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Factors of adherence to treatment with trospium in employees

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ABSTRACT

Aim: To conduct a comprehensive study of adverse factors and decreasing patients' adherence during treatment with trospium.
Materials and methods: During 12 months, 977 patients receiving trospium were studied regarding demographic, socioeconomic, and medical parameters by studying employer's records, extracts from income tax returns, questionnaires OABq-SF, MOS SF-36, ICIQ-SF, and questionnaires concerning demographic and social status, voiding diaries, and uroflowmetry.
Results: In total, 54.4% and 35.5% of patients preserved adherence to treatment with trospium during 6 months and 12 months, respectively. The average time of reaching a 30-day break in trospium administration was 182 days. Patients diagnosed with urge urinary incontinence and overactive bladder OAB (56.1%; 40.7%), having severe incontinence symptoms (56.1%), showing objectively high treatment efficacy (25.3%), and individuals subjectively satisfied with treatment outcome (57.5%) prevail among adherent patients, a significant minority is heavy coffee drinkers (14.5%).
Individuals who are healthcare and education employees having annual and monthly income significantly higher than the mean income of patients receiving trospium also prevail among adherent patients (25.0%; 32.5%). Adherent patients are significantly older (56.3) than patients less adherent to the treatment.
Conclusion: This experiment allowed for the first time the determination of the complexity of heterogeneous medical, socioeconomic, and demographic factors affecting patients' adherence in treatment with trospium.

1. Introduction

The prevalence rates of lower urinary tract symptoms (LUTS) and, particularly, overactive bladder (OAB) symptoms remain consistently high worldwide.[1,2] The prevalence of OAB is significantly higher in the elderly and women.[3] The mean incidence of OAB symptoms "at least sometimes" for all races is 26–33% in men and 27–46% in women.[4] Furthermore, 8% of men and 20% of women at the age of 18–70 years reported to have OAB symptoms "frequently".[5,6]

LUTS are often accompanied with depression, anxiety, decreased mental and physical activity, social isolation, and sexual health problems.[7,8] Apart from its negative effect on health-related quality of life in many men and women, direct costs for LUTS treatment are very high; in 2009, they amounted to $ 22.3 billion only in the USA. The presence of LUTS causes substantial losses for the employer and the employee and decreased work productivity, as observed in individuals suffering from asthma or chronic arthritis.[9–11]

Efficacy and safety of the available range of antimuscarinic drugs (AM) is generally recognized at the moment.[12] Additionally, new advanced drugs appear having the mechanism of therapeutic effect associated with affecting β_3-adrenoceptors. Nevertheless, LUTS management continues to be a challenge currently. One of the reasons include poor adherence of patients to treatment with AM drugs.[13,14]

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In previous researches, we drew our attention to the patient's poor adherence to AM drugs treatment,[15–17] which is consistent with the other authors' data.[18]

Poor adherence to physician's prescriptions may be determined by medical, social, economic, demographic, psychological, and other factors.[19,20] We have established correlation between adherence to prescriptions and efficacy of AMs, development of side effects, a regimen and a method of AM administration, and pharmacology of different drugs. Sometimes the results of the studies differ significantly among different authors. For example, in one of the studies, it was found that adherence to treatment with fesoterodine is significantly higher than that with solifenacine and lolnerodinum.[21] In other studies, conclusions were not so unambiguous.[22,23]

It was found that adherence to treatment with AM drugs is significantly affected by the cost of the drug, a possibility to get insurance treatment, and the number of days of disability leave.[24] However, we failed to find studies in the available literature regarding correlation between adherence to treatment with a certain AM drug and a wide range of medical, pharmacodynamic, socioeconomic, and demographic factors that could affect the patient's choice. We were also unable to determine information regarding comparison of significance of such factors in the making of a patient's behavioral decision.

In our earlier works, we studied the effect of combination of some AM drugs, particularly trospium, of decreased and increased dosage, on the activity of OAB symptoms. Trospium chloride is a quaternary ammonium compound, which does not affect the central nervous system and causes no side effects, associated with influence on the central nervous system.[25] We have suggested that studying a wide range of factors, affecting adherence to treatment with trospium, could help to identify the most significant of them. Probably, the understanding of significance level of different factors and possibility to affect some of them would help to improve the adherence and manageability of treatment process.

Therefore, the purpose of this study was to study the significance of the factors affecting adherence to treatment with trospium in the cohort of employees to increase the efficacy of management of various LUTS forms.

2. Methods

2.1. Background information about the experiment

The study design is presented in Figure 1. The study was conducted at the premises of the Regional Diagnostics Center of the City Polyclinic No. 3 of Vladivostok from June 1, 2013 until February 5, 2015. It was a randomized, blinded prospective experiment regarding the factors affecting patients' adherence to treatment with trospium. According to the experiment protocol, among all the patients aged 18–60 years who visited the above institutions concerning LUTS, we selected patients admitted on the odd-numbered days of the month and prescribed with a long-term (> 1 year) treatment with trospium only.[25] Selection of patients into groups with various forms of LUTS was performed using stratified randomization ensuring equal gender representation. The selection scheme is presented in Figure 2. Electronic patient records and their test results were anonymized (they were assigned with numbers) to blind the members of the study group performing analysis of the results. To calculate the sample size, we considered the confidence level of 95% and a confidence interval of ±5%.

2.2. Inclusion/exclusion criteria and factors studied

Patients with the following diagnoses were included in the groups for participation in the experiment: overactive bladder, OAB (ICD-9-CM: 596.51 converts directly to 2015 ICD-10-CM N32.81); urge incontinence, UUI (ICD-9-CM: 788.31 converts directly to 2015 ICD-10-CM N39.41); mixed incontinence, MI (ICD-9-CM: 788.33 converts directly to 2015 ICD-10-CM N39.46); and nocturia (ICD-9-CM: 788.43 converts directly to 2015 ICD-10-CM R35.1).[26] The diagnosis was confirmed by the data from voiding diaries, questionnaires OAB questionnaire short form (OABq-SF), and results of uroflowmetry.[27]

Furthermore, the criteria for inclusion in the group were employment for at least 6 months before the start of the experiment and availability of the policy of obligatory medical insurance. The exclusion criteria were terminal cancer, administration of AMs within 6 months before the start of the experiment, and unemployment.

During the active phase of the experiment (12 months), all the patients were administered with trospium chloride as monotherapy 15 mg twice a day after meal, as prescribed by the urologist.

Every day during the year, the patients completed voiding diaries. In these diaries they noted data regarding the amount, volume, time, and specific characteristics of urination, urgency episodes, incontinence, side effects, and time of trospium intake. The diaries were also supplemented with a column wherein the patients included information about smoking and consumption of caffeinated food and drinks as well as alcohol.

Before the study, after the 6th month (1st checkpoint) and in the end of the follow-up period (2nd checkpoint), all patients underwent the following diagnostic procedures: (1) uroflowmetry, evaluation of urodynamics during the evacuation phase with calculation of urine volume (mL), average urine flow rate (Q_{aver}, mL/s), maximum urine flow rate (Q_{max}, mL/s), which provides objective evaluation of urination disorders; (2) completion of the questionnaire OABq-SF to specify the form and severity of urination disorders; a score of > 8 was considered as urination disorder of the certain type; (3) completion of the questionnaire "The Medical Outcomes Study 36-Item Short-Form Health Survey" (MOS SF-36) to determine the general effect of health on the quality of life. The questionnaire MOS SF-36 consists of eight items, each characterizing a certain aspect of quality of life: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH). The scale ranges from 0 to 100;[28] (4) completion of the questionnaire "International Consultation on Incontinence Questionnaire-Short Form" (ICIQ-SF), a specialized tool helping to determine the effect of urinary incontinence (UI) on the quality of life (maximum score is 21);[29] (5) completion of free-form questionnaires, containing information about main descriptive demographic and social characteristics of patients; and (6) studying of employer's records (an extract from the employment agreement), statement of income from the tax inspectorate.

Medical factors under study included a form of urination disorder, severity of UI symptoms, presence of side effects due to trospium administration, treatment efficacy, treatment satisfaction, experience of treatment with any other AMs, awareness of methods of LUTS treatment, comorbid conditions (Charlson Comorbidity Index), administration of drugs concerning other diseases, bad habits, and sleep–wake cycle disturbances.[30] Additionally, we studied the characteristics of the urination disorder. The degree of UI was defined as severe when more than three episodes were observed during the day. Defining caffeine abuse, we assumed that the highest daily dose of caffeine recommended by the manufacturers does not exceed 300 mg.[31] Smoking of more than five cigarettes a day was defined as tobacco abuse, and the score > 8 on the AUDIT scale was defined as alcohol abuse.[32,33]

Socioeconomic factors under study included annual salary and average monthly salary; number of individuals with the level of income lower than the living minimum wage; number of sick leave