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Review Article

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"SAFETY OF AYURVEDIC HERBS AND FORMULATIONS IN PREGNANCY AND LACTATION: A CRITICAL REVIEW"

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ABSTRACT:

Background: Herbal and traditional medicines are widely used during pregnancy and breastfeeding, often in the belief that natural products are inherently safe. In India, Ayurvedic preparations are prescribed by practitioners, recommended by family members and bought without prescription. Pregnant and lactating women are, however, among the groups for whom drug safety data are most limited. **Objective:** To review the classical Ayurvedic guidance on medicines to be avoided in pregnancy, and to summarise current evidence on the safety of herbal medicines, the risk of heavy-metal exposure from herbomineral products, and the status of pharmacovigilance for Ayurvedic medicines in pregnancy and lactation. **Methods:** Charaka Samhita, Sushruta Samhita, Ashtanga Hridaya and Kashyapa Samhita were reviewed for antenatal prohibitions and harmful factors. PubMed was searched up to October 2026 for studies on herbal medicine use and safety in pregnancy and lactation, heavy metals in Ayurvedic products, and adverse drug reactions to Ayurvedic medicines. Findings were synthesised narratively. **Results:** The classical texts prohibit sharp, hot and strongly eliminative drugs and therapies during pregnancy and list many factors harmful to the foetus. About one-third of pregnant women worldwide use herbal medicines, and most do not disclose this to their doctors. Pooled observational evidence does not show a general increase in adverse offspring outcomes with herbal use, but signals exist for individual herbs, and data for most Ayurvedic products are absent. Lead, mercury and arsenic have been detected in a substantial proportion of Ayurvedic products, particularly Rasa shastra preparations, and lead poisoning has been documented in pregnant women and children using them. Hospital pharmacovigilance shows adverse reactions to herbal, herbomineral and Panchakarma treatments. **Conclusion:** Ayurvedic medicines should not be assumed safe in pregnancy or lactation. Prescribing should follow classical prohibitions, avoid unnecessary herbomineral products, use quality-tested medicines and be accompanied by active pharmacovigilance.

KEYWORDS: Garbhini, Garbhopaghatakara bhava, herbomineral formulations, heavy metals, pharmacovigilance, lactation

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INTRODUCTION

Pregnancy and lactation present a particular problem for drug safety. Ethical constraints exclude pregnant and breastfeeding women from most clinical trials, so information on the effects of medicines on the embryo, foetus and breastfed infant comes largely from animal studies, case reports and observational research. At the same time, women frequently seek remedies for common complaints of pregnancy, such as nausea, constipation, fatigue, oedema and anxiety, and for perceived problems of lactation, such as low milk supply.

Herbal medicines fill much of this gap. A systematic review of 111 cross-sectional studies from 51 countries found that 34.4% of women used herbal medicines during pregnancy, mainly because they considered them safer and more natural than conventional drugs, while only 27.9% of users disclosed this to their healthcare providers[1]. In India, Ayurvedic medicines are additionally recommended by registered practitioners, sold over the counter and widely used through family tradition; in one community survey of pregnant women in Tamil Nadu, more than half reported self-medication, and Ayurvedic medicines accounted for 22.2% of self-medicated products[2].

Ayurveda itself has never regarded medicines as harmless. The classical texts describe a detailed regimen for the pregnant woman, list a large number of factors that harm the foetus, and specifically warn against potent drugs and procedures during pregnancy[3–6]. Modern concerns add two further dimensions: the presence of heavy metals in some Ayurvedic products, especially those of the Rasa shastra (herbomineral) tradition, and the near absence of systematic safety data for most Ayurvedic formulations in pregnancy and lactation. The aim of this review is to bring together classical guidance and current evidence to support safer prescribing.

METHODOLOGY

This narrative review was prepared in two parts. First, the primary classical texts of Ayurveda, namely Charaka Samhita (Sharira sthana, chapters 4 and 8), Sushruta Samhita (Sharira sthana, chapter 10), Ashtanga Hridaya (Sharira sthana, chapter 1) and Kashyapa Samhita, were studied with their standard commentaries for antenatal prohibitions, factors harmful to the foetus (Garbhopaghatakara bhava) and guidance on the use of medicines and therapies in pregnancy and the puerperium[3–6]. Second, PubMed was searched for literature published up to October 2026 using combinations of the terms Ayurveda, Ayurvedic, herbal medicine, pregnancy, lactation, galactagogue, lead, mercury, arsenic, heavy metals, Rasa shastra, bhasma, herbomineral, adverse drug reaction and pharmacovigilance. Systematic reviews, meta-analyses, observational studies, surveillance reports and case reports were considered. Every reference cited in this article was checked against its PubMed record for authors, title, journal, year, volume, pages and digital object identifier. Retracted publications identified during the search were excluded. The findings are synthesised narratively rather than statistically.

CLASSICAL AYURVEDIC GUIDANCE ON MEDICINES IN PREGNANCY

1. The pregnant woman as a special patient

The classical texts treat the pregnant woman (Garbhini) as a patient requiring exceptional care, because any therapy given to her also acts on the foetus. Charaka compares the pregnant woman to a vessel filled with oil that must be carried without spilling, and advises that she should be treated with gentle, pleasant and nourishing measures[3]. Treatment of illness during pregnancy is to be undertaken with drugs that are mild, sweet, cooling and safe for the foetus, and strong measures are to be avoided except in emergency[3,5].

2. Garbhopaghatakara bhava

Charaka lists a range of factors that harm the foetus or cause miscarriage, including excessive physical exertion, heavy, hot or pungent food, intoxicating drinks and meat in excess, suppression of natural urges, travel on jolting vehicles, fasting, emotional disturbance and the use of sharp (Tikshna) and hot (Ushna) substances[3]. Sushruta and Vagbhata give comparable lists and advise against purgation, emesis and other eliminative procedures in pregnancy[4,5]. These prohibitions reflect a pharmacological intuition that potent, irritant and strongly eliminative drugs disturb the uterus and the foetus, an intuition consistent with modern concerns about uterotonic, cathartic and cytotoxic agents.

3. Contraindicated drugs and procedures

On the basis of these principles, Ayurvedic practice has traditionally avoided the following groups of

medicines during pregnancy: strong purgatives (Tikshna virechana dravya), such as Jayapala (*Croton tiglium*) and Snuhi (*Euphorbia neriifolia*); emetics; drugs described as Tikshna and Ushna, including many Vishadravya (toxic plants) such as Vatsanabha (*Aconitum ferox*) and Kupilu (*Strychnos nux-vomica*), even in their purified forms; and drugs used classically to expel the foetus or the placenta, such as Langali (*Gloriosa superba*). Panchakarma procedures of Vamana, Virechana and Nasya are generally avoided, while Anuvasana basti is reserved for the later months as a preparatory measure for labour[3,5]. Kashyapa similarly emphasises the vulnerability of the foetus and the need to protect it from harsh treatment[6]. These classical prohibitions are a valuable starting point, but they do not cover the many proprietary formulations that now dominate the market, nor do they address contamination or manufacturing quality.

EVIDENCE ON HERBAL MEDICINE SAFETY IN PREGNANCY

1. Use and disclosure

Herbal use in pregnancy is common across all regions. Beyond the global estimate of about one-third of pregnant women[1], a meta-analysis from Iran, a country with its own strong traditional medicine system, estimated that 49% of pregnant women used complementary and alternative medicine, most often in the first trimester and on the advice of family and friends, and that only 31% disclosed it to their healthcare provider[7]. Low disclosure means that potential adverse effects are rarely attributed to herbal products and that interactions with conventional drugs go unrecognised. The global review also found a correlation between disclosure of herbal use and better maternal and child health indicators[1].

2. Offspring outcomes

The most comprehensive recent synthesis included 111 studies, comprising 39 randomised trials and 72 observational studies, on prenatal herbal medicine use and offspring outcomes[8]. Observational studies adjusted for confounding did not show significant overall associations between herbal use and birth defects, miscarriage, stillbirth or preterm birth. Exploratory analyses, however, suggested signals for particular products, including *Glycyrrhiza* (liquorice, Yashtimadhu in Ayurveda) and almond oil with preterm birth, betel quid with low birth weight, and Coptidis Rhizoma with nervous system and genital malformations; the authors stressed that these signals rest on limited data and require cautious interpretation[8]. An earlier systematic review of 35 studies concluded that some medicinal plants have toxic, teratogenic or abortifacient potential, especially in the first trimester, because their active constituents can cross the placenta[9]. Liquorice is of particular relevance to Ayurvedic practice, since Yashtimadhu is a common ingredient of formulations used in pregnancy.

3. Evidence for herbs used for pregnancy symptoms

Ginger (Shunthi) is the best-studied herb for nausea and vomiting of pregnancy. A meta-analysis of 33 randomised trials of complementary therapies found that ginger reduced nausea scores compared with placebo and was comparable to conventional drugs on some measures, but the quality of evidence was low and the effect on vomiting was not significant against placebo[10]. The authors reported that complementary therapies appeared at least as safe as comparators within the trials, though the trials were not designed to detect rare foetal harms[10]. For most other herbs and almost all compound Ayurvedic formulations used in pregnancy, there are no controlled safety data.

HEAVY METALS IN HERBOMINERAL PRODUCTS

1. Prevalence of contamination and intentional inclusion

Rasa shastra is the branch of Ayurvedic pharmaceutics in which metals and minerals, including mercury, lead, arsenic, gold, iron, copper and zinc, are processed with herbs to produce Bhasma and other herbomineral preparations. Proponents argue that classical processing (Shodhana, Marana) renders these preparations safe; critics point to their measurable metal content. In a study of 193 Ayurvedic medicines purchased over the internet from manufacturers in the United States and India, 20.7% contained detectable lead, mercury or arsenic; Rasa shastra medicines were more than twice as likely as non-Rasa shastra medicines to contain metals and had higher median lead and mercury concentrations, and all metal-containing products exceeded one or more standards for acceptable daily intake[11]. Seventy-five per cent of the metal-containing products claimed good manufacturing practices[11].

2. Lead poisoning in pregnancy and childhood

The consequences are well documented. The New York City health department investigated six cases of lead poisoning in pregnant women who had used ten Ayurvedic medications made in India; blood lead levels ranged from 16 to 64 µg/dL, some products contained up to 2.4% lead, and several also contained mercury or arsenic[12]. The report noted that foetal lead exposure can impair neurodevelopment, reduce foetal growth and increase the risk of preterm birth and miscarriage[12]. A subsequent ten-year review of 584 health remedy samples collected in New York found that Ayurvedic medications could contain very high levels of lead, mercury and arsenic, that blood lead levels in adult users were associated with estimated cumulative lead intake, and that users of Ayurvedic medicines had higher blood lead levels than users of other remedies[13]. Similar cases have been reported in a child in the United States[14], in an adult who bought Ayurvedic products online and developed lead poisoning with anaemia[15], and in three patients in India with blood lead levels of up to 122 µg/dL who required chelation[16].

3. Implications for pregnancy and lactation

Lead crosses the placenta and is mobilised from maternal bone during pregnancy and lactation, so exposure before or during pregnancy can affect the foetus and breastfed infant. Mercury and arsenic are similarly toxic to the developing nervous system. Whatever the debate about the safety of properly prepared Bhasma in adults, there is no adequate evidence of safety for herbomineral preparations containing lead, mercury or arsenic in pregnancy or lactation, and the documented cases of poisoning in pregnant women[12] justify a precautionary approach. Preparations based on calcium (such as Praval and Mukta pishti) or iron (Mandura and Lauha preparations) pose different considerations, but their quality and contamination status still depend on manufacturing standards.

PHARMACOVIGILANCE OF AYURVEDIC MEDICINES

Adverse effects of Ayurvedic medicines are underrecognised because of the belief that they are free of side effects. A prospective one-year pharmacovigilance study in an Ayurvedic teaching hospital identified 52 confirmed adverse drug reactions, an incidence of 1.14% among patients; 44% were related to Panchakarma procedures, 25% to herbal formulations and 12% to herbomineral (Rasa aushadhi) formulations, and the gastrointestinal tract and skin were most commonly affected[17]. Individual case reports describe cutaneous reactions to Punarnava mandura, an iron-based formulation widely used for anaemia, including in pregnancy[18], and skin rashes after a polyherbal decoction combined with a proprietary syrup[19]. A German hospital-based surveillance study of drug-induced liver injury identified an Ayurvedic herb as the probable cause in one of ten herb-related cases[20].

None of these studies was specific to pregnancy, and there is no published pregnancy registry for Ayurvedic medicines. India's national pharmacovigilance programme for Ayurveda, Siddha, Unani and Homoeopathy drugs provides a reporting framework, but its usefulness in pregnancy depends on clinicians recording gestational exposure and following up birth outcomes.

LACTATION

Ayurveda places great importance on breast milk (Stanya) and describes galactagogue (Stanyajanana) drugs, such as Shatavari (*Asparagus racemosus*), Vidari (*Pueraria tuberosa*) and Jivanti, as well as measures to purify breast milk (Stanyashodhana)[3,6]. Safety data for these herbs in breastfeeding are limited. The most studied herbal galactagogue, fenugreek (Methika), increased breast milk volume compared with placebo in a network meta-analysis of a small number of trials, but was inferior to some other comparators[21]. These trials were small and were not designed to assess infant safety. Topical herbal compresses for breast engorgement have been evaluated in randomised trials; a Cochrane review judged the evidence to be of low certainty and noted occasional skin irritation[22]. The same considerations about heavy metals apply in lactation, since lead and mercury can be transferred to the infant through breast milk and maternal bone stores are mobilised during breastfeeding.

DISCUSSION

This review shows that classical Ayurveda and modern pharmacology agree on the central principle that potent drugs and procedures should be avoided in pregnancy. The classical lists of Garbhopaghatakara bhava and the prohibition of Tikshna, Ushna and eliminative therapies[3–5] remain sound guidance. The

safety problems of Ayurvedic medicines in pregnancy today arise less from the classical materia medica than from modern conditions: proprietary products of uncertain composition, herbomineral preparations containing toxic metals, unregulated online sales, self-medication and inadequate surveillance.

The evidence base is uneven. For the herbal medicines used most widely, pooled observational data are reassuring at a general level but contain specific signals, notably for liquorice[8]. For ginger, randomised data support modest benefit and short-term safety in nausea of pregnancy[10]. For most classical compound formulations used in pregnancy, including Phala ghrita, Garbhapala rasa and various Ksheerapaka preparations, no controlled safety data were identified. The heavy-metal evidence is the most consistent: internet-sold and imported products frequently contain lead, mercury or arsenic, and poisoning has been documented repeatedly, including in pregnant women[11–16].

Several practical recommendations follow. First, practitioners should ask every pregnant and breastfeeding woman about Ayurvedic, herbal and home remedies, since most do not volunteer this information[1,7]. Second, prescriptions in pregnancy should be restricted to clear indications, the minimum effective number of drugs and the lowest effective dose, avoiding drugs prohibited by the classical texts. Third, herbomineral preparations containing mercury, lead or arsenic should not be used in pregnancy or lactation unless safety has been established, and all products should come from manufacturers who provide batch-wise heavy-metal testing in line with pharmacopoeial limits. Fourth, blood lead testing should be considered in pregnant women with a history of Ayurvedic medicine use and unexplained anaemia, abdominal pain or neurological symptoms[12,15]. Fifth, suspected adverse reactions, including those to Panchakarma procedures, should be reported to the national pharmacovigilance programme, with gestational age and pregnancy outcome recorded.

For research, priorities include prospective pregnancy exposure registries for commonly used Ayurvedic formulations, heavy-metal surveys of products marketed specifically for pregnancy and lactation, measurement of herbal constituents and metals in breast milk, and properly designed trials of galactagogues that report infant outcomes.

CONCLUSION

Ayurvedic medicines are widely used during pregnancy and lactation, often without disclosure to doctors. Classical Ayurveda provides clear guidance to avoid sharp, hot and strongly eliminative drugs in pregnancy, and this remains valid. Current evidence does not show a general increase in adverse foetal outcomes with herbal medicines, but signals for individual herbs, repeated detection of toxic metals in herbomineral products and documented lead poisoning in pregnant women demand caution. Safe practice requires restraint in prescribing, avoidance of toxic-metal preparations, quality-assured products, routine enquiry about herbal use and active pharmacovigilance.

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