

Уважаемые коллеги!

Высылаем специальный выпуск «Issue of ELLA Abstracts» Special UEGW

A. Esophageal Stenting and related topics

1

Abstract: P0050

Citation: Gut 2008; 57 (Suppl II) A 114

COMPARISON OF THE DOUBLE-LAYERED AND COVERED NITI-S STENTS FOR PALLIATION OF MALIGNANT DYSPHAGIA

INTRODUCTION: Covered metal stents have been accepted as the treatment of choice for malignant dysphagia due to esophageal and gastric cardia cancer, but stent migration is a major shortcoming. A double-layered Niti-S stent was therefore introduced to obviate this problem.

AIMS & METHODS: We aimed to compare double-layered and covered Niti-S stents regarding safety, efficacy, and feasibility in the treatment of malignant dysphagia. Thirty seven consecutive patients with malignant dysphagia due to inoperable esophageal or gastric cardia cancer were enrolled in a prospective, randomized study. Main outcomes were technical success, improvement in dysphagia score after stent insertion, and complications.

RESULTS: Technical success was achieved at a similar rate in both groups (covered, 19/19 [100%] vs. double-layered, 16/17 [94%]). A week after stent insertion, the mean dysphagia score improved significantly in the covered and double-layered groups compared to baseline (from 2.95 ± 0.52 and 2.88 ± 0.33 to 1.00 ± 0.47 and 1.06 ± 0.24 , respectively; $p < 0.001$). There was no difference in survival of the patients in the two groups. The overall complications, including stent migration and tumor overgrowth, occurred more frequently with covered stents (11/19 [58%]) than double-layered stents (2/17 [12%]) ($p = 0.006$).
CONCLUSION: Newly developed, self expanding metal stents, (covered and double-layered Niti-S stents) were equally effective and feasible treatments for malignant dysphagia. However, double-layered Niti-S stents are preferable due to their favorable safety profile.

2

Abstract: P0051

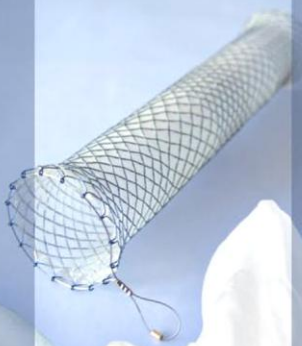
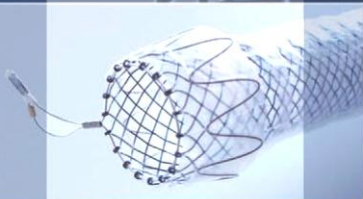
Citation: Gut 2008; 57 (Suppl II) A 115

ESOPHAGEAL INSERTION OF SELF-EXPANDING METALLIC STENTS (SEMS) WITHOUT FLUOROSCOPY IN NON OPERABLE MALIGNANT ESOPHAGEAL STRICTURES

INTRODUCTION: Over the last 15 years, SEMS have increasingly been used for the palliation of malignant dysphagia and the sealing of malignant esophagorespiratory fistulas¹. Fluoroscopy is routinely used to guide the placement of SEMS, although recently stent deployment under endoscopic guidance only has been described [2,3]. A method of inserting SEMS with endoscopic guidance alone is described here.

AIMS & METHODS: This technique relies on a clear endoscopic view of the proximal end of the stent (Ultraflex covered proximal release stent, Boston Microvasive). Firstly, a thin gastroscope (Fujinon EC- 250WL5, Japan) with an outer diameter of 9 mm was passed into the stomach, allowing measurement of stricture length and the exact distance of the proximal margin of the stenosis from the mouth. A Savary guide wire was then inserted through the working channel and left inside the gastric cavity. In cases of tight strictures dilation with Savary bougies up to 10 mm was carried out. The endoscope was then

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reinserted and placed alongside the guidewire giving direct visualization of the proximal margin of the stricture. A suitable size of stent was chosen in all cases based on the length and the estimated diameter of the strictures. The stent delivery device was passed over the guide wire, traversing the stricture. The proximal end of the stent was positioned 6-8 cm above the stricture, under endoscopic visualisation and the stent was deployed.

RESULTS: Sixty six consecutive patients (12 women, mean age = 69.32±7) with inoperable esophageal malignancy (13 squamous cell cancers of the median third of esophagus, 45 adenocarcinomas of the lower third and esophagogastric junction and 21 for obstructive non small cell lung cancer) underwent endoscopic placement of self-expanding metal stents as palliative treatment (n = 61 dysphagia palliation, 12 esophagotracheal fistula). Mean stricture length was 6.28±2.5 cm. Deployment in satisfactory position without fluoroscopy was successful in all patients; there were no immediate complications. Esophageal stent migration was noted in 4 cases (range 6-400 days). Adequate symptoms relief was noted in 57 (86.3%) of patients. Symptoms relapse occurred in 31 patients (mean relapse interval 210 days, range 45-400 days).

CONCLUSION: SEMS can be accurately and safely positioned without fluoroscopy for palliative treatment of esophageal malignancy.

3

Abstract: P0706

Citation: Endoscopy 2008; 40 (Suppl 1) A 246

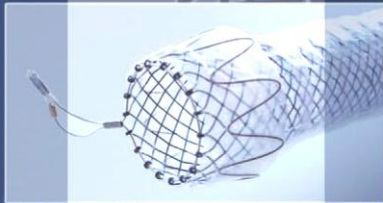
HIGH COMPLICATION RATE IN LONG-TERM ESOPHAGEAL STENTING FOR NON-MALIGNANT DISEASE

INTRODUCTION: Self-expandable metal stents (SEMS) have been used for a variety of non-malignant esophageal conditions. It is generally advised to remove these stents within 4-8 weeks. Although some of these stents are labelled removable, extraction can be complicated. In this cohort study we investigated the efficacy of SEMS extraction in patients who were treated with a SEMS for a benign esophageal condition for 6 weeks or longer.

AIMS & METHODS: To determine the safety and efficacy of esophageal stent insertion for more than 6 weeks in benign diseases. All consecutive patients with a benign esophageal condition who were treated by placement of a SEMS at our hospital between 2001 and 2008, were extracted from a prospective database.

RESULTS: Thirty patients were identified. Indications for stent insertion included; Boerhaave's syndrome (n = 12), iatrogenic perforations (n = 13), mediastinal radiation stenoses (n = 1), caustic stenoses (n = 2), refractory achalasia (n = 1), and fistula after surgery (n = 1). Stent removal was performed within 6 weeks in 23 patients (group I). Stents were removed in 7 patients after 6 to 37 weeks (median: 7 weeks) (group II). Reasons for leaving the stent in place beyond 6 weeks were: persistent symptoms (n = 5) and refusal of stent extraction (n = 2). SEMS were removed by using a grasping forceps. Stent extraction was successful and without complications in all patients in group I (100%) vs 2 patients in group II (29%). Complications in group II were: self-limiting bleeding (n = 1), and stent fracture (n = 4). In 2 patients complete removal was successful after 3 attempts, 1 patient required gastrotomy, and in 1 patient the stent was incompletely removed after 9 attempts. The latter patient subsequently developed a stenosis and a thoracic empyema, 26 and 47 months after incomplete stent extraction respectively.

CONCLUSION: Self-expandable metal stents for non-malignant esophageal conditions should be removed within 6 weeks after insertion. SEMS longer in place could not be easily removed in the majority of patients and complications occurred in 71%.



4

Abstract: P0053

Citation: Gut 2008; 57 (Suppl II) A 115

OESOPHAGEAL STENT INSERTION UNDER DIRECT ENDOSCOPIC VISION IS SAFE, EFFECTIVE, AND ASSOCIATED WITH LOW RATES OF STENT MIGRATION AND TUMOUR OVERGROWTH

INTRODUCTION: Placement of self-expanding metal stents (SEMS) under direct endoscopic vision is a recently established method for palliating malignant dysphagia. It enables early intervention without the need for fluoroscopy, helping maintain quality of life and nutritional intake in patients with limited life expectancy. The rates of complication and stent failure are yet to be fully established.

AIMS & METHODS: To assess the rate of complication and stent failure following SEMS placement under direct endoscopic vision in a single unit over a 4 year period. A retrospective review of the unit's endoscopy database was performed, and patients who underwent endoscopic oesophageal stent placement for malignant disease were identified. Patient demographics and diagnosis was recorded. Repeat endoscopic procedures or interventions were noted, and case records were scrutinised to establish date of death.

RESULTS: Between September 2004 - May 2008, 93 endoscopic SEMS insertions were performed in 77 patients. In all 41 (53%) were male, 36 (47%) were female, and the average age was 73.7 years (range 39-95). 57% (n = 44) had adenocarcinoma of the oesophagus, 34% (n = 26) squamous, with 7 (9%) other malignancies. 15 (19%) underwent pneumatic dilatation prior to SEMS insertion. Uncovered stents were deployed on 60 occasions (65%), covered stents were used in 24 (26%), 9% not documented. There was one case of failure of stent deployment, however successful stenting was achieved in all cases, and there were no significant procedural complications recorded. Post-stenting complications were observed following 23 (25%) procedures and consisted of food bolus obstruction (n = 7), stent migration (n = 3), tumour ingrowth (n = 4), stent overgrowth (n = 7) and oesophago- bronchial fistula (n = 2). 12 patients (16%) required a total of 16 further SEMS to be placed endoscopically. Average follow-up was 4.9 months (range 0.5-17 months). Overall mortality was 79% (n = 61) and the average survival after stent insertion was 4.8 months (range 0.1-17 months).

CONCLUSION: Endoscopic SEMS can be reliably placed under direct vision without the need for fluoroscopy, and procedural complication rates are very low. Rates of stent migration and tumour overgrowth were small in our patient group, and although a number of procedures were followed by some form of stent related complication, the majority of patients (84% in this study) did not require further endoscopic stent placement.

5

Abstract: P0702

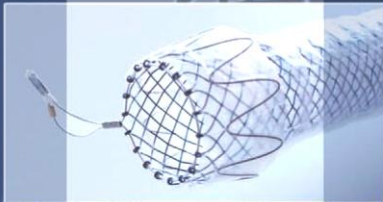
Citation: Endoscopy 2008; 40 (Suppl 1) A 245

OESOPHAGEAL STENTING IN THE PALLIATION OF MALIGNANT DYSPHAGIA; A PROSPECTIVE MULTI-CENTRE AUDIT

INTRODUCTION: Despite advances in treatment, majority of oesophageal cancers are inoperable and palliative treatment remains the mainstay of care. Oesophageal stent insertion provides an effective palliation of dysphagia in such patients

AIMS & METHODS: This prospective audit was undertaken to assess the success rate and complications in 5 UK district general hospitals which provide upper GI cancer service as

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multidisciplinary network group. Data was collected by the dedicated upper GI cancer specialist nurses on the pre-designed audit proforma

RESULTS: In this study period of one year 135 patients underwent 140 oesophageal stent insertions. The mean age was 74.3 years (range 44-92) and 69% (93/135) were males. The ASA status was 3 or greater in 65% of the patients. The indication for stenting was extrinsic oesophageal compression secondary to lung cancer in two patients whilst all others had oesophageal malignancy. The site of oesophageal cancer was; upper third (3%), middle third (34%), lower third (47%) and junctional (16%). Histological study revealed adenocarcinoma in 73.6% (98), squamous cell carcinoma in 25.5% (34) and was inconclusive in 0.75% (1) of the cases. The mean length of the tumour needed to stent was 6.1 cms (range 2-13 cms). Stenting was carried out by Gastroenterologists (60%), Radiologists (35%) and Surgeons (5%) using either endoscopic or fluoroscopic approach or by combination technique. Pre-stent oesophageal dilatation (10-13 mm) was done in 14% (20) of procedures. Different stents were inserted; Flamingo (59), Ultraflex (37), NITI-S (14), Hanarostent (11), Ella stent (8), Choo stent (4) and others (7). Pre stent dysphagia score was 2 or more (mellow & pinkas score) in 93% of patients and 87% noticed improvement in their dysphagia on day 7 following stenting. The average length of hospital stay was 3.8 days (range 0-40) and no procedure related deaths were recorded. 5 patients died during their hospital stay post-stenting but no procedure related complications were recorded in this cohort. Early complications occurred in 32 procedures (23%); chest pain 19 (13.5%), misplacement 8 (5.7%), aspiration 2 (1.4%), obstruction 2 (1.4%) and bleeding in 1 (0.7%). Late complications occurred in 21 procedures (15%); obstruction due to tumour ingrowth or overgrowth 6 (4%), continuing chest pain 5 (3.5%), stent migration 4 (3%), severe reflux 4 (3.5%), fistula 1 (0.7%) and oesophageal wall erosion in 1 (0.7%).

CONCLUSION: Oesophageal stenting is safe and provides effective palliation for dysphagia in patients with inoperable malignancy. No procedure related deaths were seen in our cohort of patients

6

Abstract: P0231

Citation: Gut 2008; 57 (Suppl II) A 151

PALLIATION OF MALIGNANT DYSPHAGIA: EXPERIENCE IN A CANCER CENTRE IN THE UK

INTRODUCTION: Esophageal cancer is a lethal malignancy and adenocarcinoma of esophagus is increasing in incidence. Most patients present with locally advanced, unresectable or metastatic disease. Dysphagia is the main presenting symptom and lead to nutritional compromise, pain and poor quality of life. Although a variety of palliative therapies are available for palliation of dysphagia, the optimal strategy is still unknown.

AIMS & METHODS: To assess the survival of patients who underwent palliative treatment for esophageal cancer in an upper GI cancer centre.

Method: We retrospectively analysed 73 patients underwent palliation of eosophgeal cancer in our institution from January 2005 for a period of two years. Chemotherapy, chemo radiotherapy and or in combination with metallic stent placements were compared for survival advantage. Survival advantage of various modalities in different cancer histology was also analysed

RESULTS: Age range 22 to 92, Males 40 Females 33, Adenocarcinoma 44, Squamous 26,

Adenosquamous 1, undifferentiated 2. Overall mean survival was 33 weeks. All modalities showed survival advantage over no treatment. There was no statistically significant survival advantage between the various modalities although survival plot suggest a tendency for marginal improvement with combined interventions. Cancer histology did not affect the survival irrespective of the treatment.

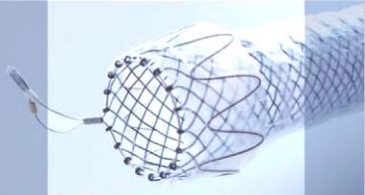


TABLE 1: Comparison of various treatment groups against no treatment group

Treatment	N	Mean (weeks)	SD	P
Chemo	10	42.70	29.8	0.0025
Stent	15	31.13	31.98	0.0463
Radiotherapy	15	43.67	39.60	0.0102
Chemo+Radio	10	51.00	38.13	0.0024
Chemo+Radio+Stent	8	48.88	57.34	0.0361

CONCLUSION: Survival after palliative therapy in esophageal cancer is short and various modalities of palliation offer similar survival pattern. Rapid, effective and long term relief of dysphagia should be the principal aim of palliation. Since there is no survival advantage between different strategies, treatment should be tailored to the individual patient depending on the local availability and expertise.

7

Abstract: OP028

Citation: Endoscopy 2008; 40 (Suppl 1) A 6

PLACEMENT OF SELF-EXPANDABLE STENTS FOR NON-MALIGNANT ESOPHAGEAL PERFORATION

INTRODUCTION: Esophageal perforation carries a high morbidity and mortality rate. There is no consensus regarding the appropriate treatment modality for this emergency. In the current cohort study we investigated the clinical value of self-expandable metal stents (SEMS) placement for non-malignant esophageal perforation.

AIMS & METHODS: To determine the safety and efficacy of SEMS in patients with a non-malignant esophageal perforation. All consecutive patients with a non-malignant esophageal perforation, who were treated by placement of a SEMS at our hospital between 2001 and 2008, were enrolled in this study.

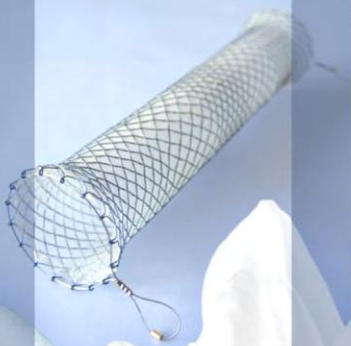
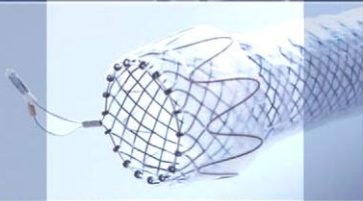
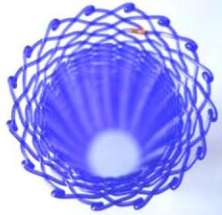
RESULTS: Twenty-five patients (72% male; median age 61 years (range: 13-87 months)) were followed after the first placement of SEMS (median follow-up 3 years (range 5-78 months)). Perforation of the esophagus was caused by either Boerhaave's syndrome (n = 12) or iatrogenic instrumentation (n = 13). Twenty-one patients received a partially-covered stent and 4 patients received a fully-covered metal stent. Placement was technically successful in all patients. Two patients with Boerhaave syndrome required esophagectomy within 2 days. Stent migration was observed in 2 patients and persistent perforation in 5 patients. In these 7 patients (28%), an endoscopic intervention was performed; stent reposition (n = 1), stent replacement (n = 1), and additional stent insertion (n = 5). Stents were removed after a median of 5 weeks post-SEMS insertion (range: 1-37 weeks). No stent-related deaths occurred. Six patients (24%) died within 2 months post-SEMS insertion, due to esophageal perforation (n = 4) and to progression of the underlying disease (n = 2).

CONCLUSION: In patients with a non-malignant esophageal perforation, endoscopic placement of a self-expandable metal stent can be effective. The re-intervention rate is considerable, however surgery can be avoided in 92% of patients.

8

Abstract: OP196

Citation: Gut 2008; 57 (Suppl II) A 42



REMOVAL SELF-EXPANDING STENT USED AS A CONTINUOUS, NON- PERMANENT DILATOR IN TREATING REFRACTORY BENIGN OESOPHAGEAL STRICTURES: A PROSPECTIVE MULTICENTER STUDY

INTRODUCTION: Refractory benign oesophageal strictures (RBOS) are difficult to treat requiring frequent dilatations or surgery. Conceptually, while maintaining luminal patency, if a dilator is kept in place continuously for several weeks and then removed, the benefits may be longer lasting. Oesophageal stents will be ideal in achieving the above. Preliminary results on using a removable self- expanding plastic oesophageal stent, Polyflex® stent (PS), for treating RBOS have been mixed and many of these studies were retrospective in design [1,2,3,4].

AIMS & METHODS: Aim: To evaluate the efficacy of PS in the treatment of RBOS. Method: A prospective multicenter study was performed on 40 patients with RBOS [mean age 60±15SD yrs, female 14 male 26, Anastomotic12 (fistula 4), Corrosive 8, Radiation 7, Pill induced 4, Post trauma 3 (fistula 3), Peptic 2, Others 4 (fistula 1)]. Continuous non-permanent dilation was performed by placing a PS and removing it after 4 weeks. The patients were then followed at regular intervals. Pre-insertion baseline data and post-removal information on dysphagia status, complications, and change in outcome were prospectively collected.

RESULTS: The technical success in stent placement and stent removal were 95% and 94%, respectively. Mean post-stent dysphagia score was 0.6±0.7SD which was significant better than pre- stent scores (3.0±0.8SD; p < 0.001). At median follow up of 53 weeks (range 11-156), only 40% (intention to treat 30%) patients were dysphagia-free without further interventions. However, the overall change in outcome from baseline options (ongoing dilatations, G-tube placement, or surgery) was 66% (dysphagia-free 12, did not want removal 2, did not remove 1, preferred long-term stenting 10). The stent was successful in closing the fistula in 5 of 8 (63%) patients. Complications observed were migration 8 (22%), severe chest pain 4 (11%), bleeding 3 (8%), perforation 2 (5.5%), GE reflux 2 (5.5%), impaction 2 (5.5%), and new fistula 1 (2.7%). There was one mortality from massive bleeding.

CONCLUSION: It was feasible to deploy and remove PS stents in the majority of patients with RBOS. Some patients achieved long term relief without further re-interventions while several others re- strictured and preferred long-term stenting over repeated dilations or surgery. The procedure carries significant risks and hence should only be considered in carefully selected patients, preferably in protocols.

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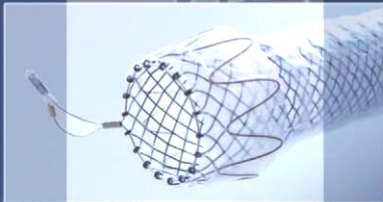
Abstract: P0707

Citation: Endoscopy 2008; 40 (Suppl 1) A 246

SELF EXPANDABLE PLASTIC STENTS (POLYFLEX®) IN THE TREATMENT OF POST-OPERATIVE ESOPHAGO-JEJUNO ANASTOMOSIS LEAK

INTRODUCTION: Self-expandable plastic stents (SEPS) are increasingly being used for treatment of postoperative oesophageal leak. This complication occurs in 4-30% of patients after radical gastrectomy, and has a high mortality rate of up to 60%. **AIMS & METHODS:** To evaluate the efficacy of SEPS (Polyflex®) in the treatment of post-operative oesophago-jejuno anastomosis leak after radical gastrectomy for gastric cancer. During a 6 months period (December 2007-May 2008) patients who underwent a radical gastrectomy in our hospital for gastric cancer and developed a postoperative anastomotic leak were prospectively included in the study after signing an informed consent form. These patients were treated with SEPS placement

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under endoscopic and fluoroscopic control for leak occlusion. The effectiveness of leak occlusion was evaluated by water-soluble contrast swallow.

RESULTS: During this period 3 patients were included in the study (2 men/1 woman). The mean interval between operation and SEPS placement was 16 days (range: 4-34). SEPS migration did not happen in our series. The evolution of patients after placement of the stent is commented separately: Patient 1: 88 yo woman with a T1N0M0 gastric cancer treated by laparoscopic radical gastrectomy with postoperative leak. A 25/21 mm diameter 9 cm long SEPS was placed without complication. After placement of the SEPS the patient referred thoracic pain which persisted until extraction of the SEPS. The extraction was easily performed 4 weeks later, and healing of the leakage was radiologically proved.

Patient 2: 65 yo man with a T2bN2M0 gastric cancer who underwent a laparoscopic radical gastrectomy with a postoperative leak. A 25/21 mm diameter 9 cm long SEPS was easily placed. In the radiological control the fistula persisted because of incomplete occlusion of the oesophageal lumen by the proximal end of the SEPS, due to its stiffness. For this reason we placed again the same stent 3 cm higher and in the same session placed a second coaxial SEPS orientated to the efferent intestinal loop. Both SEPS were left in place for 8 weeks and afterwards were easily extracted. The radiological contrast study confirmed healing of the fistula. Patient 3: 89 yo man with a T2N0M0 gastric cancer treated with radical gastrectomy with a postoperative leak. Ten days after surgery we easily placed a 25/21 mm diameter 12 cm long SEPS. Unfortunately by the time the SEPS was placed the patient had already develop a mediastinitis which got worse despite SEPS placement, antibiotic therapy and an apparently good drainage of the mediastinum. He finally passed away 3 days after SEPS placement.

CONCLUSION: The placement of SEPS is an appealing minimally invasive alternative to surgical repair for patients with postoperative anastomotic leak. It seems to be technically feasible, safe and effective and it probably reduces the morbidity and mortality of this life-threatening complication.

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Abstract: OP029

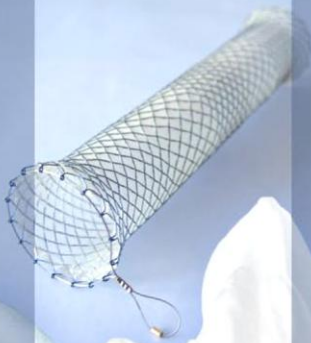
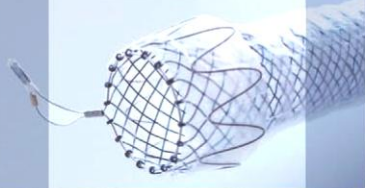
Citation: Endoscopy 2008; 40 (Suppl 1) A 6

SELF-EXPANDING PLASTIC STENTS FOR INOPERABLE MALIGNANT STRICTURES OF THE CERVICAL ESOPHAGUS

INTRODUCTION: Dysphagia and respiratory complications are the major problems in patients suffering from inoperable malignant strictures of the cervical esophagus. Recent reports support encouraging results with the use of self-expanding metal stents (SEMS), providing significant relief of dysphagia with an acceptable safety profile. Self-expanding plastic stents (SEPS) are regarded as a cost-effective alternative to SEMS in the treatment of malignant and benign obstructive diseases of the middle and distal segment of the esophagus.

AIMS & METHODS: To evaluate the efficacy of SEPS in inoperable malignant strictures of the cervical esophagus, 23 patients underwent Polyflex stent (Boston Scientific Corporation, MA) placement. These patients suffered from various malignant obstructive diseases of the cervical esophagus (19 men and 4 women, mean age 65 years), including esophageal carcinoma (n = 10), laryngeal cancer (n = 7), lung cancer with esophageal invasion (n = 5) and metastatic breast cancer (n = 1). Tracheo-esophageal fistula was documented in 5 patients. Stent placement was performed under fluoroscopic guidance. In all cases, pre-stent placement dilatation was required in order to introduce the stent's catheter through the stricture. Technical success rate, improvement of dysphagia grade (on a scale from 0 to 4) and stent-related complications were recorded after stent placement.

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RESULTS: Stent insertion was successfully achieved in all cases, namely in 20 patients at the first stent placement attempt (87%) and in 3 patients after a second attempt (100%). Dysphagia was notably improved after 24 hours (by at least 2 grades). Acute mediastinitis and tracheal compression were observed in 2 cases, successfully treated by conservative means and parallel tracheal SEMS placement under bronchoscopic assistance, respectively, without the need of stent extraction. Barium swallowing studies demonstrated complete sealing of all fistulas. Foreign-body sensation that gradually disappeared within the first week after stent placement was observed in 8 patients (34.8%). Recurrence of dysphagia occurred in 3 patients, due to hyperplastic tissue proliferation and tumor overgrowth. Reinterventions with balloon dilation and laser ablation were required in order to secure adequate dysphagia relief. Late migration of the stent was detected in one case 67 days later.

CONCLUSION: SEPS placement is an effective and safe palliative treatment for malignant strictures of the cervical esophagus. Main advantages of SEPS include easy retrievability, ease of repositioning, an equal expansive force as SEMS and half the cost of SEMS in Europe.

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Abstract: P0698

Citation: Endoscopy 2008; 40 (Suppl 1) A 244

SIMPLE METHOD OF ENDOSCOPIC OESOPHAGUS STENTING

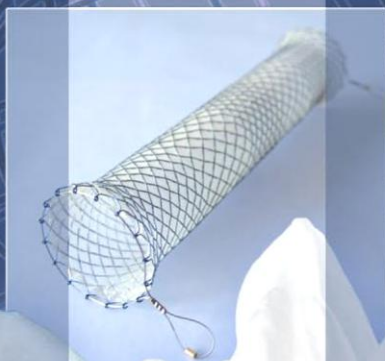
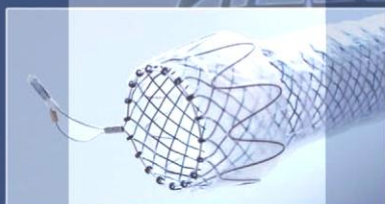
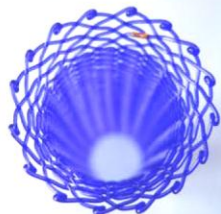
INTRODUCTION: Endoscopic stenting of esophagus have so far been performed by a combination of endoscopic visualisation and marking of the upper (and lower) boarder of esophageal stricture. Therafter the stent have been placed and relaxed by using x-ray usually at the radiotherapy department.

AIMS & METHODS: To develop a esophageal stent which can be inserted without using x-ray, that's to perform the procedure at the gastroenterology laboratorium. Together with Endo-flex we have developed a transparent covered stent with distal release and proximal fixation. The placement and release, after visualisation of the lenght of the stricture or esophageal-bronkial fistulae, is performed by endoscopic visualisation. We have used Olympus standard endoscope, by first performing a dilatation of the stricture for measuring the length and visualisation of distal part of stricture if nessessary and placement of guidewire. After insertion of the stent over the guidewire, the gastroscope is intubated paralell to the stent release set, down to the upper boarder of the stricture. Therafter, by visualisation of the proximal end of the stent trough the transparency covering, the correct release position according at the upper part of the stricture is performed. The release procedure is performed from distal. Therafter if necessary there is the possibility to ajust the stent position by a biopsy forcept or to dilatate with a ballone in the stent.

RESULTS: We have performed with this stent successfully 8 stent insertions because of malignancy; 6 of the esophagus because of malignant strictures, and 2 procedures because of tracheo-bronchial- esophageal fistuales. The procedures have all been performed under conditions usually used by routine gastroscopy, iv. sedation and with additional analgetics. The time from start of the gastroscopy until stent release is 10-15 minutes. The patients is allowed to drink after 4-6 hours. We have visualized the fully expanded stent after 24 hours by taking a chest x-ray.

CONCLUSION: This method of esophageal stent placement for malignant disease seems to be cost-effective, easy to perform and safe. The procedure is performed in our gastroenterogical unit and must from the patients experience be considered no more than a extented gastroscopy procedure.

This work has been performed in collaboration with EndoTech, Norway and Endo-Flex, Voerde, Germany



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Abstract: P0694

Citation: Endoscopy 2008; 40 (Suppl 1) A 243

SUCCESSFUL REMOVAL OF IMPACTED SELF EXPANDABLE METALLIC STENT BY INSERTION OF COVERED METALLIC STENT

INTRODUCTION: Self-expanding metal stents (SEMS) have proven efficacy and then are recommended for palliation of dysphagia due to malignant strictures. More recently, removable SEMS were used in case of benign oesophageal or colonic strictures. The principal risk of this procedure is the impaction of the stent due to tissue ingrowth. Insertion of plastic covered stent was proposed to induce ischemia of the hyperplastic tissue facilitating extraction of impacted stent[1]. We present here our technique using removable fully covered metallic stent to allow removal of impacted stent.

AIMS & METHODS: 3 patients (2 female, 1 man) were referred in our department for management of impacted metallic stent. SEMS was initially placed for peptic oesophageal stricture in 2 cases and for post-surgical colonic stricture in 1. SEMS was inserted since 1 month, 3 month and 3 years

respectively. Impaction of SEMS was secondary to hyperplastic tissue ingrowth avoiding endoscopic removal. In 1 cases, endoscopic attempts entailed partial dislocation of the stent. Endoscopic procedure used to withdraw impacted stent was to insert firstly a second fully covered SEMS (CHOOSTENT® - MI TECH; length 14 cm and diameter 18 mm) was then placed without prior dilation covering entirely the previous SEMS, under fluoroscopic guidance, using general anesthesia. One month later, a new endoscopy was performed under general anesthesia and oro-tracheal intubation. Both stent were removed under fluoroscopy, pulling the lasso attached to the proximal or the distal part of stent with a rat-tooth forceps.

RESULTS: Removal of SEMS was possible in all cases. In 1 case, spontaneous migration of both stent was observed into the stomach. Minor bleeding occurred in all cases. None patient required transfusion and no perforation occurred.

CONCLUSION: Our retrospective study confirms that insertion of a second stent is an efficient technique in case of failure of endoscopic removal of oesophageal stent. This technique is also possible for impacted colonic stent. We choose SEMS because this device is easier to insert due to a smaller calibre of the delivery system and to remove thanks to the lasso attached to the proximal and distal end. Furthermore, SEMS have stronger radial force maybe involving more efficient ischemia of the hyperplastic tissue.

B. Gastric outlet (GO) and duodenal stenting and related topics

13

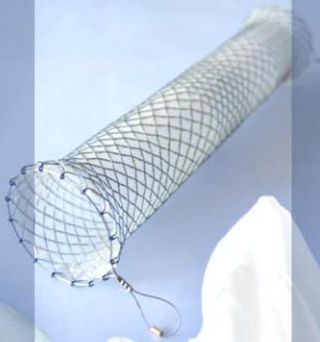
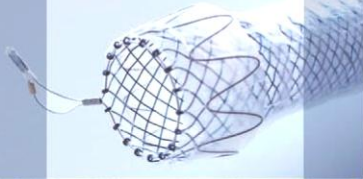
Abstract: P0564

Citation: Gut 2008; 57 (Suppl II) A 218

COMPARISON OF UNCOVERED AND COVERED STENT FOR ENDOSCOPIC TREATMENT OF INOPERABLE MALIGNANT GASTRODUODENAL OBSTRUCTION

INTRODUCTION: Self-expandable metallic stents (SEMS) insertion has been simple, safe, and effective palliative treatment for malignant gastric outlet obstruction. Uncovered stents has been reported to have a high rate of tumor ingrowth and covered stents have the disadvantage of stent migration. In most of studies about covered stent, stents were inserted with non-endoscopic method. There has been no comparison study of endoscopic insertion of covered and uncovered stent for

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malignant gastroduodenal obstruction. The aim of this study is to compare technical and clinical outcome, patency duration, complication rates of covered and uncovered SEMS for the treatment of malignant gastroduodenal obstruction.

AIMS & METHODS: From Jan 1998 to June 2007, patients with symptomatic malignant gastroduodenal obstruction were included. They were not candidate for curative surgery. We excluded the patients with postoperative anastomosis site obstruction and with hemodynamic instability, severe pulmonary insufficiency, or coagulopathy. Technical and clinical success was evaluated. Patients were followed up for clinical outcomes and stent patency (every 1 to 3 months).

RESULTS: Covered and uncovered stents were inserted in 70 and 84 patients, respectively.

Demographic features of both groups were not different. Most of underlying malignancy of gastroduodenal obstruction was advanced gastric cancer. All of covered and uncovered stents were successfully inserted (70/70 vs 84/84). Clinical success rate was not significantly different in covered and uncovered stent groups (98.6% vs 96.4%). The risk of early stent migration was significantly higher in covered stent than uncovered stent groups (5/69 vs 0/84, $P = 0.019$). Early tumor ingrowth and overgrowth rate was not different in both stent groups. The risk of late stent migration was significantly higher in covered stent group than uncovered stent (7/69 vs 0/81, $P = 0.004$). Late tumor ingrowth was significantly frequent in uncovered stent than in covered stent group. (2/69 vs 13/81, $P = 0.012$). Tumor overgrowth rate was not different in both groups. Stent patent duration and patient survival time were not different according to stent types.

CONCLUSION: Covered and uncovered SEMS insertions are technically feasible and clinically effective for palliative treatment of primary malignant gastroduodenal obstruction. Stent type was not significant factor for the palliative treatment of malignant gastroduodenal obstruction. For prolongation of stent patency, new type stent (combined stent of covered and uncovered type or woven type stent) are necessitated.

14

Abstract: P0695

Citation: Endoscopy 2008; 40 (Suppl 1) A 243

DOUBLE LAYERED COMBINATION SEMS FOR GASTRIC OUTLET OBSTRUCTION BY STOMACH CANCER

INTRODUCTION: Endoscopic stent placement is palliative treatment of choice for gastric outlet obstruction from gastric cancer, it still has problems such as tumor ingrowth and migration. Preliminary study using double layered stent showed excellent results that improved clinical effect and prevented complications.

AIMS & METHODS: To know the technical and clinical efficacy of combination stent. Twenty four patients received combination stents (an outer uncovered stent to prevent migration and an inner covered stent to overcome tumor ingrowth). Interposing membrane is PTFE (polytetrafluoroethylene). Both bared portions are 0.5 cm, respectively.

RESULTS: Technical and clinical success were 100% (24/24) and 91.7% (22/24), respectively. There was no tumor ingrowth. Migration occurred in 3 patients (12.5%). Tumor overgrowth occurred in 4 patients (16.7%).

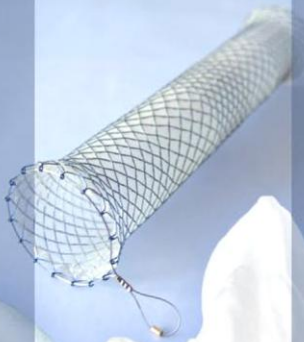
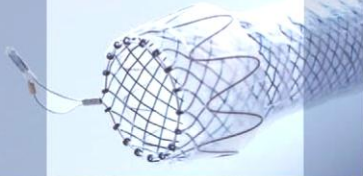
CONCLUSION: Although combination stent show superior result about tumor ingrowth, it has some limitation to prevent stent migration. To reduce migration, modifying techniques such as clipping or enlogation of the proximal bare portion are needed.

15

Abstract: OP030

Citation: Endoscopy 2008; 40 (Suppl 1) A 6

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GASTRO-DUODENAL STENT INSERTIONS; A LARGE SINGLE CENTRE EXPERIENCE

INTRODUCTION: The use of self-expandable metal stents is an established method for treating symptoms of inoperable malignant gastro duodenal obstruction. It is minimally invasive and provides good palliation of symptoms thus improving quality of life in patients with limited life expectancy.

AIMS & METHODS: The aim of this study was to evaluate the technical, clinical success and complications of gastro duodenal (GD) stent insertions in a UK tertiary hospital.

All procedures were recorded in a prospectively maintained database from June 2001 to October 2007. Data was extracted by review of case notes and integrated care pathways. All patients were followed until death by a dedicated Radiology specialist nurse.

RESULTS: During the six-year period, 145 patients underwent 166 GD stent insertions. The mean age was 68.2 years (range 37-95) of whom 63% were males. The indications were gastric cancer in 61 patients (42%) cancer of the head of pancreas in 52 (35.8%), metastatic peritoneal cancer in 22 (15%), anastomotic recurrence in 8 (5.5%), ampullary cancer in 2 (1.3%). Two patients received general anaesthetic, whilst all others were given a combination of intravenous pethidine (mean dose 41.6 mg) or fentanyl (mean dose 65.7 ug) and midazolam (mean dose 7 mg) as premedication. Electroencephalogram based bispectral index (BIS) was used for monitoring conscious sedation. Combined endoscopic and fluoroscopic approach was used to deploy Enteral Wallstent in 75 cases (45%); Hanaro stent in 55 (33%); Choo stent in 28 (16.8%); Polyflex in 4 (2%) and two each of Niti-S (1%) and EntElla (1%). 16 patients (9.6%) had two stents deployed while one patient had three stents. our patients required balloon dilation prior to stent placement.

The time taken for the procedure varied from 15-185 minutes. Technical success rate was 95% and clinical success rate was 89%. Median pre stent dysphagia score (mellow & pinkas score) was 4 (range 3-4) and seven-day post stent dysphagia score was 2 (range 0-4), there was significant improvement in the post-stent dysphagia score ($p < 0.001$). The restenting rate in this cohort was 8%. Complications occurred in 22 cases (13%) including stent obstruction in 15 (9%); stent migration in 3 (1.8%); persistent pain in 2 (1.2%) and one (0.6%) each of guide wire perforation and pancreatitis. The mean survival following stent insertion was 92.9 days (range 1-955). One patient died during the procedure due to cardiac arrest secondary to pulmonary embolism. All other deaths were due to the natural course of underlying malignancy.

CONCLUSION: GD stenting is safe, performed with great technical success and very effective in palliation of symptoms in malignant GD obstruction. Complications in the majority are due to disease progression.

16

Abstract: P0699

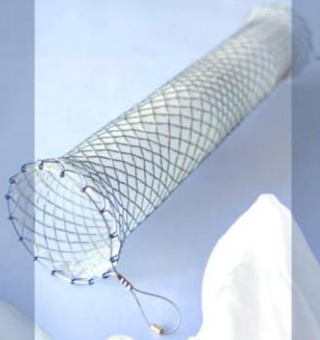
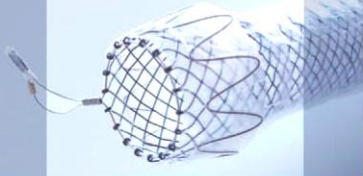
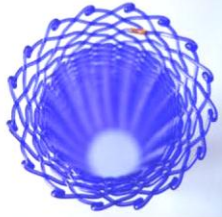
Citation: Endoscopy 2008; 40 (Suppl 1) A 244

GASTRODUODENAL STENTING

INTRODUCTION: Stomach and duodenum are often involved by advanced gastro-enteric cancers. Malignant obstruction of stomach or duodenum sometimes disturbs patients to continue their anti- cancer treatment and make their quality of life deteriorate. Gastro-enteric stent is available in some countries although it is not in Japan so far.

AIMS & METHODS: Benefits and problems are analyzed for self-expandable gastro-enteric metallic stent to the malignant obstruction. Methods: Self-expandable metallic stent (Niti-S Pyloric Stent D-type 22 mm x 6-10 cm; Taewoong) has been

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placed through the endoscope under fluoroscopy to malignant obstruction of stomach and duodenum at Gunma Prefectural Cancer Center since Mar 2007. The usage of this type of stent was approved by Gunma Prefectural Cancer Center Institutional Review Board. Symptomatic changes, hospital course, complications, and survival time were analyzed.

RESULTS: Fourteen patients have been placed the self-expandable metallic stent to their stenotic stomach or duodenum. Seven patients suffered pancreatic cancer and six had gastric cancer. One patient had stenotic duodenum due to peritoneal recurrence of sigmoid colon cancer. Male to female ratio was eight to six. Mean age was 66.6 years old. All of their cancers belonged in unresectable conditions. Although all fourteen patients had had nausea and thirteen had had concomitant vomiting, stents improved those symptoms apparently in thirteen patients. Diet intake before stenting was as follows: NPO (8), liquid diet (5), and soft diet (1). Two patients could not progress diet even with stenting. Other twelve patients have enjoyed soft diet (11) or normal diet (1) after stenting. Five complications have happened in four patients: a) malposition (1), b) tumor ingrowth of the duodenal stents (2), c) obstructed cholangitis (1), and d) obstructive jaundice (1). a) Re-stenting, b) tumor abrasion with microwave abrasion, c) additional biliary stenting, and d) biliary stenting have resolved each problems. Nine patients were discharged and three of them continued their anti-cancer treatment (chemotherapy). Median survival time was 99+36 days.

CONCLUSION: Self-expandable metallic stent improved quality of life for the patients with malignant obstruction in stomach or duodenum. More than half of the patients were discharged home after its placement and some of them got chances to continue anti-cancer treatment after stenting. Complications tend to happen more in duodenal stenting than in gastric, although they were not lethal. We hope the self-expandable metallic stent would become available for the gastro-enteric malignant obstruction in our country in the near future.

17

Abstract: OP197

Citation: Gut 2008; 57 (Suppl II) A 42

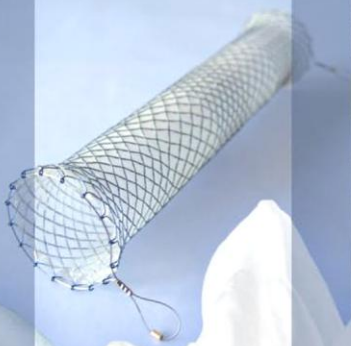
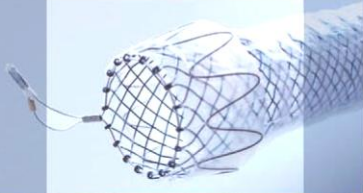
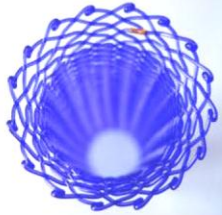
GASTROJEJUNOSTOMY VERSUS STENT PLACEMENT FOR PALLIATION OF MALIGNANT GASTRIC OUTLET OBSTRUCTION: MULTICENTER RANDOMIZED TRIAL

INTRODUCTION: Gastric Outlet obstruction (GOO) is a complication of inoperable distal stomach, periampullary or duodenal carcinoma. Although both gastrojejunostomy (GJJ) and duodenal stent placement are commonly used for palliation of obstructive symptoms, it is unclear which treatment is the preferable one.

AIMS & METHODS: In a multicenter randomized trial 21 hospitals in the Netherlands participated, but only 11 included patients between 2006 and 2008. Thirty-eight patients with malignant GOO were randomized to stent placement or GJJ and were followed-up until death. Primary outcome was the total area under the survival curve, adjusted for the ability to eat at least soft solids (Gastric Outlet Obstruction Scoring System (GOOSS) score >2). Secondary outcomes were medical effects, quality of life and costs. Analysis was by intention-to-treat.

RESULTS: Eighteen patients were randomized for GJJ (mean age 66 + 11 yrs, 50% male) and 20 for stent placement (mean age 66 + 13 yrs, 55% male). Food intake improved more rapidly after stent placement than after GJJ (GOOSS score >2: 4 vs. 7 days; $p < 0.01$), but long term (>60 days) relief of obstructive symptoms was better after GJJ. After GJJ, patients had more days with a GOOSS >2 adjusted for survival than after stent placement (72 vs. 50 days; $p = 0.05$). More late major complications (5 in 4 pat. vs. 0; $p < 0.05$) were seen and more reinterventions were indicated (11 in 8 pat. vs. 2 in 2 pat.; $p < 0.01$) after stent placement than after GJJ. There was no difference in median survival (46 vs 78 days). Mean hospital stay was 8 days shorter

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after stent placement than after GJJ ($p < 0.05$). Quality of life was maintained after both treatments with no difference between GJJ and stent placement. Total costs for GJJ were higher compared to stent placement (€7065 vs. €3240; $p < 0.05$). CONCLUSION: Despite slow improvement, GJJ gave better long-term relief of obstructive symptoms in patient with malignant GOO. Since GJJ was also associated with fewer complications and reinterventions on the long-term, we recommend it as the primary treatment for relief of obstruction in patients with an expected survival of 2 months or more. Nevertheless, as stent placement was associated with a rapid improvement of food intake, short hospital stay and lower costs, this treatment is preferable for those expected to live shorter than 2 months.

(*on behalf of the Dutch SUSTENT study group)

18

Abstract: OP031

Citation: Endoscopy 2008; 40 (Suppl 1)

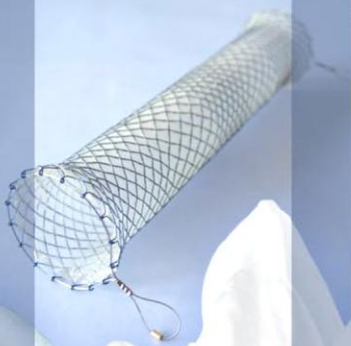
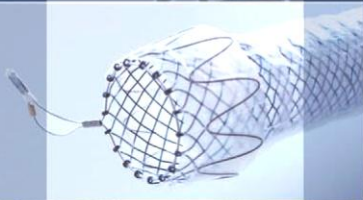
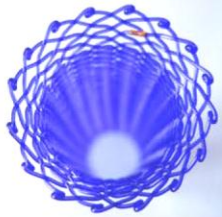
A 6 SHORT TERM EFFICACY OF THE NEW D-WEAVE NITI-STM STENT IN MALIGNANT GASTRIC OUTLET OBSTRUCTION: RESULTS OF THE FIRST EUROPEAN PROSPECTIVE, MULTICENTER STUDY

INTRODUCTION: Gastric outlet obstruction (GOO) is a late complication of advanced gastric, periampullary and duodenal malignancies. Palliation of symptoms of obstruction is the primary aim of treatment in these patients. Self-expandable metal stents (SEMS) have emerged as a promising treatment option.

AIMS & METHODS: The aim of this prospective multicenter study is to investigate the efficacy of a new enteral stent, the D-Weave Niti-STM stent (Taewoong Medical, Seoul, Korea) in patients with symptoms of malignant gastro-duodenal obstruction due to incurable distal gastric, periampullary or duodenal malignancy. Consecutive patients who fulfilled the patient selection criteria and presenting at one of the participating hospitals are included. In case of biliary obstruction, adequate drainage of the biliary tree with metal stents is achieved prior to stenting. Patients' characteristics, GOOSS-score (Gastric Outlet Obstruction Scoring System, a 4-point scoring system from 0 (no oral intake) to 3 (normal diet)), general condition (Body Mass Index (BMI) and WHO performance status), additional therapy (chemotherapy, radiotherapy) and quality of life questionnaires are collected prior to enteral stent placement. Procedure-related data are recorded by the treating physician. Follow-up data are prospectively collected by telephone on a two-weekly basis, until patients' death. As this is an ongoing study, we report here the changes of the GOOSS-score at 7 and 30 days after stent placement, technical success, time until regain of oral intake and stent-related complications within 30 days.

RESULTS: A total of 40 patients have been included (21 male, mean age 66 years) so far. The main cause of GOO was pancreatic cancer (23 patients, 58%). Thirty-eight (95%) procedures were technically successful; in 2 patients the guide wire could not be placed across the stricture, one underwent a gastrojejunostomy and one refrained from further treatment. In total 43 enteral stents were placed in 38 patients: 33 required one stent and 5 required two stents. Comparing the mean GOOSS-score prior to stenting with the score 7 and 30 days after stent placement showed a significant improvement from 0.83 to 2.34 (7 days) and to 2.70 (30 days) (Wilcoxon signed ranks test – two-sided; $p < 0.001$). Oral intake was resumed at a mean of 0 days (0-11 days) after stent placement. Stent-related complications within 30 days occurred in 3 patients (7.5%); there was tumor ingrowth in all cases.

CONCLUSION: This prospective cohort study shows that in patients with non-resectable malignant GOO placement of a D-Weave Niti-STM enteral stent has good short term results: it is safe and provides a significant relief of obstructive symptoms.



C. Biliary and pancreatic stenting, and related topics

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Abstract: OP083

Citation: Endoscopy 2008; 40 (Suppl 1) A 17

A MULTI-CENTER, SINGLE ARM, PROSPECTIVE STUDY OF A NEW PARTIALLY COVERED NITINOL SELF-EXPANDING STENT FOR THE PALLIATIVE TREATMENT OF MALIGNANT BILE DUCT OBSTRUCTION

INTRODUCTION: Covered self-expanding metal stents (SEMS) are widely used for the management of malignant biliary duct strictures. Recently, randomized studies have compared bare and covered biliary SEMS. A new family of biliary SEMS is being introduced, the Fully Covered, Partially Covered, and Uncovered WallFlex biliary SEMS (Boston Scientific, Natick, MA, USA). **AIMS & METHODS:** The new WallFlex™ Biliary Partially Covered Stent is indicated for palliative treatment of bile duct obstructions caused by malignant neoplasms. Enrollment in a 70 patient prospective multi-center trial is complete and follow-up is 87% (60/69) complete. Primary endpoint is adequate palliation defined as absence of recurrent biliary obstruction until 6 months or death. Secondary measures include evaluation of success of stent placement, complications, and seven common biliary obstructive symptoms assessed at baseline and at each follow-up visit. One consented patient did not receive a stent because of failure to cannulate.

RESULTS: Patients are 52% male, mean age 69. Malignancy was pancreatic carcinoma in 68% (47), bile duct in 13% (9), gallbladder in 4% (3), ampulla in 6% (4), gallbladder in 4% (3), other in 9% (6). 67 patients received 1 stent and 2 patients received 2 stents. 56% of patients received the SEMS de novo and 44% in exchange of a previously implanted plastic stent. Mean procedure duration was 28 minutes. Technical success at stent placement was 97%. To date 24 (35%) patients have completed follow-up to 6 months and 36 (52%) have died. There have been 5 (7.2%) cases of recurrent biliary obstruction to date: 3 (4%) due to stent migration (day 2, 111, 189), 1 stent occlusion due to tumor overgrowth (day 36), and 1 due to sludge (day 108). From baseline to 1 month the mean number of reported obstructive symptoms improved from 3.2 to 0.8 and total bilirubin levels reduced on average by 73%. At 1 month 66% of patients were free of all obstructive symptoms. Thus far there were 8 (11.6%) device related complications: 3 stent migration, 2 cholecystitis, 1 pancreatitis, 1 RUQ abdominal pain, and 1 fever.

CONCLUSION: This new self-expandable partially covered nitinol stent has proven to be easily implantable, safe, and effective in the long-term palliation of symptoms of biliary obstruction secondary to inoperable cancer.

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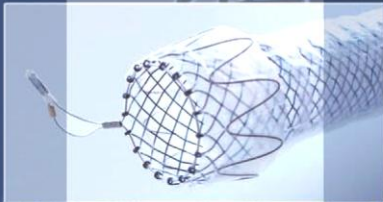
Abstract: P1547

Citation: Endoscopy 2008; 40 (Suppl 1) A 414

ACOMPARISON OF NITI-D BILIARY UNCOVERED STENT® & UNCOVERED WALLSTENT® IN MALIGNANT BILIARY OBSTRUCTION

INTRODUCTION: A conformability of uncovered self-expandable metal stents (SEMS) is the ability to bend at curved duct portion with maintaining luminal patency. However, SEMS conformability generally tends to be in inverse relation with its

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radial force which plays an important role in patency. It is not verified yet whether increased conformability of stent can really prolong the duration of SEMS patency.

AIMS & METHODS: The aim of this study was to examine the efficacies and complication rates of Niti- D biliary uncovered metal stent® (NMS) that is intended to be more conformable compared with uncovered conventional Wallstent® (WMS). The clinical outcomes of 101 patients who underwent endoscopic retrograde biliary drainage with NMS (n = 43) or WMS (n = 58) for the palliative management of malignant biliary obstruction between March 2005 and September 2007 were retrospectively reviewed.

RESULTS: Stent occlusion occurred in eleven patients (27.5%) in NMS and 17 patients (29.8%) in WMS. The mean duration of stent patency tends to be longer in the NMS (237 days) than the WMS group (150 days) but the difference was not statistically significant (p = 0.2). Mean duration of overall survival of patients was 191 days in NMS and 174 days in WMS. As of complication, pancreatitis occurred in 3 in NMS and 5 in WMS. Significant bleeding occurred in one case in each group. 27 patients (NMS 13, WMS 14) had proximal biliary obstruction among total 101 patients. Until stent obstruction or patient death with patent stent, mean duration was 239.2±137.9 days in the NMS group and 102.3±83.9 days in the WMS group, which had statistical difference (p = 0.004).

CONCLUSION: For the palliative endoscopic management of malignant biliary obstruction, there is no significant difference in patency, complication and patient's survival between metal stent (NMS) with more conformability and conventional metal stent (WMS). In patients with malignant obstruction involving hilum or high degree-angled duct deformation, NMS might be one of good treatment choices for palliation.

21

Abstract: P1541

Citation: Endoscopy 2008; 40 (Suppl 1) A 413

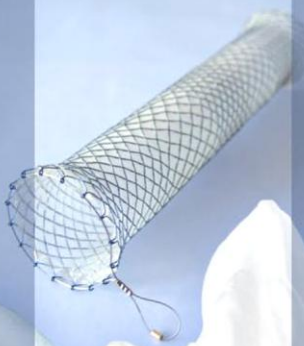
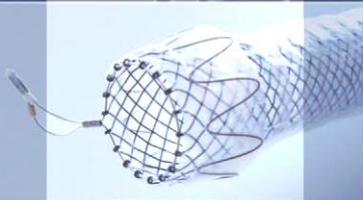
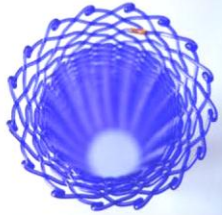
AMULTI-SITE, SINGLE ARM, PROSPECTIVE STUDY OF A NEW NITINOL, SELF-EXPANDING, BILIARY FULLY-COVERED STENT FOR THE PALLIATIVE TREATMENT OF MALIGNANT BILE DUCT OBSTRUCTION

INTRODUCTION: The aim of this prospective study was to evaluate the safety and effectiveness of a new fully-covered Platino™ self expanding stent in patients (pts) with inoperable distal biliary obstruction. The stent is designed with flared and looped-wire ends to minimize the risk of migration and to reduce tissue trauma. This investigational device has not yet received FDA clearance or CE Marking. All data are preliminary (IDE G060132).

AIMS & METHODS: All treated pts received a 10 mm diameter WallFlex™ biliary fully-covered stent (Boston Scientific, Natick, USA) in 40, 60, or 80 mm lengths. Clinical success was defined by the absence of stent occlusion during 6 months or until death, whichever came first. Also assessed were technical success, re-interventions, bilirubin levels, stent patency, time to stent occlusion and adverse events.

RESULTS: 65 stents were used in 60 pts (53% male; mean age 67). Most pts (75%) were diagnosed with pancreatic cancer. Technical success was 98% (59/60). Angulation of the delivery catheter prevented placement in 1 pt. Three stents were deployed but immediately removed due to inaccurate length (1), failure to provide decompression (1), and failure to fully deploy (1). Pt follow-up is complete (29 deceased, 24 completed 6 mo F/U, 5 withdrew, 1 lost to F/U). Re-intervention was required in 1 pt due to obstruction at day 142. Total bilirubin decreased from the baseline mean of 9.4 mg/dl to 1.3 mg/dl at 1 mo. Biliary obstruction symptoms declined from a baseline mean of 2.5/pt. to 0.4/pt. At 6 months. Device-related adverse

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events included: cholecystitis (2), abdominal or back pain (2), stent obstruction & cholangitis (1), pancreatitis (1), abdominal rigidity (1), nausea (1), and stent material failure (1).

CONCLUSION: When used in pts with unresectable malignant CBD strictures, the WallFlex™ Biliary Fully-Covered stent yielded technically successful placement, clinically appropriate reduction in bilirubin levels and minimal occurrence of migration and occlusion. Acute removal, when required, was uneventful in 3 pts. These results suggest this novel fully covered metal stent may successfully palliate most pts with malignant distal biliary obstruction.

22

Abstract: P0493

Citation: Endoscopy 2008; 40 (Suppl 1) A 203

AN INTERIM ANALYSIS OF LARGE METAL STENTS FOR TRANSPAPILLARY BILIARY ACCESS IN PATIENTS WITH COAGULOPATHY AND CHOLEDOCHOLITHIASIS

INTRODUCTION: Patients with severe coagulopathy are at a high risk of uncontrolled papillary bleeding following sphincterotomy or papillary dilation.

AIMS & METHODS: The aim of this study was to evaluate the CBD stone removal following deployment of transpapillary metal stent. Between April 2003 and September 2007, 12 patients with cholangitis and CBD stone at MRCP underwent the procedure. All patients had Child-C cirrhosis. Patients underwent ERCP procedure with transpapillary SEMS placement (Shim Hanarostent - MI Tech, Seoul, Korea, 11 mm × 60 mm, Covered) without prior papillotomy. Patients underwent daily KUB and ERCP with stone extraction was attempted following loss of waist on a plain abdominal film. **RESULTS:** The mean age was 74.3 yrs; the mean diameter of stones were 7±0.8 mm (range, 4-9 mm); mean number of stones were 1.3±1.1 (1-3). In 7 (58%) patients stones were removed without mechanical lithotripsy; in 3 (25%) patients the stones required mechanical lithotripsy and in 2 (17%) patients, stones could not be removed due to angulation of SEMS with CBD. In these patients, only one session was performed to remove the stones. All stents were successfully removed following biliary sweeping (2.7±1.6 days) (2-5 days).

CONCLUSION: Transpapillary SEMS facilitates stone removal in patients with uncorrectable coagulopathy as a result of advanced cirrhosis and avoid sphincterotomy and/or papillary dilation. This technique appears to be effective and safe in a select cohort. Further studies will help evaluate the effectiveness of this modality.

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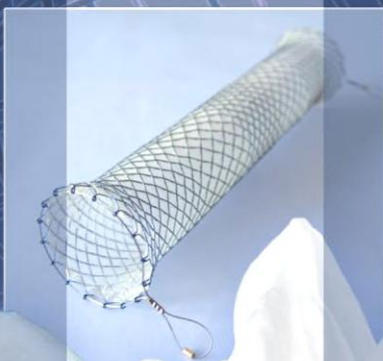
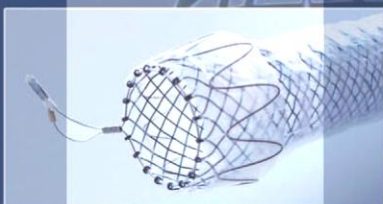
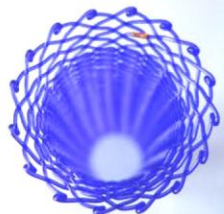
Abstract: P1532

Citation: Endoscopy 2008; 40 (Suppl 1) A 411

BILE DUCT INJURIES AFTER LAPAROSCOPIC CHOLECYSTECTOMY: LONG-TERM FOLLOW-UP AFTER ENDOSCOPIC PLACEMENT OF INCREASING NUMBERS OF STENTS

INTRODUCTION: Postoperative bile duct injuries (PBDI) are significant clinical problem. Surgical drainage is considered the most definitive treatment. There are, however, numerous reports of nonsurgical treatment with results comparable with those achieved with surgery, with lower morbidity and mortality. The outcome of endoscopic biliary dilatation and stent insertion for PBDI was retrospectively and prospective evaluated and long-term follow-up provide the most accurate information on success rates and complications.

Стенты «Ella-cs»



AIMS & METHODS: The aim of this study is to evaluate the long outcome bile duct patency, complications of this therapy and to identify predictors of a good outcome. A total of 71 patients were treated from 1995 to 2005 with sequential endoscopic insertion of stents in increasing numbers (1 to 5 stents), of increasing diameter, or both with stent exchange every three months to avoid cholangites. The remaining 71 patients (17 men, 54 women); mean age 48.5 years (range 13 to 88 years) were included in the study. The PBDI was classified by Bismuth/Strasberg (24 E1: 21 E2; 16 E3; 06 E4 e 04 E5). The clinical presentation of the BDI was pain (29.1%), cholangites (21.3%), fever with chill (42.7%), jaundice (93.2%), pruritus (66.0%), biliary pancreatitis (15.5%).

RESULTS: 71/77 (92.2%) patients could be treated. The endoscopic therapy was successful in 61/71 (86%). Seven patients failed endoscopic treatment and three interrupted. Complications occurred in three patients and 6 (stent occlusion <3 months). No procedure-related mortality was observed. The mean duration of treatment was 15.1±3.3 months (range 3-25 months) with mean number of ERCPs was 4.1±1.3 (range 2 to 8). The mean duration of stenting was 14.2 months (range 4 to 36 months). The mean follow-up was 67.5 months (range 36 to 144 months). The maximum number and diameter of the stents summarize in table 1. The prospective follow-up was obtained in January 2007 by all patients. Nine had died without symptomatic, 50 were freeing symptomatic and 2 were symptomatic.

CONCLUSION: Endoscopic retrograde cholangiopancreatography is a safe and feasible mode of therapy for patients presenting with PBDI. This study confirmed the success of endoscopic therapy in PBDI after 5 years. This form of intervention should be considered as the initial step in the treatment of postcholecystectomy laparoscopic complications.

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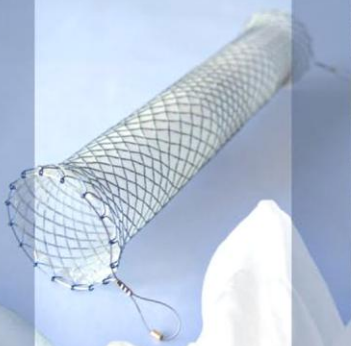
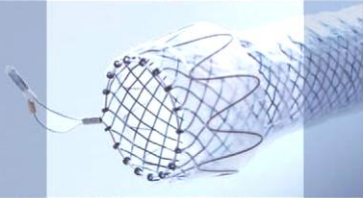
Abstract: OP082

Citation: Endoscopy 2008; 40 (Suppl 1) A 17

CAN PANCREATIC DUCT STENTING PREVENT POST-ERCP PANCREATITIS IN PATIENTS WHO UNDERGO PANCREATIC GUIDEWIRE PLACEMENT FOR ACHIEVING SELECTIVE BILIARY CANNULATION? A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

INTRODUCTION: Although pancreatic guidewire placement (P-GW) for achieving selective biliary cannulation is reported to be effective in patients with difficult cannulation of the bile duct in endoscopic retrograde cholangiopancreatography (ERCP), this technique entails a possible increased risk of post- ERCP pancreatitis. **AIMS & METHODS:** We conducted a prospective randomized controlled trial to evaluate the prophylactic effect of pancreatic duct stenting on the frequency of post-ERCP pancreatitis in patients who underwent P-GW. **Design and setting:** A prospective randomized controlled trial, single-center. **Subjects and methods:** Between November 2004 and April 2008, 69 patients who underwent P-GW for achieving selective biliary cannulation were included in this study. Patients were randomly assigned to either a pancreatic duct stent placement group (n = 34) or a no-stent group (n = 35). The pancreatic duct stent used was a 5-Fr, 4-cm-long stent with a single pigtail at the duodenal end. **Primary endpoints:** The frequency and severity of post-ERCP pancreatitis. **Interventions:** Selective biliary cannulation with the help of pancreatic guidewire placement and pancreatic duct stenting

RESULTS: Selective biliary cannulation was achieved in 79% (27 patients) of the stent group and in 94% (33 patients) of the no-stent group (P = 0.14). Pancreatic duct stenting was successful in 91% of the patients. Post-ERCP pancreatitis occurred in 13% (9 patients, mild). In one patient of the stent group who developed migration of the stent during the procedure, mild pancreatitis occurred after the procedure. The frequency of post-ERCP pancreatitis in the stent group was significantly lower than that in the no-stent group (2.9% vs. 23%, Relative Risk = 0.13, C.I., 0.017, 0.97). All patients who developed post-ERCP



pancreatitis improved with conservative therapy in a few days. Both post- sphincterotomy hemorrhage and acute cholangitis occurred in one patient of the stent group. There were no other procedure-related complications in the no-stent group.
CONCLUSION: Pancreatic duct stenting after P-GW for achieving selective biliary cannulation can reduce the incidence of post-ERCP pancreatitis.

25

Abstract: P1539

Citation: Endoscopy 2008; 40 (Suppl 1) A 413

DEVELOPMENT OF A BIOABSORBABLE STENT TO TREAT BENIGN BILIARY STENOSIS

INTRODUCTION: Balloon dilation and stent placement, non-surgical procedures to treat benign biliary stenosis, are often followed by restenosis. To address this issue, we have been developing bioabsorbable biliary stents that degrade within the body after having propped the narrowed bile duct open for a certain period of time. At DDW 2007, we presented a stent made of polylactic acid. The problem with this stent was that it took long time, three to six months, to get fragile, forming a bile plug at three months after placement. Then we have prepared and evaluated a bioabsorbable stent made of polyglycolic acid that gets fragile in the body in about three weeks.

AIMS & METHODS: Hybrid pigs (weighing 10 to 30 kg) were laparotomized under general anesthesia, and the extrahepatic bile duct was identified and its hepatic side was ligated at about 1 cm from the papilla of Vater. A week later, animals were re-laparotomized to remove the ligature. The duodenum was opened and a stent of polyglycolic acid (5 mm in diameter when expanded) was inserted through an Atom tube into the narrowed area of the bile duct while identifying the papilla of Vater. The duodenal end of the stent was placed at about 5 mm from the papilla of Vater towards the duodenum, which was closed with sutures. The narrowed area was histologically examined four months after stent placement.

RESULTS: All animals survived four months after stent placement. At four months, the stent was not found in the narrowed area, which became indistinguishable from other parts of the extrahepatic bile duct. Histology demonstrated good epithelial regeneration in the narrowed area, while none of the animals showed biliary enzyme elevation on blood chemistry.

CONCLUSION: The stent is being tested in an increasing number of animals with encouraging results. This bioabsorbable stent seems useful for treatment of benign biliary stenosis.

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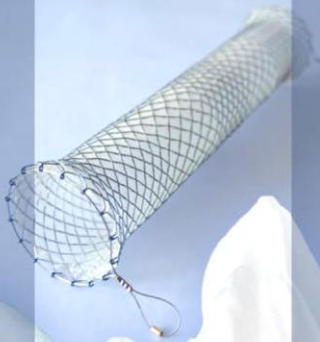
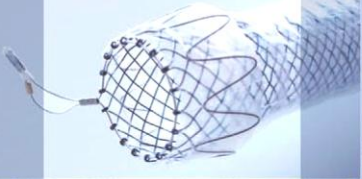
Abstract: P0648

Citation: Gut 2008; 57 (Suppl II) A 234

DEVELOPMENT OF AN ARTIFICIAL BILE DUCT MADE OF BIOABSORBABLE POLYMER TO BE USED FOR TREATMENT OF BILIARY STENOSIS

INTRODUCTION: It has been reported that choledochoenterostomy to treat biliary stenosis and other disease is associated, in the long term, with postoperative bile duct cancer at an incidence of about 5 to 10%. Along with the recent widespread use of laparoscopic cholecystectomy and living-donor liver transplantation, complications involving the biliary system are increasing. Stent or T-tube insertion is a common treatment for bile duct stenosis by which the papilla of Vater can be preserved. However, there are some disadvantages with both stents and T-tubes, and new means of treatment have been called for. We investigated whether an artificial bile duct made of bioabsorbable polymer could substitute for a narrowed bile duct.

Стенты «Ella-cs»



AIMS & METHODS: Hybrid pigs were laparotomized under general anesthesia and the extrahepatic bile duct was identified. Then a portion of the duodenal side of the bile duct was resected, 3 cm in major axis, and substituted by a bioabsorbable polymer tube of the same size. It was made of a P (CL/LA) 50:50 reinforced with a PGA fiber mesh and was designed to degrade in six to eight weeks in the body. There was no prior cell seeding onto the graft. Animals were re-laparotomized three months after implantation and gross, histological and blood chemical studies performed.

RESULTS: All recipient pigs survived until they were sacrificed for collection of graft sites three months after implantation. All of them gained weight. On gross examination, the artificial duct was found to have been absorbed and the graft site was indistinguishable from the native extrahepatic bile duct. Stricture was not found on cholangiography, adhesion to surrounding tissue was mild and the graft site could be freed manually. Histology revealed a neo-bile duct growing in the graft site with the epithelium of highly uneven thickness and increased accessory glands compared with the native duct. Blood chemistry data at three months post implantation did not show change from baseline values.

CONCLUSION: This study demonstrated that biliary stenosis could be treated by resecting the narrowed portion and substituting it with this artificial bile duct. Thus, the artificial duct can be used in place of T-tubes or stents in transplantation surgery and gastrointestinal surgery, or can be used as a prosthesis after surgery for localized lower bile duct cancer.

27

Abstract: P1533

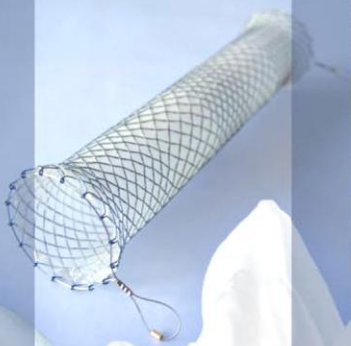
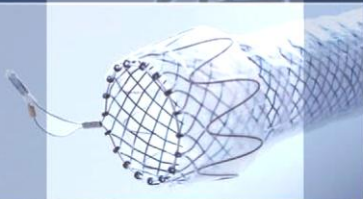
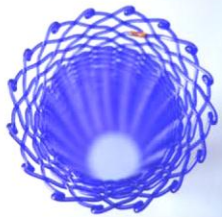
Citation: Endoscopy 2008; 40 (Suppl 1) A 411

DOES HEPARIN COATING REDUCE OCCLUSION IN BILIARY PLASTIC ENDOPROSTHESES?

INTRODUCTION: Biliary stenting using plastic endoprotheses is limited by early occlusion. The resulting scheduled stent exchange is expensive and uncomfortable. In urological endoprotheses covalent binding of glycosaminoglycans to polyurethane stents proved to reduce incrustation. Since development of urological and biliary stent occlusion shows parallels, the aim of the study was to evaluate the efficacy of heparin coating of biliary endoprotheses to prevent stent occlusion.

AIMS & METHODS: Study design was prospective, randomised, single centre, cross over. All stents used were Amsterdam type (10Fr, 9 cm, polyethylene). The covalent heparin coating was performed by UroNova GmbH, GERMANY. Before implantation, weight of all stents was determined. Due to randomisation, coated or standard stents were then implanted in jaundiced patients suffering from malignant biliary obstruction. Scheduled stent exchange was performed after 90 days implanting new coated or standard stents according to the cross over design for the same duration. After explantation, stents were stored at -18°C. Immediately before analysis stents were dried at 50°C for 24 hours, then weighed and finally longitudinally opened to visualize incrustation and discolouration. Occlusion was measured by the increase of stent dry weight. Statistical analysis was done using the Wilcoxon-Test.

RESULTS: In total 32 patients were randomized. Twenty-two patients dropped out due to short duration of stent implantation or missing cross over. In 10 patients (3 male/7 female, 58-79 yrs.) study was completed. Premature stent removal was necessary in 3/10 standard stents, because of new jaundice or cholangitis, but in none of the coated stents. After longitudinal incision, all three stents showed total or partial occlusion. Altogether, coated stents showed less visible occlusion and discolouration than standard stents. On average the weight of standard stents was twice as high as of coated stents (standard: 32±12 (16-56) mg; coated: 15±4 (9-24) mg), although the duration of stent implantation was not significantly different between both groups (standard: 80±21 (30-106) days; coated: 87±13 (56-101) days). In total, the weight of removed coated stents was lower than the weight of the standard stents in 9/10 patients.



CONCLUSION: With respect to development of stent occlusion, heparin-coated plastic biliary endoprotheses are significantly superior to standard polyethylene stents. Further studies have to show whether this effect allows the stent to remain in situ for a longer period of time to reduce the frequency of scheduled stent exchange.

28

Abstract: P1534

Citation: Endoscopy 2008; 40 (Suppl 1) A 412

EMERGENCY PANCREATIC DRAINAGE WITH POSTPONED BILIARY SPHINCTEROTOMY IN PATIENTS WITH ACUTE BILIARY PANCREATITIS: SPARING LITTLE TIME MAY SAVE A LOT

INTRODUCTION: Patients (pts) with severe attack of acute biliary pancreatitis (ABP) proved to benefit from early ERCP, EST and ductal decompression [1]. However, the therapeutic window is quite narrow as ranging from 24 to 48 h, and thereafter irreversible pancreatic necrosis will emerge [2]. The aim of the present pilot study was to study the effect of emergency ERCP and PD stenting with small calibre prophylactic stents on the clinical outcome of ABP in pts, in whom biliary EST was failed or contraindicated.

AIMS & METHODS: During the last year 70 consecutive pts with ABP referred to emergency ERCP. Non-alcoholic pts with acute pancreatitis associated with biliary abnormalities on US (gallbladder stones or dilated CBD) and concomitant early elevation (>1.5 N) of obstructive LFTs were selected. In 55 ABP pts successful ERCP, EST, and stone extraction were performed. In the remaining 15 pts small calibre (4-5 F, 4 cm, Geenen) pancreatic stent insertion was applied. The indication of PD stenting with postponed sphincterotomy was failed selective biliary access in 8 pts (due to juxtapapillary diverticulum, impacted distal CBD stone or severe peripapillary edema); and poor as well as instantaneously uncorrectable blood coagulation status (due to Warfarin therapy or concomitant liver disease) in 7 pts. All pts were hospitalised for medical therapy and were followed up.

RESULTS: The mean age, the symptom to ERCP time, the Ranson scores, and also the amylase and CRP levels at initial presentation were not significantly different in the PD stent versus EST groups: 64.2 vs. 64.8 years; 14 vs. 16 h; 2.1+1.0 vs. 2.1+1.6; 1760 vs. 1455 U/l; and 129 vs. 123 U/l, respectively. More importantly, the complication rate (13% vs. 18%) and mortality (0 vs 1.8%) were comparable, reasonably low and demonstrated no statistically significant differences. Removal of PD stents, biliary EST and bile duct clearance were successfully done after the resolution of ABP (on average 5.3 days later) in all pts.

CONCLUSION: Temporary PD stenting with small calibre stents may offer sufficient drainage to reverse the process of obstructive, biliary pancreatitis in pts with failed or contraindicated biliary sphincterotomy, and may improve the overall outcome of emergency ERCP and EST in ABP. Prospective, randomized studies are necessary to support our approach.

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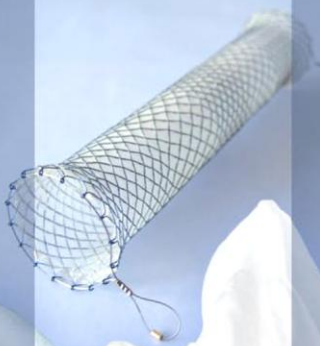
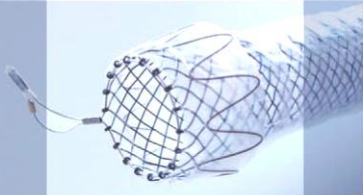
Abstract: P1538

Citation: Endoscopy 2008; 40 (Suppl 1) A 412

ENDOSCOPIC BILIARY DRAINAGE IN HILAR CHOLANGIOCARCINOMA

INTRODUCTION: Endoscopic management of biliary obstruction due to hilar cholangiocarcinomas is controversial with respect to optimal types of stents and extent of drainage.

Стенты «Ella-cs»



AIMS & METHODS: Evaluate the efficacy of the palliation of patients with hilar cholangiocarcinoma with self-expandable metallic stents (SEMS), evaluate the best strategy to stent insertion according to Bismuth classification and also to compare the efficacy of SEMS with the use of plastic stents (PS). Data on all patients receiving endoscopic biliary drainage for hilar cholangiocarcinoma between September 1995 and December 2007 was retrospectively reviewed. Early (within 30 days of stent placement) and late complications, early and late stent occlusion, stent patency, and biliary reintervention rates were recorded. Patients were divided in 3 groups according to Bismuth classification (group 1 - type I; group 2 - type II, group 3 - type >3). **RESULTS:** 343 patients were studied (45-96 years, mean age 74.3). Insertion was achieved in 322 patients (93.8%). Group 1 had 157 patients with technical success in 96.8% (n = 152); group 2 had 114 patients with technical success in 93% (n = 106) e group 3 had 76 patients with technical success in 84.2% (n = 64). In group 1, 87 patients were palliated with PS and 65 with SEMS; in group 2, 52 patients were palliated with PS (34 had bilateral stents) and 54 (32 patients had bilateral stents) with SEMS; In group 3, 29 patients were palliated with PS and 35 with SEMS. Early complications were only recorded in patients palliated with plastic stents (N = 9; 5.36%) and included stent occlusion with cholangitis (6 patients) e stent migration (3 patients); Late complications were recorded in 96 patients (57.1%) palliated with PS and included stent occlusion in 88 patients (52.4%) of which 58 had associated cholangitis, and migration in 8 patients (4.8%); 43 patients (27.9%) palliated with SEMS had stent occlusion with 7 cases of associated cholangitis. The remain 111 patients (72.1%) palliated with SEMS need no further intervention. Median stent patency was: 22 weeks in group 1 palliated with PS e 32 weeks in group 1 palliated with SEMS (SEMS vs PS p < 0.05); In group 2, 15 weeks with one PS and 18 weeks with bilateral PS; 23 weeks with 1 SEMS and 28 weeks with bilateral SEMS (SEMS vs PS p < 0.05); 11 weeks in group 3 palliated with PS and 16 weeks in group 3 palliated with SEMS (SEMS vs PS p < 0.05).

CONCLUSION: SEMS are much superior to PS in hilar cholangiocarcinoma endoscopic palliation and PS should be reserved to pre-surgery biliary drainage; although bilateral stenting in Bismuth II has a better outcome is not fundamental to a good palliation; the outcome of biliary drainage in patients with advanced hilar tumour (Bismuth III or IV) was poorer than hilar tumours at earlier stages (Bismuth I or II).

30

Abstract: P0492

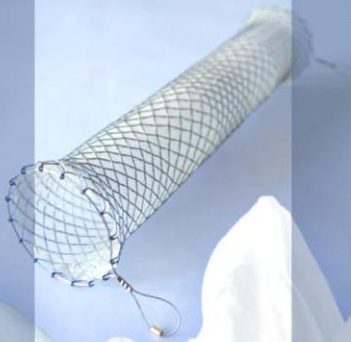
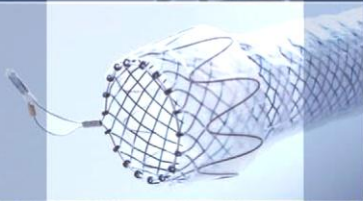
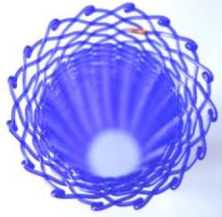
Citation: Endoscopy 2008; 40 (Suppl 1) A 203

ENDOSCOPIC TREATMENT OF MALIGNANT HILAR STRICTURES: PLEA FOR UNILATERAL DRAINAGE WITH A SINGLE EXPANDABLE METALLIC STENT

INTRODUCTION: The management of hilar strictures with a palliative endoscopic approach is complex. There are numerous studies recommending complete drainage of the biliary system by endoscopic and/or radiologic approach. Our retrospective study reports the success of a single metallic stent procedure with respect to regression of jaundice in function of stage of disease and hepatic duct drainage (left or right) and follows the long term complications of stent insertion.

AIMS & METHODS: From Jan 2006 to May 2007, 99 patients (M/F = 53/46, mean age 71 yrs) with a malignant hilar stricture were included. Nine patients with a bilateral hepatic drainage were excluded from the study. The stricture was due to cholangiocarcinoma in 50, hepatocarcinoma or intrahepatic metastatic disease in 28, gallbladder cancer in 14, cancer of the pancreas in 4 and hilar lymphatic metastasis in 3. Opacification of the biliary system by retrograde or antegrade (after crossing the stricture with the sphincterotome) approach was accomplished bilaterally in 50 and unilaterally in 44 patients. The stricture was classified as type I in 25, type II in 27, type III in 30 and type IV in 17 before metallic stent insertion.

Стенты «Ella-cs»



RESULTS: Stent insertion was successful in 90% (89/99 pts). Failure was due to duodenal stenosis in 2, failure of biliary cannulation in 3, and failure to cross the stricture with a guidewire in 5. The metallic stent was placed in the left hepatic duct in 28 and in the right lobe in 61 cases. The clinical success after stent insertion was 68% when considering all stages of hilar stricture. Clinical success in relation to hepatic duct drainage was 89% (25/28 pts) in case of stent insertion in the left hepatic duct and 59% (36/61 pts) in the right hepatic duct ($p = 0.09$). This difference was significant for Klatskin tumour stage III and IV with regression of jaundice in 81% (14/17) in left hepatic duct drainage versus 25% (7/28) for the right hepatic drainage ($p < 0.05$). Early complications of the procedure occurred in 7% such as cholangitis (4), papillary hemorrhage (2) and acute necrotizing pancreatitis (1). Late complications occurred in 18% due to either occlusion of the stent or extension of the biliary stricture outside the stent in 18% (18/89 pts) with a median stent patency of 212 days in cases of intra-biliary stents placement and 184 days in transpapillary stent position ($p = 0.78$). Two patients died with cholangitis post ERCP.

CONCLUSION: This study shows that placement of a single metallic biliary stent is sufficient in patients with malignant hilar stenoses. The placement of a single metallic stent in the left hepatic duct of patients with stages III to IV disease was particularly effective with regression of jaundice in 85% of patients. A prospective study of these patients after attempt to preferentially place a metallic stent in the left duct is actually underway to confirm our results.

31

Abstract: P1542

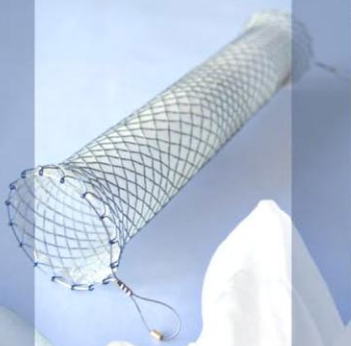
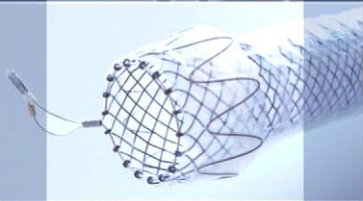
Citation: Endoscopy 2008; 40 (Suppl 1) A 413

ENDOSCOPIC TREATMENTS FOR BILIARY STRICTURE AFTER ADULT LIVING DONOR LIVER TRANSPLANTATION

INTRODUCTION: Endoscopic intervention is considered to be the primary treatment for biliary stricture after adult living donor liver transplantation (ALDLT).

AIMS & METHODS: The aim of the present study is to evaluate (1) risk factors of biliary stricture, (2) the clinical outcomes of endoscopic treatment (ET) and (3) the predictors for the success of ET as a first modality of biliary dilation. Two hundred and thirty nine patients received ALDLT between January 2000 and December 2006 and biliary stricture occurred in 69 (28.9%) patients. Twenty nine patients with anastomotic biliary stricture were managed by ET (initial ET in 26 patients, ET after initial percutaneous biliary dilation in 3 patients). Plastic stents and balloon dilation were performed in 28 patients and only balloon dilation was tried in 1 patients. The duration of Stent insertion was 6.3 ± 2.9 months. The number of stent was 1.03 ± 0.2 . The mean follow-up period after ECP was 40 months (range, 7-81 months). Failure of endoscopic treatment was defined as technical failure of initial dilation and immediate restenosis after removal of stents.

RESULTS: The risk factors of biliary stricture, on multivariate analysis, were as follows; Graft of multiple bile ducts (OR 3.25, CI 1.2-8.7, $p = 0.02$), bile leakage (OR 28.1, CI 3.3-238.1, $p = 0.01$) and hepatic artery stenosis (OR 9.7, CI 2.3-41.4, $p = 0.01$). Endoscopic biliary dilation was technically possible in 19 patients (19/29, 65.5%). Long term outcome of ET was successful in 18 patients (18/29, 62%). Immediate restenosis occurred in one patient just after stent removal. The clinical factors of ET predicted successful outcome were the time lapse between liver transplantation and the occurrence of stricture (17.5 weeks in the success group and 30.6 weeks in the failure group, $p < 0.05$), gamma glutamyl transpeptidase at diagnosis (152.6 ± 46.0 IU/dl in success group and 265.2 ± 73.2 IU/dl in failure group at diagnosis, $p < 0.04$) and intrahepatic duct dilation (55.5% in success group and 100% in failure group, $p < 0.05$). Bile leakage, Graft anatomy and surgical maneuver of biliary reconstruction



didn't affect clinical outcome of ET. Procedure-related complications (6.4% cholangitis, 9.4% pancreatitis and 3.2% bile leakage) were all successfully managed by conservative treatment.

CONCLUSION: Endoscopic balloon dilatation and stenting are safe and effective management of anastomotic biliary strictures after ALDLT. The Success rate of ET is higher in patients with early biliary stricture and absence of intrahepatic duct dilatation and low level of gamma glutamyl transpeptidase at diagnosis.

32

Abstract: OP249

Citation: Endoscopy 2008; 40 (Suppl 1) A 55

ENDOSCOPIC ULTRASOUND-GUIDED FINE NEEDLE ASPIRATION BIOPSY IN PATIENTS WITH OBSTRUCTIVE JAUNDICE: DOES A BILIARY STENT INTERFERE WITH THE FINAL DIAGNOSIS?

INTRODUCTION: EUS-FNA has a high accuracy, but in patients with obstructive jaundice, especially if a stent has been previously placed in the biliary tract, the accuracy and the NPV seems to decrease because of fibrosis and artifacts.

AIMS & METHODS: The aim of this prospective study was to assess the yield of EUS-FNA in the diagnosis of pancreatobiliary malignancy in 2 groups of patients with obstructive jaundice treated or not with biliary stent. Group A: 49 consecutive patients referred to our Unit to undergo EUS-FNA. All of them had been previously admitted to other Hospitals where EUS-FNA was unavailable and treated with ERCP and stent placement. Brushing or biopsies performed during ERCP had given inconclusive results. Group B: 49 patients admitted to our Institution with a suspected pancreatic mass. EUS was performed with Pentax echoendoscopes; 22 or 25 G needles (Wilson-Cook) were used. A cytopathologist was present in the endoscopic room during FNA. The final diagnosis was given by either surgical specimens or clinical follow up of patients not eligible for surgery.

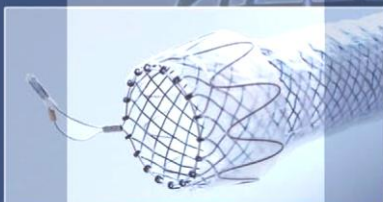
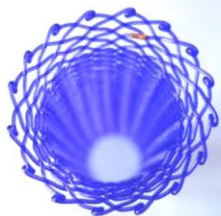
RESULTS: Pancreatic adenocarcinoma and CBD cholangiocarcinoma were diagnosed in 79 (81%) and 6 (6%) patients respectively without a significant difference between the 2 groups. Other diagnoses were: neuroendocrine tumor (2; 2%); focal mass in chronic pancreatitis (8; 8%); benign intraductal papillary mucinous tumor or serous cystic adenoma (3; 3%). EUS detected the lesion in nearly all patients. The size of the lesion ranged from 15 to 60 mm (mean: 31±9 mm). with no significant difference between the 2 groups. An average of 2.7 needle passes (range 1-7) was made before reaching the cytological adequacy. The 2 groups didn't show any significant difference when needle-gauge or number of passes were considered. A cytological diagnosis of malignancy was reached in 85 (87%) patients. In the remaining 13 patients no malignancy was detected on cytology. However, the subsequent clinical course revealed that in 4 patients with carcinoma a false negative result had occurred. In our study population with a cancer prevalence of 89%, the sensitivity, specificity, PPV, and NPV of EUS-FNA were 95% (C.I. 93-95%), 100% (C.I. 75-100%), 100% (C.I. 95-100%) and 69% (C.I. 52-69%), respectively. Overall accuracy was 96% (C.I. 91-96%).

When the diagnostic accuracy of EUS-FNA was evaluated separately in each patient group, no significant difference was elicited meaning that biliary stents neither interfere with the detection of pancreatic or biliary mass, nor affect significantly the cytological diagnosis of malignancy.

CONCLUSION: The diagnostic accuracy of EUS-FNA in pancreatobiliary malignancy in patients with obstructive jaundice is very high and is unaffected by the presence of biliary stents.

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Abstract: P1536



Citation: Endoscopy 2008; 40 (Suppl 1) A 412

ENDOSONOGRAPHY-GUIDED BILIARY DRAINAGE: A VERSATILE SUBSTITUTE FOR PTBD IN THE TREATMENT OF OBSTRUCTIVE JAUNDICE

INTRODUCTION: Endoscopic biliary drainage (EBD) is the treatment of choice for obstructive jaundice due to unresectable malignant biliary stricture. When EBD is technically difficult or impossible, percutaneous transhepatic biliary drainage (PTBD) or surgical drainage is applied. On the other hand, endosonography-guided biliary drainage (ESBD) is recently drawing attention as an option for biliary drainage.

AIMS & METHODS: The aim of this study was to assess the feasibility and usefulness of ESBD for replacement of PTBD in the treatment of obstructive jaundice in difficult EBD. From January 2007 to March 2008, 13 patients (5 males; average age, 71 years old) with difficult EBD were included in this study. Six patients had pancreatic cancer, 3 had biliary cancer, 1 had gastric cancer, 1 had ampullary cancer, 1 had nodal metastasis from colonic cancer, and the remaining one had acute cholangitis with bile duct stones. The cause of unsuccessful EBD was pyloric/duodenal stenosis due to cancer invasion in 7 patients, tight biliary stricture in 3, posthepaticojejunostomy state in 1, frequent recurrence of stent failure in 1, and duodenal stenosis due to ulcer in 1. Using an electric curved linear array echoendoscope (GF-UC240P, Olympus Co.), the bile duct was punctured with a 19 G needle (Echo Tip, Cook Co.). After aspiration of bile, a guidewire was introduced into the bile duct through the outer sheath of the needle, followed by dilatation of the puncture route with a dilator balloon or a tapered catheter, which was fed over the guidewire, to facilitate smooth deployment of a stent. Finally, a 7Fr plastic tube stent (Flexima, Boston Scientific Co.) was deployed. In the patient with acute cholangitis, nasobiliary drainage was attempted.

RESULTS: ESBD was attempted transgastrically in 4 (intrahepatic duct 3, extrahepatic duct 1), transduodenally in 7 (all intrahepatic), and transesophageally in 2 (intrahepatic). Technical success and successful biliary decompression was achieved in 100% (13/13) and in 92.3% (12/13), respectively. In one patient, temporary transesophageal ESBD was performed to allow deployment of a metallic stent in the middle extrahepatic duct via the fistula. As for complications, migration of the guidewire followed by localized peritonitis was encountered in one patient, which was treated conservatively without sequelae.

CONCLUSION: ESBD is a useful technique for patients with difficult EBD. ESBD is expected to replace PTBD in many situations as it is less-invasive and allows recovery of physiological flow of bile.

34

Abstract: P1537

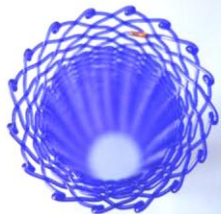
Citation: Endoscopy 2008; 40 (Suppl 1) A 412

METHOD TO IMPROVE BILATERAL STENTING AND REVISION IN PATIENTS WITH HILAR CHOLANGIOCARCINOMA: USEFULNESS OF SLIMMER AND OPEN CELL TYPE ZILVER STENT

INTRODUCTION: Although endoscopic bilateral metal stenting in a "stent in stent" fashion is currently used to treat patients with unresectable hilar cholangiocarcinoma, this method has limitation for application in cases of tight stricture and revision in cases of tumor recurrence.

AIMS & METHODS: Eighteen patients with unresectable Bismuth type II or higher hilar cholangiocarcinoma were included. For endoscopic bilateral metal stenting in "stent in stent" method, first, a Y stent with central wide open mesh was inserted. And, then, easily dilated Zilver stent, which is preloaded in a slim delivery system (7Fr), was placed into the contralateral hepatic duct through the central portion of the Y stent. We evaluated the clinical efficacy of

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bilateral metal stenting using a Zilver stent which is slimmer (7Fr) and open cell type (easily dilated and keeping shape of dilated state).

RESULTS: Technical and functional success was achieved in 100% (18/18) and 94.4% (17/18), respectively. The early complication rate was 0%. During follow up period, cholecystitis occurred in 2 patients and managed by PTGBD. Stent obstruction by tumor ingrowth or/and overgrowth occurred in 7 patients (38.9%). Four patients were managed by bilateral plastic stents in bilateral metal stents (4/7, 57.1%) and one patient by unilateral plastic stent and contralateral PTBD. Two patients were managed by PTBD because of multiple segmental dilations.

CONCLUSION: Slimmer Zilver stent seems to improve achieving bilateral stenting in patients with advanced hilar cholangiocarcinoma. Open cell type Zilver stent also is likely to be useful for reinserting plastic stents endoscopically in case of tumor recurrence.

35

Abstract: P0514

Citation: Endoscopy 2008; 40 (Suppl 1) A 208

NEW ENDOSCOPIC APPROACH TO HIGH DOSE-RATE INTRALUMINAL BRACHYTHERAPY IN THE MANAGEMENT OF MALIGNANT BILIARY OBSTRUCTION

INTRODUCTION: High dose-rate intraluminal brachytherapy (HDR-ILBT) for treatment of inoperable malignant biliary obstruction was previously described using the percutaneous approach. HDR allows better and more precise targeting of the desired area of irradiation than low dose-rate brachytherapy.

AIMS & METHODS: The aim of this study was to determine the feasibility, safety and outcome of novel endoscopic approach for management of malignant biliary obstruction using HDR-ILBT through self-expandable metal biliary stents.

Ten patients with unresectable hilar (n = 2) and extrahepatic (n = 8) biliary carcinomas were treated with intraluminal HDR-Ir192 inserted endoscopically through metal stent. Satisfactory biliary drainage using 1-3 self-expandable metal stents was achieved in all patients before ILBT. One patient had combined endoscopic and transcutaneous approach in view of previously inserted percutaneous biliary drainage. ILBT was delivered by an HDR-Ir192 source using the Micro-Selectron afterloading system Nucletron and the dose was calculated within 10 mm from the center of the source. Fractional doses of 5 Gy were given at daily intervals for 4-5 consecutive days in total dose of 20-25 Gy.

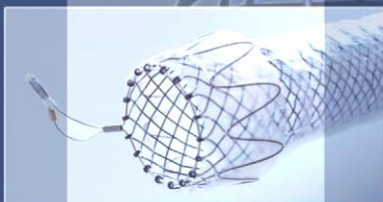
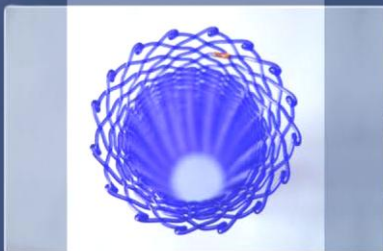
RESULTS: Nine patients completed treatment. In one patient the last dose of radiotherapy was not delivered due to poor compliance. The median time of stent patency was 6 months (range, 4-20). There was no technical problem with regard of Ir192 source migration and source entrapment within the catheter. The source of HDR was continuously moved within the endoscopically placed catheter according to pre-programmed coordinates during each treatment session. Cholangitis occurred in one patient and hemobilia in one. Overall median survival was 11 months, (range 4-26).

CONCLUSION: HDR ILBT through endoscopically inserted self-expandable metal stents is a novel technique that appears feasible with no documented technical problems with HDR-Ir192 source and acceptable toxicity.

36

Abstract: P1535

Citation: Endoscopy 2008; 40 (Suppl 1) A 412



PERFORMANCE CHARACTERISTICS OF A NEW UNCOVERED METAL STENT (WALLFLEX®) IN MALIGNANT BILIARY OBSTRUCTION. PRELIMINARY RESULTS IN A CASE SERIES

INTRODUCTION: Self expanding metallic stents (SEMS) have been successfully used in endoscopic treatment of unresectable malignant tumors causing biliary obstruction. Wallflex® (Boston Scientific, Natick, Massachusetts, USA) is a new platinum-cored nitinol SEMS, which offers theoretical advantages, such as more flexibility while maintaining lumen patency, increased number of fluoroscopic markers and enhanced radiologic visibility), flared and looped ends that potentially reduce the migration rate and the risk of local mucosal trauma respectively.

AIMS & METHODS: We carried out a retrospective chart review of all the patients with malignant biliary stenosis undergoing ERCP in whom Wallflex® SEMS was used. We compared the general performance results and occlusion-free time with equal numbers of consecutive patients receiving Wallstent® SEMS (Boston Scientific, Natick, Massachusetts, USA).

RESULTS: Since its introduction in the Center for Endoscopic Research and Therapeutics (University of Chicago Medical Center) in May 14, 2007, Wallflex® SEMS was used in 13 patients until August 20, 2007. A similar number of cases of previously placed Wallstent® SEMS in our institution were identified for comparison. Except for the age (Wallflex® 62.8 y. vs Wallstent® 73.3 y; p = 0.026), both groups were similar in baseline characteristics, nature and location of malignant stenoses and number/size of placed SEMS. After a median follow-up of 114 and 96 days respectively, the rate of SEMS occlusion was 38.5% (5/13) in the Wallflex® group and 23.1% (3/13) in the Wallstent® group. We noted a shorter post-stenting occlusion-free time in the Wallflex® group compared with the Wallstent® group (median 12 vs. 61 days; p = 0.029), with a cumulative incidence of SEMS occlusion at 60 days of 48% and 15% (RR = 4.3; 95% CI 0.84-22.4).

TABLE 1:

	Wallflex® (n = 13)	Wallstent® (n = 13)	p
Follow-up (days) Median (min-max)	114 (1-272)	96 (7-425)	0.094
SEMS occlusion n (%)	5 (38.5)	3 (23.1)	0.671
Occlusion-free time (days) Median (min-max)	12 (1-210)	61 (7-425)	0.029

Occlusion and occlusion-free time in both groups.

CONCLUSION: Wallflex® SEMS is associated with early occlusion compared to Wallstent SEMS.

Prospective multi-center studies are required before advocating the use of biliary Wallflex® SEMS for malignant biliary stenosis in clinical practice.

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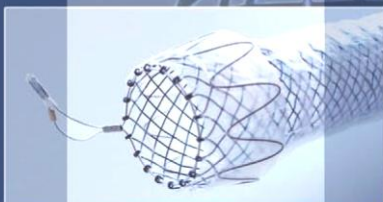
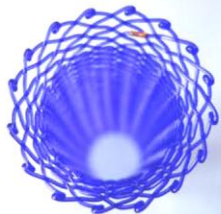
Abstract: P1546

Citation: Endoscopy 2008; 40 (Suppl 1) A 414

PLASTIC OR METAL STENTS FOR BENIGN BILIARY OBSTRUCTION: A SYSTEMATIC REVIEW OF THE LITERATURE

INTRODUCTION: Benign biliary strictures most frequently occur as a consequence of a surgical procedure, chronic pancreatitis or iatrogenic ampullary stenosis. Stent placement is increasingly being employed for this indication.

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AIMS & METHODS: A systematic review of the available literature searching PubMed and EMBASE on stent placement for benign biliary obstructions with regard to outcome and complications was performed. 76 Studies with detailed data on outcome of stent placement in 1870 patients were identified. None randomized controlled trials (RCT) were found. One non-randomized study compared one plastic stent with multiple plastic stents, whereas in another non-randomized study one plastic stent was compared with an uncovered self-expanding metal stent (uSEMS). 74 Case-series evaluated 1100 patients with single plastic stent, 279 patients with multiple plastic stents, 386 patients with uncovered self-expanding metal stent (uSEMS) and 93 with covered SEMS (cSEMS). Data were pooled and evaluated for technical and clinical success, and complications. Clinical success was defined as no need for further treatment after stent placement or total relief of symptoms or a significant decrease in bilirubine.

RESULTS: Indications included biliary strictures following surgery (39.2%), chronic pancreatitis (21.3%), liver transplantation (20.8%) or others (18.7%). Median stenting time was longest for multiple plastic stent (12.5 (range 4.6-14) mo), followed by single plastic stent (10.0 (1-24) mo), cSEMS (4 (1- 28) mo) and uSEMS (20 (0.5-60) mo). Technical success was 100% for multiple plastic stents, 98.5% for uSEMS, 96.5% for cSEMS and 95.3% for single plastic stent. Clinical success was most optimal after placement of multiple plastic stents (88.3%) followed by cSEMS (75%), uSEMS (62.4%) and single plastic stent (58.7%). The best clinical success in chronic pancreatitis was obtained with uSEMS placement (80.4%), compared to single plastic stent placement (36.5%). After liver transplantation, best clinical success was seen with single plastic stents (80.1%) compared to uSEMS (50%). No difference in clinical success was seen in patients with strictures following surgery (uSEMS (59.6%) vs. single plastic stent (58.2%)). Procedure-related and long-term complications occurred less frequently after multiple plastic stents (22.6%) followed by cSEMS (39.6%), single plastic stent (40.1%) and uSEMS placement (49.6%).

CONCLUSION: This systematic review shows an absence of RCTs for stent placement in benign biliary strictures. Based on clinical succes, multiple plastic stent placement is currently the best choice for this indication. The clinical value of cSEMS needs further elucidation.

38

Abstract: P0495

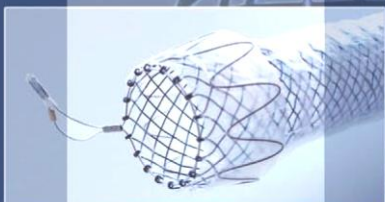
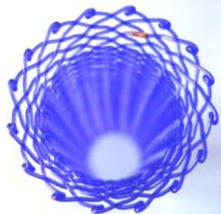
Citation: Endoscopy 2008; 40 (Suppl 1) A 204

ROLE OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY IN MANAGEMENT OF POSTOPERATIVE BILE DUCT INJURIES

INTRODUCTION: Postoperative bile duct injuries (POBDI) constitute a serious and difficult management problem. Although surgical management is the definitive treatment, it is associated with high morbidity and mortality. Biliary endoscopic procedures may be a less invasive procedure that is suitable for a subset of patients.

AIMS & METHODS: This retrospective work presents the experience of a single center during a period of 13 years in endoscopic management of POBDI. In Mansoura Gastroenterology Surgical Center, Mansoura University, Egypt between 1995 and 2008 ERCP had been performed to 353 patients suspected to have POBDI. All patients were subjected to clinical examination, complete laboratory workup and abdominal ultrasound. Magnetic resonance cholangiopancreatography (MRCP) was done for all late cases. Patients shown to have complete transaction of bile duct were prepared for definitive surgery. For the remaining patients, therapeutic procedures like sphincterotomy, biliary stenting and balloon dilatation were performed according to the standard techniques. The stents were removed after an interval of 6-8 weeks. If residual stones were seen in the common bile duct (CBD), sphincterotomy was followed by stone extraction using dormia basket or balloon.

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RESULTS: The mean age was 45.3 years and 210 (59.5%) were males. The previous surgery was open cholecystectomy (n = 154, 43.6%), laparoscopic cholecystectomy (n = 97, 27.5%), T tube (n = 78, 22.1%), and others (24, 6.8%). Twenty three (6.5%) patients were operated at our center whereas 330 patients (93.5%) were operated outside. The presentation was bile leakage from the wound, drain site, or after percutaneous drainage of abdominal collection (n = 141, 40%), progressive jaundice (n = 115, 32.5%), and recurrent cholangitis (n = 97, 27.5%). The time interval between ERCP and initial surgery was about 3 weeks. ERCP failed in 17 patients (4.8%). For successfully cannulated cases (n = 336, 95.2%), the type of bile duct injury diagnosed at ERCP was ligated CBD (n = 31/336, 9.2%) and they were subjected to surgery. Bile leakage from cystic duct, CBD/CHD, accessory bile duct, sectorial duct or the site of T tube was detected in 174/336 patients (51.8%). All those patients had endoscopic sphincterotomy and stent insertion, and the leak stopped in all of them. Biliary stricture was diagnosed in 33/336 patients (9.8%) and 17 of them had repeated balloon dilatation with stenting while the remaining had surgical correction. Stones were found in 29 patients (8.6%) and were successfully removed endoscopically by basket or balloon after sphincterotomy. Cholangiogram was normal in 86 patients (25.6%).

CONCLUSION: Endoscopic therapy is safe and effective in the management of POBDI. MRCP should be routinely performed before ERCP for selection of the best candidate for endoscopic treatment.

39

Abstract: P0510

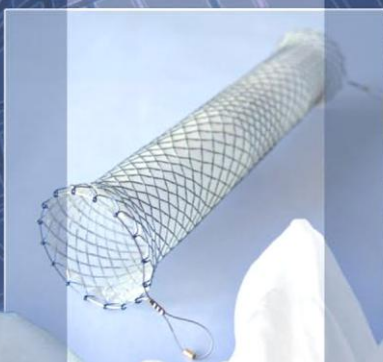
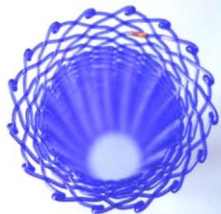
Citation: Endoscopy 2008; 40 (Suppl 1) A 207

TECHNIQUES, DIFFICULTIES AND SUCCESS RATE OF ENDOSCOPIC REMOVAL OF DIFFERENT TYPES OF BILIARY SELF-EXPANDABLE METAL STENTS (SEMS)

INTRODUCTION: Benign strictures misdiagnosed as malignant (Vibert, Surgery'05) or stent dysfunction (Familiari, GIE'05) often require biliary SEMS removal. Temporary placement of covered SEMS may enhance endotherapy of benign biliary strictures (Kahaleh, GIE'08). However, reported ERCP removal techniques for uncovered SEMS fail >60% & further proof of removability is needed before covered SEMS can be safely used in benign disease.

AIMS & METHODS: To assess techniques and results of biliary SEMS removal at ERCP. Pts with attempted biliary SEMS removal at ERCP over a total of 9 yrs were identified at 3 Sites. Retrospective data were pooled for diagnosis, indication for removal, SEMS type, removal technique (basic = rat tooth/snare mobilization & traction up to SEMS breakdown; advanced = any cautery/intraductal forceps; salvage = any unreported), time interval (early <1 mo; intermediate = 1-4 mo; late >4 mo), difficulties & success. Fisher's test and logistic regression analysis were used for comparisons.

RESULTS: Endoscopic removal of 68 SEMS was attempted, 34 partially covered biliary Wallstents (CW), 32 fully covered Hanarostents (CH, 28 biliary 10-mm & 4 customized tracheal 16-mm), 2 uncovered biliary Wallstents (UW), in 62 pts (male/female:48/14; age range:37-90yr). Removal was in 47 after intentional temporary placement (34 benign biliary strictures, refractory stones in 7, miscellaneous in 5, & 1 malignancy - myeloma prior to chemo), in 14 for accidental reasons (7 SEMS malposition/dysfunction & 7 complications - 5 cholecystitis, 2 pancreatitis), and incidental in 1 (UW in Mirizzi mistook for Klatskin). Initial success was obtained with basic techniques in 49 and in a further 5 with advanced techniques (76.5%). Removal with basic and/or advanced techniques (14/8) failed in 14 due to ingrowth (2 UW, 3 CW, 3 CH with lost cover) or a SEMS embedded in the CBD despite an intact cover (6 CH). No further attempts were made in 4/14 initial failures (3 surgery, 1 SEMS left in situ). 2 salvage techniques were tried in the remaining 10: a second coaxial SEMS was placed aiming to cause ingrowth necrosis in 9, with subsequent removal at a repeat ERCP, and a biopsy forceps under choledochoscopy was used to



disembled proximal SEMS filaments from the CBD, with snare removal in the same session. Salvage succeeded in 10/10, for an overall rate of 94%. Initial failure was more likely in late Vs intermediate Vs early attempts at removal ($p < 0.001$), but salvage equally effective throughout.

CONCLUSION: Time interval affects biliary SEMS removability. A second coaxial SEMS is a simple, effective salvage technique for failed endoscopic biliary SEMS removal.

40

Abstract: P1529

Citation: Endoscopy 2008; 40 (Suppl 1) A 411

TEMPORARY PLACEMENT OF COVERED SELF EXPANDABLE METALLIC STENTS (CSEMS) IN ANASTOMOTIC BILIARY STRICTURES AFTER LIVER TRANSPLANTATION

INTRODUCTION: Endoscopic treatment of anastomotic biliary strictures after liver transplantation includes balloon dilation and stent placement. Plastic stents have limited patency rates, requiring frequent replacement. Compared to plastic stents, CSEMS have a larger diameter. Compared to uncovered self expandable metallic stents, CSEMS have a better patency rate, and the added advantage of being removable by endoscopy. The aim of this study was to prospectively study the ability of placement and removal of partially CSEMS in anastomotic biliary strictures after liver transplantation.

AIMS & METHODS: 13 patients (10 men, 3 women, aged 40.9 ± 17.8 years) with anastomotic biliary strictures after liver transplantation were included between February 2007 and January 2008. 12 patients had previously undergone ERCP with plastic stent placement, left in place for 5.1 ± 4.6 months. CSEMS (Permalume covered Wallstent, Boston Scientific, 60, 80 or 100 mm) were placed. The length of the distal end of the CSEMS protruding in the duodenal lumen had to exceed 5 mm. CSEMS was left in place for 2 months, then removed. A cholangiogram was performed at the time of CSEMS removal. Patients were then reviewed with clinical examination and liver function tests, 1, 3, 6, 9 and 12 months after CSEMS removal. Primary endpoint was the ability to remove the CSEMS.

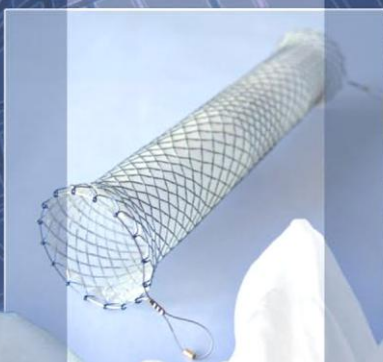
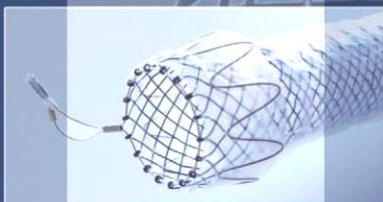
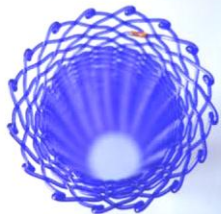
RESULTS: CSEMS placement could be performed in all patients, after endoscopic dilation of the stricture in 4 patients, and biliary sphincterotomy in 11 patients. Complications associated with placement were minor and included post ERCP pancreatitis ($n = 2$), pain ($n = 1$) and cholangitis ($n = 1$). CSEMS removal could be performed after 2 months in all patients, with a snare ($n = 4$), a rat tooth ($n = 4$), or both ($n = 2$). Proximal migration of the csems occurred in 3 patients. In these patients removal was performed with a rat tooth after infundibulotomy ($n = 1$) or Argon Plasma coagulation of the papilla ($n = 2$). After removal, cholangiogram showed resolution of the stricture in 11 patients and a persistent stricture in one patient, treated with CSEMS placement. Mean follow up after CSEMS removal was 8.9 ± 3.4 months. Recurrence of anastomotic stricture occurred in 4 patients after 5 ± 2.4 months, treated with CSEMS placement.

CONCLUSION: Temporary placement of CSEMS in anastomotic biliary strictures after liver transplantation is feasible. CSEMS removal was possible in all cases. Proximal migration of the stent may occur, thus requiring a combination of techniques for removal. Totally covered self expandable metallic stents could be useful. Optimal duration of endoscopic treatment remains unknown.

41

Abstract: P1446

Citation: Gut 2008; 57 (Suppl II) A 395



USEFULNESS OF CURVED MULTIPLANAR REFORMATTED IMAGES OF MULTI-DETECTOR CT FOR DIFFERENTIATION OF BILIARY STENT OBSTRUCTION IN MALIGNANT BILIARY OBSTRUCTION PATIENTS

INTRODUCTION: Biliary stent obstruction is caused by biliary sludge clogging, or tissue ingrowth such as tumor ingrowth or epithelial hyperplasia. Until now, there is no way to predict the etiology of biliary stent obstruction by noninvasive methods. **AIMS & METHODS:** We evaluate the usefulness of curved multiplanar reformatted (MPR) images of multi-detector CT (MDCT) for the noninvasive assessment of cause of biliary stent obstruction. From December 2004 to July 2007, among malignant biliary obstruction patients who had undergone biliary stent insertion, 15 patients who were suspected of biliary stent obstruction and underwent ERCP after MDCT were enrolled. Curved MPR images were obtained along the pathway of biliary stent. We defined as contrast-enhancement when the Hounsfield unit (HU) is increased over 10 HU comparing pre- and post-contrast CT scan at the region of interest inside the biliary stent, and read as tissue ingrowth or biliary sludge clogging whether it is increased or not. We confirmed the presence of obstruction in biliary stent and whether tissue ingrowth or biliary sludge clogging using ERCP and then compared with MDCT finding.

RESULTS: Among 6 patients who were read as tissue ingrowth on MDCT, 5 patients were diagnosed as tissue ingrowth on ERCP. Among 9 patients who were read as biliary sludge clogging on MDCT, 8 patients were diagnosed as biliary sludge clogging on ERCP. The diagnosis of MDCT and ERCP was the same except for 2 patients. The sensitivity and specificity of MDCT for tissue ingrowth is 83.3% and 88.9% respectively.

CONCLUSION: Curved MPR image of MDCT is a useful noninvasive modality for the prediction of etiology of biliary stent obstruction and it is helpful to plan for the medical management of such patients.

D. Colorectal stenting and related topics

42

Abstract: OP034

Citation: Endoscopy 2008; 40 (Suppl 1) A 7

BRIDGE TO SURGERY STENTING WITH WALLFLEX COLONIC STENT: SPANISH PROSPECTIVE MULTICENTER REGISTRY

INTRODUCTION: Emergency surgical treatment of acute malignant colorectal obstruction is associated with high morbidity and mortality rates. Endoscopic colonic stent insertion can effectively decompress the obstructed colon allowing bowel preparation and elective resection with primary anastomosis.

AIMS & METHODS: The aim of the study is to assess the effectiveness and safety of Wallflex colonic stent (Boston Scientific, USA) in patients with acute malignant colorectal obstruction suitable of curative tumoral resection. A multicenter registry documenting the performance of Wallflex colonic nitinol self-expanding stent has been carried out in 27 Spanish hospitals, including both palliative and bridge to surgery (BTS) indications. Results on the BTS group are presented. Technical success, clinical success, safety (complications) and surgery outcomes were evaluated.

RESULTS: 96 BTS patients (59 males. Mean age 71.7) were included. Tumors were located at the rectum (7.3%), recto-sigmoid junction (8.3%), sigmoid colon (44.8%), descending colon (27.1%), splenic flexure (9.4%), transverse colon (2.1%), hepatic flexure (1%) and ascending colon (1%). 89 patients (92.7%) presented with sub-occlusive symptoms or complete obstruction. Technical success was achieved in 93 cases (96.9%). Failures were due to improper stent placement (2) and improper stent expansion (1). Clinical success was achieved in 87 cases (90.6%). Failures were due to colonic perforation in 5 patients and stent obstruction due to fecal impaction in 1 case. Procedural complications (during or within 6 hours of placement) occurred in 5 patients (5.2%): perforation (2), bleeding (1), fever (1) and abdominal pain (1). Postprocedural complications (between



stent placement and surgery) occurred in 5 patients (5.2%): perforation (3), migration (1) and fecal impaction (1). One patient died because of colonic perforation after stenting (1%). Elective resection with primary anastomosis could be performed in 86 patients (89.5%). Mean time between stent placement and surgery was 14.4 days.

CONCLUSION: 1. Wallflex colonic stent is effective in patients with acute malignant colonic obstruction as a bridge to surgery treatment, restoring luminal patency and allowing elective surgical resection with primary anastomosis. 2. The use of this stent is safe and associated with an acceptable complication rate, considering reported data about other stents and emergency surgical treatment.

43

Abstract: OP032

Citation: Endoscopy 2008; 40 (Suppl 1) A 6

CLINICAL EXPERIENCE WITH A NITINOL SELF-EXPANDING COLONIC STENT IN THE WALLFLEX-ER COLONIC INTERNATIONAL REGISTRY

INTRODUCTION: Self expanding metal stents (SEMS) are an alternative to surgery for malignant large bowel obstruction, avoiding stoma for palliate incurable pts (PAL) and facilitating bowel decompression as bridge to surgery for curable pts (BTS). **AIMS & METHODS:** Surgeons and gastrointestinal endoscopists in academic and community hospitals completed enrollment of 213 pts with malignant colo-rectal obstruction into a web-based worldwide registry. Pts received a WallFlex™ Colonic Stent (Boston Scientific, Natick, USA). Follow-up is ongoing to death (PAL) or surgery (BTS) up to 12 m. To date 135 pts completed follow-up. Primary endpoint: relief of obstruction and adequate stool transit. Secondary endpoints: technical success, complications, survival.

RESULTS: 135 pts, 96 PAL and 39 BTS. Technical success (adequate stent placement) in 122/135 (90%) pts. Incorrect stent placement in 13 pts (10 PAL/3 BTS). Clinical success (improvement in passage of stool without need for reintervention from baseline to surgery (BTS) or 30d (PAL)) in 121/135 (90%) pts. 14 clinical failure pts underwent surgery (8), unspecified retreatment (1), no treatment (5). Procedural complications occurred in 9 pts: perforation (2), pain (3), obstruction (4). Post-procedure complications between stent placement and surgery (BTS) or 30d follow-up (PAL) occurred in 19 pts: reobstruction by fecal impaction (3), stent migration (5), colon perforation (1), bowel impaction in stent (1), other (9). Mean time from stenting to surgery 19d (range 1-93).

CONCLUSION: Colonic SEMS used per local standards of practice provide safe and highly successful treatment of malignant colo-rectal obstruction, allowing most curable pts to have one-step resection after decompression by SEMS and providing most incurable pts minimally invasive palliation instead of surgery.

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Abstract: P0692

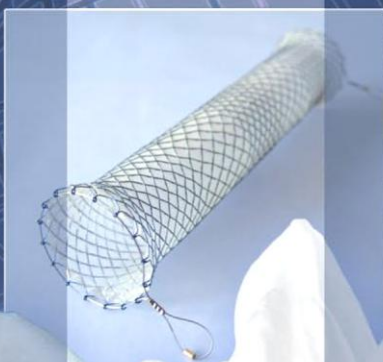
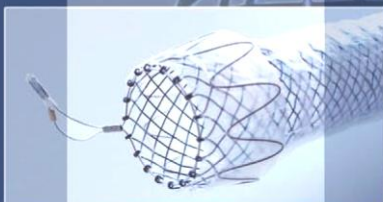
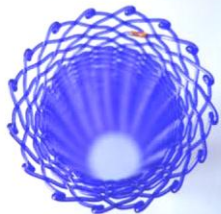
Citation: Endoscopy 2008; 40 (Suppl 1) A 243

COLONIC STENT PLACEMENT WITHOUT FLUOROSCOPY: A SERIES OF 34 STENTS

INTRODUCTION: Colonic stent placement is often performed under fluoroscopic control. However, fluoroscopy is not always required. We present a series of 34 consecutive colonic stents placed without fluoroscopy, in 31 patients.

AIMS & METHODS: AIM: to prove feasibility, safety and efficiency of this technique, in a retrospective study.

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METHODS: Thirty-four stents were placed without fluoroscopy, between 11.2002 and 4.2008, in 31 patients (M: 17, F: 14; mean age: 69.1, range: 40-93). Indications: stenoses related to colorectal cancer (20 patients, 22 stents) or ovarian cancer (2 patients, 2 stents - with fistula: 1, without fistula: 1), fibrous anastomotic stenoses without (4 patients, 4 stents) or with fistula (1 patient, 1 stent), non neoplastic fistulae without stenosis (2 patients, 3 stents), or radiation stenoses (2 patients, 2 stents). Localizations of fistulae and/or stenoses were: rectum or sigmoidorectal junction (n = 21), sigmoid (n = 8), or left colon (n = 2). Mean distance from anal margin was 19.5 cm (8-51) for distal end of stenoses and 18 cm (15-23) for fistulae. Mean length of stenoses was 6.2 cm (5-10).

RESULTS: Procedure was performed under (n = 16, 47%) or without (n = 18, 53%) general anaesthesia. Stenoses were crossed by a gastroscope (diameter: 5.9 or 8.8 mm) in 28/29 patients (96.6%). Stent placement succeeded in all cases. In 30/34 (88.2%), stents were released from below to above, under permanent and exclusive control with a gastroscope placed in a parallel direction. Twenty-one stents out of 30 (70%) were uncovered (diameter: 30 mm, length: 5.7, 8.7 or 11.7 cm) and 9/30 (30%) were covered oesophageal stents (diameter: 23 or 28 mm, length: 10, 12 or 15 cm). In 4/34 (11.8%), uncovered TTS enteral stents were placed (diameter: 22 mm, length: 11 or 14 cm). Mean length of stents was 10.9 cm (5.7-14), and mean diameter 28 mm (22-30). Mean distance of the lower end of the stents from anal margin was 17.6 cm (6-48). In 3 patients, a second stent was necessary, respectively 4, 7 and 185 days after the first one. In 29/34 (85.3%), early efficiency of stents occurred. In 5/34 (14.7%), stents were ineffective or not tolerated. Neither perforation nor bleeding occurred. Migration was noted for 10/34 stents (29.4%), leading to stent removal within 24 h to 90 days (mean: 27.8 days). These migrations concerned covered stents in 7/10 (70%) and non covered ones in 3/10 (30%), and occurred in patients with fistulae without stenoses in 3/10 (30%), non neoplastic stenoses in 6/10 (60%), and a neoplastic stenose in 1/10 (10%). Among covered stents, 7/9 (77.8%) migrated, versus 3/25 (12%) for uncovered ones (Fisher test: p = 0.0007).

CONCLUSION: Colonic stent placement without fluoroscopy was feasible in all patients. General anaesthesia was not required in 53% of patients. Early efficiency was observed in 85% of stents. The only observed complication was stent migration (29.4%), which was mainly observed in covered stents (70% of migration cases).

45

Abstract: OP033

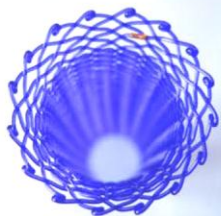
Citation: Endoscopy 2008; 40 (Suppl 1) A 7

COLONIC STENTING AS BRIDGE TO SURGERY VERSUS EMERGENCY SURGERY FOR MANAGEMENT OF ACUTE LEFT-SIDED MALIGNANT COLONIC OBSTRUCTION: A MULTICENTER RANDOMIZED TRIAL (STENT- IN 2 STUDY)

INTRODUCTION: Conventionally, patients with acute left-sided malignant colonic obstruction are treated with emergency surgery to restore luminal patency. These emergency operations have a high mortality and morbidity rate. Stent placement as bridge to elective surgery has been suggested to improve the patient's clinical condition, thus decreasing mortality, morbidity and the number of colostomies. The objective of this study is to compare the effectiveness and costs of these two treatment algorithms.

AIMS & METHODS: This study is a prospective multicenter (25 centers) randomized controlled trial. Eligible patients with acute left-sided malignant colonic obstruction are randomly allocated to either emergency surgery (current standard treatment) or colonic stenting as bridge to elective surgery. Effectiveness is evaluated in terms of quality of life, morbidity and mortality. Quality of life is measured with standardized questionnaires (EORTC QLQ-C30, EORTC QLQ-CR38, EQ-5D and EQ-VAS). The total costs of treatment are evaluated by counting volumes and calculating unit prices. Patients are followed for a period of 6

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months. Including 120 patients on a 1:1 basis will have 80% power to detect an effect size of 0.5 on the EORTC QLQ-C30 global health scale, using a two group t-test with a 0.05 two-sided significance level. After inclusion of 60 patients an interim analysis is performed.

RESULTS: In 12 months 29 patients (13 men, mean age 69 years) were enrolled by 13 centers. Fourteen patients were randomly assigned to emergency surgery and 15 to endoluminal stenting as bridge to elective surgery. All patients randomized for emergency surgery were treated accordingly. Of those randomized to endoluminal stenting 6 did not receive an enteral stent: 4 appeared to have a diverticular stenosis, 1 patient had a tumor fistula to the small bowel and in 1 patient there was a logistic problem. Pathology confirmed malignancy in 13 of the 14 patients assigned to emergency surgery and in 11 of the 15 patients allocated to enteral stenting.

CONCLUSION: Endoscopic colonic stent placement as bridge to elective surgery seems to be an attractive alternative to emergency surgery in patients with acute left-sided malignant colonic obstruction. Its effectiveness and costs are currently investigated in a 25 centers randomized trial in the Netherlands.

46

Abstract: P0435

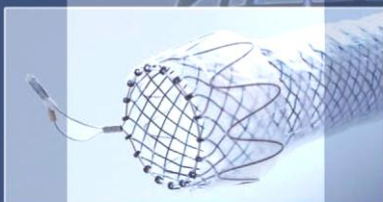
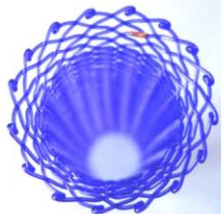
Citation: Endoscopy 2008; 40 (Suppl 1) A 192

COLORECTAL STENTING FOR COLONIC OBSTRUCTION: THE INDICATION, EFFECTIVENESS, COMPLICATIONS, AND OUTCOME; CONSECUTIVE STUDY INVOLVING 135 CASES

INTRODUCTION: Self-expandable metal stent (SEMS) are used to treat malignant colorectal obstruction (MCRO). SEMS may be used as bridge to surgery or as a palliative treatment.

AIMS & METHODS: This was a retrospective study in a single university hospital center with three senior gastroenterology and four trainees. The patients were those who present with MCRO. A total of 135 colorectal SEMS were inserted during a 6 years period (July 2001 to February 2008). This study aims to evaluate the use of SEMS for MCRO in a single university center endoscopic practice. The outcome measures were the technical and clinical success and possible differences according to several groups of patients (peritoneal carcinosis; indications; clinical symptoms; using fluoroscopy or not to control the insertion of the stent, length of the stenosis, endoscopic features).

RESULTS: Median patients age was 78 years (27 to 98 years). 60% were men and 40% women. The median length of the stenosis was 5 cm. The site of obstruction was the rectum in 21%, rectosigmoid in 61%, splenic flexure in 6%, transverse in 6% and right colon in 6%. Successful placement was achieved in 123 patients (91.1%) and colonic decompression was achieved in 118 patients (87.4%). There were differences between several sub-groups: clinical success was 67% for patients with peritoneal carcinosis, 78.9% for patients with complete obstructive symptoms; 89.3% with partial obstructive symptoms. The stent was inserted by endoscopy alone in 66.7% and 33.3% by endoscopy with control by fluoroscopy. Clinical success for the group who had the stent inserted by endoscopy with a fluoroscopic control was 93.2% versus 84.1% when the stent was inserted with endoscopy alone. SEMS was inserted as a bridge to surgery in 31% and as a palliative treatment in 69%. There were no differences when the stent was inserted before surgery (89%) or as a palliative treatment (90%). The median delay before surgery was 7.5 days. The major complication was perforation in 4 patients (4%) and led to death in 2 patients (1.6%). There were less severe complications in 16%. Median survival after the stent placement was 69 days (one day to 3 years).



CONCLUSION: In this study success rates for SEMS placement and colonic decompression in MCRO is safe and effective without serious complications. It appears that SEMS are more effective in patient without peritoneal carcinosis and symptomatic partial colonic obstruction and when it is inserted by endoscopy with a fluoroscopic control.

47

Abstract: P1311

Citation: Gut 2008; 57 (Suppl II) A 367

IS COLONIC STENTS THE FIRST LINE OF MANAGING MALIGNANT BOWEL OBSTRUCTION?

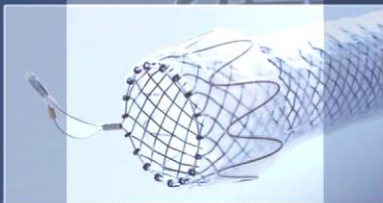
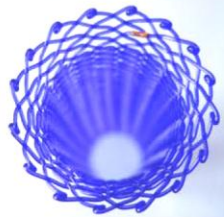
INTRODUCTION: Emergency surgery for acute bowel obstruction due to cancer has a mortality of 12% and a morbidity of 39%. More than 50% of these patients will require a stoma. Colonic stents have been increasingly used for emergency acute bowel obstruction and could replace surgery as the first line management.

AIMS & METHODS: Our aim is to look at the outcome of patients who had undergone colonic stenting for bowel obstruction in our institution and to compare our results with existing published data on this topic. We collected information from endoscopy reports and patient notes over a 3 years period on patients who had colonic stent insertions in our institution. A review of published data on this topic was also performed in PubMed, Pre Medline, EMBASE, Medline and Google. The selection criteria for our search was for patients who had colonic stents for bowel obstruction due to bowel cancer.

RESULTS: In our institution we have reviewed 63 patients who had colonic stent over the last three years. All patients had bowel obstruction due to malignant stricture. 62 patients had successful insertion. In one patient stent could not be placed due to tight stricture and difficult angle. Stent migration occurred in 2 patients. Two patients required further stent placement due to stent occlusions. 10 patients had this performed as a bridge to definitive surgery, and had primary anastomosis without stoma. Median duration of stent patency was 106 days (range 68-288). The average survival after the stent was 141 days for palliative cases. Patients had a very short stay following stent placements. Technical success rate in colonic stents was reported with average of 92% compared to our rate of 98%. Clinical success rate was reported with average of 87% compared to 93% our data. Median stent migration was reported as around 5% compared to 1% in our series, and median perforation rate of 3% compared to 1.5% in our series, Rate of re-obstruction reported is around 12% compared to 2.5% in our data. This difference could be attributable to single operator performance, experience and expertise, thus gathered.

TABLE 1: Comparison of our data with published studies

	Technical success rate	Perforation rate	Migration rate	Survival after stents (days)	Clinical success rate
Queens Hospital	98.4%	1.5%	1%	141	98%
Wyatt AM Analy 88 studies	92%	4.5%	11%	106	not available
Our own Analy 15 studies	92%	3%	5%	51	87%



CONCLUSION: Our experience in colonic stents in malignant bowel obstruction is consistent with the published data and is safe, effective and is associated with reduced morbidity and no mortality. Although randomised controlled studies are sparse, available evidence indicate the use of colonic stents as the first line management in malignant bowel obstruction.

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Abstract: P1310

Citation: Gut 2008; 57 (Suppl II) A 367

STENTS OR SURGERY FOR ACUTE COLORECTAL OBSTRUCTION IN PATIENTS WITH NON METASTATIC COLORECTAL CANCER OR WITH RESECTABLE METASTASIS

INTRODUCTION: Treatment of acute obstruction due to colorectal cancer with self-expanding metal stent (SEMS) has been used as a bridge to curative surgery for patients with non metastatic colorectal cancer or with resectable metastasis. Our aim was to compare results for patients treated with SEMS before surgery and patients treated only with surgery.

AIMS & METHODS: Between 2000 and 2007, 44 patients were referred to our center for acute obstruction due to resectable colorectal cancer. Twenty had an attempt of SEMS implantation before curative surgery (group 1) and 24 had emergency open surgical management (group 2). Number of stoma, mortality, morbidity, length of stay, time to chemotherapy and survival were compared. **RESULTS:** The 2 groups were comparable for median age, sex, ASA score and site of obstruction. Three patients in group 1 and 2 in group 2 had resectable metastasis. In group 1, SEMS were successfully inserted for 18 patients (90%) and could not be implanted in two patient therefore treated with a Hartmann's procedure. All patients with SEMS had secondary surgery within a mean time of 8 ± 6 days: fourteen resections with anastomosis (4 with protective colostomy) and two resections without anastomosis. A total of 6 patients had colostomy. Closure was achieved for 5 after a mean time of 145 ± 96 days. One patient had definitive ileostomy.

In group 2, open operations were 12 resections with anastomosis and 4 with colostomy, 4 colostomy and 4 Hartmann's procedures. Twelve patients (50%) had an initial colostomy (ns), five (21%) kept a definitive one ($p < 0.0001$). In group 1, no mortality was observed after SEMS placement, but one patient (5%) died one month after surgery. In group 2, mortality was 17% (ns). Early morbidity (within 30 days) was 45% in group 1 (33% needing reanimation and 22% surgery for complication), 54% in group 2 (77% needing reanimation and 23% surgery for complication). Late morbidity (after 30 days) was 5% in group 1 and 25% in group 2 ($p = 0.47$). Mean length of stay was 25 days in group 1 and 48 days in group 2 ($p = 0.042$). Chemotherapy was administrated in 55% of patients in group 1 and 50% in group 2, with a mean time to first chemotherapy being 43 and 53 days respectively (ns).

Median survival was respectively 17, 3 and 17, 5 months (ns). At the end of the study, 10% patients in group 1 and 50% in group 2 had died.

CONCLUSION: Treatment of acute obstruction due to colorectal cancer without metastases, or with resectable ones, with SEMS decreases the median length of stay, late morbidity and in case of stoma creation decreases the number of definitive stoma. This procedure does not affect survival and does not defer chemotherapy. SEMS should be considered for emergency treatment in this situation.