Research Article

The Development of an Electrochemotherapy Patient Tool to Assess Patient Experiences of Electrochemotherapy in the Treatment of Cutaneous Malignancies

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ABSTRACT

There are no specific scales to assess patients quality of life or overall experience following electrochemotherapy (ECT). The aim of this study is to design an Electrochemotherapy Patient Assessment (EPA) questionnaire that assesses patient experience of ECT including any side effects.

Sixty two patients with cutaneous malignancies who were registered in an ECT trial at Cork University Hospital were invited to participate in a telephone interview. 46 patients met inclusion criteria, 21 patients agreed to participate and 20 participated. Patients who consented answered 19 questions collated from previously validated tools. All data collected was anonymised and statistically analysed using SPSS.

Survey respondents (n=20; 60% female) had a mean (standard deviation) age of 67.8 (10.0). 85% of patients reported the highest-level recommendation of ECT, and 75% reported preference of ECT over other options. Post-procedure, 60% of patients reported the lowest possible pain grade and 75% reported the most positive response to the tolerability of side effects. In our patient cohort, ECT is well tolerated with high patient satisfaction and minimal impact from side effects. Our EPA questionnaire may be of benefit to health care professionals treating patients with and in research of ECT.

INTRODUCTION

The incidence of cutaneous malignancies is increasing, due to a number of factors including advancing age. According to the American Cancer Society and the National Cancer Institute over 15.5 million people were living with a history of cancer in 2016 and 47% were aged 70 years and older, with this number due to steadily rise [1]. The aging population suffers from age-dependent diseases, and poly-morbidity can affect treatment [2]. The challenges facing cancer survivors have become a major focus for oncology health professionals [1]. As Clinical Nurse specialists, we strive to provide optimal outcomes and experiences for our patients. Targets of cancer treatment include cure, progression free and overall survival; however improving patients quality of life is often the primary outcome [2]. Patients perceptions, quality of survivorship and their overall experiences of treatments really matter.

There is great interest in the development of novel cancer treatments across medical specialities. Since it's introduction in 2006, electrochemotherapy (ECT) has been an option for patients with many different cancer types [3]. ECT is a localised targeted treatment, which can be used to treat cutaneous metastasis of any histology [4,5,6]. It

involves the use of a chemotherapeutic drug such as bleomycin or cisplatin [7] and electroporation. These drugs would normally find it difficult to cross the cell membrane. However, this can be aided by delivering a series of short electrical pulses through a probe directly across the tumour [8] which causes the cells to become temporarily permeable, thus allowing the chemotherapeutic drug to enter the cells [9]. Cork University Hospital is the only centre in the Republic of Ireland to offer ECT treatment to patients. On average we treat 25 patients annually. The ECT team in Cork contribute to the International Network for Sharing Practices on Electrochemotherapy (InspECT), which is a pan -European data base aimed at producing high quality collaborative research.

Recently, trials of ECT have focused on treatment efficacy as an endpoint, confirming universally good response. However there is minimal data concerning the patient experience related to ECT treatment [10,11]. There are no specific scales to assess patients quality of life or overall experience following ECT. The aim of this study is to design a Electrochemotherapy Patient Assessment (EPA) questionnaire that assess the patient experience of ECT including any side effects.

MATERIALS AND METHODS

With ethical approval from the Clinical Research Ethics Committee, University College Cork, a retrospective study of a cohort of patients using quantitative analysis was performed. Patients with cutaneous malignancies who were registered in an ECT trial [6] at our institution were invited to participate in a telephone interview, containing questions concerning their experience with ECT therapy.

Sample and setting

A total population of 62 patients who were enrolled in a ECT for cutaneous malignancies were identified. 46 patients' met inclusion criteria, 21 patients agreed to participate and 20 participated (Figure 1).

Methods and variables

A specific EPA questionnaire was formulated for patients with cutaneous tumours, who had received ECT, regarding their patient experience and satisfaction. In the absence of dedicated quality of life and experience scores for ECT, we relied on other previously validated scoring systems assessing health status, quality of life, standard of care, patient education, pain, wound management and cosmetic outcome.

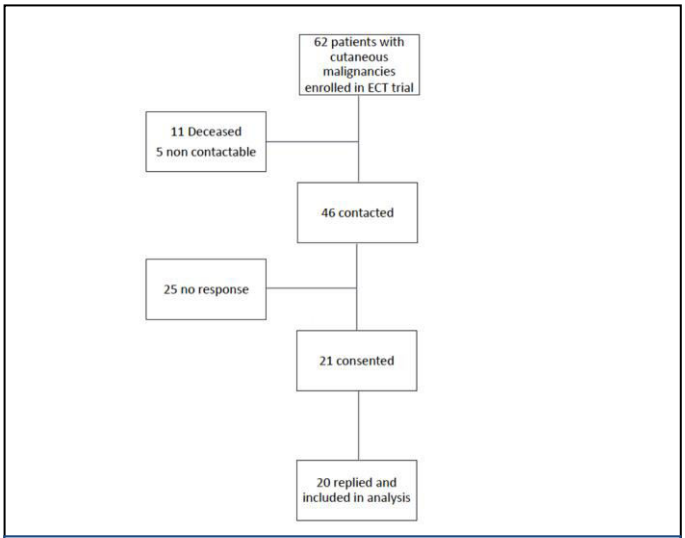

Figure 1: Flow Diagram of Electrochemotherapy in Patients with Basal Cell Carcinoma (n=62). 46 patients were contactable, 21 consented and 20 replied and returned Electrochemotherapy Patient Assessment questionnaire.

Upon review and discussion by our multidisciplinary team, we amalgamated a number of specific questions solely relevant to ECT pertaining to our patients experiences from the following sources:

1. The NHS Patient Reported Outcome Assessment questionnaires [12,13]
2. Patient Reported Adverse Outcome Questionnaire [13,14]
3. The (NHS Inpatient-Day case questionnaire) NHS Adult Inpatient Survey is part of the National Patient Survey Programme (NPSP) [15].
4. Visual Analog Score (VAS) pain score [16].

Patients were sent an invitation letter, a participant information leaflet, and consent form. Patients who returned consent forms were enrolled into the study, and contacted via phone for the telephone questionnaire. Questions were collated to make a questionnaire consisting of 19 questions concerning all aspects of patient experience of ECT treatment (Table 1). These questions collected quantitative data on an ordinal scale to allow easy comparison and to assess the patients agreement on a range of statements concerning ECT treatment.

For analysis of this data, the results from the EPA questionnaire were categorised into three categories; how well informed the patient felt (information transfer), how the patient felt while having the procedure and how tolerable any side effects were

(peri/post-procedure) and comparator questions pertaining to how likely they would be to undergo the procedure again. Initially, each of the three categories of questions were analyzed individually to give an overall impression of how each section was answered. The data of each of the three categories of questions were given total scores.

Table 1: Electrochemotherapy Patient Assessment (EPA) Questionnaire.

	Question	***Rating: 1 – Strongly disagree; 5 – Strongly agree***				
1	Where did you hear about ECT?	**GP**	**Internet**	**CCRC**	**Medical Staff**	**Other**
	Information Transfer					
2	I felt I understood enough about ECT treatment to feel comfortable	1	2	3	4	5
3	I knew what to expect before the ECT treatment	1	2	3	4	5
4	I knew what to expect after the ECT treatment	1	2	3	4	5
5	I was supported in making decisions before the ECT	1	2	3	4	5
6	I was supported in making decisions after the ECT	1	2	3	4	5
7	I knew who to contact concerning my ECT treatment	1	2	3	4	5
	Peri/ Post Procedure					
8	Please rate any pain experienced during the procedure. 1 – barely any pain, 10 – worst pain you have experienced	1 2	3 4	5 6	7 8	9 10
9	Please rate any pain experienced after the procedure. 1 – barely any pain, 10 – worst pain you have experienced	1 2	3 4	5 6	7 8	9 10
10	Any side effects experienced were tolerable	1	2	3	4	5
11	I only needed a small amount of help with my wound care	1 Lots of help	2	3	4	5 Small amount of help
12	I found the wound care easy enough to manage	1	2	3	4	5
13	Any follow up care required was tolerable	1	2	3	4	5
14	I understood what to expect and what to do during my follow up care	1	2	3	4	5
15	I am pleased with the cosmetic outcome of the treatment	1	2	3	4	5
16	I am concerned about any scarring from the treatment	1	2	3	4	5
	Comparator					
17	The ECT treatment was beneficial to my health	1	2	3	4	5
18	I would recommend ECT to others	1	2	3	4	5
19	Do you have any preference between ECT and other cancer treatments?	1 Other Tx	2	3 Neutral	4	5 ECT

Abbreviations: ECT-electrochemotherapy; GP-general practitioner; CCRC-Cork cancer research centre; Tx-treatment.

Information transfer section

The first category of questions in the EPA questionnaire was how well the patient felt about ECT informed. There were six questions addressing this in the EPA questionnaire, each containing a statement, with a corresponding ranked answer out of five; one being strongly disagree and a negative response, and five being strongly agree and a positive response. These questions addressed whether patients had enough information to feel comfortable with the treatment, whether they knew what to expect pre and post treatment, whether they felt supported in their decisions and had suitable points of contact. There was a maximum of five for each

question, which across the six questions, made a total out of possible 30.

Post/ Peri-procedure section

The second category of questions covered any side effects from the procedure and any pain experienced. Questions were once again ranked on a 1-5 scale. There were nine questions in this category thus making a total of 45.

Comparator section

The third category of questions is that of the comparator questions. There are three questions in this category, addressing whether the patient thought the treatment was beneficial, whether they would recommend the treatment to others, and whether they have any preference between ECT and other cancer treatments.

RESULTS

Information transfer section

Across all six of the questions (Figure 2, Questions 2-7 on Table 1) in this category, there was a high level of satisfaction with the level of information provided to the patient; 12/20 (60%) strongly agreed that they understood ECT before treatment. Half of the patients knew what to expect before treatment and 11/20 (55%) knew what to expect after treatment. The total information score was high, with 13/20 (65%) of patients achieving ³28/30 which is a very positive result, and 6/20 (30%) of patient achieving the total score of 30 for information satisfaction. There were only a few outliers across the six questions (Figure 2).

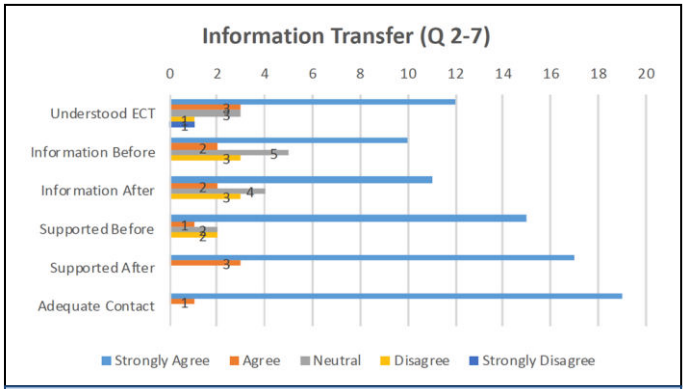

Figure 2: Information Transfer Questions Bar Graph (Questions 2-7 of Electrochemotherapy Patient Assessment (EPA) Questionnaire).

Abbreviations: ECT-electrochemotherapy

Post/ Peri-procedure section

Across all nine questions (Questions 8-16), the responses were generally positive, with many highly ranked answers. There was again a positive overall response, a small range of responses with minimal outliers. The maximum score was 55 with 35% of patients achieving maximum score. 50% of patients reported [3] 54 giving a very positive overall response to side effects experienced and follow up care. Figure 3 (questions 10-16 in Table 1) depicts post/ peri-procedure outcome measures other than pain scores.

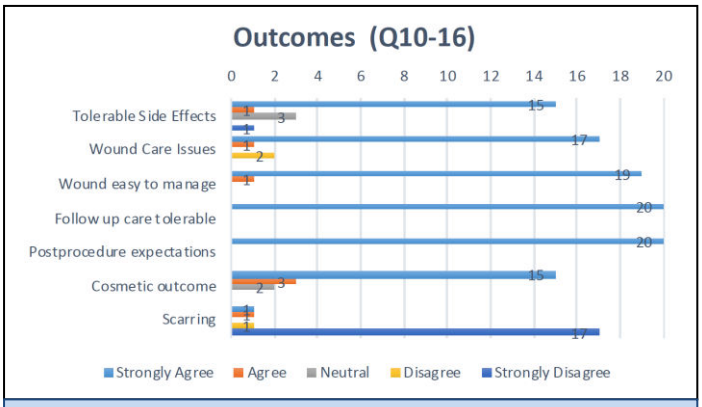

Figure 3: Outcomes Questions Bar Graph (Questions 10-16 of Electrochemotherapy Patient Assessment (EPA)).

Abbreviations: VAS-visual analogue score; ECT-electrochemotherapy

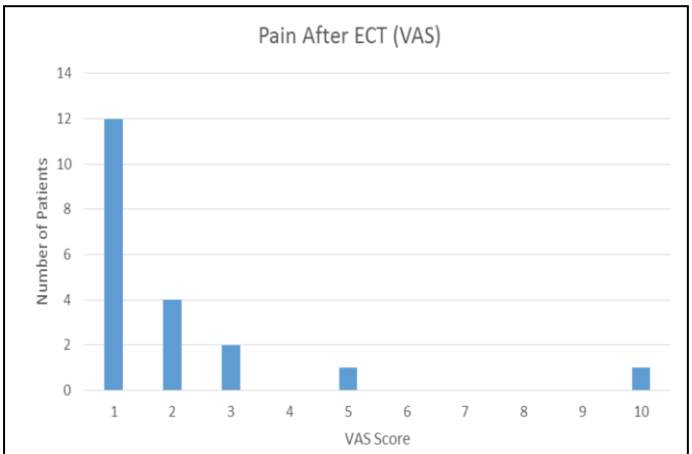

Figure 4: Post Procedure Pain Bar Graph using Visual Analog Score Pain Scale (Question 9 of Electrochemotherapy Patient Assessment (EPA)).

Both peri and post procedure pain were recorded. Peri procedure pain was recorded as 1/10 on VAS pain score by all patients. Post-procedural pain was assessed (Figure 4) with the overall response being positive, 60% of patients reported

the lowest possible pain grade of 1 on the visual analogue scale. 90% reported grade 3 or less (20% reported grade 2, 10% reported grade 3). 5% (one patient) reported grade 4, and 5% (1 patient) reported grade 10. Of note, the one patient outlier who reported grade 10 on the visual analogue scale had electrochemotherapy treatment to a periorbital location and reported severe localised pain.

Comparator section

These questions were positively answered (Figure 5, Questions 17-19 on Table 1), with 20/20 (100%) of patients reporting that they strongly agreed that ECT was beneficial to their health.17/20 (85%) of patients would recommend ECT to others and 15/20 (75%) preferred ECT to other cancer treatment options.

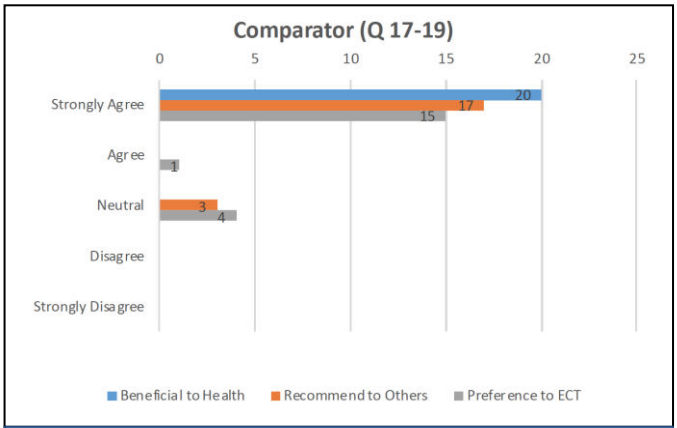

Figure 5: Comparator Questions Bar Graph (Questions 17-19 of Electrochemotherapy Patient Assessment (EPA)).

Abbreviations: ECT: Electrochemotherapy

DISCUSSION

It is essential to evaluate patient experience in any evaluation of the efficacy of cancer care. Whist there has been reported improvement in patients quality of life following ECT, this has not been evaluated using ECT specific scales [3,6]. Here we evaluate an ECT specific EPA questionnaire to assess overall patient experience which we believe may have a use in assessing patient experience. In this selected population, the overall patient experience of ECT is very positive, with most patients likely to undergo the procedure again and preferring ECT to other treatment options. All patients felt that ECT was beneficial to their health.

The results above can be broken down into the three categories of questions. The first category, concerning how well informed the patient felt about ECT, both before and after the procedure was answered positively across patients. However in our patient cohort, our questionnaire identified a suboptimal level of knowledge of what to expect before and after ECT treatment. This lead to the development of new illustrated and written patient information leaflets which are now discussed with our patients before and after the procedure.

The second category concerned any side effects experienced, and the tolerability of any follow up care. Of note, the outlier result of grade 10 reported by one patient was experienced after periorbital ECT. Post procedure pain may be influenced by pre-existing pain and tumour ulceration and identification of these clinical parameters can help analgesia planning [17].

The third category included the three comparator questions, assessing the patients overall view of their experience of ECT. The first of these questions addressed whether patients felt the procedure was beneficial to their health, and 100% of patients reported the highest possible grade of 5 in agreement with this statement. This question gives a good subjective view of the procedure from the patient's opinion, and whether they felt the procedure was worthwhile undergoing. The second question addressed the patient's likelihood to recommend this treatment option to others and 85% of patients reported the highest level of recommendation of the treatment. This also gives a good indication as to the patient's opinion of ECT and whether they found it a tolerable and beneficial experience. The third question asked whether patients preferred ECT to other cancer treatments, and 75% of patients reported "strongly agree" as their answer, which represents full preference of ECT, and 25% reported indifference between treatments at "neutral" or "agree" representing slight preference of ECT to other cancer treatments. No patients preferred other cancer treatments over ECT. The results from these three comparator questions combined gives good support to the likelihood of patients willingness to undergo ECT again.

STRENGTHS

The study has outlined an ECT specific set of patient experience questions that could be used in further research. It addressed important clinical factors and information when offering ECT to a patient, and may be used for ECT in other oncology areas.

The answers were recorded as ranked answers, which enabled comparison between answers and quantitative statistical analysis to take place.

LIMITATIONS

A major limitation of this study was that this is a selected retrospective population and results are open to bias. Of the 62 patients who were eligible, 20 patients were included which is a significant reduction in patient population studied. The average age of patients in the original study was 67 and thus reasons for inability to enrol in our analysis included patient mortality, comorbidities and age during the 5 year clinical trial [6]. It is probable that this lead to significant bias with our population of 20 patients including healthier patients with better outcomes. A questionnaire at an early post-operative outpatient appointment may have reduced this bias. Our results need to be interpreted with this in mind. It is possible that this may have had an effect on the results, as only those who have either improved, or at least not deteriorated significantly since the procedure have been able to respond.

Another potential confounding factor of the responses was the fact that the time between ECT treatment and phone interview varied. Recollection of the treatment and their current perception of ECT would therefore influence patient answers.

Another possible limitation, and a point of consideration, was that of healthy-user bias. There is a possibility that those who recovered, experienced a more successful result with ECT treatment and therefore may be more likely to respond and consent to be included in this study, as they may have a bias to wanting the procedure to become a mainstay treatment option. However, this effect would have been reduced by the validity and reliability of the questionnaires combined to create the questionnaire used in the study.

Another limitation was occasional difficulties with the patient's understanding of the ranked answer system over the phone. This is a limitation of phone interviews in general. In future, it may be easier to bring the questionnaires to a setting such as an outpatient's clinic, where the communication may be easier. The patient response rate may also be higher in this setting.

CONCLUSION

In this study population, ECT is a very well-received procedure and patients have a positive recollection of the treatment. This report has helped to provide useful insight into the patient experience of ECT. With validation in a larger prospective patient cohort, our EPA questionnaire may be of benefit to guide clinicians offering ECT as a treatment option to their patient with cutaneous malignancies.

The authors have no conflicts of interest to disclose. All authors contributed equally to research.

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