Clustering patients and caregivers for technology design: A step prior to the design of an innovative technological device for the detection of epileptic seizures

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1. Introduction

Epileptic seizure detection can provide significant benefits to patients [1], especially when they have drug-resistant epilepsy which forces them to be more proactive in the management of their symptoms. Wearable seizure detection devices can make it possible to better detect crises and therefore prevent their consequences, but also to ensure more objective monitoring [2]. More specifically, seizure detection using deep learning for heart rate variability offers new perspectives for capturing nonconvulsive seizures, although it remains a technical and clinical challenge [1].

Even if the apparatus is technologically valid, to be efficient it has to meet the patients and their caregivers' expectations, and more generally to integrate their way of life in the conception process [2]. This seems pretty obvious in view of the fact that the patients will be the end users, but caregivers can also assert specific preferences on the characteristics of a technical device [3]. However, it has been shown that patients and caregivers differ, for example in terms of perceptions of seizure freedom, seizure control, communication priorities, and treatment goals [4]. Requirements and preferences of both patients and caregivers should thus be taken into account from the earliest stages of the design process, since they may influence acceptance.

Technology acceptance theory has conceptualised factors that may influence seeks users' intention to use a technological device through the development of the Unified theory of acceptance and use of technology (UTAUT) [5]. This model has been validated for a very large number of information technologies (e.g. in the case of a wearable health technology) [6]. However, in health settings this approach must be supplemented by an evaluation when the technology to correctly take into account patients' needs or beliefs [7]. The addition of an evaluation of the self-efficacy is particularly important to specify if the adoption of the technology will be voluntary or mandatory.

In this preliminary study, we aim to investigate how the introduction of a patch connected to a companion application, intended to detect epileptic seizures by an automated analysis of the heart-rate variability using artificial intelligence (AI), and which is being developed, could be related to the factors of acceptability and could establish the convergences and divergences of perceptions among patients with epilepsy and caregivers. More particularly, the objective was to define users' profiles (for patients and caregivers) intended to promote the design of a patch connected to a companion application to support the early detection of epileptic seizures in drug-resistant patients, and to address the possible links between the profiles and the perception of the manifestations of the disease. In order to better support the design process and to take it into account in technological developments, it is indeed necessary to

better understand to what extent acceptability is or is not associated with the different perceived manifestations of epilepsy.

2. Methods

2.1. Participants

All the participants agreed to respond after a call for participation posted on the Facebook page of the association "France epilepsie" and on the website of the La Teppe health center. The sample was made up of 68 patients with epilepsy and 33 caregivers of patients with epilepsy. The patients' sample was composed of 48 females (70,59%) and 20 males (29,41%). Their average age was 38,07 years (standard deviation =12,75). The caregivers' sample was mostly composed of parents (88,85%), giving help to 12 female patients (36,36%) and 21 male patients (63,64%). Their average age was 38,07 years (standard deviation =12,75).

2.2. Material

The 31-item Quality of Life in Epilepsy (QOLIE-31) [8] scale, adapted from the more comprehensive 89-item scale, was used to measure four dimensions of quality of life : anxiety for seizures, psychic functioning, cognitive functioning and social functioning.

Self-efficacy for new technology was measured using the 10 items Modified Computer Self Efficacy Scale (MCSES) [7].

The perception of the occurrence of seizures was evaluated using a Likert scale that ranged from 0 (never) to 5 (once or several times a day, every day).

A 21-item questionnaire derived from the UTAUT 2 model [9] was used to determine the connected patch acceptability. It does not mention the value and habit indicators, because they did not correspond to the situation. It was based on the following dimensions: behavioral intention (BI), expected performance (EP), expected effort (EE), social influence (SI), enabling conditions (EC), and hedonic motivation (HM).

The material was available in two versions: one for patients, and one for patients' caregivers. In the version of the questionnaire intended for caregivers, the formulations have been adapted so that the participants respond to the patients to whom they are caregiving. Even if the questionnaires have not been validated with caregivers, we used the same items to question the group of patients and the group of caregivers in order to have results that can be compared.

2.3. Technology Presentation

The patch connected to a companion application powered by AI, under consideration in this study, is being designed for self-management of epilepsy seizures, and clinical follow-up in patients with heart-rate variability [10]. The device is in development, and will consist of a patch attached to the ribs on the left side and a mobile phone application integrating a deep learning analysis system.

The technology was presented through a short video presentation lasting 1.56 minutes [1]. The video starts with a description of the technology. It continues with the description of the goal of the technology, on how it is functioning, technically and in daily living, and finally on the expected benefits for the final users. In order not to raise false expectations, it is clearly specified that this future device will not concern all forms of epilepsy and is still in draft form. It ends by giving the internet address of the association in charge of the design, to allow participants to obtain more information if they wish

2.4. Procedure

Data was collected using two separate surveys (one for patients with epilepsy and another for caregivers) created using Qualtrics survey software. After expressing their consent to participate, participants responded to questions about their socio-demographic characteristics, and about the occurrence of seizures, to the QOLIE-31, and to the MCSES. Secondly, they watched the video presenting the technological development project. Finally, they had to answer the UTAUT questionnaire.

2.5. Data analysis

All the analyses were conducted on SPSS 25.0 software. A K-means clustering hierarchical analysis by dynamic cloud was performed on the dataset concerning the acceptance factors for the connected patch, in order to determine groups that stand out according to the differing data models. Analysis of the final central clusters by means of the elbow method have suggested that solutions of three groupings were the most significant and parsimonious for patients and also for caregivers. Kruskall Wallis analysis of variance for non parametric data

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[1] The video is available on the Univ. Grenoble Alpes video website (https://videos.univ-grenoble-alpes.fr/video/13790-aura-patch/).

were also used to compare the three classes for the scores obtained in the QoL-31, the MCSES, and the perception of the frequency of epileptic seizures.

3. Results

3.1. Patients

The most significant and parsimonious final cluster centers are presented in figure 1. Cluster 1 is made up of persons manifesting the highest acceptability. Cluster 2, an intermediary cluster, is made up of persons manifesting moderate acceptability. The variance analyses have shown that the three clusters enable the differentiation of the participants for the six factors of the UTAUT questionnaire, indicating that they enable the connected patch acceptability to be clearly distinct [BI: $F_{(2, 65)} = 49.54$; $p < .0001$ – EP: $F_{(2, 65)} = 50.16$; $p < .0001$ - EE: $F_{(2, 65)} = 28.90$; $p < .0001$ – SI: $F_{(2, 65)} = 36.88$; $p < .0001$; EC: $F_{(2, 65)} = 36.84$; $p < .0001$ - HM: $F_{(2, 65)} = 19.24$; $p < .0001$]. There was no differences in age between the three clusters [$F_{(2, 65)} = 4.44$; NS], and clusters were not linked to patients' gender [$\chi^2(2) = 2.99$; NS].
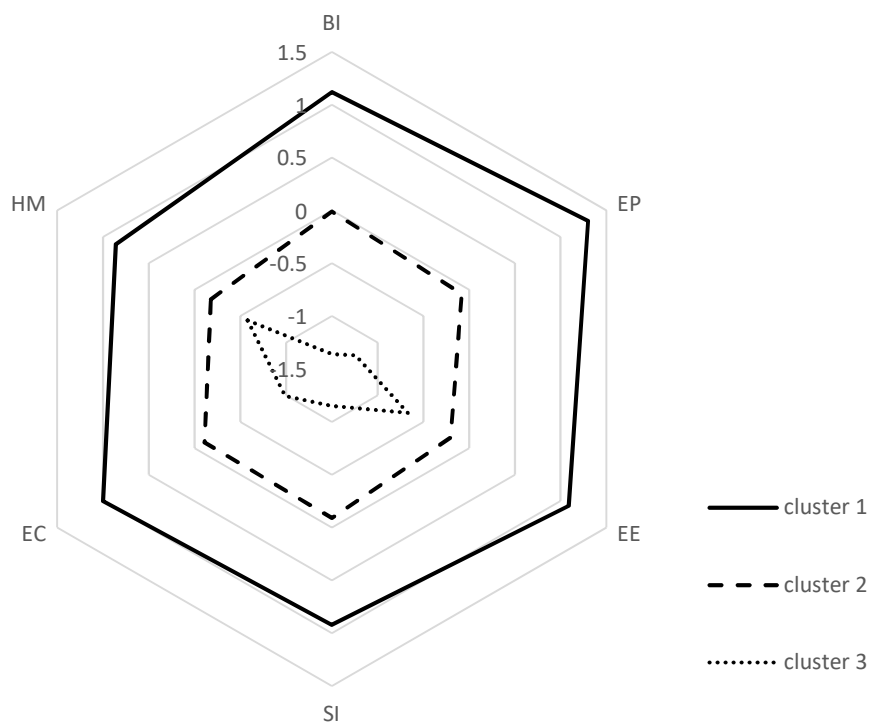

Figure 1. Final cluster centres for patients UTAUT factors

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The three clusters also enable the distinction between participants in the MCSES rating, and seizure frequencies, but not in the QoL-31 ratings (Table 1). Thehighest MCSES scores are observed for cluster 2 and the lowest for cluster 3.

	Cluster 1 (n = 16)	Cluster 2 (n = 18)	Cluster 3 (n = 34)	Total (n = 68)	F
Psychic functioning	130.44 (45.27)	129.90 (42.40)	147.44 (49.67)	134.67 (45.05)	10.71
Cognitive functioning	43.00 (20.36)	41.21 (21.13)	45.77 (18.65)	42.84 (20.11)	0.69
Social functioning	109.61 (53.96)	125.69 (57.72)	149.41 (55.99)	128.18 (57.40)	4.45
Seizure anxiety	22.48 (14.87)	29.94 (18.49)	32.24 (22.59)	28.73 (19.01)	2.10
MCSES	82.19 (15.00)	68.41 (18.15)	59.17 (17.59)	69.21 (18.94)	14.75**
Seizure frequencies	2.31 (1.01)	2.24 (1.02)	1.39 (1.09)	2.03 (1.09)	10.19*

* $p < .05$ ** $p < .01$

Table 1 – The estimated relative values (mean ratings and standard deviations) for the clusters 1, 2 and 3 and comparison between the clusters for the four dimensions of QoL-31, MCSES, and seizure frequencies' perception by means of Kruskall Wallis ANOVAs (n=68)

3.2. Caregivers

The most significant and parsimonious final cluster centres are presented in figure 1. Cluster 1 is made up of caregivers manifesting the highest acceptability for their relative with epilepsy, with positive perceived use intention, associated with expected performance and effort, hedonic motivation, very high enabling conditions and high perceived social influence. Cluster 2 is made up of caregivers perceiving a lower behavioral intention to use the technology for their relative than in cluster 1, associated with low-expected performance and effort, very low hedonic motivation and but also with moderate enabling conditions and high social influence . Cluster 3 is made up of caregivers manifesting the lowest acceptability for their relative, with negative perceived intention of use, associated with low-expected performance and effort, very low perceived influence social, as well as weak enabling conditions, but also with moderate hedonic motivation. The variance analyses have shown that the three clusters enable the differentiation of the participants for the six factors of the UTAUT questionnaire, indicating that they enable the connected patch acceptability to be

clearly distinct [BI: $F_{(2, 30)}$ = 20.87; $p < .0001$ – EP: $F_{(2, 30)}$ = 21.73; $p < .0001$ - EE: $F_{(2, 30)}$ = 22.75; $p < .0001$ – SI: $F_{(2, 30)}$ = 18.82; $p < .0001$; EC: $F_{(2, 30)}$ = 18.02; $p < .0001$ - HM: $F_{(2, 30)}$ = 11.63; $p < .01$]. Clusters were not linked to caregivers' role [$\chi^2(2)$ = 3.14; NS], and there was no difference in age of the patients helped by caregivers between the three clusters [$F_{(2, 30)}$ = 1.01; NS]. However, we note that cluster 1 was more present among caregivers who helped a male patient and cluster 3 was more present among caregivers who helped a male patient [$\chi^2(2)$ = 6.97; $p < .05$].
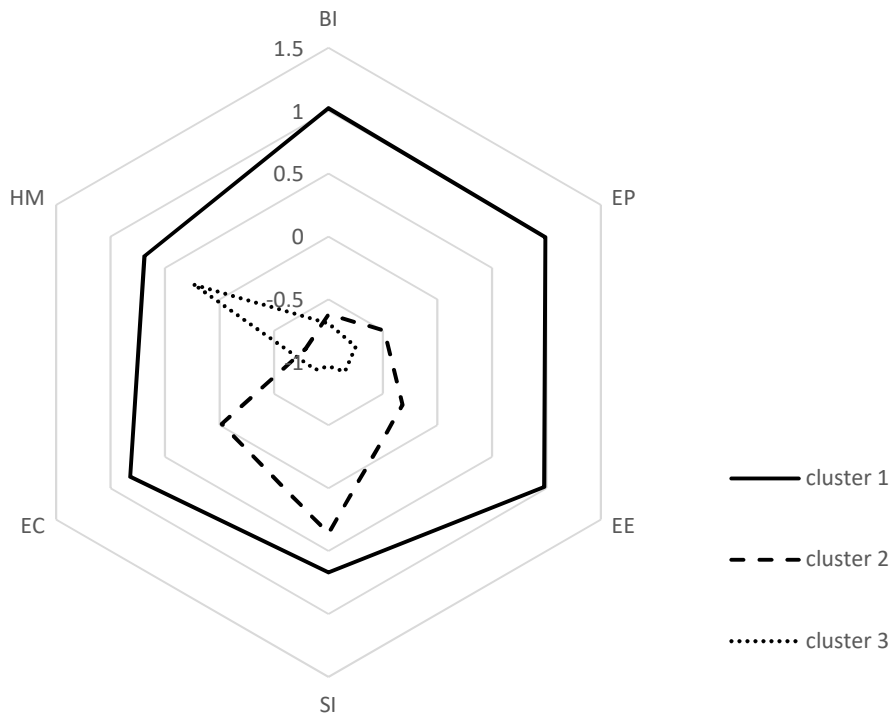

Figure 2. Final cluster centres for caregivers UTAUT factors

A trend of distinction between the three clusters of participants was found in the MCSES rating, but not in the QoL-31 ratings and the perception of the frequency of epileptic seizures (Table 2). The highest MCSES scores are observed for cluster 1 and the lowest for cluster 3.

	Cluster 1 (n = 13)	Cluster 2 (n = 8)	Cluster 3 (n = 12)	Total	F
Psychic functioning	134.12 (48.12)	133.69 (37.89)	105.86 (44.50)	123.74 (44.29)	2.25
Cognitive functioning	33.18 (23.12)	49.44 (25.92)	25.74 (21.77)	34.42 (24.41)	4.61
Social functioning	126.06 (64.01)	117.64 (40.53)	87.34 (50.91)	109.94 (55.66)	3.94
Seizure anxiety	31.59	35.17	28.83	31.45	0.80

	(18.33)	(12.32)	(24.64)	(19.34)	
MCSES	82.83	70.63	61.75	71.91	5.67*
	(15.90)	(25.05)	(17.47)	(20.32)	
Seizure frequencies	2.31	2.38	2.58	2.03	0.30
	(1.32)	(0.74)	(1.09)	(0.90)	

*$p = .06$

Table 2 – The estimated relative values (mean ratings and standard deviations) for the clusters 1, 2 and 3 and comparison between the clusters for the four dimensions of QoL-31, MCSES, and seizure frequencies' perception by means of Kruskall Wallis ANOVAs (n=33)

4. Discussion

Engagement is supposed to be able to reduce information asymmetry, as it is conventionally observed in care relationships [11]. Self-management and implication in clinical management are therefore an approach that must be favored from the early design phases of health devices. So, if seizure detection using deep learning methods constitutes a promising avenue, patient empowerment must be considered as early as possible. This empowerment also has to take into account caregivers in the conception process, because of the importance of caregivers' support, especially in patients with the most serious disorders [12]. For this purpose, promoting patients and caregivers centered models of seizure detection and management involves specifying these types of users. This perspective is in line with the aim to better understand the socio-technical interactions of a new technological device to avoid future difficulties of use.

Considering this, the results make it possible to consider the heterogeneity of the profiles of these patients and caregivers according to their acceptability of the connected patch in a participatory design approach of this device. Our findings support the differentiation of patients with epilepsy and caregivers into three distinct groups according to their level of willingness to accept a patch connected to a companion application. This distinction is based on all the factors of acceptability, but also on the self-efficacy and on the importance of seizure occurrence perceptions. More specifically, the cluster analysis suggests that patients can be described as generally supportive, indeterminate, or reluctant to use the technology.

According to the cluster analysis, caregivers can also be described as generally supportive, or whether reluctant to use the technology, either with sensitivity to their environment (social and material), or with hedonic motivation. These clusters also seem to be linked to the supposed self-efficacy of the patients being helped. Contrary to what has been observed in patients, the importance of identified epileptic seizures is not associated with the acceptability of the technological device intended to allow their control. However, these

results agree with the observation that acceptance of highly innovative products such as AI-based intelligent devices, may be more influenced by beliefs about technology than by utilitarian factors [13].

In addition to the need created by the frequency of epileptic seizures, self-efficacy, or trust in patients skills may constitute relevant values for caregivers and professionals [3], and thus constitute a fundamental element of the technological design. It appears as a sensitive factor that would distinguish those who are reluctant from those who are already well disposed to use the technological device, before any use. We can note that this is particularly pregnant among caregivers who assume that their loved ones will not adopt the technology, although they may have a playful interest in the technology. This result is also consistent with those obtained in patients trained in the use of a wearable device [14], which showed that a main factor is the ability to control the device. The connected patch will have to be developed systematically with appropriate methodological design and testing with different types of patients and caregivers, to ensure acceptability, and then acceptance in real-life settings. Our results suggest that this factor can be identified prospectively, before the technological device is available. Beyond providing functional support, it will be necessary to support behavioral change in caregivers, to develop their appreciation of the skills of the patients to whom they help.

Together with the small number of participants, a main limitation of the present study is the absence of any objective indication on the severity of the epilepsies, on the comorbidities and on the history of the pathologies. Further studies will have to consider more contextualised analyses according to variety of forms of epilepsy, so that the connected patch can take its place in each particular habit. Yet, patients and caregivers groups are not matched, and the differences in profiles obtained by the cluster analysis do not account for the real disjunction between patients and caregivers it will then be necessary to clarify the link between patients' caregivers' disjunctions and acceptability. However, it should be noted that these findings may have been influenced by selection bias. The patients with epilepsy and caregivers who agreed to answer cannot be considered representative of the entire population of patients with epilepsy and of caregivers. In particular, the study involved having received the information, being able to connect to the Internet and maintaining one's attention to respond to the end. For example, it is possible that standpoints would have been different if patients and caregivers faced with the greatest difficulties had been included as participants. Consequently, these limitations and the fact that the questions were asked in reference to a particular technology do not allow to generalize the results obtained to other wearable seizure detection devices.

In brief, the evaluation of acceptability of a patch connected to a companion application provides support that both patients and caregivers must be taken into account to better understand how it can take its place in their daily life, with varied positioning, including reluctance associated with a hedonic perspective, or a functional perspective. Furthermore, reluctance is linked to the importance of seizure occurrence perceptions, and also to a low sense of self-efficacy for technologies in general, which can better characterise future user groups. These preliminary results are in line with the need to call on AI-based intelligent devices to better support epileptic seizures, but also with te need to think of development modalities that are responsible. They will allow us to further our knowledge on the specific brakes and levers identified through this cluster analysis in order to adapt the device in a participatory design approach [12]. Moreover, these data will guide in supporting patients and their caregivers in the use of the connected patch.

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