Study Protocol

Protocol Title: **Effectiveness of the video-assisted umbilical fascial closure in laparoscopic cholecystectomy: Prospective randomized clinical trial**

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I. Abstract

This prospective randomized trial aims to compare two umbilical closure techniques for trocar site hernia (TSH) in laparoscopic cholecystectomy. A prospective randomized study will be performed including consecutive patients who underwent an elective laparoscopic cholecystectomy for symptomatic cholelithiasis during the 18 months.

II. Background and Significance/Preliminary Studies

Laparoscopic cholecystectomy is currently the gold standard in the treatment for symptomatic cholelithiasis that offers a variety of advantages over conventional open surgery such as shorter recovery time, better cosmesis, less wound complication rates, and less pain.[1,2] Despite these advantages, LC can result in unique complications. Among these complications, trocar site hernia (TSH) is one of the most important complications because laparoscopic cholecystectomy promises smaller abdominal incisions and better cosmetic outcomes. A second surgical intervention due to TSH may overshadow the gains of the previous laparoscopic surgery. In studies conducted to date, the rate of trocar hernia in laparoscopic cholecystectomy has been presented at very different rates. Many studies have shown that the most frequent site of TSH is the umbilical trocar site.[3-6]
To avoid this important complication of laparoscopic cholecystectomy, many different techniques have been described to date for trocar port fascia repair. [7-12] Most of these techniques require special devices. In addition, a few studies compare these techniques with standard fascial closure, which is mostly used by surgeons.[11,12]

III. Study Aims

We hypothesized that the fascial closure of the umbilical trocar incision under the intraabdominal vision with the laparoscopic camera could be reduced TSH. This prospective randomized controlled study aims to assess whether fascial closure of umbilical trocar site under direct laparoscopic vision in LC can reduce the incidence of TSH.

IV. Administrative Organization

Department of General Surgery, Samsun Training and Research Hospital

V. Study Design

All consecutive patients with symptomatic cholelithiasis who underwent elective LC between January 2020 and June 2021 will be considered for enrolment in the study.

Patients who required urgent surgery due to acute cholecystitis will be excluded. The other exclusion criteria will be age under 18 years, previous umbilical hernia repair, and pre-existing umbilical hernia. All patients who enrolled in the trial will be provided an informed consent form

The sample size calculation was based on the data of a previous study. TSH rate was 6.6% in patients who underwent laparoscopic cholecystectomy. With a statistical power of 80% and a significance level of $p < 0.05$, the required sample size was 92 patients. Statistical analysis was performed using IBM SPSS Statistics version 20.0 (SPSS Inc., Chicago, IL, 2011) for Windows. Results were compared by the Student-t test or Mann-Whitney-U test for continuous variables and Chi-square or Fisher exact tests were used categorical variables. A p-value <0.05 was considered to represent statistical significance.

The primary outcome endpoint in the study is the presence of a TSH. Secondary endpoints are operative complications, wound infection, hematoma, pain, and length of hospital stay. Patients will be evaluated by clinical examination. If the surgeon suspected a TSH, abdominal ultrasound and/or abdominal computed tomography will be carried out. Any wound hematoma will be considered as a postoperative complication when they limited daily activities or required drainage. Wound infection will be defined as the presence of pain, redness, and purulent discharge at the umbilical trocar incision.

VI. Study Procedures

All consecutive patients with symptomatic cholelithiasis who underwent elective LC between January 2020 and June 2021 will be considered for enrolment in the study. Patients who required urgent surgery due to acute cholecystitis will be excluded. The other exclusion criteria will be age under 18 years, previous umbilical hernia repair, and pre-existing umbilical hernia.

Operations will be performed by four experienced surgeons. A supraumbilical transverse skin incision followed by an open technique with a vertical incision will be performed. Four trocars will be used. One 10-mm trocar was placed, and pneumoperitoneum will be obtained. A 30-degree endoscope will be inserted through this trocar. One 10-mm trocar (at the epigastrium) and two 5-mm trocars (at the right subcostal and lower right quadrant) were inserted under direct visualization. The gallbladder will be removed through the umbilical incision with an endo bag. The umbilical incision will be enlarged if needed to be for extraction of the gallbladder. After the extraction of the gallbladder, the size of the fascial defect will be measured directly using a ruler. The method of umbilical fascial closure for each patient will be determined using the computerized random generation of a number just before the operation. The number was given to the surgeon and the previously assigned umbilical fascial closure technique (assigned to that number) will be used. Patients will be randomly assigned to the umbilical closure non-video-assisted (UC) and umbilical closure with video-assisted (UCVA) groups.

In the UC group, the umbilicus incision will be closed with an interrupted suture with synthetic absorbable 0 suture (Pedesente®, Dogsan A.S., Trabzon, Turkey). In the UCVA group, the laparoscope will be inserted the epigastric trocar and the umbilical fascial defect will be visualized intraabdominal. Then the defect will be closed an interrupted suture with synthetic absorbable 0 suture (Pedesente®, Dogsan A.S., Trabzon, Turkey) including all layers of the abdominal wall under the direct reverse vision of the defect with a 30° laparoscopic camera.
The skin closure will be performed using a 3/0 polypropylene suture (Sterilen®, Dogsan A.S., Trabzon, Turkey). Patients' operative characteristics will be recorded after the operations.
All patients will receive standard postoperative care, including mobilization and returning to a normal diet as quickly as possible. Patient-controlled analgesia (tramadol 100 mg) will be provided for the first 24 h after surgery. A nonsteroidal anti-inflammatory agent (diclofenac 25 mg, intramuscular, two times daily) will be given until discharge from the hospital.
Visual analog scale (VAS; range 0- 10) will be evaluated one day before the surgery (VASP). Also, postoperative (PO) first day (VAS1) were recorded.
Follow-up
All patients will be scheduled to return for an outpatient visit in the second week and every three months after the surgery.

VII. References

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