

## Gastroenterología y Hepatología



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#### **ORIGINAL**

# Antral localization worsens the efficacy of enteral stents in malignant digestive tumors

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Received 27 July 2010; accepted 6 December 2010

#### **KEYWORDS**

Self-expandable metal stents; Malignant gastric/duodenal obstruction

#### Abstract

Background and aims: Malignant gastric outlet obstruction can be treated by means of enteral stenting or surgical gastrojejunalanatomosis. We evaluated in a prospective and multicentre study the efficacy of the enteral stent on food intake, the quality of life impact, and the relationship between efficacy and determined clinical and technical parameters.

Patients and methods: Seventy one patients affected by symptoms arising from gastroduodenal obstruction due to malignant tumors, with criteria of irresecability, metastatic disease or very high surgical risk, were treated by means of self expanding metal stents. We used the GOOSS index to evaluate efficacy, and the Euro Qol-5D index to evaluate quality of life.

Results: Before stenting patients with GOOSS 0 and 1 were 68 (98.5%). After stenting patients with GOOSS 2 and 3 (semisolid and solid food) were 58 (84,1%) (P<.0001). The Euro Qol-5D index measured before and a month after stenting were 10.17 and 10.04 respectively (P=.6). The median survival was 91 days (9-552). The enteral stents for localised tumors in the duodenum and the gastrojejunalanastomosis were effective in 26 patients (70.2%) and 13 patients respectively (86.6%), while the enteral stents of tumors in the antrum were effective in only 5 patients (29.4%).

Conclusions: The palliative treatment of malignant gastric outlet obstruction with a uncovered metal stent produces a significant improvement of oral food intake and maintains the overall quality of life index. The antral localization is associated with a lower efficacy of the procedure. © 2010 Elsevier España, S.L. All rights reserved.

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#### PALABRAS CLAVE

Prótesis enteral autoexpandible; Obstrucción gástrica/duodenal maligna

### La localización antral empeora la eficacia de las prótesis enterales en tumores digestivos malignos

#### Resumen

Antecedentes y objetivos: La obstrucción maligna del tracto de salida gástrico puede tratarse mediante el implante de una prótesis enteral o mediante anastomosis yeyunogástrica. Mediante un estudio multicéntrico y prospectivo, evaluamos la eficacia de las prótesis enterales en la ingesta de alimentos, su repercusión en la calidad de vida y la relación entre eficacia y parámetros clínicos y técnicos determinados.

Pacientes y métodos: Un total de 71 pacientes afectados por síntomas derivados de una obstrucción gastroduodenal ocasionada por neoplasia, con criterios de irresecabilidad, metástasis o riesgo quirúrgico muy elevado, fueron tratados con prótesis metálicas autoexpandibles. Utilizamos el índice GOOSS para evaluar la eficacia, y el Euro Qol-5D para evaluar la calidad de vida. Resultados: Antes de implantar la prótesis, 68 (98,5%) pacientes puntuaban GOOSS 0 y 1. Después del implante, el número de pacientes con GOOSS 2 y 3 (alimentos semisólidos y sólidos) era 58 (84,1%) (p < 0,0001). El valor del índice Euro Qol-5D antes y un mes después del implante fue 10,17 y 10,04, respectivamente (p = 0,6). La mediana de supervivencia fue 91 días (9-552). Las prótesis enterales colocadas para tumores en el duodeno y la anastomosis yeyunogástrica resultaron eficaces en 26 (70,2%) y 13 pacientes, respectivamente (86,6%), mientras que las prótesis colocadas en el antro solo resultaron eficaces en 5 pacientes (29,4%).

Conclusiones: El tratamiento paliativo de la obstrucción por neoplasia del tracto de salida gástrico con una prótesis metálica sin recubrir produce una mejora significativa de la ingesta oral de alimentos y mantiene la calidad de vida general. La localización antral se asocia con una eficacia inferior del procedimiento.

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#### Introduction

Intolerance to food intake in patients with gastroduodenal obstruction caused by malignant upper digestive tumors deteriorates the patient's nutritional state, determines the associated treatment, and deteriorates quality of life, which could finally reduce patient survival.

Treatment of gastroduodenal obstruction caused by malignant tumor remains controversial, and there is debate as to whether gastrojejunal surgical anastomosis or endoscopical placing of an enteral stent is more effective in relieving obstruction. Various studies have shown the efficacy of endoscopical enteral stents as palliative treatment of these patients. 1-4 However, these studies are heterogeneous, and include little information on the impact of enteral stents on quality of life and on factors affecting efficacy and security of palliative endoscopic treatment. This lack of information feeds the debate about opting for surgical palliative treatment or endoscopic palliative treatment, and choice between each other depends mostly on availability and experience in each particular hospital setting. The aim of this study was to assess the efficacy of endoscopic stents in alleviating gastroduodenal obstruction caused by upper digestive malignancy, producing intolerance to food intake.

#### Methods and material

We carried out a multicentric, prospective study in five Spanish hospitals. We included all patients admitted to hospital with gastroduodenal obstruction caused by digestive or

Table 1 Food intolerance (Alder DG).		
GOOSS (Gastric Outlet Obstruction Scoring System)		
Food intolerance	Score	
Intolerance or very deficient	0	
Liquid diet	1	
Soft diet	2	
Normal diet	3	

extra-digestive malignant tumors. All patients had an unresectable tumor, or metastatic disease, or very high surgical risk. Patients with obstructive symptoms due to plastic linitis were excluded. Endoscopic stents were placed in all these patients, with no surgical group control. Intolerance to food intake was defined as repetitive vomiting of food remnants in the next 24hours after food intake and residual food in stomach during gastroscopy performed after 9 h fasting. The degree of obstruction was graded using a food tolerance scale called GOOSS (Gastric Outlet Obstruction Scoring System)<sup>5</sup> (table 1).

The main variable studied was improvement of oral food intake after endoscopic stent placement, measured with GOOSS. The secondary variable was the quality of life, measured with Euro Qol-5D questionnaire. <sup>6,7</sup> Other variables were: the survival, the length of hospital stay, and the need for successive stenting during follow-up. Early and late complications of stent placing such as stent migration, gastroduodenal perforation, bleeding, biliary tree obstruction and abdominal pain were also recorded.

Tolerance to food intake after stenting was considered adequate when patients were able to eat a semisolid or solid diet without vomiting (GOOSS score 2-3).

We considered stenting as efficient when an increase of at least 2 points in the GOOSS scale was observed one month after stenting. In order to perform statistical analysis, we classified upper digestive obstruction in three different localizations: duodenal, gastric, and gastrojejunal anastomosis obstruction.

We registered and analysed the following data and their relationship with enteral stent efficiency:

- Patient-related data: age, sex, average functional status by means of Karnofsy scale and degree of gastric outlet obstruction by GOOSS.
- Tumor-related data: histologic type, primary localization
- Stenting procedure-related data: type of stent, number of stents placed, stent placing under simple endoscopic control or under combined endoscopic-radiologic control, need for pneumatic balloon dilation of stenotic area before stent placing, duration of endoscopic procedure and hospital in which stent was placed.
- Data related to active treatment administered after stent placing: adjuvant chemotherapy, or none.

All stents used were uncovered Self-Expanding Metal Stents (SEMS) manufactured by Boston Scientific Corp. (Natick, Massachussets, USA), diameters between 18 and 22 mm and length appropriate for each lesion.

Informed consent were obtained in all patients before the procedure.

Therapeutic protocol before stent placing was as follows: patients were kept fasting during at least 24 hours before stenting; antibiotic prophylaxis was adminstered in patients with risk factors for bacteremia finally, enteral stent were placed under sedation according to standard protocol and technique in each hospital.

In brief, a therapeutic endoscope (working channel 3.7 mm/4.2 mm), either forward or side viewing, was used to insert the stents. Under fluoroscopy, the stricture was traversed with a 0.035-inch guidewire (Boston Scientific Corp., Mass.) and then delineated with the introduction of a radio-opaque contrast agent. The expandable metallic stent was advanced through the endoscope over the guidewire until it passed the distal end of the stricture; after this the stent was deployed under continuous fluoroscopic and endoscopic control.

We considered adequate endoscopic stent placing when the proximal and distal end showed adequate opening in the radiologic or endoscopic control.

In cases without radiologic control and extremely tight stricture, predilation with endoscopic balloon (CRE wireguided 12-13.5-15; Boston Scientific Corp., Mass) was required to allow passage of a pediatric endoscope (diameter 5.9 mm) to ensure proper placement of the guide.

Treatment protocol after stent placing included administration of dextrose and saline intravenous solutions, omeprazole 40 mg/day i.v., and on-demand analgesics (metamizole 1 g i.v). Liquid oral intake was started 6 hours after stenting. If tolerance was good, a semi-liquid diet was given. Hospital discharge was considered 24 hours after the

patient had been able to tolerate semi-liquid oral diet. One week after good semi-liquid diet tolerance, a soft diet with no vegetal fibre was allowed, with slow, progressive inclusion of more consistent food according to tolerance, advising patients to eat slowly, chew thoroughly, avoid raw or fibrous vegetables, and drinking one or two carbonated drinks per day. They were also prescribed omeprazole 20 mg once a day.

After discharge, patients were followed up in order to assess the impact of stenting on the outcome of symptoms and on quality of life. Follow up was carried out either as outpatients or by phone if the patient was not fit enough to go to the Hospital.

For statistical analysis, we used the  $\chi^2$  test or the exact Fisher test (depending on the sample size) to compare the qualitative variables. We used the McNemar test to check the non parametric distribution variables, and we compared the continuous variables with the Student t-test. For survival analysis we used the Kaplan-Meier method. (We considered that a statistically significant difference existed when P was <.05). All statistical calculations were made with the SPSS 12.0 software (SPSS, Chicago, Ill).

#### Results

Stent placing was attempted in 77 consecutive patients. In 6 patients (7.8%) stent placement was not achieved and were excluded from analysis.

Adequate stent placement was performed in 71 patients: 31 men, 40 women, age  $73.1\pm12.4$  years, Karnofsky index  $64.86\pm12$ . Two patients died during the hospital stay, because of nosocomial pneumonia and central catheter infection respectively.

The localization of the tumor was antrum in 18 patients (25.4%), duodenal in 38 patients (53.5%) and in the gastro-jejunal anastomosis in 15 patients (21.1%). The histology of the tumor is shown in table 2. The clinical indication of placement was defined as palliative in 45 patients (63.4%), palliative followed by adjuvant with chemotherapy in 25 patients (35.2%) and as «bridge to an eventual surgery» in 1 patient (1.4%).

The type of stents were: Wallflex stents in 54 patients (76%); Wallstent stents in 12 patients (16.9%), and Ultraflex stents in 5 patients (7%).

The length of the endoscopic procedure for stent placement was  $20.49\pm8.6$  minutes. Combined endoscopic and radiologic control was used in 36 stent placements (50.7%); the remaining 35 procedures (49.3%) were performed under

 Table 2
 Histology of the tumors.

Tumor histology	n (%)
Gastric adenocarcinoma	29 (40.8)
Pancreatic adenocarcinoma	20 (28.2)
Duodenal adenocarcinoma	5 (7)
Gallblader adenocarcinoma	4 (5.6)
Metastases	5 (7)
Cholangiocarcinoma	3 (4.2)
Ampulloma	3 (4.2)
Myeloma	1 (1.4)

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st stenting (GOOSS).		
Pre-stenting	Post-stenting	Р
68 (98.5%)	11 (19.2%)	<.0001
1 (1.5%)	58 (84.1%)	
	68 (98.5%)	Pre-stenting Post-stenting 68 (98.5%) 11 (19.2%)

endoscopic control only. Duration of endoscopic procedure for stent placement, with and without radiologic control, was  $22.2\pm9.7$  and  $18.7\pm7$  min respectively (P=.1).

Before stenting, pneumatic balloon dilation of the lesion was performed in 10 patients (14%). Length of hospital stay after stent placing was  $3.35\pm3.4$  days.

Before stenting, the number of patients who could not eat any sort of food, or only liquids (GOOSS 0 and 1), was 68 (98.5%). After stenting, 58 (84,1%) patients were able to take semi-liquid (mashed) or solid foods without vomiting (GOOSS 2 and 3) (P<.0001) (table 3).

We found no significant correlation between stent efficacy and: hospital where stent was placed, type of stent placed, previous pneumatic balloon dilation, combined radiologic-endoscopic control, length of procedure, patient age, Karnofsky index or adjuvant chemotherapy (table 4). In contrast, there was a statistically significant correlation between stent efficacy and tumor location. Stent placed in neoplasic stenosis of gastric antrum was only effective in 5 patients (29.4%), and did not improve symptoms of obstruction in 12 patients (70.5%). On the contrary, stents placed in duodenal or in gastrojejunal anastomosis stenotic tumors were effective in 26 patients (70.2%) (*P*<.002) and 13 patients (86.6%) respectively (*P*<.002).

Median survival after stent placement was 91 days (range, 9-552). Survival in patients receiving (n=25) and not receiving (n=46) chemotherapy after stenting was  $108\pm3.12$  and  $83\pm7.55$  days, respectively (P=.24).

Eleven patients (14.8%) had complications due to stent placement: self-limiting bleeding, 5 patients (7%); late perforation not dilatation related, 2 patients (2.8%); intense pain (controlled with analgesia), 2 patients (2.8%); and early tumor obstruction requiring surgical treatment, 2 patients (2.8%). Pneumatic balloon stent dilation due to insufficient stent expansion was required in 3 patients (4.3%). Immediate telescopic placing of a second stent due to insufficient coverage of the whole tumor with the first stent was required in 3 patients (4.3%). There was no statistical cor-

**Table 4** Efficacy (GOOSS increase 2 or 3 points). Statistical correlation parameters.

Variables	Р
Adjuvant chemotherapy	0.7
Hospital	0.2
Type of stent	0.1
Previous pneumatic balloon dilation	0.6
Radiological control	0.4
Quality of life index	0.1
Age	0.7
Previous Karnofsky index	0.9
Stenting time	0.1
Stenosis localization	0.002

relation between the occurrence of complications and: type of stent used, localization of neoplastic stenosis, pneumatic balloon tumor dilation before stenting, and use of radiologic control or not.

In 9 of the 35 patients (25%) in which stent placement was carried out without radiologic control, the endoscopic team considered to perform pneumatic balloon dilation before stenting and then advance a pediatric endoscope to ensure the correct placement of the stent. During follow-up, 10 patients (14%) required the placement of a second stent because of re-stenosis due to tumor growth into the stent lumen.

The Euro QOL-5D index was measured before and one month after stent placing. Complete answer to both questionnaires was obtained from only 29 patients (40%). The index value was 10.17 before and 10.04 one month after stent placement (P=.6).

#### Discussion

Endoscopic placement of enteral stents as palliative treatment of gastroduodenal obstruction caused by malignant tumors has been proposed as an alternative to surgical derivative treatment.<sup>8</sup> A review of the 32 published series, including more than 600 cases of endoscopic stenting, shows clinical improvement in 87% of patients, occurrence of serious complications in 1.2%, stent migration in 5%, stent obstruction in 18% and a median survival of 12.1 weeks.<sup>9</sup>

The published comparative studies between endoscopic stent placement and surgical treatment (gastrojejunal anastomosis) show that stenting shortens the time lapse until resumption of food intake, causes less procedure-related morbidity, and reduces hospital stay and hospital costs. <sup>10–17</sup>

The results of our study clearly show that endoscopic stenting improves symptoms of gastric outlet obstruction. The use of a semiquantitative index such as GOOSS allows to objectively compare the results of different series.

The statistical significance of the improvement of oral food tolerance after stenting probably depends on the increment of GOOSS score that investigators choose as definitory of clinically relevant improvement. In our case, we consider that an increment of 1 point alone in the GOOSS score does not constitute a sufficient clinical improvement. So we decided to define as clinically relevant food tolerance improvement an increase of GOOSS score of >2 points after stenting. This requirement reinforces the efficiency results of endoscopic stenting obtained in our patients.

The analysis of the efficiency of the enteral stents in improving symptoms of gastric outlet obstruction did not show any differences among hospitals, type of stent used, pneumatic balloon dilation of tumoral stenosis before stent placement, duration of procedure, age, quality of life score, or Karnofsky score. In contrast, our study shows that antral localization of stenotic tumor worsens the efficiency of

endoscopic stents, in comparison with duodenal or gastroenteral anastomotic tumors. We do not know of the reason for this phenomenon, which has not been described in previous series. We could speculate some of possibilities, such as: loss of antral motility caused by the antral invasive tumor; in order to cause obstruction, antral tumors usually have to be larger than duodenal or gastroenteral anastomotic tumors, with higher risk of invasion of deep gastric wall layers and perigastric structures, causing antral rigidity with loss of motility and elasticity. These same reasons could also explain the bad results of surgical gastrojejunostomy often reported in patients with large antral tumors causing gastric outlet obstruction.

In most published studies, duodenal stents are placed combining endoscopic and radiologic control. <sup>18–24</sup> The probable reason for this is the belief that, in the duodenum, morphologic and topographic characteristics of the stenotic lesion are better determined with double (endoscopic and radiologic) control, while radiology offers a better image of stent positioning and expansion in the suprastenothic segment, eventually allowing, if placement and/or expansion are not satisfactory, the immediate replacement of the stent.

In our experience, simple endoscopic control (without radiologic aid) has been usually enough to correctly place antral, duodenal, and gastroenteral anastomotic stents, and the lack of radiologic control has not increased the duration of the procedure or the number of complications. However, it is noteworthy that, in our study, we performed a larger number of pneumatic balloon dilations before stent placement. A pediatric endoscope was sometimes used to advance through the stenosis and assess the correct placement of the guidewire.

This study offers information on the impact of endoscopic stents on quality of life (QOL) in patients with obstructive gastroduodenal cancer. The quality of life index chosen, the EuroQOL-5D, has been already used in a variety of upper digestive diseases, and includes a vertical qualification scale of five parameters: mobility, personal care, daily activities, pain and discomfort and, finally, anxiety and depression. Our results are in accordance with those obtained by other authors, 25 and indicate that the QOL index is not significantly modified after the placement of the endoscopic stent. In patients with untreated gastric outlet obstruction, the normal expected outcome is a progressive worsening of QOL. However, in our series, after stent placement the QOL index remained stable and did not worsen, probably due to the relieving effect of the stent, allowing an improvement in food intake, with no influence on the rest of the parameters included in the EuroQOL-5D index. In conclusion, our results suggest that the improvement of food tolerance after stenting has a positive influence in the natural history of the

In our serie, the overall complication rate was 14.8%. The most frequent complication was bleeding, usually was self-limited and requiring only conservative measures. Two patients had abdominal pain after stenting, requiring analgesics; pain spontaneously resolved in a few days. Perforation is the most serious complication, and may require surgical treatment if the general condition of the patient allows surgery. Tumor growth into the stent lumen through an uncovered metallic mesh is another possible complica-

tion. This complication is expectable mainly in the later stages of the neoplastic disease, but can be observed a few weeks after stent placement. Sometimes it can be difficult to differentiate stent obstruction caused by tumor growth through the open mesh or by solid food remnants. When stent obstruction happened, we treated our patients with the placement of a new, open metallic stent. It is possible that restenting with covered or partially covered stents could be more efficient for relieveing tumoral gastric outlet obstruction, as it has recently been published.<sup>26</sup>

Treatment with chemotherapy has been shown to extend the patency of the enteral stents. 18,25 Our patients receiving adjuvant chemotherapy after stenting achieved a slightly longer survival compared with those not receiving chemotherapy, but this difference was not statistically significant. It should be noted, in our study, that indication of adjuvant chemotherapy was not randomized, and was established regarding age, tumor local staging, comorbidity, patient general condition, and survival expectancy. The patient subgroup treated with chemotherapy had better baseline general condition and life expectancy, compared to the subgroup not receiving chemotherapy; thus, both groups are not amenable to statistical comparison. As a consequence, the observed positive effect of chemotherapy on survival could be the result of a population bias.

In summary, palliative treatment of malignant gastric outlet obstruction with metallic stents improves significantly the tolerance to food intake and helps maintaining the overall quality of life. The efficacy of stents in relieving obstruction is lower if the obstructing tumor is located in gastric antrum. Endoscopic stent placement can be performed without radiologic control, with similar results regarding efficiency and security, but may often require previous endoscopic balloon dilation of the obstructive segment.

#### Conflicts of interest

Drs. C. Dolz, A. Vilella, P. González Carro, F. González Huix, JC. Espinós, S. Santolaria, F. Pérez Roldán, M. Figa, C. Loras and H. Andreu have no conflicts of interest or financial ties to disclose.

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