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Comparative mortality and neurological outcomes in term newborns with severe perinatal asphyxia treated with combined magnesium sulphate and erythropoietin or magnesium sulfate alone

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Abstract: *Background:* Severe perinatal asphyxia (PA) remains a leading cause of neonatal mortality and long-term neurological disability in low- and middle-income countries (LMICs) where therapeutic hypothermia is largely unavailable. Pharmacological neuroprotective agents may offer cost-effective alternatives. *Methods:* The institutional Ethics Committee approved the protocol. We conducted a prospective, randomized, controlled trial of erythropoietin and magnesium sulfate on term neonates with severe PA (hypoxic-ischemic encephalopathy [HIE] stages II–III) at the Federal Medical Centre, Asaba, Nigeria, in 2024. They were randomized to either $MgSO_4$ plus EPO (Group I, n = 50) or $MgSO_4$ alone (Group II, n = 50). Group II. The primary outcome was in-hospital 28-day mortality. Secondary outcomes included time to resolution of neurologic symptoms and neurological status at 28 days. *Results:* 130/ 1370 (9.4%) in-hospital deliveries had PA; 598 of these were admitted. 205/ 803 (25.53%) total admissions to the Neonatal unit were outborn; 88 had PA. Mortality was significantly lower in group I (4%; 2/50) compared with group II (18%; 9/50, p = 0.025). Combination therapy resulted in faster seizure control (1.34 ± 1.61 vs 2.71 ± 2.23 days, p = 0.002), earlier recovery of: suck (4.7 vs 7.9 days, p = 0.014), grasp reflex (5.3 vs 8.5 days, p = 0.028), and tone normalization (16.1 vs 21.3 days, p = 0.037). Logistic regression identified low birth weight, low APGAR score, and out-of-hospital delivery as significant predictors of mortality. *Conclusion:* Combination therapy with Erythropoietin significantly reduced mortality and improved neurological recovery in term neonates with severe PA. This combination could representa feasible, cost-effective alternative for LMICs.

Keywords: Perinatal asphyxia, Hypoxic-ischaemic encephalopathy, Pharmacological Neuroprotection.

Résumé: *Contexte:* L'asphyxie périnatale (AP) severe demeure une cause majeure de mortalité néonatale et d'invalidité neurologique à long terme dans les pays à revenue faible et intermédiaire (PRFI) oùl'hypothermie thérapeutique est largement indisponible. Les agents neuroprotecteurs pharmacologiques pourraient offrir des alternatives rentables. *Méthodes:* Le comitéd'éthiqueinstitutionnel a approuvé le protocole. Nous avons mené un essai prospectif, randomisé et contrôlé portant sur l'érythropoïétine et le sulfate de magnésium chez des nouveau-nés à terme attaints d'AP sévère (encephalopathy hypoxique -ischémique [EHI] stades II à III) au Centre medical federal d' Asaba, au Nigéria, en 2024. Les nouveau-nés ont été randomisés pour recevoir soit du $MgSO_4$ plus EPO (Groupe I, n = 50), soit du

$MgSO_4$ seul (Groupe II, n = 50). Le critère d'évaluation principal était la mortalité hospitalière à 28 jours. Les critères d'évaluation second daires comprenaient le délai de résolution des symptoms neurologiques et l'état neurologique à 28 jours.
Résultats: 130/1 370 (9,4 %) des accouchements en milieu hospitalier ont étésuivis d'une AP; 598 d'entre euxont été admis. 205/803 (25,53 %) des admissions en unite néonatale étaient des naissances externes; 88 d'entre eux ont été suivis d'une AP. La mortalité était significativement plus faible dans le groupe I (4 % ; 2/50) que dans le groupe II (18 % ; 9/50, p = 0,025). Le traitement combiné a permis un contrôle plus rapide des crises (1,34 ± 1,61 jours contre 2,71 ± 2,23 jours, p = 0,002), une récupération plus précoce de la succion (4,7 jours contre 7,9 jours, p = 0,014), du réflexe de préhension (5,3 jours contre 8,5 jours, p = 0,028) et une normalisation du tonus (16,1 jours contre 21,3 jours, p = 0,037). Une regression logistique a identifié un faible poids de naissance, un faible score d'APGAR et un accouchement extrahospitalier comme facteurs prédictifs significatifs de mortalité.
Conclusion: Le traitement combiné par érythropoïétine a significativement réduit la mortalité et amélioré la recuperation neurologique chez les nouveau-nés à terme atteints d'AP sévère. Cette association pourrait constituer une alternative viable et rentable pour les pays à revenue faible ou intermédiaire.

Mots-clés: Asphyxiepérinatale, Encéphalopathiehypoxique-ischémique, Neuroprotection pharmacologique

Introduction

Perinatal asphyxia (PA) continues to be a major cause of neonatal mortality and long-term disability worldwide. [1] Globally, about one million neonatal deaths annually are from birth asphyxia, and among survivors, many develop cerebral palsy, epilepsy, developmental delay, and learning disabilities.[2] The burden is particularly severe in sub-Saharan Africa, where health facility utilisation for maternal care, limited access to quality perinatal and neonatal care contributes to higher incidence and worse outcomes.[3-6]

Nigeria has one of the highest neonatal mortality rates globally,[4] with perinatal asphyxia contributing significantly.[7] While therapeutic hypothermia (TH) is the standard of care in high-income countries, it is rarely accessible in LMICs for several reasons.[9] Thus, alternative, affordable, and scalable interventions are urgently needed in LMICs.

Pharmacological neuroprotection is emerging as a promising strategy. Magnesium sulphate ($MgSO_4$), long used in obstetrics for seizure prevention, has demonstrated neuroprotective effects in neonates by stabilizing neuronal membranes, reducing calcium influx, and mitigating excitotoxic injury. [10-12] Erythropoietin (EPO), a haematopoietic cytokine, has potent anti-apoptotic, anti-inflammatory, antioxidant, and neurotrophic properties. Preclinical studies and clinical trials in high-income settings have suggested that EPO can enhance neurological recovery and improve outcomes when administered early in neonates with hypoxic-is chaemicencephalopathy.[13-15]

$MgSO_4$ primarily acts to limit the cascade of neuronal injury immediately after hypoxic insult, whereas EPO promotes neuronal repair, angiogenesis, and neurogenesis in the recovery phase. [16-18]Their combined use may provide both immediate and sustained neuroprotection. However, despite their promise, there is limited evidence on combined therapy in LMIC settings where the need is greatest.

Objective

This randomized controlled trial evaluates the comparative effectiveness of $MgSO_4$ alone versus $MgSO_4$ combined with EPO in improving 1st 28 days survival and neurological outcomes among term neonates with severe perinatal asphyxia in a Nigerian tertiary hospital.

Methods

Research Ethics Approval

Ethical approval was obtained from the Institutional Ethics review Board. Written informed consent was obtained from parents or guardians of the study cases prior to enrolment.

Sample size & Sampling
Sample size determination.

The sample size formula for the comparison of groups was used to calculate the sample size for this study:[19]

$$n = \frac{(Z_\alpha + Z_\beta)^2\{p1(1-p1) + p2(1-p2)\}}{(d)^2}$$

Fifty (50) participants will be recruited in each of the two groups. A total of 100 subjects were recruited for the study.
Variables used were obtained from the study done by Bhat[97] and colleagues in their work: Magnesium Sulphate in severe perinatal asphyxia: a randomized control placebo-controlled trial.

Study Design and Setting

This was a prospective randomized controlled clinical trial conducted at a Tertiary centre in South-South Nigeria, from January to October 2024. This tertiary referral hospital serves a large population in South-South Nigeria. The facility conducts approximately 1500 deliveries annually and has a functional neonatal intensive care

unit (NICU) equipped with respiratory support devices and monitors.

Participants
Eligibility

Inclusion Criteria

Eligible participants were term neonates (≥37 weeks) with severe PA, defined by the presence of HIE stage II or III according to the modified Sarnat and Sarnat criteria.

Additional criteria included low Apgar scores (≤5 at 5 or 10 minutes), delayed cry at birth, or need for prolonged resuscitation.

Exclusion Criteria

Exclusion criteria were congenital anomalies, prematurity, severe sepsis at presentation, or refusal of parental consent.

Randomization and Interventions

One hundred eligible neonates were enrolled and randomized in a 1:1 ratio into two groups using sealed opaque envelopes.
Intervention group I: $MgSO_4$ (250 mg/kg intravenously daily for 5 days) + EPO (1000 IU/kg subcutaneously daily for 3 days). Magnesium sulfate was infused with a syringe driver over 45minutes daily for five days. Whilst EPO was administered subcutaneously.
Control group II: $MgSO_4$ (250 mg/kg intravenously daily for 5 days) only.

All newborns were fully evaluated on admission using the Thompson score. They were monitored continuously with multi-parameter monitors or 2-hourly 1st 24 to 48 hours; thereafter for 4-hourly up to week one and subsequently 12-hourly until home discharge. The monitoring activities covered observations for the events included in the primary and secondary outcomes, as well as other events that occurred. These clinical findings were documented, as well as the associated interventions, as needed. Pre-discharge examination findings or events preceding mortality were all recorded. All neonates received standard supportive care, including oxygen therapy, intravenous fluids, antibiotics when indicated, temperature regulation, and assisted feeding.

Study recruitment Process

All eligible newborns that were recruited into any arms of the study were enrolled following an individual counselling process and informed parental/caregiver written consent

Information obtained at the individual interview included

The socio-demographic and obstetric data, consisting of the age, parity, gestational age, tribe, level of education, occupation, spouses' occupation and level of education, were recorded on a pretested proforma. Details of the newborn, which included cry at birth or APGAR scores at birth, sex, gestational age.
Further Counselling of Parents of Asphyxiated Newborns
Parents were provided counselling as and when there were any new changes in the baby's condition or at discharge. They were particularly counselled on the need to participate in the post-discharge neonatal follow-up plans, which will involve scheduled outpatient's visits for evaluations & other departments' evaluation of the babies. They were equally informed, before home discharge, of the need for some of the babies who may need further rehabilitation therapy as would be applicable.

Outcomes

Primary outcome: In-hospital mortality within 28 days of life.

Secondary outcomes:
- Time to seizure control.
- Recovery of primitive reflexes (suck, grasp, Moro).
- Normalization of muscle tone.
- Time to the establishment of full breastfeeding.
- Thompson score improvement.
- Duration of hospital stay.
- Complications such as seizures, jaundice, disseminated intravascular coagulation (DIC), persistent pulmonary hypertension (PPHN), and acute kidney injury.

Statistical Analysis

Data were analyzed using SPSS version 27. Categorical variables were expressed as frequencies and percentages and compared using chi-square or Fisher's exact test. Continuous variables were expressed as means ± standard deviation or medians (IQR) and compared using Student's t-test or Mann–Whitney U-test as appropriate. Logistic regression analysis was used to identify predictors of mortality. A p-value <0.05 was considered statistically significant.

Results

Incidence and Baseline Characteristics

During the study period, 1370 live births occurred, of which 130 neonates had severe perinatal asphyxia, giving an incidence of 9.4%.
Table 1 features the characteristics of the study participants and the interventions. Caesarean section delivery

was common among the combination therapy asphyxia cases. Most of the participants received intervention at less than 12 hours of age.

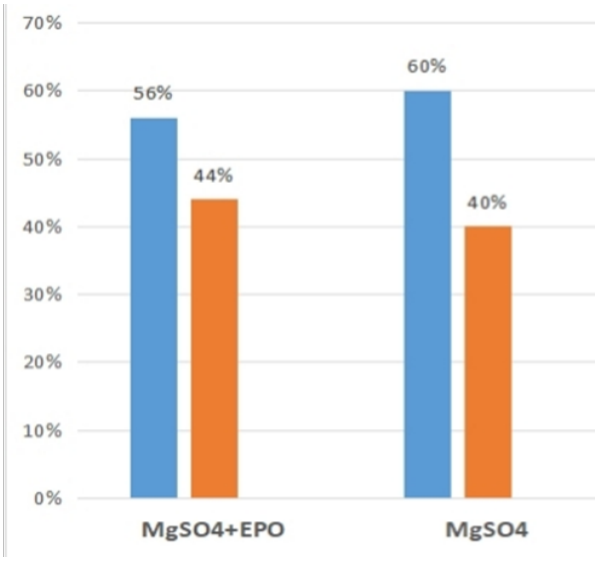
Table 1: Characteristics of study participants and intervention received

Variable	Intervention MgSO4+EPO (n=50)	MgSO4 (n=50)	$\chi 2$	P-Value
Booking Status				
Booked	20 (40.0)	23 (46.0)	0.367	0.545
Unbooked	30 (60.0)	27 (54.0)		
Place of Birth				
Inborn	30 (60.0)	26 (52.0)	0.649	0.420
Outborn	20 (40.0)	24 (48.0)		
Mode of Delivery				
C/S	31 (62.0)	21 (42.0)	4.006	0.045*
SVD	19 (38.0)	29 (58.0)		
Age at Intervention				
≤12hrs	41 (82.0)	42 (84.0)	0.071	0.790
>12hrs	9 (18.0)	8 (16.0)		
Duration of labour (in hours)	27.62 ± 16.57	24.26 ± 19.28	0.935^t	0.352
APGAR Score at 10^{th} minute	7.26 ± 1.35	7.08 ± 1.58	0.613^t	0.541
Sex				
Male	22 (44.0)	24 (48.0)	0.161	0.688
Female	28 (56.0)	26 (52.0)		
Birth Weight (kg)	3.18 ± 0.55	3.03 ± 0.49	1.458^t	0.148
GA at Birth (in weeks)	38.36 ± 1.17	38.64 ± 1.32	2.981^t	0.078

t = Independent T-test; *Significant

Grades of HIE of study participants

Fig 1: highlights the similarity in the grades of HIE for both study and control patients.

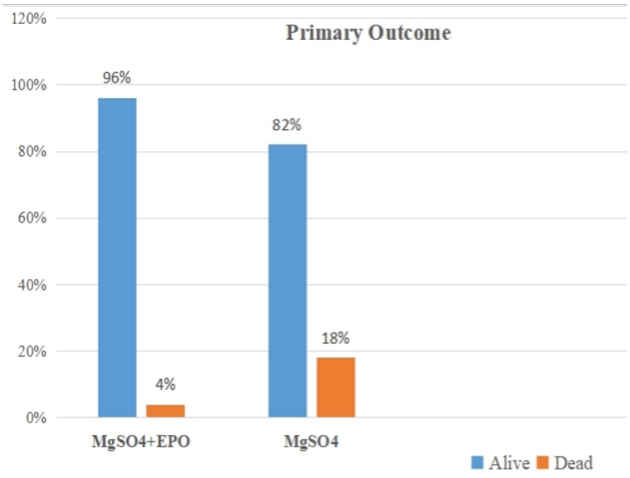


$\chi 2$ =0.164, p = 0.685

Primary Outcome (mortality)

Fig 2: shows that the in-patient mortality rate was significantly higher in the group that received $MgSO_4$ alone, $\chi 2$ = 5.005 p = 0.025. Such mortality occurred in the 1st few days of their admission. No additional case fatalities were observed among participants up to the 28th day in both study subgroups.

Fig 2: In-hospital mortality rate following intervention
Predictors of Mortality



Binary logistic regression identified:

- Low birth weight (<2.5 kg)
- Low 10-minute Apgar score
- Out-of-hospital delivery

These were independent predictors of mortality regardless of treatment group.

Discussion

This randomized trial demonstrated that combining $MgSO_4$ with EPO significantly improved survival and short-term neurological recovery among neonates with severe PA compared to $MgSO_4$ alone. The 14% absolute reduction in mortality (from 18% to 4%) is clinically

meaningful, especially in LMICs where neonatal survival remains a pressing challenge. Previous trials with EPO as an adjunct to TH did not show significant mortality reduction in the cooled babies receiving added EPO.[20] The observed degree of mortality reduction herein might suggest the potential value of the combination pharmacological neuroprotection therapy, especially for the LMICS like Nigeria, where Asphyxia mortality rates remain high and TH is not accessible.

Reasons for the observed reduction in mortality

The improved outcomes can be explained by the synergistic action of the two agents, given their complementary mechanisms of action. $MgSO_4$ attenuates excitotoxic neuronal injury through NMDA receptor antagonism, while EPO enhances neuro-repair via anti-apoptotic, angiogenic, and neurogenic pathways. The accelerated seizure control and earlier recovery of primitive reflexes in the combination group highlight this synergistic effect. Earlier studies with the EPO combination had made similar observations of enhanced neuroprotection. [21-22]

Comparison with studies of EPO combinations with TH

Our findings align with international studies where EPO, when combined with therapeutic hypothermia, enhanced neurological outcomes. [15,21] However, this is among the first studies to demonstrate the benefits of EPO combination with another pharmacologic neuroprotection agent in the absence of TH in a resource-limited setting. This has important implications, as TH remains largely unavailable in Nigeria and similar contexts.

Implications for the observed predictors of mortality

The predictors of mortality identified in our study—low birth weight, low Apgar scores, and outborn delivery—are consistent with global literature.[23-24] These reinforce the importance of strengthening maternal care, improving intra-partum monitoring, and expanding access to skilled delivery services. Indeed, the finding of LBW in a cohort of babies > 37 weeks would suggest some degree of coexisting intra-uterine malnutrition; such causes can be proactively detected at the ANC visits and early preventive intervention in the mother might impact on the neonatal Intra-uterine growth and nutrition. The role of IUGR in immediate and long-term neonatal outcomes is well documented.[26] Addressing systemic barriers while deploying cost-effective pharmacological interventions could yield significant reductions in neonatal mortality.

Role of maternal Health issues; SBA on immediate neonatal outcomes

Higher C-section rate in the combination therapy group emphasises the point for the value of skilled attendance at birth. These babies, though severely asphyxiated, might have received the needed timely quality care, which might have contributed to better outcomes for the group of PA babies. In this study, 44% of the babies were from the outborn babies; although much is not known about their place of birth, they might have been born at home. Such conditions might have contributed to the PA rates. However, in the context of this study setting, where antenatal clinic uptake and skilled attendance at delivery remain low, focus should be placed on alternate strategies to address maternal health issues that affect peri-partuum care so as to improve neonatal outcomes.

Conclusion

This survey highlights the potential value of the combination therapy with Magnesium sulfate and EPO in perinatal asphyxia for mortality and morbidity reduction in LMICS settings like Nigeria.

Limitations of the study

This work is limited by the shortfall in neuroimaging studies that would have enabled the observation of deep-brain tissue injuries. Echocardiographic studies would have equally allowed for the measurement of the pulmonary artery pressure and strengthened the diagnosis of pulmonary hypertension. The sample size is small, and this survey is a single-centre study

Recommendations

1. More trials on a larger scale, multi-centre cohorts in LMICS settings be conducted to verify outcomes of this modality of combination therapy.
2. The Governments of LMICS settings should make more investments in maternal health and broaden the scope of ANC and SBA to the communities.
3. More investments should be made in strengthening the capacity for the delivery room resuscitation skills on a wider scale.

Author Contributions
JNA: Conceptualization, Preparation of Proposal draft, Field Work implementation, & Investigation, Data curation & Formal Analysis, Manuscript Writing – original draft, – review & editing of Final draft.
AAO: Conceptualization, Supervision of Proposal writing, Preparation of Proposal draft, Supervision of Field Work implementation, & Investigation, Review of Data & Formal Analysis, Manuscript Writing – original draft, – review & editing of Final draft.
COO: Supervision of Proposal writing, Conceptualization, Preparation of Proposal draft, Supervision of Field Work implementation, & Investigation, Review of Data & Formal Analysis, Manuscript Writing – original draft, – review & editing of Final draft.
OUC: Review of Proposal draft, Supervision of Field Work implementation, Manuscript Writing – original draft, – review & editing of Final draft.
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Consort flowchart