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Safety and efficacy of Contiflo OD (Tamsulosin) on catheterized patients treated for acute urinary retention caused by benign prostatic hypertrophy in Ekiti State, Nigeria

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This study aims to assess the safety and efficacy of Contiflo OD (Tamsulosin) on catheterized adults treated for Acute Urinary Retention (AUR) caused by benign prostatic hypertrophy (BPH). In this randomized double blind prospective study, patients that reported at the Accident and Emergency Department of Ekiti State University Teaching Hospital (EKSUTH) with AUR and had successful urethral catheterization were recruited. Those that met the inclusion criteria were assigned to receive Tamsulosin (Contiflo OD) 0.4 mg once daily or no Tamsulosin while on admission for three days (72 h). On removal of catheter, patients were assessed for ability to void spontaneously without difficulty. Results revealed over a period of twenty-four months, hundred men with AUR were randomized to Tamsulosin with catheter (50) or catheter alone (50). Thirty-four men taking Tamsulosin with catheter and 7 on catheter alone were able to void without difficulty and did not require re-catheterization after discharge (68 and 14% respectively), $P<0.05$. Tamsulosin showed a synergetic efficiency of 54%. Patients on Tamsulosin with catheter stayed longer (8 h, 11 min) compared with those on catheter alone (3 h, 19 min) before requiring re-catheterization on failure of TWOC, $P>0.05$ (STD=5.79, 95% CI=1.4-1.9). Sixteen (16) men (32%) of those on Tamsulosin and 9(18%) of those on catheter alone had side effects such as weakness, orthostatic hypotension, decreased libido; a ratio of 2:1; $P>0.05$. Thirty (30) out of 34 men on Tamsulosin (88%) had successful TWOC and did not require re-catheterization over a period of three months. Thus, Contiflo OD can be said to be effective and safe in treating patient with acute urinary retention secondary to BPH and can reduce the chances of recurrence in this environment.

Key words: Acute urinary retention (AUR), benign prostatic hypertrophy (BPH), Contiflo OD

INTRODUCTION

Acute urinary retention (AUR) is defined as a sudden inability to urinate associated with severe discomfort or pain except in patients with a neurological aetiology (Adegun et al., 2011; Herbert, 2005). It is an extremely life threatening and uncomfortable condition which is always a urological emergency requiring urgent and prompt attention.

AUR commonly occurs in men with underlying benign prostatic hypertrophy (BPH); it may also be precipitated by other conditions such as exposure to cold weather, excessive alcohol consumption, or ingestion of certain medications e.g. cholinergic antagonists for depression, Parkinson disease, overactive bladder (OAB) or a-adrenergic agonists for cold remedies (Zeif and

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Subramonian, 2009).

AUR due to BPH should be managed by immediate and complete bladder decompression through urethral catheterization except when there is associated urethral obstruction, in which case, a suprapubic cystostomy may be employed. Failure to decompress the bladder could lead to some untoward events that may result in serious mortality (Agrawal et al., 2009).

After successfully decompressing the bladder, catheter may be removed and some men may continue to void naturally until definitive surgery instituted while others may require re-catheterization. In those whose trial without catheter (TWOC) fails, continued catheterization may be necessary if surgery is not possible immediately. It is to be noted that prolonged catheterization is associated with risks such as infection, discomfort, spontaneous removal and can affect the quality of life (Qol) to mention but a few. It is therefore not palatable to continue with prolonged catheterization (Ikuerowo et al., 2007; Drinka, 2006).

Some authors have reported that men who experience an episode of AUR are at higher risk for subsequent episode, despite a successful TWOC. The likelihood of a second episode of AUR immediately following a TWOC ranges from 38 to 56% (Kadhim et al., 2005; Djava et al., 1998). Any intervention which aims at increasing the rate of a successful TWOC following AUR episode would be considered potentially beneficial (Zeif and Subramonian, 2009; Agrawal et al., 2009).

In recent times various authors have demonstrated TWOC to be successful in men treated with alpha blockers such as Tamsulosin, Alfuzocin and Doxazocin (Adegun et al., 2011; Zeif and Subramonian, 2009; Agrawal et al., 2009; Ikuerowo et al., 2007; Kadhim et al., 2005; Djava et al., 1998; Brain et al., 2008; Lucas et al., 2005; McNeill, 2001; Kin et al., 2001; Padraig et al., 2009). These alpha blockers act by relaxing the smooth muscle in the prostate and the bladder neck through systemic blockade of alpha 1a-adrenergic receptors, thus decreasing the blockage of urine flow (Milani and Djavan, 2005; Altrac, 2006). More importantly, Tamsulosin which is one of the 3rd generation alpha blockers is less associated with cardiovascular side effects. This singular characteristic appears to put Tamsulosin at a higher advantage than other alpha blockers from other generations. However, Tamsulosin is not without some adverse drug reactions such as immunologic reaction due to its sulfa moiety component, and ophthalmologic effect wherefore it is reported to be associated with development of floppy iris syndrome (Kuritzky, 2005). In addition, impotence, decreased libido, ejaculation disorders, dizziness, breast disorders etc, have been reported in various percentages (Kuritzky, 2005).

In Ekiti State of Nigeria, management of AUR secondary to BPH has been by catheterization alone whenever surgery is not possible leaving most of the patients to be on prolonged catheterization with its attendant complications.

This study was designed to prospectively assess the efficacy and safety of Tamsulosin in the management of AUR secondary to BPH in Ekiti State University Teaching Hospital, Ado-Ekiti, Nigeria.

PATIENTS AND METHODS

Over a period of two years (2010-2012), patients presenting in accident and emergency (A&E) Department of Ekiti State University Teaching Hospital (EKSUTH) whose working diagnosis was BPH with acute urinary retention and had successful urethral catheterization were assigned in a randomized double blind fashion to receive Tamsulosin 0.4 mg daily or no Tamsulosin. The blinding was done by an independent observer by putting the code (T) for Tamsulosin and (NT) no Tamsulosin in a sequentially numbered, sealed envelopes deposited in the A&E Department. As soon as the patient met the criteria and had given informed consent to participate, the attending doctor picked one form from the sealed envelopes and administered whatever was in the envelope.

The study number of the patient was written on the envelope which was collected at the end of the study. The patient was admitted and the catheter removed for trial of voiding without catheter (TWOC) after 72 h and the patient observed for 24 h. Those who had successful TWOC were discharged home to continue with Tamsulosin or no Tamsulosin as the case may be and were given outpatient clinic appointment. Patients who had failed TWOC were re-catheterized. Successful TWOC was taken as the ability to void without difficulty or the aid of catheter. There was no adverse event to warrant discontinuation of management.

Patients with initial catheterization volume greater than 1500 ml suggestive of chronic retention and those with features of renal or hepatic dysfunction were excluded from the study. Others excluded were those with evidence of malignancy, severe cardiac disease neurological deficit and those who had taken retention enhancing or precipitating medications and men older than 80 years.

Ethical approval was obtained from Ekiti State University Teaching Hospital Research Ethical Committee.

Data extraction and management

For proper data extraction and management, a case report form (CRF) was filled for each patient. The CRF was collected and kept in a safe place. All the data of individual patient were entered into a screening log as collated and dated. Blinding was opened at the conclusion of the study. The number of men with recurrent AUR and the time taken to require re-catheterization were recorded. Patient with missing data were excluded. All patients were analyzed based on the intent-to-treat analysis.

Data analysis

Various cases from 'Case Report Form' was cross-tabulated with one another and corresponding to patients social demography characters, to see if there were association, hence R-Square test was employed to ascertain their level of association.

Frequencies analysis approach was employed for some variables, where pie or bar-chart was plotted to see the distribution of the outcomes of the study.

T test was used to analyze continuous variables while chi square (X^2) test was employed for categorical variables. P value less than 0.005 ($p<0.05$) was taken as statistically significant.

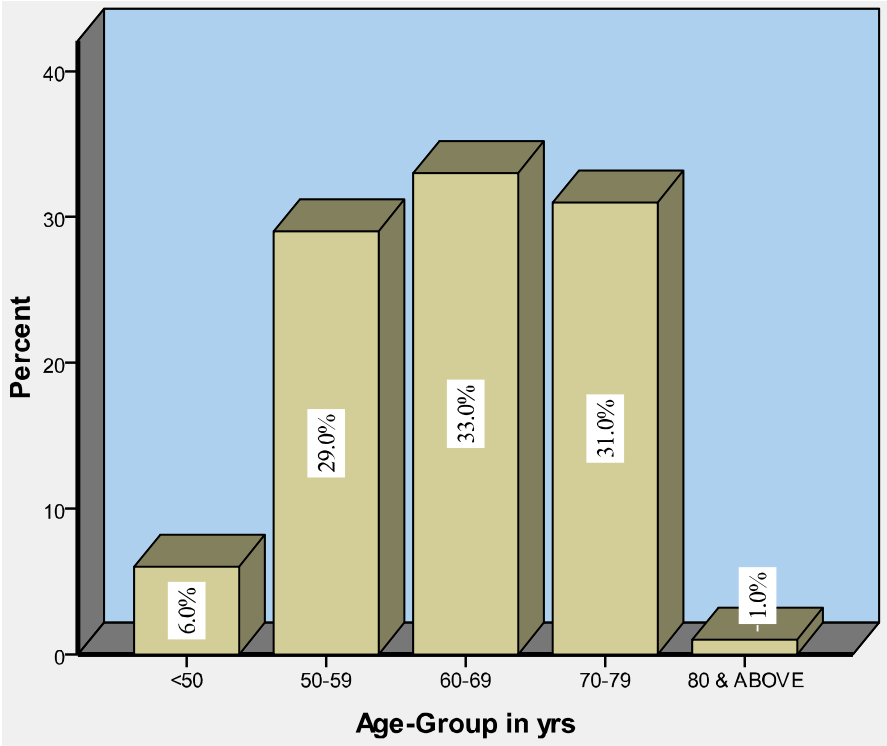

Figure 1. Age distribution of men with AUR.

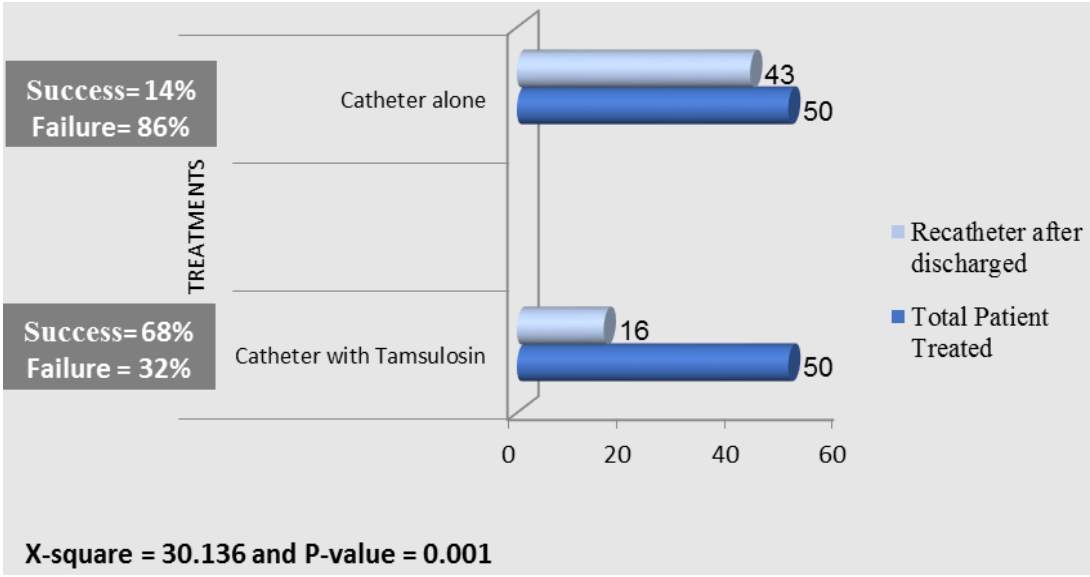

Figure 2. Outcome of treatment after 72 h.

RESULTS

Between the period of October 2010 and September 2012, a total of 100 patients with AUR who were successfully catheterized were seen in Ekiti State University Teaching Hospital, Ado-Ekiti, Nigeria. Figure 1 shows the age distribution of men with AUR. Figure 2 shows the outcome of treatment after 72 h. In the group

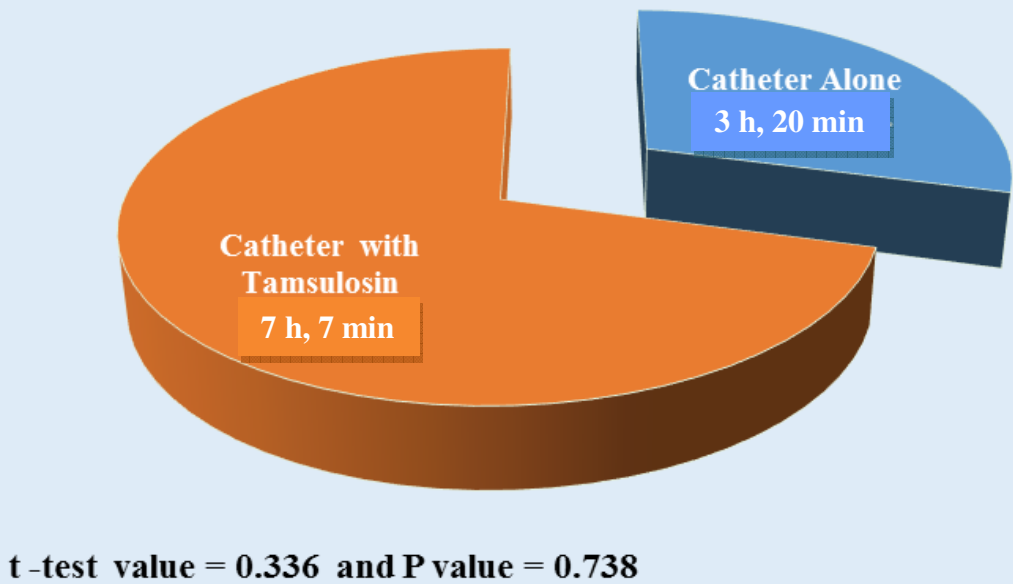

Figure 3. Average time interval between removal of catheter and re-catheterization in patients managed with catheter alone and those managed with catheter and Tamsulosin.

that had catheter alone, 43(86%) were re-catheterized after removal of catheter within 72 h. While 16(32%) men needed recatheterization in the group that had catheter and Tamsulosin combined. This effect was statistically significant with a P value of <0.05.

The total time interval between removal and catheterization for patients that required re-catheterization was 137.15 h with a mean time interval of 3.19 h (Figure 3).

In the group that had catheter and Tamsulosin, the total time interval was 123.40 h with a mean time interval of 7.71 h. The difference between the mean time interval between the two group was however not statistically significant, P value was >0.05 with (STD=5.79, 95% CI=1.4-1.9).

The side effects recorded in patients treated with catheter and Tamsulosin combined and catheter only was represented in a bar chart (Figure 4). The difference in side effects was not statistically significant, P>0.05. Also, patients that had Tamsulosin showed different types of side effects. Out of the 50 patients that had Tamsulosin and catheter, 16(32%) had side effects (Figure 5).

Out of the 34 patients treated successfully initially, 4(11.8%) came back for re-catheterization, while 30(88.2%) patients did not come for re-catheterization (Figure 6).

DISCUSSION

Acute Urinary Retention (AUR) is a common urological emergency characterized by a sudden and painful inability to pass urine (Adegun et al., 2011; Herbert, 2005). The incidence of AUR due to BPH has been reported to vary from 0.4 to 25% making this clinical condition of serious global concern.

This study has demonstrated that AUR is commonest at the age range of 60 to 79 years where the percentage was 64%. This may be due to the fact that BPH is also found to be commonest at this age range in this environment as reported in our earlier study on survey of BPH amongst patients with prostatic disorders in Ado-Ekiti, Nigeria (Adegun and Popoola, 2011).

Immediate bladder decompression by catheterization is the recommended mode of treatment to prevent any casualty before a definitive surgery is instituted. In the past, subsequent management consisted of emergency prostatectomy with its attendant complications (Fitzpatrick and Kirby, 2006). Even then, emergency prostatectomy was a big issue in many developing countries, especially in Ekiti, Nigeria due to the dearth of specialist.

However, the sympathetic nervous system has been discovered to play a significant role in the myogenic tone of the bladder outlet which is partly responsible for urinary outflow resistance. Therefore, the introduction of alpha (1)-adrenoceptor antagonists has revolutionized the management of BPH-induced AUR (Milani and Djavan, 2005; Altrac, 2006).

Amongst the alpha (1)-adrenoceptor antagonists, Tamsulosin and Alfuzosin tend to demonstrate high selectivity for the prostate and bladder. While others have been reported to be associated with high risk of postural hypotension, Tamsulosin has low risk which was also

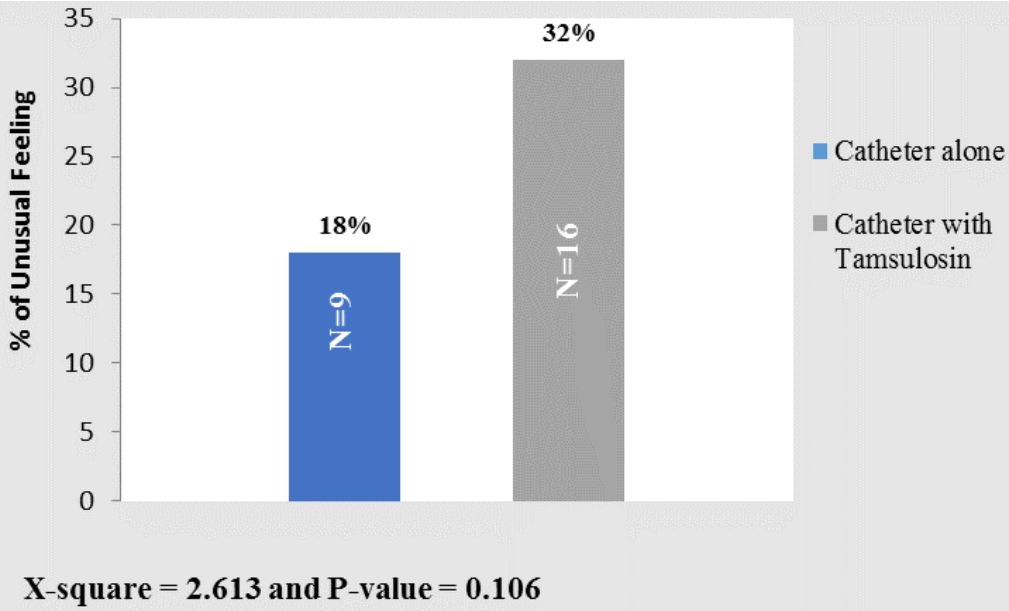

Figure 4. Bar chart showing the side effects recorded in patients treated with catheter and Tamsulosin combined and catheter only. There was no statistically significant (P>0.05) difference in side effects observed.

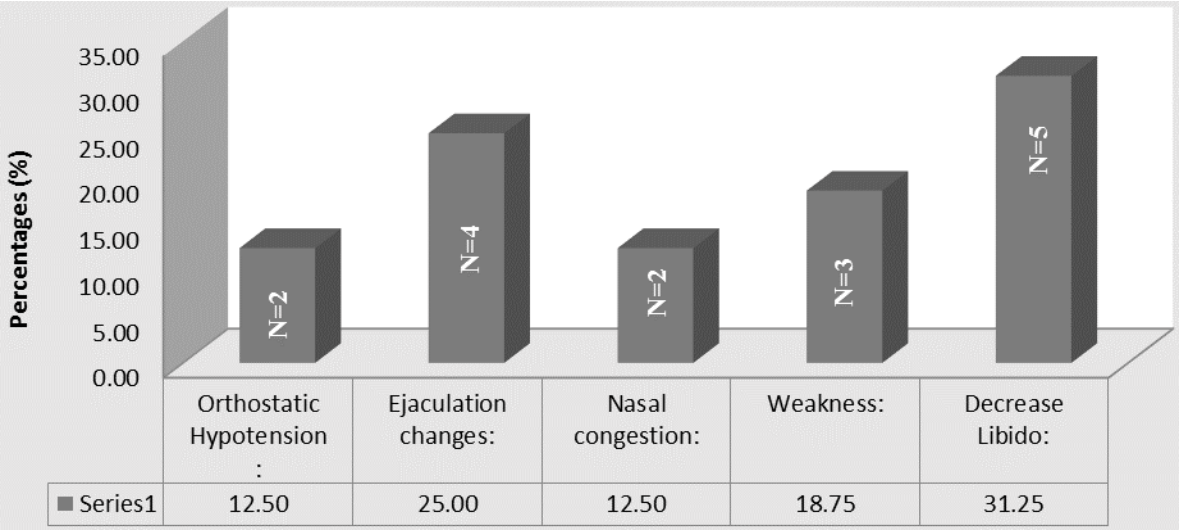

Figure 5. Distribution of types of side effects in patients that had Tamsulosin.

demonstrated in this study (Kuritzky, 2005). In addition, the side effects such as orthostatic hypotension, ejaculation changes, and weakness were not sufficiently disturbing to warrant discontinuation of treatment.

Furthermore, the high success rate of TWOC recorded in this study following the use of Tamsulosin is in agreement with the study of Agrawal et al. (2009). However, the fact that all the patients did not respond to this management is an indication that a lot of work is still required to improve the efficacy of this drug for general acceptability in future because any drug that can improve the efficacy to 90% will surely be considered superior.

Nonetheless, the higher time interval required for re-catheterization in those that had Tamsulosin may help in reducing urethral injury as a result of decreased urethral edema following the initial attempt. However, the report in

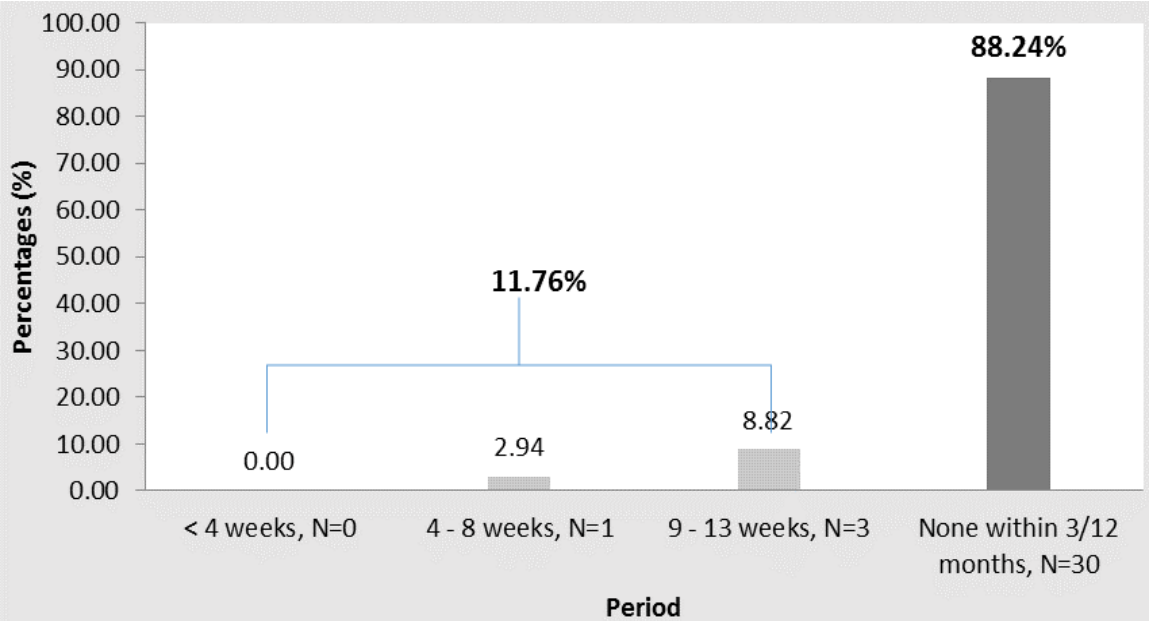

Figure 6. Period of re-catheterization after stoppage of Tamsulosin within three months in those with successful TWOC.

this study was not significant probably because of limited sample size.

The success rate of TWOC of 14% in using catheter alone still gives hope that this form of management may not be totally discarded especially for those in the rural areas who may not have access to Tamsulosin immediately. Besides, the obstruction in this group may be mechanical rather than dynamic and may never respond to Tamsulosin. However, repeated catheterization should be discouraged because the inherent potential urethral injury may predispose to urinary tract infection or urethral stricture (Ikuerowo et al., 2007). It is therefore advisable to consider immediate surgery once there is recurrence.

This study has further demonstrated that in patients who responded to Tamsulosin, there is higher efficacy even for about three months as only few patients suffered recurrence. The economic implication and quality of life (QoL) to these patients may have been enhanced (Okeke, 2006).

Besides, the time gained in successful TWOC may be sufficient to prepare patients adequately for safe surgery, especially in the developed world, where fund or other logistics may be a challenge. This may also contribute to reducing morbidity and mortality associated with immediate prostatectomy in this environment.

Conclusion

This study has demonstrated that Tamsulosin (Contiflo OD) is efficacious in the management of BPH induced AUR in this environment and that it is safe to use the drug as there were very few but non-significant side effects. This study, to the best of our knowledge, is one of the few prospective randomized study on TWOC in AUR in this environment especially using Contiflo OD.

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