Original Article

An observational study on usefulness of Bromium 30C in atopic respiratory complaints by assessing serum immunoglobulin E levels

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Abstract

Background: Atopic disorders represent a major health problem worldwide affecting 5%-30% of the population. The present study evaluates the action of Bromium 30C in reducing serum IgE levels. Objective: To assess the variation of serum IgE levels before, during and after intervention with Bromium 30C. Materials and Methods: Thirty cases of atopic respiratory complaints (diagnosed based on clinical history, CMDT guidelines and serum IgE values during the first visit) were selected as per the inclusion criteria using purposive sampling technique. Bromium 30C was prescribed for these cases and followed for 3 months. Bromium 30C was repeated twice daily for 2 weeks and placebos were administered in between. Serum IgE values were checked every month. The data was statistically analysed using mean, standard deviation and analysis of variants (ANOVA). Results: ANOVA for repeated measures showed \( P = 0.000 \), which is highly significant. Pairwise comparison of serum IgE levels in before and during, during and after treatment groups showed \( P = 0.007 \), which is highly significant. Pairwise comparison of serum IgE levels in during and after treatment group showed \( P = 0.016 \), which is significant. Conclusion: There is a significant reduction in serum IgE levels in cases of atopic respiratory complaints during and after homoeopathic treatment with Bromium 30C.

Keywords: Analysis of variants, Atopic respiratory complaints, Bromium 30C, Serum immunoglobulin E

Introduction

Atopic disorders represent a major health problem worldwide affecting 5%-30% of the population. Immediate or Type I hypersensitivity reaction, where production of immunoglobulin E (IgE) antibody causes various changes such as release of vasoactive amines and other mediators from mast cells, recruitment of inflammatory cells, etc., is well understood in the pathogenesis of atopic respiratory complaints.[1] A randomised controlled trial using the homoeopathic preparation Galphimia glauca 6C with placebo in hay fever/rhinitis cases demonstrated the efficacy of Homoeopathy using one indicated remedy and was defined as high quality by three meta-analyses of Homoeopathy.[2-4]

Passalacqua et al. conducted a systematic review on complementary and alternative medicine for rhinitis and asthma, concluded that the evidence for a specific effect of Homoeopathy is weak.[5] A pilot study done in India assessed the efficacy of homoeopathic remedies, chosen strictly on

individualisation and symptom similarity, in bringing changes in serum IgE level, absolute eosinophil count and allergic rhinitis symptom scores.[6]

Reilly et al.[7] studied homeopathic treatments of hay fever and asthma in one hundred and fifty-eight patients. The responses were judged by using a visual analogue scale, which showed a significantly greater response to the homeopathic therapy and a corresponding reduction in the need for antihistamines in these patients.

There have been a few reviews of randomized, controlled trials published regarding the use of Homeopathy for asthma treatment. Six trials were included in a recent review.[8-9]

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These trials were of variable quality and the results of the studies are conflicting in terms of effects on lung function. The authors underlined that standardized treatments in these trials are unlikely to represent common homeopathic practice where treatment tends to be individualized. There is a need for observational data to document the different methods of homeopathic prescribing and how patients respond.[10]

Homoeopathic remedy Bromium has a marked effect on the respiratory system, especially the larynx and trachea.[11] Many of the respiratory symptoms of Bromium bear a close resemblance to atopic respiratory symptomatology. Thus, this observational, cohort, single arm, interventional study was conducted to assess the variation of serum IgE values in cases of atopic respiratory complaints where Bromium 30C is prescribed. This study tries to integrate the knowledge of disease (atopic respiratory complaints), knowledge of medicine (Bromium) and application of this knowledge to confirm whether there exists any role for the remedy Bromium to alter the serum IgE values in atopic respiratory complaints. The present study becomes unique as the action of Bromium 30C alone is studied in relation with serum IgE levels.

**Objective**
To assess the variation of serum IgE levels before, during and after treatment in cases of atopic respiratory complaints where Bromium 30C is prescribed.

**Materials and Methods**

**Period of study**
The study was conducted on the cases available from April 2014 to March 2016.

**Sample size**
The sample consisted of thirty cases of atopic respiratory complaints visiting the OPD, IPD and Peripheral Centres of Father Muller Homoeopathic Medical College, Mangalore during the specified period.

**Type of study**
This was a single-arm, quasi-experimental, interventional, prospective, before, during and after treatment comparison pilot study without control.

**Inclusion criteria**
- Both sexes aged between 18 and 50 years
- Cases of atopic respiratory complaints in which serum IgE levels are above 200 IU/ml[12]
- Cases of atopic respiratory complaints where Bromium is indicated and prescribed the same in the 30th potency were included in the study.

**Exclusion criteria**
- Patients who were on homeopathic medicines other than Bromium 30C
- Taking medicines from other systems for any other complaint.

**Materials and Standardised case record**
Serum IgE levels were assessed using Cobas - 6000 fully automated analyser.

**Method**
Thirty cases of atopic respiratory complaints were selected as per the inclusion criteria using purposive sampling technique. Diagnoses of the cases were made based on relevant clinical history, and serum IgE values obtained during the first visit according to CMDT guidelines.[13] The 30 potency of Bromium was prescribed for the above cases and was followed for a period of 3 months.[11] The data were presented in standardised case record (SCR).

**Remedy used**
The 30 potency of homoeopathic medicine Bromium, manufactured by Father Muller Homoeopathic Pharmaceutical Division (which prepares the drug according to Homoeopathic Pharmacopoeia of India), was used in the study. Three globules of Bromium 30C (number 40 size) were given twice daily for a period of 2 weeks and placebos were administered in between if needed. Follow-ups were watched and analysed as per criteria set up in each case according to standard guidelines of Homeopathy using the symptomatology of the patient as mentioned below.

**Follow up and Symptomatic assessment**
Each follow up was of 2 weeks duration, and assessed according to the guidelines given in standardised case record follow-up sheet where each symptom of the patient pertaining to allergic respiratory complaint was graded according to the intensity, aggravation, amelioration, presence or absence. The major symptoms considered in cases of allergic rhinitis were coryza, sneezing, itching of nose and nose block, and in cases of atopic asthma were breathlessness, cough and wheezing with a strong history of atopy in both diagnoses.

An estimation of serum IgE value for each case was done in the beginning before starting homeopathic treatment. Over a period of time, when a patient came for consecutive follow-ups, serum IgE values of each patient were estimated again, minimum twice, which was after 1 month and after 3 months of treatment. This provided an idea for comparing serum IgE values in atopic respiratory complaints before, during and after treatment, after prescribing Bromium 30C. The flow chart of study given as Figure 1.

**Statistical analysis**
The collected data were analysed by mean, standard deviation and analysis of variants (ANOVA).

**Research hypothesis**
There is a significant decrease in serum IgE values in atopic respiratory complaints during and after homoeopathic treatment with Bromium in the 30th potency.

**Null hypothesis**
There is no significant decrease in serum IgE values in atopic respiratory complaints during and after homoeopathic treatment with Bromium in the 30th potency.
Figure 1: Flow chart of the study

RESULTS

This study of thirty patients showed a higher female prevalence (67%) with the 18-23 years' age group being the most affected (33.33%) by atopic respiratory complaints. Allergic rhinitis constituted the maximum number of cases (80%) and atopic bronchial asthma constituted 20% of the cases [Table 1]. Thirty diagnosed cases of atopic respiratory complaints (allergic rhinitis and atopic bronchial asthma) were studied for a period of minimum 3 months. Serum IgE values were checked thrice, (before, during and after the treatment) with a minimum 1-month interval between each measurement. The following observations were made: mean serum IgE levels before, during and after treatment were 1067.39, 913.59 and 852.393 IU/ml, respectively. ANOVA for repeated measures shows $P = 0.000$, which denotes a highly significant reduction in mean serum IgE values before, during and after homoeopathic treatment with *Bromium 30C* in atopic respiratory complaints [Table 2].

Pairwise comparison of serum IgE levels in before and during treatment group shows a mean difference of 153.795, and $P = 0.007$ denotes that there is a highly significant reduction in serum IgE levels before and during treatment with *Bromium 30C*. Pairwise comparison of serum IgE levels in during and after treatment group shows a mean difference of 61.99, and $P = 0.016$ denotes that there is a significant reduction in serum IgE levels during and after treatment with *Bromium 30C*. Pairwise comparison of serum IgE levels before and after treatment group shows a mean difference of 214.993, and $P = 0.007$ denotes that there is a highly significant reduction in serum IgE levels before and after treatment with *Bromium 30C* [Table 3].
Akhil: Bromium 30C in atopic respiratory complaints using serum immunoglobulin E levels

A single-arm, experimental, interventional, prospective, non-randomised, before and after comparison pilot study without control was carried on thirty participants suffering from allergic rhinitis in India.[6] The trial was aimed to assess the efficacy of homoeopathic remedies, chosen strictly on individualisation and symptom similarity, in bringing changes in serum IgE level, absolute eosinophil count and allergic rhinitis symptom scores (approved by the Institutional Review Board) by comparing the score before medication (baseline) with score after medication. Outcome measures were assessed and analysed after 1 year. After 1 year of homoeopathic treatment, reduction in serum IgE level, absolute eosinophil count and symptom score were statistically highly significant.[6]

This study assessed the action of a single remedy Bromium 30C (in contrast to various homoeopathic medicines in the above study) and assessed only variations in serum IgE levels before, during and after treatment. The other study assessed changes in absolute eosinophil count also apart from changes in serum IgE but did not include atopic bronchial asthma. Both of these studies followed a similar methodology to study atopic respiratory complaints, though varying parameters and outcome measures were used in the assessment. However, both studies are non-randomised pilot studies which involved only a small group of thirty patients.

A review article published in India comprised 10 selected publications of observational studies and drug oriented studies where Homoeopathic treatment was used for the management of asthma. This review concluded positive outcome in controlling acute episodes of asthma, reducing the frequency and intensity of subsequent episodes and weaning of bronchodilators and other allopathic drugs. But, Homoeopathic medicine Bromium was not prescribed in none of the 10 constituent studies mentioned under the review. The review also recommended further pragmatic trials including randomized control studies, as only observational studies had been conducted.[15]

**DISCUSSION**

It was observed that there was a highly significant reduction in serum IgE values in before and after, and before and during treatment groups. Significant reduction in serum IgE value was observed in during and after treatment group.

The strengths of this study are utilising the specific effect of Homoeopathy in allergic rhinitis and atopic asthma using Bromium 30C as the medicine and incorporating Serum IgE levels for the same. The weaknesses are small sample size (n=30), no control group selected to compare the results and no randomisation done.

One systematic review involving a single homoeopathic remedy (G. glauca) for treating allergic rhinitis had been published in English.[14] Three out of four studies included in that review reported significant results in favour of the intervention; however, it only included one homoeopathic medicine. Two important drawbacks of this review were that of the included trials, neither used validated outcome measures nor intention-to-treat analyses. Apart from Ernst, no systematic review evaluating only homoeopathic treatment for allergic rhinitis had been published in English. This study provides scientific evidence in Homoeopathy by nullifying the main drawbacks of the above study using serum IgE values and by utilising intention to treat analysis.

Passalacqua et al.,[5] conducted a systematic review on complementary and alternative medicine for rhinitis and asthma, concluded that the evidence for a specific effect of Homoeopathy is weak. This study provides a strong evidence for specific effect of Homoeopathy in rhinitis and asthma using Bromium 30C as the medicine.

**CONCLUSION**

There is a significant reduction in serum IgE levels with symptomatic improvement in cases of atopic respiratory complaints during and after homoeopathic treatment with Bromium 30C.

**Limitations**

- The sample size is small (n = 30)
- No control group was included along with the study group to compare test results.

**Recommendations**

- A study on a larger scale with randomisation and double blinding could be undertaken
- Bigger sample with extended time of research would provide better results
- A quality of life questionnaire for atopic bronchial asthma could be added to the parameters used in this study.

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**Table 2: Mean serum immunoglobulin E levels before, during and after treatment**

<table>
<thead>
<tr>
<th>N</th>
<th>Mean</th>
<th>Std Deviation</th>
<th>95% Confidence Interval for Mean</th>
<th>ANOVA F for repeated measures</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>30</td>
<td>1067.39</td>
<td>1128.51</td>
<td>645.99</td>
<td>1488.78</td>
</tr>
<tr>
<td>During</td>
<td>30</td>
<td>913.59</td>
<td>1039.54</td>
<td>525.42</td>
<td>1301.76</td>
</tr>
<tr>
<td>After</td>
<td>30</td>
<td>852.39</td>
<td>984.064</td>
<td>484.938</td>
<td>1219.849</td>
</tr>
</tbody>
</table>

ANOVA: Analysis of variance; HS: Highly significant

**Table 3: Pairwise comparisons – Serum immunoglobulin E levels before, during and after treatment**

<table>
<thead>
<tr>
<th>Factor 1</th>
<th>Mean difference (I–J)</th>
<th>SE</th>
<th>Change (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After</td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>I</th>
<th>J</th>
<th>Mean difference (I–J)</th>
<th>SE</th>
<th>Change (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>During</td>
<td>153.795</td>
<td>46.246</td>
<td>14.41</td>
<td>0.007 (HS)</td>
</tr>
<tr>
<td>During</td>
<td>After</td>
<td>214.993</td>
<td>48.401</td>
<td>20.14</td>
<td>0.000 (HS)</td>
</tr>
<tr>
<td>After</td>
<td></td>
<td>61.993</td>
<td>20.285</td>
<td>6.70</td>
<td>0.016 (S)</td>
</tr>
</tbody>
</table>

HS: Highly significant; S: Significant; SE: Standard error

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Financial support and sponsorship
Nil.

Conflicts of interest
None declared.

REFERENCES
Eine Studie zur Wirksamkeit von Bromium C 30 bei atopischen Atemwegserkrankungen durch die Beurteilung des Serum-Immunglobulin-E-Spiegels

Abstrakt


Ziel: Beurteilung der Schwankungen der Serum-IgE-Werte vor, während und nach der homöopathischen Behandlung bei atopischen Atemwegserkrankungen, bei denen Bromium C 30 verschrieben worden ist.


Ergebnisse: ANOVA bei wiederholte Maßnahmen zeigte P = 0,000, was sehr signifikant ist. Der paarweise Vergleich der Serum-IgE-Spiegel der vor und während, während und nach Behandlungsgruppen zeigte P = 0,007, was hoch signifikant ist; ebenso wie der paarweise Vergleich der Serum-IgE-Spiegel während und nach der Behandlungsgruppe, der P = 0,016 ergab, was signifikant ist.

Fazit: Es gibt eine signifikante Reduktion des Serum-IgE-Spiegels bei atopischen Atemwegserkrankungen während und nach der homöopathischen Behandlung mit Bromium C 30.
Une étude sur l’efficacité de Bromium 30 dans les cas de troubles respiratoires atopiques en évaluant les taux d’immunoglobulines E sérées

Résumé

Contexte: Les troubles atopiques représentent un problème de santé majeur à travers le monde entier touchant 5 à 30 % de la population. L’étude actuelle évalue l’action de Bromium 30 dans la réduction des taux d’IgE sérées.

Objectif: Évaluer la variation des taux d'IgE sérées avant, pendant et après le traitement homéopathique dans les cas de troubles respiratoires atopiques où le Bromium 30 est prescrit.

Matériels et Méthodes: Trente cas de troubles respiratoires atopiques (diagnostiqués selon les antécédents cliniques, les directives de CMDT et les valeurs d'IgE sérées lors de la première visite) ont été sélectionnés selon les critères d'inclusion à base de la technique d'échantillonnage par choix raisonné. Il a été répété deux fois par jour pendant 2 semaines et des placebos ont été administrés de temps en temps. Les valeurs d’IgE sérées ont été contrôlées chaque mois. L’hypothèse a été analysée statistiquement par l’écart moyen, l’écart-type et l’analyse de la variance (ANOVA).

Résultats: L’ANOVA pour les mesures répétées a montré que P = 0,000, ce qui est très significatif. La comparaison par paire des taux d'IgE sérées chez les groupes avant et pendant le traitement, et pendant et après le traitement a montré que P = 0,007, ce qui est très significatif. La comparaison par paire des taux d'IgE sérées chez les groupes pendant et après le traitement a montré que P = 0,016, ce qui est significatif.

Conclusion: Il y a une réduction significative des taux d'IgE sérées dans les cas de troubles respiratoires atopiques pendant et après le traitement homéopathique avec Bromium 30.