Innovation of EUS-guided Transmural Gallbladder Drainage using a Novel Self-Expanding Metal Stent

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Disclosure

- Dr. Sang Hyub Lee is the inventor of the Tornado stent.
- Gyeong Hwan Kim is full-time employee of S&G Biotech Inc.
- Sung Gwon Kang is CEO of S&G Biotech Inc.
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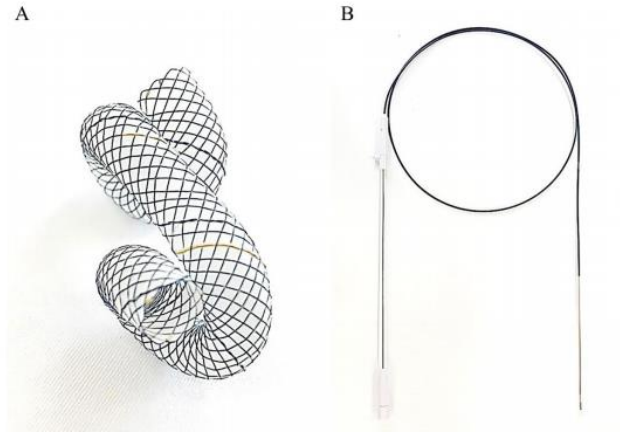
Objective

- To evaluate the feasibility the feasibility, safety and removability of Tornado stent in EUS-guided transmural gallbladder drainage using pig models

Development of novel stent

- **Tornado stent**
  - ✓ **<u>A newly designed twisted fully covered SEMS with spiral coiled ends</u>**
  - ✓ Made of nitinol wire and fully covered with silicone
  - ✓ 8mm (diameter) x 9cm (length; straight 3cm, both coiled ends 3cm)
  - ✓ 8F delivering catheter



- **Expected advantages**
  - ✓ **<u>Relatively large diameter</u>** (stent patency) – *compared to plastic stent*
  - ✓ **<u>Sufficient anchoring capability</u>** (lower risk of bidirectional migration) – *compared to conventional FC-SEMS*
  - ✓ **<u>Easy removal</u>** after formation of the fistula (lower risk of buried stent, bleeding) – *compared to LAMS*

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Methods

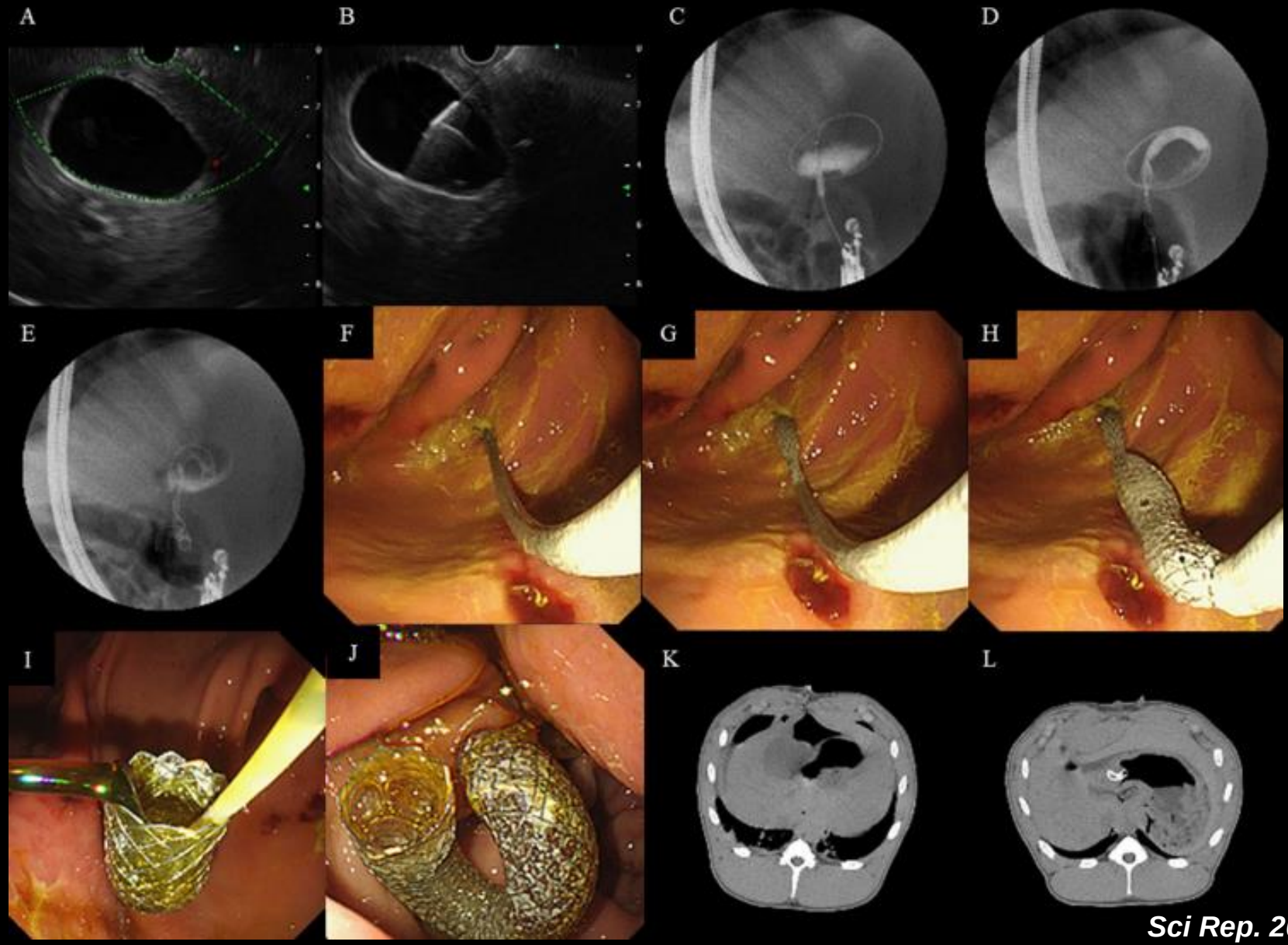
- **Steps of experiment**
- **Preparation of animal model**
  - ✓ Eight male mini pigs (*Sus scrofa*) weighing 24 – 36kg
  - ✓ Ligation of common bile duct (CBD) (D-5)

- **Procedures**
  - EUS-guided cholecysto-gastrostomy (stent insertion)
  - **Monitoring of adverse events**
    - ✓ **28 days (n=2), 35 days (n=2), 42 days (n=2), 49 days (n=2)**
  - Follow-up endoscopy (stent removal)
    - ✓ Stent patency, migration, removability, fistula track formation
  - **Necropsy**

- **Primary outcome**
  - ✓ **Technical success**
    - Successful placement of a stent between the gallbladder and the stomach

- **Secondary outcomes**
  - ✓ Adverse events
  - ✓ Stent dysfunction because of migration or occlusion
  - ✓ Stent removability
  - ✓ Presence of cholecysto-gastric fistula track in radiologic and histopathologic exams

EUS-guided cholecysto-gastrostomy using Tornado stent



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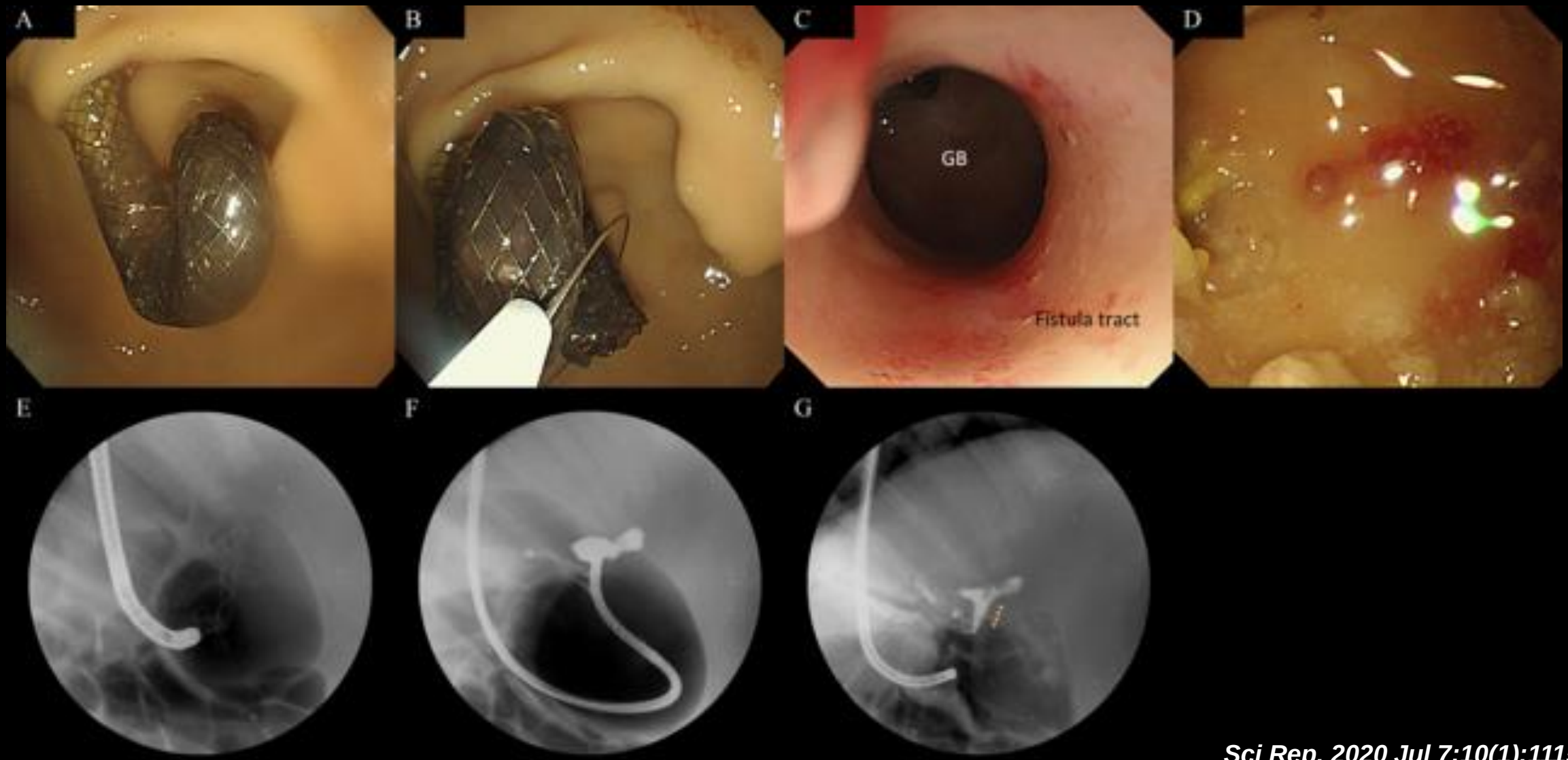
Stent removal and evaluation of GB lumen through the fistula tract

Scheduled removal at 28 days (n=2), 35 days (n=2), 42 days (n=2), 49 days (n=2)



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Results

	Technical success	Procedure time[a] (minutes)	Maintenance period (days)	Patent stent	Removal success	Adverse event		Fistula tract
						Early	Late	
Pig 1	Y	42	28	Y	Y	N	N	Y
Pig 2	Y	31	28	Y	Y	N	N	Y
Pig 3	Y	21	35	Y	Y	N	N	Y
Pig 4	Y	24	35	Y	Y	N	N	Y
Pig 5	Y	22	42	Y	Y	N	N	Y
Pig 6	Y	19	42	Y	Y	N	N	Y
Pig 7	Y	13	49	Y	Y	N	N	Y
Pig 8	Y	15	49	Y	Y	N	N	Y

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Summary

- This animal study demonstrated the **feasibility, safety, and removability** of EUS-guided transmural gallbladder drainage using newly developed stents (Tornado stent)
  - ✓ Feasible, technically easy
  - ✓ Successful stent removal and fistula track formation at **28 – 49 days**
  - ✓ Passage of slim endoscope through the fistulae was possible
  - ✓ No adverse event

- **Potential advantages** of Tornado stent
  - ✓ Twisted ends could minimize risk of **stent migration**
  - ✓ Relatively flexible ends could minimize risk of **serious adverse events** like bleeding or buried stents

Conclusion

- Tornado stent might be expected to be **another good option for endoscopists** to avoid the technical difficulties and complications in other types of stents in the near future.

- **Further clinical studies in patients with different clinical settings** are warranted to prove its feasibility, safety and efficacy in real practice