Is antibiotic prophylaxis in breast augmentation necessary? A prospective study

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BACKGROUND: The role of prophylactic antibiotics in breast augmentation remains controversial. However, the majority of surgeons are administering antibiotics.

OBJECTIVE: To investigate the effect of antibiotic(s) use in the incidence of infection and capsular contracture following breast augmentation.

METHODS: From September 2004 to November 2010, 180 patients underwent primary bilateral breast augmentation. They were prospectively divided into two equal groups: in group A (n=90), no antibiotics were given and, in group B (n=90), only one intravenous dose of cephalosporin was administered during the induction of general anesthesia. Preoperative data included age, body mass index, smoking status, medical history and implant volume. All operations were performed by the same surgeon using the same surgical technique and implant type. No drains were used. Operative data included operative time and estimated blood loss. Patients were evaluated for complications such as infection, hematoma and capsular contracture. The study concluded when all of the patients underwent the one-year follow-up. The Student's *t* test was used to analyze the results.

RESULTS: All patients completed the study and both groups had similar demographic data. No differences in operative data were observed. The mean operative time was 35 min and the mean blood loss was found to be minimal. In group A, no implant infections were reported, while a wound infection that occurred was treated successfully with oral antibiotics. In group B, no implant or wound infection was noticed. No capsular contractures or hematomas were observed.

CONCLUSIONS: The number of patients who underwent primary breast augmentation without antibiotics (n=90) was insufficient to draw any definitive conclusions. However, the present prospective study demonstrated that prophylactic use of antibiotics in breast augmentation had no significant effect on infection and capsular contracture rates. Further randomized clinical trials, in combination with guidelines from aesthetic plastic surgery societies, appear to be warranted.

Key Words: Antibiotics; Breast augmentation; Implants; Infection

La prophylaxie antibiotique est-elle nécessaire en cas d'augmentation mammaire? Une étude prospective

HISTORIQUE : Le rôle de la prophylaxie antibiotique est controversé en cas d'augmentation mammaire. Toutefois, la majorité des chirurgiens en administrent.

OBJECTIF : Examiner l'effet des antibiotiques sur l'incidence d'infections et de contractures capsulaires après une augmentation mammaire.

MÉTHODOLOGIE : De septembre 2004 à novembre 2010, 180 patientes ont subi une augmentation mammaire primaire bilatérale. Prospectivement, elles ont été divisées en deux groupes égaux. Aucun antibiotique n'a été administré dans le groupe A (n=90), tandis que dans le groupe B (n=90), une seule dose de céphalosporine a été administrée par voie intraveineuse pendant l'induction de l'anesthésie générale. Les données préopératoires incluaient l'âge, l'indice de masse corporelle, le tabagisme, les antécédents médicaux et le volume des implants. Le même chirurgien a procédé à toutes les opérations, selon la même technique chirurgicale et à l'aide du même type d'implants. Il n'a pas utilisé de sonde. Les données opératoires incluaient la durée de l'opération et la perte de sang estimative. Les chercheurs ont évalué les patientes pour déterminer les complications telles que les infections, les hématomes et les contractures capsulaires. Ils ont mis fin à l'étude après une année de suivi auprès de toutes les patientes. Ils ont utilisé le test de Student pour analyser les résultats.

RÉSULTATS : Toutes les patientes ont terminé l'étude, et les deux groupes présentaient des données démographiques similaires. Les chercheurs n'ont observé aucune différence à l'égard des données opératoires. L'opération durait 35 minutes en moyenne, et la perte de sang moyenne était minimale. Dans le groupe A, aucune infection des implants n'a été signalée, tandis qu'une infection de la plaie a été traitée par des antibiotiques par voie orale. Dans le groupe B, aucune infection des implants ou des plaies n'a été signalée. Aucune contracture capsulaire ni hématome n'a été observé.

CONCLUSIONS : Trop peu de patientes ont subi une augmentation mammaire primaire sans prise d'antibiotiques (n=90) pour en tirer des conclusions définitives. Cependant, la présente étude prospective a démontré que la prophylaxie antibiotique en cas d'augmentation mammaire n'a pas d'effet significatif sur le taux d'infections et de contractures vasculaires. D'autres essais cliniques aléatoires, combinés à des lignes directrices des sociétés de chirurgie plastique, semblent justifiés.

Breast augmentation is the most common cosmetic procedure in the United Kingdom (UK) and one of the most popular procedures in plastic surgery worldwide (1). In the United States, >330,000 patients underwent augmentation mammoplasty for cosmetic purposes in 2012 (2). Complications reflect significantly on surgeons, patients and hospitals from a clinical, emotional and financial perspective. A good example of the financial impact of this procedure is the replacement of PIP implants, which was reported to incur a considerable cost for the National Health Service (NHS) in the UK in 2012 (3). Several complications, such as bleeding, infection, seroma, implant rupture, capsular contracture, and pain and corrective operation(s), are the risks that patients must acknowledge before consenting to the procedure (4). Inevitably, surgeons have tried to optimize techniques and patient

selection to minimize risks and the two most common complications: infection and capsular contracture. However, the infection rates in cosmetic breast augmentation have been reported to be quite low compared with other surgical procedures, with an average rate of 1% (6), the consequences of an infected implant could be devastating for the patient and the surgeon. Treatment involving potential admission to the hospital for antibiotics and implant removal could compromise patient safety and satisfaction for the most popular cosmetic surgical procedures.

Prophylactic antibiotic administration remains an area of controversy in breast augmentation. As a surgical wound, the procedure should be classified as 'clean', where no antibiotics are required; however, the use of implants appears to have made the use of either a

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TABLE 1
Patient characteristics

Characteristic	Group	
	A*	B†
Age, years, mean (range)	29 (19–45)	31 (21–45)
Body mass index, kg/m ² , mean	26	26
Smokers, cigarettes/day, n (range)	15 (12–21)	13 (14–20)
Implant volume, mL, mean (range)	290 (200–400)	270 (200–375)
Medical history	Nil	Nil
Complete follow-up, years	1	1

*No antibiotics; †750 mg cefuroxime

TABLE 2
Perioperative data

	Group	
	A (no antibiotics)	B (750 mg cefuroxime)
Operating time, min, mean	35	35
Blood loss	Minimal	Minimal

preoperative or postoperative course mandatory. In the NHS, the most recent antibiotic guidelines recommend a dose of intravenous antibiotic on induction of anesthesia without a postoperative regimen (7,8). In private practice, there is no uniformity because neither the British Association of Aesthetic Plastic Surgeons or American Society of Aesthetic Plastic Surgery have published any guidelines. Reviewing the literature, we found several different approaches. We found two recent studies comparing a preoperative regimen versus a combination of preoperative and postoperative antibiotics, with no differences in infection rates, capsular contracture incidence or overall complications (9,10). Two similar studies before 1991 (11,12) compared prophylactic antibiotics versus no antibiotics or placebo, concluding in not identifying a difference between infection and capsular contracture in the two groups of patients. A further meta-analysis of the above studies reported that there was little evidence available to change current practice and suggested that further studies are needed (6). The present prospective study was an attempt to investigate the effect of antibiotic(s) use in the incidence of infection and capsular contracture following breast augmentation.

METHODS

From September 2004 to November 2010, 180 patients underwent primary bilateral breast augmentation. All patients consented to participate in the study and appropriate ethics approval was granted. They were prospectively divided in two groups according to the administration of antibiotics: in group A (n=90), no antibiotics were given; in group B (n=90), only one dose of cephalosporin was given during the induction of general anesthesia. The antibiotic of choice was 750 mg of cefuroxime as common guidance (7,8) in antibiotic prophylaxis in breast surgery and according to local antibiotic practice. Preoperative data included age, body mass index, smoking status, medical history and implant volume. The Student's *t* test was used for statistical analysis; no statistically significant difference was found between the characteristics of the two groups. Patients with diabetes, peripheral vascular disease, paraplegia and previous breast surgery were excluded from the study because these conditions were considered to be risk factors for developing infections.

In an attempt to estimate an adequate sample size to achieve significant results, a power analysis was performed using SPSS Sample Power (IBM Corporation, USA). To proceed with the analysis, an estimation of the infection rate without antibiotics was required. The expected infection rate with antibiotics was estimated to be 1%. The criterion for significance (α) was set at 0.05, and the study had a power of 80% to yield a statistically significant result. If a difference of 4% was assumed between the two groups, therefore, the minimum clinical

TABLE 3
Incidence of infection, hematoma and capsular contracture

	Group	
	A (no antibiotics)	B (750 mg cefuroxime)
Wound infection	1	0
Implant infection	0	0
Hematoma	0	0
Capsular contracture	0	0

Data presented as n

effect to make use antibiotic necessary would require two groups of 285 patients to reject the null hypothesis. Similarly, two groups of 90 patients would be an appropriate sample size for a minimum increase of 10% in the infection rate. Consequently, studies with larger sample sizes are needed to draw more definitive conclusions.

Operative data included operative time and estimated blood loss. Patients were evaluated for complications such as infection, hematoma and capsular contracture. The study concluded when all of the patients underwent the one-year follow-up.

To standardize the study, all operations were performed by the same surgeon, using the same surgical technique with round, high-cohesive, textured silicone implants (5).

Surgical technique

All operations were performed under general anesthesia, with the patient prone and the arms abducted 80°. All patients received round, high-cohesive, textured silicone prostheses through an inframammary fold incision. The mean length of the incision was 5 cm (range 4.5 cm to 6 cm). The surgical field was prepared with chlorhexidine. Infiltration of 5 mL of lidocaine with adrenaline 1:200,000 was used on the incision sites. A scalpel was used to cut the epidermis and the dermis; the dissection was performed using unipolar foot-switching needlepoint electrocautery forceps in the coagulation mode.

A subfascial technique was used to insert the implant as the dissection was performed under the pectoralis fascia. Following completion of dissection of the first pocket, four wet swabs with normal saline were inserted into the pocket and then the other breast was operated on. The mean time for pocket dissection was 13 min (range 5 min to 35 min). After the second pocket was completed, four wet swabs were inserted and returned to the first pocket. The pocket was meticulously inspected for any bleeding. Before implant insertion, the pocket was rigorously cleaned using one or two fingers covered with a dry swab. Using this manoeuvre, the authors tried to mimic the handling of the implant during insertion and placement in the pocket.

The implant packaging was opened only when the implant was ready to be inserted. The prosthesis was immersed in betadine solution and the incision site was also cleaned with it. A swab with the above solution was placed just below the incision site to minimize contact of the implant with the patient's skin. After changing gloves, the implant was inserted into the pocket. The implant was in contact with the air for only 1 s to 2 s, and contact with the patient's skin was avoided.

Closure was performed in three layers using Monocryl 3/0 and 4/0. No drains, bandages or straps were used. Steri-Strips (3M, USA) and Mepore (Mölnlycke Health Care, USA) were the only dressings used.

RESULTS

All patients completed the study. Patient characteristics in both groups were similar (Table 1). The follow-up period was one year. No differences in operative data were observed. The mean duration of the operation was 35 min in both groups (range 22 min to 50 min), and blood loss was minimal (Table 2).

In group A, no infection of the implant was reported, while a wound infection occurred and treated with oral antibiotics successfully. In group B, no implant or wound infections were noticed. There was no statistically significant difference between the two groups. No capsular contractures or hematomas were observed (Table 3).

DISCUSSION

Because our study did not find any differences between patients who received one dose of antibiotics and those who did not, it would be tempting to apply this approach to our daily practice. However, because of the small number of patients enrolled, we could not be conclusive and the need for large randomized control trials is warranted.

Wound and implant infection, although not common, can complicate patient recovery and satisfaction to a significant degree. Although the infection rate in cosmetic breast augmentation is considered to be quite low (close to 1%), we note a deviation from this number in some studies (4,5). To explain this, we should consider factors that result in different infection rates before concluding whether antibiotics are necessary in breast augmentation.

Different surgeons use different techniques and different protocols, which may alter their approach depending on the patient. This statement affects the treatment pathway of a patient who undergoes breast augmentation. The lack of uniformity in antibiotic regimens that a surgeon will choose for prophylaxis represents another obstacle toward achieving conclusive results. Some surgeons favour the use of drains, which has been reported to increase infection rates (5). On the other hand, povidone-iodine and antibiotic irrigation is being used as a method of reducing capsular contracture with unclear contributions to infection control (13,14).

Comparing current clinical practice in similar procedures, we find that American Society of Plastic Surgeons guidelines for reduction mammoplasty recommend the use of antibiotic prophylaxis but do not suggest a treatment regimen (15). However, these guidelines appear to be based primarily on studies investigating the role of antibiotics in breast cancer surgery rather than aesthetic surgery (10). We should not forget that infection rates in reduction mammoplasty have been estimated to be 10 times higher than in augmentation procedures. In implant-based breast reconstruction, infection rates have been reported to be as high as 20% and, still, there is no consensus regarding antibiotic prophylaxis, with no benefit found in patients who received more than a one-day course of antibiotics (16). Similar findings apply to autologous breast reconstruction using microsurgery; there is no reduction in surgical-site infection rates among patients who received postoperative antibiotic prophylaxis for >24 h (17).

Considering the risk-to-benefit ratio, we should mention the potential complications associated with the liberal administration of antibiotics. *Clostridium difficile* infection is the most common cause of antibiotic-associated diarrhea, occasionally resulting in intensive care

unit admission, colectomy and life-threatening complications (18). Cephalosporins, the most widely prescribed prophylactic antibiotics, are believed to have the greatest potential to induce *C. difficile* colitis. Additionally, the use of antibiotics has been associated with patients developing methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and, therefore, could lead to MRSA infections. In the UK, we notice a rising number of clinical negligence claims for health care-associated infections that are recognized to be largely avoidable. Over the past decade, there has been a particular focus on infections caused by MRSA and *C. difficile*, with the extent and costs of the related legal claims to be poorly appreciated by clinicians (19). Less threatening – but not negligible – risks associated with the unnecessary use of antibiotics include benign gastrointestinal upset, yeast infections and allergic reactions.

The lack of clear guidelines from the scientific societies creates a clinical and legal gap that the individual surgeon's clinical decision and training must compensate for. The dilemma of administering antibiotics is a question that does not have a clear answer, with major clinical implications and potential contribution to the growth of microbial resistance to antibiotic treatments. At the same time, bacterial biofilm of the implant is considered to have an impact on capsular contracture (20). Presently, however, a surgeon not administering antibiotics, outside of a study frame, could be found solely liable for a complication because some of the available guidelines still recommend at least one dose of antibiotics to always be given.

CONCLUSION

The 90 patients who underwent primary breast augmentation with no antibiotics is not a sufficient number to draw definitive conclusions. We also believe that the surgical technique could be a key factor in minimizing infection and hematoma rates. The same applies to the incidence of capsular contracture; however, a follow-up period >1 year would be ideal. Overall, the present prospective study demonstrated, to a degree, that prophylactic use of antibiotics in breast augmentation has no significant effect on infection and capsular contracture rates. The need for larger randomized clinical trials, in combination with guidelines from aesthetic plastic surgery societies, appears to be warranted.

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