

Arq Neuropsiquiatr 2007;65(Supl 1):58-62

DEMONSTRATION PROJECT ON EPILEPSY IN BRAZIL

Outcome assessment

Li M. Li^{1,2}, MD PhD; Paula T. Fernandes^{1,2}, MSc PhD;
Ana L.A. Noronha^{1,2}, MD PhD; Lucia H.N. Marques³, MD PhD;
Moacir A. Borges³, MD PhD; Karina Borges³, MSc; Fernando Cendes¹, MD PhD;
Carlos A.M. Guerreiro¹, MD, PhD; Dirce M.T. Zanetta⁴, MD, PhD;
Hanneke M. de Boer^{5,6}; Javier Espíndola⁷, MD, PhD; Claudio T. Miranda⁷, MD, PhD;
Leonid Prilipko^{5,8}, MD; Josemir W. Sander^{6,9}, MD, PhD, FRCP

ABSTRACT - Purpose: To assess the outcome of patients with epilepsy treated at primary care health units under the framework of the demonstration project on epilepsy in Brazil, part of the WHO/ILAE/IBE Global Campaign Against Epilepsy. **Method:** We assessed the outcome of patients treated at four primary health units. The staff of the health units underwent information training in epilepsy. The outcome assessment was based on: 1) reduction of seizure frequency, 2) subjective perception from the patient's and the physician's point of view, 3) reduction of absenteeism, 4) social integration (school and work), and 5) sense of independence. **Results:** A total of 181 patients (93 women - 51%) with a mean age of 38 (range from 2 to 86) years were studied. The mean follow-up was 26 months (range from 1 to 38 months, 11 patients had follow-up of less than 12 months). Seizure frequency was assessed based on a score system, ranging from 0 (no seizure in the previous 24 months) to 7 (>10 seizure/day). The baseline median seizure-frequency score was 3 (one to three seizures per month). At the end of the study the median seizure-frequency score was 1 (one to three seizures per year). The patients' and relatives' opinions were that in the majority (59%) the health status had improved a lot, some (19%) had improved a little, 20% experienced no change and in 2% the health status was worse. With regard to absenteeism, social integration and sense of independence, there were some modest improvements only. **Discussion:** The development of a model of epilepsy treatment at primary health level based on the existing health system, with strategic measures centred on the health care providers and the community, has proved to be effective providing important reductions in seizure frequency, as well as in general well being. This model can be applied nationwide, as the key elements already exist provided that strategic measures are put forward in accordance with local health providers and managers.

KEY WORDS: epilepsy, anti-epileptic drug, seizure, primary care.

Projeto demonstrativo em epilepsia no Brasil: avaliação do desfecho

RESUMO - Objetivo: Avaliar o resultado do tratamento de pacientes com epilepsia na atenção básica sob o modelo proposto pelo Projeto Demonstrativo no Brasil, como parte da Campanha Global Contra a Epilepsia da WHO/ILAE/IBE. **Método:** Avaliamos o resultado do tratamento nos pacientes acompanhados em quatro unidades básicas de saúde. As equipes de saúde fizeram um treinamento padrão. O resultado do tratamento foi baseado em cinco aspectos: 1) redução da frequência das crises, 2) percepção subjetiva dos pacientes e dos médicos, 3) redução de absenteísmo, 4) integração social (escola, trabalho), e 5) senso de independência. **Resultados:** Um total de 181 pacientes (93 mulheres - 51%), com uma média de 38 anos (variando de 2 a 86 anos) entraram nesta análise. O tempo médio de seguimento foi de 26 meses (variou de 1 a 38 meses, 11 pacientes tinham seguimento menos de 12 meses). A frequência das crises foi categorizada variando de 0 (sem nenhuma crise nos últimos 24 meses) a 7 (>10 crises/dia). O escore mediano da

¹Department of Neurology, Faculty of Medicine, UNICAMP, Campinas, SP, Brazil; ²Assistência à Saúde de Pacientes com Epilepsia - ASPE, Campinas, SP, Brazil; ³Department of Neurology, Faculty of Medicine of São José do Rio Preto, São José do Rio Preto, Brazil; ⁴Department of Epidemiology, Faculty of Medicine of São José do Rio Preto, São José do Rio Preto, SP, Brazil; ⁵Global Campaign Against Epilepsy Secretariat, Geneva, Switzerland; ⁶Epilepsy Institute of the Netherlands, SEIN, Heemstede, Achterweg 5, 2103 SW Heemstede, the Netherlands; ⁷Pan-american Health Organization, Washington DC, USA; ⁸Department of Mental Health and Substance Abuse World Health Organization, Geneva, Switzerland; ⁹Department of Clinical and Experimental Epilepsy, UCL Institute of Neurology, London UK.

freqüência de crises no começo era de 3 (uma a três crises por mês). O escore mediano da freqüência de crises no final era de 1 (uma a três crises por ano). A opinião dos pacientes e familiares é que a maioria (106 casos) houve uma melhora importante na saúde, 34 tiveram pouca melhora, 37 não tiveram mudanças e em quatro houve piora. Em relação ao absenteísmo, integração social e senso de independência houve pouca melhora. *Discussão:* O modelo desenvolvido de tratamento de epilepsia na atenção primária com base na estrutura de saúde existente, com estratégias centradas nos profissionais de saúde e na comunidade, provou ser efetivo com redução importante na freqüência das crises bem como na melhora em geral da saúde. Esse modelo pode ser aplicado em âmbito nacional, pois os elementos chaves já existem, desde que essas estratégias sejam pactuadas com os organismos locais de saúde.

PALAVRAS-CHAVE: epilepsia, droga anti-epiléptica, crises, atenção primária.

In the 1980s, health in Brazil underwent an important reform in the public sector, producing a public policy of universal health care delivery. This led to the institution of the *Sistema Único de Saúde* (SUS - Unified Health System) in 1988, an expression of the policy of social inclusion. Challenges faced by SUS include dealing with agendas imposed by infectious, contagious and chronic diseases. In the 1950s and 60s, the main health problems in Brazil were predominantly related to acute diseases of short duration, often bacterial or viral in nature. These still frequently occur, but are usually controlled by drugs¹. Today, chronic diseases are the main causes of health problems and negatively affect the quality of life. The advent of new technologies and scientific knowledge provide treatment for most illness, in that diseases rarely lead to immediate death as they used to in the past. However, the novel resources do not provide improvement of well-being to patients, and their relatives, with disabling conditions involving physical, social and psychological domains with numerous practical implications¹.

Epilepsy is an example of this type of chronic disease. Epilepsy is the most frequent serious non-communicable neurological disease worldwide, and is one of the major conditions which affects behaviour and quality of life, imposing complex challenges to health professionals². In addition to the problems of having seizures, epilepsy imposes a psychological burden with direct and indirect social consequences and economic impact.

The National Demonstration Project (DP) on Epilepsy³, part of the Global Campaign Against Epilepsy under the auspices of the World Health Organization, the International League Against Epilepsy and the International Bureau of Epilepsy, launched on the 27th September 2002 and executed by the *Assistência à Saúde de Pacientes com Epilepsia* (ASPE, a charitable non-governmental organization), assessed a series of actions with the overall aim of developing and testing a self-sustaining model of epilepsy assistance

within the existing primary health care system. This study is part of the Phase VI of the Demonstration Project on Epilepsy part of the Global Campaign Epilepsy Out of the Shadows-WHO-ILAE-IBE in Brazil³.

METHOD

The DP is divided into three main stages of progress evaluation: Situation assessment, Intervention assessment, Control assessment.

The Situation and Intervention assessments have been discussed in other papers, and here we consider the Control assessment. All the staff from the health units of the study area underwent a standard training (see article 2). The Control assessment is based on the outcome of people with epilepsy treated in the catchment areas, Barão Geraldo, Village, Santo Antonio, Jaguaré.

From the epidemiological survey of Phase I of the DP, those people identified as having epilepsy were invited to participate in the study, and were given information on the nature of the study; consent forms were signed. The study carried a minimal risk and was approved by the Ethics Committee of the Faculty of Medical Sciences of UNICAMP (number 331/2002). The epidemiological survey⁴ identified 122 people with epilepsy in Santo Antonio, 194 in Jaguaré, 132 in Barão Geraldo and 48 in Village. These patients, as well as any other patients from the catchment area of health unit who wished to, were invited to participate in the DP. The nature of the study was explained to all potential participants. It is important to note that, although we enrolled in the study only those who signed informed consent forms, all patients had access to health care assistance. All health workers involved in the project underwent standard training. The patients were asked to return on average every two months, and they were questioned in regard to their seizure frequency, their perception of well-being, and social activity. In this paper for outcome assessment we used only the baseline and the last entry datasets. We only assessed those patients who were still enrolled in the study; those who had dropped out were excluded.

The outcome assessment was based on: 1) reduction of seizure frequency, 2) subjective perception from patient's and physician's point of view, 3) reduction of absenteeism, 4) social integration (school and work), and 5) sense of independence.

Seizure frequency was classified using a score system: score 0=inactive epilepsy (no seizure in the previous 24

months), score 1=one to three seizures per year, score 2= four to eleven seizures per year, score 3=one to three seizures per month, score 4=one to six seizures per week, score 5=one to three seizures per day, score 6=four to ten seizures per day, score 7=more than ten seizures per day. All participants were asked to record their seizures in a diary.

Subjective perception was divided into: 'improved a lot', 'improved a little', 'no change' and 'worsened'.

Reduction of absenteeism, social integration (school and work) and sense of independence were assessed on direct interview using, for comparison, the period of six months prior to baseline and that of six months prior to the end of the study.

RESULTS

The initial study population consisted of 100 patients at health units in Santo Antonio, 90 in Jaguaré, none in Barão Geraldo, and 17 in Village. At the end of the study, the study population consisted of 133 patients at Santo Antonio, 37 at Jaguaré, none at Barão and 11 at Village. These patients were identified during the Phase I - epidemiological survey⁴. The final population, a total of 181 patients (93 women - 51%) with a mean age of 38 years (range 2 to 86 years), was studied, and their results described herein. The mean follow-up was 26 months (range 1 to 38 months, 11 patients had follow-up less than 12 months). The baseline median seizure-frequency score was 3 (interquartile range 1 to 4). At end of the study the median seizure-frequency score was 1 (interquartile range 0 to 3). Figure 1 shows the distribution of

seizure-frequency scores before and after the DP. There was a significant reduction in seizure frequency after treatment at the health units (Wilcoxon Signed Ranks Test Results= -8.160, p<0.001).

With regard to the overall health status at the end of the DP, the opinions of patients and relatives were that in 59% health had improved a lot, in 19% it had improved a little, in 20% there was no change and in two percent the situation was worse. The physicians assessment were fairly similar to those of the patients (Cohen's Kappa = 0.58). Physicians' opinions were that 56% had improved a lot, 22% had improved a little, 20% had experienced no change, and three percent had become worse.

We assessed school attendance in those aged less than 18 years and with a follow-up period of more than 12 months. At baseline, 20 out of 22 patients were at school, and eight of 20 (40%) had problems with epilepsy and with absenteeism due to seizures. At end of the study, 19/22 were at school, and four out of 19 (21%) had problems with epilepsy and with absenteeism due to seizures. The "problems with epilepsy" reported were all related to discrimination. In this aspect, it was at times difficult to disentangle whether absenteeism was truly due to temporary post-ictal incapability (somnolence, malaise) or whether it was more psychology related. We assessed employment in 131 subjects aged between 18 and 65 years and with a follow-up of at least 12 months. At

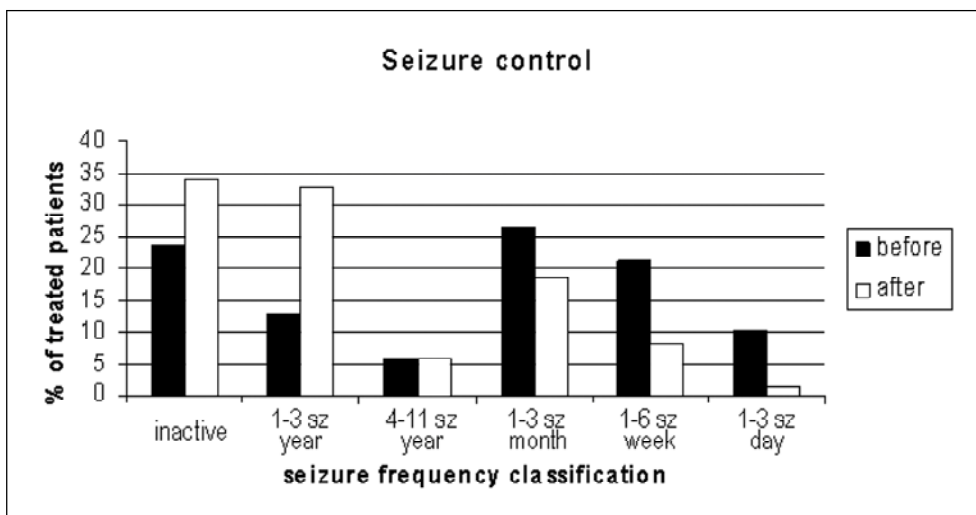


Fig 1. Distribution of scores of seizure frequency at the baseline and at the end of the study. The mean follow-up was 26 months (range 1 to 38 months, 11 patients had follow-up less than 12 months). The baseline median seizure-frequency score was 3 (interquartile range 1 to 4). At end of the study the median seizure-frequency score was 1 (interquartile range 0 to 3). There was a significant reduction in seizure frequency after treatment at health units (Wilcoxon Signed Ranks Test Results= -8.160, p<0.001).

baseline, 27 of 65 (42%) people who were working experienced interference in their work due to epilepsy (including seizures or consequences of stigma), and 35/65 (54%) had a formal job (signed contract guarantee by Law). At the end of the study, 11 out of 44 (25%) experienced interference in work due to epilepsy, and 20/44 (45%) had a formal job. Four patients who had never worked started working (informal job) after treatment, and two received a monthly income of U\$270.00 (R\$600,00). This can be considered a good income; however, more important is the behavioural change, from a state of stagnation to a pro-active attitude.

With regard to social activity and sense of independence, at baseline 116/181 were able to go out alone, and 90 people engaged in social activity. At the end of the study 119/181 were able to go out by themselves, and 100 people engaged in social activity.

We also conducted individual interviews with patients, relatives and health professionals on overall aspects of the DP. The patients and relatives noted that it was convenient for them to be assisted at a place near home. The most important factor was that there was a reference person in the health unit that they could rely on, and all agreed on the importance of having the regular group meetings. The physicians' opinion was that the protocol was simple and that they felt more confident managing epilepsy after the training (see article 2); all agreed that it was essential to have the facility of referral in cases of doubt.

DISCUSSION

Setting: success and failure – The four health care units had distinct outcomes. The health unit of Barão Geraldo had a series of problems with infrastructure and increased turnover of staff. Another major problem faced at Barão Geraldo was lack of interest from patients in participating in the study. This became apparent when all of the first 30 patients invited defaulted their initial appointments. The main reason given was that they were already under treatment elsewhere. The health unit at Village performed well. This unit is an extension of the Barão Geraldo health unit for the rural areas, which was convenient for patients who did not need to travel long distances for treatment. The health unit of Jaguaré had an excellent start with good attendance and acceptance by patients. However, the situation changed after a management change. The new manager reallocated a nurse who had been the liaison person between patients and the health unit. This broke the bond

and the monthly patients meeting ceased. Most patients went to another service (at a tertiary centre), and were invited by a physician for a monthly group meeting, and ended up being followed at that service. The health unit of Santo Antonio was very successful; although there were four changes of managers, a nurse stayed as a liaison person and monthly meetings took place. Over time, the health unit assumed the status of a "reference centre" for epilepsy, as some people with epilepsy who were not from its catchments area came for treatment. The differences observed in these four health units show the necessity for a liaison person and for regular group meetings. In interviews with patients, it became clear that one of the advantages of treatment provided by the DP, particularly at Santo Antonio, was that the programme went beyond drug prescription, and the patients felt cared for in all senses. Assistance was clearly provided by the liaison person and by the regular meetings, when patients could express their daily life problems and share mutual experiences. In the Jaguaré health unit, which was performing quite well initially, once the liaison person and the meetings were removed, patients move to alternate settings. This experience demonstrates that health assistance of people with epilepsy requires a holistic approach including psycho-social support.

The physicians expressed the view that after the DP they started to see patients with epilepsy in a different perspective, as people who could be treated at primary health level. They mentioned, however, that the presence of a tertiary centre for referral was very important.

During the study period the AED supply was predominantly regular, although there were two occasions when the supply was briefly interrupted without causing problem to the patients.

Medical outcome – The impact on seizure control was clear in that, on average, patients were initially having monthly seizures and by the end of the assessment this had been reduced to one to three seizures a year.

The subjective perception of the physicians and the patients and relatives was largely concordant, expressing satisfaction with the results. Side-effects recorded by the patients were considered of minimal effect that did not interfere with daily activities. It was not possible to ascertain the effect of drop-out due to medication intolerance, as there were other confounding factors for loss to follow-up, such as the

fact that people in the study area tend to move, (as was observed in the Phase I - epidemiological survey).

Social outcome – The effect on seizure control had direct consequences in reduction of absenteeism observed in school and the work environment. Nevertheless this effect was not consistent. With regard to employment the effect was minimal, with changes in very few individuals. Suggestions for improving this situation include: training patients for activity, different work schedules, acceptance of the work environment, follow-up. We are currently working on a project aiming to develop a partnership with the private sector for employment. The effect on independence and participation in social gatherings was also small. We observed that psychological intervention can help patients improve self-confidence and self-esteem, but we also observed that there were other variables, such as the local society, lack of social skills, and years of being sedentary, which influence the patients' attitudes. We are currently testing a complementary treatment (G.I.S. - *Grupos de Interação Social* - Social Interaction Groups) aiming to empower people with epilepsy, to improve their resiliency and to provide their social inclusion.

Final remarks and future direction – We developed a model of epilepsy treatment at primary health level based on the existing health system with strategic measures centred on health care providers and the community.

We demonstrated that, using this model, people with epilepsy can be effectively treated at the primary health level, with important reductions in seizure frequency, as well as improvements in general well being.

This model can be applied nationwide, as the key elements already exist⁵, provided the strategic measures are put forward in accordance with local health providers and managers.

The four year DP was instrumental in providing data on the magnitude of the burden of epilepsy on society, and for developing alternate cost-effective strategies to bring epilepsy out of the shadows. Over this period there was an open dialogue with the Ministry of Health for construction of public policy for users, and it became clear that it was necessary to institute a protocol for epilepsy assistance at primary care setting. This constitutes the concrete first steps towards creation of a National Program for Epilepsy.

REFERENCES

1. Guimarães SS. Psicologia da Saúde e doenças crônicas. In Kerbauy RR, (Ed). *Comportamento e saúde: explorando alternativas*. São Paulo: ARBytes Editora Ltda, 1999:22-45.
2. Baker G. The Psychosocial burden of epilepsy. *Epilepsia* 2002;43:26-30.
3. Li LM, Sander JW. National demonstration project on epilepsy in Brazil. *Arq Neuropsiquiatr* 2003;61:153-156.
4. Noronha AL, Borges MA, Marques LH, Zanetta DM, Fernandes PT, de Boer HM, Espindola J, Miranda C, Prilipko L, Bell GS, Sander JW, Li, LM. Prevalence and pattern of epilepsy treatment in different social-economic classes in Brazil. *Epilepsia*, **(*)1-6, 2007, doi:10.1111/j.1528-1167.2006.00974.
5. Li LM, Fernandes PT, Mory S, et al. Managing epilepsy in the primary care network in Brazil: are health professionals prepared?. *Rev Panam Salud Publica* 2005;18:296-302.