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Research Article

Vagal Electrical Treatment in Patients of the Neurosurgery Service of Hospital Dr. José María Carabano Tosta. Maracay-Aragua State. 2005-2015

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Abstract

Epilepsy is a chronic brain disease that affects people in all countries and is characterized by recurrent seizures. Seizures are brief episodes of muscle contractions that can affect a part of the body or its entirety and are sometimes accompanied by loss of consciousness and sphincter control. Epilepsy, in general, is treated based on the cause, which consists in the majority of cases in pharmacological therapy, however if this does not provide favorable results, a surgical alternative is considered. One of the new therapeutic alternatives is the installation of a neurostimulator device in the trunk of the vagus nerve. Electrical stimuli could inhibit synchronization in different nuclei that must discharge in unison so that normal brain electrical activity becomes an epileptic seizure, completely correcting epilepsy for a certain period of time. Vagal stimulation is performed by a pulse generator that sends electrical signals to the vagus nerve through an electrode, in order to reduce the frequency of epileptic seizures. Due to the little deepening of this issue, Venezuela's benefits are not enough, and its benefits in the guild of this study are not well documented, the review of the medical records of the Dr. José María Hospital is proposed. Carabano Tosta de Maracay-Venezuela, of the cases where the Vagus nerve stimulator was implanted with a sample of approximately 60 patients in order to know the benefit of surgery and the improvement (if any) of epileptic seizures.

Keywords: Epilepsy; Seizures; Neurostimulator; Vagus Nerve; Neurosurgery; Refractory Epilepsy

Introduction

Epilepsy is a chronic brain disease that affects people in all countries and is characterized by recurrent seizures. Seizures are brief episodes of muscle contractions that can affect a part of the body (partial seizures) or its entirety (generalized seizures) and are sometimes accompanied by loss of consciousness and sphincter control [1].

These episodes are due to excessive electrical discharges of brain cell groups. Discharges can occur in different parts of the brain. Seizures can range from very short episodes of absence or muscle contractions to prolonged and severe seizures. Its frequency can also vary from less than one a year to several a day [1].

A single seizure does not mean epilepsy (up to 10% of the world's population suffers a seizure throughout their life). Epilepsy is defined by two or more unprovoked seizures [1].

Epilepsy, in general, is treated based on the cause, which consists in the majority of cases in pharmacological therapy that would provide favorable results, in other cases it will lead to the last instance that would be the surgical alternative when the pharmacological treatment does not work, or with it, we do not obtain the expected results that favor the patient, we call it “refractory epilepsy”.

Refractory epilepsy has certain characteristics, among them we can give as an example intractable seizures, cognitive impairment,

psychosocial dysfunction, dependent behavior, a restricted lifestyle, an unsatisfactory quality of life and an increased mortality of 15% compared to drug-controlled epilepsy [2]. The International League Against Epilepsy has stated that when two years of treatment without seizure control have elapsed after having taken two first-line antiepileptic drugs, monotherapy and associated, a pre-surgical assessment should be performed [14]. About 30% of patients have epilepsy resistant to all pharmacological interventions [2]. However, there is no unified definition that produces conformity with regard to the specific criteria of refractory epilepsy [14].

Today found the existence of certain patients who have a type of refractory epilepsy [1] with this we want to say is resistisng to pharmacotherapy because of this have developed news alternative therapies, of which among the higher preponderance installing a device neurostimulator in the trunk of the vagal nerve. Electrical stimuli could inhibit synchronization in different nuclei that must discharge in unison so that normal brain electrical activity becomes an epileptic seizure, completely correcting epilepsy for a certain period of time.

The first time that vagus nerve stimulation was used in humans was in 1988 in Miami [8]. Subsequently, two multicentre, randomized, controlled and double blind clinical trials have been carried out [10]. Since then more than 1000 patients have participated in 7 clinical trials in 26 countries and there is experience in more than 2000 patients. Trials in animal and human models seem to demonstrate a decrease in the frequency, duration and intensity of epileptic seizures, with reduction in the severity and duration of post-symptomatic symptomatology [1].

Vagal stimulation is performed by a pulse generator that sends electrical signals to the vagus nerve through an electrode, in order to reduce the frequency of epileptic seizures. The vagus nerve transmits information to the brain, through the brainstem. Its stimulation reaches the brain and little by little the crises diminish. It has the advantage that it is an intervention that is not bloody and of short duration.

The implantation is performed on the neck of the left side, on the inner border of the sternocleidomastoid muscle where the is separated the Jugular vein, Common Carotid Artery and Vagus Nerve; Subsequently, three (3) spiral electrodes are placed around the Vagus nerve and then tunneled to the infra clavicular region on the same side (sub cutaneous) where an electric pulse generator has been fixed as if it were a cardiac pacemaker. Once the electrodes are installed and connected to the generator, the specialist programs the device to automatically generate a stimulus or newspaper throughout the day for continuous periods of 30 seconds, intercalating 5 minutes of inactivation [5].

In Venezuela it is known that by the year 2011 approximately 150 surgeries of vagal neurostimulator facilities had been performed [13]. In 2006, in Venezuela, 19 patients were studied in terms of crisis control and quality of life, measured through income in the intensive care unit and its manifestations, demonstrating significant impact on the quality of life of patients with a time greater than or equal to 6 months of implants [14].

However, it is concluded that the study of this therapeutic alternative is not adequately deepened, the cases are not sufficient, because the benefits of health in the Neurology guild are not well documented and therefore there is not knowledge of any study that indicates the usefulness of implantation of the neurostimulator in patients with refractory epilepsy. For this reason, a review of the medical records of the Dr. José María Carabano Tosta Hospital in Maracay-Venezuela is proposed, of the cases where the vagus nerve stimulator was implanted with a finite sample of 59 patients is and subsequently, an interview will be carried out with them, in order to know the benefit of surgery and the improvement (if any) of epileptic seizures.

To carry out this study, the general objective was: To determine the benefits of vagal electrical stimulation in the treatment of epilepsy in patients of the Dr. José María Carabano Tosta Hospital in Maracay Aragua State who underwent this surgery. And as specific objectives:

- Distribute the sample by age and sex.
- Define the epilepsy diagnoses presented in the sample patients.
- Know the frequency of the pre - crisis and post-implantation of nerve stimulator property has percentage of decrease of number of crisis, depending on the diagnostic type of epilepsy.
- Establish the improvement of the post-implantation patients of the vagal neurostimulator.

The research aims to break down aspects related to the implementation of vagal stimulation as an alternative treatment for refractory or drug resistant epilepsy. Finally, we hope to conclude in a reliable way the analysis of the effectiveness of the implantation of a device that, by means of direct electrical impulses to the trunk of the vagus nerve, causes the cessation or decrease of epilepsy and define what are the advantages and disadvantages of the implantation of said treatment. Likewise, we propose to estimate and point out the limitations and consequences that could get to be presented to implement this after the same treatment, thus giving an view more complete and accurate about this alternative to conventional treatments.

Patwardhan and colleagues presented as objective, knowing the effects of VNS on seizure frequency and quality of life. With the term intermittent vagal stimulation, the authors refer to a neurostimulation technique applied to patients with epilepsy refractory to conventional pharmacological treatment. In this study were retrospectively analyzed thirty-eight children aged 11 months to 16 years with medically refractory epilepsy, which were subjected to the implantation Vagus Nerve stimulators. Before the operation, the age of onset of the crisis, the duration of the epilepsy, the type of crisis and the frequency were recorded. Likewise, the age of implantation, duration of follow-up, type of epilepsy and frequency, and change in quality of life were recorded after the operation. They were assigned a quality score from -1 (much worse) to 1 (much better) [3].

The follow-up was 12 months in children between 10-18 months. Eleven (29%), with 90% reduction, 15 (39%), with 50-90% reduction and 5 (13%) with less than 50% frequency reduction. For all children, reduction of seizures by type of attack was as follows: atonic (80%), absence (65%), partial complex (48%), and generalized tonic-clonic (45%). The average change in the quality of life score was 0.61. Eighty-six percent (86%) of the children scored quality of life scores of 0.5 (better) or higher [3]. In conclusion, vagus nerve stimulation provides improvements in seizure control in most children, regardless of age. The quality of life improved in the majority of children with vagus nerve stimulation. The vagus nerve stimulation should be considered for children with drug-resistant epilepsy that has no potentially resectable focus [3].

Amar et al, pointed out as the research objective to argue in favor of the clinical application of vagus nerve stimulation, discuss the highlights of patient selection and nuances of the surgical technique, and present observations and the results of the Method application [4].

In this study, 18 patients with medically refractory epilepsy and at least six complex or secondary generalized partial seizures were subjected to the placement of an impulse generator (Cybernetic Neuro Prosthesis) in the chest, connected to helical platinum wires applied to the left the trunk of the vagus nerve of the cervix. Patients were randomly studied in a double design (two groups) to receive any of the levels (high or low) of vagus nerve stimulation. Reduction in the frequency of crises was observed. Global assessments of quality of life, physiological measurements, and adverse events were recorded over a period of 3 months. Patients in the low stimulation group are subsequently taken to high stimulation levels during a 15-month extension trial [4].

As a result, all operations were successful, without incident, and without adverse postoperative sequelae. Of the seven patients initially assigned to discharge stimulation, the average reduction in seizure frequency was 71% at 3 months and 81% at 18 months. Five (72%) of these patients had a reduction greater than 75% in the frequency of seizures, and one (14%) remained seizure free after more than 1.5 years of follow-up. The average reduction in the frequency of crises among the low stimulation group was only 6% at 3 months. Concluding it is established that vagus nerve stimulation has proven to be a safe and feasible, and potentially effective method of reducing seizures in selected patient populations. However, the elements of strict definition for the application of the method require further study [4].

Materials and Methods

A non-experimental, descriptive, transectional research with exploratory features was performed. It is affirmed that it is not experimental since no variable was deliberately annihilated, that is, they did not carry out any type of experiments or any type of treatment was applied to the population studied, only the phenomena were observed as they occur in their context natural, to later analyze it [15]. It is descriptive because it aimed to achieve the accuracy of the study event, it seeks to specify the cases of the application of vagal surgery [16-19]. It is also considered transectional, since data is collected in a single moment, in a single time [15]. And finally it is considered as an exploratory position, generally, these are new or little known research problems [15].

It is a contemporary univariable mixed source transectional design, because the description of the event is obtained through the combination of data provided by live sources or by the application of instruments directly to the study units, with the data obtained from documents and records made previously; since the description of the event, which in this case is the benefits provided by the vagal neurostimulator in the treatment of epilepsy, is obtained through the combination of data provided by live sources or by the application of the instruments directly to the units of study [15].

The level of research was exploratory as previously mentioned: since its main objective is to capture a general perspective of the problem, it is usually carried out when the objective is to examine a topic or research problem that has not been studied or has not been previously addressed in Venezuela. They identify potential relationships between variables and set the tone for more rigorous subsequent investigations. They are characterized by being more flexible in their methodology compared to descriptive or explanatory studies, they are also more extensive and dispersed than these other two types [12].

In statistics, population is the set of things, people, animals or situations that have one or several common characteristics or attributes. In our study, the type of population is a population that is a limited population, which is the set consisting of a limited amount of elements [17], in this case it is made up of all the patients, who attended the neurosurgery consultation of the Dr. José María Carabano Tosta Hospital in Maracay and during the period 2005 to 2015.

Sample defines your finite set of a population. The number of elements that make up the sample is called the sample size [17]. The sample used in this work will be a non-probabilistic sample, since the choice of the elements studied (patients) does not depend on the probability but on causes related to the characteristics of the investigation [15], and this case was made up of 59 patients from Dr. Jose Maria Carabano Tosta de Maracay Hospital, underwent surgery for the implantation of the vagal neurostimulator.

The data collection technique was a survey type, through a questionnaire, which is an instrument that groups a series of questions related to a particular event, situation or subject, about which the researcher wishes to obtain information [16]. The design of the questionnaire includes the selection of topics or areas to be covered and how to present them to the people chosen to answer it, in terms of order of the topics, format, formulation of the questions, among others.

As for the instrument, information collection sheets were prepared, which contains the following aspects: age of the patients under study, number of crises, types of crises, age of implantation of the device, and number of drugs; these data referring both before and after the implantation of the vagal neurostimulator.

Results

Table 1 shows the distribution of the sample by age and sex. A total of 59 were studied pacients, which were 35 men (57.89%) and 24 women (42.11%), the mean age was 18.80 years, which the largest percentage were aged between 13 to 22 years age (38.60%) and the lowest percentage between 43 and 52 years of age (1.75%).

	F		M		Total	
Ages	**N**	**%**	**N**	**%**	**N**	**%**
3 to 12	4	7.02%	13	22.81%	17	29.82%
13 to 22	10	17.54%	12	21.05%	22	38.60%
23 to 32	9	15.79%	6	10.53%	15	26.32%
33 to 42	1	1.75%	1	1.75%	2	3.51%
43 to 52	0	0.00%	3	1.75%	3	1.75%
Total	**24**	**42.11%**	**35**	**57.89%**	**59**	**100.0%**

Table 1: Sample distribution by age and sex. Patients of the neurosurgery service of the Dr. Jose Maria Carabano Tosta Hospital. Maracay Aragua State, 2005-2015 period.

Source: Data obtained by the authors.

Table 2 shows the distribution of the sample by age of onset of crisis. A total of 59 patients were studied, with an average age of onset of 3.76 years. Of which the highest percentage had the age of onset of crisis the interval of less than 1 year of age (33.00%), the ages between 5 to 8 years and 9 to 14 years (15.10%) as the lower proportion and 14.80% did not know the age of onset of crises.

Table 3 shows the distribution of the sample by age of implantation of the neurostimulator. A total of 59 patients were studied, with an average age of 17.94 years. Of which the highest percentage has as a device implantation age the interval of 12 to 21 years (34.78%), and the intervals of 32 to 41 years and 52 to 61 years (2.17%) as those of lower proportion.

Ages	N %	
Under 1 year	19	33.00%
1 to 4 years	14	22.00%
5 to 8 years	9	15.10%
9 to 14 years	9	15.10%
Unknown	8	14.80%
Total	**59**	**100.00%**

Table 2: Distribution of the sample by age at onset of the crisis of patients in the neurosurgery department of the Dr. Jose Maria Carabano Tosta Hospital. Maracay Aragua State, period 2005 -2015.

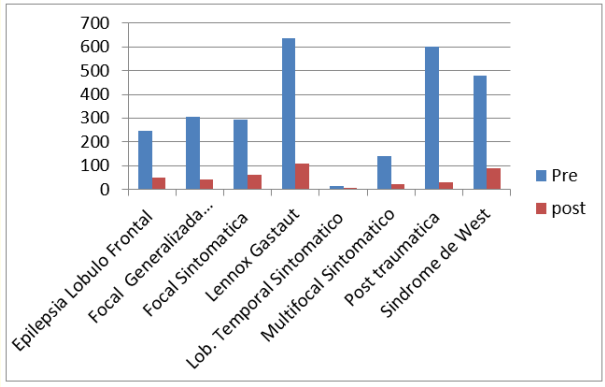
Source: Data obtained by the authors.

Edades	N %	
2 a 11	18	32,61%
12 a 21	21	34,78%
22 a 31	13	23,91%
32 a 41	2	2,17%
42 a 51	3	4,35%
52 a 61	2	2,17%
Total	59	100,00%

Table 3: Distribution of the sample by age of implantation of the neurostimulator of the crisis of the patients of the neurosurgery service of the Dr. Jose Maria Carabano Tosta Hospital. Maracay, Aragua State, period 2005-2015.

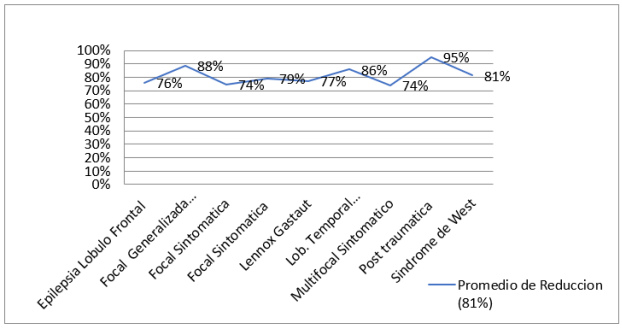
Source: Data obtained by the authors.

In graphic 1 is represented the distribution of the sample by diagnoses average number of pre and post crises and implantation. A total of 59 patients were studied, of which all presented a reduction in the number of monthly crises, with an average of monthly pre-implantation crises of 349.4 and an average of monthly post-implantation crises of 61.4. The patients diagnosed with Post Traumatic Epilepsy presenting the greatest percentage reduction before and after implantation, with a 95% reduction, and patients diagnosed with Multifocal Syndrome, with a reduction of 74%, were the lowest percentage reduction before and after implantation.



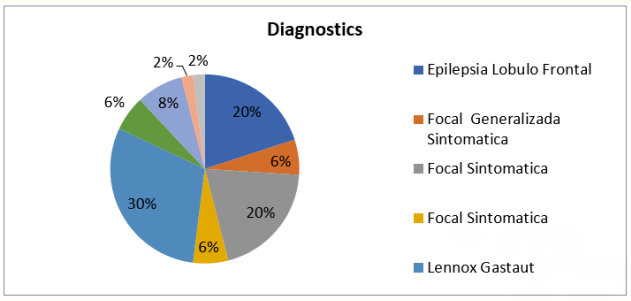
Graphic 1: Distribution of the sample according to its diagnosis and average number of pre and post implantation crises in patients of the neurosurgery service of the Dr. Jose Maria Carabano Tosta Hospital. Maracay, Aragua State, 2005-2015 period.

In graphic 2, the average of pre and post implantation crisis of the sample is represented. A total of 59 patients were studied, with an average reduction of 81%, of which the highest percentage reduction rate was patients with Post Traumatic Epilepsy, with an average monthly crisis reduction of 95%, and the lowest reduction the patients had a percentage with symptoms of symptomatic Focal and Symptomatic Multifocal with a percentage reduction rate of 74%.



Graphic 2: Average of pre and post implantation crises in patients diagnosed with Frontal Lobe Epilepsy of the neurosurgery department of the Dr. Jose Maraa Carabano Tosta Hospital. Maracay, Aragua State, period 2005-2015.

In graphic 3, the distribution of the sample according to its diagnosis of type of epilepsy is represented. A total of 59 patients studied, of which the most common diagnostic was the Lennox Gastaut Syndrome (30%) and diagnoses smaller proportion in the sample were patients with epilepsy Post Traumatic and West syndrome (two%).



Graphic 3: Distribution of the sample according to their diagnosis of type of Epilepsy in patients of the neurosurgery department of the Dr. Jose Maria Carabano Tosta Hospital. Maracay, Aragua State, period 2005-2015.

Discussion

In spite of that and studies made previously in different investigations, does not have a broad - based research, were able to collect works of special academic value, which show results matching the thrown in the research development of this work. "The efficacy of vagus nerve stimulation in children with drug resistant epilepsy" [3]. He presented as objectives, to know the effects of vagus nerve stimulation on the frequency of crisis and the quality of life. Thirty-eight children aged 11 months to 16 years with medically refractory epilepsy were analyzed retrospectively, who underwent implantation of vagus nerve stimulators.

The follow-up was 12 months, obtaining a reduction in seizures by type of attack was the following: atonic (80%), absence (65%), partial complex (48%), and generalized tonic-clonic (45%) [3]. In the current investigation, we worked with the type of epilepsy and not with the type of attack, however satisfactory results were obtained in 59 patients of the neurosurgery service of Hospital Jose Maria Carabano Tosta de Maracay, Aragua State, with a reduction of 288 monthly crises, after the implantation of the vagal neurostimulator.

In another research entitled: "An institutional experience with stimulation is vague nerve trunk for medically refractory epilepsy: Fundamentals, Techniques and Results" [4] where 18 patients with medically refractory epilepsy undergoing placement of a vagal pulse generator were evaluated, it was obtained that of the seven patients initially assigned to the stimulation, the average reduction in the frequency of the attacks was 71% at 3 months and 81% at 18 months. Five (72%) of these patients had a reduction of more than 75% in the frequency of seizures, and one (14%) remained seizure free after more than 1.5 years of follow-up [4], which is equivalent to the results obtained in this work.

Conclusions

The majority of the sample used was represented by male patients aged between 3 years and 22 years, which may or may not have something to do with the incidence of epileptic disease.

The majority of patients without gender predisposition, began to present epileptic seizures in the first 12 months of life, however it was also observed that with almost the same number of patients, the beginning of epileptic seizures in ages between 1-4 years, it was also frequent, with this it can be concluded as to the early diagnosis of epileptic syndrome, the sample was within the acceptable ranges.

It was evident that the implantation of the device is more frequent among patients aged between 12 years and 21 years, although the age group between the ages of 2 and 11 years also represented a significant amount within the study, allowing to specify that the Implantation of the vagal neurostimulator at an early age is of greater benefit and prevents complications or greater resistance to the method or treatment.

The contrast between the amount of crisis prior to the implantation of the vagal neurostimulator and the post-implantation of the vagal neurostimulator, allowed to certify that the decrease in said amount was significant in all patients, thus indicating that the implantation of the vagal neurostimulator is really effective and beneficial for the treatment of seizures.

The most representative diagnosis of the patients that made up the sample is Lennox Gastaut Syndrome, the second most frequent being frontal lobe epilepsy, this being related to studies that show that these are at the top of frequency among patients with epileptic syndrome.

It is suggested to maintain and improve, prevention at the primary and secondary level using an appropriate perinatal and pediatric consultation to recognize these pathologies early and thus obtain a timely diagnosis for an early intervention that would avoid future sequelae.

It is very useful to know in a better way the benefits of the alternative treatment of drug-refractory epilepsy with the neurostimulator device of the vagus nerve between the neurology guild, to a greater number of patients.

It should offer an individualized service patient orientation refractory epilepsy drug, thereby giving the best therapeutic alternative

It should develop investigations in all patients implanted with the neurostimulator trunk of the vagus nerve in order to have a better understanding of their advantages and disadvantages in the long run.

Provide training to a greater number of neurosurgeons and neurologists on the device, so that there are a greater number of applicants and treating specialists, thus increasing the number of patients treated with this therapeutic alternative.

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