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ABSTRACT FINAL ID: S1427;

TITLE: Anchoring flap versus flared end of fully covered self-expandable metal stent for anti-migration effect in patients with benign biliary stricture: an interim analysis of multi-center prospective randomized trial

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ABSTRACT BODY: Background: Recently placement of fully covered self-expandable metal stent (FCSEMS) has been proposed as the alternative management of benign biliary stricture. However, stent migration was not uncommon due to the nature of an FCSEMS. Although an FCSEMS with anchoring fins for anti-migration have become available (Viabil, Conmed, Utica, NY), removal may be problematic because of the multiple anchoring fins, which caused the bile duct mucosal ulceration and bleeding as the FCSEMS was extracted.

Objective: To compare the efficacy including anti-migration effect and removal, and complication rates of newly designed distal anchoring flap (M.I.Tech, Seoul, South Korea) versus flared end (Standard Sci Tech, South Korea) of FCSEMS, we conducted this multi-center prospective randomized trial (registered as clinicaltrials.gov identifier: NCT00945516).

Patients: A total 39 patients with benign biliary stricture who were candidate for placement of FCSEMS were randomly assigned to the anchoring flap (20 patients; 6 in chronic pancreatitis, 12 in biliary stones, and 2 in post surgical of AF group) or the flared end of FCSEMS (19 patients; 6 in chronic pancreatitis, 10 in biliary stones, 1 in liver transplantation, and 2 in post surgical of FE group).

Results: Median duration of stent placement was 4 months (interquartile range 4-6 months). Median follow-up period was 7 months (interquartile range 6-9 months). 0% (of 20 patients) in AF group and 26 % (5 of 19 patients) in the FE group had stent migration (P=0.02; proximal migration in one, distal migration in two, and partial distal migration in two of FE group). In per protocol analysis, removal rate of FCSEMS was 100% in both groups (20/20 in AF and 17/17 in FE). Complete and partial resolution rate of biliary stricture was 90% (18/20) in AF and 88% (15/17) in FE group. Rate of post-stenting pancreatitis was 10% (2/20, mild grade) in AF and 5% (1/19, mild grade) in FE group. During follow-up periods, one had cholangitis in both group. During the endoscopic stent removal, sludge impaction without liver dysfunction was observed in one patient (5%, 1/20) in AF group and two patients (12%, 2/17) in FE group. There is no removal complication including pain and pancreatitis in both groups.

Conclusions: With regard to anti-migration effect of FCSEMS for benign biliary stricture, distal anchoring flap of FCSEMS may be superior to the distal flared end of FCSEMS. Up to 6months, both stents (AF and FE) can be endoscopically removed without removal complication.

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