

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 selfexpandable 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

Retrospective comparative observation studies

Retrospective observation studies (single arm) with n > 10 patients.

Exclude: Case reports, conference abstracts, animal studies

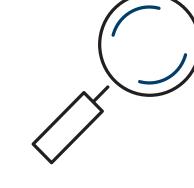
PICO table descriptions

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



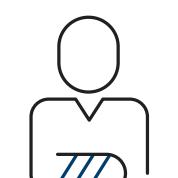
24 STUDIES

Met the inclusion criteria



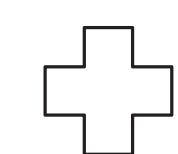
INTERVENTIONS/COMPARATORS

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



POPULATION

Malignant biliary obstruction



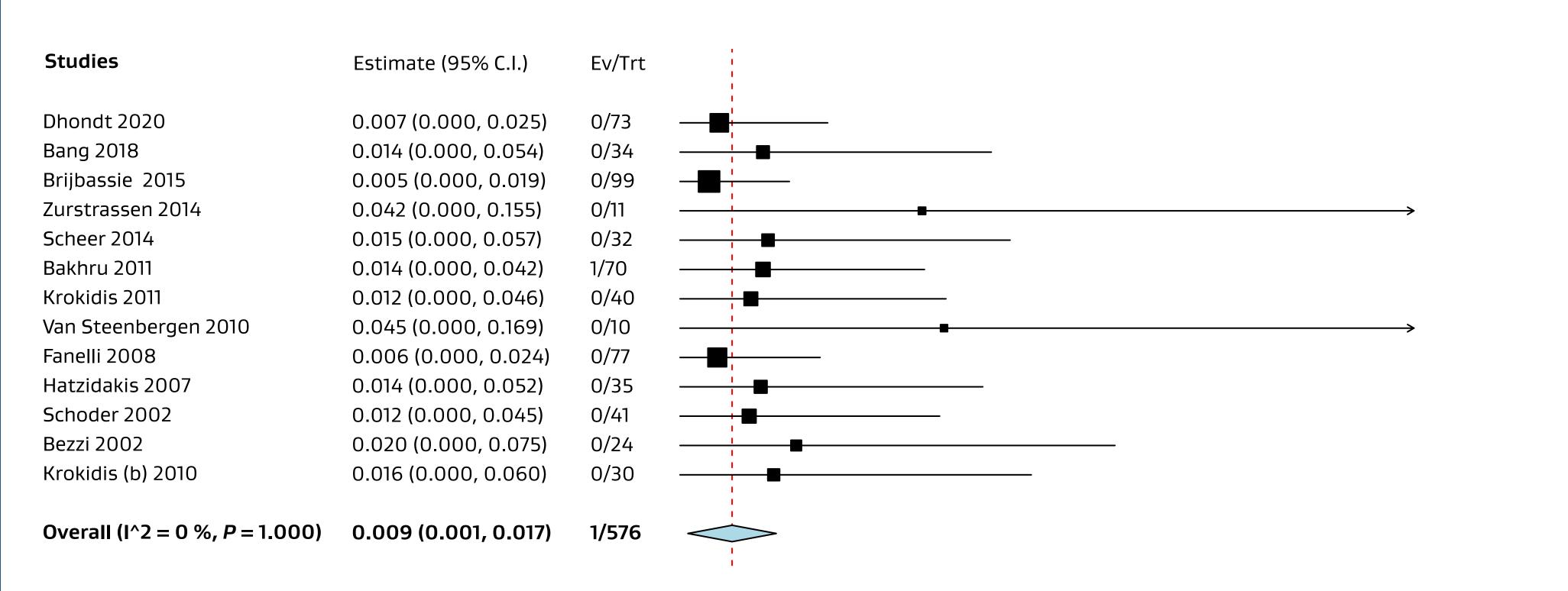
OUTCOMES

- Migration
- Patency

VIABIL® Device forest plot – migration







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

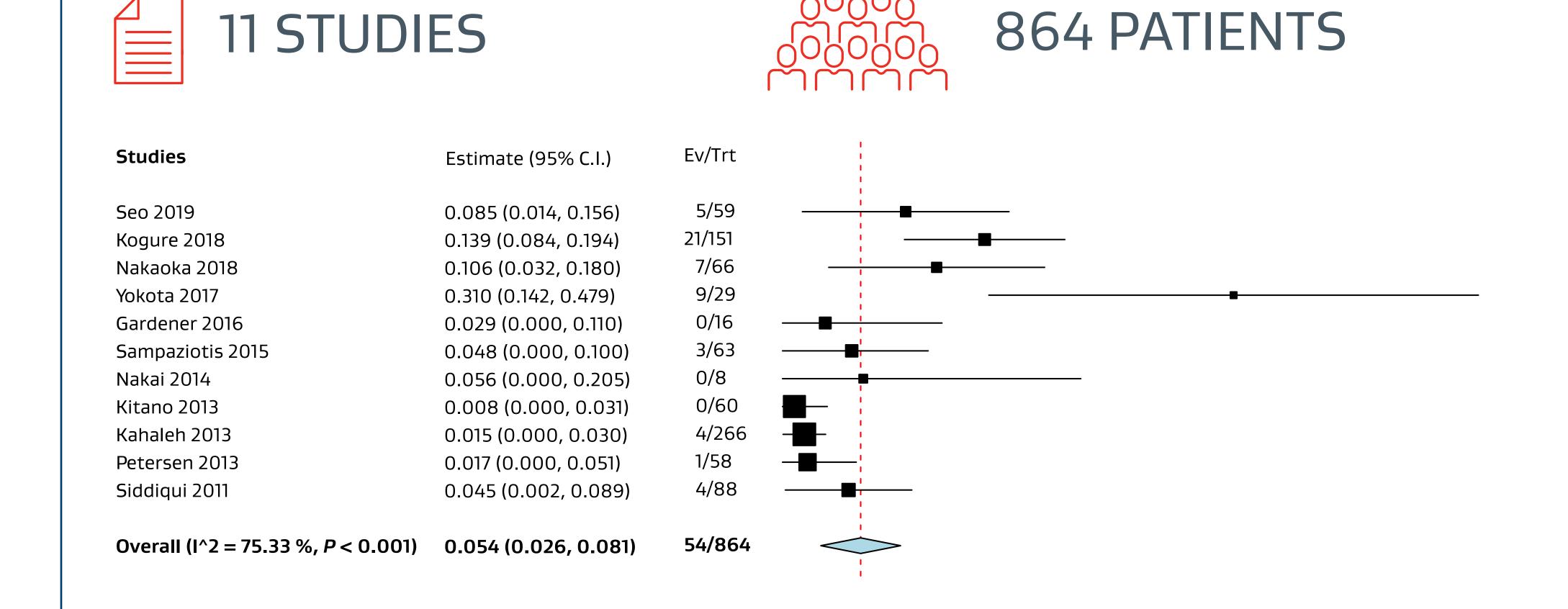
Designed to demonstrate low migrations:

. Atraumatic anchoring fins³ Holds the device within the duct to minimize migration

2. Nitinol-based stent³ 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



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		

Estimated cost savings with GORE® VIABIL® Device per year (assuming 100 patients):

\$200,937

Conclusions

is approximately \$5,029 (CMS database, 2021).

- 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