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Development of a Trauma-Specific Quality of Life Measurement

John Paul Wanner, BS¹, Terri deRoos-Cassini, PhD¹, Lisa Kodadek, MD¹, and Karen Brasel, MD¹

¹Division of Trauma and Critical Care, Department of Surgery, Medical College of Wisconsin, Milwaukee, WI 53226, USA

Abstract

Background—Complex, disease-specific factors help to determine post-traumatic quality of life, but current practice utilizes outcome measures generated from the general population. Trauma survivorship has grown rapidly while defining the factors that influence post-traumatic quality of life has lagged. This study sought to develop a valid and reliable trauma-specific quality of life measure to help guide future post-traumatic research and clinical care.

Methods—Qualitative data were collected from adult trauma patients and their caregivers (Phase 1). Subsequent analysis of these data resulted in the development of a 59-item quality of life (QoL) questionnaire. The 59-item trauma-specific QoL questionnaire (T-QoL) was then administered to adult trauma patients (n=394) and a factor analysis was conducted. The validity of the final TQoL measurement tool was assessed (n=111) using the Medical Outcomes Study 36-Item Short Form Health Survey version 2 and the PTSD Checklist-Civilian Version (Phase 2).

Results—A 5-component structure using 43 items appeared to best represent the data. The 5 components included: Emotional Well-Being, Functional Engagement, Recovery/Resilience, Peri-Traumatic Experience, Physical Well-Being. Four of the five components were found to have strong Cronbach's alpha scores (>0.7), demonstrating consistent inter-item reliability. All subscales of the T-QoL correlated negatively with the PCL-C ($p < .01$), demonstrating that as the T-QoL increases, the likelihood of PTSD decreases. The physical well-being subscale of the T-QoL correlated significantly with the SF-36v2 PCS as did the emotional well-being subscale with the SF-36v2 MCS ($p < .05$).

Conclusions—This study utilized the experiences of trauma victims and their informal caregivers to develop a five-component, 43-item questionnaire with domains that are unique to

Correspondence John Paul Wanner, Medical College of Wisconsin, Surgery/Trauma & Critical Care, 9200 W. Wisconsin Ave, Milwaukee, WI 53226, Fax: 414-805-8641, Phone: 440.487.8215, ; Email: jwanner@mcw.edu.

Terri deRoos-Cassini – tcassini@mcw.edu

Lisa Kodadek - lkodade1@jhmi.edu

Karen Brasel – brasel@ohsu.edu

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Author Contribution

JPW executed the literature search, statistical analysis and drafted the manuscript. TD participated in the design of the study, lead statistical analysis and assisted with drafting of the manuscript. LK participated in the study design, data collection and editing of the manuscript. KB supervised and participated in the design of the study, statistical analysis and drafting of the manuscript.

trauma populations. Its accuracy and validity was confirmed using the PCL-C and the SF-36v2. We believe that the TQoL represents a novel and sensitive tool that can be used by trauma professionals to positively impact research efforts and clinical care.

Level of Evidence—Level II – Prognostic and Epidemiological

Keywords

Quality of life; measurement tool; trauma-specific

Background

Advances in trauma-specific medical care, coupled with an expanding population, have culminated in a trauma survivorship whose needs and care-related issues are only beginning to be understood.¹ From 2001 to 2010, the Centers for Disease Control (CDC) estimates the total number of annual, nonfatal trauma injuries to have increased from 58.1 million to 63.9 million.² These injuries account for the loss of more disability-adjusted life years than any other disease, but many of the instruments and measurements used to assess outcome in this population are non-standardized or are adapted from other populations.^{3,4} Additionally, the acute cost associated with each patient, when medical care and work loss are considered, is around \$66,150 or \$406 billion annually.^{1,5} Thus, it is essential that a concerted effort be made to improve post-traumatic quality of life, thereby easing the current and future burden of the disease.

Previously, quality of care was predicated solely on the clearly defined and measurable outcome of mortality. However, as survivorship has increased, it has become apparent that the road to functional recovery is much more complex, requiring the comprehensive application of a bio-psychosocial view of care. Research, driven by such a view of care, has resulted in an increased appreciation for the necessity of multi-faceted quality of life (QoL) measurements.⁶⁻¹⁰ QoL can be measured using both generic and disease-specific instruments. Generic instruments allow measurement of population health and comparison across populations, while disease-specific instruments are more sensitive to change in an individual patient.

While specific QoL instruments exist for a wide range of diseases and populations, the development of a trauma-specific instrument is in its infancy. Historically, QoL within the trauma population has been predominately assessed using two generic measurements: The Quality of Well-Being Index (QWB) and the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36).¹¹⁻¹⁴ While both generic instruments have provided valuable information about the QoL of trauma patients in general, they lack the specificity required to accurately predict QoL post-trauma in individual patients.

The importance and usefulness of a trauma-specific QoL measurement that attempts to accurately apply a bio-psychosocial view of patient care is being increasingly recognized.¹⁵⁻¹⁷ Using the psycho-social experience of traumatic patients and their caregivers as a foundation, the aims of this study were to develop and pilot a trauma specific QoL tool informed by trauma patients and their caregivers.^{18,19}

Methods

This study consisted of two phases. Initially, qualitative data were collected from adult trauma patients and their caregivers (Phase 1). Subsequent analysis of the data resulted in the development of a 59-item QoL questionnaire. In Phase 2, the 59-item trauma- QoL (T-QoL) questionnaire was then administered to adult trauma patients (n=394) and a factor analysis was conducted to reduce the number of items and to determine possible sub-factors of trauma QoL. The validity of the final QoL measurement tool was assessed in a subset of these patients (n=111) using the Medical Outcomes Study 36-Item Short Form Health Survey version 2 (SF-36-v2) and the PTSD Checklist-Civilian Version (PCL-C).

Recruitment of Focus Groups (Phase 1)

Focus groups were composed of a non-random, purposeful sample of adult trauma patients as well as their spouses, family members or others who served as informal caregivers. Trauma patients (n = 26) were recruited by phone within 12 months of blunt or penetrating injury, as identified by the trauma registry at a Level 1 Trauma Center. The informal caregivers (n = 11) of patients who sustained a blunt or penetrating injury within the preceding 12 months were also recruited. Excluded were individuals with head injury resulting in impaired communication, individuals under age 18, and incarcerated individuals. No patients or caregivers were excluded on the basis of gender, race, or ethnicity. Participants were asked to complete one focus group lasting no longer than 2 hours. All study activities were approved by the Institutional Review Board of the participating institution and written consent was obtained from all participants.

Qualitative Data Collection (Phase 1)

Over the course of six months, four patient focus groups and three caregiver focus groups were held. Each group met for one to two hours and consisted of no more than ten participants. Questionnaires were administered to gather basic information such as age, sex, ethnicity, type of trauma, time since injury, involvement in litigation, the life impact of the trauma experience, and the impact upon various areas of psycho-social importance. Interview questions were developed through a collaboration of healthcare providers and researchers with experience in caring for trauma patients and/or conducting focus group research. (The patient and caregiver participant questionnaires are available upon request.) Each focus group was audio recorded, allowing all comments to be collected without any initial analysis or grouping, and responses were generated in an open discussion format.

Data Analysis (Phase 1)

Data analysis began with written transcription of the audio recordings from each focus group. These qualitative data were then coded using a grounded theory approach. The patient and caregiver data were analyzed separately. Two members of the research team independently coded each patient transcript. The research team then convened to review each code and determine inter-coder agreement. Deliberation established a final code for each phrase or idea. Similarly, three members of the research team independently coded each caregiver transcript. Patient codes (n=752) and caregiver codes (n=145) were sufficient to achieve theoretical saturation in the respective data sets. Computer software was used to

model the data (NVivo; QSR International, Melbourne, Australia). Domains of importance were then identified from the codes, ensuring faithful data representation and accurate description of the areas under study.

Trauma Quality of Life (T-QoL) Instrument Construction (Phase 1)

The domains of importance derived from the patient focus group data resulted in a 59-item quality of life instrument. The pilot instrument was first distributed to a subset of trauma surgeons as well as trauma/critical care fellows, nurses and surgical residents for review and editing. The instrument was further edited and the language clarified to achieve a Flesch-Kincaid grade 6.0 reading level.

Each item has response options presented as a Likert scale; scoring of the instrument allows for a single numerical measurement of quality of life, with a higher score indicating higher quality of life. Some item responses are qualified within a finite time frame; one week was used as the time frame of reference. This time frame was selected based on previous studies that have demonstrated recall ratings will be inflated relative to averaged momentary ratings, particularly over a longer time span, given the effects of recall bias.^{20,21} As such, a shorter time span (one week) was chosen as opposed to a longer time span (four weeks), to obtain the most accurate assessment.

Pilot of the 59-Item T- QoL Instrument (Phase 2)

Survivors of traumatic injury who were admitted to the trauma surgery service at a level 1 trauma center were recruited to participate in phase 2 of the study. Potential participants were identified through the trauma registry three months ($\pm$ 2 weeks) following injury and contacted via phone. 394 participants agreed to an assessment over the phone that included a questionnaire to collect basic demographic information (Table I) as well as the 59-item Trauma Quality of Life instrument. In order to conduct a validity assessment, the final 111 of these participants were also asked to complete the SF-36v2, a well validated and standardized measure of general QoL and the PCL-C. The PCL-C was specifically chosen due to its reliability, internal consistency and validity which allow for accurate assessment of post-traumatic stress disorder. It was felt that any trauma-specific quality of life measurement tool should be able to quantify post-traumatic stress disorder symptom severity accurately. The 111 subjects used to conduct the validity assessment were drawn consecutively from the 394 subjects and were similar demographically, ensuring minimal variability (Table I).

Data Analysis (Phase 2)

Exploratory factor analysis (EFA) was conducted to identify underlying structures within the 59-item T-QoL measure. It was found that close to 60% of the cohort was unemployed at the time of injury and thus six items pertaining to employment were discarded. The retained 53-items were subjected to principal component analysis (PCA) which identified the final 5-component, 43-item T-QoL measure. The T-QoL measure was then correlated with the SF-36v2 and the PCL-C to assess its validity, as non-disease specific QoL is significantly correlated with posttraumatic stress disorder following traumatic injury.

Results

Trauma Quality of Life Instrument Construction (Phase 1)

Trauma Patient and Caregiver Focus Groups—Four trauma patient focus groups were held ($n=26$). Mean age was 51.3 ± 13.4 years, 73% of the patients were male; 62% Caucasian, 31% African American and 7% were of other races. Mechanism of injury was motor vehicle or motorcycle crash (27%), fall (27%), assault (19%), gunshot or stab (15%) and other mechanisms (12%). Mean time since injury was 230 ± 142 days. Twelve percent of patients reported involvement in litigation associated with the injury.

Both patients and caretakers were asked to answer the question, “On a scale of 1-10 (with 10 being the highest), how much did the trauma experience affect your life?” Patients reported a mean life impact score of 7.7 ± 2.8 and caregivers reported a mean life impact score of 8.1 ± 3.0 .

The most frequently coded peri-trauma and inpatient variables were perception of injury severity (26.6%), perception of medical care (19.6%), causal attribution (12.4%), loss of consciousness (11.7%), pain medication (6.5%), and physical impairment (5.8%). The most frequently coded post-trauma codes were impact on activities of daily living (8.5%), impact on relationships (6.5%), reliance on others (5.7%), post-injury outlook (5.3%), perception of physical recovery (5.0%), pain severity (4.7%), emotional impact on others (3.9%), faith/belief system (3.9%), impact on leisure activities (3.4%), and scars (3.4%).

Pilot of the Trauma Quality of Life Instrument (Phase 2)

Factor Structure of the T-QoL—Three hundred ninety-four participants were included in the initial exploratory factor analysis. 60% of the sample was not working prior to the trauma and therefore six T-QoL items related to employment (i.e., I have lost my job since my injury) were excluded from analyses. Thus, fifty-three items were included in the analysis and were subjected to principal components analysis (PCA) using SPSS Version 19. The dataset was suitable for factor analysis: inspection of the correlation matrix revealed a number of correlations greater than 0.3, the KMO value was 0.91, exceeding the recommended value of 0.6 and Bartlett's test of Sphericity was significant ($p < .001$), supporting the factorability of the correlation matrix.

PCA revealed 13 components with eigenvalues greater than 1, explaining a total of 64.0% of the variance. Inspection of the scree plot suggested a clear break after the first component, but a more subtle break after the third and fourth component. The results of Parallel Analysis showed eigenvalues of five components exceeded the criterion value (1.79) for a randomly generated data matrix of the same size (53 variables $\times$ 394 respondents). Therefore, the PCA was re-run with an oblique (direct oblim) rotation forcing a three, four, and five factor solution separately. Inspection of the pattern matrices of the three solutions revealed that the five factor solution appeared to best represent the data in a parsimonious way. The four factor solution had one factor with less than three items and the three factor solution had a number of items with strong cross-loadings. Thus, the final five components identified were as follows: Emotional Well-Being (16 items), Functional Engagement (8 items), Recovery/Resilience (6 items), Peri-Traumatic Experience (5 items), Physical Well-Being (8 items).

The five-component solution explained a total of 44.8% of the variance, with Emotional Well-Being contributing 26.3% of the variance, Functional Engagement contributing 6.1%, Recovery/Resilience contributing 4.8%, Peri-Traumatic Experience contributing 4.2%, and Physical Well-Being contributing 3.5%. The rotated five factor solution revealed that all five components had a number of strong loadings and most variables loaded substantially on only one component. Review of item communalities (values regarding how much of the variance an item contributes to a component) suggested that nine items had weak contributions to their respective components, and one item did not load on any of the five components, resulting in 43 retained items for the T-QoL.

Four of the five components were found to have strong Cronbach's alpha scores (>0.7) which demonstrated consistent inter-item reliability. However, the peri-traumatic experience component had a poor Cronbach's alpha (0.25) which points to a varied, poor inter-item reliability (Table II).

Validity of the Trauma Quality of Life (T-QoL) instrument was assessed using the PTSD Checklist – Civilian Version (PCL-C) and the Short Form 36 Health Survey Version 2 (SF-36v2). All subscales of the T-QoL correlated negatively with the PCL-C ($p<.01$), demonstrating that as the T-QoL increases, the likelihood of PTSD (as measured by the PCL-C) decreases. The physical well-being subscale of the T-QoL correlated significantly with the SF-36v2 PCS score while the emotional well-being subscale correlated significantly with the SF-36v2 MCS ($p<.05$), adding further support to its validity (Table III).

Discussion

Advances in medical care have greatly extended the lives of patients in all areas of medicine. These patient populations emerge from disease with unique experiences and needs that affect their current and future quality of life. An accurate and specific measurement of quality of life is needed to increase the sensitivity in which clinical care can be applied and studied. This study utilized the experiences of trauma victims and their informal caregivers to inform the creation of a trauma-specific quality of life measurement tool. The five-domain, 43-item questionnaire resulted in domains that are unique to trauma populations: emotional well-being, functional engagement, recovery/resilience, peri-traumatic experience and physical well-being.

We found that a 5-domain structure explained the highest percent of variance and was the best fitting model for trauma QoL. Each of these domains are highly relevant to the trauma population. Prior studies have verified that post-traumatic symptoms are associated with lower outcome scoring in almost all of the domains identified, particularly functional outcomes.²² Pain (a significant component of the physical well-being domain) is also strongly associated with reduced functioning across both physical and psychosocial domains.²³ Finally, a recent study by Lefering et al. found similar quality of life domains of importance: physical, psycho-social and functional capacity.²⁴ Concurrent research identifying similar domains lends further credence to the T-QoL's 5-domain structure. This may provide clinicians with the opportunity to use an instrument that's more sensitive to change in individual trauma patients.

Validity of the Trauma Quality of Life (T-QoL) instrument was assessed using the PTSD Checklist – Civilian Version (PCL-C) and the Short Form 36 Health Survey Version 2 (SF-36v2). Both of these instruments were chosen due to their prevalent use and repetitive validation. When compared to the PCL-C, four out of the five components (except physical well-being) demonstrated consistent, statistically significant negative correlations. Thus, as the T-QoL score rises, the risk of PTSD as measured by the PCL-C decreases. Similarly, Kiely et al. found that PTSD was correlated with lower MCS scores in the SF-36v2.²⁵ This correlation further demonstrates concurrent validity between our T-QoL measure and existing post-trauma outcome measures as compared to the SF-36v2. This gives us confidence that the T-QoL not only captures existing factors that affect post-trauma quality of life but extends into areas important to survivors and their families that have been previously unexplored.

The physical engagement score from the T-QoL correlated significantly and positively with the physical component score (PCS) from the SF-36v2 suggesting construct validity with a similar measure. Weak positive correlations were also seen between the PCS and the physical well-being as well as recovery/resilience domains of the T-QoL but these were not statistically significant. Conceptually, these correlations may represent a similar thread of “functionality” but the T-QoL items also tie in an emotional and social dynamic that may not be present in the SF-36v2. As a result, the two instruments may be measuring a similar construct from two different clinical lenses. The T-QoL emotional well-being correlated positively ($p=0.05$) with the MCS of the SF-36v2, again demonstrating the construct validity of the T-QoL. The remaining four components showed weak, positive correlations that were statistically insignificant.

One limitation of this study is the researcher bias introduced when using coded qualitative data. Researcher interpretation and biases were minimized as multiple researchers coded the qualitative data individually to establish true inter-coder agreement. Furthermore, this type of study design allowed patients and their caregivers to guide and dictate areas of importance, ridding the measurement of preformed expectations and biases of the investigators. A second limitation is that the data was derived from a single level 1 trauma center. However, analyses of the patient and caregiver populations during phase 1 and 2 of the study demonstrated demographics similar to many typical trauma populations. Finally, one of the five retained components showed statistically weak correlations compared to the other four. The peri-traumatic experience domain resulted in a low Cronbach's alpha score. When viewed individually, the five items in this domain seem to logically affect post-trauma quality of life but their overall thematic grouping is difficult to define and is not statistically well-supported. While we elected to keep this domain in the measure, future research needs to establish the performance of this domain to inform its retention or deletion.

This is the first step towards defining an accurate and valid measurement of post-trauma quality of life. Continued research is needed to help tease out strengths and weaknesses that can improve the measurements sensitivity and usefulness to both clinicians and researchers. A broad, multi-center national study will help to alleviate these concerns and establish the 43-item T-QoL as a measure that can guide and improve both future research and clinical care.

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Table I

Demographic comparison of the instrument cohort and that used in the validity assessment.

Demographics:	Instrument Pilot		Validity	
Age	n=394		n=111	
Mean	53.9		52.4	
Standard Deviation	±20.0		±20.3	
Sex	Percent	(n)	Percent	(n)
Male	61%	239	54%	60
Female	39%	155	46%	51
Ethnicity				
Caucasian	75%	297	78%	86
African American	18%	66	16%	17
Non-White/Latino	2%	9	2%	2
Other	5%	18	5%	5
Trauma				
Assaultive	11%	43	12%	13
Non-Assaultive	89%	340	88%	98
Litigation				
Yes	25%	96	26%	28
No	75%	293	74%	80

*Not all participants completed all items of the questionnaire to obtain these data; totals may not add to N=394.

Table II

Factor loadings for items included in the Trauma Quality of Life measure (43 items)

Items	Factor				
	1	2	3	4	5
Emotional Well-Being (16 items)					
I have felt more “on edge” or “jumpy” lately	0.67				0.31
My scars from the injury bother me	0.58				
My appetite has changed since the injury	0.48				0.37
My eating habits had to change because of physical problems after the injury	0.42				
I still feel fear when I think about the injury	0.61				
My mood has become worse since the injury	0.71				
I have been more irritable since the injury	0.72				
I am angry that I got injured	0.67				
I feel safe on a day-to-day basis	0.55				
My injuries were hard to deal with emotionally	0.69				
I am able to handle any physical limitations I have from the injury	0.41		0.34		
I am able to handle the changes in my mood since the injury	0.53				
I am more negative about my future than I was before the injury	0.47		0.32		
I have to rely on others, such as my family, friends, social security, or community support programs because of my current financial limitations	0.44				
My injuries have negatively changed my relationships with my family, friends, or intimate partner	0.59				
My injuries have had a negative emotional effect on my family and friends	0.59				
Functional Engagement (8 items)					
I need help: driving		0.56			
I need help: walking up stairs		0.70			
I need help: walking on flat surfaces		0.69			
I need help: dressing		0.74			
I need help: bathing/showering		0.80			
I need help: eating		0.68			
I need help: going to the bathroom		0.80			
I need help: cooking/preparing meals		0.66			
Recovery/Resilience (6 items)					
My physical healing has improved as I expected			0.45		
I have been able to heal without problems			0.41		
I have been able to make changes to handle my current limitations			0.35		
I am more positive about my future than I was before the injury			0.65		
Even though I was injured, my life is better now than it was before the injury			0.51		
My recovery was shorter than I expected			0.56		
Peri-traumatic Experience (5 items)					
Overall, the care I got in the hospital was good			0.32	0.52	
I thought the physicians and nurses did a good job			0.30	0.51	
I am able to remember how I was injured				0.62	

Items	Factor				
	1	2	3	4	5
I felt fear when I was injured				0.63	
I felt strong emotions when I was injured	0.53			0.63	
Physical Well-Being (8 items)					
I currently have physical limitations					0.58
I am able to exercise like I used to					0.60
I am able to continue my normal leisure activities					0.49
I have pain on a daily basis					0.63
I take pain medications daily					0.50
Pain limits what I am able to do					0.61
I have trouble sleeping at night	0.42				0.52
I have less energy during the day					0.56

Table III

Component Correlation and Validity Table

Subscales	1	2	3	4	5	6	7	8
1. Emotional Well-Being	--							
2. Physical Functioning	0.50**	--						
3. Recovery/Resilience	0.54**	0.40**	--					
4. Peri-Traumatic Experience	0.41**	0.14**	0.21**	--				
5. Physical Well-Being	0.68**	0.56**	0.60**	0.21**	--			
6. PCL-C	-0.84**	-0.42**	-0.34**	-0.36**	-0.57	--		
7. SF-36v2 PCS	-0.16	0.39**	0.07	-0.08	0.14	0.22	--	
8. SF-36v2 MCS	0.51**	0.07	0.06	0.16	0.19	-0.61	-0.57	--
Mean	2.85	3.38	2.66	3.03	2.33			
Standard Deviation	0.09	0.08	0.35	0.70	0.05			
Scale Mean	45.53	27.03	15.94	15.13	18.62	33.93	36.10	41.97
Standard Deviation	12.24	5.91	3.94	2.52	7.01	18.24	7.52	8.98
Cronbach's Alpha	0.91	0.87	0.73	0.25	0.88			
Number of Items	16	8	6	5	8			

*Correlation is significant at the 0.01 level (2-tailed)

PCL-C=PTSD Checklist-Civilian Version; SF36v2=Short-Form 36 Health Survey Version 2; PCS=Physical Component Score
MCS=Mental Component Score

**
Correlation is significant at the 0.05 level (2-tailed)