Current status of the debate on laparoscopic hernia repair

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There is continued debate as to the role of laparoscopy in recurrent, bilateral inguinal and incisional hernias. Further clinical trials are needed in all of these areas. For patients with a primary inguinal hernia laparoscopic repair can no longer be recommended as the repair of choice unless it is undertaken in an expert centre in minimal access surgery.

Introduction

Although laparoscopic repair of a groin hernia was first performed by Ralph Ger in 1982, it was not until 1990 that its role in hernia surgery began to be explored by the general surgeon. This coincided with two events: the introduction of laparoscopic cholecystectomy some years previously and the acceptance by surgeons of the use of mesh for primary inguinal hernia repair. Unlike laparoscopic cholecystectomy, however, laparoscopic hernia repair was quickly submitted to rigorous assessment by controlled clinical trials. Many of these trials were small (<100 patients) and, while they yielded valuable data on postoperative pain and return to normal activity, they provided little information on outcomes such as recurrence and chronic pain. The results of four large randomized trials have been published, and the results of one ongoing trial are likely to be published in the next year or two. As part of this debate we would first like to review the results of these trials as they probably reflect the outcome of laparoscopic hernia repair in the hands of the general surgeon. We will also look at the results of laparoscopic hernia repair reported by experts publishing large prospective series.

Randomized controlled trials (Table 1)

Liem and colleagues

The trial performed by Liem et al. was the first large randomized trial to be published comparing open and laparoscopic surgery for inguinal...
hernia repair. This study confirmed that patients undergoing laparoscopic surgery had less pain and a more rapid recovery than their counterparts undergoing open surgery. At a median follow-up of 607 days, 6% of patients in the open group had a recurrence of their hernia compared with 3% in the laparoscopic group \((P = 0.05)\). In addition, 14% of patients in the open group had chronic pain compared with 2% in the laparoscopic group.

One of the major criticisms of this study was that it compared laparoscopic mesh repair with open non-mesh techniques. The open techniques were generally performed by surgical trainees while the laparoscopic procedures were undertaken by consultants. The open operations included herniotomy alone, herniotomy with narrowing of the internal ring, Bassini repair, Shouldice repair and Bassini–McVay repair. All patients in the laparoscopic group had a totally extraperitoneal repair.

**Medical Research Council**

The MRC trial\(^3\) compared laparoscopic hernia repair with predominately open mesh repair, and therefore was a more accurate reflection of what was then, as it is now, regarded as standard clinical practice. It confirmed the findings of Liem et al.\(^2\) regarding acute pain and return to normal activity; however, unlike the Liem study, there were no recurrences in the open group at 1 year follow-up while 1.9% of patients in the laparoscopic group had a recurrence. This difference was significant [95% confidence interval (CI) for difference, 0.5–3.4%; \(P = 0.017\)]. In addition, this study also confirmed that patients in the laparoscopic group had less chronic pain at 1 year follow-up.

As with the Liem trial, most open operations were performed by surgical trainees, albeit they were all supervised by consultants, and most laparoscopic operations were performed by consultants. There were three major complications in the laparoscopic group, including one bladder perforation and a trocar injury to the left common iliac artery. This reflects the inherent danger associated with obtaining access during laparoscopic procedures, which of course is common to all operations where this technique is used. The study was initially based on a sample size of 2000, but this was reduced to 1000 during the course of the trial. This change reflected that fact that open repair had rapidly changed from open suture

<table>
<thead>
<tr>
<th></th>
<th>Liem Open (507)</th>
<th>Lap. (487)</th>
<th>MRC Open (460)</th>
<th>Lap. (468)</th>
<th>Neumayer Open (994)</th>
<th>Lap. (989)</th>
<th>SMIL 1 Open (524)</th>
<th>Lap. (518)</th>
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<tr>
<td>Return to normal activities (days)</td>
<td>10</td>
<td>6</td>
<td>14</td>
<td>10</td>
<td>5</td>
<td>4</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Recurrence (%)</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>1.9</td>
<td>4.9</td>
<td>10.1</td>
<td>0.6</td>
<td>1.2</td>
</tr>
<tr>
<td>Chronic pain (%)</td>
<td>14</td>
<td>2</td>
<td>36.7</td>
<td>28.7</td>
<td>14.3</td>
<td>9.8</td>
<td>3.2</td>
<td>10.4</td>
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Lap., laparoscopy.
to open mesh repair, with anticipated lower recurrence rates, in the time between applying for the grant and commencing the trial.

**Swedish Multicentre Trial of Inguinal Hernia Repair by Laparoscopy**

In many European countries, including Sweden, the Shouldice repair was the open repair of choice for inguinal hernia. Therefore the Swedish Multicentre Trial of Inguinal Hernia Repair by Laparoscopy (SMIL) compared laparoscopic [transabdominal preperitoneal (TAPP)] repair with Shouldice repair. Patients had less pain and returned to normal activity more rapidly in the laparoscopic group. Chronic pain was more frequent in the open group, and recurrences were similar at short-term follow-up.

This trial was different from the previous trials in that the laparoscopic operations were performed by 12 surgeons with an interest in laparoscopy while the open operations were performed by 13 Shouldice experts. To confirm that proper technique was used in both operations, surgeons were assessed by an independent observer during the trial. Laparoscopic operations were also videotaped and reviewed.

**Neumayer and colleagues**

The trial performed by Neumayer et al. was the largest of the major trials, randomizing almost 2000 patients. The trial compared open mesh with laparoscopic mesh repair of an inguinal hernia. At a median follow-up of 2 years 10.1% of patients in the laparoscopic group had recurred compared with 4.9% in the open group [odds ratio (OR), 2.2; 95% CI, 1.5–3.2]. Follow-up was complete in 85.5% of patients. Recurrence in the laparoscopic group was related to the experience of the surgeon (250 procedures), in contrast with the open group where there was no correlation between recurrence and experience. As with the MRC trial, life-threatening complications occurred more frequently in the laparoscopic than in the open group. There were two deaths in the laparoscopic group: one resulted from an intestinal injury and the other occurred as the result of a pulmonary embolism on postoperative day 3.

Participating surgeons in this trial had to perform at least 25 open and 25 laparoscopic repairs in order to enter patients into the trial. The presence of an attending surgeon at the operating table throughout the procedure was required for both operations.

**Long-term follow-up of randomized controlled trials (Table 2)**

Additional longer-term follow-up on the patients has been published. Liem et al. performed a clinical follow-up on 83% of their trial patients at 4 years and reported a recurrence rate of 4.9% in the laparoscopic
group and 10% in the open group \((P = 0.006)\). Chronic pain continued to be significantly reduced in the laparoscopic group \((OR, 0.33; 95\% CI, 0.20–0.53; P < 0.00005)\). A cohort of patients in the MRC trial were followed up by an independent observer annually for 5 years.\(^7\) Recurrences remained low (2%) in both the laparoscopic and open arms of the trial with no difference in severe chronic pain between the groups. All patients in this trial received a questionnaire regarding chronic pain at 2, 3 and 5 years.\(^8\) Although there were slight differences in favour of the laparoscopic group, this was observed only for those with mild or very mild pain. The SMIL study had the most comprehensive long-term follow-up; a total of 920 (88%) patients were examined at a median follow-up of 61 months.\(^9\) The cumulative recurrence rate at 5 years was 6.6% in the TAPP group and 6.7% in the Shouldice group. Forty of these patients were operated on or had positive herniography, and interestingly significant differences in the pattern of recurrence between TAPP and Shouldice repair were demonstrated. In the TAPP group there were nine indirect and 10 direct recurrences, while in the Shouldice group there was only only one indirect recurrence and 20 direct recurrences.

Finally in a study by Douek \textit{et al}\(^{10}\) comparing TAPP with open mesh repair recurrences of 2% and 3%, respectively, were observed at 5 year follow-up. However, 10% of patients in the open operation had groin pain compared with 2% in the laparoscopic group.

### Meta-analyses

A number of meta-analyses and systematic reviews have been performed on the randomized comparisons of laparoscopic with open surgery\(^{11–14}\). The largest and most detailed of these was sponsored by the EU Biomed Programme and included 45 relative comparisons in 41 eligible trials involving over 7000 patients.\(^{11}\) Individual patient data were available for 4165 patients. Meta-analysis was performed using individual patient data where possible. The laparoscopic repair was associated with a reduced recurrence rate when compared with open non-mesh repair, but

<table>
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<tr>
<th></th>
<th>Wright Open (151)</th>
<th>Lap. (149)</th>
<th>Douek Open (120)</th>
<th>Lap. (122)</th>
<th>SMIL 1 Open (524)</th>
<th>Lap. (518)</th>
</tr>
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<tbody>
<tr>
<td>Recurrence</td>
<td>3 (2%)</td>
<td>3 (2%)</td>
<td>3 (3%)</td>
<td>2 (2%)</td>
<td>6.7%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>3 (2%)</td>
<td>2 (1.3%)</td>
<td>12 (10%)</td>
<td>2 (2%)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Para-umbilical hernia</td>
<td>2 (1.5%)</td>
<td>1 (0.7%)</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Wound sinus, infected mesh</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>–</td>
<td>–</td>
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Lap., laparoscopy.
was not different to open mesh methods (OR, 1.26; 95% CI, 0.76–2.088; \(P = 0.4\)). There were six visceral injuries in the laparoscopic group: four bladder injuries, one bowel injury and one gastric perforation. There were three vascular injuries: one to the left common iliac artery and the other two were not specified. Patients in the laparoscopic group had a lower incidence of persistent pain. This effect was present for comparisons with both open non-mesh and open mesh repair, but should be interpreted with caution as the definition of pain varied from study to study and therefore prevalence rates varied widely between trials.\(^{14}\)

**Economics**

A detailed cost analysis of open versus laparoscopic groin hernia repair was performed as part of the MRC trial.\(^{15}\) The results from this study showed that laparoscopic hernia repair would cost an extra £323.85 per patient. These extra costs were mainly due to additional theatre time, additional equipment required and sterilization costs. The estimated incremental cost per quality-adjusted life-year (QALY) of the laparoscopic over the open method was £55,548 (95% CI, £47,216–£63,885). If disposable equipment was used, the difference in costs decreased to £143.49. In this scenario the cost per QALY of moving from open to laparoscopic surgery would be £24,612. Laparoscopic operations took on average 15 min longer than open surgery, and a sensitivity analysis was performed to calculate the reduction in operating time costs that would have to be achieved for the laparoscopic procedures to break even with the cost of an open repair. The authors found that an operating time of 34 min was the threshold at which the cost of a laparoscopic repair would be equivalent to that of an open repair. It is interesting to note that a randomized trial carried out by Wellwood \textit{et al.}\(^{16}\) comparing TAPP with local anaesthetic open mesh repair demonstrated a cost difference between laparoscopic and open repair of £334.60 per patient, almost identical with the figure obtained in the MRC trial.

In a detailed study of 51 randomized controlled trials and >1.5 million hernia repairs, Stylopoulos \textit{et al.}\(^{17}\) concluded that a laparoscopic approach could be a cost-effective treatment option for inguinal hernia repair. Clinical outcome and quality of life expected from treatment options was assessed using a Markov–Monte Carlo decision model. Four treatment strategies were modelled: laparoscopic repair, open mesh repair, open non-mesh repair and expectant management. The projected lifetime costs of laparoscopic repair were 5% less than those of open mesh repair and 35% less than those of open non-mesh repair. These results are likely to be significantly affected by the recent Veterans’ Administration trial and are disputed by UK economists.\(^{18}\)
Results from expert centres

There is no doubt that results from expert centres for hernia repair are significantly better than those achieved in the community. This seems to apply irrespective of the technique used. Recurrent rates have been consistently reported as <1% with few instances of chronic pain. These differences can in part by explained by self-selection of patients and lack of rigorous follow-up. Nevertheless it is clear that both short- and long-term outcomes are affected by the experience of the surgeon. This is well illustrated in a prospective series of over 8000 transperitoneal hernioplasties reported by Bittner et al.\textsuperscript{19} Median operating time dropped from 50 min in the first 600 cases to 42 min thereafter, morbidity decreased from 9.3% to 2.6% and the rate of recurrence decreased from 4.8% to 0.4%. Similar results are reported for the totally extraperitoneal (TEP) approach. Tamme \textit{et al.}\textsuperscript{20} reported a recurrence rate of 1.8% in over 5000 repairs in the first 2 years of the study, which fell to 0.3% in subsequent years. It is interesting to note that, despite the excellent results from laparoscopic experts, visceral injury continues to be reported. In the series reported by Bittner \textit{et al.}\textsuperscript{19} there were eight bladder and nine bowel injuries among the 6479 patients undergoing TAPP repair. In the study by Tamme \textit{et al.}\textsuperscript{20} eight bladder injuries were observed in 3868 patients undergoing TEP. Neither series encountered a major vascular injury and only one patient died, with the death occurring as a result of a pulmonary embolus.

One of the difficulties in assessing visceral injury following laparoscopic hernia repair is the relative lack of good comparative data from large numbers of open hernia repairs. In the Scottish Audit of Groin Hernia Repair only one visceral injury was encountered in over 5000 patients undergoing open hernia repair while three were reported in the 229 patients having laparoscopic repair (relative risk, 33; 95% CI, 6–197; \(P < 0.001\)).\textsuperscript{21} Obviously, this rate appears excessive and may reflect the learning curve of some surgeons just starting the procedure. Nevertheless, large audits assessing the rate of injury due to access at laparoscopy confirm that visceral injury occurs in about one in 500 cases.\textsuperscript{22}

Population-based studies

These studies indicate that laparoscopic hernia surgery has only been embraced by a small percentage of surgeons. In the UK around 4% of all inguinal hernias are repaired using this method.\textsuperscript{21,23} Similar rates have been observed in Denmark.\textsuperscript{24} However, in certain European countries such as Germany up to 30% of all hernias are repaired laparoscopically. A number of countries have issued guidelines on surgery for inguinal hernias. In January 2001, the National Institute for Clinical Excellence...
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(NICE) issued guidance that stated: ‘For repair of primary inguinal hernias open mesh should be the preferred surgical procedure’.25 Interestingly, such guidelines appear to have little impact; after issue of the NICE guidance the rate of laparoscopic repair for primary inguinal hernias increased slightly by 0.14% per year.23 However, it is not known whether this increase reflected a trend towards laparoscopic repair for primary bilateral inguinal hernias broadly supported by NICE or was due to an increase in repair of both unilateral and bilateral hernias. In addition, there are no details of what happened with laparoscopic repair of recurrent hernias during the same time period.

Drawbacks of laparoscopic hernia repair

There are drawbacks to laparoscopic hernia repair, the most serious of which is the long learning curve. This is compounded by the fact that the average surgeon only repairs around 50 inguinal hernias per year. If, as Neumayer et al.5 suggest, the learning curve is >250 repairs, few surgeons would be encouraged by the fact that it could take them 5 years to become competent at this operation. Another factor to be considered is that, while many inguinal hernias in the UK will be treated in a dedicated day-case list, >50% will still be repaired on general surgery in-patient lists.23 Such lists do not lend themselves to a longer operating time for what is generally regarded as a simple, straightforward and rapid operation.

A further serious drawback of laparoscopic hernia repair is the rare but serious occurrence of vascular and visceral injury. As already stated, these complications are inherent in obtaining access during laparoscopy; visceral injury occurs in about one in 500 operations and major visceral injury occurs in one in 1000 operations.22 Although such injuries should be less frequent with TEP, they can occur with both TEP and TAPP and are undoubtedly related to the experience of the operator.

If these problems did not exist for laparoscopic hernia repair, then one could undoubtedly trade off the other disadvantages of increased hospital costs and general anaesthesia against less acute and chronic pain and a more rapid return to normal activity (Table 3). The cost differences can be reduced by using reusable rather than disposable equipment, and with increasing experience operating time should become as least as fast as that for open repair.

Advantages of laparoscopic hernia repair

One of the major advantages of laparoscopic hernia repair is that it offers a minimal access approach to pre-peritoneal hernia repair. This makes it the experienced laparoscopic surgeon’s operation of choice for
repair of recurrent groin hernias. It also has advantages for repair of bilateral hernia in patients who are anxious to return to work and normal activities rapidly. Although there is no level one evidence to support this, as the number of patients in the various randomized trials with recurrent or bilateral hernias is too small to show significant advantages, it makes intuitive sense. Laparoscopic preperitoneal repair provides much better views of what one is doing than open repair, and avoids a large incision and a large mesh to cover that incision in order to prevent incisional hernia.

In a recent analysis of the cost effectiveness of laparoscopic surgery for bilateral hernias the Health Services Research and Health Economics Research Unit of the University of Aberdeen concluded that it was likely that laparoscopic repair was more cost effective than open mesh repair for the management of symptomatic bilateral hernias. This was because differences in operating time are reduced and differences in convalescence are more marked in favour of the laparoscopic approach. However, the authors also concluded that further randomized trials were required in the area of bilateral and recurrent hernias to confirm or refute their findings.

The only prospective study that has specifically looked at laparoscopic bilateral inguinal hernia repair reported the following results. In a series of 168 patients median operating time was 75 min (range 32–165 min) and hospital stay was 1 day. Complications were low and only 2.7% of hernias had recurred at 3 years. Excellent results can also be achieved by simultaneous local anaesthetic open mesh repair, and the authors of the above study are currently conducting a multicentre randomized controlled trial comparing laparoscopic with open mesh procedures for simultaneous repair of bilateral inguinal hernias.

**Conclusions**

There is good evidence that laparoscopic repair of a groin hernia is associated with excellent results when performed by experts from specialist...
centres. There is also good evidence that these results cannot be reproduced in the surgical community as a whole and that results are inferior to open mesh repair for a primary inguinal hernia under local or general anaesthesia. The debate continues for bilateral and recurrent hernias but, while the outcome of ongoing trials is awaited with interest, laparoscopy is likely to be indicated only in the hands of surgeons with appropriate training in minimal access surgery.

Incisional and other ventral hernias

Introduction

Repair of an incisional hernia by laparoscopy was first reported in 1993. Unlike the situation in groin hernia repair, there have been no large randomized trials comparing it with open repair. Comparisons are complicated by the fact that there is no accepted standard approach to open repair. Surgeons still employ a variety of sutured repairs, and among those who use mesh there is no consensus as to whether it should be in the onlay, inlay or sublay position. While onlay with a wide (5 cm) overlap of the defect would seem the easiest approach, the most appropriate mesh to use in this situation is still under investigation. The same applies to laparoscopic repair, where expensive composite meshes that allow fibrous ingrowth on the abdominal wall side and prevent adhesions on the peritoneal cavity side have gained popularity. This is happening against a background where there is no scientific evidence to support the use of such materials and the long-term effects of some of the products are largely unknown. As part of the debate on laparoscopic incisional hernia we will first look at the outcome from large prospective series and then address the limited number of clinical trials or comparative studies examining laparoscopic and open repair.

Prospective series

Heniford and colleagues

Heniford et al. collected data prospectively in 85% of 850 consecutive patients undergoing laparoscopic repair of a ventral hernia. A total of 819 patients had the operation completed laparoscopically, 13.2% had a postoperative complication and hospital stay averaged 2.3 days. At a mean follow-up of 20.2 months (range 1–94 months) the hernia had recurred in 4.7% of patients. This series was compiled by four surgeons from four different centres over a 9 year period. Gore-Tex Dual Mesh was used in 97% of cases and fixed with a combination of full-thickness ePTFE stitches passed through the abdominal wall and...
5-mm spiral tacks placed 1–1.5 cm apart. No long-term fistulas were reported, although one patient presented with a bladder fistula 9 months after repair which was not thought to be related to the foreign material used.

**Franklin and colleagues**

Franklin et al.\(^{30}\) reported 11 years of experience with 394 patients. Primary and recurrent umbilical, spigelian and incisional hernias were included in this series, of which 96% were completed laparoscopically. Postoperative complications occurred in 10.1% and hospital stay was 2.9 days. At an average follow-up of 47.1 months (range 1–141 months) hernias had recurred in 2.9% of patients. In contrast with the study by Heniford et al.,\(^{29}\) polypropylene mesh was used in 75% of repairs and at the time of the report no patient had become obstructed or developed a fistula related to the mesh.

**Carbajo and colleagues**

Carbajo et al.\(^{31}\) repaired 270 incisional hernias laparoscopically over a 6 year period. Conversion to open surgery was required in one patient (0.3%), the mean hospital stay was 1.5 days and 14% of patients suffered a postoperative complication. At an average follow-up of 44 months the hernia had recurred in 4.4% of patients. The prosthetic material used in this study was Dual-mesh; however, unlike the previous reports, it was secured with a double row of spiral tacks placed 1–2 cm apart without any suture fixation.

**LeBlanc and colleagues**

LeBlanc et al.\(^{32}\) reported on laparoscopic repair of incisional hernias, although a small number of umbilical, spigelian and other abdominal hernias were included. Two consecutive series with 100 patients in each series were examined. There were seven conversions (3.5%), hospital stay was 1.25 days and 18% of patients had a postoperative complication. The average follow-up was 36 months and the hernia recurred in 13 patients (7.5%). As with the other series, no patients had developed an obstruction or fistula at the time of the report.

**Other series**

Many series of laparoscopic incisional and ventral hernia repairs with >100 patients have been published (Table 4).\(^{29–35}\) All report equally impressive results with short hospital stay and a low complication rate. However, one of the major drawbacks of this operation is unrecognized intestinal injury. This has resulted in postoperative mortality and emphasizes the need for experienced laparoscopic surgeons to undertake this procedure.\(^{29,33}\) Another drawback has been trocar site
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Clinical trials and comparative studies

Although there have been a number of comparative studies comparing laparoscopic and open surgery there has only been one significant randomized clinical trial. In this study 60 patients were randomized to open or laparoscopic mesh repair of major ventral hernias. Operating time, hospital stay and postoperative complications were significantly greater in the open group. At a mean follow-up of 27 months there were two recurrences in the open group and one reoperation for intestinal obstruction, and two meshes required removal for chronic infection. In contrast, no hernia relapses or late complications occurred in the laparoscopic group. It is not clear from the study where the mesh was positioned in the open group and how this may have influenced the poor outcome for these patients.

In general, other comparative studies have found similar results regarding postoperative complications and hospital stay but differed on the issue of operating time. This is likely to be related to the fact that the mesh was secured with a double row of spiral tacks in some of the patients in the Carbajo trial, whereas the other investigators used both sutures and tacks in all cases which adds considerably to operating time.

A more recent prospective cohort study of 136 ventral hernia repairs (65 laparoscopic and 71 open) also found that operating time was longer for laparoscopic repair; however, hospital stay was similar (1.1 versus 1.5 days) and hospital costs were 33% greater for the laparoscopic group. Although minor complications were more frequent in the open group, one patient in the laparoscopic group had an unrecognized intestinal perforation and two required mesh removal.

Comparison with laparoscopic inguinal hernia repair

There are many similarities between laparoscopic inguinal and laparoscopic incisional hernia repair. Like inguinal repair, laparoscopic incisional
hernia repair is associated with less postoperative pain and a more rapid return to normal activity. Wound complications are reduced, but infrequent serious complications, such as unrecognized intestinal perforation, are increased, as are hospital costs. Cost is largely influenced by the use of disposable equipment and expensive composite meshes. Although few studies have examined the learning curve for laparoscopic incisional hernia, it undoubtedly exists and, as with inguinal hernia, is likely to be long. This provides an even greater obstacle to the general implementation of this operation as the average surgeon is likely to operate on 10–20 ventral hernias per year, some of which will not be suitable for laparoscopic repair.

One of the major differences in any comparison between laparoscopic and open surgery for inguinal and incisional hernia is that in the latter situation the open operation is not standardized. While there is good evidence from at least two randomized trials that mesh reduces recurrence rates in ventral hernia repair, surgeons are slow to accept this and many still prefer a sutured repair. The issues of where the mesh should be placed (onlay or sublay) and what type of mesh gives the best results in terms of recurrence and chronic pain are also still under investigation.

Conclusion

There is an urgent need for large multicentre randomized clinical trials comparing laparoscopic with open repair of incisional and other suitable ventral hernias. Although standardization of the open approach is lacking, onlay mesh with a 5 cm margin along the defect is probably the simplest and easiest approach. In order to make comparisons, these trials should focus predominantly on long-term outcome measures such as recurrence, chronic pain, chronic infection, admission for obstruction and fistula development.

References