Reviewer's report

Title: BIOLAP: Biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: Study protocol for a randomized multicenter, self-controlled clinical trial

Version: 0 Date: 10 Aug 2018

Reviewer: Friedrich Kalllinowski

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The proposal describes a test of two procedures already in clinical use. The liberal use of the terminology "biological versus synthetic mesh" has to be sharpened. As it stands in Lns 167 - 169, the biological mesh should be a perforated, non-cross-linked, acellular, collagenous matrix. The synthetic mesh should be large-pored, lightweight and made of polypropylene, polyester or polyvinylidene fluoride. There are a variety of meshes in this description and this reviewer envisions the danger of a non-standardized application process. Since many more synthetic or biological meshes are on the market, care should be taken to avoid the liberal use of "synthetic or biological" as a description of the specific meshes used. Rather, the names and trade marks of the meshes selected should be stated and the presumed number of each individual mesh to be implanted should be precalculated in order to assess the power of the trial as well as the number needed to treat to reach both end points named - superior in pain and not inferior in recurrence. It is assumed that both end points need different numbers needed to treat to reach a conclusion.

The liberal use of glue for fixation opens another door for the interpretation of the data and potentially alters the number needed to treat for each hernia mesh. In the Guidelines ref. 17. it is proposed to use fixation of hernia meshes with a small overlap or those bridging large hernia sizes. Since both endpoints might be influenced by fixation, this technical aspect should be standardized.

The technical procedures during surgery may be crucial as stated above. Therefore, an objective assessment of the operative results, e.g. a photo of the placed mesh with a scale, to document the final mesh: defect area ratio, the overlap or the area for fixation or other should be used rather than the subjective description of the surgeon.

The technique used for the follow-up might be crucial for the results as well. The manuscript gives in Ln 53/160 "a clinical follow-up visit" and "an assessment of endpoints". The structure of the visit and the methodology for the assessment of endpoints was not found by this reviewer in the text. A phone call or a structured clinical assessment will have different recall and outcomes. The description in Ln 57-59/ 162-3 pg. 6 reads: "If a hernia recurrence is suspected, a verification with ultra sound, MR or CT-scan must be performed." The level of suspicion will be different in an interview on the phone performed by a technician and in a clinical examination by an experienced surgeon.

The points raised should be clarified to strengthen the clinical relevance of the trial.
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