Proceedings Paper:
Bayman, N., Appel, W., Ashcroft, L. et al. (2018) OC-0537: Prophylactic irradiation of tracts (PIT) in patients with pleural mesothelioma: a phase III trial. In: Radiotherapy and Oncology. ESTRO 37, 20-24 Apr 2018, Barcelona, Spain. Elsevier, S286-S287. ISSN: 0167-8140. EISSN: 1879-0887.

https://doi.org/10.1016/S0167-8140(18)30847-8

Prophylactic irradiation of tracts (PIT) in patients with pleural mesothelioma: a phase III trial

Same authors as world lung

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Purpose/Objective

It has been widespread practice across Europe to irradiate diagnostic or therapeutic chest wall (CW) intervention sites in patients with malignant pleural mesothelioma (MPM) post-procedure - a practice known as prophylactic irradiation of tracts (PIT). This study aims to determine the efficacy of PIT in reducing the incidence of CW metastases following a chest wall procedure in MPM.

Material/Methods

In this multicentre phase III randomised controlled trial, MPM patients following a chest wall procedure were randomised 1: 1 to receive PIT (within 42-days of procedure) or no PIT. Large thoracotomies, needle biopsy sites and indwelling pleural catheters were excluded. PIT was delivered at a dose of 21Gy in 3 fractions over 3 consecutive weekdays using a single electron field adapted to maximise coverage of the tract from skin surface to pleura. The primary outcome was the incidence of CW metastases within 6 months from randomisation, assessed in the intention-to-treat population. Stratification factors included epitheloid histology and intention to give chemotherapy. Trial registration number NCT01604005.

Results

375 patients (186 PIT and 189 no PIT) were randomised between 06/2012-12/2015 from 54 UK centres. Comparing PIT vs no PIT, %male patients was 89.8/88.4%, median age 72.8/74.6 years, %ECOG PS (0,1,2) 32.2,56.5,11.3/23.8,56.1,20.1%, %confirmed epithelioid histology 79.6/74.1%, and %with intention to give chemotherapy 71.5/71.4%. The chest wall procedures were VATS (58.1/51.3%), open surgical biopsy (2.7/5.3%), local-anaesthetic-thoracoscopy (26.9/27.0%), chest drain (5.9/8.5%) and others (6.5/7.9%) for the PIT vs no PIT arm respectively. Radiotherapy was received as intended by 181/186 patients in the PIT arm. The proportion of CW metastases by 6 months was 6/186 (3.2%) vs 10/189 (5.3%) for the PIT vs no PIT arm respectively (odds ratio 0.60 [95% CI 0.17-1.86]; p=0.44) and by 12 months 15/186 (8.1%) versus 19/189 (10.1%) respectively (OR=0.79 [95% CI 0.36-1.69];p=0.59). Cumulative incidence of CW metastases at 6months/12 months/24 months was 3.3/8.5/10.0% in the PIT arm vs 5.6/10.9/18.7% in the no PIT arm. Evaluable patients who developed CW metastases reported a mean increase in visual analogue scale pain score of 13.3 ($p<0.01$) compared to baseline. Skin toxicity was the most common radiotherapy-

related adverse event in the PIT arm with 96(51.6%) grade 1, 19(10.2%) grade 2, and 1(0.5%) grade 3 radiation dermatitis (CTCAE V4.0). There were no other grade 3 or higher radiotherapy-related adverse events.

Conclusion

There was no significant difference in incidence CWM between the 2 groups and the increase in VAS pain score in patients with CWM was below the 20% increase which we considered clinically significant. There therefore is no role for the routine use of PIT following diagnostic or therapeutic CW procedures in patients with MPM.

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