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Analysis of clinical management of infected breast implants and of factors associated to successful breast pocket salvage in infections occurring after breast reconstruction

Simonetta Franchelli[a,*], Marianna Pesce[a], Ilaria Baldelli[a], Anna Marchese[b,c], Pierluigi Santi[a], Andrea De Maria[d,e]

[a] SC Chirurgia Plastica e Ricostruttiva, Policlinico San Martino, Largo Rosanna Benzi 10, Genoa 16132, Italy
[b] UOC Microbiologia, Policlinico San Martino, Largo Rosanna Benzi 10, Genoa 16132, Italy
[c] Sezione di Microbiologia, DISC, Università di Genova, 16132 Genoa, Italy
[d] Clinica Malattie Infettive, Programma Infettivologia dell'Ospite Immunocompromesso Policlinico San Martino, Largo Rosanna Benzi 10, Genoa 16132, Italy
[e] Department of Health Sciences, University of Genova, 16132 Genova, Italy

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ABSTRACT

Objectives: Considerable efforts have been devoted so far to improve salvage procedures of infected breast implants in absence of defined guidelines or validated clinical protocols. Within a cohort of prospectively recruited patients who underwent breast reconstruction, we performed a retrospective review of proven implant infections in order to describe factors contributing to management success.
Methods: We collected data in 1293 consecutive patients who underwent two stage (expander + prosthesis) breast reconstruction with at least 12 months of follow-up. Demographic data, timing of infection, type of microorganism, intent of salvage, fate of the implant, type of antibiotic treatment and follow-up were recorded in a prospective data collection on clinical records.
Results: Implant infections occurred in 103 of 1293 patients (8%). Among these, 73 (71%) were proven infections with confirmed microbiology. Implant pocket salvage was attempted in 43/73 (59%). patients A higher proportion of expander implant pockets were successfully saved compared to prosthetic pocket (p = 0,04). Gram-positive microrganisms represented the majority of etiologic agents, with coagulase negative staphylococci prevailing over *Staphylococcus aureus*. No association was observed between success rate and type of infecting microorganism. A higher proportion of patients with previous or intraoperative radiotherapy or with perioperative chemotherapy underwent an attempt of implant salvage (p = 0,081 and 0,0571 trend, respectively). No single antibiotic regimen was superior to the others in terms of success rate. Implant pocket salvage was higher in expanders compared to prostheses (74% vs 33% p = 0,04). Higher success rates in implant pocket salvage were evident when implant replacement was preceded and followed by antibiotic treatment compared to inpatient antibiotic treatment alone (100% versus 57%, p = 0,035).
Conclusion: Patient selection in clinical practice leads to differences in patients with breast implant infection who are considered for attempts at implant salvage vs. those who are treated with implant removal. Salvage of breast implant pockets can be obtained in the majority of patients with combined one-step implant replacement surgery and antibiotic treatment. Increased efforts and protocols to recruit patients into pocket salvage management are needed.

Introduction

Implant-based breast reconstruction is the most common surgical option for women with breast cancer and post-mastectomy breast defects. Among a long list of possible postoperative complications (Georgiade et al., 1982; Schuster

* Corresponding author at: Plastic and Reconstructive Surgery Department, Policlinico San Martino, Largo R. Benzi 10, Genoa 16132, Italy.
E-mail addresses: simonettafranchelli@yahoo.it (S. Franchelli), mariannap86@hotmail.com (M. Pesce), ilaria.baldelli@unige.it (I. Baldelli), anna.marchese@unige.it (A. Marchese), plsanti@unige.it (P. Santi), de-maria@unige.it (A. De Maria).

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et al., 1990; Pusic and Cordeiro, 2003), implant infection represents a devastating event for the patient and a discouraging situation for the surgeon. Infection after implant-based reconstruction occurs at a mean rate of 8% (1–35%) and may vary according to clinical setting and type of procedure (Armstrong et al., 1989; Cordeiro and McCarthy, 2006; Nahabedian et al., 2003; Spear et al., 2004; Franchelli et al., 2015).

Over recent years, a consistent clinical focus targeted risk factors associated to post-implant infection, causative microorganisms isolated from infected implants (Brand, 1993; Rieger et al., 2013; Reish et al., 2013; Momoh et al., 2014; Kronowitz and Robb, 2009), and prevention (Barr et al., 2016). Once breast implant infection is detected, there is general clinical agreement that antibiotic treatment should be provided and, most importantly, that attempts should be made to ultimately salvage the implant. There is a considerable degree of disagreement, however, on the definition of implant salvage and on standardized clinical management. Indeed, “implant salvage” this may include salvage either of the aesthetic reconstructive result (Rieger et al., 2013; Spear and Seruya, 2010), of the implant pocket, or of the original implant itself (Wilkinson et al., 1985).

Similarly widely diverging views and clinical approaches exist on optimal clinical management aiming at implant salvage. Standard management of breast implant infection combines implant removal with antibiotic treatment followed by delayed positioning of a new implant weeks-months after antibiotic treatment of the previous infected pocket (Armstrong et al., 1989). This approach requires multiple surgical procedures (e.g., 1 removal, 1 insertion) with proportionally increased associated risks and costs. In addition, in some of these instances, the delayed implant re-insertion may be technically more difficult due to pocket resorption and tissue fibrosis (Reish et al., 2013).

Considerable effort has been devoted to improve salvage procedures minimizing the waiting time between implant removal and reimplantation. Several protocols proposed by North American and European groups may allow tissue debridment and implant replacement during the same surgical procedure including systemic empiric antibiotic therapy with wound drainage (Courtiss et al., 1979), pre- and postoperative antibiotic therapy with capsulotomy wound irrigation and implant replacement (Weber and Hentz, 1986) or irrigation of implant pocket with saline solution combined with antibiotic therapy and implant exchange with or without capsulectomy (Chun and Schulman, 2007; Laveaux et al., 2009; Prince et al., 2012; Missana et al., 2012). The mentioned series are uncontrolled studies on a mix of proven and possible infections (i.e. without microbiological isolation) with overall limited number of patients and with highly variable and sometimes limited follow-up (i.e., 1–6 months).

When considering actual infections, Staphylococci are the predominant cause of breast implant infection. Empiric initial treatment is based on this fact and on the relative local prevalence of methicillin-resistant staphylococci. Gram negative microorganisms are detected in a minor proportion of cases, are addressed by current guidelines for SSI (surgical site infection) prophylaxis (Berrios-Torres et al., 2017) and, when present may be associated with lower rates of device salvage (Spear and Seruya, 2010; Franchelli et al., 2012).

In view of the present paucity of structured indications for management and treatment and of the need to improve our clinical approach to patients with reconstructive breast implant infection, we performed a retrospective review on breast implant infections and of implant salvage procedures at our center. This analysis shows that there are discrepancies in patient selection and in outcome when an unstructured approach of antibiotic treatment and surgery is active.

Patients and methods

Between February 1st 2009 and June 30st 2015, 1293 consecutive patients underwent two-stage (expander + implant) immediate or delayed implant reconstruction after mastectomy or implant replacement at the Policlinico San Martino in Genoa. Clinical data of all patients at our institution are kept on record. Written signed consent for data use for clinical purposes was obtained from all the patients, according to approved institutional policy. The present work is a retrospective elaboration of institutional record data.

Implant infection was defined as previously described (Franchelli et al., 2012). Briefly, criteria for possible infection included: fever, minimal local edema and inflammation; probable infection was defined by cellulitis, leukocytosis, systemic inflammation, echographic evidence of inflammation or peri-prosthetic liquid accumulation without microorganism isolation. Proven infections are defined by the presence of purulent discharge and/or microorganism isolation in addition to other clinical signs. Implant infections are further subdivided into “early” (<60 days from surgery, DFS) and “late” (>60 DFS) infections (Franchelli et al., 2015).

Patients were censored at a post-operative follow-up of at least 12 months, in order to include late infections (i.e. occurring >180 DFS).

All patients underwent surgery by the same surgical team. The same type of expander and prosthesis was used (Allergan, Marlow International, Parkway, United Kingdom). Expanders and prostheses had the same textured surface (Biocell: Allergan, Marlow International, Parkway, UK) and external envelope structure (Intrashiel: Allergan, Marlow International, Parkway, UK) made by three overlapped layers of silicone rubber. Expanders were positioned in a submuscular pocket after mastectomy, and progressively inflated; prostheses were positioned as a replacement of a previous expander after its inflation or during a contralateral augmentation mammaplasty. Antibiotic prophylaxis using Cefazolin 14–20 mg/kg (1 g followed by 2 doses q8 h) was always administered. In patients allergic to beta-lactams (surgeons ASop, 2018; Phillips et al., 2016) Clindamycin was used.

The following patient data were collected: age, tumor stage and recurrence, chemo/radio–therapy, type of implants, timing and clinical appearance of infection, type of microorganism, intent of pocket salvage, fate of the implant (removal or salvage), type of antibiotic treatment, follow-up after implant salvage.

We defined as “perioperative chemotherapy” any chemotherapy performed around breast reconstruction surgery either before or after the procedure.

Standard management options for patients with proven implant infection were: (i) implant removal and antibiotic treatment, (ii) attempt of implant pocket salvage with antibiotic treatment alone, (iii) combined implant replacement. Implant removal without any pocket salvage attempt is considered at our Center whenever at least one of the following conditions is present: implant exposure following cutaneous subcutaneous necrosis, cutaneous fistula, extensive inflammation with intense redness, pain and edema involving ≥3 breast quadrants.

Clinical record analysis was used to identify all those patients who were considered for an attempt of implant pocket salvage (“intent of salvage”). Patients for whom no prospective intent was stated in the clinical record were defined as “salvage intent unknown” and were included in the group “no intent of salvage” (Figure 1).

Successful salvage of the surgical implant was defined as retention of the implant for ≥12 months after surgery. Cultures from multiple sites including wound, drainage fluid, periprosthetic seroma, capsular tissues and the prosthetic material itself, when removed, were performed to identify the infecting

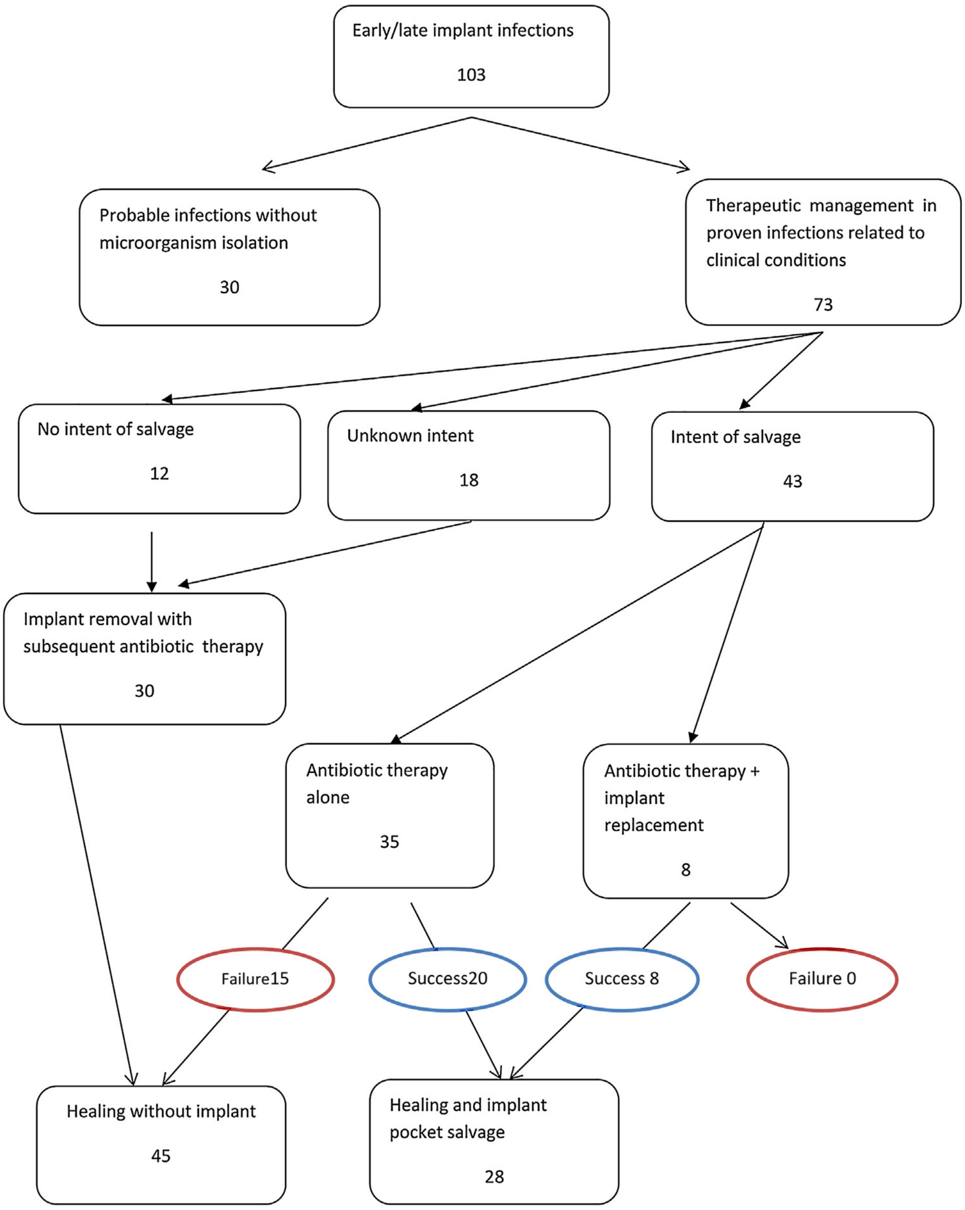

Figure 1. Therapeutic management in early and late infections.

pathogens. Susceptibility testing was performed using the Vitek 2 AES automated system (bioMerièux, Marcy-l'etoile (France) and interpreted according to EUCAST standards (EUCAST, 2018).

Antibiotic treatment was administered for 10–12 days. When combined with debridement and implant replacement (Antibiotic treatment and Implant Replacement, AIR) based on available microbiological isolate sensitivity, surgery for implant replacement was performed 3–4 days after onset of antibiotic treatment.

Surgical procedures during combined salvage management included capsular debridment up to capsulectomy, depending on breast tissue thickness, and implant pocket irrigation with saline solution. A complete exchange of surgical instruments/towels and surgical coats was performed during the procedure before implant replacement accompanied by patient disinfection.

To evaluate group differences, statistical analysis was performed employing two-sided tests as required (JMP 10.0 Statistical software, SAS Institute Inc. Mann). Chi-square analysis, Fisher's exact test and Mann–Whitney test were performed as appropriate to test for differences between groups.

Results

Patient management and salvage attempts.

Implant infections were observed in 103 of 1293 patients (8%). Among these patients, 73 (71%) had proven infections (PI) (Figure 1). Patients without microbiologically confirmed infection were excluded from further analysis since management and clinical outcome in these cases cannot be linked to a specific microorganism(s) or to true infection. We next analyzed the clinical management of these 73 patients with microbiologically confirmed PI. Implant pocket salvage attempts were performed in 43 of 73 patients (59%), while 30 cases (41%) underwent implant removal followed by antibiotic treatment due to extensive cellulitis and/or overwhelming breast implant infection (Figure 1). No associations were detected between age, tumor stage, type of implant and infection staging defined both as time after surgery and as type of infection based on microbiological identification (Table 1). A higher proportion of patients with previous or

Table 1
Demographic data of proven breast implant infections.

	Proven Infections (n = 73) Salvage intent			Significance
	Tot N	No N (%)	Yes N (%)	
N°	73	30	43	
Mean age	54	52	55	ns
Stage 0	3	3 (10)	0	ns
Stage 1	10	2 (7)	8 (19)	ns
Stage 2	19	7 (23)	12 (28)	ns
Stage 3	18	10 (34)	8 (19)	ns
Unknown stage	4	1 (3)	3 (7)	
Relapse or recurrence	19	7 (23)	12 (28)	ns
Radiotherapy (1)	26	6 (20)	22 (51)	P = 0,0081
Chemotherapy (2)	41	21 (70)	20 (46)	P = 0,0577
Expander	61	27 (90)	34 (79)	ns
Prosthesis	12	3 (10)	9 (21)	ns
Early infection	49	19 (64)	30 (70)	ns
Late infection	24	11 (37)	13 (30)	ns
Probable infection	0	0	0	
Proven infection	73	30 (100)	43 (100)	

(1) Previous or intraoperative; (2) Perioperative Chemotherapy (pre-infection); n.s.: not significant; Tot: total; (%) proportion of patients with a given parameter according to salvage intent.

intraoperative radiotherapy (IORT) or perioperative chemotherapy underwent an attempt of breast implant pocket salvage (p = 0,081 and p = 0,0571 trend, respectively).

Outcome of salvage attempts according to patient characteristics and to microbiological isolate

We next stratified patients according to the outcome (success vs. failure) of clinical management in those who underwent clinical attempts at implant pocket salvage. As shown in Table 2, there was no association between outcome and age, tumor stage, relapse and radio- or chemotherapy nor with time of infection after surgery (early vs late infections). A higher proportion of expander implant pockets were successfully saved compared to prosthetic pocket (p = 0,04). This difference was independent from the onset of infection after surgery both in terms of early vs late onset with a limit set at 60 days from surgery (Table 2) as well as in terms of absolute number of days from surgery to infection (p = 0,161n.s.)

Among 85 microbiological isolates obtained from 73 patients with PI, the vast majority were Gram positive microorganisms (83%). As shown in Figure 2 staphylococcal infections largely prevailed over Gram negative infections (65/85, 76,5% vs 13/85,

Table 2
Clinical parameters in patients with proven infections who underwent salvage attempts of implant pocket according to infection outcome.

	All infections	Success	Failure	Significance
N° 43	43	28 (65)	15 (35)	
Mean age		57	52	ns
Stage 0	0	0	0	
Stage 1	8	6 (75)	2 (25)	ns
Stage 2	12	9 (75)	3 (25)	ns
Stage 3	8	4 (50)	4 (50)	ns
Unknown stage	3	2 (67)	1 (33)	
Relapse or recurrence	12	7 (58)	5 (42)	ns
Radiotherapy (1)	22	12 (55)	10 (45)	ns
Chemotherapy (2)	20	13 (65)	7 (35)	ns
Expander	34	25 (74)	9 (26)	P: 0,04
Prosthesis	9	3 (33)	6 (67)	
Early infection	30	22 (73)	8 (27)	ns
Late infection	13	6 (46)	7 (54)	ns

(1) Previous or intraoperative radiotherapy; (2) Perioperative Chemotherapy (pre-infection); n.s.: not significant.

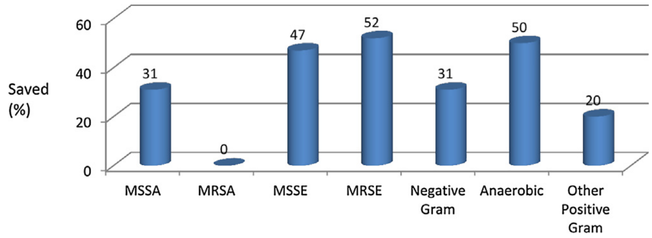

Figure 2. Proportion of saved implant pockets stratified by causative microorganisms.

15,3%). Among thesestaphylococci, 49% were represented by methicillin sensitive cocci. Higher proportions of coagulase negative cocci compared to *Staphylococcus aureus*, (43% vs 34%, respectively) were isolated from capsular tissue and peri-prosthetic fluid.

Clinical management and outcome of infection

In order to verify whether successful treatment of breast implant pocket could be associated to the type of causative microorganism we next stratified the isolates by treatment outcome.

Among staphylococcal infections a trend towards a higher rate of successful salvage was recorded for Coagulase Negative Staphylococci when compared to *S. aureus* infections with 18/36 vs 8/29 successful treatments, respectively (p = 0,0798). In addition a much lower proportion of infections were due to MRSA when compared to MSSA (3,5% vs 30,6%).

These data confirm previous observations showing Staphylococci (Brand, 1993; Barr et al., 2016) as the main aetiologic agents in breast implant infections, albeit these reports had higher proportions of *S. aureus*. Here, indeed, a prevalence of Coagulase-negative staphylococci over *S. aureus* emerges and confirms previous reports at our clinical site (Armstrong et al., 1989; Franchelli et al., 2015).

Since factors associated to the outcome of an infection may be related to the host, to the microorganism or to the choice of antibiotic/clinical management, we next studied the antibiotic regimens administered to the patients together with their surgical management. Overall, a high number of different antibiotic regimens, according to the choice of molecule(s), dosage and duration of administration that were administered to the 43 patients for whom an attempt of implant salvage was performed. Eight of these patients also underwent combined surgical replacement of the implant (Figure 1). Antibiotic regimens were grouped into 4 groups based on antibiotic class composition and are shown in Table 3. While none of these 4 regimens was superior to the others in terms of implant salvage success rate, a significantly higher proportion of success was detected when the clinical management that included systemic antibiotic administration and surgical removal (AIR) was compared to antibiotic treatment alone (8/8,100% vs 20/35, 57%respectively, p = 0,035).

Discussion

The present work analyzes the management of proven infected implant-based breast reconstructions and treatment strategies in a single-center unit within the frame of everyday clinical practice after stratification of outcome (salvage vs. failure) to retain implant pocket.

Proven infections represented the majority of all the infections cared for (71%). A relevant proportion of patients with PI (n 30 or

Table 3
Comparison between implants saved using antibiotic therapy plus implant replacement and implants saved using antibiotic therapy alone.

	Success		Failure		Significance
	Antibiotic	Antibiotic and replacement	Antibiotic	Antibiotic and replacement	
βlactam ± inhibitor o ± clindamicin	13	1	6	0	ns
Glycopeptide ± rifampicin/trimethoprim-sulfamethoxazole	3	1	3	0	ns
Levofloxacin	1	1	0	0	ns
Daptomicin + rifampicin	3	5	6	0	ns
Total	20	8	15	0	p = 0,035

NS: not significance.

41%) did not undergo an attempt to rescue the implant, and were managed with immediate implant removal and antibiotic treatment. We observed that exclusion from pocket salvage attempts was associated with current chemotherapy, while the reverse was observed for radiotherapy. Therefore, in addition to the local extent of the infection the need to undergo chemotherapy early after breast reconstruction represents a compelling element that conditions clinical management of these patients. Accordingly, the need for chemotherapy after breast implant-based reconstruction not only represents an established risk factor for infection (Reish et al., 2013; Yii and Khoo, 2003), but also negatively affects the subsequent management once breast implant infection occurs.

When considering the group of patients who were managed with an attempt at implant pocket salvage an overall success rate of 65% was recorded. It should be noted that we included also patients with implant skin exposure and also excluded unproven infections to avoid a bias of overstating the effect of treatment in sterile sites (Spear and Seruya, 2010; Chun and Schulman, 2007; Prince et al., 2012; Missana et al., 2012). Therefore, the observed overall rate of implant pocket salvage is encouraging compared to other reports (Spear and Seruya, 2010; Bennett et al., 2011) and represents a positive outlook for everyday practice in proven implant infections.

Interestingly within this frame, a significantly increased success rate was recorded (100% vs. 57%), when combined antibiotic treatment and implant replacement (AIR) was compared with systemic antibiotics treatment alone. This higher success rate compared better to other reports (Spear and Seruya, 2010; Yii and Khoo, 2003; Bennett et al., 2011; Albright et al., 2016; Meybodi et al., 2015).

When compared to more invasive management (e.g. removal and delayed reconstruction) requiring repeated hospitalization, AIR has the advantage of decreased hospitalization, decreased surgical procedures (1 procedure vs. repeated procedures), and may allow for the prosecution of chemotherapy. Indeed successful infected implant salvage with AIR just anticipates the positioning of the definitive prosthesis/implant without additional medical and economic burdens.

In view of the greater success rate in implant pocket salvage, which was observed for attempts performed on expanders as compared to definitive prosthetic devices and unrelated to an increased exposure to CT or RT, earlier referral or self-referral or close follow-up of patients with prosthetic devices could be advised.

In line with other series (Spear and Seruya, 2010; Chun and Schulman, 2007) we here detected a wide spectrum of microbiological flora in infected implants including anaerobes, Gram negative rods, *S. aureus* and coagulase negative Staphylococci. Isolates were not associated to different rates of salvage failure. A comparable success rate of treatment was observed for *Staphylococcus epidermidis* infections (both methicillin sensitive and resistant) compared to *S. aureus*. Overall, however, coagulase negative Staphylococci represented significantly more common infecting agent compared to *S. aureus* in agreement with previous reports (Franchelli et al., 2015; Prince et al., 2012). Methicillin resistance was not a factor negatively affecting the possibility to rescue the implant pocket and successfully treat the patient. This is in contrast to previous reports (Prince et al., 2012; Bennett et al., 2011), where however a very high number (33–70%) of unproven infections were included, thus possibly overestimating failures in the presence of methicillin resistant cocci. In view of the high proportion of isolates from proven infections that were not covered by the antimicrobial spectrum of the prophylactic antibiotics, the recommendation for a change of antibiotic agent may be indicated according to previous observations and current recommendations (Berrios-Torres et al., 2017; Feldman et al., 2010). The limited number of Gram negative infections (18%), on the contrary, may not need additional changes in prophylactic treatment, but rather should be considered for guiding initial empiric treatment with culture results pending.

None of the antibiotic regimens evaluated here showed any outcome advantage, in line with the wide dispersion of treatments and with the design of the study that was not suited to the purpose. Since there are to our knowledge no studies or recommendations on antibiotic treatment in patients with breast implant infection (Phillips et al., 2016; Feldman et al., 2010), this identifies the need for clinical focus in future work.

According to the present observations of high rates of MRSE and Coagulase-negative Staphylococci and of possible Gram negative presence, empiric treatment pending cultures of surgical samples could best include piperacillin/tazobactam and an anti-staphylococcal agent active on Coagulase negative Staphylococci and MRSA.

The present analysis is limited by its retrospective and uncontrolled design. Controlled studies using standardized clinical management will be needed to verify the present observations. On the other hand, the present limits and bias also provide a useful insight into the pitfalls of unstandardized clinical practice and outline the need for a more standardized approach to clinical management of breast implant pocket infections in cancer patients. On the other hand, even with these limitations, the study has the novelty of addressing some points that have been so far neglected in clinical practice. There is a general lack of comprehensive analyses on the actual management of these patients in everyday life in conditions where structured management, advice or specific protocols are not available. In this respect the present data represent a first-in-kind with several points of novelty over previous experience on identification and management of infected breast implants. Indeed the present study far from representing a single-surgeon series, includes all the patients that were sequentially seen at a single large center by a team of independent reconstructive surgeons. The study uses a careful classification of infection, includes only microbiologically proven infections in the analysis, and performs for the first time a detailed analysis of everyday management decisions and outcome.

In conclusion, based on the present analysis, implant pocket salvage of proven implant infections after breast reconstruction represents a possible option for the majority of patients. Future prospective work will be needed to avoid clinical bias in recruitment of eligible patients and to further improve and simplify treatment protocols.

Conflicts of interest

All authors concurred to the work and approved the manuscript. There are no conflicts of interest for all authors actual or potential. No outside funding was received.

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