Original Article

Magnesium sulphate optimises surgical field without attenuation of the stapaedius reflex in paediatric cochlear implant surgery

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ABSTRACT

Background and Aims: The anaesthesia technique for paediatric cochlear implantation should be modified to achieve an optimised surgical field and allow neuromonitoring. Total intravenous anaesthesia (TIVA) provides good surgical condition without affecting intraoperative electrical stapaedial reflex threshold (ESRT). Though magnesium sulphate ($MgSO_4$) is a cheap, readily available drug for controlled hypotension, it can decrease the amplitude of motor-evoked potentials. This study aimed to evaluate the effect of $MgSO_4$ infusion on quality of surgical field, intraoperative ESRT, and anaesthetic requirements in paediatric cochlear implant surgery performed under TIVA. **Methods:** In this randomised controlled trial, 66 children (1-6 years) undergoing cochlear implant under TIVA were randomly assigned to control group or $MgSO_4$ group. The primary outcome was quality of surgical field, and the secondary outcomes were mean arterial blood pressure (MAP), heart rate (HR), ESRT, and the intraoperative anaesthetic requirements. The incidence of adverse events was recorded as well. **Results:** The quality of surgical field was better in group M than group C, $P < 0.02$. The number of children who achieved optimum surgical conditions (scores ≤2) was significantly better in the group M (n = 23/33, 70%) compared with group C (n = 13/33, 39%), $P < 0.001$. MAP, HR, and anaesthetic requirements were significantly lower in group M, $P < 0.05$. There were no differences between both groups regarding ESRT response. **Conclusion:** Magnesium sulphate IV infusion optimised surgical field and decreased anaesthetic requirements without attenuating the ESRT in paediatric cochlear implant surgery performed under TIVA.

Key words: Cochlear implant, ESRT TIVA, hypotensive anaesthesia, magnesium sulphate, paediatric anaesthesia, quality of surgical field

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INTRODUCTION

Cochlear implants have been one of the greatest advances for rehabilitation of patients with irreversible sensorineural hearing loss.[1] Challenges to anaesthesiologist during cochlear implantation includes: bloodless surgical field, limited use of muscle relaxants to facilitate neuromonitoring (facial nerve and ESRT) and avoidance of postoperative nausea, vomiting.[2] Total intravenous anaesthesia (TIVA) has been used in cochlear implantation as it does not suppress the ESRT.[3] TIVA also achieves better haemodynamic parameters during the operation, decreases emergence time of anaesthesia, and decreases postoperative complications such as nausea, vomiting, and vertigo.[2] A bloodless operative field is essential to facilitate microsurgery. A combination of physical techniques and controlled hypotension is used to minimise bleeding. Various drugs can achieve controlled hypotension such as high doses

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of inhalational anaesthetics, vasodilators, opioids, alpha--beta--adrenergic blockers, alpha-2 adrenergic agonist, and magnesium sulphate ($MgSO_4$).[2]

Magnesium is a non-competitive N-methyl-d-aspartate (NMDA) receptor antagonist and a calcium channel blocker.[4] It is a cheap, readily available drug, and has an anaesthetic, analgesic, vasodilator, and muscle relaxant effects.[4] $MgSO_4$ along with general anaesthesia can provide adequate controlled hypotension.[4] However, its combination with TIVA can decrease the amplitude of motor evoked potentials.[5] $MgSO_4$ has been used safely in various paediatric procedures.[6]

The aim of this study was to evaluate the effect of $MgSO_4$ infusion primarily on the quality of surgical field, and secondarily on the intraoperative measurement of the ESRT and anaesthetic requirements in paediatric cochlear implant surgery performed under TIVA.

METHODS

This prospective, randomised, double-blind study was carried out during the period from June 2014 to August 2018 after approval of the local research ethics committee (05/05/2014) and registered in clinical trials.gov: NCT03722940. Written informed consent was obtained from the parents of all children. The study included 66 children belonging to American Society of Anesthesiologists physical status I or II, aged 1–6 years, undergoing cochlear implant surgery under general anaesthesia. Children with history of uncontrolled hypertension, diabetes mellitus, liver disease, kidney disease, heart disease, allergy to $MgSO_4$, or situations in which operative difficulties are predicted such as syndromic hearing loss, congenital cochlear abnormality, auditory neuropathy, and intracochlear ossification were excluded from the study.

Children were randomised to one of two equal groups ([control (C) or magnesium (M)]. Each group included 33 children. Randomisation was done by an independent investigator using 66 opaque, sealed, sequentially numbered, envelops indicating the group of each child. The study drugs were prepared by anaesthesia technician as per the randomisation. Either magnesium or control (normal saline) was aspirated in covered, master coded 60 mL syringes.

Administration of the study drug and anaesthesia management was done by an independent anaesthesiologist who did not participate in the data recordings. All data recordings were performed by a trained staff, who was unaware of the group assignment. In addition, surgeon was blinded to the group assignment.

All children underwent preoperative assessment 1 week before the date of surgery. Complete blood picture, clotting time, and bleeding time were requested. A fasting of 6 h for solid, 4 h for breast milk, and 2 h for clear fluids was ordered. On the day of surgery, premedication consisted of oral midazolam 0.5 mg/kg, 45 min before the operation. An intravenous access was obtained using topical anaesthetic. The monitors used during anaesthesia included: electrocardiogram, noninvasive arterial pressure, heart rate (HR) pulse oximetry, end-tidal CO_2, temperature from oropharyngeal probe. On arrival at the operating room, HR and mean arterial pressure (MAP) and oxygen saturation (SpO_2) were recorded. A peripheral nerve stimulator was used at the adductor pollicis to monitor neuromuscular block. A bispectral index and facial nerve monitoring were used to assess the depth of anaesthesia and the integrity of the facial nerve, respectively.

Before induction of anaesthesia, children in group M received a IV bolus dose of magnesium sulphate (magnesium sulphate ampoule 1 gm/10 ml, Eipico, Egypt) 40 mg kg^{-1} over 5 min followed by 15 mg kg^{-1} h^{-1} IV until the start of skin closure as follows: magnesium sulphate 1000 mg was drawn up to 50 ml (each ml containing 20 mg magnesium sulphate). 2 ml kg^{-1} (40 mg kg^{-1}) were given over 5 min followed by 0.75 ml kg^{-1} h^{-1} (15 mg kg^{-1} h^{-1}) IV until the start of skin closure. Similarly, Children in group C received equivalent volumes of isotonic saline solution over the same period instead of magnesium sulphate. The study solutions were infused using an infusion pump (Fresenius Kabi®, Injectomat Agilia, Germany).

After preoxygenation using 100% oxygen for 2 min, anaesthesia was induced by IV fentanyl 1 μg Kg^{-1}, and propofol 1% 2.5 mg Kg^{-1}. Following loss of consciousness, cisatracurium 0.1 mg kg^{-1} IV was given and intubation was done when train of four count (TOF) was 0. No additional cisatracurium was given to allow intraoperative monitoring of the facial nerve and the ESRT. The lungs were mechanically ventilated (Drager Fabius@ Plus, Germany) to maintain an end tidal carbon dioxide tension at 30–35 mmHg.

Anaesthesia was maintained with oxygen/air mix (Fio_2 = 0.4). IV Propofol infusion 250 µg kg^{-1} min^{-1} was initiated; then it was titrated to maintain the bispectral index level between 40 and 50. This rate was changed by increments of 20 µg kg^{-1} min^{-1} if the BIS value went out of the targeted range for more than 15 s. Fentanyl 0.5 µg kg^{-1} IV bolus was given when BIS level remained within the targeted range while MAP and/or HR exceeded 20% of baseline values or with patient movement. Hypotension (MAP <50 mmHg) or bradycardia (HR <60 bpm) were treated with ephedrine 0.3 mg kg^{-1} or atropine 0.02 mg kg^{-1}, respectively. Ringer solution was continuously infused at rate of 5 ml kg^{-1} h^{-1} and normothermia was maintained by forced air warmer.

Five minutes before start of surgery, all patients received subcutaneous infiltration with 0.5 ml^{-1} kg^{-1} of NaCL 0.9%, containing adrenaline 1:200,000 along a 3 cm extended endaural incision with a 23 G hypodermic needle administered by the surgeon. The basic surgical technique consisted of a 3 cm extended endaural incision, cortical mastoidectomy, posterior tympanotomy, and round window cochleostomy. After drilling of the device seat in a tight periosteal pocket, all children were implanted unilaterally using MED-EL® SONATA Ti implant system with standard electrode.

At the start of surgical wound closure, propofol infusion was discontinued, and dexamethasone 0.2 mg kg^{-1} IV and paracetamol 15 mg kg^{-1} IV were administered as prophylaxis for postoperative vomiting and to provide postoperative analgesia, respectively. At the end of surgery, atropine 0.02 mg kg^{-1} IV and neostigmine 0.04 mg kg^{-1} IV were given for reversal of any residual muscle relaxant, and extubation was done after train of four was greater than or equal to 0.9 and the patient was awake. Then the patients were sent to the postanaesthesia care unit (PACU).

The primary outcome was quality of surgical field which was assessed by the surgeon at the end of surgery using Fromme's--Boezaart scale[7] [Table 1]. A score of less than or equal to 2 was considered to be optimal surgical condition.[8] Secondary outcomes were MAP and HR at baseline, 1 min after induction, 1 min after intubation, 1 min after surgical incision, then every 10 min until end of surgery, 1 min before extubation, 1 min after extubation, and at PACU admission. The ESRT responses were assessed by the surgeon after insertion of the electrode and after reversal of any residual muscle relaxant (TOF response >0.9), at the basal, middle, and apical areas of the electrode array by visual monitoring of the stapaedius muscle using direct microscopic examination.[9] In addition, intraoperative anaesthetic requirements and incidence of side effects such as hypoxia, hypotension, bradycardia, or any signs of hypermagnesemia (flushing, vomiting, hypotension, bradycardia, and somnolence) were also recorded.

Table 1: Quality of surgical field

Grade	Assessment
0	No bleeding, virtually bloodless area
1	Mild bleeding, not a surgical nuisance
2	Moderate bleeding, a surgical nuisance, but does not interfere with dissection
3	Moderate bleeding that moderately interfered with dissection
4	Heavy controllable bleeding but, significantly interfered with dissection
5	Heavy uncontrollable bleeding at the end of surgery.

The mean and standard deviation of the quality of surgical field score from a previous study were respectively 2.8 and 0.7.[10] A sample size of 30 patients per group was needed to detect the difference of 0.51 in the surgical field score, with a type 1 error of 5% and a power of 80%. A total sample size of 66 patients were included to allow for a dropout rate of 10%.

Data were analysed using SPSS 16.0 software. Variables were expressed as counts or as mean ± SD. The independent Student's *t*-test was used to analyse the mean differences (intraoperative anaesthetic requirement). The Mann–Whitney U test (MWU) was used to analyse the quality of surgical field. The Chi-square test (X^2 test) was used to analyse the categorical variables (ASA classification, gender). Repeated-measures ANOVA was used to analyse the MAP and HR over time between two groups. All tests were two tailed and *P* values of below 0.05 were considered significant.

RESULTS

We studied 66 children [Figure 1]. Patient demographic data and anaesthetic requirements in both groups are described in Table 2. There was no significant difference between the two groups as regards demographic data. However, fentanyl and propofol requirement were significantly lower in the magnesium (group M) in comparison to the control group (group C).

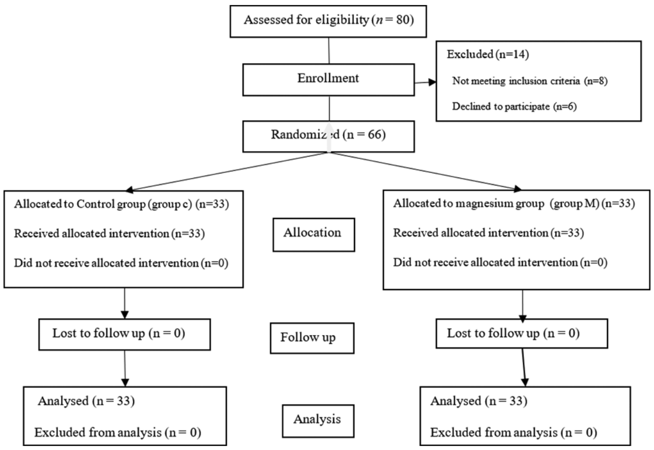

Figure 1: Flow chart in the study

The quality of surgical field was better in the magnesium group (group M) than the control group (group C) ($P < 0.02$) by MWU [Table 3]. The number of children who achieved optimum surgical conditions (scores less than or equal 2) was significantly better in magnesium group (group M) ($n = 23/33$, 70%) compared with the control group (group C) ($n = 13/33$, 39%), $P < 0.001$, Chi-square test (X^2 test). The MAP and HR are illustrated in Figures 2 and 3. Baseline MAP and HR were not significantly different between the two groups ($P > 0.05$). However, the MAP after induction of anaesthesia and thereafter, and the HR after intubation, after surgical incision, after extubation, and at PACU admission were significantly lower in the magnesium group ($P < 0.5$).

The ESRT had no significant difference between the two groups ($P > 0.05$) [Table 4]. Consistent ESRT could be obtained in all children in both groups. The thresholds ranged from 12.4 to 26 current units (CUs). There were no adverse events related to anaesthesia. No patient developed any signs of hypermagnesemia.

DISCUSSION

Our study found that magnesium sulphate IV infusion optimised surgical field and decreased anaesthetic requirements without attenuating the ESRT in paediatric cochlear implant surgery performed under TIVA.

Although a large number of studies have showed that magnesium sulphate could achieve controlled hypotension[11,12] and reduce anaesthetic requirements,[13,14] this study is the first to evaluate the effect of magnesium sulphate infusion in combination with TIVA in providing optimal surgical field during cochlear implant surgery in paediatric patients.

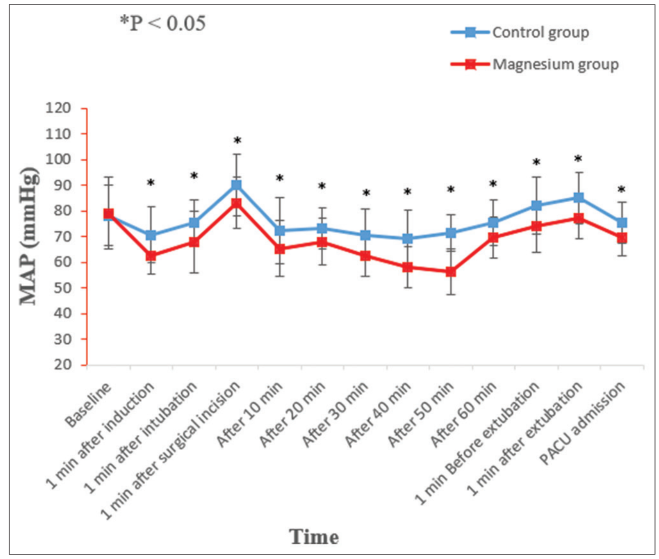

Figure 2: Mean (SD) of mean arterial blood pressure (MAP, mmHg) in both groups. M = Magnesium sulphate group; C = control group; PACU = postanaesthesia care unit

Table 2: Demographic data, and intraoperative anaesthetic requirements

Item	Group C Control (*n*=33)	Group M Magnesium (*n*=33)	*P*
Age in years	3.5 (1.9)	4.1 (1.6)	0.1
Weight in kg	18.5 (4.6)	19.4 (4.3)	0.4
Sex (Female/Male)	20/13	18/15	0.6
ASA classification (I/II)	30/3	28/5	0.8
Surgical time (min)	70 (12)	70 (8)	0.2
Anaesthesia time (min)	83 (14)	80 (13)	0.3
Fentanyl (μg kg^{-1})	1.55 (0.5)	0.96 (0.4)	0.0001*
Propofol (μg kg^{-1} min^{-1})	170 (48.3)	135 (45)	0.0052*

Numerical data are expressed as mean±SD. Categorical data as sex and ASA classification are expressed as numbers

Table 3: Quality of surgical field

Predefined scale	Group C Control (*n*=33)	Group M Magnesium (*n*=33)	*P*
0	1	4	<0.02*
1	5	8	
2	7	11	
3	20	10	
4	0	0	
5	0	0	

Data are expressed as numbers. *P*<0.05 considered significant. *Significant to control group

Table 4: ESRT in both groups

ESRT	Group C Control (*n*=33)	Group M Magnesium (*n*=33)	*P*
3 (apex)	16.4 (4)	17.5 (5.3)	0.368
9 (middle)	17.9 (10.6)	18.2 (5.5)	0.891
20 (base)	19.5 (6.5)	20.2 (5.2)	0.6468

Data are expressed as mean±SD. *P*<0.05 considered significant

In line with a previous study, which compared between remifentanil and magnesium sulphate in

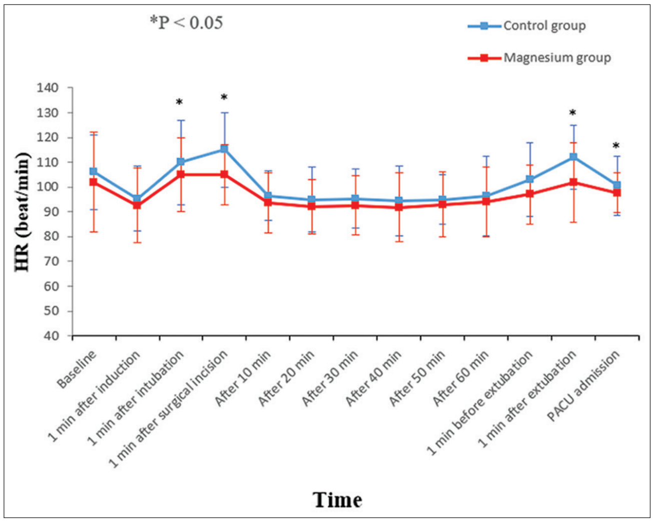

Figure 3: Mean (SD) of heart rate (HR, beat/min) in both groups. M = Magnesium sulphate group; C = control group; PACU, postanaesthesia care unit

patients undergoing middle ear surgery it was found that both drugs could produce deliberate hypotension, but magnesium sulphate was associated with less postoperative pain, postoperative nausea, vomiting, and shivering compared with remifentanil.[15] Similarly, one study examined the effects of magnesium sulphate on controlled hypotension in adults undergoing choroidal melanoma resection and concluded that magnesium sulphate could provide good surgical conditions with no need for adding potent hypotensive agents.[16] Another study compared between dexmedetomidine and magnesium sulphate in patients undergoing middle ear surgery and it was found that both drugs successfully induced controlled hypotension in adult patients undergoing middle ear surgery.[17] However, magnesium sulphate provided an additional benefit of shorter recovery time and earlier discharge from the PACU compared with dexmedetomidine.[17] This in contrast to a study comparing between dexmedetomidine and magnesium sulphate in children undergoing cochlear implant surgery under inhaled anaesthesia which found that dexmedetomidine provided a better quality of surgical field with no significant difference recovery time.[10] In our study, we have found that the number of children who achieved optimum surgical conditions (scores ≤2) was better in magnesium group compared with the control group. This is probably due to the combination of magnesium with TIVA providing better surgical field than combination with inhaled anaesthetics.

Magnesium sulphate is known to enhance the action of non-depolarising neuromuscular blocking agents[18-20] and can decrease the amplitude of motor evoked potentials.[5] In the present study, the intraoperative ESRT could be obtained in all children in both groups and was not attenuated by magnesium.

Unfortunately, the serum magnesium level was not checked. However, it is well recognised that the serum magnesium level does not represent total body magnesium content.[21] Arnold *et al*.[22] showed that the measurement of serum magnesium level does not predict its magnesium levels in other body tissues.

We have not assessed recovery time and postoperative analgesic requirements.

CONCLUSION

The combination of magnesium sulphate infusion with TIVA during paediatric cochlear implant could optimise surgical field by decreasing MAP and HR, reduce intraoperative anaesthetic requirements without affecting ESRT.

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Conflicts of interest

There are no conflicts of interest.

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