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Safety Surveillance Of *Swarnaprashana* Practices In Children: A Pharmacovigilance Perspective.

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Abstract:

Swarnaprashan, an Ayurvedic immunomodulatory practice involving the administration of purified gold (*Swarna Bhasma*) with honey and ghee to children, is gaining recognition as a preventive healthcare approach. With its increased use, particularly in Paediatric populations, it is vital to implement pharmacovigilance to monitor safety.

A comprehensive review of the manufacturing protocols, posology, therapeutic indications and contraindications, adverse effects, drug interactions, preservation methods, and dosage calculations—including their pharmacodynamic and pharmacokinetic implications was conducted based on classical *Ayurvedic* literature and peer-reviewed research articles on *Swarnaprashan* published in reputed journals from 2001 to 2024. Reports on safety and adverse events were retrieved, organized, and assessed for their occurrence rate, intensity, and underlying cause.

Despite the traditional use and claimed therapeutic benefits of *Swarnaprashan* in Ayurvedic medicine, questions regarding its long-term safety remain due to the presence of metallic gold in nano- or colloidal form. Although it is generally considered safe when properly prepared, isolated reports of adverse reactions highlight the need for systematic pharmacovigilance and standardization.

Current evidence suggests that properly prepared *Swarnaprashan* rarely causes significant adverse effects, though mild, transient gastrointestinal symptoms may occur. Regular safety assessments, including organ function and neurodevelopmental monitoring, are recommended to ensure long-term safety and build public trust in this traditional practice.

Keywords: *Swarnaprashan*, Pharmacovigilance, safety, Surveillance, Children

Introduction :

The World Health Organization defines pharmacovigilance (PV) as "It is a pharmacological science which deals with safety of drugs and activity which concern to assess, detect, understand and prevent adverse effects or the drug-related problem."

The aim of PV are to reinforce patient safety concerning medicine use by providing a system to collect, evaluate, and distribute drug safety data.

Despite widespread use, there is a conspicuous lack of pharmacovigilance data regarding its safety, particularly in neonates and infants. Pharmacovigilance in Ayurveda remains underdeveloped, with limited reporting systems for adverse drug reactions (ADRs) and poor integration with modern surveillance tools. Given the potential risks of heavy metals and pediatric administration, a systematic review of pharmacovigilance practices around Swarnaprashan is warranted.

Swarnaprashan (oral administration of processed gold with ghee, honey, and herbs) is a traditional Ayurvedic practice mentioned in *Kashyapa Samhita*, aimed at improving immunity, intellect, and longevity in children. It is commonly administered on auspicious days (e.g., *Pushya Nakshatra*) and is increasingly adopted in integrative pediatric care.

The Need of Pharmacovigilance in *Swarnaprashan* practice

Despite its long history of traditional use, the increasing adoption of *Swarnaprashan* warrants rigorous scientific scrutiny, especially regarding its safety profile in children. Pharmacovigilance for Ayurvedic preparations is crucial to identify, assess, understand, and prevent adverse drug reactions (ADRs) or any other drug-related problems. This is particularly important for vulnerable populations like children, who may exhibit different pharmacokinetic and pharmacodynamic responses compared to adults.

1.Vulnerable Population: Children

Children are more susceptible to adverse drug reactions (ADRs) due to immature metabolic systems and developing organs.The lack of robust data on pediatric safety makes pharmacovigilance essential to prevent toxicity or delayed adverse effects.

2. Safety Monitoring

Swarna Bhasma, though traditionally purified, contains metallic elements that may accumulate or interact unfavorably if not properly prepared. Improper dosage, contamination, or non-standard preparation can lead to heavy metal toxicity—a serious risk in children. Regular monitoring is essential to ensure the safety of the formulation and rule out adverse effects on organs such as the liver, kidneys, or nervous system.

3. Standardization and Quality Control

There is often a lack of standardization in preparation and dosage across different practitioners or brands. Pharmacovigilance can ensure uniform quality, validate safety profiles,batch-to-batch consistency, and safe dosage ranges. and avoid adulteration or contamination.

4. Adverse Drug Reactions (ADRs)

Although considered safe in classical Ayurveda, individual responses to Swarnaprashan may vary. Pharmacovigilance systems help record, analyze, and learn from any unexpected or adverse reactions in children.

5. Drug Interactions

Many parents combine Swarnaprashan with modern vaccinations, antibiotics, or supplements.Understanding interactions through pharmacovigilance data is important for ensuring safety in integrative approaches.

6. Long-Term Safety Data

There is a need for long-term studies on repeated or prolonged use of *Swarnaprashan* in children. Pharmacovigilance can help gather real-world evidence over time.

7 . Building Public Trust and Scientific Validation

Documentation of safety and efficacy through structured pharmacovigilance helps bridge the gap between traditional knowledge and modern medicine. It provides scientific legitimacy and boosts confidence among healthcare providers and parents.

Ancient way of Preparation and Administration of *Swarnaprashan*

Historical roots in Kashyapa Samhita and other classical Ayurvedic texts.

Swarnaprashan has its historical roots in the ancient Ayurvedic text *Kashyap Samhita*, where it is described as a unique pediatric practice for administering gold to infants. *Acharya Kashyapa,* considered a pioneer in Ayurvedic pediatrics *(Kaumarbhritya*), is credited with coining the term and systematizing the ritual.

[1,2]In *Kashyap Samhita's Sutrasthana*, particularly the chapter "*Lehadhyaya*," the administration of gold (*Swarna)* with honey and ghee is explained as part of *Jatakarma*, the postnatal ritual for newborn care. The original preparation suggested by *Kashyapa* involved triturating pure gold (*Kanaka*) with water, honey, and ghee on a clean stone, facing east, and giving it to the infant to lick. This was done for its purported benefits, including:

Medha- Enhancement of intellect , *Agni*- Promotion of digeston and metabolism , *Bala* Vardhanam- Strength and immunity , Ayushyam- Prolongation of life ,*Mangalam*- Auspiciousness ,*Varnyam* - Improvement of complexion ,*Vrushyam* - Aphrodisiac, *Grahapaham* - Protection from evil spirits and microorganisms

Kashyap Samhita uniquely describes specific benefits based on duration: administering *Swarnaprasahn* for 1 month is said to make a child highly intelligent (*Param medhavi*) and disease-resistant *(vyadhirbhi na ch Ghrushyate*), and for 6 months, it enhances extraordinary memory (*Shrutadhara).*

This practice is considered one of the oldest traditional forms of pediatric immunomodulation and cognitive enhancement in Ayurveda.

There are few methods of ***Swarnaprashan*** *(Suvarnaprashan)* described by ***Acharya Kashyap***, ***Acharya Vagbhata***, ***Acharya Sushrut*** each with distinct procedures and herbal combinations:

Text	Key Ingredients	Method	Timing/ Duration	Benefits
Kashyap Samhita[3]	Gold, honey, *Ghee*	Triturated, licked facing East	At birth; 1–6 months	Intelligence, immunity, memory
Ashtanga Hridaya[4]	Gold,herbs, honey/*Ghee*	Triturated linctus, licked	After birth, up to 1 yr	Growth, intellect, strength
Sushruta Samhita[5]	Gold, *Ghee*,herbs, honey,	Licked with ring finger	First 3–4 days of life	Health, longevity, ritual purity
Ashtanga Sangraha[6]	Gold,herbs, honey/*Ghee*	Licked, small dose	After birth	Intelligence, longevity, strength

Classical claims on SP

SP is mentioned to help in growth and development of body, intellect, strength, wisdom, and overall metabolism of children.[7] It also helps the child to fight against infectious diseases. It is claimed in Ayurvedic texts that after continuous administration of *Swarnaprashan* for 1 month, the child becomes extremely intelligent and is also not attacked by diseases easily. Also, continuous application of this procedure for 6 months causes the child to become extreme intelligent, such that the child can retain whatsoever he/she hears.[8] Acharya *Vagbhata* has opined that continuous application of SP for 1 year facilitates growth and development of infants. It also helps increase strength and intellect in the children.[9]

Increasing interest in traditional practices for immunity and cognitive development.There is a notable increase in interest in traditional practices, particularly Ayurveda, for improving immunity and cognitive development in children.*Swarnaprashana* (administration of preparations containing gold, honey, ghee, and sometimes herbal extracts) has gained popularity as a pediatric intervention. Modern studies reflect its immunomodulatory and neuroprotective effects, citing benefits such as reduced infections, enhanced memory, better growth indices, and overall healthier development in children under five .[10,11,12]

Materials and Methods :

systematic literature search was conducted across major electronic databases including PubMed, Scopus, google scholar and AYUSH Research Portal, using keywords such as "Swarnaprashan," *Swarnayog, Swarnabinduprashan swarnamritprashan* "gold nanoparticles," "Ayurveda," "pediatrics," "adverse effects," and "pharmacovigilance." Inclusion criteria focused on studies reporting on human subjects, specifically children, and those detailing safety outcomes or adverse events related to *Swarnaprashan* administration.

A total of 53 articles related to *Swarnaprashan* (SP), 62 on Swarna Bhasma, and 41 on pharmacovigilance or safety monitoring of immunization in children were retrieved from databases such as PubMed, Scopus, and Medline, as well as Ayurvedic research repositories. All articles addressing clinical safety, adverse events following administration, and monitoring protocols for *Swarnaprashan* and *Swarna Bhasma* in pediatric use were selected. After a critical analysis of the downloaded articles, 15 articles focusing directly on SP in children, 10 on *Swarna Bhasma* pharmacodynamics and safety, and 8 articles covering general methods and case studies in pharmacovigilance for pediatric immunization were shortlisted.

Results:

Established Clinical Safety and Efficacy: Multiple clinical studies and systematic reviews demonstrate that various gold-containing Ayurvedic formulations including *Swarnaprashan, Suvarna Bindu Prashan, Suvarna Vacha, and Kumarabharana Rasa* have been administered to children for a variety of indications, such as chronic tonsillitis, upper respiratory tract infections (URTI), and general immunity enhancement. Across these studies, administration in regulated doses with proper purification has not been associated with any reported adverse or toxic effects.[13]

Immunomodulatory and Growth Benefits Without Adverse Effects: Randomized controlled trials (RCTs) involving Swarna Bhasma formulations show significant modulation of immunoglobulin levels (IgG), reduced frequency of infections, and improved weight gain in children, with no evidence of interference in normal growth or biochemical parameters. No adverse events were reported during trials or follow-up periods, supporting the safety of these formulations when prepared and administered appropriately.[14,15]

Animal Toxicity Studies Support Human Findings:Chronic toxicity studies in rodent models receiving *Swarna Bindu Prashan* have shown no mortality, behavioral changes, or damage to vital organs, as corroborated by histopathology and normal clinical chemistry values, confirming non-toxic effects under standard dosing.[16,17,18]

Potential Risks Identified in Non-Standard Practice: Evidence cautions that the use of unpurified gold, incorrect dosing, or lack of regulatory oversight poses risks of adverse outcomes or metal accumulation. These findings underline the importance of stringent quality control, purification, and dosing standards to ensure child safety.[19]

Gold Nanoparticle Research Insights: Investigations into gold nanoparticles reveal that while they are not inherently cytotoxic and do not induce cell death, they accumulate within dendritic cells and have the potential to alter cytokine profiles, underscoring the necessity for caution with novel gold particulates and ongoing vigilance regarding immune modulation.[20]

Discussion :

No notable adverse drug reactions (ADRs) or clinical toxicity were reported during clinical trials or follow-up periods in infants and children administered *Swarnaprashan* prepared as *Swarna Bhasma* mixed with honey and ghee.[14]

Published research on *Swarnaprashan* reports that when prepared according to classical Ayurvedic methods and properly dosed, it demonstrates a high degree of safety in children, with no significant adverse effects observed in multiple clinical and observational studies.[21]

While classical Ayurvedic texts describe *Swarnaprashan* as safe and beneficial for immunity and cognition, modern medical standards demand rigorous clinical trials, toxicological evaluations, and post-administration monitoring to validate safety and efficacy.

the studies proves the role of *Swarnaprashana* in enhancing cognition and protection against diseases by enhancing immunity. *Swarnaprashana* acts on multiple levels and can be given for better growth and development in children. *Swarnaprashana* is safe for children. Clinical and pharmacological studies show immunomodulatory, nootropic, and therapeutic effects of *Swarnaprashan* as therapy.

Formulation Standardization Challenges :Significant variation in ingredients, dosages, and preparation methods among practitioners leads to formulation inconsistencies, complicating the assessment and comparison of safety outcomes.[22]

Biochemical and clinical safety: Hematological and biochemical monitoring in research settings consistently found no toxic effects; growth parameters and general health indices remained within normal ranges.

Pre-clinical toxicity studies: Animal studies indicated no mortality or toxicity even with acute and chronic dosing of *Swarna Bhasma* at levels exceeding those typically used in children.[23]

Traditional cautions concerning impurities and improper use: Classical and modern reviews highlight that improper preparation—such as using impure or unprocessed gold, or incorrect dosing—can lead to toxicity, including mental disturbances and potential organ damage, especially in children with developing systems.Improper purification of *Swarna Bhasma* intensifies the risk of heavy metal accumulation, with adverse effects potentially arising from prolonged or excessive consumption. However, study trials report no adverse drug reactions when prepared and administered appropriately.[24]

Underreporting of Adverse Events :There is very limited reporting of adverse drug reactions due to lack of practitioner awareness, absence of standardized reporting systems, and the mistaken belief among parents that natural products are inherently safe.

Integration with National Pharmacovigilance Programs : It is essential to include Ayurvedic medicines like *Swarnaprashan* in national programs such as the Pharmacovigilance Programme of India (PvPI) and encourage systematic reporting of adverse events by clinics and practitioners.

Clinical Trials and Post-Marketing Surveillance : Controlled clinical studies are needed to comprehensively evaluate safety profiles and efficacy claims, followed by robust post-marketing surveillance for real-world data collection.

Education and Awareness : Training programs should be established for Ayurveda practitioners on pharmacovigilance principles, and educational initiatives are necessary for parents regarding adverse drug reaction recognition and reporting.

Ethical Considerations : Ethical pediatric care demands informed consent, transparency, and the avoidance of exploitative practices in the administration of *Swarnaprashan*.

Future Directions : The development of a specialized pharmacovigilance framework for Ayurvedic pediatric formulations, digital ADR reporting systems, and interdisciplinary collaboration between Ayurveda and modern pharmacology are vital for future safety and efficacy assurance

Conclusion :

Swarnaprashan shows promising traditional value, but Pharmacovigilance is essential to ensure its safe, rational, and scientific use, especially in children.

The diversity in ingredients, dosages, and preparation methods employed by different practitioners highlights the need for standardization of the preparation process to ensure safety, efficacy, and reliable pharmacovigilance of *Swarnaprashan*. No acute or chronic adverse effects have been reported when *Swarnaprashan* is prepared with purified Swarna Bhasma and administered in recommended doses to healthy children so it is safe to administerd in child.

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