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PROJECT TITLE: Supportive care in the management of severe pneumonia in Nigerian children.

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SUMMARY:

According to 2008 estimates, about 177,000 children under the age of five years died of pneumonia in Nigeria, which was the third commonest cause of the 1 million deaths in Nigerian under-5s. Detecting hypoxemia with the use of simple pulse oximeters and providing immediate, cost- effective oxygen treatment may be effective in decreasing the mortality due to childhood pneumonia in Nigeria. During the period June 1, 2010 through August 31, 2010 children aged between 2 and 59 months with severe and very severe pneumonia were enrolled and treated with standard therapy as well as supplemental oxygen via oxygen concentrator or cylinder at University College Hospital, Ibadan. There were no significant differences found in the socio-demographic data (age, sex, socioeconomic class) between the oxygen concentrator and cylinder groups ($p>0.1$ for each variable). Forty-five out of 80 patients (56%) admitted were hypoxic ($SpO_2 < 90\%$). Twenty-three were commenced on oxygen therapy via oxygen concentrator and 22 via oxygen cylinder. The majority of patients (98%) recovered without sequelae (44). 6 patients experienced complications during admission and one child died. There were no significant differences found in the outcome parameters between the two groups ($p>0.05$) except a decrease in the days to resolution of nasal flaring in the oxygen concentrator group ($p<0.05$)The data that has been gathered in this study suggests that the use of oxygen concentrators as a mode of oxygen delivery for hypoxemic children with pneumonia is as effective as the use of oxygen cylinders.

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Introduction

The leading cause of death in children across the globe is pneumonia with the vast majority of these deaths occurring in low-resource areas.[1] Each year there are 156 million cases of pneumonia globally in children under 5.[2] Of these new cases, 151 million occur in the developing world with approximately 35 million occurring in Africa.[3] In Nigeria, pneumonia is the third commonest cause of mortality in children under 5 and the most common vaccine-preventable disease.[4] There are close to 180,000 pneumonia deaths and over 6 million new cases of clinical pneumonia among under 5s in Nigeria each year.[3,4] With these figures Nigeria ranks second among the 15 countries with the highest estimated number of deaths due to clinical pneumonia and fifth among the 15 countries with the highest estimated absolute number of new cases of clinical pneumonia.[5] Most severe pneumonia is bacterial, due mainly to *Streptococcus pneumoniae* (pneumococcus) and *Haemophilus influenzae*, usually type b (Hib), in both well-nourished and malnourished children.[3,6]

The World Health Organization (WHO) case definition for pneumonia uses straightforward clinical signs, like tachypnea, nasal flaring, and lower chest wall indrawing which have proven to be reliable signs in the diagnosis of pneumonia and are appropriate for case management in primary healthcare programs.[7] Effective intervention strategies and protocols for pneumonia prevention and treatment in developing countries exist, however there is great variation in the utilization of these interventions at the country level. Numerous challenges exist in the management of community acquired pneumonia (CAP) in the developing world and include, but are not limited to, limited access to care, insufficient treatment, increasing rates of antibacterial resistance and the prevalence of sickle cell disease and HIV infection.[8] Several risk factors related to host, environment and infection need to be accounted for when assessing causes and outcomes in clinical pneumonia. Rudan et al.[3] identified three categories of risk factors – definite, likely, and possible – for the development of pneumonia. Definite risk factors included malnutrition, low birthweight, non-exclusive breast feeding, indoor air pollution and crowding. Likely and possible risk factors included mother's education, concomitant disease, rainfall (humidity) and zinc deficiency[3]

A simple three-pronged solution that has the potential to save more than a million children globally from dying of pneumonia each year has been developed by the WHO and UNICEF in the form of the Global Action Plan For Prevention and Control of Pneumonia (GAPP). These are: protect, prevent, and treat. Interventions such as adequate nutrition (including exclusive breastfeeding, vitamin A supplementation and zinc intake), reduced indoor air pollution, and immunization against common pathogens including pneumococcal conjugate vaccination can decrease the incidence of pneumonia in children. Pertussis and measles immunizations have traditionally been a part of the Nigerian national programmes. Vaccinations against pneumococcus and Hib, estimated to cause more than 50% of deadly pneumonias have yet to be included despite regional evidence of high burden of Hib related disease and local high burden of Hib and pneumococcal diseases.[5,9,10]

In order for there to be wide-spread implementation of adequate treatment of pneumonia in limited-resource settings, there must first be consensus and a definition of "best practice" based on available evidence.[11] Improved access to early care in which appropriate intervention, including referral if necessary, is provided is the most valuable intervention to decrease deaths

related to pneumonia.[11] In terms of treatment, health providers must be adequate in number and training and be able to diagnose and treat children with pneumonia with appropriate antibiotics and supportive care including oxygen therapy in a timely manner.[12,13] The use of standard protocols for antibiotic use has been a major part of control programs for pneumonia throughout the world.[14] Even though hypoxia is a major risk factor for death in children with pneumonia in developing countries and occurs in around 20% of children presenting with pneumonia, there have been major challenges in the treatment of hypoxemia in pneumonia patients in limited resource settings.[15,16] The detection of hypoxemia requiring treatment, generally defined as an oxygen saturation (SpO2) less than 90%, can represent a challenge. [17] Additionally, oxygen is often not part of first line treatment because it is not readily available in low resource areas due to high cost and the complexity and logistics of oxygen cylinder transport.[18] Unavailability and shortage of oxygen is common and, as a consequence, oxygen is only given to the most seriously ill children, whose outcome is poor. Attempts to quantify the effect of oxygen in pneumonia are likely to be considered unethical. Consequently, it is necessary to develop a strategy for the diagnosis of hypoxemia and the use of oxygen in childhood pneumonia. A simple oximeter would make detection easier, and oxygen concentrators are more cost effective than bottled oxygen.[18] Successful attempts to treat hypoxemia have been made in limited-resource areas with the introduction of pulse oximetry and oxygen concentrators as a mode of oxygen delivery.[19,20]

The city of Ibadan is urban and has a population of about 4 million with children below the age of 5 years constituting approximately 25% of the population. The exact infant and under 5 mortality rates for the area are unknown, but they are believed to be at least as high as the national averages (IMR 110/1000 live births and U5MR 210/1000). The main causes of morbidity and mortality are pneumonia, malaria, diarrhoeal diseases, malnutrition, measles and tuberculosis. Malaria is the commonest single cause of morbidity and mortality in the under-5s in the area being responsible for about 36% of mortality while pneumonia is the second commonest cause and is responsible for about 16%.[10] A retrospective review of admissions at University College Hospital (UCH) Ibadan, from June 1, 2009 to August 31, 2009 showed that there was a case fatality rate of 9.1% for children with severe or very severe pneumonia. (unpublished data, AG Falade, personal communication) Since, CAP is a common cause of pediatric morbidity and mortality in Ibadan, outcomes may be improved by using supplemental oxygen based on pulse oximetry results.

Materials and Methods

Study population

A convenience sample of children between the ages of 2 and 59 months admitted into the Children's Emergency Room (CHER), University College Hospital (UCH), Ibadan, Nigeria from June 1, 2010 through August 31, 2010 with features compatible with case definitions for severe and very severe CAP were recruited into the study.

Case definition

Severity of CAP was classified as shown below:[21, 22]

Non-Severe Pneumonia

- Cough or difficult breathing and **fast breathing:**
  - age 2 up to 12 months : $\geq$ 50 breaths/min
  - age 1 up to 5 years : $\geq$ 40 breaths/min

Severe Pneumonia

Cough or difficult breathing plus **at least one** of the following signs:

- Lower chest wall indrawing;
- Nasal flaring;
- Grunting (in infants).

Very Severe Pneumonia

Cough or difficult breathing plus **at least one** of the following:

- Central cyanosis;
- Inability to breast feed or drink, or vomiting everything;
- Convulsions, lethargy or unconsciousness in the absence of malaria and meningitis;
- Severe respiratory distress.

Only children with severe and very severe pneumonia were enrolled into the study.

Inclusion criteria

a) All children between the ages of 2 months and 59 months admitted consecutively into the CHER from June 1, 2010 through August 31, 2010 with features compatible with case definitions for severe and very severe CAP and presenting with oxygen saturation <90%;
b) Those whose parents/guardians gave informed written consent.

Exclusion criteria

a) Age less than 2 months or 60 months and greater;
b) Stridor or any other evidence of upper airway obstruction present;
c) Evidence of recent treatment for pneumonia;
d) Documented history of use of antibiotics within the previous one week; and
e) Parents'/guardians' refusal to give informed written consent.

Study design and objectives

This was a prospective study of severe and very severe cases of community acquired pneumonia (CAP) admitted into the Children's Emergency Room (CHER), University College Hospital (UCH), Ibadan, Nigeria.

The objectives of this study were:

a) To determine the proportion of under-5 Nigerian children with pneumonia who presented with hypoxia to the Children Emergency Room (CHER), University College Hospital, Ibadan.
b) To describe the bacterial pathogens causing CAP in children under 5 in Ibadan, Nigeria and their antimicrobial susceptibility.
c) To document the usefulness of the oxygen concentrator in reversing the hypoxic state (SpO2<90%) in under-5 children admitted with severe CAP by documenting outcomes such as length of stay, complications, and status at discharge (return to baseline health, recovery with sequelae, death).
d) To determine the case fatality rate among children with pneumonia admitted into CHER during a 3-month period (June 1, 2010 through August 31, 2010).

Clinical and laboratory observations

Study participants all received standard care including venipuncture for blood culture, chest radiography, and standard antibiotics following the protocol of the Department of Paediatrics for treatment of pneumonia (Figure I). Upon enrollment, study participants had their presenting symptoms documented and vital signs recorded, including respiratory rate, heart rate, and oxygen saturation as determined by pulse oximetry. Signs of respiratory distress such as flaring of nares and suprasternal, supraclavicular, intercostal and subcostal retractions were also documented.

The respiratory rate was counted over 60 seconds with the patient preferably awake and calm. However, if this was not achievable, this procedure was carried out with the child asleep or breastfeeding. In addition, monitoring of heart rate, oxygen saturation, temperature and signs of respiratory distress (nasal flaring, grunting, suprasternal, supraclavicular, intercostal and subcostal retractions) were also monitored. This monitoring took place at least four times a day: 8.00 am, 12 noon, 4.00 pm and 8.00 pm in addition to the continuous monitoring of the nursing staff and physicians. In patients with severe and very severe pneumonia, continuous oxygen saturation monitoring was employed until improvement was achieved.

Laboratory data from blood samples for complete blood count, electrolytes and urea, and blood culture were collected from each participant if available. Although it is standard practice at the centre to obtain samples for blood culture on all patients with severe and very severe CAP, it is not always feasible on account of financial constraints.

In compliance with WHO guidelines, nasal prongs were used to deliver oxygen from the oxygen concentrator to hypoxic children (SpO2 <90%). Twenty-three patients were given oxygen therapy via oxygen concentrator and 22 via oxygen cylinder. The decision about which patients would receive oxygen by concentrator and which by cylinder was based on a number of logistic factors. The primary factor in decision making was availability of the oxygen concentrator. There were three functioning oxygen concentrators in the CHER. If the concentrator was available, children were commenced on concentrator. Numerous factors affected concentrator availability including whether or not there was electricity on the wards, and whether or not the concentrators were in use by other patients. Cost was also a factor as the cost of using the

concentrator was slightly less than the oxygen cylinder. Factors such as clinical presentation and level of hypoxemia were not considered. On the whole, and particularly in the interest of safety, as well as conforming to the WHO recommendations, nasal prongs were used to deliver oxygen from the oxygen concentrator to the hypoxic children in this study. If the patient required a nasogastric tube for feeding, a nasal catheter was used in lieu of nasal prongs for oxygen delivery. The start flow rate was 1 l/min and was progressively increased until the SpO_2 reached at least 90%. If adequate oxygenation was not achieved at a flow rate of 4 l/min, alternative methods, such as the use of nasal catheter or nasopharyngeal catheter, were tried. If there was any evidence of respiratory failure, the patient was transferred to the Intensive Care Unit for further management.

Description of the study site

The UCH is a tertiary centre, the first and largest teaching hospital in the country, located in the city of Ibadan, southwest Nigeria. It serves as the major referral centre for the south-western part of the country and offers specialist inpatient and outpatient care for all age groups across various specialties. The hospital has 820 beds and, of these, 160 are dedicated to pediatric admissions. This study assumed that approximately 90 per cent of children with severe and very severe CAP in the city of Ibadan would attend the Department of Paediatrics clinics in the UCH, Ibadan during the period of study based on general referral patterns.

Data Collection

A data collection tool was developed to collect data on patient demographics as well as document outcomes of children admitted with severe and very severe CAP. Data collected included information concerning possible socioeconomic and environmental risk factors such as birth order of the child, marital and educational status of the mother and father, socioeconomic class, and demographic data including home location (in order to infer likelihood of crowding and indoor air pollution). Additionally, complaints at presentation such as fever, cough, difficulty breathing, fast breathing, vomiting, irritability, and reduced feeding, were documented along with the clinical diagnosis. Findings on examination were recorded as well as the results of laboratory investigations and chest x-ray findings. Finally, the clinical assessment including days to normalization of temperature, respiratory rate and clinical signs of respiratory distress were recorded along with status at discharge and number of days of admission.

Data management and analysis

Data was entered (double entry) into a computer using Epidata and checked for errors by generating frequencies of all variables. Statistical analysis was done using the SPSS software package. Quantitative variables with normal distribution were compared using Student's T test and Analysis of Variance (ANOVA). Proportions were compared using Chi-Square. All statistical tests were carried out at the 5% significance level.

Ethics and consent

Ethical approval was obtained from the University of Manitoba Health Research Ethics Board (Bannatyne Campus) and the Ministry of Health, Oyo State Ethics Committee, Ibadan, Nigeria.

Enrolment into the study was voluntary after explanation of the intents and purpose of the study to the mothers or caregivers. A written consent was obtained before enrollment. The consent form was also translated to Yoruba, which is the local language. Patients were free to withdraw from the study without loss of benefits.

Results

Proportion of children presenting with hypoxia

During the study period there were 80 cases of severe or very severe pneumonia in children 2 to 59 months admitted to the CHER. Of those, 45 were noted to be hypoxic at presentation, thus requiring oxygen therapy. The proportion of children with pneumonia presenting with hypoxia at CHER, UCH from June 1 2010 to August 31 2010 was 56%.

Bacterial pathogens causing CAP

Due to challenges experienced at the study site, data on the bacterial pathogens causing CAP in children under 5 presenting with severe or very severe pneumonia were not available to be collected.

Case Fatality rate amongst children admitted into CHER during study period

Previous analysis of the admissions of the CHER, UCH, Ibadan, in the period from 1 June 2009 through 31 August 2009 revealed that there were 44 cases of severe or very severe pneumonia that matched the case definition for the study. There were a total of 484 admissions to the CHER during that time period, making severe pneumonia 9.1% of total admissions. Among the 44 pneumonia admissions there were four deaths, making the case fatality rate for pneumonia 9.1%. (unpublished data, AG Falade, personal communication) During the study period there were 45 cases of severe or very severe pneumonia. The total number of admissions during that period was 688, making severe pneumonia 6.5% of total admissions. There was just one death amongst all the admissions making the case fatality rate for pneumonia 2.2%.

Usefulness of oxygen concentrator

45 patients were enrolled into the study between June 1 2010 and August 31 2010. Of these, 23 were commenced on oxygen therapy via oxygen concentrator and 22 via oxygen cylinder. There were no significant differences found in the socio-demographic data (age, sex, socioeconomic class) between the oxygen concentrator and cylinder groups. The mean age of patients on concentrator was 11.24 months while the mean age of patients on oxygen cylinders was 10.46 months ($p>0.05$). There was no significant differences in age or sex between the two groups nor was there a significant difference in socioeconomic class (Table I). There were no significant differences found in the clinical parameters apart from a decrease in the days to resolution of nasal flaring in the oxygen concentrator group ($p<0.05$) (Table II).

The majority (98%) of patients recovered without sequelae (44). 6 children developed complications while on admission(3 in each of the cylinder and concentrator groups) and one child died. The one death occurred in a child who was later found to have underlying co-

morbidities. No significant difference was found between the outcomes of those receiving oxygen therapy by oxygen concentrator or oxygen cylinder ($p>0.05$).

Discussion

The proportion of children with pneumonia presenting with hypoxemia (56%) at CHER, UCH, Ibadan during the study period is significantly higher than those reported in other studies (about 20%).[15] It is reasonable to expect a certain degree of variation among studies, however, this difference in rates of hypoxemia in patients can be easily accounted for by the setting of this study. While the study of pneumonia in limited resource settings often takes place in rural or primary care hospitals, UCH is not only a tertiary hospital, but also the main referral center for southwest Nigeria. Hence, patients presenting to the CHER might be expected to be sicker, especially if they had been referred from another centre, as is often the case.

During the study period, June, 1 2010 to August 31, 2010, the microbiology labs hospital-wide were experiencing technical difficulties, including unavailability of blood culture bottles and damaged machinery for running cultures. As a result, we were unable to collect cultures or retrieve results for patients that were enrolled in the study. Studies on the most common pathogenic etiologies of pneumonia had already been conducted at the study site in the past.[10] During the planning of this project, the Government of Nigeria, through the Ministry of Health and National Primary Care Development Agency was planning on introducing a new national vaccination scheduled that included Hib and pneumococcal vaccinations in April 2010 which could have potentially changed the etiology of pneumonias presenting on the ward. However, this plan was aborted by the government and, therefore, it can be assumed that the previous etiological data is likely still accurate.[10]

The reported case-fatality rate for severe pneumonia decreased during the study period as compared to historical controls from the previous year during the same time period (from 9.1% to 2.2%). There is no significant difference in case-fatality between the two years. Additionally, it is difficult to determine whether or not the decrease in mortality was due to the use of concentrators themselves or simply due to implementation of a new oxygen protocol that took place during the time of the study. For instance, oxygen concentrators had previously not been in regular use for all patients and were used only for patients who had no money to pay for oxygen by cylinder. Additionally, oxygen saturation was not regularly monitored by the staff and was not recorded as a presenting vital sign when patients present to the CHER. Staff were given mobile finger pulse oximeters before the start of the study and instruction on the use and effectiveness of oxygen concentrators. Wide scale implementation of oxygen delivery systems, including staff retraining and consistent maintenance, have proven to be effective in both mortality and cost reduction in other settings. [19] Previous to the introduction of the study, pulse oximetry was not routinely available nor was the practice of routine saturation monitoring and, thus, decisions about the initiation of oxygen therapy was made on clinical features alone, which has been shown to be unreliable in predicting hypoxemia.

Anecdotally, it was noticed from June 1, 2011 to July 31, 2011, when an attempt was made to increase the sample size of the study following the completion of the study the year previous, that routine maintenance and use of the oxygen concentrators and pulse oximeters had

significantly decreased. For instance, the portable finger pulse oximeters that had been provided a year previous had all either been lost or broken, save one, and were replaced with a larger, less mobile pulse oximeter that was much more difficult to use and carry. Additionally, all of the manuals that had been provided about the use of the oxygen concentrators had disappeared and a false belief that the concentrators could not be run continuously had developed among the clinical staff. Awareness and training on the use of this equipment had not been kept up as changes were made to clinical staff. It is, therefore, reasonable to extrapolate that improved outcomes may have been due at least in part to the introduction of a more efficient oxygen delivery protocol (routine oxygen saturation monitoring and increased use of oxygen delivery systems) that were developed during the initial study period.

As predicted, there was no significant difference in outcomes found between children who used oxygen concentrators and oxygen cylinders as a mode of oxygen delivery. Due to the lower cost of the oxygen concentrator as a means of oxygen delivery, we were initially concerned that with a convenience sample there might be selection bias with patients of lower socioeconomic status favouring oxygen concentrator use. However, we did not find any significant difference in the socioeconomic parameters between the two groups. This preliminary data is promising and indicates that in a well-controlled setting, the use of oxygen concentrators for hypoxemic patients in limited-resource environments can work as effectively as traditional oxygen cylinders. The benefit, of course, is that using oxygen cylinders significantly reduces the cost of oxygen delivery, making them potentially ideal for low-resource settings.[18] However, the data is preliminary given the small number of participants in the study. Other studies have shown that implementation of oxygen programmes that use oxygen concentrators have both a financial and mortality benefit, but none have shown whether or not the concentrators themselves have equivalent outcomes to using oxygen cylinders, as this study has attempted to quantify. The only parameter to reach significance was that of the number of days to resolution of nasal flaring, which was slightly less in the concentrator group. As a whole, due to the low numbers of participants in the study at this time point, no conclusions can be made as of yet regarding the comparative efficacy of using oxygen concentrators to supply oxygen to pediatric patients with pneumonia and hypoxemia compared to conventional oxygen delivery via cylinder. Low numbers of participants in the initial study may be related to the fact that the study was performed at a tertiary centre, which in Nigeria is a more expensive option for a population with incredibly high rates of poverty. Future investigations will need to consider strategies to make treatment more accessible to individuals in the region.

Unique challenges of study site and Future of the study

The drawback of using concentrators in the treatment of hypoxemia in low-resource settings is that they are reliant upon a constant and stable power supply.[20] One of the challenges that was faced in the second attempt at patient recruitment was that of an inconsistent power supply. For the majority of the study period in 2011, the CHER at UCH did not have a consistent power supply making it unethical to initiate or maintain patients on oxygen concentrators. Additionally, as noted previously, it was noted that there is a need for additional staff training on the use of oxygen concentrators and pulse oximeters and the potential benefits that they offer towards the improvement of patient care. This has been successfully achieved in other centers.[19] Maintaining the equipment that is available is also a critical issue if an oxygen delivery system using the concentrators is going to work.

Summary

The role of oxygen saturation monitoring and supplemental oxygen therapy in improving outcomes in severe and very severe pneumonia is supported by the data from this study. The use of oxygen therapy by oxygen concentrator appeared to be equally effective as oxygen provided by oxygen canister although there remain a number of logistical challenges with consistently providing oxygen therapy in this setting.

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Table I: *Demographic comparisons between oxygen concentrator group and oxygen cylinder group*

Demographic	Oxygen Concentrator	Oxygen Cylinder	p value
Mean Age (in Months)	11.23	10.45	0.80
Sex (Male)	11	14	0.29
Sex (Female)	12	8	
Socioeconomic class 1	2	3	0.84
Socioeconomic class 2	5	7	
Socioeconomic class 3	7	7	
Socioeconomic class 4	7	5	

Table II: *Comparison of clinical parameters between oxygen concentrator group and oxygen cylinder group.*

Parameter	Oxygen Concentrator	Oxygen Cylinder	P value
Axillary temperature (max; ^{o} C)	37.97^{o}	38.16^{o}	0.64
Axillary temperature (min; ^{o} C)	36.2^{o}	36.41^{o}	0.06
Days to normalize temperature (<37.5^{o})	1.50	1.63	0.68
Respiratory Rate (max; breaths/minute)	75.78	69.27	0.09
Days for respiratory rate to normalize	2.47	2.09	0.29
Flaring ala nasae, days to resolve	1.90	2.53	0.05
Lower chest wall indrawing, days to resolve	2.10	2.57	0.15

**all of the above are t-tests with equal variances assumed*

Figure I

Algorithm for the antibiotic treatment of community-acquired pneumonia in children ages 2 months to < 5 years