Original Article

Early Seroma Treatment Protocol Based on US-Guided Aspiration in DTI Prepectoral Reconstruction: A Prospective Study

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Abstract

Seroma is a common complication after prepectoral prosthetic breast reconstruction with ADM, leading to wound dehiscence, infection and even loss of implant at last. We enrolled 406 patients who underwent mastectomy and 1-stage prepectoral reconstruction with ADM in which we applied a new US-protocol through which we were able to promptly manage and treat seroma, decreasing additional complications rate, particularly wound dehiscence

Introduction: Seroma is a common complication after prepectoral prosthetic breast reconstruction with ADM, leading to wound dehiscencse, infection, and even loss of reconstruction at last. A new ultrasound (US) guided follow-up protocol has been applied to compare primary and secondary complications incidence and their treatment, and evaluate the effect of precocious seroma detection and its evacuation in reducing secondary complications. **Methods:** We enrolled 406 patients from January 1st, 2021 to July 1st, 2023 who underwent mastectomy and 1-stage prepectoral reconstruction with ADM. Experimental group counted 96 patients, whom have been treated as protocol fashion, therefore with multiple US-guided evaluations and eventual evacuations along with postoperative period; control group (310 patients) has exclusively been clinically evaluated. **Results:** Seroma incidence detected rate among experimental group, after 1-year follow-up, was 32.2%, compared to 16.8% in control cohort, additionally no other secondary complications were detected in the first group. Referring to the wound dehiscence incidence, a statistically significant higher frequency was observed in control group compared with treatment 1 (21.2% vs. 0%; $P = .0027$). **Conclusions:** Seroma and correlated secondary complications may lead to additional surgeries, higher sanitary costs and even reconstructive failure. With a seriated US follow-up protocol application, the surgeon could promptly manage and treat seroma, decreasing additional complications rate, particularly wound dehiscence.

Level of Evidence: III.

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Introduction

Direct-to-implant (DTI) prepectoral prosthetic breast reconstruction with acellular dermal matrix (ADM) has many advantages, the most appreciated are: natural breast shaping and ptosis, more defined inframammary fold and proper breast contour.[1,2] In addition, operative time is slightly reduced, such as postoperative pain, discomfort, and bleeding.[3] Moreover, there is no risk of animation deformity or reduction in shoulder range of motion.[4,5]

On the other hand, as commonly seen, there are no positive aspects without the negative counterparts.[6-8] In literature few clinical studies claimed higher postoperative complications rate when ADMs are applied.[9] Particularly early ones have been described as more frequent: seroma, hematoma, infection, dehiscence of surgical site and loss of implant. Native skin necrosis is probably the

The study was conducted according to the guidelines of the Declaration of Helsinki, *and approved by the Institutional Review Board.*

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most severe early complication which may happen but it is considered more related to an aggressive mastectomy procedure rather than a reconstructive fault. Shortly afterwards comes seroma which appears to be the most frequent 1 and represents itself a risk factor promoting the other complications. Therefore, these may be seen as secondary occurrences.[10,11]

Despite seroma is not the most severe complication in reconstructive breast surgery, it could lead to reconstruction loss, with huge psychological impact on already fragile patients.[12] Furthermore, a prolonged antibiotic administration, additional surgeries and hospitalization, adjuvant chemotherapy delay and additional costs may be associated. Overall, it results in a poorer prognosis and lower patient satisfaction.[13]

Nowadays, there is none common strategy in managing seroma in a 1-stage prepectoral reconstruction with ADM setting, nor in facing and preventing its related secondary complications.[14-16] Several studies have already explained various possibilities in seroma treatment with multiple aspirations, performed with ultrasound (US) guidance or blind. These studies specifically focus on the aspiration technique and are mainly dealing with tissue expanders (TE) in aesthetic breast surgery or breast reconstruction.[8,17] Treating seroma with a definitive implant underneath needs a completely different approach, more focused in preventing a major seroma, implant damage, and secondary complications .

Literature does not provide a standardized protocol for seroma treatment in these cases; our study proposes the application of a new US guided follow-up protocol for patients undergone 1-stage prepectoral reconstruction with ADM, aiming to evaluate, find and precociously treat seroma occurrence with seriate US guided evacuations.[18]

The purpose of this study is to evaluate the impact that the new US guided follow-up protocol has on the incidence of seroma-related secondary complications such as surgical site dehiscence, surgical site infection and loss of implant.

Materials and Methods

This multicentric prospective study was conducted at the Plastic and Reconstructive Surgery Units of Azienda Sanitaria Universitaria Giuliano Isontina (ASUGI) in Trieste (Italy) and Azienda Sanitaria Universitaria Friuli Centrale (ASUFC) in Udine (Italy) over a one and half year period, from January 1st, 2021 to July 1st, 2023. The study has been performed in full accordance with the Helsinki declaration, and an informed consent was obtained from each patient who enrolled in the study.

The study includes all patients who underwent mastectomy and DTI reconstruction with ADM between January 2021 and March 2022, in our institutions. We enrolled 410 female patients, who underwent DTI reconstruction with ADM after mastectomy—both for breast cancer or risk-reducing surgery in BRCA1/2 patients. Reconstructive surgery has been performed using definitive mammary prothesis (CPG Gel Breast Implant Cohesive III, Mentor Medical Systems, Irvine, CA) with ADM completely positioned in a prepectoral plane. Porcine derived non-cross-linked ADM (Braxon Decomed S.r.l., Marcon-Venezia, Italy) has been used in this study.

The exclusion criteria were: missing data in health documentation, inflammatory breast cancer, autologous reconstructions, DTI reconstruction without ADM, TE reconstruction, mastectomy without any reconstruction, cutaneous necrosis needing surgical revision, BMI>30, untreated diabetes.

DTI reconstruction technique applied consisted of placement of definitive prepectoral implant with ADM (Braxon® Decomed S.r.l., Marcon-Venezia, Italy), using the "ravioli" coating technique (100% of the implant is covered) with muscular and mastectomy flaps fixation for the latter.[19] A single drain was positioned at the inframammary sulcus and left until less than 30 mL/24 hours output was observed for at least 2 consecutive days. Nevertheless, no drain was kept for more than 21 days.

Experimental group was prospectively enrolled, control group derives from a retrospective evaluation of our datasets.

Follow-up US protocol has been applied on experimental group—as properly explained in the article—with first US examination 7 days after drain removal and, if no seroma is detected, seriated US controls every 7 days for 30 day. In case of liquid collection detected, US guided aspiration is performed after proper quantification and measurement on images, collected liquid is then analyzes in case of infection suspect. Patient then undergoes seriated aspirations every 7 days until no liquid is found at 2 examinations in a row (Figure 1).

Among control group clinical examinations are not US guided; controls have been performed after 2 weeks from surgery—for stitches removal—and after 1-month, anticipation in case of need.

All data acquired during patients' follow-up evaluation are entered into a specific database, including possible complications (Surgical Site Infection, Dehiscence, Implant Removal, Reoperation) that may have occurred during the first 6-months after surgery.

For each patient has been evaluated how protocol application influences seroma related complications onset, thus infection, wound dehiscence, and loss of implant.

A statistical analysis with Fisher's exact test was performed to evaluate the homogeneity of the 2 groups in terms of demographic characteristics (age, body mass index [BMI], comorbidities, smoking status, radiotherapy, chemotherapy).

The statistical analysis was also performed and completed for both the cohorts using the Student *t* test (SPSS statistics 20 software (IBM Corp, New York, NY).

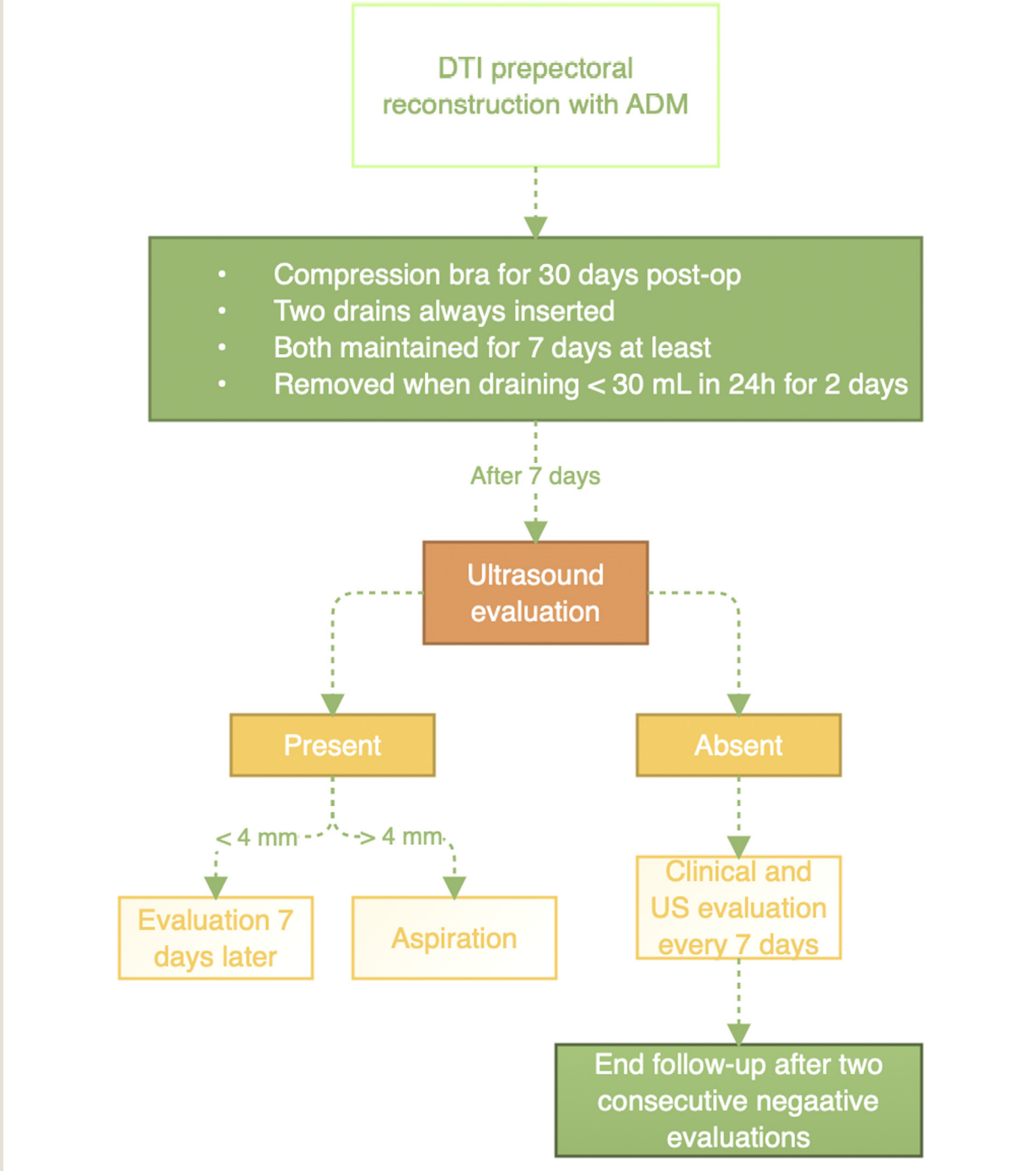
Results

The study examined 406 patients, 96 of which were enrolled with the application of experimental protocol - that envisaged the execution of multiple postoperative USs scans - while 310 were enrolled as control group, which envisaged exclusively clinical controls.

All the patients' variables examined are properly listed in Table 1. No significant demographics differences existed between the 2 groups of patients for the variables of age at mastectomy, history of preoperative breast radiation or chemotherapy, BMI, diabetes, or history of smoking.

In the experimental group 31 seromas were detected in 96 patients (32.2% of incidence). No seroma recurrence was reported, as well as no secondary complications such as surgical wound dehiscence, surgical site infections, re-intervention, and implant loss. No major complications were encountered.

Figure 1 Algorithmic approach for an early treatment of seroma.



In the control group 52 seromas were detected with clinical exam in 310 patients (16.8% of incidence). In this group of seroma patients managed with clinical examination, there were 11 wound dehiscence (21.2% of incidence), 3 infections (5.8% of incidence), and overall, 2 implant losses (3.9% of incidence). Taking into consideration the patients who developed seroma, the rates of secondary complications arising in the experimental group and in the control, one was compared. Referring to the wound dehiscence incidence, a statistically significant difference was observed in the

Figure 2 Patient who underwent nipple-sparing mastectomy and DTI prepectoral reconstruction with ADM: left - 12-day postoperative picture, clinically no seroma detection and removal of the last drainage; center - 20-day postoperative with seroma; right - 3-month postoperative after seriate drainage and seroma resolution.

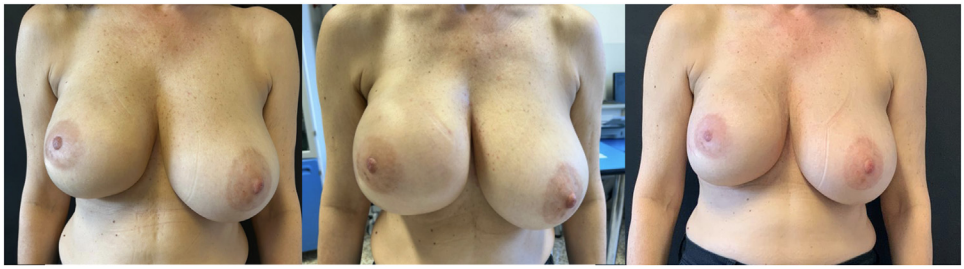


Table 1 Population Description

Characteristics	Mean or Count	
	Ultrasound Protocol	Clinical Exam
Age	52.4	57
BMI (Kg/m^2)	23.3	23.9
Comorbidities		
Hypertension	22	59
Hashimoto t.	9	17
Psoriasis	5	4
FA	3	33
Connectivity's	3	11
Current smoker	24	52
Diabetes	10	23
Excised gland weight (g)	241	345
Implant volume (mL)	328	375
Type of mastectomy		
Skin-sparing	20	82
Nipple-sparing	61	175
Skin-reducing	15	53
Premastectomy radiation	2	7
Postmastectomy radiation	12	24
Adjuvant chemotherapy	33	91
Neo-adjuvant chemotherapy	14	39

control group compared with the experimental 1 (21.2% vs. 0%; $P = .0027$). On the opposite, no statistically significant differences in infection rate (5.8% vs. 0%; $P = .09$). and loss of implant rate (3.9% vs. 0%; $P = .14$). between the 2 group was noticed. An example of successful seroma treatment was reported in Figure 2.

A significant reduction in seroma related complications (ie, wound dehiscence) has been shown with US protocol application. (Table 2)

Discussion

Implant-based breast reconstruction has grown fast in the last 10 years.[20] This procedure is really appreciated because is safe, timesaving and aesthetically satisfying. In particular, the new frontier in this field is direct-to-implant prepectoral procedure which allows to achieve a 1-shot definitive result and pectoralis major sparing. Moreover, prepectoral placement leads to higher patient satisfaction compared to subpectoral.[21-24] This would be an appealing solution, but it is surely not a 1-size-fits-all.[25-27] Thus, patient selection based on risk factor comprehension, is a cornerstone for successful outcomes.[26,28,29] Inadequate choices would lead to higher complication and failure rates.

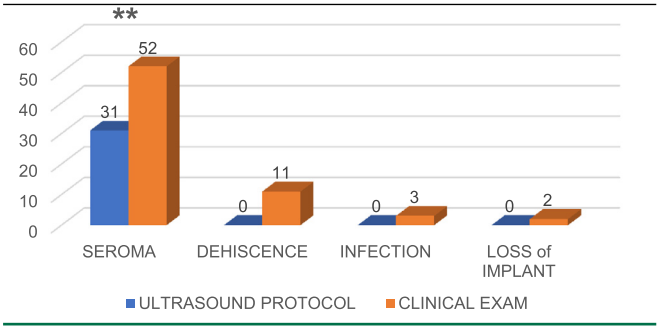
This selection must be assessed both preoperatively and intraoperatively. Heavy smoking, diabetes, high/low BMI, connective tissue diseases may be considered relative contraindication to prepectoral with ADM placement.[13,30,31] Moreover, a careful mastectomy flap vascular supply assessment needs to be performed in the operatory room before any definitive choice may be made.[32]

Within this background, seroma represents the most significant postoperative complication in breast reconstruction in terms of frequency and because it could determine itself other secondary consequences.[8,12,33] In this perspective ADMs, which are a main tool in DTI prepectoral reconstruction, appear to further increase seroma formation.[25,34] In a review of 34 studies published in 2016 the pooled incidence of seroma with ADM was found to be 6.7 percent, compared with 3.8 percent without ADM.[8] The same study evidenced then that ADM was associated with an increased relative risk for seroma of 1.83.

Three other published meta-analyses demonstrated a statistically significative association between seroma ad use of ADM as well: Chun et al. reported a 4.24-fold increase in the risk of seroma in the presence of ADM;[35] Antony et al.[36] in a comparative study which involved 153 case of breast reconstruction - demonstrated a seroma rate of 7.2% with ADM and 1.6% without; Parks et al.[37] with a retrospective study that included 346 patients - reported a seroma rate of 29.8% with ADM and 15.8% without. Seroma in an ADM setting is even more worrisome because could lead to inappropriate matrix integration which, when extended, needs a surgical revision.[38,39]

This may lead to prolonged hospitalization, costs, infections adding the possibility of reconstruction loss which could be really devastating for the patient itself.

Table 2 Blu Columns—Treatment Group; Red Columns—Control Group. Even if Treatment Group is Clearly Smaller Than Control We are Able to Appreciate Higher Seroma Detection Rate But no Complication Thanks to Early Seroma Treatment Approach



Because of these reasons seroma must be prevented, early diagnosed, and rapidly treated. To set up an effective protocol a step back to basics needs to be done.

Seroma formation is still a quite poorly known process. In general, our body tents to fulfill dead spaces with fluids, but seroma do not appear to be just due to extravasation.[40,41] Cytological analysis of seroma fluid has generated various hypothesis from being an inflammatory exudate to lymph. Bonemma et al. evidenced a low cell content, low protein levels and no fibrinogen, but in literature various fluid compositions are described. Probably the answer stays in the middle: seroma is having a multifactor pathophysiology.[40,42] Although some major causes may be detected: (1) inflammation; (2) lymphatic disruption. The inflammatory process is somehow unavoidable because electrocoagulation damage, foreign body reaction due to implant placement, postsurgical inflammatory stimulus and hypovascular environment are on 1 hand fundamental to perform the reconstruction and on the other hand main seroma causes.[41,43] Similarly, lymphatic disruption (surgical trauma, axillary dissection, and sentinel lymph node) is part of the oncological treatment.

Seroma needs to be prevented as much as possible limiting these elements but, above all, rapidly treated to reduce secondary drawbacks.[8,12]

Patient developing a clinically noticeable seroma, undergo a significative higher risk of additional complications as largely demonstrated in current literature. In a series of 1605 prosthetic breast reconstructions and 48 seromas, a major infection occurred in nearly one-fifth of patients with seroma (18.8%), with a 4.01-fold increased risk ($P < .05$). Despite aggressive management with aspiration and prophylactic antibiotics 7 of 9 infected expanders required implant removal (risk increased by 6.71 times, $P < .05$).[35] Woerderman et al. estimated a seroma-related risk of implant loss of 4.28-fold (95%).[13] Similarly, Weichman et al. reported 5 of 10 breasts with seroma that were associated with infectious complications, resulting in a 6.38- fold seroma-related risk of infection.[44] Parks et al.[37] in their comparative study estimated, in the presence of seroma, an increased risk of implant loss of 4.56 times.

Scientific evidence on prevention and treatment of this complication are still weak and not systematically described. Innovative diagnostic approaches able to decrease the seroma clinical impact and more accurate treating scenarios are needed.[18]

Given all these, we proposed a prospective cohort study to evaluate our new US early treatment protocol for seroma in DTI prepectoral reconstructions with ADM. Even if in our institution multiple matrices are available, only one was included to reduce biases. The treatment group was prospectively enrolled. Drains were maintained for at least 10 days postoperatively and then removed when fluid drainage was less than 30 mL in 24 hours. Then, a first US is always performed 7 days after both drainages were removed. In case a relevant seroma was found a US-guided aspiration was performed. This procedure may be repeated every week until no relevant seroma was detected.

Our first interesting finding consists of a higher rate of seroma detection in the treatment group compared to control group (32.2% vs. 16.8%); among literature the incidence of seroma after prosthetic breast reconstruction varies from 0.2 to 20 percent.[8]

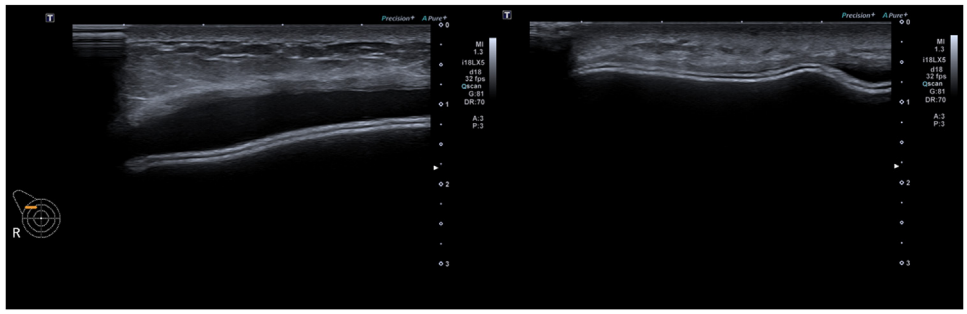
While rates of seroma in control group are fully in line with actual literature, incidence obtained with our protocol application shows a higher percentage.[6,33,34,45] This may be easily explained. US evaluation is a much more sensitive and specific tool to diagnose this complication. More accurate and early diagnosis leads to better treatment. Early aspiration of the liquid allows to remove the tissue adhesion obstacle and avoids tissue tensions on the already fragile mastectomy flap.[39]

In our study, wound dehiscence rate among seroma patients was 21.2% in control group while no dehiscence occurred with application of our early treatment protocol ($P = .0027$).

The possibility of seroma early detection, particularly with US protocol application, is therefore important both in seroma management and in reducing secondary complications such as dehiscence rate. Our cohort is still quite limited so there were no possibilities to evidence other complications decrease. Infection rate in larger group may be interesting because aspiration may be a path through which Gram-positive bacteria may enter. On the other hand, no infections occurred both in treatment and in control group, thus this variable could not be evaluated.

US exam evidenced to be a reliable and low-cost tool which precisely diagnose and quantify liquid collection. In Figure 3 US aspiration is represented. At the same time, it enables to immedi-

Figure 3 Seroma ultrasound (US) in implant-based reconstruction: left—before US-guided aspiration; right—after US-guided aspiration.



ately treat seroma through guided aspiration. It also allows to avoid implant injury. Early seroma treatment demonstrated to prevent secondary complications onset. Furthermore, this procedure itself has a fast-learning curve and is almost pain-free without local anesthesia need and has a low patient discomfort. In our opinion, this protocol may be applied to TE reconstruction. However, a blind suction with TE is safer rather than with an implant, therefore we considered US guidance an overtreatment. However, it could be an interesting training means before approaching a definitive implant US suction.

In conclusion, we reckon that the creation of a standardized postoperative protocol, implementing clinical exam with US evaluation, represents a key point for an effective seroma management.

This is a prospective pilot study which surely needs to be implemented and improved but would be a starting point. Undoubtfully some limitations are present: small sample size, nonblinded conduction, operator-dependent US technique and a low incidence complication rate; larger samples and longer follow up time would determine better and more accurate correlation between the application of US protocol and secondary seroma related complications reduction.

Conclusions

Seroma is still an open topic in our field. It surely represents one of the most frequent complications and, moreover, with ADM introduction it became even more relevant. Preventing this condition and its consequences is a priority.

Application of the proposed early postoperative US protocol in DTI prepectoral reconstruction with ADM would allow plastic surgeons to manage seroma occurrence actively and promptly, and, above all, preventing secondary complications which could also occasionally lead to final reconstruction failure. Particularly, lowering seroma related dehiscence, should also reduce secondary reinterventions, hospitalization, and healthcare costs.

Clinical Practice Points

- Direct-to-implant (DTI) prepectoral prosthetic breast reconstruction with acellular dermal matrix (ADM) has many advantages. On the other hand, as commonly seen, there are no positive aspects without the negative counterpart. Seroma, hematoma, infection, dehiscence of surgical site and loss of implant are the most see complications. Despite seroma is not the most severe complication in reconstructive breast surgery, it could lead to reconstruction loss, with huge psychological impact on patients.
- There is not a common strategy in managing seroma in a 1-stage breast prepectoral reconstruction with ADM setting, nor in facing and preventing its related secondary complications. Several studies have already explained various possibilities in seroma treatment with multiple aspirations, performed with ultrasound (US) guidance or blind. These studies specifically focus on the aspiration technique and are mainly dealing with tissue expanders in aesthetic breast surgery or breast reconstruction. Treating seroma with a definitive implant underneath needs a completely different approach, more focused in preventing a major seroma and secondary complications rather than treating it. US exam evidenced to be a reliable and low-cost tool which precisely diagnose and quantify liquid collection. In Figure 3 US aspiration is represented. At the same time, it enables to immediately treat seroma through guided aspiration. It also allows to avoid implant injury.
- Early seroma treatment demonstrated to prevent secondary complications onset. Furthermore, this procedure itself has a fast-learning curve and is almost pain-free without local anesthesia need and has a low patient discomfort.
- In conclusion, we reckon that the creation of a standardized postoperative protocol, implementing clinical exam with US evaluation, represents a key point for an effective seroma management.

Disclosure

The authors have stated that they have no conflicts of interest.

Patient Consent Statement

All patients gave consent for their photographs and medical information to be published in print and with the understanding that this information may be publicly available.

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