

Hospital Edmundo Vasconcelos

“Comparison of midline aponeurosis incision closure with the use of Trocar of 10-12 mm using Polydioxanone and Polyglactin in video-laparoscopic surgeries: Randomized Clinical Trial”

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Study Design

This is a controlled randomized clinical trial, partially blinded, conducted at Hospital Edmundo Vasconcelos. The study will compare the incidence of postoperative incisional hernia in patients undergoing elective or urgent video-laparoscopic surgeries (cholecystectomy, appendectomy for acute appendicitis, and laparoscopic inguinal hernia repair), using 10-12 mm trocars. The closure of the umbilical aponeurosis will be performed with polyglactin 0 or polydioxanone 2-0 using a standardized technique. After informed consent, patients will be randomized into two arms (polyglactin and polydioxanone), with approximately 125 patients per group (total of 250, accounting for loss to follow-up). Data will be collected during evaluations at 7 days, 30 days, 6 months, and 12 months postoperatively, with outcomes focused on the incidence of incisional hernia and complications.

Introduction

The use of 10-12 mm umbilical trocars in video-laparoscopic surgeries is associated with the occurrence of postoperative umbilical hernia, with reported incidences ranging from 0.14% to 22%. The aponeurosis closure technique and the type of suture material are determining factors for preventing these complications. Slowly absorbable sutures, such as polydioxanone, have shown promise in reducing hernias compared to rapidly absorbable sutures like polyglactin. However, there are no randomized clinical trials directly comparing these sutures for umbilical trocar closure in elective or urgent video-laparoscopic procedures.

Justification

Determining the superiority of a suture material with slower absorption characteristics and lower inflammatory response in preventing hernias can directly influence surgical protocols, reducing complications and reoperations. Additionally, standardizing the closure technique may lead to better functional outcomes and less chronic pain.

Hypothesis

The use of polydioxanone 2-0 suture will result in a lower incidence of incisional hernia compared to polyglactin 0 suture for midline incision closure using 10-12 mm trocars.

Objectives

Primary Objective

- Compare the incidence of incisional hernia after aponeurosis closure with polyglactin 0 and polydioxanone 2-0 in elective or urgent video-laparoscopic surgeries.

Secondary Objectives

- Identify early complications (infection, seroma, dehiscence) and late complications (chronic pain, granuloma)
- Compare abdominal pain across different periods.
- Correlate the incidence of incisional hernia with comorbidities (BMI, diabetes, smoking)
- Differentiate costs between the materials.

Methodology

Study Type

- Type: Controlled, prospective, randomized, partially blinded clinical trial.
- Blinding: Partial (surgeons not blinded, postoperative evaluators blinded).
- Location: Hospital Edmundo Vasconcelos.
- Groups: 2 randomized arms
 - Use of Polyglactin 0
 - Use of Polydioxanone 2-0

Population

- **Inclusion Criteria:**
 - Adults (>18 years) undergoing elective or urgent video-laparoscopic cholecystectomy or inguinal hernia repair
 - BMI < 35 kg/m².
 - Signed informed consent.
- **Exclusion Criteria:**
 - Pre-existing/large umbilical hernias, converted surgeries, pregnant women, immunocompromised patients, collagenoses, local infection, contraindication to video-laparoscopy.

Randomization and Blinding

- Allocation by simple randomization, surgeon not blinded, postoperative evaluators and VAS applicators blinded.

Intervention

- Procedure: Elective or urgent video-laparoscopic surgeries with 10-12 mm trocar incision.
- Closure Technique: Aponeurosis closure with polyglactin 0 or polydioxanone 2-0 suture in standardized "X" stitches.

Evaluation and Outcomes

- Outpatient follow-up: 7 days, 30 days, 6 months, and 12 months.
- Physical examination to detect incisional hernia by a masked examiner and abdominal wall ultrasonography at 6 and 12 months for all patients.
- VAS questionnaires, functional assessment (optional: SF-12).
- Analysis of surgical complications (infection, seroma, dehiscence) and recording of preoperative comorbidities.
- Outcomes:
 - Primary: Incidence of incisional hernia.
 - Secondary: Surgical complications, pain, cost, chronic pain, bulges, granulomas

Statistical Analysis

- Sample Size: Based on incidences of 15% (polyglactin 0) and 5% (polydioxanone 2-0), with a 10% difference, one-sided test ($\alpha=0.05$, power=80%), an estimated 108 patients per group (total of 216). To account for losses to follow-up, 125 patients per group will be recruited (total of 250).
- Statistical analysis: Comparisons between groups will use Fisher's exact test or chi-square for categorical variables and Student's t-test or Mann-Whitney for numerical variables, following data normalization after collection.

Ethical Aspects

- Approval by the Ethics Committee
- After study approval by the ethics committee, publish the study protocol in clinical trial registries (such as the Brazilian Registry of Clinical Trials - ReBEC) or journals (such as SciELO, LILACS) to ensure transparency and compliance with ethical and scientific standards
- Informed consent from participants
- No conflicts of interest with the pharmaceutical industry

Discussion and Limitations

It is expected that the choice of suture material will influence the quality of aponeurosis healing. Previous studies suggest that slowly absorbable sutures, such as polydioxanone, may promote a less intense inflammatory response, potentially reducing the incidence of incisional hernias and associated complications.

The inclusion of multiple surgeries broadens applicability, but the 12-month follow-up may not capture late hernias, and the study is limited to a single center. Standardizing the closure procedure across multiple surgeries will allow the differences between the sutures to be evaluated in isolation.

A limitation when comparing with the literature, which primarily presents comparisons with non-absorbable suture, such as polypropylene (Prolene), as in the study by Bisgaard et al. (2021), which reported 1.8% hernias with Prolene vs. 3.5% with polydioxanone. The absence of studies directly comparing polyglactin and polydioxanone for trocar sites, combined with variability in rates (0.14% to 22%), justifies the estimates of 15% and 5%.

Its relevance lies in directing aponeurotic closure protocols in minimally invasive surgeries, aiming for lower complication rates and the need for new procedures in patients.

Timeline and Study Flow:

- Phase 1 – Approval and training (2 months).
- Phase 2 – Patient inclusion (12 months).
- Phase 3 – Follow-up (12 months post-last patient)
- Phase 4 – Analysis and writing (3 months).
- Phase 5 – Publication and dissemination.

Expected Impact:

- This study aims to provide robust evidence to support the choice of suture material in video-laparoscopy, with potential to improve clinical outcomes and reduce long-term hospital costs.

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