

Stepwise Multicenter Introduction of Intensity Modulated Radiation Therapy for Anal Cancer in the United Kingdom: From Consensus Guidance to Large-Scale Prospective Audit, Prior to Future Clinical Trials

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Purpose/Objective(s):

The ACT 2 trial determined the standard UK radiotherapy technique in chemoradiotherapy for anal cancer. Intensity-modulated radiotherapy (IMRT) is increasingly used due to reduced acute toxicity, however the implementation in a multicenter setting is challenging. We planned a stepwise implementation of IMRT prior to the PLATO study; an anal cancer trial due to open in 2016, investigating optimization of radiotherapy dose. We developed a consensus guidance document, adapting the ACT 2 doses and volumes for IMRT, and this was presented and published in 2014 [1]. We then performed an audit of clinical practice prior to the opening of the PLATO trial.

Materials/Methods:

The Royal College of Radiologists carried out a prospective national audit, over a 6-month period between February and July 2015. All UK cancer centers were asked to submit details of consecutive anal cancer patients receiving radiotherapy over that period.

Results:

Two hundred and forty-two cases were received from 41 centers. Median age was 62 (range = 29 to 90), with a female to male ratio of 2.8. 99% had invasive squamous cell, basaloid, or cacogenic carcinoma. T1/2 and T3/4 constituted 53.5% and 46.7% of tumors respectively. 49.6% had positive lymph nodes. 64.5% and 28.1% underwent Mitomycin / 5FU and Mitomycin / Capecitabine respectively. Initial analysis reveals 187 (77.3%) received treatment using inverse planning of which 148 patients received full dose radiotherapy using the doses and delivery proposed in the guidance. For toxicity comparisons the grade 3 + 4 toxicity in 3 groups were compared; those treated as per consensus guidance, those treated using the ACT 2 protocol within the audit and the published toxicity from the ACT 2 trial. Toxicity was as follows: Non-hematological - 40%, 49%, and 62%; hematological - 17%, 13%, and 26%; skin - 26%, 43%, 48%; and pain - 12%, 17%, 26%. Diarrhea was reported in 12%, 2%, and 9%. Further analysis demonstrated this was different in capecitabine-based and 5FU-based chemotherapy regimens; 16% versus 6%. The median treatment time was 38, 39, and 38 days; the number of interruptions in radiotherapy treatment was 5%, 11%, and 15%; the number of patients completing chemotherapy was 84%, 89%, and 77%; treatment-related deaths were 0%, 4%, and <1%.

Conclusion:

This large-scale UK audit demonstrates the reduced toxicity of IMRT, implemented using consensus guidance, in comparison to the previous ACT 2 protocol. This stepwise implementation of novel

radiotherapy techniques, prior to their use in a large trial, is likely to have beneficial implications for investigators due to reduced requirements for training, education, and possibly quality assurance.