study, we evaluated the ano-rectal function using a novel scoring system for evaluation of bowel dysfunction.
Materials and Methods: We conducted a cross-sectional study based on a patient administrated questionnaire. The questionnaire has been developed and validated in patients treated for colo-rectal cancer and includes the St. Marks fecal incontinence grading system, the Wexner incontinence score and questions on how bowel symptoms affected the quality of life (QL). A condensed ano-rectal dysfunction score (ARD) consisting of 5 items (fecal frequency, urgency and incontinence, clustering of stools and soiling) is extracted from the questionnaire. The study included 372 PC patients treated with RT from 1999–2007 and 249 patients treated with radical prostatectomy (RP) from 2005–2007 at Aarhus University Hospital with at least 3 years follow-up time.
Results: A total of 90% (564 patients) returned the questionnaire. 42% (135/323) of the patients treated with RT and 20% (42/214) of the patients treated with RP reported minor or moderate ARD (OR=2.95 (95% CI: 1.97–4.42; $p < 0.001$)). Rectal bleeding (OR=4.81 (95% CI: 2.957.83; $P < 0.0001$), fecal urgency (OR=3.96 (95% CI: 2.66–5.90 $P < 0.0001$) and fecal incontinence (OR=3.16 (95% CI: 2.05–4.88; $P < 0.001$)) were more frequent in the RT group compared to the RP group. A ROC-analysis revealed that the ARD score correlated significantly with QL (sensitivity 68%; specificity 79%).
Conclusion: The risk of rectal bleeding, urgency, and fecal incontinence was significantly higher in RT patients compared to RP patients and a condensed score covering 5 items on ano-rectal dysfunction correlated significantly with patients QL in RT patients.

7029 POSTER

Quality of Life in Patients With Conformal Radiation Therapy for Prostate Cancer − a 5-year Longitudinal Study

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Background: This study was designed to prospectively evaluate the time course of health related quality of life (QoL), anxiety and depression in patients receiving definitive conformal radiation therapy (CRT) for localized prostate cancer.
Materials and Methods: From 11/2001 to 4/2003 78 patients receiving definitive CRT were recruited. QoL, anxiety and depression were evaluated before CRT as well as 12, 24 and 60 months post treatment with the EORTC Quality of Life Questionnaire-C30, the prostate cancer module PR25 and the Hospital Anxiety and Depression Scale (HADS).
Results: At 5 years 18% had developed a biochemical recurrence, 7% experienced distant metastasis and 10% had died (one due to prostate cancer). One and 2 years after CRT all functional QoL scores as well as global QoL were within or slightly above pre-treatment levels. At 5 years physical functioning ($p < 0.001$) and role functioning ($p = 0.004$) dropped below pre-treatment levels, while the other scales were within the baseline. The deterioration was of clinical relevance (difference of $\geqslant$10 points) for physical functioning only. HADS anxiety dropped significantly below pre-treatment values at 1 and 2 years post CRT and reached baseline levels at five years. HADS depression changed in parallel with anxiety but not as pronounced. PR25 urologic symptoms dropped slightly below pre-treatment values at 2 years and reached baseline levels at 5 years. PR25 bowel symptoms did not change significantly over time. Except for emotional functioning patients with a biochemical recurrence had no inferior QoL as compared to men without recurrence. Anxiety, depression and fatigue explained 31% − 64% of the variance of the functional/global QoL scores, while rectal symptoms and urological symptoms explained only 5−20% and 3−24%, respectively. At 5 years 52% of the patients stated to have at least some worries about the future course of their disease. These patients had considerably lower functional and global QoL scores ($\leqslant$20 points) than those without worries ($p < 0.001$). They also displayed much higher anxiety and depression scores ($p < 0.001$).
Conclusions: As compared to pre-treatment levels QoL is minimally impaired at 5 years after CRT for prostate cancer. Anxiety, depression and fatigue explain much more variance of QoL than treatment or disease related symptoms. Worries about the future course of the disease appear to be a problem for a significant fraction of the patients.

7030 POSTER

Outcomes of Intensity-Modulated Radiation Therapy Combined With Neoadjuvant Hormonal Therapy for High-risk Prostate Cancer

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Background: To date, there have been few reports investigating outcomes of high-dose intensity-modulated radiation therapy (IMRT) for a cohort of patients with high-risk prostate cancer treated in combination with neoadjuvant hormonal therapy (NA-HT). We analyzed outcomes of NA-HT followed by IMRT to patients with T1c-T4N0M0 high-risk prostate cancer without adding adjuvant hormonal therapy (A-HT).
Materials and Methods: Between October 2002 and May 2006, 128 Japanese patients with T1c-T4N0M0 adenocarcinoma of the prostate were definitively treated by IMRT. The median age was 71 years old (range 51−83 years old). Pre-treatment prostate-specific antigen (PSA) values ranged between 4 and 179 ng/ml (mean: 35 ng/ml). Among the 128 patients, 25 and 103 cases were classified into high-risk (PSA >20, or Gleason Score >7) T1c-2N0M0 and T3−4N0M0, respectively. NA-HT (3−15 months, median: 6 months) was given to all cases. In principle, 78 Gy in 2 Gy per fraction was delivered to the planning target volume (prostate and proximal two-thirds of the seminal vesicles plus margins), although the dose was reduced to 70 or 74 Gy in 21 patients with unfavorable risks for high-dose radiation such as severe diabetes mellitus and anticoagulant therapy. A-HT was not given to any patients after the completion of IMRT. PSA values were monitored with one- to six-month intervals after the IMRT. Salvage hormonal therapy (S-HT) was essentially started when PSA value exceeded 4 ng/ml in monotonically increasing manner.
Results: Median follow-up period was 68 months (range: 21−93 months). So far, S-HT was initiated to 33 patients, and PSA values at the initiation of S-HT ranged 2.7 to 32.2 ng/ml with a median value of 6.1 ng/ml. The 5-year Caplan-Meyer estimate of the biochemical relapse-free survival rate based on the Phoenix definition was 70.3% (95% CI = 62–78.5%). The S-HT-free survival rate at 5 years was 75.4% (95% CI = 67.5–83.3%). The 5-year prostate cancer-specific and overall survival rates were 98.4% (95% CI = 96.1–100%) and 94.5% (95% CI = 90.5–98.5%), respectively. The 5-year likelihood of developing grade 2−3 late genitourinary and urinary toxicity base on the RTOG criteria were 5.5% (95% CI = 1.5−9.5%) and 6.7% (95% CI = 2.2−12%), respectively. No grade 4 toxicities were observed.
Conclusions: The finding indicated that high dose delivery with IMRT for high-risk prostate cancer is well tolerated and is associated with excellent intermediate-term tumour-control and survival outcomes despite giving no A-HT. This approach of NA-HT plus high dose IMRT with relatively early initiation policy of S-HT may be an alternative for high-risk prostate cancer because three fourths of patients maintained hormone-free status at 5 years as well as excellent survival outcomes.

7031 POSTER

The Toxicity of Dose Escalated External Beam Radiation Therapy After Elective Pelvic Nodal Irradiation − Evaluating the Utility of the QUANTEC Rectal Dose Thresholds

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Background: Elective pelvic nodal irradiation (EPNI) increases the volume of the rectum subjected to moderate doses (40−50 Gy) of EBRT. Some evidence suggests that EPNI may reduce the tolerance of small rectal volumes to high doses. Using data from rectal DVHs this study evaluates the QUANTEC thresholds and the correlation between late rectal bleeding and dose in a cohort of uniformly treated patients.
Material and Methods: ASCENDE RT is a trial for unfavorable risk patients with clinical stage $\leqslant$T3a and PSA $\leqslant$40 ng/mL that combines androgen deprivation therapy (ADT; 12 months total, 8 months neoadjuvant) and EPNI with randomization to either a high dose 3D conformal EBRT boost (Arm 1) or a ^{125}I brachytherapy boost (Arm 2). The study sample consists of all Arm 1 patients who completed treatment by Dec. 31, 2008 (N = 119). After removing identifiers, the planning CTs were copied and rectal contours were outlined by 3 trained observers. To minimize bias, observers were blinded the other contours and to the rectal bleeding status of the subjects. By including the original contours, four independent rectal DVHs were acquired for each patient providing an N of 476 for analysis.
Results: The median age was 67 years. All but one individual received ADT as per protocol; 97% (N = 116) received radiotherapy by protocol (78 Gy

in 39 fractions). The median follow up was 59.4 months. There were 15 subjects with grade 2 rectal bleeding, three with grade 3, and none with $\geqslant$ grade 4. The 5 year K-M estimates are 16.5% for grade 2+ and 2.8% grade 3. The mean time from the start of radiation to late grade 2+ rectal bleeding was 16.0 ($\pm$15.1) months. CT scans from 57 subjects have been contoured thus far (N = 228). The median V70 was 29.0%(SD 3.7%) and for V75 was 16.7%(SD 2.3%). While there is minimal intra- and inter-observer variance in the high dose part of the rectal DVH, in the low/moderate dose region, there was a relatively large total variance with an overlap index of ~65%. The variance consists of actual anatomic variation and errors in contouring.
Conclusion: This study reveals non-uniform variance in rectal DVH where the variance is low in the high dose region and high in the low/moderate dose region. We submit that this pattern of non-uniform variance is intrinsic, making multiple blinded observers essential if investigators seek a valid and quantitative answer to the question: Does EPNI reduce the radio-tolerance of small rectal volumes to high doses and thereby increase the risk of rectal bleeding?

7032 POSTER

Bile Acid Malabsorption After Intensity Modulated Radiotherapy for Prostate Cancer

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Background: Intensity modulated radiotherapy (IMRT) is a significant technological advance in the treatment of prostate cancer, allowing increased dose delivery to tumours, with sparing of normal tissues from high radiation doses. IMRT planning employs strict dose constraints to nearby organs to limit toxicity. Typically the entire bowel is regarded as a single structure, and its tolerance is quoted as 46 Gray (Gy) delivered in 2 Gy per fraction.
Bile acid malabsorption (BAM) is a treatable condition that presents with symptoms similar to those of radiotherapy (RT)-related toxicity (diarrhoea, urgency, frequency, flatulence, abdominal pain and faecal incontinence). It has not previously been described in patients who have received contemporary RT for prostate cancer. We describe new onset BAM in a series of men after IMRT for prostate cancer.
Materials and Methods: New onset BAM was diagnosed by i) development of typical symptoms, ii) a selenium homocholic acid taurine (SeHCAT) scan with 7 day retention of <15% and iii) an unequivocal response to treatment with a bile acid sequestrant. In these patients the original RT plan was located and the terminal ileum (TI) identified by a consultant radiologist. The radiation dose received by the TI was calculated and compared with accepted dose-volume constraints.
Results: Five patients with new-onset BAM were identified (median age 65 years) out of a total of 423 men treated in a prospective series of high dose prostate and pelvic IMRT. All patients reported normal bowel habit prior to RT. The volume of TI which could be confidently identified ranged from 26 cc to 141 cc and the maximum radiation dose received by the TI varied between 8.13 Gy and 59.3 Gy. 3/5 patients had areas of TI treated in excess of 46 Gy (in 2 Gy per fraction) with volumes ranging from 1.5 cc to 48.0cc. 1 patient had mild BAM (SeHCAT 7 day retention of 10−15%), 2 moderate (SeHCAT 5−10%), and 2 severe (SeHCAT <5%). The 3 patients whose TI received $\geqslant$ 46 Gy developed moderate-severe BAM, whereas those whose TI received <46 Gy had only mild-moderate BAM.
Conclusions: Radiation delivered to the TI during IMRT may be associated with new onset BAM. Identification of the TI from unenhanced RT planning CT scans is difficult and may impede accurate dosimetric evaluation of the TI. Thorough toxicity reporting and close liaison between oncologist and gastroenterologist will allow timely diagnosis and treatment of BAM, the symptoms of which may be mistaken for late RT toxicity.

7033 POSTER

Initial Results of a Comparison of Localisation of the Prostate Gland Using an Electromagnetic Tracking System With Cone Beam CT

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Background: The Calypso® system uses electromagnetic transponders to localise and track the prostate position during radiotherapy without the use of ionising radiation. A Calypso® system was installed at the Royal Marsden NHS Foundation Trust and Institute of Cancer Research in January 2010. Initial patients were treated as part of a quality assurance and implementation programme assessing the accuracy of Calypso® with respect to cone beam CT (CBCT) used to image the Calypso transponders as markers. Preliminary results for the first 17 patients are reported here.
Material and Methods: Patients referred for radical radiotherapy to the prostate had three Calypso® electromagnetic transponders (8 mm x 2 mm) implanted in the prostate at the right base, left base and apex using a 14G needle guide. Patients were set-up to skin marks and prostate displacement from the isocentre measured using Calypso® and cone beam CT (CBCT) with the transponders used as fiducial markers (FM). Calypso® localisation co-ordinates were recorded simultaneously with CBCT displacements following registration of the FM and CBCT with the reference image. A comparison of set-up displacements from skin marks using Calypso® and CBCT was made in order to establish its accuracy in our department.
Results: Seventeen patients completed treatment between July 2010 and February 2011. All had Calypso® transponders implanted in the prostate with no adverse effects and no loss or migration of transponders. A total of 263 fractions were imaged and 1481 displacements have been analysed. The number of fractions with a displacement in any direction of >3 mm, 5 mm and 10 mm were 79% 22% and 0.7% respectively. The systematic errors measured with Calypso and FM/ CBCT displacements were similar (see Table 1). The mean difference between Calypso and FM/CBCT displacements (mm) were RL −0.1 ($\pm$0.6), SI −0.2 ($\pm$0.5), AP 0 ($\pm$0.5) (Right, inferior and posterior are positive).

Table 1. Population systematic and random errors using Calypso and FM/CBCT and skin marks

	Population systematic error (mm) Σset-up			Population random error (mm) σset-up		
	RL	SI	AP	RL	SI	AP
Calypso	2.2	1.8	3.9	1.9	2.4	2.5
FM/CBCT	1.9	2.5	4.0	1.9	2.2	2.4

Conclusions: The quality assurance and implementation programme is ongoing. Preliminary results confirm Calypso® is an accurate method of localising the prostate with close agreement with the current gold standard of fiducial markers and radiological imaging.

7034 POSTER

High Dose Rate Brachytherapy Combined With External Beam Radiotherapy for Localized Prostate Cancer − Correlation Between Clinical and Dosimetric Parameters and Incidence of Urethral Adverse Events

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Background: This study investigated whether clinical factors (initial international prostate symptom score (IPSS), volume of the prostate and history of maximum androgen blockade (MAB) therapy for $\geqslant$3 months) or dosimetric parameters (UV125, UV150, UD90, UD30, and UD5) affect the incidence of Grade 2 or worse early and late urethral adverse events after HDR-BT combined with external beam radiotherapy (EBRT).
Material and Methods: Between January 2005 and March 2008, 82 patients with localized prostate cancer were treated using HDR-BT combined with EBRT at Kochi Medical School Hospital, Japan. The fractionation schema for HDR-BT and EBRT was prospectively changed. Distribution of the fractionation schema used in patients was as follows: 9 Gy $\times$2 + 2 Gy $\times$20 in 56 patients (Group 1); and 9 Gy $\times$2 + 3 Gy $\times$13 in 26 patients (Group 2). Median duration of follow-up was 54 months (range, 36−75 months). Toxicities were graded based on the National Cancer Institute-Common Terminology Criteria for Adverse Events v3.0.
Results: Five patients (6.0%) developed grade 2 urethral adverse events in the early phase (<3 month) and 26 patients (31.7%) in the late phase. In view of the distribution of fractionation schema, no significant differences were found between Groups 1 and 2. No significant correlation was seen between patients with grade 2 or worse urethral adverse events in the early and late phases. No significant differences were found between incidence of grade 2 or worse urethral adverse events and the following factors: initial IPSS; prostate volume; history of MAB therapy; and any dosimetric parameters.
Conclusions: No significant correlations between incidence of urethral adverse events and initial IPSS, prostate volume, history of MAB therapy and any dosimetric parameters were found in this study. However, further follow-up and additional investigations are required.