

# TOPICAL TREATMENT OF ACUTE OTITIS EXTERNA: CLINICAL COMPARISON OF AN ANTIBIOTICS OINTMENT ALONE OR IN COMBINATION WITH HYDROCORTISONE ACETATE

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## Objectives

The study was designed to investigate the potential contribution of hydrocortisone acetate to the efficacy and safety of an antibiotics ointment in the treatment of acute otitis externa (AOE).

## Methods

In a double-blind study 151 patients with a unilateral acute bacterial otitis externa were randomized either to receive an ointment with polymyxin-B sulfate (7,500 I.E./g) + bacitracin (300 I.E./g) alone (AB) or the same antibiotic ointment with 10mg hydrocortisone acetate /g ointment (AB+HC).

## Outcome measures

Primary efficacy endpoint was the change of an aggregate clinical symptom score (CSS) (subscores: redness, swelling, pain and secretion) found at Visit 2 vs. baseline (Visit 1). Secondary outcome parameters were the change of the CSS from Visit 1 to the study termination, and the changes in the subscores and of a visual analog scale (VAS) for pain.

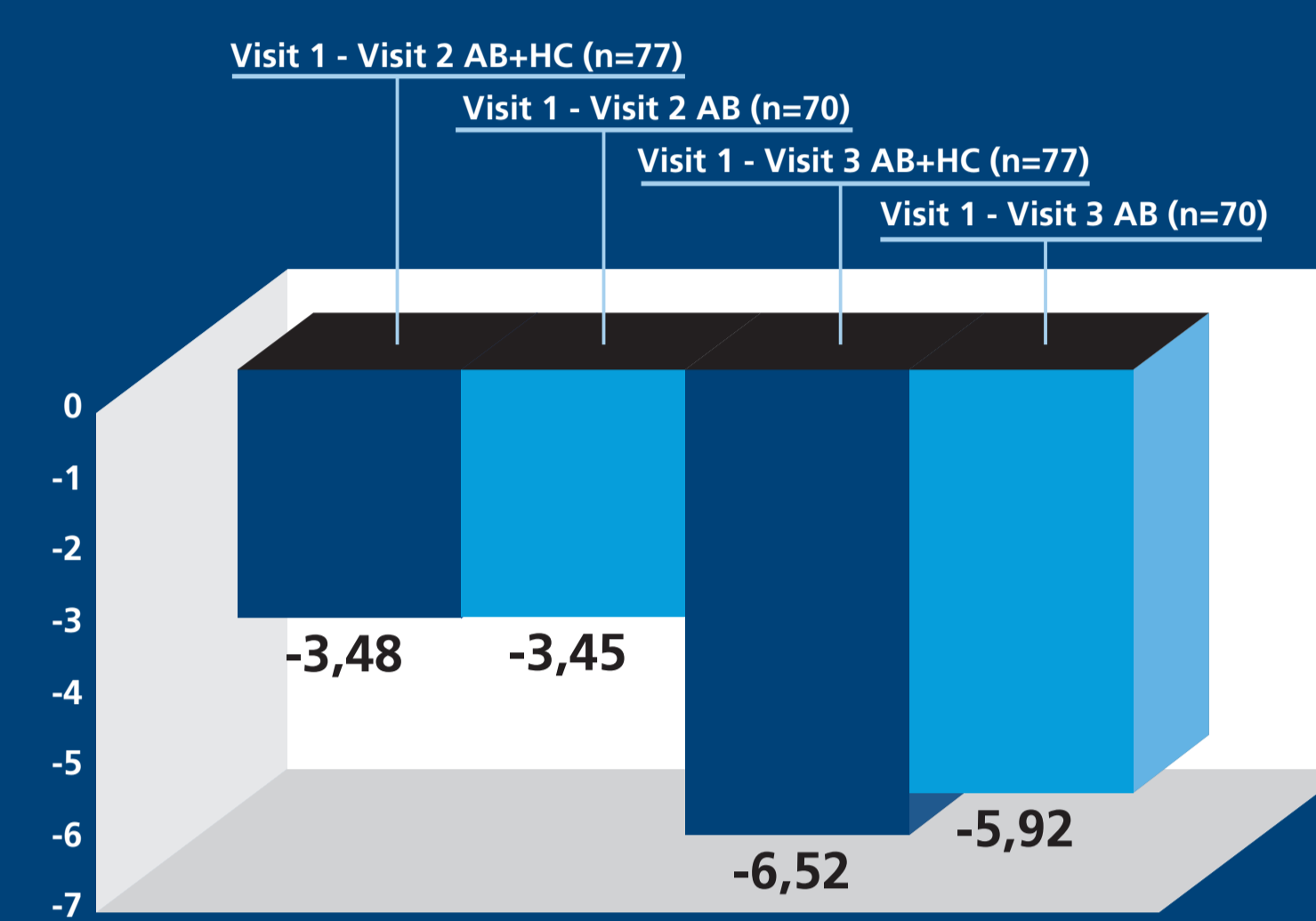
## Results

In the group treated with AB+HC, significantly more patients with severe redness (14 (56%) vs. 7 (28%),  $p=0.045$ ) or severe secretion (23 (70%) vs. 10 (40%),  $p=0.024$ ) at inclusion were symptom-free at the last visit. Fewer pain-relieving tablets ( $1.1 \pm 2.2$  vs.  $2.3 \pm 4.6$  paracetamol tablets) were used in the AB+HC-group. In the steroid group there was a slightly larger though not significant reduction in CSS at Visit 2 and Visit 3 vs. baseline. Similar results were documented for redness, pain and secretion. No serious adverse events occurred.

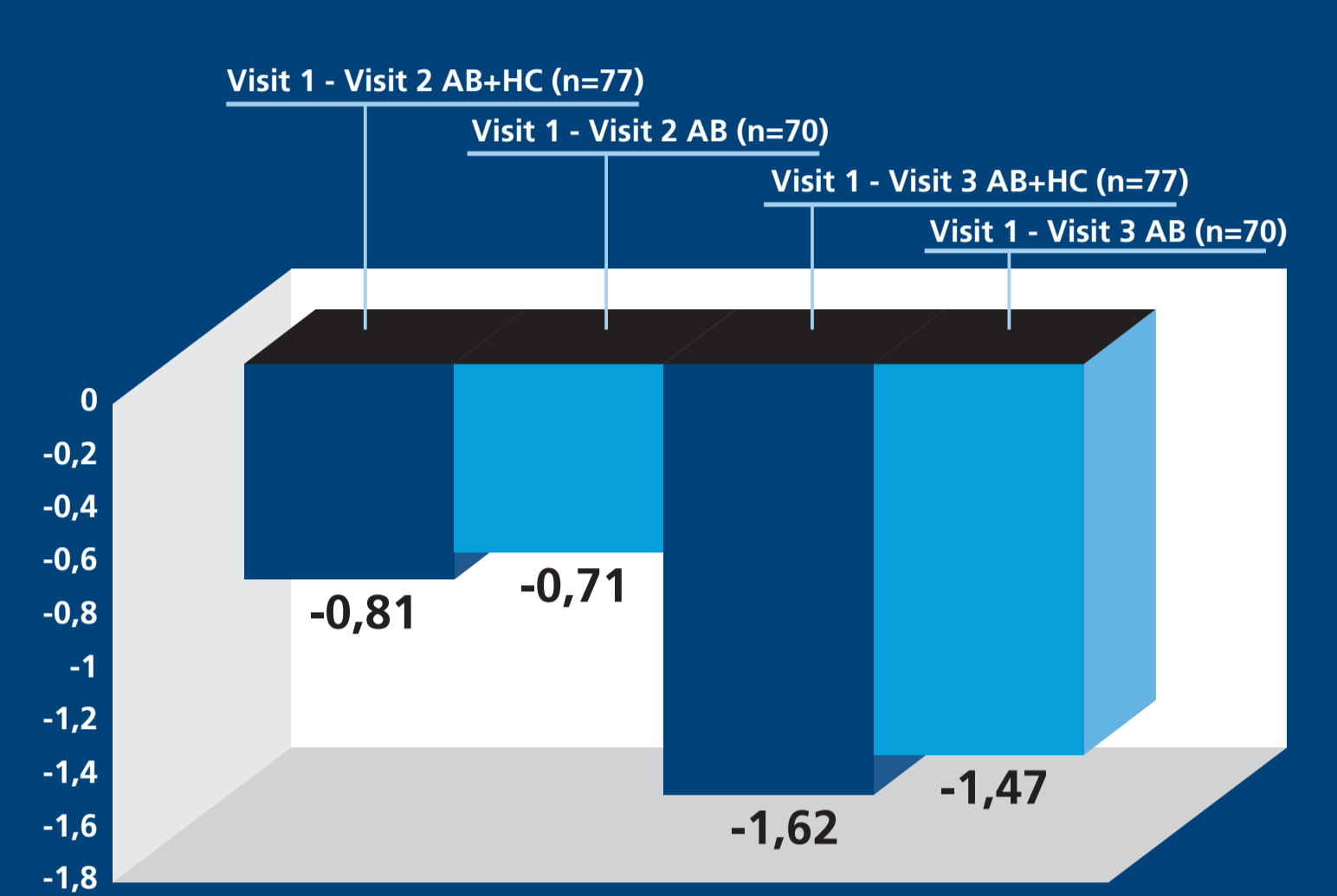
## Conclusion

Both ointments are effective and safe in the topical treatment of AOE. Hydrocortisone acetate combined with the antibiotics improved individual symptoms better as did the steroid - free ointment.

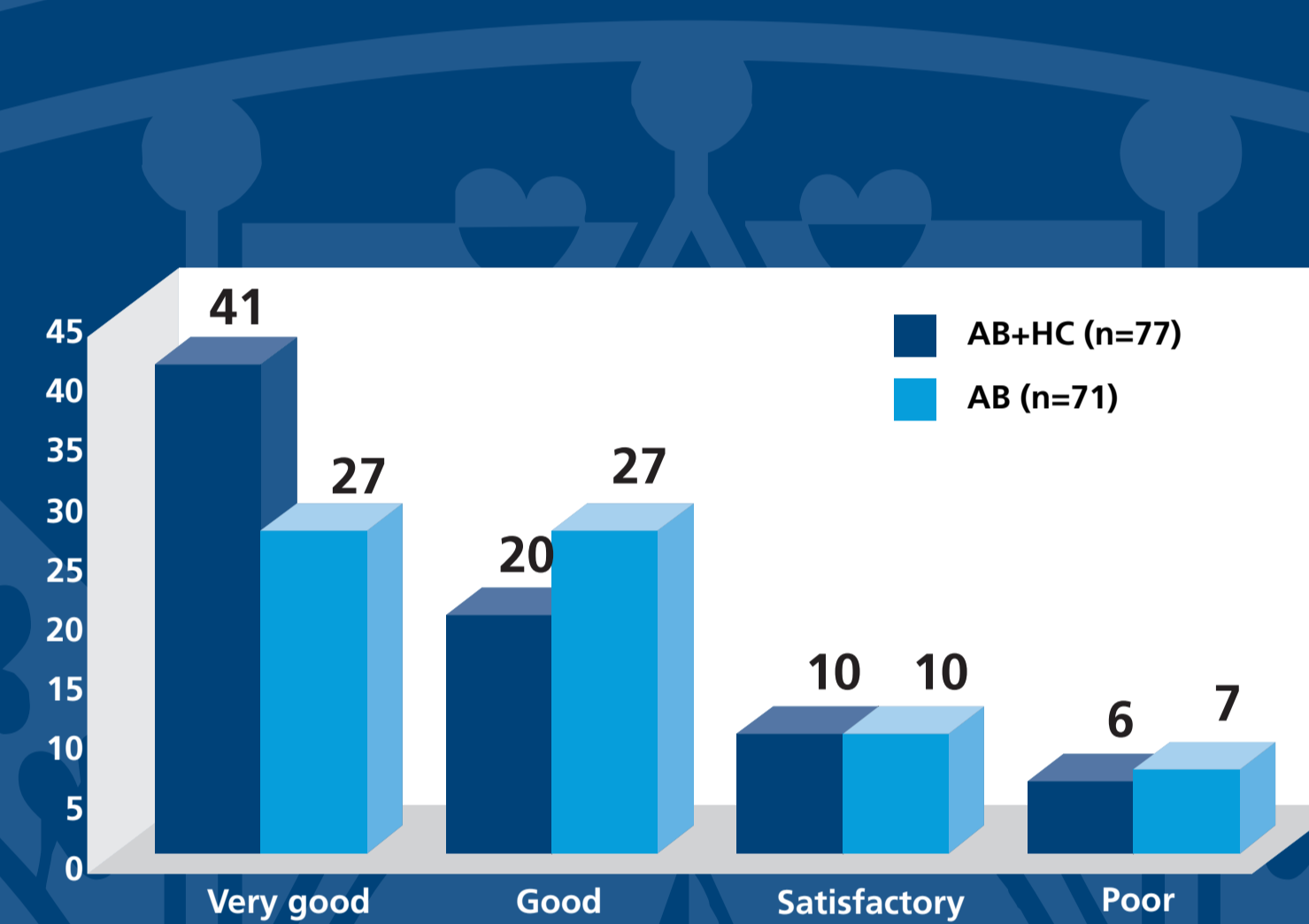
Mean change of the CSS (ITT)



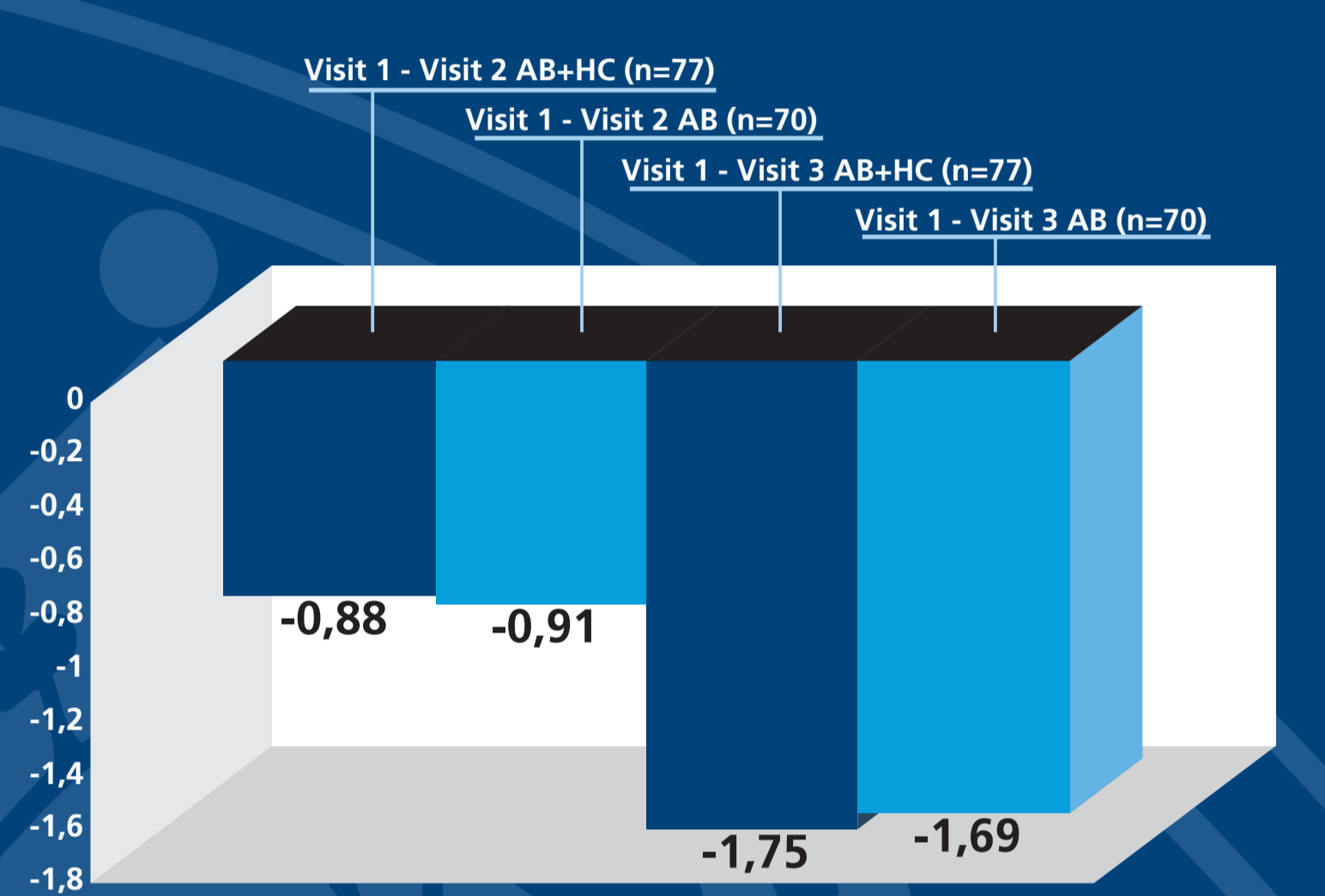
Mean change of redness (ITT)



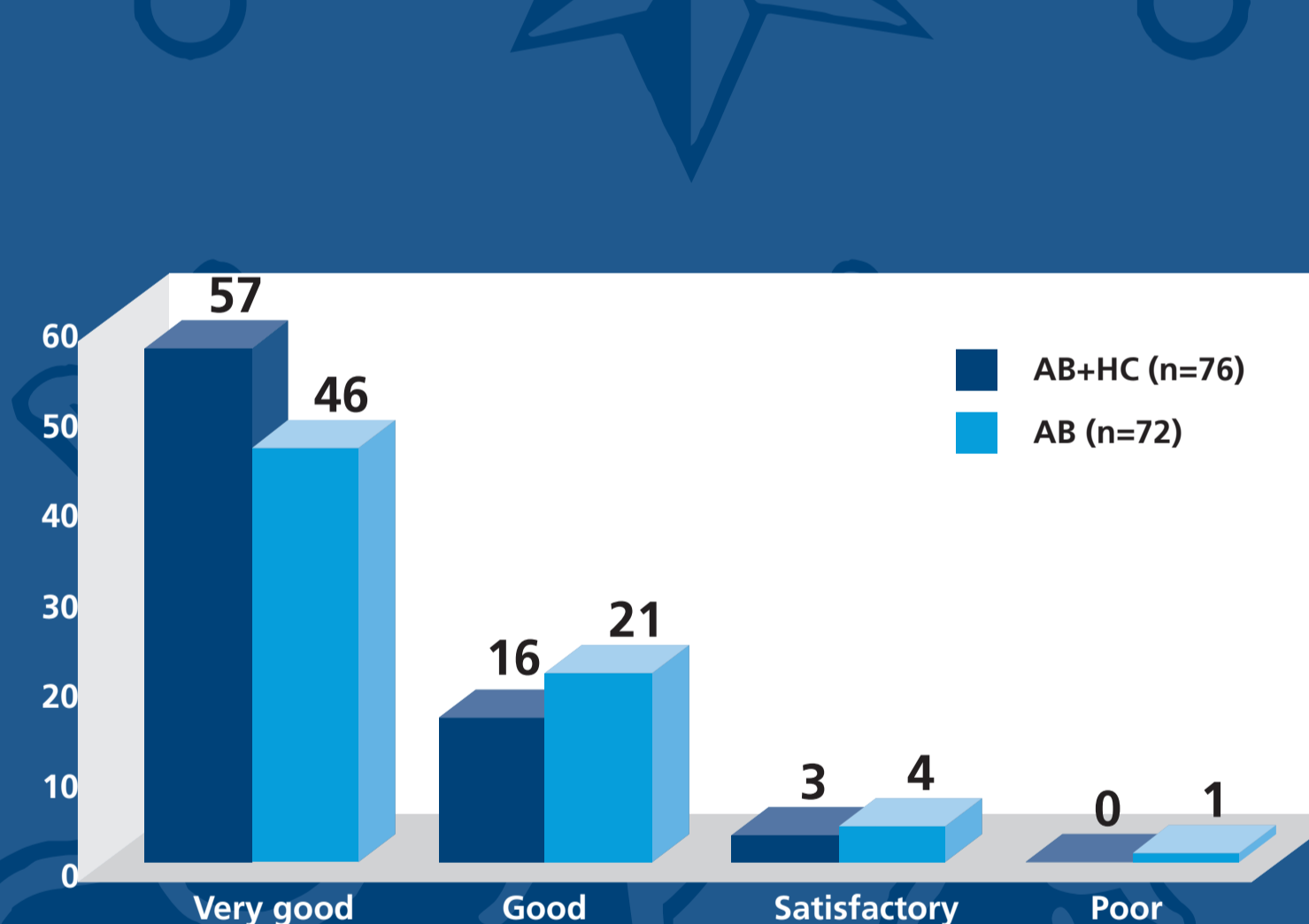
Efficacy - Patients (ITT)



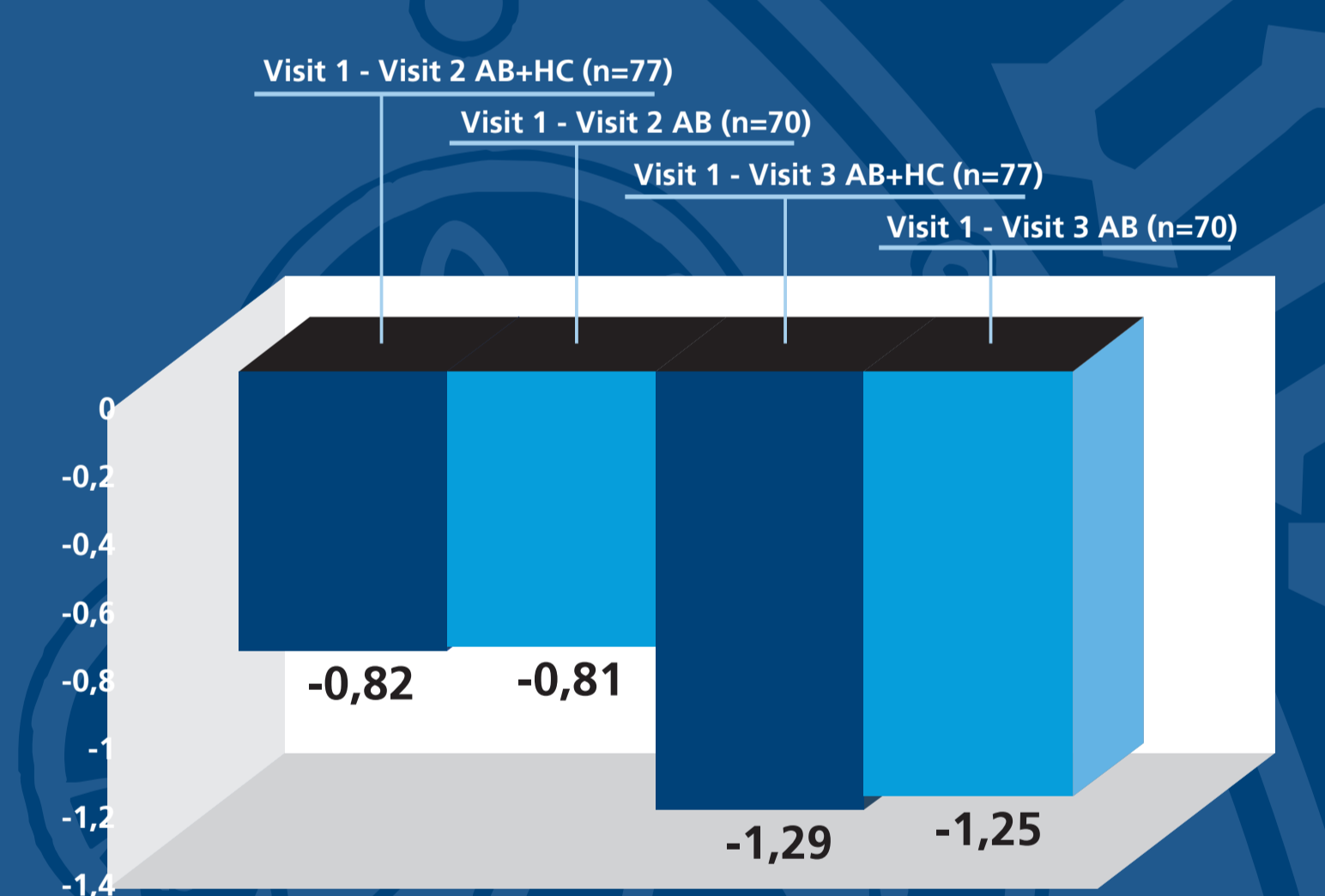
Mean change of swelling (ITT)



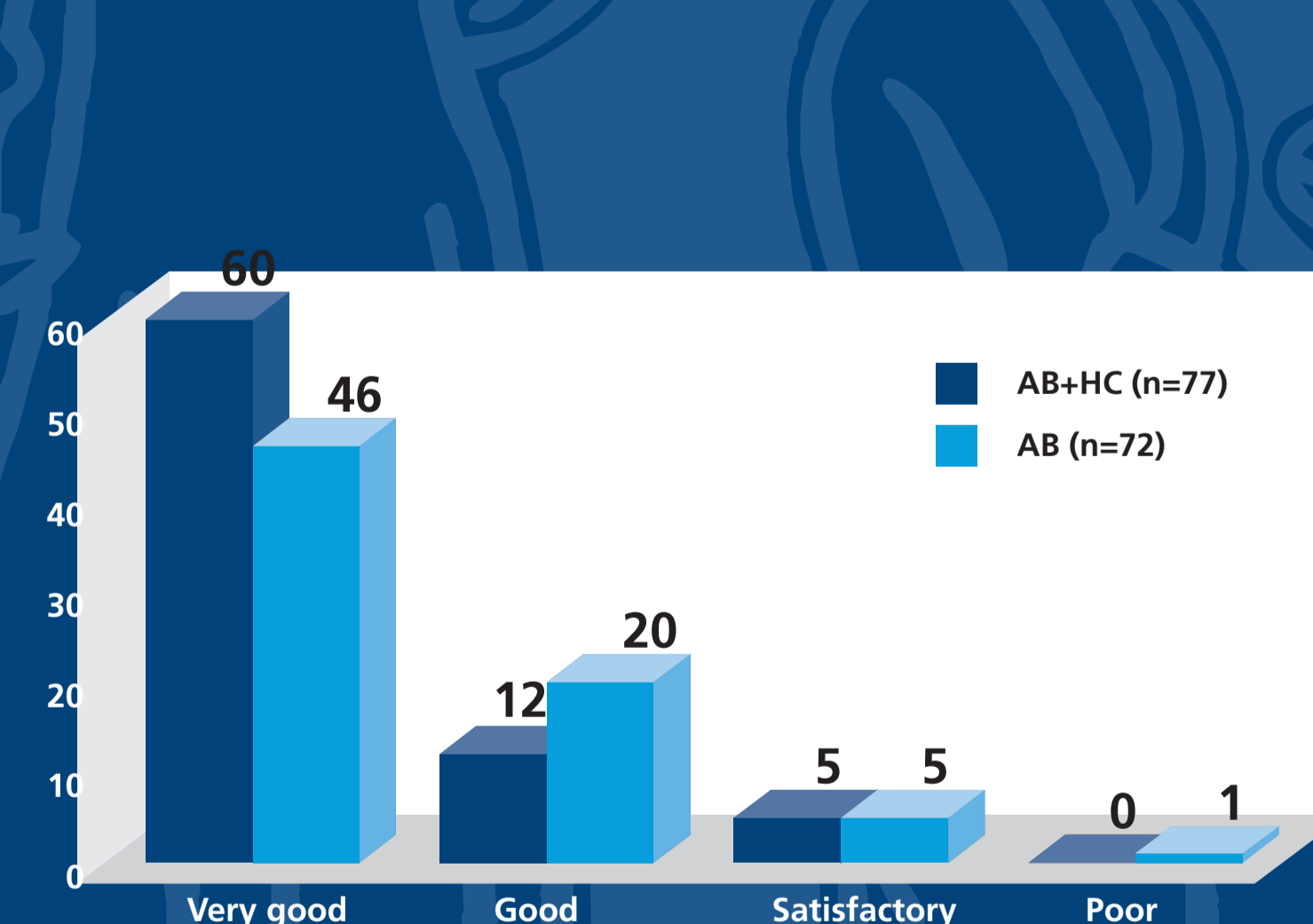
Tolerability - Patients (ITT)



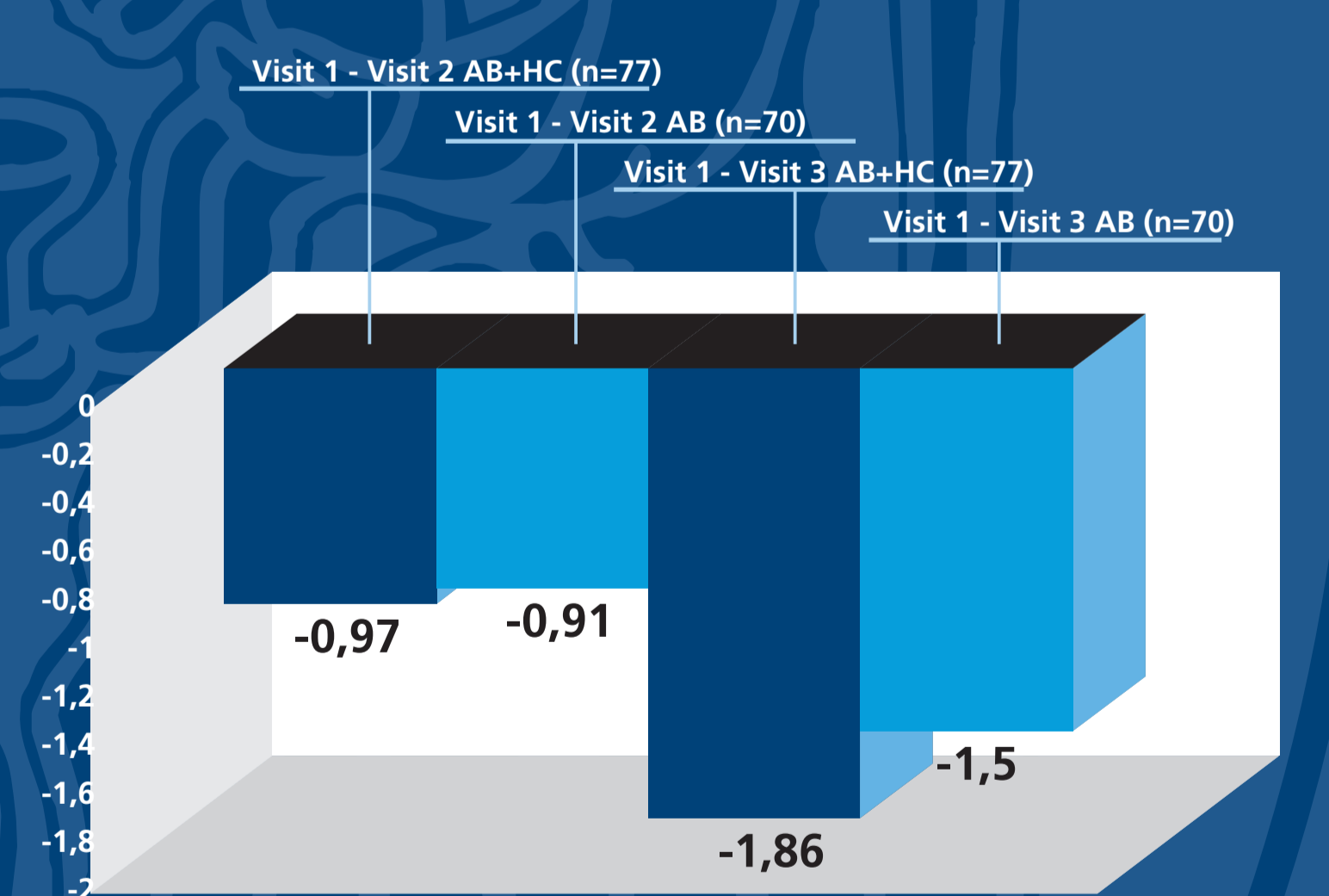
Mean change of pain (ITT)



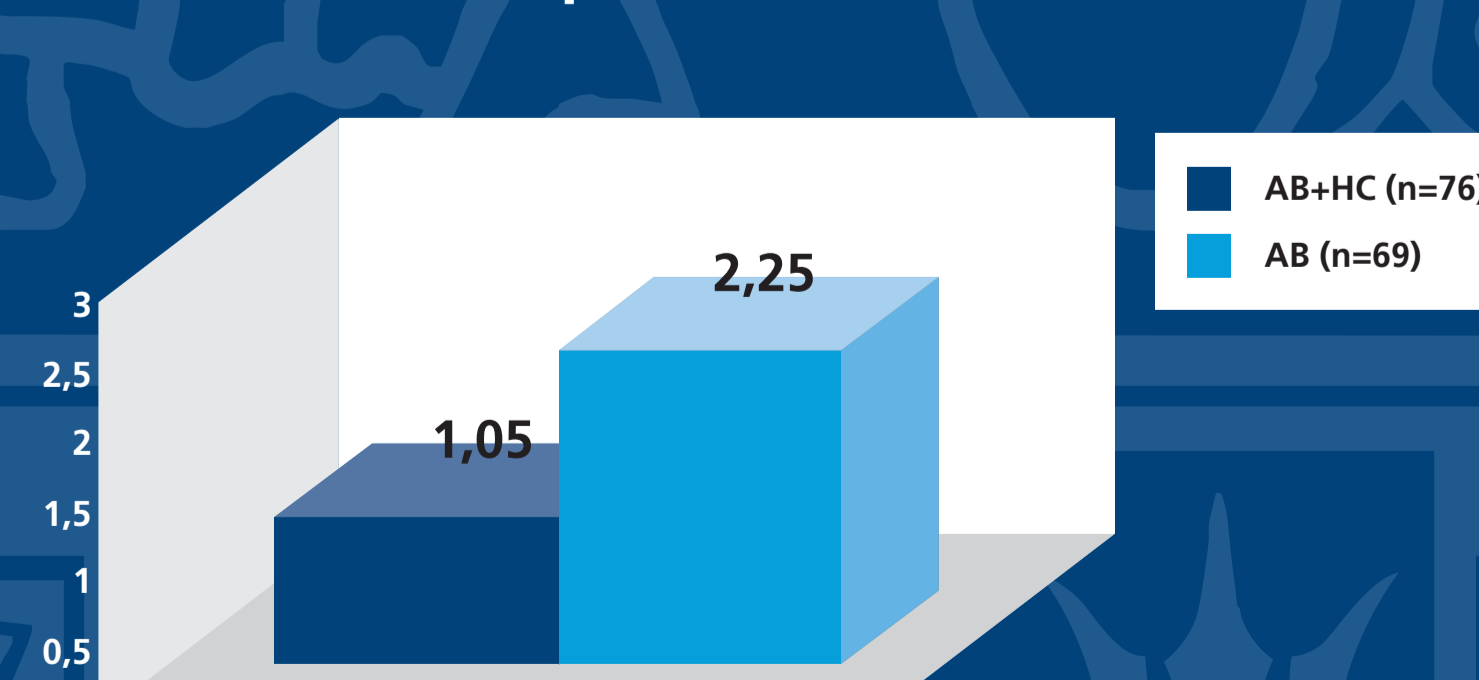
Tolerability - ENT Specialists (ITT)



Mean change of secretion (ITT)



Mean intake of paracetamol tablets (ITT)



Changes of the VAS from Visits 1 to Visits 3 (ITT)

