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Efficacy of Sulfate Magnesium on neurological improvement in patients with moderate and sever head trauma

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A B S T R A C T

The car accident is causes of 16000 deaths in a day. Central nerves system injury is one of the most important causes of morbidity and mortality. After head trauma neuron cell may be has dysfunction but the recovery is possible yet. This recovery needs to suit cares. This study attempts for confirmation of efficacy of Sulfate Magnesium in moderate and sever head trauma. This study is a pilot study and clinical trial in 201 until 2011. The patients divided to two groups. First; sever head trauma (GCS \leq 8), second; moderate head trauma ($8 \leq$ GCS \leq 12). Intervention group in both of groups was injected 250 micromole/kg sulfate magnesium besides definitive cares and witnessed group only have taken definitive cares. The study suggested in moderate and severe head trauma neurologic and radiologic outcome more acceptable in intervention group after injection sulfate magnesium.

Introduction

Accidents and injuries as major public health challenges of the new century. These injuries are always a significant cause of

death and its complications. The importance of these kinds of injuries increases with the progression of the technology. Accidents

and injuries accounts for the 205 of all disabilities (1). The importance of this topic is very significant in our country due to the high percent of the young and active population. Following to the accident, the injuries of the central nervous system is the main cause of the mortality and morbidity. The brain is at a high risk for injuries following the head traumas and this is the key factor of final outcome(2).

The activity of the neurons, glial cells and endothelial cells faces with impairment following to the focal injuries. But this injury can be reversed in favorable conditions; these cells can recover over time. However, if events such as hypotension, increased intracranial pressure and hypoxemia are leaved untreated these cells will be lost. In these patients, we can help the recovery of the damaged cells with maintaining the perfusion of the brain cells, controlling of the intracranial pressure and preventing the secondary traumas(3-4).

Although the improvement in the primary resuscitation and early diagnosis and surgery is at a fixed ration, but the improvement in the primary health cares improved the outcome significantly (5-6). Now, control of the CBF (cerebral blood flow) and metabolism in prevention and treatment of ischemia associated with pharmacological neuroprotective treatments get the best hope for improving the outcome of these patients (7).

Since the trauma is the most common cause of the mortality in patients under the 45 years and the brain injuries is the most important predictor of the outcome in traumatic patients. So any activity which can improve the brain activity can increase the quality of life in these kinds of patients (3-4).

Nowadays most of the researches is about the molecular and biochemical mechanisms of neural responses to the trauma and the cell recovery, findings of these researches have made the neurosurgeons to believe that the post traumatic first levels is vital and the success of upcoming treatments are related to adequate care at this phase. Excitatory receptors and their activity following the trauma and their role in cell death is of the related study topics (8-9)

It is now proven that the severe stimulation of these receptors following the trauma can facilitate the cell death so the inactive cells in viable situation developed to death. The stimulation of these receptors can start some mechanisms that lead to cell death. If we can prevent or block their stimulation, the cell death rate can be decreased significantly and increase the possibility of the recovery.

Magnesium can prevent the cell death and increase the cell recovery. This issue is now proven in animal studies and its accuracy is under experience in human beings. Since the traumatic patients is one of the major problems of health care system in our country, like all other countries-and with regard to statistical reports which shows the Iran on top of the countries with traffic accidents mortalities in 2006, the importance of studies related to 1st, second and third degree of prevention is understood. With regard to the number of attending patients in Emam Reza Hospitals, we conducted the present study and the results are as below.

Methods and Materials

In a clinical trial study in Emergency Department of Tabriz University of Medical Sciences on patients with $GCS \leq 12$, we evaluated the efficacy of Magnesium sulfate on prognosis of patients.

We randomly enrolled all the patients with $GCS \leq 12$ who referred to emergency department in the first 12 hours of the trauma. The patients with brain death and patients who did not refer for further follows were excluded from the study. Patients was divided into two groups with severe head trauma and mild head trauma ($GCS < 8$ and $9 < GCS < 12$ respectively). Forty patients were studied in every group and 50% of patients underwent Magnesium sulfate administration 250 micro mol/kg.

Patients was examined primarily in emergency department and the in neurosurgery ward. The examiner physician was blinded for patients groups.

From the point of ethical considerations, it was not possible to get consent from the patients because of low GCS levels of patients, and since most patients was attended to emergency department solely or with no identification documents. Based on the data of previous studies, this dose of Magnesium sulfate is completely safe which means this dose of Mg Sulfate produces 1.8 micromole/liter serum levels, while the toxicity of Mg sulfate is produced in 2-4 micromole/Liter doses which causes paresthesia and nausea.

The injection is slow and once, so there no risk for the patients and consents was cancelled.

Problems and Limitations: Reducing the number of cases in follow up period was of the major problems.

Statistical Analysis

The collected data were analyzed by SPSS-17 statistical software. The collected data were expressed as percentage and mean \pm SD. Continuous (quantitative) variables were compared by Independent samples and

Paired t test. Categorical (qualitative) variables were compared by contingency tables and Chi-square test or Fisher's exact test. P-value ≤ 0.05 was considered statistically significant.

Result and Discussion

Evaluation of age and sex in patients of two groups was shown in table I. Improvement of at least 2 points in GCS time and Normalized neurological symptoms in patients of two groups were shown in table II. Radiological state of patients in two groups was shown in table III. Normalized Radiological states in patients of two groups were shown in table IV. Hospitalize duration in patients of two groups were shown in table V.

From the point of age distribution, most of the patients were in the range of 15 years to 50 years(65 %) which is matched with the age distribution in other studies, The head trauma was significantly higher in male patients(75 % male compared 25 % female). The indicator of recovery was the minimum 2 points of increase in GCS and the recovery was better and faster in patients receiving Magnesium sulfate ($P=0.037$).

In patients who underwent the administration of magnesium sulfate, the mean time of neurologic sings normalization in the first day and third day was significantly faster than patients in control group($P=0.005$ and $P=0.007$ respectively), after the day 3 there is no significant difference in two groups.

Therefore, we can conclude that the time required for normalization in case group is significantly lower compared to the time required for normalization of the symptoms in control group, but the conclusion will be more complete with more case numbers.

Table.I Evaluation of age and sex in patients of two groups

| | | Case Group | | Control Group | |
|-----|------------|------------|---------|---------------|---------|
| | | Moderate | Sever | Moderate | Sever |
| Age | <15 year | 3(15%) | 4(20%) | 3(15%) | 2(10%) |
| | 15-50 year | 13(65%) | 12(60%) | 13(65%) | 14(70%) |
| | > 50 year | 4(20%) | 4(20%) | 4(20%) | 4(20%) |
| Sex | Male | 13(65%) | 15(75%) | 16(80%) | 16(80%) |
| | Female | 7(35%) | 5(25%) | 4(20%) | 4(20%) |

Table.II Improvement of at least 2 points in GCS time and Normalized neurological symptoms in patients of two groups

| | | Case Group | | Control Group | | P |
|-----------------------------------------|---------------|------------|---------|---------------|---------|-------|
| | | Moderate | Sever | Moderate | Sever | |
| Improvement of at least 2 points in GCS | 1 day later | 19(95%) | 15(75%) | 14(70%) | 1(5%) | 0.037 |
| | 3 days later | 1(5%) | 5(25%) | 6(30%) | 6(30%) | |
| | 7 day later | 0(0%) | 0(0%) | 0(0%) | 3(15%) | |
| | 1 month later | 0(0%) | 0(0%) | 0(0%) | 0(0%) | |
| | Not improved | 0(0%) | 0(0%) | 0(0%) | 10(50%) | |
| Normalized neurological symptoms | 1 day later | 6(30%) | 0(0%) | 0(0%) | 0(0%) | 0.007 |
| | 3 days later | 13(65%) | 1(5%) | 10(50%) | 0(0%) | |
| | 7 day later | 1(5%) | 8(40%) | 9(45%) | 2(10%) | |
| | 1 month later | 0(0%) | 7(35%) | 0(0%) | 5(25%) | |
| | Death | 0(0%) | 4(20%) | 1(5%) | 13(65%) | |

Table.3 Radiological state of patients in two groups

| | Case Group | | | | Control Group | | | | P |
|-----------|-------------|---------------|-------------|---------------|---------------|---------------|-------------|---------------|--------|
| | Moderate | | Sever | | Moderate | | Sever | | |
| | 7 day later | 1 month later | 7 day later | 1 month later | 7 day later | 1 month later | 7 day later | 1 month later | |
| Grade I | 16(80%) | 20(100%) | 1(5%) | 5(25%) | 5(25%) | 12(60%) | 0(0%) | 1(5%) | P<0.05 |
| Grade II | 4(20%) | 0(0%) | 8(40%) | 7(35%) | 13(65%) | 7(35%) | 1(5%) | 3(15%) | |
| Grade III | 0(0%) | 0(0%) | 3(15%) | 4(20%) | 2(10%) | 0(0%) | 3(15%) | 3(15%) | |
| Grade IV | 0(0%) | 0(0%) | 8(40%) | 0(0%) | 0(0%) | 0(0%) | 16(80%) | 0(0%) | |
| Death | 0(0%) | 0(0%) | 0(0%) | 4(20%) | 0(0%) | 1(5%) | 0(0%) | 13(65%) | |

Table.4 Normalized Radiological states in patients of two groups

| | Case Group | | Control Group | | P |
|---------------|------------|--------|---------------|--------|--------|
| | Moderate | Sever | Moderate | Sever | |
| 1 day later | 0(0%) | 0(0%) | 0(0%) | 0(0%) | P<0.05 |
| 3 days later | 3(15%) | 0(0%) | 0(0%) | 0(0%) | |
| 5 day later | 11(55%) | 1(5%) | 6(30%) | 0(0%) | |
| 7 day later | 6(30%) | 9(45%) | 14(70%) | 2(10%) | |
| 1 month later | 0(0%) | 6(30%) | 0(0%) | 5(25%) | |

Table.5 Hospitalize duration in patients of two groups

| | Case Group | | Control Group | | P |
|-----------|------------|--------|---------------|--------|------|
| | Moderate | Sever | Moderate | Sever | |
| 0-7 day | 15(75%) | 0(0%) | 11(55%) | 0(0%) | 0.07 |
| 8-14 day | 5(25%) | 3(15%) | 6(30%) | 3(15%) | |
| 15-21 day | 0(0%) | 6(30%) | 3(15%) | 6(30%) | |
| 22-28 day | 0(0%) | 3(15%) | 0(0%) | 3(15%) | |
| > 30 day | 0(0%) | 4(20%) | 0(0%) | 4(20%) | |

In patients with head trauma, the time of first neurologic recovery in the group receiving magnesium sulfate was significantly lower than the control group; this time was also significant in 1st, 3rd, 7th and 30th days after the trauma. The fast recovery time of neurologic signs can show the positive effect of magnesium sulfate in these patients.

In the patients of case group, we observed the recovery of at least 2 GCSs but in the control group, 505 of patients did not show any recovery.

The comparison of two groups from the point of symptoms normalization was not different in 1st and 3rd days but the symptoms normalization was faster in 7th and 30th the days in case groups (P=0.033 and P=0.010 respectively).

In patients with severe head trauma, the mortality rate was significantly lower in Magnesium sulfate group (P=0.010).

The radiologic improvement rate after 1 day was significantly higher in magnesium sulfate group, 9 patients had radiologic improvement in case group while there were no cases of radiologic improvement in control group, this difference was

statistically meaningful (P=0.0024) which indicates that Magnesium sulfate had improved the radiologic findings in 2 days of trauma.

In patients with mild trauma, the radiologic improvement was significantly higher in Magnesium sulfate group until the day 5 (P=0.026) this rate was equal in two groups in the upcoming days. This also indicates that Magnesium sulfate administration can cause the radiologic improvement to be faster while the neurologic effects improvement was faster than the radiologic effects.

Radiologic normalization in two groups was not assessable until the day 5 but it was significantly higher in the magnesium sulfate group from the 7th day which shows that the radiologic improvement was better and more comparing to control group, This improvement is later in mild trauma group and can be due to the severity of the trauma which more time is needed for complete improvement.

There was no significant difference in the outcome in mild head trauma patients, but the recovery was functionally faster in magnesium sulfate group.

In patients with severe head traumas, the outcome in 7th day was statistically better in Mg sulfate group (P=0.010) and Mg sulfate could improve the final recovery in the 7th day, the outcome was also better in the 30 the day in the Mg sulfate group significantly (P=0.023).

The mean time of hospitalization was 5.38 ±1.82 days in case group comparing with 7.92 ± 2.32 days in control group, the difference between two group in hospitalization days was not significant(P=0.070). However, in the patients with severe head traumas, the mean time of hospitalization was significantly lower in Magnesium sulfate group. A motor vehicle accident was the major cause of head traumas in our study.

Conclusion

In the patients with mild head trauma, the radiologic and neurologic recovery was faster in intervention group comparing to control group but this few number of cases could not prove the improvement in hospitalization and outcome. However, the rate of recovery was significant and requires more studies. In the patients with severe head traumas, the MG sulfate administration can significantly cause the neurologic and radiologic recovery. Hospitalization period and outcome was better comparing to control group. Mg sulfate could reduce the mortality significantly in the intervention group. The cases was also few to generalize the results. So it is recommended to conduct other trials with more number of cases. However, it can be concluded that inject able Magnesium sulfate can improve the recovery time and outcome in patients with severe head trauma in the first 12 hours of trauma and reduce the mortality rate; this agent can make the recovery process faster in mild head traumatic patients.

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