Experts forum

Questions for the Experts

Laparoscopic Colorectal Surgery
Where Do We Go From Here?

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Few, if any, major surgical trials have caused as much of a stir as the Clinical Outcomes in Surgical Therapy (COST) study (Nelson et al. N Engl J Med. 2004;350:2050-2059). The release of the long-awaited results in May marked the beginning of a new, minimally invasive age in colon cancer treatment. The study showed conclusively that, in experienced hands, laparoscopic colectomy offers the same oncologic outcomes as the open procedure—with shorter hospital stays and less postoperative pain.

But the publication triggered as many questions as it answered about the future of colon cancer surgery. Before the trial, the main issue was whether laparoscopic colectomy was a safe procedure; now, it is how to ensure that it stays safe.

Some surgeons worry about a repeat of the cholecystectomy debacle of the early 1990s, when mortality and morbidity rates shot up as laparoscopy was adopted. They fear wound metastases and complication rates from laparoscopic colectomy will rise if inexperienced surgeons push too far, too quickly. Surgical societies, hospitals, industry and surgeons face difficult decisions about how to educate and train physicians for the new procedure.

In clinical trials and laboratories, too, the focus has changed. With the main study over, investigators are zeroing in on questions that until now were in the background of the laparoscopic colectomy debate.

Of these, none has garnered as much attention as research suggesting laparoscopic surgery offers better oncologic results than open surgery. Some basic science and animal studies indicate that minimally invasive surgery provides greater oncologic benefits because of a shorter period of cell-mediated immunosuppression following surgery. In July 2002, Lacy and colleagues published a highly controversial single-center, randomized study, in which they concluded this effect was evident in humans. They reported that stage III cancer patients had the most dramatic benefit in oncologic outcomes when patients underwent laparoscopic, rather than open, surgery (Lancet. 2002;359:2224-2229). Other single-center studies showed similar survival benefits for laparoscopic surgery (Milsom et al. J Am Coll Surg. 1998;187:46-57; Poulin et al. Ann Surg. 1999;229:487-492; Franklin et al. Surg Endosc. 2000;14:612-616).

Trials are ongoing to establish best surgical techniques, patient selection criteria and cost-effectiveness of laparoscopic colectomy.

For this last installment of our laparoscopic colectomy series, General Surgery News interviewed a group of colorectal specialists to share their thoughts on what’s ahead for colon cancer treatment. The panel includes Heidi Nelson, MD, the lead investigator in the COST trial; Morris Franklin, MD, and John Marks, MD, world-renowned laparoscopic specialists and instructors; Richard Whelan, MD, a COST trial participant who is spearheading one of the largest research projects in the immunologic consequences of minimally invasive surgery; Eric Haas, MD, a private-practice surgeon who completed a colorectal fellowship last year; and Richard P. Billingham, MD, a well-known advocate for the open approach to colon cancer surgery.
Expert forum

GSN: What was your reaction to results of the COST trial?

Dr. Nelson: I was excited for the patients that we serve to get a good surgical outcome.

Richard P. Billingham, MD: The study shows there’s no apparent disadvantage to doing oncologic colon cancer surgery. However, there was no protocol for postoperative care, so the reason for the shorter length of stay may be simply that surgeons were treating laparoscopic cases differently from open cases.

John Marks, MD: I think this is a monumental paper in that it has completely shifted the dialogue in the surgical treatment of colon cancer. It puts an end to a lot of the discussion around laparoscopic treatment of colon cancer. It puts an end to a whole lot of issues that, in my mind—and to those experienced in laparoscopic surgery—were quite clear for some time, but now we have scientific data to back up our opinions.

The surgical leadership to this point hasn’t exhibited the proper amount of foresight to prepare people for this day.

— John Marks, MD

Richard Whelan, MD: My first reaction is it’s great we now have a multicenter trial with long-term results. But we were one of the few anticipating a benefit for laparoscopic surgery. We’re awaiting the results of other randomized trials, because we still hold out the belief that oncologic methods may be associated with improved results over the open. There is evidence to suggest that, although it has not been proven in a randomized setting in a multicenter trial.

Morris Franklin, MD: The results were exactly as I thought they were going to be. We knew from the first report, before the trial was closed, that it was probably going to show equality. Those of us who do a lot of laparoscopic surgery were a little disappointed that laparoscopic surgery wasn’t better. But, given the 25% conversion rate, that’s to be expected.

Eric Haas, MD: I was thrilled, not at all surprised. It felt like a weight had been lifted in that I could now offer my patients a better option.

GSN: How do you feel this study will affect the treatment of colon cancer?

Dr. Marks: This is probably one of the most important studies to come out in the last decade and, looking forward in the next five to 10 years, it’s going to dramatically impact the surgical approach to colon cancer.

Dr. Nelson: Over time, it will change the practice of surgery for colon cancer to the laparoscopic approach. Now that we’ve shown that laparoscopic surgery is OK in cancer patients, the next step is for enough surgeons to be able to do it so that the majority of patients can have it done laparoscopically. We’re moving to more and more advanced laparoscopic surgery. In some cases, you can do the entire operation through small holes and remove the specimen through the anus and do a total laparoscopic surgery.

Dr. Haas: I expect that once the learning curve has been met, there will be important implications for treatment. With patients recovering sooner and returning to their activities more expeditiously, perhaps they can begin adjuvant chemotherapy earlier. I’ve noticed that in my practice, some patients are getting enrolled in adjuvant chemotherapy programs sooner than they probably would have with traditional surgery.

Dr. Franklin: Immediately, I don’t expect a great deal of impact, but ultimately, quite a bit. The question now becomes: Is the surgeon capable of doing it laparoscopically? And what does the patient want to do? As patients become more educated, they are going to demand it more and more.

Dr. Whelan: I agree. This will have huge impact because a lot of surgeons were waiting for evidence like this, so they could start doing it more commonly. Young doctors and people on the sidelines have been waiting for this papervivus at the end. Also, it’s received a fair amount of attention in the press. This procedure may become patient-driven. With more and more patients aware of this option, this paper is going to make a big impact on what happens in the United States and worldwide.

Dr. Billingham: I think it will encourage more people to try laparoscopic colectomy for cancer. Some of these people will not have had the training or the experience to do this well, so there will be a potentially detrimental effect in the short term.

GSN: How will news of the COST trial affect referring physicians and the public? What would your message be to each of these groups?

Dr. Haas: Eventually, there will be a push to find surgeons who can offer this technique. Both patients and referring doctors will be asking for this procedure. However, I have yet to see a direct impact, and the COST trial has not been very widely referred to. I’m the one doing the educating by giving patients the option. The news is then getting back to the referring physicians, and thereafter is spreading. My message is that the trial was a well-designed study with experienced surgeons. Along those lines, it is very important that if you are going to investigate laparoscopic surgery, investigate the experience of your surgeon.

Dr. Franklin: I have found that other than surgeons, and specifically surgeons trained in laparoscopy, very few referring physicians even know about the trial. My advice to physicians would be to find a surgeon who does a good job open, find a surgeon who does a good job laparoscopically and give the patients their options. If you give the patients all of the information in a non-prejudicial manner, they will generally make the right decision.

Dr. Nelson: Gradually, referring doctors are going to want laparoscopic surgeons and they are going to have to develop a network of capable, trained surgeons who can offer the laparoscopic approach. It’s not going to be an overnight transition from open to laparoscopic. It’s going to happen by word of mouth and by media, as people become aware of the fact they can get out of the hospital faster and have less pain. When you actually experience this with patients in terms of watching them through the surgery, you see more difference in individuals than you see in the numbers cumulatively—it’s hard to overlook that. But the key message that everybody is trying to impress is that when you make sure the patients are going to surgeons who are familiar and skilled with this approach, if a surgeon’s not comfortable with it, they should not be doing it.

Dr. Billingham: Everyone wants to believe that laparoscopic colon surgery is better and they will not go to the data, but simply go to this one paper and say, look, the New England Journal says this is great and we’re going to start doing it; without considering the detrimental things about it. I don’t think you should base anything on a single paper, even though it comes from multiple institutions. There are other studies coming out and I would personally wait for those.

Dr. Whelan: For referring physicians, it’s going to affect their referral pattern. Provided the surgeon they are referring to has experience, they are going to send more patients there because the short-term recovery is better. Again, patients are becoming much better educated about this and will push for laparoscopic surgery. We see them come in all the time with questions about the laparoscopic operation, or they are shopping around for a surgeon who does laparoscopic surgery.

Dr. Marks: It’s going to have a tremendous effect on people as they realize that this is a safe operation in experienced hands. It’s going to change the world of laparoscopic colon surgery, and the message coming out stresses the need for high-quality, high-volume surgeons to be performing the laparoscopy.

GSN: What are the challenges facing the surgical community in training surgeons in this procedure?

Dr. Nelson: To a certain extent, it’s a challenge to retain some of the surgeons who are out there. But, because the study has been going on for 10 years, in the meantime there have been many residents and fellows trained in laparoscopic surgery. The technology has advanced, and our general abilities in laparoscopy have advanced. Groups of surgeons who are coming out now are trained in much more complex surgery. It’s not as big a gap as close to some body who has never done laparoscopic surgery trying to do the most complex. Some training has occurred, residency programs have grown, young surgeons have been taking it up in a systematic way, so I don’t think the gap is huge. I think surgeons who are retiring won’t take it up, and surgeons who aren’t close to retiring may feel compelled to pick it up and decide for themselves if it’s worth it.

Dr. Haas: The challenges are twofold: educating surgeons who may not have trained in the laparoscopic era and educating laparoscopic surgeons in how to apply oncologic principles to colon surgery. The fear that I have is that there will be training in which surgeons not trained in oncologic techniques are performing oncologic procedures laparoscopically and the long-term results will not be as favorable as the COST trial.

The criteria have to be set up by the people who have done the surgery, not people who want to control the surgery but who haven’t done it.

— Morris Franklin, MD

Dr. Billingham: Most people feel that, in order to do laparoscopic surgery for cancer, a surgeon should have experience with 30 to 50 cases for benign disease. Most general surgeons do 11 colectomies a year, so it will take at least three to five years to get the average general surgeon trained if all of those are benign cases. Typically, an average general surgeon will see more malignancies than benign cases, so it will take longer than five years for each surgeon to have adequate training. It’s going to be concentrated on the very high-volume surgeons.
I would love to believe in this, I would love to have this be better, but it ain't, and we can't make it be that way by wishing it so.

— Richard P. Billingham, MD

Dr. Whelan: This operation takes a long time to figure out how to do. Exactly how long, I don't know—I've been doing this for about 12 years. You improve as the number of cases you've done increases. We've got to find a way to make sure surgeons are not embarking on this if they don't have the experience. We also need to provide an educational avenue for young surgeons. One way you can do that is fellowships that provide good training in laparoscopy. For surgeons to really cut their teeth, they need to do animal cases, take courses, and do apprenticeships or be preceptored. And then they begin in their own hospital, doing the benign cases first and then moving on to polyps and then to cancers. Those of us who are experienced need to make ourselves available, which is what we're doing. The others have to be responsible—if you're really not ready for one of these things, hold off until you become more experienced with benign cases.

Dr. Franklin: I think the main challenge is the lack of an adequate number of people who can do it well and can then turn around and teach it, or surgeons who can do it well who are willing to teach it. We need some method of compensating surgeons who are taking time out of their practices and who are not university-based—the vast majority of surgeons who do this aren't university-based. It takes time to proctor surgeons. As an example, I can do a colon resection of the right colon in 50 minutes if I'm teaching someone, it may take three hours. But do we want surgeons who don't know how to do it or do we want surgeons who are well-trained? On-the-job training is not acceptable. Surgeons who don't know how to do it will find it hard because they haven't been trained properly, end up condemning the procedure.

GSN: How would you approach credentialing?

Dr. Nelson: That's a difficult question. There are a number of societies—ASCRS [American Society of Colon and Rectal Surgeons] is one of them—that have made clear statements about credentialing. A surgeon should have experience with 20 benign cases before they do any laparoscopic cancer cases, should be familiar with cancer surgery and the details of how to do laparoscopic surgery properly this way. Ideally, they should be credentialled by some body, but there is no body to turn to yet. That makes it a difficult thing for people who aren't associated with colleagues or an institution where others have been credentialled already.

Dr. Marks: Credentialing and education have to be done hand-in-hand. Surgeons who don't have advanced laparoscopic skills are going to have to attend didactic courses and hands-on training. But that, in and of itself, is clearly not going to be sufficient for surgeons to be ready to perform these operations, especially for cancer. They are going to need to be involved with mini- or maxi-fellowship, visit operating rooms where surgeons are doing this. The number that's been thrown out has been 20 cases, but it's going to vary depending on what the basic skill set of the surgeon is when they start performing laparoscopic operations.

Dr. Billingham: Currently the way this is done in most places is, if you do 10 laparoscopic colectomies under supervision, or if you had a specific training pro-

gram that incorporates at least this much training, then you can go ahead and do it anytime you want to, whether it's for cancer or not. There's no effort on the part of hospitals to say you can do this for one diagnosis but not for another diagnosis.

Dr. Whelan: Credentialing has to be done on a hospital-by-hospital basis. Someone knows exactly how many you need to do. The COST trial was based on the assumption that you needed to do 20, but I think we probably underestimated that. I say it's at least 30 to 50, for an initial set of training cases. It's hard to say if surgeons should do a set number of cases, or if we should have a panel of surgeons who view a tape that a surgeon submits. I don't think that we have the answer to that, but it is a very important issue.

Dr. Franklin: It has to be a local thing. The criteria have to be set up by the people who have done the surgery, not people who want to control the surgery but who haven't done it. It's ridiculous for those people to set up the criteria for this. The credentialing criteria should be set up by people who have been doing it for a while, through the ins and outs and what it takes to get people trained.

Dr. Haas: It's important that every hospital set up a committee. I believe that at a minimum, the criteria should be based on the selection criteria used for surgeons in the COST trial.

GSN: What changes need to be made in training for surgeons?

Dr. Franklin: Surgeons have to become proficient in laparoscopy early on, preferably in medical school. They need to learn the anatomy as viewed through the laparoscope. We need to find teachers who can teach people how to do this properly. Currently with gallbladder surgery, about half the time, surgeons are not taught the proper technique. We need to give surgeons the tools, so they can move on and do advanced laparoscopic procedures by bringing in people who can do the surgery, by establishing laboratories and setting up programs where people can gain the skills they need.

Dr. Whelan: Yes, there needs to be faculty that can teach this, and the residents need to be exposed to it. But I'm of the opinion that it takes an extra year of training or a fellowship in order to get the number of cases needed to do this. Our fellow finished up yesterday, and he did 120 of these in a year. That's very good training. We need to make sure that's available.

Dr. Haas: Some residency programs offer a vast experience, but most have limited exposure to laparoscopic colon surgery. The problem that may arise is when a surgeon completes their training and is in the community, they feel pressure to do these procedures laparoscopically and may not have sound training. After residency and a fellowship, I felt that I had a baseline to begin at the bottom of the learning curve. I attended several lap colectomy courses, mainly sponsored by the industry, to become more comfortable with the techniques. I also feel that the learning curve—which many people talk of as being 20 to 30 cases—is a sharper curve if you use the hands-on approach. I'm not certain. In my experience, there's still a learning curve beyond 20 or 30 cases.

Dr. Nelson: Thirty a year is a difficult number. Again, it's a personal decision. Most who do 30 colon resections, and are not going to retire right away, will probably want to learn how to do this, particularly if they do other laparoscopic surgery.

Dr. Marks: I think the short answer is yes. It's going to have to be a part of a surgeon's armamentarium. It's a matter of building their practice and protecting their practice by providing the highest level of care for the patients in their area, and they'll be recognized as such. Another alternative, if they want to keep those cases in their practice, is to look at hiring someone who already has those skill sets. They will be the surgeons who will perform all the cases in that practice, as well as—ideally—being the person within the practice who promotes their partners.

Dr. Billingham: The enthusiasm for laparoscopic colectomy is driven by the public. I hope people will discover that and quit offering this more costly procedure to those who don't need it. If we find out there are no benefits to doing it this way, then fine. But, as a midcareer general surgeon, we won't go out and do this.
Dr. Haas: I think the important question is, of those 30 resections, how many are for colon cancer? If you possess sound surgical techniques for colon cancer resections and perform laparoscopic surgery in your practice, then you're very responsible to begin training for laparoscopic colectomies. However, if you lack experience with oncologic resections or do not possess advanced laparoscopic skills, it's going to take quite a commitment to achieve those goals.

Dr. Whelan: It's hard to imagine somebody in that category who does not do laparoscopic cholecystectomies, possibly Nissen fundoplications or other advanced laparoscopic procedures. You start doing laparoscopic appendectomy and then move on to other cases that are reasonable—elective diverticulitis, rectal prolapse. The other thing is the different methods you can pick up—there's the straight laparoscopic operation and hand-assisted methods. Hand-assisted methods we're pushing pretty hard, for people who want to pick up lap colectomy who have already finished their training. With one hand in, the surgeon is better oriented. It's much easier to teach, we've convinced ourselves of that. Some call it a bridge, but I think, on its own, it's reasonable.

GSN: As laparoscopic colorectal surgery expands, do you think the benefits of laparoscopic versus conventional resection will be even greater than described in the COST trial report?

Dr. Marks: My answer is unequivocally yes. Clearly, after 500 cases, I'm a much better laparoscopic surgeon than I was after 20 cases. As we become more expert laparoscopically, the benefit curve is going to verge wider, and that's a great advantage for our patients.

Dr. Billingham: We all hope to see more benefits. It just hasn't happened in the 12 years in which laparoscopic colectomy has been done. You say the benefits are even greater—what were the benefits? The benefit was that at two weeks there was an improved quality of life, a diminished need for pain meds and a shorter hospital stay. The shorter hospital stay was because they were treating the laparoscopic patients differently—no one had done 100 colectomies. We've had a rush to perform the surgery before one is properly trained with benign disease.

Dr. Nelson: I think the benefits will increase. The COST study was designed to make sure laparoscopic surgery of cancer of the colon was OK, we weren't jeopardizing patients' health by doing this. That being the case, we didn't really do anything to make the quality of life better. With the cancer issue now resolved, we can look at how can we improve the quality of life. I'm perhaps overly optimistic that we won't see undue complications from the introduction of laparoscopic colon surgery. It's been over a decade since it was originally introduced, and when it first came out, there were problems and there were issues. It's been better studied, it's been methodically described as a technical exercise, and there are enough people with large experience to be able to identify the best approaches and to spread some of that knowledge, so that we can offer the best experience to people. It will be done more responsibly with laparoscopic colectomy because the trial really slowed down the rapid acceptance of it.

GSN: Is the surgical community leaning too far one way or the other, laparoscopic or open, in colon surgery?

Dr. Billingham: Absolutely. The laparoscopic enthusiasm is thinks everything can be done laparoscopically. We may find out there are certain patients who benefit from a laparoscopic approach—those who do not require an incision 3 or 4 or 5 cm to get the colon out, patients who are very thin or patients who are very fat. But the message that laparoscopic is better is wrong, according to today's data.

Dr. Whelan: It's in a midcourse correction right now. Four months ago, it was leaning too far against laparoscopy in terms of the community of general surgeons and colorectal surgeons. But I think, now, everybody is afraid that people are going to be demanding it. I don't think it's leaning too far towards laparoscopic, but we need to be cautious about its use.

Dr. Nelson: Everything I've heard so far is that laparoscopy is starting to take its proper place in the options that surgeons can present to patients with colon cancer. I think we can convert 30% to 50% of colon cancer will be done laparoscopically. A lot of people have been waiting for these results and I respect them for waiting. Most of them obviously won't wait any longer. Every colon cancer patient I see now, if it's an appropriate indication—I would offer it to them.

Dr. Marks: Clearly, the surgical community has been very hesitant to adopt laparoscopy as a means of addressing colon pathology. While there have been appropriate concerns in terms of the treatment of cancer, little was done in benign disease to get people ready for this day. Of 250,000 colon resections performed a year in the United States, roughly 5% to 10% are being done laparoscopically. There's a tremendous amount of hesitation on the part of surgeons to adopt it. I think that we are in the middle of what I would call a phase shift in that technique. The surgical hierarchy has been very slow to adopt this. That has been the story of minimally invasive surgery dating back to cholecystectomy where real leaders in that field were all outside of the academic centers in the early years.

—Heidi Nelson, MD

Dr. Whelan: We're believers that there will be more benefits. The Barcelona trial suggested a survival benefit down the line. We haven't proven and immunologic benefits that may be associated with this. The other thing is the different methods you can pick up—there's the straight laparoscopic operation and hand-assisted methods. Hand-assisted methods we're pushing pretty hard, for people who want to pick up lap colectomy who have already finished their training. With one hand in, the surgeon is better oriented. It's much easier to teach, we've convinced ourselves of that. Some call it a bridge, but I think, on its own, it's reasonable.

Dr. Franklin: Absolutely. The outcomes will be better. Dr. Lacy's study [Lancet 2002:359:2224-2229], there's my study in 1996 [Dis Colon Rectum 1996; 39(10 suppl):S35-S46]. There's Dr. Fielding's reports that showed a 78% survival rate—that's better than anything reported for the open surgery. They are still single-center studies, but there are a lot of people who would argue that prospective, prospective studies do give the lowest common denominator. It does nothing to raise the standard of care. It shows that if you have minimal standards and minimal skills, these are the results you are going to see. But no one who has done 100 colectomies. We've been very responsible in consideration of patient outcome, by waiting for the results of the COST and other trials.

Dr. Marks: My answer is unequivocally yes. Clearly, the surgical community has been very responsible in consideration of patient outcome, by waiting for the results of the COST and other trials. Everything I've heard so far is that laparoscopic colorectal resections will be considered the "gold standard" over time?

Dr. Marks: I think that is entirely dependent on what additional studies come out and what they show. There's always going to be another segment that says it all should be done laparoscopically. I'm leaning towards the last group. My philosophy is we're going to put a scope in—to make sure we can do laparoscopically, we're going to work on it. If we run into a roadblock, we'll convert.

Dr. Nelson: I don't like to think of the two procedures as having to compete for the gold standard position. They are both fine options. I think laparoscopic surgery will be preferred by patients, now that it's an option. There will always be a place for open surgery in perhaps as many as 30% of patients.