Long-Term Outcome of Randomized Trial Between Cryoablation and External Beam Therapy for Locally Advanced Prostate Cancer (T2c-T3b)

Introduction and Objective: Our primary objective is to assess and compare the survival outcomes between cryoablation (CRYO) and External Beam Radiation Therapy (EBRT) in locally advanced prostate cancer (T2c−T3b).
Materials and Methods: Patients with cT2c−cT3b prostate cancer (CaP) (PSA < 25ng/ml, negative metastatic evaluation on CT and bone scan), initially recruited for the trial from 1999 to 2002, were randomized to either primary CRYO (Cryocare System, Endocare Inc., Irvine, CA, USA) or EBRT (66 Gy in 33 fractions, administered at 2 Gy per day, 5 days a week for 6.5 weeks, directed at the prostate, seminal vesicles, and peri-prostatic region). All patients received neoadjuvant hormonal therapy (HT) for 3 months prior and continued for 3 months after the procedures. Patients underwent regular trans−rectal ultrasound and biopsy till 24 months of follow−up (at 3, 6, 12, 18, 24 months for CRYO and at 18, 24 months for EBRT) and as clinically indicated thereafter. Biochemical failure was based on the Phoenix criteria (PSA nadir + 2ng/dl). Biochemical disease-free survival (bDFS), disease-specific survival (DSS) and overall survival (OS) were analysed with Kaplan-Meier curve.
Results: Median follow−up was 105.2 (± 35.8) months. Accrual was limited due to newer data favoring longer neoajuvant HT and higher EBRT dose for patients for locally advance CaP. Sixty-two patients completed the trial. Preoperative demographic and clinicopathological characteristics of both groups were comparable. Prostate volume before therapy was smaller in the CRYO group (31.3 ml vs 40.9 ml) (p≤0.01). There was greater reduction in prostate volume in the CRYO group after intervention (−54% vs 34%) (p≤0.01). DSS and OS were comparable between both groups. The 8−year bDFS rate was significant lower in the CRYO group (17.4% vs 59.1%) (p=0.01); however, median time to bDFS was not significantly different (Figure).
Conclusion: This randomized trial showed that CRYO was inferior in attaining bDFS close to 9 years in patients with locally advanced CaP (cT2c-T3). A recent randomized trial for more localized CaP showed favorable outcome with CRYO cancer. CRYO may be more suited for less bulky CaP or longer neoadjuvant HT is required for optimal bDFS.

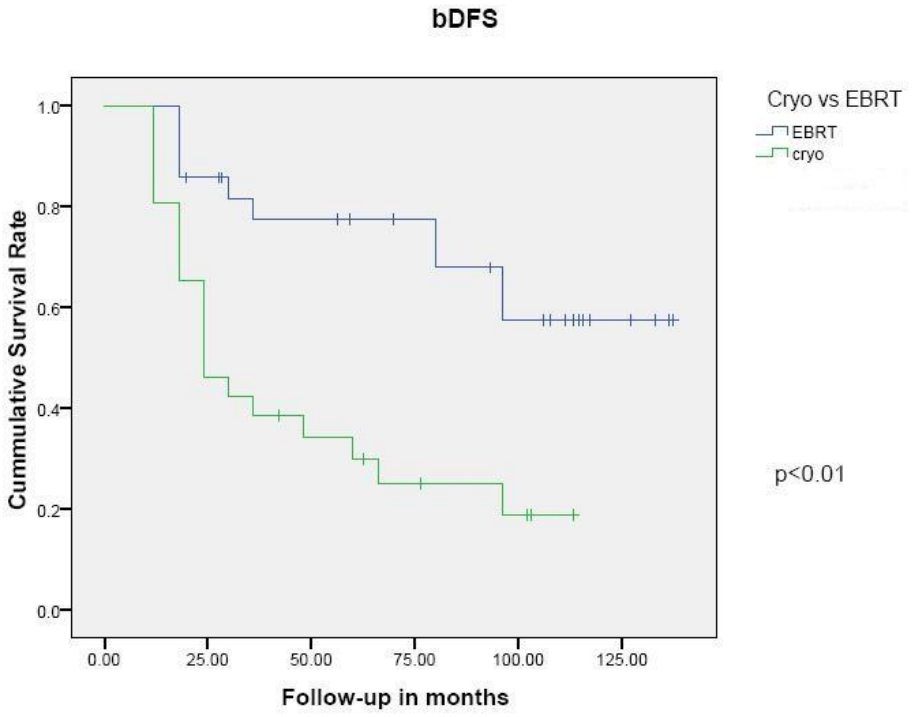

Figure: Kaplan Meier curve for biochemical disease-free survival (bDFS) of external beam radiotherapy (EBRT) group versus cryoablation (CRYO) group (p<0.01)