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QUALITY ASSURANCE GUIDELINES FOR PLACEMENT OF GASTRODUODENAL STENTS

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Introduction

Gastroduodenal obstruction is often a preterminal event in advanced upper gastrointestinal malignant disease. Patients with gastric outlet and duodenal obstruction often exhibit intractable nausea and vomiting, inability to eat and "food fear". The consequences are gastric distension, weight loss, anorexia, dehydration and electrolyte imbalance, leading to a markedly impaired quality of life (1,2,3,4,5,6). Furthermore, these patients are at constant risk of aspiration and pneumonia (3,6).
In view of their advanced disease, curative surgery is not possible and without some form of palliative intervention to maintain enteral nutrition these patients die in hospital. In the past, surgical gastroenterostomy, either at a laparotomy or via laproscopy, with a technical success rate of 90% was the only therapeutic option (7,8). However, the invasiveness of this procedure, compounded by the poor general condition of these patients resulted in a complication rate of 25 – 35% (7,9,10,11) and a perioperative mortality rate of 2% (9,10). Surgery is associated with prolonged stay in hospital (10,12,13,14,15) and, significant cost (10,13,14,15). Poor function of the gastroenterostomy with persistent nausea and vomiting occurs in as many as 90% of cases (10,13,15,16).

Percutaneous jejunostomy or gastrojejunostomy may be employed but the long-term results are poor. The catheters sometimes become occluded or dislocated (17,18,19), are a source of infection, serve to constantly remind patients of their illness (18,19), do not allow oral intake of solids (20,21) and carry a risk of aspiration (6,18,19).
Nasogastric tubes provide gastric decompression but cannot be used for enteral feeding. Two-valve nasojejunal tubes enable both gastric decompression and enteral feeding but long-term placement is very uncomfortable and does not improve the patient's quality of life (6).
Radiological insertion of large-diameter, self-expanding stents can overcome gastroduodenal obstruction and re-establish oral feeding in patients who are in poor general condition. With refinement of the technique and the development of enteral stents, this procedure is becoming the method of first choice in the palliation of gastric outlet and duodenal obstruction in patients with advanced upper gastrointestinal malignant disease.

Definition

Gastroduodenal stenting is a minimally invasive imaging-guided palliative procedure that involves the placement of a large diameter self expanding metal stent across an intrinsic or extrinsic gastroduodenal obstructing lesion resulting in re-establishment of the normal anatomical conduit and permitting oral feeding.

Technical success is defined as successful placement and deployment of the stent across the stricture. (22)

Clinical success is defined as relief of symptoms and /or improvement of oral intake (22) obviating the need for palliative surgery. (12,23)

Indications (3,5,6,12,17,21,22,23,24,25,26,27,28,29,30,31)

- Unresectable or untreatable malignant disease resulting in gastrointestinal obstruction.
    a. Intrinsic or extrinsic tumours, which are unresectable or untreatable resulting in gastrointestinal obstruction such as stomach and duodenal cancers. Curative resection is not possible in 40% of gastric cancers (32,33).
    b. Extrinsic gastroduodenal obstruction due to pancreatic malignancy, cholangiocarcinoma, malignant lymphadenopathy, localised intraperitoneal metastasis or lymphoma. Curative resection is not possible in 80-95% of pancreatic cancers (32-35).

- Anastomotic recurrence in the afferent or efferent loop of the gastrojejunostomy following definitive or palliative surgery for upper gastrointestinal malignancy (25,31,36,37).
- In patients who have residual malignancy or in whom repeated dilatations have failed to deal with pyloric obstruction due to dysfunction after gastric pull up operation for oesophageal carcinoma (38,39).
- Covered stents for treatment of malignant fistulas in the stomach and duodenum to adjacent organs (12,25,26).
- Benign strictures secondary to chronic ulcer disease where surgery is not feasible and repeated balloon dilatation has failed (3, 20, 30, 40,41).

Contraindications

Absolute

1) Clinical and radiological signs of free gastrointestinal perforation with peritonitis (5,26).
2) Co-existence of distal small bowel obstruction, which cannot be accessed for stent insertion (26,28).

Relative

1) Documented peritoneal carcinomatosis (22,26).

2) Abnormal coagulation profile. Stenting can proceed under cover of fresh frozen plasma and platelets.

Patient selection

Following upper gastrointestinal imaging and investigations to allow accurate staging of the tumours, including evaluation of the length and location of the strictures, treatment options should be discussed by a multidisciplinary team, which includes interventional radiologists, gastroenterologists and upper gastrointestinal surgeons. (3,21,29,30)

It is important to exclude stenosis or obstruction in the distal small bowel, which can compromise the passage of intestinal contents. This can be difficult in patients with very tight strictures of the gastric outlet and duodenum (5). If it is not possible to exclude significant distal bowel disease with CT, follow-through examination after oral administration of contrast medium or entroclysis may be helpful (37).

Pre procedure preparation

The interventional radiologist must obtain informed consent from the patient or (if necessary) his family, having explained the procedure, the intended benefits and possible complications.

A full blood count and coagulation screen should be performed.
A large bore (16G) nasogastric tube should be inserted and left on free drainage 12-24 hours before the procedure to ensure adequate gastric decompression (3,5,21,37). An empty stomach becomes cylindrical and permits easier catheter manipulation and advancement of the stent delivery device (17). If the stomach is distended, the risk for aspiration is higher. In addition, in a distended stomach the introducer will pass along the greater curve, increasing the distance it has to traverse before reaching the stricture. This results in the introducer falling short of the stricture in some patients (3,27).

Technique (1,3,5,6,17,21,27,30,37)

Gastrointestinal stent insertion is performed via the peroral route. In case of failure of the peroral route the gastrostomy route can be tried.
The procedure can be guided with fluoroscopy alone or with fluoroscopy combined with endoscopy (3,5). However, fluoroscopy is essential for positioning the stent (3,27).
The procedure is performed under conscious sedation and analgesia (3,24) (e.g. intravenous midazolam and fentanyl). The pharynx is anaesthetised with 1% lidocaine spray. With the patient in the lateral decubitus position, ideally on a tilting table with the head end raised to reduce the risk of aspiration during the procedure, access can be gained using a 100cm 5F or 6F angled tip catheter. With the catheter in the body of the stomach, iodinated contrast medium is injected to identify the proximal end of the stricture. Under fluoroscopic guidance, the catheter and guide wire (Bentson's guide wire or Terumo guide wire) are manipulated across the stricture. Looping of the catheter-guide wire system can be reduced by use of a stiff overtube, such as an 11F Mullin's sheath (William Cook, Europe Bjaevershov, Denmark).
Once the catheter has passed beyond the stricture, water soluble contrast medium is injected to delineate its distal end. Injection of air improves delineation of the stricture.

When the catheter has been advanced into the proximal jejunum the guide wire is replaced with a 260 cm exchange length super stiff Amplatz wire. Predilatation of the stricture is not advisable, as it increases the risk of perforation (3,12,23,30,42). However, in very tight stenoses, gentle predilatation with a 10mm balloon can be performed to allow easy passage of the stent delivery system (12,17,25,27).

A stent of adequate diameter (minimum 18mm) (6,27) and length is chosen. The stent is deployed under fluoroscopic guidance and should be 2-4 cm longer than the stricture to reduce the risk of tumour overgrowth. Irrespective of the length of the stricture, longer stents are preferable because shorter stents are more easily displaced (as per personal experience) and are less likely to conform to the curvature of the duodenum (28) and thus be kinked (6). If more than one, coaxially placed, stents are required, the distal stent should be positioned first. There should be at least 2cm overlap between stents in order to reduce the risk of separation as a result of peristalsis (5).

It is important to ensure that the distal end of the stent is within the lumen of a straight segment of the duodenum. If it abuts the wall it can lead to stent obstruction (37) and may later erode through the bowel wall (12,26,28). Because of this consideration, it is helpful to use a long stent or to insert additional stents extending beyond the junction of the second and third parts of the duodenum even if it is not involved by the tumour (37).

Once the stent / stents are deployed, there is no need for post dilatation as most self expanding stents will gradually reach their full diameter. Dilatation carries a risk of stent dislodgment during manipulation of the balloon catheter through the partially expanded device (17,27).

Local injection of contrast medium is used to assess the patency and position of the endoprosthesis and rule out perforation.
In some patients it proves impossible to cannulate the stricture under fluoroscopic guidance because of constant coiling of the catheter-guide wire system in the capacious stomach. In such cases direct visualisation of the proximal end of the stricture with an endoscope may prove useful. Using an endoscope has the additional advantage of preventing coiling of the device within the stomach (5,27,28). The stent is deployed through the endoscope using fluoroscopic guidance.

In a minority of patients it is not possible to negotiate the stricture via the peroral route. In these cases, a shorter, more direct route to the stricture via a gastrostomy may prove useful. After gastropexy using T-fasteners (Brown/Muller T-fasteners, Boston Scientific) the anterior gastric wall is punctured and a 9F peel away sheath is placed in the stomach. The stricture is negotiated using catheter and guide wire technique as described for the per oral route and stent deployment is performed via this access. After the procedure, the introducer sheath is replaced by a 9 –12F catheter, which is left in place for 10-15 days to permit tract maturation and avoid peritoneal leakage of gastric contents. In case of failure of stent insertion by this route, it may be impossible to retrieve the gastrostomy tube.

In patients in whom the stricture involves the second part of the duodenum the Ampulla of Vater may be involved resulting in obstructive jaundice. In such patients
biliary and duodenal stenting can be carried out during the same session (43). First, access to the biliary tree is gained via a percutaneous transhepatic approach and a guide wire is passed through the biliary obstruction into the duodenum. The duodenal stricture is intubated and crossed with a guide wire. Uncovered stents are then positioned across both strictures, with the biliary endoprosthesis being deployed first, so that both stents lie side by side in the duodenal lumen (43). Alternatively the duodenal stent can be deployed first, with the biliary endoprosthesis placed through its the mesh (28,37).

Aftercare (27)

The patient should fast overnight and be monitored for signs of perforation and peritonitis.
The following day an upper gastrointestinal study with water-soluble contrast medium is performed to assess stent position, expansion and adequacy of lesion coverage. The patient is then allowed to eat, building up gradually from a liquid to a solid diet. Patients are advised to chew their food well and to avoid high fibre foods in order to reduce the risk of food bolus obstruction. Intake of carbonated drinks at meals helps to maintain stent patency (24,27).

Metallic stents used in the stomach and duodenum

Enteral stents should be flexible, should have sufficient radial force to expand within fibrosis and tumour and adequate length to prevent kinking (6,30) and should resist migration and prevent tumour ingrowth (5).

Many types of stent have been used in the upper gastrointestinal tract, but the Enteral Wallstent (Boston Scientific) is the only stent approved by the Food and Drug Administration for use in the gastric outlet and duodenum (1,26).

This uncovered stent is flexible, simple to deploy, opens immediately and has good radial force (6). It is wide (18 – 22 mm) and available in 60mm and 90mm lengths. It is pre-loaded on a 10F delivery system (5) that is suitable for crossing most strictures. The delivery device is 160cm long, which is sufficient to reach stenoses up to the duodeno-jejunal flexure, without making the system too unwieldy for radiological placement (1).
The disadvantage of the enteral Wallstent is that it is not yet available in a covered version and hence cannot resist obstruction by tumour ingrowth or tissue hyperplasia. In addition, the bare ends of the stent can cause ulceration (44) and perforation of the bowel wall (45).
Other uncovered stents used in the upper gastrointestinal tract are the Gianturco Z stent, the oesophageal Wallstent, the vascular Wallstent, the Ultraflex oesophageal stent, the Esophacoil (5), the Memotherm stent and the Choo stent (37).
Uncovered stents are more flexible and resist migration. However when used for long-term palliation they are subject to tumour ingrowth (5).

Covered stents (eg. Choo stent, Niti-S Stent, Song stent) have the advantage of resisting tumour ingrowth, (26) but are more rigid, difficult to deploy at distant locations through tortuous delivery paths, require larger delivery systems and are more likely to migrate. If deployed in the second part of the duodenum across the Ampulla of Vater, they can lead to biliary obstruction (17,25).

To overcome the problems of migration of covered stents, Jung et al (46) introduced coaxial placement of uncovered and covered expandable nitinol stents. This method has not been widely accepted.

There are relatively few publications on the use and efficacy of covered stents. Small series have shown that they have a higher rate of migration (26%) than uncovered stents (23,25,29). Partially covered stents have a lower rate of migration than fully covered devices (23,25). As most patients receiving enteric stents have a short life expectancy (6,27) obstruction of uncovered stents by tumour ingrowth or overgrowth is uncommon (20,37).

Outcome Measures

Criteria	**Published data**
Technical success	97% (22)
Clinical success	89% (22)
Time to final resolution of symptoms	3.0 days (15) – 3.7 days (22)
Hospital free survival	4 wks (47) – 13 wks (15)

Technical success

It is possible to cross most strictures, but sometimes complicated anatomy, severe stenosis or looping within a dilated stomach may lead to failure (22,37,44). These patients may require a surgical bypass.

Clinical success

Some patients continue to have symptoms after stent placement. This may be due to previously undiagnosed distal small bowel strictures (20,21,25,29,37), progression of the disease (22), lack of propulsive peristalsis in a chronically obstructed stomach (21,37), or functional gastric outlet obstruction from neural (coeliac axis) involvement by tumour (26).

Hospital free survival

Following stenting and return to oral feeding, patients can be discharged home or to a hospice (24) within a few days (15). With resumption of oral feeding patients can function normally and lead relatively independent lives (15,48).

Complications

Major Complications	
Procedural mortality	0% (22)
Perforation	<1% (22)
Bleeding	<1% (22)
Minor Complications	
Stent obstruction	17.2% (22)
Stent migration	2.7% uncovered (48) 10% covered (48)
Pain	2.5% (22)
Biliary complications	1.3% (22)

Perforation
This is a life threatening complication requiring urgent surgical treatment. Early perforation (within 24 hours of the procedure) may be caused by guide wire manipulation and balloon dilatation. Perforation by a guide wire is usually not associated with any sequelae (3). Perforation following balloon dilatation is more serious with surgery required in most cases (3). Late perforation is caused by erosion of the bare ends of the stent through the wall of the intestine (21,26,31,37,45).

Haemorrhage
Bleeding can be minor requiring only conservative treatment (21,24). In patients with large exophytic vascular tumours stenting can cause ulceration by pressure necrosis and result in life threatening haemorrhage requiring vascular embolization (23).

Stent Obstruction
Obstruction can be caused by food bolus, tumour ingrowth or overgrowth. The cause can be established by endoscopic examination. In food bolus obstruction, the impacted food should be removed endoscopically (27). Tumour ingrowth or overgrowth can be treated by coaxial placement of another stent. Secondary stent patency rates are 80-100% (6).

Stent Migration
Stent migration can be partial or complete, proximal or distal (29). It can be managed by insertion of another stent. Proximally migrated stents can be removed from the stomach using a nitinol snare (37). Distally migrated stents if non-obstructing can be left and have occasionally passed per rectum without any complications (25,29,37). If the stent is impacted and causing obstruction, surgical removal is necessary (37).

Pain
Abdominal pain usually resolves spontaneously. It is mild to moderate, lasts for 24-72 hours after stent insertion and can be treated with analgesics (22,25,44).

Biliary problems

Tumours involving the second part of duodenum usually cause biliary obstruction, which can be treated by percutaneous transhepatic insertion of metallic stents (31). There have been case reports of cholangitis (22) and fistula formation to the biliary tree following duodenal stenting. Treatment of these unusual complications is difficult and warrants individual case assessment.

BIBLIOGRAPHY

1. Lopera JE, Brazzini A, Gonzales A, et al. Gastroduodenal Stent Placement: Current Status. Radiographics 2004; 24:1561-1573.

2. Khullar SK, Di Sario JA. Gastric outlet obstruction. Gastrointest Endosc Clin N Am 1996; 6(3): 585-603.

3. Zollikofer CL, Jost R, Schoch E, et al. Gastroduodenal and colonic stents: Review article. Seminars in Interventional Radiology 2001; 18(3): 265-280.

4. Mergener K, Kozarek RA. Stenting of the gastrointestinal tract. Dig Dis 2002; 20:173-181.

5. Mauro MA, Koehler RE, Baron TH. Advances in gastrointestinal intervention: the treatment of gastroduodenal and colorectal obstructions with metallic stents. Radiology 2000; 215: 659-669.

6. Zollikofer CL, Jost R, Schoch E, et al. Gastrointestinal stenting. Eur Radiol. 2000; 10: 329-341.

7. Weaver DW, Wiencek RG, Bouwman DL et al. Gastrojejunostomy: is it helpful for patients with pancreatic cancer? Surgery 1987; 102: 608-13.

8. Nagy A, Brosseuk D, Hemming A, et al.Laproscopic gastroenterostomy for duodenal obstruction. Am J Surg 1995; 169: 539-42.

9. Lillemoe KD, Vameron JL, Hardacre JM, et al. Is prophylactic gastrojejunostomy indicated for unresectable periampullary cancer? A prospective randomised trial. Ann Surg 1999; 230: 322-8.

10. Van Wagensveld BA, Coene PP, Van Gulik TM, et al. Outcome of palliative gastric bypass surgery for pancreatic head carcinoma in 126 patients. Br J Surg 1997; 84(10): 1402-6.

11. Potts JR, Broughan TA, Hermann RE. Palliative operations for pancreatic carcinoma. Am J Surg 1990; 159: 72-78.

12. Gukovsky-Reicher S, Lin RM, Sial S, et al. Self-expandable metal stents in the palliation of malignant gastrointestinal obstruction: Review of the current literature data and 5-year experience at Habour-UCLA Medical centre. Medscape General Medicine 5(1), 2003.

13. Doberneck RC, BerndtGA. Delayed gastric emptying after palliative gastrojejunostomy for carcinoma of the pancreas. Arch Surg 1987; 122:827-9.

14. Johnsson E, Thune A, Liedman B. Palliation of malignant gastroduodenal obstruction with open surgical bypass or endoscopic stenting: clinical outcome and health economic evaluation. World J Surg 2004; 28(8): 812.

15. Del Piano M, Ballare M, Montino F, et al. Endoscopy or surgery for malignant GI outlet obstruction? Gastrointest Endosc 2005; 61(3): 421-426.

16. Weaver D, Winczek R, Bowenian H, et al. Gastrojejunostomy: is it helpful in patients with pancreatic cancer? Surgery 1987; 107: 608-613.

17. Acunas B, Poyanli A, Rozanes I. Intervention in gastrointestinal tract: the treatment of oesophageal, gastroduodenal and colorectal obstructions with metallic stents. Eur Radiol 2002; 42:240-248.

18. Shike M, Latkany L, Gerdes H et al. Direct percutaneous endoscopic jejunostomies for enteral feeding. Gastrointest Endosc 1996; 44: 536-540.

19. Guiliamo M, Lomis NNT, Yoon HC, et al. Experience with large bore percutaneous gastrostomy and gastrojejunostomy feeding tubes. J Vasc Interv Radiol 1999; 10 (suppl): 218-219.

20. de Baere T, Harry G, Ducreux M, et al. Self expanding metal stents as palliative treatment of malignant gastroduodenal stenosis. Am J Roentgenol 1997; 169: 1079-1083.

21. Pinto Pabon IT, Diaz LP, de Adana JCR et al. Gastric and duodenal stents: Follow up and complications. Cardiovasc Intervent Radiol 2001; 24:147-153.

22. Dormann A, Meisner S, Verin N et al. Self expanding metal stents for gastroduodenal malignancies: systematic review of their clinical effectiveness. Endoscopy 2004; 36 (6): 543-550.

23. Lopera JE, Alvarez O, Castano R, et al. Initial experience with Song'scovered duodenal stent in the treatment of malignant gastroduodenal obstruction. JVIR 2001; 12(11): 1297-1303.

24. Lindsay JO, Andreyev HJN, Vlavianos, et al. Self-expandable metal stents for the palliation of malignant gastrointestinal obstruction in patients unsuitable for surgical bypass. Aliment Pharmacol Ther 19(8): 901-905,2004.

25. Song HY, Shin JH, Yoon CJ, et al. A dual expandable nitinol stent: experience in 102 patients with malignant gastroduodenal strictures. JVIR 2004;15(12): 1443-1449.

26. Baron TH, Harewood GC. Enteral self expandable stents. Gastrointest Endosc 2003; 58 (3): 421-433.

27. Morgan R, Adam A. Use of metallic stents and balloons in the esophagus and gastrointestinal tract. J Vasc Interv Radiol 2001; 12: 283-297.

28. Razzaq R, Laasch HU, England R et al. Expandable metal stents for the palliation of malignant gastroduodenal obstruction. Cardiovasc Intervent Radiol 2001; 24: 313-318.

29. Jung GS, Song HY, Kang SG et al. Malignant gastroduodenal obstructions: Treatment by means of a covered expandable metallic stent – Initial experience. Radiology 2000; 216: 758-763.

30. Binkert CA, Ledermann HP, Jost R, et al. Metallic stenting of gastroduodenal and colonic stenosis. Abdom Imagign 1998; 23: 580-586.

31. Mosler P, Mergener KD, Brandabur JJ, et al. Palliation of gastric outlet and proximal small bowel obstruction with self-expandable metal stents. A single centre series. J Clin Gastroenterol 2005; 39(2): 124-128

32. Kurtz RC, Sherlock P. Carcinoma of the stomach. In: Berk JE, Harbrich WS, Kalser MH, Roth JLA, Schaffner F, eds. Bochus gastroenterology. 4th ed. Philadelphia, PA: Saunders, 1985; 1278-1304.

33.Wade TP, Neuberger TJ, Swope TJ, et al. Pancreatic cancer palliation: using tumour stage to select appropriate operation. Am J Surg1994; 167: 208-213.

34. Warshaw AL, Castillo CF. Pancreatic carcinoma. New Engl J Med 1992; 326: 455-465.

35. Yeo CJ. Pancreatic cancer: update. J AM Coll Surg 1998; 187: 429-442.

36. Yim HB, JacobsonBC, SaltzmanJR, et al. Clinical outcome of the use of enetral stents for palliation of patients with malignant upper GI obstruction. Gastrointest Endosc 2001; 53: 329-332.

37. Bessoud B, de Baere T, Denys A, et al. Malignant gastroduodenal obstruction: palliation with self expanding metal stents. JVIR 2005; 16(2, Part1): 247-253.

38.Cowling MG, Goh P, Mason RC et al. Self expanding metallic stents in the management of pyloric dysfunction after gastric pull-up operations. Eur Radiol 1999; 9: 1123-1125.

39. Cowling MG, Goh P, Mason RC et al. The role of self expanding metal stents in the relief of gastric outflow obstruction. Cardiovasc Intervent Radiol 1998; 21(suppl 1): 130

40. Scott-Mackie P, Morgan R, Ferrugia M et al. The role of metallic stents in malignant duodenal obstructions. Br. J Radiol 1997; 70: 252-255.

41. Binkert CA, Jost R, Steiner A, et al. Benign and malignant stenosis of the stomach and duodenum: Treatment with self-expanding metallic endoprostheses. Radiology 1996; 199: 335-338.

42. Deans GT, Krukowski ZH, Irwing ST. Malignant obstruction in the left colon. Br J Surg 1994; 81: 1270-1276.

43. Kaw M, Singh S, Gagneja H. Clinical outcome of simultaneous self-expandable metal stents for palliation of biliary and duodenal obstruction. Surg Endosc 2003; 17: 457-461.

44. Tang T, Allison M, Dunkley I, et al. Enteral stenting in 21 patients with malignant gastroduodenal obstruction. J Royal Soc Med 2003; 96: 494-496.

45. Thumbe VK, Houghton AD, Smith MS. Duodenal perforation by a wallstent. Endoscopy 2000; 32: 495-497.

46. Jung GS, Song HY, Seo TS, et al. Malignant gastric outlet obstructions: treatment by means of coaxial placement of uncovered and covered expandable nitinol stents. J Vasc Interv Radiol 2002; 13(3): 275-283.

47. Lee DW, Chan AC, Ng EK et al. Through-the-scope stent for malignant gastric outlet obstruction. Hong Kong Med J. 2003; 9(1): 48-50.

48. Holt A, Patel M, Ahmed M. Palliation of patients with malignant gastroduodenal obstruction with self –expanding metal stents: the treatment of choice? Gastrointest Endosc 2004; 60(6): 1010-1017.