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Original Research Article

REFERRAL AND PRESCRIPTION PRACTICES AT A PEDIATRIC NEUROLOGY CLINIC IN A TERTIARY CARE HOSPITAL; A STUDY FROM WESTERN INDIA

Santosh Kondekar[1], Unmesh Dev M[2], Surbhi P Rathi[3], Prasoon Bansal[4]

[1]*Associate Professor, Department of Paediatrics, TNMC and BYL Nair Charitable Hospital, Mumbai, India.*
[2]*Senior Resident, Department of Paediatrics, TNMC and BY LNair Charitable Hospital, Mumbai, India.*
[3]*Professor and Head, Department of Paediatrics, TNMC and BYL Nair Charitable Hospital, Mumbai, India.*
[4]*Assistant Professor, Department of Paediatrics TNMC and BYL Nair Charitable Hospital, Mumbai, India.*

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Corresponding Author:
Dr. Unmesh Dev M,
Senior Resident, Department of Paediatrics, TNMC And BYLNair Charitable Hospital, Mumbai, India.
Email:drkondekar@gmail.com

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ABSTRACT

Background: The literature tries to entail the practical difficulties encountered both by clinicians and patients in routine OPD practices. Objectives: To study patterns of referrals (e.g. OT, PT, AST, Ophthalmology, Radiology, etc) and drug prescription practices in patients attending Pediatric neurology OPD in under 12 years.

Materials and Methods: Children presenting to Pediatric neurology clinic and finishing first 3 months of follow up were enrolled in the study. Data of 118 cases enrolled over 6 months. A descriptive analytical study was planned.

Results: Out of 118 cases were enrolled, with a mean age of 6.8 years. Almost every case was referred for at least one evaluation of some or other services. 63.55% were referred for neuroimaging, all the referred children underwent the test within 3 months. The percentages of cases that could not get the benefit of referral services within 3 months of reference were 32.4%, 30.7%, 26.6% respectively for ST, OT, PT. 3 groups of drugs were mainly prescribed - Antiepileptics, neuropsychiatric medicines & Nutrition supplements. 70.76% cases were on monotherapy with antiepileptic drug, along with nutritional supplements. 19 cases were on polytherapy with 2 or 3 antiepileptics. Only 25% of names were in generics. On an average each patient was prescribed 4 medicines.

Conclusion: Delay upto 4-8 weeks is common in getting subspeciality referrals completed which may be minimized by dedicating coordinating teams.

Keywords: Reform is needed in neurology OPD practices by clubbing of services bat least few times a month so that unnecessary delay can be avoided.

INTRODUCTION

Pediatric neurological issues frequently require a comprehensive team approach to evaluate and manage patients, both routinely and in urgent situations. In a specialized pediatric neurology clinic, ensuring adequate staffing and resources is essential to ensuring timely intervention and care for every child. According to the World Health Organization's definition, drug utilization research encompasses the entire process of drug marketing, distribution, prescription, and usage within society, with a particular focus on understanding the medical, social, and economic impacts, ultimately aiming to assess rationality1.

The objective of this study is to examine the logistical support provided by other disciplines in terms of personnel, time, and resources for handling pediatric neurology cases at our institution, particularly in managing the current influx of referrals from the pediatric neurology clinic.

These support or referral systems primarily include neuroimaging (CT/MRI) and EEG services, genetic/metabolic testing, multidisciplinary services such as occupational therapy, speech therapy, physical therapy, vision and hearing assessments, referrals to neurosurgery and pediatric surgery, and

additional consultations with professionals such as dieticians, psychiatrists, and orthopedic surgeons as required.It's expected that these referrals will be likely in most of the cases. An objective of this study was to predict human resource and infrastructure needed at referral facilities in accordance with the workload avoiding a waiting list that will result in delays in evaluation, cure and outcome of potential disabilities. It was also predicted that lack of insight or knowledge and increasing work load at the pediatric neurology clinics may make the clinicians get delayed evaluations or interventions from referred services and make them see patients in hurry and being carried away by clinical diagnosis or pharmacotherapeutics, whereas holistic development of the child through multidisciplinary therapies may stay neglected.

A large number of chronic pediatric neurological disorders are likely to be tried with many different molecules in varying dosages; at times deviating from guidelines. Most such molecules may have potential side effects and also there may not be enough studies, research for use of same in pediatric age groups. Also, the form of medicine may not have been devised for pediatric use. These dosages, forms, combinations, repurposing and cocktail preparations in some cases has a potential to make a treatment or prescription irrational.

MATERIALS AND METHODS

The study commenced after obtaining approval from the institution's ethics committee. It was a prospective cross-sectional study conducted at a pediatric neurology clinic in Mumbai, Western India. Children aged 0-12 years presenting to the pediatric neurology outpatient department and who had completed at least 3 months since their first visit to the center were enrolled after obtaining appropriate written informed consent from their guardian or assent from the child, as applicable.

Data collection took place over a 6-month period from March 2019 to August 2019, and a total of 118 cases were enrolled. Information on demographics, disease morbidity, referrals, treatments, and provisional diagnoses was gathered solely from the patient's medical records. Prescription drug details were compared against the guidelines outlined in the National Formulary of India (NFI) 2016 (New Delhi: Indian Pharmacopoeia) and the British National Formulary (BNF) 73rd Edition, March-September 2017 (London: BMJ and Pharmaceutical Press) for indications, dosages, frequencies, and formulations. Off-label prescriptions were identified and evaluated separately based on the guidelines from BNF and NFI. Reasons for off-label use were documented along with relevant comments.

Microsoft Excel was used for data management and presentation of demographic information, while statistical analysis, including Student's t-test where applicable, was employed to analyze the use of monotherapy versus polytherapy, referral practices in children with and without developmental delays, and the use of drugs versus drugs and nutrients across different age groups and developmental stages.

RESULTS

A total of 118 cases were enrolled. Males (n=72) were 1.6 times more than females (n=46). Youngest case enrolled was a 5-month-old case of hypo-calcaemic seizure. The oldest case was a 12-year-old GBS. Mean age was 6.8 years. Median age was 5.3 years. The disease profile of the patients is as shown in Figure 1.

Prescribed Referrals

Almost every case was referred for at least one evaluation of some or other services in the institute. A total of 63.55% that is a total of 75 references were for neuroimaging. That was the maximum number of references to a single service facility. And almost all the referred children underwent the test within 3 months. Fifty-two new cases (43.91%) were referred to Occupational Therapy (OT) but only 36 children had their first session in 3 months. Amongst the 30 cases referred for Physical therapy (PT) only 22 could get first assessment done within 3 months. The percentages of cases that could not get the benefit of referral services within 3 months of reference were 32.4%, 30.7%, 26.6% respectively for Speech therapy, occupational therapy, physical therapy. There were 3 cases referred to neurology department that too only for Nerve Conduction Velocity and 4 ADHD cases were referred to psychiatry for Child Guidance and Counselling services.

Prescription practices

There were mainly 3 groups of drugs prescribed-Antiepileptics, neuropsychiatric medicines & Nutrition supplements (table 1). Amongst 65 cases of seizures (n=65) Monotherapy with antiepileptic drug was noted in total of 46 cases [70.76%] that included 12 cases with carbamazepine, 9 cases with phenytoin and 11 cases with valproate, 6 cases with phenobarbitone and 8 cases with levetiracetam. The choice of drug was decided as per clinical semiology for new cases and in 35 cases [76.08%] out of these 46 cases on anticonvulsants monotherapy, the previous antiepileptic was not changed. The remaining 19 cases [29.23%, n=65], had received more than one anticonvulsant. Thus 70.76% cases were on monotherapy with antiepileptic drug, along with nutritional supplements. Nineteen cases of seizure disorder were on polytherapy with 2 or three antiepileptics, primarily valproic acid or levetiracetam being added as first add on and clobazam as second add on in refractory seizures. Amongst them one was a case of Lennox-Gastaut Syndrome. The West syndrome was treated with valproate and levetiracetam. There was no

documentation of reason for polytherapy. Only 25% of names were in generics.

In total 118 cases, every case was issued a prescription. Total 475 medicines were prescribed including nutrients. On an average each patient was prescribed 4 medicines.

Table 1: Showing the nutritional supplements and pharmacotherapy prescribed in study subjects. [Table 1]

Table 1: Nutritional supplements and Pharmacotherapy prescribed

Nutritional supplement	No of cases (n)	Anti-convulsant therapy (ACT) drugs	No of cases (n)
Calcium and Vitamin D3	109 (92.37%)	Phenytoin	9
Vitamin B2	6 (5%)	Phenobarbitone	6
Iron	56 (47.4%)	Levetiracetam	22 (8 as monotherapy)
Folate	56 (47.4%)	Carbamazepine	12
Multivitamin	109 (92.37%)	Valproate	16 (11 as monotherapy)
Carnisure	5 (4.2%)	Clobazam	5
Omega 3	3 (2.5%)	ACT polytherapy	19 (29.232%S)
Total	344	ACT monotherapy	45 (70.76%)

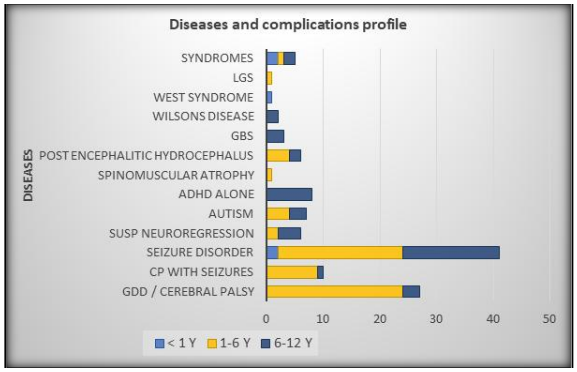

Figure 1: Diseases and complications profile

Figure 1: Shows the disease profile of the patients enrolled. (LGS – Lennox-Gastaut Syndrome, GBS-Guillain-Barre syndrome, ADHD – attention deficit hyperactivity disorder, CP - Cerebral Palsy, GDD – Global developmental delay).

DISCUSSION

Examining prescription audits is essential for monitoring, evaluating, and recommending changes to the prescribing practices of medical professionals in order to enhance care quality according to established standards. However, no studies have yet been conducted to audit referral practices.

Off-label use refers to administering pharmaceutical drugs for unapproved indications, age groups, dosages, or routes of administration not specified by regulatory agencies. While not illegal unless it breaches safety or ethical guidelines,[2] off-label use often occurs when standard therapies are ineffective or options are limited.[3]Frequent off-label use can lead to clinical trials and potential regulatory approval, enhancing drug reliability in terms of safety and efficacy.

A recent Spanish survey highlighted that off-label drugs are predominantly used in oncology, neurology, rheumatology, nephrology, and hematology.[4]A 2001 study showed that over 50% of anticonvulsant prescriptions from office-based physicians were off-label, while a 2004 study found that about 47% of prescriptions from a U.S. headache unit were for off-label uses. This suggests that off-label drug use is a well-established and routine part of neurological practice.[5,6]

The British National Formulary (BNF) reported a 44% off-label use rate compared to 20% in the National Formulary of India (NFI).[7]A similar study in China found off-label drug use at 34.7%. 3.According to BNF and NFI data, the proportion of prescriptions containing at least one off-label drug was 32% and 30%, respectively. In the NFI, the most common off-label issues were related to "Indication" (32%), followed by "Frequency" (32%) and "Dose" (19%), reflecting the ongoing exploration of new uses for drugs in neurology.[3,8]

In our study, no significant correlation between cost and off-label drug prescriptions was observed. Of the 317 off-label drugs recorded in the BNF, 84 were categorized as unlicensed, meaning there are no licensed alternatives available or the drug is used beyond the terms of its regulatory approval.The most common off-label drugs identified were piracetam, cobalamin, and clonazepam. Off-label use should be backed by scientific evidence, and such data should be shared with regulatory authorities for safer drug utilization. Prescription auditing was not the focus of this study.

We did not wish to see the legibility and accuracy or writing rules of prescription. The aim of the study was to see only prescription practices [load] and referral practices [load], so that we can estimate capacities of ancillary services including pharmacy and other human resources needed in referral system. Previous studies about drug utilisation in a hospital was conducted with sample size of 150 in a multi- speciality hospital in Gujrat by Nilay D Solanki et al in 2015. They pointed that hospital committee of drug procurement need to be more vigilant9.A study from Dhaka, studied 1684 cases over a year in 2014-2015 as a pilot prescription audit.[6]

The sample size of 118 cases from our study was dominant with boys accounting for 61.01% cases compared to girls. Most children (57.62%) were from age group 1 to 6 years. A total of 55 children presented with developmental delay; of these 7 were

autism, 6 had lost the previously attained milestones, this all attributed to high possibility of referrals to various therapies.Seizure cases 63.5% warranted neuroimaging and EEG. The 3 months buffering period was considered to study the duration required for referral services. Despite this, a significant number of children could not get the specific evaluation done or therapy started. Those who were referred for speech therapy appointments only 67.6% of cases could get the therapy started in 3 months; in contrast OT and PT assessments were done in 69.3% and 73.4% cases respectively. Mean duration to get the first assessment done with OT PT and ST were 41, 21 and 72 days respectively from the date of referral.So, on an average in 30 % cases, early intervention could not be initiated in 100 days due to logistic issues.

Exceptionally, in all the kids who were advised EEG,CT Brain or MRI Brain, these tests were done to a great extent with in the 3 months period with mean duration to get these tests done being 58 days. MRI brain took the maximum time to get it done, and the mean time for MRI was 82 days. Fastest referrals that were attended were by NCV department.

The reasons for some referral or evaluations being not attended to in a specific time may be different, like say from the prerequisites for the appointment procedures, ease of taking the appointment, distance of the referral service centre from the OPD clinic and felt seriousness of a specific referral or test by the parent depending on their individual perception and cost involved in same. In fact, the therapy needs to start even before the diagnostics.

Calcium and vitamin D supplements were prescribing in 92.37% subjects. Monotherapy for epilepsy was a common practice as seen in 70.76% cases. 29.23% cases had more one ACT prescribed. Drugs like Piracetam, Trihexyphenidyl were used off-label.

Probable reasons for off-label neuropsychiatric drugs in children are plenty; mainly due to lack of evidence in pediatric population. So many drugs may be used as extrapolation from its use in adults.

Limitations

1. Novel study on referral practices
2. Small sample size
3. Lack of data on rationality of medicines
4. Nonavailability of comparable study or criteria

CONCLUSION

This is first such study to audit referral practices. Frequent referral audits may be helpful to learn the discrepancies in manpower of referring and referred department. Delay up to 4 to 8 weeks is common in getting assessed from the date of referral to different specialities. This may be affected by various factors like ease of getting appointment, cost of the same and whether it is done with a machine or without. Referral delays can be minimised by dedicated coordinating team, which will help parents get early referral dates and may be by having the representative of referral department in the clinic itself.

About prescription audit, it's noted that nutritional supplementation to each child following to neurology OPD is common irrespective of the diagnosis. Polypharmacy in children being treated in neurology OPD is common even with unusual nutrients are prescribed. Off label prescription may be more common in pediatric neurology clinic.

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