The therapeutic effects of *Pygeum africanum* for the management of benign prostate hyperplasia condition in dogs

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1. Abstract

The herbal agent *Pygeum africanum* is used to treat benign prostatic hyperplasia (BPH) through the inhibition of the proliferation of prostate stromal cells from BPH tissues. The present investigation sought to examine the effect of *Pygeum africanum* on testosterone-induced hyperplasia of the prostate in a dog model. A total of six sexually mature Egyptian baladi dogs (age:2-4 years old; weight: 20-25 kg) were used. Animals were subdivided into 2 equal groups: the Control group, which continued to receive the same diet without treatment until the end of the study, and the BPH group, which received Testosterone (75 mg/dog) and Estradiol Benzoate (0.75 mg/dog) via intramuscular injection on days 0, 21, 42, and 63 of the induction period. The testosterone doses were doubled on days 21, 42, and 63. The same animals, after induction (*n=3*), were used as the *Pygeum africanum*-treated group. These BPH dogs received 100 mg\dog\daily of *Pygeum africanum* extract to treat BPH for 30 days. Prostate volume, and prostatic artery Doppler parameters including peak systolic velocity (PSV), end-diastolic velocity (EDV), resistance index (RI), and pulsatility index (PI) were measured at days 0 (the day of the first injection), 63 (after induction of BPH), and 30 days after treatments of *Pygeum africanum*. Blood samples were collected on days 0 and 63 during the induction period and after 30 days of treatment. Serum testosterone (T) and prostate-specific antigen (PSA) were assayed. The results showed that the BPH group significantly ($P < 0.05$) increased prostate volume and Doppler parameters (PI, PSV, and EDV). *Pygeum africanum* reversed these results. PSA levels significantly ($P < 0.05$) increased in the BPH group compared to controls, but decreased in the treated group, while testosterone levels dropped significantly ($P < 0.05$) in the BPH group compared to the control group, with no significant difference from the treated group.

Key words: Benign prostatic hyperplasia, *Pygeum africanum*, PSA, Ultrasound, Dogs.

2. Introduction

The Egyptian Baladi dog is a native street dog and ranks among the most prevalent breeds in Egypt [1]. Baladi dogs are mixed-breed canines that originated from a combination of Pharaoh hounds, Salukis, and Canaan dogs, and have interbred with additional breeds [2]. Benign prostatic hyperplasia (BPH) is recognized as the most prevalent prostatic disorder in dogs [3]. While it predominantly occurs in unneutered male dogs over five years of age, it can sometimes be observed in younger breeding males [4]. The exact cause of BPH is still inadequately understood. It is

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recognized that the primary cause is a hormonal imbalance between testosterone and estrogen due to aging. This imbalance is characterized by reduced androgen levels and increased estrogen levels, which disrupts endocrine homeostasis [5]. This leads to a heightened density of androgen receptors in the prostate, enhancing the effects of testosterone. This imbalance significantly enhances the conversion of testosterone to dihydrotestosterone (DHT) through the enzyme 5α-reductase [6]. Elevated DHT levels induce several prostatic changes, including glandular cell enlargement, hyperplasia, angiogenesis, and localized oxidative stress observed in dogs [7].

The hormonal and structural changes caused by BPH significantly impact reproductive health. Canines with BPH frequently display reduced sperm quality due to hormonal imbalances, particularly altered testosterone and estrogen levels, which disturb normal sperm production and maturation. Additionally, BPH induces oxidative stress and changes the composition of prostatic fluid, such as reduced zinc and altered osmolarity, creating a harmful environment for sperm. These factors collectively lead to decreased sperm motility, a higher proportion of morphologically abnormal sperm, and compromised sperm DNA integrity by damaging sperm membranes, impairing mitochondrial function, and increasing DNA fragmentation, ultimately resulting in poorer sperm quality [8,9].

BPH is recognized histologically by nodular proliferation of both epithelial and fibromuscular tissues primarily in the transition zone and periurethral areas of the prostate gland. Multiple pleiotropic processes are involved in the remodeling of prostatic tissue; nevertheless, the pathophysiology of BPH is still not fully understood [10]. The morphometric predominance of fibromuscular stroma suggests that is mostly due to fibrotic changes and an overabundance of prostate stromal cell (PSC) hyperproliferation. Myofibroblasts contribute to the reactive stroma of BPH, associated with alterations in cytokines, growth factors, and extracellular matrix constituents [11]. A chronic inflammatory condition can lead to tissue damage, stimulate cytokine release, increase growth factor levels, and commence a local harmful cycle. Proinflammatory cytokines play a crucial role in the pathogenesis of chronic inflammation linked to BPH [12]. Thus, alleviating inflammation has been suggested as a method for addressing BPH [13].

Pygeum africanum (syn. Prunus africana (Hook. f.) Kalman), known as the African cherry, is a member of the Rosaceae family and is an evergreen species found throughout Africa. The bark has been utilized for its medicinal properties. *Pygeum* bark contains fat-soluble sterols and fatty acids as its primary active components, including phytosterols like beta-sitosterol. These phytosterols possess anti-inflammatory properties that effectively inhibit the formation of pro-inflammatory prostaglandins in the prostate gland [14]. *Pygeum* bark comprises pentacyclic triterpenes, ferulic acid, n-docosanol, and tetracosanol, which contribute to the reduction of prolactin levels and the inhibition of cholesterol synthesis in the prostate. *Pygeum* extracts standardized to 13%–14% phytosterols have been extensively examined in animal research and human clinical trials [10].

P. africanum bark extract (PABE) demonstrates notable biological properties, including the inhibition of leukotriene chemotactic activity, suppression of growth factors (basic

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fibroblast growth factor [bFGF]), reduction of fibroblast proliferation, improvement of prostatic histology, inhibition of prostatic myofibroblast and fibroblast proliferation, and restoration of secretory activity in prostatic and bulbourethral epithelium [15, 16].

The oral administration of *pygeum* mitigates symptoms of benign prostatic hyperplasia (BPH), such as reduced urine flow and partial bladder emptying after urination [17]. Therefore, the present study sought to assess the therapeutic efficacy of *P. africanum* in managing benign prostatic hyperplasia (BPH) in canines.

3. Materials and Methods

3. 1. Animal Ethics

The animals used during the experiment were handled following the Institutional Animal Care and Use Committee (IACUC) of Animal Reproduction Research Institute (Approval No: Vet CU 2125)

3. 2. Animals and Management

The present study was conducted at Faculty of Veterinary Medicine, Cairo University, Egypt (latitude 30°01″ N; longitude 31° 21′ E) from October 2023 to January 2024. Six sexually mature Egyptian baladi male dogs (n=6), aged 2-4 years and weighing 20-25 kg. Throughout the trial, all animals were accommodated in enclosures with concrete flooring and an outside, sheltered area that protected them from direct sunlight. The dogs were provided commercial dry meals once daily and had unrestricted access to water throughout the day. One pill of praziquantel and pyrantel pamoate (10 kg/body weight) was administered as an anti-parasitic agent during the first two weeks of preparation (Prazitab®).

3.3. Experimental design

The subjects were categorized into two equivalent cohorts: the Control group (n = 3), which maintained the dog on a consistent diet throughout the research, and the BPH group (n = 3).

The experiment was structured into two sequential phases (Figure 1): Phase 1 is a 63-day BPH induction period succeeded by a one-month treatment phase. on days 0, 21, 42, and 63 of the induction periods (day 0 being the initial hormone injection). The testosterone dosages were doubled on days 21, 42, and 63 [18]. The generated benign prostatic hyperplasia has been validated using prostate volume assessment via B-mode ultrasonography. The produced BPH has been corroborated using prostate volume evaluation utilizing B-mode ultrasonography. Phase 2 utilized BPH experimental dogs (n=3) for the *P. africanum* treatment groups. A dog afflicted with BPH received 100 mg of *P. africanum* extract orally (Prostacure®: 2 capsules daily, OCTOBER PHARMA S. A. E.) for 30 days to treat BPH [19]. However, the control group (n=3) received no herbal extract treatment.

3.4. Ultrasonography examination

A 7.5 MHz transducer (EXAGO, France) was employed for the trans-abdominal ultrasonographic evaluation of the prostate on day 63 of the induction phase and 30 days after the treatment. All machine parameters, including focal depth and gain, were calibrated during the initial test to enhance image quality. These configurations were employed for all subsequent trials. Each dog was positioned in dorsal recumbency and evaluated without sedation [20, 21]. Following cleansing, the hair on the prepuce was clipped and shaved on both sides, and coupling gel was applied to the skin to enhance contact. The transducer

was positioned on the abdominal wall adjacent to the prepuce to obtain longitudinal and transverse pictures of the prostate [22].

Sagittal and transverse images (Figure 2) were utilized to evaluate the required parameters prior to and during the administration of lemongrass oil treatment. The bladder served as a metric for evaluating prostate volume (PV), employing width measurements in the axial plane and height and length measurements in the sagittal plane [23]. Sagittal imaging was employed to ascertain the prostate's length, defined as the maximum diameter of the gland along the urethral axis; both transverse and sagittal images were applied to assess the prostate's height, evaluated as the diameter along a line bisecting the gland's two lobes. Transverse imaging was employed to evaluate the prostate's width, characterized as the maximum diameter perpendicular to the height axis. The primary method for evaluating prostate size entails calculating the maximum total prostatic width through the elliptical volume formula: Volume = length × width × height × 0.523 [24].

3.5. Blood sampling and biochemical assays

Blood samples were obtained from the cephalic vein into standard glass tubes on days 0 and 63 prior to hormone delivery, during the induction period, and 30 days post-treatment. Blood serum was extracted by centrifuging blood samples at 3000 rpm for 10 minutes. Upon completion of the experiment, serum samples were stored at -20°C. Serum testosterone (T) was measured utilizing commercial ELISA kits (DiaSino Laboratories Co., Ltd., Zhengzhou, China) in accordance with the manufacturer's guidelines. The intra-assay and inter-assay coefficients of variation were 3.3% and 4.8%, respectively. The sensitivity of the test was 0.05 ng/ml. Prostate-specific antigen (PSA) levels were measured using an enzyme immunoassay competition method, resulting in fluorescence detection by ELFA (VIDAS® Total Prostate Specific Antigen (TPSA) kits, bioMérieux, France). The PSA kit exhibited a sensitivity of less than 4.0 ng/ml.

3.6. Statistical analysis

Statistical analysis was performed using GraphPad Prism 5. To evaluate the effectiveness of BPH induction, comparisons were made between the control group (n-3) and the BPH-induced group (n=3) by using an independent t-test. To assess the treatment effect, measurements from the BPH-induced group before and after treatment (n=3) were compared by applying a paired t-test. A P value below 0.05 was considered statistically significant.

4. Results

4.1. Effect on prostatic volume

Data presented in Table 1 shows the changes in the volume of a dog's prostate gland using B-mode ultrasonography. A statistically significant ($P<0.05$) difference was observed between the groups in prostatic volume. An increase in prostatic volume was noticed, where maximum volume appeared after 63 days in the BPH-affected group compared to the *africanum*-treated control group (Table 1). In addition, the prostatic volume in the P. *africanum*-treated group was significantly ($P<0.05$) less than that in the control one (Table 2).

4.2. Effect on prostatic volume

There was no significant difference in Resistive Index (RI) between the groups. However, PI, END and PSV were significantly ($P<0.05$) higher in the BPH group compared to the control group

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(Table 3). On the other hand, the treatment with *P. africanum* increased EDV and PSV significantly (P<0.05) than those obtained in the untreated BPH-induced group (Table 4).

4.3. Effect on testosterone and PSA level

PSA showed a statistically significant (P<0.05) increase in the BPH group compared to the control one (Table 5). Moreover, PSA decreased significantly (P<0.05) in the *P. africum-treated* group compared to the BPH group (Table 6). Testosterone levels showed a significant (P<0.05) decrease in the BPH group compared to the control group (Table 7). On the other hand, there was no significant difference in testosterone levels between the *P. africanum*-treated group and the BPH group (Table 8).

5. Discussion

The findings of the present study reveal that *P. africanum* extract significantly attenuates key pathological markers associated with benign prostatic hyperplasia (BPH) in testosterone-induced dogs. These results are consistent with and expand upon previous studies evaluating phytotherapeutic agents for the management of BPH in canine models.

In the current study, treatment with *P. africanum* resulted in a significant reduction in prostate volume after BPH induction. These findings align with those of Carbin *et al.* [25] and Andro and Riffaud [26], who reported that *P. africanum* extract reduced prostate size and improved lower urinary tract symptoms (LUTS) in dogs and human subjects, respectively. The observed reduction in prostate volume may be attributed to the anti-proliferative effects of phytosterols such as beta-sitosterol, which inhibit fibroblast proliferation and androgen-mediated growth pathways [27].

The function of beta-sitosterol in the prevention and treatment of BPH has been examined in both tissue cultures and clinical trials; however, there is a paucity of research about its involvement in prostate cancer. Beta-sitosterol was shown to suppress the proliferation of LNCaP cells and cause apoptosis via the activation of the sphingomyelin cycle. Beta-sitosterol was also reported to impede the proliferation and dispersion of PC-3 cells both in vitro and in vivo [28]. Cambronero *et al*. [29] observed that a 6-month therapy with *P. africanum* considerably improved quality of life and lower urinary tract symptoms in individuals with benign prostatic hyperplasia, resulting in high satisfaction and compliance, without adverse effects. Furthermore, Quiles *et al*. [11] proposed that *P. africanum* has antiproliferative and apoptotic effects on proliferative prostate fibroblasts and myofibroblasts. The mechanisms of action include the downregulation of TGFB1 and the suppression of FGF2-specific signaling, which enhances the overall symptoms of BPH.

This study, to our knowledge, is the first investigation of the effects of *P. africanum* on prostatic hemodynamics by Doppler in canines with BPH. The current investigation showed that therapy with *P. africanum* considerably reduced some Doppler measures, including P1, PSV, and EDV, in comparison to the BPH group. According to our findings, the RI, a dependable indicator in human medicine for distinguishing between BPH and healthy individuals, is ineffective for diagnosing BPH in canines, as corroborated by the studies of Günzel-Apel *et al.* [30] and Polisca *et al.* [31].

A significant decrease in serum prostate-specific antigen (PSA) levels

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after *P. africanum* treatment is consistent with the findings of Cai *et al*. [32], who reported reduced PSA levels in BPH models and clinical trials using phytotherapy. PSA is a sensitive marker for prostatic inflammation and secretory activity; thus, its reduction indicates an alleviation of hyperplastic and inflammatory states in the prostate.

The unchanged serum testosterone levels between the BPH and treated groups in this study reflect findings by Nicholson and Ricke [33], who observed that while hormonal induction of BPH lowers endogenous testosterone due to feedback inhibition, phytotherapeutic intervention does not significantly restore systemic androgen levels.

This suggests that *P. africanum* primarily exerts its effects locally at the prostatic level, rather than altering systemic hormonal regulation.

Compared to other herbal treatments such as Sabal serrulata extract [34] and Serenoa repens (saw palmetto) [35], they have also demonstrated efficacy in reducing prostate volume and improving urine flow in dogs and humans. *P. africanum* offers a complementary mechanism of action by targeting both inflammatory and fibromuscular proliferation pathways. This suggested that combining multiple phytosterol-rich herbs could offer synergistic benefits in BPH therapy.

While previous studies have mostly focused on human subjects or rodent models, the use of a canine BPH model in this study offers a more clinically relevant insight for veterinary applications. Canine BPH shares many pathophysiological and hormonal similarities with human BPH, making it a valuable translational model [36].

A limitation of the present study is the absence of continuous monitoring and assessment throughout the treatment phase. Although key parameters were evaluated before and after treatment, incorporating more frequent assessments during this phase would provide a clearer understanding of the therapeutic response dynamics. Acknowledging this is essential, and future research should include regular monitoring to better understand the progression and effectiveness of the intervention.

6. Conclusions

In conclusion, the current study demonstrates that *P. africanum* is an effective therapeutic agent for managing BPH in dogs. Its efficacy in reducing prostate size, improving vascular function, and lowering PSA without altering systemic testosterone highlights its potential for safe, non-hormonal treatment.

Conflict of interest: Nothing to declare

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Table (1): Effect of induction of benign prostatic hyperplasia (BPH) on Prostatic volume (Mean ± SEM).

	Control group (n=3)	BPH group (n=3)
Prostatic volume (cm^3)	14.08 ± 0.94^a	38.47 ± 3.9^b

Means with different superscripts (a, b) within the same row were significantly different at P<0.05

Table (2): Effect of *Pygeum africanum on* prostatic volume in dogs treated for benign prostatic hyperplasia (Mean ± SEM).

	BPH-before treatment (n=3)	*BPH-after treatment* (n=3)
Prostatic volume (cm^3)	38.47 ± 3.9^a	17.91 ± 1.18^b

Means with different superscripts (a, b) within the same row were significantly different at P<0.05

Table (3): Effect of induction of benign prostatic hyperplasia (BPH) on serum levels of Prostate Specific Antigen (PSA) (ng/dl) and testosterone (ng/ml) (Mean ± SEM).

	Control group (n=3)	BPH group (n=3)
Testosterone (ng/ml)	3.70 ± 0.23^a	1.56 ± 0.08^b
PSA (ng/dl)	0.005 ± 0.0002^a	0.053 ± 0.0008^b

Means with different superscripts (a, b) within the same row were significantly different at P<0.05

Table (4): Effect of *Pygeum africanum* extract on serum levels of Prostate Specific Antigen (PSA) (ng/dl) and testosterone (ng/ml) (Mean ± SEM).

	BPH-before treatment (n=3)	*BPH-after* treatment (n=3)
Testosterone(ng/ml)	1.56 ± 0.08^a	1.26 ± 0.06^a
PSA (ng/dl)	0.053 ± 0.0008^a	0.024 ± 0.0008^b

Means with different superscripts (a, b) within the same row were significantly different at P<0.05

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Table (5): Effect of induction of benign prostatic hyperplasia (BPH) on prostatic blood flow (Mean ± SEM)

	Control group (n=3)	BPH group (n=3)
PSV	40.65±0.48[a]	63.50±0.96[b]
EDV	6.19±0.33[a]	8.11±0.14[b]
RI	0.85±0.005[a]	0.86±0.003[a]
PI	2.74±0.08[a]	3.28±0.05[b]

Means with different superscripts (a, b) within the same row were significantly different at P<0.05. RI: Resistance Index, PI: Pulsatility Index, PSV: Peak Systolic Velocity, EDV: End-Diastolic

Table (6): Effect of *Pygeum africanum* extract on prostatic blood flow in dogs treated for benign prostatic hyperplasia (BPH) (Mean ± SEM).

Parameter	BPH-before treatment	*BPH after treatment*
PSV	63.50±0.96[a]	43.64±1.1[b]
EDV	8.11±0.14[a]	6.47±0.29[b]
RI	0.86±0.003[a]	0.85±0.008[a]
PI	3.28±0.05[a]	2.67±0.07[b]

Means with different superscripts (a, b) within the same row were significantly different at P<0.05. RI: Resistance Index, PI: Pulsatility Index, PSV: Peak Systolic Velocity, EDV: End-Diastolic

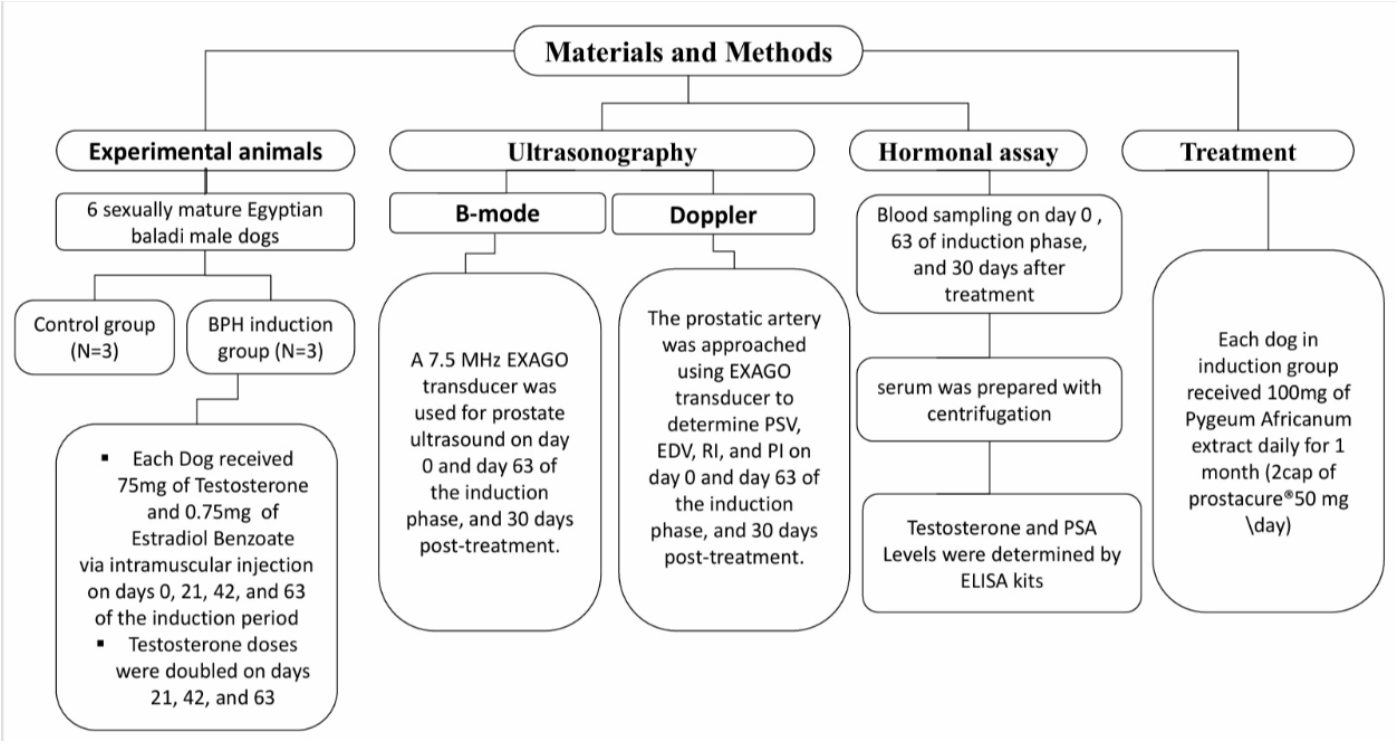
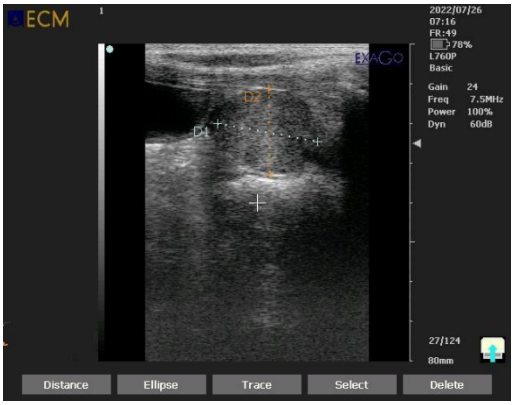
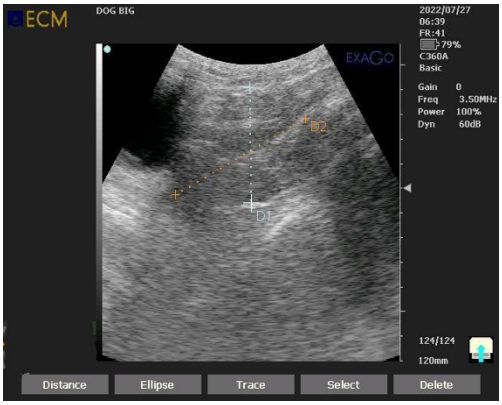


Figure (1): Materials and Methods Process Diagram



Sagittal ultrasonographic image of the prostate that indicates the measured parameters. Parameters: D1 = Length, D2 = Height



Transverse ultrasonographic image of the prostate that indicates the measured parameters. Parameters: D1 = Height, D2 = Depth

Figure (2): Sagittal and transverse images

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