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Electrostatic Precipitation in Low Pressure Laparoscopic Hysterectomy and Myomectomy

David Levine, MD, Gregory F. Petroski, PhD, Tracy Haertling, DO, MS, Teresa Beaudoin, RN, BSN

ABSTRACT

Background and Objective: The purpose of this study was to evaluate the impact of using electrostatic precipitation to manage the surgical plume during low pressure laparoscopic gynecologic procedures.

Methods: This was a prospective, blinded, randomized controlled study of women with a clinical indication for laparoscopic hysterectomy (n = 30) or myomectomy (n = 5). Patients were randomized to either use electrostatic precipitation (EP) during the procedure, or not (No EP, hysterectomy group only).

Results: Low pressure surgery could be undertaken in 87% of hysterectomy cases (13/15) when using EP to manage the surgical plume, compared to only 53% (8/15) in the No EP group. Overall average rating of the visual field was excellent with EP vs fair for No EP. Average CO_2 consumption was reduced by 29% when using EP (16.7L vs 23.5L, p = 0.152). The average number of procedural pauses to vent smoke was lower with EP than the No EP group (1.5 per case vs. 3.7 per case, p = 0.005). Average procedure duration for the EP vs No EP group was 40.5 min vs. 46.9 min (p = 0.987). There were no measurable differences between groups for body temperature, end-tidal CO_2, and discharge pain scores. In myomectomy, all five cases could be performed at low pressure, with an excellent visual field rating.

Conclusion: Electrostatic precipitation enhances low pressure laparoscopic hysterectomy and myomectomy. This was achieved by minimizing interruptions to surgery and exchange of CO_2; providing a clear visual field throughout the procedure; and eliminating surgical smoke at the site of origin.

Key Words: Laparoscopic, Low pressure, Visualization.

INTRODUCTION

Advances in laparoscopic surgery have significantly decreased recovery time, infection, and inpatient days.[1] Laparoscopic instrumentation has improved efficiency and safety by creating power sources that minimize spread to adjacent tissues. Cauterization is an effective surgical tool, but the smoke generated fills the abdomen partially or totally obscuring the surgeon's view which has safety implications. Smoke clearing strategies vary from releasing the smoke to using CO_2 exchangers. Studies have evaluated potential dangers associated with surgical smoke in the operating suite.[2] Approaches to improve visibility and prevent smoke release rely on dilution of the smoke-containing CO_2 with fresh CO_2 from the insufflator. Attempts have been made to quantify the clinical effects of high pressure and CO_2 volumes. Studies have shown that maintaining pneumoperitoneal pressure at no more than 10 mmHg may improve patient outcomes.[3] A recent prospective randomized controlled study in 178 patients who underwent total laparoscopic hysterectomy reported that low pressure laparoscopy is an effective and safe technique for the reduction of postoperative pain and laparoscopy-induced metabolic and vegetative alterations following laparoscopic hysterectomy for benign indications.[4]

Electrostatic precipitation (Ultravision™ Visual Field Clearing System, Alesi Surgical Ltd) offers a new technique to improve visualization and smoke management during laparoscopic surgery. The Ultravision™ System is an FDA approved device indicated for the clearance of smoke and other particulate matter created during

Department of Obstetrics and Gynecology, Mercy Hospital, 621 S. New Ballas Rd, St. Louis, Missouri (Dr. Levine).

Biostatistics & Research Design Unit, University of Missouri – Columbia School of Medicine, 182C Galena Hall, Columbia, Missouri (Dr. Petroski).

Mercy Research, 3231 S. National Ave., Ste 210, Springfield, Missouri (Ms Haertling).

Mercy Research, 615 S. New Ballas Rd, Ste 2010, St. Louis, Missouri (Ms Beaudoin).

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Address correspondence to: Dr. David Levine, Department of Obstetrics and Gynecology Mercy Hospital St. Louis, 621 S. New Ballas Road, St. Louis, Missouri 63141. Telephone: 314-251-7650, Fax: 314 251-7651, E-mail: David.Levine@Mercy.net.

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laparoscopic surgery. Electrostatic precipitation is unique in that it eliminates smoke particles without CO_2 exchange within the abdomen. It has been shown previously in laparoscopic cholecystectomy to minimize CO_2 exposure and provide a more stable pneumoperitoneum.[5]

Although consistent with the labeled indications for use, electrostatic precipitation use during laparoscopic gynecologic procedures has not been reported in the literature. Laparoscopic hysterectomy and myomectomy generate considerable smoke and present an appropriate setting for further evaluation.

This study aimed to determine if electrostatic precipitation can maintain visual field clearance under low pressure laparoscopic conditions using a standard insufflator, thereby facilitating low pressure surgery whilst reducing patient CO_2 exposure.

MATERIALS AND METHODS

Study Design

This is a prospective blinded, randomized controlled study comparing laparoscopic hysterectomy, the most common laparoscopic gynecological procedure, with electrostatic precipitation (EP), Arm 1, versus laparoscopic hysterectomy without electrostatic precipitation (No EP), Arm 2. Study Arm 3 included patients undergoing laparoscopic myomectomy with electrostatic precipitation. Arm 3 was included because, although less frequently performed, myomectomy is a procedure that often creates large amounts of surgical plume and hence (a) generates data from an additional procedure; and (b) was considered to present at least as significant a challenge as hysterectomy for the device under evaluation.

Subjects

Inclusion criteria for the study were: $\geq$ 21 years of age, clinically indicated to undergo laparoscopic hysterectomy (with or without unilateral or bilateral oophorectomy or salpingo-oophorectomy) or myomectomy; willingness to attend all follow-up assessments; and ability to provide written informed consent. **Table 1** summarizes the clinical indications that presented during the study.

Exclusion criteria included: pregnancy and existing comorbidities that would be contraindications for laparoscopic surgery, such as inability to tolerate general anesthesia or multiple previous abdominal surgeries.

Informed consent was obtained from all patients.

Outcomes

The study outcomes assessed both performance and safety of electrostatic precipitation during laparoscopic hysterectomy and myomectomy. The primary outcome measures were quality of surgical field visualization as assessed by the investigator and the amount of carbon dioxide consumed from the time of placement of all surgical ports to colpotomy (hysterectomy) or closure of last uterine defect (myomectomy). Secondary outcomes included the number of ventilating and lens cleaning episodes and other pauses during the procedure; loss of pneumoperitoneum due to smoke evacuation, maximum intra-abdominal pressure, and duration at maximum pressure; number of changes or increases in pressure during the procedure and reason for change; body temperature and end-tidal CO_2 measured during the procedure; procedure duration; duration of postoperative hospital care; postoperative pain assessments; and medication utilization for pain and adverse events.

Randomization

For eligible patients undergoing laparoscopic hysterectomy, randomization was performed after obtaining informed consent. Patients were enrolled consecutively. The study was designed to compare 30 laparoscopic hysterectomies using a 1:1 randomization with 15 subjects allocated to the EP group and 15 subjects to the No EP group. Randomization was achieved using an envelope system, with each envelope containing either an "Ultravision" or a "Non-Ultravision" card. The study coordinator opened one envelope immediately prior to surgery and allocated the patient to Arm 1 or Arm 2, according to the text on the card. The investigator was blinded to the group assignment until the subject was transferred to recovery and the intra-operative and immediately postoperative data collection (i.e. that involving surgeon feedback) was complete. A third nonrandomized group of five patients undergoing myomectomy with electrostatic precipitation (Arm 3) was also evaluated.

Intervention

Pre-operative evaluations were obtained according to the current standard of care.

Table 1.
Patient Characteristics

	EP (n = 15)	No EP (n = 15)	Myomectomy (n = 5)
Age (years)	45.5 (± 10.2)	46.1 (± 8.5)	37.2 (± 9.7)
Ethnicity			
White/Caucasian	11 (73.33%)	12 (80%)	2 (40%)
Black/African-American	4 (26.67%)	2 (13.33%)	3 (60%)
Hispanic/Latino	0 (0%)	1 (6.67%)	0 (0%)
BMI (kg/m^2)	30.4 (± 7.2)	33.3 (± 10.5)	32.7 (± 9.7)
Diagnosis (procedure indication)			
Uterine fibroids	4	10	5
Abnormal Uterine Bleeding	3	0	0
Pelvic pain	7	4	0
Ovarian mass	1	0	0
Uterine prolapse	0	1	0
Abdominal Ultrasound findings			
Adenomyosis	2	0	0
Fibroids	5	8	5
Ovarian mass/cyst	1	1	0
Other*	2	3	0
Normal	1	0	0
Not done	4	3	0

EP, electrostatic precipitation; BMI, body mass index.
Age and BMI – Mean (Standard Deviation); Ethnicity – frequency (%).
*Other ultrasound findings included enlarged heterogenous uterus, heterogenous uterus with fluid-filled cavity, thickened endometrial canal and isthmocele.

The Ultravision System consists of a standalone battery-operated generator unit and the Ionwand™ electrode, which is introduced into the abdomen through either the Ultravision™ 5 mm Trocar or a 2.5 mm percutaneous catheter. The electrode provides the source of electrons that create the negative ions that transiently charge the surgical smoke particles and accelerate their sedimentation.

Electrostatic precipitation was set up for all procedures. The electrode was introduced as described per the Instructions for Use. Investigator blinding was created for the EP and No EP groups by placing the generator behind the surgeon and covering the system such that the electronic display, indicating whether the system was on or off, was not visible to the investigator. Device set up was conducted by supporting personnel such that the surgeon was not aware if the system was on or off. The speaker was turned down to minimize any audible indicators. The system was turned off for all procedures for subjects in the No EP group.

All surgical procedures were performed by the same surgeon, the study principal investigator.

A starting pneumoperitoneal pressure of 10 mmHg was used, delivered from a conventional insufflator. A total hysterectomy with or without adnexectomy by laparoscopy at 10 mmHg was performed using standard technique. All abdominal entry was performed using a 3 mm port at Palmer's point, as advised by the manufacturer and to provide consistency between patients. Once the abdominal cavity was clearly visualized, a 5 mm umbilical port and three additional 5 mm ports were placed lateral to the inferior epigastric vessels. The electrostatic precipitation electrode was placed in the left upper quadrant through the previous port site. All procedures were undertaken in steep Trendelenburg. After the uterus and adnexa were delivered vaginally, the cuff was closed using 3 figure-of-eight sutures of polydioxanone. Cutaneous closure was performed with skin glue for all 5 mm ports. The lateral myomectomy 10 mm port was

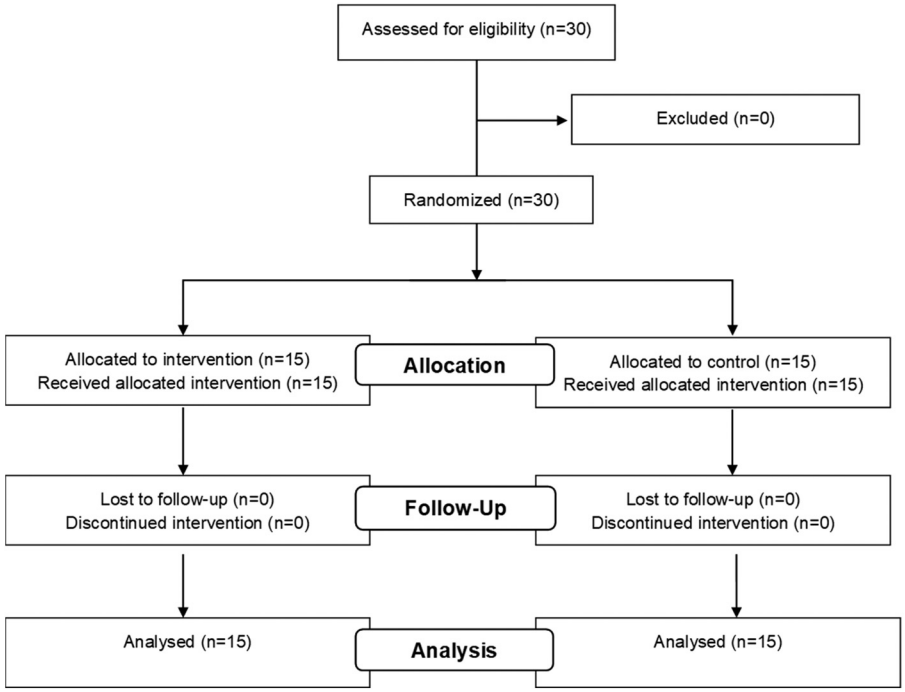


Figure 1. Study flow diagram.

closed using the Carter Thomason closure device and a 4-O subcutaneous suture.

Outcomes related to the procedure and intra-operative period were collected in real-time during the procedure by the study coordinator. The procedure duration was defined as the time all ports were in place to completion of colpotomy for hysterectomy and to closure of last uterine defect for myomectomy. Overall procedure duration was defined as the time all ports were in place to completion of the procedure.

Immediately following each procedure, the investigator answered the following questions:1) the proportion of operating time with effective visibility on a 1 to 100 numerical rating scale, and 2) the overall rating of visibility on a scale from 1 to 5 where 1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor and 5 = Bad.

Post-Operative Period

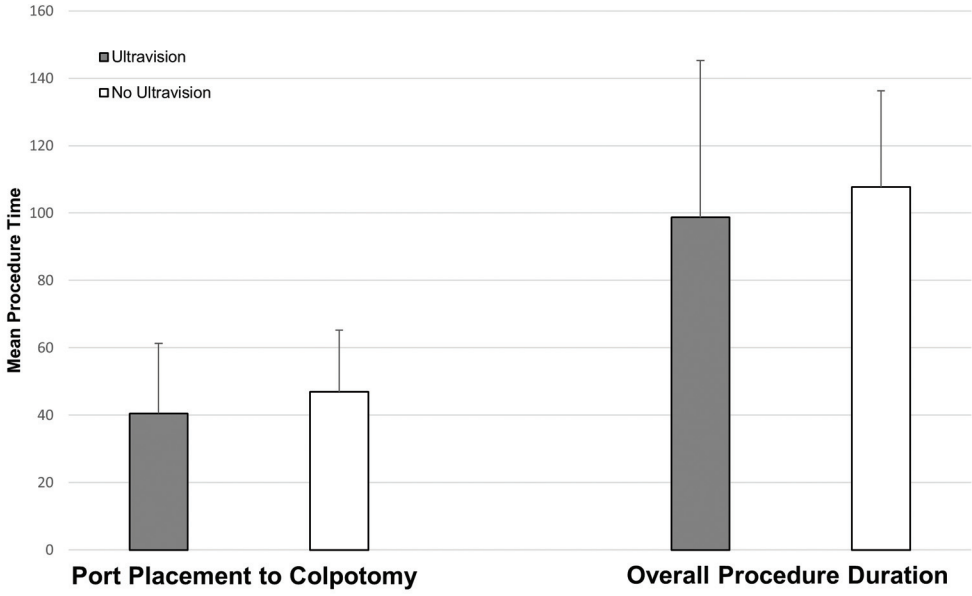
Postoperative care was provided and subjects were seen for a two-week follow up clinic visit, which is the current standard of care. Postoperative outcomes included duration of postoperative care, pain medication utilization, and pain assessments. The duration of postoperative hospital care was defined as time of entry to postoperative recovery to discharge. Pain score and pain location documented in the medical record during postoperative recovery, prior to discharge and at the two-week follow-up visit was collected.

Data Collection

Data were collected on a prospective basis. Collection points occurred at baseline (to assess eligibility for inclusion, 1 to 3 months prior to date of surgery); pre-operatively (to confirm eligibility, within 24 h of surgery); during the procedure (performance data); in recovery (time in recovery, pain medications, and score); immediately prior to discharge (pain medication and score) from the hospital; and two weeks post-discharge, per standard of care (pain score).

Statistical Analysis

Significance testing was used to compare outcomes for the EP and No EP groups. Summary statistics for the myomectomy group are included for descriptive purposes. Fisher's Exact Test was used for group comparisons on categorical variables and the two-sample t test or Wilcoxon Rank Sum Test for continuous variables. Body temperature and end-tidal CO_2 were measured at 15-min intervals. A two-way repeated measures analysis of variance with group by time interaction was used to test if there were group differences



Group	Variable	N	Mean	Std Dev	Median	Min	Max	p Value
No Ultravision	Port to Colpotomy	15	46.9	18.3	51	19	97	
	Overall	15	107.7	28.6	108	62	158	
Ultravision	Port to Colpotomy	15	40.5	20.8	34	22	95	0.097
	Overall	15	98.7	46.6	80	57	236	0.152

Figure 2. The average procedure time in minutes. Error bars are standard deviation and a p-value ≤ 0.05 was considered significant.

in these outcomes over the first 60 min of the procedure. All p values are for two-sided alternatives, and those ≤ 0.05 were considered to indicate statistical significance.

RESULTS

During the study period, 30 patients with clinical indication for laparoscopic hysterectomy were evaluated for eligibility, randomized, and all were included in the final analysis (**Figure 1**). Five patients were eligible for Arm 3, laparoscopic myomectomy. All five patients underwent the procedure using electrostatic precipitation and completed follow up. Data for all five patients were analyzed. Characteristics of the included patients are listed in **Table 1**.

Procedural Characteristics

There were 14 subjects in the EP group and 12 in the No EP group who underwent hysterectomy with bilateral salpingo-oophorectomy, and one patient in the EP group and three in the No EP group who underwent hysterectomy with unilateral oophorectomy and unilateral salpingo-oophorectomy. The same electrostatic precipitation system set up, generator (serial number 2014-A00195) and (Ionwand™, batch number 17161827), was used for all procedures (n = 35). The Covidien VLFT10GEN diathermy system was used for all procedures (n = 35) with Covidien harmonic and Storz bipolar tools used for all procedures.

Procedure Duration

Procedure time and overall procedure duration, as defined above, for the EP (Arm 1) and No EP (Arm 2) groups is summarized in **Figure 2**. For Arm 3, the average time from insertion of all ports to closure of last uterine defect was 56.8 min (± 31.5 min).The average overall procedure duration for the myomectomy group was 92.4 min (± 29.5 min) for (data not shown).

CO_2 Utilization

The mean volume of CO_2 consumption during the procedure, measured during the period between all trocars being inserted to the completion of the colpotomy, for the EP and No EP groups (p = .125) is shown in **Figure 3**. Average CO_2 consumption was reduced by 29% when using electrostatic precipitation (16.7L vs 23.5L, p = .152). See **Figure 3**. The mean volume of CO_2 consumption

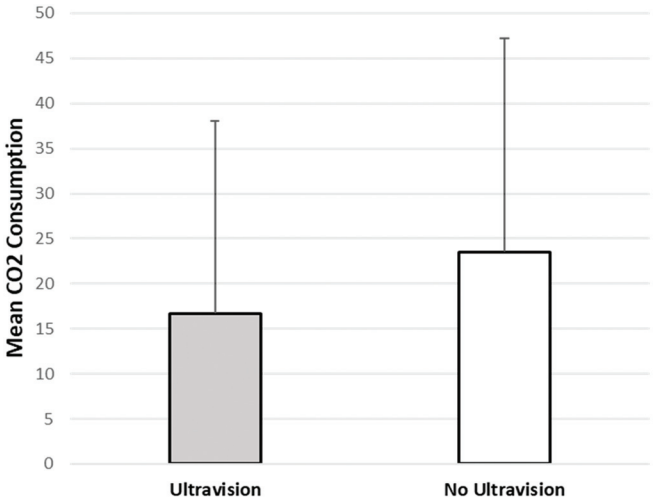


Figure 3. Average procedural CO_2 consumption in liters. N = 15, Error bars are standard deviation and a p-value ≤ 0.05 was considered significant.

during the procedure for the myomectomy group was 25.7L (± 25.3).

Procedural Pauses

Figure 4 summarizes the number of pauses during the procedure and the reason for the pause for the EP and No EP groups. Comparing EP to No EP, there was a 42% improvement in visibility (p = .043), a 56% reduction in smoke (p = .011), and a 59.5% reduction in venting (p = .005). There was a significant difference in the average number of pauses to clear the smoke, 1.5 per case for EP vs 3.7 for No EP (p = .005).

Of the four subjects in the myomectomy group where pauses occurred, three subjects had one pause and one subject had three pauses. Reasons for pauses included temporary poor visibility and camera cleaning.

Intra-Abdominal Pressure

An initial intra-abdominal pressure of 10 mmHg was confirmed for all subject procedures (n = 35). When intra-abdominal pressure was increased, all increases were to 15 mmHg and due to insufficient working space. There were two increases in the EP group and seven increases in the No EP group. The mean duration of the pressure increase was 31.5 minutes (± 6.4) for the EP group and 59.8 minutes (± 37.4) for the No EP group. No more than one pressure increase was noted. Using a standard insufflator, low pressure surgery could be undertaken in 87% of cases (13/15) when using electrostatic precipitation compared to only 53% (8/15) when electrostatic precipitation was not used. No increases in pressure were noted for the five subjects in the myomectomy group.

Clinical Outcomes

All subjects (n = 35) were discharged on the same day as the procedure (within 24 h of procedure).

Pain Assessments

The mean discharge pain score was 2.7 out of 10 (± 2.4) for the EP group and 2.7 out of 10 (± 1.8) for the No EP group (p = .832). The mean discharge pain score for the myomectomy group was 2.8 (± 1.9). No patients reported shoulder pain at discharge.

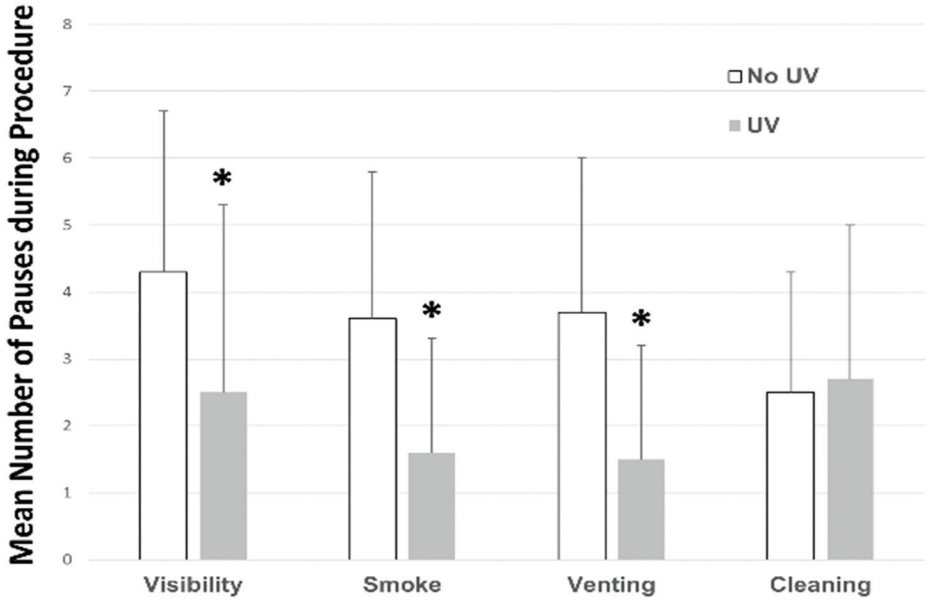
At the two-week follow up, two patients in the EP group reported pain, with ratings of 2/10 and 9/10 respectively. Neither patient reported shoulder pain. Two patients in the EP group rated their pain 0/10 but reported shoulder pain. One patient in the No EP group reported pain (2/10). Of the 15 patients in the No EP group, four rated their pain 0/10 but reported shoulder pain. All five patients in the myomectomy group reported 0/10 pain and none reported shoulder pain.

Pain Medication Utilization

Table 2 summarizes pain medication utilization for all three study groups across study time points by medication type. Immediately postoperatively, a prescription for a narcotic was written for the first 2 to 3 days, to be used as needed, until the patient felt able to convert to an NSAID non-narcotic medication. For both the EP and No EP groups, 12/15 (80%) subjects received postoperative opioid pain medication (p = 1.0). The discharge medication list of all 15 patients in both the EP and No EP groups included an oral opioid medication. At the two-week postoperative visit, 10/15 (67%) subjects in the EP group and 7/15 (47%) in the No EP group reported taking opioid pain medication (p = .462). One patient in the EP group and the No EP group used pyridium postoperatively and post-discharge. One patient in the No EP group received gabapentin postoperatively.

Body Temperature and End-Tidal CO_2

Body temperature and end-tidal CO_2 levels were recorded at 15-min increments throughout the procedure. Captured



Group	Variable	N	Mean	Std Dev	Median	Min	Max	*p* value
No UV	Visibility	15	4.3	2.4	4	1	8	
	Smoke	15	3.6	2.2	3	1	8	
	Venting	15	3.7	2.3	3	1	8	
	Cleaning	15	2.5	1.8	2	0	6	
	Total Pauses	15	5.6	2.8	5	1	10	
UV	Visibility	15	2.5	2.8	2	0	8	**0.043**
	Smoke	15	1.6	1.7	1	0	5	**0.011**
	Venting	15	1.5	1.7	1	0	5	**0.005**
	Cleaning	15	2.7	2.3	2	0	7	0.926
	Total Pauses	15	4.2	3.6	3	0	10	0.203

Figure 4. Procedural pauses for the electrostatic precipitation versus no electrostatic precipitation groups. Summary of the number of pauses and reasons for pauses. Error bars are standard deviation and a *p*-value ≤ 0.05 was considered significant (*and bold font).

Table 2.
Post-Operative Pain Medication Utilization

Study Time Point	Post-Operative Hospitalization		Discharge Medications		2-Week Follow-up	
Medication Type	Opioid[1]	Nonopioid[2]	Opioid	Nonopioid	Opioid	Nonopioid
EP (n = 15)	12	14	15	5	10	10
No EP (n = 15)	12	14	15	8	7	9
Myomectomy (n = 5)	5	5	5	1	5	1

EP, electrostatic precipitation.
[1]Postoperative opioid medications included intravenous and/or oral opioids.
[2]Nonopioid medications included acetaminophen and/or nonsteroidal anti-inflammatory medications.

Table 3.
Average Intra-Operative Body Temperature and End-Tidal CO_2 Levels

Group	n	0 Min	15 Min	30 Min	45 Min	60 Min
Body Temp (°C)						
EP	15*	35.93 (0.49)	35.93 (0.44)	35.99 (0.48)	36.03 (0.51)	36.19 (0.52)
No EP	15	35.75 (0.51)	35.87 (0.30)	35.93 (0.29)	36.09 (0.36)	36.05 (0.30)
Myomectomy	5	35.96 (0.48)	36.14 (0.39)	36.18 (0.33)	36.42 (0.22)	36.20 (0.40)
End-Tidal CO_2 Level						
EP	15*	35.4 (3.0)	35.7 (3.7)	35.1 (4.2)	35.9 (2.8)	36.1 (3.1)
No EP	15	35.1 (2.6)	36.1 (2.4)	35.8 (3.4)	35.4 (3.5)	35.0 (2.8)
Myomectomy	5	33.6 (2.0)	34.2 (1.3)	34.0 (1.0)	35.4 (1.7)	35.8 (1.6)

EP, electrostatic precipitation.
Mean and (Standard Deviation).
*At the 60 min timepoint, n = 14 for the EP group.

data points became limited after 60 min due to variance in procedure duration. Therefore, analysis was performed on data up to 60 min. **Table 3** summarizes average temperature and end-tidal CO_2 levels across timepoints for the three study groups. Effects from the analysis of variance for body temperature (p = .092) and end-tidal CO_2 (p = .328) were not statistically significant. Only the time effect for body temperature was statistically significant (p = .012) reflecting slight warming in both groups over the 60-min period of analysis.

Adverse Events

There were no reports of device-related adverse events.

Visualization and Surgeon Satisfaction

Immediately following each procedure, the investigator answered the following questions:1) what was the proportion of operating time with effective visibility on a 1 to 100 numerical rating scale? 2) what was the overall rating of visibility on a scale from 1 to 5 where 1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor and 5 = Bad?

Table 4.
Surgeon Overall Rating of Visibility

	Excellent	Good	Fair	Poor	Bad
EP	9	2	3	1	0
No EP	1	2	7	4	1
Myomectomy	5	0	0	0	0

EP, electrostatic precipitation.

For the surgeon assessment of the proportion of operating time with effective visibility on a scale from 1 – 100, the average was 90.7% (± 10.2) of the time for the EP group versus 74.3% (± 12.1) for the No EP group (p = .0006). For the myomectomy group, the proportion of operating time with effective visibility was 100% for all five subjects.

The overall rating of visibility during the procedure on a scale from 1 to 5 is summarized for each subject procedure in **Table 4**.

DISCUSSION

Laparoscopic hysterectomy is typically performed using an intra-abdominal pressure of 15 mmHg. However, studies have shown that maintaining pneumoperitoneal pressure, at no more than 10 mmHg, may improve patient outcomes.[3,4] Although there are modern, advanced insufflators that offer the potential to operate at low pressure, there has been a recent report that use of such high flow insufflators results in operating room air becoming entrained into the abdomen, increasing the potential for gas embolism with poorly absorbed oxygen and nitrogen.[6] The present study was initiated to evaluate electrostatic precipitation when laparoscopic hysterectomy is performed under low intra-abdominal pressures using a conventional insufflator.

When hysterectomy was attempted at low pressure (10 mmHg) it could only be completed in 53% of cases without electrostatic precipitation, as compared to 87%

with electrostatic precipitation (p = .109). This study demonstrates that low pressure (10 mmHg) laparoscopic hysterectomy can be performed more easily with fewer interruptions using electrostatic precipitation as compared to traditional valve-venting techniques alone.

The potential additional advantages of a low and constant intra-abdominal pressure environment include maintenance of a constant core body temperature and the protective effect to the peritoneal tissues. The negative effects of cold, dry CO_2 have been shown in rat models demonstrating extensive mesothelial desquamation and disruption of underlying connective tissue.[7] Those findings and others have suggested a benefit of humidified CO_2.[8] However, a 2016 Cochran review concluded that there is no clear clinical benefit to humidified and warmed CO_2 in laparoscopic abdominal surgery.[9] Because extraction of smoke-containing CO_2 is not required in order to maintain a clear operative field of view, the use of electrostatic precipitation reduced CO_2 consumption by 29% (p = .125). The present study did not look at the difference between cold, dry CO_2 to humidified and warmed CO_2 which has been evaluated in the past.

The annoyance of smoke plume created by desiccation and coagulation of tissues causes the surgeon to stop and purge the abdominal cavity of smoke. The present study clearly showed a significant decrease in the number of times the surgery was halted because of poor visibility (p = .043), waiting for smoke to clear (p = .011), and venting of smoke into the operating room because of poor visibility (p = .05). This not only decreased the operating time, but also enhanced the surgical experience by preventing multiple pauses in the surgery.

An additional danger associated with purging the smoke into the operating room is the potential effect on the surgeon and other operating room personnel. Studies have demonstrated an association between smoke plumes from electrosurgery and acute headaches, eye, nose and throat irritation; dermatitis, and acute and chronic pulmonary conditions.[10] Purging of smoke was no longer required when using electrostatic precipitation, due to its mode of action in clearing the visual field without requiring CO_2 removal and replenishment.

The system tested in this study is different to other reported means of facilitating low pressure surgery in that, rather than utilizing a high flow of carbon dioxide to rapidly extract smoke-containing CO_2 and dilute remaining smoke with fresh CO_2, its mode of action utilizes electrostatic precipitation. This technique requires a generator that supplies a low power (80mW maximum output) DC energy supply to the pneumoperitoneum via an electrode, introduced via a percutaneous catheter. In use, this creates a constant flow of negatively charged, low-energy gas ions that migrate towards the patient tissue due to the patient return electrode ("ground pad") on the patient, which is also connected to the generator. As they migrate, the ions collide and temporarily associate with particulates and water vapor, which accelerates the natural sedimentation that otherwise occurs to the mass of the combusted matter. As the charged particles land, the charge is released back to the generator via the patient return electrode. Uniquely, this electrostatic interaction requires no gas exchange and therefore allows for low CO_2 use, a stable pneumoperitoneum and, as evidenced by these data, facilitates the ability to perform surgery at low abdominal pressure.

It is noteworthy that, unlike alternative approaches, the mode of action results in the retention of organic particulate matter within the abdomen. Although it would be possible to remove this using postsurgical lavage, this is not included in the instructions for use and was not performed during the study. As reported in the previous study,[5] there were no reports of any patient-related adverse events relating to this during surgery, in recovery or post discharge. Examination of the Manufacturer and User Facility Device Experience adverse event database using the product brand name yielded no adverse event reports in the USA to date.

An attempt was made to demonstrate a difference in pain scores and pain medication utilization postoperatively. There was no significant difference between the two groups even though the CO_2 consumption was significantly less in the electrostatic precipitation group. Given that 70% of the procedures (21 out of 30 patients) were successfully carried out at 10 mmHg, this result is unsurprising. Having established the feasibility of this technique, a recommended follow-up study would be to compare the clinical outcomes from a cohort of patients where electrostatic precipitation is used at low pressure compared to one that used electrostatic precipitation at conventional, 15 mmHg pressure.

LIMITATIONS

There are several limitations to this study. The sample size included in the study does not provide statistical power. As a result, this small sample size may overestimate the magnitude of associations seen between the group where electrostatic precipitation was used and where it was not

used, and the myomectomy group was too small to draw any conclusions. With the small sample size, the ability to adjust for potential confounding variables may be limited. Furthermore, variables that may impact the surgical procedure including uterine size, parity, and surgical findings such as pelvic adhesions, were not collected. While there may be benefits to having a single surgeon perform all procedures in terms of less variability in surgical technique, overall patient management, and consistency in perception of visual field quality, there may also be limitations. The ratings of the visual field are based on a single surgeon's perspective, who was also the Principal Investigator, which may be limited by bias. Findings with other surgeons may vary on the surgeon's level of experience with the procedure, surgical techniques, and use of the smoke clearing device.

CONCLUSION

In this feasibility study, the use of electrostatic precipitation was found to facilitate low pressure laparoscopic hysterectomy using a standard insufflator. This was also demonstrated in myomectomy, although without a comparator. This was achieved by minimizing interruptions to surgery and exchange of CO_2, providing a clear visual field throughout the procedure, and eliminating surgical smoke at the site of origin.

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