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• BRIEF REPORT •

Treatment of malignant digestive tract obstruction by combined intraluminal stent installation and intra-arterial drug infusion

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Abstract

AIM **To study the palliative treatment of malignant obstrution of digestive tract with placement of intraluminal stent combined with intra-arterial infusion of chemotherapeutic drugs.**

METHODS **A total of** 281 **cases of digestive tract malignant obstruction were given per oral** (**esophagus, stomach, duodenum and jejunum**), **per anal** (**colon and rectum**) **and percutaneous transhepatic** (**biliary**) **installation of metallic stent. Among them,** 203 **cases received drug infusion by cannulation of tumor supplying artery with Seldinger's technique.**

RESULTS **Altogether** 350 **stents were installed in** 281 **cases, obstructive symptoms were relieved or ameliorated after installation. Occurrence of restenotic obstruction was** 8-43 **weeks among those with intra-arterial drug infusion, which was later than** 4-26 **weeks in the group with only stent installation. The average survival time of the former group was** 43 (3-105) **weeks, which was significantly longer than** 13 (3-24) **weeks of the latter group.**

CONCLUSION **Intraluminal placement of stent combined with intra-arterial infusion chemotherapy is one of the effective palliative therapies for malignant obstruction of the digestive tract with symptomatic as well as etiological treatment.**

Subject headings digestive tract disease; treatment; stent; therapeutic embolization chemotherapy; infusion, local

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INTRODUCTION

Intraluminal installation of stent in digestive tract is being more and more widely used[1-31]. Drug infusion via supplying artery and embolization therapy have been used in clinical practice as an effective way of suppressing the growth of malignant tumors[32-43] But up to now there have been few reports of the combined use of the two in the treatment of malignant stenotic lesions[44,45]. We have used the combined therapy in cases of malignant stenosis of digestive tract and have obtained good results in relieving symptoms, improving quality of life and prolongation of survival time. We managed 281 cases from October 1996 to May 2000 and the therapeutic results are reported below.

MATERIAL AND METHODS

Patients

A total of 281 patients with malignant obstruction of digestive tract were treated. Among them, 182 were males and 99 females, age ranged from 20 to 93 years, with an average of 65 years. The cause of obstruction was stenosis or obstruction of the digestive tract by infiltration or pressure of the malignant tumor. All cases belonged to late stages of tumor, impossible for surgical resection. One hundred and seventy-seven cases had operative histories of primary tumor resection, with reconstruction of digestive tract, biliary endostomy, bypass drainage or laparatomy, etc, 6 had histories of four operations, 83 cases of one operation . The primary disease included carcinoma of esophagus, 79 cases; stomach cancer 55 cases; carcinoma of liver, 25 cases; carcinoma of pancreas, 53 cases; colorectal cancer, 39 cases; cholangiocarcinoma, 10 cases; and other carcinomas, 20 cases. Pathological types: adenocarcinoma, 96 cases; squamous cell carcinoma, 74 cases; and others, 111 cases. Among the 281 cases, site of stenosis and obstruction at esophagus, 119 cases; at stomach (including gastrointestinal stoma), duodenum and jejunum, 76 cases; colorectal segment, 28 cases; and biliary tract, 58 cases. Some cases had more than two sites of stenosis or obstruction. They were divided in to groups A and B by patient or close relative's choice. Group A (203 cases) received treatment by installation of intraluminal stent combined with intra-arterial cannulation for drug infusion via supplying artery. Group B (78 cases) received only installation of intraluminal stent and again according to their choice supplemented with intravenous chemotherapy, radiotherapy or traditional Chinese medicinal treatment. Those with impaired liver and /or kidney function due to the cancer, or very poor general condition not suitable for intravenous chemotherapy and radiotherapy were advised to join group A. In group A, there were 132 males and 71 females, aged 20 - 93 years, averaging 61 years. Of them, 82 cases could not meet the requirements of routine radiotherapy and chemotherapy such as blood routine, liver and kidney

function or abnormalities of some other tests. In group B, there were 50 males and 28 females, age ranged from 28 - 87 years, averaging 58 years. Fourteen cases could not meet the requirements of routine radiotherapy and chemotherapy. Karnofsky quality of life evaluation in group A was 10-80 (average 36.2) score and 20 - 80 (average 40.2) score in group B.

Metallic intraluminal stent

Woven type nickel-titanium alloy stent was mainly used. The tubular meshwork, the whole some structure somewhat like wallstent was woven by single fine threads of nickel-titanium alloy of 0.20mm-0.32mm in diameter. Membranous stent was coated with polyurethane or silica gel on the mesh of the stent main body. For biliary tract, straight-neted duct stent was used without trumpet ends. The diameter of the tube is 0.8cm - 1.6cm, and the length 6cm - 10cm. The stent used for esophagus, stomach, duodenum and jejunum is of the type with trumpet opening on one end or both ends. The proximal end is basin-trumpet in shape, and the distal end cup or mushroom in shape. The tubular diameter of the stent main body is 1.1 cm - 1.5 cm at cervical segment, 1.8 cm - 2.8 cm at thoracic and abdominal segment of the esophagus. At stomach body, it is 2.0cm-2.5cm, and at duodenum and jejunum 1.8 cm - 2.0 cm; the length of the stent is 3.5 cm - 14cm. The stent for the use of colon and rectum has both ends of ball or mushroom shape trumpet opening. The tubular diameter of the stent main body is 2.0cm - 2.2cm at transverse colon, 2.5cm - 2.8cm at descending colon, and 2.5cm - 3.2cm at sigmoid colon and rectum; the length of the stent is 8cm-14cm. The width of the trumpet opening of all stents is 0.4cm-0.7cm. Some stents are specially made for specific requirements. Other stents we have used are home made"Z" shape esophageal stent, Wallstent for biliary and esophageal use (Schineder) and Memotherm biliary stent (Agmidel).

Transporter and auxilliary instruments

Wallstent and Memotherm stents were provided with a disposable coaxial two duct type transporter. Home-made "Z" shape stent was fixed with a sheath tube type pusher. Home made biliary and esophageal stents for cervical segment were used together with a sheath tube type pusher of Cook Company. For other stents we used self-made posterior positioned coaxial three ducts type transporter. Other auxilliary instruments included 6F Corber transmitting catheter, 2600mm long Torumo Radifocus guide wire, 2600mm-3000mm long soft head super-hard guide wire, 1300mm long exchange catheter, bulb dilating catheter of 25mm in diameter and double-channel imaging catheter made from used bulb catheters. Gastroscope, colonoscope, microwave or diathermic apparatus were also available.

Treatment modalities

Installation of intraluminal stent. Stent was placed perorally to esophagus, stomach, duodenum and jejunum. Radiopaque guide wire was inserted via gastroscope or perorally. The pusher attached with the stent was introduced by the guide wire so that the stent could be slowly released after passing through the stenosed segment. For the installation of stent in duodenum and jejunum, super-hard guide wire was introduced via exchange catheter, and the stent was put by the pusher introduced by the hard guide wire. Biliary stent was installed by percutaneous puncture and insertion method. The puncture needle was inserted percutaneously and transhepatically into biliary tract. Radifocus guide wire was introduced through the puncture needle along the intrahepatic biliary tract into the common bile duct, and then through the stenosed segment deep into the small intestine. Through exchange soft head hard guide wire, sheath tube or coaxial two ducts type transporter put the stent into the stenosed segment. Colonic and rectal stent was inserted through anus. Radifocus guide wire was inserted through the stenosed segment by the catheter or via colonoscope. Exchange catheter was introduced and replaced the super-hard guide wire. The hard guide wire introduced the coaxial two ducts type transporter that releases the stent.

Intra-arterial drug infusion

Two to eight days before the installation of the stent or 0d-4d after it, chemotherapeutic infusion via cannulation of the supplying artery of the tumor was given. The Seldinger's technique was used. According to the primary lesion or the infiltration field of the metastatic site, the supplying artery of the tumor was chosen as the target artery. Generally, the main trunk of the supplying artery was chosen for cannulation or multiple target points were chosen for cannulation at one time. The target arteries chosen for cannulation are: external jugular artery, inferior thyroid artery, or subclavicular artery bronchial artery, esophageal propriae artery, intercostal artery, hepatic artery (or coeliac artery trunk), superior mesenteric artery, inferior mesenteric artery, internal iliac artery, etc. The perfusing drugs used with dosage calculated according to surface area of the body were epirubicin 25mg·m^2, carboplatin 200mg·m^2, 5-Fu 500mg·m^2 forming triad drug group for use. For patients with abnormal liver and /or kidney functions (all caused by the malignant factors), dosage will be decreased accordingly. For those patients having normal routine profiles with better general condition, VM26 50-100mg·m^2 was added. For those with impaired cardiac function, adriamycin was substituted by pirarubicin 300mg·m^2. For some suitable patients emulsified 40% lipiodol and chemotherapeutics were given for superselective emolization. Patients with arterial venous fistula were first given gelfoam strips to block the fistular tract and then drug infusion. The second treatment was administered three weeks afterwards, and the third treatment was given after another 3 -5 weeks. From then on, the interval could be prolonged to 1.5-5 months.

RESULTS

Installation of stent (Table 1)

A total of 350 stents were installed in 281cases. Among them 144 were esophageal stents (23 in cervical segment, 69 in thoracic segment and 52 in abdominal segment of esophagus). Ninety-eight stents were put in stomach duodenum and jejunum (21 in gastric body and pyloric region, 22 in gastrointestinal anastomotic oriface, 49 in descending and horizontal part of duodenum and 6 in proximal jejunum); 30 in colon and rectum (9 in transverse colon, 5 in descending and 16 in sigmoid colon and rectum). Seventy-eight were biliary stents. Among the 144 esophageal stents, 142 were home-made woven type tubular mesh stents (127 with attached membrane and 15 without membrane), one was home-made "Z" type stent with attached membrane. There

was one wallstent without membrane. Among 98 stents used in stomach, duodenum and jejunum, 97 were home made (35 with attached membrane, 62 without). One Wallstent without membrane was used. Thirty stents used in colon and rectom (20 with membrane and 10 without) and 71 of 78 biliary stents were all home made. There were 4 Wallstents and 3 Memotherm stents. Biliary stents were all without membrane. The distribution of stents installed in groups A and B are shown in Table 1.

Drug infusion (Table 2)

Group A (203 cases) had received cannulation of supplying artery with infusion of chemotherapeutics (a total of 708 times). The minimum was one time (9 cases) and maximum was 14 times (one case). The average time was 3.49. Table 2 shows different patients undergoing drug infusion. Among the nine cases receiving treatment only once, which was refused by their relatives in 5 cases, and discontinued due to deterioration of their general condition in 2 cases, and the remaining 2 cases died. Three out of the 203 cases had received lipiodol emulsion embolization for 7 times, 11 cases had gelfoam embolization for 18 times. Besides occational hematoma at the puncture site, few cases complained of pain at the site of drug infusion and embolization treatment and 37% of cases had reversible lowering of blood counts, and no other arterial interventional procedure related complication was noted.

Clinical symptomatic impro ement

Among 119 cases with installation of esophageal stent, 18 had stent in the cervical segment and they all could take low residue regular diet. In 101 cases with stent in the thoracicor abdominal segment, those with simple stenosis basically restored to normal meals. Among 13 patients with esophagotracheal or esophagothoracic fistula, 11 could take normal meals after complete obliteration of the fistular tract, one still had some irritating cough while eating. Another case was a patient who developed esophageal stenosis with esophagothoracic fistula after unilateral pneumonectomy. Four days after installation of stent and obliteration of the fistula, the patient developed obvious irritating cough during eating. Imaging demonstrated proximal orifice of the stent protruded into the thoracic cavity forming another fistular tract. Among 76 patients with stent in stomach, duodenum or jejunum, 71 restored to normal meals and 5 had the obstructive symptoms improved, but could only take liquid diet. Twenty-eight cases with stent in colon or rectum had immediate relief of intestinal obstructive symptoms after installation, one of them who had colonic pelvic fistula had no more exudative leakage from the fistula tract after the installation. A case of rectal vaginal fistula had much less fecal exudation from vagina after installation. In 58 cases with installation of stent into the biliary tract, jaundice was significantly decreased, 39 cases had serum bilirubin returned to normal within a week. Nineteen cases had serum bilirubin dropped below 70mmol/L. Clinical symptomatic improvement were similar between groups A and B shortly after treatment. Among 82 cases in group A whose conditions could not reach the requirements of laboratory profiles for routine radiotherapy or chemotherapy, 46 cases fulfilled the requirements after two drug infusions. Among 14 cases of group B, only 3 cases approached the requirements after 1-2 months. As the disease progressed, the number of patients whose original profiles were normal but became abnormal when the disease got worse, was significantly larger in group B than in group A. Comparison of Karnofsky life quality evaluation between the two groups at 4 - 6 week after installation of stent showed that the average score in group A increased from 36.2 to 53.2, while in group B, from 40.2 to 46.2. There was significant difference between the two groups.

Maintenance of efficacy and survival time

In group B, 23 restenotic obstructions occurred 4-26 weeks after treatment in 15 (23.1%) cases. In group A, 29 (14.3%) had 38 restenotic obstructions 8-43 weeks after treatment (Table 3). The survival time in group A was 3-105 weeks, averaging 43 weeks, while 3-24 weeks in group B averaging only 13 weeks. The survival time of group A was more significantly prolonged than group B (Table 4).

Table 1 Installation of stents

Site	Group A		Group B		Total	
	No.of cases	No.of stents	No.of cases	No.of stents	No.of cases	No.of stents
Esophagus	81	95	38	49	119	144
Stomach, small intestine	55	64	21	34	76	98
Colon, rectum	19	20	9	10	28	30
Biliary tract	48	53	10	25	58	78
Total	203	233	78	116	281	350

Table 2 Drug infusion

Site	*N*	Infusion (*n*)	Total infusion times	Max. per case	Min. per case	Average per case
Esophagus	119	81	310	12	2	3.83
Stomach, small intestine	76	55	229	14	1	4.16
Colon, rectum	28	19	39	8	1	2.94
Biliary tract	58	48	130	9	2	3.65
Total	281	203	708			3.49

Table 3 Maintenance of efficacy (groups A / B)

Site	*n*	Restenosis		Restenosis (wk)
		n	No.of times	
Esophagus	81 / 38	15 / 10	20 / 12	12-35 / 04-17
Stomach, small intestine	55 / 21	06 / 04	07 / 05	17-42 / 07-16
Colon, rectum	19 / 09	02 / 00	02 / 00	26-43 / 0
Biliary tract	48 / 10	06 / 04	09 / 06	8-33 / 05-26
Total	203 / 78	29(14.3) / 15(23.1)	38 / 23	08-43 / 04-26

Table 4 Comparison of survival time (groups A / B)

Sites	Cases	Survival (*n*)	Death (*n*)	Survival (wk)	
				Range	Average
Esophagus	81 / 38	23 / 03	58 / 35	5-103 / 5-20	36 / 14
Stomach, small intestine	55 / 21	09 / 02	46 / 19	4-105 / 2-17	38 / 11
Colon, rectom	19 / 09	02 / 00	17 / 09	3-98 / 3-13	33 / 08
Biliary tract	48 / 10	06 / 01	42 / 09	6-54 / 3-24	30 / 18
Total	203 / 78	40 / 06	163 / 72	3-105 / 3-24	43 / 13

$P<0.05$, for all sites.

DISCUSSION

Significance and technical difficulties

Digestive tract is the necessary passage of alimentation digestion, absorption and excretion of waste metabolites. Obstruction of digestive tract interferes with food intake, bowel movement, or causes obstructive jaundice. All these seriously affect the quality of life of the patients and even accelerate death. In 1983, Frimberger first reported the use of metallic stent to treat esophageal stenosis[46]. Domschke in 1990 successfully used self-expansible woven mesh type metallic stent to treat a case of esophageal malignant obstruction[47]. Thus it was made possible the relief of obstruction of digestive tract by non-surgical procedures. Karnel *et al*[48], Goldrn *et al*[49], Keymling *et al*[50] and others had respectively tried to use metallic intraluminal stent in treating colonic, biliary and duodenal obstruction. Their success had laid the basis of the expanded use of digestive tract intraluminal stent. As intraluminal installation of stent in digestive tract is a non-surgical method with mini-invasive technique to render the stenosed digestive tract becoming patent again, thus providing a new approach in the palliative treatment of digestive tract malignant obstruction. Comparing with the conventional surgical operation, treatment by intraluminal installation of stent has the characteristics of mini-invasion, fast, effect, good clinical sutclins and repeatablity of the procedure. This avoids the damage caused by surgical operation. For those with no indication for operation or too weak to stand the operation, treatment with intraluminal installation of stent can provide palliation to the patients with symptomatic relief and improved quality of life.

Compared with vascular lumen and other non-vascular lumens, the various lumens at different parts of the digestive tract have special histologic structures and functional characteristics. For example, the cervical segment of esophagus has strong contractive force and is very sensitive to foreign body. Duodenum and jejunum are quite distant from mouth, their lumens are tortuous with frequent peristalsis. Colon has a haustral structure with a strong group contractile force. The peculiar tissue structure and functional characteristics make the procedure of installation of intraluminal stent somewhat difficult. So, up to now, the clinical use of installation of digestive tract intraluminal stent is still limitted to esophagus and biliary tract. We have chosen nickel-titanium alloy in the form of single fine threads woven longitudinally and transversely into a flexible mesh tabular stent according to the common feature of digestive tract structure and function. For the installation of stent in the high position cervical segment of esophagus, we made tolerance dilatation test and used small caliber so as to ameliorate foreign body or pain sensation, thus succeeding in putting the stent in the cervical segment of esophagus. We used high hardness, small friction and elongation coefficient, not easily restored once deformed material, polytetrafluroethylene, to make coaxial duct and put it in between the external and internal ducts made of polyethylene, which is soft, easily to be restored with big friction force. The coaxial duct type transporter was made in this way that can be introduced into tortuous intestinal tube to release the coaxial duct type transporter of the stent. We also used endoscope to help the insertion of the guide wire. Super-hard guide wire helps enlarge the turning angle of the colonic loops. All these measures solve the difficulty encounted in the remote release of the stent. This not only increased the success rate of installation of duodenal and proximal jejunal intraluminal stent orally[11], but also facilitated the installation of stent at high level transverse colon via anal route[17]. At the same time, we selected big caliber with high degree hardness double bulb shaped or mush room shaped trumpet orifice stent. This not only increased the expanding force but also increased the compliance of the connecting segment between the terminal opening of the sent and the normal intestinal tract. The therapeutic effect of colonic and rectal stent installation was thus elevated and its complication reduced.

Drug infusion via supplying artery of tumor

Intraluminal stent treatment can build up the basis for the patients for further treatment by the relief of digestive tract obstructive symptoms and improvement of life quality of late tumor cases. The advanced patients with tumor can rarely tolerate the toxic or side effect of traditional radio-and/or chemotherapy. In fact, the sensitivity toward traditional radio- and chemotherapy in absolute majority of patients with solid tumor of digestive tract is rather poor. As

chemotherapeutics have killing and injurious effect to most tumor cells, the difference of therapeutic effect is mainly determined by whether the drug in the target organ can reach effective antitumor blood drug concentration or not. The general effect of traditional chemotherapy makes it difficult to reach an effective blood drug concentration in the target organ of gastrointestinal tract at safe dosage. As a result, clinical efficacy is low, while toxic and side effects are severe. Interventional chemotherapy by drug infusion of supplying artery can make the blood drug concentration in the vascular network of the tumor area reach an effective antitumor level by relative safe dosage, thus decreasing toxic and side reactions and increasing therapeutic efficacy. Intraluminal installation of stent in combination with drug infusion of supplying artery can release obstruction, improve life quality and at the same time inhibit growth of the malignant tumor. In the present study, the average survival time of our group B patients was 13 weeks, close to that reported by Turegano-Fuentes *et al*[51], Cwikiel *et al*[52] and P Scott Mackie *et al*[53]. The average survival time was 44 weeks in group A, significantly longer than the former. The restenosis was also more significantly prolonged in group A than in group B. This showed that interventional chemotherapy by arterial cannulation can produce in certain extent inhibition of the malignant tumor growth by its therapeutic effect. In conclusion, intraluminal stent therapy in combination with intra-arterial cannulation of interventional chemotherapy can be considered as an effective therapy with regard to symptomatic and etiological treatment and should be used more widely in the near future.

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