Original Article

Clinical Evaluation of Patients with Benign Prostatic Hyperplasia Grade II in a Family Medicine Unit

Evaluación clínica de pacientes con hiperplasia prostática benigna grado II en una unidad de medicina familiar

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Summary

Objective: to evaluate the clinical evolution of patients with Benign Prostatic Hyperplasia grade II in the Family Medicine Unit (FMU) No. 77. **Methods:** longitudinal study conducted from January to October 2019, 206 patients selected by a systematized random sampling, diagnosed with Benign Prostatic Hyperplasia grade II, without a history of surgery of the urinary system; the International Prostatic Symptom Score (IPSS) was used on three occasions (zero, three and six months) to evaluate the evolution of prostatic symptoms. Measures of central tendency were used for the descriptive analysis, and the McNemar test to compare results. **Results:** in the first application 174 patients presented mild symptoms, 29, moderate symptoms, and 3, severe symptoms; in the second application 172 presented mild symptoms, 34, moderate symptoms, and none presented severe symptoms; in the third application 174, presented mild symptoms, 26, moderate symptoms, and 6 severe symptoms. The McNemar test was not statistically significant when comparing the three results. **Conclusions:** most of the studied patients in treatment maintained stable prostate symptoms.

Keywords: Prostatic Hyperplasia, Urinary Tract, Neoplasms

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Resumen

Objetivo: evaluar la evolución clínica de pacientes con hiperplasia prostática benigna grado II en la Unidad de Medicina Familiar (UMF) No. 77. **Métodos:** estudio longitudinal realizado de enero a octubre de 2019, se seleccionaron 206 derechohabientes de forma aleatoria sistematizada, diagnosticados con hiperplasia prostática benigna grado II, sin antecedentes quirúrgicos del aparato urinario; para evaluar la evolución de los síntomas prostáticos se utilizó el cuestionario internacional de síntomas prostáticos (IPSS) en tres ocasiones (cero, tres y seis meses). Para el análisis descriptivo se utilizaron medidas de tendencia central y para comparar los resultados la prueba McNemar. **Resultados:** en la primera aplicación 174 pacientes presentaron síntomas leves, 29, síntomas moderados y 3, síntomas severos; en la segunda aplicación 172, presentaron síntomas leves, 34, síntomas moderados y ninguno presentó síntomas severos; en la tercera aplicación 174, presentaron síntomas leves, 26, síntomas moderados y 6, síntomas severos. La prueba de McNemar no resultó estadísticamente significativa al comparar los tres resultados. Conclusiones: la mayoría de los pacientes estudiados con tratamiento mantuvieron síntomas prostáticos estables.

Palabras Clave: hiperplasia prostática, tracto urinario, neoplasias

Introduction

Benign Prostatic Hyperplasia (BPH) is the most common tumor in men over 40 years.[1-6] In 2014, more than 40,000 new cases were registered in Mexico, 96% of which were 45 years old or older.[7] In 2017, 43,203 cases were reported to the Mexican Institute of Social Security (IMSS).[8] BPH presents irritative and obstructive symptoms of the lower urinary tract as one of the main ailments.[9,10]

In Mexico, approximately 61% of the population over 45 years reports prostate symptoms; at the age of 55, 25% reports obstructive data, and at the age of 75, 50% comments that they also present the symptoms.[11] Family medicine units make a high financial investment in pharmacological treatments focused on decreasing symptoms.[12]

In order to detect complication, the evaluation of prostate symptoms in patients with treatment should be periodic at the Primary care level through the International Prostate Symptom Score (IPSS).[13]

The IPSS is a standardized, validated, and self-administered questionnaire,[14] which helps assess the need for treatment and monitors the evolution of symptoms.[15,16] This instrument was developed and validated by the American Urological Association, and includes seven questions that assess: frequency, nocturia, weak urinary flow, urinary hesitancy, intermittency, incomplete emptying, and urgency; it has a Cronbach's alpha=0.86 and a test-retest reliability of r=0.92.[17]

Patients with mild and moderate symptoms of BPH that do not require drugs can be surveilled; when symptoms are severe, pharmacological treatment is indicated in order to avoid surgery. The treatment includes alpha-blockers whose mechanism of action is to relax the smooth muscle of the prostate and bladder neck, the effect is observed since the first days, can lead to a significant decrease in symptoms and maintain its effectiveness from 6 to 12 months; on the other hand, 5-alpha-reductase inhibitors decrease the size of the prostate and the dihydrotestosterone concentrations.[18,19] After treatment, lower urinary tract symptoms may decrease by 15-30% and prostate volume by 18-28%.[20] Finally, muscarinic receptor antagonists and phosphodiesterase-5 inhibitors relax detrusor muscle; combined drug use is an option for reducing the risk of acute urinary retention, prostate growth, and obstructive symptoms.[21]

Monitoring the severity of obstructive and irritative symptoms is essential to prevent complications, especially in those patients who do not require surgical treatment. For this reason, the objective of this study was to evaluate the clinical symptoms of patients with BPH Grade II at the FMU No. 77 of the Mexican Institute of Social Security.

Methods

A longitudinal study, approved by the local research committee, conducted from January to October 2019. 206 patients, assigned to the FMU, who signed a previous informed consent form, were included. Patients with a diagnosis of BPH Grade II assessed by a second care level urologist, with treatment for prostatic hyperplasia, with or without the presence of chronic-degenerative diseases such as diabetes mellitus and high blood pressure, without diseases that cause variations in the perception of lower urinary tract symptoms, were included. The excluded patients were those with a history of prostate cancer, a history of repetitive or chronic urinary tract infections, previous invasive treatments for urinary flow obstruction, carriers of renal failure, who have had pelvic surgical treatments, a history of urethral trauma, who have received a renal transplant, or cognitive disorders that make them unable to respond to the complementary research forms.

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With a universe of 858 eligible subjects, the sample size calculation was performed using the formula for finite populations. Patients were selected by a systematized random sampling. Data were provided by the information area and clinical file of the unit.

Sociodemographic data were collected; in order to quantify prostate symptoms and evaluate clinical evolution, the IPSS questionnaire was applied in three moments: first, when the patient was captured; second after three months, and third after six months, with the purpose of comparing the intensity and severity of the symptoms after the second care level assessment.

The IPSS consists of seven questions which are scored from 0 to 5 points, increasing according to the severity of the symptoms; the results are divided into three grades according to the total points obtained in the questionnaire: mild 0-7 points, moderate 8-19 points and severe 20-35 points.[15, 10, 17]

The statistical analysis was carried out with the statistical program SPSS v.23. Descriptive statistics with simple frequencies, proportions, central tendency and dispersion measures were made; the evaluation of the results in the IPSS was developed by the McNemar test.

Results

206 patients with BPH grade II were analyzed, from 41 to 78 years of age, (from ±6.03), CI 95 %: 56.43-58.09; the average weight was 80.24 kilograms (from ±14.02), CI 95%: 78.31-82.16; average height was 1.66 m. 115 patients did not present chronic degenerative diseases, 20 patients had diabetes mellitus, 38 presented systemic arterial hypertension and 33, presented both diabetes and hypertension. In terms of schooling,

Table 1. Characteristics of the population

Age	Frequency	Percentage
40-49 years	14	6.8 %
50-59 years	154	74.8%
60-69 years	26	12.6 %
70-79 years	12	5.8%
Marital Status		
Single	13	6.3%
Civil union	13	6.3%
Married	176	85.4%
Divorced	2	1.0%
Widow	2	1.0%
Schooling		
Elementary	55	26.7%
Junior High-School	71	34.5%
High-School	37	18.0%
Technician	8	3.9%
University (bachelor's degree, engineer)	17	8.3%
Knows how to read and write	18	8.7%
Medication		
None	4	1.9%
Prazosin	1	0.5%
Finasteride	1	0.5%
Tamsulosin	175	85.0%
Tamsulosin/Finasteride	15	7.3%
Tamsulosin/Sildenafil	4	1.9%
Tamsulosin/Tolterodine	2	1.0%
Tamsulosin/Prazosin	1	0.5%
Tamsulosin/Oxybutynin	3	1.5%
Comorbidity		
None	115	55.8%
Type 2 Diabetes mellitus (DM2)	20	9.7%
High blood pressure (HBP)	38	18.4%
Type 2 DM and HBP	33	16.0%
Weight		
	Minimum	43.7kg
	Maximum	141kg

Table 2. Results of the three IPSS applications

		Mild	Moderate / severe	Total
1st application	Frequency	174	32	206
	Percentage	84.5%	15.5%	100%
2nd application	Frequency	172	34	206
	Percentage	83.5%	16.5%	100%
3rd application	Frequency	174	32	206
	Percentage	84.5%	15.5%	100%

Table 3. Comparison of IPSS Symptom Intensity vs. Treatment

	1st IPSS		2nd IPSS		3rd IPSS	
Treatment	Mild	Moderate / severe	Mild	Moderate / severe	Mild	Moderate / severe
None	1	3	3	1	1	3
Prazosin	1	0	1	0	1	0
Finasteride	1	0	1	0	1	0
Tamsulosin	154	21	150	25	154	21
Tamsulosin/ Finasteride	10	5	11	4	10	5
Tamsulosin/ Sildenafill	4	0	1	3	4	0
Tamsulosin/ Tolterodine	1	1	2	0	1	1
Tamsulosin/ Prazosin	1	0	1	0	0	1
Tamsulosin/ Oxybutynin	1	2	2	1	2	1

34.5% had junior high school, and the treatment for BPH that predominated was tamsulosin, see Table 1.

The evaluation of the clinical evolution of the lower urinary tract symptoms (see Table 2) remained stable in most of the patients, with a predominance of mild symptoms in the three questionnaire applications; the increase in severity was secondary to acute urinary tract infections. For statistical analysis, it was dichotomized in two groups, the first one corresponded to mild symptoms and the second one to moderate/severe.

The comparison of results was made by the McNemar's statistical test; by comparing the first application of the IPSS questionnaire with the second, the first application with the third, and the second application with the third, then it was determined that in all these tests referred to there was no statistical significance ($p>0.05$).

When evaluating the association of pharmacological treatments with the result of symptom severity (see Table 3) the χ^2 statistical test was used, the results obtained were statistically significant in the first and third application ($p=0.001$), while in the second application the result was not statistically significant ($p=0.096$).

Discussion

When evaluating the symptoms evolution, it was determined that more than half of the population presented slight symptomatology; similar data have been reported to those observed in studies with participants from countries such as France, Spain, United States and even in Mexico;[10] this is related to the time of evolution of BPH, since the shorter the time of the initial manifestation of the symptomatology, its exacerbation towards more advanced stages will be also less.

The IPSS questionnaire allows monitoring the evolution and measuring the severity to establish the clinical picture in the BPH with the purpose of having more elements to select the treatment in patients with symptoms in the inferior urinary tract.[9,12,18] In this respect, it is required to give continuity and a correct management to this type of patients to avoid future complications.

The 5-alpha-reductase have their pharmacological effect after six months of treatment; in the case of alpha-blockers, the complete effect can be seen after a few weeks, or even in the first days.[19-21] In this study, considering that the patients already have established and adjusted pharmacological treatment in their last annual consultation with the treating urologist, the results of the IPSS show few changes in the evolution of lower urinary tract symptoms related to prostatic changes, so the severity remained stable.

At least 30% of patients do not respond to short-term medical treatment and a subset requires surgery.[22,23] In the present study, six patients with severe symptoms were reported in the last application of IPSS, which represents less than 3% of the population with poor clinical evolution; notwithstanding this figure, it is very important to make an adequate approach in all patients, putting special emphasis on those who, due to their genetic or clinical condition, may develop a greater degree of severity.

In the evolution of prostatic symptoms in patients during the six months of follow-up, no significant changes in severity were observed in most of them, while the severe symptoms were due to infections of the lower urinary tract. The course of the disease is modified by variables that were not included in this study, such as metabolic syndrome, depressive symptoms, alcohol consumption, and chronic prostatic inflammation due to different etiologies;[23] it should be considered a limitation of this study that these variables were not included since the planning stage, due to the direct impact in the clinical evolution of the patients with BPH, and the relevant information provided for an appropriate approach in this type of patient.

Conclusion

The evaluation of the clinical evolution during this period in patients with BPH grade II shows that the severity of prostate symptoms remains stable. However, it is important to consider the infectious processes of the urinary tract as a cause of exacerbation of lower urinary tract symptoms and to consider other comorbidities that may lead to worsening of symptoms. It should always be taken into account that the IPSS should be used by the family physician as a practical and simple tool to monitor the clinical evolution of these patients.

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