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# Palliative surgical outcome score (PSOS) in patients treated palliatively with self-expanding metal stent (SEMS) for malignant incurable colorectal obstruction

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## ARTICLE INFO

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## ABSTRACT

**Aim:** The palliative surgical outcome score (PSOS) was proposed for evaluation of the effect of palliative surgical interventions. As a surrogate measure for successful symptom control, it is defined as the proportion of days outside the hospital of the remaining life time up to six months after a palliative intervention. In this study we evaluate the PSOS in patients treated palliatively with self-expanding metal stents (SEMSs) for incurable malignant colorectal obstruction.

**Methods:** All eligible patients endoscopically treated with palliative intent with SEMSs were identified. Demographics and clinical characteristics, including complete follow-up, were recorded, and the PSOS was calculated. Non-parametric tests were used for comparisons, and survival was evaluated by univariable and multivariable analyses.

**Results:** Between 2005 and 2013, 116 patients (median age 71.5 years; 53.4% women) were identified. Most obstructions were caused by primary colorectal cancers. Technical- and clinical success rates were 94.0% and 87.1%, respectively. Procedure-related complications occurred in 17 (14.7%) of the patients, and most were minor. A PSOS > 70 (regarded as excellent palliation) was achieved in 79 (68.1%) patients. This goal was significantly more often achieved in patients who survived at least 6 months than in those with shorter survival ( $p < 0.001$ ). No clinical variables at the time of the endoscopic palliative procedure could predict a PSOS > 70. However, in patients who survived at least 6 months ( $n = 69$ ), a PSOS > 70 was independently associated with better survival in the multivariable Cox analysis.

**Conclusions:** PSOS could be used as a practical proxy or a pragmatic tool for the effectiveness of palliative interventions, when such interventions are compared. Clinical factors that could significantly add to the clinical decision-making and predict a PSOS > 70 in an individual patient were not identified for this specific group of patients.

## 1. Introduction

Approximately 20% of patients with colorectal cancer (CRC) will present with unresectable or metastatic disease [1]. A significant proportion of these patients will present with obstruction of the large bowel as the first symptom, including patients who present in an emergency setting. Malignant large bowel obstruction is also

encountered in patients with other malignancies, including gynaecological cancers, breast cancer, lung cancer, and non-colorectal gastrointestinal cancers [2–6]. Thus, decompression of the colon must be considered as an elective or urgent procedure in a heterogeneous group of patients, which is often characterized by higher age and the presence of significant comorbidities [7].

Currently, there are no validated instruments for the general

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assessment and comparison of outcomes after palliative procedures [8]. More than a decade ago, McCahill and co-workers [9] proposed a palliative surgical outcome score (PSOS) to better evaluate beneficial achievements of the treatments employed in patients with advanced malignancies. This score is based on the absence of severe symptoms or postoperative complications after the palliative intervention that allow the patient to stay out of the hospital, and is considered an indicator of the patients' well-being [8,10]. In order to clarify the structure and content of this score, we have outlined this (Fig. 1) by expanding on the Correa and co-workers' comments on palliative surgical care in the Surgical Oncology Manual of the University of Toronto [8].

Self-expanding metal stents (SEMSs) have been reported as an advantageous approach in patients with colorectal obstruction [3,11,12]. Relief of bowel obstruction symptoms has been achieved in both the short and long terms [13,14]. Concerns have been raised, particularly about variations in reported clinical success rates and procedure-related complications in palliative care patients and about long-term adverse events including perforation and stent migration. To avoid potentially risky overtreatment (i.e., surgery in frail patients) or an excessively nihilistic approach, individually tailored and pragmatic use of SEMSS has been suggested [15,16].

This study was performed to evaluate the use of PSOS in patients with incurable malignant large bowel obstruction treated with SEMS in a palliative context, and to investigate if additional clinical information could add any support to the PSOS as a measure of successful palliative treatment.

## 2. Materials and methods

### 2.1. Patients

All patients treated palliatively with SEMSs for malignant large bowel obstruction at the Stavanger University Hospital between 2005 and 2013 were included. Palliative treatment goals focus on alleviating symptoms caused by the cancer disease (e.g. abdominal pain due to bowel obstruction), to improve the subjective well-being of the patient, but without any intention of curative treatment for the advanced malignancy. The large bowel obstructions were caused by locally advanced or metastatic colorectal cancer or other malignant intraabdominal diseases. Patients treated with SEMS as a bridge to surgery were excluded.

The hospital services a population of at least 360 000 and is the only hospital in the region. Patients were identified by electronic search in the hospital's database and in the consecutive procedure database of the endoscopy suite using the appropriate procedure codes. The procedures were recorded consecutively. The pertinent information was retrieved from the hospital records.

Functional status (i.e. Eastern Cooperative Oncology Group (ECOG) class 0–4) was assessed according to the criteria described previously [17], and patient physiological status was categorized based on the definitions given by the American Society of Anaesthesiologists (ASA score I–VI) [18].

The results are reported according to the STROBE guidelines for observational studies [19].

### 2.2. The endoscopic procedure

Patients were selected for SEMS treatment based on an initial clinical evaluation and diagnosis, including a pre-procedure CT scan. Colonoscopy was performed with intravenous sedation and analgesia and with continuous observation of vital signs and oxygen saturation levels. The length of the obstruction was determined with a guide wire through the colonoscope, and the SEMS was deployed under fluoroscopic control. Patients were observed clinically for the effect of decompression or possible procedure-related adverse events. A Wallstent™ Endoprosthesis (Boston Scientific, MA, USA), either 90 or 120 mm in length, was used in 95 (81.5%) patients. The remaining had a WallFlex™ colonic stent or an Ultraflex™ colonic stent. The majority of the stents had a body diameter of 22 mm fully expanded. A few (e.g. Ultraflex) had an expanded diameter of 25 mm.

### 2.3. Definitions

*Technical success* was defined as a correctly positioned stent as recognized by the endoscopist at the end of the procedure and/or a print-out of the fluoroscopic image showing a waist in the middle of the stent and the expansion of the flared oral end.

*Immediate clinical success* was defined as relief of the symptoms of obstruction and was also indicated by colonic decompression within 24 h [4].

The PSOS was calculated and used according to the criteria described by McCahill and co-workers [9](Fig. 1). This score takes into consideration both treatment success (i.e., symptom relief) and treatment failure (i.e., symptom recurrence and surgical complications) and monitors the hospitalization time associated with both. The PSOS indicates the percentage of postoperative days in the 6 months following the surgical treatment during which a patient was not hospitalized and was free of or minimally encumbered by the symptoms that the intervention (i.e., stent) was intended to treat. For the patients who died before 6 months, the PSOS was calculated as the percentage of days until death with the score criteria above fulfilled. A PSOS > 70 is considered as a good to excellent goal for interventional palliation [8–10]. Accordingly, the PSOS is an overall measure of the benefit of palliative interventions and does not assess specifically any particular

## Palliative Surgical Outcome Score(PSOS)

$$PSOS (\%) = \frac{SFD^{\S}}{POD^{\#}}$$

§ SFD = 'Symptom-Free-Days'; i.e. Number of days of a patient without symptoms and not in the hospital. The symptoms refer to the ones that were meant to be treated, and include complications related to the surgical procedure/intervention

# POD = 'Postoperative days'; i.e. Number of total days of life after the operasjon/intervention (up to 180 days=6 months)

A PSOS>70 is regarded as an excellent result

Fig. 1. Palliative surgical outcome score (PSOS).

diseases or symptoms. Thus, as a proxy for an overall achieved treatment goal (i.e. be able to stay outside the hospital) of an individual patient, this score allows for comparison of treatment effects between groups.

*Complications* were categorized according to the Clavien-Dindo classification system as follows [20]: no or minor complications are grade 0–2; complications that need any surgical, endoscopic or radiological intervention are grade 3; life-threatening complications requiring intensive care unit (ICU) treatment with single organ or multi-organ failure are grade 4; and death of the patients is grade 5. Complications with Clavien-Dindo grade 3 or higher were considered *major complications*. In addition, any milder adverse events that obviously affected the patient's comfort or ability to return to their pre-treatment living situation, or any temporary complication that prolonged inpatient treatment or required hospital readmission or additional outpatient visits beyond the scheduled routine follow-up visits were regarded as *major complications* in this particular context.

#### 2.4. Follow-up

A complete follow-up was achieved. The pertinent information was retrieved from the consecutive hospital records. The date of death for patients who did not survive was obtained by the link between the patients' electronic hospital record and Statistics Norway.

#### 2.5. Statistics

IBM SPSS Statistics version 25 for Mac was used for the statistical calculations. A non-normal distribution of variables was assumed. Continuous variables are expressed as medians (interquartile range (IQR)) and were compared by the non-parametric Mann-Whitney *U* test. Categorical variables are reported as numbers and percentages, and the Chi-square test or Fisher's exact test was used for the comparisons of categorical variables, as appropriate.

To evaluate if any clinical variables predicted a PSOS > 70, a logistic regression was performed. Age, sex, ASA category, ECOG class, stage, and obstruction location were included. Age was used as a continuous variable but was also tested as a categorical variable (< vs ≥ median age). Obstruction was dichotomized and recorded as right-sided versus left-sided location (including left colon flexure) and colonic obstruction (including colon descendens) versus a recto-sigmoid/rectum location. Goodness of fit was checked by the Hosmer and Lemhow test. The Kolmogorov-Smirnov test was used for evaluation of a normal distribution of continuous variables.

Survival curves were estimated by the Kaplan-Meier method and compared by the log-rank test. Overall survival was calculated from the date of the first stent intervention until death.

To evaluate the ability of PSOS to predict further survival, we also evaluated the overall survival beyond 6 months for those who survived at least 6 months, re-starting time at that time point.

ECOG classes were re-categorized and merged into 3 groups (i.e., class 0 and 1 into group 1, class 2 remained group 2, and class 3 and 4 into group 3) which we think better reflects clinically important functional differences between palliative patient groups in this context.

A p-value < 0.050 was considered as statistically significant.

#### 2.6. Ethics

The study was approved by the institution's Research and Data Security Review Board (IRB) (ID #2012/31).

### 3. Results

#### 3.1. Patients

In total, 116 patients (62 women; 53.4%) with a median age of 71.5

**Table 1**

Demographics and functional characteristics of 116 patients treated with palliative intent with self-expanding metal stents for malignant large bowel obstruction.

Age, years	
median (range)	71.5 (33–96)
<b>Proportions (%)</b>	
● Women	62/116 (53.4%)
● Patients ≤ 75 years of age	64/116 (56.3%)
<b>ASA score</b>	
I	19 (16.4%)
II	49 (42.2%)
III	47 (40.5%)
IV	1 (0.9%)
<b>ECOG class</b>	
0	23 (19.8%)
1	36 (31.0%)
2	37 (31.9%)
3	16 (13.8%)
4	4 (3.4%)

Percentages are given as proportions of all patients.

years (range, 33–96 years) were included in this analysis. The patient demographics and physiological and functional characteristics according to the ASA criteria [18,21] and ECOG classification [17] are displayed in Table 1. The clinical characteristics are presented in Table 2. Symptoms and signs of bowel obstruction were most commonly encountered. Most obstructions were caused by primary colorectal malignancies, and most patients (79.3%) had advanced stage IV malignant disease (Table 2). Approximately two-thirds of the bowel obstructions were in the distal part of colon and in the upper rectum.

#### 3.2. SEMS treatment

Technical success was achieved in 109 patients (94.0%), with a clinical success rate of 87.1%. The main cause of technical failure was extensive tumour stricture that did not allow the passage of a guide wire through the obstruction.

Forty-six (39.7%) patients underwent palliative systemic chemotherapy treatments, 4 (3.4%) patients received radiation therapy as a single modality, and 5 (4.3%) patients were treated with combined radio-chemotherapy.

**Table 2**

Clinical and treatment characteristics of 116 patients treated with palliative intent with self-expanding metal stents for malignant large bowel obstruction.

<b>Main symptom</b>	
Obstruction	112 (96.6)
Bleeding	4 (3.4)
Both	6 (5.2%)
<b>Cause of bowel obstruction</b>	
Colorectal cancer	106 (91.4)
Pancreatic cancer	1
Ovarian cancer	5
Gastric cancer	1
Cholangiocarcinoma	1
Prostate cancer (post radiation)	1
Lung cancer	1
<b>Localization of the large bowel obstruction</b>	
Ascending	3 (2.6)
Right flexure	13 (11.2)
Transversal	11 (9.5)
Left flexure	4 (3.4)
Descending	9 (7.8)
Sigmoid	33 (28.4)
Recto-sigmoid	18 (15.5)
Rectum	25 (21.6)
<b>Stage of disease</b>	
Locally advanced (Stage III)	24 (21.7)
Advanced disease (Stage IV)	92 (79.3)

Most SEMS placements (99 patients; 85.3%) were completed without any procedure-related complications. Complications related to the endoscopic procedures were encountered in 17 (14.7%) of the patients and were categorized as minor complications (i.e., Clavien-Dindo 1–2) in 12 patients (10.4%), and major complications (i.e., Clavien-Dindo 3 or more) in 5 patients (4.3%).

Stent migration was eventually observed in 5 patients (4.3%), 6 patients (5.2%) experienced a bowel perforation, and a fistula eventually occurred in 6 patients (5.2%).

With a median follow-up time of 9 months (IQR, 2–18 months), only one patient was still alive at the last follow-up. The 30- and 90-day mortality rates were 12.9% (n = 15) and 30.2% (n = 35), respectively. In-hospital mortality occurred in 10 patients (8.6%), who were all fragile and sick patients (ECOG 3–4) because of advanced disease. Their very short survival time was limited to a median of 7.5 (IOR 5–20) days after the stent procedure. Causes of early death included infections (n = 8), myocardial infarction (n = 1), and bleeding after the stent procedure (n = 1).

As shown in Fig. 2a, a significantly better overall survival was observed in patients younger than 71.5 years (median age) compared to the elderly group (p < 0.001). Additionally, the functional status at the time of diagnosis as shown by different ECOG categories was of significant importance for overall survival (p < 0.001) (Fig. 2b). A similar significant difference (p < 0.001) was also observed between ASA categories. Moreover, males had a significantly (p = 0.012) better overall survival than females, and patients with left-sided obstructions had longer survival (p < 0.001) than those with right-sided obstructions (survival curves not shown). In contrast, the stage of disease (stage III vs IV) did not impact survival (p = 0.909). In a multivariable Cox regression model (with age, sex, ASA category, ECOG class, and right-sided vs left-sided tumour location included in the model), only ECOG class 3–4 (HR 2.60; 95% confidence interval (CI); 1.50–4.52; p = 0.001) and left-sided tumour location (HR 0.50; 95% CI 0.31–0.79; p = 0.003) provided independent prognostic information.

### 3.3. The palliative surgical outcomes score (PSOS)

A PSOS > 70, regarded as good to excellent palliation [9], was achieved in 79 (68.1%) of the patients. The PSOS score had a non-normal distribution (p < 0.001, Kolmogorov-Smirnov test). The median PSOS score was 90 (inter quartile range (IQR), 40–100) for the study population. Among the patients who survived < 6 months after the first stent treatment, a PSOS > 70 was achieved in 20 of 47 (42.6%) patients compared to in 59 of 69 (85.5%) patients who were still alive at 6 months (p < 0.001).

We sought to determine any characteristics at the time of diagnosis that could possibly be associated with a favourable PSOS > 70. Age, sex, ASA category, ECOG classes and tumour location (right vs left colon; colon versus rectum) were investigated, but none showed any significant differences with regard to PSOS category ≤ / > 70. Of note, a significant trend (p = 0.02 for linear-by linear association) was observed in favour of more patients with a low ECOG class at the time of the stent procedure in the group of patients who eventually achieved a PSOS > 70. The multivariable logistic regression model with the same variables as above did not identify any variables that independently predicted a PSOS > 70.

The PSOS focuses on, by definition, the first 6 months after a palliative intervention has been employed. As seen in Fig. 2, the prognosis was dismal for most patients, and only few patients survived more than 2 years. To further evaluate possible valuable aspects of the PSOS categories (< / ≥ 70), we focused on 69 (59.5%) patients who were still alive more than 6 months after the palliative intervention with SEMS. The clinical characteristics and demographics of these 69 patients were similar to those of the entire study population. As shown in Table 3, age (dichotomized by the median age) (p < 0.001), tumour location (right versus left) (p = 0.003), and PSOS category (p = 0.025) were

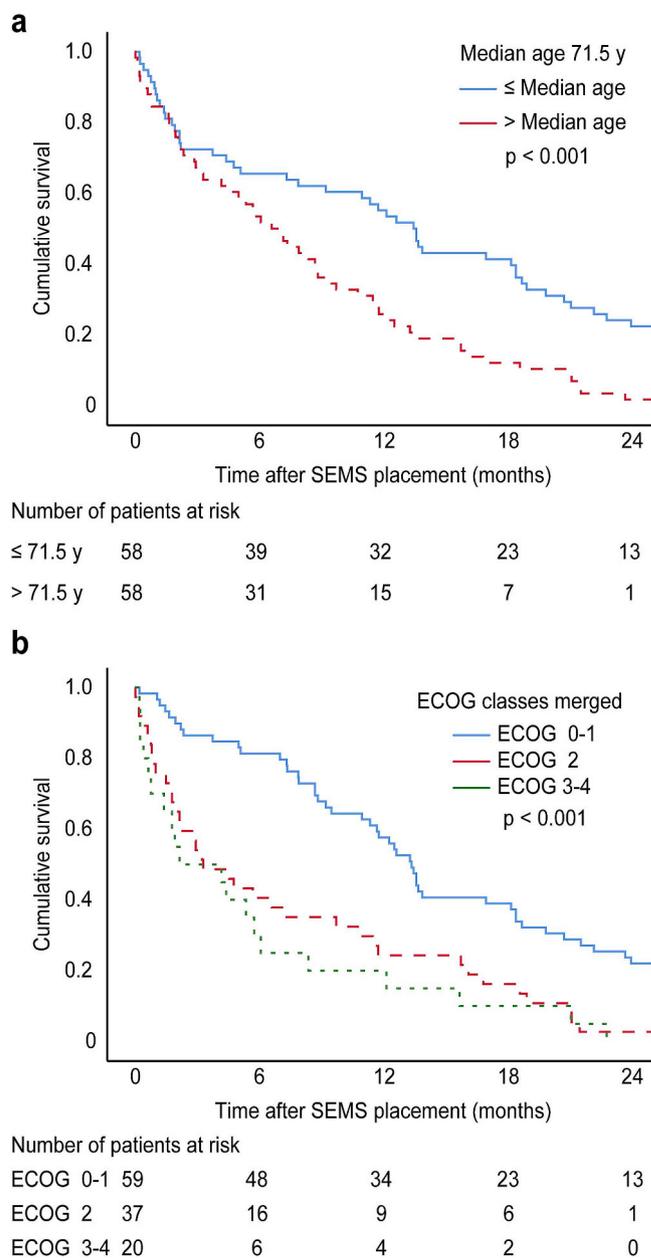


Fig. 2. Overall survival according to median age (panel a), and ECOG classes (panel b) for 116 patients palliatively treated with SEMS for malignant large bowel obstruction.

statistically significantly associated with overall survival beyond 6 months in the univariable analyses. This is displayed for the PSOS categories in Fig. 3. Adjusted for other variables in a multivariable survival analysis, PSOS category (p = 0.045) remained statistically significant, with a shorter survival time in patients who did not achieve a PSOS < 70 during the first 6 months after the stent procedure. Only tumour localization (p = 0.018) and PSOS category (p = 0.045) provided independent prognostic information, with a significantly decreased survival in patients with right-sided tumours compared to those with left-sided tumours.

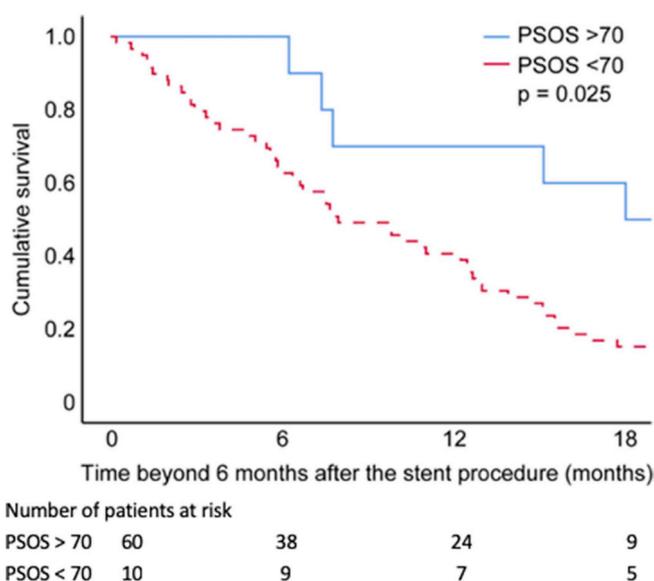
## 4. Discussion

The PSOS was developed in order to offer a surrogate endpoint within the first 6 months after surgical intervention to better determine if a pragmatic treatment goal (i.e., symptom control that allowed the patients to stay outside the hospital) was achieved [9]. This proxy is of

**Table 3**  
Univariate and multivariate Cox survival analyses of 69 patients who survived at least 6 months after SEMS treatment.

	Univariate P-value	Multivariate		
		HR	95% CI	P-value
Sex	0.117			
Age				
- categorised ≤/ > 71.5 years	< 0.001			
- as a continuous variable		1.020	0.997–1.044	0.085
ASA	0.193			
ECOG	0.161			
Tumour location				
- colon vs rectum	0.245			
Tumour location				
- right vs left	0.003	2.442	1.166–5.114	0.018
PSOS ≤/ > 70	0.025	0.466	0.221–0.983	0.045

HR denotes hazard ratio.  
CI denotes confidence interval.



**Fig. 3.** Overall survival according to PSOS category for 67 patients who survived beyond 6 months after treatment with SEMS.

clinical relevance for the evaluation of applied treatments and for research on palliative interventions, e.g., comparisons of outcomes in different series, given that study populations are comparable. The present study is, to our knowledge, the first one since the PSOS was launched to address its use in a cohort of patients treated with a palliative intervention. It shows that the PSOS was useful to depict the beneficial effect of SEMS for the treatment of colorectal malignant obstructions when surgical resection was not an option.

However, we could not identify any distinct factor or combinations of factors that significantly and independently predicted a PSOS > 70. The overall clinical impression that patients with advanced malignant disease are more likely to have better outcomes if they are younger, have a good functional status (low ECOG class) and sufficient physiological capacity (low ASA score) is common sense. As indicated in this study and in others [22,23], the basic ECOG class seems to be of importance for prognostication in patients with advanced gastrointestinal malignant disease.

Despite the lack of evaluation in independent palliative patient populations, the concept of PSOS has been adopted in routine practice as described in the Surgical Oncology Manual of the University of Toronto [8]. In this collaborative work between the breast, hepatopancreatobiliary and general surgical oncology fellowship programs, a

concise and practical guide has been launched to support learning and comprehension for the clinically busy resident or fellow. Efforts to improve the knowledge, attitudes, and perceived skills in palliative decision-making in the palliative care setting may add to the quality of care for these patients [24]. A mutual transition of knowledge between routine practice and clinical research will likely be of benefit for both – and also for this particular group of patients.

A recent trial (S1316 study) with a mixed randomized approach was launched in USA to address the clinical conundrum of malignant bowel obstruction (MBO) [25]. The primary outcome measure was, in line with the principles of the PSOS; to assess the quality of life outcomes of ‘good days’, defined as the number of days alive and outside of hospital within the first 91 days (13 weeks ≈ 3 months). Eligible patients are those with MBO who receive surgical intervention in comparison with patients who undergo non-surgical intervention. While results from this study are still pending, the topic and design of the study underlines the importance of a general measurement tool that embraces the complex clinical challenges related to the individual patients with large bowel obstruction. Which time frame is the best for evaluations of procedure-related or patient-reported outcomes likely depends on the clinical condition and patients’ characteristics, and may vary accordingly. Of note, only 69 (59.5%) of our patients were still alive after 6 months. Accordingly, care givers should take into consideration proper treatment approaches and the organization of health care for this group of patients with a detrimental prognosis.

The present study was based on data from consecutive patients with incurable malignant large bowel obstruction due to advanced disease. The data provided is regarded as population-based, and the data quality was high, with a virtually complete dataset on a few well-documented and easily retrievable variables. A complete follow-up was possible, including the date of death, which was provided by the official population registry based on the unique 11-digit personal identifier given to all registered inhabitants in Norway. These are all strengths of this study.

On the other hand, the limitations include the retrospective design and the lack of outcome measures as reported by the patients themselves. Moreover, systemic palliative chemotherapy employed in a number of these patients would likely influence these patients’ clinical condition, and reliable information to retrospectively judge associated discomfort or side effects in this context was not available. In addition, we do not have detailed information on the type or amount of symptom directed palliative care these patients received from local caregivers, family or friends while at home [26,27]. This may result in a bias regarding the need for hospitalization in an individual patient.

Nevertheless, McCahill and co-workers [9], who introduced the PSOS, had a mixed and a smaller study population (n = 59), with patients surgically treated both with curative and palliative intent. Moreover, the median age of our 116 patients was 71.5 years compared to 59 years in McCahill’s series. The PSOS indicates the percentage of days in the 6 months after surgery during which a patient is not hospitalized, has sufficient control of symptoms that the intervention was intended to treat and is unaffected by any major surgical complication [8,9]. McCahill [9] reported a PSOS > 70 in 64% (n = 21) of the 33 symptomatic patients, which they regarded as an excellent result. This corresponds well with the overall PSOS > 70 of 69% observed in this study. We observed a PSOS > 70 of 44.6% in patients with short survival times (i.e., < 6 months after the stent procedure), which was slightly better than the 36% reported by McCahill and co-workers [9]. It is worth noting that due to the differences mentioned between the two study populations (e.g., age, treatment intention, and type of treatment), direct comparisons are difficult.

As shown in this study, patients who achieve a good or excellent palliative treatment, as judged by a PSOS > 70, within the first 6 months after receiving the intervention will likely have a better overall survival. Whether this is an advantageous achievement as perceived by the patients, remains to be evaluated by proper instruments. In this

regard, attention should primarily be paid to the individual needs of the patients, and hence to the patients' subjective perception of daily life.

Colorectal obstruction is one of the most common surgical challenges encountered in patients with advanced gastrointestinal cancer [6,7], including also some other primary malignancies [6,22,28]. Appropriate individual clinical decision-making has to take into consideration not only patient-related factors but also treatment-related factors, including the urgency of the treatment. Not only the procedure-related morbidity and mortality and the overall survival, but also other measures should be considered to evaluate the efficacy and the appropriateness of various palliative interventions [8,10,29,30].

PSOS may add a valuable dimension beyond the simple evaluation of technical or clinical immediate success rates when palliative endoscopic procedures are employed. Reporting on overall survival as a single end-point for these vulnerable group of patients with advanced disease would also be of limited relevance. Nevertheless, as a well-defined and reliable variable, the survival time will add to the clinical appraisal when various managements are under evaluation. Palliative care outcome measurements are of importance to monitor and document, and eventually to make necessary changes to improve how this healthcare is delivered and ultimately organized [31]. The quality of palliative healthcare has a number of dimensions, and available validated instruments are hampered by various limitations [32]. While PSOS is suggested a readily and well-defined score, it remains a matter of discussion if the applied cut-off level of 70 is a well-chosen definition of 'excellent palliation', as suggested by McCahill and co-workers [9]. Nevertheless, to bring palliative surgical care a step forward, and to be able to compare results from different studies, the use of well-defined definitions and criteria, and validated instruments, is of importance. In this context, the PSOS should be considered as a useable instrument in future studies.

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## Conflicts of interest

All authors confirm there are no conflicts of interest related to this study.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.suronc.2019.04.006>.

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