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Empowerment of primary health care in an Outreach resource-limited district in Punjab: A strategy for improving adherence to Antiepileptic drug treatment in children with Epilepsy.

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EMPOWERMENT OF PRIMARY HEALTH CARE IN AN OUTREACH RESOURCE-LIMITED DISTRICT IN PUNJAB: A STRATEGY FOR IMPROVING ADHERENCE TO ANTIEPILEPTIC DRUG TREATMENT IN CHILDREN WITH EPILEPSY.

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ABSTRACT:

Introduction: There is wide acknowledgement of the need for community involvement in the optimal management of children with epilepsy (CWE) in outreach financially constrained districts of the developing countries, but there is scarce data on comprehensive community-based childhood epilepsy treatment programs assessment.

OBJECTIVES: The objective of this study is to weigh impact of local primary care empowerment upon anti-epileptic drugs (AEDs) adherence assessed by self-reporting method in an outreach financially constrained district: Bhakhar in Pakistan.

Methods: During this snap-shot study, 240 children with epilepsy aged 4months to 18years, on treatment with AED(s) at least 3 months prior to the camp dates, were selected for data collection. Of the total, 160 were being managed in the empowered private charity primary health care while 80 had the first contact and were taken as control. The three parts of the data were: 1) demography of the study population 2) AEDs adherence profile assessed by the "Morisky Medication Adherence Scale-8" (MMAS-8) and 3) usefulness of multimodal strategy of the "Community Childhood Epilepsy Center" (CCEC) on antiepileptic drug adherence. Ethical approvals were attained from the institutional ethics committee.

RESULTS: Age ranged from 04 months - 18 yrs with female to male ratio of 1: 1.26. AED(s) self-report adherence was 85% (in 2014 it was 42% without support and intervention) amongst the patients treated at community childhood epilepsy center with the provision of free consultations and AEDs, whereas adherence was 40% amongst the patients not intervened by the community center: without any gender preference in either group. Unaffordability of childhood epilepsy treatment cost was the most important cause of non-adherence to AEDs among the study population.

CONCLUSION: Marked improvement in AEDs adherence (85% VS 40%) was documented after empowering the local community with the help of visiting the consultant pediatric neurologists from the cosmopolitan city to an outreach resource-constrained district in Pakistan.

INTRODUCTION

Epilepsy is amongst the most frequent neurological disorders prevalent in the children. More than 50% of epileptic seizures among adults have their onset in the paediatric age group^[1]. This disease is estimated to be affecting 50 million people worldwide with higher prevalence and incidence among those populations living in Low and Middle-income countries (LMICs)^[2, 3]. The management of the epilepsy is complex as it

involves avoidance of precipitating factors and suppression of recurrent seizure by prophylactic therapy with antiepileptic drugs (AEDs). The term 'adherence' outlines the degree to which an individual takes the drugs as suggested with respect to medicine quantity and medicine dosing intervals^[4]. Adherence to medication is the backbone to the effectiveness of therapy for epilepsy. Unfortunately, the adherence to anti-epileptic drugs among patients diagnosed as epilepsy is sub-optimal, more prevalent among the

residents of resource-limited communities^[5,6]. Adherence to AEDs among adult epilepsy patients usually varies from 40% to 60% and for children with epilepsy; it varies from 25% to 75%^[7]. It is frequently disputed that the non-availability of AEDs is the most significant hurdle to the care of patients with epilepsy^[8]. Non-adherence in kids with epilepsy presents a continuous challenge of achieving a key satisfying objective of no seizures. No interventional strategy associated with improvement to AEDs adherence among paediatric population has been evaluated in Pakistan. In agreement, in 2014 we documented AEDs nonadherence up to 58% among children with epilepsy, no services for childhood epilepsy in Bhakhar city and started multimodal intervention strategy to improve AEDs adherence among epileptic children living in Bhakhar district^[9]. Hence the current study intended to assess the effectiveness of childhood epilepsy integrated into primary health care in outreach financially-constrained district and providing free, regular uninterrupted supply of AEDs, monthly free childhood epilepsy consultations and interventional camps to improve AEDs adherence among children with epilepsy.

MATERIALS AND METHODS

This community based prospective interventional cross-sectional study was conducted by the Top-Down-Bottom-Up-Childhood-Epilepsy-Program (TDBUCEP) at the free outpatient paediatric neurology camps in Bhakhar city, which is the last district in South Punjab, 450 Km from Lahore: the capital of Punjab. After documenting very high nonadherence to AEDs and epilepsy treatment gap amongst kids having epilepsy in 2014, we started TDBUCEP by regular monthly free educational and interventional paediatric epilepsy camps for one whole day in different parts of the city. Since then these camps are held regularly and all patients attending these camps are evaluated, educated and prescribed (if required) till the last patient is in the camp. After recognizing the cultural perspectives, standards, views and community customs of the target population, in December 2016, we adopted a multimodal modality to improve AEDs adherence among paediatric population with epilepsy in Bhakhar district. In this strategy, we integrated childhood epilepsy in Rukhsana Shafqat Memorial Charity Primary Health Care Center (RMPHCC) in the city center. In addition to the regular (monthly basis) free of cost paediatric neurology medical camps, we have trained local paediatrician and nurses, have arranged free undisturbed anti-epileptic drugs which are being dispensed on monthly basis in this primary health care. After completion of this endeavor for two

years, we designed this cross-sectional study to evaluate its impact upon AEDs adherence among CWE attending randomly two free paediatric neurology camps held in different non-contiguous areas of the city held on 7th and 8th December 2018: to avoid the biases of RMPHCC efficacy. This involved primary data collected through interviews/medical records of the consenting CWE/ their parents living in Bhakhar district who were diagnosed and prescribed antiepileptic drugs (AEDs) at least three months prior to camp dates were analyzed. The study included parents of outpatient epileptic children aged 4months- 18 years, who consented and/or assented to participate in a study and prescribers who were treating epileptic children at the designated primary health care center. However, children with a diagnosis of childhood epilepsy prescribed AEDs at least 3 months prior to the dates of the camp and visited these camps for the first time (controls) were included also. Consent from the participants or/and assent from older children (7-18 years) who met the inclusion criteria and were willing to be enrolled to participate in the study was sought. The study excluded parents/guardians of an outpatient epileptic patient aged less than 4 months or over 18 years of age and those who did not consent and/or assent to participate to study. A pre-constructed semi-structured questionnaire was used to gather data from parents/guardians on issues of AEDs adherence and factors influencing adherence Unquestionably, at hand no “gold standard” method is available for assessing adherence; however, usage of a range of approaches has been described in the literature^[10]. In our study data were composed by interviewing and questioning participants and studying patients records by trained data collectors. Self-reported 8point “Morisky Medication Adherence Scale” (MMAS-8) was used to gather data on the patient’s adherence to their anti-epileptic drugs^[11]. The MMAS-8 comprises of 8 things with a score of 0 and 1 for “yes” and “no” respectively documented for primary 7 items and a 5-point Likert answer for the remaining 1. The scores are added and are scaled as low adherence if it’s between 3-8; medium adherence if 1-2 and a score of 0 as high adherence. In this study, we categorized all those patients as non-adherent who are scored low or medium adherence on the scale. In order to keep up the worth of this data, data collectors were initially trained and the English version of the questionnaire was translated to “Suraikee” (locally spoken language) and back-translated to English. The data gathering tool was also pretested. Amongst the 290 contributors/participants, 240 had comprehensive data and were considered. The chief conclusion of our learning and study was adherence to AEDs and its

influencing factors. Two hundred and forty (240) CWE who met the inclusion criteria were recruited by research assistants after consultation; then they were referred to the respective principal investigators for the consenting and administration of the questionnaire. At these camps, there were 6 prescribers (4 visiting and 2 local) during study days. All consecutive patients coming to these camps were enrolled until all the patients were finished.

CONFIDENTIALITY:

Names of the participant were not recorded anywhere on any study tool but instead codes which bare no link to the identification of the participant was used for statistical purposes. Interviews were conducted in a private room and all other forms including consent forms were being kept privately by the investigator. Patients were assured that their identity will not appear anywhere in the study documents or publications.

STATISTICAL ANALYSIS;

The data of this was stated as frequency (in percentage). Descriptive statistical analysis was used to evaluate the data, and univariate study with chi-square analysis was done to detect the relationship between adherence and variables. In order to predict the different factors of adherence to drug treatment, Binary logistic regression analysis was applied. A statistical significance was considered if p-value was less than 0.05.

RESULTS

This cross-sectional study included 240 children and adolescents who met the criteria and agreed to participate. The researchers could complete a questionnaire for each patient within 10-15 minutes and this analysis was of adherence/nonadherence and factors associated with adherence/nonadherence. The patients' mean age was 10.6 years (range, 6months –18years). Out of 240 patients, 72(30%) were nonadherent and 168 (70%) were adherent to their AED(s) therapy. There was no statistically significant association of demographic features such as age and gender with AED adherence/nonadherence. Among 240 patients, males were 134 (56%) while females were 106 (44%) with a female to male ratio of 1:1.26. The highest percentage of the patients were between >5 yrs –10 yrs years of age. The distribution of patients according to age, gender and AEDs adherence/nonadherence is illustrated in Table-1. Of the total 240 children , 160(66.6%) started getting treatment from RMPHCC while 80(33.4%) were diagnosed/ followed by other treating bodies. The most

commonly identified factors associated with adherence were the cost and distance from residence. As illustrated in comparison among 160 patients seeking treatment and being followed at RMPHCC, nonadherence to AEDs was 15%, whereas, this was 60% among the 80 patients who never sought treatment from RMPHCE Table 2. On further analysis of the cohort bearing their own expenses, 26 (54%) of the 48 nonadherent to AEDs reported that the cost of the childhood epilepsy treatment was the predominant cause of their nonadherence, whereas this was reported only among 2 (8.3%) of the 24 nonadherent supported by the RMPHCC. Among the patient being provided free treatment no response to AEDs (uncontrolled seizures) and misleading by local quacks were the predominant cause of nonadherence. Though the no patients in this category were small, still these were associated with nonadherence 33.3% and 25% of these patients, respectively. Presence of antiepileptic medication side effects (8.3%) was another factor of nonadherence among these children with epilepsy. Poor counseling and non-availability of AEDs were reported less prevalent causes of nonadherence in both these groups. An association between various potential influencing factors and non-adherence level is presented in Table 3.

Table 1

Demographic and adherence/nonadherence among children with epilepsy in Bhakhar district in 2018.

| Age | Gender | Adherent (%) | Nonadherent (%) | Relative risk | P value |
|-----------------|-----------|--------------|-----------------|---------------|---------|
| 6 Mon –2 yrs | Boys=28 | 19 (68) | 09(32) | 1.02 | 0.3 |
| | Girls=21 | 14 (67) | 07(33) | | |
| >2 yrs –5 yrs | Boys=32 | 24(69) | 08(31) | 1.13 | 0.1 |
| | Girls=18 | 12 (67) | 06(33) | | |
| >5 yrs –10 yrs | Boys=48 | 34(71) | 14(29) | 0.98 | 0.3 |
| | Girls=36 | 26 (72) | 10(28) | | |
| >10 yrs –15 yrs | Boys=20 | 13(65) | 07(35) | 1.03 | 0.2 |
| | Girls=19 | 12 (63) | 07(37) | | |
| >15 yrs –18 yrs | Boys=06 | 04(67) | 02(33) | 0.80 | 0.05 |
| | Girls=12 | 10 (83.4) | 02(16.6) | | |
| Total: | Boys=134 | 94(70) | 40 (30) | 1.0 | 0.99 |
| | Girls=106 | 74 (70) | 32(30) | | |
| Total CWE | 240 | 168(70) | 72(30) | | |

Table 2: Demographic characteristics of children with epilepsy (CWE) nonadherent to antiepileptic drugs in Bhakhar- Pakistan, 2018 (N=240).

| Age | CWE seeking treatment from Rukhsanashafiq Memorial Primary Health center (n=160, 100%) | | | CWE seeking treatment on their own (n=80,100%) | | | | |
|-------------------|--|---------|-------------|--|------------------|------------|------------|-------------|
| | Male | Female | Total (%) | Nonadherent (%) | Nonadherent. (%) | Total (%) | Female | Male |
| 6 Mon –2 yrs | 18 | 15 | 33 (20.65%) | 06(3.50%) | 10(12.5%). | 16 (20%) | 6 | 10 |
| >2 yrs –5 yrs | 22 | 10 | 32 (20%) | 04(2.50%) | 11(14%). | 18 (22.5%) | 8 | 10 |
| >5 yrs –10 yrs | 34 | 24 | 58 (36.25%) | 08(5%) | 15(19%). | 26 (32.5%) | 12 | 14 |
| >10 yrs –15 yrs | 10 | 15 | 25 (15.6%) | 04(2.50%) | 10(12.5%). | 14 (17.5%) | 4 | 10 |
| >15 yrs –18 yrs | 04 | 08 | 12 (7.5%) | 02(2.50%) | 02(2.5%). | 06 (7.5%) | 4 | 2 |
| Total: 160 (100%) | 88 (55%) | 72(45%) | 160 (100%) | 24(15%) | 48(60%). | 80 (100%) | 34 (42.5%) | 46 (57.5 %) |

Table 3: Reasons for nonadherence to AED(s) among children with epilepsy in Bhakhar- Pakistan (N=74).

| Patients Non-adherent to AED(s) Following at Top-Down-Bottom-Up Center (n=24,100%) | | | Patients Non-adherent to AED(s) Not Following at Top-Down-Bottom-Up Center (n=48,100%) | | |
|--|---|----|--|------------|----|
| No | Reasons for non-adherence to AED(s) | No | Percentage | Percentage | No |
| 1 | Cost of AED(s) | 02 | 08.3 | 54 | 26 |
| 2 | No response to AED(s) | 08 | 33.3 | 12.5 | 06 |
| 3 | Counseling by local faith healers | 06 | 25.0 | 12.5 | 06 |
| 4 | Side-effects of AEDs | 04 | 16.8 | 04 | 02 |
| 5 | Poor/no counseling by the treating physician(s) | 02 | 08.3 | 10.5 | 05 |
| 6 | Non availability of AED(s) | 02 | 08.3 | 06.5 | 03 |
| Total | | 24 | 100 | 100 | 48 |

DISCUSSION

Recognizing and pinpointing the factors associated with anti-epileptic drug nonadherence would permit the expansion of approaches to increase adherence. This study delivers vital material and data on the impact of the integration of childhood epilepsy into primary care and chief reasons of non-adherence paediatric population to AEDs in outreach financially constrained communities. We documented epilepsy drugs non-adherence among 58% of the children with epilepsy prescribed AEDs in 2014, while the parents were affording all treatment for childhood epilepsy on their own^[9]. In our current study, nonadherence was identified among 60% of similar patients in 2018. There was no local study available of AEDs adherence /nonadherence among children; however 43.3 % nonadherence to AEDs has been reported in the hospital-based study for mixed children and the adult population from Lahore^[12]. Similar to our study, in Nigeria, a study was done by Ogboi S et al. in which AEDs nonadherence was documented in 64.7% among adult patients^[13]. We could not find any statistically significant association of demographic features such as age and gender with AED adherence, Table 1. This finding is similar to other studies describing the factors related to adherence to AEDs^[14,15]. Most of the barriers can be very effectively removed by promoting and setting childhood epilepsy health services in the native area, because its diagnosis does not require extensive sophisticated investigation and the treatment is not very costly. In December 2016, we incorporated and implemented childhood epilepsy services into the Rukhsana Shafqat Memorial Primary Health Care (a charity primary health center) in Bhakhar city. After completion of two years of this endeavor, we documented during the two monthly free childhood neurology camps (not in the designated center) that the 85% cohort of children with epilepsy being followed at this community center was adherent to AEDs, as compared to the 40% of the cohort not being followed at this center. It is recognized in WHO endorsements, in LMIC locations epilepsy should be identified and managed at primary care level by specially trained

health care staff^[16] and we have been doing this during the camps. Earlier studies have established that 60-80% of epilepsy patients can be properly managed with drugs although adherence to AEDs must also be observed^[17]. The price tag of medicines may confine caregivers from buying them in circumstances these are not availed at the healthcare settings due to other priorities. Among the nonadherent cohorts of the CWE who were buying AED(s) were about three times more likely as to be nonadherent in comparison with persons who were getting them free of charges: as long-term nature of epilepsy management might add for this relationship. The discovery of this study was constant with the studies piloted in other developing and under developed countries^[18]. Our epilepsy centre obtains no government finance and is mainly financed from private sources, primarily charity and philanthropic contributions. In agreement, other studies have highlighted the importance of community help in improving AEDs adherence^[19]. Similarly, among our 48 patients nonadherent to AEDs and affording their own treatment, 26(56%) stated that the nonaffordability of the treatment is the predominant cause of their nonadherence. In agreement, Nawazzi et al, documented that the main basis given for omitted medicines was a deficiency of medicines because of their extraordinary price as stated by 36(48.7%) of study contributors^[20]. Medication adherence is a very tricky phenomenon, when in remission; patients may query the need for continuous drugs, while uncontrolled seizures may tempt hopelessness and resignation. Nonadherence was considerably related to poor seizure control in our study. Ten (31.5%) of non-adherent patients being followed at the center stopped the drugs as there was insufficient seizure control, as compared to the 12% of the cohort not being followed at the community center. In agreement, others studies have documented that uncontrolled seizures are found to be the predominant cause of nonadherence to AEDs^[21, 22]. When most of the barriers are removed, misguidance by local health healers was the predominant cause of nonadherence among 8(25%) of the children with epilepsy being followed in our center as compared to 6(12%) of the cohort not being followed at the center. This is similar to the world wide believe that supernatural powers and spirits influence human being and affect their wellbeing and health especially in epilepsy^[23,24]. Even though, the pharmacological managements of epilepsy have been revealed to be effective in mitigating different kinds of epilepsies, the side effects of these drugs end in adverse effects on the patients' quality of life, frequently resulting in low compliance^[25, 26]. All of these studies are mainly for the adult population. Among our paediatric population, 4

patients in each cohort discontinued their AEDs due to the significant side effects of drugs. One of the aspects that cause AEDs nonadherence and treatment gap in epilepsy in LMICs is the deficiency of a nonstop and inexpensive source of AEDs [27, 28]. About 19 % (no very small) of these nonadherent children with epilepsy were prescribed AED(s) not available at our center pharmacy, where these were prescribed in 10% of the cohort not following at our center. Contrarily, we improved adherence to 85% by providing free and uninterrupted supply of the required AEDs. Our study gives important information that our multimodal strategy for the care of paediatric population with epilepsy by the integration of childhood epilepsy into charity local primary health care is functioning very well and has improved AEDs adherence from 38% in 2014 to 85% in 2018, in addition to marked economical the impact upon the community. Our monthly free childhood epilepsy camps, provision of free AEDs and support with Telepaedsneurology are effective in improving the adherence to AEDs and we hope extension of such programs to other outreach districts in Pakistan. Our study has limitations, as we used the imperfect method of self-report method as it is predisposed to recall bias, particularly where caregivers report on adherence and are likely to overemphasize it [29]. The effectiveness of the interventional strategy has been assessed by the intervening team, would have been more authenticated if evaluated by unknown researchers.

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CONCLUSION

Proper adherence to AEDs among children with epilepsy assessed by self-report and was good, at 85 % of those being fully supported by local primary health care, but unfortunately was 40% among those not being supported. It is proposed that there is a necessity for a decentralized model of childhood epilepsy care at the local level, with the pediatrician being the focal person to the program, a pediatric neurologist working as a nodal person, and the primary health center medical officer as the delivery agent. The integration of childhood epilepsy facilities into local community primary health care along with the provision of free consultations and AEDs in outreach poor communities could play a major role in improving adherence to AEDs. A Vision for change acknowledges the need for funding to support increased community-based care generally and for specific at-risk population; children with epilepsy.

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Muhammad Akbar Malik; concept, data collection, data analysis, manuscript writing, manuscript review

Arshad Rafique; data collection, data analysis, manuscript writing, manuscript review

Ahmed Omar Virk; data collection, data analysis, manuscript writing, manuscript review