



## Variations in consenting practice for laparoscopic cholecystectomy

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### ABSTRACT

**INTRODUCTION** To compare the variations in consenting practice amongst trainees and consultant surgeons for laparoscopic cholecystectomy with specific reference to the documentation of significant risks of surgery.

**PATIENTS AND METHODS** A proforma was devised which included significant and/or commonly recognised complications of laparoscopic cholecystectomy. This was then cross-referenced with the consent forms for the 80 patients included in the study and the documented risks explained in each case were noted.

**RESULTS** The results showed that there is considerable variation between the three grades of clinicians involved in obtaining a patient's consent for laparoscopic cholecystectomy. There was a clear difference in emphasis of the significant complications depending on the seniority of the consenter. Over 80% of the consents in this study were still being obtained by junior staff.

**CONCLUSIONS** More often than not, patients are not provided with consistent information to make an informed choice. We suggest that a preprinted consent form will provide a more uniform approach to consenting practice for laparoscopic cholecystectomy.

### KEYWORDS

Laparoscopic surgery – Laparoscopic cholecystectomy – Variations in consent – Consenting for surgery

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The issue of informed consent is much debated amongst surgical practitioners. Whilst verbal consent, and thus informed consent, may have improved, written documentation of consent remains anecdotally poor.

There is currently no legal requirement to have specific written consent; however, it remains the simplest means of providing evidence of such consent in a court of law. A patient's signature on a consent form is evidence that the patient has given consent but is not proof of valid consent.

Medicolegally, when evidence of informed consent is required, this may include an assessment of the consent form, including written evidence of the proposed procedure, benefits of the procedure, significant complications, risks of not treating and alternative treatments.

This retrospective observational study aims to compare the variations in consenting practice amongst trainees and consultant surgeons for laparoscopic cholecystectomy with specific reference to the documentation of significant risks of surgery.

### Patients and Methods

A proforma was devised which included significant and/or commonly recognised complications of laparoscopic cholecystectomy following a Medline literature search. The

18 most commonly occurring risks with an incidence of greater than 0.1% were deemed to be significant for the purposes of this study.

All patients having laparoscopic cholecystectomy ( $n = 80$ ) from February 2003 to February 2004 were included. Patients who had planned open cholecystectomy ( $n = 3$ ) were excluded from the study as were patients whose consent forms could not be located ( $n = 4$ ) or where notes were missing ( $n = 16$ ).

A senior house officer and a preregistration house officer analysed the consent forms for all patients included in the study and cross referenced them with the proforma recording the documented complications on the consent form in each case.

### Results

Of the 80 consent forms assessed, 16 were completed by the consultant surgeon personally, 33 were completed by the registrar or middle-grade, and the remaining 31 by senior house officers (Fig. 1). Policy at North West London NHS Trust currently prohibits all preregistration house officers from consenting practice. As can be seen from Figure 1, 80% of the consenting practice in our hospital is currently performed by junior trainees.

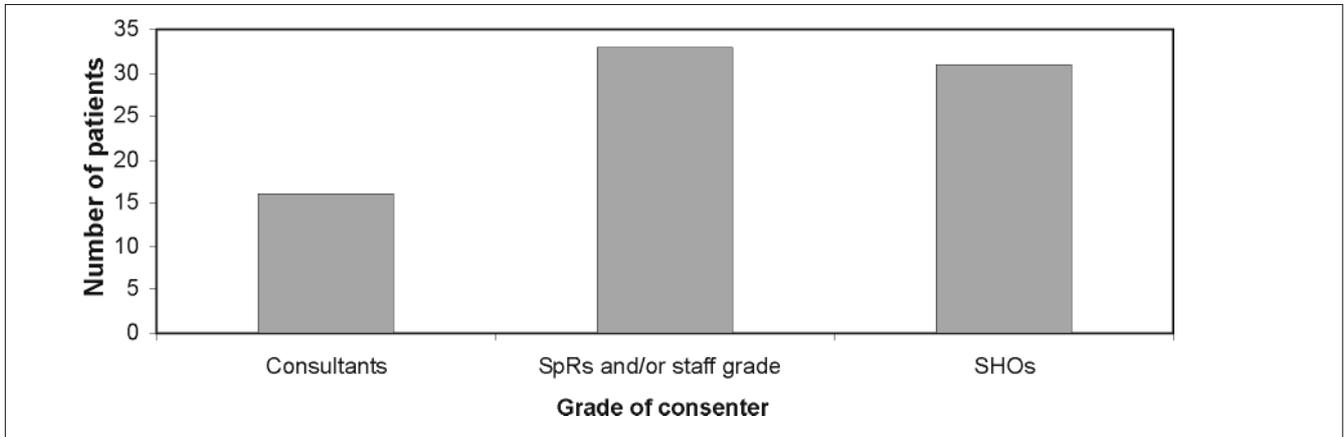


Figure 1 Breakdown of consents by staff grade.

As can be seen from Figure 2, in consents done by the consultant, conversion to open cholecystectomy is the only complication consistently documented in all consents performed. Bleeding is mentioned 56% of the time, postoperative wound infection 63% of the time, and retained stones in the biliary tree 44% of the time. Other complications were more rarely mentioned – bile duct injury 25%, bile leak 13% and injury to other organs 25% of the time. No mention was made by consultants of port site hernias, adhesions, abnormal wound healing, myocardial infarction or death.

The registrars (Fig. 3), in contrast, mention bleeding 91% of the time and conversion to open cholecystectomy 88% of the time. Bile duct injury and biliary leaks are more commonly mentioned, at 76% and 45%, respectively. Retained stones were mentioned 42% of the time. Postoperative wound infection was mentioned less commonly (36% of the time), as were deep venous thrombosis and/or pulmonary embolism. Again, there is little mention of port site hernias, adhesions, persistent symptoms, abnormal wound healing, myocardial infarction or death.

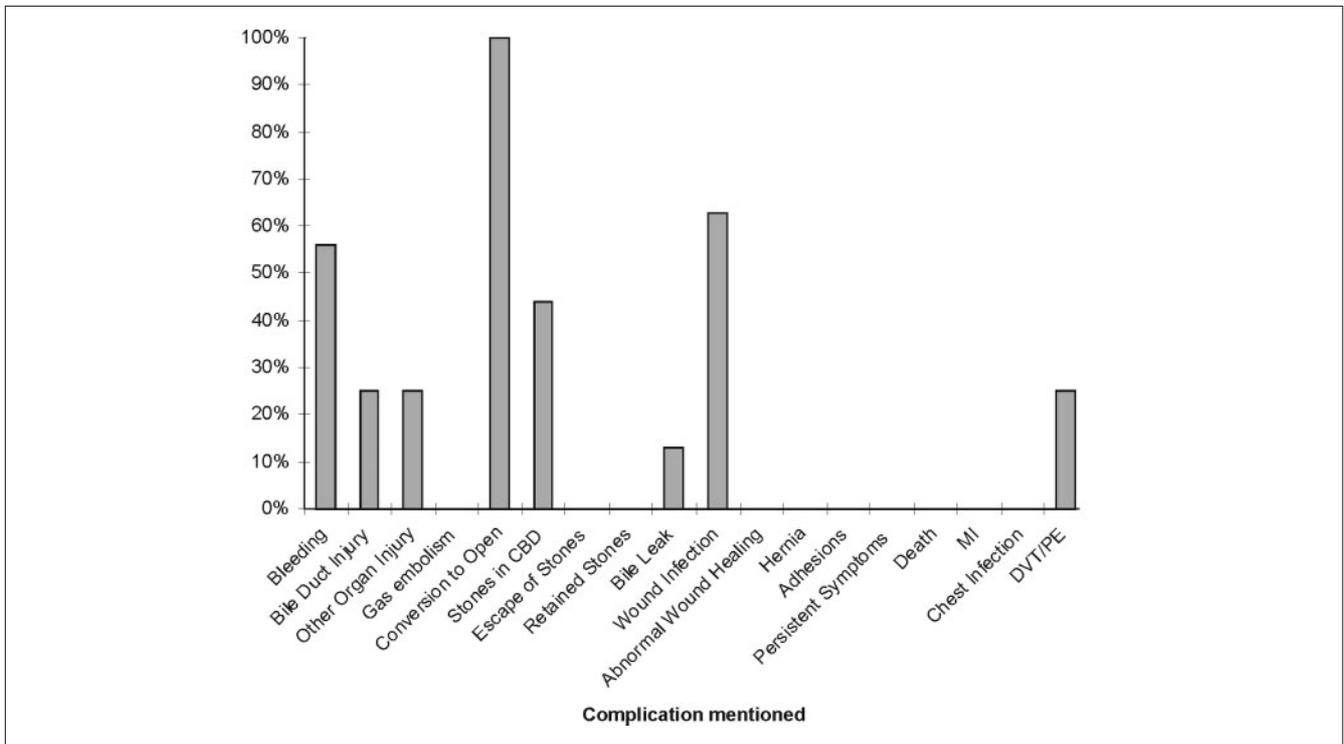


Figure 2 Complications following consultant consents.

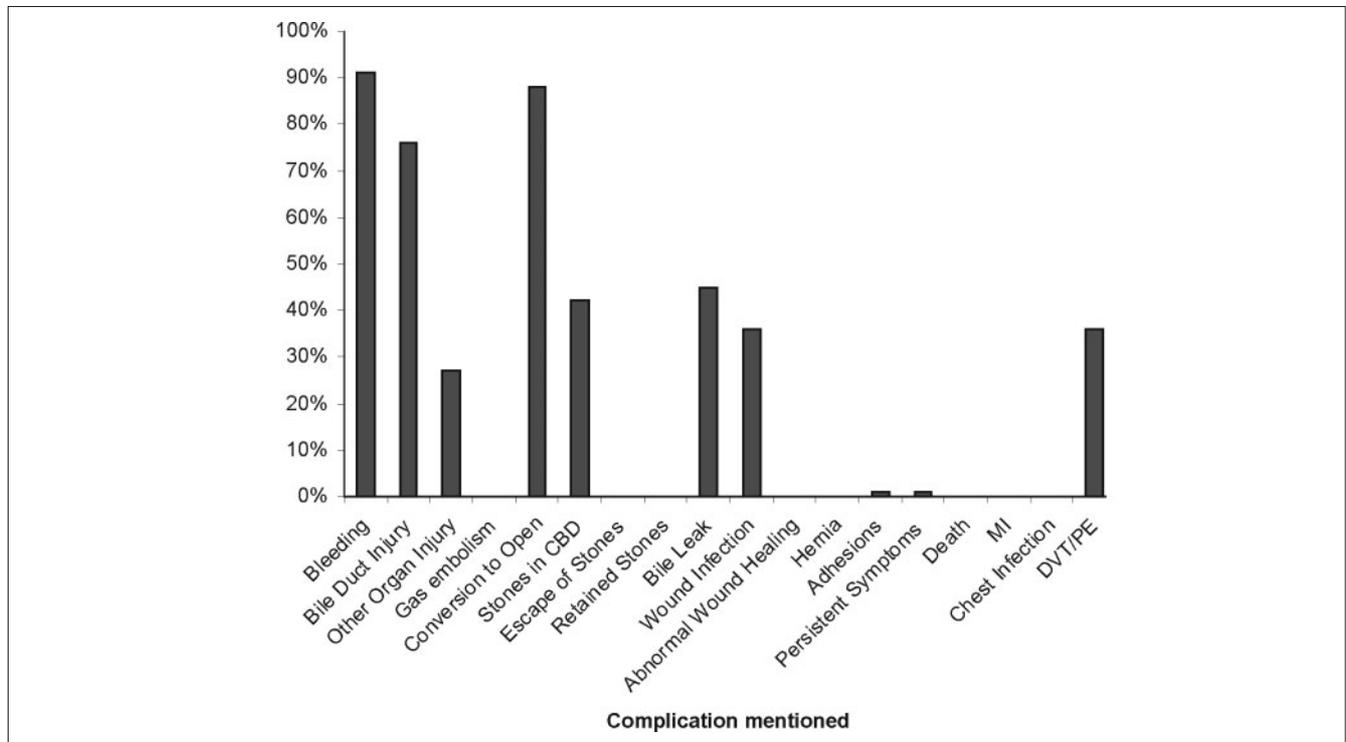


Figure 3 Complications following specialist registrar consents.

Figure 4 shows the results from the consents obtained by senior house officers. Bleeding is mentioned in 87% of consents and conversion to open cholecystectomy in 84% of cases. The senior house officers are less likely to mention bile duct injury (45%), other organ injury (23%) or retained biliary stones (32%). Persistent symptoms, death, myocardial infarction, adhesions, port site hernias are almost never mentioned.

**Discussion**

The results showed that there is considerable variation between the three grades of clinicians involved in obtaining a patient’s consent. The provision of information is, of course, central to the consent process. However, other than conversion to open cholecystectomy, bleeding and

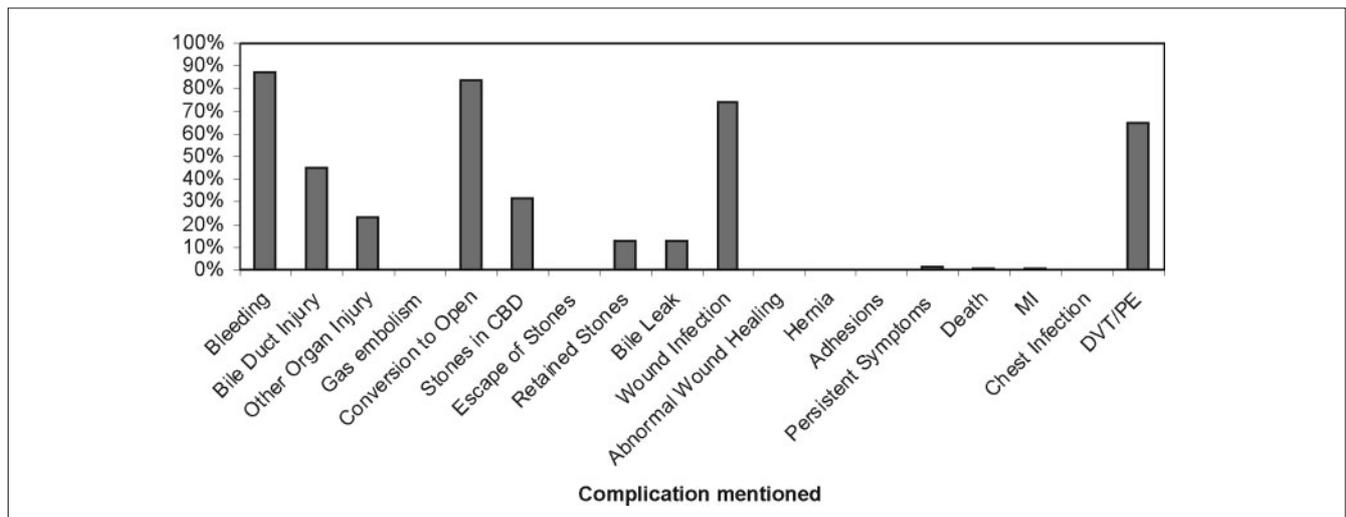


Figure 4 Complications following senior house officer consents.

infection, there appears to be no consensus on what complication requires discussion with the patient.

The legal position regarding the provision of information derives from the 1985 case of *Sidaway v Board of Governors Bethlem Royal Hospital (Sidaway v Board of Governors Bethlem Royal and the Maudsley Hospital [1985] 2 WLR 480)*, where the House of Lords held that the legal standard to be used in deciding whether adequate information had been given to a patient would be the same as that in judging whether a doctor had been negligent in their care.

In the past, a doctor would not be held negligent if it was found that he acted in accordance with a reasonable body of medical opinion. However, cases decided since *Sidaway* have shown that the courts have been willing to criticise even a reasonable body of medical opinion.

Current case law, therefore, places the burden on the clinician obtaining the consent to make a balanced judgement regarding what information needs to be disclosed to the patient. The only guide it offers is that all 'material' and 'significant' complications should be disclosed. The General Medical Council (GMC) has recommended that clinicians go one stage further, and take into account patients' individual needs and requirements in making this decision.

It is, therefore, not surprising that such variation between clinicians exists on what constitutes a material or significant complication.

One method of eliminating this disparity amongst clinicians has already been adopted by surgeons in both Queensland and Cambridge; it involves the use of a preprinted consent form which details a list of 'significant' complications, evidence based depending on the frequency with which they occur. This can act as a source of information for the patient as well as an *aide memoir* for the surgeon.

## Conclusions

It is apparent from our study that, more often than not, patients are not provided with sufficient information to make an informed choice. We hope that such a standardised consent form, adapted for each individual surgeon's practice, will provide a more uniform approach to consenting for laparoscopic cholecystectomy. We accept that such consent forms can overwhelm certain patients with unnecessary information. However, we believe that in the increasingly educated patient population, there will be a

growing demand for the provision of this level of information before the patient's consent can truly be considered to be both legally and ethically valid.

One final conclusion to our study seems to be that consultants, when taking consent, do not mention complications as much as trainees do. This may result in them being more likely to run into legal problems. If indeed trainees are better at taking consent, then perhaps the task of consenting patients should be left to them!

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