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Comparing Conventional and Valveless Trocar Insufflation During Laparoscopic Renal Surgery

THESIS

submitted in partial satisfaction of the requirements
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MASTER OF SCIENCE

In Biomedical and Translational Science

by

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DEDICATION

To

my parents, friends, co-workers, and mentors

in recognition of the support and opportunity I have been given daily

Thank you

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ABSTRACT OF THE THESIS

Comparing Conventional and Valveless Trocar Insufflation During Laparoscopic Renal Surgery

By

Philip Bucur

Master of Science – Biomedical and Translational Science

University of California, Irvine, 2015

Professor Jaime Landman, Chair

We compared the variation in pneumoperitoneum, physiologic effects, and postoperative outcomes of patients undergoing laparoscopic renal surgery using a conventional insufflation system (CI) versus the valveless trocar insufflation (VI) system.

This is a prospective, randomized comparative study with fifty-six patients undergoing laparoscopic renal surgery with valveless trocar insufflation or conventional insufflation. Patients in the valveless insufflation arm (n=28) underwent surgery using the AirSeal valveless trocar insufflation system whereas patients in the conventional treatment arm (n=28) underwent surgery using standard laparoscopic trocars connected to a Storz insufflator with the insufflation pressure set to 15 mm Hg. We compared the groups with respect to stability of pneumoperitoneum, intraoperative and postoperative outcomes, and physiologic parameters.

The coefficient of variation in pressures was significantly lower in the valveless trocar group compared to the conventional treatment group (7.9% vs. 15.6%, $p<0.001$) with significantly less time spent above insufflation pressures of 20 mm Hg. Estimated

blood loss was significantly higher in the valveless trocar group than conventional group (155 vs. 75 cc, p=0.03). End-tidal CO_2 (ET CO_2) was significantly lower at 10 minutes (34.3 vs. 36.6 mmHg, p=0.029) and 25 minutes (35.8 vs. 37.6 mmHg, p=0.047) in the valveless trocar group compared to the conventional treatment group. There were no other significant differences across physiologic parameters or outcomes.

In conclusion, compared with a conventional insufflation system, the valveless trocar insufflation system provides a significantly more stable pneumoperitoneum during laparoscopic renal surgery and lower end-tidal CO2 at 10 minutes, but with an increased risk of blood loss.

INTRODUCTION

With the increased utilization of laparoscopic and robotic surgery worldwide, there has been an emergence in technologies aimed at optimizing minimally invasive surgery. A critical component of most laparoscopic and robotic-assisted surgery is CO2 insufflation. CO2 insufflation is achieved by placing small surgical trocars in the abdominal wall and connecting one port to a CO2 insufflator, using tubing. The CO2 insufflator continuously introduces CO2 into the peritoneal cavity until reaching a specified pressure, which is typically set at 15 mm Hg. As the gas enters the abdomen, the pressure expands the peritoneal cavity allowing for improved visualization and an easier working environment for laparoscopic surgery.

The physiologic effects of abdominal insufflation during laparoscopic surgery are well described and include an increase in airway pressure, increase in CO_2 elimination due to peritoneal uptake, increased systemic vascular resistance and mean arterial pressure, and an increase in heart rate with a fall in cardiac output and stroke volume[1]. These effects can be mitigated by maintaining pneumoperitoneum, defined as the presence of gas in the abdominal cavity, at an insufflation pressure of 15 mm Hg or less throughout the procedure[2]. Abrupt decreases in intra-abdominal pressure during pneumoperitoneum can have a negative impact on surgical performance by disrupting surgical exposure, which potentially increases the risk for intraoperative complications and prolongs operative and anesthesia times. Prolonged increases in intra-abdominal pressure have been shown to cause end organ damage, arrhythmias from arterial acidosis, and hypercarbia in patients with chronic obstructive pulmonary disease (COPD)[3-6].

Since 2007, there have been two types of insufflation devices, which have been used routinely in laparoscopic surgery, conventional automated insufflation (CI) and valveless trocar insufflation (VI). The mechanical insufflator was introduced in 1960 by Semm and colleagues, which eventually gave rise to conventional automated insufflation after laparoscopy became widely accepted in the 1980's[7]. CI uses a one-way valve trocar, which allows instruments to be passed in and out of the peritoneum. An advantage of CI has been the familiarity of the device amongst more experienced surgeons and lower cost in comparison to the valveless trocar insufflator. An adverse effect of CI has been the loss of gas in the abdomen when CO_2 escapes as instruments are passed through the trocar or when suction is used. Additionally, CI with one-way trocars is associated with moisture accumulation at the camera lens and the need for surgical smoke plume evacuation with a suction device, or manual venting into the operating room through the stopcock of a conventional trocar.

A valveless trocar insufflation system (AirSeal, SurgiQuest, Milford, CT) was developed in 2007 designed to improve upon the difficulties associated with CI. The goal of the newer system was to maintain a stable pneumoperitoneum as instruments are passed through the trocars by using a pressure barrier, which expels CO2 into the environment if intra-abdominal CO2 levels are too high. In addition, the VI continuously evacuates smoke without the need of an additional suctioning device or manual venting into the operating room[8]. Other advantages, in initial evidence in both retrospective and prospective, non-randomized studies, has suggested VI may lower the rate of CO_2 uptake, decrease the volume of CO_2 consumed, and decrease operative time[9-11]. Disadvantages of VI have been less familiarity among experienced surgeons, increased cost, and initial retrospective

evidence suggesting blunting of end tidal CO2 levels may mask detection of intraoperative pneumothorax[11].

There is increasing pressure for medical device companies to compete with existing technology. Therefore, new devices enter the market with FDA approval but with limited data and few head to head comparisons against the current standard of care. Frequently in surgery, the differences in devices are not truly understood by the operator and selection of the device is driven by comfort or the hospital's accessibility to the device. Laparoscopic insufflators have been traditionally used for the same reasons, driven by surgeon familiarity and availability. The performance of the insufflators and the impact of this performance on patient's outcomes have yet to be compared *in vivo* in a randomized, comparative study. The primary aim of this study is to investigate how well pneumoperitoneum is maintained during laparoscopic surgery by comparing the variation in intra-abdominal pressure when using CI compared to VI. The secondary aims of this study are to investigate the physiologic impact, intraoperative outcomes, and post-operative outcomes of CI compared to VI.

CHAPTER 1: METHODS

Following Institutional Review Board approval (IRB# 2012-9088), consent was obtained from patients over the age of 18 undergoing laparoscopic renal surgery. Patients were excluded if they were under 18 years of age, were incapable of providing consent or understanding the research questionnaire, if they had ascites, uncontrolled diabetes mellitus, metastatic disease, were undergoing an emergent procedure, were pregnant, or if they were enrolled in another investigational trial. Preoperative patient characteristics were collected at the patient's initial visit, which included, age, gender, ethnicity, race, body mass index, and Charlson Comorbidity Index.

After being enrolled, we randomized patients to the valveless trocar insufflation or conventional insufflation treatment arm based on a schedule generated using simple computer-generated randomization. Only the research coordinator had access to the randomization order. On the morning of surgery when a new patient was enrolled the operating room staff was informed of the study arm the patient would be included in to ensure the appropriate equipment was available.

Protocol: All patients received standard anesthesia care including endotracheal intubation and positive pressure ventilation. Patients were kept relaxed with cisatracurium titrated to keep train-of-four at 1-2 twitches throughout surgery. Ventilation was performed using a volume-control ventilator mode and anesthesiologists were asked to maintain end-tidal CO_2 in the range of 33-37 mm Hg when possible.

Patients in the CI group had their laparoscopic procedures performed using the Endopath XCEL (Ethicon, Somerville, NJ) and a 5 mm Endotip trocar (Storz, Culver City,

CA), with insufflation provided via a 12 mm assistant port connected to a standard insufflator (Storz, Culver City, CA). In the AirSeal valveless trocar treatment arm, insufflation was provided via a 12 mm AirSeal Access Port (SurgiQuest, Milford, CT) connected to an AirSeal IFS insufflator (SurgiQuest, Milford, CT), with Endopath XCEL and 5mm Endotip trocar used for assistant and other instrument ports. A single fellowship-trained laparoscopic surgeon at one institution performed all surgical procedures.

Primary Outcome: The primary outcome for the study was variabilty in pneumoperitoneum around the standard 15 mm Hg set point during all laparoscopic cases. The device with less variability in pneumoperitoneum was considered to have higher intraoperative performance. True insufflation pressure was measured by an independent pressure transducer connected to a side port of a non-insufflating trocar. Data from this transducer were continuously recorded throughout the case using custom data collection software. Variability was assessed in two different ways. First, we computed the mean coefficient of variation by taking the coefficient of variation of within each individual case for each group and than calculating the mean coefficient over variation across all cases for each group. Second, we computed the percentage of time spent within three insufflation pressure ranges defined *a priori* as "acceptable" (12-18 mm Hg), "borderline" (10-12 and 18-20 mm Hg), and "unacceptable" (less than 10 mm Hg and greater than 20 mm Hg).

Secondary Outcomes: Secondary outcomes collected during the study included intraoperative outcomes, postoperative outcomes, and physiologic parameters. Intraoperative outcomes collected include duration of surgery, estimated blood loss, urine output, lack of pneumoperitoneum, passage of instruments, cleaning of the camera lens, and smoke evacuations. Intraoperative complications were reviewed from the surgery

dictation postoperatively. Surgeon assessment of the image quality was documented during each procedure.

Postoperative outcomes investigated were pain, length of hospital stay, and postoperative complications. General pain and shoulder pain were documented on a 0-10 scale for a subjective assessment of pain at 1 hour after surgery, 1 day postoperatively, day of discharge from the hospital, and at the first follow-up appointment. An objective assessment of pain was made based on analgesia requirements in the form of morphine equivalents abstracted from the medicine administration record. Postoperative complications were reviewed through chart review of the patient's hospital course and categorized using the Clavien-Dindo Classification.

Physiologic parameters were divided into two categories: cardiovascular and respiratory. Intraoperative cardiovascular parameters were collected 5 minutes prior to insufflation, upon insufflation, and for 30 minutes after insufflation. The cardiovascular parameters recorded include, cardiac index, stroke volume index, heart rate, mean arterial pressure, and flow time. These were measured using an esophageal Doppler probe and monitor (Deltex Medical, Greenville, SC). This and the other anesthesia monitors were connected to a computer running custom data collection software that continuously recorded data throughout the case. For analysis, these values were collapsed down to 5 minute intervals to correspond to respiratory data points. Respiratory data were recorded by hand at 5 minute intervals beginning 5 minutes prior to insufflation, upon insufflation, and until 30 minutes after insufflation. Respiratory parameters included tidal volume, peak airway pressure, end-tidal CO_2, pulmonary compliance, and CO2 elimination rate, which was estimated using the equation described by Wolf and colleagues[12].

Statistical Analysis: This study was powered to our primary outcome. The target sample size for this study was 60 patients, 30 patients in both arms, which was calculated using a 92% power to achieve a 0.05 significance level to a ratio of 3.6 between the variances of the pressure measurements. All Statistical analysis was performed using SPSS software (IBM, Armonk, NY) and variables were considered significant with a p-value < 0.05. All preoperative patient characteristics and procedures performed were analyzed using an unpaired T test and Fisher exact test. To determine the primary outcome, the mean coefficient of variation each group was determined and compared using an F-test. Percentage of time spent within each pressure range and median number of pressure spikes per case of each group were calculated and compared between groups using a Wilcox-Mann-Whitney test. All physiologic parameters were compared at each 5 minute interval between groups using an unpaired T test. Intraoperative and postoperative outcomes were analyzed using an unpaired T test was used for continuous variables and a Fisher exact test was used for categorical variables.

CHAPTER 2: RESULTS

A total of 60 patients met the inclusion criteria and were included in this study; there were 30 patients in each arm. 3 patients were excluded following surgery due to metastatic disease found intraoperatively. 1 patient had no intraoperative data captured from both respiratory and cardiovascular devices and was excluded. The 56 patients who were used for analysis included 28 patients in each arm. Patient demographic and surgery data is presented in Table 2.1. There were no statistically significant differences between groups when analyzing patient characteristics and procedures performed. Of these, 20 patients underwent laparoscopic partial nephrectomy, followed by 17 radical nephrectomies, 9 cryoablation procedures, 4 nephroureterectomies, 3 pyeloplasties, 1 simple nephrectomy, 1 retroperitoneal mass excision, and 1 ureteral re-implant. There were 41 males and 15 females with a mean age of 63.7 years. The mean body mass index (BMI) was 28.3 and mean Charlson Comorbidity Index was 3.4.

Table 2.1: Patient characteristics and procedures performed

Variable	**Overall** N=56	**VI** n=28	**CI** N=28	**P-Value**
Age, mean (sd)	63.7 (14.1)	62.5 (15.3)	64.8 (13.1)	.544
BMI, mean (sd)	28.3 (5.2)	27.9 (6.2)	28.7 (4.1)	.580
CCI, mean (sd)	3.4 (2.1)	3.6 (2.4)	3.2 (1.7)	.408
Gender, n (%)				.227
Male	41 (73.2)	23 (82.1)	18 (64.3)	
Female	15 (26.8)	5 (17.9)	10 (35.7)	
Ethnicity, n (%)				.500
Hispanic	3 (5.4)	1 (3.6)	2 (7.1)	
Non-Hispanic	53 (94.6)	27 (96.4)	26 (92.9)	
Race, n (%)				.841
Caucasian	46 (82.1)	22 (78.6)	24 (85.7)	
Black	2 (3.6)	1 (3.6)	1 (3.6)	
Asian	3 (5.4)	2 (7.1)	1 (3.6)	
Hawaiian or PI	1 (1.8)	1 (3.6)	0 (0.0)	
Other	4 (7.1)	2 (7.1)	2 (7.1)	
Treatment, n (%)				.696
Radical nephrectomy	17 (30.4)	9 (32.1)	8 (28.6)	
Simple nephrectomy	1 (1.8)	0 (0.0)	1 (3.6)	
Partial nephrectomy	20 (35.7)	9 (32.1)	11 (39.3)	
Nephroureterectomy	4 (7.1)	3 (10.7)	1 (3.6)	
Cryoablation	9 (16.1)	4 (14.3)	5 (17.9)	
Pyeloplasty	3 (5.4)	2 (7.1)	1 (3.6)	
Ureteral implantation	1 (1.8)	1 (3.6)	0 (0.0)	
Retroperitoneal mass excision	1 (1.8)	0 (0.0)	1 (3.6)	

Primary Outcome: All 56 cases were included in analysis of the primary outcome. There was significantly less variability in pressure readings with a lower mean coefficient of variation during VI compared to CI (7.9% vs. 15.6%, $p<0.001$) (Table 2.2). The average variability between groups can be further illustrated across all 56 cases in Figure 2.1. There was significantly less time spent within the 'borderline' range with pressure readings ≥ 18 mm Hg (0.2% vs. 9.2%, $p<0.0005$) and ≤ 12 mm Hg (12.5% vs. 12.9%, $p=0.013$) during VI

compared to CI. Additionally, there was significantly less time spent with pressure readings in the 'unacceptable' range of ≥ 20 mm Hg (0.1% vs. 2.1%, $p<0.0005$) and ≤ 10 mm Hg (1.8% vs. 7.2%, $p<0.0005$) during the cases with VI compared to CI. There were significantly fewer median pressure spikes above 20 mm Hg when using VI compared to CI (0 vs. 16, $p<0.0005$) (Table 2.2).

Table 2.2: Comparing intra-abdominal pressure variation and percentage of time in each pressure range between conventional and valveless trocar insufflation.

	Valveless Insufflation n=28	**Conventional Insufflation** n=28	**P-value**
Intra-abdominal pressure variation			
Mean pressure, mean (sd)	14.0 (1.3)	14.7 (1.7)	
Mean SD (per patient), mean (sd)	1.1 (0.4)	2.3 (0.7)	
Mean coefficient of variation, mean (sd)	7.9 (3.1)	15.6 (5.3)	<0.001
Percentage of operative time in each pressure range			
Pressures ≥18 mm Hg, mean % (sd)	0.2 (0.8)	9.2 (14.2)	<0.0005
Pressures ≤12 mm Hg, mean % (sd)	12.5 (25.5)	12.9 (20.3)	0.013
Pressures ≥20 mm Hg, mean % (sd)	0.1 (0.2)	2.1 (7.0)	<0.0005
Pressures ≤10 mm Hg, mean % (sd)	1.8 (4.8)	7.2 (18.0)	<0.0005
Spikes >20 mm Hg, median number per case	0	16	<0.0005

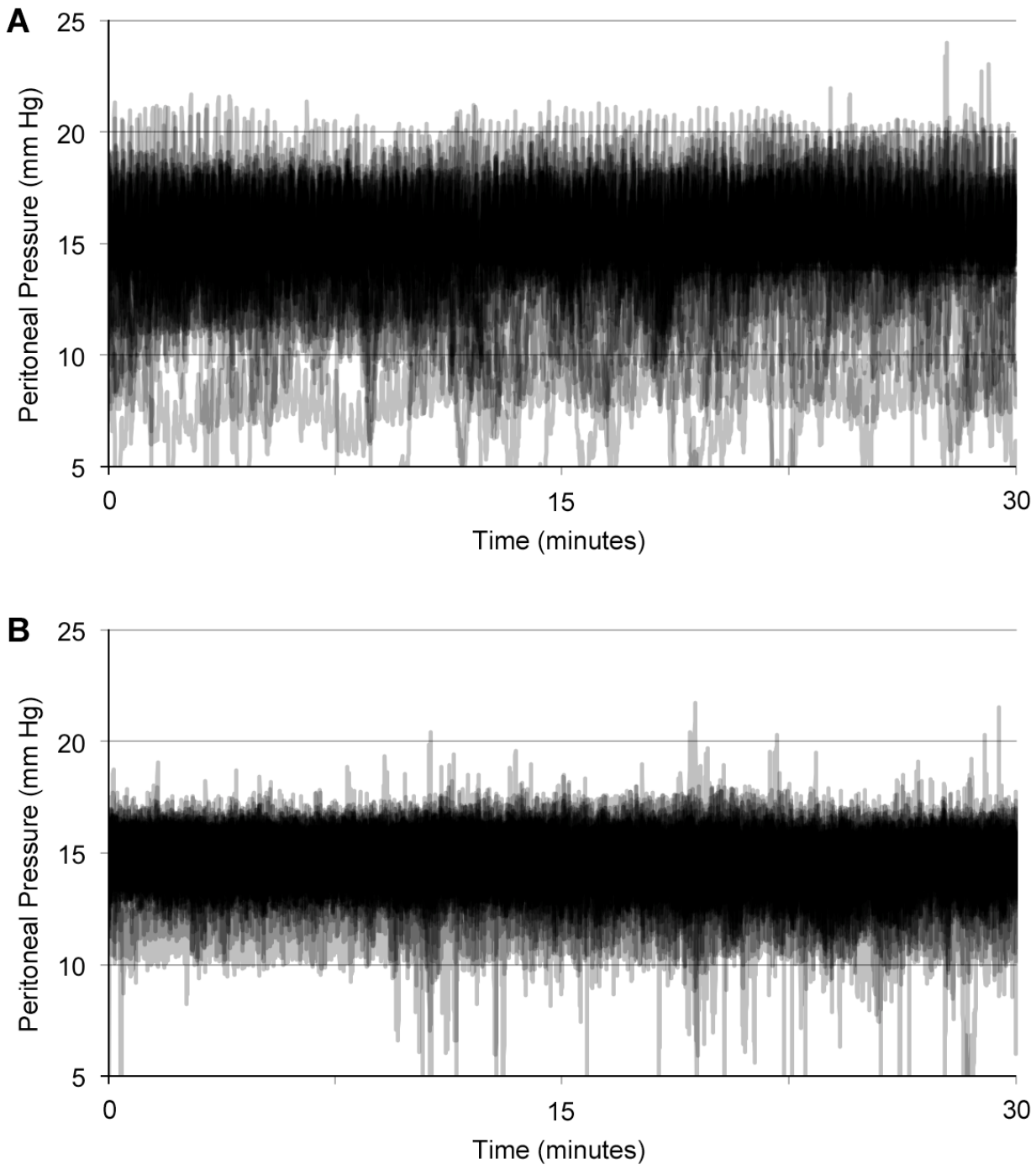

Figure: 2.1: The average variation in pneumoperitoneum between conventional insufflation (A) and valveless trocar insufflation (B) for the first 30 minutes of all 56 laparoscopic cases.

Secondary Outcomes: Intraoperative outcomes analysis included all 56 patients. Estimated blood loss was significantly higher in the VI group compared to the CI group (155 vs. 75 mL, p=0.033). There were no significant differences in urine output (356 vs. 334 mL, p=0.69) or surgery length (151 vs. 130 mins, p=0.066) between the VI group and CI group, respectively. There were no significant differences in the mean number of laparoscope cleanings (2.5 vs. 2.4, p=0.697) or mean number of surgical instruments passed through the trocars (32.4 vs. 17.4, p=0.51) between the VI and CI groups, respectively. The CI group required smoke evacuation in 5 cases compared to 1 case in the VI group (p=0.19). Pneumoperitoneum was lost in 2 cases in the CI group compared to none in the VI group, (p=0.25; see Table 2.3). Surgeon assessment noted less smoke in the surgical field of view, superior image quality, and less suctioning needed by the first assistant when using VI insufflation compared to CI insufflation.

Table 2.3: Intraoperative outcomes analysis when comparing conventional and valveless trocar insufflation.

	Valveless Insufflation n=28	**Conventional Insufflation** n=28	**P-value**
Intraoperative Outcomes			
Estimated blood loss, mean mL (sd)	154.6 (168.0)	75.1 (91.0)	0.033
Urine output, mean mL (sd)	334.1 (224.0)	356.0 (182.3)	0.690
Surgery time, mean minutes (sd)	151.3 (48.0)	130.2 (35.0)	0.066
Smoke evacuations, n	1	5	0.19
Lack of pneumoperitoneum, n (%)	0 (0)	2 (7.1)	0.25
Scope cleaning, mean	2.5	2.4	0.697
Number of surgical instruments passed, mean	32.4	17.4	0.52

Postoperative outcomes analysis included all 56 cases. The average length of stay was 2.2 days for the VI group vs. 2.5 days for the CI group (p=0.25). When assessing pain both subjectively and objectively, there were no significant differences in general and shoulder-tip pain post-operatively at 1 hour, 1 day, day of discharge, and at the first follow-up visit. There was no significant difference in the total complications (10 vs. 5, p=0.136), intraoperative (2 vs. 1, p=0.56) or postoperative complications (8 vs. 4, p=0.19) when comparing CI to VI, respectively (Table 2.4).

Table 2.4: Postoperative outcomes between conventional and valveless trocar insufflation.

	Valveless Insufflation n=28	**Conventional Insufflation** n=28	**P-value**
Postoperative Outcomes			
Length of stay, mean days (sd)	2.2 (1.2)	2.5 (1.1)	0.249
General pain 1 hr	4.7 (2.4)	4.8 (3.0)	0.961
Shoulder pain 1 hr	1.0 (1.9)	0.6 (0.8)	0.249
Pain MEQ 1 hr	9.0 (6.9)	8.5 (6.0)	0.779
General pain 24 hr	3.7 (2.2)	3.8 (2.1)	0.950
Shoulder pain 24 hr	1.6 (2.1)	1.9 (2.6)	0.689
Pain MEQ 24 hr	10.4 (11.1)	15.8 (24.9)	0.301
General pain discharge	2.8 (2.0)	2.9 (2.0)	0.840
Shoulder pain discharge	0.8 (0.8)	0.80 (0.6)	0.853
Pain MEQ discharge	8.1 (10.9)	6.6 (8.0)	0.559
General pain follow-up	1.7 (1.6)	1.4 (1.1)	0.476
Shoulder pain follow-up	1.1 (0.8)	1.1 (0.6)	0.822
Pain MEQ follow-up	2.0 (4.6)	2.2 (4.9)	0.838
Total Complications, n (%)	5 (17.9)	10 (35.7)	0.136
Intraoperative complications, n (%)	1 (3.6)	2 (7.1)	0.561
Postoperative complications, n (%)	4 (14.3)	8 (28.6)	0.199
Clavien Scores, n (%)			
I	2 (7.1)	4 (14.3)	
II	2 (7.1)	2 (7.1)	
IIIa	-	1 (3.6)	
IIIb	1 (3.6)	1 (3.6)	
Iva	-	2 (7.1)	

Subjects with complete data were compared at each physiologic parameter. Due to incomplete data, the total number of subjects analyzed is different for each parameter as seen in Tables 2.5 and 2.6.

Respiratory data was not collected if the ventilator was not registering the respiratory parameter on the monitor. There was a statistically significant lower end-tidal CO_2 at 10 minutes (34.3 vs. 36.6, p=0.029) and 25 minutes (35.8 vs. 37.6, p=0.047) during VI compared to CI. However, there were no significant differences in end-tidal CO_2 at other

time points between the VI and CI groups. There were also no significant differences in peak airway pressure, tidal volume, pulmonary compliance, and CO2 elimination rate between the two groups (Table 2.5).

Cardiovascular data was lost as a result of poor esophageal probe placement and loss of signal during procedures due to factors including interference from electrocautery devices, patient repositioning, or movement of the probe. In the patients with complete data, there were no significant differences in cardiac index, stroke volume index, heart rate, mean arterial pressure, and flow time between the two groups (Table 2.6).

Table 2.5: Ventilation parameters compared between conventional and valveless trocar insufflation prior to insufflation (-5), at insufflation (0), and post-insufflation (5-30) for 30 minutes. TV - tidal volume, Peak – peak airway pressure, ET CO2 – end-tidal CO2, MV – minute ventilation, Comp – pulmonary compliance, CO2 Elim – CO2 elimination rate

Ventilation Parameter at Time, units	Group	N	Mean	Std. Deviation	P-Value
TV -5, mL	Valveless	26	532.8	70.5	.303
	Conventional	25	556.0	87.8	
TV 0, mL	Valveless	27	526.9	70.3	.051
	Conventional	28	572.5	95.9	
TV 5, mL	Valveless	27	520.9	73.8	.159
	Conventional	27	555.0	100.0	
TV 10, mL	Valveless	27	541.0	85.4	.640
	Conventional	27	552.9	100.0	
TV 15, mL	Valveless	28	538.6	80.0	.321
	Conventional	28	562.6	98.3	
TV 20, mL	Valveless	28	521.4	118.1	.236
	Conventional	28	557.5	107.3	
TV 25, mL	Valveless	28	547.7	76.0	.809
	Conventional	28	553.4	99.3	
TV 30, mL	Valveless	28	558.1	75.5	.656
	Conventional	28	569.0	103.5	
Peak -5, cmH20	Valveless	19	19.4	4.9	.309
	Conventional	19	21.1	5.4	
Peak 0, cmH20	Valveless	20	20.2	5.0	.140
	Conventional	23	22.5	4.9	
Peak 5, cmH20	Valveless	26	23.8	4.1	.114
	Conventional	26	25.9	5.3	
Peak 10, cmH20	Valveless	26	24.0	4.1	.128
	Conventional	26	27.0	5.3	
Peak 15, cmH20	Valveless	27	23.9	4.1	.120
	Conventional	27	26.6	4.0	
Peak 20, cmH20	Valveless	27	23.6	5.5	.138
	Conventional	27	26.3	4.0	
Peak 25, cmH20	Valveless	27	24.8	4.3	.112
	Conventional	28	26.6	4.1	
Peak 30, cmH20	Valveless	27	24.7	3.9	.063
	Conventional	28	26.6	3.6	

ET C02 -5, mm Hg	Valveless	26	32.3	2.6	.156
	Conventional	26	33.8	4.9	
ET C02 0, mmHg	Valveless	26	32.7	2.5	.375
	Conventional	28	33.5	3.9	
ET CO2 5, mmHg	Valveless	27	33.0	4.3	.156
	Conventional	27	34.6	4.0	
ET CO2 10, mm Hg	Valveless	27	34.3	4.2	.029
	Conventional	27	36.6	3.4	
ET CO2 15, mm Hg	Valveless	28	35.4	3.6	.158
	Conventional	28	36.7	3.3	
ET CO2 20, mm Hg	Valveless	28	35.6	3.4	.107
	Conventional	28	37.0	2.9	
ET CO2 25 mm Hg	Valveless	28	35.8	3.4	.047
	Conventional	28	37.6	3.3	
ET CO2 30, mm Hg	Valveless	28	35.9	3.2	.156
	Conventional	28	37.3	3.9	
MV -5, mL/min	Valveless	26	5781.2	1176.0	.449
	Conventional	23	6072.4	1493.0	
MV 0, mL/min	Valveless	27	5677.0	1169.7	.412
	Conventional	26	6009.9	1717.5	
MV 5, mL/min	Valveless	27	5777.2	1053.1	.980
	Conventional	26	5768.2	1536.2	
MV 10, mL/min	Valveless	27	6072.3	1201.3	.558
	Conventional	26	5826.7	1784.8	
MV 15, mL/min	Valveless	28	6041.0	1143.1	.714
	Conventional	27	5896.0	1725.6	
MV 20, mL, min	Valveless	28	5814.5	1482.3	.988
	Conventional	27	5821.4	1807.0	
MV 25, mL/min	Valveless	28	6144.0	1050.3	.416
	Conventional	28	5826.5	1762.0	
MV 30, mL/min	Valveless	28	6285.2	1104.6	.617
	Conventional	28	6093.0	1691.1	
Comp -5, L/cmH20	Valveless	19	29.1	6.5	.519
	Conventional	19	27.7	7.4	
Comp 0, L/cmH20	Valveless	21	27.2	7.9	.952
	Conventional	23	27.0	6.6	
Comp 5 L/cmH20	Valveless	26	22.6	4.2	.696
	Conventional	26	22.1	5.0	
Comp 10 L/cmH20	Valveless	26	22.9	5.2	.257

	Conventional	26	21.2	5.3	
Comp 15 L/cmH20	Valveless	27	22.9	4.8	.290
	Conventional	27	21.5	4.4	
Comp 20, L/cmH20	Valveless	27	22.3	5.1	.530
	Conventional	27	21.4	4.8	
Comp 25, L/cmH20	Valveless	27	22.5	4.5	.334
	Conventional	28	21.2	5.0	
Comp 30 L/cmH20	Valveless	27	22.9	4.4	.400
	Conventional	28	21.8	5.3	
CO2 Elim -5, mL/min	Valveless	26	2.98	0.6	.308
	Conventional	27	3.18	0.7	
CO2 Elim 0, mL/min	Valveless	27	2.97	0.6	.541
	Conventional	27	3.08	0.7	
CO2 Elim 5, mL/min	Valveless	28	3.06	0.8	.924
	Conventional	27	3.04	0.7	
CO2 Elim 10, mL/min	Valveless	26	3.33	0.8	.528
	Conventional	28	3.21	0.7	
CO2 Elim 15, mL/min	Valveless	27	3.46	1.0	.494
	Conventional	27	3.30	0.7	
CO2 Elim 20, mL/min	Valveless	28	3.33	1.1	.811
	Conventional	27	3.27	0.7	
CO2 Elim 25, mL/min	Valveless	28	3.55	0.9	.358
	Conventional	27	3.35	0.7	
CO2 Elim 30, mL/min	Valveless	27	3.64	0.9	.449
	Conventional	26	3.47	0.7	

Table 2.6: Hemodynamic parameters compared between conventional and valveless trocar insufflation prior to insufflation (-5), at insufflation (0), and post-insufflation (5-30) for 30 minutes. CI – cardiac index, SVI – stroke volume index, HR – heart rate, MAP – mean arterial pressure, FT – flow time.

Hemodynamic Parameter at Time, units	Group	N	Mean	Std. Deviation	P-Value
CI -5, L/min/m^2	Valveless	17	5.1	1.7	.967
	Conventional	17	5.1	1.4	
CI 0, L/min/m^2	Valveless	21	4.5	1.3	.492
	Conventional	18	4.8	1.1	
CI 5, L/min/m^2	Valveless	17	4.1	1.1	.927
	Conventional	14	4.1	.9	
CI 10, L/min/m^2	Valveless	21	4.4	1.4	.519
	Conventional	16	4.7	1.0	
CI 15, L/min/m^2	Valveless	22	4.4	1.7	.596
	Conventional	23	4.6	1.9	
CI 20, L/min/m^2	Valveless	22	4.9	1.3	.968
	Conventional	23	4.9	1.3	
CI 25, L/min/m^2	Valveless	20	4.7	1.2	.343
	Conventional	23	5.1	1.4	
CI 30, L/min/m^2	Valveless	20	4.7	1.2	.154
	Conventional	24	5.3	1.5	
SVI -5, ml/m^2/beat	Valveless	18	37.9	7.8	.524
	Conventional	17	40.1	12.0	
SVI 0, ml/m^2/beat	Valveless	22	35.3	10.6	.367
	Conventional	19	38.2	9.3	
SVI 5, ml/m^2/beat	Valveless	21	29.5	6.4	.937
	Conventional	17	29.6	7.1	
SVI 10, ml/m^2/beat	Valveless	23	34.1	7.8	.390
	Conventional	19	31.5	11.3	
SVI 15, ml/m^2/beat	Valveless	26	30.8	13.6	.073
	Conventional	23	37.0	9.6	
SVI 20, ml/m^2/beat	Valveless	24	36.6	8.2	.823
	Conventional	24	37.2	9.2	
SVI 25, ml/m^2/beat	Valveless	21	37.2	7.9	.679
	Conventional	24	38.5	12.4	
SVI 30, ml/m^2/beat	Valveless	21	36.9	10.9	.482
	Conventional	26	39.2	11.7	

HR -5, beats/min	Valveless	17	61.4	9.6	.323
	Conventional	19	65.1	12.3	
HR 0, beats/min	Valveless	21	62.7	10.6	.509
	Conventional	21	65.0	12.1	
HR 5, beats/min	Valveless	24	66.2	12.1	.882
	Conventional	21	65.7	11.8	
HR 10, beats/min	Valveless	26	65.5	11.3	.437
	Conventional	20	68.4	13.6	
HR 15, beats/min	Valveless	27	62.8	17.3	.453
	Conventional	21	66.2	11.8	
HR 20, beats/min	Valveless	26	65.7	12.7	.976
	Conventional	22	65.6	11.7	
HR 25, beats/min	Valveless	25	65.7	12.4	.827
	Conventional	23	65.0	11.0	
HR 30, beats/min	Valveless	26	59.3	21.3	.243
	Conventional	23	65.2	11.5	
MAP -5, mm Hg	Valveless	19	78.4	10.0	.115
	Conventional	20	72.9	11.3	
MAP 0, mm Hg	Valveless	24	79.2	13.7	.464
	Conventional	22	76.4	12.2	
MAP 5, mm Hg	Valveless	26	86.3	23.2	.996
	Conventional	22	86.3	26.8	
MAP 10, mm Hg	Valveless	27	93.0	15.1	.344
	Conventional	22	97.3	16.4	
MAP 15, mm Hg	Valveless	26	83.8	33.1	.279
	Conventional	24	91.8	13.9	
MAP 20, mm Hg	Valveless	26	91.9	12.8	.744
	Conventional	22	90.6	15.2	
MAP 25, mm Hg	Valveless	24	89.6	13.5	.273
	Conventional	24	85.4	12.3	
MAP 30, mm Hg	Valveless	23	89.1	12.7	.179
	Conventional	24	84.1	12.4	
FT -5, mL/min	Valveless	18	350.8	29.6	.127
	Conventional	17	329.8	48.0	
FT 0, mL/min	Valveless	23	326.4	40.2	.797
	Conventional	20	322.1	66.4	
FT 5, mL/min	Valveless	25	304.0	55.0	.348
	Conventional	17	318.1	32.3	

FT 10 mL/min	Valveless	27	319.6	50.6	.456
	Conventional	20	302.9	99.0	
FT 15 mL/min	Valveless	27	299.2	103.0	.091
	Conventional	23	341.2	59.4	
FT 20, mL/min	Valveless	25	322.5	84.7	.478
	Conventional	24	337.1	54.4	
FT 25, mL/min	Valveless	25	304.5	98.7	.710
	Conventional	25	314.7	92.8	
FT 30 mL/min	Valveless	25	294.1	99.3	.062
	Conventional	26	336.8	55.0	

CHAPTER 3: DISCUSSSION

The incidence of minimally invasive surgery continues to rise as technology continues to improve with roughly 3 million procedures performed during 2009 in the United States alone[13]. Understanding the performance of the surgical devices being used on a daily basis is imperative to enhancing procedure quality and improved surgical outcomes for patients. The AirSeal valveless trocar insufflation system entered the market in 2009 and has been used routinely in laparoscopic urologic, bariatric, and robot-assisted laparoscopic surgeries. However, there are no randomized, comparative studies showing the intraoperative performance of conventional insufflation to valveless trocar insufflation for maintaining pneumoperitoneum within an acceptable (12–18 mm Hg) range.

The results of this study suggest valveless trocar insufflation maintains more precise control of pneumoperitoneum with pressures remaining in the acceptable range 87.3% of the time compared to 77.9% using conventional insufflation. This was previously only supported by *in vitro* studies which suggested VI maintains pneumoperitoneum within a more precise pressure range than CI during periods of suctioning and passage of instruments into the abdomen[8]. Procedures performed with CI also spent 7.2% of the time compared with 1.8% using VI in the 'unacceptable' range of less than 10 mm Hg. Spending more time in this range may have been the reason there was an unacceptable loss of pneumoperitoneum in 2 CI cases when compared with no episodes in the VI group. Though this was not statistically significant, loss of pneumoperitoneum places the patient at inadvertent risk of injury to tissue. Fortunately, we did not observe any complications during both cases of unacceptable loss of pneumoperitoneum. Cases using CI also spent

2.1% of the time compared with 0.1% using VI with insufflation pressures greater than 20 mm Hg, and had significantly more pressure spikes throughout the cases compared to VI. Previous documentation suggested higher insufflation pressures may lead to decreased urine output, decreased cardiac output, increased peak airway pressures, and increased end-tidal CO2; however in this study only end-tidal CO2 was found to be higher in the CI group at 10 and 25 minutes[4,14,15]. Upon subjective assessment by the surgeon, VI provided a clearer surgical view with less smoke obscuring vision consistently throughout the cases. This did not translate to any significant difference in objective outcomes, which included the number of smoke evacuations, scope cleanings, or mean operative time, as previously seen in retrospective and *in vitro* studies[8,9].

Though VI was able to maintain pneumoperitoneum with less variation compared to CI, this effect did cause any significant improvement in intraoperative or postoperative outcomes for patients randomized to VI. In fact, the average estimated blood loss was significantly higher in the VI group despite a subjectively clearer working view and no loss of pneumoperitoneum. This may suggest consistently higher pneumoperiteum pressures in the CI group may have had a tamponade effect on venous oozing throughout the cases. Differences in all other intraoperative and postoperative outcomes were not statistically significant. Of those outcomes, general pain and hospital length of stay were of most interest as these may be used as quality of care metrics for hospitals in the near future. Unfortunately, a small sample size most likely contributed to our study not reporting any statistically significant difference in either group between these outcomes. Complications are another important outcome measured as these can contribute to higher readmission rates and longer hospital stays. There were fewer total complications in the VI group,

intra-operatively and post-operatively, which was not statistically significant. The majority of these complications were post-operative urinary retention, possibly a result of residual anesthetic effects on the bladder at the time of Foley catheter removal. Prior studies have suggested VI may be associated with higher incidence of subcutaneous emphysema and may mask the ability to detect intraoperative pneumothorax due to blunted end-tidal CO2 levels [9-11,16]. This study did not have any cases of subcutaneous emphysema or pneumothorax as complications in either group.

This study also attempted to investigate any physiologic benefit to using VI compared to CI. No significant benefit was seen amongst the cardiovascular parameters, which was limited by using the esophageal doppler as a measuring device. The doppler was frequently displaced and lost signal causing incomplete data collection. With a more reliable measuring device and a larger sample size, cardiovascular differences may be identified between the two devices leading to preferred usage in patients with high cardiovascular risk factors.

Among the respiratory parameters evaluated, end-tidal CO_2 at 10 minutes and 25 minutes after initial insufflation was different between groups, however end-tidal CO_2 was not different for all other time points. These results are partially consistent with previous retrospective and prospective nonrandomized studies, which showed decreased end-tidal CO_2 in the VI group potentially leading to lower volumes of CO_2 elimination rates and lower CO_2 absorption[9,10]. Due to the lack of difference in end-tidal CO_2 throughout most of the case, there were no significant differences in CO_2 elimination rates between the 2 groups at any time points. The inconsistency of our results with previous studies may be a consequence of our anesthesia team noticing the steeper rise in end-tidal CO_2 after

insufflation and making intra-operative adjustments with the ventilator to blow off CO_2 in the CI group. With a larger sample size, further respiratory differences may have been seen, which would make one device more preferred for patients with obstructive lung disease such as COPD.

This study is also limited by potential bias as all procedures and subjective assessments were performed by a single surgeon at a single site. Given the nature of the intervention, blinding the surgeon to the group assignment at the time of surgery was not feasible because of differences in the equipment used. Additionally, the study was statistically powered to achieve significance with our primary outcome of intra-abdominal pressure variation, and may not have been sufficiently powered to demonstrate physiologic, intraoperative, and post-operative outcomes that may have reached significance with a larger sample size.

Further study incorporating larger sample sizes is warranted to understand the true physiologic benefits of each insufflation device. Since valveles trocar insufflation has been shown to consistently maintain pneumoperitoneum within a specified pressure range, further research should also explore the cardiovascular and respiratory effects of performing procedures at a lower pressure ranges and comparing them to the standard range to improve postoperative outcomes. Understanding the physiologic effects and outcomes of each device in different patient sub-populations would also benefit laparoscopic surgeons moving forward as bariatric laparoscopy and minimally invasive cardiothoracic surgery fields target patients with higher co-morbidities and higher intraoperative risk factors.

In conclusion, this randomized, comparative study shows valveless trocar insufflation is able to maintain pneumoperitoneum within an acceptable range more consistently than conventional insufflation during laparoscopic renal surgery. However, the clinical benefits of maintaining more stable pneumoperitoneum are still not well understood with the only beneficial respiratory effect being lower end-tidal CO2 10 and 25 minutes after insufflation, but with the added risk of increased perioperative bleeding.

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