185

ERECTILE IMPLANTS IN FEMALE-TO-MALE TRANSSEXUALS: OUR EXPERIENCE IN 130 PATIENTS

Lumen N.[1], Monstrey S.[2], Decaestecker K.[1], Opdenakker Y.[1], Beysens M.[1], Hoebeke P.[1]

[1]University Hospital Ghent, Dept. of Urology, Ghent, Belgium, [2]University Hospital Ghent, Dept. of Plastic Surgery, Ghent, Belgium

Introduction & Objectives: Female-to-male transsexuals who desire sexual intercourse still need an erectile implant in their reconstructed phallus. Less is known about the complications of this surgery in female-to male transsexuals. We reviewed the complication rate of erectile implant surgery at our centre.

Material & Methods: On a total of more than 300 female-to-male transsexuals, 130 patients received an erectile implant between December 1997 and October 2007. Different types of prostheses were implanted: Dynaflex© in 9 patients, AMS CX©, AMS Ambicor© and Porges© in 68, 47 and 6 patients respectively. Mean follow-up was 22.2 months (range: 1-118 months). We reviewed the explantation rate and the cause of explantation in each group.

Results: Of the 130 patients, 72 patients (55.4%) still have their original implant in place. Fifty-eight patients (44.6%) needed to undergo either removal of the prosthesis due to infection or erosion (18 patients-13.8%) or revision due to dysfunction or leak (40 patients-30.8%). In the Dynaflex©-group, 8 of 9 patients needed revision due to dysfunction (88.9%) but no removals due to infection, protrusion or leakage were reported. In the Porges©-group, only 1 of 6 patients (16.7%) needed revision due to dysfunction but no other complications were reported. In the AMS CX©-group, 33 of 68 patients (48.5%) needed explantation due to infection, erosion, dysfunction or leakage in respectively 8 (11.8%), 2 (2.9%), 11 (16.2%) and 12 (17.6%) patients. In the AMS Ambicor©-group, 16 explantations (34%) were done because of infection, erosion, dysfunction and leakage for 4 patients each.

Conclusions: Despite a high explantation rate (44.6%) due to infection, erosion, dysfunction or leakage implantation of an erectile implant is the only valuable option for female-to-male transsexuals to obtain satisfactory intercourse. Patients must absolutely be informed about these possible complications but should not be discouraged.

186

SIX-MONTH CONCOMITANT AND ADJUVANT HORMONAL TREATMENT WITH EXTERNAL BEAM IRRADIATION IS INFERIOR TO 3-YEARS HORMONAL TREATMENT FOR LOCALLY ADVANCED PROSTATE CANCER: RESULTS OF THE EORTC RANDOMISED PHASE III TRIAL 22961

Bolla M.[1], De Reijke Th.M.[2], Van Tienhoven G.J.[3], Van Den Bergh A.C.M.[4], Oddens J.[5], Poortmans P.M.P.[6], Gez E.[7], Kil P.J.M.[8], Musat E.[9], Collette L.[10], EORTC Radiation Oncology and GU Groups

[1]CHU de Grenoble, Dept. of Radiotherapy, Grenoble, France, [2]Academic Medical Centre, Dept. of Urology, Amsterdam, The Netherlands, [3]Academic Medical Centre, Dept. of Radiotherapy, Amsterdam, The Netherlands, [4]University Medical Centre Groningen, Dept. of Radiotherapy, Groningen, The Netherlands, [5]Jeroen Bosch Hospital, Dept. of Urology, s'Hertogenbosch, The Netherlands, [6]Dr. Bernard Verbeeten Institute, Dept. of Radiotherapy, Tilburg, The Netherlands, [7]Rambam Medical Centre, Dept. of Oncology, Haifa, Israel, [8]St. Elisabeth Hospital, Dept. of Urology, Tilburg, The Netherlands, [9]EORTC Data Centre, Dept. of Medical Affairs, Brussels, Belgium, [10]EORTC Data Centre, Dept. of Statistics, Brussels, Belgium

Introduction & Objectives: After EORTC trial 22863, 3 years of endocrine treatment is now standard adjuvant treatment to 3-D external beam irradiation (EBRT) for locally advanced prostate cancer (PCa). In EORTC trial 22961 70 Gy EBRT and 6 months of combined androgen deprivation (SADT arm) was randomly compared to the same treatment followed by 2.5 further years of LH-RH agonist (62% triptoreline) monotherapy (LADT arm), aiming non inferior overall survival (OS) and possibly earlier recovery of testosterone on the SADT-arm

Material & Methods: Eligible patients had T1c-2b N1-2 or pN1-2, or T2c-4 N0-2 M0 PCa (UICC 1992) with PSA <150ng/ml. Non-inferior OS was defined as a morality hazard ratio (HR) ≤ 1.35 for SADT vs. LADT. Non inferiority at 80% power and 1-sided α=0.05 required 275 deaths. After an interim analysis conducted in September 2006, the Independent Data Monitoring Committee recommended the disclosure of the study results. Final results are thus presented at 1-sided α=0.0429, owing to one interim analysis. OS is compared with the LogRank test.

Results: 970 patients were randomized (483 SADT and 487 LADT). At 6.4 years median follow-up, 230 patients had died (132 vs. 98). The patient characteristics were well balanced: median age 69 years, WHO PS 0 in 84.0%, 87.4% of the patients had T≤T3cN0pN0 PCa. Progression (mostly biochemical and/or bone progression) occurred in 281 pts (196 on SADT vs. 85 on LADT) and was treated by secondary hormonal manipulation. The 5-year overall survival rate with SADT was 81.1% versus 85.1% with LADT (HR=1.47, 95.7% CI: 1.12-1.94), and failed to prove non-inferiority (the lower bound of the CI being >1.0). Clinical progression-free survival was significantly worse on SADT with 5-year event-free rate of 68.7% vs. 80.5% on LADT (HR=1.77, P<0.0001). Likewise, the 5-year biochemical progression-free survival rate was 56.8% on SADT vs. 77.7% on LADT (HR=2.20, P<0.0001). The results were similar in the subgroup with T≤T3cN0pN0 PCa.

Conclusions: The study indicated that survival with 6 months ADT after irradiation was significantly shorter than with to 3 years adjuvant ADT for patients with locally advanced PCa. Progression-free survival was also shorter with SADT

187

EXTERNAL-BEAM RADIATION THERAPY INCREASES THE RATE OF SECONDARY MALIGNANCIES RELATIVE TO RADICAL PROSTATECTOMY IN MEN WITH PROSTATE CANCER

Suardi N.[1], Jeldres C.[1], Perrotte P.[1], Da Pozzo L.F.[2], Raber M.[2], Shariat S.[1], Saad F.[1], Montorsi F.[2], Karakiewicz P.I.[1]

[1]Cancer Prognostics and Health Outcomes Unit, University of Montreal Health Centre, Dept. of Urology, Montreal, Canada, [2]Vita-Salute University, Scientific Institute San Raffaele, Dept. of Urology, Milan, Italy

Introduction & Objectives: Several previous reports addressed the effect of external-beam radiation therapy (EBRT) on the rate of secondary malignancies in patients with localized prostate cancer. Conflicting results were reported. We addressed the association between EBRT exposure and secondary malignancies rate in a large administrative database.

Material & Methods: The study population consisted of 10,333 men treated with radical prostatectomy (RP) (n=6196) or EBRT (n= 4137) between 1983 and 2004 without neo- or adjuvant hormonal therapy. The diagnosis of bladder, lung and colorectal cancer were established with the ICD-9 and surgery codes, that defined extirpative interventions aimed at eradicating these three malignancies (cystectomy, lobectomy or pneumectomy and colectomy with or without rectal resection). Univariable and multivariable Cox regression analyses addressed the rate of secondary malignancies (bladder, lung and rectal cancer).

Results: Overall, 92 (0.9%) cystectomies, 82 (0.8%) lung cancer surgeries and 228 (2.2%) surgeries for colorectal cancers were performed. In univariable analyses, the rate of cystectomies (log-rank p=0.002), of treatments for lung cancer (log-rank p<0.001) and for colorectal cancers (log-rank p<0.001) were higher in patients treated with EBRT relative to patients treated with RP. At multivariable analyses, after adjusting for age, baseline comorbidities and year of treatment (coded in quartiles), EBRT predisposed to a 3.0-fold higher rate of cystectomy for bladder cancer (p=0.04), to a 1.8-fold higher rate of lung cancer resections (p=0.02) and to a 1.7-fold higher rate of rectal cancer (p=0.02).

Conclusions: The increased rate of secondary malignancies after EBRT should be considered in localized prostate cancer treatment decision-making.

188

PHASE II STUDY OF HYPOFRACTIONATED RADIOTHERAPY (HYPORT) IN LOCALISED PROSTATE CANCER: REPORT ON ACUTE AND 18 MONTH LATE TOXICITY

Garcia-Rojo D.[1], Macias D.[2], Gonzalez D.[1], Gallardo D.[3], Martos D.[4], Ropero D.[4], Vicente D.[4], Abad D.[4], Hannaoui D.[4], Prera D.[4], Prats D.[4]

[1]Hospital Sabadell, Dept. of Urology, Sabadell, Spain, [2]Hospital General Catalunya, Dept. of Radiotherapy, Sant Cugat, Spain, [3]Hospital Sabadell, Dept. of Medical Oncology, Sabadell, Spain, [4]Hospital Hospitalet, Dept. of Urology, Sabadell, Spain

Introduction & Objectives: Radiobiological studies and preliminary results HYPORT trials seems to show that dose per fraction over 2 Gy is safe and can increase the therapeutic ratio. Before 10/2004 dose to prostate Planning Target Volume (PTV) in curative radiotherapy was 80-82 Gy in 2 Gy-fraction in 8.2 weeks at our institution. Our objective to implement HYPORT was to decrease late toxicity while maintaining same biochemical control (to keep same equivalent dose). Total treatment time reduction (34%) could be more convenient to patients and National Health System.

Material & Methods: The study includes 98 consecutive patients with localised prostate cancer (PCa). Exclusion criteria: pelvis node irradiation (N1 probability >15% according Roach formula). Technique: 6 fields 3D-Conformal RT. Minimum dose to PTV: 95% prescribed dose. Set-up control was off-line: days 1-2-3, weekly afterwards. Dose per fraction 2.6 Gy. Dose to PTV: 67.6-70.2 Gy in 5.2-5.4 weeks. This dose are Equivalent to 79.1-82.2 Gy in conventional fractionation (PCa α/β 1.5 Gy).

Results: Minimum follow-up 18 months. Low risk group=56.1%, intermediate=29.6%, high=14.3%. Exitus=4 (2ndneoplasia=3, myocardial infarction=1). Biochemical control 95.74%(90/94).Patients without HT (59.18%): Nadir (1.08±0.94ng/dl) at 16.6±4.4 months. Toxicity: Prospective analysis were scored using the RTOG criteria. Acute toxicity: Urological grade 0+1=69.38%, 2=29.59%, 3=1.02%. Rectal 0+1=87.75%, 2=12.24%, 3=0%.18 month Late toxicity: Urological grade 0=82.98%, 1=15.96%, 2=1.06%, 3=0%. Rectal 0=88.30%, 1=8.51%, 2=3.19%, 3=0%.

Conclusions: Hypofractionated accurate radiotherapy in localized prostate cancer is feasible with minimal significant acute or late toxicity. In our study Acute and 18-months late Toxicity is similar or lower than published high dose normofractionated radiotherapy studies. No grade 3-4 side effects were observed.