Laparoscopic surgery for treatment of colon cancer

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Findings by SBU Alert

Laparoscopic surgery has been tested as an alternative to traditional open surgery in patients with colon cancer. Moderate* scientific knowledge concerning the short-term medical effects suggests that more rapid mobilization after surgery is possible, thereby shortening the duration of medical care. Poor* knowledge is available concerning the long-term medical effects. Some of the case descriptions suggest a suspected increased risk for relapse of cancer in the abdominal wall. Based on the material available, definite conclusions cannot be drawn concerning the risk for relapse. The effects on costs and the quality of life have not been evaluated. The assessment by SBU Alert suggests that this method should be used only within the scope of randomized controlled studies until further evidence becomes available.

*This assessment by SBU Alert uses a 4-point scale to grade the quality and evidence of the scientific documentation. The grades indicate: (1) good, (2) moderate, (3) poor, or (4) no scientific evidence on the subject. For further information please see “Grading of evidence”.

Alert is a joint effort by the Swedish Council on Technology Assessment in Health Care (SBU), the Medical Products Agency, the National Board of Health and Welfare, and the Federation of Swedish County Councils.

Technology

Laparoscopy has been used since the beginning of the century, mainly in diagnostics and in the field of gynecology. Since 1987 – when the first laparoscopic biliary surgery on humans was reported – interest in the method among surgeons has increased rapidly, and it has been tested as treatment for several diseases. In addition to treating gallstones, the method is considered to be an established treatment for, eg, inguinal hernia and appendicitis. The first colon resection was performed in 1991.

The laparoscopic technique involves accessing the abdominal cavity, not via a long incision in the abdominal wall, but via four or five 1 cm incisions, through which the surgeon creates special ports to insert various optical and surgical instruments. Optical instruments are connected to a high-resolution video camera outside the abdominal cavity, and TV screen provides the surgeon with "virtual reality" images. To gain sufficient working space inside the abdominal cavity, anesthesia and muscle relaxants are required, and the abdominal wall is raised by injecting gas (carbon dioxide). The bowel specimen is removed via a short incision in the abdominal wall. Some techniques allow the entire operation to be performed within the abdominal cavity, with the bowel specimen being removed via the rectum. These techniques, however, have been used restrictively.

Studies of laparoscopic biliary surgery have shown that patients experience less stress to the body, less postoperative pain, and more rapid mobilization. Some studies reported shorter episodes of care and shorter absenteeism from work compared to open surgery, hence, a decrease in the total cost compared to conventional treatment. The hope has been that similar results could be achieved with colon surgery.

Target group

In Sweden, colon cancer affects approximately 3 200 people annually, mainly those aged 60 years or older. Approximately 4 400 patients are hospitalized with a malignant tumor of the colon, consuming approximately 80 000 patient days. Surgery is the only curative treatment available. Given current knowledge, laparoscopy is not appropriate for all patients, eg, emergency cases involving ileus and in severely overweight patients. The target group, however, is estimated to be approximately 2 000 patients per year.

Relation to other technology

The alternative to laparoscopy in the treatment of colon cancer is traditional open surgery. Few believe that open surgery will be replaced entirely, but future indications for the different methods are uncertain.

Patient benefits

Approximately 30 published reports address the short-term results of laparoscopic methods. With few exceptions, they are follow-up studies of patients without a control group, consecutive patient series with an historic control group, results from voluntary registries, and retrospective reports. The series are heterogeneous and many of the reports include surgery for rectal cancer. The databases cover between 8 and over 1 000 patients (the latter results are from a voluntary registry in the United States).

Most studies suggest that laparoscopic surgery, compared to open surgery, results in longer operating times, less postoperative pain, more rapid return to normal bowel function, and a shorter duration of medical care.

Two smaller prospective randomized controlled studies are published and support the experiences described above.

- A Spanish study from 1995 included 51 patients. Significant differences were found with laparoscopic surgery in terms of longer operating times (approximately 30 minutes), a 50 per cent reduction in the time before patients can take food by mouth and resume bowel function, a reduction in the length of stay by 3 days, and postoperative complications of 8 per cent compared to 31 per cent (wound

infection, wound rupture, bleeding, myocardial infarction, etc) [1].

- A Danish study from 1997 included 34 patients. This study found that operating times were 55 minutes longer for laparoscopic surgery, a somewhat less postoperative pain, a 3-day reduction in the length of stay, and greater stress on patients during the operation. The study, however, excluded patients who were transferred from laparoscopic surgery to open surgery [2].

Several smaller evaluations, most of which are based on limited or weak evidence, address the short-term medical effects of the method. Knowledge is extremely limited concerning the long-term effects of the method, regarding both long-term complications, eg, ileus and incisional hernia, and cancer-free survival.

Two studies from the United States report on long-term effects.

- A prospective study (nonrandomized) monitored nearly 400 patients who had received curative surgery for an average 2 years and found – apart from confirmation of the short-term results above – that relapse, cancer-free survival, and mortality did not differ between open and laparoscopic surgery.

- A retrospective review of 372 laparoscopic operations from 16 centers monitored patients for a minimum 15 months, and found that relapse rates and cancer-free survival rates were similar to those reported from open surgery – adjusted for disease stage at the time of surgery. Non-cancer-related complications were not analyzed [4].

Risks and side effects

Overall, no increase in complication rates has been shown in laparoscopic surgery compared to open methods. Several studies reported that some complications specific to colon surgery were somewhat lower with laparoscopic surgery. A smaller study reported a notably high rate of complications related to blood clot formation. Unintentional damage to large vessels or bowels during blind insertion of needles or surgical instruments through the abdominal wall is also reported, as in other laparoscopic surgery.

Port site metastases are complications receiving the greatest attention. The term refers to relatively early relapse of cancer in the abdominal wall, both in the wound through which the bowel specimen was removed, and in the wounds used as laparoscopic ports, which were never in direct contact with the tumor.

As early as 1994, 30 such cases had already been reported, causing major concern, especially since isolated cases were found in patients with cancer at a relatively early stage. Initially, the incidence was estimated to be approximately 4 per cent [5], but the long-term studies from the United States mentioned above reported an incidence of 1 per cent to 1.5 per cent, which is similar to that estimated for open surgery. However, in smaller, isolated studies, the rate of port site metastases has been reported to be as high as 20 per cent.

Costs and cost-effectiveness

Laparoscopic surgery for conditions other than colon cancer is offered today in most departments of surgery in Sweden. Hence, the basic equipment obtained can be used without modifications in operations of the colon. In addition, there are costs for disposable instruments, which may be in the range of 15 000 SEK per operation, plus the added costs for prolonged operating times reported in several studies, but which have not been estimated. It is unlikely that other additional expenditures are needed, eg, renovation, personnel, etc. Many surgeons claim the procedure is facilitated by using a so-called "harmonic scalpel" (ultrasound knife), which is not a necessity and has not been evaluated. The basic expenditure required for such equipment is approximately 175 000 SEK.

At least three studies have compared the hospital costs of laparoscopic and open surgery for colon cancer. Two of these studies found that laparoscopic surgery is less expensive than open surgery, while one reported that it is more expensive. No study has, however, compared total costs, ie, post-discharge medical care, lost productivity, etc.

Hence, it is likely that the surgical costs are higher. However, analyses addressing the extent to which these costs are offset by shortened lengths of stay or a decrease in lost productivity, are not available in Sweden or abroad, and require further study.

Structure and organization of health services

Surgery for colon cancer is available at all the surgical departments in Sweden that offer more than day-surgery. We know little of the future scope and indications for the laparoscopic method. As more reliable evidence is being gathered concerning the method's efficacy and the surgeon's learning curve, the use of laparoscopy should be limited to a few units and applied only within the scope of randomized controlled assessments. If the method enters routine medical practice in the future, it is likely to be available in all regional and county departments, and perhaps in some county district hospitals.

Ethical aspects

In curative surgery for malignant disease, any potentially positive short-term effects and economic savings are secondary objectives. The essential question is whether or not the method impacts positively on cancer-related survival, relapse rates, and total survival. Before laparoscopic methods can enter routine clinical practice, they must be equally as good as open surgery in terms of curing disease and other advantages, ie, patient benefit or lower costs.

The method is highly controversial. Critics suggest that the method encourages abandoning established principles concerning how cancer surgery should be performed. However, the most frequently voiced criticism concerns port site metastases.

Diffusion in Sweden

The exact number of departments in Sweden that have used, or are using, this method of cancer surgery, and the number of procedures performed, is uncertain. Approximately ten departments are included in a prospective randomized study (COLOR, see below) and by May 1998, had performed over 40 laparoscopic operations within the scope of the study. An estimated 100 to 200 operations have been performed in Sweden.

Current evaluation research

A prospective study (COLOR) is in progress in Europe, mainly in the Netherlands and Sweden, which intends to randomize 1 500 patients between open and laparoscopic surgery. Over one hundred patients had been recruited by early June, 1998. The most important outcome indicator of the study is 3 years of cancer-free survival. At the earliest, results from the study are estimated to be available in 2001. In Sweden, studies addressing quality of life and total costs will be performed within the framework of the investigation. A similar study – the Intergroup 0146 Trial – of 1 200 patients has started in the United States and has recruited more than 400 patients to date. A study (CLASSIC) in Great Britain has recruited approximately 300 patients.

Experts

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