



International Journal of Homoeopathic Sciences

E-ISSN: 2616-4493

P-ISSN: 2616-4485

www.homoeopathicjournal.com

IJHS 2023; 7(3): 287-290

Received: 15-05-2023

Accepted: 19-06-2023

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An open label observational clinical study to assess the role of Calcarea group of medicines in various diseases of children

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DOI: <https://doi.org/10.33545/26164485.2023.v7.i3e.923>

Abstract

Homoeopathy medicines are safe, cost effective, having no adverse effect, easy to administer in children. Calcarea represents a group of homoeopathic medicines which are prepared from various compounds of Calcium. In several literatures by many stalwarts from past to recent studies, Calcarea was prescribed frequently particularly in cases of children. But no research studies were done particularly on Calcarea group of medicines to elicit its effect on children. So this study was done to elicit effect of Calcarea group of medicine in diseases of children.

Keywords: Homoeopathy, children, Calcarea, WHOQOL-BREF, CGI scale

Introduction

Children with age of 0 to 14 years is the most important age group of all society, it constitutes about 40% of the total population^[1]. In developing countries health of children is a burning problem as poverty inflicts much health problem. Consistent with institution for Health Metrics & Evolution (IHME) the worldwide Burden of Disease (GBD) 2013 update found that child death rates dropped by 48% globally between 1990 and 2013. Yet, per annum millions of children still die before their fifth birthday^[2]. Under 5 mortality rate is 34 in India^[3]. In West Bengal Neonatal mortality rate (NNMR) is 15.5, Infant mortality rate (IMR) 22.0, Under-five mortality rate (U5MR) 25.4^[4]. Govt had taken many policies to promote health, prevent diseases, and to screen out high risk children for their treatment. Reproductive, Maternal, New born, Child and Adolescent Health (RMNCH+A) was launched in 2013, the popular scheme aims to reduce the rates of maternal, new-born and child mortality, Janani Shishu Suraksha Karyakaram (JSSK) introduced in 2011, the JSSK scheme motivates expecting mothers to choose for institutional delivery, through which they will avail several protective facilities before and after the birth of the baby. Rashtriya Bal Swasthya Karyakram (RBSK), Integrated Child Development Service (ICDS) which were designed for children between 0 and 6 years, Rashtriya Kishor Swasthya Karyakram (RKSK) for adolescents in the age group of 10 to 19 years fall into the ambit of this relatively recent scheme launched in 2014 by the Ministry of Health and Family Welfare (MHFW), Mission Indradhanush & Intensified Mission Indradhanush (IMI) was launched in December 2014. Leading causes of deaths are diarrheal diseases, respiratory infections, malnutrition, infectious diseases and other febrile diseases. Health problems of school age children indicates malnutrition, infectious diseases, intestinal parasites, diseases of skin, eyes, ears, dental caries^[1]. In spite of so many schemes, health education, health promotion, immunization, tertiary institutions, child health is still a big issue.

Homoeopathy is a popular treatment of choice among parents for their children. This system of medicine is based on principle of similia similibus curantur which means let like be cured by like. Medicines are prescribed in minimum dose according to the symptom similarity with the drug which was proved previously on healthy human being. Because of its extremely diluted medicine in very minimum dose, it is very safe^[5] for children. Chances of adverse effect is very low rather negligible. Small globules or sugar of milk are very easy to administer in children and also attractive for its sweetness. Calcarea group of medicines are one of the most frequently indicated medicines in diseases of children. It is prepared from calcium compounds.

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Calcium is an important constituent of human body, it contributes 2% of the body weight, of which bones & teeth contain 99%. The remaining 1% is distributed in different tissues as muscles, plasma, RBC, lymph & aqueous humour, cerebrospinal fluid etc [6]. Before homoeopathy Calcium was used as food supplement in calcium deficiency diseases [7]. Dr. Samuel Hahnemann proved calcium compound and unearth its pathogenetic power [8]. It was his 'a favourite' medicine for sick children [9]. Dr Vitoulkas claimed, it is interesting that a large percentage of infants and children seems to need Calc. carb. Although it should never be prescribed routinely to infants or children, it is nevertheless true that it is probably the most commonly prescribed remedy within the age bracket. To him, this fact suggests that one among the foremost fundamental disturbances within the human organism is that which affects calcium metabolism [10]. Dr. Grauvogl mentioned it as "nutritional remedies" [7]. It modifies the nutrition of the vegetative system and as a result there are changes in the composition of the blood that terminate in certain constitutional diseases [11]. Many recent and old homoeopaths used Calcarea group of medicines for treatment of children but no scientific study was done to evaluate the effect of this group particularly on children.

Materials and Methods

The study was done on 1 to 14 years aged children of both sexes, registered in the Out Patient Department of D N De Homoeopathic medical college and Hospital from October 2019 to march 2021.

Cases if children which meets the inclusion exclusion criteria were recruited for the study. The diagnosis was done on the basis of symptomatology available and investigations done were required. The study protocol was approved by the institutional ethical committee. Written informed consent was taken from the parents.

Sample design: Clinical, open label, observational, non-randomized, single armed study.

Study period: About 18 months.

Sample size: 52 cases were recruited in the study in order to avoid the error arising from shorter sample size due to drop out.

Inclusion criteria

- All persons of age group of 1 yr. to 14 yrs.
- Patients of all religions & both the sexes.
- Patients fulfilling symptomatology from selected Calcarea group of medicines.

Exclusion criteria

- Child with age < 1 yr.
- Child with congenital disorder or surgical conditions.
- Child with severe systemic disease.
- Child already undergoing homoeopathic treatment.
- Using other modes of treatment.
- Taking immune suppressive therapy.
- Child suffering from malignancy/ tuberculosis/ HIV.

Methods

Every child attending paediatric outpatient department of D. N. De Homoeopathic Medical college and Hospital was screened with screening form. Children satisfying the

inclusion exclusion criteria with symptomatology of Calcarea group of symptoms matching the screening from are included. Every case was measured with WHOQOL-BRIEF scale at baseline and at the end of the treatment in evaluate whether quality of life improved after treatment. The twenty-six questionnaire was filled with the help of the parents as the patient was a minor. A through case taking was done with the help of case taking proforma and medicine from Calcarea group was prescribed. Single medicine was prescribed, selection of dose and potency and repetition was done based on the Homoeopathic principles. Cases was reviewed at 2 weeks interval. Improvement of the physical complain was assessed with Clinical Global improvement and severity scale at baseline and end of the study.

Outcome assessment

WHOQOL-BREF scale and CGI, CGS scale used for outcome measures.

Results

There was significant improvement in every domain of WHOQOL-BREF ($p < 0.05$) after treatment. The mean of total score of 4 domains was before treatment 39.2 ± 5.0 and after treatment 43.1 ± 6.7 . In CGI – S scale the mean score before treatment was 4.5 and after treatment 2.9. There was significant reduction in severity. To test the significance 't' Test (Test of difference between two sample means) had been done which indicated that p value was significant at 95% confidence interval. Significant improvement in CGI scale and WHOQOL-BREF scale indicates the effectiveness of Calcarea group of medicines in various diseases of children.

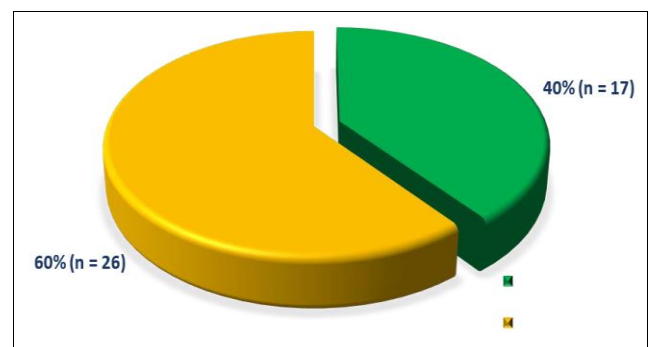


Fig 1: The distribution of age frequency

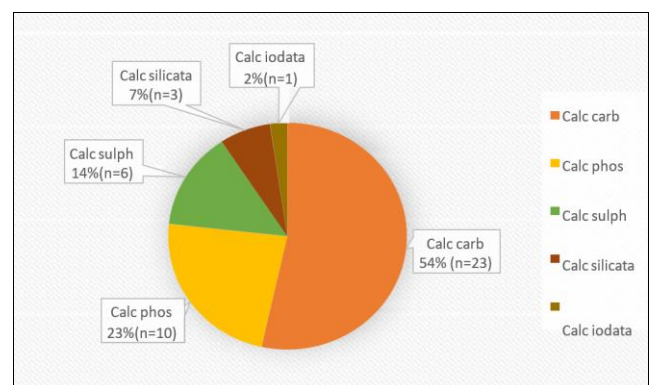


Fig 2: Frequency distribution of Calcarea group of medicines

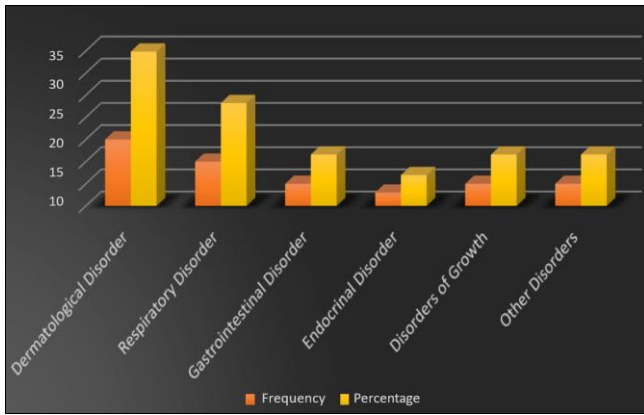


Fig 3: Frequency of diseases in the study

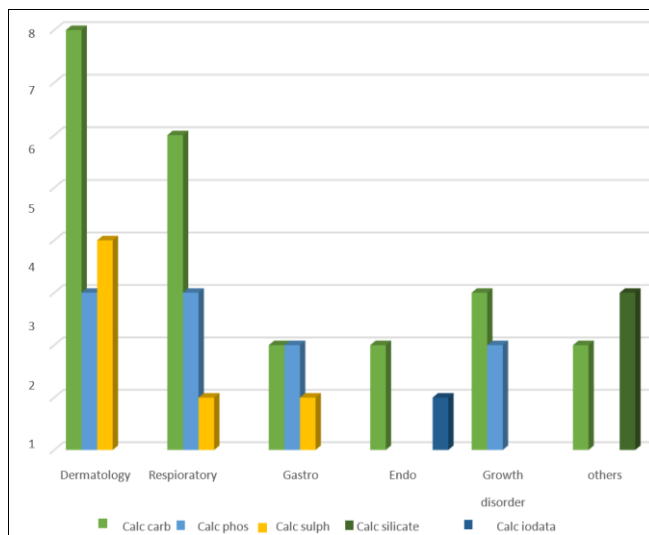


Fig 4: Frequency distribution of Calcarea group in various diseases.

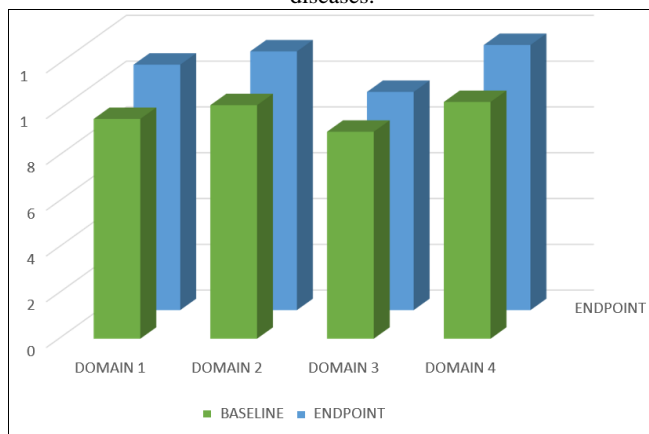


Fig 5: Showing changes after treatment

Discussion

In this study age group of children varied from 2 to 12 years. Majority of children were of school age group. Among them 23 cases were treated with Calcarea carb, Others in decreasing order Calc. phos, Calc. sulph, Calc. sil, Calc. iod. Calc. carb was the maximally indicated medicine among Calcarea group as it was clinically verified by many stalwarts [12-17].

Dermatological problems cover the maximum cases (n=15) which includes molluscum contagiosum, scabies, pityriasis, acne, tinea corporis, infected wart. In respiratory disorders maximum cases were of URTI or common cold. Others

were tonsillitis, nasal polyp, allergic rhinitis and cervical lymphadenopathy. Other complain includes Gastrointestinal disorders, Endocrinal disorders, Disorders of growth and development.

CGI-S and CGI-I scale is assessed at baseline and at end of the study. The mean of CGI-S Scores at baseline was 4.5 and standard deviation (SD) was 0.9, where after treatment the mean of the scores reduced to 2.9 and SD was 1.4. That means the severity was reduced after treatment. Two tailed Paired t test was done comparing the before and after treatment values. Calculated t value = 4.071, p-value = 0.0002. which indicates that the role of Calc carb was significant. In CGI-I Scale out of 43 cases, total improved cases were 32 mostly treated with Calcarea carb. Every case was assessed at beginning and end of treatment by WHOQOL-BREF questionnaire. There were 26 questions. Scores are analyzed by 4 domains. Domain 1 represented physical health, Domain 2 Psychological health, Domain 3 Social relationship, Domain 4 environment. After analyzing the baseline and endpoint scores there was improvement in the end point score. The mean of baseline data of Total score was 39.2 (SD ± 5.0), and after treatment it increased to 43.1 (SD ± 6.7). The mean difference observed between them was 3.9. Paired t test was done. Calculated t value for Total score was 5.699, p-value < 0.001. The result also signifies that Calcarea group of medicines had significant role in children’s diseases.

Limitations and Recommendations

Though Calcarea was indicated in diseases of children and various diseases may be treated with this group of medicines but this cannot be used generously in every case of diseases of children. After proper individualization if totality of symptom indicates Calcarea group, then only it can be prescribed. Even as most of the cases of Molluscum contagiosum were recovered by Calcarea carb, every case of Molluscum cannot be treated with Calcarea carb. Medicines cannot be chosen according to the name of the disease. It is against our principle of Homoeopathy. But if constitution indicates towards Calcarea group whether it is scabies or molluscum we may think of Calcarea. The no. of cases in this clinical study is 43 which may be insufficient to conclude or generalize the study. No control group (placebo) was maintained to see the effectiveness. Due to a shorter sample size RCT could not be performed, so it will be more scientific to perform RCT with control group simultaneously in near future to verify the effectiveness of treatment. Due to pandemic situation regular follow, up at 14 days’ interval was not possible. We had to follow up the case at an interval of one month which might affect the result of the study. Through this study although the efficacy of Calcarea group was quite evident, it could be considered as just the beginning of journey, as in homoeopathy very few studies or research works had been done in this particular topic, so this will give us a lot of scope to learn and discover more in future.

Conclusion

Homoeopathic medicine is always popular in cases of children. Among many homoeopathic medicines Calcarea is also a popular choice for children among practitioners. This study was aimed at eliciting the role of Calcarea group of medicines in children’s diseases. Improvement of disease was assessed by CGI-S & CGI-I scales. Quality of life was

assessed by WHOQOL-BREF scale. Significant improvement was seen in both scales. Before and after treatment scores were compared by paired t test. The critical t value was significant at 95% confidence interval. Which rejects null hypothesis and accepts alternative hypothesis as true, means Calcarea group of medicines have significant role in diseases of children.

Acknowledgments

I would like to express my profound gratitude to my Guide Mr. Naba Kumar Gantait, Ex- HOD, of Materia Medica department and Mr. Soumya Bhattacharjee sir, lecturer, department of Materia Medica and our Principle Dr Shyamal Kumar Mukherjee sir for their contributions to the completion of my project. Finally, I must express my very profound gratitude to my parents and to my elder brother for providing me with unfailing support and continuous encouragement throughout my years of study.

Conflict of Interest

Not available

Financial Support

Not available

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How to Cite This Article

Ghosh S, Ghosh S. An open label observational clinical study to assess the role of Calcarea group of medicines in various diseases of children. *International Journal of Homoeopathic Sciences*. 2023;7(3):287-290.

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