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Hyperactivity, concentration difficulties and impulsiveness improve during seven weeks' treatment with valerian root and lemon balm extracts in primary school children

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ABSTRACT

Background: Valerian root and lemon balm extracts have previously shown efficacy and excellent tolerability in children < 12 years suffering from restlessness and insomnia. We now examined whether treatment with a fixed combination of both may also improve concentration, hyperactivity and impulsiveness.

Methods: 169 primary school children suffering from hyperactivity and concentration difficulties but not meeting ADHS criteria were treated in an observational study by 27 office based pediatricians with a recommended daily dose of 640 mg valerian root extract WS[®] 1014 and 320 mg lemon balm extract WS[®] 1303 (Sandrin[®]), and evaluated by pediatricians and parents using standardized questionnaires at baseline, weeks 2 and 7.

Results: The fraction of children having strong/very strong symptoms of poor ability to focus decreased from 75% to 14%, hyperactivity from 61% to 13%, and impulsiveness from 59% to 22%. Parent rated social behavior, sleep and symptom burden showed highly significant improvements. Only in two children mild transient adverse drug reactions were observed.

Conclusion: In primary school children with restlessness, concentration difficulties and impulsiveness treatment with WS[®] 1014 and WS[®] 1303 (Sandrin[®]) provides a viable option in addition to counseling and education.

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Introduction

Attention deficits, hyperactivity and impulsiveness in children cause problems in families, school and other social relations (Storebø et al., 2011). In Germany, up to 700,000 children are affected by ADS/ADHS (Saß et al., 2003) and even more suffer from single symptoms or symptom combinations of milder or fluctuating intensity not fulfilling the criteria for ADHS diagnosis according to DSM-IV or ICD-10. Consequently, prescription drugs are not indicated, but parents suffer so much from this burden that they ask for medical help (Gebhardt et al., 2008). Moreover, subthreshold juvenile ADHS is a risk factor for addiction disorders and impaired social interactions in adults (Shankman et al., 2009).

Herbal medicines are frequently administered to children because they are excellently tolerated and well accepted by parents (Kraft, 2008; Larzelere et al., 2010). Valerian (*Valeriana officinalis* L.) has been shown to improve sleep disturbances in adults (Fernández-San-Martín et al., 2010; HMPC, 2007) and in children (Francis and Dempster, 2002) when used as a monotherapy or in combination with other herbal remedies. It has also been suggested as medication for treatment of respiratory and cardiovascular disease (Circosta et al., 2007): Lemon balm (*Melissa officinalis* L.) promotes relaxation and helps to get to sleep, and in addition improves attention in young adults (Kennedy et al., 2002). A combination of valerian and lemon balm extracts improved sleep disturbances to a similar extent as did benzodiazepines but without having their sedative side effects (Cerny and Schmid, 1999; Dreßing et al., 1996). An observational study in 900 children reported good results in the treatment of restlessness and sleep disturbances for this combination (Müller and Klement, 2006).

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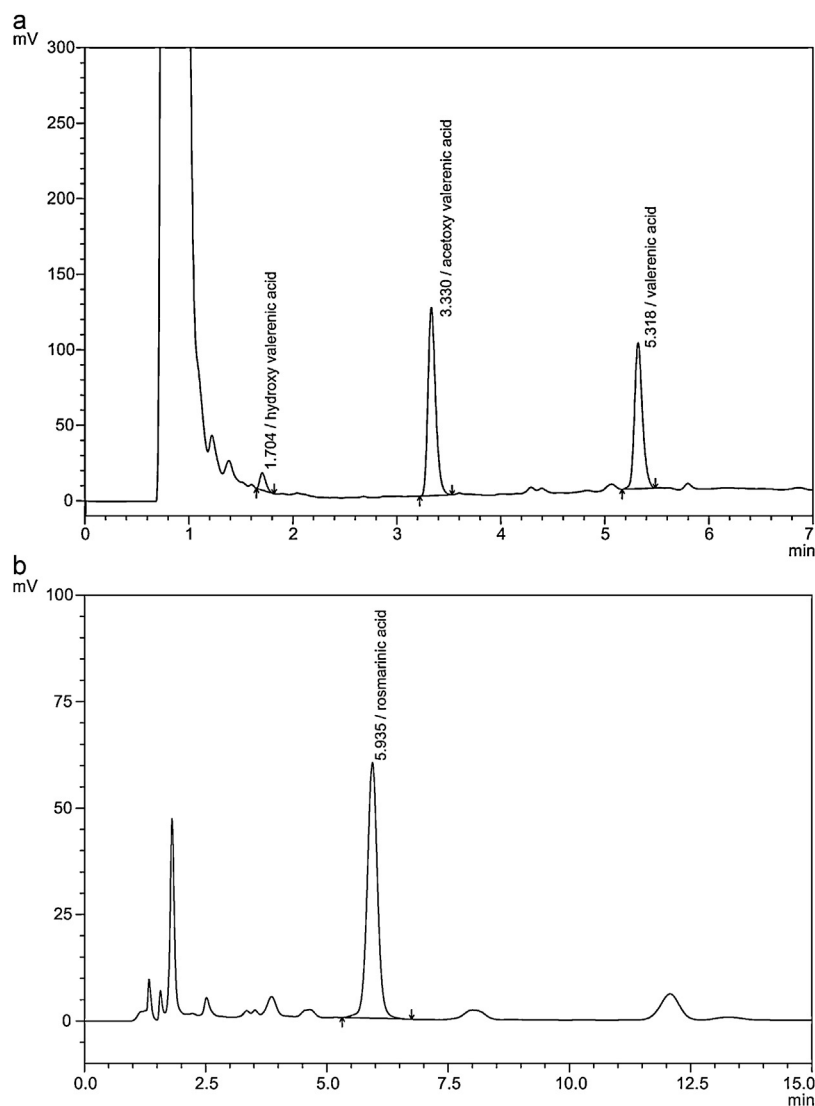


Fig. 1. Chromatographic analysis of extracts used in the trial. (a) Chromatogram of valerian root extract (analytical marker: hydroxyvalerenic acid; acetoxyvalerenic acid; valerenic acid). (b) Chromatogram of lemon balm leaf extract; (analytical marker: rosmarinic acid).

We therefore investigated the effects of a highly dosed preparation containing valerian and lemon balm on a wide range of symptoms and everyday life situation of children with hyperactivity, attention and concentration deficits but not fulfilling criteria for ADHD diagnosis in a routine office-based pediatric setting.

Materials and methods

Sample preparation for extract analysis

The coated tablets of the herbal combination remedy (Sandrin®) contain 320 mg of the quantified dry extract WS® 1014 from valerian root (drug/extract ratio 3–6: 1, solvent ethanol 62% (m/m)) and 160 mg of the quantified lemon balm dry extract WS® 1303 (drug/extract ratio 4–6: 1, solvent ethanol 30% (m/m)). These original tablets are used for chromatographic analysis (Fig. 1a) according to the current version of the monographs for balm leaf extract and valerian extract in the *Official European Pharmacopoeia* (Ph. Eur. 7.1/1898; Ph. Eur. 7.0/2524). Briefly, to analyze valerian extract, 1.2 g pulverized tablets were suspended in 25 ml methanol, sonicated for 30 min and filtered using a 0.45 µm filter.

To analyze lemon balm extract 145 mg of pulverized tablets were suspended in 50 ml ethanol 60%, sonicated for 10 min and centrifuged for 10 min at 3590 × g. The supernatant was used for HPLC analysis.

HPLC analysis was performed using Shimadzu LC 20 equipment. To analyze valerian root extract, sesquiterpenic acids, calculated as valerenic acid, were used as a marker. The assay was run using an RP 18, e.g., Chromolith performance 100 mm × 4.6 mm column; acetonitrile, 5 g/l solution of phosphoric acid (20:80 V/V) as eluent A; 5 g/l solution of phosphoric acid, acetonitrile (20:80 V/V) as eluent B. The gradient profile was 0–1.25 min 60% A/40% B, 1.25–5 min 60% A/40% B to 20% A/80% B, flow rate 2.0 ml/min. Absorption was detected at 220 nm. Calibration was performed by preparing at least 3 reference solutions corresponding to different valerenic acid concentrations (50–150 µg/l ml in methanol), using valerian standardized dry extract CRS.

To analyze lemon balm dry leaf extract, the extract was applied to an RP 18, e.g., Nucleosil 100, 5 µm, 125 mm × 4 mm column. The solvent was water: acetonitrile 2-propanol at a ratio of 100:27:3 (V/V/V)+0.4% citric acid (m/V). The flow rate was 1.0 ml/min. Compounds were detected at 332 nm. Calibration was performed using rosmarinic acid dissolved in 60% ethanol, with at least 3

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