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## **THESES**

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**HEALTH ECONOMIC EVALUATION OF CHRONIC  
UROLOGIC DISEASES**

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**Department of Health Economics**

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## **I. Theoretical background and aims of the dissertation**

In my thesis I provide analysis of the health economic aspects of chronic urologic diseases including benign prostatic hyperplasia, bladder cancer, female and male urinary incontinence, lower urinary tract symptoms and overactive bladder syndrome. Due to the ageing of the population the prevalence and social burden of these diseases increase substantially. These diseases already at present have major cost impacts and the related costs are expected to rapidly increase further in the near future. The disease incidence within the specified age groups appears to be fairly constant, however due to the increasing life expectancy of the population and to the more and more effective therapeutic agents, the total number of patients rise significantly.

The costs rise constantly since these chronic diseases are long-lasting and require ongoing medical care. Due to the constantly increasing patient number and social burden these issues receive special attention in more and more developed countries. Some countries develop “ageing strategies” and health economic research of ageing is in the mainstream of health economic research. Substantial data are required in order to make adequate health policy decisions and to find sustainable finance solutions.

Little is known about the epidemiology and social burden of chronic urologic diseases in Hungary which makes adequate decision-making in health policy and finance remarkably difficult.

In order to come to know the social burden we need to be aware of the epidemiology of these diseases including the number of new cases (incidence), the total patient number (prevalence), the number of patients in the subgroups important from disease severity aspects (since the costs are related to disease severity), the direct and indirect costs associated with the disease and the quality of life implications of the disease.

These pieces of information are necessary in order to assess the real social importance of the diseases and to calculate the budget impact and cost-effectiveness of the newer and newer and more and more expensive therapies which is an obligation of the social

security system and is also essential to develop a sustainable health care finance system.

The research published in the thesis includes the health economic evaluation of several chronic urologic diseases since we need to compare these results. In order to make ranking possible for health policy and financing purposes it is necessary to know the number of patients with the diseases concerned, the direct and indirect costs and the implications on quality of life and work i.e. the social burden. The aims and the hypotheses set for the specific diseases under investigation differed with consideration to the characteristics of the field and the available Hungarian and international literature, so did the methodology applied differ as well.

The research results published in the thesis previously were not available either in Hungary or in the wider region, furthermore we have successfully found and published several results for the first time in the literature. The research results fill a knowledge gap and can be of use for promoting decision making in health policy and finance.

## **I.1 Objectives**

### **I.1.1 Assessing disease burden and cost of illness in benign prostatic hyperplasia**

The detailed objectives of the health economic analysis of benign prostatic hyperplasia (BPH) were the following:

- reviewing and analysing the international and national literature related to social burden and cost of illness in benign prostatic hyperplasia
- assessing cost of illness and quality of life in Hungarian patients diagnosed with benign prostatic hyperplasia, undergoing treatment.

### **I.1.2 Cost of illness of bladder cancer in Hungary**

Objective of the health economic analysis of bladder cancer patient data:

- assessing cost of illness in bladder cancer patients, especially the cost of medications

### **I.1.3 Female and male urinary incontinence and the epidemiology of lower urinary tract symptoms in Hungary**

The objective of our research on male and female urinary incontinence was to study the following attributes:

- studying the epidemiology of female urinary incontinence,
- studying the epidemiology of male incontinence and the prevalence of lower urinary tract symptoms

### **I.1.4 Health economic analysis of the treatment of overactive bladder syndrome**

In our overactive bladder syndrome (OAB) research we set the following objectives:

- cost-utility analysis of the treatment of overactive bladder syndrome

## **II. Methodology**

### **II.1 Assessing social burden, cost of illness and quality of life in benign prostatic hyperplasia**

#### **II.1.1 Literature review**

We performed a systematic literature research for the 2005—2015 interval in Medline PubMed, which is the most comprehensive medical literature database. Our strategy was to search for the free text appearances of terms like cost of illness or cost analysis related to benign prostatic hyperplasia in the articles. The following data were collected from all included studies: study design, year of publication, geographic location, perspective of cost analysis, number of patients, evaluated cost categories, year of cost and cost results.

#### **II.1.2 Cross-sectional questionnaire survey (2014)**

We conducted a non-interventional, multicenter cross-sectional study between June and October 2014. Six urology centres participated in the study. Out of patients diagnosed with BPH, our study included only those who did not have a prostate surgery in their anamnesis. The first part of the questionnaire was completed by the patients: this included questions about demography and job, the clinical attributes related to the condition of patients, the severity of illness based on self-assessment, quality of life questionnaires related to health and questions about availing health services 12 months before the filling of the questionnaire. The second part of the questionnaire was completed by urology specialists. The filling of this part was done partly based on patient documentation in which related data on how long the illness has been present and what kind of diagnostic tests and treatments were used were present. The questionnaire collected data from the last 12 month before completing the survey.



We measured the patients' general, health-related quality of life with the EQ-5D-3L questionnaire (hereinafter EQ-5D). For measuring the severity of illnesses, a test for the symptoms of prostate diseases (I-PSS) were used. The effect of BPH on work productivity was measured with The Work Productivity and Activity Impairment (WPAI) questionnaire. Cost calculation was done from a societal perspective including medical, direct non-medical and indirect costs in the past 12 months related to BPH.

## **II.2 Cost of illness of bladder cancer in Hungary**

### **II.2.1 Analysis of the National Health Insurance Fund's drug and patient flow database**

For the study of Hungarian bladder cancer patient care international and national statistical data along with the National Health Insurance Fund's drug and patient flow database were used.

### **II.3 Female and male urinary incontinence and the epidemiology of lower urinary tract symptoms in Hungary**

We studied the epidemiology of urinary incontinence with questionnaire survey. Anyone could fill out the survey who wanted to participate voluntarily. Questions were compiled based on the professional proposal of the Hungarian Society of Urology and the Incontinence Patient Association.

The questionnaire contained 13 questions about urinating habits and the possible problems with urinary continence and urination. The study of the Hungarian surgical practice of female incontinence and urogenital prolapse was conducted at around the same time. The questionnaire was compiled by the leaders of the Hungarian Continence Society's working group. The aim of this was to study Hungarian surgical treatments quantitatively and qualitatively. We requested head physicians leading Hungarian Urology and Gynaecology Departments to fill the survey titled

“Questionnaire about the surgical treatment of female urinary incontinence and genital prolapse” in a postal letter between August 2011 and February 2012.

#### **II.4 Health economic analysis of the treatment of overactive bladder syndrome**

The clinical efficacy and cost-utility of solifenacin were studied in overactive bladder syndrome. Other medicines also can be given in this indication: currently Detrusitol® (tolterodin IR), Ditropan® – Uroxal® (oxybutynin IR) and Emselex® (darifenacin CR) are marketed in Hungary. Because of similar indications, we also evaluated the cost efficiency of oxybutynin and darifenacin in our study. The objective of our study was to compare the effectiveness and costs of different treatment strategies currently marketed and financed by social insurance in Hungary. Detrusitol® (containing tolterodin) is free-pricing, so we did not include it in our study.

Cost efficiency analysis was conducted with a decision tree model. Aided by this model, we conducted the comparison of the costs and clinical efficacy of solifenacin, darifenacin and oxybutynin IR therapies.

### **III. Main results**

#### **III.1 Assessing disease burden and cost of illness in benign prostatic hyperplasia**

##### **III.1.1 Literature search**

Literature research yielded 159 matches and we included 11 publications which both met the inclusion and exclusion criteria. Four studies were done in European countries and seven in The United States.

Sample size varied between 1000 and 40 253 capita. Nine studies used payer perspective for cost calculation, one study used societal perspective and one study used both. The time horizon of the studies was between 1 month and 20 years (life expectancy of BPH patient at the time of diagnosis); the most commonly used time horizon was 1 year. Cost year marked in the studies was between 1998 and 2012.

direct medical costs of BPH showed a big difference in individual studies. Direct annual medical costs per patient fluctuated between 255 USD and 5729 USD in the United States, while in Europe, the same costs fluctuated between 253 EUR and 1251 EUR. In Norway, costs on the 4-year and on the 15.5 year horizon fluctuated between 1703 and 7638 EUR and 3924 EUR and 8307 EUR respectively, depending on treatment modalities and cost calculation perspective.

The dominant cost drivers were pharmaceuticals since they were accountable for nearly three-quarters of the whole treatment cost (the amount of this varied between 40% in France and 89% in Poland). The costs of surgical treatments were accountable for 15% of total cost, while the costs of diagnostic tests were accountable for 8% of total cost. More severe illness was accompanied with higher costs both in the cases of urination (mild: 673 USD; moderate: 906 UDS; severe: 960 EUR), and in the cases of continence symptoms (mild: 623 USD; moderate: 865 EUR; severe: 1043 EUR).

## **Discussion**

In our study, we summarized BPH related cost of illness results of eleven studies published in the last 10 years. These studies were conducted in 8 countries of Europe and the United States. Direct medical costs per patient fluctuated annually between 255 USD and 5729 USD in the United States and annually between 253 EUR and 1251 EUR in Europe. Despite there were no new data available on the nationwide expenditures from most countries, the estimated total costs based on per patient results were significant in all countries.

BPH is an age-related illness which is more and more common over the age of 40. Due to demographic aging, continually increasing life expectancy and the high prevalence of illness, BPH means a high economic burden to the healthcare budget of developed countries. Due to demographic factors and the expected novelties in the field of urologic surgery, costs of BPH will likely rise in the future.

### **III.1.2 Cross-sectional survey: cost of illness and quality of life of patients diagnosed with benign prostatic hyperplasia**

A total of 246 patients were included in the survey. The average age was 70.6 (SD=8.1 years), the average duration of the disease was 6.5 years (SD 6.2 years). According to the Body Mass Index (BMI), 182 patients (74%) were overweight or obese (BMI>25).

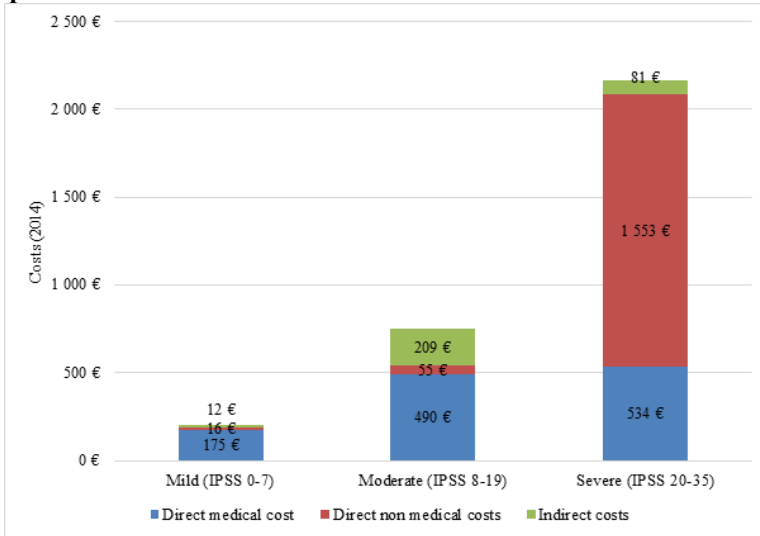
The average of the EQ-5D index and the EQ VAS scores of patients were 0.85 (SD=0.9) and 68.4 (SD=15.5) respectively. For 111 patients (45%), the EQ-5D index was 1. In total, 8%, 19%, 28%, 30% and 31% reported moderate or severe problems in self-care, usual activities, anxiety/depression, pain/discomfort and mobility. The average of the I-PSS scores was 12.8 (SD=6.3) in the sample. According to the I-PSS score, 52 (23%), 136 (61%) and 35 (16%) patients were in the mild, moderate and severe BPH groups, respectively.

Out of the 246 patients 244 (99%) received outpatient care, and 25 (10%) were admitted to hospital because of BPH in the past 12 months. A total of 211 patients (86%) were treated with medication, and 35 (14%) were under observation/watchful waiting, 7 of whom had indications for surgery. The total annual per-patient cost of BPH was 876 € (SD=1829 €).

The costs broke down as follows: direct medical costs 46%, direct non-medical costs 31% and indirect costs 23%. Medication costs amounted to 43% of direct costs (173€). A major part of the total medication cost (77%) came from fitotherapy (81€) and alpha-blockers (55€). In addition, informal care (243€) and visits to private medical professionals (132€) also resulted in significant costs. Indirect cost amounted to a total of 204 €, where presenteeism was 41% and absenteeism was 59%

There was no significant correlation between the total cost and either age, or the duration of the disease or BMI. Age, however, had a positive correlation with direct non-medical costs ( $r=0.268$ ,  $p<0.001$ ) and was inversely proportionate to indirect costs ( $r=-0.147$ ,  $p<0.001$ ). No significant correlation was observed between costs and catheter use in the research period or between costs and acute urinary retention (AUR) in the past 12 months. We found that there was moderately strong correlation between the total cost and the I-PSS score ( $r=0.429$ ,  $p <0.001$ ). However, there was only weak correlation with the EQ-5D index ( $r = -0.307$ ,  $p <0.001$ ) and the EQ VAS ( $r = -0.229$ ,  $p = 0.001$ ). Direct medical costs correlated only with the I-PSS score ( $r = 0.305$ ,  $p <0.001$ ), while direct non-medical costs correlated with the I-PSS ( $r= 0.374$ ,  $p <0.001$ ), the EQ-5D ( $r=-0.416$ ,  $p <0.001$ ) and the EQ VAS ( $r = -0.368$ ,  $p <0.001$ ) as well. There was no significant correlation between indirect costs and any of the quality of life measures.

**Figure 1. Average yearly cost per patient by cost category in the I-PSS severity groups**



## Discussion

In the present research, we estimated the annual costs of lower urinary tract symptoms associated with BPH in Hungary. Cost calculation was conducted from a social perspective, and included all direct medical, direct non-medical and indirect costs related to BPH. Costs were significantly different in the I-PSS groups. There is a considerable cost/patient (approx. 270k HUF). There is a significant number of patients, so the social burden is important, and it is important to note that patients bear a major part of the costs.

We were the first in Hungary to publish presenteeism data involving BPH patients - this cost element is already significant today and it is going to increase as the retirement age increases.

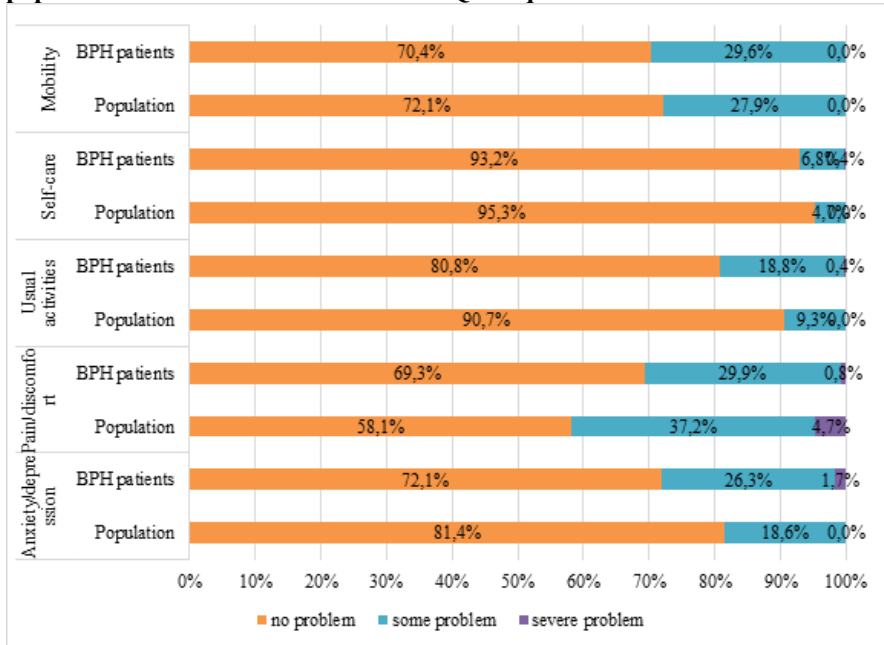
### **III.1.3 Cross-sectional questionnaire survey; quality of life of patients with benign prostatic hyperplasia**

At the time of the survey nearly half of the patients had urinary problem despite the treatment. In the 12 month before the questionnaire was completed, 10% of patients were admitted to hospital because of urinary problems (90% of such patients once, 10% twice), 18% of the patients visited their GP and 76% visited a urologist because of the symptoms. A total of 42 patients (17%) were waiting for prostate surgery, average age: 70.93 (SD 6.82), the average age of the 194 patients not waiting for surgery was 70.39 (SD 8.42) (for 10 patients age was not provided).

The average of the I-PSS scores was 12.8 (SD=6.3) in the sample. According to the I-PSS score, 52 (23%), 136 (61%), and 35 (16%) patients were in the mild, moderate and severe BPH groups, respectively.

The average of the EQ-5D index and the EQ VAS scores of patients were 0.85 (SD=0.19) and 68.4 (SD=15.5) respectively. For 111 patients (45%), the EQ-5D index was 1. In total, 7%, 19%, 28%, 30%, and 31% reported moderate or severe problems in self-care, usual activities, anxiety/depression, pain/discomfort and mobility. (Figure 2). Average EQ-5D scores were examined in the I-PSS groups and statistically significant differences were found. We have only found significant difference ( $p<0.05$ ) between BPH patients and the age- and sex-matched general population in the 45-49 and 55-59 age groups.

**Figure 2. Comparison of BPH patients and age- and sex-matched general population in the 5 dimensions of the EQ-5D questionnaire**



## Discussion

In our study, the clinical characteristics and health-related quality of life were examined in BPH patients. We would like to highlight from our results that almost 50% of patients had urinary problems despite the treatment with medication, most of the time urinary frequency and a compelling urge to urinate. The majority of the patients in the sample considered their general health good, according to the EQ-5D, almost half of the patients (45%) reported no problems in any of the 5 dimensions of the questionnaire. The average EQ-5D index of BPH patients in the 45-49 age group was lower than that of the sex and age-matched general population, the results were the same in the 60-64 age group, while in the 50-54, 55-59 and 65-74 age groups it was higher in BPH patients.



The average of the EQ-5D index in the whole sample was 0.85 (SD=0.19), which was similar to the findings of studies in other countries. The values are the following in the various countries: Spain: 0.90, SD=0.14, average age: 63 years (33), France: 0.84, SD=0.19, average age: 72 years (34), Korea: 0.85, SD=0.19, average age: 76 years (35), and the United Kingdom: 0.71-0.87 depending on severity, average age: 73 years (36). International comparison is made difficult by the fact that the BPH quality of life studies were partly randomized controlled clinical studies, partly cross-sectional studies related to drug trials. The EQ-5D scale were used only in a smaller part of the BPH quality of life surveys, and where it was applied, no comparison with the population average was provided. Inclusion criteria were also different, so international comparison is difficult.

As the total I-PSS score increased, the value of the EQ-5D index significantly decreased, i.e. as the disease became more severe, general quality of life dropped. There was significant, but weak correlation between EQ-5D and the I-PSS score, and also the I-PSS quality of life scale.

Based on our results, it can be established that the health related quality of life of BPH patients who are treated with medication is, on average, not worse than that of the general population, however, in the youngest age group, significantly lower quality of life values were established. There was no difference in the 60-64 age group. In the 45-49 age group, the quality of life of BPH patients was significantly lower than that of the general population.

## **III.2 Cost of illness in patients with bladder cancer in Hungary**

### **III.2.1 Cost of illness in bladder cancer patients, analysis of pharmaceutical sales data by the OEP, 2008-2014**

A study analysing the years 2007 and 2008, published in 2010 (OEP Elemzési, Orvosszakértői és Szakmai Ellenőrzési Főosztály - 2010), provides an overview of the costs paid by the Országos Egészségbiztosítási Pénztár (OEP) for bladder cancer (ICD C67). According to the report, in 2007 the OEP paid 1.8 bn HUF on the treatment of bladder cancer (BNO C67) 75% of which was provided to inpatient care. In 2008, total costs exceeded 2 bn HUF, 71.5% of which went to inpatient care. Social security expenditure in this diagnosis increased by 33%, by more than 100 million HUF, between 2007 and 2008 (2007: 314,425 million HUF, 2008: 418,193 HUF million).

In 2008, OEP provided 58.89 billion HUF social security funding for the oncology medication of cancer patients.

We analysed pharmaceutical sales data by OEP for the 2008-2014 period. For the analysis, we could only take into account the medicinal products that are paid for by the OEP exclusively for the treatment of bladder cancer, based on indication, with special reimbursement, to prevent the recurrence of tumour locally, in the bladder. However, these constitute only a segment of the therapies that may be used for the treatment of the bladder, and do not include the drugs used in systemic chemotherapy, painkillers, antibiotics or other medication, and drugs used during hospital treatments.

### **Discussion**

By analysing the pharmaceutical turnover data, it is apparent that costs of treating urinary bladder cancer via medication is significant on a national level. Even during a one-year interval (2007 vs 2008), it is clear that the medication costs can significantly

rise (with more than 33% meaning 100 million HUF between 2007 and 2008). In the analysis of the 2008-2014 interval, we have focused on the turnover of mitomycin which was the most significant active agent financially in 2008, as well as two other products (epirubicin and bcg vaccine) which can only be used with funding only in case of this disease and incur significant charges. Due to the changes implemented in the social security funding between 2008 and 2014, withdrawals and restrictions, we have found radical restructuring in product turnover for all three products. Mitomycin expenses have been reduced to zero by 2014, although its 20 mg variation gave 33% of the total medication expenses for urinary bladder cancer back in 2008. Meanwhile, the turnover of epirubicin increased while the turnover of bcg vaccine significantly decreased from 2013. In total, the social security funding of these three active agent have been reduced with 112 million HUF between 2008 and 2014 (from 234,5 to 112,7 million HUF). According to the summarizing analysis of the 2017 European clinical policies, mitomycin may decrease the chance of recurrence in certain cases which means that the reasons and consequences behind the absence of mitomycin turnover in Hungary by 2014 require further investigation.

### **III.3 Epidemiology of female and male urinary incontinence and lower urinary tract symptoms in Hungary**

#### **III.3.1 Surgical treatment practice of female urinary incontinence and urogenital prolapse in Hungary**

A total of 10 403 women (18 or older) took part in the survey, with the average age of 43,0 (SD 13,8). In the survey, 3506 (33,9%) women answered regarding the incontinence related question that they have experienced leakage - they were included in the incontinence subgroup analysis. The average age of the adult female incontinence subgroup is 47,0 (SD 12,7).

Urine leakage occurred rarely (e.g. during a cold) with 3103 (90,4%) women, and 296 (8,6%) said they experience it more times a day; a total of 33 (1,0%) women said this means a constant issue to them. Detailed questions regarding the occurrence of urine leakage revealed that urine leaks mostly occur during coughing/sneezing (2437 women, 69,5% of the incontinent subgroup; 23,7% of all the participants) or in case of strong urinary urgency (823 women, 23,5% of the incontinent subgroup; 7,9% of all the participants). The amount of leaked urine is only a few drops in case of the majority (3172, 94,1%), a bigger amount for 28 women (0,8%), and 170 women (8,0%) marked the answer as “flowing”. As to the question of how much they are irritated by involuntary urine leakage, 1319 (39,9%) women said sometimes, 1170 (35,4%) said very much and 33 (1,0%) said they are being restricted in their everyday activities.

## **Discussion**

The Hungarian studies revealed that 90,4% of women (a total of 10403 adult female participant, 3506 incontinence and 3103 urine leakage replies) “sometimes” experience OAB symptoms. In case we compare it to the results of United Kingdom and Sweden, that means that 791-1040 women (25,5-33,5%) are irritated moderately and 118-270 are very much irritated by these symptoms. (Projected to 1000 incontinence patients, 76-100 women are moderately irritated by OAB symptoms, while this number is 255-335 women in case of 1000 OAB patients with incontinence.) Third of the participants (33,9%) reported that they experienced urine leakage, meaning they had an incontinent episode. More than third of the participants (41%) reported urinary urgency. It can be assumed of these patients that OAB may be in the background.

### **III.3.2 The prevalence of male lower urinary tract symptoms in Hungary**

The average I-PSS score was 4.2 (SD 3.9) in our study. The distribution between mild, moderate and severe categories happened accordingly: I-PSS=0–7: 6378 men (86.4%) average age was 38.2; I-PSS=8–19: 919 men (12.7%) average age was 46.1; I-PSS=20–35: 85 men (0.9%) average age was 55.2.

Most of the participants were in age group 30-39, their average I-PSS score was 3.52. They were followed by age group 40-49 with average I-PSS score of 4.01 then age group 20-29 with average I-PSS score of 3.26. The number of participants above the age of 50 was 1614. Moving on to higher age groups, the participants' average I-PSS score was increasing. We have studied the proportion of participants reporting mild, moderate or severe symptoms in each age group.

Surprisingly, there were some participants who were in age group 20-29 but still got an I-PSS score that relates to moderate or severe symptoms (2 men had a score for severe and 102 men had a score for moderate symptoms). Most of the participants reporting moderate symptoms belonged to age group 50-59 (245 men), whereas most of the participants reporting severe symptoms were from age group 50-69 (total of 55 men).

### **Discussion**

More surveys have been conducted worldwide within the adult male population in order to get a better knowledge on the epidemiologic background of BPH and the patients' urinary symptoms. Our own results show that a smaller proportion of the participants reported "rather voiding" symptoms in all the age groups. This ratio ranges between 14-28%. The distribution of "rather voiding" and "rather storage" related complaints is 38% vs 60% in favor of "rather storage" amongst patients with moderate and severe symptoms. The average score was 8.28 with patients above 60, which translates to moderate symptoms/complaints and may require medication or surgical therapy depending on the nature of the symptoms. One of the deficiencies of this study is that the surveys do not provide any data on BMI scores, medical history,

medications, any treatments that relate to prostate or bladder, surgeries and other important factors.

### **III.4 Health economic evaluation of the treatment of overactive bladder syndrome**

#### **Results and discussion**

We have studied the cost effectiveness and cost efficiency of solifenacin, oxybutynin and darifenacin therapies with a decision making tree. The quality-adjusted life years are very similar for all of these active agents. The total costs during a three-month interval, is different for each type of therapy based on the distribution of medication costs and other costs. The lowest of the total costs is for oxybutynin (19 687 HUF), but the medication costs constitute only the 29%. The same rate for darifenacin and solifenacin is significantly higher, more than 70%. The related costs of darifenacin and solifenacin therapy are almost the same (41 674 HUF, 41 749 HUF). However, the highest QALY of the three therapies belongs to solifenacin (0.17486 QALY). Even though there are some cost efficiency studies available for these active agents, those cannot be directly compared to our results due to the different utility measurements used.

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## V. Publications of the author related to the thesis

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