International drug study shows rapid improvement in overactive bladder symptoms

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Patients with overactive bladders who took part in a multi-centre study to measure the effectiveness of solifenacin noticed improvements in as little as three days, according to research published in the November issue of *BJU International*.

Just over a hundred urology centres from 14 countries took part in the study of 863 patients led by Professor Linda Cardozo from the Department of Urogynaecology at King's College Hospital in London.

During the 16-week double-blind randomised study, neither the researchers nor the patients were aware of which were taking solifenacin and which were taking the placebo or dummy drug. Three times as many patients took the active drug as the placebo.

The aim of the study was to see what effect the drug had on overactive bladder problems, in which patients feel an urgent need to pass urine and some can become incontinent. A number of novel and subjective outcome measures were used to assess urgency.

"This is the first study to assess urgency as the primary endpoint using the Patient Perception of Intensity and Urgency Scale (PPIUS), which ranges from zero to four with grades three and four representing urgency and urgency incontinence" explains Professor Cardozo.

"We also used the six-point Patients Perception of Bladder Condition score, visual analogue scales and patient diaries."

Researchers found that on average patients taking solifenacin reported a 70 per cent reduction in severe urgency and urgency with incontinence, as measured by the PPIUS, compared with 50 per cent for those taking the placebo.

There were also statistically significant improvements when it came to all levels of urgency, maximum urgency intensity and urgency bother.

The clinicians taking part in the study reported that they recorded significant improvements in the patients taking solifenacin when they attended their one-week clinic visit after starting to take the drug.

"Solifenacin was significantly more effective than the placebo as early as day three" says Professor Cardozo. "Patients reported that they passed urine less frequently and also reported significant reductions in the number of daily incontinence and urgency incontinence episodes.

"Less than four per cent of the patients reported mild or moderately severe side effects when they took 5mg or 10mg doses of the drug and just 3.6 per cent of the solifenacin group stopped taking the drug.

"Looking at the solifenacin study group as a whole, just under 16 per cent reported dry mouth problems and seven per cent reported constipation.

"Just over two per cent of patients on the placebo also reported side effects. Three per cent reported dry mouth problems and two per cent reported constipation.

"It is common to notice a quite strong placebo effect in overactive bladder trials and this study is no exception. However, even a relatively small difference between active treatment and placebo outcomes might have a large influence on quality of life and treatment success."

The study was carried out in two eight-week segments. In the first eight weeks 640 patients (74 per cent) were given 5mg daily of solifenacin and the remaining 223 received the placebo.

At the end of eight weeks, 46.5 per cent of patients receiving solifenacin requested a dose increase as did 66 per cent of the patients receiving the placebo.

Half of the solifenacin patients had their dose doubled from 5mg to 10mg and the other half were left on 5mg. The results from this secondary analysis will be published at a later date.

Approximately nine out of ten study participants were female and their average age was 58. Most had suffered from an overactive bladder for three to four years.

Patients were selected if they had suffered from an overactive bladder for more than three months and had had three or more urgency episodes, with or without incontinence, in the last three days. They had to be willing and able to keep a diary on when they emptied their bladder and the level of urgency and degree of bother they experienced.

"The rapid improvement that patients taking solifenacin reported is very important as patient expectations are high when they experience this highly distressing condition and they can become easily disillusioned if they don't see early results" says Professor Cardozo, who wrote the international paper with experts from Germany, Italy, Spain, Belgium and The Netherlands.

"Our study found that solifenacin was consistently effective at reducing urgency and other symptoms associated with an overactive bladder and that simple scoring scales, such as the PPIUS, are a reliable way of measuring treatment outcome."

Source: Wiley