

Patient experience with intraprostatic injection of CAN-2409 or placebo followed by valacyclovir in a phase 3 clinical trial for localized prostate cancer in combination with standard of care radiation therapy with or without androgen suppression



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Background

Significant advances have been made in the detection and treatment of prostate cancer, yet it is still the cause of more than 30,000 annual deaths in the US alone. Currently available treatments are associated with significant side effects and loss of quality of life. Intratumoral oncolytic viral immunotherapy has the potential to induce a specific immune response against the patient's own tumor neoantigens, while minimizing systemic toxicity. CAN-2409 (aglatimagene besadenovec) is an adenoviral gene construct, which is being tested in localized prostate cancer in an ongoing phase 3 clinical trial under a Special Protocol Assessment agreement with the FDA. Here we describe the patient experience after intra-prostatic injection of CAN-2409 or placebo.

Methods

- Patient population: Localized intermediate risk or a single NCCN high risk factor
- Trial design: Randomized-controlled blinded phase 3
 - Randomized 2:1 to intra-prostatic injection with CAN-2409 or placebo followed by oral valacyclovir prodrug + radiation therapy ± ADT
 - Three courses of injection + valacyclovir before and during radiation therapy
 - Ultrasound-guided transrectal or transperineal injections, 0.5 ml delivered into each of 4 quadrants with a 22G needle in the outpatient setting
- Patient experience questionnaire added to inform future implementation of this approach from a patient-centric perspective
 - Tolerability of the injection procedure compared to prostate biopsy on a 1-5 scale (1-much easier to 5-much harder to tolerate than prostate biopsy).
 - Overall feeling positive about their involvement in the study.

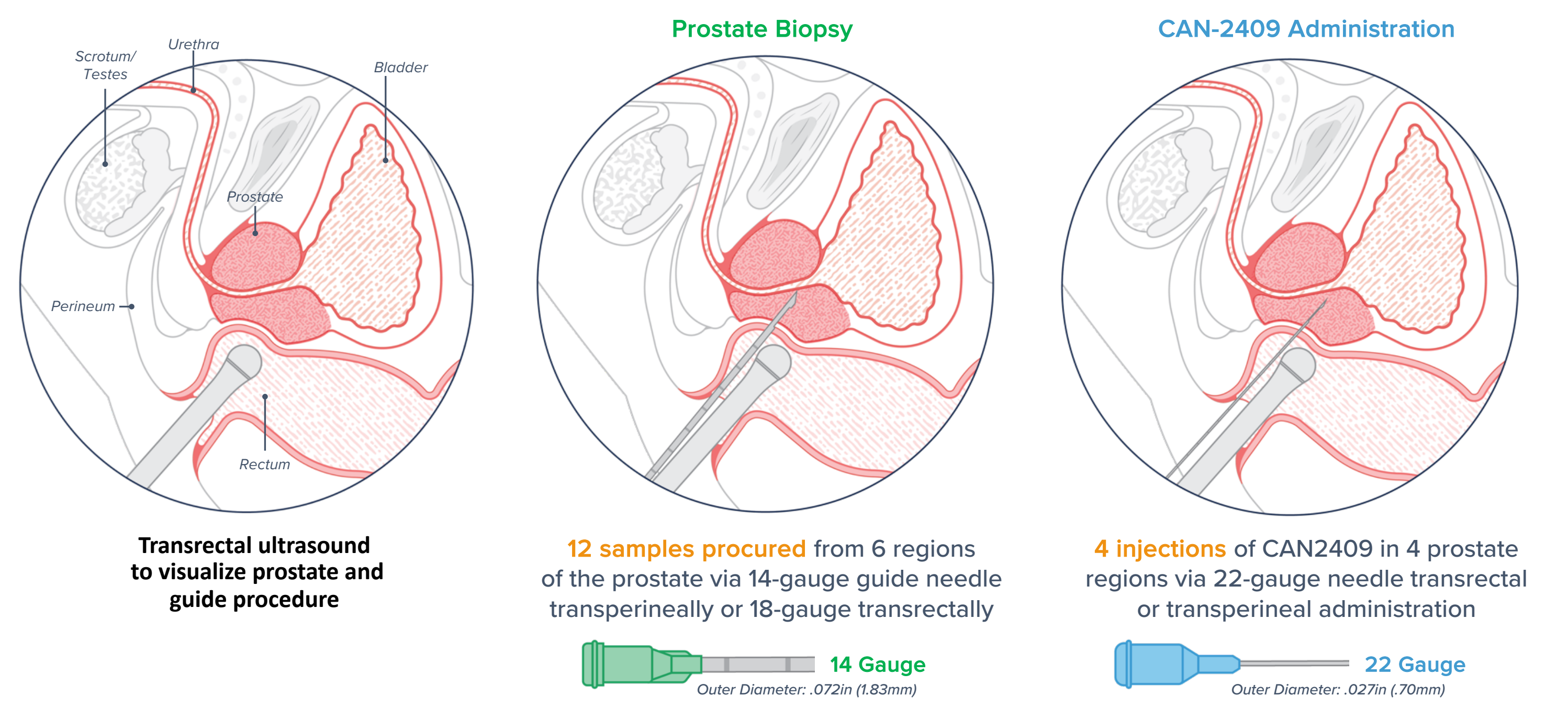


Figure A: Prostate Biopsy procedure and CAN2409/Placebo Administration procedure.

Demographics

Table 1: Characteristics of the 51 participating sites

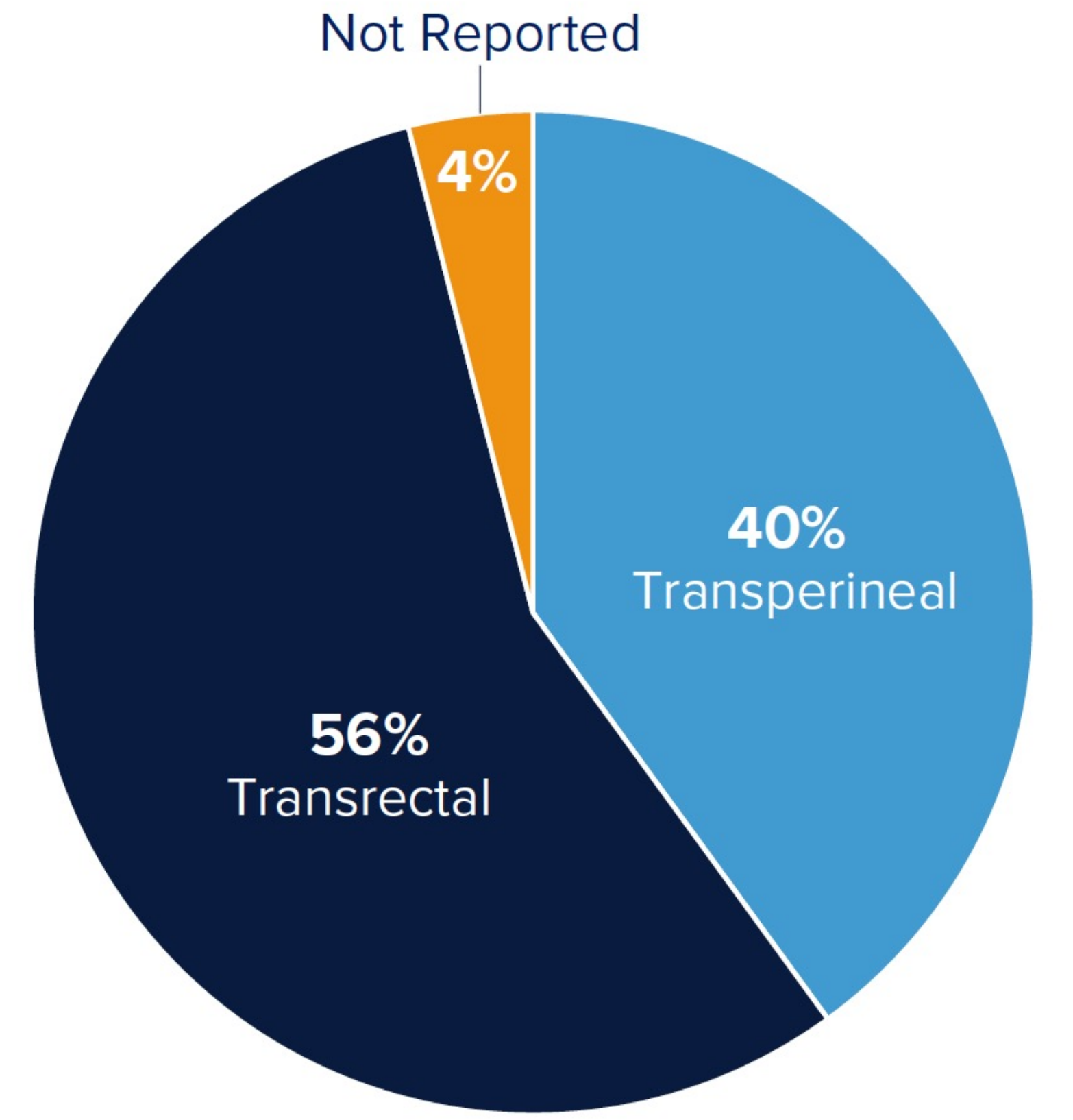
Clinical Site (n=51)	n(%)
Site Type	
Private	26 (51)
Veterans Affairs	18 (35)
Academic	6 (12)
Military Hospital	1 (2)
Site Principal Investigator	
Urologist	37 (73)
Radiation-Oncologist	14 (27)

Table 2: Patient demographics of 745 patients enrolled

Patient Demographics (Total enrolled patients=745)	
Age	
Median Age	69
Range	47-88
Race	
White/Caucasian	591 (79.3)
Black/African American	121 (16.2)
Asian	4 (0.5)
Native Hawaiian or Pacific Islander	2 (0.3)
American Indian or Alaskan Native	2 (0.3)
Not Reported	25 (3.4)
Ethnicity	
Hispanic or Latino	71 (9.5)
Not Hispanic or Latino	552 (74.1)
Not reported	122 (16.4)

Injection Procedure Administration Route

More than **2,000 injection procedures** have been performed. Across all clinical sites, the injection procedure has been performed using the following administration routes:

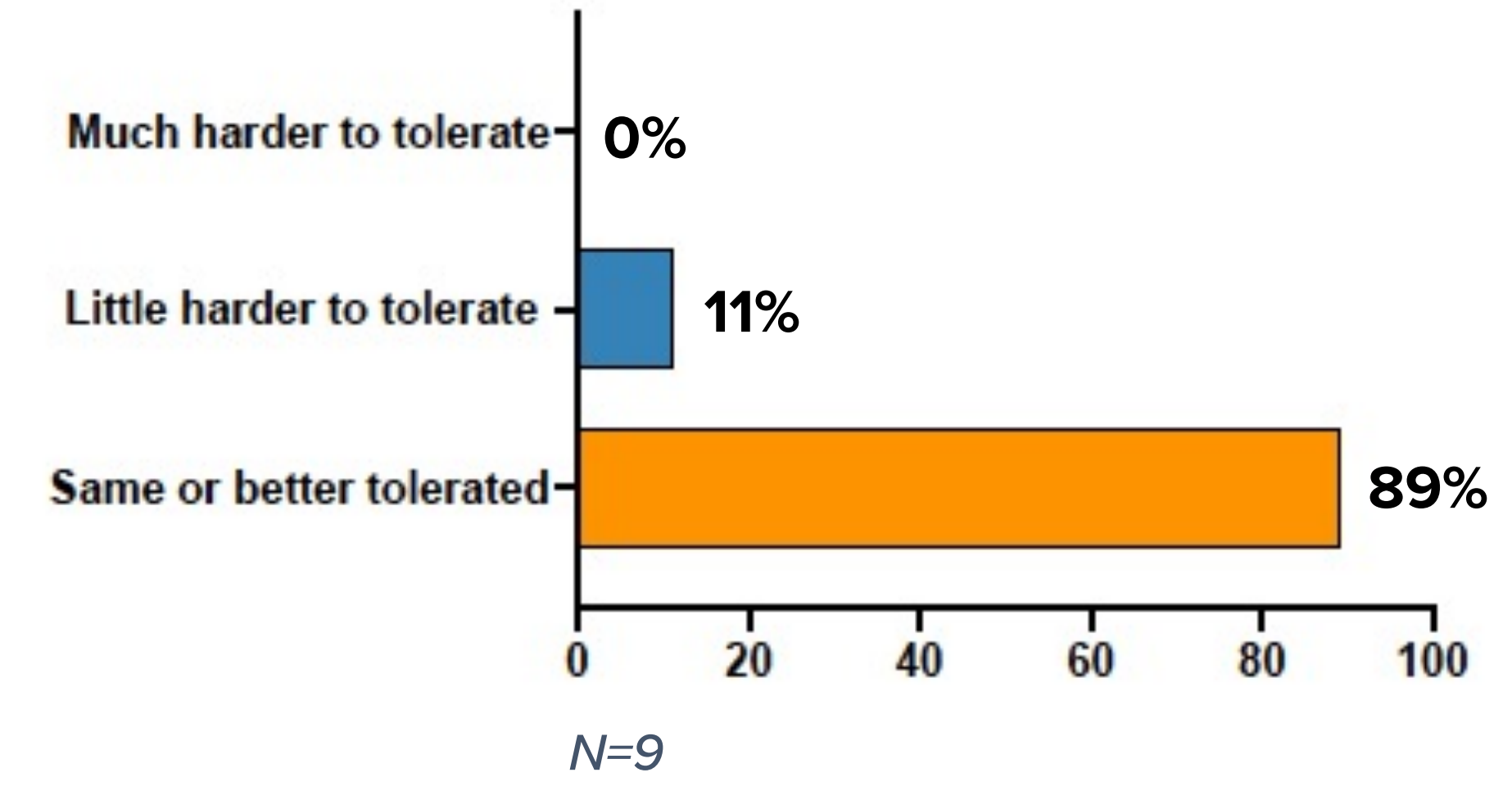


Results

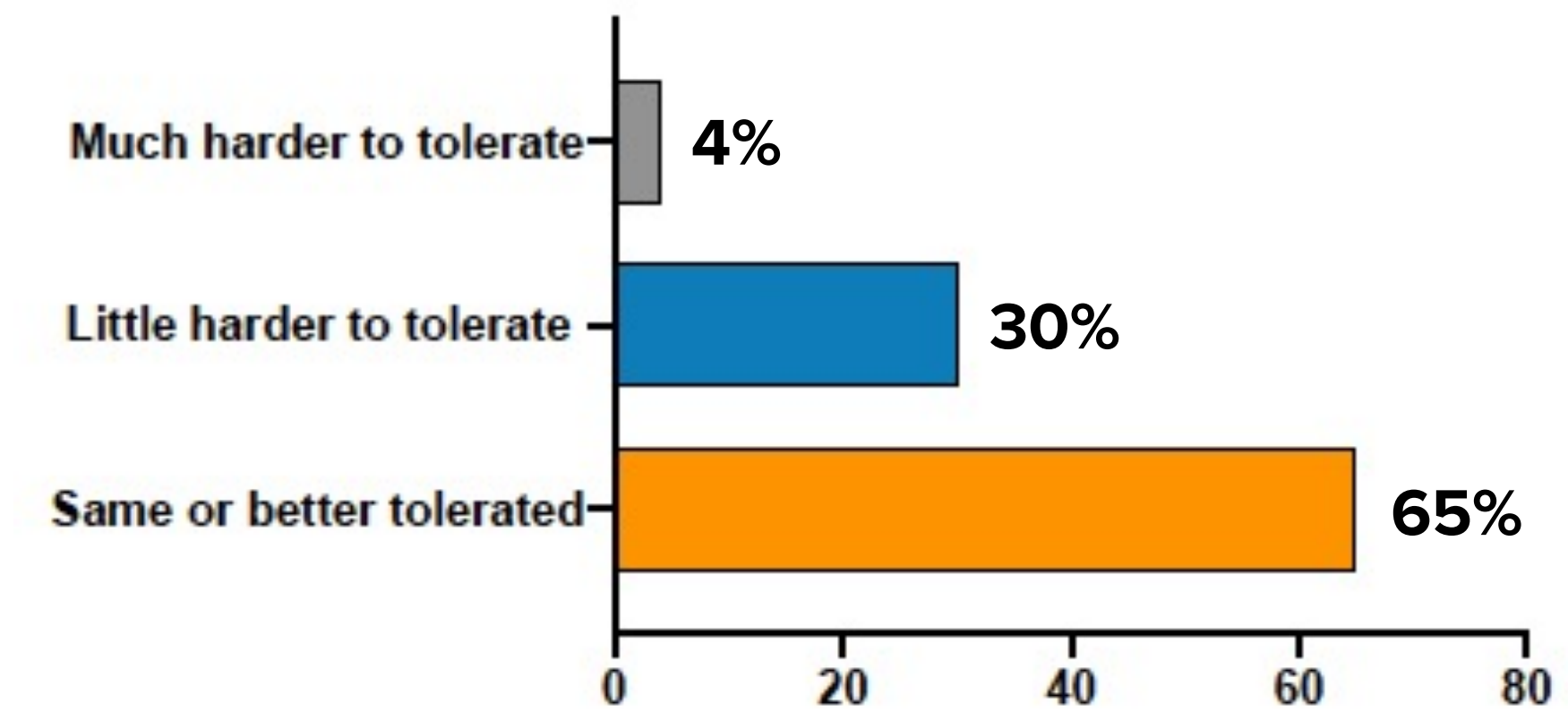
Patient Questionnaire : Rate tolerability of study procedure compared to prostate biopsy

N=32 patients completed questionnaire within 3 months of completing treatment

For transrectal procedures:



For transperineal procedures:



N=23, *83% of patients who underwent transperineal procedures also had rectal spacer placement.

All patients (100%) reported overall feeling positive about their involvement in the study.

Conclusions

Intraprostatic injections of CAN-2409 in men with prostate cancer undergoing radiation are feasible and generally well accepted by patients.

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