

Using the Dermatology Life Quality Index to Assess How Breast Radiodermatitis Affects Patients' Quality of Life

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ABSTRACT

PURPOSE: The purpose of this study is to report the initial validation process for using the Dermatology Life Quality Index (DLQI) for radiodermatitis of the breast.

METHODS: This is an additional analysis of a study designed to report a longitudinal study in skin-related and global quality of life in women with breast radiodermatitis. A total of 40 participants completed the DLQI instrument weekly while receiving external radiotherapy of the female breast. At week 5 on treatment, 31 (78%) participants provided narrative feedback on how each DLQI item affected her life. Agreement between participant DLQI numerical ratings and narrative feedback on items was assessed. Construct validity was estimated using principal component analysis (PCA). Internal consistency of the DLQI was assessed using Cronbach alpha.

RESULTS: Percentage of agreement between participant DLQI ratings and narratives ranged from 71% to 98%. Each participant responded "no" to the work and study item leading to zero variance and removal from our analyses. Principal component analysis supported the inclusion of all of the remaining items. The DLQI with nine remaining items demonstrated moderately good internal consistency ($\alpha = .69$).

CONCLUSIONS: The results of our examination of the DLQI when used for breast radiodermatitis are promising. Next steps include additional larger studies among more diverse populations.

KEYWORDS: breast cancer, quality of life, radiodermatitis, Dermatology Life Quality Index, agreement, validity

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Introduction

A majority of women receiving external beam radiotherapy for breast cancer experience radiation-induced skin changes.¹ The current standard of care in radiation oncology is to describe the physical attributes of radiodermatitis as a skin toxicity.² However, results of studies have demonstrated that women receiving external beam radiotherapy for breast cancer experience more than physical alterations in health-related quality of life (HRQOL). For example, Pignol et al³ found a highly significant correlation between the development of moist desquamation, an increase in reported breast symptoms ($P = .0028$), and patient-defined pain score on a visual analog scale ($P < .0001$). Women actively receiving external beam radiotherapy for breast cancer in a study by Miller et al⁴ reported, on the Skindex-16, experiencing itching, burning, stinging, pain, irritation, embarrassment, depression, decreased social interaction, and diminished ability to show affection. The profound effect radiodermatitis has on quality of life (QOL) causes some women to withdraw from treatment.⁵ Radiodermatitis is related to a constellation of physical factors such as radiation-induced skin changes, inflammatory responses, and genetic variations.^{6,7} Furthermore, these physical factors directly impact QOL among women receiving external beam radiotherapy for invasive breast cancer. In addition, a relationship

between season of the year and amount of skin bother, a component of skin-specific HRQOL, is seen in radiodermatitis.⁸

No skin-related QOL instruments independently validated for use in radiodermatitis were found. As a result, we remain unable to effectively assess the usefulness of topical agents that could decrease suffering, prevent treatment delays or early termination, and improve QOL for thousands of breast cancer patients. To accurately assess the impact of radiodermatitis on HRQOL, a valid and reliable patient assessment is needed. By improving our approach to the assessment of radiodermatitis and QOL experienced during this toxicity, we may determine the best methods to prevent and treat this problem. One potential solution includes using a QOL instrument specifically designed for skin conditions (ie the Dermatology Life Quality Index [DLQI]) to improve assessment of patient perception of QOL during the presence of radiodermatitis. The DLQI is an instrument well-validated for weekly clinic use in a number of dermatologic conditions including eczema.⁹ Although the DLQI was developed for psoriasis and eczema, the symptoms assessed (eg itching, embarrassment, and difficulty with physical activity)⁹ mirror the complaints reported by patients experiencing radiodermatitis. However, the DLQI has not been formally validated for use in radiodermatitis. In this pilot study,



we report initial reliability and validity assessment of the DLQI when used to measure skin-specific HRQOL among women experiencing breast radiodermatitis.

Methods

The design and methods of the primary study have been described previously and are briefly summarized here.¹⁰⁻¹² A purposive sample of English-speaking women about to undergo external radiotherapy for primary breast cancer stage 0 to III was recruited at a Midwestern cancer program in a community setting. The women were invited to join the study at the initial radiation oncology appointment or at the computed tomography (CT)-simulation visit. After written informed consent, baseline measures (eg demographics, biometrics, global HRQOL, and DLQI) were completed; then, the women were followed weekly throughout radiotherapy. Skin-specific HRQOL data were collected via a survey instrument (ie DLQI) and a data collection form (ie radiation skin changes questions). Participants completed the DLQI at baseline and each week while on radiotherapy during the main study. Radiodermatitis intensity was expected to begin to peak at the fifth week on radiotherapy and some participants received an accelerated treatment regimen. Therefore, the participants were asked to provide written feedback on how the DLQI items affected their lives at this time, which item was most important and why, and additional comments. Participants wrote this feedback on the radiation skin changes questions data collection form.

Instruments

Dermatology Life Quality Index. The purpose of the DLQI is to provide a simple and reliable instrument that can be easily and routinely administered weekly in a clinic setting for any skin condition. The DLQI was initially developed from information provided by 120 dermatology patients who answered an open-ended question about how their skin condition affected their life.¹³ Next, 49 aspects of impact on life were identified in the first 70 responses.¹³ No new aspects emerged in the remaining 50 responses.¹³ The aspects were ranked by frequency of citation and 10 aspect-based questions were developed.¹³ The 10-item instrument was piloted in 20 patients, revised slightly, and then piloted again in another 20 patients.¹³ The DLQI contains 10 scaled items including one that is partly dichotomous. The recall period used is “over the last week.”¹⁴ The scaled items focus on physical sensations; embarrassment; interference with activities at home; clothing selection; impact on social activities; difficulty participating in a sport; preventing work or school attendance; causing a problem with relationships among close friends, relatives, or a partner; sexual difficulties; and impact of treatment on life and lifestyle.¹⁴ The dichotomous item inquires whether or not the skin condition prevented the respondent from attending work or school.¹⁴ The 10 DLQI items can be grouped into

six subscales for analysis including the following: symptoms, feelings (items 1 and 2), daily activities (items 3 and 4), leisure (items 5 and 6), work/school (item 7), personal relationships (items 8 and 9), and treatment (item 10).¹⁴ Eight of the scaled items include options of “very much,” “a lot,” “a little,” “not at all,” and “not relevant.”¹⁴ Two additional items include the previous options except “not relevant.”¹⁴ A DLQI cumulative score of 0-1 represents no effect, 2-5 a small effect, 6-10 a moderate effect, 11-20 a very large effect, and 21-30 an extremely large effect on the patient’s life.¹⁴

Radiation skin changes questions. The radiation skin changes questions data collection form was developed by the research team to collect participant’s narrative responses to a question about each DLQI item (ie “How has this affected your life?”) and a final open-ended question inquiring “Which issue is most important and why?” The data collection process is discussed in greater detail in the section on concurrent validity.

Validity testing

There are many components in the process of validating an instrument.¹⁵ Each process measures a different aspect of the instrument’s strengths or weaknesses. We estimated the concurrent, content, and construct validity; and reliability of the DLQI among women with breast radiodermatitis in this analysis.

Concurrent validity and informant agreement. Concurrent validity focuses on the extent to which a measure such as the DLQI adequately reflects the individual’s perspective on a criterion.¹⁶ We measured the concurrent validity of the DLQI by assessing the agreement of participant’s responses on the DLQI and their narrative responses to a survey (ie radiation skin changes questions) about the DLQI, both at 5 weeks on radiotherapy. Participant agreement was measured at 5 weeks on treatment when skin toxicity begins to peak and because participants receiving accelerated radiotherapy would no longer be routinely seen on a weekly basis in the department. An extra copy of the DLQI and a single copy of the radiation skin changes form were given to the participant. Each woman was instructed to look at the extra copy of DLQI. Next, participants were invited to write narratives about how each item on the DLQI affect their life on the radiation skin changes form. A total of 31 (78%) of the 40 participants provided narratives. The principal investigator (PI) abstracted the week-5 DLQI responses and the narratives on impact. The data were entered into a form with a column for the ordinal score on the DLQI (ie very much, a lot, a little, and not at all), a column for a verbatim copy of the narrative, and a column for researcher-rated level of agreement. Three researchers jointly coded the agreement score (ie agree and disagree) for the DLQI item ratings and narrative for the first participant. Subsequently, each researcher coded her perceived level of agreement for the

remaining participant responses independently. The PI combined the agreement ratings by each researcher into one master document. The document was shared with each researcher, the agreement ratings were discussed, and consensus formed for items on which the agreement ratings did not originally agree. Percentage of agreement was calculated by dividing the number of paired responses where the participant's DLQI rating was congruent with her narrative response by the total number of participant responses for each DLQI item.

Content validity. Content validity focuses on whether the instrument represents the domain of interest.¹⁶ In this study, it was assessed by soliciting feedback on the DLQI from 12 expert radiation oncology nurses at a chapter meeting of the Oncology Nursing Society. A hard copy of the DLQI was given to each nurse. The nurse was instructed to read the items on the DLQI and provide written feedback on the items, including whether additional items are needed or if some seem unnecessary.

Construct validity. Construct validity focuses on the extent that items on a measure such as the DLQI are consistent with the concept of interest.¹⁶ It was assessed using principal component analysis (PCA) of the DLQI items. Principal component analysis allows summarization of the information in the data into factors. A variety of participant per factor ratios are suggested in the professional literature, ranging from 3 to 15 participants for each factor.¹⁷⁻²¹ We had 40 participants and 10 items yielding a ratio of 4:1. Our sample size adequacy was also examined using the Kaiser-Meyer-Olkin (KMO) statistic and then communalities after extraction, both with values greater than .5 if the sample size is adequate.²² All of the DLQI items focus on skin-related HRQOL and are likely correlated. Therefore, a direct oblimin rotation was employed.²¹ Bartlett test of sphericity was used to examine the homogeneity of variance.

Reliability. The reliability of the DLQI items was assessed using Cronbach alpha analysis and examining the inter-item correlations. An alpha of .7 or higher and inter-item correlation of .3 or greater are considered acceptable.²²

Statistical analyses

The IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows Version 22.0 was used to analyze the quantitative data.²³

Results

Participant sample

All 40 participants were female with stage 0 to III breast cancer.¹⁰⁻¹² They ranged in age from 40 to 82 years with a mean age of 58 years.¹⁰⁻¹² The typical participant was non-Hispanic

White (97%), had some level of college education (74%), worked in a professional occupation (42%), earned more than US\$75,000 annually (45%), was normal weight (39%) or obese (39%), and did not currently smoke (94%).¹⁰⁻¹² Overall, 7 women received accelerated external beam treatment using fractions of 266 cGy and 33 women received normofractionated doses of 180-200 cGy.¹² Of the 40 participants in the main study, 31 provided usable narrative responses about the DLQI items.

Validity

Concurrent validity/informant agreement. The percentage of agreement between participant ranked responses on the DLQI and narrative responses on the radiation skin changes form ranged from 71% to 98%. The percentage of agreement between the participant-scored ratings on the DLQI and narratives about radiation skin changes is presented in Table 1. There is no established standard for acceptable percentage of participant agreement. However, Graham et al²⁴ suggest using a range of 75% to 90% absolute agreement as a measure of inter-rater agreement. Our results closely parallel that range.

The first item on the DLQI inquires about three sensations (ie pruritus, pain, and stinging) and had the lowest level of agreement. The participant needed to mention these three sensations to meet the requirements for agreement. The content of the stem of each DLQI item is provided in Tables 1 and 2. The item that focuses on sports had the highest level of agreement. However, most participants responded that their skin did not impact their ability to do any sports because they did not frequently engage in sporting activities. A pattern of seasonality effects was seen in narratives regarding the item focusing on choice of clothing. Participants receiving radiotherapy during summer months reported more difficulty selecting clothing to cover their irradiated skin as compared with participants receiving radiotherapy during the winter.

Content validity. The radiation oncology nurses did not recommend additions to or deletion of any DLQI items. They suggested a few minor word changes. For example, "not relevant" might be changed to "does not apply." We determined whether the content validity of the DLQI was sufficient based on radiation oncology nurse expert opinions.

Construct validity. Our KMO statistic was .72 and the communalities ranged from .61 to .97, indicating a sufficient sample size to complete a PCA.²⁰ Bartlett test of sphericity ($\chi^2(10) = 221.03, P < .001$) indicating the correlations between items was sufficiently large for PCA, but not a perfect correlation. Each participant responded "no" to DLQI item 7 that inquires whether the participant's skin prevented her from working or studying during the past week. Since there was 100% agreement among participant responses to this question,

Table 1. Percentage of agreement between participant-scored ratings on the Dermatology Life Quality Index (DLQI) and narratives of the radiation skin changes form.

DLQI ITEMS ^A	AGREEMENT % (N=31)
Symptoms and feeling subscale	
1. Over the last week, how <i>itchy, sore, painful, or stinging</i> has your skin been?	.71
2. Over the last week, how <i>embarrassed or self-conscious</i> have you been because of your skin?	.87
Daily activities subscale	
3. Over the last week, how much has your skin interfered with you going <i>shopping</i> or looking after your <i>home or garden</i> ?	.74
4. Over the last week, how much has your skin influenced the <i>clothes</i> you wear?	.90
Leisure subscale	
5. Over the last week, how much has your skin affected any <i>social or leisure</i> activities?	.87
6. Over the last week, how much has your skin made it difficult for you to do any <i>sport</i> ?	.98
Work and school subscale	
7. Over the last week, has your skin prevented you from <i>working or studying</i> ?	.97
Personal relationships subscale	
8. Over the last week, how much has your skin created problems with your <i>partner</i> or any of your <i>close friends or relatives</i> ?	.74
9. Over the last week, how much has your skin caused any <i>sexual difficulties</i> ?	.97
Treatment subscale	
10. Over the last week, how much of a problem has the <i>treatment</i> for your skin been, for example, by making your home messy, or by taking up time?	.74

Percentage is rounded to two place values. Percentage of agreement was calculated by dividing the number of paired responses where the participant's DLQI rating was congruent with her narrative response by the total number of participant responses for each DLQI item.

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there was zero variance between the responses. This item was automatically removed from the PCA by the SPSS program because the variance was zero. All of the DLQI items focus on skin-related QOL and were likely correlated in our population. Therefore, a direct oblimin rotation was implemented.²¹ Eight of the rotated DLQI items, sans the work and study item, loaded exclusively on one of three components that together explained 87% of the total variance in the analysis, supporting the retention of these items. The items that clustered on component one include a focus on embarrassment or self-consciousness; shopping, home care, or gardening; social or leisure activities; participation in a sport; problems with a partner, close friends, or relatives; and sexual difficulties. The item that focuses on itchy, sore, painful, or stinging skin sensations loaded exclusively on component two. The item focusing on treatment-related problems was the only factor that loaded on component three. The clothing selection item loaded on components one and two. Since every participant answered no to the item on prevention of work or study, the variance for that item was zero and was automatically removed from PCA by the SPSS program. See Table 2 for additional information.

Reliability. The work and study item was removed from analysis because the variance was zero. The remaining DLQI items demonstrated moderately good internal consistency ($\alpha = .69$). The greatest increase in alpha would come from deleting the treatment subscale. Removal of this item would improve alpha by .15. The items focusing on itchy, sore, painful, stinging, and treatment had inter-item correlations less than .3.

Discussion

The DLQI was specifically selected for use in this study since it was designed to minimize survey burden when used weekly to measure skin-related QOL. It was the first instrument designed to measure skin-related QOL and includes only 10 items.^{9,13,14} In comparison, the Skindex-16 was informed by the DLQI, consists of 16 items, and was not designed to be used weekly.²⁵

The overall validity and reliability of the DLQI in our pilot study was moderately good. The percentage of participant agreement between the DLQI ratings and narrative comments was respectable, ranging from 71% to 98%. Upon assessing the content validity of the DLQI, radiation oncology nurses

Table 2. Measures of reliability and validity for the Dermatology Life Quality Index (DLQI) items in a sample with breast radiodermatitis (n=40).

DLQI ITEM ^a	CORRELATION WITH OTHER ITEMS	ALPHA IF ITEM IS REMOVED	DLQI SUBSCALE	ROTATED FACTOR LOADINGS ^{b,c}		
				1	2	3
Over the last week, how <i>itchy, sore, painful, or stinging</i> has your skin been? (Item 1)	.26	.69	Symptoms and feelings	–	.934	–
Over the last week, how <i>embarrassed or self-conscious</i> have you been because of your skin? (Item 2)	.63	.65	Symptoms and feelings	.799	–	–
Over the last week, how much has your skin interfered with you going <i>shopping or</i> looking after your <i>home or garden</i> ? (Item 3)	.64	.64	Daily activities	.784	–	–
Over the last week, how much has your skin influenced the <i>clothes</i> you wear? (Item 4)	.49	.64	Daily activities	.513	.454	–
Over the last week, how much has your skin affected any <i>social or leisure</i> activities? (Item 5)	.66	.62	Leisure	.844	–	–
Over the last week, how much has your skin made it difficult for you to do any <i>sport</i> ? (Item 6)	.57	.65	Leisure	.856	–	–
Over the last week, has your skin prevented you from <i>working or studying</i> ? (Item 7) ^d	–	–	Work and study	–	–	–
Over the last week, how much has your skin created problems with your <i>partner</i> or any of your <i>close friends or relatives</i> ? (Item 8)	.63	.65	Personal relationships	.918	–	–
Over the last week, how much has your skin caused any <i>sexual difficulties</i> ? (Item 9)	.61	.65	Personal relationships	.788	–	–
Over the last week, how much of a problem has the <i>treatment</i> for your skin been, for example by making your home messy, or by taking up time? (Item 10)	.10	.84	Treatment	–	–	.981

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^bDirect oblimin (orthogonal) rotation.

^cLoadings < .4 are suppressed.

^dEvery participant responded “no” to this question, leading to zero variance between the responses and no factor loading; was removed from reliability analysis.

suggested a few small changes in the wording of the DLQI (eg change “not relevant” to “does not apply”). However, changing the DLQI would alter its established reliability and validity.²⁶ In addition, this instrument is copyrighted and its authors will not permit changes.¹⁴ Each participant responded “no” to the work and study item leading to a variance of zero and was removed from the PCA and reliability analysis. The zero variance likely reflects the fact that radiotherapy almost always follows surgery and often systemic therapy in addition. As a result, breast cancer patients may discontinue work or study long before radiotherapy begins. Those patients who are able to work or study soon after surgery and throughout systemic therapy may have enough resolve to continue working or studying through radiotherapy. An estimate of construct validity using PCA with a direct oblimin rotation supported the remaining DLQI items. The reliability of the remaining items demonstrated moderately good internal consistency with $\alpha = .69$ and would be .7 if rounded to one place value. Similarly,

the inter-item correlation for the item focusing on itchy, sore, painful, or stinging of .26 would round to the desired .3. The creators of the DLQI reported a Cronbach alpha of .83 when used for dermatologic conditions.⁹

Seasonality, the predictable effects of calendar-related fluctuations in weather condition (eg cold weather during winter and hot weather during summer),²⁷ influenced some participant responses on the DLQI in our study. For example, women who participated during summer months commented about needing to cover up and avoid sun exposure to radiated areas. Embarrassment was an issue because summer clothes are more revealing than winter clothes. Conversely, winter participants commented that clothing was not an issue because everyone is bundled up during winter in the Midwest. Schnur et al⁸ found similar findings in a study of breast radiodermatitis. In addition to avoiding sun exposure and covering skin changes from view, Schnur et al's⁸ study participants reported issues with body odor related to radiodermatitis being an issue during the

summer. Seasonality also affected our participant's responses to the question about sports. Women who liked to golf were bothered if they received treatment during the summer, but not if treatment was scheduled in the winter. These findings suggest that the results studies focusing on skin-related QOL may be influenced by the season and geographic location when data are collected. This effect could confound studies of radiodermatitis prevention or management.

We sought to begin the validation process for using the DLQI for radiodermatitis in our pilot study. The DLQI's performance was not perfect, but was acceptable in our pilot study. Further studies are needed to continue the validation of the DLQI for use in breast cancer radiodermatitis.

Strengths and limitations

The strength of this study is that it can serve as a pilot for future, larger studies. Our sample size was modest, yet statistical testing for adequacy of sample size suggests it was large enough for a pilot study. Caution must be taken regarding applying our results to other populations with greater diversity and living outside of community settings in the Midwestern United States since this was a single-site pilot study. Because the work and study item was removed from our PCA and alpha Cronbach analysis, it may be inappropriate to compare our findings against those of other researchers using the DLQI. However, since the variance in the work and study item was zero, we are curious to learn whether this phenomenon is common among breast cancer patients.

Conclusions

Breast radiodermatitis has a profound impact on QOL. Our initial analysis of using the DLQI to describe these QOL effects provides beginning value for this approach. Additional larger studies of this phenomenon are needed using more diverse populations. In particular, the impact of breast radiodermatitis on work and study needs further exploration. Since the variance in the work and studying item was zero, we are curious to learn whether this phenomenon is common among breast cancer patients receiving radiotherapy. Also, seasonal effects must be considered for longitudinal studies or when study accrual extends across seasons when skin-specific HRQOL is measured.

Author's note

Marcia Grant has now retired.

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Author Contributions

LCB contributed to concept development, study design, data collection and analysis, interpretation of the results, manuscript writing and ascertainment of funding for the project. MG contributed to the study design, data analysis, interpretation of the results and manuscript writing.

Ethical Approval and Informed Consent

This study was approved by the University of Utah Institution Review Board (UIRB) and was conducted in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. A reliance agreement was created between the UIRB and the health care system affiliated with the cancer program. Each woman provided her informed consent prior to inclusion in the study. Only the principal investigator had access to participants' personal health information. A unique participant identification number was assigned to promote anonymity and confidentiality with other investigators. This number was used to link all study documents for each participant.

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