



Feasibility of the placement of a novel 6-mm diameter threaded fully covered self-expandable metal stent for malignant hilar biliary obstructions (with videos)

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Background and Aims: Uncovered self-expandable metal stents (USEMSs) are used to treat unresectable malignant hilar biliary obstructions (MHBOs). However, ingrowth is not prevented, and reintervention is often troublesome. A novel 6-mm threaded fully covered self-expandable metal stent (T-FCSEMS) is available that may mitigate these issues. We aimed to clarify the safety and efficacy of T-FCSEMS placement for MHBO.

Methods: Thirty patients underwent T-FCSEMS placements for MHBOs between 2014 and 2015. T-FCSEMSs were used for initial stenting in 17 patients (initial group) and for reinterventions for USEMS occlusions caused by ingrowth in 13 patients (reintervention group). The technical success rates, times to recurrent biliary obstruction, and the reintervention success rates were evaluated.

Results: The technical success rates were 94% (16/17) and 92% (12/13) in the initial group and reintervention group, respectively. Intrahepatic bile duct occlusions caused liver abscesses 8 days and 22 days after T-FCSEMS placements in 2 cases (7%) in the initial group, in which T-FCSEMSs were placed across the intrahepatic bile duct bifurcation. The median times to recurrent biliary obstruction were 210 days in the initial group after bilateral placement and 112 days and 152 days in the reintervention group after bilateral and unilateral placements, respectively. During reintervention, T-FCSEMS removal was successful in all patients in whom it was attempted, and the success rate of endoscopic reintervention was 100% in both groups.

Conclusions: T-FCSEMS placement is a promising option for both initial stenting and reintervention for MHBO. However, we should consider the possibility of intrahepatic bile duct occlusion.

For biliary drainage of an unresectable malignant hilar biliary obstruction (MHBO), an uncovered self-expandable metal stent (USEMS) has better long-term patency than a plastic stent.^{1,2} However, the optimal drainage method, including the most suitable stent, is

under debate.^{3,4} Recently, chemotherapy has advanced,⁵ and thus, recurrent biliary obstruction (RBO) often occurs even when a USEMS is deployed,⁶ and reintervention is required. However, it can be difficult for a USEMS to prevent tumor ingrowth, and it can

Abbreviations: MHBO, malignant hilar biliary obstruction; RBO, recurrent biliary obstruction; T-FCSEMS, 6-mm threaded fully covered self-expandable metal stent; USEMS, uncovered self-expandable metal stent.

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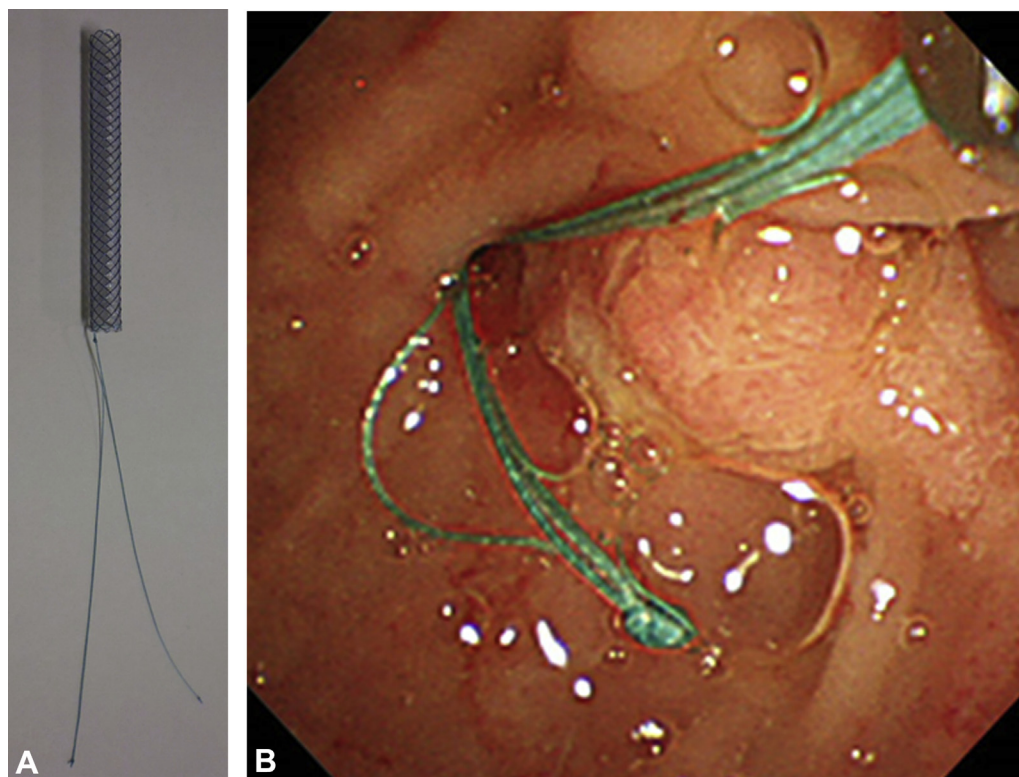


Figure 1. The novel 6-mm threaded fully covered self-expandable metal stent (TaeWoong Medical Co, Ltd, Seoul, Korea). **A**, The thread is tied to the duodenal side of the stent. **B**, The threads are drawn from the duodenal papilla into the duodenum.

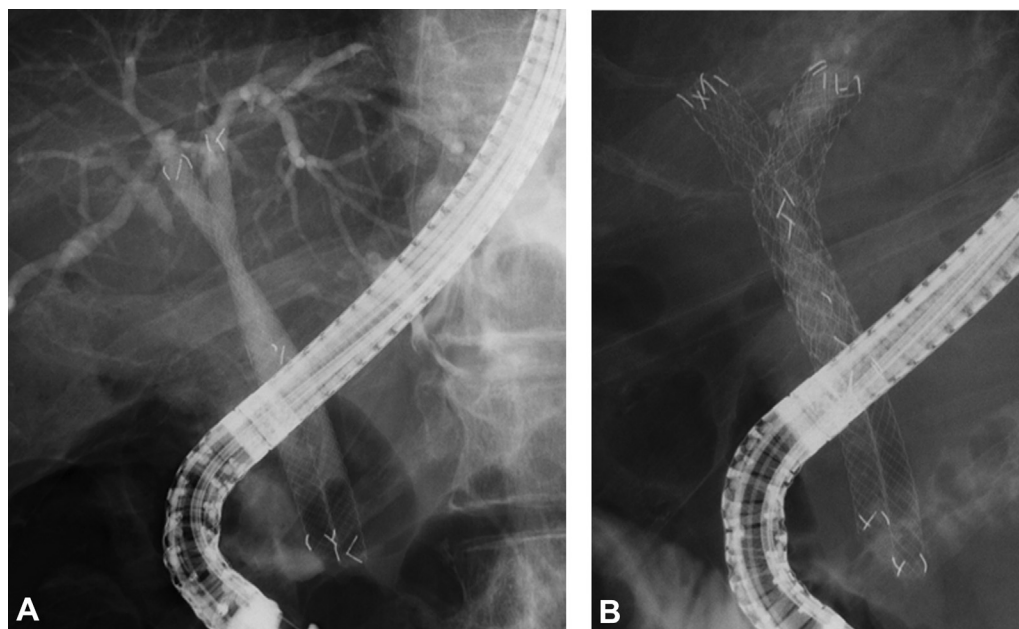


Figure 2. **A**, A threaded fully covered self-expandable metal stent is placed by using the side-by-side method as initial stenting of the left and right ducts. **B**, A case of occlusion caused by tumor ingrowth after the placement of an uncovered self-expandable metal stent by using the partial stent-in-stent method; a threaded fully covered self-expandable metal stent is placed to cover the site of ingrowth.

never be removed; thus, reintervention for RBO is often troublesome.^{4,6}

A novel 6-mm threaded fully covered self-expandable metal stent (T-FCSEMS) is available that may mitigate these issues.

Using this novel stent prevents tumor ingrowth, and reintervention may be more straightforward because the stent can be removed. This study aimed to clarify the safety and efficacy of the placement of the novel T-FCSEMS for MHBO.

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