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Evaluation of a Novel Port-Site Closure Device with Protected Needles and Local Transverses Abdominis Plane (TAP) Block with Review of the Literature

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Abstract

Laparoscopic and robotic surgery have become the preferred approach for complex gynecologic and gynecologic oncology cases. The first step in these procedures, and the last step, is dealing with trocar entry and then trocar closure to prevent hernia formation in these patients. Although the incidence of trocar site hernia is relatively low at 0.5% - 5.2%, these are the recognized hernias and may be an understatement of the true incidence. The study aims to evaluate the effectiveness of this new technique with prevention of postoperative hernias compared to standard techniques and to also evaluate the speed of closure, postoperative pain and recovery in this group of patients compared to a similar cohort of patients done by same physician.

Background and Objectives: This study was prospectively designed to include 100 patients undergoing robotic surgery before the device was approved and then 100 patients after the device was approved. All patients had their right lower quadrant port site closed with either the Carter Thomason device or the M-Close device. Closure time, time to first pain medication, total doses of pain medication, time to discharge, pain at 2 weeks visit, dimpling of skin (If present) and resolution if occurred were recorded. Hernias, infection, dimpling and hematoma were recorded at 2 week and 6 weeks visit.

Results: A total of 217 female patients were enrolled in the study with 100 of them having the standard fascial closure with the Carter-Thomason device and then 117 with the M-Close device. Time to closure was different in both groups with the average in the control group being 64.2 seconds while the average in the M-Close group was 43.8 seconds and the range was 39 - 148 seconds versus 37 - 56 seconds. Time to first postoperative pain medication in the recovery room was similar in

both groups (22 min vs 23 min) but only 68 patients (58%) in the M-Close required a narcotic versus 87 (87%) in the control group required the narcotic pain medication. None of the M-Close patients required a 2nd dose of narcotics, while 9 (9%) of the control group required a second narcotic dose. Average time to discharge home was longer in the control group 91.2 min versus 74 minutes ($p < 0.01$).

Conclusion: The novel device is quicker to use than even the standard procedure with no exposed needle and less narcotic use with faster discharge home times.

Introduction

Minimally invasive surgery has become the norm and not the outlier. Using both laparoscopic as well as robotic surgery, all specialties have developed procedures that are universally done by minimally invasive techniques. The minimally invasive techniques have obvious benefits of laparotomy such as less pain, faster recovery, less blood loss, less narcotic usage, smaller incisions, shorter hospitalization and all with comparable surgical outcomes. Laparoscopic and robotic surgery have become the preferred approach for complex gynecologic and gynecologic oncology cases. The first step in these procedures, and the last step, is dealing with trocar entry and then trocar closure to prevent hernia formation in these patients. Although the incidence of trocar site hernia is relatively low at 0.5% - 5.2%, these are the recognized hernias and may be an understatement of the true incidence [1-3]. Factors that may lead to hernias include, faster return to function and lifting prior to recommended time frame due to patients feeling better from the minimally invasive surgery. However, hernias with small incisions can be associate with serious complications such as bowel strangulation or bowel obstruction which may require re-operation. Even when the fascia Is closed, hernias can still occur below the fascia and between the peritoneum known as Spigelian hernias [4]. For this reason, it is recommended that when trocar sites are greater than 8 mm, that the fascia and peritoneum be closed.

Surgeons will usually close the trocar site by hand but this can become difficult in obese patients and is difficult to do through the small incisions used in minimally invasive surgery. Many times, the only thing that is truly closed is the subcutaneous tissue and not the fascia and not the peritoneum when it is done as a hand closure technique. It is not uncommon for some of the procedures to take more than 5 minutes and much frustration and sometimes requires the skin incision to be widened. These frustrations are even more pronounced in obese patients as the surgery becomes more difficult and the risk of hernias increases to 6.3% in patients with a body mass index of > 30 kg/m^2. Many novel techniques have been developed to be able to use direct line of sight to be able to make sure that the fascia and the peritoneum are closed. Many of these techniques introduce needles into the abdomen and increase the risk of bowel injury abdominal wall vascular injury. A new trocar site closure device has been developed that uses the same entry port and pulls up against the abdominal wall without exposing free needles into the abdomen. The device also allows for introduction of local anesthetic into the pre-peritoneal space where the nerve plexus is located. The study aims to evaluate the effectiveness of this new technique with prevention of postoperative hernias compared to standard techniques and to also evaluate postoperative pain and recovery in this group of patients compared to a similar cohort of patients done by same physician.

Materials and Methods

Patient Selection

This study was prospectively designed to include 100 patients undergoing robotic surgery before the device was approved and then 100 patients after the device was approved. All patients undergoing gynecologic or gynecologic oncology surgery greater than 18 years of age that had at least one 10 mm trocar site and that consented to the study were included. A central IRB was used and patients were consented in their language on the surgical day. Patients with prior hernia surgery were excluded.

Prior to beginning with the new device, 100 pa-

tients had all port sites greater than or equal to 10 mm closed with the Carter Thomason device using 0-Vicryl suture. Once approved, the next 100 patients had all port sites greater than or equal to 10 mm closed with the M-Close device, New Wave Endo-Surgical, Coconut Creek, Florida (Figure 1). The process of function includes passing the device either through the actual trocar and removing the trocar or passing the device with the T bullet end closed into the abdomen and then opening the bullet. Once the bullet is open the needles are deployed to 1st click and then pulled back into the fascia to include the peritoneum. The local anesthetic is then injected and then the needles are deployed to the 2nd click to lock into the bullet. A guide wire then runs the 0-Vicryl suture through the device and then the device is removed and the suture is tied down. All fascial closures were done by the same 2 surgical assistants during the entire study.

Study Design and Assessment Parameters

All patients had their right lower quadrant port site closed with either the Carter Thomason device or the M-Close device. Closure time was defined as the time from when the device touched the skin until the suture was tied down and cut. All demographic data was collected and patients were followed in the recovery room and at the 2 week and 6-week postoperative visit. Recovery room staff was not informed about the type of closure technique used and pain and discharge data were recovered from charts. Closure time, time to first pain medication, total doses of pain medication, time to discharge, pain at 2 weeks visit, dimpling of skin (If present) and resolution if occurred were recorded. Hernias, infection, dimpling and hematoma were recorded at 2 week and 6 weeks visit.

Results

A total of 217 female patients were enrolled in the study with 100 of them having the standard fascial closure with the Carter-Thomason device and then 117 with the M--Close device. The mean age in the control and M-Close groups were 51.4 and 53.2 years with similar ranges of 18 - 87 and 18 - 84 years respectively. Twenty-nine patients (29%) in the control group had surgery for malignant reasons while 38 patients (32.5%) in the M-close group had surgery for malignant reasons. The majority of surgeries in both groups included hysterectomy with other ancillary procedures including oophorectomy and lymphadenectomy, sacrocolpopexy and others. Patients were similar in size with the control group having and average height and weight of 61.4 inches and 165.3 lbs respectively. The study group had a height and weight of 62.7 inches and 160.9 pounds. The ranges in weight were 118 - 271 lbs for the control group and 110 - 258 lbs for the M-Close group. All trocar sites were closed with all sites being 12 mm ports. Eighty-two and 84% percent of the right lower quadrant trocar sites had tissue extraction through vagina or within the trocar while the others required minimal dilatation for tissue extraction with endoscopic bags. Time to closure was different in both groups with the average in the control group being 64.2 seconds while the average in the M-Close group was 43.8 seconds which was statistically significant ($p < .01$). Even more significant was the range which was 39 - 148 seconds versus 37 - 56 seconds. In the control group 11 patients require a re-application of the suture due to lack of peritoneal closure while only 1 in the M-Close required a reapplication due to mistakenly pulling suture out of device. Time to first postoperative pain medication in the recovery room was similar in both groups (22 min vs 23 min) but only 68 patients (58%) in the M-Close required a narcotic versus 87 (87%) in the control group required the narcotic pain medication. None of the M-Close patients required a 2nd dose of narcotics, while 9 (9%) of the control group required a second narcotic dose. Average time to discharge home was longer in the control group 91.2 min versus 74 minutes ($p < 0.01$). Pain was similar in both groups at the 4-week appointment with ranges of 1 - 3 in the control group versus 1 - 4 in the M-Close group. However, of those that had pain, 44 of 48 (91.7%) had it localized to the 12 mm port site (Right lower quadrant site) while only 32 of 46 (69.5%) in the M-Close group had it localized to the right lower quadrant 12 mm site.

Dimpling of the skin occurred in 12 (12%) of the control patients versus 5 (4.3%) of the M-Close patients at the 2-week appointment. Echymosis was evident in 8% of patients in both groups at the trocar site but no hematomas were palpated or required drainage. The majority of the dimples resolved at the 6 week (7 and 4 patients) or at the 10 weeks follow-up (11 and 5 patients) with 1 patient lost to fol-

low-up. No port site hernias were documented at the 2, 6- or 10-week follow-up period in either group.

Discussion

In this study, a novel device was evaluated with focus on closure ease, speed of closure, postoperative pain and time of discharge and postoperative complications. There are many laparoscopic and robotic cases done throughout the world and the port-site closure does not seem to be a big issue to most surgeons, but there are about as many ways and devices used to close the port sites as there are surgeons. Studies have used device such as straight needles, curved needles and even Deschamps ligature carrier to close the port-sites as we are all looking for faster and more efficient ways to close the port site [8-10,12]. Many of these studies do not even evaluate the closure via camera and do the procedure blindly. Some of these trials even used long unprotected needles into the abdominal cavity [12]. Of the many devices trialed and researched, the Carter-Thomason seems to be the most widely used and the fastest which is the reason we chose to compare this new device with the Carter-Thomason device [11]. We compared a new device, M-Close, to our standard fascial closure device, Carter Thomason device. The patient characteristics were similar and not statistically different with respect to age, weight, BMI and surgery type. All closures were done under direct visualization to assure fascial and peritoneal closure.

The use of the novel device led to a faster closure of the fascia even during the first 100 uses of the device not allowing for early learning curve. The average closure time was 21 seconds faster with the novel device than with our standard control. This shows the ease of use of the device and even more important was that there was never an exposed needle within the abdomen that can lead to bowel injury during closure by the assistant. Probably even more important the longest closure with the novel device took under 1 minute while the control device went as long as 2.5 minutes more than twice as long. Other studies have shown faster closures with other devices over hand closures, but even their tastes times were twice, 85-96 seconds which is almost twice the time for the M-Close device [13]. The closure with the novel device also included the peritoneum which is not done in hand closures and can lead to Spigelian hernias as bowel can get into space between fascia and peritoneum.

Postoperatively it was important to recognize that all patients required pain medicines at the same time but more patients in the control group, 87% vs 58%, required narcotics and 9% of patients required a second dose prior to release from the recovery room while none of the M_Close patients required a second pain medication dose. This is thought to be due to the injection of the anesthetic in the pre-peritoneal area similar to a TAP block. The time to discharge home, related to pain control, was almost 20 minutes faster which clears up space in the recovery room for new patients.

At follow-up visits, the novel device showed less localized pain to the fascial closure site and less dimpling of the skin at postoperative visits. Most of the skin dimpling cases will resolve at the 6- or 10-week appointment but it is a point of concern for patients during that postoperative time period. Neither device had recognized port site hernias but these are rare events and therefore would require a larger sample to evaluate and as such is a potential weakness of the study. In a study by Moran [5], there was a 1.23% risk of port-site hernia which in our study may have produced 2 cases. Therefore, a much larger study would have to have been done to power the study to look at pet-site hernias. In a separate study by Singal R, et al [6], 200 patients did not even have a 10 mm trocar site closed and they did not see a hernia in a 6-8-month follow-up. In a much larger literature review of over 18,000 patients in multiple trials, Gutierrez et al, showed a trocar site hernia rate of 0.104% in both 5 mm and 10 mm trocar sites [7]. These trials suggest that although we did not have any trocar site hernias, we had a relatively low number of patients in the trial and this is a weakness of the trial although it was not a primary outcome for the trial.

In conclusion, this novel device is at least equivalent to the standard and leads to important improvements including faster closure, no exposed intra-abdominal needles, less narcotic requirements, faster discharge times, and less postoperative pain and dimpling. There have been many novel procedures and tools to close the fascia with devices and without devices but all of them require exposed

needles into abdomen and all can include a lot of subcutaneous tissue especially in obese patients. This novel device introduces the needles much lower in the abdominal wall without exposing the needles and is faster than conventional method.

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