Newly Developed Two-in-one Covered and Uncovered Metal Stent for Inoperable Malignant Distal Biliary Obstruction

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- **CONFLICT OF INTERESTS**

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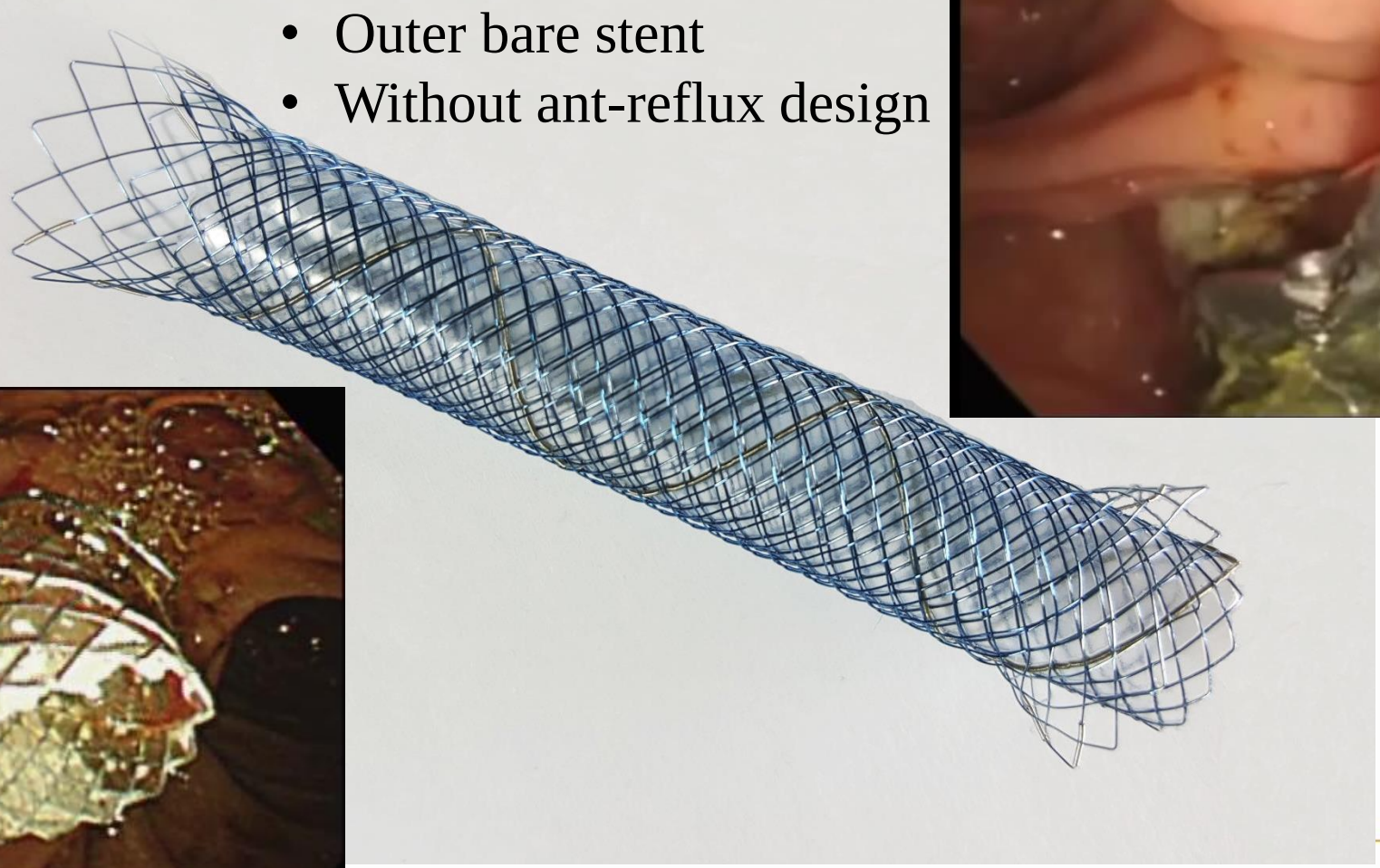
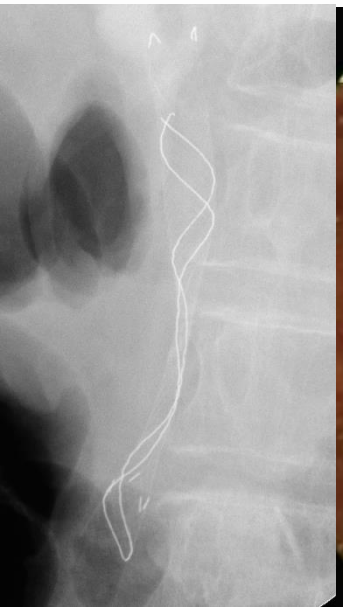
Introduction

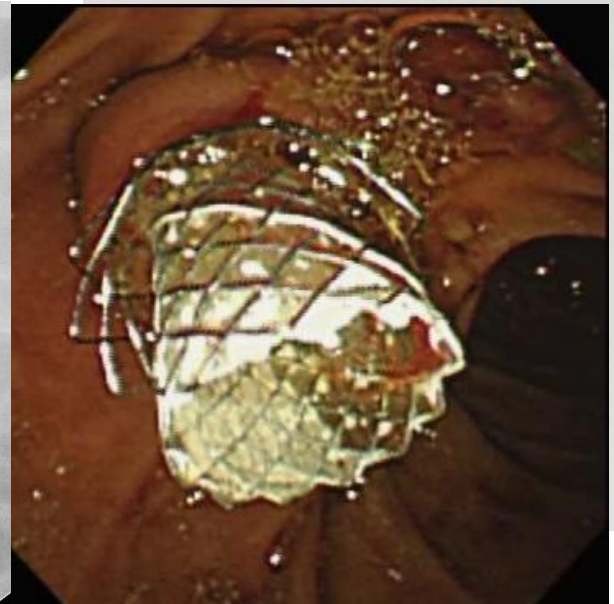
- Endoscopic placement of a biliary metal stent is a principle palliative method for inoperable malignant distal biliary obstruction.
- One-time stent insertion for the rest of patients' life
- Stent designs to overcome the biliary stent dysfunction
  - Bile encrustation : large diameter metal stent
  - Tumor ingrowth : covering material
  - Stent migration : bare metal mesh
  - Food influx : anti-reflux design
  - Tumor overgrowth : -

Two-in-One Biliary Metal Stent

- Inner covered stent
- Outer bare stent
- Without ant-reflux design





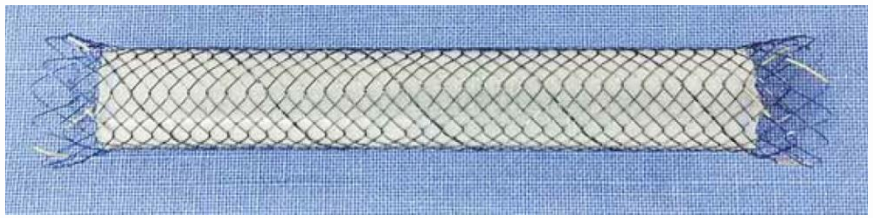


Study Aims

- We aimed to evaluate the clinical efficacy and safety of a newly developed Two-in-one covered and uncovered SEMS (Two-in-one stent®) in patients with inoperable malignant distal biliary obstruction, and compare its outcomes with conventional partially covered SEMS.

Patients

- Two-in-one stent group (n=58)
  - Prospectively between May 2016 and April 2019
  - Patents with a follow-up period of > 6months
  - Two-in-one stent (Taewoong Medical, Korea)
- Conventional stent group (n=51)
  - between January 2010 and October 2014
  - conventional partially covered SEMS (Bonastent, Standard Sci Tec, Korea)



Results

- The patient survival times were 163 days and 219 days in the Two-in-one and conventional groups (*P*=0.957).
- The covered stent (inner stent) dysfunction occurred in 14 patients (24.1%) in the Two-in-one group and 17 (33.3%) in the conventional group (*P*=0.288).

Results

- Inner covered stent removal was successful in all 14 patients.
- The third quartile covered stent patency time was 197 days in the Two-in-one group and 184 days in the conventional group (P=0.112).
- Overall stent patency was significantly longer in the Two-in-one than in the conventional group (mean: 891 vs. 299 days, P<0.001).

Conclusions

- Endoscopic placement of a newly developed Two-in-one covered and uncovered SEMS is feasible and effective and may be a promising option for inoperable malignant distal biliary obstruction.