

Complications of Entry Using Direct Trocar and/or Veress Needle Compared with Modified Open Approach Entry in Laparoscopy

Six-Year Experience

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Purpose: To compare the results obtained from three routine laparoscopic entry techniques, including Direct Trocar (DT), Veress Needle (VN), and Open Approach (OA).

Materials and Methods: Safety and efficacy of three main laparoscopic entry techniques were evaluated prospectively in 453 consecutive patients who had undergone laparoscopy either with DT, VN, or modified OA technique in recent six years.

Results: Of 453 patients, 105 (23.2%) were operated on with the DT, 168 (37.1%) with the VN, and 180 (39.7%) with the modified OA technique. Statistical differences were seen among the groups in terms of mean age ($P = .003$), male-to-female ratio ($P < .001$), indications for the operation ($P < .001$), and mean trocar insertion time ($P < .001$). Three major complications (1 colon perforation and 2 iliac artery injuries) occurred in DT and one (iliac artery injury) in VN group and modified OA group had no major complication ($P = .04$). Four major complications required laparotomy. Minor complications were seen in 6 (5.8%), 9 (5.4%), and 17 (9.4%) patients ($P = .274$) and gas leakage in 4 (3.8%), 16 (9.5%), and 27 (15%) patients ($P = .01$) in DT, VN, and modified OA groups, respectively.

Conclusion: Although DT and VN are rapid and relatively safe, they can be associated with major complications. Therefore, modified OA seems to be safe, feasible, and most acceptable due to less major complications.

Keywords: laparoscopy, pneumoperitoneum, complications

INTRODUCTION

Establishing an acceptable pneumoperitoneum is the first and most important stage of laparoscopy. The best entry technique into the abdominal cavity is always a dilemma, and may result in complications and severe morbidity.⁽¹⁻³⁾ Major vascular and bowel injuries are rare, but serious complications of laparoscopic surgery.

Generally, the insertion technique is done with Direct Trocar (DT), which has the potential for injury.⁽⁴⁾ Although Veress Needle (VN) is widely used as another popular technique, it is associated with slow insufflations rates and potentially life-threatening complications.⁽⁴⁾ The Open Approach (OA) is relatively more safe; hence, is a good alternative to DT and VN techniques, even if it is considered cumbersome by many surgeons.

Although OA is credited with reducing the incidence of vascular and visceral complications to nil, a 0.2% incidence of complications among 10 840 open gynecologic laparoscopies and a 0.06% incidence of bowel injuries have been reported.⁽⁵⁾ Some surgeons use a new version of OA as Modified Hasson's Technique.^(6,7) Furthermore, some surgeons use OA for percutaneous nephrolithotomy.⁽⁸⁾ To compare and evaluate the safety and efficacy of these entry techniques, we designed this prospective, nonrandomized, clinical study and discussed the results.

MATERIALS AND METHODS

This study was approved by Urology & Nephrology Research Center, Hamadan University of Medical Sciences as well as Chancellor of Research and Technology of Hamadan University of Medical Sciences, Hamadan, Iran. After ethic committee approval was obtained based on Declaration of Helsinki, this observational study was conducted prospectively at Shahid Beheshti, Ekbatan, Besat, and Fatemieh academic hospitals affiliated with Hamadan University of Medical Sciences in Hamadan, Iran from January 2005 to January 2011. These hospitals are the main centers for laparoscopic surgery in Hamadan province with a population of more than 1 700 000 people in the west of Iran.

During the period of six years, all patients with any age who had undergone laparoscopic surgery were enrolled in the study. The only criterion for the technique selection was the

surgeon's preference. Exclusion criteria were any contraindication for laparoscopy, such as uncorrectable coagulopathy, intestinal obstruction, significant abdominal wall infection, massive hemoperitoneum or hemoretroperitoneum, generalized peritonitis, and suspected malignant ascites. Furthermore, 34 patients were excluded from the study due to previous abdominopelvic surgery, body mass index more than 40 kg/m², and refusal of surgery.

Finally, 453 patients were evaluated as: group 1, DT (n = 105); group 2, VN (n = 168); and group 3, modified OA entry technique (n = 180). Various surgeons with different specialty, who have been employees of Hamadan University of Medical Sciences with at least assistant professor degree, and had certification for laparoscopic surgery and complete learning curve, performed the operations.

After full pre-operative assessment, including history taking, general physical examination, laboratory evaluation, and diagnostic studies, patients were admitted to the hospital on the day of the procedure or one day prior for some major operations.

Data, such as gender, age, body weight, surgery indications, intra and postoperative complications, and mortality and morbidity rates, were compared among the groups. Complications of the entry techniques were classified as two groups; major complications that were defined as those requiring conversion to an open procedure or re-intervention (mesenteric or iliac vessels, the bowel, or solid organ injury) and minor complications, which were defined as those not influencing the length of hospital stay (subcutaneous emphysema, extraperitoneal insufflations, or small abdominal wall vessels injury).

Statistical Analysis

Data were analyzed by SPSS software (the Statistical Package for the Social Sciences, Version 13.0, SPSS Inc, Chicago, Illinois, USA) and expressed as mean \pm standard deviation. Independent *t* test was used for quantitative parameters and Chi-Square for others. A *P* value of less than .05 was considered statistically significant.

Surgical Procedure

After general anesthesia induction, Foley fixation, and plac-

ing the patients in appropriate position, in group 1, a 12-mm incision was made just below the umbilicus. First, a 5-mm incision was made on the rectus muscle sheath. Then, a 10 to 12-mm disposable shielded trocar was passed vertically into the peritoneal cavity. Entry into the abdominal cavity was confirmed by an audible click sound of the locking shield. The obturator was removed, and carbon dioxide gas was insufflated into the peritoneal cavity at 2 L/min and a pressure of 12 to 14 mmHg. Subsequently, other trocars were inserted.⁽⁹⁾

In the VN group, a pneumoperitoneum was created with disposable or metal VN (70 or 120 mm, 14 gauge, and 2 mm outer diameter). The VN was inserted through a created supraumbilical incision in supine or lateral decubitus position. Entry into the peritoneal cavity was confirmed by the syringe test. After the optimum insufflations of carbon dioxide, a 10-mm trocar was inserted in a similar manner to group 1.⁽⁸⁾

In the modified OA group, after a 10-mm periumbilical or midclavicular incision in obese patients, incision medial edge was held with a blunt homeostasis, and Metzen was used for dissection onto the fascia. After elevation of the abdominal cavity with the towel clips, followed by an under vision small incision by surgical blade, the fascia was dilated about 10 mm by Metzen, which was fit to trocar external caliber. Entry to peritoneal cavity was performed downwardly by closed Metzen and with empty bladder. Metzen was set back in open manner to prevent solid or hollow organ injury. After visual and digital confirmation of entry into the peritoneal cavity, a 10-mm trocar was inserted and the optimum insufflation of carbon dioxide was performed. Trocar was fixed with towel clips to prevent instability and probable gas leakage if need.^(6,10)

RESULTS

Of 453 patients, 105 (23.2%) were operated on by DT, 168 (37.1%) by VN, and 180 (39.7%) by Labbafinejad Urology Center modified OA technique. Patients' demographic data are presented in Table.

The main indications for the operation were urologic (renal cyst, undescended testes, inguinal hernia, and ureteral stone), general surgery field (cholecystectomy, splenectomy, and appendicitis), and gynecologic diseases (diagnostic laparos-

copy, tubal ligation, and infertility).

No mortality was observed in each group. There were statistical differences among the groups in terms of mean age ($P = .003$), male-to-female ratio ($P < .001$), indications for the operation ($P < .001$), and mean trocar insertion time ($P < .001$).

Complications were not associated with the surgeons' experience. There were three major complications (1 colon perforation and 2 iliac artery injuries) in group 1 and one (iliac artery injury) in group 2 whereas no major complication was detected in group 3 ($P = .04$). These four major complications required a re-intervention, such as laparotomy. One patient with iliac artery injury in the VN group improved after one-week intensive care unit admission.

As Table shows, 32 minor complications occurred during insertion technique. These complications were seen in 6 (5.8%), 9 (5.4%), and 17 (9.4%) patients in the DT, VN, and OA groups, respectively ($P = .274$). There was no other subject that required a significant early or late intervention for any unrecognized intra-abdominal injury. Gas leakage occurred in 4 (3.8%), 16 (9.5%), and 27 (15%) patients in the DT, VN, and OA groups, respectively ($P = .01$). About 5% of the VN patients needed more than one try for successful trocar insertion.

DISCUSSION

Although some studies have been carried out to compare laparoscopy entry techniques, adequate data are not yet available. Vilos and colleagues in 2007 concluded that optical trocar was better than other techniques. They also stated that the visual entry cannula system may represent an advantage over traditional trocars, since it allows a clear optical trocar entry, but this advantage has not been fully explored and they suggested more investigation.⁽⁹⁾

Altun and associates compared DT and VN techniques and reported 2.2% major complication for VN, but nothing for DT. They also reported 6.7% minor complication for VN and 2.05% for DT. They concluded that surgeon's preference, skill, anatomic knowledge, and experience are determining factors in the selection of technique.⁽⁵⁾ Simforoosh and colleagues described outcome of 3000 patients that underwent laparoscopic procedure during 10 years in Labbafinejad

Data of different entry techniques in 450 patients who had undergone laparoscopy.

Variable	Direct Trocar group (n = 105)	Veress Needle group (n = 168)	Open Approach group (n = 180)	P
Mean age ± SD, y	41.37 ± 1.27	35.13 ± 1.61	30.49 ± 1.23	VN/DT: .003 VN/OA<.001 DT/OA: .023
Female, n (%)	86 (81.9%)	91 (54.2%)	35 (19.4%)	< .001
Male, n (%)	19 (18.1%)	77 (45.8%)	145 (80.6%)	< .001
Mean BMI ± SD, kg/m ²	25.2 ± 6.3	26.8 ± 13.1	24.4 ± 5.8	.615
Mean trocar insertion time ± SD, sec	176.94 ± 96.426	331.02 ± 64.405	375.36 ± 63.808	< .001
Urologic cases, n (%)	11 (10.5%)	15 (8.9%)	131 (72.8%)	< .001
Gynecologic cases, n (%)	78 (74.3%)	25 (14.9%)	27 (15%)	< .001
General surgery cases, n (%)	16 (15.2%)	128 (76.2%)	22 (12.2%)	< .001
Minor complications, n (%)	6 (5.8%)	9 (5.4%)	17 (9.4%)	.274
Subcutaneous emphysema, n (%)	1 (1.0%)	5 (3.0%)	6 (3.3%)	.314
Abdominal wall vessel injury, n (%)	5 (4.8%)	2 (1.2%)	9 (5.0%)	.314
Omental hernia, n (%)	0 (.0%)	2(1.2%)	2 (1.1%)	.314
Major complications, n (%)	3 (2.9%)	1 (0.6%)	0	.04
Mesenteric vessel laceration	0	0	0	-
Intestinal injury, n (%)	1 (1%)	0	0	.085
Solid organ injury	0	0	0	-
Major vessel injury, n (%)	2 (1.9%)	1 (0.6%)	0	.085
Gas leakage, n (%)	4 (3.8%)	16 (9.5%)	27 (15%)	.01

SD indicates standard deviation; BMI, body mass index; VN, Veress Needle; DT, Direct Trocar; and OA, Open Approach.

Medical Center. They concluded that a new version of OA as Modified Hasson's technique is the preferred method.^(6,7,10) Bemelman and associates compared DT, VN, and OA techniques in 2000. They reported a significant difference for mean trocar insertion time between groups ($P < .001$), but not for morbidity and gas leakage.⁽¹¹⁾ Some other studies did not observe any significant difference in major complications rates between the VN and the DT entry techniques.^(2,12,13) In our study, DT, VN, and modified OA technique, were mainly used by gynecologists, general surgeons, and urologists, respectively. Because of more incidences of some diseases, such as undescended testes and varicocele, in young men, mean age in modified OA group was significantly lower than other groups ($P < .05$). Furthermore, most patients in DT group were women ($P < .001$). Mean trocar insertion time and gas leakage were significantly more in modified OA technique group ($P < .001$ and $P = .01$, respectively), which were expected based on the technique. More occurrence of

major life-threatening complications were seen in DT than other groups ($P = .04$). Although minor complications were more in VN and modified OA technique than DT, which is consistent with other studies, it was not significant ($P = .274$). Our study was not without limitations. To eliminate possible confounding factors, such as morbid obesity and previous abdominopelvic surgery, we suggest enrolling more patients and designing a randomized study to enhance the power of the investigation and decrease biases. Furthermore, since various surgeons were involved, surgeon's experience can influence time of entry.

CONCLUSION

We concluded that modified OA is more safe, feasible, and acceptable due to less life-threatening major complications.

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CONFLICT OF INTEREST

None declared.

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