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A Randomized Controlled Comparative Study of Covered Versus Uncovered Self-Expandable Metal Stent for Malignant Biliary Obstruction

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BACKGROUND/AIM: Self-expandable metal stents (SEMS) with various designs have been developed to improve clinical efficacy for treatment of malignant biliary obstruction. However, a lot of articles previously published for SEM Sstudy reported a variety of efficacy of covered SEMS. **We performed this study to compare the safety and clinical efficacy of membrane-covered SEMS (Shim-Hanarostent, M.I.Tech, Seoul, Korea) and uncovered SEMS (Hanarostent, M.I.Tech, Seoul, Korea) in a prospective randomized controlled trial.**

METHODS: There were 43 consequent patients, including 26 men and 17 women, with a mean age of 70 years (range, 49-87) who were diagnosed as malignant biliary obstruction. The etiology of the strictures included pancreatic cancer (17), cholangiocarcinoma (17), ampullary cancer (4), and gall bladder cancer (5). Patients were randomly assigned to covered or uncovered stent. After insertion of the stent, we followed up symptoms, LFT and abdominal US. We performed ERCP & mother-baby scopy in occluded cases. In case of stent malfunction, we inserted plastic stent into the metal stent. The survival rates of the patient and the stent's patency rates were calculated using Kaplan-Meier survival analysis. Serum bilirubin, amylase and lipase levels were evaluated in regular interval, and the mean differences of these data before and after stenting were evaluated using a Wilcoxon signed-rank test. The average follow-up duration was median 5.3 months (range, 0.8-29 months).

RESULTS: Endoscopic procedures were successful (including complete relief of jaundice) in all cases. **Late complications such as tumor ingrowth etc. occurred in 11 of 21 patients with uncovered stents, as compared with 4 of 22 patients in the covered group** ($p < 0.05$). **Median stent patency of covered and uncovered stent were 216 days (range 76 to 760 days) and 127 days (range 25 to 447 days),** respectively ($p < 0.05$). Life table analysis showed similar survival in both groups.

CONCLUSION: **Membrane-covered selfexpandable biliary metal stents have a significantly better palliation than uncovered metal stents** in the treatment of patients with malignant biliary obstruction.

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