Published in final edited form as:
Support Care Cancer. 2012 December ; 20(12): 3105–3113. doi:10.1007/s00520-012-1435-6.

Acute Skin Toxicity-Related, Out-of Pocket Expenses in Patients with Breast Cancer Treated with External Beam Radiotherapy: A Descriptive, Exploratory Study

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Introduction

Radiotherapy is a critical component of breast cancer treatment, and nearly half of all breast cancer patients receive radiotherapy [1]. During the course of external beam radiotherapy for breast cancer, the vast majority of patients (74%–100%) will report some degree of skin toxicity [2–5], which generally presents as erythema (redness, warmth, rash-like appearance), dry desquamation (dryness, itching, peeling), or moist desquamation (moist, oozing, tender, redness and exposure of the dermis) [6–9]. Literature indicates that these skin changes can be associated with sensations of pain, burning, itching, pulling, tenderness, and increased sensitivity [10,11]. Furthermore, skin toxicity is associated with impairments in quality of life including: fatigue, body image disturbance, sleep problems, emotional distress, reduced treatment satisfaction, and changes in day-to-day functioning [3,4,12].

During the course of radiotherapy, patients seek out and use a wide variety of self-care and symptom management strategies to cope with skin toxicity [12,13]. Many of these patient-initiated approaches are associated with out-of-pocket expenditures. For example, patients have been found to: purchase items to reduce discomfort, buy more comfortable clothes/ undergarments, replace clothes/bras which have been stained or otherwise damaged by

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Conflict of Interest

None of the authors have a financial relationship with the NCI which sponsored the research. Authors have full control of all primary data, and we agree to allow the journal to review the data if requested.

prescribed skin care products, buy cosmetic products to conceal skin color changes, and use complementary/alternative medicine (CAM) approaches for symptom and side-effect control [12]. Yet to date, we have no clear estimate of the economic burden associated with skin toxicity.

Published studies examining the "hidden costs" of cancer have not addressed the cost issues of breast cancer radiotherapy patients experiencing skin toxicity [14]. Furthermore, a recent review of patient-rated measures of skin toxicity revealed no measures assessing out-of-pocket costs to patients [15]. This gap in the literature is concerning because nonmedical out-of-pocket spending related to skin toxicity is not only important in and of itself, but could also be an important outcome variable in evaluating skin toxicity prevention and control interventions [16]. For example, if a new cream were developed to help patients manage skin toxicity, which did not stain bras/clothes, it could lead to less out-of pocket spending, and consequently be more attractive to patients. Similarly, it will be important to note whether new accelerated radiotherapy regimens to the whole breast or partial breast radiotherapy [17,18] not only reduce the overall treatment time and incidence/duration of skin toxicity, but also reduce associated out-of-pocket spending.

To address this gap in the literature, our group developed a new scale, the "Skin Toxicity Costs" (STC) questionnaire, based on our previously published qualitative research [12]. The STC assesses direct nonmedical out-of-pocket costs associated with skin toxicity in women undergoing breast cancer radiotherapy. Direct nonmedical costs are those expenses which occur as a result of breast cancer (including expenditures for symptom management), but do not include medical services. So for example, direct nonmedical costs might include CAM use, new clothing related to treatment side effects, or purchasing over the counter creams [19,20].

The primary aim of the present descriptive, exploratory study was to assess the feasibility of using the STC with breast cancer radiotherapy patients. Secondary aims were to: assess the utility of the STC in providing an estimate of the magnitude and range of nonmedical out-of-pocket costs associated with skin toxicity from the individual perspective; examine the specific nature of the costs associated with acute skin toxicity; explore potential background predictors of personal expenditures; and explore the relationship between patient-reported dermatologic quality of life and expenditures.

Methods

Design—This retrospective study was designed as a one-time survey of breast cancer radiotherapy patients who were in their fifth week of radiotherapy. The fifth week was chosen for three reasons: 1) literature suggests that 100% of patients will experience skin toxicity by this point in their treatment [3]; 2) it is close to the end of treatment, which enables participants to reflect back over their entire radiotherapy experience; and 3) after week 5, patients' treatment plans begin to differ – some patients will go on to receive a radiotherapy boost, some will not. Consequently, week 5 data collection allowed for the largest and most homogenous sample.

Participants—Participants were recruited from three radiation oncology clinics: at Mount Sinai Medical Center (n=31), at Roswell Park Cancer Institute (n=9), and at Weill Cornell Medical Center (n=10). In total, this convenience sample consisted of 50 participants. See Table 1 for descriptive information on the sample. All participants were treated between January 2009 and June 2010.

Eligibility criteria for the present study included being: scheduled for a standard (5–7 week) course of external beam radiotherapy for breast cancer, able to speak and read English (as the measures were all in English); over age 18; female; willing to complete study assessments; and Stage 0, I, II or III breast cancer. Exclusion criteria were having any co-morbid major psychiatric diagnoses (e.g., any disorder with psychosis) or significant cognitive impairment (identified by physician) which could render women unable to follow the study procedures or give informed consent (as determined by medical chart review), or having metastatic disease.

This study was approved by the Institutional Review Board at each of the three sites, and was therefore performed in accordance with the ethical standards laid down in the 1964 Declaration of Helskini. All participants gave their informed consent prior to their inclusion in the study.

Measures

Skin Toxicity Costs (STC) questionnaire—As noted above, no standardized or validated measure exists to assess out-of-pocket costs associated with acute skin toxicity in breast cancer radiotherapy patients. Therefore, we developed the STC, based on our previously published qualitative research [12], to evaluate such costs.

The STC is a 7-item, open-ended self-report survey (see Figure 1). For each item, patients are asked to report: a) amount spent in dollars, and b) nature of the expenditure (i.e., on what the money was spent). Items inquire about the purchase of new undergarments, new clothes, new products/equipment/services to manage skin toxicity, and items bought to conceal skin changes. There is a final question asking “Were there any other economic expenses associated with skin changes? If so please describe, and let us know how much they cost.” Patients’ responses are restricted to the active radiotherapy treatment period, and do not include costs associated with other breast cancer treatments (e.g., mastectomy bras and wigs are excluded).

In order to ensure that the scale was understandable to most patients, readability was evaluated. Specifically, we used the Tests Document Readability online utility (http://www.online-utility.org/english/readability_test_and_improve.jsp). This utility calculates the US grade level needed to understand the text. As recommended, indices were averaged to yield an overall readability statistic [21,22]. Specifically, the Coleman Liau index, the Flesh Kincaid Grade Level, the ARI (Automated Readability Index) and the SMOG index were used. Based on these indices, the average grade level needed to understand the STC is 6.5. This result is consistent with guidelines suggesting that printed materials should be at or below an 8th grade reading level [23].

Background questionnaire—Patients were also asked to complete a ten-item background questionnaire inquiring about: age, cancer stage, chemotherapy history, surgical history, race, ethnicity, marital status, employment, education, and household income.

The Skindex 16 [24] is a 16-item measure of dermatologic quality of life. This measure has demonstrated test-retest reliability (r=0.88–0.90), good internal consistency (Cronbach’s alpha = 0.86–0.93), and both content and construct validity. The Skindex 16 has 3 subscales – Emotion (e.g., worry about your skin condition), Symptoms (e.g., your skin condition itching), and Functioning (e.g., the effects of your skin condition on your daily activities). Each item is rated from 0=Never Bothered to 6=Always Bothered, “during the past week.” The measure has previously been used in studies of skin toxicity in breast cancer radiotherapy patients [25].

Procedure—Patients scheduled for radiotherapy for primary breast cancer were referred by their radiation oncologist. Patients who agreed to participate were told that they would be given the STC and the background questionnaire to complete on a day convenient for them in their fifth week of treatment. On that day, research assistants met the patients, distributed the questionnaires, and gave patients the option of completing the measures in a private room in the radiation oncology clinic or completing them at home and returning them the next day. Both research assistants and referring physicians were available to answer any participant questions.

Data analyses—All analyses were performed using SAS 9.2 [26]. If any cost item had missing data, we assigned it a dollar value of zero to be conservative in our estimates. In a preliminary step, we checked for between-site differences; that is, whether costs differed significantly between Mount Sinai, Weill Cornell, and Roswell Park. No significant between-site differences were found in terms of costs ($F(2, 47) = .70$; $p = .50$). Therefore, all further analyses were conducted on the combined sample.

Results

Primary Aim

Feasibility—In this preliminary study, the STC proved practical and feasible to administer. Participants were able to complete the questionnaire in less than 5 minutes, and no eligible patient refused to complete the measure.

Secondary Aims

Description of the magnitude and range of nonmedical out-of-pocket costs associated with skin toxicity—Table 2 presents descriptive statistics on the entire sample, as well as on the subsample of women who spent more than $0. Results indicate 94% reported some direct costs (e.g., money spent to manage skin toxicity). Mean direct costs in the entire sample were $131.64 (95% CI: 84.05–179.23).

Examination of the specific nature of the costs associated with acute skin toxicity—An item level analysis yielded information on distributions of spending, as well as on the nature of the spending (see Table 3). From the quantitative perspective, results indicate that the most frequently endorsed items were STC#1 (new undergarments) and STC#3 (products to manage skin toxicity). The least frequently endorsed items were STC#4 (equipment), STC#5 (CAM and other services), STC#6 (concealment), and STC#7 (other costs).

Exploration of potential background predictors—Examination of the distribution of costs revealed that (as is typical of cost data) the data were positively skewed and leptokurtic. Therefore, we used the BOXCOX transformation in PROC TRANSREG in SAS [26] to transform the data. Box-Cox [27] transformations, one of the most common types of transformations, are used to identify optimal transformations of a dependent variable. However, in order for this procedure to produce successful results, all values of the dependent variable (i.e., costs) must be greater than zero. Consequently, we added a constant (0.0001) to all values. We then proceeded with running PROC TRANSREG, with the default LAMBDA= list of –3 TO 3 by increments of 0.25. Results revealed an optimal lambda of 0.25. Accordingly, we transformed the cost data by raising them to the power of . 25. These transformations reduced skewness and kurtosis to within acceptable limits, and all following inferential statistics were performed on transformed data.

The relationship between background factors and transformed costs were examined using univariate and multiple linear regression analyses (note: ethnicity was excluded from these analyses as there were too few Hispanic women in the sample). Results of univariate analyses revealed that race, education, and household income were significantly related to costs (see Table 4) such that Whites spent more than other races, more educated women spent more, and those with higher household income spent more. Effect sizes for race and household income were in the small range [28]. The effect size for education was in the medium range.

We then entered all three significant predictors of costs (race, household income, education) into the same model. Initially, we assessed for multicollinearity by examining tolerance and the Variance Inflation Factor (VIF). Generally, a tolerance value of less than 0.1 and a VIF of greater than 10 are considered to suggest that multicollinearity may be an issue. In our case, all tolerance values were greater than 0.1 (race=.87, education=.59, salary=.66), and all VIF values were less than 10 (race=1.15, education=1.69, salary=1.51) indicating that multicollinearity was not a concern. The model revealed that together, race, household income, and education accounted for nearly 26% of the variance in direct costs [$F(3, 46) = 5.33$, $p = .003$; $R^2 = .258$]. When examining the unique contributions of each variable, neither race [$F(1,46)=1.74$, $p=.193$] nor household income [$F(1,46)=0.04$, $p=.850$] contributed to direct costs. Education did uniquely contribute to the prediction of direct costs [$F(1, 46)=5.79$, $p=.020$]. Results revealed that more educated women (with at least a college degree) spent more money related to their skin toxicity. This analysis controlled for other variables in the model.

Exploration of potential relationship between dermatologic quality of life and expenditures—Using the transformed cost data, we correlated direct costs with the three subscales of the Skindex-16: Emotion, Symptoms, and Functioning. We found that direct costs were significantly associated with Skindex-16 Functioning ($r=.27$, $p=.050$), but were not significantly associated with Skindex-16 Emotion ($r=.02$, $p=.891$) or Skindex-16 Symptoms ($r=.21$, $p=.114$). Greater impairment in Functioning was associated with greater costs.

Discussion

Results of the present study reveal the hidden, nonmedical, out-of-pocket costs associated with acute skin toxicity in the context of a traditional course of breast cancer radiotherapy. Patient out-of-pocket costs are an important component of patients' experiences [19], yet these costs are rarely included in breast cancer cost-of-illness studies [29]. To our knowledge, this study is the first to quantify individual costs associated with this particular treatment side-effect, as well as the first to present a scale specifically designed to assess such costs. Broadly speaking, results indicate that: 1) the STC is a practical, brief, easy-to-administer measure; 2) skin toxicity is associated with patient financial burden; 3) the STC is a useful measure of skin toxicity-related costs, and can indicate specific areas of patient expenditures and need; 4) education significantly predicts patient expenditures; and 5) impaired functioning due to skin toxicity was significantly associated with increased direct costs. Each point and associated implications will be discussed below.

First, the STC adds to the extant scales to assess nonmedical costs in cancer (e.g., COIN form [19], Economic Impact of Breast Cancer measure [30]) by uniquely assessing costs associated with skin toxicity in breast cancer radiotherapy patients. The feasibility results show that the STC is brief, acceptable to patients, readable, that it yields valuable information on nonmedical costs, and that it is sensitive to individual differences in spending.

Second, nearly all women (94%) reported at least some out-of-pocket costs associated with skin toxicity. This result is consistent with reports indicating that nearly all women report skin toxicity during radiotherapy [2–5].

Third, results demonstrate that the types of patient spending most greatly affected by skin toxicity are spending on new undergarments (specifically new bras) and spending on products to directly manage skin toxicity. In terms of undergarments, the "type of expenditure" responses to STC item 1 suggest that patients are generally buying new bras either to be more comfortable (e.g., bras without underwire are less irritating) or to replace old ones which have been stained/damaged by prescribed creams or treatment markers. These data suggest that patients could potentially benefit from skin toxicity management approaches which are less damaging to clothing. In terms of products, as can be seen in Table 3, patients reported using 21 different products to try to manage skin changes on their own. This data is consistent with qualitative reports [12], and suggests both that patients are actively searching for ways to ameliorate this side effect and that current skin-toxicity management approaches may be insufficient to meet all of patients' needs.

Fourth, the results revealed that education level was the only variable which was uniquely and significantly associated with patient spending. These results are consistent with research which has shown increased education to be significantly related to increased alternative or complementary healthcare use [31,32]. Past literature has hypothesized that increased education may increase the chances that people will: 1) be exposed to various types of healthcare through their own reading on the subject; 2) educate themselves about their illnesses and the variety of possible treatments; and/or 3) question the authority of conventional practitioners. Future research, with larger sample sizes, should focus on better understanding the education-spending relationship [31].

Fifth, the results revealed that higher levels of participant spending were associated with greater functional impairment due to skin toxicity. Interestingly, spending was not associated with either emotional reactions to skin changes or with skin symptoms. This suggests that patients are spending money more to help minimize the effects of skin toxicity on daily living, and less to feel better (either emotionally or physically). Future research should explore this issue further, and work to identify which aspects of functional impairments lead to increased spending.

The present study is not without its limitations. First, this study used a relatively small sample size. This sample size was sufficient to achieve our primary aim of testing the feasibility of using the STC to describe nonmedical costs associated with skin toxicity feasibility. However, future research should use larger samples to more precisely specify the cost estimates obtained here. Second, the STC was only administered to women undergoing a traditional course of breast cancer radiotherapy (in the fifth week of treatment), and excluded women who were treated with hypofractionated regimens. As recent randomized trials support the regular use of hypofractionated regimens for adjuvant whole-breast radiotherapy in some women with early breast cancer [33,34], future research should consider including both women undergoing standard and hypofractionated regimens. In this way, the STC could be used to compare out-of-pocket costs between the two radiotherapy regimens. Such research should include assessment points both during radiotherapy as well as in the weeks afterwards. Third, the present study relied entirely on patient self-report data. We recognize that a more stringent approach may have been to ask patients to save and return receipts to verify expenditures. However, we agree with other authors [30] that such an approach has the potential to be overly burdensome for patients, as well as the potential to lead to inadvertent disclosure of personal financial information (e.g., credit card account information). Fourth, the data were collected in a retrospective fashion, and results were

based on patient recall. Future research should consider collecting STC data prospectively (e.g., starting at the beginning of treatment and on a weekly basis afterwards) to limit any potential recall bias [35]. Fifth, the sample is unique in that each of the three institutions from which the sample was drawn has implemented some cost-saving measures for patients (e.g., some creams are provided to patients free of charge, coupons are provided in the clinic for some of the creams). Therefore, it should be noted that the present results may actually *underestimate* out-of-pocket costs associated with skin toxicity due to these clinic programs. It is not clear whether such procedures are standard practice across institutions, and therefore generalizability of the present findings should be examined in future research. Sixth, future studies may wish to expand the use of the STC beyond the radiotherapy treatment period in order to capture additional expenditures associated with late effects of radiotherapy.

After future replication studies, we anticipate that the STC could be used as an *outcome* variable (e.g., to facilitate cost-effectiveness analyses, to allow for cost comparisons across different treatment or skin management regimens [30,35]), as a *behavioral indicator* of symptom burden (e.g., perhaps those women who suffer more functional impairments spend more to ameliorate such impairments), as one component of *quality of life* (e.g., a component of "economic well-being"), or as part of a *needs assessment* (e.g., do patients need help paying for bras, for creams, etc?). Additionally, the information provided by the STC may help patients plan more accurately for their radiation treatment experience, and may help healthcare professionals inform their patients about what costs to expect [30,35,35].

Acknowledgments

Preparation of this manuscript was supported by the National Cancer Institute (K07 CA131473) and by the American Cancer Society (RSGPB-04-213-01-CPPB). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Cancer Institute, National Institutes of Health, or American Cancer Society. We would like to express our sincere gratitude to Ms. Bari Scheckner, Ms. Bianca Love, and Ms. Frances Harfouche for their invaluable help in the data collection. Most importantly, we would like to thank all of the study participants for so graciously sharing their experiences.

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STC		
We are interested in learning more about the economic impact of skin changes due to radiation. In other words, how much skin changes from radiation have cost you in terms of out-of-pocket expenses. Please answer each of the questions below to the best of your ability. If you don't remember exact numbers, that's fine, please just give us your best guess. Thank you.		
	Total Cost	**What was the money spent on? Please itemize.**
Example	$100	$60 for 2 bras, $40 for 5 camisoles, $10 for skin cream
1. How much have you spent on new bras or undergarments?		
2. How much have you spent on new clothes (other than undergarments)?		
3. How much did you spend on products to manage skin irritation or changes (e.g., creams, calendula, aloe)?		
4. How much did you spend on equipment to manage skin irritation or changes (e.g., fans, pillows)?		
5. How much did you spend on services to manage skin irritation or changes (e.g., psychotherapy, group therapy, yoga, meditation, acupuncture, hypnosis)?		
6. How much did you spend to conceal skin irritation (e.g., makeup, scarves, etc.)?		
7. Were there any other economic expenses associated with skin changes? If so please describe, and let us know how much they cost.		
Total		

Fig 1.
Skin Toxicity Costs Questionnaire

Table 1

Sample Characteristics

	Descriptive Information
Age Range: 36–84 years	***M(SD)***
	54.88 (11.84)
Race	**n (%)**
White	39 (78%)
Other	8 (16%) Black, 3 (6%) Other
Ethnicity	
Hispanic	3 (6%)
Non-Hispanic	47 (94%)
Education	
College degree or post-graduate degree	34 (68%)
< College degree	16 (32%)
Marital Status	
Currently married	32 (64%)
Not currently married	18 (36%)
Employment	
Full-time	26 (52%)
Less than full-time	24 (48%)
Income	
< $60,000	20 (40%)
≥ $60,000	30 (60%)
Previous breast cancer surgery	
Lumpectomy	35 (70%)
Mastectomy	15 (30%)
Prior chemotherapy	
Yes	28 (56%)
No	22 (44%)
Cancer Stage	
0	13 (26%)
I	19 (38%)
II or III	18 (36%)

Table 2

Summary of Patient Expenditures in US Dollars.

	n	**% total *n***	**Mean $**	**SD $**	**Median $**	**Min $**	**Max $**
All women	50	100%	131.64	167.44	75.00	0.00	770.00
All women who spent >$0	47	94%	140.04	169.30	75.00	1.00	770.00

Table 3

STC Item and Reported Expenditures	Frequency by Cost		Total Cost Range
1. Undergarments: New bras (including sports bras, bras without underwire), New camisoles, New pajamas, Undershirts, Replacing bras stained by creams, Replacing bras stained by color treatment markers, Replacing bras which are uncomfortable	**$0**	42%	**$0–$305**
	$1–$100	34%	
	>$100	24%	
2. Clothes: New t-shirts, New cotton clothing (instead of wool)	**$0**	76%	**$0–$400**
	$1–$100	20%	
	>$100	4%	
3. Products to manage toxicity: Herbal/Mineral (Aloe, Vitamin E, Calendula, Arnica, French Green clay), Over the Counter (Eucerin, Vaseline, sunscreen, Medline remedy cream, baby shampoo, Cortaid, shea and honey moisturizer, Lubriderm, Noxema cold cream), "Natural" (natural soap, natural cream), Prescribed (Aquaphor, Xeroform bandages, non-adhesive gauze, Xclair, Cortisone)	**$0**	34%	**$0–$400**
	$1–$100	60%	
	>$100	6%	
4. Equipment to manage toxicity: Pillows to support the breast (including body pillows, u-shaped pillows, moist allergy pillows), Nursing Pads, Frozen Peas	**$0**	90%	**$0–$45**
	$1–$100	10%	
	>$100	0%	
5. CAM and other services: Acupuncture, Group therapy	**$0**	98%	**$0–$450**
	$1–$100	0%	
	>$100	2%	
6. Concealment: Scarves	**$0**	96%	**$0–$50**
	$1–$100	4%	
	>$100	0%	
7. Other expenses: Cab rides	**$0**	94%	**$0–$81**
	$1–$100	6%	
	>$100	0%	

Table 4

Univariate relationships between background variables and costs.

	COSTS				
	F	**df**	**p**	**R^2**	**f^2**
Age	0.81	1, 48	.374	.017	.017
Race	5.78	1, 48	.020	.108	.121
Education	7.97	1, 48	.007	.143	.166
Marital Status	0.34	1, 48	.563	.007	.007
Employment	0.31	1, 48	.578	.007	.007
Income	4.33	1, 48	.043	.083	.090
Surgery Type	0.93	1, 48	.934	.000	.000
Prior Chemotherapy	0.01	1, 48	.940	.000	.000
Cancer Stage	0.31	2, 47	.732	.013	.013

Note: An f^2 of .02 is considered small, .15 is considered medium, and .35 is considered large. Shaded cells in this table are significant at $p < .05$.