

Operative Laparoscopy: Redefining the Limits

Camran Nezhat, MD,^{1,2,3,4,5,6} Farr Nezhat, MD,^{1,2,4,5,6} Ceana Nezhat, MD,^{1,2,4,5,6} Daniel S. Seidman, MD²

ABSTRACT

The continually changing definition of operative laparoscopy as well as the ever-widening boundaries of its use are discussed in this report. It is important to prepare residents to adequately undertake advanced laparoscopic surgery as laparotomy is gradually replaced by laparoscopy for many routine procedures. Since degree of training and experience strongly correlate with complication rates, more focus on laparoscopy during graduate education would be beneficial to residents in order to keep them up to date with the rapid development of this field.

Key Words: Laparoscopy, Surgical training, Training programs, Advanced laparoscopy.

INTRODUCTION

Laparoscopic surgery has undergone exciting developments over the last decade.^{1,2} The rapid pace of progress made by laparoscopic surgeons, however, has resulted in some concern and criticism as the role of operative laparoscopy has continued to be redefined.³⁻⁵ For instance, many conditions considered to represent absolute contraindications for laparoscopy only a short time ago are now accepted as indications for this method of intervention. These conditions include obesity,⁶ severe adhesions,⁷ previous laparotomies,⁸ cancer,⁹ abdominal hernia,¹⁰ pregnancy,¹¹ and bowel perforation with generalized peritonitis.¹² A growing experience with operative laparoscopy is also evident from the fact that few operations still necessitate laparotomy, for example, organ transplants and massive debulking. Complicated cases such as removal of large uteri or the presence of severe adhesions or endometriosis are now routinely performed with laparoscopic assistance. Similarly, certain operative complications such as injury to the ureter,^{13,14} or blood vessels¹⁵ can be safely treated laparoscopically by the experienced surgeon.

Technology still exerts a strong influence on operative laparoscopy, as witnessed by the recent introduction of small diameter laparoscopes that offer good resolution and light intensity.^{16,17} This technologic breakthrough has made laparoscopy suitable even for patients who cannot withstand general anesthesia. Small diameter laparoscopy can be offered for emergency diagnosis and management of patients presenting with acute hemodynamic instability and suspected active intra-abdominal bleeding due, for instance, to an ectopic pregnancy. Small diameter laparoscopy is likely to be adopted as a critical bedside diagnostic tool, and even as an office procedure in certain settings, in the near future.

The concerns raised following the generally successful introduction of operative laparoscopy stem to a large extent from the very nature of surgical research.¹⁸ The introduction of new forms of medical treatment is regulated by federal agencies demanding prolonged, multi-phase study schemes. In contrast, new surgical procedures are usually developed by individual surgeons without controlled comparative research protocols and though randomization has been advocated in surgical trials, few surgeons view this as a realistic suggestion.¹⁹

¹Stanford Endoscopy Center for Training and Technology, Stanford, California.

²Department of Gyn/OB, Stanford University School of Medicine, Stanford, California.

³Department of Surgery, Stanford University School of Medicine, Stanford, California

⁴Nezhat Institute for Special Pelvic Surgery, Palo Alto, California.

⁵Center for Special Pelvic Surgery, Atlanta, Georgia

⁶Department OB OB/GYN, Mercer University School of Medicine.

Address reprint request to: Camran Nezhat, MD, 900 Welch Road, Suite 403, Palo Alto, CA 94304, USA. Telephone: (650) 327-8778, Fax: (650) 327-2794

Even experienced surgeons must undertake a number of operative procedures before they feel comfortable in performing that procedure. Thus, comparing new laparoscopic operations to conventional procedures demands completing a certain learning stage. The challenge of introducing new surgical techniques is further complicated by the difficulty in recruiting a sufficient number of patients to provide adequate statistical power to reveal differences in outcome. Usually, multicenter studies are required to gain these numbers. In addition, it can be difficult to gather a large, typically heterogeneous group of surgeons who are familiar enough with a new surgical procedure to lend validity to the study. If the surgeons differ in skill and technique when performing either the conventional or the laparoscopic operation, the validity of the results may be biased. On the other hand, restricting randomized studies to a limited group of expert surgeons will usually limit this source of bias, but it will decrease the ability to generalize the results. Randomizing the patients in "blocks" - for each individual surgeon - may improve the ability to control for the effect of variation in surgical skill and experience.

These difficulties commonly result in simpler surgical procedures being studied first in a randomized fashion.²⁰ This occurred in the study of laparoscopic surgery, with simple procedures, such as insertion of trocars, first studied in a randomized fashion.^{21,22} Subsequently more complex procedures, such as hysterectomy, were the subject of randomized trials.^{23,24}

The implementation of large multi-center studies, the "gold standard" of evidence based medicine,²⁵ has been rarely utilized for laparoscopic surgery. The implementation of complex trials is often curtailed by the difficulty in obtaining the necessary funding and medical insurers are very reluctant to approve financial coverage to a "random" procedure. The need to evaluate the outcome of some operations with a second-look laparoscopy is even less likely to be covered by managed care organizations.

The use of a placebo or a "sham operation" is especially important when the outcome is subjective improvement of symptoms, such as pelvic pain.²⁶ Although laparoscopic sham procedures occasionally have been used with success in a blinded and randomized manner,²⁷ few insurers currently agree to pay for a trial of blinded "sham" versus real procedures and it can be very difficult to persuade patients to do so. Unlike the introduction of new drugs, little direct profit results from such studies. Major sources of funding, such as the pharmaceutical companies, are therefore less involved with surgical research, unless the use of specific new instruments is examined.

It is understandable that when the effects of treatment are large, and their value self-evident, randomized trials may

not be necessary to confirm these observations.²⁶ The benefits of laparoscopy compared to laparotomy, however, fall mostly within the frame of improving quality of life and do not substantially affect survival.²⁶ For example, while the life-saving role of surgical treatment for ectopic pregnancy did not require a randomized trial to prove its merits, the benefits of using laparoscopy over laparotomy to treat ectopic pregnancies clearly justify such a controlled study.²⁸ However, the obvious advantages of laparoscopy in terms of rapid recovery and superior cosmetic results led to strong patient demand and rapid adoption of these techniques into general practice. Thus, by the time randomized trials were designed, few patients were willing to undergo surgery using a large abdominal surgical incision. Even when two types of laparoscopic operations are compared, patient consent may not be readily given. It has been very difficult to randomize patients to undergo either laparoscopic supracervical or total hysterectomy, since many patients have a clear opinion regarding what is best for them, despite the fact that the relative merits of both procedures have not yet been definitely proven.

The highly technical nature of laparoscopic surgery and the rapid rate with which new instruments are introduced, require a high intensity of surgical training. At a time when growing numbers of procedures are being performed on an outpatient basis, few residency programs can adequately prepare their residents for independently undertaking advanced laparoscopic surgery. The situation is further accentuated by the overall decreasing number of operations performed because of improved medications replacing surgical procedures, such as methotrexate for ectopic pregnancy, or the application of less invasive surgical procedures such as endometrial ablation instead of hysterectomy for menorrhagia. As the degree of training and experience strongly correlate with complication rates, the success of laparoscopy is very much dependent on the surgeon's skills. Future training programs must find a way to include participation in a substantial number of surgical procedures which is essential for acquiring proper technical skills and for gaining adequate knowledge of patient selection, preparation for surgery, and postoperative care.

Physicians must be very careful before adopting new techniques. Many procedures can be simplified by combining laparoscopic surgery with either vaginal procedures or a minilaparotomy. This hybridization reduces the need for intracorporeal suturing and lengthy removal of tissue from the abdomen. Many common gynecologic operations, such as myomectomy or cystectomy, can be easier to perform if the superior exposure provided by laparoscopy to explore the abdomen is first utilized. The ovary or fibroid can then be grasped and an extracorporeal conventional procedure can be completed through a minilaparotomy incision.²⁹

Laparoscopy has attracted more criticism than any other form of surgery, despite the fact that the difficulties in evaluating new surgical procedures are not unique to this approach.¹⁸ The results of large, uncontrolled series currently attest to the efficacy, safety and practicality of all major forms of laparoscopic pelvic surgery.³⁰ The continuing acceptance of laparoscopy is likely to depend on better randomized trials as insurers will demand more concrete evidence of its superiority over conventional surgery. Laparoscopy has come to a point where the experienced surgeon can successfully perform almost every known surgical procedure. For example, one of the most challenging surgical procedures is the management of extensive endometriosis of the pelvis, especially when it extends to the parametrium and involves the ureter and rectovaginal septum. In this instance, a multidisciplinary team including gastrointestinal, genitourinary, and gynecologic (pelvic) surgeons are often required.

We believe as years go by and the experience of surgeons increases, laparotomy will be performed less and less. Future generations of surgeons will not have to learn laparotomy first and then progress to laparoscopy. Time will prove that learning operative laparoscopy is preferable to laparotomy and the complications of operative videolaparoscopy are less than those of laparotomy. Even most complications of operative videolaparoscopy will be managed by this method and not by laparotomy. As acknowledged above, only a few exceptional operations, such as extensive tumor debulking, removal of giant tumors and organ transplants, will demand a large laparotomy exposure. However, even portions of these procedures can be assisted by the laparoscope, which may reduce the size of the incision. Extending the many benefits of minimal access surgery to an ever growing number of patients is greatly dependent on our ability to provide proper training in advanced operative laparoscopy.

Gradually, postgraduate trainees will be exposed to more laparoscopies than laparotomies. This trend will continue until video-assisted operative laparoscopy replaces laparotomy in almost all cases. In the United States, our best estimate suggests this reality will occur by the year 2020.

References:

1. Tadir Y, Fisch B. Operative laparoscopy: a challenge for general gynecology? *Am J Obstet Gynecol.* 1993;169:7-12.
2. Nezhat CR, Nezhat FR, Luciano AA, Siegler AM, Metzger DA, Nezhat CH, eds. *Operative Gynecologic Laparoscopy: Principles and Techniques.* New York: McGraw-Hill; 1995.
3. Pitkin RM. Operative laparoscopy: surgical advance or technical gimmick. *Obstet Gynecol.* 1992;79:441-442.
4. Grundfest W. Laparoscopic surgery: the need for self control. *J Laparoendosc.* 1992;2:131-132.
5. Treacy PJ, Johnson AG. Is the laparoscopic bubble bursting? *Lancet.* 1995;346:23.
6. Singh KB, Haddleston HT, Nandy I. Laparoscopic tubal sterilization in obese women: experience from a teaching institution. *South Med J.* 1996;89:56-59.
7. Kaali SG, Bartfai G. Direct insertion of the laparoscopic trocar after an earlier laparotomy. *J Reprod Med.* 1988;33:739-740.
8. Schrimmer BD, Dix J, Schemig RE Jr, Aguilar M, Urch S. The impact of previous abdominal surgery on outcome following laparoscopic cholecystectomy. *Surg Endosc.* 1995;9:1085-1089.
9. Childers JM, Hatch K, Surwit EA. The role of laparoscopic lymphadenectomy in the management of cervical carcinoma. *Gynecol Oncol.* 1992;47:38-43.
10. Stoker DL, Spiegelhalter DJ, Singh R, et al. Laparoscopic versus open inguinal hernia repair: randomized prospective trial. *Lancet.* 1994;343:1243-1245.
11. Curet MJ, Allen D, Josloff RK, Pitcher DE, Curet LB, Miscall BG, Zucker KA. Laparoscopy during pregnancy. *Arch Surg.* 1996;131:546-551.
12. O'Sullivan GC, Murphy D, O'Brien MG, Ireland A. Laparoscopic management of generalized peritonitis due to perforated colonic diverticula. *Am J Surg.* 1996;171:432-434.
13. Nezhat C, Nezhat F. Laparoscopic repair of resected ureter during operative laparoscopy to treat endometriosis: a case report. *Obstet Gynecol.* 1992;80:543-544.
14. Gomel V, James C. Intraoperative management of ureteral injury during operative laparoscopy. *Fertil Steril.* 1991;55:416-418.
15. Nezhat C, Childers J, Nezhat F, Nezhat CH, Seidman DS. Major retroperitoneal vascular injury during advanced laparoscopic surgery. *Human Reprod.* In press.
16. Grochmal SA. Gynaecological applications of optical catheters (microhysteroscopy and microlaparoscopy). In Grochmal SA, ed. *Minimal Access Gynecology.* Oxford: Radcliffe Medical Press; 1995:274-299.
17. Bauer O, Kupker W, Felberbaum R, Gerling W, Diedrich K. Small-diameter laparoscopy (SDL) using a microlaparoscope. *J Assist Reprod Genet.* 1996;13:298-305.
18. Hoerton R. Surgical research or comic opera: questions, but few answers. *Lancet.* 1996;347:984-985.
19. Chalmers TC. Randomization of the first patient. *Med Clin N Am.* 1975;59:1035-1036.

20. van der Linden W. Pitfalls in randomized surgical trials. *Surgery*. 1980;87:258-262.
21. Nezhat FR, Silfen SL, Evand D, Nezhat C. Comparison of direct insertion of disposable and standard reusable laparoscopic trocars and previous pneumoperitoneum with Veress needle. *Obstet Gynecol*. 1991;78:148-150.
22. Byron JW, Markenson G, Miyazawa K. A randomized comparison of Veress needle and direct trocar insertion for laparoscopy. *Surg Gynecol Obstet*. 1993;177:259-262.
23. Nezhat F, Nezhat C, Gordon S, Wilkins E. Laparoscopic versus abdominal hysterectomy. *J Reprod Med*. 1992;37:247-250.
24. Summit RL Jr., Stovall TG, Lipscomb GH, Ling FW. Randomized comparison of laparoscopy-assisted vaginal hysterectomy with standard vaginal hysterectomy in an outpatient setting. *Obstet Gynecol*. 1992;80(6):895-901.
25. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what is and what isn't. It's about integrating individual clinical expertise and the best external evidence. *Brit Med J*. 1996;312:71-72.
26. McLeod RS, Wright JG, Solomon MJ, Hu X, Walters BC, Lossing A. Randomized controlled trial in surgery: issues and problems. *Surgery*. 1996;119:483-486.
27. Sutton CJG, Ewen SP, Whitelaw N, Haines P. Prospective, randomized, double-blind, controlled trial of laser laparoscopy in the treatment of pelvic pain associated with minimal, mild, and moderate endometriosis. *Fertil Steril*. 1994;62:696-671.
28. Gray DT, Thorburn J, Lunderoff P, Strandell A, Lindblom B. A cost-effectiveness study of a randomized trial of laparoscopy versus laparotomy for ectopic pregnancy. *Lancet*. 1995;345:1139-1143.
29. Nezhat C, Nezhat F, Bess O, Nezhat CH, Mashiach R. Laparoscopically assisted myomectomy: a report of a new technique in 57 cases. *Int J Fertil*. 1994;39(1):39-44.
30. Nagele F, Molnar BG, O'Connor H, Magos AL. Randomized studies in endoscopic surgery - where is the proof? *Curr Opin Obstet Gynecol*. 1996;8:281-289.