

The Mesh-RTL Project for Prevention of Incisional Hernia. Clinical Trial of Non-inferiority to Compare Two Aponeurotic Closure Techniques in Midline Laparotomy in Patients With Elevated Risk for Hernia.

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Introduction:

The laparotomy is a surgical incision into the abdomen cavity performed to examine the abdominal and retroperitoneal organs. It is classified according to the medical indication: exploratory, therapeutic, stagemaker, and recently added "damage-control" laparotomy.

There exists so many ways to access the abdominal cavity, usually in relation with the organ or structure to treat; being classified in midline laparotomy, paramedian, transversal, oblique, abdominal-thoracic, etc.

Either an emergency or scheduled procedure, the more usual and functional continues being the midline laparotomy, since it allows a broader and faster approach, with less bleeding and easily to extend if it becomes necessary.

Both the evisceration/eventration and the hernia are considered the most frequent complication of the midline laparotomy with a high morbidity and mortality related. Conditions that will require a second intervention, in Mexico represent the seventh cause of elective surgery and fourth cause of emergency procedures.

So far only the use of the mesh has proven useful in reducing this complication. Our group published in 2016 a clinical trial where it showed that the technique is safe and effective to reduce the presence of incisional hernia, however the use of the mesh brings with it problems such as cost, possibility and use in contaminated cavities and postoperative pain. Therefore, the use of the RTL technique as an alternative means to this will help to have one more option for the management of patients with a high risk of incisional hernia.

Problem Statement:

Does the RTL closing technique in the midline laparotomy has the same incident of herniation than the close with supraaponeurotic mesh in patient with elevated risk?

Justification

The presence of postincisional hernia need to be considerate as a serious disease, insomuch as it carry on highs rates of morbimortality. The presence of this eventuality is among 0.4-1.2% in elective

surgery and up to 30% in emergency procedures.

It is calculated in de U.S.A. an approximate of 1 million of reinterventions a year to correct this condition, with the respective monetary, time and suffering cost to the patient and the health system.

Given the seriousness, the ultimate global consensus has determinate three main axes to the surgical community to board:

- Identify the relevance of the problem
- Improve the theoretical knowledge and technical capacity in the closing of the abdominal wall
- Implement prophylactic measures in the patients, especially in those with elevated risk.

With the present study we aim to contribute to this global recommendations, comparing two closing techniques of the abdominal wall after a midline laparotomy in patients with elevated risk of herniation. Both techniques are proved safe and useful in other studies, with no comparison to date.

Demonstrate that the use of RTL technique has a similar incidence of herniation than the mesh, in an attempt to prevent postincisional hernias after a midline laparotomy, will bring to the surgical community a cheaper and practical alternative to the mesh.

Objectives:

General:

To determinate if the incidence of post-incisional hernia in patients with high risk after a midline laparotomy are similar between the closure of the abdominal wall with the RTL technique and the supraaponeurotic mesh closure reinforcement.

Specifics:

- To identify the patients with high risk using de validated HERNIA-Project Score.
- To determinate the incidence of post-incisional hernia after one year of the initial midline laparotomy.
- To compare the incidence of post-incisional hernia between the two groups.
- To describe the complications related to each closure technique.

Hypothesis:

Ho Hypothesis:

There is no difference in the incidence of post-incisional hernia between the RTL technique and the reinforcement with supraaponeurotic mesh closure wall.

H1 Hypothesis:

There is difference in the incidence of post-incisional hernia between the RTL technique and the reinforcement with supraaponeurotic mesh closure wall.

Sample size:

The sample size was calculated according to the formula published by Bouemn et all 2015, and based on the results of Kholer and collaborators 2019, where they found in which a percentage of

success was estimated with the standard treatment of 18.5% compared to the experimental management of 7.2%, with a margin of no less than 3%, with an alpha for a tail of 0.05%, and a beta of 20 %, with a percentage of estimated losses of approximately 10%, a total of 195 patients per group was obtained.

Statistical analysis Data are presented as frequency and percentage, comparisons between groups were using the χ^2 test for binary data or Fisher's exact test. Continuous variables are presented as median and range interquartile range and were compared using the Mann-Whitney U-test or t student test if they meet normal criteria. p-Values of less than 0.05 were considered significant. Statistical analyses were performed with SPSS version 25.0.0. Analysis by intention to treat was used.

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Interventional Study Model:	Parallel Assignment
	Clinical trial of non-inferiority
Number of Arms:	2
Masking:	Triple (Participant, Care Provider, Investigator)
Allocation:	Randomized
Enrollment:	390 [Anticipated]

Primary Outcome Measure:

1. Incisional Hernia

any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination

[Time Frame: 12 and 24 months]

Secondary Outcome Measures:

2. postoperative complications

an undesirable and unintended result of an operation affecting the patient that occurs as a direct result of the operation. Haematoma, Facial dehiscence, mesh removal, ileus, reinterventions, re-admissions and death

[Time Frame: 1 month, 1 and 2 years]

Elegibility:

Minimum Age:	18 Years
Maximum Age:	70 Years
Sex:	All
Gender Based:	No

Accepts Healthy Volunteers: Yes

Criteria:

Inclusion Criteria:

- Patients older than 18 years undergoing midline laparotomy, independently of diagnostic or condition, elective or emergency surgery
- Patients with a score equal or greater than 7 of the hernia score
- Patients who accept to participate and sign the informed consent

Exclusion Criteria:

- Patients managed with open abdomen or with the impossibility of close the wall
- Patients who had a previous incisional hernia or patients who are participating in another trial
- Patients with a life expectative less than 12 months
- Pregnant patients Patients with the antecedent of rejection of prosthetic material

Revised Hernia Score.

$$\text{Revised HERNIA score} = 1 \times (\text{BMI} \geq 25 \text{ kg/m}^2) + (1 \text{ COPD}) + (5 \times \text{extended laparoscopy}) + (6 \times \text{laparotomy}) + (3 \times \text{earlier abdominal operation})$$

The revised HERNIA score was developed and low risk was assigned 0 to 6.9 points, medium risk was assigned 7.0 to 9 points, and high risk was assigned ≥ 9 points.

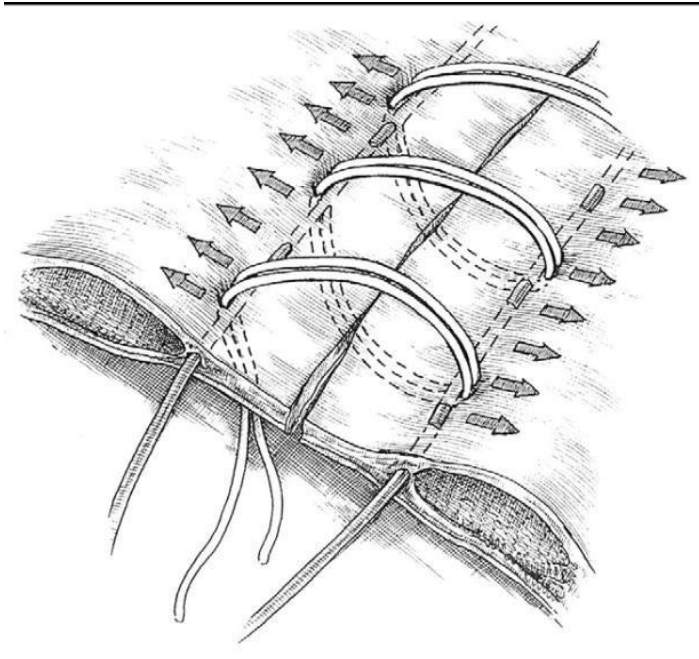
Arms and interventions:

Active Comparator: Onlay Mesh Reinforcement group

The midline fascia was closed with running, slowly absorbable sutures (PDS 1-0) with a recommended suture length to wound length ratio of 4:1. An anterior plane with a width of about 8 cm was created between the anterior fascia and the subcutis. A Lightweight polypropylene mesh was used and placed on the anterior rectus fascia with an overlap of 3 cm. The mesh was fitted in the dissected space and it was fixed with PDS 2-0 suture. Fixing points are placed taking the mesh and the anterior fascia of the rectus muscle, at a distance of 3 cm between each point until completing its circumference.

Experimental: RTL reinforcement group

The RTL suture is placed parallel at a distance of 0.5 cm from the fascial margin. Ideally the thread should lie between the anterior and the posterior rectus muscle sheath; there should be no contact with the rectus muscle. A nonabsorbable monofilament polypropylene thread and a 65-mm $\frac{1}{2}$ needle are used. Around this longitudinal thread, the continuous suture for fascial closure is introduced immediately lateral to the thread; with running, slowly absorbable sutures (PDS 1-0) with a recommended suture length to wound length ratio of 4:1. An anterior plane with a width of about 8 cm was created between the anterior fascia and the subcutis.



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