Reviewer's report

**Title:** Cost-minimization analysis in a blind randomized trial on small-incision versus laparoscopic cholecystectomy from a societal perspective. Sick leave outweighs efforts in hospital savings.

**Version:** 1  **Date:** 7 May 2009

**Reviewer:** Vincent B Nieuwenhuijs

**Reviewer's report:**

This study focuses on the economic aspects of small incision cholecystectomy (SIC) vs. laparoscopic cholecystectomy. The clinical outcomes of this well-designed RCT have been published recently. Since there were no major differences in clinical outcomes between the 2 techniques the authors postulate that costs may be an important ground to prefer one method above the other. This paper describes the cost analysis of the previously published RCT.

**Major comments:**

Length of hospital stay is an important variable determining hospital costs. On p. 6 it is mentioned that patients left the hospital as soon as they were able to do so. Was the decision to leave the hospital completely left to the patient? If so how was the patient instructed to chose the time of discharge. It is well known that pre-operative information and expectations are a major factor for patients to accept that discharge is safe. Did all patients receive standard information about the procedures and was this information the same for both SIC and LC? What was the role of the doctor on the ward and the nurse in the decision to discharge a patient? Where there any standard discharge criteria? How did they encourage the patient to be discharged? And were they blinded for the operating technique?

Table 1. Why were preoperative costs recorded and included in the analysis? Have the authors done an analysis on the post-randomisation costs. Would their conclusions be any different?

Small incision cholecystectomy is a difficult procedure to learn. Due to minimal exposure to the assisting surgeon it may a difficult procedure to supervise. What was the presumed learning curve? Did all residents and surgeons go through the learning curve? Was there any difference in resident experience between the groups. If the LCs were done by less experienced residents this would lead to longer operating time and thus higher costs.

What was the effect of the shorter operative time to estimated costs, since SIC was significantly faster (11.5 min). If this would be the main reason for SIC to be the more economic procedure (operation theatre related costs), than the conclusion would be that the fastest cholecystectomy is the cheapest. This may not be true since 11 min OR time may not lead to less costs for society. Please comment.
Discussion: when no differences in primary outcomes are found several secondary outcome measures such as costs may be important to prefer one technique over the other. In the paper reporting the clinical outcomes cosmesis was not reported. Which method was preferred on cosmetic grounds by the patient? A couple of well disguised small incisions (LC) may give a better cosmetic result than a single 8 cm incision.

Table 4: Unfortunately an outlier in the SIC group skewed the data in this group. Please describe the details of this case. Please also describe the outlier in the LC group. The authors justify the exclusion of the outliers by stating that the data may be distorted. Complications may dependent of the operating technique. It should be made clear that the complications for the outlying case were not procedure related. If the complication is related to the small incision technique it is questionable whether the intention to treat analysis may be aborted. Especially since the conclusion of the study is completely reversed from LC to SIC as being the cheaper method.

Table 5: employed patients. Probably the outliers were not employed. In this subgroup the difference in total cost is not significant. In the discussion on p.14 the authors hypothesize (based on 21000 cholecystectomies annually in the Netherlands) that a possible reduction of sick leave may result in 8.6 million euro. Both return to work and costs were not significantly different in this subgroup. It is inappropriate to state that SIC may lead to lower costs based on return to work and procedure related costs on non-significant differences. This unfounded assumption should be omitted from the paper.

The authors are very firm in their recommendation that SIC is the procedure of choice based on costs. This is however only supported after exclusion of an outlier thereby neglecting the intention to treat principle. This affects the credibility of the trial. The conclusions in the title, abstract, discussion and conclusion should be less firm in favor of SIC. In the literature the data is also conflicting. I don't feel this trial will once and for all prove that SIC is less expensive.

Has SIC replaced LC as the method of choice for a cholecystectomy in the hospitals of the authors? If so, please add that to the discussion of the manuscript. This would confirm that the authors are willing to change their local policy according their strong recommendation in their manuscript. If not, why not?

Minor comment
In the methods section registrars are mentioned whereas in the discussion they are called residents, please use one term.

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.