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## RESEARCH ARTICLE

# DELIBRATE SEVERANCE OF ILIOINGUINAL NERVE & USE OF LIGHT WEIGHT POLYPROPYLENE MESH TO PREVENT INGUINODYNIA FOLLOWING TENSION FREE INGUINAL HERNIA REPAIR: A RANDOMIZED CONTROLLED TRIAL

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## **ABSTRACT**

**Background:** A large volume of hernia repairs are performed worldwide, of which many are affected by chronic groin pain. Since this has direct impact on most of the daily activities, it's an important aspect in the outcome of hernia surgery. We carried out this study to assess the success of delibrate severance of Ilioinguinal nerve & use of light weight mesh to prevent inguinodynia following tension free hernia repair.

**Methods:** 93 male patients who underwent open inguinal hernioplasty were divided into 3 groups. 31 patients in group 1 underwent delebrate severance of ilioinguinal nerve with use of Light weight polypropylene mesh, 31 patients in group 2 underwent delebrate severance of ilioinguinal nerve with use of Heavy weight polypropylene mesh, and 31 patients in group 3 underwent careful preservation of ilioinguinal nerve with random use of heavy or light weight polypropylene mesh. The 3 groups were compared for incidence of chronic groin pain, NRS pain scores, loss of sensation, paraesthesias at 3 months postoperatively.

**Discussion and Conclusion:** Intentional severance of ilioinguinal nerve during repair of inguinal hernia along with the use of lightweight mesh can effectively prevent debilitating inguinal pain at an expense of mild and not so troublesome loss of sensation at upper medial aspect of thigh and paraesthesia. The use of light weight mesh does not have any added advantage of decreased incidence of chronic post-operative pain in the background of severed Ilioinguinal nerve. Although, further well-structured trials with improved standardization of hernias may be required for supporting above.

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# **INTRODUCTION**

A large volume of hernia repairs are performed worldwide, of which 2-4% are adversely affected by chronic groin pain. This is significant considering the volume of operations performed worldwide. Since chronic pain has direct impact on most of the daily activities, it's an important aspect in the outcome of hernia surgery (Poobalan *et al.*, 2001). Also, avoiding chronic groin pain should be a prime goal for any hernia surgeon, considering that 5-7% of patients with post-herniorhaphy groin pain will sue their surgeons (Dittrick *et al.*, 2004). Additionally, it has an impact on the quality of life, thus on the health system and economy (Van Hanswijck de Jonge *et al.*, 2008). The main reasons hypothesised for chronic groin pain for a long time are believed to be peri-operative nerve damage,

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post-operative fibrosis, or mesh-related fibrosis. The three nerves potentially involved are the Ilioinguinal Nerve (IIN), Iliohypogastric Nerve (IHN) and genital branch of the Genitofemoral Nerve (GFN). These nerves can be damaged either by trauma during dissection or retraction of tissues, or nerve entrapment from post-operative fibrosis, mesh related fibrosis or sutures used to fix the mesh. As all three nerves arise from T12-L1 nerve roots, it is extremely difficult to identify the exact nerve involved in causing the pain because of the overlapping nature of their sensory innervations and peripheral communication between the nerves (Smeds et al., 2010). PP is one of the most widely used meshes in abdominal wall surgery. It elicits an intense desmoplastic reaction in tissue, accompanied initially by serous exudation and resulting eventually in the formation of a sheet of scar that uses the mesh as a scaffold for its formation (Bringman et al., 2010; Sergent et al., 2010). This mesh integration process in the abdominal wall and extent of scar tissue are regulated by the amount and structure of the incorporated material. The initial deployment

of abdominal wall meshes developed meshes with small pore size and accordingly heavy weight. The clinical consequence was an impairment of the abdominal wall compliance: so 20-38% of the patients complained of reduced flexibility of the abdominal wall ("stiff abdomen") (Read et al., 1993; Klinge et al., 1997). To reduce the incidence of abdominal stiffness and chronic pain, macropore lightweight PP meshes strong enough to resist maximal physiologic stress of the abdominal wall were developed (Klinge et al., 1998). In this study, we target two potential cause of inguinodynia following Lichenstein's open hernioplasty which is the involvement of the ilioinguinal nerve and use of light weight mesh, by assessing the patient postoperatively in terms of pain score, neuropathic pain, loss of sensation, paraesthesia and look for recurrence. Standard surgery for inguinal hernia described by Lichtenstein et al. (1989) in 1989. By using prosthetic mesh, Lichtenstein showed that inguinal hernias could be repaired without distortion of the anatomy and, most importantly, without any tension along the suture line. In spite of various modifications over the last two decades, Lichtenstein hernia repair (LHR) is still considered the gold standard in the management of inguinal hernia by open technique (Zhao et al., 2009), with significant reduction in recurrence with LHR, the most common morbidity has been chronic groin pain. International Association for the Study of Pain (IASP) described chronic groin pain as "groin pain reported by the patient at or beyond 3-months following inguinal hernia repair" (Merskey et al., 1994). Major consensus currently has been to take 3 months as a cut-off point to differentiate between patients with post-operative pain and chronic groin pain due to various causes (Loos et al., 2008). The aim of our study to evaluate the success of deliberate severance of Ilioinguinal nerve & use of light weight mesh to prevent inguinodynia following tension free hernia repair.

indirect inguinal hernia were included in the study. Male patients were included between the ages of 18 to 60 years with groin hernia (Direct/ Indirect inguinal hernia). Irreducible/ obstructed/ strangulated hernia was excluded. Patients were randomized into three groups by computer generated randomization.

Group 1: 31 patients who underwent delebrate severance of ilioinguinal nerve with use of Light weight polypropylene mesh

Group 2: 31 patients who underwent delebrate severance of ilioinguinal nerve with use of Heavy weight polypropylene mesh

Group3: 31 patients who underwent careful preservation of ilioinguinal nerve with random use of light or heavy weight polypropylene mesh

**Operative Methodology:** Tension free hernioplasty was carried out using light weight prosthetic polypropylene mesh, without distortion of the anatomy and, most importantly, without any tension along the suture line. Identification and intentional Severance of the Ilioinguinal nerve was carried out

**Follow up:** Patient was followed up post operatively 1 week after discharge, followed by monthly visit for 3 months. During the follow up patient was assessed for, inguinodynia in terms of NRS pain score, loss of sensation and paraesthesia along the upper medial aspect of thigh and recourence.

**Assessment tool used for diagnosing inguinodynia:** A detailed history and clinical examination is essential. NRS pain (Numeric rating scale for pain) score. Score < 3 corresponds with no lifestyle hampering without use of pain medications. 3-

Group GROUP 2 GROUP 1 GROUP 3 P Value Mean  $\pm$  Std. Mean  $\pm$  Std. Mean  $\pm$  Std. Group 1 vs-2 Group 1 vs-3 Group 2 vs-3 Deviation Deviation Deviation 0.855 0.591 NRS Pain score 1st wk  $4.94 \pm 1.39$ 0.660  $4.39 \pm 1.82$  $4.87 \pm 1.12$ NRS Pain score at 1 month  $0.65 \pm 0.66$  $1.16 \pm 1.21$  $3.65\pm1.05$ 0.107 < 0.001 < 0.001  $0.16 \pm 0.37$  $3.19 \pm 0.98$ 0.074 < 0.001 < 0.001 NRS Pain score at 3 months  $0.71 \pm 1.19$ 

Table 1. Comparing mean pain score amongst 3 groups

Table 2. Loss of sensation of groin region and paraesthesia amongst the 3 groups

		Group			Total	P Value		
		GROUP 1	GROUP 2	GROUP 3		Group 1 vs. 2	Group 1 vs. 3	Group 2 vs. 3
Paraesthesia	Absent	22(70.97)	21(67.74)	29(93.55)	72(77.42)	0.783	0.020	0.010
	Present	9(29.03)	10(32.26)	2(6.45)	21(22.58)			
Total		31(100)	31(100)	31(100)	93(100)			
			group		Total		P Value	
		GROUP 1	GROUP 2	GROUP 3		Group 1 vs. 2	Group 1 vs. 3	Group 2 vs. 3
Loss of sensation	Absent	19(61.29)	24(77.42)	30(96.77)	73(78.49)	0.168	0.001	0.023
	Present	12(38.71)	7(22.58)	1(3.23)	20(21.51)			
Total		31(100)	31(100)	31(100)	93(100)			

Table 3. Reccurence noted amongst 3 groups

		Group			Total	P Value		
		GROUP 1	GROUP 2	GROUP 3	Total	Group 1 vs. 2	Group 1 vs. 3	Group 2 vs. 3
Recurrence at 3 months	No	31(100)	29(93.55)	30(96.77)	90(96.77)	0.151	0.313	0.554
	Yes	0(0)	2(6.45)	1(3.23)	3(3.23)			
Total		31(100)	31(100)	31(100)	93(100)			

# MATERIALS AND METHODS

**Study Design:** 93 male patients who underwent open inguinal hernioplasty in Ramakrishna mission Seva Pratishthan, Kolkata from September 2015 to March 2016 with direct/

6 corresponds to no lifestyle hampering with use of pain medications. Score>6 corresponds to lifestyle hampering inspite of pain medications. NRS pain score above 3 at 3 months visit considered as chronic groin pain or inguinodynia.

# Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 20.0.1 and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. One-way analysis of variance (one-way ANOVA) was a technique used to compare means of three or more samples for numerical data (using the F distribution). p-value  $\leq 0.05$  was considered for statistically significant.

## **RESULTS AND ANALYSIS**

Differences in pain score amongst all three groups were found to be insignificant at 1st wk post operation. Difference in pain scores amongst group 1 and 3 & amongst group 2 and 3 at 1st month were significant. Thus delebrate severance of IIN significantly reduces pain scores at 1st month. There was no significant difference amongst group 1 and 2 at 1st month. Thus use of light weight mesh alone does not significantly reduce pain at 1st month. Difference in pain scores amongst group 1 and 3 & amongst group 2 and 3 at 3<sup>rd</sup> month were significant. Thus delebrate severance of IIN significantly reduces pain scores at 3<sup>rd</sup> month also. There was no significant difference amongst group 1 and 2 at 3<sup>rd</sup> month. Thus use of light weight mesh alone does not significantly reduce pain at 3<sup>rd</sup> month also (Table-1). Difference in paraesthesia and loss of sensation of groin area amogst group 1 & 3, amongst group 2 &3 were found to be significant. Thus as expected, delebrate severance of IIN during hernia surgery is associated with loss of sensation and paraesthesias (Table-2). Difference in recurrence amongst all three groups was found to be insignificant at 3 months post operatively (Table-3).

## **DISCUSSION**

In the current study, the number of patients amongst group 1 experiencing pain progressively decreased over time, none qualified for the criteria of chronic inguinodynia by the 3rd month. However, 9(of 31) patients experienced paraesthesias while 12(of 31) had loss of sensation at upper medial aspect of ipsilateral thigh. None of these patients complained of alterations in lifestyle due to above. Amongst group 2 who had also underwent severance of IIN, one qualified for the criteria for chronic inguinodynia by 3<sup>rd</sup> month. 10(of 31) patients experienced paraesthesias and 7 (of 31) experienced loss of sensation in the post operatively. When compared to group 3, 10 (of 31) patients experienced groin pain qualifying for inguinodynia which hampered regular activities. Also the mean NRS pain score for group 3 was 3.19±0.98 as compared to 0.16  $\pm$  0.37 for group 1 and 0.71  $\pm$  1.19 for group 2. Traditional teaching has always been to preserve the nerve, but recent studies have looked into the intentional severance based on the concept of "no nerve, no pain" (Wantz, 1998). RCTs comparing deliberate IIN neurectomy vs preservation have shown conflicting results. Two RCTs have shown significant reduction in chronic groin pain post-neurectomy (Mui et al., 2006), whereas two other studies concluded there was no influence of neurectomy on pain rates (Ravindran et al., 2006; Picchio et al., 2004). All the above studies had taken only Ilioinguinal nerve into account. Thus to my understanding, the

contrast results may be due to different pain assessment tools or difference of surgical hand and post op pain management. Our findings were comparable to a recent study by Karakayali *et al* which showed significant reduction in chronic groin pain with IIN and IHN neurectomy in comparison with all 3 nerves preserved. Though the study has shown a high incidence of groin numbness and sensory loss following deliberate neurectomy of the inguinal nerves, no significant differences have been shown in the quality of life with such neurosensory changes (Karakayali *et al.*, 2010). A Cochrane systematic review is currently being undertaken to address these issues.

Most studies comparing light and heavy weight mesh showed significant better results for LW meshes (Khan *et al.*, 2010). Most of these studies were included incisional hernias rather than inguinal hernias. One does not expect similarly significant difference when investigating the use of two types of mesh in inguinal hernias, as the pain in inguinal hernia repair may be a neuropathic pain due to a trapped nerve. In our study we similarly see no major difference of pain scores using lightweight mesh over Heavyweight mesh with severance of ilioinguinal nerve in both the groups. The scope of further improved studies with proper standardization of hernia types, size, content and proper standardization of operations persists for more accurate results.

#### Conclusion

Intentional severance of ilioinguinal nerve during repair of inguinal hernia along with the use of lightweight mesh can effectively prevent debilitating inguinal pain at an expense of mild and not so troublesome loss of sensation at upper medial aspect of thigh and paraesthesia. Severance of ilioinguinal nerve alone also decreases the incidence of inguinodynia. The use of light weight mesh does not have any added advantage of decreased incidence of chronic post-operative pain in the background of severed Ilioinguinal nerve. Although, further well-structured trials with improved standardization of hernias may be required for supporting above.

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