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Audit of antibiotic therapy in surgical neonates in a tertiary hospital in Benin City, Nigeria

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ABSTRACT

Objective: To report the outcome of commonly used antibiotic combinations in surgical neonates in sub-Saharan African settings. **Methods:** A retrospective analysis that determines the outcome of commonly combined antibiotics in surgical neonates between January 2006 and December 2008 at two referral paediatric surgical centres in Benin city was carried out. **Results:** Ampicillin ampiclox, metronidazole, gentamicin, cefuroxime and ceftriaxone were variously combined in the management of 161 neonates with a mean age at presentation of 9.2 ± 2.6 days, mean weight 3.1 ± 1.4 kg and a male:female ratio 1.6:1. Polymicrobial postoperative wound infections and sepsis caused by *Staphylococcus aureus*, *Escherichia coli*, *Neisseria meningitidis*, *Klebsiella pneumonia*, *Pseudomonas aeroginosa* and anaerobes, were mainly encountered. The most common aerobes isolated from wound cultures were *S. aureus* and *P. aeroginosa* while the ones from that of blood cultures were *E. coli* and *K. pneumonia.* Overall postoperative infections recorded were: wound infection 19 (11.8%), sepsis 16 (9.9%) and sepsis-related deaths 6 (3.7%). **Conclusion:** Combinations of gentamicin/metronidazole/cefuroxime and gentamicin/cefuroxime were adequate for gastrointestinal and extra-gastrointestinal neonatal operations, respectively, in these sub-Saharan African settings, which may be useful in similar regions.

Key words: Antibiotics, combinations, sub-saharan Africa, surgical neonates

INTRODUCTION

Poorly developed cell-mediated and humoral immunity may increase the risk of sepsis, which poses a major challenge in the newborn, especially in those delivered preterm.[1-3] This is compounded by the presence of surgical pathology that may require invasive intervention which exposes the neonate to infection and makes the use of antibiotics a necessity during management.[4] Also, unlike in the adults and older children, the poorly developed humoral and cell-mediated responses in neonates often lead to the occurrence of polymicrobial infections, with a large proportion caused by normally harmless commensal organisms.[1,5,6] Consequently, the use of a broad spectrum antibiotic that takes care of both gram positive and negative aerobic as well as anaerobic bacterial infections is important when managing surgical neonates. Despite the emergence of newer broad spectrum antibiotics, no single agent has been discovered to give equally effective coverage against all the possible infective bacteria.[1,4,7,8] This is notably so in many developing countries where the rarity of such a single agent requires combinations of antibiotic(s) with proven effectiveness against aerobic and anaerobic bacteria that often cause polymicrobial infections.[2,3,7]

Intrauterine diagnoses of surgical pathologies, foetal intervention and planned delivery in hygienic environment with prompt and appropriate surgical management of affected neonates are feasible in many centres.[9] Time lag between the birth of a surgical neonate and commencement of appropriate management is crucial. Initiation of prophylactic antibiotic(s) before the onset of sepsis has resulted in a considerable reduction in postoperative infections in neonates with excellent surgical outcomes.[4,9] Although the incidence of sepsis is low in many sophisticated centres, postoperative wound infection and sepsis are, nonetheless, still major causes of mortality and morbidity that increase the length of hospitalisation and cost of treatment in sub-Saharan Africa.[10-13] This is because of poor obstetric care, delivery in unhygienic environment and septic handlings of the newborns.

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Moreover, majority of the surgical neonates who are delivered outside tertiary care centres are presented for treatment very late with established resistant sepsis.[2,6,10-13] Therefore, knowledge of adequate combinations of antibiotics that give the best outcome is important when managing surgical neonates in sub-Saharan Africa.

A 3-year retrospective study was undertaken at two referral paediatric surgical centres in Nigeria to determine antibiotic combinations that give the best results in managing surgical neonates in sub-Saharan African settings.

PATIENTS AND METHODS

Ethical approval was obtained from the University of Benin Teaching Hospital Local Ethics Committee. Thereafter, the case files of all surgical neonates managed at the University of Benin Teaching Hospital and Leadeks Medical Centre, both in Nigeria, between January 2006 and December 2008 were retrieved and analysed in this retrospective study. The two centres were run by three consultant paediatric surgeons and one consultant neonatologist during the period. The choice of antibiotic combinations used was influenced by the system(s) involved by the surgical pathology, clinical state of the neonate on arrival and familiarity of the consultants with the antibiotics. All babies delivered in the centres, which had early surgical attention, and all those with extra-gastrointestinal surgical pathology received prophylactic antibiotics. However, therapeutic antibiotics were commenced either preoperatively or on induction of anaesthesia and continued for a minimum of 7 days after surgery in other neonates. Data collated to determine the effectiveness and drawbacks to the use of antibiotic combinations included age of the neonates at presentation, sex, clinical condition on arrival, surgical pathology, surgical procedures, antibiotic combinations, wound infection, sepsis, monitoring, assessment of effectiveness, outcome and follow-up. Nine neonates who were assessed as ASA 4 (using American Society of Anaesthesiology score) were excluded. These neonates either died before or shortly after surgery due to severe life-threatening multiple congenital anomalies in three and late presentation of six who were in endotoxic shock on arrival.

Assessment method was adapted locally using postoperative wound infection, clinical features of postoperative sepsis, in addition to results of wound swabs and systemic specimens obtained for microscopy/cultures/sensitivity. Absence of postoperative wound infection was scored as normal, peri-incision hyperaemia with no pus expressed was scored as mild, superficial wound infection with positive culture as moderate and deep wound infection with positive culture as severe. Similarly, absence of postoperative clinical features of sepsis was scored as normal, minor features of sepsis with negative culture results as mild, obvious features of sepsis with positive culture(s) results as moderate and florid features of sepsis with positive culture(s) results as severe. A normal/mild assessment in both wound infection and sepsis screening indicates effective antibiotic combination, a moderate score indicates moderately effective and severe score indicates ineffective combination.

The data were analysed using SPSS version 13 software package (SPSS, Chicago, IL, USA) and presented as counts, frequency and percentage. Continuous data were expressed as means ± standard deviation, while categorical data were analysed using Chi-square test with P values <0.05 regarded as significant.

RESULTS

One hundred and sixty-one neonates comprising 21 (13%) who were delivered preterm between the 29th and 34th weeks of gestation were treated for surgical diseases during the period. Their mean age at presentation was 9.2 ± 2.6 days (range 1–30 days), mean weight was 3.1 ± 1.4 kg (range 1.4–5.9 kg) and male:female ratio was 1.6:1 (98 males to 63 females). Of the total neonates, approximately only a quarter [41 (25.5%)] were delivered at the study centres while the rest [120 (74.5%)] were referred from other hospitals. Among the babies referred, 53 (44.2%) were brought very late and in clinical compromise. This was due to fluid and electrolyte derangement in 31, nutritional derangement in 22 and clinical features of sepsis (excluding those who arrived in endotoxic shock) in 19 neonates. As shown in Table 1, majority of the neonates [125 (77.6%)] had surgical pathology involving the gastrointestinal system, genitourinary involvement was in 11 (6.8%), musculoskeletal in 8 (5.1%), cardiothoracic in 6 (3.7%), maxillofacial in 5 (3.1%), craniospinal in 4 (2.5%) and subcutaneous in 2 (1.3%) neonates. Operation was deferred until after the neonatal age in other neonates seen during the period whose lesions were not life threatening. Therefore, colostomy creation in 51 (40.8%) neonates for anorectal anomaly and Hirschsprung's disease, corrective surgeries for intestinal atresia in 18 (14.4%), gastroschisis in 16 (12.8%), ruptured omphalocoele in 8 (6.4%), malrotation in 9 (7.2%), necrotising enterocolitis with surgical complications

Table 1: Systems involved by surgical pathology, antibiotic combinations used and outcome in 161 surgical neonates

Systemic involvement	Antibiotic combinations	No.	Local wound infection			Sepsis			Death
			Mild	Moderate	Severe	Mild	Moderate	Severe	
Gastrointestinal	Gentamicin/metronidazole/ampiclox	2	0	2	0	0	0	2	1
	Gentamicin/metronidazole/ampicillin	4	1	3	0	0	2	0	1
	Gentamicin/metronidazole/cefuroxime	49	2	0	0	0	0	0	0
	Metronidazole/ceftriaxone	8	0	2	0	1	0	0	0
	Cefuroxime/metronidazole	33	0	4	0	0	0	1	0
	Gentamicin/cefuroxime	29	1	0	3	0	0	3	1
Genitourinary	Gentamicin/cefuroxime	9	0	0	0	0	0	1	1
	Gentamicin/ceftriaxone	2	0	0	0	1	0	0	0
Musculoskeletal	Gentamicin/cefuroxime	8	0	0	0	0	0	0	0
Craniospinal	Gentamicin/cefuroxime	3	1	0	0	0	2	0	0
	Gentamicin/ceftriaxone	1	0	0	0	0	0	0	0
Maxillofacial	Gentamicin/cefuroxime	3	0	0	0	0	0	0	0
	Gentamicin/metronidazole/cefuroxime	2	0	0	0	0	0	0	0
Cardiothoracic	Gentamicin/cefuroxime	2	0	0	0	0	0	2	2
	Gentamicin/metronidazole/cefuroxime	4	0	0	0	0	1	0	0
Subcutaneous	Ampiclox/metronidazole	1	0	0	0	0	0	0	0
	Ampiclox/gentamicin	1	0	0	0	0	0	0	0
Total	—	161	5	11	3	2	5	9	6

in 10 (8%), bladder exstrophy in 6 (4.8%), spontaneous bowel perforation in 6 (4.8%) and vitellointestinal duct prolapse in 5 (4%) neonates, were the main indications for gastrointestinal surgeries in them.

Homeostasis was maintained; adequate tissue perfusion and urinary output were ensured before the antibiotics, particularly, aminoglycoside were commenced. The commonly used/combined antibiotics in neonates were aminoglycoside, penicillin, metronidazole and second/third generation cephalosporins to cover the common infective organisms. Available/affordable agents and the doses used during the period were ampicillin 100 mg/kg/24 hours, ampiclox 200 mg/kg/24 hours, metronidazole 5–7 mg/kg/dose, gentamicin 5 mg/kg/24 hours, cefuroxime 50–100 mg/kg/24 hours and ceftriaxone 50–100 mg/kg/24 hours. These were combined variously as depicted in Table 1. Wound infection and sepsis were more common following gastrointestinal and cardiothoracic surgeries as well as among babies delivered outside the study centres and that had therapeutic antibiotics. Gastrointestinal and cardiothoracic surgeries accounted for five (83.3%) of the six sepsis-related deaths recorded ($P < 0.0001$). There were, however, no significant statistical differences observed when wound infection and sepsis were compared between preterm and term neonates ($P = 0.2914$).

The majority of wound swabs and systemic specimen cultures yielded mixed growths of bacteria that included *Staphylococcus aureus*, *Escherichia coli*, *Neisseria meningitidis*, *Klebsiella pneumonia* and *Pseudomonas aeroginosa*. However, the most common bacteria isolated from wound cultures were *S. aureus* and *P. aeroginosa* while those isolated from blood cultures were *E. coli* and *K. pneumonia*. The resistance and sensitivity patterns of the common aerobes obtained from laboratory corresponded with clinical outcomes [Table 2]. When combined agents were applied during sensitivity testing, outcomes were better than the sum total effects of the agents (*in vitro* synergism). However, facilities were not available to culture anaerobes during the period. But the addition of metronidazole to the regimen significantly improved outcomes in gastrointestinal and cardiothoracic operations, indicating polymicrobial infections by both aerobic and anaerobic organisms.

Table 2: Sensitivity pattern of common isolates of aerobes to commonly combined agents

Isolates/sensitivity	Gentamicin	Ampiclox	Ampicillin	Cefuroxime	Ceftriaxone	Metronidazole
S. aureus	0	+++	++	++	+++	0
E. coli	+++	++	++	+++	+++	0
N. meningitidis	0	++	++	++	+	0
K. pneumonia	+++	0	0	+++	+++	0
P. aeroginosa	+++	0	0	0	+++	0

0 = resistant, + = weakly sensitive, ++ = moderately sensitive, +++ = strongly sensitive

In gastrointestinal surgeries, therefore, better results were achieved using combinations that included a second/third generation cephalosporins either as a double or triple combination with other agents ($P < 0.0001$). Consequently, a triple combination of gentamicin, metronidazole and cefuroxime was discovered to have the best overall clinical outcome [Table 1]. This was because only 2 (4.1%) of 49 neonates who had this combination recorded mild wound infection with no sepsis or sepsis-related death. This outcome was better than the results of double combinations of cefuroxime and metronidazole, cefuroxime and gentamicin, ceftriaxone and gentamicin, ceftriaxone and metronidazole or the other combinations shown in Table 1. Similar results were also recorded with the combination of gentamicin, metronidazole and cefuroxime in cardiothoracic operations. On the other hand, double combinations of gentamicin and second/third generation cephalosporin were found to be sufficiently effective for extra-gastrointestinal surgeries. Wound infection and sepsis were rare in these cases excepting a neonate who presented late with posterior urethral valve, but died of overwhelming sepsis after surgery. Triple combinations that included metronidazole did not give added advantage in extra-gastrointestinal operations. The overall rates recorded during the period was: postoperative wound infection 19 (11.8%), sepsis 16 (9.9%) and sepsis-related deaths 6 (3.7%).

DISCUSSION

Postoperative infections have been reported[1-3] to significantly increase morbidity and mortality rates of surgical patients, especially the neonates. Many authors have drawn attention to the adverse impacts of surgical site infections.[1,14] Overall rates recorded in this study for postoperative wound infection 11.8%, sepsis 9.9% and sepsis-related deaths 3.7% approached reports from studies in developed countries despite the unique challenges.[1,4,9] This could be attributable to adequate culture and sensitivity testing that influenced combinations of antibiotics which gave the best coverage against bacteria earlier reported[2,6,10-13] as major causes of neonatal sepsis and postoperative wound infections in this subregion. Although wound infection and sepsis were commonly associated with gastrointestinal and cardiothoracic surgeries, and among babies delivered outside the study centres, there were no significant statistical differences observed when wound infection and sepsis were compared between preterm and term neonates. These findings agreed with similar studies in this subregion.[10-13] They were, however, at variance with results from developed countries where no significant statistical difference was observed when postoperative wound infection was compared between gastrointestinal and extra-gastrointestinal surgeries, and where prematurity was the major factor that increased the risk of postoperative wound infection and sepsis.[1,4,15-17]

The risks of postoperative wound infection and sepsis are increased at the extremes of age, the neonatal period being a stage of immune compromise.[1-3] Several defects in antibacterial host immunity, including defective quantities of immunoglobulin, complement components and neutrophil functions have been reported, that, in combination, render a neonate immunocompromised.[1] This condition is compounded by the presence of surgical diseases, invasive surgical treatments and presence of comorbid illnesses.[1,4,15] Consequently, a surgical neonate is susceptible to infection with bacteria that are typically of low virulence, such as coagulase-negative staphylococci. Such opportunistic organisms are usually resistant to many antibiotics most commonly used for perioperative prophylaxis in neonates as seen in this and other similar studies.[1,2,6,10-13] Moreover, immune compromise in these neonates helped in the establishment of polymicrobial infections that were notable challenges in this study. The challenges were compounded by late referral and delayed treatment of affected babies, especially those delivered outside the study centres. As a result, many postoperative wound infections, sepsis and deaths occurred in these babies despite the use of combination antibiotics because time lag allowed the bacteria enough time to establish in the 'immunocompromised' neonates.

Additionally, the chance of bacterial contamination was increased by the mode and place of delivery as well as late commencement of appropriate antibiotic therapy in this and other centres in this subregion.[2,6,10-13] The development of postoperative infection was reported[1-3,16] to relate to the degree of bacterial contamination and the virulence of the infective organisms. Bacterial contamination in this study may have been from both exogenous and endogenous sources. Exogenous factors such as the state of delivery rooms, birth attendants, instruments used and airborne organisms from the unhygienic environment favoured the contamination.[2,15] Also, endogenous sources such as microflora of the skin of the neonates, respiratory, genitourinary and gastrointestinal systems, which were reported by other authors[15] to significantly increase the risk of bacterial contamination, were notably present in this study. Moreover, the infectivity of the contaminating organisms was

enhanced by suitable conditions for microbial growth such as pH, oxygenation, anaerobiosis, temperature, proteins and carbohydrate nutritional requirement that were favourable in these babies as reported by others.[1-3,10-13] Effects of polymicrobial infections in these surgical neonates were devastating perhaps because of microbial synergism and the production of certain toxins.[3,17,18] Microbial synergism is reported[3] as a process whereby the products of one organism, such as fibrinolysins, lecithinases and proteases, enhance and facilitate the establishment and rapid growth of another organism. The unique conditions in sub-Saharan Africa were reported to enhance the evolution of different species of bacteria causing neonatal sepsis.[2,6,10-13] These differences also resulted in different antibiotic sensitivity patterns between the developed countries and many centres in sub-Saharan Africa.[4,5,7,19-21] Consequently, polymicrobial infections that were resistant to many common/affordable agents especially when administered alone were a challenge in this study, which influenced combinations of antibiotics based on the sensitivity pattern obtained from the laboratory.

The inappropriate or indiscriminate use of antibiotics has been reported to increase the cost of treatment, risk of drug toxicity and selection of resistant strain.[2,3,17,18] The realisation of these facts influenced restriction of antibiotic combinations to a few drugs reported[1-3] with proven safety and efficacy profiles as well as use of cost-effective drugs in neonates in this setting. Nevertheless, the lack of facilities to isolate and culture anaerobes was a major drawback with a resultant earlier poorer outcome compared to the later part of the period under review during which metronidazole was empirically added to the combination with a dramatic improvement in outcome. In developed centres, many newer agents such as imipenem/cilastatine are used with excellent effectiveness against aerobes and anaerobes but these are neither available nor affordable in this subregion.[1-3] This resulted in a search for the best combinations among the available/affordable agents in many resource-poor regions.[1-3] The unique pharmacokinetics in neonates made other authors[2,3] recommend compliance with minimum inhibitory (MIC) or minimum bactericidal concentrations (MBC) of antibiotics and also that lowest required dosages which are widely spaced should be used especially in the presence of compromised clinical states. Also in other studies,[2,4,8] regular estimations of serum concentration of antibiotics were recommended as a guide for accurate dosing for each neonate. These were not feasible in this study; hence the standardised dosage regimens[3] were strictly adhered to. Multidrug combinations have been reported[2,3] to result in indifference, when the effect of the two drugs equals that of each drug administered singly, and antagonism when the action of one agent inhibits the actions of the other drug(s) in the combination. The desired advantage of antimicrobial drug combinations is synergism, whereby the total antibiotic activity is greater than the expected sum of the combined agents.[22,23] The *in vitro* synergism recorded in the laboratory with the drugs commonly combined corresponded with *in vivo* clinical effects of these drugs in this study. In gastrointestinal and cardiothoracic surgeries in this study, therefore, the combination of metronidazole, gentamicin and cefuroxime gave the best synergism with excellent clinical outcome. On the other hand, the synergism obtained between gentamicin and cefuroxime was adequate for extra-gastrointestinal surgeries.[24,25] The limitations of this study, however, are many: a retrospective design, the study being mainly on clinical outcomes of very few available and affordable antimicrobial agents, which did not elaborate on the type of culture and sensitivity testing done, the lack of facilities to isolate anaerobic organisms, and no separate analysis of therapeutic and prophylactic uses of the agents. These are the pitfalls that require cautious generalisation of findings from this study.

CONCLUSION

Polymicrobial postoperative wound infection and sepsis with unique bacteriology and antibiotic sensitivity pattern that influenced antimicrobial combinations were common in this setting. The synergism obtained from combinations, especially that of gentamicin, metronidazole and cefuroxime, gave the best coverage in gastrointestinal and cardiothoracic surgeries in surgical neonates compared to the other combinations. Similarly, combining gentamicin with cefuroxime or ceftriaxone gave equally good results in neonates who had extra-gastrointestinal surgeries. In similar resource-poor settings where newer agents may either not be available or affordable, the use of these combinations may be advocated in surgical neonates.

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