

## Chronic pain after hernia surgery –An Informed Consent Issue

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Accepted 25 April 2007

**Keywords:** Inguinal hernia, pain, chronic, consent

### SUMMARY

Chronic severe pain following inguinal hernia repair is a significant post-operative problem. Its exact cause and lack of evidence-based treatment path present problems in the effective management of this surgical complication. We retrospectively reviewed the records of patients diagnosed with chronic pain following open inguinal hernia repair between November 1995 and November 2000, who were under the care of the senior author. Over the five-year period, 146 patients underwent inguinal hernia repair. 88 (60%) had suture repair (darn & modified Bassini's) and 58 (40%) underwent a Lichtenstein mesh repair. Thirteen patients (9%), (3 in suture vs. 10 in mesh group,  $p=0.004$ ) developed chronic severe pain. Examination revealed maximal tenderness over the genitofemoral nerve (GF) distribution ( $n=5$ ), over the medial end of the scar ( $n=3$ ), over the pubic tubercle ( $n=1$ ) and in the ilioinguinal nerve distribution ( $n=1$ ). No abnormality was detected on clinical examination in the cases of three patients. Treatment involved GF nerve block ( $n=5$ ), local injection of Chirocaine and Methylprednisolone acetate into the medial end of the scar ( $n=3$ ), Chirocaine and Methylprednisolone acetate into the pubic tubercle ( $n=1$ ), ilioinguinal nerve block ( $n=1$ ), re-exploration with re-suturing of the mesh ( $n=1$ ), and Amitriptyline ( $n=2$ ). At a median follow up of 45 months (range: 24-87), 10 (77%) are completely pain free; two (15.4%) had mild pain and one patient still has significant persistent pain. To conclude, chronic severe pain occurred in nine percent of patients following primary open inguinal hernia repair. The majority of patients were successfully treated by therapeutic injection into the point of maximal tenderness.

### INTRODUCTION

Chronic groin pain following inguinal hernia repair is a potentially incapacitating complication, and presents a diagnostic and therapeutic challenge to the clinician. The exact cause for the pain is not clear. However, it is believed to be due to entrapment of the ilioinguinal, iliohypogastric or genital branch of the genitofemoral nerve either in the sutures, mesh or scar tissue<sup>1-3</sup>. Both routine preservation and division of the genital branch of the genitofemoral nerve have been advocated to prevent pain<sup>2,4,5</sup>. It is not clear from the literature whether careful preservation of the ilioinguinal nerve is associated with lower incidence of chronic pain<sup>2,6</sup>. To date, the evidence for the ideal management of chronic groin pain is unclear. We describe our experience of managing chronic groin pain patients with nerve blocks. This involved injection of local anaesthetic, with or without steroid, into the area of

maximal tenderness on clinical examination, with or without the addition of anti-neuropathic medication.

### MATERIALS AND METHODS

The records of all surgical patients who underwent an inguinal hernia (including Gilmore's groin) repair, under the care of the senior author at the City Hospital, Belfast, between November 1995 and November 2000 were reviewed. Their recorded demographic, clinical, operative, and follow-up details were analysed. Details of sporting activity, professional status, and history of injury (in the form of groin strain) were also obtained. Patients with pre-operative groin pain and obscure hernia had a herniogram to confirm the presence of hernia before surgery.

Informed consent, including explanation of the risk of chronic pain, was obtained from all patients in an outpatient setting. All patients, particularly those with groin pain due to suspected Sportsman's hernia, were informed that surgery may not relieve their symptoms. All patients were consented by either the senior author or by the senior registrar who would be performing the operation, either under the senior author's supervision or independently.

All surgery was performed under general anaesthesia. Operative techniques included nylon darn, modified Bassini's and Lichtenstein mesh repair (the latter technique was utilised in the later part of the series). Ilioinguinal nerve was identified and preserved in all patients. Patients were reviewed in the surgical outpatients' clinic four to six weeks following their hernia repair. A detailed discharge letter, with a request to contact the senior author if patients developed any post-operative complications was sent to each patient's General Practitioner. Eighteen patients were referred back to the surgical outpatient clinic because of persistent pain. Chronic pain was defined as pain persisting beyond the normal tissue healing time: 3 months<sup>7</sup>. Each patient was asked to describe the character, site, and severity of the pain. Patients were also asked about whether pain was interfering with their daily routine and/or physical/sporting activity. Pain severity was classified into mild, moderate, and severe on a three point verbal scale. All patients were examined either by the senior author or by a senior registrar. Examination included inspection and palpation of the operation site with the patient supine and erect, both with, and without, performing the

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Valsalva manoeuvre. All eighteen patients, following the exclusion of hernia recurrence as a cause, were referred to the pain clinic run by anaesthetists with a special interest in the management of chronic pain.

Treatment depended mainly upon the nature of the reported pain. Patients with predominantly neuropathic symptoms were treated with Amitriptyline. Patients with somatic pain and a well-defined tender area were treated with nerve blocks using either 0.5% Chirocaine® (Abbott) alone or with 20mg of Methylprednisolone acetate (Depo-Medrone®, Pharmacia). Patients with mixed nature pain were treated by the use of a nerve block, all administered by a consultant anaesthetist using the technique described by the New York School of Regional Anaesthesia (NYSORA) and Amitriptyline. All patients were evaluated by the pain clinic every three months. On the day of their last follow-up, the first author contacted all patients by telephone to determine whether they were still experiencing pain.

### STATISTICAL ANALYSIS

Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) for Windows, version 11 (SPSS, Chicago, Illinois, USA). Chi-square ( $\chi^2$ ) test was used to examine the association between type of repair and the presence of chronic pain.  $P < 0.05$  was significant.

### RESULTS

There were 146 open inguinal hernia repairs performed under the care of the senior author between November 1995 and November 2000. 88 (60%) patients had suture repair (Darn & modified Bassini's) and 58 (40%) underwent mesh repair in the later part of the series. Eighteen patients (12.3%) reported persistent groin pain 3 months after surgery. Five patients were excluded from the study. Four of the five had mild groin pain and no obvious abnormal findings after physical examination and a herniogram. The use of oral analgesia alone gave complete pain relief. The fifth patient came six months after surgery, with numbness over the medial end of the scar and the lateral aspect of the upper thigh. The patient was referred to the pain clinic, but failed to attend. Of the remaining thirteen patients, 10 were male and 3 female with a median age of 58 years (range: 27-72). The median duration of chronic pain was six months (range: 4-16).

Four patients reported a history of 'groin strain' injury; three were professional footballers and the other patient's work involved the lifting of heavy weights. Of the thirteen patients, eight had indirect inguinal hernias, two direct inguinal hernias and three Gilmores' Groin - diagnosed in patients with a tear in the external oblique aponeurosis<sup>8</sup>. Apart from one patient with an irreducible indirect hernia, all the other hernias were repaired on an elective basis. Ten patients underwent Lichtenstein mesh repair and three had suture repair ( $p=0.004$ ). The mean hospital stay was 1.7 (range: 1-4) days. One patient developed a wound haematoma requiring evacuation.

On examination there was tenderness over the genitofemoral nerve distribution in five patients. One of these five patients also had tenderness over the pubic tubercle on the operated side, and one had tenderness over the scar. All five patients were treated with a genitofemoral nerve block using 0.5%

Chirocaine® (Abbott) in combination with 20mg of Depo-Medrone® (Pharmacia) injection. In addition, one patient was also treated by a local injection of Chirocaine® over the pubic tubercle, and a repeat genitofemoral nerve block after two months. Two of the five patients also received Amitriptyline. Amitriptyline was started with a small dose of 10 mg/once a day and gradually increased to 50mg/day over a period of three to six months.

Three patients had tenderness over the medial end of the scar with no obvious hernia and all were treated by a local injection of Chirocaine® and Depo-Medrone® into the affected area. One patient required three repeat injections at bimonthly intervals. Another patient had tenderness over the pubic tubercle, and again, the use of a local injection of Chirocaine® and Depo-Medrone® achieved complete analgesia. Two patients, with neuropathic pain were treated by Amitriptyline alone, and had complete symptom relief at 44 and 48 months.

One patient who was still having severe pain in the wound a year after surgery was initially treated with an injection of Chirocaine® into the wound; but this was not successful. So the groin was re-explored, revealing that the prolene mesh had pulled off the inguinal ligament; causing recurrence of the hernia. The mesh was therefore re-sutured. The patient was completely pain free at 85 months.

One patient had groin pain along the distribution of the ilioinguinal nerve, and as the physical findings were normal, was treated by an ilioinguinal nerve block using Chirocaine® and Depo-Medrone®. However, no significant reduction in the intensity of the pain was experienced.

At a median follow up of 45.5 months (range: 24.1-86.7), 10 of the 13 patients (77%) had complete pain relief. Three patients still had pain at the time of their last follow up. Of the three, two had pain of mild intensity which did not affect their physical or sporting activities. The third patient still had significant pain interfering with her household duties at 45 months following the hernia repair. The details of hernia type, method of repair, nature of pain, examination findings and treatment received are summarised in Table I

### DISCUSSION

The incidence of chronic pain after inguinal hernia has been estimated to be between 1% and 19%<sup>4,9,10</sup>. In the present study, an internationally accepted standard definition of pain (pain beyond 3 months) was used<sup>7</sup>. We observed chronic, severe pain in nine percent of patients. In a multicentre prospective study looking at the incidence of chronic pain, Alfieri *S et al* observed chronic severe pain in 0.5% of patients at 1-year follow-up<sup>11</sup>. In a questionnaire study, Cunningham *et al* noted that 12% respondents (315 of 883 patients: 36% response rate) had moderate or severe pain one year after open hernia surgery<sup>10</sup>. Callesen *et al* reported that 19% of patients complained of some pain and 6% of patients complained of moderate to severe pain at 1 year following hernia repair<sup>12</sup>.

One of the major drawbacks of our study is that we have completely relied on General practitioners to refer patients with chronic pain to senior author's outpatient clinic. Regular follow up of all patients beyond three months would have given the true incidence of chronic pain in this group of

TABLE I.

## Details of examination findings and treatment

No	Type of hernia	Type of repair	Nature of pain	Examination findings	Treatment	Response	Follow up (Months)
1	Indirect	Mesh	Burning sensation	Normal	Amitriptyline	Good	45.5
2	Gilmore's groin	Mesh	Somatic	Tender over medial end of scar	Local injection Chirocaine® and Depo-Medrone®	Good	53
3	Direct	Modified Bassini's	Tingling and hyperesthesia in the ilioinguinal nerve distribution	Normal	Amitriptyline	Good	48.8
4	Indirect	Mesh	Somatic	Normal	Re-exploration and re-suturing of mesh	Good	85.9
5	Gilmore's groin	Darn	Mixed nature	Tender in the region of *GF-area	GF block and Amitriptyline	Mild pain	68.7
6	Indirect	Mesh	Somatic	Tender in the region of GF-area and over the scar	GF block	Good	40.7
7	Indirect	Mesh	Somatic	Tender in the region of GF area and trigger point over pubic ramus	GF block and local injection over tender spot with Chirocaine®	Mild pain	45
8	Gilmore's groin	Modified Bassini's	Somatic	Tender GF area	GF-block	Good	76.9
9	Direct	Mesh	Somatic	Tender over ilio inguinal region	ilioinguinal nerve block	No relief	42
10	Obstructed indirect	Mesh	Somatic	Tender spot over medial end of scar	Local injection with Chirocaine and Depo-Medrone®	Good	42.7
11	Indirect	Mesh	Somatic	Tender spot over medial end of scar	Local injection with Chirocaine and Depo-Medrone®	Good	86.7
12	Indirect	Mesh	Somatic	Tender over pubic tubercle	Local injection with Chirocaine and Depo-Medrone®	Good	30
13	Indirect	Mesh	Mixed nature	Tender over GF area	GF block and Amitriptyline	Good	24

\*GF=Genitofemoral nerve

patients. Therefore, the reported nine percent incidence of chronic pain may be an underestimation of the actual incidence of chronic pain.

It is not clear from the literature whether mesh repair is associated with increased incidence of chronic pain. Callesen *et al.* observed a non-significant increase in chronic pain in patients who had mesh repair than compared to patients who had suture repair<sup>13</sup>. In a randomised controlled trial of

primary inguinal hernia repair by surgical trainees, Miedema *et al* compared Lichtenstein and suture repairs (McVay and Shouldice) for recurrences and chronic groin pain. The authors noted higher incidence of chronic pain following Lichtenstein repair (38%) than Shouldice repair (7%) ( $P<0.05$ )<sup>14</sup>. However, a meta-analysis study of 58 randomised controlled trials by the European Hernia Trialists Collaboration found that mesh repair was associated with lower incidence of both hernia recurrence and late post-operative pain (overall persistent

pain: 120 in 2,368 vs. 215 in 1,998; OR 0.36, 95% CI 0.29-0.46;  $P < 0.001$ ) when compared with non-mesh repairs<sup>15</sup>. In a questionnaire study, Bay-Nielsen *et al* observed moderate to severe pain in 3.9 percent of patients with no significant difference between open mesh, Shouldice and Marcy repair<sup>16</sup>. We found an increased incidence of chronic pain in patients who had a mesh repair compared with those who had a suture repair (17.2 vs. 3.4%,  $p=0.004$ ). It is difficult to explain the higher incidence of pain in our mesh group. It may partly be due to the fact that the senior author was much more experienced in performing suture repairs than Lichtenstein repair at the time of the study. Due to the small sample size and the non-randomised nature of the study it is difficult to draw any conclusions about the higher incidence of pain in the mesh group and cautious interpretation of our results is recommended.

The exact cause of the post-herniorrhaphic pain is not clear. Entrapment of the ilioinguinal, iliohypogastric or genitofemoral nerve is thought to be responsible for the pain. Both preservation and routine division of the ilioinguinal and genitofemoral nerves have been advocated<sup>1,4,12</sup>. In a randomised controlled trial; Mui *et al* randomly assigned one hundred patients undergoing open mesh inguinal hernia repair into two groups. One group received prophylactic ilioinguinal and iliohypogastric neurectomy, and the second group did not. The authors noted a lower incidence of chronic pain in the neurectomy group compared to the non-neurectomy group (8% vs. 28.6%;  $P = 0.008$ )<sup>17</sup>. In a non-randomised retrospective study, Dittrick *et al* compared the incidence and severity of neuralgia in patients who had elective ilioinguinal nerve division with patients whose ilioinguinal nerve was preserved. A significant increase was noted in the incidence of neuralgia in the non-neurectomy group<sup>18</sup>. However, in a small randomised controlled trial involving 20 patients with a bilateral inguinal hernia; Ravichandran *et al* evaluated the difference in the incidence of pain between the ilioinguinal nerve 'preserved' and 'divided' sides and did not find any significant difference in the pain and numbness between both sides<sup>19</sup>.

The evidence base for the effective treatment of post-operative chronic groin pain is unclear. Surgical exploration with division of all three nerves with, or without, the removal of the mesh is associated with mixed results<sup>20-22</sup>. In a series of 20 patients with chronic pain following mesh repair, Heise *et al* observed favourable outcomes in 60% of patients following removal of the mesh, with or without, neurectomy<sup>22</sup>. Amid *et al* observed complete elimination of pain in 39 (80%) out of 49 patients within one month following a triple neurectomy in patients with chronic post-herniorrhaphic pain<sup>20</sup>.

In our series, we obtained similar results with the use of inexpensive, non-operative, less invasive techniques which were performed on an outpatient basis. We achieved a 75% success rate using a combination of nerve blocks and anti-neuropathic medication. Methyl prednisolone acetate is a synthetic corticosteroid providing long-term pain relief when injected into localised areas of chronic and acute inflammation. It acts by inhibiting the inflammatory response and late effects of inflammatory reaction at the site of injection. It is used in combination with local anaesthetic to avoid the pain associated with its injection. We have used Amitriptyline

either alone, or in combination with, Methylprednisolone/Chirocaine in few patients with good results. As a tricyclic antidepressant, amitriptyline is mainly used in the treatment of depression but it is also effective in relief of neuropathic pain (although currently unlicensed) such as in post-herpetic neuralgia, phantom limb pain, trigeminal neuralgia etc. Like Methylprednisolone, the role of Amitriptyline in the use of chronic neuropathic pain following inguinal hernia repair is not fully established.

Some of the drawbacks of these non-surgical options are that the effect may not last long and some patients may require several repeated injections, as we have observed in two of our patients. Nerve blocks or local injections may not work in patients with clinically non-obvious recurrent hernia. It is important to identify patients who do not respond to the non-operative treatment earlier to avoid unnecessary delay in the surgical exploration of groin.

Chronic pain following open inguinal hernia repair can be disabling, sometimes seriously affecting quality of life. It is, therefore, very important to discuss the possibility of resulting chronic severe pain when obtaining pre-operative informed consent. Inguinal hernia surgery is one of the most common operations performed in the UK, accounting for approximately 10% of the general surgical workload<sup>23</sup>. In the UK nearly 80,000 inguinal hernia operations are performed every year<sup>23</sup>. Trainees rarely operate nowadays without supervision unless they are experienced. Trainees, particularly junior ones, may not be knowledgeable enough about the risks involved in inguinal hernia repair<sup>24</sup>. Angelos *et al* used a questionnaire study with 18 first year residents - who are normally asked to obtain informed consent - about their knowledge of the possible risks, benefits, and procedural alternatives for open inguinal hernia repair, laparoscopic cholecystectomy, thyroidectomy, oesophagogastricomy, and abdominal aortic aneurysm repair. They also asked residents to answer the questions that patients may pose about the operation. It was noted that less than half of the residents were able to answer all the questions posed by the patients. Additionally, they found that only a few residents correctly listed all risks, benefits and alternatives for the above-mentioned procedures. It was concluded that even though first year residents were obtaining 'informed consent' for common operations, many are unable to provide enough information about the risks, benefits, and alternatives for consent to be informed<sup>24</sup>. In the UK the guidance is that consent should be taken by a trainee who is able to perform the operation, or by a consultant. This paper highlights the importance of education of junior trainees about the appropriate issues and skills needed to get informed consent. We believe that each patient must be informed about the possibility of chronic, severe pain and its impact on their quality of life should it occur.

## CONCLUSIONS

Chronic severe pain following inguinal hernia repair is a significant problem which has only recently been recognised. It poses major diagnostic and therapeutic challenges to the clinician. We found chronic severe pain in nine percent of patients, mostly following mesh repair. Treatment options vary depending upon the nature of the pain and the physical findings. The majority of patients in this series were successfully managed with nerve blocks. Surgical exploration

should be reserved for patients who do not respond to non-surgical treatment (and then only after careful selection and counselling) and for patients with obvious recurrent hernia on clinical examination. All patients undergoing inguinal hernia repair, irrespective of type, should be informed about the risk of severe and chronic groin pain following a hernia repair. This should be clearly recorded on the consent form.

The authors have no conflict of interest.

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