### Editorial

## Prophylactic portasystemic shunt in non-cirrhotic portal fibrosis: is it worthwhile? Nobody knows

Non-cirrhotic portal fibrosis (NCPF) causing bleeding from esophago-gastric varices is rarely encountered in North America. In our experience over the past 48 years with more than 3,000 portasystemic shunts performed for bleeding esophagogastric varices, no more than a handful of patients had NCPF. In contrast, NCPF is common in India, and experience with portasystemic shunt treatment of bleeding caused by NCPF at the All India Institute of Medical Sciences in New Delhi is substantial. Therefore, the report in this issue of the *Journal*<sup>1</sup> on the use of prophylactic portasystemic shunt in patients with NCPF who have never bled warrants serious attention and careful scrutiny.

In order to establish a rationale for the use of prophylactic portasystemic shunt in patients with NCPF, the following must be shown by scientifically acceptable data:

1. Prophylactic shunt must be associated with a significantly lower incidence of subsequent variceal bleeding than the incidence observed in a comparable group of unshunted subjects.

2. The reduction in the incidence of variceal bleeding must be attributable to a patent, functioning portosystemic shunt by regular follow-up studies of shunt patency using Doppler duplex ultrasonography.

3. The mortality rate of shunted patients must be significantly lower than the mortality rate of a comparable group of unshunted subjects.

4. Sequelae attributable to the portasystemic shunt must be documented by direct and careful observation by the investigators, and must be shown to occur in the presence of documented patency of the shunt.

5. There must be long-term follow up by the investigators, for at least 5 years and preferably for 10 years.

Unfortunately, the study of Pal *et al*<sup>1</sup> does not fulfill these requirements and, therefore, does not warrant conclusions based on the study.

This study involved a retrospective review of medical records and has the usual serious flaws of retrospective studies. It did not involve comparison with a comparable group of unshunted subjects. Furthermore, no studies of shunt patency are reported, which makes it inappropriate to attribute outcomes, good or bad, to a functioning shunt. Long experience has shown that the proximal (conventional) splenorenal shunt has a substantial longterm incidence of shunt occlusion, so that proof of shunt patency is essential.

Additionally, the accuracy of follow-up data is in question: The authors state that "patients who defaulted were sent postal questionnaires." They do not state how many of their patients were in this category, and how many patients who were sent questionnaires returned them according to the stated follow-up schedule "every three months for the first year, every six months for the second, and yearly thereafter." Follow up by questionnaire has well-known shortcomings, all the more so in a study such as this, that was confined to poor patients who live in rural areas far from medical centers.

Another shortcoming of the study is the selection of patients for the study. According to the Table, in 17 of the 45 patients hypersplenism alone was the indication for prophylactic surgery. Our extensive experience indicates that hypersplenism has a questionable indication and does not warrant inclusion in a study aimed at determining "the results of prophylactic operations to prevent variceal bleeding." A substantial majority of our patients with portal hypertension have had hypersplenism and we have never found it appropriate to perform a portasystemic shunt to treat the hypersplenism. Furthermore, the inclusion of two patients treated by splenectomy alone and two patients treated by splenectomy and devascularization undermines what should have been the main objective of the study, i.e., to determine the effectiveness of prophylactic portasystemic shunt. In actual fact, only 27 patients with esophageal varices underwent prophylactic portasystemic shunt, a rather small study population.

Some comment on the use of proximal splenorenal shunt is warranted. Substantial data indicate that direct portacaval shunt has a much higher long-term patency rate than splenorenal shunt. In our longterm follow-up studies of 1,000 patients who underwent elective therapeutic portacaval shunt,<sup>2</sup> and 400 patients who underwent emergency therapeutic

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portacaval shunt,<sup>3</sup> the long-term shunt occlusion rates were 0.3% and 0%, respectively. Relief of hypersplenism is not an indication for choosing splenectomy and splenorenal shunt, since our studies have demonstrated conclusively that relief of portal hypertension by direct portacaval shunt consistently relieves hypersplenism in patients with cirrhosis<sup>4</sup> and in those with extrahepatic portal hypertension.<sup>5</sup> It is not clear from this report why Pal *et al* favored the splenorenal shunt.

From the standpoint of surgical technique, it is unclear why Pal *et al* used a thoraco-abdominal incision to perform splenectomy and proximal splenorenal shunt since, with proper positioning of the patient, it is possible to perform the entire operation without entering the chest. Thoraco-abdominal incisions are associated with much more early and long-term postoperative pain than abdominal incisions. We discontinued the use of thoracoabdominal incisions 45 years ago.

We have had no experience with prophylactic portasystemic shunt. Ever since three prospective randomized clinical trials of prophylactic portacaval shunt reported in 1968 and 1969 that there was no benefit from the prophylactic operation, we have been unwilling to undertake prophylactic surgery.<sup>6-9</sup> It should be recognized, however, that these studies were conducted more than three decades ago, and that the results might be different if similar trials were performed today.

Although we have had little experience with NCPF, it might be informative to consider our results of therapeutic portasystemic shunt in the treatment of patients who were bleeding or had bled from esophago-gastric varices since, if prophylactic surgery is to be used, it will have to produce better results than those associated with delaying surgery until the patient bleeds. In a study reported in 2002,<sup>10</sup> we performed portasystemic shunts in 200 consecutive patients with extrahepatic portal hypertension caused by portal vein thrombosis, after they had recovered from at least two episodes of bleeding esophago-gastric varices requiring blood transfusions. None of the patients had liver disease. Postoperative survival to leave the hospital was 100%. Actuarial 5-year, 10-year, and 15-year survival rates were 99%, 97%, and 95%, respectively. Five patients (2.5%), all with central end-to-side splenorenal shunts, developed thrombosis of the shunt, and these were the only patients who had recurrent variceal bleeding. During 10 or more years of follow-up, 97% of the eligible patients were shown to have a patent shunt and were free of bleeding. No patient developed portal-systemic encephalopathy, liver function tests remained normal, liver biopsies in 100 patients showed normal architecture, and hypersplenism was corrected.

In a study reported in 1998 and again in 2001,<sup>2,11</sup> we performed elective therapeutic portacaval shunt for variceal hemorrhage in 1,000 patients with biopsy-proven cirrhosis who were followed up for more than 5 years. Follow-up rate was 99.6%; 89% of the patients were in Child's risk classes B and C. Operative mortality rate was 1.6%. Long-term shunt patency was demonstrated in 99.7% of patients. Survival rates were 95% at one year, 71% at 5 years, 65% at 10 years, and 61% at 15 years. Five-year survival in 621 patients who abstained from alcohol was 91%.

Finally, in a study of emergency portacaval shunt in 400 unselected patients with cirrhosis and acutely bleeding esophageal varices, we observed that patients in Child's risk classes A and B had operative survival rates of 100% and 88%, respectively; 5-year survival rates of 98% and 79%, respectively; and 10-year survival rates of 78% and 76%, respectively. The long-term shunt patency rate was 100%.

In their concluding remarks, Pal et al state: "We believe that NCPF patients with high-risk varices, who have not bled, should be primarily offered endoscopic variceal ligation or sclerotherapy with or without propranolol for variceal eradication." Further, "Despite the efficacy of surgery in preventing variceal bleeding, the high incidence of post-shunt morbidity does not justify its routine use in the prophylactic setting in patients with NCPF." On the basis of their study, neither of those recommendations is warranted. What is needed to determine whether or not prophylactic portasystemic shunt is worthwhile in patients with NCPF is a prospective randomized clinical trial of surgical versus nonsurgical treatment. With their long experience and large population of patients with NCPF, no group is in a better position to conduct such a study, and I can only hope that such a study will be done.

#### Marshall J Orloff

Distinguished Professor of Surgery, School of Medicine, University of California, San Diego, USA

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