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## Neuropathic Pain in Breast Cancer Survivors: Using the ID Pain as a Screening Tool

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### Abstract

Neuropathic pain (NP) is a debilitating symptom experienced by a number of patients with cancer. We evaluated the validity of ID Pain as a screening tool for NP in breast cancer survivors using the S-LANSS and a reported diagnosis of NP as criterion measures. Two hundred and forty breast cancer survivors with a mean age of 58 years ( $SD=16$ ) participated in this survey. Forty-five percent of the sample reported having pain in the past week. Of those reporting pain, 33% reported that they had been diagnosed by their health care provider for NP, 39% had a positive ID Pain ( $\geq 2$ ) score and 19% had a positive S-LANSS score. The most commonly endorsed ID Pain item was “hot/burning” ( $n=48$ ), followed by feeling “numb” ( $n=47$ ) and “pins and needles” ( $n=45$ ). Total ID Pain score was significantly associated with a clinical diagnosis of NP ( $r=0.41$ ;  $P<0.001$ ) and the S-LANSS total score ( $r=0.54$ ;  $P<0.001$ ). Receiver Operating Curve analysis demonstrated that ID Pain has a predictive validity of 0.72 and 0.70 for diagnosis of NP as made by clinicians and the S-LANSS, respectively. We also found that an ID Pain score of  $\geq 2$  corresponded with the likelihood of NP in this sample, consistent with the original ID Pain development study. This study provides evidence for ID Pain as a valid screening measure of NP for breast cancer survivors.

### Keywords

Neuropathic pain; ID Pain; epidemiology; breast cancer; symptoms; survivorship

### Introduction

Breast cancer is the most prevalent cancer diagnosis in women. It is a significant cause of mortality and morbidity in the United States, with an estimated 182,460 new cases of invasive breast cancer and 40,480 new deaths in the year 2008 (1).

Steady improvements in the survival rates of patients with breast cancer have been observed in recent years. It is estimated that there are more than 2 million survivors of breast cancer in

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the United States, alone (an individual is considered a cancer survivor from the time of diagnosis, through the balance of his or her life (2)). Although most women with a history of breast cancer have a favorable prognosis, breast cancer and its treatment are associated with debilitating symptoms. Neuropathic pain (NP), defined as “pain arising as a direct consequence of a lesion or disease affecting the somatosensory system” (3), is a debilitating symptom experienced by as many as 40% of patients with cancer pain (4–6). Understanding the epidemiology of NP in breast cancer patients has high clinical and public health significance.

NP in cancer patients may be caused by tumor invasion of the peripheral nerve or as a side-effect of chemotherapy, radiotherapy and/or surgery (7–23). Several patient-reported measures of neuropathic pain have been developed, including the Neuropathic Pain Scale (NPS) (24), the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) (25), the Self-Report Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) (26), the Neuropathic Pain Questionnaire (NPQ) (27), the Neuropathic Pain Questionnaire-Short Form (NPQ-SF), the Neuropathic Pain Symptom Inventory (NPSI) (28), the Neuropathic Pain Diagnostic Questionnaire (DN4) (29), and the Pain Quality Assessment Scale (PQAS) (30), among others. These measures assess more than one component or quality of NP, and were designed to classify pain as being neuropathic vs. nociceptive, for detecting treatment outcome, or both.

More recently, the 6-item ID Pain was developed as a brief, self-administered screening tool for detecting NP in primary care settings (31). Given the anticipated increase in number of breast cancer survivors over the next few decades, primary care providers will be faced with the challenge of providing timely and appropriate post-treatment care to a diverse population of cancer survivors (32). In this study, we assessed the validity of ID Pain as a screening tool for NP in patients with breast cancer using the S-LANSS and a reported diagnosis of NP as criterion measures. We hypothesized that, if the ID Pain is valid as a screening measure for neuropathic pain in women who are breast cancer survivors, there would be a strong and significant association between the ID Pain score, and the S-LANSS score and a clinical diagnosis of NP. In addition, we identified the best cutoffs for the ID Pain score for differentiating between neuropathic and nociceptive pain in the sample, computed measures of sensitivity and specificity for this purpose, and compared the ability of ID Pain to differentiate those participants with and without a history of NP, relative to S-LANSS. Finally, we assessed the predictive validity of ID Pain using S-LANSS and ID Pain as criterion measures.

## Materials and Methods

We conducted a cross-sectional study of breast cancer survivors who previously received treatment at M. D. Anderson Cancer Center. From the institutional databases, we identified 635 breast cancer patients who previously participated in clinical trials for taxanes, 430 of whom were alive and had contact information as of July 2007. Patients were contacted by telephone (up to three times) and after verbal consent, were given detailed explanation of the study. Questionnaires were subsequently sent to the patients' residences up to three times. A total of 240 (56% response rate) of these breast cancer patients consented to participate in our study. Informed consent forms included in the questionnaire packet were signed by participants in accordance with procedures approved by the M. D. Anderson Cancer Center Institutional Review Board.

### Pain Prevalence and Severity

The prevalence of pain was assessed with the question “Have you had pain in the past week?,” and average pain intensity in the past week was assessed using a 0-10 numeric rating scale (with 0 = “no pain” and 10 = “worst pain as severe as it could be”).

## Measures of Neuropathic Pain

The *ID Pain* is a 6-item, patient-completed screening tool designed to help differentiate nociceptive and neuropathic pain (31). The items include (1) “Did the pain feel like pins and needles?” (2) “Did the pain feel hot/burning?” (3) “Did the pain feel numb?” (4) “Did the pain feel like electrical shocks?” (5) “Is the pain made worse with the touch of clothing or bed sheets?” (6) “Is the pain limited to your joints?” “Yes” answers to questions 1–5 are scored as 1, while a “yes” answer to question 6 is scored as –1. Higher scores suggest a neuropathic component to the pain. In the initial scale development study, the ID Pain items were found to accurately predict diagnoses of neuropathic pain determined by pain specialists, with concordance *c* indices in the studies of 0.73 and 0.69. Cut-points were defined to minimize false negatives (sensitivity) in relation to false positives (specificity), and were as follows: NP very likely (score = 4 or 5), NP likely (score = 2 or 3), NP possible (score = 1), and NP unlikely (score = 0 or –1).

The *Self-Report Leeds Assessment of Neuropathic Symptoms and Signs* (S-LANSS) is a 7-item instrument that identifies pain of predominantly neuropathic origin. A score of 12 or more (out of a maximum of 24), regarded as a “positive” score, identifies neuropathic pain with a sensitivity and specificity of 79% and specificity 100% in patients with head and neck cancer (33). It has been found to be valid and reliable in both clinical and mail-survey settings (26).

**Reported Diagnosis of Neuropathic Pain and Co-Morbid Conditions**—A clinical diagnosis of NP was based on the patient’s response to the question “Have you ever been diagnosed by your physician or health care provider for neuropathic pain?” In addition, co-morbid conditions were assessed, including hypertension, diabetes mellitus, cerebrovascular accident, rheumatoid arthritis, and osteoarthritis. To better describe the study population, patients were also asked: “Did you have a recurrence (cancer came back) in the breast, lymph nodes or chest wall?” and “After your first diagnosis of breast cancer, has your cancer spread (metastasized) to other sites, such as lung, liver or bones?”

## Statistical Analysis

We first assessed the normality distribution of ID Pain using a one-sample Kolmogorov-Smirnov test. Parametric and non-parametric measures of correlation were conducted to test the hypothesized associations between ID Pain and a diagnosis of NP, and between ID Pain and S-LANSS.

Because the ID Pain was originally developed for primary care patients, we also explored possible cutoff boundaries for its use in breast cancer survivors. Using both the S-LANSS (<12; ≥ 12) and a self-reported diagnosis of NP (0=No; 1= yes) as criteria, we explored the possible boundaries for unlikely, possible, and likely cut-points for ID Pain. We tested three possible boundaries for unlikely and possible NP: (1) a cut-point between -1 and 1; (2) a cut-point between 1 and 2; and (3) between 2 and 3. For possible and likely NP, we evaluated whether a cut-point between 2 and 3 or between 3 and 4 was optimal for distinguishing possible and likely NP. In total, there are four possible combinations in which to distinguish these three levels of NP. To help determine the best cutpoints, we performed four separate analyses of variance using the S-LANSS (0–24) and logistic regression using self-reported diagnosis of NP (no=0; yes=1) as dependent variables and S-LANSS (<12 or ≥ 12). The larger F-statistics from ANOVA and beta coefficient from logistic regression should be associated with the cut-points that maximally discriminate between the three levels of NP.

We calculated the sensitivity (proportion of actual positives which are correctly identified) and specificity (proportion of negatives which are correctly identified) of ID Pain (≥ 2) on the bases of a self-reported clinical diagnosis of NP (“yes” response) and S-LANSS score (score ≥ 12)

and compared the ability of ID Pain to differentiate those participants with and without a history of NP, relative to S-LANSS, by conducting logistic regression analyses. Finally, we assessed the predictive validity of ID pain as a measure of a clinical diagnosis of NP and S-LANSS using ROC curve analysis.

## Results

### Sample Description

Two hundred and forty breast cancer survivors with a mean age of 58 years ( $SD = 16$ ) participated in this survey. Mean time since original diagnosis was 9.5 years ( $SD = 2.1$ ). Ninety-seven percent of the participants were white. A little over 70% of the women were married and at least 80% had a high-school education. Sixty percent of the patients were working part-time or full-time. Eight percent of the sample had local recurrence and 8% had progressed to metastatic disease. The most common comorbid condition was hypertension (34%), followed by osteoarthritis (29%), diabetes (10%), and rheumatoid arthritis (6%).

Forty-five percent of the sample reported having pain in the past week, 25% and 26% rating their pain as moderate (score of 5–6) and severe (score of 7–10), respectively. Of those reporting pain, 33% reported that they had been diagnosed by their health care provider for NP; 39% had positive score for ID Pain ( $\geq 2$ ) and 19% had positive S-LANSS score for NP. With regard to history of surgery and radiotherapy (Table 1), 51% had modified radical mastectomy; 27% had segmental with axillary lymph node dissection; 14% had segmental with sentinel biopsy; and 6% had total mastectomy. Only 60% received radiotherapy. Neither a history of surgery nor radiotherapy was associated with reports of diagnosis of NP, ID Pain, or S-LANSS.

### Clinical Diagnosis of Neuropathic Pain and ID Pain

Overall, 18% of the sample reported that they had been diagnosed by their health care provider for NP. Using the original ID Pain cut-points, we found that 68.7% ( $n = 160$ ) of the participants were unlikely to have NP; 12.5% ( $n = 29$ ) to possibly have NP; 16.7% ( $n = 39$ ) were likely to have NP; and 2.1% ( $n = 5$ ) very likely have NP. Table 2, 2nd column shows that the most commonly endorsed item among those reporting pain was “hot/burning” ( $n = 48$ ), followed by feeling “numb” ( $n = 47$ ) and “pins and needles” ( $n = 45$ ).

The Kolmogorov-Smirnov  $Z$  test showed ID Pain was not normally distributed ( $P < 0.001$ ). The ID Pain score was significantly correlated with a clinical diagnosis of NP (Spearman  $r = 0.41$ ;  $P = 0.0001$ ). Table 2, 3rd column, shows the distribution of ID Pain items and the Spearman rank correlation coefficient of these items to a report of being diagnosed by their health care provider with NP. The most strongly correlated item with a reported diagnosis of NP was the “hot/burning” item ( $r = 0.40$ ;  $P < 0.005$ ), followed by “pins and needles” ( $r = 0.36$ ;  $P < 0.005$ ). As might be expected, the item “Is the pain limited to your joints?” had the lowest correlation ( $r = -0.07$ ,  $P = NS$ ) with a reported diagnosis of NP.

### Self-Report Leeds Assessment of Neuropathic Symptoms and Signs and ID Pain

Twelve percent of the sample had positive S-LANSS score ( $\geq 12$ ) indicating neuropathic pain. The correlation between the ID Pain score and S-LANSS score was statistically significant ( $r = 0.58$ ;  $P < 0.005$ ). Of the ID Pain items, “Did the pain feel like pins and needles?” and the “Did the pain feel numb?” items showed the strongest associations with the S-LANSS scores ( $r = 0.56$  and  $0.43$ , respectively;  $P < 0.05$ ).

## Categorizations for NP in Breast Cancer Survivors

We wanted to determine if there were categories for the likelihood of NP that might be described as unlikely, possible, and likely NP for this sample. We explored cut-points for these categories as described in the Methods section. Table 3, Panel A and B, shows that using two categorizations for ID Pain (positive versus negative, with cut-point of  $\geq 2$  for ID Pain) was most optimal for predicting self-reported NP and positive S-LANSS, by as much as 5-fold (OR= 5.5) and 7-fold (OR=7.0), respectively (Panel B, Table 3).

## Specificity and Sensitivity of ID Pain

Table 4, Panel A shows the sensitivity and specificity of the ID Pain (score of  $\geq 2$ ) for a clinical diagnosis of NP. Of those diagnosed with NP, 50% had a positive ID Pain score for NP and 86% of those who did not report being diagnosed with NP also had negative ID Pain.

Using S-LANSS as a measure of NP (score  $\geq 12$ ), we found that 67% of those with positive S-LANSS had positive ID Pain (score of  $\geq 2$ ) and conversely, we found that 33% of those who scored positive for ID pain also scored positive for S-LANSS. Ninety three percent of those with negative S-LANSS also had negative ID Pain.

We compared the ability of ID Pain to differentiate those participants with and without a history of NP, relative to S-LANSS, by conducting logistic regression analyses. Table 5 shows that ID Pain was significantly associated with self-reported diagnosis of NP. Those who had a positive ID Pain score were more likely (OR= 4.62; 95% confidence interval [CI] = 2.0–10.68;  $P < 0.0001$ ) to have a reported diagnosis of NP. For a positive S-LANSS, we also found that ID Pain was significantly associated by as much as four-fold (OR=4.85; 95% CI = 1.75–13.45;  $P < 0.002$ ).

## Predictive Validity of ID Pain

Using ROC analysis, we assessed the validity of the ID Pain (score  $\geq 2$ ) in predicting a reported diagnosis of NP and positive S-LANSS. Results showed area under the curve = 0.72 and 0.70, for the clinical diagnosis of NP and for the S-LANSS, respectively.

## Discussion

Knowledge of the epidemiology of NP in breast cancer survivors is limited. A lack of universally-accepted and validated clinical diagnostic criteria for NP makes it difficult to have precise estimates of NP. While earlier studies suggest that nearly 40% of patients with cancer pain suffer from NP (5), a more recent study of 167 patients with advanced cancer found that 36%, 22% and 42% were found to have definite NP, likely NP, or unlikely NP, respectively (34). In this study, we found that of those reporting pain, 33% reported that they had been diagnosed by their health care provider for NP, 39% had a positive score for NP using the ID Pain ( $\geq 2$ ), and 19% had a positive score for NP using the S-LANSS. The wide variability in these estimates underscores the need for a better case-definition for NP in women with a history of cancer. Indeed, a quick and valid screening tool, such as the ID Pain, that may be used to stratify patients for a more focused evaluation of cancer pain, especially since cancer pain typically has a mixed pain mechanism.

Studies have found considerable overlap with the clinical presentation of patients with NP and those with unlikely NP (35). However, in this sample of breast cancer patients previously treated with paclitaxel, we found that the ID Pain items “hot and burning,” “numb” and “pins and needles” were frequently endorsed. As a chemotherapy agent, paclitaxel promotes the formation of abnormal bundles of microtubules within the cytoplasm, leading to the disruption of normal cell function and proliferation (36). While this mechanism results in the desired

effect on the tumor, the same mechanism can render taxanes toxic to normal tissue. Microtubules are important for the development and maintenance of neurons by providing structural support and serve as major mediators of axonal transport. Studies continue to explore the mechanisms underlying NP associated with paclitaxel therapy.

Except for the ID pain item assessing “joint” pain, all the ID Pain items had a significant correlation with a reported diagnosis of NP and the total score for S-LANSS. This is expected since the “joint” pain item was meant to discriminate pain from NP versus other types of pain.

Originally developed for use in primary care patients, ID Pain has four levels of classifying patients with a score of 2 or greater as the cut-point to indicate whether a patient is a likely NP case. Using three possible boundaries to classify patients as unlikely, possibly and likely NP, we similarly found that a score of 2 and 4 as cut-point for classifying a patient as possible and likely NP case in this breast cancer population. Additional studies are needed to assess if these cut-points may be used among survivors of different types of cancer.

Of those reporting a history of diagnosis of NP, 50% had a positive ID Pain score for NP and 86% of those who did not report being diagnosed with NP also had negative ID Pain. Using S-LANSS as a measure of NP, we found that 67% of those with positive S-LANSS had positive ID Pain and 93.3% of those with negative S-LANSS also had negative ID Pain. These findings indicate that, although ID Pain is a sensitive measure, it may be less specific than the S-LANSS. This finding is consistent with a recent study of NP in cancer patients, where S-LANSS was found to have a specificity of 91.4% and a sensitivity of 29.5% at baseline (34). Of note, we found that relative to S-LANSS, a positive ID Pain score were more than four times likely to have a self-reported diagnosis of NP.

ID Pain is a 6-item tool that was originally developed for screening of primary care patients for NP. ID Pain is not a multidimensional tool; it does not provide metrics for pain intensity nor pain characteristics. As a screening tool, however, the major goals for its development are ease of use, validity and predictive accuracy. In this study of breast cancer survivors, we found that ID Pain has a predictive validity of 70% and 73% using the S-LANSS and self-reported diagnosis of NP as criterion measures. Arguably, the Neuropathic Pain Questionnaire Short-Form has fewer items than ID Pain (3 versus 6 items); however, it appears to be less specific than ID Pain (78.6% vs. 84%) (28).

There are limitations to this study that should be considered when interpreting the results. First, it important to note that screening tools for NP only serve to highlight the need for further assessment and a clear distinction has to be made between identifying features of NP (which screening tools have generally achieved in clinic studies) and making a diagnosis of NP (for which screening tools are not designed) (37). Thus, future research should include more objective measures (e.g., present clinical diagnosis confirmed by two clinicians to ensure reliability) to confirm the present findings. Others (3) also suggest that the presence of NP should be assessed using the following criteria: (1) pain with a distinct neuroanatomically plausible distribution; (2) a history suggestive of a relevant lesion or disease affecting the peripheral or central somatosensory; (3) demonstration of the distinct neuroanatomically plausible distribution by at least one confirmatory test; and (4) demonstration of the relevant lesion or disease by at least one confirmatory test. It could also be argued that we have a small sample of patients (56% response rate), limiting the generalizability of our findings. It also important to note, that NP may result from other factors that were not assessed in this study. We also did not evaluate these patients for other types of neuropathic pain (e.g., diabetic neuropathy, postherpetic neuralgia) conditions.

## Conclusion

NP is a distressing consequence of cancer therapies; yet it is often under-recognized and undertreated. Screening of cancer patients for NP would help facilitate case identification which could then result in further clinical/neurological evaluation and effective treatment. The present results indicate that the ID Pain is valid for this purpose in breast cancer survivors.

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**Table 1**

## History of Surgery and Radiotherapy

Characteristics	N(%)
Surgery	
Modified radical mastectomy	101 (51)
Segmental with axillary lymph node dissection	53(27)
Segmental with sentinel biopsy	28(14)
Total mastectomy	11(6)
Radiotherapy	
Yes	119 (60)
No	79(40)

Note: No statistically significant association with reports of diagnosis of NP, ID Pain, or S-LANSS.

**Table 2**

Correlation of items for ID pain and Neuropathic Pain and S-LANSS

ID Pain Item	<i>n</i> (%)	Self-Reported Diagnosis of NP	S-LANSS
1) Did the pain feel like pins and needles?	45 (22%)	0.36 <sup><i>b</i></sup>	0.56 <sup><i>a</i></sup>
2) Did the pain feel hot/burning?	48 (24%)	0.40 <sup><i>b</i></sup>	0.29 <sup><i>a</i></sup>
3) Did the pain feel numb?	47 (23%)	0.29 <sup><i>b</i></sup>	0.43 <sup><i>a</i></sup>
4) Did the pain feel like electrical shocks?	29 (14%)	0.32 <sup><i>b</i></sup>	0.27 <sup><i>a</i></sup>
5) Is the pain made worse with the touch of clothing or bed sheets?	15 (8%)	0.20 <sup><i>a</i></sup>	0.28 <sup><i>a</i></sup>
6) Is the pain limited to your joints?	26 (13%)	-0.07	-0.13

NP = neuropathic pain.

<sup>*a*</sup>  $P < 0.05$ .<sup>*b*</sup>  $P < 0.005$ .

**Table 3**

F-Statistics for Likelihood of NP Based on Various Test Criteria

<b>PANEL A</b>						
<b>Possible Boundary Models</b>		<b>S-LANSS<sup>a</sup> (0-24)</b>	<b>S-LANSS (score &lt; 12) (score ≥ 12)</b>	<b>Self-Reported Diagnosis of NP<sup>b</sup></b>		
<b>Unlikely</b>	<b>Possible</b>	<b>Likely</b>	<b>F-statistic</b>	<b>Beta (OR)</b>	<b>Beta (OR)</b>	<b>Beta (OR)</b>
<b>Model 1</b>	0, -1	1,2	3,4,5	16.46	1.56 (4.7)	1.25 (3.5)
<b>Model 2</b>	0, -1, 1	2	3,4,5	19.68	1.39 (4.0)	1.24 (3.5)
<b>Model 3</b>	-1,0,1	2,3	4,5	21.55	1.57 (4.8)	1.54 (4.6)
<b>Model 4</b>	-1,0,1,2	3	4,5	15.05	1.50 (4.5)	1.62 (5.0)
<b>Panel B</b>						
Positive vs. Negative						
<b>Score ≥ 2</b>				1.95 (7.0)		1.70 (5.5)

NP = neuropathic pain; OR = odds ratio.

<sup>a</sup>F-statistic.

<sup>b</sup>Beta coefficient.

**Table 4**

## Sensitivity and Specificity Analyses

<b>Panel A. Self-Reported Diagnosis of Neuropathic Pain<sup>b</sup></b>			
		<b>Positive</b>	<b>Negative</b>
ID Pain <sup>a</sup>	Positive	50%	50%
	Negative	14%	86%

<b>Panel B: S-LANSS <sup>c</sup></b>			
		<b>Positive</b>	<b>Negative</b>
ID Pain <sup>a</sup>	Positive	67%	33%
	Negative	6.5%	93.5%

<sup>a</sup>ID Pain score of  $\geq 2$ .

<sup>b</sup>Have you ever been diagnosed by a health care provider for neuropathic pain?

<sup>c</sup>S-LANSS score of  $\geq 12$ .

**Table 5**

ID Pain as Predictor of Self-Reported NP and S-LANSS

<b>Panel A. Self-Reported Diagnosis of NP<sup>b</sup></b>			
<b>Variable</b>	<b>P-value</b>	<b>OR</b>	<b>95% C.I.</b>
ID Pain <sup>a</sup>	0.0001	4.62	2.0, 10.68
S-LANSS <sup>c</sup>	0.206	1.97	0.68, 5.68

<b>Panel B. S-LANSS<sup>c</sup></b>			
<b>Variable</b>	<b>p-value</b>	<b>OR</b>	<b>95% C.I.</b>
Self-reported Diagnosis of NP <sup>b</sup>	0.206	1.97	0.68, 5.68
ID Pain <sup>a</sup>	0.002	4.85	1.75,13.45

NP = neuropathic pain; OR = odds ratio; CI = confidence interval.

<sup>a</sup>ID Pain score of  $\geq 2$ .

<sup>b</sup>Have you ever been diagnosed by a health care provider for neuropathic pain?

<sup>c</sup>S-LANSS score of  $\geq 12$ .