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Original Article

Inter sphincter rectal resection with and without Malone ante grade continence enema in cases with low rectal cancer: A randomized, prospective, single-blind, clinical trial

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Abstract

Background: Fecal incontinence is the main morbidity of inter-sphincteric resection (ISR) in ultra-low rectal cancer. Malone Ante grade Continence Enema (MACE) has been proposed for these patients. We aimed to compare the quality of life outcomes in cases with ultra-low rectal cancer who had undergone ISR±MACE.

Methods: The current randomized clinical study was accomplished for two years from December 2016 to February 2018 in Imam Khomeini Hospital (Sari City, I.R.Iran) on 30 patients (15 in each group) with rectal cancer. The inclusion criteria of the study were stage 1 and 2a of low rectal cancer with type 2 and 3 of Rullier's classification, those who received neoadjuvant chemo radiotherapy. The exclusion criteria were comorbidity diseases, immune deficiency, poor follow-up. The follow-up period was one year. The Quality of Life (Qol) was reported as primary endpoint. The EORTC QLQ-C30 score and Wexner questionnaires were used. SPSS Version 22 was used. A *p*-value less than 0.05 was considered statistically significant.

Results: The mean age of patients was 56.23±8.72 years. The overall Qol score was better in the ISR-MACE (P=0.023). The overall Qol was lower in women than in men in both groups. Low anterior resection syndrome score was lower in the ISR plus MACE group than the ISR group (P=0.030). The Wexner score revealed better scores in the ISR with MACE group than the ISR without MACE group (p<0.0001).

Conclusion: Patients who underwent ISR plus MACE surgery had better defecation control and better quality of life than patients without MACE.

Keywords: Inter-sphincteric resection, Rectal cancer, Quality of life

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Colorectal cancer has become a major medical and social problem since the beginning of the 21st century, with nearly 44,180 new rectal malignancy patients reported in the United States (1, 2). Generally, the rectal cancer survival rate has improved (3, 4). Surgical morbidity is a problem that changes the patients' lifestyle and quality of life (QoL). Almost, rectal cancer procedure requires colostomy, especially for very low rectal cancer cases who need Abdomino-Perineal Resection (APR). The presence of a colostomy is one of the most important surgical morbidities that can negatively affect the patients in the long time. Psychological complications such as anxiety about the bad smell and leakage of exhalation material or appearance of stoma from underwear that attracts the attention of others are the most important negative effects. About 25% of patients with stoma suffer from psychological disorders, including depression and anxiety, and other negative mood disorders (5).

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quality-of-life measurements, the research community and the number of samples examined. We believe that women have a central role in the family. Their greater responsibility towards the family and the caring their children cannot take over this responsibility following disease condition and the long stages of treatment, which causes tensions and psychological stresses in them.

Recent studies have shown a decline in the functional status with quality of life associated with health in colorectal cancer patients although this relationship may be weaker in long-term survivors of cancer(19). A recent study has shown lower pre-operative functional status with lower physical scores using QLQ-C30/CR38 and CF-12 questionnaires (20, 21). Based on the EORTC QLQ-C30 questionnaire, role, cognitive, and functional status in Azizi et al.'s study (13) received the highest scores (100, 100, and 93) in association with appendicostomy.

In the present study, LARS score was lower in the ISR plus MACE group. Major LARS was reported in half of the subjects in the ISR group and one third of ISR plus MACE patients. It seems that colonic irrigation using MACE could decrease the LARS symptoms in patients who had undergone LAR using ISR procedure. LARS was very commonly reported after low anterior rectal resection and improved during 2 postoperative years, but it persisted longer in nearly 60% of patients, 50% of whom had the major form. A minority of cases had access to several therapeutic strategies available such as motility drugs colonic irrigations (e.g. MACE), and sacral neuro-modulation (22). Sacral nerve stimulation (SNS) in adults with fecal incontinence who had not responded to medical therapy resulted in > 50% improvement in symptoms in approximately 80% of patients. According to recent reviews, SNS for fecal incontinence in LARS has had success rates comparable to its use for other types of fecal incontinence (23, 24). Further surgery and hospitalization cost was reported in the ISR + MACE group patients in our study. Since MACE procedure increases the costs and surgery duration to be done in all patients with low rectal cancer, it is recommended that this procedure should be performed on demand when incontinence and LARS are not treated otherwise. The strengths of our study are the prospective data collection, the use of a validated questionnaire, and the high rate of questionnaire completion by the patients. However, there are also limitations. First, the sample size of patients was relatively small. Second, our 1-year follow-up period was relatively short. Third, baseline overall QoL score was added to the study, retrospectively. Fourth, no objective measurement of bowel function such as anorectal manometry was performed. As the information available about MACE for patients with early-stage rectal cancer treated with MACE at the time of the study design was zero, no power calculation was performed for these outcomes. Despite these limitations, the results of this trial should be used in future studies comparing the outcomes of ISR and MACE with other treatment modalities. In conclusion, in our prospective trial of patients with early stage (T1-2N0, T3N0) low rectal cancer treated with ISR plus MACE, the functional score was similar to the ISR alone patients one year after the surgery.

However, during the same postoperative period, patients reported a significant decrease in nausea and vomiting domains and LARS score of the ISR plus MACE patients. Overall, QoL in ISR plus MACE patients was better than those without MACE. Female sex may have an impact on QOL outcome. Given all the above, it is best to perform an appendicostomy on demand in the second procedure via McBurney's incision when incontinence and LARS are not treated otherwise.

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