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Review article

EBCOG position statement about the use of herbal medication during pregnancy

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ABSTRACT

Pregnant women often resort to herbal medication to ameliorate the disturbing symptoms associated with pregnancy in the mistaken belief that these are safe and carry no potential harmful effects to the developing fetus. Healthcare personnel must be cognizant of the potential adverse side effects of these substances to be able to better advise their patients.

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During pregnancy, women may experience a plethora of uncomfortable symptoms due to the physiological and structural changes that occur throughout pregnancy. Because of the general belief that standard pharmaceutical preparations may be harmful to the fetus, many pregnant women may consider self-medication with over-the-counter preparations based on herbal medicinal products or tea infusions, in the belief that these are natural and therefore safe.

The availability of all pharmaceutical preparations is rigidly controlled by European Parliament legislation, which requires extensive pre-clinical testing of all medicinal products, whatever their origin. The EU pharmaceutical product legislation applies also to herbal medicinal products that are defined “as any medicinal product,

exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or a combination of the two”. However, this legislation also provides for allowing the continuing use of herbal medicinal products that have a long tradition of usage (at least 30 years, including 15 years in the EU) without the need to be submitted to the rigors of pre-clinical testing [1].

The European Parliament legislation set up a Committee for Herbal Medicinal Products (HMPC)¹ which was tasked with identifying and reviewing safety profile for those traditional herbal medicinal products with a long history of use. The HMPC identified thirteen products that were considered as long-usage traditional herbal medicinal products and where their continuing use could be allowed without requiring submission to pre-clinical testing. These traditional herbal medicinal products included: the calendula flower, the purple coneflower herb, bitter and sweet fennel, witch-hazel, aniseed, ironwort, thyme, and grapevine leaf; the roots of the ginseng

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and valerian; and the oils from the tea tree and peppermint. However, for all these botanical medicines, the HMPC recommended that these items should not be used during pregnancy and lactation since their safety profile in these circumstances has not been established [2]. Unfortunately, many of these products are available as over-the-counter or as simple herbal teas and, therefore, pregnant women cannot be adequately warned of the HMPC recommendations.

Plant infusion teas have enjoyed a long history and have increased in popularity. These infusions encompass a wide range of plants products used singly or in combination. Their sale and distribution are not rigidly controlled, and they are made available as over-the-counter products by several health and wellness retailers. Plant products however can have pharmacological effects, and may have adverse side-effects when used during pregnancy or lactation. Many plants, including ginger, raspberry, devil's horsewhip, fenugreek, evening primrose oil, blue and black-cohosh, floradix, motherwort, and chanlibao, have been reported to have oxytocic-type action and promoted as useful in inducing labour and having a positive effect on the progress of labour. A recent systematic review and meta-analysis of the literature has indicated that while some of the herbal medicines described above appear to be effective for induction of labour, safety for the baby needs to be established. The reviewers recommend that the use of herbal medicines to induce labour should be avoided until they are confirmed to be safe [3]. Adverse events have been reported using blue cohosh and evening primrose oil [4]. Blue cohosh is often promoted as a labour-inducing agent. In vitro studies have suggested teratogenic, embryotoxic and oxytocic effects [5]. A review of the literature has suggested that blue cohosh possesses abortifacient properties, and has been associated with cases of perinatal stroke, acute myocardial infarction, and severe multi-organ hypoxic injury [6]. Similarly, evening primrose oil has been promoted as a labour-inducing agent supposedly improving cervical ripening and shortening duration of labour. A randomised clinical trial has failed to confirm its effectiveness showing no change in Bishop Score or on the duration of labour [7]. Its peripartum use has however been associated with the development of petechiae in a neonate [8].

Some herbal substances, such as blessed milk thistle, fenugreek, malunggay, garlic, shatavari, goat's rue, and fennel, have been variously promoted as galactagogues useful in supporting breastfeeding. A systematic review of the literature however concluded that the available scientific evidence is equivocal and inadequate to guide clinical recommendations. While the studies failed to show definite therapeutic usefulness, the use of these herbal substances may have an adverse effect on the infant. Fenugreek may cause side effects such as diarrhoea in the child, while milk thistle may cause an allergic reaction and have a laxative effect. Because garlic crosses into the breast milk, the infant may find the odour and taste offensive deterring from breastfeeding [9].

Herbal medicinal products that do not have a long tradition of use fall under the provisions of the EU Directive 2001/83/EC. This requires every medicinal product on the market to have undergone physico-chemical, biological or microbiological, pharmacological and toxicological tests, and clinical trials proving its quality, safety and efficacy [10]. To circumvent this EU directive and avoid the rigors of pre-clinical testing, many companies simply market their herbal products as nutritional supplements. The availability and sale of these products within the EU is regulated by Directive 2002/46/EC. This specifically refers to 'food supplements' defined as products serving as concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form and designed to be taken in measured small unit quantities. Food supplements may incorporate a wide range of nutrients and other ingredients that might also include vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts. Food supplements cannot be presented as medicines or as a substitute for medicines [11]. A person's requirements for different nutrients are related to his or her energy

requirements, age, height, and weight. They will differ according to different physiological conditions, such as whether a woman is pregnant or lactating. Special attention should be given to compounds that may have implications for the health of pregnant women [12]. The daily recommended micronutrient intakes for pregnant and lactating women have been clearly defined by the World Health Organization [13]. Such food supplements, including those of plant origin, should not be used indiscriminately without a definite clinical indication.

Practitioners should keep themselves well-informed about the range of herbal products available on the market and should know how to access authoritative and unbiased information sources as to the efficacy and side-effects of these botanical medicines [14]. In counselling their pregnant and lactating women about the use of herbal products, healthcare professionals should maintain an open-mind policy providing guidance on reputed beneficial herbal products but emphasising the absence of reliable information on benefit and on robust safety data, where this is the case [15].

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- [1] European Parliament. Directive 2004/24/EC of the European Parliament and of the Council. Off. J. Eur. Union 2004;31(March)85–90 L 136: Available at: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0085:0090:en:PDF>.
- [2] Committee for Herbal Medicinal Products. Directive 2008/911/EC - Commission Decision of 21 November 2008 establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. 2010 Available at: <https://eur-lex.europa.eu/eli/dec/2010/180/oj>.
- [3] Zamawe C, King C, Jennings HM, Mandiwa C, Fottrell E. Effectiveness and safety of herbal medicines for induction of labour: a systematic review and meta-analysis. *BMJ Open* 2018;8(10):e022499.
- [4] Dante G, Bellei G, Neri I, Facchinetti F. Herbal therapies in pregnancy: what works? *Curr. Opin. Obstet. Gynecol.* 2014;26(2):83–91.
- [5] Kennelly EJ, Flynn TJ, Mazzola EP, et al. Detecting potential teratogenic alkaloids from blue cohosh rhizomes using an in vitro rat embryo culture. *J. Nat. Prod.* 1999;62:1385–9.
- [6] Dugoua JJ, Perri D, Seely D, Mills E, Koren G. Safety and efficacy of blue cohosh (*Caulophyllum thalictroides*) during pregnancy and lactation. *Can. J. Clin. Pharmacol.* 2008;15(1):e66–73.
- [7] Kalati M, Kashanian M, Jahdi F, Naseri M, Haghani H, Sheikhsari N. Evening primrose oil and labour, is it effective? A randomised clinical trial. *J. Obstet. Gynaecol. (Lahore)* 2018;38(4):488–92.
- [8] Wedig KE, Whitsett JA. Down the primrose path: petechiae in a neonate exposed to herbal remedy for parturition. *J. Pediatr.* 2008;152(1):140.
- [9] Bazzano AN, Hofer R, Thibeau S, Gillispie V, Jacobs M, Theall KP. A review of herbal and pharmaceutical galactagogues for breast-feeding. *Ochsner. J.* 2016;16(4):511–24.
- [10] European Parliament. Directive 2001/83/EC of the European Parliament and of the Council. Off. J. Eur. Union 2001;6(November)67–128. L 311: Available at: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>.
- [11] European Parliament. Directive 2002/46/EC of the European Parliament and of the Council. Off. J. Eur. Union 2002;10(June)51–7. L 183: Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=DA>.
- [12] Anadón A, Martínez-Larrañaga MR, Ares I, Aránzazu Martínez M. Evaluation and regulation of food supplements. In: Gupta RC, editor. *Nutraceuticals - Efficacy, Safety and Toxicity*. Oxford: Academic Press; 2016. p. 895–923. Available at: https://www.researchgate.net/publication/292606452_Nutraceuticals_Efficacy_Safety_and_Toxicity.
- [13] World Health Organization. Good Maternal Nutrition - The Best Start In Life. Available at: Copenhagen: WHO Regional Office for Europe; 2016. http://www.euro.who.int/_data/assets/pdf_file/0008/313667/Good-maternal-nutrition-The-best-M.
- [14] Mills E, Dugoua JJ, Perri D, Koren G. Herbal Medicine In Pregnancy and Lactation - A Evidence-Based Approach. Available at: Oxon: Taylor & Francis; 2006. <http://file.zums.ac.ir/ebook/365-Herbal%20Medicines%20in%20Pregnancy%20and%20Lactation%20-%20An%20Evidence-Based%20Approach-Edward%20Mills%20Jean-Ja.pdf>.
- [15] Ramasubramaniam S, Renganathan L, Vijayalakshmi G, Visitation MB. Use of herbal preparations among parturient women: is there enough evidence - A review of literature. *Int. J. Herb. Med.* 2015;2(5):20–6.