

# Metal prosthesis for palliation of advanced colon cancer

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## Abstract

The colonic stent placement is a new tool reaching two intends: creating a bridge to prepare the patient safely to the surgical procedure and/or definite palliation in those cases in which the clinical condition is not feasible. The cost-benefit analysis push advantages to the endoscopic assess with new models of stents, however another endpoints should be raised such as Hospital structure, trained nurses, follow up and cost effectiveness conditions according to the regional policy. In this context, a multidisciplinary approach and Institutional review board approval should be stated in all cases. Obviously, short and long term results solidified by a follow up could be designing prospective studies.

## Key words

Palliation, colonic cancer, metal stent.

## INTRODUCTION

The first reported use of a colorectal stent for treatment of malignant stenosis was published by Dohmoto et al. in 1991 (1). Thanks to prior experience in the use of stent for palliation of malignant esophageal disease, the technique began to rapidly spread throughout the international medical community. Soon after, the first publications including small series of patients reported encouraging results in terms of the technical and clinical success of the procedure including low rates of complications (2, 3). Undoubtedly, the high morbidity and mortality rates of emergency surgery for patients with obstructions caused by neoplastic diseases in the early 1990's (4) made the new non-surgical therapy with lower mortality rates an alternative of great interest. Thus, in the second half of the 1990's, indications for stent placement in patients with acute neoplastic colon obstruction had become fully established (5). Two possible scenarios were considered: as a procedure prior to surgical resection of the lesion, and as a method for final mitigation.

These same scenarios are still in use today. In the late 1990's the first publications about the use of these stent to treat benign stenosis and fistulas without stenosis also began to appear (6-8). These less common indications are reserved for specific situations, as discussed below, although they are still in full force.

The endoscopic equipment manufacturing companies have been on top of this situation, and over the years have developed and marketed stent specifically designed for this location. The colon's own anfractuosity, especially that of the sigma, requires increasingly flexible and atraumatic stent delivered by a system that can progress along the working channel of the colonoscope to reach proximal stenosis easily. Both of these particularities have been taken into account by the industry. Today there is a wide range of stent available for colorectal use, to which we shall refer as this article proceeds. The use of each of these stents is more or less restricted depending on the laws of each particular country.

As with any therapeutic endoscopic procedure, colorectal stent placement is not free of complications. In recent

years publications have appeared (9) which place particular emphasis on these circumstances. The possibility of complications in patients who have undergone stent placement has increased because the probability that patients will survive has increased as a consequence of better cancer treatment and the use of more aggressive treatments (10). This fact, together with the publication of research showing that palliative tumor resection in patients with stage IV colorectal cancer is associated with improved survival (11, 12), has led to a renewed debate about how to re-evaluate and clarify the explanations, directions and intent of stent placement in these patients.

In this article we review the types of colorectal stents currently available, placement techniques, indications for malignant and benign diseases, technical and clinical results and the incidence of complications associated with the procedure.

## TYPES OF STENT

Today there is a great variety of stents made by different producers of endoscopic materials on the market. The availability of one or the other varies in each country according to that country's law and business relationships, so it seems appropriate to ignore brand names and make some general observations on these stents.

Most colorectal stents available today are self-expandable nickel and titanium (nitinol) grid stents. Other metals can be added to the alloy to give stents greater visibility and radial strength. Steel stents, used until recently, have fallen into disuse. Stents can be uncovered, partially covered, or completely covered by a silicone outer coating. These stents' morphology is funnel shaped, with the proximal end or both ends of greater diameter than the main body of the stent. The diameters and lengths of these stents vary according to each company's business models. In general, diameters range between 20 mm and 25 mm and lengths range between 4 cm and 14 cm.

These stents are mounted on catheter stent carriers and held in place by a thread or, more commonly, by a plastic outer sheath. This catheter carrier and the plastic sheath usually carry radiopaque markings indicating the location of the ends of the stent and, in some models, the point from which you can not correct the release of the stent, information that is useful in the placement process. The release of the stent is performed by either pulling the thread or by proximal displacement of the plastic sheath. In the latter case, some systems can deliver up to 70% of the stent while maintaining the possibility of fully resleeving it if deemed necessary for repositioning of the stent.

The entire delivery system consists of the carrier catheter, the stent and a folded clamping mechanism. The caliber of

systems varies between 10 French and 30 French. Small stents have a good number of uncovered gaps, while large stents may be covered or uncovered. The length of the delivery system varies between 40 cm and 230 cm. These differences are important. If the system length is 230 cm, and its caliber is 10F, it is possible to advance the delivery system of the stent through the working channel of a colonoscope (known colloquially as "through the scope" or "TTS"). This greatly facilitates the procedure, especially for proximal lesions. Whatever the delivery system's dimensions, it will have a central internal light that allows passage of a 0035 guide wire.

Recently self-expandable stents made of biodegradable material have become available. These stents are made of polydioxanone, and, although they have not been specifically designed for the colon, they may be indicated for benign pathologies. Double funnel stents are 25 mm in diameter at their midpoints and 31 mm in diameter at the ends. Available lengths include length of 60 mm, 80mm, 90mm, 110mm and 135 mm. Because of their physical characteristics, these stents should be loaded in the delivery system just moments prior to placement. The delivery system's caliber is 28 F and its length is 75 centimeters. Currently, covered and uncovered stents are both available.

## FITTING TECHNIQUE

Preparation of the patients prior to the procedure is important. Poor preparation can lead to failure of technique or, at best, a longer scan, leading to unnecessary hyperinflation of the colon that can be very dangerous for a patient with an obstruction and a pre-stenotic, dilated colon. In the case of patients with complete or almost complete obstruction of the colon, oral preparation does not seem advisable. These patients should be prepared with the use of cleansing enemas (13). Depending on the location of the stenosis to be treated, more or fewer enemas and more or less volume will be required.

There is no common approach to the use of prophylactic antibiotics. Some authors recommend it for completely blocked patients because of the risk of symptomatic bacteremia after the procedure (5).

Sedation of these patients is another important aspect (14). If the location of the stenosis is very low, in the rectum or distal sigmoid colon, theoretically the procedure should not be particularly uncomfortable for the patient. However, it is just as true that one cannot foresee the duration of exploration as it is influenced by the degree of difficulty of opening a path to the lesion with a guide. Consequently, our practice is to routinely perform deep sedation with propofol for all patients except those with tracheal intubation.

With the patient well sedated and prepared, the first step of the technique is to reach the stenosis with the colonoscope. Prior to any manipulation, the remaining colonic lumen must be identified. This detail must be taken into account because in most cases the obstruction is such that the diameter of the orifice is minimal. If the delivery system of the stent to be implanted requires that it move through the working channel of the endoscope, a large channel therapeutic colonoscope should be used. In other cases any type of scope may be used.

Once the stenosis has been reached, it is advisable to introduce contrast under fluoroscopic control in order to make an estimate of the morphology and length of the stenosis (15). If the patient has had an enema prior to the procedure, something which is becoming less common, this maneuver should not be necessary.

The next step, passing a guide through the stenosis to be treated, is without doubt the most difficult and important. In the vast majority of cases it determines the success or failure of the procedure. The choice of guide is relevant. A 0.035 French guide with an atraumatic tip and rigid consistency that can support further progression of the stent delivery system should be used. If the lesion can be found without difficulty, it is usually not necessary to use any accessory catheter to advance the guide. However, it may be helpful to use a rotary sphincterotome to orient the direction of the guide for lesions of in the sigma or in very anfractuous stenoses (16). When the guide cannot be passed through rectal or sigma lesions with conventional maneuvers, it may be helpful to use an ultrathin endoscope followed by conventional or therapeutic colonoscope. Never attempt to force or push the guide to make it progress because this increases the risk of causing a perforation. This is more an exercise in patience and the ability to reposition the guide by pressing it lightly and guiding its progression through the residual lumen. Once the atraumatic tip of the guide has passed the stenosis, the guide should be kept as straight as possible and advanced far enough into the colonic lumen to arrive near the stenosis.

At this point there is a controversial issue: whether or not it is desirable to dilate the stenosis. It is our view that it should not be dilated for two reasons. First, in our experience dilation provides few benefits. It is absolutely exceptional, once the guide is positioned, that the delivery system cannot place the stent even in cases of complete obstruction. Also, once the stent is released, the radial force of it is enough to reach its full expansion. Thus, it seems unnecessary to have to dilate the stenosis for procedure to be a success. Second, that there is added risk involved in expansion is widely attested to in the literature which documents increased incidences of complications, especially perforations and subsequent stent migration (17).

After positioning the guide, the next step depends on the type of stent to be implanted. If a high caliber stent delivery system which is not advanced through the working channel of the endoscope is being used, the colonoscope is withdrawn leaving the guide in position for a later return. Upon return, the guide will be reintroduced, and, once the stenosis has been reached, introduction of the stent release system along the guide and parallel to the colonoscope will proceed. If a "through the scope" delivery system is used, the colonoscope will remain in place and the system will advance on the guide inside the working channel of the colonoscope.

The choice of the stent to be implanted depends on the type and length of the lesion. Stent length should be chosen to allow a margin of 2 to 3 cm on both sides of the stenosis. Except under very specific circumstances, the stents used today are those that can be positioned through the working channel of the endoscope.

The stent delivery system should be advanced through the stenosis under fluoroscopic control with the guide wire taut. When using TTS systems, the tip of the colonoscope should be as close as possible to the distal margin of the stenosis in order to provide support for the delivery system and avoid angling or buckling. With the help of the radiopaque markings on the carrier catheter, the stent should be centered in the stenosis in order to reduce the risk of subsequent migration.

The stent must be carefully released, if possible under fluoroscopic control. Release requires participation of a second person, usually the assisting nurse, who either performs the release or holds the endoscope. As with any other type of self-expandable stent, the carrier catheter must be held tightly immobile while the stent is released either by pulling the string or by removing the coating. At the beginning of the release, special attention should be paid to the end of the stent that is above the stenosis to make sure that has completely expanded. If it has not, it may be because the stent is too short (presumably an exceptional situation), or that is located too far from the center of the stenosis. In this case, it may be useful to begin the release with the stent slightly off center on the proximal side of the stenosis, so that once it has completely expanded, it can be relocated into the center of the stenosis. The rest of the stent should be slowly released, checking at all times that the position is correct.

Once the stent is released, a few seconds should be allowed to pass to permit the minimum necessary expansion of the central part of the stent needed for removal of the stent delivery system. After that it should be possible to remove it without any friction. In our point of view, the stent should not be dilated in order to accelerate its expansion, nor to advance the progress of the colonoscope,

because both maneuvers only lead to increases in the incidence of complications.

## INDICATIONS

The two primary indications for colorectal stents are large bowel obstructions caused by the presence of stenosing malignant neoplasms, and as a temporary measure to allow decompression prior to surgery or definitive treatment. Another much less common indication is a malignant fistula, with or without stenosis, between the rectum, colon and neighboring anatomical structures. Third in importance are certain benign conditions such as postoperative stenoses, acute inflammatory processes, fistulas or iatrogenic perforations secondary to surgery or endoscopy, and diseases in which stents are temporarily placed.

Whatever the pathology which indicates the need for stenting, the procedure is contraindicated when there is suspicion of diffuse peritonitis caused by colorectal perforation, the lesion itself, or by distention of the colon over the stenosis (5). Other conditions which may contraindicate stenting include inflammatory plastrons, local abscesses due to hidden perforation, the existence of more than one stenosis at different levels of the intestine, severe bleeding, and anticoagulation therapy which has not been reversed (18). Rectal tumors deserve special consideration. In these cases stenting is not advisable in the lower third of the rectum when the distance between the distal margin of the lesion and the inner boundary of the anal canal is less than 5 cm. The reason is that it has been shown that in this location the stent causes such pain, urgency and incontinence, that these conditions eclipse any intended improvements in the quality of patients' lives that might otherwise be gained by avoiding a temporary colostomy (19). Another controversial issue is whether or not it is advisable to use stents for rectal tumors that will be treated with chemotherapy and radiotherapy. While some published work does not find higher rates of complications in these cases, our experience is the opposite. We have witnessed that the combination of stenting and neoadjuvant therapy is associated with increased incidence of micro-perforations which complicate and darken the results of elective resections (20).

### 1. Malignant stenoses

Until the appearance of colorectal stents, acute neoplastic colon obstructions were treated surgically. However, urgent surgical treatment of these patients was shadowed by high morbidity and mortality rates, and permanent colostomies came to be routinely performed on up to 40% of these patients (21). These patients' situations are generally very unfavorable, not only because of the underlying tumors,

but also because of dehydration and electrolyte imbalances that make them high-risks for undergoing surgery. In addition, the colon wall is usually friable because it has been distended by the obstruction. All of these factors cause the rate of complications to skyrocket (5). An early study showed that, while morbidity rates for emergency surgery were around 39%, and mortality rates for emergency surgery were 12%, they descended to 23% and 3.5% respectively for elective surgery (4). Despite advances in surgical techniques, a recent publication shows that differences in morbidity rates between emergency surgery and elective surgery continue to be very big with a reported morbidity rate for emergency surgery of 31.4%, but a reported rate for elective surgery of only 5.9% (22).

Stent implantation in these patients aims to resolve occlusions without need for emergency surgery. When this is done, the extent of neoplastic disease can be properly assessed at a later date, and the patient can be properly prepared for possible elective surgery in terms of cleansing of the colon and performance of a complete colonoscopy to rule out synchronous lesions. In addition, cost analysis shows that the insertion of a colonic stent followed by elective surgery is more effective and less costly than emergency surgery (23).

Placement of stents as a method of definitive palliation is currently a controversial topic. Given advances in surgical technique and cancer treatment for these patients, metastases do not necessarily rule out surgical treatment. Each patient must be assessed individually to analyze the extent and location of metastasis and to determine if any comorbidity is present. In patients with reasonable life expectancies, stenting should be seriously considered as a bridge to surgery rather than as a final treatment (24). Also, for patients who are not candidates for surgery and who have no clinical occlusion, prophylactic placement of stents is not indicated since we cannot forget that this technique has complications.

### 2. Neoplastic fistulas

A second indication for placement of a colorectal stent is the existence of a malignant enterocolonic fistula, colovesical fistula or colovaginal fistula. These can present with or without associated stenosis and may be produced either by a primary colorectal tumor or by an extracolonic neoplasia (7, 8, 25). The intent of the procedure is palliative and is generally definitive. Patients who are usually treated have very advanced neoplastic disease.

### 3. Benign pathologies

Experience with colorectal stenting for benign stenosis is still limited, but some retrospective and prospective stu-

dies have been published and are available in the literature (26, 27). Stenting for benign stenosis may be subsidiary to treatment for postoperative stenosis after anastomosis, after radiotherapy, in the context of fibrotic response to Crohn's disease, and for acute diverticular inflammatory processes (although the last is more controversial). While immediate results in terms of resolution of occlusions are good, very frequently complications arise in the short and medium term. These frequently require additional surgery the medium to long term. For this reason it seems advisable that this indication should be a bridge to elective surgery as soon as the patient's condition permits.

Small studies have been published showing good results for the use of stents to treat perforations or iatrogenic fistulas postoperatively or after endoscopic procedures. In these cases stenting should be done as early as possible, and should be temporary (28).

## RESULTS

The numerous published studies (especially those about the treatment of malignant neoplasia located in the left colon) report different rates of technical and clinical success. Nevertheless both concepts, technical and clinical success, are commonly used in most of these studies. Technical success is defined as the correct positioning and release of the stent at the level of the lesion. The definition of clinical success varies more in terms of the condition to be treated and in terms of study design. For malignant and benign neoplasms, most studies define clinical success as the resolution of obstructive symptoms within the 72 hours following stent implantation. In the cases of fistulas and perforations, clinical success has been defined as formation of a mechanical seal.

A meta-analysis of stenting in cases of malignant obstructions by Watt et al. (21) showed a technical success rate of 96% and a clinical success rate of 92%. While previous studies have reported worse outcomes in patients stented as a bridge to surgery (29), this analysis did not differentiate according to the description of the procedure. The main cause of technical failure is impossibility to advance the guide through the stenosis, while the most important cause of clinical failure is the incidence of early complications. A recent randomized study (30) showed no differences in the rates of clinical success between covered and uncovered stents, although covered stents have a greater tendency to migrate.

The results of stenting in cases of malignant fistulas are difficult to assess. While it is true that isolated cases with good results have been reported (7, 8, 25), there are no series in the literature which provide more reliable conclusions.

The results of recently published series about treating benign stenoses with stents are encouraging. The technical success rate was 100% and the clinical success rate was 76% in a retrospective study published by Keränen et al. (31) which included 21 patients with benign stenosis. The worst results were found in cases of stenosis secondary to acute diverticulitis. A prospective study by Small et al. (32) of 23 patients reported technical success a rate of 100% and a clinical success a rate of 95%. Both studies report high rates of complications: 43% in the Keränen study, and 38% in the Small study. Most complications were associated with acute diverticulitis and occurred after the seventh day following the procedure. This suggests that stent implantation should be temporary in order to prepare the patient for early surgery. Other authors have even come to question whether stenting is indicated for stenosis secondary to diverticular acute inflammatory processes because of the already mentioned high rates of complications (27).

Finally, there have been isolated cases of iatrogenic perforations and postoperative fistula which have been successfully treated by temporary placement of covered stents. A recently published series which included two patients with endoscopic perforations and three patients with postoperative fistulas, technical and clinical success rates were both 100% after stents had been in place an average of 5 weeks (28). For these patients, the use of biodegradable covered stents may be of great interest.

## COMPLICATIONS

Colorectal stent implantation is a technique that is not free of complications which can occur during the procedure itself, either locally or remotely, or which can be delayed and related to the stent rather than to the procedure.

In a recent publication, the Mayo Clinic group (17) analyzed factors related to patients, techniques and therapeutic management of patients after stent placement that may influence the onset of complications. Being male, having a complete obstruction and having a distal location of the tumor in the colon were considered to be risk factors, as were inexperienced endoscopists, use of small caliber stents, use of steel stents, and dilation of the stenosis prior to stenting. Also, chemotherapy with antiangiogenic agents such as bevacizumab appears to be an unfavorable factor.

Perforation, without a doubt, is the most serious of the major complications associated with this procedure. Other major complications include migration and obstruction of the stent. Other complications include bleeding, abdominal pain, rectal tenesmus, stent breakage and incomplete expansion of the stent.

Although perforation is often associated with mortality, asymptomatic microperforations without clinical consequences (usually discovered during elective surgery after the implantation of a stent) have also been reported (20). The average incidence of perforations is estimated to be about 5% (33). A perforation may occur in connection with the procedure, because of local handling of the guide wire or the stent, or stent in proximal segments of the colon because of hyperinflation. It may also appear at a late stage as the result of the mechanical effect of the stent on the wall of the colon. Dilation of a stenosis associated with a tumor triples the risk of early perforation (17). Similarly, the use of antiangiogenic chemotherapy significantly increases the risk of perforation. This is probably because it weakens the colon wall. This might explain the high incidence of perforations presented by some publications (34). In our experience (20), neoadjuvant radiotherapy for rectal cancer also increases the risk of perforation.

Migration of the stent may occur at the moment it is placed, but this is almost always due to errors during implementation, or, more usually, when the stent is released either early or late. It has been reported that most stent migrations occur on or after the fourth day following placement (35). Migration occurs because the stenosis does not retain the stent with sufficient force and/or because of predisposing factors existing prior to dilation of the stenosis. These factors include the use of small caliber stents, covered stents and the of administration cancer treatment (17). Stent migration is not related to whether the stenosis is benign or malignant, or to its location. Obviously, the risk for stent migration is greatest when there is no stenosis as in the cases of treatment of fistulas and perforations. The median incidence of this complication is 11% (21).

Tumor growth through the mesh or at the ends of the stent is the main cause of stent obstruction. Other documented causes include fecal impaction, mucosal prolapse and obstruction by peritoneal implants (5, 17). The length of time after stent placement is the most decisive factor influencing stent obstruction. Chances of a stent becoming obstructed by tumor growth increase as times passes after placement. To date, it has not been clearly demonstrated that covered stents significantly reduce the incidence of stent obstruction (30). Patients who have had stents implanted have great variations in the rate of occurrence of stent obstructions. The median incidence rate is 12% (21).

If bleeding occurs after stent insertion, it occurs soon after placement, but is not usually clinically significant. Most often it is due to manipulation of the tumor which usually presents a certain degree of friability. A multicenter

study in Spain (36) reported an incidence of 0.6% for this complication.

Abdominal pain usually occurs in relation to gas insufflation during the procedure and may continue for several days following the procedure. It is usually mild and easily controlled with the usual analgesics.

Rectal syndrome, with tenesmus, painful bowel movements and incontinence occasionally appears in rectal cancer when the distal end of the stent is near the anal canal. Its incidence is around 2.5% (36). It appears soon after the stent is placed and is sometimes difficult to differentiate from the symptoms induced by the tumor. On occasion it can be very disabling and may require the removal of the stent.

Other less frequent complications include stent ruptures in patients who have had stents for long periods of time (37) and incomplete expansion of stents. This usually occurs as the result of poor choice of stent length or poor stent release technique (not properly centered on the lesion). In our experience, this complication is not as exceptional in colonic stenoses which occur in the context of a frozen pelvis caused by endometriosis.

## FINAL CONSIDERATIONS

Currently, the placement of a self-expanding metallic stent should be considered as the choice treatment alternative for a patient with acute neoplastic obstruction of the left colon. Rectal and right colon tumors should be assessed individually on a case by case basis, as urgent surgery continues to occupy an important place in their treatment. For most of these patients, stenting should be the first step in preparation for subsequent curative or palliative elective surgery. Only for those patients whose life expectancies are short, either because of neoplastic disease or comorbidity, should stenting be considered as definitive palliation.

Strict use of proper technique, avoidance of unnecessary maneuvers such as dilation of the stenosis before and after placement of the stent, and proper choice of the stent to be implanted, can all contribute to very high rates of technical and clinical success of these procedures and minimization of minimize complications. For this reason, uncovered stents which use TTS delivery systems should be considered as first options, while covered stents should be reserved for treatment of fistulas and perforations.

In cases of benign pathology, implantation of a stent should be temporary. In most cases it should be a bridge to surgery. When the intention is to achieve closure of an iatrogenic perforation or fistula, treatment may be definitive, but the stent must always be removed by the established time.

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