Cheyo *et al. African Journal of Urology* (2026) 32:6
https://doi.org/10.1186/s12301-026-00555-9

African Journal of Urology

RESEARCH Open Access

Randomized comparison of the effectiveness of phytotherapy (Uriphytol) versus Tamsulosin in management of benign prostatic enlargement at Kilimanjaro Christian medical centre: a pilot study

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Abstract

Background Phytotherapy is commonly used in Africa for various health conditions including lower urinary tract symptoms (LUTS) related to benign prostatic enlargement (BPE). However, high-level evidence supporting its effectiveness in BPE remains limited. We compared the effectiveness of Uriphytol, a phytotherapy from *Cucurbita pepo* and *Curcuma longa*, with Tamsulosin in managing benign prostatic enlargement.

Methods This was a 6-months, parallel-designed, randomized, open-label, non-inferiority pilot trial at Kilimanjaro Christian Medical Centre in Tanzania. It included men aged ≥ 40 years with benign prostatic features and prostatic specific antigen (PSA) density less than 0.15ng/mL^2. Participants were block randomized using computer-generated numbers in sealed envelopes into intervention or control arms by a research assistant, receiving either Uriphytol 500 mg three times daily or Tamsulosin 0.4 mg once daily. The primary outcome was the change in the International Prostate Symptom Score (IPSS) with a 3-point non-inferiority margin. Secondary outcomes included changes in post-void residual volume (PVR) and change in International Index of Erectile Function (IIEF-5) score. Analysis of non-inferiority was done by using the fixed-margin (95%-95% method). The trial was registered in Pan African Clinical Trials Registry on 19th April, 2023 with registration number PACTR202304488683045.

Results Between August 2023 and July 2024, 87 participants were recruited (43 in the intervention arm, 44 in the control arm), with 82 completing the study (40 on Uriphytol, 42 on Tamsulosin). Two participants in the intervention and one in the control arm experienced urine retention, and one participant in each arm was lost to follow-up. At the endpoint, there was no significant difference in IPSS reduction, but Uriphytol showed a significant improvement in IPSS-related quality of life (QoL) [Uriphytol vs. Tamsulosin, IPSS: 16.20 ± 7.38 vs. 15.52 ± 5.38, $p = 0.206$; QoL: 5.45 ± 0.99

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vs. 4.81 ± 1.17, $p = 0.0049$]. No significant difference in PVR changes was noted, but erectile function improved significantly in the Uriphytol group ($p = 0.044$).

Conclusion This study has demonstrated that a full-scale prospective non-inferiority randomized clinical trial to determine the effectiveness of phytotherapy versus tamsulosin is feasible in our setting. We found that Uriphytol was not inferior to Tamsulosin in managing BPE, offering better erectile function and quality of life. These findings suggest that Uriphytol could be an alternative to tamsulosin for managing symptoms of BPE.

Keywords Uriphytol, Cucurbita pepo, Curcuma longa, Tamsulosin, LUTS, BPO

1 Background

Lower urinary tract symptoms (LUTS) due to benign prostatic enlargement (BPE) from benign prostate hyperplasia (BPH) are seen in 30%–40% of men in their 40 s, with the prevalence rising to 70–80% in men over 80 years of age [1, 2]. The reported prevalence of BPH in Tanzania is about 60% [2]. BPH is histologically defined by an increase in epithelial and stromal cells in the prostate's periurethral zone [3].

Severe LUTS significantly impairs quality of life in affected individuals [4]. Absent or delayed treatment of bladder outlet obstruction may increase the risk of irreversible changes in the urinary tract that may cause severe complications with a reported prevalence estimated up to 14% in 10 years [5]. Severe LUTS, is also associated with sexual dysfunction, attributed to mechanisms such as reduced nitric oxide availability, adrenergic hyperactivity, pelvic atherosclerosis, and hormonal imbalances [6, 7]. Therefore, assessing sexual function is recommended to guide effective management and enhance patient outcomes [8].

Medical therapy is considered the first-line treatment for men with LUTS due to BPE without imperative indications for surgery, effectively reducing symptom severity, post-void residual volume, and improving urine flow. However, many patients turn to alternative medicine due to the severity of side effects from conventional treatments, including concerns about preserving sexual function [9, 10]. In Africa, the use of traditional therapy has reached up to 80% for general health care needs [11, 12]; among these, phytotherapeutic agents have become increasingly popular in managing urological symptoms including LUTS due to BPE [13]. Their popularity stems from accessibility, acceptance, cost-effectiveness, and cultural beliefs, with perceived fewer adverse effects compared to conventional drugs [12, 13]. However, a huge gap still exists on the therapeutic values of these agents as they are available in different ingredients, with lack of documentation on their effectiveness and safety, which minimizes their credibility in policy-making and incorporation into Primary health care of the community [14].

Common phytotherapies for BPE include, *Serenoa repens* (saw palmetto), *Pygeum africanum*, and steroid intermediates, *Cucurbita pepo*, the oil extracted from pumpkin seeds, with a percent usage of about 14–28% [15]. The proposed mechanisms of action for *C.pepo* include competitive inhibition of dihydrotestosterone binding, inhibition of 5-alpha reductase enzyme, IFN-gamma-mediated anti-inflammatory effects, and uniquely promotes smooth muscle relaxation through nitric oxide (NO) release, a mechanism not observed in other phytotherapies like *Serenoa repens* or *Pygeum africanum* [16]. The combination of *Cucurbita pepo* and *curcumin* may provide dual-action relief of LUTS by targeting hormonal and inflammatory pathways, while improving erectile function which is a key advantage [17]. However, there is scarcity of high-level evidence-based studies on the synergistic role of this combination.

Uriphytol is a standardized extract of *Cucurbita pepo* and *Curcuma longa*. Preclinical studies have demonstrated the biological activity of curcumin in BPH models including suppression of epithelial-mesenchymal transition (EMT), alleviation of hyperplasia and reduction of inflammation. Additionally, clinical studies on pumpkin seed soft extract, a key ingredient of Uriphytol have shown symptomatic relief, improvement of IPSS and quality of life, and maintenance of sexual wellbeing in men with moderate LUTS suggestive of BPH [18, 19].

Clinical studies on the efficacy and safety of these regimes, reveal that majority of them have been providing moderate effect on the relief of symptoms with a low side effect profile and preservation of sexual function when compared to conventional drugs like tamsulosin or finasteride [20]. A recent trial comparing pumpkin seed oil to tamsulosin found both effective, though tamsulosin had more side effects, warranting further research on pumpkin seed oil's therapeutic role [21].

Our hypothesis was that a non-inferiority randomized trial to compare the effectiveness of phytotherapy (Uriphytol) versus Tamsulosin in decreasing the severity of symptoms, improving quality of life, changes in post-void residual and erectile function among patients with benign prostatic enlargement can be conducted with good adherence to protocol in our setting.

2 Materials and methods

2.1 Study design and study population

This was a 6-month, parallel-designed, randomized, open-label, phase 2 non-inferiority pilot trial that was conducted between August 2023 and July 2024 at Kilimanjaro Christian Medical Centre (KCMC), a tertiary hospital of the northern zone of Tanzania. The calculated sample size was 78 participants (at least 38 participants per arm) to attain a power of 80% for clinical relevance. A total of 98 male patients from the age of 40 years, who presented for the first time at the Urology clinic with mild to severe LUTS according to the International prostate symptoms score (IPSS) without an absolute indication for surgery were found and evaluated. Inclusion criteria were the presence of benign features on digital rectal examination of the prostate, prostate specific antigen density (PSAD) of less than 0.15ng/mL/prostate volume (cc) as determined by kidney-ureter-bladder (KUB) ultrasonography, and not being on other forms of treatment for BPE. The study excluded patients with concomitant benign prostate enlargement and uncontrolled Diabetes mellitus, Congestive cardiac disease, urethral stricture disease, cystitis, and patients who were lost to follow up after recruitment. Ethical approval was obtained from the Institutional Review Board of Kilimanjaro Christian Medical University college before commencement of the study, (CRERC, PG.02/2023).

2.2 Randomization and allocation

About 87 participants were found eligible. Computer-generated random numbers sealed in opaque envelopes were used to allocate participants into comparison groups and block randomization with a block size of 10 participants was done. Those who were randomized in the intervention arm ($n = 43$) received an oral dosage of Uriphytol capsules 500 mg 8 hourly a day, and a drug refill was done 30 days from the prescription date and a participant had to report the number of capsules remaining in the bottle. The control arm ($n = 44$) received oral dosage of tamsulosin capsules 0.4 mg once a day, and it was also similarly refilled. At baseline the IPSS, a validated, self-administered, quantitative measure was used to assess the severity of symptoms in which there are 7 symptom questions with scores ranging from 0 (no symptoms) to 35 (severe symptoms); where a score of 1 to 7, 8 to 19 and 20 to 35 considered as mild, moderate, and severe LUTS, respectively. There is an additional 8th question that assesses the quality of life in relation to the severity of symptoms, the scores ranging from 0 (delighted) to 6 (terrible). The International Index of Erectile Function (IIEF-5) questionnaire was self-filled by participants who reported being sexually active. The postvoid residual volume (PVR) was the determined by KUB ultrasonography and repeated by the bladder scanner, and these parameters were re-assessed on 3rd and 6th months' follow-up visits (Fig. 1). The primary outcome was a change in the IPSS in which a 3-point change was considered a good response to treatment 6 months of treatment. Secondary outcomes were changes in PVR; in which a volume of less than or equal to 100 cm^3 was considered non-significant and changes in erectile function scores (IIEF-5 scores) for sexually active men. Participants were supposed to report in case they experienced any immediate side effects during the time of treatment.

2.3 Statistical analysis

The sample size was determined by a formula by Kothari (2004), which randomly selected the number of participants within the urology clinic and a pooled standard deviation of the comparison group from previous studies was 4.7 [22]. Data cleaning, processing, and analysis were done in the SPSS 25 version (IBM Corporation, USA). Intent-to-treat (ITT) analysis for changes in IPSS, IPSS related Quality of life scores, changes in PVR, and changes in IIEF-5 scores from baseline, to 3 and 6 months of follow-up were completed. The Shapiro-Wilk test of normality was done considering the sample size in each treatment arm, and the respective test of comparison to be used was decided based on the test output. The Wilcoxon signed-rank test was used to assess changes in IPSS, IPSS related quality of life scores, PVR, and IIEF-5 scores within groups of treatment at different follow up points while the Mann-Whitney U test was used to compare changes in QoL scores, PVR measures and IIEF-5 at 6 months between treatment groups. An independent t-test was used to compare the change of IPSS between the comparison groups at 6 months. The changes were reported using mean and standard deviations, with their respective 95% confidence intervals. Statistical significance was considered at $p < 0.05$. All the findings have been summarized in tables. The non-inferiority margin of 3-point changes in IPSS was used, based on empirical ground. Two participants had missing data on follow-up variables. A complete-case analysis was conducted, as the missingness appeared to be random and did not affect the overall findings.

3 Results

Between August 20, 2023, and July 31, 2024, about 98 men with LUTS were screened for eligibility at the Urology clinic and 11 (11%) of them were found ineligible. The remaining 87 patients were recruited and randomized into treatment arms; (43 in the intervention arm, 44 in the control arm), with 82 (40 on Uriphytol, 42 on Tamsulosin) reached the endpoint and were included in Intent-to-treat analysis. Overall, the study protocol was adhered to in 94% of patients. In 6% the patient experienced retention of urine before the first follow up visit

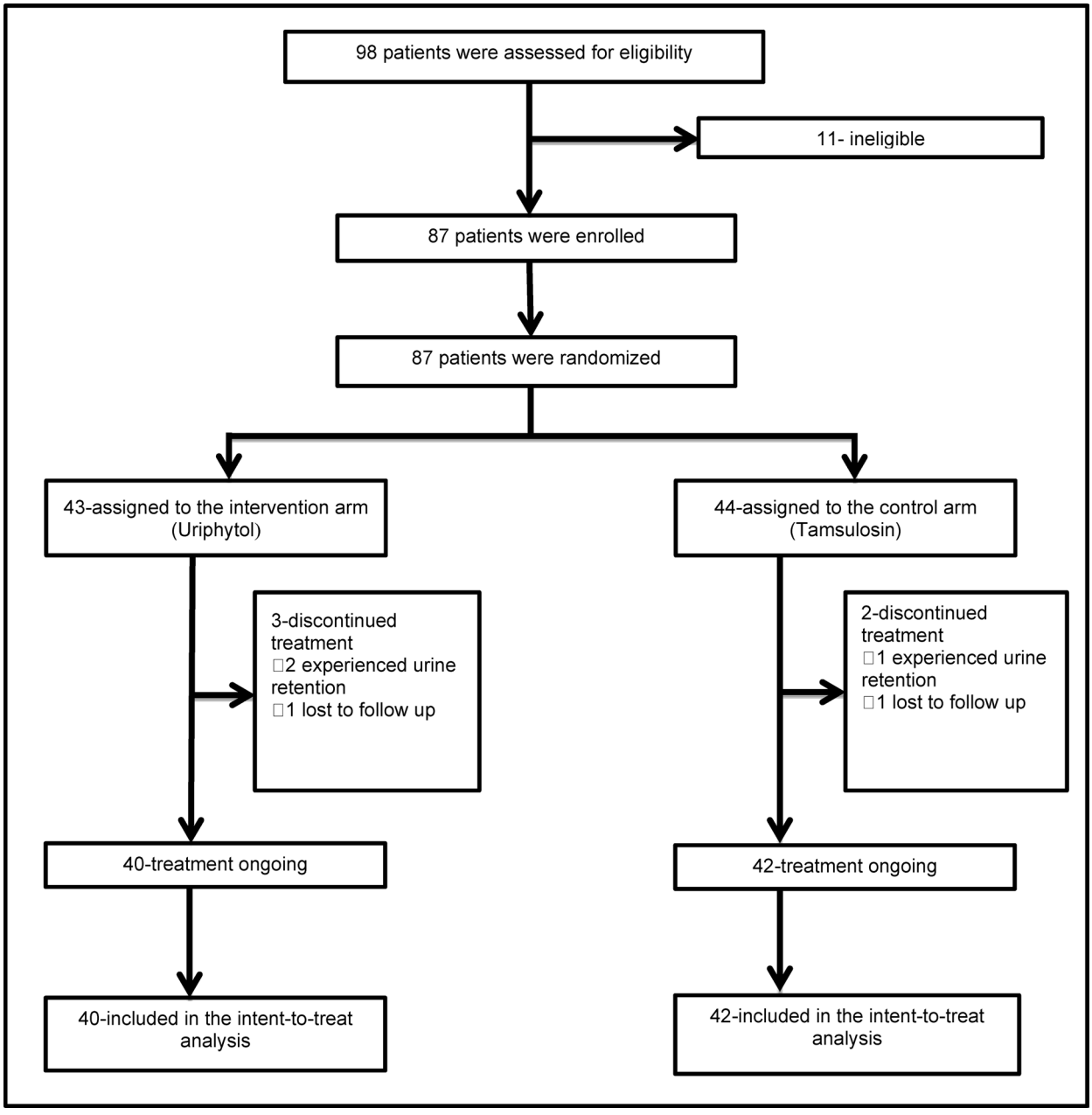

Fig. 1 Trial profile

Table 1 Protocol adherence by trial arm

Trial arm	Adherent	Non adherent	Missing Data
	n (%)	*n* (%)	*n* (%)
Uriphytol arm (*n* = 43)	40 (93)	2 (7)	1 (2)
Tamsulosin arm (*n* = 44)	42 (96)	1 (5)	1 (2)
Total (*n* = 87)	82 (94)	3 (4)	2 (2)

(3 months) ended up into transurethral resection of the prostate (TURP), and in 2% of patients, data were missing as they did not come back for follow up due to change of residence (Table 1). The mean age of participants was 67.33 ± 10.62 years. There was no significant difference between treatment groups in BMI, IPSS, QoL, and PVR, PV, PSA, PSAD and serum creatinine (Table 2).

3.1 Changes in IPSS and qol: uriphytol vs. Tamsulosin

A significant decrease in IPSS was observed in both treatment arms from baseline to endpoint ($p < 0.001$), but these changes were not significantly different between the treatment arms at baseline to 3 months [Mean change ± SD, 95% CI: Uriphytol: 13.35 ± 7.38 (10.99–15.71) vs. Tamsulosin: 12.35 ± 5.38 (10.68–14.03), $p = 0.081$], baseline to 6 months [Uriphytol: 16.20 ± 7.19 (13.89–18.50) vs. Tamsulosin: 15.52 ± 6.13 (13.61–17.43),

Table 2 Baseline characteristics of study participants (*N* = 82)

Baseline characteristics	Total (*n* = 82)	Uriphytol (*n* = 40)	Tamsulosin (*n* = 42)	*p*-value*
	Mean(± SD)	Mean(± SD)	Mean(± SD)	
Age (years)	67.33 ± 10.62	67.05 ± 10.23	67.60 ± 11.10	0.818
Body Mass Index (kg/m^2)	24.87 ± 3.76	24.51 ± 4.31)	25.21 ± 3.16	0.403
Severity of symptoms, IPSS (0–35)	20.15 ± 7.26	20.33 ± 7.89	19.98 ± 6.70	0.672
Quality of life scores (0–6)	5.59 ± 0.86	5.75 ± 0.67	5.43 ± 0.99	0.059
Postvoid Residual (in ml)	77.55 ± 63.25	76.70 ± 56.08	78.35 ± 70.07	0.784
Prostate volume (cc)	49.51 ± 31.43	49.89 ± 23.43	49.15 ± 37.79	0.328‡
PSA (ng/ml)	1.07 ± 1.85	2.18 ± 2.29	1.57 ± 1.26	0.319‡
PSA Density (ng/ml/cc)	0.05 ± 0.06	0.05 ± 0.06	0.04 ± 0.05	0.788‡
Serum Creatinine (µmol/l)	84.02 ± 14.08	85.12 ± 15.48	82.28 ± 13.23	0.253

n, number; SD, standard deviation;

* Analysis done by Mann-Whitney U-test;

‡ Analysis done by independent t-test

$p = 0.206$], and from 3 to 6 months follow up [Uriphytol: 2.85 ± 3.51 (1.73–3.97) vs. Tamsulosin: 3.17 ± 3.93 (1.94–4.39), $p = 0.409$], respectively. Despite the significant improvement in QoL of patients in both treatment arms from baseline to endpoint, this change was significantly higher in the Uriphytol arm as compared to the Tamsulosin arm at 3 and 6 months: [Mean change ± SD, 95% CI: Uriphytol, 4.68 ± 1.47 (4.20–5.15) vs. Tamsulosin, 3.90 ± 1.32 (3.49–4.32), $p = 0.003$] and [Uriphytol, 5.45 ± 0.99 (5.13–5.77) vs. Tamsulosin, 4.81 ± 1.17 (4.44–5.18), $p = 0.005$], respectively (Table 3).

3.2 Changes in PVR: uriphytol vs. Tamsulosin

The measures of the PVR volume were significantly decreasing in each treatment arm from baseline, at 3 months and 6 months follow-up visits (p-values: Uriphytol, 0.003 and Tamsulosin arm, < 0.001), however, these changes were not significantly different between the treatment arms from baseline to 6 months, respectively: [Mean change ± SD, 95% CI: Uriphytol, 33.90 ± 50.09 (17.88–49.92) vs. Tamsulosin, 30.55 ± 54.72 (13.50–47.61.50.61), $p = 0.537$] (Table3)).

3.3 Changes in IIEF-5 scores: uriphytol vs. Tamsulosin

About 45 (54.88%) [21 (46.67%) in the Uriphytol arm, 24(53.33%) in the Tamsulosin arm] of study participants were sexually active during the study period, and upon evaluation of their erectile function by IIEF-5 scores at 6 months, the erectile function scores increased significantly among those participants who were randomized in the Uriphytol arm than those who were in Tamsulosin arm, [Mean increase in IIEF-5 scores ± SD, 95% CI: Uriphytol, −3.71 ± 5.42 (−6.18-(−1.25)) vs. Tamsulosin, −1.00 ± 5.49 (−3.32-1.32.32.32), $p = 0.044$] (Table 3).

In testing for non-inferiority, the fixed-margin 95%–95% method was used in which prior randomized placebo trials for Tamsulosin already pre-specified the non-inferiority margin, Δ = −3 for Tamsulosin. As it states, non-inferiority can only be concluded when the difference between the new drug and the active comparator does not exceed the pre-specified margin. In this study, the observed mean difference between the two changes in IPSS between treatment groups at endpoint was 0.68 (95% CI: −2.26–3.61.26.61), hence, confirming the non-inferiority of Uriphytol as compared to Tamsulosin in relieving the severity of LUTS (Fig. 2).

4 Discussion

This study demonstrated that it is possible to conduct a full-scaled non-inferiority clinical trial to compare the effectiveness of Uriphytol and Tamsulosin in managing BPE. Recruitment of participants in both treatment arms exceeded the predetermined target and there was consistent recruitment of participants with good adherence to the protocol until the endpoint.

In the past two decades, phytotherapy usage has been increasing significantly in the world, and the highest usage has been reported in Africa where herbal medicines are considered the cornerstone for traditional medicine practice [12]. This increase in the reliability of these regimes and a high consideration as alternatives for medical treatment in patients without absolute indications for surgical interventions has led to the development of the Committee on Herbal Medicinal Products (HMPC) by the European Medicines Agency (EMA), and currently, the committee's evaluation confirms a well-established use of Serenoa repens, hexane extract for BPE, with Cucurbita pepo extracts being considered only for traditional therapeutic usage for relief of LUTS related to BPE or overactive bladder [20].

According to this study, after six-months, both treatments provided a significant reduction in IPSS, quality of life scores, and post-void residual volume, however, there was no statistically significant difference in the mean change of IPSS between the Uriphytol arm and Tamsulosin arm (16.20 vs. 15.52, $p = 0.206$, respectively), but a significant difference in the changes of quality of life scores was observed (5.45 vs. 4.81, $p = 0.005$). There was no significant difference in the mean decrease of post-void residual volume measures at six-months of follow up (33.90 ml vs. 30.55 ml, $p = 0.537$) but Uriphytol improved erectile function scores significantly compared to tamsulosin (−3.71 vs. −1.00, $p = 0.044$).

The change in severity of symptoms in the current study is consistent with the previous work as reported

Table 3 Comparison of changes in IPSS, QoL scores, PVR, and IIEF-5 scores among patients with BPO managed with uriphytol vs. Tamsulosin at 6 months ($N=82$)

Outcome measure	Uriphytol ($n=40$)	Tamsulosin ($n=42$)	*P*-value*
	Mean ± SD (95% CI)	Mean ± SD (95% CI)	
IPSS scores			
Baseline IPSS	20.33 ± 7.89 (17.80–22.85.80.85)	19.98 ± 6.70 (17.89–22.06)	0.672
IPSS at 3 months	6.98 ± 3.24 (5.23–8.72)	7.62 ± 5.34 (5.95–9.28)	0.471
IPSS at 6 months	4.13 ± 3.24 (3.09–5.16)	4.45 ± 3.07 (3.50–5.41)	0.356
P-value	< 0.001†	< 0.001†	
IPSS change from baseline to 3 months	13.35 ± 7.38 (10.99–15.71)	12.35 ± 5.38 (10.68–14.03)	0.081‖
IPSS change from baseline to 6 months	16.20 ± 7.19 (13.89–18.50)	15.52 ± 6.13 (13.61–17.43)	0.206‖
IPSS change from 3 to 6 months	2.85 ± 3.51 (1.73–3.97)	3.17 ± 3.93 (1.94–4.39)	0.409
Quality of Life scores			
Baseline QoL score	5.75 ± 0.67 (5.54–5.96)	5.43 ± 0.99 (5.12–5.74)	0.059
QoL score at 3 months	1.08 ± 1.37 (0.64–1.51)	1.52 ± 1.04 (1.20–1.85)	0.014
QoL score at 6 months	0.30 ± 0.79 (0.05–0.55)	0.62 ± 0.88 (0.34–0.89)	0.027
P-value	< 0.001†	< 0.001†	
QoL change from baseline to 3 months	4.68 ± 1.47 (4.20–5.15)	3.90 ± 1.32 (3.49–4.32)	0.003
QoL change from baseline to 6 months	5.45 ± 0.99 (5.13–5.77)	4.81 ± 1.17 (4.44–5.18)	0.005
QoL change from 3 to 6 months	0.78 ± 0.97 (0.46–1.09)	0.90 ± 0.96 (0.61–1.20)	0.372
Post-void Residual volume (in ml)			
Baseline PVR (ml)	76.70 ± 56.08 (57.77–94.64)	78.35 ± 70.07 (56.51–100.19.51.19)	0.784
PVR at 3 months (ml)	45.51 ± 39.01 (33.04–57.99)	60.12 ± 50.29 (44.46–75.79)	0.222
PVR at 6 months (ml)	42.80 ± 28.19 (33.78–51.82)	43.61 ± 43.61 (34.21–61.39)	0.731
P-value	0.003†	< 0.001†	
PVR change from baseline to 3 months	31.19 ± 51.59 (14.69–47.69)	18.23 ± 72.79 (−4.45–40.91.45.91)	0.447
PVR change from baseline to 6 months	33.90 ± 50.09 (17.88–49.92)	30.55 ± 54.72 (13.50–47.61.50.61)	0.537
PVR change from 3 to 6 months	2.71 ± 31.12 (−7.24-(12.67)	12.33 ± 52.87 (−4.15–28.80.15.80)	0.158
IIEF-5 scores	($n=21$)[a]	($n=24$)[a]	
Baseline IIEF-5 score	13.95 ± 4.87 (11.73–16.17)	16.25 ± 5.19 (14.06–18.44)	0.040‖
IIEF-5 score at 6 months	17.67 ± 6.08 (14.90–20.43.90.43)	17.25 ± 5.05 (15.12–19.38)	0.522
P-value	0.005†	0.381†	
IIEF-5 change from baseline to 6 months	−3.71 ± 5.42 (−6.18-(−1.25))	−1.00 ± 5.49 (−3.32-1.32.32.32)	0.044

SD, Standard deviation; CI, Confidence interval[a]Analysis included only sexually active participants; *Analysis done by Mann-Whitney U-Test;‖ Analysis done by Independent T-test;† Analysis done by Wilcoxon signed rank test

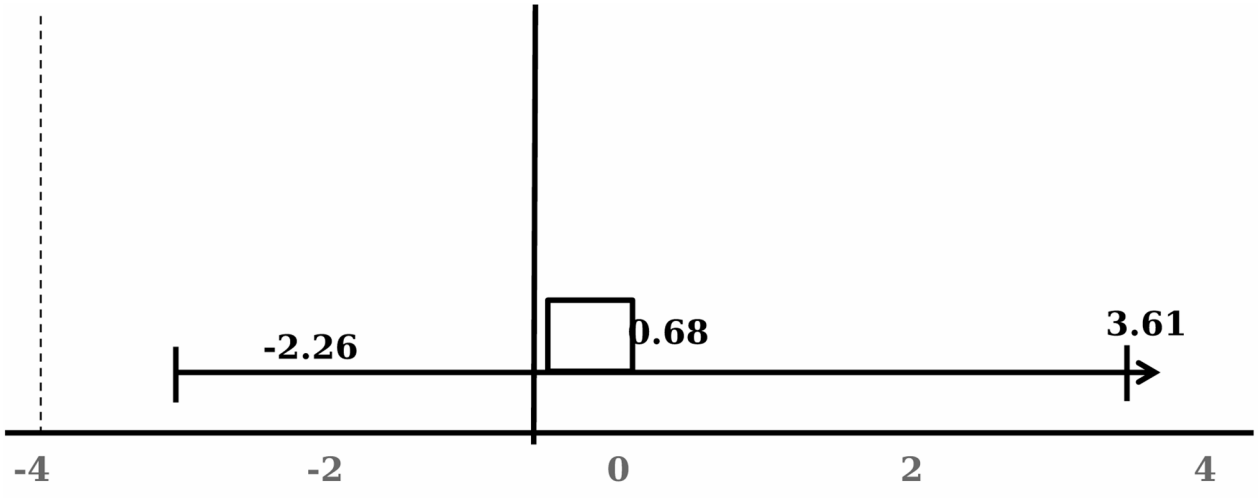

Fig. 2 A graph representing the direction of non-inferiority between Uriphytol and Tamsulosin in providing relief of LUT symptoms: The observed mean difference between the two changes in IPSS between treatment groups at endpoint was 0.68 (95% CI: −2.26–3.61.26.61), which does not exceed − 3, a pre-specified non-inferiority margin

by Hong and colleagues, in which a change of symptom severity assessed by the IPSS tool among patients who were kept in a Cucurbita pepo-based phytotherapy was found to be 12.4 after 6 months of treatment and the corresponding change in the quality of life score was by 3.4 points [23]. This suggests the therapeutic role of phytochemicals in providing relief of lower urinary tract symptoms that are caused by BPE, which could be explained by the role of phytosterols in competitive inhibition of dihydrotestosterone binding, inhibition of alpha-reductase enzyme, interferon-gamma mediated anti-inflammatory effects and muscle relaxation through nitric oxide release resulting into decrease in prostate volume and also bladder comfort [16].

A similar non-inferiority trial which involved the use of Cucurbita pepo extract vs. Tamsulosin in Iran found a significantly higher decrease of IPSS among patients who were kept in Tamsulosin than those kept in C.pepo phytotherapy at 3 months-endpoint; 5.33 vs. 3.19, p = 0.020, and there was no significant difference in the mean change of quality of life scores between the two treatment arms, 0.97 vs. 0.74, p = 0.465, respectively [21]. These differences could be due to the difference in the doses of C. pepo used compared to the current study (half the dose), as it was the only available dose in the whole country during their study period and it is slightly lower than the dose which has been used in multi-centre trials and other placebo trials [24]. Furthermore, the addition of curcumin in the current regime could explain the difference in changes of severity of symptoms and their related quality of life scores as Curcumin suppress epidermal like growth factors (EGFR) and vasculo-endothelial growth factors resulting into inhibition of cell proliferation and angiogenesis, respectively, and promotes cellular apoptosis by preventing phosphorylation within prostatic cells [25, 26].

We observed a significant higher improvement in IPSS-related quality of life scores than the conventional medication, and this is higher than the change observed in previous study in Italy, where a comparative change in IPSS related quality of life scores was found, 1 vs. 1, p = 0.20 between Tamsulosin alone and Tamsulosin combined with Cucurbita regimes [27]. This difference could be accounted by the shorter time of follow up, as the current study followed participants for 6 months while the prior study only followed them for 1 month and 10 days. Generally, due to the high correlation between the reduction of severity of symptoms score and improvement in quality of life, long term treatment has been achieving the significantly desired effects among patients as it is stated in prior literature, hence, the time of treatment being a significant factor as long as the quality of life is concerned [28]. This improvement in LUTS-related quality of life scores may also be due to the increase in the erectile function scores in the current study as it has been reported in prior literature regarding the increase in quality of life as sexual function increases [25].

The current study has found a significant decrease in postvoid residual volume in both treatment arms at 6 months however these changes were not significantly different between the two groups (p = 0.537). Similarly, previous study in Iran revealed PVR changes from baseline to the third month of follow up were 9.56 ml in the Tamsulosin arm vs. 7.67 ml in C. pepo extract, p = 0.563, though these changes were not statistically significant within independent treatment groups [21]. Weakening of the bladder detrusor muscles and eventual inability to completely empty urine is a common pathophysiological effect of bladder outlet obstruction due to BPE, and whenever treatment is employed long-term duration may be recommended to counteract the detrusor function [29]. So, the shorter duration of follow-up in the prior study could explain the lack of a significant decrease in PVR during their treatment as compared to the current study.

Regarding postvoid residual and detrusor function, Cucurbita pepo has been reported to play a role in muscle relaxation through nitric oxide release [16], a potent which is responsible for upregulating bladder-urothelial afferent signaling hence increasing the sensation of muscarinic receptors present in the bladder urothelium, as it has been shown in recent literature that patients with detrusor underactivity due to bladder outlet obstruction tend to have lower expression of nitric oxide, affecting bladder sensation [30, 31].

We have observed significant improvement in erectile function scores among participants in Uriphytol arm compared to those in Tamsulosin arm a consistent finding as the one observed in Lebanon [32]. This is due to the role of C. pepo in promoting nitric oxide release, enhancing penile smooth muscle relaxation and vasodilation, key processes for achieving and maintaining erection. Furthermore, the presence of Curcumin in Uriphytol increases endothelial nitric oxide synthase (eNOS) activity which promotes vasodilation in penile tissue and reduces oxidative stress by neutralizing reactive oxygen species (ROS) that impair nitric oxide function and damage endothelial cells, this supports better blood flow to the pelvic region [33].

To the best of our knowledge, this is the first study conducted in an African setting comparing phytotherapy (Cucurbita pepo combined with Curcuma longa extracts) with Tamsulosin in managing LUTS due to benign prostatic enlargement. A major limitation in this study was the lack of urodynamic parameters due to unavailable equipment, preventing us from determining the detrusor muscle function at baseline and also the changes in the maximum flow rate. This might be the reason for some

of the patients to experience urine retention after being enrolled in the study. Furthermore, lack of blinding may subject participants into selection and performance bias as most of Africans favor traditional medicines.

In conclusion, we have demonstrated that a full-scale prospective non-inferiority randomized clinical trial to determine the effectiveness of phytotherapy (Uriphytol) versus tamsulosin is feasible in our setting. We found that Phytotherapy (Uriphytol) was not inferior to tamsulosin in relieving lower urinary tract symptoms severity and reducing post-void residual volume after 6 months of treatment and was superior in improvement of quality of life and erectile function. The findings from this study suggest that Uriphytol could be an alternative to tamsulosin for managing symptoms of BPE. This information could help users make informed choices about their treatment options [11]. We recommend thorough monitoring throughout the study procedures during a full-scale clinical trial.

Abbreviations

BPE	Benign Prostatic Enlargement
BPH	Benign Prostatic Hyperplasia
IPSS	International Prostate Symptoms Score
IIEF	International index of erectile function
KUB	Kidney, ureter, bladder
LUTS	Lower urinary tract symptoms
PSA	Prostate Specific Antigen
PSAD	Prostate specific antigen density
PVR	Post-void Residual volume
QoL	Quality of life
WHO	World Health Organization

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12301-026-00555-9.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Author contributions

Z.C. conceptualized the study, developed the methodology and the protocol, participated in data collection, analyses, interpretation, and drafted the manuscript. O.M. planned the study, developed the methods and the protocol, supervised this project, and drafted the manuscript. B.N. planned the study and supervised data interpretation and manuscript development. S.L. developed the methodology and supervised data analyses. F.B. planned the study and supervised the work. J.M. planned the study and supervised the work. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Funding

No funding was received for conducting this study. The phytotherapy (Uriphytol) was supplied freely by the iPhytos company Tanzania LTD. These suppliers had no role in any aspect of this study.

Data availability

Data is provided within the supplementary information files.

Declarations

Ethics approval and consent to participate

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the College Research Ethics and Review Committee (CRERC) of the Kilimanjaro Christian Medical University College (PG.02/2023). Written informed consent was obtained from all participants. The trial was also registered in Pan African Clinical Trials Registry (PACTR) on 19th April, 2023 under the registration number PACTR202304488683045.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 14 January 2025 / Accepted: 30 January 2026
Published online: 17 February 2026

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