treatment for pT3N0M0 prostate cancer, used after completion of radical prostatectomy, to decrease mortality, loco-regional / distant recurrence and PSA failure rates.

METHODS: A meta-analysis of randomized controlled trials (RCT) was performed comparing adjuvant RT treatment for pT3N0MO prostate cancer to observation. The MEDLINE, EMBASE, CANCERLIT and Cochrane Library databases, and abstracts published in the annual proceedings were systematically searched for evidence. Relevant reports were reviewed and the references from these reports were searched for additional trials.

RESULTS: The review identified three RCTs, yielding 1691 patients. There were less locoregional failure after RT (112/717 = 15.6%) versus observation (195/713 = 27.3%, p<0.00001). The likelihood of PSA failure was 0.37-fold lower (95% CI 0.29 - 0.46, p<0.00001) in RT arms. The RCT quality scores were of 4 point in a 5 point scale. Pooled results from this three randomized trials of adjuvant RT did not show a significant reduction of mortality (p=0.26) and distant failure rates (p=0.27).

CONCLUSIONS: This combination of randomised trial data suggest that there is an unequivocal capacity for adjuvant RT after radical prostatectomy to approximately halves the chance of having a future PSA-detectable and tumour recurrence in pT3 or margin positive patients. PSA relapse and disease recurrence may lead to adverse consequences, including the necessity of using adjuvant therapies, like hormonal therapy. This is associated to higher osteoporosis events, sexual dysfunction, hot flashes and reduced quality of life. Moreover, further follow-up is needed to assess the effect on overall survival and distant failure. The results of these trials should promote further randomised studies comparing adjuvant RT vs. early salvage RT using contemporary PSA assays.

Source of Funding: None

525

SALVAGE CRYOTHERAPY FOR RECURRENT PROSTATE CANCER AFTER RADIATION FAILURE. THE UK EXPERIENCE

Mohamed Ismail, Marcia Hicks, Shwan Ahmed, John Davies. Guildford, United Kingdom.*

INTRODUCTION AND OBJECTIVE: In this study we report on the largest UK experience of salvage cryotherapy for recurrent prostate cancer after radiation failure, evaluating the biochemical outcome, complications and management and quality of life.

METHODS: Between May 2000 and November 2005,100 patients underwent salvage targete cryoablation of the prostate (TCAP) for recurrent prostate cancer after radiotherapy. The mean follow-up was 33.5 months. All patients had biopsy proven recurrent prostate cancer. Biochemical recurrence-free survival (BRFS) was defined using prostate specific antigen (PSA) level < 0.5 ng/ml and by applying the American Society for Therapeutic Radiology and Oncology (ASTRO) definition for biochemical failure. Patients were stratified into 3 risk groups, high-risk (n=68), intermediate-risk (n=20) and low-risk (n=12).

RESULTS: There were no operative or cancer related deaths. The five years actuarial biochemical recurrence free survival was 73%, 45% and 11% for the low, intermediate and high-risk groups respectively. Complications included incontinence (13%), erectile dysfunction (86%), lower urinary tract symptoms (16%), prolonged perineal pain (4%), urinary retention (2%), and rectourethral fistula (1%).

CONCLUSIONS: Our series suggests that TCAP is safe, well tolerated, and an effective option for salvage treatment of prostate cancer. It is associated with low morbidity rate (except for erectile dysfunction) and for patients who failed their radiotherapy it offers additional hope of cure. High-risk patient showed the least favourable outcome hence, patient selection is essential prior to the treatment. Further research into long term survival and quality of life is recommended.

Source of Funding: The Prostate Project Foundation.

526

OUTCOMES FROM A PHASE I TRIAL OF AN ADENOVIRUS/PSA VACCINE FOR PROSTATE CANCER

David M Lubaroff, Badrinath R Konety, Brian K Link, Timothy L Ratliff, Tammy Madsen, Richard D Williams. Iowa City, IA.*

INTRODUCTION AND OBJECTIVE: We have conducted a Phase I clinical trial of an adenovirus/PSA (Ad/PSA) vaccine for prostate cancer. Men with measurable metastatic disease were injected once with the vaccine. Toxicity, immune responses, changes in PSA doubling times, & patient survival have been assessed.

METHODS: Thirty-two patients with stage D2 or D3 prostate cancer were treated with a single subcutaneous injection at 1 of 3 dose levels of the Ad/PSA (10^6, 10^7, or 10^8 pfu/ml). At each dose level, 3 patients were injected with the virus suspended in an aqueous solution and 3 patients received the virus suspended in Gelfoam® matrix that has previously been shown to potentiate the induction of immune responses by Ad5-PSA. The final group that received 10^8 pfu/ml contained 10 patients each, aqueous or Gelfoam®. All patients returned for physical and clinical chemistry examinations at 14 and 21 days, 2, 4, 8, and 12 months after injections.

RESULTS: Patient median age was 71 years (52-89), median enrollment PSA was 128 ng/ml (1.31-3110), median follow-up was 12 months (2-12), and median survival was 18 months (2.5-71). The vaccine was deemed safe at all doses, whether administered as an aqueous suspension or in the Gelfoam® matrix with no vaccine-related adverse events. The most prevalent AE was localized erythema/ecchymoses in 9 patients with cold/flu-like symptoms in 5, fatigue with proteinurea in 3, and a transient decreased ANC in 1. Immune responses to PSA were measured and identified in at least 40% of patients. Anti-PSA antibodies were produced by 42% of patients and anti-PSA T cell responses, the responses documented to mediate tumor destruction, were produced by 71% of patients. The evaluation of effect the vaccination may have had on each patient's prostate cancer was evaluated by: 1) changes in PSADT, 2) any change in survival different than that predicted by the Halabi nomogram. PSADT was increased in 48% of the patients in the trial while 57% of the vaccinated patients survived longer than predicted by the nomogram. The longest survival was 71 months, almost 6 years after the single vaccination.

CONCLUSIONS: The final outcome of the Phase I clinical trial of the Ad/PSA vaccine demonstrated its safety, its ability to induce anti-PSA antibody and T cell responses, and to seemingly affect the prostate cancer of 48% to 57% of the patients. Although the latter data are only derived from a small number of patients in this Phase I trial, they are encouraging enough to pursue further studies. A Phase II trial, designed to expand on our initial findings, has recently been approved by the FDA.

Source of Funding: Holden Comprehensive Cancer Center, VA Research Enhancement Award.

527

RESULTS OF A PROSPECTIVE PILOT CLINICAL TRIAL ADMINISTERING ACUPUNCTURE FOR HOT FLASHES IN PATIENTS UNDERGOING HORMONAL THERAPY FOR PROSTATE CANCER

Jillian L Capodice, Zhezhen Jin, Brian A Stone, James M McKiernan, Carl A Olsson, Aaron E Katz. New York, NY.*

INTRODUCTION AND OBJECTIVE: Androgen ablation utilizing leutinizing hormone receptor hormone (LHRH) agonists continues to be the main treatment for patients with advanced prostate cancer (CaP). Unfortunately the most common side effect in patients treated with LHRH agonists is hot flashes which often interfere with patient quality of life. To date, hot flashes have not responded well to conventional medications which often also cause undesirable side effects. We report the results of the first prospective clinical trial testing the safety and efficacy of acupuncture in reducing hot flashes in advanced CaP patients undergoing hormonal therapy.

METHODS: An IRB approved, prospective pilot clinical trial was initiated in April 2006. The entry criteria included men >45 years, CaP Stage 3 or Stage 4 (no M1), receiving any LHRH agonist ± any anti-androgen, reporting >4 flashes/day (a standardized value on the Expanded Prostate Cancer Index (EPIC)-hormone questionnaire). Following consent, patients received standardized full body acupuncture 1x/week (wk) for 14 wks. Patients were evaluated at 0, 7, 14 and a 14-wk follow-up (F/U) (28-wks). At 0 and 14 wks serum testosterone was measured. At the 0, 7, 14 and 28-wk evaluations EPIC and patient reported hot flash frequency were administered. Endpoints are number of flashes as determined by the EPIC and patient report, and testosterone levels.