had died. The use of nimorazole improved the loco-regional tumour control with an 18 months post-randomisation cumulative failure rate of 31% versus 54% in the control group, yielding a risk difference of 23% (CI 2%–45%; P= 0.03). The corresponding values for overall death was 39% versus 68%; risk difference 28% (CI 4%–52%; P= 0.02).

Conclusions: Although the trial was incomplete and suffered from small and incomplete number of patients, did the analysis indicate a loco-regional control and survival benefit in patients given the hypoxic modifier nimorazole in addition to accelerated fractionation for advanced HNSCC. However, the trial also revealed that conducting multicenter and multinational clinical studies combining drug and radiotherapy in developing countries, may suffer from uncontrolled and unsolvable problems.

OC-0188
IAEA randomised study on optimization of treatment of locally advanced NSCLC using radiotherapy and chemotherapy
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Purpose/Objective: Patients with incurable locally advanced non-small cell lung cancer (NSCLC) (mainly Stage IIIb) usually receive palliative treatment with either radiotherapy (RT) alone (39 Gy in 13 fractions or 10–17 Gy in 1–2 fractions) or receive palliative treatment with either radiotherapy (RT) alone (39 Gy in 13 fractions or 10–17 Gy in 1–2 fractions) or palliative chemotherapy (CHT) regimens. In order to optimize treatment approach in this disease and improve access to RT in limited resource setting, International Atomic Energy Agency conducted a prospective randomised study (NCT00864331) comparing protracted RT course with CHT followed by one or two fractions of RT. Treatment groups were balanced with respect to various variables (Table 1). Treatment compliance was also given in Table 1.

Results: Treatment groups were balanced with respect to various variables (Table 1). Treatment compliance was also given in Table 1.

Materials and Methods: Total of 65 patients from 7 institutions aged ≥ 18 years, with histologically confirmed NSCLC, stage IIIa/IIIb, Karnofsky performance status (KPS) 60–90, previously not treated for NCSLC were randomised, 31 to arm A and 34 to arm B. Exclusion criteria were RT field > 200 cm² and pregnancy. In arm A, RT consisted of 39 Gy in 13 fractions. In arm B, 2 to 3 platinum-based CHT cycles were prescribed, and were followed by 10 Gy given in a single fraction or 16 Gy given in 2 fractions separated by one week. Further treatments depended on disease progression and patient condition and were left to the discretion of involved radiation oncologist. Primary outcome was overall survival.

Results: Treatment groups were balanced with respect to various variables (Table 1). Treatment compliance was also given in Table 1.

Conclusions: There were no differences in survival, relapse patterns and symptoms between the two arms. When compared to high-dose palliative RT, CHT followed by one or two fractions of RT produced similar results. It can be recommended as treatment approach, especially in limited resource setting, where access to RT remains inadequate.

OC-0189
Irradiation of the supraclavicular nodal region in post-mastectomy radiotherapy; an IAEA randomized trial
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With follow-up through Feb 2014, 6/65 remained alive, 3 in each arm (all 6 being lost to follow-up at > 1 yr of observation). Median survival for all 65 patients was 0.66 yr (maximum 5.0 yr), while median survival was 0.59 and 0.68 yr for the two arms, respectively (log-rank p=0.4 by study arm, and p=0.6 by Cox regression, stratified by country and sub-stage). One- to three-year survival rates for the two arms were 29%, 9% and 9% vs 41%, 12% and 6%, respectively (Figure 1).

There was no difference in any of the following endpoints (all values, p>0.5): any failure, occurring in 26 cases each in A and B; local failure, occurring in 18 cases each; regional failure, occurring in 6 and 8 cases in the two arms, respectively; contra-lateral thoracic disease, occurring in 3 cases each; and distant failure, occurring in 13 and 14 cases in the two arms, respectively. Post-initial treatment, in arm A more courses of palliative RT were administered (17 courses in 11 cases, vs. 4 in 4 cases in arm B), along with slightly more palliative CHT cycles (19 cycles in 7 cases, vs. 11 in 2 cases in arm B).

Conclusions: There were no differences in survival, relapse patterns and symptoms between the two arms. When compared to high-dose palliative RT, CHT followed by one or two fractions of RT produced similar results. It can be recommended as treatment approach, especially in limited resource setting, where access to RT remains inadequate.
Purpose/Objective: The irradiation of lymph node regions in the post-mastectomy setting has not been a matter of uncertainty. EORTC trial tested the irradiation of the internal mammary chain (IMC) and medial supraclavicular nodal region (SNR) in node-positive medial/central tumours and detected a 1.6% benefit in survival and 3% benefit in DFS at 5 years. The preliminary results of the MA.20 suggest that regional irradiation may reduce distant metastases. A meta-analysis of randomized trials concluded that irradiation of the lymph node regions improves outcomes.

Materials and Methods: The IAEA conducted a prospective randomized clinical trial to compare the local control, regional control, overall and disease-free survival of stage IIA - IIIA breast cancer patients randomly assigned to post-mastectomy radiotherapy with or without irradiation of the SNR, and to compare the acute and late adverse events associated with radiotherapy in both study arms. Between July 2007 and December 2012, women with mastectomy (minimum 6 removed nodes but not more than 9 positive) and negative margins, who had received adjuvant chemotherapy, were centrally randomized to receive, as adjuvant, 40 Gy in 15 fractions to: the chest wall concurrent with 40 Gy in 15 fractions to the SNR; or chest wall (CW) irradiation alone. There was no attempt to irradiate the IMC. Recurrences were classified relative to the irradiation volumes as ‘local’ (in the CW fields), ‘regional’ (in the SNR location), and ‘others’.

Results: There were 469 women randomized, 237 to CW+SNR irradiation and 232 to CW only. The mean follow-up was 3.4 years from mastectomy. By order of SNR and CW there were no statistically significant differences for: 7 vs. 1 local failure; 8 vs. 3 regional failures; and 37 vs. 33 distant failures. These events affected 75 patients (crude 16%). With 60 deaths (crude 12.8%) the overall survival by Kaplan-Meier was 84% at 5-yr from mastectomy. This was not statistically different between trial arms (82% CW+SNR vs. 87% CW, p=0.17 by stratified analysis, further adjusted for stage and negative receptor status).

In 283 patients with 1-3 positive axillary nodes, and with a 3.4 years median follow-up, the overall survival was equivalent, and very similar results were also observed for the 57 cases with only upper-inner quadrant primaries, of whom 52 were node-positive in the axilla. There was no difference in the experience of toxicities including arm lymphedema.

Conclusions: There was no difference in local, regional or distant failures or in toxicities across study arms. Hypofractionation was adopted by participating centres, thus sparing resources. Long term follow-up is needed for a definitive conclusion on the postoperative value of SNR irradiation in addition to effective systemic therapy. Although well tolerated, SNR irradiation did not show a clinical outcome benefit under the conditions of this randomized trial.

References:


