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**Level of empowerment and decision-making style of women with epilepsy in childbirth age**

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**Abstract**

**Objectives:** This research investigates level of empowerment, decisional skills, and the perceived relationship with the clinician, of women in childbirth age, also in relationship with clinical variables such as epilepsy type, seizure frequency, therapy, and pregnancy status. In particular, as concerning therapy, we were interested in women who take Valproic Acid (VPA), for its specific balance of risks and benefits, especially in pregnant women.

**Methods:** The sample is composed of 60 women with epilepsy (6 were excluded), who underwent a standardised clinical protocol for assessment of level of empowerment, decisional skills and of their judgment about how they feel to be involved by their clinician in medical decision making.

**Results:** Overall, the sample does not show signs of low empowerment level nor of abnormal decision-making patterns.

The type of epilepsy, the frequency of seizures and the treatment type (VPA versus no VPA) do not impact on empowerment, nor on decision styles nor on medical relationship, with the only exception of a specific decision style, the avoidant style, that is more frequent in women treated with VPA with respect to those taking other therapies.

Interestingly, regarding VPA dosage, we found that patients taking equal or more than 700 mg/day of VPA have lower scores on empowerment in all dimensions compared to women with a VPA dosage lower than 700 mg/day.

**Conclusions:** Shared decision-making including improved decision quality, more informed choices and better treatment concordance, should be a central part of epilepsy care. In addition, for clinicians it would be useful to have specific tools to know if the patient has really understood the risks and benefits of AEDs, particularly VPA, and all treatment alternatives.

**Keywords:** epilepsy, empowerment, decision-making style, valproate, valproic acid, pregnancy

## 1. Introduction

It is well known that involving patients in healthcare decisions may lead to positive consequences for healthcare outcomes, adherence to treatment recommendations and increased trust in health professionals. Several studies have assessed patients' wishes about the possibility to have adequate information and permission to participate in decisions which affect them, the possibility to be told about the options for treating or managing their condition and the possibility that their preferences might be taken into account [1]. To obtain positive effects of patients' involvement, it is necessary for clinicians to involve patients in the process of understanding the nature and uncertainties of the problem, potential harm and benefits and the understanding that the patients can, if they wish, influence the decision themselves [2].

Psychological empowerment is, generally speaking, a construct that links individual strengths and competencies, with larger environmental and social contexts; it may be viewed as an internal disposition to control and cope with life events and to influence other people [3]. The individual sense of empowerment arises when people perceive that they can adequately cope with events, situations, and/or the people they confront, whereas it decreases when they believe that they are unable to cope with the physical and social demands of their environment, or when they feel powerless. In this sense, empowerment is a process by which people gain control over their lives, also through a critical understanding of their actual situation [4], and a process enabling individuals, also in cooperation with others, to achieve their primary personal goals [5]. In medical settings, patients' sense of empowerment has been shown to affect the way in which each patient reacts to his/her illness, understands his/her clinical condition, forms an opinion about possible treatments, adheres to treatments,

cope with treatment side effects, and interacts with the whole health care process [2]. This is even more relevant in chronic diseases. Chronic disease management strategies recommend that patients be empowered to self-manage.

Within this perspective, in the present work we investigated the sense of empowerment experienced by a group of women with epilepsy in childbirth age, their decisional styles (i.e. the individual characteristic mode of perceiving and responding to decision making tasks), and their satisfaction on how the clinician takes the decisions about treatment, treatment side effects, and more generally about disease management. We also investigated whether clinical characteristics of epilepsy, such as onset time, epilepsy type, seizure frequency, therapy, and pregnancy status interfere with empowerment, decision styles and the satisfaction about feeling involved in ones' own cure. In particular, as concerning therapy, we were interested in women who take Valproic Acid (VPA), because of the specific characteristics of the VPA itself. For the management of generalized epilepsy, VPA can be the only therapeutic option for some patients including pregnant women or women of childbearing potential, for whom other treatments have failed. However, recently new data has emerged regarding the risks of congenital malformations and impaired cognitive development to children prenatally exposed to VPA [6]. This issue is so crucial that a Task Force of the Commission on European Affairs on the International League Against Epilepsy (CEA-ILAE) and the European Academy of Neurology (EAN), following strengthened warnings from the Coordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh) of the European Medicines Agency (EMA), was put together, in order to discuss it [7-8]. In this context, many patients began to ask for information about the risks of VPA, and in some cases they decided to reduce or stop VPA assumption without any clinical recommendation.

## **2. Materials and methods**

### **2.1 Participants**

A total of 60 women (6 were excluded) were enrolled in a time-frame of 12 months from April 2017 to April 2018, at the Epilepsy Center-Child Neuropsychiatry Unit, San Paolo Hospital, University of Milan: 25 consecutive outpatients (46.3%) were recruited at the Epilepsy Center and 29 (53.7%) consecutively from outpatient clinic dedicated to pregnant women with epilepsy. Women were enrolled by three physicians. Two women refused to participate in the study.

Inclusion criteria were: women of childbearing age (from 16 to 45 years), education level equal to or higher than primary school (8 years), normal intelligence ( $IQ \geq 85$ ) according to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition classification (DSM-5) estimated by the neurologist clinically, and Italian native speakers.

We excluded patients with progressive neurological pathologies and severe axis I disorders.

The diagnosis of epilepsy was based on the International League Against Epilepsy (ILAE) classification [9]. Seizure types were classified according to clinical semiology provided by description from a witness or when possible by EEG or video-EEG recording of the episode. Patients were considered seizure-free if they were without clinical seizures for at least 1 year, using the last clinical visit documenting seizure status as the end point of follow-up.

## **2.2 Questionnaires**

To investigate the extent to which patients feel involved in the therapeutic process, their feeling of empowerment and their decision style, we used three scales widely used in medical decision-making literature: the Psychological Empowerment Instrument [10-11], the General Decision Making Style (GDMS) scale [12-13] and the Observing Patient Involvement (OPTION) scale [14].

The Psychological Empowerment Instrument comprised 12 items. Each item is a sentence that participants are required to evaluate using a seven-point Likert scale, ranging from 1 (*strongly disagree*) to 7 (*strongly agree*). Four subscales, composed of three items each, measure four

empowerment dimensions: Meaningfulness (the value of a goal or purpose, judged in relation to an individual's own ideals or standards); Competence (or self-efficacy, the individual's belief in his/her capability to perform activities with skill); Self-determination (the individual's sense of having choice in initiating and regulating actions) and Impact (the degree to which an individual feels to be able to influence the environment/situation). We used the Italian version of this scale [10-11].

The GDMS is composed of 25 items, in the form of sentences which the participant is required to evaluate through a five-point response scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*). Five subscales, composed of five items each, measure the five cognitive styles identified by the authors: Spontaneous (characterized by a sense of immediacy and a desire to get through the decision-making process as soon as possible); Dependent (characterized by a search for advice and direction from others); Rational (characterized by a thorough search for and logical evaluation of alternatives); Avoidant (characterized by attempts to avoid decision making) and Intuitive (characterized by a reliance on hunches and feelings). For instance, the item: "I double-checked my information sources to be sure I have the right facts before making decisions" is an item from the Rational style scale, whereas "When I make a decision, I trust my inner feelings and reactions" is an item from the Intuitive style scale. We used the Italian validation of the GDMS [12-13].

Both these questionnaires do not ask participants to evaluate the sentences referring to a specific time frame; however, participants are asked to refer to their current or recent experience.

Finally, the OPTION scale assesses the extent to which clinicians actively involve patients in decision making, as perceived by patients. It consists of 12 items regarding the presence of specific clinicians' behaviours, to be rated on a 5-point scale ranging from 0 (*strongly disagree*) to 4 (*strongly agree*). It has no subscales. By way of example, some items are as

follows: “The clinician *states* that there is more than one way to deal with an identified problem”, “The clinician explores the patient’s expectations (or ideas) about how the problem(s) are to be managed” [14]. This questionnaire asks patients to answer referring to a specific clinician-patient relationship; we asked participant to refer to their epileptologist.

The participants were informed of the experimental conditions before starting the experiment, and they filled out a written consent form. The test phase took place in a quiet room, in the presence of the experiment coordinator. The questionnaires administration took about half-an-hour.

The protocol was carried out in accordance with the ethical standards of the Declaration of Helsinki, and The Ethics Committee of San Paolo Hospital reviewed and approved the study protocol.

### **2.3 Data analysis**

Data are presented as means and standard deviations (SDs). Statistical analyses were performed using SPSS version 22. Significance was set at a p value of 0.05.

Demographic, clinical variables and questionnaire scores of women were compared with U of Mann-Whitney or the T-Student for independent samples, depending on the distribution.

We used Bonferroni correction for multiple comparisons.

We compared questionnaires dividing participants according to years of education (<diploma versus  $\geq$  diploma), age (age 15-24 versus >24), type of epilepsy, frequency of seizures, VPA assumption, VPA dosage, pregnancy status, and pregnant women with VPA vs. pregnant women with other AEDs.

### **3. Results**

Sixty patients were enrolled in study; six of them had to be excluded for the following reasons: two showed borderline intellectual functioning (BIF), three patients were not Italian

native speakers (2 Hispanic and 1 Arabic), and one patient suffered from severe Axis I disorder.

### **3.1 Patient characteristics and clinical variables**

Characteristics of patients are presented in Table 1.

### **3.2 Psychological variables**

As for the empowerment level, the whole sample presents, on average, scores in line with empowerment norming scores (e.g., [10] and [15]).

Age has no impact on the empowerment level, but the education level acts as a covariate on the Competence scale: the subsample with a diploma or a higher educational level shows higher score ( $F=3.23$ ;  $p=0.02$ ). Probably a higher level of schooling is correlated with more skills and with a higher perceived expertise in disease management.

As regards the GDMS, on the whole sample the frequency distribution of decision styles is equally allocated in all the five components. However, significant differences were found taking into account age as a covariate: younger women (age 15-24) showed less avoidance style than older ( $F=4.22$ ;  $p=0.02$ ).

Finally, as concerning the feeling of being involved in the therapeutic process, in the OPTION Scale women show a good perception of participation in medical choices, meaning that they think they are adequately involved in treatment decisions, and in the management of therapeutic options.

Table 2 shows mean scores for each scale for the three psychological tests used in the study.

### **3.3 Clinical variables x psychological variables**

We evaluated some clinical variables on psychological constructs.

The type of epilepsy and the frequency of seizures have no impact on empowerment, on decision styles nor on medical relationship. However, regarding the number of seizures, it is

important to notice that the frequency of seizures per month is low (mean=0.5; SD=1.3; range 0-12).

In relation to treatment (VPA versus no VPA), we found no differences on the psychological dimensions investigated, with the exception of the “avoidant” decision style: patients taking VPA tend to be more avoidant in choices (mean=17.24, SD=2.63) than patients not taking VPA (mean=15.65, SD=2.78), (T-Test corrected for multiple comparisons:  $F=0.13$ ;  $t=2.094$ ,  $p=0.041$ ).

Regarding VPA dosage, we divided our VPA group by the threshold of 700 mg daily dose according to Eurap study group who defined, by categorisation algorithm, the rates of major congenital malformations at different dose ranges [16]. We found that women taking equal to or more than 700 mg/day of VPA have lower scores on empowerment in all the dimensions (T-tests for independent samples, with Bonferroni correction for multiple comparisons: T-tests comprised between 3.274 and 2.207,  $p$  comprised between 0.012 and 0.039) compared to women with a VPA dosage lower than 700 mg/day. Table 3 shows mean scores of the two patients' subgroups.

Finally, with respect to pregnancy status (pregnant women vs. no pregnant women) and pregnant women with VPA vs. other AEDs, we found no differences in any of the psychological dimensions we investigated (Table 4).

#### **4. Discussion**

In our Epilepsy Center we have an outpatient clinic for women who want to plan a pregnancy and pregnant women. Counseling the patient regarding the treatment during pregnancy is essential due to the teratogenic potential of AEDs. Since a significant percentage of pregnancies are unplanned, it is important to discuss these issues with all women with epilepsy of childbearing age prior to conception following the PRAC and the Task Force's recommendations that include the following: (1) where possible, VPA should be avoided in

women of childbearing potential; (2) the choice of treatment for girls and women of childbearing potential should be based on a shared decision between clinician and patient; (3) for seizure (or epilepsy) types where VPA is the most effective treatment, the risks and benefits of VPA and other treatment alternatives should be discussed; (4) VPA should not be prescribed as a first-line treatment for focal epilepsy; (5) VPA may be offered as a first-line treatment for epilepsy syndromes where it is the most effective treatment, including idiopathic (genetic) generalized syndromes associated with tonic-clonic seizures; (6) VPA may be offered as a first-line treatment in situations where pregnancy is highly unlikely (e.g., significant intellectual or physical disability); (7) women taking VPA require regular follow-ups for ongoing consideration of the most appropriate treatment regimen [7-8]. VPA is unique among older AEDs because it is effective in treating all forms of seizures, including absence, focal, and primary generalized. Its mechanism is partially similar to that of phenytoin and carbamazepine, in that it prolongs recovery of voltage-activated sodium channels from inactivation, but it may also act by increasing gamma-aminobutyric acid levels in the brain. It is particularly useful for the management of generalized epilepsies, for which treatment alternatives are few. However, during the past few years an increasing amount of evidence has been built up to indicate that intake of VPA during pregnancy is associated with a significant risk of dose-dependent teratogenic effects (three major birth defects: neural tube defects, facial clefts, and hypospadias), impaired postnatal cognitive development and autism spectrum disorder in the offspring [16-18]. On the other hand, the lack of data on outcomes of pregnancies where VPA treatment has been withdrawn during pregnancy is highly unsatisfactory. High-quality evidence supports the use of sodium valproate as the first-line treatment for individuals with generalized tonic-clonic seizures (Cochrane) and some data indicate that withdrawal of or switch from VPA during the first trimester could lead to loss of seizures control [6]. On the basis of all these considerations, every patient must be fully

informed of the risks associated with VPA use during pregnancy as well as of the risks and benefits of treatment alternatives. A patient information leaflet should always be provided and a Risk Acknowledgement Form should be signed by both specialist and patient.

As a general result, our data shows that the empowerment level of women with epilepsy is comparable with the one of general population and the one of other populations with chronic diseases, such as diabetes and chronic pain disorders [19]. For instance, as concerning patients with chronic back pain, mean scores obtained in each subscale ranged from 12.9 (Impact scale) to 14.7 (Meaningfulness subscale). Thus, the impact of epilepsy in women seems not to determine an evident impairment on empowerment meaning that the overall sense of self-efficacy and the ability to cope with the disease is unimpaired by the disease.

The concept of empowerment is a process of interaction between people and personal resources with the environment that helps patients to improve their health and well-being. In this regard, a good level of empowerment allows patients with epilepsy to develop skills, confidence and knowledge to interact in a functional way with their environment, and to improve their health by moving from a patient condition as a passive recipient of treatment to an active patient condition involved in healthcare.

We also found that women with higher levels of education are more skilled at participating in making their own treatment decisions.

As concerning decision styles, we found that patients are balanced with respect to the different styles, in a manner which is parallel to the distribution of the general population; this means that the disease did not affect their inner way of perceiving and responding to decision tasks, moving it toward a certain style to the detriment of another. Also, such result does not change depending on the different clinical characteristics of epilepsy.

However, we found that younger patients (from 16 to 24 years) have a less avoidant decision style compared to older women; this is consistent with other studies [20-21] that found similar age-related patterns also in healthy individuals.

As concerning the relationship with the clinician, and in particular how the patients perceive to be actively involved by clinicians in medical decisions, participants reveal a feeling of global satisfaction about involvement. Also, they refer to feel able to deal with an identified medical problem with their doctor, to feel free to express their point of view and to discuss with the neurologist about expectations and worries about epilepsy and AEDs.

One of the most common reasons for patient dissatisfaction is feeling improperly informed about treatment or management options; on the contrary, shared decision-making helps to address these concerns by attempting to involve the patient and clinician equally in the decision-making process, providing more patient-centred care [22]. Women in our sample seem to have a satisfying level of sharedness in decision processes about their care and treatment in partnership with their neurologists.

Considering the clinical variables, results show that the type of epilepsy and the epilepsy onset do not influence the answers to the questionnaires. In addition, seizure frequency does not affect the psychological variables that we assessed. This is an interesting result, as we could argue that the more the pathology is serious in terms of seizures frequency, the less patients would feel empowered, and the less they would look for participation in the decision-making process. However, such result might be partially due to the fact that overall participants' frequency of seizures is low; it would be interesting to conduct a further study with a sample suffering from pharmaco-resistant epilepsy.

As concerning treatment, the only significant difference we found comparing women with VPA versus those taking other AEDs, is that the former show higher scores for avoidance in making decisions. Avoidant style corresponds to the tendency to postpone a decision, and to

tolerate elements of uncertainty in a given situation, waiting to see how it will evolve. More in detail, the 5 items addressing this style are the following: “I avoid making important decisions until the pressure is on”; “I postpone decision making whenever possible”; “I often procrastinate when it comes to making important decision”; “I generally make important decision at the last minute”; “I put off making important decisions because thinking about makes me uneasy”. Within this respect, participants taking VPA seem to be more resistant to change and more apt to stay in an uncertain situation, before taking a decision. As a tentative explanation, this might suggest that patients who tolerate less the uncertainty status, with a higher clarity need, and reluctant to see how a certain situation will evolve before taking a decision, maybe are less likely to accept the uncertainty given by the assumption of VPA in a context in which a certain risk of VPA use is perceived. The risk of major congenital malformations is influenced not only by type of antiepileptic drug, but also by dose, which should be taken into account in the management of epilepsy in women of childbearing potential. For this reason, taking into account only women treated with VPA, we found that patients taking equal or more than 700 mg/day (40%) tend to feel less empowered than women taking a lower dosage. However, VPA dosage was not the only difference between the two subgroups: indeed, whereas 50% of patients with a VPA dosage equal or higher than 700 mg/day were in polytherapy, compared to 26.6% of patients with VPA lower than 700 mg/day. Also, 20% of patients with  $VPA \geq 700$  had seizures in the last month, compared to 6.6% of patients with  $< 700$  mg/day. Such data suggest that women taking an equal or higher dose of VPA might have a more severe condition than the others; therefore, maybe the greater severity of their condition is the reason they perceive themselves as less self-competent and less skilled in health management. Unfortunately, the sample size does not allow more fine-grained statistical analysis in order to disentangle the role of different factors.

Finally, with respect to pregnancy status (pregnant women vs. no pregnant women) and pregnant women with VPA vs. pregnant women with other AEDs, there were no significant differences for any of the psychological dimensions. It has to be noticed that this might also be due to the fact that the overall relationship with the physician is generally good, however, results show that participants maintain a high level of empowerment, a good relationship with their clinicians, and an equilibrate decisional style, also in a situation in which they might experience more uncertainty, such as a pregnancy and in which they might feel more vulnerable and worried.

This study has an important strength: to our knowledge this is the first work to investigate the influence of empowerment and decisional skills in women with epilepsy. A big limitation of our research is that we conducted a single center study reflecting the practice style of our Epilepsy Center, however we always follow all the guidelines and reports generated by the ILAE. Moreover, this issue needs to be more thoroughly investigated, in particular as concerning shared decision making and the treatment choice in relation to empowerment processes and to the disease severity.

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None of the authors have any conflicts of interest to disclose.

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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