CLINICAL STUDY

Ten-year Retrospective Study of Treatment of Malignant Colonic Obstructions with Self-expandable Stents

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ABSTRACT

Purpose: To describe the use of self-expandable metallic stents to manage malignant colorectal obstructions and to compare the radiation dose between fluoroscopic guidance of stent placement and combined endoscopic and fluoroscopic guidance.

Materials and Methods: From January 1998 to December 2007, 467 oncology patients undergoing colorectal stent placement in a single center were included in the study. Informed consent was obtained in all cases. All procedures were performed with fluoroscopic or combined fluoroscopic and endoscopic guidance. Inclusion criteria were total or partial colorectal obstruction of neoplastic origin. Exclusion criteria were life expectancy shorter than 1 month, suspicion of perforation, and/or severe colonic neoplastic bleeding. Procedure time and radiation dose were recorded, and technical and clinical success were evaluated. Follow-up was performed by clinical examination and simple abdominal radiographs at 1 day and at 1, 3, 6, and 12 months.

Results: Of 467 procedures, technical success was achieved in 432 (92.5%). Thirty-five treatments (7.5%) were technical failures, and the patients were advised to undergo surgery. Significant differences in radiation dose and clinical success were found between the fluoroscopy and combined-technique groups ($P < .001$). Total decompression was achieved in 372 cases, 29 patients showed remarkable improvement, 11 showed slight improvement, and 20 showed clinical failure. Complications were recorded in 89 patients (19%); the most significant were perforation (2.3%) and stent migration (6.9%). Mean interventional time and radiation dose were 67 minutes and 3,378 dGy·cm^2, respectively.

Conclusions: Treatment of colonic obstruction with stents requires a long time in the interventional room and considerable radiation dose. Nevertheless, the clinical benefits and improvement in quality of life justify the radiation risk.

Colorectal cancer is an important public health concern: there are nearly one million new cases of colorectal cancer diagnosed worldwide and 500,000 deaths each year (1). Between 10% and 30% of diagnosed patients have complete or partial obstruction of the colon at the time of presentation (2). Prostate, bladder, ovarian, and endometrial cancers may also present with obstructive symptoms secondary to extrinsic luminal compression or infiltrative invasion (3).

Traditionally, surgery has been used to treat intestinal obstruction resulting from colon cancer (4), but emergency surgery in a patient with an unprepared colon is associated with high morbidity and mortality rates (5). If it is feasible, emergency surgery in the form of a Hartmann procedure or subtotal or segmental colonic resection with primary anastomosis are the best options (6), but, in practice, only 40% of left-sided colonic obstructions secondary to carcinoma undergo primary anastomosis (7). The majority of these patients need a stoma to prevent anastomotic leaks and resultant sepsis, with a remarkable negative impact on their quality of life (8,9). Although restoration of continuity can be considered at a later date, only 60% of these stomas are later reversed (2).

Patients with colon cancer who present with colonic obstruction have a 5-year survival rate of less than 20%, a far

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poorer prognosis than patients who present without obstruction (10). Additionally, mortality rates decrease from 15%–20% to 0.9%–6% in cases of elective surgery (11).

Metallic stent placement is an adequate alternative to emergency surgery, and it can provide effective nonsurgical decompression of the obstructed left colon, avoiding emergency colostomy (12). Other nonsurgical treatments such as balloon dilation, endoscopic laser ablation, and use of decompression tubes have been used, with limited effectiveness (13).

The present retrospective study evaluates the most recent 10 years of the 18-year total experience with colonic stent placement at a single center in patients with malignant colonic obstruction that required palliation or a "bridge" to surgery. As a secondary objective, we also wanted to compare the radiation dose between fluoroscopically guided stent placement and combined endoscopically and fluoroscopically guided stent placement.

MATERIALS AND METHODS

Patients

The data for this study were compiled at a single center in Spain between January 1998 and December 2007. Eligibility was predicated on the presence of total or partial large-bowel (rectum, rectosigmoid junction, sigmoid, descendent, transverse colon, and hepatic flexure) obstruction secondary to malignancy. Exclusion criteria were terminal condition (life expectancy $<$ 1 mo), American Society of Anesthesiologists classification greater than 4 (14), suspected perforated colon, and severe colonic neoplastic bleeding.

Acute colonic obstruction was diagnosed based on the classical clinical and imaging findings (abdominal distension and/or nausea and vomiting without normal emission of stool or air). A complete obstruction was defined when the patient was unable to pass stool or air. When a small amount of air could be expelled, or if there was pseudodiarrhea, the obstruction was considered to be partial. Neoplastic origin was confirmed in all cases by biopsy before or after the interventional procedure. Stent implantation was considered to be an emergency procedure when the patient showed abdominal distension, nausea, vomiting, and cecal distension greater than 10 cm on radiography, and the stent was placed within 12 hours after the request. Other cases were not considered to be emergencies.

The assignment of patients to undergo palliative treatment versus surgery was based on unacceptable surgical risk in view of advanced age or comorbidities, and on the presence of locally advanced or distant metastases. Survival time regarding to chemotherapy treatment and stent type was also recorded. In all cases, informed consent and patient agreement were obtained before the intervention was performed.

Stent Placement

All procedures were performed in the interventional room with fluoroscopic guidance alone or combined with endoscopic guidance. The colorectal stent placement technique used was described by our group in 1998 (15) (**Fig 1**). Endoscopic guidance was always available, and was used in cases predicted to be difficult to resolve based on location of the lesion. Interventional radiologists were trained to perform diagnostic endoscopic procedures. The stents were not deployed through the endoscope, and insufflation was not routinely used. (**Fig 2**).

None of the patients required preparation before the intervention or preoperative prophylactic antibiotic therapy. Anesthesia was not routinely used, but if the patient was uncooperative, conscious sedation and analgesia was administered.

Two types of stents were implanted: Wallstents (Boston Scientific, Galway, Ireland) 16–25 mm in diameter and 50–90 mm long and SX-ELLA intestinal stents (Ella, Prague, Czech Republic) 22–30 mm in diameter and 82–112 mm long. The most appropriate size was selected after contrast-enhanced fluoroscopy of the stenotic area was performed. This was not a randomized study, and patients were not specifically selected to receive either stent type.

Outcomes

Technical success was defined as accurate stent deployment across the stricture as well as at least 2.5 cm of normal colon proximal and distal to the lesion. Clinical success was defined as radiologically and clinically measurable improvement of the colonic obstruction and improvement of obstructive symptoms. Clinical success was evaluated by the operator and the patient (immediately, 24 h, and 48 h after the procedure) and was stratified into three degrees: complete success, notable improvement, and slight improvement. Complete obstruction resolution was considered when all the air and stool retained was expelled, the abdominal distension disappeared, and there was a normalization of the abdominal air pattern on the 24-hour radiograph. Notable improvement was considered when a high quantity of air and stool was expelled but there was still some abdominal distension, and air on the 24-hour and 48-hour radiographs was normal without any treatment. Slight improvement was considered when cleaning enemas were necessary to normalize the abdominal distension and air pattern on the 48-hour radiograph. Stent patency was defined as an absence of clinical symptoms and radiologic findings of intestinal obstruction.

For all procedures, total intervention time and radiation dose were recorded. Radiation doses were measured in two ways because two different x-ray equipment setups were used. The Allura Xper FD20 system (Philips Healthcare, Best, The Netherlands) measured the dose–area product directly, whereas the Integris 3000 system (Philips) measured it indirectly (based on kV, mA, and opening of the collimator). Total intervention time was measured from the first fluoroscopic image obtained to the last one (including periods of time with and without radiation). Intra- and postprocedural complications were recorded and classified according to Society of Interventional Radiology standards (16).

Patients were followed up with clinical examinations and abdominal plain radiographs at 1 day and at 1, 3, 6, and 12 months. In the palliative treatment group, two subgroups were created—those who did and did not receive chemo-

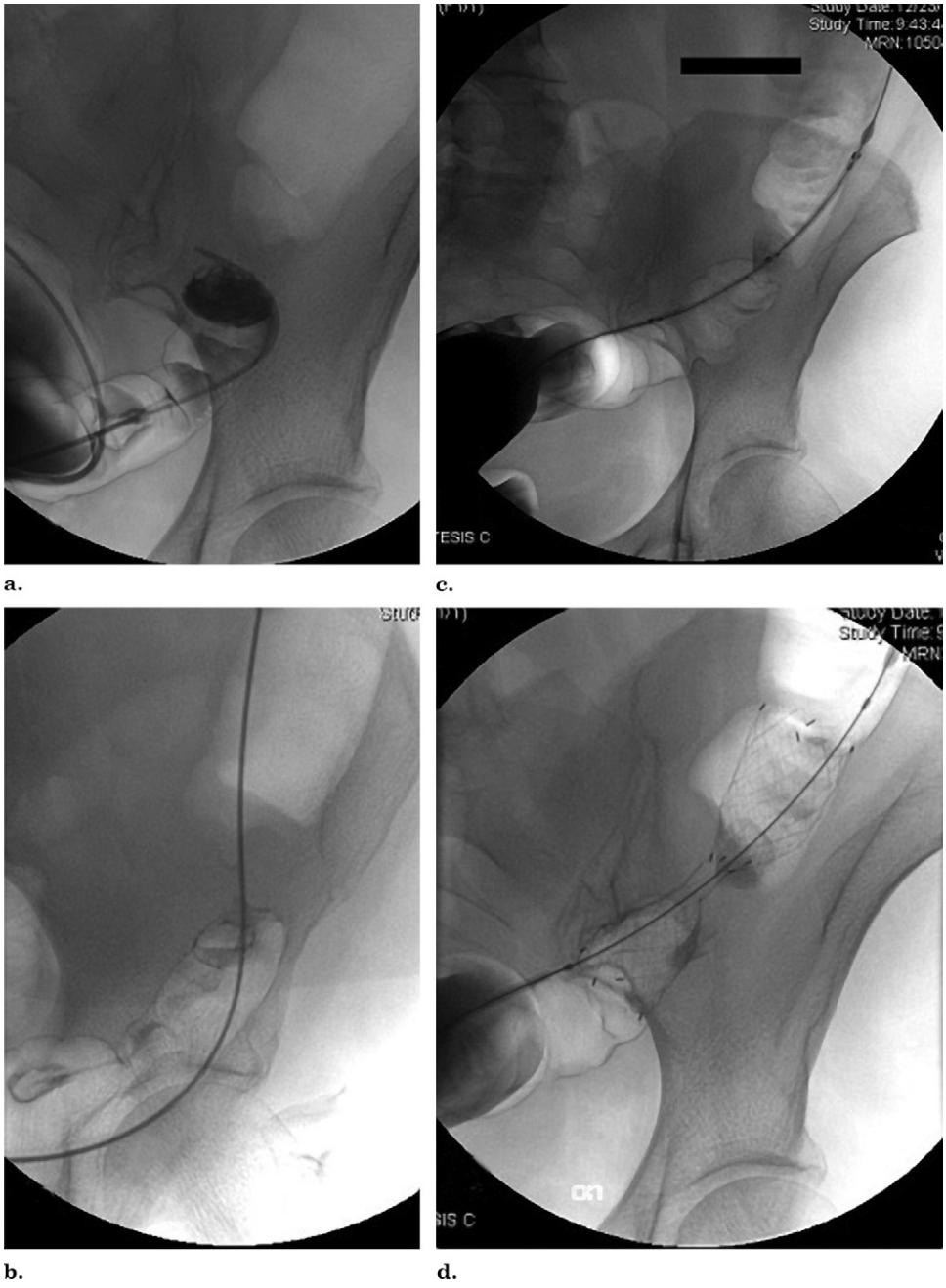


Figure 1. Conventional fluoroscopic technique with contrast medium in anterior projection shows tumor in left descending colon. **(a)** A catheter and guide wire are used to approach to the lesion, **(b)** the catheter is placed across the stricture, **(c)** the stent delivery system is placed across the lesion, and **(d)** the stent is opened completely.

therapy—according to the decision of the cancer committee of the hospital. The aim of this treatment was to "rescue" these patients for elective surgery.

Statistical Analysis

Statistical analysis was performed with SPSS software 15 (SPSS, Chicago, Illinois). An α error of 0.05 and a power of 90% was established for the statistical analysis. A χ^2 test was applied to compare qualitative variables, a Student *t* test was used to compare time of procedure, a Mann–Whitney test was used to compare length of stay (in d), and survival time among groups was compared with Kaplan–Meier survival analysis and log-rank comparisons.

RESULTS

During the 10-year study period, 467 patients underwent colorectal stent placement for large bowel obstruction secondary to malignancy. The median age of the patients was 68.9 years ± 9.5 (range, 38–96 y). Other patient data are summarized in **Table 1**.

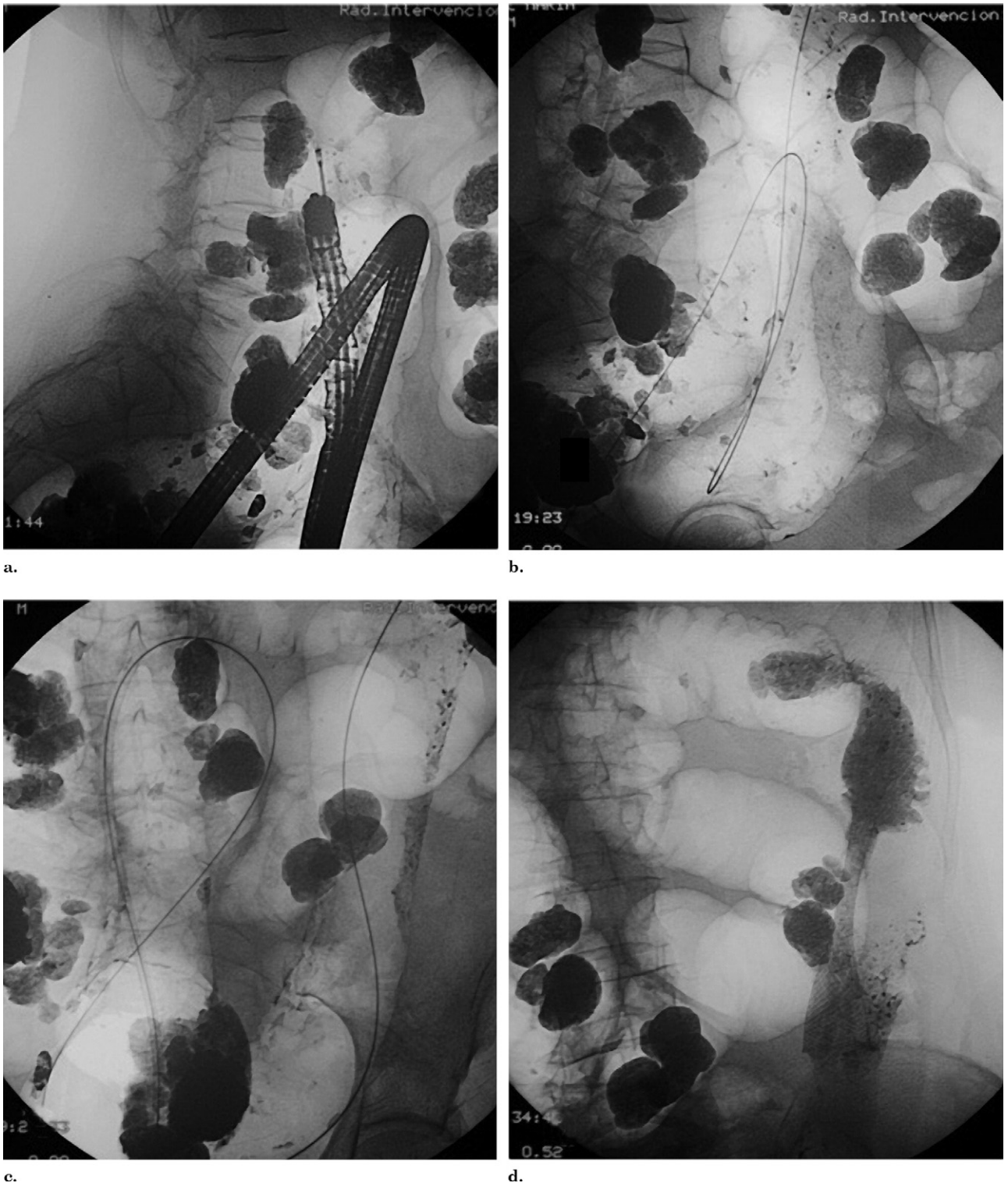


Figure 2. Images of a difficult case treated with combined radiologic and endoscopic guidance. **(a)** Endoscopy is performed across the stricture, in the descendent colon, with help of biopsy forceps. **(b)** Several guide wire and catheter loops are seen in the descendent colon. **(c)** Panoramic view of the loops needed to reach the lesion. **(d)** The stent is deployed in the stricture area.

Technical Success

Of the 467 attempts at implantation, 432 (92.5%) were successful. The other 35 (7.5%) attempts were considered technical failures because the stent could not be deployed or was incorrectly positioned; six of these attempts were considered to be for palliative indications and 29 were considered to be surgical bridge treatments. The main causes of technical failure were inability to get

Table 1. Patient Data on Colorectal Stent Placement for Neoplastic Large Bowel Obstruction (N = 467)

Characteristic	Incidence
Sex	
Male	289 (61.9)
Female	178 (38.1)
ASA classification	
1	168 (36.0)
2	221 (47.3)
3	65 (13.9)
4	13 (2.8)
Occlusive syndrome	
Complete	312 (66.8)
Partial	155 (33.2)
Stricture location	
Proximal location	223 (47.75)
Hepatic flexure	16 (3.4)
Transverse colon	29 (6.2)
Left colon	178 (38.1)
Distal location	244 (52.24)
Sigmoid	95 (20.4)
Rectosigmoid junction	134 (28.7)
Rectum	15 (3.2)
Malignancy etiology	
Primary colonic	417 (89.3)
Gynecologic	20 (4.3)
Prostate	12 (2.6)
Bladder	7 (1.5)
Other cancer	11 (2.3)
Treatment status	
Emergency	356 (76.2)
Nonemergency	111 (23.8)

Note.—Values in parentheses are percentages. ASA = American Society of Anesthesiologists.

across the stricture with a guide wire (4.7%), previous perforation diagnosed after opacification of the colon and iatrogenic colonic perforation (2.3%), and proximal migration of the stent (0.4%). When a perforation was detected, it was usually difficult to ascertain if it was iatrogenically caused. In two cases in which the stent migrated proximally, another stent was deployed correctly at the stricture site, without further complications. In the remaining 27 cases, the patient had to be referred for emergency surgery.

In 396 of the 432 successful implantations (91.7%), a Wallstent was used. In the other 36 cases (8.3%), an SX-ELLA colorectal stent was used. No differences were found in terms of technical success with regard to the type of stent. In addition, technical failure was not significantly correlated with tumor location.

Clinical Success

Different grades of clinical success were achieved in 412 patients (95.4% of cases of technically successful implantation, 88.2% of the 467 total patients; **Table 2**). The scheduled surgery dates for the cases that were considered clinical failures had to be rescheduled earlier. The main causes of clinical failure were paralytic ileus, recurrent obstruction caused by fecal impaction, early perforation, and misplacement of the prosthesis. Technical and/or clinical failure of therapy was seen in 17.8% of patients.

Complications

Complications were recorded in 89 patients (19%; **Table 3**). The most common minor complications of stent placement were minor rectal bleeding and transient anorectal pain. Minor rectal bleeding was resolved by medical treatment, and there were no cases in which blood transfusions were necessary. Tenesmus was also treated medically.

The main major complications were perforation and malignant recurrent obstruction. All cases of intraprocedural perforation were considered to be technical failures and the patients were referred for emergency surgery (**Fig 3**). In cases of recurrent stent obstruction as a result of tumor ingrowth, a new stent was deployed coaxially within the old stent. The mean time between deployment of the stent and assessment of recurrent obstruction was 281 days ± 4.5 (**Fig 4**). Malpositioning of the stent occurred in two cases and was also considered to represent technical failure. Another stent was correctly deployed across the stricture in each case.

Fecal obstruction was considered a minor complication when it was treated medically (ie, with diet and cleaning enemas) and a major complication when had to be corrected by endoscopic mechanical recanalization and lavages. Recurrent stent obstruction caused by fecal obstruction was seen at a mean time of 185 days ± 11.3.

Stent migration was a major complication in 28 of the 432 cases, in which it caused recurrent obstruction; a second stent was correctly placed at the stricture site in each case. In the remaining four cases, stent migration was observed at the follow-up examination, but because the colonic obstruction had been relieved and the patient did not show any further signs of obstruction, the stent was left in place and no further treatment was administered.

Bridge to Surgery versus Palliative Treatment

When the tumor extension study (thoracic and abdominal CT) had been performed, the implantation was considered to be a bridge to surgery for 326 patients (75.5%) and palliative treatment for 106 patients (24.5%).

Stent Patency and Survival

All patients with operable tumors survived until elective surgery. None of these patients needed a colostomy, and each surgery was performed in one stage. The mean time between stent placement and surgery was 11.4 days (range, 5–21 d). The 30-day mortality rate in this group was 4.3%

Table 2. Clinical Successes and Failures in Treating Malignant Colon Obstructions with Stent Placement

Outcome	Indication		Treated Total	Technical Success (%)	Percent of Total
	Palliative	Bridge to Surgery			
Patient sample size	106	326	432	432	476
Clinical success					
Complete	91 (85.8)	281 (86.1)	372	86.1	79.6
Notable improvement	9 (8.4)	20 (6.1)	29	6.7	6.2
Slight improvement	4 (3.7)	7 (2.1)	11	2.5	2.3
Clinical failure	2 (1.8)	18 (5.5)	20	4.6	4.3

Note.—Values in parentheses are percentages.

Table 3. Complications in the Study Population (N = 467)

Complication	Incidence
Total complications	89 (19)
Total intraprocedural	35 (7.5)
Minor	24 (5.1)
Anal bleeding	16 (3.4)
Tenesmus	6 (1.3)
Malpositioning of stent	2 (0.4)
Major	11 (2.3)
Perforation	11 (2.3)
Total postprocedural	54 (11.5)
Minor	14 (3.0)
Migration	4 (0.9)
Fecal obstruction	10 (2.1)
Major	40 (8.5)
Migration	28 (6.0)
Fecal obstruction	2 (0.4)
Malignant reobstruction	10 (2.1)
Total minor complications	38 (8.1)
Total major complications	51 (10.9)

Note.—Values in parentheses are percentages.

(19 cases). Six patients died of postsurgical complications from elective or emergency surgery. The other 13 patients died of causes related to their tumor or from medical complications related to neoplastic disease; ie, their deaths were not directly related to the stent implantation procedure.

In the palliative treatment group, the follow-up mean time was 15.6 months (range, 1–25.3 mo). The rate of primary patency without complications in this group was 52.9%, and the cumulative secondary patency was 100%. In this group, there were no significant differences in primary patency curves between cases treated with chemotherapy and those without chemotherapy ($P = .655$).

The mean survival time in the palliative treatment group was 234 days ± 8.37, with significant differences between patients who underwent chemotherapy and those who did not ($P < .001$). None of the patients treated for palliative indications required a stoma after stent decompression.

Procedure Time and Radiation Dose

The mean procedure time was 67 minutes (range, 21–168 min), and the mean radiation dose was 3,378 dGy·cm^2 (range 1,026–6,789 dGy·cm^2).

Comparisons between Guidance Methods

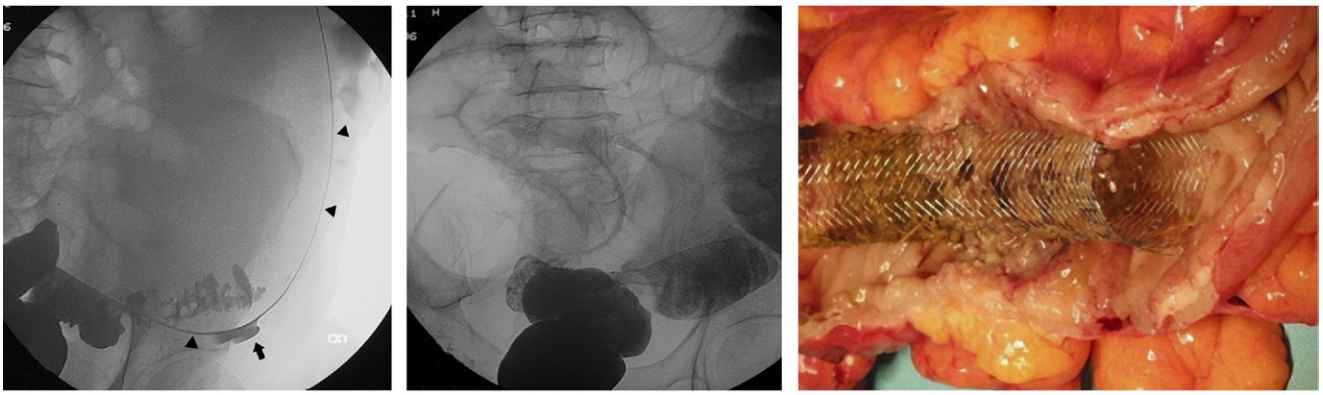
Four hundred and one procedures (85.9%) were performed with fluoroscopic guidance only, and 66 procedures (14.1%) were performed with fluoroscopic and endoscopic guidance. Mean procedure times were 67 minutes (range, 21–168 min) for fluoroscopy alone and 65 minutes (range, 24–106 min) for combined fluoroscopy and endoscopy. Therefore, there was a 2.3% decrease in procedure time when both fluoroscopy and endoscopy were used ($P = .541$). The radiation dose decreased by approximately 12.5% when the combined technique was used, and the dose was significantly lower than that in the fluoroscopy-only group ($P < .001$). The technical success and complication rates did not differ significantly between the groups, but the clinical success rate was markedly higher in the fluoroscopy-only group (**Table 4**).

DISCUSSION

Colonic self-expanding metallic stents were first used by Dohmoto et al in 1990 (17). Metallic endoprostheses are deployed as a palliative treatment to manage the acute phase of large-bowel obstruction in patients with colonic malignancy (12,18,19). In 1994, Tejero and colleagues (12) described the use of stents as a bridge to surgery.

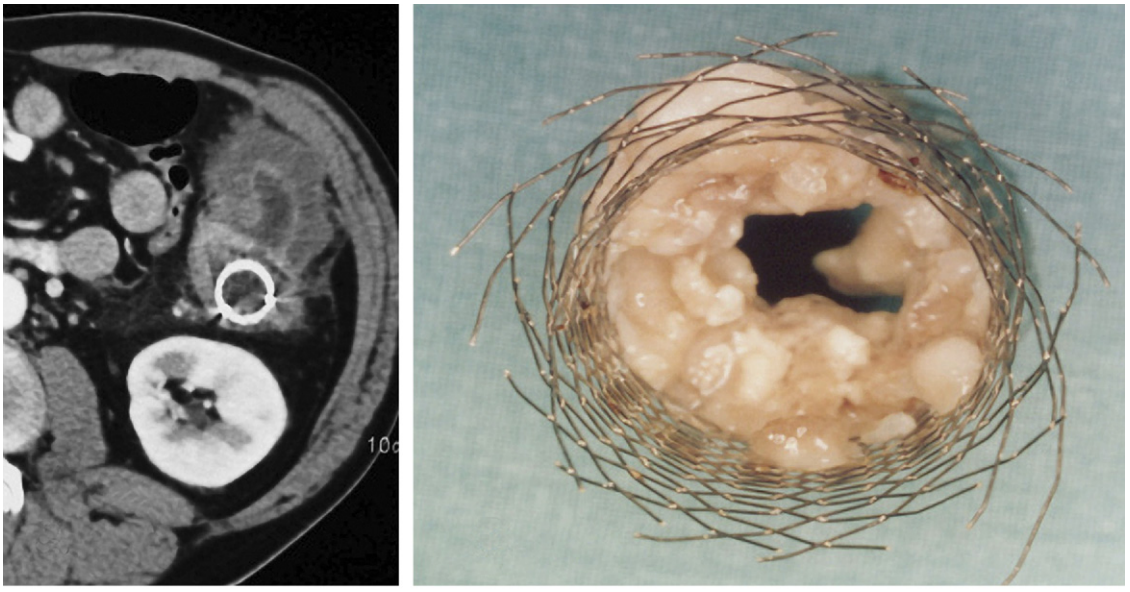
With more than 20 years of experience, we have found metallic stents to be beneficial in palliative treatment and as a bridge to surgery (15,20). The technical and clinical success and survival and complication rates described here are acceptable, and similar to those of other authors (21–26).

In our opinion, the major problems related to metallic stent implantation lie in the entry approach, the long time spent in the interventional room, and the difficulty in guiding the catheter and guide wire to and across the obstruction site. A cause for further concern is the possible high radiation dose for the patient and operators (in the present



a. b. c.

Figure 3. **(a)** In a case of iatrogenic asymptomatic perforation, barium contrast agent can be observed extraluminally (arrow), and the guide wire is outside of the colon (arrowheads). **(b)** Correct stent implantation. **(c)** Surgery specimen 8 days after stent deployment. The patient remained asymptomatic, but a small focal peritonitis was observed at the perforation site. (Available in color online at *www.jvir.org*.)



a. b.

Figure 4. Recurrent obstruction of the stent caused by tumor ingrowth. **(a)** CT scan shows replenishment of large bowel. **(b)** Post-surgical specimen shows the stent invaded by tumor ingrowth. (Available in color online at *www.jvir.org*.)

Table 4. Comparative Results with Fluoroscopy versus Fluoroscopy/Endoscopy Guidance

Guidance Method	No. of Pts.	Procedure Time (min)	Radiation Dose (dGy·cm^2)	Success		Complications
				Technical	Clinical	
Fluoroscopy	401	67.11 ± 19.76	3,439.4 ± 891.9	372 (92.8)	363 (90.5)	87 (21.7)
Fluoroscopy and endoscopy	66	65.53 ± 17.47	3,009.8 ± 644.6	60 (90.9)	49 (74.2)	12 (18.2)
P value	–	0.541*	<.001*	0.595†	<.001†	.517†

Note.—Values presented as means ± SD where applicable. Values in parentheses are percentages.
* Student *t* test.
† χ^2 test.

study, a mean dose of 3,378 dGy·cm2 was reached) (27,28). Adequate training in radiation protection and reasonable use of fluoroscopy are important to reduce this exposure.

Although the first publications in this area were reported by teams of radiologists, nowadays most of the publications come from endoscopists. In their endoscopic

series, Garcia-Cano et al (29) reported technical and clinical success rates similar to those in radiologic series. Some authors argue that the endoscopic technique decreases the total time of the procedure and consequently the dangers of irradiation (29). However, to our knowledge, there are no comparative studies that evaluate the radiation doses of the two techniques, and most publications of combined techniques lack radiation data. In our series, we observed differences in length of procedure and radiation dose (2.3% less time and 12.5% less radiation with the combined guidance technique); the difference in radiation dose was highly significant, although these results are not comparable because of the difference in numbers of patients treated with each guidance technique. Statistically significant differences were also observed between the two groups in terms of clinical results, being better in the fluoroscopy-only group; however, this statistical observation may not have a clinical meaning because it could be biased by the nonrandomized study design, and the groups are not numerically comparable (85.9% patients in the fluoroscopy-only group and 14.1% in the combined guidance group).

Perforation is the main complication in all published series regardless of radiologic guidance, endoscopic guidance, or a combination of the two. In the present work, 11 perforations were recorded during the procedure; these patients were referred to emergency surgery. In a systematic review of 58 publications (598 cases) of stent placement for the treatment of colorectal obstruction (30), the perforation rate was 4%, and other reported perforation rates range from 7%–10% in radiologic series and 7%–10% in endoscopic series (25,29,31–37).

In the present series, no perforations were diagnosed after the procedure. As discussed previously, it is often difficult to know if these perforations were iatrogenically caused, preexistent, or worsened by manipulation (31). However, other authors have reported late perforations after stent placement (30,31,38).

Prosthesis migration does not directly depend on the technique used for placement, but rather on the stent type and on the degree and location of the stenosis, because it is caused by a lack of fixation of the metallic mesh to the tumoral tissue (39).The narrower the stenosis, the less the possibility of prosthesis migration. Migration rates are higher in the distal third of the descendent colon and sigmoid colon because of the greater mobility of these segments. A higher rate of migration has been described in covered stents because of their lower degree of fixation to bowel walls (40,41). Migration incidence varies from 4% to 26% (32,34,35,42) and is one of the more frequent complications observed at early follow-up (43,44).

Obstruction can recur as a result of fecal impaction or tumor ingrowth (27). Growth of the tumor through the mesh is the main disadvantage of uncovered stents, and its incidence varies from 2% to 20% (29,30,34). In the present study, we observed recurrent obstruction by tumor ingrowth in 2.1% of cases and by fecal impaction in 2.6% of cases. The use of covered stents could prevent this complication, but with the potential inconvenience of a higher rate of migration. In the present series, we treated tumor-related recurrent obstruction of the stent with placement of a new stent and fecal impaction–related recurrent obstruction by means of cleaning enemas.

In our experience, treating malignant colonic obstruction with stent placement is a safe, feasible, and effective radiologic procedure. It can be used to avoid an emergency open surgery that often results in stoma creation, with a negative impact in the quality of life of the patients. However, colonic stent placement involves a large amount of time in the interventional room and a considerable radiation dose, but this can be reduced by using combined guidance techniques. In most cases, the important clinical benefits and the improvement in quality of life for the patient justifies the radiation risk. Collaborative and prospective randomized studies should be performed to establish the effectiveness and safety of metallic stent implantation versus emergency surgery.

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