419

Cabarrocas X[1], Lois P[1], López R[1]
1. *Laboratorios Salvat*

PHARMACODYNAMICS OF SVT-40776 IN OVERACTIVE BLADDER PATIENTS

Hypothesis / aims of study

SVT-40776 has shown pharmacological activity in a multiple dose study in healthy volunteers[1]. A pharmacodynamic study of SVT-40776 in patients suffering from Overactive Bladder syndrome was performed to obtain first efficacy and tolerability data in this population.

Study design, materials and methods

The study was randomised, double-blind, placebo and active-controlled. Patients received SVT-40776 at the dose of 0.1 or 0.2 mg, tolterodine 4 mg or placebo o.d. during 4 weeks, just after a 2 week single-blind wash-out period in which all patients received placebo. Urodynamic assessments were performed at baseline and after 4 weeks administration.

Results

A total of 133 patients were randomised and 72 completed the study and were included in the ITT population. The proportion of males was 65% and mean age was 43 years old.

There was no dose-response relationship for SVT-40776, and the results for the 0.1 mg dose were slightly better than for 0.2 mg.

SVT-40776 0.1 mg produced the highest increase in volume at first desire to void (60 mL), compared to tolterodine (33 mL) and placebo (17 mL). The same happened with the parameter volume at strong desire to void. The increase was 71 mL for the 0.1 mg dose and 42 mL for tolterodine, while the volume decreased 10 mL after placebo treatment. Finally, the results were similar for the endpoint 'infused volume'. After the 0.1 mg dose of SVT-40776 the volume increased by 73 mL, 20 mL after tolterodine treatment and decreased 10 mL after placebo.

All treatments were well tolerated. The incidence of treatment emergent adverse events was 25% for SVT-40776 0.1 mg, 33% for 0.2 mg, 36% for tolterodine 4 mg and 27% for placebo.

Interpretation of results

These are the first data showing pharmacological activity of SVT-40776 in OAB patients. The drug showed good pharmacological activity and was well tolerated by patients.

Concluding message

A higher pharmacological activity has been seen after 0.1 mg of SVT-40776 during 4 weeks compared to tolterodine 4 mg and placebo in a population of patients suffering from OAB. More studies are needed in order to characterise the efficacy and tolerability of this new antinuscarinic drug.

References

Abstract no. 460, 37th ICS annual meeting, August 2007.

Specify source of funding or grant	**Study funded by Laboratorios Salvat**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Diacon Hospital, No.360 19th Main, First Block, Rajaji Nagar, Bangalore**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**