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None declared.

Efficacy and safety of preoperative radiotherapy versus chemoradiotherapy in advanced rectal cancer: A randomized controlled meta-analysis

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Review question / Objective: **Rectal cancer is one of the most common malignant tumours of the gastrointestinal system, ranking 3rd in global incidence of malignant tumours; furthermore, the incidence has been increasing in recent years. The 5-year survival rate of traditional surgical treatment for rectal cancer is less than 50%, and the postoperative recurrence rate remains high even when combined with postoperative CRT. Recently, a large number of studies have shown that preoperative radiotherapy (RT) and preoperative chemoradiotherapy (CRT) can reduce the tumour stage, increase resection and anal-preserving rates, reduce the local recurrence rate, and improve the quality of life of patients with rectal cancer. Compared with postoperative adjuvant therapy, preoperative adjuvant therapy for rectal cancer can reduce tumour volume and tumour stage, facilitate surgical resection, and enhance the anal-preserving rate for low rectal cancer. Therefore, comprehensive preoperative treatment based on neoadjuvant RT or neoadjuvant CRT has been regarded as the standard treatment for locally advanced rectal cancer. Nevertheless, the results of neoadjuvant RT and neoadjuvant CRT in various clinical trials are inconsistent. Accordingly, in this study, randomized controlled trials (RCTs) of neoadjuvant RT and neoadjuvant CRT for the treatment of locally advanced rectal cancer were systematically examined by meta-analysis to provide evidence-based data for clinical treatment and related research.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 September 2021 and was last updated on 13 September 2021 (registration number INPLASY202190035).

INTRODUCTION

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years. The 5-year survival rate of traditional surgical treatment for rectal cancer is less than 50%, and the postoperative recurrence rate remains high even when combined with postoperative CRT. Recently, a large number of studies have shown that preoperative radiotherapy (RT) and preoperative chemoradiotherapy (CRT) can reduce the tumour stage, increase resection and anal-preserving rates, reduce the local recurrence rate, and improve the quality of life of patients with rectal cancer. Compared with postoperative adjuvant therapy, preoperative adjuvant therapy for rectal cancer can reduce tumour volume and tumour stage, facilitate surgical resection, and enhance the anal-preserving rate for low rectal cancer. Therefore, comprehensive preoperative treatment based on neoadjuvant RT or neoadjuvant CRT has been regarded as the standard treatment for locally advanced rectal cancer. Nevertheless, the results of neoadjuvant RT and neoadjuvant CRT in various clinical trials are inconsistent. Accordingly, in this study, randomized controlled trials (RCTs) of neoadjuvant RT and neoadjuvant CRT for the treatment of locally advanced rectal cancer were systematically examined by meta-analysis to provide evidence-based data for clinical treatment and related research.

Condition being studied: The safety and efficacy of preoperative radiotherapy (RT) combined with surgery and preoperative chemoradiotherapy (CRT) combined with surgery for locally advanced rectal cancer.

METHODS

Participant or population: Patients with advanced rectal cancer.

Intervention: Preoperative radiotherapy combined with surgery.

Comparator: Preoperative chemo-radiotherapy combined with surgery.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: (1) The study was a randomized controlled trial; (2) the language is English; (3) the type of primary hernia was a direct hernia, indirect hernia, unilateral hernia, or hernia; (4) the full text of the published literature can be retrieved; (5) mesh-plug herniorrhaphy and Lichtenstein herniorrhaphy were used in the trial and control group, respectively, and the two were compared; and (6) the outcomes included operation time, groin discomfort, haematoma, seroma, infection, time to return to normal activities, incidence of postoperative chronic pain, recurrence rate, and at least one of the outcomes included in the literature.

Information sources: PubMed, EMBASE and Cochrane Library.

Main outcome(s): The pathological complete response rate, lymph node negative rate, R0 resection rate, 5-year local recurrence rate, 5-year survival rate, anal-preserving rate, anastomotic fistula rate, and grade III/IV adverse reaction rate.

Quality assessment / Risk of bias analysis: The Cochrane bias risk assessment tool was used to evaluate the quality of the RCTs by including items such as random sequence, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias.

Strategy of data synthesis: After data extraction, RevMan 5.3 software provided by Cochrane Collaboration Network was used for meta-analysis. Heterogeneity analysis was performed on each outcome index. If $P \geq 0.05$ and $I2 < 50\%$, a study was considered to be non-statistically heterogeneous, and a fixed effect model was used; if P50%, a study was considered to be statistical heterogeneous, and a random effect model was used. The odds ratio (OR) and 95% confidence interval (CI) were employed as index analysis statistics for dichotomous variables and the mean difference (MD) and 95% confidence interval (CI) as index analysis statistics for continuous variables.

Subgroup analysis: If sufficient data were available, we conducted subgroup analysis and sensitivity analysis to explore sources of heterogeneity.

Sensitivity analysis: Sensitivity analyses were performed by excluding each study individually.

Country(ies) involved: China.

Keywords: rectal cancer; radiotherapy, chemoradiotherapy, meta-analysis.

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