Effect of 13-valent pneumococcal conjugate vaccine on the proportion of children under five with pneumonia at Bashair Teaching Hospital, Khartoum, Sudan

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ABSTRACT

Introduction: Pneumonia is a major respiratory infection that threatens children under five worldwide. The study aimed to estimate the proportion of children under five with pneumonia at Bashair Teaching Hospital in Khartoum, Sudan, the effect of the 13-valent Pneumococcal Conjugate Vaccine, and to examine correlations with gender, age, household size, mother's occupation and education, birth weight, breastfeeding in the first six months, immunization, previous pneumonia, and chronic disease.

Method: An observational cross-sectional study was conducted between May and September 2019. The chi-square test was used to analyse the association between the development of pneumonia infection and documented risk factors. A binary logistic regression was made for each risk factor with a p-value ≤ 0.05 and a 95% confidence interval.

Results: The proportion of pneumonia among the target children was 26.0%, compared to 36.2% in 2011 and 31.6% in 2012. Association of pneumonia was statistically significant (P ≤0.05) with vaccination status (OR=5.059, 95% CI 1.485 - 17.2367, p = 0.010), and chronic disease (AOR=0.147, 95% CI 0.032-0.674, p=0.014).

Conclusion: A reduced proportion of pneumonia has led to a decrease in mortality among children under five following the introduction of the candidate vaccine. Further studies are needed to establish associations between other risk factors and the development of pneumonia to support children's health.

Keywords: pneumonia risk factors, pcv13, immunization coverage, measles vaccination, children under five years, Sudan

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Introduction

Pneumonia is an acute lung infection causing painful breathing and hypoxia. [1] Classified as CA40 in the International Classification of Diseases, it includes infectious pneumonia but excludes pneumonitis. Infectious pneumonia presents

with fever, chills, and cough with sputum. It is mainly caused by *Streptococcus pneumoniae* and respiratory syncytial virus, with less common causes such as *Haemophilus influenzae* type b and *Pneumocystis jiroveci*.[1-3] Risk factors include malnutrition, low birth weight, early breastfeeding during the first four months, immunization, indoor pollution, and overcrowding.[4-6]

Both global and regional data show decreases in pneumonia-related child deaths,[7-9] but vaccine failure has been observed in some areas.[10] Pneumonia remains the leading cause of death in children under five, accounting for 14%, especially in sub-Saharan Africa.[1] In 2014, a survey found children under five make up 15% of Sudan's population, with pneumonia causing 10% of hospital deaths, making it the second leading cause after septicaemia.[11] According to the Ministry of Health's Annual Statistical Report, the proportion of pneumonia among children visiting Bashair Teaching Hospital (BTH) in Khartoum State, Sudan, was 36.2% in 2011 and 31.6% in 2012.

Evidence shows that Sudan introduced the first dose of 13-valent Pneumococcal Conjugate Vaccine (PCV13) in 2013, but its evaluation is limited. Few independent studies assess its impact on pneumonia in children under five. This paper examines PCV13's effectiveness on pneumonia cases among children under five at BTH.

Method

An observational cross-sectional procedure between May and September 2019 was designed targeting children under five years old who completed the three primary doses of PCV13 at 6, 10, and 14 weeks (Expanded Programme on Immunization, Ministry of Health, Sudan, 2019)

Study setting: BTH is a public health facility 16 Km south of Khartoum, adjacent to Al-Nasr Administrative Unit, Jabel Aulia Locality (JAL).

Sample size and sampling technique: Sample size was calculated based on the number of children under five targeted for routine vaccination at BTH in 2019. The following Slovin's Formula was used:

$$n = N/ (1 + N. e2)$$

Where: n = Sample size

N = Total Study Population in BTH

e = margin of error (set at 0.05)

Two hundred parents of the targeted children were randomly selected and interviewed. Samples were collected from the vaccinated children at the hospital in accordance with Standard Operating Procedures (SOPs). Structured questionnaires were administered to respondents. The pneumonia proportion (PP) among children was estimated based on completion of PCV13 doses, including only children over 14 weeks of age (inclusion criteria) and excluding those with a different vaccination schedule (exclusion criteria). Professional diagnoses for all selected children were reviewed in reference to the hospital's treatment protocol. Investigation tests for each case of pneumonia were displayed and documented on the admission sheet. Non-infectious pneumonia due to other complications/pneumonitis (CA70) was excluded.

PP = The number of pneumonia cases/ Total number of children under five years x 100.

PP was compared with the proportions in 2011 and 2012. The latter were calculated from morbidity and mortality records at the BTH.

Data Analysis: Statistical Package for the Social Sciences (SPSS) version 20 and Excel 2016 were used for descriptive and inferential statistics. The chi-square test was also used to analyse the association between the development of pneumonia and documented risk factors. A binary logistic regression was made for each risk factor with a p-value ≤ 0.05 and a 95% confidence interval.

Study variables:

- Dependent variable: pneumonia among children under five.
- Independent variables:
  - Sociodemographic factors: Age, sex, household size, mother's education status, mother's occupation
  - Health facility and childcare factors: measles vaccination, exclusive breastfeeding, weight at birth, previous pneumonia infection, and chronic diseases (non-communicable diseases, e.g., cardiovascular diseases, diabetes, asthma, etc).
- Environmental risk factor: indoor pollution

Ethical consideration:

Ethical approval was obtained from the Ethics Committee at Khartoum Ministry of Health (KMOH-REC-1-2020). All participants' parents or guardians gave informed consent. Data were secured and coded to ensure confidentiality.

Results

Proportion of pneumonia infection among children

Pneumonia (CA40) was recorded in 26% (52) of the study samples, compared with 74% (148) for other diseases or complications. Figure 1 shows a reduction in PP to 26.0% among the target under-five children in 2019, compared with 36.2% and 31.6% in 2011 and 2012, respectively. Demographic and other relevant variables for children under 5 years old with pneumonia are shown in Table 1.

Effect of 13-valent pneumococcal conjugate vaccine on pneumonia proportion

Cross tabulation–chi-square test analysis showed a statistically significant association (Pearson chi-square = 7.993, p=0.005) between clinical diagnosis (pneumonia and non-pneumonia) and vaccination (non-completed vaccination and completed vaccination). Other pneumonia-related risk factors are also presented in Table 2.

Modelling of factors associated with the development of pneumonia infection

Clinical diagnosis (pneumonia and non-pneumonia) was analysed using a binary logistic regression model (chi-square = 29.810, p = 0.002), with an overall accuracy rate of 75.9%. The model showed that vaccination status is five times more likely (OR = 5.059, 95% CI 1.485-17.236, p = 0.010) to contribute to the development of pneumonia. The analysis reveals other factors that contribute to the disease: percentage of variation in independent variables, adjusted odds ratios, and p-values are presented in Table 3.

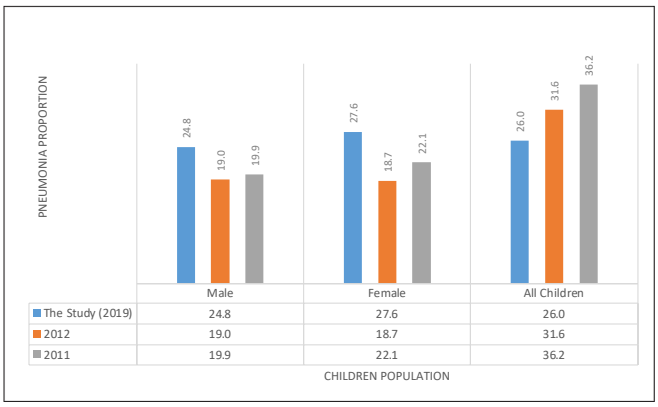

Figure 1. Pneumonia proportion among children under study at Bashair hospital; Data source: Annual Statistical Report at Bashair Hospital/ Khartoum, Ministry of Health

Table 1. Characteristics of under-five children infected with pneumonia (N=52)

Variable	n (%)
Sex	
Male	28 (53.8%)
Female	24 (46.2%)
Age	
≥4M ≤ 2Y	44 (84.6%)
>2Y <5Y	8 (15.4%)
Household size	
≤3 member	2 (3.8%)
4-7 members	20 (38.5%)
8+ member	30 (57.7%)
Mother occupation	
Employed	9 (17.3%)
Non-employed	43 (82.7%)
Mother education	
Illiteracy	14 (26.9%)
Primary level	26 (50.0%)
Secondary level or above	12 (23.1%)
Measles vaccination	
Completed	49 (94.2%)
missed 1st dose	2 (3.8%)
missed 2nd dose	1 (2.0%)
Immunization card	
Available	50 (96.2%)
Unavailable	2 (3.8%)
Weight at birth	
Standard weight range	51 (98.1%)
low birth weight	1 (1.9%)
Exclusive breastfeeding	
≥6 months	35 (67.3%)
< 6 months	17 (32.7%)
Previous Pneumonia infection	
Yes	18 (34.6%)
No	34 65.4%)
Chronic Disease	
Yes	2 (3.8%)
No	50 (96.2%)

Table 2. Cross tabulation between pneumonia and child background factors (N=200)

Independent variable	Non-pneumonia n (%)	Pneumonia (CA40) n (%)	p-value
Vaccination			
Non-completed vaccination	35 (23.6%)	3 (5.8%)	Pearson chi-Square 7.993, p=0.005*
Completed vaccination	113 (76.4%)	49 (94.2%)	
Child age			
4m - 2y	108 (73%)	44 (84.6%)	Pearson chi-Square 2.860, p=0.091
> 2 y < 5 y	40 (27%)	8 (15.4%)	
Child sex			
Male	85 (57.4%)	28 (53.8%)	Pearson chi-Square 0.201, p=0.654
Female	63 (42.6%)	24 (46.2%)	
Household size			
≤ 3 members	12 (8.1%)	2 (3.8%)	Pearson chi-Square 3.300, p=0.192
4 - 7 members	71 (48.0%)	20 (38.5%)	
8+ members	65 (43.9%)	30 (57.7%)	
Mother occupation			
Employed	19 (12.8%)	9 (17.3%)	Pearson chi-Square 0.639, p=0.424
Not-employed	129 (87.2%)	43 (82.7%)	
Mother education			
Non-educated	48 (32.4%)	14 (26.9%)	Pearson chi-Square 0.546, p=0.460
Educated	100 (67.6%)	38 (73.1%)	
Indoor pollution			
Non-smoker parent	92 (62.2%)	30 (57.7%)	Pearson chi-Square 0.323, p=0.570
Smoker parent	56 (37.8%)	22 (42.3%)	
Birth weight			
Low birth weight	7 (4.8%)	1 (1.9%)	Fisher's Exact Test 0.683
Standard weight range	140 (95.2%)	51 (98.1%)	
Exclusive breastfeeding			
< 6 months	61 (41.2%)	17 (32.7%)	Pearson chi-Square 1.175, p=0.278
≥ 6 months	87 (58.8%)	35 (67.3%)	
Previous pneumonia infection			
No	108 (73.0%)	34 (65.4%)	Pearson chi-Square 1.076, p=0.300
Yes	40 (27.0%)	18 (34.6%)	
Chronic disease			
No	118 (79.7%)	50 (96.2%)	Pearson chi-Square 7.723, p=0.005*
Yes	30 (20.3%)	2(3.8%)	

(*) mean statistically significant p-value

Table 3. Binary logistic regression analysis of factors associated with the development of pneumonia infection (N=200)

Explanatory variables	Coefficient of contribution	Standard error	Chi-square	p-value	AOR (95% CI)
Age	-0.461	0.466	0.978	0.323	0.630 (0.253-1.573)
Sex	0.02	0.358	0.003	0.956	1.020 (0.506-2.056)
Household size	0.411	0.304	1.83	0.176	1.509 (0.831-2.739)
Mother occupation	-0.431	0.515	0.701	0.403	0.650 (0.237-1.784)
Mother education	0.395	0.396	0.991	0.319	1.484 (0.682-3.227)
Indoor pollution	0.147	0.367	0.161	0.689	1.159 (0.564-2.381)
Birth weight	0.844	1.168	0.522	0.47	2.326 (0.236-22.972)
Exclusive breastfeeding	0.465	0.374	1.551	0.213	1.592 (0.766-3.311)
Previous pneumonia infection	0.529	0.383	1.907	0.167	1.698 (0.801-3.599)
Chronic disease	-1.918	0.777	6.093	0.014	0.147 (0.032-0.674)
Vaccination status	1.683	0.653	6.633	0.01	5.381 (1.495-19.367)
Intercept*	-4.901	2.859	2.938	0.087	0.007

(*) The predicted value of the development of pneumonia variable when all explanatory variables in the regression model are zero

Discussion

This study has revealed a reduction in the PP compared to 2011 and 2012, prior to the introduction of the pneumococcal vaccine. Data reviewed at the Ministry of Health, Khartoum State, indicate an overall decline in the PP from 2011 through 2018. This aligns with information on PCV13 cumulative coverage in the Al-Nasr Administrative Unit for the BTH, JAL, and Khartoum State. It represents high coverage, approximately 95%, except in 2013, when the pneumococcal vaccination campaign began. This high vaccine coverage may provide community-level protection against pneumonia. Such a scenario of herd immunity has been supported by Fine et al (2011).[12] Evidence shows that the introduction of the pneumococcal vaccine in low-income countries in Africa has been successful.[9,13]

However, data on PP at BTH show a dissimilar picture, and various conclusions may be drawn from this, including the selected participants' characteristics and the season during which the study took place. It seems that the study's inclusion criteria may have a consequence on the proportions of diseases recorded. Failure of pneumococcal vaccination was rarely observed in a systematic literature review by Oligbu G, et al [2016].[10]

This study has identified vaccination and chronic disease as statistically associated with the development of pneumonia in children under five. However, the data showed a higher percentage of the infected children had completed vaccination. Moreover, a high proportion of children with pneumonia had no chronic disease, which is not in line with expectations. Such disparities in vaccination completion could be explained by measles vaccine coverage, which in Khartoum State has been below 95% from 2013 through 2018, compared with above 95% at JAL since 2015 onward. Vaccine coverage in the Al-Nasr area, including BTH, was below 95% in 2017. The 95% identified by the Federal Ministry of Health as the target percentage was intended to create herd immunity, which is important for community protection. Because of social interaction in less-protected areas, outbreaks have flared up, but JAL, with vaccine coverage above 95%, has also reported measles outbreaks. The continuous outbreaks of measles could then mean that getting the measles vaccine itself prior to the first year of life is not the only essential condition to protect children against the disease. It seems that other contributing factors related to vaccination processes, such as vaccine quality and storage conditions, and administration technique, could be incriminated. Therefore, the same conditions associated with effective measles vaccine coverage may also be considered risk factors for the development of pneumonia. On the other hand, data on the presence or absence of the chronic disease were not clinically verified for each studied child. This might have confounded the data.

Other reviewed risk factors showing no statistically significant association with the development of pneumonia infection might be attributed to dependence on the parents' recall information without verification, which may have affected the interpretation of the results. However, this might be exemplified by a child's birth weight recorded on immunization cards and the denial by the respondent of the mother's smoking habit, among others. In this study, the risk factors are similar to the findings of Jackson et al. (2013) and Onyango et al. (2012), who found that immunization and co-morbidity, among others, were significantly associated with severe acute lower respiratory infections and also played a role in the development of severe pneumonia in children under five.[5,14]

Within the framework of public health interventions to improve the quality of life for children under five, counselling should focus on mothers and carers. Decision-makers should ensure that health services are more affordable for children under five with chronic illnesses.

Conclusion

In conclusion, a reduction in the PP after the use of PCV13 in children under five at the BTH was observed. No obvious association between some risk factors and the development of pneumonia infection has been established. Further research on the efficacy of PCV13 is recommended for the sustenance of children's health and growth in similar health contexts.

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