

**ARI Control Programme:
Standard Case Management
Guidelines vs Conventional
Treatment —
An Open Study**

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Acute respiratory infections (ARI) are the leading cause of fewer than five deaths in developing countries. Pneumonia is responsible for majority of ARI deaths (1). Since pneumonia is usually bacterial in etiology, mortality is potentially preventable, if treated in time with appropriate antibiotics (2).

The National ARI Control Programme recommends use of benzyl penicillin for severe pneumonia and chloramphenicol for very severe pneumonia (3). Conventionally, pneumonia was being treated with a combination of benzyl penicillin and chloramphenicol (4). The present study was conducted to determine whether

single drug therapy as advised in Standard Case Management Guidelines (SCMG) is as useful as conventional treatment with a combination of benzyl penicillin and chloramphenicol.

Material and Methods

This prospective, randomized, controlled, open study was conducted at Kasturba Hospital, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha. All children presenting to the Pediatric OPD/ Emergency Unit with the complaints of cough and/or breathlessness were screened according to Standard Case Management Guidelines (3). All children with severe pneumonia and very severe pneumonia were hospitalized in Pediatric ward and were assigned to one of the treatment groups, viz., children with severe pneumonia were treated with benzyl penicillin or a combination of benzyl penicillin and chloramphenicol and children with very severe pneumonia were treated with chloramphenicol or a combination of benzyl penicillin and chloramphenicol. Oxygen was administered to all children in very severe pneumonia group and those with respiratory rate >70 breath/minute in severe pneumonia group. Intravenous fluids were given to children who were in shock, had cyanosis, abdominal distention, vomiting or were considered at risk of aspiration. Hemoglobin per cent, total and differential leucocyte counts, peripheral smear for presence of toxic granules, band cells, vacuolation in neutrophils and chest roentgenograms were performed in all children.

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BRIEF REPORTS

These investigations had no bearing on the management of children who were given antibiotics as per the group to which they were assigned. All children who deteriorated or did not improve even after 48 hours of antibiotic therapy were treated as cases of suspected Staphylococcal pneumonia, with parenteral cloxacillin and gentamicin. Clinical response was defined when children with very severe pneumonia started taking feeds and children with severe pneumonia started taking feeds and children

with severe pneumonia had no retractions. Infants below two months of age were excluded as the guidelines for their treatment are same as conventional treatment. Children who were known cases or were proved to have reactive airway disease, foreign body, chromosomal anomalies, tuberculosis congenital heart disease or nervous system pathology were excluded from analysis. Statistical analysis were carried out using Chi square test or Students 't' test.

TABLE I- Characteristics and Results of Treatment in Two Subgroups of Severe Pneumonia

Characteristics	Severe Pneumonia		Very Severe Pneumonia	
	Group I (n=29)	Group II (n=28)	Group III (n=9)	Group IV (n=18)
Age				
2-6mo	14	19	7	7
12-60mo	15	9	2	1
Sex distribution				
Male	21	23	6	6
Female	8	5	3	2
Residential Status				
Rural	24	24	8	5
Urban	5	4	1	3
Socio-economic status				
Lower middle	10	9	3	4
Lower	17	19	5	4
Severe malnutrition*	4	5	1	0
Fast breathing (> 70/ min)	23	21	7	0
Retractions	29	28	9	8
Cyanosis	0	0	2	2
Inability to drink	0	0	9	8
Altered sensorium	0	0	2	2
Convulsions				
Crepitations	29	27	9	8
Positive X-ray	27	23	9	8
No. of patient's who required change of antibiotics	3	0	0	2
Clinical response (Mean duration days)	3.1±1.5	2.8±1.3	2.4±1.3	3.1±1.7
Clinical cure (Mean duration days)	5.6±2.3	5.2±2.4	5.5±3.1	5.9±2.9
Number of deaths	0	0	1	1

* Grades III and IV of Indian Academy of Pediatrics Classification

Groups II and IV were treated with benzyl penicillin plus chloramphenicol, Group I received benzyl penicillin and Group III received chloramphenicol

Results

A total of 74 children of severe and very severe pneumonia were included for analysis in this study. Of these, 57 were children with severe pneumonia and 17 with very severe pneumonia. *Table I* depicts the characteristics and treatment results. Forty four children required oxygen administration in severe pneumonia group. Intravenous fluids were given to seven and 13 children in two groups, respectively. The data suggest that randomization could successfully achieve almost identical groups for comparison of outcome and that there was no difference in the outcome between subgroups within each group.

Discussion

In the present study, almost all children belonged to lower or lower-middle socio-economic status from the rural area, the population towards which National ARI Control Programme is targeted. The present study clearly shows that benzyl penicillin and chloramphenicol used separately as a single drug are as effective in respective groups as a combination of the two. The only other study(4) which had compared the usefulness of chloramphenicol in 'severe pneumonia' had defined the severity by one or more of the clinical or investigative findings (chest X-ray or total leucocyte counts) and thus can include cases other than those of very severe pneumonia as defined in Standard Case Management Guidelines. Another study(5) proved efficacy of SCMG in hospitalized children but did not compare it with the conventional treatment.

A comparative study between two modes of treatment for any illness should try to remove all bias as far as possible. From this

point of view, a double blind controlled trial between two treatment groups would have been a better study design. However, because of the technical problems in blinding a combination of two drugs, it was not possible at our hospital. Thus an open study was conducted. Nevertheless as the major criteria for the outcome was death and other criteria for outcome were strictly defined and with characteristics matched in two groups because of randomization, the results should be acceptable.

Thus, we conclude that the Standard Case Management Guidelines for severe pneumonia and very severe pneumonia are as effective as conventional combination of benzyl penicillin and chloramphenicol, and should be widely used.

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