Theme: Clinical

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Abstract Title: Two-Fraction Stereotactic Body Proton Therapy (PT2) for Localized Prostate Cancer: A Phase II Trial in progress

Author Names: Darren M.C. Poon[1], Oi Lei Wong[2], Jing Yuan[2], Bin Yang[3], Sin Ting Chiu[4], Cindy Xue[2], George Chiu[4], Siu Ki Yu[3].
[1]Comprehensive Oncology Center; [2]Research Department, [3]Medical Physics Department; [4]Department of Radiotherapy, Hong Kong Sanatorium & Hospital, Hong Kong SAR China

Background / Aims:

- The high-cost limits the accessibility of proton therapy (PT), particularly for socioeconomically disadvantaged patients.
- Hypofractionation offers a potential solution to enhance affordability without sacrificing efficacy.
- A phase II, single-arm, non-randomized trial has been designed to evaluate the safety and feasibility of two-fraction stereotactic body proton therapy (PT2) with MR guidance and real-time tumor tracking
- The study design and protocol will be reported

Subjects and Methods:

- 35 localized low or intermediate risk prostate cancer patients will be enrolled in this study.
- MR visible fiducial markers and rectal spacer will be implanted prior to the treatment planning.
- CT and MR images were acquired in treatment position during treatment simulation.
- 25 Gy in two fractions of SBRT will be delivered at least 6 days apart and completed within 2 weeks.
- Daily MRI-based adaptive planning, combined with real-time X-ray tumor tracking, ensures precise dose delivery.
- Follow-up assessments will be scheduled at 1-. 3-. 6-, and 12-months post-treatment in the first year followed by biannual evaluation for up to 5 years
    - Patient-reported outcomes
    - PSA levels
    - Clinician-reported outcomes (Common Terminology Criteria for Adverse Event version 5.0, CTCAE v5.0)
- Primary endpoint: incidence of > grade 2 genitourinary and gastrointestinal adverse events at 3 and 24 months post treatment
- Secondary endpoints: report late toxicities, biochemical control and survival outcomes.
- By condensing treatment from five to two fractions, PT2 would reduce cost by approximately 50%, thereby improving assess for underserved populations.
- Advanced image guidance is expected to maintain toxicity profiles comparable to 5-fraction SBPT

Conclusion:

- This trial respresents the first investigation of 2-fraction PT for prostate cancer.
- The results of this trial may facilitate wider adoption of proton therapy by demonstrating its cost-effectiveness while preserving therapeutic efficiancy