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Title: Clinical assessment of chemotherapy induced peripheral neuropathy: A discrete choice experiment of patient preferences

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Declaration

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As part of the development of the online survey, cognitive interviews were conducted. Participants were recruited from Breast Cancer Network Australia (BCNA) Review and Survey Group. This is a national, online group of Australian women living with breast cancer who are interested in receiving invitations to participate in research. We acknowledge the contribution of the women involved in the Review and Survey Group who participated in this project.

Conflicts of interest/competing interests (include appropriate disclosures)

n/a

Ethics approvals

Ethics approval was received from the Human Research Ethics Committee, University of Technology Sydney (ETH19-3464 and ETH18-2507) for this study.

Consent to participate/publication

On the information page, respondents were given the following information in regards to participation and publication.

What will happen to information about me?

Submission of the online questionnaire is an indication of your consent. By continuing to answer the survey questions you consent to the research team collecting and using personal information about you for the research project. All this information will be treated confidentially. No identifying information will be collected as part of study nor will the researchers have access to identifying information. The data will be stored securely.

Data collected will be used for the purpose of this research project and potentially in future research projects that aim to improve on the methods used to design questionnaires of this general type. In all instances, results from the survey will be published in a form that does not identify you

We plan to discuss the results among the researchers involved in this project and with our partner organisation, the IN FOCUS Study. IN FOCUS are interested in using these results to inform the development of a potential peripheral neuropathy assessment tool. As mentioned previously, no identifying information will be collected and in any publication, results will only be in the form of summary quantitative information.

Availability of data and material (data transparency)

Please contact the authors for further details.

Code availability (software application or custom code)

Software application: R Studio

Authors' contributions (optional)

n/a

Abstract (150-250 words)

Purpose: Up to 40% of cancer patients treated with neurotoxic chemotherapies experience chemotherapy-induced peripheral neuropathy (CIPN). Currently, there is no gold standard assessment tool for CIPN and there is little information in the literature on patient preferences for such assessments. This study aims to address this gap by identifying the features of a CIPN assessment tool that cancer patients' value.

Methods: An online Discrete Choice Experiment (DCE) survey of neurotoxic chemotherapy-treated patients was implemented. Respondents completed 8 choice questions each. In each choice question, they chose between two hypothetical CIPN assessment tools, each described by six attributes: impact on quality of life; level of nerve damage detected; questionnaire length; physical tests involved; impact on clinic time; impact on care.

Results: The survey was completed by 117 respondents who had a range of cancers of which breast cancer was the most common. Respondents favoured an assessment tool that includes a physical test and that asks about impact on quality of life. Respondents were strongly opposed to clinicians, alone, deciding how the results of a CIPN assessment might influence their care especially their chemotherapy treatment. They were concerned about small changes in their CIPN, independent of clinical relevance. Respondents were willing to add half an hour to the usual clinic time to accommodate the CIPN assessment.

Conclusion: The findings of this DCE will assist clinicians in choosing an assessment tool for CIPN that is satisfactory to both clinician and patient.

Keywords (4-6 words): chemotherapy induced peripheral neuropathy, patient preferences, discrete choice experiment, CIPN assessment tools

Introduction

Chemotherapy induced peripheral neuropathy (CIPN) has been estimated to affect 30-40% of patients treated with neurotoxic chemotherapy agents such as taxanes, platinum compounds, vinca alkaloids, thalidomide and bortezomib [1-5]. CIPN can lead to impairments in the detection of touch, vibration and/or proprioception (awareness of position and movement of the body) [5]. Symptoms can include, but are not limited to, paraesthesia or 'pins and needles', numbness, loss of balance and difficulty with fine motor tasks [6,4,5].

CIPN symptoms can have a significant negative impact on the quality of life of cancer patients and survivors [7]. For instance, if CIPN symptoms manifest as numbness in the hands, daily activities such as cooking or cleaning become cumbersome and even hazardous. The chances of falling are increased if a patient experiences loss of balance or numbness in the feet. For some patients, CIPN symptoms have been reported to persist years after chemotherapy treatment has ceased [1-3]. For these reasons, assessing for the presence of CIPN and the development of CIPN symptoms while patients are undergoing chemotherapy treatment can lead to delays or dose reductions in chemotherapy and is also an important part of survivorship planning.

Despite this, there is no gold standard CIPN assessment tool or any guidelines for how cancer patients should be routinely assessed [4,5]. A recent systematic review by McCrary et al. [4] identified 117 unique CIPN assessment tools reported in the literature. In order to identify optimal assessment tools, a two stage Delphi survey was conducted with a multidisciplinary group with expertise relevant to the assessment of CIPN. While patient reported outcome questionnaires were rated highly for comprehensiveness, depth and feasibility, no consensus was reached about which CIPN assessment tool could be considered the gold standard.

In identifying a 'best' CIPN assessment, it is important to consider what aspects are relevant and meaningful to both clinician and patient. Increasingly there is greater emphasis on the importance of patient reported outcomes in toxicity assessment, to better quantify symptom burden from the patient perspective. However, there is little to no information in the literature about what patients consider relevant and important when they are assessed for CIPN. The aim of this study is to address this gap. Specifically, this study utilises a discrete choice experiment (DCE) to identify the features of a CIPN assessment tool that cancer patients' value. DCEs are a stated preference technique that has used across many disciplines including marketing, transport and economics. In particular, they have gained prominence within the field of health economics as a tool to measure people's preferences for health programs and policies [8,9].

Methods

Study design

The DCE was designed to identify features of a CIPN assessment tool that patients consider important and to estimate the relative value they place on these features. The DCE was implemented as an online survey via the online platform, Survey Engine. The survey was launched on the 9th of October 2019 and closed on the 11th of December 2019. Ethics approval was received from the Human Research Ethics Committee, University of Technology Sydney (ETH19-3464 and ETH18-2507).

Sample and inclusion criteria

Participants invited to complete the DCE were obtained from a sample of neurotoxic chemotherapy-treated cancer patients enrolled in a larger research survey [10] who had agreed to be contacted for future research. Participants were eligible to participate in the DCE if they had a diagnosis of cancer and had received chemotherapy treatment for their cancer. Participants self-reported demographic and clinical characteristics including sex, age and cancer type.

Development of choice questions

Identification of attributes and levels

In this DCE, respondents were asked to complete a series of choice questions. In each choice question, respondents were asked to choose between two possible CIPN assessment tools. Each potential CIPN assessment tool was described by 6 attributes. Each attribute is presented at one of a set number of assigned levels, with different presented levels in different choice questions. Preference information is generated because respondents choose their preferred CIPN assessment tool from each of the choice questions shown to them. This preference information allows the identification of the attribute levels that patients most value [11].

The initial identification of attributes and levels to be used in the choice questions was based on a prior systematic review and Delphi survey of CIPN assessment tools McCrary et al. [4] .These were further refined through feedback from clinicians and patient representatives [10] to develop the initial draft survey including initial choice questions.

Qualitative methods
The draft choice questions and overall survey were then refined based on a discussion session with DCE experts and health economists, and piloted in a set of cognitive interviews with cancer patients, using methods based on "think aloud" responses [12-14]. Participants were asked to verbalise their thinking process as they read and completed the draft version of the survey, with an interviewer present. Cognitive interviews were conducted with six current and former breast cancer patients recruited from the Breast Cancer Network Australia (BCNA). Breast cancer patients were considered suitable interviewees because they are often treated with neurotoxic taxane-based chemotherapy [15,16]. The final set of attributes and levels were based on the feedback received from the cognitive interviews and focus group session (see Table 1).

Table 1 Attributes and Levels

Attribute	**Levels**
Symptoms and Usual Activities	The assessment asks about your symptoms
	The assessment asks about how your symptoms impact on your usual activities
Level of Detail	The assessment will only pick up major nerve damage and large changes in your condition
	The assessment will pick up minor and major nerve damage, including small changes in your condition whether it is important or not
Questionnaire	No questionnaire
	3 questions to answer
	12 questions to answer
	20 questions to answer
Physical Test/s	No physical test
	Clinician administered test e.g. sharp and dull test, tuning fork test
	Patient activity based test e.g. peg board test, sway test
	Technical test e.g. nerve conduction studies
Impact on Clinic Time	During usual clinic time
	Usual clinic time plus 10 minutes extra
	Usual clinic time plus 30 minutes extra
	You require a separate appointment, which can take up to 60 minutes
How will results influence care/treatment	The doctor will discuss the results with you, and together you can decide what they mean for you and your care/treatment
	The doctor may change your general care (e.g. medications to help relieve symptoms, physiotherapy, walking aids) if there are significant changes in your condition over time
	The doctor may change your chemotherapy/cancer treatment if there are significant changes in your condition over time

Final DCE Survey
The final survey consisted of four main sections. A copy of the survey can be found in the supplementary material. Screening ensured that respondents met the eligibility criteria; that is, they had a diagnosis of cancer and had received chemotherapy treatment for their cancer. Eligible respondents who chose to continue the survey were presented with background information that explained CIPN and the attributes used in the choice questions. Instructions on how to complete the choice questions were also provided. Respondents were randomly assigned to one of four blocks of 8 choice questions. Each choice question began with the same

context scenario that respondents were asked to imagine as they made their choice. Figure 1 provides an example of the context scenario and a choice question. After completing all 8 choice questions, respondents were asked to evaluate the ease of undertaking the choice questions. The final section consisted of questions related to their cancer and general demographics.

Figure 1 Example of a Choice Question

We would like you to imagine that you have been given a chemotherapy drug where peripheral neuropathy is a known side effect. Imagine that during the time you are undergoing chemotherapy, you will also be assessed for peripheral neuropathy. In addition to talking with your clinician, you may be asked to complete a questionnaire prior to your appointment and/or undergo some physical test/s during your appointment.

If these were your only options, which peripheral neuropathy assessment tool would you prefer? A or B?

	Assessment A	Assessment B
Symptoms and usual activities	The assessment asks about how your *symptoms impact on your usual activities*	The assessment asks about your *symptoms*
Level of detail	The assessment will pick up *minor and major nerve damage*, including *small changes* in your condition whether it is important or not	The assessment will pick up *minor and major nerve damage*, including *small changes* in your condition whether it is important or not
Questionnaire	12 questions to answer	20 questions to answer
Physical test/s	No physical test	Patient activity based test e.g. peg board test, sway test
Impact on clinic time	Usual clinic time plus 30 minutes extra	Usual clinic time plus 10 minutes extra
How will results influence care/treatment	The *doctor will discuss* the results with you, *and together* you can decide what they mean for you and your care/treatment	The *doctor may change your chemotherapy/cancer treatment* if there are significant changes in your condition over time
Which would you choose?	○ Assessment A	○ Assessment B

Choice questions design

A generator- developed experimental design was used, as described in Street, Burgess [17], for instance, and implemented using code written by Burgess [18]. Details of how the choice questions were constructed are available as part of the supplementary material.

Statistical analyses

All analyses were conducted in R Studio [19] using the gmnl package [20]. A mixed logit (MXL) model was estimated as it allows for heterogeneous preferences. In a MXL model each respondent is allowed to have their own coefficient estimate which has been assumed to be drawn from a normal distribution. The MXL estimates the parameters of this underlying distribution. To decide on the MXL model, initially a model allowing all parameters to be random was estimated. Alternative specifications were then tested. The final model assumed parameters that had a significant standard deviation were random. The preferred model was chosen based on the Akaike's Information Criterion (AIC) and the Bayesian Information Criterion (BIC).

MXL model results are available as part of the supplementary material. To interpret findings, MXL model coefficients were used to calculate choice probabilities.

Results

Sample

In total, 131 respondents commenced the survey and 117 respondents completed the survey. Of the non-completers, two were screened out and 12 chose to discontinue the survey. Error! Reference source not found. presents the key demographic characteristics of respondents.

Table 2 Summary of Demographics

Demographics (n= 117)	No.	%
Age in years		
Median	64	
SD	10	
Gender		
Female	91	78%
Male	26	22%
Education level		
No school certificate/ other qualifications	2	2%
Secondary school	19	16%
Trade or apprenticeship	5	4%
TAFE or vocational college	35	30%
Bachelor's degree	33	28%
Postgraduate degree	23	20%
Years since first cancer diagnosis		
≤ 5 years	46	39%
6 to 10 years	45	38%
>10	26	22%
Cancer Type (can select more than one)		
Breast cancer	56	39%
Bowel cancer	28	20%
Myeloma	14	10%
Other	34	24%
Other (unspecified)	10	7%
Type of chemotherapy drugs received (can select more than one)		
Docetaxel (Taxotere, Dotax, Oncotaxel)	28	17%
Oxaliplatin (Eloxatin, Oxalatin, Oxaliccord, Xalox, FOLFOX, XELOX)	26	16%
Paclitaxel (Taxol, Anzatax, Plaxel, Abraxane)	24	14%
Carboplatin (Carbaccord)	12	7%
Bortezomib (Velcade)	10	6%
Cisplatin (cisplatinum, Platinol)	9	5%
Thalidomide (Thalomid)	9	5%
Lenalidomide (Revlimid)	9	5%
Pomalidomide (Pomalyst)	6	4%
Vincristine	3	2%
Vinblastine	2	1%
None of above	6	4%
I don't know	22	13%

The median age of respondents was 64, and most were females (78%). The high proportion of females reflects the large number of breast cancer patients in the sample. Respondents were generally well educated, with 48% of the sample being university educated.

For the majority of respondents, it had been 10 years or less since they were first diagnosed with cancer. In terms of cancer diagnosis, breast cancer, bowel cancer and/or myeloma were the most frequently selected diagnoses. Fifteen per cent of respondents were receiving chemotherapy treatment at the time of the survey.

The majority of respondents (57%) had completed their treatment within the last five years. The majority of patients reported receiving chemotherapy associated with CIPN, with only six of the 117 respondents reporting not receiving a chemotherapy drug associated with the development of CIPN symptoms. However, 22 respondents indicated that they were unsure of the drug they were treated with. Thirty-nine per cent of respondents stated they recalled being assessed for CIPN previously, which suggests that a large minority of respondents had at least some knowledge or experience of being assessed for CIPN.

Influence of attributes

Table 3 shows those attributes that the MXL modelling found to be homogeneous across respondents. Results are described in terms of the probability that a particular level would be chosen, holding all other attributes constant. Using the attribute 'Symptoms and Usual Activities' as an example, holding all other attributes constant, the modelling estimates that there is a 60% probability that respondents would choose an assessment which asks about how symptoms impact their usual activities and a 40% probability that respondents would choose an assessment which asks only about their symptoms. In other words, respondents prefer an assessment that asks about the impact of symptoms rather than one that asks about symptoms alone.

Similarly, respondents would be more likely to choose an assessment that contains a questionnaire of any length as opposed to one that contains no questionnaire. In addition, respondents are indifferent between a shorter or longer questionnaire as there is a similar probability of each questionnaire length being chosen. Respondents were also more likely to choose an assessment that contained a physical test with a patient activity based test most likely to be chosen.

Table 3 Attributes with no preference heterogeneity

Attributes with no significant standard deviations	**Choice probability**
Symptoms and Usual Activities	
The assessment asks about your *symptoms*	0.405
The assessment asks about how your *symptoms impact on your usual activities*	0.595
Questionnaire	
No questionnaire	0.181
3 questions to answer	0.276
12 questions to answer	0.268
20 questions to answer	0.276
Physical Test/s (PhyT)	
No physical test	0.092
Clinician administered test e.g. sharp and dull test, tuning fork test	0.263
Patient activity based test e.g. peg board test, sway test	0.381
Technical test e.g. nerve conduction studies	0.265

Table 4 contains the attributes with at least one level that the modelling found to be heterogeneous across respondents. For the attribute 'Level of Detail', on average, respondents were strongly in favour of an assessment that picks up small changes in their condition whether it was important or not (85%). The choice probability distribution emphasises this preference with 75% of respondents having a 59% or stronger probability of choosing this level. In other words, although respondents had varying preferences, this was in relation to the strength of positive preference for this level rather than indicating differing preferences.

Examining 'Impact on Clinic Time', respondents, on average, were least likely to choose an assessment that required a separate appointment; this option had a probability of about 18%. However, the choice probability distribution was quite variable, and 25% of respondents had a probability of choosing an assessment that required a separate appointment, compared to the other levels, of 46%.

Table 4 Attributes with preference heterogeneity

Attributes with significant standard deviations	Choice probability	Choice probability quantiles		
Level of Detail	**Mean**	**0.25**	**0.5**	**0.75**
The assessment will only pick up *major nerve damage* and *large changes* in your condition	0.150	0.409	0.148	0.041
The assessment will pick up *minor and major nerve damage*, including *small changes* in your condition whether it is important or not	0.850	0.591	0.852	0.959
Impact on Clinic Time				
During usual clinic time	0.275	0.317	0.276	0.180
Usual clinic time plus 10 minutes extra	0.305	0.352	0.306	0.199
Usual clinic time plus 30 minutes extra	0.242	0.279	0.243	0.158
You require a separate appointment, which can take up to 60 minutes	0.177	0.052	0.176	0.462
How will results influence care/treatment				
The *doctor will discuss* the results with you, and *together* you can decide what they mean for you and your care/treatment	0.460	0.753	0.556	0.341
The doctor *may change your general care* (e.g. medications to help relieve symptoms, physiotherapy, walking aids) if there are significant changes in your condition over time	0.236	0.116	0.237	0.386
The doctor *may change your chemotherapy/cancer treatment* if there are significant changes in your condition over time	0.208	0.131	0.207	0.273

Finally, for the attribute 'How will results influence care/treatment', holding all other attributes constant, the modelling estimates there is a much greater probability, on average, of respondents choosing the situation where the doctor and patient decide together what assessment results mean compared to the situations where the doctor alone decides on changes to care or treatment. Respondents were particularly sensitive to the situation where the doctor may decide to change the treatment without consulting the patient. Although respondents had varying preferences for this particular level, the choice probability distribution had a relatively narrow range with 75% of respondents having a 27% or lower probability of choosing an assessment with such a feature.

Discussion

The results of this study provide a basis for the design of a CIPN assessment tool which reflects patients' preferences. In particular, research participants indicated that CIPN assessment tools should include some measurement of the impact of symptoms on daily activities. Respondents also prefer to know about even small changes in their CIPN – whether or not they are clinically meaningful. The results also indicated that the inclusion of a physical test in a CIPN assessment tool is important, in particular, physical tests that involve patients having an active role would be preferred e.g. pegboard test, sway test. This suggests that respondents prefer a test that is objective but also involves patient input. Respondents also generally preferred the inclusion of a questionnaire, and were not particularly concerned about the length of the survey. In general, although respondents were willing to allocate additional time for a CIPN assessment, most were not willing to attend a separate appointment. A minority of respondents indicated they would like more focus on CIPN and preferred a separate a separate appointment, up to 60 minutes long, devoted to it.

Regardless of the CIPN assessment tool, respondents strongly preferred shared decision-making. It was particularly important to respondents that they be involved in deciding how the CIPN assessment results would influence their general care and especially their chemotherapy treatment. Respondents were particularly opposed to the clinician making solitary decisions regarding the impact of assessment results on their chemotherapy treatment. This may reflect the importance patients place on outcomes such as the progress of cancer treatment as well as the impact of side effects. The outcomes of cancer treatment have been shown to be an important attribute for consideration in cancer treatment decisions by patients. In a recent systematic review by Bien et al. [21] examining patient preferences for attributes related to cancer treatment, outcome attributes including progression-free survival and side effects of treatment were shown to be significant attributes for consideration by patients. Similarly, semi-structured interviews with women with breast cancer highlighted the importance of treatment completion and demonstrated that patients consider the effectiveness of treatment when reporting CIPN symptoms to clinicians (Salgado et al 2020). The fear of treatment discontinuation was identified as a deterrent to reporting CIPN symptoms, while sufficient appointment time and a positive relationship with the

oncology team promoted CIPN symptom reporting [22]. Improved patient–clinician communication has also been highlighted as an important consideration to improve CIPN assessment, with CIPN discussed in less than 50% of audio-recorded clinical visits with patients undergoing neurotoxic chemotherapy [23]. Combined with our results, this suggests that systematically improving assessment and communication of CIPN symptoms leading to joint clinical decision-making would be a priority for patients.

As far as the authors are aware, this is the first study to formally examine patient preferences for the design of a CIPN assessment tool. As such, the results add a unique and important perspective to the design of a CIPN assessment tool. The study recruited respondents who had been diagnosed with cancer and had chemotherapy previously. In addition, 39% of respondents reporting recall of having previously been assessed for CIPN. However, it is acknowledged that the sample size was small (117 respondents in total). Further, given that the respondents had already participated in CIPN research, they may have been particularly motivated to seek CIPN assessment and more likely to have personal experience of CIPN which could affect their preferences. Finally, the sample was dominated by female breast cancer patients. While this cohort is frequently treated with neurotoxic chemotherapy and typically represents a prominent sample in CIPN research, their preferences for CIPN assessment may not reflect those of cancer patients more generally. Replication of this study in a larger cancer population or in other relevant populations would be valuable in validating the results. Comparison of findings with a general population sample would also be useful to understand the differences or similarities in preferences with a population that has no personal experience with CIPN or its assessment tools.

While there has been a strong promotion of patient reported outcomes (PROs) as more directly relevant to the patient experience, this study demonstrates that patients also assign value to objective and instrumental assessment tools. In comparing the current findings to the CIPN assessment tool literature, it is interesting to note that in McCrary et al. [4] three of the six assessments which were considered the 'best' based on different assessment criteria, were patient reported outcomes (PRO). The other three included a clinical grading scale and a composite of clinical grading and objective measures. Findings from the current study indicate that patients would respond positively to objective measures and lend support to their inclusion as a core aspect of the CIPN assessment process. This would support the call for multimodal assessment strategies including both PROs and objective grading of neuropathy [24]. In particular, a key theme that emerged from the results was a preference for both patient and clinician input. This is demonstrated by the preference for a physical test i.e. an objective measure where patients were actively involved and also by a strong preference for patient and clinician involvement in decisions regarding care or treatment.

Much of the literature on CIPN assessment tools has focused on the psychometric properties, comparison with other tools and validation in cancer populations [25-28]. The current study contributes to a complementary area of literature that aims to incorporate patients' perspectives into the process of evaluating the validity and significance of different CIPN assessment tools. The inclusion of an attribute to assess patient preferences for the usage of the results of a CIPN assessment tool has highlighted strong patient preferences for shared decision-making. Accordingly, findings from the current study can assist clinicians in selecting a CIPN assessment tool to use in their routine clinical practice.

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