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Evaluation of Skin Reactions in Breast Cancer Patients after Application of Essential Oils- Standard Care Compared to Care with Niaöl©.

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Abstract

Introduction: Skin reactions are common side effects of radiotherapy in breast cancer patients. This work investigates the efficacy of essential oils using the example of Niaöl© compared to standard care and no skin care. The aim is to examine whether Niaöl© influences skin reactions and the quality of life of patients and can be considered as an alternative to standard care.

Methodology: The retrospective study included 223 breast cancer patients undergoing radiotherapy, who were divided into three groups: no skin care (n=91), standard care (n=80), and Niaöl© (n=52). Parameters such as skin reactions (erythema, itching, dryness) and quality of life (EORTC QLQ-C30 questionnaire) were recorded. These were analyzed for significant differences between the groups.

Results: The analysis showed that there were no significant differences between the Niaöl© and the standard care groups in terms of most skin reactions. Both groups performed better than the group without care. Niaöl© showed significant improvements in dryness and pain as well as in work ability compared to the group without care.

Discussion: The results suggest that Niaöl© could be an effective alternative to standard care. The use of Niaöl© had a positive effect on the skin dryness and pain sensation of the patients, leading to an improvement in their quality of life.

Conclusion: The study confirms that Niaöl© has no adverse effects compared to standard care and may even offer benefits in certain aspects such as pain reduction. Further studies with larger groups of subjects and different study designs are needed to fully assess the efficacy of Niaöl© and to evaluate a possible superiority over standard care.

Keywords: Skin reactions, EORTC QLQ-C30, Niaöl©, Breast cancer, Radiotherapy.

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Introduction

Skin problems are one of the most important side effects of radiotherapy in breast cancer patients. They can significantly impair the patient's quality of life and make it more difficult to continue treatment. Therefore, there is a need for effective and well-tolerated skin care products that can alleviate these side effects.

In recent years, there has been an increased interest in natural and holistic therapies, including the use of essential oils in skin care. Essential oils have a variety of therapeutic properties, including anti-inflammatory, antimicrobial and skin-soothing effects. Niaöl©, also known as Melaleuca quinquener*via* oil, is an essential oil extracted from the leaves of the Niaouli tree. Traditionally used in natural medicine, it is well known for its potential healing properties for skin conditions [1,2].

Niaöl© contains various bioactive compounds that may have a beneficial effect on radiation-associated dermatitis, including:

- 1,8-cineole (eucalyptol): Known for its anti-inflammatory and expectorant properties [3,4].
- α-pinene and β-pinene: Have antimicrobial and anti-

inflammatory effects [5,6].

- limonene: A monoterpene that exhibits antioxidant and antimicrobial properties [7].
- Viridiflorol: A sesquiterpene alcohol with antimicrobial properties [8].

The present work investigates the efficacy of Niaöl© as an alternative skin care option for patients undergoing radiotherapy for breast cancer. The aim of this study is to evaluate the potential benefits of Niaöl© in alleviating radiotherapy-induced skin problems and to determine whether it is a safe and equally effective alternative to conventional skin care concepts.

Materials and Methods

The data of 223 breast cancer patients who were treated at the Cologne-Merheim radiation therapy center were used. The data was collected retrospectively for a period of 3 years, from March 1, 2020 to May 1, 2023. Only data from adult female patients of legal age and capacity with primary breast cancer or a precancerous condition (ductal carcinoma in situ) were considered. All patients were irradiated with 46.2/2.6 Gy or 50.4/1.8 Gy and the boost irradiation was taken into account in the data analysis. Lymph node status and previous therapy were otherwise not considered. In addition, age, height, weight, body mass index, bra cup size and PTV Mamma in cm^3 (planning target volume), as well as nicotine consumption, medication, secondary diagnoses and Karnofsky index were recorded. Furthermore, skin type, diagnosis, affected side and localization, TNM classification, grading, hormone receptor status, Ki67, CTS5 score, as well as data on surgical therapy and chemo- and/or endocrine therapy were recorded.

Patients with recurrent breast cancer or DCIS, patients who had a mastectomy, or who were irradiated with a different concept were excluded. Patients with distant metastases are also not included in the study.

The treating physicians assessed skin reactions at the end of radiotherapy and at the follow-up appointment on the basis of selected criteria based on the Common Toxicity Criteria according to EORTC and RTOG. These criteria include: Dryness, erythema, papules, blisters, itching, pain, pigmentation, epithelial breakdown, fatigue and edema. The classification is divided into grades 0 to 4 specifically for each symptom. In addition, the EORTC QLQ-C30 questionnaire was completed before the start of radiotherapy, after completion of radiotherapy and at the follow-up appointment. In the present evaluation, the focus is on questions 6, 9, 19, 29, 30, i.e., on the presence of pain and possible restrictions in (working) everyday life.

In addition, the use of the skin care products offered was investigated. The Niaöl© was offered to the patients as a voluntary alternative to the recommended standard care. This resulted in three cohorts: standard care (n=80), Niaöl© (n=52) and no care (n=91).

Before evaluating the skin reactions and quality of life, the three cohorts were checked for significant differences in baseline data such as age, body mass index, etc. Normal distribution was not present in all cases. Therefore, a statistical evaluation was carried out using a single-factor analysis of variance (ANOVA or Kruskal Wallis) with a subsequent t-test to determine the significance level (p=0.05). In order to avoid Type 1 errors in multiple testing, the Bonferroni correction was also carried out if necessary.

Results

First of all, there were no significant differences between the groups with regard to the chosen radiation concept, including a boost application, so that the groups can be assumed to be comparable in this respect. A significantly different distribution was only found with regard to the confounder skin type. Patients in the group without skin care had 8% fewer skin type 1 and 8% more skin type 4 (p=0.011). This can be seen in Table 1.

The analysis in Table 2 shows that there are no significant differences in skin reactions after radiotherapy between the standard care and the Niaöl© group.

However, there are significant differences compared to the group that did not use any care. For the criteria “erythema” (Niaöl© p=0.001; standard care p=0.004) and “itching” (Niaöl© p=0.004; standard care p= 0.0004) there are significant differences to the other two groups.

There is also a significant difference in the assessment criterion “dryness” between the Niaöl© group and the group without care (p=0.007). With Niaöl©, about 25% of the subjects showed less “no skin dryness” and 25% more “mild dryness” than the subjects without care. Regarding the assessment criterion “pain”, there is a significant difference between the standard care group and the group without care (p=0.008). In the standard care group, there are fewer pain-free patients and about 5% more patients with a toxicity level of 2. See Table 2.

In the aftercare, there are hardly any significant differences between the three groups, as can be seen in Table 3. Only the criterion “pain” shows a significant difference between the Niaöl© group and the standard care group (p=0.016). In the Niaöl© group, 65.38% reported no pain.

The statistical analysis of the questions on quality of life was carried out using the same statistical tests. Detailed evaluations can be found in the table in the appendix. The questions were answered by the subjects before and after irradiation and as part of the follow-up. The information directly after irradiation and during follow-up is particularly relevant for the evaluation.

Table 1. *Distribution of possible confounders between the groups.*

				p-value (ANOVA)	p-value (t-test)		
	Standard skin care		No		No skin care	No skin care *vs.* standard	Niaöl©
		Niaöl©	Skin care		*vs.* Niaöl©		*vs.* standard
Number (n)	80	52	91				
Age							
Mean value	59,6	58,8	62,4	0,084			
Min	38	33	34				
Max	88	83	87				
BMI (kg/m²)							
Mean value	26,9	26	25,9	0,426			
min	17,7	17,6	15,9				
max	43,7	43,8	39,4				
pTNM							
T0	6,3	3,8	7,7				
T1	57,5	63,5	60,4				
T2,	25	15,4	15,4				
T3,	1,3	1,9	0				
Tis,	8,8	15,4	15,4				
Tmic	1,3	0	0				
Tx,	0	0	1,1				
Chemotherapy							
No	75	82,7	73,6	0,452			
Yes	25	17,3	26,4				
Skin types				0,033	0,117	0,011	0,533
1	10	7,7	2,2				
2	45	48,1	40,7				
3	38,8	30,8	41,8				
4	6,3	13,5	14,3				

5	0	0	0				
6	0	0	1,1				
Partial Breast Irradiation			0,823				
No	90	86,5	87,9				
Yes	10	13,5	12,1				
Diagnosis				0,028	0,914	0,01	0,01
C50.1	2,5	1,9	1,1				
C50.2	7,5	5,8	11				
C503	7,5	5,8	3,3				
C50.4	60	57,7	40,7				
C50.5	8,8	5,8	18,7				
C50.8	12,5	7,7	14,3				
C50.9	0	3,8	0				
D05.1	1,3	11,5	9,9				
D05.7	0	0	1,1				
Hormone receptor			0,944				
Positive	86,3	86,5	87,9				
Negative	13,8	13,5	12,1				
Radiotherapy dose (Gy)			0,438				
41,6	86,3	88,5	92,3				
50,8	13,8	11,5	7,7				
Axilla irradiation				0,393			
no	87,5	88,5	93,4				
yes	12,5	11,5	6,6				
Boost (Gy)				0,116			
0	33,8	38,5	54,9				
10	46,3	42,3	35,2				
16	7,5	7,7	4,4				
Simultaneous	12,5	11,5	5,5				

Table 2. *Skin reactions during radiotherapy.*

				p-value (ANOVA)	p-value (t-test)			p-value (Kruskal-Wallis with Post-Hoc Dunn-test)		
	Standard skin care		No		No skin care	No skin care *vs.* standard	Niaöl©	No skin care	No skin care *vs.* standard	Niaöl©
		Niaöl©	Skin care		*vs.* Niaöl©		*vs.* standard	*vs.* Niaöl©		*vs.* standard
Number (n)	80	52	91							
Dryness				0,027	0,007	0,294	0,075	0,007	0,259	0,096
0	43,8	25	53,8							
1	52,5	73,1	42,9							
2	3,8	1,9	2,2							
3	0	0	1,1							
4	0	0	0							
Erythema	43,8	25	53,8	0,002	0,001	0,004	0,651	0,018	0,012	0,885
0	7,5	0	6,6							
1	55	67,3	80,2							
2	37,5	30,8	13,2							
3	0	1,9	0							
4	0	0	0							
Blisters				0,084	0,062	0,038	0,868	0,267	0,24	0,943
0	80	78,8	90,1							
1	17,5	21,2	9,9							
2	2,5	0	0							
3	0	0	0							
4	0	0	0							
Itching				0,001	0,004	0	0,619	0,017	0,004	0,909
0	63,8	63,5	89							
1	28,8	34,6	7,7							
2	7,5	1,9	3,3							

3	0	0	0							
4	0	0	0							
Pain				0,03	0,095	0,008	0,514	0,221	0,04	0,566
0	58,8	63,5	75,8							
1	35	34,6	23,1							
2	6,3	0	1,1							
3	0	1,9	0							
4	0	0	0							
Edema				0,613	0,379	0,504	0,727	0,587	0,759	0,79
0	35	36,5	40,7							
1	55	55,8	37,4							
2	10	7,7	20,9							
3	0	0	1,1							
4	0	0	0							
Fatigue				0,546	0,574	0,255	0,705	0,851	0,443	0,633
0	40	48,1	44							
1	51,3	38,5	52,7							
2	7,5	13,5	3,3							
3	1,3	0	0							
4	0	0	0							

Table 3. *Skin reactions in follow-up.*

				p-value (ANOVA)	**p-value (t-test)**			**p-value (Kruskal-Wallis with Post-Hoc Dunn-test)**		
	Standard skin care	**Niaöl©**	**No Skin care**		**No skin care *vs.* niaöl©**	**No skin care *vs.* standard**	**Niaöl© *vs.* standard**	**No skin care *vs.* Niaöl©**	**No skin care *vs.* standard**	**Niaöl© *vs.* standard**
Number (n)	80	52	91							
Edema breast				0,378	0,25	0,226	0,98			
0	71,25	67,31	54,95							

1	18,75	26,92	39,56							
2	10	5,77	5,49							
3	0	0	0							
4	0	0	0							
Edema arm				0,34	0,187	0,131	0,83			
0	97,5	98,08	100							
1	2,5	1,92	0							
2	0	0	0							
3	0	0	0							
4	0	0	0							
Pain				0,051	0,142	0,226	0,016	0,237	0,299	0,041
0	46,25	65,38	54,95							
1	45	32,69	38,46							
2	7,5	1,92	6,59							
3	1,25	0	0							
4	0	0	0							
Retraction				0,715	0,806	0,421	0,655			
0	90	92,31	93,41							
1	10	7,69	6,59							
2	0	0	0							
3	0	0	0							
4	0	0	0							
Hyperpigmentation				0,818	0,523	0,791	0,698			
0	66,25	61,54	68,13							
1	32,5	38,46	30,77							
2	1,25	0	1,1							
3	0	0	0							
4	0	0	0							
Teleangiektasia				0,789	0,689	0,489	0,83			

0	97,5	98,08	98,9							
1	2,5	1,92	1,1							
2	0	0	0							
3	0	0	0							
4	0	0	0							
Fibrosis				0,139	0,058	0,176	0,482			
0	60	55,77	70,33							
1	38,75	40,38	28,57							
2	1,25	3,85	1,1							
3	0	0	0							
4	0	0	0							

EORTC QLQ-C30 Question 6: Were you restricted in your work or other regular daily activities?

There is a significant difference between the no-care and standard-care groups (pfor completion=0.004; pfor follow-up=0.009). In the group without skin care, about 18% more people reported no impairment. In the standard care group, more than twice as many patients reported a severe impairment in their daily lives, both immediately after radiation and at follow-up. However, both groups improved overall in the "no complaints" assessment at follow-up.

EORTC QLQ-C30 Question 9: Have you had any pain?

At the end of the radiotherapy, there was a significant difference (pfinal=0.025) between the standard care group and the group without skin care. The results of the skin reactions were confirmed by the evaluation of the questionnaires in this point. The evaluation of the follow-up also showed a significant difference to the Niaöl© group (pfollow-up=0.006, p=0.028). Overall, the standard care group reported more severe pain symptoms.

EORTC QLQ-C30 Question 19: Did pain affect you in your regular daily activities?

Immediately after radiotherapy, there was a significant difference between the group without skin care and the other two groups (pNiaöl©=0.039; pstandard=0.001), which no longer occurred during follow-up. The group without skin care had significantly more patients without complaints.

EORTC QLQ-C30 Question 29: How would you rate your overall health during the last week?

The groups without care and with Niaöl© assessed their state of health as steadily improving and, towards the end, significantly better. There was no significant improvement in the standard care group. The significance only arose in the aftercare between the standard and without care groups (paftercare=0.010).

EORTC QLQ-C30 Question 30: How would you rate your overall quality of life during the last week?

At no time was there a significant difference between the groups. The evaluation of quality of life also shows that Niaöl© is no less effective than the currently accepted standard care. With regard to the symptom "pain", Niaöl© shows a positive effect. In the Niaöl© group, 19.13% more patients reported "no pain".

The group without skin care showed fewer complaints overall. We assume that in this group, due to the low side effects, there was no need for care or intervention.

The team at the radiotherapy center in Merheim is overwhelmingly convinced of the oil's effectiveness. To compare the opinions of the treating physicians with those of the patients, 27 patients who had used Niaöl© were interviewed by telephone after their therapy was completed. 22 of the respondents would use Niaöl© again, one person with restrictions and four people did not comment.

Discussion

In clinical practice, natural products and essential oils are playing an increasingly important role, particularly in the context of mind-body medicine and other holistic approaches. However, conventional products available from industry have so far been used as a matter of course to prevent the side effects of radiotherapy. Even though the evidence for the effectiveness of essential oils in this

context is still limited, there are promising indications in animal models and *in vivo* in the literature that they can play a role [9-11].

A study by Lin *et al*., explains the anti-inflammatory and skin barrier-repairing effects of vegetable oils. In particular, the jojoba and almond oils also contained in Niaöl© show moisturizing and soothing properties. In addition, it is known that phytomedical products, including essential oils, can support wound healing and reduce skin inflammation [5]. A review by Kalekhan *et al*. then examined the preventive benefits of natural products, including essential oils, in avoiding radiation-induced dermatitis [2]. Here, too, a positive effect was observed overall. A 2016 publication reports on three female patients who used Niaöl© for 14 days before the start of their radiotherapy and reported a positive effect on dermatological side effects [12]. Due to the small number of cases, no evidence can be derived here. Only in the context of a pilot study from 2014 could no significant effect of essential oils be demonstrated [10]. In summary, these sources suggest that essential oils, including Niaöl©, are promising options to support skin care in breast cancer patients undergoing radiotherapy.

Our study also confirmed the positive effect of Niaöl© in this context. The essential oil was not inferior to standard care in any of our criteria, and the patients' quality of life was good when Niaöl© was used.

However, no statement can be made regarding a possible superiority of the essential oils on the basis of the data available here. A limitation of our data is the evaluation of the skin reactions, which, despite standardized criteria, remains subject to the subjective assessment of the respective physician. This would have to be further objectified in future studies if possible.

Summary

Niaöl© is equivalent to standard care in preventing skin reactions during radiotherapy for breast cancer patients in terms of side effects and quality of life for patients and can be offered as an alternative if necessary.

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Angabe für EORTC QLQ (Lebensqualität)

Basic Data	Values in [%]						
	Standard-skin care	**niaöl©**	**No skin care**	**p-Wert (Anova)**	**p-Wert (T-Test)**		
					no skin care -> Niaöl	no skin care -> Standard	Niaöl -> Standard
Number (n)	80	52	91				
Frage 6 (n) -k.A.	74	52	84	**0,053**	**0,015**	**0,328**	**0,126**
1	31,08	28,85	42,86				
2	37,84	34,62	29,76				
3	25,68	26,92	22,62				
4	5,41	9,62	4,76				
Frage 6 Abschluss RTX (n) -k.A.	80	52	88	**0,009**	**0,064**	**0,004**	**0,365**
1	28,75	26,92	46,59				
2	42,50	50,00	36,36				
3	18,75	23,08	12,50				
4	10,00	0,00	4,55				
Frage 6 Nachsorge RTX (n) -k.A.	79	52	87	**0,026**	**0,231**	**0,009**	**0,227**
1	40,51	46,15	59,77				
2	26,58	32,69	18,39				
3	22,78	17,31	17,24				
4	10,13	3,85	4,60				
Frage 9 (n) -k.A.	80	51	88	**0,005**	**0,010**	**0,003**	**0,964**
1	30,00	31,37	50,00				
2	43,75	39,22	35,23				
3	17,50	17,65	10,23				
4	8,75	11,76	4,55				
Frage 9 Abschluss RTX (n) -k.A.	79	51	90	**0,068**	**0,383**	**0,025**	**0,244**
1	21,52	21,57	32,22				
2	43,04	50,98	47,78				
3	24,05	25,49	14,44				
4	11,39	1,96	5,56				
Frage 9 Nachsorge RTX (n) -k.A.	79	50	91	**0,011**	**0,900**	**0,006**	**0,028**
1	22,78	34,00	40,66				
2	39,24	40,00	39,56				
3	26,58	24,00	14,29				
4	11,39	2,00	5,49				
Frage 19 (n) -k.A.	77	50	84	**0,007**	**0,019**	**0,003**	**0,717**
1	44,16	46,00	61,90				
2	27,27	24,00	23,81				
3	18,18	26,00	11,90				
4	10,39	4,00	2,38				
Frage 19 Abschluss RTX (n) -k.A.	78	51	83	**0,003**	**0,039**	**0,001**	**0,315**
1	39,74	37,25	56,63				
2	32,05	47,06	30,12				
3	20,51	15,69	10,84				
4	7,69	0,00	2,41				
Frage 19 Nachsorge RTX (n) -k.A.	73	49	85	**0,197**	**0,649**	**0,091**	**0,282**
1	49,32	51,02	62,35				
2	23,29	38,78	24,71				
3	17,81	8,16	8,24				
4	9,59	2,04	4,71				

Angabe für EORTC QLQ (Lebensqualität)
Basic Data Values in [%]

	Standard-skin care	niaöl©	No skin care	p-Wert (Anova)	p-Wert (T-Test)		
					no skin care -> Niaöl	no skin care -> Standard	Niaöl -> Standard
Frage 29 (n) -k.A.	76	51	83	**0,647**	**0,359**	**0,680**	**0,562**
1	0,00	0,00	0,00				
2	2,63	1,96	1,20				
3	13,16	13,73	9,64				
4	19,74	21,57	26,51				
5	30,26	29,41	24,10				
6	28,95	25,49	33,73				
7	5,26	7,84	4,82				
Frage 29 Abschluss RTX (n) -k.A.	77	50	82	**0,655**	**0,077**	**0,480**	**0,345**
1	1,30	0,00	1,22				
2	2,60	4,00	1,22				
3	14,29	12,00	7,32				
4	23,38	20,00	18,29				
5	40,26	30,00	30,49				
6	15,58	30,00	34,15				
7	2,60	4,00	7,32				
Frage 29 Nachsorge RTX (n) -k.A.	72	49	85	**0,029**	**0,321**	**0,010**	**0,179**
1	4,17	0,00	0,00				
2	1,39	2,04	0,00				
3	8,33	10,20	4,71				
4	26,39	14,29	21,18				
5	20,83	34,69	18,82				
6	33,33	30,61	37,65				
7	5,56	8,16	17,65				
Frage 30 (n) -k.A.	76	51	83	**0,264**	**0,141**	**0,970**	**0,122**
1	0,00	0,00	1,20				
2	5,26	3,92	1,20				
3	17,11	5,88	7,23				
4	18,42	19,61	25,30				
5	21,05	31,37	24,10				
6	28,95	25,49	33,73				
7	9,21	13,73	7,23				
Frage 30 Abschluss RTX (n) -k.A.	77	50	82	**0,168**	**0,738**	**0,128**	**0,069**
1	2,60	2,00	1,22				
2	9,09	6,00	3,66				
3	14,29	12,00	6,10				
4	27,27	8,00	18,29				
5	28,57	38,00	30,49				
6	15,58	28,00	31,71				
7	2,60	6,00	8,54				
Frage 30 Nachsorge RTX (n) -k.A.	72	49	85	**0,083**	**0,627**	**0,031**	**0,166**
1	1,39	2,04	0,00				
2	4,17	0,00	1,18				
3	5,56	12,24	4,71				
4	23,61	12,24	18,82				
5	26,39	22,45	20,00				
6	31,94	36,73	37,65				
7	6,94	14,29	17,65				

Assessment of reaction/skin reaction (based on Seegenschmiedt MH 1998) (CTC: Common Toxicity Criteria according to EORTC and RTOG)

Symptom	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Dry skin	Not present	+	++	+++	++++
Erythema	------	Mild	Severe	Very severe	Life threatening
Papules and Vesicles	-------	+	++	+++	++++
Itching	------	+	++	+++	++++
Pain	------	+	++	+++	++++
Pigmentation	------	+	++	+++	++++
Epitheliolysis	------	Dry scaling	Blistering, isolated moist erythema	Extensive moist erythema	Skin necrosis
Edema breast	------	+	++	+++	++++
Edema arm	------	+	++	+++	++++
Fatigue	------	+	++	+++	++++

Assessment of late skin reactions/late effects

Symptom	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Edema breast	------	Asymptomatic	Symptomatic	Secondary dysfunction	------
Edema arm	------	Mild (2-4 cm)	Significant (4-6 cm)	Massive >6 cm	Dysfunction
Subjective pain	------	Mild hypersensitivity/ Pruritus	Intermittent and tolerable	Permanent and severe	Unaffected, very distressing
Retraction	------	Present	------	------	------
Hyperpigmentation	------	Mild, intermittent	Permanent	------	------
Telangiectasia	------	Present	------	------	------
Fibrosis	------	Slight hardening	Moderate hardening	Pronounced fibrosis, retraction, fixation	------
Ulceration	------	Only epidermis <1 cm	Only dermis >1 cm	Subcutaneous	Necrosis bone visible