



# Headache treatment with the fixed dose combination ibuprofen plus caffeine (400/100 mg)

## Results from a pharmacy-based patient survey

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Headache affects many people and can – in most cases – be successfully treated with over-the-counter analgesics. What are the patients' characteristics? How do they experience the effects of the treatment with ibuprofen plus caffeine (400/100 mg; IbuCaff)? How does the treatment response to IbuCaff compare with other treatments? A pharmacy-based patient survey run in German community pharmacies sheds light on these questions.

Two recent publications report on a pharmacy-based study on patients treating headache with over-the-counter medicines [1, 2]. Data from patients who were buying an IbuCaff product and gave their consent to fill out a questionnaire at their own discretion after intake of the product to treat an acute pain episode were collected [1]. The questionnaires were to be sent to the institute which collected and analyzed the data (Winecker Norimed

GmbH, Nuremberg, Germany). The survey was completely anonymous.

In total, 1124 analyzable questionnaires were collected. IbuCaff was taken by 895 participants (304 without, and 538 with concomitant shoulder/neck pain) to treat headache, 229 provided no data or used the product for other types of pain (these data were not analyzed further). Mean age of headache

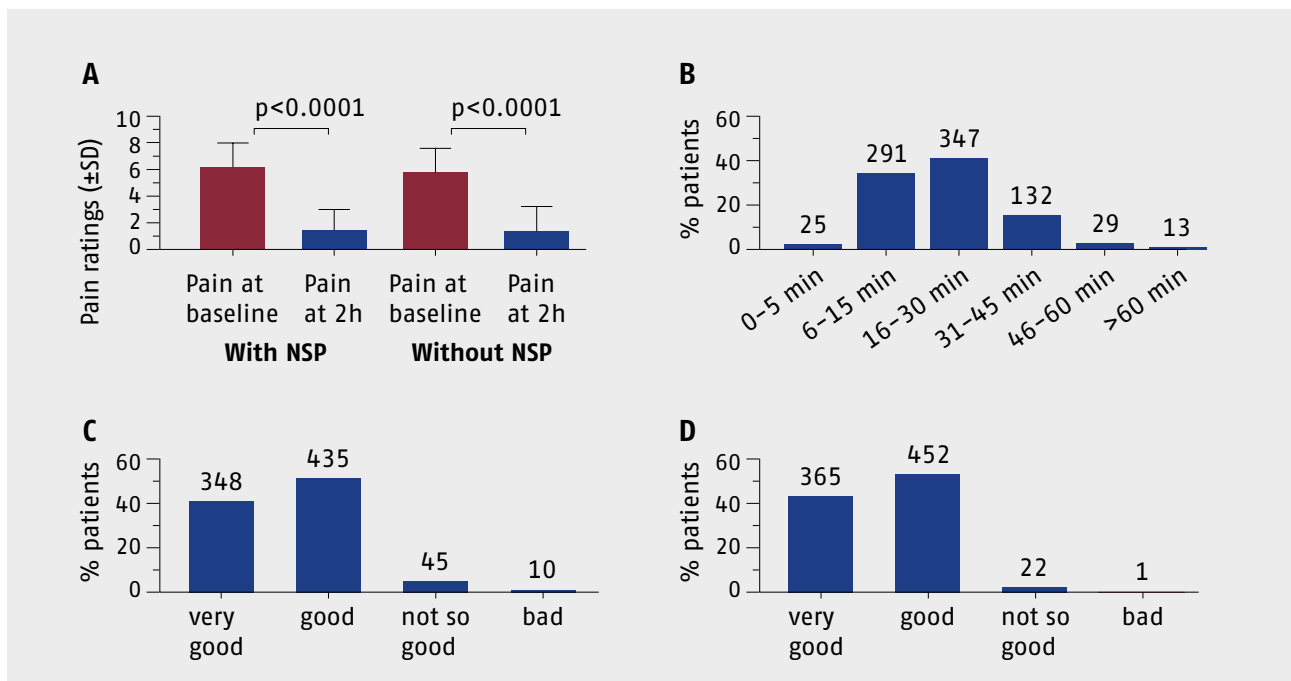


Fig. 1. (A) Pain ratings (means ± standard deviation [SD]) reported by participants before and 2 h after intake of IbuCaff (NSP: shoulder-/neck pain). (B) Patient-reported onset of pain relief. (C) Patient ratings for IbuCaff efficacy. (D) Patient ratings for IbuCaff tolerability. Numbers of patients for the different groups are shown on top of columns in (B) to (D). Figure adapted from [1].

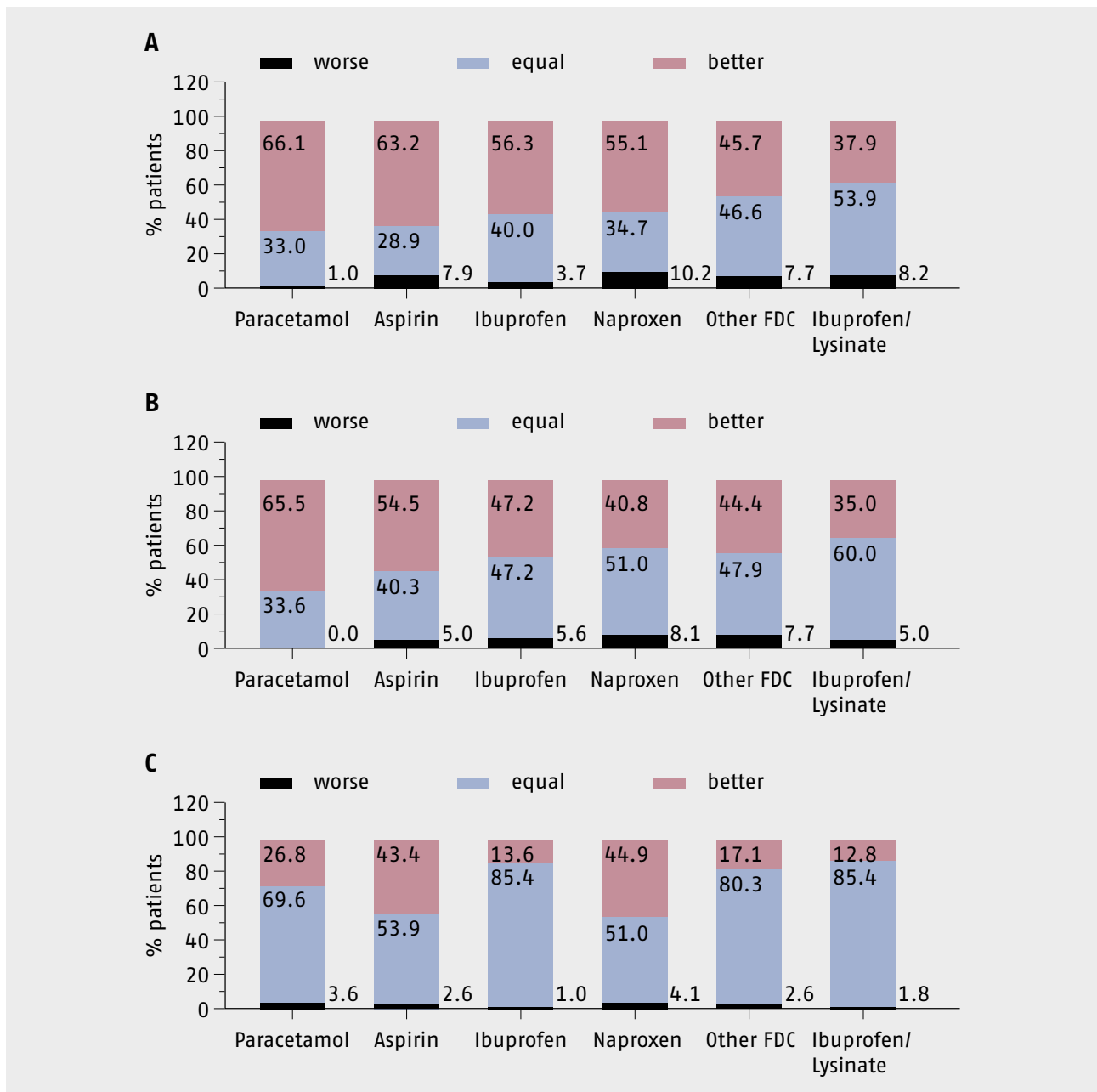


Fig. 2. Patient perception of IbuCaff compared to the last acute medication to treat a similar pain period. (A) Assessment of efficacy. (B) Assessment of speed of analgesic action. (C) Assessment of tolerability. FDC: fixed dose combination analgesic. Figure adapted from [2].

sufferers was  $\approx 42$  years, the majority were female ( $\approx 70\%$ ). Mean pain intensity was higher in those suffering from concomitant shoulder/neck pain (6.3 points on a 10-point pain scale), compared to those without (5.8 points).

In both groups, pain reduction at 2 h after intake was similar (to about 1.5 points) (Fig. 1A). Pain reduction by 50% at 2 h was reached in 90% of patients, and 57% (64%) became pain-free within 2 h. Onset of pain relief within 15 min was reported by 38%, and within 30 min by 79% (Fig. 1B). The rating “very fast” or “fast” onset of action was given by 70% of participants. Efficacy and tolerability were rated as “very good” or “good” by 93% and 97%, respectively (Fig 1C and 1D). Early onset of pain relief was positively correlated with percent pain reduction at 2 h, assessment of efficacy, and interestingly also with assessment of tolerability.

In addition to the treatment effects participants perceived, they were asked which analgesic they have taken for the last similar pain period, and how IbuCaff compared to it (in terms of onset of analgesic effect, perceived efficacy and tolerability) Ibuprofen and ibuprofen lysinate were taken by about 34 and 24%, other fixed-dose combinations by about 13%, paracetamol by 12%, and aspirin by 8%; data from [2]; Fig. 2). Only low percentages rated IbuCaff as worse compared to the last other pain treatment. Efficacy was ranked better by 35% (in comparison to ibuprofen lysinate) to 65.5% (in comparison to paracetamol) (Fig. 2A). Between 37.5% (ibuprofen lysinate) and 66.1% (paracetamol) found IbuCaff to act faster (Fig. 2B), and tolerability was ranked higher by 12.8% (ibuprofen lysinate) to 44.9% (naproxen) (Fig. 2C).

According to data from clinical trials this relatively positive

assessment of IbuCaff is not surprising. In a head-to-head comparison of IbuCaff with 400 mg ibuprofen, 100 mg caffeine and placebo in the dental extraction pain model IbuCaff showed faster onset of action, better pain reduction, and a higher response rate than ibuprofen alone (as well as the other treatments; [3]). The high response rate in this model (about 70% of patients experienced relevant pain relief) is usually only reached with prescription-only analgesics [4].

## Summary

Taken together this real-world evidence study in patients treating their headache with the fixed-dose combination ibuprofen plus caffeine (400/100 mg) showed that patients reported fast onset of action and robust pain reduction at 2 h. High percentages assessed efficacy and tolerability as “very good” or “good”. Many patients found IbuCaff to act faster, more effective, and at least as tolerable compared to their last headache treatment.

## Literature

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