

persistence patterns. The objectives of this study are to describe the utilization rates of breast cancer adjuvant hormonal therapies (tamoxifen, letrozole, anastrozole, and exemestane) in a U.S. commercially insured population and to describe the persistence of breast cancer adjuvant hormonal therapies.

Methods: A U.S. commercial research databases containing linked medical, prescription, and enrollment health information from 1998 through 2004 for over 12 million persons was used. Subjects included in the study had to have at least one prescription for tamoxifen or an aromatase inhibitor between July 1998 and December 2003 with the first prescription defined as the index prescription, had to have an ICD-9-CM or DRG indicative of breast cancer (ICD-9-CM = 174***, 198.81, 233.0; DRG = 257-260, 274, 275) and had to have complete medical and prescription claims information for at least 6 months prior and 12 months following their index prescription. The annual initiation rates of tamoxifen, letrozole, anastrozole, and exemestane and switching rates between compounds were computed. Persistence was defined as continuous use of tamoxifen or an AI without a gap between in therapy greater than of 60 days. Sensitivity analyses of the gap were computed. Medication possession ratios were computed by calculating the days of therapy divided by the person time in the study. A Cox Proportional Hazards model was used to explore factors associations with persistence.

Results: A total of 16,900 person met inclusion criteria with an average of 59.7 years and nearly all are female. A majority of persons initiated therapy on tamoxifen (81%) and 14% and 4% initiated therapy on anastrozole and letrozole respectively. Of those initiating therapy of tamoxifen, 90% stayed on tamoxifen until discontinuation or until study end. The crude persistence was lower for those discontinuing tamoxifen than for those later switching to an AI (512 vs 832 days). Factors associated with persistence and adherence will be presented.

Conclusions: Utilization of aromatase inhibitors is increasing and persons switched to from tamoxifen to an AIs persist longer on therapy than those discontinuing therapy without a switch to an AI. Recently superior efficacy of AIs over Tam has been demonstrated in large phase III adjuvant AI trials - (BIG1-98, ATAC, IES) and this may explain the increase in utilization but further investigation needs to be made.

Wednesday, 22 March 2006

16:00-16:45

POSTER SESSION

Radiotherapy

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Poster

The positive influence of quality assurance in 2 consecutive large EORTC trials involving radiotherapy for breast cancer

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Introduction: To evaluate the influence of quality assurance procedures in the EORTC trials 22881/10882 (conducted from 1989 to 1996) investigating the boost in breast conserving therapy and 22922/10925 (conducted from 1996 to 2004) investigating regional radiotherapy, we compared the agreement between the data collected in an early stage of both trials with the data collected during a later phase of the trials.

Methods: In the 22881/10882 trial, a set of patient, tumour and treatment related data on 5 randomly selected patients was evaluated at the beginning of the trial. This was compared for the 9 major participants to similar data from 5 other patients at the end of the trial. In the 22922/10925 trial, all centres were asked to perform a "dummy run" consisting of a treatment plan on 3 slices for 2 patients each with and without irradiation of the regional lymph nodes respectively. This was compared to a set of patient, tumour and treatment related data on 3 patients with and 3 patients without regional irradiation that was collected in the early phase of the trial for 19 major participants.

Results: In the 22881/10882 trial, we found a very limited number of deviations from the guidelines for eligibility, staging, surgery and pathology. Compliance to radiotherapy requirements was good with the exception of a too low minimal dose in 30% and the lack of target volume delineation in

the majority of the evaluated patients. The comparison of the late with the early review of patient data demonstrated an improvement of the quality of data reporting by 6% and of target volume delineation from 33% to 53%. In the 22922/10925 trial, the dummy run particularly yielded information on specific treatment techniques. The individual case review collected additional patient- and tumour-related data, showing the use of anatomical information for treatment planning. A comparison between both procedures revealed that the treatment of real trial patients concurred more accurately with protocol guidelines than the dummy run.

Conclusion: In both trials, we found that the quality assurance programme positively influenced the adherence to the protocol guidelines by providing specific suggestions to the participants.

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Poster

Axillary radiotherapy as adjuvant treatment in sentinel node positive breast cancer patients

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Introduction: The gold standard in adjuvant treatment for sentinel node (sn) positive breast cancer patients is axillary lymph node dissection. It is known however that adjuvant axillary radiotherapy might be a good alternative with less morbidity. In 2001 the AMAROS trial was designed to compare both treatment modalities in a prospective randomised setting. Before participating in this trial we performed a feasibility study in our centre for axillary radiation in sn positive patients.

In this study we looked at locoregional recurrence and morbidity after radiation.

Methods: Retrospectively we looked at all patients who had a positive sn and were treated with axillary radiation between 1998 and 2001. T1-2 34 patients were identified, of which 4 were excluded from analysis because of previous malignancy (1) and synchronous bilateral breast carcinoma (3), leaving 30 patients for evaluation. It concerned T1-2 tumours mostly and 5 patients had micrometastases and 25 had macrometastases. Median follow up was 47 months.

We asked all patients to undergo a thorough physical examination and anamnesis.

Results: All patients had a normal shoulder function without signs of neurological impairment. There was no significant oedema of the ipsilateral arm as compared with the contralateral arm.

There was one locoregional recurrence during follow up.

Conclusion: In this small group axillary radiotherapy proves so far to be a satisfying adjuvant treatment in sn positive breast cancer patients. We had one locoregional recurrence treated with axillary lymph node dissection. There was no shoulder impairment nor significant oedema in the ipsilateral arm. This study is small and nonrandomised. The question whether axillary radiotherapy is the better alternative to axillary lymph node dissection will hopefully be answered by the AMAROS trial.

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Poster

Forward-planned dose compensation for intensity modulated radiotherapy of the breast and internal mammary nodes using multi leaves collimator sub-fields

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Introduction: We report dosimetric results and tolerance of consecutive breast cancer irradiated on breast/chest-wall and internal mammary nodes (IMN) with 2 partial wide tangents beams modulated by a Virtual Compensator (VCOMP) able to generate sequential Multi-Leaves Collimators (MLC) subfields to approximate a continuous missing tissue compensator.

Material and Methods: Since early 2003, all breast cancer radiation techniques are defined on virtual simulation software. Target volumes of breast/chest-wall, nodal areas (IMN in the 3 first intercostal spaces) are defined, as well total lung volume, and heart for left side irradiation. Beams and compensator information are exported to the in-house VCOMP software, which sorts, discretizes and optimizes the subfields and leaves position by a least squares approximation with a multi-step function. The MLC subfields (average number of 6) are imported into treatment planning software for dose calculation and DVH generation. Over 16 months, 25 breast cancer women stage IIIA-IIIB have been irradiated on chest-wall/breast and nodal areas including IMN nodes using a single isocentre 3-4 fields VCOMP technique. We report the dosimetric results with coverage, conformity and homogeneity (HI) indexes and early follow-up.

Results: The minimum dose delivered to IMN was 92±6% of the prescribed dose and the maximum dose was 119±6%. In optimal case, the