

Reviewer's report

Title:Laparoscopic versus open adhesiolysis for small bowel obstruction - a multicenter, prospective, randomized, controlled trial

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Reviewer:Salomone Di Saverio

Reviewer's report:

Overall this is an interesting and original randomized investigation on a topic which has not been previously investigated by other RCTs.

The Study protocol, registered on ClinicalTrials.gov, is overall well written and the statistics, particularly the sample size calculation, seems to be correct.

However I would like to raise some issues regarding the inclusion and exclusion criteria, that need to be clarified and should be at least discussed within the discussion (since they can not be changed because the Trial is already registered and already recruiting).

- Why the trigger for operation is considered the failure of passage of Water Soluble Contrast in the colon within 8 hours? In the literature most authors consider 24-36 hours to be the time limit for considering failed the trial of NOM for ASBO with Gastrografin. Please explain the decision to choose the limit of 8 hours to proceed to surgery. Don't you think some of these patients could have resolved SBO in the following hours? Please give a reason for that.

- There are probably too many exclusion criteria and this in my opinion can make the enrolment a bit challenging. Furthermore I do not agree with some of these exclusion criteria. E.g.:

1) Previous (change earlier to previous please) generalized peritonitis should not be an exclusion criteria; in my experience it can rather be a predictive factor of finding diffuse matted adhesions (although this is not demonstrated and not always true) and can therefore be associated with higher risk of conversion, but it is not an absolute contraindication to approach ASBO laparoscopically.

2) Previous obesity surgery; in obese patients laparoscopy is rather an advantage!!! Furthermore surgical procedures for obesity are usually performed in the supramesocolic region and most often they are not associated with significant adhesions causing ASBO or strangulating bands needing surgery. Why consider previous obesity surgery an exclusion criteria?

3) Suspicion (PRE-operative suspicion I assume) of other cause of obstruction than adhesions. Once again in such cases a diagnostic laparoscopy is rather indicated and if a different cause is found at laparoscopy, the patient will be dropped out from the study. There is no need to exclude preoperatively such patients, unless you clarify that patients with CT scan finding of SBO caused by a clear intrabdominal cancer or mass, will be excluded. In all other patients the suspicion should not be enough to consider the patients excluded from the

possibility to be enrolled. If the cause of obstruction is other than ASBO then the patient will be excluded (drop out) and perhaps the procedure can still be carried out laparoscopically without need for conversion

4) Previous abdominal operation within 30 days should not be contraindication to laparoscopy in my experience neither to the enrolment in such a Trial, if the first operation was done laparoscopically (if it was done via open laparotomy the risk of fascial breakdown with pneumoperitoneum is consistent). I.e. a patient underwent lap appy and presenting with SBO 20 days later suspected for adhesion SBO, should be approached laparoscopically and can be enrolled.

5) Previous surgical operation for aorta or iliac vessels surgery; this is also not an absolute contraindication but rather a predictor of failure of laparoscopy

6) I can not also understand why over 1 week of hospital stay directly prior surgical consultation should be an exclusion criteria for enrolment in the Laparoscopic Trial. In addition I would like to ask to the authors what exactly that sentence does mean? Please clarify

I suggest to the authors to explain and discuss more the reason for choosing the above exclusion criteria.

Regarding the criteria for conversion:

- If peritoneal carcinomatosis is found, why not to take advantage of laparoscopy and spare the patient a painful and useless median laparotomy? A biopsy can be done laparoscopically and eventually if needed, a loop ileostomy proximal to the obstruction, can be fashioned without need for conversion.

Finally I would consider an additional endpoint to be the conversion rate / success rate of laparoscopic approach, since this is one of the biggest debated issues and of the most often reported data by the relevant literature on this topic.

Level of interest:An article of importance in its field

Quality of written English:Needs some language corrections before being published

Statistical review:Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests