ORIGINAL ARTICLE

Indonesia Journal of Biomedical Science (*IJBS*) 2020, Volume 14, Number 1: 17-20
P-ISSN.2085-4773, E-ISSN.2302-2906

The effectiveness of tamsulosin in Benign Prostate Hyperplasia (BPH) patients with Lower Urinary Tract Symptoms (LUTS): a multi-centre cohort retrospective study

Ida Bagus Putra Pramana[1*], Anak Agung Gede Oka[2], Gede Wirya Kusuma Duarsa[2], Kadek Budi Santosa[2], I Wayan Yudiana[2], Pande Made Wisnu Tirtayasa[2], Johan Renaldo[3], Lukman Hakim[3]

ABSTRACT

Introduction: Lower urinary tract symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH) is a common condition in the ageing male. The first-line treatment of LUTS due to BPH is medical management with α-blockers or 5α-reductase inhibitors (5-ARIs). This study aims to analyze the effectiveness of tamsulosin to improve patients symptoms with LUTS due to BPH

Methods: A cohort retrospective study was conducted among 62 respondents with BPH at dr. Soetomo Hospital and Airlangga University Hospital from 2014-2016. The data collected related to characteristics of patients were age, prostate volume, Prostate-Specific Antigen (PSA), IPSS score, IPSS voiding score, IPSS storage score, IPSS quality of life, Qmax, voided volume and post voiding residual urine (PVR). All of the data were analyzed using SPSS version 17.0 for Windows.

Results: There were 62 samples with a mean age of 62.28 ± 7.3 years old. The average prostate volume was 36.09 ± 8.3 cc, and the PSA level was 2.8 ± 1.45 ng/dl. Most of the respondents were in moderate LUTS criteria (54.8%). IPSS and Qmax score significantly improved in a comparison between pre-treatment, 1 month and 3 months after treatment ($p<0.01$). There was no adverse event or severe side effect reported.

Conclusion: Tamsulosin 0.4 mg daily resulted in statistically significant improvements of IPSS score, IPSS storage score, IPSS voiding score, IPSS Quality-of-life score, Qmax, Voided Volume and PVR through 1 month, but it also significantly improved IPSS score and uroflowmetry results in 3 months after treatment.

Keywords: BPH, Tamsulosin, IPSS Score, Uroflowmetry, LUTS

Cite this Article: Pramana, I.B.P., Oka, A.A.G., Duarsa, G.W.K., Santosa, K.B., Yudiana, I.W.Y., Tirtayasa, P.M.W., Renaldo, J., Hakin, L. 2020. The effectiveness of tamsulosin in Benign Prostate Hyperplasia (BPH) patients with Lower Urinary Tract Symptoms (LUTS): a multi-centre cohort retrospective study. *IJBS* 14(1): 17-20. DOI:10.15562/ijbs.v14i1.214

[1]Urology Surgeon, Faculty of Medicine, Universitas Udayana, Universitas Udayana General Hospital, Bali, Indonesia
[2]Urology Surgeon, Faculty of Medicine, Universitas Udayana, Sanglah General Hospital, Bali, Indonesia
[3]Urology Surgeon, Faculty of Medicine, Universitas Airlangga, Dr. Soetomo General Hospital, Surabaya, Indonesia

*Corresponding to:
Ida Bagus Putra Pramana;
Urology Surgeon, Faculty of Medicine, Universitas Udayana, Universitas Udayana General Hospital, Bali, Indonesia;
baguspUtra@unud.ac.id

Received: 2019-09-13
Accepted: 2020-02-15
Published: 2020-03-03

INTRODUCTION

Benign Prostatic Hyperplasia (BPH) and Lower urinary tract symptoms (LUTS) are progressive diseases. Treatment of LUTS patients due to BPH using α-blockers as monotherapy or in combination with 5α-reductase inhibitors (s-ARIs) is the first-line therapy.[1] LUTS prevalence caused by BPH increases along with age, moderate to severe LUTS symptoms occur in 40% man aged 60 years.[2]

Several studies have shown an inverse proportion between LUTS complaints and quality of life.[1,2] The goal of BPH treatment is to reduce complaints, reduce the progression of the disease, and improve the quality of life of patients. Some guidelines recommend treatment with alpha-blockers and 5-alpha reductase inhibitors (5ARI), as monotherapy or combined as appropriate treatment.[3]

Tamsulosin is a selective alpha 1a adrenergic receptor antagonist, which blocks adrenergic receptors causing relaxation of smooth muscle in bladder neck and prostate.[2] It will increase the maximum flow rate and reduce BPH complaints. Tamsulosin has an onset time of 48 hours after the consumption, with maximum effect at 4-6 weeks. Side effects of tamsulosin treatment are sexual dysfunction, ejaculation dysfunction, dizziness, weakness/fatigue, and blurred vision (amblyopia). Several drugs that can be used in treating LUTS due to BPH include Doxazosin, Terazosin, Sildenafil, Silodosin, Vardenafil, Alfuzosin, Dutasteride, Finasteride, Tadalafil, and Teltoradine.[2]

Currently, in Indonesia, tamsulosin is commonly given to patients with BPH due to health insurance policy system, which only provides some medicines as choices for BPH patients such as tamsulosin, dutasteride or finasteride. This study aims to investigate the effectiveness and safety of tamsulosin as a monotherapy treatment for patients

with LUTS due to BPH for 3 months of therapy. The effectiveness of treatment comparatively evaluated IPSS, uroflowmetry and post-void residual urine (PVR) values before treatment and after treatment.

METHODS

This study was a cohort retrospective study, in which patients with Lower Urinary Tract Symptoms (LUTS) due to Benign Prostate Hyperplasia (BPH). This study used and analyzed data retrospectively from the medical record in RSUD dr. Soetomo from January 2014 until October 2016 and Airlangga University Hospital from January 2015 until October 2016.

Inclusion criteria in this study were patient who consumed tamsulosin 0.4 mg daily for at least 3 months, minimum patient's age was 45 years, as well as patients with mild LUTS, Moderate LUTS, and severe LUTS due to BPH. The diagnosis of BPH was confirmed by histopathology and PSA examinations, patients who had a history of urinary retention due to BPH and had performed TWOC. In our department, we obtained PSA examination for all patients with LUTS complaints or urinary retention suggestive to prostate enlargement. An indication of the prostate biopsy was PSA ≥10 ng/ml and result of a digital rectal examination suggestive of prostate cancer. Patients with PSA 4 - 10 ng/ml with PSAD > 0.15 had performed a prostate biopsy.

The exclusion criteria were patients with prostate cancer, or pathology results was atypical acinus, ASAP (atypical small acinar proliferation), PIN (prostatic intraepithelial neoplasia), AAH (atypical adenomatous hyperplasia), Incomplete medical record, Patients who consumed Doxazosin, Terazosin, Sildenafil, Silodosin, Vardenafil, Alfuzosin, Dutasteride, Finasteride, Tadalafil, and Teltoradine or combination therapy. Also, patients with prior prostate surgery and LUTS due to Bladder neck stenosis, neurogenic bladder, and urethral stricture were excluded in this research.

Total IPSS Score, IPSS quality of life score, IPSS Voiding Score, IPSS Storage Score, Q max, Voided Volume, and post-void residual urine (PVR) were comparatively evaluated before treatment, 1 month after treatment, 2 months after treatment, and 3 months after treatment.

Data interval and ratio are displayed in the mean and standard deviation. Data nominal and ordinal are displayed in percentage. Data interval and ratio with normal distribution were analyzed using ANOVA test and correlation test with Pearson. Data with abnormal distribution were analyzed with Wilcoxon test and Spearman correlation test. Wilcoxon test and Spearman correlation test were used for data nominal and ordinal. We used one-way ANOVA repeated test and Friedman test to compare four groups' data before treatment, 1 month after treatment, 2 months after treatment and 3 months after treatment. Data were processed and analyzed using SPSS version 17.0.

RESULTS

We analyzed 62 LUTS patients due to BPH, with their mean age was 62.28±7.3 years old, and an average prostate volume was 36.09±8.3 cc. In this study, the average PSA was 2.8 ± 1.45 ng/dl. We found that 22.6 % of the patients has mild LUTS, 54.8 % was moderate LUTS and 22.6 % was severe LUTS. (Table 1). There was significant improvements of total IPSS, IPSS quality of life, IPSS Voiding, IPSS Storage, Q max, Voided Volume and PVR in 1 month after treatment compared to before treatment ($p < 0.01$), as well as 2 months after treatment compared with 1 month after treatment ($p < 0.01$). In comparison between 3 months and 2 months after treatment, there was a significant improvement in total IPSS, IPSS quality of life, IPSS Voiding, Q max, and PVR ($p < 0.01$). There were significant improvements in total IPSS, IPSS quality life, IPSS Voiding, IPSS Storage, Q max, Voided Volume and PVR 3 months after treatment compared to 1 month after treatment ($p < 0.01$) (Figure 1 and 2).

IPSS score significantly improved in a comparison between pre-treatment, 1 month, and 3 months after treatment (14.56±6.7; 13.3±6.38; 7.87±3.9; $p<0.01$, respectively). IPSS storage score significantly improved, in a comparison between pre-treatment, 1 month and 3 months after treatment of tamsulosin 0.4 mg daily 6.16±3.69; 5.6±3.6; 3.67±2.05; $p<0.01$, respectively). IPSS voiding score and IPSS Quality-of-life score significantly improved, in a comparison between pre-treatment, 1 month and 3 months after treatment of tamsulosin 0.4 mg daily (IPSS Voiding Score 8.56±3.47; 7.7±3.25; 4.09±2.1; $p<0.01$, respectively), (IPSS Quality of life score 4.4±0.8; 4.2±0.68; 2.2±0.6; $p<0.01$, respectively). Tamsulosin improved the Q max (9.57±1.4; 10.3±1.4; 12.8±1.4 ml/sec; $p < 0.001$, respectively), voided volume (199.4±42.9; 207.17±36.4; 231.6±3.78 cc; $p<0.01$, respectively) and decreased the PVR volume from baseline pre-treatment (Q max,), (68.2±18.30; 59.9±15/.9; 32.3±9.22 cc; $p<0.01$, respectively) (Figure 1 and 2).

IPSS score, IPSS storage score, IPSS voiding score, and IPSS Quality-of-life score significantly improved in a comparison between pre-treatment, 1 month, 2 months and 3 months after treatment ($p<0.01$). Tamsulosin improved the Q max, voided volume and decreased the PVR volume from

Table 1. Baseline characteristic of respondents

Variables	Respondents (N=62)
Age (years) (mean±SD)	62.29 ± 7.3
Prostate Volume (cc) (mean±SD)	36.09 ± 8.3
PSA (ng/dl) (mean±SD)	2.8 ± 1.45
LUTS Criteria (N,%):	
Mild	14 (22.6)
Moderate	34 (54.8)
Severe	14 (22.6)

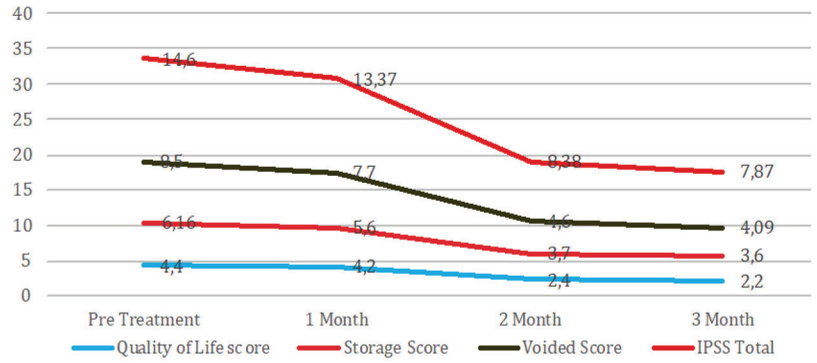

Figure 1. The comparison score of total IPSS, IPSS quality of life, IPSS Voiding, and IPSS storage in pre-treatment, 1 month, 2 months, and 3 months following treatment (P<0.01).

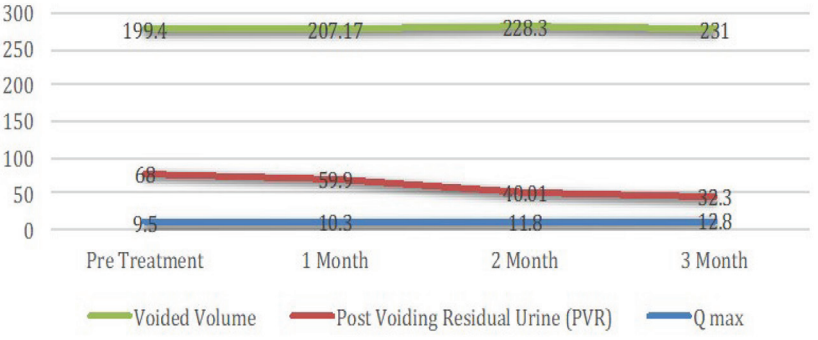

Figure 2. The comparison score of Qmax, Voided Volume, and post-void residual urine (PVR) in pre-treatment, 1 month, 2 months, and 3 months following treatment (P<0.01).

Table 2. The side effect of tamsulosin 0.4 mg daily after 1-month treatment

Side Effect	Percentage (%)
Retrograde Ejaculation	6 (9.6)
Dizziness	6 (9.6)
Decreases Libido	5 (8.0)
Orthostatic hypotension	4 (6.4)
Nausea and Vomiting	3 (4.8)

baseline pre-treatment (p < 0.01). IPSS score, IPSS storage score, IPSS Quality-of-life score, Q max, and PVR will continue to improve until 3 months after treatment. IPSS voiding and voided volume will improve in two months after treatment (Figure 1 and 2).

There were 6 (9.6%) patients complained about retrograde ejaculation, 5 (8 %) patients complained about decreased libido, 4 (6.4%) patients had an orthostatic hypotension, 3 (4.8 %) patients complained of nausea and vomiting, and 6 patients (9.6%) complained about dizziness after 1 month consuming tamsulosin 0.4 mg daily, but all of the patients had good compliance with continuing medical treatment. There was no adverse event or severe side effect reported from the patients (Table 2).

From 15 patients with previous urinary retention history, 11 patients successfully performed TWOC (Trial Without Catheter) after consuming tamsulosin 0.4 mg daily for 2 weeks before the catheter was released while 4 patients had recurrent urine retention.

DISCUSSION

There were 62 samples with an average age of 62 years and an average prostate volume of 36 cc. This result was consistent with the study conducted by Mathias Oelke et al., in which the mean age of patients with BPH was 63.5 years of age. This was consistent with existing theories that BPH may occur in 8% of male patients aged 30 to 40 years and increase to as much as 80% in men over the age of 80 years.[4-7]

In this study, there was a significant improvement of total IPSS Score, IPSS quality of life score, IPSS Voiding Score, IPSS Storage Score, Q max, Voided Volume, and post voiding residual urine (PVR) in patients who had consumed tamsulosin treatment 0.4 mg daily for 1 month until 3 months in comparison with groups before treatment. It means that after patients had consumed tamsulosin 0.4 mg daily for 1 month, 2 months, and 3 months, there was an improvement of LUTS symptoms. In this study, total IPSS score significantly decreased in comparison with studies conducted by Mathias Oelke et al. with total IPSS score decreased after 3 months of tamsulosin therapy.[4]

Our study found a decrease in the quality of life score before treatment and decreased significantly in the 3 months of treatment. This result showed that tamsulosin could decrease the score of quality of life. This result is better than research conducted by Mathias Oelke et al., where there was an improvement in IPSS Quality of Life score with Tamsulosin 0.4 mg daily for 12 weeks.[1,4]

In this study, there was an improvement of IPSS Voiding score after 3 months of treatment. Average Improvement in IPSS voiding score was 3.61 from baseline until 3 months of the therapy. This result is almost similar to the research that had been done by Mathias Oelke et al., of which the improvement of IPSS Voiding score after 12 weeks of treatment.[1,4]

The average of Q max was increase significantly in 3 months of treatment. This improvement of Q max corresponds to the results of a study conducted by Mathias Oekle et al., with average IPSS improvement after treatment 12 weeks.[1,4] An increase of voided volume also increased from 199.4 ± 42.9 cc before treatment became 231 ± 34.78 cc after 3 months of treatment. This result is not significantly different from the research done by Mathias Oekle et al., whereas the improvement in voided volume was increase after 12 weeks of treatment tamsulosin 0.4 mg daily.[1,4]

The recent findings suggest a decrease in PVR after 3 months of treatment. This result was consistent with the study conducted by Mathias Oelke et al., where the average PVR decrease was as much as 10.2 ± 59.2 cc after treatment with tamsulosin 0.4 mg daily for 12 weeks.[1,4] Based on side effects, Mathias Oelke et al., also found as much as 3.6% of patients with dizziness.[4] Studies conducted by Roehrborn et al. only found that 1% of patients experienced retrograde ejaculation and 1% of patients who had decreased libido.[1] In this research, the complication was higher than another study, in which we found 9.6% of the complaints were about retrograde ejaculation and 9.6% patient complaint dizziness. However, in this study for 3 months, there was no adverse event caused by consuming tamsulosin 0.4 mg daily reported. No patient stopped the therapy because of a side effect. This was not in accordance with the research conducted by Roehrborn et al and other studies which obtained as much as 4% of patients stopped treatment because of an adverse event caused by consuming tamsulosin 0.4 mg daily.[1,8,9]

CONCLUSION

Tamsulosin 0.4 mg daily resulted in significant improvements in patients with LUTS due to BPH. In addition, tamsulosin improved IPSS score, IPSS storage score, IPSS voiding score, IPSS Quality-of-life score, Qmax, Voided Volume and PVR through 1 month, but it also significantly improved IPSS score and uroflowmetry results in 3 months after treatment. There was no adverse event or severe side effect had been reported after consuming tamsulosin 0.4 mg daily for 3 months of therapy. Tamsulosin was effective for patients with first-time urinary retention and wants to perform TWOC.

CONFLICT OF INTEREST

There is no competing interest regarding the manuscript

ETHICS CONSIDERATION

Ethics approval has been obtained from the Ethics Committee of Faculty of Medicine, Universitas Udayana, Universitas Udayana General Hospital, Bali, Indonesia prior to the study being conducted.

FUNDING

None

AUTHOR CONTRIBUTION

All of the authors are equally contributed to the study from the conceptual framework, data gathering, data analysis, until reporting the results of study.

REFERENCES

1. Roehrborn CG, Siami P, Barkin J, Damião R, Major-Walker K, Nandy I, et al. The effects of combination therapy with dutasteride and tamsulosin on clinical outcomes in men with symptomatic benign prostatic hyperplasia: 4-year results from the CombAT study. Eur Urol. 2010;57(1):123-31.
2. Miller J, Tarter TH. Combination Therapy with Dutasteride and Tamsulosin for the Treatment of symptomatic enlarged prostate. Clin Interv Aging. 2009;4:251-8.
3. Yuan JQ, Mao C, Wong SY, Yang ZY, Fu XH, Dai XY, et al. Comparative Effectiveness and Safety of Monodrug Therapies for Lower Urinary Tract Symptoms Associated with Benign Prostatic Hyperplasia. A Network Meta-analysis. Medicine (Baltimore). 2015;94(27):e974
4. Oelke M, Giuliano F, Mirone V, Xu L, Cox D, Viktrup L.. Monotherapy with tadalafil or tamsulosin similarly improved lower urinary tract symptoms suggestive of benign prostatic hyperplasia in an international, randomised, parallel. placebo-controlled clinical trial. Eur Urol. 2012;61(5):917-25.
5. Thorne MB, Geraci SA. Acute urinary retention in elderly men. Am J Med 2009;122(9):815-9.
6. Jacobsen SJ, Girman CJ, Guess HA, Rhodes T, Oesterling JE, Lieber MM. atural history of prostatism: Longitudinal changes in voiding symptoms in community-dwelling men. J Urol. 1996;155(2):595–600.
7. Oh WK, Hurwitz M, D'Amico AV, et al. Neoplasms of the Prostate. In: Kufe DW, Pollock RE, Weichselbaum RR, et al., editors. Holland-Frei Cancer Medicine. 6th edition. Hamilton (ON): BC Decker; 2003. Chapter 111. Available from: https://www.ncbi.nlm.nih.gov/books/NBK13489/
8. Bruskewitz RC. Benign prostatic hyperplasia: drug and nondrug therapies. Geriatrics. 1992;47(12):39-42
9. Pradidarcheep W, Wallner C, Dabhoiwala NF, Lamers WH. Anatomy and histology of the lower urinary tract. Handb Exp Pharmacol. 2011;(202):117-48.