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Fully covered self-expanding metal stents for endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous cholangiography (PTC) in the management of malignant biliary obstruction: A U.S. cost consequence analysis.

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Background

- ERCP and PTC are commonly performed procedures in the management of malignant biliary obstruction.[1]
- Randomized controlled trials have demonstrated that fully covered self-expandable metal stents (FCSEMS) provide lower rates of stent dysfunction compared to bare or partially covered self-expandable metal stents.
- However, stent migration remains a challenging adverse event associated with FCSEMS, resulting in re-interventions and secondary complications.[1]

Objectives:

- To compare the migration and patency rates of two fully covered self-expanding metal stents available in the U.S.
- Determine the budget impact for re-interventions from the perspective of the U.S. payer.

Meta-analysis study design

Hierarchy of evidence for all interventions and comparators:

- Randomized control trials
- Retrospective comparative observation studies
- Retrospective observation studies (single arm) with n > 10 patients.

Exclude: Case reports, conference abstracts, animal studies

PICO table descriptions

Time frame and setting: Studies published from January 2000 through September 2021 in all countries

24 STUDIES
- Met the inclusion criteria

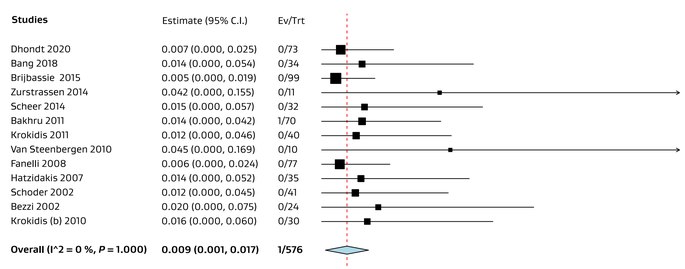
INTERVENTIONS/COMPARATORS
- Include GORE® VIABIL® Short Wire Biliary Endoprosthesis and BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
- Exclude bare metal stent

POPULATION
- Malignant biliary obstruction

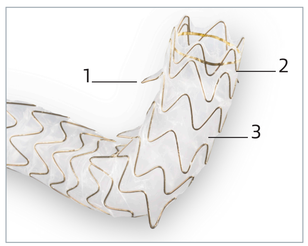
OUTCOMES
- Migration
- Patency

VIABIL® Device forest plot – migration

13 STUDIES 576 PATIENTS



Average migration rate: 0.9% (0.1% - 1.7%)

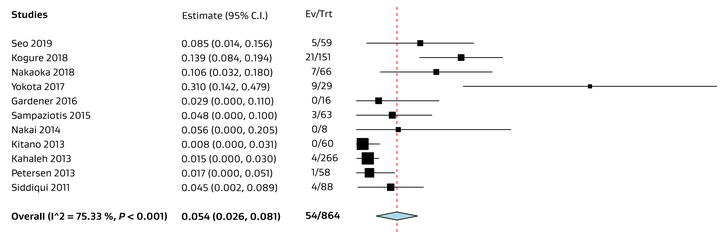


Designed to demonstrate low migrations:

1. **Atraumatic anchoring fins**[3]
   Holds the device within the duct to minimize migration
2. **Nitinol-based stent**[3]
   Stent design has low axial : Moderate radial force
3. **FEP/ePTFE liner covering entire stent**[2,3,8]
   Allows for conformability and reduces tissue in-growth

WALLFLEX Device forest plot – migration

11 STUDIES 864 PATIENTS



Average migration rate: 5.4% (2.6%–8.1%)

Health economics data

	GORE® VIABIL® Device	WALLFLEX Device
Migration rate	0.9%	5.4%
Estimated number of re-interventions to manage migration	1	6
Estimated patency at 6 months[4-10]	83.4%	62.6%
Estimated number of re-interventions	17	38
Total number of re-interventions per year	18	44
Estimated additional cost due to ERCP (Stent + Procedure)*	$130,600	$331,537

*The average cost of a hospital inpatient ERCP with stent placement for patients without complications is approximately $5,029 (CMS database, 2021).

Estimated cost savings with GORE® VIABIL® Device per year (assuming 100 patients): **$200,937**

Conclusions

- GORE® VIABIL® Device is more cost-effective for the management of malignant biliary obstruction compared to the WALLFLEX Device.
- This potential cost-saving is driven by a reduction in the rate of migration, patency, and associated ERCP procedures.
- Robust studies may still be required comparing efficacy of:
  – FCSEMS and multiple plastic stents (MPS).
- Different FCSEMS, to inform clinical and economic decision making at a national level.

References

1. Medicine. 2021;100(3):e23938. **2.** Am J Gastroenterol. 2013;108(11):1713-1722. **3.** Gastrointest Endosc. 2009;70(1):37-44. **4.** J Vasc Interv Radiol. 2002;13(6):581-589. **5.** Eur Radiol. 2008;18(5):911-919. **6.** Cardiovasc Intervent Radiol. 2007;30(5):950-958. **7.** J Clin Gastroenterol. 2013;47(8):695-699. **8.** Cardiovasc Intervent Radiol. 2011;34(2):352-361. **9.** BMC Gastroenterol. 2017;17(1):105. **10.** Minim Invasive Ther Allied Technol. 2014;23(6):366-373.

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