

Author's reply: safety of prophylactic cholecystectomy does not mean it is recommendable

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Dear Editor:

Thank you for the opportunity to reply to the well-advised comments of Dr. Kyo Young Song about our article published (online ahead of print) in *Gastric Cancer* titled “The Cholegas study: safety of prophylactic cholecystectomy during gastrectomy for cancer. Preliminary results of a multicentric randomized clinical trial” [1]. His interest in this work is highly appreciated. We will try to clarify the issues raised by this colleague as follows.

To the best of our knowledge, our trial was the first targeted directly to answer the question whether prophylactic cholecystectomy, during gastric surgery for cancer, is justified. In fact, almost all the data in the literature are retrospective, reporting indirect or conflicting results with weak statistic reliability [2], and eventually leaving the decision to each surgeon's preference.

Therefore, a randomized clinical trial is the cornerstone to approaching this issue, and obviously a Local Ethic Committee approval was requested from any single participating center after the presentation of the study design and rationale. We also stated in the title that the published article reported, to date, only preliminary data of the safety of concomitant prophylactic cholecystectomy during gastric surgery for cancer, as clearly requested by the Local Ethic Committee [3] both as an interim analysis and as an endpoint of recruitment evaluation. If the groups had showed substantial difference in perioperative outcomes (i.e., complications), the trial would have

been stopped during enrollment or prophylactic cholecystectomy would not be deemed safe now, at the end of recruitment. Hence, at the moment we can only state that prophylactic cholecystectomy is safe, but no conclusions, as declared in the study, can be drawn on whether this additional procedure is useful and therefore recommended. This last consideration will be highlighted during further follow-up.

In conclusion, we do not claim the necessity of prophylactic cholecystectomy during gastrectomy, as hypothesized by Dr. Kyo Young Song, but we confirmed the ethnicity and rationale of the design only. Therefore, more reliable results are expected with final follow-up (minimum 3 years for each patient enrolled).

Sincerely,

Lapo Bencini, MD, PhD; Marco Bernini, MD, PhD and Marco Farsi, MD on behalf of all the authors

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