

Chronic pain following inguinal hernia repair: Assessment of quality of life and medico-legal aspects



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Chronic pain following inguinal hernia repair: Assessment of quality of life and medico-legal aspects

The aim of our study was to evaluate the quality of life (QoL) of a group of patients who underwent tension-free inguinal hernia repair in light of the possible medicolegal implications.

We conducted a retrospective study on the QoL of patients who underwent inguinal hernioplasty. One hundred and fifty patients who answered the SF-36 questionnaire were included in the study. Twenty-six (17.3%) had chronic pain, 18 (12%), sensory deficits, and 106 (70.6%) did not complain of any symptoms.

There was no a significant deterioration in QoL compared to the reference population. In the group with chronic pain, 10 patients (38.4%) reported being very limited in performing "physically demanding activities"; 18 (69.2%) reported a deficit of performance in activities of daily living; 8 (30.7%) complained of a reduction of time spent at work because of emotional disorders. In one case the pain was particularly severe and required surgical treatment.

The answers obtained through the questionnaire show that tension-free hernioplasty does not degrade patients' QoL. However in the group of patients with chronic pain examined one year after surgery, QoL had deteriorated so much that it affected the employment sphere and the social and relational sphere. Although there is a relatively low incidence and frequency of problems relating to chronic pain following inguinal hernioplasty, chronic pain can sometimes have serious effects on QoL and socio-economic and legal implications.

KEY WORDS: Chronic pain, Inguinal hernia repair, Quality of Life

Introduction

Inguinal hernia is an extremely common pathology which affects 10% of adult males and 1% of adult females in the world. The lifetime risk of developing this type of hernia is 27% for men and 3% for women ¹.

Hernioplasty is an operation associated with low morbidity rates but there is a risk of complications such as seroma, hematoma, infection of the prosthetic material and/or the surgical wound, testicular atrophy, and chronic pain. Chronic groin pain is the most important complication after hernioplasty, with an incidence that can exceed 50% (range 0-53%) ^{2,3}. The importance of this complication lies in its negative effect on patients' quality of life (QoL) and its socioeconomic and medicolegal repercussions. It is currently estimated that chronic pain after inguinal hernioplasty reduces a patient's daily activities by 5-10% ⁴ and this clearly has negative social and economic effects both for the patient and for the entire community. The medicolegal aspects are equally important and the number of law suits over this postoperative complication is on the rise.

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The aim of our study was to evaluate the QoL of a group of patients who underwent tension-free hernioplasty and any possible medicolegal consequences of a reduction in QoL.

Materials and Methods

Our retrospective study drew on a study from the University of Aberdeen (UK) on the QoL of patients who underwent hernia surgery ².

Our study sample consisted of patients who underwent tension-free hernioplasty at the Department of Surgery of the Monserrato Polyclinic-University of Cagliari in the period from May 2009 to December 2010. A total of 212 patients were selected from the patient database. One hundred and fifty were successfully contacted and responded to a telephone questionnaire and were therefore included in the study.

There were 126 males (84%) and 24 females (16%) with an average age of 61.5 years (range 16-82 years). Only 30 patients (20%) had jobs or played sports, the rest were retirees who did not report engaging in work or sports activities.

The patients had the following types of hernias: direct inguinal (54; 36%), oblique external (76; 50.6%), inguinoscrotal (15; 10%) and recurrent hernia (5; 3.3%). They had all been treated with Lichtenstein tension-free repair. Chronic pain was defined as postoperative pain persisting more than 3 months after the operation, refractory to traditional analgesics and negatively affecting a patient's work or other daily activities.

The minimum duration of follow-up was 1 year.

QUESTIONNAIRE

A specific and validated phone questionnaire, the short form health survey (SF-36®) was administered to each

of the selected patients to assess the impact their physical and emotional health in the postoperative period (12 months after surgery) had on their daily activities, work, and social life. The SF-36 is made up of a series of 36 questions aggregated in 8 scales and 11 items, which make it possible to evaluate a patient's QoL as defined by the patient's perception of his/her health. The summary measures of the survey are physical health and mental health.

Based on the results of the SF-36 it was possible to divide the patient cohort into the following 3 subgroups: patients who reported chronic postoperative pain (group A), those who reported postoperative sensory changes (group B), and those who did not complain of any symptoms (group C). There were 26 patients in group A (17.3%), 2 of whom were female (M/F 12:1), 18 in group B (12%) 2 of whom female (M/F:8:1), and 106 in group C 20 of whom female (70.6%) (M/F:4.3:1). The values of the SF-36 scales in our study cohort were compared to those obtained from a reference group drawn from the general population. The significance of the differences was evaluated using Student's t-test for differences between means ⁵⁻⁸.

Results

The patients to whom the questionnaire was administered answered all 11 items.

The study cohort did not have lower scores than those of the general population for 7 out of 8 scales. The only scale in which our patients had a slightly lower score was that of "General Health" (Table I).

The results described here in detail are those with the greatest connection to the study, i.e. those most closely regarding chronic pain after inguinal hernioplasty. The first question concerned the patient's perception of his/her health: "would you say that in general your health is...". The most common responses, "good" in 75% of

TABLE I - SF 36 Questionnaire. The scores of the study sample in 7 out of the 8 scales are not any lower than those of the reference population (shown below). The only scale in which our patients had scores that were slightly, but significantly, lower than those of the reference population was that of "General Health". PF: physical functioning.

Studio	PF	RP	RE	EF	EWB	SF	BP	GH
Media	86,8	75,3	91,1	62,5	75,8	88,5	83,1	59,8
DS	20,0	29,5	20,7	13,6	10,9	13,9	21,5	16,8
	1,64	2,42	1,70	1,12	0,90	1,14	1,76	1,38
Pop. Rif.	PF	RP	RE	EF	EWB	SF	BP	GH
Media	84,5	78,2	76,2	61,9	66,6	77,4	73,7	65,2
DS	23,2	35,9	37,3	20,7	20,9	23,3	27,7	22,2
	0,51	0,80	0,83	0,46	0,46	0,52	0,61	0,49
p	0,17	0,26	0,00	0,60	0,00	0,00	0,00	0,00

Legend: RP: role – physical functioning; RE: role – emotional functioning; EF: emotional functioning; EWB: existential well-being; SF: social functioning; BP: bodily pain; GH: general health.

cases, and “passable” in 20%, indicated that patients had a feeling of relative well-being. Only 5% of the patients, all of them over 70 years of age, defined their state of health as “poor” due to comorbidities (rheumatological diseases).

As regards the group of questions about whether their physical health limited their daily activities almost all patients with chronic groin pain (Group A) (Fig. 1) answered no (“no, not limited at all”). Only 10 (38.4%) answered that it greatly limited their performance of physically demanding activities such as running, lifting heavy objects, engaging in strenuous sports. (“yes, limited a lot”) (question 3).

The fourth group of questions regarded limitations on daily activities and/or work that were due to the patient’s health in the 4 weeks before he/she took the SF-36. It was especially significant that 21 patients (80%) answered “yes” to the following question: “Did you have to limit some kinds of work or other activities?”. However the patients did not feel this had serious repercussions as regards time required, productivity, and difficulty in carrying out the activities in question.

The fifth group of questions investigated the effects the patient’s emotional state (anxiety, depression) had on daily activities, including work, in the 4 weeks before he/she took the SF-36.

Eighteen patients (69.2%) had had problems in performing their daily activities and work; 8 patients (30.7%) had cut down on work/other activities (Fig. 2).because of changes in their emotional state.

The sixth item assessed the effects the patients’ emotional and physical health had on their social life and personal relationships (Fig. 3). A large part (14 patients,



Fig. 2: Patients with chronic pain: relationship between emotional state and limitation of daily activities. Limitations of daily activities: less time dedicated to activities, lower productivity, poorer concentration.

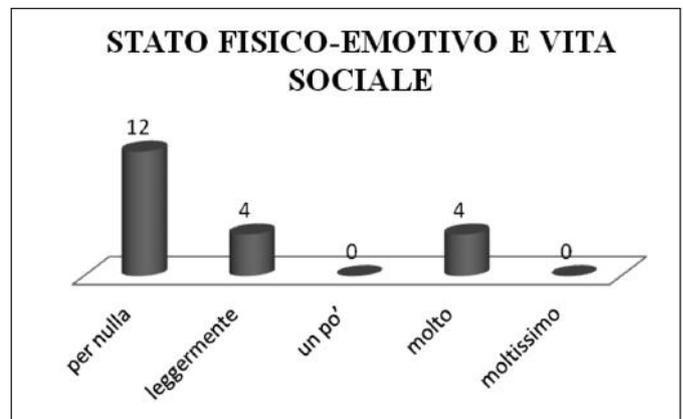


Fig. 3: Patients with chronic pain: physical/emotional state and social life.

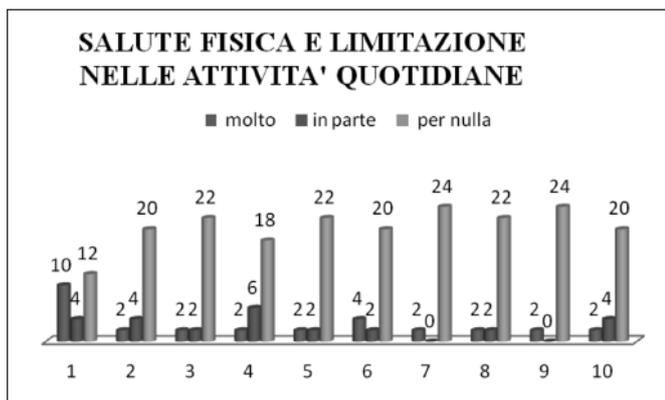


Fig. 1: Patients with chronic pain: Physical health and limitations of daily activities. Limitations of daily activities of patients: 1 very strenuous activities like running, lifting heavy objects, engaging in tiring sports. 2 moderately strenuous activities like moving aside a table, using a vacuum cleaner, playing boules, bicycling; 3 lifting up or carrying a bag of shopping, 4 climbing a few flights of stairs, 5 climbing one flight of stairs, 6 bending, kneeling, 7 walking for 1 kilometer, 8 walking for several hundred meters 9 walking for circa 100 meters 10 taking a bath or getting FIGURE dressed alone.

53.8%) felt that their health had not at all affected these aspects of their lives.

One patient in group A had such severe chronic pain that it was necessary to remove the prosthesis and transect the genito-femoral nerve. One year after this operation the patient did not have any pain or neurological symptoms although he had limitations in the performance of daily activities and had quit his job because of his psychological and physical condition.

Discussion

Near the end of the 20th century various procedures resulting in quicker recovery after hernioplasty and lower recurrence rates were developed ^{1,9,10}. These involved the use of prosthetic materials which were themselves a possible source of complications such as chronic groin pain.

Postoperative pain is common in patients who undergo hernia repair. Acute pain is pain in the immediate post-

operative period that responds to analgesic therapy, resolving within 15-30 days after surgery.

Postoperative pain is considered to be chronic (moderate to severe), when it persists for more than 3 months after surgery, does not respond to analgesics, and causes the patient to become, to some degree, an invalid who is unable to continue performing his/her habitual daily activities and work¹¹⁻¹³.

A Danish study showed that 28.7% of inguinal hernioplasty patients complain of chronic pain of varying degrees and in 11% the pain is such that it interferes with normal daily activities¹⁴. Other recent studies also reported a high incidence of postoperative pain, 5-30% thus confirming the importance of the problem¹²⁻¹⁴. This complication is associated with all hernioplasty techniques¹. Various studies discuss the clinical picture and diagnosis of chronic inguinal pain after hernioplasty but its true etiopathology remains elusive. Predictive factors for chronic pain that have been identified include: psychosocial factors, early development of postoperative pain, intraoperative manipulation of neural structures or iatrogenic nerve damage, and surgical technique (open vs. laparoscopic^{4,14-16}).

Chronic pain after inguinal hernioplasty can be either neuropathic or non neuropathic¹⁷. The first has three main causes: compression of the genito-femoral/ilio-hypogastric/ilio-inguinal nerves by perineural fibrous tissue, sutures or prosthetic material (mesh or plug), partial or complete transection of these nerves, or neuroma formation¹⁸. The second can develop as a result of scarring, pressure of the prosthesis on, for instance, the ductus deferens, or a periosteal reaction to the sutures placed to fix the mesh to the pubic tubercle. As regards the association with surgical technique, there is a lower incidence of chronic postoperative pain after "tension-free" repair than after other procedures¹⁹.

Intraoperative nerve damage is a complex matter. It is most commonly the result of partial or complete nerve transection, neuroma formation, trauma, or entrapment²⁰. Statistical analysis has shown that the risk of developing moderate to severe groin pain is significantly reduced if the genito-femoral, ilio-hypogastric and ilio-inguinal nerves are identified and spared. An Italian prospective multicenter study confirmed that failure to identify these nerves or transection of them are factors significantly associated with a high risk of chronic pain and that the greater the number of nerves not identified or transected the greater the risk²¹. The relative risk (RR) of developing moderate to severe chronic groin pain increases from 2.2 when one nerve is not identified to 19.2 when none of the three is identified. This suggests that sparing of these nerves offers protection against chronic postoperative pain.

Some studies report that there are no studies that have established what the causes of chronic pain after inguinal hernioplasty are. It is not always possible to identify a definite cause. The pain is not necessarily due to a defect

in technique and sometimes can just be related to the presence of a foreign body (mesh) in the inguinal canal. In fact, the tissue response varies depending on the structure and porosity of the prosthesis²²; prosthetic mesh is a dynamic not an inert object inside the inguinal canal^{1,23} whether or not the dissection is accurate and care is taken not to injure the surrounding structures can influence the patient's postoperative course and the development of chronic pain^{12,13,18}. There is no scientific evidence in favour of one surgical technique rather than another and it has been observed that young age and a history of preoperative pain are important risk factors for chronic pain²⁴⁻²⁷.

Clinically typical chronic pain after inguinal hernioplasty is nociceptive and arises at the insertion of the inguinal ligament on the pubic tubercle. This pain which often radiates to the homolateral scrotum or the upper thigh, is made worse by physical effort and trauma. In some ways it is similar to the pubalgia experienced by sportsmen.

Chronic postoperative groin pain is reported to resolve in 70-80% of patients after surgical treatment, although so far follow-up has been of short duration¹⁸.

Surgical treatment is reserved for patients who do not benefit from correctly administered medical treatment and the treatment protocol most often cited is that proposed by Amid²⁸ according to which it is essential to send patients to a pain therapy center before attempting surgical management. Surgery, indicated only if this treatment proves ineffective, consists of triple neurectomy of the ilio-inguinal, ilio-hypogastric and genito-femoral nerves with implantation of the proximal stump of the nerve into the internal oblique muscle²⁸.

In cases of "meshoma", i.e. a dislocated prosthesis forming a shapeless mass, the prosthesis itself is removed as well. Histological examination of the mesh may reveal perineural fibrosis, a condition which can occur spontaneously after hernioplasty, or iatrogenic nerve damage. A finding of iatrogenic nerve damage may lead the patient to sue the surgeon who performed the hernioplasty²⁸.

Chronic pain after hernioplasty can have negative effects on various aspects of patients' lives; work, daily activities, relationships and more specifically their sex life²⁹. Negatively affected sexual function, though little investigated, has its place on the list of sequelae of hernia repair and its reported incidence ranges from 1 to 26%³⁰. It can consist of reduced libido, and erectile or ejaculation problems present singly or together.

Chronic pain can have a strong psychological impact, negatively affecting a patient's mood and self esteem and thus his/her ability to adapt to the pain. If the pain persists beyond a certain time point and becomes intolerable, patients may limit their activities out of fear of increasing their physical suffering. Thus their daily activities may be compromised and they may develop anxiety and depression which can increase their pain by

affecting their perception of it. All of this clearly worsens their general QoL.

Although our study is limited by the small number of patients, it reflects the problems of patients suffering from chronic pain after inguinal hernioplasty. In fact out of 26 patients with chronic pain, 10 reported severe pain after strenuous physical activity, 18 reported lower productivity in their daily activities and work, and 8 reported dedicating less time to both due to psychological and emotional problems (anxiety /depression).

The questionnaire we used did not show that the patients' QoL was significantly worse than that of the reference population. The only scale in which they had scores that were slightly but significantly lower was that of "General Health". This can be explained by several factors: there was a large number of patients above the age of 70, and since our polyclinic is a referral center for rheumatology it seems likely that the patients selected had certain comorbidities, especially rheumatological diseases.

Overall we can say that the patients who underwent inguinal hernioplasty did not have a QoL substantially different from that of the reference population. However there was a subgroup of patients who, although marginal from a statistical point of view, had important postoperative complications.

Chronic pain is currently the second most common cause of absence from work due to medical problems in Italy and if not promptly recognized and treated has a notable impact on the lives of both of the patients and of their families and of society as a whole. It can cause long term disability linked not only to the pain itself but to additional problems of a psychological nature. In fact it has been reported (and confirmed by our study) that 50% of patients with chronic pain suffer from a form of reactive depression and 40% have anxiety disorders.³¹ Moreover due to the pain patients may have difficulty working which can lead both to missing many days of work due to frequent visits to the doctor and to poorer performance at work, compromising quality and productivity³².

Chronic pain has a restricting effect on patients' lives sometimes to the point of impeding their performance of normal daily activities, as confirmed by our study. The resulting social costs are very high and affect the socioeconomic system of the country at various levels.

Because of the psychophysical, economic and social ramifications, an individual with chronic pain after inguinal hernioplasty may be considered to be legally disabled. In Italy legal disability is defined by art.2 of law 118 of 30/03/1971, as a condition that involves difficulty in performing typical daily activities or maintaining typical relationships, due to a physical or psychological impediment, and can without doubt affect the individual's performance at work with the result that he is unable support himself and his family³³.

Moreover, disability is defined as a reduction in work/earning ability. The work ability is understood to

mean possession of psychophysical qualities necessary to work effectively and earning ability is defined as the capacity to earn a suitable income by regularly performing a productive activity³⁴.

A legally recognized disability status confers the right to receive care and financial assistance after medicolegal assessment has been completed. Moreover, those who were working before they became legally disabled are assured of help from the job placement office³³. As is well known, this situation can only aggravate the already difficult socioeconomic situation of the individual and society as a Whole.

Conclusions

Reduction of postoperative discomfort and, more importantly, limitation of chronic inguinal pain, should be key objectives of surgeons performing inguinal hernia surgery since these complications can be the forerunners of complex psychosocial and economic problems, such as disability, which affect both the patients and society as a whole.

The answers obtained with the questionnaire allow us to conclude that in general hernioplasty does not significantly change the QoL of patients, but that the QoL of some patients suffering from chronic postoperative pain, who were examined 1 year after the operation, was substantially worse both as regards work and social relationships.

Although in series of inguinal hernioplasty patients, including ours, the incidence of problems related to chronic pain after the procedure is relatively low, there may be serious socioeconomic, and medico-legal developments as regards QoL, and inguinal hernioplasty comes close to being an important cause of chronic pain worldwide.

It is important to keep in mind that from a medico-legal point of view chronic pain after inguinal hernioplasty can be considered a postoperative complication and as such can have personal and socio economic repercussions as well as affecting a patient's ability to work, and can lead to legal disability.

Riassunto

Obiettivo del nostro lavoro è stato quello di valutare la qualità di vita di un gruppo di pazienti operati di ernioplastica tension-free, anche alla luce delle possibili ripercussioni medico-legali.

È stato condotto uno studio retrospettivo finalizzato alla valutazione della qualità di vita dei pazienti. Sono stati oggetto di valutazione 150 pazienti sottoposti ad intervento chirurgico di ernioplastica che hanno aderito allo studio rispondendo alle domande del questionario. 26 soggetti (17,3%) presentavano dolore cronico, 18 pazien-

ti (12%) deficit sensitivi, 106 pazienti (70,6%) non lamentavano alcuna sintomatologia.

Non vi è stato un significativo peggioramento della qualità di vita rispetto alla popolazione di riferimento. Nel gruppo con dolore cronico, 10 pazienti (38,4%) hanno riferito di essere molto limitati nell'eseguire "attività fisicamente impegnative come correre, sollevare oggetti pesanti, praticare sport faticosi". 18 pazienti (69,2%) hanno riferito un deficit di rendimento nello svolgimento delle attività quotidiane; 8 pazienti (30,7%) hanno lamentato una riduzione del tempo dedicato al lavoro a causa del manifestarsi di alterazioni della sfera emotiva. In un caso il dolore è risultato particolarmente rilevante.

Le risposte ottenute attraverso il questionario somministrato ci permettono di affermare che l'intervento di ernioplastica tension-free con posizionamento di protesi non peggiora la qualità di vita dei pazienti, ma, nel gruppo di pazienti affetti da dolore cronico esaminati a distanza di un anno dall'intervento chirurgico, la qualità di vita ha subito un peggioramento che ha interessato tanto la sfera lavorativa quanto quella sociale e relazionale. Nonostante la problematica relativa al dolore cronico post-ernioplastica inguinale sia caratterizzata da una frequenza ed una incidenza relativamente basse, può talvolta avere pesanti risvolti di natura socio-economica, medico-legale e in termini di qualità di vita del paziente.

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