Breast Cancer Research and Treatment (2019) 176:159–164
https://doi.org/10.1007/s10549-019-05175-2

CLINICAL TRIAL

Improving surgical efficiency of immediate implant-based breast reconstruction following mastectomy

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Received: 11 February 2019 / Accepted: 16 February 2019 / Published online: 11 April 2019

Abstract

Purpose Traditionally, during a mastectomy with implant-based reconstruction, the surgical oncologist completes their operative procedure prior to the reconstructive surgeon entering the room. In this scenario, two separate instruments kits and tables are utilized. In our institution, we created a combined instrument kit for use by both surgical teams. We compared set-up and operative times for each process and the subsequent savings associated with this novel approach.

Methods Sixty-eight patients undergoing mastectomy with implant-based reconstruction were divided into two groups—those who underwent the procedure with separate oncology and reconstructive kits and those who underwent the procedure with combined instrumentation. Set-up time, procedure time, and clinical outcome endpoints were compared. Costs associated with each process were estimated.

Results Surgical set-up time was lower using the combined kit versus separate kits [mean for unilateral cases, 25.1 ± 9.6 min vs. 35.7 ± 10.4 min ($p < 0.01$) and mean for bilateral cases, 33.1 ± 10.3 min vs. 43.5 ± 9.9 min ($p = 0.31$)]. Procedure time was significantly lower using the combined kit versus separate kits [mean for unilateral cases, 156.2 ± 31.7 min vs. 172.1 ± 33.0 min ($p < 0.05$) and mean for bilateral cases, 207.3 ± 39.3 min vs. 228. 8 ± 42.7 min ($p = 0.03$)]. Post-operative outcomes were not significantly different between the two groups at 6 months post-surgery ($p = 0.72$). Due to a decrease in operating room utilization and costs associated with instrumentation, we estimated $134,396 to $206,621 with unilateral cases and a $289,167 to $465,967 in yearly savings with bilateral cases by using the combined process.

Conclusion Mastectomy with implant-based reconstruction utilizing combined instrumentation, with surgeons working simultaneously, led to decreased operating room utilization and costs without impacting clinical outcomes.

Level of evidence II

Keywords Plastic surgery · Surgical oncology · Breast reconstruction · Mastectomy · Surgical efficiency · Cost savings

Introduction

Approximately 252,000 women are diagnosed with breast cancer in the United States each year [1]. Increasingly, women who require a mastectomy for treatment of their breast cancer are able to undergo both mastectomy and implant reconstruction as a single operation. In fact, the use of breast implants for reconstructive procedures has surpassed that for cosmetic indications. Given the trend towards mastectomy and immediate breast reconstruction, it has become necessary to optimize surgical technique to improve surgical efficiency and reduce hospital costs [2].

Most studies examining operating room (OR) efficiencies have focused on the elimination of unnecessary instruments from surgical kits and the resulting time and cost

"E-Poster Presentation" at the American College of Surgeons, Clinical Congress 2018.

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savings [3–11]. In an investigation conducted by Farrokhi et al., the elimination of 70% of unused instruments from two neurosurgery kits decreased surgical set-up time by 37% and projected a possible $2.8 million in institutional savings per year [5]. Similarly, Farrelly et al. observed that a 59.9% decrease in instruments across five pediatric surgical kits lead to a decrease in instrument costs between $53,193 and $531,929 [4]. Moreover, Greenberg et al. further demonstrated that streamlined surgical kits with fewer instruments were not only cost effective for cesarean procedures but were also satisfactory in terms of patient safety and ease of use for surgeons [12]. Despite the availability of research detailing the benefits of optimization of surgical protocol, no studies have been conducted to assess OR efficiency using a combined instrument kit for mastectomy and immediate breast reconstruction.

Historically, our institution considered mastectomy with implant-based reconstruction as two separate procedures—with distinct instrumentation, table set-up and time out. Often, the reconstructive surgeon would not arrive into the operating room until the surgical oncologist has finished, and the nursing staff had counted and broken-down surgical oncology instrumentation. Many times, the patient would be re-draped with a new set of surgical drapes in between the two procedures.

In 2017, we proposed that our operating room protocol considers mastectomy with implant-based reconstruction a single procedure. Therefore, we eliminated separate mastectomy and reconstruction instrument kits and created a combined mastectomy with reconstruction instrument kit with dramatically fewer instruments. Additionally, we allowed the surgical oncologist and reconstructive surgeon to work simultaneously during bilateral cases. We hypothesize that treating mastectomy with reconstruction as a single procedure, with combined instrumentation and surgeons working in parallel, would reduce OR set-up time, procedure time, and instrument utilization without an increased risk to patients, thereby mitigating hospital costs.

Methods

Study design

Institutional review board (IRB) approval was obtained with a waiver of informed consent. Data from two series of patients, who underwent mastectomy followed by implant-based breast reconstruction with tissue expanders or direct to implant, were collected at a tertiary academic medical center. We identified thirty-four consecutive patients, from September 2017 to January 2018, based on the new protocol which used a streamlined instrument kit. This cohort was then, retrospectively compared with thirty-four additional patients, from April 2016 to December 2017, who were treated with the old protocol which used separate instrument kits.

The combined mastectomy and breast reconstruction kit was created by consensus of all surgical oncologists ($n = 4$) and all reconstructive surgeons ($n = 6$) at our institution, prior to initiating our new protocol (Fig. 1).

Data collection

Set-up time and procedure time were prospectively recorded by operating room personnel on a data sheet. Set-up time was defined as the time the surgical nurses and technologists began to open any instruments, equipment, or supplies until the set-up and count of all materials was completed. Procedure time was defined as incision time to incision closure.

Retrospective chart review was conducted to obtain patient demographics such as age, BMI (kg/m^2), diabetic status, and history of smoking. Furthermore, procedure-specific characteristics included were surgical oncologist,

Fig. 1 The comparison of **a** original mastectomy surgical instrument kit, **b** original breast reconstruction instrument kit. Number of instruments with separate kits = 167. **c** Combined mastectomy and breast reconstruction surgical instrument kit, number of instruments with combined kits = 84

plastic surgeon, laterality of procedure, indication for surgery, type of mastectomy, sentinel node biopsies, axillary dissections, type of breast reconstruction, tissue expander or implant size, and use of Foley catheters.

Surgical cases in both cohorts were controlled based on surgical oncologist and plastic surgeon team, laterality, and reason for surgery. Surgical oncologist and plastic surgeon team was controlled in order to prevent either surgeon's personal techniques from affecting surgical times. We further matched for laterality due to length of procedure time and the overall number of instruments needed. Lastly, reason for surgery, cancer versus prophylaxis, was controlled for due to the need to stage the axilla at the time of mastectomy for patients undergoing mastectomy for breast cancer. Type of mastectomy procedure, skin-sparing mastectomy versus nipple-sparring mastectomy, as well as type of reconstruction procedure, tissue expansion versus direct to implant, were also considered when matching both cohorts since each procedure varies in length.

Costs associated with each protocol were estimated. Costs of disposable and non-disposable products were provided by the Director of Operations at our institution and central sterilization processing labor costs of non-disposable instruments were estimated as defined by Stockert et al. [6]. Estimates of each protocol were multiplied by total number of mastectomy and immediate breast reconstruction procedures performed at our institution performed in 2017 to estimate total instrument cost savings per year. Additionally, labor savings for SPD decontamination and assembly per case were estimated by the Director of Operations at our institution. Using Massachusetts surgical technician wage data from the U.S. Department of Labor, Bureau of Labor Statistics, labor cost savings, per year, were extrapolated [13].

Operating room cost savings were calculated by summing the average set-up and procedure time difference, of unilateral and bilateral cases, using separated versus combined kits, then multiplying the combined time difference by the range operating room costs of \$37–\$62/min as previously defined by the published literature [14, 15] and the corresponding number of mastectomy and immediate breast reconstruction procedures performed at our institution in 2017.

Statistical analysis

Data were analyzed using SPSS 24 (IBM Corp., Armonk, NY). Univariate analysis was conducted to compare patient characteristics between instrument groups. Pearson Chi-square testing was used for categorical variables, including post-operative infection. A Shapiro–Wilk test was used to test for normality among continuous variables. BMI and operating time were non-normally distributed and analyzed using a Mann–Whitney test. The remaining continuous variables were compared using student's *t*-test. Statistical significance was defined as $p < 0.05$.

Results

In 2017, the total number of patients who underwent mastectomy with breast reconstruction procedures performed at our institution was 328. Out of those, 107 cases were unilateral, and 221 cases were bilateral.

Patient characteristics

Thirty-four patients (58 breasts) undergoing mastectomy followed by immediate implant-based reconstruction comprised each cohort. Ten patients in each group underwent unilateral mastectomy with reconstruction and twenty-four underwent bilateral mastectomy with reconstruction. The mean age of women undergoing mastectomy with reconstruction was no different for those utilizing the separate kits compared to the combined kits, 50.5 ± 9.5 years versus 50.6 ± 11.8 years, ($p = 0.88$). Additionally, there was no difference in mean BMI between the two groups, 24.0 ± 4.1 kg/m^2 for separate kits versus 25.8 ± 5.0 kg/m^2 for combined kit, ($p = 0.15$). Implant size did vary between groups, as the use of combined kits was associated with a larger implant size (470.29 ± 156.3 mL) compared to separate kits (386.2 ± 140.1 mL) ($p = 0.02$). Finally, there were no significant differences in mastectomy type, sentinel lymph node biopsy, axillary lymph node dissection, diabetes status, and history of smoking (Table 1).

Operating time

Unilateral cases performed using separate kits had a mean surgical set-up time of 35.7 ± 10.4 min while unilateral cases performed using the combined kit decreased the mean surgical set-up time to 25.1 ± 9.6 min ($p = 0.00$). Unilateral procedure time decreased from 172.1 ± 33.0 min with the use of separate kits to 156.2 ± 31.7 min with the use of the combined kit ($p < 0.05$).

Bilateral cases performed using the separate kits had a mean surgical set-up time of 43.5 ± 9.9, while those performed using the combined kit decreased the mean surgical set-up time to 33.1 ± 10.3 min, ($p = 0.31$). Bilateral procedure time decreased significantly from 228. 8 ± 42.7 min with the use of separate kits to 207.3 ± 39.3 min, ($p = 0.03$), with the use of combined kit (Table 2).

Interestingly, the use of a Foley catheter was reduced with the new protocol; 38% of patients had a Foley catheter placed for their operation when separate kits were used while only 15% of patients had a Foley catheter placed for their operation using the combined kit protocol

Table 1 Patient characteristics

Variable	Total	Separate kits (%)	Combined kit (%)	p
Number of patients	68	34	34	
Number of breasts	116	58	58	
Laterality				
Unilateral cases	20	10	10	
Bilateral cases	48	24	24	
Reason for surgery				
Breast cancer	62	31	31	
Prophylaxis	6	3	3	
Mastectomy type				0.74
Nipple-sparing	57	29	28	
Skin-sparing	11	5	6	
Sentinel node biopsy	61	30	31	0.69
Axillary dissection	9	4	5	0.72
Reconstruction type				
Direct to implant	46	23	23	
Tissue expander	22	11	11	
Foley catheter during surgery	17	12	5	0.004
Mean age ± SD, year	50.5 ± 10.7	50.5 ± 9.5	50.6 ± 11.8	0.88
Mean BMI ± SD, kg/m^2	24.9 ± 4.6	24.0 ± 4.1	25.8 ± 5.0	0.15
Mean implant size ± SD, mL[a]	428.2 ± 153.3	386.2 ± 140.1	470.29 ± 156.3	0.02*
History of diabetes	2	0	2	0.15
History of smoking	2	1	1	0.98

SD standard deviation, *BMI* body mass index

*Statistically significant ($p < 0.05$)

[a]Mean implant size included both immediate implant size and tissue expander volume

Table 2 Surgical times in procedures utilizing separate versus combined mastectomy and breast reconstruction instrument kits

Outcome	Combined kits	Separate kits	Difference	p
All cases				
Set-up time ± SD, min	30.7 ± 10.6	41.2 ± 10.5	− 10.5 ± 0.1	0.00*
Procedure time ± SD, min	192. 2 ± 43.6	212.2 ± 47.5	− 19.9 ± 3.9	0.05*
Unilateral cases				
Set-up time ± SD, min	25.1 ± 9.6	35.7 ± 10.4	− 10.6 ± 0.8	0.00*
Procedure time ± SD, min	156.2 ± 31.7	172.1 ± 33.0	− 15.9 ± 1.3	0.05*
Bilateral cases				
Set-up time ± SD, min	33.1 ± 10.3	43.5 ± 9.9	− 10.4 ± 0.4	0.31
Procedure time ± SD, min	207.3 ± 39.3	228. 8 ± 42.7	− 21.5 ± 3.4	0.03*

*Statistically significant ($p < 0.05$)

($p = 0.004$). Between the two cohorts, there was no significant difference in post-operative outcomes of infection, hematoma, and skin necrosis at 6-month follow-up from surgery ($p = 0.72$). For study purposes, post-operative infection, hematoma, and skin necrosis were defined as an infection, hematoma, or skin necrosis that required re-operation.

Cost savings

By combining mastectomy and breast reconstruction instrument kits, the number of surgical instruments decreased by 50.3%, from 167 number of instruments to 84 number of instruments. Fewer instruments used per surgical procedure decrease cost of cleaning, repackaging,

Table 3 Instrument and labor costs associated with using a separate and combined mastectomy and breast reconstruction instrument kit per mastectomy with reconstruction

Cost variable	Savings per instrument	Savings per case	Savings per year
Disposable products		$10	$3280.00
Cleaning and repackaging	$0.51	$42.33	$13,884.24
Maintenance and repair	$0.23	$19.09	$6261.52
Decontamination and assembly		$12.43	$4077.04
Total	$0.74	$83.85	$27,502.80

maintaining and repairing of non-disposable instruments. Labor savings for SPD decontamination and assembly were approximated to 80% less per case. Table 3 demonstrates related cost savings regarding disposable products replacement, cleaning and repackaging of instruments, maintenance and repair of instruments, as well as decontamination and assembly labor expenses. Total cost data extrapolated per year demonstrated a total instrument and labor savings of $27,503 at our institution.

A 27-min decrease in overall surgical time for unilateral cases was calculated by combining the 10.6 min saved in set-up time with the 15.9 min saved for the procedure time. Therefore, we estimate for unilateral cases performed with the combined kit protocol total operating room savings were $999–$1674 per case. Thus, when considering the 107 unilateral procedures performed annually at our institution, savings were further projected to $106,893–$179,118 per year. For bilateral mastectomies with reconstruction, there was a 32-min decrease in overall surgical time 10.4 min in set-up time and 21.5 min in procedure time. Using the combined mastectomy and breast reconstruction kit resulted in savings estimated as $1184–$1984 per case. When considering the 221 bilateral procedures performed annually at our institution, savings was further projected to $261,664-$438,464, as depicted in Table 4. When combining total instrument and labor savings with total operating room savings, $134,396 to $206,621 is saved in unilateral cases while $289,167 to $465,967 was saved in bilateral cases with the implementation of a combined mastectomy and breast reconstruction surgical kit.

Discussion

Optimization of surgical technique in mastectomy and breast reconstruction procedures has become critical in improving quality of care for breast cancer patients. This study effectively evaluated patient outcomes and cost savings following the use of a novel approach to treating mastectomy and immediate breast reconstruction as a single procedure.

By reducing the overall number of instruments, surgical personnel had fewer materials to set up prior to operative cases. As such, we observed that set-up time was reduced by 10.6 min in unilateral cases and 10.4 min in bilateral cases. Streamlining one surgical kit for both specialties also allowed surgical oncologists and plastic surgeons to transition smoothly and often work simultaneously decreasing procedure time by 15.9 min in unilateral cases and 21.5 min in bilateral cases. Notably, these differences did not compromise patient care or post-operative complications.

Similar studies have noted that such decreases in set-up time and operative time allow for more rapid turnover between procedures, thereby increasing available operating room time. This, in turn, renders the surgical staff more available, which allows for redistribution of time for other cases and increases efficiency. In addition, studies predict that fewer instruments included in each kit will lead to fewer counting errors [4, 6]. It is necessary to evaluate error in instrument set-up in future studies to better assess the viability of streamlined instrumentation kits.

We reported a $134,396 to $206,621 in institutional savings in unilateral cases and a $289,167 to $465,967 in institutional savings in bilateral cases due to decreased instrumentation processing and labor costs as well as operating room savings. The number of instrument wash cycles was difficult to assess, as our institution may run partial loads.

Table 4 Operating room cost savings using a combined mastectomy and breast reconstruction instrument kit

	Overall difference in surgical time (min.)	Estimate savings per case	Estimated savings per year
All cases	30	$1110–$1860	$364,080–$610,080
Unilateral cases	27	$999–$1674	$106,893–$179,118
Bilateral cases	32	$1184–$1984	$261,664–$438,464

Instrument transport remained unaffected as all kits were transported in a single case cart. Furthermore, central processing costs were calculated based on published data from an institution similar to our own, while labor costs were specific to our institution. Based on these estimates, we anticipate that the 50.3% difference in number of instruments between each kit will translate to lower central processing and labor costs.

Our study was limited in its investigation of a single tertiary academic center. With a restricted amount of surgical cases, it has potential to limit generalizability and could allow for small sample bias. Nonetheless, by focusing our research on a specific institution, we ensured that surgical set-up protocol, practice, and policy were consistent throughout cases. Moreover, the implementation of novel techniques in any setting is known to produce a learning curve. Such learning curve of implementing the combined surgical kit was evident at our institution. Time delays specifically resulting from the kits, such as replacing missing instruments or including extra instruments, decreased with repeated use of the combined kit. Thus, true time saving could be greater as the staff acclimates to the combined kit.

However, the strength of this study was its implementation of a streamlined surgical instrument kit specifically for mastectomy and breast reconstruction procedures. By controlling for variation in patient and surgeon variables, we effectively assessed time measures, patient outcomes, and institutional costs. Our study proved that a streamlined kit containing fewer surgical instruments led to a shorter procedure set-up time. In addition, by allowing the surgical oncology and plastic surgery team to work with the same kit, procedure time decreased. This investigation parallels previous studies that demonstrate the safety and efficacy of combined surgical instrument kits.

Conclusion

Mastectomy with implant-based reconstruction utilizing combined instrumentation led to decreased instrument set-up and procedure time. Combined instrumentation also does not increase patients' risks of complications. Costs savings associated with the combined approach were realized in fewer instruments to purchase and maintain as well as in a reduction in operating room utilization. These findings warrant the attention of surgical personnel and hospital administrators. Further studies are needed to evaluate how surgical efficiencies may further improve patient experience.

Compliance with ethical standards

Conflict of interest Eric Liao M.D. Ph.D has consultant agreements but is explicitly not a speaker for Musculoskeletal Transplant Foundation and Allergan Inc., manufacturers of FlexHD and AlloDerm, respectively. No funds were received for this clinical study.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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