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Consenting practice for laparoscopic cholecystectomy – Are we doing enough to warn patients about their operation?☆

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ABSTRACT

Introduction: Provision of informed consent prior to surgery is fundamental in allowing patients to make balanced choices about their care. This study compares consenting practice amongst different grade of surgeons for Laparoscopic Cholecystectomy (LC) with specific reference to the documentation of the complications of surgery. Timing and delivery of source of information is also evaluated.

Methods: Retrospective review of medical notes of all patients undergoing LC at London district general hospital between September 2006 to April 2009.

Results: Records were successfully retrieved for 163 patients. The five most commonly mentioned complications were bleeding (99%), infection (95%), conversion to open (93%), bile duct injury (82%) and visceral injury (65%). There were 27 documented complications in 23 patients and in 9 of these patients (39%) the specific complication was not discussed during the written consent process. Consultant surgeons tended to focus on important operation-specific risks such as bile duct injury whereas junior surgeons tend to focus on a broad range of general complications.

Conclusion: Consenting practice for LC remains variable and is resulting in failure to warn patients of significant complications. This can lead to potential medico-legal implications. Having a structured consent form detailing all significant and common risk is one way of improving the consent process.

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1. Introduction

Laparoscopic cholecystectomy (LC) is one of the most commonly performed elective procedures in general surgery with almost 50,000 cases performed annually in the United Kingdom (UK).[1] Most of the cases are performed in the elective setting. Despite being a common procedure, it is not free of complications and can sometimes bring considerable morbidity and rarely mortality to patients. It is critical that meticulous and consistent consenting practices are observed for this procedure.

Informed consent is defined by the General Medical Council (GMC) as "providing sufficient information, in a way patients can understand, to enable them to exercise their right to make informed decisions about their care".[2] Informed consent is one of the cornerstones of good medical practice and when performed correctly, acts as a shield towards the ever-rising claims of malpractrice made by patients against doctors. Claims for medical negligence within the National Health Service (NHS) almost totals over half a billion pounds a year, with almost 40% of these due to consenting errors in the UK.[3] As a result, there has never been a more appropriate time than now to explore consenting practice in detail.

The legal stance on the issue of consent provision is based on the 'Bolam' Principle whereby it is felt that information should be given to patients that is deemed sufficient with a reasonable body of medical opinion.[4] However, cases since this has demonstrated that the courts criticise even a reasonable body of medical opinion.[5,6] The GMC currently feels that all significant complications that could bring considerable morbidity or possible mortality – no matter how rare they may be – should be disclosed.[2] In addition, they suggest that patient's individual needs and requirements be taken into consideration when providing consent.[2] In addition, the GMC advises that additional up-to date resources should be offered to patients to enable them to make decision about treatment options.[2]

There is currently no legal requirement to have written consent. A patient's signature on a consent form is reasonable evidence that

Abbreviations: LC, Laparoscopic cholecystectomy; SpR, Specialist registrar; SHO, Senior House Officer; NHS, National Health Service; GMC, General Medical Council.

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the patient has consented to having the procedure but it is not proof of valid consent. Despite this, written documentation remains the simplest means of providing proof of the actual consent practice in a court of law. Medicolegally, the consent form may be scrutinised for information such as the name of the proposed procedure, grade of the consentor, alternative treatment, perceived benefits and potential complications of having the procedure. Although providing a copy of the consent form is not essential, it is good practice to offer this to patients. This statement is usually provided at the bottom of the consent form in the UK and acts to remind consentors to offer these forms.

Whilst verbal consent – and thus informed consent – may have improved, written documentation of the consent process remains inadequate. Previous studies have shown a marked variation in the written documentation of the consent process for laparoscopic cholecystectomy (LC).[7] This variation was also demonstrated for open inguinal hernia repairs.[8,9] These studies also demonstrated differences in the quality of the consent between different grades of surgeons.[7–9]

This retrospective observational study aims to compare variations in consenting practice amongst different grade of surgeons for laparoscopic cholecystectomy with specific reference to the documentation of the risks and complications of surgery. The study also evaluates the adequacy of consent in terms of whether actual complications encountered were previously discussed with patient. The timing and delivery of sources of information about the procedure is also evaluated.

2. Methods and materials

The study period was September 2006 and April 2009. All patients undergoing elective LC were identified by the information system within the trust and audit department. Patients under 18 years, those requiring emergency operations and those planned for an initial open operation were excluded from the study. Overall, 228 patients were identified. 65 notes could not be retrieved due to being missing (28) or not traceable (37) and so was excluded from the study.

The notes and consent forms were examined for each individual patient. A proforma was designed to collate the adequacy of completion of consent, to identify the grade of the consentor, whether additional leaflet was provided and the timing of the consent process. The proforma included a list of the most significant and/or commonly recognised complication of LC. We felt that any complications occurring more than 0.1% incidence was deemed significant for our study. A senior house officer (SHO) and a specialist registrar (SpR) analysed the consent forms for all patients included within the study and cross-referenced them with the proforma, recording the documented complication on the consent form in each case. Any complications encountered were also noted.

3. Results

There were 163 patients included in the study. Of these, 39 patients were male and 124 patients were female. The average age of the patient was 48.04 years (range 18–88 years). The average length of hospital stay was 2.4 days (range 0–23 days). Fig. 1 shows the breakdown of the consent forms in terms of grade of surgeons. Only 32 patients (19.6%) were consented by a consultant surgeon. Therefore, 80.4% of patients in this study were consented by a junior surgeon. In 100 cases (64.5%), the consentor was actually involved in the operation. In 38 cases, the consentor was the primary surgeon whilst in 62 cases, the consentor was an assistant. In 63 cases (35.5%), the consentor did not take part in the operation.

We then explored the timing of the consent process. We found that 94 patients (57.7%) were consented on the day of surgery. 43 patients (26.4%) were consented less than 6 weeks before surgery whilst 26 patients were consented more than 6 weeks before surgery (15.9%). Table 1 shows the provision of sources of information material during the consent. 51 and 84 patients were given a leaflet and a copy of the consent form respectively. 27 patients

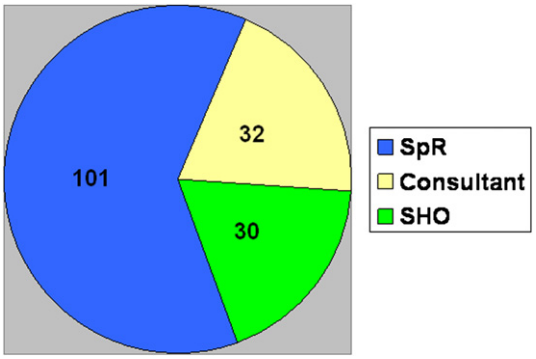

Fig. 1. Breakdown of the consent process given by grade of consenter.

(16.6%) were given no written form of information to supplement the consent process prior to LC.

Fig. 2 shows the actual complications stated on the consent form by all grades of surgeon. Bleeding (99%) and infection (95%) was stated by the majority of forms. The possibility of conversion to an open procedure was documented in 90% cases. The possibility of bile duct injury was mentioned in 82% cases. Other specific yet important complications were documented less frequently such as bile leak (55%) and retained stones (20%). Certain complications were very poorly mentioned such as neurovascular injuries, port-site hernia, intra-abdominal collection and cardiorespiratory compromise. The documented complications that were discussed during the consent process by each grade of surgeon are shown in Fig. 3. Consultants were more likely to mention bile duct injury (89% vs 65%) and retained stones (32% vs 14%) compared to junior staff. However, consultants were less likely to mention important general complications such as scar (14% vs 29%), thromboembolic complications (20% vs 50%) and anaesthetic risks (6% vs 66%) compared to junior surgeons. Interestingly, no consultants mentioned important complications such as port-site hernia, persistence of symptoms, intra-abdominal collections and cardiorespiratory compromise.

In total, there were 27 complications encountered in 23 patients (14.1%) in the study population. These are listed in Table 2. In the 23 patients who suffered a complication, 9 patients (39.1%) were not specifically warned about the complication prior to LC as demonstrated on the consent forms.

4. Discussion

LC is a frequently performed elective procedure in the UK. Despite this, there a number of common and serious complications that can have profound effects on the quality of life for the patient and lead to litigations being pursued. The act of consent remains an important bridge between the surgeon and patient and therefore adequate attention to this part of the consultation should be regarded with utmost care.

Our study showed that the majority of patients were consented on the day of surgery. There are advantages of having consent on the day of surgery. This includes the fact that most of the

Table 1
Provision of source of information material.

	Number of patients	% of patients
Given leaflet only	99/163	31.3%
Given a copy of the consent form only	84/163	51.5%
Given both consent form and leaflet	54/163	33.1%
Given neither	27/163	16.6%

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