Gynecol Surg (2004) 1:225–226
DOI 10.1007/s10397-004-0069-1

EDITORIAL

Jeremy Wright · Saikat Banerjee

Informed consent for endoscopic surgery—myth or reality?

Abstract Patients, we are told, expect evidence-based information on which to base their consent if they are to undergo an operative procedure. Much evidence is, however, lacking, and few have any concept of the meaning of 'risk'. This editorial examines this and the risks of diagnostic laparoscopy with a plea for more multi-centre international audits of risk.

In the United Kingdom we are constantly being offered unctuous good advice from a myriad of organisations who employ the great and the good to opine on their behalf. The General Medical Council, our senior regulatory body, gives us the self evident advice that we should be 'polite to patients and always have a chaperone'; the National Institute for Clinical Excellence (NICE), a shadowy organisation, employs anonymous-seeming people to tell us how to interpret cardiotocographs and when and how we should do Caesarean sections. Advice that we should disregard at our peril, it seems; advice that is politically correct, as evidence-based as possible, but probably for the individual concerned, inappropriate.

Our own Royal College is now following the trend and issuing a series of advisories called 'Green Top' forms. These offer potentially controversial advice such as the role of salpingectomy in ectopic pregnancy. More recently, a new series has been published, called 'Advice on Consent'. Much of this is predicated on the view that we require to pass on to our patients some idea of the risks of the procedure they are about to undergo. Most of us, though, have a limited grasp about what 'risk' means. We worry about living next to power lines or microwaving our grey matter with mobile phones while continuing to smoke 30 cigarettes a day and becoming obese on a diet of saturated fats. Our assessment of individual risk is very different from our understanding of actuarial risk or the probability of a particular event happening to you. Few quoted risks have confidence limits around the point estimate when I see them. Any surgical complication, however trivial, is a risk to which a patient would not have dreamt of exposing him or herself and may be the subject of vociferous complaint. In fact, a lot of hospitals in the UK have organisations designed specifically to help people complain, called the Patient Advisory and Liaison Service. PALs, to you and me, are paid to act as patients' advocates.

These people come and bang on my door in outpatients to tell me that either I, or another doctor working in the clinic, has 'upset our client, and will I see them again and make it allright'—and thereby stopping formal complaints either to me or the hospital, but extending my clinic to such an extent that the nurses have gone home and the security man wants to lock up.

Complaints following surgery are subject to minute, if ill-informed enquiry and Incident Forms (locally an unphotocopyable blue) are now part of the confetti of our 'no-blame' culture.

Against this background, what should one advise one's patients about the risks of laparoscopic surgery, which is interchangeably 'the new way forward', or 'doctors with toys nearly killing their patients'?

What are the risks and can they be quantified? In keeping with the new NHS, there comes a new consent form in which one is expected to have given the patient some insight into the benefits of the procedure, the serious risks they may face, the more minor risks, possible complications and alternative procedures. Clearly our explanations about these risks must be evidence-based, and herein, of course, lies the problem. Most of us try hard not to advertise our failures, and really serious risks are so rare they are unlikely to arise in any one clinician's practice—but when they do they are likely to result in exhaustive enquiry and potential litigation. The enquiries will inevitably be secret, the litigation resolved out of court and the details with any learning experience attached will be lost in the mists of time.

What, though, can we tell our patients about the risks of the procedure? A consensus meeting was held in Middlesbrough in 1997 and Professor Ray Garry [1]

J. Wright (✉) · S. Banerjee
Ashford and St Peter's NHS Trust,
Guildford Road, Chertsey, Surrey, KT12 0PD, UK
e-mail: jwrighta@cix.co.uk

produced a leading article with a meta-analysis. Chapron [2] and some other brave Frenchmen pooled their results as did Jansen [3] and some equally brave Dutchmen. From the rest of us, there has been a deafening silence apart from an RCOG report dating from the early 1970s, when diathermy burns were all the rage, but the equipment was more primitive. Diathermy burns continue to feature with monotonous regularity, but nowadays with less disastrous consequences.

What advice should we give patients undergoing a diagnostic laparoscopy? Pooling the data from Garry, Chapron and Jansen, the chances of dying as a result of a diagnostic laparoscopy are in the order of 3.3 per 100,000. Death in these circumstances results from catastrophic haemorrhage that the surgeons fail to control. From these figures, too, it is possible to calculate that the risk of having a laparotomy as a result of complications from a diagnostic procedure and injury from the primary trocar insertion is between 0.6 and 1 per 1,000. Secondary trocar insertion seems to carry similar risk, despite presumably being put in under direct vision, and there would seem to be a distressing lack of awareness of the position of the inferior epigastric artery.

What else should you tell your patient? Is port site bleeding or bruising a risk of the procedure, or is it like shoulder-tip pain from diaphragmatic irritation, an annoying but inevitable side effect? Little is said about uterine manipulation with its inherent risk of fundal perforation, or the risk of pelvic infection or catheterisation.

Should all patients be aware of the risk of bowel damage and possible temporary stoma formation, as a result of undergoing the procedure, or, if they are undergoing sterilisation, their lifetime risk of a further pregnancy is 1:200, well above the risk level of other forms of contraception?

All these risks clearly multiply the more complex the procedure, but broadly these risks soon become those of the open procedure. One rapidly reaches the position of equipoise, when there is little additional risk to having procedures performed laparoscopically as distinct from a traditional method. This seems to be becoming the position after a steep learning curve with laparoscopically assisted hysterectomy.

With all this patchy information, it is clearly difficult to give our patients honest and unbiased advice. Shared data, shared advice standards with universally agreed information leaflets would go some way to help us and our patients to understand the value and danger of the surgery we undertake. With the small numbers of serious incidents and large numbers of procedures, only honest data sharing can answer the questions of risk. Small samples, though reporting the results of generalists undertaking laparoscopy, and local audit point to significant numbers of failed entry, abandoned procedures and minor complications [4]. They are of course universal, but rarely reported. To know the true incidence would be very valuable and possibly help us understand why. We should, however, always remember that what seems right for an individual via informed consultation with a competent doctor is often not what the apparent evidence-based majority view would say. Patients have a right to take that view, which should be respected.

A Europe-wide database of all laparoscopic procedures and their outcome would help us answer these questions of risk. It would be possible and relatively easy to set up in our cyber world, but might well fail for political reasons. The strength of the ESGE and the potential of this journal may help us overcome political problems and may perhaps help us to lead the world in honest data collection and appraisal.

We could start tomorrow, if you are interested.

References

1. Garry R (1999) Towards evidence-based laparoscopic entry techniques: clinical problems and dilemmas. 1999 Gynaecol Endosc 8:315–326
2. Chapron et al (1998) Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases. Hum Reprod 13:867–872
3. Jansen et al (1997) Complications of laparoscopy: a prospective multicentre observational study. BJOG 104:595–600
4. Richardson R, Sutton C (1999) Complications of first entry: a prospective laparoscopy audit. Gynaecol Endosc 8:327–334