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Evaluation of phytotherapy in *Plantago major* and *Solanum aculeastrum* vs α -blocker treatment of benign prostate hyperplasia by using IPSS, clinic and ultrasound in Goma

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Abstract

Herbal medicine is an ancient or millennium practice. The World Health Organization has recognized its practice for several decades.

The present study is motivated by the decrease of patients with voiding disorders in the consultation of the hospitals of Goma, apart those with acute urinary retention. Yet, it was noted their presence in number in the traditional practitioner.

Benign prostatic hyperplasia, an essential cause of voiding disorders in elderly men, has been the beneficiary of herbal medicine around the world with satisfactory results.

The aim of our study was to evaluate the results of herbal medicine with *Plantago major* and *Solanum aculeastrum*, plants used in traditional medicine in Goma, compared to conventional treatment. The sample was made of males aged 60 and over. Two randomly distributed groups of 68 patients each benefited from either herbal medicine or α -blocker treatment (Alfuzosin tablet 10 mg / day) for a period of 27 months.

The results were evaluated according to, in addition to the International prostatic symptoms score, Quality of life, the clinic (digital rectal examination), the Prostatic specific antigen and ultrasound.

After analysis, the results were better after herbal medicine compared to those obtained by the α -blocker molecule.

It is thus possible to suggest to modern practitioners the use of this herbal medicine. Further study on its safety and, where possible, its pharmacokinetics and pharmacodynamics is recommended.

Keywords: HBP phytotherapy, IPSS, QoL, PSA, ultrasound, clinical outcome

Introduction

The history of herbal medicine dates back 60.000 years when Neanderthals used plants.

In addition, shamans played an important role in collecting, learning to use, and imparting knowledge of plants during the evolution of *Homo sapiens*. Plants were used extensively in food, in the management of certain diseases, and in reaching a more spiritual world^[1].

The World Health Organization (WHO) has recognized herbal medicine since 1998^[2-4]. Also, it is currently an integral part of the medical treatment of voiding disorders of which benign prostatic hyperplasia (BPH) is the most common cause in males aged 50 or over, or even from 40 years^[5-9].

According to McFarlane G J *et al.* in 1995^[10] and Breekman T J and Mynderse L A in 2005^[11], their frequency was 25% between 40-49 years. Vouga L claimed that 80% of men over 70 suffered from it and the root cause was BPH^[12].

In recent years, there has been a growing interest in the use of medicinal plants even in developed countries because they have been found to be safe and harmless compared to synthetic drugs^[13-17].

Bitton A said at the 3rd day of phytotherapy in Romandie that due to increasing pressure from the media and patients, many doctors, including urologists, resort more and more frequently to the use of phytotherapeutic substances. Especially since the issues of economy, which is not spare the health sector, push staff to prescribe effective, safe and inexpensive substances^[18].

Herbal medicine for HBP ranks alongside $\alpha 1$ blockers and anti 5α reductases in the medical treatment of BPH [11, 19]. Voiding disorders due to BPH have a great impact on the quality of life but also are characterized in Africa and the DRC in particular by significant morbidity and mortality mainly due to open surgery, the only recourse in our limited context on the plateau technique [20-28].

In Goma, having noted the low attendance of these patients from official health institutions [22], we conducted a study, which showed us a high prevalence of voiding disorders in elderly males in the city [29].

Due to ignorance and the high cost of care, many of these patients were found with the traditional healer. From where a first evaluation on the herbal medicine of BPH with *Plantago* major and *Solanum aculeastum* on a small sample was carried out and led to satisfactory results rated by the International Prostatic Symptoms Score (IPSS) and the Quality of life (QoL) [30].

By the present study, we wanted to extend the evaluation of the results on a larger sample by the IPSS, the QoL, the digital rectal examination (DRE), the rate of the Prostatic Specific Antigen (PSA) and the ultrasound in the aim to determine the effectiveness of this herbal medicine.

These two plants are recognized at the Lwiro National Herbarium, the first recorded at No. 2193 by Christiansen A R on March 20, 1958, the second at No. 2993 by Troipin G on January 20, 1957 [31].

The plants mentioned above, rich in chemical substances, have been found to be effective on several pathologies apart from BPH. The choice of these local plants was justified by their use by local traditional medicine, by the abundant literature which recognizes their effectiveness, availability, harmlessness, and finally by the choice of authors according to geography.

Material and Methods

Our study consisted of a clinical trial on two cohorts of patients recruited and distributed randomly according to the rule of Durand CI [32] or 68 were receiving the phyto-medication whose dosage was described in the previous study [30] and 68 with Alfuzosin 10 mg tablet, at a dosage of 10 mg per day.

Were included in this study all patients who had at least 60 years

old with moderate or severe but uncomplicated IPSS and without decompensated comorbidities with a QoL ≥ 3 , that means unhappy patients of their condition.

The duration of the study was 27 months that we divided into 3 episodes of 9 months each. The study focused on the comparative assessment of IPSS, QoL, clinic (mainly examination of the abdomen combined with digital rectal examination), PSA and ultrasound.

IPSS and QoL were assessed using the American Association of Urologists Index Score (AUA-Is) questionnaire recommended by WHO in 1992 [33].

- The PSA was performed using the Ichroma II machine from Boditech Med Int (South Korea 2018) (Normal level 0-4 ng / ml).
- The endorectal ultrasound performed by a single doctor specializing in medical imaging using the Bruel and Kjaer model ultrasound (BK Medical 7.5MHZ USA 2005). All prostate weighted above 30 grams was pathological in adults. The classification of Ultrasound results was as follows: 30-60 g (small volume), 60-80 g (moderate), and > 80 g (large)- A doctor specializing in histopathology did examination of biopsy sample using the "tru cut" and a sampling needle mounted on an ultrasound probe (6 per side).

Every nine months, the data were recorded, encoded and analyzed on the monitoring sheets. We present the results from the beginning of the study to January 1, 2019 and those from the end to March 31, 2021 for better concision.

Data processing was done by SPSS version 23 and interpretation by test χ^2 ($p < 0.05$).

The rules of medical ethics have been observed and the work has obtained the prior approval of the ethics commission of the Faculty of Medicine of the University of Lubumbashi (reference CEM UNILU No Approval: UNILU / CEM / 121/2018 of November 06, 2018). All patients were consenting and well informed about the risk and benefit of the study.

Result

1. IPSS

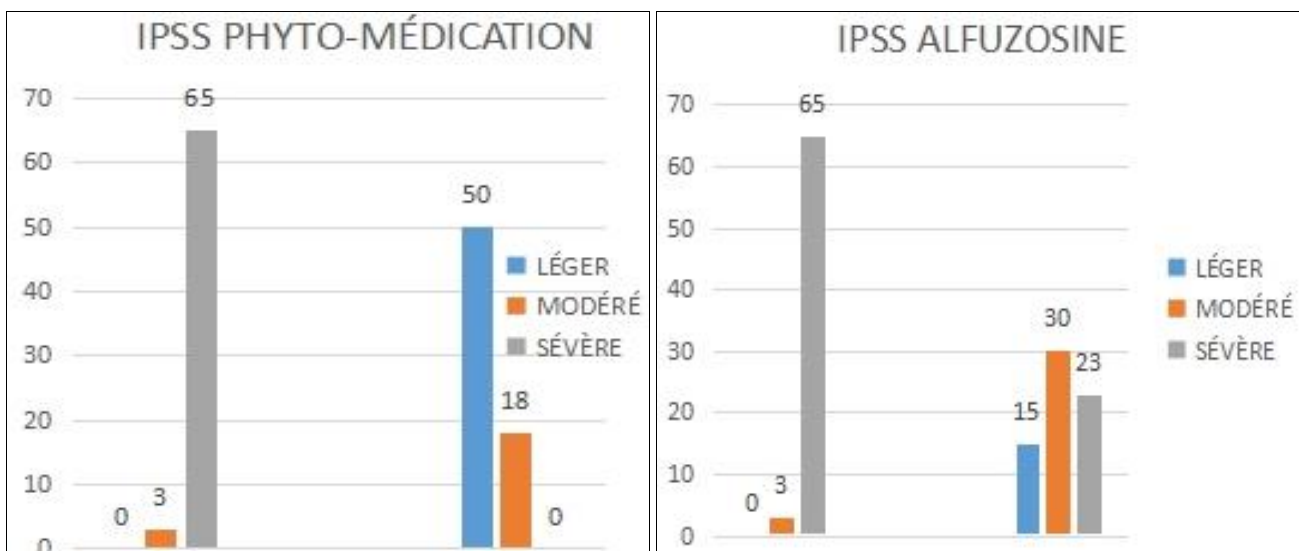


Fig 1: IPSS

Ninety-five percent of the herbal medicine provided better relief to patients compared to treatment with Alfuzosin. There were no

more severe cases after herbal medicine (Chi-square = 44.84 and P-value 0.00 < 0.05).

2. QoL

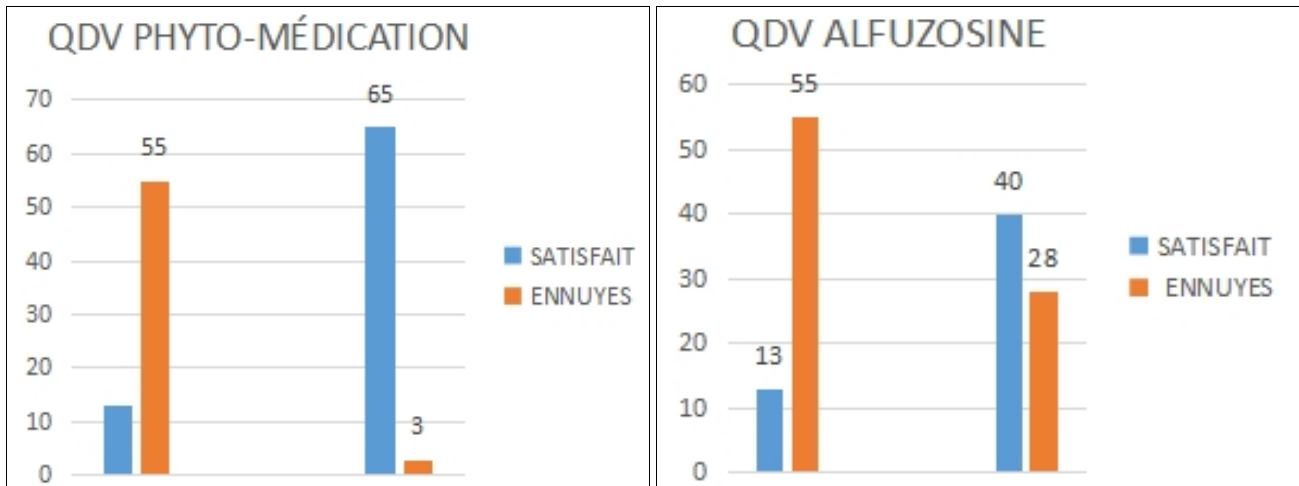


Fig 2: QoL

The patients were more satisfied after phyto-médication. Indeed, 13 satisfied versus 55 bored at the start in the two series, and at the end, 40 satisfied versus 28 bored in the Alfuzosin series versus 65 satisfied versus 3 bored in the phyto-médication series

(chi-square = 26, 11 and P-value 0.00 <0.05).

3. DRE

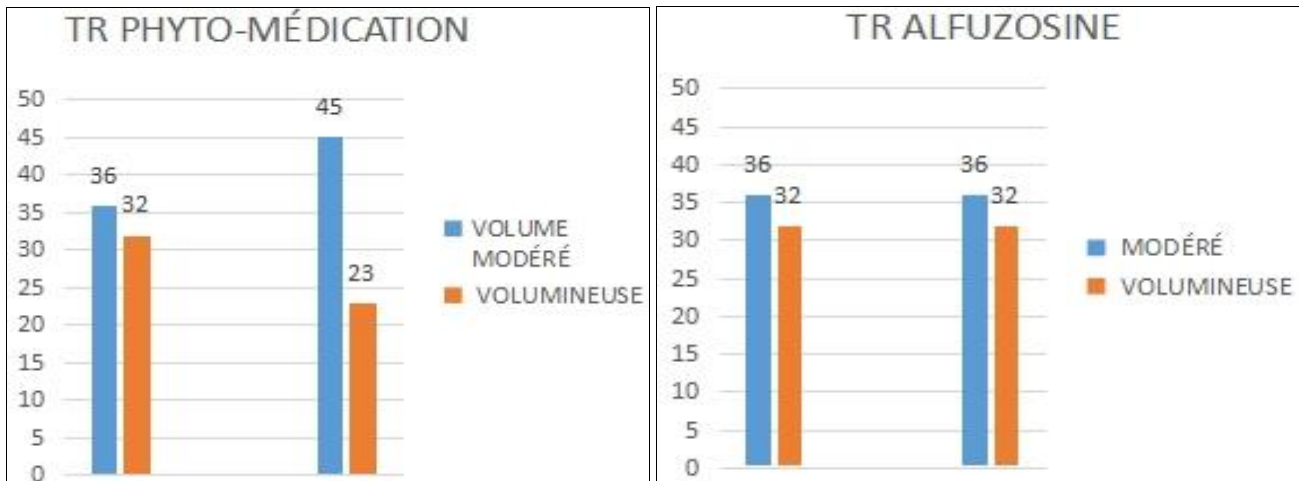


Fig 3: Prostate volume after treatment

No significant difference between the two groups (chi-square = 2.473 and P-value 0.116 > 0.05), the size of the prostate is not related to the treatments but to another factor in 95% of cases.

4. PSA



Fig 4: PSA level at the end of the treatment

In the phyto-medication series, the rate is normalized in 60 cases instead of 40, ie an improvement of 50%, a better result than for Alfuzosin (Chi-square = 12.706 with P-value = 0.000 <0.005).

5. Ultrasound

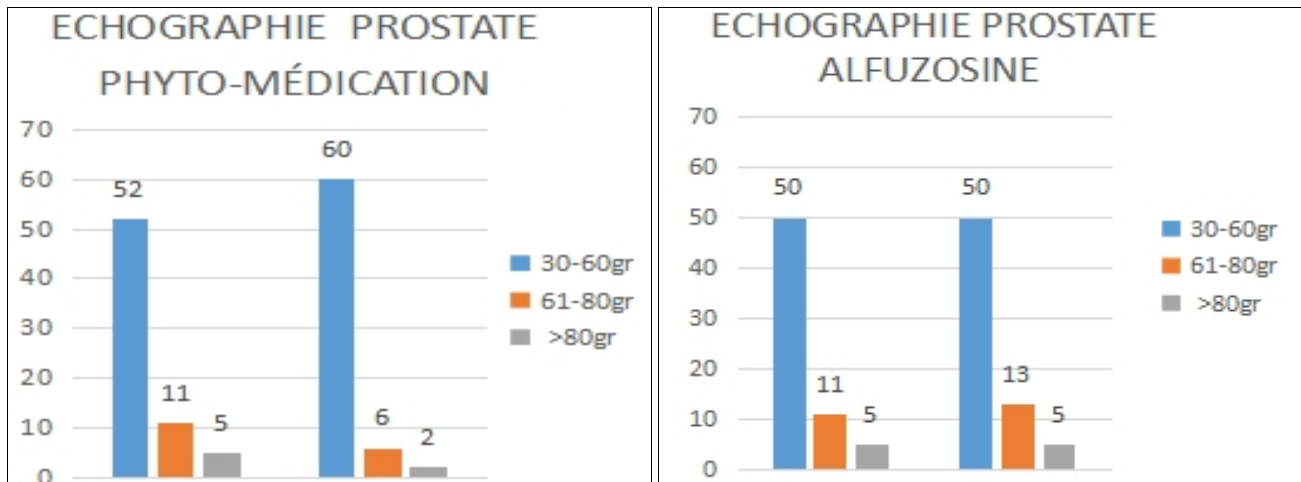


Fig 5: Initial ultrasound and control

A greater improvement was noted in the phyto-medication group: the number of cases with a volume between 30-60 cm³ progresses from 52 to 60 cases that is an improvement of 15%. In the Alfuzosin series: there were no change. The chi-square test is 5.376 with P-value = 0.01 > 0.05, we accept the dependence of these two variables.

Discussion

1. IPSS et QoL

From the point of view of patients' evolution at the end of treatment, at 95% the phyto-medication relieved the patients better compared to Alfuzosin (p 0.05) with regard to IPSS and QoL.

It seems obvious that, based on the responses of patients to questions on severity and quality of life, the results obtained with plants are far better than those obtained with conventional treatment.

For Curtis N *et al.*, the IPSS-QoL and the PSA are, after the interrogation, the physical examination (including the TR) and the objective examination of the urine, the starting point for the diagnosis and the follow-up of the patients voiding disorders linked to BPH [34]. Seisen Th *et al.* said that IPSS and QoL [35] assess the impact of functional urinary signs. Duperron C [36] supported by the French College of urology [7] set the stages of the examination of the patient to arrive at the diagnosis. These are, after the compulsory interrogation, the PSS and QoL. They are used to assess functional signs. Cottaz V even added the recommendation to rewrite the IPSS and QoL by adapting them to other global aspects of the patient's social relationship with the well-being of the "prostate patient" [37].

In our study, we used the only questionnaire recommended by WHO based on the AUA-Is score [33], namely the IPSS-QoL score. We only used dual therapy according to the local traditional practice and did not find the opportunity to combine our herbal medicine with conventional molecules like Vita Nunes R *et al.* in Brazil who did so with *Serenoa repens* + tamsulosin or *Serenoa repens* + selenium + lycopene [38] nor to the polyphytherapy applied in Korea, China, India, Japan, or even in Côte d'Ivoire [39, 40, 41, 42, 43, 44].

Also in Brazil, Calogero AE *et al.* [45] recommended the combination of α - blocker and a 5-Phospho-diesterase inhibitor (5-IPDE) through counseling. For Soukaina el Hadrati, 5-IPDE

leads to a relaxation of the smooth musculature and therefore to the improvement of the irrigation of the erectile organs and thus improves the erection [46]. Indeed erectile dysfunction is cited as a usual sign of BPH, it has even been the subject of an adaptation of the IPSS questionnaire by Schwartzman P *et al.* in Israel [47].

Our study, with regard to subjective results, had the only tools the IPSS -QoL questionnaire and in which we did not integrate other social parameters as recommended by the authors above. In our study, these parameters improved better after taking the phyto-medication.

The High Authority of Health (HAH) in France recommended that men with uncomplicated BPH with moderate symptoms that they deem acceptable (if there is no impact on the bladder or on the upper device) should not be processed.

The initiation of medical treatment depends mainly on the discomfort caused by the symptoms and the impact on QoL [48]. Levy A and Samraj G P concurred in saying that it is necessary to treat when QoL is impaired because many patients are asymptomatic [49].

We confirm that our study took these recommendations into account, since only patients with moderate or severe uncomplicated IPSS were eligible for treatment with, however, a QoL ≥ 3 , that is to say patients without satisfied with their condition.

2. Digital rectal examination (DRE)

There was no significant difference between the two groups (p 11.6). We can say that the size of the prostate is not affected by the treatment but by other factors.

Although the results of this examination did not show any significant difference, it should be noted all the same that the approach was justified by the respect of the steps as recommended by the authors [5, 7, 8, 34, 35] to know the DRE and the PSA after the IPSS and the QoL.

Seisen [35] asserted that the DRE is a useful test to refer to a biopsy because it already differentiates BPH and cancer.

Note, however, that the size of the prostate does not always match the extent of functional urinary signs. On the other hand, we cannot exclude the fact that this examination is "examiner-dependent" and therefore depends on the perception of the clinician [50].

Indeed, the national association of accreditation and evaluation in health (ANAES) in France made it clear by noting the absence of parallelism between the high frequency of BPH, anatomical fact, and the lower frequency of Patient-reported SBAU.

She added that there are no predictors of the progression of BPH^[51]. The HAH, still in France, added that the volume alone does not constitute an indication for starting treatment^[48].

Bengaly S, as other authors previously cited, has said that non-symptomatic BPH does not require medical treatment.

Otherwise, the treatment must take into account the functional repercussions, the complications and the patient's situation^[52].

We can affirm that in our study, we obtained a clinical improvement in our patients even in front of the non-reduction of the volume of the prostate perceived with the DRE. We may believe that plants, without reducing the size of the prostate, would have an effect on the dynamic component of voiding disorders as recognized by α -blockers.

3. Prostate specific antigen (PSA)

In the phyto-medication series, the PSA level normalized in 50% of cases, a better result than for Alfuzosin.

The whole discussion in the process of diagnosing an enlarged prostate lies in the differential diagnosis between benign hypertrophy and cancer. This is why the second step after IPSS and QoL is DRE and PSA.

The latter is dependent both on cellular activity and on volume and therefore likely to be elevated in both cancer and BPH^[35]. It retains its orientation value towards the biopsy that alone can confirm the diagnosis^[7, 35, 50]. Babey R recommended requesting it with blood creatinine before the DRE since it can be disturbed by the latter maneuver that involves even light prostate massage^[53].

In our study, it was requested before the DRE. The Indonesian authors recognized that PSA and Gleason score are prostate tumor markers aimed at detecting prostate cancer. They added that the higher their values, the lower the patient's quality of life^[54]. For this reason Curtis N *et al.*^[34] only recommended this examination in subjects 10 years of age and over with life expectancy.

Indeed, in such subjects, the early discovery of cancer could benefit from curative surgery. At the same time, these are the best cases eligible for surgery even for BPH.

In The Common Resident Course of July 2019^[55], it was confirmed the rapid effect of α -blockers without impact on either prostate volume or PSA. Our plants, however, have reduced the PSA, so they would have a non-proliferative effect.

Grammatikopoulou MG *et al.* in Greece^[56] demonstrated that many antioxidants have little or no effect on PSA including lycopene, selenium, curcumen, coenzyme Q10, phytoestrogens (isoflavones, flavonoids), green tea, fruits, nuts and supplements..

Another characteristic of PSA was observed by Fonseca RF *et al.*^[57] who noted the drop in PSA after transurethral resection of the prostate without the free fraction being interested and were therefore reassured of the absence cancer and were able to say there, that the treatment which reduces the PSA would confirm the benignity of the hypertrophy of the prostate.

We observed a certain variability in the response of PSA to various treatments according to the authors, but retained that PSA has a diagnostic orientation value.

In our study, the improvement in the level of this marker could make us accept the existence of the non-proliferative properties of these plants recognized by 5α -reductase inhibitors.

4. Ultrasound

It was noted in our study, a greater decrease in the phyto-medication group either a number of cases with volume between 30-60 cm³ from 52 to 60 cases, or an improvement of 15%, no improvement in the Alfuzosin series.

The discrepancy noted between the ultrasound results and the examiner-dependent aspect of the result of the DRE could explain those of the DRE. On the contrary, also, ultrasound can give a result contradicted by surgical exploration. However, if we trust these results alongside those of PSA, we can say that the plants used would have some non-proliferative effect. The reduction in prostate size is indeed recognized by anti- 5α reductases (Finasteride, Dutasteride) because they oppose androgens, which promote prostate growth^[8].

Darchy E recognized the virtue of reducing prostate volume similar to that of anti- α -5 reductases in *Serenoa repens* and *Pygeum africanum* as well as other plants known in the West (*Ortica dioica*, *Hypoxis rooperi*) at the same time as results similar to those of α -blockers^[58].

Saidi S *et al.* in Macedonia recognized that *Serenoa repens* improved PSA, flow rate, post-voiding residue (PVR) and IPSS, but not the reduction in prostate size^[59].

Poirier J likewise recognizes in *Serenoa repens* as well as in *Pygeum africanum*, the oldest plants known in the West, the quality of anti-inflammatory drugs and regulators of the testosterone-estrogen balance but not that of anti-androgens therefore non-reducing in volume^[60].

However, the Korean authors have recognized their polyphytotherapy made from six local plants to reduce prostate volume and PSA by studies on rats whose BPH was induced by testosterone^[39].

For our part, these contrasting results recommend us to explore further, through studies of the cultures of these molecules on prostate tissues, to verify the real effect of our plants that would have the qualities recognized in the two groups of conventional BPH drugs.

As to the usefulness of ultrasound in the diagnosis of BPH, ANAES^[51] recommended it to explore the upper urinary tract, PVR and allow ultrasound-guided biopsy. The French College of Urologists^[7] recommended it to identify RPM, detrusor, kidney, diverticula and lithiasis that are complications. The French Association of Urology (AFU) has recommended it if surgery is scheduled to determine bladder volume, wall thickening, RPM and upper apparatus^[61].

Similarly, Seisen Th *et al.* spoke of vesico-renal ultrasound for the exploration of the upper apparatus, the morphology of the bladder (diverticulum, stones, detrusor state), the volume of the prostate and especially the median lobe^[35]. Chirador M and Baradanane M have said that in the era of magnetic resonance imaging (MRI) ultrasound still has a place for surgery^[62].

For all these reasons, our study has enabled us to confirm the usefulness of ultrasound in the initial diagnosis and control of BPH. For us, it was a valuable complement to the DRE, the ultrasound-guided biopsy and the follow-up of our patients.

It allowed us to state the beneficial effect of our plants in the sense that, at a minimum, we did not notice any cases of enlargement of the prostate.

Conclusion

After the presentation of herbal medicine for benign prostatic hyperplasia with *Plantago major* and *Solanum aculeastrum*, plants used in Goma, we found that the clinical, PSA and ultrasound results were better than those of conventional treatment.

They consisted of improving the quality of life of the patients, the level of PSA and somehow the reduction of the size of the prostate. We can recommend their prescription to modern practitioners. A study on their safety, and as far as possible, their pharmacokinetics and pharmacodynamics, remain useful tools for confirming their safe efficacy.

What this study adds

The use of *Plantago major* and *Solanum aculeastrum* in the management of benign prostatic hyperplasia have shown clinical and ultra-sonographic improvement among patient in Goma. The study will raise awareness among modern practitioners on regarding safety, accessibility and efficiency of *Plantago major* and *Solanum aculeastrum*.

Conflicts interests

The authors declare no competing interests

Authors' contributions

Swedi ME collected the plants and did their preparation. Tshilombo KF, Banza CL, Odimba BE made a substantial contribution to data analysis and interpretation, and to the correction of this article. Arung KW is the promoter of the overall work and the main supervisor. Kasali MF and Bakary AS are professors of pharmacy at the Official University of Bukavu and the University of Lubumbashi, respectively, and have helped set the dosage of the phyto-drug.

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