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Original article

ASSESMENT OF PLACEMENT OF THE ESOPHAGEAL SELF-EXPANDABLE METALLIC STENT IN ESOPHAGEAL CANCER IN PATIENTS WITH OR WITHOUT CITORREDUCTION THERAPY

Avaliação do emprego de prótese metálica auto-expansível no câncer avançado do esôfago em pacientes com ou sem terapia citorredutora

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ABSTRACT – ***Background*** - Placement of self-expanding metallic esophageal stent in patients with advanced esophageal cancer offers excellent palliation of dysphagia and tracheo-esophageal fistulas. However, the safety of stent in patients undergoing radio and/or chemotherapy is controversial, in terms of the greater risk of complications in cases where these two treatments are used in conjunction. ***Aim*** - To assess the use of stent in patients with advanced cancer of the mid-thoracic esophagus, by comparing patients undergoing cytoreductive therapy with patients who have not undergone this treatment, in relation to improvement in the dysphagia, rate of complications, period of effectiveness and survival time. ***Methods*** - Fifty seven patients were evaluated retrospectively (16 women and 41 men, with an average age 62 years) with advanced squamous cell carcinoma of the mid-thoracic esophagus who underwent placement of the Ultraflex™ self-expandable metallic coated stent, at the Gastrointestinal Endoscopy Unit of São Paulo University Medical School between October 1988 and October 2004. Out of the 57 patients, 24 patients received adjuvant cytoreductive therapy, and 33 patients were only treated with the stent placement. ***Results*** - After stent placement, there was improvement in dysphagia in both groups; there were no differences in the rate of complications, such as migration, pain, fistula, obstruction and compression of the airways; the period of effectiveness was significantly higher in the group submitted to cytoreductive therapy (average 123 days compared to 63 days), as was the survival time (average of 210 days, compared with 120 days). ***Conclusions*** - Improvement in dysphagia was statistically significant in both groups, irrespective of whether the patient had undergone adjuvant cytoreductive therapy; there were no differences in the rate of complications between the two groups and both the period of effectiveness of the stent treatment and the survival time were higher in the group with adjuvant cytoreductive therapy.

HEADINGS - Esophageal neoplasms. Combined modality therapy. Palliative care. Comparative study.

INTRODUCTION

Treatment of esophageal cancer is still predominantly palliative, bearing in mind that the majority of tumors are found in an advanced state, more than 60% are not resectable at the time of their diagnosis, and the five years survival rate is around 5 to 10%[11,12,43]. Dysphagia is the main symptom of advanced disease, causing discomfort and complications such as regurgitation, aspiration pneumonia, cachexia, and significantly worsening the quality of life of the patient[23]. The main objectives of palliative treatment are to maintain oral ingestion, to minimize hospital stay and symptoms relief related to the disease. Those treatment options includes surgical, endoscopic and cytorreductive therapy such as radio and/or chemotherapy (RT/CT).

The placement of self expandable metallic stent (SEMS) is one of the main options for palliative endoscopic treatment, mostly when the tumor compromises the mid-esophagus. The main advantages include: conscious sedation during the procedure, stent placement in stricture segments without need of excessive dilation, its malleability adapts better to bends or curvatures in some stenosis and it is the treatment of choice in tracheo-esophageal fistulas with a success rate of more than 70%[2,6,7,9,20,29,30,31].

Like every palliative procedures, the placement of SEMS can cause complications, both minor (stent migration, obstruction, and thoracic pain) and major (hemorrhage, esophageal perforation, fistula formation, and airway compression), which can be life threatening. These occurrences may be linked to the histological type and location of the tumor, the properties of the stent, such as the configuration of the metal mesh, the type of metal used, and whether the stent was coated or not[4,19,27].

Multivariate studies comparing isolated stent placement versus stent placement with adjuvant cytorreduction therapy showed a high rate of complications in the group submitted to RT/CT[1,13,25,26]. However, in an equivalent number of studies, no difference was observed between the two groups of patients, and a longer survival time was obtained in the patients who underwent cytoreductive therapy. On

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the other hand, the combination of treatments may provide immediate improvement of the dysphagia in relation to the RT/CT, and enable cytoreductive therapy in patients with tracheo-esophageal fistulas[8,16,22,32,43]. These facts suggest that the combined treatment is still controversial, and there is a need for further analysis on the risks and benefits of this association.

The aim of this study was to evaluate two groups of patients with mid-esophageal squamous cell carcinoma (SCC). The first group underwent SEMS and adjuvant cytorreductive therapy and the second group only SEMS placement. It was compared improvement in the dysphagia score, rate of complications, the time period of effectiveness and the survival rate.

METHODS

The criteria for inclusion in the study were: patients with obstructive esophageal tumor located in the mid-thoracic portion and considered inoperable (i.e. in the stage in which the tumor infiltrates the adjacent organs (T4), lymph nodes (N1) and/or produces distance metastases (M1) (Stages III – T4NqM0 and T3N1M0 and IV – TqNqM1, according to the TNM classification – U.I.C.C. 1987); squamous cell carcinoma; patients submitted to Ultraflex™ stent placement; patients who underwent RT/CT before or after stent placement;

The criteria for exclusion were: patients with other histological tumor types; patients who received other types of prosthesis (In stent™ and Z stent™); tumors located in the cervical or distal portion of the esophagus; tumors larger than 12 cm in length; patients who could not be included in the study due to insufficient data.

Retrospective study was carried out, in which 88 patients underwent Ultraflex™ stent placement at the Gastrointestinal Endoscopy Unit of São Paulo University Medical School during the period October 1998 to October 2004. Of these, eight were diagnosed with adenocarcinoma, two with cancer of the small cells, two with pulmonary neoplasia invading the esophagus, one with breast cancer metastasis and 75 with SCC. Of the 75 patients with SCC, six patients underwent Ultraflex stent placement at the cardia position, and these were excluded, and 69 patients underwent stent placement in the mid-esophagus. Of the 69 patients included, 12 were excluded due to insufficient data, and hence 57 patients were included in this study.

The SEMS analyzed is made from nitinol mesh and partially coated with polyethylene, model Ultraflex™ (Boston Scientific Corporation, Natick, MA)(Figure 1).

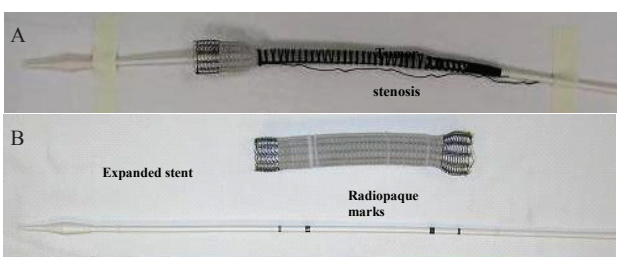


FIGURE 1 - A and B - Ultraflex™ SEMS releasing

Of the 57 patients included in the study, 24 patients underwent SEMS and adjuvant cytoreductive therapy (Group I) and 33 received only SEMS treatment (Group II). Patients with cytoreductive therapy included all those who underwent RT/CT, before or after placement SEMS. The therapeutic regime, the decision to continue or discontinue the RT/CT, and the criteria for administering these treatments to patients, were practices adopted by the Oncology Unit of our Institution.

The placement of Ultraflex™ SEMS was carried out fluoroscopically using a standard upper endoscope and intravenous sedation with meperidine, midazolam and propofol. The upper edge of the esophageal tumor was marked endoscopically with the submucosal injection of iodinated poppy-seed oil as a contrast agent (Lipiodol®), as recommended by Raijiman et al.[24] and, when it was not possible to pass the endoscope through the malignant esophageal stenosis, a metallic guide-wire was inserted to dilate the stenosis, with Savary-Gilliard thermoplastic bougies, up to a maximum of 13 mm (39 French) in diameter. Once the endoscope was passed beyond the lesion, the distal edge of the lesion was marked with Lipiodol®. After demarcating the edges of the tumor and maintaining the metallic guide wire in the stomach, the stent insertion device was placed in the esophagus, guided by means of fluoroscopy, according to the demarcated edges of the tumor. The stent used was 4 cm longer than the length of the tumor, due to longitudinal shortening of the stent after its deployment.

After introduction of the SEMS, an upper endoscopy was carried out after one week, and again after one month. New endoscopic examination was scheduled to be carried out if some complication were to arise relating to the stent, such as recurrence of dysphagia, signs of bronchial aspiration, severe thoracic pain, migration of the stent, or hemorrhage.

The introduction of the stent was considered well succeeded when there was no need for immediate intervention due to complications such as migration of the stent, perforation of the esophagus or hemorrhage, while carrying out this procedure.

The clinical characteristics of these patients were analyzed, such as gender, age, race, pre-existing diseases, epidemiological history, the stage of the tumor according to the TNM classification – UICC 1987, nutritional state (body mass index (BMI), serum albumin, hematocrit and hemoglobin), the life's quality according to the Karnofsky Performance Status Scale, the presence or absence of a tracheo-esophageal fistula, and the size of the tumor.

Degree of dysphagia was evaluated before and after SEMS placement, being classified as grade 0 – normal diet; grade 1 – difficulty ingesting solid foods; grade 2 – difficulty ingesting paste foods; grade 3 – difficulty ingesting liquid foods and grade 4 – patient unable to swallow his/her own saliva. Like the studies of Bethge et al.[3] and Kaneko et al.[20], the dysphagia was considered improved, when there was decrease of at least one degree of dysphagia, one week after the intervention.

The rate of complications was also observed. Complications that were considered minor included: stent migra-

tion, thoracic pain and obstruction of the endoprosthesis by tissue hyperplasia, growth of the tumor, or impaction by ingested food and those that were considered major included life threatening complications such as esophageal perforation, formation of a tracheo-esophageal fistula, and airway compression[21,26].

The period of effectiveness was defined as the time during which there was no need for intervention due to the recurrence of dysphagia or other complications, after stent placement. Finally, the survival time of these patients, following stent placement, was also analyzed.

Laboratory and clinical characteristics, the degree of dysphagia, complications, the period of effectiveness of the stent and survival time, were compared between the groups I and II.

The stastistical analysis was made comparing the qualitative variables, for the two groups of interest carried out using the Chi-Square Test or Fisher's Exact Test.The Student t-Test was used in comparing the two groups. A level of significance of 0.05 (α= 5%) was adopted, and descriptive levels (*P*) lower than this value were considered significant.

RESULTS

Of the 57 patients included in this study, 41 were men and 16 women. The average age was 62.07 years (with a variation of 42 to 88 years). All the patients presented were stage III or IV esophageal cancer, according to the TNM classification. Comparing the clinical-laboratory characteristics of the patients with cytoreductive therapy and SEMS (Group I) versus SEMS alone (Group II), the results obtained can be seen on Tables 1, 2 and 3.

TABLE 1 - The clinical and epidemiological characteristics of the patients with (Group I) and without cytoreductive therapy (Group II)

Parameters	Group I (n = 24)	Group II (n = 33)	*P*
Age (years)			
average ± d.p.	59.38 ± 10.81	64.03 ± 10.81	0.123
minimum – maximum	38 – 88	42 – 81	
Sex – n (%)			
male	15 (62.5)	26 (78.8)	0.177
female	9 (37.5)	7 (21.2)	
Race – n (%)			
Caucasian	19 (79.2)	22 (66.7)	0.266
Non-caucasian	5 (20.8)	11 (33.3)	
Odynophagia – n/n1 (%)			0.752
yes	10 / 24 (41.7)	12 / 32 (37.5)	
Regurgitation – n/n1 (%)			0.163
yes	6 / 24 (25.0)	15 / 32 (46.9)	
Alcohol use – n/n1 (%)			0.088
yes	13 / 24 (54.2)	25 / 33 (75.8)	
Smoking – n/n1 (%)			0.579
yes	19 / 24 (79.2)	28 / 33 (84.8)	

Among the characteristics reported, the Karnofsky Performance Status Scale index, which measures physical function of the patient, was significantly higher (*P*=0.015) in the group who underwent SEMS with adjuvant RT/CT. The esophageal tumor length was larger in the group which only underwent SEMS placement (*P*=0.049). Other characteristics, such as gender, race, epidemiological history, presence of fistula, regurgitation, odynophagia, BMI, albumin, hemoglobin and hematocrit, did not show any statistical significance when comparing the two groups.

TABLE 2 - Characteristics of the tumor, comparing Group I and Group II

Parameters	Group I (n = 24)	Group II (n = 33)	*P*
Size of tumor (cm)			
average ± d.p.	6.52 ± 1.86	7.63 ± 1.90	**0.049**
minimum – maximum	4 – 11	4 – 11	
Tracheo-esophageal fistula n/n1 (%)			0.102
present	9 / 24 (37.5)	6 / 33 (18.2)	
Stage of tumor – n (%)			
III	15 (62.5)	28 (84.8)	0.101
IV	9 (37.5)	5 (15.2)	

TABLE 3 - Physical and nutritional characteristics of patients in Groups I and II

Parameters	Group I (n = 24)	Group II (n = 33)	*P*
Karnofsky Performance Status Scale			
average ± d.p.	75.00 ± 16.15	63.03 ± 18.11	**0.015**
Median	80	60	
minimum – maximum	40 – 100	30 – 90	
BMI (kg/m²)			
average ± d.p.	19.34 ± 3.50	18.04 ± 2.98	0.138
minimum – maximum	13.2 – 28.0	12.8 – 24.9	
Albumin (g/dl)			
average ± d.p.	3.73 ± 0.50	3.48 ± 0.62	0.112
minimum – maximum	2.2 – 4.4	2.4 – 4.7	
Hemoglobin (g/dl)			
average ± d.p.	12.30 ± 1.55	12.47 ± 1.77	0.697
minimum – maximum	7.9 – 14.9	7.5 – 14.9	
Hematocrit (ml/dl)			
average ± d.p.	36.60 ± 4.31	37.34 ± 5.38	0.579
minimum – maximum	21.8 – 46.2	21.8 – 46.2	

It is important to note that the group who underwent cytoreductive therapy included patients submitted to different types of radiochemotherapeutic regimens and at different times in relation to SEMS placement. In order to observe similarities in clinical and laboratory characteristics to mitigate the heterogeneity of the SEMS and adjuvant RT/CT group, comparisons were carried out between the subgroups that comprised patients who received adjuvant RT/CT before and after SEMS placement. And these findings showed that there was no significant difference found relating to the clinical characteristics of the group with adjuvant cytoreductive therapy.

Comparing the degree of dysphagia before and after stent placement, there was improvement of at least two degrees for both groups analyzed. There was no difference statistically significant in relation to dysphagia score improvement in both groups (Table 4).

TABLE 4 - Comparison of the degree of dysphagia before and after placement SEMS, between Groups I and II

Degree of dysphagia	Group I	Group II	Total
Before SEMS (average ± d.p.)	2.71 ± 1.00	3.16 ± 0.88	2.96 ± 0.94
After SEMS (average ± d.p.)	0.62 ± 0.65	1.10 ± 0.8	0.87 ± 0.79
Differences in the degrees of dysphagia*	2.09	2.06	2.09

* *P*=0.928

In relation to the rate of complications occurring after stent placement, in Group I, two patients had a tracheo-esophageal fistula (8.3%); six presented with obstruction (25%) and 13 reported thoracic pain (54.2%). Meanwhile, Group II presented with upper gastrointestinal bleeding in two patients (6.3%); two with tracheo-esophageal fistula (6.3%); compression of the airways caused after attempting to close a tracheo-esophageal fistula of 2 cm in diameter in one patient (3.1%); obstruction of the stent in 10 cases (40%); migration of the stent in 13 patients (9.4%) and thoracic pain in 21 patients (66%). Perforation of the esophagus was not observed in either of the two groups analyzed (Tables 5 and 6).

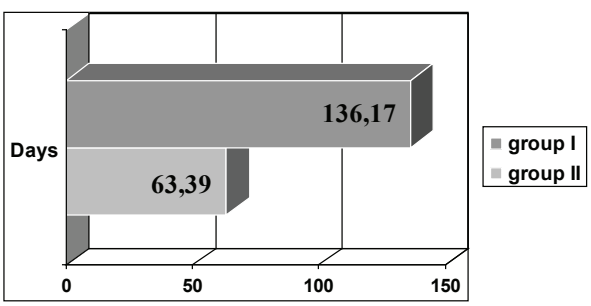
TABLE 5 - Level of minor complications for the patients of Groups I and II

Parameters	Group I (n = 24)	Group II (n = 33)	*P*
Obstruction of the stent- n1/n (%)			
yes	6 / 24 (25.0)	10 / 32 (31.25)	0.665
Thoracic pain - n1/n (%)			
yes	13 / 24 (54.2)	21 / 32 (66.0)	0.311
Migration of the stent - n1/n (%)			
yes	4 / 24 (16.7)	3 / 32 (9.4)	0.447

TABLE 6 - Level of major complications for the patients of Groups I and II

Parameters	Group I (n = 24)	Group II (n = 33)	*P*
Tracheo-esophageal fistula after insertion – n1/n (%)			1.000
yes	2 / 24 (8.3)	2 / 32 (6.3)	
Hemorrhage – n1/n (%)			0.501
yes	0 / 24 (0.0)	2 / 32 (6.3)	
Compression of the airways – n1/n (%)			1.000
yes	0 / 24 (0.0)	1 / 32 (3.1)	

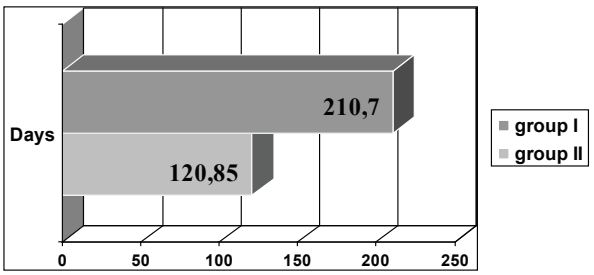
The period of effectiveness of the stent, i.e. the time period from stent introduction to the time when interventions were required due to the occurrence of complications, was measured. This period, expressed as the number of days from stent placement to the intervention, was significantly lower in the group which had not undergone cytoreductive therapy (average 63 days compared to 123 days; with variation of 0 to 222 days, compared to seven to 337) (Figure 2).



P< 0.001

FIGURE 2 - Comparison of the period of effectiveness between Groups I and II

The survival time for the two groups was compared, from the moment of introduction of the stent, until the death of the patient. The group which underwent SEMS and adjuvant cytoreductive therapy showed a higher survival rate, compared with the group without this treatment (average of 210 days, compared with 120 days; with variation of 33 to 414 days, compared with one to 584 days) (Figure 3).



P< 0.01

FIGURE 3 - Comparison of survival time between the patients of Groups I and II.

DISCUSSION

There are many available methods of palliative treatment of esophageal cancer, which include surgical, endoscopic and chemoradiation. All the above mentioned methods are effective for relieving dysphagia. However, in patients who do not generally survive for longer than six months[11,28], it is essential to alleviate those symptoms immediately after starting palliative treatment, and to ensure that the morbidity and mortality rates are as low as possible.

There are many advantages to SEMS, and these include the following: easy insertion, with success rate for placement of almost 100%[5,18,20,31,35,36,37,38,40], large internal diameter, low risk of perforation of the esophagus during the procedure, it can be used as a sole therapy and be inserted in stenoses without the need for excessive dilation of the organ, it adapts better to angled stenoses due to its malleability, it requires conscious sedation of the patient, and in general, palliation of dysphagia occurs immediately in the majority of cases. SEMS is also effective when coated occluding tracheo-esophageal fistulas with a success rate between 70% and 100%[30,37,42].

There is no consensus among the studies carried out in relation to the risk of complications of SEMS placement in patients who have undergone RT/CT treatment. It is believed that after this treatment, vasculitis and ischemia of the esophageal tissue occurs, and that the pressure exerted by the stent can produce local necrosis which can increase the rate of complications, such as migration of the stent, perforation, hemorrhage and the fistula formation[3,34,37,41]. On the other hand, stent placement with adjuvant cytoreductive therapy can ensure earlier oral food ingestion, prevent stenosis secondary to the radioactive therapy, and allow RT/CT therapy in patients with tracheo-esophageal fistula.

Kinsman et al.[14] and Siersema et al.[33] describe com-

plications rate raising such as perforation, hemorrhage and fistula formation, and increase in mortality during the procedure, for patients who have undergone prior RT/CT treatment.

A prospective study carried out by Sumiyoshi et al.[34] observed 22 patients with advanced SCC, who presented recurring dysphagia following treatment with chemoradiotherapy, and who subsequently received SEMS. Following this procedure, six out of eight patients with stageT4 tumors and neoplasic invasion of the aorta, died of massive hemorrhage due to stent placement. Those who did not have this type of complication died of causes not related to stent placement, which leads to conclusion that patients with stage T4 esophageal tumor with prior aortic invasion and RT/CT, should be carefully considered before treatment with a stent, due to the risk of death from massive hemorrhage.

Contrary to results of studies described above, Kozarek et al.[18], comparing patients who received SEMS (n=27) and patients who received conventional rigid stents (n=32) and similarly, Raijiman et al.[25,26], using the Wallstent™, in retrospective studies did not observe an increased rate of complications in the groups with prior RT/CT treatment, compared with patients who did not undergo these treatments[39].

There is some fear that the metal mesh may dangerously influence the action of the radiotherapy, increasing the risk of complications or reducing the effectiveness of the treatment. However, there is still no evidence that these facts occur. Li et al.[15] carried out in vitro study on the behavior of different commercially available metal stents made from stainless steel, cobalt-chrome league (Elgiloy) and nickel-titanium league (Nitinol), and in the form of ring (Wallstent™, Ultraflex™, Z stent™) or shell (In stent™) inserted in conjunction with the use of external radiation therapy or brachytherapy. An overdose of radiation was observed in the esophagus wall adjacent to the stent. These disturbances, caused by the presence of the SEMS, need to be recognized and studied further[17].

There are few studies in which RT/CT is used after SEMS placement. Zhong et al.[43] carried out prospective study including patients with SCC of the thoracic esophagus; 16 with combined treatment, ie SEMS and adjuvant radiotherapy (RT), and 18 with a stainless steel stent (Jiangsu Sigma™). Radiotherapy was initiated four to five days after stent placement. In this study, the author demonstrated that the metal stent had little influence on absorption and compensation effects on radiation therapy. The survival time for the group which received RT was longer (37.5% in 12 months, compared with 11.1%) and there was no difference in complications between the two groups. The author believes that SEMS placement not only alleviates dysphagia, but also guarantees oral nutrition during radiotherapy, and prevents narrowing of the tract due to edema and the formation of scar tissue. In order to reduce the complications that may occur in patients undergoing radiotherapy in conjunction with SEMS, Shin et al.[32] treated patients with stent for a temporary period, removing it after four weeks of radiotherapy. Compared with the group which kept the stent indefinitely, a lower rate of complications was observed in the group with a scheduled removal, but this was not statistically significant, and the survival rate was significantly higher in this group. The applicability of this study was to use the stent with the aim of restoring earlier oral ingestion and preventing actinic stenoses during the initial period of radiotherapy. Despite these results, there are still some reservations, since the two samples were from different periods, with the more recent group scheduled for removal of the stent being studied prospectively, and the other group being studied retrospectively.

Although there are hypothesis and studies which support the higher risk of complications in the group submitted to RT/CT, an equivalent number of studies observed no difference in the rate of complications for the two groups of patients, which leads to the conclusion that the association of these two treatments is still controversial and requires additional prospective and randomized studies.

The aim of the present study was to reduce the variations in relation to stent type, tumor histology and tumor location, when compared to other studies. It was decided to restrict this study to patients with SCC, who received just one model of SEMS and in whom the tumoral lesion and the stent were located in the position of the mid-thoracic esophagus. However, as it was a retrospective study, the criteria for selecting the patients and the cytoreductive therapy regimen were carried out by the oncology service. This may explain the differences between treatments carried out with RT/CT, before or after stent placement and the selection of patients with a higher Karnofsky Performance Status Scale that those who did undergo to combined treatment. This heterogeneity was accepted in the study after comparing the subgroup formed by patients with RT/CT before and after stent placement, and verifying that they have similar clinical and laboratory characteristics, and similar rate of complications, effectiveness and survival rates.

Among the clinical characteristics assessed, there were no statistical differences in relation to sex, race, epidemiological history, presence of fistula, regurgitation, odynophagia, BMI, albumin, hemoglobin and hematocrit. The Karnofsky Performance Status Scale, which measures the physical condition of the patient, was significantly higher (P=0.015) in Group I and the size length of the esophageal tumor was larger in Group II (P=0.049). These differences may be justified, since Group I, which was partially submitted to cytoreductive therapy before stent placement, may have undergone a reduction in the size of the tumor, providing a better physical condition and reduced tumor length.

In relation to the treatment of dysphagia, the stent used in this study led to a significant improvement after its insertion, with an average difference of more than two degrees for both groups, which indicates successful palliation of dysphagia in patients with SCC of the mid-thoracic esophagus, irrespective of whether cytoreductive treatment was administered. In relation to the cases with minor complications, even though the rate of thoracic pain

was higher than that found in the literature, all the patients who reported following stent placement were clinically controlled with analgesics, and did not require removal of the stent. For the patients in whom stent migration occurred, all them were removed or replaced by endoscopy and a second stent was inserted in three patients, replaced in one patient and nasoenteral tube was placed in two patients. In one patient it was decided not to insert a new stent, since they were able to orally ingest paste foods. Of those patients with obstruction, six underwent argon plasma coagulation treatment, two received a second stent, nasoenteral tube was placed in three patients and in five patients endoscopic dilation was carried out.

The time of effectiveness of the stent and the survival rate were significantly higher in the group with SEMS and adjuvant cytoreductive therapy. This can be explained by the fact that this group presented a higher physical´s state, according to the Karnofsky Performance Status Scale than the other group, and mainly by the RT/CT treatment itself, which can postpone infiltration to the adjacent organs that lead to patient's death.

The analysis of the results for the combination of the two treatments showed consistent improvement in the level of dysphagia in both groups, and a similarity in the levels of complications, with longer period of effectiveness of the stent and a longer survival time in the group with RT/CT. However, the need to continue this analysis should be considered, with prospective, randomized studies, and a higher number of patients, in order to agree or disagree with the findings of this study.

CONCLUSIONS

In relation to clinical condition and complications, there was no significant difference between the patients who underwent combined radiotherapy and/or chemotherapy, and those who did not. The combination of SEMS placement and adjuvant RT/CT led to a greater period of effectiveness without complication and the combined treatment led to a longer survival time.

Kamiyama G, Sakai P, Moura EGH, Ishioka S, Cecconello I, Carrilho FJ. Avaliação do emprego de prótese metálica auto-expansível no câncer avançado do esôfago em pacientes com ou sem terapia citorredutora. ABCD Arq Bras Cir Dig 2007;20(3):154-60.

RESUMO - ***Racional*** - A colocação de stent esofágico metálico e auto-expansível em pacientes com câncer esofágico avançado oferece boa paliação para disfagia e fístulas traqueoesofágicas. No entanto, a segurança do stent em pacientes submetidos à rádio e/ou quimioterapia é controversa, podendo gerar maior risco de complicações em casos onde estes dois tratamentos são utilizados em conjunto. ***Objetivo*** - Avaliar o uso de stent em pacientes com câncer médio-torácico de esôfago avançado, comparando os pacientes submetidos à terapia citoredutora aos que não foram submetidos a este tratamento, com relação a melhora da disfagia, índice de complicações, período de efetividade e tempo de sobrevivência. ***Métodos*** - Foram avaliadaos retrospectivamente 57 pacientes (16 mulheres e 41 homens, com idade média de 62 anos) com carcinoma de células escamosas avançado na região esofágica médio-torácica. Estes foram submetidos à colocação do stent metálico auto-expansível Ultraflex™, na Unidade de Endoscopia Gastrointestinal do Hospital de Clínicas da Universidade de São Paulo durante outubro de 1988 a outubro de 2004. De um total de 57 pacientes, 24 receberam terapia citoredutora adjuvante e 33 somente o tratamento através da colocação de stent. ***Resultados*** - Após a colocação do stent, houve melhora com relação a displasia em ambos os grupos; não houve diferenças com relação ao índice de complicações, como enxaquecas, dores, fístulas, obstrução e compressão das vias aéreas; o período de efetividade foi significativamente maior no grupo submetido à terapia citoredutora (média de 123 dias comparados à 63 dias), assim como no tempo de sobrevivência (média de 210 dias comparados a 120). ***Conclusão*** - Melhora estatisticamente significante foi encontrada em ambos os grupos com relação à displasia, independentemente se o paciente foi submetido ou não à terapia citoredutora adjuvante; não houve diferenças quanto ao índice de complicações entre os dois grupos e tanto o período de efetividade do tratamento com stent como o tempo de sobrevivência foram maiores no grupo com terapia citoredutora adjuvante.

DESCRITORES - Neoplasias esofágicas. Terapia combinada. Assistência paliativa. Estudo comparativo.

REFERENCES

1. Baron TH. Expandable metal stents for the treatment of cancerous obstruction of the gastrointestinal tract. N Engl J Med. 2001;344:1681–7.
2. Bartelsman JFW, Bruno MJ, Jensema AJ, Haringsma J, Reeders JWAJ, Tytgat GNJ. Palliation of patients with esophagogastric neoplasms of a covered expandable modified gianturco-z endoprosthesis: experiences in 153 patients. Gastrointest Endosc. 2000;51:134-8.
3. Bethge N, Sommer A, Kleist DV, Vakil N. A prospective trial of self-expanding metal stents in the palliation of malignant esophageal obstruction after failure of primary curative therapy. Gastrointest Endosc. 1996;44:283-6.
4. Chan ACW, Shin FG, Lam YH, Ng EKW, Sung JJY, Lau YW, Chung SCS. A comparison study on physical properties of self expandable esophageal metal stents. Gastroint Endosc. 1999;49:462-5.
5. Christie NA, Buenaventura PO, Fernando HC, Nguyen NT, Weigel TL, Ferson PF, Luketich. Results of expandable metal stents for malignant esophageal obstruction in 100 patients: short-term and long term follow-up. Ann Thorac Surg. 2001;71:1797–802.
6. DeMeester TR, Barlow AP. Surgery and current management for cancer of the esophagus and cardia: part II. Curr Probl Surg. 1988;541–97.
7. Dorta G, Binek J, Blum AL, Buhler H, Felley CP, Koelz HR, Lammer F, Lang C, Meier R, Meyenberger C, Meyer-Wyss B, Michetti P, Protiva P, Sheurer U, Weber B, Wiesel P, Vogel S. Comparison between esophageal wallstent and ultraflex stents in the treatment of malignant stenoses of the esophagus and cardia. Endoscopy. 1997;29:149–54.

8. Funami Y, Tokumoto N, Miyauchi H, Kuga K, Sato S. Improvement of oral ingestion in patients with inoperable esophageal cancer treated with radiotherapy, chemotherapy and placement of a self-expanding nitinol stent. Dis Esophagus. 1999;12:289–93.
9. Gevers A M, Macken E, Hiele M, Rutgeerts P. A comparison of laser therapy, plastic stents, and expandable metal stents for palliation of malignant dysphagia in patients without a fistula. Gastroint Endosc. 1998;48:383–8.
10. Ginsberg GG. Endoscopic palliation of dysphagia in esophageal cancer. Esophageal Cancer. 2000;25–31.
11. Gore RM. Esophageal cancer - clinical and pathologic features. Radiol Clin N Am. 1997;35:243–63.
12. Homs MY, Hansen BE, Blankenstein MV, Haringsma J, Kuipiers EJ, Siersema PD. Prior radiation and/or chemotherapy has no effect on the outcome of metal stent placement for oesophagogastric carcinoma. Eur J Gastroenterol Hepatol. 2004;16:163-70.
13. Kinsman KJ, DeGregorio BT, Katon RM, Morrison K, Saxon RR, Keller FS, Rosch J. Prior radiation and chemotherapy increase the risk of life-threatening complications after placement of metallic stents for esophagogastric malignancy. Gastrointest Endosc. 1996;43:196-203.
14. Li X A, Chibani O, Greenwald B, Suntharalingam M. Radiotherapy dose pertubation of metallic esophageal stents. Int J Radiation Oncology Biol Phys. 2002;54:1276–85.
15. Ludwig D, Dehne A, Burmester E, Wiedemann GJ, Stange EF. Treatment of unresectable carcinoma of the esophagus or the gastroesophageal junction by mesh stents with or without radiochemotherapy. Int J Oncol. 1998;13:583-8.
16. Kaneko K, Ito H, Konishi K, Kurahashi T, Katagiri A, Katayose K, Kitahara T, Ohtsu A, Mitamura K. Implantation of self-expanding metallic stent for patients with malignant stricture after failure of definitive chemoradiotherapy for T3 or T4 esophageal squamous cell carcinomas. Hepatogastroenterol. 2002;49:699–705.
17. Kozarek R A, Raltz S, Brugge WR, Schapiro RH, Waxman I, Boyce W, Baillie J, Branch S, Stevens P, Lightdale CJ, Lehman GA, Benjamin S, Fleischer DE, Axelrad A, Kortan P, Marcon N. Prospective multicenter trial of esophageal Z-stent placement for mallignant dysphagia and tracheoesophageal fistula. Gastrointest Endosc. 1996;44:562–7.
18. Kubba AK, Krasner N. An update in the palliative management of malignant dysphagia. Eur J Surg. Oncology. 2000;26:116–29.
19. May A, Hahn EG, Ell C. Self-expanding metal stents for palliation of malignant obstruction in the upper gastrointestinal tract (comparative assessment of three types implemented in 96 implantations). J Clin Gastroenterol. 1996;22:261–6.
20. May A, Selmaier M, Hochberger J, Gossner L, Muhldorfer S, Hahn EG, Ell C. Memory metal stents for palliation of malignant obstruction of the oesophagus and cardia. Gut. 1995;37:309–13.
21. Muto M, Ohtsu A, Miyata Y, Shioyama Y, Boku N, Yoshida S. Self-expandable metallic stents for patients with recurrent esophageal carcinoma after failure of primary chemoradiotherapy. Jpn J Clin Oncol. 2001;31:270–4.
22. Raijman I. Endoscopic management of tracheoesophageal fistulas. Endoscopy in context: a multidisciplinary approach. ; 45–6. DDW: May, 2001.
23. Raijiman I, Kortan P, Haber GB, Marcon NE. Contrast injection to identify tumor margins during esophageal stent placement. Gastrointest Endosc. 1994;40:222–4.
24. Raijiman I, Siddique I, Lynch P. Does chemoradiation therapy increase the incidence of complications with self-expanding coated stents in the management of malignant esophageal strictures? Am J Gastroenterol. 1997. 92:2192–6.
25. Raijiman I, Siddique I, Ajani J, Lynch P. Palliation of malignant ysphagia and fistulae with coated expandable metal stents: experience with 101 patients. Gastroint Endosc. 1998;48:172–8.
26. Reddy AV, Alwair H, Trewby PN. Fractured esophageal nitinol stent: report of two fractures in the same patient. Gastrointest Endosc. 2003;57:138–9.
27. Reed CE. Comparison of different treatments for unresectable esophageal câncer. World J Surg. 1995;19:828–35.
28. Rozanes I, Poyanli A, Acunas B. Palliative treatment of inoperable malignant esophageal strictures with metal stents: one center's experience with four diferent stents. Eur J Radiol. 2002;43:196-203.
29. Sarper A, Oz N, Cihangir C, Demircan, Isin E. The efficacy of self-expanding metal stents for palliation of malignant esophageal strictures and fistulas. Eur J Cardio-Thor Surg. 2003;23:794–8
30. Segalin A, Bonavina L, Carazzone A, Ceriani C, Peracchia A: Improving results of esophageal stenting: a study on 160 consecutive unselected patients. Endoscopy. 1997;29:701–9.
31. Shin JH, Song HY, Kim JH, Kim SB, Lee GH, Park SI, Han YM, Kang W. Comparison of temporary and permanent stent placement with concurrent radiation therapy in patients with esophageal carcinoma. J Vasc Interv Radiol. 2005;16:67–74.
32. Siersema PD, Hop WCJ, Dees J, Tilanus HW , Blankenstein MV. Self-expandable metallic coated stents versus late protheses for esophagogastric cancer with special reference to prior radiation and chemotherapy: a controlled, prospective study. Gastrointest Endosc. 1998;47:113–20.
33. Sumiyoshi T, Gotoda T, Muro K, Rembacken B, Goto M, Sumiyoshi Y, Ono H, Saito D. Morbidity and mortality after self-expandable metallic stent placement in patients with progressive or recurrent esophageal cancer after chemoradiotherapy. Gastrointest Endosc. 2003;57:882-5.
34. Vakil N, Morris AI, Marcon N, Segalin A, Peracchia A, Bethge N, Zuccaro G, Bosco JJ, Jones WF. A prospective, randomized, controlled, trial of covered expandable metal stents in the palliation of mallignant esophageal obstruction at the gastroesophageal junction. Am J Gastroenterol. 2000;96:1791–6.
35. Xinopoulos D, Dimitroulopoulos D, Moschandrea I, Skordilis P, Bazinis A, Kontis M, Paraskevas I, Kouromalis E, Paraskevas E. Natural course of inoperable esophageal câncer treated with metallic expandable stents: quality of life and cost - effectiveness analysis. J Gastroenterol Hepatol. 2004;19:1397–402.
36. Weigert N, neuhaus H, Rosch T, Hoffmann W, Dittler HJ, Classen M. Treatment of esophagorespiratory fistula with silicone-self-expandable metallic coated stents. Gastroint Endosc. 1995;41:490–6.
37. Wengrower D, Fiorini A, Valero J, Waldbaun C, Chopita N, Landoni N, Judchack S, Goldin E. Esophagocoil: long-term results in 81 patients. Gastrointest Endosc. 1998;48:376–82.
38. Won JH, Lee JD, Wang HJ, Kim GE, Kim BW, Yim H, Han KS, Park CH, Joh CH, Kim KH, Park KB, Shin KM. Self-expandable covered metallic esophagel stent impregnated with beta-emitting radionuclide: an experimental study in canine esophagus. Int J Radiation Oncology Biol Phys. 2002;53:1005–13.
39. Wu WC, Katon RM, Saxon RR, Barton RE, Uchida BT, Keller FS, Rosh J. Silicone-covered self-expanding metallic stents for the palliation of malignant esophageal obstruction and esophagorespiratory fistulas: experience in 32 patients and a review of the literature. Gastrointest Endosc. 1994;40:22-33.
40. Yakami M, Mitsumori M, Sai H, Nagata Y, Hiraoka M, Nishimura Y. Development of severe complications caused by stent placement followed by definitive radiation therapy for T4 esophageal câncer. Int J Clin Oncol. 2003;8:895–8.
41. Yang HS, Zhang LB, Wang TW, Zhao YS, Liu L. Clinical application of metallic stents in treatment of esophageal carcinoma. World J Gastroenterol. 2005;11:451-3.
42. Ziberstein B, Pinotti HW, Cecconello I, Ibraihim RE. Tratado de clínica cirúrgica do aparelho digestivo – câncer de esôfago. In: Pinotti, HW., editor. Tratado de clínica cirúrgica do aparelho digestivo. São Paulo: Atheneu. 1994;415.
43. Zhong J, Wu Y, Xu Z, Liu X, Xu B, Zhai Z. Treatment of medium and late stage esophageal carcinoma with combined metal stenting and radiotherapy. Chin Med J. 2003;116:24–8.

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