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Comparison of Chloral Hydrate and Hydroxyzine in Pediatric Electroencephalogram Recording; Sedation Successes and changes in Vital Signs

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Abstract: During electroencephalogram (EEG) recording of children, sedatives are frequently needed. It's reported that Chloral hydrate (CH) and Hydroxyzine (H) have negligible negative effect on EEG and are safe. The effect of CH and H on vital signs has not been studied in detail previously. We compared the sedation success, side effects, and effects on vital signs of CH and H during pediatric EEG recording. A total of 60 children with a mean age of 43.3±33 months (CH) and 39.7±29 months (H) were involved in the study. Oral CH (50 mg/kg) was given to thirty children, and oral H (1 mg/kg) to another 30. Vital signs were recorded during the procedure. Sedation success of CH (96.6%) was higher than H (76.6%) (p=0.023). Mean Ramsay Sedation Score (RSS) of CH (4.8±0.7) was higher than H (3.5±1.6) (p=0.00). The mean procedure time in CH group was significantly longer (p=0.000). The CH significantly reduced the mean systolic and diastolic blood pressure compared to H (p=0.007, p=0.003, respectively). SO_2 of a patient from CH group decreased to 87%, and vomiting (6.6%) and agitation (3.3%) were observed in two patients. Our findings indicate that CH, due to it's higher success rate, can be preferred in children who need sedation for EEG. However, in patients who have limited time, H with a shorter total procedure time can be preferred. More comprehensive studies are required about the effects of decreased blood pressure on systems, caused by CH. © 2021 NTMS.

Keywords: Child, Chloral Hydrate, Electroencephalogram, Hydroxyzine, Sedation.

1. Introduction

Electroencephalogram (EEG) is an auxiliary method used to detect abnormal electrical activities in the brain or to diagnose epilepsy.

In order to make the abnormality prominent during standard EEG, provocation methods such as hyperventilation and photic stimulation are applied (1).

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Another provocation method is sleep EEG (1-3). It is generally required to administer sedative agents to children who cannot be put to sleep or are unable to communicate in order to reduce anxiety and muscle movements for EEG (2-6).

Chloral hydrate (CH) and hydroxyzine (H) have been used for a long time in short-term sedation procedures, and current publications indicate that they have a negligible effect on EEG and are relatively safe at recommended doses (3-7). Although there are studies about the effects of sedation successes of CH and H on vital signs and side effects in EEG recording (3-8), in most of these studies there is no information about the detailed monitoring results of vital signs during sedation.

In this study, we aimed to compare the adequacy of the sedation level provided by these two drugs in children during EEG recording, their side effects, and especially their effects on vital signs.

2. Material and Methods

Pediatric patients who underwent EEG at Atatürk University, Faculty of Medicine, Department of Pediatrics between April and May 2008 were included in the prospective study. Informed consent was obtained from the families of the patients. Patients in whom an optimal recording could not be obtained due to incompatibility, and who could not sleep spontaneously after 20 minutes of waiting time for sleep EEG were included in the study. Patients who could be communicated with were ensured to defecate before sedation. Attention was paid to ensure that patients had at least four-hour fasting and vigil periods before sedation.

The medical requirements recommended by the American Society of Anesthesiologists (ASA) and the American Academy of Pediatrics (AAP) are established before sedation (9, 10). Patients with a history of drug allergy, signs of diseases in that sedation is contraindicated, and signs of obstruction in the upper respiratory tracts were excluded. The patients were taken to the quiet and dark sedation room near by the EEG room with their mothers, and were waited to sleep spontaneously. ASA class-I-II patients (9), who could not sleep spontaneously within 20 minutes (min) were sedated.

Body temperature was measured by the axillary method with a digital thermometer. Vital signs (blood pressure, heart rate, respiratory rate, and oxygen saturation) were continuously followed via a monitor (NIHON KOHDEN BSM-2301 K, Tokyo, Japan). The values measured while the patient was calm before sedation were recorded as basal values. The patients were grouped as Seizure, Seizure (Neuromotor developmental retardation is present), other causes (acute encephalopathy, ataxia, speech disorder, etc.). The chloral hydrate (CH) and hydroxyzine (H) group was formed from similarly diagnosed patient groups (Table 1).

During the study, we administered CH to approximately half of the patients whom we decided to include in the study and H to the remaining half in daily program. The study was terminated when the number of patients in each group reached 30. A 50 mg/kg CH was administered orally by dissolving it in 2-3 cc juice. It was re-administered with a dose of 25 mg/kg to patients who were not sedated within one hour after the first administration. H, in suspension form, was administered orally at a dose of 1 mg/kg. It was re-administered to patients who were not sedated within one hour at a dose of 1 mg/kg. If sedation could not be achieved within one hour after the second dose for both drugs, the sedation procedure was deemed to be unsuccessful.

The sedated patients were taken to the EEG recording table were monitorised. Electroencephalogram recordings were performed with the same device in all patients (NIHON KOHDEN-Neurofaks, Tokyo, Japan). During the recording, vital signs of all patients were monitored, and data were recorded every 10 minutes. Non-sedated patients were monitored for 20-90 minutes to observe the side effects of the drugs. While evaluating the data, the following definitions were used.

Transition time to sedation (sleep): The time from drug administration until the patient closes his eyes and becomes irrelevant to the environment. Sedation time: The time until he wakes up spontaneously after sleeping. Successful sedation: Providing sedation at a level that allows successful electroencephalogram recording. Prolonged sedation: A situation in which the patient does not wake up after two hours have passed since the beginning of sedation. Procedure time: Time from drug administration to discharge. Minimal hypoxia: Oxygen saturation between 90-95%. Desaturation: Oxygen saturation below 90%. Hypothermia: Body temperature of <36 C^{o}. Bradycardia: Heart rate below the average values for age. Tachycardia: Heart rate above the average values for age. Hypotension: Systolic blood pressure values below 50 percentile (p) for age and gender or systolic blood pressure at least 20 mmHg reduction. Diastolic blood pressure at least 10 mmHg reduction. Hypertension: Systolic or diastolic blood pressure values above 90p for age and gender (11-14). The sedation level achieved was rated with the sedation score determined according to Ramsey Sedation Scoring (RSS) (15).

Patients who could not be sedated with hydroxyzine were scheduled for another day to achieve sedation by CH administration.

Patients who underwent EEG recording were waited to wake up spontaneously. Patients who were crying after waking up or having their eyes open for 30 seconds and continued to be interested in the environment were

considered to be awakened. Patients with sedation longer than two hours were awakened by tactile stimulation. Patients were discharged when the discharge criteria of AAP were met.

2.1.Statistical Analysis

"Statistical Package for the Social Science" (SPSS) 17.0 Windows statistical package program was used for statistical analysis. Numerical values showing normal distribution were given as Mean±Standard Deviation and categorical data as numbers and percentages. The student's t-test was used for comparison of numerical values, and the Chi-square test was used in comparison of the frequencies. P<0.05 was considered as the statistical significance level.

3. Results

A total of 60 patients were included in the study with an age range of 6 months to 12 years. 30 patients received CH, and 30 patients received H. Statistical analysis showed that the groups were comparible in terms of the gender distribution, age, body weight and averages of vital signs measured before medication (body temperature, heart rate, systolic blood pressure, diastolic blood pressure, oxygen saturation and respiratory rate) p>0.05 (Table 2).

Drug applications for sedation in both groups are given in Figure 1. In the first sedation attempt, sufficient sedation was achieved in 96.6% of CH group, and in 76.6% of H group. Seven patients who could not be sedated with H were given CH on another scheduled day (second attempt), and successful sedation was achieved.

An 8-month-old male patient with cerebral palsy+metabolic disease +epilepsy could not be sedated in the CH group (3.3%). Neuromotor developmental retardation was present in 4 of seven patients (23%) who were given H and could not be sedated (Table 1). The comparison of groups in terms of sedation data and side effects in the first sedation attempt is given in (Table 3). Minimal hypoxia was observed in 53% of the CH group and 30% of the H group. The SO_2 (blood oxygen saturation level) of one patient who was given CH decreased to 87%. Although the sedation success rate of CH was significantly higher when compared to H, the frequency of side effects was statistically higher (p = 0.023 and P=0.03, respectively) (Table 3). During sedation, the body temperature of 20% of the CH group (6/30) and 16.6% of the H group (5/30) remained between 35-36ºC for short times. When groups were compared, mean body temperature, heart rate, and respiratory rate were statistically similar in repeated measurements during sedation (p>0.05).

The mean decrease in SO2 was significantly higher in CH group when compared to H group (%3.0±2, %1.6±1.5, respectively) (p=0.046) (Table 3). Systolic and diastolic blood pressure decreased in 33% (10/30) of the patients in the CH group and 23% (7/30) of the patients in the H group. However, Diastolic blood pressure decreased in 30% (9/30) of patients in the CH group and in 16% (5/30) of patients in the H group. Chloral hydrate significantly reduced mean systolic and diastolic blood pressures when compared to H (p=0.007, p=0.003) (Table 3). However, compared to H, CH significantly reduced mean diastolic blood pressure, especially at 60 and 80 minutes (p=0.023). The mean Ramsey Sedation Score (RSS) was significantly higher in the CH group than in the H group (4.8±0.7, 3.5±1.6, respectively) (p<0.001).

Table 1: Patients' diagnosis and final sedation successes of CH and H**.**

Patients' diagnoses	CH	H	P Value
Seizure	17	15	
Successful	17	12	0.09
Failed	0	3	
Seizure (Neuromotor developmental retardation is present)	9	9	
Successful	8	5	0.09
Failed	1	4	
Other causes (acute encephalopathy, ataxia, speech disorder, etc.)	4	6	
Successful	4	6	-
Failed	0	0	

Abbreviations: CH, Chloral hydrate; H, Hydroxyzine, p<0.05 represents a statistically significant difference**.**

4. Discussion

It is generally required to administer sedative agents to children for EEG recording. Some patients do not sleep, and in some muscle movements and anxiety disrupts the recording (2-6). Faytrouny M. et al (8) stated that it is complicated to compare the clinical results with different drugs used in sedation procedures due to the use of different methodologies and criteria.

The sedation success of the CH and H in EEG recording is reported between 70-93% (40-100mg/kg) and 83-89.6% (1-2 mg/kg), respectively, and varies according to dose of the drug, ASA classes of patients, and patient profile (4-8). In present study, the sedation success of CH was 96%, and it was significantly higher than that of H (76.6%) (p=0.023). Although the sedation success rate obtained with H was lower, it was close to the reported rates in the literature. While three of the four patients were sedated with repeated CH administration, no sedation was achieved in any of the seven patients with repeated H administration. Successful sedation was achieved in all patients when CH was administered on another scheduled day to the patients who could not be sedated with H. These data show that CH is more effective in terms of sedation success (Figure 1).

Some studies have reported that the drugs have low sedation success in patients with neuromotor developmental retardation (5-6). The data obtained in present study indicate that although difference was not significant, the sedation success of H is lower in

patients with neuromotor developmental retardation (Table 1).

In the literature, it has been reported that the transition time to sedation in imaging procedures is between 16.2-30 minutes for CH and 23.7-34.6 minutes for H. (3,7,16,17). In our study, the mean transition time to sedation was 19.8±12.4 minutes for CH and was consistent with the literature, and it was 14.6±13.4 minutes for H and was shorter than the literature.

For CH and H, the sedation time has been reported in the range of 20-88 min and 30-85 min, respectively (3, 5, 7, 18). In present literature, it is difficult to comment on the actual sedation time of both drugs, since there is insufficient information about whether patients are immediately awakened by anesthesiologist or waited to wake up spontaneously. In our study, patients whose sedation time was extended to two hours (CH:11/30, H:2/30) were accepted as prolonged sedation and were awakened with tactile stimulation at the end of the second hour. Therefore, the maximum sedation time was two hours. So, the mean sedation time provided by CH was (93±30 minutes) significantly longer than the average sedation time provided by H (45.3±42 minutes) ($p<0.0001$).

The consciousness levels of the patients during the sedation process are determined through scales such as Ramsay Sedation Score (RSS) (15, 19). Fallah R et al. (5) reported the mean RSS as 4.53±1.63 of the patients sedated with CH (40 mg/kg) in EEG recording. To our knowledge, there is no study investigating any sedation score in pediatric patients who received H. In our study, the mean RSS in CH group was 4.8±0.7, and it was significantly higher than the H group (3.5±1.6) ($p<0.001$). The value found for CH was consistent with the literature.

Studies have reported that there may be a transition from planned sedation level to a higher sedation level in the sedation procedures of children (16, 20, 21). In our study, all patients remained at the level of minimal-moderate sedation, and a severe and more advanced sedation was not observed. This result was considered to be associated with the inclusion of patients with ASA class-I-II. The mean total procedure time in CH group was (132±39 min) statistically longer than the mean total procedure time of the H group (74±52 min) ($p<0.0001$). This feature of H may be preferred for sedation in patients who has limited time for outpatient evaluation.

The American Academy of Pediatrics (AAP) recommends recording the heart rate, respiratory rate, blood pressure, and oxygen saturation of pediatric patients who were given drugs for sedation at least every 5 minutes. However, they also reported that the patient's blood pressure could be observed with an interval of 10-15 minutes; if the patient is well balanced, O_2 saturation is good, and peripheral circulation is healthy (9, 22). In our study, while heart rate and oxygen saturation were continuously monitored, other vital signs were recorded every 10 minutes since no significant deterioration was observed. Although the ASA classes of the patients have not been specified in most studies comparing CH and H in EEG recordings (3, 6, 7), it was stated that patients with ASA class-I-II are eligible candidates for minimal and moderate sedation (9, 22). In our study, absence of any significant hemodynamic impairment and side effect support the opinion that ASA Class-I-II patients are suitable candidates for mild-moderate sedation.

Table 2: Demographic data of the groups and the mean of basal vital values measured before medication.

	CH	***H***	***P Value***
Gender			
Female N (%)	15 (25)	15 (25)	p>0.05
Male N (%)	15 (25)	15 (25)	p>0.05
	Mean±SD	**Mean±SD**	
Bodyweight (kg)	14.0±5.2	13.7±5.5	p>0.05
Age (months)	43.3±33	39.7±29	P>0.05
Body temperature (^oC)	36.7±0.29	36.6±0.29	p>0.05
Heart rate (pulse/min)	115.8±13.2	117.3±15.6	p>0.05
Systolic blood pressure (mmHg)	105.6±10.1	102.1±14.1	p>0.05
Diastolic blood pressure (mmHg)	62.5±11.3	54.7±12	p>0.05
O_2 saturation (%)	96.4±1.1	96.3±1.0	p>0.05
Respiratory rate (min)	20.6±2.8	21.8±4.5	p>0.05

Abbreviations: CH, Chloral hydrate; H, Hydroxyzine; SD, Standard deviation, $p<0.05$ represents a statistically significant difference.

Table 3: Comparison of the groups in terms of sedation data and side effects

	CH(N=30)		*H(N=30)*		*P Value*
Sedation Data	**Mean±SD**		**Mean±SD**		
Transition time to sedation (min)	19.8±12.4		14.6±13.4		0.127
Sedation time (min)	93.0±30		45.3±42		0.000
Ramsey Sedation Scoring (RSS)	4.8±0.7		3.5±1.6		0.000
Reduction in body temperature (%)	1.5±1.1		1.2±10		0.214
Reduction in respiratory rate (%)	12±40		10±5.9		0.318
SO_2 reduction (%)	3.0±20		1.6±1.5		0.046
Reduction in heart rate (%)	14±8		13±7		0.706
Reduction in systolic blood pressure (%)	14.0±70		8.9±8.2		0.007
Reduction in diastolic blood pressure (%)	24±23		17±11		0.003
Total time of the procedure (min)	132±39		74±52		0.000
	N	**%**	**N**	**%**	**P Value**
Sedation success (%)	29	96.6	23	76.6	0.023
Side effects					
Prolonged sedation (n)	11	36	6	20	0.03
Vomiting (n)	2	6.6	-	-	
Agitation (n)	1	3.3	-	-	
Those with saturation <90 (n)	1	3.3	-	-	

Abbreviations: CH, Chloral hydrate; H, Hydroxyzine**;** SD, Standard deviation, p<0.05 represents a statistically significant difference.

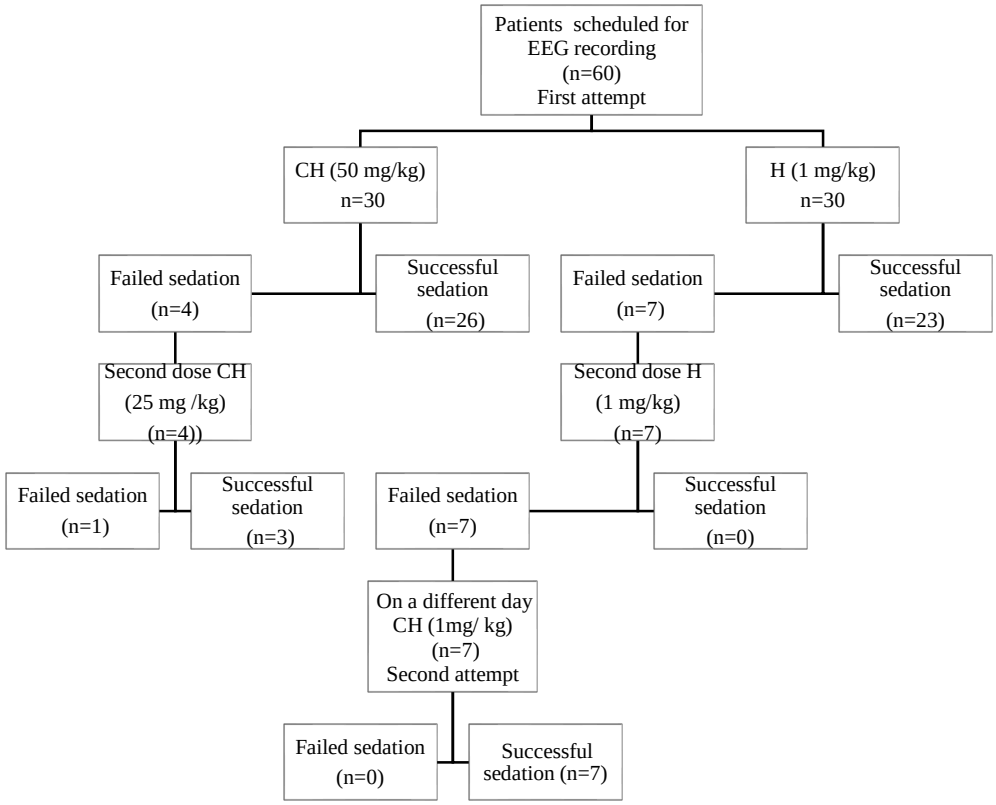

Figure 1: Flow chart of sedation success with CH and H. CH, Chloral hydrate; H, Hydroxyzine.

In ASA class-I-II children, during imaging procedures, Magnetic resonance imaging (MRI), Computerized tomography (CT), Echocardiography (ECO), Electroencephalogram (EEG), etc.), the side effects reported for CH (50-100 mg/kg) are mild hypoxia (4-9%), moderate to severe hypoxia (0.5%), prolonged

sedation (3-3.3%), vomiting (0.4-4%), agitation (0.5-6%), apnea (0.03%), laryngospasm (1.4%), hypercarbia (6.6%), and hypotension (0.4%). They were irritable behavior (4.2%) and nausea-vomiting (2.8%) for H (1-2 mg/kg) (3, 17, 23, 24). A mean reduction of 3±2% was observed in oxygen saturation in the CH group and 1.6±1.5% in the H group (p=0.046). However, in 53% (16/30) of CH group and 30% (9/30) of H group SO_2 ranged between 90-95% (minimal hypoxia) for short episodes. Oxygen saturation of these patients returned to normal spontaneously without any intervention. The SO_2 of one patient who was given CH decreased to 87%. The patient's head was brought to extension, and oxygen was delivered with a mask, and the saturation increased within 4-5 minutes. The minimal hypoxia rates determined in our study were higher than those given in the literature. The SO_2 value was measured as 95% before recording in 5/30 patients in the H group and 7/30 patients in the CH group. This low initiation value may have made it easier for patients to fall below 95%.

An average reduction of 1.5±1.1% in the body temperature was detected in the CH group, and 1.2±1% in the H group (p>0.05). During sedation, there were times when the body temperature of 20% of the patients in the CH group (6/30) and 16.6% of the patients in the H group (5/30) remained between 35-36 ºC. This decrease in body temperature may be related to the temperature of the environment or the decrease in the body temperature of the sedated patients. There was no information in the literature that both drugs cause hypothermia.

In a study performed by Heistein LC. et al. (17) 1092 pediatric patients were given CH for sedation before echocardiography, and it was found that the heart rates of the sedated patients decreased at an average of 14±10%, and their blood pressures decreased at an average of 23±13%. It was also pointed out that the changes caused by sedative drugs in heart rate and blood pressure were similar to changes occurring during sleep.

In this study, an average of 14±7% decrease in systolic blood pressure and an average of 24±23% decrease in diastolic blood pressure were detected in the CH group, while an average of 8.9±8.2% decrease in systolic blood pressure and an average of 17±11% decrease in diastolic blood pressure were detected in the H group. The CH significantly reduced the mean systolic and diastolic blood pressure compared to H (P=0.007, p=0.003).

Systolic and diastolic blood pressures decreased of 33% (10/30) of patients in the CH group and 23% (7/30) of patients in the H group. However, diastolic blood pressures decreased of 30% (9/30) of the patients in the CH group and 16% (5/30) of the patients in the H group. These decreases, which did not cause clinical findings and were normalized during follow-ups, were not intervened. Also, compared to H, CH significantly reduced diastolic blood pressure, especially at 60th and 80^{th} minutes (p=0.023).

In a study performed on healthy pediatric patients, Soergel et al. (25) found a 13.6±6% reduction in systolic blood pressure and a 23±9% reduction in diastolic blood pressure during sleep at night, and suggested using pediatric reference values separately to assess blood pressure while awake and asleep. In our study, a mean reduction of 14±8% in the CH group and 13±7% in the H group were found in heart rate. None of the patients developed bradycardia. The heart rate and blood pressure reduction percentages of the patients who were administered CH and H during the sedation were compatible with the literature. These reductions may either be the result of the drugs or sedation itself.

In addition, nausea, vomiting, and irritable behaviors were observed in a small patient group, and no severe reactions were encountered (3, 7, 23, 26). In our study, no severe side effects were seen, and no intervention was required for both drugs.

It was reported that both drugs were safe with similar side effects when the following conditions suggested by the AAP (9, 22) were established in the sedation applications of pediatric patients; the patients with hypoxia risk should be excluded before the procedure, the sedation process should be managed by appropriately trained personnel, and appropriate doses of CH and H should be used.

Fong CY et al. analyzed 13 studies comparing CH administration with other sedative drugs and music therapy in children who were undergoing CNS imaging and EEG recording. They stated that in the analyzed studies, only a few of them had given information about operation success, additional sedative agent requirements, and the level of sedation determined through reliable and valid scales. They also highlight the need for further studies on the adverse effects of CH (27). In our study, the effectiveness of CH and H and their effects on vital signs were investigated more comprehensively. In addition, our study contributes to the literature in order to overcome the shortcomings mentioned above.

5. Conclusions

Our study results indicate that CH, which has high sedation success in EEG recording in pediatric patients, can be preferred primarily. However, in patients with limited time for EEG recording, H may be preferred because of the significantly shorter total procedure time. The mean Ramsey Sedation Score (RSS) was significantly higher in the CH group than in the H group. During EEG recordings of patients with neuromotor developmental retardation, CH may be preferred for sedation. More comprehensive studies are required about the effects of CH blood pressure-lowering effect on human body systems.

Main points of the article

*It is generally required to administer sedative agents to children who cannot be put to sleep or are unable to communicate in order to reduce anxiety and muscle movements for EEG. Chloral hydrate (CH) and
*Hydroxyzine (H) have been used as sedative agents in many EEG centers for a long time.
*The effect of CH and H on vital signs has not been studied in detail previously.
*Our study results indicate that CH, which has high sedation success in EEG recording in pediatric patients, can be preferred primarily.
*The CH significantly reduced the mean diastolic blood pressure compared to H
*The mean Ramsey Sedation Score (RSS) was significantly higher in the CH group than in the H group. Therefore during EEG recordings of patients *with neuromotor developmental retardation, CH may be preferred for sedation.

Restrictions of the study

The relatively low number of patients, medications not to be given in different doses, absence of control group is the restriction of our study.

Ethics Committee Approval

The Ethics Committee's approval of the Atatürk University Faculty of Medicine is obtained for the study. (Decision number 25 of 07.12.2007 dated meeting no. 6).

Informed Consent

Informed Consent from Family

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Conflict of Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Author Contributions

Concept-M.A.G., HT.; Design-M.A.G., M.G., H.T.; Supervision-H.T.; Data Collection and/or Processing-M.A.G; Analysis and/or Interpretation - M.A.G., M.G., H.T; Literature Search-M.A.G., M.G; Writing Manuscript-M.A.G., M.G., H.T.; Critical Review-M.A.G., M.G., H.T.

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