



Feasibility and efficacy of modern minilaparoscopy with 2.9 mm laparoscope for diagnostic and level II gynaecological procedure

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Objective

Laparoscopy has now become a state-of-the-art technique for many diagnostic and therapeutic procedures with known advantages over laparotomy. There is scarce literature from India regarding minilaparoscopy, as per our literature review. Therefore, we performed this study with a 2.9-mm laparoscope to determine its feasibility and efficacy for diagnostic purposes and level II surgeries with the aim of reducing postoperative pain and better cosmesis.

Methods

This was a prospective study conducted from June 2019 to March 2020. Diagnostic modern minilaparoscopy with a 2.9-mm telescope was performed under general anesthesia by a single surgeon. Operative intervention was performed depending on the intraoperative findings.

Results

The mean age was 29.3 years. The most common indication for laparoscopy was infertility (98%). Only diagnostic laparoscopy was performed in 76% of patients, while 24% underwent operative laparoscopy. The various operative procedures performed were cystectomy, salpingectomy, ovarian drilling, and adhesiolysis. The mean visual analog scale scores at 1 hour and 2 hours postoperatively and discharge were 1.57 ± 0.59 , 1.41 ± 0.51 , and 1.29 ± 0.47 , respectively. Mild pain was present in 70 (72.2%) patients at the time of discharge, and only one patient had severe pain. Five or more analgesic tablets were required in only 16.5% of patients in the postoperative period. There was no wound infection or port-site hernia at follow-up.

Conclusion

Modern minilaparoscopy with a 2.9-mm laparoscope is a feasible and safe option for diagnostic laparoscopy and level II gynecological procedures with minimal postoperative morbidity, such as pain and wound infection, and provides good cosmetic outcomes.

Keywords: Minilaparoscopy; Visual analog scale score; Laparoscopy; Infertility; Cosmesis

Introduction

Laparoscopy has now become a state-of-the-art diagnostic and therapeutic procedure due to its known advantages over laparotomy, such as reduced patient morbidity, shorter hospital stay, fewer complications, and better cosmetic results. In 1980, diagnostic laparoscopy was performed by abdominal surgeons using a 4-mm rod lens in blunt abdominal trauma patients [1]. Over the years, laparoscopic surgical procedures have shown refinements in an attempt to minimize abdomi-

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nal wall trauma and improve cosmesis by decreasing the number of ports or reducing the port size. Improvements in light sources, videos, and optics have made it possible to use micro-endoscopy [2]. Many gynecologists still use larger 10-mm endoscopes owing to their familiarity and their larger field of view. O'Donovan and McGurgan [3] categorized laparoscopy according to the outer sheath diameter as conventional (>5 mm), minilaparoscopy (2-5 mm), and microlaparoscopy (<2 mm). According to the Unify criteria [4], laparoscopy may be classified as traditional laparoscopy (5 mm or more), conventional minilaparoscopy (4.9-3.5 mm), modern minilaparoscopy (3.4-2 mm), and micro minilaparoscopy (<2 mm).

It has been known that with minilaparoscopy, various complications, such as wound infection and herniation at the trocar site, have been markedly reduced [5-7]. Although miniaturized endoscopes have many advantages, they are fragile because of their small size and have reduced resolution and depth of the field as compared to larger endoscopes. Another difference is that smaller laparoscopes are available only at 0°, whereas larger laparoscopes based on rod lenses are available in different degrees of view, such as 0°, 30°, and 45° [8]. It has been reported that minilaparoscopy is mainly performed using a 5-mm laparoscope with ancillary ports of 3 mm or smaller [9,10]. Very few studies have been performed with laparoscopes less than 5 mm [11-13]. However, conventional laparoscopy is commonly used in India, even for diagnostic purposes. Very few surgeons have shifted to the use of a 5-mm laparoscope. In other areas of the world, surgeons use a smaller laparoscope without compromising the outcome results with fewer complications. There is a lack of literature from India regarding minilaparoscopy, per our literature review. In a previous study by Roy et al. [12], they performed a randomized comparative study on conventional minilaparoscopy (5 mm) and modern minilaparoscopy (2.9 mm) and found them comparable with respect to operating time, postoperative pain, and hospital stay. With this idea from the previous study, the present study included a comparatively larger number of patients to determine the feasibility of minilaparoscopy for operative intervention. We aimed to study its role in some level II gynecological surgeries. Therefore, we performed this study with a 2.9-mm laparoscope for diagnostic purposes and a few level II surgeries. Level 1 gynecological surgeries include diagnostic laparoscopy, laparoscopic simple cyst aspiration, laparoscopic steril-

ization, and laparoscopic ovarian biopsy. Level 2 gynecological surgeries include adhesiolysis for filmy adhesions, laser/diathermy for polycystic ovaries, salpingectomy or salpingostomy for ectopic pregnancy or infertility, and laser/diathermy or excision for mild endometriosis. The Revised American Fertility Society stages I and II included laparoscopic laser management of endometriomas, laparoscopic myomectomy for pedunculated myomas, laparoscopic uterosacral nerve ablation, laparoscopic ovarian cystectomy, laparoscopic salpingo-oophorectomy, and laparoscopically assisted subtotal/vaginal hysterectomy in the absence of any significant pathology [14].

Material and methods

This was a prospective study conducted in the Department of Obstetrics and Gynecology from June 2019 to March 2020. Ethical clearance was obtained from the Institute Ethics Committee for Postgraduate Research, IEC PG-273/29.05.2019. No funding was obtained. The trial was registered under clinical trial registry-India. We recruited a total of 100 women with body mass index (BMI) <8 kg/m² undergoing diagnostic laparoscopy for infertility or chronic pelvic pain or with preoperative findings that may require level II gynecological procedures, such as adhesiolysis, fulguration of endometriotic spots, cystectomy for small cysts (<3 cm in size), salpingectomy for hydrosalpinx, or unruptured ectopic pregnancy. Patients with large adnexal masses or fibroids requiring major operative procedures or with any contraindication for laparoscopic surgery, such as cardiopulmonary compromise, previous abdominal surgery, or tubo-ovarian mass, were excluded from the study. Written informed consent was obtained from each participant.

Diagnostic modern minilaparoscopy with a 2.9-mm telescope was performed under general anesthesia by a single surgeon (Fig. 1). A single dose of prophylactic antibiotic was administered 30 minutes prior to incision. A 3-mm sub-umbilical semilunar incision was made. After lifting the abdominal wall, a trocar (Fig. 2, 3 mm trocar) was introduced using the direct entry technique. Pneumoperitoneum was created by insufflating approximately 2 liters of CO₂. One accessory port of 3 mm was inserted for manipulation or further operative procedures. The abdominal cavity was explored, and the following findings were noted: the size and surface of the uterus, status of the bilateral

tubes and ovaries, and any abnormal findings. The quality of the images was assessed. The efficacy of a 2.9-mm laparoscope for definitive diagnosis was also noted. A chromopertubation test was performed if the patency of the tubes needed to be checked by injecting 30 mL of diluted methylene blue dye through an intrauterine Foley catheter. Operative intervention was performed depending on the intraoperative findings. Instead of suturing, adhesive plaster was applied to approximate the skin edges. The time from incision for the primary port to the end of the laparoscopy procedure was recorded. We also noted any requirement of conversion from a 3-mm to a 5-mm port, done in cases of operative intervention requiring the insertion of a harmonic scalpel, retrieval of a specimen, and port closure.

The primary outcome measure was the degree of postoperative pain assessed using the visual analog scale (VAS) at 1 hour and 2 hours postoperatively and at the time of discharge. The VAS score was graded from 0 to 10, signifying no pain to the worst pain, respectively. The pain was scored as mild [1-3], moderate [4-6], or severe (>6). No analgesics were administered on a regular basis after discharge since non steroidal anti-inflammatory drugs were only administered for postoperative pain as needed. Patients were contacted postoperatively through telephone at 24 hours and 48 hours. They were asked to report their pain, other complaints, and postoperative analgesic tablets requirement. Patients were called after 7 days to assess the approximation of the skin site or any complications. The secondary outcome measures were total duration of postoperative hospital stay, postoperative analgesic requirement, readmission rate, patient satisfaction level (graded as highly satisfied, satisfied, less satisfied, or dissatisfied), and cosmetic outcome. Any intraoperative or postoperative complications, such as blood loss, bowel/bladder/vessel injury, and wound infection, were noted.

An earlier pilot study by Roy et al. [12] had shown that the operating time was 8.7 minutes, with a standard deviation of 1.5, presuming the width of 95% confidence interval is

0.6 minutes. The adequate number of patients required to meet statistical significance at a 5% level of significance was 100. Hence, 100 women fulfilling the inclusion criteria underwent diagnostic laparoscopy with few level II therapeutic procedures using a 2.9-mm laparoscope with a smaller ancillary port.

Data analysis was performed using STATA version 12.0 (StataCorp; College Station, TX, USA). Continuous variables were tested for normality using the Kolmogorov-Smirnov tests. For variables that followed a normal distribution, descriptive statistics, such as mean, standard deviation, and range, values were calculated. For non-normal data, the median and interquartile ranges were calculated. Postoperative pain was classified using the VAS score, classified into mild, moderate, and severe, and are expressed as number and percentage values. Subgroup analysis was performed according to the patient type (infertility and chronic pelvic pain). Comparison of means, such as operating time and hospital stay, was performed using student's independent *t*-test. Postoperative pain status was compared using the chi-square or Fisher exact test. Image quality was assessed based on the satisfaction level of the surgeon. For all statistical tests, a two-sided probability of $P < 0.05$ was considered statistically significant. Patient satisfaction was subjectively assessed as highly satisfied, satisfied, and less satisfied.

Results

The patients' age ranged from 21-38 years, with a mean age of 29.3 years. The mean BMI was 27.2 kg/m². The various indications for laparoscopy included primary infertility (68%), secondary infertility (30%), and chronic pelvic pain (2%). The most common indication for laparoscopy was infertility (98%). Only diagnostic laparoscopy was performed in 76



Fig. 1. A 2.9-mm telescope for laparoscopy.



Fig. 2. A 3-mm trocar used for laparoscopy.

(76%) patients, while 24 (24%) patients underwent operative laparoscopy (Fig. 3). Out of these 24 patients, 1 patient underwent ovarian endometriotic cystectomy (3x2 cm endometriotic cyst), 4 underwent salpingectomy for a hydrosalpinx (pre-*in vitro* fertilization), 8 underwent ovarian drilling, 9 underwent adhesiolysis, 1 underwent fimbrial cystectomy, and 1 underwent left salpingectomy for hydrosalpinx along with paratubal cystectomy (3x2 cm). Furthermore, among the 24 women who underwent operative laparoscopy, one ancillary port was converted to 5 mm for the insertion of a harmonic scalpel and specimen retrieval. A skin suture was applied at the 5-mm port site. Three patients were excluded from the intraoperative and postoperative analyses. In one case, dense adhesions were found after the insertion of a 2.9-mm telescope. A tubo-ovarian mass was found in the second case, which was missed on ultrasound. In the third case, a hydrosalpinx was densely adherent to the bowel. Hence, in view of anticipated prolonged surgery and the

need for a wider field of view, the primary port was converted to a 10-mm port. The mean VAS scores at 1 hour, 2 hours, and at discharge were 1.57 ± 0.59 , 1.41 ± 0.51 , and 1.29 ± 0.47 , respectively. Mild pain (VAS score ≤ 3) was experienced by 47 (48.5%) patients, whereas only 4 (4.1%) had severe pain (VAS score ≥ 7) at 1 hour postoperatively. On the other hand, 70 (72.2%) patients had mild pain at the time of discharge, and only 1 (1%) had severe pain (Table 1). There was a significant reduction in the VAS score ($P=0.000$) from 1 hour and 2 hours until the time of discharge. The mean duration of surgery was 423.8 ± 238 seconds. The mean hospital stay was 148 ± 43.43 minutes. The image quality was satisfactory in 99% of cases, and a definitive diagnosis could be made in 99% of the patients. Only two patients experienced complications due to inferior epigastric artery injury, which was managed conservatively by bipolar coagulation through a 3-mm ancillary port. Application of stitch at the 3-mm port was required in two patients: one at the primary port site and one at the ancillary port site due to bleeding at the port site. No analgesic tablet was required postoperatively in 34% of patients, and 13.4% required only a single dose of postoperative analgesia (Table 2). Only 16.5% required 5 or more analgesic tablets in the postoperative period. The mean postoperative analgesic tablet requirement was 2.4 ± 2.86 . The analgesic tablet requirement was higher in the operative group (Table 2). There was a significant correlation between the VAS score and the duration of surgery, hospital stay, and postoperative analgesia requirement (Table 3). Patients who underwent operative laparoscopy had higher VAS scores than the patients who only underwent diagnostic laparoscopy (Table 4). None of the patients required readmission or had a wound infection. The majority (99%) of the patients were satisfied with laparoscopy.

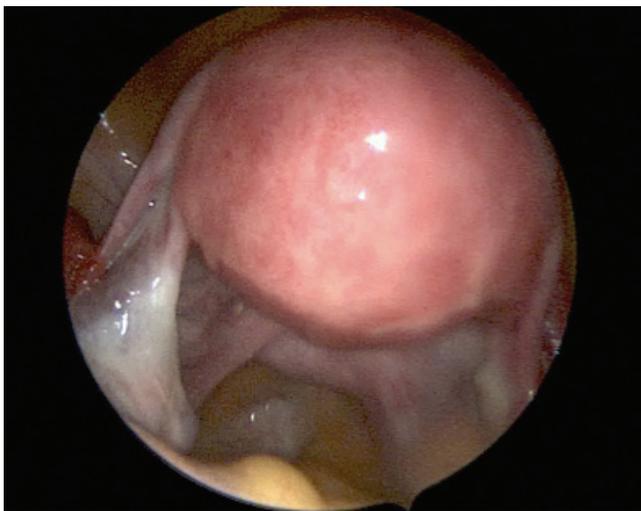


Fig. 3. A normal uterus as seen via 2.9-mm modified mini laparoscopy.

Table 1. VAS score at 1 hour and 2 hours postoperatively and at the time of discharge

Duration since surgery	Mild VAS score (VAS 1-3)	Moderate VAS score (4-6)	Severe VAS score (7-10)
At 1 hour postoperatively	47 (48.5)	46 (47.4)	4 (4.1)
At 2 hours postoperatively	59 (60.8)	37 (38.1)	1 (1.0)
At discharge	70 (72.2)	26 (26.8)	1 (1.0)
P-value (McNemar test)		0.001	

Values are presented as number (%).
VAS, visual analog scale.

Discussion

Laparoscopic surgery has revolutionized the surgical field and has seen many leaps and bounds over the years. Most commonly, gynecological laparoscopy is performed using a 10-mm endoscope. Gradually, there has been a shift from larger (10 mm) to smaller endoscopes (5 mm). Nowadays, there has also been a shift to even smaller minilaparoscopes (3 mm) with the aim of reducing postoperative pain and hernia formation, and better cosmesis [8]. Minilaparoscopy in gynecology emerged in the last two decades [2,15]. With the advent of fiber optic technology, the optical performance of the minilaparoscope has shown improvements, comparable to that of a conventional laparoscope [16]. The first case of minilaparoscopy in gynecology was reported in 1991 [15].

Haeusler et al. [17] performed a study including 52 patients who underwent laparoscopy with a 20-mm microlaparoscope and a 10-mm conventional laparoscope in the same session and found that the diagnostic accuracy of microlaparoscopy was comparable. Roy et al. [12] found that 2.9-mm modern minilaparoscopy was effective in diagnosing infertility, chronic pelvic pain, and endometriosis. In our study, modern minilaparoscopy was found to be efficacious as a diagnostic technique in 99% of cases. In a study of 135 patients, Kovacs et al. [18] found that the microlaparoscope was the instrument of choice for diagnostic laparoscopy due to the reduced postoperative pain and requirement of postoperative analgesics. Ghezzi et al. [9] compared laparoscopy for benign adnexal masses using 5-mm ancillary trocars or 3-mm instruments and found that the postoperative pain score was

Table 2. Number of postoperative analgesic tablet requirement in patients undergoing diagnostic and operative minilaparoscopy

Number of postoperative analgesic tablets required	Number of patients in diagnostic group (n=73)	Number of patients in operative group (n=24)
0	26 (35.6)	6 (25.0)
1	09 (12.3)	4 (16.7)
2	16 (21.9)	0
3	6 (8.2)	4 (16.7)
4	5 (6.8)	4 (16.7)
5	2 (2.7)	2 (8.3)
6	3 (4.1)	1 (4.2)
7	2 (2.7)	1 (4.2)
8	1 (1.4)	1 (4.2)
9	1 (1.4)	0
15	2 (2.7)	0

Values are presented as number (%).

Table 3. Bi-variate correlation coefficients between the different study variables

	VAS 1 hour	VAS at 2 hours	VAS at discharge	DOS	Hospital stays	Postop analgesia
VAS 1 hour	1.00	0.786 ^{a)}	0.626 ^{a)}	0.330 ^{a)}	0.330 ^{a)}	0.562
VAS at 2 hours		1.00	0.786 ^{a)}	0.425 ^{a)}	0.425 ^{a)}	0.641 ^{a)}
VAS at discharge			1.00	0.422 ^{a)}	0.422 ^{a)}	0.681 ^{a)}
DOS				1.00	0.491 ^{a)}	0.411 ^{a)}
Hospital stays					1.00	0.483 ^{a)}
Postop analgesia						1.00

VAS, visual analog scale; DOS, duration of surgery.

^{a)}Significance at $P < 0.001$.

less with 3-mm instruments. These had equal effectiveness and safety and did not compromise the surgeon's ability to conduct procedures or increased complications. Roy et al. [12] performed a prospective comparative study on laparoscopy with a 5-mm laparoscope and modern minilaparoscopy with 2.9-mm optics and found no difference in postoperative pain score. The pain score was in the mild range (VAS score 1-3) in 95% of cases who underwent laparoscopy using a 2.9-mm laparoscope. We also found results similar to those of Ghezzi et al. [9], who reported lower postoperative pain scores. Mild pain was felt by 48.5% of patients at 1 hour postoperatively, and the percentage increased to 72.2% at the time of discharge. Only 4.1% of patients had severe pain at 1 hour postoperatively, which was reduced to only 1% at the time of discharge. No or only a single dose of analgesic tablets was required in 34% of patients in the postoperative period. Only 16.5% of patients required ≥ 5 analgesic tablets during the postoperative period.

Gradually, the use of minilaparoscopy has shifted from diagnostic to more complex therapeutic procedures. Dorsey and Tabb [15] used an optical catheter and an Adair Verres insufflation needle passed through a 3-mm plastic sheath for visualization. Two additional 3-mm ports were inserted for adhesiolysis, biopsy of the endometriosis, and laser myomectomy. Minilaparoscopic hysterectomy was first described in 1999 [19].

Ikeda et al. [20] analyzed 16 cases of microlaparoscopy using a 2-mm telescope and performed therapeutic surgeries such as endometriosis resection, cauterization, salpingostomy for ectopic pregnancy, adhesiolysis, and myomectomy. Two 5-mm accessory punctures were made depending on the size of the sample to be removed from the abdominal cavity. They found it to be effective in diagnostic procedures and some therapeutic procedures, with less postoperative pain. Karabacak et al. [11] conducted a prospective study in 1997 with 1.75-mm optics (small diameter laparoscopy) and found that it was effective in diagnosing the macroanatomy of the pelvis and coarse pelvic pathologies. It was also useful for some surgical procedures, such as biopsies, pelvic fluid aspiration and diagnosis, and tubal ligation. However, it should be cautiously used in micro-oriented conditions, such as infertility, endometriosis, and pelvic pain. Comparable results were also observed in our study. In our study, 24 patients underwent operative procedures, namely, adhesiolysis (9 patients), ovarian drilling (8 patients), salpingectomy (4 patients), fimbrial cystectomy (1 patient), endometriotic ovarian cystectomy (1 patient), and salpingectomy with paratubal cystectomy (1 patient). One of the ancillary ports was converted to 5 mm from 3 mm for operative procedures with harmonics due to the unavailability of 3-mm instruments for operative purposes and retrieval of the specimen. Hence, certain level II gynecological surgeries, such as adhesiolysis, salpingectomy, and cystectomy, can be performed with a 2.9-mm laparoscope. The VAS score was higher in patients who underwent operative procedures than in patients who underwent only diagnostic laparoscopy, probably due to the increased operative time, more invasive intervention or handling of tissues, and the application of a suture at the 5-mm port site.

The quality of the image (size and resolution) was not the same as in the 10-mm laparoscope. A small optical diameter leads to reduced light intensity; hence, the tip of the minilaparoscope should be placed closely to the viscera for a more precise visualization [2]. In a study by Roy et al. [12], the size and quality of images projected on the screen were satisfactory during diagnostic laparoscopy with a 5-mm and 2.9-mm laparoscope. Ghezzi et al. [9] also found that the clarity, resolution, and light carrying capacity during minilaparoscopy were comparable to conventional laparoscopy during laparoscopic hysterectomy. In our study, the image quality was satisfactory in 99% of the cases, although the

Table 4. Comparison of VAS at 1 hour and 2 hours postoperatively and at discharge. DOS, hospital stay between diagnostic and operative groups

		Value	P-value
VAS at 1 hour	Diagnostic	3.56±1.72	0.070
	Operative	4.3±1.69	
VAS at 2 hours	Diagnostic	2.95±1.59	0.058
	Operative	3.65±1.33	
VAS at discharge	Diagnostic	2.43±1.46	0.073
	Operative	3.04±1.29	
DOS (sec)	Diagnostic	348.65±186.60	0.000
	Operative	675.39±224.31	
Hospital stay (min)	Diagnostic	143.73±40.50	0.040
	Operative	164.8±49.61	

Values are presented as mean±standard deviation. VAS, visual analog scale; DOS, duration of surgery.

image size and light intensity were decreased. Nonetheless, a definitive diagnosis could be made in 99% of the cases.

Minilaparoscopy can also be used prior to insertion of the primary cannula to visualize intra-abdominal adhesions and perform adhesiolysis in patients with previous abdominal surgeries, reducing the risk of serious vascular or bowel injury [13]. Major surgeries, such as hysterectomy, have also been effectively performed with minilaparoscopy [10,21]. Berlit et al. [22] found that minilaparoscopy is a feasible alternative for hysterectomy, though its use should be carefully determined as certain surgical procedures might be impaired, such as vessel sealing, due to the smaller size of the instruments. However, it is an effective alternative for diagnostic or smaller ablative procedures. Aydoğmus et al. [21] compared conventional total laparoscopic hysterectomy (TLH) vs. minilap TLH and found that the requirement of postoperative analgesia and duration of hospital stay was lower and scar score was better in the MLH group. Minilaparoscopy may also be used for laparoscopic surveillance during operative hysteroscopy [2].

Acton and Salfinger [10] reported reduced operating time with a smaller laparoscope in a hysterectomy procedure with a 10-mm laparoscope and 5-mm ancillary ports, compared to a 5-mm laparoscope and 5-mm ancillary ports. Some studies found no difference in the operative duration using smaller instruments [12,23]. The mean duration of surgery was 423.8 ± 238 seconds in our study. The duration might have been reduced as no suture had to be applied at the port site.

Several studies have compared the safety of minilaparoscopy to conventional laparoscopy, although the number of patients in each study was small. Further research was conducted, but these showed no difference in the complication rates, such as rate of infection, conversion to open readmission rate, and blood loss [10,12,23]. Subcutaneous and subfascial hematomas were less common in minilaparoscopy [24]. Small Layne et al. [25] reviewed the literature and found that minilaparoscopy was safe with good cosmetic results and had similar operative duration and complication rates. In our study, only 2 patients had complications in the form of inferior epigastric artery injury, which was managed conservatively by bipolar coagulation through a 3-mm ancillary port. No major complications were observed.

One of the disadvantages of minilaparoscopy is the difficulty in removing surgical specimens for which either one of the ports has to be kept bigger or has to be extended after surgery to remove the specimen [25]. In our study, one of the

ancillary ports was converted to 5 mm for specimen retrieval.

The duration of hospital stay was the same regardless of whether laparoscopy was performed with a 5-mm or a 2.9-mm laparoscope [12]. The mean hospital stay was 148 ± 43.43 minutes.

Ikeda et al. [20] found better cosmesis as no suture was applied, less infection rates, and less chances of incisional hernia due to the small size of the incision. Despite the small sample size of 20 patients, Ferreira et al. [23] observed a statistically significant difference in cosmesis for sacrocolpopexy cases between standard laparoscopy and minilaparoscopy. In our study, none of the patients had wound infections or were readmitted. As 3-mm ports do not require the closure of the fascia or skin, the cosmetic outcome was good, and the scar was almost invisible at follow-up at 7 days in our study.

Almost all (86%) postoperative hernias occur when 12-mm or bigger trocars were used, while only 2.7% occurred with 5-mm trocars. This will be further reduced with the use of 2.9-mm trocars [5-7]. No incisional hernia developed in the study by Aydoğmus et al. [21]. Incisional hernia occurrence is approximately 0.23% with 10-mm and 0.31% with 12-mm operative laparoscopes [6]. None of our patients developed a hernia during follow-up.

Modern minilaparoscopy with a 2.9-mm laparoscope is a feasible and safe option for diagnostic laparoscopy and level II gynecological procedures with minimal postoperative morbidity, such as pain and wound infection, and it provides good cosmetic outcomes.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Ethical approval

Ethical clearance was obtained from the Institute Ethics Committee for Postgraduate Research, IEC PG-273/29.05.2019. The study was performed in accordance with the principles of the Declaration of Helsinki.

Patient consent

Written informed consent and the use of images from patients are not required for the publication.

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