



Role of Capitonage and Fibrin Sealant in Reducing Seroma Formation after Breast Conservation Surgery: A Randomized Clinical Trial

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ARTICLE INFO

Received:
3 May 2014
Revised:
20 May 2014
Accepted:
25 Jun 2014

Keywords:
Seroma,
capitonage,
breast Conservative
therapy

ABSTRACT

Background: Seroma formation is a common complication after breast cancer surgery. Several techniques such as tube drainage, fibrin sealant and suturing have been employed to prevent or reduce seroma formation. Capitonage, a suturing method widely used following hydatid cyst removal, has been used after breast surgery in limited studies. Our aim was to compare the effectiveness of tube drainage, fibrin sealant and capitonage to prevent early complications.

Methods: Eligible patients with breast cancer undergoing breast conserving surgery were enrolled and randomized into three different groups (tube drainage, capitonage, and capitonage plus fibrin sealant). Patients were revisited on 5th, 12th and 19th days after surgery and examined for possible complications.

Results: A total of 90 patients were enrolled. In both tube drainage and capitonage groups one patient developed seroma. However, no participants from capitonage plus fibrin sealant group experienced the complication. Five patients developed surgical site infection, and three of them underwent tube drainage. Three patients who were treated with capitonage plus fibrin sealant protocol developed limited skin necrosis.

Conclusions: Based on our observations, the capitonage alone or in combination with fibrin sealant yields no significant differences in frequency of complications after breast cancer surgery such as hematoma, seroma and surgical site infection.

Introduction

Despite major improvements in breast cancer

surgery, several complications are still encountered. Seroma, an abnormal collection of serosal fluid in the dead space of skin or axillary fossa, is known as a common complication in up to 81% of patients.¹⁻⁷ Seroma formation can further lead to incisional infection, delayed healing, hematoma, skin flap necrosis, wound dehiscence and lymphedema.^{8,9}

Different methods are currently used to prevent

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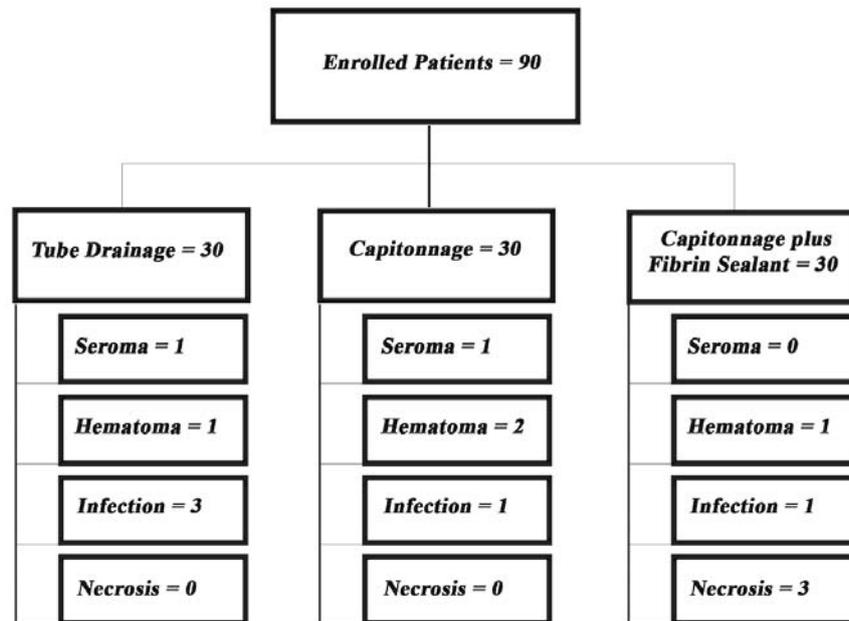


Figure 1. Numbers of patients with early complications in each group.

seroma formation such as pressure dressing, placement of closed suction drains, fibrin sealant and surgical techniques to reduce dead space left after surgery.¹⁰ Closed suction drainage is widely used following breast cancer surgery to avoid seroma formation by obliterating the dead space.¹¹ Some authors have suggested that to reduce treatment costs by decreasing the length of hospitalization patients can be discharged one or two days earlier after surgery with the drain still in place.^{12,13} With insitu drains, the rate of surgical site infection is high and the patients discharged early after surgery with the drain are concerned about position in bed, dressing themselves, fatigue and pain.^{14,15}

Recently, various studies investigated the effectiveness of fibrin sealant in preventing seroma formation,¹⁶ in which decreases fluid infiltration and seroma formation⁸ through producing proper coverage over blood and lymphatic vessels. Studies have provided different results for fibrin sealant which are inconsistent to some extent.¹⁷⁻²² Various surgical techniques are also used to prevent or reduce seroma after breast surgery by obliterating axillary dead space.¹⁰ These techniques including flap to fascia or flap to muscle sutures, subcutaneous, mattress type, and buttress sutures can lead to significant reduction in seroma formation.^{10,23,24} Moreover, closed suction drainage might not be necessary in surgical approach.^{25,26} Capitonnage, a suturing method widely used following hydatid cyst removal, is aimed to approximate the opposing surfaces of a cavity but rarely has been employed after breast surgery.²⁷

The current study was conducted to identify alternatives for closed suction drainage with lower or at least equal frequency of seroma formation

and without the disadvantages of tube drainage. To the best of our knowledge, this was the first study to compare the effectiveness of capitonnage alone or in combination with fibrin sealant with conventional methods to prevent early complications of axillary lymph node dissection (ALND) in patients with breast cancer undergoing breast conserving surgery (BCS) and ALND.

Methods

Study design

The study was an open-label randomized clinical trial. Patients were assigned into three groups using block randomization: tube drainage (T), capitonnage (C), capitonnage plus fibrin sealant (CF). Due to nature of the study and the techniques used in the study groups, blinding was not applicable.

The trial was conducted in a referral teaching hospital between March 2010 and February 2012 in Tehran, Iran. Study protocol was in accordance with Declaration of Helsinki for investigation on human subjects and was approved by Ethical Committee of Tehran University of Medical Sciences. Written informed consent was obtained from all participants prior to enrollment.

Study population

The population included female patients aged 18 years and above, with histopathologically confirmed diagnosis of breast cancer candidate for BCS and ALND. Subjects were excluded, if they had any of the following conditions; history of bovine protein intolerance, indications of mastectomy, those who had axillary dissection through breast incision, and pregnancy at the time of intervention.

**Table 1.** Baseline characteristics of study population with respect to three arms of trial.

	Tube drainage	Capitonnage	Capitonnage+ fibrin sealant	P-value
Age	47.3 ± 12.1	50.0 ± 10.4	43.8 ± 10.3	0.108
Weight	69.7 ± 10.1	72.9 ± 11.6	70.0 ± 9.8	0.383
Height	163.1 ± 6.2	161.0 ± 4.9	162.2 ± 4.8	0.632
BMI	26.3 ± 4.4	28.2 ± 5.1	26.7 ± 4.2	0.229
Breast Size	79.6 ± 6.0	81.8 ± 7.1	80.1 ± 5.1	0.460
Cup Size				
A	3 (10%)	1 (3.3%)	1 (3.3%)	0.341
B	21 (70%)	18 (60.0%)	16 (53.3%)	
C	5 (16.7%)	10 (33.3%)	13 (43.3%)	
D	1 (3.3%)	1 (3.3%)	0 (0.0%)	

Table 2. Surgical and histopathological information of patients in study groups.

	Tube drainage	Capitonnage	Capitonnage+ fibrin sealant	P-value
Tumor Size (mm)	30.0 ± 18.3	32.3 ± 14.5	29.0 ± 14.6	0.709
Tumor Size Categories				
T1	8 (26.6%)	1 (3.3%)	9 (30.0%)	0.094
T2	20 (66.7%)	26 (86.7%)	19 (63.3%)	
T3	20 (66.7%)	3 (10%)	2 (6.7%)	
Excised LNs	12.3 ± 4.3	12.9 ± 5.4	13.0 ± 5.4	0.842
Involved LNs	3.9 ± 2.8	4.3 ± 4.3	3.0 ± 3.1	0.344
Tumor Location				
UOQ	13 (43.3%)	12 (40.0%)	13 (43.3%)	0.862
UIQ	4 (13.3%)	4 (13.3%)	8 (26.7%)	
LOQ	3 (10.0%)	2 (6.7%)	1 (3.3%)	
LIQ	1 (3.3%)	1 (3.3%)	1 (3.3%)	
Central	9 (30.0%)	11 (36.7%)	7 (23.3%)	

Treatment protocol

All patients received a single dose broad-spectrum antibiotic for wound infection prophylaxis. After performing BCS and dissection of level 1 and 2 axillary lymph nodes, three different methods were applied before closure of surgical site.

For the first group, a hemovac drain was placed in the surgical site. Tubes were removed after the fifth day of surgery if the total drain output was less than 30 ml/24 h. Capitonnage technique was performed for the second group to approximate claviclepectoral fascia containing the fat pad of the anterior surface of subscapularis muscle (using 2-0 Vicryl suture). For the last study group, in addition to capitonnage technique, a fibrin sealant (ChitoTech Inc., Alborz, Iran) was applied to axillary fossa before tying the sutures.

Follow-up and study endpoint

All patients were advised to mobilize the ipsilateral arm within a few hours after surgery. The patients were visited on 5th, 12th and 19th days after surgery and assessed for possible complications. The study end point was the occurrence of early postoperative complications such as seroma, hematoma, skin necrosis and infection.

Statistical analysis

Analyses were performed using SPSS software version 21 (IBM Inc., NY, USA). Variables were compared using Chi square and Analysis of Variance (ANOVA). The criterion level for statistical significance was held at 0.05.

Results

A total of 90 patients with invasive ductal carcinoma were enrolled in the study with mean age of 46.9±11.0 years. The most common size and site of tumors were T2 (71.1%) and upper outer quadrant of breast (42.2%), respectively. The total number of axillary lymph nodes that were excised during surgery was 12.7±5.0 (ranging from 3 to 26), whilst the mean number of positive lymph node was 3.7±3.4 (ranging from 0 to 16). The result of sentinel lymph node biopsy was only positive in 16 (17.8%) of patients. Comparison of baseline demographic and histopathological characteristics of patients among three study groups showed no significant differences (Tables 1 and 2).

Numbers of patients with early complications in each group are shown in Figure 1. One month after surgery, only two patients experienced seroma; one subject in T group and the other in C group (P= 0.6). A total of five patients developed surgical site infection, three of them underwent tube drainage and one patient in each C and CF group had the

**Table 1.** Baseline characteristics of study population with respect to three arms of trial.

	Tube drainage	Capitonnage	Capitonnage+ fibrin sealant	P-value	Total
No complication	25 (83)	26 (86.7)	25 (83.3)	0.570	76 (84.4)
Seroma	1 (3.3)	1 (3.3)	0 (0)	0.459	2 (2.2)
Hematoma	1 (3.3)	2 (6.7)	1 (3.3)	0.484	4 (4.4)
Infection	3 (10)	1 (3.3)	1 (3.3)	0.332	5 (5.6)
Flap necrosis	0 (0)	0 (0)	3 (10)	0.209	3 (3.3)

mentioned complication ($P=0.429$). The frequency of hematoma formation did not differ significantly among study groups ($P=0.770$). Two patients in C group and one participant in each CF and T group were diagnosed with hematoma. Flap necrosis was the only complication with a considerable different frequency among the three study groups. While the frequency of this complication was 0 in C and T arms, 3 (10%) of CF patients suffered from flap necrosis. In these three patients, flap necrosis was not extensive and resolved uneventfully with conservative management. Considering the fact that neither of demographic nor histopathological variables had significant association with skin necrosis and that the treatment group was the only associated variable, no multivariate analysis was performed.

Discussion

Seroma formation is a common problem after breast cancer surgery.¹¹ Excessive accumulation of serous fluid requires repeated aspirations that cause patients' discomfort and lead to longer hospitalization.²⁸ Although several surgical techniques have been identified previously to prevent seroma formation, this was the first time that the effectiveness of capitonnage technique was compared to the conventional treatment.

We found no significant differences between the study groups comparing the frequency of hematoma or seroma formation and surgical site infection. The only outcome that differed significantly among the three arms of trial was the development of small flap necrosis which had a higher frequency in patients who underwent capitonnage in combination with fibrin sealant. This finding might be due to the additive effects of sutures (capitonnage) and fibrin sealant in reducing blood flow to skin flap. Nevertheless, this needs to be assessed in further studies with larger sample sizes.

Previous studies have evaluated the effectiveness of fibrin sealant in comparison with suction drainage and showed that patients in the former group had lower incidence of seroma formation and pain scores after surgery.²² Johnson *et al* reported that fibrin sealant leads to non significant decrease in seroma formation; but they postulated that due to higher cost and difficulties of this technique, it has no advantages over conventional treatment.¹⁸ Our

study failed to show that fibrin sealant has significant advantage over closed suction drainage in preventing seroma formation.

Multiple studies have reported the efficacy of suturing the skin flap to underlying muscles to prevent seroma formation.^{27, 29, 30} Some authors used this suturing in combination with suction drainage and claimed that the amount of suctioned fluid and frequency of seroma formation was reduced as a result of eliminating axillary dead space following surgery.^{29, 30} Contrary to previous studies that used surgical techniques in mastectomy site, we employed capitonnage method to eliminate axillary dead space. In the current study, frequencies of complications did not differ significantly between patients who underwent the surgical closure of dead space (capitonnage) and classic closed suction drainage.

Considering the low frequency of observed outcomes, the relative small number of enrolled patients was one of the most important limitations of the current trial. Prior to recommending as a routine surgical technique, further studies with larger sample sizes are required to prove the effectiveness of this method.

Based on our observations, it seems that capitonnage alone or in combination with fibrin sealant does not lead to significant differences in frequency of complications after breast cancer surgery such as hematoma, seroma and surgical site infection. According to these results, capitonnage of axillary fossa with or without fibrin sealant after ALND can be considered as an alternative for classical tube drainage. Assessing patients' satisfaction and defining appropriate criteria for classifying those who benefit more from each of the mentioned methods can help clinicians to choose the most appropriate treatment option.

Conflict of interests

The authors declare no conflict of interest.

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