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International Journal of Surgery

journal homepage: www.theijs.com

Original research

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

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ARTICLE INFO

Article history:

Received 25 June 2011

Received in revised form

13 August 2011

Accepted 24 August 2011

Available online 16 September 2011

Keywords:

Consent

Laparoscopic

Cholecystectomy

Complication

Litigation

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 malpractice 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.

☆ **Presentation:** Presentation on 03/09/3009 at Association Of Upper Gastrointestinal Surgery (AUGIS), Annual Congress, Nottingham Conference Centre, Nottingham, UK. Presentation At The World Congress Of Hepatopancreaticobiliary Surgery, Buenos Aires, Argentina on 18/04/2010.

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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 consenter, 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 consenter, 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 consenter was actually involved in the operation. In 38 cases, the consenter was the primary surgeon whilst in 62 cases, the consenter was an assistant. In 63 cases (35.5%), the consenter 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

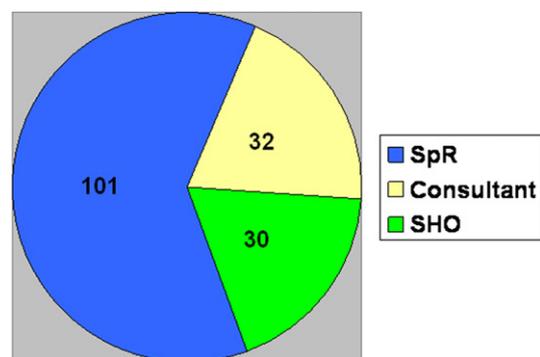


Fig. 1. Breakdown of the consent process given by grade of consenter.

(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%

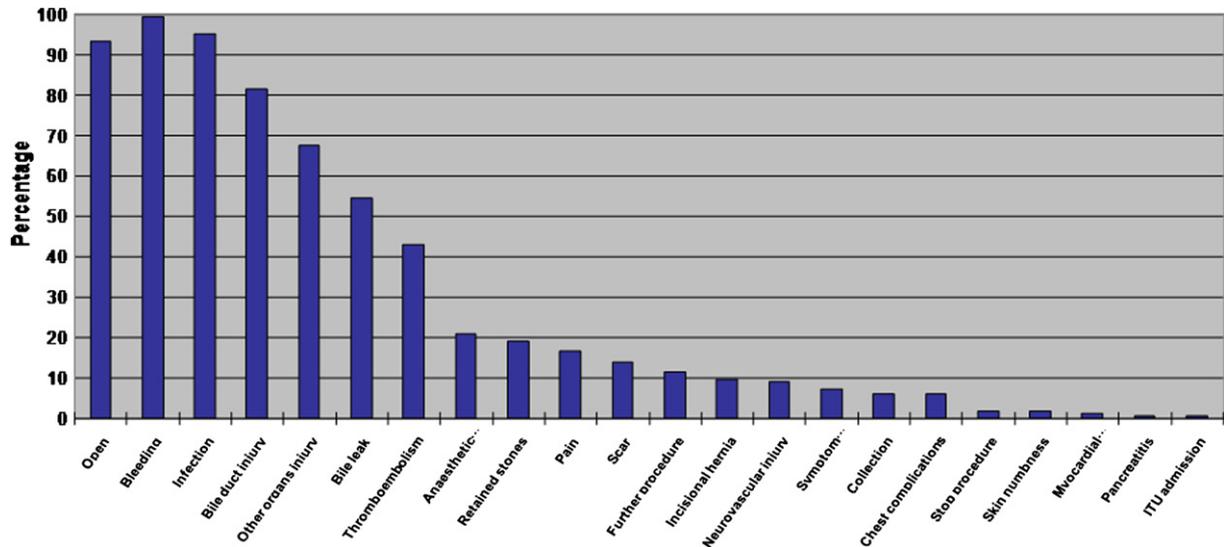


Fig. 2. Frequency of complications stated by all grades of surgeon.

information relayed will be remembered by the patient at the time of the procedure. The longer the timing of the consent process before surgery, the poorer the recall of the consent process.¹⁰ It has been shown that patients are most informed and information recall is best immediately after signing the consent form (around 81%).¹⁰ However, consenting patients so close to their operation and in an unfamiliar environment may promote a feeling of anxiety and compromise the consent process. On the other hand, there are advantages of having the consent done earlier such as in outpatient clinics. The advice is clearly given very early in the encounter so most patients are aware of exactly what they will have done a long-time before they have their surgery. The waiting period provides patients with a significant window of time to consider the risks and benefits of operative intervention from various perspectives, to seek information from a variety of sources, and to experience the efficacy of alternative forms of symptom management. Increasingly, consent is considered to be a process rather than a one-off event and a cooling off period, during which the patient may consider their position may become increasingly prevalent. As a result, we feel that consent would be best in the pre-assessment clinic. These nurse-led sessions are now well established and a useful addition to screen for occult co-morbidity in addition to

allowing time for further discussion about the surgery in a relaxed environment.

Most patients in our study were consented by a junior trainee surgeon (SpR or SHO). The GMC has proposed that a junior member of staff can obtain consent from the patient once that clinician 'has sufficient knowledge of the proposed investigation or treatment and understands the risks involved'.² However, the perception is that consultants represent the most experienced member of the surgical team who have a wealth of information that they can share with patients. As a result, patients feel that they are also more capable of answering any questions that may arise with a consultant surgeon. Previous studies have shown that junior surgical trainees lacked sufficient knowledge of several common procedures such as LC and inguinal hernia repairs to properly obtain consent for these procedures.^{11,12} In the same studies, they were also shown to not be able to correctly answer questions typically posed by patients on these procedures.¹¹ However, other studies have shown that consultants do not mention complications in the same depth as trainees do which may result in them being more likely to run into legal problems. A study by Shiwani and Gosling showed that nerve injury, testicular problems or visceral and vascular damage was never mentioned in the consent form for inguinal hernias completed by

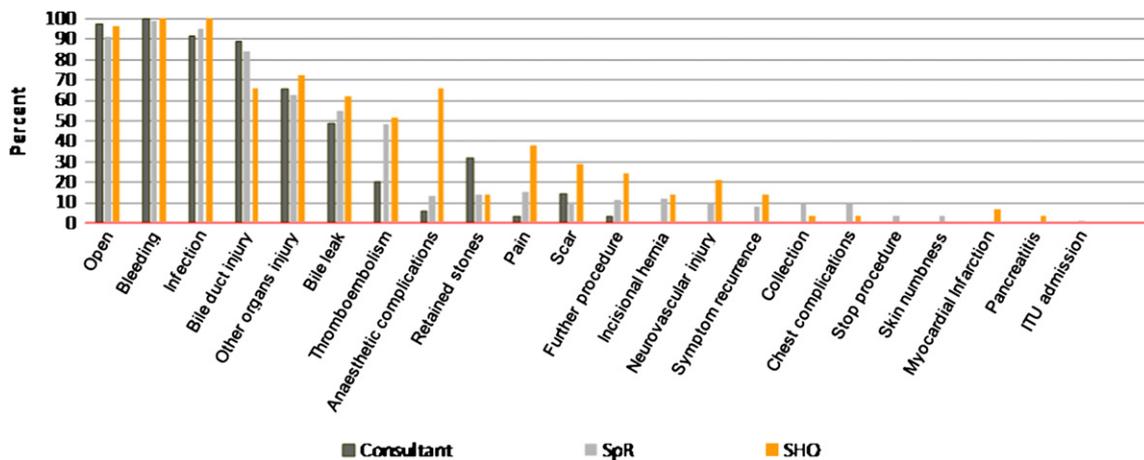


Fig. 3. Frequency of complications stated by individual grades of surgeon.

Table 2
Complications encountered by patients and correlation with written discussion of these complications during the consent process.

Complication	No. of patients who suffered this complication	No. of patients not warned prior to surgery
Conversion to open	10/163	0/10
Common Bile Duct injury	1/163	0/1
Bleeding	2/163	0/2
Bile leak	1/163	1/1
Respiratory complications	4/163	3/4
Retained stone	2/163	1/2
Wound infection	1/163	0/1
Pancreatitis	1/163	0/1
Urinary retention	1/163	1/1
Post-op collection	2/163	2/2
Cardiac complication	1/163	0/1
Recurrent symptoms	1/163	1/1

consultants, unlike junior staff.⁸ In addition, the same study showed that the consultant surgeons were less likely to comment on recurrences to their patient.⁸ In our study, we found wide variation mentioned by surgeons of various grades. We have shown that consultants tend to elaborate on a few specific and important complications such as bile duct injuries, conversion to open and retained stones whilst junior trainees cover general complications more extensively such as cardiorespiratory compromise, thromboembolism and risk of anaesthesia.

Our results showed that there is considerable variation in the complication documented by the clinician whilst obtaining written consent for LC. Chen et al. assessed the quality of the written consent after laparoscopic cholecystectomy.⁷ They have also shown disparity amongst different grades of surgeons in terms of the complications discussed. In both our study and those by Chen et al.⁷ it is clear that certain complications were hardly mentioned such as port-site hernia, wound problems, adhesions, persistence of symptoms, myocardial infarction and death. In both studies, infection, bleeding and conversion were relatively well covered. In another study conducted by McManus and Wheatley, most consultant general surgeons would consent for conversion to open procedure (83%), but important complications such as bile duct injuries, and retained stones were only mentioned in 49% and 57% cases respectively.¹³ Their study also shows consultant would rarely discuss general post-operative complications such as thromboembolism, respiratory events and wound infections compared to operation-specific risks.¹³ One method of eliminating these disparities amongst clinicians has been adopted by health authority in Cambridge and Queensland.¹⁴ This involves use of a pre-printed consent form which highlights a list of 'significant' complication, evidence based depending on the frequency with which they occur. Such comprehensive forms can act as 'aide memiore' for the surgeon as well as a source of information for patients.

Over half the study population were given a copy of the consent form. Although it is legally not mandatory before operative intervention, signing a consent form is a statutory requirement when biomedical research, organ procurement or medically assisted reproduction is involved.¹⁵ Written consent is traditionally not advised in some countries like France because it is considered to alter the patient's trust in his or her doctor.¹⁶ In the UK, verbal discussion followed by signing of the consent form by the patient remains the mainstay of the consent process. It was written proof that the consent process has taken place and helps preserve recall of important information that was discussed. It is important to understand that a signed form is by itself insufficient to validate, and therefore make lawful, consent; however, its completion provides evidence of at least some form of interaction and is regarded as good surgical practice.

The importance of a detailed discussion about LC is very important as many patients are fascinated by keyhole surgery but unable to visualise how it is possible to perform such a procedure with small incisions. As the procedures get more advanced and technical, they necessitate a more sophisticated understanding of the process before a patient can consent to it. The provision of written material e.g. booklets and video-recordings is one method of improving the delivery of information especially about laparoscopic surgery. The GMC now recommends the use of 'up to date written material, visual and other aids... where appropriate and/or practicable' in their guidance of consent.² The most commonly used in the NHS are information leaflets. In our study, 51 patients (31.3%) were given leaflets prior to their LC. This leaflet lists all the 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. The role of leaflets has been limited because of patient differences in age, sex and socioeconomic classes, requiring different levels of information. They are also not suitable for people with impaired cognitive function or those who are unable to read. Other centres have introduced other means of providing information which has improved understanding about a surgical operation. This includes watching video presentation of the operation and multimedia programs on CD/DVD for procedures like LC.^{17,18} These multimedia programs offer patients access to high quality information regarding their upcoming surgery in combination with policies of the local hospital and treating surgeon. The interactive nature of the program allows patients to choose from a broad table of contents, to the depths they desire. This offers a real advantage over simple written materials and personal consultation in the area of desired information intensity. Patients should be briefed about the availability of these adjuncts, the information offered and where to gain access, thus giving them freedom of choice.

It is reasonable to assume that some patients tend to retain the information which supports the decision to have surgery whilst suppressing the bad risks such as complications. This theory has been supported by many studies including one done by Hutson and Blaha.¹⁹ A previous study on a group of patients undergoing laparoscopic surgery demonstrated a 27% recall rate of pre-operative information when patients were questioned 5 days after surgery.²⁰ Alkhaffaf and Decadt showed that there were around 418 claims made by patients who had LC in England between 1995 and 2009, of which 13 cases were due to consenting errors.²¹ They showed that bile duct injuries, visceral/vascular injuries and bile leak featured in over 70% of all litigations, with the highest average payouts for patients suffering with vascular and bile duct injuries.²¹ In our study, we had 27 complications that were encountered in 23 patients. Worryingly, 9 patients were not informed about their complication prior to LC such as cardiorespiratory complications (3 cases), bile leak (1 case), persisting symptoms (1 case) and intra-abdominal collections (2 cases). These and other serious complications need to be accounted for at a much greater frequency than seen in our study, ideally reaching 100%. As a result, we feel it is very important to prompt patients on these important complications and provide a thorough written confirmation on the consent form detailing a list of all important complications to ensure that patients are fully informed about their decisions, thereby preventing potential medical lawsuits from arising.

As mentioned earlier, pre-printed consent forms, which are procedure-specific, have been advocated by several authors. These can be locally devised by local health authorities or there may be a role for nationally recognised bodies such as National Institute Of Clinical Excellence (NICE). This can appease increasingly demanding patients who are becoming more aware of their condition and seek more information. However, there several potential pitfalls to

implementing such strategies into clinical practice such as the difficulty in enforcing such forms for so many different procedures, the disparity in opinions as to what complications should be included in such document, the impracticability and the unavailability of these forms when required. There is also a risk of confusing the patient with excessive information and multiple complications. It is equally important to realise that a good consenting process cannot completely indemnify the clinician against a claim for negligence if a complication does indeed occur.

4. Conclusion

Based on the quality of the written consent, this study points to gaps in the consenting process. In addition, there are huge variations in the consenting practice for LC. Consultants generally focus on a few important operation-specific risks whereas junior surgeons focus more on a broader range of general surgical complications. However this study is only an analysis of the written consent and is unable to analyse what exactly the patients were told. As such it cannot draw conclusions about whether “informed decisions” were or were not made by patients. Despite this, incomplete written documentation of the consent process leaves open the door to litigation. Ultimately, a detailed methodology of consent, whereby all serious significant risks are mentioned on a written form and without any omissions, may benefit both patient and the surgeon.

Ethical approval

None declared.

Funding

None declared.

Conflict of interest

None declared.

Author contribution

MM Uzzaman – study design, data collections, data analysis, writing, final corrections

S Tayeh – study design, data collections, data analysis, writing, final corrections

S Sinha – study design, data analysis, writing, final corrections

K Ratnasingham – study design, data analysis, writing, final corrections

D Stoker – study design, data analysis, Final corrections

Acknowledgements

Nil acknowledgements disclosed.

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