



Real-world data confirm effectiveness of a thyme-ivy extract combination

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From October 2019 to April 2020, the phytopharmaceutical Bronchipret® Drops, which contains a thyme-ivy extract combination (BNO 1200), was investigated in a large, practice-oriented, pharmacy-based observational study. The results show that the OTC drug quickly and sustainably alleviates bronchitis symptoms as well as severity of coughing, and reduces coughing bouts during the day and cough-associated sleep disturbances at night effectively.

Acute cough is one of the most common symptoms of acute bronchitis or the common cold. Although most cases are self-limiting and have no long-term effects, acute cough has a significant impact on patients' quality of life (QoL) and is often associated with work absences, or at least loss of productivity. Due to the predominantly viral genesis, the treatment of cold-related acute cough with antibiotics is not indicated; on the contrary, it favours the occurrence of side effects and the development of resistances. To alleviate the patients' considerable discomfort, the focus is instead on symptomatic treatment, which is usually carried out as part of self-medication. More often than in many other indications, herbal medicines are also used, some of which have been scientifically evaluated in clinical trials or observational studies. A recently published study from this field evaluated the effectiveness of the thyme/ivy preparation Bronchipret® Drops for acute cough in a large, practice-oriented, pharmacy-based observational study [1]. With regard to its significance, the typical limitations of non-placebo-controlled studies arise. Furthermore, it should be taken into account that only subjective parameters were collected by the participants and that about one third of the questionnaires distributed to the pharmacies were returned.

Patient population typical for self-medication

The evaluation of the study included data from a total of 730 adult participants who were suffering from acute cough and therefore sought advice at the pharmacy. The subjects were given 2.6 ml of a thyme-ivy extract combination (BNO 1200) three times a day until their symptoms subsided. Data were collected using a cough-specific questionnaire that patients were asked to complete before starting the

first dose (day 0), on day 4 and on the last dose day (day 7 on average). The 'Bronchitis Severity Score (BSS)' was used to assess the symptoms. This is a validated questionnaire for acute bronchitis which, in addition to the main symptoms of cough and sputum, also records breathing sounds (rattles), chest pain during coughing, and dyspnea. Each of the five symptoms is rated on a scale from 0 (not present) to 4 (very strong) and the individual scores are added to create a total score (0 to 20). At the beginning of the observational study, the mean BSS was 8.7 ± 3.8 , which corresponds to moderate acute bronchitis, as is typical in the realm of self-medication.

Overall symptoms significantly improved within a few days

Response to the medication was calculated as an absolute and a relative change in the BSS compared to baseline. After a four-day treatment with the thyme-ivy extract combination, the reported BSS already decreased significantly to 5.8 ± 3.3 , which corresponds to an absolute reduction of 2.9 points ($p < 0.0001$) or a relative reduction of 31.0%. At the end of the treatment, the mean BSS was 2.4 ± 2.6 , corresponding to a significant reduction of 6.3 points compared to baseline or a relative reduction of 70.0% ($p < 0.0001$; cf. Fig. 1). Patients whose symptoms had been present for a longer period of time or were more severe before the start of treatment ($BSS \geq 8$) showed a more significant BSS reduction during and after treatment. The data show that the thyme-ivy extract combination already significantly reduces the overall symptoms of acute bronchitis within seven days, while the main symptom of acute bronchitis, the cough, lasts an average of 18 days without treatment [2].

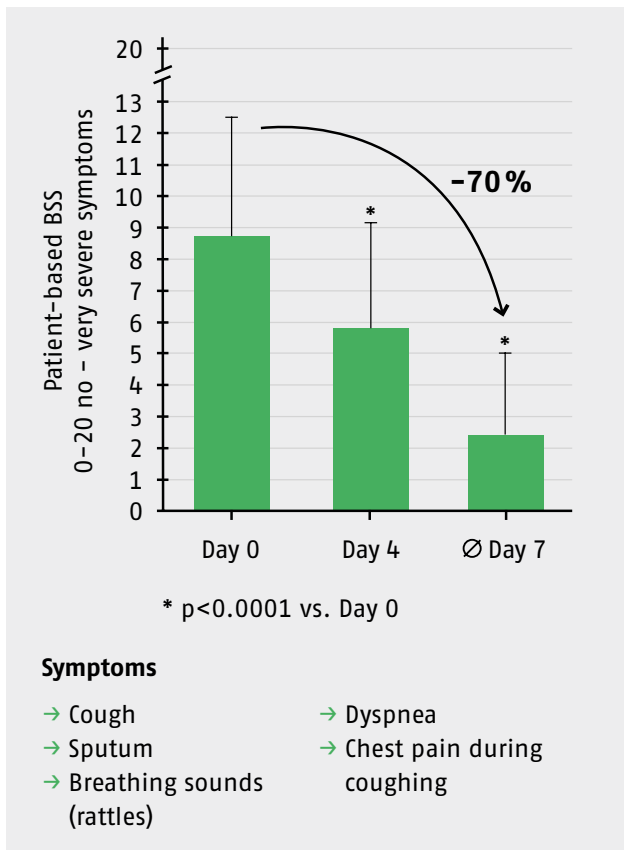


Fig. 1. Significant reduction in the Bronchitis Severity Score (BSS) [1]

Significant reduction in coughing bouts and cough-associated sleep disturbances

A post-hoc analysis of the study data [1] also showed that the thyme-ivy extract combination significantly reduced the number of daily coughing bouts. For example, the number of patients who self-reported “all of the time”, “most of the time” or “several times during the day” having coughing episodes in the previous 24 hours decreased by 67% in the first four days of treatment (p<0.0001; Fig. 2). This also had positive effects on sleep: while at the beginning of the study 56.7% of the subjects complained of cough-related sleep disturbances, at the end of the study 79.4% reported their sleep was disturbed either “hardly any of the time” or “none of the time” by coughing. Furthermore, after four days of treatment with the thyme-ivy extract combination, 68% (p<0.0001) fewer study participants reported having “all of the time”, “most of the time” or “a good bit of the time” suffered from cough-related sleep disturbances in the previous 24 hours compared to the start of treatment (Fig. 2). This is presumably due to the fact that, in contrast to most typical expectorants, the preparation studied can still be taken in the evening and thus can also alleviate cough irritation at night. The reduction in coughing episodes during the day and the reduced sleep disturbance at night are also reflected in an improved quality of life (QoL, determined using the Leicester Cough Questionnaire [LCQ]). On average, on a scale of 3 (lowest QoL) to 21 (highest QoL) at baseline, patients scored 12.2 ± 3.3 points and improved to 18.5 ± 2.7 points (p<0.0001) by the end of treatment. The minimum clinically important difference of at least two points in the LCQ questionnaire was achieved by 90.9% of patients at the end of the treatment.

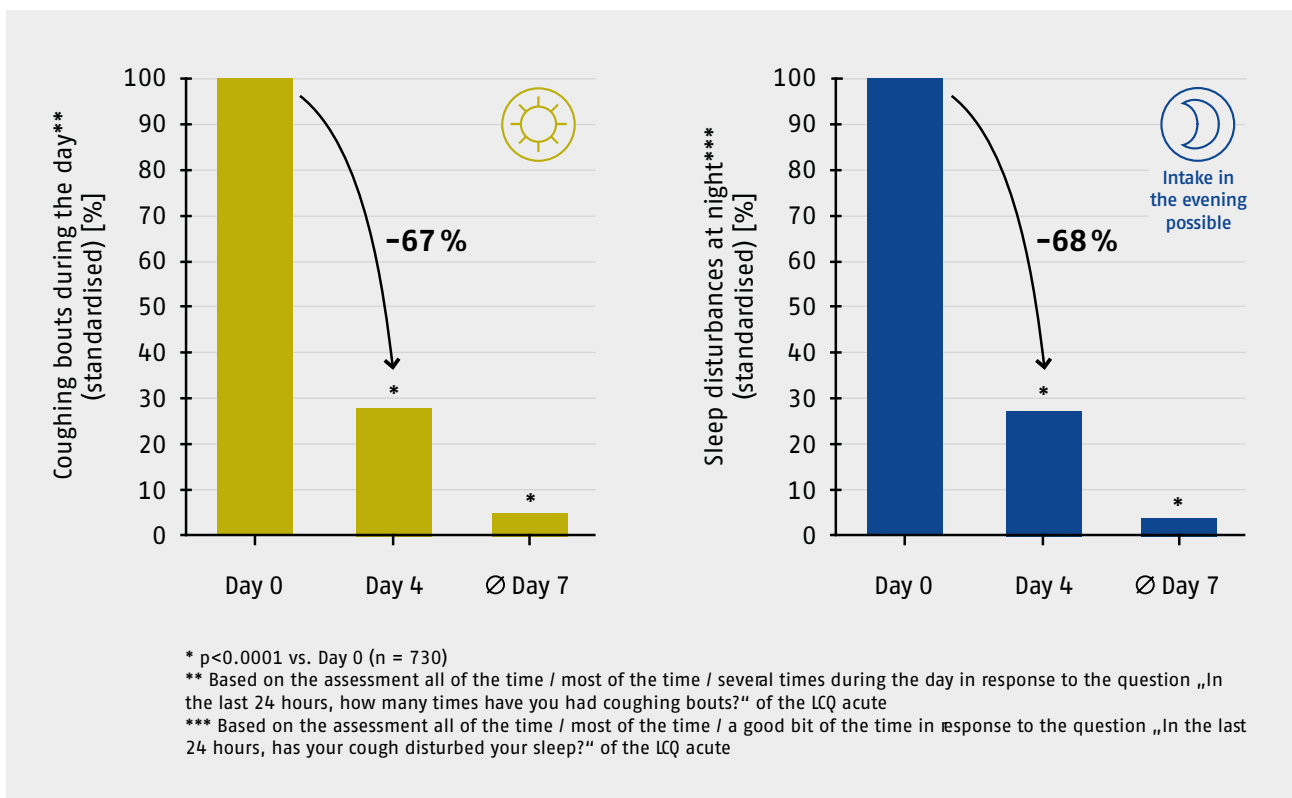


Fig. 2. Both the frequency of daily coughing bouts and cough-related sleep disturbances decreased significantly under the intake of the thyme-ivy extract combination (BNO 1200) (modified according to [1]).

Less severe coughing bouts

In addition to the number of coughing bouts, their severity also decreased. Measured on a validated 100-mm Visual Analogue Scale (100-mm VAS), cough severity decreased in the patients' assessment from 58.2 ± 20.4 mm at the beginning to 36.0 ± 18.9 mm ($p < 0.0001$) on day 4 and to 14.9 ± 17.0 mm ($p < 0.0001$) at the individual end of treatment (Fig. 3).

Clinically relevant improvements, defined by changes of at least 17 mm on the 100-mm VAS, were reported by 87.2% of patients at the end of treatment. Within an average of seven days, the severity of the cough was reduced by 74%, which means significantly fewer painful coughing bouts for those affected.

High patient satisfaction

The effectiveness of the thyme-ivy extract (BNO 1200) was rated as "good" or "very good" by 93.5% of the patients, with more than half of all patients confirming "very good" efficacy for the phytopharmaceutical. At the same time, the preparation is characterised by its tolerability, which was rated as good or very good by 98% of the patients; no adverse drug reactions were reported. This positive assessment of efficacy and tolerability was also reflected in the overall satisfaction with the treatment, which was rated as "very good" or "good" by 92.3% of the patients. The positive effects described can be attributed to the thyme-ivy extract combination, which loosens thick mucus, soothes the urge to cough and exerts anti-inflammatory effects on the bronchial tubes, and whose efficacy has also been proven in clinical trials [3]. On the basis of the convincing data, the combination of thyme and ivy can be included in the therapy of acute cough which is in line to the current German guidelines (S3 Guideline of the DEGAM and S2k Guideline of the DGP) [4, 5].

Literature

1. Kardos P, et al. Effectiveness and tolerability of the thyme/ivy herbal fluid extract BNO 1200 for the treatment of acute cough: an observational pharmacy-based study. *Current Medical Research and Opinion* 2021;10:1837–1844, DOI: 10.1080/03007995.2021.1960493
2. Ebell MH, et al. How long does a cough last? Comparing patients' expectations with data from a systematic review of the literature. *Ann FAM Med* 2013;11(1):5–13, DOI: <https://doi.org/10.1370/afm.1430>
3. Kemmerich B, et al. Efficacy and tolerability of a fluid extract combination of thyme herb and ivy leaves and matched placebo in adults suffering from acute bronchitis with productive cough: a prospective,

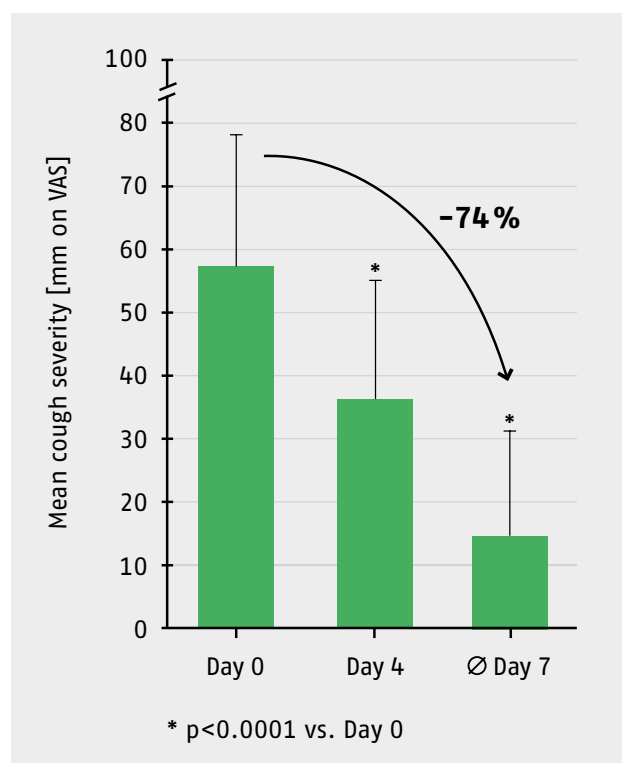


Fig. 3. Significant reduction in cough severity [1]

double-blind, placebo-controlled multicentre clinical trial. *Arzneimittelforschung* 2006;56(9):652–660; DOI: 10.1055/s-0031-1296767

4. DEGAM S3-Leitlinie Husten [Cough Guideline], AWMF Register No. 053-013, p. 35 & 38
5. DGP S2k-Leitlinie Husten [Cough Guideline], AWMF Register No. 020-003, p. 71. DOI: 10.1055/a-0808-7409

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