Author's Reply

Study on the Postoperative Pain Calls for More Methods to Control Potential Bias

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We thank Dr. Liu *et al*. very much for their attention on our recent article. In that paper, we reported a prospective randomized clinical trial comparing outcomes between traditional laparoscopic cholecystectomy and single-incision laparoscopic cholecystectomy (SILC). It revealed that the SILC-treated patients had a significantly lower pain score only at postoperative 6 hours, but at 24 hours and longer after surgery pain scores were not different between the two groups.

In the earlier reports of clinical trials of SILC from 2007 to 2011, the safety and feasibility of the SILC have been confirmed by many studies.[1-3] However, besides the obvious better cosmesis, whether the SILC had more benefits, such as less postoperative pain, shorter hospital stays, faster return to work, and routine activity, was unknown.[4,5] Therefore, we set the postoperative pain as the primary outcome in this randomized controlled trial.

The visual analog scale (VAS) is a psychometric response scale which lacks objectivity, but at present, it is regarded as the most common measurement instrument to evaluate the postoperative pain. Hence, it was used in the clear majority of the clinical trial of single-incision laparoscopic surgery. We totally agree with Dr. Liu *et al*. that the preoperative psychological disorders would affect postoperative pain score. However, unfortunately, we did not find a well-designed trial as a satisfactory reference before the date of recruitment, November 1, 2011. Moreover, we were afraid that paying too much attention to the psychological factors would bring more bias to the study when lacking a better measurement instrument than VAS.

All the patients underwent general anesthesia without any special medication such as dexamethasone. Actually, we had noticed that single-dose preoperative dexamethasone would decrease VAS.[6] Hence, all the anesthetists were told not to use dexamethasone when the patient was recruited. Furthermore, to exclude all potential affecting factors and control the potential confounding bias, we did not use any local anesthetic, such as wound infiltration, subhepatic infiltration, or the combined.

In the present clinical trial, the sample size was calculated based on mean VASs obtained in our initial study. The reason has been mentioned that the pain scores were quite different from those in papers published earlier than October 2011 in PubMed. As regarding the analgesic requirement, we did not set it as the primary outcome in this study. Therefore, we would look specifically at the analgesic requirement in a future study if it is really an interesting issue.

In conclusion, the postoperative pain is one of the most important outcomes of a surgical procedure. By far, the VAS is the most common instrument to evaluate the pain, although

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it lacks objectivity. We believe that, with more emphases on "patient-report study," there must be better methods to control the potential bias.

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