Journal Pre-proof

Drainage on augmentation mammoplasty: Does it work?

Luiz Charles-de-Sá , Natale Ferreira Gontijo-de-Amorim , Julia Klein Rossi , Alexandre Malta da Costa Messeder , Luciana Nogueira de Araujo Jorge , Denize Salles Coelho da Mota , José Horácio Aboudib

PII: S1748-6815(20)30557-X
DOI: https://doi.org/10.1016/j.bjps.2020.10.059
Reference: PRAS 6829

To appear in: *Journal of Plastic, Reconstructive & Aesthetic Surgery*

Received date: 11 May 2020
Accepted date: 20 October 2020

Please cite this article as: Luiz Charles-de-Sá , Natale Ferreira Gontijo-de-Amorim , Julia Klein Rossi , Alexandre Malta da Costa Messeder , Luciana Nogueira de Araujo Jorge , Denize Salles Coelho da Mota , José Horácio Aboudib , Drainage on augmentation mammoplasty: Does it work?, *Journal of Plastic, Reconstructive & Aesthetic Surgery* (2020), doi: https://doi.org/10.1016/j.bjps.2020.10.059

Original Article

Title:

Drainage on augmentation mammoplasty: Does it work?

Authors:

[1]**Luiz Charles-de-Sá, MD, PhD**

Professor of the Department of Plastic, Reconstructive and Aesthetic Surgery, Training and Research State University Hospital of Rio de Janeiro- UERJ-RJ; Brazil, Perfoma Clinic –Natal and Pitanguy Institute . e-mail: clinicaperorma@uol.com.br

[2]**Natale Ferreira Gontijo-de-Amorim, MD, PhD.**

Perfoma Clinic – Rio de Janeiro and Pitanguy Institute – Rio de Janeiro. e-mail: natalefga@yahoo.com.br

[3]**Julia Klein Rossi, MD**

Resident of Department of Plastic Surgery of the Pitanguy Institute – Rio de Janeiro.Brazil. e-mail: juliaklein@hotmail.com

[4]**Alexandre Malta da Costa Messeder, MD**

Head of Radiology Department of State University of Rio de Janeiro.UERJ-RJ.Bras l e-mail : messederalexandre@gmail.com

[5]**Luciana Nogueira de Araujo Jorge, MD**

Ultrasonographer of the Radiology Department of State University of Rio de Janeiro.UERJ-RJ.Brasil. e-mail : lunogueira.aj@hotmail.com

[6] **Denize Salles Coelho da Mota, MD,PhD**.

Professor of the Department of Plastic, Reconstructive and Aesthetic Surgery, Training and Research State University Hospital of Rio de Janeiro- UERJ-RJ; e-mail: denisedamota@hotmail.com

[7]**José Horácio Aboudib, MD,PhD.**

Head of Department of Plastic, Reconstructive and Aesthetic Surgery, Training and Research State University Hospital of Rio de Janeiro-Brazil- UERJ. e-mail:jhaboudib@gmail.com

Correspondence:

Luiz Charles-de-Sá, M.D.:
Address: Av. Joana Angélica, 124/602. Ipanema. Rio de Janeiro-Rj-Cep: 22420-030. Brazil.
Cellphone: 0055 21 99856280.
Fax: 0055 21 2521 0192
E-mail: clinicaperforma@uol.com.br

Summary:

Background*:* Breast prostheses could be associated with complications, despite the many studies on surgical materials and techniques.the role of surgical drainage in preventing complications on breast prostheses surgery is controversial

Objectives: This study aimed to evaluate the role and effectiveness of vacuum drainage in the augmentation mammoplasty

Methods: A prospective multicentric randomized comparative clinical trial was conducted, with 150 patients, candidates for breast augmentation. The candidates were split into two groups to analyze the breast drain role. Group1: closed-suction drainage. Measurements were taken every 24 hours for 48 hours. Group2: Control (no drainage). All the patients were submitted to a clinical and postoperative ultrasonography evaluation (7^{th} day and 3^{rd} month). In the late consultations (1^{st}, $2^{nd,}$ and 3rd-year post-operative time) were carried out to identify any complication such as infection, seroma, hematoma, asymmetry, hypertrophic scarring, rippling, implant position, visible edges, and sensibility alteration

Results: A total of 150 female patients were operated with 300 breast implants placed into sub glandular pocket. In the first 24 hours postoperative (D1), the volume drainage ranged from 12 ml to 210 ml (mean= 74.90 ml. SD= 43.29 ml). After 24 hours, on the second day (D2), the collected volume ranged from 10 ml to 120 ml (mean= 44.76 ml. SD= 24.80 ml). The total drainage volume in the 48 hours ranged from 22 ml to 320 ml (mean= 119.7 ml. SD= 62.20 ml). The Breast ultrasonography series (BUSGS) analysis was done in the 7^{th} day and 3^{rd} month in both groups. There was no significant difference between the G1 and G2 groups (p=0.05 and 0.25, respectively). In the follow-up, some patients (33-44%) declared sensitivity disturbing on the nipple-areola complex (NAC) and lower breast segment.

Conclusions*:* The closed-suction breast drainage in breast augmentation was associated with more cost and time-consuming and not demonstrated any benefit in a recent post-operative time

Key Words:
Drainage, Breast augmentation, breast, implant

Level of Evidence: Level IV, multiple series study

Drainage on augmentation mammoplasty: Does it work?

INTRODUCTION

The first use of the gel filled silicone breast implant for cosmetic breast surgery dates 1962 and began the modern era of breast augmentation, and since then, the breast implants have evolved to encompass a wide array of commercially available implants today.[1] Breast augmentation has become very popular, and in many countries, it is the most common cosmetic procedure with a high rate of patient satisfaction.[1] According to data from the American Society of Plastic Surgery, breast augmentation corresponds to the main cosmetic surgical procedure in the United States, and the number increases year to year, corresponding to 345 thousand cases in 2017 and a 31% increase in the last ten years (1.5 million breast implants inserted in 2016, according to International Society of Aesthetic Plastic Surgery global survey). [2]

Silicone gel implants have evolved through multiple generations of design, which are differentiated most significantly by the consistency of the silicone gel and the new technology of the surrounding shell.[1]

Breast prostheses could be associated with complications, despite the many studies on surgical materials and techniques. Capsular contracture is the most common complication, in the long term, of breast augmentation, ranging from 4 to 74% in the literature, according to Baker's classification. The capsular contracture, presence of rippling on the implant surface,

asymmetry, implant position, visible edges, extravasation and rupture of the implant and others must be investigated. This large variation is due to the lack of a uniform classification of the clinical aspect, variable postoperative period, and type of non-uniform implants of the studied samples. [3]

The contracture has a multifactorial cause not well wholly understand. Although its pathogenesis is not fully understood, many factors seem to contribute to its development, including hemorrhage, seroma, infection, and, more recently, biofilm on the implant. Some surgeons suggest that the problem is *Mycobacterium sp*., which is difficult to culture. [4-6]

In sense to avoid blood collections and/or seromas, drainage of prostheses pockets is useful; however, the role of surgical drainage in preventing complications on breast prostheses surgery is controversial. Not every surgeon is in favor of routine use of surgical drainage on augmentation mammoplasty simply because they feel it is unnecessary either because it adds discomfort to a very demanding group of patients or because they believe that could increase the risk of infection. [7] Studies, however, have shown that despite meticulous perioperative hemostasis, the amount of fluid present in the drain reservoir 12-15 h after surgery was consistently greater than the immediate postoperative amount.[7] They also revealed a significantly higher incidence of capsular contracture in patients submitted to non-drained augmentation mammoplasty.[3, 7-9]

OBJECTIVE

The aim of this study was to evaluate the role and effectiveness of vacuum drainage in the augmentation mammoplasty

METHODS

A prospective multicentric randomized comparative clinical trial was conducted from august 2016 to august 2019, with 150 healthy female patients, aged between 18 and 54 years, candidates for breast augmentation at the University of State of Rio de Janeiro, Brazil (UERJ), Pitanguy Institute- Rio de Janeiro and Performa Clinic. Selective criteria screened all the 200 eligible candidates to breast augmentation. At the end of the selection process, 150 individuals were randomized non-consecutively and allocated in different groups according the proposed investigation. They were introduced to our database, and randomization was created (using web-based software: *www.randomization.com)* and performed on a 3:3 ratio. All of the patients were split into two groups (group 1 and group 2), following this randomization and study propose. (Figure 1)

The candidates were split into two groups to investigate the drain role in augmentation mammoplasty. Group 1 with 75 patients used closed-suction drainage (Porto-VAC® vacuum drain - 4.8 mm diameter; How-medical UK Ltd) at the end of surgery for 48 hours (group 1-drainage) and another group of 75 patients did not use drains (group 2-no drainage). In group 1, the amount of fluid drained was measured for 48 hours postoperative.

All individuals were submitted to the same surgical protocol: silicone implants were performed under local anesthesia with a solution of 0.5% lidocaine with epinephrine (diluted 1:200,000 IU) and sedation. All prostheses

were placed in the subglandular plane (dissection by electrocautery) through an inframammary incision. In the postoperative follow-up, these individuals were submitted to clinical and ultrasound evaluations at 7th postoperative day (POD) and 3rd month postoperative in an appropriate screening. All the patients were followed clinically for three years and answered a questionnaire remotely through the electronic survey. The survey was performed using the software (SurveyMonkey. Microsoft corporation. USA.).

The recruitment of patients was carried out between August 2016 and august 2017. The 150 included patients after being accepted to participate in the research project by verbal invitation, signed the Informed Consent Form document, and were sent to clinical, cardiologic evaluation, laboratory and mammographic ultrasound examination. This study was carried out in accordance with the ethical principles of the Helsinki 2000 and Istanbul 2008 declarations. This work followed the Brazilian standards of resolution 466/12 and subsequent Council National Health / Brazilian Ministry of Health. This clinical trial was approved for the ethical board protocol (no. 2.013.473)

All research data were recorded on the protocol board. The clinical and imaging evaluations were performed in the pre and postoperative period in 2 intervals: 7th day and 3rd month of postoperative time. In these evaluations, the presence and quantification of the liquid collection in the implant pocket was done by ultrasound in a blind examination and performed mostly by a single examiner (80% of cases). Excluded criteria were the non-attendance to the ultrasound exams, as well as pregnant, hematoma, and infection. The inclusion and no inclusion criteria were adopted to select the patients, as listed below:

Inclusion criteria:

- Feminine gender;
- Age between 16 and 55 years;
- Primary breast surgery;
- Subglandular placement of the prostheses;
- Pinch test ≥ 2 cm [10]

No Inclusion criteria:

- Associated comorbidities;
- Previous thoracic surgery;
- Association with another procedure in the same surgical time;
- Clinical, laboratory and radiological changes that made surgery impossible;
- Psychological instability or inadequate expectation of surgical outcome
- Positive B-HCG test;
- Patient with a pinch test less than 2 cm and who will undergo surgery through the submuscular plane or through another access incision.
- Refusal of the patient to participate in the study;

Augmentation Mammoplasty

The surgery was performed under sedation and local anesthesia with 0.4% lidocaine, 0.75% Ropivacaine, and 1:200.000 IU epinephrine. All patients received intravenous Cefazolin 1g at anesthetic induction and each 8

hours in the first 24 hours; after the first postoperative day, for one week, the patient used oral cefalexin (500 mg four times daily).

During surgery, an incision of 3 to 5 cm in the inframammary sulcus was performed, followed by dissection of the implant pocket in the subglandular plane with electrocautery, and if necessary, also using digital maneuver. Before the sutures, a Port-VAC® drain of 4.8 mm in diameter (How-medica UK Ltd) was introduced in each pocket, with exit by the anterior axillary fold and its fixation with 3-0 mononylon (Ethicon Inc/Johnson & Johnson São Paulo-SP-Brazil) to the group 1 (figure 2). The amount of fluid in the drainage reservoir was measured and recorded, up to 48 hours postoperatively, when the drains were removed. In the postoperative period, all patients used a moderate compression bra continuously for a month and avoided any type of effort and local trauma.

The complete follow-up on this series was three years.

Clinical Evaluation

All patients went through a preoperative consultation where personal information was collected, the breasts examined and the size, shape, coating of the implant and access incision determined. Anthropometric measurements were taken. All patients submitted to ultrasonographic examination of the breasts in the preoperative period and those over 30 years old did also mammography exam.

In patients with aspiration drainage, measurements of the drain secretion were done, and the first measurement was done 24 hours after the end of

the surgery (D1). Measurements were taken every 24 hours for 48 hours (D2) after surgery.

Regarding the postoperative consultations, all the patients went through clinical and ultrasonography consultations that were performed on the 7th day and 3rd month postoperative. The follow-up of all the patients was carried out until 3rd year postoperative. The group 1 and 2 were submitted to a questionnaire remotely through the electronic survey on the 3rd year postoperative, using the software *SurveyMonkey* (Microsoft corporation. USA).

Ultrasonography Exam

The evaluation of presence of liquid collection in the implant pocket and its quantification were recorded through ultrasound examination of breast soft tissues and implant pocket. It was used the linear transducer, with a frequency of 7-15 Mhz, in the Medison Sonoace Pico Apparatus (2008), which was performed by a single examiner in 80 % of the cases. This evaluation was blind, that is, the examiner did not know the patients who used or not the drains in the postoperative period.

Ultrasound examination was performed during the postoperative consultations in the following periods: 7th day and 3rd month postoperative. The evaluations looked for the presence and quantification of liquid collection in the implant pocket (seroma, late seroma, collections, abscess), integrity of mammary prostheses (rippling, capsule formation and others), possible extravasation and its extension, and soft tissues alterations.

Statistical Analysis

Parametric and nonparametric tests were performed to evaluate the data normality distributions and differences between the two groups. The *t-student* test was used to parametric analysis between two groups with similar features and different variable. An overall α-level of 0.05 was used as the limit of statistical significance. The Graph Pad Prism 5 software (USA) was used to analyze the data. The results were expressed as mean ± standard deviation (SD).

RESULTS

A total of 150 female patients were included in the study and 300 breast implants were placed into sub glandular pocket. They ranged in age from 19 to 48 years old (mean age = 30.93. SD: 6.8) to the group 1 and 18 to 54 years old (mean age = 30.59. SD: 7.17) to the group 2. The body mass index BMI in group 1, ranged from 23.6 to 29.5 (mean=25.8 .SD=2.9) and from 24.1 to 30.2 (mean=25.32 .SD=3.6) in group 2. Six patients were excluded (2 patients with hematoma and 4 patients by non-attendance to the ultrasound exams and clinical evaluation in the postoperative period). Figure 1 shows a flowchart of patient through of the group allocation.

All patients were operated under a same surgical protocol to breast augmentation. The implants volume ranged from 250 ml to 380 ml (Mean=302.4 ml .SD= 28.33 ml). In the group 1 and group 2, the volume mean was 302.5 ml (SD=26.39) and 300.4 ml (SD=30.61), respectively. (Figure 3).

All patients from drainage group 1 (N=73) and control group 2 (N=71) were submitted to a clinical and breast ultrasonography screenings (BUSGS)

to measurement of the liquid presence inside of the implant pocket on 7th day and 3rd month intervals.

The patients of group 1 were submitted to breast drainage for 48 hours in the post-operative time (Figure 4). The drainage volume collected in 24 and 48 hours postoperatively (PO) were recorded and analyzed. In the first 24 hours postoperative (D1), the volume drainage ranged from 12 ml to 210 ml (mean= 74.90 ml. SD= 43.29 ml). After 24 hours, on the second day (D2), the collected volume ranged from 10 ml to 120 ml (mean= 44.76 ml. SD= 24.80 ml). The total drainage volume in the 48 hours ranged from 22 ml to 320 ml (mean= 119.7 ml. SD= 62.20 ml). In this drainage series, just a patient collected 210 ml (pac.55), and another patient collected 200 ml (pac.123) in the D1. The "pac.55" developed a hypertension attack. Both two patients presented clinical and ultrasonography positive signs to a large liquid collection and were submitted to a second surgical procedure to hematoma control.

The Breast ultrasonography series (BUSGS) on 7th day, group1 ranged from 0 ml to 17.3ml; (Mean= 2.5 ml SD=4.36 ml). The group 2 ranged from 0 to 14.10 ml. (Mean= 2.4 ml.SD=3.6). BUSGS on 3rd month; the group1 ranged from 0 ml to 4.1ml; (Mean= 0.5 ml SD=1.0 ml). Group 2 ranged from 0 to 3.0 ml. Mean= 0.82 ml.SD=1.2) The Breast ultrasonography series (BUSGS) analysis in both groups demonstrated that there was no significant difference between the G1 and G2 groups considering the profile to the liquid in the implant pocket on 7th day and 3rd month intervals (p=0.05 and 0.25, respectively) (Figure 5). (Table 1).

The clinical follow-up was assessed by observation, examination with palpation, BUSG, as well as, pre and postoperative photographs, at least during the postoperative period of 3 years. In this series of patients in both groups, were evaluated to identify some infection, necrose, implant extrusion and other alterations (Table 2).

Table 1: Data of the baseline study characteristics

	Group 1	Group 2
Age (ranged from 45-65)	Mean: 56.6 (SD:4.89)	Mean:58.4 (SD:3.71)
BMI	Mean= 25.80 (SD: 2.9)	Mean=25.32 (SD:3.6)
Implant Size (vol. ≦ / .> 300ml)	N=150: 85 (56.6%) /65 (43.3 %)	N=150: 82(54.6 %) / 68
Inframammary incision	N=75	N=75
Sub glandular pocket	N=75	N=75
Drainage (ml) – 48 hrs.	Mean=119.7ml.SD=62.2ml 62.20	0 ml
Breast USG -7th Postop. day (ml)	Mean= 2.5 ml SD=4.36 ml *	Mean=2.4 ml.SD=3.6ml *
Breast USG -3rd Postop. month(ml)	Mean=0.55 ml.SD=1.0ml*	Mean=0.82ml.SD=1.2 ml*

** Difference between the 7th day and 3rd month intervals in the G1 and G2 was not significant (pv=0,36 and 0.62, respectively). Difference between group 1 and group 2, considering the liquid in the implant pocket measured by USG (ultrasonography) on 7th day and 3rd month intervals, was not significant. (pv=0.05 and 0.25, respectively). (N=number; SD=stander desviation)*

Table 2: *Questionnaire was answered by groups 1 and 2 remotely through the electronic survey. The survey was performed using the software (SurveyMonkey. Microsoft corporation. USA)*

		Group 1 (n=56)	Group 2 (n=56)
Satisfaction	**Very satisfaction**	54.57%	47.62%
	satisfaction	31.14%	28.57%
	Less satisfaction	9.71%	12.29%
	No satisfaction	4.57%	9.52%
Scar quality	**excelent**	59.14%	30.57%
	good	23%	47.62%
	satisfactory	14.30%	11.52%
	bad	0%	14.29%
	worst	3.58%	0%
Nipple-areola sensibility impare	**no**	66.67%	65.90%
	yes	33.33%	34.10%
Lower polo sensibility impare	**no**	60.29%	55.38%
	yes	39.71%	44.62%
Implanty edge visible	**no**	90.29%	83.71%
	yes	9.71%	16.29%
Stria	**no**	70%	80.71%
	very few	12.71%	0%
	few	13.71%	19.29%
	many	3.57%	0%
	excessivily many	0%	0%
breast discomfort	**no**	65.86%	66%
	yes	34.14%	34%
breast mobility Impaired	**no**	90.86%	93.48%
	yes	9.14%	6.52%

DISCUSSION

In the current study, was investigated the role of suction breast drainage and its influence on the incidence of seroma-hematoma, infection and capsular formation. The breast augmentation has been the most frequent cosmetic surgery in the world.[11] Since the beginning of breast implant to the cosmetic and breast reconstruction surgeries, many advances have been achieved to improve this practice. Silicone gel prostheses have evolved through multiple generations of design, with difference in the consistency of the silicone gel and types of the surrounding shell.[12,13] However, the breast prostheses are still associated with complications, capsular contracture being the most common and responsible for the implant exchange. Capsular contracture represents the most frequent complication after implant-based breast surgery and is the leading cause of reintervention.[14] Due to this scenario; clinical trials have addressed to understand and prevent its formation. Prevention and management of capsular contracture evolve nonsurgical therapies such as leukotriene inhibitors, ultrasound therapy, massage, handle (close capsulectomy), nonsteroidal anti-inflammatory agents, and other maneuvers. The surgical approach includes capsulectomy (partial or complete), pocket change, device exchange and use of Acellular dermal matrix.[15-18]

Several early complications can occur after breast implant. Liquid and blood collection are an essential concern on the clinical management of the breast augmentation surgery. The closed-suction drainage into the pocket is considered as the most effective tool to control blood collection and de-

creased peri-implant dead space, reducing the early seroma and hematoma rates after surgery.[19] Studies have related the presence of the subclinical hematoma with a more inflammatory reactions, early seroma, infection, and capsular formation.[20] Some surgeons claim that suction-drain represent a useful method to reduce the complication rate of seroma and hematoma. The primary concern with a seroma is its likelihood to lead to an infection and implant explantation. The appropriated management of seroma depends on if occur early after surgery (within 1 year) or late (>1 year).[21] Early seroma formation seems to correlate with hematoma; however, late seroma formation is far more likely to occur with textured surface devices compared to smooth.[21] Nowadays, textured implants have been associated with the development of anaplastic large cell lymphoma (ALCL) that can appear with a late seroma.[22]

On the other hand, the breast drainage device can create open access to bacteria and infection, outweighed the benefit of drainage.[23] Nowadays, few studies have addressed a direct relation with hematoma-seroma and late complications as capsular contracture formation. *Codner et al.* .[24] study has mentioned hematoma like a risk factor for the subsequent development of capsular contracture.[25]

In our series, the breast drainage measurements ranged from 22 to 320 ml (mean= 119.7 ml) in 48 hrs. Between the first and second postoperative days, there was a 50 % reduction of drainage flux approximately. Two patients were excluded from trial due to developed hematoma in 24 hours postoperative (one patient during the drain placing, and another, due to a hypertension attack). In group 1, mostly of patients drained a volume under

150 mL/48hrs. (mean= 119.7 ml. SD= 62.20 ml), which indicates a low risk of developing a seroma. *Pagliara* analysis[20] has corroborated with this finding. Obviously that the hematoma rate is influenced by a myriad of factors such as intraoperative bleeding, personal evaluation of bleeding (resident and senior surgeon), patient coagulation status, surgical time, local approach (eg, nonendoscopic axillar approach present higher rates of hematoma)[26], pocket dissection (blade or electrocautery) and others. The closed-suction drainage is associated with patient discomfort, cost, and a specialized health care. The timing of suction-drainage still controversial, however mostly surgeons have removed it once the drain output is less than 40 to 50 ml/day.[27] Some studies have addressed a bacteriologic analysis of liquid drainage as a predictable infection rate.[28] Several studies have associated increased infection rates when suction drain was used.[29-32] No clinic infection was registered in our study, according Disease Control and Prevention (CDC) criteria.[33] The potentiators behind the inflammatory process are incompletely characterized, but key players are thought to be bacterial contamination or biofilm, tissue trauma, blood-serum, and silicone gel bleed. [15-17]

In our study, the patients had a vacuum drain in protheses pockets for 48 hours postoperative, during hospital internment, maintaining all asepsis for their manipulation and using intravenous antibiotic therapy with cefazolin (8/8 hours), during hospitalization and another 05 days of the oral administration after discharge. The drains were removed in a hospital environment, so the risks were then become minimal. *Chintamani et al*. study demonstrated the use of closed-suction drainage without any increase of infection.[34]

The ultrasonography evaluation showed a similar and small volume mean in group 1 (vol.=2,5ml.SD=4.36) and group 2 (vol.=2.4 ml.SD=3.6) in the 7th POD. A decreased and similar profile of the liquid collection in the pocket at 3rd month post-surgery was noticed (group 1 and 2: vol. mean= 0.55 ml (SD=1.0) and 0.82 ml (SD=1.2), respectively). The differences between the two groups were not statistically significant in both intervals (pv=0.05 and 0.25, respectively). In the first moment, it could have been expected a higher volume collection index in group-2 (no vacuum drain) compared to group 1 (close drainage-48 hrs.). These data can be attributed to the high capacity of breast lymphatic drainage. On the other hand, it is mandatory to correlate these groups with late capsular formaion after five years postoperative time. These analyses will be done in second study time.

A non-presential evaluation by a remote survey was carried out due the COVID-19 pandemic crisis. Patients of the group 1 and 2 declared sensitivity disturbing on the nipple-areola complex (NAC) and lower breast segment that ranged to 66.6-61.90% and 64.29-52.38%, respectively. *Araco*[35], *Greuse*[36], *Mofid*[37] studies have mentioned sensory loss. *Okwueze et al*.[38] demonstrated sensory disturbing in the lower pole. The nipple and areola have a dense sensory distribution provided mainly by 4° intercostal nerve that lies behind the breast gland.[39] Subglandular dissection can produce direct damage with partial or permanent impaired to NAC sensitivity (Figure 2 B).

Study limitations were a small number of patients, no comparative analysis between reconstructive and cosmetic breast implant surgeries, the BUSG evaluation in the 6th and 12th month post-operative intervals to identify late

seroma formation and other breasts disturbing, as well as the analysis of different factors affecting the breast drainage (eg: BMI, Age, surgical time, implant volume and others). The closed-suction breast drainage in breast augmentation was associated with more cost and time-consuming and not demonstrated any benefit in a recent post-operative time.

Acknowledgment

We would to thank to institutional support of LifeSil that provided some material and software.

Conflict of interest Statement: The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding Statement: The authors received no financial support for the research, authorship, and publication of this article

REFERENCES

1. Fiala TGS, Lee WPA, May JW. Augmentation mamoplasty: results of a patient survey. Ann Plast Surg. 1993; 30(6):503.

2. ASPS National Clearinghouse of Plastic Surgery Procedural Statistics 2015, www.PlasticSurgery.org

3. Hipps CJ, Raju DR, Straith RE. Influence of some operative and postoperative factors on capsular contracture around breast prostheses. Plast Reconstr Surg. 1978; 61(3):384

4. Clegg HW, Bertagnoll P, Hightower AW, Baine WB. Mamoplasty-associated mycobacterial infection: A survey of plastic surgeons. *Plast Reconstr Surg.* 1983; 72:165–169.

5. Wirth GA, Brenner KA, Sundine MJ. Delayed silicone breast implant infection with Mycobacterium avium-intracellulare. Aesthetic Surg J. 2007; 27:167–171

6. Hall-Findlay, E. J Breast Implant Complication Review: Double Capsules and Late Seromas. Plastic and Reconstructive Surgery. 2011; 24-37

7. Gherardini, G.; Zaccheddu, R.; Milner, S. M.; El-Shazlyl, M.; Liapakis, I. Breast augmentation with silicone implants: the role of surgical drainage—report on 502 consecutive patients. Eur J Plast Surg. 2006; 29: 9 –12.

8. Fanous N, Salem I, Tawilé C, Bassas AE. Absence of capsular contracture in 319 consecutive augmentation mamoplasties: dependent drains as a possible factor. Can J Plast Surg. 2004; 12(4):193.

9. Spear SL, Rottman SJ, Glicksman C, Brown M, Al-Attar A. Late Seromas after Breast Implants: Theory and Practice. Plastic and Reconstructive Surgery. 2012; 105-8

10. Tebbetts JB, Adams WP. Five critical decisions in breast augmentation using five measurements in 5 minutes: The high five decision support process. Plast Reconstr Surg. 2005;116:2005–2016

11. Cosmetic surgery national data bank statistics. AesthetSurg J. 2017;37(suppl_2):1-29.

12. Calobrace M B. Anatomic Gel Implants: From Concept to Device. *Plast Reconstr Surg*. Supplement 2014, Volume 134, Number 3S-9S.

13. Cronin TD, Gerow FJ. Augmentation mammoplasty: new "natural feel" prosthesis. In: *Transactions of the Third International Congress of Plastic Surgery, October18, 1963*. Amsterdam: Excerpta Medica Foundation; 1963:41–49.]

14. Duxbury, P.J., Harvey, J.R. Systematic review of the effectiveness of polyurethane-coated compared with textured silicone implants in breast surgery. Journal of Plastic, Reconstructive & Aesthetic Surgery. 2016; 69, 452-460.

15. Spear SL, Mesbahi AN. Implant-based reconstruction. *Clin Plast Surg*. 2007; 34:63–73; abstract vi.

16. Adams WP Jr. Capsular contracture: what is it? What causes it? How can it be prevented and managed? Clin Plast Surg. 2009; 36: 119–126, vii.

17. Nahabedian MY, Spear SL. Acellular dermal matrices for secondary revisions following prosthetic breast reconstruction. Aesth Plast Surg. 2011; 31 (7 suppl):38s–50s.

18. Spear SL, Seruya M, Clemens MW, et al. Acellular dermal matrix for the treatment and prevention of implant-associated breast deformities. Plast Reconstr Surg. 2011;127;1047–1058.

19. O'Dwyer PJ, O'Higgins NJ, James AG. Effect of closing dead space on incidence of seroma after mastectomy. Surg Gynecol Obstet. 1991; 172: 55–56.

20. Paglara D, Maxia S, Faenza M, Dessena L, Campus G, Rubino C. Low Versus High Vacuum Suction Drainage of the Submuscular Pocket in Primary Breast Reconstruction. A Retrospective Study. Ann Plast Surg. 2018 Apr; 80(4): 339-343

21. Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: core study results at 10 years. Plast Reconstr Surg. 2014; 133: 1354–1361.

22. Clemens MW, Nava MB, Rocco N, et al. Understanding rare adverse sequelae of breast implants: anaplastic large-cell lymphoma, late seromas, and double capsules. Gland Surg. 2017;6: 169–184.

23. Hadad E, Wiser I, Rosenthal A, Landau G, Ziv E, Heller L, Suction drains in aesthetic breast implant exchange are associated with surgical site infections: A retrospective cohort study, British Journal of Plastic Surgery (2017)

24. Codner MA, Mejia JD, Locke MB, et al. A 15-year experience with primary breast augmentation. Plast Reconstr Surg. 2011; 127(3):1300-1310.

25. Hood K(1), Ganesh Kumar N(2), Kaoutzanis C, Higdon K.K. Hematomas in Aesthetic Surgery. Aesthet Surg J. 2018 Aug 16; 38(9):1013-1025.

26. Roxo ACWR, Marques RG, De Castro CC, Aboudib JH. Utility of Video-Assisted Endoscopy in Transaxillary Breast Augmentation. Aesthet Surg J. 2015, 35(3): 265–272.

27. Phillis BT, Wang ED, Mirrer J, et al. Current practice among plastic surgeons of antibiotic prophylaxis and closed-suction drains in breast reconstruction: experience, evidence, and implications for postoperative care. Ann Plast Surg. 2011;66:460–465

28. Yoon, Chung JH, Hwang NH, Lee BI, Partk SH, Yoon ES. Bacterial profile of suction drains and the relationship thereof to surgical-site infections in prosthetic breast reconstruction. Arch Plast Surg. 2018 Nov; 45(6):542-549.

29. Pittet B, Montandon D, Pittet D. Infection in breast implants. Lancet Infect Dis 2005; 5: 94106.

30. Armstrong RW, Berkowitz RL, Bolding F. Infection following breast reconstruction. Ann Plast Surg. 1989; 23: 284-8.

31. Washer LL, Gutowski K. Breast implant infections. Infect Dis Clin North Am. 2012; 26:111-5.

32. Costerton JW, Montanaro L, Arciola CR. Biofilm in implant infections: its production and regulation. Int J Artif Organs 2005;28:1062-8

33. Horan TC, Andrus M, Dudeck MA. CDC/NHSN surveillance definition of health care associated infection and criteria for specific types of infections in the acute care setting. Am J infect Control 2008; 36: 309-32.

34. Chintamani, Singhal V, Singh J, et al. Half versus full vacuum suction drainage after modified radical mastectomy for breast cancer. A prospective randomized clinical trial [ISRCTN24484328]. BMC Cancer. 2005; 5:11.

35. Araco A, Araco F, Sorge R, Gravante G. Sensitivity of the Nipple-Areola Complex and Areolar Pain following Aesthetic Breast Augmentation in a Retrospective Series of 1200 Patients. Plastic and Reconstructive Surgery. 2011; 128(4): 984-989.

36. Greuse M, Hamdi M, DeMey A. Breast sensitivity after vertical mammaplasty. Plast Reconstr Surg. 2001; 107: 970–976.

37. Mofid MM, Dellon AL, Elias JJ, Nahabedian MY. Quantitation of breast sensibility following reduction mammaplasty: A comparison of inferior and medial pedicle techniques. Plast Reconstr Surg. 2002; 109: 2283–2288

38. Okwueze MI, Spear ME, Zwyghuizen AM, et al. Effect of augmentation mammaplasty on breast sensation. Plast Reconstr Surg. 2006; 117: 73–83; discussion 84–85.

39. Sarhadi NS, Shawdunn J, Soutar DS. Nerve Supply of the breast with special reference to the nipple and areola. Clin.Anat. 1997;10 (4): 283-288.

FIGURE LEGEND:

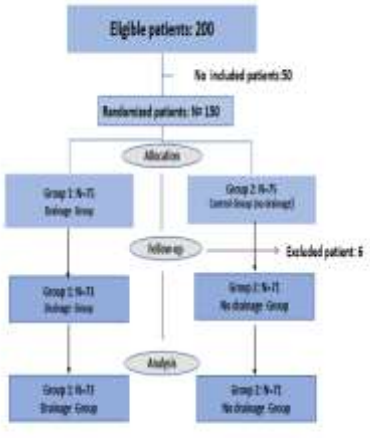
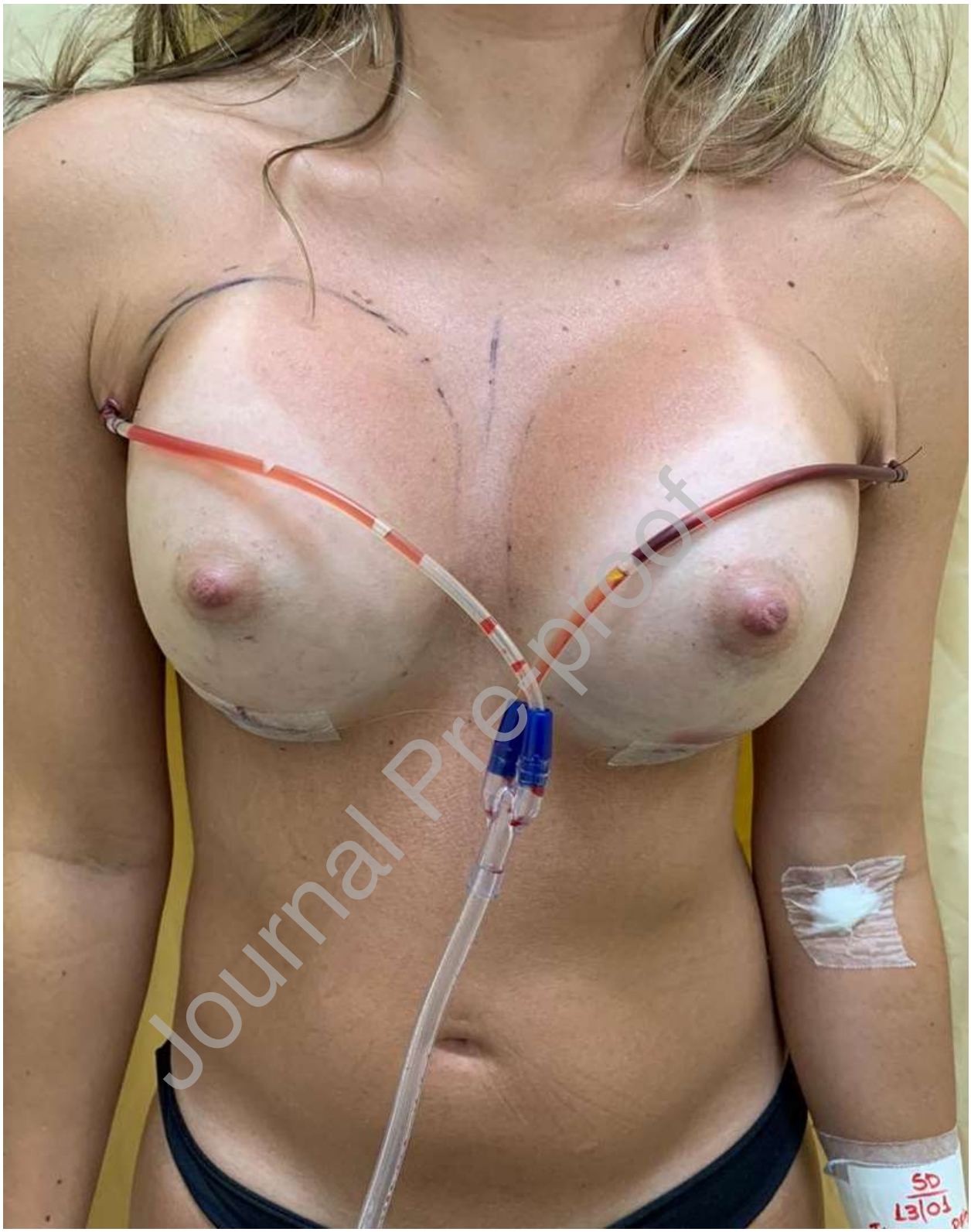


Figure 1: The flowchart shows patient distribution.



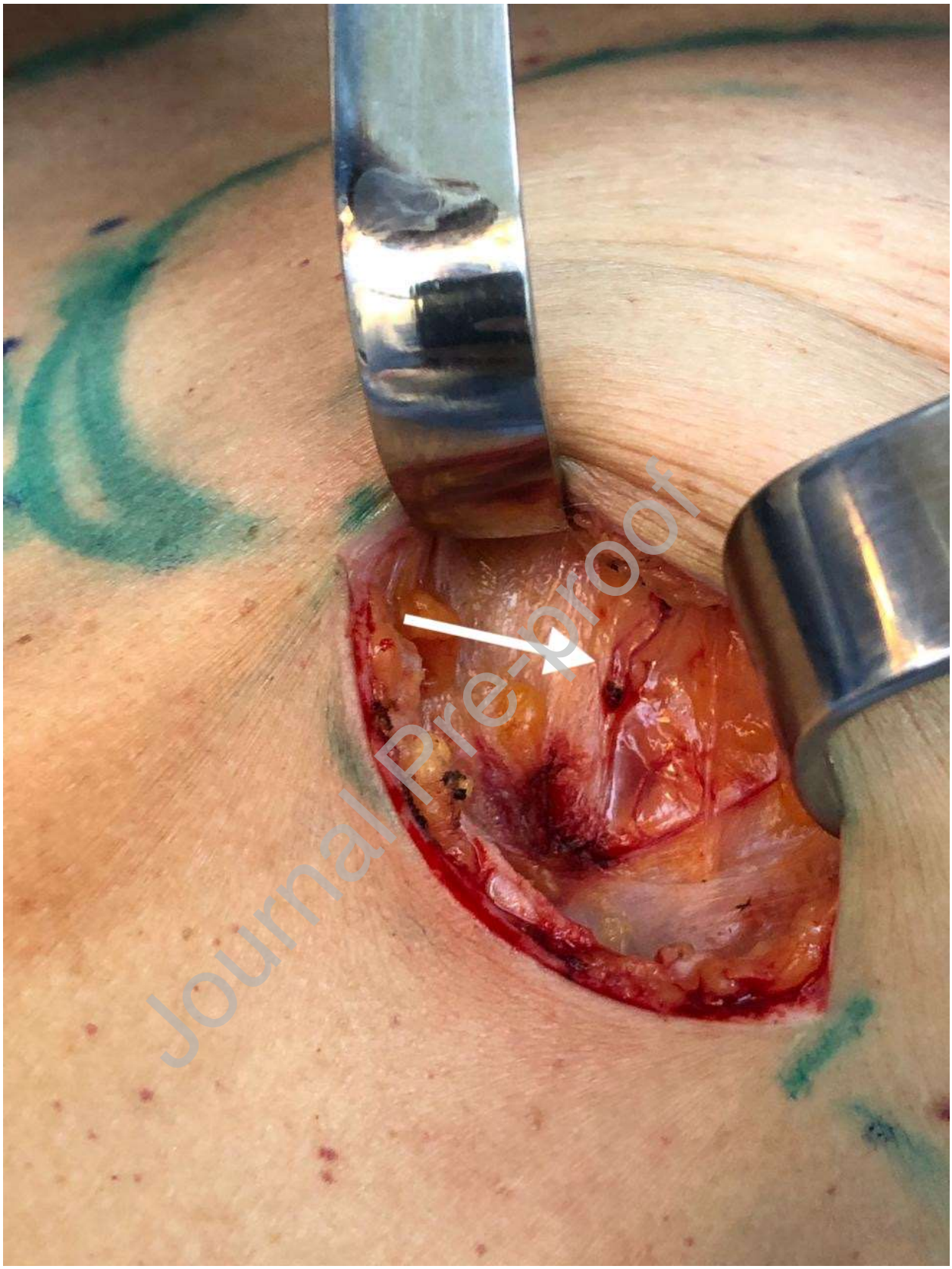


Figure 2: (A): Patient group 1-drainage in 1st postoperative day (B): sub mammary fold incision. In the subglandular plane is possible to identify the 4° intercostal nerve (white arrow).

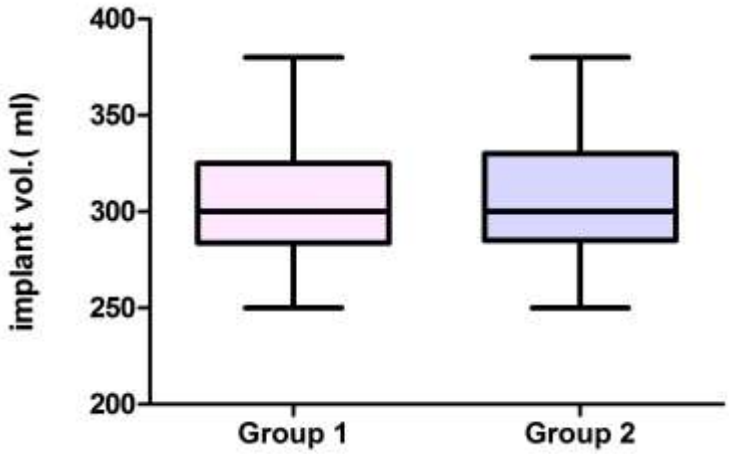


Figure 3: Implant volume ranged from 250 ml to 380 ml in both groups (*n*= 300. Mean=302.4 ml .SD= 28.33 ml). Group1 and Group 2, the implant volume Mean and SD were the 302.5 ml (SD:26.39) and 300.4 ml (SD:30.61), respectively.

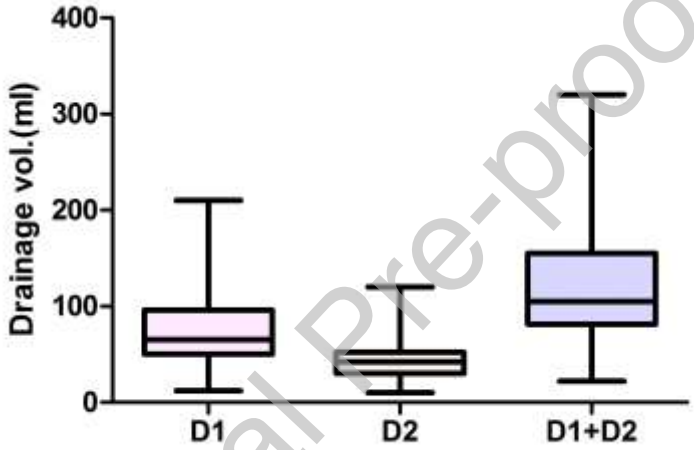


Figure 4: On the first day (D1), the volume drainage ranged from 12 ml to 210 ml (mean= 74.90 ml. SD= 43.29 ml). The second day (D2), the collected volume ranged from 10 ml to 120 ml (mean= 44.76 ml. SD= 24.80 ml). The total of drainage volume in 48 hrs. ranged from 22 ml to 320 ml (mean= 119.7 ml. SD= 62.20 ml). there was a decreased drain flow between first and second day (*pv*< 0.0001)

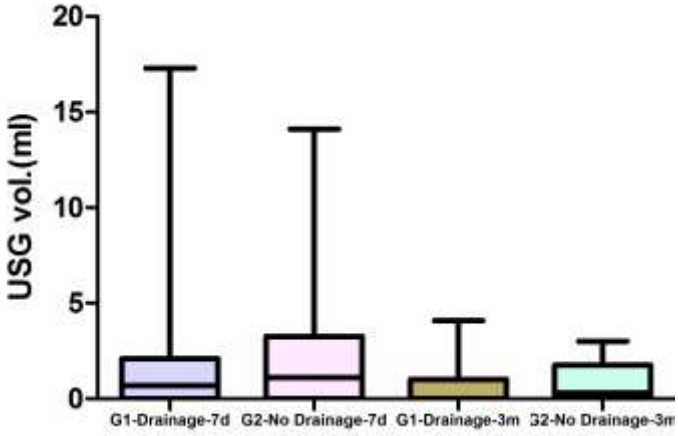


Figure 5: Breast ultrasonography(BUSG) in 7th post-operative day in both groups showed a similar volume profile liquid in the implant pocket. Group1 ranged from 0 ml to 17.3ml (Mean= 2.5 ml; SD=4.36 ml). Group2 ranged from 0 to 14.10 ml (Mean= 2.4 ml; SD=3.6). BUSG in 3° month post-op: Group1 ranged from 0 ml to 4.1ml (Mean= 1.7 m; SD=1.8 ml). Group2: ranged from 0 to 3.0 ml (Mean= 0.82 ml; SD=1.2). The difference in the 7th POD and 3rd month between G1 and G2 has not been significant (*pv*=0.05 and 0.25, respectively).