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Original Article

A Randomized Controlled Trial Comparing Laparoscopic Access with the Direct Trocar and Veress Neddle

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ABSTRACT

Objective: Establishing a safe pneumoperitoneum in laparoscopic surgery is the beginning of the surgery. This study aimed to compare Veress needle insertion (VNI) and direct trocar insertion (DTI) methods.

Methods: A total of 122 patients who underwent laparoscopic intervention mainly laparoscopic cholecystectomy, between August 2017 and February 2018, in the general surgery clinic were randomized. Among all patients, 62 were insufflated and operated using VNI and 60 with DTI method. The number of laparoscopic entrances, time of entry, complications, and postoperative pain were compared between the groups.

Results: The two groups were similar in terms of demographic characteristics. A statistically significant difference was observed between the DTI and VNI groups regarding the entry time, pneumoperitoneum formation time, and gas leakage variables. A statistically significant difference was also observed between the DTI and VNI groups in the number of insertions. For the other variables, no statistically significant difference was observed between the DTI and VNI groups.

Conclusion: In DTI, the duration of the generation of the pneumoperitoneum was significantly shorter. However, gas leakage was higher in the DTI group. No significant difference was observed in other variables. The DTI may be preferable to VNI according to time.

INTRODUCTION

As a minimally invasive procedure, laparoscopy has several advantages. In addition, major complications are seen at a similar rate with laparotomy, but minor complications are less frequently observed.[1] Complications mostly occur during creation of pneumoperitoneum.[2] These can be life-threatening complications such as subcutaneous emphysema, bowel and bladder trauma, infection, and major abdominal blood vessels injury. Injuries due to trocar entry constitute 40% of all laparoscopic surgical complications.[3] There are four main methods of choice for abdominal access: direct trocar insertion (DTI), Veress needle insertion (VNI), direct optical trocar entry, and Hasson technique. VNI, Hasson technique, and DTI laparoscopy are the most commonly used laparoscopic entry methods.[4] However, there is no consensus regarding optimal access technique. None of the access techniques used are sufficient to prevent these complications.[5] This study aimed to compare the VNI and DTI techniques prospectively.

MATERIALS AND METHODS

This study was carried out in our general surgery clinic between August 2017 and February 2018 with the approval of the ethics committee (Approval no: 2017-9 / 11). The study was managed under the guidance of Consort. In the analysis of statistical power with an alpha value of 0.05, and 1-β (power) = 0.80, at least 60 patients from each group and a total of 122 patients were evaluated in the study. Patients were randomized with drawing lots with sealed envelopes. Patients aged between 18 and 70 years were included in the study. Patients younger than 18 years and over 70 years of age, those with chronic liver disease, chronic renal failure, and malignancy were excluded from the study. All patients were informed about the procedure, and written informed consent was obtained from them. Clinical and surgical data were entered in a computerized system.

Patients were evaluated in terms of age, sex, height, weight, American Society of Anesthesiologists (ASA) score, comorbidity, and body mass index (BMI).

The patients were divided into VNI and DTI groups. During formation of pneumoperitoneum, the number of entries with the applied technique, the time to entry, and creation of pneumoperitoneum, the technique-related problems and complications (gas leak, non-peritoneal insufflation, visceral injury, vascular injury, port site hematoma), the need for fascia suturing of port entry site, need for switch to the open surgery, postoperative pain score (Visual Analog Scale or VAS score), and mortality rates were recorded. The results were obtained using descriptive statistics, frequency table, and one-way analysis of variance (ANOVA). P value of <0.05 was considered statistically significant.

Surgical Technique

All patients were placed in the supine position under general anesthesia. In the VNI group, a 1-cm incision was made on the right side of the umbilicus, and a Veress needle was passed through the subcutaneous tissue. After the second click sound, saline drop test was performed. When the laparoscopic pneumoperitoneum pressure after CO_2 insufflation reached 5–6 mmHg, abdomen was entered using a 10-mm automatic knife trocar (Versaport Plus Auto Suture, Covidien, USA). Camera port was entered through this trocar, and intra-abdominal control was achieved. The time interval between the skin incision and insertion of the laparoscope into the abdomen was recorded as laparoscope entry time. The time interval between the skin incision and achievement of intra-abdominal pressure of 12 mmHg was recorded as the duration of pneumoperitoneum formation.

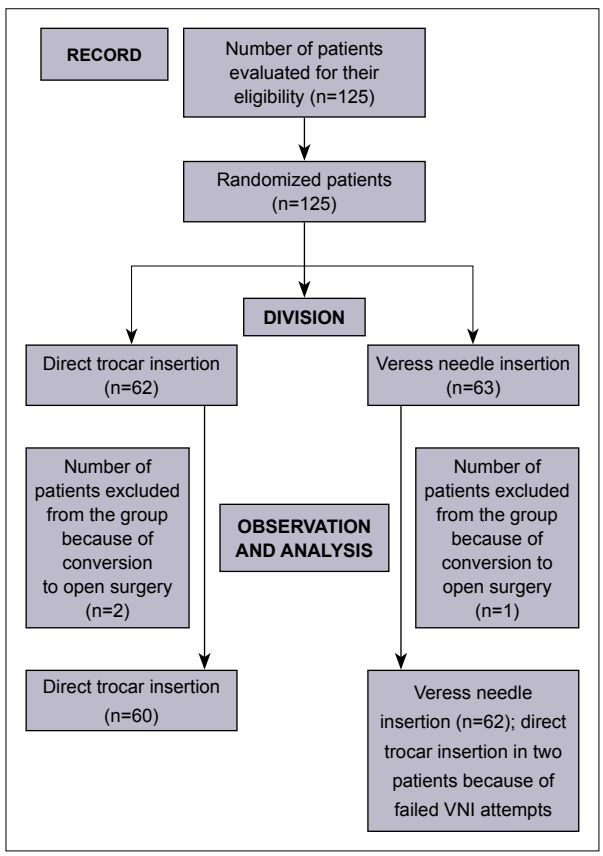

Figure 1. Consort flow diagram.

In the DTI group, after 1-cm incision was made from the right side of the umbilicus, the wall of the abdominal wall was retracted with towel clamp, and CO_2 insufflation was performed after entering the abdomen directly with 10-mm trocar. Then the camera was inserted and explored. The time passed when the trocar was inserted through the skin incision into the abdomen in both groups was recorded as entry time, and the time elapsed till the intra-abdominal pressure reached 12 mmHg after CO_2 insufflation was recorded as the time for the creation of pneumoperitoneum. Then, surgical procedures were performed in both groups.

RESULTS

The study was completed with 122 patients (62 patients in the VNI group and 60 in the DTI group) (see the Table 1). Both groups were similar in terms of age, gender, BMI, comorbidity, and ASA score. Compared to the VNI group, the time required for intra-abdominal entry and time spent for creation of pneumoperitoneum were significantly shorter in the DTI group. However, the gas leakage problem was significantly higher in the DTI group. The number of entries was greater in the Veress needle group. No significant difference was observed between the two groups in terms of postoperative VAS scores and complications. Two patients in the DTI group were excluded from the trocar insertion group because these patients were switched to open surgery for different reasons (Fig. 1).

In one patient, laparoscopic operation could not be completed because the gall bladder was adherent to adjacent structures. One patient had mesenteric cyst and could not be excised laparoscopically; so we switched to open surgery. These two patients were excluded from the DTI group, and also from the study to evaluate postoperative pain scores correctly.

Entry attemps with VNI failed in two patients.

Omental insufflation occurred in one patient in the DTI group and two in the VNI group. None of the patients had visceral injury during insertion of Veress needle or trocar insertion. In the VNI group, however, duodenal injury occurred during laparoscopic procedure that was not caused by trocar entry; so laparoscopic open surgery was performed in these patients. This patient was removed from the VNI group. No vascular injury or mortality was observed in both groups.

DISCUSSION

In recent years, laparoscopic procedures have been performed by greater number of surgeons.[6] The pneumoperitoneum stage is one of the most important stages in laparoscopy, and most of the complications are related to this procedure.[2] Intra-abdominal entries using Veress

Table 1. Patients characteristics and results of laparoscopic access according to insertion technique.

		DTI (n=60)	VNI (n=62)	p
Age		47.53±1.73	49.13±1.60	0.500
BMI (kg/m^2)		30.63±0.88	28.86±0.65	0.110
Entry time		102.68±6.02	150.90±13.93	0.002*
Pneumoperitoneum creation time		163.26±7.38	273.33±24.94	0.000*
VAS score on postoperative 1. day		3.93±0.23	3.70±0.19	0.437
ASA score	1	15	23	0.250
	2	38	33	
	3	7	6	
Gender	Male	17	14	0.502
	Female	43	48	
Previous surgery (or surgeries)	Yes	18	15	0.508
	No	42	47	
Comorbid diseases	Yes	21	16	0.299
	No	39	46	
Number of entries	1	59	55	0.061**
	2	0	2	
	3	1	3	
	4	0	1	
	5	0	1	
Gas leak	Yes	25	5	0.000*
	No	35	57	
Fascial suture to the umbilicus	Yes	46	54	0.148
	No	14	8	
Need for conversion to open surgery	Yes	0	0	
(related to trocar access)	No	60	62	
Extraperitoneal insufflation	Yes	0	1	0.323
	No	60	61	
Omental insufflation	Yes	1	2	0.572
	No	59	60	
Visceral injury	Yes	0	0	
	No	60	62	
Vascular injury	Yes	0	0	
	No	60	62	
Port site hematoma/bleeding	Yes	1	3	0.321
	No	59	59	
Mortality	Yes	0	0	
	No	60	62	

*P<0.05 a statistically significant difference was found among variables of Entry time, pneumoperitoneum creation time, hospital stay (days), gas leak, and drain in DTI, and VNI groups with a margin of error of 5%. **P<0.10 a statistically significant difference was found between variable of number of entries in the DTI, and VNI groups with a margin of error of 10%.

Since p values related to other variables are higher than 0.05 and 0.10, technique of intra-abdominal entry in DTI and VNI groups did not differ statistically significantly. Note: ± values in the first six rows are mean ± SE (standard error) values related to the corresponding variable. DTI: Direct trocar insertion; VNI: Veress needle insertion.

needle or directly with trocar are the most frequently used intra-abdominal laparoscopic access routes.[4] Although studies report that the intra-abdominal entry using a Veress needle is safer than the direct trocar insertion, this issue is still controversial.[7] Major complications such as vascular and organ injury associated with intra-abdominal entry are life threatening, but they are very rarely seen. In a meta-analysis of seven randomized control studies including 2940 patients, Jiang et al.[8] observed a total of four major complications (liver injury n=2, small bowel injury n=1, mesenteric laceration n=1); and all of them were reported during the insertion of the Veress needle.

All major injuries reported in this meta-analysis were encountered in a randomized controlled trial performed by Agresta et al.[9] in 598 (non-obese) patients. In the study of Agresta et al., no major complication was reported due to direct trocar access, whereas a high rate of (1.3%) complications was reported in the Veress group. This finding

was also supported in two Cochrane meta-analyses performed by Ahmad et al.[10] However, in the same analysis, it was stated that tens of thousands of study patients are required for randomized controlled studies to make an accurate interpretation because of the rare occurrence of major complications. In 134,917 Veress needle and 16,739 direct trocar entries reported in a meta-analysis of total of 51 studies (incl. both retrospective and prospective trials), the rate of intestinal and vascular injuries were found in 0.08% of Veress needle and 0.05% of direct trocar insertion attempts.[11]

No major complication was observed in our study. However, one patient in the VNI group had duodenal injury that was not related to the trocar access. We switched to open surgery in this patient who was excluded from the group to evaluate postoperative pain scores accurately. Minor complications such as subcutaneous emphysema, extraperitoneal insufflation, omental injury, and port site bleeding are more common due to intra-abdominal entry and pneumoperitoneum formation. Angioli et al.[7] compared Veress needle, direct trocar, and open access techniques, and reported a total of 31 (0.52%) minor complications in 595 gynecological procedures. They reported that there were a significantly greater number of minor complications in Veress needle entries relative to direct trocar entries and open technique. The most common minor complications in the Veress needle group were reported as extraperitoneal insufflation and omental injury.

Similar findings were supported in studies performed by Günenç et al.[12] and Zakherah,[13] who reported that the extraperitoneal insufflation is almost entirely a Veress needle entry-related complication. As a possible explanation of this situation, it is thought that failed and multiple insertions with the Veress needle presumably have led to extraperitoneal insufflation. It is also known that misleading may be obtained related to the extraperitoneal area in the tests such as aspiration and water flow tests performed during introduction of Veress needle.

Although it is perceived as a simple complication, there are cases of gas embolism and death due to extraperitoneal insufflation reported in the literature.[14] In our study, in the VNI group, extraperitoneal insufflation was observed in one, omental insufflation in two, and port site bleeding in three patients; while in the DTI group, omental insufflation was detected in one and port site bleeding in one patient. However, no significant difference was observed between the groups for these complications.

In a randomized retrospective study performed by Borgotta et al.,[15] omental injury was reported in 6.3% of the patients in the Veress needle group and 3.9% of the cases in the direct trocar entry group. Similar findings were supported in a systematic review by Merlin et al.;[16] and it was stated that minor complications such as omental injury can be significantly reduced by direct trocar access. Total omental injury rate was 2.4% (n=3) in our study, and it was 1.6% (n=2) in the Veress needle group and 0.8% in direct trocar group (n=1).

The rates of bleeding arising from the trocar site did not show a statistically significant difference between both groups in accordance with the literature.[10]

One of the important parameters that determine the effectiveness of intra-abdominal entry method is the short duration of the procedure and decreased complication rate.

There is an almost consensus in the literature that direct trocar access is faster than Veress needle entry.[16,17] In our study, direct trocar access was found to be a faster method in accordance with the literature. However, it should always be kept in mind that the time spent during entry does not make any sense when the total duration of surgery is considered and a safe entry is an important issue. No significant difference was observed in VAS scores between the Veress needle and DTI groups. Although many studies comparing these two groups are indicated in the literature, there were no studies comparing postoperative VAS scores between the groups. Therefore, this study can create a difference.

CONCLUSION

Compared to VNI, DTI is significantly shorter in terms of duration of entry and time to creation of pneumoperitoneum. However, gas leakage is higher in DTI group. No significant difference was observed in other variables. DTI may be preferred over VNI technique because of its shorter duration. We think that both methods are acceptable and effective in patients. Besides it would be appropriate to select the first method according to the experience of the surgeon and the center; and if any method fails, the other method can be safely used.

Ethics Committee Approval

Approved by the local ethics committee.

Peer-review

Internally peer-reviewed.

Conflict of Interest

None declared.

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Laparoskopik Girişlerde Veress İğnesi ile Direkt Trokar Girişlerini Karşılaştıran Randomize Kontrollü Çalışma

Amaç: Laparoskopik cerrahide güvenli pnömoperitoneum ameliyatın başlangıcı ve en kritik aşamalarından biridir. Laparoskopik girişlerde batına değişik farklı giriş metotları vardır. Amacımız sık kullanılan Veress iğnesi girişi (VİG) ile direkt trokar giriş (DTG) metodlarını karşılaştırmaktır.

Gereç ve Yöntem: Ağustos 2017–Şubat 2018 tarihleri arasında genel cerrahi kliniğinde başta laparoskopik kolesistektomi olmak üzere laparoskopik girişim yapılacak toplamda 122 hasta randomize edilerek çalışmaya dahil edildi. Altmış iki hasta VİG, 60 hastaya DTG uygulanarak insuflayon yapıldı. Gruplarda laparoskopik giriş sayısı, giriş süresi, komplikasyonlar ve ameliyat sonrası oluşan ağrı karşılaştırıldı. Tanımlayıcı istatistikler, Frekans tablosu ve tek yönlü varyans analizi (ANOVA) kullanılarak sonuçlar elde edildi.

Bulgular: İki grup demografik özellikler açısından benzerdi. Giriş süresi, pnömoperiton oluşturma süresi ve gaz kaçağı değişkenlerinin DTG ve VİG gruplarına ait değerleri arasında istatistiksel açıdan anlamlı farklılık vardı. Giriş sayısı değişkeninin DTG ve VİG gruplarına ait değerleri arasında istatistiksel açıdan anlamlı farklılık vardı. Diğer değişkenlere ait P değerleri 0.05 ve 0.10'dan büyük olduğu için giriş şekli DTG ve VİG grupları arasında değişkenler açısından istatistiksel açıdan anlamlı bir farklılık yoktu.

Sonuç: Direkt trokar giriş VİG ile karşılaştırıldığında giriş süresi, pnömoperiton oluşturma süresi anlamlı olarak kısadır. Ancak gaz kaçağı DTG grubunda daha fazladır. Diğer değişkenlerde anlamlı fark görülmemektedir. DTG süre olarak VİG'ye tercih edilebilir.

Anahtar Sözcükler: Direkt trokar girişi; laparoskopik giriş teknikleri, Veress iğnesi ile giriş.