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Research Article

# A Randomized Controlled Clinical Study on the Effect of *Swarnaprashan* (Gold Electuary) on Serum IgG, Anthopometry, and Morbidity Status in Children in Recurrent Upper Respiratory Tract Infections (URTI)

**Kalpana Patni[1], Nisha Pandey[2], Gaurav Sinha[3*]**

1. Assistant Professor, Department of Kaumarbhritya/ Balroga Faculty of Ayurveda, IMS, BHU, Varanasi. India.
2. Ph D Scholar, Department of Kaumarbhritya/ Balroga Faculty of Ayurveda, IMS, BHU, Varanasi. India.
3. Assistant Professor, Department of Panchakarma, Goel Ayurvedic Medical College and Hospital Lucknow, Uttar Pradesh, India.

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## Abstract

Background: Recurrent upper respiratory tract infections (URTIs) in children represent a major public health concern, especially in developing countries. These infections are among the leading causes of morbidity in immunocompromised and susceptible pediatric populations. In India, respiratory infections contribute to nearly 15% of deaths occurring during infancy and childhood. Aim of the study: To study the Effect of *Swarnaprashan* (Gold Electuary) on Serum IgG, Anthopometry, and Immune status in Children. Methods: A randomized, open-label clinical study was conducted on 120 children aged 6 to 12 years of both sexes, having low immunity and frequent upper respiratory tract infections. Participants were randomly allocated into two groups of 60 each. Group A received the trial drug SP, while Group B was administered *Madhu* and *Ghrita* as the control for a duration of two months. Evaluation Parameters: The study parameters included the incidence of recurrent upper respiratory tract infections (URTI) as reported by participants, the duration and severity of each episode, serum IgG levels, and anthropometric measures. Results: Group A showed significant improvement in morbidity scores(<0.0001), and serum IgG levels (0.0424) whereas Group B demonstrated insignificant changes (>0.05). Conclusion: This clinical trial indicates that SP may serve as an effective intervention for enhancing immune status, reducing the recurrence of upper respiratory tract infections, and promoting the overall growth of children.

**Keywords:** Ayurveda, Children, IgG, Immunity, Morbidity Status, *Swarnaprashan*, Upper Respiratory Tract Infection.

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## Introduction

Child mortality and illness is a significant challenge, mainly in developing countries. More than half of children (53.7%) are suffered by several health problems related to compromised immune system. Globally, acute respiratory tract infections are the prime causes of mortality and morbidity in children. Developing countries report approximately 1.9 million deaths from childhood ARTIs, with 20% of them occurring in India. In India, around 14.3% of infant mortality and 15.9% of deaths among young children are attributed to ARTIs.(1) Children are particularly vulnerable to infections due to their underdeveloped immune systems. Consequently, maintaining the health of this sensitive age group is vital, as recurrent illnesses can hinder growth and development, ultimately influencing the nation's overall health status. *Lehana yogas* (electuaries), traditional Ayurvedic formulation, have long been recommended to enhance children's overall well-being. These preparations promote general health and immunity, ensure proper nourishment, improve digestion and metabolism, and aid in cognitive and speech development, including cases of delayed milestones. (2) SP is a specific *Lehana* formulation designed to enhance *Medha* (intelligence), *Agni* (appetite, digestive, and metabolic functions), and *Bala* (immunity and strength). It can be administered to children as an immunomodulatory agent during their developmental phase, a period marked by increased vulnerability to infections due to an immature immune system. SP is traditionally believed to promote *Ayushya* (longevity), *Mangalam* (happiness and health), *Punyam* (auspicious), *Varnyam* (complexion), and *Grahapaham* (protects against negative entities and harmful microbes. (2) According to Acharya Kashyapa, administering this formulation for one month makes the child *Parama Medhavi* (highly intellectual) and less susceptible to illnesses. Continued administration for six months is said to grant quality of *Shrutadhara,* the remarkable ability to retain and recall information immediately after hearing it. (3)

Upper respiratory tract infections (URTIs) include conditions such as the common cold, laryngitis, pharyngitis, tonsillitis, acute rhinitis, acute sinusitis, and acute otitis media. URTIs are among

*** Corresponding Author:**
**Gaurav Sinha**
Assistant Professor, Department of Panchakarma, Goel Ayurvedic Medical College and Hospital Lucknow, Uttar Pradesh, India.
Email Id: sinhagaurav416@gmail.com

the most common reasons for paediatric consultations and are considered a leading cause of school absenteeism. Typical signs and symptoms include coughing, sneezing, nasal congestion, runny nose, mild fever, loss of appetite, and muscle aches.(4) The management of viral URTIs primarily focuses on symptomatic relief, as antibiotics have only a limited role in treatment. (5) To relieve fever, nasal congestion, and cough associated with viral upper respiratory tract infections (URTIs), various treatment options are available. These include medications like antihistamines, antipyretics, anti-inflammatory drugs, anti-tussive like dextromethorphan, expectorants, and decongestants as pseudoephedrine(6). Despite advancements in controlling infection transmission, emerging challenges such as increasing environmental stress and the growing antimicrobial resistance among pathogens continue to pose challenges for immune system. The immune system has evolved to defend the body against a wide range of ever-changing pathogenic microorganisms and to eliminate toxic or allergenic agents entering through mucosal surfaces.

Although the National Immunization Schedule has been effectively implemented, India still continues to experience a high rate of child mortality. Vaccinations are administered from the first day of life. They provide protection against specific diseases; however, they cannot safeguard children from all types of infections. Hence, there is a need for non-specific immune-enhancing agents that strengthen the overall immune response in children. Ayurveda provides a variety of formulations aimed at enhancing immunity, among which SP holds particular significance. SP is composed of *Swarna Bhasma*, *Madhu* (honey), and *Ghrita* (ghee), all of which known for their proven immunomodulatory properties. Gold nanoparticles are known to encapsulate active pharmaceutical compounds and enhance their bioavailability. Considering the potential benefits of such formulations in promoting non-specific immunity, cognitive development, and overall growth, there is a strong rationale for encouraging their inclusion in child health promotion programs.

**Aim and objectives of the study**

The aim of this clinical study was to assess the effect of SP on recurrent URTI, serum IgG levels, and anthropometric measures in children.

## Methodology

This randomised controlled clinical trial, conducted as an open-label study using the block randomisation method, included two groups with 60 participants each, comparing SP with a combination of Madhu (honey) and Ghrita (clarified butter) as the comparator. The study was conducted between June 2023 and June 2024.

**Duration of the Trial -** 2 months.

**Ethical clearance**

Ethical approval for the clinical study on human participants was obtained from the Institutional Ethical Committee, Institute of Medical Sciences, Banaras Hindu University (BHU), Varanasi. The registration number is ECR/526/Inst/UP/2014/RR20/19.05.2020.

**CTRI registration**

The study was registered with the Clinical Trials Registry of India (CTRI) under reference no. REF/2023/04/066327 and registration no. CTRI/2023/05/052450.

**Consent of the parents/guardians:**

Written informed consent from the child's parents, or guardian was obtained prior to enrolment in the trial.

**Clinical Proforma-** A structured proforma was prepared to document a comprehensive profile of the study participants, including their chief complaints, history of the present illness, signs and symptoms, and the assessment criteria employed.

**Selection of cases**

A total of 120 patients were enrolled from the Outpatient Department (OPD) of Kaumarabhritya/Balroga, OPD No. 25/IPD, Kashyap Ward, Sir Sunderlal Hospital, Ayurveda Wing, Institute of Medical Sciences (I.M.S.), Banaras Hindu University (B.H.U.), after thorough screening.

**Inclusion Criteria**

Children of either gender, aged 6 to 12 years, with a history of three or more episodes of recurrent URTI in the last two months and whose parents provided written consent were included in the study.

**Exclusion criteria**

Children with significant chronic illnesses requiring long-term treatment, those taking additional medications (particularly corticosteroids), those with comorbidities such as uncontrolled pulmonary dysfunction, a history of hypersensitivity to the investigational drug or its components, or prior participation in any other clinical study within the last three months were excluded from the study.

**Discontinuation Criteria**

Children who developed any severe illness during the trial or whose parents were unwilling to continue the treatment were withdrawn from the study.

**Grouping of Subjects**

A total of 120 patients were randomly divided into two groups, with 60 patients in each group: Group A received the trial drug (SP = SB + *Madhu* + *Ghrita*), and Group B received *Madhu* and *Ghrita*.

**Assessment criteria**

The outcomes of the clinical trial were evaluated based on the observations of clinical characteristics and laboratory investigations. The following criteria were utilised to assess patients before, during, and after the treatment.

**Clinical profile**

This included various manifestations of poor immune status with a history of three or more episodes of recurrent URTI in the last two months assessed on the basis of Morbidity score and in children in URTI including recurrent rhinorrhoea, nasal obstruction, enlarged tonsils, headache, fever, cough and sore throat.

Morbidity score was calculated as:

Morbidity score = Incidence in the last 2 months × severity

Laboratory parameters (haematological and biochemical parameters)

Following parameters were adopted for the assessment of the patients under trial: Serum IgG, Hb gm%, total leukocyte count (TLC), neutrophil count, lymphocyte count, eosinophil count, erythrocyte sedimentation rate (ESR), LFT, RFT

**Trial drug: *Swarnaprashan***

Premium-grade *Swarna Bhasma* (incinerated gold particles), weighing 100 mg (Batch No. P22110056), was procured from a reputed pharmaceutical company, Shree Dhootapapeshwar Limited (SDL), India. Honey (Lot No. BT01212), certified under GMP standards, was obtained from Dabur Private Limited (DPL), India. Traditionally prepared homemade A2 Desi cow *Bilona* ghee (clarified butter) was used. Each ingredient was evaluated in accordance with the guidelines of the Ayurvedic Pharmacopoeia of India.(7) The study formulation *SP*(2) was prepared in the form of oral drops - a mixture of *SB*, *Ghrita*, and *Madhu* - to facilitate easy administration in paediatric patients.

**Presentation of trial drug**

The trial drug was packaged in 10 mL vials and administered orally in the form of drops.

**Posology**

Pure *SB* was triturated with *Ghrita* using a mortar and pestle by churning it clockwise for 3 hours. A total of 200 mg SB was processed with 10 mL of *Ghrita*. Consequently, 1 mL (approximately 20 drops) of the ghee contained 20 mg of SB, with each drop containing 1 mg of SB. Before administration, the mixture was gently warmed in a water bath to liquefy it and then shaken well to ensure a homogeneous mixture of SB and *Ghrita*. The formulation was administered for a duration of two months.

Dosage: 2 drops (2mg SB) SB+ *Ghrita* mixture with 4 drops of Honey, daily orally in the morning empty stomach and evening with the instruction not to take anything orally for next half an hour.

**Statistical analysis**

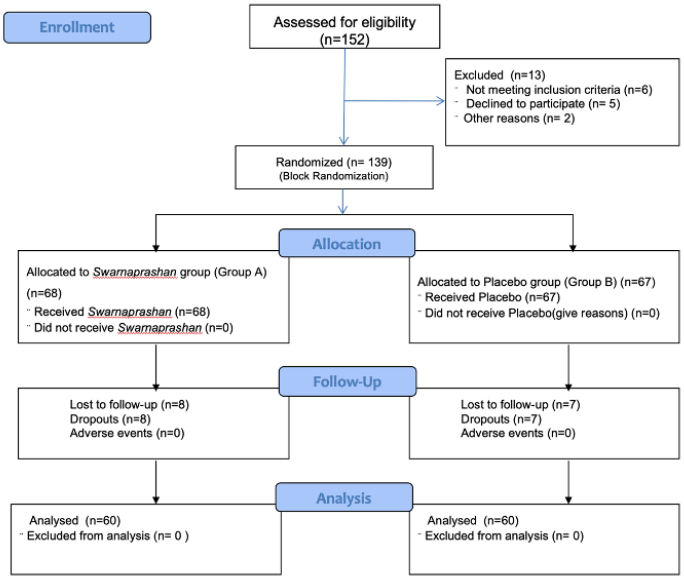
The clinical efficacy of the medication was statistically analysed based on all parameters defined in the assessment criteria. Morbidity scores were recorded before treatment, and at the end of the study period. Consequently, the results obtained from each group were statistically evaluated using Students paired T test to determine intra-group variations and the significance of observed effects. For intergroup comparisons, the Mann–Whitney *U* test was applied, as the data did not meet the normality assumptions required for parametric testing. All parameters, including morbidity features and laboratory values, were subjected to statistical evaluation.

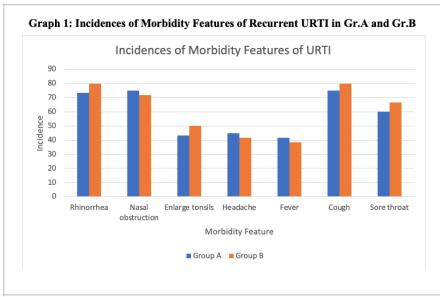
## Results

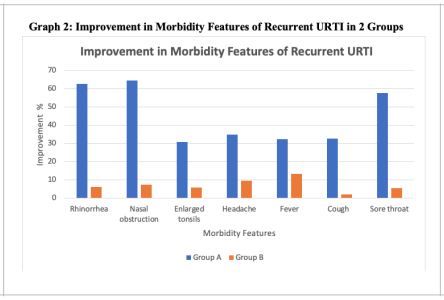
A total of 152 children with upper respiratory tract infections were screened. After pre-assessment 139 children were registered in the clinical study and were randomly distributed into 2 groups, 68 in gr. A and 67 in gr. B. Out of these 15 subjects discontinued the trial. The study was completed on 120 subjects with 60 in each in each group and the details are presented in the CONSORT flow chart. [Figure 1] Demographic Observation of clinical trial at baseline are displayed in Table 1. It was observed that out of 120 enrolled subjects, maximum 94 (78.33%) subjects were suffering from recurrent episodes of rhinorrhoea, followed by 88 (73.33%) with nasal obstruction, 56 (46.67 %) with tonsillitis, 52 (43.33 %) with headache, 48 (40.00 %) with fever, 93 (77.50%) with cough, and 76 (63.33 %) with sore throat. [Graph1].[Table 1] [Graph 1]. In Gr. A, which received the trial medication (SP), highly significant improvements were observed in several morbidity symptoms, including rhinorrhoea, nasal obstruction, headache, fever, and sore throat, while significant relief was noted in cases of enlarged tonsils. In contrast, Gr. B exhibited statistically insignificant changes in all morbidity parameters [Table 2]. The percentage of overall improvement following treatment in both groups is illustrated in [Graph 2]. Intergroup comparison revealed highly significant improvement in rhinorrhoea, nasal obstruction, and cough, along with significant improvement in enlarged tonsils, headache, fever, and sore throat in Group A compared to Group B [Table 3] [Graph 3].

In laboratory parameters, statistically highly significant improvements were observed in haemoglobin (Hb%) levels, eosinophil count, and erythrocyte sedimentation rate (ESR). A statistically significant reduction was noted in total leukocyte count (TLC), along with a significant decrease in neutrophil and lymphocyte counts and an increase in serum IgG levels. These findings indicate the efficacy of the trial medication [Table 4]. In Group B, however, the changes observed in Hb%, eosinophil count, ESR, TLC, neutrophil and lymphocyte counts, and serum IgG levels were statistically insignificant. [Table 4].

**Figure 1: Consort 2010 flow diagram**



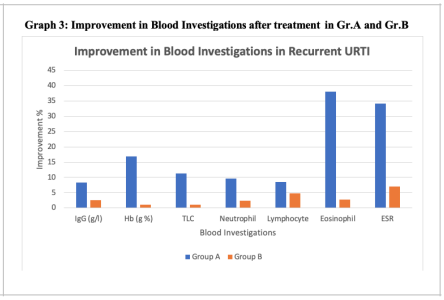



**Table 1: Demographic Observation of clinical trial**

| Feature | Classification | Group A (*n*=60), *n* (%) | Group B (*n*=60), *n* (%) | Total, (*n*=120), *n* (%) |
|---|---|---|---|---|
| Age (years) | 6-9 | 40 (67.00) | 36 (60.00) | 76 (68.33) |
| | >9-12 | 20 (33.33) | 24 (40.00) | 44 (36.67) |
| Sex | Male | 34 (56.67) | 38 (63.33) | 72(60.00) |
| | Female | 26 (43.33) | 22 (36.66) | 48 (40.00) |
| Family | Nuclear | 40 (67.00) | 44(63.33) | 84 (70.00) |
| | Joint | 20 (33.33) | 16 (26.67) | 36(30.00) |
| Religion | Hindu | 42 (70:00) | 44(73.33) | 86 (71.67) |
| | Muslim | 13 (16.67) | 11 (26.67) | 24(20.00) |
| | Sikh | 05 (8.33) | 04 (6.67) | 09 (7.50) |
| | Christian | 00 (0.00) | 01 (1.60) | 01 (0.83) |
| Socioeconomic status | Middle | 38 (63.33) | 36 (60.00) | 74 (61.67) |
| | Lower middle | 16 (26.67) | 14(23.33) | 30 (25.00) |
| | Lower | 06 (10.00) | 10 (16.67) | 24 (20.00) |
| Gestational age | Preterm | 05 (8.33) | 06 (10.00) | 11 (9.17) |
| | Full-term | 54 (90.00) | 52 (86.67) | 106 (83.33) |
| | Post-term | 01 (1.60) | 02 (3.33) | 03 (2.50) |
| Duration of exclusive breast feeding (months) | 6 | 10 (16.67) | 12 (20:00) | 22 (18.33) |
| | 4 | 17 (28.33) | 19 (31.67) | 36 (30.00) |
| | <4 | 22 (36.66) | 20 (33.33) | 42 (35.00) |
| | Top feeding | 11 (18.33) | 09 (15.00) | 20 (16.67) |
| *Prakriti* | *Vata-Pitta* | 13 (21.67) | 12 (20:00) | 25 (20.83) |
| | *Vata-Kapha* | 35 (58.33) | 33 (55:00) | 68(56.67) |
| | *Kapha-Pitta* | 12 (20:00) | 15 (25.00) | 27 (22.50) |
| Weight per age | Average | 16 (26.67) | 15 (25.00) | 31 (25.83) |
| | Underweight | 33 (55.00) | 34 (56.67) | 67 (55.83) |
| | Overweight | 10 (16.67) | 11 (18.33) | 21 (17.50) |
| Immunization status | Complete | 48 (80.00) | 50(83.33) | 98 (81.67) |
| | Partial | 12 (20:00) | 10 (16.67) | 22 (18.33) |
| Morbidity features | Rhinorrhea | 44 (73.33) | 48 (80.00) | 92 (76.67) |
| | Nasal obstruction | 45 (75.00) | 43 (71.67) | 88 (73.33) |
| | Enlarge tonsils | 26 (43.33) | 30 (50.00) | 56 (46.67) |
| | Headache | 27 (45.00) | 25 (41.67) | 52 (43.33) |
| | Fever | 25 (41.67) | 23 (38.33) | 48 (40.00) |
| | Cough | 45 (75.00) | 48 (80.00) | 93 (77.50) |
| | Sore throat | 36 (60.00) | 40 (66.67) | 76 (63.33) |

**Table 2: Statistical analysis of Morbidity features before treatment and after treatment**

| Morbidity features | Group | Mean±SD | | Mean difference | Gain (%) | *t* | *P* | Remark |
|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | |
| Rhinorrhea | A | 11.96±4.076 | 4.44±1.5645 | 7.61 | 62.751 | 11.413 | <0.0001 | HS |
| | B | 11.416±3.64 | 10.71±3.665 | 0.721 | 6.242 | 1.083 | 0.2881 | NS |
| Nasal obstruction | A | 11.58±3.892 | 4.183±2.223 | 7.418 | 64.721 | 11.223 | <0.0001 | HS |
| | B | 10.17±4.228 | 9.42±3.946 | 0.746 | 7.396 | 1.394 | 0.1791 | NS |
| Enlarged tonsils | A | 5.418±2.236 | 3.751±1.485 | 1.667 | 30.714 | 3.082 | 0.0105 | S |
| | B | 4.942±2.587 | 4.648±2.696 | 0.296 | 5.949 | 2.063 | 0.05612 | NS |
| Headache | A | 4.301±1.896 | 2.801±1.196 | 1.507 | 34.88 | 5.844 | <0.0001 | HS |
| | B | 4.729±2.266 | 4.274±2.513 | 0.455 | 9.512 | 1.554 | 0.1352 | NS |
| Fever | A | 4.856±1.956 | 2.785±1.476 | 2.073 | 32.351 | 5.385 | <0.0001 | HS |
| | B | 6.01±5.185 | 5.21±2.306 | 0.808 | 13.334 | 1.805 | 0.1051 | NS |
| Cough | A | 9.715±4.325 | 6.525±3.077 | 3.197 | 32.825 | 5.935 | <0.0001 | HS |
| | B | 7.697±2.364 | 7.523±2.314 | 0.175 | 2.212 | 0.3225 | 0.753 | NS |
| Sore throat | A | 8.811±4.132 | 3.668±1.907 | 5.144 | 57.879 | 5.943 | <0.0001 | HS |
| | B | 8.436±2.129 | 7.958±2.206 | 0.479 | 5.681 | 1.327 | 0.1992 | NS |

HS: Highly significant, S: Significant, NS: Not significant, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment

**Table 3: Statistical analysis of inter group comparison after treatment**

| Morbidity | Group | Mean±SD | SE | Mann-Whitney (U) | *P* | Remark |
|---|---|---|---|---|---|---|
| Rhinorrhea | A | 7.49±3.082 | 0.6572 | 497.52 | <0.0001 | HS |
| | B | 0.708±3.194 | 0.6525 | | | |
| Nasal obstruction | A | 4.546±1.82 | 0.3933 | 467.1 | <0.0001 | HS |
| | B | 0.751±2.642 | 0.5393 | | | |
| Enlarge tonsils | A | 1.61±1.272 | 0.2848 | 327.1 | 0.00241 | S |
| | B | 0.456±1.373 | 0.2923 | | | |
| Headache | A | 1.668±1.875 | 0.5414 | 170.61 | 0.00141 | S |
| | B | 0.295±0.585 | 0.1428 | | | |
| Fever | A | 2.072±1.44 | 0.3848 | 110.01 | 0.0204 | S |
| | B | 0.81±1.397 | 0.4423 | | | |
| Cough | A | 3.20±2.465 | 0.5374 | 408.50 | <0.0001 | HS |
| | B | 0.175±2.587 | 0.5397 | | | |
| Sore throat | A | 3.669±3.116 | 0.8990 | 107.511 | 0.0092 | S |
| | B | 1.634±1.733 | 0.5223 | | | |

HS: Highly significant, S: Significant, NS: Not significant SD: Standard deviation, SE: Standard error

**Table 4: Statistical analysis of state of Anthropometric measurements before treatment and after treatment**

| Anthopometric Measurement | Group | Mean±SD | | Within the group comparison (paired t test) BT- AT |
|---|---|---|---|---|
| | | BT | AT | |
| Weight (In kg) | Group A | 21.83±3.461 | 25.10±3.681 | -3.266 ± 1.016<br>t=17.632<br>p=.0001 |
| | Group B | 23.731±4.456 | 23.632±4.422 | -0.101 ± 1.063<br>t=0.515<br>p=0.611 |
| | Between the group comparison (unpaired t test) | t=3.7841<br>p=.0001 | t=0.5082<br>p=0.615 | |
| BMI ($kg/m^2$) | Group A | 14.578±1.606 | 15.983±1.772 | -1.4051 ± 0.693<br>t=11.1201<br>p=.0001 |
| | Group B | 15.7021±1.9632 | 15.469±1.828 | -0.232 ± 1.049<br>t=1.207<br>p=0.238 |
| | Between the group comparison (unpaired t test) | t=4.589<br>p=.000 | t=1.050<br>p=0.298 | |
| Weight for age % | Group A | 85.57±9.453 | 98.10±12.595 | -13.534 ± 5.654<br>t=13.108<br>p=.000 |
| | Group B | 89.231<br>±8.433 | 88.472<br>±9.022 | 0.7671± 3.511<br>t=1.1961<br>p=0.2412 |
| | Between the group comparison (unpaired t test) | t=2.882<br>p=0.0061 | t=2.6980<br>p=0.0091 | |

**Table 5: Statistical Analysis of Investigations after treatment in Gr.A and Gr.B**

| Morbidity features | Group | Mean±SD | | Mean difference | Gain (%) | *t* | *P* | Remark |
|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | |
| IgG (g/l) | A | 9.44±2.681 | 10.231±2.181 | -0.79 | 8.391 | 2.1241 | 0.0424 | S |
| | B | 10.14±1.796 | 9.90±1.881 | 0.27 | 2.482 | 1.3071 | 0.2021 | NS |
| Hb (g %) | A | 10.766±1.524 | 12.572±1.362 | -1.81 | 16.791 | 8.7442 | <0.0001 | HS |
| | B | 11.866±1.334 | 12.004±1.332 | -0.15 | 1.148 | 1.2351 | 0.2273 | NS |
| TLC | A | 11482±4182.895 | 10178±3264.82 | 1305 | 11.348 | 3.3179 | 0.0024 | S |
| | B | 10.829±2.211 | 10.938±1.912 | -0.110 | 1.012 | 0.635 | 0.5304 | NS |
| Neutrophil | A | 49.031±13.237 | 44.272±14.784 | 4.76 | 9.702 | 2.1081 | 0.0433 | S |
| | B | 47.121±9.446 | 46.05±7.751 | 1.07 | 2.281 | 0.7914 | 0.4352 | NS |
| Lymphocyte | A | 46.014±13.895 | 42.114±9.278 | 3.91 | 8.461 | 2.5012 | 0.0183 | S |
| | B | 41.201±9.917 | 39.21±9.12 | 1.99 | 4.862 | 1.5602 | 0.1302 | NS |
| Eosinophil | A | 4.718±1.9111 | 2.919±1.5642 | 1.78 | 38.161 | 11.6421 | <0.0001 | HS |
| | B | 6.058±4.0141 | 5.89±4.05491 | 0.167 | 2.752 | 1.9812 | 0.0573 | NS |
| ESR | A | 22.866±17.496 | 15.066±8.734 | 7.80 | 34.121 | 3.9151 | 0.0004 | HS |
| | B | 15.668±10.195 | 16.769±11.311 | -1.102 | 7.022 | 1.2731 | 0.213 | NS |

HS: Highly significant, S: Significant, NS: Not significant, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment, IgG: Immunoglobulin G, HB: Hemoglobin, TLC: Total leukocyte count, ESR: Erythrocyte sedimentation rate

## Discussion

*Acharya Chakrapani* has elaborated the term *Vyadhikshamatva* (immunity) as *Vyadhi Bala Virodhitvam* (reducing the virulence of disease already present) and *Vyadhi-utpaada Pratibandhakatvam*. (prevention of occurrence of disease).(8) To increase the immunity of children, Ayurveda drugs having *Rasayana*, *Balya*, and *Ojovardhaka* property can be used to increase the *Yuktikrita Bala*. This concept of Ayurveda is used in the present study to enhance immunity in pediatric patients. In the current study, maximum numbers of patients were of 6-9 years of age, i.e., 68.33 % (67% in Gr. A and 60 % in Gr. B). Boys (56.67 % from Gr. A and 63.33% from Gr. B) were found to be more susceptible than girls. It supports the study that IgM levels in girls are higher and different from that in boys.(9) Most of the cases (Gr. A – 67% and Gr. B – 63.33%) enrolled in the study were belonging to nuclear families. Nuclear families have less time to take care of the diet and health condition of their children because in most of the families both parents are working. (10)

Maximum numbers of children were Hindus (Gr. A – 70% and Gr. B – 73.33 %). More number of Hindus may be because of higher prevalence of Hindu community in the region. To draw any inference, further extensive study is needed in large population. Majority of the patients belong to middle class (Gr. A – 63.33% and Gr. B – 60%) followed by lower middle class (26.67%) and lower class (23.33%). This may be attributed to the fact that families from middle- and lower-income groups more frequently seek treatment at government healthcare facilities due to their affordability. Additionally, such families often have limited awareness regarding the importance of proper health care and nutrition for their children. The socioeconomic status of the subjects was assessed using the Kuppuswamy Scale. (11) The majority of cases were full-term deliveries (Gr. A – 90% and Gr. B – 86.67%) while 9.17% were preterm and 2.5% post-term births. It is well established that children born with assisted delivery may develop problems in the future life, especially that related to proper growth and development. In the present study, out of 120 subjects, maximum 42 (35%) subjects had duration of breast feeding for less than 4 months followed by 36 (30%) subjects having 4 months, 22 (18.33%) subjects have duration of breast feeding for six months, and 20 (16.67%) subjects did not receive breast feeding. The American Academy of Pediatrics (AAP) and World Health Organization (WHO) recommends exclusive breastfeeding for the first six months, followed by complementary feeding for up to two years or beyond.(12) The data indicate that most mothers preferred breastfeeding over other forms of milk, possibly because 90% of the births were full-term, minimizing complications related to milk production and secretion. Breast milk provides the ideal balance of nutrients required for an infant's growth and development. It also offers protection against pathogens due to its antibacterial and antiviral properties. Moreover, breast milk has been associated with reduced risks of allergies, autoimmune disorders, inflammatory bowel diseases, and certain cancers.(13) It provides protection against gastrointestinal, urinary tract, and respiratory infections, as well as bacterial meningitis and necrotizing enterocolitis. Research also highlights that breast milk is rich in immune components that nourish and strengthen the child's immune system. (14) The *Prakriti* (constitution) of children was assessed using the Child Personality Questionnaire (CPQ)**.** (15)

The majority of subjects were identified as having *Vata-Kapha Prakriti* (Gr. A – 55%; Gr. B – 53.33%). Since *Kapha dosha* predominates during childhood, there is an increased susceptibility to disorders associated with *Kaphasthana*, the head and neck region, making children more prone to such ailments. Upper respiratory tract infections (URTIs) are more prevalent among pediatric patients, often due to *Aparipakva Dhatu*(immature body tissues) leading to *Alpa Ojas* (low immunity). Also, children of *Vata Prakriti* are characterized by *Alpa Bala* (reduced strength and immunity). This suggests that children with *Vata-Kapha Prakriti* are more susceptible to URTIs [Table 2]. 67 (55.83%) and 21 (17.50%) subjects were underweight. Decrease in body weight is indicative of degenerative changes in the body or certain organs. An increase in weight and BMI indicates a healthy growth trajectory in children. The findings demonstrated that *Swarnaprashana* significantly improved anthropometric measures, indicating its effectiveness in promoting growth and development. SP supports overall health by enhancing immunity, improving digestion and metabolism, and maintaining the balance of *Tridoshas*. As a result, children remain resilient to seasonal variations and attain proper growth and development. (16) Majority of subjects, i.e., 80.83%, were completely immunized as per schedule. No and partial immunization were found in 0% and 19.17 %, subjects, respectively. The reasons for no or partial immunization were primarily lack of awareness and prevalent myths about vaccination among the lower socioeconomic population. Statistical data indicate that morbidity rates are higher among partially or unimmunized children compared to those who are fully immunized. (17) [Table 2] In Gr. A which received the trial medication (SP), highly significant improvements were observed in several morbidity symptoms, including rhinorrhea, nasal obstruction, headache, fever, and sore throat, while significant relief was noted in cases of enlarged tonsils. In contrast, Gr.B showed statistically insignificant outcomes for all morbidity symptoms [Table 2]. The percentage of overall improvement after treatment in both groups is illustrated in [Graph 2]. Intergroup comparison showed highly significant improvement in rhinorrhea, nasal obstruction and cough. Significant improvement was observed in, enlarged tonsils, headache. fever and sore throat in Gr. A over Gr. B [Table 3] [Graph 3]. Regarding laboratory parameters, statistically highly significant improvements were recorded in hemoglobin (Hb%) levels, eosinophil count, and erythrocyte sedimentation rate (ESR). Statistically significant reductions were observed in total leukocyte count (TLC), neutrophil count, and lymphocyte count, along with a significant increase in serum IgG levels. These findings collectively support the efficacy of the trial medication [Table 4]. In Group B, however, the results for Hb%, eosinophil count, ESR, TLC, neutrophil and lymphocyte counts, and serum IgG levels were statistically insignificant [Table 5].

A study on the *Madhu-Ghrita-Swarna-Vacha* formulation in neonates demonstrated a significant influence on humoral immunity, as evidenced by activation of the immune system and increased total protein and serum IgG levels.(18) Gold is well recognized for its immunity-boosting and memory-enhancing properties. Pharmacological evaluations of *Swarna Bhasma* (SB) have revealed its immunomodulatory(19) and nootropic effects. (20,21) SB serves as the principal component of SP, a formulation designed for infants and young children. Its therapeutic action is largely attributed to its antioxidant potential, particularly its ability to scavenge free radicals. Furthermore, SB has been shown to suppress various cell-mediated immune responses to multiple mitogens and antigens. Gold compounds, in general, are known for their potent immunomodulatory properties.(22) It improves memory, and when administered in

very low doses over a specific period, it is believed to improve both cognitive capacity and immunity. Animal studies using pure gold ash have shown that administering *Swarna Bhasma*(SB) at doses ranging from 12.5 to 50 mg/kg body weight in mice stimulates peritoneal macrophages, which play a key role in fighting infections. This macrophage activation is thought to occur due to the fine emulsified form of gold particles gaining access to cells. Classical gold preparations are also known for their rejuvenating and antioxidant properties.(23) As the main ingredient of SP is SB which strengthens immunity through its phagocytic action and has shown beneficial effects in motor neuron diseases even at small doses.(24) Symptoms such as runny nose, nasal blockage, sore throat, enlarged tonsils, breathing difficulty, and cough are categorized under *Urdhwajatrugata Vikaras* (diseases of the head and neck) in Ayurveda. These are primarily associated with the vitiation of *Vata* and *Kapha doshas*. SB helps restore the balance among the three *doshas*. In upper respiratory tract infections (URTIs), cough usually arises from postnasal drip and infections of the throat and respiratory passages. Both SB and *Madhu* (honey) possess anti-inflammatory(24) and antibacterial(25) properties, which help relieve cough and associated symptoms. The immunomodulatory effects of SB(22) contribute to the observed clinical efficacy of the trial medication in alleviating URTI symptoms. By enhancing immune responsiveness, these properties help reduce morbidity and provide long-term protection. Additionally, honey exhibits notable antibacterial activity,(26) which further aids in relieving symptoms such as enlarged tonsils, sore throat, fever, and other manifestations of URTI.

## Conclusion

Study demonstrates that SP acts as an effective immuno-modulator, significantly reducing the frequency and severity of illnesses and lowering morbidity in children without adverse effects. In Group A (SP-treated), there was a highly significant improvement in most morbidity symptoms, whereas Group B (control) showed no significant changes. SP administration led to increased hemoglobin and Serum IgG levels, along with decreased eosinophil count, ESR, total leukocyte count, neutrophils, and lymphocytes. Intergroup comparison showed marked improvement in rhinorrhea and cough, with notable benefits in nasal obstruction, enlarged tonsils, and fever frequency, confirming SP's therapeutic efficacy.

**Abbreviations**

- IgG – Immunoglobulin G
- SB – *Swarna Bhasma*
- SP – *Swarna Prashana*
- URTI - Upper Respiratory Tract Infections
- Gr. - Group

**Author contribution**

KP: Project administration, Conceptualization, Resources, Supervision, original draft. GS: Conceptualization, Formal analysis, Writing - review & editing. NP: Methodology, Data collection.

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**Conflict of interest**

The authors declare no conflict of interest.

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