

Efficacy of pollen extract in association with group B vitamins for pain relief in chronic prostatitis/chronic pelvic pain syndrome: A survey of urologists' knowledge about its clinical application

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Summary *Introduction and aim of the study: Chronic prostatitis/chronic pelvic pain syndrome (CP/CPSS) is a pathology of high prevalence in Italian male population, difficult to diagnose and to treat and with poor response to conventional therapy.*

Aim of this study was to review the evidence of the literature about the therapeutic effects of a plant product containing flower pollen extracts and group B vitamins on symptoms resolution and amelioration of CP/CPSS patients' quality of life and to investigate the knowledge among practicing urologists about the clinical application of this product.

Materials and methods: A group of 38 urologists was submitted to an investigational survey of the knowledge of the clinical applications of a plant product containing flower pollen extracts and group B vitamins

Results: 71% of the urologists interviewed prescribed the plant product for CBP and CP/CPSS at least one time in a month and 11% prescribed it more than 5 times; 67% had evidence of clear ameliorations in pain relief and on patient's quality of life and 47% reported that the effectiveness is comparable to NSAIDs; 39% also reported a significant effect for the improvement of the urinary symptoms of patients. No gastric or general side effects have been noticed during the administration period of this plant product. Finally, the cost of the product has always reported to be sustainable for the patients.

Conclusions: From the results of this investigational survey, we can state that the plant product containing flower pollen extracts and group B vitamins is well-known and demonstrated beneficial effects on symptoms resolution and amelioration of quality of life in patients with chronic prostatitis/chronic pelvic pain syndrome.

KEY WORDS: *Chronic prostatitis; Chronic pelvic pain syndrome; Prostatic benign diseases; Inflammation; Pollen extracts; Group B vitamins.*

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INTRODUCTION

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPSS) has a very high prevalence in Italian population, estimated by a recent multicenter observational study to affect about 13.8% of the male population with an age between 25 and 50 years old.

Several studies in Literature evaluate the prevalence of

CP/CPSS in male population. This disorder, difficult to treat, has multiple consequences on lifestyle and on sexual life.

Furthermore, CP/CPSS is a chronic disease, with unsatisfactory results from conventional therapy. Among the multiple therapeutic approaches, long term administration of pollen extracts has been demonstrated to have a precise role in the limitation of flogistic process.

Bacterial and non-infectious chronic prostatitis could represent inciting factors leading to tissue hyper-proliferation and chronic inflammation, probably by an immuno-modulation mediated by prostatic stromal cells, enabling them to induce and sustain intra-glandular immune responses. Group B vitamins have been demonstrated to be capable to interfere with this mechanism, reducing the inflammatory component of CP/CPSS.

Finally, folic acid is well known for its anti-oxidant properties, who join a central role in the reduction of the Intracellular reactive oxygen species (ROS). Several recent studies reported the active role of this vitamin in reducing this component. This factor has a role in the IPB/ Inflammatory pathogenesis.

Commonly CP/CPSS requires a prolonged treatment with anti-inflammatory drugs like corticosteroid or non-steroidal anti-inflammatory drugs (FANS) in combination with antibiotics that can lead to gastrolesive and nephrotoxic side effects. About that aspect, really relevant for clinicians who face this pathology, phytotherapeutics are hopeful options of treatment due to their generally minimal side effects. Many studies in literature have shown that pollen extract and B vitamins induced a significantly and durable reduction of symptoms in patients with CP/CPSS with a relevant improvement in quality of life.

The aim of this paper is to review the actual state of art for clinical application of *Deprox 500*[®] (flower pollen extracts and group B vitamins) in the treatment of CP/CPSS. Furthermore, we realized an internal survey in our department to investigate the actual knowledge and application of this supplement in current clinical practice in an area of Italy.

No conflict of interest declared.

MATERIALS AND METHODS

Deprox 500[®] is a phytotherapeutic composed of flower pollen extract (1000 mg), B1 vitamin (1.4 mg), B2 vitamin (1.6 mg), B6 vitamin (2.0 mg), B12 vitamin (1.0 µg), folic acid (300 µg), PP vitamin (18 mg). It can be used for treatment of prostate chronic inflammatory processes often cause of irritative and obstructive symptoms: bacterial prostatitis, abacterial prostatitis, prostatodynia. Its posology is two tablets in a single dose daily and it can be administered for prolonged time for it generally minimal side-effects. Clinical use of this phytotherapeutic is based of molecular effect of its components and their synergic effects.

In order to understand how this dietary supplement is prescribed, in which patients and with which symptoms, we drafted a rapid and concise survey (Table 1). We administered this questionnaire to 10 residents in urology at the *University of Modena and Reggio Emilia* and to 28 urologists working in the provinces of *Modena and Reggio Emilia*.

The questionnaire was answered by mail or through direct compilation, anonymously. The sample was limited, but representative of the two provinces of Modena and Reggio Emilia, who have a population of about 1.3 million of citizens.

RESULTS

Investigational survey on *Deprox*[®]

All the 38 physicians completed the questionnaire in all its parts demonstrating that *Deprox 500*[®] is a known product in this area, with a wide diffusion between young and senior urologists.

By the results (Table 2), it is evident that CBP and CP/CPSP are common pathological conditions. The 58% of physicians have diagnosed those pathologies in 3-6 patients during a month, and 13% of them in more than 6 patients during the same period of time.

11% of physicians surveyed did not believe in the use of dietary supplements for the treatment of any medical condition and consequently refused the use of *Deprox 500*[®] whereas 71% prescribed *Deprox 500*[®] at least one time in a month and 11% prescribed it more than 5 times.

The clear majority of physicians who utilized *Deprox 500*[®] prescribed it correctly for CBP and CP/CPSP.

9% of physicians who prescribe *Deprox 500*[®] haven't noticed a significant improvement in pain relief and on patient's quality of life suffering from CBP or CP/CPSP, while the 67% had evidence of clear ameliorations and 47% reported that the effectiveness is comparable to NSAIDs. Furthermore 39% also reported a

significant effect for the improvement of the urinary symptoms of patients.

No gastric or general side effects have been noticed during the administration period of *Deprox 500*[®]. Finally, the cost of the integrator has always reported to be sustainable for the patients.

Table 1.
Investigational Survey on *Deprox*[®].

<ul style="list-style-type: none"> • How many times have you diagnosed Chronic Bacterial Prostatitis (CBP) or Chronic pelvic pain syndrome/chronic prostatitis (CP/CPSP) during the last month? <ul style="list-style-type: none"> • 0-3 times • 4-6 times • > 6 times
<ul style="list-style-type: none"> • Do you trust in alimentary supplement (non pharmacological therapy) for the treatment of urological disorders? <ul style="list-style-type: none"> • yes • no
<ul style="list-style-type: none"> • How many times have you prescribed <i>Deprox</i>[®] during the last month? <ul style="list-style-type: none"> • 0 times • 1-5 times • > 5 times
<ul style="list-style-type: none"> • For which urological diseases have you prescribed <i>Deprox</i>[®] ? <ul style="list-style-type: none"> • none • Chronic Bacterial Prostatitis (CBP) in combination with antibiotic therapy chronic prostatitis or Chronic pelvic pain syndrome/chronic prostatitis (CP/CPSP) • others urologic diseases (specify)
<ul style="list-style-type: none"> • Have you noticed an improvement in the quality of life of patients affected of Chronic Bacterial Prostatitis (CBP) or Chronic pelvic pain syndrome/chronic prostatitis (CP/CPSP) with combination of <i>Deprox</i>[®] + antibiotic therapy? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • yes • no
<ul style="list-style-type: none"> • Have you noticed an improvement in pain symptoms? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • yes • no
<ul style="list-style-type: none"> • Have you noticed ameliorations comparable with the results obtained with Fans? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • yes • no
<ul style="list-style-type: none"> • Have you noticed an improvement in urinary symptoms? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • yes • no
<ul style="list-style-type: none"> • Have patients reported occurrence of gastric side effects after assumption of <i>Deprox</i>[®]? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • yes • no
<ul style="list-style-type: none"> • Have patients reported occurrence of other side effects after assumption of <i>Deprox</i>[®]? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • Yes (specify) • no
<ul style="list-style-type: none"> • Is the cost of <i>Deprox</i>[®] affordable for the majority of patients? <ul style="list-style-type: none"> • I do not use <i>Deprox</i>[®] • yes • no

Table 2.
Survey results.

	a n (%)	b n (%)	C n (%)
• How many times have you diagnosed Chronic Bacterial Prostatitis (CBP) or Chronic pelvic pain syndrome/chronic prostatitis (CP/CPPS) during the last month?	11 (29%)	22 (58%)	5 (13%)
• Do you trust in alimentary supplements (non pharmacological therapy) for the treatment of urological disorders?	34 (89%)	4 (11%)	
• How many times have you prescribed Deprox® during the last month?	7 (18%)	27 (71%)	4 (11%)
• For which urological diseases have you prescribed Deprox® ?	9 (24%)	28 (73%)	1 (3%)
• Have you noticed an improvement in the quality of life of patients affected of Chronic Bacterial Prostatitis (CBP) or Chronic pelvic pain syndrome/chronic prostatitis (CP/CPPS) with combination of Deprox® + antibiotic therapy?	9 (24%)	26 (67%)	3 (9%)
• Have you noticed an improvement in pain symptoms?	9 (24%)	26 (67%)	3 (9%)
• Have you noticed ameliorations comparable with the results obtained with Fans?	9 (24%)	18 (47%)	11 (29%)
• Have you noticed an improvement in urinary symptoms?	9 (24%)	15 (39%)	14 (37%)
• Have patients reported occurrence of gastric side effects after assumption of Deprox®?	9 (24%)	0 (0%)	29 (76%)
• Have patients reported occurrence of other side effects after assumption of Deprox®?	9 (24%)	0 (0%)	29 (76%)
• Is the cost of Deprox® affordable for the majority of patients?	9 (24%)	29 (76%)	0 (0%)

DISCUSSION

From the investigational survey on *Deprox 500*®, it can be assumed that it is a dietary supplement widely used by the urologists in our area. The absence of side effects makes it easily and safely administrable for long periods, especially when compared to NSAIDs, which for many physicians are not considered superior for long-term pain control and expose patients to the risk to of gastric or renal side effects. The number of physicians surveyed is limited, but the data reported on the amount of prescriptions and on patient feedback to their physicians indicate that the product has a positive impact on long-lasting diseases as CBP or CP/CPPS.

Flower pollen extracts contained in *Deprox 500*® have an antioxidative action that presents an important role in treatment of many prostate inflammatory diseases.

The product is similar to *Cernilton* that was used by *Rugendorff et al.* in their study to evaluate the effect of treatment with pollen extract in chronic prostatitis and prostatodynia. In this research, 56 of 90 (78%) treated patients had a favorable response, in particular 26 (36%) recovered from their symptoms and 30 (42%) showed a functional improvement, with an increase in flow rate and a decrease of microbiological and physical infection related markers in urine and ejaculate (1).

Another interesting study realized by *Kamijo T et al.* shows the effect of cernitin pollen extracts on experimental sex-hormone induced nonbacterial prostatitis in rats. Cernitin pollen extract consist in a preparation composed by eight different pollens, of a water soluble fraction (T-60) and of a fat soluble fraction (GBX).

These fractions were administered separately. They observed that pollen extracts protect acinar epithelial cells mainly by GBX and inhibits stromal proliferation in

association with enhanced apoptosis mainly by T-60 (2). *Wagenlehner et al.* conducted in 2009 a multicenter, prospective, randomized, double-blind, placebo-controlled phase 3 study comparing the pollen extract (*Cernilton*) to placebo in patients affected by CP/CPPS. They demonstrated that, compared to placebo, the pollen extract significantly improved total symptoms, pain, and QoL in men with inflammatory CP/CPPS without any relevant side-effect. A 12-week administration of pollen extracts resulted in a significantly symptom improvement compared to control group, without any kind of side-effects.

The effects of *Cernilton* were also assessed for the treatment of benign prostate hyperplasia, that is a condition often related to chronic prostatitis with a systematic review by *Macdonald et al.* who pointed out that *Cernilton* is well tolerated and modestly improves urological symptoms associated with prostate hyperplasia (3).

Many studies in literature show an important role of group B vitamins in chronic pain molecular path-ways. *Mader et al* evaluated the vitamin status of inpatients with chronic cephalgia and dysfunction pain syndrome and demonstrated the benefic effects of a vitamin supplementation. They demonstrated that 65% of the patients involved into the study had a subclinical vitamin deficiency and they divided them in two groups treated respectively with a vitamin supplementation and with a placebo. A clear reduction in pain was presented in the active-treatment group and a deterioration of pain was more frequently observed in the placebo group (4).

Wang et al. investigated the analgesic role of the B vitamins thiamine (B1), pyridoxine (B6) and cyanocobalamin (B12) in rats with neuropathic pain. They assessed that these vitamins at high doses can effectively reduce

pain and thermal hyperalgesia caused by peripheral sensory neuron injury. Repetitive administration of B vitamins produces a long-term inhibition in both severity and duration of pain and thermal hyperalgesia. This study suggests the clinical utility of the B vitamins in treatment of neuropathic pain due to injury, degeneration or other disorders in the nervous systems (5).

Deprox 500[®], due to its composition, can potentially induce the benefic effects of both components: flower pollen extract and B group vitamins.

Cai et al. realized a meaningful study to evaluate the efficacy of pollen extract in association with vitamins (*Deprox 500*[®]) for pain relief in order to improve the quality of life of young patients affected by chronic prostatitis type IIIb (CP/CPPS). In this study, 20 young men with clinical and instrumental diagnosis of CP/CPPS underwent a treatment consisting of 2 tablets of *Deprox 500*[®] in a single daily dose for 30 days. The main outcome assessment was the improvement of quality of life evaluated by questionnaires about the symptomatology. The treatment significantly improved total symptoms, pain and QoL in patients, without relevant side effects. The association with vitamins seemed to improve the antioxidant activity of the pollen extract and the protective effect on the nerves against chronic hyperalgesia (6). The absence of severe side effects is relevant, because CP/CPPS requires a prolonged treatment and common antiinflammatory drugs like FANS can result in relevant side effects.

About that, *Cai et al.* realized a randomized controlled phase III study, including 87 young patients treated with *Deprox 500*[®] or ibuprofen to evaluate the effect of pollen extract in associations with vitamins treatment in order to early pain relief in patients affected by chronic prostatitis/chronic pelvic pain syndrome. Of the 87 enrolled patients 41 received *Deprox 500*[®] and 46 received 600 mg ibuprofen. *Deprox 500*[®] significantly ameliorated the total symptoms, pain and quality of life compared with ibuprofen without severe side effects (4). These results are encouraging and justify the clinical application of *Deprox 500*[®] in these pathological conditions.

CONCLUSIONS

Many studies in Literature have shown that pollen extract and B vitamins induced a significantly and durable reduction of symptoms in patients with CP/CPPS with a relevant improvement in quality of life. Moreover, the absence of

several side effects during prolonged treatment is really considerable. Our investigational survey about the use of *Deprox 500*[®] by physicians has showed that the product is recognized and has a proved beneficial effect.

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