ARTÍCULO ORIGINAL

UASLP
REVISTA MEXICANA DE INVESTIGACIÓN CLÍNICA

Preliminary results on a randomized controlled trial comparing post-operative pain between the ONSTEP and Lichtenstein inguinal hernia repair techniques.

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ABSTRACT

Purpose: The aim of the study is to comparepostoperative inguinal pain using theInguinal Pain Questionnaire (IPQ) and numerical pain scale, in post-operative patients of Lichtenstein and Onstep technique at one week, 1 month, 3 and 6 months. We used a validated the Inguinal Pain Questionnaire was translated to Spanish. **Methods:** This is a randomized, doubleblinded, clinical trial. It was included 40 patients with unilateral inguinal hernia and were randomized in the group of Lichtenstein and Onstep. **Results :** There is no difference in inguinal pain between both techniques using the IPQ and numeric pain scale. The score IPQ was 11.35 ± 5.1 at the first week, 7.3 ± 4.4 at one month, 7.5 ± 6.2 at 3 months in the Lichtenstein group and 10.35 ± 5.5 at first week, 7.45 ± 5.5 at one month, 7 ± 4.9 at 3 months in the Onstep group. The numeric pain scale at 1 week is 1.9 ± 1.8, at 1 month 0.8 ± 0.89, at 3 months 0.9 ± 1.8 and at 6 months 0.10 ± 0.3 in the Lichtenstein technique and 2.85 ± 2 at first week, 1.4 ± 1.6 at one month, 0.9 ± 1.7 at 3 months and 0.6 ± 1.5 at 6 months in the Onstep technique (p = 0.013, 0.15, 0.9 and 0.1). For the validation of the IPQ in Spanish the Cronbach's alfa was 0.753 (0.696-0.816 95%CI) and Spearman's rho of 0.597 (p=0.004). **Conclusions:** There is no difference in inguinal pain between both techniques using the Inguinal Pain Questionnaire and numeric pain scale after a follow up of 3 months.

PALABRAS CLAVE
Inguinal hernia, ONSTEP, Lichtenstein, postoperative inguinal pain,
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INTRODUCTION

Since the routine use of meshes for inguinal repair, the problem of recurrence has diminished and more attention has been paid to affect the quality of life and the incidence of postoperative inguinal pain. [1-8] Different techniques are currently performed trying to achieve it, while maintaining a recurrence rate and acceptable costs. [7-12] The recurrence of inguinal hernias with mesh is 1.1% to 6.6% with an average of 1.9% in the Lichtenstein technique and 0.6% in the Onstep technique. [13-16] Pre-peritoneal techniques, such as the Onstep technique, try to avoid manipulating nerves to reduce chronic post-surgical inguinal pain. [18-22] Chronic inguinal pain is defined by the "International Association for the Study of Pain" as one that occurs for more than 3 months after surgery, and may affect daily activities. Post-surgical chronic inguinal pain occurs frequently in a wide range of 0.7 - 43.3%, with an average of 7.2% and a higher frequency in women of 8.8% versus 0.5% in men. [3,9,10,15] There is an incidence of severe chronic pain of 2 to 9%, this reflects a socioeconomic problem considering the number of plasties performed. (3) As age increases, chronic inguinal pain occurs less frequently, it has been described that the patient who has inguinal pain prior to surgery will develop pain after it in up to 88% of cases. Preoperative and early postoperative pain are independent risk factors for developing chronic pain. [20]

There are a large number of tools reported in the literature to evaluate the outcome after inguinal plasty, however, there is no standardization, since most studies are retrospective and there are no preoperative data available. [3] The inguinal pain questionnaire (IPQ) was developed by U. Fränneby et al. And published in 2008 as a tool to measure the behavior of pain after inguinal plasty. Evaluate the current inguinal pain, the worst pain experienced in the last week and interference of daily activities for pain, there are a total of 18 questions with a duration of less than 10 minutes to complete it. The questionnaire produces valid and reliable information on the frequency and severity of inguinal pain. [11]

The main objective of this study is to compare postoperative inguinal pain using the Inguinal Pain Questionnaire (IPQ) validated in Spanish and numerical pain scale, in post-operative patients of Lichtenstein and

Onstep technique at week, month, at 3 and 6 months. The secondary objective was the validation of the IPQ questionnaire in Spanish.

MATERIAL AND METHODS:

The sample size was calculated using the Browne RH method [23]. Simple randomization of 40 patients older than 16 years was performed, with unilateral inguinal hernia, in two groups of 20 patients, the first group were performed Lichtenstein technique and the second Onstep technique. Patients with COPD, chronic cough, obesity, diabetes mellitus, cirrhosis, collagen diseases and previous surgeries in the inguinal region were excluded. The study was carried out in the General Surgery service of the Central Hospital Dr. Ignacio Morones Prieto, considered a second level care center of the Ministry of Health.

The Lichtenstein technique was performed by different surgeons and polypropylene mesh was used for repair.

The Onstep procedure was performed by a surgeon skilled in the technique as described in the original article by Rosenberg [6] and Bard 3DMAXTM mesh was used. The Onstep technique is simple, the duration of the surgery is short and consists of a series of standardized steps. It combines an anterior approach with a preperitoneal approach. It consists of making a lateral incision to the rectus abdominis muscle and above the inguinal canal, dissecting to a plane between the fascia of the external and internal oblique, dissecting spermatic cord and reducing the sac, either directly or indirectly. It affects the transversalis fascia towards the preperitoneal space. The preformed mesh is placed laterally to reinforce the deep inguinal ring and medially accommodates in the pre-dissected preperitoneal space. The mesh was attached to Cooper's ligament, pubic tubercle and rectus abdominis muscle with 2-0 polypropylene suture. [6.13]

The validated questionnaire in Spanish (Fig1) and visual pain scale were applied at the first consultation a week and by telephone a month, 3 and 6 months after surgery by two evaluators who did not know the surgical technique used. Statistical analysis of the results of the questionnaire and visual pain scale in patients operated with Onstep and Lichtenstein technique was performed with Student's t and Fisher's exact tests.

For the validation of the survey in Spanish, the translation of the IPQ questionnaire from English to Spanish was made[11], then the retranslation from Spanish to English by a person proficient in the English language and the translation from English to Spanish was made again making adjustments to the initial translation. The survey in Spanish (Fig 1) and numerical pain scale was applied to 21 postoperative patients of unilateral inguinal plasty, older than 16 years, with Lichtenstein or laparoscopic technique (PET and TAPP), performed by different surgeons. The first survey was conducted in the consultation at the first week of surgery, the second was applied by telephone at 4 weeks, both conducted by evaluators familiar with the survey and outside the knowledge of the surgical technique used. The survey data analysis was performed using Cronbach's Alpha for internal validation, Re-test with the Spearman's rho test to compare the variability of the responses over time and finally the survey responses were compared with the score of the numerical pain scale.

The study was carried out under the guidelines established by the Ethics Committee of the Central Hospital Dr. Ignacio Morones Prieto, with approval number of protocol 48-18 and registration CONBIOETICA-24CEI-001-20160427. All patients included in the study accepted and signed written informed consent.

RESULTS:

40 patients were included in the study from March 2018 to March 2019, in the Onstep group there were 2 women and 18 men and in the Lichtenstein group 5 women and 15 men. The average age was X years in the Lichtenstein group and 42.23 ± 13.2 years in the Onstep group ($p = 0.4$). In the Lichtenstein group 5 (20%) patients were Nyhus IIIB, 4 (16%) type II and 3 (12%) type I. In the Onstep group there were 2 (8%) Nyhus I, 5 (20 %) Nyhus II, 3 (12%) of type IIIA and 3 (12%) of type IIIB. (Table 2) The visual scale of basal pain (1 week) is 1.7, 0.8 at the first month and 0.6 al 3 months in Lichtenstein technique and 3.5 at the first week, 1.9 at the first month and 1.3 at 3 months in the Onstep technique ($p = 0.01$, 0.06 and 0.34). (Figure 4) In the Lichtenstein group there is no significant difference between the baseline pain score and the 1-month score, there is a significant difference between the baseline score and the 3-month score ($p = 0.043$). In the Onstep group there is a significant difference between the baseline pain score and the 1 and 3 month score ($p = 0.027$ and 0.003). The score in the inguinal pain survey (EDI) was 20.0 a week, 16.9 a month and 14.6 at 3 months in the Lichtenstein group and 22.1 a week, 18.2 a month and 16.6 at 3 months in the group of Onstep ($p = 0.3$, 0.52, 0.34). (Table 3, Figure 5) In the Lichtenstein group there is no significant

difference between baseline and 1 month EDI score. There is a significant difference between the baseline EDI score and the 3-month score (p = 0.0028). In the Onstep group there is a significant difference between the baseline and 3-month EDI score (p = 0.029), there is no difference between the baseline and 1 month, as well as between 1 month and 3 months.

In the group for the validation of the Inguinal Pain Questionnaire (IPQ), a survey was conducted on 21 patients, of which 17 are men and 4 women, the average age is 47 years. The Nyhus classification was used for the type of inguinal hernia, 6 of the patients were type I, 5 were type II, 5 of type IIIA, 4 of IIIB and 1 type IV (table 1). 100% of the patients answered the survey a week and 4 weeks. Cronbach's alpha analysis for internal validation had a result of 0.753 (0.696-0.816 95% CI). Re-test to compare the variability of the responses with time reflects Spearman's rho 0.597 (p = 0.004), there was a decrease in the survey score over time, which is expected (fig2). An analysis of the correlation between the numerical pain scale data and the survey score was performed, for each point in the survey increases 0.05 points on the pain scale with a p = 0.044 (fig3).

DISCUSSION:

In this study we found that there is no significant difference in the results of chronic inguinal pain between the Lichtenstein technique and the Onstep technique at 6 months of follow-up. In the study published by Andresen and collaborators in 2016, they reported similar results, they used three questionnaires to assess the presence of pain and the quality of life in which they found no difference between the two techniques.

[7] In the study by Lourenco et al **[13]**, they reported an

incidence of chronic inguinal pain after the Onstep technique of 0%, which is different in our study, finding even results in the postoperative pain scale greater than week and similar to the Lichtenstein technique at 3 and 6 months using both measurement tools. In the visual pain scale there is a greater difference between the two groups at week and month, being smaller at 3 and 6 months, however, this difference is not statistically significant. In both groups there tends to be a decrease over time in the value of the numerical pain scale, which is significant between 1 week and 3 months. There is no significant difference in the results of the inguinal pain survey between the Lichtenstein and Onstep group, in the same way there is a decrease in the score over time, being statistically significant between the week and 3 months in both groups.

The survey to evaluate postoperative chronic inguinal pain originally performed and validated by U. Fränneby has proven effective in detecting the degree of pain the patient suffers and the impact on his daily life. In this study we have shown that the survey can be used safely in Spanish, it is simple to apply with patients, with adequate internal validity and reliability. It is a tool to assess the postoperated patient of inguinal plasty in a comprehensive and useful way to detect those patients who have chronic inguinal pain and impairment of their quality of life.

This study demonstrates no inferiority of the Onstep technique against the Lichtenstein technique, which is currently considered the gold standard for the previous approach, in relation to postoperative inguinal pain. Several retrospective series have reported a higher risk of femoral hernia after inguinal hernia repair with a risk up to 15 times higher compared to the incidence of spontaneous femoral hernia. Bay-Nielsen et al. reported 13% femoral recurrence after Lichtenstein plasty. Nishiwada et al. They found that 17% of 35 patients with femoral hernia had had a previous inguinal repair. [24] Therefore, the Onstep technique may be an adequate proposal for the previous repair since it combines the benefits of a preperitoneal approach with the coverage of the femoral ring, with a technique that requires lower cost and supplies and a lower learning curve compared to laparoscopic techniques.

As strengths of the study is that it is a controlled study, with adequately randomized patients, the sample was homogeneous, both the patients and the evaluators were unaware of the technique used, so there was no bias in obtaining the pain results, two tools were used of different evaluation one of which was validated in our environment with a different group of patients and both were compared proving to be efficient for pain measurement.

The limitations of the study are the small number of patients, the follow-up was only 6 months, Lichtenstein plasties were performed by several surgeons and the Onstep technique by a single surgeon.

A prospective study is needed that compares the Onstep technique with the laparoscopic technique, and assesses the impact on cost and benefit that demonstrates the superiority and simplicity of the Onstep technique over other approaches.

CONCLUSION:

The Lichtenstein technique and the Onstep technique are effective for inguinal repair since it was demonstrated that they are similar in the effectiveness of inguinal repair, however, superiority in the decrease of chronic pain of the Onstep over the conventional technique is not demonstrated, only offering the technical advantage of the Onstep for the quality in the dissection of the anatomical elements.

CONFLICTS OF INTEREST

There are no conflicts of interest on the part of the authors of this study.

REFERENCES:

1.Gil-Galindo G, Mayagoitia-Gonzalez JC, Ramírez LR, Blas-Azotla R, Cisneros-Muñoz HA, Álvarez-Quintero R, et al. Tratamiento de la hernia inguinal en el adulto. [en línea] México: Asociación Mexicana de Cirugíá General A.C; 2014. [Consulta: 06 feb 2020]. Disponible en: https://amcg.org.mx/images/guiasclinicas/hernia_inguinal.pdf

2.Fitzgibbons RJ Jr, Forse RA. Clinical practice. Groin hernias in adults. N Engl J Med. 2015 19;372(8):756-63.

3.Staerkle RF, Vuille-Dit-Bille RN, Fink L, Soll C, Villiger P. Chronic pain and quality of life after inguinal hernia repair using the COMI-hernia score. Langenbecks Arch Surg. 2017 Sep;402(6):935-947.

4.Andresen K, Burcharth J, Rosenberg J. ONSTEP versus laparoscopy for inguinal hernia repair: protocol for a randomised clinical trial. Dan Med J. 2015;62(12):A5169.

5.Andresen K, Burcharth J, Fonnes S, Hupfeld L, Rothman JP, Deigaard S, Winther D, Errebo MB, Therkildsen R, Hauge D, Sørensen FS, Bjerg J, Rosenberg J. Sexual dysfunction after inguinal hernia repair with the onstep versus lichtenstein technique: a randomized clinical trial. Surgery. 2017 Jun;161(6):1690-1695.

6.Rosenberg J, Andresen K. The onstep method for inguinal hernia repair: operative technique and tips. Surg Res Pract. 2016;2016:6935167.

7.Andresen K, Burcharth J, Fonnes S, Hupfeld L, Rothman JP, Deigaard S, Winther D, Errebo MB, Therkildsen R, Hauge D, Sørensen FS, Bjerg J, Rosenberg J. Chronic pain after inguinal hernia repair with the ONSTEP versus the Lichtenstein technique, results of a double-blinded multicenter randomized clinical trial. Langenbecks Arch Surg. 2017 Mar;402(2):213-218.

8.Van Hee R. History of inguinal hernia repair. Journal of Surgery. 2011;7(3):301-319.

9.Alfieri S, Amid PK, Campanelli G, Izard G, Kehlet H, Wijsmuller AR, Di Miceli D, Doglietto GB. International guidelines for prevention and management of post-operative chronic pain following inguinal hernia surgery. Hernia. 2011 Jun;15(3):239-49.

10.Aasvang E, Kehlet H. Surgical management of chronic pain after inguinal hernia repair. Br J Surg. 2005 Jul;92(7):795-801.

11.Fränneby U, Gunnarsson U, Andersson M, Heuman R, Nordin P, Nyrén O, Sandblom G. Validation of an Inguinal Pain Questionnaire for assessment of chronic pain after groin hernia repair. Br J Surg. 2008 Apr;95(4):488-93.

12.Gopal SV, Warrier A. Recurrence after groin hernia repair-revisited. Int J Surg. 2013;11(5):374-7.

13.Lourenço A, da Costa RS. The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions. Hernia. 2013;17(3):357-64.

14.Pélissier EP, Monek O, Blum D, Ngo P. The Polysoft patch: prospective evaluation of feasibility, postoperative pain and recovery. Hernia. 2007 Jun;11(3):229-34.

15.Aasvang E, Kehlet H. Chronic postoperative pain: the case of inguinal herniorrhaphy. Br J Anaesth. 2005;95(1):69-76.

16.Sevonius D, Sandblom G, Agger E, Smedberg S, Montgomery A. The impact of type of mesh repair on 2nd recurrence after recurrent groin hernia surgery. World J Surg. 2015 Feb;39(2):315-232.

17.Pélissier EP, Blum D, Ngo P, Monek O. Transinguinal preperitoneal repair with the polysoft patch: prospective evaluation of recurrence and chronic pain. Hernia. 2008 Feb;12(1):51-56.

18.Andresen K, Rosenberg J. Open preperitoneal groin hernia repair with mesh: a qualitative systematic review. Am J Surg. 2017 Jun;213(6):1153-1159.

19. Aasvang EK, Bay-Nielsen M, Kehlet H. Pain and functional impairment 6 years after inguinal herniorrhaphy. Hernia. 2006 Aug;10(4):316-21.

20.Zhong C, Wu B, Yang Z, Deng X, Kang J, Guo B, Fan Y. A meta-analysis comparing lightweight meshes with heavyweight meshes in Lichtenstein inguinal hernia repair. Surg Innov. 2013 Feb;20(1):24-31.

21.Sevonius D, Montgomery A, Smedberg S, Sandblom G. Chronic groin pain, discomfort and physical disability after recurrent groin hernia repair: impact of anterior and posterior mesh repair. Hernia. 2016 Feb;20(1):43-53.

22.Klinge U, Junge K, Mertens PR. Herniosis: a biological approach. Hernia. 2004 Dec;8(4):300-1.

23.Browne RH. On the use of a pilot sample for sample size determination. Stat Med. 1995 15;14(17):1933-40.

24. Nishiwada S, Ishikawa H, Tsuji Y, Nakamura K, Mukogawa T, Matsusaka M, Ko S, Watanabe A. Kugel patch method prevents the development of a femoral hernia after inguinal herniorrhaphy. Surg Today. 2015 Jan;45(1):57-62.