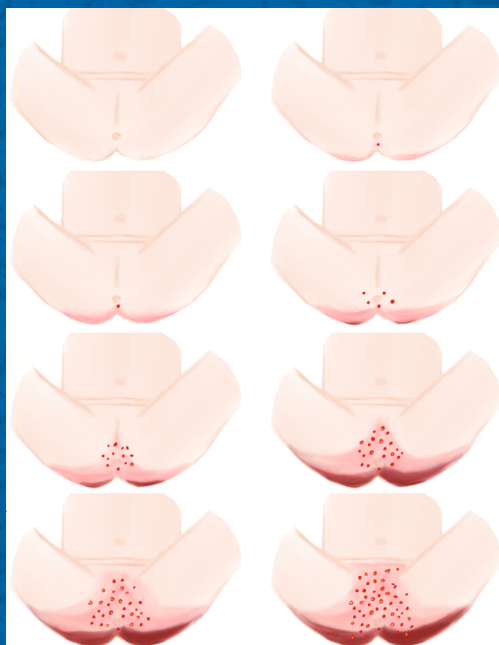


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# An Update on Quality of Life in Malignant Melanoma and Nonmelanoma Skin Cancers

Tubanur Çetinarşlan, Mustafa Kürşat Evrenos<sup>1</sup>, Aylin Türel Ermertcan<sup>2</sup>

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## Abstract

Skin cancer is the most common type of cancer. Nonmelanoma skin cancers (NMSCs) are more common than malignant melanoma. It is expected that the incidence of skin cancer will increase in the future. Although the mortality rate is low, cancer wording can be frightening for patients. Because skin cancers are most commonly located in the head and neck, unwanted cosmetic consequences can occur as a result of treatments. Therefore, the quality of life (QOL) of patients could be affected negatively. Today, there are various scales that assess the QOL of patients. These can be grouped as general, disease-specific, and cancer-specific questionnaires. Studies have been carried out and are still in progress to develop scales of QOL specific to skin cancers. In this paper, the questionnaires used in malignant melanoma and/or NMSCs and studies on this subject are reviewed.

**Keywords:** Nonmelanoma skin cancer, quality of life, skin cancer

## INTRODUCTION

Skin cancer is the most common type of cancer in human and grouped under two main headings: nonmelanoma skin cancers (NMSCs) and malignant melanoma (MM).<sup>[1]</sup> The incidence has increased dramatically over the past 20 years, especially among women and people aged 30–39 years, as a result of excessive exposure to ultraviolet radiation.<sup>[2,3]</sup> Unfortunately, NMSCs occur in the most conspicuous location of the body, with approximately 80% occurring in the cervicofacial region; the nose alone accounts for roughly 25% of all cutaneous malignancies and is followed closely by the external ear and surrounding skin.<sup>[4]</sup> It has been suggested that patients have a 52% risk of developing a second NMSC within 5 years after the diagnosis of squamous cell cancer (SCC), with the highest risk during the first year after diagnosis.<sup>[5,6]</sup> Morbidity assumes greater importance than mortality in many patients with cutaneous malignancies, making quality of life (QOL) a more relevant endpoint in the assessment of the disease process.<sup>[7]</sup> Although skin cancer itself is the most important factor affecting the QOL, the QOL of patients can

be impaired due to the unexpected results and side effects of treatment methods. While a variety of effective treatment options exist for managing these cancers, such as excision, electrodesiccation and curettage, Mohs micrographic surgery, and topical chemotherapies, patients' QOL can be affected by these treatments as well as by potentially cosmetically unsatisfying results.<sup>[8]</sup> Minor as well as major degrees of facial disfigurement can result in high levels of anxiety, depression, and social isolation, the severity of which often bears little relationship to the magnitude of the defect itself.<sup>[9]</sup>

Patient-reported outcomes are increasingly being used to capture patients' perception of a disease, its treatment, and impact on daily living.<sup>[10]</sup> Several scales have been developed to evaluate the QOL and studies are still underway to develop new scales specific to disease. In dermatology, QOL can be assessed utilizing generic QOL questionnaires, dermatology-specific questionnaires, disease-specific questionnaires, or cancer-specific questionnaires.<sup>[11]</sup>

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In this article, QOL questionnaires used in patients with MM or NMSC are discussed and studies about the QOL in patients with MM or NMSC published in PubMed between 2003 and 2019 are reviewed and summarized.

## QUALITY OF LIFE INSTRUMENTS USED FOR EVALUATION OF SKIN CANCERS

The questionnaires which dermatology-specific, skin cancer-specific or cancer-specific to assess the QOL in skin cancers have been shown in Table 1.

### Dermatology-specific questionnaires

Dermatology-specific or disease-specific instruments include aspects of the health-related QOL (HRQoL) that may not be captured by a generic instrument. Disease-specific instruments are more responsive to disease activity and treatment outcome and are therefore often used to reflect the patient perspective in clinical trials and observational research.<sup>[12]</sup>

### The Dermatology Life Quality Index

The Dermatology Life Quality Index (DLQI), the first dermatology-specific HRQoL questionnaire, was published in 1994.<sup>[13]</sup> DLQI is a self-administered tool, developed to assess the disease-specific effects of skin conditions on patients' QOL. It consists of 10 items. The items of the DLQI include symptoms and feelings, daily activities, leisure, work or school, personal relationships, and the side effects of treatment.<sup>[14]</sup> Each item is scored 0–3, yielding a maximum score of 30. Higher scores indicate lower levels of HRQoL. The questions refer to the past week.<sup>[14,15]</sup>

### Skindex

In 1996, Chren *et al.* developed a 61-item self-administered survey instrument called Skindex. Skindex has eight scales, each of which addresses a construct, or an abstract component, in a comprehensive conceptual framework: cognitive effects, social effects, depression, fear, embarrassment, anger, physical discomfort, and physical limitations.<sup>[16]</sup> The questionnaire measures QoL in the previous 4 weeks, on the assumption that

this is a “reasonable timeframe to expect equilibrium after a change in treatment”.<sup>[17]</sup> There are four versions of the Skindex including the original 61-item and the reduced versions: Skindex-29, Skindex-17, and Skindex-16.<sup>[17,18]</sup>

The Skindex-16 is a one-page version measuring how patients are bothered by their skin condition. This includes skin symptoms (i.e., itching, burning), feelings (i.e., frustration, embarrassment, depression), and effects on function (i.e., interactions with others, daily activities, ability to work). The instrument was not developed to measure surgical issues (i.e., scarring) and treatment satisfaction. It may not be regarded as a suitable scale for assessing QOL in skin cancer patients.<sup>[1]</sup>

### Cancer-specific questionnaires

Functional Assessment of Cancer Therapy – General version (FACT-G) and the European Organization for Research and Treatment of Cancer QOL Questionnaire (EORTC QLQ-C30) are two of the most widely used cancer-specific QoL measures. Both instruments have undergone rigorous validation and have been translated and field-tested in approximately 24 different languages, making them suitable for use in multinational clinical trials of cancer therapy and to allow cross-cultural comparisons of people who come from diverse backgrounds.<sup>[19]</sup>

### Functional Assessment of Cancer Therapy– General version

The FACT-G was developed by Cella and colleagues in the United States. The FACT-G meets or exceeds all requirements for use in oncology clinical trials, including ease of administration, brevity, reliability, validity, and responsiveness to clinical change. The five-phase validation process of FACT-G involved 854 patients with cancer and 15 oncology specialists.<sup>[20]</sup>

The FACT-G has undergone several modifications over the past 20 years, and the version that is in use at is present Version IV, which comprises 27 items.<sup>[19]</sup> The FACT-G is comprised of four subscales: Physical well-being (7-items, score range 0–28), social/family well-being (7-items, score range 0–28), emotional well-being (6-items, score range 0–24), and functional well-being (7-items, score range 0–28). Users of the FACT-G are able to generate an overall score and four subscale scores with ranges and distributions that are sample-specific. All questions in the FACT-G use a 5-point rating scale (0 = not at all; 1 = a little bit; 2 = somewhat; 3 = quite a bit; and 4 = very much). Provided more than 50% of the items comprising a subscale are answered, a subscale score is computed as the prorated sum of the item responses for that subscale.<sup>[21]</sup>

### European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30

The EORTC QLQ-C30 contains subscales for global health status, physical, emotional, role, cognitive and social function, with higher scores indicating better functioning.

**Table 1: Quality of life instruments used for evaluation of skin cancers**

Dermatology specific questionnaires	Skin cancer-specific questionnaires	Cancer-specific questionnaires
DLQI	SCQOLIT	FACT-G
Skindex-16	FACT-M	EORTC-QLQ-C30
Skindex-17	SCI	
Skindex-29	EORTC-QLQ-M	
	EORTC-QLQ-MEL38	

DLQI: Dermatology Life Quality Index, SCQOLIT: Skin Cancer Quality of Life Impact Tool, FACT-G: Functional Assessment of Cancer Therapy- General Version, FACT-M: Functional Assessment of Cancer Therapy-Melanoma, EORTC-QLQ-C: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, EORTC-QLQ-MEL: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Melanoma Module, SCI: Skin Cancer Index

Symptom subscales include pain, nausea/vomiting, fatigue, dyspnea, appetite loss, insomnia, diarrhea, and constipation (higher scores indicate greater symptom severity). Extensive evidence is available supporting the reliability, validity, and responsiveness of the EORTC QLQ-C30 in different cancer populations.<sup>[22]</sup>

EORTC-QLQ-30 is a measure which was originally devised by Aaronson and colleagues in the Netherlands. The questionnaire was administered before treatment and once during treatment to 305 patients with nonresectable lung cancer from centers

in 13 countries. Their results support the EORTC QLQ-C30 as a reliable and valid measure of the QOL of cancer patients in multicultural clinical research settings.<sup>[22]</sup> Müller *et al.* validated EORTC-QLQ-C30 in their study in 172 patients with NMSC.<sup>[23]</sup>

**Skin cancer-specific questionnaires**

Among the scales used in skin cancer, Skin Cancer Index (SCI) is used in NMSCs. There are two scales used specifically for melanoma. The first one is EORTC-QLQ-M a disease-specific QoL measure developed from EORTC-QLQ-30. The second

**Table 2. Skin Cancer Index (SCI)<sup>[24]</sup>**

<b>Skin Cancer Index (SCI)</b>					
<b>During the past month how much have you.</b>	<b>Very much</b>	<b>Quite a bit</b>	<b>Modaretaaly</b>	<b>A little bit</b>	<b>Not at all</b>
1. Worried that your skin cancer will spread to another part of your body?	( )	( )	( )	( )	( )
2. Felt anxious about your skin cancer?	( )	( )	( )	( )	( )
3. Worried that family members may also develop skin cancer?	( )	( )	( )	( )	( )
4. Worried about the cause of skin cancer?	( )	( )	( )	( )	( )
5. Felt frustrated about your skin cancer?	( )	( )	( )	( )	( )
6. Worried that your tumor become a more serious type of skin cancer?	( )	( )	( )	( )	( )
7. Worried about new skin cancers occurring?	( )	( )	( )	( )	( )
8. Felt uncomfortable when meeting new people?	( )	( )	( )	( )	( )
9. Felt concerned that your skin cancer may worry friends or family?	( )	( )	( )	( )	( )
10. Worried about the length of time before you can go out in the public?	( )	( )	( )	( )	( )
11. Felt bothered by people’s questions related to your skin cancer?	( )	( )	( )	( )	( )
12. Felt embarrassed by your skin cancer?	( )	( )	( )	( )	( )
13. Worried about how large the scar will be?	( )	( )	( )	( )	( )
14. Thought about how skin cancer affects your attractiveness?	( )	( )	( )	( )	( )
15. Thought about how noticeable the scar will be to others?	( )	( )	( )	( )	( )

**Table 3. SCQOLIT Questionnaire<sup>[28]</sup>**

<b>Skin Cancer Quality of Life Assessment Tool (SCQOLIT)</b>				
The purpose of this questionnaire is to measure how much having skin cancer has affected your quality of life OVER THE LAST WEEK. Please tick one box for each question and answer all questions.				
	<b>Very much so</b>	<b>Modaretaaly so</b>	<b>Somewhat</b>	<b>Not at all</b>
Over the last week, how much have you been concerned that your skin cancer might come back?	( )	( )	( )	( )
Over the last week, how much have you felt that you need more information on how to recognize skin cancer or prevent it?	( )	( )	( )	( )
Over the last week, how much have you worried about covering up your skin and keeping out of the sun?	( )	( )	( )	( )
Over the last week, how much have you felt a need for reassurance from your doctor or nurse, in respect to your skin cancer or its treatment?	( )	( )	( )	( )
Over the last week, how much have you felt emotional, anxious, depressed, guilty or stressed, in respect to your skin cancer or its treatment?	( )	( )	( )	( )
Over the last week, how much have you bothered about disfigurement or scarring, in respect to your skin cancer or its treatment?	( )	( )	( )	( )
Over the last week, how much have you felt shock or disbelief about having been diagnosed with skin cancer?	( )	( )	( )	( )
Over the last week, how much skin discomfort or inconvenience have you experienced, in respect to your skin cancer or its treatment?	( )	( )	( )	( )
Over the last week, how much have you had concerns about dying from your skin cancer?	( )	( )	( )	( )
Over the last week, to what extent have you felt the need for emotional support from your family or friends, in respect to your skin cancer or its treatment?	( )	( )	( )	( )

melanoma-specific scale is FACT-melanoma (FACT-M). Skin Cancer QOL Impact Tool (SCQOLIT) is developed for use in patients with either non-metastatic MM or non-metastatic NMSC skin cancer.

**The Skin Cancer Index**

In 2005, Rhee *et al.* developed Facial SCI as a new disease-specific QOL instrument for patients with NMSC of the head and neck.<sup>[7]</sup> SCI is a 15-item disease-specific QOL instrument [Table 2].<sup>[24]</sup> It is a sensitive and responsive QoL instrument for patients with NMSC. The SCI consists of three subscales: Emotion (i.e., anxiety, worry, frustration), social (i.e., meeting new people, time away from public), and appearance. There is also an appearance subscale with questions addressing scar visibility, size, and effects on attractiveness. Distinct demographic and clinical variables that impact QoL have been demonstrated using this multidimensional, disease-specific instrument.<sup>[24,25]</sup>

Unlike the SCI, there are no distinct subscales in the DLQI, although the individual items do address some similar concerns as in the SCI. However, the DLQI items appear to be more tailored for chronic, benign skin conditions such as psoriasis or eczema because they emphasize physical complaints of itchiness and irritation and do not capture issues related to scarring, disfigurement, and worry about recurrence or

new lesions.<sup>[25]</sup> Compared with other dermatological QOL tools, the SCI captures issues specific to facial skin cancers such as scarring, disfigurement and concerns about possible recurrence [Table 2].<sup>[26]</sup>

Rhee *et al.* validated SCI in their study with 211 patients presenting with cervicofacial NMSC. In this study, they found that the emotional and appearance subscales had lower standardized scores and therefore, demonstrated greater negative effect on QoL with cervicofacial NMSC.<sup>[24]</sup>

**Skin Cancer Quality of Life Impact Tool**

Burdon *et al.* developed a questionnaire specifically for use in patients with either non-metastatic MM or nonmetastatic NMSC skin cancer, and named the SCQOLIT [Table 3]. In this study, in 100 patients with nonmetastatic skin cancer [50 with MM and 50 with NMSC] was included. The patients with NMSC, 45% were concerned about the possibility of scarring or disfigurement, particularly on the face.<sup>[27]</sup> The SCQOLIT consists ten questions. Each question asks to what extent the patient has been concerned about that particular theme, in the last week. Scoring for each question is: (3) Very much so; (2) Moderately so; (1) Somewhat; (0) Not at all. To obtain the total score the responses to all questions are summed, and a maximum total score of 30 is possible.<sup>[28]</sup> Also Burdon-Jones *et al.* performed SCQOLIT validation study.

**Table 4: Functional assessment of cancer therapy-melanoma questionnaire<sup>[30]</sup>**

Melanoma subscale	Not at all	A little bit	Some-what	Quite a bit	Very much
I have pain at my melanoma site or melanoma surgical site	0	1	2	3	4
I have noticed new changes in my skin (lumps, bumps, color)	0	1	2	3	4
I worry about the appearance of surgical scars	0	1	2	3	4
I have been shorth of breath	0	1	2	3	4
I have to limit my physical activity because of my condition	0	1	2	3	4
I have had headaches	0	1	2	3	4
I have had fevers	0	1	2	3	4
I have swelling or cramps in my stomach area	0	1	2	3	4
I have a good appetite	0	1	2	3	4
I have aches and pains in my bones	0	1	2	3	4
I have noticed blood in my stool	0	1	2	3	4
I have to limit my social activity because of my condition	0	1	2	3	4
I feel overwhelmed by my condition	0	1	2	3	4
I isolate myself from others because of my condition	0	1	2	3	4
I have difficulty thinking clearly (remembering, concentrating)	0	1	2	3	4
I feel fatigued	0	1	2	3	4
<b>Melanoma Surgery Scale</b>					
I have swelling at my melanoma site	0	1	2	3	4
I have swelling as a result of surgery	0	1	2	3	4
I am bothered by the amount of swelling	0	1	2	3	4
Movement of my swelling area is painful	0	1	2	3	4
Swelling keeps me from doing the things I want to do	0	1	2	3	4
Swelling keeps me from wearing the clothes or shoes that I want to wear	0	1	2	3	4
I feel numbness at my surgical site	0	1	2	3	4
I have good range of motion in my arm or leg	0	1	2	3	4

FACT-M: Functional assessment of cancer therapy-melanoma



**Table 5: Quality of life studies**

First of author	Years	Population	Number of patients	Measure of QOL	Time	Treatment modality	Mean age	Study type	Country	Localization	Results
Rhee et al. <sup>[46]</sup>	2003	NMSC	121	FACT-G, SF-36	Before surgery, 1 month after surgery, and 4 months after surgery	Surgery	63	Prospective	USA	Head and neck	Sun-protective behaviors were positively associated with certain QOL subscale scores. General QOL instruments demonstrated minimal impact of NMSC on patients at initial diagnosis. General measures may not be sensitive to the impact of nonmelanoma skin cancer
Rhee et al. <sup>[44]</sup>	2004	NMSC	121	DLQI	Before and after 4 months surgery	4 Surgery	63	Prospective	USA	Head and neck	General dermatology QOL instruments demonstrated minimal handicap at initial diagnosis and little change after treatment of NMSC
Newton-Bishop et al. <sup>[60]</sup>	2004	Melanoma	426	MOS-SF36	At 1 months, 3 months, 6 months, 1 year, and 2 years after surgery	Surgery	62.2	Prospective	UK	All	Patients with a 3 cm excision margin reported significantly poorer mental and physical functioning compared with those with a 1 cm excision margin. However, within 6 months, the difference in impact on health-related quality of life between the two groups was no longer significant, except for persisting concern about the scar in the 3 cm excision group
Dixon et al. <sup>[62]</sup>	2006	Melanoma	674	EORTC-QLQ-C30	At baseline, 3, 6, 12, 24, 36, 48 and 60 months for a subgroup of patients	Interferon alpha-2a		RCT	UK		As assessed by the EORTC QLQ-C30, statistically significant differences were found in terms of role functioning, emotional functioning, cognitive functioning, social functioning, and global health status. Symptom scores in the IFN group were significantly worse for fatigue, nausea/vomiting, dyspnoea, appetite loss, constipation and diarrhoea
Rhee et al. <sup>[24]</sup>	2006	NMSC	211	SCI		Surgery	63	Validation	USA	CF	SCI is a reliable and valid QOL instrument
Chren et al. <sup>[48]</sup>	2007	NMSC	633	Skindex-16	At baseline, 12, 18, and 24 months after treatment	Mohs, surgery and electrodesiccation and curettage	66.1	Prospective	USA	All	For NMSC, quality-of-life outcomes were similar after excision and Mohs surgery, and both therapies had better outcomes than ED and C. The skindex-16 scores of NMSC patients were relatively low in all treatment groups
Cormier et al. <sup>[30]</sup>	2008	Melanoma (Stage I-IV)	273	FACT-M	At months 3, 6, 12 and follow up visits		52	Validation	USA	All	The FACT-M questionnaire is a reliable and valid instrument for patients with melanoma that can be used for the assessment of QOL in clinical trials
Berganmar et al. <sup>[59]</sup>	2010	Melanoma	144	EORTC-QLQ-C30	Before randomization, and at 3, 9, and 15 months after inclusion	Surgery	60.4	Prospective	Sweden	Trunk or extremities	No difference was found in emotional distress or health-related QoL between patients randomized to narrow or wide excision

Contd...

**Table 5: Contd...**

First of author	Years	Population	Number of patients	Measure of QOL	Time	Treatment modality	Mean age	Study type	Country	Localization	Results
Waldmann <i>et al.</i> <sup>[52]</sup>	2011	Melanoma	450	EORTC-QLQ-C30	15 months and 39 months after postdiagnosis	Surgery	63 (male) 56 (women)	Prospective	Germany	All	Clinically relevant changes did not occur between postdiagnosis and 2 years after across all scales of the EORTC QLQ-C30 of patients with stable disease
Loquai <i>et al.</i> <sup>[61]</sup>	2011	Melanoma	30	EORTC-QLQ-C30	At baseline and every 3 months during treatment	PEG-IFN-a-2b	50.8	Retrospective	Germany	All	QOL documented by physicians was significantly higher than QOL from the patients' questionnaires in all QOL dimensions. PEG-IFN-α2b has measurable effects on QOL. Measuring QOL based only on physicians' patient files without explicitly determining patients' assessments leads to a profound underestimation of impairment of QOL
Revicki <i>et al.</i> <sup>[63]</sup>	2012	Melanoma (Stage I-IV)	676	EORTC-QLQ-C30	Baseline to week 12	Ipilimumab	56.2	RCT	USA		Ipilimumab at 3 mg/kg with and without gp 100 vaccine does not have a significant negative impact on HRQL in patients completing the baseline and week 12 follow-up, during the treatment induction phase compared with gp 100 alone
Caddick <i>et al.</i> <sup>[26]</sup>	2012	NMSC and melanoma	53	SCI	Before and after 3 months surgery	Surgery	70% patients aged 66 years above	Prospective	UK	Head and neck	Surgical excision improves social, emotional, and cosmetic well-being in patients with facial skin malignancies
Burdon-Jones and Gibbons <sup>[58]</sup>	2013	NMSC and Melanoma	120	SCQOLIT	At 7 days, and the other half at 3 months	Surgery	67 (MM), 73 (NMSC)	Validation	Australia		The SCQOLIT is a validated disease-specific QOL questionnaire for use in patients following treatment of nonmetastatic skin cancer. Higher SCQOLIT scores are observed in MM patients than NMSC patients, but diminish with time in the MM group
Vinding <i>et al.</i> <sup>[45]</sup>	2014	NMSC	101	SCQOLIT, DLQI	Before surgery, 3 months after	Surgery	69.4	Responsiveness	Denmark	All	No statistically significant difference was found for the total score testing responsiveness
Tromme <i>et al.</i> <sup>[58]</sup>	2014	Melanoma	395	EQ-5D-5L, VAS, FACT-M	1-24 months after surgery	Surgery	52.6	Prospective	Belgium		The VAS and the FACT-M were found to be less sensitive. The EQ-5D-5L questionnaire seems adequate to provide utilities and DWs in patients with melanoma. Lower HRQoL in female patients with melanoma is probably linked to lower HRQoL in the general population

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**Table 5: Contd...**

First of author	Years	Population	Number of patients	Measure of QOL	Time	Treatment modality	Mean age	Study type	Country	Localization	Results
Hawkins <i>et al.</i> <sup>[8]</sup>	2015	NMSC and Melanoma	161	Skindex-16, SCI	At baseline and 2, 6 weeks, and 3 months post-IL1	Isolated limb infusion	44	Prospective	USA	All	There is a modest impact on quality of life in young patients with skin cancer based on the Skindex-16 and SCI. Young skin cancer survivors may benefit from patient counseling, which addresses risk assessment and future risk reduction
Jiang <i>et al.</i> <sup>[64]</sup>	2015	Melanoma	28	FACT-M	At time of diagnostic, 7 days after surgery, and 5 months after surgery	Surgery	69.6	Prospective	USA	Extremities	Using a validated HRQOL measure, quality of life was not impacted by ILI for advanced extremity melanoma
de Troya-Martín <i>et al.</i> <sup>[50]</sup>	2016	NMSC	88	SCI	Beginning or prior to treatment	Surgery	62.5	Responsiveness	Spain, Australia, USA	CF	Their results confirm the ability of the Spanish version of the SCI to discriminate changes in the HRQL of patients with CFNMSC
Müller <i>et al.</i> <sup>[23]</sup>	2017	NMSC	172	EORTC-QLQ-C30	Beginning or prior to treatment	Surgery	70	Validation	Germany	All	QLQ-C30 to be a suitable tool for the assessment of QL in patients with NMSC

MOS-SF36: Medical Outcomes Survey-Short Form 36, RCT: Randomize clinical trial, CF: Cervicofacial, FACT-G: Functional Assessment of cancer Therapy- General Version, SF-36: Short Form 36, QOL: Quality of life, NMSC: Nonmelanoma Skin Cancers, DLQI: Dermatology Life Quality Index, EORTC-QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, SCI: Skin Cancer Index, FACT-M: Functional Assessment of Cancer Therapy-Melanoma, HRQL: Health-Related Quality of Life, BCC: Basal cell carcinoma, SCQOLIT: Skin Cancer Quality of Life Impact Tool, MM: Melanoma, VAS: Visual Analogue Scale, CFNMSC: cervicofacial non melanoma skin cancer, IFN: interferon, PEG-IFN-α2b: pegile interferon-α2b

The SCQOLIT was constructed and administered initially to 120 patients with non-metastatic skin cancer, 60 with MM and 60 with (NMSC following treatment, then repeated at seven days, and at 3 months. They found higher SCQOLIT scores in MM patients than NMSC patients, but diminish with time in the MM group. The SCQOLIT is a validated disease-specific QOL questionnaire for use in patients following treatment of non-metastatic skin cancer.<sup>[28]</sup>

**Functional Assessment of Cancer Therapy-Melanoma**

The melanoma module for the FACT-G has been developed and validated by Cormier *et al.* as an independent tool and an add-on to the FACT-G; when the FACT-G and the melanoma module are administered together, they constitute the FACT-M. The MM-specific health QoL (FACT-M) was developed for clinical trial purposes involving 273 high risk patients with stages I–IV melanoma, including those with metastatic disease who have lower survival rates than most patients with melanoma in the general population and who receive additional surgical and / or systemic therapy. The FACT-M includes a melanoma module comprised of 24 total items [Table 4]. 24 items encompassing three HRQoL domains: physical, emotional, and social well-being. The melanoma module consists of 16 items related to melanoma and an additional 8 items pertaining to the surgical treatment of melanoma.<sup>[29]</sup> The FACT-M has been shown to be responsive and sensitive in patients with melanoma at all stages of disease.<sup>[30]</sup>

**European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-MEL38**

Winstanley *et al.* developed EORTC QLQ-MEL38 that a new EORTC Melanoma Module in their study. In this study, fifty-six issues were rephrased as questions and piloted with 132 patients. EORTC-QLQ-MEL38 is a measure 38-item questionnaire. It comprises 33 scoring items, two single items and three items associated with clinical trials. Responses to 14 scoring items relate to patient experience “during the past 4 weeks” and the remaining 19 items relate to experience “during the past week.”<sup>[31]</sup>

EORTC-QLQ-M a disease-spesifik QoL measure developed from EORTC-QLQ-30. Winstanley *et al.* tested the cross-cultural reliability and validity of the EORTC QLQ-M. They suggested that many of the important issues could be viewed as “generic”; however, a cross-cultural instrument does not presently exist to gather together all the relevant items that adequately represent a melanoma patients experience.<sup>[31]</sup>

The another melanoma module of the EORTC-QLQ-C30 is designed for patients only with advanced (stage IV) disease in 1994 by Sigurdardottiret al. This module consists of 13 items and evaluates disease-specific symptoms related to disease treatment and progression.<sup>[29,32]</sup>

**QUALITY OF LIFE IN NONMELANOMA SKIN CANCERS**

Although NMSCs are the most common cancers in humans, it has a low mortality rate (0.1%–0.3%), but its tendency to

affect the face and to recur in the same subject produces a high morbidity rate.<sup>[33]</sup>

The scarring sequelae secondary to surgery are often unsightly and are sometimes associated with functional disorders, such as ectropion, epiphora, corneal erosion, nasal obstruction, oral incompetence, microstomia, inability to use hearing aids or spectacles and facial paralysis.<sup>[4,34]</sup> If detected early, even high risk NMSCs can be successfully treated and serve as a wake-up call for behavioral change and enhanced HRQoL.<sup>[35]</sup> Worries about possible facial disfigurement and potential scarring are important patient-level concerns that may present barriers to early treatment.<sup>[36]</sup>

Less than 5% of all BCC cases become locally advanced or metastatic.<sup>[37]</sup> Locally advanced BCC occurs when BCC extends into subcutaneous and soft tissues or other critical structures, and surgery or radiation therapy may be undesirable or contraindicated. BCC that metastasizes to distant sites is rare, accounting for <1% of cases of BCC.<sup>[38]</sup> Patients with nonadvanced or locally advanced and metastatic BCC experience disease-related symptoms that affect their HRQoL, activities of daily living, emotional well-being, and social and/or leisure activities.<sup>[39]</sup> Steenrod *et al.* compared symptoms and impact of varying stages of basal cell carcinoma.<sup>[40]</sup> Similar to Mathias *et al.*,<sup>[39]</sup> Steenrod found that impacts on emotional well-being and daily activities were common and more frequently reported in patients with more advanced disease.<sup>[37,40]</sup>

Previously studies have shown a change of sun behavior towards more sunprotective behaviors especially among younger cohorts after surgery for NMSC.<sup>[41-44]</sup> However, it may be speculated that a reduction in the score of the domain function may be seen with time as people get more used to the behavior one had to adapt after being diagnosed with skin cancer – e.g., protection of skin, using a sunscreen etc., and this simply becomes a lifestyle.<sup>[45]</sup> Rhee *et al.* performed a cross-sectional study of 121 patients with NMSC of the head and neck using the Medical Outcomes Study Short Form 36-item Health Survey (SF-36) and the Functional Assessment of Cancer Therapy-General (FACT-G). They found sun-protective behaviors were positively associated with certain QOL subscale scores in the population in the study. General QOL instruments demonstrated minimal impact of NMSC on patients at initial diagnosis.<sup>[46]</sup> For the BCC/SCC population, general dermatology instruments (Skindex, DLQI) with or without generic (e.g., Short Form 36-item Health Survey, United Kingdom Sickness Impact Profile) or cancer-specific (e.g., Functional Assessment of Cancer Therapy-General) instruments have been used but generally show minimal effects on QoL.<sup>[35,46,47]</sup> Although the results of Finlay and Khan suggest that atopic eczema, pruritus, and psoriasis have a greater impact on HRQoL than BCC, the items were geared more toward these skin conditions rather than skin cancer.<sup>[13]</sup> As these instruments were not developed for the NMSC population, they may not be sensitive to capture relevant QoL issues.<sup>[1]</sup>

BCC can be treated with many modalities such as surgical excision, topical immunomodulations, Mohs micrographic surgery, photodynamic therapy, electrodesiccation and curettage (EDC), and X-ray therapy. Other treatment modalities such as laser, photodynamic therapy, and topical immunomodulators are non-surgical treatment options. In certain situations, nonsurgical treatments may offer some advantages in terms of reduction of scarring and better cosmetic results. Currently, surgical removal, remains the mainstay for the vast majority of patients with NMSC.<sup>[25]</sup> Chren researched a prospective cohort study of 633 patients with NMSC, evaluating QoL outcomes of EDC, surgical excision and Mohs micrographic surgery (MMS) at baseline, 12, 18 and 24 months. The Skindex-16 scores of NMSC patients were relatively low in all treatment groups.<sup>[48]</sup> On the contrary, Caddick *et al.* found that surgical excision improves social, emotional, and cosmetic well-being in patients with facial skin malignancies. This is likely to reflect reassurance experienced by the knowledge a lesion has been completely removed.<sup>[44]</sup>

Vinding *et al.* used SCQOLIT twice-before the operation and 3 months after surgery in 101 patients with NMSC. In their study no statistically significant difference was found for the total score testing responsiveness.<sup>[45]</sup> Reported outcomes are dependent on the time point of questionnaire completion, therefore differences in the postoperative time interval between NMSC surgery and questionnaire completion may cause disparities in reporting of outcomes.<sup>[45,49]</sup>

Age, gender, stage, local or metastatic disease and localization are the factors which affect the QOL in NMSCs. Rhee *et al.* demonstrated female sex was predictive of poorer QoL as a main effect for the SCI total score, SCI appearance subscale, and the DLQI. Female sex also predicted greater improvement in QoL over time for the SCI appearance subscale. They suggested that the SCI is a highly sensitive and clinically responsive measure of QoL changes for NMSC patients.<sup>[25]</sup> de Troya-Martín *et al.* investigated responsiveness of the Spanish Version of the SCI in 88 NMSC patients at time of diagnosis, 7 days after surgery, and 5 months after surgery. They found that HRQoL to be more severely affected among female patients and patients of both sexes aged under 65 years.<sup>[50]</sup>

Consequently, studies using dermatology-specific QoL and generic health QoL measures have shown only minimal impact of NMSC on patients.<sup>[5,51]</sup> In contrast, studies using open-ended questions for NMSC<sup>[27]</sup> have identified a number of significant QoL issues-especially emotional concerns.<sup>[5,51]</sup>

## QUALITY OF LIFE IN MALIGNANT MELANOMA

Melanoma affects all age groups and parts of the body, and the treatment pathway varies considerably according to the stage of the disease.<sup>[31]</sup> Rising incidence rates of MM are of worldwide concern, in particular in the white population.<sup>[52]</sup>

For many people, there are significant emotional, social, and psychological consequences to having melanoma. A diagnosis



of melanoma may change many aspects of an individual's life from self-identity, self-esteem, body image, and perceived well-being, to family roles and relationships, lifestyle behaviors, sexuality, career opportunities, friendships, and finances. Patients often experience shock, fear, sadness, anger, and sometimes guilt at the time of diagnosis, and some will also have to face progressive illness and approaching death.<sup>[53]</sup>

In a recent systematic review of literature, studies showed that approximately 30% of all patients diagnosed with MM report levels of psychological distress indicative of the need for clinical intervention. This level of clinical distress is equivalent to that identified in patients with breast and colon cancer.<sup>[54-56]</sup>

About 80% of patients will survive MM, but will remain at risk of disease progression for many years.<sup>[57]</sup> MM, therefore, can be considered a chronic disease with a considerable impact on patients' HRQoL, defined by the WHO as "an individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns."<sup>[31]</sup>

Tromme *et al.* submitted three questionnaires (EQ-5D-5 L, VAS and FACT-M) to 395 MM patients. They found that the relatively good HRQoL of patients with stage IV MM in remission, similar to patients with stage 0–II MM in remission.<sup>[58]</sup> Burdon-Jones *et al.* demonstrated that scores for the MM group (independent of Breslow thickness) were greater than the NMSC group, suggesting an awareness among MM patients of a having had a more potentially serious skin cancer. It is possible that a further reduction in SCQOLIT scores, to clinically significant levels, may be seen over time, as patients became more confident of a favorable outcome following successful treatment of their skin cancer, adapted their behavior to minimize excess sun exposure, and became better informed about skin cancer and recognizing it.<sup>[28]</sup>

Waldmann *et al.* performed (QoL) study in a total of 450 melanoma patients who filled out the EORTC QLQ-C30, 15 months post diagnosis and follow-up questionnaires two years after. They found that clinically relevant changes did not occur between post diagnosis and 2 years after across all scales of the EORTC QLQ-C30 of patients with stable disease. They suggested the EORTC QLQ-C30, a generic QoL instrument, is not sensitive enough to measure QoL-related issues that are specific to melanoma.<sup>[52]</sup>

Currently surgery remains the cornerstone of treatment for patients with cutaneous malignancies.<sup>[26]</sup> In the studies performed, skin-cancer-specific questionnaires were used to examine the effects of excision margin and pathological stage on QoL, in patients with MM. Bergenmar *et al.* investigated the effect of excision margin, a total of 144 patients, using the EORTC QLQ-C30 on QoL in cutaneous melanoma. They found no differences in emotional distress or health-related QoL between patients randomized to narrow or wide excision. Wider excision resulted in no increased emotional distress or reduced HRQoL up to 15 months after the operation, despite

larger scars that often included skin grafts.<sup>[59]</sup> In contrast, in a surgical randomized controlled trial of high-risk patients with melanoma, patients with a 3-cm excision margin reported significantly poorer mental and physical functioning compared with those with a 1-cm excision margin. However, within 6 months, the difference in impact on HRQoL between the two groups was no longer significant, except for persisting concern about the scar in the 3-cm excision group.<sup>[53,60]</sup>

Adjuvant interferon-alpha (IFN- $\alpha$ ) is well established as adjuvant therapy in patients with thick primary MM and those with resected regional lymph node metastases. Loquai *et al.* demonstrated that the PEG-IFN- $\alpha$ 2b (Pegile interferon- $\alpha$  2b) treatment adversely affected patients' QoL in most dimensions of the EORTC QLQ-C30. They found that the function domains were impaired consistently, while within the symptom domains fatigue and appetite loss were more affected than the others.<sup>[61]</sup> Also Dixon *et al.* randomized 674 MM patients to interferon alpha-2a (3 megaunits three times per week for 2 years or until recurrence) or placebo. As assessed by the EORTC QLQ-C30, statistically significant difference was found in terms of role functioning, emotional functioning, cognitive functioning and global health status.<sup>[62]</sup>

Revicki *et al.* investigated EORTC-QLQ-C30 in 676 previously treated advanced unresectable stage III or IV MM patients. They randomized patients in this trial 3:1:1 to receive either ipilimumab (3 mg/kg q3w x 4 doses) + gp100 (peptide vaccine; 1 mg q3w x 4 doses; ipilimumab plus gp100); gp100 vaccine + placebo (gp100 alone); or ipilimumab+ placebo (ipilimumab alone). They suggested that ipilimumab at 3 mg/kg with and without gp100 vaccine does not have a significant negative impact on HRQoL in patients completing the baseline and week 12 follow-up, during the treatment induction phase compared with gp100 alone.<sup>[63]</sup>

Jiang *et al.* investigated quality of life using FACT-M in 28 advanced extremity MM patients treated with ILI (isolated limb infusion). They found using a validated HRQoL measure, quality of life was not impacted by ILI for advanced extremity MM.<sup>[64]</sup> Quality of life studies in NMSC and MM have been shown in Table 5.

## CONCLUSION

Skin malignancies are the most common cancers in humans. Patient-reported outcomes are increasingly being used to capture patients' perception of a disease, its treatment and impact on daily living.

The DLQI is general dermatology measure and further evaluations suggest that the items do not reflect what is important to patients with skin cancer. The Skindex provides more promising properties for patients with NMSCs but most evaluations have included a general dermatological population of patients with small subsamples of patients with NMSCs. The Skindex and DLQI may not be sensitive enough to capture relevant outcomes specific to skin cancer. The SCQOLIT is

applicable to both NMSC and MM, but is not specific to NMSC, nor does it elicit detailed cosmetic concerns. The SCI has been specifically formulated and validated in patients with NMSC and it demonstrates the most usefulness in patients with NMSC.

It is often difficult to capture disease-specific issues even with the administration of a combination of instruments. For example, in patients with melanoma, issues such as lymphedema and post-surgical scarring would not likely be assessed with most available QOL instruments. The FACT-M was developed to address melanoma-specific issues related to QOL for patients with all stages of melanoma. The FACT-M has more promising characteristics for patients with MMs, especially those with advanced disease and the EORTC-M may also be an attractive option. Consequently, the use of disease-specific scales is likely to be more effective in understanding the effect of the disease on the QOL of the patient. Skin cancer specific measures should be preferred over general dermatology scales in evaluating the QOL in skin cancer patients.

Future studies will lead to the development of more specific questionnaires for melanoma and NMSCs. In this way the impact of skin cancers on the QOL will be better understood and the surgical, topical or systemic treatment effect on QOL of skin cancer patients will compare more easy. Furthermore, we performed cultural adaptation, validation, and reliability study of the SCI which was developed for evaluation of non-metastatic NMSC. We hope to publish the results of this study soon.

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### Conflicts of interest

There are no conflicts of interest.

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# Psychiatric Disorders, Family Functions, and Parent Psychiatric Symptoms in Children and Adolescents with Chronic Dermatological Diseases Treated with Phototherapy

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## Abstract

**Objective:** The aim of this study was to examine comorbid psychiatric disorders, family functioning, and parental psychiatric symptoms in children and adolescents with chronic dermatological diseases and compare them with those of healthy controls. **Materials and Methods:** The research sample consisted of patients between the age of 9 and 18 years ( $n = 45$ ) with alopecia areata, vitiligo, or psoriasis and a control group (CG) of healthy children and adolescents of the same age ( $n = 42$ ). The psychiatric diagnoses of cases were established using Schedule for Affective Disorders and Schizophrenia for School Aged Children Present-Lifetime Version. Family assessment device (FAD) was used to evaluate family functioning levels. Parental psychiatric symptom levels were obtained by the Symptom Checklist-90-R. **Results:** Children and adolescents with chronic dermatological diseases had significantly higher rates of any anxiety disorders and any axis I comorbid psychiatric disorders than healthy controls after adjusting for socioeconomic status ( $P < 0.05$ ). There were no significant differences in parental psychiatric symptom levels and family functioning levels between two groups; however, families of patients with comorbid psychiatric disorders had significantly higher scores in problem-solving and communication subscales of the FAD when compared to those of patients without psychiatric disorders and CG. **Conclusions:** Our findings suggest that children and adolescents with chronic dermatological diseases have higher risk for anxiety disorders. When psychiatric disorders co-occur with the dermatological disease in children and adolescents, they may adversely affect the family functioning, in the domains of problem-solving and communication skills.

**Keywords:** Alopecia, children, psoriasis, psychopathology, vitiligo

## INTRODUCTION

Psoriasis is a chronic, inflammatory skin disease that affects approximately 1% of the children and adolescents.<sup>[1]</sup> Although the etiology of the disease is not yet known, it is thought to be a T-cell-dependent autoimmune disorder caused by genetic and environmental factors.<sup>[2]</sup>

Vitiligo is another chronic dermatological illness characterized with depigmented macules due to loss of epidermal melanocytes. The prevalence of vitiligo is roughly 0.1%–2% worldwide.<sup>[3]</sup> Intrinsic defects within melanocytes which make these cells less tolerant to stress, activation of innate immunity, cytotoxic T cells associated with melanocyte destruction and

autoimmunity, and genetic factors play a major role in vitiligo development.<sup>[4]</sup>

Alopecia areata (AA) is a complex genetic, immune-mediated disease that targets hair follicles. The disease affects children and adults and is characterized by round or oval patches of hair loss, loss of all scalp hair or body hair.<sup>[5,6]</sup> AA nearly affects males and females equally. Its lifetime prevalence is approximately 1.7% and as many as 60% of patients with AA have their first patch before 20 years of age.<sup>[7]</sup>

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These chronic, disfiguring skin diseases negatively affect a person's appearance, self-esteem, and quality of life.<sup>[8-10]</sup> In significant amount of cases, the onset of these diseases is before 18 years of age, yet there are limited data regarding co-occurring psychiatric disorders in children and adolescents.

In recent years, there has been an increasing interest in the differences in patients' responses to chronic diseases. Individual factors such as temperament and coping styles, and environmental factors such as family functioning, parent's psychopathology, and social support are found to be contributing factors regarding differences in individual responses.<sup>[11,12]</sup> There are a few studies demonstrating that family functioning is an important indicator of treatment adherence, quality of life, and well-being in children and adolescents with chronic medical illnesses.<sup>[13-15]</sup>

In the present study, we aimed to compare children and adolescents with a diagnosis of psoriasis, vitiligo, or AA with a healthy control group (CG) in terms of family functioning levels, psychiatric comorbidities, and parental psychiatric symptom scores.

## MATERIALS AND METHODS

### Participants

The sample included 45 patients (study group [SG]) and 42 children and adolescents free of any chronic disease (CG), aged between 9 and 18 years. Psoriasis ( $n = 16$ ), vitiligo ( $n = 12$ ), and AA ( $n = 17$ ) patients who were referred to the Phototherapy Unit for ultraviolet B treatment were recruited. This was a cross-sectional study, and all patients were under treatment. The exclusion criteria were the presence of mental retardation, pervasive developmental disorders, and significant neurological illness including history of head injury leading to loss of consciousness. Research Ethics Committee approved the study with the protocol number 09.2016.144.

### Procedure

All patients were examined by a dermatologist in the phototherapy unit. Disease severity was assessed by Psoriasis Area and Severity Index (PASI) and Severity of Alopecia Tool (SALT) score in psoriasis and AA patients, respectively. Psoriasis patients with a PASI score below 5 and AA patients with a SALT score below 50% were considered to have mild disease. No severity assessment tool was used for vitiligo, rather, the disease was classified as localized or generalized. There are studies reporting that body surface area involvement in vitiligo patients may be useful in assessing the severity of the disease.<sup>[16]</sup> The sociodemographic data of all sample were collected by a researcher using a detailed form and socioeconomic status (SES) was calculated based on parents' education and income levels. Written informed consent was obtained.

### Measures

#### *Schedule for Affective Disorders and Schizophrenia for School-Aged Children Present-Lifetime Version*

The psychiatric diagnoses were established using Turkish

version of Schedule for Affective Disorders and Schizophrenia for School Aged Children Present-Lifetime Version. K-SADS, developed by Kaufman *et al.*, is a semi-structured diagnostic interview designed to assess current and past episodes of psychopathology in children and adolescents, according to DSM-IV criteria.<sup>[17]</sup> The validity and reliability study in Turkey was carried out by Gokler *et al.* in 2004.<sup>[18]</sup>

#### *Family assessment device*

Family assessment device (FAD) is a 60-item tool based on the McMaster Model that assesses family functioning on six different dimensions: problem solving (ability to resolve problems), communication (exchange of clear and direct verbal information), roles (division of responsibility for completing family tasks), affective responsiveness (ability to respond with appropriate emotion), affective involvement (family members are involved and interested in one another), and behavior control (express behaviors of family members against problems). The FAD also includes an independent dimension of general functioning (overall functioning of family). FAD items require individuals to rate their level of agreement/disagreement on specific family behaviors using a 4-point Likert scale ranging from 1 (strongly agree) to 4 (strongly disagree). Higher scores are indicative of poorer family functioning.<sup>[19]</sup> The Turkish validity and reliability study of the scale was conducted by Bulut<sup>[20]</sup> In our study, one of the parents was asked to fill this scale.

#### *The Symptom Checklist-90-R*

The Symptom Checklist-90-R, a self-report screening tool, was used to assess the presence of psychiatric symptoms in parents. The scale was developed by Derogatis and Unger in 1973 and the reliability and validity study of the scale was conducted by Dağ in 1991. It generates scores for nine dimensions of symptoms (somatization, obsessive-compulsive behavior, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism), as well as a sum score-Global Severity Index.<sup>[21,22]</sup> In our study, one of the parents was asked to fill this test.

### Statistical analysis

The data were evaluated using the IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp. Descriptive statistics were shown as mean-standard deviation, median, interquartile range, or frequency (%). A 95% confidence interval was used to assess the data. The Chi-square test was applied to categorical variables for comparing gender distributions and psychiatric diagnosis between two groups of children. Student's *t*-test was used to evaluate mean scores for age and SES, Mann-Whitney U-test was used to determine the differences in family functions and parent's psychiatric symptom levels between two groups, and Kruskal-Wallis test was used for comparing family functioning between three groups. SES was adjusted by one-way analysis of covariance. Significance was set at  $P < 0.05$ .

## RESULTS

There were no significant differences between groups in terms

of age and gender distributions; however, SES of the children with chronic dermatological diseases were significantly lower than the CG [Table 1].

The mean duration of disease in patients with psoriasis was  $5.6 \pm 4.1$  years;  $4.4 \pm 1.7$  for patients with vitiligo and  $5.7 \pm 3.6$  for patients with AA. According to the PASI score, 61% of the patients with psoriasis were mild (PASI <5); according to the SALT score, 55.6% of the AA patients were mild (SALT <50%); and 57.2% of vitiligo cases had localized disease.

Comorbid psychiatric disorder rates were 52.9% in AA, 56.3% in psoriasis, and 75% in vitiligo patients. There was no statistically significant difference between the disease groups in terms of psychiatric comorbidity rates ( $P = 0.441$ ). The prevalence of at least one psychiatric disorder, and among them, the rate of comorbid anxiety disorder was significantly higher in the SG than CG, even when SES was controlled for [Table 1].

When the psychiatric symptom levels of the parents were examined; there was a significant difference between groups in terms of only the phobic anxiety subscale, but when the SES was controlled, the significant difference disappeared [Table 2].

No significant difference was found between the SG and CG in terms of family functions assessed with the FAD [Table 2]. All cases were classified according to the presence of comorbid psychiatric disorder: parents of children with chronic dermatological diseases plus psychiatric disorders (Group 1), parents of children with chronic dermatological diseases without psychiatric disorders (Group 2), and parents of healthy controls without psychiatric disorders (Group 3). The scores of the family assessment scale were re-evaluated. Problem-solving and communication subscale scores were significantly higher in Group 1 compared to Group 2 and Group 3, while there was no significant difference between Group 2 and Group 3 [Table 3].

## DISCUSSION

In recent years, studies about the psychological effects of

various skin diseases and the quality of life of individuals with these diseases have been increasing. Although skin diseases such as psoriasis, vitiligo, and AA that may adversely affect the external appearance usually onset in childhood and adolescence, studies regarding comorbid psychiatric disorders in children are limited. In this study, 45 healthy children and adolescents aged 9–18 years with psoriasis, vitiligo, and AA who were under phototherapy treatment at Marmara University, Department of Dermatology, and 42 healthy children and adolescents who were free of any dermatological disease were compared in terms of psychiatric comorbidities, family functioning, and parental psychiatric symptoms.

In our study, at least one psychiatric disorder was found in 60% of patients with chronic dermatological disorders. Similar to our study, in a study, in which psychiatric diagnoses were determined through structured interviews, at least one psychiatric disorder was reported in 78% of children and adolescents with AA.<sup>[23]</sup> In a study conducted with adult AA patients using structured interviews, the rate of psychiatric disorders was found to be 66%.<sup>[24]</sup> In a new study from Turkey, the prevalence of presence of at least one psychiatric disorder and comorbid psychiatric disorders in children and adolescents with psoriasis was higher than the CG.<sup>[25]</sup>

Our study revealed that anxiety disorders were more frequent in cases with chronic dermatological disease than the controls. There are still considerable differences in the results of previous studies regarding psychiatric comorbidities in patients with chronic dermatologic diseases. For example, Ghanizadeh reported major depression and obsessive–compulsive disorder as the most frequent disorders in patients with AA,<sup>[23]</sup> whereas Bilgiç *et al.* found that children and adolescents with AA had higher anxiety and depression symptom levels compared to controls.<sup>[26]</sup> In another study, depressive symptoms were reported to be more common in children and adolescents with psoriasis than CG.<sup>[27]</sup> Similarly, Chu *et al.* found 2.23 time increase in the risk of depression in AA patients under 20 years of age.<sup>[28]</sup> In a study of vitiligo patients, no significant difference was found compared to healthy controls

**Table 1: Sociodemographic and clinical characteristics of children with chronic dermatologic diseases and healthy controls**

	Study group (n=45), n (%)	Control group (n=42), n (%)	$\chi^2/t$	P	OR (95% CI) adjusted <sup>a</sup>
Age (mean±SD)	12.6±2.2	11.9±1.3	1.85	0.063	
Sex: Female	25 (55.6)	18 (42.9)	1.40	0.23	
SES (mean±SD)	11.7±2.3	14.1±2.4	4.75	0.000***	
Any Axis I disorder	27 (60)	7 (16.7)	17.13	0.000***	1.90 (0.04-0.44)**
MDD	7 (15.6)	1 (2.4)	4.51	0.059	1.81 (0.01-1.56)
Anxiety disorders	13 (28.9)	3 (7.1)	6.84	0.009**	1.49 (0.05-0.95)*
ADHD	12 (26.7)	5 (11.9)	3.01	0.083	0.88 (0.11-1.46)
OCD	4 (8.9)	0	3.91	0.11	0.10 (0.56-1.44)
Tic disorders	2 (4.4)	0	1.91	0.49	0.15 (0.63-2.12)
Enuresis nocturna	3 (6.7)	0	2.90	0.24	0.05 (0.64-1.75)
Axis I comorbidity	15 (33.3)	3 (7.1)	9.08	0.003**	1.70 (0.04-0.76)*

<sup>a</sup>Adjusted for SES, \* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$ . SES: Socio-economic status, MDD: Major depressive disorder, ADHD: Attention deficit hyperactivity disorder, OCD: Obsessive compulsive disorder, SD: Standard deviation. OR: Odds ratio, CI: Confidence interval

**Table 2: Comparison of family functioning and parent's symptom levels between study and control groups**

	Median (IQR)		Z (P), unadjusted	F (P), adjusted <sup>a</sup>
	Study group	Control group		
Family assessment device				
Problem-solving	1.6 (1.3-2.3)	1.6 (1.5-2.2)	0.10 (0.91)	0.01 (0.92)
Communication	1.8 (1.4-2.3)	1.6 (1.2-2.1)	1.57 (0.11)	1.47 (0.22)
Roles	2.0 (1.7-2.5)	2.0 (1.6-2.3)	0.51 (0.60)	0.009 (0.92)
Affective responsiveness	1.5 (1.1-2.0)	1.5 (1.0-2.0)	1.01 (0.31)	0.10 (0.74)
Affective involvement	2.4 (2.0-2.8)	2.1 (2.0-2.5)	1.49 (0.13)	0.31 (0.57)
Behavior control	2.1 (2.0-2.4)	2.1 (1.8-2.3)	1.45 (0.14)	0.71 (0.40)
General functioning	1.5 (1.3-2.1)	1.6 (1.2-2.0)	0.24 (0.81)	0.10 (0.75)
The symptom checklist-90-R				
Somatization	0.8 (0.4-1.4)	0.8 (0.2-1.1)	0.74 (0.45)	0.01 (0.89)
Anxiety	0.4 (0.2-0.9)	0.4 (0.2-0.8)	0.42 (0.67)	0.06 (0.80)
Obsessive compulsive	0.7 (0.3-1.5)	0.8 (0.5-1.4)	0.16 (0.87)	0.08 (0.77)
Depression	0.8 (0.3-1.3)	0.8 (0.3-1.0)	0.49 (0.61)	0.01 (0.90)
Interpersonal sensitivity	0.6 (0.3-1.7)	0.5 (0.2-1.1)	0.88 (0.37)	0.84 (0.36)
Psychoticism	0.2 (0.0-0.7)	0.2 (0.1-0.6)	0.72 (0.47)	0.05 (0.81)
Paranoid ideation	0.6 (0.2-1.5)	0.7 (0.3-1.0)	0.29 (0.76)	0.13 (0.71)
Hostility	0.6 (0.3-1.2)	0.5 (0.3-0.8)	1.18 (0.23)	0.82 (0.36)
Fobic anxiety	0.1 (0.0-0.5)	0.0 (0.0-0.1)	2.67 (0.008)*	0.69 (0.40)
Additional score	0.7 (0.2-1.3)	0.5 (0.2-1.0)	1.33 (0.18)	0.72 (0.39)
Global severity index	0.6 (0.3-1.2)	0.5 (0.3-0.8)	0.54 (0.58)	0.13 (0.71)

\*P<0.01, <sup>a</sup>Adjusted for SES. Z: Mann-Whitney U test, F: One-way ANCOVA. IQR: Interquartile range, ANCOVA: Analyses of covariance, SES: Socio-economic status

**Table 3: Assessment of family functioning in three groups**

	Median (IQR)			P	Contrasts
	Group I (n=22)	Group II (n=18)	Group III (n=30)		
Problem-solving	2.0 (1.6-2.5)	1.5 (1.1-1.8)	1.5 (1.4-2.0)	0.028*	1>2* 1>3* 2=3
Communication	2.1 (1.6-2.4)	1.6 (1.3-2.0)	1.4 (1.2-1.9)	0.004**	1>2* 1>3* 2=3
Roles	2.3 (1.6-2.5)	1.9 (1.7-2.2)	1.9 (1.6-2.1)	0.28	1=2=3
Affective responsiveness	1.9 (1.1-2.2)	1.4 (1.1-1.5)	1.2 (1.0-1.8)	0.064	1=2 1>3* 2=3
Affective involvement	2.4 (2.0-2.7)	2.4 (2.1-2.8)	2.1 (2.0-2.5)	0.26	1=2=3
Behavior control	2.1 (1.8-2.3)	2.1 (2.0-2.4)	2.0 (1.7-2.3)	0.09	1=2 1=3 2>3*
General functioning	1.5 (1.2-2.2)	1.4 (1.2-1.7)	1.4 (1.0-1.9)	0.42	1=2=3

\*P<0.05, \*\*P<0.01. Group I: Chronic dermatologic disease plus psychiatric morbidity, Group II: Chronic dermatologic disease without psychiatric morbidity, Group III: Healthy controls without psychiatric morbidity. IQR: Interquartile range

in terms of depression and anxiety symptoms.<sup>[29]</sup> In another study conducted with a large sample of adolescents aged 16–18 years from Israel, anxiety disorders in patients with psoriasis were significantly higher than controls, similar to our findings.<sup>[30]</sup> A population-based large-sample study in Denmark also presented an increased risk of depression, alcohol and substance abuse, and eating disorders in patients with psoriasis under 18 years of age compared to the CG.<sup>[31]</sup> Some studies have indicated higher levels of depression

symptoms in childhood than in adolescence in patients with chronic dermatological disease, while others have not reported any difference in adolescents.<sup>[26,27,32]</sup>

Family functioning and parental mental health of the youth with chronic dermatological disease was relatively less studied. In this study, although the family functioning areas of the patients were like healthy controls, the families of patients in the chronic dermatological disease plus psychiatric disorders

group had significantly more deficits in the problem-solving and communication skills. In one previous study, it has been reported that there was a significant deterioration in the family functions of patients with psoriasis and vitiligo.<sup>[33]</sup>

Manzoni *et al.* reported that depression and anxiety levels were higher in caregivers of children with dermatological disease compared to healthy controls.<sup>[34]</sup> Tollefson *et al.* examined the impact of childhood psoriasis on parental health-related quality of life and founded that emotional well-being of parents was the mostly affected dimension.<sup>[35]</sup> In another study, the Beck Depression Inventory scores of the parents of children with vitiligo were reported to be significantly higher than the CG.<sup>[29]</sup> However, there were no significant relationship between chronic dermatological disease and parental psychiatric symptom levels in our sample. Since the disease severity was low-to-moderate level and some of the patients were in remission, we might have failed to show a difference in parental psychiatric symptom levels between the patients and the healthy controls.

Psoriasis, vitiligo, and AA patients were not analyzed separately but grouped altogether. This is one of the limitations of the present study. However, number of patients in each of the three groups was too low to make individual comparisons. Furthermore, the fact that all patients were under treatment may have caused patients and their parents to report lower problems. Another limitation in our study is that VASI, which is a reliable instrument to measure disease severity in vitiligo patients, was not used. Despite these limitations, the finding that anxiety disorders are more frequent in children and adolescents with chronic dermatological disorders than healthy controls is remarkable. As anxiety and stress can have negative effects on the immune system, it is important to screen youths with dermatological diseases of immunological origin in terms of psychiatric disorders, especially anxiety disorders. As with most chronic medical diseases, both patients with dermatological diseases and their families will benefit from early psychotherapeutic interventions. Since the number of studies examining family functioning and mental status of parents of children with chronic dermatological disease is scarce, our findings regarding the deteriorations in the problem-solving and communication skills in the families of patients with chronic dermatological disorder and comorbid psychiatric disorders may contribute to the related literature.

## CONCLUSIONS

Our work highlighted that children and adolescents with chronic dermatological diseases had significantly higher rates of psychiatric disorders, especially anxiety disorders were more commonly encountered. Co-occurrence of psychiatric disorders in youth with chronic dermatological diseases puts the families under a risk of potentially dysfunctional relationships, especially in terms of communication and problem-solving skills. Therefore, further studies need to be done to promote psychotherapeutic interventions targeting patients with chronic dermatological diseases.

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## Conflicts of interest

There are no conflicts of interest.

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# The Severity of Diaper Dermatitis and the Effects of Caregivers' Habits on Infants' Behaviors

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## Abstract

**Objectives:** To investigate the behavioral characteristics of infants with diaper dermatitis as well as the habits of their caregivers and the effects of those habits on infants with diaper dermatitis. **Methods:** The participants' demographic features, the infants' behavior, and the caregivers' habits were evaluated using a questionnaire. The severity of diaper dermatitis was scored using the Cincinnati Children's Hospital Diaper Dermatitis Grading Scale. **Results:** A statistically significant difference in terms of the infants' behavioral changes was found in relation to the different maternal education level groups ( $P < 0.001$ ). Three well-known discomfort behaviors, namely easy crying, changes in eating habits, and changes in sleeping patterns, were observed in infants with diaper dermatitis who were being raised by uneducated caregivers. **Conclusions:** The growth and development of babies with recurrent diaper dermatitis may be affected over time if adequate protection methods are not applied to prevent diaper dermatitis. Both diaper dermatitis and recurrent attacks can be prevented by adequate training of the caregivers of babies prone to diaper dermatitis. Babies who are not restless and whose sleeping and eating patterns are not disturbed may develop healthier growth.

**Keywords:** Behavior, breastfeeding, development, growth, habit

## INTRODUCTION

Diaper dermatitis is a form of inflammatory dermatitis that is caused by skin immaturity in newborns and infants. Perianal and inguinal involvement can sometimes be seen in cases of diaper dermatitis.<sup>[1]</sup> Diaper dermatitis develops as a result of multiple factors that cause irritation to the skin, including increased moisture, prolonged exposure to urine and feces, and contact with detergents.<sup>[2]</sup> It is most commonly seen in infants aged 9–12 months, and it occurs in around 50% of infants.<sup>[3]</sup>

Diaper dermatitis can cause significant discomfort in infants as well as anxiety in their caregivers.<sup>[2,4]</sup> In fact, 25% of caregivers consult their primary care physicians with complaints related to diaper dermatitis during the first year of their infant's life.<sup>[5]</sup>

A number of prior studies have investigated the etiology of diaper dermatitis, in addition to the associated prevention and treatment methods.<sup>[6,7]</sup> Some such studies have focused on parents' education.<sup>[8,9]</sup> For example, a recent global study

investigated the effects of caregivers' behavior in relation to diaper dermatitis.<sup>[8]</sup> However, the effects of caregivers' habits and the impact of those habits on the discomfort behaviors of infants with diaper dermatitis, including changes in their eating and sleeping patterns, have not yet been investigated.

The present study sought to examine the behavioral characteristics of infants with diaper dermatitis as well as the habits of their caregivers and the effects of those habits on infants with diaper dermatitis.

## METHODS

This cross-sectional study was conducted from January 2017 to October 2017 in a tertiary hospital. Some 106 healthy infants aged from 0 to 24 months who were full-time diaper users and their caregivers were enrolled in the study.

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In the diaper area; infants with erythematous papules starting with bright erythematous lesions and presenting with edema and desquamation over time were evaluated as diaper dermatitis. Affected hip, thighs, lower abdomen and groin area, labia major, and scrotum were interpreted in favor of diaper dermatitis. Infants were excluded if they had any chronic skin disease, infection, autoimmune or metabolic disease, or candida infection in the diaper area. The required data were collected by asking the caregivers to evaluate the demographic features of themselves and their infants, the infants' behavior, and the caregivers' habits. If a candida infection was suspected, a potassium hydroxide examination was performed. The degree of the infants' diaper dermatitis was scored using the Cincinnati Children's Hospital Diaper Dermatitis Grading Scale and are shown in Table 1 and Figure 1.<sup>[10]</sup> Written informed consent was provided by all the caregivers before the study commencing. The tertiary hospital's ethics committee approved the study (diary number: 16.12.14, date: December 08, 2016).

**Statistical analysis**

The SPSS software (version 15.0 for Windows; SPSS Inc, Chicago, IL, USA) for Windows was used for all the statistical analyses in the present study. In terms of descriptive statistics, the categorical variables were given as numbers and percentages, while the numerical variables were given as the mean, standard deviation, minimum, and maximum. The group comparisons of those numerical variable >2 were performed using the Kruskal–Wallis test because the normal distribution condition was not met in the groups. The subgroup analyzes were performed using the Mann–Whitney U-test and then interpreted using the Bonferroni correction. The rates in the groups were compared via a Chi-square analysis. The alpha significance level was accepted as  $P < 0.05$ .

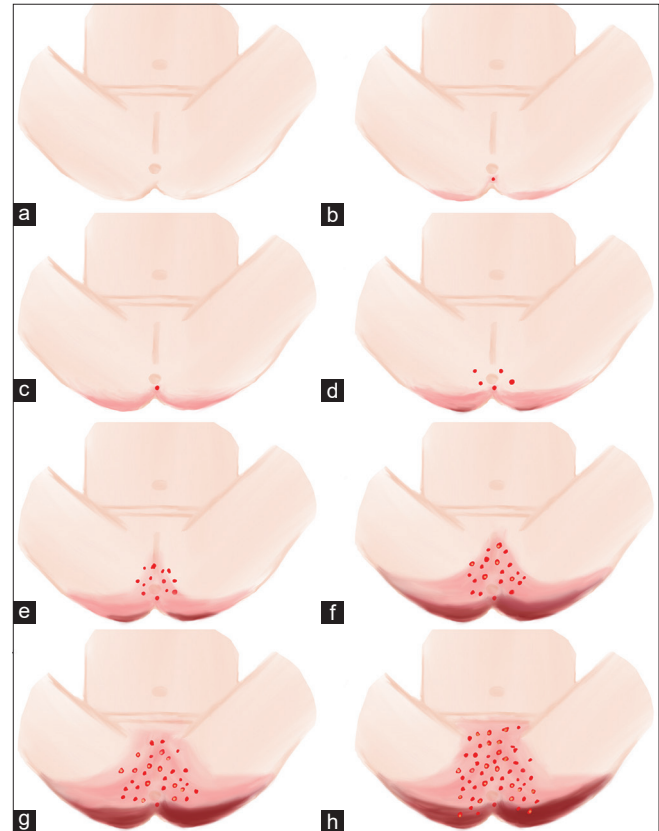
**RESULTS**

Of the 106 infants, 75 (70.8%) were female. The mean duration of the participating infants' diaper dermatitis was  $2.20 \pm 2.10$  months (range: 1–10 months). The mean grade of their diaper dermatitis was  $2.16 \pm 0.57$  (range: 0.5–3). The general characteristics of the infants and their caregivers are summarized in Table 2.

**Caregivers' habits, hygiene practices, and education levels**

The clinical features of the infants with diaper dermatitis and the habits of their caregivers are presented in Table 3.

The rate of exclusive breastfeeding among the uneducated caregivers was found to be high in those who had graduated from high school and university. Moreover, among the infants, the rate of being fed via breastfeeding and complementary foods was also found to be high. The use of solid foods by the uneducated mothers was high, while the use of mixed foods was high for those who had graduated from high school



**Figure 1:** The diagram shows the severity of the diaper dermatitis. According to the areas of involvement and the color of erythema and the presence of papule-pustules, 0 (none), 0.5 (slight), 1 (mild), 1.5 (mild to moderate), 2 (moderate), 2.5 (moderate to severe), 3 (severe) respectively (a-h)

Grade	Erythema	Rash	Severity
0	None	Papule one	-
0.5	Faint-definitely pink, <2%	Papule one	Slight
1.0	Faint-definitely pink, 2%-10% or definitely red <2%	Papules 2-5 scattered	Mild
1.5	Faint-definitely pink >10%, definitely red 10%-50%, or very intense red 2%	Papules slightly scattered over $\geq 1$ areas, <10%	Mild to moderate
2.0	Faint-definitely pink >50%, definitely red 10%-50%, or very intense red 2%	Papules $\geq 1$ areas 10%-50%, pustules 0-5	Moderate
2.5	Definitely red >50% or very intense red with edema 2%-10%	Papules: multiple >50% or pustules numerous or both	Moderate to severe
3.0	Very intense red with edema >10%	Papules large areas, numerous, confluent	Severe

**Table 2: The general characteristics of infants and caregivers**

	<i>n</i> (%)
Age of infants, mean±SD (minimum-maximum) (months)	10.1±5.5 (2-24)
Age of caregivers, mean±SD (minimum-maximum) (years)	30.8±7.4 (18-43)
Gender	
Girl	75 (70.8)
Boy	31 (29.2)
Range of ages (months)	
0-6	25 (23.6)
7-12	51 (48.1)
13-24	30 (28.3)
Presence of atopy	52 (49.1)
Presence of allergy	12 (11.3)
Fitzpatrick skin type	
2	13 (12.3)
3	40 (37.7)
4	42 (39.6)
5	11 (10.4)
Localization	
Urban	90 (84.9)
Rural	16 (15.1)
Socioeconomic status*	
Low	69 (65.1)
Medium	25 (23.6)
High	12 (11.3)
Education level of caregivers	
No education	46 (43.4)
Primary school	52 (49.1)
High school	5 (4.7)
University	3 (2.8)

\*Low (<300 dolar) medium (300-1000 dolar) high (>1000 dolar).  
SD: Standard deviation

and university. The diaper change frequency was found to be 1–4 times per day among those caregivers who were uneducated and who had graduated from primary school, while it was 5–8 times per day among those caregivers who had graduated from high school and university graduates. The use of wet wipes and antibiotics was higher among the caregivers who were high school and university graduates.

### Infants' behavioral changes

The behavioral changes exhibited by the infants with diaper dermatitis are presented in Figure 2.

A statistically significant difference in terms of the infants' behavioral changes was found in relation to the different maternal education level groups ( $P < 0.001$ ). The uneducated mothers and the primary school graduate mothers had infants who exhibited a high degree of easily crying, changes in sleeping patterns and eating disorders. A statistically significant difference was also found with regard to the infants' behavioral changes based on the utilized feeding methods ( $P = 0.003$ ). Those caregivers who exclusively breastfeed their infants reported a high degree of easily crying,

**Table 3: Clinical features of infants with diaper dermatitis and habits of caregivers**

	<i>n</i> (%)
Frequency of feeding, mean±SD (minimum-maximum)	6.13±3.41 (2-15)
Frequency of defecation, mean±SD (minimum-maximum)	3.9±1.58 (1-8)
Grading scale of DD, mean±SD (minimum-maximum)	2.16±0.57 (0.5-3)
Feeding methods	
Exclusive breastfeeding	26 (24.5)
Breastfeeding and complementary feeding	37 (34.9)
Only complementary feeding	43 (40.6)
Complementary foods	
Liquids	32 (40.5)
Solids	25 (31.6)
Mix	22 (27.8)
Frequency of diaper changes (times/day)	
1-4	48 (45.3)
5-8	41 (38.7)
>8	17 (16.0)
Use of topical cream	93 (87.7)
Types of topical cream	
Barrier	27 (28.4)
Antifungal	2 (2.1)
Corticosteroid	11 (11.6)
Antifungal + corticosteroid	50 (52.6)
All of them	5 (5.3)
Air the diaper area out	69 (65.1)
Diarrhea	27 (25.5)
Use of wet wipes	45 (42.5)
Types of wet wipes	
Alcohol based	22 (48.9)
Alcohol free	23 (51.1)
Skin cleansing agents	
Water soaked wipe	23 (30.3)
Soap soaked wipe	28 (36.8)
Only water	25 (32.9)
Use of antibiotics (last 1 month)	46 (43.4)

\*Only complementary feeding: Foods other than breast milk or infant formula, \*\*Liquids: Juice, cow milk, soup etc., \*\*\*Solids: Meats, poultry, cereal, vegetables, fruits and eggs etc. Presence of diarrhea in last 1 week, use of antibiotics in last one month was questioned. DD: Diaper dermatitis, SD: Standart deviation

changes in sleeping patterns, and eating disorders among their babies [Figure 2].

There was a statistically significant difference found in the mean of the grade of the infants' diaper dermatitis in relation to the different feeding methods ( $P < 0.001$ ). The mean grade of the diaper dermatitis seen in the infants who were exclusively breastfed was statistically significantly higher than that seen in those who were fed via breastfeeding and complementary food and those who were fed with only complementary food ( $P < 0.001$  for both). No significant difference was found in the mean grade of the diaper dermatitis seen in the infants who were fed via breastfeeding and complementary



foods and those who were fed with only complementary foods ( $P = 0.061$ ) [Figure 3].

A statistically significant difference was found in the infants' behavioral changes based on the caregivers' use of cream ( $P < 0.001$ ). The rate of the change in sleeping and eating habits was lower in those infants who were treated with cream when compared with those whose caregivers did not use cream. In terms of the cleaning of the diaper area, the change in sleeping habits was high in the infants who were cleaned with only water ( $P < 0.001$ ). The rate of easily crying, changes in sleeping patterns, and eating disorders was high in those infants who were cleaned with wet wipes ( $P < 0.001$ ), while the rate of easily crying was significantly higher in those who were cleaned using alcohol wipes ( $P = 0.004$ ). The rate of easily crying and changes in sleeping patterns was significantly lower in the infants whose caregivers allowed the diaper area to air out.

## DISCUSSION

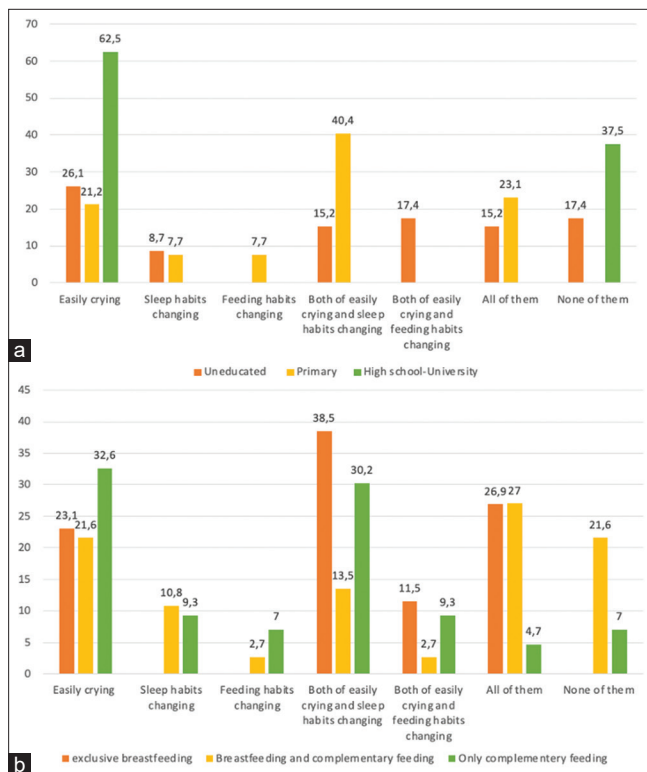
Diaper dermatitis is a preventable form of dermatitis. However, if caregivers have insufficient diaper hygiene training to adequately deal with, it can turn into a chronic condition with recurrent episodes.<sup>[9]</sup> Due to causing discomfort among

infants, diaper dermatitis can cause anxiety among caregivers. In addition, recurrent episodes of diaper dermatitis are likely to result in frequent referrals to healthcare professionals, which leads to a burden on the healthcare system.<sup>[11]</sup>

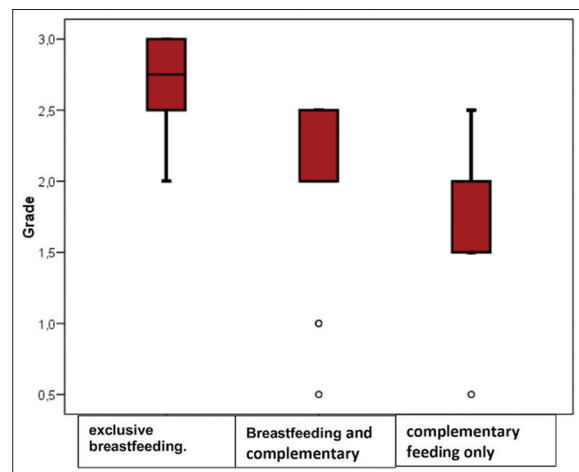
In our study, as the education level of caregivers increases, exclusive breastfeeding decreases; while the frequency of diaper change, use of wet wipes, and antibiotic use increase in infants. As the education level of caregivers decreases, the severity of diaper dermatitis and in relation to this, the effects of infants' behavior (easily crying, changes in sleeping patterns, and eating disorders) are increasing.

Previous studies have shown that breastfeeding is effective in terms of preventing diaper dermatitis.<sup>[12,13]</sup> It is thought that the feces of infants who are fed via breastfeeding exhibits a lower pH as well as less protease and lipase activity than the feces of infants who are fed via other methods, resulting in it being less of an irritant in the diaper area.<sup>[14]</sup> When it comes to its ability to heal diaper dermatitis, Farahani *et al.* reported that human milk with a high anti-inflammatory content is as effective as hydrocortisone 1% ointment when applied to the diaper area.<sup>[15]</sup> However, in a study conducted among 1036 infants in China, no relation was found between breastfeeding and the severity of diaper dermatitis.<sup>[16]</sup>

In the present study, the severity of diaper dermatitis was found to be higher in the breastfed infants. This may be due to the highest breastfeeding levels being seen among the uneducated caregivers. At the same time, the uneducated caregivers were found to more frequently combine the addition of solid foods to their infants' diet with breastfeeding. Moreover, the uneducated caregivers were found to less frequently change their infants and allow the diaper area to air out. This finding may suggest that the severity of diaper dermatitis is high among the infants of those caregivers who do not have sufficient knowledge of the condition. Most of the infants in our study were girl babies. It is thought that girls may be more susceptible to diaper dermatitis since their diaper areas are wider and more



**Figure 2:** (a) Infants behavioral changes according to caregivers education level: The uneducated mothers and the primary school graduate mothers had infants who exhibited a high degree of easily crying, changes in sleeping patterns, and eating disorders ( $P < 0.001$ ). (b) Infants behavioral changes according to feeding methods: Those caregivers who exclusively breastfeed their infants reported a high degree of easily crying, changes in sleeping patterns, and eating disorders among their babies ( $P = 0.003$ )



**Figure 3:** Grade minimum, maximum, 25%–75% percentile, median levels in the feeding methods of infants

open to mucous membranes. Because of these features, baby girls may have been more exposed to irritants (urea, feces), as diaper changes are performed less frequently (1–4 times/day) at 45.3% according to the results of our study.

The causes of diaper dermatitis have been found to differ in various studies. While, Li *et al.* recently reported that diarrhea is the most important factor in relation to diaper dermatitis,<sup>[16]</sup> they previously stated that its occurrence can be prevented by the use of barrier cream and increasing the frequency of diaper changes.<sup>[8,11]</sup> Similarly, in a large-scale study conducted in the United States, more frequent diaper changes and longer periods of non-diapered time were shown to decrease diaper dermatitis.<sup>[17]</sup> With regard to the results of the present study, the uneducated caregivers were likely unaware of the severity of diaper dermatitis, which indicates the need to increase their knowledge of the associated prevention methods.

To the best of our knowledge, although caregivers' habits have been investigated in previous studies, this study is the first to examine the discomfort behaviors of infants in relation to diaper dermatitis.

In the present study, the change in sleep and/or eating behaviors seen among the infants with diaper dermatitis whose caregivers used cream (barrier, topical antifungal, corticosteroid, antifungal + corticosteroid) and aired the diaper area out was significantly lower. In prior studies, it has been found that keeping moisture and irritants away from the diaper area through the use of barrier creams and breathable diaper technologies is important in relation to protecting infants from diaper dermatitis.<sup>[7,18]</sup> In a global study, it was observed that the severity of diaper dermatitis was lower in the infants of caregivers who kept their babies out of diapers for a long time during the night.<sup>[8]</sup>

When the caregivers' diaper area hygiene practice involved the use of alcohol-based wet wipes, it was observed that the rate of easy crying among the infants was high. Wet wipes for babies contain approximately 75% isopropyl alcohol (IPA), and IPA is a known skin irritant.<sup>[19]</sup> A small amount of IPA on the skin is generally not dangerous, although repeated exposure can cause itching, redness, rash, drying, and cracking. The sensation of discomfort associated with diaper dermatitis may increase in infants due to the irritation caused by IPA. Thus, caregivers should take care to use alcohol-free wet wipes in their diaper area hygiene practice.

In the present study, the most striking finding was that all the investigated discomfort behaviors, namely easily crying, changes in sleeping patterns, and eating disorders, were observed in infants with diaper dermatitis who were being raised by uneducated caregivers.

It is believed that caregivers who do not receive sufficient diaper hygiene training will be unable to adequately protect their infants from developing diaper dermatitis. A study conducted in 2001 found that, as a result of neonatal skincare practice that involved new literature being given to nurses in

neonatal intensive care units, significant improvements were observed in the skin of newborns due to the increase in the knowledge of nurse.<sup>[20]</sup>

### Limitations

Since our study is a cross-sectional study, the evaluation of the resulting cause-effect relationship is not as valuable as in cohort studies. Therefore; Epidemiological criteria (relative risk, odds ratio, attributed risk, preservation speed) were not obtained to evaluate the cause-effect relationship. Sufficient information could not be obtained from some immigrant caregivers who had language problems. Although all babies with diaper dermatitis admitted to our outpatient clinic were taken in order, the number of girl babies was higher than boys. It would be preferable if there was no significant difference between the genders.

### CONCLUSIONS

In many countries; there is breastfeeding (breastfeeding) counseling that solves the problems mothers experience while breastfeeding. However, very few countries have counseling or any unit that provides training for caregivers regarding the care of the diaper area. Whereas; considering the education level of the caregivers, the care of the diaper area should be explained in detail. Complications from diaper dermatitis are rare; but, if prevention methods are not adequately explained to caregivers and adequate treatment is not applied, in addition to the bacterial and fungal superinfections that occur, an increase in the severity of the skin shedding and discomfort behavior in babies are observed. Over time, changes in eating and sleeping behaviors can cause babies to experience more distress.

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### Conflicts of interest

There are no conflicts of interest.

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# The Pattern of Medication Used by Acne Patients: Study from a Tertiary Care Center of North India

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## Abstract

**Background:** Acne vulgaris is a common cutaneous condition seen globally and has a considerable psychosocial impact. Many patients with acne try various forms of self-medication, alternative therapies, and prescription medicines for the treatment of acne. **Methods:** We studied various patterns of acne treatments used in a cross-sectional study among patients presenting in a tertiary care hospital. A 2-part questionnaire was used to evaluate the socio-epidemiologic factors and responses to treatments used by acne patients presenting at our center for the first time. The patients used self-medication, alternative therapies (e.g., Ayurveda), treatments from general practitioners, and also specialists. **Results:** Most of the patients reported either no treatment response or even deterioration. Several patients even used topical steroids and suffered adverse effects (corticosteroid-induced rosacea-like facial dermatitis). **Conclusion:** The findings of our study stress the role of appropriate counseling of acne patients in management. Improvement in the doctor-patient relationship is also essential to enhance the treatment efficacy in acne.

**Keywords:** Acne vulgaris, alternative therapy, physician-patient relations, self-medication, treatment outcome

## INTRODUCTION

Acne is one of the most common inflammatory cutaneous disorders, affecting the pilosebaceous units of the skin of the face, as well as the neck, chest, and upper back. Epidemiological data indicate the prevalence figures of acne varying from 50% to 80% in various studies.<sup>[1,2]</sup> While managing cases of acne, the treating physician should factor in issues relating to patient compliance, education level, and socio-economic aspects as well as the availability of a range of treatment options. However, due to the common and pleomorphic nature of this common condition, many patients do resort to self-medication, over-the-counter medications, and advice from friends/relatives, etc.<sup>[3]</sup> Acne has considerable potential for scarring which may be significant and can lead to psychosocial issues not only in females but also in males.<sup>[4,5]</sup>

Many acne patients may continue to suffer for months to years before seeking appropriate therapeutic advice from a qualified professional. As stated earlier, these patients may use alternative treatments, self-medications, topical steroids, etc., Many of these treatments may not be effective

at all, while others may result in considerable adverse reactions, for example, topical steroid damaged/dependent face (TSDF,<sup>[6]</sup> or corticosteroid-induced rosacea-like facial dermatitis<sup>[7]</sup> due to misuse of topical steroids on the face, and particularly in certain geographical areas/regions.<sup>[6,8]</sup> Acneiform eruptions are also known to occur due to the inadvertent use of steroids and occasionally due to other medications.<sup>[9]</sup> Furthermore, demographic variables such as race, the gender of the patient, payment methods for therapeutic services provided, as well as the type of therapy have also been shown to factor in patients' behavior.<sup>[10]</sup> All these contributing factors lead to dissatisfaction among the patients, leading to noncompliance and therapeutic failure.

Today's media-savvy patients have easy availability of several healthcare resources such as the World Wide Web (internet), printed materials, and e-books which may result in self-medication. All these might also easily quench

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the “thirst” for knowledge of patients but would also create confusion about the treatment process. Patients usually have unrealistic expectations about a visible improvement shortly after treatment initiation, typically within 2–3 weeks, or even earlier.<sup>[10,11]</sup> For proper therapeutic alliance, it is essential to answer these queries. The first step, therefore, would be to understand and explore the different treatment methods in acne patients and also factors that affect the choice of patients. Second, to analyze the effects of the different prescriptions as well as self-medication on acne. Hence, this study was undertaken to overview the current pattern of anti-acne medications in patients who present for treatment in a tertiary care teaching hospital.

## METHODS

This was a cross-sectional, descriptive study of newly diagnosed acne patients presenting to the dermatology outpatient department of a tertiary care teaching hospital located in North India. Approval of the Institutional Ethics Committee was obtained before the commencement of the study and patients were recruited after written informed consent. Patients already on treatment at our center were excluded from the study. Patients were recruited from August 2017 to October 2018. The patients filled a 2-part questionnaire; the first part consisted of sociodemographic profiles, for example, age, gender, marital status, address (urban/rural), etc., and the second part of the duration and severity (Grade I–IV) of acne,<sup>[12,13]</sup> and prior treatments. Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 21.0 (IBM, Inc., Armonk, New York, USA). Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± standard deviation (SD) and median. The data were analyzed using the Student's *t*-test and the Chi-square test. A *P* < 0.05 was considered statistically significant.

## RESULTS

A total of 640 responses were obtained. The mean age of the respondents was 20.2 years (SD: 3.9); maximum patients were from the age group ≤20 years (357; 55.8%). The study patients included 276 (43.1%) males and 364 (56.9%) females. More than three-fourths (487; 76.1%) of the patients were unmarried [Table 1]. The mean duration of acne was 19.4 months with scarring present in 407 (63.6%) patients; acne severity grade II was the most common (280; 43.8%) [Table 2]. Self-medication (304; 47.5%) was the most common treatment method used followed by treatments from general practitioners (245; 38.3%), dermatologists (168; 26.2%) and others (ayurvedic and homoeopathic doctors; 127; 19.8%) [Table 3]. As per response to earlier treatments, 92 (14.4%) reported improvement, 223 (34.8%) reported no improvement in acne, and more than 50% (325) patients reported deterioration; the difference was statistically significant in all the 3 age groups (≤20; 21–25; and 26–30 years) and both genders. The difference remained significant with patterns of

**Table 1: Patient demographic characteristics**

Characteristics	Patients (n=640)
Age (years)	
≤20	357
21-25	249
26-30	34
Gender	
Male	276
Female	364
Marital status	
Unmarried	487
Married	153
Residence	
Rural	286
Urban	354

**Table 2: Distribution of acne of study subjects**

Acne	Frequency (%)
Scarring	
Present	407 (63.59)
Absent	233 (36.41)
Severity grade	
I	22 (3.44)
II	280 (43.75)
III	229 (35.78)
IV	109 (17.03)
Duration (months)	
Mean±SD	19.4±21.4
Range	2-84

SD: Standard deviation

**Table 3: Treatment modalities used by the study subjects**

Earlier treatment	Frequency (%)
General practitioners	245 (38.28)
Specialist dermatologists	168 (26.25)
Others (Ayurvedic, homeopathics, indigenous therapies)	127 (19.84)
Self-medication (pharmacy, friends etc.)	304 (47.50)

medications (i.e. treatment from a general practitioner, specialist dermatologist, etc.; and various medications used: topical and systemic retinoids and antibiotics and topical steroids [misuse]). As per the final analysis, “no improvement in acne” was the most common in self-medication, with systemic retinoids, and with systemic antibiotics, while deterioration was the most common in specialist dermatologist group, which was a surprising finding. This probably reflected a better response expectation while on therapy by a specialist dermatologist; or maybe a recall bias. Most patients also developed TSDF (corticosteroid-induced rosacea-like facial dermatitis) if they misused topical steroids for acne.

## DISCUSSION

Acne vulgaris remains one of the most common dermatological

conditions globally. Studies show that acne can significantly affect body image perception in adolescents as well as adults.<sup>[14]</sup> This is one of the probable reasons for self-medication or using alternative therapies (ayurvedic or homeopathic medicine) by the patients.<sup>[3]</sup> Improper medication use is likely to not only be non-efficacious but may also cause a plethora of adverse reactions.<sup>[8,9]</sup> Many of our cohorts used alternative medicines and suffered from deterioration in their acne. Magin *et al.* have shown that patients may prefer complementary and alternative products for acne because of the “natural” and “no adverse effect” tags associated with them. However, the reported self-efficacy of these complementary/alternative medicines was found to be relatively more for acne than other conditions in this study; this may be due to a placebo effect.<sup>[15]</sup>

Most of our patients, who took any treatment before presenting to us, either reported “no improvement” or reported deterioration in their acne; this was true for all the four groups i.e., self-medication, or a general practitioner, or alternative therapies, or even a specialist dermatologist. These findings may be explained by the fact that patients want an early improvement in their condition<sup>[10]</sup> and may leave the treatment if they feel the therapy was not working. Afterward, they might present to other doctors and at our center for better treatment. Almost similar findings have been reported in acne as well as in other diseases by many workers.<sup>[3,11,16,17]</sup> This finding indicates the significance of recognizing, and improving the noncompliant behavior of the patients as the medication may not work if not used properly, and also early in the therapy. Therefore, adherence to a proper regimen remains an essential component for the therapeutic efficacy of any acne medication.<sup>[18-20]</sup>

Most of our patients who used topical steroids developed TSDF, which is a significant adverse effect as well as indicates widespread medication misuse.<sup>[6,8]</sup> This fact indicates the importance of an effective and compassionate physician-patient relationship.<sup>[10,21,22]</sup> The patients also need to be sensitized about the adverse effects of topical steroid misuse and also the fact that it is not a therapeutic agent for acne. Most of our patients also reported no improvement in acne or deterioration with topical and systemic retinoid use. This fact is corroborated as topical retinoids may cause adverse effects such as burning or photosensitivity. Systemic retinoids may cause an initial flare in acne as well.<sup>[23]</sup> Topical antibiotics also work relatively slowly in acne and patients are liable to leave therapy early as they may think that the medication was not working.<sup>[18,20]</sup> Similar findings were also seen in our study.

## CONCLUSION

To conclude, in our study, most patients suffered from deterioration or no improvement in their acne and also suffered significant adverse effects (TSDF) if they used topical steroids. Therefore, early treatment with adequate counseling is essential in the management of this common disorder. Early diagnosis and specialist treatment of acne are important to prevent

scarring as well as to reduce the psychosocial impact of acne in all age groups.<sup>[3,24]</sup> Attempts should also be made to prevent medication misuse and acne patients should be sensitized about significant adverse effects associated with topical steroids use.

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## Conflicts of interest

There are no conflicts of interest.

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