# SHORT-TERM RESULTS OF CURCUMIN, QUERCETIN, HYALURONIC ACID AND CHONDROITIN SULFATE (IALURIL SOFT GEL®) IN THE MANAGEMENT OF CHRONIC PROSTATITIS/PRIMARY PROSTATE PAIN SYNDROME: A SINGLE-CENTER PROSPECTIVE STUDY.

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## Introduction

Management of Chronic Prostatitis/Primary Prostate Pain Syndrome (CP/PPPS) is challenging and characterized by conflicting results.
The philosophy for the management of chronic pelvic pain is based on a bio-psychosocial model. This is a holistic approach with patients' active involvement.

**Figure 1.** Phenotyping of pelvic pain - UPOINT classification

| Phenotyping | Assessment |
|---|---|
| Urology | Urinary flow, micturition diary, cystoscopy, ultrasound, uroflowmetry. |
| Psychology | Anxiety about pain, depression and loss of function, history of negative sexual experiences. |
| Organ specific | Ask for gynaecological, gastro-intestinal, ano-rectal, sexological complaints. Gynaecological examination, rectal examination. |
| Infection | Semen culture and urine culture, vaginal swab, stool culture. |
| Neurological | Ask for neurological complaints (sensory loss, dysaesthesia). Neurological testing during physical examination: sensory problems, sacral reflexes and muscular function. |
| Tender muscle | Palpation of the pelvic floor muscles, the abdominal muscles and the gluteal muscles. |
| Sexological | Erectile function, ejaculatory function, post-orgasmic pain. |

## Aim of the study

This study aimed to evaluate the efficacy of a food supplement based on Curcumin, Quercetin, Hyaluronic Acid and Chondroitin Sulfate (Ialuril Soft Gel®) in CP/PPPS treatment.

## Study Design, Methods and Materials

This is a **single cohort pilot study**.

Data of consecutive male patients who referred to our Institution for CP/PPPS were prospectively collected between Oct-2022 and Jan-2023.

**Exclusion criteria**:
- maximum flow rate < 15 ml/s,
- post-void residual > 150 ml
- previous prostate surgery were excluded.

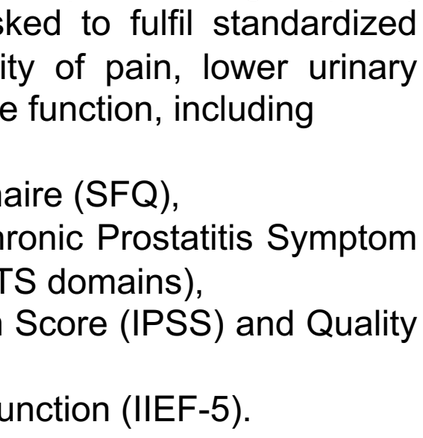
Variables including age, body mass index (BMI), prostate volume (PVol) and serum prostate specific antigen (PSA) were collected. Patients were asked to fulfil standardized **questionnaires** to assess severity of pain, lower urinary tract symptoms (LUTS) and erectile function, including
- Symptom Severity Index (SSI),
- Symptom Frequency Questionnaire (SFQ),
- National Institutes of Health Chronic Prostatitis Symptom Index (NHI/CPSI) (pain and LUTS domains),
- International Prostate Symptom Score (IPSS) and Quality of Life score (IPSS-QoL), and
- International Index of Erectile Function (IIEF-5).

Changes in standardized questionnaires were evaluated at baseline, 30- and 90-days after enrolment.

Patients were administered with **Ialuril Soft Gel®** (curcumin 200 mg, quercitin 200 mg, hyaluronic acid 100 mg, chondroitin sulfate 200 mg) 2 gel caps **once a day** for 60 days.

**Table 1.** Ialuril Soft Gel composition.

| | 2 gel caps dose (mg) |
|---|---|
| Curcumin | 200 |
| Quercitin | 200 |
| Hyaluronic Acid | 100 |
| Chondroitin sulfate | 200 |




## Results

Twenty patients were analyzed. Baseline features were age [median 50 years (IQR 46-51)], BMI [24.2 (22.8-28.3)], PVol [42 ml (30-52)], PSA [1.0 ng/ml (0.8-1.8)], SSI [54 (27-55)], SFQ [20 (13-26)], NHI/CPSI [pain domain 10 (8-13); LUTS domain 7 (4-8)], IPSS [13 (10-18)], IPSS-QoL [3 (2-3)] and IIEF-5 [17 (14-22)].

SSI and SFQ scores showed statistically significant differences both at 30- [SSI 45 (22-49), p < 0.001; SFQ 16 (11-20), p = 0.035] and 90-days [SSI 33 (17-42), p < 0.001; SFQ 13 (9-16), p < 0.001].

IPSS and NHI/CPSI pain and LUTS domains showed statistically significant differences at 30-days [IPSS 12 (10-13), p = 0.002; NHI/CPSI pain domain 6 (5-9), p < 0.001; NHI/CPSI LUTS domain 7 (2-9), p = 0.033, respectively], but not at 90-days (all p > 0.05).

IPSS-QoL and IIEF-5 scores did not report any statistically significant difference during follow-up (p=0.12 and p=0.23, respectively).

**No adverse events** were recorded.

**Table 2.** Validated questionnaires results at baseline, 30 days of treatment, 90 days after starting treatment (= 30 days after end of treatment).

| | Baseline | 30 days of treatment | | 90 days after starting treatment | |
|---|---|---|---|---|---|
| SSI | 54 (27-55) | 45 (22-49) | **p < 0.001** | 33 (17-42) | **p < 0.001** |
| SFQ | 20 (13-26) | 16 (11-20) | **p = 0.035** | 13 (9-16) | **p < 0.001** |
| NHI/CPSI | pain domain 10 (8-13) LUTS domain 7 (4-8) | pain domain 6 (5-9) LUTS domain 7 (2-9) | **p < 0.001** **p = 0.033** | pain domain 7 (5-11) LUTS domain 8 (3-9) | p = 0.2 p = 0.33 |
| IPSS | 13 (10-18) | 12 (10-13) | **p = 0.002** | 11 (10-13) | p=0.6 |
| IPSS-QoL | 3 (2-3) | 3.2 (2-4) | p=0.12 | 3.3 (2-4) | p=0.15 |
| IIEF-5 | 17 (14-22) | 18 (13-21) | p=0.23 | 18 (14-22) | p=0.3 |

## Interpretation of results

PPPS is a complex condition which needs of a multimodal and phenotypically directed treatment options.

The food supplementation based on Curcumin, Quercetin, Hyaluronic Acid and Chondroitin Sulfate may positively impact pain, QoL and urinary symptoms in men.

## Conclusions

Ialuril Soft Gel® seems to be effective in reducing the severity of pain and urinary symptoms in CP/PPPS patients at short-term follow-up.
Further powered studies are mandatory to better comprehend the role of Ialuril Soft Gel ® in the management of CP/PPPS.

## References

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## Disclosure

**Funding This study has been supported by IBSA - Caring Innovation**
Clinical Trial, No Subjects, Human Ethics Committee: Comitato Etico Lazio1 Helsinki Yes Informed Consent Yes