Transplant International

LETTER TO THE EDITORS

Does the temporary porto-caval shunt have any beneficial impact in orthotopic liver transplantation?

doi:10.1111/j.1432-2277.2011.01267.x

Dear Prof. Muhlbacher,

I would like to write some critical remarks on the article by Davide Ghinolfi *et al.* published in the last issue of *Transplant International* (Volume 24, Issue 3, Pages 243–250). This article covers the beneficial impact of temporary porto-caval shunt in liver transplantation (LTx).

First, I would like to dwell on statistical analysis and its drawbacks. Incorrect statistical analysis leads to erroneous conclusions and thus, questions the value of the study. Despite the authors stating in the ''statistical analysis'' section that they used Mann–Whitney *U*-test when non-normally distribution was present, the data in tables show us that that was not the case. One could only guess how the number of transfused units of red blood cells or platelets can be negative: 12.2 ± 14.2 for packed red blood cells (PRBC) and 3.8 ± 9.8 for platelets. It means that some patients received −2 packs of PRBC and some received −6 packs of platelets. It makes no sense. It clearly shows us that these variables are non-normally distributed and thus the data cannot be represented by mean ± SD, but should be represented only by median and range in brackets, because standard deviation (SD) cannot be calculated for non-normally distributed data.

After deep analysis of all data in the tables, we can see that the vast majority, if not even all the variables that are depicted as if they were normally distributed, (by mean ± SD) are non-normally distributed. This fact puts under suspicion that the appropriate statistical tests (Mann–Whitney *U*-test) were used to define differences between the two groups [temporary porto-caval shunt (TPCS) and non-TPCS]. Thus, we cannot say that the difference between the two groups in number of PRBC transfused is statistically proven. Moreover, we cannot say that there are no other differences between the two groups because it is statistically unproven due to the use of inappropriate statistical methods.

Now I would like to dwell on analysis of graft and patient survival. The authors said that ''one of the most important differences in our series is the improvement in 30-day graft and patient survival in TPCS group''. I hardly believe that there is any ground for such optimistic conclusion. In TPCS group, only one patient died (1 of 58) within first 30 days after LTx and in the non-TPCS group, nine patients died within first 30 days after LTx (9 of 90). Analysing these data with Fisher's exact test, we will receive statistically significant differences ($P = 0.0458$) between these two groups. I would like to note that if only eight patients died in the non-TPCS group, we would not receive any statistically significant difference ($P = 0.0710$). Thus, if that patient with duodenal perforation died not on 30th day but on 31st day after LTx, there would be no difference between the two groups in 30-day mortality. Moreover, I would like that we look closer at the data. There were seven patients with primary graft non-function (PNF) in non-TPCS group and only three of them were retransplanted. All four patients with PNF and without retransplantation died within 30 days. In the TPCS-group were three PNFs and all those patients were retransplanted, but one died within 30 days. Therefore, the difference in 30-day mortality can partially be explained by the fact that in the non-TPCS group not all patients with PNF were retransplanted. Poor graft quality and organ shortage (I guess there were no organs to perform retransplantation) led to patient's death. The temporary porto-caval shunt could play little, if any, role in reducing the incidence of primary nonfunction.

One could hardly argue the authors' statement that portal vein clamping leads to increased pressure in the splanchnic system which reflects on the microcirculation with increased permeability of the membranes, interstitial oedema and endothelial damages. Patients with temporary porto-caval shunt theoretically would avoid all these effects of increased splanchnic pressure. Also theoretically, venous congestion in the intestine could damage the epithelial lining of the intestine wall and lead to bacterial translocation and to sepsis. It is interesting that as a cause of death, sepsis was recognized in seven of 11 patients in TPCS group and only in four of 12 in non-TPCS group.

As the benefits of temporary porto-caval shunt is still a matter of ongoing debate, one can assume that the benefit and improvements are not too big, if even there are any, and to determine them the researcher should enroll big number of patients in his trial. The study by Davide

Ghinolfi *et al*. is underpowered (the number of patients enrolled is small) to find any benefits of temporary porto-caval shunt. With such patient numbers, this study could determine only if there were big differences between these the two groups. So this fact puts in to doubt the value and the need to perform such trial.

In conclusion, I would like to say that this article is very questionable in terms of how the study was organized, in terms of its statistical analysis and conclusions made by the authors. I think that it is still the authors' opinion, and there is no evidence drawn from their study supporting the theory that temporary porto-caval shunt has any beneficial impact.

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