



Prostatic injection of botulinum toxin is not inferior to optimized medical therapy in the management of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a randomized clinical trial

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OBJECTIVE: To explore efficacy and safety of Botulinum Neurotoxin Type A (BoNT-A) prostatic injection in patients with lower urinary tract symptoms (LUTS) due to benign prostatic hyperperplasia.

MATERIALS AND METHODS: A phase 3 multicenter open-labeled study randomised patients to receive BoNT-A prostatic injection or optimized medical therapy. BoNT-A injection consisted in trans-rectal injections of 200 UI in the transitional zone of the prostate. Optimal medical therapy consisted in oral medication with any drug patented for LUTS. One month (M1) after randomisation patients in the BoNT-A group were asked to stop any medical therapy related to LUTS. The main judgment criterion was the IPSS score at M4. Per-protocol analysis was performed with a non-inferiority hypothesis (Δ IPSS < 3).

Résumé en anglais

RESULTS: 127 patients were randomised to BoNT-A (n = 64) or medical therapy (n = 63). At randomisation mean IPSS was 16.9 ± 7.2 in the BoNT-A group vs 15.7 ± 7.3 in control. In the BoNT-A group, 44 patients (73.3%) could interrupt medical therapy for LUTS from M1 to M4. At M4, mean IPSS score was 12.0 ± 6.7 in the BoNT-A group vs 11.8 ± 6.9 in control. After adjustment for baseline IPSS, delta IPSS between groups was 0.01; 95% CI [- 2.14; 2.11] leading to accept the non-inferiority hypothesis.

CONCLUSIONS: Four months after BoNT-A injection, most of the patients could interrupt LUTS-related medical treatments. In these patients, IPSS improvement was not inferior to optimized medical treatment, but the study design did not allow to conclude that this improvement was related with study drug rather than with sustained placebo effect.

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