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Effect of prenatal magnesium sulphate on hearing function in premature newborns

Prematüre yenidoğanlarda doğum öncesi magnezyum sülfatın işitme fonksiyonu üzerine etkisi

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ABSTRACT

Aim: The study aimed to evaluate the potential neuroprotective effects of antenatal magnesium sulfate (MgSO4) on sensorineural hearing and auditory nerve development in premature newborns.

Methods: This retrospective study included premature newborns (<37 weeks) born between November 1, 2022, and December 31, 2023, at Etlik City Hospital. Newborns were divided into two groups: those exposed to antenatal MgSO4 (study group, n=40) and those unexposed (control group, n=126). Antenatal MgSO4 was administered at 2 grams/hour for at least 8 hours after a 6-gram loading dose. Hearing screening was conducted using auditory brainstem response (ABR) tests within the first month after birth. Maternal and neonatal characteristics, including gestational age, birthweight, and APGAR scores, were analyzed. Statistical comparisons between groups were performed using appropriate tests, with a significance level of $p<0.05$.

Results: The failure rate in hearing screening tests did not significantly differ between the MgSO4 group (10%) and the control group (6.3%) (p=0.437). However, the MgSO4 group had lower gestational age at birth (median: 30.0 vs. 34.0 weeks, $p<0.001$), lower birthweight (median: 1424 vs. 2325 grams, $p<0.001$), and higher rates of APGAR scores below 7 at both the 1st and 5th minutes. Placental abruption, retinopathy of prematurity, and bronchopulmonary dysplasia were associated with hearing abnormalities in the overall cohort.

Conclusion: Antenatal MgSO4 administration did not demonstrate a significant protective effect against hearing impairment in premature newborns. Larger prospective studies are warranted to clarify MgSO4's role in auditory neuroprotection.

Keywords: Magnesium sulphate (MgSO4), antenatal neuroprotection, premature newborn, sensorineural hearing loss

ÖZ

Amaç: Bu çalışma, antenatal magnezyum sülfatın (MgSO4) prematüre yenidoğanlarda sensorinöral işitme ve işitsel sinir gelişimi üzerindeki potansiyel nöroprotektif etkilerini değerlendirmeyi amaçlamaktadır.

Yöntem: Retrospektif olarak planlanan bu çalışmaya, 1 Kasım 2022 - 31 Aralık 2023 tarihleri arasında Etlik Şehir Hastanesi'nde doğan prematüre (<37 hafta) yenidoğanlar dahil edilmiştir. Yenidoğanlar, antenatal MgSO4 alan (çalışma grubu, n=40) ve almayan (kontrol grubu, n=126) olmak üzere iki gruba ayrılmıştır. Antenatal MgSO4, 6 gramlık yükleme dozunun ardından en az 8 saat süreyle 2 gram/saat hızında uygulanmıştır. İşitme taramaları, doğumdan sonraki ilk ay içerisinde odyolojik beyin sapı yanıtı (ABR) testleri ile gerçekleştirilmiştir. Gestasyonel hafta, doğum ağırlığı ve APGAR skorları gibi maternal ve neonatal özellikler analiz edilmiştir. Gruplar arasındaki istatistiksel karşılaştırmalar uygun testlerle yapılmış ve $p<0,05$ anlamlı kabul edilmiştir.

Bulgular: İşitme tarama testlerinde başarısızlık oranı, MgSO4 grubu (%10) ile kontrol grubu (%6,3) arasında anlamlı bir fark göstermemiştir (p=0,437). Ancak MgSO4 grubunda daha düşük gestasyonel hafta (ortanca: 30,0 hafta vs. 34,0 hafta, $p<0,001$), daha düşük doğum ağırlığı (ortanca: 1424 gram vs. 2325gram, $p<0,001$) ve 1. ve 5. dakika APGAR skorlarının 7'nin altında olma oranları daha yüksektir. Total hasta grubunda işitme anomalisi ile plasental dekolman, prematüre retinopatisi ve bronkopulmoner displazi arasında ilişki bulunmuştur.

Sonuç: Antenatal MgSO4 uygulaması, prematüre yenidoğanlarda işitme bozukluklarına karşı anlamlı bir koruyucu etki göstermemiştir. MgSO4'ün işitsel nöroproteksiyon üzerindeki rolünü netleştirmek için daha geniş kapsamlı prospektif çalışmalara ihtiyaç vardır.

Anahtar Kelimeler: Magnezyum sülfat (MgSO4), antenatal nöroproteksiyon, prematüre yenidoğan, sensorinöral işitme kaybı

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INTRODUCTION

In the last fifty years, the development of evidence-based care practices and interventions has significantly improved mortality outcomes for premature infants. Specifically, the use of antenatal corticosteroid applications and neonatal surfactant replacement has greatly reduced early deaths due to respiratory failure in very preterm (<32 weeks of gestation) newborns. However, significant long-term neurological morbidities have been observed in surviving infants. Developing, evaluating, and implementing strategies to reduce the frequency and severity of neurological sequelae is a priority in perinatal care (1-4).

The disease burden imposed by neurosensory disorders and impairments on surviving premature infants is considerable. Major morbidities such as cerebral palsy, blindness, deafness, and developmental delays are observed. Furthermore, school-aged children exhibit cognitive deficits, including academic problems, executive dysfunction, and behavioral disorders such as attention deficit hyperactivity disorder (ADHD), with increasing rates (5–8).

Today, magnesium sulfate (MgSO4) is widely used in obstetric care for various indications to improve obstetric outcomes. These include reducing the risk of eclampsia and its use as a tocolytic agent. However, its efficacy as a tocolytic agent is still debated (9). The current view is that MgSO4 may be neuroprotective for the immature fetal central nervous system and may reduce the incidence of major neurological morbidities, particularly cerebral palsy (CP), in premature newborns (10). Based on current research, magnesium has been extensively studied for its neuroprotective effects, and guidelines for antenatal MgSO4 administration in preterm births have been established. MgSO4 infusions are recommended to protect the fetal central nervous system in premature infants and to reduce preterm birth rates in patients presenting with preterm labor threats (9).

Despite reductions in mortality rates associated with prematurity, the incidence of sensorineural hearing loss remains high, ranging from 2% to 64% (11). Hearing loss, which affects speech and language development, is a significant disability closely linked to the newborn's social and physical development and has a substantial impact on quality of life. Congenital hearing loss is a universal health issue and is one of the health measures used to determine health-related quality of life (12). Early diagnosis and appropriate treatment regimens can mitigate adverse outcomes. Therefore, neonatal hearing screening programs have been widely initiated, and hearing screening within the first month of life is recommended for all infants (13).

There is a lack of evidence-based data regarding the effectiveness of MgSO4 in preventing hearing loss in premature infants. Previous studies evaluating magnesium for neuroprotection primarily focused on CP as the primary outcome, but there is insufficient data on cochlear function (9). Some studies suggest that magnesium may have a beneficial effect on noise-induced hearing loss in adults (14). However, the mechanisms of noise-induced hearing loss and congenital hearing loss are different. Considering the widespread use of MgSO4 in obstetric care, this study aims to evaluate the potential neuroprotective effect of antenatal MgSO4 on auditory nerve development and sensorineural hearing in premature newborns.

METHODS

Our study included patients who delivered between November 1, 2022, and December 31, 2023, at Etlik City Hospital's Obstetrics and Gynecology Department, with follow-up and treatment completed at our center, including postnatal neonatal follow-ups. The medical records of the study patients were retrospectively reviewed. The study was approved by the local ethics committee (approval number: AEŞH-BADEK-2024-087).

Newborns born to mothers who received antenatal MgSO4 for various indications at least eight hours before delivery were included in the study group. Newborns who did not receive MgSO4 formed the control group. Those with fetal disease or maternal systemic conditions (Body Mass Index (BMI)>30, history of chronic mental or physical illness, severe renal, hepatic, gastrointestinal, acute/chronic inflammatory disease, hyperthyroidism, hypothyroidism, hypertension, type 1/2 diabetes mellitus, polycystic ovary syndrome (PCOS) history, malignancy history, smoking, or alcohol use) were excluded from the study.

Antenatal MgSO4 was administered intravenously at a dose of 2 grams/hour continuously. The infusion duration was at least 8 hours, following a loading dose of 6 grams, as recommended. The indications for MgSO4 included neuroprotection. When indicated, antenatal corticosteroids were administered in two intramuscular doses of 12 mg betamethasone. In our study, patients who received two doses of betamethasone were considered for standardization purposes.

The primary outcome measure was the failure rate in newborn hearing screening. Auditory brainstem response (ABR) allows for the neurophysiological evaluation of brainstem maturation and the auditory pathway in newborns. The effect of antenatal MgSO4 infusion was the main variable.

Since all newborns were premature and had risk factors for hearing loss, they were subjected to hearing screening within the first

month after birth. The results of the hearing screening tests were evaluated, and comparisons were made between the study and control groups. Hearing tests were performed using the Madsen Accuscreen (Otometrics, Denmark). The tests consisted of a click stimulus at up to 30 dB, using disposable hydrogel electrodes, and the device standard was EN-60645-7 type 2.

According to the recommended algorithm for newborn hearing screening, newborns were classified as "passed" if the screening test produced a response in both ears at the 30 dB-NHL stimulus level, and "failed" if it did not.

Maternal characteristics that could affect neonatal outcomes, such as maternal age, parity, prelabor rupture of membranes, amniotic fluid volume, mode of delivery, gestational age at birth, birth weight, placental abruption, and APGAR scores, as well as neonatal characteristics, were also recorded. Additionally, neonatal parameters evaluated within the first 28 days, such as the need for mechanical ventilation, neonatal sepsis, intraventricular hemorrhage, respiratory distress syndrome (RDS), retinopathy of prematurity, necrotizing enterocolitis, and bronchopulmonary dysplasia, were analyzed as composite outcomes. Pathological electroencephalography (EEG) and visual evoked potentials were also analyzed.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 29.0 (IBM Corp., Armonk, NY). Continuous variables were presented as median and interquartile range (IQR), and categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. For comparisons between groups, the Mann-Whitney U test was used for continuous variables that did not follow a normal distribution, while the Student's t-test was applied for normally distributed continuous variables. For categorical variables, the chi-square test or Fisher's exact test, where appropriate, was used. A p-value of less than 0.05 was considered statistically significant.

RESULTS

During the study period, 166 pregnant patients were included. Among the 166 newborns, 40 (24%) received MgSO4 for neuroprotective purposes, while 126 newborns (75%) did not receive MgSO4.

The median maternal age at birth was similar between the study and control groups (median values were 27.5 and 28, respectively, p = 0.35). Body mass index, parity, and mode of delivery were also found to be similar between the two groups (Table 1).

Table 1. Comparison of maternal, neonatal and birth characteristics between patients receiving neuroprotective magnesium ınfusion and control groups

Variables	Neuroprotection Group N:40	Control Group N:126	P Value
Maternal age in years, median (IQR)	27.5 (24.0, 30.0)	28.0 (24.0, 33.0)	0.350
Maternal body mass index at booking in kg/m2, median (IQR)	26.0 (24.0, 31.0)	28.0 (25.0, 31.0)	0.436
Nulliparity, n(%)	19 (47.5)	53 (42.1)	0.546
Oligohydramnios, n(%)	19 (47.5)	28 (22.2)	**0.002**
Mode of delivery, n(%)			0.619
Vaginal	17 (42.5)	48 (38.1)	
C/S	23 (57.5)	78 (61.9)	
Time period until birth in days, median (IQR)	2.50 (0.75, 5.25)	0.00 (0.00, 1.00)	**<0.001**
Gestational age at birth in weeks, median (IQR)	30.0 (27.5, 31.3)	34.0 (33.0, 35.0)	**<0.001**
Birthweight in grams, median (IQR)	1424 (948, 1845)	2325 (1980, 2633)	**<0.001**
Neonatal Gender, n(%)			0.829
Male	23 (57.5)	70 (55.6)	
Female	17 (42.5)	56 (44.4)	
APGAR score <7 at 1th minute, n(%)	17 (43.6)	15 (12.1)	**<0.001**
APGAR score <7 at 5th minutes, n(%)	9 (23.1)	6 (4.8)	**<0.001**
Neonatal abnormal hearing test, n(%)	4 (10.0)	8 (6.3)	0.437

p-value of less than 0.05 was considered statistically significant
C/S: Cesarean section, IQR: Interquartile range

Table 2. Comparison of maternal and neonatal outcomes between hearing abnormality and control groups

Variables	Hearing Abnormality Group N:12	Control Group N:154	P Value
Placental abruption, n (%)	2 (16.7)	3 (1.9)	**0.004**
Gestational age at birth in weeks, median (IQR)	30.5 (28.8, 31.0)	34.0 (32.0, 35.0)	**<0.001**
Birthweight in grams, median (IQR)	1660 (1251, 1903)	2230 (1768, 2583)	**0.006**
APGAR score <7 at 1th minutes, n (%)	4 (33.3)	28 (18.5)	0.214
APGAR score <7 at 5th minutes, n (%)	2 (16.7)	13 (8.6)	0.353
Neonatal Outcomes, n (%)			
EEG patology	2 (16.7)	4 (2.6)	**0.012**
Retinopathy of prematurity	7 (58.3)	34 (22.1)	**0.005**
Resuscitation requirement	4 (33.3)	24 (15.6)	0.114
Respiratory distress syndrome	2 (16.7)	26 (16.9)	0.985
Surfactant requirements	3 (25.0)	23 (14.9)	0.355
Cardiac inotrope requirement	2 (16.7)	10 (6.5)	0.190
Sepsis	3 (25.0)	18 (11.7)	0.192
Intraventricular haemorrhage	0 (0.0)	8 (5.2)	0.418
Necrotising enterocolitis	0 (0.0)	3 (1.9)	0.626
Pulmonary Hypoplasia	0 (0.0)	3 (1.9)	0.626
Bronchoulmonary Dysplasia	2 (16.7)	6 (3.9)	**0.049**

The neuroprotection group had significantly higher rates of oligohydramnios (47.5% vs. 22.2%, p = 0.002). The time period until birth was also longer in the neuroprotection group (median: 2.50 days, IQR: 0.75-5.25 vs. 0.00 days, IQR: 0.00-1.00, p < 0.001). Additionally, the neuroprotection group had a significantly lower gestational age at birth (median: 30.0 weeks vs. 34.0 weeks, p < 0.001) and lower birthweight (median: 1424 grams vs. 2325 grams, p < 0.001). APGAR scores below 7 at both the 1st and 5th minutes were more common in the neuroprotection group (1st minute: 43.6% vs. 12.1%, p < 0.001; 5th minute: 23.1% vs. 4.8%, p < 0.001). However, no significant differences were observed in abnormal hearing test results (p = 0.437) (Table 1).

Placental abruption was significantly more common in the hearing abnormality group compared to the control group (16.7% vs. 1.9%, p = 0.004). Additionally, gestational age at birth was lower in the hearing abnormality group (median: 30.5 weeks, IQR: 28.8-31.0 vs. 34.0 weeks, IQR: 32.0-35.0, p < 0.001) as well as birthweight (median: 1660 grams, IQR: 1251-1903 vs. 2230 grams, IQR: 1768-2583, p = 0.006). There were no statistically significant differences in APGAR scores at the 1st or 5th minute between the two groups (Table 2).

Regarding neonatal outcomes, EEG pathology was significantly more frequent in the hearing abnormality group (16.7% vs. 2.6%, p = 0.012), as well as retinopathy of prematurity (58.3% vs. 22.1%, p = 0.005), and bronchopulmonary dysplasia (16.7% vs. 3.9%, p = 0.049). Other neonatal outcomes, such as resuscitation requirement, respiratory distress syndrome, and sepsis, did not show significant differences between the groups (Table 2).

DISCUSSION

The prevention of neurological and developmental disorders in premature newborns remains a challenging health issue today. All reported studies show improvement with the optimal organization of antenatal and postnatal care (15).

The use of MgSO4 is primarily recommended for eclampsia prophylaxis and, more recently, for the protection of the fetal central nervous system in preterm births before 32 weeks (9). The purpose of the present study was to evaluate whether MgSO4 has a neuroprotective effect on hearing in premature newborns. Our findings indicate that the failure rate in the hearing screening test

did not significantly differ between the group of newborns exposed to antenatal MgSO4 and those who were not.

Magnesium is an essential element for many physiological processes in the body. In this context, magnesium contributes to cochlear physiology and plays a role in the hearing process. Despite its known neuroprotective effects and protective action against CP, data on magnesium's effect on sensorineural hearing are limited. In a study with guinea pigs, a negative correlation was observed between cochlear magnesium levels and hearing loss. It was shown that magnesium has a regulatory function in the inner ear and prevents the formation of reactive oxygen species after noise exposure (16,17). Moreover, there is evidence of cellular damage related to oxidative stress associated with magnesium deficiency (18). Additionally, protective effects of oral magnesium supplementation on acoustic trauma-related hearing loss have been demonstrated in adults (14). Most of these studies were conducted on animals or adults, specifically evaluating noise-induced cochlear damage. This evidence led the present study to evaluate the potential protective effects of magnesium on sensorineural hearing in premature newborns. Premature newborns were specifically assessed in this population due to their higher incidence of hearing loss, which is associated with delayed neurodevelopment. Although several mechanisms can be proposed for the development of hearing loss in premature newborns, prematurity alone is a well-established risk factor (19). This is because fetal audiological development primarily occurs between the 20th and 33rd weeks of gestation.

In a previous study examining risk factors for hearing loss in preterm newborns, it was suggested that the etiology of hearing loss is multifactorial rather than due to a single factor (20). For this reason, clinical factors were separately evaluated in both groups in this study. Comparisons between the groups revealed that newborns in the study group who received antenatal MgSO4 had significantly lower birth weights and lower APGAR scores at the first and fifth minutes, which may be related to earlier gestational ages at birth.

In a study conducted by Crowther et al. with 1,047 participants, hearing loss was not evaluated separately but was instead considered a component of moderate neurological impairment. The authors did not report a significant difference in sensory or neural impairments between the patient groups receiving magnesium and those who did not (21).

Antenatal corticosteroid applications have been reported to reduce the risk of hearing loss (22). Most studies evaluating the neuroprotective effects of magnesium note that participants also received corticosteroids, as was the case in the present study. In another recent study evaluating the effects of antenatal steroid administration solely on hearing function in newborns, no association was found between corticosteroids and hearing screening results (23). In a further study, repeated doses of antenatal steroids, rather than a single dose, did not provide benefits according to newborn hearing test evaluations (24). In our study population, patients who received two doses of betamethasone were evaluated for standardization of newborn outcomes.

Although this study includes all premature newborns (<37 weeks) over a one-year period, the study population is relatively small, and the retrospective nature of the study is another limitation. Additionally, the difference in gestational age between the groups with and without MgSO4 administration is a limitation, as the target population for antenatal neuroprotective interventions is primarily those born before 32 weeks. However, despite the gestational age difference, the similar hearing test results in the neuroprotective MgSO4 group are promising in terms of its potential contribution to sensorineural development. We believe that large-scale studies designed with different methodological approaches to eliminate gestational age differences will provide more objective evidence.

Magnesium sulfate has demonstrated sustained beneficial effects even at lower total doses in previous studies; however, current evidence remains insufficient to establish the minimum effective dose or the ideal administration regimen. There is a lack of comprehensive data on optimal maternal loading and maintenance doses necessary to maximize neonatal benefits while minimizing risks. Given the possibility that magnesium sulfate may exert both neuroprotective and potentially harmful effects on the fetus depending on dosage and exposure, further research in this area is essential (25). Furthermore, in our study, all patients who met the inclusion criteria between the specified study dates were included in the study and no power analysis was performed when determining the sample size. This is considered as a limitation of the study.

CONCLUSION

Our findings do not demonstrate a clear and definitive benefit of antenatal MgSO4 infusion in terms of hearing impairment in premature newborns. To reach a definitive conclusion regarding the use of MgSO4 as a neuroprotective intervention against hearing impairment in premature newborns, the results need to be supported by larger-scale, carefully designed studies.

Ethics Committee Approval: The study was approved by the local ethics committee (approval number: AEŞH-BADEK-2024-087).

Conflict of Interest: There is no evidence of any potential conflict of interest relevant to this article.

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