European Review for Medical and Pharmacological Sciences 2011; 15: 840-844

Cagliari University Hospital (CUH) Protocol for immediate alloplastic breast reconstruction and unplanned radiotherapy. A preliminary report

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Abstract. – *Introduction:* **Alloplastic breast reconstruction necessitating postmastectomy radiotherapy (PMRT) is at increased risk for complications such as capsular contracture, infection, extrusion, and poor cosmetic results. However, often the indication for PMRT is not decided until a permanent histological examination with review of the permanent sections is carried out, and the expander has already been inserted. Techniques described to face this issue (delayed-immediate reconstruction and Memorial Sloan Kettering Cancer Center protocol) both have disadvantages.**

Materials and Methods: **The protocol we suggest is based on (1) reconstruction with tissue expander placement at the time of mastectomy; (2) complete tissue expansion during postoperative chemotherapy; (3) radiotherapy, as suggested by oncologists; (4) two or three fat grafting session, according to Coleman's technique, 4-6 months after RT; (5) exchange of the tissue expander for a permanent implant approximately 3 months after the completion of fat grafting. Ten patients were treated according to these guidelines.**

Results: **Results at 15 months have been encouraging, with no grade 3-4 Baker's capsular contracture.**

Discussion: **Although the group of patients treated according to our CUH Protocol for immediate implant-based breast reconstruction and radiotherapy is small, and follow-up is short; nevertheless, results are encouraging.**

Key Words:

Lipofilling, Radiotherapy, Alloplastic breast reconstruction.

Introduction

Immediate breast reconstruction with tissue expanders and implants remains an important option for women undergoing mastectomy. It is generally accepted that this kind of breast reconstruction cannot be the gold standard for those patients who are at an increased risk for conditions necessitating postmastectomy radiotherapy (PMRT). The rationale is based on RT-associated increased incidence of capsular contracture, infection, extrusion, and poor cosmetic results[1-7]. However, often the indication for PMRT is not decided until a permanent histological examination with review of the permanent sections[7] is carried out, and the expander has already been inserted. The decision is delayed until this point because preoperative imaging of the axillary lymph nodes cannot identify micrometastases[8-10], intraoperative evaluation of sentinel lymph nodes is associated with a high false-negative rate[8-10] and use of fine-needle aspiration or stereotactic core biopsy instead of open excisional biopsy for diagnosis – an increasingly common practice – means that the amount of invasive tumor within the breast parenchyma cannot be assessed until the permanent sections are available.

Until recently, PMRT was generally recommended only for patients with tumor-positive margins, T3 tumors, or four or more tumor-positive lymph nodes[11]. However, several clinical trials have documented a survival advantage for patients with stage II tumors and fewer than four involved nodes who receive adjuvant radiotherapy[12-17]. Therefore, an increasing number of mastectomy patients will undergo PMRT in the future and this will lead plastic surgeons to face with higher rates of complications for prosthetic breast reconstruction.

In this paper we describe the Cagliari University Hospital (CUH) Protocol for lipofilling application in patients undergoing immediate prosthetic breast reconstruction and unplanned RT, which has been previously presented[18].

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Materials and Methods

From November of 2008 to June of 2011, 10 patients were treated with the CUH Protocol, 8 of whom where operated by the senior Author (D.R.) at Cagliari University, and 2 at the San Gallicano Hospital, Rome. Ages ranged from 46 to 55 years.

Timing was as such: (1) reconstruction with tissue expander placement at the time of mastectomy (Figure 1), (2); complete tissue expansion during postoperative chemotherapy (Figure 2A) (3); radiotherapy, as suggested by oncologists; (4) two or three fat grafting sessions, according to Coleman's technique, 4-6 months after RT (Figure 2B, C); (5) exchange of the tissue expander for a permanent implant approximately 3 months after the completion of fat grafting (Figure 3A, B).

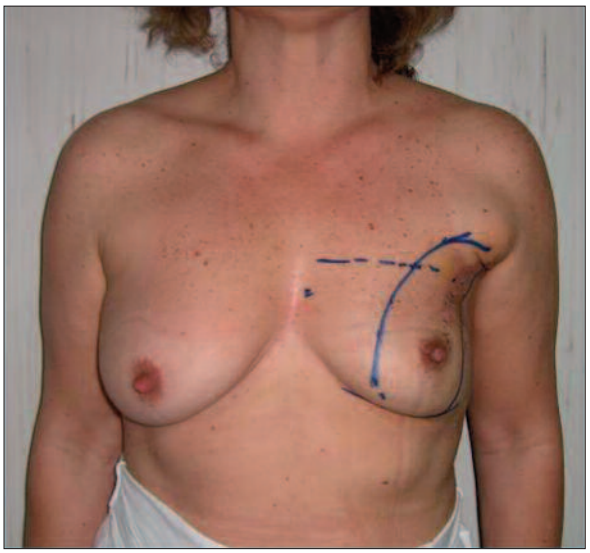

Figure 1. Preoperative view of a 52 years old patient, with marks for a modified mastectomy and immediate alloplastic reconstruction with tissue expander.

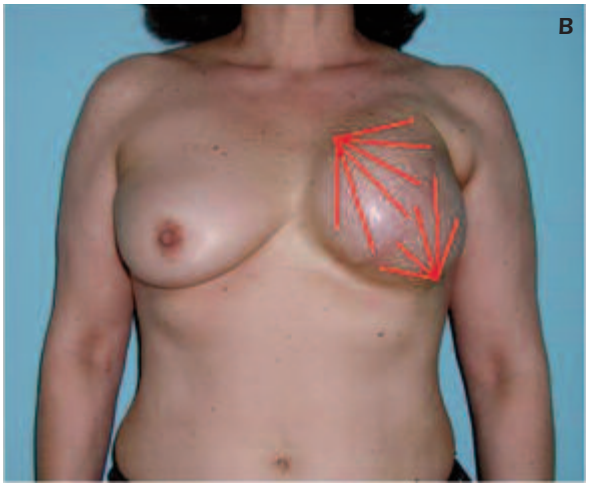

Figure 2. ***A,*** The same patient, after complete tissue expansion during postoperative chemotherapy. ***B,*** Four-month view after radiotherapy and two sessions of fat injections in the left breast. Gray lines show the multiple tunnel created to inject fat grafts subcutaneously and multidirectionally, from superficial to deep layers, spreading the fat in the whole irradiated area. ***C,*** The same patient, lateral view after radiotherapy and two sections of fat injection.

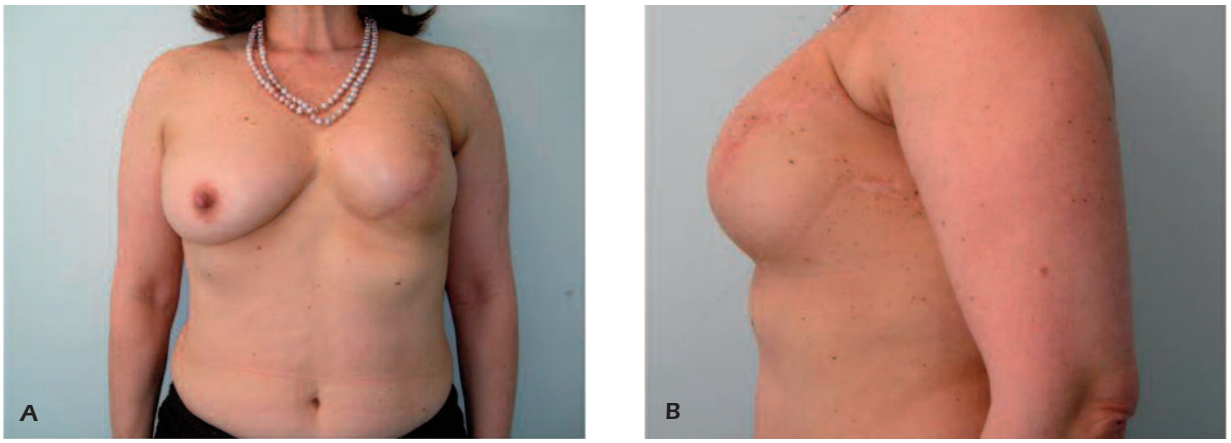

Figure 3. ***A,*** The same patient, three months view after the completion of fat grafting and exchange of the tissue expander for a permanent implant. ***B,*** The same patient, final postoperative view.

Indications for fat grafting according to the CUH protocol included immediate postmastectomy reconstruction with tissue expander followed by indication for radiotherapy, and a contralateral breast mammogram negative for malignancy. All patients signed a separate consent form discussing potential complications of infiltrating fat into the breast and agreed to undergo routine postoperative mammography. Anesthesia was general (two patients) or sedation with local infiltration. Fat was grafted in one to three operating sessions, with an average of 110 cc of fat per operation per breast.

The technique of structural fat grafting has been described previously by Coleman[19,20] in detail. Fat was harvested using a 10-ml syringe attached to a two-hole Coleman harvesting cannula. After centrifugation and refinement, the fat was then transferred to 3-ml syringes. Blunt infiltration cannulas were used to place the fat through 2-mm incisions. Fat was injected subcutaneously and multidirectionally, from superficial to deep layers, spreading the fat in the whole irradiated area over the muscle, including the mastectomy scar (Figure 2B). Multiple tunnels were created, so that fat grafts did not pile up in the same place and were thus able to revascularize. In total, the procedure lasted approximately 50 minutes.

Results

Follow-up controls were obtained at 12 and 18 months after the exchange of the tissue expander for the permanent implant. Patients treated did not present short- or long-term complications as Baker's grade 3-4 capsular contracture, infection, extrusion or radiodermatitis sequelae. Both patients and surgeons were very satisfied with the aesthetic results achieved.

This group of patients was compared with a control group of 15 patient that underwent immediate prosthetic reconstruction and PMRT without fat grafting to the reconstructed breast between 2006 and 2008. In this group we reported 3 cases of delayed local infection with final extrusion of the implant. All these patients were treated in the beginning with antibiotics, but finally it was necessary to remove the implant and plan a salvage reconstruction with autologous tissue (latissimus dorsi flap/DIEP flap).

Discussion

It is generally accepted that patients undergoing immediate breast reconstruction and RT are not the ideal candidates for alloplastic breast reconstruction because of both short-term (seroma, hematoma, infection and extrusion) and long-term complications (capsular contracture[21], pain or thinning of the skin with possible extrusion[1-7]).

In their report, Spear and Onyewu[22] concluded that 48 percent of irradiated breasts with saline implants ultimately required addition of or replacement by a flap, although their series included only a small group of patients, with large differences in the timing of the irradiation. In the same way, Vandeweyer et al[23] evaluated six patients who received RT after reconstruction with implants and observed 100 percent grade 3 and 4 capsular contracture and concluded that good cosmetic results could not be obtained among irradiated patients.

In order to deal with these complications, several protocols from different renowned Breast Cancer Centers have been proposed, none of which has solved the problem.

Probably the most used protocol to deal with unexpected PMRT has been described at Memorial Sloan Kettering Cancer Center (MSKCC) by Cordeiro et al[2]. He has proposed a roadmap based on (1) reconstruction with tissue expander placement at the time of mastectomy; (2) ultrarapid tissue expansion during postoperative chemotherapy; (3) exchange of the tissue expander for a permanent implant approximately four weeks after the completion of chemotherapy; and (4) chest wall irradiation beginning 4 weeks after the exchange[2]. Although they concluded that even if irradiated patients might exhibit higher rates of complications, overall patient satisfaction and aesthetic results were not significantly different from those for patients who did not receive RT, in our thought such a fast tissue expansion (four weeks) followed by the exchange for a permanent implant might produce a "*stretching*" instead of a real "*expansion*", resulting in suboptimal results for that step of reconstruction.

Another possibility to deal with this problem is the "delayed-immediate" reconstruction proposed by Kronowitz et al[7], which consists in deflating the tissue expander, placed at the time of mastectomy, after the completion of chemotherapy, but before the beginning of radiation therapy. His algorithm is based on the large potential space within the scar capsule that persists during radiation therapy, when the expander is deflated, this facilitates reinflation of the expander after radiation therapy, and protects against seroma-related complications. On the other hand, deflating the expander before RT might reduce the quality and the amount of skin over the implant.

As the radiodamage itself is not avoided, we strongly believed that those different immediate reconstructive strategies to reduce the radiation-related effects on the implants would be ineffective in the end. To prevent the radiation-related phenomena their pathophysiology should be contrasted.

Among the last generation of surgical procedures, it has been shown that the transplant of lipoaspirates containing adipose-derived adult stem cells is a highly effective therapeutic approach for the treatment of degenerative, chronic lesions induced as late effects by oncologic radiation treatments, reporting dramatic improvement of symptoms with a statistically significant decrease of LENT-SOMA scores before and after cell therapy[24]. Recently, some Authors have proposed the use of autologous fat injections to reach this objective, although in delayed reconstructions. Salgarello et al[25] have transplanted autologous fat in many stages to restore irradiated breast tissue, thus preparing it for subsequent breast alloplastic reconstruction. This should reduce the radiation related complications on the implants. Serra-Renom et al[26] presented a protocol for breast reconstruction consisting of (1) the placement of the expander and the fat grafts in the upper quadrants after a year from the mastectomy; (2) the placement of the prosthesis and the fat grafts in the region around the prosthesis and in the lower medial and lateral quadrants in the second intervention. This approach achieves a very low capsular contracture index and a highly satisfactory aesthetic outcome. Other techniques involving lipofilling together with alloplastic reconstruction have been described by Berrino[27] and Khouri and Del Vecchio[28]. All these last alloplastic breast reconstruction procedures seem to be promising.

To the best of our knowledge, no procedure for patients who underwent mastectomy and *immediate* alloplastic breast reconstruction followed by unexpected RT has been reported. Although the group of patients treated according to our CUH Protocol for implant-based breast reconstruction and radiotherapy is small, and follow-up is short, nevertheless results are encouraging.

One to three sessions of fat grafting between skin and muscle in patients with first stage alloplastic breast reconstruction, six months after the end of RT, and four months before the final exchange of the tissue expander for a permanent implant, revitalized the affected tissues, favoring their biological and mechanical restoration after the stress for the soft tissue from the "the stretching" of the expansion and the RT. A follow-up of 15 months shows the absence of grade 3/4 capsular contracture and radiodermitis sequelae providing good aesthetic and functional results not experienced from implant placement in irradiated breasts without lipofilling treatment. With further studies and experience, fat grafting to the breast may provide a safer option for patients undergoing implant-based immediate breast reconstruction and radiotheraphy.

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