"All In One Mesh Hernioplasty" device for inguinal hernia repair.
Results of 400 cases

Ann. Ital. Chir., 2018 89, 5: 438-442
pii: S0003469X18028919

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"All In One Mesh Hernioplasty" device for inguinal hernia repair. Results of 400 cases

BACKGROUND: *Our intention in this study was to evaluate the effectiveness of a new open mesh hernia repair procedure, the "All in One Mesh Hernioplasty", for the treatment of primary inguinal hernias in adults.*
METHODS: *Between February 2014 and February 2016, we performed the All In One Mesh Hernioplasty procedure on 400 patient suffering from primary unilateral inguinal hernia at our Institution. The prosthesis was placed on the floor of the inguinal canal, as described in the original technique, and later covered by the fibrocremasteric sheath. Follow-up visits with the evaluation of postoperative pain using Numerical Rating Scale, and of short and long-term complications were performed after 1, 6, and 24 months.*
RESULTS: *All patients were discharged within three hours after surgery. The majority of patients reported only slight pain at discharge and 31,7% of them were completely painless . One week after surgery 83% of patients reported no pain and no other symptoms. 91 % of patients returned to their normal daily activities within 2-3 days after surgery. We didn't record any case of postoperative neuralgia or recurrence after a 24 months follow up.*

KEY WORDS: All In One Mesh Hernioplasty, Neuralgia post-hernioplasty, Tension free hernia repair

Background

Presently, the most important issue of hernioplasty procedures is the risk of development of postoperative neuralgia and of foreign body sensation [1-4]. Our purpose in this study was to check the effectiveness of a new open mesh hernia repair procedure (All in One Mesh Hernioplasty) which was first ideated and described by Guttadauro [5] with the aim to reduce the complications mentioned above.

Methods

We enrolled 400 patients suffering from primary unilateral inguinal hernia. Hernia degree was determined according to the European Hernia Society classification [6]. All patients were treated with the All In One Mesh Hernioplasty surgical technique. According to this newly devised technique, we employed a smaller semi-resorbable mesh (70% polyglycolide and 30% polypropylene) of new design and placed it on the floor of the inguinal canal in order to strengthen all areas of weakness from which hernias may originate.
The prosthesis is produced by Assut Europe and consists in 3 sections: section A, a ring-shaped portion designed to surround the deep inguinal orifice; section C, a trapezoidal-shaped part of the mesh studied to lay on the floor of the inguinal canal; and section B, a thin bridge-section connecting the previous two (Fig. 1). With a medial incision we dissect the fibro-cremasteric sheath up to the inguinal ligament. The hernia sac is dissected from the cord elements and tucked away into the abdominal cavity, according to the state of the art. Section A of the prosthesis surrounds the spermatic ele-

Pervenuto in Redazione Luglio 2018. Accettato per la pubblicazione Agosto 2018
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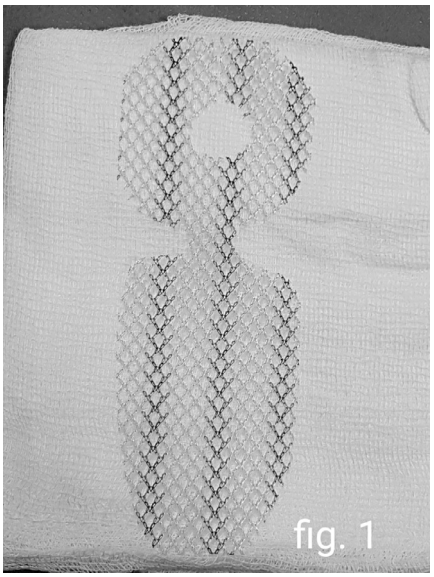

Fig. 1

Fig. 3

Fig. 2

Fig. 4

ments by forming a conical ring around them and is placed beneath the rim of the deep inguinal orifice strengthening the lateral weakness area (Fig. 2). Section B protrudes from the ring and fans out to form the C segment which is positioned with a slightly medial orientation, resting on the floor of the inguinal channel and strengthening the medial weakness area (Fig. 3). An absorbable running suture closes the lower edge of the deep ring over the section B of the prosthesis. The tip of section C overlaps the pubic tubercle and is sutured in place while taking care to avoid the periosteum. The medial margin of the fibro- cremasteric sheath is identified, transposed beneath the spermatic cord and fixed to the medial muscular structures with an absorbable running suture so that it completely covers the mesh preventing it from coming in contact with neural structures (Fig. 4).

The was designed and carried out in accordance with the code of ethics of the World Medical Association (Helsinki declaration). Written informed consent was obtained from each patient included.

Local anesthesia with 7.5 mg of Ropivacaine and sedation with Midazolam were adopted for all patients. All procedures were carried out as "day surgery" and patients

TABLE I - *Postoperative complications*

Complications	Patient (%)
Early complications:	
– Bruising of external genitalia	9(2.2)
– Limitation of normal activities	36(9)
Late complications:	
– Neuralgia	0(0)
– Sensation of foreign body	0(0)
– Disconfort and recurrence	0(0)

TABLE II - *Postoperative pain*

Postoperative time	Average value NRS
24 hours	3
First week	1.6
Second week	0
Third week	0

were discharged within three hours of surgery. Between February 2014 and February 2016 we treated 400 adult patients for primary inguinal hernia, 384 males and 16 females with an average age of 56 years (range: 19-93). At discharge, all patients received a data sheet designed for the evaluation of postoperative pain using the Numerical Rating Scale (NRS) score and of postoperative discomfort. Postoperative discomfort was assessed in terms of limitation in daily activities. Patients were also asked for an overall opinion on the operation. These data were recorded by patients themselves on the data sheet at one, two and three weeks after discharge and later collected by the study investigators. The first clinical evaluation was made seven days after surgery by a member of the surgical team. The second and third week interviews were made on the phone. Follow-up visits were performed in the outpatient clinic at 1, 6 and 24 months after surgery by a member of the surgical team and evaluated the presence of local anomalies, chronic pain, foreign body sensation and signs of recurrence. All data were collected in a dedicated database.

Results

Nine patients (2.2%),treated with anticoagulants, suspended before surgery, showed bruising of the external genitalia in the immediate postoperative period. No further early complications were reported (Tab. I). The average pain level reported by patients after the first 24 hours from surgery was 3 on the NRS scale, pain was localized at the surgical incision site. All patients received Nimesulide betaciclodestrina as pain medicament: 1 sachet in the evening of surgery and 1 sachet in the morning of the day after. Average NRS score after the first postoperative week was 1.6 and 400 patients (100%) reported no need of pain medications during this period. During the second and third postoperative week, no patient complained of pain (Tab. II). Normal daily activities were resumed 2-3 days after surgery by 364 patients (91%). 36 patients (9%) experienced limitations of normal activities during the first week, all of them either suffered from chronic cardiac condition or were obese. At the end of the follow up period none of our patients suffered from postoperative neuralgia, foreign body sensation or discomfort. We recorded no cases of recurrence (Tab. I).

Discussion

The progress in surgery allows, nowadays, to perform inguinal hernioplasty procedures in a day surgery context. There are numerous techniques available for the treatment of inguinal hernia all of them are related to a variable risk of chronic postoperative neuralgia [7-9]. The use of meshes itself is associated to two main issues: nerves entrapment during the inflammatory reaction that follows surgery and consequent neuralgia [10-13] and persistence of a foreign body sensation in the groin. Most surgeons merely trim preformed meshes during hernioplasty based on the concept that smaller meshes may be burdened with a greater risk of recurrence. To avoid neuralgia, some also choose to dissect inguinal canal nerves [14-16]. However, because of the possible onset of neurinomas on the severed nervous stump, this measure may not always be effective.Over the last few years, authors have proposed different surgical techniques and kinds of meshes in the attempt to reduce postoperative neuralgia, but results were not completely satisfactory [17-20]. This led to the definition of guidelines for prevention and management of post-operative chronic pain [21].
The idea behind the surgical method we tested in this study is to use a smaller prosthesis to reinforce the hernial weakness and to position it avoiding contact with nerve structures with the objective of a better patient comfort. It is a tension free technique and thus has the advantage of a containment of recurrence rates. The A component of this new prosthesis allows to reinforce the internal orifice the same way as would happen with a "flat plug" but without the risk of migration in the abdomen. To our knowledge, the only existing data in literature on this technique to date is the experience reported by the inventors themselves [22]. In our experience, the technique is simple to perform and requires a short learning curve. It allows to avoid manipulation and therefore damage to the nerve structures of the inguinal canal minimizing the risk of neuralgia. The use of a reduced size prosthesis prevents onset of the "foreign body sensation" and does not appear to be associated

with an increased risk of recurrence. This is perhaps due to the direct placement of the mesh on the floor of the inguinal canal. The technique also appears to be simple and easy to learn, so that results can be reproduced at distance even when the operation is performed by a less experienced surgeon.

Conclusion

In our experience, the new "All In One Mesh Hernioplasty" is simple to perform and avoids nerve manipulation. The reduced mesh size and the way of its positioning allow to effectively reinforce the weak areas of the inguinal canal and minimize post-operative complications. A larger multicenter trial with a longer follow-up period would be needed for further validation.

Riassunto

Con questo studio abbiamo voluto valutare l'efficacia di una nuova procedura di riparazione di ernie con rete a maglia larga e semiriassorbibile, la "All In One Mesh Hernioplasty", per il trattamento delle ernie inguinali primitive negli adulti.
Tra febbraio 2014 e febbraio 2016, abbiamo eseguito la procedura di Hernioplasty All In One su 400 Mesh pazienti affetti da ernia inguinale unilaterale primitiva presso la nostra istituzione. La protesi è stata posta sul pavimento del canale inguinale, come descritto nella tecnica originale, e successivamente coperta dalla guaina fibro-cremasterica. Le visite di controllo successive sono state effettuate alla scadenza di: 1,6 e 24 mesi con valutazione del dolore postoperatorio utilizzando la scala di valutazione numerica, e le eventuali complicanze a breve e lungo termine.
Tutti i pazienti sono stati dimessi entro tre ore dall'intervento. La maggior parte dei pazienti ha riferito solo lieve dolore alla dimissione e il 31,7% di essi era completamente privo di dolore. Una settimana dopo l'intervento l'83% dei pazienti non ha riferito dolore né alcun altro sintomo. Il 91% dei pazienti è tornato alle normali attività quotidiane entro 2-3 giorni dall'intervento. Non abbiamo registrato alcun caso di neuralgia o recidiva postoperatoria dopo un follow-up sino a 24 mesi.

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