THIRD GENERATION CRYOSURGERY FOR PROSTATE CANCER - EUROPEAN EXPERIENCE

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Introduction & Objectives: The technical advances of 3rd generation cryosurgery have produced a radical and salvage prostate cancer treatment option for patients with excellent outcomes and acceptable morbidity. A pan-European approach has lead to the development of a Proctoring system and standardisation of the technique of prostate cryosurgery and an agreed treatment protocol across the major European Cryosurgery sites.

Material & Methods: The combined results from 3 major European Cryosurgery centres were analysed to give detailed outcomes of 440 patients (pts) with a maximum follow-up of 7 years and a median follow-up of 36 months. Mean age was 66,05 years. 228 pts had no previous prostatectomy and 212 were salvage cases including 120 radiation failures. 137 pts. were classified low risk according to D’Amico classification and 183 intermediate or high risk. Patients were treated with third generation cryotherapy devices SeedNet or Pressice (Galil-Medical, Israel). Depending on the length of the prostate needles generating short or long iceballs were used.

Results: 36 pts. (8,1%) died, 6 of those due to prostate cancer (1,4%). 32 pts. (7,3%) underwent a second cryotherapy. 70 pts. (15,9%) showed progression of prostate cancer. 4 pts created a fistula. Mean procedure time including learning curve and life cases at workshops was 129 minutes. 11.1% underwent a transurethral necrosis removal due to obstructive voiding symptoms. 4,3% of pts are incontinent. Only about one third of the pts. are sexually active before the cryotherapy. Two thirds out of the sexually active lost their erectile function at one year. Outcomes related to subgroups will be presented.

Conclusions: This combined analysis from the major European centres of Cryosurgery is the largest series of 3rd generation prostate cancer cryosurgery patients yet analysed. The stratified group results give a clear indication for primary and salvage prostate cancer patients for each separate patient group and is a clear indication of the place of cryosurgery in the management of prostate cancer patients. These data will allow us to counsel patients with greater knowledge and accuracy about their expected outcomes and success from a valuable minimally-invasive technology.

FISTULA, IMPOTENCE AND INCONTINENCE RATES 12 MONTHS AFTER PROSTATE CRYOSURGERY IN 4449 PATIENTS STRATIFIED ACCORDING TO TOTAL OR PARTIAL GLAND ABLATION MODALITY FROM THE COLD REGISTRY

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Introduction & Objectives: The COLD-Registry is a web-based data collection and management tool designed to address the specialized clinical inputs associated with physicians performing prostate cryosaturation in order to track outcomes data. This study aimed to analyze the correlation between patient outcomes and treatment modality (total or partial gland ablation). The Cryosurgery Society of Europe (CSE) has produced a list of complications stratified according to types of procedure performed (total or partial gland cryosaturation or salvage cryosurgery). 2 verify if there is a specific treatment modality that can be considered less risky then another and to evaluate how previous radiotherapy affects the complications outcomes.

Material & Methods: Participants in the COLD Registry agree that, to the extent required and/or appropriate, they obtain any authorizations, informed consents, institutional or private board approvals and/or other required approval prior to submitting data. Complication outcomes in 4449 patients enrolled in the COLD-Registry from several institutions and countries that accomplished at least 12 months follow-up have been stratified and analysed. From this large group of patients, only patients with full data for each type of complication have been stratified in Table 1. Note: The “# of patients” are those who did not report the condition prior to cryotherapy.

PRIMARY FULL GLAND PROSTATE CRYOABLATION: UPDATED RESULTS FROM 3209 PATIENTS TRACKED WITH THE COLD REGISTRY

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Introduction & Objectives: To present the outcomes of primary full gland prostate cryosaturation at a number of centres which have participated in the Cryo-On-Line Database (COLD) Registry.

Material & Methods: 3209 pts. who had undergone treatment were stratified according to the D’Amico risk classifications. Biochemical failure was defined according to the ASTRO and the PHOENIX definition. Biopsy was performed at the philosophy site, but mostly for a rising or suspicious PSA. Inconsistency was defined by the use of pads. Return to intercourse was defined as the ability to penetrate and complete intercourse with or without assistance. But mostly for a rising or suspicious PSA. Incontinence was defined by the use of pads. Return to intercourse was defined as the ability to penetrate and complete intercourse with or without assistance.

Results: 3209 pts. who had undergone treatment were stratified according to the D’Amico risk classifications. Biochemical failure was defined according to the ASTRO and the PHOENIX definition. Biopsy was performed at the philosophy site, but mostly for a rising or suspicious PSA. Inconsistency was defined by the use of pads. Return to intercourse was defined as the ability to penetrate and complete intercourse with or without assistance.

Table 1: MORBIDITY at 12 Months

<table>
<thead>
<tr>
<th># of Patients</th>
<th>Full Gland (n=1839)</th>
<th>Partial Gland (n=1360)</th>
<th>Salvage (n=175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercourse</td>
<td>25%</td>
<td>30%</td>
<td>40%</td>
</tr>
<tr>
<td>Incontinence</td>
<td>44%</td>
<td>44%</td>
<td>55%</td>
</tr>
<tr>
<td>FISTULA</td>
<td></td>
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</tbody>
</table>

Conclusions: Results confirm that the advancement in cryo-technology allows precise control of the extension of the freezing processes together with the capability to provide a tailored ice-bulb where needed, avoiding lesions to the surrounding tissues and subsequent risk of causing incontinence and bladder. The research remains future. The most challenging group of patients - the post-therapy cryotherapy ones. As expected, intercourse rates are significantly better for those patients that underwent partial/focal treatment, sparing the nerves of one side while achieving an adequate oncological margin on the other. Regarding the recovery of intercourse, we may expect an improvement with longer follow-up times because cryo damage is known to permit an asymptotic regress that may take 5 years to happen. Fistas are a relatively rare complication at least for the virgin patients and have been handled in the majority of the few cases with a successful conservative approach without major surgery like bowel diversion. Our data demonstrate that the fear of complications should not prevent the urological community from considering cryosurgery as an option for prostate cancer treatment.

PROGNOSTIC SIGNIFICANCE OF TUMOR VOLUME AFTER RADICAL PROSTATECTOMY

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Introduction & Objectives: Prognostic parameters regarding recurrence and progression of prostate cancer after radical prostatectomy include pre-op PSA, Gleason score, pathologic status, surgical margins and tumor volume. While clear association between tumor volume, Gleason score and pathologic status exists, the prognostic significance of tumor volume as statistically independent factor in uni- and multivariate analysis remains still controversial. The aim of the present study is to establish the prognostic significance of tumor volume after radical prostatectomy in terms of biochemical recurrence.

Material & Methods: We collected 230 radical prostatectomy specimens performed between 2004 and 2008 to determine tumor volume on whole-mount prostate sections by adding volume of each prostate tumor focus measured by an image analyser (sections scanned on a HP Scanjet 8200, and binary images analysed with the Ilyona VisionMaster Pro 511). Serum PSA levels were determined at least twice a year by each patient and biochemical recurrence was defined by a single postoperative detectable PSA superior than 0.2 ng/ml. Median follow-up time was 26 months (2 – 56 months). Uni- and multivariate analysis were performed using log-rank test and proportional hazards model to determine whether tumor volume is or not a statistically independent parameter of tumor recurrence and progression.

Results: Pathological parameters were as follows: 24 pT2a, 12 pT2b, 131 pT2c, 43 pT3a, 18 pT3b and 2 pT4. Mean tumor volume was 1.91 cc for pT2 (0.88 for pT2a, 1.2 for pT2b, 2.17 for pT2c, 4.86 for pT3a, 6.55 for pT3b) and 14 for pT4. Applying univariate analysis, tumor volume was a statistically significant parameter (p = 0.001). In multivariate analysis looking at tumor volume, Gleason score, surgical margin and pathologic status, tumor volume (p = 0.02) and Gleason score (p = 0.04) were found as independent prognostic factors.

Conclusions: In our study, tumor volume, as well as Gleason score, revealed as independent factors to predict prostate cancer recurrence and progression after radical prostatectomy. Tumor volume should be more considered in the therapeutic choice of prostate cancer, while more accurate tools to estimate it preoperatively are needed.