

A Randomized, Prospective Study Comparing the Use of the Missile Trocar and the Pyramidal Trocar for Laparoscopy Access

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Background: The missile trocar was developed for smooth abdominal penetration of the primary port. It contains a longitudinal tunnel connecting the abdominal cavity with the outside.

Objective: To evaluate the efficacy of the missile trocar compared with the traditional method using the Veress needle.

Material and Method: The times required to enter the abdominal cavity and the difficulty of the procedure were compared with the traditional Veress needle. A blind technique was used on 100 consecutive patients in a randomized fashion.

Results: The missile trocar technique took 2.7 ± 1.6 minutes to perform compared with 3.9 ± 1.3 min in the Veress needle group ($p = 0.001$), and the difficulty of the procedure was 2.1 ± 1.9 cm ($p = 0.433$) rated from 10-cm scale. No carbon dioxide leakage or serious complications occurred in any patient.

Conclusion: The results of the present study indicate that a long-tip missile trocar technique may be used safely when the technique is fully understood. This procedure is a relatively quick alternative approach for laparoscopy.

Keywords: Missile trocar, Primary port, Laparoscopy, Randomized trial

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Reusable trocars have the advantage of being more cost-effective than disposable trocars. However, the reusable trocar does lose its sharpness though repetitive insertion. Moreover, its wide base of conical or pyramidal tip requires relatively high puncture force for it to penetrate through the strong rectus sheath. Increased entry force at this step, in critical situations, especially in a rush case done by a fatigued surgeon, could result in less than optimal control and sudden pushing of the trocar into the abdomen could occur. This is a potential cause of serious visceral and vascular injuries. Disposable trocars are expensive, but the sharpness of the knife helps to facilitate smooth

insertion. In addition, disposable trocars have a safety shield system designed to decrease abdominal organ injury, though the potential problem of bleeding from the abdominal wall port site has yet to be resolved. A novel ultrasonic vibrating trocar that does not lose its sharpness even with repetitive insertion has been developed recently. This trocar also helps to prevent bleeding by means of an ultrasonic cavitation effect^(1,2). Other surgeons prefer threaded hollow cannula⁽³⁻⁵⁾, radially dilating trocar⁽⁶⁻¹²⁾, or optical access system⁽¹³⁻¹⁵⁾. But difficulty of assembling, the expensive delicate parts, the complicated procedures and the cost of maintenance prevent these devices from being used widely. To lessen the trocar entry force and minimize the fascial sheath damage, the authors would like to introduce a modified reusable trocar device and technique for minimal invasive surgery. This trocar

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technique has been developed as an alternative to the use of both the Veress needle and a standard conical or pyramidal trocar. It is called the missile trocar laparoscopy.

Before the authors proceeded with the present study, the authors had practiced on cadavers⁽¹⁶⁾ and carefully conducted a study to determine the efficacy and the potential complications of the missile trocar. The blind trocar insertion was counterbalanced with a rectus sheath hooking instrument instead of the towel clips. The missile trocar was used for primary port establishment without carbon dioxide insufflation in the previous case series of the forty diagnostic laparoscopies. In the present study, there were six patients with moderate obesity; their BMI was 30-33 kg/m². Ten had a history of previous pelvic surgery. Most of this group had Pfannenstiel incision. The patients with midline incisional scar from a previous laparotomy were excluded from the present study. Half of them had linear omental adhesion of the anterior abdominal wall along the line of abdominal scar. Seven were second-looked laparoscopy with umbilical puncture scar. No adhesions of the laparoscopic portal sites were seen. The abdominal access procedure was successful in all the patients. After passing the learning curve period, the average of the procedure times of the last twenty patients was 3.5 min, ranging from 2.1 to 5.6 min. No intestinal perforations or retroperitoneal hematoma were detected. The resident performing the diagnostic procedure had been requested not to repair the sheath in some patients because of the small sheath aperture in the thick abdominal wall to avoid intestinal injury during the stitch placement in a tight place.

Material and Method

The missile-shaped trocar tip is approximately twice longer than the conventional conical tip. This cone is designed to minimize puncture resistance for controllable movements of the port establishment by gradual change of the angle between the tip and the shaft (Fig. 1). The passed-through longitudinal canal connects the opening of the trocar tip to the mushroom-shaped handle. This allows spontaneous adjustment of the intra-peritoneal pressure during peritoneal perforation, when the penetrated rectus sheath is secured by a hook in an adequate umbilical incision. When the rectus fascia is firmly secured and suspended with the hook, the sharp missile trocar tip is engaged in the fascial defect created beneath the fascial hook (Fig. 2). After the rectus sheath is fully dilated with a twisting motion of the missile trocar under constant pressure,

then a slow and gradual entry into the elastic peritoneal cavity is accomplished by aiming at the uterus in the pelvis. Thereafter the trocar is advanced in the abdominal cavity under constant pressure. A successful procedure is perceived by a sudden loss of puncture resistance and confirmed by the laparoscopic view of the shiny highly vascular omentum. Then, insufflation of carbon dioxide was performed under vision or an alternative gasless device can be installed (Fig. 3).

To evaluate this technique's effectiveness, the time required and the difficulty of the procedure were evaluated prospectively in 100 consecutive patients in a randomized controlled trial. The present study protocol had been approved from the internal review board of the institute. After a pilot study of 10 subjects in each group, the sample size was increased to 50 for each study group so that the procedure times of port establishment and other parameters could be evaluated. The patients were allocated either to the missile trocar technique or the insufflation Veress needle and reusable pyramidal trocar group by simple randomization. Three fellows who were in the process of gaining experience in laparoscopic surgery ran the trial in diagnostic laparoscopy. None of these fellows had prior experience on the use of this missile trocar. The patients suspected of having intestinal adhesion around the umbilical region, such as the patients who had undergone prior abdominal surgery and had midline vertical subumbilical incisions, or having past history of peritonitis, were excluded from the trial. Another exclusion criterion was the patients with a large abdominal or pelvic mass; such as a large adnexa cyst.



Fig. 1 The missile trocar lies between the pyramidal trocar and the cannula. The other one was inserted into the cannula and ready for abdominal access procedure



Fig. 2 The missile trocar was replaced the pyramidal tip trocar and was engaged in the defect of the rectus sheath created by the traction force of the hook



Fig. 3 The abdominal cavity was inspected after insufflation. The missile trocar and the hooks lied on the suprapubic region of the patient

Supplemental oxygen mask with a bag and a single intravenous dose of Pethidine (75 mg) and Midazolam (Dormicum, 5 mg) were administered 10 min before the procedure. Local anesthesia was infiltrated around the umbilical area of the initial port establishment. In the control group beginning with 1 L/min. of carbon dioxide insufflation, after confirming the intraperitoneal placement of the insufflation needle, approximately 5 L/min. was introduced to the abdominal cavity via a Veress needle until 15 mmHg was achieved. Then two towel clips secured the edge of the umbilical skin incision on both sides during pyramidal trocar insertion. The reusable flap valve port canulae (Strotz, Germany), with different trocar specific for each group: the missile trocar or a pyramidal trocar, were assigned to the subjects, divided into two groups in a randomized fashion.

The procedural difficulty of the operators, pain of the patients at the puncture wound at 3 and 24 hours postoperative period, and the patient satisfaction were measured by visual analogue scale.

Statistical analysis

Descriptive statistics mean \pm Standard Deviation of the baseline data and outcome results, student unpaired t-tests were used to compare between the two groups. A two tailed p-value < 0.01 was considered significant different.

Results

There was no difference in ages, diagnoses, and body mass indexes between the groups. The patients were referred from the infertile clinic for lapa-

roscopic diagnosis. The symptoms included pelvic pain, infertility or suspected pelvic mass. The most common pathological finding was endometriosis with or without endometriotic cysts at the adnexa and myoma uteri. Some patients had normal findings. The missile trocar technique took 2.7 ± 1.6 minutes to perform compared with 3.9 min in the Veress needle group ($p = 0.001$), and the difficulty of the procedure was 2.1 ± 1.9 cm ($p = 0.433$) in the experimental group compared to 2.5 ± 1.9 cm in the control group, rated from 10-cm scale. No carbon dioxide leakage, abdominal wall hematoma or any serious complications occurred in all of the patients. The patients were discharged from the observation room in the evening of the same day of the operation.

Discussion

The missile trocar technique should be classified as direct trocar insertion. Direct trocar insertion may reduce the risk of gas embolism by insufflating only after intraperitoneal placement has been confirmed. Moreover, it allows immediate recognition and rapid treatment of major blood vessel laceration. When compared to other available methods of gaining peritoneal

Table 1. Baseline data of the two groups

Baseline Data	Group	Mean \pm SD
Age (years)	Missile	33.4 \pm 4.6
	Veress	34.6 \pm 4.8
BMI (Kg/m ²)	Missile	21.3 \pm 3.2
	Veress	21.4 \pm 3.3

Table 2. Results of the experiments measured for evaluation of the missile trocar device

Outcome	Group	Mean \pm SD	2-tailed significance
Procedure time* (min)	Missile	2.7 \pm 1.6	0.001
	Veress	3.9 \pm 1.3	
Difficulty of procedure	Missile	21.2 \pm 19.3	0.433
	Veress	24.6 \pm 18.7	
3 hr pain	Missile	9.0 \pm 13.5	0.145
	Veress	14.3 \pm 18.7	
24 hr pain	Missile	15.7 \pm 13.8	0.325
	Veress	10.2 \pm 14.9	
Patient satisfactory	Missile	99.5 \pm 2.4	0.921
	Veress	99.5 \pm 2.9	

*The time required for abdominal entry procedure starts from the umbilical skin incision and ends at recognition of the abdominal contents. This parameter which is statistically significantly different from the control group was compared between groups in seconds and reported in minutes

access for laparoscopy, direct trocar insertion followed by insufflation of carbon dioxide under vision can be performed with the same degree of safety⁽¹⁷⁾. The authors have introduced the rectus sheath hooking technique as an alternative method to towel clips for securing the abdominal fascia during trocar insertion of primary port establishment. The fascial hook has some advantages over towel clips such as less skin trauma and less space occupation. To ensure correct placement in the rectus abdominis muscular layer or sheath, direct vision using a mosquito clamp separating the incision is recommended. If the first hook is placed in the subcutaneous tissue, another hook should replace the first one in the fascial layer while the first one elevates and secures the abdominal wall. In entering the abdomen directly with a trocar, critical surgical points are emphasized: adequate patient relaxation, sharp or less resistant trocars, adequate umbilical skin incision, elevation and suspension of the abdominal wall with any tools, and insertion of the trocar into the true pelvis⁽¹⁸⁾. Though the missile trocar has a long tip, abdominal entry is still safe with a longer oblique distance between the elevated umbilical musculo-fascial wall and the organs in the pelvis. Injury to retroperitoneal structures, resulting from excessively deep entry of the long-tip missile trocar, is under control using a lesser amount of force. This design of the trocar makes it easier to stop once the abdominal cavity is entered. But the Hasson open method of abdominal entry should be obligatorily performed in the cases where abdominal adhesion around the umbilical area is suspected. This method is advisable for safety reason, although it is more cumbersome in many ways.

There was no difference in age, diagnoses, and body mass index between the groups. The average time for the missile trocar procedure was only 2.7 ± 1.6 minutes (mean \pm SD) comparable with other direct trocar insertions⁽¹⁹⁾. This is statistically and significantly different from the conventional method (p value = 0.001). The authors emphasized the fascial hooking procedure as the most critical part since the authors believed that serious complications could be minimized by gradually controlling trocar insertion through the tissues. The operators spend their times freely in this hooking procedure to ascertain correct hooking of the rectus sheath. The missile trocar tip produced less friction and resistance by its design and it dilated the musculofascial layer without cutting tissue fibers as conical trocar tip did. There was no statistically significant difference in both groups with regard to difficulty of the procedure as rated by the operators. Each tech-

nique has their advantages and disadvantages when performed by experienced operators with appropriate indications. Indeed preference should be given to the method with which the surgeon feels most comfortable and fully confident. In one medium-sized patient allocated to the missile trocar procedure, the operation was unsuccessful because of the thick fatty and muscular layers of the abdominal wall. After 10 minutes of trying, the operator decided to induce pneumoperitoneum via Veress needle, and then he inserted the missile trocar successfully with a hook secured to the fascial sheath. If the skin incision was done in the base of the umbilicus, this condition could be avoided. Because at the umbilicus, all layers blend together, and the thickness of the wall is minimized in this area. After the end of the present study, two operators still prefer induction of pneumoperitoneum via Veress needle before trocar insertion since they had the most experience with the technique.

No significant difference was found with regards to amount of postoperative pain (scores according to visual analogue scale) both at 3 hours and 24 hours post-operative. Postoperative pain depended on many factors. The real difference might exist if both trocars were used in the same patients⁽¹⁰⁾. Though the hook is used to effectively secure the rectus sheath during the trocar insertion, the fascial hooking procedure can cause significant abdominal musculature trauma depending on the experience of the operator. For confirmation of the rectus sheath fastening and elevation by the hook for the missile trocar penetration, all the operators often repeated hooking until the fleshy muscular fibers were clearly seen in the incisional wound.

No statistically significant differences were observed between the groups with regard to patient satisfaction. The patients rated this scale in the recovery room before they were discharged as day cases. The scores were very high. Presenting the same pleasant and caring nurse, as the only influencing factor, may explain the very high scores of both groups. This measurement was less sensitive and not relevant in the present study because of the small sample sizes in both groups and the short abdominal entry procedures in both groups. The procedure was not complicated and aggressive enough to cause the patients bad influence and disturbance postoperatively.

No significant differences were observed between the groups with regard to wound appearance accessed by the patients. This outcome revealed that the missile trocar technique might not be an aggres-

sive procedure to the abdominal wall soft tissues. Abdominal bruising was not present in any patient of the two groups. Bleeding around the umbilicus may migrate to suprapubic region or labia majora as a result of the gravitation. But, no patients reported this echymosis. For a large group of patients, the missile trocar group may reveal some degree of abdominal trauma caused by the fascial hooking device tearing the minute fascial or muscular branches of the abdominal vasculature⁽²⁰⁾. But securing the fascia is better than securing the skin during the trocar insertion. Securing the skin with a pair of towel clips could produce direct trauma to the skin and increase the distance within the abdominal wall by separation of the subcutaneous tissue from the underlying fascial and muscular layer. For this reason, the towel clips or any fascial fixation device should be placed at the rectus sheath or the rectus muscle in the incisional wound rather than at the skin.

The closed technique or blinded trocar insertion is more popular, though scientific evidence shows that this technique has a higher risk of causing an injury than the open technique has⁽²¹⁾. The presence of adhesions in the umbilical region cannot be absolutely excluded. Severe adhesions involving the bowel, which would have presented a serious potential risk with blind placement of the primary trocar, were encountered in 0.4% of the patients with no abdominal surgical history and the risk increased to 31.5% in patients who had a laparotomy with a midline incision⁽²²⁾. Bowel injuries often went unrecognized in which case they were highly lethal, the mortality rate in this group was 21%⁽²³⁾. Without adhesions, the slippery and mobile bowel loops cannot be easily harmed by any sharp-tip trocar. A mechanical splinting of the abdominal wall or pneumoperitoneum should be used whenever trocars are inserted to keep all the viscera far away, and the axial force on the trocar should be controlled to avoid too far penetration of the trocar and having the trocar tip come into contact with the retroperitoneum⁽²³⁾.

Conclusion

The results of the present study indicate that a long tip missile trocar technique may be a safe and relatively quick alternative approach for laparoscopy.

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การศึกษาไปข้างหน้าแบบสุ่มระหว่างแกนเจาะท้องทรงจรวดและแกนเจาะแบบเดิมเพื่อทำผ่าตัดผ่านกล้อง

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แกนเจาะทรงจรวดได้รับการออกแบบให้เกิดความนุ่มนวลในการสอดผ่านผนังหน้าท้องในการติดตั้งปลอกสอดกล้อง มีรูที่ทอดยาวตลอดแกนที่ยอมให้อากาศภายนอกไหลเข้าสู่ในช่องท้องได้อย่างอิสระในขณะที่ทำการแทงเพื่อทดสอบประสิทธิภาพเบื้องต้นของเครื่องมือนี้ ผู้วิจัยได้ทำวิจัยในคนไข้ 100 คน โดยวิธีสุ่ม เพื่อเปรียบเทียบเวลาของการเจาะเข้าสู่ช่องท้องเทียบกับวิธีมาตรฐาน แกนเจาะทรงจรวดใช้เวลาการเจาะเข้าสู่ช่องท้องเฉลี่ย 2.7 ± 1.6 นาที ในขณะที่วิธีการมาตรฐานใช้เวลา 3.9 ± 1.3 นาที ($p = 0.001$) ความยากของการเจาะเข้าสู่ช่องท้องคือ 2.1 ± 1.9 ซม. ($p = 0.433$) โดยมีสเกลเต็มเท่ากับ 10 ซม. ไม่มีการรั่วของก๊าซจากในช่องท้อง หรือมีผลแทรกซ้อนใด ๆ เกิดขึ้นกับคนไข้ ผลของการทดสอบชี้ว่า เครื่องมือและขั้นตอนที่ออกแบบนี้ อาจสามารถใช้งานได้อย่างปลอดภัย ด้วยความเข้าใจต่อกลไกการทำงานของเครื่องมือนี้ วิธีการนี้จัดเป็นทางเลือกหนึ่งที่ทำให้ค่อนข้างเร็วในการทำผ่าตัดผ่านกล้อง