Short-term outcome of Colonic Stent (WallFlex) prospective feasibility study

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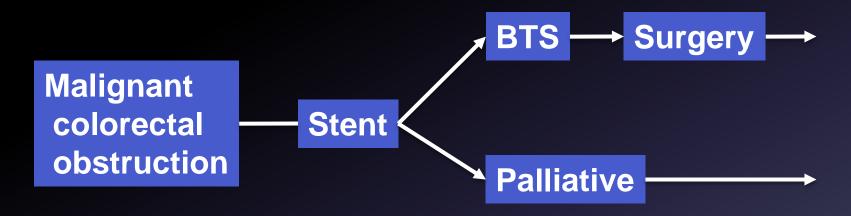
Conflicts of Interest

The author have no financial conflicts of interest.

Background and Aims

- ➤ The self-expandable metal stent (SEMS) can alleviate malignant colonic obstruction and avoid emergency decompression surgery.
- ➤ The colorectal SEMS was not approved by the Japanese Ministry of Health, Labour and Welfare until 2011.
- ➤ The aim of our study was to evaluate the efficacy and safety of SEMS in patients with malignant colorectal obstruction.

Short term outcome within 7 days



- Study design: Prospective, Observational study
- Technical success rate
- Clinical success rate
- Safety profiles: short term



Inclusion/ Exclusion criteria

- ➤ Patients requiring palliative and bridge to surgery treatment of colorectal obstruction by malignant neoplasms.
- Only patients with no previous colonic stenting will be included in the registry.
- Previous colonic stent placement
- Enteral ischemia
- Suspected or impending perforation
- Intra-abdominal abscess/perforation
- Contra-indication for endoscopic procedure
- Benign stricture
- Any use of the stent except outlined indication for use

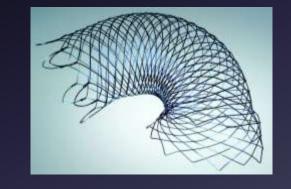
Device and Procedure

➤ WallFlex Enteral Colonic Stent (Boston Scientific)

Uncovered type

Diameter 22 and 25mm

Length 6, 9, and 12cm



Under endoscopic and fluoroscopic guidance

Patient cohorts

N=517: Procedural Success Analysis Enrolled Patients (ITT)

5 excluded

3 not enough stenosis

1 no evidence of stenosis

1 benign stricture

N=512: Per-protocol Analysis Cohort

Baseline characteristics 1

		N=512
Age, median(range), yea	ars 72	2 (25-101)
Sex, male/female, n	2	289/ 223
Symptoms of obstruction	on	
Constipation, %		90.0
Abdominal pain/ cram	nps, %	72.5
Bloating, %		79.7
Nausea/ Vomiting, %		47.1
Performance Status		
0/ 1/ 2/ 3/ 4, n	<mark>221/ 13</mark> 6/	64/66/25
CROSS		
0/ 1/ 2/ 3/ 4, n	183/ 150 <i>/</i>	72/77/30



Technical success data

	% (n/512)
Yes	97.9 (501)
No	2.1 (11)
Impossible to pass guidewire	1.4 (7)
Perforation by guidewire	0.4 (2)
Perforation by ERCP catheter	0.2 (1)
Not accessible by endoscope	0.2 (1)

Clinical success data

Clinical success defined as a resolution of symptoms and radiological relief of the obstruction within 24 h.

	% (n/512)
Yes	96.1 (492)
No	3.9 (20)
No technical success	2.1 (11)
Poor expansion	0.6 (3)
Perforation	0.6 (3)
Inadequate decompression	0.2 (1)
Multiple obstruction	0.4 (2)

Safety profile within 7days

	% (n/492)
Migration	1.6 (8)
Re-obstruction	1.2 (6)
Perforation	0.6 (3)
Multiple-obstruction	0.4 (2)
Tenesmus	0.2 (1)
Appendicitis	0.2 (1)

Summary

- >Technical success rate was 97.9%.
- Clinical success rate within 24h was 96.1%.
- **▶ Perforation rate was 1.8% (9/512).**

Conclusion

In our multicenter prospective study, the WallFlex Colonic Stent provided a safe and highly successful short-term treatment of malignant colorectal obstruction.