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Editorial

The world has been in the pandemic mode for a year and a half. Coronavirus disease-2019 (COVID-19) continues to spread at a slow burn and intermittent lockdowns done in past are now near normal. Till now estimated 275 million people have been infected worldwide, and 2.25 million are dead. The pandemic's course in 2021 will depend greatly on the arrival of a vaccine, and on how long the immune system stays protective after vaccination or recovery from infection. There is so much we still do not know about this virus, but we may hope that after a world-sweeping outbreak, the virus could burn itself out and disappear by 2021.

This virus is going to stay with us for quite some time and we will have to learn to live in harmony with it. As a minimal access surgeon, we must continue our services to the needy in this pandemic. Anesthetists and laparoscopic surgeons are at risk in the operation theater. Although we did not find any scientific evidence to support it and we hope that more data come to light in near future. If clear data come, we can have streamlined decision-making to reduce the risk to the surgeon. Despite the reduction in the number of elective laparoscopic surgeries conducted, many emergency and semi-emergency laparoscopic surgeries will need to be done. Although still there is no documented evidence, laparoscopic procedures have a theoretical risk of generating aerosols during the creation of pneumoperitoneum, and while using energy devices due to the generation of fume.

In this challenging time, minimal access surgical societies felt the need to take immediate action to define ways to protect surgeons who are caring for suspected or confirmed COVID-19 patients. The World Association of Laparoscopic Surgeons (WALS), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), and The European Association for Endoscopic Surgeons (EAES), in their joint recommendations, have advised that RT-PCR test should be done in every patient before surgery. Most of the operation theaters have positive pressure ventilation which prevents nonsterile air to enter in OR but there is the risk of the spread of aerosols faster. Therefore, negative pressure ventilation is required to prevent this from happening.

Port incisions should be optimum to just allow the port to pass and there should not be any unnecessary gap for pneumoperitoneum leak. The pre-set pressure of the CO_2 insufflator should be kept at 12 mm Hg. We recommend that a smoke evacuation system should be used in laparoscopic surgery and we should be minimum use of energy devices and cold hemostasis should be used whenever possible. We should also use appropriate filters for suction devices as they can be a potential source of virus dissemination. These strategies increase the cost of the surgery but could improve safety. Between two cases, a minimum of 1 hour gap should be there to disinfect the OR, and 1% hypochlorite solution should be used for cleaning OT tables and anesthesia instruments.

We advise that all of you, after finishing surgery, should remove scrub clothes and consider having a shower before changing into home clothes to prevent infection to your loved one. We should wash hands frequently and maintain safe social distancing. This pandemic has given a major challenge to surgeons who practice minimally invasive surgery, but we hope that some solution will come soon, and we will operate normally in the coming year 2021.

At last, I wish all of you a happy, healthy, and prosperous new year 2021.

RK Mishra
Editor-in-Chief
Chairman
World Laparoscopy Hospital
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ORIGINAL ARTICLE

Mortality and Morbidity in Peptic Ulcer Perforation: A Comparison between Radical Open Repair vs Conservative Laparoscopic Repair

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Abstract

Introduction: Currently, in the era of robotic surgery and advancement of laparoscopic technology, the place of open surgery has been reduced. However, the use of laparoscopic surgery for peptic ulcer disease is not yet a consensus.

Materials and methods: All patients who had been operated for perforated peptic ulcer (PPU) disease from January 2005 to December 2014 in our hospital were reviewed retrospectively. Patient demographics, perioperative and intraoperative details, and surgical outcomes were evaluated. The objective of our study is to compare the clinical and surgical outcomes of patients who underwent either laparoscopic or open procedure as well as to demonstrate if laparoscopic repair (LR) technique has advantages to open repair (OR) in terms of morbidity and mortality.

Results: We diagnosed 159 patients with PPU during the study period. LR was performed for 65 (41%) patients, and the remaining patients underwent OR. Morbidity of medical and surgical complication was higher in open groups (21 vs 2) (p value = 0.0001). The most frequent complication in both groups was medical complication. Overall, 16 patients in the OR group had medical complications vs 2 patients in the LR group (p value = 0.009). Surgical complication was higher in open groups (7 vs 0) (p value = 0.04). Mortality was statistically higher in the open group. We did not report any death in the laparoscopic group. However, six deaths were identified in the OR group (p value = 0.04).

Conclusion: Our results indicate that LR for PPU was a safety option with fewer rates of morbidity, reoperation, and mortality compared to OR.

Keywords: Laparoscopic repair, Morbidity, Perforated peptic ulcer.

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Introduction

Peptic ulcer is a current disease. Complications such as acute hemorrhage or perforation have been well documented.[1,2]

Despite the progress of medical treatment [proton pump inhibitor (PPI) and eradication therapy for *Helicobacter pylori*], the incidence of perforated peptic ulcer (PPU) did not decreas.[3,4]

Currently, in the era of robotic surgery and advancement of laparoscopic technology, the place of open surgery has been reduced.[5]

However, laparoscopic surgery for peptic ulcer disease was not yet recommended by consensus.[6]

It is for this reason that the practice is often confused, which procedure to choose to cure a patient?

In the literature, superiority of laparoscopic repair (LR) technique in PPU compared to open repair (OR) surgery was controversial.[7]

The objective of our study is to compare the clinical and surgical outcomes of patients who underwent either LR or OR.

Materials and Methods

We retrospectively reviewed all patients who underwent surgical repair for PPU in our surgical unit from January 2005 to December 2014.

The puncture site was juxtapyloric for all patients.

The data analyzed included age, sex, American Society of Anesthesiologists (ASA) classification, operative details, details of postoperative complications, operative time, the analgesic requirement, length of postoperative, hospital stay, and return to normal daily activities. Patients with a history of previous upper abdominal surgery, evidence of concomitant ulcer bleeding, gastric outlet obstruction, or large and suspicious ulcers were excluded.

The goal of the study was to compare the results of PPU LR with OR.

The primary end points were morbidity specific complications (intra-abdominal, abscess; anastomosis leakage; secondary peritonitis; surgical-site infection) and nonspecific complications (urinary tract infection, pulmonary and cardiovascular complications) and mortality.

The second end point was operation time, the average duration of nasogastric tube, the average of drainage stays, the average of nasogastric tube, longer time of Foley, total analgesic dose, time to return to normal diet, and overall duration of hospitalization.

The decision regarding the method of repair (laparoscopic or open) was dependent on laparoscopic surgical skills of surgeons and anesthesiologist recommendation.

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All ORs were performed using an upper midline incision.

After identification of the site of the perforation, pyloroplasty with radical vagotomy was done. Thorough peritoneal toilet was done. Finally, the drain was left.

In LR, the patient was placed in supine position and legs spread with reverse Trendelenburg tilt. The operating surgeon stood between the patient's thighs. The open method was used for insertion of the initial 10 mm umbilical port. A 30° laparoscope was then introduced. Three additional working ports were inserted at the level of the trans-pyloric plane at the midclavicular line on both sides and the third ports in mid-epigastrium.

First, we started by peritoneal cavity exploration and searched meticulously the perforation of pyloroduodenal region.

Second, we sutured the ulcer perforation using dissolving suture (2.0) with intracorporeal stitch and finally laparoscopic lavage was done.

All statistical analyses were performed using the statistical package SPSS version 15.0 for Windows.

Categorical variables were described using frequency distributions, and continuous variables with descriptive statistics were calculated and reported as mean ± SD (if distribution was normal) or median with range (if distribution was skewed). For statistical analysis, Student *t* test was used to compare means of numerical variables. Pearson chi-square test was used for nominal variables, and Fisher's exact test was used in instances with low expected frequencies. A p value < 0.05 was accepted as statistically significant.

Results

From January 2005 to December 2014, a total of 159 patients were diagnosed with PPU during the study period.

There were 143 (90%) males and 16 (10%) female patients. The mean patient age was 41 years (range, 19–88 years).

Fifty-nine (59%) patients were found to have free gas under the diaphragm on an erect chest X-ray.

Thirteen (7.6%) of the patients had a known history of PPU.

Twenty-eight (16.4%) patients had a history of non-steroidal anti-inflammatory drugs (NSAIDs) intake.

LR was performed for 65 (41%) patients, and the remaining patients underwent open repair (Flowchart 1).

Among the 94 (59%) patients who underwent direct open surgery, 9 of them had unstable hemodynamic at presentation.

There were no conversions in the laparoscopic groups.

The demographics and characteristics of the patient's populations in the LR and OR group are summarized in (Table 1).

There were no significant differences in baseline characteristics between the groups in terms of gender, American Society of Anesthesiologists (ASA) physical status score, comorbidities, temperature, and white cell count (WCC) on presentation. Patients with shock at presentation were included only in the OR group.

Operative details for LR and OR groups are presented in (Table 2).

The mean operative time for LR was (151 minutes), significantly shorter than OR (216 minutes) (p value = 0.0001).

The average of nasogastric tube duration was shorter in LR group (mean, 3 days vs 4 days) (p value = 0.0001) as well as the average of drainage stay (mean, 2 days vs 3 days) (p value = 0.007), and Foley catheter had been maintained for longer time in the OR group (3 vs 2 days) (p value = 0.001).

Analgesic postoperative time was longer for the OR group (5 days) than for the LR group (4 days) (p value = 0.001). Postoperative pain was well controlled using oral paracetamol alone in all the patients with LR, whereas two patients in the OR group required oral tramadol for pain control and one required intramuscular opioids. In addition, patients who had LR were able to return to normal diet and full mobilization significantly earlier if they had undergone LR. All these factors enabled these patients to be discharged significantly earlier from the hospital.

Morbidity of medical and surgical complication was higher in open groups (21 vs 2) (p value = 0.0001) (Table 3).

The most common complication in both groups was medical complication. Overall, 16 patients in the OR group had medical complications such as respiratory, cardiovascular, and postoperative sepsis vs 2 patients in the laparoscopic group (p value = 0.009).

More cases of pneumonia occurred in OR group compared to LR group (3 vs 1 case), respectively, but this was not statistically significant (p value = 0.64).

Table 1: Comparison of patient demographics and admission characteristics between laparoscopic and open repair groups

	Open	*Laparoscopic*	*p*
Mean age (*y*)	45	36	0.001
Sex			0.1
Male	82	61	
Female	12	4	
ASA	69	58	0.6
I	24	7	
II	1	0	
III	1	0	
IV			
Temperature (°C)	38	38.5	0.9
WCC ($\times 10^9$)	16.438	16.620	0.8

ASA, American Society of Anesthesiologists Physical Status Classification 2014; WCC, white cell count

Table 2: Preoperative data of the laparoscopic and open patient cohorts

	Open	*Laparoscopic*	*p*
Operative time (min)	216	151	0.0001
NG tube utilization (days)	4	3	0.0001
Abdominal drain usage (days)	2	3	0.007
Urinary catheter usage (days)	3	2	0.001
Time to resume normal diet (days)	2	1	0.001
Time to oral analgesia (days)	5	4	0.001
Time to full mobilization (days)	3	1	0.0001
Hospital stay (days)	4	1.5	0.0001

Flowchart 1: Flow diagram showing inclusion and exclusion of studies

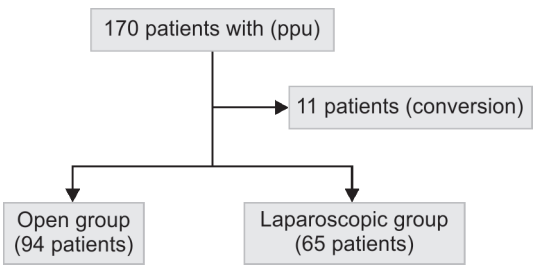

Table 3: Surgical outcomes of laparoscopic and open repair group

	Open	*Laparoscopic*	*p*
Leaks	3	0	0.2
Wound infection	2	0	0.5
Intra-abdominal abscess	2	0	0.5
Pneumonia	3	1	0.64
Cardiovascular	4	0	
UTI	2	0	0.51
Sepsis	7	0	
Overall morbidity	21	2	0.0001
Medical complication	16	2	0.009
Surgical complication	7	0	0.04
Mortality	6	0	0.04

UTI, urinary tract infection

Specific complication (surgical complication) was higher in OR group (7 cases vs 0) (p value = 0.04). There were two patients in our series who had intra-abdominal abscess postoperatively only in the OR group and no case from the LR group. Intravenous antibiotics and percutaneous drainage with a good clinical outcome managed intra-abdominal abscess.

Two patients had a surgical site infection in the OR group and none from the laparoscopic group. Revision surgery for suture site leakage occurred in three patients in the OR groups vs none in the laparoscopic groups.

Mortality was statistically higher in the OR group. There was no death in the LR group, while 6 deaths were recorded in the OR group (p value = 0.04).

Correlation analysis was done between mortality and shock on presentation, and it was statistically significant (p value = 0.001) but had no correlation between mortality and laparotomy (p value = 0.06).

Discussion

In this present study, LR was associated with a shorter operative time (p value = 0.0001), reduced analgesic requirements (p value = 0.01), a shorter hospital stay (p value = 0.001), and earlier return to normal daily activities compared to open repair. Concerning morbidity, it was low in LR group compared to open groups (p value = 0.0001).

Effectively, laparoscopic procedure was associated with fewer medical complications (p value = 0.009) compared to open repair.

No postoperative surgical complications in the LR group, such as abscesses, wound infection, or revision surgery, occurred compared to the OR group (p value = 0.04).

Mortality was statistically higher in the OR group (6 vs 0) (p value = 0.04). In our practice, patients with shook does not receive LR. Correlation analysis was done between mortality and shock on presentation, and it was statistically significant (p value = 0.001) but had no significant correlation between mortality and laparotomy (p value = 0.06).

Therefore, this result was due of the selection bias of patients having shook at presentation.

Therefore, mortality was related to shock on presentation and not to surgical technique.

Several studies have shown results similar to our study. In fact, some authors report that laparoscopic approach has several benefits such as confirmation of the diagnosis and[8–12] shorter operative time, reduced postoperative pain and analgesic requirements, a shorter hospital stay, and an earlier return to normal daily activities.

The recent study of Siow et al.,[5] including 131 patients who underwent emergency repair for PPU (LR, n = 63, 48.1% vs OR, n = 68, 51.9%) have demonstrated that LR group had fewer complications compared to the OR group (p value = 0.005). When considering specific complications, the incidence of surgical site infection was statistically significant (p value = 0.003). The LR group had a significantly shorter mean hospital stay (p value = 0.008) and reduced postoperative pain (p value < 0.05). However, mortality was similar in both the groups (p value < 0.99).

The meta-analysis study of Zhou et al.,[12] including nonrandomized controlled studies (NRS) and five randomized controlled trails (RCTs), demonstrated a lower mortality rate in the LR group in NRS. However, in the analysis of five RCTs, the mortality was the same in both groups.

In the randomized controlled study reported by Siu et al.,[8] 130 patients with a clinical diagnosis of PPU were randomly assigned to undergo either open or laparoscopic omental patch repair and showed that the complication rate for LR was low.

However, some authors showed that LR compared to open abdominal surgery for peptic ulcer disease was not superior and may even have worse outcomes, including longer operative time. In addition, open abdominal surgery provides efficient and easy training without the constraints and difficulties for young surgeons.[9,13]

On the other hand, some study found that LR and OR was equal. Indeed, in the meta-analysis of RCTs published by Tan et al.,[13] LR had similar operative time as OR for PPU (WMD: 9.15, 95% CI: −1.83 to 20.12, p value > 0.05) and the same postoperative hospital stays, yet LR had shorter nasogastric tube duration than OR for PPU, similar time to resume diet as OR, and the mortality was similar in both the groups (p value > 0.05).

Cochrane report,[7] concerning three randomized clinical trials, found no statistically significant differences between LR and OR in the abdominal septic complications (OR 0.66; 95% CI 0.30–1.47) and pulmonary complications (OR 0.43; 95% CI 0.17–1.12).

In a recent study published by Wang et al.,[14] including 119 patients operated for PPU, no significant differences were found in operation time, morbidity of postoperative complication, and mortality. The authors concluded that LR was preferable for treating PPU than OR; nevertheless, some preventive action must be taken to avoid the risk of postoperative leak in perforation site.

Our results indicate that LR for PPU was feasible and safe option with fewer rates of morbidity, reoperation, and mortality compared to OR. It can be considered as a treatment of choice. Nevertheless, certain limitations apply to the current study. First, the study was retrospective by nature. A selection bias of patients having shook at presentation was included only in the open groups. Therefore, this could explain the high rates of mortality in OR compared to LR groups.

In conclusion, our series ensures that the LR became a gold standard in PPU. Therefore, we need more randomized prospective trial.

Ethics Approval and Consent to Participate

This work had been made with all due respect to the code of ethics under the supervision of the medical and ethics committee of the Salah Azaiez Institute.

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ORIGINAL ARTICLE

The Outcome of Laparoscopic Ovarian Drilling in Patients with Clomiphene-resistant Polycystic Ovarian Syndrome in Ogbmoso, Nigeria: A Prospective Evaluation

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Abstract

Background: Polycystic ovary syndrome (PCOS) is commonly encountered in women with anovulatory infertility. The surgical ovarian drilling procedure aims to restore spontaneous ovulatory cycles. This function is similar to the goal of clomiphene citrate and/or metformin.

Objective: We conducted this study to determine the outcome of laparoscopic ovarian drilling (LOD) among patients who presented with clomiphene-resistant PCOS.

Materials and methods: The study was prospective in design. We studied 43 patients with clomiphene-resistant PCOS who had laparoscopic ovarian drilling (LOD) using monopolar diathermy at the Bowen University Teaching Hospital, Ogbomoso. The study took place between January 2014 and June 2016. Clinical data recorded at different intervals of follow-up included the menstrual pattern and reproductive history.

Results: We successfully performed laparoscopic ovarian drilling without any complication. Four (9.3%) of the patients were lost to follow-up. Thirty (76.9%) of the remaining 39 patients resumed regular menstrual cycles with spontaneous ovulation, while 23 (59.1%) patients achieved spontaneous pregnancy within 6 and 18 months following LOD. No record of multiple pregnancies. Factors associated with failed LOD treatment included obesity and a long duration of infertility.

Conclusion: LOD is a feasible and effective first-line treatment option in patients with clomiphene-resistant PCOS in sub-Saharan Africa. Emphasis should be on weight reduction with early application of LOD to treat patients with clomiphene-resistant PCOS. This will reduce the time to achieve pregnancy and the need for gonadotropins to induce ovulation.

Keywords: Clomiphene-resistant polycystic ovary syndrome, Laparoscopic ovarian drilling, Treatment outcome.

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Introduction

The most common endocrinopathy in women within the reproductive-age group is polycystic ovary syndrome (PCOS). It affects about 6–8% of this age-group.[1–4] PCOS forms a spectrum of disorders from a heterogeneous collection of signs and symptoms. Its presentation may be mild in some, while reports show severe disturbance of reproductive, endocrine, and metabolic functions in others.[5] The prevalence of PCOS varies among races and ethnicities with a range between 5 and 10%[3]

Previous data reported the highest prevalence rate of 52% among the South Asian immigrants in Britain, of whom 49.1% had menstrual irregularity.[2] About 10% of the diagnosis of PCOS is made during gynecologic visits.[2] Approximately 30–75% are obese, while 50% of patients have hirsutism[3]

In Nigeria, Ugwu et al.[1] and Omokanye et al.[4] reported prevalence rates of 18.1% and 31%, respectively. In their series, the majority of the patients presented with infertility and oligomenorrhea.[2] PCOS is responsible for about 75% of anovulatory infertility.[6]

PCOS predisposes women to diabetes mellitus, endometrial carcinoma, and cardiovascular disease.[7–9]

The exact pathophysiology in PCOS is unknown. However, a genetic component is likely, since the condition tends to run in families. Also, the pattern of inheritance is X-linked dominance.[10] Furthermore, studies have shown the occurrence of PCOS in approximately 50% of first-degree relatives.[11] We can make a presumptive diagnosis of PCOS based on the history and examination findings. According to an international consensus, the syndrome can be diagnosed using the "Rotterdam criteria (presence of at least two of the following conditions): Oligomenorrhea or amenorrhea, hyperandrogenism, and polycystic ovaries on ultrasound. Researchers defined the

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morphology of polycystic ovaries as an ovary with 12 or more follicles measuring 2–9 mm in diameter and increased ovarian volume (>10 cm^3) on transvaginal ultrasound (TVS)".[12]

The goals of the "symptom-oriented" PCOS management are to restore normal menstruation, ovulatory cycles, and fertility and prevent endometrial hyperplasia/cancer. It also involves the treatment of acne and infertility. Clinicians achieved ovulation induction in women with PCOS using various means in the past.[7] The first-choice treatment presently in PCOS women is administration of clomiphene citrate (CC).[7,8] We termed those who fail to ovulate with a maximum dose of clomiphene citrate (i.e., a daily dose of 150mg) "Clomiphene Citrate Resistant (CCR)".[13] Clomiphene citrate is successful in 80% of cases. The remaining 20% of patients who did not ovulate this drug are declared CCR.[14]

The use of gonadotropins and metformin and ovarian drilling are the treatment modalities for those with CCR.[13]

Gjonnaess first described LOD in 1984.[15] The introduction of this procedure reawakened interest in the surgical management of patients with CCR. This procedure involves the use of cautery or laser vaporization to create multiple perforations in the ovary. Previous data reported an increase in spontaneous ovulation and conception rates following LOD, along with improved responsiveness to subsequent medical therapy.[15–17] Clinicians can do LOD as an outpatient procedure with less trauma and fewer postoperative adhesions. Conversely, although useful, gonadotropins expose the patients to a series of complications, such as multiple pregnancy and hyperstimulation. Furthermore, gonadotropins are expensive, and they require repeated doses and intensive monitoring.[13]

This study aimed at evaluating patients' characteristics as well as the results of LOD in patients with CCR polycystic ovarian syndrome in our center.

Materials and Methods

Study Setting

The study is prospective in design. We studied patients who had LOD at the gynecological endoscopy unit of the Obstetrics and Gynaecology Department, Bowen University Teaching Hospital, Ogbomoso, between January 01, 2014, and June 30, 2016. The center started gynecological endoscopy procedures in 2007 though mainly diagnostic. Operative procedures began in 2013.

Inclusion and Exclusion Criteria

We recruited patients with PCOS diagnosis based on the Rotterdam criteria[12] who have had up to a daily dose of 150 mg clomiphene citrate without evidence of ovulation. We excluded those with absolute contraindication for laparoscopy. We also excluded patients with tubal pathology, severe endometriosis, severe male factor, and those who refuse LOD as a treatment modality.

Methods

We obtained sociodemographic data and other important information from the patient at the presentation. Information on the patient's level of education and the husband's occupation was also collected to group them into different social classes (i.e., socioeconomic classes 1 to 5).[18] We further regroup the patients as upper, middle, and lower classes. We group classes 1 and 2 as upper social class, class 3 as a middle social class, while classes 4 and 5 were grouped as a lower social class to aid data analysis.

Investigation results, including transvaginal ultrasound (TVS) results, hormonal profile results (before and after LOD), body mass index (BMI), and the number of perforations per ovary during the procedure, were recorded in a proforma. Patients were followed up on a clinic basis and on the phone to get information on the resumption of menses, ovulation, and pregnancy. We confirmed ovulation with the ovulation test kit (Predict ®), day 12 to 14 follicular TVS study, and pregnancy after the procedure. We carried out data analysis with Statistical Package for Social Sciences (SPSS) version 20. A p value of <0.05 was considered statistically significant.

Definition of Term

- Failed LOD; failure to resume regular menses with ovulation within 6–8 weeks following LOD.
- Clomiphene citrate-resistant PCOS; PCOS patients who failed to ovulate with 150 mg/day dose of clomiphene citrate

Outcome Variables

Primary outcome variables include the resumption of menses with spontaneous ovulation and clinical pregnancy rates. We define clinical pregnancy as the presence of fetal cardiac activity on ultrasound. We define the clinical pregnancy rate as the percentage of patients with clinical pregnancy to the total number of participants at the end of the study. Other outcome measures included were live birth rate, miscarriage rate, multiple pregnancies, and OHSS rates.

Procedure

We obtained informed consent for LOD. After general anesthesia and skin preparation, we use the Veress needle to create pneumoperitoneum. With the assistant lifting the anterior abdominal wall, the surgeon inserted the needle through a stab incision in the umbilicus's inferior crease in the mid-line. We perform Veress needle insertion with the patient in the supine position. After this, the surgeon then places a 10-mm infra-umbilical (primary) port on the infraumbilical crease through a transverse incision. We also place two 5-mm lateral (secondary) ports in the right and left iliac fossae lateral to inferior epigastric vessels using the baseball diamond concept. The surgeon then inserts a 0-degree 10 mm telescope through the primary port and carries diagnostic laparoscopy with chromopertubation for tubal patency.

The surgeon then lifts the ovaries out of the ovarian fossa with an irrigation cannula inserted through the ipsilateral secondary ports. The cannula is wedged against the cervicouterine junction, giving a robust platform for drilling. We use a uterine manipulator to manipulate the uterus. The monopolar needle is then introduced from the contralateral secondary port and approaches the ovaries at right angles. We usually carry out 4–10 drills on each ovary based on the size of the ovary. We then carried out suction irrigation of the ovaries and peritoneal lavage using normal saline after the drill. The surgeon carries out irrigation to cool the ovaries and clear the pelvis of any blood clots and debris. After the procedure, the assistant removes the hand instruments and lets out pneumoperitoneum through the secondary ports. We remove these ports under the vision, followed by the laparoscope, and the 10-mm trocar. The surgeon then closes the port wounds with subcuticular suturing using Vicryl 2/0.

Treatment Protocol

Research assistants fill the forms as part of the postoperative instructions for a repeat hormonal profile, especially for those who resume menses before their follow-up visits. A repeat Day

2/3 FSH and LH, and Day 21 serum progesterone assay were done in patients with spontaneous menses post-LOD to assess for ovulation. Subsequent ovulation monitoring was done by either follicular tracking with TVS or the use of ovulation prediction kits from day 10 to 16 of the cycle. Patients who resumed spontaneous ovulation were observed for 6 months for conception to occur while on ovulation monitoring and timed intercourse (TI). After that, we subjected to either superovulation induction (SI) with timed intercourse (TI) or intrauterine insemination (IUI) on case-to-case basis. We offered patients who failed to conceive by these methods IVF. Patients who failed to ovulate following LOD will use other forms of second-line management of PCOS.

Ethical Consideration

We obtained ethical clearance for this study from the Bowen University Teaching Hospital's ethical review board, Ogbomoso. During data collection, we informed the individual patient about the purpose of the study, confidentiality, and the right not to participate or withdraw at any time without affecting their health or other services. We obtained written consent from each of the participants before the commencement of the study.

Results

We analyzed the patients' characteristics, hormonal profile, and the outcome of 43 eligible patients. Of the 430 patients who had infertility consultation at our facility, we diagnosed 80 (18.6%) as a PCOS case. Forty-three (53.8%) patients with clomiphene citrate-resistant PCOS underwent LOD. We followed the patients up for an average duration of 11.2 ± 6.3 months (range 9–36 months), during which we lost four (9.3%) patients to follow-up. The patients aged 21–43 years with a mean age of 29.5 ± 4.8 years. Thirty (69.8%) had primary infertility, 39 (90.7%) were nulligravida, while 28 (65%) belonged to low social class. The duration of infertility ranged from 1 to 18 years (6.5 ± 3.7). We recorded irregular cycles in 40 (93%) patients, while 28 (65.1%) had altered LH–FSH ratio (>2.0). The Body Mass Index (BMI) ranged from 24.3 to 39.7 kg/m^2 (26.3 ± 8.5). The number of drills per ovary ranged from 4 to 10 (6.5 ± 2.7).

Thirty (76.9%) of the remaining 39 patients with irregular cycles resumed regular menses with spontaneous ovulation with a mean duration of 5.2 ± 2.6 days and 3.4 ± 2.3 weeks, respectively. Most of those who resumed regular menses (66.7%) did so within 4 to 6 days post-LOD. Twenty-three (59%) patients had spontaneous conception (mean time of conception post drilling was 4.8 ± 1.6 months). Four patients (10.3%) of 39 had an early first-trimester miscarriage and 19 (48.7%) successful delivery. There was no record of complication of laparoscopy, multiple pregnancies, or ovarian hyperstimulation syndrome (OHSS).

There was a significant association between failed LOD and maternal age above 35years ($\chi^2 = 10.063$, p value = 0.004), ≥5 years of infertility ($\chi^2 = 4.587$, p value = 0.036), and moderate to morbid obesity($\chi^2 = 6.453$, p value = 0.012).

According to the logistic regression, women who were aged 35 years and above were twice more likely to have failed LOD than their younger age-group (OR = 2, CI = 1.5–45, p value = 0.003). Women with altered LH/FSH (i.e., ratio > 2.0) were twice less likely to have failed LOD compared to those without altered LH/FSH (OR = 0.5, CI = 0.1–0.8, p value = 0.004). Other predictors of failed LOD were infertility duration of 5 years and above (OR = 3, CI = 2.2–6.7, p value = 0.005), obesity (OR = 4, CI = 2–6, p value = 0.002) (Tables 1 to 4).

Table 1: Baseline characteristics of patients

Variables	*Frequency (n = 43)*	*Percentage*
Age (years)		
21–25	18	41.9
26–30	8	18.6
31–35	6	14.0
>35	11	25.5
Range 21–43	Mean = 29.5 ± 4.8	
Type of infertility		
Primary	30	69.8
Secondary	13	30.2
Infertility duration (years)		
1–5	22	51.2
6–10	14	32.6
>10	7	16.2
Range 1–18	Mean = 6.0 ± 3.7	
Social class		
Upper	7	16.2
Middle	8	18.6
Low	28	65.2
Irregular cycles		
Yes	40	93
No	3	7
Altered LH/FSH ratio (≥2.0)		
Yes	28	65.2
No	15	34.8
	Mean = 3.9 (±1.8)	
BMI (kg/M^2)		
<25	2	4.7
25–29	18	41.9
≥30	23	53.4
Range 24.3–39	Mean = 30.3 (3 ± 6.5)	

Table 2: Outcome variables studied in the patients

Outcome variables	*Frequency*	*Percentage*
Resumption of spontaneous regular menses/ovulation		
Yes	30	76.9
No	9	23.1
Total	39	100.0
Clinical pregnancy		
Yes	23	59.0
No	16	41.0
Total	39	100.0
Conception after drilling (in months) $n = 23$		
1–3	4	10.3
4–6	12	52.2
≥7	7	37.5
Mean time of conception post-drilling 4.8 ± 1.6 months		
Pregnancy outcome		
Miscarriage	4	10.3
Live birth	19	48.7
Total	23	59.0

Table 3: Association between baseline characteristics of the patient and failed LOD

	Failed LOD				
Variable	*Yes, n (%)*	*No, n (%)*	*Total*	X^2	*p value*
Age (years)					
≤35	3 (10.3)	26 (89.7)	29 (100)	10.063	$p = 0.004$*
>35	6 (60)	4 (40)	10 (100)		
Types of infertility					
Primary	6 (22.2)	21 (77.8)	27 (100)	0.035	$p = 0.576$*
Secondary	3 (25)	9 (75)	12 (100)		
Duration of infertility					
≤5 years	2 (9.5)	19 (90.5)	21 (100)	4.587	$p = 0.036$*
>5 years	7 (38.9)	11 (61.1)	18 (100)		
Altered LH/FSH ratio (≥2.0)					
Yes	3 (11.5)	23 (88.5)	26 (100)	5.700	$p = 0.024$*
No	6 (46.2)	7 (53.8)	13 (100)		
BMI (Kg/M^2)					
<30	1 (5.3)	18 (94.7)	19 (100)	6.453	$p = 0.012$*
≥30	8 (40)	12 (60)	20 (100)		

*p values are Fisher's exact test

Table 4: logistic Regression showing predictors of failed LOD among the patients

	Failed LOD		
	N = 9 (%)		
Variables	*OR*	*95% CI*	*p*
Age (years)			
(Ref = ≤35)			
>35	2	1.5–4.5	0.003
Duration of infertility			
(Ref = ≤5 years)			
>5 years	3	2.2–6.7	0.005
Type of infertility			
(Ref = primary)			
Secondary	2	0.5–3.5	0.35
Altered LH/FSH (>2.0)			
(Ref = yes)			
No	0.5	0.1–0.8	0.004
BMI (kg/M^2)			
(Ref = <30)			
≥30	4	2–6	0.002

Discussion

In this study, the prevalence rate of PCOS was 18.6%. This finding is similar to the prevalence rate of 18.1% reported in Enugu by Ugwu et al.[1] but lower than the 32% and 31% reported by Pembe et al. in Tanzania in 2009[19] and Omokanye et al.[4] in Ilorin, North-Central Nigeria respectively. A lower prevalence rate of 12.2% was reported by Ogueh et al.,[20] respectively. The variation in prevalence rates may be due to differences in the prevalence rates of PCOS's genetic and environmental determinants in the various populations or discrepancies in the study populations.

The majority of the women in this study were within the age-group 21–35 years, with a mean age of 29.5 years. This result is similar to the findings in Enugu, Nigeria, with a mean age of 30 years[1] although slightly higher than the mean age of 27 years recorded in Nnewi, Nigeria.[20] However, this is not surprising as the PCOS is a complex endocrine disorder affecting women in their reproductive years.[1,20]

A common feature of PCOS is menstrual cycle disturbance. A previous study reported that about 87% of participants in an earlier study had oligomenorrhea. Approximately 26% of those with secondary amenorrhea who presented in a gynecological clinic in that study have polycystic ovaries on ultrasound.[21] In our study, we recorded irregular cycles in 93% of the patients. Elevated serum LH concentrations, seen in 40–60% of the PCOS patients led to a reduced chance of conception and increased miscarriage risk.[22] Lean patients with PCOS have elevated LH levels. While a high LH–FSH ratio is pathognomonic of the disease, it is not required to diagnose PCOS. Reports have also suggested that PCO patients may secrete LH isoforms with high biological activity. Research has observed that patients with high baseline LH levels have a better prognosis.[22] Our study shows an increase in the LH–FSH ratio in 65.2% of patients with an average LH–FSH ratio of 2.1 (±1.8). This finding compares favorably to the discovery of Mandeep et al.,[14] where 62% of the respondents had LH–FSH ratio >2.

For this study, we chose the number of punctures empirically based on the size of the ovary. Between 4 and 10 diathermy punctures (each 3 mm in diameter, 2–4 mm depth) per ovary was applied using a power setting of 40 W for 4 seconds delivering between 640 J and 960 J of energy per ovary. "About 640 J is the lowest effective dose recommended".[23] However, the clinical response depends on the dose with higher ovulation and pregnancy rates observed by increasing thermal energy quantities up to 600 J/ovary, irrespective of ovarian volume.[24] Conversely, adjusting thermal dose based on ovarian volume (60 J/cm^3) has better reproductive outcomes with similar postoperative adhesion rates than a fixed dose of 600 J/ovary.[25]

We performed bilateral ovarian drilling for the patients in this study. Despite lack of convincing evidence and a significant reduction in operative time, most gynecologists still perform bilateral rather than unilateral drilling.[26–28]

We used a monopolar diathermy needle (Tritome) in this study for LOD. Researchers proposed different modifications of the classic needle electrode techniques. These modifications include using the bipolar needle, laparoscopic ovarian multi-needle intervention, LOD using a monopolar hook electrode, LOD using the harmonic scalpel, and office micro laparoscopic ovarian drilling.[29–32] Researchers also developed various transvaginal methods such as transvaginal hydrolaparoscopy (fertiloscopy) and transvaginal sonography–guided ovarian interstitial laser treatment.[33–35] However, more extensive prospective studies are needed to validate use, safety, efficacy, and long-term effects of alternate techniques.

The exact mechanism of LOD is unknown. The destruction of androgen-producing stroma was the proposed beneficial effect. There is a reduction in the circulating and intra-ovarian levels. Previous data showed that LOD also has a modulating effect on the pituitary–ovarian axis.[23] The resumption of regular cycles and ovulation is due to the rapid endocrine changes that may last for months to years.[24] The assessment of tubal patency and diagnosis of other pelvic pathologies, done simultaneously, is an additional advantage of LOD. Previous evidence showed that the sensitivity of the ovaries to ovulation induction agents increases after the procedure. Other benefits of LOD include more orderly growth of follicles, reduced chances in cycle cancellation, and decreased risk of OHSS.

An environment with low androgen, AMH, LH levels, and relatively fewer follicles are more favorable for proper follicular growth.

The majority (76.9%) of the patients resumed menses with spontaneous ovulation. This finding is similar to 84.2% and 77.7% reported in Japan[25] and Poland,[27] respectively, but lower than finding from Ilorin[4] South-Western Nigeria. The higher ovulation rate in the study done in Ilorin may be because the patients were started on clomiphene citrate on the resumption of menses following LOD.

The clinical pregnancy rate of 59% falls within the range of 43–84% reported by some studies[14,15,24,25] although slightly higher than Ilorin's rate. The difference may be due to the effects of other infertility factors not excluded in the Ilorin study.

Previous reports have shown that PCOS patients have higher miscarriage rates as compared to the general population. Elevated LH is the main culprit. Other significant contributors to the increased miscarriage rates in PCOS patients include hyperinsulinemia and obesity.[28] LOD reduces LH levels as well as the risk of miscarriage. Previous data reported a miscarriage rate of 14% after LOD than the 30 to 40% expected rate in PCOS patients.[24] The miscarriage rate in this study was 10.3%. This result is comparable to 14% reported by Ikechebelu et al.[13] The live birth rate in this study was 48.7%. This discovery is similar to the finding of Mandeep et al.

There was no record of multiple pregnancies or OHSS in the study participants, which further established the safety of LOD over gonadotropins.

Predictors of failed LOD in this study were aged above 35 years, duration of infertility above 5 years, and moderate to morbid obesity. These are similar to the findings of other studies.[13,14]

To our knowledge, this study is one of the very few studies that assessed prognostic factors for an ovarian response following laparoscopic electrocautery using a logistic regression model with prospective data collection in West Africa. Other studies done so far are either cross-sectional or retrospective, while few other prospective studies did not look out for failed LOD predictors. LOD had a higher successful pregnancy outcome in patients with normal BMI and BMI of <30 kg/m^2 than those with a BMI of >30 kg/m^2. This finding is similar to that observed in a cross-sectional done by Omokanye et al.;[26] hence, alternative treatment methods may need to be used for this group of patients, such as weight reduction, metformin treatment, gonadotropin therapy, or IVF to achieve conception.

The infertility duration of 5 years and below had the most substantial impact as a predictor of success. This result is in agreement with the previous study.[26] A possible explanation for the role of infertility duration may be the emergence of other subfertility factors as the duration of infertility increases.[26]

One of LOD's main shortcomings is iatrogenic adhesions due to bleeding from the ovarian surface or premature contact between the ovary and the bowel after cauterization. Adhesion rates ranged from 0 to 100%,[12,33,34,36,37] involving higher risks with laser.[36,37] This higher figure is probably due to less thermal penetration (2–4 mm) by the cone-shaped laser drilling lesions compared to cylinder-shaped lesions (8 mm) of monopolar electrocoagulation. Most studies reported mild-to-moderate adhesions, which do not seem to affect pregnancy rates after LOD. Adhesion prevention strategies such as liberal peritoneal lavage, adhesion barriers like intercede,[38] and adhesiolysis performance at early second-look laparoscopy[39] are not effective in preventing *de novo* adhesions or in improving pregnancy rates.[38] We raised the ovaries before applying energy in this study and saline washed after the procedure to decrease the temperature, reducing the risk of injury.

Another potential risk is premature ovarian failure, significantly if the ovarian blood supply is damaged inadvertently or if the surgeon makes a large number of punctures, leading to excessive destruction of ovarian follicular pool or production of anti-ovarian antibodies.[36] When applied correctly, as done in this study, the coagulation puncture does not appear to compromise the ovarian reserve. A prospective comparative study found that the extent of ovarian tissue damage was limited, ranging from 0.4% after four to 1% after eight coagulation punctures, each of 40 W for 5 seconds.[37] We can interpret changes in ovarian reserve markers as normalization of ovarian function rather than reducing ovarian reserve. Surgeons should not do coagulation within 8–10 mm of the ovarian hilum.[40] The use of unilateral drilling,[28,41] use of the harmonic scalpel,[32,42] and use of bipolar energy[15,43] are associated with a less risk of adhesions and Decreased Ovarian Reserve (DOR)[44] but with equivalent reproductive outcomes with bilateral drilling using monopolar diathermy.

Readers should interpret the findings from this study in light of some limitations. First, the small sample size makes it difficult for the results to be generalized. Also, the limited laboratory resources at the study center made it difficult to assay some hormones that could have added to this study's quality.

Nevertheless, our findings have significant implications for Nigeria's reproductive interventions since anovulatory infertility is a significant public health issue in our area and globally.

Conclusion

Laparoscopic ovarian drilling is a feasible, safe, and effective first-line treatment option in patients with clomiphene-resistant PCOS in sub-Saharan Africa. Emphasis should be on weight reduction with early recourse to LOD in managing patients with clomiphene-resistant PCOS. Early recourse will reduce the time to achieve pregnancy and the need for ovulation induction using gonadotropins.

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ORIGINAL ARTICLE

Laparoscopic Entry Using Direct First Trocar Insertion without a Prior Pneumoperitoneum: A Prospective Cohort Study

Jawad K Shunayeh AL-Dhahiry

Abstract

Purpose: This study aimed to assess safety, feasibility, complications, and time of direct first trocar insertion (DFTI) with carbon dioxide (CO_2) insufflation and operating time in laparoscopic surgery.

Materials and methods: This study was a prospective cohort study (clinical original) performed at AL-Karama Teaching Hospital/College of Medicine, Wasit University, Iraq, from April 2011 to December 2017. The study enrolled 687 patients prepared for different laparoscopic procedures using direct first trocar insertion techniques for laparoscopic entry. Conversion of laparoscopic entry to Veress needle (VN) or open technique was performed when direct first trocar insertion technique failed. Recorded data were age, sex, indications for laparoscopic surgery, time of direct first trocar insertion with CO_2-insufflation,operating time, and direct first trocar insertion-related complications.

Results: Direct first trocar insertion technique was successful in 684 (99.57%) patients and failed in 3 patients when trocar entry was converted to Veress needle technique. These three patients were excluded from the statistical analysis of the study data. Demographic distribution of the patients was as follows: 90 (13.2%) males and 594 (86.8%) females. This study had no major complications, while minor complication rate was 1.31%. Mean ± standard deviation (SD) of direct first trocar insertion with CO_2-insufflation time for males, females, and total patients was 2.32 ± 0.57 minute (m), 1.89 ± 0.53 m, and 1.95 ± 0.56 m, respectively. *p* value was 0.03 and was statistically significant. This study had no mortality.

Conclusion and clinical significance: Direct first trocar insertion is a safe and cost-effective laparoscopic entry technique. It has a high feasibility rate, low complication rate, fast laparoscopic entry, and fast creation of pneumoperitoneum.

Keywords: Direct first trocar insertion, Gallstones, Laparoscopy, Pneumoperitoneum.

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Introduction

Insertion of the primary trocar and successful creation of a pneumoperitoneum are essential steps in laparoscopic surgery, as more than 50% of complications during laparoscopic surgery occur at the time of Veress needle (VN) or the first trocar entry, independent of the complexity of surgery.[1–3]

Bateman et al.[4] reviewed data on 2,324 laparoscopic procedures that were performed by the same surgical team and reported that more complications occurred during VN and trocar insertion than during the operative procedures that were performed. Therefore, optimizing the entry technique is essential. Techniques that are currently used for laparoscopic entry are VN, open laparoscopy (Hasson's technique), optical trocar, threaded or radially expanding devices, and direct first trocar insertion (DFTI) without a prior pneumoperitoneum.[5] The existence of many laparoscopic entry techniques indicates that none has completely been established as standard or complication-free[6] or they are equally highly effective.

Laparoscopic entry and creation of a pneumoperitoneum with a VN may be associated with complications such as extraperitoneal insufflation, which increase the difficulty and time of the procedure.[7] A meta-analysis performed by Jiang et al.[7] reported that the VN technique was associated with a significantly increased risk of minor complications. Additionally, the possibility of multiple insertion attempts and entry failure were significantly higher in the VN technique than in other techniques.[8] Despite being considered safe by some laparoscopic surgeons, the VN technique may cause serious vascular and visceral abdominal injuries, usually in obese patients and those with intra-abdominal adhesions.[9]

Hasson's open laparoscopic technique reduces vascular injuries but does not reduce bowel injuries.[10] This may reflect a selection bias because Hasson's technique may be used in high-risk patients for visceral and vascular injuries.[10] The DFTI technique was reported to be associated with low complication rates and is preferred by some laparoscopic surgeons.[11]

The DFTI technique without a prior pneumoperitoneum for laparoscopic entry was first reported by Dingfelder in 1978.[12] The reported benefits of this technique are its short laparoscopic entry, short insufflations and operative times, ability to immediately recognize vascular and visceral injuries, minimal entry failure, and low carbon dioxide (CO_2) embolism.[1,13]

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Jansen et al.[6] found that 57% of complications occurred during the insertion of the first trocar, and 43% of these complications were related to surgical experience. Failure to create and maintain a pneumoperitoneum may influence these complications.

Günenç et al.[11] reported that VN and DFTI are blind techniques and can result in severe visceral and vascular injuries. To avoid such injuries, laparoscopic surgeons and gynecologists seek safe and effective laparoscopic access techniques. DFTI without a prior pneumoperitoneum was reported to be a safe alternative to the VN technique.[14]

Direct first trocar insertion is not contraindicated in thin or obese patients in non-emergency situations.[15] Although it is a blind technique, DFTI decreases the number of blind steps from three steps with VN (insertion, insufflation, and trocar insertion) to one. The most important advantage of the DFTI technique is that it can be used to prevent complications associated with the use of a VN, such as failure of the pneumoperitoneum, extraperitoneal insufflation, bowel insufflation, and CO_2 embolism.[16] The experience of the surgeon determines whether laparoscopic access can successfully be achieved, not CO_2 pneumoperitoneum or trocars.[17] A controllable, easy-to-follow technique and the surgeon's experience are more reliable factors than any design of the surgical instrument.

The DFTI technique is faster than other techniques for laparoscopic entry;[18] however, it is the least-used technique in laparoscopic surgery today.[19] The insufflation-related complications of DFTI technique are low and should be evaluated further.[20]

This study reported the 6.5-year experience of one consultant laparoscopic surgeon who routinely uses the DFTI technique without a prior pneumoperitoneum for laparoscopic entry. In particular, the safety, feasibility, complications, DFTI with CO_2 insufflation time, and operative time during laparoscopic surgery were assessed.

Materials and Methods

Ethical Considerations

This study was approved by the ethics committee of the Medical College of Wasit University, Iraq, in March 2011. All enrolled patients were informed of the procedure and its potential complications and provided written informed consent prior to inclusion in the study.

Study Design, Setting, and Participants

This prospective cohort study enrolled 687 patients who underwent different laparoscopic procedures using the DFTI technique. Patients with an umbilical hernia, pregnant women, those with previous laparotomy incisions other than a gridiron incision for appendectomy, and those with a Pfannenstiel incision for obstetric and gynecologic pathologies were excluded. Three patients underwent conversion to the VN technique due to failure of the DFTI technique and were excluded from the analysis.

This study was performed at the Al-Karama Teaching Hospital, College of Medicine, Wasit University, Iraq, from April 2011 to December 2017. Routine investigations, including abdominal ultrasonography, chest radiography, electrocardiography, complete blood count, blood type, fasting blood sugar level, blood urea, Hepatitis B, and Hepatitis C, were performed. Antithrombotic measures such as subcutaneous heparin (the prophylactic dose was administered according to the patient's body mass index) and elastic stockings were used in obese and high-risk patients. All 687 operations were laparoscopically performed by one consultant laparoscopic surgeon using DFTI without a prior pnuemoperitoneum. Data on age, sex, indications for laparoscopic surgery, DFTI-related complications, complications that were unrelated to DFTI, DFTI-CO_2 insufflation time, and operative time were recorded.

Direct First Trocar Insertion Technique

Each patient was placed in the supine position. After anesthesia was induced, he or she was then prepared and draped. A transverse 1-centimeter infraumbilical incision was made using a scalpel gauge 11 (Demotek manufactured by Demophorius Healthcare Ltd, Cambridge,United Kingdom). In obese patients prepared for laparoscopic cholecystectomy (LC), the incision was made 3–4 cm above the umbilicus. The operating surgeon and his well-trained assistant elevated the anterior abdominal wall by pulling it up with their left hands. While elevating the anterior abdominal wall away from the underlying viscera, the surgeon held a 10-mm trocar, with his right index finger positioned 3 cm away from the trocar tip to guard against sudden uncontrolled entry of the trocar into the abdomen. The trocar was inserted at a 45° angle in non-obese patients and at a 90° angle in obese patients. Then, the trocar was advanced in a controlled fashion into the peritoneal cavity with a twisting, semicircular motion. In contrast to the insertion of a VN, during which the surgeon can feel penetration through the fascia and peritoneum separately, during DFTI, a distinct single "pop" signified that the trocar had pierced the fascia and peritoneum. Then, a laparoscope was introduced, proper intraperitoneal placement was ascertained, and a pneumoperitoneum was created with high-flow insufflation. Then, the patient was tilted into the reverse Trendelenburg's position. Intraperitoneal placement of the first trocar was determined by observing the initial gas flow pressure rates. The intraperitoneal structures were carefully inspected for any injury or incidental pathology. Other trocars were inserted under direct vision.[2,7,9,15]

Statistical Analysis

This study's data were statistically analyzed using IBM SPSS Statistics V22.0 (IBM Corp., Armonk, N.Y., USA.). A p value < 0.05 was considered statistically significant.

Results

A total of 684 patients (age range: 16–77 years; mean: mean $\pm$ standard deviation: 39.21 $\pm$ 12.04 years; 95% confidence interval: 38.31–40.12 years) had successful DFTI entry. A total of 594 (86.8%) women and 90 (13.2%) men underwent different laparoscopic procedures. There were no major complications or deaths (Table 1). The pathologic distribution of the laparoscopic procedure is presented in Table 2.

DFTI-related complications occurred in nine (1.31%) patients, including seven (1.02%) patients with extraperitoneal CO_2 insufflation. These patients were all women, possibly due to the fact that Camper's fascia is thicker in women than in men. Two patients (0.3%; one man, one woman) had bleeding at the infraumbilical port site. The bleeding stopped spontaneously in both patients.

Regarding complications unrelated to DFTI, one woman developed a hernia; 10 patients (1.46%) (three men and seven women) developed intraoperative bleeding at Calot's triangle unrelated to DFTI, which spontaneously stopped; and 14 patients (2.04%) (2 men and 12 women) developed port-site infections that were conservatively treated (Table 3).

Table 1: Patient demographics

			Age at statistical analysis/Year				
				95% confidence interval			
Sex	*No.*	*%*	*Mean ± SD*	*Lower boundary*	*Upper boundary*	*Range*	*p value*
Male	90	13.2	46.01 ± 12.62	43.37	48.65	20–77	0.00
Female	594	86.8	38.18 ± 11.62	37.25	39.12	16.75	
Total	684	100.0	39.21 ± 12.04	38.31	40.12	16.77	

SD, standard deviation

Table 2: Pathologic distribution of the study patients

	Sex			
Pathology	*Male*	*Female*	*Total*	*%*
Chronic calculous cholecystitis	43	509	552	80.7
Acute calculous cholecystitis	14	25	39	5.7
Chronic acalculous cholecystitis	4	7	11	1.6
Empyema of the gallbladder	10	15	25	3.64
Mucocele l of the gallbladder	12	18	30	4.40
Acute appendicitis	4	7	11	1.6
Ovarian pathology	0	4	4	0.6
Abdominal trauma	3	4	7	1.03
Others*	0	5	5	0.73
Total	90	594	684	100

*Two women, migrating intrauterine device; three patients, acute mesenteric lymphadenopathy

Table 3: Perioperative complications during the study period

		Sex				
Complications		*Male*	*Female*	*Total*	*%*	*p value*
DFTI-related complications	Extraperitoneal insufflation	0	7	7	1.02	0.179
	Port-site bleeding	1	1	2	0.3	
	Vascular injury	0	0	0	0	
	Visceral injury	0	0	0	0	
Total		1	8	9	1.31	
DFTI non-related complications	Hernia	0	1	1	0.15	0.442
	DFTI-unrelated intraoperative bleeding	3	7	10	1.46	
	Port-site infection	2	12	14	2.04	
Total		5	20	25	3.65	

Table 4: Direct first trocar insertion (DFTI)-CO_2 insufflations time and intraperitoneal operative time

				95% confidence interval for mean				
Time (minute)		*No*	*Mean ± SD*	*Lower boundary*	*Upper boundary*	*Minimum*	*Maximum*	*p value*
DFTI-CO_2 insufflations time	Male	90	2.32 ± 0.57	2.20	2.40	1.00	4.00	0.03
	Female	594	1.89 ± 0.53	1.85	1.93	1.00	5.00	
	Total	684	1.95 ± 0.56	1.90	1.99	1.00	5.00	
Operative time	Male	90	35.92 ± 9.73	33.88	37.96	18.00	70.00	0.03
	Female	594	30.82 ± 7.60	30.21	31.43	18.00	70.00	
	Total	684	31.49 ± 8.09	30.88	32.10	18.00	70.00	

The mean ± standard deviation of the DFTI-CO_2 insufflation times were 2.32 ± 0.57 m, 1.89 ± 0.53 m, and 1.95 ± 0.56 m for men, women, and all patients, respectively. The 95% confidence intervals were 2.20–2.40, 1.85–1.93, and 1.90–1.99 for men, women, and all patients, respectively. The mean ± standard deviation operative time was 35.92 ± 9.73 m, 30.82 ± 7.60 m, and 31.49 ± 8.09 m for men, women, and all patients, respectively. The 95% confidence intervals were 33.88–37.96, 30.21–31.43, and 30.88–32.10 for men, women, and all patients, respectively (all *p* value = 0.03; Table 4).

Discussion

The aim of this study was to evaluate the safety, feasibility, complications, and time of performing the DFTI technique. DFTI has a very high feasibility rate, low complication rates, and less need for instrumentation, and a pneumoperitoneum can be created quickly. The DFTI technique is a safe alternative to the insertion of a VN and other laparoscopic entry techniques. However, performing the DFTI technique requires good experience.

Insertion of the first trocar and creation of a pneumoperitoneum are the most critical steps in laparoscopic surgery. Subcutaneous emphysema, port-site bleeding, and vascular and visceral intraperitoneal injuries are serious complications that may occur during laparoscopic entry and creation of a pneumoperitoneum. Four basic techniques are used for laparoscopic entry and to establish a pneumoperitoneum: blind VN, DFTI, insertion of an optical trocar, and open laparoscopy.[2] The DFTI technique was first described by Dingfelder in 1978[13] and later reported by Copeland et al. in 1983.[21] The latter reported that adequate abdominal wall relaxation, a proper skin incision, and the use of a sharp trocar are essential for successfully performing DFTI; other authors advised elevating the rectus sheath for a successful outcome.[15] Innovations in shielded trocars have encouraged use of DFTI, but no experimental or clinical study has established the superiority of the shielded trocar to the non-shielded trocar.[1,21,22]

The rationale for using the DFTI technique before the creation of a pneumoperitoneum is based on the fact that many complications that occur during laparoscopic surgery are directly related to the insertion of a VN.[22,23] It was reported that the DFTI technique was a safe alternative to the VN technique.[20,24] Additionally, the DFTI technique was associated with minimal insufflation-related complications such as gas embolism and was faster than most other laparoscopic entry techniques.[20]

Theodoropoulou et al.[1] reported that the DFTI feasibility rate was 99.5%, which was compatible with the feasibility rate that was found in this study. In a randomized, prospective study that enrolled 84 patients, Prieto-Diaz-Chavez et al.[25] reported that the complication rates for DFTI and VN insertion were 2.3% and 23.8%, respectively. Yerdel et al.[24] enrolled 1,567 patients in their study and reported that the complication rates after DFTI and VN insertion were 0.9% and 14.4%, respectively. In a study that included 698 thin and very obese patients, Agresta et al.[26] found that DFTI was safe, with a slightly higher feasibility rate than the VN technique, and was related to minimal minor complication rates, but they reported that there were no differences in the rates of major complications. DFTI may be a safe technique in thin patients.[26,27] The DFTI technique did not lead to major complications in this study. There were minor rates of DFTI-related and DFTI non-related complications. The total minor complication rate was significantly lower than that of VN as reported in previous studies.[20,24,26]

Byron et al.[18] reported DFTI and VN insertion times of 2.2 m and 5.9 m, respectively. Zakherah et al.[28] reported DFTI and VN insertion times of 2.2 ± 0.7 m and 8.2 ± 1.4 m, respectively. Thus, in this study, the DFTI-CO_2 insufflation time was comparable with the DFTI time of these studies,[18,27] but a pure DFTI time without a CO_2 insufflations time was significantly shorter than that of the DFTI and VN insertion times.

Agresta et al.[26] study showed that DFTI was feasible in 100% of cases, and conversion to open laparoscopy was not necessary.

Although the open trocar technique with Hasson's cannula is considered a safe alternative, it is not complication free and is a time-consuming entry technique; thus, many laparoscopic surgeons use it very selectively.[16,26] Past studies[16,22,26] revealed that none of the available techniques create a pneumoperitoneum during laparoscopic entry and is free of complications. Each was associated with different advantages and limitations when performed by experienced surgeons for appropriate indications.[29] This study has some limitations that were:

- Unavailability of some laparoscopic instruments that can shorten the operative time such as multifire reusable clip applier and those instruments that can reduce the entry-related injuries such as the optical trocars.
- Poor quality of some laparoscopic instruments such as electrocautery hooks and graspers.

Conclusion and Clinical Significance

When performed by an experienced laparoscopic surgeon, DFTI is a safe, fast, and cost-effective technique for laparoscopic entry and pneumoperitoneum creation. Additionally, it has a very high feasibility rate, low complications, few instrumentation, and fast creation of pneumoperitoneum. Thus, DFTI technique is a safe alternative to VN insertion and other laparoscopic entry techniques. This study findings suggest that successful DFTI requires a good surgical experience. I recommend large-scale combined studies by the colleges of obstetricians and gynecologists and surgeons to assess laparoscopic entry, CO_2-insufflation and operative times, and complication rates of the different laparoscopic entry techniques.

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ORIGINAL ARTICLE

Barbed vs Polyglactin 910: A Comparative Study of the Efficacy in Laparoscopic Vaginal Cuff Closure

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Abstract

Context: Total laparoscopic hysterectomy (TLH) is a popular mode of hysterectomy in the recent times. One of the principal steps is vaginal cuff closure, with many variations in surgical technique and materials. Intracorporeal suturing and knot-tying are crucial steps and are considered to be the most technically difficult skills. To overcome these challenges and learning curve, various measures have been emerging. One among them is the introduction of barbed suture, a new class of suture material.

Aim: To evaluate whether the use of barbed suture for vaginal cuff closure during TLH reduced the surgical difficulty and suturing time when compared to polyglactin 910 suture.

Materials and methods: This randomized comparative study included 100 patients divided into two groups of 50 each, who underwent TLH with vault closure using either barbed sutures or polyglactin 910. Demographic details, indication for surgery, intraoperative complications, mean suturing time, surgeon difficulty, and average hospital stay were compared between the two groups.

Statistical analysis: Student *t* test for continuous variables and Fischer exact test for categorical variables. *p* values ≤ 0.05 were considered significant.

Results: Use of barbed suture has significantly reduced the suturing time for vaginal vault closure (5.39 vs 6.9 minutes, *p* value < 0.0001) as well as the technical difficulty in laparoscopic suturing (*p* value < 0.0001) when compared to that with polyglactin 910.

Conclusion: The introduction of barbed sutures for vault closure during TLH not just reduces the suturing time but is also technically less demanding, making it a potential asset in laparoscopic hysterectomies.

Keywords: Barbed suture, Polyglactin 910, Total laparoscopic hysterectomy, Vault closure.

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Introduction

Hysterectomy is the most frequently performed gynecological surgery in the world.[1] This procedure can be performed through abdominal, vaginal, or laparoscopic access. Besides, robotic-assisted laparoscopy and single-port hysterectomy have been developed in the recent years.

Harry Reich performed the first laparoscopic hysterectomy in 1988 in Pennsylvania.[2] Since then, laparoscopic hysterectomy has proven to be a safer choice than traditional surgery for benign gynecological conditions. The progress in the field of minimally invasive surgery has transformed laparoscopic hysterectomy into most popular mode of hysterectomy in the recent times due to its cosmetic superiority, shorter hospital stay, quicker resumption of day-to-day activities, and reduced morbidity.[3]

In total laparoscopic hysterectomy, there are significant variations in the vaginal cuff closure with respect to mode of suturing, suturing technique, and suture materials used. Vaginal vault closure is done by intracorporeal sutures or transvaginal sutures, by continuous or interrupted sutures, and in single or double layers using knotted or unknotted stitches.[4,5] Although widely used, conventional sutures may become loose or entangled, requiring constant traction by an assistant or the operating surgeon, all of which may cause instrument collision and tissue tearing leading to prolongation of suturing.[6] Laparoscopic intracorporeal closure has several advantages, such as longer postoperative vaginal length, minimizing granulation tissue as the vault margins are not everted into the vagina and provide an excellent vault support by incorporating the pericervical ring.[7] To prevent vaginal vault dehiscence, the knots performed laparoscopically should be as safe as the traditional approach.

However, intracorporeal suturing and knot tying are considered to be the most technically difficult skills. The fundamentals of a perfect knot-tying demands easiness, rapid execution, tight knot, easily reproducible steps, and, also very importantly, the type of suture material used. Performing this laparoscopically is most challenging and necessitates adequate skill and experience.

Therefore, it becomes essential to seek a more convenient technique and safer surgical material to overcome the learning curve required for intracorporeal suturing. One such has been the introduction of barbed sutures, which maintain the tensile strength evenly along the entire length of the wound and reapproximates tissue without the use of surgical knot. The favorable results obtained in several studies suggest that the suture material has the

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potential to become an asset in gynecological surgery. The purpose of this study is to compare the efficacy of barbed suture with that of Polyglactin 910 for vaginal cuff closure in patients undergoing total laparoscopic hysterectomy (TLH) at our hospital.

Materials and Methods

This comparative study includes 100 patients who underwent total laparoscopic hysterectomy during a period of 12 months. Considering 1-year statistics at our hospital for laparoscopic hysterectomies, i.e., 147 and compensating dropouts, 100 was taken as the sample size, with 50 in each group.

$$S = Z^2 pq / d^2$$
$$= 1.96 \times 1.96 \times 0.08 \times 0.92 / 0.05 \times 0.05$$
$$= 113$$

Following approval by the institutional ethics committee, patients diagnosed with benign gynecological conditions were included and those excluded were malignancies, infected masses, and immunocompromised status. The patients were selected by simple random sampling to avoid bias and were divided into two groups (50 each).

All patients were admitted 4 to 6 hours before surgery after detailed preoperative workup. TLH in both groups were performed by the same surgeon following standard surgical technique. After removal of the uterus, needles were introduced and the vaginal vault closed with continuous intracorporeal sutures using Barbed suture No.1/Polyglactin 910 No.1, where suture was taken starting from the right side through vaginal angle incorporating the right uterosacral, anteriorly through vaginal mucosa followed by posterior vaginal mucosa up till the left uterosacral and left vaginal angle. Then, the needles were removed through the peripheral trocars.

Intraoperatively, mean suturing time, defined as the time taken from beginning of the first stitch and cutting of the last stitch, was noted and compared between the two groups. The amount of blood loss was recorded intraoperatively. The difficulty perceived by the surgeon in operating was graded using a visual analog scale (VAS) ranging from 1 (low difficulty) to 10 (high difficulty). Incidence of intraoperative complications were noted. Postoperatively, the duration of hospital stay was noted. All patients were advised sexual abstinence and avoid heavy lifting of weights for 6 weeks after surgery.

Statistical analysis was carried out using Student *t* test for continuous variables and Fischer exact test for categorical variables. *p* values ≤ 0.05 were considered significant.

Results

A total of 100 women undergoing total laparoscopic hysterectomy were studied, among which 50 intracorporeal vaginal cuff closures were performed using polyglactin 910 sutures (group I), while another 50 women (group II) were sutured with barbed sutures. Comparison between demographic characteristics is listed in Table 1.

Mean age of women in group I was 45.74 years (SD = 4.96 years) and that in group II was 44 years (SD = 6.29 years) without significant differences in age. There was no significant difference in BMI between the two groups, although 6 patients belonged to the obese category with BMI in the range of 30 to 34.9kg/m^2. Most common medical comorbidity noted among the patients was diabetes mellitus ($n = 4$) followed by hypertension ($n = 3$). Among 27 patients with a history of previous abdominal surgery, 19 (70%) patients had undergone LSCS and 5 patients had a history of appendicectomy. No statistical significance was noted between the two groups in terms of medical comorbidity and previous abdominal surgery.

Table 2 depicts the indication of surgery in both groups. Uterine fibroid was the most common indication for surgery in both the groups followed by endometrial hyperplasia.

The average time taken for suturing vaginal vault was 6.9 minutes (SD = 1.27 minutes) while using polyglactin 910 suture, whereas in group II where barbed suture was used, the suturing time was 5.39 minutes (SD = 0.76 minutes) with a significant *p* value of <0.0001. Significant reduction in the difficulty of operation was noted while using barbed sutures for vault closure. The degree of surgical difficulty was lower in the group using barbed sutures (VAS of 3.5 vs 8; *p* value < 0.001) (Table 3).

There were three intraoperative complications reported of which two cases had bladder injury due to previous LSCS and one case had a rectal serosal injury due to dense endometriotic adhesions. These were not related to the suturing technique but were related to the surgical difficulty due to adhesions. All patients were discharged on the second postoperative day other than the patients with intraoperative complications who stayed longer for further management.

Discussion

Hysterectomies have been performed vaginally, abdominally, or with laparoscopic or robotic assistance. Laparoscopic hysterectomy has many proven benefits over the other traditional methods, such as shorter hospital stays, faster resumption of routine activities, lower intraoperative blood loss, and fewer wound infections.[3] However, longer operative duration and higher rates of complications, such as secondary hemorrhage, lower urinary tract injuries, and vaginal cuff dehiscence, have been reported more in laparoscopic than abdominal hysterectomy probably

Table 1: Demographic and clinical details of 100 patients

	Polyglactin 910 group (n = 50)	*Barbed group (n = 50)*	*p value*
Age (years), mean (SD)	45.74 (4.96)	44 (6.29)	0.12
BMI (kg/m^2), mean (SD)	26.77 (2.20)	26.45 (2.02)	0.44
Medical comorbidity	5 (10%)	7 (14%)	0.5
Previous abdominal surgery *n* (%)	17 (34%)	10 (20%)	0.1

Table 2: Indications for hysterectomy

	Polyglactin 910 group (n = 50)	*Barbed group (n = 50)*
Fibroid uterus	26 (52%)	20 (40%)
Endometrial hyperplasia	10 (20%)	6 (12%)
Adenomyosis	7 (14%)	6 (12%)
Endometrial polyp	2 (4%)	12 (24%)
Endometriosis	3 (6%)	4 (8%)
PID	0 (0%)	2 (4%)
Fibroid with endometriosis	1 (2%)	0 (0%)
Chronic cervicitis	1 (2%)	0 (0%)

Table 3: Mean suturing time

	Polyglactin 910 group (n = 50)	*Barbed suture group (n =50)*	*p value*
Suturing time (minute), mean (SD)	6.91 (1.27)	5.39 (0.76)	<0.0001
Degree of surgical difficulty (VAS)	8.16 (0.77)	3.18 (0.85)	<0.0001
Intraoperative complications	1 (2%)	2 (4%)	0.6
Duration of hospital stay (days)	2 (96%)	2 (98%)	NA

SD = Standard deviation

due to increased use of thermal energy by electrocoagulation.[8–11] These limitations are mostly due to longer learning curve required for laparoscopic procedures as well as for laparoscopic closure of vaginal vault.[9]

In laparoscopic surgeries, the surgeon enters the body cavity through a small incision and operates with a limited range of motion. The endpoints of the instruments move in the opposite direction to the movement of the surgeon's hands making the procedure laborious and difficult to learn. In addition to this, the proximity to vital anatomical structures and the limitation in gaining direct access to it in case of an emergent situation adds on to the complexity of laparoscopic procedures.[12] A recent survey done by Weizman et al.[13] suggested that the key factor limiting laparoscopic surgery includes laparoscopic suturing along with other technical and practical limitations. Laparoscopic intracorporeal suturing remains one of the most challenging and time-consuming tasks for surgeons, with the primary reason for this being the need to tie the knots in a confined space with limited visibility.

Suturing during vaginal cuff closure is considered a challenging step in laparoscopic hysterectomy, and the surgical difficulties can result in vault complications such as vaginal cuff dehiscence. Uccella et al. reported a higher incidence of vaginal cuff dehiscence (0.64%) for laparoscopic when compared to open transvaginal cuff closure (0.18%). Probable reason for this is that the magnified view during laparoscopic procedure causes the surgeon to involve less tissue and tension in closure.[14]

Although widely used, conventional sutures carry the drawbacks of requirement for tying knots for anchorage, need to maintain constant tension on the suture which requires traction by the operating surgeon or an assistant, leading to prolongation of suturing. Thus, it becomes essential to simplify intracorporeal laparoscopic suture, knotting skills and reduce the relative technical requirements. Numerous strategies were undertaken, one such has been the introduction of barbed sutures.

Barbed sutures are absorbable sutures with a surgical needle at one end and an annular coil component at the other end. This suture self-anchors at approximately every 1 mm of tissue, resulting in an evenly distributed tensile strength along the total length of the wound without the need for tying knots. The presence of tiny barbs spaced evenly in a helical array require less technical skill for performing swift suturing and less time than conventional suturing.[15]

The first use of barbed sutures in gynecologic surgery was reported in 2008 by Greenberg and Einarsson.[15] Since then it has been used in procedures such as laparoscopic myomectomy, hysterectomy as well as re-anastomosis of fallopian tubes and sacro-colpopexies.

In the present study, we observed a significant decrease in time required for vaginal vault closure with the use of barbed suture compared to polyglactin 910 suture. Kim et al.[16] compared V-Loc ($n = 64$) and Vicryl sutures ($n = 106$) for laparoscopic vaginal cuff closure and they reported a significant reduction in vaginal cuff closure time (7.2 minutes, SD: 1.2 minutes for V-Loc and 12.2 minutes, SD: 3.3 minutes for Vicryl; $p < 0.0001$) which is consistent with the finding of this study.

Similar results were observed in a single-port total laparoscopic hysterectomy done by Song and Lee, where laparoscopic suturing was adopted for cuff closure in both the groups with experimental group using V-Loc suture (43 cases) and control group applying conventional laparoscopic vaginal cuff suture (59 cases). The V-Loc suture group not only dramatically decreased vaginal stump suturing time (11.4 vs 22.5 minutes; p value < 0.001) and total operation time (92 minutes vs 105.2 minutes; p value $= 0.002$) but also reported reduced difficulty in suture procedure.[17]

Furthermore, a randomized trial by Alessandri et al. comparing unidirectional barbed suture with the traditional continuous suture for laparoscopic myomectomy found that the time required to suture the uterine wall defect and intraoperative blood loss was much less while using barbed sutures.[18] Barbed sutures have significantly reduced the time required for suturing and the degree of surgical difficulty in a randomized clinical study by Ardovino et al.[19] comparing the feasibility and safety of barbed bidirectional sutures vs standard sutures for vaginal cuff closure following total laparoscopic hysterectomy and lymph node dissection for early endometrial cancer.

Generally, for gynecologists, transvaginal suturing is widely preferred, as it is technically easier and has shorter learning curve. However, statistical analysis suggests that in TLH procedure, barbed sutures used in vaginal cuff closure reduced the suturing duration as well as technical difficulty experienced by the surgeon, which is in accordance with the above-mentioned literature reports.

With the introduction of a new technology, complications will invariably arise. One of the rare yet potentially serious complication from the use of barbed suture is bowel obstruction. If the cut end of the barbed suture is left long, it may become attached to the overlying bowel or mesentery producing kinking and acting as a transition point of obstruction. Rombaut et al. reported a case of bowel obstruction due to bidirectional suture causing terminal ileal strangulation following laparoscopic myomectomy.[20] In another case report by Thubert et al., the patient was diagnosed 1 month after undergoing laparoscopic sacrocolpopexy with peritoneal closure using a barbed suture, with small bowel volvulus and mesenteric rupture.[21] However, there were bowel complications among patients in both groups in the present study.

Conclusion

In conclusion, this study demonstrated that the use of barbed sutures for laparoscopic vaginal vault closure reduces the suturing time as well the operative difficulty. Based on the results and literature, the use of barbed sutures is an efficient alternative to conventional sutures for laparoscopic vaginal vault closure.

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RESEARCH ARTICLE

Safety and Feasibility of Laparoscopic Sleeve Gastrectomy with Loop Duodenal Switch Surgery for Obesity in Indian Patients

Amar Vennapusa[1], Ramakanth Bhargav Panchangam[2], Charita Kesara[3], Tejaswi Chivukula[4]

Abstract

Aim: Laparoscopic sleeve gastrectomy with loop duodenal switch (SLDS) surgery is a loop modification of biliopancreatic diversion with duodenal switch (BPD-DS) aimed at reducing malabsorption without compromising on the efficacy. This study aimed to analyze the safety and feasibility of SLDS surgery in Indians suffering from obesity.

Materials and methods: This was a retrospective study analyzing 169 patients who underwent SLDS surgery between November 2013 and June 2020. The cohort was divided into two subgroups based on the common channel length—2.5 and ≥3 m. Weight-loss parameters, diabetes remission, and investigations at 6 months and 1 year follow-up were analyzed in the total cohort and common channel subgroups. The percentage of total weight loss (%TWL) ≥25% was considered as a successful weight-loss outcome. HbA1C <6% without the need for antidiabetic medications was considered as complete diabetes remission. Safety was analyzed in terms of intraoperative and postoperative complications.

Results: Mean preoperative body mass index was 45.39 ± 7.6 kg/m^2. 48.52% of the patients were suffering from type II diabetes. Mean %TWL was 30.91 ± 4.98 and 41.86 ± 7.63% and complete diabetes remission was 81.82 and 89.06% at 6 months and 1 year follow-up, respectively. The percentage of total weight loss was inversely proportional to the common channel length. Complete diabetes remission was not significantly affected by the common channel length. Serum albumin <3 gm/dL was significantly high in patients with a common channel length of 2.5 vs ≥3 m—25 vs 4.65% at 6 months and 40 vs 7.14% at 1 year follow-up, respectively. Thirty-day mortality was zero.

Conclusion: Sleeve gastrectomy with loop duodenal switch surgery appears to be effective and safe in Indian patients. Malabsorption risk is greatly reduced when the common channel length is ≥3 m.

Clinical significance: Sleeve gastrectomy with loop duodenal switch surgery with the common channel length ≥3 m simplifies BPD-DS, gives excellent weight loss and diabetes remission with minimal malabsorption. Restricting the biliopancreatic limb to ≤55% prevents adverse malabsorptive consequences.

Keywords: Bariatric surgery, Biliopancreatic diversion with duodenal switch, Diabetes, Diabetes remission, Metabolic surgery, Obesity, One anastomosis gastric bypass, Single anastomosis duodenoileal bypass with sleeve, Sleeve gastrectomy, Weight loss.

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Introduction

Bariatric surgery offers durable weight loss and diabetes remission with minimal complications. Hormonal and physiological alterations are mainly responsible for the metabolic effects after bariatric surgery.[1] Metabolic outcomes are significantly better after laparoscopic biliopancreatic diversion with duodenal switch (BPD-DS) compared to standard surgeries like laparoscopic Roux-en-Y gastric bypass (RYGB). But nutritional deficiencies are also higher after BPD-DS.[2] It is not widely performed because of its technical complexity and increased risk of severe malabsorption.

Single anastomosis duodenoileal bypass with sleeve (SADI-S) is a loop modification of duodenal switch with a 2–2.5 m common channel.[3] It simplifies the procedure and reduces malabsorption to some extent. But even with 2.5 m common channel malabsorption can be significant in SADI-S. Increasing common channel length to 3 m can effectively reduce malabsorption.[4] Several loop duodenal switch (LDS) surgeries were described in the literature with different common channel lengths.[5]

Sleeve gastrectomy with loop duodenal switch (SLDS) is a loop modification of BPD-DS (Fig. 1).[6] It is technically simple with only one anastomosis, compared to BPD-DS. One main advantage is common channel length can be tailored according to the individual requirement and depending on the total bowel length. There is no literature available from the Indian subcontinent about this procedure. We analyzed our experience with this surgical technique in Indian patients suffering from obesity to ascertain its safety, feasibility, and efficacy.

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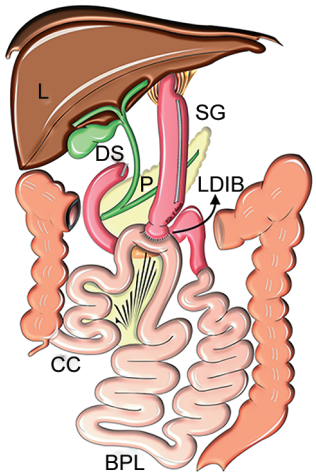

Fig. 1: Schematic diagram of sleeve gastrectomy with loop duodenal switch: BPL (biliopancreatic limb); CC (common channel); DS (duodenal stump); L (liver); P (pancreas); LDIB (loop duodenoileal bypass); SG (sleeve gastrectomy)

Institutional ethics committee approval was obtained and detailed written informed consent was taken from all the participants in this study. Our study complied with the ethical norms proposed by the Helsinki declaration for research involving humans.

Technique

Four ports were used in all the patients. Devascularization of greater curvature was performed starting opposite to angular incisure. Dissection was continued up to 5 cm beyond the pylorus and behind the first part of the duodenum until the gastroduodenal artery was identified (Fig. 2). The lesser omental layer over the caudate lobe was divided from behind the stomach to create a window. The right gastric artery (RGA) was divided at its origin using a vessel sealer. This step was a modification compared to the classical SADI-S described by Sánchez-Pernaute et al.[7,8] This step ensured free mobility of gastric sleeve, pylorus, and the first part of the duodenum as a single unit after the duodenal transection.[9] A lax sleeve gastrectomy (SG) was performed around a 38 French calibration tube starting 4 cm proximal to the pylorus. After completion of SG, the duodenum was transected using staplers (Fig. 3 and 4). The divided first part of the duodenum was

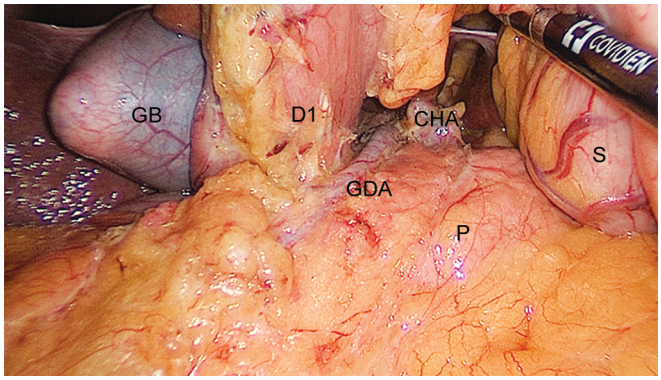

Fig. 2: Operative photograph of the duodenal dissection: CHA (common hepatic artery); D1 (part of the duodenum); GB (gallbladder); GDA (gastroduodenal artery); P (pancreas); S (stomach)

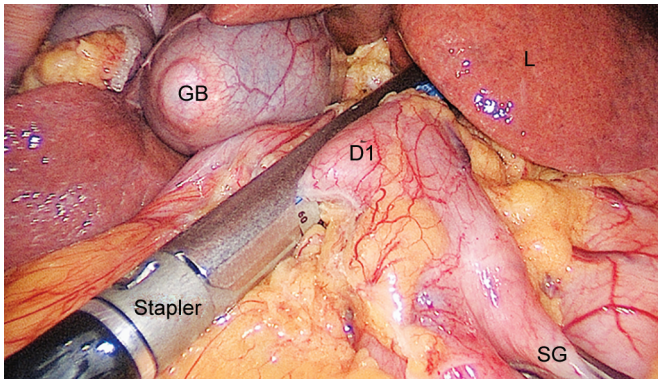

Fig. 3: Operative photograph of the duodenal transection: D1 (part of the duodenum); GB (gallbladder); L (liver); SG (sleeve gastrectomy)

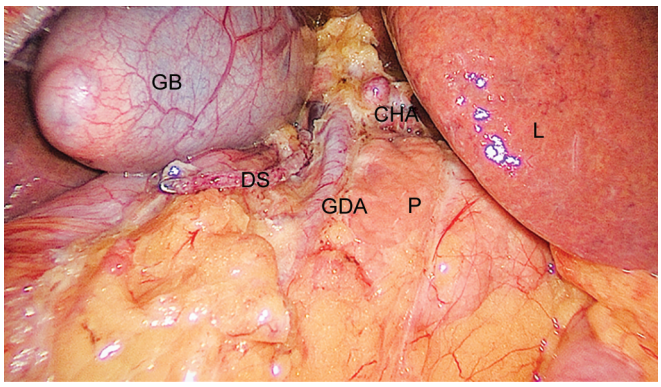

Fig. 4: Operative photograph of the duodenal stump: CHA (common hepatic artery); DS (duodenal stump); GB (gallbladder); GDA (gastroduodenal artery); L (liver); P (pancreas)

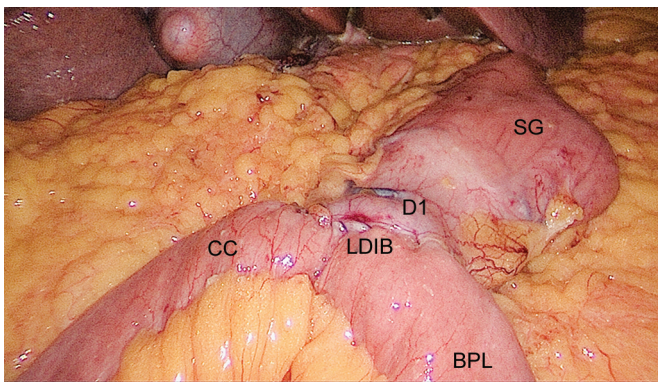

Fig. 5: Operative photograph of loop duodenoileal bypass: BPL (biliopancreatic limb); CC (common channel); D1 (part of the duodenum); LDIB (loop duodenoileal bypass); SG (sleeve gastrectomy)

Materials and Methods

It was a retrospective study of 169 patients who underwent SLDS surgery between November 2013 and June 2020. Patients with body mass index (BMI) ≥30 kg/m^2, those in whom surgery was performed as a primary surgery were included in this study. Those who underwent LDS as a revision surgery were excluded from this study.

anastomosed to distal ileum, in the antecolic end to side fashion using 3-0 continuous absorbable sutures in two layers (Fig. 5). In the fixed common channel (FCC) variant of SLDS surgery, the common channel length was fixed at 2.5, 3, or 3.5 m proximal to the ileocecal junction. In the fixed ratio bypass (FRB) variant of SLDS surgery, a fixed percentage of the jejunoileal length was bypassed.

Patients were discharged on the second postoperative day. Contrast X-ray and an abdominal sonography were performed 1 week and 1 month postoperatively to screen for leak and bleeding. Patients were prescribed lifelong bariatric multivitamin, mineral supplements, and ursodeoxycholic acid for 18 months.

Weight and BMI were documented at 6 months and 1 year follow-up and percentage of excess weight loss (%EWL) with BMI reference point of 25 kg/m^2 and percentage of total weight loss (%TWL) were calculated. The percentage of total weight loss ≥25% was considered as a successful weight-loss outcome. The percentage of excess weight loss ≥50% was taken as an alternative reference point to define a successful outcome. Complete diabetes remission was defined as HbA1C <6% with no antidiabetic medications needed for glycemic control. Partial diabetes remission was defined as HbA1C ≥6% but <6.5% in the absence of antidiabetic medications. Diabetes improvement was defined as a statistically significant reduction in HbA1C not meeting the criteria for complete or partial remission or decrease in requirement for antidiabetic medications. Differences in %TWL, %EWL, and HbA1C at 6 months and 1 year follow-up in subgroups based on the common channel were calculated using independent samples t test. The effect of common channel length on the weight-loss parameters was analyzed using simple linear regression and multiple regression analysis. The effect of common channel length on the weight-loss success rates and diabetes remission rates was calculated using logistic regression analysis. IBM SPSS version 26 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. *p* value of <0.05 was considered significant in various statistical tests.

Major complications, such as, internal bleeding and leak, were documented. Nutritional parameters including total protein and serum albumin at 6 months and 1 year follow-up were documented.

Results

A total of 171 patients underwent SLDS surgery between November 2013 and June 2020. One hundred and sixty-nine patients who met the inclusion criteria were analyzed. The mean age was 40.53 ± 10.07 years (16–68). Male:female ratio was 87:82. BMI of 24.85% (42/169) patients was ≥50 kg/m^2. 48.52% (82/169) patients were suffering from type II diabetes. 30.18% (51/169) patients had prediabetes. The average common channel length was 3.33 ± 0.41 (2.5–4.32) m. A fixed common channel variant was performed in 144 patients (the common channel was fixed at 2.5, 3, and 3.5 m in 26, 16, and 102 patients, respectively). Fixed ratio bypass variant was performed in 25 patients (the common channel length was 55% in 1, 50% in 13, 45% in 8, and 40% in 3 patients). 98.7% (152/154) and 91.24% (125/137) patients were available at the 6 months and 1 year follow-up, respectively.

Weight and BMI parameters of patients at different time intervals are summarized in Table 1. Overall weight and BMI were significantly less at 6 months and 1 year follow-up compared to preoperative values (Table 1). The percentage of total weight loss and %EWL with BMI reference point of 25 kg/m^2 in the total cohort and common channel subgroups at 6 months and 1 year follow-up after surgery are summarized in Table 1. Independent samples t test showed significantly more %TWL in patients with 2.5 m common channel compared to those with ≥3 m. Simple linear regression and multiple regression analysis showed that %TWL was inversely proportional to the common channel length at 6 months and 1 year follow-up. The percentage of excess weight loss was similar between the subgroups and the common channel length effect on %EWL was found to be insignificant (Table 1). The weight-loss success rate was 91.45% (139/152) and 99.2% (124/125) at 6 months and 1 year follow-up when %TWL ≥25% was taken as a reference point. These values were 97.37% (148/152) and 100% (125/125) at 6 months and 1 year follow-up when %EWL ≥50% was taken as a reference point. There was no significant difference in the weight-loss success rates between the common channel subgroups.

HbA1C in the total cohort and common channel subgroups at 6 months and 1 year follow-up are summarized in Table 2. HbA1C was significantly low at 6 months and 1 year follow-up compared to preoperative values. There was no significant difference in HbA1C between the common channel subgroups at 6 months follow-up. But HbA1C was significantly low in patients with common channel length 2.5 vs ≥3 m at 1 year follow-up.

Complete diabetes remission, partial diabetes remission, and diabetes improvement with HbA1C <6% reference point in the total cohort and common channel subgroups at 6 months and 1 year follow-up are summarized in Table 2. There was no significant difference in the percentage of complete diabetes remission between common channel subgroups. There were no symptoms of hypoglycemia or dumping syndrome in any of our patients. Responses of different comorbid conditions to SLDS surgery are summarized in Table 3.

Indicators of nutritional status are detailed in Table 4. Protein-energy malnutrition with serum albumin levels <3 gm/dL was significantly high in patients with a common channel length of 2.5 vs ≥3 m—25 vs 4.65% at 6 months and 40 vs 7.14% at 1 year follow-up, respectively. In patients with common channel length ≥3 m, all the patients with serum albumin <3 gm/dL at 6 months and 1 year follow-up had biliopancreatic limb length of >55%. Poor nutritional intake coupled with malabsorption was responsible for protein-energy malnutrition in these patients. Marked hypoalbuminemia (<2.5 g/dL) with clinical manifestations in eight patients (5 and 3 from 2.5 m and ≥3 m common channel subgroups, respectively) was corrected using intravenous amino acid injections, a high protein diet, and regular exercises. Hypoalbuminemia improved in all these patients except in two of them, one from each subgroup, who lost life >1 year after surgery. All patients who developed mild vitamin and mineral deficiencies responded well to oral supplements.

Concomitant cholecystectomy was performed in 10 patients, adhesiolysis in 21, and different types of hernia repairs in 11 patients. The mean duration of surgery was 191.49 minutes. Intraoperative injury to RGA with 250 mL blood loss occurred in one patient. Bleeding was controlled with a vessel sealer. 1.18% (2/169) patients developed postoperative bleeding on the first postoperative day, requiring diagnostic laparoscopy and lavage. All these patients recovered without any adverse postoperative events. One patient developed a localized leak 10 days after surgery but recovered with conservative treatment. 28.18 and 27.08% patients complained of diarrhea, 80 and 66.67% steatorrhea, 74.55 and 65.63% foul-smelling gas, and 11.82 and 8.33% incontinence at 6 months and 1 year follow-up after surgery, respectively, when their diet contained oil, spice, or chilly. 4.55 and 3.13% of patients complained of constipation at 6 months and 1 year follow-up after surgery, respectively. Thirty-day mortality was zero. None of the patients had gastroesophageal reflux, marginal ulcers, or internal herniation.

Discussion

Laparoscopic SG has gained a lot of popularity and became the most commonly performed surgery worldwide.[10] Its technical simplicity,

Table 1: Weight parameters

		Preoperative		*6 months follow-up*		*1 year follow-up*	
Parameter		*N*	*Mean ± SD*	*N*	*Mean ± SD*	*N*	*Mean ± SD*
Weight (kg)		169	125.46 ± 24.7	152	85.72 ± 15.68	125	71.23 ± 11.83
[a]Significance					$p < 0.001$ (A–B)		$p < 0.001$ (A–C)
BMI (kg/m^2)		169	45.39 ± 7.6	152	31.12 ± 4.77	125	26.01 ± 3.59
[a]Significance					$p < 0.001$ (A–B)		$p < 0.001$ (A–C)
% Excess weight loss							
Overall		—	—	152	74.53 ± 19.21	125	99.24 ± 20.62
[a]Significance							$p < 0.001$ (B–C)
Common channel length	2.5 m	—	—	26	70.9 ± 8.45	23	101.87 ± 8.45
	≥3 m	—	—	126	75.28 ± 20.69	102	98.64 ± 22.46
[b]Significance					$p = 0.081$		$p = 0.258$
[c]Simple linear regression					$p = 0.78$ (B = 0.011)		$p = 0.272$ (B = −0.051)
% Total weight loss							
Overall		—	—	152	30.91 ± 4.98	125	41.86 ± 7.63
[a]Significance							$p < 0.001$ (A–C)
Common channel length	2.5 m	—	—	26	35.98 ± 5.49	23	51.23 ± 6.55
	≥3 m	—	—	126	29.87 ± 4.18	102	39.75 ± 6.13
[b]Significance					$p < 0.001$		$p < 0.001$
[c]Simple linear regression					$p < 0.001$ (B = −0.052)		$p < 0.001$ (B = −0.087)
[c]Multiple regression analysis					$p < 0.001$ (B = −0.045)		$p < 0.001$ (B = −0.068)

[a]Paired samples *t* test
[b]Independent samples *t* test
[c]Significance when the common channel length was taken as an independent variable

easy reproducibility, and low complication profile made it the most popular bariatric surgery. But its main drawback is increased risk of long-term weight regain and recurrence of comorbid conditions.[11] Several of these patients require revision surgery.[12]

Roux-en-Y gastric bypass and its loop variation, one anastomosis gastric bypass (OAGB), lead to more durable weight loss and diabetes remission.[13–15] Roux-en-Y gastric bypass has limitations, such as, inability to monitor remnant stomach endoscopically, increased risk of calcium, and iron deficiencies due to complete duodenal bypass, dumping due to bypass of the pylorus, lack of endoscopic access to the biliary tract, marginal ulcer risk due to unopposed exposure of the jejunum to gastric juice and internal hernias due to mesenteric defects.[16] One anastomosis gastric bypass became more popular because of technical simplicity and an easy learning curve.[17] It can address marginal ulcers and internal hernias to some extent but other problems persist. The risk of calcium and iron deficiencies is relatively more in OAGB.[18] Even though these complications are outweighed by their advantages, novel surgeries to obviate those problems were attempted.[19]

BPD-DS is the most effective surgery in terms of the durability of weight loss and diabetes remission.[20] Preservation of the pylorus and the first part of the duodenum can address calcium and iron deficiencies to some extent but extensive intestinal bypass leaving only 1 m for absorption, increases the risk of severe protein-energy malnutrition, severe nutritional deficiencies, and renal stones.[21]

To reduce malabsorption and simplify the BPD-DS procedure, Sánchez-Pernaute et al. proposed a loop modification of the duodenal switch in 2007, by anastomosing the duodenum directly to a loop of ileum 2 m proximal to the ileocecal junction.[7] Increasing common channel from 1 m in BPD-DS to 2 m in SADI-S addressed malabsorption to some extent. But it was still a concern. To address this malabsorption issue, later they increased the common channel from 2 to 2.5 m.[22] Mitzman et al. proposed increasing common channel to >2.5 m in LDS surgeries. They published their experience with 3 m common channels in LDS surgeries which showed excellent metabolic outcomes and reduced risk of malabsorption.[23] Theoretical benefits of LDS surgeries over BPD-DS include a reduced risk of complications with similar weight loss and health benefits.[5]

Sleeve gastrectomy with loop duodenal switch is a loop modification of BPD-DS. The advantage of LDS surgery is the scope of adjusting limb lengths to suit individual requirements. Our results showed that SLDS surgery was a very effective surgery to induce significant weight loss. Moon et al. showed %TWL of 23.1% at 6 months and 37.1% at 12 months after LDS surgeries. The percentage of excess BMI loss was 41.9% at 6 months and 68.1% at 12 months follow-up.[24] Cottam et al. showed that there was a significant reduction of BMI from baseline 46.8 ± 5.8 to 29.8 ± 4.4 kg/m^2 at 1 year follow-up after LDS surgeries.[25] Weight-loss response in our patients was similar to the results shown in these studies. Studies have shown similar %TWL after LDS surgeries and BPD-DS.[4,24] In our patients, increasing common channels from 2.5 to ≥3 m, reduced efficacy of surgery in terms of weight-loss response but the success rate remained unaltered. So, our results showed that the common channel can be increased from 2.5 to ≥3 m without altering the efficacy of surgery.

Our results indicate that SLDS surgery is a very powerful metabolic surgery for diabetes remission. Cottam et al. showed diabetes remission of 96.3% at a 1 year follow-up after the single anastomosis duodenal switch (SADS).[25] Diabetes remission was

Table 2: Variance in HbA1C and diabetes remission

Category	*Subgroups*		*Preoperative*		*6 months follow-up*			*1 year follow-up*	
Variance in HbA1C		*N*	*Mean ± SD*	*N*	*Mean ± SD*		*N*	*Mean ± SD*	
Overall		82	8.71 ± 1.82 (5–12.1)	77	5.47 ± 0.81 (3.9–10)		64	5.08 ± 0.76 (4–8.9)	
[a]Significance					$p < 0.001$			$p < 0.001$	
Common channel length	2.5 m	11	8.91 ± 2.07 (6.1–11.8)	11	5.28 ± 0.59 (4.6–6.5)		11	4.63 ± 0.6 (4–6.2)	
	≥3 m	71	8.67 ± 1.79 (5–12.1)	66	5.5 ± 0.85 (3.9–10)		53	5.18 ± 0.76 (4–8.9)	
[b]Significance			$p = 0.694$		$p = 0.41$			p = 0.029	
Diabetes response		—	—	—	*N*	*CR%*	*PR and DI%*	*N*	*CR%*	*PR and DI%*
Overall		—	—	—	77	81.82%	18.18%	64	89.06%	10.94%
Common channel length	2.5 m	—	—	—	11	81.82%	18.18%	11	90.91%	9.09%
	≥3 m	—	—	—	66	81.82%	18.18%	53	88.68%	11.32%
[c]Significance						$p = 1$			$p = 0.829$	
[d]Univariate logistic regression						$p = 0.186$			$p = 0.178$	

[a]Paired samples *t* test
[b]Independent samples *t* test
[c]Pearson's chi-square test
[d]Common channel length was taken as an independent variable
CR, complete diabetes remission, PR and DI, partial diabetes remission and diabetes improvement

similar in the common channel subgroups in our study indicating that the common channel length can be increased from 2.5 to ≥3 m in LDS surgeries, without altering metabolic efficacy. The anastomosis is placed distally in the ileum in LDS surgeries, and this probably correlates with a potent ileal brake mediated by an enhanced secretion of Peptide YY and GLP1 which stimulate early satiety.[3]

The resolution of hypertension, hyperlipidemia, and obstructive sleep apnea was significant in our patients. Surve et al. showed hypertension resolution of 75% and hyperlipidemia resolution of 94% following the SADS procedure.[26] While Shoar et al. showed hypertension resolution of 96.3% and hyperlipidemia resolution of 68.3% and obstructive sleep apnea resolution of 63.3% after LDS surgeries.[27]

Major intraoperative complications were <1% and postoperative complications requiring surgical intervention were <2% in our patients. Surve et al. showed the short-term and long-term complication rates of 4.3 and 0%, respectively, and zero mortality rate.[26]

The presence of loop anastomosis in LDS surgeries reduces the chances of anastomotic leak and internal herniation by minimizing the number of anastomoses and mesenteric gaps. To facilitate tension-free anastomosis and make it technically simple, we modified LDS surgery by dividing RGA at its origin and creating a window in the lesser sac. This modification allows bringing the duodenum down toward the ileum for the anastomosis, rather than taking ileum to the first part of the duodenum into the right subhepatic space. This modification results in a freely mobile sleeve, pylorus, and the first part of the duodenum, facilitating tension-free anastomosis and avoids the need to divide greater omentum to facilitate the same. None of our patents required division of greater omentum. Sánchez-Pernaute et al. in their proposed SADI-S technique did not divide RGA.[7] Dallegrave proposed division of RGA while performing LDS surgeries.[8] He suggested that the division of RGA reduces the risk of marginal ulcers and bile reflux. A large gap is left behind anastomosis in our modification. This large gap perhaps allows free movement of intestinal loops behind without causing an obstruction. None of our patients developed obstruction or strangulation due to internal herniation. Gebelli et al. showed that LDS surgeries with RGA ligation can be performed safely.[9]

Preservation of the pylorus reduces the risk of acid exposure to the anastomosis, thereby reducing the risk of marginal ulcers. In their pooled analysis, Surve et al. showed that the anastomotic leak, ulcer, and bile reflux occurred in 0.6% (9/1328), 0.1% (2/1328), and 0.1% (2/1328), respectively. None of their patients had an internal hernia. Loop duodenal switch surgeries may cause fewer anastomotic complications compared with RYGB and BPD-DS.[28,29]

Table 3: Comorbid conditions

		Percentage of response	
Comorbid condition	*% of total patients*	*6 months follow-up*	*1 year follow-up*
Hypertension	46.75% (79/169)	77.03% (57/74)	87.69% (57/65)
Hyperlipidemia	56.21% (95/ 169)	88.64% (78/88)	94.12% (64/68)
Osteoarthritis	10.65% (18/169)	76.47% (13/17)	76.92% (10/13)
Obstructive sleep apnea	22.49% (38/169)	85.29% (29/34)	92% (23/25)

Table 4: Investigations

Investigation	Preoperative (A) *N*	Preoperative (A) *Mean ± SD*	6 months follow-up (B) *N*	6 months follow-up (B) *Mean ± SD*	6 months follow-up (B) *Significance*	1 year follow-up (C) *N*	1 year follow-up (C) *Mean ± SD*	1 year follow-up (C) *Significance*
Serum vitamin B_{12} (pg/mL)	109	394.1 ± 278.33	89	584.17 ± 414.02	$^{a}p < 0.001$ (A–B)	70	699.1 ± 548.85	$^{a}p < 0.001$ (A–C)
Serum vitamin D total (ng/mL)	102	14.01 ± 9.23	89	26.71 ± 20.47	$^{a}p < 0.001$ (A–B)	74	27.54 ± 21.15	$^{a}p < 0.001$ (A–C)
Serum calcium (mg/dL)	110	9.39 ± 0.56	88	9.22 ± 0.47	$^{a}p = 0.012$ (A–B)	73	9.08 ± 0.52	$^{a}p = 0.016$ (A–C)
Serum iron (µg/dL)	110	71.71 ± 28.59	90	70.14 ± 28.99	$^{a}p = 0.4$ (A–B)	74	72.72 ± 31.19	$^{a}p = 0.308$ (A–C)
Blood hemoglobin (g/dL)	115	13.43 ± 1.82	91	13.01 ± 1.68	$^{a}p = 0.043$ (A–B)	75	12.17 ± 1.86	$^{a}p < 0.001$ (A–C)
Total protein (g/dL)	132	7.34 ± 0.55	106	6.67 ± 0.68	$^{a}p < 0.001$ (A–B)	90	6.46 ± 0.77	$^{a}p < 0.001$ (A–C)
in 2.5 m common channel subgroup	20	7.33 ± 0.57	20	6.32 ± 0.84	$^{b}p = 0.009$	20	5.74 ± 0.94	$^{b}p < 0.001$
in ≥3 m common channel subgroup	112	7.34 ± 0.55	86	6.75 ± 0.61		70	6.66 ± 0.57	
Serum albumin (g/dL)	132	4.03 ± 0.38	106	3.65 ± 0.46	$^{a}p < 0.001$ (A–B)	90	3.5 ± 0.66	$^{a}p < 0.001$ (A–C)
in 2.5 m common channel subgroup	20	4 ± 0.34	20	3.4 ± 0.5	$^{b}p = 0.006$	20	2.93 ± 0.66	$^{b}p < 0.001$
in ≥ 3 m common channel subgroup	112	4.04 ± 0.39	86	3.71 ± 0.43		70	3.66 ± 0.57	
Albumin deficiency with <3 g/dL cut off			≥3 g/dL	<3 gm/dL		≥3 g/dL	<3 g/dL	
in 2.5 m common channel subgroup			75% (15/20)	25% (5/20)	$^{c}p = 0.003$	60% (12/20)	40% (8/20)	$^{c}p < 0.001$
in ≥3 m common channel subgroup			95.35% (82/86)	4.65% (4/86)	$^{d}p = 0.012$	92.86% (65/70)	7.14% (5/70)	$^{d}p = 0.005$

[a]Paired samples *t* test
[b]Independent samples *t* test
[c]Pearson's Chi-square test
[d]Logistic regression with common channel length as an independent variable

None of our patients had an anastomotic leak or marginal ulcers. None of our patients required readmission because of major postoperative complications. Patients who underwent BPD-DS or LDS surgeries have a unique risk of duodenal stump leakage, though incidence is very low. The superior quality of staplers and the presence of anastomosis farther away from the duodenal stump probably reduce risk of stump leak. Nelson et al. reported a duodenal stump leak of 1.45% (1/69).[30] None of our patients had duodenal stump leakage.

Since all of our patients were kept on regular vitamin and mineral supplements, we noticed significantly increased serum vitamin D total and B12 levels at 6 months and 1 year follow-up. Moon et al. noted low levels of serum vitamin D at 6 and 12 months following SADS.[24] Shoar et al. reported that serum vitamin A, selenium, and iron deficiency were the most common nutritional deficiencies after LDS surgeries with 3 m common channel.[27] Surve et al., in the pooled data analysis of SADS surgeries, did not find any statistically significant difference between most of the pre- and postoperative nutritional data.[28]

In our patients, the extent of hypoalbuminemia significantly reduced from 40 to 7.14%, when the common channel was increased from 2.5 to ≥3 m. Sánchez-Pernaute et al. showed low levels of protein in 34% of patients and albumin in 13.7% of patients after SADI-S with 2 to 2.5 m common channel.[22] Enochs reported protein and albumin deficiency in 7.6 and 3.1% of the SADS patients with 3 m common channels, respectively, at 1 year follow-up.[31] Surve et al. showed that 6.6 and 6.2% of the patients had abnormal protein and albumin levels, respectively, after LDS surgeries with 3 m common channel.[26] Our study showed that Indian patients are at significantly higher risk of protein deficiency after LDS surgeries when the common channel was 2.5 m compared to those with ≥3 m. Since all the patients who had serum albumin levels <3 gm/dL had biliopancreatic limb length of >55%, we recommend measuring total jejunoileal length in all the patients and restrict biliopancreatic limb length to ≤55%, to prevent protein malnutrition.

Increasing biliopancreatic limb beyond 2 m in RYGB or OAGB increases the risk of protein-energy malnutrition, nutrient malabsorption, and diarrhea.[32] Biliopancreatic limb length is directly proportional to the efficacy of surgery.[33] Preservation of pylorus and the first part of the duodenum perhaps play a role in reducing malabsorption in LDS surgeries. Pylorus controls gastric emptying, allowing a greater length of the intestine to be bypassed without malabsorptive consequences.[33] Preservation of pylorus reduces the risk of dumping syndrome. This is again related to the control of gastric emptying.[23] Pylorus also prevents the reflux of ileal contents into the stomach.[33] With our technical modification, once anastomosis is completed — sleeve, pylorus, the first part of the duodenum, and anastomosis lie in a straight vertical line. This theoretically reduces the risk of reflux into the esophagus as well as reflux of ileal contents into the sleeve. We presume this adds extra protection against reflux in addition to the pylorus. None of our patients had postoperative symptoms of esophageal reflux.

One disadvantage of LDS surgeries is the loss of endoscopic access to the biliary tract. If anyone develops cholangitis or choledocholithiasis, the only option is laparoscopic common bile duct exploration. To reduce the incidence of cholelithiasis, all our patients were kept on prophylactic ursodeoxycholic acid. Studies showed that fewer complications like chronic diarrhea, smelly stools, and flatulence were reported in LDS surgeries with

3 m common channel compared to BPD-DS.[4,29] In our study, we observed that these bowel problems were triggered when there was oil, spice, or chilly in the food. So, our patients were advised to avoid these items after surgery.

Conclusion

This study showed that SLDS surgery is safe and feasible. Nutritional complications significantly come down when the common channel is increased to ≥3 m without compromising on the metabolic efficacy of the procedure. More studies with long-term follow-up are needed to determine the ideal common channel length to standardize this promising procedure.

Clinical Significance

Sleeve gastrectomy with loop duodenal switch surgery with common channel length ≥3 m simplifies BPD-DS, gives excellent weight loss and diabetes remission with minimal malabsorption. Restricting biliopancreatic limb to ≤55% prevents adverse malabsorptive consequences.

Disclaimer

We hereby declare that there are no hidden conflicts of interests either financial or plagiarism related or any other related to the clinical content and work of this manuscript.

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RESEARCH ARTICLE

Factors Predicting Success of Laparoscopic Adrenalectomy: Our Experience

Varun Agarwal[1], Amit Sharma[2], Mukund Andankar[3], Hemant Pathak[4]

Abstract

Introduction: Adrenal is one of the most feared organs owing to its anatomical position. However, adrenalectomy by laparoscopic means has now been adopted as the procedure of choice to treat benign and malignant functioning and nonfunctioning adrenal tumors. We describe our experience with laparoscopic adrenalectomy (LA) in 37 patients at a tertiary institute and try to predict factors for open conversion.

Materials and methods: Thirty-seven patients who underwent LA from August 2013 to February 2018 were retrospectively analyzed and factors leading to conversion to open adrenalectomy assessed.

Results: Among 37 patients, 31 had pheochromocytoma on histopathology and 1 patient had adrenal hyperplasia leading to Cushing's syndrome. Five out of 37 patients had to be converted to open technique—multiple adhesions with the bowel, retrocaval tumor extensions, difficult dissection, and prolonged operative time due to large tumor size (in two patients) and severe hepatomegaly were the reasons for conversion to open.

Conclusion: Laparoscopic adrenalectomy is safe and feasible for large adrenal lesions.

Keywords: Adrenalectomy, Laparoscopic, Success.

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Introduction

Adrenalectomy is often performed by surgeons with an interest or training in endocrine surgery. Adrenal is one of the most feared organs because of its deep retroperitoneal location and close relation to vital structures. Adrenalectomy by laparoscopic means is one of the successful applications of minimally invasive surgical techniques. It has now been adopted as the procedure of choice to treat benign and malignant functioning and nonfunctioning adrenal tumors.[1] Adrenalectomy was initially done by open surgery when Sargent performed the first planned adrenalectomy in 1914.[2] However, laparoscopic adrenalectomy (LA) is now being done also for hypervascular tumors and large benign and malignant adrenal tumors.[3]

We report our experience in 37 patients who underwent LA and the factors which affected their conversion to open in 5 cases.

Materials and Methods

Thirty-seven patients who underwent LA from August 2013 to February 2018 were retrospectively analyzed based on age, sex, and detailed history which would suggest a syndromic association or past history of abdominal surgery. The weight and height of patients were taken to calculate the body mass index (BMI).

The department of endocrinology at our institute primarily evaluated these patients. Depending on the suspected pathology, an appropriate hormonal workup was done and patients with functional as well as nonfunctional tumors were referred to us for surgical management. The ones with functional tumors like pheochromocytoma and Cushing's syndrome were stabilized preoperatively.

All patients underwent contrast-enhanced computerized tomography (CECT) and/or magnetic resonance imaging (MRI) for delineating the size of the gland, relation with inferior vena cava (IVC) on the right side, the renal vein on the left side, and the presence or absence of lymph nodes.

The success of laparoscopic surgery was defined as completion of the entire surgery by laparoscopic means. If, at any point during the surgery, there occurred a difficulty or a complication that was not manageable laparoscopically, the patient was converted to open surgery.

Patients with suspicion of malignancy, tumor invasion of adjacent organs, and patients who were high risk due to cardiopulmonary disease were excluded from the study.

All specimens, after extraction, were sent for a histopathology examination.

Technique

All patients were operated on under general anesthesia and a lateral transabdominal flank approach was used with an intra-abdominal pressure of 12 mm Hg. Wherever necessary hemostasis was achieved using bipolar coagulation, Harmonic scalpel, Ligaclips, Hem-o-lok clips.

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Right Adrenalectomy

(Fig. 1) Four ports were used normally. Three ports of 10 mm (1 for 30 degree scope and 2 as working ports) each were placed along the right costal margin and one 5 mm port at the xiphisternum for liver retraction. An additional 5 mm fifth port would be inserted for liver retraction if required, in the right anterior axillary line.

The triangular ligament was first cut and the peritoneum was incised along with the liver as far as the diaphragm so that the right lobe of the liver falls away medially. The plane was created between liver and adrenal and dissection proceeded medially reaching the adrenal vein.

After complete dissection of the vein, it was cut between clips. The gland was then dissected free using a hook with monopolar coagulating current and delivered after placement in endobag. The specimen was extracted via a 10 mm port, by enlarging the incision. The port sites were closed using the standard technique.

Left Adrenalectomy

Port placement on the left side was similar to the right. Four ports were used.

The peritoneum was incised along the White Line of Toldt in a "T" shaped manner.

The two horizontal limbs of T extended from colon caudally to splenocolic ligament in the cephalad direction till the greater curvature of the stomach was visible.

This allowed complete retraction of the spleen and the colon by positional gravity and exposed the kidney enveloped in the Gerota's fascia. The vertical limb of "T" was the line of dissection between the tumor and spleen. Dissection was done at the site of the renal hilum, for identification of the adrenal vein, which was clipped and divided. The adrenal gland was then dissected free from the surrounding structures and delivered in a retrieval bag.

Results

The demographic details and patient characteristics have been summed up in Table 1. Out of 37 patients, 32 were evaluated and found to have functional tumors. Eventually, 31 of them had pheochromocytoma on histopathology and 1 patient had adrenal hyperplasia leading to Cushing's syndrome. One patient had sudden cardiovascular collapse at the time of induction but was resuscitated on time and the patient went on with the surgery successfully. Most of the patients had intraoperative fluctuations of blood pressure which was managed successfully by an anesthetist. These patients eventually had pheochromocytomas on histology. The patient who was pregnant had intraoperative accelerated hypertension with a maximum recording of 230/110 mm Hg, managed by inj. nitroprusside and nitroglycerine (NTG) drip.

Five out of 37 patients had to be converted to the open technique. One of them had multiple adhesions with the bowel because of past abdominal surgery for duodenal perforation which made the separation of bowel difficult. One patient had retrocaval tumor extensions and was densely adherent to IVC and liver with a size of 8.5 × 7 cm. It eventually turned out to be adrenocortical carcinoma. Two patients were converted to open because of the difficulty in dissection and prolonged operative time due to large tumor size. One of the patients had severe hepatomegaly. Despite adding a fifth retraction port, separation of tumor from the liver bed was difficult, so the decision was taken to proceed with open surgery. The characteristics of patients converted to open along with reasons for the same have been summed up in Table 2.

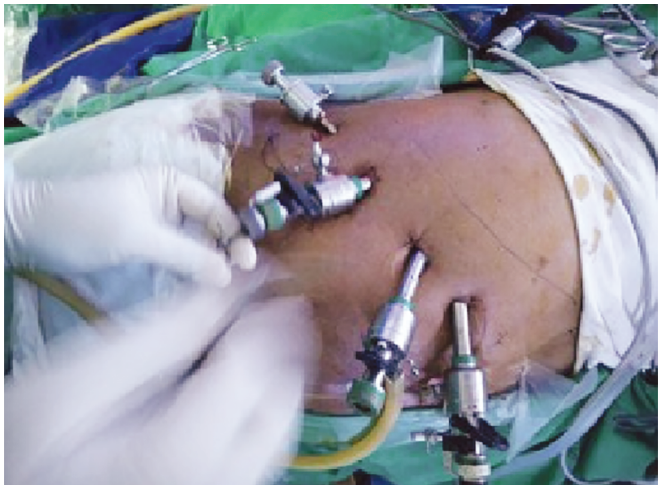

Fig. 1: Port placement for right adrenalectomy

Discussion

Studies have suggested that large tumors are not a contraindication for LA, but some authors do not approve laparoscopic approach for large tumors because of increased risk of malignancy, especially in tumors with infiltration to surrounding structures on computerized tomography (CT), which may even lead to peritoneal dissemination

Table 1: Patients' characteristics

Total patients	37
Mean age in years (range)	46 (27–65)
Sex	Male—15 (40.54%)
	Females—22 (59.45%)
Average BMI in kg/m^2 (range)	
Side	Right—16 (43.24%)
	Left—20 (54.05%)
	B/L—1 (2.7%)
Any significant history	1 female—5 months pregnant
	1 male—past history of abdominal surgery for duodenal perforation
Mean size in cm (range)	6.05 cm (2.5–9.6 cm)
Functional tumors	32 (31 pheochromocytomas and 1 patient of Cushing's disease)
Final histopathology	Nonfunctioning adenomas—4
	Pheochromocytoma—31
	Adrenocortical carcinoma—1
	Adrenal hyperplasia—1

Table 2: Reasons for conversion to open adrenalectomy

No. of patients converted to open	*Reason for conversion*
1	Hepatomegaly in a right-sided tumor
1	Adherent to kidney, liver, and retrocaval extension—eventually malignant
2	Large tumor size
1	Past abdominal surgery leads to adhesions with bowel

or port site recurrence.[4–7] In the present study, the laparoscopic approach was adopted in all patients with adrenal tumors regardless of tumor size. Two patients were converted to open adrenalectomy because of large tumor size.

However, the size of the tumor can be regarded as the most important factor for conversion.[8]

In recent literature, contraindications for LA are invasive adrenocortical carcinoma, large tumor >10–12 cm in diameter, and malignant adrenocorticotropic hormone (ACTH) secreting pheochromocytoma with lymphadenopathy and adrenocortical carcinoma with caval thrombus.[9] Patients with malignancy or suspicion of malignancy were not included in the study.

One patient in our study underwent bilateral LA for adrenal hyperplasia because of ectopic ACTH secreting adenoma in the lung. Here, the laparoscopic approach is much preferred when compared with the open approach, as bilateral laparoscopic adrenal surgery leads to much less tissue injury in immunocompromised patients with a risk of delayed wound healing. It also enables better visibility of the surgical field because of an additional advantage of magnification, thus decreasing the risk for retained remnants and adrenal rest tissue.[10]

Right adrenal gland—more retrocaval and a shorter adrenal vein than left adrenal gland, so right side is a more challenging and time-consuming procedure than left-sided adrenalectomy.[11] However, Po-Hui Chiang et al. did not find any difference in conversion rates based on the laterality of tumors.[12]

Prior abdominal surgery[13] leads to prolonged operating times, increased technical difficulty, increased risk in initial entry into the abdominal cavity, and increased chances of causing injury to the surrounding organs. Morris et al. showed a trend for longer operative times in patients with previous surgery; however, the difference was not significant.[14]

Pheochromocytomas, being larger and more vascular when compared with other adrenal neoplasms, are a challenge to resect and lead to more complications, longer operative times, and more conversions to open procedure.[15]

Zografos et al., in their study, have linked obesity with a higher incidence of conversions because of difficult cannula placement, excessive intraperitoneal fat obscuring the anatomy, excessively thick abdominal wall causing difficulties in the manipulation of instruments, thereby leading to longer operating times.[16]

Conclusion

Laparoscopic adrenalectomy can be adopted even for large adrenal lesions and is safe and feasible. The laparoscopic attempt should be given even for large and malignant adrenal tumors; however, conversion to open surgery should not be delayed to avoid an adverse outcome.

There is an increased risk of conversion to open surgery in patients with:

- Large tumors (≥5 cm), (size—most important).
- Malignancy.
- Right-sided tumors.
- History of past abdominal surgery.

This information can help in appropriate counseling and taking of preoperative consent of candidates for LA.

Laparoscopic adrenalectomy can also be carried out safely in a pregnant woman without harm to the fetus.

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RESEARCH ARTICLE

Cost Analysis of Blood Group and Antibody Screening for Emergency Appendicectomy: Should We Stop?

Ian S Farrell[1], James Hall[2], James Hill[3]

Abstract

Introduction: The rate of transfusion associated with emergency laparoscopic general surgery has been shown to be 0.36%. A significant number of patients undergo group and antibody screening due to perceived risk of hemorrhage. All NHS hospitals have massive transfusion policies with immediate availability of O-negative blood. Blood group and antibody screening carries a cost of £35. The aim of this study was to determine the cost-effectiveness of group and antibody screening vs crossmatching where required.

Materials and methods: All patients undergoing emergency appendicectomy over a 3-year period were retrospectively identified. The transfusion service then identified whether blood had been issued.

Results: A total of 645 emergency appendicectomies were identified: 603 were laparoscopic and 42 open. One (0.2%) patient received a transfusion of 2 units.

Discussion: Our study has shown a rate of transfusion of 0.2%. If patients were crossmatched as required rather than group and screening, this would give a cost saving of £35 per patient or £22345 across our trust. There are 50,000 appendicectomies per year in the United Kingdom. If this saving were extrapolated, it would generate a saving of £1.1M.

Conclusion: Our recommendation would be to crossmatch where required. The cost saving to the NHS could be up to £1.1M with little impact on the demand for O-negative blood.

Keywords: Appendicectomy, Laparoscopy, Transfusion.

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Introduction

The rate of blood transfusion associated with any form of laparoscopic general surgery is low. A recent single-center study looking at elective laparoscopic day case surgery revealed no transfusions in a 2-year period in 532-day case patients.[1] Similarly, a study investigating transfusions during emergency laparoscopic appendicectomy, cholecystectomy, and diagnostic laparoscopy found the rate of transfusion to be less than 0.4% in the peri-operative or immediate postoperative period (Day 1 postoperative) in 562 patients.[2]

There is a perception that there is an increased risk of major hemorrhage during laparoscopic surgery from anesthetic and surgical staff, despite the evidence that transfusion rates are low. In addition to this, there is no national guidance on preoperative blood screening for emergency laparoscopic surgery. In our trust, it remains policy that patients undergoing emergency laparoscopic procedures have group and screen tests carried out prior to theater.

The purpose of group and screen is to screen for unusual antibodies and also to allow transfusion laboratories to store samples to crossmatch if blood is required. This test takes approximately 45 minutes. Blood crossmatch takes approximately 60 minutes before blood is available, this shows that there is no presence of unusual blood antibodies.[3] For major hemorrhage scenarios, all NHS hospitals are required to have a massive transfusion policy with immediate O-negative blood availability in major hemorrhage scenarios.[4] Conventional wisdom dictates that all perioperative transfusions should be type specific in order to minimize risk of transfusion reactions; however, transfusion of O-negative blood only carries a very low additional risk of non-ABO-alloantibody incompatibility. Studies have shown an incidence of hemolytic transfusion reactions in only 1 in 70,000 O-negative transusions.[5]

Routine blood group and antibody screening prior to surgery has an associated cost of approximately £17.50 per sample in our unit. The requirement for two samples prior to transfusion brings the cost of screening to £35 per patient.

The aim of this study was to determine the cost-effectiveness of blood group and antibody screening for appendicectomy compared to crossmatching as required together with the use of O-negative blood when massive peri-operative transfusion is required.

Materials and Methods

All patients undergoing appendicectomy in our center over a 3-year period were retrospectively identified. All patients under 16 and all nonemergency cases were excluded. The patient records were examined to determine whether preoperative group and antibody

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screening had been requested. The transfusion laboratory then identified which of these patients had been issued blood in the perioperative or postoperative period and whether this was type specific or O-negative blood.

Results

A total of 645 emergency appendicectomies were identified of which 603 were laparoscopic cases and 42 open. There were 334 male and 311 female patients with a median age of 29 (range 16–83).

Of all 645 cases, 1 (0.2%) patient received a blood transfusion (1 unit in recovery and 1 unit in the postoperative period). Both these units were type-specific blood following full crossmatch.

Table 1: Total number of appendicectomies identified in our unit over a 3 year period and the surgical approach

Total emergency appendicectomies	645
Laparoscopic	603 (93%)
Open	42 (7%)

Table 2: Cost breakdown of screening and blood usage

Cost per patient of group and screen	*Total cost of group and screen*	*Cost per unit of blood*	*Total cost of transfusions (2 units)*
£35.00	£22,470.00	£132.72	£265.44

Discussion

In our study, in a cohort of 645 patients, we established that the incidence of perioperative transfusion was 0.2%, comparable to the previously published rate of 0.36%.[2] In our study, there were no massive transfusion events requiring O-negative blood. The one patient who required blood was able to wait for type-specific blood to be available.

At present, the National Transfusion Service charge the same for a unit of blood regardless of blood type (£132.72).[6] It has been proposed that O-negative blood should attract an additional charge[6] (£180), the reason being that O-negative blood is the universal donor group and thus stocks of this should be protected. The differential charge would be to encourage use of type-specific blood where possible.

If blood products are required in the vast majority of cases, the use of blood products is an urgent clinical need but not an emergency requiring activation of a major hemorrhage protocol; in our study, no patients required an emergency transfusion. A wait of up to 60 minutes for blood to be available would not constitute a significant clinical risk. Not having a prior group and screen would add approximately 15 minutes to this process due to the need to sample blood and deliver it to the hematology laboratory. The risk of unexpected antibodies at group and screen is approximately 1.5%.[7] Therefore, if 0.2% of cases require transfusion, the chance of a patient undergoing emergency appendicectomy needing blood and it not being available is negligible (0.003%) (Tables 1 and 2).

If routine crossmatch was removed from our trust, this would have saved £22,435. It is estimated that there are approximately 50,000 emergency appendicectomies carried out in the United Kingdom every year.[8] If our data were extrapolated to these 50,000 cases, then crossmatching when required rather than routinely group and antibody screening every patient would save £1.1M. Further advantages of this strategy are reducing burden on the blood transfusion service and to remove a potential delay in patient transfer to the theater whilst waiting for group and screen tests to be carried out, with the associated potential to increase morbidity from the condition. By transfusing O-negative blood in massive hemorrhage and carrying out crossmatch on an as-required basis, the need for preoperative screening is removed and therefore a reason for potential delay can be avoided.

Conclusion

To conclude, our study has confirmed that the rate of transfusion in appendicectomy is extremely low, suggesting that the routine use of blood group and antibody screening is unnecessary. Our recommendation would be to crossmatch on an as-required basis and use O-negative where urgent blood is required. The potential cost saving of this practice to our trust would be £22345, and if this were extrapolated across the NHS, this could be in the region of £1.1M with very little impact on the demand for O-negative blood.

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REVIEW ARTICLE

Minimal Access, Optimal Dryness: A Review of Laparoscopic Repair of Vesicovaginal Fistula

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Abstract

Background: Vesicovaginal fistula (VVF) is an embarrassing condition for women. Various routes of surgical intervention exist for the management of VVF. Laparoscopic repair is safe and effective.

Aim and objective: To review the success rate of laparoscopic repair of VVF and to highlight the benefits/advantages of the laparoscopic approach.

Materials and methods: Using various databases, previous studies of patients who underwent laparoscopic VVF repair between 2008 and 2018 were reviewed. Outcome measures from these studies were success rate, mean blood loss, mean operating time, length of hospital stay, major intraoperative complications, and conversion to open surgery.

Results: Fourteen retrospective studies (full-text articles) were retrieved and reviewed. Two hundred and sixty-nine patients had a laparoscopic repair. The pooled success rate was 96.7%. Mean blood loss ranged from 30 to 400 mL, length of hospital stay ranged from 1.1 to 7.8 days while the mean operating time ranged from 54 to 229 minutes. There was only one major intraoperative complication. Only four patients had to be converted to open surgery.

Conclusion: Laparoscopic repair of VVF has a high success rate and is a safe, patient-friendly, and cost-effective route for surgical management of VVF.

Keywords: Abdominal repair, Laparoscopic route, Vesicovaginal fistula.

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Introduction

Vesicovaginal fistula (VVF) is an abnormal communication between the epithelium of the bladder and that of the vagina which leads to continuous/total involuntary leakage of urine. It is a condition that not only affects the health of the woman but also imposes a great deal of social embarrassment and psychological trauma on the patient. It is considered as one of the most dehumanizing conditions that affect and reduce the quality of life of women.[1]

The etiology of VVF is largely influenced by socioeconomic development/standard of healthcare delivery system. In underdeveloped/developing countries, prolonged labor accounts for over 90% of VVF; however, in developed countries, it is usually from iatrogenic causes particularly from hysterectomies for benign gynecological conditions, radiation therapy, and advanced reproductive tract malignancies.[2]

It has been estimated that there are about 3 million women with unrepaired fistula globally, with about 150,000 new cases every year.[3]

Ever since the first successful VVF repair pioneered by James Marion Sim, various methods and techniques have subsequently been discovered and employed to surgically treat VVF. For the route of repair, there is no consensus regarding the best route, as this is influenced by various factors like the site, size, etiology, surgeons' choice, and level of expertise/competence.[4]

Vesicovaginal fistula can be repaired by two routes: Vaginal and abdominal. The abdominal route repair has been performed predominantly by open surgery (laparotomy) and is associated with more morbidities; these morbidities can be minimized/avoided via minimal access surgery.[5]

Minimal access surgery has reformed the field of gynecology; becoming established in everyday practice and is gradually becoming the norm and gold standard in gynecological practice and diagnosis and treatment of various gynecological conditions including repair of VVF. Laparoscopic repair of VVF has been conducted with remarkable success.[6]

The purpose of this article is to review the success rates of the laparoscopic repair of VVF and also highlight some of the benefits/advantages of the laparoscopic repair.

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Materials and Methods

Search Strategy

Relevant studies/publications were searched for using PubMed, Google Scholar, Cochrane library, ScienceDirect, Embase, and Medline. The databases were searched using the relevant medical subject headings (MeSH) terms. Search words included: vesicovaginal fistula, laparoscopic repair, abdominal route. No restriction was placed on the language of publication.

Study Selection

Studies selected were original research articles published in the last 10 years with >7 patients. Studies >10 years from the date of publication and/or studies with <8 patients were excluded.

Data Extraction

The data assessed from the studies included: Success rate, mean blood loss, mean operating time, length of hospital stay, major intraoperative complications, and conversion to open surgery.

Results

Within the limits of the literature search, 14 full-text articles met the aforementioned criteria. All articles were retrospective, there were no prospective studies or randomized controlled trials. From this review, a total of 269 patients underwent laparoscopic repair of VVF. Two hundred and thirty-one (85.9%) cases were primary repairs, while 38 (14.1%) cases had previous failed repairs. Nine out of the 14 series reviewed reported a success rate of 100%, the other series reported success rates of 98, 95.5, 91.6, 87.5, and 86%, respectively. Laparoscopic repair failed in only 9 out of the 269 patients (2 out of these 9 patients were those with previously failed repair). The pooled/overall success rate was 96.7%, while the success rates for those undergoing primary and previously failed repair were 96.9 and 94.7%, respectively. Mean blood loss ranged from 30 to 400 mL, length of hospital stay ranged from 1.1 to 7.8 days while the mean operating time ranged from 54 to 229 minutes. There was only one major intraoperative complication (bleeding), giving a complication rate of 0.37%. Two hundred and sixty-five (98.5%) cases were completed laparoscopically; only four patients had to be converted to open surgery due to severe adhesions, the overall/pooled conversion rate was 1.5% (Table 1).

Discussion

The first laparoscopic VVF repair was reported by Nezhat in 1994.[16] Like any advancement in medical practice, it was initially greeted with a lot of skepticism and criticism. However, over the years, this approach has come to be embraced and has gained more acceptance among fistula repair surgeons because of the available evidence which has proved it to be very effective. Meta-analysis and comparative studies have found the success rates between laparoscopic and open laparotomy to be comparable with a statistically significant shorter hospital stay and reduced blood loss.[6,12,20]

Previously, it was thought that the laparoscopic route may be associated with a lot of conversions to open surgery, this review has disproved that, as only 4 out of the 256 repairs were converted to open surgery. Interestingly, conversions were not due to a complication of laparoscopy *per se* but rather from dense intra-abdominal adhesions/fibrosis (due to previous surgeries) which in itself is a relative contraindication to laparoscopy.

It was also thought that laparoscopic repair may not be suitable for patients with previously failed repair; however, this review has revealed that the success rate for primary repair and those with previously failed repairs are comparable.

With a complication rate of <1% from this review, credence has been lent to the safety of the laparoscopic approach to VVF repair. The safety and minimal blood loss in laparoscopic repair may be attributed to the enhanced/magnified vision during surgery which affords the surgeon the benefit of dissecting tissues with a high degree of precision and accuracy without iatrogenic injury to adjacent structures. The pneumoperitoneum also functions as a hemostatic tamponade to help minimize blood loss.

The quick recovery period, reduced hospital stay, and better cosmesis associated with laparoscopic repair have shown that this approach confers on the patient some cost-benefit or cost-utility.

Laparoscopic repair of VVF is a highly technical and advanced laparoscopic procedure which involves a lot of intracorporeal suturing and knot tying, this underscores the need for proper training and skill acquisition to attain expertise and competence before it should be embarked upon. However, the advent of barbed sutures, which eliminates the need for knot tying, can enhance surgical efficiency and significantly shorten the operating time.[21]

Conclusion

The laparoscopic approach to the surgical management of VVF is effective, safe, and associated with minimal complications.

Fistula repair surgeons (particularly) in developing countries should acquire the necessary skills and acquaint themselves

Table 1: Outcome of laparoscopic vesicovaginal fistula repair

Studies	*No. of patients*	*Cure rate*	*Mean blood loss (mL)*	*Hospital stay (days)*	*Mean operating time (minutes)*	*Complication*	*Conversion*
Utrera et al.[7]	8	100	No data	4.7	150	0	0
Abdel-Karim et al.[8]	15	100	110	3.1	171.6	0	0
Miklos and Moore[9]	44	98	39	1.1	144.8	0	0
Sharma et al.[10]	22	100	75	5	140	0	0
Shuah[11]	22	86	180	4.5	145	0	3
Xiong et al.[12]	22	95.5	52	5.6	98.6	0	0
Chu et al.[13]	11	100	229.4	No data	80.2	0	0
Abreu and Tanaka[14]	8	87.5	No data	No data	No data	1	1
Javali et al.[15]	22	100	35	1.5	75	0	0
Mallikarjuna et al.[16]	20	100	30	2.5	54	0	0
Rizvi et al.[19]	8	100	60	No data	145	0	0
Zhang et al.[18]	18	100	95	5	135	0	0
González et al.[19]	36	91.6	No data	7.8	140.4	0	0
Ghosh et al.[20]	13	100	58.69	4	No data	0	0

with this route of repair in order for patients to benefit from the advantages which this approach confers.

Studies done so far on the laparoscopic repair of VVF have been retrospective studies. There is a need for prospective and randomized controlled trials to further substantiate and strengthen the already existing body of evidence.

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REVIEW ARTICLE

Antenatally Diagnosed Ovarian Cysts with Torsion Managed Laparoscopically

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Abstract

Aim and objective: To study the various types of laparoscopic management of antenatal ovarian torsion, their advantages, disadvantages, and its outcome in pregnancy.

Background: Ovarian torsion in pregnancy occurs at a rate of about 1 in 5,000 cases. It is a life-threatening condition if not attended to and intervened promptly. Recent years have seen the advent of laparoscopy as a preferred means of management for ovarian torsion in pregnancy. This review article analyzes a series of articles over a span of 5 years from 2014 to 2018 on laparoscopic management of ovarian torsion in pregnancy and its outcome.

Results: Various procedures like ovarian detorsion, cystectomy, ovarian cyst puncture, ovariopexy, shortening of the utero-ovarian ligament, and oophorectomy are performed by expert hands. While advantages include quick recovery and early discharge from hospital, disadvantages are a long learning curve and increased need for training. This has led to many uneventful pregnancies with term live births.

Conclusion: Each type of laparoscopic management for antenatal ovarian torsion has its pros and cons. Nevertheless, the outcome of the pregnancy has been excellent in the majority of the laparoscopically managed cases.

Clinical significance: Laparoscopic management of antenatal ovarian torsion has reduced intraoperative blood loss, improved postoperative pain, and led to a quick recovery, early discharge from hospital, and return to daily activities. Clinicians need to be adequately trained to be competent in performing various laparoscopic surgeries.

Keywords: Antenatal ovarian torsion, Laparoscopic ovarian detorsion, Utero-ovarian ligament.

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Background

Ovarian torsion is a common gynecological emergency. It is found to be the fifth most common gynecological surgical emergency.[1,2] This involves the twisting of the ovary in its pedicle, leading to ovarian infarction if it is not unwounded in time. Prompt identification and intervention are crucial in the management of ovarian torsion. Nevertheless, the clinical presentation can present as a diagnostic challenge for clinicians. Studies have shown 23–66% of cases were given accurate presurgical diagnosis.[3] Transvaginal ultrasound is the most widely used imaging modality to confirm clinical findings though it can be inconclusive at times.[4] Laparoscopy has enhanced the efficacy of management of ovarian torsion in pregnancy with advantages like less pain, speedy recovery, and shorter hospital stays[5] with an uneventful pregnancy.

Results

This review article analyzes a few articles related to laparoscopic management of ovarian torsion in pregnancy over 5 years between 2014 and 2018 to study its efficacy and its outcome in pregnancy. It includes retrospective case–control study, single-center study, and case reports that were selected manually from PubMed online. The results of the analysis of the selected articles are explained below with regards to various laparoscopic techniques in the management of ovarian torsion which ranges from ovarian detorsion, cystectomy, ovarian cyst puncture, ovariopexy, oophoropexy, shortening of the utero-ovarian ligament and oophorectomy, their advantages and disadvantages, and finally the outcome of pregnancy following the minimally invasive procedure.

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Management of ovarian torsion during pregnancy aims at saving not only the ovary but also the current and future pregnancies. Early intervention helps to possibly retain blood supply to the ovary and thereby avoiding oophorectomy due to gangrenous changes. Unwinding the torted utero-ovarian ligament re-establishes the blood supply. Oelsner et al.[6] did a retrospective analysis of 102 patients managed with surgical interventions for adnexal torsion. They reported that 91.3% of patients with bluish-black ovary regained normal function following detorsion. None of the patients developed pelvic or systemic thromboembolism which is a risk presumed to occur following detorsion of the adnexa.

At times, cystectomy is required in the case of a simple ovarian cyst or dermoid cyst. Ding et al.[7] had suggested removal of dermoid cyst in an endobag to avoid spillage into the abdominal cavity through laparoendoscopic single-site surgery (LESS).[7]

This procedure has been extensively studied as a safe mode of management as it involves easy removal of the specimen. With LESS, abdominal entry is safely accomplished using an open-entry technique. No additional incisions or ports are required. Also, it enhances the safety of the open-entry technique and facilitates directly visualized fascia closure. This is a relatively new technique that has been considered for surgery between 10 weeks and 20 weeks.[8] One concern with regards to LESS is the possibility of umbilical hernia, especially because of the laxity and abdominal stress during pregnancy. Nevertheless, a recent report revealed an overall low risk of umbilical hernia with the LESS procedure with a running mass closure with delayed absorbable suture.[9] Other drawbacks are technical difficulties and limited working space.

Blind abdominal access techniques, such as, direct insertion of trocars or use of a Veress needle should be performed carefully to avoid causing injury to the enlarged gravid uterus or displaced viscera. One should aim to practice minimal handling of the gravid uterus in any laparoscopic management of ovarian torsion.

Ovariopexy involves the fixation of the ovary to the abdominal wall. Munshi et al.[10] have done ovariopexy after ovarian detorsion and puncture of bilateral torted ovarian cyst in a case of spontaneous ovarian hyperstimulation syndrome in a singleton pregnancy. This secures the ovaries to its anatomical sites, reducing the recurrence of torsion.

Hosny[11] has illustrated oophoropexy as a method of management in emergency cases of ovarian torsion. This involves the fixation of the ovary by transfixing the trocar site closure needle with absorbable vicryl 2-0 suture through the ovary then picking the suture from another transfixing point through the ovary then tying the suture out around the sheath. Oophoropexy is a debatable procedure. While it is easier, faster, and more comfortable for managing ovarian torsion in pregnancy, it requires more training for suturing by laparoscopy.

Weitzman et al.[12] have elaborately explained about the shortening of the utero-ovarian ligament by laparoscopic Endoloop as an alternative to oophoropexy in the management of recurrent ovarian torsion. In this novel approach, a grasping forceps was passed through an Endoloop and then used to tent up the utero-ovarian ligament in the midsection. The Endoloop was then tightened, pulling the ovary close to the uterus, and shortening the utero-ovarian ligament. This method decreases ovarian mobility and the risk of bleeding. As much as this technique sounds promising, technical expertise is required and surgeons have to be trained appropriately.

Adnexal torsion with or without additional surgical procedures does not have much of an effect on the gestational age at delivery. Neither does it cause any adverse maternal or fetal outcome. Daykan et al.[13] did a retrospective case–control study of pregnancy outcomes after surgical intervention for adnexal torsion, in which both study and control groups provided similar results. The gestation age at delivery was around 38 weeks in both groups, so was the rate of preterm delivery. Also, there was no significant difference between the two groups in terms of neonatal outcome. Postoperatively, there was a 3.5% first-trimester miscarriage. This study further emphasizes the efficacy and safety of laparoscopic management of ovarian torsion in pregnancy.

Discussion

Torsion of the ovary is more commonly seen in the right ovary than the left ovary as the right tubo-ovarian ligament is longer and also due to the presence of a sigmoid colon on the left side. It is also evident in a patient with a history of *in vitro* fertilization and ovarian hyperstimulation syndrome.[10,14–16] As the ovary enlarges, it twists on its vascular pedicle and undergoes torsion. Pregnancy itself increases the risk of ovarian torsion. Other factors identified include the previous cesarean section and large ovaries, ovarian tumors, and prior tubal ligation. Intraoperatively, findings range from a mature teratoma like a dermoid cyst,[7] simple ovarian cyst,[17] benign para-ovarian cyst, and corpus luteal cyst.[18]

This condition is more commonly seen in the reproductive age group though it can be seen in any age group. Also, in pregnancy, it is encountered mostly during the first trimester with a few cases seen in the second trimester as well. While some antenatal women have unilateral ovarian torsion, bilateral torsion has also been cited, not to mention the recurrence of torsion on the same or contralateral side.[12]

Antenatal women usually present with abdominal pain, nausea, and vomiting with tenderness and rebound tenderness on abdominal palpation. However, clinical findings alone can be misleading, involving a spectrum of differential diagnoses. Hence, a transvaginal ultrasound plays a pivotal role in contributing to the clinical diagnosis. Doppler ultrasonography is highly specific for the adnexal torsion, but it is not a sensitive test.[19] Arterial blood flow may be seen in adnexal torsion cases, leading to false-negative results. The presence of flow does not exclude the torsion, instead suggests the viability of the ovary. Since torsion may be intermittent or one of the arteries may be twisted (uterine or ovarian) or only venous thrombosis may occur, blood flow may be observed in Doppler findings. The sonographic diagnosis is inaccurate in a third of cases.[20] Torsion without the involvement of the ovary does not exhibit any of the classic ultrasound findings other than a torted pedicle and therefore a sonographic diagnosis may be difficult. Discolored ovaries had a normal appearance at future surgeries, reinforcing the concept that an oophorectomy (after detorsion) should be the exception rather than the rule even if the ovary is bluish-black. This has some implications in our clinical practice. Training in pelvic ultrasound to complement clinical judgment and regular audits of treatment must be conducted to minimize pitfalls in diagnosis and management. An ultrasound examination cannot be used as a sole diagnostic criterion to confirm or exclude torsion and a clinical assessment takes precedence.

Until 1989, salpingo-oophorectomy has been the standard method of management for ovarian torsion until Mage et al.[21] introduced ovarian detorsion as a conservative alternative method for the same condition. This has proved to be a great success as the majority of ovarian torsion occurs in the reproductive age group where fertility is the main concern. By preserving the ovaries, one avoids premature ovarian failure and its consequences. In certain situations, even if the ovaries appear bluish-black or hemorrhagic intraoperatively, detorsion has been fruitful. The ovarian function has been observed following that in subsequent transvaginal ultrasound for follicular study, future unrelated laparotomy, and *in vitro* fertilization. As much is said regarding the benefits of detorsion, the risks associated with this procedure include sepsis, peritonitis due to toxins released by the ovary following reperfusion, and probable pulmonary embolism.

While laparoscopic ovarian detorsion helps to restore blood supply to the ovaries and preserve its function, one cannot predict the possibility of retorsion of the same ovary in the future. There are many novel approaches found by experts to prevent detorsion,

some of them being ovariopexy, oophoropexy, and shortening of the utero-ovarian ligament. These upcoming procedures can be promising but require clinicians to be adequately trained in performing them in an emergency.

Follow-up of patients managed laparoscopically for ovarian torsion in pregnancy is crucial. Postoperatively, they should be briefed about warning symptoms and signs like acute abdominal pain, nausea, vomiting and if so, to report to their clinicians as soon as possible. If there is any pathological finding during the surgery, the patient should be informed of the same and advised to follow-up with the concerned specialist following delivery. This completes the care plan for an antenatal patient diagnosed and managed laparoscopically for ovarian torsion.

Conclusion

Early diagnosis and appropriate surgical management of adnexal torsion is the only way to prevent complications and preserve the pregnancy. Laparoscopic surgery in early pregnancy causes no harm to the fetus and should be encouraged once the diagnosis is confirmed. Minimal handling of the gravid uterus in laparoscopy also plays a role in saving the pregnancy while performing various procedures to deal with ovarian torsion. Delaying the operation may lead to serious infection and jeopardize both the fetus and the mother. Each type of laparoscopic management has its pros and cons. Keeping in mind, clinicians require to be adequately trained in the same to be competent enough to operate in an emergency.

Clinical Significance

Laparoscopic surgery to correct ovarian torsion antenatally has its benefits and risks. The pros of treating ovarian torsion laparoscopically include less intraoperative blood loss, no need for large incisions on the abdomen, small or minimal scar postoperatively, less postoperative pain, shorter hospital stay, quick recovery, and faster return to daily activities. Just like a double-edged sword, laparoscopic management has its disadvantages that any clinician or patient should be aware of. Some of them include failure of entry into the abdomen, inadvertent injury to blood vessels like inferior epigastric artery in the abdominal wall while introducing the trocars through lateral ports, or injury to major abdominal vessels like aorta causing hemorrhage and blood transfusion, injury to organs like bowel and the probable need to convert to laparotomy. Hence, clinicians should be well acquainted with a prompt diagnosis of the condition, timely intervention, keeping in mind the risks associated with the procedure.

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CASE REPORT

Endoscopic Ectopic Thyroidectomy

Ramakrishnapillai Padmakumar[1], Aravind Balakrishnan[2], Madhukara Pai[3], Kevin J Chiramel[4], Farish Shams[5], Premna Subin[6]

Abstract

Aim and objective: To show the advantage of endoscopic approach for lateral ectopic thyroid removal.

Background: Ectopic thyroid tissue lateral to midline is very rare. Because of its unusual location, lateral ectopic thyroid gland can cause diagnostic difficulties when diseased.

Case description: Here we are presenting a case of a male patient with submandibular ectopic thyroid tissue with multinodular goiter and absent thyroid tissue in normal anatomic site. He underwent endoscopic-assisted total thyroidectomy. This technique for ectopic thyroid removal has not been reported in the literature so far.

Conclusion: Endoscopic approach for removal of the diseased gland will allow for a magnified view of the adjoining structures and better cosmesis for the patient.

Clinical significance: Lateral ectopic thyroid should be in differential diagnosis of lateral neck swelling.

Keywords: Ectopic thyroid, Endoscopic, Endoscopic thyroidectomy, Minimal access surgery, Submandibular region.

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Background

Ectopic thyroid tissue usually occurs in the midline and that too most commonly in cervical region (lingual 90%).[1–4] Its prevalence is approximately 1/100,000 to 1/300,000.[5] The remaining ectopic thyroid glands (10%) can be found in infrahyoid, submandibular, prelaryngeal, mediastinum, esophagus, heart, diaphragm, and parapharyngeal regions. In most of the cases, the ectopic thyroid gland will be the only functioning gland. Ectopic thyroid tissue lateral to midline is very rare. These lateral ectopic thyroid tissues when diseased may lead to difficulty in diagnosis due to its unexpected location. Here we are going to present a case of a male patient with submandibular ectopic thyroid tissue with multinodular goiter and absent normal tissue in normal anatomic site. He underwent endoscopic-assisted total thyroidectomy. This technique for ectopic thyroid removal has not been reported in literature so far.

Case Description

A 58-year-old male patient presented to our department with complaints of a swelling in the upper neck on left submandibular region for about 6 months.

It was associated with rapid increase in size. There were no other associated symptoms. On examination, a 5 × 3 cm painless swelling was noted in the left submandibular region. The lump was soft in consistency. Thyroid tissue was not palpable in the normal anatomical location (Fig. 1).

Ultrasonography revealed a well-circumscribed heterogeneously hyperechoic nodule in the left submandibular region with absent thyroid gland in the thyroid bed—possibly ectopic thyroid nodule. Fine-needle aspiration biopsy of the swelling was taken which revealed colloid goiter. Thyroid scintigraphy revealed an area of increased radionuclide uptake in the submandibular region and no radionuclide uptake was seen in the neck in the thyroid bed.

Preoperative thyroid hormones and biochemical tests were normal. As gland was enlarging rapidly in size, endoscopic-assisted complete removal of ectopic thyroid tissues was done under general anesthesia. Initially, the gland was approached from left axillary breast ports. We dissected the gland from the surrounding tissues by endoscopic method. For retrieval of specimen, we put a

Fig. 1: Extended neck showing submandibular ectopic thyroid gland

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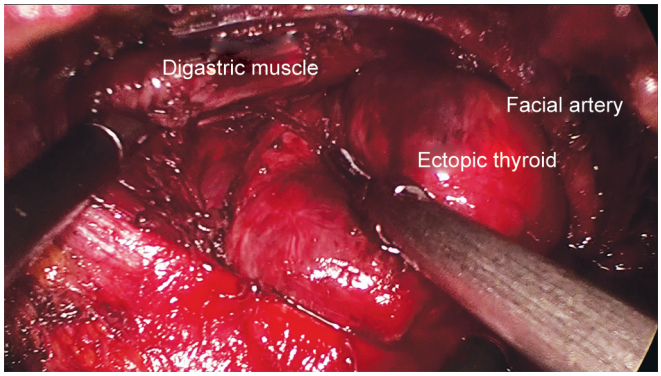

Fig. 2: Ectopic thyroid in relation with surrounding structures

small skin incision in the submandibular region and the specimen was removed in toto (Fig. 2). This helped in significantly minimizing the scar in cervical region.

Postoperative period was uneventful, and he was discharged on third postoperative day. Thyroxine 100 µg was started, as there was no other functioning thyroid gland. Histopathology report showed features consistent with multinodular colloid goiter.

Discussion

Ectopic thyroid in the submandibular region was first described by Helidonis et al.[6] They speculated that the ectopic thyroid has a parahyoid location and because of its dimension resembled a submandibular gland anomaly. Abnormalities of thyroid gland during embryologic development and migration may result in ectopic thyroid gland. Normally, migration of the thyroid gland is from the foramen cecum to the pretracheal position.[7] In addition to normal migration pathway of the thyroid gland, ectopic thyroid tissue can be seen even in mediastinal, intracardiac, gastrointestinal, and intraperitoneal locations.[4,8,9] Ectopic thyroid tissue is mostly (90%) localized in sublingual position.

Asymptomatic ectopic thyroid tissue may become symptomatic, particularly in the adolescence and pregnancy period due to increase in thyroid-stimulating hormone level and due to thyroid tissue hyperplasia.[10,11] All diseases that involve thyroid tissue in its normal location can also involve ectopic thyroid tissue. The differential diagnosis should include thyroglossal duct cyst, hyperplastic lymphoid tissue, lymphangioma, fibroma, lipoma, dermoid cyst, squamous cell carcinoma, minor salivary gland tumor, lymphoma, and vascular tumors.[12,13]

Ultrasonography (USG), scintigraphy, computerized tomographic scan (CT), and magnetic resonance imaging (MRI) are the methods that can be used in the diagnosis. Thyroid scintigraphy is a sensitive and specific method in determining that thyroid gland is not in its normal location.[13] USG and CT are beneficial in the diagnosis but have low sensitivity and specificity. In MRI, ectopic tissue is observed to be iso- or hyperintense compared to muscles.[13] In addition to imaging of the normal thyroid tissue, thyroid scintigraphy is also important to show the functions of the lingual thyroid tissue. In our case, we performed USG followed by FNAC and then thyroid scintigraphy was performed for confirmation of our diagnosis. All the surgeries performed for lateral ectopic thyroid so far has been by open method. We performed an endoscopic-assisted total thyroidectomy which has not been reported in literature so far. Endoscopic approach for removal of the diseased thyroid gland will give a magnified view of the adjoining structures and better cosmesis for the patient.

Conclusion

Lateral ectopic thyroid tissue is a very rare condition of which most common site is in submandibular location. Endoscopic approach for removal of the diseased ectopic gland has not been reported earlier. The procedure is very safe and gives a much better cosmetic outcome.

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CASE REPORT

Laparoscopic Management of Suspected Vault Recurrence Following Staging Surgery of Endometrial Cancer

Ajay Agrawal[1], Kuan-Gen Huang[2]

Abstract

Background: Postoperative issues with the vaginal vault after hysterectomy for benign or malignant conditions are not common. However, these include vault hematoma, granuloma, keloid, incisional hernia, vascular formation, and recurrence of pelvic malignancy at the vault.

Case description: A 47-year-old woman with a history of breast cancer surgery under tamoxifen developed endometrial carcinoma stage 1 for which she underwent staging laparoscopy 1 year ago. She presented with a vaginal cuff tumor of 3 cm detected vaginally 3 months later which was suspicious of recurrence. Laparoscopic management was done and circumferential excision of vaginal cuff margin and repair was done. The final pathology report revealed infection and granulation tissue in the excised margin.

Conclusion: Management of vaginal cuff complications following hysterectomy can be feasible by minimally invasive surgery regardless of indication of primary surgery.

Keywords: Endometrial cancer, Laparoscopic management, Vault recurrence.

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Background

Postoperative issues with the vaginal vault after hysterectomy are not very common. These complications include vault hematoma, granuloma, keloid, incisional hernia, vascular formation, fistula, prolapse of the oviduct, and recurrence of pelvic malignancy at the vault.[1] Out of these, vaginal vault granulation is a commonly observed benign sequela of hysterectomy. Regarding the recurrence of pelvic malignancy, approximately 6–13% of all patients with endometrial cancer will develop the recurrent disease and most of these are located at the vaginal vault.[2] Indications for surgical treatment depend on resectability, site and size of the tumor, and performance status of the patient. Both these conditions have a common initial presentation with vaginal bleeding, discharge, and fleshy growth in the vaginal cuff. Here, we present a case of a woman who was suspected to have vaginal cuff recurrence following staging laparoscopy done for endometrial cancer.

Case Description

A 47-year-old woman with right breast infiltrative ductal carcinoma had surgical treatment in 2015 at Chang Gung Memorial Hospital, Linkou, Taiwan and was under regular follow-up. She was under tamoxifen with yearly surveillance of her endometrial thickness. Three years later, she had abnormal endometrial thickness which on hysteroscopic biopsy was proven to be endometrial cancer. So, she underwent staging laparoscopy with total hysterectomy and adnexal removal in January 2019. Histopathology revealed The International Federation of Gynecology and Obstetrics (FIGO) stage 1a grade I endometrial cancer.

Three months later, she presented with a vaginal discharge of 2 weeks duration. On vaginal exam using a colposcopy, there was a cuff lesion with the appearance of ulcer or granulation tissue, over a nodule of 3 cm, which was angry red, velvety, and bled on touch (Fig. 1). Vaginal biopsy showed acute on chronic inflammation and magnetic resonance imaging (MRI) of the abdomen revealed

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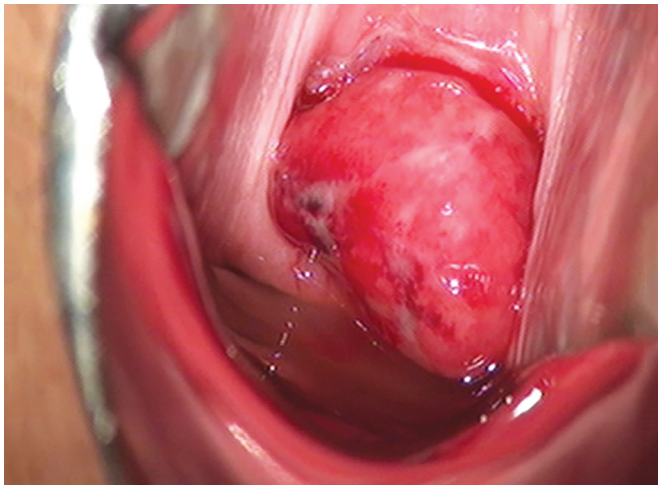

Fig. 1: Colposcopy shows red, velvety vaginal cuff with some swelling which bled on touch

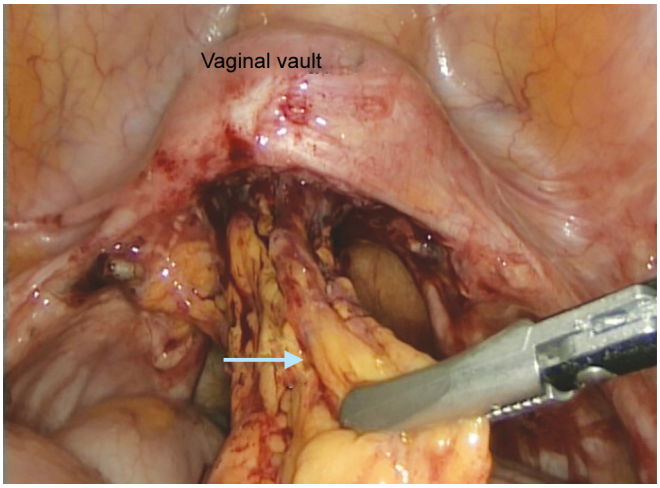

Fig. 2: Vaginal vault with the loop of omentum adhered (arrow)

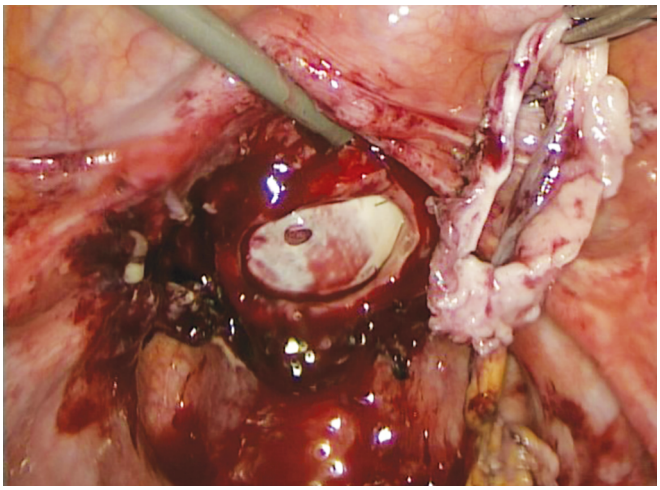

Fig. 3: Excised margin with remaining vaginal cuff ready for repair

nodularity at the tip of the vaginal stump, with focal M-shape folding. Its impression was postoperative change with superficial recurrence cannot be completely excluded. Following this four-port laparoscopy with 10 mm primary port at umbilicus was done. Intraoperatively, adhesiolysis was done for the loop of omentum adhered to the vault (Fig. 2). The assistant inserted gauze on sponge forceps in the vagina to push it through the vagina to show margins of the vault. Dissection was done all around the mass to excise the unhealthy cuff and get a good healthy cuff margin (Fig. 3) for better repair and healing. Once excised, the specimen is retrieved vaginally and sent for a frozen section which revealed granulation tissue with inflammation which was confirmed later. Closure of vaginal cuff with 1-0 suture (absorbable) in double-layer was done. Intraperitoneal drain was inserted to reduce the risk of infection and coverage with postoperative antibiotics for 1 week was given. She had an uneventful postoperative period and was discharged on 3rd day. Her follow-up till 6 months post-surgery was uneventful with healed vaginal cuff.

Discussion

Vaginal vault recurrence after hysterectomy for gynecologic malignancies is a well-recognized problem, and this has led to protocols for adjuvant therapy to prevent their occurrence.[3]

Women often do not seek gynecologic care, particularly after hysterectomy. Additionally, women with a history of gynecologic malignancy may be followed by various primary care physicians, and oncologic surveillance may be focused more on distal than the local disease. The vaginal vault may be the first site of recurrence of genital tract neoplasms. Once vault recurrence is diagnosed, treatment is planned after the completion of a metastatic workup. The standard treatment is radiotherapy (RT) which is effective for local control and the effect has been documented in prospective studies. Surgical treatment has also been advocated in isolated vault recurrence.

However, signs and symptoms of vault recurrence frequently mimic extensive vault granulation. This is a common postoperative complication after total hysterectomy for benign or malignant lesions but little reports have been published. Most of the time small granulation over the cuff is self-limiting and can be treated by chemical coagulation, such as, silver nitrate or thermal coagulation. A large lesion as described in this case report needs excision.

The proper recognition and differentiation between granulation tissue and possible recurrent malignant tissue are most important in patients who have been operated upon for malignant disease of the female pelvis. A biopsy of apparent granulation tissue in such patients is, therefore, necessary before treatment is instituted.

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Innovative Technique to Control the COVID-19 Transmission by Laparoscopic Fume: Could It be Possible to Capture the Betal inside the Bottle?

Ashok Kumar[1], Nalinikanta Ghosh[2]

Abstract

Aim and objective: This article aims to conceptualize the modification in the laparoscopic port to minimize the risk of COVID-19 virus transmission through the aerosol during laparoscopic procedures.

Background: A recent situation of COVID-19 pandemic has produced so many new unknown challenges for surgeons. Surgical fume is a known theoretical biohazard for the operating team. There are many suggestions from the international and national surgical societies and already available equipment which could minimize the risk transmission. Still, there is no technique available to contain and discharge surgical fume in the proper way. Here, we conceptualize a technique to reduce the risk of COVID-19 transmission in the operating team.

Technique: Here, we have suggested the modification in the laparoscopic port. We advise adding an intermediate transparent, pliable, polythene/silicon bag that could able to contain the leaked surgical fume and safely discharge in an underwater seal bottle, filled with sanitizer liquid.

Conclusion: The theoretical, potential risk of COVID-19 transmission during laparoscopic surgery has raised many doubts and apprehension of virus transmission through the surgical fume. There are many suggestions and available equipment to minimize the spread; however, no definite solution already out surgical fume; here, our suggestion of modification in port could be a permanent solution to the surgical fume problem. However, this is an initial concept that has the potential to addition and suggestion to improve the technique.

Clinical significance: The theoretical risk of surgical fume causing COVID-19 virus transmissions completely changes our surgical practice. Here, in this article, we suggested our concept and technique contain and safely discharge of surgical fume during laparoscopic surgery.

Keywords: COVID-19, SARS-CoV-2, Surgical smoke, Viral transmission.

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Background

The recent scenario of the COVID-19 pandemic has changed the indications of emergency surgery and has been making significant changes in the algorithm of surgical disease management. The theoretical concern of COVID-19 viral transmission during open or laparoscopic surgeries is the main topic of debate in a recent situation. There are known advantages of minimally invasive surgery, e.g., less postoperative pain, early recovery, shorter hospital stay, in turn, is increasing availability of beds in limited recourses and ultimately better outcomes.[1] However, we are unable to take the full advantages of laparoscopic surgery in the COVID-19 pandemic due to concern of virus transmission through surgical fume. Laparoscopic surgery provides a self-contained operative field which significantly minimized the risk of direct contact with biological fluid or tissue.[2] There are many suggestions and available equipment to minimize the risk of transmission. However, no advice or device contained unavoidable leaked fume which is already out from the abdominal cavity. Here, in this article, we conceptualized and proposed the technique to contain and discharge the surgical fume.

Technique

Concept behind This Technique

All reported advantages of laparoscopic surgery over open surgery in the COVID-19 scenario, in terms of shorter hospital stay and less chance of spread of infection (fewer chances of exposure to biological fluids and tissue are taken away from due to a theoretical risk of COVID-19 transmission). This is theorized that aerosol and fume generated during the use of energy sources may cause transmission of virus infection. There are few steps during laparoscopic surgery where the operating team might come in contact with aerosol/surgical fume.

- At the time of insertion of the first port where the pneumoperitoneum created with a closed technique.
- Insertion of other ports for instruments or cameras.
- Repeated insertion of scope or instruments during the procedure (where CO_2 can leak by the side of the instrument).
- The usual practice of deflation CO_2 through the stopcock at the time of repeated fogging of a camera lens.
- At the end of the procedure during deflation of the abdomen.

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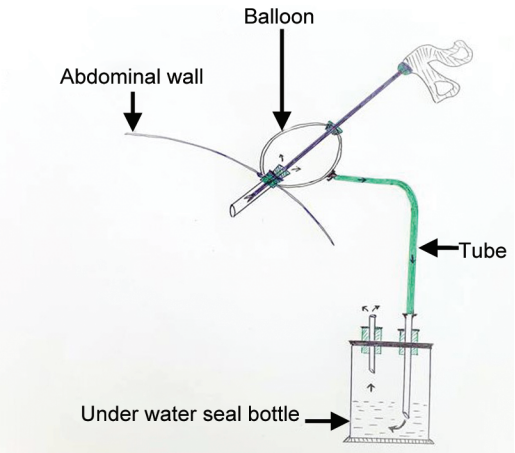

Fig. 1: Proposed concept of an innovative technique to contain and discharge the surgical fume

Two main goals to control surgical fume during laparoscopic surgery.

- Containment of leaking, CO_2/aerosol fume during a laparoscopic procedure, and deflation.
- Safe discharge of surgical fume/CO_2.

Chance of further leak is less?

- The volume of the leak will be less in comparison to abdominal CO_2 gas volume and continuously discharging in an underwater seal bottle.
- The pressure inside the balloon is less as compared to the inside of the abdomen (compressed air).
- All surgical fume/CO_2 collected inside the balloon could also be drained underwater seal bottle intermittently.

Here, we have suggested modification in laparoscopic port to contain the surgical fume by placing intermediate reservoir balloon on which could be pliable and transparent to allowed hazel free insertion and movements of the instrument during the laparoscopic procedure and with one outlet nozzle (with stopcock) for controlled discharge of surgical fume in underwater seal bottle which is already filled with sanitizer/viricidal liquid. Underwater seal drain prevents the backflow of fume and filled viricidal liquid could able to kill the virus (Fig. 1).

Here, we utilized Jackson–Pratt abdominal drain to make a prototype of this device. We utilized a drain bulb (pliable and transparent) for purpose of the intermediate reservoir balloon and have an outlet port and tube with stopper for control discharge of fume. As shown in Figures 2 and 3, we placed the port sleeve through the inside of the balloon and another (shorten) same size port sleeve with cannula handle in the opposite wall of a balloon in the same trajectory. Here, we have to place the laparoscopic instrument through the outer port go through the balloon, inner port then inside the abdominal cavity, which allows us to collect the leak fume inside the balloon and could discharge in water seal intercostal drain (ICD) bottle that is already filled with viricidal liquid. The above modification in the laparoscopic port might be able to stop any egress of any aerosol during all steps of laparoscopic surgery in the operation theater atmosphere.

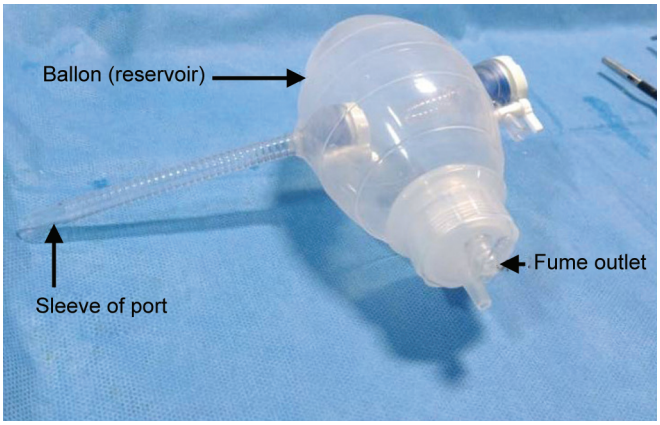

Fig. 2: Modified port: Made by Jackson–Pratt abdominal drain bulb

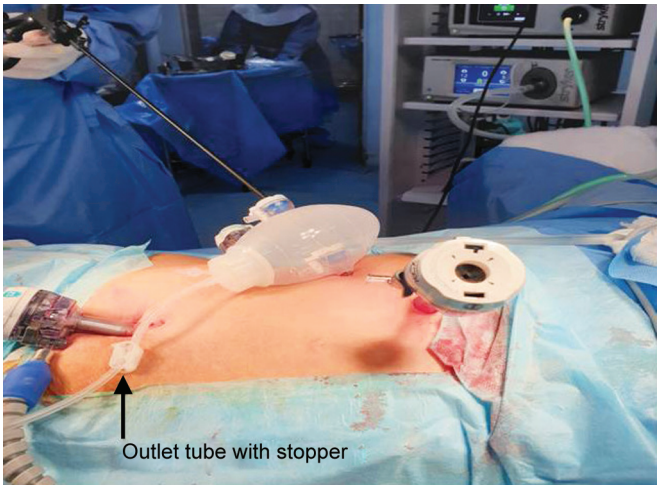

Fig. 3: Performing a laparoscopic procedure with a modified laparoscopic port

Discussion

The scenario of the COVID-19 pandemic has completely changed the surgical practice due to doubts and the risk of transmission during surgical procedures. The vulnerability of virus transmission forces the surgeon communities to make changes in their strategies and adopt innovative safety practices. There are well-documented advantages of laparoscopic surgery, e.g., short hospital stay (more availability of a bed in limited resources in the recent scenario) and self-content operative field which further decreases the chances of viral transmission. The theoretical risk of COVID-19 transmission during laparoscopic surgery due to compressed CO_2 leak or fume/aerosol, form during the use of energy source created invalidated doubt and fear. The risk of transmission is not only limited to laparoscopic surgery, open surgery also has equal chances of transmission of COVID-19 due to direct contact of the intestinal mucosa, biological fluid, and surgical aerosol formed during the use of energy sources. Complete control of the peri-instrument leak of CO_2 (port leak) during the laparoscopic procedure is unavoidable. However, if anyhow we could able to contain aerosol and discharge in control way then we could possible to avoid leakage and could get all the advantages of minimally invasive surgery.

There are several reports where the virus, e.g., hepatitis B virus (HBV), human immunodeficiency virus (HIV), bovine papillomavirus, and human papillomavirus (HPV) harvest from surgical plume generated by energy sources. Most of the published reports on the risk of transmission seen *in vitro* analyzes. There are reports of HPV transmission during the treatment of laryngeal papillomatosis.[3] Although there was no biological activity or transmission potential seen in obtained viral DNA.[4] Although there are reports of viable HIV that have been harvested in cell culture; however, the potential risk of contamination by fume could not able to prove,[5,6] and there are not enough data available which able advice to differing the laparoscopic surgery or its replacement by open surgery.[7]

Although there are reports which suggested the presence of virus DNA in the laparoscopic plume; however, no study was able to prove their potential risk for transmission of viral. Several international and national surgical societies have suggested strategies and recommendations minimize the risk of transmission.

According to the Royal College of Surgeons, laparoscopy should only be considered in select individual cases. The Society of American Gastrointestinal and Endoscopic Surgeon (SAGES) states that in the recent pandemic, the use of filters for the released CO_2 during laparoscopy and robotic surgery should consider avoiding the COVID-19 transmission. There are many suggestions by experts and adopted strategies from surgical societies to decrease the risk of viral transmission. Most important is to avoid the traditional practice of opening port outlet stopcock at the time of fogging of a camera lens and uncontrolled deflation of the abdomen at the end of laparoscopic procedures. This entire maneuver should control and under the vision to avoid diffusion of surgical fume in the operation theater. Better to avoid the practice to reuse laparoscopic ports with a tear or damaged one-way valves during procedures.

There are many different insufflation systems and independent smoke evacuation system which could supplement with conventional insufflators in the present situation of COVID-19 pandemic. ConMed Air Seal® and PneumoClear are available integrated insufflators, PneumoClear has the added feature of controlled deflation at the end of the procedure.[8] There is much advice from experts to decrease the chance of virus transmission. Operating on low intra-abdominal CO_2 volume and keeping insufflation pressure, lower than the standard 12–15 mm Hg[9,10] looks more logical and feasible. This way we could able avoids gush of CO_2/fume during port manipulation/instrument exchange. Some experts also suggested keeping low settings of energy devices.

Although there are many suggestions given by surgical societies and experts, e.g., keeping energy sources on lower settings, keeping the low intra-abdominal CO_2 volume and low pneumoperitoneum pressure, and under vision evacuation of CO_2/surgical fume. However, there are no strategies to contain the surgical fume when it is already out through the port.

Here, we have described the technique where we can contain the fume in the transparent/pliable bag and could safely discharge in the sanitizer-filled (underwater seal) system.

Conclusion

The recent pandemic of the COVID-19 virus which highly contagious came with many challenges in the surgical field. Most important is the risk of transmission through aerosol/surgical fume produced during laparoscopic surgery. Here, we have not any evidence basis for the above statement; however, the existence of transmission cannot deny. There are so many suggestions and tactics by surgical societies and experts and few already available devices to reduce fume leak. Still, there is a suggestion or solution to contain the fume/CO_2 which is already out from the abdominal cavity. Here, we conceptualized a technique to contain the leaked CO_2/aerosol and its safe discharge. This concept further needs addition and improvement could provide all advantages of laparoscopic surgery in a safe and fearless environment.

Clinical Significance

COVID-19 pandemic came with a theoretical risk of surgical fume causing disease transmission. However, no reports mentioned that surgical fume could transmit the infection, yet we could not deny its existence till we find any further evidence basis. In this article, we have suggested an innovative technique to contain the surgical fume in an intermediate balloon and its proper discharge. We hope that our concept and technique would able to control surgical fume and provide a fearless and safe environment for the operative team.

Declaration of Patient Consent

We have obtained consent from patients or close kin for the images and other clinical information to be reported in the journal. They understand that the names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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