

https://doi.org/10.21608/zumj.2025.427241.4220

Volume 31, Issue 12, December. 2025

Manuscript ID:ZUMJ-2509-4220 DOI:10.21608/zumj.2025.427241.4220

ORIGINAL ARTICLE

Assessment of Ethyl Alcohol as Sclerosing Agent in Treatment of Post Mastectomy Seroma

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 Submit Date
 26-09-2025

 Accept Date
 13-10-2025

 Modify Date
 17-10-2025

ABSTRACT

Background: Post-mastectomy seroma is a common complication characterized by fluid accumulation at the surgical site, which can delay recovery and increase the risk of infection. Despite various treatment modalities, management remains challenging, especially for persistent seromas. Ethyl alcohol sclerotherapy has emerged as a minimally invasive option that induces fibrosis and obliteration of the seroma cavity, but its efficacy and safety require further evaluation. This study aimed to assess the role of ethyl alcohol as a sclerosing agent in the management of post-mastectomy seroma

Methods: This prospective interventional study conducted on 39 patients who developed seroma after mastectomy underwent ethanol sclerotherapy. A single session of 70% ethanol was instilled for 15–30 minutes, with repeat sessions for persistent collections. Outcomes evaluated included first-session success rate, number of sessions, total ethanol volume, complications, and recurrence.

Results: Mean patient age was 53.9±2.3 years; 69.2% were housewives and 43.6% had comorbidities. First-session resolution occurred in 61.5% of cases. Success was not influenced by age, occupation, marital status, comorbidity, leukocyte count, or albumin. Tumor grade and histology were significant predictors: T1–T2 lesions and lobular carcinoma had 100% success versus 0% in T3 and 42.3% in invasive ductal carcinoma (p<0.0001). Failures required more sessions and higher ethanol volumes (median 400cc vs. 100cc; p<0.0001). Complications were infrequent (infection 10.3%, no flap necrosis), and recurrence occurred in 15.4%, correlating with lower albumin, lower leukocyte count, higher ethanol volume, and T3 grade (all p <0.05).

Conclusion: Ethanol sclerotherapy is a safe, effective first-line treatment for post-mastectomy seromas in selected patients, particularly those with smaller cavities (T1–T2) and lobular histology.

Keywords: Post-Mastectomy Seroma; Ethanol sclerotherapy; Sclerosing agent.

.INTRODUCTION

Breast cancer is the leading cause of cancer-related deaths among women globally, with greater incidence rates in wealthy nations and lower but recently rising rates in developing nations and Japan [1]. In Egypt, breast cancer is the most prevalent cancer among females, accounting for 33% of all female cancers. Surgery has historically been the primary treatment for breast cancer; however, advancements in cancer therapies

such as radiotherapy, hormonal therapy, and chemotherapy have improved management of advanced cases.[2].

With incidence rates between 15% and 81%, seroma is the most common postoperative complication after breast cancer surgery. It commonly occurs after mastectomy and is increasingly regarded as an expected surgical side effect rather than a complication, although not all patients exhibit clinical symptoms[3]. Seroma is defined as a

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collection of serous fluid accumulating under skin flaps post-mastectomy or in the axillary dead space following axillary dissection, resulting from lymphatic disruption and capillary bed oozing[4].

Despite not being fatal, seroma can result in serious complications, such as infection that can cause flap necrosis, wound dehiscence, a higher risk of sepsis, a longer recovery period, more doctor visits, and a delay in the start of adjuvant medication [5].

AIM OF THE WORK:

The aim of this study is to assess the role of ethyl alcohol as a sclerosing agent in the management of post-mastectomy seroma.

METHODS

This interventional prospective clinical study was conducted at the General Surgery Department, Faculty of Medicine, Zagazig University Hospitals, between July 2024 and January 2025. The study included 39 patients who developed post-mastectomy seroma following breast cancer surgery. Eligible participants were female patients aged 18 years or older who had undergone mastectomy and developed seroma formation after removal of suction drain. All patients were medically fit for the sclerotherapy procedure and had no contraindications to local anesthesia. Exclusion criteria comprised patient refusal to participate, known ethyl alcohol allergy, and patients who were lost during the follow-up period. Approval was obtained from the research ethical committee and the institutional review board (IRB# 379/26-May-2024) of the Faculty of Medicine at Zagazig University. Each patient gave their informed consent to take part in the research. The 1964 Declaration of Helsinki and the World Medical Association's Code of Ethics for research with human beings were followed in the conduct of the study.

Sample size calculation was based on the frequency of post-mastectomy seroma attending Zagazig surgery outpatient clinic, 1.

estimated at 48 patients within 6 months, with a reported success rate of seroma ablation of 15% according to Smith et al. [6]. The total sample size of 39 patients was calculated using OpenEpi-Info software with 95% confidence interval.

Preoperative data were collected for all patients and included demographic characteristics such as age, marital status, and special habits of medical and surgical importance. Clinical history encompassed analysis of chief complaints including pain or discharge, detailed present history regarding onset, duration, and progression of symptoms, color and volume of post-mastectomy seroma discharge, time elapsed since mastectomy operation, presence of chronic diseases including cardiac conditions, diabetes mellitus, and liver disease, and history of ethyl alcohol allergy. Physical examination included general assessment for fever and local examination to evaluate the site and size of fluid collection at the post-mastectomy scar, presence of discharge, signs of inflammation, wound infection, or dehiscence. Laboratory investigations included complete blood count for total leukocytic count and serum albumin levels.

Technique:

All sclerotherapy sessions were performed in the one-day operating room under local anesthesia using complete aseptic conditions. With the patient positioned supine, the aspiration area was sterilized using 10% Povidone Iodine solution. A wide-bore cannula (14 or 16 French gauge) was inserted to aspirate seroma fluid to near completion. Following complete aspiration, In order to fill the seroma cavity and keep the opposing walls from contacting without generating maximal distension, 70% ethanol was injected into it in a variable amount. After retaining the ethanol for 15 to 30 minutes, it was fully aspirated and the skin's surface was covered with a sterile bandage Figure

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Figure (1): Trial of seroma aspiration

Postoperative Care and Data Collection:

Postoperative care included monitoring for immediate complications such as pain, bleeding, or local irritation. Analgesics and antibiotics were administered as clinically indicated. Follow-up assessments were scheduled at one week and one month postsclerotherapy, with additional visits prompted by patient complaints of fever, signs of infection, or changes in the mastectomy flap. During each follow-up visit, seroma status was evaluated by superficial probe ultrasonography at the mastectomy site or by needle aspiration of suspected fluid collections. In cases of seroma recurrence, reaspiration was performed under aseptic conditions, the volume of aspirated fluid was recorded, and repeat ethyl alcohol sclerotherapy was administered using the same 70% concentration and volume protocol as the initial session.

Data collected during follow-up included time to seroma resolution, number of sclerotherapy sessions required, total volume of ethanol used, incidence of procedure-related complications (infection, flap necrosis, wound dehiscence), and any delays in initiation of adjuvant therapy. Study endpoints comprised complete seroma resolution without recurrence within one month and absence of major complications.

Statistical analysis

All information was gathered, tabulated, and statistically examined using IBM Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY). The mean \pm standard deviation for normally distributed variables and the median (range) for non-normally distributed variables were used to express the quantitative data. The Mann-Whitney U test was used for non-normally distributed data, and the Student's t-test was used to compare regularly distributed continuous variables between two groups. Frequencies percentages were used to express the data. The qualitative proportions categorical variables were compared between groups using the chi-square test. statistical test was two-sided, and a p-value of less than 0.05 was regarded as statistically significant, while a p-value of more than 0.05 was regarded as statistically non-significant.

RESULTS

Table 1 summarizes the demographic profile of the 39 enrolled patients. The mean age was 53.9 ± 2.3 years (range, 50-59). Most participants were housewives (27/39, 69.2%) and married (24/39, 61.5%). Associated medical history; 9 (23.1%) of women hypertensive and 8(20.5%) diabetics. Tumor grade distribution was T1 in 11 patients (28.2%), T2 in 20 (51.3%), and T3 in 8 (20.5%). Invasive ductal carcinoma comprised 26 cases (66.7%), and lobular carcinoma 13 cases (33.3%).

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One sclerosing session doing for 24 patients (61.5%) with an amount of 120cc ethyl alcohol and second sclerosing session doing for 11 patients (28.2%) with an amount of 120cc ethyl alcohol. while third sclerosing session doing for 4 patients (10.3%) with an amount of 50 cc ethyl alcohol. Allover amount of ethyl alcohol consumed in sclerosis Post Mastectomy Seroma ranged from 50 to 530CC ethyl alcohol with median value 120CC (table 2). Clinical Outcome table 3 Sclerotherapy was successful after the first session in 24 patients (61.5%) and failed in 15 (38.5%).

Table 4; showed that there were no significant differences in total leukocyte count or serum albumin between success and failure groups (both p > 0.05). The above table define that a significant high success of sclerosing in treatment in first session of post mastectomy seroma in tumor grade T1, T2, than T3 tumor grade, p<0.001. Also a significant high success of sclerosing in first session of post mastectomy seroma in Lobular carcinoma than Invasive ductal carcinoma, p<0.001. Success rates were significantly higher for T1 (100%) and T2 (65.0%) tumors compared to T3 (0%),

and for lobular carcinoma (100%) compared to invasive ductal carcinoma (42.3%) (both p < 0.001). There was a significant less amount of ethyl alcohol used in success cases with median 100 cc and (range 50-120cc), compared to 400 cc with (range 270-530) in failed cases, p<0.001.

Early Postoperative complications are; infection in 10.3% of cases, occurrence of flap necrosis none (0%), Recurrence of stroma cyst occurred in 6 cases (15.4%) table 5.

Table 6; showed that there was a significant lower albumin, WBC in recurrence cases than cases passed without recurrence, p<0.05.

There was a significant large amount of ethyl alcohol used in recurrence cases with median 530cc and (range 400-530cc), compared to 120 cc with (range 50-4000) in passed without recurrence, p<0.001. The above table defines that a significant high percent of recurrence in tumor grade T3 than T1, T2, tumor grade, p<0.05 but no difference in recurrence of seroma regarding its pathological types, p>0.05.

Table 1: Demographic and Clinical Characteristics of Patients (n=39)

Variables					
Age per years	Mean ± SD (range)	53.9±2.3 50-59			
	(range)	0.7			
	Employee	n.			
Occupation	Employee	6	15.4		
	Farmer	6	15.4		
	housewives	27	69.2		
Marital status	Married	24	61.5		
Wai itai status	Widow	15	38.5		
Associated medical h	nistory	n.39	%		
Comorbidity					
Yes	17	43.6			
No		22	56.4		
Type of Comorbidity					
Hypertension		9	23.1		
Diabetes Mellitu	S	8	20.5		
Clinical Characteristics		n.	%		
	T1	11	28.2		
Tumor grade	T2	20	51.3		
	Т3	8	20.5		
Pathology	Invasive ductal	26	((7		
	carcinoma	26	66.7		
	Lobular carcinoma	13	33.3		

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Table (2): Number of session and amount of Ethyl Alcohol as Sclerosing Agent in Treatment of Post Mastectomy Seroma, (n 39):

Variable	n.	%		
	One	24	61.5	
Number of sessions	Two	11	28.2	
	Three	4	10.3	
Amount of ethyl alcohol (cc)	First session	120 (20 (50-300)	
	Second session	100 (50-300)	
	Third session	50(5	50-80)	
	Total amount	t 120(50-530)		

Table 3: Incidence of success of ethyl alcohol in management of post mastectomy seroma in first session (n. 39):

Va	n.	%	
Outcome	Success	24	61.5
	Failed	15	38.5

Table (4): Comparison of outcome regarding WBC or albumin value and tumor characters

	Suc	cess 24	Fail n.15						total	t	р
WBC (thousand) Mean ±SD	10.7	±1.8	10.2±1.13		10.5±1.58	0.94	0.36				
Albumin (g/ml) Mean ±SD	4.1±	1±0.27 4.1±0.37		4.1±0.31	0.47	0.64					
Tumor characters	Outcome		total	2	n volue						
Tumor characters		cess 24	Fail n.15				total χ 2 p-v		p-value		
Tumor grade											
T1	11	100.0	0	.0	11						
T2	13	65.0	7	35.0	20	19.78	0.0001*				
Т3	0	.0	8	100.0	8						
Pathology											
Invasive ductal carcinoma	11	42.3	15	57.7	26	12.19	0.0001*				
Lobular carcinoma	13	100.0	0	0.0	13	12,19	0.0001				
Number session											
1	24	100.0	0	.0							
2	0	.0	11	73.3		39.0	0.0001*				
3	0	.0	4	26.7							
Total Amount of ethyl alcohol Median(range)		00 120)	400 (270-530)							5.3	0.0001*

p>0.05=no- significant

χ 2 Chi square test

*p<0.05= significant

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Table (5): Incidence of postoperative complications

Postoperative complication	n.(%)	
Early complications	infection	4(10.3%)
	Flap necrosis	0(0.0%)
Late Complications	recurrence	6(15.4%)

Table (6): Comparison of recurrence regarding age, Serum albumin, WBC characters and tumor characters (n. 39):

	Recurrence						p-value
Variables	yes		no		t		
	n.6		n.33				
Age years							
Mean ±SD	55.7±3.1		53.6±4.2		1.61		0.12
Serum albumin (g/dl)							
Mean ±SD	3.8±0.26		4.2±0.28		3.2		0.003*
WBC (thousand)							
Median (range)	9(9-10)		11(8-13.5)		2.0u		0.045*
Total amount of sclerosing							
Median (range)	530(400-530)		120(50-440)		3.7u		0.0001*
Recurrence stroma regarding	y	es	no		total	., 2	w walna
tumor characters	n	n.6		n.33		χ2	p-value
Tumor grade							
T1	0	0.0	11	100.0	11		
T2	2	10.0	18	80.0	20	9.8	0.007*
Т3	4	50.0	4	50.0	8		
Pathology							
Invasive ductal carcinoma	6	23.1	20	76.9	26	f	0.14
Lobular carcinoma	0	0.0	13	100.0	13	ı	

U: Mann whitnney test, *p<0.05= significant, p>0.05=no-significant γ2 Chi square test *p<0.05=significant

DISCUSSION

In this study, the mean age of studied women was 53.9±2.3 years (range 50–59 years). Majority of studied patients were housewives (69.2%) and 24 of them were married 61.5%. In the 39 cases included, 17 of them had medical history; 9 (23.1%) of women were hypertensive and 8 (20.5%) were diabetics. The tumor grade was distributed as follow; T1 in 11 (28.2%), T2 in 20 (51.3%) and T3 in 8 (20.5%). According to lesion pathology invasive ductal carcinoma in 26 (66.7%) of lesions and Lobular carcinoma13 (33.3%) are lobular carcinoma.

Smith et al. [6] examined 20 seromas that were removed from 19 individuals, whose ages ranged from 49 to 79 years old. Among the procedures were axillary nodal dissection (5/20, 25%), lumpectomy (5/20, 25%),

mastectomy (45%, 9/20), and chest wall surgery (1/20, 5%).

In a study by Ebner et al. [7]; The inclusion criteria were met by 581 patients. At diagnosis, their median BMI was 25.6 kg/m2, and their median age was 60 years.

Mastectomy was performed on 60 individuals (10.3%).

In our study, one sclerosing session was done for 24 patients (61.5%) with an amount of 120 cc ethyl alcohol and second sclerosing session was done for 11 patients (28.2%) with an amount of 120 cc ethyl alcohol. While the third sclerosing session was done for 4 patients (10.3%) with an amount of 50 cc ethyl alcohol. Allover amount of ethyl alcohol consumed in sclerosis. Post-mastectomy seroma ranged from 50 to 530 cc ethyl alcohol with median value 120 cc with incidence of

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success of sclerosis modalities in post mastectomy seroma is 61.5%.

There is a significant less amount of ethyl alcohol used in success cases with median 100 cc and (range 50-120cc), compared to 400 cc with (range 270-530) in failed cases. But Smith et al. [6] had a study where the mean pre-ablation seroma volume was 146 \pm 165 ml. There was a mean of 1.4 prior aspiration attempts (range, 0-3). A mean of 39 ml (range, 8-60 ml) of ethanol was injected. Smith et al. [6] discussed their ethanol ablation results for recurring postoperative seromas in a single institution. Breast and axillary seromas are usually not abated by single-treatment ethanol sclerotherapy, and 85% of patients experience the recurrence of clinically significant seromas. There was only a higher reported chance of success in patients with a smaller pre-ablation seroma (36 ± 24 ml). Nonetheless, recurring seromas were generally around one-third lower in volume, indicating that ethanol ablation may be beneficial.

The review by Sood et al. [8] believed that sclerotherapy, which uses a variety of sclerosing agents, was a generally successful treatment for symptomatic seromas; however, almost all of the trials also included compressive bandages. In order for sclerosing agents to cause local fibrosis, they must first cause inflammation.

The fibrotic process's incapacity to join the opposing walls and eliminate the possible space is one possible reason for ablative failure [9]. Compressive bandages are therefore frequently used in seroma treatment algorithms for different body parts Sood et al. [8], although no prospective randomized trials have independently studied their impact Janis et al. [10]. Although compressive bandages can be applied with ease in some anatomical sites, their vast surface area, asymmetry in the size of the chest wall architecture (for unilateral mastectomy), and patient compliance make them challenging to utilize successfully in postoperative breast patients. Several researchers have looked at the impact of keeping a collapsed seroma cavity, with varying degrees of success. Anand et al.

conducted a short trial in which they found that repeated aspirations of asymptomatic seromas resulted in considerably higher costs of care and did not eliminate seromas faster than symptom-driven aspirations [11]. A trial by Wu et al [9] discovered that using indwelling cannulas for continuous draining did result in a quicker time to resolution of the seroma as compared to needle aspiration; however, external compression was also used in this research. More research is required to determine how certain mechanical and technological elements affect seroma resolution. In a study by Smith et al. [6], A relatively limited pre-ablation volume (36 ± 24 ml) was the only predictor of seroma ablation success. This result is not surprising because lower volume seromas have less potential space to resolve. Although seroma production has been linked to the type and extent of surgery performed, their investigation did not find this relationship [12].

Beyond just the type of surgery, there might be variations in the surgical approach affecting these outcomes. More extensive research is required. According to van Bemmel et al. [13], age has a contentious relationship with seroma risk, but their findings showed no relationship with seroma production. Before conclusive conclusions can be made, more patients must be evaluated.

In our study, the incidence of success of sclerosis modalities in post mastectomy seroma is 61.5%. There was no difference of between success cases and failed regarding demographic character, WBC or albumin value as the mean WBCs count in the success cases was 10.7 ± 1.8 versus 10.2 ± 1.13 in failed cases and mean Albumin level was 4.1±0.27 in success cases versus 4.1±0.37 in failed cases. This study showed a significant high success of sclerosing in treatment in first session of post mastectomy seroma in tumor grade T1, T2, than T3 tumor grade, p<0.001. Also a significant high success of sclerosing in first session of post mastectomy seroma in Lobular carcinoma than Invasive ductal carcinoma, p<0.001.

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We had experienced post operative complications as early postoperative complications as infection in 10.3% of cases, occurrence of flap necrosis none (0%), late complications as recurrence of stroma cyst occurred in 6 cases (15.4%).

There was a significant lower albumin (3.8±0.26 versus 4.2±0.28), WBC (9 vs 11) in recurrence cases than cases passed without recurrence. There was a significant large amount of ethyl alcohol used in recurrence cases with median 530 cc and (range 400-530cc), compared to 120 cc with (range 50-4000) in passed without recurrence. There was a significant high percent of recurrence in tumor grade T3 than T1, T2, tumor grade. But no difference in recurrence of seroma regarding its pathological types.

Multiple sclerosing treatment procedures and a variety of sclerosing agents must be used in prospective investigations. Additionally, since the size reduction for recurrent seromas was statistically significant, serial sclerotherapy treatments have to be looked into.

LIMITATIONS

The study's main drawback is its very small sample size (n = 39), which may limit the findings' generalizability and statistical capacity to identify minute variations among subgroups. Additionally, the single-center design may introduce institutional practice biases, and the lack of a comparative control group limits conclusions regarding ethanol's efficacy relative to other sclerosants or mechanical interventions.

CONCLUSION

Ethanol sclerotherapy offers a safe and effective first-line option for managing post-mastectomy seromas, particularly in patients with relatively small, persistent collections that are refractory to limited aspirations. In this study, a single 70% ethanol instillation achieved seroma resolution in over 60% of cases, with minimal complications. However, success is highly dependent on seroma cavity size and histologic factors: T1–T2 tumors and lobular carcinoma demonstrated the greatest treatment response, whereas larger cavities in T3 lesions required multiple sessions and yielded lower success rates

Conflict of Interest: None of the writers have any conflicting interests.

Financial Disclosures: No specific grant from a governmental, private, or non-profit funding organization was obtained for this study.

Data availability: Upon reasonable request, the corresponding author will make the datasets created and/or examined during the current investigation available.

Contribution of the writers: The authors were in charge of writing and getting the work ready for publication in addition to gathering and analyzing the data. The final version was examined and approved by all authors.

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Citation

Ahmad Ali Askary, M., Abdelhamid, M., El Kilany, M., Attia, A. Assessment of Ethyl Alcohol as Sclerosing Agent in Treatment of Post Mastectomy Seroma. *Zagazig University Medical Journal*, 2025; (5844-5852): -. doi: 10.21608/zumj.2025.427241.4220

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