

Kuwai, Toshio¹; Kyo, Rika²; Yoshida, Shuntaro³; Isayama, Hiroyuki⁴; Yamada, Tomonori⁵; Maetani, Iruru⁶; Sumida, Yorinobu⁷; Tomita, Masafumi⁸; Matsuzawa, Takeaki⁹; Moroi, Rintaro¹⁰; Kushiyama, Yoshinori¹¹; Matsushita, Hiro-o¹²; Saito, Shuji¹³; Hirakawa, Tomio¹⁴; Saida, Yoshihisa¹⁵,

¹Department of Gastroenterology, Kure Medical Center and Chugoku Cancer Center, Kure. ²Department of Gastroenterology, Saiseikai Yokohamashi-Nambu Hospital, Yokohama. ³Department of Endoscopy and Endoscopic Surgery, The University of Tokyo, Tokyo. ⁴Department of Gastroenterology, The University of Tokyo, Tokyo. ⁵Department of Gastroenterology, Japanese Red Cross Nagoya Daini Hospital, Nagoya. ⁶Division of Gastroenterology and Hepatology, Department of Internal Medicine, Toho University Ohashi Medical Center, Tokyo. ⁷Department of Gastroenterology, Kyushu Medical Center, Fukuoka. ⁸Department of Digestive and General Surgery, Kishiwada Tokushukai Hospital, Osaka. ⁹Department of Digestive and General Surgery, Uonuma Institute of Community Medicine, Niigata University Medical and Dental Hospital, Minamiuonuma. ¹⁰Department of Gastroenterology, Iwate Prefectural Isawa Hospital, Oshu. ¹¹Department of Gastroenterology, Matsue Red Cross Hospital, Matsue. ¹²Digestive Disease Center, Akita Red Cross Hospital, Akita. ¹³Division of Surgery, Gastrointestinal Center, Yokohama Shin-Midori General Hospital, Yokohama. ¹⁴Department of Gastroenterology, Toyonaka Midorigaoka Hospital, Osaka. ¹⁵ Department of Surgery, Toho University Ohashi Medical Center, Tokyo, Japan.

INTRODUCTION

- Endoscopic stenting with self-expandable metallic stents (SEMSs) is a widely accepted procedure for treating malignant colonic obstruction.
- This procedure was included under the coverage of National Health Insurance in Japan in January 2012.
- We formed the Colonic Stent Safe Procedure Research Group to compile instructions regarding safe stenting procedures, and conducted the present prospective feasibility study of palliation (PAL) using SEMS for treating malignant colorectal obstruction in Japan.

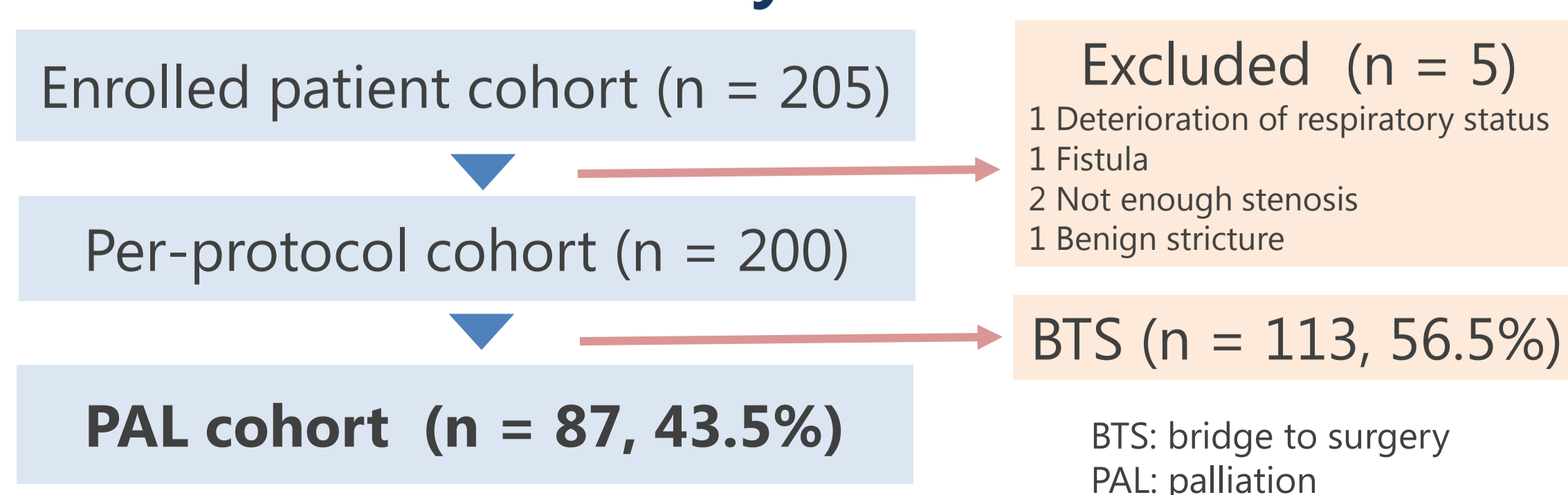
AIMS

Our objectives were to estimate the long-term efficacy and feasibility of palliative stenting with SEMS for treating malignant colorectal obstruction in a Japanese population.

METHODS

We conducted a prospective, observational, single-arm, multicenter clinical trial from October 2013 to May 2014. Thirty-two facilities participated in this study. An uncovered Niti-S™ D type Enteral Colonic Stent (Taewoong Medical) was placed in each patient. Patients who underwent palliative stenting were followed up for 1 year after SEMS placement or death.

Patient analysis flow chart



RESULTS

Patient characteristics in PAL cohort

Age, years, median (range)	78 (61-85)
Sex, male, % (no)	48.3 (42/87)
ECOG performance status, % (no)	
0	17.2 (15/87)
1	29.9 (26/87)
2	27.6 (24/87)
3	20.7 (18/87)
4	4.6 (4/87)
Etiology of colorectal obstruction, % (no.)	
Primary colorectal cancer	69.0 (60/87)
Locally recurrent colorectal cancer	2.3 (2/87)
Other extrinsic origin	28.7 (25/87)
Symptoms of obstruction, % (no.)	97.5 (195/200)
CROSS before stent placement, % (no)	
0	31.0 (27/87)
1	20.7 (18/87)
2	24.1 (21/87)
3	19.5 (17/87)
4	4.6 (8/87)

Tumor characteristics in PAL cohort

Complete obstruction, % (no.)	79.3 (69/87)
Location of obstruction, % (no)	
Left	58.6 (51/87)
Right	40.2 (35/87)
Both	1.1 (1/87)
Stricture length, cm, median (range)	4 (3-7)

Long-term outcomes in PAL cohort

The overall survival rate at 1 year after SEMS placement, %	35.4
The stent patency probability at 1 year after SEMS placement, %	78.9

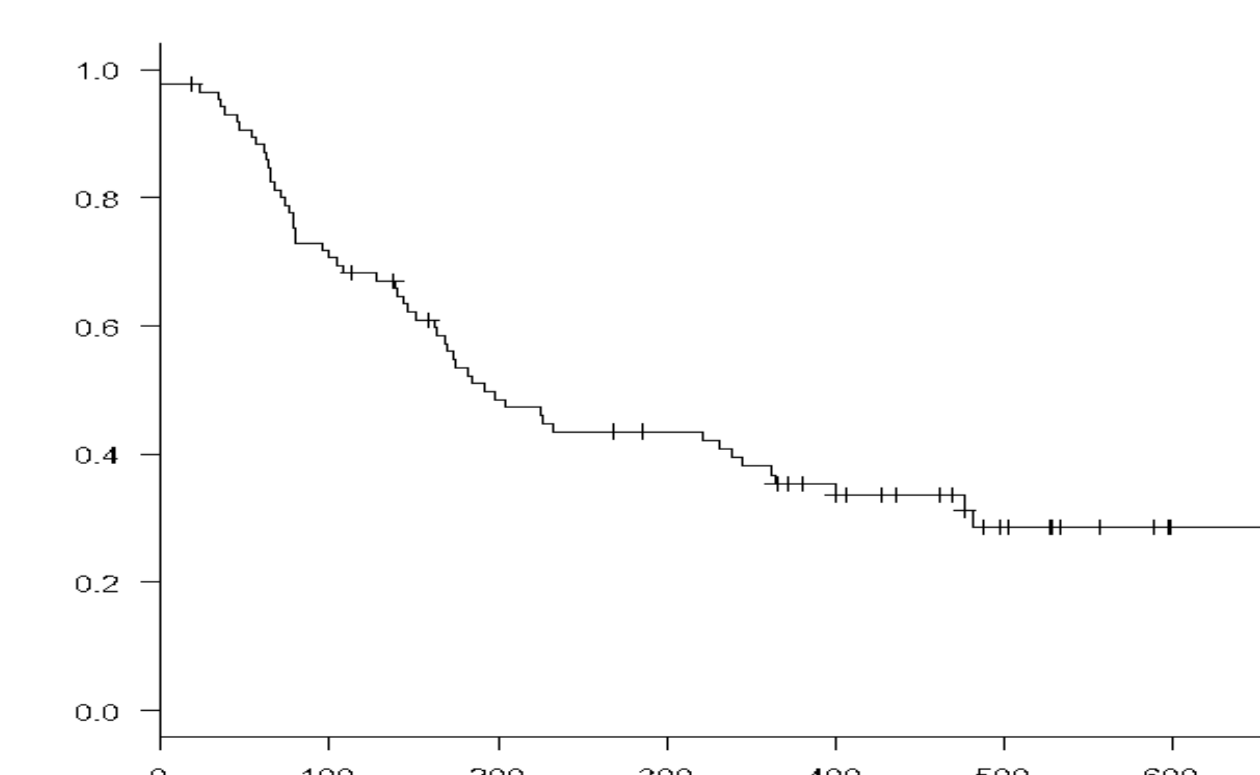
Technical and clinical success rates in PAL cohort

Technical success rate, % (no.)	97 (84/87)
Procedure time, min (mean) ± SD	37.2 ± 22.8
Clinical success rate, % (no.)	92 (80/87)
Clinical failure, % (no.)	
Insufficient expansion of stent	1 (1/87)
Acute respiratory failure	1 (1/87)
Sepsis	1 (1/87)
Stent migration	1 (1/87)
Chemotherapy after SEMS, % (no.)	30 (26/86)

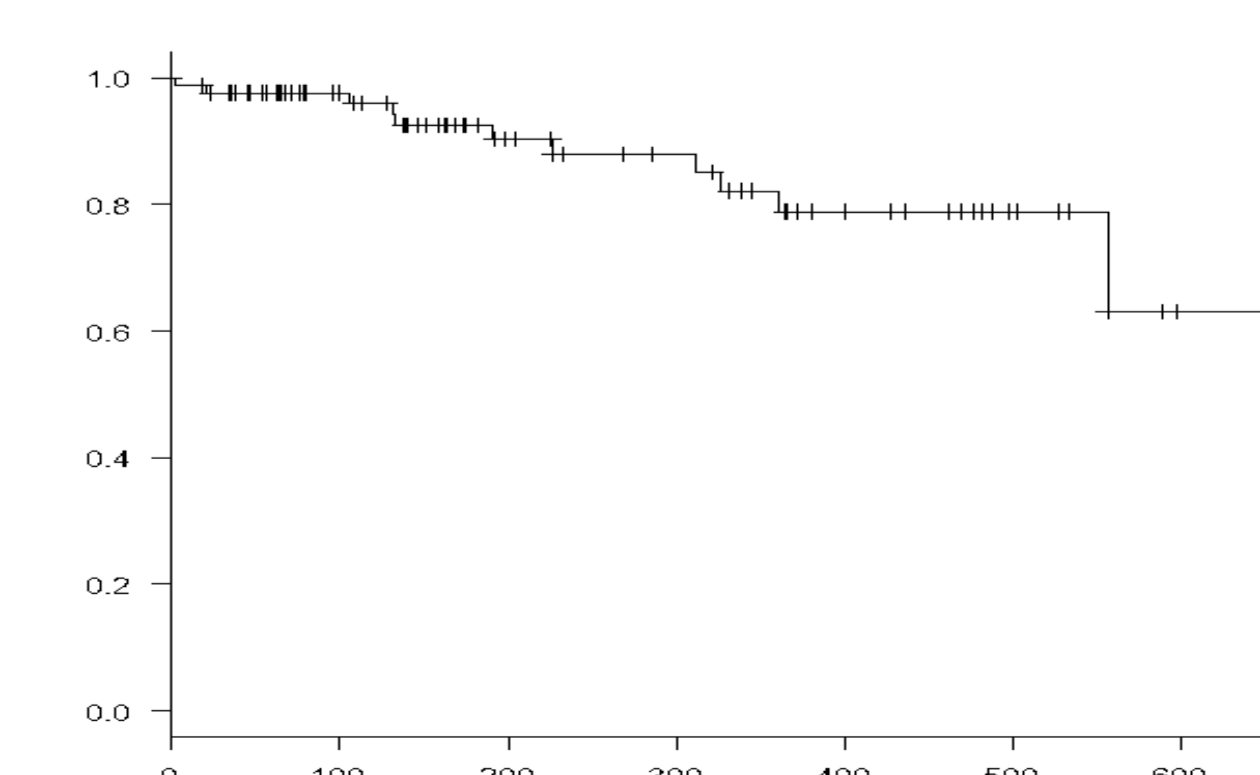
Complication rates and mortality in PAL cohort

The overall complication rate (including minor), % (no)	33.4 (33/87)
Perforation	2.3 (2/87)
Stent migration	6.9 (6/87)
Stent occlusion due to tumor ingrowth/overgrowth	9.2 (8/87)
Stent occlusion due to fecal impaction	1.1 (1/87)
Insufficient stent expansion	2.3 (2/87)
Sepsis due to obstructive colitis	1.1 (1/87)
Gastrointestinal obstruction due to other site	6.9 (6/87)
Poor peristalsis due to peritoneal dissemination	1.1 (1/87)
Acute respiratory failure	1.1 (1/87)
Mortality, % (no)	2.3 (2/87)
Acute respiratory failure immediately after stent placement	1.1 (1/87)
Sepsis due to obstructive colitis	1.1 (1/87)

Overall survival rate



Stent patency probability



SUMMARY

- 200 patients constituted the per-protocol cohort. Of these, 113 patients (56.5%) underwent stenting as BTS and 87 (43.5%) for PAL.
- Colorectal obstruction was caused by primary colorectal cancer in 60 patients (69.0%), locally recurrent colorectal cancer in two patients (2.3%), and other malignant diseases in 25 patients (28.7%).
- The technical and clinical success rates were 96.6% (84/87) and 91.9% (80/87), respectively.
- Twenty-six patients (30.2%) received chemotherapy after SEMS placement.
- The overall complication rate (including minor complications) was 33.4% (33/87). Major complications included perforation in 2.3% (2/87) patients, stent occlusion in 10.3% (9/87) patients, gastrointestinal obstruction at another site in 6.9% (6/87) patients, and stent migration in 6.9% (6/87) patients.
- Two patients (2.3%) succumbed to complications, and both died within 7 days after the stent placement.
- The overall survival rate 1 year after a SEMS placement was 35.4%. The stent patency probability 1 year after a SEMS placement was 78.9%.

CONCLUSION

This large, multicenter, prospective study demonstrated the feasibility of palliative stenting with SEMS for a malignant colorectal obstruction. SEMS was a safe and effective procedure for palliation in malignant colonic obstruction.

DDW 2017 CONFLICT OF INTERESTS Toshio Kuwai

I and some co-authors have the following financial relationships to disclose.
 Honoraria from: Boston Scientific Japan, Century Medical Inc., ZEON Co., Taewoong Medical Devices Inc., Piolax Medical Device Inc., MC Medical Inc., and Olympus Medical Systems Coep.
 Dr. Hiroyuki Isayama has the following financial relationships to disclose.
 Grant / Research funding form: Boston Scientific Japan, Century Medical Inc.
 Dr. Yoshihisa Saida has the following financial relationships to disclose.
 Grant / Research funding form: Olympus Medical Systems Coep.