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Acute bronchitis in children: Treatment with Santasapina cough syrup

Clinical study to investigate the efficacy and tolerability of a plant remedy

The fresh-plant preparation, Santasapina, an alcohol-free cough syrup manufactured from fresh shoot tips obtained from Norway spruce *(Picea abies)* was investigated in an open multi-centre observational study involving 83 children suffering from acute bronchitis with sputum production. Children aged 1 to 3 years received half a teaspoonful 4 times a day, while children aged 3 to 10 years were given one teaspoonful 4 times a day. During the course of the 8–10 day treatment period, both cough and nocturnal waking rapidly improved. The sputum became more liquid and clear, and was expectorated more easily. In more than two-thirds of the cases, Santasapina was assessed to be effective. Apart from three children who did not tolerate its taste, Santasapina was extremely well tolerated. No adverse events were observed, and 75% of the children would take Santasapina again when required.

Typically, acute bronchitis follows a viral or bacterial contamination of the upper airways. In the early phase, associated cough is dry, frequently painful and is treated with antitussive agents that inhibit the cough reflex. This is then followed by the secretion phase, during which treatment with an expectorant is applied to clear the bronchi as completely as possible. Expectorants facilitate the coughing up of mucus by increasing and liquifying secretion. Secretolytic agents stimulate the secretory cells, mucolytic agents liquify the bronchial secretion, and secretomotor agents stimulate the activity of the ciliated epithelial cells.

Shoot tips of Norway spruce are one of the traditionally employed remedies for loosening the mucus in the airways. Since 1976, Santasapina has been approved for use as an expectorant by the Intercantonal Supervisory Office for Medicines (Interkantonale Kontrollstelle für Heilmittel: IKS, Bern) and by the Federal Institute for Drugs and Medical Products (Bundesinstitut für Arzneimittel und Medizinprodukte: BfArM, Berlin). Although the active principles and mode of action have not been clarified, both the tolerability and efficacy of the preparation in children and adults have been well documented. Santasapina is manufactured solely from freshly harvested shoot tips. Integral standardization of the active substances is ensured by the constancy of the harvesting location, the use of a validated manufacturing process, and the pooling of individual batches to give annual batches.

Using a newly developed process, it is now possible to manufacture alcohol-free Santasapina. Its active ingredient content has remained unchanged: 100 g Santasapina contains 20 g fresh shoot tips or 1.32 g native Norway spruce extract (drug : extract = 15.2 : 1).

The present study was carried out with the aim of demonstrating the tolerability and efficacy of paediatric doses of the alcohol-free cough syrup.

Study design and patient selection

The open, multi-centre study was carried out between February and April, 1996, in the form of a prospective observational study by 8 physicians in general practice (including 6 paediatricians) under the direction of Dr. Paul Trost, CH-5630 Muri. The monitoring carried out to ensure data quality in accordance with the Rules of Good Clinical Practice (GCP) was the respon-

sibility of PFC, CH-8604 Volketswil. The duration of treatment was 8 to 10 days. **Table 1** shows the dosages tested.

The study contained 83 children in whom productive bronchitis lasting less than 10 days was diagnosed. The children comprised 31 one-to-three year-olds, 51 three-to-ten year-olds, and a 14 year-old girl. The gender distribution was virtually identical (42 girls and 41 boys).

The following exclusion criteria were applied: chronic lung diseases, pneumonia, infections other than flu, asthma, hay fever, diabetes, autoimmune diseases and the use of impermissible medication such as antibiotics and mucolytic agents in the two weeks immediately preceding the start of the trial.

The following parameters were assessed and recorded by the care-providing physician: coughing frequency, expectoration, sputum viscosity, sputum colour, nocturnal waking (as recorded in the «patient's diary»), overall effectiveness, tolerability, adverse events, compliance and acceptance.

In 17 of the 83 patients, treatment failed to comply with the protocol: 3 drop-outs, 9 cases receiving medication in dosages or forms other than those prescribed by the protocol, 4 cases using impermissible additional medication, and 1 case that exceeded the inclusion age limit.

For the assessment of tolerability, all the patients participating in the study were evaluated. Assessment of efficacy was based both on the results seen in the entire group, and on those observed in patients complying with the protocol.

Results

Efficacy overall

The assessment of the efficacy of the eight to ten day period of treatment is shown in **Figures 1 and 2**. In more than two-thirds of the cases, the efficacy of Santasapina

Age	Single dose	No./day	Daily dose (Tsp = teaspoon)
1 to 3 ys.	1/2 teaspoon	4× daily	2 Tsp 10 ml syrup (2.8 g drug)
3 to 10 ys.	1 teaspoon	4× daily	4 Tsp 20 ml syrup (5.6 g drug)

Table 1: Multi-centre observational study in children with acute bronchitis (n=83): Dosages for treatment with alcohol-free Santasapina.

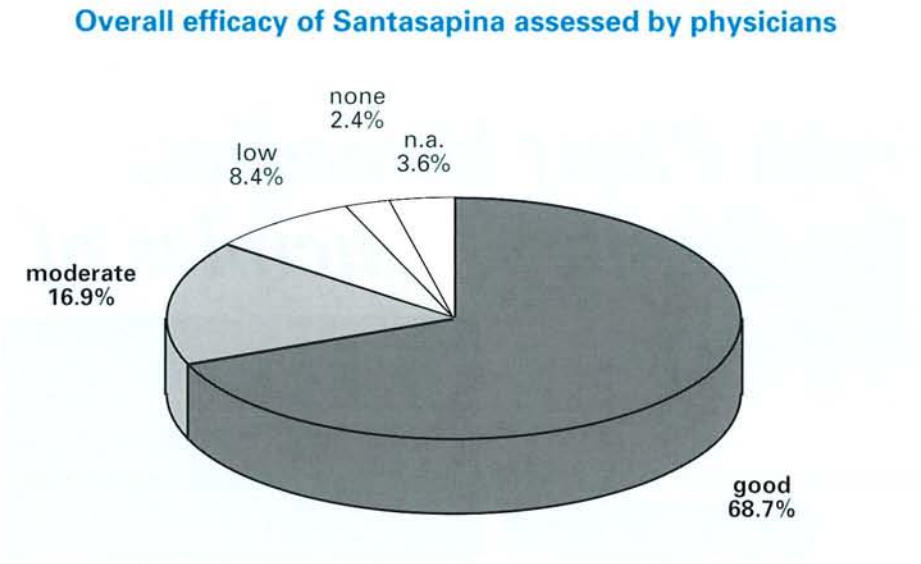

Figure 1: Multi-centre observational study in children with acute bronchitis (n=83): Overall efficacy of treatment with alcohol-free Santasapina as assessed by physicians.
n.a. = not assessable.

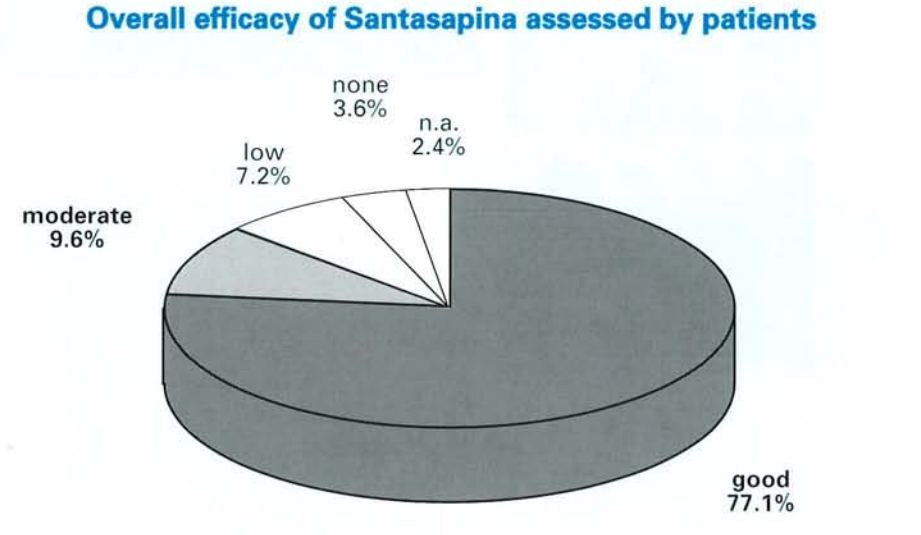

Figure 2: Multi-centre observational study in children with acute bronchitis (n=83): Overall efficacy of treatment with alcohol-free Santasapina as assessed by patients.
n.a. = not assessable.

Overall efficacy	good	moderate	poor	ineffective
Assessment, doctor	47 (71.2%)	12 (18.2%)	6 (9.1%)	1 (1.5%)
Assessment, patient	53 (80.3%)	7 (10.6%)	5 (7.6%)	1 (1.5%)

Table 2: Multi-centre observational study in children with acute bronchitis (n=66): Assessment of overall efficacy of treatment with alcohol-free Santasapina in the «per-protocol» cases.

Assessment parameter	commonest reports		
	Day 0	Day 5	Day 11
Cough	84% frequent	60% rare	57% n.a.
Nocturnal waking	45% 3–4 times	42% never	66% never
Sputum viscosity	39% medium	60% liquid	82% n.a.
Sputum colour	39% n.a.	49% n.a.	81% n.a.
	41% white*	69% clear*	56% clear*
Expectoration	37% moderate	49% good	70% n.a.

Table 3: Multi-centre observational study in children with acute bronchitis (n=83): Course of illnesses under treatment with alcohol-free Santasapina. * = most common reports by the assessable cases (100% = all assessable cases); n.a. = patients with no reportable symptoms and patients in whom, for whatever reason, symptoms were not assessable, were assigned to the category «not assessable» (n.a.).

Assessment parameter	commonest reports		
	Day 0	Day 5	Day 11
Cough	86% frequent	64% rare	53% n.a.
Nocturnal waking	47% 3–4 times	44% never	71% never
Sputum viscosity	41% medium	64% liquid	80% n.a.
Sputum colour	38% n.a.	47% n.a.	77% n.a.
	46% white*	71% clear*	60% clear*
Expectoration	36% moderate	50% good	68% n.a.

Table 4: Multi-centre observational study in children with acute bronchitis (n=66): Course of illnesses under treatment with alcohol-free Santasapina in the cases complying with the protocol. * = most common reports by the assessable cases (100% = all assessable cases); n.a. = patients with no reportable symptoms and patients in whom, for whatever reason, symptoms were not assessable, were assigned to the category «not assessable» (n.a.).

was assessed to be good. The assessment of the physicians corresponded closely with that of the patients themselves. The evaluation based on the 66 per-protocol cases alone shows slightly better results (**Table 2**).

Efficacy as related to various symptoms

The course of the illnesses under treatment with alcohol-free Santasapina may by summarised as follows: Both cough and nocturnal waking decreased rapidly. Mucus liquified, became clear and was easier to expectorate.

Tolerability and acceptance

Alcohol-free Santasapina was extremely well tolerated. In none of the 83 patients treated did any adverse events occur. In the three (3.6%) cases in which tolerability was assessed to be poor, the assessment was based purely on the children's rejection of its taste. In the case of future need, 62 (75%) of the 83 patients would again take Santasapina.

Conclusions

In the present study, alcohol-free Santasapina cough syrup was tested in 83 children with acute productive bronchitis. Children aged between 1 and 3 years were given a dose of 1/2 a teaspoonful 4 times daily, those aged between 3 and 10 years received 1 teaspoonful 4 times daily. At this dosage the new formula was extremely well tolerated and proved highly effective in the treatment of productive acute bronchitis.

A list of references may be obtained from the authors.

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