Evidence for Self-Medication
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Acetylsalicylic acid 1,000 mg: strong evidence and good tolerability in acute headache management

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Headaches are most prevalent in middle age and not only have an immediate impact on the quality of life of those affected but also significantly influence their work and overall productivity. The majority of sufferers manage acute headaches through self-medication. National and international guidelines recommend acetylsalicylic acid (ASA) as a first-line treatment, with the scientific evidence for its effectiveness rated at the highest level.

Acute headaches in self-medication

Nearly everyone experiences headaches at some point in their life, with a global lifetime prevalence of 96%. Women are more frequently affected than men [1]. The two most common types are tension headaches and migraines. Tension headaches are characterised by a bilateral dull or pressing pain, perceived as mild to moderate in intensity and not worsened by physical activity. The reported prevalence of tension headaches varies globally, affecting 30.8% of women and 21.4% of men [2].

Migraines typically present as a unilateral, pulsating or throbbing pain, perceived as moderate to severe and often exacerbated by physical activity. Associated symptoms can include nausea, vomiting, and sensitivity to light and sound. The global prevalence of migraines is estimated at 18.9% in women and 9.8% in men [2].

More than half of migraine sufferers do not consult a doctor for treatment, and the figure is significantly higher for those with tension headaches. This highlights the importance of providing advice on the tolerability and effectiveness of acute medications for self-medication [3].

ASA 900 mg/1,000 mg: first-line treatment in guidelines for tension headaches and migraines

A recently published guideline by the German Society of Neurology (DGN) [4], developed in collaboration with six other professional associations from Germany, Austria, and Switzerland, focuses on the treatment of tension headaches. For acute therapy, the authors consider monotherapy with ASA (500–1,000 mg), paracetamol, and ibuprofen to be the most well-supported options. However, due to the risk of developing medication-overuse headaches, these analgesics should not be used for more than 15 days per month. According to the guideline, combination preparations of these active substances with caffeine demonstrated higher efficacy comparatively but were associated with lower tolerability. Therefore, the use of such combination preparations is recommended only as a secondary option and should be limited to a maximum of 10 days per month. A multimodal approach that integrates both non-pharmacological and pharmacological interventions may be more effective than pharmacotherapy alone. For the treatment of acute migraine attacks, another DGN guideline [5], developed in collaboration with professional associations from Germany, Austria, and Switzerland, confirms the efficacy of ASA (900–1,000 mg) and non-steroidal anti-inflammatory drugs (NSAIDs), as well as their combination with caffeine. For mild-to-moderate migraine attacks, treatment should initially begin with these preparations.

The European Federation of Neurological Societies (EFNS) offers comparable recommendations in its guidelines. For tension headaches [6], over-the-counter (OTC) analgesics such as ASA (500–1,000 mg) and other NSAIDs are considered first-line treatments, preferred over combinations with caffeine. Similarly, in alignment with the German guidelines, the EFNS recommends ASA (1,000 mg), ibuprofen, naproxen, diclofenac, paracetamol, and combinations with caffeine for the treatment of acute migraine attacks [7].

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Innovative formulation: rapid disintegration – rapid action

By providing rapid and effective pain relief, the need for patients to take additional medications to enhance efficacy is reduced, potentially avoiding unwanted side effects.

A recent pooled retrospective analysis of three studies (BAY 15120, BAY 15529, and BAY 15722) reported the time to initial pain reduction as 20 minutes for ASA (N = 684) and 18.6 minutes for paracetamol (PCM) (N = 273). Both active substances demonstrated comparable efficacy in terms of initial and effective pain reduction, and were significantly better than placebo [8]. Participants were not allowed to eat or consume beverages containing alcohol or caffeine from six hours before the study and throughout the study period.

In two of the three studies that formed the basis of the pooled analysis, the study medication was a tablet with a new, rapidly dissolving formulation. These oral tablets contain the active ingredient in micronized form, as well as an effervescent component composed of sodium carbonate. It has been shown that this new formulation significantly reduces both the dissolution time and the time to maximum plasma concentration in vivo. The small particle size of the active ingredient provides a larger surface area compared to conventional ASA tablets, leading to faster dissolution and thus more rapid absorption [9].

ASA 1,000 mg: comparable tolerability to placebo

A recent pooled retrospective analysis [8] confirmed the good tolerability of a single dose of 1,000 mg ASA. In the evaluated studies, 94.7% of participants reported no gastrointestinal side effects (N = 684), compared to 91.4% in the placebo arm. Regarding gastrointestinal symptoms such as nausea and vomiting, both ASA and PCM were comparable to placebo.

A comparison between the aforementioned rapidly dissolving tablets and a conventional formulation regarding gastrointestinal adverse events [10] produced a surprising result: participants who took ASA in the rapidly dissolving formulation reported fewer medication-induced gastrointestinal side effects than the placebo group. The study authors suggested that the better subjective overall condition due to the rapid pain relief following the intake of the innovative tablets could be a reason for this outcome. In contrast, participants who took regular ASA formulations had a significantly higher risk of medication-related side effects compared to placebo. Regarding the safety profile, there were differences between participants taking ASA and placebo, but no differences between those taking conventional ASA tablets and those taking the rapidly dissolving tablets.

Dosage (0–500 mg versus 501–1,000 mg) had no impact on the occurrence of either drug-independent or drug-induced adverse events. Out of 9,288 participants, 6,029 took ASA and 3,259 took a placebo. Of the 6,029 participants in the ASA group, 827 took a combination of ASA and pseudoephedrine, while the remaining participants took ASA monotherapy, including 796 participants who took the rapidly dissolving tablets.

Summary

Consumers require an acute pain reliever that offers rapid onset of action and noticeable pain relief, while also being well tolerated overall. Acetylsalicylic acid (ASA) has remained a first-line treatment for mild to moderate pain, such as tension headaches or mild-to-moderate migraine attacks, for more than 125 years [4–7], owing to its onset of action at approximately 20 minutes [9], effective pain reduction [8], and good tolerability [10]. A new, rapidly dissolving formulation of ASA further reduces the onset of action to 16.3 minutes (for 1,000 mg tablets [9]) and lowers medication-induced gastrointestinal adverse events to below placebo levels [10].

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