Questions and Answers session - EPISODE 6 - 4th June 2020

Paper: Robotic Inguinal vs transabdominal laparoscopic inguinal hernia repair: the RIVAL randomized clinical trial. JAMA Surg 2020

Please note that the following text is not an accurate reproduction of the minutes of the online session. They have been extensively edited to make it more informative and useful to readers.

Do you think 25 is an adequate learning curve number for laparoscopic inguinal hernia repair - TAPP in this case?

It is difficult to define a specific number of procedures needed to reach proficiency, a lot will depend on previous experience of a surgeon with laparoscopy. There are various papers available and the number of cases needed to fulfill the learning curve as reported in literature is very variable, ranging from 14 to 50.

What do you think of the 'comparator'? Is that valid?

The comparator chosen by the authors is TAPP hernia repair - this may not necessarily be the standard treatment in many centres, but the presenters believe this was used because of the similarities in surgical approach between TAPP and robotic hernia repair - both are transperitoneal, the mesh is preperitoneal.

What do you think is the key outcome that you would be interested in with regards to hernia surgery? Has that been included?

Key outcomes in this context would be recurrence rate and groin pain, the authors are plan to evaluate this at follow-up and present the results later; however the present study does not present them.

No sample size calculations in a RCT! Is this a valid approach?

Overall the opinion of the meeting is that in RCTs, sample size calculations should have been done. This could have been done based on data available from laparoscopic TAPP repair and choosing other appropriate parameters including power, type I error and effecti size. The reasons given by the authors for not doing sample size calculations does not appear to be valid. This seems to be a significant limitation of the trial.

What is the 'main outcome'? how does this differ from primary outcome?

When we talk about primary outcomes in RCT we talk about the outcome that we are primarily looking at when comparing two different interventions. Sample size calculations are designed based on this primary outcome, although some studies report on two primary outcomes and calculate sample sizes for both of these outcomes and use the larger estimated sample size to design the study. The main outcome(s) in this specific trial are

those identified by the authors as relevant to this procedure, but given that no sample size calculations was run, they are said to differ from the 'primary outcome'. As mentioned before, the validity of this approach is open to question.

When was the randomization done? Was allocation concealment ensured and how? Were patients excluded after randomization?

Randomisation was performed at pre-assessment, allocation concealment was aided by the use of block randomisation. Patients were excluded after randomisation (on the day of surgery or intraoperatively - the paper is not clear about this) when an incidental contralateral hernia (exclusion criteria) or no hernia was identified. This approach violates the intention to treat principle and is controversial. This approach has not been justified in the reporting of this paper.

How was blinding achieved? What is your opinion of this?

Given the similarities in terms of number of incisions (3) and position of the ports, blinding was achieved by not telling the patient what procedure was performed. Assessors were not blinded to the procedure, which is a limitation of this trial.

What do you think about the generalisability of the trial findings?

Applicability of these findings is limited as the laparoscopic TAPP is not standard in many centres. The robot is not available for routine hernia surgery in many parts of the world and is probably not justified in view of the exorbitant costs and lack of proven impact on any relevant long term outcomes. The journal club attendees felt that the robotic approach for simple inguinal hernia repair is not warranted given the effectiveness of current techniques and limitations on resources available for health care.

Edited by Josh Lau, Gio Perin and Saba Balasubramanian