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11C-Choline-PET/CT determines potentially curative patients with prostate cancer recurrencies

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Background: The purpose of the study was to assess the utility of 11C-Choline-PET/CT in detecting single pelvic lymph nodes, isolated local recurrence or distant lymph nodes in patients with rising PSA-levels after radical prostatectomy.

Methods: 31 patients (pts.) (age:xm 63.1y, 06/2002 until 02/2003) with rising prostatic specific antigen levels (PSA) after radical prostatectomy (RPE) were investigated. All patients underwent dedicated 11C-Choline-PET/CT examination (GE Discovery LS) from neck to prox. femur region. Data acquisition started 10 min after injecting 1080 Mgq 11C-choline and a non-ionic contrast agent. Image fused PET/CT was used to determine local recurrence or lymph node involvement. All CT detected lymph nodes (lnn.) were measured, localised and compared to PET; in case of focal increased 11C-choline uptake the size of the lnn. was correlated to the SUV. In PET SUV was measured in case of local recurrence, single lnn. relapse or distant lnn.metastasis and correlated to the PSA levels.

Results: All 31 Pts. suffered from rising PSA-levels. In 11/31 pts. PET/CT revealed no additional information, but in these cases the average increase of PSA was very low (0.03 ng/ml/month). In 20/31 pts. 11C-choline PET/CT detected a local relapse (n=4) or lnn. recurrence (n=13) with an average increase/month of 1.59 ng/ml. In 4 pts. rising PSA level indicate a systemic tumor spread out. 9/13 pts.were selected for potentially curative therapy with single lymph nodes. Increasing tumor mass correlated with an increase of PSA. SUV xm in single lnn. metastasis was 2.1, in massive lymph node involvement 3.44 and in local recurence 2.31.

Conclusions: In detecting single lnn. 11C-Choline-PET/CT is superior to CT. 11C-Choline-PET/CT demonstrates isolated local recurrence, neither seen in CT nor in MRI or TRUS. 11C-Choline-PET/CT can separate potential curative patients for surgery or conformal radiation therapy, depending on isolated local recurrence or single manifestation in locoregional lymph node regions.

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Phase II study of low dose thalidomide and interferon-alpha in metastatic renal cell carcinoma (RCC)

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Background: Limited options are available in metastatic RCC. Interferon- ± (IFN) and Thalidomide are active in RCC. Because of the antiangiogenic properties of each agent at low doses, we conducted a clinical trial combining low dose IFN- ± and Thalidomide.

Methods: Since February 2001, 19 patients with progressing RCC, WHO performance Status (P.S) ≤2 consented to receive IFN- ± 3× 10^6 U/day and Thalidomide 100 mg/day. Dose reduction for grade 3-4 toxicity and ≥ grade 2 neuropathy was applied only to IFN- ± at 2 and subsequently 1× 10^6 U/day. Survival times were calculated with Kaplan-Meier survival curves using Epistat 5.0. Responses were assessed by the RECIST criteria*Results:* Pt's Characteristics were: m edian age- 64 (45-81) years, WHO P.S. 1(0-2) and disease free interval of 14.6 (0.8-102.7) months. Metastases occurred in lung-16 (84%), lymph nodes- 7 (36%), renal bed- 6 (30%), bone- 4 (21%), and soft tissue, adrenal or liver each in 2 (10%) Pt's. Six (32%) Pt's received prior IFN- ±, one as an adjuvant. Toxicity data is available in all Pt's. IFN- ± was reduced in 10 Pt's (52.6%) due to 11 grade 3 episodes: asthenia- 6 (37.5%) Pt's, and headache; neutropenia; neutropenic fever and grade 2 tremor; dyspnea, vomiting and vertigo; and gastrointestinal toxicity. Two (10%) Pt's discontinued the treatment due to mild visual cerebrovascular event, and persistent headache. While treated, 1 Pt died unrelated to therapy. Fourteen Pt's are assessable now for response: 3 Pt's (21.4%) achieved Partial Response (lung- 2 and lung + soft-tissue-1), 7 Pt's (50%) obtained stable disease, with an overall non-progression rate of 71.4% (10 Pt's- 95%, CI 41.9% - 91.6%). Over all survival is at a mean of 17.4 (1.4+ - 20.3) months. Sixteen Pt's (84.2%) are still alive.

Conclusion: Low doses Thalidomide and Interferon is feasible and active in metastatic RCC. Further accrual with initial IFN- ± 2× 10^6 is ongoing.

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Urinary incontinence in prostate cancer patients treated with external beam radiotherapy

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Purpose/Objective: To describe the incidence of urinary incontinence among prostate cancer patients treated with external beam radiotherapy (RT) and to investigate associated risk factors.

Materials/Methods: 1192 patients with >= 24 months follow-up were the subjects of this series. All patients received between 50-72Gy in 20-37 fractions (median 66Gy/33#). Post-RT urinary incontinence was scored according to the modified RTOG/SOMA scale: Grade 1- occasional use of incontinence pads, Grade 2 - intermittent use of incontinence pads, Grade 3 persistent use of incontinence pads, Grade 4 permanent catheter. Risk-factors investigated were: age, diabetes, TURP prior to RT, elapsed time from TURP to RT, clinical stage, RT dose and presence of grade >=2 acute GU toxicity. Non-parametric, actuarial univariate (Kaplan-Meier) and multivariate tests (MVA, Cox regression) were performed.

Results: Median follow-up for the group is 52 months(24-109). 34 patients (2.9%) had incontinence prior to RT, which was more common in TURP patients (7.8% vs 1.6% p<0.001). These are excluded from further analysis. 57 patients (4.9%) developed grade 1 incontinence, 7 (0.6%) grade 2, and 7 (0.6%) grade 3. There was no grade 4 incontinence. Actuarial rates for grade >=1and >=2 incontinence at 5 years are 7% and 1.7% respectively. Risk factors on MVA associated with the development of grade 1 or worse incontinence are pre-RT TURP (5-year rates 10% vs. 6%, p=0.026), presence of grade >=2 acute GU toxicity (5-year rates 11% vs. 5%, p=0.002). Age, diabetes, clinical stage, elapsed time from TURP to RT, and RT dose or fraction size were not significant. Patients who underwent post-RT TURP or dilatation for stricture (4.3%), were more likely to develop grade 2-3 incontinence (5-year rate 8% v 1.5%, p=0.0015).

Conclusions: Grade 2 or greater urinary incontinence is rare among patients who have been treated with external beam radiotherapy. Associated risk factors are pre-RT TURP and the presence of increased acute GU toxicity. Post-radiation TURP increases the risk of incontinence five-fold.

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Intravesical gemcitabine in the treatment of intermediate risk superficial transitional cell carcinoma (TCC) of the bladder: a marker lesion study

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Introduction: A phase I study has shown a good tolerability and a high complete response (CR) rate of 2000 mg intravesical gemcitabine administered in BCG resistant patients refusing radical cystectomy. Marker lesion studies in intermediate risk superficial bladder cancer are safe and should always precede phase III studies when assessing the efficacy and tolerability of a new intravesical agent. We designed the following study in order to study the ablative or reductive activity of gemcitabine administered intravesically on a single papillary marker lesion. Side affects and hematological parameters during and after the treatment constituted the secondary end point.

Patients and methods: 24 patients with a history of papillary recurrent Ta-T1, G1-G2 bladder TCC (intermediate risk), a normal upper urinary tract at IVU and no high grade atipia at preoperative urine cytology were consented to undergo a resection of all visible lesions except a single 0,5-1 cm papillary marker lesion. After histological confirmation, 2000 mg in 50 ml saline solution of gemcitabine were administered intravesically for 1 hour weekly for 6 weeks starting the 7th postoperative day. Full blood count, renal and hepatic function, urine culture were assessed before any treatment administration. Postoperative urine cytology, cistoscopy plus cold biopsy of the base of implant or resection of the marker lesion were performed within 2 weeks from the end of the treatment. CR was defined as the absence of any histologically confirmed recurrence of bladder TCC and/or a negative urine cytology. Anything else than CR was defined as non response (NR).

Results: All patients completed the treatment. A mild nausea was reported by 4/20 patients and hypostenia by 2/20. Six patients complained of dysuria. Both full blood count and biochemistry parameters were not significantly altered over the treatment course. We recorded only grade I