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Subjective effects of *Lepidium meyenii* (Maca) extract on well-being and sexual performances in patients with mild erectile dysfunction: a randomised, double-blind clinical trial

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Summary

Lepidium meyenii (Maca) is a cultivated root belonging to the brassica family used in the Andean region for its supposed aphrodisiac properties. We carried out a double-blind clinical trial on 50 Caucasian men affected by mild erectile dysfunction (ED), randomised to treatment with Maca dry extract, 2400 mg, or placebo. The treatment effect on ED and subjective well-being was tested administrating before and after 12 weeks the International Index of Erectile Function (IIEF-5) and the Satisfaction Profile (SAT-P). After 12 weeks of treatment, both Maca- and placebo-treated patients experienced a significant increase in IIEF-5 score ($P < 0.05$ for both). However, patients taking Maca experienced a more significant increase than those taking placebo (1.6 ± 1.1 versus 0.5 ± 0.6, $P < 0.001$). Both Maca- and placebo-treated subjects experienced a significant improvement in psychological performance-related SAT-P score, but the Maca group higher than that of placebo group ($+9 \pm 6$ versus $+6 \pm 5$, $P < 0.05$). However, only Maca-treated patients experienced a significant improvement in physical and social performance-related SAT-P score compared with the baseline ($+7 \pm 6$ and $+7 \pm 6$, both $P < 0.05$). In conclusion, our data support a small but significant effect of Maca supplementation on subjective perception of general and sexual well-being in adult patients with mild ED.

Introduction

Lepidium meyenii (Maca) is an Andean cultivated root that belongs to the brassica (mustard) family. Dried Maca root is rich in amino acids, iodine, iron and magnesium. Traditionally, Maca root has been used in the Andean region for its supposed aphrodisiac and/or fertility-enhancing properties (Rowland & Tai, 2003). Some but not definitive support exists for its ability to improve male sexual function. In 1549, the visiting Spanish Encomandero of Soto Mayor was given Maca as a tribute which he subsequently used to improve the fertility of livestock in Spain (Obregon, 1998). Despite anecdotal evidence, different studies carried out in sexually experienced and naïve rodents suggest that Maca may improve sexual behaviour independently of its eventual action on spontaneous locomotor activity (Zheng *et al.*, 2000; Cicero *et al.*, 2001, 2002). The sexual behaviour improvement is also associated to an improvement of some reproductive parameters such as epididymal sperm count (Gasco *et al.*, 2007) and daily sperm production in the rat (Gonzales *et al.*, 2006), but also protection of sperm vitality against some noxae such as reduced air oxygen saturation (Gonzales *et al.*, 2004) or toxic agents (Bustos-Obregon *et al.*, 2005; Rubio *et al.*, 2006). Other pre-clinical data show that Maca root has other positive

andrological effects such as prostate hyperplasia preventing action (Gonzales *et al.*, 2008) and regression of testosterone-induced prostate hyperplasia (Gonzales *et al.*, 2007).

Scientific studies on humans are limited to some observations by Gonzales *et al.* In one preliminary study, carried out on nine young adult subjects to evaluate the effect of a 4-month oral treatment with tablets of Maca (1500 or 3000 mg per day) on seminal analysis, the authors observed a significantly increased seminal volume, sperm count per ejaculum, motile sperm count, and sperm motility without modification in sexual hormones serum level (Gonzales *et al.*, 2001). These data were subsequently confirmed in two 3-month, randomised, double-blind trials (Gonzales *et al.*, 2002, 2003). In this context, we carried out a double-blind randomised, clinical trial on Caucasian men affected by mild erectile dysfunction (ED) in order to test the Maca efficacy in subjects different than Peruvians and the efficacy relation with subjective well-being beyond direct sexual effect.

Materials and methods

The double-blind, randomised clinical trial was carried out on consecutively enrolled 50 young adult subjects (mean age 36 ± 5 years old) affected by mild ED not related to serious psychiatric diseases, endocrinological diseases, active cardiovascular diseases or consumption of drugs known to alter sexual performances. All patients were in fact selected on the basis of absence of comorbidities, preliminary psychological evaluation and the results of laboratory analyses (gonadotrophins, prolactin, total and free testosterone, glycaemia, total and free prostate-specific antigen). The ED level was defined as an International Index of Erectile Function (IIEF-5) score comprised between 17 and 21 (Rosen *et al.*, 1997).

The enrolled patients were double-blindly randomised to treatment with pulverised dehydrated Maca root tablets (directly imported from Peruvian Andes and kindly provided by Ibersan Srl, Forli, Italy), 1200 mg two times daily, or fully similar placebo tablets 1200 mg two times daily for a period of 12 weeks.

The effects of Maca intake on ED and subjective well-being was tested before and after 12 weeks of treatment using the IIEF-5 (Rosen *et al.*, 1997) and the Satisfaction Profile (SAT-P) (Majani *et al.*, 2000), and comparing the baseline hormonal level with the final one.

The IIEF-5 test is made up of five questions aimed at investigating the sexual life health of the man, with specific attention to the presence and degree of ED. Each answer has a grading from 1 to 5; the final score consent to discriminate patients with severe (5–7 points), moderate (8–11 points), mild-to-moderate (12–16 points), mild (17–21 points) and no ED (22–25 points) (Rosen *et al.*, 1997). This test was performed by the physician.

The SAT-P test is made up of 32 items related to the satisfaction of different daily life aspects in the last month: physical, psychological, cognitive, social and professional performance. The final score was calculated in a range going from 0 to 100 (Majani *et al.*, 2000). This test was given to the patient for self-filling. All patients gave their informed consent to participate in the study whose protocol had been approved by the ethics committee.

Data management and statistical analysis

Sampled data were inserted and encoded in a specific database by trained personnel. A complete descriptive analysis was evaluated. The baseline IIEF and SAT-P test score of Maca- and placebo-treated groups were compared with the Mann–Whitney *U*-test, while the pre-treatment versus post-treatment scores were compared by the Wilcoxon test. The correlation between baseline IIEF-5 score and treatment efficacy was tested by a linear regression. A $P < 0.05$ was considered as statistically significant for all tests (Norman & Streiner, 2007).

Results

At baseline, Maca- and placebo-treated patients had similar scores of IIEF and SAT-P tests. Eighty per cent of patients, equally distributed among the treatment groups, exhibited some psychological complaints, relative to mild depressive symptoms such as asthenia, desire lack and problem solving difficulties.

After 12 weeks of treatment, both Maca- and placebo-treated patients experienced a significant increase in IIEF-5 score ($P < 0.05$ for both). However, patients taking Maca experienced a more significant increase than those taking placebo (1.6 ± 1.1 versus 0.5 ± 0.6, $P < 0.001$). The Maca improving effect on IIEF-5 score appears to be inversely related to the baseline IIEF-5 score ($B = -0.733$, Beta $= -0.831$, $t = -7.164$, $P < 0.001$) (Fig. 1).

The change in the different components of the SAT-P test in both treatment groups is shown in Table 1. Both Maca- and placebo-treated subjects experienced a significant improvement in psychological performance-related SAT-P score, but it was higher in the Maca group than in the placebo group ($+9 \pm 6$ versus $+6 \pm 5$, $P < 0.05$). However, only Maca-treated patients experienced a significant improvement in physical and social performance-related SAT-P score compared with the baseline ($+7 \pm 6$ and 7 ± 6, both $P < 0.05$). No significant differences were observed with regard to cognitive and professional performance-related SAT-P score in both treatment groups

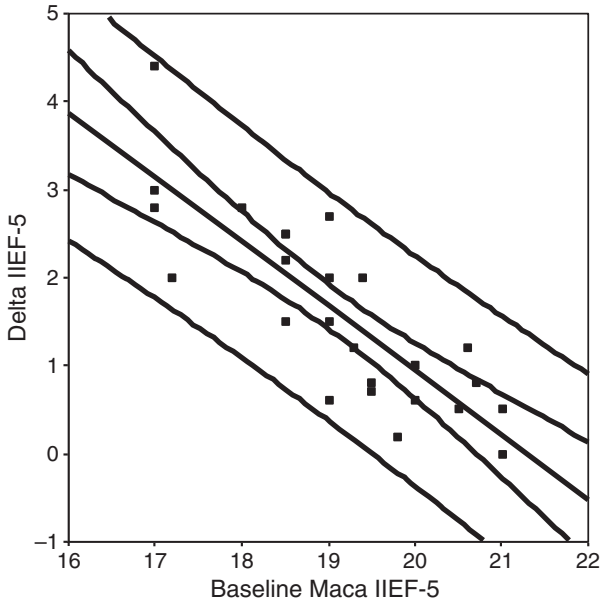

Fig. 1 Relationship between International Index of Erectile Function (IIEF-5) baseline score and Maca efficacy expressed as IIEF-5 change after treatment (n = 25).

when compared with the baseline values. No significant change was observed at the end of the study with regard to the hormone levels (Table 2). No complaints of adverse events were registered in both treatment groups.

Discussion

Erectile dysfunction is a widely diffuse disease defined as the inability to achieve and/or maintain an erection for a satisfactory sexual intercourse. In the adult male population, it is estimated to have a prevalence ranging from 12 to 52% (Rosenberg, 2007). The aetiology is often multifactorial, with a psychological basis (Hunt & McHale, 2007) frequently overlapping a sub-clinical or clinically known organic cause (Sivalingam *et al.*, 2006). In this context, a placebo response of 25–50% has been recorded in clinical trials with effective agents (Moyad, 2002), and it explains also why dietary supplements and complementary treatment use is widely accepted by patients with ED even if supported by relatively small scientific evidences (Tamler & Mechanick, 2007). Andean Maca is one of the most commonly cited natural drugs on internet as sexual dysfunction improvers. This claim is supported by a relatively large pre-clinical evidence (Zheng *et al.*, 2000; Cicero *et al.*, 2001, 2002) and from small trials carried out by a single research group on Peruvian subjects (Gonzales *et al.*, 2001, 2002, 2003). However, some authors suggest that Maca has no direct androgenic activity (Bogani *et al.*, 2006) and that at least part of its effect is due to its nutritional property being rich in essential aminoacids and minerals (Balick & Lee, 2002). Moreover, a recent pre-clinical study has shown that acute and short-term administration of Maca produced a small effect of rat male sexual behaviour without interaction with anxiety levels (Lentz *et al.*, 2007). In our study, we tested the Maca supplementation effect on the subjective perception of general and sexual well-being in young adult patients with mild ED. After 12 weeks of treatment, both Maca- and placebo-treated patients experienced a significant increase in IIEF-5 score, however, patients taking Maca experienced a more significant increase than those taking placebo. Both Maca- and placebo-treated subjects experienced a significant improvement in psychological performance-related SAT-P scores, but it was higher in the Maca group than in the placebo group. Therefore, only Maca-treated patients experienced a significant improvement in physical and social performance-related SAT-P scores compared with the baseline. No significant differences were observed regarding cognitive and

Table 1 Baseline and post-treatment mean SAT-P scores divided for each SAT-P questionnaire item in patients taking Maca or placebo

	Maca-treated patients		Placebo-treated patients	
Performance	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Physical	74 ± 7	81 ± 7*	72 ± 7	76 ± 7
Psychological	71 ± 7	80 ± 7*	70 ± 6	76 ± 6*
Cognitive	75 ± 7	76 ± 6	77 ± 7	76 ± 7
Social	72 ± 7	79 ± 7*	71 ± 6	75 ± 7
Professional	67 ± 6	69 ± 6	68 ± 6	67 ± 6

SAT-P, Satisfaction Profile.
*P < 0.05 when compared with the baseline value.

Table 2 Baseline and post-treatment serum level of gonadotrophins, prolactin, total and free testosterone in Maca and placebo-treated subjects

	Placebo-treated subjects		Maca-treated subjects	
	Baseline	Post-treatment	Baseline	Post-treatment
FSH (mU ml^{-1})	5.2 ± 0.8	5.3 ± 0.6	5.4 ± 0.5	5.3 ± 0.7
LH (mU ml^{-1})	5.1 ± 0.9	5.2 ± 0.8	5.3 ± 0.6	5.2 ± 0.8
Prolactin (ng ml^{-1})	15.9 ± 1.1	15.6 ± 1.2	15.4 ± 1.0	15.2 ± 0.9
Total testosterone (ng ml^{-1})	6.2 ± 0.7	6.0 ± 0.9	5.9 ± 0.8	6.1 ± 0.9
Free testosterone (pg ml^{-1})	12.1 ± 1.1	11.8 ± 0.9	12.4 ± 1.2	12.5 ± 1.0

FSH, follicle-stimulating hormone; LH, luteinising hormone.
Values are expressed as mean ± standard deviation.

professional performance-related SAT-P scores in both treatment groups when compared with the baseline values.

Of course, our study has some limitation, such as the relatively small number of studied subjects, their young age and mild level of ED, which could have reduced the possibility to observe higher efficacy of Maca in patients with more serious disease. In fact, we observed that the Maca improving effect on IIEF-5 scores appears to be inversely related to the baseline IIEF-5 scores. Another limitation was the lack of measurement of fertility parameters, but this was not the aim of our study. Instead, we aimed at evaluating the possible efficacy and tolerability of a Maca treatment in ED patients with regard to their subjective perception of their problem. Moreover, a further potential limit of the study is its relatively short length to observe the maximal achievable effects on a chronic disease such as ED; however, it is a preliminary trial, and its length is similar to that tested by Gonzales *et al.* (2002, 2003).

Because a Maca action on central nervous system has been supposed (Rubio *et al.*, 2007) and because well-being perception is strongly related to sexual performances (Wylie, 2008), it is yet difficult to discriminate if Maca exerts its action primarily on erectile function or centrally or both. In conclusion, our data support a small but significant effect of Maca supplementation on subjective perception of general and sexual well-being in young adult patients with mild ED.

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