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Discussion

PROF. A. JOHNSON (Sheffield, United Kingdom): It is very nice to see a well-designed prospective trial. It is also important to look at these different types of costs—the hospital costs, the societal costs, and the costs to the patient—and to analyze them separately, as you have done. The difficulty with laparoscopic hernia trials is to decide which standard repair one is going to compare it with: of the trials that have been published, each one has used a different sort of conventional repair. With the new enthusiasm for the Lichtenstein repair, which is claimed to have all the advantages that you have suggested in terms of pain relief, and other outcomes, perhaps that is the one that ought to be compared.

There are many myths about hernia repairs and return to work. We did a study where we asked our family doctors at what time they would send different groups of people back to work after a hernia repair. It ranged from 1 week to 16 weeks for exactly the same patient, same age, and same work. When I was a student, in the late 1950s, patients were kept in bed for 3 weeks after hernia repair because the Army had given instructions in the Second World War that this should be done! Now we do exactly the same operation, and patients go home the same day. There was a good trial done in 1993 when naval recruits were either sent back to work at 2 weeks after a conventional repair, and there was no difference in recurrence. So somehow we have to control all those factors if we are going to do a trial like this, and that is what is so difficult.

My questions are: 1) At what stage did you do the SF36? How soon after the operation? and 2) What was your pain relief method in both groups?

Finally, I would take issue with you doing a special pleading at the end of the paper by suggesting ways in which laparoscopic surgery could be made cheaper. Alterations could also be made to the way standard repairs were done that would also make them cheaper (*e.g.*, using local anesthesia). So I don't think you proved your final point, but you have done a very useful study that is well documented and well analyzed.

PROF. A. FINGERHUT (Poissy, France): Thank you also for the opportunity to comment on this study. I heard about it before this meeting, and I would just like to say that as far as a randomized study is concerned, the advantages are obvious, but there are problems that have to be dealt with. For instance, the recurrence rate. We cannot underestimate the way people are followed up. How many patients were lost to follow-up? Everybody knows that if you don't follow your hernias, you will not find any recurrence. How were these patients examined? Everybody knows, since the study from England, that people who examined themselves had no hernia, but when a doctor or surgeon examined them, they did have a hernia. How were the recurrences found, and how long after operation? Recurrence can occur at any time during the course of follow-up, and 50% of recurrences occur after 2 years. This means that at least 95% of patients must be followed for at least 2 years to determine the true recurrence rate. We do not know the recurrence rate for mesh repairs yet.

As for the randomized part of your study, how did you select the 276 patients out of 1000? Are they representative of the 1000 people, or did they represent the overall population of your country? And finally, what about the intention-to-treat part of your trial? Were there patients who were allocated to laparoscopic repair who did not undergo it? How were they treated, and how were they analyzed?

Thank you very much for the opportunity to comment on this paper, and congratulations on a very interesting study.

DR. M. S. L. LIEM (Closing Discussion): Let me start with Prof. Johnson, who commented on whether we should compare laparoscopic repair with the Lichtenstein technique. If we had done that, it would not bear any relation with the way inguinal hernia repair is practiced in the Netherlands. In the Netherlands, we do not perform many Lichtensteins, and we wanted to compare laparoscopic repair with common practice (*i.e.*, not a standardized technique) because otherwise it would not result in any change in the Netherlands. In fact, there were some Lichtensteins done in the Netherlands, and these were also included in our trial, but only 3% of our conventional repairs were done in this fashion. When you look at national figures, you see that 3% of the inguinal hernia repairs are being treated with a Lichtenstein technique.

Considering the problem of return to work, this was recognized before the trial, so we gave equal guidelines for all patients. We provided these guidelines in the hospital and sent letters to family physicians explaining that patients were participants in a randomized trial and that they should be treated equally. All patients also received a letter with this information, and they were called by phone after the operation and told that they should return to activity whenever they felt it was possible. This was done both for the conventional group and the laparoscopic group.

The Short Form 36 was applied at baseline (before surgery), of course, and it was applied at 1 and 6 weeks after surgery. We gave equal pain relief to both groups, so there is no apparent bias after randomization from this point.

What about equal costs? The results would not become better if we changed the costs of the conventional repair, which were already cheaper than laparoscopic repair. This would then not alter the decision making, because conventional repair is already being performed in the Netherlands. What we tried to do was give our government some tools for making decisions about laparoscopic repair and to explore how robust the analysis is when important variables are changed. Changing costs for conventional repair—making the repair cheaper—would not have any consequences.

Prof. Fingerhut talked about problems of recurrence rate. We recognized these problems beforehand and did complete follow-up for all our patients. For those who were unable or unwilling to attend hospital follow-up, we visited these patients at home and physically examined them (an experienced resident in inguinal surgery). So all these patients were followed up, including physical examination. In fact, we lost only 3% of patients because they were unreachable or would not allow a physician to come to their homes.

Patients were followed up in this study for a median of 607 days. We are still following them, and of course we will try to achieve a 97% follow-up percentage rate at 5 years and even at 10 years if possible. The 273 patients who were "selected" were in fact not truly selected, because we chose to include the last consecutive 273 patients of the randomized trial. It was just a logistical reason.

Finally, the question concerning intention to treat. All patients who were initially operated on laparoscopically and whose operation was converted to a conventional repair were included in the original group. Costs necessary for this conversion were added into the laparoscopic group. Thus, our analysis is a true intention-to-treat analysis.