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: Bo Göran Ericzon

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Review of “Biliary reconstruction with or without an intraductal removable stent in liver transplantation”.

This is a multicenter randomized control trial in France including several centers performing liver transplantation. The aim is to investigate whether intraductal stenting of the bile duct in patients were either the donor or the recipient duct is less than 7 mm in diameter. In the control group, no stents will be used. The novelty of this technique is that the stent is short enough to remain within the choledochus/hepaticus communis and not enter the duodenum or being connected externally as a regular T-tube. This will also necessitate, at time of removal, a more extensive approach with an ERC-investigation including a small papillotomy. Thus, the aim of the study is not only to see whether post transplant biliary complications such as stenosis or leakage are different in the two groups, but also if there is a price for a routine ERC to remove the stent. Although, various forms of stenting has been used for decades in liver transplantation in order to avoid biliary complications, focus has also been on an easy removal of the stents when no longer needed. In the present study, the stent is hidden in the bile duct allowing a preserved sphincter function, at least until papillotomy is performed when the stent is removed. It is important that the stent is placed both above and below the bile duct anastomosis. It is not clear from the manuscript how a 2 cm long tube without fixation will remain in position to maintain an adequate anastomosis. This is maybe clarified in the video that is accessible for the study center at randomization, but is not available for the present review. The size of the study seems adequate when considering the typical incidence of biliary complications and what can be expected from this technique if the multicenter study obtains the same outcome as indicated by the pilot study performed by the principal investigator earlier. The study is less likely to effect the more common multiple intra-hepatic strictures related to ischemia to the graft during the peritransplant period. Indirectly, by reducing ascending bacterial cholangitis the tested technique may also influence such strictures. A significant shortcoming of the study is the length of follow-up decided to be 6 months after transplantation. The investigators state themselves in the background section of the study “biliary strictures mainly occur later, within 5-8 months, and up to one year in the great majority”. Thus, a follow-up of one year would be more relevant to evaluate outcome in the study groups.