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Evaluation of Axillary Lymphadenectomy Without Axillary Drainage for Patients Undergoing Breast-Conserving Therapy

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Background: The routine use of drainage after axillary node dissection in patients undergoing breast-conserving therapy (BCT) is being questioned. To determine the value of routine drainage, we evaluated the postoperative course of patients with primary breast carcinoma who underwent axillary dissection with or without axillary drainage.

Methods: A retrospective review of 69 patients prompted a prospective randomized trial of 46 patients undergoing BCT at our tertiary cancer center. Variables studied were age, treatment (drain or no drain), number and tumor status of excised lymph nodes, size of primary tumor, duration of drainage or aspiration, number and volume of aspirations, number of office visits, incidence of complications and degree of pain, change in arm or forearm circumference, and body mass index (BMI). Data from prospective and retrospective studies were pooled for analysis.

Results: Of 115 patients, 72 were treated with a drain (Drain group) and 43 were not (No-drain group). Overall there was no difference in the number or tumor status of excised nodes, the size of the primary tumor, or the incidence of complications between the two groups. Aspiration was required in 50% of the No-drain patients and 8.3% of the Drain patients. The incidence of drain placement or replacement postoperatively was 9.3% for the No-drain patients and 4.2% for the Drain patients. The No-drain patients had more office visits (5.1 ± 0.4 vs. 3.6 ± 0.1; $P = .0002$) and a longer interval between operation and last aspiration or drain removal (16.2 ± 1.4 days vs. 11.3 ± 0.6 days; $P = .0040$). Findings were similar in the subgroup of 46 prospectively studied patients, who included 24 Drain patients and 22 No-drain patients. In this group, pain evaluation using a scale of 0 to 10 showed a mean rating of 4.2 ± 2.6 in Drain patients and 2.7 ± 0.4 in No-drain patients ($P = .0062$).

Conclusions: Axillary node dissection can be managed with or without a drain. More office visits but less pain can be expected if a drain is not used.

Key Words: Breast cancer—Conservative therapy—Axillary drain—Lymphadenectomy—Seroma.

Breast-conserving therapy (BCT) for women with primary breast carcinoma has become commonplace since the realization that lumpectomy with axillary node dissection and radiation therapy yields survival rates equivalent to those of mastectomy.[1] Because axillary dissection is invariably followed by serous drainage and seroma formation, axillary drainage is undertaken to minimize seroma formation, on the premise that seroma represents a good culture medium and therefore predisposes the patient to infection.[2,3] Although axillary drainage has been the standard of care after mastectomy and axillary lymph node dissection, placement of an axillary drain can cause considerable discomfort. The drain can cause pain by irritating tissue as it moves with normal physical activity, and the external portion of the drain can interfere with clothing, daily activities, and body image. Recent studies have suggested that axillary lymphadenectomy can be performed safely without closed suctioned drainage.[4,5] Our study was undertaken to determine what can be expected if the axilla is not

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drained, and to examine the clinical benefits and complications of drainage versus no drainage.

PATIENTS AND METHODS

This study had prospective and retrospective components, which were analyzed separately and in combination. The prospective component was a randomized investigation of women undergoing treatment for stage I or stage II breast cancer at the John Wayne Cancer Institute between May 1995 and August 1996. The retrospective component was a review of equivalent patients treated between June 1994 and May 1995.

The following parameters were recorded for all patients: age, height and weight; number and tumor status of excised lymph nodes; size of primary tumor; incidence of infection, hematoma, and lymphedema; duration of axillary drainage; duration of aspiration (time from operation to last aspiration); postoperative drain placement; number and volume of aspirations; and number of postoperative visits. Each patient's body mass index (BMI) was calculated as weight (kg) divided by height (m^2). In addition, patients in the prospective study underwent evaluation of pain and ipsilateral arm or forearm circumference at four time points: postoperative (days 1 to 6); week 1 (days 7 to 13); week 2 (days 14 to 20), and week 3 (days 21 to 27). Circumference in centimeters was measured using a tape measure at the maximum circumference. Pain was graded subjectively on a scale from zero to 10, with zero being no pain and 10 being the worst pain ever experienced.

All procedures were done by one senior surgeon (A.E.G.). Axillary dissection of levels I and II and a portion of level III was performed through a transverse incision. A complete level III dissection was performed if the axillary nodes contained grossly palpable disease. The intercostal–brachial nerve was preserved unless there was gross tumor in the axilla. At the completion of the dissection, patients in the prospective study were intraoperatively randomized to Drain or No-drain groups. Patients in the Drain group received a Jackson-Pratt closed-suction drain, placed through a separate incision and secured with sutures. All axillary incisions were closed with subcutaneous absorbable approximation and skin staples for the skin incision. Drains remained in place until 24-hour output was less than 30 mL. Fluid accumulation or seromas were aspirated at outpatient visits if the patient was symptomatic. Aspirations were performed with an 18-gauge needle using sterile technique. No prophylactic antibiotics were given unless preexisting conditions required antibiotic coverage for invasive procedures.

Statistical Analyses

The two-sample *t*-test was used to analyze any differences between prospective and retrospectively studied patients with respect to the number and tumor status of excised lymph nodes, the number and volume of aspirations, the duration of aspiration or drainage, and the number of office visits. Fisher's exact test was used to analyze any differences between the two groups in terms of primary tumor size, infection, hematoma, and lymphedema. This test also was used to analyze the correlation between number of aspirations and rate of infection. The Wilcoxon rank sums test was used to analyze the association between duration of aspiration and rate of infection.

Statistical analysis was then performed to identify differences between treatment groups (Drain vs. No-drain). The two-sample *t*-test was used to compare age, the number and tumor status of excised nodes, postoperative pain and arm or forearm circumference through week 1, and number of office visits. The *t*-test also was used to compare the rates of infection and duration of drainage. Fisher's exact test was used to compare rates of infection, hematoma formation, and primary tumor size, and to analyze the effect of the number of aspirations on the rate of infection. The Spearman correlation test looked for a correlation between BMI and duration of drainage (Drain group) or duration of aspiration (No-drain group). The Wilcoxon rank-sums test compared differences in pain rating and arm or forearm circumference during weeks 2 and 3. The Wilcoxon rank-sums test also was used to analyze the association between BMI and infection and between duration of drainage and infection.

RESULTS

There was no statistically significant difference between prospectively and retrospectively studied groups. Of the 115 patients studied, 72 were treated with closed suction drainage and 43 were not. There was no difference between Drain and No-drain groups with respect to number of excised lymph nodes (mean 19.8 ± 9.4 vs. 17.8 ± 6.3, respectively; $P = .1955$); number of tumor-positive lymph nodes (mean 2.2 ± 5.6 and 0.9 ± 2.5, respectively; $P = .0892$); or size of the primary tumor ($P = .157$; Table 1).

Half of the No-drain patients required at least one aspiration. By comparison, only 8.3% of the Drain patients required at least one aspiration after drain removal. Among patients undergoing aspiration, there was no treatment-related difference in aspirate volume (85.8 ± 25.0 mL for Drain patients vs. 109.4 ± 10.0 mL for No-drain patients; $P = .2975$), but the Drain group re-

TABLE 1. *Size of primary tumor in 115 prospectively and retrospectively studied patients*

Tumor size	Drain group	No-drain group
T1a	2	2
T1b	9	11
T1c	32	15
T2	24	15
T3	5	0

quired significantly fewer aspirations (mean 1.5 vs. 2.6; $P = .0277$).

The duration of drainage and the duration of any aspiration performed after drain removal in Drain patients was compared with the duration of aspiration in No-drain patients. Drains placed postoperatively were not included in this analysis. Duration of drainage was unknown in 13 Drain patients; the mean for the remaining 59 Drain patients and the 22 No-drain patients was 11.3 ± 0.6 and 16.2 ± 1.4 days, respectively ($P = .0040$). Postoperative drains were replaced in 3 (4.2%) Drain patients and were placed in 4 (9.3%) No-drain patients.

There was no difference in infection rates between the Drain and No-drain groups ($P = .708$). For those patients who required aspiration, the incidence of infection as a function of the number of aspirations was examined; there was no correlation ($P = .595$; Table 2). For those patients with a drain, the incidence of infection as a function of duration of drainage was examined; there was no correlation ($P = .518$; see Table 2). There was no difference in the incidence of hematoma ($P = .629$) or lymphedema ($P = 1.0$) between Drain and No-drain groups.

The number of office visits was significantly higher for the 43 No-drain patients (5.1 ± 0.4 vs. 3.6 ± 0.1; $P = .0002$).

Prospective Study

Of the 46 prospectively studied patients, 24 were in the Drain group. Duration of drainage was unavailable for two patients whose date of drain removal was not recorded. There was no difference between Drain and No-drain groups with respect to age (overall median 58.2 and 59.6 years, respectively) or number of nodes removed (overall median 15.3 and 15.7, respectively). The number of tumor-positive lymph nodes was 3.9 ± 8.6 for Drain patients and 1.4 ± 3.4 for No-drain patients, not a significant difference ($P = .1984$). There was also no significant difference in the distribution of primary tumor size between the two groups ($P = .514$); most patients in each group had T1c or T2 tumors.

Sixty-four percent of the No-drain patients required at least one aspiration (mean 2.7 ± 1.0); none of the Drain patients required aspiration. Mean aspirate volume was 101.1 ± 32.2 mL. The mean duration of drainage in 23 Drain patients was significantly less than the mean duration of aspiration in the 14 No-drain patients requiring aspiration (9.5 ± 0.6 vs. 15.6 ± 1.8 days; $P = .0067$). One (4.2%) of the Drain patients had a drain replaced after drain removal, and two (9.0%) of the No-drain patients were eventually managed with a drain.

TABLE 2. *Overall incidence of infection according to drain placement, number of aspirations, and duration of drainage*

	Infection	No infection
No-drain group (n = 43)	2	41
Drain group (n = 72)	6*	66
Number of aspirations		
1	2	6
2	0	7
3	1	7
4	0	5
Mean duration of drainage	11.7 ± 4.6 days (n = 6)	10.6 ± 3.4 days (n = 51)

* All infections in the Drain group consisted of erythema around the drain site, which required treatment with antibiotics.

Only two patients in each group developed infection. In the No-drain group, there was no correlation between number of aspirations and rate of infection ($P = .780$; Table 3). In the Drain group, there was no correlation between duration of drainage and rate of infection ($P = .1457$; see Table 3). There was no difference in the incidence of hematoma between Drain and No-drain groups ($P = 1.0$). No patients developed lymphedema, and there was no difference in arm circumference between the two groups. The mean number of office visits was significantly higher for the 22 No-drain patients (5.6 ± 2.5) than for the 24 Drain patients (3.5 ± 1.0; $P = .0009$).

BMI had no correlation with the duration of drainage ($P = .6034$), the duration of aspiration ($P = .0681$), or the incidence of infection in Drain patients ($P = .6182$) and No-drain patients ($P = .2067$). No-drain patients had a 1.1-cm greater arm or forearm circumference change postoperatively than did the Drain patients (Table 4), but no other circumference differences were signifi-

TABLE 3. *Incidence of infection in prospectively studied patients according to number of aspirations (No-drain group) and duration of drainage (Drain group)*

	Infection	No infection
Mean duration of drainage	6.5 ± 1 days	9.8 ± 3 days
Number of aspirations		
1	1	2
2	0	2
3	1	4
4	0	4

TABLE 4. *Circumference measurements in prospectively studied patients*

Postoperative week	Drain group*	No-drain group*	*P* value
Arm circumference			
0	−.36 cm, or .031% (16)	0.73 cm, or .031% (16)	.0093
1	7.7 cm, or .327% (10)	−0.04 cm, or .0006% (12)	.2729
2	−1.3 cm, or .048% (3)	0.29 cm, or .012% (7)	.0641
3	−0.46 cm, or .019% (6)	0.29 cm, or .01% (7)	.2208
Forearm circumference			
0	−.22 cm, or .011% (16)	0.43 cm, or .02% (16)	.0609
1	−0.56 cm, or .025% (10)	.58 cm, or .03% (12)	.2007
2	0.5 cm, or .023% (3)	−0.43 cm, or .02% (7)	.1313
3	−0.92 cm, or .043% (6)	−1.21 cm, or .01% (7)	.3113

* Number of patients is shown in parentheses.

cant. Likewise, the pain measurements were significantly different between the two groups only in the postoperative period (Table 5). Pain was more severe in the Drain patients (mean rating of 4.2 ± 2.6 vs. 2.7 ± 0.4; P = .0062).

DISCUSSION

Seroma formation is much more likely if the axilla is not drained after node dissection. Some authors believe that seromas interfere with healing, cause infection and lymphedema, and delay further treatment.[3,6] A study of the effect of 1-day drainage versus no drainage found a higher incidence of infection without drainage but no difference in the incidence of hematoma, lymphedema, wound dehiscence, or frozen shoulder.[7] Among the several strategies devised to decrease the incidence of seroma are the use of multiple drains in the axilla and closure of the axillary fossa dead space with tacking sutures.[6,8] However, it may not be prudent to extrapolate experiences with mastectomy to BCT, because mastectomy has a higher incidence of wound complications associated with seroma formation and epidermolysis.[2]

Several factors have been implicated in seroma formation. One study reported that the total amount of drainage increased with a large number of tumor-positive lymph nodes and no previous surgical biopsy, but was not affected by age, weight, height, and level of axillary dissection.[6] Another study suggested that the total amount of drainage reflected the magnitude of lymphatic interruption.[3] There was no reported difference in wound drainage associated with immediate versus delayed shoulder exercises.[9]

TABLE 5. *Pain measurements in prospectively studied patients*

Postoperative week	Drain group*	No-drain group*	*P* value
0	4.2 ± 2.6 (18)	2.0 ± 1.6 (16)	.0062
1	3.5 ± 2.8 (11)	4.0 ± 5.8 (12)	.7596
2	4.3 ± 4.5 (3)	3.4 ± 3.1 (7)	.8181
3	1.0 ± 1.7 (6)	0.5 ± 0.5 (6)	.9282

* Mean pain rating (±SE) on a scale of 1 to 10. Number of patients is shown in parentheses.

Our study found that postoperative treatment was prolonged without closed suction drainage. However, this difference applied only to patients who required aspiration and was only about 6 days, which is not an unreasonable delay before starting further treatment. Our overall infection rate was quite low and not significantly different between the two treatment groups. All infections in the Drain group were associated with cellulitis around the drain site that, in the judgment of the senior surgeon, required antibiotics.

The important differences between Drain and No-drain groups were treatment time, number of office visits, pain in the immediate postoperative period, and arm circumference in the immediate postoperative period. The higher number of office visits in the No-drain group reflected a more frequent need for aspiration. The more pronounced pain in the Drain group reflected movement of the drain inside the wound underneath the flap. This difference vanished after the postoperative period, corresponding to removal of most of the drains. Changes in arm (but not forearm) circumference were greater in No-drain patients, but only during the postoperative period. Increased swelling in the nondrained arm did not appear to be permanent or long-lasting.

Results of this study indicate that axillary node dissection can be performed safely without closed suction drainage. It may be the preferred choice of women who are concerned about body image and the inconvenience of a drain, and who do not mind more frequent office visits and a slightly longer time for resolution of their wound.

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