

EVALUATION OF THERAPEUTIC EFFECT OF DARIFENACIN IN PATIENTS WITH OVERACTIVE BLADDER USING BLADDER DIARY IN RESPONDERS

HYPOTHESIS / AIMS OF STUDY

The Overactive bladder (OAB) syndrome is defined by the International Continence Society as the symptoms of urgency, with and without urge incontinence, usually with frequency and nocturia.

OAB is a common condition that adversely affects the quality of life of approximately 17 percent of adults worldwide.

Antimuscarinics are the first-line pharmacological treatment of the OAB. It is well known that this treatment is not always effective and that it is associated with side effects, limiting its clinical use.

Darifenacin is a selective muscarinic M3 receptor antagonist. It is a tertiary amine with moderate lipophilicity, well absorbed from the gastrointestinal tract after oral administration, and extensively metabolised in the liver.

Darifenacin has been developed as a controlled-release formulation, which allows once-daily dosing. Recommended dosages are 7.5mg/d and 15mg/d. Darifenacin had a rapid onset of effect, with significant improvement compared with placebo.

The clinical efficacy of Darifenacin has been documented in several randomized controlled trials.

Patients receiving antimuscarinics experienced clinically significant improvements in most bladder diary variables compared with placebo.

Frequency volume chart (FVC) records the volumes voided as well as the time of each micturition, day and night, for at least 24 hours. FVC is a useful tool and it is defined as the simplest form of urodynamics in functional urology.

The purpose of this analysis was to determine the changes on pre and post treatment FVC in Darifenacin responders.

STUDY DESIGN, MATERIALS AND METHODS

In a retrospective study, we analyzed one-day FVC in 16 patients with idiopathic detrusor overactivity Darifenacin treatment responders (received a diary single dose of 7.5 mg. Darifenacin). Treatment was considered as responsive when urgeincontinence episodes decreased to 50% or less.

A one-day FVC was given to each individual to fill in for a 24-hour period before starting darifenacin treatment and again 15 days after. On the diary they recorded the number of diurnal voids, number of Nocturia episodes and volume of each micturition.

The parameters extracted from the FVC were nocturnal frequency (nocturia episodes), daytime frequency and 24-h total voided volume. All definitions conform to ICS Standardization Committee recommendations. Mean functional bladder capacity and mean nocturnal bladder capacity were calculated. Nocturnal polyuria was calculated by the Nocturnal Polyuria Index (NPi = ratio of nocturnal urinary volume to maximum voided volume).

Initial and repeat FVC were compared.

Fisher-test was used for quantification data, P values less than 0.05 were considered statistically significant.

RESULTS

The study included 7 women and 9 men (16 patients), with a mean age of 62.8 ± 11.4 years (range 44 to 86 years).

Darifenacin significantly reduced diurnal voids and nocturia, increasing functional bladder capacity and nocturnal bladder capacity as shown in table I.

Table I
VOIDING DIARIES PARAMETERS RESULTS

	Pre-treatment Mean	Post-treatment Mean	T test values	P
24 hour volume (ml.)	2319	2062	0.31	
Total diurnal # voids	10.3	8.0	0.01	
Total night # voids (Nocturia episodes)	2.56	1.37	0.01	
Functional bladder capacity (ml.)	184	223	0.02	
Nocturnal Bladder Capacity (ml.)	230	318	0.03	
NPi (%)	38.2	9.1	0.05	

INTERPRETATION OF RESULTS

Darifenacin at doses of 7.5 mg provided a significant improvement in dairy bladder parameters in responders. Data from 24hour FVC concerning urinary frequency, nocturia and urine volumes vary significantly after Darifenacin treatment. Mean reduction in NP_i was due to the fact that in 6 patients had no more nocturia episodes.

CONCLUDING MESSAGE

Responders patients receiving Darifenacin showed a significant mean change in FVC variables.

References

1. Honjo H, Kawauchi A, Ukimura O, Nakao M, Kitakoji H, Miki T. Analysis of bladder diary with urinary perception to assess overactive bladder symptoms in community-dwelling women. *Neurourol Urodyn*. 2009;28(8):982-5.

Disclosures

Funding: NONE **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** Is a standard treatment for OAB **Helsinki:** Yes **Informed Consent:** Yes