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Minimizing Risk of Retroperitoneal Major Vascular Injury with Abdominal Wall Elevation Device during Abdominal Entry for Laparoscopic and Robotic Surgery

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ABSTRACT

Objective: Retrospective clinical report to demonstrate the use of abdominal wall elevation device with closed technique direct entry with 3-mm port.

Design: An abdominal wall elevation device (LevaLap 1.0) was used during abdominal entry for laparoscopic and robotic gynecologic procedures. The primary outcomes were major vascular or visceral injury. Other events assessed included number of entry attempts, failed entry, and adverse events during entry. Descriptive statistics were used to characterize the patient population and the incidence of abdominal entry injuries or events.

Setting: Tertiary hospital.

Patients: Female patients undergoing laparoscopic gynecologic procedures with or without robotic assistance using an abdominal wall elevation device with direct entry technique from July 2023 to May 2024. Exclusion criteria were patients less than 18 years of age.

Interventions: Use of abdominal elevation device at initial entry.

Measurements and Main Results: The elevation device was used in 25 patients with a 3-mm direct trocar. Entry was achieved on the first attempt in all cases. There were no major vascular, visceral injuries, or failed entry events.

Conclusion: Use of a device to elevate the abdominal wall in a standardized fashion is feasible with direct entry using 3-mm port may help reduce the risk of retroperitoneal major vascular injury; however, larger comparative studies are required to confirm efficacy.

Key Words: Abdominal entry and major vascular injury, Abdominal wall elevation device, Laparoscopic and robotic complications.

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INTRODUCTION

More than half of the complications of laparoscopic surgery occur at the time of entry.[1] The rate of major injury with the Veress needle is reported at 0.9/1,000 cases.[2] Rates of Veress entry-related bowel injury was 0.4/1,000 cases.[2–5] Although major vascular injury is rare, it carries a significant risk of morbidity or death.[6,7] Additionally, it can have devastating effect on the patient and their families, both physically and psychologically, as well as major psychosocial impact on the surgeon and the operating team as second victims. The available evidence is low quality supporting the superiority of one entry method.[1,8]

Preoperative tests such as transabdominal visceral slide may mitigate injury at the abdominal entry location by predicting obliterating paraumbilical adhesions and decrease the risk of visceral injury.[9,10] A method that

may mitigate risk of vascular injury on entry is to use hands or towel clips to elevate abdominal wall; however, it is operator dependent with extreme variability on the distance created from the major retroperitoneal vessels. The LevaLap 1.0 (Core Access Surgical Technologies), uses standardized operative room suction to raise the abdominal wall into a clear plastic bell. Use of abdominal wall elevation at initial entry standardizes abdominal elevation and significantly increases the distance between the paraumbilical anterior abdominal wall to vena cava, iliac vessels and aorta by greater than 5 cm.[11] Although there was an insignificant increase in distance from paraumbilical abdominal wall to the underlying bowel, when placed at Palmer's point at the left upper quadrant, the distance from anterior abdominal wall to underlying colonic viscera was greater than 2 and 5 cm from the retroperitoneal vessels.[11]

Previous studies have demonstrated use of the LapLeva1.0 device with Veress needle entry.[11] The objective of this study is to demonstrate the feasibility and share our experience of using the LevaLap 1.0 using a direct closed entry technique a with 3-mm port at various abdominal entry locations. Our direct trocar technique has been fully described previously in a cohort of 1,385 patient undergoing standard laparoscopic gynecological procedures.[12] A recent systematic review comparing Veress and direct entry found no significant differences in occurrence of major entry complications (bowel injury, major vascular injury, port site hernia).[13] However, direct trocar entry had advantages, including a lower risk of subcutaneous emphysema, extraperitoneal insufflation, omental emphysema, omental bleeding, and a lower number of failed entry attempts.[13] Thus, use of direct trocar entry along with an abdominal elevation device may be a suitable technique for surgeons to integrate in their practice.

METHODS AND MATERIALS

This is a retrospective clinical report describing our perioperative outcomes using an abdominal wall elevation device. The study population included female patients who underwent laparoscopic gynecological surgery using the LevaLap 1.0 abdominal elevation device using a direct closed entry technique with a 3-mm port between July 2023 and May 2024. The exclusion criteria were patients less than 18 years of age. This study was determined to be exempt by the Institutional Review Board (IRB) review.

Demographic information reported included age, race, body mass index (BMI) and pertinent medical and history of abdominopelvic surgery through medical records and patient encounters. Abdominal access using LevaLap 1.0 was performed by direct entry with 3-mm port. The primary observational outcome was major vascular injury or visceral injury. Other entry-related events were documented including failed entry and number of entry attempts. Surgical history and insight from the preoperative screening tests and surgeon preference determined abdominal entry location. These locations included the umbilicus and left upper quadrant at Palmer's point.

Figure 1. CAST LevaLap 1.0 device.

After induction of anesthesia, an orogastric tube is inserted, standard positioning in the modified dorsal lithotomy position and draping are performed, and the bladder is drained. LevaLap 1.0 device consists of a transparent dome with a central entry pass-through port (**Figure 1**). The dome is connected to a standard wall suction via a lateral port. This suction in conjunction with the device elevates the anterior abdominal wall into the dome, effectively bringing the anterior abdominal wall structures away from major vascular structures. The LevaLap 1.0 device is placed over the umbilicus or desired entry point. With intraoperative ultrasound, underlying viscera is not brought into the LevaLap device as demonstrated in **Figure 2**. With this method, we used a 3 mm trocar and port, 10 cm length, for initial entry. Our direct trocar technique has been described previously.[12] Intraperitoneal access was confirmed with a laparoscope and gas connected. This method allowed for immediate

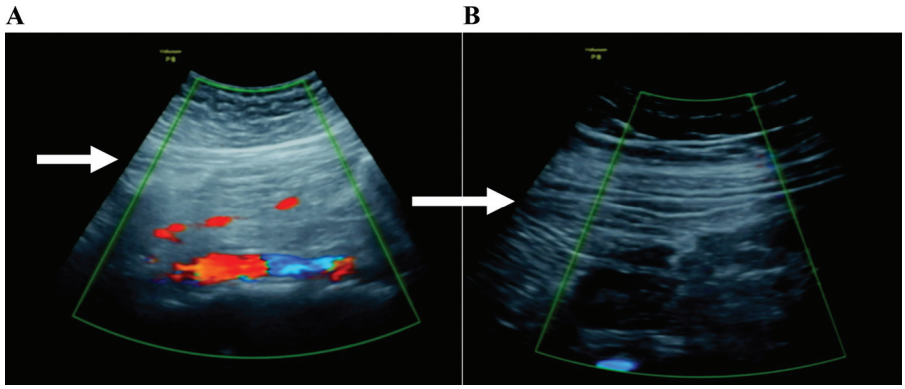

Figure 2. Ultrasonography before and after abdominal wall elevation device application (**A**) Prior to LevaLap 1.0 application. (**B**) After LevaLap 1.0 application. Arrow identifies peritoneal layer. No bowel visually brought into the LevaLap 1.0 dome.

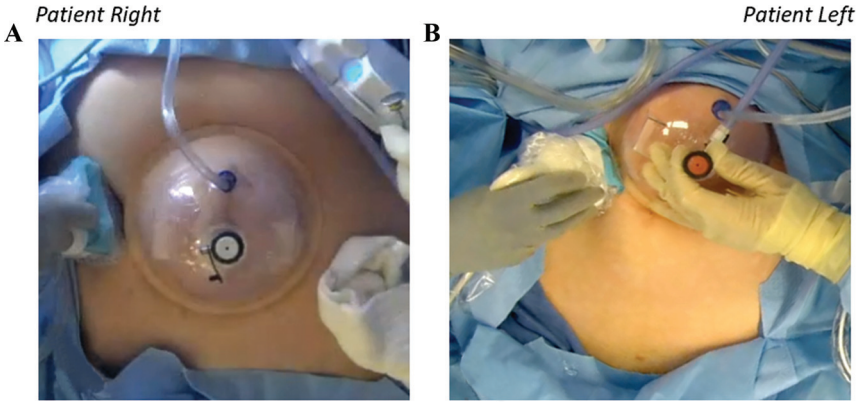

Figure 3. Entry methods used with abdominal wall elevation device. LevaLap 1.0 compatible with closed technique (**A**), direct entry using 3-mm trocar at the umbilicus (**B**), and direct technique using 3-mm trocar at left upper quadrant at Palmer's point.

visual confirmation of correct placement. Once adequate insufflation was achieved, the LevaLap 1.0 device and 3-mm port were removed, and replaced by the desired port size, usually either a 5-mm (conventional video laparoscopy) or 8-mm port (robotic assisted).

For patients with a history of midline laparotomy or a high likelihood of dense periumbilical adhesions, abdominal entry at a site distant from the umbilicus may be desired. Various sites of entry besides the umbilicus, left upper quadrant at Palmer's point, mid upper at Lee-Huang's point[14] and lateral to the umbilicus at Jain point.[15] Left upper quadrant site of entry is often considered when patients have suspected or known paraumbilical adhesions, history of umbilical hernia, or after 3 failed insufflation attempts at the umbilicus[16] (**Figure 3**).

Events of vascular and visceral injury were noted. Additionally, failed entry, number of entry attempts, or other adverse events during entry were recorded. Descriptive statistics were used to explain the data. Results were reported as mean, standard deviation (SD), range of values, or number and percent.

RESULTS

Twenty-five patients that underwent laparoscopy between July 2023 and May 2024 met inclusion criteria. Eighty-four percent (21/25) of the patients were White, 8% (2/25) were African American, and 8% (2/25) were Asian. Mean age was 42.6 years (range 22–72, SD 12.8). About half (48%) of the patients were nulliparous. Mean BMI was 26 kg/m^2 (range: 18–38 kg/m^2, SD: 5.5). More than half (52%) of the patients had some form of prior abdominal surgery, 40% had at least one prior laparoscopic procedure, and 16% had at least one prior laparotomy. **Table 1** describes the study cohort and history of surgeries.

Table 1.
Patient Demographics and Surgical History

	Range	Mean (±SD)
Age	22–72	42.6 ± 12.8
BMI	18–38	26 ± 5.5
	N =	**Percentage**
Any surgery	13	52.0%
Any laparoscopy	10	40.0%
0	15	60.0%
1	4	16.0%
2	2	8.0%
>3	4	16.0%
Any laparotomy*	4	16.0%
0	21	84.0%
1	1	4.0%
2	1	4.0%
>3	2	8.0%

*Types of laparotomy: 1 patient with umbilical hernia repair and 2 cesarean sections; 1 patient with endometriosis resection, cystectomy, and hysterectomy; 2 patients had 2 prior cesarean sections and 2 patients had 1 prior cesarean section.

LevaLap 1.0 was used successfully in all 25 patients with direct trocar entry using a 3-mm port. The umbilicus was the site of entry for 21/25 (84%) patients, and the left upper quadrant for the remaining 4 (16%) patients. There were no events of major vascular injury or visceral injury. There were no instances of failed entry when using the LevaLap 1.0 device (**Table 2**). No device-related complications, such as bruising or ecchymosis, were observed in our series. No patients in this series experienced wound infection or port-site hernia. The development of port-site hernia is generally influenced by patient factors, port size, and method of fascial closure, and we do not believe the use of the LevaLap 1.0 device has a direct or indirect effect on its occurrence.

DISCUSSION

Abdominal entry using the LevaLap 1.0 device had no major vascular injury or visceral injury. These findings are consistent with current estimates in literature that major vascular injury occurs at 0.01% to 1.0% and visceral injury occur at 0–0.5%.[3] Although "rare" by incidence, the absolute occurrence in context of near 13 million laparoscopic procedures a year globally means that many patients are still at risk for abdominal entry injury. Although the incidence is low, when an entry complication occurs, it can be catastrophic, leading to possible death or long-term consequences to the patient and their family. The occurrence of such a complication can also have a lasting psychological impact on the surgeon and operating team as second victims.[17] Thus, efforts must be made to proactively mitigate the risk of entry complications via education, awareness, and implementing preventive strategies. Traditional methods of abdominal wall elevation each have notable limitations. Elevation with one hand is highly operator-dependent, varying with hand size and strength; two-handed elevation has similar drawbacks and requires an additional assistant. Towel clip elevation has the same limitations, and can also traumatize the abdominal wall, with risk of skin tearing depending on the applied force. By contrast, the LevaLap 1.0 provides standardized abdominal wall elevation that is independent of operator variability, while minimizing trauma.We share our surgical experience to demonstrate the use of a device that has the potential to standardize appropriate elevation of the abdominal wall at the time of entry that may potentially minimize major vascular injury and visceral injury.

Table 2.
Abdominal Entry Methods and Related Events

Entry Methods	Number (N)	Percentage (%)
Successful first attempt entry	25	100.0%
Entry location		
Umbilicus	21	84.0%
Left upper quadrant	4	14.0%
Major vascular injury	0	0%
Bowel injury	0	0%
Failed entry	0	0%

The reported first-pass failure rate of the Veress needle is 14.5%.[18,19] The risk of needle-related injury after the second attempt increases to between 16.3% and 37.5%, with even higher rates reported with subsequent attempts.[20–22] Failed entry may occur with either Veress or direct techniques but more so with Veress.[8] A prior study of 55 cases with a similar abdominal wall elevation device, showed 89% successful entry on the first attempt with Veress needle.[23] Direct trocar insertion is a minimally invasive entry technique where the primary trocar is placed without prior insufflation. Generally, for this technique, the primary trocar is directly inserted through the umbilicus or desired site, with elevation of the anterior abdominal wall

either manually or with towel clips.[23] In this study, we demonstrate direct entry while using the LevaLap 1.0 device for abdominal wall elevation. Direct entry is faster than other entry techniques and avoids the potential complications of Veress entry, including failed pneumoperitoneum, preperitoneal or intestinal insufflation, or the rare, but very serious carbon dioxide embolism.[14] There are no well powered randomized controlled studies comparing occurrence of vascular or bowel injury by various methods of entry; however, a Cochrane review found a reduction in failed entry, omental injury, and extraperitoneal insufflation with the direct entry technique compared to Veress needle.[1]

For direct entry technique, we employed blind placement of primary trocar through layers of the fascia until loss of resistance was felt. The direct entry technique allowed for immediate confirmation of intraperitoneal access. For direct entry, a 3-mm diameter 10-cm length trocar is the surgeon's preference. However, one drawback to using a 3-mm port for entry is that both the LevaLap 1.0 device and port must be removed and replaced by a larger port size, usually either a 5-mm for conventional video laparoscopy or an 8-mm port for robotic-assisted procedures.

Available low-quality evidence suggests that one method of entry is not superior to another but there was an advantage of direct trocar entry over Veress needle entry for failed entry.[8] The LevaLap 1.0 device was Food and Drug Administration (FDA)-approved for Veress needle insufflation for laparoscopic entry at the umbilicus. It was reasonable to apply the benefits of the abdominal wall elevation device with direct entry techniques and alternative entry sites as the use of the device was not deemed to be a deviation from standard of care. It is notable to mention skin of the abdominal wall does not always sit flush at the pass-through point and can leave distance to the skin of the abdominal wall. This information is important when selecting length of entry method. There are various locations of abdominal access noted in the literature.[22]

Our study was limited due to its small size. Given the rarity of outcome measures, a very large sample size would be necessary to capture these adverse events in a randomized clinical trial. This study had participants in the obese BMI Class I and Class II, but no participants were from the Class III range. Additionally, one limitation of the current LevaLap 1.0 device is that after using the 3 mm trocar for direct entry, one has to remove the port along with the suction device and then reinsertion of a new larger size port that is appropriate for the surgical procedure. We anticipate the future modification of the LevaLap device where it could be split and removed without the need of removal of the already inserted port, thus more applicable for direct trocar entry with a 3-, 5-, or 8-mm port depending on the indication for surgery, using mini-laparoscopic technique, conventional laparoscopy or robotic-assisted procedures. The LevaLap 1.0 provides standardized abdominal wall elevation that is independent of operator variability, while minimizing trauma. Although the device adds the cost of a disposable instrument, we believe this drawback is outweighed by its potential. Further investigation may include analyses of operative workflow, procedure duration, and cost-effectiveness.

Despite these limitations, this study is novel and adds value by demonstrating the feasibility of using an abdominal wall elevation device with use of a direct trocar entry at multiple abdominal entry sites, which has not been previously published. Although our findings support feasibility, we acknowledge that claims of risk reduction remain speculative without direct comparative studies or larger sample sizes. Future studies should include higher-BMI patients, those with more extensive surgical histories, and broader surgical cohorts to improve generalizability.

CONCLUSION

The use of the LevaLap 1.0 device to elevate the abdomen in a standardized fashion is feasible for laparoscopic abdominal entry. Use of abdominal wall elevation along with existing preoperative precautions may be an additional step for improving safety during initial abdominal laparoscopic entry, standardizing elevation methods, and minimizing the risk of major vascular injury. However, given the low prevalence of entry complications, large comparative studies, ideally randomized, are necessary to determine whether standardized abdominal wall elevation with the LevaLap device is superior to manual or towel clip elevation.

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