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Ethical issues in laparoscopic hysterectomy

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Abstract

Hysterectomy is performed for a wide range of benign and malignant conditions, such as fibroids, menorrhagia and pelvic pain, and gynaecological malignancies. One in four women has a chance of undergoing hysterectomy in her lifetime. Conventionally abdominal hysterectomy is done through the open approach. However, many patients assume that the modern laparoscopic hysterectomy is superior to the standard approach. Laparoscopic surgical centres are mushrooming in major cities. This article presents ethical considerations involved in the decision-making process of choosing from the surgical options available.

Key words: ethics, laparoscopic hysterectomy.

Laparoscopic hysterectomy is an innovation in the gynaecologist's armamentarium. It is a minimal access procedure that allows patients to recover faster and with less pain than does the same procedure performed through the conventional open approach. The internet is flooded with information on this procedure and every literate patient requiring a hysterectomy opts for this form of treatment. This means the operating surgeon as well the patient should be aware of the potential ethical issues involved.

Indications for laparoscopic hysterectomy

In private practice, the commonest indication for laparoscopic hysterectomy is dysfunctional uterine bleeding. Most often the patients are young and are advised this procedure without undergoing full medical or hormonal treatment. One should remember that the laparoscopic route is not ideal for severe pelvic adhesions, very large uterine fibroids and adnexal masses. Moreover, only in Type V laparoscopic hysterectomy (Richardson's staging) is the uterus removed entirely through the abdominal route. Vaginal surgery completes the procedure in Types I to IV. If the patient is multiparous, laxity of pelvic supports provides easy manoeuverability to the vaginal surgeon even in the presence of significant uterine enlargement. In fact, many cases of laparoscopic hysterectomies would have been easily operated vaginally anyway.

Protracted learning curve

The time taken for the procedure is significantly longer for laparoscopic hysterectomy compared to abdominal hysterectomy (1). In one study, in the initial training period, the mean duration was 162 minutes for the laparoscopic hysterectomy group while abdominal hysterectomy averaged 98 minutes (2). It required 36 initial attempts to complete the surgery within a time frame comparable to abdominal hysterectomy (1). Unlike laparoscopic cholecystectomy, laparoscopic hysterectomy has a longer learning curve during which the risk of complications is relatively higher than open abdominal hysterectomy. This is seldom acknowledged by practising consultants.

Informed consent

Informed consent is an integral part of any surgical procedure. The patient must be well informed regarding the rationale, the intended benefits, the alternatives, the risks and cost implications. The rate of major complication for laparoscopic surgery is twice what it is for abdominal approaches. For every 20 women undergoing laparoscopic hysterectomy, one will experience a complication additional to those likely to be experienced by women undergoing abdominal hysterectomy (3). Urinary tract damage, in particular ureteric injury, remains the major concern in relation to the laparoscopic approach. In a series of 13,885 hysterectomies, the incidence of urinary tract injuries was highest with the laparoscopic approach (2.2 per cent) and lowest with the vaginal hysterectomy at 0.04 per cent (4). The complications related to trocar entry and CO_2 pneumoperitoneum are exclusive to the laparoscopic route. The patient should be warned about the possibility of converting the procedure to laparotomy. In the initial years of a laparoscopic surgeon's practice, up to 25 per cent of laparoscopic procedures may have to be converted to a laparotomy. This increases the length of operative hours, postoperative morbidity and, finally, the cost.

There are very few Indian studies published regarding the safety of laparoscopic hysterectomy. In a retrospective study of 60 patients who had undergone laparoscopic assisted vaginal hysterectomy (LAVH), complications occurred in 13 per cent and conversion to laparotomy in five per cent of patients (5). The main indications for LAVH in this series were uterine enlargement, limited vaginal access, absence of uterine descent, need for concomitant adnexectomy, suspicion of adhesions, endometriosis and a clear-cut indication for exploring the remainder of abdomen. In such cases, a simple vaginal hysterectomy would have increased operative risks such as haemorrhage and bladder and ureteric injuries and a conventional surgeon would have preferred open abdominal hysterectomy**.** However, vaginal hysterectomy is advantageous compared to abdominal hysterectomy in terms of morbidity, hospital stay, cost and resumption to work. It was therefore suggested that in appropriately selected cases a LAVH would be preferable to either an abdominal hysterectomy or a vaginal hysterectomy alone.

In the absence of contraindications, a simple vaginal hysterectomy is always preferable and should not be substituted by LAVH. Thus LAVH may expand the scope of vaginal hysterectomy and not replace it (5).

In another series involving 2,328 cases of laparoscopic hysterectomy performed in two major private hospitals, there were 26 bladder repairs (1.1 per cent), 11 ureteric injuries (0.47 per cent), 9 cases of bowel trauma (0.38 per cent) and 8 intraoperative haemorrhages requiring laparotomy (0.34 per cent). The authors opined that the laparoscopic approach for hysterectomy, though popular, is not immune from complications (6).

Ethical regulations for innovative surgical procedures

There are no clear national guidelines to govern and monitor innovative surgeries. In a survey of 59 articles on innovative surgeries published between 1992 and 2000 in the USA, the corresponding authors were sent an anonymous questionnaire; only 35 per cent responded. Only seven authors had mentioned the innovative nature of the procedure in the informed consent form and only six had sought prior Institution Regulatory Board (IRB) clearance. Two-thirds of the respondents stated that government regulations for the protection of human subjects of innovative surgery would not be appropriate. The survey concluded that the current system of definitions, ethical guidelines, and voluntary professional guidelines to protect patients from unwittingly becoming experimental subjects in a new procedure may be inadequate to meet the challenge of surgical innovation (7).

Hence, there is a need to bring innovative surgery under regulation, based on medical ethics, common law, and sound social policy. This should protect patients while enabling progress within the surgical field.

Cost analysis, training and credentialing

At present, postgraduate training in India is limited to conventional surgeries and diagnostic laparoscopies in some premier institutions. There is no degree or diploma programme in operative laparoscopy. Gynaecologists usually learn the technique by undergoing very short training programmes which involve substantially high fees; this may not include "hands on" surgical training but training on mannequins or virtual simulators. The cost of a laparoscopic surgical setup is very high. Many gynaecologists do not consider ethical guidelines when recruiting patients for laparoscopic hysterectomy in their practice. Another concern is that surgeons may reuse disposable accessories to reduce costs.

All gynaecologists planning to perform laparoscopic hysterectomies should have experience in basic laparoscopic procedures such as ovarian cystectomies, fulguration of endometriotic implants, adhesiolyis and ectopic pregnancies. Additional training in a hands-on, approved didactic and practical course should then be completed, and actual surgical procedures on patients observed. The initial three to five cases should be carefully supervised by another surgeon fully credentialed and experienced in laparoscopic hysterectomy (8). Early and effective accreditation is crucial to maintaining a high level of patient care and minimising adverse surgical results.

Conclusion

This short communication illustrates the importance of negotiating rational and acceptable choices with fully informed patients. Many patients assume that the more modern laparoscopic techniques are intrinsically preferable to standard approaches. The system of family medicine seems to be appropriate in the Indian context at this juncture. In western countries, family physicians are involved in several layers of this decision. They begin the process of informing patients and helping them work out the optimal surgical options. They are also called on after the surgical consultation to interpret the information conveyed by the surgeon and help the patient to make the best decision for her. Family physicians should be familiar with the outcomes of their own referral surgeons. The intended and optimal benefits of laparoscopic hysterectomy can be achieved in trained, skilled hands in clearly indicated cases.

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