Balloon Dissection Facilitated Laparoscopic Extraperitoneal Hernioplasty

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BACKGROUND: **With the goals of minimizing perioperative morbidity and obtaining direct inguinal access without transgressing the peritoneal cavity, we developed a balloon dissection device to facilitate laparoscopic extraperitoneal hernioplasty.**

PATIENTS AND METHODS: **We have performed balloon facilitated dissection on 113 patients (105 males) on an outpatient basis. Some patients were repaired under regional anesthesia. A total of 150 hernias have been repaired: 72 indirect, 70 direct, 3 scrotal, 2 sliding, 2 spigelian, and 1 femoral.**

RESULTS: **Mean operating time was 60 minutes. All patients were ambulatory on discharge. Half reported minimal or no immediate postoperative pain. Over 80% had only minimal irritation or discomfort on the third postoperative day. Nearly 60% returned to work within 2 weeks. None required hospital readmission for an immediate complication of hernioplasty. With a mean follow-up of 6.3 months, only three recurrences are reported. Except for one persistent neuropathy which resolved after staple removal, there were no significant complications.**

CONCLUSIONS: **We conclude that balloon dissection facilitates laparoscopic extraperitoneal hernioplasty and obviates the need for general anesthesia. Our approach minimizes perioperative pain. It can be done on an outpatient basis and permits prompt return to full activity including physical work.**

More than 500,000 inguinal herniorrhaphies are performed annually in the United States.[1] Various open techniques have proven efficacious over the years.[2] Most patients who undergo them experience significant postoperative pain and a long period of disability.[2] Since the success of laparoscopic cholecystectomy, laparoscopic hernioplasty has been proposed as an alternative to open hernia repair.[3] There have been reports of diminished pain and shorter disability following laparoscopic herniorrhaphy.[4-10] Nonetheless, its status remains uncertain.[11]

The initial reports of Ger[12] and Ger et al[13,14] on inguinal hernioplasty described a transabdominal laparoscopic approach, and most subsequent authors have followed his example.[4-9,15,16] The requirement for peritoneal violation and the associated pneumoperitoneum make general anesthesia mandatory. These techniques also carry potential risks of intra-abdominal organ injury and complications associated with the pneumoperitoneum.[17-19] To obtain direct inguinal access without transgressing the peritoneal cavity and to eliminate mandatory general anesthesia, we have developed a minimally invasive technique using a balloon dissection device. We here report a nonrandomized trial to evaluate and establish the safety and efficacy of balloon facilitated endoscopic hernioplasty.

PATIENTS AND METHODS

Since 1991, 105 men and 8 women have received balloon facilitated laparoscopic extraperitoneal herniorrhaphies on an outpatient basis at two medical centers. Their ages ranged from 20 to 83 years. A total of 150 hernias have been repaired: 72 indirect, 70 direct, 3 scrotal, 2 sliding, 2 spigelian, and 1 femoral. Seventy-seven patients had unilateral hernias and 36 bilateral hernias. One patient had bilateral direct inguinal hernias and a left femoral hernia. Although most procedures were done under general anesthesia, approximately 30% were performed successfully under regional anesthesia.

Technique

A balloon dissection device (Spacemaker Balloon Dissector, General Surgical Innovations, Palo Alto, California) is inserted via a 1.5-cm periumbilical incision (**Figure 1**). It is advanced caudally, ipsilateral to the hernia within the rectus sheath, past the arcuate line to the pubic tubercle (**Figure 2A**). The nonelastomeric balloon is filled with 600 mL of normal saline to create a reliable, consistent extraperitoneal "cavity" (**Figure 2B**). During inflation the balloon unrolls sideways and exerts a perpendicular force along the sagittal axis on the rectus muscle anteriorly and on the endoabdominal fascia with peritoneum posteriorly. At the same time the balloon moves along the coronal plane, propagating a blunt tissue cleavage line between the endoabdominal fascia and peritoneum.

The balloon's intraluminal pressure during the insufflation phase typically ranges from 50 to 100 mm Hg. The final distention pressure is between 100 and 140 mm Hg. No balloon ruptured. We avoid air or CO_2 for inflation because gases are compressible and insufflation of a particular volume of gas does not guarantee a cavity of a certain size. Additionally, inadvertent balloon rupture with gas could result in a sudden egress of compressed gas with resultant vascular gas emboli.

The balloon is removed and the cannula of the dissector is advanced into the created cavity, locked in place, and connected to a CO_2 gas line. The cavity, which conforms to the previous maximum inflation size of the balloon, is inflated to a pressure of 8 to 10 mm Hg (**Figures 2C** and

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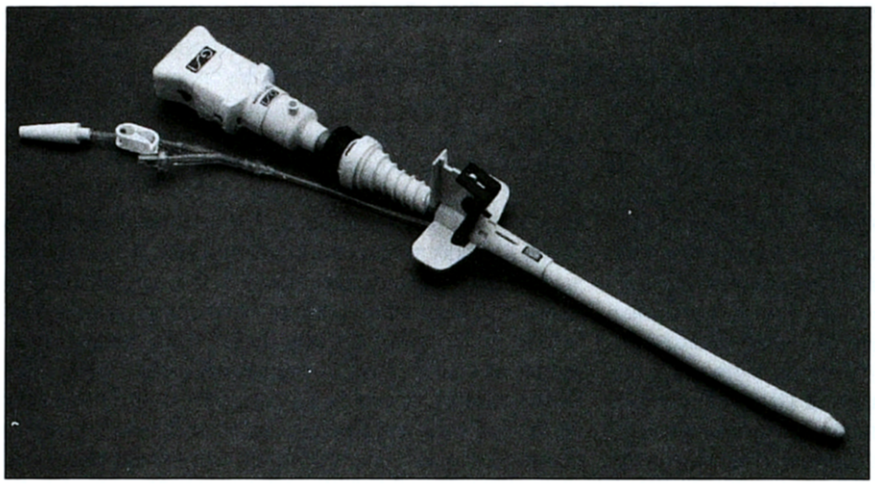

Figure 1. A balloon dissection device (Spacemaker Balloon Dissector, Genera Surgical Innovation, Palo Alto California).

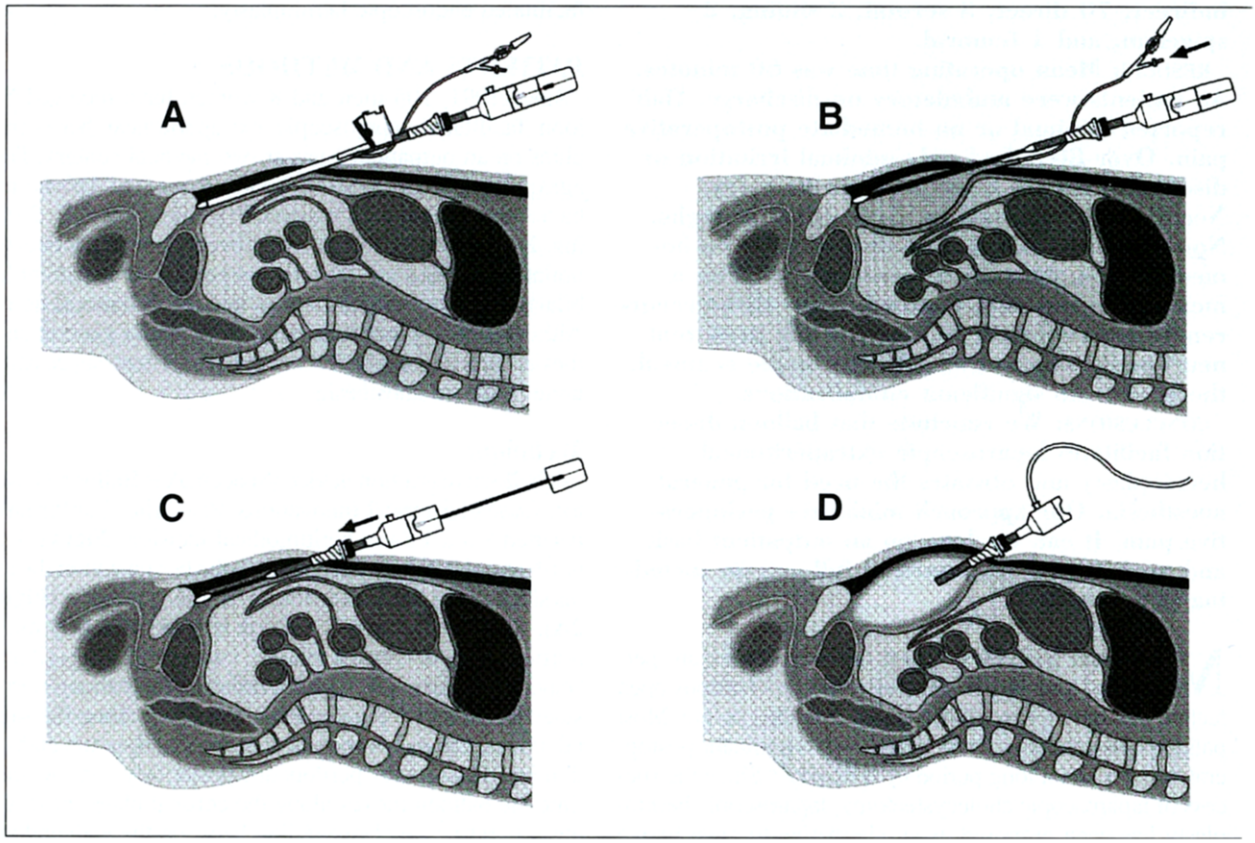

Figure 2. A. The dissector is advanced within the rectus sheath to reach the pubic tubercle. **B.** The balloon is filled with 600 mL of norm saline to create an extraperitoneal cavity. **C, D.** After removal of the balloon, the cannula is advanced into cavity and connected to CO_2. Tl cavity is inflated to a pressure of 8 to 10 mm Hg.

2D). Bleeding during this step is uncommon. Two additional working cannulas are subsequently introduced into the cavity (preperitoneal space) via two 1.5-cm incisions located in the midhypogastric and suprapubic areas (**Figure 3**). Alternative sites for inserting the working cannulas are also shown in Figure 3. Manual laparoscopic dissecting instruments are inserted via these cannulas.

Landmarks, including Cooper's ligament, the inferior epigastric and iliac vessels, spermatic cord, and internal inguinal ring are readily identified with little or no additional dissection. Attention is paid to the small crossing pubic branch of the obturator artery over the lateral po tion of the Cooper's ligament. The spermatic cord (no tr tunics) is explored near its entrance into the internal i guinal ring to search for a hernia sac. If no indirect sac found, the inguinal canal floor is explored and tested f a weakness or defect by external palpation. The presen of a femoral space defect is also pursued if indicated.

If an indirect hernia sac is identified and is small, an a tempt is made to reduce it into the abdominopelvic ca ity. If the sac is too long, the neck is controlled with e ther an instrument or a circumferential suture and t

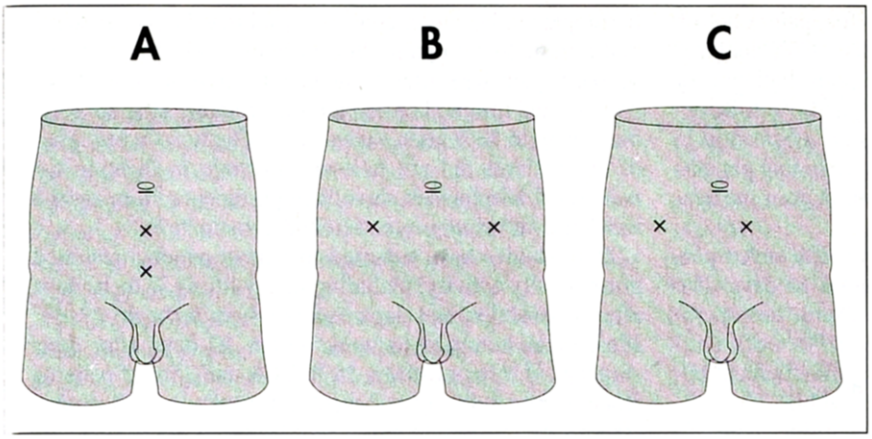

Figure 3. Location options for working cannulas (marked by "X"). **A.** Midline positioning. **B** and **C.** Alternative horizontal placement.

ontent is reduced. Subsequently, the sac is ligated and ivided leaving the distal segment in place. If indicated, similar process is used to search for a contralateral herıia via the same cavity.

To reinforce the floor defect on one side, an 8- × 10-cm iece of polypropylene mesh is inserted through the 12nm cannula into the cavity. It is spread to cover the myıpectineal orifice.[15] The mesh is stapled to Cooper's ligaıent medially and to the abdominal wall anterolaterally ı total of three or four staples). It is important not to anhor any staples over, laterally to, or posterior to the iliac essels, to avoid potential nerve entrapment or vascular inury. A second piece of mesh, if indicated, is inserted to epair the contralateral side.

The cavity is flushed with 50 mL of 0.125% Marcaine Sanofi Winthrop Pharmaceuticals, New York, New ork) solution and the CO_2 is released. Skin incisions are ıjected with 10 mL of the same anesthetic solution. The avity is deflated and instruments and cannulas are reıoved. The mesh, sandwiched in place between the periıneum and endoabdominal fascia, maintains conformaon with the region. The skin incisions are closed with -0 absorbable subcuticular stitches. On occasion the midle incision fascia is closed, depending on the level of the cuate line.

ESULTS

perating Time

Mean operating time was 60 minutes (range 30 to 130). ive to 10 minutes were used to insert the balloon dissecon device. As we gained experience, the operating time onsistently approached 30 minutes per hernia.

omplications and Postoperative Course

Of 113 patients, only 5 required conversion to open reair due to technical difficulties.

In 1 patient, a pneumoperitoneum was identified after ıe extraperitoneal cavity was inflated. The periumbilical ıcision had been made vertically with the intention to exnd it down through the anterior rectus sheath. During ıe extension, the peritoneum was violated in the midline. Ve now used a transverse incision and lateral retraction the rectus abdominis muscle for balloon dissector inrtion, and insert the balloon device at a shallow oblique ıgle to body wall.

Two patients, early in the series, incurred tears into the hernia sac during spermatic cord exploration. These holes resulted in the creation of a pneumoperitoneum, and the extraperitoneal cavity collapsed. Venting the peritoneal cavity with an angiocatheter was only marginally effective for decompression.

During one operation, the laparoscopic equipment failed. In 1 patient, a very large indirect hernia sac was found. It was our first large indirect sac, and we were unable to reduce it behind the fascial defect. Since this experience, we have ligated and divided many similar sacs and were able to repair the myopectineal orifice successfully.

All 5 patients who were converted to open repair attained good results without sequelae.

No patient sustained injury to the inferior epigastric, iliac, or testicular vessels. About one-third of our patients were noted to have a mild postoperative pneumoscrotum, which resolved within 24 hours. Surprisingly, no patient attributed any significant pain to this.

Only 2 patients failed to be discharged home the same day after recovering from anesthesia. One, who had the operation under epidural anesthesia late in the afternoon, was admitted overnight for recovery. The other was admitted overnight after his hernia repair was converted to an open repair due to pneumoperitoneum. All patients were ambulatory on the same day after the operation. No patient required readmission due to a complication of the laparoscopic technique.

Recovery and Follow-Up

All patients were reexamined at 1 week and 1 month. All were instructed to return to work without any restriction as soon as they felt able. They were also asked to notify their surgeon if any problem developed after the 1 month follow-up visit. Follow-up after 1 month was through mail or phone correspondence, unless a patient complained of a difficulty.

Postoperative pain. At 1 week follow-up, all patients were asked to report the severity of pain related to their postoperative course. In the immediate postoperative period, 52% reported minimal or no pain, 35% mild to moderate pain, and the remaining significant pain which was controlled with oral pain medication. Eighty-three percent reported minimal discomfort on the third postoperative day. Ninety-six percent reported minimal discomfort or mild irritation after 1 week. Fifty percent required only acetaminophen or

nonsteroidal anti-inflammatory agents for pain control. Thirty-nine percent took 1 to 20 tablets of Tylenol #3, Darvocet (Eli Lilly Laboratories, Indianpolis Indiana), or Vicodin (Knoll, Whippany, New Jersey), and 6% took between 21 and 30 tablets of similar narcotic medication in the immediate perioperative period. The remaining patients could not characterize the type or amount of pain medication consumed.

Return to work and normal activity. Fifty-seven percent of the patients returned to work within 14 days. The earliest return to work occurred on the fourth postoperative day. Twenty-six percent did not return to work until at least 1 month following surgery. Thirty-five percent began heavy lifting or engaged in sports within 2 weeks. Twenty-three percent returned to similar activities between 2 and 4 weeks, and 17% after 4 weeks. A few patients waited 10 weeks before engaging in strenuous activities. Twenty-five percent avoided strain permanently due to old age, physical disabilities, or being overly cautious. They were included in the above percentages.

Other postoperative complications. Three patients developed recurrent inguinal hernias approximately 3 to 6 weeks after surgery. These patients were among the first 20 patients in the series. They were subsequently found to have recurrent indirect inguinal hernias which were repaired by the open technique. Our recurrence rate is thus 3 in 150 (2%).

Two patients had small subcutaneous hematomas near their skin incisions. These resolved spontaneously. Four patients had mild to moderate transient neuropathies. One experienced a persistent neuropathy which resolved soon after the staples were removed via a second extraperitoneal approach. The polypropylene mesh in this patient was found to be firmly adherent to the abdominal wall by ingrowth of fibrous tissue. This allowed the removal of all staples without compromising the repair of the myopectineal orifice. One patient had urinary retention which required a single in-and-out bladder catheterization. No wound infection was detected.

COMMENTS

Laparoscopic herniorrhaphy boasts several theoretical advantages when contrasted to standard open techniques. Diagnostic clarity is enhanced, bilateral hernias can be treated in a nonimposing way, recurrent defects can be managed definitively, and tension-free repair reduces postoperative pain and ensures a rapid return to work. Many studies employing transabdominal laparoscopic approaches have confirmed these virtues.[4-10,15] In a recent, prospective, randomized study at a single institution, Payne et al[20] demonstrated that endoscopic hernioplasty, when contrasted with open tension-free repair, permitted patients to resume active status after a significantly shorter recuperation. A second prospective, nonrandomized trial reported similar advantages.[21] Ninety percent to 100% of reported transabdominal laparoscopic herniorrhaphies have been done on an outpatient basis.[4,6,7,9] All of our patients underwent their operations on an outpatient basis, and all were ambulatory on discharge.

Quilici et al[5] found that 96% of patients had only minimal pain or discomfort within 72 hours after endoscopic hernioplasty. Newman et al[4] reported that 51% of patients had minimal or no pain after 24 hours and 93% were essentially pain-free after 1 week. Fifty-two percent of our patients had minimal or no pain immediately after surgery, increasing to 83% after 3 days and 96% after 1 week. Half of our patients did not take any narcotic medication for pain relief. Diminished narcotic requirement minimizes the incidence of urinary retention and constipation.

Many studies have reported that most patients resumed normal daily activity, including heavy lifting, 7 to 10 days after transabdominal laparoscopic herniorrhaphy.[4,5,7,8,10] Most or all returned to work within 10 days after their surgery.[6,7,9,10] In our study, 35%, 58%, and 75% of patients resumed heavy lifting at 2 weeks, 4 weeks, and 10 weeks. One fourth did not do any heavy lifting or sporting activity after 10 weeks due to old age, physical disabilities, or excessive caution. Fifty-seven percent of our patients returned to work within 14 days. Seventeen percent are retirees. Our nearly 60% rate of return to work within 2 weeks is quite similar to Payne and coworkers'[20] prospective data. In addition, more than a third of our patients resumed heavy lifting or sporting activities within 2 weeks.

Although the proportions of our patients who achieved these recovery milestones in the designated periods are not as high as some reported in the literature, they are significant and can be improved by careful patient selection and a greater focus on reassuring and encouraging patients. Most laborers want to take the whole allowable interval of time off work following repair of a hernia. If and when third party reimbursers minimize the requisite recovery interval, the fiscal impact of laparoscopic hernioplasty will become far more attractive.

Disadvantages of transabdominal preperitoneal laparoscopic hernioplasty (TAPP) have included the necessity of general anesthesia. This requirement can be avoided with our extraperitoneal laparoscopic approach. We omitted general anesthesia in one third of our patients. We contemplate the application of intravenously supplemented local anesthesia in the near future.

The long-term impact of avoiding violation of the abdominal cavity is unknown. At least, our technique obviates the reported TAPP-related complication of bowel entrapment within the peritoneal incision.[22] Finally, the durability of endoscopic approaches, and particularly of our balloon facilitated procedure, is unknown. In contrast, the resilience of the open preperitoneal hernioplasty is well established.[15,23]

As Lichtenstein et al[16] advocated for their open technique, mesh insertion is the cornerstone of a tension-free repair and leads to a late recurrence rate of 0.25%. Stoppa[2] and Hoffman[23] used mesh for open preperitoneal repair, resulting in a lower recurrence rate than preperitoneal repair without a mesh. There has been no significant complication reported with the insertion of the mesh.[16]

Reported hernia characterizations in a number of series have included: 59% to 77% indirect, 28% to 46% direct, 1% to 2% femoral, 7% to 31% bilateral, and 6% to 16% combined.[4-9,23] In our study, there were fewer indirect (48%) and a greater incidence of direct (47%) hernias found. A similar distribution was reported by Ferzli et al.[24] His series is notable for a 26% incidence of indirect and 71% inci-

dence of direct hernias repaired using the laparoscope. This discrepancy in the ratio of indirect to direct hernias is not readily explained. It may be due to overdiagnosis of direct and/or past underdiagnosis of indirect hernias.

Our recurrence rate of 2.0% is comparable to those of both open and transabdominal laparoscopic techniques.[4-10,14,15,23,24] Admittedly, we are reporting this rate after a rather short mean follow-up of 6.3 months. Careful long-term follow-up is essential, as are prospective comparative trials to disclose true recurrence rates.

Numerous complications have been reported after laparoscopic herniorrhaphy. They include pneumoscrotum (8.3% to 59%), inguinal seroma (1.3% to 12%), urinary retention (1% to 12%), transient mild to moderate neuropathies (0% to 8.3%), incisional wound infection (0% to 5%), incisional hernia at the cannula sites (1% to 2%), and severe hemorrhage due to trocar laceration of inferior epigastric vessels (1% to 4%).[4-10,13,15,24] There have been no reports of injury to the testicular vessels or vas deferens. Hoffman et al[23] reported rates of 1.5% infection, 4% hematoma, 1% seroma, and 4% transient neuropathy after open preperitoneal prosthetic herniorrhaphy. Our incidence of the various complications is as low as those of open preperitoneal and transabdominal laparoscopic approaches.

CONCLUSIONS

Our nonrandomized study demonstrates that application of a safe and simple balloon insufflation to facilitate dissection readily permits laparoscopic extraperitoneal herniorrhaphy. The advantages include minimal postoperative morbidity and disability. There is no need to enter the peritoneal cavity, and regional anesthesia can be used. With experience, the required operating time for this technique approaches that of uncomplicated open repair. Treatment of bilateral hernia and secondary reconstruction are facilitated. The incidence of complications is low. Longer follow-up is needed to assess the recurrence rate, efficacy, and durability.

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DISCUSSION

Melvin W. Twiest, MD (Albuquerque, New Mexico): Laparoscopic herniorrhaphy remains in my view a controversial and investigational procedure. The best way of doing laparoscopic hernia repairs, if there is a best way, is unknown at this point. Similarly, the indications for the use of these techniques are debatable, and of course, long-term recurrence rates are not known. All reports of these techniques, including the present one, need to be seen as preliminary work. Currently, the only reasonably clear advantage to laparoscopic herniorrhaphy appears to be reduced postoperative pain resulting in an earlier return to normal activity. One distinct disadvantage is the need in almost all these techniques for general anesthesia at a time when more and more conventional hernia repairs are being done under local. Another disadvantage is the violation of the peritoneal cavity, which can lead to a variety of complications. It is primarily this problem that the authors' technique, extraperitoneal herniorrhaphy, is designed to obviate.

The technique is a variation on one of three methods of laparoscopic herniorrhaphy being studied, the others being transabdominal preperitoneal repairs and intraperitoneal on-

lay mesh repair. Strictly speaking, of course, the authors' technique is not a laparoscopic repair, since the peritoneal cavity is not entered. But laparoscopic instrumentation is used and thus the terminology. The technique builds on reliable methods of preperitoneal herniorrhaphy developed by Nyhus, Stoppa, and others and is, I believe, based on sound anatomic principles. As such, the concept is appealing.

The authors report a series of 113 patients with a total of 150 hernias of a variety of types, more than half of them indirect, and only a few recurrent. My first question concerns the indications for the technique. While you apparently can do the repair for all types of hernias, do you see your technique as more appropriate to the repair of certain types, say bilateral or recurrent hernias? Another way of asking that question is to ask what is the advantage of this technique over the currently used nonlaparoscopic techniques in unilateral indirect hernias in young people, for example.

Next, are you recommending this technique for general consideration and use now or do you see it as still investigational? If investigational, what do you feel will be an adequate follow-up time to prove or disprove the utility of the approach? Your mean follow-up time currently is extremely short. If the technique does prove itself, what is its learning curve? How many procedures would one have to do to become proficient? How should one approach one's education, generally, in the area of laparoscopic hernia repairs?

I suspect that some type or types of laparoscopic hernia repairs will eventually find a place in the overall approach to the problem of inguinal hernia. I think the authors' technique or something like it could have some real advantages over the other types of laparoscopic hernia repairs currently utilized. I would encourage the authors to continue their investigations.

Richard Koehler, MD (Oakland, California): It seems to me that CO_2 is a lot cheaper than medical grade plastic. I would like to ask the authors what evidence they have that their balloon technique is any easier than simply dissecting bluntly with your fingertip into the preperitoneal space via your initial infraumbilical incision, and then putting the port in and insufflating with CO_2. It doesn't seem very difficult to create an initial blunt dissection and then place a cannula in and insufflate with CO_2. With costs here already being a major consideration against laparoscopic herniorrhaphy, you are adding yet another cost. Did you consider comparing your balloon insufflation with simple blunt dissection and CO_2 insufflation?

David B. Roos, MD (Denver, Colorado): I have seen at least three articles discussing the advantages and cost of open herniorrhaphy compared to laparoscopic herniorrhaphy. They all stated that the time in hospital was the same for the two types of procedures, the time of return to work was exactly the same, but the cost was about triple for the laparoscopic herniorrhaphy. In the present atmosphere of cost restraints, contracts with industry, and health reforms coming that favor minimizing cost, I wonder if the authors feel that this technique warrants continuing development. Do they feel that the rest of us should purchase the expensive equipment and go through the learning curve to perform an operation that seems to have 5 to 8 times the recurrence rate at triple the cost of open herniorrhaphy?

Stanley R. Klein, MD: I'll try to put some light on the questions that Dr. Twiest and others have asked. All of these patients were initially on protocol. We were interested in asking the question, are there other ways to deal with problematic patients—namely, patients with bilateral hernioplasty and recurrent hernioplasty. We all know the problems. That's how it really first started out. Then it was extended because of our volume and availability. What we are trying to do is get a handle on this and look at the learning curve as we go along.

Some of the cost issues that Dr. Roos raised are encumbered in this. If we can obviate the need for general anesthesia, and if we can eliminate the expense of stapling, both procedural costs will fall. And the surgeon will gain an alternative for difficult hernioplasty.

Why use a balloon as opposed to CO_2? As everyone knows, what we would like to do is create a well defined working cavity with very little bleeding. The device does this. Since it is a nonelastic balloon, it will give rise to a very reproducible cavity in the inguinal area, as opposed to CO_2 which will dissect along the plane.

It is for these issues that we really wanted to look at this. As I said, I think the most important thing is, this should be done on an investigational protocol. I'm not advertising this for everyone to go out and learn. It takes time and it is very skill dependent. We had three "recurrences" where we really just missed the indirect inguinal sac. In reality, although we classified them as recurrences, they really are operating surgical errors. We just didn't realize what had happened very early on in our activity. We feel the technique is justified in that down the line it may provide a method to deal with otherwise difficult hernioplasty.