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ORIGINAL ARTICLE

The effect of physiotherapy on shoulder function in patients surgically treated for breast cancer: A randomized study

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Abstract

The effect of physiotherapy on shoulder function in patients surgically treated for breast cancer was examined through a randomized controlled trial. One hundred and thirty-nine patients with newly diagnosed breast cancer were enrolled in the study. Sixty-two (45%) had Breast Conserving Therapy and 77 (55%) had Modified Radical Mastectomy (Axillary dissection of level I and II was included in both procedures). Enrolled patients were randomized to either group A or group B. Group A was offered, team instructed physiotherapy consisting of 12 sessions of 60 min, two sessions a week. The treatment was instituted between the sixth and eight postoperative week. Group B was also offered team instructed physiotherapy, consisting of 12 sessions of 60 minute two sessions a week, but not until the 26th postoperative week. The patients were seen for follow-up examinations four times during the first postoperative year (after 7, 13, 26 and 56 weeks). Shoulder function was assessed by the Constant Shoulder Score preoperatively and at the four follow-up examinations. Team instructed physiotherapy was found to improve the shoulder function significantly in patients treated surgically for breast cancer. The effect of the treatment was influenced by the type of surgery performed, and in mastectomised patients, also by the application of radiation therapy. Compromised shoulder function is a less frequent and less severe side effect to breast conserving therapy as compared to modified radical mastectomy.

Impaired shoulder function is a well-known and frequently seen sequela to the treatment of early breast cancer [1–4]. It is usually ascribed to the surgical trauma and scarring caused by the axillary dissection in combination with the fibrosing effect of adjuvant radiation therapy [5–13]. As Sentinel lymph node biopsy has become a standard procedure in the surgical management of early breast cancer, node-negative patients are spared axillary clearance. Still, all node positive patients receive full axillary dissection. Even though all our patients received physiotherapy treatment during the first postoperative days, complaints of decreased shoulder function are frequent. The aim of this study was to evaluate the effect of additional postoperative physiotherapy on shoulder function, when administered for a longer period of time and instituted after the immediate postoperative recovery phase.

Material and methods

Protocol

Breast cancer patients scheduled for surgery at Aarhus University Hospital, in the time period August 1998 to April 2000 were asked to participate in the study. The inclusion criteria were: unilateral surgery planned according to the guidelines from the Danish Breast Cancer cooperative Group (DBCG). The exclusion criteria were: a) reported illnesses affecting the upper extremities preoperatively and b) patients unable to give written or oral consent. The day before surgery, patients were given written and oral information and were asked to participate in the study. Patients who fulfilled the inclusion criteria and who were willing to participate in the study, where examined preoperatively. On the first or second postoperative day, the patients were enrolled in the study and randomised to one of the two

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treatment groups (group A and B). Patients who did not want to participate were offered the standard treatment of the ward. The standard treatment included daily demonstrations and instructions in shoulder and vein pump exercise during the first postoperative week. Instructions were given by a physiotherapist, and the patients were encouraged to continue exercising when discharged from the hospital.

Ethics

The study protocol was approved by the Local Ethical Comity for the county of Aarhus. Signed informed consent was obtained from all enrolled patients.

Study population

A total of 139 patients were enrolled in the study. The patients were either subjected to a) Breast Conserving Therapy (BCT); including axillary lymph node dissection of level I and II, followed by radiation therapy of the remaining breast parenchyma (48 Gy/ 24 fractions + boost 10 Gy/ 5 fractions) or b) Modified Radical Mastectomy (MRM) *ad modum* Cady, including axillary dissection of level I and II. Patients were classified as in low or high risk of recurrence depending on the tumour size, the histopathological grade, the presence of axillary metastasis, the menopausal status, and the estrogen receptor status. Low risk patients had no adjuvant treatment except radiotherapy treatment in case of breast conserving surgery. Adjuvant treatment to high-risk premenopausal patients included nine series of chemotherapy CEF (cyclophosphamide 600 mg/m2, epirubicin 60 mg, 5-fluorouracil 600 mg/m^2) and in case of axillary metastasis, also radiation therapy to the parasternal, infraclavicular lymph node basins (48 Gy/ 24 fractions). Treatment with Tamoxifen was instituted in case of oestrogen receptor positivity. High-risk postmenopausal patients with axillary metastasis were given radiation therapy to the parasternal and infra-clavicular lymph node basins (48 Gy/ 24 fractions) and tamoxifen treatment was instituted if the tumour was estrogen receptor positive. Receptor negative patients received nine series of CMF (cyclophosphamide 600 mg/m2, methotrexate 40 mg/m^2, 5-fluorouracil 600 mg/m^2). Patients with tumours larger than 5 cm or with a tumour invasion of the profound fascia had radiation therapy to the chest wall (48 Gy/ 24 fractions). Radiotherapy was planned be instituted before the sixth postoperative week. Patient characteristics in relation to the randomisation group, surgical technique, and radiotherapy treatment are shown in Table I.

Planned intervention

Enrolled patients were randomized to either group A or group B. Group A was offered the standard treatment of the ward and in addition, team instructed physiotherapy consisting of 12 sessions of 60 min, two sessions a week. The treatment was instituted during the sixth to eighth postoperative weeks. Group B was offered the standard treatment of the ward and in order to prevent dropouts the patients were offered the same team instructed physiotherapy as group A, consisting of 12 sessions of 60 min, two sessions a week but after the 26th postoperative week. The patients were seen for follow-up examinations, four times during the first postoperative year (after 6, 12, 26 and 56 weeks). At the follow-up examinations, the shoulder mobility was assessed by the Constant Shoulder Score [14–16]. All physical examinations were performed by the same physician. The flow chart is shown in Figure 1.

In order to obtain a sufficient number of patients on the individual teams, patients were enrolled into treatment teams over periods of three weeks. To

Table I. Patient characteristics in relation to randomization groups, type of surgery and radiation therapy.

	Group A		N = 72	Group B		N = 67
	MRM + RT	MRM	BCT	MRM + RT	MRM	BCT
Median age yr. (range)	49 (40–70)	60 (37–74)	54 (31–79)	51 (29–70)	63 (32–77)	54 (42–69)
Median number of lymph nodes (range)	14 (10–23)	13 (8–23)	13 (10–20)	15 (10–40)	14 (11–26)	15 (10–21)
Number of patients with axillary metastasis (%)	17/20 (85%)	5/21 (24%)	13/31 (42%)	19/23 (83%)	3/13 (23%)	12/31 (41%)
Number of patients who recieved chemotherapy (%)*	13/20 (70%)	3/21 (14%)	10/31 (32%)	11/23 (48%)	4/13 (31%)	6/31 (21%)
Number of patients taking tamoxifen	7/20 (40%)	6/21 (29%)	12/3 (39%)	8/23 (35%)	2/13 (15%)	7/31 (24%)

MRM: modified radical mastectomy; BCT: breast conserving surgery; RT: radiation therapy.

* Including three patients in Group A and one patient in Group B, who received high dose chemotherapy and autolog bone marrow transplantation.

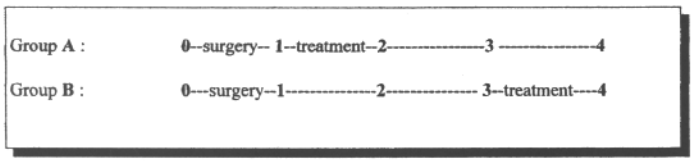

Figure 1. Planned intervention. **0**: Preoperative assessment. **1**: First follow-up at 7 weeks. **2**: Second follow-up at 13–15 week. **3**: Third follow-up at 25–27 week. **4**: Fourth follow-up at 55–56 week. (Median values).

ensure that the patients received uniform treatment the same two physiotherapists handled all sessions and used an exercise program especially created for the study. No individual therapy was applied. The exercise program consisted of exercises based on extension and relaxation, strength training, vein pump therapy and instruction in stretching of scar tissue in order to increase the mobility of the skin above the pectoral major muscle and in the area of the axilla [30]. The patients were encouraged to perform the exercises on a regular basis at home.

At each follow-up, the shoulder function was assessed by the Constant Shoulder Score, a 100 point score, composed of a number of both subjective parameters, and objective measurements of active motion range and shoulder strength. In the CSS, 35 points are allocated for subjective assessment of shoulder pain and assessment of the ability to perform the normal activities of daily living. Forty points are allocated for objective measures of range of movement (ROM). Assessment of ROM is based on the active range of composite movements that allow placement of the upper limb in functionally relevant positions, with a goniometer to measure forward and lateral elevation, and positioning of the hand in relation to the head and trunk for assessment of inner and outer rotation. Twenty-five points are allocated for the assessment of strength in lateral elevation. For testing strength the arm is positioned in 90 degree of elevation in the scapular plane, with the elbow extended and the forearm pronated. A strap is placed around the wrist and attached to an ISOBEX device. The ISOBEX measures the relatively constant upward force, 10 times per second for five seconds and calculates a mean value. The average of five measurements is used for allocating points. The CSS was assessed on both the ipsilateral and contra lateral shoulder, using the contra lateral side as baseline reference. The CSS on the ipsilateral shoulder was subtracted from the CSS on the contra lateral shoulder, generating the difference in CSS (ΔCSS). The presence of "strings" in the axilla (referred to as aseptic lymphangitis or a vascular ring in previous publications [17–20] was noted at each follow-up. Information on the number of lymph nodes removed, metastatic involvement of the axilla and adjuvant oncological treatment was obtained from the DBCG registry.

Statistics

The statistical analyses were completed on an intention to treat basis. Preoperative CSS values on both the operated and non-operated side were adequately approximated by a normal distribution whereas postoperative CSS and ΔCSS values on the operated side were not. Therefore, non-parametric statistics were used for all analyses. The results are expressed as median values and quartile. A Mann-Withney U-test with a 95% level of significance was used for comparing the ΔCSS values. For analysing the difference in proportions the χ^2 tests with a 95% level of significance were used. All analyses were performed by the computer program SPSS/WINDOWS (9.0).

Sizing of the target sample

The target sample size was calculated by:

$$N = \frac{\pi 1(1 - \pi 1) + \pi 2\,(1 - \pi 2)}{(\pi 1 - \pi 2)(\pi 1 - \pi 2)} f(\alpha, \beta)$$

α = risk of type 1 error, β = risk of type 2 error; $\pi 1$ = expected response with standard treatment; $\pi 2$ = expected response with new treatment.

The effect of physiotherapy on range of shoulder motion in a previously conducted study [21], were used to estimate the response probability for given ($\pi 2 = 0.3$) and for standard treatment ($\pi 1 = 0.1$). The risk of a type one error was set at $\alpha = 0.05$, the risk of a type two error was set at $\beta = 0.2$ and the f (α, β) = 7.9. The estimated sample size was 60 completing patients in each group, 120 patients in all. It was planned to include 20 additional patients to ensure that enough patients would complete the study.

Assignment

Patients were randomized individually. The allocation was computer generated, and was concealed in sequentially numbered opaque, sealed envelopes on folded paper. Allocation was performed by a third person that also kept the code during trial. The

person in question was not a member of the staff on the breast cancer or physiotherapy wards. The code was not broken until the end of the study and only after all data were computerized.

Masking

The physiotherapists were not blinded for allocation groups, as it was obvious whether the patient was eight weeks or six months postoperatively. It was intended that the physiotherapist would call in patients for all examinations, allowing the examining physician to be blinded for allocation groups. This was not possible because of logistic problems. Thus, successful blinding of the examiner was not accomplished. The failed blinding was compensated for by giving appointments for both intervention and control group on the same days and by making appointments for patients with different follow-up times on the same day.

Results

Participants flow

During the trial period 309 patients were scheduled for breast cancer surgery. Of these, nine patients declined to participate in the study. The main reason for declining was the amount of time and expense involved in travelling to the hospital.

One hundred and twenty-two patients did not fulfill the inclusion criteria mainly because of conditions affecting shoulder function, i.e., rheumatism, frozen shoulder and previous shoulder surgery. Thirty-nine patients were missed for inclusion. A total of 139 patients were enrolled in the study. Fourteen patients dropped out of the trial including two patients who died and two patients who had terminal disease, disabling them in attending the final follow-up.

There was no statistical difference in the timing of the four postoperative follow-ups between group A and B. A flow chart is shown in Figure 2. The number of attended physiotherapy sessions is shown in Table II.

Physical findings

No difference in shoulder function was found between group A and group B at the preoperative assessment and at the first follow-up. At the second follow-up, after the six weeks' treatment period in group A, the patients in group A had a significantly better shoulder function on the operated side as compared to the patients in group B ($p = 0.001$). A significant difference was also seen at the third follow-up six months postoperatively ($p = 0.001$). At the fourth follow-up after both groups had received physiotherapy treatment, no significant difference in shoulder function was found between the two groups. The results are presented in detail in Table III.

The type of surgery was included in the analyses by dividing the patients in each randomisation group according to the type of surgery. The BCT and the MRM patients were then evaluated separately. No difference in shoulder function on the operated side was found between the BCT patients in the two randomization groups at any follow-up.

The MRM patients in group A had a significantly better shoulder function on the operated side at the second ($p < 0.001$) and third follow-up ($p < 0.001$) as compared to the MRM patients in group B. At the final follow-up, when both groups had received physiotherapy, equal values were obtained in both randomization groups. Details are presented in Table IV.

Radiation therapy was included in the analyses by further dividing the mastectomised patients into two groups, those who had received radiation therapy (MRM+RT) and those who had not (MRM-RT). The MRM-RT patients in group A had a significantly better shoulder function on the operated side at the second ($p = 0.003$) and third follow-up ($p = 0.003$) as compared to the MRM-RT patients in group B. At the final follow-up, one year postoperatively, when both groups had received six weeks of physiotherapy, no difference in shoulder function was found between the MRM-RT patients in groups A and B. The MRM+RT patients in group A had lower values of ΔCSS when compared to the control patients in group B at both the second and third follow-up, but the difference was not statistically significant. Details are presented in Table V.

When comparing the MRM+RT, the MRM-RT and the BCT patients in the individual randomisation groups, the BCT patients in both randomization groups had significantly better shoulder function on the operated side as compared to the MRM+RT patients at all postoperative assessments. No difference in shoulder function was found between the MRM-RT and the MRM+RT patients in group B at any time. The MRM+RT patients and MRM-RT patients in group A had equal shoulder function at the first postoperative follow-up. At all three examinations, following physiotherapy, the MRM-RT patients in group A had a significantly better shoulder function on the operated side as compared to the MRM+RT patients in group A ($p = 0.005$, $p = 0.003$, $p = 0.001$).

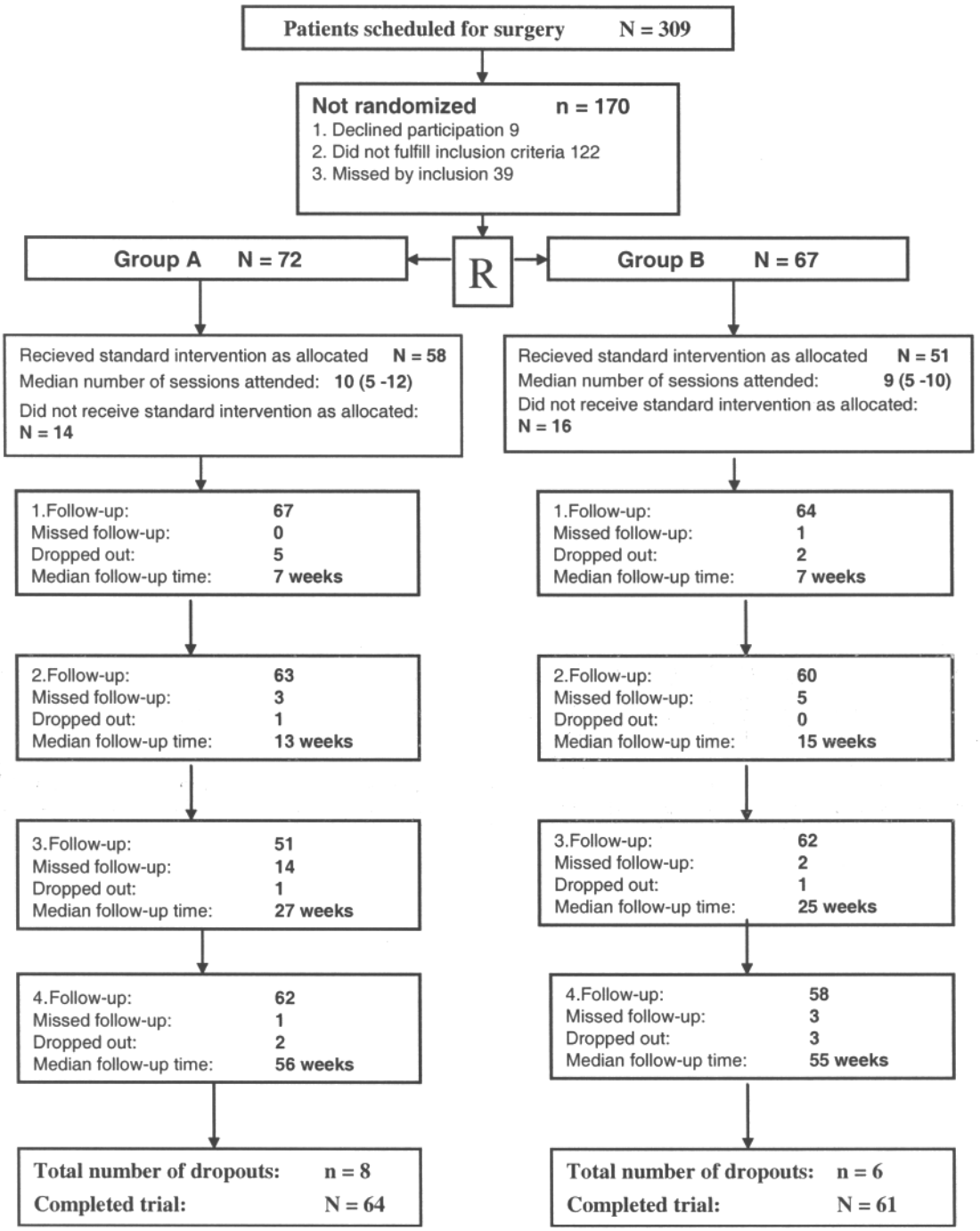

Figure 2. Patients flow.

Equal CCS values were obtained on the non-operated shoulders, in both randomization groups and in all subgroups, at all times.

Axillary "strings"

At the first postoperative follow-up 79 (57%) patients had "strings" in the axilla on the operated side. The number decreased to 43 (31%) patients at the second follow-up and to 21 (15%) at the third follow-up, six months postoperatively. At the final one-year follow-up, none of the patients had strings in the axilla. Overall 86 (62%) of the patients were found to have axillary strings at one or more follow-ups. The presence of "strings" was equally distributed in group A and in group B at all times and was

Table II. Median number of physiotherapy sessions attended in relation to randomization group and type of surgery.

	Group A	N = 72	Group B	N = 67
	MRM n = 41	BCT n = 31	MRM n = 36	BCT n = 31
median number of sessions attended (range)	11 (0–12)	9 (5–12)	9 (0–11)	8 (0–11)
median number of sessions missed	1	3	2	3
number of patients not attending any sessions	4 (10%)	3 (10%)	3 (8%)	6 (19%)
number of patients attending less than six sessions	3 (7%)	3 (10%)	2 (6%)	5 (16%)
number of patients attending six or more sessions	34 (83%)	24 (80%)	31 (86%)	20 (65%)

MRM: modified radical mastectomy; BCT: breast conserving surgery.

not influenced by type of surgery or radiation therapy.

Discussion

This randomized controlled study clearly demonstrates that team instructed physiotherapy instituted at the sixth to eighth postoperative week, improves the shoulder function in patients surgically treated for breast cancer. It also demonstrates that the same treatment can improve shoulder function significantly even when instituted as long as six months postoperatively.

Most of the literature concerned with physiotherapy of breast cancer patients focuses on the effect on lymph oedema while shoulder mobility receives less attention. The part of the literature that includes shoulder mobility, often describes institution of physiotherapy during the first postoperative week [22–28]. The follow-up time is often only a few months and the effect of the adjuvant treatment is not yet seen. Only a single study has evaluated the effect of physiotherapy instituted after the first postoperative weeks. This study describes an improvement of shoulder function following physiotherapy instituted several years postoperatively [21]. Several factors are believed to be of importance in the development of decreased shoulder mobility. The age of the patient, the extent of axillary dissection, the surgery on the breast as well as the nature of adjuvant treatment are some of the factors most frequently discussed. The randomization ensured an equal distribution of these confounding factors in Group A and B.

Table III. Median ΔConstant Shoulder Score (quartiles) in relation to randomization groups.

Follow-up	Group A	Group B
0	0 (−1;1) n = 72	0 (−1;1) n = 67
1	21 (9;30) n = 67	17 (9;27) n = 64
2	4 (0;11) n = 63	9 (4;17) n = 60
3	2 (0;7) n = 51	7 (2;18) n = 62
4	1 (0;8) n = 62	2 (−1;6) n = 58

MRM: modified radical mastectomy; BCT: breast conserving surgery.
Follow-up: 0 = preoperative; 1 = 7 weeks; 2 = 13–15 weeks; 3 = 25–27 weeks; 4 = 55–56 weeks.

Our study demonstrates that BCT patients generally had less frequent and less severe reduction in shoulder function, as compared to mastectomised patients. The average BCT patient seemed to have a spontaneously recovery of shoulder function. Physiotherapy after this type of surgery seemed of less importance. However, the result could be biased as six BCT patients in group B and one BCT patient in group A, were referred by the oncological department for additional physiotherapy treatment four weeks postoperatively. The reason for this was that these patients had considerably decreased shoulder mobility, and that they were not able to assume the position needed for radiotherapy treatment. Hence the importance of operation method and the effect of physiotherapy to BCT patients could be underestimated.

The mastectomised patients where shown to benefit largely from the physiotherapy treatment. However, the effect of the physiotherapy seemed to be influenced by the application of radiotherapy. The MRM-RT patients significantly improved shoulder function after both early and late physiotherapy treatment, but the applied physiotherapy did not improve the shoulder function significantly in MRM+RT patients. A type two error may be present in the subanalyses. The type of surgery and the postoperative radiation therapy was not considered in either the power calculations or the randomization procedure. In the first part of the study, patients in group A received radiation therapy during the intervention period. Then regimes changed, the waiting time for radiotherapy extended to 12 weeks, and for several months patients in group A ended their physiotherapy training before the institution of radiation therapy. Furthermore, radiotherapy was postponed in some patients till after end of chemotherapy, thus, patients in group B received radiation therapy during physiotherapy, where as patients in group A finished physiotherapy before

Table IV. Median Constant Shoulder Score (quartiles) in relation to randomization groups and type of surgery.

	Intervention group A	N = 72	Control group B	N = 67
Follow-up	MRM n = 41	BCT n = 31	MRM n = 36	BCT n = 31
0	0 (−1.; 1) n = 41	0 (−1; 1) n = 31	0 (−1; 2) n = 36	0.6 (−1; 2) n = 31
1	24 (19; 31) n = 37	12 (5; 22) n = 30	20 (13; 30) n = 35	11 (7; 22) n = 29
2	4 (0; 10) n = 35	3 (0; 12) n = 28	12 (8; 19) n = 32	6 (1; 13) n = 28
3	2 (0; 8) n = 29	2 (0; 7) n = 22	14 (4; 23) n = 34	3 (0; 15) n = 28
4	2 (0; 12) n = 36	1 (0; 6) n = 26	3 (0; 7) n = 30	1 (−1; 6) n = 28

MRM: modified radical mastectomy; BCT: breast conserving surgery.
Time: 0 = preoperative; 1 = 7 weeks; 2 = 13–15 weeks; 3 = 25–27 weeks; 4 = 55–56 weeks.
* p = 0.05.

they began radiation treatment. It is possibly that the effect of the early treatment could have been more pronounced at the second to fourth follow-up in both BCT and MRM + RT patients, if the treatment in group A had been applied during or after radiotherapy instead of before.

The patient compliance was high during the trial. The BCT patients attended fewer physiotherapy sessions than the MRM patients, and the BCT patients in group A attended more sessions than the BCT patients in group B. This reflects the fact that the BCT patients generally had less severe and less frequent shoulder problems and felt no need for physiotherapy especially at six months postoperatively.

The internal validity of the study was compromised because complete blinding of the examiner was not achieved. However, only part of the CSS was based on objective measurements, the remaining points were allocated based on subjective parameters. Although decreased, shoulder mobility is a well-known sequela to the treatment of breast cancer; the causes of the condition are rarely discussed. We do not believe that changes in the shoulder joint *per se* is the primary cause of the reduced shoulder mobility in breast cancer patients. The adherence between muscles, subcutaneous tissue, and the skin in the axilla and the pectoral area mechanically inhibit shoulder movement, and adjuvant radiation and chemotherapy adds to the firm fibrous attachment among the structures. As part of the breast ablation, the fascia overlying the major pectoral muscle is removed. The subcutaneous tissue on the skin flaps grows to the raw muscle and adheres firmly. This may inhibit the usual smooth sliding between the muscle, the subcutaneous tissue and the skin when the arm is abducted, flexed or outer rotated maximally and the pectoral muscle has to be fully extended. By the axillary dissection the lateral part of both the major and minor pectoral muscles are affected, and because the axillary fat is removed the skin flaps in the axillary area can adhere in the same way to the muscles lining the axilla and to the thoracic wall.

Even though BCT patients have adjuvant radiation therapy of the remaining breast parenchyma, they had a lower frequency of, and a less severe reduction in, shoulder function as compared to the MRM patients. The major difference between the two surgical procedures is that in breast conserving surgery none or only a small part of the pectoral fascia is removed. Therefore, the function of the major pectoral muscle is not affected in the same way. Our findings are supported by those of others [3,29]. When equal adjuvant treatment and axillary surgery has been applied, mastectomy compared to breast conserving surgery, increases the risk of shoulder disability.

Table V. Median ΔConstant Shoulder Score (quartiles) in relation to randomization groups, type of surgery and radiation therapy.

	Group A		N = 72	Group B		N = 67
Follow-up	MRM + RT	MRM	BCT	MRM + RT	MRM	BCT
0	0 (−1; 2) n = 18	0 (−2; 0) n = 20	0 (−1; 1) n = 31	0 (−1;1) n = 21	0 (0;1) n = 11	1 (−1;2) n = 31
1	29 (19;38) n = 17	22 (17;29) n = 19	12 (5;22) n = 30	20 (14;31) n = 21	20 (2; 26) n = 11	11 (7;22) n = 29
2	8 (4;18) n = 16	1 (−1; 7) n = 19	3 (0; −12) n = 28	12 (8; 20) n = 19	13 (4;18) n = 11	6 (1;13) n = 28
3	6 (2;20) n = 11	0 (0; 3) n = 17	2 (−1; 7) n = 22	15 (5;34) n = 20	9 (2;18) n = 11	3 (0;15) n = 28
4	10 (1;24) n = 16	0 (−1; 2) n = 19	1 (0; 6) n = 26	2 (0;9) n = 18	1 (−1;5) n = 11	1 (−1;6) n = 28

MRM: modified radical mastectomy; BCT: breast conserving surgery.
Time: 0 = preoperative; 1 = 7 weeks; 2 = 13–15 weeks; 3 = 25–27 weeks; 4 = 55–56 weeks.

The application of physiotherapy during the first postoperative week is important in order to show the patients that they are allowed to use the shoulder. However, the immediate postoperative sequela hinders full range exercises, and during the first postoperative months side effects of radiation therapy and the axillary strings limit the rehabilitation. In our experience, the axillary strings develop during the first postoperative month, and present clinically as tight strings running from the chest wall through the axilla to the elbow or even to the wrist. The first couple of weeks, the strings are very sore, therefore, full range movements are painful for the patients during this period. Even though the pain disappears, the strings usually persist in several months and when present unable full abduction and flexion of the shoulder. Many patients are afraid to overcome the tightening of the strings and the firm attachment of the scar tissue even when the painful side effects of radiotherapy and aseptic lymphangitis pass. They accept the limitations in mobility and try to compensate by using the other arm or by changing work procedures. The application of additional physiotherapy during radiotherapy or shortly after, encourage the patients to use the shoulder in full scale. The extension of the scar tissue and the muscles reduces the firm attachment of the skin to the underlying tissue and reduces the shortening of the muscles. Hence, the shoulder mobility is improved.

Conclusion

Team instructed physiotherapy improves the shoulder function in patients surgically treated for breast cancer. The effect of the treatment is influenced by the type of surgery performed and by the application of radiation therapy in mastectomised patients. Compromised shoulder function is a less frequent and less severe side effect to breast conserving therapy as compared to modified radical mastectomy.

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