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Radiotherapy and Oncology 72 (2004) 15–24

RADIOTHERAPY
& ONCOLOGY
JOURNAL OF THE EUROPEAN SOCIETY FOR
THERAPEUTIC RADIOLOGY AND ONCOLOGY

www.elsevier.com/locate/radonline

Sphincter preservation following preoperative radiotherapy for rectal cancer: report of a randomised trial comparing short-term radiotherapy vs. conventionally fractionated radiochemotherapy[☆]

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Received 27 August 2003; received in revised form 21 November 2003; accepted 30 December 2003

Available online 12 February 2004

Abstract

Background and purpose: The aim was to verify whether preoperative conventionally fractionated chemoradiation offers an advantage in sphincter preservation in comparison with preoperative short-term irradiation.

Patients and methods: Patients with resectable T3–4 rectal carcinoma without sphincters' infiltration and with a lesion accessible to digital rectal examination were randomised into: preoperative 5 × 5 Gy short-term irradiation with subsequent total mesorectal excision (TME) performed within 7 days or chemoradiation to a total dose of 50.4 Gy (1.8 Gy per fraction) concomitantly with two courses of bolus 5-fluorouracil and leucovorin followed by TME after 4–6 weeks. Surgeons were obliged to base the type of operation on the tumour status at the time of surgery.

Results: Between 1999 and 2002, 316 patients from 19 institutions were enrolled. The sphincter preservation rate was 61% in the 5 × 5 Gy arm and 58% in the radiochemotherapy arm, $P = 0.57$. The tumour was on average 1.9 cm smaller ($P < 0.001$) among patients treated with chemoradiation compared with short-term schedule. For patients who underwent sphincter-preserving procedure, the surgeons generally followed the rule of tailoring the resection according to tumour downsizing; the median distal bowel margin was identical (2 cm) for both randomised groups. However, in the chemoradiation group, five patients underwent abdominoperineal resection despite clinical complete response.

Conclusions: Despite significant downsizing, chemoradiation did not result in increased sphincter preservation rate in comparison with short-term preoperative radiotherapy. The surgeons' decisions were subjective and based on pre-treatment tumour volume at least in clinical complete responders.

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Keywords: Rectal cancer; Sphincter preservation; Preoperative radiotherapy

[☆] Presented at the 21st Annual European Society for Therapeutic Radiology and Oncology Meeting, Praha, Czech Republic, 17–21 September 2002.

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