



Critical appraisal of oncological safety of stent as bridge to surgery in left-sided obstructing colon cancer; a systematic review and meta-analysis

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ABSTRACT

This meta-analysis aims to determine the long-term oncological outcomes of SEMS as bridge to surgery (BTS) versus emergency surgery (ES). A systematic search without restrictions was conducted, and all studies comparing SEMS with ES reporting on long-term outcomes were included. Methodological quality was assessed using the appropriate tools. Twenty-one comparative studies were selected, reporting on 1919 patients. Meta-analysis showed no significant difference regarding three- and five-year overall survival (OR = 0.85 (0.68-1.08) and OR = 1.04 (0.68-1.57), respectively), disease-free survival (OR = 0.96 (0.73-1.26) and OR = 0.86 (0.54-1.36), respectively) and local recurrence rate (OR = 1.32 (0.78-2.23)). Permanent stomas were significantly lower in the SEMS group (OR 0.49 (0.32-0.74)). Sensitivity analysis on three-year survival showed opposite outcomes, with a trend towards worse survival in the SEMS group when only RCTs are taken into account. In conclusion, when in experienced hands, SEMS placement as BTS seems oncologically safe.

1. Introduction

Traditionally, acute malignant colonic obstruction has been managed with emergency surgery (ES), either consisting of acute resection or decompressing stoma construction. Resection in the emergency setting might be associated with a substantial risk of mortality and morbidity rates, especially in patients with high operativerisk (Tanis et al., 2015; Dohmoto, 1991; Vitale et al., 2006). This resulted in the search for alternative treatment approaches. In 1991, Dohmoto first proposed the placement of a self-expandable metallic stent (SEMS) to relief colonic obstruction (Saida et al., 1996). SEMS placement potentially enables an elective (laparoscopic) resection in a patient with an optimized clinical condition with the potential to avoid a stoma.

Almost 30 years after its first introduction, SEMS placement for left-sided obstructing colon cancer is still surrounded by controversy. Initial meta-analyses of cohort studies comparing SEMS as bridge to surgery (BTS) with ES showed favorable short-term outcomes in the SEMS group (Arezzo et al., 2017a; Sabbagh et al., 2013). Several randomized controlled trials (RCTs) have been performed thereafter, but were often prematurely terminated because of stent-related complications. Meta-

analyses of these RCTs could not confirm an impact of SEMS on post-operative mortality, but did reveal a higher risk of undergoing laparoscopic surgery, lower morbidity rates, fewer temporary stoma constructions and higher primary anastomoses rates (Maruthachalam et al., 2007; Avlund et al., 2018; Sloothaak et al., 2014; van Halsema et al., 2014; Moher et al., 2009).

Even though the short-term benefits of SEMS as BTS have been established in recent years, many physicians remain hesitant to place stents in a curative setting, since it has been suggested to negatively influence oncological outcomes (Higgins Julian et al., 2011). Concerns include an altered pathology after stent insertion (Sterne et al., 2016; Kim et al., 2013; Saida et al., 2003). To what extent these histological findings translate into worse survival remains unclear. Additionally, concerns have been raised about the prognostic impact of a SEMS-related perforation (Alcantara et al., 2011; Tung et al., 2013). Since SEMS-related perforations occur in about 8% of the patients, it is important to further investigate the oncological consequences (Ghazal et al., 2013). Because of the on-going debate and the increasing body of relevant literature, this systematic review and meta-analysis was aimed to determine long-term oncological outcomes after SEMS as BTS

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compared to ES.

2. Methods

This systematic review and meta-analysis was performed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to minimize risk of bias. (Arezzo et al., 2017b)

2.1. Search strategy and study selection

A systematic literature search was conducted in MEDLINE (PubMed), EMBASE (Ovid) and Cochrane Library. There were no restrictions to the search. The final search was conducted on December 20th 2017. The search terms used were synonyms for stent and colonic obstruction. The exact search as used in EMBASE was: (stent:ab,ti OR SEMS:ab,ti OR 'bridge to surgery':ab,ti OR 'staged resection':ab,ti) AND ('acute obstruction':ab,ti OR ileus:ab,ti OR 'colon obstruction':ab,ti OR 'colonic obstruction':ab,ti OR 'intestinal obstruction':ab,ti OR 'malignant obstruction':ab,ti OR 'rectosigmoidal obstruction':ab,ti OR 'left sided obstruction':ab,ti OR 'left-sided obstruction':ab,ti OR 'distal obstruction':ab,ti OR 'large bowel obstruction':ab,ti). MEDLINE and the Cochrane Library were searched using similar terms. Articles deemed potentially relevant were screened full text for inclusion by two authors (FA and TB) independently. In addition, references of all included studies were hand-searched for additional studies. Final inclusion of the articles was based on consensus.

2.2. Inclusion/exclusion criteria

In- and exclusion criteria were predefined. Studies were considered eligible for inclusion when they met the following criteria: 1) comparative study between SEMS placement as BTS and emergency surgery, 2) reporting on at least one long-term oncological outcome measure; overall survival, disease free survival and/or any type of recurrence, 3) all included patients in the studies had to be treated with curative intent, and 4) a median follow-up time of minimally two years. Studies were excluded if: 1) a language other than Dutch, English, German or French was used, or 2) there was no possibility to extract the exact numbers for outcome measures. In addition, conference abstracts without subsequent publication were excluded.

2.3. Data extraction and study outcomes

A priori, a data sheet was created and data were extracted independently by two authors (FA and TB). Disagreements were resolved by re-examination of the relevant study until consensus was reached; in case of disagreement a third author (EC) was involved for the final decision. For each included study, the primary author's name, publication year, design and duration of the study, number of included patients, median follow-up, and baseline characteristics were collected. Baseline characteristics entailed age, sex, tumor location, American Society of Anesthesiologists-score (ASA), comorbidity, and adjuvant chemotherapy.

Primary outcomes were three and five-year overall and disease free survival. Overall recurrence rate, local recurrence rate, and permanent stoma rate were considered as secondary outcome measures. If the study provided only a Kaplan-Meier survival curve and not absolute survival rates, the rate was extracted as accurately as possible from the figure, and combined with the number of patients still in the study to reconstruct the number of events. In order to prevent overestimation of the precision of the effect measure, survival rates determined from a Kaplan Meier graph were only taken into account if at least two-third of the patients were still at follow-up after three and/or five years post-operatively. Whether more than two-third of the patients were still in follow-up after three and/or five years postoperatively was determined by counting the number of censored patients, or by looking at the

median follow-up and its inter-quartile range. Local recurrence was defined as a recurrence at the anastomosis, tumor bed, mesentery, draining lymphatic system, surgical scar, or port sites. Overall recurrences included all cases of local recurrence as well as synchronous distant metastases.

2.4. Quality assessment

All included studies were critically and independently appraised by two authors (FA and TB). For RCTs, the Cochrane Collaboration's tool for assessing the risk of bias was used (Quereshy et al., 2013). Observational comparative studies were appraised using the ROBINS-I tool for assessment of risk of bias (Gorissen et al., 2013).

2.5. Statistical analysis

Data analyses were performed using Review Manager 5.3 software (the Cochrane Collaboration 2012, Denmark). Pooled odds ratios (OR) with 95% confidence intervals (95%CI) for overall survival, disease free survival, overall recurrence, local recurrence, and permanent stoma were calculated using a random effects model. The OR represents the odds of an adverse event (e.g. mortality or disease recurrence) occurring in the experimental group (SEMS as BTS) versus the control group (ES). An OR < 1 favored the SEMS as BTS group. The point estimate OR was considered statistically significant when the p-value was < 0.05 and the 95%CI did not include the value 1. Heterogeneity among the included studies was assessed using graphical exploration of funnel plots, the Cochrane Q-statistic ($p < 0.1$ was considered representative of statistically significant heterogeneity) and the I^2 statistic ($I^2 > 50\%$ was considered to represent substantial heterogeneity) (Gianotti et al., 2013). A random-effects model was used for analysis given the variability of methods and populations in the included studies. Furthermore, sensitivity analysis on three-year overall survival across six variables was conducted in order to investigate the robustness of the findings of this meta-analysis; variables included study design, region of the study, number of patients treated with SEMS, technical success rate of SEMS placement, publication year and perforation rate.

3. Results

3.1. Study selection

The initial search yielded 2573 relevant articles. After removal of duplicates, 1913 studies remained, of which 1886 studies were excluded based on title and/or abstract (Fig. 1). Eventually, the full text of 27 articles was evaluated, with eight more studies being excluded. Reasons for exclusion were; non-comparative study ($n = 1$), review article ($n = 1$), Chinese language ($n = 1$), comparison with elective surgery ($n = 2$), no exact data retrievable ($n = 2$) and meta-analysis ($n = 1$). Two additional studies were added following manual cross-reference.

The included studies were published between 2003 and 2017, and reported on a total of 1919 patients: 938 in the SEMS as BTS group versus 981 in the ES group (Higgins Julian et al., 2011; Kim et al., 2013; Tung et al., 2013; Flor-Lorente et al., 2017; Dastur et al., 2008; Choi et al., 2014; Ho et al., 2017; Amelung et al., 2016; Kim et al., 2016; Li et al., 2016; Kwak et al., 2016; Yan et al., 2017; Gibor et al., 2017; Sotelo et al., 2015; Zhang et al., 2012; De Ceglie et al., 2013; Small et al., 2010; Lee et al., 2015; Williams et al., 2011; van Hooft et al., 2014; Broholm et al., 2017). The number of patients in the individual studies ranged from 26-240. Five studies were RCTs (Tung et al., 2013; Choi et al., 2014; Ho et al., 2017; Li et al., 2016; Lee et al., 2015), four reported on prospectively collected data (Amelung et al., 2016; Kim et al., 2016; Kwak et al., 2016; Small et al., 2010), and twelve studies had a retrospective design (Higgins Julian et al., 2011; Kim et al., 2013; Flor-Lorente et al., 2017; Dastur et al., 2008; Yan et al., 2017; Gibor

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