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PREDICTOR FACTORS FOR SUCCESSFUL TREATMENT OF SOLIFENACIN IN PATIENTS WITH OVERACTIVE BLADDER

Hypothesis / aims of study

It is important to identify the factors potentially affecting the efficacy of the pharmacologic treatment of overactive bladder (OAB). If we an predict which patients will not benefit from antimuscrinic agents before treatment, we can avoid giving these patients ineffective medication and reduce potential drug-related adverse effect. Thus, the aim of this study is to investigate the predictive factors of therapeutic success after solifenacin in patients with OAB.

Study design, materials and methods

A total of 365 consecutive OAB patients (71% male, age 72.5 ± 12.0 years) were prospectively enrolled in this post-marketing study. All patients received 5 mg solifenacin once a day. Uroflowmetry, IPSS-V, IPSS-V, IPSS-T, quality of life (QOL), Overactive Bladder Symptom Score (OABSS) , the indevus urgency severity scale (USS) questionnaires were assessed at baseline, 1-month, 3-month, 6-month and 12-month, respectively. The successful treatment was defined as a reduction of USS of 2 or greater from baseline or the USS value was 0 at 3-month visit.

Results

Table 1 showed that compared with baseline, IPSS-S, IPSS-T, QOL, OABSS and USS value were significantly improved at 1-month and the therapeutic effect were persisted up to 12 months. Table 2 showed that compared with failure group, patients with successful treatment had statistically significantly higher baseline maximal uroflow rate (Qmax), higher USS score and high percentage of OAB wet. Gender, male with BPH, medical diseases or diabetes mellitus had no significant effects on the efficacy of solifenacin. 34.7 % patients had dry month and 23.0% had constipation at 3 months.

Interpretation of results

Our finding is similar to a recent post hoc analysis of beta-3 agonist for the treatment of overactive bladder from three randomized phase 3 trials. Mirabegron is effective for treatment of OAB symptoms in incontinent patients and its effect increases with increasing severity of incontinence. Tolterodine has also found that patients with great baseline symptom intensity had greater treatment associated improvement. Recent study has showed that a higher USS recorded in a voiding diary is strongly correlated with the urodynamic detrusor overactivity. Thus, higher success rate of either beta-3 agonist or antimuscarinic agent in patients with a higher USS score is quite reasonable.

Concluding message

Solifenacin is effective and safe for patients with overactive bladder up to 12 months. Baseline high Qmax, high USS value and OAB wet patients are predictive factors for successful treatment.

Table 1. Comparisons of baseline and post-treatment data (up to 12 months) after solifanacin treatment

	baseline	1 M	3 M	6 M	12 M
Patient number	365	325	245	199	175
Qmax (ml/sec)	12.8±7.4	13.4±7.5	12.5±7.6	13.9±8.0	13.4±9.4
Voided Volume (mL)	182±120	213±128	185±122	179±102	189±119
PVR (mL)	48±56	67±75	57±57	76±60**	60±85
IPSS-V	6.7±5.0	6.1±5.5	6.3±5.4	5.9±4.4	4.7±4.5**
IPSS-S	6.9±3.4	4.4±3.2***	4.7±3.0***	4.6±3.3***	4.2±2.8***
IPSS-T	13.5±6.6	10.5±7.1***	11.0±7.4*	10.4±6.1	8.9±6.0***
OABSS	6.4±3.8	4.4±3.3***	4.6±3.1***	4.7±3.3***	4.1±3.0***
USS	3.1±1.3	2.1±1.4***	2.3±1.4**	2.3±1.4*	2.1±1.5***
QoL	3.8±1.3	2.3±1.2***	2.5±1.1***	1.9±0.7***	2.0±1.1***

*: p-value < 0.05 compared with baseline, **: p-value < 0.01 compared with baseline,
***: p-value < 0.001 compared with baseline

Table 2. Comparison of general characteristics, baseline uroflowmetry, IPSS score, OABSS and USS value in both groups.

	Successful treatment	Failed treatment	P-value
Qmax (mL/sec)	14.4±6.5	11.7±6.7	0.01
Void volume(mL)	203±133	174±121	0.15
PVR (mL)	33±45	53±57	0.06
Bladder capacity (mL)	233±151	220±141	0.77
IPSS-V	6.6±5.4	7.2±5.1	0.53
IPSS-S	6.9±3.5	7.0±3.5	0.86
IPSS-T	13.5±7.0	14.3±6.7	0.59
OABSS	6.3±3.2	7.0±4.2	0.63
USS	3.4±1.2	2.9±1.3	0.02
QoL	3.8±1.2	3.9±1.2	0.72
Gender (M v.s F)	69.5% v.s. 30.5%	72.8% v.s 27.2%	0.71
BPH (only male)	43.9%	44.1%	1
OAB type	wet 81.4%	wet 58.0%	0.004
Medical diseases (%)	28.8%	30.8%	0.85
DM (%)	16.9%	21%	0.67

References

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Disclosures

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