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Original Research Article

Randomized comparative study of conventional minilaparoscopy (5mm) versus modern minilaparoscopy (2.9mm) in patients of infertility

Kallol Kumar Roy¹, Nandini Joshi nee Jahagirdar^{2*}, Murali Subbaiah³,
Sunesh Kumar Jain¹, J. B. Sharma¹, Neeta Singh¹

¹Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences, New Delhi, India.

²Department of Obstetrics and Gynaecology, Kamineni Academy of Medical Sciences and Research Center, Hyderabad, Telangana, India

³Department of Obstetrics and Gynaecology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, Tamil Nadu, India.

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***Correspondence:**

Dr. Nandini Joshi nee Jahagirda,

E-mail: jahagirdar.nandini@gmail.com

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ABSTRACT

Background: To compare diagnostic conventional minilaparoscopy (5mm) with diagnostic modern minilaparoscopy (2.9mm) in patients of infertility in terms of operating time, post-operative pain, hospital stay.

Methods: A prospective randomized comparative study was done in a tertiary care centre involving eighty patients of infertility undergoing diagnostic laparoscopy. Diagnostic laparoscopy was done using 5mm laparoscope (Conventional minilaparoscope-Group I) in 40 patients and using 2.9mm laparoscope (Modern minilaparoscope-Group II) in 40 patients. Operating time was measured from the point of skin incision to closure, post op pain was assessed with VAS scoring system, total hours of hospital stay from shifting to day care recovery ward till discharge was noted.

Results: Both conventional minilaparoscopy and modern minilaparoscopes were comparable to each other. Operating time in both groups was similar (7.7min in Group I vs 8.7min in Group II). In both groups, there was no statistically significant difference in post-operative pain as assessed by VAS scoring System (39 in Group I vs 38 in Group II had mild post-op pain and 1 in Group I vs 2 in Group II had moderate pain). The difference in duration of post-op hospital stay in both Group I and group II was not statistically significant (3.5 hours vs 3.3 hours).

Conclusions: Both conventional minilaparoscopy (5mm laparoscope) and modern minilaparoscopy (2.9mm laparoscope) are comparable with respect operating time, post-op pain, hospital stay. Modern minilaparoscopy is no better than conventional minilaparoscopy.

Keywords: Conventional minilaparoscopy, Direct trocar entry, Modern minilaparoscopy, Mean hospital stay

INTRODUCTION

The role of laparoscopy is invaluable in evaluation of patients with infertility Jan Boosteels et al, both as a diagnostic and therapeutic tool. Since the dawn of its invention, the major concerns were, the need for subjecting patient to general anesthesia, post-operative

pain and discomfort, safety of the procedure per se, cost-effectiveness, possible adhesion formation and other long term sequelae like trocar site hernia Fear et al, Montz FJ et al, Rabinerson et al.¹⁻⁴ These potential loop-holes have led to the discovery of minilaparoscopes having diameters smaller than 5 mm. Hence a study was conducted to compare both laparoscopes. There is no universally agreed nomenclature for procedure performed

with small diameter laparoscopes. Various terms such as miniature laparoscopy, minilaparoscopy, microlaparoscopy, accusergery, needlescopesurgery or mini site surgery have all been used by various authors.² O'Donovan defined these miniature scopes as.⁵

- Microlaparoscope - Diameter < 2mm
- Minilaparoscopy- Diameter of 2-5 mm.

According to Unify criterion, these are classified as:⁶

- Traditional laparoscopy: >5mm
- Conventional minilaparoscopy: 5-3.5mm
- Modern minilaparoscopy: 3.4-2mm
- Microlaparoscopy: <2mm

The field of minimally invasive surgery has evolved tremendously in recent years. Thus, conventional minilaparoscopy and modern minilaparoscopy has in many cases replaced traditional laparoscopy. Smaller ports not only offer cosmetic advantages but also offer comparable diagnostic accuracy.^{4,7} Further these instruments have many advantages over larger ones such as anaesthesia requirements, less postoperative discomfort,⁸ decreased risk of adhesion formation and reduced risk of incisional hernias.⁷⁻¹¹ To the best of our knowledge, this is the only largest prospective randomized comparative study comparing various parameters in diagnostic laparoscopy of infertility patients using 5 mm and 2.9 mm minilaparoscopes. The concept of small is beautiful is more justified when it comes to laparoscopy in evaluation of patients of infertility.

METHODS

This was a prospective randomized comparative study conducted in Obstetrics and Gynaecology Department of a tertiary care center as a day care procedure.

Institutional review board approval and Ethical clearance were taken. An informed and written consent was taken from the participants.

Inclusion criteria

All patients of primary or secondary infertility where diagnostic laparoscopy was indicated and patients with BMI < 25. The exclusion criteria were any previous abdominal surgery, need for operative procedure, any contraindication of laparoscopy.

A complete infertility work up was done in all cases. Diagnostic laparoscopy was done between 5th and 15th day of the menstrual cycle.

A total of eighty patients with infertility were recruited in the study after exclusions. Patients were randomized into two groups using computer generated randomization

number. Forty patients underwent diagnostic laparoscopy using 5mm KARL STORZ conventional minilaparoscopy (Group I) with 30-degree view and another 40 patients underwent diagnostic laparoscopy with 2.9mm KARL STORZ modern mini laparoscopy (Group II) with 30-degree view.

Diagnostic laparoscopy was performed under general anaesthesia by a single surgeon in both groups. A sub umbilical semi lunar incision of sizes 5mm and 3mm were made in Group I and Group II respectively. After lifting the abdominal wall, trocars were introduced by direct entry technique in both the groups. Pneumoperitoneum created by insufflating approximately 2 L of CO₂ under vision, one accessory side port was introduced of size 5mm and 3mm respectively in Group I and Group II.

The following findings were noted using a minigrasper, in both groups- size and surface of the uterus, bilateral ovaries, fallopian tubes and abdominal cavity. Tubal patency test was done by chromopertubation injecting 30ml of methylene blue through an intrauterine foley catheter.

Total operating time was recorded from incision to skin closure. In both Groups, sutures were not applied to close the port insertion site. Instead, an adhesive plaster was applied to approximate the edges.

Postoperative pain was assessed by visual analogue scale (VAS). Visual analogue scale was graded from 0 to 10 as 'no pain' to 'worst pain'. Pain is scored as mild (1-3), moderate (4-6) and severe (>6). Total duration of post-op hospital stay was recorded.

Statistical analysis

The above data was computed and a comparative statistical analysis was done using Pearson's chi-square test, Student's T test, Stuart-Maxwell, Satterthwaite's degrees of freedom and ANOVA by using software SPSS 15 where ever applicable. P value of <.05 was considered as statistically significant.

RESULTS

Clinical data of the patients included in the study is shown in Table 1. Patients in two groups did not differ with respect to age, BMI, type of infertility. Result of the various parameters which were compared in the study are tabulated in Table 2.

The intra operative findings of both groups were comparable (Figure 1).

Certain conditions like tuberculosis, endometriosis, pelvic inflammatory disease and adhesions which are commonly seen patients of infertility could be diagnosed accurately.

Table 1: Clinical Data of patients.

Variable	Conventional minilaparoscopy Group I (5mm)	Modern minilaparoscopy Group II (2.9mm)	P value
No. of patients	40	40	-
Age (Mean,years±S.D)	27.4±4.2	28.1±5.3	0.267
BMI	22.9±1.8	22.8±1.7	0.819
Type of infertility			
Primary vs Secondary	28vs12	29vs11	0.805

Table 2: Comparison of various intraoperative and post-operative parameters between Group I (5mm) and Group II (2.9mm).

Variable	Conventional minilaparoscopy Group I (5mm)	Modern minilaparoscopy Group II (2.9mm)	P value
Mean operating time	7.7 minutes	8.7 minutes	.9
Post-operative pain	Mild (39 patients)	Mild (38 patients)	.556
Mean hospital stay	3.5 hours	3.3 hours	.34

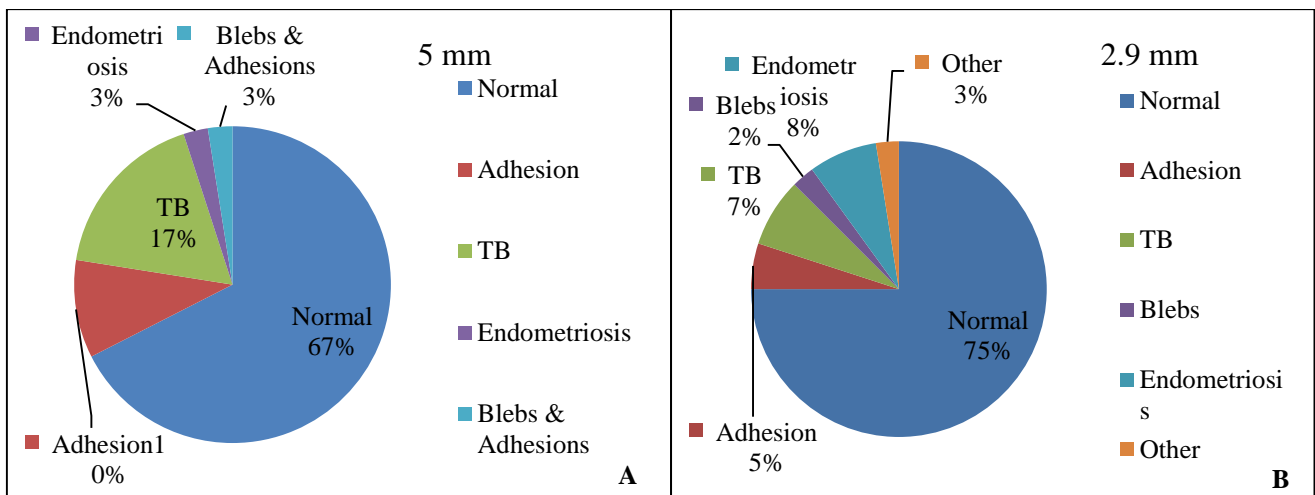


Figure 1: Showing intra-operative findings in both the groups (5mm (A) vs 2.9mm (B)).

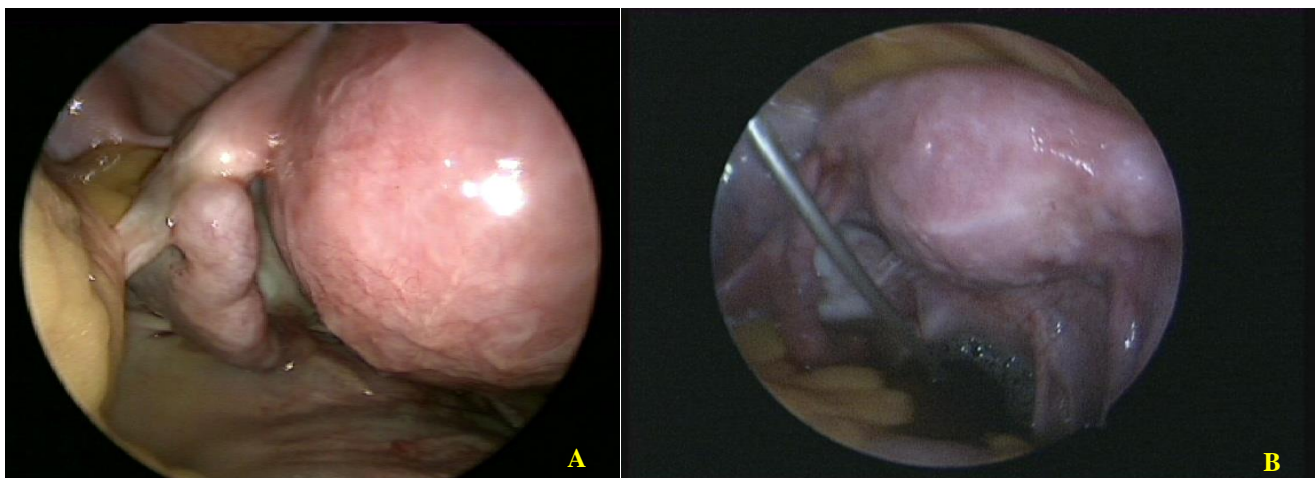


Figure 2: Diagnostic laparoscopy using 5mm (A) scope vs 2.9mm (B).

The image quality and size of the image projected on the screen were satisfactory (figure 2) in both Group I (5mm) and Group II (2.9mm).

Mean operating time in Group I (5mm) was 7.7 minutes (Range: 3-20min) and in Group II (2.9mm) 8.7 minutes (Range: 4-20min). However, this difference was not statistically significant as (P value-.9). Operating time was longer in few cases in both the groups due to the presence of florid tuberculosis and dense adhesions.

Post-operative pain as assessed by VAS scoring revealed mild pain in 39 patients in Group I (5mm) and moderate pain in 1 patient. In Group II (2.9mm), 38 patients had mild pain and 2 patients had moderate pain. The difference was not statistically significant (P value -.556).

Mean hospital stay in Group I (5mm) was 3.5 hours and in Group II (2.9mm), 3.3 hours and the difference was not statistically significant (P value -.34).

DISCUSSION

Initial studies in the field of small diameter laparoscopy concentrated on evaluating diagnostic accuracy of the small diameter laparoscopes, but their studies were hampered by instruments that produced low levels of light, reduced fields of view, and generally poor resolution Dorsey and Tabb et al, Risqué et al.^{7,8} Later, with the development in fiberoptic technology, the optical performance of microlaparoscopes was shown to be comparable with conventional laparoscopes (O Bauer et al).⁹ Two other prospective studies on a series of 20 patients Molly D et al and 52 patients Haeusler et al concluded that the accuracy of microlaparoscope is comparable to that with the conventional 10mm laparoscope.^{10,11} Further in 1997, Faber et al conducted a comparative study of diagnostic accuracy using 2mm and 10mm scopes in 10 patients.¹² In this study, in order to avoid single observer bias, two investigators independently reported their findings using two different scopes on a single patient in the same sitting. In our study, we used two laparoscopes of different diameters (5mm in Group I and 2.9 mm in Group II) with fiber optic rigid rod lens system and a single surgeon performed the diagnostic laparoscopy. The 2.9mm laparoscope is considered as reliable as 5mm laparoscope for diagnosing tubal, ovarian and uterine abnormalities. Fuller et al in 1995 also concluded that microendoscopes are adequate for diagnostic and minor operative procedures.¹³

The Karabacak et al in 1997 in their prospective self-controlled study of 37 patients compared visual quality, diagnostic accuracy, and surgical merits of small diameter laparoscopy (SDL) of 1.75mm diameter with conventional laparoscopy.¹⁴ They concluded that SDL seems a good alternative to conventional laparoscopy in diagnosing macro-pelvic anatomy and coarse pelvic

pathologies and may also be good in performing surgical procedures such as: tubal ligation, biopsies and differential diagnosis of pelvic fluids. But SDL must be used cautiously in micro oriented, functional conditions such as infertility, pelvic pain, endometriosis and adhesion scoring or treatment. SDL may be regarded as a less invasive but less sensitive tool with limited surgical merits. But in our study, all the pelvic pathologies like tuberculosis, endometriosis, pelvic inflammatory disease and adhesions could be diagnosed with equal efficacy in both the groups. Hence, as a diagnostic tool, 2.9mm scope can be used safely in patients of infertility as compared to 5mm scope with equal efficacy.

Since entry into the abdomen was made directly with the trocars, time taken to complete the procedure was less compared to other studies as in Karabacak et al. Mean operating time in Group I (5mm) was 7.7min ranging from 3 min to 20 min and in Group II (2.9mm) was 8.7min ranging from 4 min to 20 min.¹⁴ The difference was not statistically significant. In few cases operating time was prolonged due to the presence of florid tuberculosis or adhesions due PID. In group II, operating time was increased as BMI increased. But no correlation found in 5 mm group. It is hypothesized that increase in BMI may affect small diameter laparoscopy but no studies available to support this evidence.

Many studies are available in the literature where SDL was performed under local anaesthesia to know the effect on post-operative pain.^{9,15-20} Zupi E et al in their prospective randomized study of 164 patients looked for affordability and reliability of minilaparoscopy under local anesthesia and conscious sedation compared to general anaesthesia.¹⁹ In their study 5.5% of those undergoing procedures under local anaesthesia and sedation required general anaesthesia. However, in our study, 39 patients in Group I and 38 patients in Group II had mild pain only. One patient in Group I (5mm) and 2 patients in Group II (2.9mm) had moderate pain. The difference between the two groups was not statistically significant.^{9,15-20}

The mean duration of post-op hospital stay was 3.5 hours in Group I (5mm) and 3.3 hours in Group II (2.9mm). The difference was not statistically significant. It has been proposed that use of analog-sedation will reduce the hospital stay as compared to use of general anaesthesia.^{15,16} Delayed regaining of consciousness following general anaesthesia was probably responsible for prolonged hospital stay in these studies. But in our study, though done under general anaesthesia, the mean hospital stay was considerably less (3.5 hours vs 3.3 hours) and comparable in both the groups.

They had a smooth post-operative recovery with mild pain. Additional analgesics were not required. No stitch was applied in both the groups. No immediate trocar site hernia was noted. None of the patients had wound infection and it was well healed. In both groups, there

was hardly any visible scar during follow up on post-op day 7.

CONCLUSION

Both conventional minilaparoscopy (5mm laparoscope) and modern minilaparoscopy (2.9mm laparoscope) are comparable with respect to operating time, post-op pain, hospital stay. Modern minilaparoscopy is no better than conventional minilaparoscopy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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