

T-tube or no T-tube for bile duct anastomosis in orthotopic liver transplantation

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Liver transplant is the established treatment for end-stage liver disease with standardized technique and reports of excellent results (1). Elective liver transplant in low risk patients have a 1-year survival rate of more than 90% (2). Improved outcomes are a result of careful patient selection, meticulous surgical techniques and attentive postoperative care. Increased survival has led to an escalation in the number of liver transplants being performed with over 15,000 patients being transplanted in the USA, Europe and China in 2010 (2). However, 10 to 30% of patients, submitted to whole organ liver transplantation, develop biliary complications with subsequent mortality of up to 10% (3,4). Approaches to reduce the incidence of biliary complications have included different techniques for anastomosis (for example side-to-side) and the use of T-tubes for duct-to-duct anastomosis.

Data on the routine use of T-tube for reconstruction of the biliary tree is not conclusive. Most studies are analyses of retrospective cohorts, and some have raised the hypothesis that the use of T-tube may actually be detrimental with higher rates of biliary complications (5-7). The few randomized controlled trials (RCTs) published have produced contrasting results (8-10). Therefore this is an important study by López-Andújar *et al.* on a question that needs elucidation (11). It is a single-center, 2-arm parallel group, 1:1 allocation, randomized controlled trial. The study evaluated the efficacy of using T-tubes, for biliary reconstruction during cadaveric donor liver transplantation when compared to biliary reconstruction without the T-tube. The participants were all patients submitted to liver transplant at a single University hospital in Spain

with extensive experience in this procedure (>1,500 liver transplants prior to the start of the trial). The outcomes chosen are very relevant. The primary outcome was the overall incidence of biliary complications and the secondary outcomes were the severity of the biliary complications and complication-free survival for each group.

The study was adequately designed and executed. A stricter adherence to the CONSORT guidelines for reporting of RCTs would facilitate the readers' capacity to evaluate the study (12). For example, explicit description of the random sequence generation and the methods for allocation concealment (beyond the use of sealed envelopes) would have been helpful. Although allocation concealment was not explained in detail, the groups seem to be well balanced regarding the major risk factor for biliary complications, i.e the bile duct diameters of both donors and recipients. Another important note is that the conclusions regarding the secondary outcomes should be made with caution as the sample size estimation was based on the primary outcome, therefore the study has sufficient power only for the conclusion regarding the primary outcome.

The number needed to treat (NNT) is an interesting measure for weighing benefit and harm (13). As the authors pointed out from the study data the NNT to avoid anastomotic stenosis would be 8, which is very impressive, i.e eight patients would have to be treated with T-tube to avoid one case of anastomotic stenosis. This number has to be viewed with caution as patients have different risks for developing stenosis, and this influences the NNT. Those most likely to develop stenosis were the cases where the

donor or recipient biliary duct diameters were less than 7 mm. This is well illustrated by the NNT of 30 for cases where either the donor or recipient has a bile duct diameter greater than 7 mm. On the other hand it is also important to consider the potential morbidity caused by the use of the T-tube itself. Twenty three percent of the patients developed T-tube inherent complications and this generates a number needed to harm (NNH) of just 4, i.e for each anastomotic stenosis avoided, two patients developed T-tube inherent complications. In this study, all T-tube inherent complications were mild and could be treated conservatively, only four required percutaneous drainage and one was submitted to endoscopic sphincterotomy with insertion of biliary prosthesis. Minimally invasive procedures (endoscopic sphincterotomy, nasobiliary drainage, percutaneous drainage) are increasingly being used for the treatment of post-transplant biliary complications (14). Two thirds of the patients who developed stenosis of the anastomosis, on the other hand, required major intervention for correction (conversion of the anastomosis to a hepaticojejunostomy). This is the information that has to be weighed when choosing to use the T-tube or not and the decision tailored for each case.

The key seems to be in the selection of the patients— not all benefit from the use of T-tube for biliary reconstruction. Patients with donor-recipient biliary calibre mismatch seem to be the ones who benefit most from T-tube use. The routine use of T-tubes in all orthotopic liver transplantation (OLT) patients, i.e in those who are likely to benefit from its use along with those who are not, is likely to drive the results towards the null hypothesis. In conclusion, as pointed out by the authors, the patients most likely to benefit from the use of the T-tubes are those that present a mismatch in the bile duct calibres and a donor or recipient bile duct of less than 7 mm. Logistic regression analysis showed the bile duct diameter of less than 7 mm as an independent predictor of stenosis, with an odds ratio of 3.96, although with a wide 95% confidence interval (95% CI: 1.18-13.25).

In summary, this study by López-Andújar *et al.*, is an important step towards better understanding of post-transplant biliary complications. The T-tube does not seem necessary as a routine for all liver transplant cases, only for those with bile duct calibre mismatch and diameter of less than 7 mm. Future RCTs on this question, should probably include only patients at risk for developing biliary complications, particularly stenosis, as they are the ones who benefit from the use of the T-tube.

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