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A Randomised Control Study on Neurosensory Outcomes of Ilioingunal Neurectomy in Lichtenstein's Hernia Repair

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Abstract

Background: Chronic groin pain is a cause of significant post-operative morbidity in open inguinal mesh hernia repair. Neurectomy is a well-established treatment modality. This study has been performed to evaluate the neurosensory outcomes of prophylactic neurectomy in open mesh hernia repair.

Aim: To assess the incidence of inguinodynia in patients undergoing open mesh hernia repair. To study, the neurosensory outcomes of sacrificing the ilioinguinal nerve in comparison to the group in which nerve is identified and preserved.

Materials and methods: A prospective double blinded study performed at Kasturba Medical College, Manipal from September 2008 to December 2009. Ilioinguinal nerve is either preserved or sacrificed according to surgeon's choice. Pain and hyposthesia were studied at defined timed intervals by a single observer.

Results: One hundred and five inguinal hernia mesh repairs were enrolled into the study. Nerve excision was done in 44 patients and preserved in 61 patients. Ninety patients were followed till six months. At post operative day one, all patients in both the groups had pain and 15.2% had numbness. Chronic post surgical inguinodynia was seen in 16.7% of the population in the study group and numbness in 5.6% of the study population at six months.

Conclusion: The severity of pain in the neurectomy group was less than control group. There was no significant difference in the neurosensory outcomes of prophylactic ilioinguinal neurectomy in open mesh hernia repair compared to nerve preservation and hence prophylactic neurectomy as of now is a surgeon's choice.

Key Words

Neurectomy; Inguinodynia; Lichtenstein's Hernia Repair; Chronic pain; Ilioinguinal nerve.

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Introduction:

Chronic groin pain can be a debilitating complication significantly affecting the quality of life following open mesh hernia repair. The overall incidence of inguinodynia was estimated to be around 25%[1]with a spectrum of severity in its intensity. Ten percent of these patients were estimated to fit into the definition of severe pain intensity[1]. Multiple treatment modalities have been suggested in the treatment of inguinodynia, starting from NSAID's to acupuncture. Surgical resection of the involved nerve has been an approach in the treatment of this debilitating pain. This prompted some surgeons to perform prophylactic neurectomy of the inguinal nerves, either single or in combination, of ilioinguinal nerve, iliohypogastric nerve and genitofemoral nerve. The theoretical benefit behind this could be the elimination of nerve injury during hernia repair and nerve entrapment by the fibrotic response during the wound healing process. If this is true, a second surgery can be eliminated and also the financial burden for the patient. Our study is aimed to assess the incidence of chronic groin pain and the neurosensory effects following the prophylactic ilioinguinal neurectomy in open mesh hernia repair in comparison to nerve preserved group.

Materials and methods:

A prospective double blinded study was conducted in Kasturba Hospital, Manipal between September, 2007 and February, 2009. Informed consents were taken from all the patients. Patients between the age groups 18 and 75 were included in the study. All the patients received spinal anesthesia, and open mesh repair was conducted in all the patients. Patients with previous inguinal or ipsilateral scrotal surgeries, recurrent hernia, irreducible or strangulated hernia, laparoscopic hernia repair, female patients, femoral hernia, anatomical tension repairs and patients in whom nerve was not identified were excluded.

Baseline measurements were done preoperatively with visual analogue scale (VAS score) for pain with scale of zero to 10 and a dichotomous scale for numbness (present/absent). To standardize the methods, 24 G needle was used to check the pain sensation. The VAS score was then coded to a four point scale (none, mild, moderate and severe). These baseline measurements were taken as control. This data was entered on a questionnaire. Patient will not be revealed to which group he belongs (neurectomy group/ nerve preserved group), thus eliminating the subjective bias. Nerve was either sacrificed or preserved as per surgeon's preference. Observer was not revealed the identity of the surgeon. At the end of the study period, the neurectomy status of the patient will be revealed to the observer, thus eliminating the observer bias (double blinded). When the nerve was sacrificed the cut ends were coagulated and buried. Standard Lichenstein mesh hernia repair was then performed in all the patients. In the patients, in whom nerve was preserved caution was taken not to include nerve in suturing and mesh placement.

Patients were followed on post-operative day one and 30 and at six months post operatively. At each visit pain and numbness were assessed in the two groups. The mean age, frequencies of sex, laterality of the hernia, and the type of hernia were studied as secondary outcomes.

Statistical analysis was performed using Statistical Package for Social Science [SPSS] version 14 software for windows. Comparisons were carried out by the Z test for proportions with a confidence level of 95%. A Z – value of more than 0.05 is considered significant.

A total of 204 patients underwent inguinal hernia repair during the study period in Kasturba Hospital, Manipal. After exclusions, 95 patients were enrolled for the study, out of which 10 patients had bilateral inguinal hernia. Therefore, a total of 105 inguinal mesh hernia repairs were enrolled into the study. In 44 hernias, neurectomy was done and 61 hernias ilioinguinal nerve is identified and preserved.

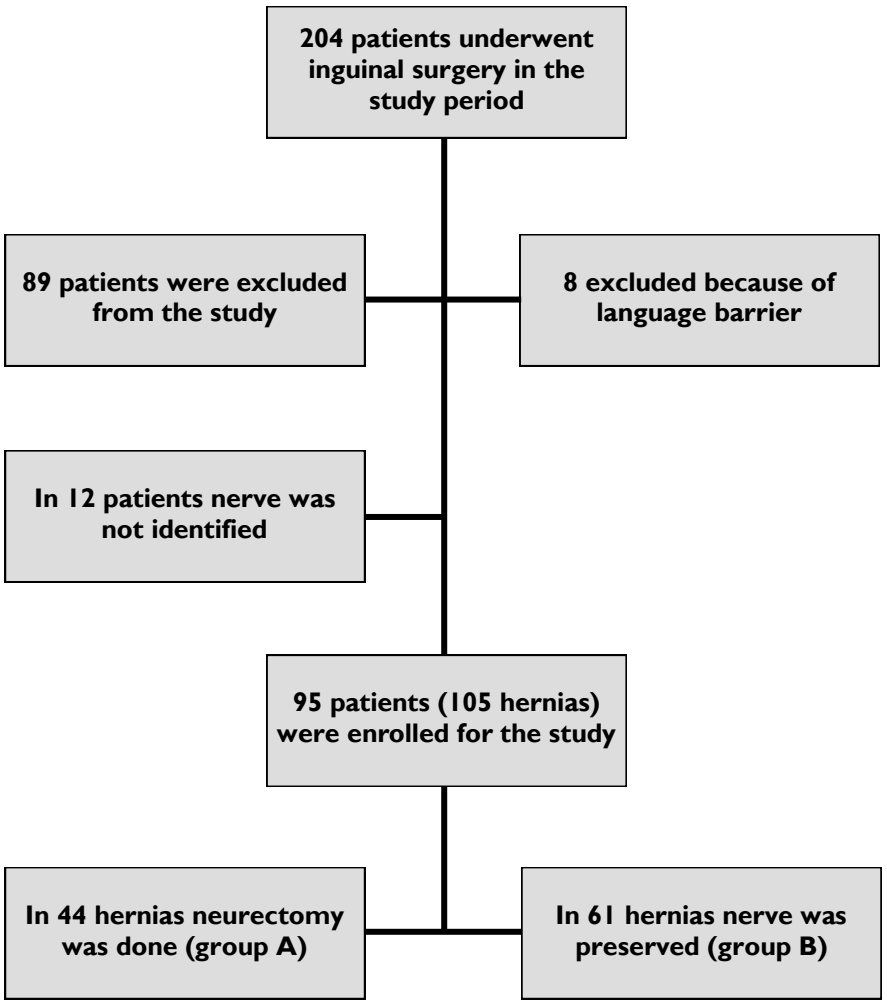

Figure 1: Flow chart of the double blinded control study

In the excluded group, ilioinguinal nerve was not identified in 12 hernias and laparoscopic hernia repair was done in 30 patients. Patients undergoing scrotal surgeries and with recurrent hernias are excluded as both cause a breach in the nerve supply in the area supplied by the ilioinguinal nerve, and thus a probable inaccuracy in assessment. As much attention could not be paid to ilioinguinal nerve in emergency situations like obstructed hernias, hence such cases were excluded. Anatomical tension repairs were known to cause severe non neuropathic groin pain, and hence excluded. In general, illiterates and some patients with whom proper communication is not possible due to language barrier were excluded to remove the subjective and observer bias.

Scrotal surgeries	21
Recurrent hernias	11
Obstructed hernias	5
Femoral hernias	3
Bassini's repair	2
Laparoscopic hernia repair	30
Femoral hernia in obstruction	1
Illiterates	16
Nerve not identified	62
Language barrier	8

Table1: Excluded cases in the study

The mean age of the patients in the study group was 57.5 years, youngest being 18 years and the maximum age was 78 years. Sixty eight patients (64.8%) had indirect hernia, 31 had direct (29.50%) and six had both indirect and direct component (5.70%).

Pre operatively all the patients were interviewed and baseline assessment of the neurosensory system done with regard to pain and numbness. 90.9% (40 of 44) of the patients in the neurectomy group and 83.6% (51 of 61) of the patients in the nerve preserved group did not complain of pain preoperatively. 13.3% (14 of 105) of the patients in the study group complained of pain. 13.6% (6 of 44) in the neurectomy and 19.7% (12 of 61) in the nerve preserved group had numbness preoperatively. The incidence of numbness in the distribution of ilioinguinal nerve preoperatively was 17.1% (18 of 105) in the study group. Statistically, both the groups were comparable. The base line measurements in the pain and numbness were taken as control post operatively. Six (42.90%) patients having pain and eight (44.40%) patients having numbness had inguino-scrotal hernias which were long standing.

On the post-operative day one, all the patients had pain. 61.6% (61/99) of the patients had mild intensity of pain - 67.5% (27/40) in neurectomy group and 55.9% (33/59) in nerve preserved group. 36.4% (36/99) of the patients had moderate intensity of pain - 32.5% (13/40) in neurectomy group and 39.5% (23/59) in nerve preserved group. Three (three percent of the total patients) patients in the nerve preserved group (five percent of the group B) had severe intensity of pain. However, there was no statistical significant difference in the incidence of pain in either group. 27.50% (11/40) in the neurectomy group and seven percent (4/59) of the patients in the nerve preserved group developed numbness post operatively on day one. There was a statistically significant difference ($Z < 0.05$) in the incidence of numbness on post-operative day one.

At 30th post-operative day (short term analysis), 21% (20/95) of the patients had mild intensity of pain and 2.2% (2/95) of the patients had moderate intensity of pain. In the neurectomy group 12.50% (5/40) and 27.30% (17/55) in the nerve preserved group had mild intensity of pain. None of them were receiving analgesics for pain. There was no significant difference in the incidence of pain between these two groups. The incidence of numbness on post-operative day 30 was 22.50% (9/40) in neurectomy group and 3.60% (2/55) in the nerve preserved group. There was ($Z < 0.05$) statistical significance in the incidence of numbness at post-operative day 30.

Six months post hernia repair (mid-term analysis), 16.70% (15/90) of the patients had pain. 7.90% (3/38) in the neurectomy group and 25.70% (12/52) in the nerve preserved group had pain. 14.40% (13) of the patients had mild intensity of pain and 2.30% (two) of the patients had moderate intensity of pain in the study group. In the 13 patients who had mild intensity of pain, three (7.90%) belong to the neurectomy group and 10 (19.20%) belong to the nerve preserved group. Both the patients (2.30% =2/90) with moderate intensity of pain at six months belong to the nerve preserved group *i.e.* 6.70% (2/52). The two patients who had moderate intensity of pain continued to have pain and were taking analgesics intermittently. There was no statistically significant difference in the incidence of pain at six months post operatively. At six months postoperatively, 10.50% and 1.90% of the patients continued to have numbness in the neurectomy group and the nerve preservation group. However there was no statistically significant difference in the

Pain assessment		Neurectomy done	Nerve preserved	Total
Pre operative pain	No pain	40	51	91
		90.90%	83.60%	86.70%
	Mild	4	10	14
		9.10%	16.40%	13.30%
Total		44	61	105
Pain on post operative day 1	No pain	0	0	0
		0%	0%	0%
	Mild	27	33	60
		67.50%	55.90%	60.60%
	Moderate	13	23	36
		32.50%	39.00%	36.40%
	Severe	0	3	3
		0%	5.10%	3.00%
Total		40	59	99
Pain at 30th post operative day	No pain	35	38	73
		87.50%	69.10%	76.80%
	Mild	5	15	20
		12.50%	27.30%	21.00%
	Moderate	0	2	2
		0%	3.60%	2.20%
Total		40	55	95
Pain at 6 months post operative	No pain	35	40	75
		92.10%	76.90%	83.30%
	Mild	3	10	13
		7.90%	19.20%	14.40%
	Moderate	0	2	2
		0	6.7%	2.30%
Total		38	52	90

Table 2: Pain assessment in the two groups at the predefined time intervals

Assessment of numbness		Neurectomy done	Nerve preserved	Total
Preoperative numbness	Present	6	12	18
		13.60%	19.70%	17.10%
	Absent	38	49	87
		86.40%	80.30%	82.90%
Total		44	61	105
Numbness on post operative day 1	Present	11	4	15
		27.50%	7.00%	15.20%
	Absent	29	55	84
		72.50%	93.00%	84.80%
Total		40	59	99
Numbness at post operative day 30	Present	9	2	11
		22.50%	3.60%	11.60%
	Absent	31	53	84
		77.50%	96.40%	88.40%
Total		40	55	95
Numbness at 6 months post operative	Present	4	1	5
		10.50%	1.90%	5.60%
	Absent	34	51	85
		89.50%	98.10%	94.40%
Total		38	52	90

Table 3 Assessment of numbness in the two groups at predefined time intervals.

Discussion:

Though it is difficult to differentiate between the neuropathic and the non-neuropathic pain, the morbidity caused to the patient and the legal issues due to this pain to the hernia surgeons, is worth noting. The concept of neurectomy was not new in surgery. Lichenstein was one of the first to suggest prophylactic inguinal nerve excision as an option in avoiding post hernia repair groin pain[2]. The theoretical benefit, that this method would remove the potential cause for the chronic pain in post hernia repair, made many surgeons to opt for prophylactic neurectomy in open inguinal mesh repair. Several randomised control trials were published on this trying to strengthen this view, and the controversies still persist. Mesh hernia repair, which is now performed for almost all cases of inguinal hernia repair, is now considered as a significant etiological factor for increased incidence of neuropathic pain in the post hernia repair owing to the degree of fibrotic reaction induced by it. Ilioinguinal, iliohypogstric and the genitofemoral nerve are the three main nerves that traverse through the surgical field and are prone to get entrapped in the fibrotic tissue and injured directly during the hernia repair.

A retrospective review by Dittrick *et al.,* found that ilioinguinal neurectomy during open, tension-free mesh repair resulted in significantly less pain after 1 year compared with routine nerve preservation, three percent and 25%, respectively[3]. A double-blinded, randomized controlled trial to investigate the effects of prophylactic ilioinguinal neurectomy following tension-free mesh repair of inguinal hernia was conducted by Mui *et al.,* with 100 male patients randomized into two groups: prophylactic ilioinguinal neurectomy or ilioinguinal nerve preservation. The incidence of chronic groin pain at six months was significantly lowered compared with the nerve preservation group (eight percent versus 28.6%, P = .0008) and there was no significant difference in the incidence of neurosensory complaints, including groin numbness and sensory loss[4]. However, Pappalardo *et al* performed unilateral iliohypogastric neurectomy on 100 men requiring bilateral inguinal hernia repair, with each patient also serving as a control. They failed to demonstrate significant difference in the incidence of sensory abnormalities between the two sides and also in the intensity of pain after seven days post repair[5]. A double-blind study by Picchio *et.al,* on 813 patients showed that, one year after surgery, pain was present in 23.5% of nerve preserved and 27% of nerve-transected patients with 95% confidence interval. Severe pain was recorded in two percent and three percent respectively. They suggested that postsurgical pain after hernia repair was not affected by elective ilioinguinal nerve division, yet sensory disturbances in the area were significantly increased[6].

This study was performed to know the incidence of the inguinodynia, and then compare the incidence between the ilioinguinal neurectomy group and the nerve preserved group. The study was double blinded to avoid the subjective and objective bias. The pre-operative data collected was used as a control.

Our study, showed that the there was no significant difference in the incidence of pain at all the time intervals studied. But, variation in the intensity of pain can was worth noting. At the end of one month and six months, none of the patients in the neurectomy group had either moderate or severe intensity of pain. The incidence of chronic inguinodynia at the end of six months was 16.7%, with 13.3% of the patients belonging to the nerve preserved group and 3.4% of the patients belonging to the neurectomy group. None of the patients in the neurectomy group had disabling pain. There was significant difference in the incidence of numbness at first post-operative day and the 30th post-operative day. At the end of six months there was no significant difference in the incidence of numbness between the two groups.

This study is the first from the Indian subcontinent, to the best of our knowledge. Considering the ethnic, cultural, literacy and the pain tolerance differences from the west, where majority of studies were performed on this issue, studies like ours in which pain is the primary outcome are debatable and cannot be generalized. Pain being quite subjective, even with the use of well-established scoring systems like visual analogue score, accuracy in assessing the intensity is questionable. As there is evidence that there will cross innervation between the nerves passing through the inguinal region, beneficial outcomes from ilioinguinal neurectomy alone are doubtful. More studies with increased sample size and decreased dropouts in the follow up, multicenter based including different ethnic and cultural groups and involving different combinations of the nerves passing through the surgical field are needed. As of now, we think that there was no reason why we should not perform a neurectomy as there was decreased intensity of pain even though there was no significant decrease in the incidence and the morbidity of numbness was insignificant.

Conclusion:

Prophylactic inguinal neurectomy offers a permanent solution to chronic inguinodynia following inguinal hernia surgery and can be offered to selective patients after a careful discussion with them.

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