

OBESITY IS ASSOCIATED WITH A MORE SEVERE OVERACTIVE BLADDER DISEASE STATE THAT IS EFFECTIVELY TREATED WITH ONCE-DAILY ADMINISTRATION OF TROSPIUM CHLORIDE EXTENDED RELEASE

Hypothesis / aims of study

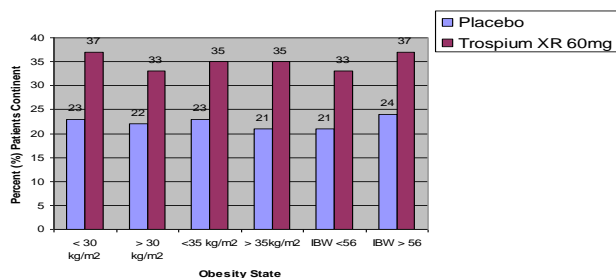
Obesity is an established risk factor for urinary incontinence, yet limited information exists as to the efficacy of anti-muscarinic agents in this population. The goal of this study is to examine the efficacy of once daily trospium chloride XR in over-weight and obese patients with the overactive bladder syndrome.

Study design, materials and methods

The primary and secondary end-points of the 1165 study subjects from the integrated trospium chloride XR pivotal trials were stratified by median Ideal Body Weight (IBW) and W.H.O. obesity levels I and II.

Results

Obesity (W.H.O. level I, II criteria and above median IBW) was associated with a more severe baseline OAB disease state ($p < 0.01$). Trospium chloride XR was more effective than placebo at reducing the primary endpoints (toilet voids, UUI, $p < 0.0001$) and at improving the secondary end-points (percent patients continent and urgency severity, $p < 0.0001$) for W.H.O obesity level I and II, and median IBW.



Interpretation of results

Obesity is associated with a more severe OAB disease state. Once daily trospium chloride XR is efficacious in the obese patient with the OAB syndrome.

Concluding message

Obesity correlates with a more severe disease state, which can be effectively treated with specific anti-muscarinics agents. The pharmacokinetic properties of antimuscarinic agents, such as hydrophilicity, metabolism and renal versus hepatic elimination may be clinically relevant in the treatment of OAB patient subsets and specifically obese patients with the OAB syndrome.

<i>Specify source of funding or grant</i>	Allergan, LLC
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Indevus
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes