Reviewer’s report

Title: Biliary reconstruction with or without an intraductal removable Stent in Liver Transplantation: A Randomized Controlled Trial An original Diffusion of the surgical methodology

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Reviewer: Andreas Schnitzbauer

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The protocol by Goumard et al. on biliary reconstruction during LT using a stent or no stent. Their preliminary retrospective experience is convincing and the findings warrant exploration and further study as proposed with this RCT.

- Inclusion and exclusion criteria are broad and therefore the study should be representative for the vast majority of patients undergoing LT.
- I did not find a comment on T-tubes used? Is it an exclusion criterion?
- how about the Berlin side to side anastomosis?
- the definition of biliary leakage is very randomly. Why not use the ISGLS criteria with an increase in serum/drainage bilirubin ratio>3 within 7 days after LT, requirement for drainage for>7d due to biliary leakage, macroscopically bile over wound or drainage distinguishing Type A (not clinically relevant because it vanishes before day 7), type B (intervention) or Type C (reoperation). It is your primary endpoint and this should be based on criteria internationally accepted, used and solid as a rock. Otherwise the definition may be a little wishy washy and very easily to manipulate. Especially, patients with cholestatic disease with initial bilirubin values >30mg/dl will have significantly increased bilirubin in drainage without any clinical relevance!!!!
- even biliary stenosis is even more difficult to define. Mostly, endoscopists describe a stenosis which comes from a diametric discrepancy of donor and recipient.
- what is a clinical and biological cholestasis? Every patient will have elevated yGT AP or bilirubin in the early postoperative course. Define cut-offs and trigger indicating that something is wrong and that a cholestasis has to be considered: e.g. 3-fold elevation from baseline within 2 days. You have to be precise and maybe redefine your protocol.
- please use Charriere and not French, as the angloamericans were unable to pronounce this beautiful French word ;-)!