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Cooperative Hernia Study

Pain in the Postrepair Patient

Johann Cunningham, M.D.,* Walley J. Temple, M.D.,† Philip Mitchell, M.D.,†
James A. Nixon, M.D.,† Roy M. Preshaw, M.D.,† and Neil A. Hagen, M.D.,‡

From the Division of General Surgery/Department of Surgery, Dalhousie University, Halifax, Nova Scotia, Canada; and the Division of General Surgery/Department of Surgery† and the Department of Clinical Neurosciences,‡ University of Calgary, Calgary, Alberta, Canada*

Background

The Cooperative Hernia Study assessed postoperative pain in a prospective trial as part of a larger study looking at the recurrence rate and other morbidity of the Bassini, McVay, and Shouldice repairs.

Methods

Patients were randomized to one of three surgical hernia repairs. Patients were seen in follow-up at 6, 12, and 24 months and were assessed for the presence of pain, numbness, paresthesia, and recurrence.

Results

Three hundred fifteen patients were seen in follow-up, with 276 seen at the 2-year mark. At 1 year, 62.9% of patients had groin or inguinal pain and 11.9% of patients had moderate to severe pain; 53.6% had pain and 10.6% of patients continued to report moderate to severe pain 2 years postoperatively. The predictors for long-term postoperative pain were as follows: absence of a visible bulge before the operation ($p < 0.001$); presence of numbness in the surgical area postoperatively ($p < 0.05$); and patient requirement of more than 4 weeks out of work postoperatively ($p < 0.004$). Three distinct chronic pains were identified. The most common and most severe pain was somatic, localized to the common ligamentous insertion to the pubic tubercle. The second was neuropathic and was referable to the ileoinguinal or genitofemoral nerve distribution. This was likely because of injury to the genitofemoral nerves, either at surgery or subsequently by encroachment of scar. The third pain was visceral, ejaculatory pain. Twenty-four percent of patients had postoperative numbness at 2 years, independent of the type of repair. Numbness was most common in the distribution of cutaneous branches of the ilioinguinal and iliohypogastric nerves.

Conclusion

Pain or numbness are common late sequelae of traditional external surgical hernia repairs. Strategies need to be developed to reduce the risk of these complications.

In Canada from 1992 to 1993, there were 48,241 inguinofemoral hernia repairs, making it the third most common surgical procedure and treatment in Canada.[1] However, there are no prospective, randomized trials assessing the long-term outcome of this treatment. One prospective trial evaluated perioperative herniorrhaphy morbidity and mortality associated with local, regional, or general anesthesia.[2] Assessment and management of inguinal region entrapment neuropathy specifically was reviewed. Other reports have highlighted the prevalence of postoperative pain or numbness as significant[3–7] and more disabling than two other recognized sequelae of hernia repair, hernia recurrence and testicular atrophy.[8,9] The natural history of postoperative pain, including its prevalence, etiology, duration, and associated disability, remain undefined.[9–12] A recent major review of hernia repairs has discussed pain as a postoperative complication but cited only neuropathic causes.[13] Others have looked at the treatment of postoperative neuropathic pain but have not defined its incidence or etiology.[14,15]

For these reasons, we undertook a randomized prospective clinical trial to evaluate the long-term outcome of pain and numbness in hernia repair. This study is part of a larger project to evaluate several outcomes of three standard hernia repair techniques: Bassini, McVay, and Shouldice repairs.[1,2,8,16–18]

MATERIALS AND METHODS

All patients 17 years of age and older presenting to their general surgeon (at two participating medical centers) for operative repair of inguinal hernias were considered eligible for the study. Informed consent was obtained at the surgeon's office or preoperatively on hospital admission. This study was approved by the University of Calgary Medical Bioethics Committee and the research and development committees at the respective hospitals. Patients were accrued from both the Calgary General Hospital and the Foothills Hospital. Patients were randomized during the operative procedure to one of the three standard hernia repairs. Entry information gathered included randomization number, hernia type, assigned repair, surgeon and family physician, and the patient's name, age, gender, address, and telephone number. It also was noted if there had been a prior hernia repair on either side and whether the current hernia repair was the repair of a recurrent hernia. The hernia type was recorded (direct, indirect, combined, sliding). Study exclusions, such as not requiring a posterior wall repair, having only a cord lipoma, or having a repair other than that given on the randomization form (such as the use of mesh), also were noted.

Patients were followed at 6 months, and then annually for 5 years. Patients were asked at a 6-month follow-up telephone call to report current pain and their recall of postoperative pain, using a numeric scale of 0 (least pain) to 10 (most pain possible). At 1 and 2 years, the patients were asked to report pain level on a four-point categorical scale at the time of the visit (none, mild, moderate, or severe). They were asked to report whether there had been a visible bulge initially, who had found the hernia (patients themselves or their physician), whether the hernia had been reducible, and the duration of the hernia before having it repaired. Patients also were asked how long they had been out of work after the hernia repair, whether they had any numbness in the area, or whether they had any other problems associated with the hernia repair.

Mild pain was defined to the patient as an occasional pain or discomfort that did not limit activity, with a return to prehernia lifestyle. Moderate pain was defined as pain preventing return to normal preoperative activities (*i.e.*, inability to continue with prehernia activities such as golf, tennis, or other sports, and inability to lift objects, without pain, that patient had been lifting before the hernia occurrence). Severe pain was defined as pain that incapacitated the patient at frequent intervals or interfered with activities of daily living (*i.e.*, a pain constantly present or intermittently present but so severe as to impair normal activities, such as walking).

At the 1-year and 2-year follow-up clinics, patients were interviewed and examined. The examiners (JC, PM, WT) were blinded to the type of repair, the surgeon, and the previous responses of the patients. The patients were examined for recurrence, new hernia, testicular atrophy, and the distribution of pain and paresthesia, if reported.

A subset of 32 patients who described persistent pain at the 2-year follow-up visit were invited to return for further assessment by a pain specialist (NH). A pain history, physical and neurologic examination, and provocative pain maneuvers were carried out.

All patients included in the analysis met study criteria and were evaluated at a minimum of one clinic. All statistical comparisons were univariate, using chi square methodology.

RESULTS

During the study, 818 patients were booked for elective hernia repair. Sixty-five patients had bilateral hernia

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Address reprint requests to Walley J. Temple, M.D., Tom Baker Cancer Centre, 1331-29 Street NW, Calgary, AB T2N 4N2 Canada.

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repairs, for a total of 883 hernias considered for the study. Of these, 558 hernias were not considered in the analyses for the following reasons. Eighty-five patients declined enrollment at the initial visit. One hundred sixty-five repairs were excluded because they did not meet study criteria, including 16 patients who had a mesh repair and 14 who had a femoral hernia component. Three hundred eight patients refused follow-up at the study center. Of these, 55 were patients who lived a great distance from the center and 10 were patients who died of causes unrelated to hernia repair before follow-up. Three hundred fifteen hernia repairs in 276 patients were seen at follow-up and are included in the analysis. Of these, 13 had only a 6-month follow-up; 46 had only a 1-year follow-up, and 256 were examined at the 2-year time period. An intent-to-treat analysis revealed that the 558 hernia repairs screened but not followed in the study were similar to the 315 hernia repairs included in the analysis with regard to age, gender, and hernia type.

Fifty-five and a half percent complained of moderate to severe pain in the immediate postoperative period. The incidence of moderate or severe pain was 11.9% at 1 year and 10.6% at 2 years. The incidence of any groin or inguinal pain at 1 year was 62.9% and 53.6%, respectively, at the 2-year follow-up visit.

Pain present 6 months or more after hernia repair was evaluated as a function of different patient-related and surgical variables. Patients with no palpable, visible bulge preoperatively ($p < 0.001$), patients with moderate or severe immediate postoperative discomfort, and patients who required a medical leave of absence from work for 4 or more weeks after surgery ($p < 0.004$) all had more long-term pain. Variables not associated with long-term pain include surgeon, type of repair, technique of external oblique closure, intraoperative nerve identification, or surgical transection of any of the ilioinguinal, iliohypogastric, or genitofemoral nerves.

On physical examination, patients with moderate to severe pain often had an area of tenderness either deep to the scar where their pain arose or inframedial to the scar where their area of numbness lay. Most patients with moderate to severe pain complained of a mild to moderate pulling, tugging, or tearing sensation in the groin area, deep to the incision. This was either worse or exclusively related to activities, especially lifting and turning. The incidence and severity decreased over time. Other patients with moderate to severe pain described a sharp, jabbing or tearing sensation deep to the incision, sometimes radiating to the penis or down the leg. It appeared that less provocation was required to cause this sharp incident pain than the scar pain, but this was not quantified. Finally, there were a few patients who had constant, severe pain in the incisional area that was so severe as to be debilitating (*e.g.*, requiring the use of canes). The latter two groups of patients had not returned to normal activities. Five patients reported that pain disrupted sexual activity; two had testicular pain only at intercourse, one of whom had pain on lying down.

At 12 months, 6.3% of patients had both pain and incisional numbness; 5.6% of patients had pain without numbness; and 25% of patients reported numbness without pain. At 24 months, these figures were 6.75, 4.1%, and 19.6%, respectively. No patient was disabled by numbness. There was a correlation between numbness and pain at 1 year ($p = 0.042$) but not at 2 years ($p = 0.064$).

Many patients reported that initial numbness had improved during the follow-up period. There was no association between numbness in the incisional area and type of repair done or which surgeon performed the procedure. ($p > 0.2$ in all cases)

On physical examination, asymptomatic numbness commonly was found. Ninety percent of patients with sensory impairment had hypesthesia, and 10% had anesthesia. Dysesthesia was uncommon, and allodynia was not noted. Paresthesia on light touch usually was infraincisional, radiating toward but not onto the scrotum. In all but two patients, no dysfunction was noted in the cutaneous sensory distribution of the genitofemoral nerve.

Thirty-two patients were identified at the 1-year and 2-year follow-up visits as having moderate or severe pain. Seventeen were willing to return for further assessment by a pain specialist after their hernia repair. Of these, seven had recovered completely[5] or had pain less frequently than at least once weekly.[2] The remaining ten patients described three discrete pain syndromes; one pain was judged to be somatic, the second was neuropathic, and the third was visceral.

Nine of the ten patients with active pain who were evaluated by the pain specialist were judged to have a somatic ligamentous pain syndrome. It was described as sharp (4 patients), pulling (4 patients), dull (3 patients), or burning (2 patients), and was reliably brought on by lifting or stretching. Only one patient used analgesics, which were effective. Most patients were able to prevent or reduce pain brought on by standing by pressing over the tender area before and during abdominal muscle activation or stretching. The median "average" weekly pain was "2/10" and the median "worst" pain each week was "7/10," with 0 being "no pain" and 10 being "worst possible pain." Flairs of pain could last for several hours, which always was made worse by abdominal muscle activation or stretching. On physical examination, all patients were tender over the medial insertion of the inguinal ligament, and the Carnett's maneuver[18] worsened pain in six patients.

Two of the ten patients with active pain had a second concurrent pain that was characterized by either unprovoked (1 patient) or movement-provoked (1 patient) electrical or jabbing, brief sharp pain that immediately would be maximal, then gone within 30 to 60 seconds. Jabs of pain could be single or could occur in rapid trains. In both patients, the neuralgic pain was less severe than the concurrent somatic ligamentous pain, and analgesic therapy had never been sought. Physical examination revealed numbness in the distribution of the genitofemoral nerve (including the medial thigh) but no Tinel's sign. Allodynia was not present.

One patient had a persistent pain syndrome characterized by a brief episode of "crampy" pain rated as "1.5/10," with onset restricted to immediately before ejaculation. Pain lasted 5 seconds, and no other precipitating factors were identified. Pain was noted to begin weeks or months after hernia repair, and physical examination did not reveal areas of tenderness.

DISCUSSION

Although associated with a low perioperative mortality, this large, prospective trial indicates that standard hernia surgical repair is associated with frequent long-term sequelae of pain and numbness. Although both tend to improve over time, 2 years after surgery, many patients remain debilitated.

A large proportion of hernia operations were enrolled, but follow-up was not possible. We speculate that this may be related to the requirement for patients to attend a special research facility, during daytime hours, for documentation of the results of surgery. For purposes of the study, follow-up information from the patients' private surgeons was not used.

This study found an incidence of 63% of hernia repairs with a complaint of either mild, moderate, or severe pain at a 1-year follow-up. This decreased to 54% at a 2-year follow-up. No follow-up has been attempted in this study beyond 2 years, so it is not known if the proportion of patients reporting pain continues to decrease. It is possible that the high refusal rate of patients to attend for follow-up (298/574 or 52%) has exaggerated the proportion with complaints of postoperative pain. For example, a patient with no complaints might be less likely to attend for follow-up than a subject with a real or imagined grievance. Therefore, we can state that, in this study, between 31% and 63% of posthernia repair patients report either mild, moderate, or severe postoperative pain at 1-year follow-up. The lower figure assumes that all patients who failed to attend for follow-up had no complaint of pain. However, we believe that the true risk of postoperative pain at 1 year is closer to 63%, and we postulate that both patients with and without pain were lost to early follow-up.

Identification of three discrete posthernia repair syndromes leads one to consider their pathophysiology, optimal management, and preventative strategies.

The most common posthernia pain syndrome is somatic and primarily incident pain. It is reproduced readily on physical examination with maneuvers that typically provoke abdominal wall pain. Authorities in this area have emphasized the risk of wrongly localizing the pain-sensitive structure within the peritoneal cavity, often leading to a fruitless search for a visceral cause.[19,20] Neuroma or neuropathic pain without neuroma has been cited as an explanation for posthernia repair pain; however, the absence of either Tinel's sign or numbness strongly associated with pain 2 years postrepair help to focus management strategies for this somatic pain syndrome away from standard approaches of neuropathic pain management. The authors particularly discourage the practice of managing somatic posthernia repair pain by ileoinguinal, ileohypogastric, or genitofemoral nerve resection. Discrete tenderness at the medial insertion of the inguinal ligament, with pain on physiologic tensing of this ligament, suggests that this site is the pain-sensitive area. No autopsy studies are available to indicate whether this process is vascular, inflammatory, or mechanical, although the authors favor the latter. In the absence of concrete data, we recommend that special care be taken at the time of surgery to avoid suture insertion to this area of periosteum and that undue tightness of the inguinal ligament be avoided.

A second less common pain syndrome is neuropathic and primarily neuralgic (with brief, sharp electrical jabs) rather than dysesthetic (constant, achy, painful numbness with allodynia). Emperic observation would indicate that such neuralgic pains should respond more readily to carbamazepine than to tricyclic antidepressants such as amitriptyline, although we did not encounter a single patient who required adjuvant analgesic management of their neuropathic pain. We speculate that such pain may have arisen from a variety of mechanisms, such as surgical interruption of nerves, damage to small cutaneous nerves, or scar resulting in nerve compression. However, neuroma formation seems less likely because neither patient with neuropathic pain described or was found to have a Tinel's sign.

A third pain syndrome, described by a single patient, is visceral pain encountered only on ejaculation. This probably is not caused by development of a stricture in the spermatic duct from scar tissue in the months after surgery, but rather, should be related to dysfunction of periurethral strictures involved in ejaculation. One possible mechanism is injury to either somatic sacral or sym-

pathetic nerves, resulting in dysynergia of ejaculatory effector muscles. The patient did not request any investigation or intervention to treat this pain syndrome.

Because newer methods of inguinal hernia repair (laparascopic, preperitoneal) inevitably are compared with older techniques, reports of pain syndromes in similar cohorts at the same time intervals should be reported.

CONCLUSIONS

Persistent pain causes significant morbidity in more than 10% of patients 2 years after hernia repair. It is more common in patients who have not had a palpable hernia preoperatively, in patients who have numbness or moderate to severe pain in the immediate postoperative period, and in patients who require more time out of work after surgery. Neither the type of hernia nor the type of repair affected long-term pain or numbness. Numbness, although present in a significant proportion of patients, was not a cause of morbidity. Although the authors have identified three discrete posthernia repair syndromes, the most common and severe is ligamentous in origin. In view of the disability that can be associated with this pain, strategies need to be developed to either prevent or treat this complication.

One approach, described by Lichtenstein,[13] advocates treatment of pain by injection according to protocol, followed by operative transection of nerves. An alternative is to transect nerves encountered in the operative site during the primary hernia repair. Neither approach has been assessed in a controlled manner.

Because the origin of this somatic pain would appear to be the insertion of the inguinal ligament at the pubic tubercle, we advocate avoiding periosteal sutures at this site as a potentially helpful preventative strategy.

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