Surgery 166 (2019) 686–690

Contents lists available at ScienceDirect

Surgery

journal homepage: www.elsevier.com/locate/surg

Improving the quality of life in breast cancer survivors at risk for lymphedema

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ARTICLE INFO

Article history:
Accepted 21 May 2019
Available online 29 August 2019

ABSTRACT

Background: Certain treatments increase lymphedema risk in breast cancer survivors. The purpose of this study was to determine whether quality of life improved with preoperative teaching by a lymphedema expert.
Methods: Preoperative breast cancer patients were prospectively randomized into intervention group 1 or control group 2. Group 1 had a discussion with the lymphedema expert and at 6 months, in addition to the preoperative surgical discussion and literature given to all. Arm measurements and quality of life evaluation with Functional Assessment of Cancer Therapy-Breast Cancer were completed preoperatively and at intervals for up to 3 years. Lymphedema was verified with a 10% increase in volume or circumference. Univariate and multivariate analysis were performed on data.
Results: There were 119 evaluable patients with no differences between groups 1 and 2. The rate of acute lymphedema was 51.5% (33 of 64) for group 1 and 47.2% (26 of 55) for group 2. Chronic lymphedema presented in 13 patients (9.3% group 1 and 12.7% group 2). Lymphedema was significantly associated with number of lymph nodes resected ($P < .001$). Significant findings in the Functional Assessment of Cancer Therapy-Breast Cancer were at 6 months for all and after diagnosis in lymphedema positive patients.
Conclusion: Structured lymphedema teaching can help to improve quality of life in lymphedema patients.

Introduction

Lymphedema (LE) is the accumulation of protein-rich fluid in the interstitial tissue as a result of disruption in lymphatic flow. It can occur as a primary disease or secondary to an intervention such as surgery, radiation, or injury, or owing to compression of or invasion into the lymphatic drainage by cancer. The incidence of LE of the upper extremities secondary to breast cancer treatment has been reported to be up to 65% and can be underreported, depending on methods of diagnosis or reporting.[1–3] Breast cancer-related lymphedema (BRCL) can result from any breast cancer treatment modality (surgery, radiation, or chemotherapy), alone or in combination, and as a result of an individual's unique healing response to those interventions.[4]

BCRL can have a devastating effect on patients who suffer from it in all aspects of life (emotional, functional, and physical), affecting quality of life (QOL). Early surveillance can reduce the incidence and severity of BCRL.[5] However, the risk of developing BCRL is lifelong, and protective measures to reduce the risk of LE are needed as part of a breast cancer survivor's education. The hypothesis of this study is that structured perioperative training by a LE expert in LE protection and awareness will decrease the negative effect of BCRL on QOL.

Methods

Approval for human subjects research was obtained from the Wayne State University Human Investigation Committee and the Department of Defense, who funded the research. HIPAA compliance was enforced throughout the study. In a prospective study of breast cancer patients undergoing surgery, randomization occurred preoperatively and after informed consent. Patients were randomly assigned to either the intervention arm (group 1, structured training by lymphedema nurse in addition to standard preoperative

Presented at the Central Surgical Association 2019 Annual Meeting, Palm Harbor, FL, March 7-9, 2019.

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https://doi.org/10.1016/j.surg.2019.05.048
0039-6060/

surgical counseling) or the control arm (group 2, standard preoperative counseling). Standard preoperative surgical counseling means preoperative discussion with the surgeon covering all aspects of surgical care, including various options for surgery, immediate postoperative care, and the risks and complications of surgery, which may briefly mention lymphedema with little protective care discussed. In addition, standard care currently includes giving surgical patients a copy of the booklet entitled, *Healing: A Woman's Guide to Recovery After Mastectomy* (R.D. Benedet, 1993). Thus, all patients began with the same baseline information. Subjects assigned to group 1 (intervention group) attended a structured, 45-minute Breast Surgery Rehabilitation class, during or immediately after the first postoperative visit. The format included group lecture and discussion. The patient education manual was provided at the class to ensure consistency of content. The following 5 categories of protective measures were taught: protection from injury, protection from infection, protection from overheating, protection from overexertion, and protection from constriction. In addition, for group 1, the LE expert met with them individually for a refresher at 6 months.

Arm measurements occurred preoperatively and at intervals for up to 3 years. To minimize inter- and intrarater variability, measurements were determined by a trained study research assistant and verified by a professional LE nurse. Various techniques and standards are used to define lymphedema throughout the world.[6] This study was funded for determination of LE by volumetric measurements that correlated with Common Terminology Criteria for Adverse Events v3.0 (https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcaev3.pdf). The volume of a frustum is considered a more accurate representation of the upper extremity. A frustum is a cone with the top cut off so that the upper surface is parallel to the base.[7,8] Preoperative circumferential measurements were made of both upper extremities at 10-cm intervals proximal to the wrist. The finger, hand, and elbow measurements were also included. The volumes for a series of frustums that represent segments of the upper extremity were added together. Subsequent interval limb volumes were compared with preoperative volume measurement on the same side. If weight changed by 4.5 kilograms (increase or decrease), then repeat circumferential measurements were made of both upper limbs and volume recalculated for a new baseline volume. For this study, the definition of lymphedema was greater than 10% change in limb volume, as compared to preoperative measurements.[9] The percentage changes from preoperative measurements were determined as follows: percent change in limb volume = (current volume − preop volume/preop volume) x 100. Evidence of infections, skin changes, condition of nails, feeling of tightness, grip strength, and range of motion of the shoulders bilaterally were recorded. Any changes in volumetric measurement were correlated with feelings of tightness, pain, and numbness. If no volumetric changes existed on the affected side, but the patient was symptomatic, then the patient would be considered to have lymphedema by subjective criteria. Each patient with volume changes that met 10% threshold or was symptomatic was evaluated by the LE study nurse who reported on presence or absence of lymphedema.

A validated QOL measure called Functional Assessment of Cancer Therapy − Breast Cancer (FACT-B) was administered preoperatively and at intervals up to 3 years. The Fact-B is a multidimensional QOL tool, which has been shown to accurately reflect QOL and includes the domains of performance status, physical well-being, functional well-being, social well-being, emotional well-being, and relationship with doctor.[10] It is a 44-item questionnaire that is composed of Fact-General (Fact-G) and a 10-item Breast Cancer Subscale (BCS).[11] This is similar to the Functional Living Index-Cancer used in the preliminary studies, with the advantage of easier administration, brevity, and greater sensitivity to change. The addition of the Breast Cancer Subscale makes it more specific for breast cancer patients. When scoring, there is a total score and subscale scores. The higher the score, the better the QOL. The internal consistency has been reported at 0.90[11] with test−retest reliability of 0.85, indicating a high degree of stability over time. Evidence of construct validity has been reported previously.[11]

The data were analyzed by univariate and multivariate analysis of variance. Exclusion criteria were previous breast cancer treatment, Stage IV breast cancer, existing upper extremity LE, planned or ultimate surgery that would not include axillary surgery, or radiation postoperatively. Two hundred and nine patients consented, with 168 evaluable for determining LE. Patients were excluded from this analysis if they did not complete a FACT-B before starting treatment and after LE diagnosis.

Results

A total of 119 patients were eligible for evaluation after reviewing the randomized, prospectively collected data. There were no differences between the intervention and control groups (group 1 versus group 2) in demographics or clinically (Tables I and II). There was a significant difference in the number of axillary lymph node dissections performed (including those performed as a result of modified radical mastectomy) and those receiving sentinel lymph node biopsy or axillary sampling (Table III). This was especially true in those who were in group 1 who were LE positive ($P = .0186$). There was no significant difference recognized when evaluating type of axillary surgery plus radiation. A total of 72 patients developed LE (60.5%). The majority (81.9%) of the LE positive patients presented acutely (less than 1 year) (Table IV).

FACT-B scores were considered at the intervals mentioned to identify any effects from intervention (Table V). There was near statistical difference in the initial FACT-B surveys, with the intervention group having a slightly higher QOL score. The 6-month set

Table I
Demographic characteristics of group 1 (intervention) and group 2 (control)

	Group 1	Group 2	*P*
n	*64*	*55*	*.9536*
Mean age, y	*52.64*	*52.76*	
Race			.8519
African American	25	17	
Caucasian	31	32	
Hispanic	2	2	
Arab/Chaldean	1	1	
Asian	0	2	
Native American	3	1	
Other	2	0	
Employment status			1
Working	29	22	
Not working	14	11	
Retired	13	9	
Not answered	8	13	
Highest education level			.823
Less than high school completion	8	3	
High school/GED	33	30	
Bachelor's degree	14	11	
Master's degree	5	6	
Doctorate/professional school	1	1	
Not answered	3	4	
Marital status			.7824
Divorced/separated	13	11	
Married/cohabiting	33	23	
Never married	10	6	
Widowed	7	10	
Not answered	1	5	

Table II
Clinical characteristics of group 1 (intervention) and group 2 (control)

	Intervention	Control	*P*
Total N = *119*	*66*[*]	*59*[*]	
Breast cancer stage	Intervention	Control	
0	10	6	.6869
I	18	20	
IIA	17	14	
IIB	12	11	
IIIA	5	5	
IIIB	4	3	
IV	0	0	
Type of breast and axillary surgery			
Mastectomy + axillary surgery	39	34	.8624
Lumpectomy + axillary surgery	21	22	
Lumpectomy only	6	2	
Number of lymph nodes submitted			.8482
≤8 LNs	32	27	
>8 LNs	33	32	
Number of positive lymph nodes			.849
0 LN positive	39	36	
1–3 LN positive	19	16	
≥4 LN positive	7	7	
Radiation therapy			.295
Yes	32	32	
No	34	27	

LN, lymph notes.
[*] 3 patients had bilateral surgeries.

Table III
The final axillary surgeries performed are tabulated on the first 3 rows. The last 2 rows indicate the number of those patients having axillary surgery who also received radiation therapy

	Group 1 LE −	Group 1 LE +	Group 2 LE −	Group 2 LE +	*P*
SLNB	8	4	8	1	.002
AS	3	3	2	6	
ALND[*]	10	33	12	22	
SLNB/AS + Radiation	5	4	5	6	.251
ALND[*] + Radiation	2	16	7	10	

ALND, axillary lymph node dissections; *AS*, axillary sampling; *SLNB*, sentinel lymph node biopsy.
[*] ALND includes modified radical mastectomy.

Table IV
Lymphedema incidence

	Group 1 (n = 64)	Group 2 (n = 55)
Lymphedema positive	39	33
Acute (occurring within 1 y)	33	26
Chronic (occurring after 1 y)	6	7

Table V
Comparison of FACT-B scores between groups and at various intervals. Significant findings include a difference in initial total scores and at 6 mo

Initial FACT-B	Intervention n = 64 115.48		Control n = 55 108.3		*P* .05
	LE + n = 39	LE − n = 25	LE + n = 33	LE − n = 22	
Initial total FACT-B	114.1 ± 17.69	117.64 ± 16.20	110.52 ± 23.96	104.96 ± 24.11	.1772
6 mo	110.57 ± 21.81	124.92 ± 14.53	108.98 ± 23.5	104.5 ± 23.23	.048
12 mo	117.46 ± 48.67	119.62 ± 12.04	118.50 ± 17.51	102.28 ± 24.80	.5
24 mo	114.14 ± 20.96	106 ± 31.40	123.62 ± 15.5	110.39 ± 17.12	.3407
36 mo	101.80 ± 36.51	105.2 ± 8.84	118.91 ± 19.47	105.85 ± 21.26	.483

Table VI
Evaluation of the FACT-B scores initially to the first FACT-B after diagnosis of LE (NS)

	Lymphedema positive only		
	Intervention	Control	*P*
Initial FACT-B	114.10 ± 17.69	110.52 ± 23.96	.3506
FACT-B after Dx	111.37 ± 40.47	120.53 ± 39.47	

NS, not significant; *Dx*, diagnosis.

of scores were significantly different ($P = .048$) in the LE negative patients, with the intervention group having higher scores. To further evaluate effect on QOL, we compared the FACT-B scores in only the LE positive patients, comparing the initial survey to the first one after diagnosis or on the day of diagnosis of LE, which had an average time interval of 12.5 months (Table VI). Although there was no statistical difference in the total FACT-B scores, comparison of the breast (B) subscale portion of FACT-B questions in the same fashion resulted in a difference that approached significance ($P = .054$) (Table VII). There appeared to be a significant relationship between the development of LE and the number of lymph nodes removed, but not necessarily with the number that was positive in this analysis (Table VIII).

Discussion

BCRL can be very impactful on the QOL of breast cancer survivors. Any potential lack of education regarding this possible sequela of their cancer treatment can leave patients frustrated and feeling a lack of care or interest in their well-being[12]. In addition, the required treatments for the management of BCRL becomes more complex with severe disease. Breast care clinicians should familiarize themselves with practices to provide best care and appropriate counseling to aid patients in reducing their risk and improving their awareness and management[13–15].

LE within the first year after surgery is acute LE, which may improve with treatment as lymphatic channels reform. We measured both acute LE and chronic LE (which occurred after the first year or persisted from the first year into subsequent years). In addition, there were more axillary lymph node dissections performed, which has a well-reported association with an increased risk of LE. The patients with LE where managed with decompressive massage and wrapping as prescribed by the LE nurse (either directly or by referral to LE therapist).

Newer methods of treatment include lymph node transfers and other lymphovascular methods, which were not available at the time of this data collection, and could be helpful in cases that do not

Table VII
Comparison of the subscale scores of the FACT-B survey in the lymphedema positive patients. The score difference approaches significance

FACT-B subscale results for lymphedema positive only					
	Intervention (Group 1)		Control (Group 2)		*P*
	Initial	First after Dx	Initial	First after Dx	
Physical	24.28 ± 4.06	22.22 ± 6.36	22.69 ± 7.25	22.68 ± 6.45	.4732
Social	23.59 ± 6.48	23.54 ± 5.44	21.69 ± 8.26	23.82 ± 4.5	.4695
Emotional	18.89 ± 3.8	17.72 ± 4.25	18.81 ± 5.01	20.15 ± 3.04	.1363
Functional	20.62 ± 6.48	21.45 ± 6.68	20.18 ± 7.5	23 ± 4.9	.299
Breast	26.69 ± 4.93	25.05 ± 5.95	22.91 ± 6.8	25.26 ± 6.82	.0544

Dx, diagnosis.

Table VIII
Relationship of lymphedema development to number of lymph nodes submitted and number of lymph nodes positive. There is a significant relationship of lymphedema development to the number of lymph nodes submitted

	P value	Lower 95%	Upper 95%
Lymphedema positive	1.67E−46	1.5675063	1.85897326
# of lymph nodes submitted	1.65E−05	− 0.0464593	− 0.0180168
# of positive lymph nodes	.490434	− 0.0428949	0.02068142

respond to conventional therapies. There were no lymphatic specific surgeries performed.

Body mass index, obesity, axillary surgery, radiation, and certain chemotherapeutic agents all increase the risk for the development of BCRL.[4] Axillary surgery in combination with radiation therapy has been shown to increase the risk of LE development. In particular, it appears that axillary lymph node dissection with radiation of the regional lymph node basins increases the risk significantly compared with sentinel lymph node biopsy or axillary sampling. In a recent meta-analysis, the odds ratio (OR) of developing LE after sentinel lymph node biopsy or axillary sampling plus breast or chest wall radiation with regional nodal irradiation was OR 1.58 (95% CI 0.54–4.66; pooled incidence 5.7 and 4.1%, respectively).[16] However, the OR of developing LE after axillary lymph node dissection with the same scenario was significantly higher (OR 2.74; 95% CI 1.38–5.44; pooled incidence 18.2 and 9.4%, respectively). In our cohort, there did not appear to be a significant difference or correlation (Table III).

Injury and lack of self-care before and after diagnosis can exacerbate the condition. Knowledge of appropriate care and what environmental or personal habits to encourage or avoid is important. Although total FACT-B scores did not show considerable improvement with the perioperative teaching, there was improvement in the breast-related subscales of FACT-B for those in the intervention group, despite having LE. Further evaluation or future investigations could possibly use the Upper Limb Lymphedema-27 to investigate QOL in survivors. It has been shown to be a more reliable survey for BCRL in a systematic review of QOL surveys, although FACT-B has been validated as a useful survey.[1,17]

From the literature, there were some groups that had lower QOL scores reported in 1 systematic review of QOL surveys. Younger women and non-Caucasian women other than had lower scores. That did not bear out with our patients. There was no significant difference by age or ethnicity or race.

Teaching residents and medical students about LE is part of training and contributes to the number of professionals equipped to provide some guidance to patients. At our institution, the multidisciplinary team assesses for LE with each visit and makes timely referrals. There is also a charitable group at the center who assists with supplies for patients who cannot afford them.

The purpose of this study was to evaluate the effect of detailed teaching on QOL in patients with BCRL. There appeared to be a mild effect on the breast specific aspect of QOL in the first 6 months. Going forward, the limitations of this study, which included unavailable, image-based detection methods, such as indocyanine green lymphography, MR lymphangiography, and the conventional lymphoscintigraphy, may be overcome with more funding for these types of methods. QOL may or may not be affected by the method of assessment for LE.

In conclusion, LE after breast cancer treatment can have a devastating effect on patients. However, early intervention and detection and a multidisciplinary approach provides the patient the best opportunity to reduce the impact of BCRL. Dedicated training preoperatively improves some breast specific aspects of QOL.

Funding/Support

(1) Supported by the Department of Defense Breast Cancer Research Program-Idea Grant (#DAMD17-00-1-0495), "Lymphedema Prophylaxis Utilizing Perioperative Education", (Principal Investigator: M. A. Kosir); salary support of research assistants, data manager, study biostatistician, principal investigator, and study nurse and (2) the Department of Surgery, Wayne State University.

Conflict of interest/Disclosure

None of the authors have a conflict of interest.

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Discussion

Dr Zahraa Al-Hilli (Cleveland, OH): Thank you. I'd like to thank the Association for the privilege of discussing the paper, and I congratulate the authors on their study.

There has been an increased focus in recent years on the diagnosis, management, education, and prevention of breast cancer–related lymphedema. Ideally, recommendations are for preoperative testing, prevention strategies, and ongoing surveillance as identification of subclinical and early stage lymphedema offers patients the greatest opportunity for treatment and resolution.

I have a few questions for the authors.

First, please elaborate on the choice of quality-of-life survey, the intervention, and the techniques used for the assessment and surveillance of lymphedema. Who performed the assessment and follow-up?

Second, multimodality treatment has been shown to be a risk factor for breast cancer–related lymphedema. Can you comment on the receipt of radiation in relation to axillary surgery type?

Third, the rate of lymphedema seems high at 60% at a median of 12.5 months. What grades of lymphedema were documented? How were patients managed and what were their outcomes? Are there any preventive strategies that are performed?

Finally, how has this work impacted your work flow and practice at your institution? I presume this is part of a larger study. What are your future directions for this work?

Dr Keiva Bland: Thank you so much. The quality-of-life survey that was chosen, the FACT-B was chosen because it was more comprehensive for the entire cancer experience and especially for breast, and that was what was available at the time, and it was more easily administered versus some of the other ones which were not as comprehensive, and they were a little bit more involved such as the MSOF and the Cares studies. They were a little bit more specific for other facets of the experience but not the overall global experience. So that's why that one was chosen.

Since that time, there's been the ULL, which is the Upper Limb Lymphedema questionnaire which I think would be more appropriate and probably can be used for future studies, but it was a well-validated quality-of-life survey that was picked.

Regarding the modalities, I had in the database the types of surgeries and the radiation that the patients received, but I did not look in detail for this particular study. It was just grouped according to whether they had surgery versus not or whether they had radiation versus not.

The data that's used actually is quite old, and so it was brought out because we are looking into future ways that we can improve lymphedema. We had a change of the guard in terms of our lymphedema specialist, to go back to your first question, who was the person who did all of the measurements for the patients. This was quite old data. The data came from 1999 to 2005. It was before the sentinel lymph node biopsy was being done routinely, and it was still in the experimental phase, and there were a variety of surgeries that were used for the axilla. There was the sentinel lymph node biopsy in some people. Axillary lymph node sampling by one surgeon who had trained in Europe, and then the axillary lymph node dissection. So the amount of axillary surgery did vary between some of the patients. That also explains probably why the lymphedema rate was so high, considering that the study was all before sentinel lymph node biopsy was regularly used.

Finally, we're not doing any special interventions like surgeries or anything like that to try to reduce the lymphedema risk, but I think there's room for us to learn that and to use as part of our treatment in the future.

With the new person coming on managing the lymphedema patients, there's plenty of opportunity for us to revisit this and then develop a more current way of evaluating the patients with the current treatment techniques that we have.

Dr William Gourash (Pittsburgh, PA): Your intervention was a teaching intervention essentially. Did you do any measurement of what the people actually retained or got out of it?

Dr Keiva Bland: That is a good question. Based on information I have, no. But that would be a great way to be able to make sure that they retained it. There was mention of it, but I don't know if there was an actual documentation or a percentage of retention that was documented. Thank you.

Dr Steven De Jong (Maywood, IL): As the study data was collected some time ago, is there anything you have done differently at your institution to avoid lymph node dissections in these patients, especially with the new data that's coming out about the treatment of breast cancer?

Dr Keiva Bland: We definitely have adopted the Z11 approach of not doing axillary lymph node dissections in those patients that qualify with the smaller tumors and two or fewer lymph nodes being positive with no extranodal extension. However, we have tried to extrapolate that based on some of the Z1071 data to try to apply to some of our mastectomy patients as well for those who have very favorable lymph node positive characteristics, very small mets, just a single lymph node, those types of things, again to decrease the amount of people that are getting surgeries.

I do think there are other methods we can try, but I have to be honest in saying that we've not been diligent as a group to try to investigate some of the newer modalities to try to reduce that risk. I think this is a good jumping off point to be able to see if we can compare newer modalities to what we did before and give our patients better outcomes.