



Medical audit

Consent and complications: risk disclosure varies widely between individual surgeons

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Aims: To assess variations in consent practice for a single operative procedure, namely laparoscopic cholecystectomy, particularly with respect to the frequency with which potential complications are discussed with patients.

Methods: Postal questionnaire sent to general surgeons in the West Midlands and to UK members of the Association of Endoscopic Surgeons of Great Britain and Ireland. Respondents were asked to estimate how often they discussed particular complications with their patients pre-operatively.

Results: Conversion to open cholecystectomy was the most frequently discussed complication. Other complications were much less likely to be mentioned overall and there was disturbing variation between individual surgeons in the frequency with which certain complications were discussed, particularly the risk of bile duct injury.

Conclusions: In order for consent to be informed, patients need to be aware of significant risks. Our results indicate a lack of consensus from surgeons as to which risks are significant for this operation and this is likely to be true for other procedures.

Key words: Informed consent – Postoperative complications – Cholecystectomy – Laparoscopy

Informed consent is currently an issue of interest and debate, both within the medical profession and in the wider media. Consenting for an operation requires an explanation of the indications, principles and risks of the procedure, as well as the consequences of not undergoing the proposed surgery and discussion of alternative treatments. Exactly what constitutes a significant risk is unclear. In UK law, a practitioner is not negligent for failing to mention a specific risk if a responsible body of relevant and reasonable professional opinion would agree and if a reasonably competent practitioner, in a similar situation, would not have mentioned the risk.^{1,2} In 1992, the high court in Australia ruled that a risk was material if

a reasonable person in the patient's position would be likely to find it significant.³ We decided to assess which risks were considered significant by doctors for a single procedure and whether there was a consensus view across a responsible body of relevant professional opinion. We chose laparoscopic cholecystectomy as an elective, non-cancer procedure with well-known, but generally uncommon, complications.

Materials and Methods

A postal questionnaire was sent in April 2000 to two groups of surgeons – consultant general surgeons in the

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Table 1 Complications in laparoscopic cholecystectomy

Bile duct injury
Retained calculi
Port site hernia
Shoulder tip pain
Conversion to open cholecystectomy
Wound infection
Respiratory complications
Thrombo-embolic complications
Death

Table 2 Frequency ratings with which each complication was discussed

0%	Never
1–25%	Rarely
26–50%	Sometimes
51–75%	Often
76–99%	Usually
100%	Always

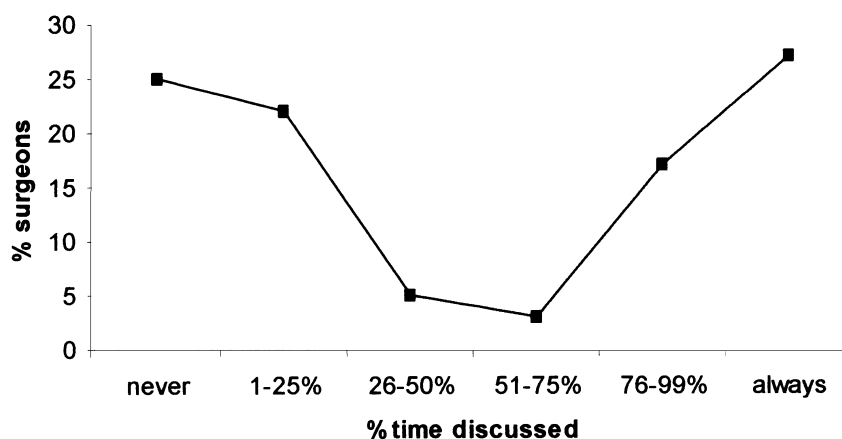


Figure 1 Informing patients: bile duct injury.

West Midlands region and UK members of the Association of Endoscopic Surgeons of Great Britain and Ireland. Surgeons in the West Midlands were identified from the current list of higher surgical training posts, and members of the Association from their mailing list. Local surgeons who were known by the authors not to perform laparoscopic cholecystectomy were excluded.

Surgeons were asked to estimate how often they or their team mentioned nine given complications to patients when consenting for laparoscopic cholecystectomy (Table 1). The list included both operation specific and systemic post-operative complications, but was not intended to be exhaustive. The frequency with which each complication was discussed with patients was expressed as a percentage of time by placing a tick in the appropriate box (Table 2).

Surgeons were also asked whether they provided written information on laparoscopic cholecystectomy to patients, what conversion rate they quoted and whether this was: (i) their own rate; (ii) that cited in the current literature; or (iii) from some other source.

Results

A total of 414 questionnaires were sent and there was a response rate of 54%. Sixteen surgeons replied that they did

not perform laparoscopic cholecystectomy and these were excluded from further calculation, leaving a total of 207.

The average (median) number of laparoscopic cholecystectomies performed annually was 72 (range, 5–300; mean, 55).

Only 44% of respondents provided written information to patients. This was mostly given out either in out-patients or in the pre-operative clinic, though a significant minority (19%) gave patients this information on the ward in the immediate pre-operative period. Examples we received ranged from a few lines on a single side of A4 paper to multiple, closely typed sheets.

The number of potential complications and the frequency with which they were discussed with patients during consent varied widely. One surgeon claimed to never mention any of the given complications, while 25 respondents usually mentioned all of them. On average, only 3 of the 9 listed complications were mentioned more than 50% of the time.

There was an astonishing dichotomy of practice with regard to informing patients of the risks of bile duct injury. Some 25% of surgeons never discussed bile duct injury with patients, and a further 22% mentioned it only rarely. However, 27% of surgeons always mentioned bile duct injury and 17% usually did (Fig. 1).

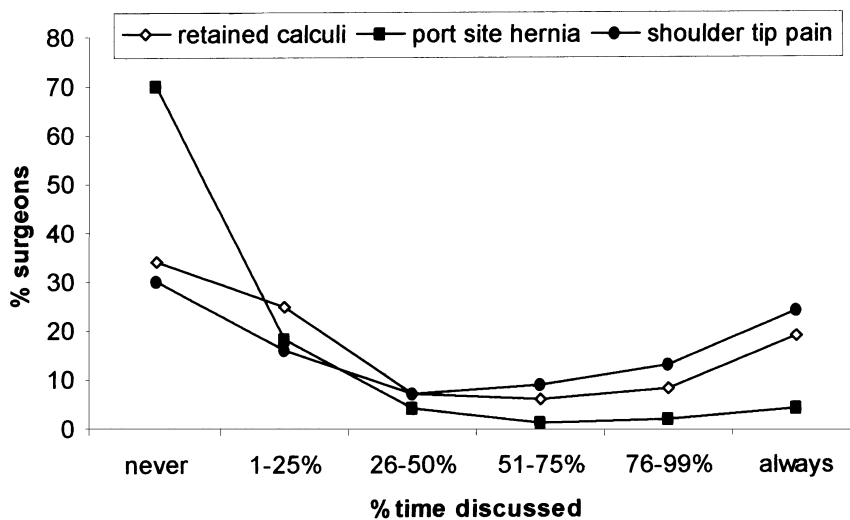


Figure 2 Informing patients: specific complications.

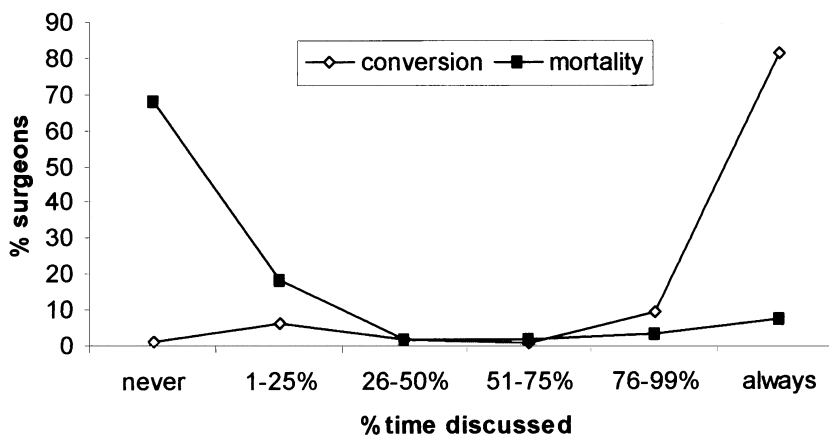


Figure 3 Informing patients: conversion and mortality.

There was a less marked, but still evident, lack of consensus on providing information about retained calculi, with 59% rarely or never informing patients of the risk and 27% usually or always doing so (Fig. 2). The response for shoulder tip pain was similar: 30% never broached the subject, 24% always did. Port site hernia was rarely mentioned; only 7% surgeons discussed it more than half the time, and over 70% never did so.

Not surprisingly, the overwhelming majority of respondents discussed the possibility of conversion to open cholecystectomy (83% always did) and equally predictably, only a small minority (10%) usually or always mentioned operative mortality (Fig. 3).

There was a mixed picture with respect to the more general postoperative complications of thrombo-embolism, respiratory events and wound infection, though these tended to be discussed less often than the operation-specific risks, on average only 25% (range, 19–30%) surgeons usually or always mentioning them (Fig. 4).

Conversion rates quoted to patients varied between 0–20% with an average of 5%. Overall, 93% of surgeons gave their own rate and the remainder quoted rates from the current literature, a unit’s rate, or varied the rate quoted depending on individual patient characteristics.

Discussion

The overall response rate of 54% was low, but not unexpected, for this type of survey. The lack of uniformity in the responses we received leads us to believe that our sample is likely to be representative; there was no identifiable pattern amongst our respondents to suggest that non-responders would represent different practices.

With the exception of conversion, our respondents were more likely not to mention these complications than to discuss them when consenting for laparoscopic cholecystectomy. For port site hernia and the systemic risks, it would appear that a responsible body of opinion

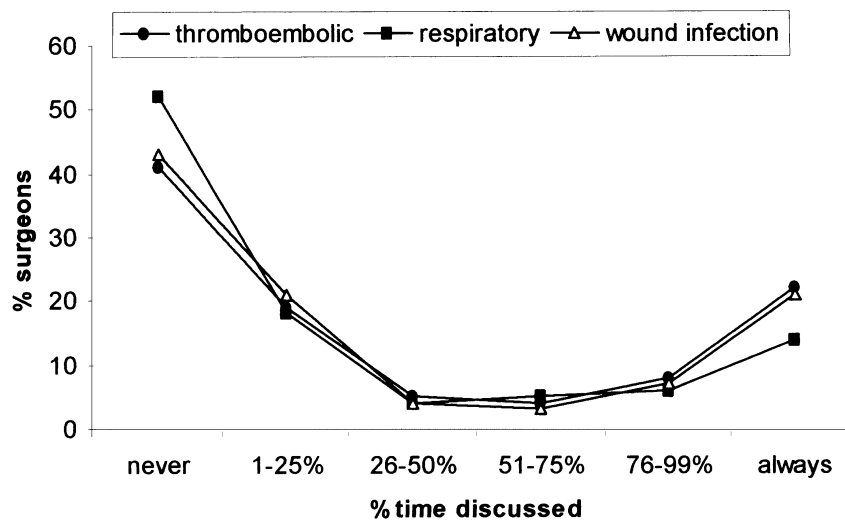


Figure 4 Informing patients: general complications.

does not deem them to be significant. If consent becomes more patient centred (as in Australia) this may become increasingly unacceptable; any complication delaying discharge after short-stay, minimal access surgery may be perceived to be significant by patients.

It is with regard to bile duct injury, however, that our results are most disturbing. It is impossible to say whether a responsible body of opinion considers this to be a significant risk or not. It is certainly an uncommon complication, with a reported incidence between 0.25–2.5%,⁴⁻⁷ but has major implications for the patient in terms of both morbidity and further management events.

The majority of the surgeons questioned did not provide written information to patients, yet the General Medical Council's guidance on consent⁸ advises that doctors 'use up-to-date written material, visual and other aids...where appropriate and/or practicable'. It is no surprise that such information is not more widely available; it has to be produced locally by individual surgeons or units and this is both time consuming and costly.

Patients increasingly wish to be better informed before undergoing surgery, particularly about the potential risks of the procedure⁹ and giving this information does not significantly increase patient anxiety.¹⁰ Our results show that, within the profession, there is no consensus on which risks are significant enough to warrant discussion with patients. This is patently unsatisfactory from both a patient's and a medicolegal point of view.

Perhaps it is time for the Colleges and/or the defence unions to define a minimum dataset of information which

should be given to patients for individual procedures and for the NHS to produce skeleton information in leaflet form or over the Internet which includes this dataset but allows surgeons to add details of their individual practice if they so wish. Attempting to do this would, at the very least, initiate debate (and hopefully consensus) on what constitutes a significant risk.

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