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ORIGINAL PAPER

Quality auditing in breast reconstruction using funnel plots and indicators: a semi-anonymous and practical method for your practice

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Abstract

Background In recent years, there is an increasing focus on the delivery of high-quality care in a cost-efficient fashion. A key strategy in improving practice is gaining insight in outcome differences. We present a simple and quick method of quality auditing in a local practice, aiming to start a discussion between surgeons and reduce complication rates by improving protocols.

Methods Patients who underwent breast reconstruction with implants were evaluated on explantation rate within 60 days of insertion. Patients were traced using administrative data. Results were compared during yearly audits between 2014 and 2017. Each year, a meeting was held in which the data of all surgeons were compared using funnel plots in a semi-anonymous manner.

Results At baseline, 6.1% (15/244) of all implants and 9.9% (9/91) of all tissue expanders had to be explanted, mainly due to infection (60.0% and 77.8%, resp.). Discussion at the audit led to the implementation of an anti-infection protocol. In the following years, explantation rates decreased to 3.8% (8/208) and 7.8% (8/102) in 2015 (infection 55.6% and 63%), and 3.4% (6/176) and 3.1% (2/64) in 2017 (infection 50% and 100%) and in 2016.

Conclusion Audit feedback and the subsequent discussion about the causes of inter-surgeon differences led to a change in practice protocols for breast implant surgery and a reduction of breast implant explantation in our center.

Level of Evidence: Level III, risk / prognostic study

Keywords Funnel plot · Quality indicator · Complication · Breast reconstruction · Plastic surgery

Introduction

In recent years, there is an increasing focus on the delivery of high-quality healthcare in a cost-efficient fashion. A key strategy to improve outcome is to measure and compare quality of care, usually to a benchmark. On a national scale, initiatives for quantifying quality of healthcare have risen using various disease registries during the past decade. With the use of registries, benchmarks are defined and outliers can be identified. The aim of outlier identification is to start a discussion on practice protocols and reduce the variability in quality of care between hospitals, thereby improving the healthcare system [1].

For example, since 2015, all implanted breast prostheses in the Netherlands are registered at the Dutch Breast Implant Registry (DBIR) [2]. The DBIR is hosted by the Dutch Institute for Clinical Auditing (DICA). The DICA presents outcomes of all registered hospitals at a public webpage in a semi-anonymous way by encrypting the data and uses funnel plots to visualize differences. In this plot, each hospital is indicated with a unique point and compared to the benchmark, which are the other hospitals. Each hospital is aware of their corresponding point, but unaware of the corresponding point of the other hospitals. In the past, on the subject of gastric

Inge Smits and Nikki Beudeker contributed equally to this work.

Highlights box This paper presents a quick and simple audit strategy in data gathering, analysis, and visual semi-anonymous presentation.
The presented strategy of quality auditing resulted in discussion on practice protocols and a change in practice, which improved quality of care and reduced the complication rate in our center.

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cancer surgery, this strategy has resulted in a dramatic 47% reduction of mortality within 3 years after showing the surgeons their clinical results from the registry [3]. Funnel plots have also been recommended by the National Clinical Audit Advisory Group and the Association of Public Health Observatories in the UK, and enable detection of outliers in quality of care on a national level [4].

In the setting of a local practice, quality of care is usually measured and controlled by means of complication meetings and local audits. Data gathering and outcome analysis provide insight in the status quo, gaps, and how to improve outcomes. However, auditing is often time-consuming and full transparency of results may not be desirable for group discussions in audits as it drifts discussion away from the goal. Therefore, the semi-anonymous strategy of DICA may be a useful approach. We present a simple and quick audit method using locally defined quality indicators, financial data, and funnel plots to visualize the general local quality of care and inter-surgeon differences in a semi-anonymous way. An example of our practice on breast reconstruction using implants was used as an illustration.

Patients and methods

Design and setting

Quality of care of breast reconstruction using implants was defined as the percentage of breast implant explantations. The results of the first audit were presented during a surgeon meeting at which determinants of general outcome and the cause of outcome differences between surgeons were discussed. Following the meeting, an intervention was implemented for the following surgeries. The results of the meeting and intervention were analyzed by two repetitive cycles of auditing, the first to monitor change and the second to monitor preservation of change.

Research members, whom were allied residents, conducted the data gathering and analysis. Patients were selected by selection of classification codes of diseases that corresponded to the implementation of a tissue expander (TE) or definite breast implant. All implants were placed by the dual plane technique without ADM. Patients that underwent implant-based reconstruction combined with autologous tissue (e.g., latissimus dorsi flap) were excluded to increase group homogeneity. Medical records of all consecutive patients with these codes were reviewed on explantation and reason for explantation (e.g., infection, skin necrosis, delayed healing, wound dehiscence, or device exposure), and exposure to radiotherapy. The following procedures were included: first time TE, change TE for another TE, change TE for definite breast implant, switch definite breast implant for another definite breast implant, and immediate definite breast implant.

Because the main purpose of the audits was to improve clinical practice rather than research, medical ethical approval for the audit was not required. The audit was conducted at two hospitals of the "Ziekenhuis Groep Twente" in the east of the Netherlands; all surgical staff members at the time ($n = 5$) participated.

Statistical analysis was performed with Microsoft Excel 2007 and IBM Statistics 22.0 (SPSS, Armonk, NY). Categorical variables were expressed as percentage and compared using the Chi-square test. Power calculations were performed with G*power. P values < 0.05 were considered to be statistically significant.

Baseline audit

The baseline audit included data of 2014. The results were presented to the participating surgeons of the department. Each surgeon was assigned a random code (letter A–E) in order to encrypt the data. Before the meeting, each surgeon received their personal code sent by one of the research members on their mobile phone. To preserve anonymity, surgeons remained oblivious of the assigned codes of the other surgeons. Each surgeon was free to disclose his or her code to the other surgeons.

The explantation rate per surgeon was plotted against the total number of cases performed by the corresponding surgeon using funnel plots. In addition, local averages and 95% control limits were added to the funnel plot as the local benchmark allowed the surgeon to interpret his/her results. Surgeons that had explantation rates above or below the 95% interval were considered to be outliers and were not depicted.

The semi-anonymous results shown in the meeting were used to provide objective as well as personalized input for discussion among the peers about practice protocols and how alterations could lead to a better overall outcome of care in our department.

Intervention and monitor of change

During the audit meeting, discussion led to implementation of an antiseptic protocol including (a) an antiseptic preparation (Hibiscrub) applied once the evening before and twice the morning before surgery by the patient, (b) mupirocin (Bactroban) nose gel four times the day before and once the day of the surgery by the patient, (c) and washing of the prosthesis in Cefazolin (500 cc NaCl with 1 g cefazolin) before placement. Mupirocin and cefazolin were chosen because we found that removed implants were mainly colonized with S. epidermis and S aureus.

After implementation of the intervention, the audit was repeated again in 2015 and in 2016 to monitor change and lasting change.

Results

Baseline audit

At the first audit, 244 breast reconstructions met the inclusion criteria. Figure 1 presents a systematic overview of all explantations in 2014 within a follow-up range of 90 days after surgery, indicating that most explantations were performed between 30 and 60 days. In order to achieve quick cycles of auditing while ensuring a high enough capture rate to perform analysis, our quality indicators were determined as explantation of breast implants within 60 days of surgery.

Within 60 days of surgery, 6.1% (15/244) of all prostheses had to be explanted (Table 1) of which 4 were in patients whom received pre- or postoperative radiotherapy ($n = 37$; explantation 10.8%). Indications for explantation included infection ($n = 9$), wound dehiscence ($n = 3$), or skin necrosis ($n = 3$). Most explantations were within the group of TEs, adding up to 9.9% (9/91) of all TEs. The main reason for TE explantation was infection ($n = 7$).

Funnel plots of individual explantation rates of all prostheses (Fig. 2a) and TEs (Fig. 2b) were plotted against procedure volume along with 95% control limits. The average explantation rates (our local benchmark) were respectively 6.1% and 9.9%. Control limits were based on average practice results. Therefore, it would be expected that the majority of explantation rates lie within the 95% control limit. None of the surgeons in our practice had an explantation rate above the 95% confidence interval of the results of all surgeons combined. Remarkably, surgeon E implanted most breast implants but also had the highest explantation rate.

The semi-anonymous funnel plots in Fig. 2 were presented at the surgeon meeting. Discussion about the outcome led to insight in inter-surgeon differences in methods of implantation in breast reconstruction. Of interest, 60% of the explantations were due to infection. Of interest was that anti-infection protocols varied between surgeons, especially on the subject of washing of the pockets with saline, betadine, or antibiotic solution. Also, postoperative antibiotics seemed to vary. Therefore, a new protocol for implant-based breast reconstruction was implemented (see methods).

The semi-anonymous way of presenting data included disclosing the key to each individual surgeon. Of note, none of the surgeons voluntarily disclosed their code to the rest of the group. Moreover, there was no feeling within the group that disclosure of each individual's code would assist or would be of benefit for the discussion concerning interpretation of the data.

Table 1 Explantation rate of tissue expanders and implants within 60 days of implantation during all audit years

Year	2014	2015	2016
All implants	15/244 (6.1%)	8/208 (3.8%)	6/176 (3.4%)
TEs	9/91 (9.9%)	8/102 (7.8%)	2/64 (3.1%)

TEs, tissue expanders

Repetitive cycles of audit

In 2015, 208 breast reconstructions met the inclusion criteria. Within 60 days of surgery, 8 (3.8%) prostheses had to be explanted; none of these patients received pre- or postoperative radiotherapy ($n = 17$; explantation 0.0%). Indications for explantations included infection ($n = 5$), wound dehiscence ($n = 2$), or skin necrosis ($n = 1$). All explantations were within the group of TEs (7.8% of all TEs ($n = 102$)).

In 2016, 176 breast reconstructions met the inclusion criteria. Within 60 days of surgery, 6 (3.4%) prostheses had to be explanted of which 1 was in a patient whom received radiotherapy ($n = 22$; explantation 4.5%). Indications for explantation included infection ($n = 3$), wound dehiscence ($n = 1$), or skin necrosis ($n = 2$). Two explantations were within the group of TEs (3.1% of all TEs ($n = 64$)). The main reason for TE explantation was infection ($n = 2$).

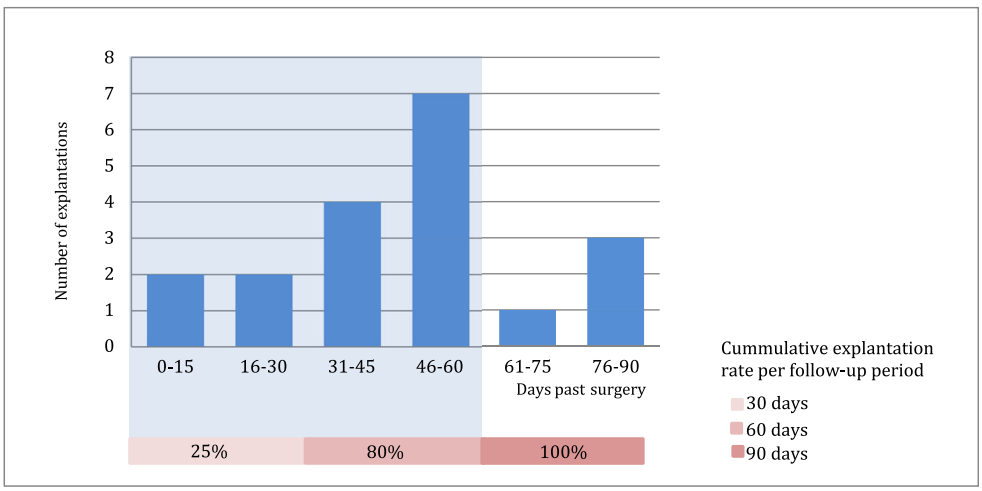

Fig. 1 Number of explantations over days past implant-based breast reconstruction in 2014. An overview of explantation numbers in time after implant-based breast reconstruction. With a follow-up period of 60 days after surgery, 80% of all explantations were included

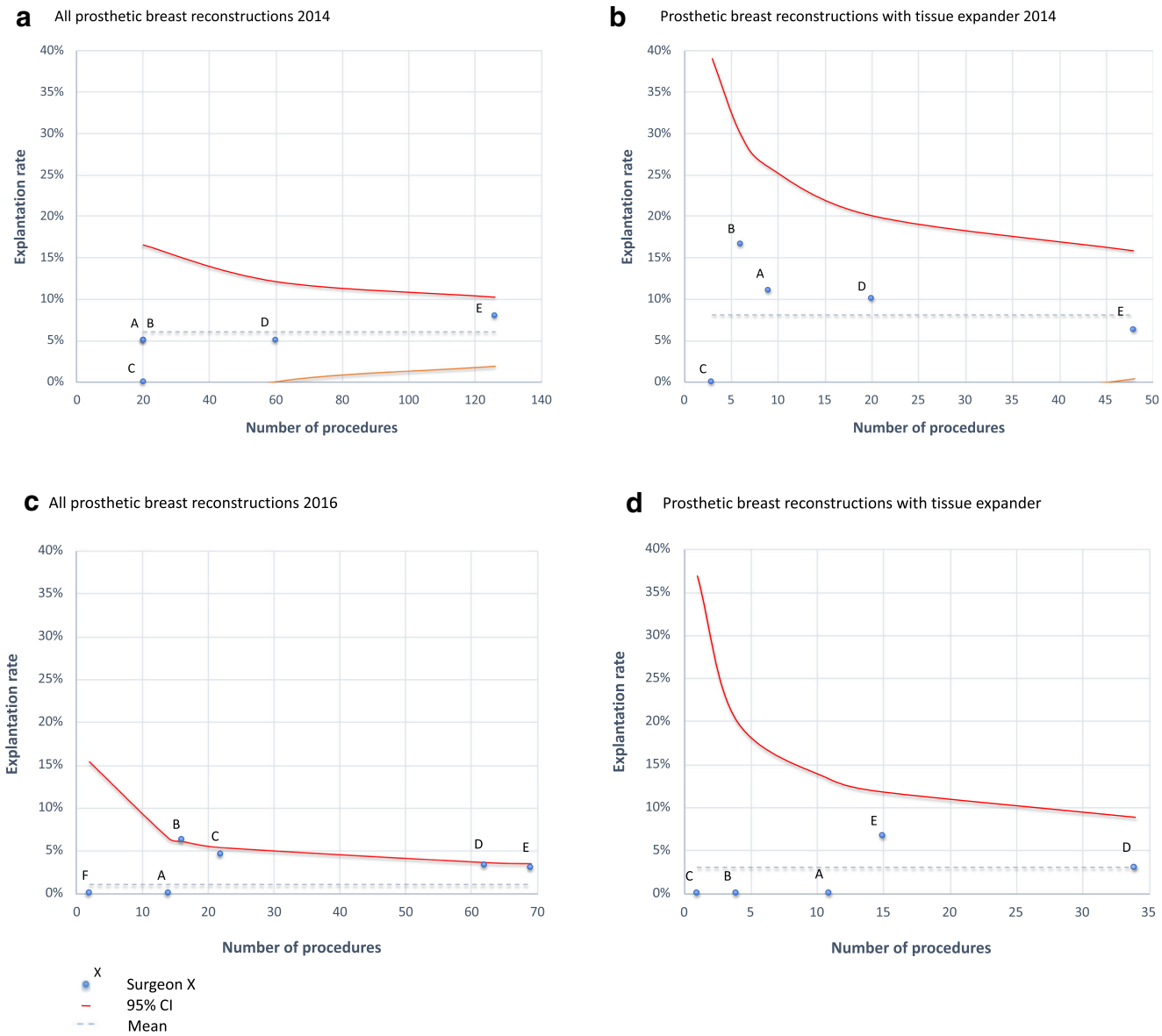

Fig. 2 Overview of the individual explantation rate of all breast implants and TEs at baseline compared to after intervention. Explantation rate of all implants and TEs in 2014 (**a** and **b**) compared to 2016 (**c** and **d**). Each letter corresponds with one and the same surgeon

Combining the data to before and after the intervention, before the intervention 6.1% (15/244) and after the intervention 3.6% (14/384) of all prostheses had to be explanted ($p = 0.14$). Concerning TEs, before the intervention 9.9% (9/91) and after the intervention 6.0% (10/166) had to be explanted ($p = 0.19$).

Discussion

Daily practice focuses increasingly on measuring quality. The aim of the current paper is to show the reader a quick and easy strategy to facilitate gathering, analysis, and discussion concerning local surgery outcomes and thereby giving aim to improve quality of care. Collection of data by means of ICD selection proved to be quick and easy. Data visualization by funnel plots during meetings was useful and informative to interpret individual results of surgeons and inter-surgeon differences in a semi-anonymous way. The audit method resulted in a quick cycle of quality improvement spending a relatively small effort.

Key in auditing is defining the right quality indicator. A good-quality indicator includes a high capture rate in registration and is dichotomous in order to provide an objective measurement. Considering the above, our indicator for implant-based breast reconstruction was the explantation rate. Another but less suitable candidate indicator would be postoperative infection, giving the equivocal clinical signs which lead to variable clinician diagnoses and inclusion or exclusion [5–7].

Next, the follow-up period needs to be defined. In literature, wide variations in follow-up period for complication rates after implant-based breast reconstruction are described,

ranging from 30 days to several years [6, 8–15]. In order to make regular yearly audits feasible, a short follow-up period is recommended. On the other hand, one needs a high capture rate. Analysis of the baseline audit in a period of 90 days showed that 25% of all explantations occurred in the first 30 days, and 80% after 60 days (Fig. 1). Consequently, a follow-up of 60 days has the highest capture rate.

Data gathering for an audit should be quick and simple. Patients were selected according to the ICD code and all medical files were reviewed on implant explantation. A quicker method than a review of all files would be a calculation of the mean costs of an ICD code and filtering patients out that show significant more expense. More expense could indicate an extra operation and therefore explantation. That way, only a small percentage of the medical files would have to be reviewed, saving time.

Finally, the prevalence of the chosen event as an indicator should be relatively high and the benefit should be as large as possible. This means that statistical significance is reached quite easily; a simple power calculation might be beneficial. For our indicator, this has proven to be a major limit in the overall outcome analysis. The needed number to treat to provide statistical significant differences calculated by power calculations showed a number needed in each group of 638 to show a reduction of 50% of explantation, setting alpha at 0.05 and beta at 0.8. Such numbers may only be reached by multicenter studies, which was not the purpose of local auditing. Although we could not show a statistically significant decrease in all prosthesis and TE explantation after implementation of the anti-infection protocol, a tendency towards less explantation was found. Over the years, less breast prostheses were implanted due to an increase of oncoplastic reductions/reconstructions instead of augmentation with reconstruction by means of prostheses.

Funnel plotting is a popular method to compare surgical outcome data and provides an easy method to single out poorly performing surgeons [4]. However, it should be noticed that pointing these surgeons out is not necessarily of use in improving quality; it harms feelings of personal safety in a discussion and could unnecessarily hamper constructive discussions. Moreover, caution should be used for using funnel plots to gauge individual performance, as no risk adjustments were made for age, co-morbidity, or use of radiotherapy because the gathering of these data is time-consuming making the audit less feasible. As the purpose of auditing is not impeaching the outliers but to reduce treatment variation between surgeons and improve quality outcomes, the data were encrypted. Of note, none of the surgeons disclosed their key to their fellow surgeons.

The benchmark in the funnel plots was defined by our own results. There are few publications in the literature focusing specifically on premature removal of TEs or implants. Premature TE and implant removal rates range from 1.8 to 16.9% [6, 15–19]. Because of the wide range, our benchmark was calculated with the use of our own local results.

In conclusion, the presented audit method proved to be a quick and simple strategy for data gathering, analysis, and visual semi-anonymous presentation of our local surgery outcomes. The audit in patients with implant-based breast reconstruction resulted in a change of practice, which seems to have improved the quality of care and reduced the complication rate in our center. This method may be used for a variety of topics.

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Compliance with ethical standards

Conflict of interest Inge Smits, Nikki Beudeker, Byrthe J.P.R. Vos, Narda Hendriks-Brouwer, Ute Schmidbauer, Yvonne C.M.M. Smulders, Oliver T. Zöphel, and Hinne A. Rakhorst declare that they have no conflict of interest.

Ethical approval The local medical ethics committee deemed that official medical ethical approval was not required.

Informed consent All medical files were analyzed by treating physicians; therefore, informed consent for insight in patient data was not required.

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