaginal cuff dehiscence, and three (0.8%) cases of vaginal cuff haemorrhage. Their findings are congruent with those of the other research mentioned.[15]
- In research conducted by Peters A et al., (2021), laparoscopic two layer vaginal cuff closure during laparoscopic hysterectomy was related with reduced risk of post-operative complications. The vaginal cuffs of 40.8 % (n=51,213) of the 2,973 women who had complete laparoscopic hysterectomies were closed using a two-layer approach and 59.2 % (n=51,760) with a one-layer technique. The use of a two-layer vaginal cuff was linked to fewer overall postoperative problems (3.5 % vs 5.7 %; P,.01). The key difference was decreased vaginal cuff issues within 180

days (0.9% vs 2.6%; P,.01); there were no changes in 30-day surgical and medical postoperative complications between both groups (2.6% vs 3.1%; P5.77). The two-layer vaginal cuff closure group had no vaginal cuff dehiscence or mucosal separation, whereas the one-layer group had 1.0% (P,.01). A two-layer closure was shown to be more protective against postoperative problems than a one-layer closure (adjusted odds ratio 0.38, 95% CI 0.19–0.74). Although postoperative problems from laparoscopic hysterectomies are uncommon, laparoscopic vaginal cuff closure in two layers is linked with fewer overall postoperative difficulties than one-layer closure. The distinction was mostly caused by cuff difficulties.[23]

MATERIALS AND METHODS

Study design: Descriptive observational study

Study Setting: Teaching hospital attached to KAHER, Belgaum.

Patients who underwent laparoscopic hysterectomy at a teaching hospital attached to KAHER, Belagavi.

Duration of data collection: 21 months

Study Period: January 2020 to September 2021

Study Population: Patients who underwent laparoscopic hysterectomy for benign conditions at KAHER's Dr. Prabhakar Kore Hospital, Belagavi.

Sample size: It is a time bound study. Patients who underwent laparoscopic hysterectomy for benign conditions from January 2020 – September 2021, at KAHER's Dr.Prabhakar Kore Hospital, Belagavi, were taken into the study.

Sampling procedure: Universal sampling method.

Inclusion criteria:

- Patients who underwent laparoscopic hysterectomy for benign conditions.

Exclusion criteria:

- Gynaecological malignancies

Ethical clearance:

Prior to the commencement, the study was approved by the Institutional Ethics Committee on Human Subjects Research, Jawaharlal Nehru Medical College, Belagavi.

(Annexure 1 - Letter number MDC/DOME/213 dated 24/12/2019)

Informed consent:

Waiver of consent has been obtained, as it is a non-interventional study.(Annexure 2- Letter number MDC/DOME/301 dated 24/12/2019)

Method of data collection:

Patients who underwent laparoscopic hysterectomy, for benign conditions, were enrolled as the participants of the study. Details regarding socio-demographic factors, indication for surgery, duration of surgery, amount of blood loss during surgery, duration of hospital stay, intra operative complications including bladder injury, bowel injury, ureter injury, major vascular injury, haemorrhage requiring blood transfusion, conversion to laparotomy, any pneumoperitoneum related complications, complications related to anaesthesia and patient position, and post-operative complications including per vaginal bleeding, fever, urinary tract infection, urinary retention, vaginal cuff dehiscence/infection / haematoma, port site infection /hernia, urinary retention, genitourinary fistula, recto-vaginal fistula or any other complication encountered (which may have not been mentioned above) were collected through a data collection proforma from the records and personal communication with the surgeon, assistants and anaesthetists who were present during that particular case and from the videos recorded. The patients were followed up on

until they were discharged, then visited again in the surgeon's clinic one week later, and then contacted by phone after one month.

Laparoscopic Hysterectomy procedure:

Before surgery, informed consent was sought. One day before the procedure, patients were admitted to the hospital. In diabetic individuals, blood sugar levels were well-controlled (postprandial blood sugar was between 8-10 mmol/l). All patients were subjected to a pelvic ultrasound examination as well as basic blood tests.

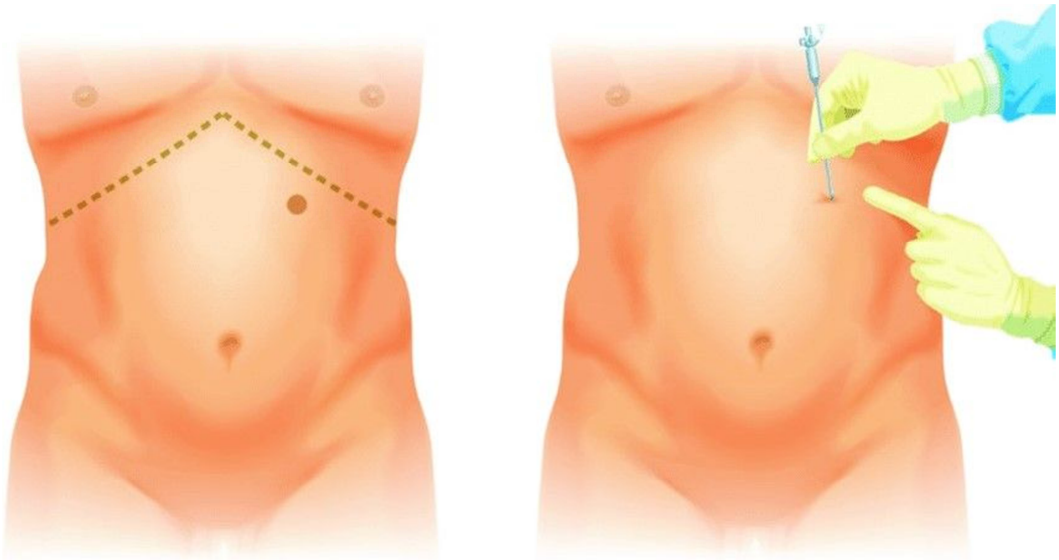
Patients were maintained on NBM for 6 hours before to surgery and were given bowel preparation (enema at night before surgery). Injection Cefudip S 2.25 gm IV was given as a prophylactic antibiotic preoperatively.

All the laparoscopic hysterectomies were performed by a team of senior gynaecologist and a laparoscopic surgeon.

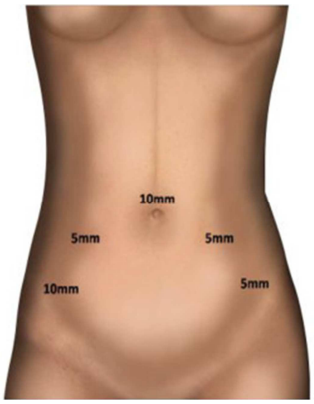
Surgery was performed under a combination of spinal and general anaesthesia with endotracheal intubation. Patients were positioned in modified lithotomy posture, with their legs flexed on Allen stirrups. Bladder is catheterised with Foley’s catheter and vaginal packing was done.

Creating the pneumoperitoneum: Pneumoperitoneum can be created by various techniques. Abdomen was accessed through direct trocar insertion or by inserting a Veress needle through Palmer's point or umbilicus. Palmer's point (2-3 cm below the left subcostal border in the midclavicular line) was used for entry in cases of prior abdominal surgery with probable adhesions in the midline. The present evidence supports direct trocar entry over using a Veress. It’s not only failed entry and

extraperitoneal insufflation, but also omental injury that is more common with Veress *vis-a-vis* direct entry. Pneumoperitoneum is insufflated to 12–14 mm Hg.



Trocar placement: Five trocars were placed



i. First is 10 mm port supra-umbilically for the laparoscope.

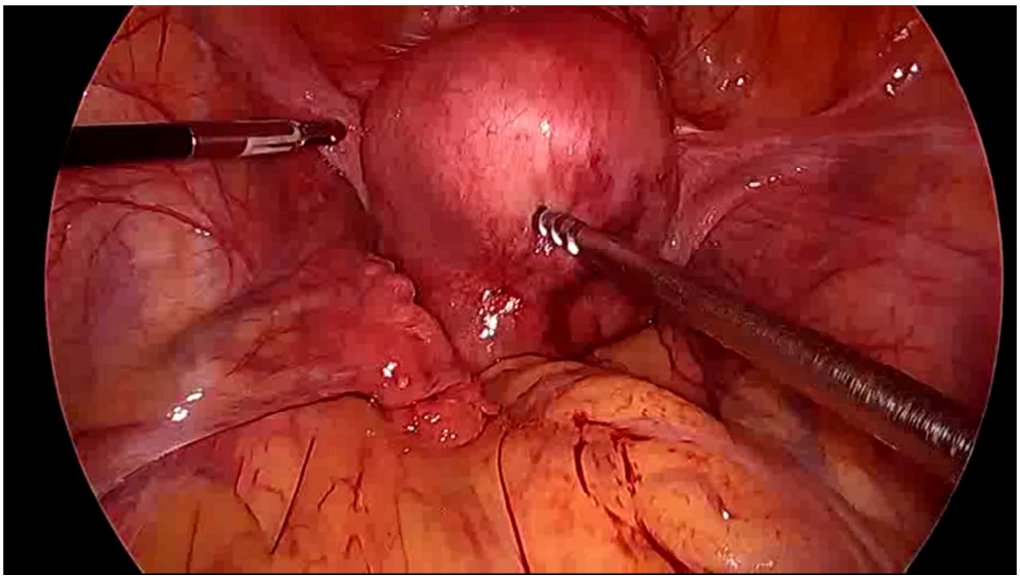
ii.Second and third ports (5 mm) is inserted lateral to rectus abdominis bilaterally at the level of umbilicus.

iii. Fourth port (5 mm) is inserted at Mac Burney's point.

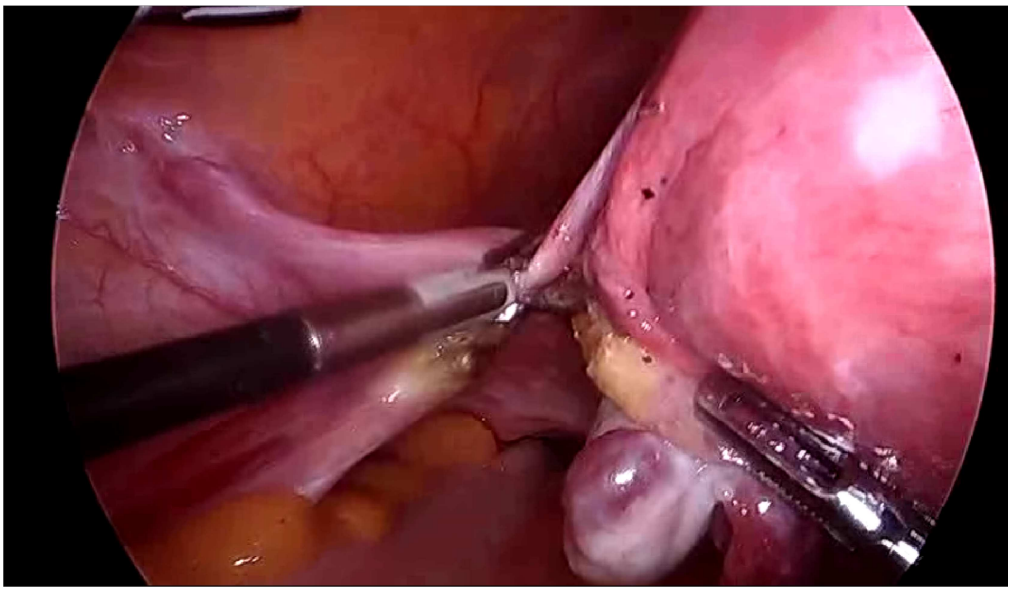
iv. Fifth port (5 mm) inserted at the corresponding point on left side.

Initial steps with exposure of operative field: Release of adhesions allows proper exposure of pelvic structures. First assistant pushes the bowel back into abdominal cavity for proper exposure. Uterus is pushed in cranioanterior position by the second assistant to facilitate beginning of surgery.

A myoma screw is inserted into the uterus to facilitate uterine manipulation.

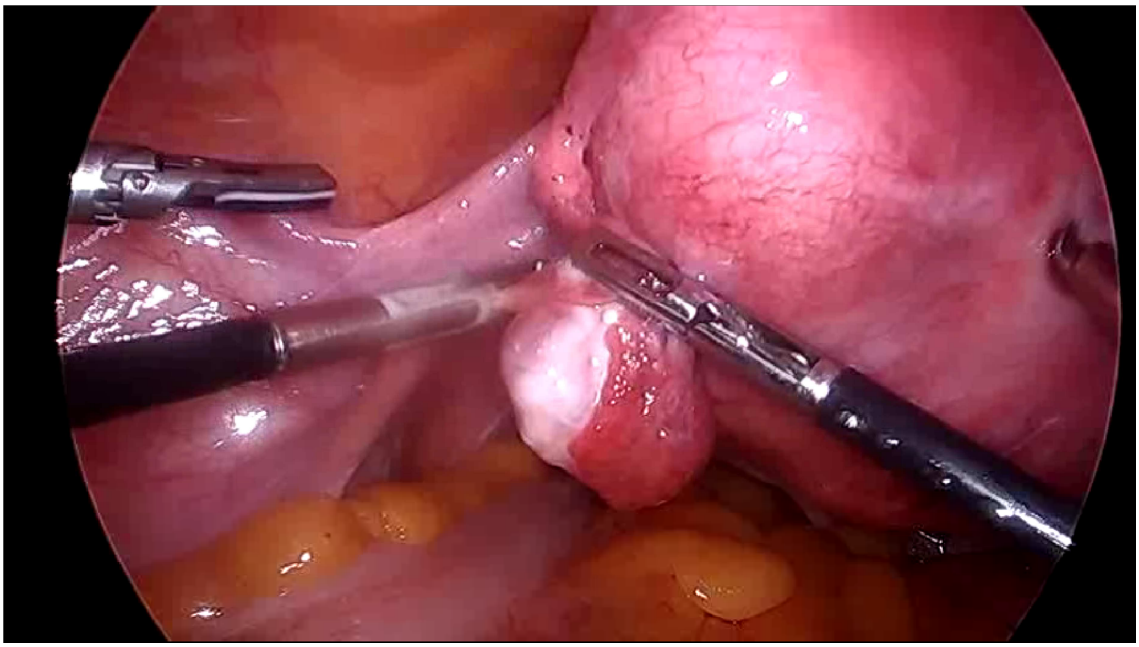


Division of round ligament: 2–3 cm medial to the pelvic attachment, a round ligament was held, cauterized by bipolar cautery and divided using laparoscopic scissors.



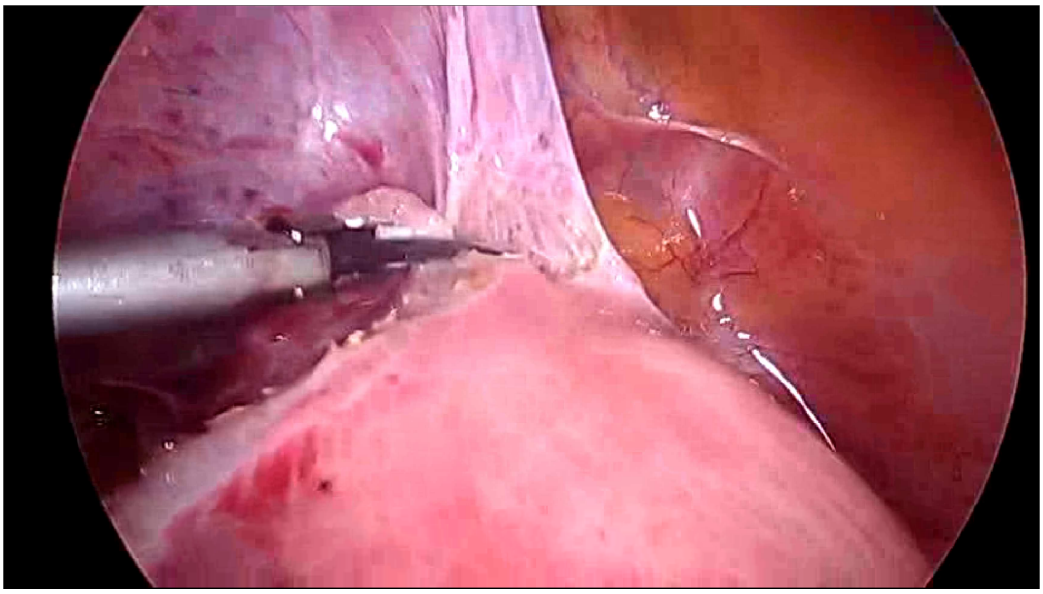
Division of infundibulopelvic ligament (for bilateral oophorectomy)/utero-ovarian ligament and tubes (for interadnexal hysterectomy):

Small vessels of posterior leaf of broad ligament were coagulated and a cut was made in it, which was extended by blunt dissection done by divergent action of instruments. The greyish area of the leaflet was dissected to avoid injury to underlying structures. To avoid damage, the ureter along with peritoneum was displaced laterally and inferiorly. Holding the round ligament stump and hauling it away from the infundibulopelvic (IP) ligament to be cut by the first assistant. The coagulation and sectioning of the IP ligament was gradual, to avoid haemorrhage. When preserving ovaries, the tube and utero-ovarian ligament are coagulated and divided.



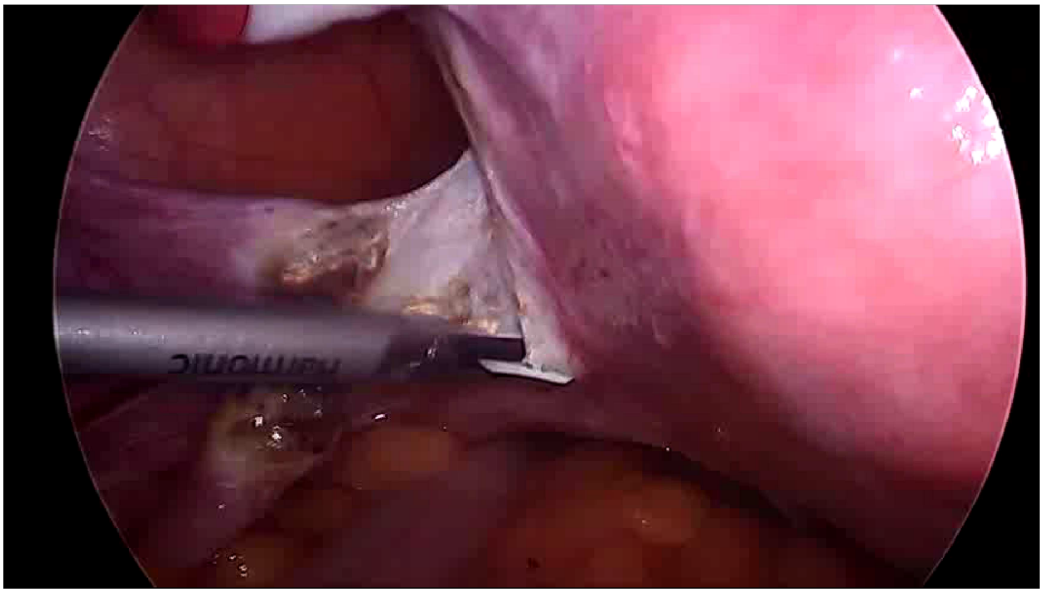
Opening anterior leaf of broad ligament and vesicouterine fold:

The second assistant maintained the uterus in elevated and slightly retroverted position. Both the leaflets of broad ligament were separated by sharp/blunt dissection. The broad ligament's anterior leaf was coagulated and cut on both sides from the round ligament to the vesicouterine peritoneal reflection.



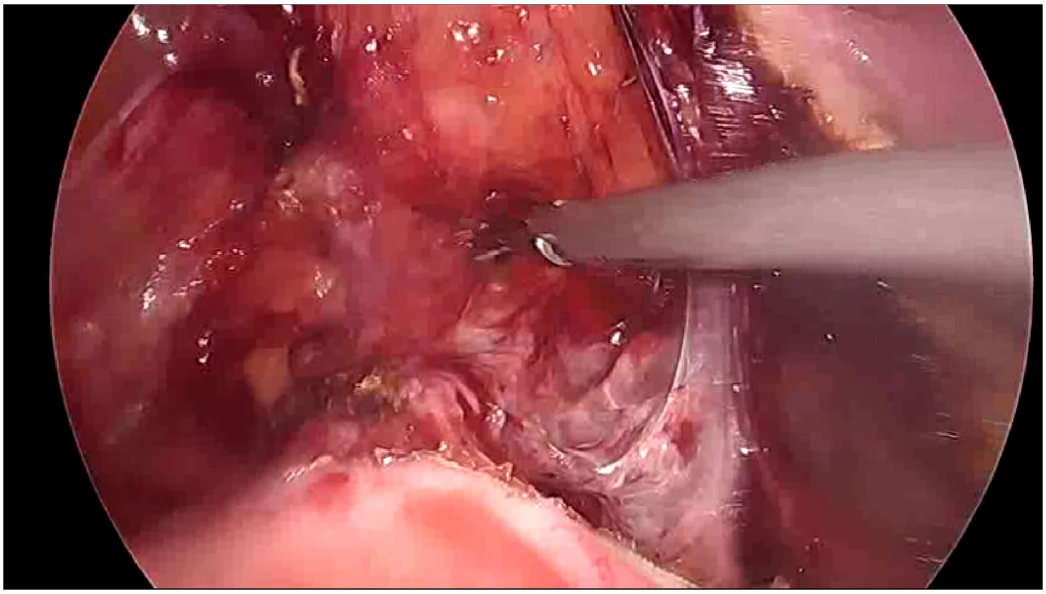
Opening posterior leaflet of broad ligament:

The posterior peritoneum of the broad ligament was dissected, coagulated and cut towards uterosacral ligament to prevent inadvertent injury to uterine vessels. The uterine pedicle was isolated like 'skeletonization' done in open surgery. All the above-mentioned steps are performed concomitantly on bilateral sides.



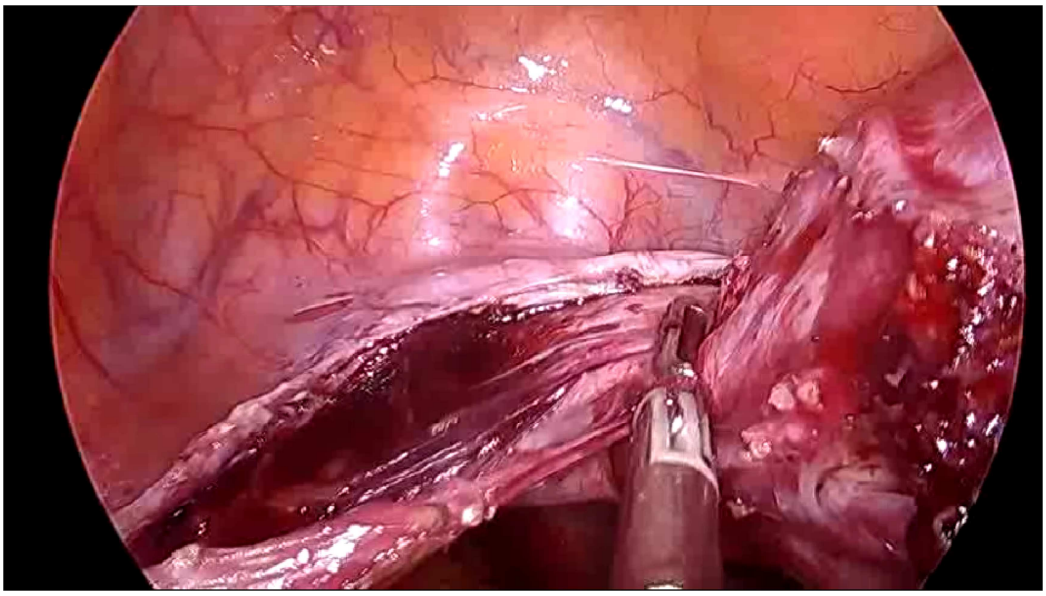
Dissecting vesicovaginal space:

Uterus was pushed cranially and slightly retroverted, exposing the vesicouterine region. The peritoneum and bladder were grasped in the midline with atraumatic forceps, and cranial traction was utilised to move the bladder away. The peritoneum and connective tissue of cervicovesical space were coagulated and dissected down to create a clear vesicovaginal plane. Vesicouterine ligaments were coagulated and cut.



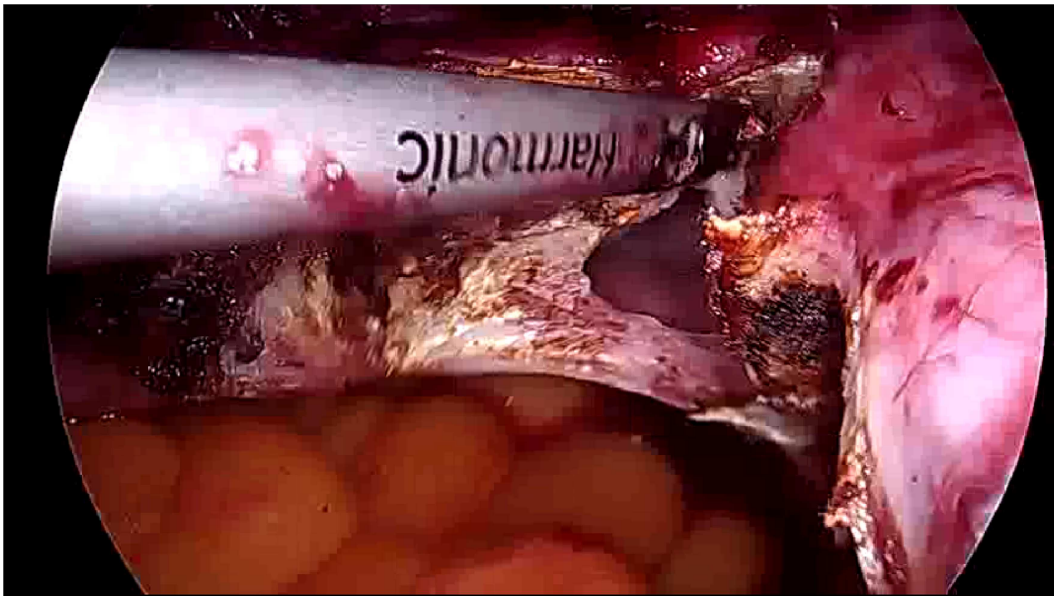
Desiccation and section of uterine vessels and uterosacrals:

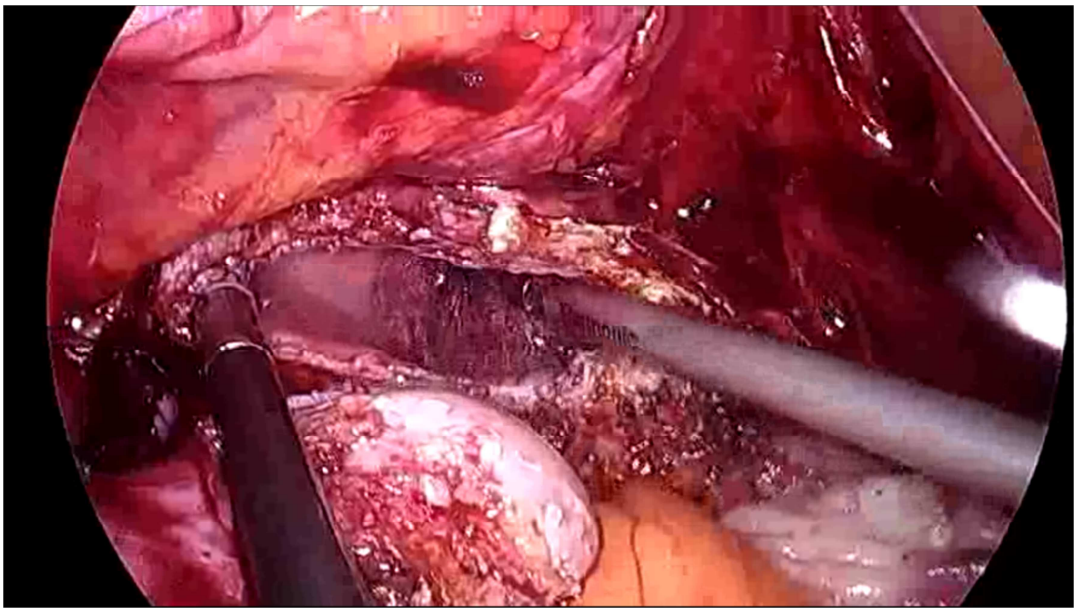
The uterus was again directed cranially and away from the side to be operated upon by the second assistant. The first assistant also aids by pulling the round ligament as desired. To enable effective bipolar coagulation, the ascending uterine artery pedicles were isolated. Gradual bipolar coagulation was performed. The pericervical fascia at the level of coagulated uterine was incised and a clear intrafascial plane is created. The uterosacral ligament at insertion were coagulated and sectioned.



Opening the vaginal vault:

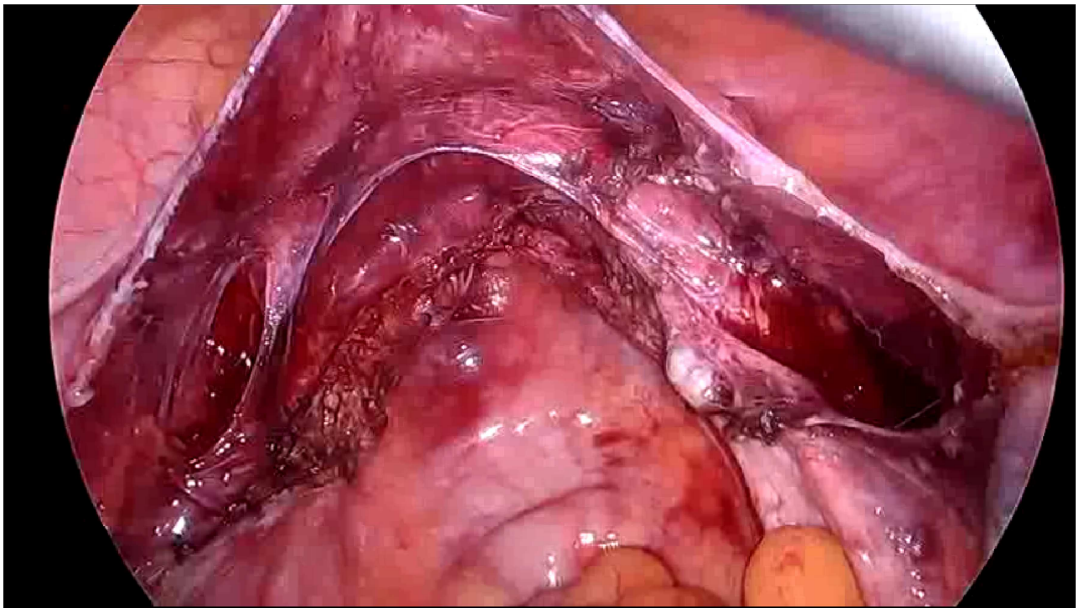
It was performed by harmonic scalpel. Sectioning begins from one side and extended to the other side anteriorly and then posteriorly.





Specimen extraction: The extraction was performed vaginally.

Vault closure: Vault was closed vaginally in most cases. In few cases, it is closed laparoscopically. Continuous closure is done in a single layer using vicryl.



Bladder integrity was checked with methylene blue.

Ureteric peristalsis was checked.

Port closure: All ports closed by inverted mattress sutures with monocryl.

The duration of operating time was documented as the time from commencement of first incision on the skin up to skin closure of final port. The total blood loss is estimated by subtracting the irrigation fluid from the suction equipment.

Postoperative management: Parenteral antibiotic prophylaxis and analgesics were continued for 24 hours and then oral antibiotics and analgesics were given for 5 days. Patient was allowed oral intake of fluids after 6 hours (after peristalsis is established) and resume normal diet the next day. Foley's catheter was removed when oral intake was started and as the patient was ambulatory. Patient was ambulated after 6 hours. Stool softener was given. Patient was discharged when she starts mobilising, tolerating soft diet and pain controlled with oral analgesics.

The patients were followed up till their discharge, then visited again in the surgeon's clinic one week later and followed up telephonically after 1 month.

RESULTS

The study was conducted at teaching hospital attached to KAHER's J.N Medical College Belagavi, from January 2020 to September 2021.

Recruitment of study participants

The total number of participants screened for this study were 105. Out of 105 screened, 104 participants were eligible for the study, and 1 participant was not eligible, as the indication for laparoscopic hysterectomy was a malignant condition (endometrial adenocarcinoma). A total of 104 participants were recruited and followed up.

The data obtained was coded and entered into the Microsoft Excel spread sheet. The data was analysed and the following results were obtained.

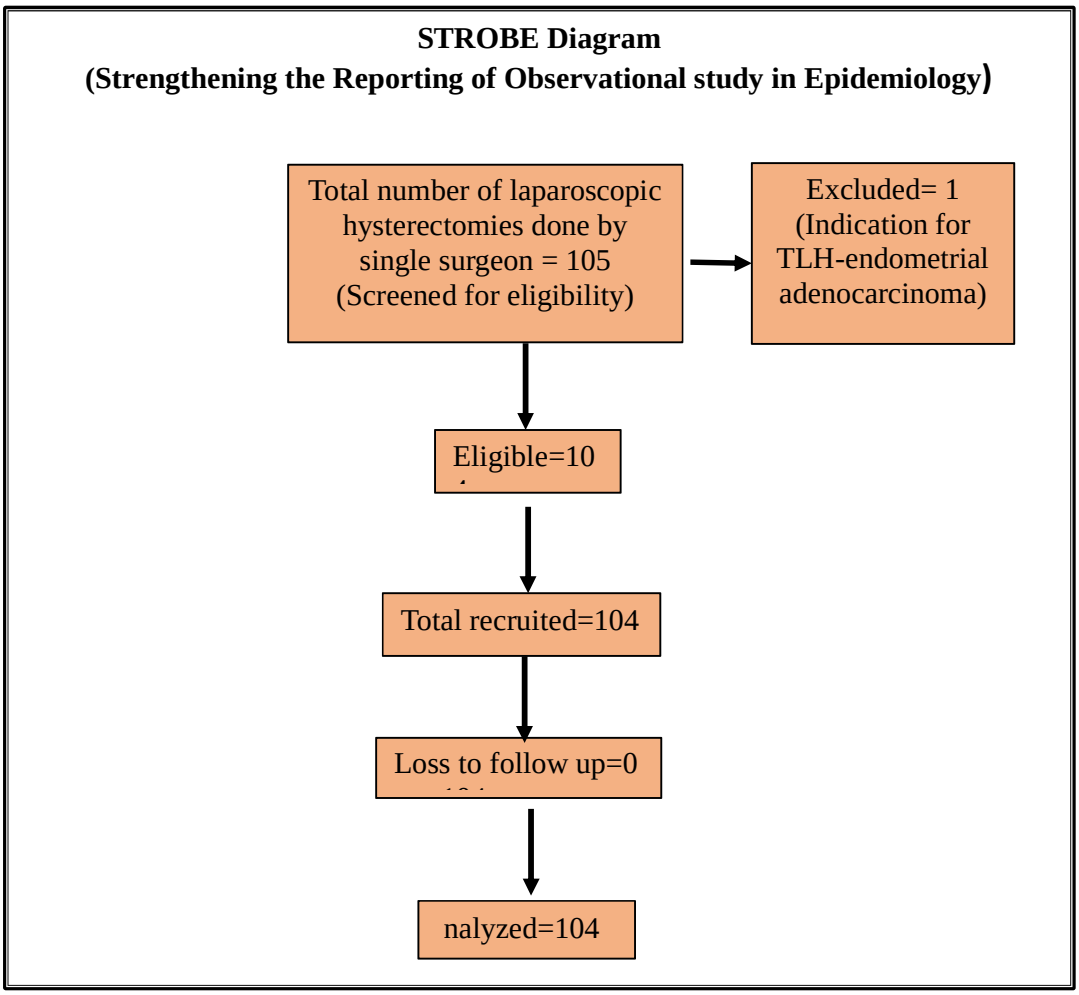


Table 4. Recruitment of study participants and distribution based on selection criteria

Total no. of screened participants	105
Total no. of eligible participants	104
Total no. of ineligible participants	1
Total no. of recruited participants	104

Table 5. Age wise distribution of study participants

Age groups	Number of cases (n=104)	Percentage
33-35 years	3	2.88%
36-40 years	19	18.27%
41-45 years	32	30.77%
>45 years	50	48.08%

From table 2, it has been observed that age ranged from 33 years to 75 years with mean age 46.28 ± 7.38 years. Majority of the participants (48.08%) in the study were >45 years of age. Three participants were in the age group of 33-35 years accounting to 2.88%. In these patients, hysterectomy was done due to multiple large fibroids, and patients themselves insisted for hysterectomy.

Figure 1: Age wise distribution

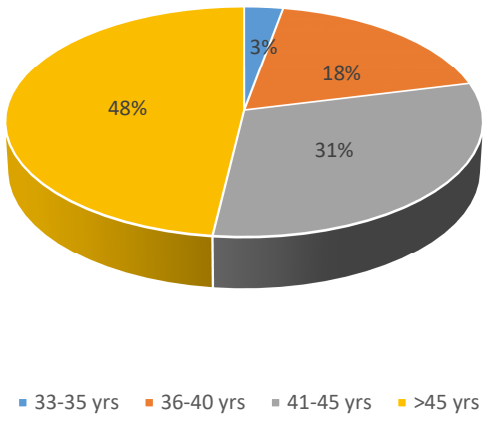


Table 6. Distribution of subjects according to BMI

BMI	Number of cases (n=104)	Percentage
<18.5	0	0
18.5-24.9	22	21.15%
25-29.9	68	65.38%
30-34.9	11	10.57 %
35-39.9	1	0.96%
≥40	2	1.92%

Majority of the subjects (65.38%) were having BMI in the overweight range. The mean BMI was 27.13 ± 4.07. Two patients had morbid obesity.

Figure 2. Distribution of subjects according to BMI

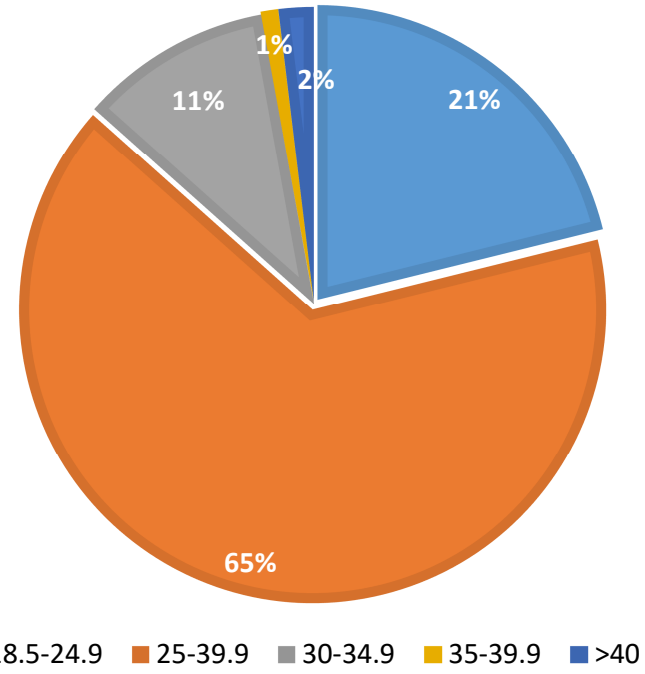


Table 7. Distribution of subjects according to comorbidities

Comorbidities	Number of cases(n=78)	Percentage
Hypertension	30	28.85%
Diabetes	23	22.12%
Hypothyroidism	20	19.23%
Asthma	2	1.92%
Bleeding/Clotting disorder	2	1.92%
Cardiac disease	1	0.96%

In our study, 78 subjects had comorbidities. 28.8% of subjects were known hypertensives and on treatment. 22.12% of subjects were diabetics on treatment. Around 19.23% had hypothyroidism and were on treatment. 2 subjects had history of intermittent bronchial asthma and so were not on any long-term therapy, but took treatment only during acute attack. One patient who had immune thrombocytopenic purpura, received platelet transfusion prior to procedure. One patient had factor V Leiden mutation with cortical venous thrombosis and was on warfarin therapy. Preoperatively warfarin was stopped and started on low molecular weight heparin till 6 hours prior to surgery. One patient is a case of rheumatic heart disease with history of mitral valve prolapse (treated 10 years ago), who was on regular penicillin prophylaxis.

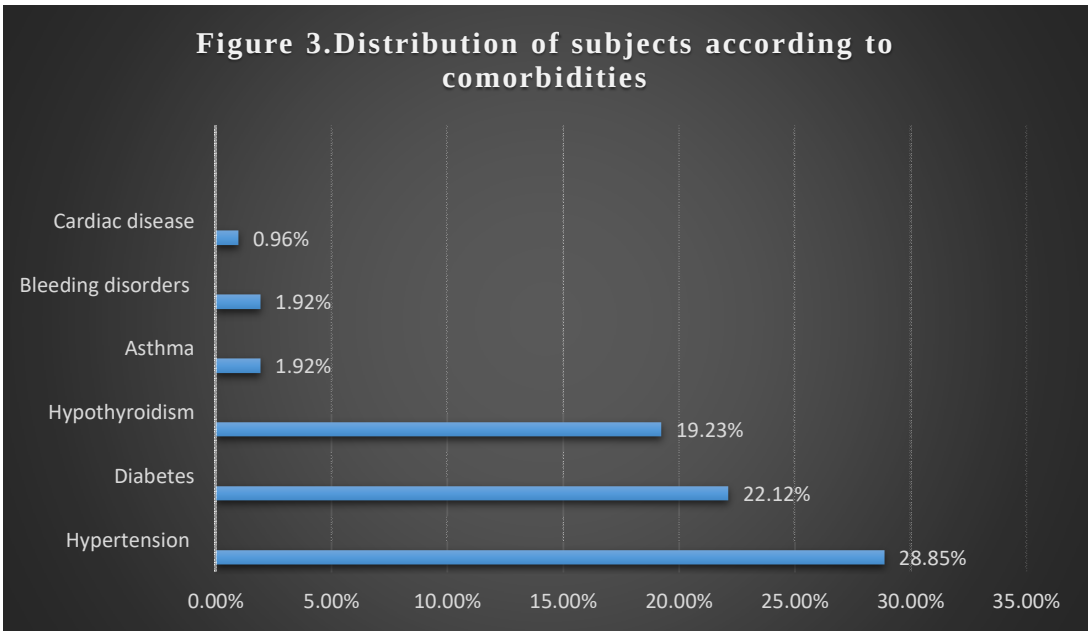


Figure 3.Distribution of subjects according to comorbidities
Cardiac disease
0.96%
Bleeding disorders
1.92%
Asthma
1.92%
Hypothyroidism
19.23%
Diabetes
22.12%
Hypertension
28.85%
0.00%
5.00%
10.00%
15.00%
20.00%
25.00%
30.00%
35.00%

Table 8. Distribution of subjects according to history of previous surgeries

86 (82.69%) subjects had history of previous surgeries.

Number of previous surgeries	Number of cases (n=86)	Percentage
0	18	17.31%
1	49	47.12%
2	28	26.92%
3	7	6.73%
4	2	1.92%

Figure 4.No. of previous surgeries

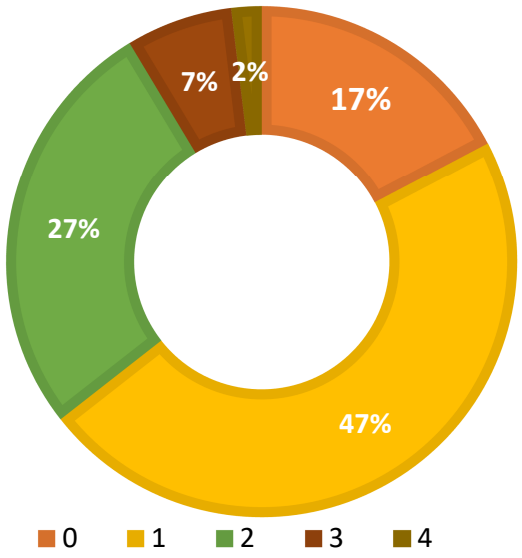


Table 9. Distribution of subjects according to size of the uterus

Size of the uterus (weeks)	Number of cases (n=104)	Percentage
<6	31	29.8%
6-12	62	59.62%
12-16	9	8.65%
16-20	2	1.92%
>20	0	0
Mean uterine size	**10.60 ± 2.6**	

Table 10. Distribution of subjects according to indication for laparoscopic hysterectomy

Indications of hysterectomy	Number of cases (n=104)	Percentage
Fibroid uterus	**59**	**56.73%**
Adenomyosis	27	25.96%
Endometrial hyperplasia	8	7.69%
Abnormal uterine bleeding not relieved by medical management	5	4.8%
Endometriosis	1	0.96%
Others	4	3.84%

The indications for laparoscopic hysterectomy are given in Table 7. The most common indication for the procedure was leiomyoma (56.73%). The second major indication was adenomyosis (25.96%).

Figure 5.Distribution of subjects according to indications for laparoscopic hysterectomy

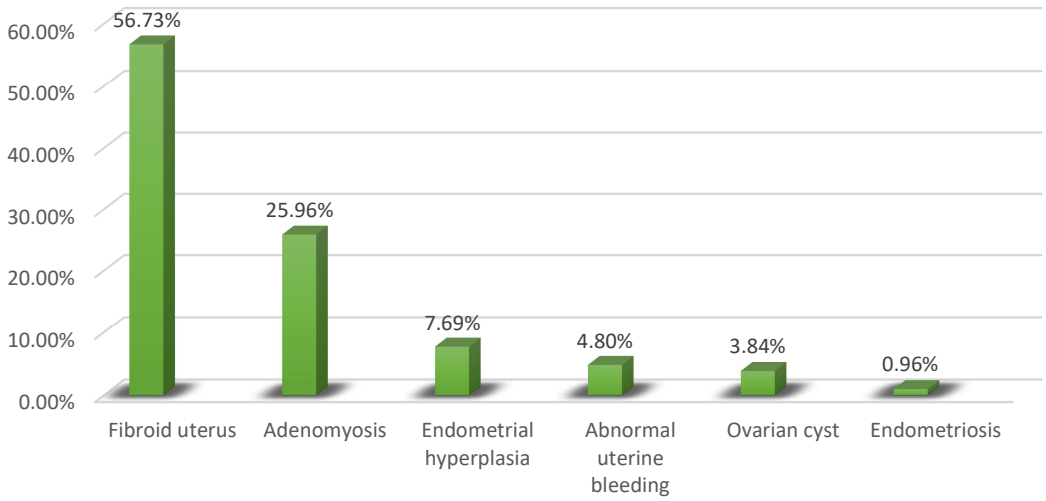


Table 11. Type of Entry technique used

Entry technique	Number of cases	Percentage
1)Direct Port entry	95	91.35%
2)Veress needle	9	8.65%
2a) At Palmer's point	7	6.73%
2b) At Umbilicus	2	1.92%

In majority (91.35%) of the cases, pneumoperitoneum was created after direct port entry. In the remaining 9 cases (2 cases with large uterine size of 16-20 weeks and 7 cases with three or more prior abdominal surgeries with suspected adhesions), Veress needle was inserted to create pneumoperitoneum.

Table 12. Abdominal wall adhesions

Abdominal wall adhesions	Number of cases(n=104)	Percentage
No	68	65.38%
Yes	36	34.62%

Even though 86 (82.69%) subjects had history of previous surgeries, abdominal wall adhesions were present in only 36(34.62%) of the cases.

Table 13. Method of specimen retrieval

Specimen retrieval method	Number of cases (n=104)	Percentage
Transvaginal, with minimal manipulation	93	89.42%
Transvaginal, after specimen myomectomy	11	10.58%
Electromechanical morcellation	0	0%

In all 104 cases, specimen was retrieved transvaginally. Electromechanical morcellation was not performed in any case. In 93(89.42%) cases, specimen could be retrieved intact with minimal manipulation. In the remaining 11 cases, due to large size of the specimen, there was difficulty in retrieving specimen transvaginally, and hence, in these cases, myomectomy was performed on the specimen to facilitate its easy removal through vaginal route.

Table 14. Method of closure of vaginal vault

Method of vault closure	Number of cases(n=104)	Percentage
Per vaginal	98	94.23%
Laparoscopic intra corporeal	6	5.77%

In our study, closure of vaginal vault was done per vaginally in majority (94.23%) of the cases. In the remaining (5.77%) of cases, vault closure was done laparoscopically.

Table 15. Type of surgery

Type of surgery	Number of cases(n=104)	Percentage
TLH	25	24.04%
TLH with unilateral salpingo-oophorectomy	6	5.77%
TLH with bilateral salpingo-oophorectomy	73	70.19%

In 25(24.04%) cases both ovaries were preserved. In 73(7019%) cases both ovaries were removed while in the remaining 6(5.77%) cases one ovary is preserved.

Table 16. Concomitant procedures

Additional procedures	Number of cases (n=26)	Percentage
Appendicectomy	11	10.58%
Cholecystectomy	3	2.88%
Hernioplasty	4	3.85%
Perineorrhaphy	6	5.76%
Lord's dilatation	1	0.96%
Ovarian cystectomy	1	0.96%

Table 17. Duration of surgery

Time (Mins)	Number of cases (n=104)	Percentage
≤60	41	39.42%
61-90	48	46.15%
91-120	14	13.46%
121-150	0	0%
150-180	1	0.96%
Average	78.7 ± 20.97	
Median (Min, Max)	75 (60, 170)	

Even though hysterectomy was completed within one hour, in some cases, time taken to cauterize minor oozes at the bladder area and vault area prolonged the operative time to more than an hour. In those cases, where a concomitant procedure was performed, operative time extended up to two hours. Only in one case, in which a major complication was encountered (bladder injury), surgery lasted for 170 minutes (maximum time taken among all cases).

Table 18. Duration of surgery depending on the type of surgery

Type of surgery	Mean Duration of surgery Median (minimum, maximum)	p-value
TLH	75.2 ± 18.4 min. 75(60, 120)	0.1279[K]
TLH with unilateral salpingo-oophorectomy	105 ± 40.37 min. 105(60, 170)	
TLH with bilateral salpingo-oophorectomy	77.74 ± 18.45 min. 75(60, 120)	

Abbreviation: K – Kruskal Wallis test.

It was observed that, the mean duration of surgery did not change significantly, based on the type of surgery. (i.e., whether one or both ovaries are preserved or removed).

Table 19. Comparison of duration of surgery between subjects with and without additional procedures

Duration of surgery (minutes)	Additional procedure		p-value
	No (n=78)	Yes (n=26)	
≤60	39 (50%)	0	**0.0015[MC]***
61-90	29 (37.18%)	21 (80.76%)	
91-120	9 (11.54%)	5 (19.23%)	
151-180	1 (1.28%)	0	
Mean ± SD Median (Min, Max)	74.87 ± 21.35 62.5 (60, 170)	90.19 ± 15 90 (60, 120)	**<0.001[MW]***

*Abbreviation: MC – Chi square test with Monte Carlo simulation, MW – Mann Whitney U test, * indicates statistical significance.*

As mentioned prior, it can be observed from table 16 that, from Chi square test and Mann Whitney U test, mean duration of surgery was significantly more in those cases where a concomitant procedure was performed.

Table 20. Estimated blood loss

Blood loss (ml)	Number of cases(n=104)	Percentage
≤50 ml	22	21.15%
51-100 ml	51	49.03%
100-150 ml	17	16.35%
150-200 ml	9	8.65%
>200 ml	5	4.81%
Mean blood loss	**110.72 ± 64.69**	
Median (Min, Max)	**100 (30, 400)**	

Table 21. Duration of post operative hospital stay

Hospital stay(Days)	Number of cases	Percentage
1	**73**	**70.19%**
2	24	23.07%
3	1	0.96%
>3	6	5.77%
Mean duration of post-op stay	**1.6 ± 1.52**	

Table 22. Complications

Out of 116 subjects, 12 (11.54%) had complications and 92(88.46%) had no complications.

Figure 6 . Complications

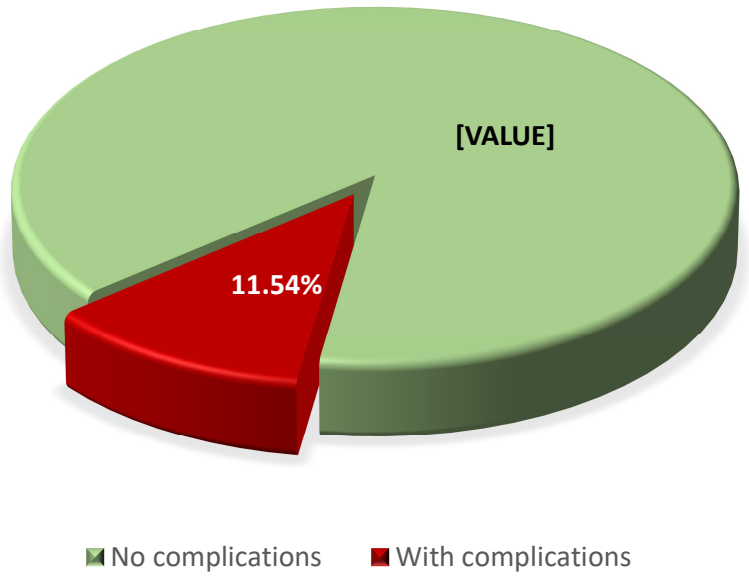
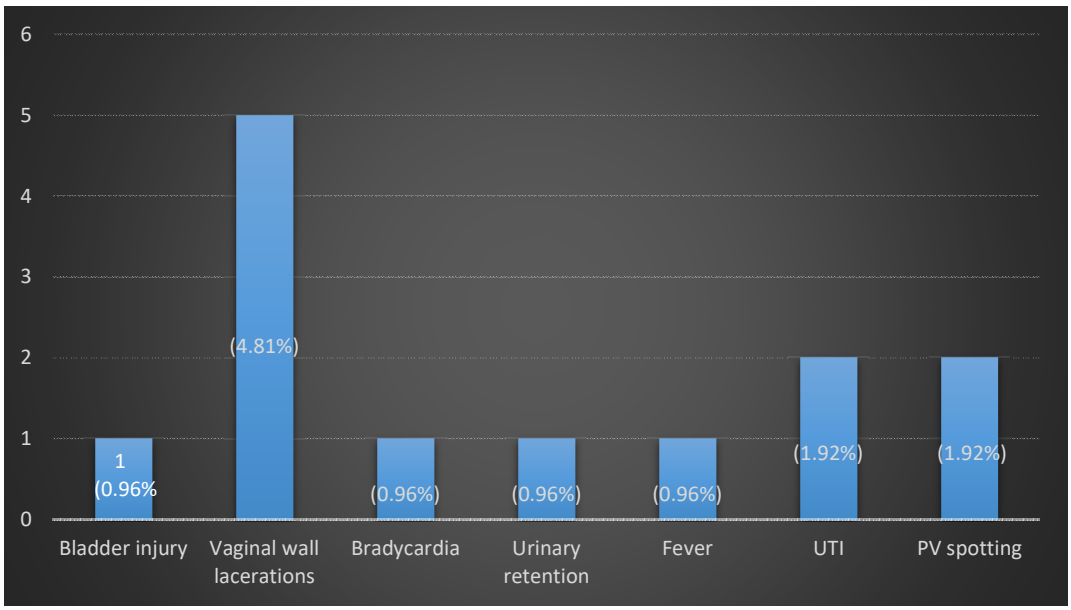


Table 23. Different types of complications

		Number of cases (n=12)	Percentage
Intraoperative	Bladder injury	1	0.96%
During specimen removal	Vaginal wall lacerations	5	4.81%
Post operative	Immediate: Bradycardia	1	0.96%
	Before discharge:		
	Urinary retention	1	0.96%
	Fever	1	0.96%
	Urinary tract infection	2	1.92%
	Within 1 month: Per Vaginal spotting	2	1.92%

Figure 7. Different types of complications



Out of the 12 cases with complications, 1(0.96%) was a major complication while the remaining 11(10.58%) cases had minor complications which could be conservatively managed.

One patient had bladder injury. This patient underwent previous two abdominal surgeries – one was laparotomy followed by left ovariotomy (in view of ovarian cyst) and the other was tubectomy. Intraoperatively, it was found that bladder was adherent to anterior abdominal wall and posteriorly to uterus. Bladder injury occurred during adhesiolysis. It was detected immediately and managed intraoperatively. After bladder injury repair, urologist opinion was taken on-table. Patient was discharged with foley catheter in-situ on fifth post operative day and was advised to take mirabegron (urinary anti-spasmodic). Catheter was removed after two weeks, following which patient had a normal functioning bladder. No further complications were reported by this patient post-operatively during the follow up period.

There were no cases with ureteric injury or bowel injury. No cases had any major haemorrhage requiring blood transfusion. No cases required conversion to laparotomy.

Five patients had vaginal wall lacerations during specimen removal, especially those with large size of specimen and had no previous vaginal deliveries.

One patient had bradycardia, with pulse rate dropping to 44 bpm in the immediate post-operative period (following extubation). This patient was diagnosed with hypothyroidism (TSH=7µIU/ml) two weeks prior to surgery (pre-operative TSH=4.8µIU/ml after starting treatment). Patient was kept under observation and was managed appropriately by the anaesthesiologist. Pulse rate returned to normal within an hour.

One patient had post operative urinary retention following catheter removal on first post operative day. Patient was re-catheterised with foley's catheter and started on bethanecol. Patient was discharged with catheter in-situ. Catheter was removed after two weeks, following which patient had a normal functioning bladder.

One patient had fever on third post operative day. Two patients had urinary tract infection post operatively prior to discharge. No complications were reported at one week follow up at surgeon's clinic. Two patients reported per vaginal spotting within one month, which were managed conservatively. None of them had any major bleeding or vault dehiscence. No cases required a repeat surgery or readmission to hospital.

Figure 8. Post operative pain grading

In our study post operative pain was assessed by Wong Baker faces pain rating scale.

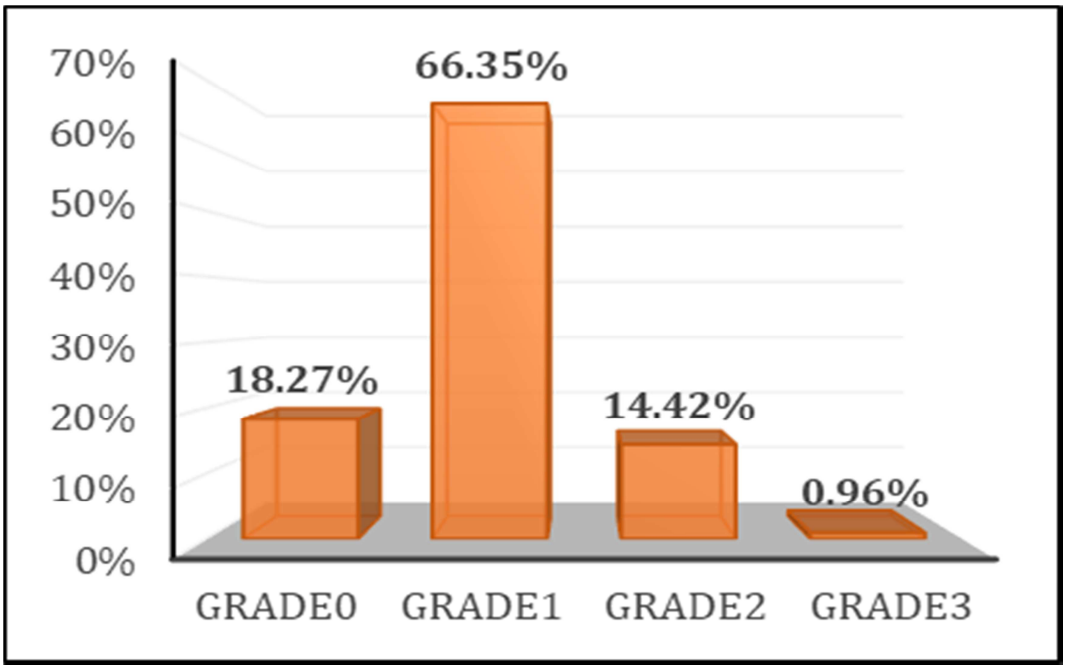


Figure 9. Post operative pain grading

Table 24. Association of different variables with complication

Variables		Complications		P value
		No	Yes	
Age (years)		45.88 ± 7.5	49.33 ± 5.79	0.1283[t]
Parity	Nulliparous	2 (2.17%)	0	0.1224[MC]
	Para 1	10 (10.87%)	5 (41.67%)	
	Para 2	51 (55.43%)	3 (25%)	
	> Para 2	29(31.52%)	4(33.33%)	
BMI		26.91 ± 3.81	28.86 ± 5.59	0.1183[t]
History of previous surgery		76 (82.61%)	10 (83.33%)	1[MC]
Diabetes		19 (20.65%)	4 (33.33%)	0.4868[MC]
Hypertension		24 (26.09%)	6 (50%)	0.1134[MC]
Hypothyroidism		16 (17.39%)	4 (33.33%)	0.2524[MC]
Asthma		1 (1.09%)	1 (8.33%)	0.2294[MC]
Bleeding/Clotting disorder		2 (2.17%)	0	1[MC]
Cardiac disease		1 (1.09%)	1 (8.33%)	1[MC]
Pre operative Hb		11.61 ± 1.33	11.56 ± 1.33	0.8912[t]
Post operative Hb		10.84 ± 1.72	10.78 ± 1.61	0.9082[t]

Abbreviation: t – Two sample t test, MC – Chi square test with Monte Carlo simulation.

From two-sample t test, we observe that there is no significant difference in mean age, BMI, pre operative Hb and post operative Hb with presence of complications.

From Chi square test, we observe that, complication is not significantly associated with variables like parity, comorbidities and history of previous surgeries.

Table 25. Association of different indications with complication

Variables (Indication)	Complications		P value
	No	Yes	
Fibroid uterus	54 (58.69%)	5 (41.66%)	0.5157[MC]
Adenomyosis	22 (23.91%)	5 (41.66%)	
Endometriosis	1 (1%)	0	
Endometrial hyperplasia	7 (7.6%)	1 (8.33%)	
Abnormal uterine bleeding	4 (4.34%)	1 (8.33%)	
Others	4 (4.34%)	0	

Abbreviation: MC – Chi square test with Monte Carlo simulation

From Chi square test, we observe that, complication is not significantly associated with any indication for laparoscopic hysterectomy.

Table 26. Association of different variables(intra operative events) with complication

Variables (intra-operative events)		Complications		P value
		No	Yes	
Entry technique	Direct Port entry	85 (92.39%)	10 (83.33%)	0.3558[MC]
	Veress needle	7(7.6%)	2 (16.67%)	
Abdominal wall adhesions		31 (33.7%)	5 (41.67%)	0.7666[MC]
Method of specimen retrieval	Through vagina, with minimal manipulation	82 (89.13%)	11 (91.67%)	1[MC]
	Through vagina, after specimen myomectomy	10 (10.87%)	1 (8.33%)	
Method of vault closure	Per vaginal	87 (94.57%)	11 (91.67%)	1[MC]
	Laparoscopic intra corporeal	5 (5.43%)	1 (8.33%)	

Abbreviation: MC – Chi square test with Monte Carlo simulation

From Chi square test, we observe that, complication is not significantly associated with variables like entry technique, presence of adhesions, method of specimen retrieval, and method of vault closure.

Table 27. Association of different variables with complication

Variables	Complications		P value
	No	Yes	
Duration of surgery	78.15 ± 19.72	82.92 ± 29.65	0.6917^{MW}
Specimen Weight (grams)	194.26 ± 155.13	323.75 ± 228.5	$\mathbf{0.0185^{MW*}}$
Estimated blood loss during surgery	106.58 ± 60.92	142.5 ± 85.08	0.124^{MW}
Duration of post-op hospital stay	1.47 ± 1.24	2.58 ± 2.78	0.1887^{MW}

*Abbreviation: MW – Mann Whitney U test, * indicates statistical significance.*

From Mann Whitney U test, we observe that there is no significant difference in duration of surgery, estimated blood loss during surgery, and duration of post operative stay with presence of complications.

However, it is observed that there is significant difference in the distribution of specimen weight with presence of complications.

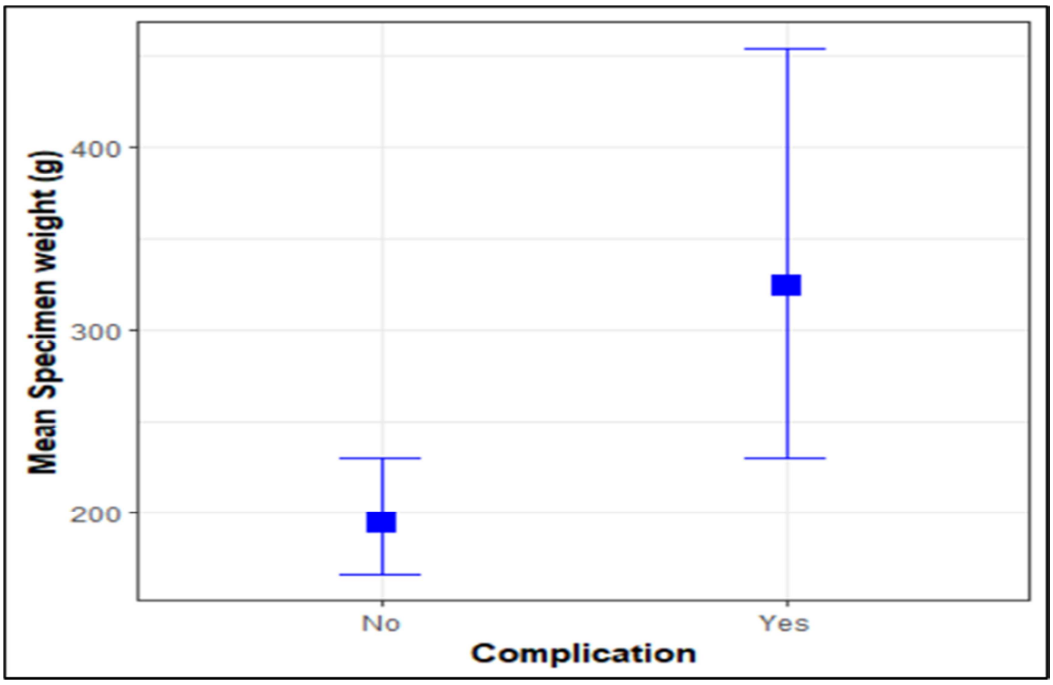


Figure 10: Mean plot of specimen weight over complication

Table 28. Association of method of vaginal vault closure and post operative per vaginal spotting

Method of vaginal vault closure	Post operative per vaginal spotting		p-value
	No	Yes	
Laparoscopic intracorporeal	6 (5.88%)	0	1^{MC}
Per vaginal	96 (94.12%)	2 (100%)	

Abbreviation: MC – Chi square test with Monte Carlo simulation

From Chi square test, we observe that, there is no significant association of method of vaginal vault closure and complication of per vaginal spotting.

DISCUSSION

The potential benefits and risks of laparoscopic hysterectomy have been widely reported since the first total laparoscopic hysterectomy was performed by Harry Reich in 1989. This study reports the outcomes for 104 TLH procedures carried out at KLES Dr. Prabhakar Kore Hospital, Belagavi. In terms of patient demographics, uterine size, operation time, and surgical morbidity, our findings are consistent with those published elsewhere. In the present study, majority of cases (48.08%) are beyond the age of 45 years and similar observations were found in other comparable studies.[27,28,29,16] Mean BMI in current study (27.13 ± 4.07) was also comparable.[15,16] Most of cases (82.69%) had history of previous surgery. Caesarean section was the most common operation in the patients with history of previous surgery. Major indication in the present study was fibroid (56.73%), which was consistent with results were found in recent comparable studies. [15,16,25,27,28,29]

Patient safety has always been a primary issue during LH. Several randomized trials have shown the advantages of operative laparoscopy as compared with laparotomy. Liu and Reich in 1994 assessed 518 patients undergoing LH and found that the risk of LH was no greater than either AH or VH in appropriately trained hands.[30] Recent studies on the relative complication rates associated with LH are less consistent. According to studies reporting modest numbers of LH conducted in single centres, LH is at least as safe as traditional AH.[31,32,33,34] The VALUE study and a comparable survey in Finland, on the other hand, revealed slightly greater complication rates with LH.[35,36] A more recent randomised study comparing LH with AH and VH in women (the eVALuate study) found that, while LH was associated with less postoperative pain, faster recovery, and better short-term quality of life than AH and VH, it required more operating time than either AH or VH and had a higher

rate of major complications than AH.[37] The incidence of major haemorrhage and urinary tract injuries were considerably greater in the LH arm of the trial than in the AH arm (4.6 percent and 3.0 percent, respectively).[37] The findings of this study, however, were challenged as some of the participating surgeons were relatively inexperienced in performing LH, and the surgical methods were not standardised.[38,39]

The complication rate in our study is comparable with rates reported in the literature[16,27,28] and in fact, lesser than some recent comparable studies.[25,29] In the present study, we encountered only one (0.96%) major intra-operative complication, which is lesser compared to other recent studies.[15,16,25,27,28,29] Prevalence of bladder injury (0.96 %) is comparable to results published in recent literature[15,29] and slightly less compared to some studies[16,25]. We had no instances of ureteric or bowel injury or any cases with major haemorrhage (requiring transfusion). However, because major complications are rare, most of the studies, including ours, were underpowered to draw clinically significant conclusions. The prevalence of minor complications was 10.58% in our study comparable to study done by Moni S.S. et al. [29], but higher compared to other studies [15,16,25,27,28]

Prolonged operating and anaesthesia times have always been considered to be an important drawback of LH.[31,32,37] The operating time in our series was lesser compared to times reported in the recent literature.[15,16,25,27,28,29] Although most studies have reported that LH takes longer to perform, it has been associated with shorter hospital stay and shorter recovery time than AH.[31,32,37] Patients who undergo LH also experience significantly less pain and require less analgesia than patients require after AH.[31,32,37] Our results are similar to those reported to date, showing that TLH can be performed safely with shorter hospitalization.

No cases were converted to laparotomy or needed reoperation during the study period. A study in France, in which 29 of 416 (7%) of TLH cases were converted to laparotomy, determined that increased body mass index, uterine width more than 10 cm, and adhesions from previous abdominal and pelvic surgery were predictive factors for laparotomy.[7] Although our data do not show an association between a history of pelvic surgery, Caesarean section, or increased body weight and a higher risk of conversion to laparotomy or any other complications, significant conclusions cannot be made because of the relatively small number of participants.

Minimally invasive surgery has known advantages over open surgery as observed in this study and in various earlier studies.

Table 29. Comparison with literature: baseline characteristics

Characteristics	Ashfaq et.al.	Isono et.al.	Mereu et.al.	Moni S.S. et.al.	Yadav N et.al.	Ingole S. et.al.	Present study
Sample size	50	323	361	118	50	270	104
Study period	16 months	60 months	54 months	60 months	12 months	60 months	21 months
Study design	Prospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Prospective
Number of surgeons	Single surgeon	Multiple surgeons	Multiple surgeons	Single surgeon	Multiple surgeons	Multiple surgeons	Single surgeon
Mean age	46.4±5.01	47.5±6.1	49.6±6.5	45.08	41.3±3	45±7.8	46.28 ± 7.38
Mean BMI	--	22.9±3.7	25.8±5.6	--	24.1±2	28.4±5.8	27.13 ± 4.07
Major indication	Fibroid (54%)	Fibroid (86%)	Fibroid (78.6%)	Fibroid (52.5%)	Fibroid	Fibroid (38.1%)	Fibroid (56.73%)
Mean operative time(min.)	124.26 ± 44.7	206.8 ± 57.2	113 ± 36	162.18	105.4 ± 22.9	146 ± 25.5	78.7 ± 20.97
Mean hospital stay(days)	2.18 ± 0.39	6.4 ± 2.2	2.6 ± 1.1	--	2.47 ± 0.5	3.12 ± 1.34	3.61 ± 2.24
Estimated blood loss(ml)	--	132.4 ± 196.8	44 ± 79	100-150 (47%), <100ml (43%)	--	106 ± 4.34	110.72±64.69

Table 30. Comparison with literature: prevalence of complications

Complications	Ashfaq et.al.	Isono et.al.	Mereu et.al.	Moni S.S. et.al.	Yadav N et.al.	Ingole S. et.al.	Present study
Overall complication	5(10%)	35(10.8%)	13(3.54%)	17(14%)	9(18%)	27(10%)	12 (11.54%)
Major complication	1(2%)	20 (6%)	7 (1.9%)	3 (2.5%)	5 (10%)	9 (3.3%)	1 (0.96%)
Bladder injury	0	0	1 (0.3%)	1 (0.84%)	1 (2 %)	4 (1.48%)	1 (0.96%)
Ureteric injury	1 (2%)	1 (0.3%)	3 (0.8%)	0	1 (2%)	1 (0.3%)	0
Bowel injury	0	1 (0.3%)	0	1 (0.84%)	1 (2%)	1 (0.3%)	0
Haemorrhage requiring transfusion	0	18 (5.5%)	3 (0.8%)	1 (0.84%)	2 (4%)	2 (0.7%)	0
Conversion to laparotomy	0	0	0	2 (1.69%)	1 (2%)	7 (2.59%)	0
Minor complication	4 (8%)	15 (4.6%)	6 (1.6%)	14 (11.8%)	3 (6%)	18 (6.6%)	11 (10.58%)

STRENGTHS OF THE STUDY

- Majority of the previous studies done in this field look into indications, complications and outcomes of hysterectomies done by multiple surgeons. Factors like technique, learning curve, and expertise with the technique will alter results of the study. But in this study, as surgeries performed by a single senior surgeon were included, confounding bias due to the above-mentioned factors was avoided.
- Most of the previous studies were of retrospective nature, where some medical records were incomplete and there might possibly be recall bias in the study. No such difficulties were encountered in the present study, as it is a cross-sectional study, and data was obtained by personal communication with the surgeon, assistants and anaesthetists who were present during that particular case and from the videos recorded.

LIMITATIONS OF THE STUDY

- Including the surgeries done by a single surgeon into the study is not only a strength, but also a limitation of the study, as the findings of the study can't be generalised due to difference in the technique, learning curve and experience among different surgeons.
- The sample size was less as the number of elective surgeries performed during COVID 19 pandemic were reduced.

CONCLUSION

In the present study, the prevalence of major intraoperative complications was found as 0.96% and that of minor complications was found as 10.58%. The different types of complications associated with this approach for hysterectomy in our study are bladder injury, vaginal wall lacerations, bradycardia, post operative urinary retention, urinary tract infection, fever and per vaginal spotting. In our study, except for specimen weight, no other risk factors had a statistically significant association with the complications. The most common indication was leiomyoma, followed by adenomyosis.

For the majority of benign pelvic diseases, laparoscopic hysterectomy is a safe and effective surgery. For a surgeon with good learning curve, it is a safe, reproducible technique with low complication rates. The benefits are less blood loss, smaller incisions with less pain, less wound infections, shorter hospital stay, faster recovery. It provides patients with benefits such as reduced peri-operative morbidity and an earlier return to activities. Thus, from this study it is evident that laparoscopic hysterectomy is a safe approach for benign pelvic conditions, and hence, offering the patients an alternative associated with low morbidity and rapid recovery.

SUMMARY

Laparoscopic gynaecologic surgery is frequently performed and provides a number of advantages. This is a hospital based descriptive cross-sectional study that was conducted for a period of 1 year 9 months from January 2020 to September 2021, at the teaching hospital attached to KAHER's J.N Medical College, Belagavi, Karnataka. A standardised approach of executing TLH by a single surgeon was evaluated in this study.

The aims of the study were to find out the prevalence of complications and the type of complications associated with laparoscopic hysterectomy, and the risk factors associated with these. The study also looked into the indications for laparoscopic hysterectomy, which are of benign nature.

Demographic information, pre-operative findings, surgical indication, intra-operative and post-operative complications, estimated blood loss, operation time, and hospital stay were all documented and analysed.

A total of 104 participants were included in the study. Mean age of the patients was 46.28 ± 7.38 years. The most common indication for surgery was fibroid uterus which accounted for 56.73 percent of all cases, followed by adenomyosis (25.96%). Mean operating time was 78.7 ± 20.97 min. and average blood loss is 110.72 ± 64.69ml. The overall prevalence of complications was 11.54%. 0.96% cases had major complications while 10.58% cases had minor complications. Conversion to laparotomy was not needed in any of the patients. Iatrogenic complications were bladder injury (n=1), which was managed laparoscopically and vaginal tears (n=5). Mean duration of post operative hospital stay was 1.6 ± 1.52 days.

Advances and innovation in equipment, energy sources and surgical training have made TLH an efficient surgery. With expertise, TLH can be performed safely

and with minimal complications. The advantages are less blood loss, smaller incisions with less pain, less wound infection, shorter inpatient stay, and rapid recovery. We observed that TLH is a safe and acceptable alternative to the open abdominal hysterectomy.

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ANNEXURE I : ETHICAL CLEARANCE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/ 213 **Date: 24/12/2019**

To,

REG. NO. BJ0119018
PG student in Obstetrics and Gynaecology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"LAPAROSCOPIC HYSTERECTOMY FOR BENIGN CONDITIONS- A HOSPITAL BASED CROSS SECTIONAL STUDY",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE II: WAIVER OF CONSENT

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to-be-University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
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Ref: MDC/DOME/ 301. **Date: 24/12/2019**

To.
REG. NO. BJ0119018
PG student in Obstetrics and Gynaecology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"LAPAROSCOPIC HYSTERECTOMY FOR BENIGN CONDITIONS- A HOSPITAL BASED CROSS SECTIONAL STUDY",** does not involve any ethical issues, as the data required for the study will be collected from the medical records and the study does not involve any interaction with cases and no identifiable information will be collected. The waiver of consent has been approved for the proposed research project and has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE III : SCREENING FORM

Screening number: | | | |

Date of screening (dd-mm-yyyy) _____
First name: _____
Middle name: _____
Last name: _____
Husband's name: _____

Age (years): | | |

IP number: | | | | | | | |

Address: H.no-_____
Street-_____
Taluka-_____
District-_____

Phone number | | | | | | | | | | |

Phone number | | | | | | | | | | |

Indication for laparoscopic hysterectomy: | |

1) Benign

2) Malignancy

If the answer to the above question is 1, the woman is enrolled into the study.

ANNEXURE IV: DATA COLLECTION INSTRUMENT

"Laparoscopic Hysterectomy For Benign Conditions-A Hospital Based Cross Sectional Study".

- Enrolment Number ☐☐☐
- Age ☐☐

- Last menstrual period: ☐☐-☐☐-☐☐
- cycles:☐

  1)regular 2)irregular

  Duration ☐☐ days
- Dysmenorrhoea(1=yes,2=no) ☐
- Passage of clots(1=yes,2=no) ☐
- Bleeding for how many days ☐
- No. of pads per day ☐
- Menopause status:

  Attained (1=yes 2=no) ☐

  If attained, age at menopause ☐☐
- Obstetric score: Para ☐ Living ☐ Abortion ☐ Death ☐
- Mode of delivery

1=Normal vaginal delivery

2=caesarean section

If delivered by caesarean section, then indication

P1 ☐----------

P2 ☐----------

P3 ☐----------

P4 ☐----------

P5 ☐----------

P6 ☐ ----------

1=yes, 2=no

- known case of diabetes mellitus ☐

  if yes,on any medication

  if yes, specify----------

- known case of hypertension ☐

  ifyes, on any medication

  if yes ,specify----------

- known case of thyroid disease ☐

  ifyes, on any medication

  if yes, specify----------

- known case of pulmonary disease ☐

  if yes, on any medication

  if yes, specify----------

- known case of pre existing cardiac disease ☐

  if yes, on any medication

  if yes, specify----------

- known case of abdominal tuberculosis ☐

  if yes, ATT started at ----------

  stopped at ----------

- known case of any bleeding disorder ☐

  if yes, specify----------

- history of any anticoagulants ☐

  If yes,specify the dose----------

  started from ----------

  stopped from----------

- history of allergy to any medications ☐

  if yes specify----------

- Any history of previous surgery and anaesthesia exposure ☐

  if yes,specify:

  surgery:----------

  type of anaesthesia:----------

- Blood pressure □□□/□□□mm of hg
- Pulse rate □□□bpm
- Height □□□cms
- Weight □□.□kg
- BMI □□.□kg/m^2
- Abdominal girth □□□cms

(1=yes,2=no)

- Pallor □
- Icterus □
- Edema □
- Breast □

(1=normal, 2=abnormal)

if abnormal, specify----------

- Thyroid □

(1=normal, 2=abnormal)

if abnormal, specify----------

- Spine □

(1=normal, 2=abnormal)

if abnormal, specify----------

- size of the uterus: □□-□□ weeks

5)Investigations:

- Blood group ----------
- Haemoglobin : pre op □□ . □g/dl
  post op □□ . □g/dl
- PCV □□. □
- total count □□□□□/mm^3
- platelet □.□ □lakhs/mm^3

- peripheral smear ☐

1)normocytic normochromic blood picture

2) normocytic hypochromic blood picture

3)microcytic hypochromic blood picture

4)dimorphic anaemia

5)neutrophilicleucocytosis

- Liver function tests

  Total bilirubin ☐.☐☐mg/dl

  Direct bilirubin ☐.☐☐mg/dl

  Total proteins ☐.☐☐gm/dl

  Serum albumin ☐.☐☐gm/dl

  A:G ratio ☐.☐

  SGOT ☐☐☐ U/L

  SGPT ☐☐☐ U/L

  ALP ☐☐☐ U/L

- Renal function test

  Serumcreatinine ☐.☐mg/dl

  serum urea ☐☐mg/dl

- serum electrolytes

  sodium ☐☐☐mEq/L

  potassium ☐.☐☐mEq/L

  chloride ☐☐☐mEq/L

  bicarbonate ☐☐☐mEq/L

- TSH ☐.☐☐mcIU/ml

(1=reactive,2=non reactive)

- HIV ☐
- HbsAg ☐
- CA-125 ☐☐. ☐

- Urine routine and microscopy☐

  (1=normal,2= abnormal)

  If abnormal,specify----------
- 2D ECHO ☐

  If abnormal, specify----------
- Ultrasound abdomen and pelvis

- Histopathology report:

6)Indication for surgery: ☐☐

1)Fibroid uterus

2)Adenomyosis

3)Chronic pelvic pain

4)Endometriosis

5)Endometrial hyperplasia

6)Cervical intra-epithelial neoplasia

7)Abnormal uterine bleeding

8)Ovarian borderline lesion

9) Post-menopausal bleeding

10)Others : if any, specify ----------

7)Duration of surgery: ☐☐☐minutes

8) Estimated blood loss during surgery: ☐☐☐☐ml

9)Duration of hospital stay: ☐☐ days

10)Complications:

1=yes, 2=no

Intra operative complications:

- Intestinal injury: ☐
- bladder injury: ☐
- ureter injury: ☐
- vascular injury: ☐

if yes

1)abdominal wall related: ☐

or 2)major vascular:

if its major vascular, then its due to ☐

1)aorta 2)vena cava3)common iliac

- hernia at trocar site: ☐
- electrosurgical injury: ☐
- haemorrhage : ☐
- conversion to laparotomy ☐
- others ☐

if yes, specify----------

Pneumoperitoneum related complications:

(1=yes, 2=no)

- hypercarbia ☐
- subcutaneous emphysema ☐
- pneumomediastinum ☐
- pneumothorax ☐
- preperitoneal emphysema ☐
- gas embolism ☐

Complications related to anaesthesia and patient position:

(1=yes, 2=no)

- nerve injury ☐

  if yes then its due to ☐

  1)brachial plexus,2)common peroneal nerve, 3)saphenous nerve

- cardiac arrhythmias ☐
- Hypotension ☐
- Raised intra cranial pressure ☐
- Deep venous thrombosis ☐
- Others ☐

  If yes, specify----------

Post-operative complications:

(1=yes, 2=no)	before discharge	f/u at 1 week	f/u at 1 month
• Port site infection	☐	☐	☐
• Port site hernia	☐	☐	☐
• Pelvic abscess	☐	☐	☐
• vaginal cuff dehiscence	☐	☐	☐
• vaginal bleeding	☐	☐	☐
• fever	☐		
• urinary tract infection	☐		
• urinary retention	☐	☐	☐
• vaginal cuff infection /abscess	☐	☐	☐
• vaginal cuff haematoma	☐	☐	☐
• subcutaneous haematoma	☐	☐	☐
• any blood or blood product transfusion	☐		
• genitourinary fistula	☐	☐	☐
• rectovaginal fistula	☐	☐	☐
• Others	☐		

if yes specify----------

LAPAROSCOPIC HYSTERECTOMY OPERATIVE RECORD

First name----middle name----last name----
I.P No.---- private/ unit----

Pre Operative Diagnosis----
Post Operative Diagnosis----
Indication for LH----

Name of the surgeon/surgeons:
Assistants:

Name of the anaesthesiologist:

Type of anaesthesia: ☐
1)general
2)general + spinal

Difficulty encountered during anaesthesia (1= yes ,2= no) : ☐
If yes, specify----

Name of the staff nurse:

Start time : ---------- End time:----------

Prophylactic antibiotic with dosage and time:

Procedure:

- Trocar entry: ☐

  1)easy
  2)difficult

- CO_2 insufflation: ☐

  1)Direct trocar entry
  2)veress needle

- Is there any complications during port entry, (1= yes ,2= no) : ☐

  If yes, specify----

- Entry technique ☐☐

  1.open entry,
  2.direct port entry,
  3.verees needle technique
  3a)Palmer's point

3b)umbilicus

- Number of ports ☐

PORT SITE	PORT SIZE	DIAGRAM
1).----------	----------	
2).----------	----------	
3).----------	----------	
4).----------	----------	
5).----------	----------	

- Insufflation pressure:☐☐-☐☐ mm of Hg
- Flow rate of CO_2 ☐☐-☐☐ L/min
- Abdominal wall adhesions(1= yes; 2=no) :☐

  If yes,adhesionolysis☐
  1.done, 2.not done
- Diagnostic laparoscopy-any findings , specify----------

- Ovaries :☐

  1)preserved
  2)removed

- Method of specimen retrieval ☐

  1.Through colpotomy incision with minimal manipulation
  2.Vaginal morcellation(mechanical)
  3.Abdominal morcellation (electromechanical)
  4.In fibroid, specimen myomectomy

- Closure of the vaginal vault:

  -method of closure ☐

  1.Per vaginal
  2. Laparoscopic intracorporeal

  -suture material used ☐

  1)Vicryl 1-0
  2)Barbed suture
  3)Quill
  4)V-loc

- Specimen weight : ☐☐☐☐ gm
- Any additional procedure: ----------

Post-operative care:

- General condition: ☐

  1.good 2.fair 3.poor

- Pain Grade(according to visual analog score) ☐

  1)Grade 0 2)Grade1 3)Grade2 4)Grade3 5)Grade4 6)Grade5

  - Analgesics used ----------

- Any blood or blood products transfusion(1= yes,2=no) : ☐

  If yes, specify----------

- Ambulation started on : POD ☐☐
- Started orally on : POD ☐☐
- Passed stool on :POD ☐☐