



Research Article

CLOBAZAM AS INTERMITTENT PROPHYLAXIS IN TYPICAL FEBRILE SEIZURES AND THEIR ANEMIC STATUS

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ABSTRACT

Febrile seizures are the age specific seizures associated with a temperature of 38.0° c or higher, unprovoked by central nervous system (CNS) infection, trauma, or metabolic abnormality. The emergence of febrile seizures was most commonly seen in 3-4% of children under the age of 5 years and most cases occur between 5 months to 5 years of age with peak age of 18 months. Therefore good control over febrile seizures is important among these age groups. This was a descriptive cross sectional observational study which was designed to evaluate the effectiveness of Clobazam as intermittent prophylaxis in preventing the recurrence of febrile seizures and role of patient counselling in improving the anemic status and medication adherence of the subjects. The study concluded that recurrence of febrile seizures was 7.31% which was less in patients who received Clobazam therapy and was more, which was 72.35% in those on alternative treatment (not on clobazam therapy). The mean Haemoglobin status before and after counselling was 7.98±1.35gms and 8.5±1.25gms respectively with a p value (0.001) which was statistically significant. The mean medication adherence before and after counselling was 3.7±1.6 and 4.5±1.50 respectively with p value of (0.001) and was statistically significant.

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INTRODUCTION

Febrile seizure is defined as age - specific seizures associated with a temperature of 38.0° c or higher, unprovoked by central nervous system (CNS) infection, trauma, or metabolic abnormality^[1]. The National Institute of Health(1980) defined febrile seizure as: an event occurring in infancy or childhood, usually between 3 months and 5 years of age, associated with fever but without evidence of intracranial infection or defined cause^[2].

Classification

Febrile seizure is further classified into either simple or complex^[5]. Simple FS is defined as generalized, lasting less than 15 minutes, comprised of generalized tonic and clonic activity without a focal component, and without recurrence within 24 hours or within the same febrile illness.

Complex or complicated FS is defined as exhibiting one or more of the following features: (1) partial onset or focal features; (2) prolonged duration of more than 15 minutes; (3) recurrent febrile seizure within 24 hours of the first episode; and (4) association with postictal neurological abnormalities, as exemplified by Todd paresis^[5].

Aetiology

Extensive genetic studies have demonstrated that various loci are responsible for familial FS. Viral infections (such as measles or other viruses) and ambient temperature are also the causes.

Provoking factors

These mainly include Genetics, Intrauterine risk factors, Vaccination [Vaccinations associated with increased risk include seasonal influenza trivalent inactivated vaccine (Fluvax Junior and Fluvax); diphtheria and tetanus toxoids and whole-cell pertussis (DTP); and measles, mumps, and rubella (MMR), Metabolic abnormalities and deficiencies.

Risk factors

The risk of recurrent febrile seizures is higher for children who have age (less than 15 months), frequent fevers, a parent or sibling who had febrile seizures or epilepsy, have a short time between the onset of fever and the seizure and had a low degree of fever before their seizure

Treatment

Intermittent therapy includes oral diazepam 0.33mg/kg, oral clobazam at doses of 5, 7.5, 10 mg once or twice daily based on body weight. Antipyretics may also be considered as treatment for fever reduction. There are strong evidences that intermittent use of oral or rectal diazepam is effective in

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preventing the seizures in a febrile episode. It is recommended to use oral diazepam in a dose of 0.33 mg/kg/dose every 8 hours from the onset of a febrile illness. But potential side effects of diazepam in such a high dose (i.e. sedation and ataxia) should be considered. There are some studies indicating that intermittent clobazam could be as effective as diazepam in preventing the seizures in a febrile illness, but ataxia is less prominent than with diazepam.

MATERIALS AND METHODS

Aim and objectives

To determine the efficacy of Clobazam as intermittent prophylaxis in typical febrile seizures.

- To observe incidence of febrile seizures in Pediatric department from October to March 2018.
- To assess the cause of fever in subjects with febrile seizures.
- To identify the risk factors in subjects with febrile seizures.
- To assess the anemic status in the subjects and evaluating the reason for being anemic by using Kuppuswamy scale.
- To determine history of worm infestations in anemia patients with febrile seizures.
- To determine the adverse effects with clobazam
- To assess the medication adherence status of subjects with febrile seizures

Study design: Descriptive Cross sectional Observational Study.

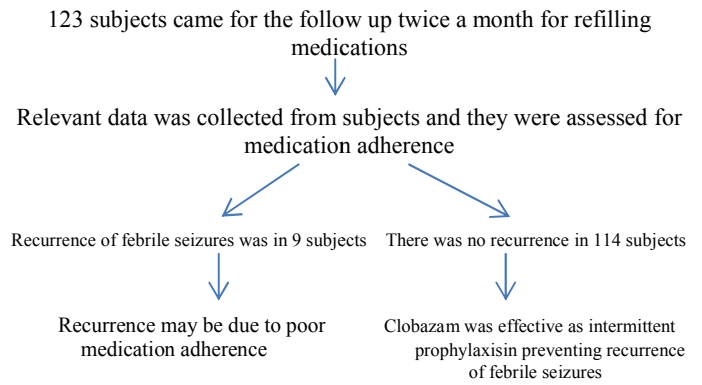
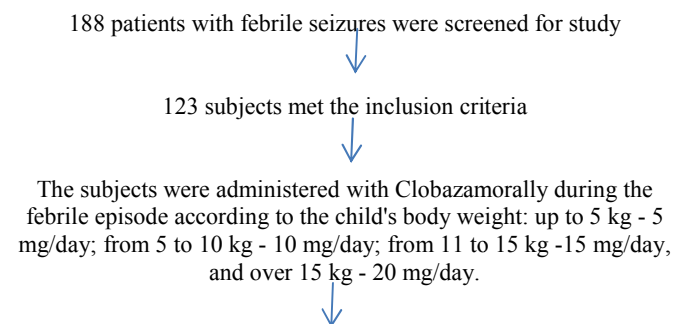
Study period: The study was conducted for a period of 6 months from October 2017 to March 2018.

Inclusion criteria: All males and females subjects above 6 months of age to 5 years who are admitted in paediatric ward and patients diagnosed with Typical febrile seizures which are new or known cases.

Exclusion criteria: Subjects below 6 months of age and above 5 years, Patients diagnosed with seizures of other nature with neurological abnormalities, progressive neurological diseases, seizures due to CNS infections and patients who are not willing to participate and give informed consent form.

Materials: Patient consent form, Patient data collection form, Patient information leaflets, Kuppuswamy scale, Morisky Medication adherence form.

Methodology: The study was conducted in Government General Hospital, Guntur, a 1187 bedded tertiary care teaching hospital.



Data analysis: The obtained data was entered in advanced microsoft excel spread sheet and evaluated. Descriptive analysis had been represented in the form of graphs. The obtained data was analyzed by using statistical tests-paired t test and correlation. Results were tabulated and analysed by using SPSS version 11.0.3.

RESULTS

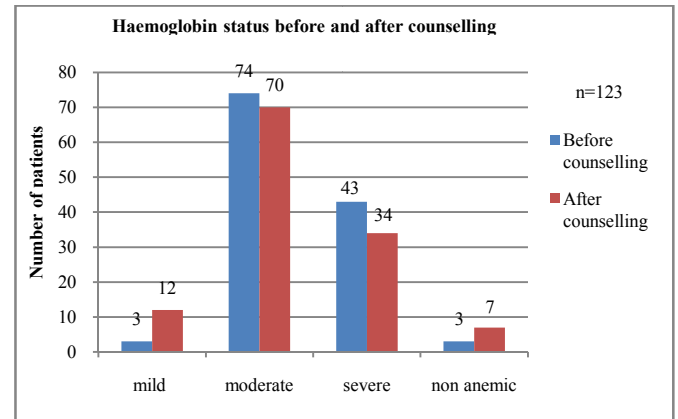


Fig 1 Haemoglobin status in subjects

Out of the total subjects involved n=123, the Mean haemoglobin status before counselling was 7.982 and after counselling was 8.537gms respectively which was analysed using paired T test. The p value was found to be 0.001 which was statistically significant.

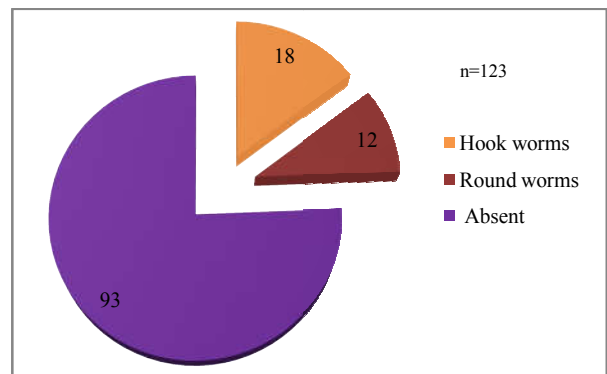


Fig 2 Worm infestations in the subjects:

The most commonly observed worm infestations were hook worms where n=18(14.63%) followed by round worms where n=12(9.75%) respectively.

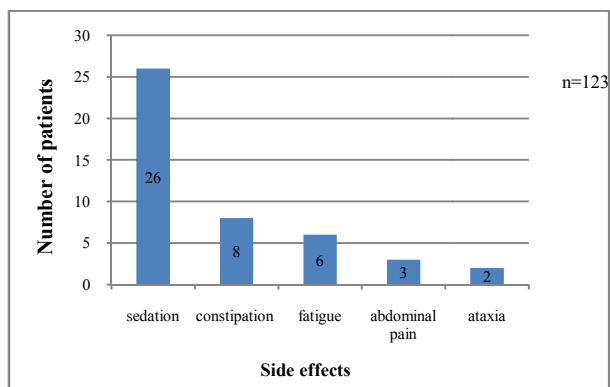


Fig 3 Adverse effects in the subjects

The most commonly observed side effect was Sedation n=26 (21.12%) followed by constipation, fatigue, abdominal pain and ataxia where n= 8 (6.50%), n= 6 (4.87%), n=3 (4.23%), n=2 (1.62%) respectively.

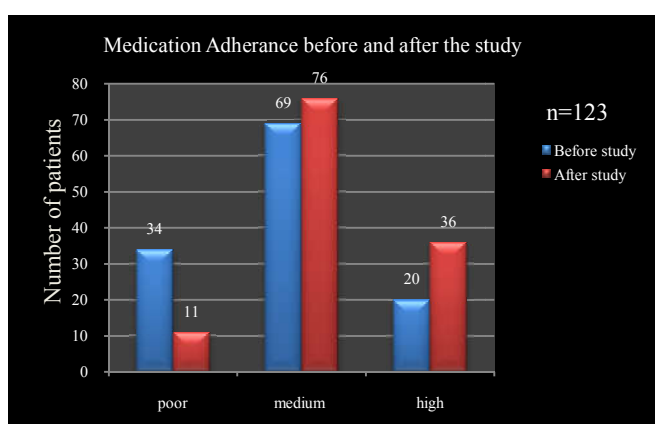


Fig 4 Medication Adherence in subjects

Medication Adherence from one subject to other subject varies before study and after study. This was analyzed using paired T test. Mean medication adherence before study was 3.788 and after study was 4.5203. By analyzing data using paired t test there was a significant improvement in medication adherence after counselling.

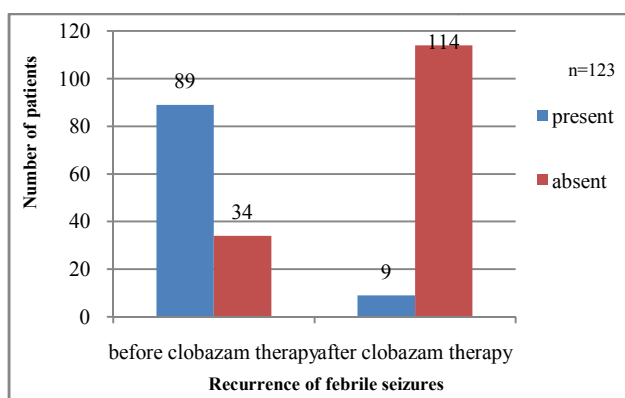


Fig 5 Recurrence of febrile seizures in subjects

The recurrence of febrile seizures was less in patients who received Clobazam therapy treatment where n=9 (7.31%) and was more in those patients who received alternative therapy (before Clobazam therapy) where n=89 (72.35%).

DISCUSSION

A descriptive cross sectional observational study on “To determine the efficacy of Clobazam as intermittent prophylaxis

in febrile seizures and their anemic status” was conducted in pediatrics population in the age group of 6 months to 5 years in tertiary care hospital for a duration of 6 months. During the study period the data was collected tabulated & analysed. On reviewing the demographic data age and gender has a major impact on incidence of febrile seizures. It was observed that the presence of febrile seizures in children aged 3-4 years was greater n=50(40.65%) and it was more in males n=66(53.6%) than in females n=57(46.3%). With respect to body weight, most of the children were found to be underweight. . On reviewing the incidence data, it was found that incidence of febrile seizures was more in the month of December n=30 (6.50%). The major cause for fever among children was found to be due to Upper respiratory tract infection(URTI) where n=72(58%) followed by malaria n=7(6%). Out of the total subjects involved 62 subjects were found to have positive family history with 1stdegree relativity n=37(30.08%) and 2nd degree relativity n=25(20.32%). Anaemia was present in n=116(94.3%) which was a major risk factor observed in the subjects and the reason for being anaemic may be due to presence of worm infestations i.e., Hook worms was n=18, round worms was n=12 and the socioeconomic status was assessed using Kuppusswamy scale where the majority of the people are from lower class i.e., lower middle class n=58(47.15%), upper lower class (16.26%) and lower class n=8 (6.5%). The mean Haemoglobin status before and after counselling was 7.98±1.35gms and 8.5±1.25gms respectively with a p value (0.001) which was statistically significant. The major risk factor was anaemia where n=116(94.3%) followed by family history n=62(50.4%), age < 15 months n=17(13.82%), and consanguinity n=11(8.94%).Here both family history and age were said to be positively correlated with a p value (0.001) which was statistically significant and family history with consanguinity was said to have positive correlation with a p value of (0.003) which shows statistically significance. Safety and effectiveness of Clobazam were determined by assessing the adverse drug reactions and parameter like recurrence. The most commonly observed side effects were Sedation n=26 (21.12%) followed by constipation n= 8 (6.50%), fatigue n= 6 (4.87%), abdominal pain n=3 (4.23%), and ataxia n=2 (1.62%). These ADRs are not so life threatening. The recurrence of febrile seizures was less in patients who received Clobazam therapy where n=9 (7.31%) and was more in those patients who received alternative therapy (other than Clobazam therapy) where n=89 (72.35%). Recurrence was observed in 9 subjects even after receiving Clobazam, this may be due to poor medication adherence. The mean medication adherence before and after counselling was 3.7±1.6 and 4.5±1.50 respectively with p value of (0.001) and was statistically significant. Medication Adherence status of the subjects was improved by counseling them in each visit and it was found to be improved after counselling.

CONCLUSION

Finally, from this study we concluded that Clobazam was effective as intermittent prophylaxis in preventing the recurrence of febrile seizures and clinical pharmacist plays a significant role in improving the anaemic status through providing counselling through diet charts and patient information leaflets and also in improving the medication adherence of the subjects through regular counselling at each follow up visit.

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