Research article

Treatment of malignant gastric outlet obstruction with stents: An evaluation of the reported variables for clinical outcome
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Abstract

Background: Malignant gastric outlet obstruction (GOO) is commonly seen in patients with advanced gastric-, pancreatic-, duodenal, hepatobiliary or metastatic malignancies. Ten to 25% of patients with pancreatic cancer will develop duodenal obstruction during the course of the disease. Duodenal stenting with self-expandable metal stents is an alternative treatment to surgical bypass procedures. Our aim was to review the published literature regarding treatment of malignant GOO with stents to reveal whether the information provided is sufficient to evaluate the clinical effects of this treatment

Methods: A literature search from 2000 – 2007 was conducted in Pub Med, Embase, and Cochrane library, combining the following search terms: duodenal stent, malignant duodenal obstruction, gastric outlet obstruction, SEMS, and gastroenteroanastomosis.

All publications presenting data with ≥ 15 patients and only articles written in English were included and a review focusing on the following parameters were conducted: 1) The use of graded scoring systems evaluating clinical success; 2) Assessment of Quality of life (QoL) before and after treatment; 3) Information on stent-patency; 4) The use of objective criteria to evaluate the stent effect.

Results: 41 original papers in English were found; no RCT’s. 16 out of 41 studies used some sort of graded scoring system. No studies had objectively evaluated QoL before or after stent treatment, using standardized QoL-questionnaires, 32/41 studies reported on stent patency and 9/41 performed an oral contrast examination after stent placement. Objective quantitative tests of gastric emptying had not been performed.

Conclusion: Available reports do not provide sufficient relevant information of the clinical outcome of duodenal stenting. In future studies, these relevant issues should be addressed to allow improved evaluation of the effect of stent treatment.

Background
Malignant gastric outlet obstruction (GOO) is commonly seen in patients with advanced gastric-, pancreatic-, duodenal, hepatobiliary or metastatic malignancies. Ten to 25% of patients with pancreatic cancer will develop duodenal obstruction during the course of the disease [1,2].
GOO may result in nausea and vomiting, leading to dehydration and cachexia, which severely reduces the patients’ Quality of Life (QoL).

Traditionally, a surgical by-pass procedure, usually a gastrojejunooanastomosis (GEA), has been the palliative treatment offered, but up to 31% of the patients do not experience sufficient symptom relief following GEA [1,3]. Furthermore, GEA has a peri-operative morbidity as high as 35% and a mortality rate of about 2% in later studies [1,4-7].

Duodenal stenting with self-expandable metal stents (SEMS) is an alternative treatment to surgical bypass procedures. In several studies, this treatment has been evaluated as safe and efficient with a technical success rate of 90–100%, a clinical success rate of 67–100%, a rate of severe complications about 7% and non-severe complication rate about 20% [2,6-8,8-47]. Compared with surgery, the patients treated with stents have fewer serious complications and less need for intensive care unit (ICU) [5] Furthermore, the hospital stay is shorter, which is essential in palliative treatment [5,9,20,32,7].

In palliative cancer treatment, improvement of QoL is a primary goal and needs to be addressed when new treatment strategies and procedures are implemented and evaluated. Relief from obstructive symptoms is the most important parameter for evaluating the clinical effect or treatment outcome following duodenal stenting of GOO, but complications, stent patency and need for re-interventions are also parameters influencing QoL. In the available reports, objective criteria of treatment effects are often missing, which make it difficult to compare results and draw conclusions concerning effects of the treatment offered.

To review the published literature regarding treatment of malignant GOO with stents to reveal whether the information provided is sufficient to evaluate the clinical effects of this treatment, and whether QoL has been assessed.

**Methods**

A search for published literature for the time period January 2000 – September 2007 was conducted in Pub Med, Embase, and Cochrane library, combining the following search terms: duodenal stent, malignant duodenal obstruction, gastric outlet obstruction, SEMS, and gastroenterooanastomosis. Reference lists were hand-searched for additional literature. Furthermore, reference lists of review articles and metaanalyses from the relevant time period were used to identify additional literature. Abstracts were not included. Only studies presenting data with ≥ 15 patients and only articles written in English were included in the present review. When studies included identical patients, the most recent study was included.(see additional file 1)

The identified studies were reviewed with regard to the following parameters:

1. The use of a graded scoring systems evaluating clinical success
2. Assessment of QoL before and after treatment
3. Information on stent-patency
4. The use of objective criteria to evaluate the stent effect

**Results**

When applying the search criteria, 41 original papers and four review articles in English were found (See table 1). The number of patients included in the original papers was 15–213. Of the studies using a combined endoscopic/fluoroscopic method for stent placement ten were prospective and 18 retrospective, corresponding numbers for the studies in which only fluoroscopy was applied were 10 and three, respectively. All prospective and retrospective studies are listed in table 2 and 3 respectively. No randomized controlled trials (RTC’s) treating ≥ 15 patients with stents were found.

**Clinical effect and scoring systems**

To evaluate the clinical effects of stent treatment, 16 out of 41 studies used some sort of graded scoring system (see table 4). The level of oral intake before and after stent treatment was divided into four to five levels, which

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**Table 1: Characteristics of studies included in the review (n = 41)**

| Characteristics                                      | n (% of total) |
|------------------------------------------------------|----------------|
| Prospective studies                                  | 20 (49%)       |
| Retrospective studies                                | 21 (51%)       |
| Stent deployed by fluoroscopic guidance              | 13 (32%)       |
| Stent deployed by combined endoscopic/fluoroscopic guidance | 28 (68%)       |
allows some comparison of the results. The scoring systems used are adapted from studies on dysphagia in esophageal cancer. One of the most frequently used is Gastric Outlet Obstruction Scoring System (GOOSS) presented by Adler in 2002 [2] (0 = no/inadequate oral intake, 1 = liquids/thickened liquids, 2 = semisolids/low residue diet, 3 = unmodified diet). This system assigns a point score based on the level of oral intake. Song et al [48] introduced another similar scoring system (0 = able to eat normal diet, 1 = able to tolerate fragmented solid food without vomiting, 2 = able to tolerate soft food without vomiting, 3 = able to tolerate only liquid diet without vomiting, 4 = not able to tolerate any oral intake without vomiting, 5 = vomiting even without oral intake), mostly used in radiological literature, in which vomiting as an important symptom of obstruction is included. The GOOSS score was applied by 6/41 studies, 1/41 applied the Song score and 8/41 used similar graded scores. Furthermore, in 2007 Lowe et al introduced a Gut function score (0 = profuse vomiting or gut not functioning, 1 = nausea and occasional vomiting, 2 = nausea only, 3 = normal gut function). This function score is used in addition to GOOSS and grades the level of nausea and vomiting. At present, the Gut Function Score has only been applied in the study, in which it was originally presented [44].

QoL in the evaluation of clinical success
No studies had objectively evaluated QoL before or after stent treatment, using standardized QoL-forms (see table 4). Seven of 41 studies used the Karnofsky performance scale before and after stent treatment (A physical performance scale from 100-0, where a scoring of 100 is normal function and 0 is dead).

Stent patency
Concerning stent patency, 32/41 studies reported on this variable (see table 4), either by reporting the exact number of stent failures and time to failure after stent deployment or by calculating the patency. The rate of re-obstruction was reported in 36/41 studies, the migration rate in 34/41 studies.

Objective criteria for stent function
An oral contrast examination was performed after stent placement in 9/41 studies (see table 4). Objective quantitative tests of gastric emptying before and after treatment were not performed in any of the evaluated studies.

Discussion
The present review demonstrates that a graded scoring system for symptom assessment was used in 40% of the evaluated papers. No studies provided information on QoL, although 17% of the studies used the Karnofsky scale.

### Table 2: Prospective studies

| Author     | Year | Patients (n) |
|------------|------|--------------|
| Jung (16)  | 2000 | 19           |
| Lopera (11)| 2001 | 16           |
| Pabon (12) | 2001 | 29           |
| J.H. Kim (13)| 2001 | 29          |
| Park (14)  | 2001 | 24           |
| Jung (17)  | 2002 | 39           |
| Lee(21)    | 2003 | 17           |
| Tang (22)  | 2003 | 21           |
| Nassif (23)| 2003 | 63           |
| Holt (26)  | 2004 | 28           |
| Jeong (27) | 2004 | 25           |
| Johnsson (5)| 2004 | 21          |
| Hayashi (47)| 2005 | 31          |
| Yoon (35)  | 2006 | 82           |
| Espinel (36)| 2006 | 24          |
| Song (42)  | 2007 | 20           |
| Mutignani(43)| 2007 | 64         |
| J.H Kim (41)| 2007 | 213         |
| Lowe(44)   | 2007 | 87           |
| Maetani (45)| 2007 | 37          |

### Table 3: Retrospective studies

| Author | Year | Patients (n) |
|--------|------|--------------|
| Yim (9)| 2001 | 29           |
| Razzaq (10)| 2001 | 23         |
| Aviv (18)| 2002 | 15          |
| Maetani (15)| 2002 | 23         |
| Adler (2) | 2002 | 36         |
| M. Kaw (19)| 2003 | 18         |
| Mittal (6) | 2003 | 16         |
| Stawawy (20)| 2003 | 24         |
| G.H. Kim (24)| 2004 | 49         |
| Lindsay (25)| 2004 | 40         |
| Telford (29)| 2004 | 176        |
| Mosler (30)| 2005 | 36         |
| Bessoud (32)| 2005 | 72         |
| Del Piano (31)| 2005 | 24         |
| Maetani (7) | 2005 | 22         |
| Mair (33)  | 2006 | 24           |
| Kazi (34)  | 2006 | 23           |
| Kiely (37) | 2007 | 30          |
| T.O. Kim (40)| 2007 | 53         |
| J. van Hooft (38)| 2007 | 62         |
| Jeurnink (8) | 2007 | 53         |

### Table 4: Evaluation criteria applied in the reviewed studies (n = 41)

| Evaluation criteria                        | n (% of total) |
|-------------------------------------------|----------------|
| Quality of Life assessment                | 0              |
| Objective criteria for stent function     | 9 (22%)        |
| Clinical effect by graded scoring         | 15 (37%)       |
| Stent patency                             | 33 (80%)       |
Information on stent patency was given in 80% of the studies and 22% had performed oral contrast examination following stent placement to objectify the stent effect. No studies quantified the effect of stent placement on rate of gastric emptying.

The main complaints of patients suffering from malignant duodenal obstruction are often nausea, severe vomiting, bloating and abdominal pain. It is questionable whether the applied scoring systems in the papers reviewed provide adequate and sufficient information about relief from these symptoms after stent placement. Improvement of symptoms estimated by a dysphagia score provides limited information concerning the effect of duodenal stenting, and should thus be used in combination with a scoring system providing information about the more characteristic symptoms of GOO. The Gut Function Score may be a step in the right direction [44], but this scoring system needs further evaluation and validation.

In the present review, no studies were identified using standardized forms to assess QoL before and after stent treatment. One randomized study used SF-36 to evaluate the QoL in 10 patients treated with duodenal stents [49], which is a validated and frequently used QoL questionnaire. This study was, however, too small for inclusion in this review. In 16% of the studies, the Karnofsky scale was used, but this scale captures only one aspect of QoL (physical function) and is today considered inadequate for evaluation of QoL [51]. Also for surgical treatment of GOO, data on the effect of QoL is limited [3]. There have been developed and validated several complex and advanced questionnaires for specific symptoms and specific diseases for the assessment of QoL [51]. EORTC C30 and the organ specific modules are now widely used for the evaluation of palliative cancer treatment. By applying these validated tools, the information about the QoL of patients is improved, and a possible discrepancy between the QoL of the patient estimated by the physician and the patient might be revealed. Studies regarding QoL in palliative cancer treatment have shown that physicians tend to overestimate improvement in QoL of the patients [52,53].

Stent-patency related to survival is an important parameter, because the need for re-interventions and re-hospitalizations most likely will reduce the patients QoL. Re-obstruction of the stent by tumor in- and overgrowth is known to occur in 15–20% of the patients [28] and is probably the most important factor influencing stent patency.

The main effect of stent treatment in GOO is re-establishing the passage of food from the stomach to the duodenum. Evaluation of the stent effect can hence be provided by measuring the rate of gastric emptying before and after stent placement. None of the reviewed studies included information on this issue. In a recent study by Maetani et al., delayed gastric emptying of a liquid meal after stent placement was demonstrated. The patients resumed oral intake after stenting and those with a severe delay of emptying had a reduced survival time [54]. Rate of gastric emptying was, however, only recorded after stenting, and the quantitative effect of stenting was thus not revealed. More detailed data on the effect of stenting on rate of gastric emptying is thus required, and can be used to improve the knowledge on the relation between GOO and obstructive symptoms. This is an important issue, since the relation between gastrointestinal symptoms and gastric emptying might be rather weak [55]. Furthermore, knowledge concerning the effect of SEMS on gastric emptying could possibly help identifying subgroups of patients, in which stenting is particularly beneficial. Gastric emptying is a complex process involving grinding and emptying of the meal, and it is not likely that the re-establishment of passage is followed by a more rapid rate of gastric emptying in all subjects treated.

Conclusion

Only 40% of the studies reviewed used a graded scoring system to evaluate the clinical effect of their treatment. Furthermore, most studies using a graded scoring system applied a point score adapted from dysphagia in esophageal cancer and did thereby not address the symptoms more specific for GOO. The presence of obstructive symptoms (severe vomiting, nausea and bloating) is probably severely reducing the patients QoL. In palliative cancer care, improvement of QoL is a main treatment goal, and data on this issue are missing in all the evaluated papers. Objective evaluation of gastric/duodenal function after stenting is limited and no studies have performed quantitative tests of gastric emptying. The present review thus indicates that the available reports do not provide sufficient relevant information of the clinical outcome of duodenal stenting. In future studies, these relevant issues should be addressed to allow improved evaluation of the effect of stent treatment.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

LL performed the systematic search and drafted the manuscript in cooperation with AWM and TH. All three authors have read and approved the final manuscript.

Additional material

Additional file 1
supplementary file including all details concerning the search.
Click here for file [http://www.biomedcentral.com/content/supplementary/1471-230X-9-45-S1.doc]
References

1. Lillemo KD, Cameron JL, Hardacre JM, Sohn TA, Sauter PK, Coleman J, et al. Is prophylactic gastrojejunostomy indicated for unresectable periampullary cancer? A prospective randomized trial. Ann Surg 1999, 230:322-328.

2. Adler DG, Baron TH: Endoscopic palliation of malignant gastrotic outlet obstruction using self-expanding metal stents: experience in 36 patients Systematic review of the efficacy and safety of colorectal stents. Am J Gastroenterol 2002, 97:72-78.

3. van Heek NT, De Castro SM, van Eijck CH, van Geemen RC, Hesselink EJ, Breslau PJ, et al. The need for a prophylactic gastrojejunostomy for unresectable periampullary cancer: a prospective randomized multicenter trial with special focus on assessment of quality of life. Ann Surg 2003, 238:894-902.

4. Choi YS: Self-expandable metal stent placement for palliation in unresectable gastric cancer. Surg Endosc 2002, 16:1620-1626.

5. Johnsson E, Thune A, Lideman B: Palliation of malignant gastroduodenal obstruction with open surgical bypass or endoscopic stenting: clinical outcome and health economic evaluation. World J Surg 2004, 28:812-817.

6. Mittal A, Windsor J, Woodfield J, Casey P, Lane M: Initial experience with the enteral Wallstent: outcomes from a matched study in 95 patients. Gastrointest Endosc 2001, 53:329-332.

7. Jeurnink SM, van Eijck CH, Steyerberg EW, Kuipers EJ, Siersema PD: Stent versus gastrojejunostomy for the palliation of gastric outlet obstruction: a systematic review. BMC Gastroenterology 2007, 7:18.

8. Tuezzi M, van Eijck CH, Stergerberg EW, Kuipers EJ, Siersema PD: Self-expandable metal stent placement for palliation in gastric outlet obstructions caused by gastric cancer: a comparison with surgical gastrojejunostomy. J Gastroenterol 2005, 40:932-937.

9. Jeurnink SM, van Eijck CH, Steyerberg EW, Kuipers EJ, Siersema PD: Stent versus gastrojejunostomy for the palliation of gastric outlet obstruction: a systematic review. BMC Gastroenterology 2007, 7:18.

10. Razzaq R, Laasch HU, Verheugen J, Hentig U, Laasch HU, et al. Palliation of patients with malignant gastric outlet obstruction with self-expanding metal stents: a prospective study. Endoscopy 2001, 33:838-842.

11. Park KB, Do YS, Kang WK, Choo SW, Han YH, Suh SW, et al. Malignant obstruction of gastric outlet and duodenum: palliation with flexible covered metallic stents. Radiology 2001, 219:679-683.

12. Jeurnink SM, van Eijck CH, Steyerberg EW, Kuipers EJ, Siersema PD: Stent versus gastrojejunostomy for the palliation of malignant gastroduodenal obstruction. J Vasc Interv Radiol 2002, 13:297-303.

13. Jung GS, Song HY, Kang SG, Huh JD, Park SJ, Koo JY, et al. Malignant gastroduodenal obstruction: treatment by means of a covered expandable metallic stent-initial experience. Radiology 2002, 224:402-406.

14. Jung GS, Song HY, Kang SG, Huh JD, Park SJ, Koo JY, et al. Malignant gastroduodenal obstruction: treatment by means of a covered expandable metallic stent-initial experience. J Vasc Interv Radiol 2002, 13:297-303.

15. Jung GS, Song HY, Seo TS, Park SJ, Koo JY, Huh JD, et al. Malignant gastroduodenal obstructions: treatment by means of coaxial placement of uncovered and covered expandable nitinol stents. J Vasc Interv Radiol 2002, 13:275-283.

16. Aviv RJ, Shyamalan G, Khan FH, Watkinson AF, Tibballs J, Caplin M, et al. Use of stents in the palliative treatment of malignant gastrotic outlet and duodenal obstruction. Clin Radiol 2002, 57:587-592.

17. Kaw M, Singh S, Gagneja H: Clinical outcome of simultaneous self-expandable metal stents for palliation of malignant biliary and duodenal obstruction. Surg Endosc 2003, 17:457-461.
41. Kim JH, Song HY, Shin JH, Choi E, Kim TW, Jung HY, et al.: Metallic stent placement in the palliative treatment of malignant gastroduodenal obstructions: prospective evaluation of results and factors influencing outcome in 213 patients. Gastrointest Endosc 2007, 66:256-264.

42. Song GA, Kang DH, Kim TO, Heo J, Kim GH, Cho M, et al.: Endoscopic stenting in patients with recurrent malignant obstruction after gastric surgery: uncovered versus simultaneously deployed uncovered and covered (double) self-expandable metal stents. Gastrointest Endosc 2007, 65:782-787.

43. Mutignani M, Tringali A, Shah SG, Perri V, Familiarì P, Iacopini F, et al.: Combined endoscopic stent insertion in malignant biliary and duodenal obstruction. Endoscopy 2007, 39:440-447.

44. Lowe AS, Beckett CG, Jowett S, May J, Stephenson S, Scally A, et al.: Self-expandable metal stent placement for the palliation of malignant gastroduodenal obstruction: experience in a large, single, UK centre. Clin Radiol 2007, 62:738-744.

45. Maetani I, Iyama H, Mizumoto Y: Palliation in patients with malignant gastric outlet obstruction with a newly designed enteral stent: a multicenter study. Gastrointest Endosc 2007, 66:355-360.

46. Hosono S, Ohtani H, Arimoto Y, Kanamiya Y: Endoscopic stenting versus surgical gastroenterostomy for palliation of malignan gastroduodenal obstruction: a meta-analysis. J Gastroenterol 2007, 42:283-290.

47. Hayashi K, Okayama Y, Gotoh K, Ohara H, Sano H, Nakazawa T, et al.: Clinical evaluation of metallic stenting for malignant duodenal obstruction using covered self-expandable metallic stent. Digestive Endoscopy 2005, 17(3):263-268.

48. Song HY, Shin JH, Yoon CJ, Lee GH, Kim TW, Lee SK, et al.: A dual expandable nitinol stent: experience in 102 patients with malignant gastroduodenal strictures. J Vasc Interv Radiol 2004, 15:1443-1449.

49. Mehta S, Hindmarsh A, Cheong E, Cockburn J, Saada J, Tigher R, et al.: Prospective randomized trial of laparoscopic gastrojejunostomy versus duodenal stenting for malignant gastric outflow obstruction. Surg Endosc 2006, 20:239-242.

50. Kostopoulos PP, Zisis MI, Polydorou AA, Premchand PP, Hendrickse MT, Sharrock CJ, et al.: Are metal stents effective for palliation of malignant dysphagia and fistulas? Dig Liver Dis 2003, 35:275-282.

51. Baier, AM, Machin D: Quality of Life. The assessment, analysis and interpretation of patient reported outcomes 2nd edition. Chichester, West Sussex P019 8Q, England: John Wiley and Sons Ltd; 2007.

52. Petersen MA, Larsen H, Pedersen L, Sonne N, Groenvold M: Assessing health-related quality of life in palliative care: comparing patient and physician assessments. Eur J Cancer 2006, 42:1159-1166.

53. McPherson CJ, ddington-Hall JM: Judging the quality of care at the end of life: can proxies provide reliable information? Soc Sci Med 2003, 56:95-109.

54. Maetani I, Iyama T, Tada T, Ikeda M, Seike M, Terada H, et al.: Gastric emptying in patients with palliative stenting for malignant gastric outlet obstruction. Hepatogastroenterology 2008, 55:298-302.

55. Abrahamsson H: Gastrointestinal motility disorders in patients with diabetes mellitus. J Intern Med 1995, 237:403-409.

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