Ilioinguinal Neurectomy and Chronic Post-Operative Pain After Inguinal Hernia Repair

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Objective: This study aims to determine the effect of preservation/division of ilioinguinal nerve in patients undergoing lichtenstein hernioraphy on severity of chronic post operative pain as well as presence/absence of groin numbness.

Method: A randomised control trial was conducted for a period of six months on 60 patient fulfilling inclusion criteria who underwent lichenstein hernioraphy at general surgery department of Liaquat National University Hospital Karachi, Pakistan.

Result: A total of 60 patients undergoing elective inguinal hernia mesh repair were included in study and divided in two groups with 30 patients each. Only male patients were included in the study as female gender was one of the exclusion criteria so gender stratification was not considered. Patients between 17 to 77 yrs of age were included in study and randomly divided in two groups. Mean age of population in group A is 42.96 +/- 17.76 and in group B is 54.23 +/- 15.0. The minimum age of the patient in Group A is 17 years and maximum age is 73 years whereas minimum age of the patient in Group B is 20 years and maximum age is 77 years.

45.9% Patients in group A (Nerve preservation group) have right inguinal hernia.

54.0% Patients in group B (Nerve Division group) have right inguinal hernia.

56.5% Patients in group A (Nerve Preservation group) have left inguinal hernia.

43.4% Patients in group B (Nerve Division group) have left inguinal hernia.

Chronic groin pain while different physical activities and groin numbness in nerve preservation and nerve division group was assessed at three and six months follow ups in all patients of the study population. 3% of the patients from nerve preservation group had mild pain during climbing stairs at three and six months follow up and the P-Value was 0.313 which is statistically not significant. 10% of the patients from nerve division group and 50% patients from nerve preservation group had pain during brisk walking at three months follow up and the P-Value was 0.001 which is statistically significant. 23% of the patients from nerve division group and 60% patients from nerve preservation group had pain during brisk walking at six months follow up and the P-Value was 0.004 which is statistically significant. 13.3% patients from nerve preservation group had moderate pain during brisk walking at three months follow up while none of the patient from nerve division group had pain and P-Value was 0.038 which is statistically significant. 6.6% of the patients from nerve preservation group had moderate pain during brisk walking at six months follow up while none of the patient from nerve division group had pain and p-value was 0.150 which is statistically in significant. 20% of the patients from nerve division group and 30% of the patients from nerve preservation group had mild groin numbness at three months follow up with P-Value of 0.371 which is statistically in significant. 33.3% of the patients from nerve division group and 30% of the patients from nerve preservation group had groin numbness at six months follow up with a p-value of 0.781 which is statistically in significant.

Conclusion: Prophylactic ilioinguinal neurectomy during Lichtenstein tension free inguinal hernia repair decreases the incidence of exertional chronic post operative pain as compare to the nerve preservation group. However the cutaneous neurosensory disturbance/groin numbness between the two groups has no difference in term of outcome.
Introduction

Ilioinguinal hernia is the most common male disease worldwide [1]. Repair of inguinal hernia is the second most commonly performed general surgery procedure [1-4]. The most annoying complication is chronic post-operative pain causes include trauma during dissection to ilioinguinal nerve passing through the surgical field, fibrosis and inflammation induced by the prosthetic mesh in close proximity to ilioinguinal nerve, stranguulation of the nerve caught by suturing etc. [1-3]. Chronic post-operative pain has been reported in 19% to 69% cases of inguinal hernia repair. Severe groin pain has been reported in 3% cases [1-3]. Chronic pain has been reported as the pain that lasts longer than the usual healing time of six weeks. Various time scales have been suggested, usually 3 or 6 months [1].

The ilioinguinal nerve encountered during open repair of the inguinal hernia as it lies immediately beneath the external oblique aponeurosis. Traditionally the nerve is preserved during repair because of the expected cutaneous sensory loss and chronic groin pain following nerve injury [2-3].

Studies on ilioinguinal neurectomy during hernia repair have shown decrease in the incidence of chronic groin pain compare to the routine nerve preservation [1]. However the results have been inconsistent. The control trials by Picchio et al. found similar incidence of loss of pain sensation between ilioinguinal nerve preservation versus division group i.e. 5% Vs 33% at six months where P-value is statically not significant. However the incidence of loss of touch sensation between the two groups is 6% Vs 29% at six months where the P-value is statically significant. It concludes that elective division of the ilioinguinal nerve negatively affects the groin numbness while it has no effects on chronic groin pain. On the other hand control trails by Dittrick et al. [2] concludes that the incidence of chronic groin pain between nerve excisions versus preservation group is 3% Vs 26% at six months where P-value is statically significant. However the incidence of groin numbness between the two groups is 18% Vs 4% at six months where P-value is statically not significant. It concludes that elective division of ilioinguinal nerve reduces post operative groin pain and has no effect on groin numbness.

The aim of this study is to assess the effect of preservation or the division of ilioinguinal nerve on post operative groin pain and numbness after open inguinal hernia repair with polypropylene mesh. The results will help to reduce troublesome complication of open inguinal hernia repair.

Objective

To determine the effect of preservation versus division of ilioinguinal nerve in patients under going inguinal hernia mesh repair on,
1. Severity of chronic post operative groin pain measured using VAS.
2. Frequency of presence / absence of groin numbness.

Operational Definitions

Chronic groin pain

Pain that lasts longer than three months duration. Clinically neuropathic pain is typically characterized as a burning or shooting pain in the distribution of the affected nerve. Severity of the pain will be calculated using Visual Analog Score.

Visual Analog Score (VAS)

A visual analog score is a useful device for accurately determining the level of pain. The patient indicates the intensity of pain he/she is feeling as mild (1-3), moderate (4-7) and severe (8-10) [2].

Groin numbness

Change in the level of sensation along the distribution of ilioinguinal nerve i.e skin over the groin region specially medial aspect of thigh, the upper part of scrotum and the penile root compared to the non operative healthy side. Technique of evaluation include needle point prick for pain and wisp of cotton for touch. Post operative presence and absence of numbness will be evaluated at three and six month.

Hypothesis

Prophylactic ilioinguinal neurlectomy significantly decreases the incidence of chronic groin pain after inguinal hernia mesh repair and has no effect on the post operative groin numbness.

Material and Methods

Setting

Department of General Surgery, Liaquat National Hospital Karachi.

Duration of study: Six months.

Sample size

P1= 3%, P2= 26%
1-beta= 80%, 1- alpha= 95%
N=60, (n1= 30 patients group A, n2= 30 patients group B)

Sample Technique

Non probability purposive sampling.

Study Design

Randomized control trials.

Sample Selection

Inclusion criteria

- Patients above 16 years.
- Patients having reducible unilateral inguinal hernia of any duration diagnosed on the basis of clinical examination of inguinal region (findings include swelling in inguinal region, positive cough impulse and positive ring occlusion test) will be selected for elective Lichtenstein repair.

Exclusion criteria

- Bilateral inguinal hernia.
- Recurrent hernia.
- Irreducible / strangulated hernia.
- Inguino-scrotal hernia.
- H/O previous abdominal incision.
- Peripheral neuropathy.
- Impaired cognitive functions.
- Limited mobility.
- Female gender.
- Patients in which ilioinguinal nerve not identified preoperatively (when the patient is under anesthesia).
- Patients operated in anesthesia other than spinal anesthesia.
Data Collection

After selecting patients according to inclusion and exclusion criteria, patient will be informed about the study and its purpose. Verbal and written consent will be taken from the patients. Patients will be included in study only if they give will consent and approval from the ethical committee of LNH has been taken. Demographic details will be taken from case file as well as directly interviewing the patient. Data will be filled by principle investigator on the perfroma attached at the end. Patients selected for the elective hernia repair undergo standard tension free herniorrhaphy. Standard tension free herniorrhaphy involves placement of an approximately 11cm × 6 cm (tailored to the individual patient requirements) mesh as an extra lamina anterior to the posterior wall and overlapping it generously in all directions including medially over the pubic tubercle. After identification of the ilioinguinal nerve during surgery a slip will be taken randomly from the box, already containing equal number of marked slips with group A/B.

This will be done per operatively (when patient is under anesthesia) because sometime ilioinguinal nerve is not identified and such patient will be excluded from study.

- Group A: Nerve preservation group
- Group B: Nerve division group (Nerve will be divided as far lateral to the deep ring as possible and medially to the point where it exit the superficial inguinal ring divided ends will be ligated with chronic 2/0). Ilioinguinal nerve will be identified by operating 3rd/4th year resident and confirmed by consultant/ supervisor (FCPS/FRCS in General Surgery with more than five years of post fellowship exposure)

Patient will be followed by the primary investigator who will not be involved in randomization process. All patients will receive the standard mesh repair procedure and will be managed in a standard clinical pathway post operatively and will be followed at three and six month in OPD (Final out come will be measured at six month). The researcher will keep a log of all patients included in the study and will take their contact numbers and will communicate with other team members so that he can be called once the patient came in OPD and in case of non arrival on the expected visits patients will be contacted by calling them on contact numbers.

Primary outcome

Primary outcome measured will be the occurrence of chronic groin pain at six months after surgery.

On the follow up visit the presence and severity of post-operative pain after following activities will be inquired from the patients.

- At rest
- After coughing
- Climbing stairs
- Vigorous walking/jogging

VAS with total 10 points (1-10) will be used to determine the severity of pain as Non(0), Mild (1-3), Moderate (4-7) and Severe (8-10).

Secondary Outcome

Post-operative presence or absence of groin numbness in each patient will be assessed and documented on their OPD follow ups visits at six month while comparing with the opposite non operative side.

Ethical Approval

An approval from hospital ethical committee has been taken. Patient/ attendant explained regarding whole procedure and there written and verbal consent taken. Further details have been mentioned in consent form attached. No external source of funding was required and sought. There is no conflict of interest in any of the two groups of study.

Results

Demographic analysis of the study population

A total of 60 patients under going elective inguinal hernia mesh repair included 30 patients in each group. None of the patients lost to follow up so all 60 patients were included in the study, as shown in Table 1.

### Table 1: Division of patients in two groups on the basis of nerve preservation versus nerve dissection.

| Group                  | Frequency | Percentage |
|------------------------|-----------|------------|
| Nerve preservation     | 30        | 50.0       |
| Nerve division         | 30        | 50.0       |
| Total                  | 60        | 100        |

Out of 60 Patients included in the study population, patients divided according to the site of hernia operated (Table 2).

### Table 2: Division of patients on the basis of site of hernia operated.

| Site     | Frequency | Percentage |
|----------|-----------|------------|
| Left     | 23        | 38.3%      |
| Right    | 37        | 61.7%      |
| Total    | 60        | 100%       |

### Table 3: Patients of the two groups divided on the basis of site of hernia operated.

| Site     | Nerve preservation | Nerve division |
|----------|--------------------|----------------|
| Left     | 13                 | 10             |
| Right    | 17                 | 20             |
| Total    | 30                 | 30             |

45.9% Patients in group A (Nerve preservation group) have right inguinal hernia.
54.0% Patients in group B (Nerve Division group) have right inguinal hernia.
56.5% Patients in group A (Nerve Preservation group) have left inguinal hernia.
43.4% Patients in group B (Nerve Division group) have left inguinal hernia.

Only male patients were included in the study as female gender was one of the exclusion criteria so gender stratification was no considered.

Patients between 17 to 77 yrs of age were included in study and randomly divided in two groups. Mean age of population in group A is 42.96 +/- 17.76 an in group B is 54.23 +/- 15.0. The minimum age of the patient in Group A is 17 years and maximum age is 73 years whereas minimum age of the patient in Group B is 20 years and maximum age is 77 years (Table 3).
Chronic groin pain while different physical activities and groin numbness in nerve preservation and nerve division group was assessed at three and six months follow ups in all patients of the study population.

Mild chronic groin pain during rest at three months follow up was observed in both nerve preservation and nerve dissection group and in both groups no change noticed because both groups have no pain.

Mild chronic groin pain during rest at six months follow up was observed in both nerve preservation and nerve dissection group and in both groups no change noticed because both groups have no pain.

Moderate chronic groin pain during rest at three months follow up was observed in both nerve preservation and nerve dissection group and in both groups no change noticed because both groups have no pain.

Moderate chronic groin pain during rest at six months follow up was observed in both nerve preservation and nerve dissection group and in both groups no change noticed because both groups have no pain.

Severe chronic groin pain at rest at three months follow up was observed in both nerve preservation and nerve dissection group and in both groups no change noticed because both groups have no pain.

Severe chronic groin pain at rest at six months follow up was observed in both nerve preservation and nerve dissection group and in both groups no change noticed because both groups have no pain.

Mild chronic groin pain during coughing at three months follow up was assessed and in both groups no change noticed because both groups have no pain.

Mild chronic groin pain during coughing at six months follow up was assessed and in both groups no change noticed because both groups have no pain.

Moderate chronic groin pain during coughing at three months follow up was assessed and in both groups no change noticed because both groups have no pain.

Moderate chronic groin pain during coughing at six months follow up was assessed and in both groups no change noticed because both groups have no pain.

Severe chronic groin pain during coughing at three months follow up was assessed and in both groups no change noticed because both groups have no pain.

Severe chronic groin pain during coughing at six months follow up was assessed and in both groups no change noticed because both groups have no pain.

Mild chronic groin pain during climbing stairs at three months follow up in both nerve preservation and nerve dissection group was assessed. One patient in nerve preservation group had pain that is 3% of the total group population and the P-Value was 0.313 which is statistically not significant (Table 4)(Figure 1).

Table 4: Patients experience pain after climbing stairs at three months follow up.

| Groups        | MILDPAIN3MCLIMBING | Total |
|---------------|--------------------|-------|
| Nerve division| 30                 | 30    |
| Nerve preservation | 29 | 30    |
| Total         | 59                 | 60    |

Mild chronic groin pain during climbing stairs at six months follow up in both nerve preservation and nerve dissection group was assessed. One patient in nerve preservation group had pain that is 3% of the total group population and P-Value was 0.313 which is statistically not significant (Table 5)(Figure 2).

Table 5: Patients experience mild pain after climbing stairs at six months follow up.

| Groups        | MILDPAIN6MCLIMBING | Total |
|---------------|--------------------|-------|
| Nerve division| 30                 | 30    |
| Nerve preservation | 29 | 30    |
| Total         | 59                 | 60    |
Moderate chronic groin pain during climbing stairs at three months follow up in both nerve preservation and nerve dissection group was assessed and in both groups no change noticed because both groups have no pain.

Moderate chronic groin pain during climbing stairs at six months follow up in both nerve preservation and nerve dissection group was assessed and in both groups no change noticed because both groups have no pain.

Severe chronic groin pain during climbing stairs at three months follow up in both nerve preservation and nerve dissection group was assessed and in both groups no change noticed because both groups have no pain.

Severe chronic groin pain during climbing stairs at six months follow up in both nerve preservation and nerve dissection group was assessed and in both groups no change noticed because both groups have no pain.

Mild chronic groin pain during brisk walking at three month follow up in both nerve preservation and nerve dissection group was assessed. Three patients from nerve dissection group had pain that is 10% of the total group population and fifteen patients from nerve preservation group had pain that is 50% of the group population and P-Value was 0.001 which is statistically significant (Table 6)(Figure 3).

Moderate chronic groin pain during brisk walking at three month follow up in both nerve preservation and nerve dissection group was assessed. None of the patient from nerve dissection group had pain but four patients from nerve preservation group had pain that is 13.3% of the total group population and P-Value was 0.038 which is statistically insignificant (Table 8)(Figure 5).

Mild chronic groin pain during brisk walking at six months follow up in both nerve preservation and nerve dissection group was assessed. Seven patients from nerve dissection group had pain that is 23% of the total group population and twelve patients from nerve preservation group had pain that is 60% of the total group population and P-Value was 0.004 which is statistically significant (Table 7)(Figure 4).
Moderate chronic groin pain during brisk walking at six months follow up in both nerve preservation and nerve dissection group was assessed. None of the patient from nerve dissection group had pain but two patients from nerve preservation group had pain that is 6.6% of the total group population and P-Value was 0.150 which is statistically insignificant (Table 9)(Figure 6).

| Groups            | MILDPAIN3MWALKING | Total |
|-------------------|------------------|-------|
| No                | Yes              |       |
| Nerve division    | 30               | 0     | 30   |
| Nerve preservation| 28               | 2     | 30   |
| Total             | 58               | 2     | 60   |

Table 9: Patients experience moderate pain after brisk walking / jogging at six months follow up.

Severe chronic groin pain during brisk walking at three months follow up in both nerve preservation and nerve dissection group was assessed. None of the patient from any group had pain.

Severe chronic groin pain during brisk walking at six months follow up in both nerve preservation and nerve dissection group was assessed. None of the patient from any group had pain.

Mild groin numbness at three months follow up was assessed in both groups. Six patients from nerve dissection group that is 20% of the total group population and nine patients from nerve preservation group that is 30% of the total group population had numbness. P-Value was 0.371 which is statistically insignificant (Table 10)(Figure 7).

| Groups            | MILDPAIN6MWALKING | Total |
|-------------------|------------------|-------|
| No                | Yes              |       |
| Nerve division    | 20               | 10    | 30   |
| Nerve preservation| 21               | 9     | 30   |
| Total             | 41               | 19    | 60   |

Table 10: Patients experience mild numbness at three months follow up.

Figure 6: Presentation of patients experience moderate pain after brisk walking / jogging at six months follow up.

Moderate groin numbness at three months follow up was assessed in both groups. None of the patients of either group had numbness.

Moderate groin numbness at six months follow up was assessed in both groups. None of the patients of either group had numbness.

Severe groin numbness at three months follow up was assessed in both groups. None of the patients of either group had numbness.

Severe groin numbness at six months follow up was assessed in both groups. None of the patients of either group had numbness.

Discussion

Chronic post operative groin pain after inguinal hernia mesh repair is becoming one of the significant problem [4]. It is important to differentiate between the chronic and acute post operative pain. Early post operative is usually seen soon after surgical intervention and easily managed with analgesics and generally resolves with in 15-30 days of surgery without the need of any further treatment [4]. On the other hand moderate to severe groin pain generally seen after surgical procedure and persisting beyond the normal tissue healing time assumed to be three months is considered to be the chronic post operative pain [4,5]. Several factors have been proposed as predictors of chronic pain such as experience of the surgeon, surgery due to recurrence, damage to the inguinal nerve, partial division, neuroma formation, nerve entrapment during mesh implantation [4]. The nerve usually divided or ligated when its course in the operating field would lead to the risk of injury or if it interfere with the positioning of mesh. Leaving the injured nerve intact will continue to generate the pain signals and remain exposed to the neuroma formation. It is important to

Table 11: Patients experience mild numbness at three months follow up.

| Groups            | MILDPAIN6MWALKING | Total |
|-------------------|------------------|-------|
| No                | Yes              |       |
| Nerve division    | 20               | 10    | 30   |
| Nerve preservation| 21               | 9     | 30   |
| Total             | 41               | 19    | 60   |

Table 12: Patients experience mild numbness at six months follow up.

Figure 8: Patients experience mild numbness at six months follow up.
In a new shell we have both types of studies in literature preservation and division with chronic post operative groin pain. Met al has been failed to show any relationship between nerve preservation group. On the other hand a study done by Picchio incidence of post operative chronic groin pain was significantly Malepour et al, Dittrick et al, Mui et al. etc showed that the incidence of post operative chronic groin pain was significantly lower in nerve division group as compare to the nerve preservation group. On the other hand a study done by Picchio M et al has been failed to show any relationship between nerve preservation and division with chronic post operative groin pain. In a net shell we have both types of studies in literature favoring ilioinguinal nerve division/preservation to be beneficial for reduction of chronic post operative groin pain after elective inguinal hernia mesh repair. This study has been conducted to assess the effect of ilioinguinal neurectomy on chronic post operative pain and groin numbness after inguinal hernia mesh repair. In this study total 60 patients were selected who fall in the inclusion criteria of the study and were randomly divided in to two groups that is nerve preservation (group A) and nerve division (group B). Mean age of population in group A is 42.96 +/- 17.76 an in group B is 54.23 +/- 15.0. All patients were male as female gender was exclusion criteria. Both groups were compared in term of post operative chronic pain and groin numbness. Patients were followed on OPD basis at three and six months. All patients were challenged by being asked to complete a series of tasks before pain assessment, including rest, after coughing, after climbing stairs and after brisk walking/jogging for five minutes. Therefore we were able to examine the effects of exertion on groin pain after surgery; this will better express their experience of pain during routine daily activities. Pain score was assessed using visual analog score as mild, moderate and severe. Groin numbness was assessed at rest using same visual analog score after comparing with the opposite non surgical site. Our randomized study revealed that the incidence of chronic groin at rest and while coughing was similar between the two groups which is similar to the findings of Picchio et al. however chronic pain on vigorous walking/jogging was higher in nerve preservation group as compare to the neurectomy group where the P-value was statistically significant (P-Value at three month follow up was 0.001 and at six months follow up it was 0.004). This also reflect that the effects of ilioinguinal neurectomy during hernia repair has better post operative results regarding daily activities and quality of life. On the other hand groin numbness between the two groups has similar out come and the P value is statistically insignificant [6-8].

Conclusion
The results of these prospective randomized control trials demonstrate that prophylactic ilioinguinal neurectomy during Lichtenstein tension free inguinal hernia repair decreases the incidence of exertional chronic post operative pain as compare to the nerve preservation group. However the cutaneous neurosensory disturbance/groin numbness between the two groups has no difference in term of outcome. So it has been recommended that ilioinguinal neuroectomy should be a routine step during inguinal hernia mesh repair as it will improve patients over all quality of life and has no effects on neurosensory disturbance.

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