

Botulinum toxin provides clinically meaningful benefit: study

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Treatment options for idiopathic OAB (IOAB) patients not adequately managed by anticholinergic therapy are limited; either highly invasive, expensive or of limited efficacy. BOTOX (onabotulinumtoxinA) may provide a minimally invasive effective treatment. Professor Chris Chapple (GB) and his group conducted the first large, double-blind, placebo-controlled, dose ranging study to systematically assess the benefit/risk balance of the use of BOTOX in IOAB across a wide range of doses. The results were presented yesterday at the Anniversary EAU Congress in Barcelona.

Chris Chapple: "IOAB patients with urinary urgency incontinence (UUI) whose symptoms are not adequately managed with anticholinergic therapy were recruited. Patients were randomised to receive BOTOX 50U, 100U, 150U, 200U or 300U or placebo. This was administered as intradetrusor injections".

Patients were followed for 36 weeks post-treatment with assessments including 7-day bladder diary, post void residual urine volume (PVR), health-related quality of life (HRQOL) questionnaires and urodynamics.

Chris Chapple: "We were happy to see durable and clinically meaningful efficacy for all BOTOX dose groups of 100U and above with significant reductions from baseline compared to placebo in patient symptoms, including being incontinence-free".

Dose response was identified in efficacy parameters; however a UUI

analysis demonstrated minimal additional efficacy at BOTOX doses above 150U and several HRQOL measures showed minimal incremental benefit above 100U.

Safety findings primarily related to local pharmacological effects on the bladder resulting in dose dependant increases in PVR. Adverse events significantly higher in BOTOX dose groups compared to placebo were UTI and urinary retention; the proportion of patients using clean intermittent catheterisation (CIC) increased with dose. Dose response was identified in safety parameters, particularly in the proportion of patients having a PVR \geq 200mL, a threshold associated with considerable increases in the use of CIC and adverse events such as urinary tract infection and [urinary retention](#).

"This double-blind, placebo-controlled study demonstrated that BOTOX provides a clinically meaningful benefit. The benefit / risk ratio has been evaluated over a broad range of [BOTOX](#) doses in the idiopathic OAB population and doses of 100U - 150U provide the appropriate benefit / risk balance. The clinically meaningful benefit is balanced with dose-dependant PVR elevation" Prof. Chapple concluded.

Provided by European Association of Urology

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