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EVIDENCE BASED STUDY OF EFFECT OF SWARNA YOGA (GOLD FORMULATIONS) IN CHILDREN: A SYSTEMATIC REVIEW

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ABSTRACT: Background: In the field of pediatrics, a number of herbo-metallic preparations are available which tend to enhance immunity in children. Various Ayurveda texts have mentioned these preparations, especially gold formulations like *Swarna Prashan*, *Suvarnabindu*, *SuvarnaVacha*, *Kumarabharana Rasa* etc. in children, and many clinical studies have also been published to establish their safety and efficacy. **Material and Method:** Subject-related published research articles from various journals were searched online through PubMed, Google Scholar and data of the articles were analyzed by following PICOS format to confirm their safety and efficacy in the paediatric population. **Results:** Total 7 clinical studies showing safety and efficacy of Ayurvedic herbo-metallic preparations in paediatric disorders such as Chronic tonsillitis, Upper Respiratory Tract Infection (URTI) and healthy children were treated with significant effect in their diseased condition and reducing the frequency of recurrent infections. No any adverse or toxic effect of any of these formulations was noticed. **Conclusion:** Gold preparations are found quite safe to use in pediatric disorders with proper dose and vehicle as well as in healthy children.

INTRODUCTION: In Ayurveda gold is having great importance, and its formulations are used from ancient time throughout the world for many purposes. In our classics, certain gold formulations are available which are supposed to enhance the immune power of children. It is believed that gold is used in Ayurvedic herbo-mineral preparations for the treatment of chronic and degenerative disease without any side effect. The use of *bhasma* from Gold, silver etc. metals and most herbo-mineral formulations of Ayurveda suffered because of some studies spoiled Ayurvedic herbo-mineral formulations as toxic and contaminated with lead, mercury, arsenic and other toxic compounds.

In the present era, immunomodulation is a strong need, especially in children who are more vulnerable for infections because of the underdeveloped immune system. There are many research studies available that show evidence of the safety and efficacy of gold preparations, but there are so many variations in methodology, formulations, etc. Hence, this type of systematic review may help us to answer the questions where the result is uncertain. Further, it will also confirm the relevance of current practice and whether there is a need to change our approach¹.

The present review edifies some of the gold preparations that were practised in Ayurveda like *Swarna Prashan*, *Suvarnabindu*, *Suvarna Vacha*, *Kumarabharana Rasa*, and *Swarnamritaprashana*. A present study has been conducted to evaluate the immunomodulatory effect of gold formulations mentioned in Ayurveda. Large numbers of formulations are mentioned in Ayurvedic classics.

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Here, an attempt was made to search the articles and compile them in a systematic format.

MATERIALS AND METHODS: Subject-related research articles published in various journals were searched and the data of the articles were analyzed to evaluate the safety and efficacy of gold formulations in children. This systematic review of studies on the efficacy of *Swarna* was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance². The search strategy included the Population, Intervention, Control, Outcome and

Study design (PICOS) pattern³ Data was extracted from research papers by using data extraction form⁴.

Types of Participants: Patients or healthy volunteers of age <16 years were included in the review. The inclusion criteria for selections of patients varied study to study according to diseases.

RESULTS: This systematic review included seven studies on the efficacy of gold formulations, out of which results were obtained in PICOS format are mentioned below in **Table 1**.

TABLE 1: STUDIES CONTAINING GOLD PREPARATION

S. no.	Basic Information	Participants	Intervention	Comparison	Outcome	Study design
1	Rao N. Prasanna <i>et al.</i> , ⁵ (2012)	n=30 3-8 year with URTI (Upper Respiratory Tract Infections)	<i>Swarnmrta Prashana</i> 1 ml daily empty stomach	Not included	Statistically significant relief in signs and symptoms of URTI	Not mentioned
2	Shailaja <i>et al.</i> , ⁶ (2013)	n=16 Chronic tonsillitis Age: Between 5 and 10 years	<i>Kumarabharana Rasa</i> 500 mg once in the morning before meal with honey; Duration: 30 days	Not mentioned	Statistical significant reversal of fever, lymphadenopathy, and other signs and symptoms	Pilot clinical study
3	Ramteke <i>et al.</i> , ⁷ (2014) (RCT)	n=120 Physical growth parameters Age: Children up to 12 years	<i>Swarnaprashana</i> 1 mg/kg body weight on every 27 th day (<i>Pushya nakshatra</i>) for total 14 days (n=30male and 30 female) Duration: 1 year and 15 days	Control (n=30): <i>Madhujala</i> Standard Group Control (n=30): Standard required measures	Significant (P<0.05) result in weight gain of male and female children in relation with control group	Randomised Control Trial
4	Arun raj <i>et al.</i> , ⁸ (2016) Nonrandomized controlled trial	n=40 Chronic tonsillitis Age: Between 5 and 10 years	<i>Kumarabharana rasa</i> 500 mg once in the morning before meal with honey Duration: 30 days	<i>Godhuma Vati</i> (placebo)	Statistically significant relief in signs and symptoms as that of placebo control	Open-labeled double-arm setting with a pre- and post-test design.
5	Dr.JaybhayVikas <i>et al.</i> , ⁹ (2016)	n= 27 0-5 years	<i>Suvarna Prashan</i>	Not included	Statistically significant increase in height, weight and head circumference	Open study design
6	PallaviDindore <i>et al.</i> , ¹⁰ (2017)	N=40 3-4 year Healthy children	<i>Suvarnabhasma</i> 4mg/dose suspended in <i>ghrita</i> and 4 drops of <i>madhu</i> Duration 6 month	Group B-No treatment	Statistically significant decrease in frequency, severity and duration of illness Also found significant reduction in mood and temperament, behaviour complaints	Open label, parallel, prospective and observational
7	Jyotsna Ahir <i>et al.</i> , ¹¹ (2018)	N=100 0-16 year with URTI	Group A- <i>Suvarna Prashana</i> 5 drops upto 5 years and 5 drop+1 drop for each additional 1 year	Group B-No treatment	Statistically significant relief in signs and symptoms	Not mentioned

TABLE 2: FORMULATIONS OF SWARNA AVAILABLE IN CLASSICAL TEXT

S. no.	Reference	Aushadhi	Sahapana	Matra	Kala
1	Charaka (Ch. Sharir 8/46)	Madhu+Ghrita	-	-	At birth (Single dose)
2	Sushruta (Su. Sh.10/15) ¹²	Swarna	Madhu+Ghrita	1 Gunja (Dalhana)	As above
3	Ashtanga Samgraha (Ashtang Samgraha Uttartantra 1/8) ¹³	Endri, Brahmi, Vacha & Shankpushpi with Swarnaspoona Swarna, Brahmi, Bala, Shatavari Swarna	Madhu+Ghrita Madhu+Ghrita Madhu+Ghrita	1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya 1 Gunja (Dalhana)	At birth (Single dose) At birth (Single dose) At birth (Single dose)
4	Ashtang Hriday (Ashtang Hriday Uttartantra 1/9) ¹⁴	Swarna & Vacha Swarna, Brahmi, Vacha, Tapyta & Haritaki Swarna and Amalaki	Madhu+Ghrita Madhu+Ghrita Madhu+Ghrita	1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya	Till 1 year At birth (Single dose) At birth (Single dose)
5	Sushruta (Su. Sh.10/73) & Ashtang Hriday (Ashtang Hriday Uttartantra 1/47-48) ¹⁵	Swarna, Balavacha, Kushtha, Kaidarya, Vacha Swarna & Arkapushpi Swarna, Matsyakshaka & Shankha Swarna, Kaidarya, Vacha Swarnachurna	Madhu+Ghrita Madhu+Ghrita Madhu+Ghrita Madhu+Ghrita Madhu+Ghrita	1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya 1 Harenu/ 1 Kalaya	Till 1 year Till 1 year Till 1 year Till 1 year Till 1 year
6	Sharangdhara (Sharangdhara PurvaKhanda 6/27) ¹⁶	Swarna, Kushtha, Haritaki, Vacha, Brahmi	Madhu+Ghrita Madhu+Ghrita	1 Ratti 1 Gunja	- As Above
8	BhaishajyaRatnavali (BhaishajyaRatnavali, 71/8) ¹⁷	Swarna, Kana (Pippali)	Madhu+Ghrita	1/4 th Ratti	At birth (Single dose)
9	Rasaratnasamucchaya ¹⁸ (22/136)	Swarna	Madhu+Ghrita	Not given	Daily from birth to 1 month or 6 months of age
11	Kashyapa Samhita (Kashyapa Sutra Lehadhyay) ¹⁹	Swarna	Madhu+Ghrita	Not given	Daily from birth to 1 month or 6 months of age

DISCUSSION: In children, some herbo-metallic formulations have also been used in routine practice as mentioned in **Table 2**. Since ancient times these formulations are extensively recommended by Ayurveda physicians. Previous researches also have proved antioxidant²⁰, anti-inflammatory, antibacterial and immunomodulatory activities of gold^{21, 22}.

Recent research shows that gold particles having anti-oxidant properties and T_H1 lymphocyte activation and thus involve in the regulation of antigen-specific immune response²³. For the past several decade's Gold nanoparticles have come into the light, which is synthesized by using various methods, which include chemical and electrochemical radiation, photochemical method, and biological techniques²⁴. AuNPs (Gold nanoparticles) have potential stability over the antibacterial activities against gram-negative bacteria like *E. coli*, *Pseudomonas aeruginosa*, and gram-positive bacteria like *Bacillus subtilis*, respectively²⁵. *Vacha* (*Acorus calamus*) is also included in some of these formulations, which may be considered to help in relieving chronic stress-induced immunodeficiency²⁶. Some other study also suggests its immunomodulatory and anti-

inflammatory properties²⁷. According to Charaka immature stage lasts up to 16 yr of age. During this period, *Dhatus* are undeveloped, various immature organs of the body. Moreover, *Bala*, *Varna* are not fully developed, and body is soft, which cannot tolerate any adversity²⁸. Therefore the use of herbometallic formulations in children may raise doubt of safety and toxicity. But in a recent study, the group of wistar male albino rats was administered *Swarnabhasma* in a dose of 5.625 mg/kg body weight along with 0.4 ml of ghee and honey by oral route for 90 days, and no significant behavioral change or mortality was noticed²⁹. Gold particles are the most promising ones which do not affect living cells and do not produce adverse effects³⁰.

In the studies mentioned above, which were included in this systematic review, most gold formulations have included ghee and honey as a vehicle that helps decrease the toxic level of gold ash. To overcome this toxic, synthesis of nanoparticles using biological conjugates such as proteins, peptides, oligonucleotide, polysaccharides, fatty acids, and amino acids might be done, reducing the toxic nature of the prepared

nanoparticles³¹. Honey is known to enhance the action of these medicines and has a potential immunomodulatory effect³². One of the study conducted on ghee reports the antioxidant properties of the high CLA enriched ghee³³. Hence, honey and ghee are found to be beneficial in enhancing potency and reducing the toxic effect of gold formulations.

Strength of the Study: The articles were searched through the most popular databases and written in a proper scientific manner with possible scientific discussion and justification were included in this study. Data were obtained by using the standardised technique PICO format.

Limitations of the Study: Some articles may be located in other databases. Many articles of Ayurveda published earlier are still not available online, and some of the research work has not been published yet. Hence, studies from them could not be included in the study. Furthermore, only a few studies were reported with proper methodology and study design.

CONCLUSION: This review regarding the clinical trials conducted on the gold formulations suggests that these preparations seem to be safe and efficacious with their multidimensional approach as an immunomodulator for children. Formulations prepared by following proper methodology, dose, and vehicle are least likely to show any evidence of toxicity in children. However, well-planned studies with proper methodology are warranted to improve the evidence to establish *Swarnaprashana* to be used as an Ayurveda immunization technique.

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