PACE-NODES

EARLY ADVERSE EVENT RESULTS

More early bowel side effects with nodal SBRT

Lancet Oncol 2026, online November 20 · Pathmanathan, Jain, et al.

DESIGN · PHASE 3, OPEN-LABEL

Early safety analysis

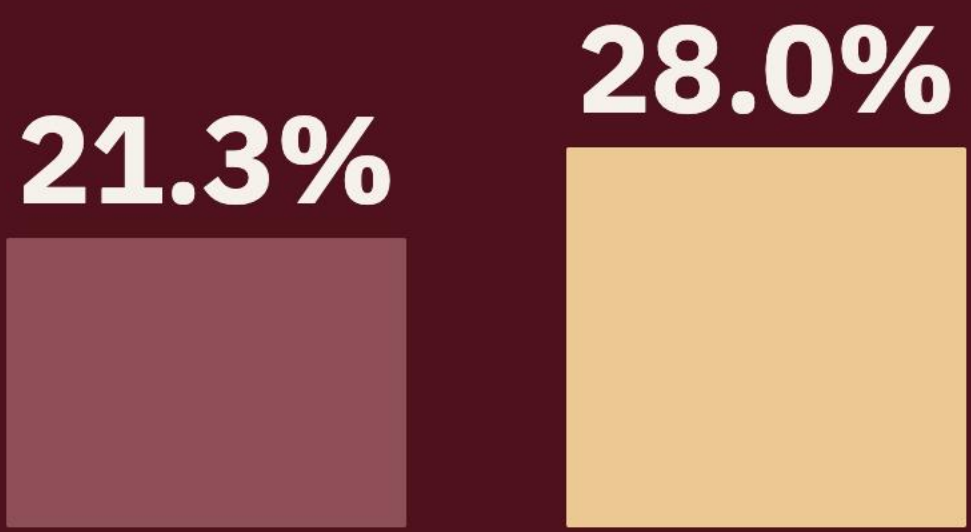
Randomised 1:1 | **5 fractions** | **Follow-up 13.8 mo**

PATIENTS	1166 · high-risk, localised, N0 M0 · ADT 12–36 months
ARMS	P-SBRT 36.25 Gy vs PPN-SBRT: same plus 25 Gy to pelvic nodes
THIS REPORT	Preplanned analysis of secondary end points within 12 weeks, by treatment received (555 vs 511)
PRIMARY	Biochemical or clinical failure: not yet reported

P-SBRT: prostate-only SBRT · PPN-SBRT: prostate and pelvic nodal SBRT

MAIN SAFETY END POINT · CTCAE WORST GRADE

Grade ≥2 gastrointestinal adverse events to 12 weeks



+6.7 percentage points (95% CI 1.6 to 11.9)

OR 1.44 (95% CI 1.09–1.91) · nominal P=0.011

Grade 3: 1.4% vs 2.2%

PATIENT-REPORTED · EPIC-26 · 99% CI

Patient-reported bowel outcomes

	P-SBRT	PPN-SBRT
EPIC-26 bowel function: decline of ≥MCID at week 4 +10.6 percentage points (99% CI 1.4 to 19.8) · P=0.0032	**54.9%**	65.5%
EPIC-26 bowel bother, week 4: moderate or big problem +5.4 percentage points (99% CI −1.3 to 12.0) · P=0.037	**14.7%**	20.1%

- Bowel bother did not meet the prespecified alpha of 0.01.
- MCID: minimum clinically important difference.

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CTCAE · BY TREATMENT RECEIVED

Time course and severity

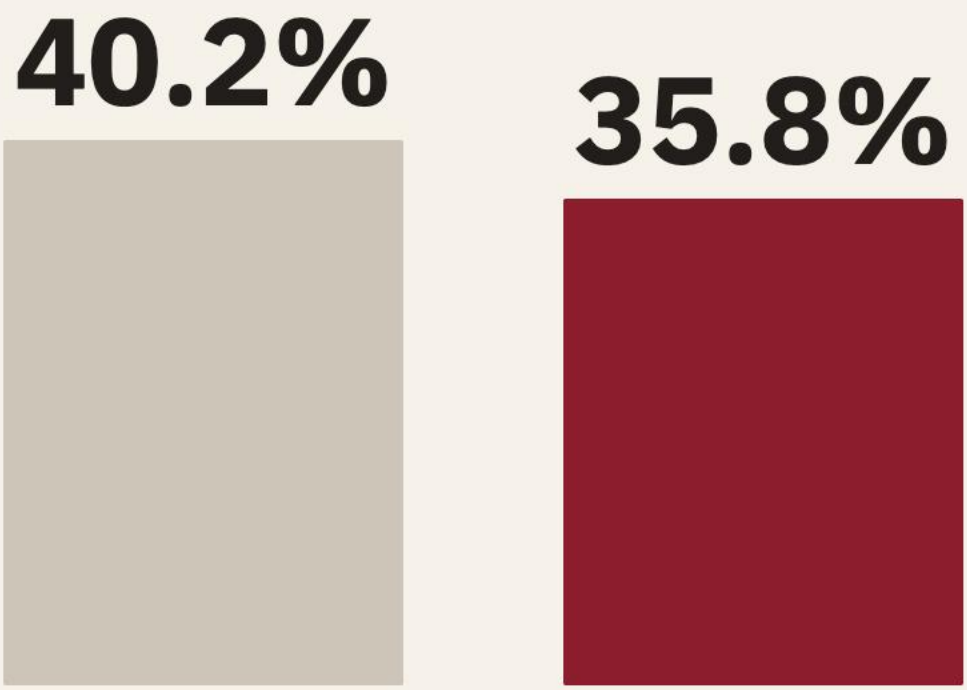
	P-SBRT	PPN-SBRT
Grade ≥2 gastrointestinal at week 2 (peak)	14.5%	19.1%
Grade ≥2 gastrointestinal at the 12-week visit +0.2 percentage points (99% CI −2.2 to 2.6) · P=0.86	2.2%	2.4%
Grade 3 gastrointestinal, up to 12 weeks Grade 4: one event (0.2%, colitis deemed unrelated) vs none	1.4%	2.2%

- No grade 5 events and no treatment-related deaths.
- No discontinuation or dose reduction for adverse events.

P-SBRT: prostate-only SBRT · PPN-SBRT: prostate and pelvic nodal SBRT

MAIN SAFETY END POINT · CTCAE WORST GRADE

Grade ≥2 genitourinary adverse events to 12 weeks



−4.4 percentage points (95% CI −10.2 to 1.5)

OR 0.83 (95% CI 0.65–1.06) · P=0.14, not significant

Grade 3: 1.3% vs 0.4%

LIMITATIONS

Analysis population and blinding

1 Analysed by treatment received: 2.9% allocated to prostate-only SBRT and 7.4% allocated to pelvic nodal SBRT received a different radiotherapy, mostly for unmet dose constraints.

2 Open-label: clinician grading and patient questionnaires were unblinded.

3 No adjustment for multiple comparisons across the two main end points. Patient-reported outcomes at baseline and 4 weeks only.

INTERPRETATION

> In patients who received five-fraction SBRT, pelvic nodal irradiation increased acute grade 2 or worse gastrointestinal adverse events; genitourinary events showed no significant difference.

REFERENCE

Pathmanathan A, Jain S, Cafferty FH, et al. Prostate and pelvic nodal stereotactic body radiotherapy (SBRT) versus prostate-only SBRT for high-risk, localised prostate cancer (PACE-NODES): early adverse event results from an international, open-label, phase 3, randomised controlled trial. Lancet Oncol 2026; published online November 20. doi:10.1016/S1470-2045(26)00465-1. ClinicalTrials.gov NCT05613023.

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Primary analysis expected in 2029.

RadiotherapyWatch