Diagnostic and Therapeutic Endoscopy

Single-Port Laparoscopy, NOTES, and Endoluminal Surgery

Guest Editors: Pedro F. Escobar, Jihad H. Kaouk, Daniel Geisler, Matthew Kroh, Amanda Nickles Fader, and Tommaso Falcone

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Editorial Board

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Editorial

Single-Port Laparoscopy, NOTES, and Endoluminal Surgery

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Minimally invasive surgery has become the standard treatment for many disease processes. In the last decade, numerous studies have demonstrated that laparoscopic approaches to various conditions have improved the quality of life with comparable surgical and oncologic outcomes to standard open procedures. Recently, an alternative to conventional laparoscopy or robotic surgery has been developed: laparoendoscopic single-site surgery (LESS), also known as single-port surgery. Single-port laparoscopy is an attempt to further enhance the cosmetic benefits of minimally invasive surgery while minimizing the potential morbidity associated with multiple incisions. In this special issue, we will focus on 2 articles relevant to the advancement and practice of LESS.

This new modality presents unique challenges, such as instrument crowding and the need to move and control a flexible camera and articulating instruments together, requiring even more advanced laparoscopic skills. Information about training and education on single-port laparoscopy is scarce in the current literature: Ramalingam et al. present their initial experience and methodology in training and education regarding this new technique. Formal training in this technique is not widely available. Expensive ports and instrumentation may be factors deterring the training. The authors address a major gap in the literature, how to train surgeons in this technique? They modified the standard laparoscopic endotrainer with improvised ports, to make it suitable for single-port laparoscopic training. For the animal lab training, they improvised ports and low-cost instruments. Thus, the overall cost of the training in LESS was reduced, and better confidence levels were achieved prior to human applications. Perhaps this will stimulate others to look at adopting this relatively low-tech technique for training in LESS.

Emerging data on LESS has been reported in general surgical, gynecologic, and urologic procedures. LESS, for renal surgery, was first reported in 2007, and, since then, a handful of authors have described variations of their techniques. Derweesh and coauthors present the first prospective report in the literature of LESS radical nephrectomy with renal vein thrombectomy and cytoreductive nephrectomy. As such, this report further corroborates that increasingly complex procedures can be safely performed with the LESS platform. The feasibility of LESS for complex surgical procedures is no longer an issue. Current research and development in single-port robotics is ongoing. A single-port robotic platform may overcome technical limitations of single-site surgery (instrument crowding, lack of triangulation, and loss of depth of perception/instability with current 2D flexible optics). More importantly, it may play an essential role in the reproducibility and diffusion of LESS. Prospective studies are needed to assess the relative benefits of LESS compared with more conventional minimally invasive approaches.

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Clinical Study

Cost Reductive Laparoendoscopic Single Site Surgery Endotrainer and Animal Lab Training—Our Methodology

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Laparoendoscopic single site surgery (LESS) is a new avenue in laparoscopic urology. The main advantage is the enhanced cosmetic benefits of single hidden scar. Lately many papers are being published on various procedures done by LESS. Like conventional laparoscopy, this approach is likely to be used more widely and hence exposure to this field is essential. However, formal training in this technique is not widely available. Expensive ports and nonavailability of endotrainer may be the factors deterring the training. We have modified the standard laparoscopic endotrainer with improvised ports, to make it suitable for single port laparoscopic training. For the animal lab training improvised ports and low cost instruments were used. Thus the overall cost of the training in LESS was reduced, and better confidence levels were achieved prior to human applications.

1. Introduction

Laparoendoscopic single site surgery (LESS) is a new avenue in laparoscopic urology. The main advantage is the enhanced cosmetic benefits of single hidden scar [1]. Lately many papers are being published on various procedures done by LESS [2]. Like conventional laparoscopy, this approach is likely to be used widely in future and hence exposure to this field is essential. However, formal training in this technique is not available. Expensive ports and nonavailability of endotrainer may be the factors deterring the training. We have modified the standard laparoscopic endotrainer. Port was improvised, to make it suitable for this procedure. For the animal lab training improvised ports and low cost instruments were used. Thus the overall cost of the training in LESS was reduced and better confidence levels were achieved prior to human applications.

2. Materials and Methods

The LESS Endotrainer. The endotrainer we have designed is a cuboidal box with the dimensions of 35 cm × 28 cm × 18 cm. These dimensions are developed, such that, they nearly correspond to the normal adult peritoneal cavity. The space is adequate for the placement of instruments and training objects. The standard laparoscopic endotrainer consists of three port sites. For single port training, we modified the central port with a multiport system measuring 2.5 cm in diameter. Various materials like rubber sheet for the multiport platform, and plastic tubes or short used 10 mm and 5 mm plastic ports for the trocars were used. Once assembled, this multiport system consisted of a 10 mm port for insertion of endocamera and two 5 mm ports for insertion of hand instruments (Figures 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10) . The endocamera could be replaced by a webcamera as in the standard endotrainer box when there is no assistant.

3. Instruments and Training

The instruments for LESS training are designed with an angulation in the distal end to prevent the clashing of instruments. Angulated Maryland dissector and curved scissors without angulation are used for dissection. Standard needle holder is used for suturing. The reticulating instruments are also used during the training.

Figure 1: LESS endotrainer with modified port (1).

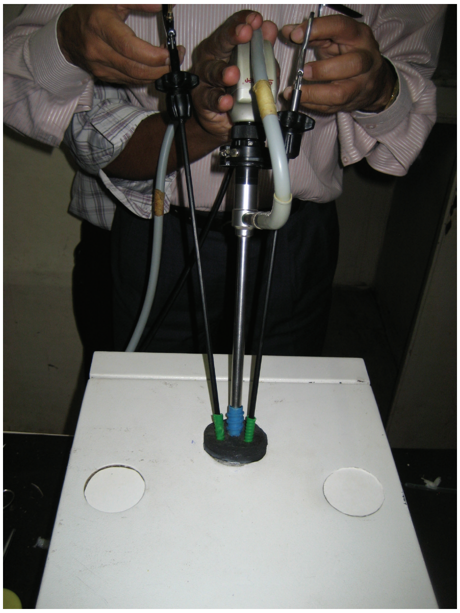

Figure 2: Modified LESS endotrainer port (2) being used for training.

Training pattern for single port laparoscopy was similar to conventional laparoscopic training. Hand eye coordination, dissection, and suturing exercises were carried out. The hand eye co-ordination exercises included transfer of objects between the instruments and transfer between bowls placed within the trainer. The technique of dissection was by peeling orange skin (Figure 11) and dissecting a chicken leg model (Figure 12). Suturing was practiced on chicken leg and cadaver bovine kidney ureteropelvic junction (UPJ) (Figure 13).

Evaluation of training. We conducted training sessions among 3 of our faculty, who are experienced laparoscopic surgeons, using our LESS endotrainer. A total of 10 sessions were carried out by each of the consultants over a period of 10 days. Objective assessment was done using the task completion time (TCT) [3] as the unit of measurement.

Figure 3: Modified LESS endotrainer port (2).

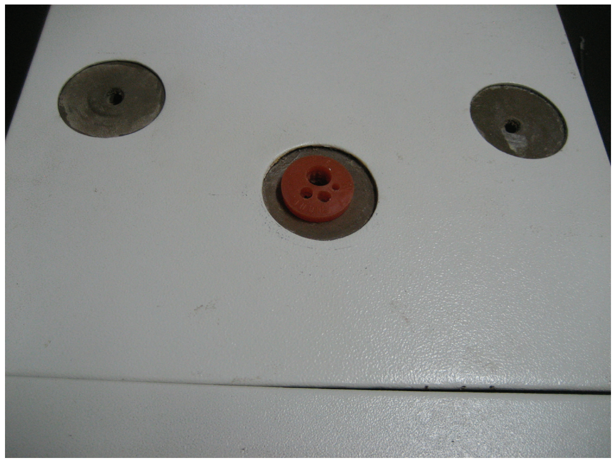

Figure 4: Endotrainer in our center with modified single port (3).

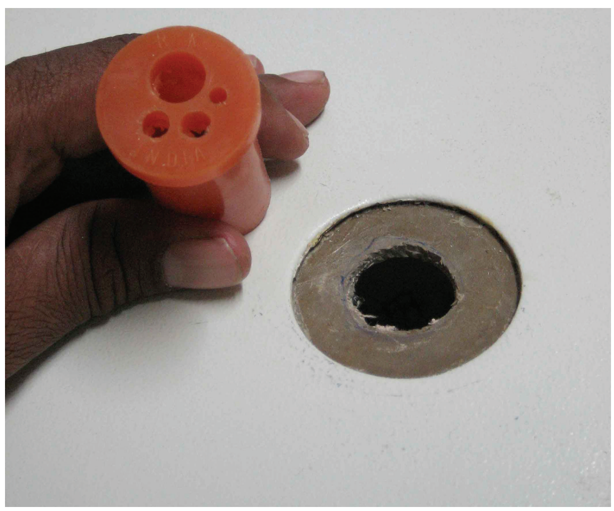

Figure 5: Standard endotrainer with modified port (3).

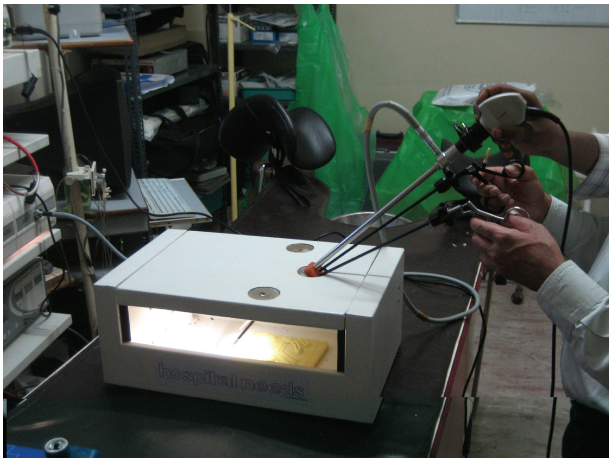

Figure 6: LESS Endotrainer with modified port (3). Note the crowding of instruments.

Figure 7: LESS Endotrainer setup.

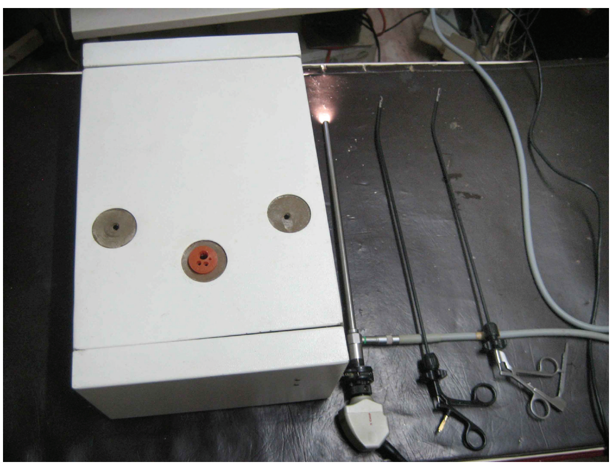

Figure 8: Single port endotrainer with angulated instruments.

Figure 9: Modified LESS port (4) lateral view.

Figure 10: Modified LESS port (4).

Complete peeling of orange and suturing of UPJ in cadaver bovine kidney (six interrupted sutures) were the two tasks assessed at the first, sixth, and tenth sessions. After completion of the endotrainer sessions, animal lab training was carried out on a live anesthetised pig using single port (Figures 14 and 15).

4. Results

The results are summarized in the form of a chart (Figure 16). The results showed that with each passing session the subjective difficulty of the procedure decreased. Statistical analysis was done using SPSS software. The average TCT decreased as the sessions progressed from the first attempt to fifth attempt and tenth attempt. The correlation coefficient of the TCT was -0.8 and -0.9 for orange peel and bovine model suturing, respectively. This shows that, with the progression of sessions, the task completion time significantly decreases. The difference in the TCT of both orange peeling and suturing between sessions 1, 5, and 10 was highly significant ($P < .0001$) (Table 1).

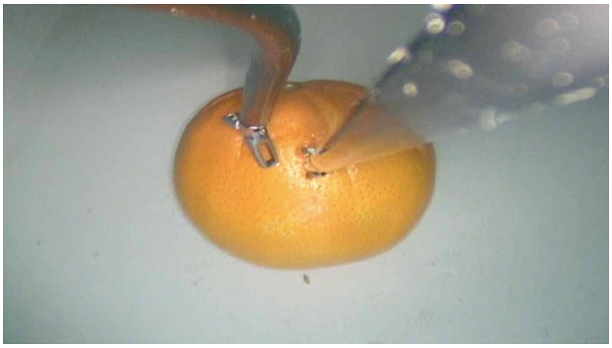

Figure 11: Orange dissection.

Figure 12: Chicken dissection in the LESS endotrainer.

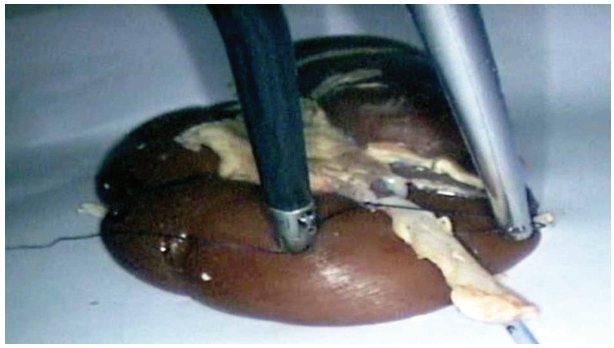

Figure 13: Suturing in Bovine kidney.

Figure 14: LESS in live pig—in progress.

Table 1: Task completion time—Results.

Task	Session	Mean duration	Variance	SD	P-values
Orange peel	1	53.33	58.33	7.6	.0009
	5	41.33	69.33	8.3	
	10	34.66	33.33	5.73	
Suturing	1	137.33	241.33	15.5	.0005
	5	112.33	366.33	19.1	
	10	99.66	276.33	16.6	

After 10 endotrainer sessions pig nephrectomy was attempted. The average duration was around 90 minutes. The average duration of conventional laparoscopic nephrectomy in the porcine model in the past used to be about 45 minutes as per the previous records of our faculty. The major difficulty encountered by the surgeons was the clashing of instruments and their orientation. No major complications were encountered during the procedure. Hemostasis was ensured using monopolar electrocautery.

5. Discussion

Wickham introduced the field of Laparoscopy to Urology [4] by performing the first laparoscopic ureterolithotomy in 1979. However laparoscopy gained momentum only after Clayman did a laparoscopic simple nephrectomy in 1991 [5]. Today more and more ablative and reconstructive laparoscopic procedures are performed widely. With experience and continuous training, the duration of surgeries got significantly reduced [6]. With the increasing interest on cosmesis, the sizes of the ports and instruments were reduced from 12 mm to 1.8 mm [7]. To make this further cosmetically appealing and minimally invasive, new avenues like natural orifice transluminal endoscopic and single site laparoscopic surgery (LESS) evolved.

LESS was introduced in Urology by Gettman et al. in 2002 by performing a transvaginal laparoscopic nephrectomy in a porcine model [8]. The first paper on LESS in humans was published by Raman et al. in 2007 [9]. Since then few centers are performing more and more of LESS procedures. In the present scenario, the duration of surgery for LESS is considerably prolonged compared to conventional laparoscopy [10].

With adequate training and experience, LESS can also be performed more widely. However compared to conventional laparoscopic training programmes, organized training programmes for LESS is not available widely at the moment. Endotrainers are also freely available for the conventional laparoscopic training. However, to our knowledge, no literature has been published on the use of endotrainers for LESS. This may be because of the cost of the single ports resources, and mentor availability. Further more, animal lab training

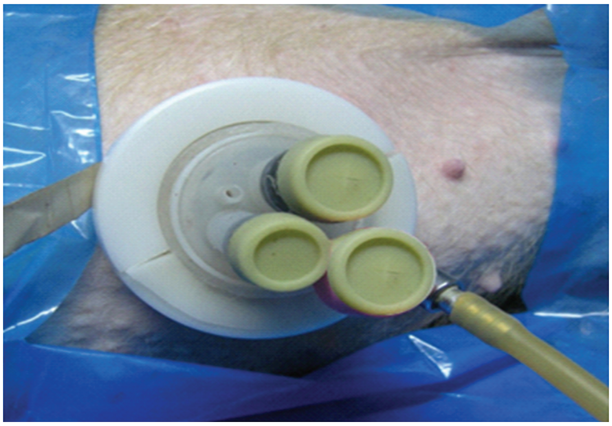

Figure 15: Modified single port in live animal.

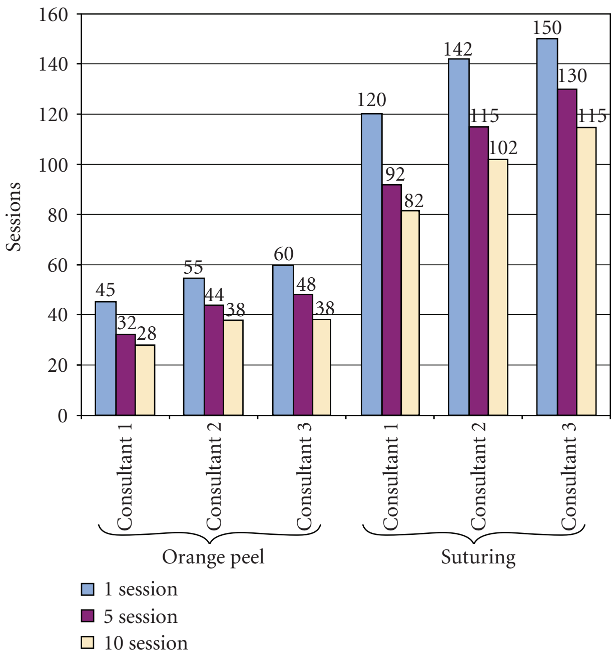

Figure 16: Task Completion Time—Chart.

without dry lab may not be ethically acceptable and can be too tiring.

Hence we have modified the conventional multiport endotrainer to a single port endotrainer for LESS training in our training programme. The cost of conversion was very minimal. The multiport and instruments for training in LESS are improvised from locally available resources. With an extra cost of 50$, the standard endotrainer could be modified to a single port trainer.

From the training among our faculty, we could appreciate that LESS was more difficult than conventional laparoscopy, even after multiple training sessions. The operating durations for the dissection and suturing both are significantly higher for LESS. We have not compared LESS training with conventional laparoscopic training in terms of trainee surgeons versus experienced surgeons.

The main disadvantage of LESS was clashing of instruments because of the closely placed ports. As triangulation of instruments is not possible; suturing needs extensive training. The transmission of the pressure and tactile feedback during dissection is different. Occasionally the right-handed angulated instrument may be on the left side of the left-handed instrument and vice versa necessitating proper orientation of instruments (crossing within the endotrainer and within abdominal cavity). These were detrimental factors in learning LESS.

All our faculties could complete the nephrectomy using single port in live animal lab with a prolonged operating time.

6. Conclusion

LESS training in endotrainer is preferable prior to training in animal lab and subsequent human surgery. Multiple sessions of LESS endotrainer practice will help to overcome the difficulties and reduce the operating time in LESS procedures. This specially designed endotrainer is a cost reductive step in LESS training programme.

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Research Article

Initial Experience of the Feasibility of Single-Incision Laparoscopic Appendectomy in Different Clinical Conditions

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Introduction. Single-incision laparoscopic surgery (SILS) is a new technique developed for performing operations without a visible scar. Preliminary studies have reported the use of the technique mainly in cholecystectomy and appendectomy. We evaluated the feasibility of the technique in various appendicitis conditions including children, fertile women and obese patients. *Materials and Methods*. SILS technique was used in a random sample of patients hospitalised for suspected appendicitis. The ordinary diagnostic laparoscopy was performed and the appendix was removed if needed. The ligation of appendix was performed by thread loop, absorbable clip or endoscopic stapler. The details regarding the recovery of patients were collected prospectively. *Results*. Ten SILS procedures were performed without conversions or complications. The patient series included uncomplicated and complicated appendicitis patients. The mean age of the patients was 37 years (range 13–63), mean BMI was 26 (range 18–31), mean operative time was 40 minutes (range 18–31), and mean postoperative stay was 2 days (range 1–5). *Conclusions*. SILS technique is feasible for obese patients, uncomplicated and complicated appendicitis as well as for exploratory laparoscopy. Most common methods to ligate appendix are feasible with SILS technique. The true benefit of the technique should be assessed by randomised controlled trials.

1. Introduction

During the era of laparoscopic surgery common trend has been towards less invasive techniques and a natural extension of the trend is to perform operations without scars. The most prominent techniques representing scarless surgery are transumbilical single-incision laparoscopic surgery (SILS) and natural orifice transluminal endoscopic surgery (NOTES). As the latter is still struggling with some technical and equipmental difficulties, SILS seems to be more ready for wider use in surgical community. There are reliable and simple equipment available for SILS procedures, and the operative technique, although different than in conventional laparoscopy, is probably easier to learn compared to NOTES technique.

Several operations have, thus, been until now performed by SILS technique including, for example, cholecystectomy, appendectomy, splenectomy, and sleeve gastrectomy. The most abundant are publications presenting results of SILS cholecystectomy [1–4] and results obtained in pediatric surgery [5–7]. All these reports have indicated that the SILS technique is safe and feasible in these surgical populations and that the operative time with this new technique is reasonable.

Appendectomy is the most common abdominal operation performed as an emergency basis in the western world [8]. The advantage of laparoscopic technique over the conventional technique has been proven especially in fertile women and obese patients [9–11]. SILS appendectomy may be even more advantageous to the patients by eliminating the scars and potentially diminishing postoperative pain. However, the role of the SILS appendectomy is still evolving since all published reports of the technique should be regarded as preliminary [5–7, 12]. More studies evaluating the technique in different clinical situations as well as randomised controlled trials are needed in order to assess the real benefits of the SILS appendectomy in general surgical practice.

The aim of the present study was to evaluate the feasibility of SILS diagnostic laparoscopy and appendectomy in heterogenic patient population presenting with symptoms suggestive for appendicitis. The suitability of different equipments for appendiceal ligation was also evaluated as well as the learning of the procedure.

2. Materials and Methods

This report is a case series of 10 patients admitted to Päijät-Häme Central Hospital due to right lower abdominal pain suggestive for appendicitis. All patients were clinically deemed to have high suspicion of appendicitis and were scheduled for emergency single-incision laparoscopy and subsequent appendectomy, if needed. The intention was to recruit a heterogeneous patient population to the procedure including, for example, children, fertile women, and obese patients. The operation was performed transumbilically using SILS port (Covidien, Norwalk, CT, USA). Firstly, intraumbilical cutaneous vertical incision was made and the umbilicus was detached from the fascia. The fascia was opened (2-3 cm) and the SILS port was introduced into the abdomen. After that, three 5 mm trocars were put through the port and the pneumoperitoneum was induced. A 5 mm 30-degree optic was used in all operations. One straight and one curved grasper (Roticulated endo grasp, Auto Suture, Norwalk, CT, USA) were introduced into the abdomen and right lower abdominal quadrant was explored and the operation was continued according to the findings. When deemed necessary, appendix was removed. In all patients mesoappendix was dealt with bipolar electrocautery and laparoscopic scissors. If extensive dissection was needed, dissecting monopolar hook was additionally used. The ligation of appendix was performed by thread loop (Endoloop, Ethicon, Somerville, NJ, USA), absorbable clip (Lapro-clip, Auto Suture, Norwalk, CT, USA), or endoscopic stapler (Endogia, Auto Suture, Norwalk, CT, USA). When clip or endoscopic stapler was used, one of the 5 mm ports was replaced by 12 mm port (Versastep, Auto Suture, Norwalk, CT, USA). The appendix was extracted with a pouch (Endocatch Gold, Auto Suture, Norwalk, CT, USA). If the appendix proved to be normal, standard diagnostic laparoscopy was performed including the examination of 100 cm of distal ileus, female genital organs, ascending colon, sigmoid colon, and gallbladder. At the end of the procedure, fascia was closed with continuous absorbable suture, umbilicus was refixed to the fascia, and the skin was closed with absorbable sutures. After discharge details of intraoperative and postoperative data were recorded.

3. Results

Altogether 10 patients were operated on by the SILS technique. There were 5 men and 5 women. Nine patients had appendectomy while one patient with sigmoid diverticulitis had only diagnostic laparoscopy. The mean age of the patients was 37 years (range 13–63), mean BMI was 26 (range 18–31), and the mean operative time was 40 minutes (range 23–50). The mean postoperative stay was 2 days (range 1–5). There were no conversions, no wound complications, or other complications among patients. The operative finding, operative time, and some other clinical details of different patients are shown in Table 1. All types of appendicitis from uncomplicated disease to disease with diffuse peritonitis were represented in our patient series. The patient with perforated appendicitis and diffuse peritonitis made an uneventful recovery although she spent 5 days in the hospital due to the therapy for diffuse peritonitis. Another patient with local dense inflammatory reaction and incipient abscessus formation could be operated by SILS technique and recovered normally. The method was also suitable for the most obese patient in our series. In the young female patient with rupture of ovarian cyst the exploratory laparoscopy with therapeutic intervention could be performed without difficulties by SILS technique.

4. Discussion

Appendectomy is the most common abdominal emergency operation in the western world. More and more appendectomies are currently performed laparoscopically due to the fact that the technique offers advantages to patients in terms of more accurate diagnosis, diminished wound infections, and more rapid recovery [9]. Compared to traditional laparoscopy, SILS appendectomy results surely in better cosmesis but additional benefits, for example, in terms of more rapid recovery have not been proven scientifically. However, randomised controlled clinical trials are urgently needed to define the role of SILS appendectomy in the modern surgical armamentarium.

Always when a new technique is introduced to the surgical community, the focus should be concentrated on the feasibility, safety, and clinical advantage of the method. Further, safety is highly dependent on how easily the new technique can be learned by average surgeons. It is well acknowledged that the implementation phase of new techniques is associated with an increased risk of complications emphasizing the importance of thorough training and education. The SILS technique differs from traditional laparoscopic technique remarkably by the use of the grasping and dissecting instruments. Due to the vicinity of the ports at the fascial plane, the operative technique necessitates crossing of the instruments (or specially designed instruments) making the procedure more challenging and initiating new learning curve for surgeon. Thus, transition from conventional laparoscopy to SILS is demanding, initiates new learning curve for surgeons, and increases initial operative time as shown in a previous study [12]. The most common conventional laparoscopic technique for appendectomy uses three ports meaning that the removal of appendix by SILS technique is performed principally similarly compared to traditional laparoscopy. Secondly, appendectomy is relatively easy operation performed in a relatively safe abdominal area decreasing the risk of disastrous complications that may happen, for example, in cholecystectomy. Further, SILS appendectomy can be performed properly by one straight instrument and one curved instrument making the procedure easier compared to use of two curved instruments.

Table 1

Patient description	Operative finding	Operation	Operative time (min)	Discharge (days)	Note
Male, 40 years	Appendicitis	Appendectomy	38	1	Typical uncomplicated appendicitis
Female, 18 years	Perforated appendicitis, covered by terminal ileum	Appendectomy	44	4	Restricted infection, incipient abscessus formation
Female, 63 years	Perforated appendicitis, diffuse peritonitis	Appendectomy, lavation	50	5	Hospital stay prolonged due to peritonitis
Male, 31 years	Appendicitis	Appendectomy	37	1	Obese patient, BMI 31, operative time reasonable
Female, 16 years	Ovarian cyst rupture	Appendectomy, explorative laparoscopy	34	2	Aspiration of pelvic fluid collection

When performing appendectomy, one must be prepared for different abdominal findings. The appendicitis may be oedematic, gangrenous, perforated with varying degree of peritonitis, or even associated with peritoneal abscess. The technique chosen to treat the patients should be suitable for all these clinical situations. In the present patient series there were both uncomplicated and complicated cases with even different degrees of peritonitis. All our patients could be operated by SILS technique without conversions or additional ports and they had an uneventful recovery. Further, the mean operating time was 40 minutes comparing well to the operating time of conventional laparoscopic appendectomy in our hospital (mean 43 minutes, range 18–103) and in a recent Cochrane review (mean 23.5–102 minutes) [9]. According to our experience, although limited, SILS technique seems to be suitable for variety of appendiceal infections.

Another issue is the feasibility of SILS technique for performing exploratory laparoscopy when surgeon encounters a normal appendix and the nature of the disease should be determined. According to our experience a proper diagnostic laparoscopy can be performed by SILS technique relatively easily and rapidly. The examination of distal ileum, female genital organs, and other organs situated in pelvic area could be accomplished without difficulties.

We tried intentionally different techniques for ligation of appendix in order to find out how feasible they are. Probably the most common methods to ligate appendiceal stump are thread loop, absorbable clip, and endoscopic stapler. All these options seemed to be suitable for SILS appendectomy. However, the easiest and fastest method in our hands was endoscopic stapler that has been suggested to lower the risk of postoperative intraabdominal surgical-site infection and the need for readmission to hospital [13], although a recent systematic review did not support this view [14].

According to literature especially obese patients benefit of laparoscopic appendectomy compared to open one and laparoscopy should be preferred technique for these patients [9–11]. It is, thus, important that new mini-invasive operative techniques are suitable for this patient population too. As shown in Table 1 a male patient with BMI 31 could be operated on by SILS technique in a reasonable time and his postoperative recovery was excellent. Although our experience with the technique is limited, it can be suggested that SILS technique for appendectomy is probably as suitable as traditional technique in obese patients.

Few of our patients were adolescent females who may be very aware of their body image. Abdominal scar may have influence on their quality of life and they may appreciate that their operations have been performed without a visible scar. However, to our knowledge there is only one small study in the literature focusing on the issue of the influence of abdominal scar on the cosmesis and body image showing no difference between open and traditional laparoscopic appendectomies [15]. As the main advantage of the SILS technique is that the visible scar can be avoided, further studies evaluating the issue urgently needed. Conventional laparoscopic appendectomy produces relatively small scars and the superiority of SILS in that respect remains to be shown. Further, the importance of abdominal scar may be age related since a limited survey among scrub nurses in our hospital revealed that young nurses would have scarless operation if it were available, but older ones did not see the issue so important.

Although SILS technique looks promising and offers some potential benefits for patients compared to conventional laparoscopy, two possible disadvantages should be considered. SILS technique may be associated with increased risk of hernias. The technique necessitates fascial incision through the abdominal midline that has been considered to be prone to hernia formation. Further, the fascial incision is more traumatic compared to 5 or 12 mm trocar wounds made with dilating trocars. The second possible disadvantage is the additional costs caused by the procedure-specific port and instruments. These extra operative costs should be taken into account in the current trend towards costeffectiveness in healthcare.

5. Conclusions

SILS technique is feasible for a variety of appendiceal inflammatory conditions and for explorative laparoscopy. The technique suits well for obese patients and different technical methods for appendiceal ligation can be easily used. Appendectomy is suitable procedure for the training of SILS technique. The technique may have few disadvantages and the true benefit of the technique remains to be shown by randomised controlled trials.

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Research Article

Laparo-Endoscopic Single-Site Surgery for Radical and Cytoreductive Nephrectomy, Renal Vein Thrombectomy, and Partial Nephrectomy: A Prospective Pilot Evaluation

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Introduction. Laparo-endoscopic single-site surgery (LESS) may diminish morbidity of laparoscopic surgery. We prospectively evaluated feasibility and outcomes of LESS-Radical Nephrectomy (LESS-RN) and Partial Nephrectomy (LESS-PN). *Methods*. 10 patients underwent LESS-RN (6) and LESS-PN (4) between 2/2009-5/2009. LESS-RN included 2 with renal vein thrombectomy, one of which was also cytoreductive. Transperitoneal LESS access was obtained by periumbilical incision. Patient/tumor characteristics, oncologic, and quality of life (QoL) outcomes were analyzed. *Results*. 3 Men/7 Women (mean age 58.7 years, median follow-up 9.8 months) underwent LESS. 9/10 cases were completed successfully. All had negative margins. Mean operative time was 161 minutes, estimated blood loss was 125 mL, and incision size was 4.4 cm. Median tumor size for LESS-RN and -PN was 5.0 and 1.7 cm ($P = .045$). Median LESS-PN ischemia time was 24 minutes; mean preoperative/postoperative creatinine were 0.7/0.8 mg/dL ($P = .19$). Mean pain score at discharge was 1.3. Mean preoperative, 3-, and 6-month postoperative SF-36 QoL Score was 73.8, 74.4 and 77.1 ($P = .222$). All patients are currently alive. *Conclusions*. LESS-RN, renal vein thrombectomy, and PN are technically feasible and safe while maintaining adherence to oncologic principles, with excellent QoL preservation and low discharge pain scores. Further study is requisite.

1. Introduction

Incidence of Renal Cell Carcinoma is increasing world wide. In 2009, approximately 57,760 patients were diagnosed with kidney cancer in the United States alone [1, 2]. Surgical excision remains the mainstay of therapy for localized disease and a cornerstone of care form appropriate patients with advanced disease. Since introduction of laparoscopic radical nephrectomy (LRN) the procedure has been refined and adopted as a standard of care for appropriate renal masses, with advantages including decreased blood loss, lower narcotic requirements, shorter hospital stays, and more rapid return to normal activities while maintaining equivalent short- and long-term oncologic efficacy compared with open radical nephrectomy [3–5]. These improved outcomes are thought in large part to be a result of the smaller incisions, and thus laparoscopy has rapidly emerged as standard of care for radical nephrectomy [6]. Similar to the introduction of LRN with its equivalent oncologic outcomes and improved morbidity profile, with the advent of improved laparoscopic surgical instrumentation and refinements in technique, LPN has emerged as a viable alternative to open partial nephrectomy (OPN) with equivalent short- and intermediate-term outcomes for selected patients [7, 8].

By combining working trocar sites and the eventual extraction site into a single location, Laparo-endoscopic single-site surgery (LESS) further limits the invasiveness of laparoscopy and may enhance advantages associated with traditional laparoscopy. Reduced incisional morbidity and improved cosmesis have largely sparked a growing interest

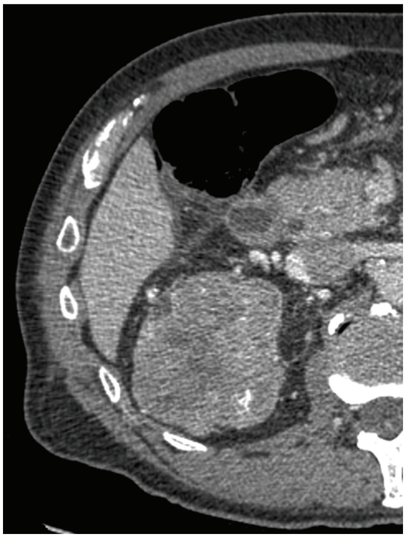

Figure 1: Representative image of a large (7×8 cm right upper pole mass) which underwent LESS-RN.

in utilization of this technique to perform upper tract urologic surgery [9–11]. Concerns regarding the applicability of LESS are significant and center around the issues of restricted freedom of movement resulting in instrument clashing and lack of triangulation [9–11]. Herein we describe our technique and our initial prospective evaluation of LESS Radical Nephrectomy (LESS-RN) and Partial Nephrectomy (LESS-PN) for excision of enhancing renal masses and evaluate its short-term disease-based and quality of life impact.

2. Methods

2.1. Patient Selection. Prospective single institutional evaluation of LESS is performed by a single surgeon (IHD). Patients were referred with renal masses with radiographic criteria for suspicious for malignancy (Figure 1). All patients underwent complete history and physical exam and staging workup (chest/abdominal/pelvic computed tomography, liver function tests, and bone scintigraphy if necessary). Exclusion criteria for LESS included patients with imperative criteria for partial nephrectomy (solitary kidney, bilateral tumors, and preexisting nondialysis-dependent renal insufficiency), and tumors which crossed the midline, or those with bulky lymphadenopathy. Patients are considered for LESS-PN if they had a renal mass that was deemed amenable to laparoscopic partial nephrectomy (LPN). Patients were considered for LESS-RN if they were not deemed to be amenable to LPN and were candidates for elective OPN, but stated an explicit preference for RN despite potential feasibility of OPN. All procedures were consecutively performed between 2/2009 and 6/2009. Patient demographic factors, tumor characteristics, perioperative variables, outcomes and complications, and quality of life (QoL) scores were recorded at time of enrollment and analyzed.

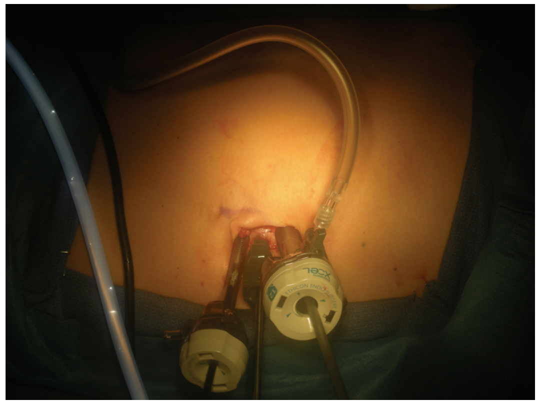

Figure 2: LESS Platform, periumbilical incision for left radical nephrectomy, demonstrating, in cranial to caudal direction (left to right): 5 mm Extralong Xcel Trocar, 5 mm short nonshielded trocar, and 12 mm Xcel Trocar.

2.2. Surgical Technique for LESS-RN. After general anesthesia, the patient is placed in a modified flank position (with the patient at a 30 degree angle with the kidney rest up and the table flexed). A 3-4 cm periumbilical incision is made and carried down to the anterior abdominal wall fascia. A 5 mm extralong (150 mm length) Xcel trocar (Ethicon-Endosurgery, Cincinnati, OH) is then inserted at the most cranial aspect of this incision, at the junction of the umbilicus with the fascia; pneumoperitoneum to 15 mmHg is obtained and a 5 mm-zero degree 35 cm-long laparoscope (Strkyer, Kalamazoo, MI) is inserted to inspect the abdomen; subsequently a 65 mm-long, nonshielded low profile (65 mm length) trocar (Ethicon) is inserted under direct vision at a position 1.0–1.5 cm caudad to the initial port, followed by insertion of a standard length (100 mm) 12 mm Xcel trocar (Ethicon) at the most caudal aspect of the incision, another 1.0–1.5 cm caudad to the prior low profile port. We minimized the intracorporeal profile of the Xcel trocars, and that in conjunction with the variety of trocar lengths allowed us to stagger the external profiles in order to minimize instrument clashing (Figure 2).

Tissue dissection is largely performed with standard extralong laparoscopic instruments (nonlocking laparoscopic deBakey bowel forceps, right angle dissector, Maryland dissector, endoshears) and 5 mm harmonic ACE 36 cm curved shears (Ethicon). Utilization of extralong instruments creates extracorporeal triangulation which compensates for the intracorporeal triangulation afforded by spaced trocars in multisite laparoscopy. Following takedown of the white line of Toldt, the 0 degree laparoscope is exchanged for a 5 mm, 45 cm, and 30 degree laparoscope with a right angle adaptor and inline camera head (Strkyer).

LESS-RN recapitulates standard LRN technique [3]. This includes incision of the descending colonic attachments to the abdominal sidewall along the white line of Toldt down to the level of the iliac vessels with subsequent medial-visceral rotation of the colon to expose the ureter and underling kidney. The ureter is identified, clipped, and cut using 5 mm Ligamax Clip applier (Ethicon) and endoshears.

Table 1: Demographics, Tumor Characteristics, Perioperative Variables, and Outcomes.

	LESS-RN ($n = 6$)	LESS-PN ($n = 4$)	P value
Demographics			
Age	58.7	58.8	.991
Sex (Male/Female)	2/4	1/3	.806
BMI (Kg/m2)	24.9	30.1	.073
Tumor size/location			
Tumor Size (cm)	5.3	1.7	.045
Tumor Location			
Upper/Mid/Lower Pole	2/2/2	1/2/1	
Renal Vein Thrombus	2	0	
Perioperative Variables			
Operative Time (minutes)	150.8	177.0	.162
Estimated Blood Loss (mL)	112.5	133.3	.679
Warm Ischemia Time (minutes)	n/a	22	
Incision size (cm)	4.6	4.1	.143
Narcotic Requirement (yes/no)	3/3	2/2	1.000
Hospital Stay (hours)	54.4	80.3	.048
Outcomes/Complications			
Conversion to open	0/6 (0%)	1/4 (25%)	.241
Negative Margins	6	4	1.000
Malignant Histology	5	2	.312
Blood Transfusion	0	0	1.000
Complications	1	0	.241
Overall Survival	6	4	1.000

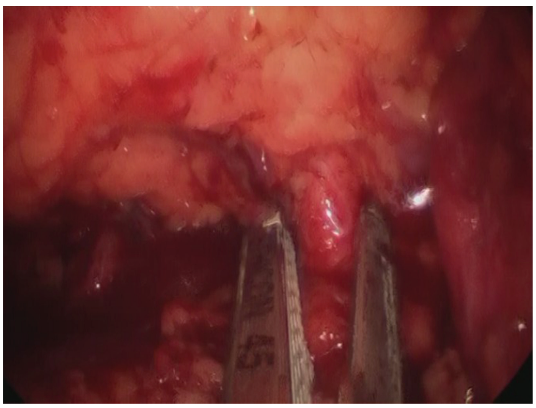

Figure 3: Ligation of right renal vein with the 45 mm Endopath ETS Flex Articulating Linear Cutter.

The cut proximal ureter is then used for retraction allowing safe access to the renal hilum, and the renal artery and vein are individually dissected. Through the 12 mm port the Endopath ETS Flex 45 Endoscopic Articulating Linear Cutter, with a white vascular reload (Ethicon), is used to ligate and incise the renal artery followed by the renal vein (Figure 3). In the case of an upper pole or locally advanced mass, the adrenal gland is then taken en bloc with the kidney and the remaining superior and lateral renal attachments are freed utilizing the harmonic scalpel, and in the case of a lower- or mid-pole mass, the adrenal gland is dropped away from the kidney (after ligation on the main adrenal vein on the left with the stapler and/or harmonic scalpel; or on the right after separation from the kidney utilizing the harmonic scalpel or Endovascular stapler). The 12 mm trocar is then exchanged for a 15 mm Xcel bladeless trocar and the specimen is placed in a 15 mm Endo Catch specimen pouch (Covidien, Mansfield, MA) and intact specimen extraction is made by extending the fascial opening between trocars.

2.3. Surgical Technique for LESS-PN with Ischemic Technique. Initial surgical steps including positioning, single-site incision, pneumoperitoneum/trocar placement, colonic mobilization, and ureteral identification and vascular dissection are identical to LESS-RN. The standard techniques of LPN are recapitulated with few modifications [12]. Following hilar control and tumor identification, Gerota's fascia is incised down to the renal capsule, preserving fat overlying the tumor. Subsequently, argon beam coagulator (ABC, Conmed, Centennial, CO) is used to circumscribe the renal capsule while leaving a healthy margin around the tumor. Renal hilar occlusion is obtained by placing laparoscopic vascular bulldog clamps (Aesculap, Center Valley, PA) on the renal artery and vein. Cold shears are then used to excise the lesion, making certain to leave a margin of healthy tissue around the specimen. Hemostasis is then achieved, first using ABC over the resected tumor bed. Next floseal (Baxter, Deerfield, IL) is placed in renal defect, followed by a surgicel bolster (Ethicon, Somerville NJ) and then sutured

Figure 4: 6 month postoperative image of surgical incision of LESS-PN.

renorrhaphy [13] with 3-0 vicryl sutures on an SH needle are precut 10 cm long with a Lapra-Ty clip (Ethicon) on the free end. Simple interrupted sutures are placed in the renal defect with second Lapra-Ty clip on the distal end. Bioglue (albumin-glutaraldehyde sealant-adhesive, Cryolife, Kennesaw, GA) is then placed to seal the renorrhaphy [14] and then the laparoscopic bulldogs are removed, and the renorrhaphy is inspected for bleeding. The specimen is then extracted through a 5 mm Endo Catch specimen pouch in a similar fashion to the LESS-RN.

2.4. Surgical Technique for Nonischemic LESS-PN. In one case, the Habib 4X (Angiodynamics, Queensbury, NY), a bipolar laparoscopic radiofrequency ablation device, was utilized to achieve a zone of parenchymal hemostasis in the absence of ischemic renal conditions prior to cold tumor excision and renorrhaphy, as described above [15, 16].

2.5. Postoperative Management and Followup. Postoperatively the patients were started on Ketorolac and tramadol for pain. Narcotics were not given unless requested by the patient for breakthrough pain. Patients were given clear liquids on the same day of surgery and were then advanced as tolerated. CBC and SMA-7 were monitored postoperatively on daily basis. Patients were discharged on tramadol pro re- nata, and seen in the outpatient clinic within 1-2 weeks. Followup exam (Figure 4), laboratory and QoL determination, and imaging studies were obtained as per protocol depending on tumor pathology.

2.6. Data Collection and Analysis. Data were prospectively collected from the consent at the first clinic visit. Demographic factors [age, race, sex, BMI (Kg/m^2), disease characteristics (tumor size, clinical and pathological stage, tumor pathology) perioperative variables [Operative time (minutes), EBL, incision size (cm), margin status, narcotic requirement (if any), time to advancement to regular diet (days) and length of hospital stay (days), and complications], quality of life- (QoL-) related outcomes [visual analog pain (VAP) score at discharge and 6 months postoperatively; time to return to normal activities (days), and SF-36 health survey (SF-36 V. 2.0; Medical Outcomes Trust, Inc., Boston, MA)], and disease outcomes (overall- and disease-specific survival) were recorded and analyzed for this initial cohort. Data was analyzed between the two groups (LESS-RN and LESS-PN) utilizing Student's t-test and Fisher's exact test, and for QoL and pain scores utilizing single-factor ANOVA with $P < .05$ is considered significant.

3. Results

Demographics, tumor characteristics, perioperative variables, and outcomes and complications for the LESS-RN and LESS-PN groups are summarized in the table. Mean age for the entire cohort was 58.7 ± 11.0 years (58.8 ± 5.9 years for LESS-PN, 58.7 ± 13.8 years for LESS-RN, $P = .991$) mean BMI was 27.0 ± 4.6 Kg/m^2. Median followup was 9.8 months (range 8–12 months). Six lesions were in the left kidney and four were in the right; four tumors were in the mid pole, 3 in the upper pole, and 3 in the lower pole of the kidney. Two tumors had renal vein thrombi, one of which also had metastatic disease. Median tumor size on final histopathologic analysis for the LESS-RN group was 5.0 (range, 2.3–9) cm, and for the LESS-PN was 1.7 (range, 1.4–2) cm ($P = .045$).

LESS-RN was successfully performed on all 6 patients without conversion to multi-site laparoscopic or open surgery; two of these included successful enbloc resection of the renal vein thrombus, and one of which was also a cytoreductive nephrectomy. LESS-PN was successfully performed on 3 of four attempts with one conversion to open PN due to failure to progress, due to the patient's prior history of prior intraabdominal surgery and radiation. No significant differences were noted between the LESS-RN and LESS-PN groups with respect to perioperative variables: Mean operative time (LESS-RN 150.8 ± 27.6 versus LESS-PN 177 ± 24.1 minutes, $P = .162$), mean estimated blood loss (LESS-RN 133.3 ± 75.3 versus LESS-PN 112.5 ± 75.0 mL, $P = .679$), and mean incision size (LESS-RN 4.6 ± 0.5 versus LESS-PN 4.1 ± 0.3 cm, $P = .143$). The median hospital stay was significantly longer in LESS-PN (80 hours; range 73–88) compared to LESS-RN (52 hours; range 29–86, $P = .048$). Median warm ischemia time (for 3 tumors performed with ischemic technique) was 24 minutes (range 19–26).

Histology revealed RCC in the majority of resected lesions, 5/6 (83%) LESS-RN and 2/4 (50%) LESS-PN. Of the seven patients with RCC, clear cell was the most common tumor (71%), one patient had a cystic RCC (14.3%) and one had a chromophobe RCC (14.3%). Three benign lesions were resected, two lipid poor angiomyolipomas and one oncocytoma. All patients had negative resection margins. 6-month postoperatively patients who underwent LESS-PN had excellent preservation of overall renal function with mean preoperative/postoperative values for serum creatinine (0.7 ± 0.1 versus 0.8 ± 0.2 mg/dL, $P = .194$) and estimated Glomerular Filtration Rate (99.3 ± 10.9 versus 86.8 ± 29.2 mL/min/1.73 m^2, $P = .419$).

One half the patients (overall and in each group) did not require further opiate supplementation of their postoperative analgesics. Mean VAP score at discharge, 1 month postoperative, 3 months postoperative, and 6 months postoperative was: $1.3 \pm 1.3, 0.9 \pm 0.7, 0.5 \pm 0.9$, and 0.4 ± 0.9, resp., $P = .204$). Mean preoperative, 1 month postoperative, 3 month postoperative, and 6 month postoperative SF-36 QoL Score was: $73.8 \pm 10.4, 67.7 \pm 10.8, 74.4 \pm 10.4$, and 77.1 ± 8.9, resp., $P = .222$). Mean time to return to normal nonstrenuous activity was 6.6 ± 2.9 days (median 6, range 3–12).

No patients required blood transfusions. One patient (10%) had a complication, a pneumothorax which was treated with tube thoracostomy decompression with resolution and tube removal within 23 hours. All patients are currently alive, and there has not been any evidence of radiographic progression in any of the patients with RCC.

4. Discussion

LESS is an emerging surgical technique which may promise further reductions in morbidity and improved cosmesis for patients. Emerging data on LESS has been reported in general surgical, gynecologic, and urologic procedures [17–22]. LESS for renal surgery was first reported in 2007 and since then a handful of authors have described variations of their technique in order to perform both RN and more recently PN for a variety of indications [10, 11, 23–25]. This report represents the first report in the literature of LESS-RN with renal vein thrombectomy and cytoreductive nephrectomy and the second group to report LESS-PN in adults. As such, this report further corroborates (partial nephrectomy) and demonstrates (renal vein thrombectomy) that increasingly complex procedures can be safely performed with the LESS platform.

In order for LESS to become a viable alternative to traditional multi-site laparoscopy, it must first be proven to be feasible, safe, and reproducible and with equivalent outcomes. While there are few reported cases of LESS procedures, the existing data has demonstrated impressive initial outcomes comparable to traditional laparoscopy [26]. This is consistent with our experience; nine of ten cases were completed without the need for conversion to open or traditional laparoscopic technique, OR times to complete these were (mean total cohort) 161 minutes, EBL was 125 mL and no patients required blood transfusions. This is comparable to existing large multi-site series which demonstrate means of 105–201 minutes OR time, 172–300 cc EBL and 4.5% transfusion rates [4, 5, 8]. All patients had negative margins, and patients who underwent LESS-PN had mean WIT under 30 minutes, without significant changes in creatinine and eGFR, consistent with excellent short-term renal preservation. While the numbers are small, this is certainly also comparable to a large multi-institutional series of multisite LPN which demonstrated a mean warm ischemia time of 30.7 minutes, and preoperative and postoperative creatinine of 1.01 and 1.18 mg/dL, respectively [8]. Complications rate was reasonable with only one patent having a significant complication despite the complexity and novelty of these procedures. As surgeons, OR staff, and technologies improve, we only anticipate these outcomes to improve further.

Once LESS has overcome the initial threshold and found to be comparable to the existing laparoscopic standard, it must offer a significant advantage for surgeons and patients to invest in this emerging technique. LESS allows RN and PN to be performed with fewer incisions as compared with traditional laparoscopic technique. The average incision size in this series was 4.42 cm with no need for any additional incisions. In addition to excellent postoperative cosmesis (Figure 4) afforded by substitution of multiple trocar sites in traditional laparoscopy by often almost imperceptible scars in the umbilical region, significant QoL benefits may be attained by minimization of abdominal incision. Prior work has demonstrated that decreasing incision size or specimen morcellation may decrease postoperative discomfort [6, 27]. However, while morcellation of renal masses may allow for reduction of incision size, it also results in distortion of renal architecture which may compromise accurate staging and grading of RCC [28]. Thus all LESS procedures were performed adhering to fundamental oncologic principles and tumors were extracted using intact specimen entrapment bags to prevent tumor seeding to the single incision site [29].

Consolidation of working trocars and the extraction incision into one site may result in reduced incisional morbidity as evidenced by limited need for narcotic medications in this series (Table 1). More than half of the patients in this cohort did not require any narcotic supplementation and of those that did, most did so for less than 24 hours postoperatively. This may in part be due to our pathway which places patients on Ketorolac immediately post operatively [30, 31]. The resultant benefits of this are translated into preserved quality of life as evidenced by low discharge mean visual analog pain score (1.3), returning to normal nonstrenuous activity in less than one week, the lack of significant difference between preoperative and postoperative SF-36 scores ($P = .222$).

Since LESS procedures are relatively new and in evolution, many techniques have been described but no widely accepted standard exists. LESS has gained recent interest, and this has lead surgeons to use traditional tools in unique ways as well as encouraging industry to develop a variety of novel platforms and innovative instruments to ease the learning curve and facilitate these procedures. The gelport laparoscopic system (Applied Medical, Rancho Santa Margarita, CA) [11] is a laparoscopic hand port which allows introduction of multiple trocars while maintaining an airtight seal. Specialty designed single-port laparoscopic systems such as the Uni-X (Pnavel Systems, Morganville, NJ) [32], R-port (Advanced Surgical Concepts, Dublin, Ireland) [10, 23, 24], and the SILS port (Covidien, Mansfield, MA) are essentially multiple fixed trocar ports that are inserted through modified Hasson technique. We believe that our technique of using multiple traditional and low-profile trocars placed through a single incision offers some significant advantages. Both the gelport and the specially designed multisite trocars add additional cost to the procedure. Furthermore, specially designed multisite ports have fixed positions which limit separation of the trocars and prevent the use of additional trocars. In 3 cases we added a 4th trocar in the most caudal aspect of the incision, a 12 mm trocar allowed for the insertion of an Endo Paddle retract

(Covidien), a retractor used for bowel retraction used for 2 patients with renal vein thrombi and one large upper pole renal mass. While some have suggested that the drawback of our method of LESS is the “swiss cheese” defect and weakening of the fascia, but we have not found this to be the case [33].

Triangulation is the primary underlying technical principle in laparoscopy and the greatest hurdle to overcome in LESS. Proximity of the working ports through the single incisions limits achievable separation which is necessary for triangulation. A variety of novel trocars, ports, and instruments have been developed specifically for or adapted for LESS. While we enthusiastically encourage the development of such products and believe that these will improve the technical feasibility of these surgeries our initial experience has been performed without the use of any such specialized tools. We believe that the benefits of using conventional laparoscopic trocars and instruments are primarily two fold: (1) surgeon familiarity and comfort, (2) cost savings [minimizing the use of flexible/articulating instruments which are disposable]. Given that our OR times, and other outcomes are consistent with those of large published series of multiport RN and LPN [4, 5, 8], we feel that our approach of utilizing conventional laparoscopic instruments facilitates surgeon comfort and safe adoption of the LESS platform with excellent results.

We believe that our utilization of extra-long laparoscopic instruments and cameras creates a zone of extracorporeal triangulation which, when applied through a peri-umbilical incision which is close to the kidney, creates sufficient working freedom and attenuates clashing. Furthermore, our utilization of staggered trocars of lengths and a right-angled camera further minimizes instrument clashing and allowed greater angulation of laparoscopic handles. Thus we have demonstrated the LESS renal surgery can be performed using essentially the same tools that might be used to perform traditional multisite laparoscopy. Articulating instruments, trocars that allow the insertion of bent instruments and flexible laparoscopes all may provide further methods of overcoming these challenges and are in the process of being further evaluated by our group.

Despite advances in LESS considerable challenges remain. The upper posterior pole of the kidney is the most difficult portion of the renal dissection. Even with the use of bariatric laparoscopic instruments this region is difficult to reach because of the greater working distance from the umbilicus, and “turning the corner” or getting over the upper pole to the posterior aspect of the kidney can be demanding with rigid instruments that do not articulate. Additionally retraction of the bowel and liver without multisite laparoscopy is challenging. While future advances in laparoscopes, trocars, and instruments may overcome these technical considerations, novices to LESS renal surgery may consider extra caution in attempting these procedures in patients with greater BMIs and patients with bulky upper pole posterior lesions. Particular consideration must be employed when attempting LESS-PN; while intracorporeal suturing is feasible for obtaining hemostasis and closure of the renal collecting system and parenchyma, tumors that may not be easily accessible from the umbilicus due to distance (such as posterior, upper pole lesions) may present further difficulties and present onerous limitation on being able to deploy laparoscopic needle drivers at a sufficient angle. Indeed, development and refinement of robotically-assisted LESS may allow a greater degree of freedom and surmount such difficulties.

Increased detection of small renal masses has required urologist to gain familiarity with procedures that ensure adequate oncologic control while preserving renal function [34]. LESS-PN allows for extraction of the enhancing renal lesion, definitive histologic confirmation with excellent preservation of renal function in this series. In a recent publication, Kaouk and Goel utilized a nonischemic technique to perform LESS-PN. After PN these authors achieved hemostasis using ABC, Surgicel and a variety of surgical adhesives, however due to inability to achieve adequate hemostasis in one case they had to convert to multiport laparoscopy [25]. We attempted a nonischemic technique in one case, utilizing the Habib 4X laparoscopic radiofrequency resection device, which easily fits through the 12 mm laparoscopic port. This device allows excision of the renal mass while maintaining hemostasis by ablating normal renal parenchyma and creating an avascular plane around the tumor allowing excision of the mass with minimal blood loss and preserving histologic integrity of the specimen [16].

Despite the novelty of these procedures we rapidly adopted an excellent comfort level for performing complex LESS-RN. Two patients had renal tumors greater then 7 cm, both with renal vein thrombi. One of these patients had widely metastatic disease and elected to undergo cytoreductive LESS-RN. Traditional laparoscopic cytoreductive nephrectomy has been demonstrated to have favorable morbidity when compared with open technique and thus we performed to our knowledge the first reported LESS cytoreductive nephrectomy [35]. The patient did well and was able to resume targeted biologic therapy on postoperative day 14.

The limited number of procedures and the lack of a direct comparison to traditional multi-site LRN and LPN limit our findings. However, this preliminary prospective series demonstrates that LESS-RN, renal vein thrombectomy, and PN is safe and technically feasible method for performing complex renal surgery while maintaining strict adherence to oncologic principles, with excellent preservation of quality of life, low discharge pain scores, and cosmetic benefit. Our encouraging pilot results have led to a prospective comparison between LESS and multiport laparoscopy, which we hope will delineate what, if any specific advantages, may lie with the LESS approach.

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Research Article

Usefulness of a Flexible Port for Natural Orifice Transluminal Endoscopic Surgery by the Transrectal and Transvaginal Routes

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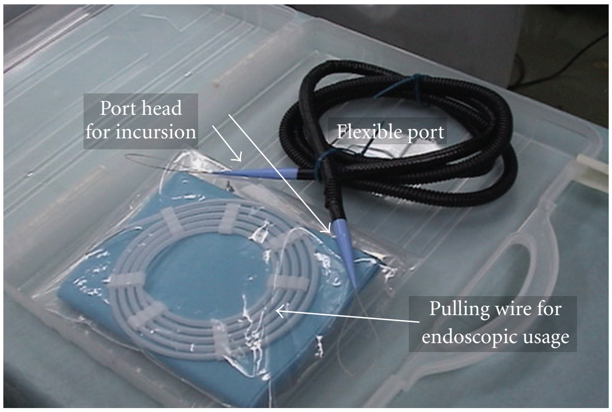
We developed a flexible port for NOTES which allows the use of conventional forceps for laparoscope-assisted surgery without change. The port is not affected by the location of the through hole in the gastrointestinal tract or vagina which elicits a problem in conventional NOTES, and its length can be adjusted during surgery by cutting the port itself. The port is made of polymer resin with a low friction coefficient. Furthermore, the port walls have a square wave structure which contributes to (1) the prevention of devices, for example, endoscope, from getting stuck at the time of insertion and retrieval, (2) the prevention of port slippage in the surgical opening for port insertion, (3) the prevention of unexpected port removal, (4) the prevention of port bore deformation, and (5) the improvement of port flexibility in the longitudinal direction. We validated the insertion and retrieval capacities of commercially available forceps for laparoscope-assisted surgery and power devices. Furthermore, we used the flexible port to conduct cholecystectomy and partial gastrectomy. We could confirm that the selection of the flexible port diameter according to the device type allowed the smooth insertion and retrieval of the device and that the port produced no air leakage. We affirmed that it is possible to conduct surgery by the cross or parallel method similarly to single port surgery. We considered that the flexible port has a potential of becoming a revolutionary port in NOTES.

1. Introduction

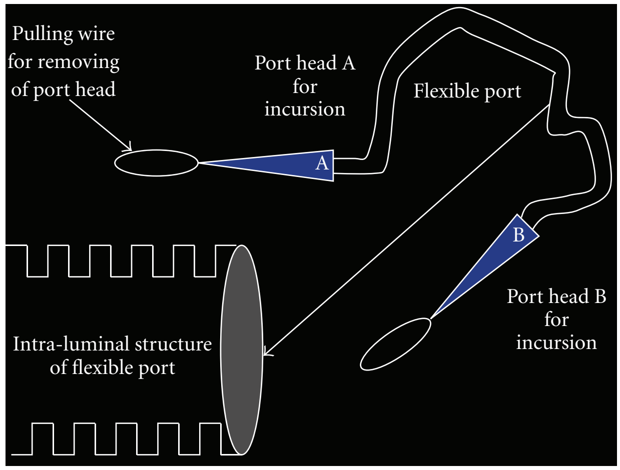
1.1. Definition of NOTES. Natural orifice transluminal endoscopic surgery (NOTES) is a surgical procedure by which an endoscope penetrates the gastrointestinal (GI) wall through natural orifices, for example, mouth, anus, and vagina, to conduct intra-abdominal surgery.

Therefore, the positional relationship among the natural orifice, the site of GI wall penetration, and the target organ for surgery is important.

1.2. Current Technical Issues. Previous studies have described an attempt to perform colectomy by the ensured intra-abdomi-nal route after setting a port for abdominal wall-penetrating laparoscope as the transrectal route [1, 2] and the use a straight port for abdominal wall-penetrating endoscope in the vaginal fornix [3]. However, the diversion of ports for laparoscope-assisted surgery has elicited the following problems: (1) shortness of port length, (2) hardness of the port, (3) and straight shape of the port. In problem (1), there are patients for whom surgery cannot be initiated because the port does not reach the site of intra-abdominal penetration in the GI tract or vagina; the port falls from the surgical opening during surgery, thus requiring a long time for reinsertion. In problem (2), the site of port insertion in the GI tract or vagina which was created to conduct NOTES is injured. Furthermore, air leakage readily occurs from the site of port insertion in the GI tract or vagina. In problem (3),



(a)



(b)

Figure 1: (a) A device set required to insert the flexible port. The set is composed of the flexible port itself, the guide wire for traction into the abdominal cavity, and the disposable surgical drape. First, prepare the flexible port set. One flexible port set allows the setting of two ports of the same diameter. (b) The sockets at both ends of the flexible port are made of polymer resin with a low friction coefficient. The loop wire at the socket apex is used for traction at the time of GI tract penetration and for guidance of the port-separated socket outside the body. The square wave structure of the port reduces friction and is useful in preventing the device to be inserted from getting stuck, the deformation of the port bore, and the slippage at the site of port insertion, and in improving the flexibility of the port in the longitudinal direction.

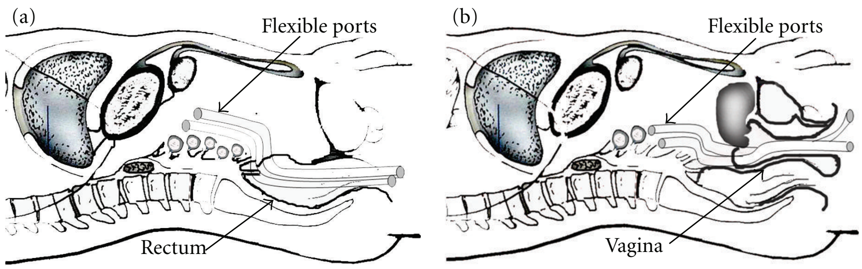


Figure 2: (a) Schematic layout of the flexible ports that were inserted by the transrectal route. (b) Schematic layout of the flexible ports that were inserted by the transvaginal route. The schemes of the transrectal route and the transvaginal route ensured by the flexible ports are shown in Figure 2. The flexible port is designed to be flexibly adaptable to the intra-abdominal structure and usable when inserted in the abdominal cavity by any route and in any direction. The transrectal route shown in Figure 2(a) and the transvaginal route shown in Figure 1(b) are considered when conducting the surgery of an upper abdominal organ by using the conventional forceps for laparoscope-assisted surgery without change. In the present device insertion study, we used the flexible port as shown in Figures 2(a) and 2(b). Furthermore, we conducted cholecystectomy and partial gastrectomy as shown in Figure 1(a).

a setting occurs in which surgical forceps and surgical knives do not reach the target organ for surgery because the surgical opening in the rectum or vagina and the target organ for surgery are not located on the same straight line as the port.

1.3. Brief Description of Improvements. We developed a port capable of exerting the following features to solve the abovementioned issues when using the conventional port and conducted an in vivo study. (1) We developed a material which allowed the adjustment of port length at will by means of a cutting device in the operating room. (2) We adopted a deformable structure for the port shape to make it fit the configuration of the rectal orifice or vagina which the port penetrates. Furthermore, we developed a sealing structure to delete air leak which occurs between the port and the device. (3) We adopted a flexible port which is freely bendable by 360 degrees and developed a structure which makes the port be adaptable to the patient's proper physique.

2. Materials and Methods

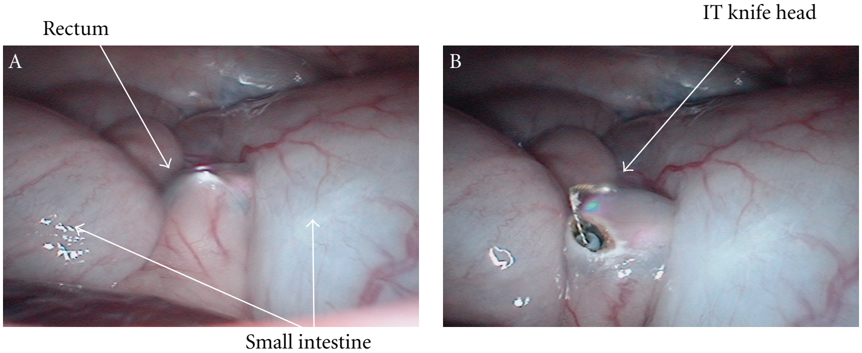
The device set required to insert the flexible port is shown in Figure 1. The set is composed of the flexible port itself, the hook wire for traction into the abdominal cavity, and the disposable surgical drape.

The features of the flexible port are listed as follows.

(1) The port material is polymer resin with a low friction coefficient.

(2) The port structure adopts a square wave structure as shown in Figure 2(a).

(a)



(b)

Figure 3: (a) Flexible port insertion procedure according to the two-surgeon method, showing the layouts of the surgeons and the forceps. (b) The surgical opening operation to insert the traction wire of the flexible port into the anterior wall of the rectum according to the two surgeon method. The safety of the procedure is ensured by an operation to be performed while monitoring the operative field with an endoscope that was inserted transgastrically.

(3) The original length of the port is 1 m, and the port can be cut at will with a knife during surgery (Figure 4).

(4) The port has one port-convertible socket at its each end, and the socket has a mechanism by which it can be detached by applying a given force for its removal after setting the port.

(5) The conical socket for admittance has a stainless alloy wire for traction at its apex. The wire has an effect to obtain a surgical opening of 2 to 3 mm in diameter which is required for passage through the GI tract and allows traction and removal of the device outside of the body.

(6) The flexible port has urethane foam bulbs for air sealing at 3 cm intervals.

(7) The flexible ports prepared are 5 mm, 7 mm, 12 mm, 18 mm, and 21 mm in diameter.

The advantages generated by the above features of the flexible port are listed as follows.

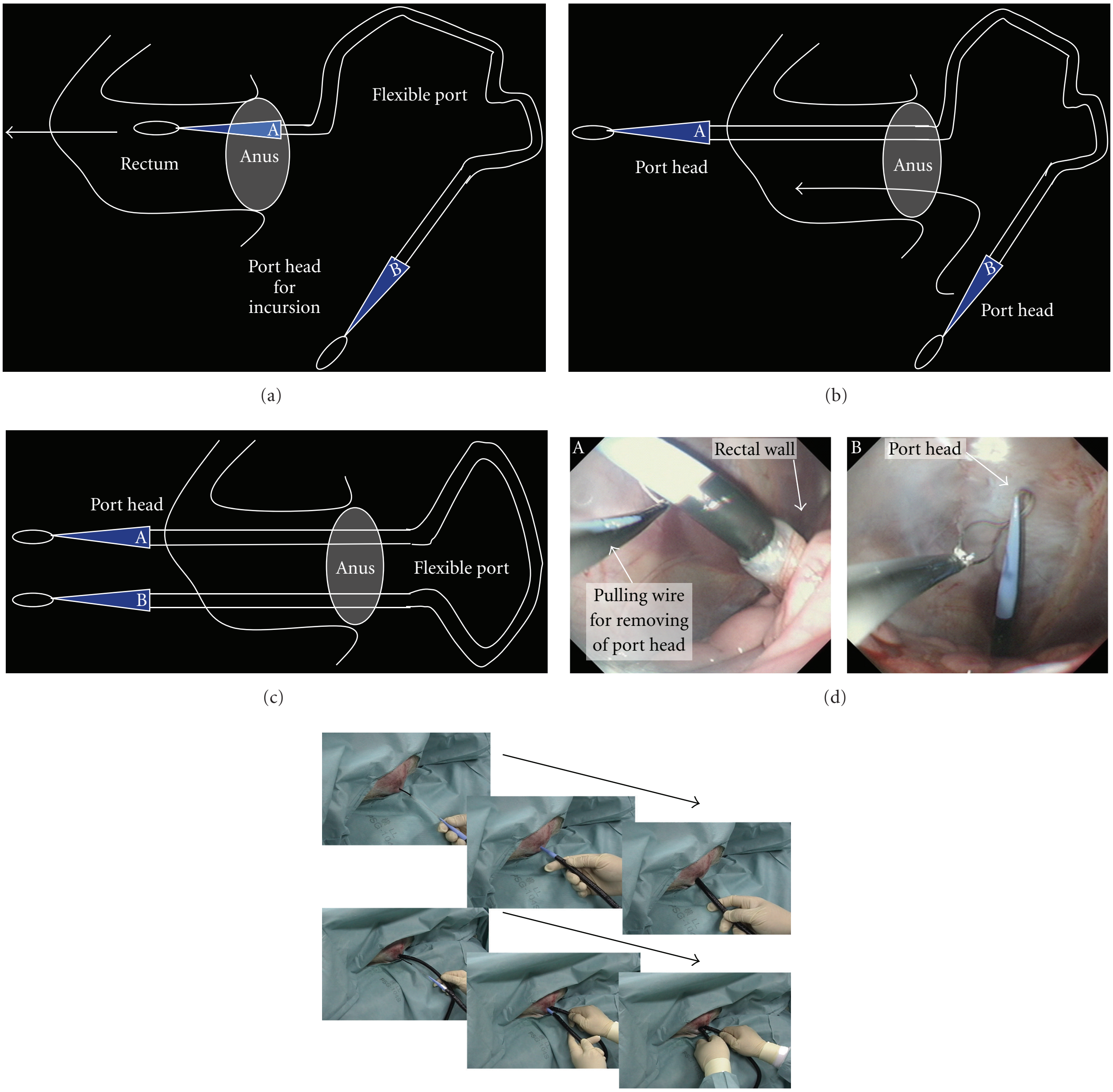
(1) Port polymer resin with a low friction coefficient is useful for the prevention of devices to be inserted from getting stuck.

(2) The square wave structure of the port reduces friction and is useful for the prevention of devices to be inserted from getting stuck. Furthermore, the increased strength of the port in the minor axis direction can prevent the deformation of the port bore and of slippage at the site of port insertion. In addition, a marked improvement in the port's flexibility has achieved the maximal flexion angle of 110 degrees.

(3) The original length of the port is 1 m, and the port can be cut at will with a knife during surgery. Namely, the flexible port provides a radical solution to the issue of anatomical individual differences.

(4) The sockets at both ends of the flexible port use polymer resin with a low friction coefficient. Therefore, the port can be smoothly inserted into the abdominal cavity if there is a surgical opening of 2 to 3 mm in diameter. Furthermore, it is easy to close the surgical wound at the site of port removal because the site of port insertion is less injured.

(5) The hook stainless alloy wire for traction, which is attached to the apex of the conical sockets for admittance, facilitates the passage of the device



(a) (b) (c) (d) (e)

Figure 4: (a) Flexible port insertion procedure: the flexible port socket of one side is inserted through the surgical opening of 2 to 3 mm in diameter which was created in the rectum. This operation of creating the surgical opening of several millimeters in the rectum is performed under monitoring with the endoscope which was inserted in the abdominal cavity through the gastric wall. The flexible port is inserted into the rectal wall with the traction wire which was attached to the port insertion set through the forceps hole of the gastric camera for monitoring. (b) The flexible port socket of the other side is inserted according to the same procedure as the method in Figure 3(a). Insertion is assisted with the traction wire which is inserted into the abdominal cavity through the forceps hole of the gastric camera for monitoring. (c) The setting of two flexible ports in one set through the operations described in Figures 4(a) and 4(b) is completed. At this moment, make sure to adjust the port length which is required for the abdominal cavity. (d) The photographs of the abdominal cavity monitoring in operations mentioned in Figures 4(a)–4(c): (1) the insertion socket with the loop wire, which is placed to the apex of the flexible port immediately after penetration through the rectal wall. (2) The scene indicates traction with the traction wire which was inserted into the abdominal cavity via the forceps hole of the endoscope through which the socket with the loop wire attached to the apex of the flexible port was guided into the abdominal cavity transgastrically. By this operation, the flexible port is inserted from the rectal wall to the abdominal cavity for a required length and is placed. (e) Photographs ex vivo in Figures 4(a)–4(c). Method of flexible port insertion: the flexible port is inserted one by one. The flexible port socket with the wire loop for traction is pulled toward the mouth with the traction wire which was drawn from the anus via the sheath that had been inserted through the forceps hole of the transgastric endoscope and is guided to the abdominal cavity.

trough the GI tract and its removal outside the body by endoscopy.

(6) Urethane foam bulbs for air sealing are placed at 3 cm intervals. Therefore, no air leak occurs even when cutting the port at any level.

(7) The flexible ports have five different diameters, thus making them adaptable to the diameters of different devices.

2.1. In Vivo Study. The in vivo study was approved by the Animal Ethics Committee at the Jichi Medical University, and three farm pigs of 30 to 40 kg in body weight were used. The transrectal route was established in two male pigs, and the transvaginal route in one female pig.

The schemes of the transrectal route and the transvaginal route ensured by the flexible port are shown in Figure 2. The flexible port is designed to be flexibly adaptable to the intra-abdominal structure and to be usable when inserted into the abdominal cavity by any route and in any direction. The transrectal route shown in Figure 2(a) and the transvaginal route shown in Figure 1(b) are considered when conducting surgery of an upper abdominal organ by using conventional forceps for laparoscope-assisted surgery without change. In the present device insertion study, we used the flexible port as shown in Figure 2(a) and 2(b). Furthermore, we conducted cholecystectomy and partial gastrectomy as shown in Figure 2(a).

We used one female pig and one male pig to conduct the device insertion study with the ports of 5 mm, 7 mm, and 18 mm in diameter. The female pig was used in the transvaginal route study, and the male pig in the transrectal route study. Multiple devices were inserted and retrieved 10 times each. The presence or absence of the stuck device and the presence or absence of air leakage were examined as endpoints (Table 1).

We used two male pigs to conduct the surgical study by the transrectal route only, that is, cholecystectomy and pyloric partial gastrectomy (Table 2).

Forceps for laparoscope-assisted surgery (Karl Storz, Tuttlingen, Germany) were used as inflexible devices, and Roticulator (Covidien, MA, USA) as flexible forceps. Furthermore, Harmonic Scalpel (Johnson and Johnson, OH, USA) and LigaSure (Covidien, MA, USA) were used as incision devices. The surgical opening in the stomach was established on the anterior wall in the greater curvature of stomach. Two endoscopes for port setting and for monitoring during surgery (240i, Olympus, Tokyo, Japan) were used.

Setting of the flexible port and surgical procedures are as follows.

(1) Setting of the camera for abdominal monitoring: the upper endoscope is used as the conventional laparoscope according to the two-surgeon method, and the intra-abdominal insertion of the flexible port is assisted. The layouts of the surgeons and the forceps are shown. First, the endoscope is orally inserted into the stomach. Subsequently, the hook knife (Olympus, Tokyo, Japan) is used to create a surgical opening of 5 mm in diameter on the anterior wall of the greater curvature of stomach, followed by the intra-abdominal insertion of the endoscope. The above procedures allow the monitoring of surgical procedures in the abdominal cavity (Figure 3(a)).

(2) Creation of a surgical opening to insert the traction wire for the flexible port on the anterior wall of the rectum according to the two-surgeon method: an ultrasonic endoscope for laparoscope-assisted surgery is used to identify the site of peritoneal reflection on the anterior wall of the rectum, and the hook knife is used to create a surgical opening of 2 to 3 mm in diameter sufficient for passage of the wire at a distance 3 cm or more away toward the mouth. All these operations are performed under monitoring with a transgastric endoscope (Figure 3(b)).

(3) Method to insert the flexible port: the flexible port socket of one side is inserted through a surgical opening of 2 to 3 mm in diameter which was created in the rectum. This operation of creating the surgical opening is performed under monitoring with an endoscope which was inserted in the abdominal cavity through the gastric wall. The flexible port is inserted into the rectal wall by using the traction wire attached to the port insertion set through the forceps hole of a gastric camera for monitoring (Figure 4(a)).

(4) The flexible port socket of the other side is inserted according to the same procedures as those described in Figure 3(a). Insertion is assisted by using the traction wire which is similarly inserted into the abdominal cavity through the forceps hole of the gastric camera (Figure 4(a)).

(5) The setting of two flexible ports in one set through the operations described in Figures 4(a) and 4(b) is completed. At this moment, make sure to adjust port length which is required for the abdominal cavity (Figure 4(c)).

(6) The photographs of the abdominal cavity monitoring in operations described in Figure 4(a) to Figure 4(c) are shown in Figure 4(d). (1) The insertion socket with the loop wire, which is placed to the apex of the flexible port immediately after penetration through the rectal wall, is shown. (2) The scene indicates traction with the traction wire which was inserted into the abdominal cavity via the forceps hole of the endoscope through which the socket with the loop wire attached to the apex of the flexible port was guided into the abdominal cavity transgastrically. By this operation, the flexible port is inserted from the rectal wall to the abdominal cavity for a required length and is placed.

(7) Photographs ex vivo in the operations described in Figure 4(a) to Figure 4(c) are shown in Figure 4(e). Method of flexible port insertion: the flexible port is inserted one by one. The flexible port apex socket with the wire loop for traction is pulled toward

Table 1: Results of the study on the efficiency of insertion of various devices for conventional laparoscope through the flexible port.

		Transrectal route									Transrectal vaginal route					
		∅ 7 mm port			∅ 12 mm port			∅ 18 mm port			∅ 7 mm port			∅ 12 mm port		
		Insertion	Tmes the device got stuck	Air leakage	Insertion	Tmes the device got stuck	Air leakage	Insertion	Tmes the device got stuck	Air leakage	Insertion	Tmes the device got stuck	Air leakage	Insertion	Tmes the device got stuck	Air leakage
∅ 5 mm devices	Forceps [Karl dtorz ∗1] [Covidien ∗2] [Novare ∗3]	○	none	none	○	none	a little	○	none	severe	○	none	none	○	none	a little
	Endo Clip [Covidien]	○	none	none	○	none	a little	○	none	severe	○	none	none	○	none	a little
	Harmonic scalpel [Johnson & Jonson]	○	2/10	none	○	none	a little	○	none	severe	○	1/10	none	○	none	a little
	LigaSureAdvance [Covidien]	○	none	none	○	none	a little	○	none	severe	○	none	none	○	none	a little
	ENDO CATCH [Covidien]	○	3/10	none	○	none	a little	○	none	a little	○	1/10	none	○	none	a little
∅ 10 mm devices	Endoscope 240i [Olympus]	×	—	—	○	4/10	none	○	none	none	×	—	—	○	2/10	none
	LigaSure [Covidien]	×	—	—	○	1/10	none	○	none	a little	×	—	—	○	1/10	none
	Anvil holder [Karl storz]	×	—	—	○	none	none	○	none	a little	×	—	—	○	none	none
	Stapler i60 [Power Medical]	×	—	—	○	none	none	○	none	none	×	—	—	○	none	none
∅ 15 mm devices	ENDO CATCH II [Covidien]	×	—	—	×	—	—	○	2/10	none	×	—	—	×	—	—

∗1 Scissors; Intestinal usage; Maryland, ∗2 Roticulator, ∗3 Real Hand (Maryland).

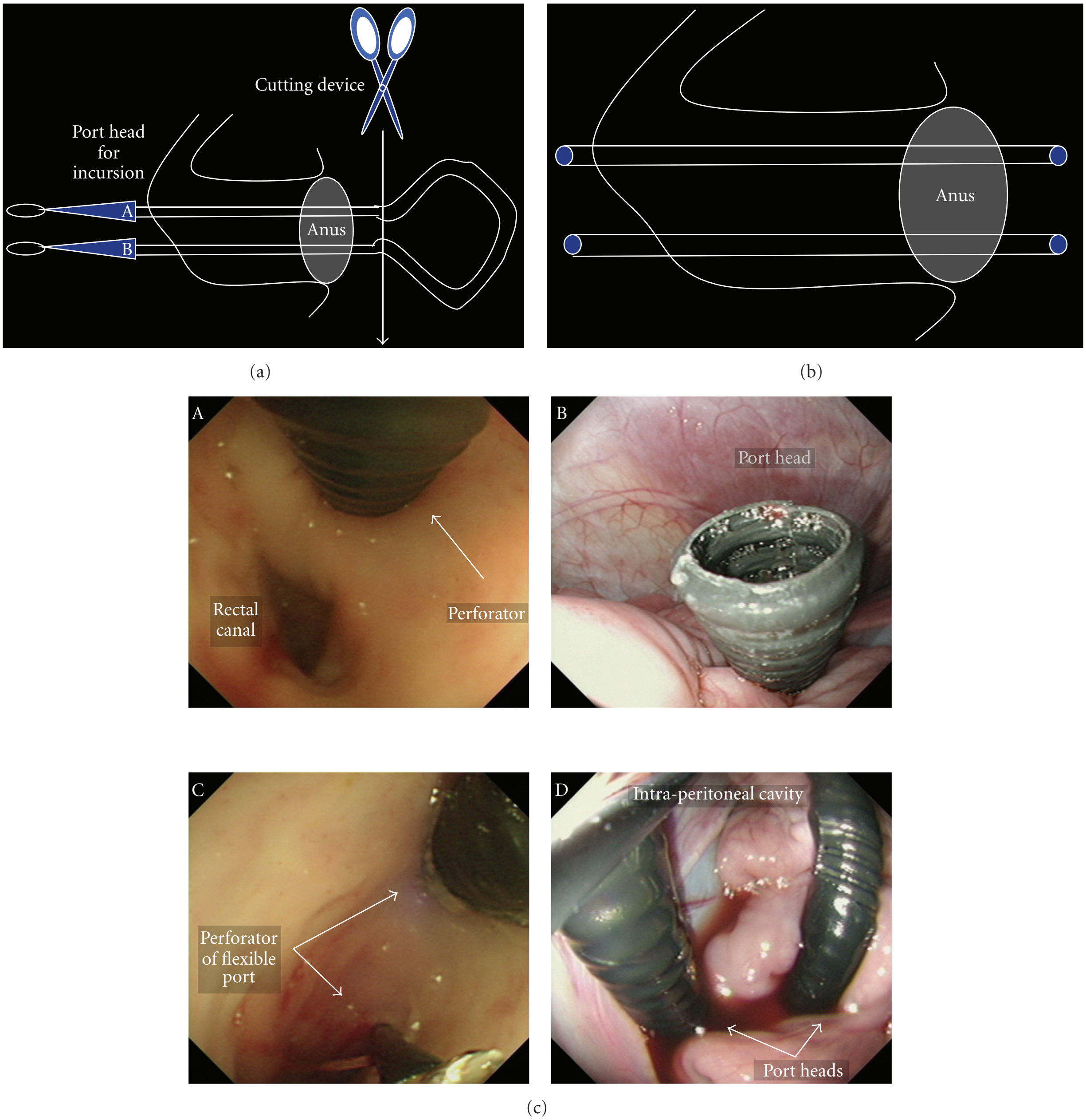
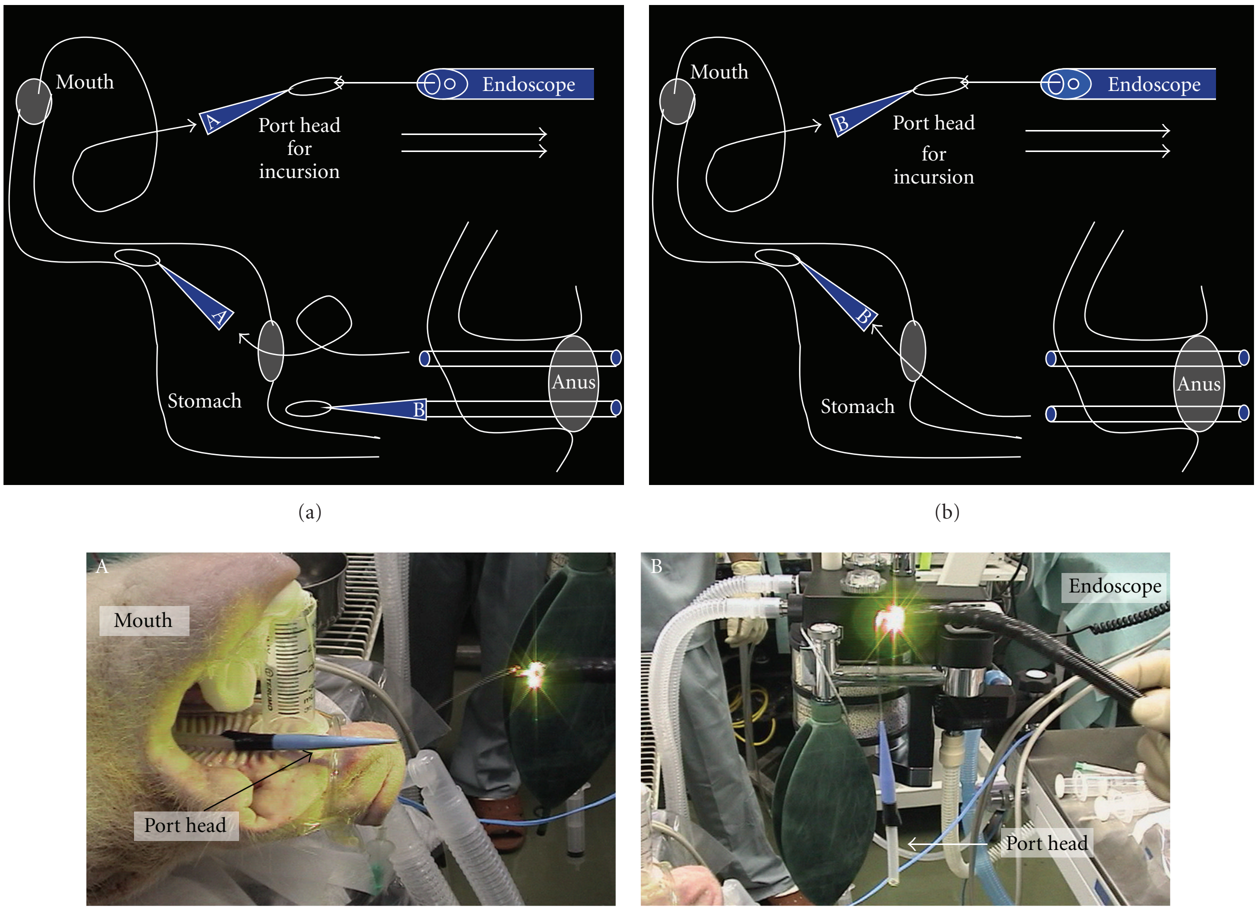


Figure 5: (a) Method to adjust flexible port length outside the body: after completing the setting of the flexible port to the rectal wall, the portion of the port which is exposed outside the body is cut at an arbitrary level. The original length of the port is 1 m. This separation operation to adjust port length can be conducted easily during surgery while checking required length. (b) Two flexible ports of the same diameter can be set in one insertion. In the case of changing the port, the setting can be made by adding the flexible ports of different diameters. (c) Flexible ports whose setting was completed in Figures 4(a) and 4(b). (1) A flexible port that was completely set to the anterior wall of the rectum. (2) Intra-abdominal picture of the first flexible port whose setting was completed. (3) The second flexible port of 5 mm in diameter was inserted. (4) Intra-abdominal picture of the second flexible port whose setting was also completed.

the mouth with the traction wire which was drawn out of the anus via the sheath that had been inserted through the forceps hole of the transgastric endoscope and is guided into the abdominal cavity.

(8) Method to adjust flexible port length outside the body: after completing the setting of the flexible port to the rectal wall, the portion of the port which is exposed outside the body is cut at an arbitrary level. The original length of the port is 1 m. This separation operation to adjust port length can be conducted easily during surgery while checking required length (Figure 5(a)).

(9) Two flexible ports of the same diameter can be set in one insertion. In the case of changing the port, the setting can be made by adding flexible ports of different diameters (Figure 5(b)).



(c)

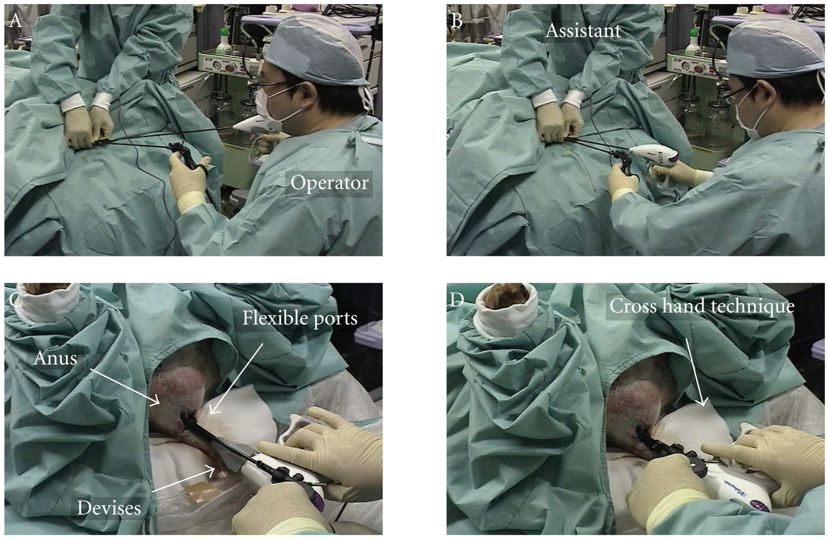
Figure 6: (a) The method to carry the apex socket for flexible port insertion out of the body after setting the flexible port: after completing the setting of the flexible port in the abdominal cavity, the apex socket for flexible port insertion is carried out of the body. The carriage is performed by grasping the wire attached to the socket apex with the traction wire which is attached to the flexible port set. The traction wire is inserted into the abdominal cavity after passage through the forceps hole of the transgastric endoscope. The removal of the apex socket from the flexible port is achieved with an instant slight force and by traction for a short distance. The socket separated from the port is carried outside the body from the mouth after passage through the gastric cavity and esophagus. (b) It is possible to set a given number of ports and to carry the sockets outside the body by repeating the procedures as those in Figure 5(a). (c) The sockets for port insertion that were carried outside the body in Figures 5(a) and 5(b): (a) indicates a scene in which the sockets for guidance of the flexible port with the loop wire are removed from the mouth. (b) indicates the sockets for guidance of the flexible ports with the loop wire which were retrieved completely.

(10) Monitoring photographs of the sites of first and second port insertions with a colonoscope which was inserted in the rectum is shown in Figure 5(c)-A and C. The gastroscopic pictures of two ports whose insertion in the abdominal cavity was completed are shown in Figure 4(c)-B and D. The colonoscopic photographs in Figure 4(c)-A and C show the tightness of the site of port admittance to prevent air leakage.

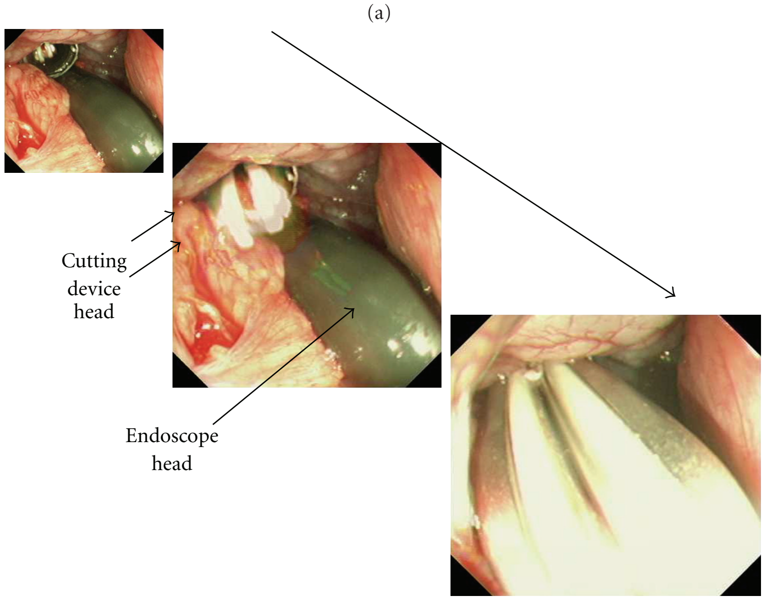
(11) The method to carry the apex socket for flexible port insertion out of the body after setting the flexible port is shown in Figure 6(a). After completing the setting of the flexible port in the abdominal cavity, the apex socket for flexible port insertion is carried out of the body. The carriage is performed by grasping the wire attached to the socket apex with the traction wire which is attached to the flexible port set. The traction wire is inserted into the abdominal cavity after passage through the forceps hole of the transgastric endoscope. The removal of the apex socket from the flexible port is achieved with an instant slight force and by traction for a short distance. The socket separated from the port is carried outside the body from the mouth after passage through the gastric cavity and esophagus.

(12) It is possible to set a given number of ports and to carry the sockets outside the body by repeating the procedures described in Figures 6(a) and 6(b).

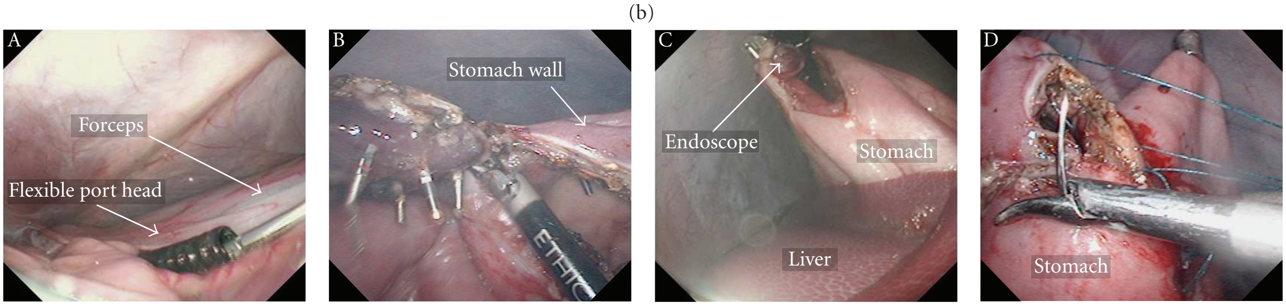
(13) The sockets for port insertion which were carried outside the body in Figure 1 and Figure 2 are shown



(a)



(b)



(c)

Figure 7: (a) A scene in which the device for conventional laparoscope-assisted surgery is used via the flexible port: a scene, in which 5 mm LigaSure and 5 mm grasping forceps are inserted from the anus into the abdominal cavity and are used, is shown (A) and (B). It is possible to conduct surgery according to the cross and parallel methods (C) and (D) similarly to SPS. (b) Single arrow: the apex of the 10 mm endoscope was inserted through the flexible port of 12 mm in diameter. The double arrow: the head of LigaSure which was inserted through the flexible port of 12 mm in diameter. (c) Full-thickness gastrectomy which was conducted with the flexible port: (A) the head of LigaSure of 10 mm in diameter which was inserted into the abdominal cavity through the flexible port. LigaSure of 10 mm in diameter made it possible to treat the great omentum and mobilize the stomach. (B) Full-thickness gastrectomy using Harmonic Scalpel: it was necessary to pull the stomach toward the tail with 45 cm grasping forceps in order to conduct full-thickness gastrectomy. (C) A scene indicating the completion of full-thickness partial resection of the stomach dummy lesion.(D) Closure of the gastric incision with a needle holder: when inserting a needle into the abdominal cavity through the flexible port, an ordinary needle is curved in the form of ski before use. A magnetic traction device developed by Ohdaira is used as the auxiliary device for resection.

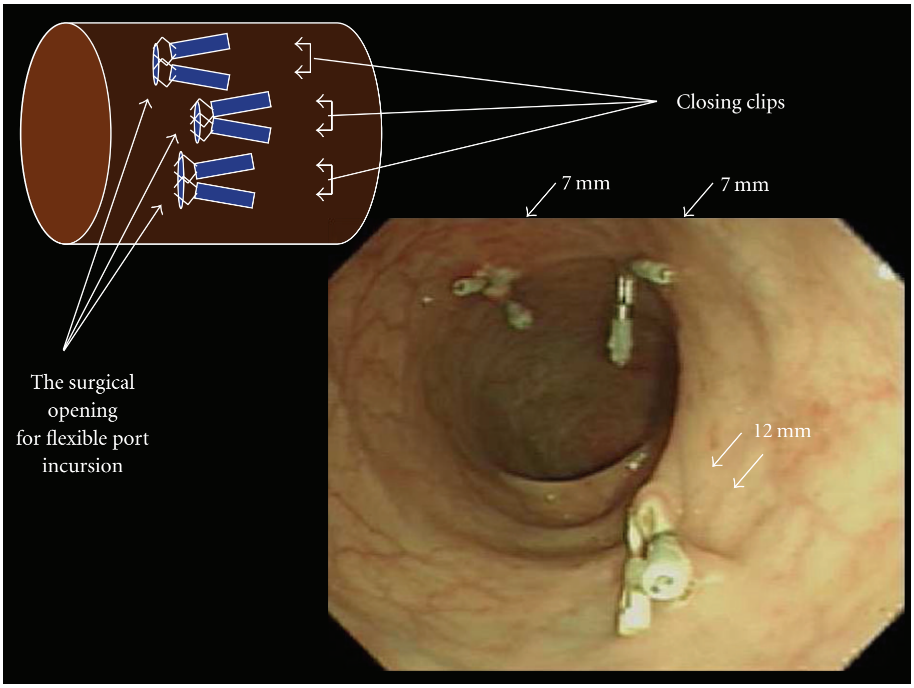


Figure 8: An endoscopic picture of the rectal wall in which the surgical opening for the flexible port was closed with a hemostatic clip. Two ports of 7 mm in diameter and one port of 12 mm in diameter were used.

Table 2: Results of the in vivo study. It was possible to perform partial gastrectomy and cholecystectomy by pure NOTES.

	Transrectal route	
	Partial gastrectomy ($n = 2$)	Cholecystectomy ($n = 2$)
The number of port-setting	12 mm (2 routes) 7 mm (1 route)	12 mm (1 route) 7 mm (2 route)
Time between gastric piercing and fully port-setting (min.)	32.5	19.5
Operation time (min.)	187.5	119
Mount of bleeding	<50 g	<50 g

in Figure 6(c). (a) indicates a scene in which the sockets for guidance of the flexible port with the loop wire are removed from the mouth. (b) indicates the sockets for guidance of the flexible ports with the loop wire which were retrieved completely.

(14) Figure 7(a) indicates a scene in which the device for conventional laparoscope-assisted surgery is used via the flexible port. A scene, in which 5-mm LigaSure and 5-mm grasping forceps are inserted from the anus into the abdominal cavity and are used, is shown (A and B). It is possible to conduct surgery according to the cross and parallel methods (C and D) similarly to single port surgery (SPS).

(15) The endoscope and the incision device, which are inserted into the abdominal cavity through the flexible port, are shown in Figure 7(b). The single arrow indicates the apex of the 10-mm endoscope which was inserted through the flexible port of 12 mm in diameter. The double arrow indicates the head of LigaSure which was inserted through the flexible port of 12 mm in diameter.

(16) The reality of full-thickness gastrectomy, which was conducted with the flexible port, is shown in Figure 7(c). The head of LigaSure of 10 mm in diameter which was inserted in the abdominal cavity through the flexible port. It was possible to treat the great omentum and to mobilize the stomach by using LigaSure of 10 mm in diameter (Figure 7(c)-A). Full-thickness gastrectomy using Harmonic Scalpel: it was necessary to pull the stomach toward the tail with the 45 cm grasping forceps in order to conduct full-thickness gastrectomy (Figure 7(c)-B). A scene indicating the completion of full-thickness partial resection of the stomach dummy lesion is shown in Figure 7(c)-C. Closure of the gastric incision with a needle holder: when inserting a needle into the abdominal cavity through the flexible port, an ordinary needle is curved in the form of ski before use. A magnetic traction device developed by Ohdaira is used as the auxiliary device for resection (Figure 7(c)-D).

(17) The flexible port is removed after completing the surgical procedures.

(18) Close the site of flexible port admittance which enlarged to approximately 7 mm in diameter. In fact, the insertion hole after the removal of the flexible port shrinks to a diameter smaller than the diameter of the inserted port. Therefore, it is possible to use a skin stapler and an hemostatic clip for endoscope. The endoscopic picture of the rectal wall where the surgical openings for ports are closed with hemostatic clips is shown in Figure 8. Two ports of 7 mm in diameter and one port of 12 mm in diameter were used.

3. Results

3.1. In Vivo Study. The results of the port insertion study are shown in Table 1. Furthermore, the results of cholecystectomy and pyloric partial gastrectomy in pigs are shown in Table 2.

Injury and deformation of the port insertion hole: after surgery, any deformation or enlargement did not occur at all to the bore of the site of flexible port setting in the rectum and vagina.

Requisite for the length of the device used: conventional forceps for laparoscope-assisted surgery were required to have a length of 35 cm or more. Both Harmonic Scalpel and LigaSure of 10 mm in diameter, which were used as incision devices, had a length of approximately 35 cm. Therefore, we occasionally needed to pull the stomach toward the tail with forceps of 45 cm in length.

Position where the surgical opening for flexible port insertion is created: forceps, whose rod could be freely controlled at hand with respect to the degree of flexion, allowed the unlimited conduct of surgical procedures. In the case of using straight forceps, it was necessary to establish the site for port setting at a distance of 3 cm or more away from the site of peritoneal reflection toward the mouth in order to avoid the forceps' hit against the pelvis.

Method to operate forceps when using the flexible port: regarding surgical procedures, it was possible to use the flexible port by the same operations of forceps as the cross or parallel method for SPS.

4. Discussion

Issues Related to Ports of Conventional NOTES and to Conventional Techniques. In conventional NOTES, there has been a risk of intra-abdominal abscess caused by bacterial intrusion from the site of endoscope admittance in the abdominal cavity when no port was used. In the case of using the port for laparoscope-assisted surgery, furthermore, there has been a risk of port fall during surgery because port length was insufficient due to port usage without change and the port surface was slippery. For the application of conventionally existing TEM technologies, an attempt has been made to insert a giant, metal, surgical opening-creating device into the anus and to create and use the transrectal route [4]. This method causes a burden to the anal sphincter and occasionally injures the anus even when using a muscle relaxant. However, the flexible port could be set to the rectum at the surgical opening of several diameters in the GI tract only via the visual field of a colonoscope. Extension of the anus was not required during surgical procedures, which verified the advantage of the flexible port in the aspect of lessening the burden to the anus. Furthermore, there is also an attempt to use as the port for NOTES an overtube port of specified length that can reach the sigmoid colon [5]. However, the attempt has the following problems: air leakage; time is required to close the surgical opening in the rectum; and greater risks of causing stenosis and ruptured suture due to the creation of a large surgical opening in the intestine that is not directly related to surgery.

Advantages of Using the Flexible Port. The cuttable flexible port allows its use regardless of anatomical individual differences. Furthermore, the use of the flexible port permits the determination of the port setting position without being influenced by port length. It is necessary to create surgical openings in the GI tract as numerous as required ports. However, we could verify that no air leakage occurred at the site of port insertion because the port was atraumatically set while dilating the pinhole. We confirmed that the use of the flexible port made it possible to use conventional long-type forceps for laparoscope-assisted surgery without change.

Comparisons of Advantages between the Flexible Port and Other Techniques. Conventional NOTES has presented technical difficulties and required skill in operations because an endoscope or an endoscope-customized surgical instrument is used to conduct surgery. Furthermore, an endoscope is used to grasp the organ. Therefore, the weakness of bearing power and traction power made is difficult to manipulate the organ without fail. The use of the flexible port allows the conduct of surgery similarly to laparoscope-assisted surgery by using the cross and parallel methods of conventional SPS. Furthermore, the operability of forceps for laparoscope-assisted surgery will further improve if it is a device which has a mechanism to adjust the angle between the handle and the rod or to permit flexion between the rod and the apical structure.

Challenges Currently Addressed in Relation to the Present Technique. Forceps with a length of 35 cm or greater is required to conduct surgery of upper abdominal target organs (e.g., stomach and gallbladder) by using the flexible port. Most incision devices currently available have a length of 35 cm. Therefore, it is necessary to use forceps of 45 cm in length in order to pull the stomach toward the tail when using a cutting device for gastrectomy. We are using the currently available forceps of 45 cm in length as the electrosurgical knife. Furthermore, we plan to use a 45 cm rod-like metal stick to displace the intestine or an organ.

Future Plan in Consideration of the Present Technique. In the future, we plan to manufacture 40-cm forceps with the bendable apex and a cutting device. A variety of devices for SPS have already been designed and are ready for commercialization. We consider that the flexible port, which permits the conduct of NOTES as a device for SPS, has a potential of revolutionizing NOTES procedures. We will successively report on whether the flexible port is usable for devices for SPS which are to be commercialized later on.

5. Conclusion

We considered that the flexible port has a potential of becoming a highly safe port which allows SPS in NOTES by the transrectal and transvaginal routes.

Acknowledgments

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Research Article

Single Incision Laparoscopic Surgery for Acute Appendicitis: Feasibility in Pediatric Patients

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Background. Laparoscopic appendicectomy is accepted by many as the gold standard approach for the treatment of acute appendicitis. The use of Single Incision Laparoscopic Surgery (SILS) has the potential of further reducing postoperative port site complications as well as improving cosmesis and patient satisfaction. *Method*. In this paper we report our experience and assess the feasibility of SILS appendicectomy in the pediatric setting. *Results*. Five pediatric patients with uncomplicated appendicitis underwent SILS appendicectomy. There were no significant intraoperative or postoperative complications. All patients were discharged within 24 hours. *Conclusions*. The use of Single Incision Laparoscopic Surgery appears to be a feasible and safe technique for the treatment of uncomplicated appendicitis in the pediatric setting. Further studies are warranted to fully investigate the potential advantages of this new technique.

1. Introduction

The rapid uptake of minimally invasive techniques has affected many areas of surgery, including the management of acute appendicitis. Laparoscopic appendicectomy is also a standard and recognised technique in the paediatric setting, with some surgeons advocating a primarily laparoscopic approach to all paediatric patients presenting with appendicitis [1]. Initial fears regarding the possibility of increased rates of postoperative complications seem to have been dispelled with improved instrumentation, technique, and growing experience both from the surgeon and ancillary staff [2]. In fact, although operating times and cost may be increased with the laparoscopic approach, this may be offset by a reduced postoperative stay compared to the standard open approach [3].

Single Incision Laparoscopic Surgery (SILS) is a new technique through which laparoscopic surgery takes place through a single umbilical incision, without the need for additional laparoscopic ports. This new method has been used for a variety of laparoscopic operations including tubal ligation [4], hysterectomy [5], appendicectomy [6, 7], cholecystectomy [8], sleeve gastrectomy [9], colectomy [10], and nephrectomy [11]. The single incision technique has the possible advantages of reduced postoperative pain, faster return to normal function, reduced port site complications, and improved cosmesis and patient satisfaction.

In this paper we present our first experiences and assess the feasibility of using SILS to treat appendicitis in the pediatric population.

2. Patients

SILS appendicectomy was carried out in 5 children in a teaching hospital in central London. All patients had a body mass index between 20 and 25, and all operations were carried out by the same consultant surgeon.

The first patient was a 12-year-old boy, who presented with a single day history of central abdominal pain that localised to the right iliac fossa. On admission his white cell count and CRP were both within normal range, but he was tender with localised peritonism in the right iliac fossa. His symptoms did not improve overnight and thus the decision was made to proceed with laparoscopy.

The second patient was a 14-year-old girl who presented with a 5-day history of worsening right iliac fossa pain with localised peritonism. She had a normal white cell count, but a raised CRP of 29 on admission and was booked for laparoscopy

The third patient was a 13-year-old boy with a 2-day history of right iliac fossa pain. His white cell count and CRP were within the normal range. However, his symptoms worsened overnight and thus he was booked for laparoscopy. The fourth patient was a 12-year-old girl with a 1 day history of abdominal pain and normal white cell count and CRP. Her symptoms also worsened overnight, and thus we proceeded to laparoscopy. The fifth and final patient was a 13-year-old boy presenting with a 12-hour history of pain and raised white cell count of 15.

3. Technique

Access was gained via an open umbilical incision. Firstly the umbilicus was everted using a Littlewoods forcep. The incision was made either vertically or transversely, with a Prolene (Ethicon, New Brunswick, NJ, USA) stay suture placed either side of the incision. Care was taken to keep the incision within the umbilical ring for the best cosmetic outcome. A mixture of sharp and blunt dissection was used down to the linea alba which was incised. The peritoneum was opened under direct vision, and a 11 mm laparoscopic port inserted. Pneumoperitoneum was then established. A 5 mm 30 degree laparoscope was used to complete a full laparoscopy. Up to 2 further 5 mm DEXIDE (Covidien, Mansfield, Massachusetts, USA) ports were then inserted through the fascia to either side of the 11 mm port.

Mobilisation of the appendix was achieved with the use of Roticulator instruments (Covidien, Mansfield, Massachusetts, USA). A window was made in the mesoappendix near the appendix base, and the appendix and mesoappendix both stapled and divided using an EndoGIA stapler (Covidien, Mansfield, Massachusetts, USA). In our third and fourth patients this procedure was assisted by the placement of a single suture, placed through the abdominal wall in the right iliac fossa. The needle was then passed through the mesoappendix near the appendix base, before being passed back up through the skin again. This formed a sling to retract the appendix ventrally, allowing easier positioning of the EndoGIA stapler (Covidien, Mansfield, Massachusetts, USA). All specimens were removed with the use of an Endo-CATCH bag (Covidien, Mansfield, Massachusetts, USA). Irrigation was carried out as required.

Closure of the wound was performed in layers, with absorbable sutures to both fascia and skin.

4. Results

SILS appendicectomy took an average of 56.4 minutes to perform (80, 48, 65, 50, and 45 minutes for patients 1, 2, 3, 4, and 5, resp.). The first patient had a macroscopically normal looking appendix. No other intra-abdominal pathology could be found and it was decided to proceed to appendicectomy. Following surgery, the patient symptoms improved and he was discharged on postoperative day 1. The other four patients all had macroscopically inflamed appendixes without evidence of gangrene or perforation. There were no significant intraoperative complications in any patients, and no need for conversion to standard laparoscopic appendicectomy. All patients were discharged within 23 hours and were brought back to clinic 6 to 8 weeks later for out-patient review. There were no postoperative wound infections, intra-abdominal abscess formation, or episodes of small bowel obstruction. Anecdotally all patients and their parents were very satisfied with their operative management, and particularly enthusiastic in regard to the single incision approach. On follow-up in clinic, the umbilical scar was very difficult to visualise once healing had been completed.

5. Discussion

Laparoscopic appendicectomy is now accepted as the gold standard for treatment of acute appendicitis in many centres. The laparoscopic approach has been demonstrated to have lower wound infection rates postoperatively, as well as having significant gains in terms of length of hospital stay and return to normal function [12]. Laparoscopic appendicectomy is also associated with a lower rate of adhesional bowel obstruction compared with the open approach [13]. Initial worries regarding rates of intra-abdominal abscess formation seem to have been refuted by recent studies [3], and it is the authors viewpoint that good peritoneal irrigation is actually aided by the improved intra-abdominal view offered with laparoscopy.

Single incision laparoscopic surgery (SILS) is a new technique that has now been utilised in many centres for appendicectomy. We have previously detailed our initial experiences with the use of SILS for appendicectomy and cholecystectomy in the adult population [14, 15]. The major difficulty with this new technique is the sacrifice that has to be made in terms of comfort and ergonomics. As all instruments and camera are inserted through the same incision, the ability to triangulate your instruments around the target is lost. Although this can be partially rectified by the use of roticulator instruments, the surgeon ends up working with his hands very close together, and finds himself often being impeded by the laparoscope and the assistant. Similarly, the surgeon's right hand will control the left-sided instrument on the screen and the left hand controls the right-sided instrument on screen. These technical difficulties do make SILS a more demanding procedure on the operating surgeon than normal laparoscopic techniques. In our experience this led to an initial significant increase in the operation time. However, with increasing exposure to the technique, operating times have been reduced significantly, and are now very similar to the average time taken for a standard laparoscopic appendicectomy. Future improvements in instrumentation may help to reduce operating times further.

Although the small size, and limited age range of the patients in this series, precludes any meaningful statistical analysis, it does demonstrate that the SILS approach may be feasible for particular cohorts within the pediatric population. This supports the results of other groups using the SILS approach in pediatric patients [16, 17]. However, applicability of SILS to very young patients was not assessed in this paper. This series also adds further to the current literature demonstrating the applicability of SILS in uncomplicated appendicitis. In the future prospective studies with sufficient power are now warranted to demonstrate any statistically significant benefits over the standard laparoscopic method. These are most likely to be in terms of postoperative pain, port site complications, cosmesis, and patient satisfaction.

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Research Article

Transvesicoscopic Repair of Vesicovaginal Fistula

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Introduction. Vesicovaginal fistula has been a social and surgical problem for centuries. Many surgical techniques have been developed to correct this abnormality, including transabdominal, transvaginal, and endoscopic approaches. The best approach is probably the one with which the surgeon feels most experienced and comfortable. Laparoscopy has become increasingly popular in urology, reducing the invasiveness of treatment and shortening the period of convalescence. We report our results of transvesicoscopic approach for VVF repair. *Materials and Methods*. Patients with VVF were offered repair using the transvesicoscopic route. With the patient under general anaesthesia and in modified lithotomy position cystoscopy was performed with gas insufflation. Under cystoscopic guidance the bladder was fixed to anterior abdominal wall and ports inserted into the bladder. The fistula was repaired under endoscopic vision. *Results*. Four women, who had VVF following abdominal hysterectomy, underwent this procedure. The operating time ranged from 175 to 235 minutes. There was minimal bleeding. Post operative complications included ileus in one and fever in another. No recurrence of VVF was noted in any patient. *Conclusions*. Transvesicoscopic repair of VVF is feasible, safe, and results in lower morbidity and quicker recovery time.

1. Introduction

Vesicovaginal fistulas present a debilitating and stressful condition for women in all parts of the world. Surgical repair remains the primary method of treatment, regardless of the etiology. Controversies still exist regarding the timing and surgical approach of Vesicovaginal fistulas repair. The goal of treatment of Vesicovaginal fistula (VVF) is the rapid cessation of urine leakage with return of normal and complete urinary and genital function. It has been stated that the best opportunity to achieve successful repair of VVF is with the initial operation [1]. Previous failed attempts at repair produce scar and anatomic distortion and may compromise potential reconstructive flaps. There is no best approach for all patients with VVF. Classically VVF has been repaired through a transvaginal or transabdominal approach. Each approach has merits, depending on the particular circumstances of the fistula, and excellent outcomes can be expected with both approaches [2]. Laparoscopic approaches to VVF have been reported [3–5]. Surgeons using laparoscopic approach claim several advantages of laparoscopic repair such as shorter hospital stay, more rapid postoperative recovery; and better cosmetic results than the traditional abdominal approach. Laparoscopy allows an excellent view and good exposure of pelvic structures and provides quick and direct access to the fistula, and relatively simple fistula resection [6]. We report our series of VVF treated by transvesicoscopic approach.

2. Materials and Methods

Patients with VVF formed the study group. A detailed history and examination was done in all patients. A three-swab test was done to confirm the clinical suspicion. A routine ultrasonography of kidney, ureters, and bladder region was done in all. Imaging studies included Cystograms, Intravenous urogram, Magnetic resonance imaging when felt necessary and appropriate. Cystoscopy was done to identify the fistula and note its size, position, and sorroundings. At the same instance vaginoscopy was done to observe the end of the fistula. VVF repair was performed at least 12 weeks after its occurrence.

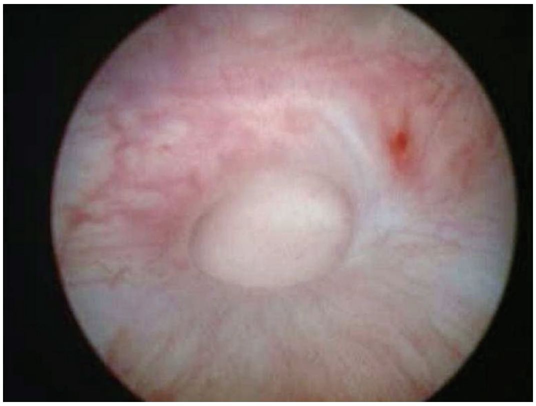

Figure 1: Transvesicoscpic vision of VVF.

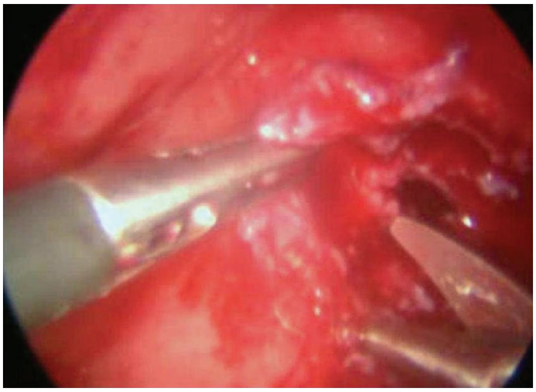

Figure 2: Circumfistula dissection being made.

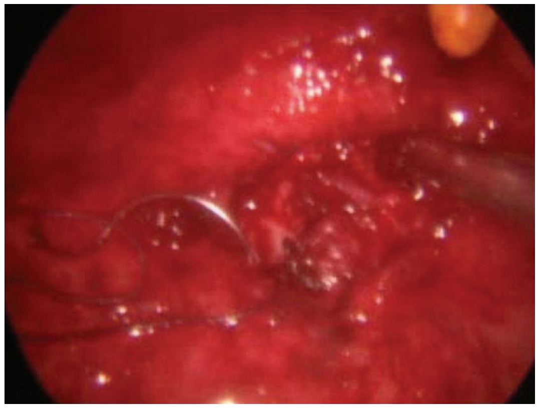

Figure 3: Closure of vagina vertically.

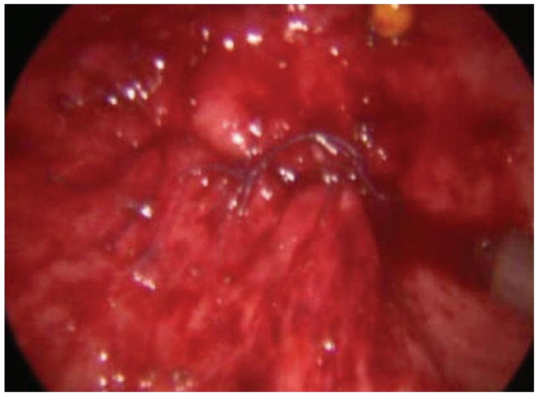

Figure 4: Bladder closure completed.

2.1. Surgical Technique. The patient was placed in modified lithotomy position. An initial cystoscopy was performed using insufflation of gas and the fistula inspected in detail (Figure 1). The bladder was fixed to the anterior abdominal wall under cystoscopic guidance. The bladder was fixed using 1/0 prolene and placed by using a technique of looping the suture material into the bladder with the help of a spinal needle and then hooking it with the same suture through a neighbouring site.

A 5 mm endoscopic port was placed into the bladder under cystoscopic guidance in the midline, halfway between the umbilicus and pubic symphysis. Two more working/instrument ports were placed 5 cm laterally and inferior to the endoscopic port on either side. Once the ports were in place the cystoscope was withdrawn and the urethra catheterised. The vagina was packed with betadine packs so as to prevent gas leak. The fistula was once again inspected. A circum fistula incision was made and the bladder dissected away from the underlying vagina (Figure 2). The edges of the fistula were excised. Once adequate dissection was achieved, the vagina was sutured vertically (Figure 3) and the bladder edges sutured horizontally (Figure 4). The bladder was closed using 4/0 vicryl. The two ureteric orifices were catheterised using 5F infant feeding tubes and brought outside the bladder for drainage. The bladder was also catheterised. The infant feeding tubes were removed after one week and the catheter removed after two weeks.

All patients underwent three-swab test, on table cystograms and cystoscopy in the follow-up period. All patients were reassessed six months after surgery. They all were requested to answer a questionnaire related to their act of micturition, satisfaction with the outcome of their surgery, and sexual performance.

3. Results

Four patients with history of VVF following gynaecologic surgical procedure presented to us for repair during the period Jan. 2008–Jan. 2009. Their ages ranged from 42 years to 58 years. All the four had undergone total abdominal hysterectomy. All the fistulas were located superior to the trigone, away from the ureteric orifices. The size of the fistulas ranged from 1 cm to 2 cm.

None of these patients had undergone previous repairs. Transvesicoscopic laparoscopy was performed in all the three patients under general anaesthesia and in modified lithotomy position. Operative time ranged from 175 minutes to 235 minutes. The first case was the one with the maximum time taken. Conversion to open was not done in any patient. Blood loss was minimal in all. Intraoperative difficulties were noted in the first case, which included fixing the bladder to the anterior abdominal wall, pressure of insufflation to maintain the pneumovesicum during port insertion and suction, suturing of the vagina and bladder with continuous urine pool, and lastly the small space for instrument movement. These difficulties were less in the second and thereafter cases as we were able to overcome these initial discomforts.

In the immediate postoperative period no obvious complications were noted, one patient developed upper respiratory tract infection and fever which subsided on its own. Another patient developed prolonged ileus more than 24 hours, which again settled on its own. Three patients were started orally within 24 hours and the patient with ileus was started orally after 48 hours. Patients were allowed to move within 36 hours. All patients had their infant feeding tubes removed on the 7th postoperative day and discharged with urethral catheters. Catheters were removed after 15 days following surgery. Follow-up ranges from 8 months to 17 months in these patients. No recurrence of VVF was noted in any one of them.

All the four patients were satisfied with the surgical outcome; voiding was near normal in all. The two patients who were sexually active prior to surgery, continued to be having sexual relationship though both experienced some discomfort initially.

4. Discussion

There is no "best" approach for all patients with VVF. Although factors such as size, location, and need for adjunctive procedures often have an impact on the choice of approach, the most important factor is commonly the experience of the operating surgeon [2]. Thus, there is no preferred approach for all fistulas, and the optimal approach to the uncomplicated postgynecologic VVF is usually the one that is most successful in the individual surgeon's hands [7]. Although it has been a long-held belief that gynaecologists prefer to fix VVF transvaginally and urologists prefer a transabdominal approach because of their respective training and experience [8, 9], this difference is becoming increasingly blurred as urologists gain more experience and comfort operating transvaginally for a number of different indications.

The majority of VVF's are amenable to a transvaginal repair. The relative advantages of a transvaginal approach compared with an abdominal approach include shorter operating times, briefer hospital stay, and less blood loss [10]. The principal disadvantages of the transvaginal approach include the relative lack of familiarity of the vaginal cuff anatomy to many urologists; the potential for vaginal shortening, especially with the Latzko approach; the difficulty in exposing high or retracted fistulas near the vaginal cuff, especially in deep, narrow vaginas or those without any apical prolapse, such as that found in nulliparous women [2]. VVF may be repaired transabdominally, and this is the preferred approach in those cases requiring augmentation cystoplasty or ureteral reimplantation. Compared with the vaginal approach, the transabdominal approach to VVF repair is associated with longer recovery time and inpatient hospitalization, greater blood loss, more cosmetic deformity, and in general, greater morbidity [2].

Minimally invasive approaches to VVF repair would be ideal. A number of case reports and small series of laparoscopic approach have already been published [3–6]. C. H. Nezhat et al. [11] first reported laparoscopic repair of a VVF. Von Theobald et al. [3] used an omental J-flap interposition during the laparoscopic repair of VVF. Recurrent VVF was similarly successfully repaired laparoscopically by Miklos et al. [4]. Their patient had previous two failed Latzko partial colpoclesis and closing the vagina and bladder with an interposed omental flap using a laparoscopic approach ultimately repaired the persistent fistula. Similar success with laparoscopic approach was described by a number of other authors [5, 12, 13]. The various authors were of the opinion that laparoscopy offered the patient several advantages which included shorter hospital stay, more rapid postoperative recovery, and better cosmetic appearance than the traditional abdominal approach. The long operative time (>300 minutes) was attributed to difficulty in identification of the fistulous tract, difficult dissection of the Vesicovaginal space, and need for intracorporeal suturing [6]. Sotelo et al. [14] incorporated concomitant cystoscopy to help guide the bladder incision, facilitating quick access to the VVF, and avoiding unnecessary dissection in the Vesicovaginal space.

With our past experience in laparoscopy and intracorporeal suturing we decided on attempting transvesicoscopic approach. Several laparoscopic surgeons have used this approach in a number of situations such as transvesicoscopic reimplantation of ureters, extraction of huge vesical calculi, and prostatectomy. All our four patients had a solitary, supratrigonal VVF away from ureteric orifices. Transvesicoscopic approach led us directly over the fistula, making dissection of bladder from vagina easy. The vision was good and the intracorporeal suturing easy.

Transvesicoscopic repair of VVF carries all the advantages of laparoscopy including minimal invasiveness, less morbidity, shorter hospital stay, early recovery, and better cosmetic appearance. The disadvantages of standard transabdominal laparoscopy, such as injury to other intraperitoneal organs, need for peritoneal drain, prolonged ileus, bleeding, are avoided in this technique. One obvious disadvantage of this procedure would be the inability to interpose healthy tissue such as omentum, in between the bladder and vagina. But with improved experience, articulated instruments, and newer devices, surgeons in future may be able to develop Martius flap and interpose in between the vagina and bladder.

5. Conclusions

Transvesicoscopic repair of a Vesicovaginal fistula is feasible, safe and provides good results. It is an additional modification to the laparoscopic transabdominal approach with all the advantages of laparoscopy.

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Research Article

Laparoendoscopic Single-Site Surgery for the Treatment of Benign Adnexal Disease: A Prospective Trial

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Background. To validate feasibility, efficacy, and safeness of laparoscopic treatment of benign adnexal diseases through a single transumbilical access (LESS) in a prospective series of patients. *Methods*. A prospective clinical trial including 30 women has been conducted at the Division of Gynecology of Catholic University of Sacred Hearth of Rome. Patients underwent different laparoscopic procedures by LESS utilizing a multiport trocar and conventional straight laparoscopic instrumentation. Intra and perioperative outcome has been reported. *Results*. Ten mono/bilateral adnexectomies and 20 cystectomies have been performed by LESS approach. Laparoscopic procedures were completed through a single access in 28 cases (93.4%). No major intra- or postoperative complications were observed. Mean hospital stay was 1.3 days. *Conclusions*. LESS approach is feasible to treat benign adnexal disease with a very low conversion rate and no early or late complications. More clinical data are needed to confirm these advantages compared to standard laparoscopic technique.

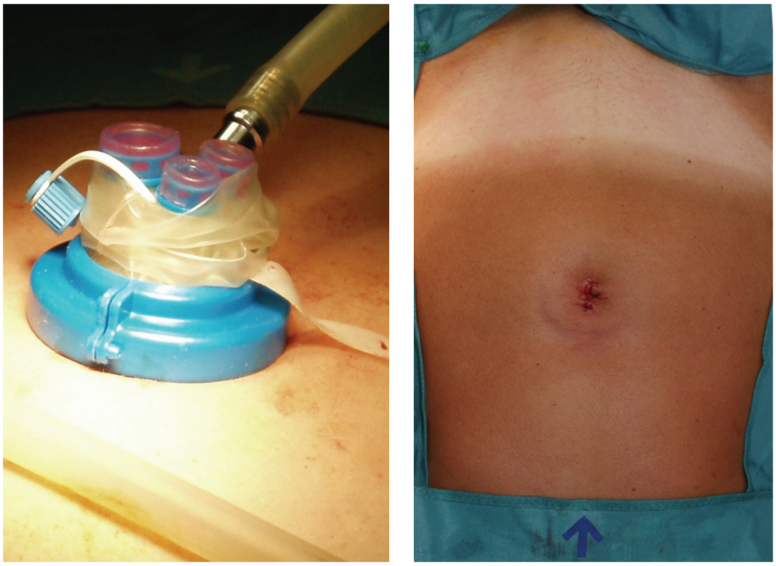
1. Introduction

Laparoscopy has been demonstrated a valid approach in many gynecologic procedures with better results in terms of minimal perioperative morbidity and shorter hospital stay, with consequent improved quality of life compared to laparotomic approach [1, 2]. Despite this well-known advantages, laparoscopy still requires 0.5 to 1.5 cm long incisions and three to five ports to be performed, each working port implying with an inherent risk of bleeding, infection, concordant organ damage, hernia formation, and decreased cosmetic outcome [3]. Recently, some efforts have been made to decrease incisional morbidity related to parietal trauma and improve cosmetic results while maintaining the same standards of surgical care [4, 5]. In this context, minilaparoscopic approaches and natural orifice translumenal endoscopic surgery (NOTES) have been developed, utilizing the mouth, anus, vagina, or urethra to access through the peritoneum. Laparoendoscopic single-site surgery has encompassed recent terminology including single-port incision laparoscopic surgery (SILS) or single port access laparoscopic surgery (SPA). NOTES and LESS techniques have emerged as viable, feasible, and widely applicable minimally invasive procedures [6–8]. Until now LESS has been mainly used in urologic surgery but recent sporadic reports in the literature have hypothesized some applications in gynaecology [9–17].

Here we report our initial experience on the treatment of benign adnexal disease by LESS.

2. Materials and Methods

This is a single-institutional prospective clinical trial including patients affected by benign adnexal diseases and treated by a LESS approach, accrued between June and July 2009 at the Division of Gynecology, Catholic University of Rome. Selection criteria were: age between 10 and 70 years old; Body Mass Index (Kg/m^2) up to 35; American Society of Anesthesiologists class score up to III; absence of actual pregnancies or acute pelvic inflammatory diseases and absence of liver or coagulative disorders. Clinical indications were: cystic adnexal masses with benign clinical features and major diameter equal or less than 8 cm; prophylactic



(a) (b)

Figure 1: (a) Positioning of the trocar at the beginning of the procedure. (b) Postoperative umbilical scar's outcome.

adnexal removal in high risk patients; ectopic pregnancies. Laparoscopic procedures intended to perform by LESS approach were: ovarian cyst's enucleations, mono (MSO) or bilateral salpingo-oophorectomies (BSO), and exclusive salpingectomies.

All patients were adequately informed on the possible risks and benefits of this experimental technique and signed a written consent agreeing to undergo the described procedure, to convert the mini-invasive access to multiaccess standard laparoscopy or laparotomy if necessary, and to allow the use of their data prospectively. An Institutional Review Board approval from the Ethical Committee of the local hospital was obtained.

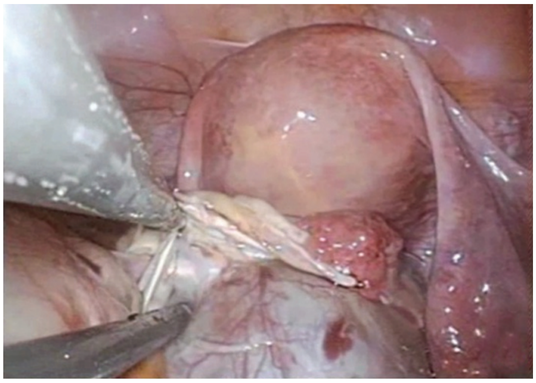
All patients were submitted to preoperative US examination and evaluation of Ca 125 serum levels. Data regarding personal history, age, BMI, clinical and diagnostic information regarding actual disease were anonymously collected in an electronic database at the time of recruitment. At the end of each procedure, intraoperative data as trocar introducing time, operative time, estimated blood loss (EBL), intra- and peri-operative complications, conversion to standard multi-access laparoscopy or laparotomy were registered. Three surgeons were involved in the protocol.

Long-term complications and histological findings were also entered in the electronic database.

2.1. Surgical Technique. Surgical procedures were performed throughout a single multiport trocar (Laparo-Endoscopic Single-Site Surgery, Olympus Winter & IBE GMBH, Hamburg, Germany), inserted in the umbilicus, as shown in Figure 1(a). The trocar is made of a doubled-over cylindrical sleeve of pliable film material which is fixed to the proximal ring and flows down around the distal ring and back up and out. To introduce the trocar, the distal ring is passed into the abdominal cavity utilizing the introducer, by an open access: a 1.5–2.0 cm longitudinal transumbilical skin incision is made, then the subcutaneous fat is opened, with exposure and consequent cold-knife incision of the abdominal fascia for approximately 1,5 cm. The parietal peritoneum is smoothly dissected with blunt scissors achieving access into the peritoneal cavity, then the introducer with the trocar distal ring is entered. Pulling on the sleeve up, the distal and the proximal ring pairs off: the procedure creates a retracting tension inside the sleeve between the rings. The valve is then positioned to fix the system, maintaining the retraction of the sleeve. This trocar is a multi-instrument access port that allows up to three laparoscopic instruments (three 5-mm cannulas or two 5-mm and one 12-mm cannula) to be used simultaneously through separate flexible channels. The cannula positions are adjustable within the flexible port, and a separate channel is available for CO2 insufflation. An intrauterine device (Uterus manipulator, Olympus Winter & IBE GMBH, Hamburg, Germany) is always utilized.

Once achieved pneumoperitoneum (12 mmHg), intra-abdominal visualization is obtained with a 5-mm 30° telescope (EndoEye, Olympus Winter & IBE GMBH, Hamburg, Germany). Working straight 5-mm instruments are inserted into the remaining 2 ports, choosing among graspers, scissors, suction/irrigation, bipolar coagulator, and a multifunctional versatile laparoscopic device which grasps coagulates and transects simultaneously (PKS Cutting Forceps, Gyrus ACMI, Hamburg, Germany) (Figure 2(b)). The combination of one standard 33 cm-long instrument with a 43 cm-long instrument is preferred in order to prevent excessive contact between surgeon's hands outside the abdominal cavity and to facilitate stripping and traction manoeuvres (Figure 2(b)). Changes in the position of the instruments and optic are carried out according to the needs of the surgeon.

In order to perform a classic stripping for ovarian cyst enucleation by LESS approach, standard laparoscopic



(a)

(b)

Figure 2: LESS operative technique: (a) internal vision, (b) external vision.

traction, orthogonal to the axis of the instruments (medial-lateral axis), is shifted to a parallel one (proximal-distal axis) (Figure 2(a)). Once achieved these helpful adjustments, LESS cyst enucleation results similar to standard laparoscopic procedure. For salpingo-oophorectomies the infundibulo-pelvic ligament, utero-ovarian ligament, and the tubal isthmus are grasped and coagulated with the multifunctional PKS bipolar Cutting Forceps and transacted by using the cold knife internal to the device. Specimen removal is achieved within an endo-bag inserted in the 12-mm port of the trocar.

To prevent consequent umbilical hernia formation each layer of the access port is separately sutured; in particular abdominal fascia is closed by singular stitches. Skin is repaired with rapid absorbable suture (Figure 1(b)).

3. Results

Thirty women have been enrolled in the study. The following procedures have been performed by LESS: BSO/MSO (n = 10); mono or bilateral adnexal cyst enucleation (n = 20). In 2 patients (6.6%), affected by an endometriotic cyst, one 5 mm additional trocar in the iliac fossa was necessary at the end of the procedure to perform adequate haemostasis. No patient scheduled for cyst enucleation, underwent monolateral salpingo-oophorectomies due to technical limits related to the LESS approach.

Median time to introduce the trocar from skin incision to achieved pneumoperitoneum has been 3 min (range 1–9). Port placement has been successfully executed in all cases without accidents or inadvertent port removal, but 2 patients (6.6%) showed an accidental engage of the omentum at the level of the inner ring of the trocar. This event did not hinder surgery; the omentum was released and haemostasis verified at the end of surgery throughout the hole of the trocar. No fascial, vascular, or visceral injuries, loss of pneumoperitoneum or intraoperative port-site bleeding occurred.

Rupture of the cyst was observed in 3 (2 benign ovarian tumors, 1 mature teratoma) of the 22 (13.6%) cases of cyst enucleation. We did not consider rupture of endometriotic cysts as an intraoperative adverse event, due to our surgical behavior, consisting in intentional rupture before their removal.

Median EBL amounted to 10 mL (range 5–150). Overall median operative time was 39.5 minutes (range 18–115). According to the type of surgery, median operative time was 33 minutes (range 18–45) and 42.5 minutes (range 20–115) for BSO and ovarian cyst enucleation, respectively. This difference showed a trend to be statistically significant (P = .09).

No wound hematoma, wound infection, delayed bleeding, or any other postoperative complications were registered immediately after surgery.

Mean hospital stay was 1.3 days (SD: 0,5) with 86.7%, 10%, and 3.3% of the patients discharged on day 1, 2, and 3, respectively.

No late complications were observed except for an asymptomatic 2 cm hematoma in the pelvis diagnosed by ultrasound in 1 patient (3,3%) 1 month later her cyst enucleation.

4. Discussion

This is a single-institutional series of patients with benign adnexal disease treated by LESS. In this series, based on simple selection criteria, in all patients considered eligible for this approach we successfully were able to complete the procedure, without conversion, early or late complications and within a reasonable operative time. Elevated BMI, previous laparotomic/laparoscopic surgery, or large cyst volume, according to our experience, do not represent a limit to perform this technique, and the introduction of the multiport trocar is simple, safe and requires progressively shorter time.

Technical, procedural, and spatial limits related to the single access approach, reported by Ramirez as reduced visualization, loss of triangulation, and instrument interference, have been progressively minimized by some practical adjustments [17]. The evidence of lower excursion degrees among the instruments inside the abdominal cavity has been overcome by shifting the traction manoeuvre from an orthogonal axis to a parallel one whereas the use of a flexible camera on the tip did not facilitate the procedure due to its wavering when crossing the instruments [13]. Thus, in our opinion the basic surgical set for the treatment of adnexal disease by LESS should consists of a 5-mm 30° telescope, one 43-cm long, and one 33-cm long straight instruments and an intrauterine device. In fact, two different long instruments have the potential advantage to avoid crossing outside the abdominal cavity and the uterine manipulator can maintain the traction in the absence of conventional assistant's grasper. Moreover, the introduction of a multifunctional device can easily overcome the limit of a reduced number of ports. Finally, the surgical team should be composed by two surgeons, one managing both the operative instruments and the other handling the optic and moving the intrauterine manipulator, when necessary.

The rupture rate of 13,6% in our series is analogous to data reported by previous studies, which estimated the rate of cyst's rupture during laparoscopy as being between 6 and 27% [18–20].

The only one late complication registered was diagnosed by ultrasound control we routinely get one month after surgery in patient group of this study population. She had no symptoms related to this finding.

In conclusion, our experience shows feasibility and efficacy of the LESS technique with good results in terms of adequate operative times, multiaccess low conversion rate, and limited complications showing that this approach can be safely recommended to patients affected by adnexal diseases. Larger, multicenter studies are needed to definitively confirm these preliminary results and to compare LESS technique to conventional multiaccess laparoscopy in the treatment of gynecological diseases.

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Review Article

Technical Refinements in Single-Port Laparoscopic Surgery of Inguinal Hernia in Infants and Children

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The techniques of minimal access surgery for pediatric inguinal hernia are numerous and they continue to evolve, with a trend toward increasing use of extracorporeal knotting and decreasing use of working ports and endoscopic instruments. Single-port endoscopic-assisted percutaneous extraperitoneal closure seems to be the ultimate attainment, and numerous techniques have mushroomed in the past decade. This article comprehensively reviews and compares the various single-port techniques. These techniques mainly vary in their approaches to the hernia defect with different devices, which are designed to pass a suture to enclose the orifice of the defect. However, most of these emerging techniques fail to entirely enclose the hernia defect and have the potential to lead to higher incidence of hernia recurrence. Accompanying preperitoneal hydrodissection and keeping identical subcutaneous path for introducing and withdrawing the suture, the suture could tautly enclose the hernia defect without upper subcutaneous tissues and a lower peritoneal gap, and a trend towards achieving a near-zero recurrence rate.

1. Introduction

Traditional inguinal herniotomy is a well-developed surgical technique for uncomplicated inguinal hernia in infants and children. It usually necessitates one small 1.5 to 2 cm skin incision, and the possible postoperative complications, such as recurrence or injury to the vas deferens, are not high [1]. Laparoscopic surgery has recently emerged as an alternative in its management. Although not as widely used as conventional open herniotomy, laparoscopic herniorrhaphy has clear advantages, especially those related to the evaluation of possible contralateral opening and a safe high ligation of the hernia sac at the internal ring without injury to the vas deferens and spermatic vessels [2]. In 1997, El-Gohary first described laparoscopic ligation of inguinal hernia in girls [3]. Subsequently, numerous technical reports for the laparoscopic hernia repair in children have evolved [2].

Although modifications on laparoscopic surgery continue to be refined, there are some technical limitations, which influence a pediatric surgeon's willingness to perform the procedure [2]. The universally known limitations of the laparoscopic surgery are (1) most of these methods employ a laparoscope inserted via an umbilical incision and two lateral ports for instruments to ligate the hernia defect [4]. The necessity for intraabdominal skills, such as intracorporeal suturing, knot-tying, and manipulation of the suture on a needle may be time-consuming and cumbersome [5]. (2) Recurrence rate after laparoscopic surgery is generally known to be higher than after open surgery [1, 4]. Partial omission of the defect circumference, strength and appropriateness of the knot, inclusion of tissue other than peritoneum in the suture with a propensity for subsequent loosening, use of absorbable sutures, and failure to detect a rare or direct hernia are some reported factors contributing to recurrence in laparoscopic surgery [2]. (3) Compared to open herniotomy with an almost disappeared wound in the skin crease, laparoscopic approach did not take any superiority in cosmesis [6]. Conversely, the procedure was thought not to be minimally invasive because of the necessity of multiple skin incisions and pneumoperitoneum

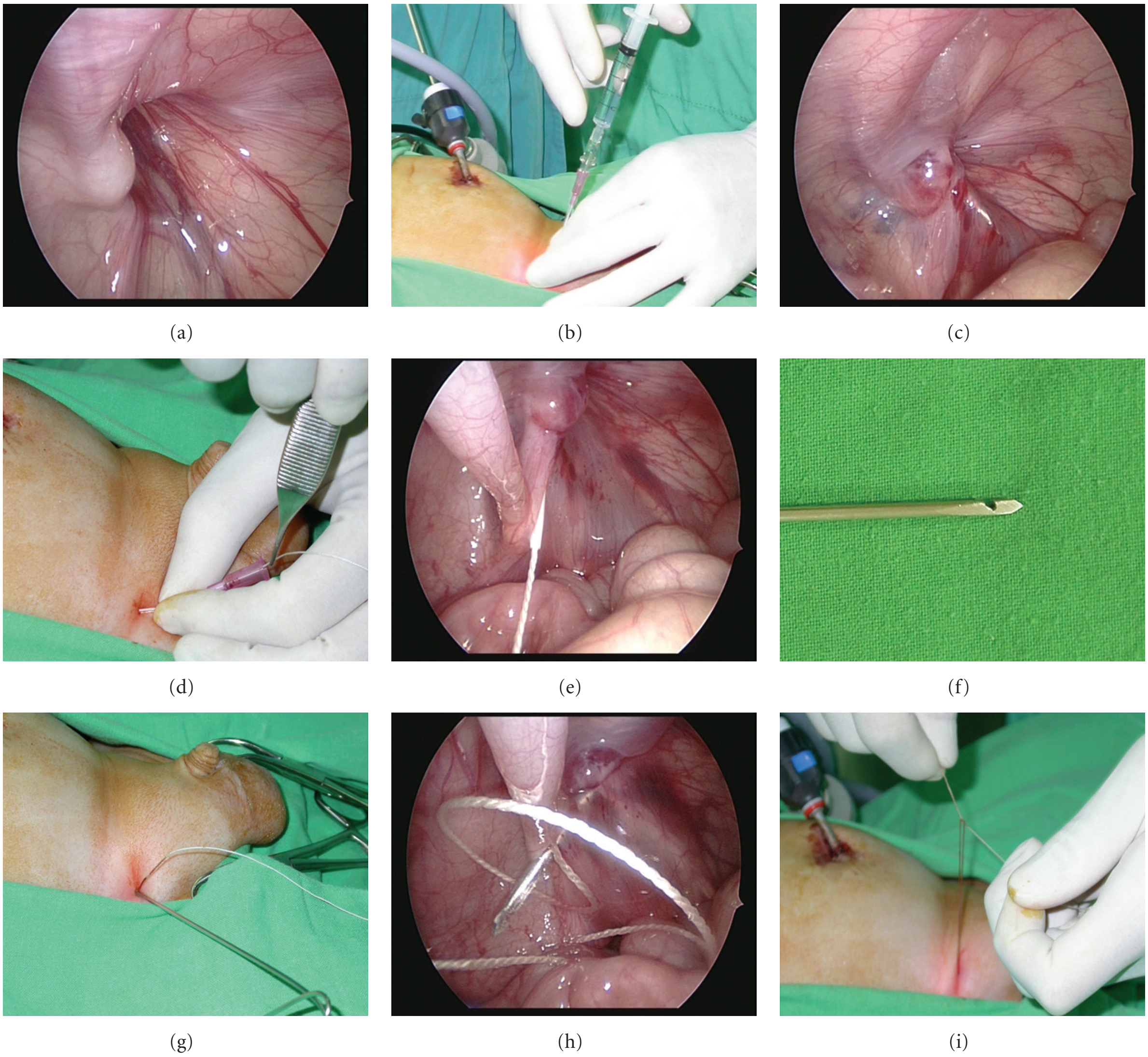


Figure 1: Intraoperative photo showing a 2-year-old boy receiving the hooked pin method. (a) Note right side inguinal hernia and the close proximity of the vas deferens (V) and testicular vessels (T) to the ring. (b) Introduction of the vascular catheter into the preperitoneal space along left side of the hernia defect. (c) The "preperitoneal hydrodissection" method. Injection of normal saline via the vascular catheter separates the vas and vessels from the peritoneum and allows the vascular catheter (arrow) to cross over. (d, e) The indwelling needle was removed, and a nonabsorbable suture was threaded through the sheath of the catheter, with the other end of the suture remaining above the skin. The sheath was then withdrawn. (f) The hook-pin device was easily made by modifying a pin used in orthopedic surgery. The device has a hook near the tip for catching hold of the suture. (g, h) Through the same stab incision, the hook-pin was introduced along the opposite side of the hernia defect into the intraabdominal space to pick up the silk, and the suture was then pulled through the abdominal wall. (i) The hernia defect was closed and the circuit suturing was tied extracorporeally.

during operation. In a single-blinded, randomized study, recovery and outcome were similar after open and three-port laparoscopic hernia repair in children. Moreover, three-port laparoscopic approach was associated with increased operative time and postoperative pain [6].

To enhance a pediatric surgeon's willingness, further development is intended to decrease the number and size of skin incisions, lower the recurrence rate, and simplify or avoid intracorporeal technique [2]. From above conception, single-port endoscopic-assisted percutaneous extraperitoneal closure seems to be the ultimate attainment and numerous techniques have mushroomed in the past decade [5, 7–11]. Herein, the author reviews the literature in an attempt to compare the various approaches of the latest advancement in pediatric hernia surgery.

2. Surgical Technique

Of single-port laparoscopic surgery for pediatric inguinal hernia, the suture was always introduced and withdrawn percutaneously at the corresponding skin of the orifice

Table 1: Reported single-port technique with extracorporeal knotting.

Studies (1st author)	Technique	Port size (mm)	Number of associated stabbing incisions	Complete ring	Subcutaneous tissue inclusion	Tensionless knot tying	Protection of vas and vessels
Harrison et al. 2005 [7]	SEAL	2.7	2 (unilateral) 4 (bilateral)	−, small gap	+	−	+, jump over them
Ozgediz et al. 2007 [8]	SEAL	2.7	2 (unilateral) 4 (bilateral)	−, small gap	+	−	+, jump over them
Patkowski et al. 2006 [9]	PIRS	2.5 or 5	1 (unilateral) 2 (bilateral)	−, small gap	+	−	+, jump over them
Bharathi et al. 2008 [5]	Modified SEAL and dual encirclage	5	At least 3 (unilateral) At least 6 (bilateral)	+	+	+, hydrodissection	+, hydrodissection
Chang et al. 2008 [10]	Hooked pin method	5	1 (unilateral) 2 (bilateral)	+	+	+, hydrodissection	+, hydrodissection
Chang et al. 2009 [11]	Hooked injection needle method	5	1 (unilateral) 2 (bilateral)	+	−	+, hydrodissection	+, hydrodissection

SEAL: subcutaneous endoscopically assisted ligation; PIRS: percutaneous internal ring suturing.

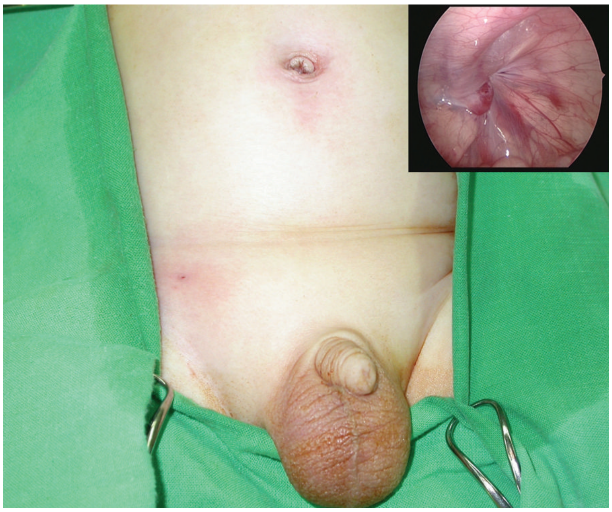


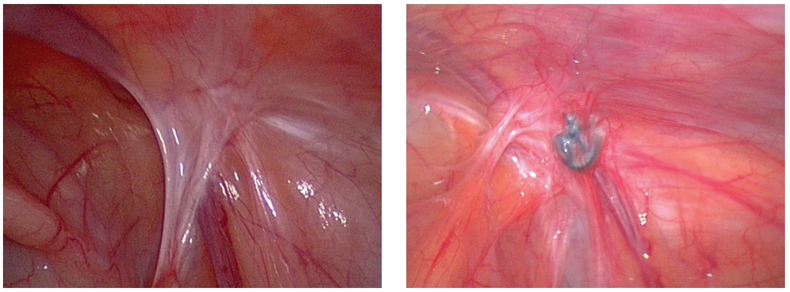
Figure 2: The final wound appearance of the inguinal hernia repair (arrows) and the hernia defect after the suture was tied (upper inset).

of the hernia defect by variable devices, and was tied extracorporeally to obliterate the hernia sac. The knot was then placed in the subcutaneous space. Reported single-port techniques with extracorporeal knotting are shown in Table 1 [5, 7–11].

2.1. Technique of Subcutaneous Endoscopically Assisted Ligation (SEAL). The first described is Harrison et al. in 2005 with subcutaneous endoscopically-assisted ligation (SEAL) of the hernia defect [7]. The SEAL technique has been performed since 2001 [8]. Using only the camera port and passing a suture on a large swaged-on needle percutaneously to enclose the defect, knot-tying was performed extracorporeally. In 2007, the same group described the early result of 300 inguinal hernias [8]. Overall complications occurred in 15.7% of patients and a recurrence rate of 4.3% was comparable to prior series of laparoscopic repairs. However, the known limitations of the SEAL technique are (1) for successful mating and guidance, the entry point of both the needle and the track should exactly match the curve of the needle. If the curve of the needle could not conform to the configuration of the ring, it would be difficult to pass the needle through the posterior hemicircumference of the ring. The needle may jump over the vas and vessels and a peritoneal gap may be left untouched. (2) Two stab incisions are necessary for the swaged-on needle and the receiving Tuohy needle, and a depression or fold of the corresponding skin might sometimes occur if the knot-tying is not placed in the correct deeper plane [5]. (3) If the size of the defect is extraordinarily large, an additional instrument to assist guidance of the needle or conversion to open herniotomy is necessary [8, 12, 13].

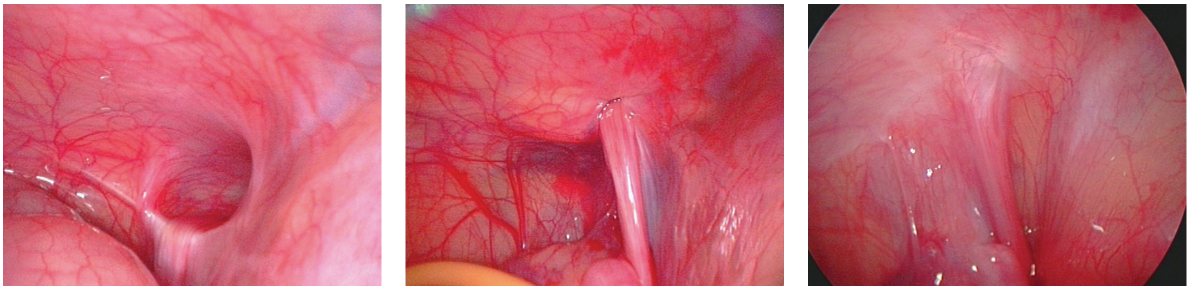
In 2008, Bharathi et al. modified the technique of SEAL [5]. A small amount of saline was injected using a hypodermic or spinal needle in the retroperitoneal space (preperitoneal hydrodissection) to lift up the peritoneum of the vas and the vessels. The suture could be then advanced to encircle the posterior hemicircumference of the defect completely. If the saline injection should fail, the authors would take as much as the circumference of the defect as was possible without collateral damage by the first suture. Then, this allowed a second, separate loop to encircle the defect. However, multiple stab incisions at the corresponding skin were always necessary.

2.2. Technique of Percutaneous Internal Ring Suturing (PIRS). In 2006, Patkowski et al. described the technique of percutaneous internal ring suturing (PIRS) for inguinal hernia in children [9]. An 18-gauge injection needle with



(a) (b)

Figure 3: Laparoscopic views of 17 months (a) and 24 months (b) after traditional open herniotomy for right side inguinal hernias. Without intraabdominal manipulation, open herniotomy still causes local intraperitoneal adhesion (arrows) at the original entrance into the hernia sac. The peritoneal adhesions may be caused by suture ligation of the sac and subsequent tissue reaction of the sutures. V, vas deferens; T, testicular vessels



(a) (b) (c)

Figure 4: A 2-year-old girl receiving the hooked pin method. (a) Note left side inguinal hernia before operation. (b) The hernia defect was closed after operation. (c) Laparoscopic surgery for other reasons was performed 94 days after operation. Note the peritoneal scarring occurred in closure of the hernia defect.

a nonabsorbable suture inside the barrel of the needle was placed through the abdominal wall into the peritoneal cavity. By moving the injection needle, the suture passed under the peritoneum around the hernia defect. The knot was tightened extracorporeally and placed in the subcutaneous space. The PIRS technique required only one umbilical port and one needle puncture point. However, as in the original SEAL technique, a peritoneal gap of the suture at the location of vas and vessels was still left untouched.

2.3. Technique with a Vascular Catheter, a Hooked Pin, and Preperitoneal Hydrodissection. In 2008, the author developed a modified technique of SEAL and PIRS [10]. Under the laparoscopic guidance, the hernia defect was enclosed by a nonabsorbable suture, which was introduced into the abdomen by an 18 Fr vascular catheter (Surflash I.V. catheter, I.D. 0.95 × 64 mm, Terumo Corporation, Tokyo, Japan) on one side of the hernia defect and withdrawn on the opposite side by a hooked pin, which was made by an orthopedic pin (I.D. 1.8 mm, MES-CF01-063-21, Mizuho, Tokyo, Japan), through one needle puncture wound (Figure 1). During the procedure, 5 to 8 mL of isotonic saline solution were infused via the needle into the preperitoneal space to obtain the preperitoneal dissection of the hernia defect. The author started to perform the surgical technique in March 2007. From March 2007 to January 2010, a total of 288 procedures were performed among 201 consecutive infants and children. Of the technique, only one umbilical trocar wound and another stab incision were made (Figure 2). Besides, the hernia defect could be enclosed completely without a lower peritoneal gap since preperitoneal hydrodissection could safely separate the peritoneum from the vas and the vessels. Since the used vascular catheter and hooked pin were long enough (64 mm and 300 mm, resp.), failure to lift up the peritoneum entirely was rare. However, some upper subcutaneous tissues, including nerves and muscles, may cause injury by their inclusion in the upper portion of the circuit suturing. The inclusion of unnecessary subcutaneous tissues in the ligature may lead to a propensity for subsequent loosening of the knot, causing later recurrence [2].

2.4. Technique with a Hooked Injection Needle and Preperitoneal Hydrodissection. Later, the author described the modification of the hooked pin method with a homemade hooked injection needle (Optiva I.V. Catheter Radiopaque, I.D. 1.8 × 50 mm, Ethicon Endo-surgery, Johnson-Johnson Company), which is designed to traverse the suture and cause hydrodissection to the preperitoneal space [11]. During the procedure, the tip of the hooked injection needle was kept beneath the fascia at the period after introducing and before pulling the suture. Thus, the suture could tautly enclose the hernia defect without upper subcutaneous tissues and a lower peritoneal gap.

3. Discussion

Postsurgical peritoneal adhesions are a consequence of injured peritoneal surface (including incision, cauterization, suturing, or other means of trauma) fusing together to form scar tissue [14]. Of the inguinal hernia sac, the endothelium is the continuity of peritoneal mesothelium. In the open herniotomy, trauma due to traverse of the suture and tissue reaction of the suture material may also cause peritoneal adhesion and fibrosis (Figure 3). Since the tensile strength of any suture may diminish eventually, the author suggests that peritoneal adhesion and fibrosis may be the leading factor for complete obliteration of the hernia defect in the long run after either open herniotomy or laparoscopic surgery (Figure 4). Thus, how can adequate peritoneal adhesions during hernia operation in the era of minimal access surgery are applied? Since partial omission of the defect circumference was the reported factor contributing to recurrence in laparoscopic surgery [2], completely enclosing the hernia defect without gaps, the same as suture ligation in the open herniotomy, is crucial to moving towards a near-zero recurrence rate.

However, in the standard three-port technique with intracorporeal knot-tying or the two-port technique with an assistant port for intraabdominal suturing, the hernia defect was always closed by N-shaped or purse-string sutures, both of which cannot enclose the defect completely and may leave multiple peritoneal gaps. The resultant peritoneal gaps cannot provide adequate peritoneal injury and may disturb or defer further peritoneal adhesion if the knot-tying is loosening gradually, leading to potential recurrence. The author suggests that complete extraperitoneal enclosing of the hernia defect could decrease peritoneal gaps, and single-port endoscopic-assisted percutaneous extraperitoneal closure may be the preferred technique. Moreover, in the single-port technique, the ligation of the hernia defect could be achieved percutaneously without the need for intracorporeal manipulation of the needle and knot-tying.

To completely enclose suture of the hernia defect without any gap in the single-port technique, preperitoneal hydrodissection must be the main step. The concept of hydrodissection during laparoscopic hernia repair has been already described in the literature [15]. In 2007, Chan et al. employed preperitoneal hydrodissection in the three-port intraperitoneal-suturing technique, and concluded that the recurrence rate could decrease from 4.88 to 0.4% after the usage of preperitoneal hydrodissection [15]. Recently, the method of preperitoneal hydrodissection has been applied in the single-port technique [5, 10, 11]. With the aid of hydrodissection, the vas and vessels could be separated from the peritoneum; therefore, a completely enclosing suture of the hernia defect could be provided without any gaps [5, 10, 11].

Meanwhile, the method of preperitoneal hydrodissection was useful in (i) providing additional space for negotiating the working instruments, (ii) keeping the device just under the peritoneum, and observing the needle sign [8], (iii) avoiding injury to the vas and vessels, (iv) making a further airtight extracorporeal knot-tying [15], and (v) decreasing postoperative hydrocele, which may be caused by interruption of testicular lymphatic drainage because of being thicker than the peritoneum bites of the encircling suture [5]. Moreover, normal saline, the solution for preperitoneal hydrodissection, could predispose the formation of peritoneal adhesions and fibrosis [16]. Therefore, during passing of the suture, preperitoneal normal saline injection may cause more tissue trauma, further promote the formation of peritoneal adhesions and minimize later recurrence (Figure 4).

However, being a technique of percutaneous closure of inguinal hernia, simultaneous ligation of subcutaneous tissues between the skin and hernia defect was inevitable [5, 7–10]. This might possibly increase the recurrence rate when subsequent loosening of the knot takes place. Accompanying preperitoneal hydrodissection and keeping identical subcutaneous path for introducing and withdrawing the suture, the latest reported single-port technique could overcome the limitations and tautly enclose the hernia defect without upper subcutaneous tissues and a lower peritoneal gap [11].

4. Conclusions

Preperitoneal hydrodissection could completely enclose the hernia defect without peritoneal gaps, whereas keeping identical subcutaneous path during traversing the suture could avoid simultaneous ligation of subcutaneous tissues between the skin and hernia defect. Furthermore, the smaller and fewer skin incisions of the single-port technique could reach the state of minimally invasive surgery. However, single-port laparoscopic surgery for pediatric inguinal hernia is a technique in evolution. More long-term follow-up concerning the recurrence rate is necessary.

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Review Article

Update on Instrumentations for Cholecystectomies Performed via Transvaginal Route: State of the Art and Future Prospectives

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Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an innovative approach in which a flexible endoscope enters the abdominal cavity via the transesophageal, transgastric, transcolonic, transvaginal or transvescical route, combining the technique of minimally invasive surgery with flexible endoscopy. Several groups have described different modifications by using flexible endoscopes with different levels of laparoscopic assistance. Transvaginal cholecystectomy (TVC) consists in accessing the abdominal cavity through a posterior colpotomy and using the vaginal incision as a visual or operative port. An increasing interest has arisen around the TVC; nevertheless, the most common and highlighted concern is about the lack of specific instruments dedicated to the vaginal access route. TVC should be distinguished between "pure", in which the entire operation is performed through the transvaginal route, and "hybrid", in which the colpotomy represents only a support to introduce instruments and the operation is performed mainly by the classic transabdominal-introduced instruments. Although this new technique seems very appealing for patients, on the other hand it is very challenging for the surgeon because of the difficulties related to the mode of access, the limited technology currently available and the risk of complications related to the organ utilized for access. In this brief review all the most recent advancements in the field of TVC's techniques and instrumentations are listed and discussed.

1. Introduction

Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an innovative approach in which a flexible endoscope enters the abdominal cavity via the transesophageal, transgastric, transcolonic, transvaginal, or transvesical route, combining the technique of minimally invasive surgery with flexible endoscopy [1]. The first report of transvaginal cholecystectomy (TVC) is devised to the American gynecologist D. Tsin who firstly performed this revolutionary approach at Mount Sinai Hospital of New York in 2003 [2]. Since then, several groups have described different modifications by using flexible endoscopes with different levels of laparoscopic assistance.

Although this new technique seems very appealing for patients, who prefer it to standard laparoscopy since it eliminates abdominal wall scares and reduces postoperative pain [3], it is very challenging for the surgeon because of the difficulties related to the mode of access, the limited technology currently available, and the risk of complications related to the organ utilized for access [4, 5]. Despite the huge interest in the development of NOTES and its applications in clinical practice, it still remains at present largely experimental [5].

In this brief review all the most recent advancements in the field of TVC's techniques and instrumentations are listed and discussed.

2. State of the Art

As described by the author who first performed it [2], TVC consists in accessing the abdominal cavity through a posterior colpotomy and using the vaginal incision as a visual or operative port. Pneumoperitoneum is achieved by introducing a 12 mm in diameter/15 mm in length trocar and, after insufflations are complete, the first trocar is replaced with a 10 mm scope which allows to introduce a 5 mm abdominal trocar under culdoscopic surveillance. According to this first report, the dissection of Calot's triangle and the cholecystectomy itself are performed by using the abdominal-inserted trocars. The vaginal route is used again only for the extraction of the specimen.

Since this initial description, an increasing interest has arisen around the TVC as demonstrated by the huge amount of articles published during the last five years, most of them including only small groups of patients [6, 7] or animal models. Nevertheless, the most common and highlighted concern is about the lack of specific instruments dedicated to the vaginal access route [1–8]. Current procedures with commercially available flexible endoscopes are technically limited by the inability to manipulate tissue or retract organs [9]. The flexibility of the endoscope shaft makes it difficult to exert sufficient distal force to manipulate the liver and to expose adequately the gallbladder: indeed, the endoscope can buckle against the hepatic lobe or move away, so that the classic traction/countertraction concept on which surgery is based is invalidated [9]. TVC shares many of the technical difficulties of laparoscopic surgery such as the use of long instruments through fixed angles but has additional problems related with orientation and rotation of the image [5]. For this reason TVC is actually slow and extremely demanding [5].

TVC should be distinguished into "pure", in which the entire operation is performed through the transvaginal route, and "hybrid", in which the colpotomy represents only a support to introduce instruments and the operation is performed mainly by the classic transabdominal-introduced instruments.

3. Pure TVC

Pure TVC avoids the need for laparoscopic assistance by introducing two flexible scopes into the abdominal cavity. De Sousa et al. [10] in 2008 described their experience of 4 women with symptomatic cholelitiasis. Due to the lack of available instruments, pneumoperitoneum is achieved by attaching a flexible plastic tube to a standard single-channel gastroscope (FUJINON, Japan) and by introducing it through a posterior 2.5 cm colpotomy performed under direct view. Subsequently, a second double-channel colonscope (FUJINON EC 410- D, FUJINON, Japan) is inserted through the same orifice. Gallbladder retraction is obtained by using the first endoscope, whilst dissection of Calot's triangle is performed through the second endoscope by using standard endoscopic instruments such us endoscopic hook, hot-biopsy forceps for cystic duct and artery dissection, polipectomy snare for gallbladder's dissection from the liver bed, and specimen extraction. According to the authors, spatial orientation and visualization were of good quality. The main difficulty was related to the fact that endoscopic devices have to be inserted into a working channel (i.e., the vagina), constraining the movement to the long axis of the endoscope, with a subsequent lack of triangulation.

Gumbs et al. [11] have recently described the first pure TVC performed in an American patient. Through a colpotomy achieved under direct visualization, a 15 mm port (Applied Medical, Rancho Santa Margarita, CA) is placed to obtain the pneumoperitoneum. Through this port, a double-channel gastroscope (Storz: 13806 NKS, Tuttlingen, Germany) is inserted and retroflexed to make sure that no pelvic or abdominal structures were injured after the first entry. The main difference comparing the previously mentioned experience is that the operative instrumentation was represented by an articulating extra long instrument (Novare, Cupertino, CA) placed into the abdomen through a second lateral colpotomy and not through the same incision. The endoscopic hook knife (Olympus Surgical America, Orangeburg, NY) and grasper biopsy forceps (Boston Scientific) are inserted in the channel of the gastroscope to dissect the structure of the Triangle of Calot. According to the experience of the authors, the most important barrier to the widespread adoption of pure TVC is the difficulty in obtaining the so-called "clinical view of safety", specifically at the level of the Triangle of Calot, due to the fact that the endoscope comes posteriorly, with an increased risk of bile duct injury. The problem of achieving adequate tension on the tissues is addressed by performing a combination of grasping with the endoscopic grasper and cutting with the endoscopic cautery device. However, the most important limit encountered by the authors was the lack of commercially available clips to perform safely the closure of the cystic duct. For this reason, the tips of the available clips (Quickclips, Olympus Surgical America) were straightened manually by using a needle holder. Finally, it is important to emphasize how the desufflation results limited by the absence of the abdominal trocars, so that the pneumoperitoneum required the aspiration via the endoscope and, furthermore, the compression of the patient's chest and abdomen while leaving the transvaginal trocar open. In any case, a lower insufflation pressure is generally used because the endoscopes work at 3–5 cm of distance to the subject [10], so there is a reduced need of wide exposure.

As demonstrated by the small amount of patients treated up to now, pure TVC has still to be considered widely experimental and its application requires a multidisciplinary team and a logistic support that is difficult to obtain even in the most advanced centers. For this reason, and due to the lack of dedicated instruments, the great number of TVCs performed to date are still based on different levels of standard laparoscopic assistance. Further large series and randomized studies are required to evaluate the middle and long term results, especially with regards to the safety and the costs/benefits rate.

4. Hybrid TVC

Most authors share the opinion that it is not yet possible to perform TVCs without the help of instruments introduced through the abdominal wall [12]. For this reason the great amount of TVCs described in literature represents a fusion of laparoscopy and endoscopic surgery, with an approach defined as "hybrid".

In this field there is a remarkable lack of accordance about the difference between "laparoscopically assisted transvaginal surgery" and "transvaginally assisted laparoscopic surgery". The first term indicates an operation performed mainly via the transvaginal access, in which most of the instruments assigned to perform the decisive dissection steps are inserted via this route and the abdominal access is used only as a support for retraction. Conversely, the second term refers to operations based mainly on the traditional laparoscopic approach and instrumentations, and the vaginal access allows the introduction of instruments for retraction.

One of the largest series of "laparoscopically assisted transvaginal cholecystectomies" is reported by Horgan et al. [13]: in 5 patients a 5 mm umbilical trocar is inserted for abdominal exploration and to determine the feasibility of the vaginal access. This trocar represents the only trans-abdominally inserted instrument since all the subsequent operative steps are performed by instruments inserted through the vagina. The difficulties encountered with this approach are related to maintaining of pneumoperitoneum, since insufflation is more difficult to manage and measure than with a standard laparoscopic port, and to dissection of the gallbladder from the liver bed, which has resulted difficult by using the endoscopic device (Olympus America, Center Valley, PA, USA), as the small size makes dissection cumbersome and longer compared to classic laparoscopic approach. Eventually, the endoscopic clips that have been used are described as not entirely occlusive and not designate to secure the cystic duct safely, underlining the importance of focusing the research in order to overcome this limit.

In another work by Noguera et al. [12] a video endoscope is introduced through the colpotomy with a rigid 12 mm in diameter/15 mm in length trocar, with the advantages of maintaining pneumoperitoneum thanks to its retension valve, stabilizing the endoscope with its length, making the movements easier, and pointing the endoscope toward the gallbladder, so reducing the risk of bile ducts and liver injury. Through the working channel of the endoscope, instruments for grasping, dissecting, cutting, and sealing are introduced, so this approach can be defined as an "*intermediate* laparoscopically assisted transvaginal cholecystectomy": indeed, despite the fact that two abdominal trocars are inserted, the main steps are performed through the vaginally inserted instruments.

On the contrary, a typical "transvaginally assisted laparoscopic cholecystectomy" is described by Ramos et al. [8] who combined their experience with bariatric and laparoscopic surgery in order to avoid the lack of specific instrumentation for TVC. In details, in 32 patients the transvaginal route was used only to introduce a 10 mm 45° rigid bariatric laparoscopic optic through a 12 mm bariatric trocar placed in the posterior vaginal fornix. The main steps of the operation were performed through a 5 mm intraumbilical port with classic laparoscopic instruments, but a 2 mm trocar had to be positioned on the right flank in order to retract the gallbladder. Also these authors have used the vagina to remove the specimen from the abdominal cavity. This work demonstrated that TVC performed by using only regular laparoscopic instruments and avoiding the introduction of endoscopes can be safely performed until specific endoscopic instruments are under development, also minimizing the need to acquire new technical skills.

A similar experience is reported by Pugliese et al. [14] who performed TVC in 18 women by introducing a 45 cm long grasper and a double-channel Karl Storz flexible gastroscope (Tuttlingen, Germany) through the colpotomy. The endoscope represents the only source of light during the procedure, whilst the grasper is used to achieve traction of the gallbladder, but not dissection. All the procedures were accomplished by using a single trocar of 5 mm placed in the left hypochondrium and not in the umbilical area to obtain a more ergonomic operative position to manipulate the gallbladder in combination with the transvaginal grasper, especially to fire clips. In contrast with authors who prefer standard rigid devices [8], these authors prefer using flexible endoscope to reach the supramesocolic region, so that the view of the biliary structures is facilitated by the flexibility of the endoscopic tips. However, endoscopes are not considered useful and safe for dissection, so this step is performed through the abdominal trocar, using, if necessary, the transvaginally inserted grasper only as a support for dissection in case of difficulties. This approach overcomes two current limits of NOTES available instruments: first, they are not flexible, long, or thin enough to reach good angulation for dissection; and second, the working channel of flexible endoscopes is too close and parallel, hindering an effective manipulation [14].

Analogously to what was previously said, an "*intermediate* transvaginally assisted laparoscopic cholecystectomy" approach is performed by Zornig et al. [1] who described one of the largest series reported in literature in which the decisive steps are performed through the umbilical port, but two instruments are inserted in vagina and only one in the umbilicus. In details, after the induction of pneumoperitoneum with a Verres needle and after performing the exploration of the abdominal cavity with a 5 mm optic, a 5 mm mandrin is inserted in the posterior fornix of the vagina and replaced by a 5 mm extra long dissector (Storz, Tuttlingen, Germany), with a 10 mm trocar inserted alongside. Through this trocar, an extra long 10 mm optic (Olympus, Hamburg, Germany) is inserted, and the umbilical optic is replaced with another dissector. Cystic duct and cystic artery dissection, positioning of clips, and gallbladder's mobilization are performed via the umbilicus by traditional laparoscopic instruments. The 10 mm vaginal trocar is used again only for specimen's extraction inside a removal bag. This large series has demonstrated that hybrid TVC is feasible in adult women of any age, even obese, previously operated or with gallbladder phlogosis. However, these authors experienced a difficulty related to the fact that the traditional flexible instruments available today for endoscopic procedures are much more difficult to use for abdominal surgery, resulting in a longer time requiring for performing the whole operation.

5. Future Prospectives

Endoscopes for TVC are required to have high resolution, large operative channels, some degree of triangulation, and a length suitable to reach any intraabdominal point. Today, only a small amount of devices address most of these points [15]. In particular, the "R" scope from Olympus and the Transport scope from USGI medical may address some problems related to access and visualization, whilst the Eagle Claw (Olympus), the Swain system (Ethicon), and the G-prox (USGI) seem able to secure better intraoperative performances, but they are still under development [15].

Many disadvantages still limit the chances of early routine operations (i.e., unstable vision, early state of development, etc.) [16]. However, the medical devices companies are racing to solve these problems and the industry is quickly producing futuristically designed instruments to overcome the barriers in TVC progress [17, 18].

Better cosmetic results, fewer wound infection rates, fewer trocar hernias, reduction or abolition of pain, and shorter hospital stay, although still theoretical, represent the strongest motivations in order to achieve the development in technology that this emerging field requires.

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Review Article

Current Limitations and Perspectives in Single Port Surgery: Pros and Cons Laparo-Endoscopic Single-Site Surgery (LESS) for Renal Surgery

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Laparo-Endoscopic Single-Site surgery (LESS) for kidney diseases is quickly evolving and has a tendency to expand the urological armory of surgical techniques. However, we should not be overwhelmed by the surgical skills only and weight it against the basic clinical and oncological principles when compared to standard laparoscopy. The initial goal is to define the ideal candidates and ideal centers for LESS in the future. Modification of basic instruments in laparoscopy presumably cannot result in better functional and oncological outcomes, especially when the optimal working space is limited with the same arm movements. Single port surgery is considered minimally invasive laparoscopy; on the other hand, when using additional ports, it is no more single port, but hybrid traditional laparoscopy. Whether LESS is a superior or equally technique compared to traditional laparoscopy has to be proven by future prospective randomized trials.

1. Introduction

Laparo-endoscopic single-site surgery (LESS) as a new alternative to conventional laparoscopy has gained popularity. Today laparoscopy has changed kidney surgery at all. Laparoscopic radical nephrectomy is gold standard when opting for radical nephrectomy in T1b-T2 renal cell cancer [EAU + AUA guidelines], but furthermore, laparoscopy is preferred for pyeloplasty and is comparable in nephron-sparing surgery for T1a renal tumors and in nephroureterectomy [1], some of them have also been described in the pediatric poplulation [2].

Various terms have been used for LESS up to date, but the final definition has been established in July 2008 by the Laparo-Endoscopic Single-Site Surgery Consortium for Assessment and Research (LESSCAR) as laparo-endoscopic single-site surgery (LESS) [3]. There are several important questions that should be answered until LESS will be equivalent with standard laparoscopy (SL). Is there any overall benefit for the patients in terms of risk of perioperative, postoperative morbidity, and oncological safety?

Should we limit surgeons comfort and confidence? Which population of patients will actually benefit and what are the optimal indications? The aim of our minireview is to critically summarize pros and cons of LESS in renal surgery.

2. Potential Advantages and Disadvantages

Although LESS is a rapidly evolving surgical minimally invasive technique, published reports are limited by numbers of patients and centers [1–9]. Meanwhile, it is very doubtful if LESS is going to further improve SL. Unproven potential advantages of single port surgery are only less scar, less discomfort, reduced postoperative pain, and thus less use of analgetic medication, followed with faster recovery and shorter hospital stay when compared to the traditional open and SL. LESS is feasible, with comparable perioperative and postoperative outcomes with limited follow up when compared to SL [1–11]. Beacause only the surgical technique itself has been modified, it is very uncertain that the oncological or clinical outcomes will be better than in SL.

LESS creates a challenge for surgeons and increases their skills and ambidexterity. From our own initial experience, we think LESS is ideal for renal, adrenal cysts, cryoablation of small renal masses; however, we prefer the lower abdomen instead of the umbilicus for single port placement. Postoperative pain does not seem to be reduced compared to the SL surgical procedure (our unpublished data). We think that the overall benefit of LESS is lacking today. Even in high-volume laparoscopic centers like ours, the key issue will be right patient selection.

The incision length varies usually from 1 to 6 cm [5, 6]. In SL for renal tumors, we use 2(1) 12 mm ports, 1(2) 5 mm port, and eventually another 5 or 12 mm port (overall length 34 mm). Of course an additional incision has to be made for organ extraction, but this is also true for LESS, unless natural orificions will be used or morcelleration like in the beginning of SL is used. The only difference is the range of few centimeters. Do we really have to measure the clinical equivalence of surgical procedure by cosmetics, or do we actually measure and compete ourselves as surgeons? The need is to critically evaluate this novel approach especially in patients with neoplasms.

The maneuverability of instruments is more difficult in the single port platform, which might be overcome with the learning curve. Easier clashing of working instruments results in limited operating fields. Therefore, using an additional port is sometimes necessary [6]; others tend to insert percutaneously 3 mm small instruments [5], without adding an additional port and thus trying to fulfill the criteria of single port laparoscopy. Introduction of these advanced technologies and instruments (roticulating forces, flexible laparoscopic scissors, graspers) tends to overcome these limitations [3], which raises the question: is this modification of basic principle necessary?

Certainly those who will not perform many cases or at least on a regular basis, do not get better results.

3. Ideal Indications

LESS is a challenging operation for an experienced laparoscopic surgeon [7]. It seems that in the future LESS will be equally efficocious and feasible to SL in high-volume centers. However, the main and probably the only advantage stays the single scar with potential increase in overall costs when compared to SL.

Who will mainly benefit from LESS renal surgery: (1) patients who are most concerned of cosmesis, (2) nonextirpative surgeries such as renal, adrenal cyst marsupialization, pyeloplasty, renal tumor ablative techniques, or simple nephrectomy for small nonfunctioning kidney, (3) radical nephrectomy with morcelation where the lengthening of an incision is not necessary, which is on the other hand an oncological compromise and clearly will reduce postoperative oncological assessments.

From our own experience, renal, adrenal cyst marsupialization and cryoblation of small renal mass were the ideal indications to start with comparable overall outcomes when compared to SL. Radical nephrectomy was feasible for an experienced laparoscopist equally in terms of perioperative and postoperative parameters as with SL. We have experienced two conversions due to adhesions in patients with previous abdominal surgery (unpublished data) to SL. Goel and Kaouk recommend cryoablation as an ideal procedure to start with single port surgery from their experience as well [12].

Patients with conventional contraindications to SL, previous ipsilateral renal surgery, or the presence of a solitary kidney should not be the candidates for LESS [8], at least initially or until the surgeon feels the same confidence as with SL.

Partial nephrectomy remains to be very challenging even for laparoscopists in high-volume centers, with an experience over 950 SL partial nephrectomy cases. The major problem was the tissue retraction and therefore the ideal candidates would be nonobese, medium height with anterior exophytic lower pole tumor less than 4 cm with no previous abdominal surgery, with the possibility of extirpation without hilar clamping [7, 13].

In general SL has a higher ischemia time than open nephron-sparing surgery and thus has not reached the full competitive potential to open nephron-sparing surgery. That is why, LESS will certainly not reduce ischemia times, which is clearly a safety issue for the further kidney-function and the health of the patient.

Maybe LESS is a crossing bridge to the integration of LESS and robotics? What has been proved by Desai et al. in robot/assisted-LESS pyeloplasty, where other working instruments were inserted through separate fascial puncture, but through the umbilical incision [6]? It looks like a logical next step, because freedom of movement in robotic surgery eliminates basic limitations of this novel approach itself.

We do have to be critical to ourselves, because to date we can review a small volume of outcomes. As far as all these reports are initial, we should not expect the better outcomes, but comparable, what seems to be proven [1].

Last but not least, the overall rate of complications of laparoscopic procedures in urology is quite low (around 0.2%) [11]. Will be the "one scar LESS surgery" related to lower incidence of complications? Comparison of SL versus hand assisted laparoscopic renal surgery so far did not prove the fact that a smaller incision has a better outcome [9]. To date limited data on postoperative, port related morbidity, and cosmetics are still to be proven in comparative prospective trials. Surgeons are doctors at first and that is why novel techniques should not result in a race and competition in surgical minimalism.

4. Future Improvements of Less Technique

Further technical improvements to minimize the invasiveness and upgrade LESS surgery are in progress. Magnetic anchoring and guidance system (MAGS) technology (by developing of magnetically controlled and anchored intracorporeal surgical instruments) seems to be a promising technique to facilitate and advance LESS surgery [14]. A generated magnetic field, as we can obtain in magnetic resonance imaging, is regarded as the least procedure that can be medically applied. One of the limitations of this procedure is that the extracorporeal electromagnetic control system is too large, that is why the size needs to be miniaturized.

Introduction of da Vinci robotic platform in combination with single port surgery is encouraging and appears to overcome some limitations of single port laparoscopic surgery itself. It is beneficial especially during intracorporeal suturing by improving ergonomics.

The second generation laparoscopic instruments and the upgraded generation of intuitive robotic systems are a must to achieve the potential goals of LESS technique.

The smaller is the incision the greater need is for smaller instruments and robots. What does it mean for the future? Development of minirobots anchored intraabdominally through the specific platforms. We are already on the beginning of the minirobotic revolution and translation from mini invasive surgery to pure intracavitary surgery. The technical potential of "in vivo robots" has to be investigated, well defined, and established in the clinical field to eliminate the difficulties in LESS surgeries [15].

5. Conclusions

LESS has a potential in reduction of postoperative pain and cosmetics, but should these benefits justify the use of single port surgery over traditional laparoscopy? One can presume that the modification of instruments of laparoscopic technique in general will not result in better clinical or even more in oncological outcomes. Certainly, we can not compete the fact that LESS is a challenging technique and increases the skills and ambidexterity of the surgeons. However, we should take LESS into account and weight against basic clinical and oncological principles. At the moment, the sufficient "yes" for LESS as a supreme technique over the traditional laparoscopy has to proven by future prospective randomized trials. We think that LESS will play a role, but a minor role in laparoscopic renal surgery.

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