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H. Sackey, K. Sandelin, J. Frisell, M. Wickman, Y. Brandberg. Ductal carcinoma in situ of the breast. Long-term follow-up of health-related quality of life, emotional reactions and body image. *EJSO - European Journal of Surgical Oncology*, 2010, 36 (8), pp.756. 10.1016/j.ejso.2010.06.016 . hal-00608924

HAL Id: hal-00608924

<https://hal.science/hal-00608924>

Submitted on 16 Jul 2011

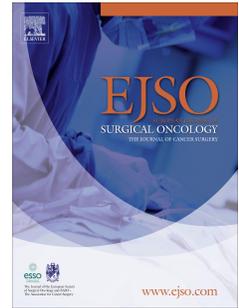
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Accepted Manuscript

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PII: S0748-7983(10)00192-7

DOI: [10.1016/j.ejso.2010.06.016](https://doi.org/10.1016/j.ejso.2010.06.016)

Reference: YEJSO 3004

To appear in: *European Journal of Surgical Oncology*

Received Date: 26 December 2009

Revised Date: 21 May 2010

Accepted Date: 7 June 2010

Please cite this article as: Sackey H, Sandelin K, Frisell J, Wickman M, Brandberg Y. Ductal carcinoma in situ of the breast. Long-term follow-up of health-related quality of life, emotional reactions and body image, *European Journal of Surgical Oncology* (2010), doi: 10.1016/j.ejso.2010.06.016

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Ductal carcinoma in situ of the breast. Long-term follow-up of health-related quality of life, emotional reactions and body image.

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Abstract**Aims:**

To investigate and compare long-term health-related quality of life (HRQoL), body image, and emotional reactions in women with ductal carcinoma in situ of the breast (DCIS) treated with different surgical methods.

Patients and Methods:

A total of 162 women were included in the study (47 had mastectomy and immediate breast reconstruction (IBR), 51 sector resection alone and 64 sector resection and postoperative radiotherapy). All women included in the study were asked to complete three questionnaires 4-15 years after surgery: the SF-36 for HRQoL, the Hospital Anxiety and Depression (HAD) scale, and the Body Image Scale (BIS). The response rate was 81%.

Results:

Women in all three study groups had, overall, a very satisfactory HRQoL in the long term, similar to women in the general population. Women who underwent mastectomy and IBR scored significantly higher on physical functioning and bodily pain than the other two study groups as well as their age-adjusted norm groups. The addition of radiotherapy to breast-conserving therapy did not seem to have any negative impact on long-term HRQoL. Our results show significant differences between the three study groups for six of ten BIS items, with a greater proportion of women in the mastectomy and IBR group reporting problems.

Conclusions:

Women treated for DCIS have a very satisfactory long-term HRQoL. However, body image appeared to be negatively affected in mastectomy and IBR patients. Our results indicate that these women need more preoperative information about what changes in body image to expect after surgery.

Introduction

Health-related quality of life (HRQoL) has been studied extensively in patients with invasive breast cancer, but long-term follow-up studies of HRQoL, emotional reactions, and body image after treatment for ductal carcinoma in situ of the breast (DCIS) are sparse. The yearly incidence of DCIS in Sweden is approximately 10% of all diagnosed cases of breast cancer [1]. Since the 1980s, breast-conserving surgery for DCIS has been recommended whenever feasible. Several randomized trials, including the Swedish National DCIS study, have unanimously shown a decreased rate of ipsilateral in situ or invasive breast cancer recurrence through the addition of adjuvant radiotherapy [2-7]. Today, national guidelines include radiotherapy up to a total of 50 Gray after breast-conserving therapy for high-risk subgroups of patients with DCIS. Mastectomy is still recommended for women with multifocal DCIS, an unfavourable proportion between tumor size and breast volume, and non-clear surgical margins after breast conservation. For these women immediate breast reconstruction (IBR) may be an alternative in order to maintain a breast contour.

In DCIS, the tumour cells do not penetrate the basal membrane and, by definition, do not metastasize. Women should therefore be expected to be cured by surgical treatment with clear margins. Nevertheless, both invasive and non-invasive recurrences do occur [8-10]. Owing to the complexity of the disease, there is still no international consensus on how extensively DCIS should be treated. The fact that the majority of DCIS is not life-threatening does not necessarily imply that women with DCIS experience less psychological distress than those with invasive breast cancer. Two qualitative studies report that women experience confusion upon the information that DCIS is not a life-threatening disease, while they are recommended a similar treatment to patients with invasive breast cancer [11, 12]. In two American studies, women with DCIS highly overestimated their future risk of recurrence and the risk that their breast cancer would metastasize [13, 14]. A Canadian study reported similar levels of anxiety and depression in women with early-stage invasive breast cancer and those with DCIS. No differences were found between the two groups regarding perceptions of the risk of developing local recurrence, distant recurrence, or breast cancer death [15]. In a Dutch study, HRQoL was compared between women with DCIS and those with early-stage invasive breast cancer [16]. No differences were found regarding HRQoL, but women with DCIS reported better physical health, sex life, and relationships with friends and acquaintances than women with invasive breast cancer.

The majority of women with DCIS have a very good prognosis. As surgery is the primary treatment for this disease, it is essential to increase current understanding of its long-term consequences. To our knowledge, there is no study comparing long-term HRQoL, body image, and emotional reactions in women with DCIS treated with different surgical

methods. The aim of the present study was to investigate and compare long-term anxiety and depression, body image, and HRQoL in women operated for DCIS by mastectomy and IBR, sector resection alone, or sector resection and postoperative RT. All women in the study would have a retained breast contour after the treatment for DCIS.

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Patients and Methods

Study population

All women who took part in the Swedish National DCIS study during the years 1991-1999 in the County of Stockholm were eligible [4]. These women had been randomized to sector resection alone or followed by radiotherapy. In addition, all women with DCIS who underwent mastectomy and IBR with an implant during the same period at the Karolinska University Hospital, Stockholm, were asked to participate in the present study. These three treatment options for DCIS defined our study groups. Exclusion criteria were: Paget's disease of the nipple, invasive breast carcinoma, lobular cancer in situ, ongoing tamoxifen treatment, and a history of present or previous malignancy (except basalioma and cervical cancer). Furthermore, women with dementia, severe brain damage, and without sufficient knowledge of the Swedish language were excluded as were those with an invasive recurrence after primary DCIS surgery. Immediate flap reconstruction was indicated in very few women and they were not included in the study. Women in the sector resection alone group and the sector resection and postoperative RT group were excluded if they had a DCIS recurrence that led to mastectomy. Prior to inclusion, all data were controlled against the Regional Oncology Centre to validate the DCIS diagnosis, and the Cause of Death Register, to ensure that patients were still alive. To further validate data from the Regional Oncology Centre, all patient charts from their respective hospitals in the County of Stockholm were reviewed. Only women with DCIS proven by final histopathology were included in the study.

In the mastectomy and IBR group, three women were excluded due to invasive breast cancer recurrence and two women due to previous malignancy. In the sector resection alone group, ten women were deceased, seven were excluded due to invasive breast cancer recurrence, nine due to DCIS recurrence that led to mastectomy, two due to previous malignancy, one due to dementia, two due to ongoing tamoxifen treatment, one did not speak Swedish, and one woman had undergone a delayed breast reconstruction. In the sector resection and postoperative RT group, six women were deceased, eight were excluded due to invasive breast cancer recurrence, one due to DCIS recurrence and re-operation by mastectomy, four due to previous malignancy, and one due to severe brain damage. In total, 162 women were included in the study.

Figure 1 shows inclusion and attrition.

Surgical procedures

According to prevailing national and regional guidelines, the breast-conserving procedure was performed as a sector resection as previously defined [17]. Women opting for mastectomy and IBR consulted with a breast surgeon and a reconstructive plastic surgeon for information about the procedure. The reconstructive method was implant-based with expander prostheses. According to previously published data, these women underwent on average 3 corrective procedures in order to complete the reconstruction[18]. Several patients later underwent minor and major adjustments to achieve a better functional and cosmetic result.

Study questionnaires

All women included in the study were asked to complete three questionnaires 4-15 years after surgery which were sent to the patients together with an information letter and a prepaid return envelope. If no response was obtained within two months, a reminder was sent.

The Swedish SF-36 Health Survey (SF-36) is used to assess HRQoL, and is a standardized questionnaire that has been widely used in international studies. The Swedish version has been validated, and normative data for Swedish women are available [19, 20]. The SF-36 consists of 36 items constituting eight domains: physical functioning (PF), role limitations as a result of physical problems (RP), bodily pain (BP), general health perception (GH), vitality (VT), social functioning (SF), role limitation due to emotional problems (RE), and mental health (MH). The first three domains (PF, RP, and BP) measure physical well-being and the last three domains (SF, RE, and MH) relate to emotional well-being. The two remaining domains (GH and VT) are associated with both physical and emotional dimensions. A high score on the subscales signifies a higher level of function and HRQoL.

The Hospital Anxiety and Depression (HAD) scale consists of 14 items, seven assessing anxiety and seven depression [21]. The possible sum score of each scale ranges from 0 to 21, with each item scoring 0 to 3 points. A high summated score represents high levels of problems. Cut-off points for each of the scales are: < 8 (within normal range), 8-10 (possible clinical case), and ≥ 11 (clinical case). The HAD scale is considered a reliable and valid instrument for the assessment of anxiety and depression in somatic, psychiatric, and primary care patients, as well as in the general population [22]. The Swedish version has been validated in breast cancer patients against diary recordings [23].

The Body Image Scale (BIS) was designed for the assessment of body image in cancer patients [24] and consists of 10 items concerning the impact of surgery on self-consciousness, physical and sexual attractiveness, femininity, satisfaction with body and scars, body integrity, and avoidance behavior. The BIS items score from 0 (not at all) to 3 (very much). A high score represent problems with body image. The BIS scale has a high reliability and good clinical validity [24]. No formal validation or reliability testing of the Swedish version has been performed. The translation to Swedish was performed by a group of five professionals (three nurses, one sociologist, and one psychologist) at the Department of Oncology, Karolinska University Hospital, Stockholm, in 1997.

Statistical methods

The scores derived from the SF-36 questionnaire were linearly transformed into a 0 to 100 scale according to the SF-36 manual [20]. A high score on the subscales signifies a higher level of function and HRQoL. The results were compared with normative data from an age-matched reference group consisting of 920 women from the general Swedish population [20]. The mean HAD subscale values were compared between groups, as well as proportions of patients in each clinical stage, as suggested by the original authors [21]. In order to determine the proportion of women who reported problems on each of the BIS items, a score of 0 was categorized as “no problem” and of 1 to 3 as “problem”.

Statistical analyses were performed using Statview version 4.5. ANOVA repeated measurement was used to evaluate differences between the three study groups on HAD subscales and SF-36 subscales. Chi2 test was used for categorical data (HAD and BIS). Student's t-test was used to evaluate differences between the study sample and normative data (SF-36). Differences between groups were considered statistically significant when $p < 0.01$.

The ethics committee of the Karolinska University Hospital, Sweden approved the study (Dnr 2002-018).

Results

In total, 162 women were included in the study and 131 (81%) responded to the questionnaires. The number of patients and reasons for attrition are presented in Figure 1. The median age was 58.5 years (range 40 to 77) for women treated with mastectomy and IBR, 65 years (range 55 to 83) for those treated with sector resection alone, and 64 years (range 48 to 89) for women treated with sector resection and postoperative RT. The mean time from surgery to the completion of the questionnaires was 7 years (SD 2.4) in the mastectomy and IBR group, 9.8 years (SD 2.8) in the sector resection and postoperative RT group and 9.9 years (SD 2.7) in the sector resection alone group.

Health-related quality of life

Mean values and standard deviations for the SF-36 subscales for the three study groups and their respective age-adjusted norm values are presented in Table 1. The scores for physical functioning (PF) and bodily pain (BP) were statistically significantly higher among the women in the mastectomy and IBR group as compared with the other two groups. The score for mental health (MH) was statistically significantly higher in the sector resection alone group than in the other two groups. Women in the mastectomy and IBR group scored statistically significantly higher on physical functioning (PF) and bodily pain (BP) than their age-adjusted norm group. No other statistically significant differences were found between the study groups and their respective age-adjusted norm groups.

Anxiety and Depression

Mean scores and standard deviations for the HAD anxiety and depression subscales and the proportion of patients scoring ≥ 11 (clinical case) is presented in Table 2. No statistically significant between-group differences were found for the mean scores on the HAD anxiety or depression subscales. No differences were found between the study groups regarding proportions of patients scoring in the clinical categories on the anxiety or depression subscale.

Body image

Numbers and proportions of women reporting problems are shown in Table 3. Overall, statistically significant differences between the three study groups were found for six of the items (self-conscious, less physically attractive, less feminine, less sexually attractive, dissatisfied with body, dissatisfied with scars) with larger proportions of women in the mastectomy and IBR group reporting problems.

Discussion

Overall, women in all three study groups appeared to have a very satisfactory HRQoL in the long term, similar to women in the general population. These findings are consistent with three other studies of long-term HRQoL among women with DCIS [16, 25, 26].

Women who underwent mastectomy and IBR scored higher on physical functioning and bodily pain than the other two study groups as well as compared to their age-adjusted norm groups. The physical functioning subscale concerns problems in daily life caused by physical restraints. It includes items about everyday life activities, for example carrying groceries, walking, climbing stairs, bowling, participating in strenuous sports. The bodily pain subscale includes items about pain levels during the past four weeks and to what extent pain has interfered with normal activities and work. The finding that women who underwent mastectomy and IBR reported better physical functioning and less bodily pain than the other two study groups as well as their age-adjusted norm groups is surprising. It might be explained by response shift. Response shift is an adaptation process in which patients with a severe disease undergo to accommodate their illness. A response shift involves changing internal standards and values and the conceptualization of quality of life [27]. Thus, it is possible that the more extensive surgical procedures and probably, a more prolonged rehabilitation period that these women have experienced, resulted in a response shift with respect to bodily pain and physical functioning. A Dutch study also showed that women with DCIS score higher than the norm group on the bodily pain subscale and the physical functioning subscale of the SF-36 [16].

The addition of postoperative radiotherapy to breast-conserving therapy did not seem to have any negative impact on HRQoL in the long term. This is consistent with the only prior study that we could find evaluating the impact of radiation therapy on long-term HRQoL in women with DCIS [26]. However, women in the sector resection alone group scored higher on the mental health subscale than the other two study groups, probably reflecting less extensive treatment.

Our results show differences between the three study groups for six of ten of the BIS items, with a greater proportion of women in the mastectomy and IBR group reporting problems. To our knowledge, this is the first study comparing different surgical treatments with respect to long-term body image among women with DCIS. Three previous studies on long-term postoperative body image among women with invasive breast cancer reported a more favourable body image among women treated with breast-conserving surgery than those treated with mastectomy alone [28-30]. Contradictory

results have been found in studies that address whether mastectomy with reconstruction results in a better long-term body image than mastectomy alone [30-32]. In addition, one long-term follow-up study failed to show any difference in body image between women treated with breast-conserving surgery and mastectomy with reconstruction [33]. It is important to consider that sector resection was not an option for most women in the mastectomy and IBR group and that the alternative – mastectomy alone – is not represented in this study. Given that mastectomy and IBR is the surgical option that provides a superior esthetical result, emphasis on preoperative information about expected postoperative changes in body image might have improved these results. During the study period two thirds of all women in Stockholm treated with mastectomy for DCIS also underwent IBR. In our unit we have long experience of IBR with implants which has thus become our method of choice. Women with DCIS are suitable candidates for implant based reconstructions as they are seldom treated with radiation therapy which is known to increase the risk for capsular contracture. If the cosmetic outcome becomes unsatisfactory, women are offered other modes of reconstructive techniques. Immediate flap reconstructions were performed in only a few cases during the study period and were not the purpose of the study. We cannot however exclude the possibility that the use of other immediate reconstruction techniques could result in a better body image. Further, among women treated with mastectomy, it is possible that those who are more concerned about their bodily appearance were overrepresented in the IBR group

One might have expected that mastectomy and IBR, a treatment implying a lower risk of recurrence, would result in less anxiety than the two other treatment options in the study. In our study, no statistically significant difference in anxiety and depression was found between the three study groups. However, our results show a trend towards increased levels of anxiety in the mastectomy and IBR group in comparison with the other two study groups. Women in the mastectomy and IBR group also scored statistically significantly lower than the other two study groups on the mental health subscales of the SF-36, although there were no statistically significant differences to their age-adjusted norm group. In an American study, perception of risk of recurrence did not diminish in women who underwent mastectomy [14]. A Dutch study found that women with DCIS had comparable perceptions of the risk of recurrence and breast cancer death to women with invasive breast cancer, despite their better prognosis [16]. We speculate that these trends, with increased anxiety and lower mental health, might reflect the more extensive and longer treatment that mastectomy and IBR implies when compared with sector resection alone or followed by radiotherapy, and that these women may have become more severely marked by their disease.

This study has a number of limitations. No women treated with mastectomy alone were included and better body image might have been expected with IBR than without. In addition, no preoperative data on our study variables were collected. Therefore, it was not possible to ascertain differences in the studied variables before surgery.

The study has a number of strengths. To our knowledge, there is no previous study evaluating long-term HRQoL and body image in women with DCIS treated with different surgical methods, including mastectomy with IBR and sector resection with or without radiotherapy. The response rate to the questionnaires was 81%, which is high considering the long time between operation and follow-up. Standardised questionnaires employed in many previous studies were used.

Conclusions: Women treated for DCIS have a satisfactory long-term HRQoL. The addition of radiotherapy to breast-conserving surgery did not seem to have any negative impact on HRQoL in the long term. However, body image appeared to be affected in mastectomy and IBR patients. Our results indicate that these women need more preoperative information about what changes in body image to expect after surgery.

Acknowledgements

This study was supported by grants from the Johan and Jakob Söderberg's Foundation, The Paola Brunetti-Jacovone's Bequest, The Swedish Cancer Foundation in Stockholm and The Swedish Cancer Society. The Swedish National DCIS study group is acknowledged for contributing the cohort of Stockholm patients.

Conflict of interest statement

We have no conflicts of interest.

Role of the funding source

The study sponsors had no involvement in the study.

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Table 1. Mean values and standard deviations for the SF-36 subscales for the three study groups and their respective age-adjusted norm values.

Variables	Mastectomy and IBR		Sector resection alone		Sector resection and radiotherapy		P-values for differences between the study samples	P-values for differences between mastectomy and IBR and the norm ²
	Mean ¹ (SD) N=40-42		Mean ¹ (SD) N=32-36		Mean ¹ (SD) N=45-52			
	Study sample	Norm	Study sample	Norm	Study sample	Norm		
Physical functioning PF	92.4 (10.4)	80.8 (20.8)	73.4 (26.6)	72.1 (24.3)	74.1 (25.5)	72.1 (24.2)	0.002	0.002
Role physical RP	90.2 (23.0)	77.8 (35.0)	75.0 (38.4)	67.2 (40.1)	79.5 (36.0)	65.5 (39.6)	NS	NS
Bodily pain BP	86.5 (19.7)	68.3 (27.4)	70.2 (28.0)	65.9 (28.4)	70.7 (28.1)	65.3 (28.5)	0.006	<0.001
General health GH	72.7 (20.5)	70.6 (23.1)	70.6 (22.4)	65.4 (23.8)	66.0 (22.4)	65.2 (23.6)	NS	NS
Vitality VT	56.4 (16.0)	67.0 (24.0)	63.6 (12.0)	65.6 (25.0)	57.8 (16.0)	63.6 (25.2)	NS	NS
Social functioning SF	86.6 (20.4)	87.0 (21.1)	93.2 (13.0)	85.3 (22.4)	85.2 (21.3)	84.4 (22.4)	NS	NS
Role emotional RE	78.9 (36.3)	83.3 (31.2)	82.9 (32.7)	77.6 (35.9)	83.7 (34.8)	76.9 (35.6)	NS	NS
Mental health MH	73.0 (20.0)	79.5 (20.3)	84.9 (13.3)	78.5 (21.3)	76.0 (18.7)	77.6 (21.3)	0.012	NS

¹Range 0 – 100 (high values represent high functioning)

²No statistically significant differences were found between the other two study groups and their norm values

Table 2 Mean scores and standard deviations (SD) for the HAD anxiety and depression subscales according to treatment, and proportions of women in the three study groups in the three categories “no case” (0-7), “possible clinical case” (8-10) and “clinical case” (≥ 11) for the HAD.

Study group	Mastectomy and IBR N=41-42	Sector resection alone N=37	Sector resection and radiotherapy N=49-50	Total N= 127-128	Statistics
Anxiety					
Mean (SD)	6.24 (5.00)	3.76 (3.25)	4.41 (4.22)		P= 0.02
“No case” N (0-7 points)	27	32	39	98	DF=4 Chi2=8.31 P=0.08
“Possible clinical case” N (8-10 points)	5	4	6	15	
“Clinical case” N (>11 points)	9	1	4	14	
Depression					
Mean (SD)	3.14 (3.72)	2.27 (2.80)	2.94 (3.33)		P=0.48
“No case” N (0-7 points)	37	35	44	116	DF=4 Chi2=1.09 P=0.90
“Possible clinical case” N (8-10 points)	3	1	3	7	
“Clinical case” N (>11 points)	2	1	2	5	

Table 3. Body image items: number and proportion of patients reporting problems (scoring 1 to 3)
according to treatment statistics for between-group differences.

Item	Total N (%)	IBR N (%)	Sector resection alone N (%)	Sector resection and radiotherapy N (%)	Statistics
1 Self conscious	No 82 (63) Problem 48 (37)	No 11 (27) Problem 30 (73)	No 32 (84) Problem 6 (16)	No 39 (76) Problem 12 (24)	DF= 2 Chi 2= 25.50 P< 0.0001
2 Less physically attractive	No 78 (60) Problem 53 (40)	No 16 (38) Problem 26 (62)	No 28 (74) Problem 10 (26)	No 34 (67) Problem 17 (33)	DF= 2 Chi 2=12.25 P= 0.002
3 Dissatisfied with appearance	No 99 (76) Problem 31 (24)	No 31 (74) Problem 11 (26)	No 31 (82) Problem 7 (18)	No 37 (74) Problem 13 (26)	DF= 2 Chi 2= 0.87 P= 0.65
4 Less feminine	No 95 (73) Problem 36 (27)	No 20 (48) Problem 22 (52)	No 33 (87) Problem 5 (13)	No 42 (82) Problem 9 (18)	DF= 2 Chi 2=19.20 P= 0.0001
5 Difficult to see self naked	No 98 (75) Problem 32 (25)	No 27 (64) Problem 15 (36)	No 31 (82) Problem 7 (18)	No 40 (80) Problem 10 (20)	DF= 2 Chi 2= 4.10 P=0.13
6 Less sexually attractive	No 74 (58) Problem 53 (42)	No 11 (27) Problem 30 (73)	No 30 (79) Problem 8 (21)	No 33 (69) Problem 15 (31)	DF=2 Chi 2= 25.50 P< 0.001
7 Avoid people	No 122 (93) Problem 9 (7)	No 37 (88) Problem 5 (12)	No 38 (100) Problem 0 (0)	No 47 (92) Problem 4 (8)	DF=2 Chi 2= 4.50 P= 0.10
8 Body less whole	No 88 (67) Problem 43 (33)	No 21 (50) Problem 21 (50)	No 28 (74) Problem 10 (26)	No 39 (76) Problem 12 (24)	DF= 2 Chi 2 28.30 p= 0.015
9 Dissatisfied with body	No 88 (67) Problem 43 (33)	No 20 (48) Problem 22 (52)	No 30 (79) Problem 8 (21)	No 38 (75) Problem 13 (25)	DF= 2 Chi 2= 10.90 P=0.004
10 Dissatisfied with scar	No 81 (62) Problem 49 (38)	No 18 (43) Problem 24 (57)	No 29 (76) Problem 9 (24)	No 34 (68) Problem 16 (32)	DF= 2 Chi 2= 10.60 P= 0.005

Legends to figures:

Figure 1: Number of patients included in the study and attrition

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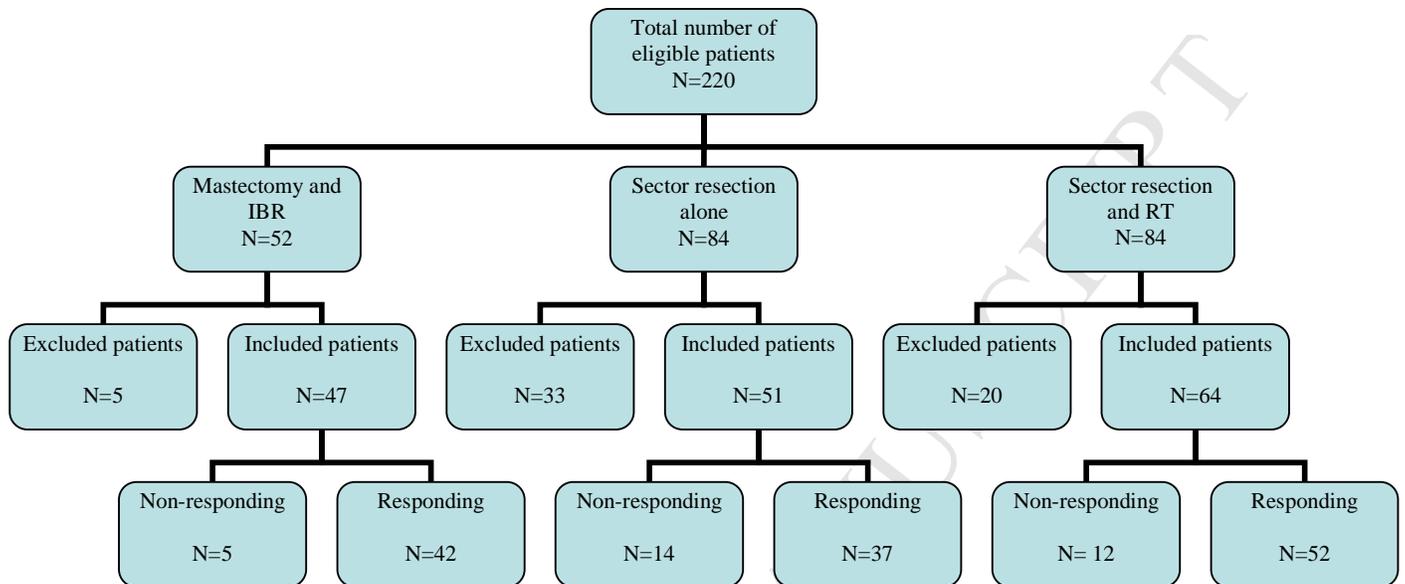


Figure 1: Number of patients included in the study and attrition