A Clinical Study of Saw Palmetto Barry for its Effects on Maximum (Peak) Flow Rate of Uroflowmetry in the Patients of Benign Prostatic Hypertrophy (BPH)

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Benign prostatic hypertrophy (BPH). The most common benign tumour in men, is responsible for urinary symptoms in the majority of men older than 50 years of age. It affects economically and quality of life. BPH is not a fatal disease. But it affects quality of life and has repercussions on individual, social and economic lives. Untreated BPH may give many complications like acute urinary retention, urinary tract infections, vesical calculus, bladder decompensation, bladder diverticulum formations, chronic renal failure, acute renal failure, bladder outlet obstruction. Apart from it BPH may result in reduction in sexual ability, painful orgasm and impotency. In this clinical study saw palmetto berry, a herbal drug which was used as a 85% fatty acid extract in the form of prepared marketed soft gel capsule (PROSTONIL) for the patients of symptoms of BPH. The study was conducted in Ajmal Khan Tibbia College & Hospital, AMU, Aligarh, on fifty patients. Pre and post-treatment patients were evaluated for maximum (peak) flow rate which was measured by uroflowmetry after giving three months duration of phytotherapy, patients were again evaluated for maximum (peak) flow rate of uroflowmetry. After completion of the follow up, the study showed no improvement in maximum (peak) flow rate of uroflowmetry also with no improvement in the symptoms of benign prostatic hypertrophy.

Keywords: Saw Palmetto Berry, Maximum flow rate, Peak flow rate, Uroflowmetry, Benign Prostatic Hypertrophy, BPH.
Introduction

Benign prostatic hypertrophy (BPH). The most common benign tumour in men, is responsible for urinary symptoms in the majority of men older than 50 years of age. It affects economically and quality of life. BPH is not a fatal disease. But it affects quality of life and has repercussions on individual, social and economic lives. Untreated BPH may give many complications like acute urinary retention, urinary tract infections, vesical calculus, bladder decompensation, bladder diverticulum formations, chronic renal failure, acute renal failure, bladder outlet obstruction, apart from it, BPH may result in reduction in sexual ability, painful orgasm and impotency.

Uroflowmetry is used to investigate possible bladder outlet obstruction and can also give a guide to detrusor contractility, to draw a meaningful interpretation of uroflowmetry, voided volume should be above 150 ml. in uroflowmetry most important and diagnostic measurement is maximum (peak) flow rate. It indicates severity of obstruction when maximum flow rate is below 10ml/sec. it indicates severe obstruction and the patient has infra-vesical obstruction and no further urodynamic study is needed. When maximum (peak) flow rate is between (10-15) ml/sec. It has equivocal value. There may or may not be obstruction. When max flow rate in excess of 15 ml/ sec. generally there is no obstruction. There are many herbs or herbal extracts other than saw palmetto berry which have been used for the treatment of BPH. Saw palmetto berry is the fruit of dwarf palm tree which is native and plentiful along the atlantic shores from Florida to South Carolina.

Saw palmetto berry is claimed to have the following properties.

* Inhibition of 5-α reductase.
* Inhibition of DHT binding to androgen receptors.
* Inhibition of 17 beta hydroxysteroid dehydrogenase.
* Anti estrogenic and anti androgenic activities.
* Reduction of growth factors induced prostatic growth.
* General reduction of edema and anti-inflammatory.

Materials And Methods

At the initial visit of the patients, a detailed medical history with special emphasis on history of urinary symptoms (frequency, nocturia, urgency, hesitancy, straining and sensation of incomplete voiding) was obtained from all patients. All the patients underwent a thorough systemic examination, which was followed by digital rectal examination to determine the prostate size, presence of nodules, smoothness of surface and
tenderness, Pre treatment, routine Haemogram, biochemical blood tests (Hb, TLC, DLC, ESR, Blood Sugar random), urine for routine and microscopic examination, Renal function tests including blood urea and serum creatinine and serum PSA, American urological association score index (AUASI), Uroflowmetry for maximum (peak) flow rate, Ultrasound for lower abdomen were done. The patients with diabetes mellitus, carcinoma of prostate and urinary bladder, urethral stricture, vesical calculus, Neurogenic bladder were excluded from the study. Urethral stricture and Neurogenic bladder were excluded by doing simple x-ray (uretherography), MRI (brain, spine) and urethral Electromyography (EMG) if the patients given associated history and clinical findings from the clinical examination. In this study, saw palmetto berry extract in the form of prepared (marketed) soft gel capsule (PROSTONIL) the capsule contains 320 mg saw palmetto extract standardized to 85% fatty acid, once daily for three months was used.the study was done on the patients of benign prostatic hypertrophy over the age of 45 years for its effects on maximum (peak) flow rate of uroflowmetry. This study was conducted on fifty patients in the Department of Jaraht, Ajmal Khan Tibbia College & Hospital, AMU, Aligarh, India.

Patients prior to giving therapy were assessed for maximum (peak) flow rate of uroflowmetry after completion of three months duration of phytotherapy they were again assessed for maximum (peak) flow rate of uroflowmetry.

Statistical Method

All the data obtained were subjected to statistical analysis to find mean value, standard deviation and p and t values by paired – t-test.

Results

Mean maximum (peak) flow rate (ml/s) of pre-treatment patients was 10.1±7.7 that was decreased to 8.3±4.8 in post treatment patients and the mean and SD of difference was 1.9±5.2.

There is a significant difference between pre-treatment and treatment patients t = 2.6, p<.05

Discussion

In our study of the role of saw palmetto for its effect on maximum (peak) flow rate of uroflowmetry in the patients of benign prostatic hypertrophy, Pre-treatment maximum (peak) flow rate (uroflowmetry)
was 10.1±7.7 (ml/s) that was decreased to 8.3±4.8 (ml/s) in post-treatment patients. In other studies of role of saw palmetto for treatment in the patients of benign prostatic hypertrophy. Where there was increase in post treatment, maximum (peak) flow rate.

Pre-treatment and post treatment maximum (peak) flow rates that were increased are as follows:

From 9.6 cc/s to 13.7 cc/s, Boccafoschi and Annoscia, et al 1983\(^4\), from 10.3 cc/s to 13.7 cc/s, Emili et al., 1984\(^5\) from 10.7 cc/s to 16.1 cc/s, Champault et al., 1983\(^6\) from 12.9 ml/sec to 16.2 ml/sec, Tasca et al., 1985\(^7\) from 6.7 cc/s to 9.7 cc/s Carbin et al., 1990\(^8\) from 5.2 cc/s to 7.7 cc/s, Romics et al., 1993\(^9\). From 9.8 to 12.2 cc/sec, Braeckman et al., 1994\(^5\) From 10.6 ml/sec to 13.3 ml/sec Carraro et al., 1996\(^10\) from 6.2 ml/sec to 8.5 ml/sec, Reese Smith et al., 1986\(^11\) Q\(_{\max}\) increased by 4.13±0.51 ml/s on average, Aliaevlu et al., 2002\(^1\) urinary flow increased by 19% (P<0.001), Nikolai Lopatkin et al., 2007\(^12\) increased by 14.07±2.56 (treatment group) versus 11.74±1.23 (placebo group) ml per second, p<0.001) Rong Shi et al., 2008\(^13\).

The studies showing the role of saw palmetto in the treatment of benign prostatic hypertrophy that had decreased or did a non-significant increase in maximum flow rate (uroflowmetry) in post-treatment patients. pre-treatment and post treatment maximum (peak) flow rates (uroflowmetry), the values that were decreased or there was non-significant increase in values are as follows:

From 13.7 to 13.0 Gerber et al., 1998\(^14\), from 11.2±0.8, to 11.8±0.7 Harry et al., 2001\(^15\) from 11.1 ml/s to 12.6 ml/s. Willets et al., 2003\(^16\) from 11.4 ml/sec to mean±SE change, 0.42±.34 ml per minute 95 percent confidence interval, –0.25 to 1.10, Bent Stephen et al., 2006\(^2\).

That above mentioned study in which maximum flow (peak) rate (ml/s) was decreased in post treatment patients is in confirmation of our study.

**TABLE**

Mean Maximum Flow Rate (ml/s) in Pre-treatment and Post-Treatment Patients

<table>
<thead>
<tr>
<th>Uroflowmetry</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>Difference</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean maximum (peak) flow rate (ml/s)</td>
<td>10.1±7.7</td>
<td>8.3±4.8</td>
<td>1.9±5.2</td>
<td>2.6</td>
<td>&lt;.05</td>
</tr>
</tbody>
</table>
Conclusion

In our study the sample size was small and the study was also an open and uncontrolled type. To draw a comprehensive conclusion, the larger sample size and double blind controlled studies are needed.

Hence, in our study it may be concluded that saw palmetto berry extract did not increase the maximum (peak) flow rate of uroflowmetry which would lessen the symptoms in the patients of benign prostatic hypertrophy.

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REFERENCES


