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Publication Summary

A randomised feasibility trial of stereotactic prostate radiotherapy with or without elective nodal irradiation in high-risk localised prostate cancer (SPORT trial)

Houlihan OA *et al*. Int J Radiat Oncol Biol Phys. 2023 Mar 7;
doi: 10.1016/j.ijrobp.2023.02.054.

BACKGROUND

- Radiotherapy (RT) with or without pelvic nodal irradiation (ENI) – in combination with hormone therapy – is a standard treatment for patients with localised high-risk prostate cancer[1]
- Evidence suggests that increasing radiation doses per fraction has therapeutic and logistic benefits[2]
- Stereotactic ablative therapy (SABR) can deliver high-dose radiation directly to the target tissue, limiting damage to surrounding organs[3]
- SABR with ENI for treating high-risk disease has currently only been studied in single-arm trials[4]

In this study, Houlihan and colleagues assessed the feasibility of a randomised trial comparing SABR to the prostate and pelvic lymph nodes (PPN-SABR) *versus* SABR to the prostate alone (P-SABR).

METHODS

Prospective, non-blinded, single-centre, randomised controlled trial

30 men aged ≥18 years* with

- ✓ Unfavourable intermediate- or favourable localised high-risk prostate adenocarcinoma
- ✓ Clinical stage T3a N0 M0 and/or Gleason score ≥7 (4+3) and/or prostate-specific antigen >20 ng/mL

Randomised 1:1 to receive once weekly for 29 days:†

P-SABR	or	PPN-SABR
36.25 Gy to prostate PTV		36.25 Gy to prostate PTV
+ 40 Gy to prostate CTV		+ 40 Gy to prostate CTV
		+ 25 Gy to pelvic nodal PTV

CTV, clinical target volume; PTV, planning target volume

- All patients received ≥3 months of neoadjuvant androgen deprivation therapy, which was planned to continue for 12–36 months total, and underwent insertion of 3 fiducial markers and a polyethylene glycol hydrogel spacer (SpaceOAR®)

Key outcomes assessed

Toxicity (acute and late)‡	Patient-reported quality of life (QoL)
Gastrointestinal (GI)	Expanded prostate cancer index composite (EPIC) score
Genitourinary (GU)	International prostate symptom score (IPSS)

RESULTS

Patient characteristics and follow-up

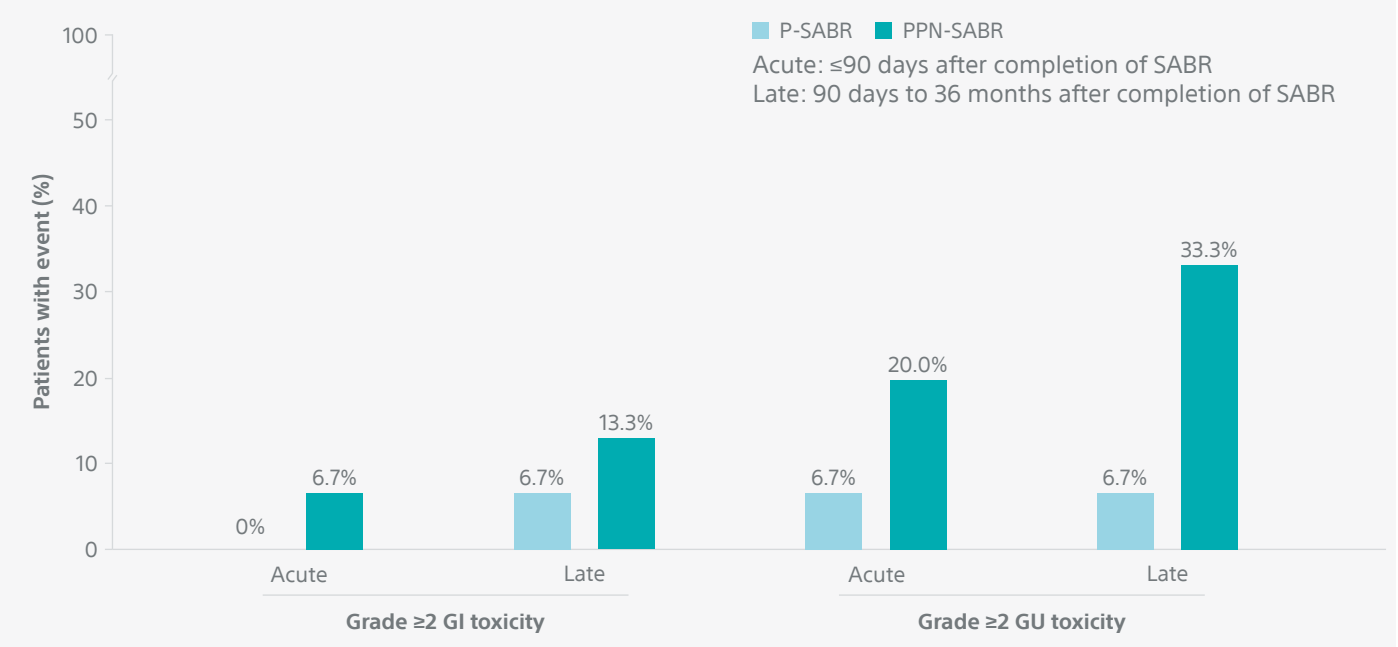
Median age: **67** years (interquartile range: 61.5–70 years)

83% had high-risk disease; **57%** had T3a N0 M0 disease

48 months follow-up (range: 30–60 months)

Toxicity rates were acceptable in both treatment arms

Figure 1: Grade ≥2 GI and GU toxicity events throughout follow-up

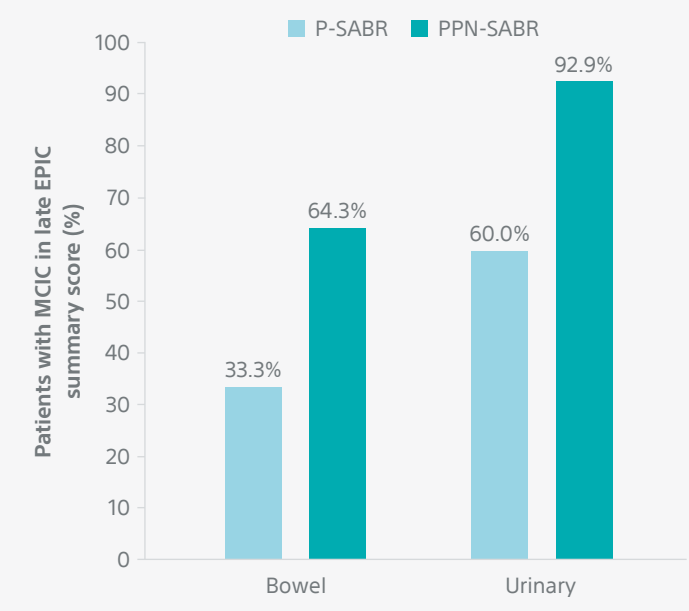


Graphical representation by Boston Scientific with data adapted from Houlihan OA *et al.*, *Int J Radiat Oncol Biol Phys*, March 2023

- The only Grade ≥3 toxicity was one case of late Grade 3 GU toxicity in the PPN-SABR arm (cystitis and haematuria)

Decline in QoL was smaller in the P-SABR arm

Figure 2. Minimally clinically important change (MCIC) in late EPIC summary score[§]



Graphical representation by Boston Scientific with data adapted from Houlihan OA *et al.*, *Int J Radiat Oncol Biol Phys*, March 2023

Increase in IPSS score from baseline to Year 2:

P-SABR: 5.8 ± 6.9	PPN-SABR:5.7 ± 6.3

Mean ± standard deviation

Strengths

- P-SABR control arm allowing direct comparison with PPN-SABR
- Blood samples blinded to researchers before biomarker analysis – eliminating measurement bias
- All patients underwent MRI after spacer/fiducial placement, aiding target and OAR delineation

Limitations

- Lack of blinding during radiation planning and delivery, and during assessment of toxicity
- Short median follow-up

CONCLUSION

- It is feasible to compare P-SABR and PPN-SABR in a randomised trial, with acceptable toxicity
- Toxicity rates and patient-reported QoL scores were comparable to those observed in previous studies

REFERENCE

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4. Houlihan OA *et al*. A randomised feasibility trial of stereotactic prostate radiotherapy with or without elective nodal irradiation in high-risk localised prostate cancer (SPORT Trial). *Int J Radiat Oncol Biol Phys*. 2023; doi:10.1016/j.ijrobp.2023.02.054.

Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

*31 patients were randomised, but 1 patient was excluded before SABR.

†An amendment to the protocol allowed an additional boost to the dominant intra-prostatic lesion (45-50 Gy in 5 fractions) for the final 10 randomised patients, due to acceptable initial toxicity rates.

‡Acute toxicity events were scored according to Common Terminology Criteria for Adverse Events (CTCAE) v4.03 criteria; late toxicity events were scored according to Radiation Therapy Oncology Group (RTOG) criteria.

§MCIC in late EPIC score was defined as a decrease of 5 points for GI and 6 points for GU toxicity between 90 days and 2 years after completion of SABR.

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