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ORIGINAL ARTICLE

Pain, sensory disturbances and psychological distress are common sequelae after treatment of ductal carcinoma *in situ*: a cross-sectional study

Birgitte Goldschmidt Mertz[a], Helle Molter Duriaud[a], Niels Kroman[a] and Kenneth Geving Andersen[b]

[a]Breast Surgery Section, Rigshospitalet, Copenhagen University Hospital, Denmark; [b]Section for Surgical Pathophysiology, Rigshospitalet, Copenhagen, Denmark

ABSTRACT

Sequelae such as pain, sensory disturbances and psychological distress are well known after treatment for invasive breast cancer (IBC). Patients treated for ductal carcinoma *in situ* (DCIS) receive a similar treatment as low-risk IBC. The aim of this cross-sectional study was to describe prevalence of postoperative pain, sensory disturbances, psychological distress and rehabilitation needs among Danish women with DCIS.

Methods: A total of 574 women treated for DCIS in Denmark in 2013 and 2014 were enrolled and 473 (82%) completed a detailed questionnaire on demographic factors, pain, sensory disturbances, psychological aspects and rehabilitation needs 1–3 years after surgery.

Results: Median age was 60 years. A total of 33% of patients reported any pain and 12% reported moderate to severe pain in the area of surgery. Younger age (<50 years OR 4.7 (95% CI: 1.6–14.0, $p = 0.006$)), aged 50 to 65 years OR 2.8 (95% CI: 1.1–7.0, $p = 0.02$) and anxiety and depression (measured by $HADS_{total} > 15$ OR of 3.1 (95% CI: 1.5–6.3, $p = 0.003$)) were significantly associated with moderate to severe pain. Approximately one-third of the patients reported sensory disturbances such as pins and needles (32%), numbness (37%) and painful itch (30%) and 94 women (20%) reported anxiety ≥8, 26 (6%) depression and 51 (11%) reported distress.

Conclusions: This cross-sectional study showed that women treated for DCIS suffered from pain, sensory disturbances and psychological impairment and had unmet rehabilitation needs. Further research is warranted, specifically addressing rehabilitation after diagnosis and treatment of DCIS.

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Introduction

Since the introduction of the National Health Service Breast Screening Program in Denmark, the number of ductal carcinoma *in situ* (DCIS) cases has increased considerably with more than 450 new cases each year and a rapidly growing population of DCIS survivors. This increase is also seen in United States, Europe, Australia and other high-income countries, where DCIS accounts for 11–25% of screen-detected breast cancer cases [1].

DCIS is a noninvasive breast condition. The treatment of DCIS resembles the loco-regional treatment of invasive breast cancer (IBC) and can include breast conserving surgery (BCS), mastectomy, sentinel lymph node biopsy (SLNB) and breast radiation therapy (RT). These treatment modalities are known to cause persistent pain, sensory disturbances and disabilities among women with IBC [2,3]. Furthermore, mastectomy is known to entail body image distress and appearance concerns among breast cancer patients [4]. Finally, a Danish study found that 43% of IBC patients reported moderate to severe distress at the time of diagnosis [5].

Patients have difficulties understanding the DCIS diagnosis and the reasons for extensive treatment [6,7]. This may cause confusion about the nature of DCIS and an inaccurate perception of the future breast cancer risk, anxiety and substantial psychological distress [8,9]. Recent studies have questioned the use of the terminology 'carcinoma *in situ*', as this can create misperceptions and confusion among both patients and health professionals, who find it difficult to distinguish between cancers and not cancers [10]. In a previous small-size exploratory study on women with DCIS who had a SLNB we likewise found that women with DCIS reported difficulties understanding the diagnosis leading to psychological problems and need for counseling. Furthermore, there were indications of sequelae similar to those experienced by IBC patients (unpublished material). In Denmark, breast cancer patients are referred to community-based physical and psychosocial rehabilitation after diagnosis and treatment, whereas no systematic rehabilitation or psychosocial support is offered to women with DCIS. Therefore, it seems important to gain more substantial knowledge on both the quantity and the quality of sequelae after DCIS treatment in order to plan targeted rehabilitation. Thus, the aims of this cross-sectional study were to describe the prevalence of persistent pain, sensory disturbances, distress, anxiety, depression and rehabilitation needs among a larger group of Danish women treated for DCIS.

CONTACT Birgitte Goldschmidt Mertz Birgitte.mertz@regionh.dk Breast Surgery Section, Rigshospitalet, Blegdamsvej 9, DK-2100 Copenhagen, Denmark
Supplemental data for this article can be accessed here.

Material and methods

Study design

A total of 574 women were registered in the Danish Breast Cancer Group (DBCG) database [11] treated for DCIS in Denmark in 2013 and 2014. The present study was a cross-sectional questionnaire study. The questionnaire was sent to all eligible patients in January 2016. Those who did not respond received a second questionnaire. Data collection ended ultimo March 2016. The study was conducted at the Breast Surgery Section, Rigshospitalet, University of Copenhagen, Denmark according to the act on research ethics review of health research projects in Denmark. The study was approved by the Danish Data Protection Board (j.nr.2012-58-0004).

Participants

All patients registered with DCIS were eligible. Exclusion criteria were patients with subsequent malignant diagnosis, those unable to understand Danish and dementia. Data regarding diagnosis, malignancy, treatment and death were extracted from the DBCG database, whereas these data were incomplete, supplemental data were obtained from electronic medical records.

Treatment

Patients were treated according to the DBCG protocol [11], receiving surgery with mastectomy or BCS. SLNB was performed in patients treated with mastectomy and in BCS patients if the DCIS had tumor characteristics, the DCIS area was more than 50 mm on mammography, if invasive disease was suspected on the picture imaging, and if the DCIS was van Nuys group 3. Patients receiving BCS were treated with RT of the residual breast. Patients treated with mastectomy were offered breast reconstruction.

Outcomes

The primary outcome was the prevalence of persistent post-surgical pain divided into well-defined treatment groups 1–3 years after surgery. Moderate to severe pain after treatment for DCIS was defined as pain in the breast area, axilla, side of body and arm on the operated side and with a pain intensity of $\geq$4 on a numerical rating scale ranging from 0 to 10. The cutoff point used is supported by a study on cutoff points in a postoperative pain setting [12]. Only ratings of pain experienced at a weekly basis or more often were regarded as persistent pain. Secondary outcomes were sensory disturbances assessed using seven questions developed for the breast cancer cohort [13] and psychological distress, anxiety and depression and rehabilitation needs. Distress was measured using the distress thermometer (DT), which is a numerical scale ranging from 0 (no distress) to 10 (extreme distress). A cutoff score of $\geq$7 was used as it has been shown to identify patients suffering from moderate to severe distress [14]. Hospital Anxiety and Depression Scale (HADS) is a commonly used measure of depression and anxiety in cancer patients [15]. The HADS is a 14-item scale measuring depression and anxiety in two subscales. The two scales are often summarized in a total score measuring emotional distress [16]. Cutoffs used here are $HADS_{total}$ $\geq$15, $HADS_{anxiety}$ $\geq$8 and $HADS_{depression}$ $\geq$8 [15]. Furthermore, health-related quality of life was assessed on the scales of Global Health, physical, role and emotional functioning and a sum score on European Organization for Research and Treatment of cancer QLQ-C30 [17]. Needs for rehabilitation services were assessed by items designed for a previous study on breast cancer patients [18] covering the need to consult healthcare providers in and outside the hospital, patient education and contact with other patients. Participants were asked to indicate any need they experienced.

Demographic data, treatment details and disease specifications were retrieved from the DBCG database. Data on psychosocial factors, pain, sensory disturbances and needs for rehabilitation were collected from the questionnaire.

Statistics

Statistical analysis was performed using SAS 9.4 for windows (SAS Institute, Cary, NC). Normality was assessed using Kolmogorov–Smirnov and Shapiro–Wilk tests, histograms and Q-Q plots. All values were expressed as number of patients, percentages, means for normally distributed data with 95% confidence intervals (95% CI) and medians for non-normally distributed data with interquartile ranges (IQR). Proportions were tested using χ^2 or Fisher's exact test. Bivariate comparison of NRS values between groups were analyzed with the Mann–Whitney–Wilcoxon test, and for three or more groups Kruskal–Wallis' test. A p value of 0.05 was considered statistically significant. Treatment groups were defined by treatment according to the treatment protocol. Patients who deviated from the protocol were put into a separate group in order to keep the others comparable and homogenous. Treatment factors and patient-related factors associated with pain in univariate analyzes were entered into a binary logistic regression model. Patients with treatment protocol deviation were not included in analysis. Factors included in the model were type of treatment and age grouped into $<$50, 50–65 and $>$65 years. HADS total ($\geq$15 vs. $<$15) was included in the model due to lower number of missing data compared to DT. Adjusted odds ratios and confidence intervals were calculated and the Wald χ^2 test was used to test the each parameter for significance.

Results

Participants

A total of 574 were identified in the DBCG database, 23 were excluded due to diagnosis of IBC or another cancer or because they were not able to understand or fill in the questionnaire. Seventy-eight patients did not reply, leaving 473 women (82%) who completed the questionnaire 12–36 months (median 24) after surgery. Their median age was 60 years. Approximately, one-third had mastectomy and SLNB,

another third had BCS and SLNB and the last third only BCS. BCS patients had adjuvant RT (Table 1).

Pain

A total of 154 (33%) of the patients reported pain at rest at least on a weekly basis in any of the four predefined areas and 57 (12%) reported moderate to severe pain. Table 2 shows the distribution of pain on treatment modalities in different areas of the body. Patients who underwent mastectomy with SLNB and breast reconstruction reported most pain in the breast (mild pain: 26%, moderate to severe pain: 11%) and the side of the chest (mild pain: 18%, moderate to severe pain: 10%). In univariate analysis, significantly more patients with reconstruction had pain ($p = 0.048$). However, there were no significant difference in pain intensity ($p = 0.06$). A logistic regression model of moderate to severe pain in the area of surgery found no significant effect of treatment type (Table 3). Younger age was significantly associated with moderate to severe pain. Patients aged 50 to 65 years had an odds ratio (OR) of 2.8 (95% CI: 1.1–7.0, $p = 0.02$) and patients aged <50 years had an OR of 4.7 (95% CI: 1.6–14.0, $p = 0.006$) compared to those older than 65 years. Furthermore, anxiety and depression measured by $HADS_{total} \geq 15$ was significantly associated with moderate to severe pain with an OR of 3.1 (95% CI: 1.5–6.3, $p = 0.003$).

Sensory disturbances

Overall 299 (63%) of the patients reported any sensory disturbance. One-third reported sensations of pins and needles, 20% of patients had experienced electric shock, burning hot sensations (12%), numbness (37%), light touch evokes pain (13%) and cold evokes pain (9%). Patients treated with mastectomy and reconstruction had significantly higher frequencies of sensations of pin and needles ($p < 0.0001$), electric shocks ($p = 0.02$) and numbness ($p < 0.0001$). Those who had BCS without SLNB suffered the least from sensory disturbances (Supplementary Appendix 1).

Psychological factors and quality of life

The mean values on quality of life are shown in Supplementary Appendix 2 along with the results of

Table 1. Population characteristics of 574 patients treated for ductal carcinoma *in situ* in denmark 2013 and 2014.

	Included	Excluded	Nonreply	Total
N (%)	473 (82)	23 (4)	78 (14)	574
Age, years, median (IQR)	60 (14)	59 (15)	62 (16)	60 (14)
Treatment, *N* (%)				
Mastectomy and SLNB	141 (30)	10 (44)	16 (21)	167 (29)
BCS and SLNB and radiotherapy	157 (33)	3 (13)	22 (28)	182 (32)
BCS and radiotherapy	150 (32)	5 (22)	22 (28)	177 (31)
Outside protocol[a]	25 (5)	5 (20)	10 (13)	40 (7)
Missing treatment data	0	0	5 (6)	5
Time from operation to questionnaire, months, median (IQR, range)[b]	24 (13, 12–36)	21 (12, 13–36)	24.5 (13, 12–36)	24 (11, 12–36)

BCS: breast-conserving surgery; IQR: interquartile range; N: number; SLNB: sentinel lymph node biopsy.
[a]Patients treated outside protocol includes BCS patients choosing not to receive radiotherapy and mastectomy patients where there was not recorded a SLNB procedure.
[b]Time from operation date to the date the questionnaires were sent.

Table 2. Pain on weekly basis in the surgical area of 473 patients treated for ductal carcinoma *in situ* 1–3 years ago.

	Mastectomy and SLNB		BCS and radiotherapy		Outside protocol	Total
	No reconstruction $N = 80$	Reconstruction $N = 61$	SLNB $N = 157$	SLNB $N = 150$	$N = 25$	473
Maximum pain, *N* (%)						
No pain	58 (73)	32 (54)	100 (64)	104 (69)	23 (92)	317 (67)
Mild pain	13 (16)	20 (33)	33 (21)	30 (20)	1 (4)	97 (21)
Moderate to severe pain	8 (10)	9 (15)	23 (15)	16 (11)	1 (4)	57 (12)
Breast, *N* (%)						
No pain	65 (81)	38 (62)	113 (72)	110 (73)	23 (92)	349 (74)
Mild pain	10 (13)	16 (26)	26 (17)	32 (21)	1 (4)	85 (18)
Moderate to severe pain	4 (5)	7 (11)	17 (11)	8 (5)	1 (4)	37 (8)
Side of chest, *N* (%)						
No pain	65 (81)	44 (72)	133 (84)	138 (92)	24 (92)	404 (85)
Mild pain	11 (14)	11 (18)	14 (9)	5 (3)	1 (4)	42 (1)
Moderate to severe pain	3 (4)	6 (10)	9 (6)	7 (4)	0 (4)	25 (5)
Axilla, *N* (%)						
No pain	70 (88)	52 (85)	133 (85)	139 (93)	24 (92)	418 (88)
Mild pain	4 (5)	7 (11)	11 (7)	7 (5)	1 (4)	31 (7)
Moderate to severe pain	5 (6)	2 (3)	12 (8)	4 (3)	0	22 (5)
Arm, *N* (%)						
No pain	71 (89)	52 (85)	142 (91)	141 (94)	24 (92)	430 (91)
Mild pain	1 (1)	5 (8)	4 (3)	0 (0)	1 (4)	11 (2)
Moderate to severe pain	7 (8)	4 (7)	10 (6)	9 (6)	0	30 (6)
Number of pain locations, median (IQR)	2 (1)	2 (1,5)	2 (2)	1 (1)		2 (2)

BCS: breast-conserving surgery; IQR: interquartile range; NRS: numeric rating scale; SLNB: sentinel lymph node biopsy.
Mild to moderate pain: NRS 1–3, moderate to severe pain: NRS 4–10.
Missing data: One patient in the mastectomy without reconstruction and one patient in the BCS without SLNB did not provide pain information.

Table 3. Binary logistic regression model of moderate to severe pain in rest in the area of surgery for 473 patients treated for ductal carcinoma *in situ*.

	Wald χ^2	Adj. OR.	95%CI	*p*
Age group (years)				
Age, years, median (IQR)				
Age <50	7.6	4.7	1.6–14.0	0.006
Age 50–65	5.1	2.8	1.1–7.0	0.024
Age >65		1		
Treatment type				
Mastectomy and SLNB	0.1	1.2	0.5–2.9	0.7
Mastectomy, reconstruction and SLNB	0.0	0.8	0.4–2.4	0.9
BCS and SLNB and radiotherapy	1.1	1.5	0.7–2.9	0.3
BCS and radiotherapy		1		
Anxiety and depression				
HADS total (cutoff ≥15)	9.1	3.1	1.5–6.3	0.003

BCS: breast conservative surgery; HADS: hospital anxiety and depression scale; SLNB: sentinel lymph node biopsy.
Binary logistic regression analysis for reporting moderate to severe pain (NRS ≥4) at least experienced at a weekly basis.
Complete case analysis: two patients with missing data on the outcome. One patient with missing HADS data, 25 patients treated outside protocol were excluded from the analysis.

Table 4. Rehabilitation needs among 473 patients treated for ductal carcinoma *in situ* 1–3 years ago.

Question	*N* (%)
Do or did you miss any kind of counseling or support related to physical, psychological or social conditions?	
Very much	25 (5)
Quite a bit	53 (11)
A little	62 (13)
Not at all	247 (52)
missing	86 (18)
Think about the needs for support that you have experienced since your treatment ended. If you could choose, which kinds of support/treatment would you most like to use? You may indicate several.	
Consultations	
With doctor or nurse regarding my diagnosis	271 (57)
With psychologist about my thoughts and feeling	147 (31)
With social worker about economy and work	28 (6)
Patient education	
On my disease and treatment	76 (16)
On relaxation and meditation	112 (24)
By a physical therapist	142 (30)
On physical activity	63 (13)
Written information about the disease	81 (17)
None	52 (11)
Counselling and contact	
Patient's associations	66 (14)
Health Centers	101 (21)
Contact to other patients	131 (28)

psychological factors. A total of 94 women (20%) reported anxiety $HADS_{anxiety}$ ≥8, 26 (6%) depression ($HADS_{depression}$ ≥8 and 51 (11%) reported distress (DT ≥7).

Rehabilitation needs

Unmet needs were reported by 29% of the patients (Table 4). When asked to indicate 'which kinds of support/treatment needed most?' more than half of the patients wished for consultation with a doctor or a nurse, and one-third wished for consultation 'about my thoughts and feelings'. A large proportion reported need for education 'in relaxation/meditation' (24%), 'by a physiotherapist' (30%) and 'written information' (17%). Finally, 14% reported need for counseling in health centers and 28% wished for contact to other patients in the same situation.

Discussion

In this cross-sectional study of 473 Danish women treated for DCIS, we found that 33% of women reported any pain, and 12% reported moderate to severe pain 1–3 years after primary surgery. To our knowledge, no other studies have specifically examined pain among DCIS patients, whereas persistent pain after breast cancer surgery has been shown to be a major problem affecting a large proportion of breast cancer patients [2,3] up to 7 years after surgery [19]. The prevalence of persistent pain in the area of surgery is similar to those reported by breast cancer patients with similar treatment [2,3,20]. The results are directly comparable to studies made using the same questionnaire on IBC patients in a prospective study with 42% with any pain and 14% moderate to severe pain [3] and in a cross-sectional study with 14% moderate to severe pain of those treated with SLNB.

Furthermore, we found that pain was strongly associated with younger age and high scores on $HADS_{total}$. Younger age has also been recognized as a predictor of persistent pain after breast cancer surgery [3]. Univariate analysis suggested more pain among patients with reconstruction of the breast, with a tendency toward higher pain scores ($p = 0.06$). However, the adjusted model rejected this with no difference between the treatment groups, which is supported by research in IBC patients [21]. The finding of an association between psychological factors and persistent pain is supported by similar findings in IBC patients [3]. Distress has been suggested to predict persistent pain [22] and a RCT on mindfulness indicated a treatment benefit on persistent pain [23], and thereby suggesting a potential treatment option. Regarding sensory disturbances our findings show that 37% of patients reported numbness 1–3 years after surgery. Again we found no other studies on the subject among DCIS patients, but this finding is in line with a review by Verbelen et al. showing an incidence of numbness ranging from 8–51% among sentinel node negative IBC patients [24]. Mejdahl et al. also found that 39% of 2411 Danish breast cancer patients, who had mastectomy and SLNB reported sensory disturbances 5–7 years after surgery [19]. The results are directly comparable to a study using the same questionnaire in IBC patients showing a prevalence of 32% of patients treated with SLNB reporting 'pins and needles' [13].

Although we found no studies focusing on pain and sensory disturbances in DCIS patients, a few studies, however, have used an overall physical function as outcome among DCIS patients. Ganz found that women with DCIS reported worse physical function than healthy women and that musculoskeletal aches and pain was the major reason [8]. On the other hand, Lauzier et al. found no significant differences after 12 months when comparing DCIS patients to IBC patients without adjuvant chemotherapy [9]. We found no impairment of neither global health status nor physical,

role or emotional functioning compared to Danish norm values retrieved from 608 healthy Danish women (mean norm scores: 74.8, 86.3, 88.1, 77.2, respectively) [25].

Our results showed a total of 20% reporting anxiety. This finding is in line with others [9,26] and may be related to inaccurate risk perception. Partridge et al. found that a substantial proportion of DCIS patients had grossly misperceptions of the risk of both recurrent DCIS and invasive cancer and that inaccurate risk perception was strongly associated with psychological distress [26]. In our previous study, interviews likewise revealed difficulties understanding the diagnosis leading to psychological problems and need for counseling (unpublished material). Patients in the present cohort reported, for example, need for consultation with a doctor or nurse, education by a physiotherapist as well as contact to other patients during the disease trajectory. These findings underline the need for appropriate support, and it seems crucial to assist patients in understanding the condition of DCIS. Health care professionals must identify patients' distress and possible misperceptions along the disease trajectory, and rehabilitation services should be offered. During the last years, attempts have been made in order to eliminate the term carcinoma *in situ*, thus potentially reducing the misperceptions of the diagnosis and improving psychological sequelae [10]. Pravettoni et al. argues, that the term carcinoma should now be abandoned and removed from conditions that cannot metastasize [10]. This seems plausible, but may need further research.

Strengths of our study include the cross-sectional design allowing for a large well-described population treated in different parts of the country and a high response rate. In addition, patients were treated according to the same nationwide guidelines. Furthermore, it is to our knowledge the first study to examine persistent pain and sensory disturbances thus contributing to the paucity of knowledge about physical problems after DCIS. The study is limited by the facts that the questionnaire was only given once, the lack of preoperative information and the cross-sectional nature precluding knowledge on causality and development over time.

Conclusions

In conclusion, our results show that 33% of patients treated for DCIS reported any pain and 12% reported moderate to severe pain in the breast, side of chest, axilla or arm at least on a weekly basis 1–3 years after surgery and that pain was significantly associated with younger age and psychological factors. Furthermore, 32% of patients reported pins and needles, 37% had numbness and 30% painful itch. A total of 94 women (20%) reported anxiety and almost one-third of patients had unmet rehabilitation needs. The findings underline the need for appropriate support and rehabilitation services for the increasing group of DCIS survivors. Further research is warranted, specifically addressing rehabilitation after diagnosis and treatment of DCIS.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article. None of the funding sources had any role in study design, data collection, analysis or interpretation of data.

Ethical approval

The study was approved by the Danish data protection authority (j.nr.2012-58-0004).

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ORCID

Birgitte Goldschmidt Mertz http://orcid.org/0000-0002-2093-8077
Niels Kroman http://orcid.org/0000-0002-6631-2993

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