

Assessment of Efficacy of Anthroposophic and Conventional Treatment with Antibiotics in Children with Acute Respiratory or Ear Infections: A Prospective Study.

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ABSTRACT

Background: Acute respiratory tract infections and otitis media (RTI/OM) are frequent among children and are commonly treated with antibiotics. In randomised trials, antibiotics have only small or negligible short-term effects on OM and RTI such as pharyngitis, bronchitis, laryngitis, and common cold, comparable to their side-effect potential. Aim of the study: To assess efficacy of Anthroposophic and Conventional Treatment with Antibiotics in Children with acute respiratory or ear infections. **Methods:** The study was conducted in the department of Department of Pediatrics and Department of General Medicine of the Mahatma Gandhi Hospital, Bhilwara, Rajasthan, India. For the study, we selected patients reporting to OPD of the pediatric clinic with chief complaint of sore throat, cough, or ear pain and onset within 7 days. A total of 60 patients were included in the study. **Results:** A total of 60 patients participated in the study. Number of male patients in Group A was 13 and in Group C was 17. On comparing the results, statistically significant results were observed with respect to response on Day 7, response on Day 14, recovery on Day 7 and on 14th. **Conclusion:** The rate of improvement of symptoms and rate of recovery with Anthroposophic treatment for acute respiratory infections and ear infections is significant and it should be encouraged in pediatric patients.

Keywords: acute, respiratory infection, Anthroposophic.

INTRODUCTION

Acute respiratory tract infections and otitis media (RTI/OM) are frequent among children and are commonly treated with antibiotics. In randomised trials, antibiotics have only small or negligible short-term effects on OM and RTI such as pharyngitis, bronchitis, laryngitis, and common cold, comparable to their side-effect potential.^[1,2] Antibiotic treatment as secondary prophylaxis in order to prevent complications of RTI/OM is difficult to justify in developed countries, where these complications are rare. Furthermore, antibiotic use increases antimicrobial resistance, increases the recurrence rate of OM, and may be a risk factor for paediatric asthma, atopic eczema, and inflammatory bowel disease. Because of these concerns, reduction of antibiotic prescription for RTI/OM has long been advocated.^[3,4] Strategies to reduce antibiotic use include educational interventions towards physicians and patients, rapid antigen testing to identify viral

disease, and delayed antibiotic prescription. In addition, using analgesics instead of antibiotics has been recommended, but analgesics may also pose risks. AM is a physician-provided integrative multimodal therapy system founded by Steiner and Wegman.^[5] AM is based on the cognitive methods and cognitive results of anthroposophy. AM medications are prepared from plants, minerals, animals, and from chemically defined substances according to Good Manufacturing Practice and national drug regulations; quality standards of raw materials and manufacturing methods are described in the Anthroposophic Pharmaceutical Codex. Toxicologically relevant starting materials (e.g., aconite, cinnabar) are highly diluted according to safety requirements of European regulations. The available evidence suggests that AM medications are generally well tolerated, with infrequent adverse reactions of mostly mild to moderate severity.^[6] Hence, we planned the study to assess efficacy of Anthroposophic and Conventional Treatment with Antibiotics in Children with acute respiratory or ear infections.

MATERIALS AND METHODS

The study was conducted in the department of Department of Pediatrics and Department of General

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Medicine of the Mahatma Gandhi Hospital, Bhilwara, Rajasthan, India. The ethical clearance for the study was obtained from the ethical board of the institute prior to commencement of the study. For the study, we selected patients reporting to OPD of the pediatric clinic with chief complaint of sore throat, cough, or ear pain and onset within 7 days. A total of 60 patients were included in the study. The patients were randomly grouped into two groups, Group A and Group C with 30 subjects in each group. The patients in Group A were assigned to Anthroposophic Treatment and patients in Group C were assigned to Conventional treatment with antibiotics. The patients were recalled for follow up after 24 hours, after 3 days, 7th day, and 14th day. The improvement and recovery of symptoms were evaluated in the patients. A detailed history was also taken from the patient at each subsequent visit. The data was recorded and subjected to statistically significant.

The statistical analysis of the data was done using SPSS version 20.0 for windows. The Student's t-test and Chi-square test were used to check the significance of the data. The p-value less than 0.05 was predetermined as statistically significant.

RESULTS

A total of 60 patients participated in the study. We observed that there were 30 patients each in both groups. Number of male patients in Group A was 13 and in Group C was 17. The mean age of subjects in Group A is 11.02 years and in Group 2 is 10.91 years. Table 2 shows the comparative post-clinical variables for both groups. From the results, this can be concluded that more relief is observed from the treatment is seen in Group 1. On comparing the results, statistically significant results were observed with respect to response on Day 7, response on Day 14, recovery on Day 7 and on 14th.

Table 1: Demographic data.

| Variables | Group A | Group C |
|----------------------|---------|---------|
| No. of patients | 30 | 30 |
| No. of male patients | 13 | 17 |
| Mean age (years) | 11.02 | 10.91 |

ND Recovery on Day 14

Table 2: comparative post-clinical variables for both groups.

| Variables | Group A | Group B | p-vslue |
|-----------------------------|---------|---------|---------|
| First improvement <24 hours | 39.8% | 22% | 0.5 |
| First improvement ≤3 days | 82% | 64.8% | 0.09 |
| Response on Day 7 | 86.33% | 65.12% | 0.001 |
| Response on Day 14 | 93.11% | 86.11% | 0.002 |
| Recovery on Day 7 | 36.75% | 31.58% | 0.01 |
| Recovery on Day 14 | 74.58% | 60.05% | 0.02 |

DISCUSSION

In the present study we compare efficacy of Anthroposophic and Conventional Treatment with Antibiotics in Children with acute respiratory or ear infections. We observed that there were 30 patients each in both groups. From the results, this can be concluded that more relief i. But the results were statistically significant. The results were compared with previous studies and results were consistent with previous studies. Hamre HJ et al studied consecutive outpatients starting anthroposophic treatment for asthma under routine conditions in Germany. Main outcomes were average asthma severity (0–10, primary outcome); symptoms (1–4); and asthma-related quality of life at 12-month follow-up (Asthma Quality of Life Questionnaire [AQLQ] overall score, 1–7, for adults; KINDL Questionnaire for Measuring Health-Related Quality of Life in Children and Adolescents, asthma module, 0–100, for children) at 12-month follow-up. Ninety patients (54 adults, 36 children) were included. Anthroposophic treatment modalities used were medications; eurythmy therapy; art therapy; and rhythmical massage therapy. Median number of eurythmy/art/massage sessions was 12, median therapy duration was 120 days. From baseline to 12-month follow-up, all outcomes improved significantly. Average improvements were: average asthma severity 2.61 points; cough 0.93; dyspnea 0.92; exertion-induced symptoms 0.95; frequency of asthma attacks 0.78; awakening from asthma 0.90; AQLQ overall score 1.44; and KINDL asthma module 14.74. All improvements were maintained until last follow-up after 24 months. They concluded that patients with asthma under anthroposophic treatment had long-term improvements of symptoms and quality of life. Hamre HJ et al conducted another 48-month follow-up analysis of all patients enrolled in AMOS in the period 1999-2005. 1,510 outpatients aged 1-75 years, starting anthroposophic treatment for chronic conditions in routine German outpatient settings, participated in a prospective cohort study. Main outcomes were Symptom Score (primary outcome, mean symptom severity on numerical rating scales), SF-36 Physical and Mental Component scores in adults, and disease-specific outcomes in the six most common diagnosis groups: asthma, anxiety disorders and migraine (numerical rating scales), depression (Center for Epidemiological Studies Depression Scale), attention deficit hyperactivity symptoms, and low back pain. Median disease duration at baseline was 3.5 years. From baseline to 48-month follow-up all ten outcomes improved significantly. Standardised Response Mean effect sizes were large for seven comparisons, medium for two comparisons, and small for one comparison. Symptom Score improved significantly with large effect sizes in adults and children, and in the four main anthroposophic

therapy modality groups. They concluded that outpatients receiving anthroposophic treatment for chronic indications had sustained, clinically relevant improvements of symptoms and quality of life.^{7, 8} Haidvogel M et al assessed the effectiveness of homeopathy compared to conventional treatment in acute respiratory and ear complaints in a primary care setting. The study was designed as an international, multi-centre, comparative cohort study of non-randomised design. Patients, presenting themselves with at least one chief complaint: acute (≤ 7 days) runny nose, sore throat, ear pain, sinus pain or cough, were recruited at 57 primary care practices in Austria (8), Germany (8), the Netherlands (7), Russia (6), Spain (6), Ukraine (4), United Kingdom (10) and the USA (8) and given either homeopathic or conventional treatment. Therapy outcome was measured by using the response rate, defined as the proportion of patients experiencing 'complete recovery' or 'major improvement' in each treatment group. The primary outcome criterion was the response rate after 14 days of therapy. Data of 1,577 patients were evaluated in the full analysis set of which 857 received homeopathic (H) and 720 conventional (C) treatment. The majority of patients in both groups reported their outcome after 14 days of treatment as complete recovery or major improvement. In the per-protocol set similar results were obtained. Further subgroup analysis of the full analysis set showed no differences of response rates after 14 days in children and adults. The unadjusted odds ratio (OR) of the primary outcome criterion was 1.40 in children and 0.92 (0.63–1.34) in adults. Adjustments for demographic differences at baseline did not significantly alter the OR. The response rates after 7 and 28 days also showed no significant differences between both treatment groups. However, onset of improvement within the first 7 days after treatment was significantly faster upon homeopathic treatment both in children and adults. Adverse drug reactions occurred more frequently in adults of the conventional group than in the homeopathic group, whereas in children the occurrence of adverse drug reactions was not significantly different. They concluded that in primary care, homeopathic treatment for acute respiratory and ear complaints was not inferior to conventional treatment. Hamre HJ et al conducted another observational study comprising 529 children <18 years from Europe or USA, whose caregivers had chosen to consult physicians offering anthroposophic (A-) or conventional (C-) treatment for RTI/OM. During the 28-day follow-up antibiotics were prescribed to 5.5% of A-patients and 25.6% of C-patients; unadjusted odds ratio for nonprescription in A- versus C-patients 6.58; after adjustment for demographics and morbidity 6.33. Antibiotic prescription rates in recent observational studies with similar patients in similar settings,

ranged from 31.0% to 84.1%. Compared to C-patients, A-patients also had much lower use of analgesics, somewhat quicker symptom resolution, and higher caregiver satisfaction. Adverse drug reactions were infrequent and not serious. Limitation was that results apply to children of caregivers who consult A-physicians. One cannot infer to what extent antibiotics might be avoided in children who usually receive C-treatment, if they were offered A-treatment.^[9,10]

CONCLUSION

Within the limitations of the study we conclude that the rate of improvement of symptoms and rate of recovery with Anthroposophic treatment for acute respiratory infections and ear infections is significant and it should be encouraged in pediatric patients.

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