

IDRACARE STUDY

A high concentration of niosomal hyaluronic acid moisturizing gel for vaginal dryness and dyspareunia. A clinical trial final results

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Objective:

Evaluate the safety and effectivity of a moisturizing vaginal gel with high concentration of hyaluronic acid niosomes, prebiotics and *Aloe vera* (Idracare® Gel) for treatment of the symptoms associated with genitourinary syndrome of menopause (GSM).

Methods:

Multicenter, prospective, single-arm, pilot clinical trial carried out in Spain. Peri/postmenopausal women aged 40 to 65 referring moderate or severe vaginal dryness and/or dyspareunia were recruited. Patients were treated with one single-dose cannula containing 5 mL of Idracare® Gel, twice a week for 12 weeks. Results on the intensity of the aforesaid symptoms –change vs baseline on a Visual Analogue Scale (VAS) where 0=no dryness/dyspareunia and 10=maximum dryness/dyspareunia– and on the Bachmann Vaginal Health Index (BVHI) at 12 weeks are presented. Satisfaction and tolerability were also evaluated.

Results:

A total of **127 patients** participated in the study

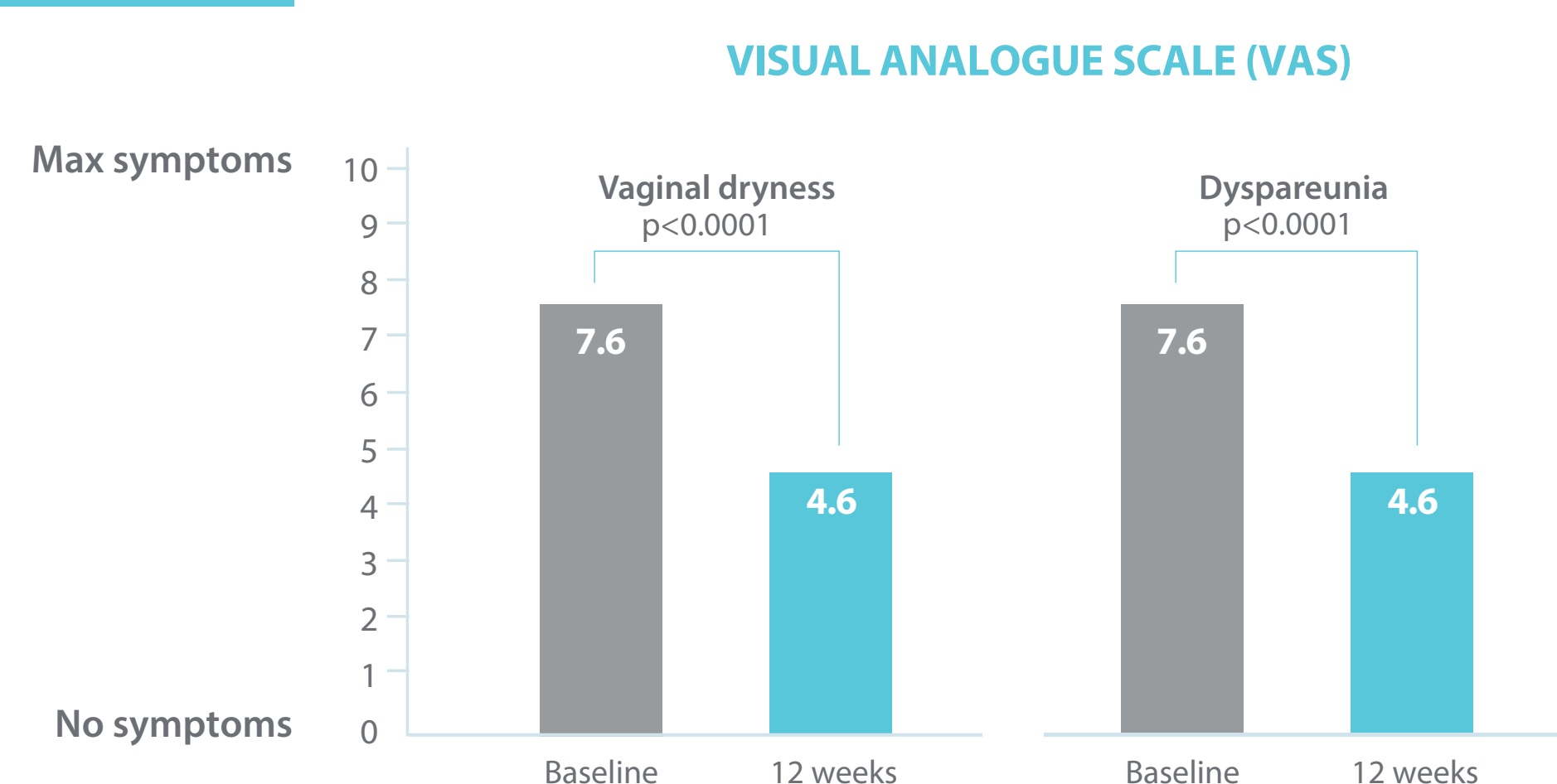


Figure 1: Punctuations obtained in the VAS for dryness and dyspareunia after 12 weeks treatment.

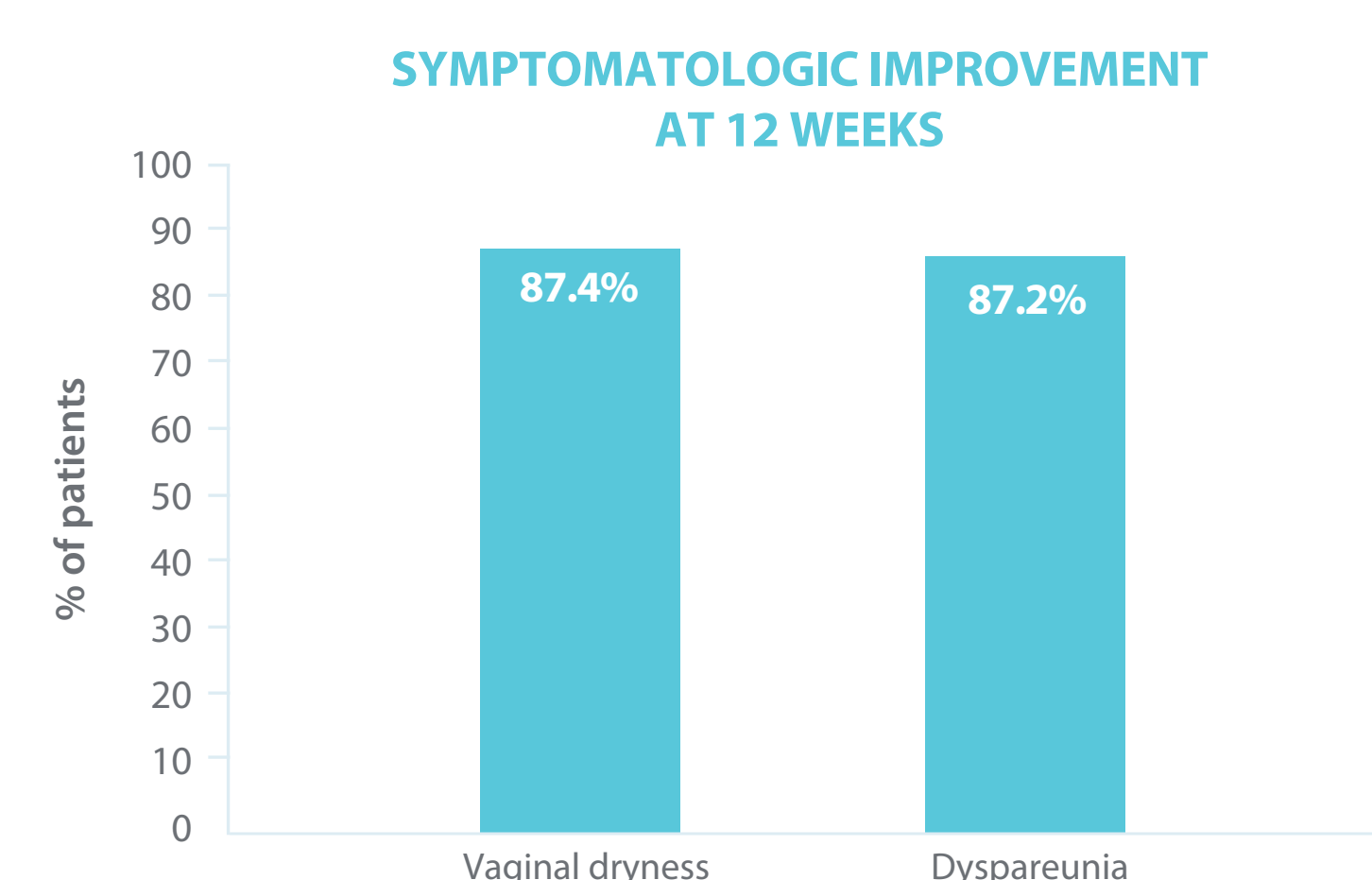


Figure 2: Percentage of women who improved vaginal dryness and dyspareunia after 12 weeks.

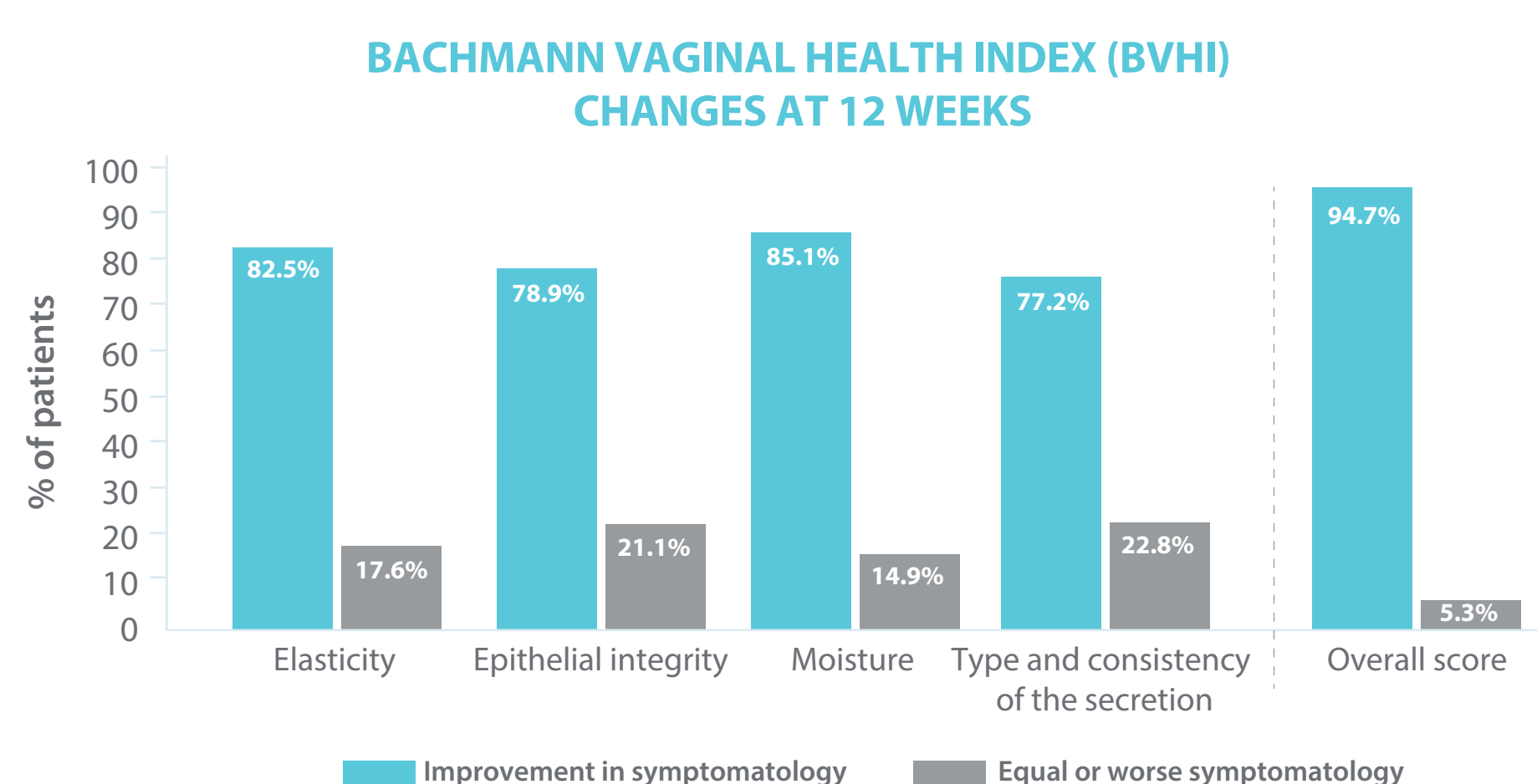


Figure 3: Percentage of patients that improved, maintained or worsened their symptomatology of vaginal health status through the BVHI at 12 weeks.

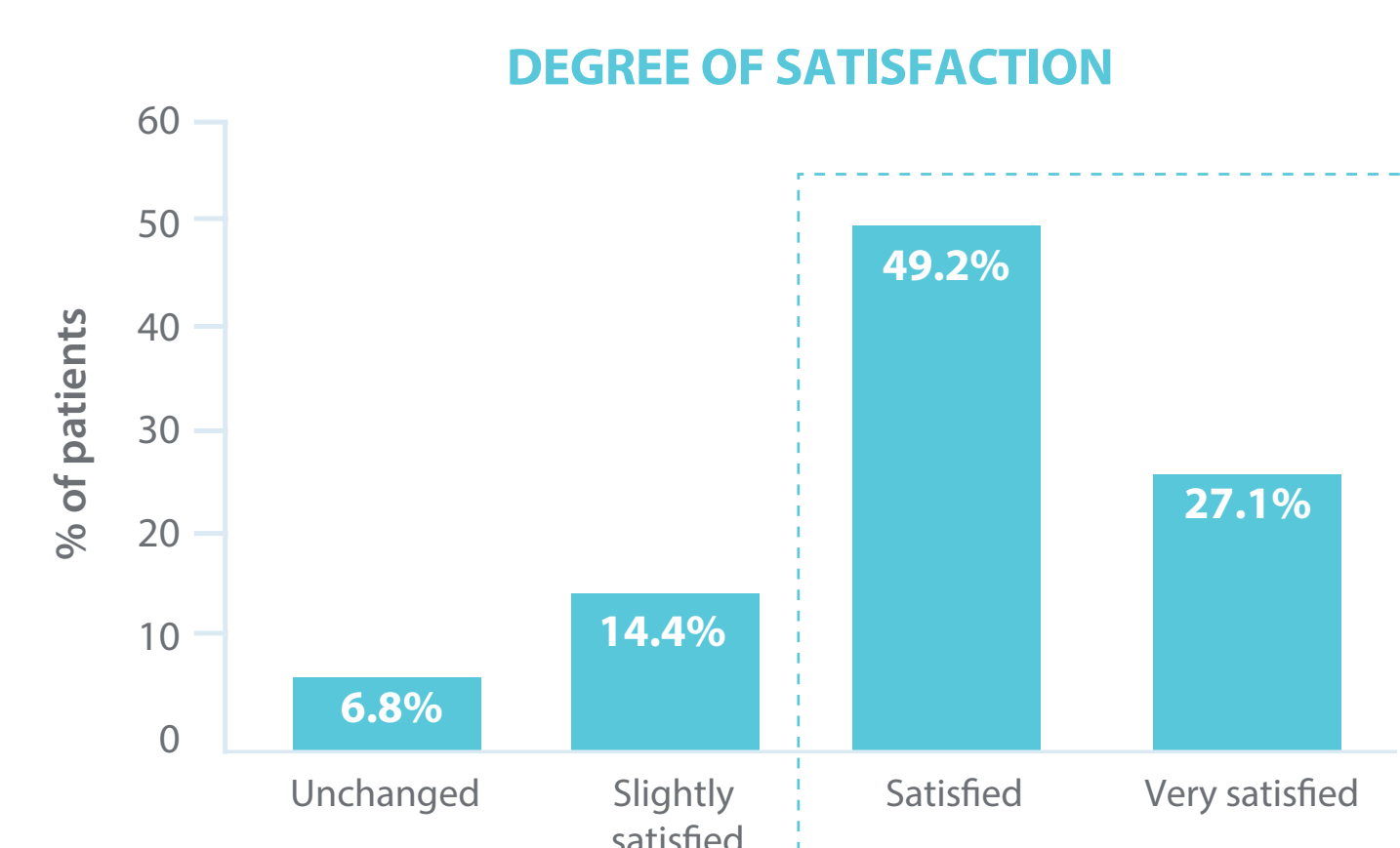


Figure 4: Percentage of satisfaction after 12 weeks of treatment using a 7 points Likert Scale from very unsatisfied to very satisfied.

*None of the participants reported any grade of dissatisfaction

No serious adverse events were reported during the study. Only 2 patients reported itching

Conclusions:

Significant improvement of vaginal dryness and dyspareunia, as well as of overall vaginal health was observed upon 12 weeks of treatment with Idracare® Gel in peri/postmenopausal women with GSM. Treatment showed a very good tolerability and high satisfaction.