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Patient's views of the consent process for groin hernia repair: Use of consent template improves compliance with best practice (Original research)

Saad U. Khan[a,*], David J. Bowrey[b], Robert N. Williams[b], Jun Yi Soh[c], Aikaterini Peleki[d], Nazli Muhibullah[e], Peter W. Waterland[d]

[a] Russells Hall Hospital, University Hospitals of Leicester, 18 Glebe Road, Leicester, LE6 0GT, UK
[b] University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary, LE1 5WW, UK
[c] University of Birmingham, Russell's Hall Hospital, Pensnett Rd, Dudley, DY1 2HQ, UK
[d] Russells Hall Hospital, Pensnett Rd, Dudley, DY1 2HQ, UK
[e] Nottingham City Hospital, Hucknall Rd, Nottingham, NG5 1PB, UK

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ABSTRACT

Background: Informed consent obtained for day case surgery has been historically incomplete. An assessment of consenting practice for groin hernia was performed relative to existing gold standards and patient's perception of the consent process was evaluated with a questionnaire. The aim of the study was to identify areas of improvement to comply with best practice.

Methods: A retrospective audit of adult patients undergoing groin hernia repair (June–November 2016) at a tertiary care centre was performed. The same cohort of patients was surveyed with a self-administered questionnaire to identify their view on consenting practice.

Results: 113 patients were identified who underwent groin hernia repair during the study period. Pre-printed consent templates-stickers (as opposed to hand-written) were used in 53(47%) cases. In 75(66%) cases, there was complete documentation of the risks and benefits of surgery. 81(72%) patients received information about the full benefits of surgery. 27(23%) patients received partial information and 7(6%) patients had no mention of benefit recorded. Postoperative recovery was fully explained to 85(75%) patients. Use of pre-printed templates ensured 100% documentation compared to handwritten consent forms (risks 37%, benefits 47%, and recovery 53%). Preference for the timing of consent was in clinic (64%), day of surgery (25%). 34(56%) felt the choice for the technique and 22(36%) felt the choice for anaesthesia. Satisfaction was non-significantly better in those consented in clinic (87% versus 76% $p = 0.74$). 49(80%) felt happy with the overall consent process. 57(93%) felt that they received support and advice. 60(98%) responders felt confidence in the National Health Service and 59(97%) would recommend treatment to family and friends.

Conclusions: The use of pre-printed consent and discharge summary templates improve compliance with best practice. Whilst patient preference favours consent in the outpatient clinic, satisfaction levels were high wherever consent was obtained. Patients should have more choice.

1. Introduction

Groin hernia repair is the most common general surgical operation performed, with over 71,000 procedures undertaken each year in England [1]. A person-centered approach is central to delivering high quality care in the modern National Health Service (NHS) [2]. Informed consent is the basic legal and ethical right of all patients able to make decisions about their healthcare and treatment, it is based on the fundamental principle of autonomy; one of the four pillars of medical ethics (autonomy, beneficence, non-maleficence and justice) [3,4].

The consent process should be an uncoerced and voluntary decision of a competent person based upon adequate information [5]. This begins at the first consultation with a discussion between healthcare professional and patient about the nature, benefits, risk and alternatives of the proposed treatment. Every detail of the consent process must be documented carefully. Patient information leaflets form an important tool in this regard. The healthcare professional undertaking the procedure is responsible for obtaining the consent. Where this is not

* Corresponding author. 1 Walcote drive, West Bridgford, Nottingham, NG2 7JQ, UK.
E-mail addresses: saad.khan1@nhs.net (S.U. Khan), djb57@le.ac.uk (D.J. Bowrey), robert.n.williams@uhl-tr.nhs.uk (R.N. Williams), junyi.soh@nhs.net (J.Y. Soh), kpeleki@doctors.org.uk (A. Peleki), zarsanga@hotmail.com (N. Muhibullah), peter.waterland@nhs.net (P.W. Waterland).

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practicable then this may be delegated to a person who is suitably trained, has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved. A delegated consent needs to be confirmed by the responsible clinician before the start of the investigation or treatment.

An undisclosed risk may potentially give rise to unrealistic expectations, patient dissatisfaction, negligence claims and in some cases, criminal charges [6]. These can cause significant financial impact on the healthcare system. Following a Supreme Court judgment in the case "Montgomery v Lanarkshire Health Board" (2015), the law now requires the doctors to disclose any material risks involved in a proposed treatment and reasonable alternatives [7].

We performed a retrospective study of consenting practice prior to groin hernia repair and surveyed the same patient cohort with a self-administered postal questionnaire. The aim of this study was to evaluate whether use of a standardized template improves compliance with national standards compared to when not used. Also to assess patient perception of the consent process, including the optimal timing for obtaining consent prior to surgery.

2. Methods

A retrospective audit of adult patients undergoing elective groin hernia operation over a six month period (between 1 June and 30 November 2016) at the University Hospitals of Leicester was performed. Institutional approval from the clinical audit standards and effectiveness board was obtained prior to commencement. British hernia society and European Hernia society criteria were selected as a gold standard [8–10] (Table 2). Patients undergoing emergency hernia repair or aged less than 18 years old were excluded. Patients were identified using the Operating Room Management Information System (ORMIS) and the medical records of patients were reviewed retrospectively to obtain the following parameters: patient demographics, outpatient consultation letters, consent form data, operation notes, hospital discharge letters, and grade of health care professional involvement, record of significant and frequent complications. The quality of the data was dependent on the documentation in the clinical notes. After confirmation of diagnosis, the consent process starts during the initial consultation, treatment options pros and cons of the proposed treatment are explained. The patient is provided with a patient-friendly information leaflet around the time he/she is booked, or pre-assessed for surgery. The signing of written consent form is variable either at the time of clinic or day of surgery.

In the second part of the study, the same cohort of patients was sent a self-administered, 6 dimensions, and 31 item questionnaire by postal mail (Table 1).

The statistical software package Statistical Package for the Social Sciences 20 (SPSS 20) was used to perform statistical analysis. The median was used as a measure of the central tendency for continuous variables. Pearson's chi-square test was employed for comparison of categorical variables. A p value of < 0.05 (2-tailed) was deemed statistically significant.

3. Results

The study population was 115 patients undergoing elective groin hernia repair during the time period 1 June to 30 November 2016. In two cases the written consent forms were missing from the medical notes but other information was available, including operation notes, clinic letter and discharge summary, these were excluded from the study.

109 (96%) were males, and 4 (4%) females. Only one (1%) patient underwent femoral hernia repair, 93 (81%) patients had primary unilateral hernia repair, 6 (5%) primary bilateral inguinal repair, 3 (3%) recurrent inguinal repair and 13 (11%) had previous contralateral surgery. The median age at repair was 60 years, 108 (94%) had repair

Table 1
Patient survey questionnaire.

Domain	Questions and response
Place or timing of written consent	Where were you asked to sign the consent form? At the first clinic appointment At the second clinic appointment or On the day of operation
Your opinion on the best time for the consent.	At the first appointment To be given information first and obtain at the next appointment On the day of operation Any of the above, and other comments
The amount of Information provided, and time allowed	Do you think you had enough time to make your decision? (Y/N) Was procedure adequately explained the way you could understand & did you feel you received enough information to make decision? yes fully, to some extent, no, Were the benefits, risks & possible alternatives explained? (Yes fully, to some extent, no) Could you change your mind or withdraw consent? (Y/N) Were you given information about the anaesthetic technique? yes fully, to some extent, no Did you receive written information or leaflet? (Y/N)
Choice	Did you have a choice in the procedure (e.g. Open operation, key hole)? Y/N Did you have a choice with regards to anaesthetic technique (e.g. done while asleep or make it numb while awake)?
Postoperative care	Were you informed about normal activities e.g. self-care, driving, light work, return to work, operating machinery, signing legal documents, drinking alcohol? (yes fully, to some extent, no) Did you experience pain after operation? (Y/N) How was it controlled (pain killers from the hospital, saw GP, re-admitted)? Did the operation improve your symptoms? (Y/N) Did you receive effective treatment, advice and support? (Y/N)
Waiting times	Approximately how long did you have to wait to see surgeon? (< 1 month, 1–4 months, > 4 months) Was this reasonable? (Y/N) How long did you have to wait in the clinic? (< 30 min, > 30 min)? Was this reasonable? (Y/N) How long did you have to wait for operation after decision was made? (< 4 moths, > 4 months)? Was this reasonable? (Y/N)
Overall Opinion	Did you have pain after the operation? (Y/N) How was this managed? (self-medication, GP, re-admission) Did you have confidence and trust in the health care person who was treating/advising you? (Yes/no)? Would you recommend the service to your family and friends? (yes/no)