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A NON-INTERVENTIONAL RETROSPECTIVE EVALUATION OF RESOURCES CONSUMED DURING THE PROVISION OF CARE FOR OVERACTIVE BLADDER SYNDROME: A REAL WORLD EVALUATION (THE REDUCE STUDY – INTERIM ANALYSIS)

Hypothesis / aims of study

The aim of this study was to evaluate resource utilization, pad use and patient satisfaction for subjects with overactive bladder (OAB) syndrome who were managed with commonly prescribed medications: solifenacin succinate, tolterodine tartrate, or trospium chloride. Reporting on the resource utilization and pad use will be deferred until study completion.

Study design, materials and methods

Data were abstracted from medical records for qualified subjects who were at least 18 years or older, with a diagnosis for OAB (at least one of urgency, frequency with or without urgency incontinence) on or before 31DEC2010. Subjects must have been on one of the study medications for at least 3 months at the time of study entry and have at least 12 months of medical records available. Subjects were excluded if: incontinence for which stress was the predominant factor, documented evidence of a neurological cause of detrusor muscle over activity, significant bladder outlet obstruction (BOO) in the opinion of the investigator, primary diagnosis of urinary tract infection (UTI), diagnosis of bladder stones, previous pelvic irradiation, urologic surgery within 6 months of the data collection period, which in the opinion of the investigator, would complicate OAB symptoms, current malignant disease of the pelvic organs, diabetic neuropathy or, women who were pregnant or nursing during the retrospective study period. The study was approved by local ethics committees and all data provided were anonymised. The patient's satisfaction with their OAB medication, and the reasons for satisfaction, were estimated by their clinician. Logistic regression analysis was used to evaluate the relationship between demographic characteristics and patient satisfaction with their OAB medication.

Results

An interim analysis was performed on subject satisfaction as perceived by the clinician on 146 of the expected 250 total subjects. Data were provided from three centers in the Czech Republic and five centers in Germany. The mean age was 67.5 years with 78.8% of subjects female. Mean time since subject was first diagnosed was 4.6 years. Of the 146 subjects, 67 were on solifenacin (5 and 10mg/day), 11 were on tolterodine (IR and ER 4mg/day) and 68 were on trospium (IR and ER 60mg/day). Overall satisfaction was greatest with the solifenacin group and was significant ($P < 0.001$) as shown in Table 1. Solifenacin was associated with the highest rate of "very satisfied" subjects (47.8%) when compared with tolterodine (27.3%) and trospium (14.7%). The extended release (ER) versions of tolterodine and trospium were associated with a higher rate of very satisfied subjects when compared with the immediate release (IR) versions.

Table 1: Frequencies for Subject Satisfaction by Medication

Medication	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied	Very Satisfied (%) [1]	P-Value [2]
Solifenacin	32	32	3	0	0	47.8	< 0.001
Solifenacin (5 mg)	16	18	2	0	0		
Solifenacin (10 mg)	16	14	1	0	0		
Tolterodine	3	6	2	0	0	27.3	
Tolterodine ER	3	4	0	0	0		
Tolterodine IR	0	2	2	0	0		
Trospium	10	49	9	0	0	14.7	
Trospium ER	8	10	3	0	0		
Trospium IR	2	39	6	0	0		

1 – The % of very satisfied is defined as: (frequency of very satisfied / all responses) * 100

2 – P-value from the Fisher exact test (for the distribution of satisfaction by medication not discriminating by dose or release)

Reasons for satisfaction included effectiveness, lack of side effects, cost of medication, impact on physical function, impact on mental function and convenience of use. The top 3 reasons for satisfaction as reported by medication were effectiveness, lack of side effects and convenience of use for solifenacin; effectiveness, lack of side effects and convenience of use for tolterodine; effectiveness, lack of side effects and cost of medication for trospium. A total of 13 medication switches were reported, with trospium having the highest "switch from" occurrence (n=4), while solifenacin and trospium had the highest "switch to" occurrence" (n=5 for each drug). A total of 9 adverse drug reactions (ADRs) were reported. Three were related to one of the three study medications and six were related to OAB medications that were not included as comparators in this study. The

subjects who experienced the ADRs not associated with one of the study medications switched to one of the three study medications during the study period, as a result of the reported ADR. The 9 ADRs were reported from six subjects, representing 4.1% of the total number of subjects available for this interim analysis. The logistic regression indicated a statistically significant relationship between the duration of time since the patient was diagnosed with OAB and satisfaction; no other demographic variables were statistically significant.

Interpretation of results

The interim analysis for subject satisfaction was based on the clinician's perception and was significant. Effectiveness and lack of side effects, the two most commonly reported reasons for satisfaction; lend support to the clinicians' perception in the absence of patient reported satisfaction. The proportion of subjects who experienced an OAB medication switch was minimal (7.5%). The patients' tendency to persist with antimuscarinic medications, observed in this study, is consistent with a previous study conducted in four European countries. [1] The convenience of use was a significant factor for solifenacin and tolterodine subjects, and may be a factor for trospium subjects as well, evidenced by a higher rate of satisfaction for trospium ER patients. For all OAB study medications, the adverse drug reaction rate was low (< 3%).

Concluding message

Among the three medications included in this study, solifenacin had the highest frequency of very satisfied responses as reported by clinicians. A low incidence of switching antimuscarinic therapy was observed in this study, which is consistent with recently published literature. The convenience of use appears to be an important factor as the satisfaction with once daily or extended release versions of antimuscarinic OAB medications tends to be greater.

References

1. Compion G, Jackson J, Janes J. Reasons for switching antimuscarinic therapy: Results from a European cross-sectional survey of physicians, and patients with OAB. EAU 2012 Abstract AM 12-2068:691

Disclosures

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