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Original research

Open retromuscular mesh repair versus onlay technique of incisional hernia: A randomized controlled trial

Zaza Demetrashvili [a, b, *], Irakli Pipia [b, c], David Loladze [b], Tamar Metreveli [a], Eka Ekaladze [d], George Kenchadze [b], Kakhi Khutsishvili [b]

[a] Department of Surgery, Tbilisi State Medical University, 33, Vazha-Pshavela ave, 0177, Tbilisi, Georgia
[b] Department of Surgery, Kipshidze Central University Hospital, 29, Vazha-Pshavela ave, 0160, Tbilisi, Georgia
[c] Institute Medical Research, Ilia State University, Tbilisi, Georgia
[d] Department of Biochemistry, Tbilisi State Medical University, 33, Vazha-Pshavela ave, 0177, Tbilisi, Georgia

HIGHLIGHTS

- No difference in frequency of hernia recurrence between the retromuscular and onlay methods.
- The retromuscular method associated with less wound complications than in onlay method.
- Previous point makes retromuscular method more preferential than onlay method.

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ABSTRACT

Introduction: The aim of this prospective randomized clinical study was to compare and analyze the results of two methods of treatment of incisional hernia: open retromuscular mesh repair and onlay technique.

Methods: 180 patients who underwent open elective surgery for middle primary incisional hernia were randomized into two groups. The retomuscular mesh repair was used in the first group and the onlay technique – in the second group. Several preoperative and intraoperative factors, also wound complications (wound infection, hematoma, seroma) and hernia recurrence rate were determined and compared between the groups.

Results: The operative time was significantly longer in the retromuscular group compared with the onlay group ($P < 0.001$). In the retromuscular group 17 (22.1%) wound complications were observed, in the onlay group–39 (50.0%) wound complications. The difference was statistically significance ($P < 0.001$). Seroma was the most frequent postoperative wound complication, ranging from 16.9% to 41.0% among the groups, respectively ($P = 0.0013$). No significantly difference has been found between groups by wound infection and hematoma. 2 (2.6%) case of hernia recurrence was marked in retromuscular group and 4 (5.1%) case of hernia recurrence – in onlay group. But there was no statistically significantly difference between the two groups.

Conclusion: Our research shows no significant difference in frequency of hernia recurrence between retromuscular mesh repair and onlay technique for treatment of incisional hernia. The usage of the retromuscular mesh repair is associated with significantly less wound complications than onlay technique. That can be considered as an advantage of retromuscular method, which makes it more preferential than onlay method.

1. Introduction

The treatment of incisional hernia tends to be one of major issues of abdominal surgery. The incidence of incisional hernia after laparotomies ranges between 11% and 20% [1–3]. Each year,

* Corresponding author. Department of Surgery, Tbilisi State Medical University, Georgia.
E-mail addresses: zdemetr@yahoo.com (Z. Demetrashvili), iraklipipia@yahoo.com (I. Pipia), davit2311@gmail.com (D. Loladze), t7metreveli@gmail.com (T. Metreveli), ekaekaladze@yahoo.com (E. Ekaladze), gugaken@yahoo.com (G. Kenchadze), kadoc72@Yahoo.com (K. Khutsishvili).

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approximately 200,000 incisional hernia repairs are performed in the United States alone [3,4].

Conventional suture repair techniques are associated with a high rate of recurrence ranging from 12% to 54% [5–7]. Due to this, the treatment of choice for incisional hernias should be mesh repair, which is characterized by lower rate of hernia recurrence [5–8]. Mesh repair can be proceeded by both, open and laparoscopic methods. By the usage of a mesh the most widely spread open methods are: sublay retromuscular repair and onlay repair [8–12]. Nowadays no consensus has been reached as to which technique is preferable. The anatomic position of the mesh placement has an impact on tissue reaction, tissue incorporation, and tensile strength of the abdominal wall. The above mentioned factors are important during hernia recurrence and postsurgery complications development [10,13,14].

The aim of this prospective randomized clinical trial was to compare and analyze the results of two methods of treatment of incisional hernia: open retromuscular mesh repair and onlay technique.

2. Methods

From January 2007 to April 2014 patients over 18 years of age who underwent elective surgery for middle primary incisional hernia via open mesh technique were enrolled in this study. The patients were operated at the surgery department of Kipshidze Central University Hospital. The inclusion criteria were a midline primary incisional hernia requiring operative treatment and patient's approval to participate in the study. The exclusion criteria were recurrent incisional hernia, strangulated hernia, a patient's preference for either operative technique, or a patient's refusal to participate in the study. The patients were assigned to one of the groups: the Retromuscular mesh group or the Onlay group. The randomization (by simple random sampling) of patients to each of the two groups described above was done before the surgical intervention. The assignment of patients to the specific groups was performed by the clinical manager not involved in the surgical procedures. The study participants were blinded regarding the type of surgical technique. All operations were performed by two skilled general surgeons. All operations were performed under the general anesthesia. All patients received a single dose of intravenous antibiotics (1.5 g cefuroxime) 15 min before operation. For all surgical interventions (in both groups) monofilament polypropylene mesh with a weight of 82 g/cm^2 and pore size 1.0 mm (Prolene, Ethicon, Somerville, New Jersey) was used.

Several preoperative factors were studied, which included sex, age, body mass index, occupation, tobacco use, risk groups by American Society of Anesthesiologists (ASA) and comorbidities. Patients with ASA groups 4 and 5 were excluded from the study.

Among the intraoperative factors, the following were evaluated: duration of the operation and the size of the hernia. The duration of the operation was evaluated as skin-to-skin time.

Among the postoperative data, the following were studied: postoperative days at the ward (hospital stay) and complications. The latter divided into two groups: early (wound) and late complications. The early complications included wound infection, hematoma, and seroma. The late complication included the hernia recurrence.

After discharge from the hospital, all patients were examined after 1 week, 15 days, 1, and 3 months at the outpatient department. Also, these patients were examined more than 1, 2, and 3 years after the operation date. The total follow-up time was calculated based on the last visit to the outpatient clinic. The Follow-up for the retromuscular group was 2–7.1 years (4.3 ± 1.2 years), whereas for onlay group it was 2.1–6.7 years (4.6 ± 1.0 years).

The study was registered on researchregistry.com (UIN: 1584).

2.1. Surgical techniques

The old midline incisional scar was excised over the complete length. After identifying the hernia sac it was carefully separated from the surrounding tissues and opened. Approximately 2–3 cm from the edges of fascial defect hernia sac would be cut, so that to keep as much peritoneum as possible to be able to close the abdominal cavity without problems. The abdominal content was checked, and adhesiolysis was performed.

We used the Rives-Stoppa retromuscular technique for first group [15,16]. The rectus sheath was opened on the both sides of wound. Dissection of the retromuscular space was performed in all directions. This dissection was stopped when an overlap of at least 5–6 cm in all directions was reached. The peritoneum and posterior fascia was closed with slowly absorbable continuous suture. An appropriate sized mesh was placed over the closed posterior fascia, in the space between the posterior fascia and the rectus muscle and fixed with some 2-0 polypropylene sutures (Fig. 1). One or two suction drains were placed above the mesh. The anterior fascia was closed using slowly absorbable continuous 2-0 suture. When the anterior fascia closing was connected with tension we use anterior component separation technique [17]. Additional subcutaneous drain was placed if indicated. Skin margins were freshened and closed (Fig. 2). Drains were removed on the third postoperative day or when the secretion was less than 30ml/24 h.

For onlay technique, after closing the hernia defect with non-absorbable polypropylene continuous 2-0 suture, the mesh of appropriate size was placed over the anterior fascia. The mesh fixed with some 2-0 polypropylene sutures (Fig. 3). The mesh covered the anterior fascia 5 cm from the hernia defect borders in all directions. Subcutaneous suction drains were placed in all patients. Skin margins were freshened and closed (Fig. 4).

2.2. Statistical methods

The sample size calculation was performed for the following parameters: confidence level 95%, power 80%, case/control ratio 1:1 and risk ratio 2.0 using OpenEpi v.3.01 software. The minimum number of subjects in each of case and control groups was estimated to equal to 67. The total minimal number of subjects in both groups was equal to 134. We have included 180 subjects for simple randomization which corresponded to approximately 25% rate of loss to follow-up. Finally data for 77 subjects from retromuscular mesh group and 78 subjects from onlay group have been analysed.

Descriptive statistics methods were used to characterize each variable. Comparison of continuous variables was performed by independent samples *t*-test or the Mann-Whitney *U* test according to the normality of the variables. Categorical variables were evaluated by two tailed Chi-square test or Fisher's exact test where appropriate. The threshold for statistical significance was set to $P < 0.05$. The statistical tests were performed by IBM SPSS Statistics v 20.0(IBM Corporation, Armonk, New York).

3. Results

From January 2007 to April 2014, 234 patients underwent open incisional hernia repair. Among these patients, 180 were randomized in two groups equally (90 patients in each group). All of these patients underwent the allocated operations. Information about 25 patients was lost during the time observation: among them–14 patients were not coming for examination, 7 patients died during observation period (the causes of death were all non-hernia surgery related), in 3 patients developed stroke, and in 1 patient