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Original Research

Totally extraperitoneal laparoscopic inguinal hernia repair using a self-expanding nitinol framed hernia repair device: A prospective case series

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HIGHLIGHTS

- self-expanding nitinol framed prosthesis could solve issues of mesh shrinkage and associated pain.
- 69 TEP-IHR procedures were performed in 54 patients using a nitinol framed prosthesis.
- Low incidence of postoperative pain, and short hospital stay.
- Quick return to normal activities.
- 1 year follow up with no recurrence.

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ABSTRACT

Background: The use of a self-expanding nitinol framed prosthesis (ReboundHRD®) for totally extraperitoneal laparoscopic inguinal hernia repair (TEP-IHR) could solve issues of mesh shrinkage and associated pain. We prospectively evaluated the use of the ReboundHRD® mesh for TEP-IHR.
Materials and methods: All patients who underwent a TEP-IHR using the ReboundHRD® Large mesh from April 2014 till May 2015, were included. No mesh fixation was performed. Follow-up assessments were performed at the day of surgery, 1, 2, and 7 days, 1, 3, 6, and 12 months. Outcome measures include postoperative pain (visual analogue scale, VAS), operative details, complications, and recurrence rate.
Results: In total, 69 TEP-IHR procedures were performed in 54 patients (15 bilateral hernias). No perioperative and 5 (9%) postoperative complications occurred, all graded Clavien-Dindo I-II. The median length of stay was 1 day (range 0–3), with 78% of the operations performed in an ambulatory setting. Median VAS score decreased from 3 (range 0–4) on the day of surgery to 1 (range 0–2) on day 7. Patients were completely pain-free at a median time of 5 (range 1–60) days. The majority (80.4%, 37/46) of the active patients went back to work within 2 weeks (maximum 6 weeks). At a median follow-up of 19 months (range 16–26 months), no recurrences occurred.
Conclusion: TEP-IHR using a self-expanding nitinol framed hernia repair device is a safe technique in longterm follow-up. The technique is associated with a low incidence of postoperative pain, a short hospital stay and quick return to normal activities.

1. Introduction

Inguinal hernia repair is one of the most commonly performed surgical procedures and several mesh or non–mesh repair techniques are used. Nowadays, recurrence rates are low: 2.0% in case of mesh-repair and 4.9% for non-mesh repair) [1,2]. Currently the focus is more on techniques that reduce the incidence of chronic pain, since this can have a negative impact on quality of life. Chronic pain occurs in 16%–62% of patients and is related to the surgical technique that is used [3]. Several studies have shown that laparoscopic repair reduces the incidence of chronic pain in comparison with open repair [4–6]. The total extraperitoneal

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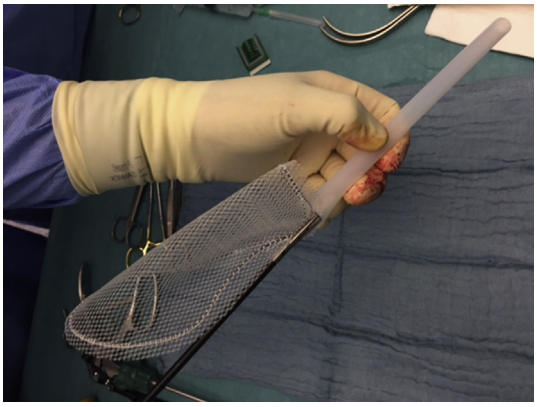

Fig. 1. The Rebound mesh® large is folded and introduced blindly through the 12-mm paraumbilical port using the loading cannula (Fig. 1).

laparoscopic (TEP) and transabdominal preperitoneal laparoscopic (TAPP) are the most common laparoscopic techniques for inguinal hernia repair. Zhu and colleagues showed that TEP is associated with shorter hospital stay, quicker return to normal activities or work, lower incidence of total postoperative complications and urinary problems when compared to open extraperitoneal repair [7]. A drawback of this technique is the long learning curve especially in terms of operation time. In general a surgeon needs to perform 60 to 80 TEP procedures in order to have enough experience [8]. The European Hernia Society guidelines suggest that the learning curve ranges between 50 and 100 procedures [9].

Besides the surgical technique, several types of hernia meshes and fixation are available for laparoscopic inguinal hernia repair. Mesh fixation type has been associated with recurrence and postoperative pain [10]. The use of light weight meshes (LWM) is associated with a reduced incidence of chronic groin pain in absence of an increased risk of hernia recurrence [11]. Mesh shrinkage as a result of scar tissue formation and scar contraction is a known problem in hernia surgery [12]. The use of LWM is associated with reduced shrinkage in comparison with heavy weight meshes (HWM) [12]. A study performed on 20 patients, utilizing a hernia repair device that combines a nitinol frame with a light weight polypropylene mesh, provided evidence of stable shape and size when used without fixation after a minimal follow-up of 6 months [13]. In this study, all patients had laparoscopic TAPP repairs.

The aim of the current study was to prospectively evaluate the use of a self-expanding nitinol framed hernia repair device, the ReboundHRD® mesh (ARB Medical, LCC, Minnetonka, Mineapolis, USA) for totally extraperitoneal laparoscopic inguinal hernia repair (TEP-IHR). The combination of the TEP-IHR procedure with a stable, non-shrinkable hernia repair device in absence of mesh fixation was assessed in terms of chronic pain and recurrence rate in patients with a minimum of 1 year follow-up.

2. Methods

2.1. Patients

This study is reported in line with the PROCESS criteria [14]. A total of 54 patients were included in a monocentric (AZ Groeninge, Kortrijk, Belgium) prospective case series study between April 2014 and May 2015. All patients underwent a TEP-IHR using the ReboundHRD® Large mesh and the operations were performed by a single surgeon (MDH) with experience of more than 80 TEP-IHR procedures. Ethics committee approval was obtained at the investigational site (B396201524310). Only patients with a minimal age of 18 years who had a primary unilateral or bilateral inguinal hernia or who needed a repair for a recurrent unilateral or bilateral inguinal hernia after non-mesh repair or Lichtenstein repair were included. Subjects who had recurrent inguinal hernias after a preperitoneal mesh repair and subjects in which it was impossible to explore and open the preperitoneal space (eg.: previous prostatectomy), were excluded from the study.

The following patient demographics at baseline were documented in the medical records: age, gender, body mass index (BMI), and American Society of Anaesthesiology (ASA) score. Presence of pre-operative pain was registered. Intra-operatively the anatomical localisation (lateral, medial, and femoral) and size of the hernia registered as 1 (≤finger), 2 (1–2 fingers) and 3 (≥3 fingers) were evaluated according to the European Hernia Society (EHS) groin hernia classification [15].

2.2. Description ReboundHRD® mesh

The Rebound HRD® large mesh (16.2 × 11.2 cm) (ARB Medical, LCC, Minnetonka, Mineapolis, USA) is a super thin macroporous lightweight condensed polypropylene mesh with a nitinol frame that does not require fixation since the mesh has a self-expanding multi-strand Nitinol frame. The elastic frame allows the device to be folded and inserted laparoscopically by using a loading cannula through a 10/12 mm trocar. Furthermore the multi-strand nitinol frame minimizes the risk of fracture or breakage and prevents mesh shrinkage.

2.3. Anaesthetic protocol

All patients underwent general anaesthesia. After preoxygenation and application of haemodynamic monitoring, including electrocardiography, non-invasive blood pressure monitoring and pulse oximetry, anaesthesia was induced with sufentanil, propofol and atracurium. Following endotracheal intubation, patients' lungs were mechanically ventilated. Positive end-expiratory pressure was set at 5 cm H_20. General anaesthesia was maintained with sevoflurane in an air-oxygen admixture. At incision, 1 g of paracetamol and 75 mg of diclofenac were administered intravenously.

2.4. Surgical technique

The surgical procedure was performed according to the well known classic TEP technique [16].

We used one 12 mm balloon trocar close to the umbilicus for the 10 mm, 30° angled camera and two 5-mm working ports: one 3 fingers below the balloon trocar at the midline and one in the ipsilateral flank. As regards to dissection, we always tried to avoid traction or using diathermy close to the spermatic cord structures. In female patients, the round ligament was always divided. Before mesh introduction a 2 cm absorbable suture was placed on the lateral side of the Rebound mesh® to facilitate orientation. The Rebound mesh® large was folded and introduced blindly through the 12-mm paraumbilical port using the loading cannula (Fig. 1). The self expanding mesh opens in the preperitoneal space. The mesh was oriented and correctly positioned against the abdominal wall at an angle parallel to the inguinal ligament. The mesh always crossed the midline medially and stretched out in the retropubic space. The mesh prosthesis leaned against the posterior aspect of the superior pubic ramus inferiorly and was lying inferolaterally over the psoas muscle, laterally and superiorly to the anterior superior iliac spine and the transverse abdominal muscle (Fig. 2). Mesh fixation was never used.