



Consenting practice for open inguinal hernia repairs – are we failing to warn patients of serious complications?

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ABSTRACT

INTRODUCTION Open inguinal hernia repairs are one of the most commonly performed procedures in the UK. The procedure can sometimes result in considerable morbidity. It is imperative that the consenting process for this procedure is meticulous. This allows the patient to make a fully informed decision as they are aware of potential complications. In turn, this reduces the risk of future litigation. The aim of this study was to examine the adequacy of consenting for open inguinal hernia repairs, in particular, focusing on serious risks associated with the procedure.

PATIENTS AND METHODS The notes of male patients who had undergone open inguinal hernia repair over a 6-month period were identified by the IT department. Inclusion and exclusion criteria were defined, giving a total of 97 male patients. Their consent forms were examined, focusing on: (i) the complications mentioned; and (ii) the grade of the consentor. A proforma was filled in for each of these patients and the data collated.

RESULTS Of the 97 patients in the study, 25.7% of patients were consented by a consultant, 54.6% 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.

CONCLUSIONS Consultants and juniors alike are not adequately consenting patients for inguinal hernia repairs, omitting serious complications such as chronic pain, recurrence and testicular complications. This leaves surgical teams vulnerable to claims for negligence. Good consenting practice may ultimately benefit both patient and surgeon.

KEYWORDS

Inguinal hernia repair – Consent – Litigation

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Open inguinal hernia repairs are one of the most commonly performed operative procedures in the UK, amounting to over 79,000 cases in the National Health Service (NHS) alone in the year 2005–2006.¹ Over 95% of these were in the elective setting. This common procedure is not free of complications, and can sometimes bring considerable morbidity and rarely mortality to patients. It is imperative that meticulous consenting practices are achieved for these and all other surgical procedures.

Consent is an expected part of clinical surgery, both professionally and legally. It gives the patient autonomy in making decisions on their care and treatment. With ever rising levels of litigation for negligence, there has never been a more appropriate time than now to explore

consenting processes in depth. 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.² The UK General Medical Council (GMC) offers guidance on warning patients of risks when gaining consent. The guidelines state that:⁵

1. Patients have a right to information about their condition and treatment available.
2. Failing to give enough information may be against a duty of care to the patient. If harm results, the patient may be entitled to compensation.
3. Account must be taken of the amount of information the individual requires to make a decision.

There are a number of complications of inguinal hernia repair that can lead to medico-legal claims being made. In 1995, The Royal College of Surgeons of England published guidelines on the management of inguinal hernias, including a comprehensive list of complications that may occur after open repair (Table 1).⁴ Serious complications such as chronic pain, testicular complications and recurrence are often disregarded. It is not uncommon to meet patients in follow-up clinic complaining of chronic pain, having not been warned of this risk at the time of consenting.

The aim of this study was to examine the adequacy of consenting practices for inguinal hernia repairs at this Trust over a 6-month period in 2006, and to compare the information given by various grades of surgeons. The study particularly focused on serious risks associated with the procedure.

Patients and Methods

All male patients undergoing inguinal hernia repair were identified by the Trust's Information Systems and Audit Department. Patients under the age of 18 years and those undergoing laparoscopic repairs were excluded from this study. Patients undergoing inguinal hernia repair in the emergency setting were excluded. Overall, a total of 97 patients were identified. The notes and consent forms were examined for each of these patients, and a proforma was designed to collate the adequacy of completion of consent, and to identify the grade of the consentor.

Results

Of the total of 97 patients included in the study, 25 (25.7%) were consented by a consultant, 53 (54.6%) by a specialist registrar or associate specialist, and 19 (19.6%) by a senior house officer. Complications of infection and bleeding were consented for at all levels and for all patients. For the complication of recurrence, 18 (72.0%) patients were consented by a consultant, 45 (84.9%) by a specialist registrar, and 12 (63.1%) by a senior house officer. For testicular complications, 18 (72.0%) patients were consented by a consultant, 23 (43.4%) by a specialist registrar, and 10 (52.6%) by a senior house officer. For the complication of nerve injury/anaesthesia/paraesthesiae, 12 (48.0%) of patients were consented by a consultant, 22 (41.6%) by a specialist registrar, and 7 (36.9%) by a senior house officer. For the complication of chronic pain, 4 (16%) of patients were consented by a consultant, 7 (15.2%) by a specialist registrar, and 5 (15.8%) by a senior house officer. For the complication of visceral injury, 16 (64.0%) of patients were consented by a consultant, 35 (66.0%) by a specialist registrar, and only 5 (26.3%) by a senior house officer.

Table 1 Complications that may occur after open repair

Complication	Example
Wound complications	Bruising Haematoma Sepsis
Scrotal complications	Ischaemic orchitis and testicular atrophy Damage to vas deferens or testicular vessels Hydrocoele Genital oedema
Special complications	Nerve injury Persistent postoperative pain Compression of femoral vessels Retention of urine
General complications	Visceral injury Pneumoperitoneum Chest infection Deep vein thrombosis and pulmonary embolism Cardiovascular accident
Operation failure	Recurrence Missed hernia during surgery Suture failure Mortality

Adapted from The Royal College of Surgeons of England guidelines on the management of inguinal hernias.⁴

These results and the consenting of all other complications are summarised in Figure 1.

Discussion

Hernia repair is a frequently performed procedure, and there are a number of common and/or serious complications that can have medicolegal implications and lead to litigation. The act of consent remains an important bridge between the clinician and patient, and adequate attention to this part of the procedure should be regarded as vital.

Our results showed some variation in consenting practices but, more importantly, significant omission of serious complications at all levels of consentor. One such example is the complication of chronic pain, which was on average consented for in only 15% of the patients in our audit. The incidence of chronic postoperative pain following inguinal

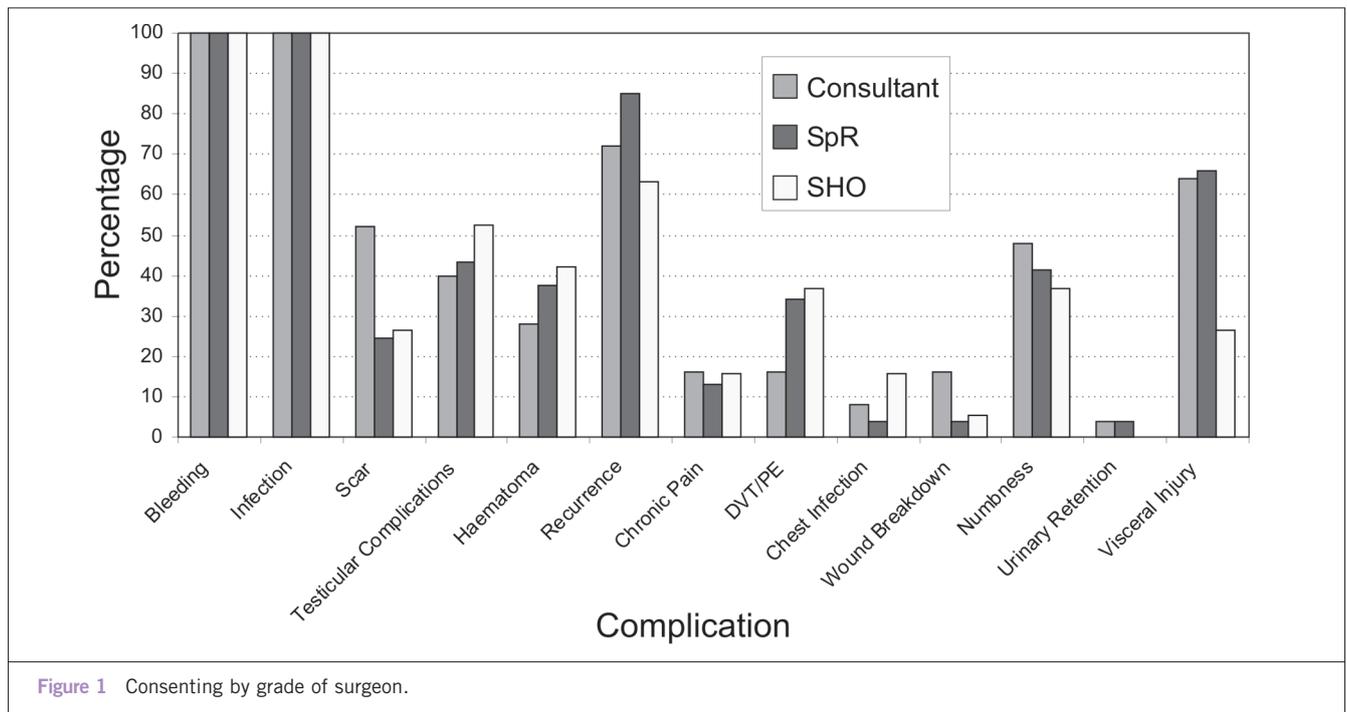


Figure 1 Consenting by grade of surgeon.

hernia repair has been reported to be as high as 36.7% (range, 0.7–36.7%),⁵ enough to interfere with work or leisure activities in some patients,⁶ stressing the need for a fundamental approach in consenting these patients. In a study of 100 consecutive claims of alleged negligence following elective open inguinal hernia repair, 30% of claims were for postoperative pain.⁸

Similarly, the complication of ischaemic orchitis and testicular atrophy are common reasons for medicolegal claims following inguinal hernia surgery.⁸ In our study, this complication was consented to at an average of 45.3% (range, 40–52.6%), clearly leaving clinical teams vulnerable to claims for negligence. These and other serious complications need to be accounted for at a much greater frequency than seen in our study, ideally reaching 100%. This would ensure that patients would be making fully informed decisions when signing the consent form. In addition, although written consent is not necessarily proof of valid consent, it does nonetheless provide evidence that the patient has given consent and is as such valid in the court of law. However, it is equally important to realise that a good consenting process cannot completely indemnify the surgeon against the claim for negligent practice if a complication results.

Pre-prepared consent forms⁷ or stick-on labels have been a suggested remedy in many instances. However, these can often be impracticable and may not always be available when required. There may be a role for nationally approved consenting forms, specific to procedures, perhaps produced by the National Institute for Health and

Clinical Excellence (NICE) to help in the consenting process. In reality, this may be difficult to enforce as there are so many operative procedures this would be needed for. Further, there would be a myriad of opinions as to what complications should be included in such a document. In some trusts (including ours), information booklets regarding the procedure are sometimes given to patients to read. These booklets list all relevant complications of the procedure, and the patient can confirm they have read and understood this by marking a tick-box on the consent form. However, only few surgeons seem to be aware of this. Finally, patients can also be referred to websites that can further participate in their understanding of the procedure and complications (*e.g.* <e-hernia.co.uk>).

Although not always practical, the information-giving process should ideally begin in the out-patient setting when the diagnosis is first made. At this point, the patient can be given an information booklet regarding the procedure and an opportunity to ask questions. Serious complications of the procedure should always be mentioned, allowing minor complications to be identified from the information booklet. Documentation of the provision of this material, both in the case notes and in any correspondence, should be deemed crucial practice. Whether the consent form is then signed at the same sitting is controversial – ideally, some time would be given for the patient to weigh the benefits and risks of the procedure before giving consent. Pre-assessment clinics have been suggested to be the ideal setting for signing the consent for various reasons. Firstly, the patient has had an interval between being made aware of the need for surgery

and the signing of the consent, allowing time for thought. Secondly, pre-assessment clinics are often nurse-led. These are usually more relaxed than conventional out-patient lists; if run alongside each other (as is the case in most trusts), the patient can be consented in detail by a senior team member.

Conclusions

Consultants and junior doctors alike are not consenting for significant and serious complications of inguinal hernia repair such as chronic pain. Therefore, patients are not able to make informed decisions about their surgery. Furthermore, incomplete consenting leaves open the door to litigation – something that is easily and best avoided. Detailed consenting methods mentioning all serious and significant risks, with no omissions, may ultimately benefit both patient and surgeon.

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