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Short-term clinical and paraclinical evaluation of the treatment of benign prostatic hypertrophy by phytotherapy with *Plantago major* and *Solanum aculeastrum*

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Abstract
Introduction: The evaluation of a new drug was presented as a learning act recommended by the authors. This motivated the current study which aimed to make the clinical (IPSS-QdV, TR) and paraclinical (PSA, ultrasound) assessment of 68 BPH patients treated 15 months ago with herbal medicine with *Plantago major* and *Solanum aculeastrum* with good results.
Material and Method: The study was cross-sectional and the results were presented in the form of histograms. The interpretation used the SSPS software and their significance was made using the χ^2 ($p \leq 0.05$).
Results and Discussion: At the end of the evaluation, the deterioration of the rates of the parameters under examination (clinical and paraclinical assessment) was noted.
Conclusion: The conclusion was that, even if similar evaluations were not found in the available documentation, this situation should lead to the resumption and continuous repetition of treatment according to the traditional practitioner's regimen in episode mode (three months of treatment, six months break followed by regular evaluation).

Keywords: Prostate hypertrophy, herbal medicine

Introduction
Already in 1993 Constandriopoulos A P *et al* said that evaluation was an activity as old as the world, banal and inherent to the very process of learning. It responded to several principles including rigor [1].
In 2019, the Development Assistance Committee (DAC) Network of the Organization for Economic Co-operation and Development (OECD) set six revised and updated evaluation criteria namely relevance, coherence, effectiveness, efficiency, impact and viability (sustainability).
These criteria are intended to support the quality of evaluations and to strengthen the contribution of this function to sustainable development [2] Philippe Michel and Valéry Ridde said that there is no single definition on evaluation and that no terminology was not shared but that one could consider that evaluation was "a process of quantitative and/or qualitative analysis which consisted in appreciating either the progress of an action or a program, or in measuring their effects (i.e., the specific effects and the consequences or impact)".
They described 7 stages of this process, of which we have retained the last one, which speaks of enhancing the evaluation by taking the recommendations into account [3].
Berbis J *et al* added that the evaluation of the effectiveness of a new drug is based on knowledge of the patients and the context of a pathology (relevance of the determinants of patient satisfaction and efficiency) confronted with the objective data [4]. All of the above justified the present study.
Indeed, in previous work, we saw that medical treatment was indicated in uncomplicated benign prostatic hyperplasia (BPH) with moderate or severe Lower Urinary Tract Symptoms (LUTS) and impaired quality of life (QOL). We also noted that medical treatment had supplanted conventional treatment, i.e. surgery alone [5].

Levy A and Samraj G P [6] in "Benign prostatic hyperplasia, when to watch when to treat? recommended that it was necessary to treat when the QoL was altered because many of the patients were asymptomatic and that one operated only in front of the complications. Poirier J added that treatment was only provided if the QoL was altered through regular monitoring [7].

The indication for BPH treatment primarily took into account the severity score and that of the quality of life assessed by the International Prostatic Symptoms Score (IPSS) coupled with the Quality of Life (QoL), self-administered questionnaires.

These were supplemented by Prostatic Specific Antigen (PSA) which reflects cell proliferation, digital rectal examination (dependent examiner) and ultrasound to assess the volume of the gland.

The blood level of creatinine and the cytobacteriological examination (ECBU) completed the primary explorations of BPH [8-16]. Medical treatment, even if it avoids complications such as frequent acute urinary retention (AUR) and surgery, still has a high cost [17].

Coulange C also said that from the 8th year it will cost as much as surgical treatment [18].

The high cost of various treatments for uncomplicated BPH justified a previous study on local herbal medicine that meets international, African and even Congolese recommendations and practices. The first signs of improvement according to Poirier [7] were for 8-14 day α-blockers.

In the previous study presented by us, they had appeared from the 14th day but confirmed at the 1st check-up (one month).

While conventional medical treatment for BPH is known to be lifelong and susceptible to side effects, improvement with *Plantago major* and *Solanum aculeastrum* phyto-medication was noted over the 27 months of the study without any toxicity [19, 20].

Objective

At the end of the previous study, it was recognized that while conventional medical treatment should be subject to periodic medical check-ups (every 6 months) [7], follow-up should also be done in patients receiving phytotherapy in in order to determine the real duration of its beneficial effects and to propose the action to be taken.

Hence the meaning of this evaluation after a 15-month break from herbal medicine with *Plantago major* and *Solanum aculeastrum* here considered as a new drug [4] against uncomplicated BPH.

Material and Methods

Type of study: this was a comparative cross-sectional study of the results of herbal medicine for benign prostatic hyperplasia with *Plantago major* and *Solanum aculeastrum* for 27 months (01-01-2019 to 31-03-2021) according to the traditional practitioner scheme and after a 15-month break, i.e. on 30-06-2022.

This break had not been determined by the traditional practitioner, it was imposed on us by the concern to better understand the effectiveness of this treatment.

Patients: 68 patients who received phytotherapy during the above period, namely male subjects aged 60 and over with uncomplicated BPH or comorbidities.

Methods: all these patients had benefited from a prior histopathological examination in the previous study, which confirmed BPH.

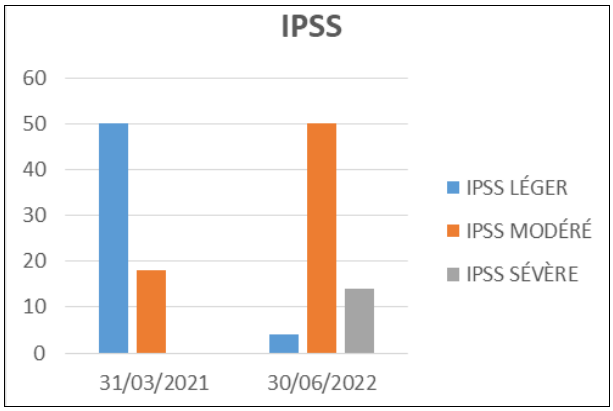
It is currently a question of evaluating by the clinic (IPSS-QdV, TR) and the paraclinical (PSA, ultrasound) in the same way as for the first study [19].

So we used

1. The IPSS-QoL questionnaire to know the degree of severity (mild, moderate, severe) and the deterioration of the quality of life (satisfied or bored).
2. to PSA to identify the level of cellular activity of the gland due to possible hyperplasia.
3. The PSA was performed using the Ichroma II automaton from Boditech Med Int (South Korea 2018) (Normal rate 0-4 ng/ml).
4. on TR and ultrasound to assess the volume of the prostate: small (≤40cm3), medium (40-70cm3), large (≥70 cm3).
5. The ultrasound was performed by a specialist in medical imaging using the Bruel and Kjaer model ultrasound scanner (BK Medical 7.5MHZ USA 2005).

Results

1. IPSS

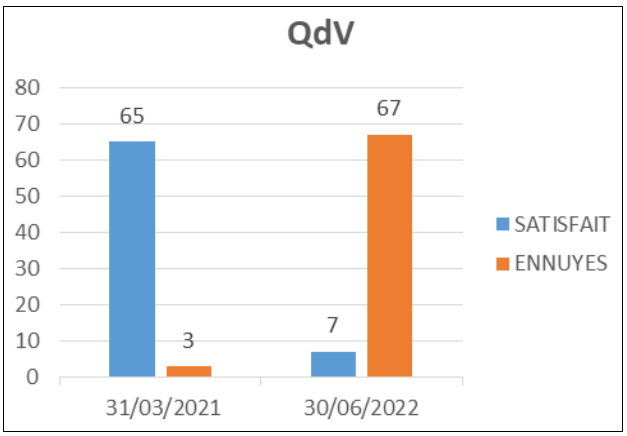


For the IPSS, it was observed that the light score cases represented 73.5% in March 2021 while it fell to 6% at the current evaluation; the moderate score represented 26.5% in 2021, whereas it was estimated at 74% at appraisal.

There was reappearance of the severe score at the evaluation with 21% of the cases.

Thus the deterioration in the health of patients in 2022 with regard to the IPSS was proven by the $\chi 2$ test ($p<0.05$) compared to 2021.

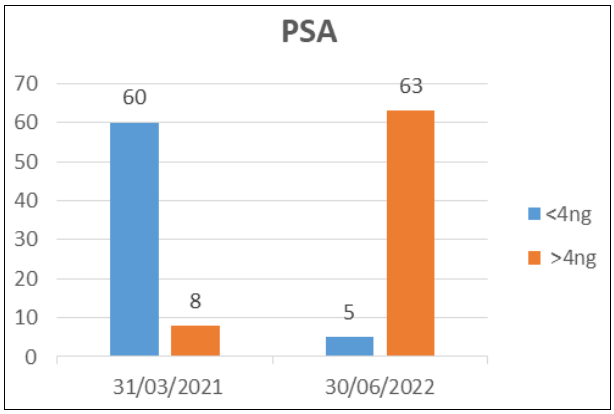
2. QdV



The number of cases with satisfaction was higher in 2021, i.e. 95.6% compared to 9.5% at appraisal. Conversely, the number of annoyed cases was estimated at 4.4% in 2021 and 90.5% at appraisal. The deterioration in the health of patients in 2022 with

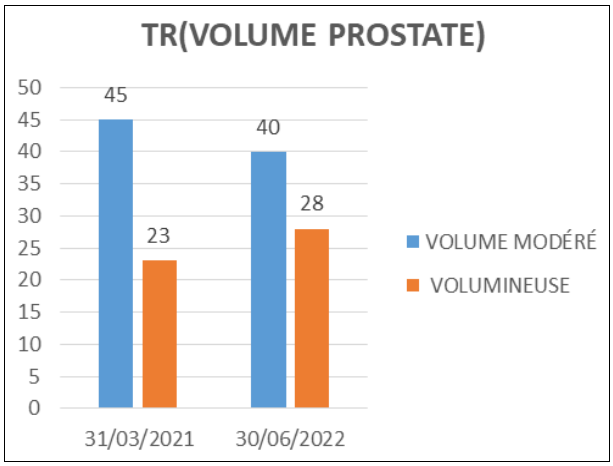
regard to QoL was proven by the

3. PSA



The number of cases with a PSA level on 03/31/2021 < 4 ng was 88.2%, well above 7.4% at assessment; conversely, the number of cases rate > 4 ng 11.8% in 2021 was lower than that found at appraisal 92.6%. This led us to accept that there was dependence in the results compared to the year 2021 and 2022. (p0.00<0.05).

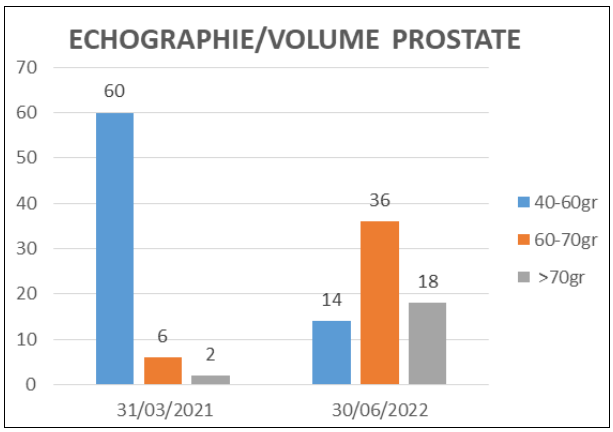
4. TR



The number of moderate volume cases, which represented 66.2% in 2021, was found to be slightly higher than 58.8% at appraisal; but the voluminous situation in 2022, i.e. 41.2%, was slightly higher than that of 2021, i.e. 33.8% of cases.

The statistical calculations reflect the independence of the results between the two years concerning the TR (p 0.524>0.05).

5. Echographie



As of March 31, 2021, the number of cases with a volume between 40 -60 g was 88.2%, far higher than 21% on 06/30/22.

Volume 60-70g cases were 8.8% and >70g at 2.94% low compared to 53% and 26% respectively at assessment.

The results were dependent on the 2 study years, i.e. the variations observed in 2022 are 95% linked to the procedures in 2021 (p 0.00 <0.05).

Discussion

Overall almost in all cases the rates for 2021 are better than those for 2022.

We did not find in our documentation any evaluation of the results of the authors quoted in the previous study who published on herbal medicine in general, that of BPH, in particular.

However, we found new authors who published on the review of medicinal plants used against BPH in Nigeria [21].

Mazin *et al* again reviewed the effectiveness of herbal medicine for urinary disorders, primarily BPH, without mentioning a treatment evaluation control schedule [22].

Leonard SM *et al* claimed that the Saw palmetto plant mix appeared to be reassuring and a very desirable option for men with uncomplicated BPH. However, it seemed to have only slightly better clinical effects than the placebo. They however noted that this mixing was associated with epithelial reduction especially in the transition zone (p 0.01) indicating its mechanism of action which underlies the significant clinical effect shown in other studies [23].

Eszter Csikós *et al* recognized that the tolerance of herbal medicine was expressed by the lesser side effects in contrast to conventional molecules.

On the other hand, that more information was needed on phytomedication in order to reassure on its safety [24]. We understood, from the above, that herbal medicine was still the subject of studies for its efficiency and that it was appropriate, on our part, to evaluate its distant results in order to draw useful recommendations.

We thought it would be useful to study the parameters that helped us with the evaluation, namely:

1. The IPSS-QdV

For Curtis N *et al*, the IPSS-Qdv and the PSA were, after the interview, the TR, and the visual examination of the urine, the starting point for the diagnosis and follow-up of patients with voiding disorders related to BPH [25].

Seisen Th *et al* said that the impact of urinary functional signs was assessed by IPSS and Qdv [26].

Duperron C [27] and the French College of Urology [8] have set the stages of the examination of the patient to arrive at the diagnosis. These are, after the interrogation, the TR, the PSS and the QdV. They are used to assess functional signs.

Cottaz V added the recommendation to rewrite the IPSS and the QoL by adapting them to other global aspects of the patient's social life in relation to the well-being of the "prostate patient" [28].

The Malaysian authors insisted on the use of IPSS, flow measurement and post-void volume in the evaluation of the medical management of BPH [29]. This step in the BPH examination is therefore important.

2. PSA

The Canadian authors considered PSA as an indicator of prostate cancer and as a predictor of the progression of BPH. They

relativized the results of herbal medicine compared to placebo because of the lack of pharmacokinetic studies and monitoring regulation.

There was also no significant difference between herbal medicine and placebo in IPSS, urine output, prostate volume, PSA and quality of life. However, they recognized the few side effects and lent it significant potential for interaction with other drugs [30].

Heldfand M *et al* have confirmed that in the case of medical treatment alone or in combination, the use of ultrasound and PSA level determination is required to assess the risk of tumor progression [31].

In this study, the significant increase in the number of patients with high PSA levels observed during this evaluation seemed to be the logical associated sign of the alteration of the parameters mentioned in point 1.

3. TR

The volume of the prostate does not always correspond to the extent of functional urinary signs.

Indeed, the National Association for Accreditation and Evaluation in Health (ANAES) in France has confirmed that this examination is "operator-dependent" and therefore also depends on the perception of the clinician [32].

She further clarified this by noting the absence of parallelism between the high frequency of BPH, an anatomical fact, and the lower frequency of LUTS reported by patients [33].

The HAS has also said that the volume alone is not an indication for starting treatment [34].

Bengaly S, said that non-symptomatic BPH does not require any medical treatment.

Indeed, the treatment must take into account the functional impact, the complications and the patient's background [35].

In our case, the little information provided by this examination could not hinder the evaluation thanks to the study of other parameters.

4. Ultrasound

The Association of Medical Ultrasound, in 2011, recognized that ultrasound was developed to assist practitioners in undertaking ultrasound examination in the practice of urology.

While no abnormality is detected on clinical examination, the use of ultrasound could maximize the probability of answering the question raised by the clinic [36].

Nur Banu Albayrak and Yusuf Sinan considered that the examination of the volume of the prostate by ultrasound offered many advantages such as carriage, the least cost, the absence of invasion and the relevance of the operation in time real [37].

Even veterinarians have been able to use ultrasound to assess the improvement in dogs with BPH treated with osaterone acetate and deslorelin acetate, anti-androgen molecules [37].

Manzoor T *et al* confirmed that acute urinary retention was one of the major complications of BPH.

This caused resistance to the flow of urine and resulted in very painful urination.

Also, ultrasound was considered the mode of choice for exploration of the prostate because of its lack of invasiveness during this clinical drama [39].

Ultrasound has enabled Delin Wang *et al* in Singapore to better determine the relationship between prostate volume and medial lobe syndrome in their responsibility for acute urinary obstruction. In fact, median lobe syndrome was more predictive of acute obstruction than prostate volume, hence the importance of its early diagnosis [40].

This shows the interest of the objective information provided by this examination during this evaluation.

Conclusion and Recommendation

The deterioration of the clinical and paraclinical parameters that were the subject of our study after a 15-month break without phytomedication led, despite the lack of analogous situations among the authors read, to the decision to go beyond the duration of the27 month treatment. The episode mode, namely three months treatment – six months break, would be respected according to the prescription of the traditional practitioner and repeated according to the severity and quality of life of the patient(s).

The evaluation after every 27 months, duration of a cure, would be recommended in order to test the efficiency and the toxicity.

Conflict of Interest

Not available

Financial Support

Not available

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