

Comparison of Dermatology Life Quality Index and Skindex-16 Questionnaires in Breast Cancer Patients with Radiation Dermatitis

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ABSTRACT

Background: Radiation Dermatitis (RD) is the most common adverse effect of radiation therapy among the cancer patients, which has the potential to lower patients' quality of life. This study aimed to assess the health-related Quality of Life (HRQOL) of breast cancer patients with radiation dermatitis using Dermatology Life Quality Index (DLQI) and Skindex-16 Questionnaires and to determine the more appropriate questionnaire to assess the breast cancer patients with radiation dermatitis. **Materials and Methods:** A prospective one arm cross over study was conducted with 31 breast cancer patients. The HRQOL was assessed weekly during radiation therapy by using DLQI and Skindex-16 questionnaires and reliability of questionnaires were analyzed. **Results:** The HRQOL of breast cancer patients with radiation dermatitis were affected on day 7, 14, 21 and 28 which was found to be improved after termination of radiation therapy ($p < 0.01$). The reliability of DLQI questionnaire was found to be high ($s = 0.805$) when compared with Skindex-16 questionnaire ($s = 0.781$). **Conclusion:** DLQI was the highly reliable instrument when compared to Skindex-16 for measuring health-related quality of life of breast cancer patient with radiation dermatitis. The shortness and ease of implementation of DLQI will aid the researcher and clinicians to choose the DLQI questionnaire for assessing the HRQOL of breast cancer patients with radiation dermatitis.

Keywords: Breast Cancer, Radiation Dermatitis, Dermatology Life Quality Index, Skindex-16, Health Related Quality of Life.

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INTRODUCTION

Breast Cancer (BC) is one of the most prevalent malignancies among women worldwide (Sun *et al.*, 2017). Radiation Dermatitis (RD) is an adverse effect that arises directly from radiation exposure during cancer treatment. RD will eventually develop in about 95% of patients receiving Radiotherapy (RT) (Iacovelli *et al.*, 2020).

Radiation dermatitis is an important adverse effect that arises directly from radiation exposure during cancer treatment. It

is more common in cancers of the breast, head and neck and perineum region, where the skin is part of the irradiated volume. Nearly 85-95% of patients experience some degree of radiation dermatitis during the course of breast cancer radiotherapy (Khanna *et al.*, 2013).

Radiation-Induced Skin Reactions (RISR) often leads to itching, pain, delays in treatment, decreased aesthetic appearance and subsequently affect the patient's quality of life and well-being. The quality of life of cancer patients receiving radiation therapy is negatively influenced by radiation dermatitis leading to decreased Health Related Quality of Life (HRQOL) (Hegedus *et al.*, 2013). The HRQOL of patients receiving RT is negatively influenced by RD. In Indian patient subset, there is limited data comparing reliability and feasibility of DLQI and Skindex-16 questionnaire among breast cancer patients with RD. The purpose of this study



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is to assess the HRQOL of BC patients with RD using DLQI and Skindex-16 questionnaire and to identify the most appropriate questionnaire

MATERIALS AND METHODS

The prospective one-arm cross-over study was conducted in the Department of Radiation Oncology at Sri Ramachandra Institute of Higher Education and Research (DU) from October 2022 to March 2023. The Institutional Ethics Committee approved the study (IEC REF: CSP/22/OCT/117/518) of Sri Ramachandra Institute of Higher Education and Research (Deemed to be University). The study included breast cancer patients undergoing radiation therapy at Sri Ramachandra Medical Centre and patients having symptoms of radiation dermatitis during treatment. Patients who do not have a history of histologically confirmed breast cancer, patients without any symptoms of radiation dermatitis, patients with other types of cancer, and patients not willing to give consent were excluded from the study. Patients were enrolled based on inclusion criteria. The study was conducted among 34 patients in which 3 patients lost their follow up and the remaining 31 patients were included. The informed consent was obtained from the recruited patients. The demographic details were collected from the patients who were requested to complete the DLQI and the SKINDEX-16 questionnaire by themselves on days 7, 14, 21, and 28 and after termination of radiation therapy. We analysed the time required to complete the questionnaire, whether the subjects had taken help in answering the questionnaire, and the reliability of both questionnaires were analysed. Then the patient counselling and the distribution of patient information leaflet was given on lifestyle modification for improving the HRQOL of breast cancer patients with radiation dermatitis.

Dermatology Life Quality Index (DLQI)

The DLQI questionnaire contains 10 scaled items which 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). Eight of the scaled items include options of “very much,” “a lot,” “a little,” “not at all,” and “not relevant.” Two additional items include the previous options except “not relevant.” 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.

Skindex-16

Skindex-16 comprises of 16 scaled items which can be grouped into three subscales for analysis including the following: symptoms (items 1 to 4), emotions (items 5 to 11), and functioning scales (items 12 to 16). The response choices are on continuous bipolar scale with seven boxes anchored by the words “Never Bothered”

and “Always Bothered” at each end. Skindex-16 scores vary from 0 (no effect) to 100 (effect experienced all the time) which is represented in the range of 0 to 20 as no effect, 21 to 40 as mild effect, 41 to 60 as moderate effect, 61 to 80 as very large effect, 81 to 100 an extremely large effect on the patient’s life.

RESULTS

A total of 34 patients were recruited, of which 3 patients lost their follow up. The remaining 31 patients were included in the study.

Table 1, summarizes the baseline clinical characteristics of the 31 BC patients. The result showed that the maximum number of participants were in the age group of 51-60 years (35%). Nearly, 65% of study participants were illiterate and had attained menopause. The socioeconomic status of 61% of participants were lower middle class. In this study, nearly 19.35% of the participants had both hypertension and diabetes mellitus, 6.4% of the participants had diabetes mellitus, 3.2% of the participants had epilepsy, 3.2% of the participants had both diabetes mellitus and hypothyroidism, 3.2% of the participants had both hypertension and hypothyroidism, 3.2% of the participants had both diabetes mellitus and hypercholesterolemia and 61.2% of the participants had no comorbid condition other than breast cancer. Nearly, 61% of participants had left breast cancer and remaining 39% had right breast cancer in this study. The RTOG grading of radiation dermatitis of the study participants. On day 7, 87% of participants had grade 1 RD and remaining 13% developed grade 2 RD. On day 14, 19% of participants had grade 1 RD and 74% of participants had grade 2 RD and remaining 7% developed grade 3 RD. On day 21, 3% of participants had grade 1 RD and 52% developed grade 2 RD and 45% developed grade 3 RD. On day 28, 16% of participants had grade 2 RD and remaining 84% developed grade 3 RD.

Table 2 indicates the scoring of DLQI questionnaire which showed that the HRQOL of 65% of participants on day 7 and 87% of participants on day 14 were mildly affected. The HRQOL of 46% of participants were moderately affected on day 21 and the HRQOL of 55% of participants were severely affected on day 28 and the HRQOL of the study participants were found to be improved after termination of radiation therapy.

The scoring of Skindex-16 questionnaire revealed that the HRQOL of 61% of participants were mildly affected on day 7 and the HRQOL of 68% of participants were mildly affected on day 14. The HRQOL of 58% of participants were moderately affected on day 21 and the HRQOL of 52% of participants were severely affected on day 28 and the HRQOL of the study participants was found to be improved after termination of radiation therapy.

Table 3, represents the time taken for completing DLQI and Skindex-16 questionnaires and the help seeking behaviour of the study participants. The result revealed that the time taken for completing DLQI questionnaire was lesser than the time required

Table 1a: Baseline characteristics of the study participants.

Characteristics		n (%) n=31
Age	31-40	4(13)
	41-50	10(32)
	51-60	11(35)
	61-70	5(16)
	71-80	0(0)
	81-90	1(3)
Educational	Literate	11(35)
	Illiterate	20(65)
Socioeconomic	Upper class	1(3)
	Upper middle	2(7)
	Lower middle	19(61)
	Upper lower	5(16)
	Lower class	4(13)
Marital	Married	26(84)
	Unmarried	5(16)
Menopause	Yes	20(65)
	No	11(35)
Food habits	Veg	7(23)
	Mixed	24(77)
Comorbids	Hypertension/Diabetes Mellitus	6(19.35)
	Diabetes Mellitus	2(6.4)
	Epilepsy	1(3.2)
	Diabetes Mellitus/Hypo thyroidism	1(3.2)
	Hypertension/Hypo thyroidism	1(3.2)
	Hyperthyroidism/Hyper cholesterolemia	1(3.2)
	No comorbid	19(61.2)
Tumor location	Right breast	12(39)
	Left breast	19(61)

for completing Skindex-16 questionnaire and the help seeking behaviour for DLQI questionnaire was lesser when compared to that of Skindex-16 questionnaire.

Table 4, suggests the comparison of DLQI and Skindex-16 questionnaires scores. The HRQOL of breast cancer patients with radiation dermatitis were affected on day 7, 14, 21 and 28 which was found to be improved after termination of radiation therapy. When comparing day 28 with post radiation scores of both the questionnaire, the HRQOL of the study participants after radiation therapy were found to be improved which was statistically significant ($p < 0.01$). The reliability of DLQI and Skindex-16 questionnaires were assessed by Cronbach's alpha coefficient (s). The result showed that the reliability of DLQI questionnaire was found to be high ($s = 0.805$) when compared with Skindex-16 questionnaire ($s = 0.7$).

DISCUSSION

In this study, 31 BC patients with RD were included. Each patient on an average received 25 cycles of radiation therapy with an average dose of 2 Gy per cycle. Majority of the patients in the age group of 51 - 60 years (35.48%) were affected and it is comparable to the study conducted by Yazmin San Miguel *et al.*, which included 1,92,932 patients and the author revealed that compared to younger women across all racial/ethnic groupings, elderly women had a higher risk of breast cancer (San Miguel *et al.*, 2020). In this study, 64.5% of participants who had attained menopause were affected with breast cancer. This result correlates with the study conducted by Aruna Surakasula *et al.*, which included 100 female patients, in which 52 patients have attained menopause. The risk for developing BC was significantly higher in women who attained menopause after age of 55 years and also for women who started menstruating before the age of 12, this is due to prolonged oestrogen exposure (Surakasula *et al.*, 2014). In this study, we found that 61.29% of participants who were under lower socio-economic status were affected with breast cancer. Rabia Ali *et al.*, reported that the lower income women were more likely to be experienced with BC symptoms, due to an inability to pay for medical appointments, treatments, and travel allowances (Ali *et al.*, 2008).

Table 1b: RTOG grading of radiation dermatitis.

RTOG grading of radiation dermatitis	No. of Participants (n) n=31			
	Day -7	Day - 14	Day - 21	Day - 28
Grade 1	27	6	1	0
Grade 2	4	23	16	4
Grade 3	0	2	14	27
Grade 4	0	0	0	0

Table 2: Scoring of DLQI and Skindex-16 Questionnaires.

DLQI and Skindex-16 Questionnaire Scoring	DLQI score	No. of participants (n) n=31				
		Day 7	Day 14	Day 21	Day 28	Post Radiation
	0 to 1 (No effect)	10	2	2	0	0
	2 to 5 (mild)	20	27	11	1	19
	6 to 10 (Moderate)	1	2	14	12	8
	11 to 20 (Severe)	0	0	4	17	4
	21 to 30 (Extreme)	0	0	0	1	0
	Skindex -16 score	No. of participants (n) n=31				
		Day 7	Day 14	Day 21	Day 28	Post Radiation
	0 to 20 (No effect)	20	8	1	0	0
	21 to 40 (Mild)	19	21	6	1	24
	41 to 60 (Moderate)	2	2	18	13	6
	61 to 80 (Severe)	0	0	6	16	1
	81 to 100 (Extreme)	0	0	0	1	0

Table 3: The time taken for completing DLQI and Skindex-16 questionnaires and the help seeking behaviour of the study participants.

Time taken to complete the questionnaire	DLQI (Time in mins)	No. of participants (n) n=31				
		Day 7	Day 14	Day 21	Day 28	Post Radiation
	1 to 2	22	21	23	22	13
	3 to 4	9	10	8	9	8
	Skindex-16 (Time in mins)	No. of participants (n) n=31				
		Day 7	Day 14	Day 21	Day 28	Post Radiation
	1 to 2	5	7	11	24	11
	3 to 4	26	24	20	7	20
Help seeking behaviour of the study participants	DLQI	No. of participants (n) n=31				
		Day 7	Day 14	Day 21	Day 28	Post Radiation
	Yes	11	12	10	13	14
	No	20	19	21	18	17
	Skindex-16	No. of participants (n) n=31				
		Day 7	Day 14	Day 21	Day 28	Post Radiation
Yes	19	18	17	19	18	
No	12	13	14	12	13	

Table 4: Comparison and reliability of DLQI and Skindex-16 questionnaires.

Comparison of DLQI and Skindex-16 questionnairescore	Follow ups	DLQI	p value
		Mean±SD	
	Day-7	3.43±3.11	0.0001
	Day-14	10.72±3.76	
	Day-21	19.04±5.48	
	Day-28	26.22±4.06	
	Post Radiation	12.59±3.47	
Follow ups	Skindex-16	p value	
	Mean±SD		
Day-7	18.11±12.62	0.0005	
Day-14	43.29±4.39		
Day-21	60.46±6.92		
Day-28	75.55±4.54		
Post Radiation	49.43±11.82		
Reliability of DLQI and Skindex-16 questionnaire	Questionnaires	No. of item per scale	Cronbach's alpha value
	DLQI	10	0.805
	Skindex-16	16	0.781

Our result suggests that 64.5% of illiterate patients have been affected with breast cancer. Katherine E *et al.*, reported a contradictory result which included 8,596 patients in which highly educated women were at greater risk for developing BC (Heck *et al.*, 1997).

We found that 77.41% of participants who consumed mixed diet have been affected with breast cancer (Khanna *et al.*, 2013) This observation was similar to the reports of Karabi Datta *et al.*, higher living standards, a higher BMI, a larger intake of deep-fried meals, and a higher weekly intake of protein and fat were all linked to increased risk and also heating oil repeatedly above 200°C may generate the highly carcinogenic chemical acrolein, which has been linked to BC (Datta *et al.*, 2009)

The present study found that there are 5 most common comorbidities among female patients with BC which, included Hypertension with Diabetes Mellitus (19.35%), Diabetes Mellitus (6.4%) and hypercholesterolemia, epilepsy and thyroid problem (3.2%). These results were comparable with the study conducted by Mei R. Fu *et al.*, which included 140 patients in which hypertension (32.8%), arthritis (32.8%), thyroid problem (22.4%) hypercholesterolemia (12.7%) and diabetes (12.0%). Numerous theories have been put out to explain the connection between high blood pressure and the risk of BC. First, a shared pathophysiological link between hypertension and BC may be mediated by adipose tissue, which raised the risk of hypertension and BC and may induce chronic inflammation (Fu *et al.*, 2015).

The decline in the levels of HRQOL was seen for the patients with severe radiation dermatitis (Grade 3). These results were coinciding with the study conducted by Marceila de Andrade Fuzissaki *et al.*, which included 100 breast cancer patients evaluated weekly during RT showed that there is a determinative effect on patients' quality of life and also experienced severe Radiodermatitis (Grade 3 and 4). This study found that the scoring of DLQI and Skindex-16 questionnaires revealed that RD have detrimental impact on the HRQOL of BC patients. The result showed that the radiotherapy related dermatitis negatively influenced the HRQOL of women with breast cancer (Fuzissaki *et al.*, 2019). The present study found that the DLQI questionnaire is highly reliable instrument for measuring HRQOL of BC patients with radiation dermatitis when compared with Skindex-16 questionnaire.

CONCLUSION

The finding of this study indicated that the DLQI questionnaire was found to be more appropriate questionnaire for measuring HRQOL among breast cancer patients with RD. The help seeking behaviour and time taken for completing DLQI questionnaire was lesser when compared to that of Skindex-16 questionnaire. Hence, DLQI is the highly reliable instrument when compared to Skindex-16 for measuring HRQOL of breast cancer patient with RD. The shortness and ease of implementation of DLQI facilitate the researcher and clinicians to choose the DLQI questionnaire for assessing the HRQOL of breast cancer patients with RD.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

BC: Breast Cancer; **RD:** Radiation Dermatitis; **RT:** Radiation Therapy; **HRQOL:** Health-Related Quality of Life; **DLQI:** Dermatology Life Quality Index; **RTOG:** Radiation Therapy Oncology Group.

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