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Citation for final published version:

Fokas, E., Spezi, E., Patel, N., Hurt, C., Nixon, L., Chu, K., Joseph, G., Staffurth, J., Abrams, R. and Mukherjee, S. 2016. P-222 Analysis of tumour contours and radiotherapy planning of 'on-trial' patients undergoing chemoradiotherapy (CRT) in SCALOP trial: does pre-trial Radiotherapy Quality Assurance (RTQA) improve the quality of 'on-trial' radiotherapy? Annals of Oncology 27 (sup. 2), ii64.3-ii65. 10.1093/annonc/mdw199.214

Publishers page: http://dx.doi.org/10.1093/annonc/mdw199.214

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Analysis of tumour contours and radiotherapy planning of "on-trial" patients undergoing chemoradiotherapy (CRT) in SCALOP trial: does pre-trial Radiotherapy Quality Assurance (RTQA) improve the quality of "on-trial" radiotherapy?

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Background: The SCALOP trial tested the safety and efficacy of gemcitabine (Gem) versus capecitabine (Cap) based CRT following induction chemotherapy and showed that GemRT was associated with greater toxicity and worse survival¹. The evaluation of investigator-delineated volumes and plan assessment from the pretrial RTQA program using a single benchmark case showed considerable variation in gross tumour volume (GTV) outlines but no major deviations in RT planning². The contours and RT planning of on-trial patients have now been centrally reviewed and is presented.

Materials and Methods: Retrospective central review of planning CT scans of patients undergoing RT as part of SCALOP trial was undertaken. The central review team consisted of two radiation oncologists and a radiologist. Only IV-contrasted planning scans of good diagnostic quality were included, and tumours were reoutlined (gsGTV). Planning target volume (gsPTV) was generated as per trial protocol. The accuracy of investigators' GTV (iGTV) and PTV (iPTV) was compared qualitatively and geometric analyses were performed using the Jaccard Conformity Index (JCI) and Geographical Miss Index (GMI). The RT plans of on-trial patients were also centrally reviewed against pre-defined protocol constraints.

Results: Planning scans from 64 (of 74 randomised patients) were suitable for analysis. The median whole volume JCI (\pm SD) of the iGTVs (compared to gsGTV) was 0.6 ± 0.19 , and the median GMI(\pm SD) was 0.1 ± 0.2 . In 1 case, the tumour was completely missed by the investigator in 3 other cases, GMI was >0.5 (implying at least 50% tumour miss). For iPTVs, the median JCI was 0.8 ± 0.17 and the median GMI was 0.04 ± 0.13 . There was good compliance with dose constraints and major deviations occurred in only 4.5% of the patients, with no case exceeding organ-at-risk constraints.

Conclusions: This is the first comprehensive on-trial RTTQA study in a prospective pancreatic trial. Pre-trial RTQA is likely to have ensured high level of protocol adherence. The JCI and GMI obtained during the trial were consistent with that obtained at pre-trial QA.

However in a proportion of patients, investigator contouring was still unsatisfactory, and our findings emphasize the need for performing detailed outlining workshops and <u>real-time</u> central review of delineations in pancreatic trials.