

Urology Times

www.urologytimes.com

The Leading News Source for Urologists



BPH symptoms, QoL improved by bacterial protoxin

Charles Bankhead

UT CONTRIBUTING EDITOR

Orlando, FL—A single injection of a bacterial protoxin activated by PSA led to greater than 50% improvement in symptoms within 3 months in a preliminary clinical study of men with BPH.

The average International Prostate Symptom Score (IPSS) decreased from 19.1 at baseline to 9.4 at 90 days in men treated with the agent known as PRX302, Canadian and U.S. researchers reported at the AUA annual meeting. Symptomatic improvement was associated with a significant reduction in prostate volume and significant improvement in quality of life.

"The impact of PRX302 on quality of life has been dramatic in most cases," said first author Peter Pommerville, MD, an investigator at Can-Med Clinical Research Centre in Victoria, British Columbia. "The effects improved with follow-up and showed that symptomatic relief was sustained.

"The patients we've treated thus far consider this to be a good alternative to prostate surgery and superior to oral medication, which often has a slow onset of action and can cause troubling adverse events, including sexual dysfunction," Dr. Pommerville told *Urology Times*.

"PRX302 provides almost immediate symptomatic relief without sexual side effects."

PRX302 is a bacterial protoxin that has been modified to permit proteolytic cleavage by PSA. Cleavage induces release of the active toxin, which forms complexes with prostate cells. The complexes create small pores that allow ion leakage, leading to loss of membrane integrity, cell death, and a reduction in prostate volume. Transperineal injection of the protoxin directly into the prostate

results in localized, tissue-specific activity.

"We hypothesize that the reduction in prostate mass reduces pressure on the urethra, resulting in a reduction in prostate symptoms," Dr. Pommerville said.

Investigators from Canada and Johns Hopkins in Baltimore presented data from 15 patients treated with PRX302 at five different dose levels, including high-dose treatment for men with large prostates. The range from lowest to highest dose represented a 14-fold difference. Both prostate lobes were treated with a single injection, consisting of three to four deposits of the protoxin into the prostate transition zone along the urethra.

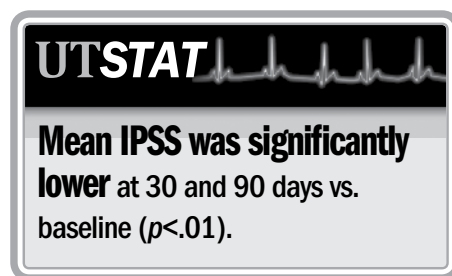


Baseline prostate volume averaged 37.8 to 56.6 cm³ in four treatment groups and 62.2 cm³ in the high-volume cohort. Baseline IPSS values ranged from 12 to 26.

Thirteen of the 15 patients had follow-up to 30 days and nine had follow-up to 90 days. Assessment by transrectal ultrasound showed that the average prostate volume decreased from 45.3 cm³ at baseline to 33.9 cm³ at 30 days and to 37.9 cm³ among patients with complete 90-day follow-up ($p < .01$).

Significant improvement noted

At 30 days, the magnitude of improvement in IPSS values ranged from 5% to 38% across the different doses and from 40% to 55% at 90 days. The mean IPSS was significantly lower at 30 and 90 days compared with baseline ($p < .01$).



At a Glance

Promising injectable » Significant reduction in gland volume, symptom scores seen at 3 months.

Mean quality of life score improved from 4.3 at baseline to 1.8 at 90 days. The difference from baseline was statistically significant at both 30 and 90 days ($p < .01$).

The protoxin was well tolerated, Dr. Pommerville noted, as no patient reported grade 3-4 adverse events. The most common adverse event was urinary frequency (three patients).

"The procedure is simple, safe, can be performed in a physician's office, and, more importantly, the beneficial effects of treatment are observed in less than 2 weeks," said Dr. Pommerville. "The marked reduction in prostate symptoms has had a profound and favorable impact on patients' quality of life."

Patients also like the fact that they can resume normal activities the day after the procedure, he added.

Dr. Pommerville is an investigator for Protox Therapeutics. One of the co-authors on this study is an employee of the company.



© Reprinted from *Urology Times*, September 2008
AN ADVANSTAR PUBLICATION Printed in U.S.A.

Protox
THERAPEUTICS

www.protoxtherapeutics.com