Published online 2021 May 16.

Research Article



# Comparison of Peritoneal Closure Versus Non-closure After Non-infected Elective Laparotomy with a Midline Incision: A Randomized Clinical Trial

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#### **Abstract**

**Background:** There is no consensus regarding closure or non-closure of peritoneum in laparotomy, and this topic remains a controversy among surgeons.

**Objectives:** This clinical trial aimed to compare short-term and long-term benefits of peritoneal closure with non-closure in an academic medical center.

**Methods:** In this double-blinded two-arm parallel-group randomized trial, 124 patients undergoing laparotomy with midline incision were assessed from March 2019 to September 2019 at Imam Hossein Medical Center, Tehran, Iran. We used the Rand function of the Excel software to randomly assign 62 patients to the peritoneal closure group and 62 patients to the non-closure group. The patients were evaluated for short-term complications including wound-related fever, infection, need for analgesics, pain in the first 2, 6, 24, and 48 hours postoperatively according to the Visual Analogue Scale (VAS), duration of hospitalization, as well as long-term complications including incisional hernia and intraperitoneal adhesion one year after the surgery. Statistical analysis was carried out with SPSS version 22 software.

**Results:** The non-closure peritoneum group had a lower rate of wound-related fever, infection, and analgesic need than the peritoneal closure group, but these differences were not statistically significant (P = 0.488, P = 0.455, and P = 0.062, respectively). The adhesion rate and incisional hernia incidence one year after the surgery were not significantly different between the two groups (P = 0.363, P = 0.586). Pain intensity was significantly lower in the non-closure group than in the closure group in the first two, six, and 24 hours (P = 0.008, P = 0.004, and P = 0.047, respectively) but not significantly at 48 hours (P = 0.146).

**Conclusions:** Peritoneum closure after non-emergency, non-infected laparotomy increases the postoperative pain while it has no benefit for long-term complications like incisional hernia or intra-peritoneal adhesion.

Keywords: Laparotomy, Peritoneum, Complications, Pain

## 1. Background

The term laparotomy is generally referred to as a vertical midline incision of the abdomen. The peritoneum is the innermost layer of the abdominal wall, which, once opened, the abdominal cavity becomes available. There is still disagreement on the closure of this layer after laparotomy. One of the reasons that some surgeons prefer to suture this layer is to maintain the anatomical structure of the abdominal wall and also to reduce the risk of infection, incisional hernia, and adhesion (1). On the other hand, the reason that other surgeons do not suture this layer is its rapid healing within 48 to 72 hours without any suture, and reductions in surgery time, the need for analgesics, and length of hospitalization (2). Therefore, the disagree-

ment over closure or non-closure of peritoneum still remains on. Most of the studies in this field have been performed on transverse incisions of the abdomen and in patients in the gynecology department, especially cesarean section patients, while the number of studies that have made this comparison in surgical patients with midline laparotomy incisions is very small.

## 2. Objectives

This study was designed to compare the short-term and long-term effects of closure versus non-closure of the peritoneal layer in midline laparotomy incisions at an academic medical center (3-5).

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Received 2020 August 11; Revised 2021 January 19; Accepted 2021 January 24.

#### 3. Methods

This double-blinded two-arm parallel-group randomized trial was conducted at Imam Hossein Medical Center, Tehran, Iran, from March 2018 to March 2019. The approval of the Ethics Committee of Shahid Beheshti University of Medical Sciences was obtained (IR.SBMU.MSP.REC 1397. 430), and informed consent was attained from all participants before entering the study. The trial was registered in THE Iranian Registry of Clinical Trials (IRCT) with code IRCT20200404046936N2.

## 3.1. Sampling

We assessed all patients who were candidates for laparotomy with midline incision during the study period, of whom 124 who met the inclusion and exclusion criteria were recruited in the study. The inclusion criteria were laparotomy with midline incision and age of equal to or greater than 16. The exclusion criteria were a history of laparotomy, diabetes mellitus, known connective tissue disorders, infection, obstetrics surgery, and emergency cases.

#### 3.2. Randomization

We performed simple randomization using the Excel software's Rand function (random number table). A mixture of numbers from 1 to 124 was made, and patients entering the study get the next code from the table in order. If the number was below 62, we assigned the patient to the control group, and if it was above 62, the patient was allocated to the intervention group. In the control group, we did not close the peritoneal layer, and in the intervention group, the peritoneal layer was closed.

## 3.3. Blinding

The patients and the postoperative care and outcome assessment team were unaware of the patient's group. A resident of surgery, unaware of the allotted group of the patients, assessed them regarding pain intensity, need for analgesics, wound-related fever, and wound infection postoperatively. Pain intensity assessment was performed via the Visual Analogue Scale (VAS). One year after the surgery, a surgeon performed a physical examination for finding an incisional hernia. Also, a radiologist unaware of the patient group performed abdominal sonography to assess adhesion and recurrence.

## 3.4. Sample Size

According to Sharami study (6) and based on the sample size formula, considering an alpha (first error of the survey) of 0.05, beta (second error of the study) of 0.2, P1

(complications in the control group) of 0.7, and P2 (complications in the adhesive group) of 0.3, 58 cases were considered for the study. Finally, with the estimation of a 10% dropout, we allotted 62 participants to each group.

## 3.5. Statistical Analysis

We used SPSS version 22 software (IBM, Inc., Armonk NY, USA) for data analysis. Mean  $\pm$  standard deviation was used to display quantitative variables and frequencies to describe qualitative variables. The comparison of quantitative variables was carried out by the independent t test, and the comparison of qualitative variables was performed using the chi-square test and Fisher exact tests. The P statistical significance value was considered less than 0.05.

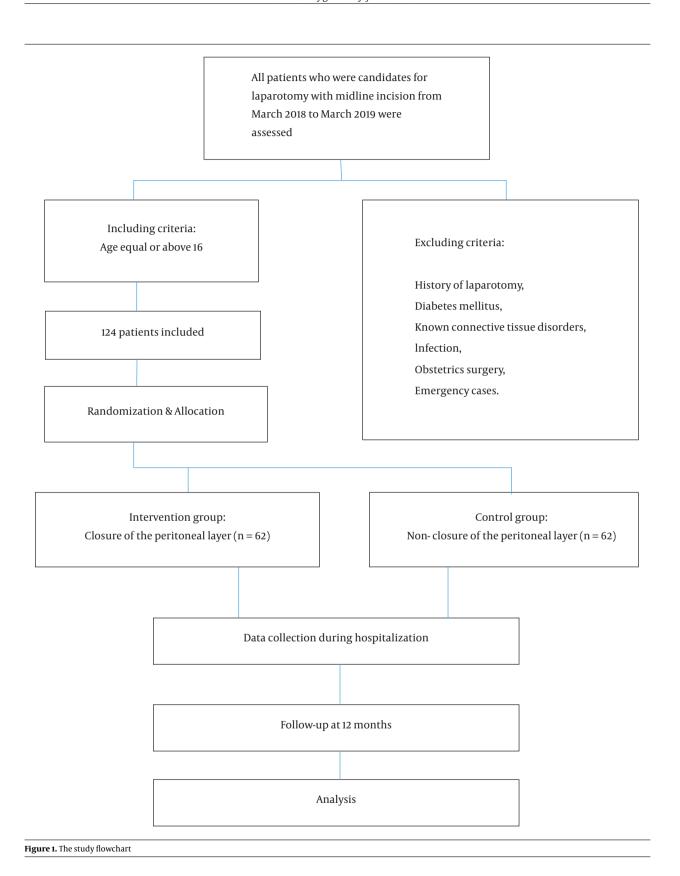
In the closure group, peritoneal closures were carried out using absorbable continuous sutures, while in the non-closure group, the peritoneal layer was not closed separately, and the abdominal fascia was closed directly. The abdominal fascia was closed using 1-0 nylon continuous sutures. The skin was closed using 2-0, or 3-0 nylon interrupted sutures. The study flowchart is shown in Figure 1.

## 4. Results

The mean age of the participants was 30.4 years, ranging from 10 to 52 years. There was no significant difference between the two groups regarding age and sex (P = 0.712, P = 0.321) (Table 1).

Patients with no peritoneal closure had a lower rate of wound-related fever, infection, and analgesic need, although these differences were not statistically significant (P = 0.488, P = 0.455, P = 0.062). The highest difference observed between the two groups was related to the need for analgesics, which was near twice higher in the closure group (Table 2). The mean length of hospitalization was 4.2  $\pm$  1.3 in the non-closure group and 2.6  $\pm$  1.4 in the closure group, but this difference was not significant (P = 0.072). The mean pain intensity in the closure group was significantly higher in the first two, six, and 24 hours (P = 0.008, P = 0.004, and P = 0.047, respectively) but not significantly higher in the first 48 hours (P = 0.146) (Table 3).

Concerning long-term complications, the rate of intraperitoneal adhesion detected by sonography one year after the surgery was non-significantly lower in the non-closure group than in the closure group (10.7 vs. 16.7%, P = 0.363). At the same time, the incisional hernia was non-significantly lower in the closure group (12.5 vs. 9.3%, P = 0.586) (Table 3).



**Table 1.** Comparison of Basic Variables Between Study Groups <sup>a</sup>

Variables	Non-closure of Peritoneum (n = 62)	Closure of Peritoneum (n = 62)	P-Value
Gender			0.712 <sup>b</sup>
Male	25 (40.3)	23 (37.1)	
Female	37 (59.7)	39 (62.9)	
Age (y)	$29.35 \pm 11.28$	$31.53 \pm 13.02$	0.321 <sup>c</sup>

 $<sup>^{\</sup>rm a}$  Values are expressed as No. (%) and mean  $\pm$  SD unless otherwise indicated.

**Table 2.** Comparison of Infection, Fever, and Analgesic Need Incidence in Study Groups <sup>a</sup>

Variables	Non-closure of Peritoneum (n = 62)	Closure of Peritoneum (n = 62)	P-Value
Fever	3 (4.8)	5(8)	0.488
Infection	3 (4.8)	6 (9.6)	0.455
Need for analgesics	11 (17.7)	20 (32.3)	0.062

<sup>&</sup>lt;sup>a</sup> Values are expressed as No. (%) unless otherwise indicated.

Table 3. Comparison of Pain Intensity (VAS), Hospitalization Length, Adhesion, and Incisional Hernia Incidence Rate in Follow-up of Study Groups a

Variables	Non-closure of Peritoneum $(n = 62)$	Closure of Peritoneum $(n = 62)$	P-Value
Pain intensity			0.008
First 2 hours	$6.3\pm1.3$	$7.0\pm0.9$	
First 6 hours	$6.4\pm1.1$	$6.9\pm0.9$	0.004
First 24 hours	$5.0\pm0.9$	$5.3\pm0.8$	0.047
First 48 hours	$3.9\pm1.3$	$4.0\pm0.2$	0.146
Hospitalization (days)	$4.2\pm1.3$	$2.6\pm1.4$	0.072
Adhesion	6 (10.7)	9 (16.7)	0.363
Incisional hernia	7 (12.5)	5 (9.3)	0.586

 $<sup>^{</sup>m a}$  Values are expressed as mean  $\pm$  SD and No. (%) unless otherwise indicated.

## 5. Discussion

The midline incision is one of the most common incisions in abdominal surgery. The midline incision's superiority is indebted to its better access to abdominal content, simple dissection of abdominal layers, better view, and less pain after the surgery in comparison with other incisions. (3). There are several choices available for a surgeon to close the abdominal wall. The surgeon can close the abdominal wall in accordance with its anatomical structure and in the order that it had been opened, or he can suture some of the layers together or not at all (such as the peritoneum) (4). One of the possible reasons to close the peritoneum is to retain the anatomical structure of the abdominal wall with an approximation of cut edges, which might result in faster healing, less infection, and adhesion (7). In contrast, some of the possible reasons not to close the peritoneum are its rapid healing without approximation of edges, and reduction of surgery duration, analgesic use, infection risk, and hospitalization length (5). If the results of studies suggest that no important complication affects the patient without the closure of the peritoneum, this method might reduce costs and duration of surgery. Most of the previous studies were performed on obstetric surgeries such as hysterectomy and caesarian, in which the overall tendency is toward peritoneum closure (8).

Postoperative pain is a common complaint, especially after laparotomy. Some other studies have shown that not closing the peritoneum is associated with less pain after the surgery. In a study by Khan et al., 60 patients underwent appendectomy among whom, 30 patients received peritoneum closure, and 30 others were operated on with the non-closure method (9). The mean pain intensity and the analgesic need were significantly lower in the non-closure group on days 0 and 1 after the surgery, which is consistent with our results. On the other hand, in another

<sup>&</sup>lt;sup>b</sup> Chi square test.

c<sub>t-test</sub>

RCT by Hugh et al., patients undergoing elective or emergency abdominal laparotomy were randomly allotted to the peritoneum closure group with catgut continuous suture and non-closure group. In their study, there was no significant difference between the two groups regarding narcotic usage, pain intensity, and complications (4). In our study, the need for analgesics in the non-closure group was almost twice lower than that in the closure group, but not statistically significantly (P = 0.062). According to the VAS, the mean pain intensity in the first two, six, and 24 hours postoperatively was significantly lower in the nonclosure group (P = 0.008, P = 0.004, and P = 0.047, respectively) while in the first 48 hours, the difference was not significant (P = 0.146). Lower pain intensity in the non-closure group might be due to peritoneum-rich innervation and poor blood supply. Suturing the peritoneum can cause tension, which might disrupt its blood supply and lead to ischemic pain (6).

As a result of peritoneal suturing, due to tissue granulation and fat necrosis, more tissue damage will be produced, which, in turn, might increase the risk of infection. Many other studies have highlighted the advantage of nonclosure peritoneum for decreasing the infection rate (10). In our study, the infection rate in the non-closure group was lower than that in the closure group, but the difference was not statistically significant (P = 0.488). Also, the incidence of wound-related fever was not significantly different between the two groups (P = 0.455).

Incisional hernia is a defect in the abdominal wall fascia and one of the long-term complications of laparotomy. Determination of the cause of incisional hernia in a specific patient might be difficult, but obesity, primary defects in wound-healing, multiple previous surgeries, previous incisional hernia, and technical faults during wound repair are some of the risk factors (11). Incisional hernia incidence has been reported from 2 to 20% after abdominal surgeries. Supporters of peritoneum closure believe that the closure of this layer will improve layer fibrosis, thereby decreasing the risk of incisional hernia (12). Our study did not confirm this result after one year of the surgery, and currently, there is no evidence regarding an association between the closure of the peritoneum and incisional hernia reduction (P = 0.586).

Intraperitoneal adhesions are a catastrophic complication of abdominal surgeries. Several factors can lead to adhesions. Some animal studies propose that retaining the peritoneal surface integrity by suturing it at the end of the surgery will help to reduce future adhesions (13). Our study does not support this view, as no significant difference was observed between the two groups in terms of intraperitoneal adhesions after one year of the surgery (P = 0.363).

## 5.1. Conclusions

The results of the current study showed that peritoneum closure after non-emergency, non-infected laparotomy increased the postoperative pain while it had no benefit for long-term complications like incisional hernia or intra-peritoneal adhesion. To confirm such results, further studies with larger sample sizes and longer follow-up duration are needed.

## **Acknowledgments**

The authors took it upon themselves to express their humble thanks and gratitude for supports of Shahid Beheshti University of Medical Sciences and also patients who helped us with this study.

#### **Footnotes**

**Authors' Contribution:** A.M.T. developed the original idea and the protocol, abstracted and analyzed data, wrote the manuscript, and is a guarantor. M.H.J. contributed to the development of the protocol, abstracted data, and prepared the manuscript.

Clinical Trial Registration Code: IRCT20200404046936N2.

**Conflict of Interests:** The authors declare that they have no conflict of interest.

Ethical Approval: IR.SBMU.MSP.REC 1397. 430.

**Funding/Support:** This work was supported by the vice-chancellor's Office in Research Affaires of Shahid Beheshti University of Medical Sciences (grant number 0981/2018).

**Informed Consent:** Informed consent was obtained from all individual participants included in the study.

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