Prostate Advanced Radiation Technologies Investigating Quality of Life (PARTIQoL): Phase III Randomized Clinical Trial of Proton Therapy vs. IMRT for Localized Prostate Cancer

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Localized Prostate Cancer

Proton Beam Therapy

Photon Beam Therapy (IMRT)

Proton beam therapy (PBT) has certain dosimetric advantages with the potential to reduce treatment-associated morbidity and improve oncologic outcomes,

More resource-intensive than intensity modulated radiation therapy (IMRT)

To address the Hypothesis that PBT results in improved patient-reported outcomes (PROs), PARTIQoL (NCT01617161) was conducted as a multi-center Phase 3 randomized trial comparing the two modalities

Materials/Methods: Patients with intermediate- or low-risk prostate cancer were randomized to PBT or IMRT, without hormonal therapy,
Stratified for institution, age, rectal spacer use, and fractionation (79.2 Gy/44 fractions vs 70 Gy/28 fractions)

Participants were followed longitudinally to assess PROs of bowel, urinary, and sexual function for 60 months (mo) after the completion of radiotherapy.

The primary endpoint was to compare changes from the baseline in bowel quality of life (QOL) using the health care software score (range 0-100) at 24 mo.

Secondary objectives include a comparison of urinary and sexual functions, toxicity, and efficacy endpoints

Results: **Between 06/2012-11/2021,**

450 patients from 30 recruiting centers were randomized:

PBT (N=226) and IMRT (N=224),

of whom 221 and 216 were eligible and started radiation on the respective arms.

Median follow-up was 60.3 mo among 424 patients still alive.

Median age was 68 yrs (range 46-89),

59% had intermediate-risk disease, 51% received hypofractionation, 48% used a rectal spacer, and 49% of PBT patients were treated with pencil beam scanning.

There was no difference between PBT or IMRT in mean change of health care software bowel score at 24 mo (p=0.836), with both arms showing only small, clinically non-meaningful decline from baseline

LBA 01 – Table 1

Health care software bowel score Mean (Std Dev)	PBT (N=221)	IMRT (N=216)	p-value
Baseline	93.7 (7.8)	93.5 (7.9)	
24 mo	91.8 (11.1)	91.9 (8.6)	
Change	-2.4 (9.7)	-2.2 (9.1)	0.836

Similarly, there was no difference in bowel function at earlier timepoints (3, 6, 9, 12, 18 mo) or later timepoints (36, 48, 60 mo).

No differences were observed in other domains (urinary, sexual, hormonal) at any time point.

There was no difference in progression-free survival (PFS) (93.4% vs 93.7% at 60 mo, HR 1.16 [0.53, 2.57], p=0.706).

There was no sustained difference in any QOL domain or PFS between arms in subgroups defined by stratification variables.

Conclusion: This prospective randomized clinical trial shows that patients treated with contemporary radiotherapy for localized prostate cancer achieve excellent QOL with highly effective tumor control, **without measurable differences between PBT and IMRT**. We continue to monitor participants for longer follow-up and the secondary endpoint ……..