Comparing Clinical Impacts Between Valveless Trocar System and Standard Insufflation in Bariatric Surgery

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Research Article

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Abstract

Purpose

In laparoscopic surgery, higher intra-abdominal pressure is needed to achieve a well-exposed surgical field in obese patients, which may results in undesirable effects on cardiopulmonary systems. The AirSeal Intelligent Flow System™ provides stable pneumoperitoneum and constant smoke evacuation. However, studies regarding VTS in bariatric surgery are rare. This study aimed to investigate the effects of VTS on laparoscopic bariatric surgery.

Methods

We conducted a retrospective study using our prospective database. Sixty patients were enrolled equally to the VTS group and standard insufflation device group. Patient characteristics, intraoperative and postoperative data were analyzed. The Visual Analog Scale (scores: 0–10) was applied to measure the intensity of shoulder pain at 1, 12, 24, and 48 h after surgery, and surgeon's satisfaction on the surgical field visualization was assessed using a numerical rating scale of 0 (not adequate) to 10 (optimal).

Results

There was no significant difference in bradycardia during insufflation, operative time, blood loss, shoulder pain, and complications as well as shoulder pain between groups. VTS group showed a significant higher scores of surgical field visualization.

Conclusions

There was no significant difference in most perioperative and postoperative outcomes; however, VTS group achieved a better surgical field visualization for surgeons.

Key Points

- Optimal pneumoperitoneum with the least adverse physiological changes is critically needed for a well-exposed surgical field in obese patients.
- Although the valveless trocar system (VTS) provides stable pneumoperitoneum, valveless trocar access, and constant smoke evacuation, studies on VTS in bariatric surgery are limited.
- This is the first study on PubMed to compare the clinical impacts of VTS and standard insufflation device (SID) in laparoscopic bariatric surgery.
- VTS can provide a better surgical field visualization for surgeons but not better outcomes of operative time, blood loss, and shoulder pain.

Introduction

Laparoscopic surgery with enhanced visualization and instrumentation has been widely performed in managing gastrointestinal diseases. It improves both operative and postoperative outcomes.[1] A working space within the peritoneal cavity is required in laparoscopic procedure, and it is commonly achieved by carbon dioxide (CO_2) insufflation. However, pneumoperitoneum with a high pressure may be needed in obese patients to achieve a well-exposed surgical field. However, this results in undesirable effects on cardiovascular and respiratory systems, including decreased perfusion of abdominal organs, bradycardia with low cardiac output, and lower respiratory compliance.[2] Shoulder pain is also common following laparoscopic surgery, especially in patients receiving high CO_2 pressure.[3]

The AirSeal Intelligent Flow System™ is a novel valveless trocar system (VTS) that may enable laparoscopic procedures with lower intraperitoneum pressure.[4] The VTS consists of a valveless trocar, a three-lumen tubing, and a specialized insufflator. It can provide high-flow insufflation, stable pneumoperitoneum, valveless trocar access, and constant smoke evacuation.[1] In standard insufflation device (SID), the mechanical valves frequently smudge the camera during insertion, fragment the specimen during removal, or stuck the needles during passage or retrieval, thus prolonging operative time. Eliminating the mechanical valve resolves these issues. The valveless design is achieved by creating a static pressure zone of a “curtain” of opposing airflow within the trocar. A system of small nozzles located in the proximal trocar that supplies pressurized high-flow CO_2, which is opposed, and neutralized, by the intrabdominal gas flowing outward. The desired intra-abdominal pressure is regulated at this curtain by CO_2 pressure sensors. Therefore, the VTS provides a stable pneumoperitoneum and automatically compensate any pressure variability caused by continuous smoke and CO_2 extraction during surgery. In addition, VTS reduces CO_2 absorption and operative time in some cases.[5, 6] However, studies on VTS on bariatric surgery are very rare. The aim of our study was to investigate the effects of the VTS on perioperative and postoperative outcomes in a cohort of patients undergoing laparoscopic bariatric surgery.

Methods

Study design

This retrospective study was conducted using prospective database. This study protocol was approved by the ethical committee of Tri-service general Hospital (B202105089) and all patients provided written informed consent with guarantees of confidentiality.

Patients aged 20–65 years and with body mass index (BMI) > 37.5 kg/m^2 or BMI > 32.5 kg/m^2 with comorbidities were included. Those who underwent open bariatric surgery and those with cirrhosis were excluded. All eligible patients were evaluated by a team consisting of a surgeon, an endocrinologist, a dietician, and a psychiatrist before bariatric surgery. We identified 70 consecutive patients who underwent bariatric surgery from June 2017 to January 2021 and grouped them according to the type of trocar we

used: VTS or SID. In both groups, patients underwent sleeve gastrectomy (SG), sleeve plus procedures, or gastric bypass. Sleeve plus procedures included the following: (1) SG with proximal jejunal bypass, (2) SG with duodenal-jejunal bypass, (3) sleeve jejunal bypass, and (4) sleeve ileal bypass. Gastric bypass procedures included Roux-en-Y gastric bypass and mini-gastric bypass/one anastomosis gastric bypass.

Surgical techniques

In all patients, three trocars were placed for SG procedures, four for sleeve plus procedures, and five for bypass procedures. The surgical instruments were standardized and did not differ within the operation groups. In the SID group, a VersaStep™ 12-mm bladeless trocar (Covidien) was placed as an umbilical port under direct vision and the pneumoperitoneum. In the VTS group, a single valveless 12-mm trocar (with 15 mm outer diameter) was used also as umbilical port. Both groups received the insufflation strategy of low flow rate to induce pneumoperitoneum followed by high-flow rate to maintain the pressure at 12 mmHg.[7] Energy devices such as monopolar cautery and LigaSure were used intraoperatively for bleeding control and dissection. After the surgery was completed, the trocars were removed to release intra-abdominal CO_2 and the abdomen was compressed by surgeons to evacuate the residual gas.

Outcomes

Demographics and patient characteristics were collected. Intraoperative and postoperative data, including bradycardia during insufflation, operative time, blood loss, end tidal CO_2 ($EtCO_2$), shoulder pain, complications, mortality, and hospital stay were analyzed. The satisfaction of surgical field visualization between groups was assessed using a numeric rating scale of 0 (not adequate) to 10 (optimal). It was rated by four engaged surgeons at the points of using and not using energy devices. The bradycardia during insufflation, operative time, and $EtCO_2$ were documented by the anesthesia team. For pain control, parecoxib 40 mg Q12H and acetaminophen 500 mg TID were routinely administered to patients in both groups for 2 days postoperatively. We used the VAS (score: 0–10) to assess the pain level at 1, 12, 24, and 48 hours postoperatively. There were no anesthetics injected at any port sites during surgery, and no additional analgesic agents were prescribed after surgery.

Statistical analysis

Statistical analyses were performed using SPSS 22.0 software (IBM, Armonk, NY, USA). The outcomes between the two groups were compared using Fisher's exact test and Mann–Whitney U test. Continuous variables were presented as mean ± standard deviation. Discrete variables were presented as numbers and proportions. A two-sided $P < 0.05$ was considered statistically significant.

Results

A total of 60 patients were included in this study, with 30 patients in each group. Table 1 shows patient demographics and characteristics. There were no significant differences between groups with regard to age, gender, BMI, American Society of Anesthesiologists physical status classification, underlying diseases, and procedure types. Overall, SG was performed for 35 patients (17 in VTS group, 18 in SID

group), sleeve plus for 18 patients (10 in VTS group, 8 in SID group), and gastric bypass for 7 patients (3 in VTS group, 4 in SID group).

Table 1
Demographics in patients undergoing laparoscopic bariatric surgery.

Characteristics	VTS (n = 30)	SI (n = 30)	*P* value
Age (years)	40.1 ± 13.8	36.3 ± 7.8	0.190
Gender, M/F	13/17	15/15	0.796
Height (cm)	165.6 ± 8.3	168.2 ± 10.2	0.276
Weight (kg)	107.7 ± 21.2	116.9 ± 16.1	0.114
BMI (kg/m^2)	38.8 ± 5.5	40.9 ± 6.3	0.155
Previous abdominal surgery, n (%)	4 (13.3%)	3 (10 %)	1
ASA classification, n (%)	7	5	0.706
Class I	19	22	
Class II	4	3	
Class III			
T2DM, n (%)	8 (26.7 %)	11 (36.7 %)	0.580
Hypertension, n (%)	27 (90 %)	24 (80 %)	0.472
Hyperlipidemia, n (%)	25 (83.3 %)	23 (76.7 %)	0.784
Moderate/Severe OSA, n (%)	5 (16.7 %)	7 (23.3 %)	0.748
INR			0.279
Procedures, n (%)			0.821
Sleeve gastrectomy	17 (56.7 %)	18 (60 %)	
Sleeve plus procedure	10 (33.3 %)	8 (26.7 %)	
Gastric bypass	3 (10 %)	4 (13.3 %)	

Data are presented as mean ± standard deviation or as the number. BMI: Body mass index ASA: American Society of Anesthesiology; INR: international normalized ratio; OSA: obstructive sleep apnea

The results of the intraoperative and postoperative data are presented in Table 2. In each group, one patient experienced bradycardia during insufflation. There was no significant difference in operative time, blood loss, and $EtCO_2$ between groups with regard to the procedure types. Leakage was noted in one patient in the VTS group, while stricture was identified in one patient in the SID group. Both complications

seem to be unrelated to the insufflation systems. There were no differences in complications, mortality rate, and hospital stay between groups.

Table 2
Perioperative and postoperative data in patients undergoing laparoscopic bariatric surgery.

Characteristics	VTS (n = 30)	SI (n = 30)	*P* value
Bradycardia during insufflation, n (%)	1 (3.3%)	1 (3.3%)	1
Operative time (minutes)	164.5 ± 52.1	153.1 ± 51.2	0.399
Sleeve gastrectomy	125.06 ± 22.0 (n = 17)	120.0 ± 28.8 (n = 18)	0.565
Sleeve plus procedure	209.9 ± 28.2 (n = 10)	188.0 ± 28.6 (n = 8)	0.123
Gastric bypass	236.3 ± 25.3	232.5 ± 23.9	0.846
Blood loss (ml)	11.3 ± 3.5	13.2 ± 7.0	0.206
$EtCO_2$ (mmHg)	40.1 ± 3.4	41.0 ± 3.3	0.308
Complications, n	1	1	1
Bleeding/leakage/stricture	0/1/0	0/0/1	
Bowel injury/ IAA/ wound infection	0/0/0	0/0/0	
SCE/DVT/PE	0/0/0	0/0/0	
Mortality	0	0	1
Hospital stay (day)	4.6 ± 3.8	5.2 ± 1.5	0.378

Data are presented as mean ± standard deviation or as the number (%); end tidal CO2; IAA: intra-abdominal abscess; SCE: subcutaneous emphysema; DVT: deep vein thrombosis; PE: pulmonary embolism.

There was no significant difference in shoulder pain incidence and pain intensity at 1, 12, 24, and 48 h after surgery (Table 3). Regarding the surgeon's satisfaction on the surgical field visualization, the duration of use of energy devices (8.8 in VTS group and 8.1 in SID group, $p < 0.001$) and overall evaluation (9.4 in VTS group and 8.6 in SID group, $p < 0.001$) were significantly different between groups (Table 4). No difference in the period without energy device was showed.

Table 3
Postoperative shoulder pain (VAS score: 0–10) in patients undergoing laparoscopic bariatric surgery.

Characteristics	VTS (n = 30)	SI (n = 30)	*P* value
Shoulder pain (+), n (%)	18 (60 %)	20 (66.7 %)	0.789
Postoperative time			
1h	0.94 ± 0.80	1.05 ± 0.89	0.768
12h	3.89 ± 0.96	3.65 ± 1.04	0.487
24h	2.61 ± 0.78	2.70 ± 1.03	0.755
48h	1.22 ± 0.81	1.10 ± 0.912	0.495

Table 4
The surgeon's satisfaction of surgical filed visualization (score: 0–10) in bariatric surgery.

Characteristics	VTS (n = 30)	SI (n = 30)	*P* value
Period of energy devices usage	8.8 ± 0.55	8.1 ± 0.70	< 0.001
Period of no energy devices usage	9.8 ± 0.40	9.7 ± 0.55	0.289
Overall	9.4 ± 0.50	8.6 ± 0.50	< 0.001
Data are presented as mean ± standard deviation.			

Discussion

VTS have been used in patients with gastrointestinal, gynecologic, and urologic diseases, and it is proven safe and feasible with no increase in overall complication rates.[8] However, studies involving VTS in bariatric surgery are very rare. Physiologically, morbidly obese patients have a higher intra-abdominal pressure at 2 to 3 times that of non-obese patients.[9] Therefore, higher pressure of CO_2 pneumoperitoneum may be required to create a well-exposed surgical view, which increase not only the risk of bradycardia and subcutaneous emphysema but also CO_2 absorption by the patient and the value of $EtCO_2$.[7, 10] Herati et al. showed that the use of the VTS significantly reduced CO_2 absorption during laparoscopy renal surgery when compared with the standard trocar.[6] However, there was no difference in bradycardia and $EtCO_2$ regarding laparoscopic bariatric surgery in our study.

VTS provides a stable pneumoperitoneum with continuous smoke extraction, allowing surgeons to focus on surgical details rather than being distracted by smoke-block visualization, smudged camera, or loss of insufflation. Theoretically, optimization of operative time is one of the advantages of VTS. However, a systemic review showed that the impact of VTS in terms of operative time was not significantly different for the majority of studies.[8] Only four studies that investigated urologic surgeries such as

prostatectomy or nephrectomy, including three robotic procedures and one laparoscopic procedure reported significantly shorter mean operative time of VTS than conventional trocar insufflation.[6, 11–13] This observed difference in operative time in various surgical fields may be due to the following reasons: (1) above-mentioned urologic surgeries require frequent instrument changes and (2) more intraoperative bleeding resulting in increased frequency of electrocautery and suction. These conditions highlight the role of VTS in keeping stable pneumoperitoneum and continuous smoke suction. In our study, as there was no significant difference in operative time between groups, we postulate that it may be related to less bleeding as in bariatric surgeries. Surgical field was easily maintained in both groups because suction and electrocautery were not frequently needed. Therefore, the effects of VTS on operative time and blood loss were not significant.

Despite no significant difference in operative time between groups in our study, a better visualization was noted in the VTS group especially when using energy devices. There was seldom sudden decrease of intra-abdominal pressure in the VTS group, which disrupted the surgical exposure and affected surgical performance. VTS enabled lower intra-abdominal pressure to perform laparoscopic surgery.[4] However, a systematic review on gynecological surgery showed that low-pressure laparoscopic surgery was associated with decreased surgical field, which can increase the risk of complications.[14]

Since VTS provides lower and more stable pressure of pneumoperitoneum, postoperative shoulder pain is another commonly discussed subject. Shoulder pain is a multifactorial symptom possibly related to the irritative effect of CO_2 and diaphragmatic stretching.[15] A systematic review on low-pressure versus standard-pressure pneumoperitoneum during laparoscopic cholecystectomy showed significant reductions in shoulder pain and analgesic requirements in low-pressure group.[16] Sroussi et al. conducted a randomized controlled trial and reported that the incidence of shoulder pain was significantly lower in the VTS group.[17] However, lower intra-abdominal pressure with 7 mmHg was used in VTS group compared to control group with 15 mmHg pneumoperitoneum. Another randomized controlled trial used equal intra-abdominal pressure (12 mmHg) in the VTS and control groups and revealed an unexpected result that the VTS group had higher shoulder pain.[18] They assumed that it might be due to the constant pressure pneumoperitoneum compared to the standard insufflator where the pressure changes during some maneuvers such as suction. In our study, an equal intra-abdominal pressure (12 mmHg) was established. All the patients underwent the same strategy of using a low flow rate to induce pneumoperitoneum followed by a high-flow rate to maintain the pressure. This strategy can reduce the severity of shoulder pain, compared with continuous high-flow rate insufflation in laparoscopic cholecystectomy.[7] There was no significant difference in the incidence and severity of shoulder pain between groups. However, the analgesic agents, which were routinely prescribed after surgery, may shade the real effects of VTS on shoulder pain.

The limitations of this study are the retrospective nature and relatively small number of patients. However, to the best of our knowledge, this is the first study on PubMed to compare VTS and SID in laparoscopic bariatric surgery. Large-scale, randomized control trials are needed to demonstrate the impact of VTS on operative time and patient outcomes in laparoscopic bariatric surgery.

In conclusion, bradycardia during insufflation, operative time, blood loss, and complications, as well as shoulder pain were not significantly different between VTS and SID groups in this study. The VTS group showed a better surgeon's satisfaction on the surgical field visualization than the SID group.

Declarations

Funding

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Conflicts of interest

The authors declare no conflict of interest.

Availability of data and material

All authors confirmed that all data and materials as well as software application or custom code comply with field standards.

Code availability

Not applicable.

Ethics approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to participate

Written informed consent was obtained from the parents.

Consent for publication

Patients signed informed consent regarding publishing their data.

References

1. Shahait, M. *et al.* (2019) Improved Outcomes Utilizing a Valveless-Trocar System during Robot-assisted Radical Prostatectomy (RARP). JSLS 23:e2018.00085
2. Nguyen, N. T. & Wolfe, B. M. The physiologic effects of pneumoperitoneum in the morbidly obese. *Ann Surg*, **241**, 219–226 (2005).

3. Yasir, M. *et al.* Evaluation of post operative shoulder tip pain in low pressure versus standard pressure pneumoperitoneum during laparoscopic cholecystectomy. *Surgeon*, **10**, 71–74 (2012).
4. Miyano, G. *et al.* Pneumoperitoneum and hemodynamic stability during pediatric laparoscopic appendectomy. *J Pediatr Surg*, **51**, 1949–1951 (2016).
5. Nepple, K. G., Kallogjeri, D. & Bhayani, S. B. Benchtop evaluation of pressure barrier insufflator and standard insufflator systems. *Surg Endosc*, **27**, 333–338 (2013).
6. Herati, A. S. *et al.* Use of the valveless trocar system reduces carbon dioxide absorption during laparoscopy when compared with standard trocars. *Urology*, **77**, 1126–1132 (2011).
7. Hsu, K. F. *et al.* A Novel Strategy of Laparoscopic Insufflation Rate Improving Shoulder Pain: Prospective Randomized Study. *J Gastrointest Surg*, **23**, 2049–2053 (2019).
8. Balayssac, D. *et al.* Clinical and Organizational Impact of the AIRSEAL(®) Insufflation System During Laparoscopic Surgery: A Systematic Review. *World J Surg*, **45**, 705–718 (2021).
9. Nguyen, N. T. & Wolfe, B. M. The physiologic effects of pneumoperitoneum in the morbidly obese. *Annals of surgery*, **241**, 219–226 (2005).
10. Lee, D. W., Kim, M. J., Lee, Y. K. & Lee, H. N. Does intraabdominal pressure affect development of subcutaneous emphysema at gynecologic laparoscopy? *J Minim Invasive Gynecol*, **18**, 761–765 (2011).
11. Annino, F. *et al.* Robotic partial nephrectomy performed with Airseal versus a standard CO(2) pressure pneumoperitoneum insufflator: a prospective comparative study. *Surg Endosc*, **31**, 1583–1590 (2017).
12. George, A. K. *et al.* Utilization of a novel valveless trocar system during robotic-assisted laparoscopic prostatectomy. *World J Urol*, **33**, 1695–1699 (2015).
13. Shahait, M. *et al.* (2019) Improved Outcomes Utilizing a Valveless-Trocar System during Robot-assisted Radical Prostatectomy (RARP). Jsls 23
14. Kyle, E. B., Maheux-Lacroix, S., Boutin, A., Laberge, P. Y. & Lemyre, M. (2016) Low vs Standard Pressures in Gynecologic Laparoscopy: a Systematic Review.Jsls20
15. Tsimoyiannis, E. C. *et al.* Intraperitoneal normal saline infusion for postoperative pain after laparoscopic cholecystectomy. *World J Surg*, **22**, 824–828 (1998).
16. Gurusamy, K. S., Vaughan, J. & Davidson, B. R. (2014) Low pressure versus standard pressure pneumoperitoneum in laparoscopic cholecystectomy.Cochrane Database Syst Rev:Cd006930
17. Sroussi, J. *et al.* Low pressure gynecological laparoscopy (7mmHg) with AirSeal(®) System versus a standard insufflation (15mmHg): A pilot study in 60 patients. *J Gynecol Obstet Hum Reprod*, **46**, 155–158 (2017).
18. Luketina, R. *et al.* Prospective randomized controlled trial on comparison of standard CO(2) pressure pneumoperitoneum insufflator versus AirSeal®. *Surg Endosc*, **35**, 3670–3678 (2021).