**Do all stage 3 rectal cancer patients downstaged following neoadjuvant chemoradiotherapy and TME require adjuvant chemotherapy?**

Introduction

No broad consensus exists for the adjuvant management of patients with rectal cancer who are down-staged following neoadjuvant chemoradiotherapy(CRT) and radical surgery. This study evaluated clinical outcomes of adjuvant chemotherapy versus surveillance in this patient cohort in a real-world setting across multiple sites.

Methods

We retrospectively evaluated the records of radically resected rectal cancer patients who had (CRT), were downstaged and then offered either surveillance(S) or adjuvant chemotherapy(AC) based on clinician’s judgement. Data was extracted from the electronic patient record (EPR) from 4 NHS trusts within Kent, UK, that covers a population of 1.8 million people.

Results

589 patients were identified between 1 Jan 2014 and 31 Dec 2019. Of these, 149 patients who had M0  disease and were later downstaged at surgery were assessed. Median age was 67 years(24-89). All patients had CRT (45Gy in 25 plus Capecitabine/5FU or 25Gy in 5). They then had total mesorectal excision surgery. 94 (63%) had AC, (Capecitabine/5FU, CAPOX or FOLFOX) while 55 (37%) were kept under surveillance. Patients in the AC group had a lower age (median 62 vs 68 years, *p*=0.0045); higher baseline tumour stage (*p*=0.012); longer time between RT and surgery (89 vs 86 days, *p*=0.027); higher rates of EMVI (70 vs 41%, *p*=0.00345); higher rates of threatened/positive circumferential-resection margin (83 vs 65%, *p*=0.01481), and a higher post-op tumour stage (*p*<0.0001). There was no significant difference in tumour grade, distance from anal verge, tumour regression grade, post RT staging, and resection margin status. Overall, there was no survival difference between AC & S with PFS of 70% vs 75%(*p*=0.1233) and 2-year OS of 91% vs 98% *(p*=0.1661), table1. Higher tumour grade at diagnosis*(p*=0.014), post-op stage *(p*=0.042) and resection margin(*p*=0.003) were associated with increased risk of death, whilst the other variables were not.

Conclusion

Results in our real-world cohort did not find any significant benefit of adjuvant chemotherapy following neoadjuvant CRT and surgery. Surveillance may avoid chemotherapy related toxicities without compromising survival. Randomised clinical trials are necessary to address this important issue.