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ORIGINAL ARTICLE

Efficacy of tamsolusin hydrochloride as medical expulsive therapy in lower ureteric calculi < 9mm in adults.

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ABSTRACT… Objectives: To determine the efficacy of Tamsolusin Hydrochloride as medical expulsive therapy in removal of lower ureteric calculi < 9 mm in adults. **Study Design:** Cross-sectional study. **Setting:** Naz Memorial Hospital Karachi. **Period:** July 2019 to December 2019. **Material & Methods:** Using non-probability convenient sampling technique was conducted for 6 months. After ethical approval patients attending outpatient department with complains of bloody urine, abdominal, flank or groin pain and diagnosed as lower ureteric calculi < 9mm on ultrasonography. Upper ureteric or kidney calculi above 9 mm, patients already on Tamsolusin and lost to follow up or not willing to participate were excluded. Time period of the study was 4 weeks. Patients were started on Tamsolusin 0.4 mg once daily for 30 days. SPSS version 23.0 was used for data analysis. Qualitative data was reported as frequency in percentages. **Results:** Age range of patients was 18-50 years with mean age of 35.54 ± 10.20 years. 48 (40%) between 6 to 7 mm. After 1 month of follow up, total of 94 (78%) of patients were found to have expulsion of ureteric calculi. From the total of 30 days, the recorded frequency of calculi expulsion was 94 (78%). Among them, 25 (27%) patients were reported to have expulsion of calculi in between 15 to 19 days.32 (34%) patients between 20-24 days, while 37 (39%) patients between 25 to 29 days. **Conclusion:** Tamsolusin was significantly effective in expulsion of calculi with most calculi reported to be expulsed between 20-29 days of treatment. Patients also reported in significant decrease in pain frequency and were satisfied with treatment with Tamsolusin for lower ureteric calculi < 9mm.

Key words: Lower Ureteric Calculi, Tamsolusin, <9 mm.

INTRODUCTION

Ureteric and colic calculi or urolithiasis incidence is reported to increase ever-so since the last few decades. It is estimated that incidence of kidney calculi in a lifetime appears to be about 5 to 10%, with the rate of recurrence hovering about 50%.[1] Moreover, incidence of ureteric calculi is on the rise which is resulting in an ever increase in economic burden to both patients and the hospital.[2] A multitude of treatment options are available for the expulsion or removal of ureteric / kidney calculi. These include medical expulsion therapy, shock wave lithotripsy, uretroscopy, open or laparoscopic removal of calculi, percutaneous nephrolithotomy, all either singly or in combination with each other.[3] Multiple factors such as age of patient, size and location of calculi, anatomic variations of calculi, preference of the clinician and characteristics of the calculi all tend to play a part in determining the different treatment option to be chosen and carried out.[4]

The most initial and non-invasive method of treatment for ureteric calculi of less than 9 mm is the medical expulsion therapy. It is not only preferred by certain physicians but by many patients due to its non-invasiveness.[5] In most of the patients, ureteric colic is because of calculus which is less than 5 mm might spontaneously get passed through or be expulsed that can be facilitated through treatment with medicine. Medical treatment is administered for pain, prevention of infection, to relax ureters and decrease edema and ureteric spasm present at

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impacted calculi's location.[6] This can be gained by giving Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) either oral or through parenteral route in order to decrease frequency of pain, alongside an antibiotic for prevention of infection and inflammation while more importantly, an alpha antagonist such as Tamsulosin for facilitating dilatation as well as relaxation of the ureters for provision of an easy passage for calculi expulsion.[7]

Ureteric calculi are a common health problem world over especially among the elderly. These calculi have accounted for around 20% of urolithiasis while amongst them, 70% of ureteric calculi's location within the lower one-third of ureter.[8] The calculi tend to make the patients undergo great bearing on health issues in addition to their quality of life. The fact that the spectrum of disease tends to different among developed and developing world probably due to delayed diagnosis, lack of resources for investigation or lack of awareness that causes to alterations in the outcome of patients.[9] Furthermore, the more advanced resources are usually not easily available in this part of the world. Therefore, it is comprehensively practiced to undertake the non-invasive, conservative medical treatment option for ureteric calculi ought to be used initially. However if medical therapy tends to fail, other treatment options can then be taken into account. Two most vital factors determining the outcome of safe passage of ureteric calculi are location and size of calculi.[10]

In the recent few years, the use of selective alpha 1 adrenoreceptor antagonists have proved to be effective, have good tolerance and be easily administered in managing patients having lower urinary tract symptoms because of obstructed neck of bladder due to stimulation of autonomic system.[11] Around 12% of the populations are reported to suffer from urinary calculi disease at some point in their life. Urolithiasis is a constituent of about 40-50% urological disorders which is about 12% in Pakistan.[12] After initial diagnosis of ureteric calculi, mean rate of recurrence are approximately 75% in 20 years. From all the calculi, 20% constitute ureteral calculi and around 70% of such calculi are reported to be distal ureteral calculi.[13]

The symptoms of urinary tract calculi may include blood in urine, abdominal, flank or groin pain which is severe and colic in nature.[14] The origination of ureteric calculi is kidney and afterwards with effect of gravity or peristalisis, they may be spontaneously be passed into the ureter.[15] Calculi present in the lower ureter seldom cause pain radiating towards testicles or groin in men and labia majora in women. Calculi of intra-mural part of ureter can mimic urinary bladder infection, urethritis or prostatitis leading to supra-pubic discomfort in addition to urinary urgency, increase in frequency of passing urine, pain in urination and blood in urine.[16]

The aim of this study was to determine the role of oral Tamsolin administration in removal of lower ureteric calculi <9 mm in size.

MATERIAL & METHODS

This cross-sectional observational study was done using non-probability convenient sampling technique for a period of 6 months from July 2019 to December 2019. After ethical approval from the Ethical Review Committee of the hospital (ERC/NMH/143/03), a total of 120 patients between were included in the study who attended the outpatient department of the hospital with complains of blood in urine, abdominal, flank or groin pain which is severe and colic in nature and diagnosed as a case of lower ureteric calculi <9mm on ultrasonography. Upper ureteric or kidney calculi above 9 mm, patients already on Tab Tamsolin and patients lost to follow up or not willing to participate in the study were excluded from the research. Written and informed consent was sought from the patients prior to the start of the study. The time period of the study was 4 weeks. Patient were started on treatment with Tab Tamsolin 0.4mg once a day for 30 days and called for follow up after the completion of treatment regimen. Alongside Tamsolin, patients were also advised a non-steroidal anti-inflammatory drug for complain of pain.

SPSS version 23.0 was used for data analysis.

Quantitative data was represented as mean and standard deviation while qualitative data was reported a frequency in percentages.

RESULTS

Among the total of 120 patients included in the study, the age range of patients was 18-50 years of age with a mean age of 35.54 ± 10.20 years. Fifty four (45%) of the patients were between 18-30 years of age, while 38 (32%) were between 31-40 years and 28 (23%) were between 41-50 years of age. 74 (62%) of the study patients were male while 46 (38%) were females [Table-I].

Forty (33%) of the calculi were between sizes 4-5 mm. 48 (40%) of the calculi were between 6 -7 mm while 32 (27%) of the calculi were between 8-9 mm [Figure-1].

After 1 month of follow up, a total of 94 (78%) of the patients were found to have expulsion of the ureteric calculi while in 26 (22%) of patients, calculi were still observed on ultrasonography [Figure-2].

From the total of 30 days, the recorded frequency of calculi expulsion was 94 (78%). Among them, 25 (27%) patients were reported to have expulsion of calculi in between 15 to 19 days. Between 20 to 24 days, a total of 32 (34%) patients reported expulsion of calculi while between 25 to 29 days, a total of 37 (39%) patients reported expulsion of calculi [Figure-3].

All the patients reported satisfactory results with Tamsolusin as well as significant decrease in pain frequency even amongst the patients still observed to have calculi on ultrasonography.

Variable		Frequency	%
Age	18-30	54	45
	31-40	38	32
	41-50	28	23
Gender	Male	74	62
	Female	46	38

Table-I. Baseline demographics of the study patients.

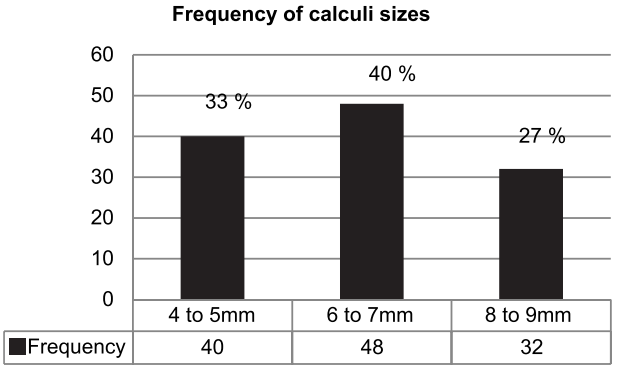

Figure-1. Graphical representation of the frequency of different sizes of calculi.

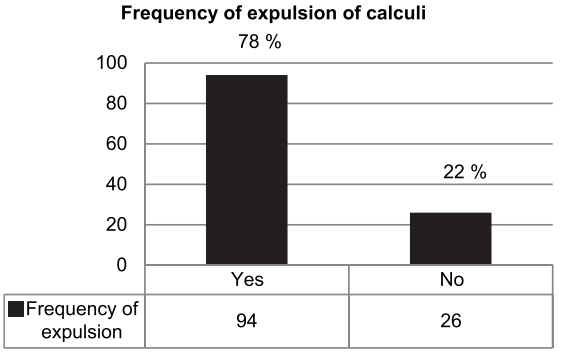

Figure-2. Frequency of expulsion of calculi.

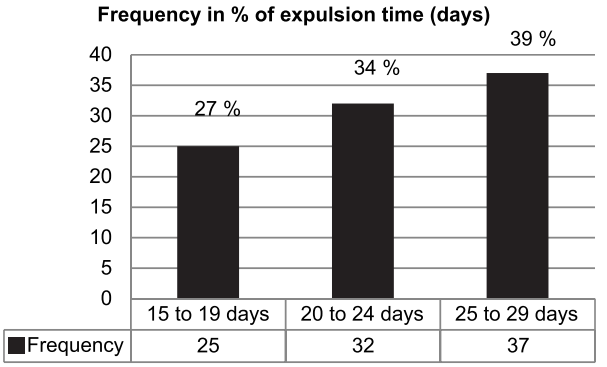

Figure-3. Graphical representation of frequency in percentage of calculi's expulsion time in days.

DISCUSSION

Lately, substantial advancements have been observed with respect to every medical field and so the uses of ESWL and ureteroscopy have become a common procedure for treating ureteric calculi.[17] Nonetheless such procedures have the potential for causing complications. Main reasons for obstructed calculi are related to spasm of the ureteral smooth muscles, edema of mucosa, infection and / or pain. It is reported that medical

therapy with drugs seems to address most if not all of these factors.[18] Multiple drugs have been observed in this regard. Steroids and calcium channel blockers are commonly used for reducing muscular spasm and reduce inflammation.[19] A study reported the use of expulsive medical therapy which consisted of prednisolone and nifidipine in treatment of ureteral calculi as large as 5 cm. The study reported an expulsion rate in spontaneous passage of calculi present in distal ureter in treatment with Doxazosin at a success rate of 71.1% and a reduction in the rate of renal colic was also observed with treatment.[20] Until recently, it has been reported that some specific adreno-receptor subtypes such as α1a / α1d are numerously present in the distal ureters.[21] In a study by Ye Z et al, a successful expulsion rate was noted in calculi removal when using Tamsulosin, an alpha blocker to the standard therapy.[22] In another study a greater effect was observed with Tamsolusin in comparison to phloroglucinol, an anti-spasmodic drug commonly used. They recorded a significantly higher rate of expulsion in the Tamsolusin group, i.e. 97.1% when in comparison to Nifedipine, i.e. 77.1% and 64.3% in the phloroglucinol group.[23] Similar in our study as well, Tamsolusin was reported to have a successful calculi expulsion rate of 78% which is line with several others studies as well. The studies have reported that using Tamsolusin, the calculi expulsion rates were significantly achieved in a shorter period of time and with fewer or no need for hospitalizations. Using Tamsolusin as first line of drug for treating distal ureteral calculi has been advocated. In addition, patients on Tamsolusin have reported lower experiences of pain as compared with Nifedipine along. Another study concluded that Tamsolusin could significantly help in reducing the calculi expulsion time periods.[24]

A study by Kupeli B et al observed Tamsolusin therapy in comparison to ESWL for lower ureteral calculi. A significant difference was reported in terms of calculi free time period with Tamsolusin as compared to the control group. Even in large sized calculi, medical therapy with Tamsolusin was found to be very effective.[25] In a study comparing different medical therapies termed for treating lower ureteric calculi reported that the highest efficacy in expulsion of calculi reported a successful expulsion rate with Tamsolusin group (79.31%) as compared with control group who received nothing (53.57%), in Doxazosin group (75.86%) and Terazosin group (78.57%).[26]

In the current study, the effect of Tamsolusin was determined in treatment of lower ureteric calculi <9 mm. However the study was not compared with other medical therapy regimens which were a lacking in the study. In addition, the study might also not be immune from observer or selection bias and the fact that the study comprised of a single hospital which is a secondary care center having a limited sample size and patients being called for follow up in out-patient department and not admitted since the use of oral medical therapy was utilized. Further, multi-centered studies with greater sample size, comparing different treatment protocols for lower ureteric calculi <9 mm would be enlightening in achieving a treatment regimen that would be easily followed by the patients, and become calculi free in limited possible time.

CONCLUSION

According to the results of the study, Tamsolusin was significantly effective in expulsion of calculi with most calculi reported to be expulsed between 20-29 days of treatment. Patients also reported in significant decrease in pain frequency and were satisfied with treatment with Tamsolusin for lower ureteric calculi < 9mm.

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