INTRODUCTION

Recently the frequency of abdominoperineal resection for rectal cancer is diminished in favor of sphincter-preserving operation. These operations offer a much better quality of life, but related to significant morbidity and mortality, where the anastomotic dehiscence is the primary concern. Anastomotic leakage is defined as a communication between the intra- and extraluminal compartments owing to a defect in the integrity of the intestinal wall at the anastomosis between the colon and rectum or the colon and anus. Leakage rates from 3% to > 20% leading to substantial postoperative morbidity and mortality have been reported (Bertelsen et al., 2010; Eberl et al., 2008). It is difficult to predict which patients will develop an anastomotic leak, and such leaks may occur even when the anastomosis is technically sound or when the risk factors for leakage are absent.

The incidence of anastomotic leakage is connected to the level of anastomosis (Marusch et al., 2002), surgical expertise (Dehni et al., 1998) and the method of reconstruction (Law et al., 2000). In the presence of generalised abdominal sepsis mortality rates of around 50% are reported (Grabham et al., 1995; Karanjia et al., 1994) and those surviving the immediate consequences of anastomotic failure can expect a poor functional result. Protective ileostomy is used to prevent anastomosis leaking in low anterior resection, but its value is still controversial. This study aims to evaluate the role of protective ileostomy in preventing anastomose leaking and the need of reoperation. This is a retrospective study of 217 cases anterior resection of middle and lower rectum. All the data was collected in the IIId Clinic of Surgery at Mother Theresa Hospital, from January 2005 to October 2015. Clinical decision, for the need of protective jejunostomy, included: tumor localization, operatory hemorrhage, lymph node removal, simultaneous resection of other organs and the level of anastomose, previous chemoradiotherapy, etc. Anastomotic leaks were found in 21 patients, or 9.7%. It was found a mortality rate of about 1.8% or 4 patients. Protective ileostomy was realized in 76 patients, of whom 9 had anastomose leak. The other 12 cases of anastomose leak were observed in patients who had not a protective ileostomy. Reoperation for fistula was performed in 10 cases, 8 of them did not had a protective stoma. Anterior resection, as the preferred treatment of low rectum cancer, has a low mortality and acceptable morbidity. As regards the value ileostomy in preventing anastomose leakage, there was no statistically difference between the two groups, but it might minimize the consequences and reduces the need for urgent reoperation.

Key words: Anastomotic leakage, Low anterior resection, Protective stoma, Rectal cancer, Total mesorectal excision.
leakage (Jung et al., 2008; Law et al., 2007; Ptok et al., 2007).

The introduction of total mesorectal excision (TME), has been a major advance in the surgical strategy for rectal cancer resulting in a reduction in local recurrence without adjuvant therapy (Karanjia et al., 1994; Mealy et al., 1992; Antonsen and Kronborg, 1987; Matthiessen et al., 2004). In radically operated patients the local recurrence rate with TME after 5 and 10 years is reported to be less than 10 % and the 5-year survival rate is 80 %. In rectal cancer surgery following the principles of TME, the distal rectum is divided 1–2 cm above the dentate line for low and mid rectal cancers, aiming at a free distal resection margin of at least 2 cm of rectal wall. In high rectal tumors the mesorectum is divided 5 cm below the tumor leaving a variable length of rectum (PME). Such a resection potentially endangers the blood supply to the residual distal rectum and leaves a large pelvic space for accumulation of clot and fluid with concomitant risk of pelvic infection. This may contribute to a high frequency of anastomotic problems with consequent septic complications. The prevention of septic complications caused by anastomotic leaks after rectal surgery is a major goal of the dedicated colorectal surgeon. There are several studies (Schmidt et al., 2003; Makela et al., 2003; Schrock et al., 1973) suggesting to fashion a protective stoma in patients after TME, with adjuvant/neoadjuvant treatment, obese patients and after technical demanding procedures.

Many solutions have been used to prevent or diminish anastomotic leakage, such as mechanical bowel preparation, drains, and intra-luminal devices. Some surgeons use a protective stoma after LAR to prevent anastomotic leakage hoping that while fecal diverting will keep the anastomosis free of material, leakage will be less likely. While other surgeons have reported that covering the protective stoma had no influence on anastomotic leakage and reoperation rates, the further complications that can be caused by the stoma itself should not be ignored, as they include discomfort and inconvenience, high output with consequent dehydration, and anastomotic complications at the stoma closure site (Bakx et al., 2004; Cipe et al., 2012; Hallböök et al., 2002; Kaiser et al., 2008; Laurent et al., 2006; Law et al., 2002; van Westreenen et al., 2012). So, although protective stomas are widely used in LAR for rectal cancer, it remains unclear whether such protective stomas are useful for patients. Therefore, we performed this study to investigate whether a protective stoma affects the outcomes of patients undergoing LAR for rectal cancer.

Patients and Methods

We analyzed the data according to the type of rectal cancer surgery, whether a protective stoma was applied, the overall mortality and morbidity, the number of clinically relevant anastomotic leakages, and the number of reoperations necessitated through a leak. The analyzed patients were considered clinically relevant even when anastomotic leakage was only radiologically detected, defined as the presence of abscess formation, in association with peritonitis and clinical signs such as fever, leukocytosis, and a tender abdomen.

TME appears to have clinically measurable short term advantages in patients with primary resectable rectal cancer. We excluded from this study the patients who had a palliative operation, no TME, or clear margins. Clinical decision, for the need of protective stoma, included: tumor localization, operatory hemorrhage, lymph node removal, simultaneous resection of other organs and the level of anastomose.

The analyzed data was collected from the patients operated to our clinic from January 2005 to January 2015 and contained 217 patients. All these patients had a low anterior resection (LAR), for a rectal cancer located in the middle and lower rectum, and meet the above criteria.

Clinical data was collected retrospectively, and statistically analyzed with the chi-squared test ($\chi^2$), to evaluate the differences between different groups of patients. P values < 0.05 were considered statistically significant.

RESULTS

There were 217 patients who had a low anterior resection, 163 of which had an anastomosis realized by a staple device, and the other 54 patients by hand. First we observed the differences between these two groups of patients. There were 21 cases of anastomotic leak, or 9.7% in total. We found 16 cases of anastomotic leakage in the first group of patients (Stapled), and other 5 cases in the second group where the anastomosis was performed by hand. The data collected from both groups was confronted using chi-squared test. The $\chi^2$ value was 0.014 and $P=0.95$. There was found no statistical difference at $P<0.95$ between two groups. Similar risk of anastomosis leakage was found in both groups.

The extracted literature can be broadly divided into 3 categories: several authors advocate a selective usage of defunctioning stomas, whereas some clearly reject, and some others suggest routine fecal diversion. Recent studies have shown that a diverting stoma minimizes morbidity and complications but does not prevent the leakage itself. We also confronted the group of patients with LAR that had a protective stoma during the first operation with the other group of patients who did not. There were 76 patients in which a protective stoma was performed, and 9 cases of anastomotic leakage in this group. The other 141 patients did not have a protective stoma in the first operation. We found 12 cases of anastomotic leak in this group. Chi-squared test was
used, to confront both groups for differences in anastomotic leakage. \( \chi^2 \) value was calculated 0.627, corresponding to a P=0.5. Considering these data, there was not observed any statistical difference at P<0.95 between both groups related to anastomotic leakage.

Even if it seems that protective stoma does not really “protect” anastomose from leakage, we took in consideration the necessity of a second operation in the patients who had an anastomotic failure. From the 9 patients with anastomose leak that had a protective stoma in the first operation, only 2 had the necessity of a second operation the others was resolved with a conservative treatment which consisted in antibiotics and external drainage. While in the other group of patients with no protective stoma, there were 8 patients who underwent to a second operation. The other 4 cases were resolved conservatively. Confronting these two groups we calculated \( \chi^2 \) value 4.073 corresponding to a P=0.044. There was a significant statistical difference between the groups at p<0.05, regarding the necessity of a second operation.

DISCUSSION AND CONCLUSIONS

Low anterior resection with total mesorectal excision (TME) is the treatment of choice in patients with cancer of middle and low rectum (Wibe et al., 2003). Considering the incidence of rectal cancer, the improvements in medical instruments, and the higher requirements of patients regarding quality of life, low anterior rectal resection has become the primary low sphincter-preserving procedure. However, this procedure is related to an increased risk of anastomotic leakage (Peeters et al., 2005). The use of a protective stoma in LAR has been considered to decrease the leakage rate and its fatal consequences by keeping the distal anastomosis relatively “clean” and reducing the intraluminal pressure of the bowel (Rullier et al., 2005; Law and Chu, 2004; Matthiessen et al., 2004; Chen et al., 2012). Also, a protective stoma can mitigate its inherent consequences (Moran, 2010). Nonetheless, the value of a protective stoma has been the subject of controversy for many years.

Related to of our findings, the use of a protective stoma is an effective approach for reducing the rate of reoperations required for anastomotic leakage, in patients who did not had it in first operation. The morbidity associated with protective stoma and the complications of stoma closure are negligible compared morbidity and mortality of the reoperation in these conditions. We did not find any advantage of protective stoma related to the rate of anastomotic leakage, so no routine use of it can be advised. Fecal diversion requires the patient to undergo two surgeries and the morbidity of the second operation should be considered, because a protective stoma does not reduce the leakage rate after LAR. Previous publications have reported that the overall leakage and reoperation rates were similar in patients with or without a protective stoma (Gastinger et al., 2005). In addition, ostomy construction and closure is associated with considerable morbidity and increased costs (Tsunoda et al., 2008). The potential disadvantages of a protective stoma include the need for another operation, a longer hospital stay, and ostomy-related complications, such as prolapse, retraction, necrosis, stenosis, peristomal abscess, parastomal hernia, and skin problems. Therefore, the benefits of a protective stoma in decreasing the rate of anastomotic leakage must be balanced against the morbidity of its construction and closure. Furthermore, even when a non-functioning stoma is constructed, there remains a considerable risk of anastomotic leakage (Pakkastie et al., 1997). Thus, the benefits conferred by a protective stoma have not been unequivocally demonstrated. Patients who should be considered for a protective stoma are the so-called high-risk patients, anyway anastomotic leakage is unpredictable, as it can also occur in patients with no obvious risk factors. Possible factors contributing to an increased leakage rate include the reduced blood supply of the anorectal remnant and the large pelvic space after TME, which may predispose a patient to fluid accumulation and pelvic infection (Ng et al., 2006). Symptomatic anastomotic leakage is the most feared complication and has been reported to occur in 1% to 24% of patients (Law and Chu, 2004); when present, the associated risk of postoperative mortality is increased to 6% to 22% (Matthiessen et al., 2004).

Overall, this analysis has certain limitations. First, there was only a small number of patients available for inclusion. Second, only patients undergoing elective surgery were taken in consideration, and third, surgeons relied on their personal experiences to predict the patients who were at high risk of an anastomotic leakage, which may have been inaccurate and is suggestive of a potential selection bias among those who underwent stoma formation.

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