Predictors of symptom recurrence and survival in patients with malignant gastric outlet obstruction treated with self-expanding metal stents

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ABSTRACT

BACKGROUND: Malignant gastric outlet obstruction (GOO) poses a substantial symptomatic burden. While various therapeutic options exist, self-expanding metal stents (SEMS) are a common palliative choice for patients who are ineligible for surgery. We studied SEMS outcomes to identify factors influencing stent dysfunction and patient survival.

METHODS: A multi-centre, retrospective review of 190 patients with GOO undergoing SEMS at three tertiary hospitals was performed over 2016–2022. Technical success, clinical success and adverse outcomes were recorded. Predictors of stent dysfunction and survival were evaluated using multivariate regression.

RESULTS: Technical success was achieved in 186/190 (97.9%) and clinical success in 156/186 (83.9%), defined as post-procedural gastric outlet obstruction symptom score (GOOSS) ≥2. Eighty-two (44.1%) patients experienced an adverse event with stent occlusion the most common (23.1%). Approximately one-third (32.3%) underwent a repeat intervention. Mean stent patency time was 67 days (standard deviation=76), and median post-stent survival was 95 days (37–197). Covered and partially covered SEMS carried three times the risk of stent dysfunction compared to uncovered SEMS (odds ratio 3.06, p=0.008). Mortality predictors were Eastern Cooperative Oncology Group score ≥2 (p=0.03), extrinsic outlet obstruction (p=0.05) and presence of ascites (p=<0.001).

CONCLUSION: SEMS demonstrated technical and clinical success but posed a high risk of recurrence, with stent patency time falling short of survival in our cohort. With an evolving landscape of therapeutics for GOO, appropriate patient selection is paramount. Individuals with reduced performance status, extrinsic obstruction and/or ascites may be better candidates for SEMS due to more limited life expectancy. In this setting, uncovered SEMS carry the lowest risk of reintervention.

Malignant gastric outlet obstruction (GOO) results from the growth of cancers interfering with normal gastric emptying. Patients with this condition frequently present with nausea, vomiting and inadequate oral intake. Cancers of gastric or pancreatic origin are the most common aetiologies and obstruction can be intrinsic from within the lumen, or extrinsic from external compression.[1,2] Several therapeutic modalities have been developed for treatment, including surgical gastroenterostomy (S-GE), self-expanding metal stents (SEMS) and, more recently, endoscopic ultrasound-guided gastroenterostomy (EUS-GE).[3–6]

SEMS were developed as a treatment modality in the 1990s and have been demonstrated as technically achievable, clinically successful and cost-effective tools for palliation of GOO symptoms.[7–9] They are less invasive than alternatives and do not require general anaesthesia to perform.[10,11] Prospective studies have also shown a swifter recovery time compared with surgery, and shorter length of hospital stay.[2,12] The combination of these factors together represent additive benefits in this population, who are generally in their last days of life.

However, the durability of SEMS has come into question.[13,14] Risk of symptom recurrence has been reported between 9.9 to 50.9%, with rates of re-intervention ranging from 3.8 to 38.1%.[15] Improving these metrics is important as systemic treatments, such as immunotherapy, continue to extend the lifespans of patients with advanced cancer.[16] Meta-analyses comparing symptom recurrence, reintervention and patency between S-GE, EUS-GE and SEMS have shown small differences between interventions; however, the majority of included studies are retrospective, non-randomised and involve low numbers of participants.[5,15,17] There have been no head-to-head randomised controlled trials comparing each of the available interventional treatments.[15]

Therefore, a degree of selection bias is expected and accurate conclusions are difficult.

With expanding capability of treatments for GOO, the specific patient, disease and technical characteristics that may be implicated in risk of SEMS dysfunction, reintervention and survival are of continued interest. Understanding these factors may help to predict outcomes for different patient profiles and therefore aid with better patient selection. Our study sought to evaluate the treatment and adverse outcomes of SEMS so we may identify relevant risk factors.

Methods

Participants

We retrospectively reviewed the medical records of all patients who had undergone endoscopic stenting procedures at three tertiary hospital centres in Auckland, New Zealand between August 2016 and December 2022. Patients were included if they had a gastric or duodenal SEMS placed for malignant GOO. Patients with non-malignant obstruction were excluded. A local ethics waiver was obtained.

Procedural data

Stent type, stent location and procedural adverse events were taken from endoscopy reports. Stents were categorised into covered (C-SEMS), partially covered (PC-SEMS) and uncovered (U-SEMS) according to manufacturer specifications. There were at least two independent proceduralists at each centre and all used a wire-guided, through-the-scope SEMS deployment method with adjunct fluoroscopy. For sedation, a combination of fentanyl and midazolam was considered standard practice.

Data collection

Electronic health records were reviewed for demographic information, disease-specific information such as diagnosis, performance status (Eastern Cooperative Oncology Group [ECOG] score), nature of obstruction, presence of peritoneal infiltration, ascites and adverse events. Systemic treatments such as chemotherapy and radiotherapy were recorded if received during the study period.

Outcome definitions

Technical success was defined as confirmed stent placement in the intended location across the point of obstruction. Clinical outcomes were defined using the gastric outlet obstruction symptom score (GOOSS).[18] A score of 0 was assigned for no oral intake, one for liquid diet, 2 for soft solids and 3 for low-residue or unmodified diet before and after intervention. Clinical success was defined as a post-SEMS GOOSS score of ≥2 at the time of discharge or by day 7.

Stent dysfunction was defined by occurrence of intestinal perforation, stent migration or stent occlusion. Reintervention rates were calculated from repeat procedures performed for recurring GOO symptoms. All deaths within 7 days of attempted SEMS were recorded. Stent patency time was defined by the number of days between stent placement and recurrence of GOO symptoms.

Statistical analysis

Statistical functions were performed to define relationships between demographics, disease factors, treatment factors, rates of stent dysfunction and risks of mortality. Chi-squared tests were used to define associations between variables, with significance defined by p-value ≤0.05. Grouped cohorts were created for age (<70 and ≥70 years), ethnicity (Māori and non-Māori), performance status (ECOG <2 and ≥2), and stent type (C-/PC-SEMS and U-SEMS). A purposeful selection of covariates approach was taken with univariate variables containing p-values <0.1 included in multivariate models to identify predictive factors. All statistical analyses were performed using SPSS version 29.0 for Windows (IBM, 2022).

Results

Participants

In total, 190 patients with malignant GOO were enrolled in the study. Participant characteristics are presented in Table 1. Mean age was 67 years, with 91 (47.9%) females and 99 (52.1%) males. Māori (Indigenous) ethnicity constituted 18.4% of the study population. Mean performance status was 1.44±1.1. Gastric cancer (38.9%) and pancreatic cancer (30%) were the most common diagnoses. Intrinsic obstructions (66.8%) were more common than extrinsic (33.2%). Presence of peritoneal disease and ascites were 27.4% and 17.4% respectively. Chemotherapy was received by 46.3% of participants during the study period.

Patient outcomes

Technical and clinical outcomes are presented

in Table 2. There were 186/190 (97.9%) technically successful SEMS. Mean pre-GOOSS was 0.20±0.57 and improved to a post-GOOSS of 2.03±0.84 after SEMS. A total of 156/186 (83.9%) achieved a GOOSS of ≥2 by discharge or day 7. The majority of stents were U-SEMS (73.1%), with PC-SEMS (10.8%) and C-SEMS (16.1%) the minority. Seventy-two percent of SEMS were located with the proximal flange in the stomach.

Adverse events, reinterventions and survival

Adverse event, reintervention and survival data are presented in Table 3. Adverse events were experienced by 82/186 (44.1%) patients over the study duration. Stent dysfunction was the most common (35.5%), followed by biliary obstruction (15.1%) and death (3.2%). Stent occlusion comprised 45/66 (68.2%) stent dysfunction events, with a smaller proportion of stent migrations (15/66, 22.7%) and perforation events (6/66, 9.1%).

Sixty patients who experienced stent dysfunction underwent 71 reinterventions (32.3% of the cohort). Of these interventions, 47/71 (66.2%) were a repeat stent and 7% comprised emergency surgery. The mean number of reinterventions per patient was 0.32±0.47 with a mean stent patency time of 67±76 days. Median post-stent survival was 95 days.

Predictive variables for adverse events

Univariate analysis for stent dysfunction events is presented in Table 4. Stent dysfunction was more common in the age <70 years cohort (odds ratio [OR] 2.33, 95% confidence interval [CI] 1.22–4.47, p=0.01), males (OR 1.94, 95% CI 1.05–3.58, p=0.05), Māori ethnicity (OR 2.27, 95% CI 1.08–4.79, p=0.03) and ECOG <2 performance status (OR 2.03, 95% CI 1.05–3.92, p=0.03).

Patients with gastric cancer as the underlying diagnosis (OR 3.30, 95% CI 1.76–6.17, p=<0.001) and intrinsic obstruction (OR 2.81, 95% CI 1.39–5.71, p=0.004) were more likely to experience stent dysfunction, while this was less likely in those with pancreatic cancer (OR 0.35, 95% CI 0.16–0.73, p=0.004).

In relation to treatment factors, patients treated with C-/PC-SEMS were more likely to experience stent dysfunction compared with U-SEMS (OR 4.71, 95% CI 2.37–9.37, p=<0.001). There were no significant differences with regard to stent location (p=0.09) or treatment with chemotherapy (p=0.22). Primary diagnosis of biliary cancer (p=0.06), duodenal cancer (p=0.18), metastatic disease (p=0.46) and/or neuroendocrine tumour (p=0.43) were all non-significant variables; likewise with peritoneal disease (p=0.39) and ascites (p=0.42).

Multivariate regression analysis on stent dysfunction events is presented in Table 5. Significantly greater stent dysfunction events were consistent in the C-/PC-SEMS group compared with the U-SEMS group overall (OR 3.06, 95% CI 1.35–6.95, p=<0.008). There were also significantly higher risks of stent dysfunction seen in those with ECOG <2 performance status (OR 2.32, 95% CI 1.08–4.99, p=0.03). No other significant associations were noted.

Sub-group analysis of the specific dysfunction events that contributed to differences between stent types revealed a higher migration risk in C-/PC-SEMS compared to U-SEMS, and this was statistically significant (OR 11.8, 95% CI 3.54–39.2, p=<0.001). There were no significant differences in occlusion (p=0.23) or perforation (p=0.45) events between groups.

Univariate and multivariate analyses of mortality data are presented in Table 6. Multivariate predictors of mortality were ECOG ≥2 (OR 1.47, 95% CI 1.03–2.09, p=0.03), extrinsic obstruction (OR 1.58, 95% CI 1.01–2.47, p=0.05) and presence of ascites (OR 2.23, 95% CI 1.39–3.58, p=<0.001). Average survival for high performers (ECOG <2) was 115 days, compared with 74 days for those with poor performance status (ECOG ≥2) (p=0.03).

Discussion

This large, multi-centre study has demonstrated that SEMS are technically achievable and clinically successful at resolving GOO symptoms, consistent with published literature.[1,7] However, a detailed examination of adverse events has shown limited treatment durability, with high rates of symptom recurrence up to 35% over patients' lifetimes. In our cohort, stent patency time was 67 days, yet average survival was 95 days—meaning patients frequently had to undergo further intervention in their last days of life.

In our cohort, high performers (ECOG <2) had significantly longer survival than low performers (ECOG ≥2) and were therefore exposed to higher cumulative risk of late stent dysfunction. This is consistent with findings from other researchers.[19] On the contrary, poor performance status, extrinsic obstruction and/or ascites were independent predictors of mortality. Ascites is an important consideration when

determining the best therapeutic approach for GOO due to the impact this has on likelihood of EUS-GE technical success. The European Society of Gastrointestinal Endoscopy suggests ascites interfering with lumen-apposing metal stent (LAMS) trajectory and/or tense (grade III) ascites as relevant contra-indications.[20] Ascites from heart failure, malignancy and liver disease are all also associated with increased peri-operative surgical risks.[21–23] Therefore, patients with ascites and/or one of the other mortality prognosticators may represent the most appropriate profiles for SEMS, which are the least invasive of the options and offer reduced length of hospital stay.[24] These findings may help contribute to the design of a decision-making support tool to guide clinicians and patients through the treatment selection process.

With respect to comparators, the first randomised study comparing EUS-GE with SEMS was published recently by Teoh et al. and showed significant differences in symptom recurrence at 6 months. One of the advantages of EUS-GE is in creation of a new tract distant from the malignant site, therefore lowering the risk of subsequent tumour in-growth.[25,26] Teoh et al. demonstrated a reintervention rate of 4% for EUS-GE versus 29% for SEMS (p=0.002).[25] Of note, there were no differences in quality of life scores between both groups at 1 month. Many published studies show comparable technical success of EUS-GE with SEMS; however, it is acknowledged that there is a substantial learning curve required to master EUS-GE techniques and still no universal agreement on the best technical approach.[27–29] There are also risks. EUS-GE stent maldeployment, for example, is a complication that requires recognition and expedient management, not infrequently with surgery, in up to 11%.[29] Overall, safety and optimal patient selection require further exploration. With a trend towards increasing centralisation of advanced endoscopy expertise, EUS-GE currently remains a technique practised only in expert referral centres.[30]

With regard to stent type, C-SEMS have been developed to reduce the risk of tumour in-growth, which is presented as one of the primary drivers of U-SEMS dysfunction.[31] In our cohort, there was no observed advantage to support this. Our findings are consistent with studies by Maetani and Hori et al., which showed no benefit for C-SEMS with regards to obstruction events, but contrast with systematic reviews and meta-analyses by Hamada, Minata, Pan and Tringali et al.[13,31–35] We found that not only was this hypothetical advantage negated, but C-/PC-SEMS carried 11 times the risk of migration compared to U-SEMS (p=<0.001). This was also the primary driver of more than three times risk of stent dysfunction overall (p=<0.008). Other studies have shown equivalent stent patency time and reintervention rates between SEMS types due to the balance in stated advantages and disadvantages of these.[36,37] U-SEMS performed better in our study, but were also the most common SEMS used and still carried a relatively high risk of re-intervention. This may be related to over-representation of high performers in our study population, with 60% of the cohort possessing an ECOG score of 0 or 1 (mean 1.44). In our cohort, most cases of SEMS dysfunction were managed with repeat SEMS, which is a documented safe and effective approach.[38–40]

The strengths of this study are in its large cohort size, the broad range of SEMS types used and the detailed examination we have performed of adverse events to identify predictor variables, which are practically useful for responsible clinicians treating these patients. The limitations are in the retrospective study design and the lack of a comparator cohort. As discussed previously, future prospective studies must consider quality of life. While outlet obstructive symptoms clearly drive morbidity, research has shown that despite a focus on and improvements in symptom scores, overall quality of life decreases, emphasising the importance of other factors that must be accounted for in a condition that is rapidly life limiting.[41]

Conclusion

SEMS are technically and clinically successful but pose a high risk of recurrence, with relatively short patency time. Ideal candidates are those with more limited life expectancy or where alternative procedures are contra-indicated. Predictors of mortality are reduced performance status, extrinsic obstruction and ascites. In these patients, covered SEMS offer no advantages over uncovered SEMS, which carry a lower risk of reintervention overall.

Table 1: Patient characteristics. Data are presented as mean ± standard deviation (SD), or number of participants (% of participants).

Parameter	**n (%)**
Age, years	67±12
Male gender	99 (52.1)
Ethnicity	
New Zealand European	76 (40.0)
Māori	35 (18.4)
Pacific peoples	35 (18.4)
Asian	24 (12.6)
Other ethnicity	20 (10.6)
Domicile hospital	
Auckland	61 (32.1)
Counties Manukau	86 (45.3)
Waitematā	43 (22.6)
Performance status (ECOG)	
Mean	1.44±1.1
<2	91 (60.5)
≥2	75 (39.5)
Diagnosis	
Biliary cancer	16 (8.4)
Duodenal cancer	18 (9.5)
Gastric cancer	74 (38.9)
Metastatic disease	19 (10)
Neuroendocrine tumour (NET)	6 (3.2)
Pancreatic cancer	57 (30)
Nature of obstruction	
Intrinsic	127 (66.8)
Extrinsic	63 (33.2)
Systemic disease	
Peritoneal infiltration	52 (27.4)
Ascites	33 (17.4)

Table 1 (continued): Patient characteristics. Data are presented as mean ± standard deviation (SD), or number of participants (% of participants).

Systemic treatment	
Chemotherapy	88 (46.3)
Radiotherapy	13 (6.8)

ECOG = Eastern Cooperative Oncology Group score.

Table 2: Patient outcomes after stent placement. Data are presented as mean ± standard deviation (SD), median (interquartile range [IQR]) and/or number of participants (% of participants).

Outcomes	**n (%)**
Technical success	186 (97.9)
Clinical success	156 (83.9)
Symptom scores	
Pre-GOOSS	0.20±0.57
Post-GOOSS	2.03±0.84
Type of SEMS	
Fully covered	30 (16.1)
Partially covered	20 (10.8)
Uncovered	136 (73.1)
Location of proximal stent flange	
Gastric	134 (72)
Duodenal	52 (28)

GOOSS = gastric outlet obstruction symptom score; SEMS = self-expanding metal stent.

Table 3: Adverse events, reintervention and survival after stent placement. Data are presented as mean ± standard deviation (SD), median (interquartile range [IQR]) and/or number of participants (% of participants).

Parameter	n (%)
Adverse events	
Any adverse event	82 (44.1)
Stent dysfunction	66 (35.5)
Perforation	6 (3.2)
Migration	15 (8.1)
Occlusion	45 (24.2)
Biliary obstruction	28 (15.1)
Death within 7 days	6 (3.2)
Aspiration pneumonia	2 (1.1)
GI bleeding	1 (0.5)
Disease progression	1 (0.5)
Other	2 (1.1)
Reintervention	
Participants having reintervention for GOO	60 (32.3)
Reintervention events	71
Dilatation	13 (7.0)
Repeat stent	47 (25.3)
Other endoscopic intervention[a]	6 (3.2)
Surgery	5 (2.7)
Mean reinterventions per participant	0.32±0.47
Stent patency time, days	67±76
Survival	
Post-stent survival, days	95 (37–197)
Days in hospital after stenting	4 (2–7)

[a] Includes placement of nasojejunal tube (4), endoscopic stent clearance (1), and treatment of tumour in growth (1).
GI = gastrointestinal bleeding; GOO = gastric outlet obstruction.

Table 4: Univariate analysis of stent dysfunction for grouped cohorts.

Variable		Stent dysfunction (%)	OR	95% CI	P-value
Age	<70 years	48 (42.9)	2.33	1.22–4.47	0.01
	≥70 years	18 (24.3)			
Gender	Male	41 (42.7)	1.94	1.05–3.58	0.05
	Female	25 (27.8)			
Ethnicity	Māori	18 (51.4)	2.27	1.08–4.79	0.03
	Non-Māori	48 (31.8)			
Performance status	ECOG <2	41 (45.6)	2.03	1.05–3.92	0.03
	ECOG ≥2	21 (29.2)			
Diagnosis	Biliary cancer	2 (12.5)	0.24	0.05–1.08	0.06
	Duodenal cancer	9 (52.9)	2.21	0.81–6.04	0.18
	Gastric cancer	38 (52.1)	3.30	1.76–6.17	<0.001
	Metastatic disease	5 (26.3)	0.62	0.21–1.81	0.46
	Neuroendocrine tumour	1 (16.7)	0.35	0.04–3.09	0.43
	Pancreatic cancer	11 (20)	0.35	0.16–0.73	0.004
Chemotherapy	Yes	35 (40.7)	1.53	0.84–2.79	0.22
	No	31 (31)			
Nature of obstruction	Intrinsic	53 (42.7)	2.81	1.39–5.71	0.004
	Extrinsic	13 (21)			
Peritoneal disease	Yes	21 (41.2)	1.4	0.72–2.72	0.39
	No	45 (33.3)			
Ascites	Yes	13 (41.9)	1.39	0.63–3.05	0.42
	No	53 (34.2)			
Proximal stent location	Gastric	53 (39.6)	1.96	0.96–4.02	0.09
	Duodenal	13 (25)			
Stent type	Covered/partially covered	31 (62)	4.71	2.37–9.37	<0.001

OR = odds ratio; CI = confidence interval; ECOG = Eastern Cooperative Oncology Group score.

Table 5: Multivariate logistic regression analysis for stent dysfunction within grouped cohorts.

Variable		Univariate p-value	OR	95% CI	P-value
Age	<70 years	0.01	1.64	0.73–3.72	0.23
	≥70 years				
Gender	Male	0.05	1.49	0.71–3.14	0.29
	Female				
Ethnicity	Māori	0.03	0.60	0.24–1.50	0.28
	Non- Māori				
Performance status	ECOG <2	0.03	2.32	1.08–4.99	0.03
	ECOG ≥2				
Diagnosis	Biliary cancer	0.06	0.32	0.05–1.97	0.22
	Duodenal cancer	0.18			
	Gastric cancer	<0.001	1.81	0.67–4.88	0.24
	Metastatic disease	0.46			
	Neuroendocrine tumour	0.43			
	Pancreatic cancer	0.004	0.58	0.20–.67	0.31
Chemotherapy	Yes	0.22			
	No				
Nature of obstruction	Intrinsic	0.004	0.92	0.32–2.65	0.88
	Extrinsic				
Peritoneal disease	Yes	0.39			
	No				
Ascites	Yes	0.42			
	No				
Proximal stent location	Gastric	0.09			
	Duodenal				
Stent type	Covered/partially covered	<0.001	3.06	1.35–6.95	0.008
	Uncovered				

OR = odds ratio; CI = confidence interval; ECOG = Eastern Cooperative Oncology Group score.

Table 6: Univariate and multivariate Cox regression analysis of mortality outcomes.

Variable		Death (%)	P-value	HR	95% CI	P-value
Age	<70 years	100 (83.3)	0.14			
	≥70 years	71 (91.0)				
Gender	Male	87 (86.1)	0.92			
	Female	84 (86.6)				
Ethnicity	Māori	33 (94.3)	0.13			
	Non- Māori	138 (84.7)				
Performance status	ECOG <2	79 (80.6)	0.04	1.47	1.03–2.09	0.03
	ECOG ≥2	68 (91.9)				
Diagnosis	Biliary cancer	2 (12.5)	0.89			
	Duodenal cancer	9 (52.9)	0.81			
	Gastric cancer	36 (49.3)	0.68			
	Metastatic disease	5 (26.3)	0.68			
	Neuroendocrine tumour	6 (100)	0.60			
	Pancreatic cancer	52 (94.5)	0.04	0.96	0.61–1.51	0.86
Chemotherapy	Yes	73 (84.9)	0.60			
	No	98 (87.5)				
Nature of obstruction	Intrinsic	111 (83.5)	0.09	0.64	0.41–0.99	0.05
	Extrinsic	60 (92.3)				
Peritoneal disease	Yes	46 (90.2)	0.36			
	No	125 (85.0)				
Ascites	Yes	32 (100)	0.01	2.23	1.39–3.58	<0.001
	No	139 (83.7)				
Proximal stent location	Gastric	122 (84.7)	0.27			
	Duodenal	49 (90.7)				
Stent type	Covered/partially covered	45 (76.3)	0.012	1.45	0.98–2.14	0.06
	Uncovered	126 (90.7)				

HR = hazard ratio; CI = confidence interval.

COMPETING INTERESTS
There are no conflicts of interest to declare.

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