

Pilot study of over-the-counter drugs applied among the pediatric population in Bulgaria

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Abstract

Herbal medicines have evolved through their traditional use in a specific or cultural context. The pharmacological effects of herbal medicines are not due to their “natural” origin, but to the complex character of biologically active substances. Pediatricians have begun to integrate the use of complementary / alternative medical therapies with conventional health care.

The first aim of the study was to make an analysis of over-the-counter (OTC) drugs (OTCDs) with a plant component. The secondary aim was to investigate OTCDs in terms of composition and nosology for use by the pediatric population in Bulgaria.

Registered OTC drugs with a herbal component for children are prescribed for the treatment of colds, pain, gastrointestinal diseases, mild sleep disorders, neurovegetative dystonias and kinetosis, urinary tract inflammation, liver disease, and are also applied topically to inflammation, trauma, urticaria and scars.

Keywords

over-the-counter (OTC) drugs, herbal, pediatric, children, diseases

Introduction

The interest in the practical use of herbal substances for medicinal purposes is continuously growing worldwide. They are among the preferred pharmaceutical products by consumers (Kilova 2020). To the extent that the use of herbal products for therapeutic purposes is substantiated by sound scientific data on quality, safety and efficacy, as required for the authorization of HMP in the European Union, their use is medicinally justified (Wegener 2017).

An alternative therapy including herbal drugs and complementary medicine is becoming increasingly popular (Stoimenova et al. 2011).

The sources of many of the new drugs and active ingredients of medicines are derived from natural products (Katiyar et al. 2012).

Approximately 50% of the pharmaceutical products originated directly or indirectly from natural products including: plants (25%), microorganisms (13%) and animals (about 3%): natural-derived products constitute an extremely important resource for global pharmaceutical companies working on the development of new medicines (Calixto 2019).

The World Health Organization (WHO) defines herbal medicines (HM) as remedies containing crude “herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredient parts of plants, or other plant materials, or combinations” (World Health Organization 2013).

Essentially, herbal remedies consist of portions of plants or unpurified plant extracts containing several

constituents which are often generally believed to work together synergistically. (Ekor 2014)

The term 'over-the-counter' (OTC) means that the doctor's prescription is unneeded and it is possible to buy them anywhere, e.g., in a pharmacy, a supermarket, at gas stations, or over the Internet (Karlłowicz-Bodalska et al. 2016; Catlin and Brass 2018).

Due to their free and wide availability, it is important that OTC drugs (OTCDs) are used correctly and rationally, therefore they are associated with a low incidence of serious adverse drug reactions or adverse events, as well as a low potential for harm in the event of abuse (Food and Drug Administration 2018).

OTCDs are defined as safe and effective to be used by the general public without a doctor's prescription (U.S. Food and Drug Administration 2012).

The use of nonprescription drugs (NPDs), including over-the-counter drugs (OTCDs) and complementary alternative medicines (CAMs), is widespread all over the world as a first course of action for a range of childhood complaints (Pileggi et al. 2015).

According to a Green et al., over-the-counter (OTC) cough and cold medications (CCMs) have been used to treat the symptoms of upper respiratory infection in children for decades (Green et al. 2017).

Many parents consider prescription medicines as safe and effective, fewer think so of OTC medicines. Thus, health care professionals should inform the parents that OTC medicines are an effective way to treat their child's minor ailments but also that OTC medicines may have side-effects (Hämeen-Anttila et al. 2011).

Some OTC products have extended this recommendation to children under 6 years of age (Aguilera 2009).

The use of self-healing in pediatrics is an increasing phenomenon despite the fact that in 2011 the FDA published a number of recommendations and restrictions on OTC drugs used for children under 12 years of age (Cristescu et al. 2018).

Materials and methods

When conducting the study, we applied a documentary method. We conducted a procedure for collecting primary empirical information from documents, reflected primarily on the official website of the BDA. We analyzed the BDA-approved summary of product characteristics of 262 OTC products.

Results

In this study we present an analysis of OTC products with a plant component, in terms of composition, indications for use among different age groups of the pediatric population in Bulgaria. On the pharmaceutical market in Bulgaria, the registered OTC products as of 25.01.20 are

999 in total, of which 262 contain herbal components and 198 are used among pediatric patients. We found that in infancy, OTC number 21 pcs (11%). The highest percentage – 54% are OTC drugs used during school age, applied in cases of colds, sore throats and nasal congestion. They usually contain a combination of a plant component and a synthetic substance (decongestant / antihistamine) or a derivative and a synthetic substance (Fig. 1).

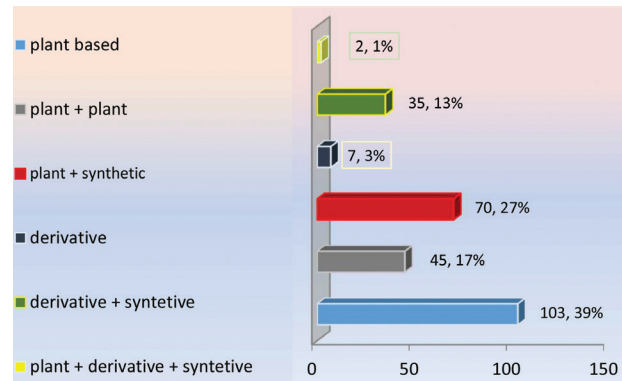


Figure 1. Grouping of plant-based OTCs by active substance.

Of all the 198 registered products containing a herbal substance, 24% are used for colds, 17% for coughs, 8% are administered orally affecting pain, 6% are used as sedatives. For other indications such as constipation, the number of registered phyto products is 6 (3%) and there are 7 products intended for local treatment of pain (3.5%), etc. The use of herbal products in pediatric patients in Bulgaria is widespread. The registered OTC products with a herbal component used in children are indicated for the treatment of colds, pain, gastrointestinal diseases, mild sleep disorders, neurovegetative dystonias and kinesis, urinary tract inflammation, liver disease, and are also applied topically to inflammation, trauma, urticaria and scars (Fig. 2).

Discussion

Based on the conducted documentary analysis of the registered OTC products in Bulgaria, we have established that during infancy the composition of the medicines is entirely based on plants. The phytochemical composition of the traditional healing plants contained in the OTC medicines is well studied and their safety profile has been established. Plant extracts such as: liquid extract of rose root (*Althaea off. extractum fluidum*); liquid extract of thyme roots (*Thymi herba extractum fluidum*); liquid extract of primrose root (*Primulae radice extractum liquidum*); liquid extract of sage leaves (*Salviae off. extractum fluidum*); dense extract of ivy leaves (*Hederae helix folium extractum spissum*); dry extract of ivy leaves (*Hedera helix folium extractum*) are contained in some of the OTC medicines. The specified extracts have been obtained from traditional healing plants whose efficiency has been proven in time.

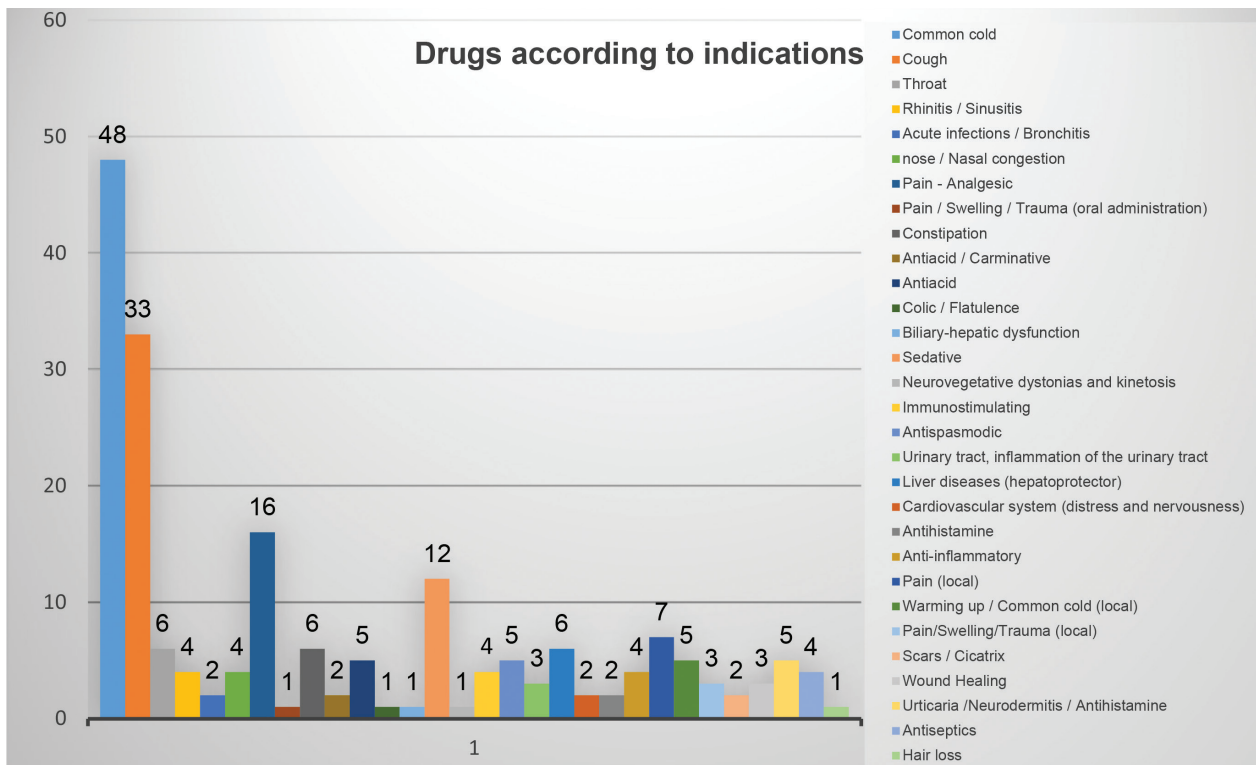


Figure 2. OTC herbal medicines administered to pediatric patients as indicated.

In addition to plant products, the OTC medicines used to treat cold also contain substances such as Paracetamol – antipyretic, Pseudoephedrine – decongestant and Pheniramine maleate – antihistamine. The presence of these substances increases the risk of unwanted reactions.

Decongestants are relatively safe if used appropriately, but their use is associated with many adverse effects resulting from their direct action on adrenergic receptors and stimulation of the central nervous system (CNS). Common adverse effects include insomnia, increased blood pressure, restlessness, anxiety, tachycardia, palpitations, arrhythmias, hallucinations, and urinary dysfunction (Blesson et al. 2018).

Considering the increased risk of manifestation of some of the unwanted reactions of the medicines in early childhood, the aforementioned combinations are applied among children who have reached school age and also in adolescence.

Conclusion

The use of OTC medicines containing a plant component is based on their “traditional use”. Despite the insufficient evidence from clinical tests, the effectiveness of these plant medicines is acceptable and there is evidence that they have been used safely in this manner for at least 30 years (of which at least 15 years in the EU). Owing to the fact that they have been registered as OTC medicines, their use does not require any medical supervision. In addition, as they have been proven to be safer compared to the synthetic medicines, they can be applied to a wider age group within the pediatric population.

Considering the diversity of plant products, it is necessary to develop new medical products and types that can be applied among children as well.

References

- Aguilera L (2009) Pediatric OTC cough and cold product safety. *U.S. Pharmacist* 34(7): 39–41.
- Blesson GO, Etzel JV, Ambzas EM (2018) The Common Cold: A Review of OTC Options. *U.S. Pharmacist* 43: 6–10.
- Calixto JB (2019) The role of natural products in modern drug discovery. *An Acad Bras Cienc* 91(Suppl 3): e20190105. <https://doi.org/10.1590/0001-3765201920190105>
- Catlin J, Brass E (2018) The Effectiveness of Nonprescription Drug Labels in the United States: Insights from Recent Research and Opportunities for the Future. *Pharmacy* 6(4, 119): 1–13. <https://doi.org/10.3390/pharmacy6040119>
- Cristescu C, Negreș S, Suciș M, Voicu A, Buda V, Suciș L, Voicu M (2018) Study regarding the parents’ use of self – medication among children under 12 years old. *Farmacia* 66(5): 811–819. <https://doi.org/10.31925/farmacia.2018.5.10>
- Ekor M (2014) The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. *Frontiers in pharmacology* 4: 177. <https://doi.org/10.3389/fphar.2013.00177>

- Food and Drug Administration (2018) Understanding Over-the-Counter Medicines. <https://www.fda.gov/drugs/buying-using-medicine-safely/understanding-over-counter-medicines> [16 May 2018]
- Green JL, Wang GS, Reynolds KM, Banner W, Bond GR, Kauffman RE, Palmer RB, Paul IM, Dart RC (2017) Safety profile of cough and cold medication use in pediatrics. *Pediatrics* 139(6): e20163070. <https://doi.org/10.1542/peds.2016-3070>
- Hämeen-Anttila K, Halonen P, Siponen S, Holappa M, Ahonen R (2011) Parental attitudes toward medicine use in children. *International Journal of Clinical Pharmac* 33(5): 849–58. <https://doi.org/10.1007/s11096-011-9549-3>
- Karłowicz-Bodalska K, Miśkiewicz K, Kurpas D, Han S, Kowalczyk A, Marciniak D, Dryś A, Glomb T, Cedzich S, Broniecka U, Kuchar E (2016) Usage of over-the-counter and herbal products in common cold in Poland: Findings from consumer survey. *Advances in Clinical Science* 878: 21–27. https://doi.org/10.1007/5584_2015_155
- Katiyar C, Gupta A, Kanjilal S, Katiyar S (2012) Drug discovery from plant sources: An integrated approach. *AYU* 33(1): 10–19. <https://doi.org/10.4103/0974-8520.100295>
- Kilova K (2020) Pilot study among pharmacists for the application of telepharmacy in Bulgaria. *Knowledge* 43(4): 859–864.
- Kilova K (2020) Telepharmacy – new opportunities for pharmacists and patients (overview). *Knowledge – International Journal* 40(5): 855–861.
- Pileggi C, Mascaro V, Bianco A, Pavia M (2015) Over-the-counter drugs and complementary medications use among children in Southern Italy. *BioMed research international* 413912: 1–8. <https://doi.org/10.1155/2015/413912>
- Stoimenova A, Savova A, Manova M, Draganov G, Petrova G, Zlatkov A (2011) Drug interactions with Ginkgo biloba. *Pharmacia*, LVIII(1–4): 83–89.
- U.S. Food and Drug Administration (2012) What are Over-the-counter (OTC) drugs and how are they approved? <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>
- Wegener T (2017) Patterns and trends in the use of herbal products, herbal medicine and herbal medicinal products. *International Journal of Complementary and Alternative Medicine* 9(6): 1–4. <https://doi.org/10.15406/ijcam.2017.09.00317>
- World Health Organization (2013) WHO traditional medicine strategy: 2014–2023. 76 pp. https://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/ [December 2013]