

Gastrointestinal Cramps in Children

Spascupreel Comparable to Hyoscine Butylbromide

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Introduction

Gastrointestinal cramps and spasms are common in children and adults. In Germany, approximately 10 million prescriptions and an unknown number of over-the-counter self-medications are used annually for these symptoms. In the United States, \$1.2 billion was spent on over-the-counter antacids, antidiarrhetics, and antigas products in 2002.

Hyoscine butylbromide is an alkaloid medication with spasmolytic and parasympatholytic properties; it is frequently used to treat acute colic. One disadvantage of this treatment is that hyoscine (scopolamine)-containing treatments can be infrequently associated with dry mouth, urinary retention, and increases in ocular pressure.

Natural medicines are increasingly used as suitable solutions for acute and chronic disease. Spascupreel is a homeopathic medication that consists of plant and mineral extracts in microdose (10^{-2} to 10^{-6}). It has been used empirically in over 50 countries primarily for spasms of smooth muscles of the stomach, intestines, bladder, and uterus.

In the present study, conducted in Germany, the effects of Spascupreel were compared with those of the conventional medication hyoscine butylbromide in children younger than 12 years who had gastrointestinal or urethral spasms.

Methods

This cohort study was prospective, observational, and non-interventional. A total of 204 children were enrolled from 57 centers. Each child received either Spascupreel or hyoscine butylbromide orally (both in tablet form). The practitioner determined the treatment for each patient. Doses were determined according to patient age and recommendations of the product information sheet. The maximum study duration was 1 week.

The patients included were children younger than 12 years who had newly diagnosed or recurring gastrointestinal or urethral spasms. The patients excluded were those 12 years or older, those already receiving treatment for gastrointestinal spasms, or those for whom one of the study treatments was contraindicated.

At the initial visit, the children were examined and data were collected (demographics; localization, intensity, and duration of spasms; etiology; auscultation findings; ultrasonographic findings; possible adjunctive diseases; possible earlier therapies; and presence of risk factors, including adiposity, asthma, diabetes mellitus, eczema, bronchitis, and decreased renal function).

The effectiveness of the respective therapies was evaluated by the effect on severity of spasms and clinical symptoms, including pain/cramps, sleep disturbances, distress, eating

or drinking difficulties, and frequent crying. The scale for these variables was from 0 to 3 (0 indicates asymptomatic; 1, mild symptoms; 2, moderate symptoms; and 3, severe symptoms).

Time to first improvement of symptoms was also recorded (after the first administration, after 12-24 hours of treatment, after 1-3 days of treatment, after > 3 days of treatment, and no improvement). The estimated total effect of treatment was determined by the physician, on a scale of 1 to 5 (1 indicates asymptomatic; 2, clear improvements; 3, moderate improvements; 4, no improvements; and 5, worsening of symptoms).

Compliance was evaluated on a 4-point scale (ranging from very good to low), given by the physician, based on information from the patient or caregiver. Tolerability was

Aconitum napellus



*Veratrum album*

evaluated by the practitioner based on a 4-point scale (very good, good, moderate, and low). Very good tolerability indicates no tolerability complaints, and low tolerability indicates a reaction after each administration.

Results

There were 2 groups in this study: the Spascupreel group ($n = 99$) and the control (hyoscine butylbromide) group ($n = 105$). There were no statistically significant differences in sex between the 2 groups, but patients in the Spascupreel group tended to be younger and, therefore, also shorter and lighter than patients in the hyoscine butylbromide group. Patients were treated for a mean of 6.1 days in both groups. There were 15 patients in the Spascupreel group and 31 in the control group who discontinued treatment. In most cases, discontinuation occurred because of the disappearance of symptoms during therapy.

The scores for all variables improved during treatment. The time to first improvement of symptoms was less than 1 day in 12% of the Spascupreel group and 13% of the control group. Most patients (80% in the Spascupreel group and 89% in the hyoscine butylbromide group) experienced an improvement in symptoms within 2

Monkshood or Wolfsbane (Aconitum napellus) and the False Hellebore, also known as White Hellebore (Veratrum album), are two of the active ingredients contained in Spascupreel.

days of treatment, without significant differences between treatment groups. No improvement during the study period was noted for only 4% of the Spascupreel group and 2% of the control group.

According to the physicians, treatment was successful (“very good”) in 75% of the Spascupreel group and 79% of the control group. Both groups had similar levels of overall satisfaction with treatment ($P = 0.44$).

During the study, the patients shifted from having predominantly severe or medium symptoms to mostly being asymptomatic for all variables. The greatest effect was seen for pain/cramps and severity of symptoms. For total score, the mean change from baseline was -7.9 in the Spascupreel group versus -6.6 in the hyoscine butylbromide group (negative values indicate symptom improvement).

Most patients reported “very good” tolerability with both treatments: 91% in the Spascupreel group and 93% in the hyoscine butylbromide group ($P = 0.83$). There were no adverse events reported for either treatment. Most patients also reported “very good” compliance in both groups: 72% in the Spascupreel group and 68% in the hyoscine butylbromide group ($P = 0.44$).

Discussion

This observational study of 2 groups of children younger than 12 years

indicates that Spascupreel (a homeopathic treatment) is comparable to hyoscine butylbromide (a conventional treatment) for gastrointestinal spasms.

Alternative treatments for various conditions, including musculoskeletal conditions, vertigo, and respiratory and gastrointestinal disorders, are being used more commonly in the industrialized world. Reasons for the popularity of alternative medical practices include the generally lower rate of adverse events with these treatments and the closer interaction between patient and practitioner.

In the present study, both Spascupreel and hyoscine butylbromide showed comparable improvements in the severity of symptoms. The tolerability of both treatments was also very good. Finally, there were no adverse effects with either treatment.

Overall, the study showed that patients who opt for homeopathic therapy for gastrointestinal spasms can be treated successfully with Spascupreel. Spascupreel proved to be very good for treating gastrointestinal symptoms and showed very good tolerability and compliance as well. ■

Reference:

Müller-Krampe B, Oberbaum M, Klein P, Weiser M. Effects of Spascupreel versus hyoscine butylbromide for gastrointestinal cramps in children. *Pediatr Int.* 2007;49(3):328-334.