Colonic stenting in acutely obstructed left-sided colon cancer

Clinical evaluation and cost analysis

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AIM: *This retrospective study aims to evaluate clinical and cost effectiveness of colonic stenting as a bridge to surgery and as a palliative treatment in acutely obstructed left-sided colon cancer.*
MATERIAL AND METHODS: *Onehundred fortyfour patients were collected between 2006 and 2012, with acute left-sided malignant colonic obstruction with no evidence of peritonitis: 96 patients underwent surgical treatment, 48 underwent decompressive stenting. For the stenting we used self-expandable metallic stent in nitinol.*
RESULTS: *Patients who had successful colonic stenting were 40, 8 underwent elective surgery within 10 days, 32 decompression stenting had only palliative intent. in 8/48 patients subjected to stenting decompression there was a technical failure (16%) and underwent emergency surgery. 40 patients had follow-up. at the time of observation 36 patients had a functioning stent, within 10 days 8 underwent elective definitive colonic resection with primary anastomosis trought videolaparoscopic thecnical, 4 (10%) had major complications and underwent emergency surgery. no patient of 40 in the stenting group required defunctioning stomas compared to 38 of 96 in emergency surgery group. we also compared the cost of decompressive stenting and emergency surgery treatment in acutely obstructed left-sided colon cancer referring to average cost of drg (1 and 2 code t-student test). the comparison of the average costs between decompressive stenting and emergency surgery was performed in the group of patients underwent palliative treatment separately from ones underwent radical treatment.*
CONCLUSION: *Colonic stenting followed by elective surgery may be safer and cost-effective, comparing to emergency surgery for left-sided malignant colonic obstruction.*

KEY WORDS: Bowel obstruction, Colonic cancer, Colonic stenting

Introduction

Colorectal cancer is the second most common cancer in men and the third most common in women. About 7% to 29% of colorectal cancers presents as acute intestinal obstruction [1]. Intestinal obstruction is a surgical emergency that requires surgery to relieve the obstruction. Moreover, emergency surgery for stenosing lesions is associated with high mortality rate of between 10% and 30% compared to <5% for elective surgery for colorectal cancer [2,3]. This includes both the surgical risk and the increased anesthetic one because of inadequate time to optimize patients before operation. Emergency surgery is associated with a higher requirement for critical care as well as with a prolonged hospital stay. To obtain a colon decompression, emergency surgery may need defunctioning stoma formation [4]. This would result in the patient requiring another surgery for stoma closure in

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the future. Patients treated by emergency resection should have similar long-term survival compared to the elective setting after they recovered from the operation. However, patients with obstructed colorectal cancer, operated in the emergency setting often have their adjuvant chemotherapy delayed or omitted because of postoperative complications, resulting in worse oncologic outcome. Self-expanding metallic stents (SEMS) is usually exploited for palliative treatment of obstructed advanced unresectable colorectal cancer. Recently, it has been taken into consideration the possibility of using the SEMS for a temporary decompression of colonic obstruction, followed by elective definitive resection of the tumor within 10 days later. The stents are therefore used as a "bridge to surgery" [5-9]. Many studies in the literature analyze the role of stenting both as a bridge to surgery and as a palliative treatment, and while there is a clinical general recognition, there is disagreement about the cost-benefit ratio. According to most of the autors, stenting decompression allows an immediate recanalization of the occluded patient, an oral refeeding in the second/third day and discharged on the third/fourth day. These patients also have the option, if there is an indication to apply a protocol bridge to surgery. The method proposed is not without risks. According to the most recent case studies complications occur about 20% of cases, and these are divided into early and late, major and minor. The early complications take place within seven days after the procedure and are present in 8.3% in the procedures for palliation and 15.4% in the procedures of "bridge to surgery", with an average of 10.3%. The late ones, occurring seven days after the procedure, amount to 16.1% and 7.7% for preoperative and palliative procedures respectively. Major complications are stent occlusion, migration and perforation (stent-induced or procedure-induced). The occlusion of the stent is in the 8th, 9% of patients undergoing palliative intervention in 4.6% of patients undergoing "bridge to surgery". As regards the migration, the percentages are 4.8% and 12.3%, for the palliative treatment and the pre-operative respectively.
The perforaction stent induced is achieved in 5.4% (for palliation) and 3.1% (BTS); The perforaction procedure induced is achieved in 3.6% (for palliation) and 1, 5% (BTS)[10-12]. A relationship between the therapy with Bevacizumab, biologic drug to use oncological, and an increased risk of perforation from colo-rectal stent has recently been proposed by two distinct work retrospective. In general, the use of this monoclonal antibody, which has as its target the VEGF receptor, has been associated with a certain risk of developing spontaneous perforations of the gastrointestinal tract, so it is likely that the association Bevacizumab - colo-rectal stent, may actually produce a significant increase in the risk of perforation [13,14]. Nevertheless, these complications are still much lower than those of emergency surgery (15.5% vs 32.9%, P = .015) [15]. There isn't the same arrangement as regards the costs. Some authors claim that the method is cost-effective others consider the method too expensive [16,17]. We proposed a retrospective study to evaluate the method of stenting decompression both from a clinical point of view and the cost.

Materials and Methods

To date, all stents available on the market are made of nitinol, latex of a metal alloy of nickel and titanium, biocompatible, that gives the prostheses the property of maintaining an elastic memory of its shape at body temperature; we can distinguish stents according to the shape, size, structure of the mesh. Another distinction for stents can be made according to the introduction mode and this can be achieved through the working channel of the endoscope (called TTS: Through The Scope) or after placement of a guide wire through the stenosis (so-called OTW: Over The wire). Stents have an OTW catheter from 16 Fr which excludes the possibility of introduction into the working channel of the endoscope; their positioning can take place under radiological control or with greater difficulty practice, under the vision of the colonoscope in parallel. They can also be used, because of their rigidity and length, only for stenosis of the rectum or sigmoid, within 30 centimeters from the anal margin. Stent passing through the working channel of the endoscope are used, for anatomical reasons for strictures located further upstream (Through The Scope).
For the clinical evaluation of the patient occluded CT with contrast plays a primary role It is essential to assess the place, the extent and nature of the stenosis, as well as to have a clearer picture regarding the abdominal status. After running the CT will be undertaken at a multidisciplinary evaluation by the surgeon, anesthetist and endoscopist. Informed consent about the procedure to be performed, must include the reasons which led physicians to the choice of stenting. In most cases endoscopy can be performed from 6 to 8 hours after diagnosis and by the subsequent therapeutic evaluation. the time is sufficient for the administration of antibacterial prophylaxis against aerobes and anaerobes, using for example third-generation cephalosporins and metronidazole, and to perform rectal evacuative enemas to clean the section of bowel downstream of the stenosis, facilitating the endoscopic exploration and the recognition of the lesion. It is necessary to have an x-ray room, a physician endoscopist, possibly expert in ERCP, two dedicated nurses or a second doctor and a nurse, instruments of different sizes to comply with all anatomical situations. A moderate sedation with benzodiazepines is generally performed. The anesthesia care is reserved for cases in which the patient is very suffering or in which clinical conditions are poor. For the prevention of aspiration pneumonia, caused by the air-induced relaxation, we recom-

mend the preliminary positioning of a nasogastric tube and its removal after recanalization. When the place of the stenosis is reached we proceed to the biopsy of the lesion with normal biopsy forceps. Usually we take samples from 6 to 8 and then it follows the washing with water to clean the field from the residual bleeding after the biopsy of a neoplastic lesion that is highly vascularized. This is followed by the overcoming the stenotic tract with a guide wire and a catheter or with the colonoscope. When the stenosis is crossed under radiological control, it withdraws the eventual guide-wire from the catheter and it perform the evaluation rx contrastographic with the injection of the water-soluble contrast medium that will confirm the position of the catheter in relation to stenosis, showing the anatomy of the stenosis and the extent of upstream colon distension, confirming the absence of perforation, or additional stenosis or synchronous lesions. To avoid an increased risk of perforation, it is recommended not to perform dilation of the stenosis before placement of the stent. the criteria for the choice of the type of stent to be placed are: the seat and the morphology of the stenosis. It is usually good practice to place a stent with a length of 3-4 cm higher than the stenosis (about 2 cm to extreme), to avoid the risk of migration and enable a better adaptation of the stent, especially when the stenosis is located in a very angled seat; this precaution also reduces the risk of perforation of the colonic wall as part of the prosthesis. After the stent advanced through the stenosis, the release should be under radiological and endoscopic help; The stent deployment must be done, as all stents placed in other locations, slowly and gradually, so as to keep under control the progress of the operation. After having positioned the stent, it is necessary to make a last endoscopic and radiologic check for evaluating the correct expansion of the stent inside the stenosis and to evaluate the passage of air and fecal material through the stenosis.

Results

EXPECTED: The stenting technical success is given by the proper stent expansion straddles the stenotic tract, while the definition of clinical success depends on the resolution of the clinical picture of occlusion and restoring of the transit. The literature reports a technical success for the procedure between 85 and 95% while the clinical success is lower, with values ranging between 70 and 85% [18,19]. This data have remained unchanged in the last ten years and this proves that the latest generation stents did not offer much more in terms of efficiency than the older ones. Data in the literature emphasize the fact that the technical and clinical success are greater in centers with a high volume of procedures/year. More complex is the analysis of the data regarding the results stenting in the palliative treatment, because most of the publications offers a limited follow-up and a reduced number of patients, with numerous biases related to various clinical conditions of patients. approximately 50% of patients develop a re-occlusion of the stent after six months, even if a new endoscopic treatment can solve the reocclusion and often for a longer time [20].

ACHIEVED: From 2006 to 2012 in O.U. General Surgery and Emergency 144 patients have came for bowel obstruction caused by colon cancer. The age range was between 65 and 92 years. Of these, 96 underwent emergency surgery (in one or two stages). In 48 patients it was run stenting decompression the colon; 20 underwent to stenting emergency for complete obstruction of these, 12 showed a poor clinical picture, a class III ASA and ASA IV underwent palliative stenting, 8 underwent stenting as "bridge-to-surgery"; 28 underwent to elective stenting for sub-occlusion. In the 8 patients who underwent to the "bridge-to-surgery" we obtained 100% of technical and clinical success. Of the 40 patients who underwent palliative stenting (12 of which urgently), 32 (76%) were successful and were admitted to follow-up phase, the remaining 8, given the technical and/or clinical failure, underwent surgery, but with increased security since the restoration of the clinical condition and with a more careful and thorough study which allowed to perform the operation in a oncologically more correct way. The follow-up of patients recorded the following data: 4 patients had a complication (perforation and displacement), 30 patients died with functioning stents and 6 up to November 2011 were alive and with functioning stent. As regards the seat, 30 showed stenosis concentric rectosigmoid, 6 had stenosis at the descending colon, 2 showed stenosis to the splenic flexure and 2 to the transverse colon (length of stenosis between 1 and 15 cm). The endoscopic team consisted of an endoscopist experienced in operating procedures, a surgery intern with training in endoscopy, a dedicated nurse, a radiology technician, and an anesthesiologist in cases where it was necessary to deep sedation (6 cases). The first endoscopic approach was performed with standard colonoscope. In 2 cases (both the sigma) it was deemed necessary to use a duodenoscope for the presence of a high angle of stenosis, which was not recognizable with the frontal view instrument. It has never been performed dilation with balloon, given the contraindications mentioned in the literature, which consider this procedure one of the major risk factors for major complications after the stent placement. The implants used were: the covered type for procedures in which we expect the only palliative treatment and the non-covered type in cases where the procedure was performed as a "bridge-to-surgery". 6 of the patients subjected to "bridge-to-surgery" underwent a laparoscopic colonic resection with a better patient outcome, with resumption of recanalization in IV GPO and eating again orally in V GPO, 2 patients underwent a colonic resec-

tion by laparotomy with resumption of recanalization in VI GPO and nutrition resumption in VII GPO. accordance with the literature, length the prosthesis was 3 cm higher than the stenosis length. Patients undergoing colon palliative stenting obtained the restoration of the transit after 12-24 hours and resumed oral feeding soon after. Patients undergoing a palliative treatment returned home on the third day post-stenting.

COST ANALYSIS

Assessing whether a procedure is cost-effective is today more than ever necessary, given the economic difficulties in which we are. To assess whether the stenting procedure responds to this requirement, we decided to perform a stenting procedure cost analysis and compare it with those commonly applied in UO of General Surgery and Emergency of the University Hospital Paolo Giaccone of Palermo. We have taken as a reference the DRG calculated by the company to which our unit belongs. in cases not yet calculated, reference was made to the simulation software on line E-drg. The cost of major DRG calculated in our study is shown in Table I.
We compared two populations represented by the 48 subjects who underwent stenting decompressive and 96 patients with colon neoplastic stenosis predominantly left (88 cases) treated surgically.
Population undergoing decompressive stenting:
– 40 palliative stenting;
– 8 stenting as a bridge-to-surgery.
8 of 40 stent placement procedures are going to meet technical failure and/or clinical and therefore were converted to the standard procedure.
4 subjects during follow-up had serious complications, 2 had a perforation and 2 a migration.
Population undergoing surgery for colon cancer stricture:
– 36 Palliative colostomy or temporary non-closed at the time of data collection:
– 4 packaged for less than 3 months;
– 8 packaged from 3 to 6 months;
– 14 packaged from 6 months to 1 year;
– 14 packaged more than 1 year.
60 underwent resection followed by recanalization:
– 54 in 1 time
– 6 in 2 time.
The average days of hospitalization shown in Table II are in accord with the literature data for both compared procedures (7.2 days) [21].
From the data collected using the t test (for comparison between means) it has been demonstrated that the procedure of stenting decompressive, taken as a whole,

TABLE I - *Main DRG attributed to each patient*

Cod.DRG	MCE	DRG Desciption	Price in the ordinary regime in €	Daily rate in €	Daily supplement over threshold in €
148	C	Major surgery on small and large intestines with cc.	9.667,39	1.883,00	114,28
149	C	Major surgery on small and large intestines without cc.	5.137,71	1.297,86	100
154	E	Operations on the esophagus, stomach and duodenum, age> 17 w cc.	11.179,11	2.164,47	129,65
155	E	Operations on the esophagus, stomach and duodenum, age> 17 without CC.	4.891,88	1.196,63	100
172	M	Malignant neoplasms of the digestive tract with cc.	3.944,18	270,62	114,03
173	M	Malignant neoplasms of the digestive tract without cc.	3.646,70	268,04	104,37
180	M	Gastrointestinal obstruction with cc.	2.768,73	257,71	102,88
181	M	Gastrointestinal obstruction without cc.	1.792,62	223,11	100
569	C	Major surgery on small and large intestines with CC with Major GI diagnosis	11476,81	2235,43	282,64
570	C	Major surgery on small and large intestines with CC without Major GI diagnosis	9283,48	1808,22	228,62

TABLE II - *Main hospitalization-days and costs.*

	Average HD	Average €
pz c	12,4166667	€ 10.625,64
pz e	8,33333333	€ 7.458,45
Int Pall C	13,4444444	€ 10.547,73
Int Pall E	8.05	€ 7.093,45
Int radicali c	11.8	€ 10.672,39
BTS	9.75	€ 9.283,48

TABLE III - *Comparison between the averages of costs in endoscopic and surgical groups.*

TEST F	€ 2,4979E-05	No dissimilar variances
TEST T 1 CODA	€ 6,1891E-08	
TEST T 2 CODE	€ 1,2378E-07	

The average of costs of decompressive stenting is significantly <= compared to that of surgical procedures.
* p-value: 0.005

TABLE IV - *Percentage of radical and palliative procedures in endoscopic and surgical groups*

Surgical Treatment	%	Endoscopic Treatment %
Radical Treatment	75	17
Palliative Treatment	25	83

TABLE V - *Comparison between the averages of costs of palliative procedures in endoscopic and surgical groups*

TEST F €	5,9349E-06	no dissimilar variances
TEST T 1 C	5,9104E-07	
TEST T 2 C	1,1821E-06	

The average of costs of palliative stenting is significantly <= compared to palliative surgical procedure
*p-value: 0.005

TABLE VI - *Comparison between the averages of costs of radical procedures in endoscopic and surgical groups*

TEST F €	5,5173E-105	no dissimilar variances
TEST T 1 CODA €	6,58641E-06	
TEST T 2 CODE €	1,31728E-05	

The average of costs the BTS Is significantly <= compared to radical surgical procedure.
* p-value: 0.005

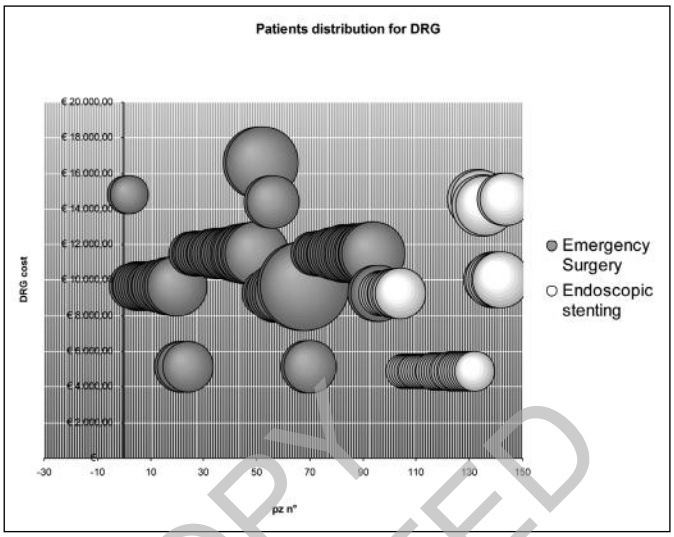

Fig. 1: Patient distribution for DRG and hospedalization days.

*The diameter of balls is directly proportional to the days of hospitalization.

is significantly more sustainable from the point of view of cost-effective compared to emergency surgical treatment (Table III).
We should make an self-criticism to our analysis, in fact stenting decompressive has been mainly used for palliation, unlike surgical treatment was radical in 75% of cases (Table IV). it is obvious that, since the palliative treatment is less expensive than those radicals, the cost of stenting is lower than that of surgical treatment. For this reason we compared before decompressive stenting with the packaging of palliative colostomy, and then stenting as a "bridge to surgery" with radical surgical treatment. in both cases, the data confirm that the decompressive stenting procedures considering them as palliative techniques and as bridge to surgery are less expensive than the corresponding surgical techniques (Tables V and VI).
Two bubble charts (Fig. 1) synthesize what we have said up to now, each bubble represents a patient, his position on the y axis indicates the cost of the DRG assigned to the benefits received from the same, while the volume of the bubble refers to days of hospitalization. The economic benefit of decompressive stenting both as palliative treatment and as bridge-to-surgery is even more enhanced when we consider that some of the patients treated with surgery may require packaging of a temporary or permanent stoma whose cost is estimated about € 180.00 per week [22].

Conclusions

The percentage of success of the endoscopic technique is approximated to that of classical surgery (99.8%), and

the risk of early complications is even greater in patients receiving emergency surgery compared to those subjected to stenting, in which, on the contraryt, late complications are more frequent. However, the risk of serious complication, in the whole, is so similar between the two techniques, that as not allow from the latter point of view, the identification of a procedure that, for greater security, can assume the role of therapeutic standard [23]. With regard to the cost aspect, it is evident the advantage of using a cost-effective method. It is therefore necessary to conclude that stenting decompressive, both for palliation, and as bridge-to-surgery, should be fully included in the routine treatment in highly specialized centers, where multidisciplinary teams can select ad hoc cases that would benefit most of the method, complete in every detail the diagnosis of cause and program when and how best to intervene, thus ensuring maximum efficiency and radicalism. It remains that the technique is complex and requires a medical and nursing qualified team, able to solve even the most complex situations, such as particularly severe, irregular stenosis, or very distant from the anus (as in the case of the right colon). Despite these maneuvers are associated with a technical and clinical success rate generally very high, much attention should be given to the problem of limited complications, and this should lead to a further improvement of the technique. Moreover including decompressive stenting in routine does not mean applying it indiscriminately but in view of a medicine tailored to the individual patient. The clinical picture should direct us to the most appropriate therapy. As evidenced by the Consensus Conference in Bologna [24]. Therefore, patients with stenosing carcinoma set cranially than the middle rectum T1-T3, Nx, Mx, will be reasonably indicated to bridge to surgery stenting in order to decompress the colon and to stage the disease better. On the contrary patients with cancer in the same locations, but to stage T4 require a simple endoscopic palliation. Unfortunately, for reasons related to the length of the stent, the middle and lower rectum are not suitable to these types of treatments.

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