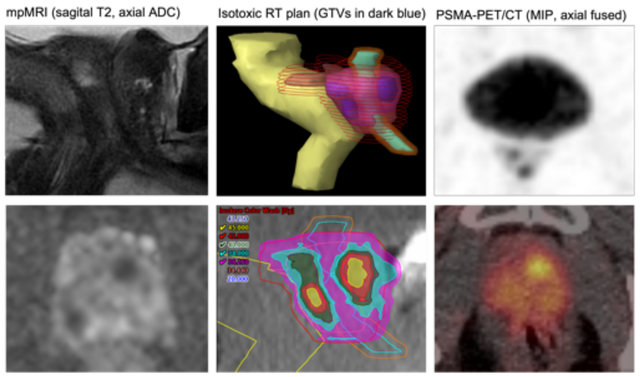
SBRT vs 20-fraction RT for any-risk prostate cancer: ePRO-measured acute toxicity in a randomised trial (OPTIMAL)

Thilo Schuler [1,2]
@th1loz
thilo.schuler@health.nsw.gov.au
Thomas Eade[1,3] George Hruby[1,3] Carolyn Kwong[1] Andrew Kneebone[1,3]

[1] *Northern Sydney Cancer Centre, Royal North Shore Hospital, Sydney, Australia*
[2] *Australian Institute of Health Innovation, Macquarie University, Sydney, Australia*
[3] *Northern Clinical School, University of Sydney, Sydney, Australia*

Background

OPTIMAL is an ongoing randomised controlled trial (RCT) comparing 5 (SBRT) vs 20 (Hypo#) fraction radiotherapy (RT) for prostate cancer (PCa) using a 1:2 randomisation. All patients receiving RT to the prostate +/- pelvic lymph nodes (LNs) irrespective of baseline urinary function or National Comprehensive Cancer Network (NCCN) risk-group were eligible. Isotoxic RT planning included intraprostatic lesion boosting and urethral sparing via MRI and PSMA-PET. Illustrative plan:



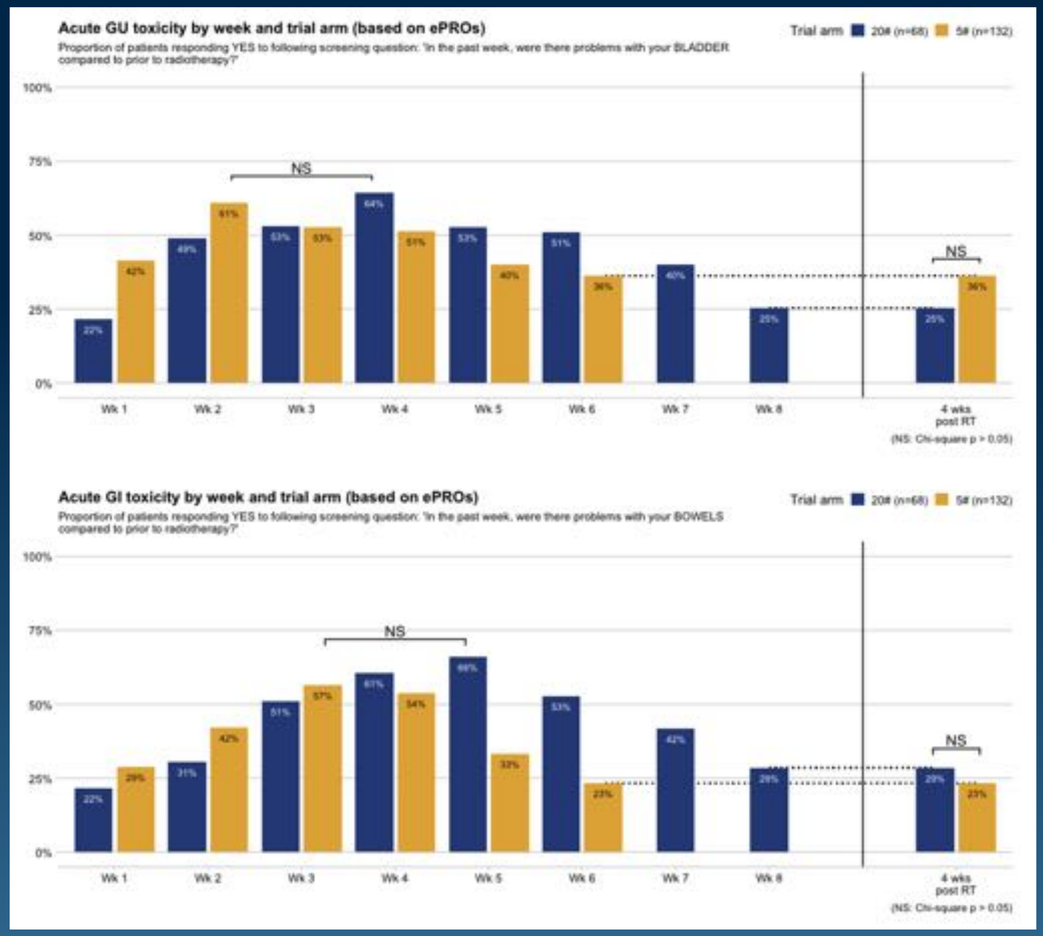
RT delivery used fiducial-based or soft tissue-matched image guidance (ClincalTrials.gov identifier: NCT03386045).

Methods

- We established a fully automated collection system for electronic patient-reported outcome (ePRO) surveys incl 1-2 reminders by email or short text message. The aim was to minimise trial staff involvement outside of the onboarding process.
- The pelvic REQUITE (www.requite.eu) questionnaire, was converted into an ePRO survey including extra logistical questions. This ePRO survey was called REQUITEplus.
- A dynamically shortened 'Peri-Treatment' variant of this REQUITEplus ePRO survey including binary genitourinary (GU) and gastrointestinal (GI) screening questions was administered weekly during and for 4 weeks after RT.
- Detailed REQUITE GU and/or GI questions were only asked in the Peri-Treatment survey if screening was positive.
- There was no manual phone reminder or oral survey administration for the Peri-Treatment ePRO survey.
- We report ePRO completion as key feasibility criterion and acute toxicity based on GU/GI screening ePRO questions after 200 of 330 planned OPTIMAL patients.

Real-world PCa RCT: SBRT vs Hypo#

- Mean age 74, any IPSS, any risk
- Weekly ePROs are feasible
- Same acute toxicity



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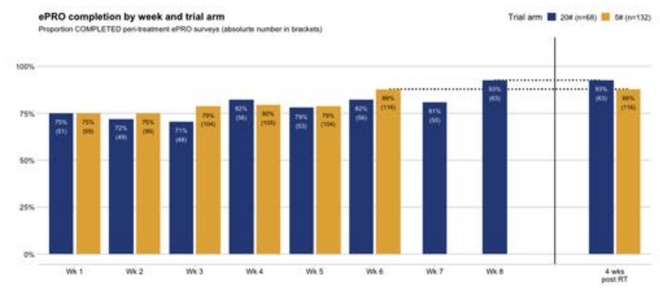
Results

Characteristics of the first 200 patients recruited at a single Australian centre between October 2018 and March 2022:

Dependent: OPTIMAL arm		Hypo# (20#)	SBRT (5#)	p
Total N (%)		68 (34.0)	132 (66.0)	
Age [yrs]	Mean (SD)	73.2 (9.7)	74.7 (7.1)	0.230
Baseline IPSS, N (%)	Mild [0-7]	45 (66.2)	67 (50.8)	0.050
	Moderate [8-19]	20 (29.4)	49 (37.1)	
	Severe [20-35]	2 (2.9)	14 (10.6)	
	(Missing)	1 (1.5)	2 (1.5)	
NCCN risk group, N (%)	Favourable intermediate	7 (10.3)	19 (14.4)	0.643
	Unfavourable intermediate	21 (30.9)	34 (25.8)	
	High risk	13 (19.1)	20 (15.2)	
	Very high risk	8 (11.8)	24 (18.2)	
	Node +ve	11 (16.2)	16 (12.1)	
	M1 disease	8 (11.8)	19 (14.4)	
LNs treated, N (%)	No	45 (66.2)	92 (69.7)	0.729
	Yes	23 (33.8)	40 (30.3)	
Intraprost. GTV volume [cm3]	Mean (SD)	4.9 (3.6)	5.7 (5.1)	0.255
Urethral D0.1cc [Gy]	Mean (SD)	59.0 (1.5)	37.1 (0.7)	<0.001
Urethral D0.1cc [% PTV dose]	Mean (SD)	103.5 (2.6)	102.3 (2.0)	0.001
Image guidance type, N (%)	Fiducials	29 (42.6)	67 (50.8)	0.348
	Soft tissue match	39 (57.4)	65 (49.2)	

Overall **ePRO completion** was 79% (1058/1336):



Regarding **acute toxicity** refer to bar graphs in middle panel.

Conclusions

- Weekly REQUITEplus Peri-Treatment ePRO surveys using a pragmatic ePRO design and a fully automated system are feasible with high and longitudinally stable completion rates despite advanced patient age.
- Consistent with PACE-B (Brand et al. Lancet Onc 2019) there was no difference in acute GU and GI toxicity (comparing peak and 4-weeks post RT rates) between the 2 arms despite a slight baseline IPSS imbalance.
- Detailed REQUITEplus analyses including regarding patient-reported late toxicity are planned. This includes longitudinal quantification & exploration of ePRO visualisation options. Use the QR code in middle panel to try out early examples...