

# 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.

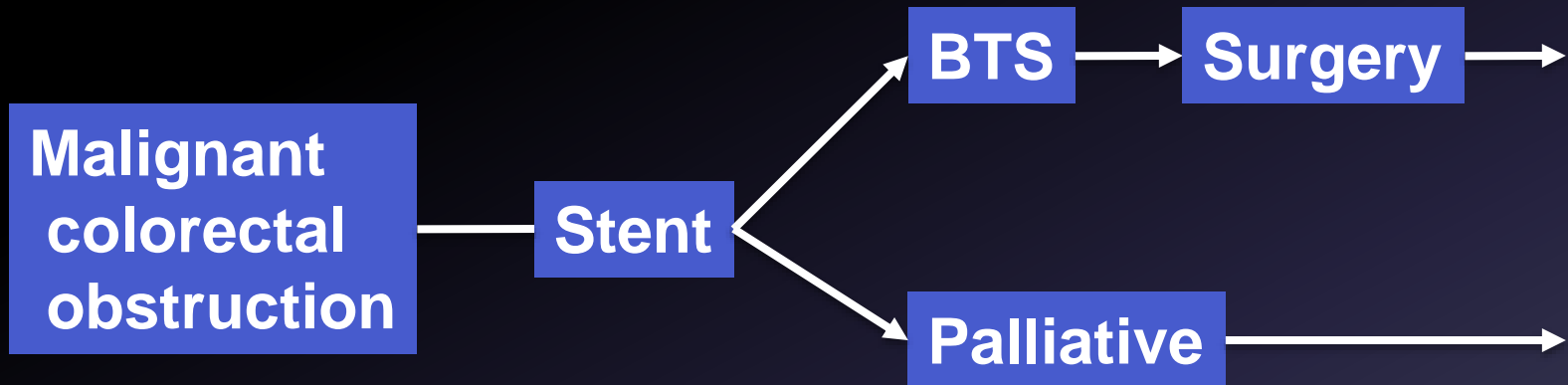


# Background and Aims

- 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



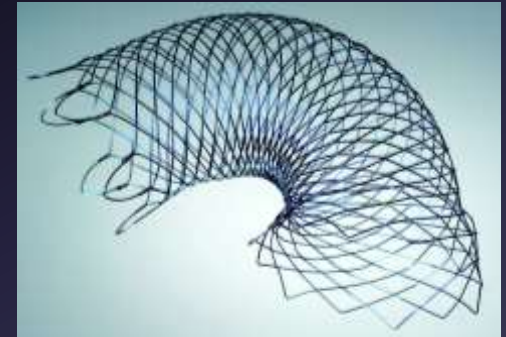
# Device and Procedure

- 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

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	<b>N=512</b>
<b>Age, median(range), years</b>	<b>72 (25-101)</b>
<b>Sex, male/female, n</b>	<b>289/ 223</b>
<b>Symptoms of obstruction</b>	
<b>Constipation, %</b>	<b>90.0</b>
<b>Abdominal pain/ cramps, %</b>	<b>72.5</b>
<b>Bloating, %</b>	<b>79.7</b>
<b>Nausea/ Vomiting, %</b>	<b>47.1</b>
<b>Performance Status</b>	
<b>0/ 1/ 2/ 3/ 4, n</b>	<b>221/ 136/ 64/ 66/ 25</b>
<b>CROSS</b>	
<b>0/ 1/ 2/ 3/ 4, n</b>	<b>183/ 150/ 72/ 77/ 30</b>

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# Technical success data

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	% (n/512)
<b>Yes</b>	<b>97.9 (501)</b>
<b>No</b>	<b>2.1 (11)</b>
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)

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# Clinical success data

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

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

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# Safety profile within 7 days

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

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# 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.**

