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Review Article

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Tamsulosin Off-Label Use in Kidney Stones: Review and Survey

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ABSTRACT

This study investigates the effectiveness and healthcare perceptions of Tamsulosin, an off-label medication for kidney stone management. Despite the documented benefits, the quest for alternative treatments like Tamsulosin persists, driven by its advantages and patient satisfaction levels. This research includes a literature review and a survey of pharmacy students' opinions on Tamsulosin, aiming to bridge the knowledge gap. This study, which involved 38 first-year professional pharmacy students, achieved a 92% response rate. The research used questionnaire that collected demographic information and assessed participants' knowledge and opinions using a Likert scale, which was integrated into a drug informatics course. We analyzed the responses using SPSS software, utilizing descriptive and chi-square statistical methods. The survey, completed by 38 participants, revealed discrepancies between current treatment practices and the students' understandings. Despite Tamsulosin's documented efficacy in facilitating stone passage, significant skepticism exists about its use without FDA approval. The research showed varied levels of understanding and skepticism towards off-label use among the students. Moreover, 70.3% of respondents recognized Tamsulosin's potential for managing kidney stones, despite its lack of FDA approval, indicating a cautious yet acknowledging attitude towards non-approved drug use for organ rejection. There's a noted need for improved education and the dissemination of evidence-based guidelines in clinical practice. The study uncovers varied knowledge and perceptions among healthcare professionals and pharmacy students regarding Tamsulosin's use in kidney stone management. The gap between clinical evidence and survey participants' awareness underscores the importance of further research and education to align clinical practices with evidence-based guidelines.

Key words: *Tamsulosin, Pharmacist, Students, Kidney stones, Howard, Off-label Use and Non-FDA*

INTRODUCTION

The management of kidney stones involves a range of treatment options tailored to the patient's specific circumstances. For small stones that can pass spontaneously, observation combined with pain management using medications like NSAIDs or opioids may suffice. Increasing fluid intake, particularly water, is often recommended to aid stone passage and prevent recurrence. In cases where intervention is necessary, treatments such as extracorporeal shock wave lithotripsy (ESWL), ureteroscopy with laser lithotripsy, or percutaneous nephrolithotomy (PCNL) may be employed to break up and remove stones. Alongside medical interventions, dietary and lifestyle modifications, including changes in diet composition and habits, play a crucial role in preventing stone formation. Ultimately, the choice of treatment depends on factors such as stone size, location, and patient preferences, with ongoing monitoring and preventive measures implemented to mitigate the risk of recurrence.

While current treatments have shown efficacy, the quest for alternative therapies continues to address unmet needs, improve outcomes, and enhance patient satisfaction. Further research is needed to establish the safety,

efficacy, and feasibility of these alternative approaches in clinical practice. One such drug that is used off-label is Tamsulosin (Flomax), which belongs to a class of medications known as alpha-blockers. It works by relaxing the muscles in the prostate and bladder, allowing urine to flow smoothly.

The goal of this study is twofold. First, conduct a literature review of the clinical use of tamsulosin. Second, to assess pharmacy students' knowledge and opinions on the use of tamsulosin in treating kidney stones. The U.S. Food and Drug Administration (FDA) has not specifically approved tamsulosin for the treatment of kidney stones. However, evidence of tamsulosin's efficacy in facilitating the passage of ureteric stones often leads to its off-label prescription for this indication.

A systemic review study was a meta-analysis including 55 RCTs involving over 5,000 patients with ureteric stones [1]. The analysis revealed a significantly higher likelihood of stone expulsion among patients treated with tamsulosin compared to placebo or standard therapy alone (odds ratio [OR] 1.50, 95% confidence interval [CI] 1.30-1.72). Subgroup analyses further demonstrated that the beneficial effects of tamsulosin were particularly pronounced in patients with distal ureteric stones and those with larger stone sizes [1].

Another systematic review meta-analysis study evaluated the effect of tamsulosin on stone passage for ureteral stones [2]. The analysis included 55 RCTs with a total of 4,365 patients. The results showed that tamsulosin significantly increased the odds of stone expulsion compared to control groups (OR 1.51, 95% CI 1.26-1.81). Moreover, subgroup analyses indicated that the efficacy of tamsulosin was dose-dependent, with higher doses (>0.4 mg/day) associated with greater stone expulsion rates.

Porpiglia and colleagues conducted a prospective, randomized trial to assess the efficacy of tamsulosin in facilitating the passage of ureteral stones ≤10 mm in size [3]. The study included 150 patients randomized to receive either tamsulosin 0.4 mg/day or placebo for a maximum of 28 days. The results demonstrated a significantly higher stone expulsion rate in the tamsulosin group compared to the placebo group (85.3% vs. 57.1%, $p < 0.001$). Additionally, the mean time to stone expulsion was significantly shorter in the tamsulosin group (9.2 days vs. 15.6 days, $p < 0.001$), highlighting the efficacy of tamsulosin in promoting stone passage.

Together, these studies show that tamsulosin works to increase the rate at which ureteric stones are passed and shorten the time it takes for stones to pass, especially in patients with stones farther along the ureteric tract and stones that are bigger. The fact that the results of different RCTs and meta-analyses were all the same shows that tamsulosin may be useful as an extra treatment for ureteric stones.

Healthcare professionals survey

Several studies have investigated the knowledge and opinions of healthcare professionals regarding the use of tamsulosin for kidney diseases. These studies provide valuable insights into the perceptions, attitudes, and understandings of clinicians regarding this medication. For example, a study surveyed urologists' opinions on the use of tamsulosin for the medical expulsive therapy of ureteral stones [4]. The findings revealed that most urologists considered tamsulosin to be an effective and safe option for facilitating stone passage.

Similarly, a survey conducted by Schoenfeld *et al*. (2020) assessed emergency physicians' knowledge and prescribing practices regarding tamsulosin for ureteral colic [5]. The results showed variability in physicians' awareness and utilization of tamsulosin, with some physicians expressing concerns about its efficacy and side effects.

Furthermore, a systematic review examined the perceptions of healthcare professionals, including urologists, emergency physicians, and primary care providers, regarding the use of tamsulosin for ureteral stones. The review highlighted the need for further education and the dissemination of evidence-based guidelines to optimize the appropriate use of tamsulosin in clinical practice [6].

When it comes to pharmacists; however, there are limited studies specifically examining the knowledge or opinion regarding the use of tamsulosin for kidney stones. However, pharmacists, as medication experts, often play a crucial role in the management of kidney stone patients by providing information about medication options, potential side effects, and drug interactions.

Therefore, the goal of this study is twofold. First, conduct a literature review on the use of tamsulosin in the management of kidney stones as shown above. Second, to assess the knowledge and opinion of pharmacy students related to the use of tamsulosin in the management of kidney stones.

MATERIALS AND METHODS

This research involved 38 first-year professional pharmacy students from a college of pharmacy, achieving a robust 92% response rate. The drug informatics course integrated the study, and participants filled out a questionnaire with eight demographic questions, including age, gender, education, pre-Howard University residency, work experience, and annual income. Additionally, the survey included five knowledge and five opinion questions, employing a Likert scale (ranging from strongly agree to strongly disagree). The survey results underwent analysis through SPSS software, utilizing descriptive and chi-square statistical analysis.

RESULTS AND DISCUSSION

Table 1 shows the demographics of the survey participants. Most participants were younger than 30 years old (82.05%), predominantly female (58.97%), evenly distributed between DC, Maryland & Virginia (DMV), and other states (50% each), and had an education level above a Bachelor of Science degree (57.89%).

Table 1. Demographics of participants

Demographics	Group	N (%)
Age	• Less than 30 years	32 (82.05%)
	• Above 30 years	7 (17.95%)
Gender	• Female	23 (58.97%)
	• Male	16 (41.03%)
Residence	• DC, Maryland & Virginia	19 (50%)
	• Other states	19 (50%)
Education	• Below BSc	16 (42.11%)
	• Above BSc	22 (57.89%)

Table 2 shows the statistics on the job, income, and work experience of all the participants. Most of the participants had non-pharmacy jobs (65.79%) before attending pharmacy school. Many of the participants made more than $30,000 annually (52.63%), and most of the participants at least had a job (87.18%) many of whom worked less than two years (57.89%).

Table 2. Statistics on Job, Income, and Work EXP

Demographics	Group	N (%)
Job Type	• Pharmacy job	13 (34.21%)
	• Non-pharmacy job	25 (65.79%)
Annual Income	• Less than $30,000	18 (47.37%)
	• More than $30,000	20 (52.63%)
Work Experience	• Worked	34 (87.18%)
	• Never Worked	5 (12.82%)
	• Less than 2 years	22 (57.89%)
	• More than 2 years	16 (42.11%)

Table 3 was all about opinion questions. The survey responses regarding the use of tamsulosin in the management of kidney stones reflect varied perspectives among participants. A significant proportion (57.89%) expressed concerns about utilizing tamsulosin due to its off-label status and lack of FDA approval, indicating a cautious approach. However, a literature search revealed more support. Additionally, a majority (73.68%) asserted that current treatment options for ureteric stones are effective, implying a reluctance towards incorporating tamsulosin into treatment regimens. Conversely, a smaller proportion (26.32%) disagreed with this notion, suggesting a willingness to explore alternative therapies.

The majority (78.95%) expressed skepticism about the use of tamsulosin despite the fact that it lacks FDA approval, emphasizing the importance of robust evidence before endorsing its off-label use. Furthermore, there

was a divide in opinions regarding the efficacy of tamsulosin for patients with smaller versus larger stones, with 39.47% believing it to be more effective for smaller stones and 60.53% disagreeing. Similarly, 47.36% of respondents agreed and 52.64% disagreed that tamsulosin offers equal benefits for patients with small or large stones. These findings highlight the complexities surrounding the use of tamsulosin in kidney stone management and underscore the need for further research and consensus-building within the healthcare community.

Table 3. Opinion-based questions

Questions	Strongly Agree/ Agree	Disagree/S. Disagree
Kidney stone is the cause of major and severe pain and I do not agree with using tamsulosin since it is not approved.	22 (57.89)	16 (42.10)
Ureteric stone has currently effective treatment options and I do not recommend using Tamsulosin.	28 (73.68)	10 (26.32)
Tamsulosin if it has enough studies to support its efficacy in kidney stones, should be used as an option for treatment even if it is not FDA-approved.	8 (21.05)	30 (78.95)
Tamsulosin Patients with smaller stones will see a better effect using tamsulosin than larger stones.	15 (39.47)	23 (60.53)
Tamsulosin offers equal benefits for those with small or large stones.	18 (47.36)	20 (52.64)

Table 4 shows knowledge-based questions on the use of tamsulosin to treat kidney stones. The comparison between participants' responses and the correct answers from the literature revealed mixed levels of accuracy. Regarding the daily dose of tamsulosin, approximately half of the participants (52.63%) correctly identified it as 0.4mg per day. However, responses regarding the approval status of tamsulosin for hypertension showed lower accuracy, with only 28.95% providing the correct answer that it is false. Although the drug was originally approved for hypertension, about ¾ of the students did not answer correctly.

Similarly, when asked about the timeframe for results from tamsulosin, a significant majority (68.42%) correctly disagreed that it takes a few weeks. It is well documented that tamsulosin, like other alpha-blocker agents, has an immediate blood-lowering effect. However, it may take time when used for non-FDA indications such as kidney stones. Conversely, opinions on tamsulosin's role as a medical expulsive therapy were evenly split, with 42.11% recognizing it as true.

Any substance can cause allergic reactions, and this is also true for tamsulosin. However, allergic reactions are not one of the common alternative dispute resolutions reported in the literature. Regarding tamsulosin's potential side effects, the majority (65.79%) correctly identified that it can cause severe allergic reactions such as swelling of the face, tongue, or throat, difficulty breathing, and blistering of the skin, aligning with the literature. Overall, while some questions demonstrated relatively high levels of agreement with the correct answers, others indicated a need for improved understanding among participants.

Overall, the true score is much lower (57.12%) than the expected pass score of 70%, showing a major gap in knowledge among survey participants. It is noteworthy that a considerable proportion of participants gave false responses to some questions, suggesting possible misunderstandings or gaps in knowledge.

Table 4. Knowledge-based questions

Questions	Correct Answers	Participants with correct answers n (%)	S. Agree/ Agree	Disagree/ S. Disagree
The daily dose of tamsulosin is 0.4mg a day	False	18 (47.37%)	20	18
Tamsulosin is approved for the treatment of hypertension.	True	25 (69.44)	25	11
Results from tamsulosin will take a few weeks even when used for FDA-approved indication.	True	12 (31.58%)	12	26
Tamsulosin can be used as a medical expulsive therapy.	False	22 (57.89%)	16	22
Tamsulosin side effects can cause severe allergic reactions.	True	25 (65.79%)	13	25

Total (Ave)	**98 (52.21)**

The aim of this study was twofold: firstly, to evaluate the level of support and evidence from the literature regarding the utilization of tamsulosin for kidney stone management, and secondly, to assess the knowledge and opinions of pharmacy students on this topic.

The literature review revealed that the prevalence of kidney stones has been increasing globally, with urinary stone recurrence reaching up to 50%. Chronic kidney disease and end-stage renal disease are associated with nephrolithiasis. Diet plays a significant role in urinary stone development, with inadequate hydration consumption being a primary dietary risk factor. The National Health and Nutrition Examination Survey data from 2007 to 2014 revealed a prevalence of 10.1% for kidney stones during 2013-2014. Males older than 60 years had the highest frequency of kidney stones, at 17.8%. The mechanism of kidney stone formation involves various factors such as supersaturation of urine with stone-forming substances, insufficient fluid intake, PH imbalance, inadequate inhibitors of stone formation, along with medical conditions such as genetics, diet, and dehydration.

Tamsulosin plays a significant role in the management of kidney stones, particularly in cases where stones are small and located in the lower urinary tract, such as the ureter. It is often used off-label for this purpose. Tamsulosin works by relaxing the muscles in the urinary tract, including the ureter, which can help facilitate the passage of kidney stones and alleviate associated symptoms like pain. Numerous studies and clinical trials have investigated its efficacy in enhancing stone passage rates and reducing the need for surgical intervention, especially in patients with distal ureteric stones and larger stone sizes. However, while some studies have shown promising results, others have yielded mixed findings, highlighting the need for further research and consideration of individual patient factors when deciding on treatment options.

Regarding the survey conducted among pharmacy students, the results revealed several insights. Most participants were younger than 30 years old, predominantly female, and had education levels above a Bachelor of Science degree. Regarding job type, income, and work experience, most participants had non-pharmacy jobs before attending pharmacy school, earned more than $30,000 annually, and had some work experience, with many having worked for less than two years.

In terms of opinion on tamsulosin use in kidney stones, a significant proportion of participants did not recommend its use despite its effectiveness. Additionally, there were differing opinions on the cause of kidney stone pain and the use of tamsulosin in FDA-approved versus non-approved scenarios. The overall score is about 57.12% showing a lack of adequate knowledge.

Limitations of the study

Some limitations of this study include a relatively small sample size of 38 first-year pharmacy students from a single institution, which may limit the generalizability of the findings. Additionally, the composition of the sample, predominantly young students with education levels below a Bachelor of Science degree, may not be representative of the broader population of healthcare providers or pharmacists. The survey utilized the Likert scale questions for both knowledge and opinion assessments. The study relied on self-reported data from participants, which may be subject to recall bias or inaccuracies. Participants' responses to knowledge-based questions may not accurately reflect their actual knowledge level, and their opinions may be influenced by personal beliefs or experiences. The study's findings may not be generalizable to other populations of healthcare providers, pharmacists, or pharmacy students outside the specific context of Howard University College of Pharmacy.

CONCLUSION

The study evaluated support for tamsulosin in managing kidney stones and assessed pharmacy students' knowledge and opinions on the topic. Most participants were under 30, mainly female, with educational backgrounds below a Bachelor of Science degree. The results showed varying perspectives on tamsulosin, with concerns about its off-label use. Knowledge-based questions revealed mixed accuracy levels. These findings highlight the complexity of tamsulosin's role in kidney stone management and emphasize the need for further research and consensus-building. However, limitations such as sample size and potential biases warrant future research to enhance understanding.

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