

Open inguinal hernia repair: better consent for a safer practice, a retrospective study

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Introduction

Mesh repair is the gold standard for elective inguinal hernias. The recurrence rate is 1–3%. Chronic pain is documented in 10–15%. Consent is an essential form to proceed with any. Our study aimed to evaluate the practice in consenting patients with inguinal hernia, according to British Hernia Society (BHS) Standards, for safer practice and better outcomes.

Patients and methods

The authors underwent a retrospective study on 242 patients. These patients were subjected to open inguinal hernia repair, and they were followed up for over 1.6 years. Patients under 18, with a history of previous repair and laparoscopic repair, were excluded from the project.

Results

The patients were divided into two groups. Group A, patients signed E-consent, which was preprepared, including all required operative details. And group B, in which written consent was used and signed on an operative day. Despite using mesh in all patients, in group B, the mesh was missed in 11.7% of the consent forms and half of the clinic letters. Postoperative readmissions were 6.4, 8.5, and 1.1% at weeks, months, and 18 months, respectively. The main reasons for readmission were pain (2%), seroma (0.4%), hematoma (0.4%), wound infection (0.8%), and recurrence (0.8%). After the follow-up, the overall complication rate was 4.4%. Although hernia recurrence and chronic pain are crucial to state formally as a postoperative complication, they were not mentioned in group B, in 10% and 15% of the cases. In contrast, nonspecific complications were documented in greater than 90%. Damage to cord structures and postoperative management plans were found in 60 and 30%.

Conclusion

All surgeons of different grades were not adequately adherent to BHS, exposing the firm to negligence and complaints. Prepared forms and leaflets are advised to improve the quality of service regarding the General Medical Council domains.

Keywords:

British Hernia Society, clinical letter, consent, follow-up plan, inguinal hernia, mesh repair, postoperative pain, recurrence

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Introduction

Different surgical techniques are adopted to repair inguinal hernias, with more than 20 million groin hernia patients globally per year [1]. The Dutch HerniaSurge Group addressed guidelines in 2017 and a consensus statement in 2020 to improve patient outcomes endorsed by different hernia societies [1,2].

The most common complication after inguinal hernia repair is chronic postoperative pain. Other possible complications include urine retention and wound infection [3]. Furthermore, hernia surgery might affect the testicular circulation, especially in huge or recurrent hernias, with the probability of testicular ischemia and atrophy. Injury to the vas deferens might lead to infertility if the injury happens bilaterally. The nerve

damage during surgery and the postoperative chronic pain may affect sexual activity [4–6].

The international guidelines strongly recommend mesh-based techniques for hernia repair. The recurrence rate is less with the mesh hernia repair, while the complications of chronic pain, seroma, hematoma, and wound infection remain insignificantly related to the mesh application, these side effects should be considered [7].

The approach to the groin hernia repair, either open or laparoscopic, remains an unsolved debate. The

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laparoscopic approach offers less postoperative pain and a less postoperative hospital stay, which provides cost-effectiveness, compared with the open surgical technique [8].

Proper consent is a cornerstone for safe practice and patient compliance and acceptance. It is one of the important WHO Surgical Safety Checklist items published since 2009 [9]. It also allows documenting all the possible risks accompanying the surgical procedure, providing the proper knowledge, and understanding to the patients, and avoiding possible medicolegal issues. Among 167 Trust in the United Kingdom, the number of reported surgical risks ranged from 4 to 18 risks related to the surgical procedure in the consent. The total number of risks mentioned was 28 surgical risks. This variability reflects the need for proper consenting practice and may be a premade standardized consent for this kind of elective surgery [9].

Malpractice complaints are rare, with less than 1% of the patients involved. Accepted claims compensation ranges from roughly between 19 000 USD and 8,000,000 USD. Compensation had been rejected in the cases when informed consent had been correctly done and the operative details were documented [10]. A litigation case and medicolegal issues are always a burden for the involved surgeon [10].

In their consent guidelines, the UK General Medical Council (GMC) and Royal College of Surgeons (RCS) agreed on the patient's right to know the severity of the problem, options of treatments, rate of hazards, and expected results. Failure to provide all required information is against the duty of care, and significant complications can provoke patients to claim compensation. A minimum amount of information should be delivered to the patient to help in decision making. Lack of information due to poor counseling is considered negligence and may lead to litigation [11,12].

This cohort aims to examine the best approach for consenting patients with inguinal hernias for hernioplasty to achieve a safe practice, following the guideline of the British Hernia Society (BHS), with the guideline of the BHS GMC four domains [13].

Patients and methods

A retrospective comparative study was designed to compare the hernioplasty's consent practice in two different district general hospitals in the United Kingdom. Hospital A used a preprepared electronic consent. After discussion with the patient in the clinic, the consent is to be sent (associated with a leaflet explaining the procedure in detail) 1 month before the operative appointment. The patients had to sign

their understanding and agreement for the procedure. Hospital B used a blank generic consent that is usually filled by one of the operating teams. This usually occurs either at the clinical appointment or on the operative day (which usually occurs while waiting on elective day-case lists for a long time; hence consent requires updating).

The research team was divided into two groups, each team was responsible for the hospitals' data collection and analysis. The research group relied on the BHS guidelines as a reference to measure the goals of the study. The main aim of the cohort was to search for the word 'Mesh' on the formal preoperative documents (clinic letter and informed consent), which indicate that the surgeon explained to the patient the desired surgical procedure, entailing mesh integration. Another secondary outcome of the study was the precise documentation of critical risk complications as a drawback of the mesh hernioplasty, such as chronic pain, mesh infection, injury to vital cord structures, orchietomy, and recurrence. The study was approved locally by each ethical trust committee. It was done over 1.6 years, and the relevant data were extracted from the records saved in the hospital archive.

Inclusion criteria for recruitment in the study were both types of inguinal hernias, both sexes, patients above 18 years old, and any associated comorbidities. Patients with previous hernia repair, nonmesh hernia repair, and those assigned for laparoscopic repair were excluded from the cohort.

Clinical letters and consent forms were utilized to collect the required information. Excel sheet Performa was designed to include the patient's sex, age, comorbidities, site of hernia, type of operation, mesh documentation, documented complications, postoperative plan, and follow-up the outcome. Also, the role and grade of the consenter were noted.

The data were analyzed using the software package of Statistical Science (SPSS) version 25 (IBM, New York, USA).

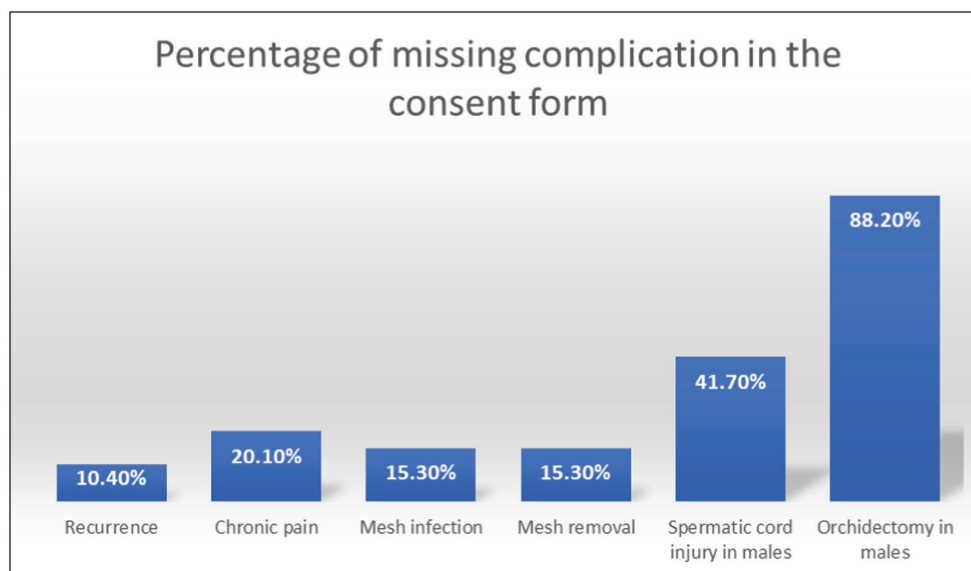
Results

Overall, 250 patients with primary inguinal hernias were recruited for the research from both hospitals. Group A included 150 participants from hospital A, and 100 cases joined group B from the second hospital. Six patients were excluded from group A, and the exclusions from group B were only two cases. The main reasons for exclusion were that the data were not traceable on the records and not sufficient to include. This issue reduced the sample to 242 cases, 144 and 98 in groups A and B retrospectively. The demographics from both groups are summarized in Table 1.

Table 1 Patients' demographics

| Demographics | Group A [n (%)] | Group B [n (%)] |
|--------------------------------|-----------------|-----------------|
| Sex | | |
| Male | 113 (78.5) | 75 (76.5) |
| Female | 31 (21.5) | 23 (23.5) |
| Median age (range) | 64 (78–91) | 60 (18*79) |
| Cardiopulmonary diseases (CPD) | | |
| Asthma | 4 (2.8) | 2 (2) |
| COPD | 19 (13.2) | 11 (11.2) |
| IHD | 11 (7.6) | 2 (2) |
| AF | 9 (6.3) | 3 (3.1) |
| Total number of CPD | 43 (29.9) | 18 (18.3) |
| Hernia side | | |
| Right-sided inguinal hernia | 87 (60.4) | 53 (54.04) |
| Left-sided inguinal hernia | 53 (36.8) | 42 (42.9) |
| Bilateral inguinal hernia | 4 (2.8) | 3 (3.06) |

AF: atrial fibrillation, COPD: chronic obstructive pulmonary disease, IHD: ischemic heart disease.

Figure 1

Complications missed during consenting group B' patients.

In group A, the electronic preprepared consent was always used in practice, it was sent to the patient 1 month before the operative appointment. The patients had to sign their understanding and agreement for the procedure.

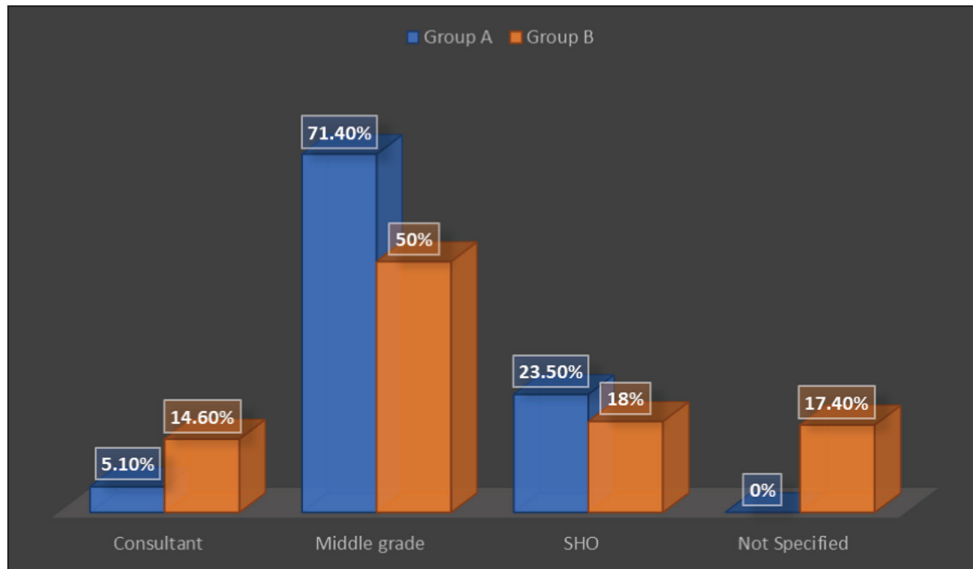
In both groups, mesh was used in all repairs (100%). Despite that, in group B, when written consent was used to explain the procedure details, the mesh was not documented on 16 consent forms (11.1%), and it was not clearly stated in 78 (54.2%) of the preoperative clinical letters. Mesh was not recorded in both documents (the consent and preoperative letter) in 13 patients, which was considered a serious concern with a significant percentage (9%). In contrast, mesh was clearly stated on the electronic consents for group A.

The complication section on the formal documents (consent forms and clinic letters) showed that recurrence risk and other serious hernia-related hazards

were missed in group B consent. Out of 98 patients in group B, 75 (76.5%) male patients were included. The consent missed informing them about the risks of spermatic cord injury and orchidectomy in 44.7 and 88.2%, retrospectively. See the percentage of missing in Fig. 1. In contrast, nonspecific and broad-term complications, for instance, deep venous thrombosis, bleeding, and postoperative infections, were all mentioned in more than 85%. Another significant aspect was the postoperative plan. Although this advice aims to improve the recovery and decrease postoperative complications and recurrence rate, a constructed plan was informed on the discharge summary in one-third of the patients. As for group A, all electronic consents included all postoperative risks, which were clearly written in professional documentation.

Figure 2 shows the grade of consent in both groups. An interesting finding was that, seven out of the

Figure 2



Grade of consenters in both groups.

Table 2 Rate of readmission (postoperative complications) in both groups

| Readmission cause | Group A [n (%)] | Group B [n (%)] |
|-------------------|-----------------|-----------------|
| Pain | 2 (1.4) | 3 (3.1) |
| Recurrence | 1 (0.7) | 1 (1) |
| Hematoma | 1 (0.7) | 0 |
| Seroma | 0 | 1 (1) |
| Infection | 1 (0.7) | 1 (1) |

21 times, when consultants went to consent the patients, they did not write the word 'mesh' formally on consents (30%). On the other hand, junior doctors never missed to write 'Mesh' repair (0%). The registrars forgot to say 'mesh' in 27.8%.

The follow-up period was 18 months, and the registered readmissions in both groups are illustrated in Table 2.

Discussion

Inguinal hernia is a routinely performed elective procedure. The Royal College of Surgeons in Great Britain enlisted a group of surgical complications that can occur postrepair (IHR). Despite the extremely low incidence, significant complications, such as injury to the cord structures and the resultant orchidectomy and/or infertility, must be informed on the consent. With an incidence of 15%, chronic pain can disable patients from routine activities and impact their quality of life, so it should be clearly mentioned on the consent [12].

While predisposing factors of hernia influence postoperative outcomes, a postoperative management plan is explained to the patient to decrease the risk of recurrence and infection, such as avoiding heavyweight

lifts, vigorous physical activities, and early management of cough, urinary symptoms, constipation, and their causes [12].

Consent is considered part of clinical surgery for professional and legal issues. It gives the patient capacity to make decisions on their treatment. With ever-rising levels of litigation for negligence, claims for medical negligence within the NHS amount to over half-a-billion pounds a year, with the cost for consenting errors running into millions. The UK General Medical Council (GMC) offers guidance on warning patients of risks when gaining consent. The guidelines state that first, patients have a right to information about their condition and the treatment available. Second, failing to provide enough information may be against a duty of care to the patient. If harm results, the patient may be entitled to compensation. Third, account must be taken of the amount of information delivered to the patient [13,14].

Our data collection showed significant concerns in different aspects. Despite using mesh in all patients for both groups, in group B, the mesh word was not written in 11% and 54% on the consent forms and clinical letters, respectively. A significant figure of 9% mesh was not mentioned in all documents. This issue was not encountered when using the preprepared electronic consent in group A. Interestingly, we noticed that 45.5% of the consultants, followed by the middle-grade group (27.2%), ignored writing mesh on the consent. At the same time, none of the junior doctors missed doing so. About 27% of the consenting physicians did not prove their position on

the formal document. Postoperative recurrence was missed in 10%. Although it is specifically related to the procedure, a serious complication like injury/damage to the cord structure was missed in 36%. As part of the planned management, postoperative advice was not found in 60%.

Similarly, these missing errors occurred with variable rates when the consentor described the postoperative risks in group B, which was never found in group A. The most common hazard missed on the written consent was orchidectomy (88.2%), followed by spermatic cord injury (41.7%), then equally mesh infection and removal (30%). Chronic pain and recurrence were ignored in 20 and 10%. In the postoperative follow-up of 18 months, five patients developed chronic pain with multiple admissions, while two patients presented with a recurrent inguinal hernia.

In 2008, Hoosein *et al.* [15] underwent research to investigate their Trust's consent practice and whether it was a safe practice. Similar to ours, it was a retrospective cohort that looked at the data of 97 males. The follow-up period was just 6 months, unlike this study, which had a follow-up three times longer. Hoosein and colleagues found that one-quarter of the patients were consented by a consultant, more than half by a specialist registrar, and 19.6% by a senior house officer/FY2. The most commonly recorded risks included infection (100%) and bleeding (100%). Serious complications, such as chronic pain (consented for at an average of 14%), testicular complications (45.3%), and visceral injury (52.1%), were poorly accounted for at all levels. Recurrence was missed in one-fifth of the consents. The complication of nerve injury (anesthesia/paresthesia) was only documented in 40% of the consents. Another important complication, such as chronic pain, was documented as follows: four (16%) of patients were consented by a consultant, seven (13.2%) by a specialist registrar, and three (15.8%) by a senior house officer. A serious risk of visceral injury was noted in 16 (64.0%) of patients who were consented by a consultant, 35 (66.0%) by a specialist registrar, and only five (26.3%) by a senior house officer [15].

Various methods reduce personal error and ensure that patients understand the planned treatment, outcomes, and possible drawbacks. Prepared consents, electronic forms, and stick-on labels are affordable options. There was a suggestion for nationally approved consents, which NICE can support to cover at least specific operations. Hernia should be included. Another suggestion would be booklets and online links to be handed to the patients, a good time before the procedure. The aim is to ensure that the patient

has sufficient time in comfortable circumstances to absorb the required information. The patient can 'tick the box' to book the operative appointment by understanding the procedure details. The outpatient clinic department may be a suitable platform where the act of consent can occur. At the clinic, leaflet, website sources, consent form, and explaining all the procedure details can be done and documented in the outcome letter. At this point, the consent can be signed or handed to the patient to be signed later to weigh the pros and cons. Finally, every Trust can draw its policy, but continuous auditing should be done to monitor safe practice and good-quality service offered to the patients [16–18].

A limitation that can be considered in this cohort was excluding data outcomes after the laparoscopic approach in inguinal hernia fixation. The study aimed to exclude these data to avoid bias in the results. The aim was to investigate the consent practice for open inguinal hernia repair and how to improve this practice to achieve a better quality of management and serve patient safety. The team recommends further investigation to explore the outcomes of laparoscopic inguinal mesh repair.

Conclusion

Adherence to consenting standards benefits both patients and doctors. In our experience, both senior and junior surgeons were not adequately adherent to BHS. This practice is considered unsafe to the patient and can expose the surgical firm to expensive compensations due to negligence. Prepared forms and leaflets are options to overcome personal error and improve the quality of service offered in respect of the GMC domains.

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Conflicts of interest

There is no conflict of interest, for this research work, in regards of data collection, writing, publishing or funding this work.

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