A prospective randomized study to evaluate propranolol in patients undergoing long-term endoscopic sclerotherapy

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Abstract:

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A prospective randomized double-blind study was conducted to evaluate the efficacy of propranolol in patients with portal hypertension undergoing long-term endoscopic sclerotherapy (EST) for recurrent variceal bleeding. Consecutive patients with portal hypertension (Child's class A or B) due to cirrhosis (n = 72), non-cirrhotic portal fibrosis (n = 29) and extrahepatic portal venous obstruction (n = 13) attending the liver clinic of a tertiary care center were included in the study. All patients had had at least one documented episode of variceal bleed in the previous 4 weeks. Fifty-eight patients received propranolol and 56 received placebo in addition to weekly EST. Rebleeding occurred in 12 (21%) patients in the placebo group and 10 (17%) patients in the propranolol group during a mean follow-up period of 24.4 +/- 10.4 months in the former and 23.8 +/- 9.2 months in the latter group (P > 0.1). The number of episodes of rebleeding (14 in the placebo and 12 in the propranolol group) were also similar (P > 0.1). The median bleeding-free period was more than 40 months in both treatment groups (P > 0.1). The mean transfusion requirements and the number of hospital admissions for rebleeding were also similar in the two treatment groups (P > 0.1). Complete obliteration of varices was achieved in 44 (78.9%) patients in the placebo group and 43 (75.5%) patients in the propranolol group (P > 0.1). Recurrence of new varices was seen in two patients in the placebo and in three of those in the propranolol group. Seven patients in the placebo group and five in the propranolol group died (P > 0.1). Complications related to EST were similar in the two treatment groups but additional adverse effects were observed in the propranolol group. The cumulative incidence of rebleeding in the placebo group was 12.7 and in the propranolol group it was 11.2 per 100 patient years of follow-up. It is concluded that the addition of propranolol in patients with portal hypertension and fair hepatic function on long-term EST does not confer any additional benefit.