*Biological and Clinical Sciences Research Journal*
*eISSN: 2708-2261; pISSN: 2958-4728*
*www.bcsrj.com*
DOI: https://doi.org/10.54112/bcsrj.v2024i1.1476
*Biol. Clin. Sci. Res. J., Volume, **2024**: 1476*
***Original Research Article***

# EFFICACY OF SOLIFENACIN FOR TREATMENT OF OVERACTIVE BLADDER IN WOMEN

**JEHAN S[1], REHMAN SU[2]*, HAYAT A[3], WAHAB A[3], IZHAR M[3]**

[1]*MMC General Hospital, Peshawar, Pakistan*
[2]*Muhammad Teaching Hospital, Peshawar, Pakistan*
[3]*Institute of Kidney Diseases Peshawar, Pakistan*
**Corresponding author`s email address:* Dr.shahzad154@gmail.com

*(Received, 25th November 2024, Revised 25th December 2024, Published 30th December 2024)*

**Abstract:** *Overactive bladder (OAB) significantly affects the quality of life in women due to symptoms such as urgency, increased frequency, and incontinence. Solifenacin, a muscarinic receptor antagonist, has been widely used to treat OAB, but its efficacy needs further validation in diverse populations.* ***Objective:*** *To determine solifenacin's efficacy for treating overactive bladder in women. Descriptive Case Series Department of Urology, Institute of Kidney, from 1st January 2023 to 30th June 2023.* ***Methods:*** *Seventy-seven female patients with overactive bladder diagnosed by consultant urologist on clinical presentation were included in this study. The WHO Sample Size calculator calculated the sample size with 92.20% efficacy of solifenacin, 80% power of the test, and 5% significance level. Clinical evaluation was done, and the baseline severity of symptoms was recorded. Baseline severity was defined according to the number of incontinence episodes/24 h, number of urgency episodes/24 h, and micturition frequency/24 h. Patients were advised of solifenacin 5 mg OD for twelve weeks. Patients were followed up in the twelfth week, and efficacy was determined regarding improvement in the severity of OAB symptoms, i.e., improvement of at least 03 points from the baseline.* ***Results:*** *As per the efficacy of Solifenacin in treating OAB symptoms, 37 (86.0%) showed effective results.* ***Conclusion:*** *Solifenacin showed significant effectiveness in terms of improvement in the severity of OAB symptoms in female patients.*

**Keywords:** Efficacy, Overactive Bladder, Solifenacin

## Introduction

Overactive bladder (OAB) syndrome is a chronic condition that affects both men and women, accompanied by a marked impairment of the patient's quality of life. Although it is more common over the fourth decade, it can affect children and young individuals (1).

Overactive bladder syndrome is a little-known condition, with different manifestations from patient to patient, which causes a great deal of frustration to the medical staff involved. The patient requires a clear explanation and the full support of the attending physician. Establishing a correct diagnosis and effective individualized treatment (2).

Although several studies (3-7) concluded that antimuscarinic drugs are safe, tolerable, and efficacious in improving patients' quality of life with OAB, the evidence comparing different drugs is less robust. Some randomized controlled data suggested that extended-release oxybutynin and tolterodine may have superior efficacy to the immediate-release preparations. In addition, solifenacin is as effective as extended-release tolterodine, and fesoterodine is superior to it. However, the incidence of adverse effects increases with an increasing dose (8).

A study reported significant improvement in OAB symptoms in 71 (92.21%) of patients treated with solifenacin compared to baseline values, as the UDI score was significantly improved after solifenacin (22.26 +/- 5.91) (9).

This study aimed to determine solifenacin's efficacy for treating overactive bladder in women, as there is much disparity in the data on the efficacy of Solifenacin in terms of urgency and episodes of urge incontinence. This study was an attempt to identify a more efficacious agent for OAB. The findings of this study will be shared with local clinicians, who will help them robustly manage such patients in our population.

## Methodology

This descriptive case series was conducted at the Department of Urology, Institute of Kidney Diseases, Peshawar, from 1st January 2023 to 30th June 2023.

Ethical approval was obtained from the Ethical Committee. The WHO Sample Size calculator calculated the sample size with 92.20%[9] efficacy of solifenacin, 80% power of the test, and 5% significance level. A nonprobability consecutive sampling technique was used for data collection.

Female patients aged 40 to 70 years with symptoms of OAB diagnosed by a consultant urologist on clinical presentation were included in the study.

Pregnant women, patients with stress incontinence, malignancy in the pelvic organs, pelvic organ prolapse, bladder stones, UTI, neurological conditions (e.g., Spinal injury, multiple sclerosis, Parkinson's disease, diabetic neuropathy), and medical conditions contraindicating the use of study drugs.

Written informed consent was obtained from all after a complete description was given. Overactive bladder (OAB) was diagnosed on a clinical presentation by a consultant urologist. Patients with urinary frequency of >07 times/day, at least 01 episode of urinary urgency/week with or without urinary incontinence, nocturia at least 01 episode/night, with duration of these symptoms more than three months and having OABS score $\geq$ 4 were labeled as having overactive bladder. (The OABS score is a symptom

assessment questionnaire designed to quantify OAB symptoms into a single score (10). The questionnaire consists of 4 questions on OAB symptoms with maximum scores ranging from 2 to 5: daytime frequency (2 points), night-time frequency (3 points), urgency (5 points), and UUI (5 points). The total score ranges from 0 to 15 points, with higher scores indicating higher symptom severity).

After a detailed history, physical examination, and calculating pre-treatment OABS score, necessary investigations like Ultrasound of the abdomen and pelvis, Post void residual urine volume (PVRV), retrograde urethrogram, Micturating cystourethrogram (MCUG), and MRI were performed where needed.

Patients were advised of Solifenacin (5mg, OD) for 12 weeks. They were called for follow-up visits to determine the drug efficacy by observing significant differences in OABS scores before and after treatment. Patients improving at least 03 points in pre-treatment OABS score were considered positive responders.

All statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 23.0. Mean+SD were calculated for numerical variables like age, duration of symptoms, and pre and post-treatment OAB score. Frequencies and percentages will be calculated for categorical variables like age groups and efficacy. Efficacy was stratified with age and duration of symptoms. Post-stratification chi-square test was applied for categorical variables and independent samples *t-test* for numerical variables, keeping *p*-value $\leq$ 0.05.

## Results

A total of seventy-seven patients were included in this study. Mean+SD for age, duration of symptoms, pre and post-treatment OABS score was 51.28$\pm$6.78 years, 4.49$\pm$1.98 days, 12.69$\pm$1.65, and 2.97$\pm$1.77, respectively (p-value < 0.001). 33 (76.7%) patients were recorded in the $\leq$ 55 years age group, while 10 (23.3%) patients were recorded in the> 55 years age group, As per the efficacy of Solifenacin in treating OAB symptoms, 37 (86.0%) showed effective results. (Table-I) 28 (75.7%) patients in the $\leq$ 55 years age group, while 09 (24.3%) patients in the> 55 years age group showed effective results (*p*-value 0.680). 23 (62.2%) patients in $\leq$ 5 days duration of symptoms while 14 (37.8%) patients in > 5 days duration of symptoms showed effective results (p-value 0.067). (Table II).

***Table 1: Demographic and Clinical Characteristics of Study Participants with Overactive Bladder (n=43)***

| **Numerical Variables** | **Mean+SD** | ***p*-value** |
|---|---|---|
| • Age (Years) | 51.28$\pm$6.780 | |
| • Duration of Symptoms (Days) | 4.49$\pm$1.98 | |
| • Pre-Treatment OABS Score | 12.698$\pm$1.65 | < 0.001 |
| • Post Treatment OABS Score | 2.907$\pm$1.77 | |
| **Categorical Variables** | | |
| Age Groups, n (%) | | |
| • $\leq$ 55 Years | | 33 (76.7%) |
| • > 55 Years | | 10 (23.3%) |
| Efficacy, n (%) | | |
| • Yes | | 37 (86.0%) |
| • No | | 6 (14.0%) |

**Table 2: Stratification of Efficacy with age and duration of symptoms (n=43)**

| **Age Groups, n (%)** | **Efficacy** | | ***p*-value** |
|---|---|---|---|
| | **Yes** | **No** | 0.680 |
| • $\leq$ 55 Years | 28 (75.7%) | 05 (83.3%) | |
| • > 55 Years | 9 (24.3%) | 01 (16.7%) | |
| **Duration of Symptoms, n (%)** | **Yes** | **No** | |
| • $\leq$ 5 Days | 23 (62.2%) | 06 (100%) | 0.067 |
| • > 5 Days | 14 (37.8%) | 0 (0.0%) | |

## Discussion

The quality of life of many patients is negatively impacted by the common but unpleasant urological illness of overactive bladder (11). Anti-muscarinic drugs are the backbone of treatment for patients with overactive bladder syndrome to preserve the bladder's retentive and conserving capabilities.

Due to their efficacy, safety, and stability, anti-muscarinic medications such as tolterodine, solifenacin, oxybutynin, trospium chloride, propiverine, and fesoterodine have been in widespread use for quite some time (12). These medications block muscarinic (M3) receptor signals in the bladder's smooth muscle. Although anti-muscarinics are widely used to treat OAB, the superior drug remains unclear (13).

Many studies have been done previously regarding OAB prevalence in women, with a reported value of 16.9%, which increased with the advancement in age, i.e., 4.8% in women with age <25 years, rising to 30.9% in those with age >65 years. (14). Another epidemiological survey done in Europe revealed an OAB prevalence of 16.6% in a population aged≥40 years and again was found to increase with age (15). Findings of this study purport that mean+SD for age was 51.28$\pm$6.78 years, 33 (76.7%) patients were recorded in $\leq$ 55 years age group while 10 (23.3%) patients were recorded in > 55 years age group, 37 (86.0%) showed effective results. (Table 1) Keeping in view the efficacy,

solifenacin 5mg OD was quite an effective drug in improving OAB symptoms. Moreover, if 5mg OD solifenacin fails as the primary drug, then 3mg TDS oxybutynin needs to be considered as it offers efficacy similar to 10mg OD solifenacin. Various studies, including randomized controlled trials, justified the superiority of solifenacin amongst other anti-muscarinic drugs, considering its safety, clinical efficacy, and cost (16, 17). However, some contrast the findings of this study, which denies the superiority of solifenacin. Kakar et al[18] compared oxybutynin, solifenacin, fesoterodine, and tolterodine with a conclusion that while tolterodine and solifenacin were equally effective for treating OAB, the oxybutynin, and solifenacin showed improved efficacy, but more adverse effects were also reported. Various clinical trials (16-18). There have been reported differences in the efficacy of various anti-muscarinic agents. However, in routine clinical practice, the veracity of such differences is not correctly validated, and therefore, many clinicians do not recommend these drugs. This study had certain limitations, including a small sample size and non-availability of data regarding the tolerability of the study drugs and assessment of drug responses at various doses.

## Conclusion

Solifenacin showed significant effectiveness in terms of improvement in the severity of OAB symptoms in female patients. However, large multicentered randomized controlled clinical trials are required for better evaluation of the efficacy of solifenacin in our local population. This was a single center with a tiny sample size. The follow-up period was also kept short due to the paucity of study duration. The emphasis was only on ascertaining the drug's effectiveness, and we did not study any long-term adverse effects associated with Solifenacin**.**

## Declarations

**Data Availability statement**
All data generated or analyzed during the study are included in the manuscript.
**Ethics approval and consent to participate**
Approved by the department concerned. (IRBEC-TCHJAD-02323/23)
**Consent for publication**
Approved
**Funding**
Not applicable

## Conflict of interest

The authors declared the absence of a conflict of interest.

## Author Contribution

***SHAH JEHAN***
*Coordination of collaborative efforts.*
***SHAHZAD UR REHMAN (SR)***
*Conception of Study, Development of Research Methodology Design, Study Design, manuscript Review, and final approval of manuscript.*
*Conception of Study, Final approval of manuscript.*
***ANWAR HAYAT***
*Manuscript revisions, critical input.*
*Coordination of collaborative efforts.*
***ABDUL WAHAB.***
*Data acquisition and analysis.*
*Manuscript drafting.*
***MUHAMMAD IZHAR***
*Data entry and data analysis, as well as drafting the article.*
*Data acquisition and analysis.*
*Coordination of collaborative efforts.*

## References

1. Leron E, Weintraub AY, Mastrolia SA, Schwarzman P. Overactive bladder syndrome: Evaluation and management. Curr Urol. 2018; 11:117–125.
2. Scarneciu I, Lupu S, Bratu OG, Teodorescu A, Maxim LS, Brinza A, Laculiceanu AG, Rotaru RM, Lupu AM, Scarneciu CC. Overactive bladder: A review and update. Exp Ther Med. 2021 Dec; 22(6):1444.
3. Chapple C, Khullar V, Gabriel Z, Dooley JA. Antimuscarinic treatments' effects on overactive bladder: a systematic review and meta-analysis. Eur Urol. 2005; 48:5–26.
4. Appell RA, Sand P, Dmochowski R, Anderson R, Zinner N, Lama D, Roach M, Miklos J, Saltzstein D, Boone T, Staskin DR, Albrecht D. Prospective randomized controlled trial of extended-release oxybutynin chloride and tolterodine tartrate in the treatment of overactive bladder: results of the OBJECT Study. Mayo Clin Proc. 2001; 76:358–363.
5. Van Kerrebroeck P, Kreder K, Jonas U, Zinner N, Wein A. Tolterodine once-daily: superior efficacy and tolerability in treating the overactive bladder. Urology. 2001; 57:414–421.
6. Diokno AC, Appell RA, Sand PK, Dmochowski RR, Gburek BM, Klimberg IW, Kell SH. A prospective, randomized, double-masked study of the efficacy and tolerability of the extended-release formulations of oxybutynin and tolterodine for overactive bladder: results of the OPERA trial. Mayo Clin Proc. 2003; 78:687–695.
7. Herschorn S, Swift S, Guan Z, Carlsson M, Morrow JD, Brodsky M, Gong J. Comparison of fesoterodine and tolterodine extended release for the treatment of overactive bladder: a head-to-head placebo-controlled trial. BJU Int. 2010; 105:58–66.
8. Robinson D, Cardozo L. Antimuscarinic drugs to treat overactive bladder. BMJ. 2012; 344:e2130.
9. Oreskovic S, But I, Banović M, Goldstajn MS. The efficacy and safety of solifenacin in patients with overactive bladder syndrome. Coll Antropol. 2012 Mar; 36(1):243-8.
10. Hung MJ, Chou CL, Yen TW, Chuang YC, Meng E, Huang ST, et al. Development and validation of the Chinese overactive bladder symptom score for assessing overactive bladder syndrome in a RESORT study. Journal of the Formosan Medical Association. 2013; 112(5):276-82.
11. Chapple C, Sievert KD, MacDiarmid S, Khullar V, Radziszewski P, Nardo C, et al. Onabotulinumtoxin A 100 U significantly improves all idiopathic overactive bladder symptoms and quality of life in patients with overactive bladder and urinary

incontinence: A randomized, double-masked, placebo-controlled trial.European Urology. 2013; 64(2):249-56.
12. Yamada S, Ito Y, Nishijima S, Kadekawa K, Sugaya K. Basic and clinical aspects of antimuscarinic agents used to treat overactive bladder. Pharmacology & Therapeutics. 2018; 189:130-48.
13. Smith AL, Wein AJ. Antimuscarinic pharmacotherapy for overactive bladder. Contemporary Pharmacotherapy of Overactive Bladder: Springer; 2019. p. 85-113.
14. Nambiar AK, Bosch R, Cruz F, Lemack GE, Thiruchelvam N, Tubaro A, et al. EAU guidelines on assessment and nonsurgical management of urinary incontinence. European Urology. 2018; 73(4):596-609.
15. Tailor VK, Digesu GA. Overactive bladder. Postmenopausal diseases and disorders: Springer; 2019. p. 133-44.19. Eapen RS, Radomski SB. Review of the epidemiology of overactive bladder. Research and Reports in Urology. 2016; 8:71.
16. Nalliah S, Gan PW, Masten Singh PK, Naidu P, Lim V, Ahamed AA. Comparison of efficacy and tolerability of pharmacological treatment for the overactive bladder in women: A network meta-analysis.Australian Family Physician. 2017; 46(3):139.
17. Basra R, Kelleher C. A review of solifenacin in the treatment of urinary incontinence. Therapeutics and Clinical Risk Management. 2008; 4(1):117.22. Kakar H, Kok B, Mokhles S, Sarwar M. Comparison of fesoterodine, tolterodine, oxybutynin, and solifenacin in patients with overactive bladder. Erasmus J Med. 2012; 2(2):20-4.
18. Kakar H, Kok B, Mokhles S, Sarwar M. Comparison of fesoterodine, tolterodine, oxybutynin, and solifenacin in patients with overactive bladder. Erasmus J Med. 2012; 2(2):20-4.



[Citation: Jehan, S., Izhar, M., Ahmad, F., Zohair, M., Shah, S.A. (2024). Efficacy of solifenacin for treatment of overactive bladder in women. *Biol. Clin. Sci. Res. J.*, **2024***: 1476*. doi: https://doi.org/10.54112/bcsrj.v2024i1.1476]