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Original article

Factors of trospium treatment compliance among unemployed older persons

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ABSTRACT

Background/Purpose: This study aims to study the factors that affect the stamina of elderly patients during trospium treatment.
Methods: To carry out the experiment, 843 men and women older than 60 years (average age, 68.4 years) who had been taking trospium for 12 months were selected. The questionnaire survey on demographic and social status, financial statement analysis, academic certificates, Overactive bladder Questionnaire short form and Medical Outcomes Study-Short Form questionnaires, bladder diaries, and uroflowmetry were used for studies of adherence to treatment.
Results: The average time of reaching the 30-day trospium-treatment-free period (compliance "survival rate") was 191 days. The percentage of patients who remained compliant for 6 months and 1 year were 58.3% and 44.0%, respectively. According to our data, the percentage of highly educated (59.3%), married (63.8%), and city (70.6%) residents who are aware of the nature of their disease (77.5%) are significantly higher in the cohort of consistent patients; yet the percentage of caffeine abusers is lower (10.9%). In this cohort, the percentage of income spent on trospium purchase (3.1%) was lower, but income and payment level for medical expenses were higher ($p \leq 0.05$ and $p \leq 0.01$, respectively, compared with other cohorts). An analysis of regressive models of changes in squared percentage of income and trospium costs has confirmed the hypothesis of the impact of these factors on treatment compliance. In the cohort of consistent patients, the average number of points of role physical, social functioning, role emotional, and mental health values that describe the health impact on the quality of life turned out to be significantly higher. Severe incontinence symptoms (70.8%) and overactive bladder (35.9%) prevailed among patients of this cohort, which were also associated with high treatment efficacy and a significantly lower number of side effects (9.3%).
Conclusion: High trospium treatment compliance among elderly men and women is determined by several uneven demographic, social, economic, and medical factors.

1. Introduction

The morbidity of lower urinary tract symptoms (LUTS), including overactive bladder (OAB) symptoms, among people is very high. LUTS have, at least occasionally, been reported in 26–33% of men and 27–46% of women of all races.[1] LUTS is known to have an adverse impact on the health-related quality of life.[2,3] Besides, the significant prevalence of LUTS is due to its high economic costs.[4,5]

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The main lineup of drugs for LUTS treatment is still considered to comprise antimuscarinic (AM) drugs. Among AM drugs, trospium chloride, a quaternary ammonium compound that neither penetrates the blood–brain barrier nor affects the central nervous system, has been widely used. It allows the avoidance of adverse side effects and increases demand for trospium during treatment of various forms of LUTS, particularly among elderly persons.[6,7]

However, when studying the efficacy and safety of various trospium dosages among elderly patients who suffered from different forms of LUTS in our previous experiments, we noticed poor patient compliance with treatment. Moreover, on adherence affect not only medical factors.[8,9] According to most researchers, absence of results, side effects, and dosage regimen are attributable to medical factors that cause low compliance.[10–12] Yet some researchers point to polymorbidity, poor awareness of patients, and some other factors as important factors that contribute to the loss of compliance.[13,14] A number of researchers cast reasonable doubt on the fact that pharmacological properties of various AM drugs affect treatment compliance level.[15] However, the issue of balance of various factors' impact on patient compliance to therapy with AM drugs, particularly trospium chloride, has been studied incompletely. Most of the available studies have been carried out in a retrospective way, without any correlation between trospium intake, a particular diagnosis, and diagnosis verification by special methods. Given these circumstances, in this experiment, we set the goal of studying heterogeneous factors that affect the stamina of elderly patients who suffer from different forms of LUTS during trospium chloride treatment to increase the manageability of OAB symptoms.

2. Methods

2.1. General information

A randomized blind prospective study on factors affecting the stamina of older patients during their trospium treatment was carried out from January 4, 2012 to January 6, 2014 at the Regional Clinical Diagnosis Center, City Outpatient Hospital Number 3, and a geriatric hospital located in Vladivostok City, Russia. A total of 843 patients (449 women and 394 men; age range, 60–87 years) participated in the experiment. The average age was 68.4 years. To “blind” the research team dealing with statistical analysis of obtained data arrays, data files were impersonalized by assigning random numbers and personal data were deleted. Stratified randomization allowed a roughly even representation of men and women during patient selection.

Scope of selection was calculated with reference to confidence probability of 95% and confidence interval of ±5%.

2.2. Inclusion/exclusion criteria and factors of the studies

Persons who visited an urologist on odd days of the months and were prescribed a standard dosage of trospium chloride (5–15 mg twice a day) as monotherapy for a prolonged period by the urologist were included in the studied group. The inclusion criterion was the presence of any of the following diagnoses: OAB (N32.81), urge incontinence (N39.41), mixed incontinence (N39.46), and nocturia (R35.1).[16]

The examination of cognitive function was conducted at the start of the study using the Montreal Scale. If a patient gained < 20 points, he/she was excluded from participation in the experiment.

In the course of the experiment, changes in the condition of patients' lower urinary tract were controlled with the use of overactive bladder questionnaire short form (OABq-SF) and uroflowmetry (at the start and 1st and 2nd control points), and also bladder diaries that were filled in on a daily basis.[17] Columns for filling in information about down-lying time, time of falling asleep, time of awakening due to the desire to urinate, amounts of consumed liquid, caffeine, alcohol, and smoked cigarettes, and the time of trospium intake were added to bladder diaries. We considered three or more episodes of urinary incontinence a day as evidence of LUTS severity.[18] At the start of the study, all participants were made aware of and given adequate information on the nature of dysfunction of accumulation and urine evacuation in LUTS, trospium's mechanism of action on the body, as well as its dosage regimen. A total of 441 (52.3%) patients used this option. At the end of the experiment, a comparative analysis of percentages of informed patients among groups with different compliance levels was conducted.

Besides, factors such as Charlson Comorbidity Index.[19] forms of associated diseases, number of used dosage forms, and awareness of LUTS therapy methods[14,20] were studied using the analysis of individual outpatient medical records of patients and questionnaire surveys.

A study on demographic, social, and economic properties was carried out using a questionnaire survey, a financial statement analysis (certificate of income issued by tax office), and copies of academic certificates.

Annual income and average monthly income; average relation between pension and living wage; monthly costs of trospium and other drugs, as well as their squared values; and percentages of such costs in total patient costs and their squared values were considered as social and economic factors. Percentages of persons with an income level below the living wage, and those dealing with physically demanding jobs and exposed to hazardous conditions during their labor activities were calculated.[21] Levels of income and expenses are shown with reference to inflation against the United States dollar value as of April 2012.

Exclusion criteria were the presence of oncological diseases in their end stages, intake of AM drugs 6 months prior to the start of this study, and the status of being employed.

2.3. Compliance and stamina estimation

A trospium-treatment-free period of 30 days during the observation period was considered as a patient stamina criterion. The level of stamina and compliance were separately calculated for each potential factor affecting patient behavior. The average level of patient stamina was defined as the percentage of days, in observation period, during which the patient was acting in accordance with the recommendations of the attending physician. To compare the impacts of heterogeneous factors on treatment compliance, patients were split into three basic cohorts: consistent members (compliance rate of ≥ 80%), moderately consistent members (≥ 50–<80%), and poorly consistent members (< 50%).[22]

2.4. Statistical analysis

A 30-day treatment-free period expectation model was used for the estimation of compliance level. To create this model, three-parameter Weibull distribution accompanied by first-type double right censoring (relevant to the 1st and 2nd control points) was used. Adjustment of distribution to actual data was carried out using the Hollander–Proschan criterion.

The impacts of demographic, social, economic, and medical factors stipulated in Clause 2.2 were estimated during the analysis of models with simple gamma distribution and a log-link function. The important factor of control for persons with different compliance levels was carried out separately, with further comparison of

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