OC-0534

No decline in patient reported outcomes following radiotherapy for breast cancer patients ≥ 60 years

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Purpose or Objective: The incidence of breast cancer is increasing in women over the age of 60 years. In this group of patients, (age associated) comorbidity is the most important factor influencing survival. The impact of treatment on daily functioning and quality of life may therefore be a more appropriate endpoint for therapy efficacy instead of standard survival outcome. Radiotherapy improves local control in elderly, however its impact on short-term physical and emotional well-being has not been well studied. This study describes patient reported outcomes measures (PROMs) during the first 6 months following radiotherapy in women over the age of 60 years, within a prospective breast cancer cohort. The effect of increasing age on PROMs was evaluated by comparing patients below and at least 70 years of age.

Material and Methods: From October 2013 on, all breast cancer patients referred to the department of Radiation Oncology were invited to enter the UMBRELLA cohort (cohort for multiple breast cancer intervention studies and long-term evaluation). Participants consented to the collection of clinical data and PROMs questionnaires before and at predefined intervals after radiotherapy. For the purpose of this study, changes in quality of life (EORTC QLQ-C30 including fatigue subscale, QLQ-BR23), anxiety and depression (HADS) were evaluated in patients at least 60 years of age, between baseline and 6 months follow-up (FU). Changes in median levels of PROMs between baseline and 6 months follow-up were evaluated with the paired sample t-test. Differences between mean levels of PROMs (continuous scale e.g. 0-100, higher scores indicate better QoL) for the two age groups were evaluated with the independent sample t-test.

Results: Between October 2013 and June 2015, a total of 848 patients were included in the cohort, with 374 patients aged ≥ 60 years. Preliminary analysis was performed in the first 158 patients. At a median FU of 5.5 months after radiotherapy, a decline in mean overall QoL (FU score 75.0, Δ 3.4; p=0.028), improvement of mean anxiety score (FU score 4.6, Δ 0.8; p=0.001) and stable mean fatigue (FU score 74.9, Δ 0.9; p= 0.578) and depression (FU score 3.5, Δ 0.1; p=0.635) scores were observed. No differences between patients 60-69 years and from 70 years of age were observed for overall QoL, anxiety, depression and fatigue scores. Severe anxiety symptoms (HADS anxiety score > 11) were reported in 8.1% and 10% in age groups 60-69 and 70 years or older, respectively.

Conclusion: In the first six months following radiotherapy, no clinically relevant decline in short-term emotional well-being and fatigue have been observed for patients at least 60 years of age. Overall well-being appears to be good in patients below and over the age of 70. Updated and more detailed results (e.g. effect comorbidity and toxicity) with an expected sample size of at least 375 patients will be presented in April 2016.

Patient characteristics	Value in n(%) unless other stated
Median age (range)	
- all patients, n=158	67 (60-85)
- < 70 years, n=102	65 (60-69)
- ≥ 70 years, n=56	73 (70-85)
Median Charlson Comorbidity Index[1] (range)	
- all patients	5 (4-10)
- < 70 years	4 (4-7)
- ≥ 70 years	5 (5-10)
WHO performance status	
- 0	133 (84%)
- 1	23 (15%)
- 2	2 (1%)
Surgery	
- breast conserving	142 (90%)
- mastectomy	16 (10%)
- sentinel lymph node biopsy	140 (89%)
- axillary lymph node dissection	16 (10%)
Disease stage	
- in situ	32 (20%)
- I	86 (54%)
- II	32 (20%)
- III	8 (5%)
Radiotherapy target volumes	
- local: breast or chest wall	129 (82%)
- regional: axillary levels I-II	3 (2%)
- locoregional (axillary levels I-II)	17 (11%)
- locoregional (periclavicular levels / III-IV)	9 (6%)
- median number of fractions (range)	16 (16-23)
- median dose (range)	42.56 (42.56-61.18 Gy)
Systemic treatment	
- neoadjuvant treatment	5 (3%)
- adjuvant chemotherapy[2]	29 (18%)
- adjuvant endocrine therapy[2]	70 (44%)
- adjuvant immunotherapy[2]	2 (1%)
- none	81 (51%)
Acute toxicity[3]	
- at least one grade II episode	36 (23%)
- grade III episode	1 (0.6%)
- > grade III	-
Late toxicity	
- at least one grade II episode	3 (2%)
- > grade II	

1: age adjusted score 2: overlap in cases with specified treatment 3: toxicity assessed according to Common Terminology Criteria for Adverse Events v4.0, with acute toxicity occurring < 90 days after start radiotherapy and late toxicity ≥ 90 days. Observed toxicities were dermatitis radiation (40%), fatigue (25%), lymphedema of the breast or chest wall (10%), breast pain (8%), pain in extremity (5%), chest wall pain (3%), edema limbs (3%), soft tissue fibrosis (2%), pneumonitis (2%) and esophagitis (2%).

OC-0535

How patient-reported urinary symptoms predict impairment of urinary QoL from RT for prostate cancer

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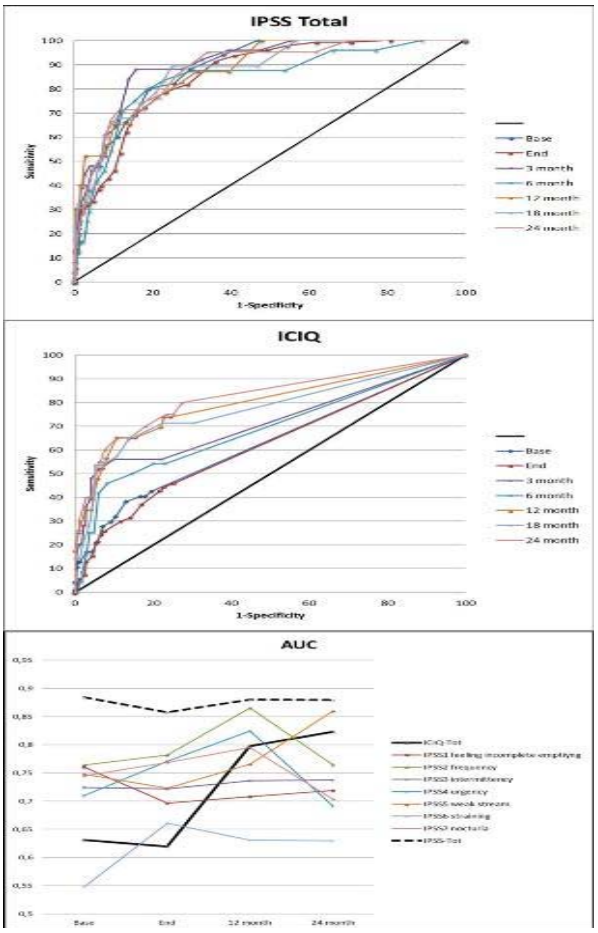
Purpose or Objective: Within a large multi-Institute observational study, patient reported urinary symptoms (PRUS) were available at baseline and at different times intervals after RT: aim of current analysis was to assess the power of the different PRUS in discriminating a severe impairment of urinary QoL.

Material and Methods: Pts treated in 9 Institutes with radical 3DCRT/IMRT for localized prostate cancer with conventional or moderate hypo-fractionation (2.35-2.7 Gy/fr) filled in several questionnaires, including IPSS and ICIQ. Questionnaires are to be filled in at baseline, at RT end, 3 and 6 months after its conclusion, and thereafter every 6 months up to 5 years. Current analysis focused on the IPSS score relative to urinary QoL (item #8, IPSS8) during the first two years after RT, considering a score ≥4 as a severe impairment. At each time interval (i.e.: baseline, RT end, 3, 6, 12, 18, 24 months after RT) the power of the different PRUS, the overall IPSS, single IPSS items (IPSS1 to IPSS7) and ICIQ scores in discriminating patients with ≥4 IPSS8 as assessed by ROC curves: AUCs were calculated for each score at each timing and ROC curves compared to detect significant differences among scores and times.

Results: The available data refer to 499, 449, 412,361, 339, 304, 238 pts at baseline, RT end, 3,6,12,18 and 24 months after RT respectively. Pts with IPSS8≥4 were 50, 126, 25, 24, 23, 28, 21 respectively. The discriminative power of the overall IPSS remained quite constant over time, ranging

between 0.84 and 0.90 without significant differences. Interestingly, the discriminative power of the single IPSS ites was different and dramatically changed over time: only IPSS6 (straining) always showed a poor value at each time (AUC: 0.55-0.65). All the remaining IPSS items showed not significantly (p>0.07) different AUCs at baseline (0.71-0.76), while exhibiting very different patterns after RT. IPSS2 (frequency), IPSS4 (urgency) and IPSS7 (nocturia) showed the highest performances in the acute phase (AUC:0.77-0.87 at RT end and at 3 months). At 24 months, weak stream showed the highest AUC (0.87) while the remaining items ranged between 0.69 and 0.76. Very importantly, the AUC of ICIQ continuously increases from baseline/RT end (AUC=0.62-0.63) up to 24 months (AUC:0.82). In Figure 1a/1b the ROC curves at the different time intervals for overall IPSS and ICIQ are shown; a summary of AUC changes is shown in Figure 1c for all scores at baseline, end RT, 12 and 24 months.



Conclusion: The analysis of a large population of prospectively followed patients with PRUS evaluation showed that the discriminative power of different symptoms in assessing a severely impaired urinary QoL significantly changes over time. As expected, the overall IPSS always captures a very large fraction of these patients, while the predictive value of ICIQ is negligible at baseline and acutely, becoming highly discriminative in the long term.

OC-0536

Course of quality of life after radiotherapy for painful bone metastases

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Purpose or Objective: In patients with painful bone metastases, radiotherapy is an effective treatment. Besides symptom control, quality of life (QoL) is an important endpoint. We focus on the course of QoL after radiotherapy.

Material and Methods: In the Dutch Bone Metastasis Study, 1,157 patients with painful bone metastases were randomized between one fraction of 8 Gray and six fractions of 4 Gray. The study proved equal effectiveness, with a pain response of 74%. Patients filled out weekly questionnaires for 13 weeks and then monthly for two years or until death. Three QoL domain scores (physical, psychosocial and functional) and a visual analogue scoring of general health were studied. Mixed modeling was used to model the course of QoL and to study the influence of several characteristics. An effect size of≥ 0.10/0.20 (binary or continuous variable, respectively) is considered a small effect and therefore clinically relevant.

Results: In general, QoL stabilizes after a month. Psychosocial QoL improves temporarily after treatment. The level of QoL remains stable for a long time, steeply deteriorating at the end of life. For most QoL domains, a high pain score and intake of opioids are associated with worse QoL, with a small effect size (-0.11 to -0.27). A poor performance score is associated with worse functional QoL, with a medium effect size of 0.41.

Figure: The modeled course of QoL after radiotherapy for painful bone metastases, represented in survival groups (patients surviving less than 3, 3-<6, 6-<12, 12-<18 and 18-<24 months after randomization). The x-axis represents the months after treatment, where month 0 is the baseline measurement before treatment and month 1 the first months after treatment. The y-axis reflects the domain score of QoL, where the average is 0, with a standard deviation of 1. The higher the score, the better the QoL.

Table: Influence of baseline and follow-up variables on QoL domains, with effect sizes