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Delayed breast implant reconstruction: A 10-year prospective study

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Summary Studies of complications following reconstructive surgery with implants among women with breast cancer are needed. As the, to our knowledge, first prospective long-term study we evaluated the occurrence of complications following delayed breast reconstruction separately for one- and two-stage procedures. From the Danish Registry for Plastic Surgery of the Breast, which has prospectively registered data for women undergoing breast implantations since 1999, we identified 559 women without a history of radiation therapy undergoing 592 delayed breast reconstructions following breast cancer during the period 1999 to 2006; 239 one-stage procedures and 353 two-stage procedures. The postoperative course through November 2009 was evaluated by cumulative incidence adjusting for competing risks for the selected outcomes; hematoma, infection, seroma, implant rupture, severe capsular contracture (modified Baker III and IV), extrusion of the implant, asymmetry/displacement of the implant, any complication, and reoperation. These analyses were performed both overall and separately according to type of procedure (one- or two-stage). The overall 10-year risk estimates were 68.1% for any complication, 7.7% for severe capsular contracture, 32.3% for displacement/asymmetry of the implant and 38.6% for reoperation. When comparing one- and two-stage procedures, we observed significantly higher risk estimates for infection, seroma and extrusion of the implant following two-stage procedures, whereas the risk of

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reoperation was significantly higher following the one-stage procedure. For both procedures, the majority of reoperations were due to asymmetry or displacement of the implant.

In conclusion, non-radiated one- and two-stage delayed breast implant reconstructions are associated with substantial risks of complications and reoperation which should be taken into consideration in the planning of breast reconstruction.

Introduction

Improved survival following a diagnosis of breast cancer has resulted in an increasing demand for breast reconstruction, which is now an important part of patient management.[1] In Denmark, the majority of breast reconstructions are implant based, either as immediate procedures at the time of mastectomy or as delayed procedures. Delayed reconstruction is an option for most patients, whereas immediate reconstruction is performed almost exclusively in patients undergoing prophylactic mastectomy or in those with early-stage disease. Based on medical evaluation, as well as surgeon and patient preference, breast reconstruction with an implant may be planned as a one-stage or two-stage procedure.[2]

Numerous studies have reported complication frequencies following breast implant reconstruction; however, long-term results and results according to type of reconstructive procedure are sparse.[3–11] Moreover, most of the studies evaluating complications have been retrospective or based on small sample sizes. In the present study, based on prospectively collected data on delayed breast implant reconstructions registered in the Danish Registry for Plastic Surgery of the Breast, we examined the occurrence of local complications among 559 Danish women without a history of radiation therapy undergoing delayed breast implant reconstruction between 1999 and 2006, thereby adding more than 200 women and more than 6 years of follow-up to our previous study of short-term complications.[3] As the, to our knowledge, first study we described postoperative outcomes separately for one- and two-stage delayed reconstruction procedures.

Patients and methods

Sources of data and study population

Details of the structure and unique resources of the Danish Registry for Plastic Surgery of the Breast have been described previously.[12;13] Briefly, the registry, established in May 1999, prospectively collects pre-, peri-, and postoperative data for women undergoing cosmetic or reconstructive breast surgery at public hospitals or private clinics of plastic surgery throughout Denmark. After giving written informed consent, women participating in the registration complete a self-administered questionnaire on medical and reproductive history and lifestyle factors. At surgery, the surgeon registers date, indication and type of operation, surgical technique, and implant characteristics. At each follow-up visit, the surgeon registers surgical and clinical outcomes, including details on any complication and need for treatment. All data are registered at patient level by use of the personal identification number, a unique 10-digit number assigned at birth to all Danish citizens encoding information on date of birth and sex. Clinical adverse outcomes recorded include infection (superficial or periprosthetic), wound rupture, hematoma, seroma, skin wrinkling, implant folding, displacement and asymmetry, capsular contracture (modified Baker grade II, III, or IV[14]), sensitivity changes, implant rupture and persistent pain in the breast. Reoperations were defined as operations not included in the planned reconstructive procedure, where the implant capsule space was accessed. During the study period in Denmark the standard procedure in delayed breast implant reconstruction was creation of a fully or partly submuscular pocket (below pectoralis major but subcutaneous in the distal part) without the use of non-autologous material such as dermal matrix.

Twenty-two private and all ($n = 9$) public hospital departments performing breast reconstruction during the inclusion period (1999—2006) contributed to the registration. Since the vast majority of breast reconstructions in Denmark are performed in public hospitals, the Danish Registry for Plastic Surgery of the Breast has virtually complete coverage for this procedure. For the present study, we initially identified 1418 breast implant reconstruction procedures registered in the Registry with a primary implantation during the period May 1999 through December 2006. No latissimus dorsi flaps were included in this group.

In order to obtain complete information on the clinical course following breast reconstruction, we performed a thorough medical record review for all but three of the study women (five procedures), who were excluded from the cohort (Figure 1). From the medical records we collected information on any missed events of postoperative complications and reoperations, and validated information already registered in the Registry. For the final analyses, approximately 30% of the reoperations and 70% of the clinical follow-up visits with complications were hereby added. Additional information on the method of reconstructive procedure (immediate or delayed) and indication (breast cancer or prophylactic mastectomy) not registered in the Registry were further obtained.

Of the 885 delayed breast reconstructions, we excluded 68 prophylactic mastectomies, 100 one-stage reconstructions with permanent fixed size implants and 125 procedures with a history of radiation therapy, in order to obtain as homogenous a group as possible. Thus, the final study population comprised 592 non-radiated delayed breast reconstructions due to breast cancer in 559 women; 239 were one-stage procedures performed with expandable