

Prospective Study on a Novel Port-site Closure Device (EZ Close): Effectiveness and Comparison with Carter-Thomason

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Study Protocol and Statistical Analysis Plan (SAP)

Study Design

We randomized eligible patients recruited between July 2017 and June 2018 in a randomized controlled trial to compare the efficacy and safety of the two port-site closure device, the EZ-close™ Port Site Closure System (Medical Impact, Seoul, South Korea) and the Carter-Thomason CloseSure System® (Cooper Surgical Inc., Trumbull, CT, USA). This study was approved by the institutional review board of St. Vincent's Hospital at the Catholic University of Korea (13 July, 2017). The design and reporting of this trial were in accordance with the criteria of the CONSORT (Consolidated Standards of Reporting and Trials) statement. The current trial is registered at ClinicalTrials.gov (#NCT03374189).

Study population

We assessed the eligibility of all patients undergoing laparoscopic or robotic surgery that used laparoscopic ports. The inclusion criteria were as follows: patients aged between 18 and 80 years, and patients who used ports with a size > 10mm. The following patients were excluded: patients who used ports with a size ≤ 10mm, patients who underwent concurrent surgery for other reasons, and patients who refused to participate in the study.

Study Intervention

After obtaining written informed consent, the participants were randomly assigned to use either the EZ or CT at the end of their surgery. All procedures were performed by a single surgeon (SJL), who was familiar with using both devices prior to the current study. As it was stated earlier, only port-sites that used laparoscopic trocars larger than 10mm were closed using either the EZ or CT. The only trocar larger than 10mm that we used was the TRO-12V1 (Lagis TRO-12V1, Taichung, Taiwan), which is a 12mm bladeless trocar with a blunt shaped tip. The procedure for the use of the CT will not be described in the current text because it is already described in other papers. The procedure for the use of the EZ is described hereafter. The EZ is composed of a body part, a cartridge and an anchor needle. There is a suture thread within the cartridge. First, the cartridge is mounted to the body. Then, the body is inserted through the port-site. The body holder is then pulled upward. This will expand the wings of the cartridge and expose the suture thread. The anchor needle is diagonally inserted along the body hole. Once the needle passes through the peritoneum and reaches the wing, the button located at the head of the needle is pressed one time and then released. Pressing the button will advance the needle with the groove inside and capture the spring connected with the suture thread. Once the spring is captured, the needle is pulled out through the body hole. The same procedure is performed for the opposite side. The body holder is pushed downward. This will fold the wings of the cartridge. Finally, the body is removed from the port-site and the suture thread is tied.

Randomization

The patients were randomly assigned to use either the EZ or CT, which was achieved using random computerized numbers created by the Excel 2007 (Microsoft, Redmond, WA, USA). Only the patients were blinded to the treatment allocation.

Study outcomes

The primary outcome was the time taken to complete the closure of the port-site using either the EZ or CT. The start of the procedure was defined as the point when the device was first inserted through the port-site and the end of the procedure was defined as the point when the device was removed from the port-site. A stopwatch was used to measure the time.

For the secondary outcomes, we examined whether there was visceral organ injury and whether there was the need for additional instruments during the procedure at the time of the surgery. In addition, we examined whether there was wound infection, wound dehiscence, hernia and ascitic fluid leakage 3 days post-op and 1 week after discharge.

Sample size and statistical analysis

We estimated that a total of 79 patients would be needed to detect a difference between the two groups, with a two-tailed α of 0.05 and a $(1-\beta)$ of 0.80, if there was a decrease of 10% in the primary outcome. The sample size included an attrition rate of 10%.

Descriptive statistics were used to describe the results. For the comparison of categorical variables, a chi-square test and Fisher's exact test were used. For the comparison of continuous variables, an independent t-test and Mann-Whitney test were used. For the comparison of continuous variables, an independent t-test and Mann-Whitney test were used, depending on the result of a Shapiro-Wilk test for normality. A p value of < 0.05 was considered statistically significant, and this was used for all of the tests. SPSS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) was used for the statistical analysis.