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Effectiveness of a Clinical Pathway for Breast Cancer Patients Undergoing Surgical Operation on Clinical Outcomes and Costs

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Purpose: This study aimed to evaluate the impact of implementing a clinical pathways (CPs) on the clinical outcomes and costs of patients undergoing breast cancer surgery.

Methods: This retrospective cohort study included patients who were newly diagnosed with primary breast cancer at the Samsung Medical Center between 2014 and 2019 (N=8482; 2931 patients in the pre-path and 5551 patients in the post-path). Clinical outcomes included reoperation during hospitalization, readmission, and emergency room visits within 30 days of discharge. The cost data for each unit were obtained from an activity-based management accounting system. We performed an interrupted time series analysis.

Results: The post-path period showed a significantly shorter hospital length of stay (LOS) than the pre-path period (6.3 days in pre-path vs. 5.0 days in post-path; -1.3 days' difference; p=.001), and fewer reoperations during hospitalization and within 30 days after discharge than the pre-path period. After adjusting for inflation rates and relative value scores, the model demonstrated savings of $146 per patient in the post-path for total costs, and $537 per patient for patient out-of-pocket costs (p=.001).

Conclusion: CPs can help reduce costs without compromising the quality of care by reducing the number of reoperations, readmissions, and complications.

Keywords: Critical pathways, Costs-effectiveness analysis, Interrupted time series analysis, Complications, Value-based health care

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Ⅰ. Introduction

The economic burden of breast cancer is substantial and is expected to increase significantly [1,2]. The total socioeconomic costs incurred by breast cancer in the gross domestic product (GDP) increased more than six-fold from 8 billion dollars in 1999 to 55.8 billion dollars in 2014 [3]. The emphasis on maximizing health outcomes while considering costs has been repeatedly highlighted. Given the limitations of available resources, a reduction in the burden of breast cancer care may have critical socioeconomic implications [4].

To improve organizational efficiency, the conceptualization of clinical pathways (CPs), which provide a standardized care plan and optimize processes, was designed [5]. CPs are expected to reduce the length of hospital stay and save costs of hospital admission and healthcare budget [6]. Several previous studies have suggested that CPs can reduce costs by 15 - 35% while achieving the same clinical outcomes [6].

Recently, CPs have been considered a key factor in improving clinical outcomes, such as quality of care [6-8]. The American Society of Clinical Oncology (ASCO) established guidelines for evaluating CPs, including improving the quality of care and reducing costs [6-8]. However, clinical evidence that CPs can improve the quality of care by reducing unnecessary variables is limited, as previous studies have primarily focused on reducing costs rather than on clinical outcomes [4,9].

This study aimed to evaluate the impact of CP implementation on the clinical outcomes and costs of patients undergoing breast cancer surgery.

Ⅱ. Materials and methods

Study design and patients

This retrospective cohort study used data obtained from the Clinical Data Warehouse (CDW) Darwin-C of the Samsung Medical Center (SMC). Recently, an interrupted time series (ITS) analysis, also called an "intervention analysis" has been used to analyze causality by longitudinally tracking before and after an intervention [10].

For the ITS, we included patients aged ≥18 years who were newly diagnosed with primary breast cancer, defined as the presence of a code for breast cancer [International Classification of Diseases-10th Revision (ICD-10) code: (C50)] and underwent breast conserving surgery (BCS) and total mastectomy (TM) at the SMC between 2014 and 2019 (N=13,356). Since the Middle East respiratory syndrome (MERS) outbreak in May 2015, the hospital was unable to operate normally until the end of the year, and patients who underwent surgery in 2015 were excluded owing to MERS. Patients who underwent reconstructive surgery, joint operations, benign tumors (N=4058), local or radical excision (N=577), and foreign patients (N=239) were excluded from the study. As not all foreign patients receive the same benefits from national health insurance as Koreans, foreign patients were excluded from this study. The final sample size was N=8482 (Figure 1). This study was approved by the Institutional Review Board of Sungkyunkwan University (IRB No. 2021-10-034). Owing to the retrospective study design, the need for informed consent was waived by the IRB.

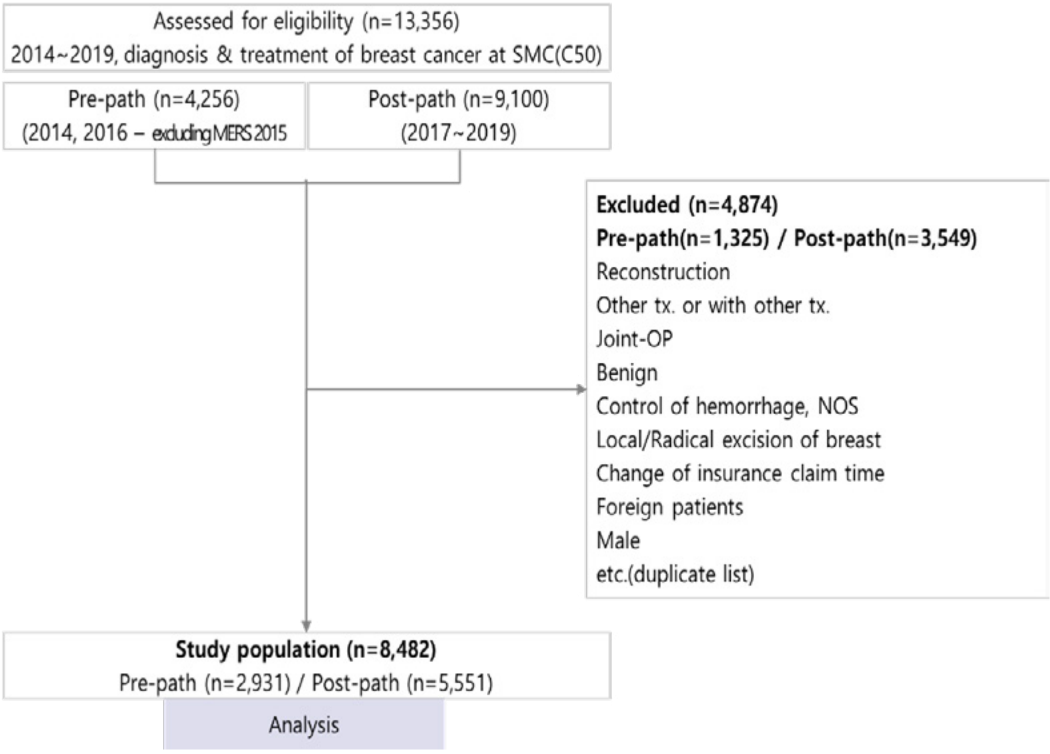

Figure 1. Legend : Completed study population (N=8,482; 2,931 patients in the pre-path group vs. 5,551 patients in the post-path group).

Measurement

Clinical Pathway

The CPs for breast cancer centers at SMC were developed collaboratively by physicians, nurses, and other healthcare professionals. A draft version of the CPs to provide valuable care was implemented as a pilot program in October 2013, and the final protocol was developed after several revisions and supplements. The current version has been in use since January 2017. The pathway components included preoperative care (inpatient care) and all the components of postoperative care until hospital discharge. Specific care protocols were pre-ordered daily for all aspects of inpatient surgical conditions. Specific aspects of the pathway include the management of all drains and tubes, wound care, medications, nutritional management, patient education, and criteria for pathway discontinuation. The pathway components did not include all the intraoperative care or pathological assessments of the specimens.

Clinical Outcomes

The clinical outcomes were selected based on the recommendations of the International Consortium for Health Outcomes Measurement (ICHOM) [11]. We examined the length of hospital stay, reoperation postoperative complications during hospitalization, readmission, reoperation, and emergency room (ER) visits within 30 days of discharge.

The length of stay (LOS) was calculated as the length of hospital stay from the day of admission to discharge, from preoperative day 1 to the day of discharge. Reoperation was defined as a repeat operation performed during hospitalization. All hospital admissions within 30 days of discharge were defined as readmissions and ER visits. Postoperative complications were assessed using several items based on the Clavien - Dindo Classification (CDC) recommendations [12,13]. The complications assessed included surgical site infections, wound infections, bleeding, hematoma, seroma, anemia, and cardiovascular complications such as arrhythmias that occurred during the hospital stay [13].

Cost Outcomes

The cost data for each unit were obtained from an activity-based management accounting (ABM) system at the SMC. The cost items included physical examination and clinic visits (basic examination cost of preoperative and outpatient consultation clinic visits), diagnostics (radiology, laboratory, and pathology costs), hospitalization (inpatient cost per day in the hospital), operative care (cost of all care in the operating room, including anesthesia), medication (other medication costs with delivery excluding anesthesia costs), nutrition (cost of food intake and counselling), intensive care (cost of all care in the intensive care units), and others (for example, oxygen use, etc.). Preoperative costs, such as clinical visits and diagnostic costs that did not coincide with the implementation period of the clinical pathway, were not included in this study. We calculated both the total cost, which confirms the volume of the total cost, and the patient out-of-pocket cost, which directly affects the financial burden of patients. Furthermore, to control for variables caused by external factors, such as the inflation rate and insurance cost changes, we calculated the adjusted cost. From 2014 to 2019, the annual inflation exchange rates were 0.7%, 1.0%, 0.7%, 1.9%, 1.5%, and 0.4% [14]. In addition, the reflection of insurance costs changed by the government and operation of breast cancer insurance costs increased by an average of 15.8%, and the Relative Value Score (RVS) changed from 15293.92 to 17703.92 [15].

Statistical analysis

We conducted descriptive analyses to compare the sociodemographic characteristics of patients who underwent surgery before and after applying the clinical pathway (pre- vs. post-path). Significance tests were performed using the chi-square test for categorical variables and the t-test for continuous variables.

For clinical outcomes, we compared the mean length of hospital stay between CPs implementations. A multivariate logistic regression model was used to determine the effects of applying the clinical pathway on complications during hospitalization and after discharge. In terms of readmission and ER visits within 30 days after discharge, and postoperative complications during the hospital stay, we calculated the Odds Ratio (OR) with a 95% confidence interval, adjusting for age (continuous), stage (I, II, III, and Neo), and operation type (BCS vs. TM).

For cost outcomes, we compared the mean total cost per patient as well as the out-of-pocket cost per patient between CPs implementations. To align the currency units with international standards, the base currency was converted from Korean won to US dollars, and the currency was 1,150 won per dollar (adopted as the average standard currency as of 2019). In addition, to control for variables influencing costs, we evaluated various assumptions regarding the association of significant cost changes with inflation and government medical policy changes before and after the implementation of CPs. Therefore, the annual currency value was corrected by applying the theory to calculate the present and future values of money.

To explore the changes in LOS and cost after CPs implementation, we presented graphical depictions fitted using a segmented regression model. The data points that aggregated the daily data of interest were divided into two segments corresponding to CPs implementation (before CPs vs. after CPs). The equation of the regression model described below was used to define the levels (e.g., y-intercepts) and slopes for each time segment.

$$Y_t = \beta_0 + \beta_1 * \text{Time} + \beta_2 * \text{Intervention} + \beta_3 * \text{Time since intervention} + \varepsilon_t$$

Time started from 0, and Intervention was coded as 0 (before CPs) or 1 (after CPs). The time since the intervention was counted as the number of days after the CPs implementation. Given that clinical or cost outcomes can be affected by the operation type, the dataset was separated into those who underwent BCS or TM. The model was fitted using the restricted maximum likelihood (REML) method, considering the autoregressive error term.

All statistical analyses were performed using SPSS software version 27 and R 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was defined using a 95% confidence interval (CI) and p-value $<$ .05.

Ⅲ. Results

Characteristics of Patients

This cohort study included 8,482 patients who underwent breast cancer surgery between 2014 and 2019 with 2,931 patients in the pre-path group and 5,551 patients in the post-path group. The pre-path group contained fewer participants than the post-path group (34.6% vs. 65.4%). However, the groups were otherwise similar in terms of percentage of age segmentation. In both cohort groups, more than two-thirds of the patients belonged to the 40 - 60s age group and underwent BCS. A significant difference was observed in the proportion of patients who received neoadjuvant treatments (Table 1).

Clinical Outcomes

The post-path period showed a significantly shorter hospital LOS than that in the pre-path period (6.3 days in pre-path vs. 5.0 days in post-path; -1.3 days' differences; Adjusted p=.001). In the segmented regression model, there were no immediate effects of CPs implementation in the BCS and TM groups (Figure 2). Decreasing trends were observed in both groups after the intervention but they were statistically significant only in the BCS group (p=.002).

Table 1. Legend: Baseline demographics and clinical characteristics of study subjects.

	Pre-path (n=2931)	Post-path (n=5551)	
	n (%)	n (%)	*p*
Age, Mean (years)	50.3	51.6	〈 .001
Operation type (cases)			〈 .001
BCS	1893 (64.6)	4275 (77.0)	
TM	1038 (35.4)	1276 (23.0)	
Cancer stage, pathology, AJCC			.040
Neo-adjuvant	120 (4.1)	517 (9.3)	
In-situ	49 (1.7)	64 (1.2)	
I	1149 (39.2)	1977 (35.6)	
II	915 (31.2)	1353 (24.4)	
III	227 (7.7)	210 (3.8)	
IV	3 (0.1)	5 (0.1)	
n/a	468 (16.0)	1425 (25.7)	

BCS= Breast Conserving Surgery; TM=Total Mastectomy; AJCC=American Joint Committee on Cancer

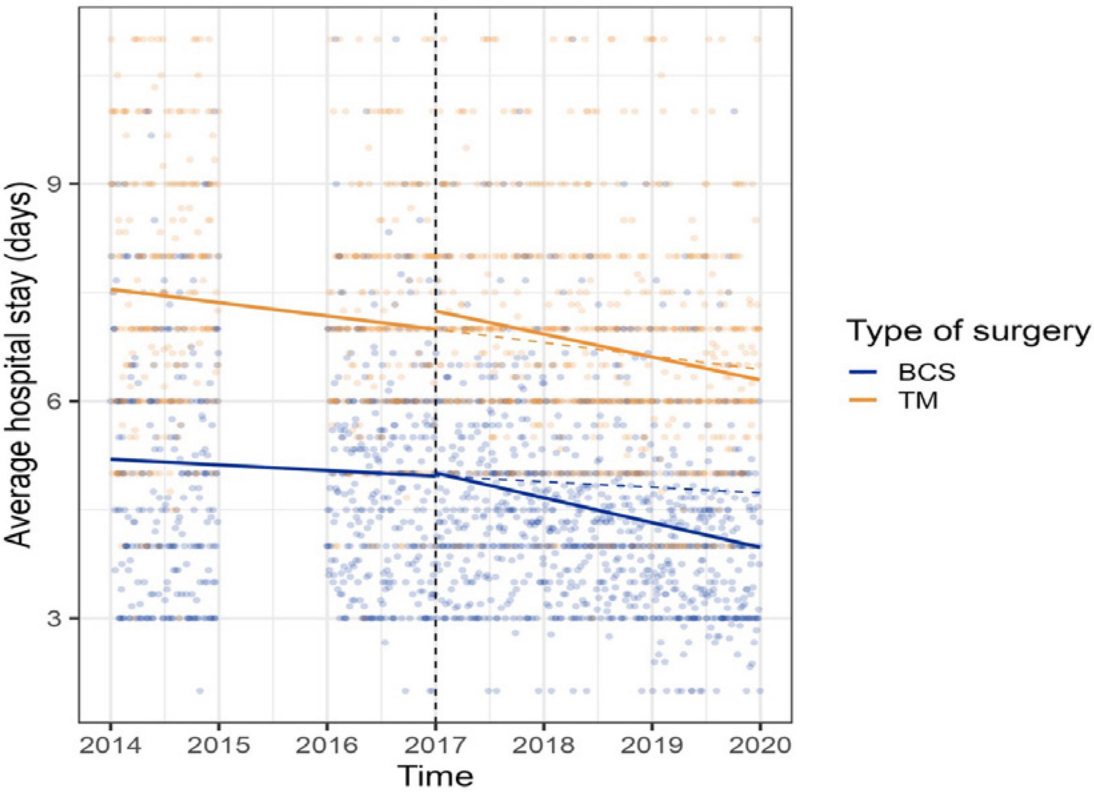

Figure 2. Legend : Changes in levels and trends of hospital stay from 2014 to 2020.

In terms of complications during hospitalization, the post-path group was less likely to undergo reoperation (0.7% pre-path vs. 0.3% post-path; OR 0.57; 95% CI 0.293-1.110) and wound care (0.4% pre-path vs. 0.1% post-path; OR 0.413; 95% CI 0.165-1.038) (Table 2) than during the pre-path period. Furthermore, the post-path period was less likely to result in readmission (11.1% of pre-path vs. 2.4% of post-path; OR 0.238; 95% CI 0.193-0.294), and reoperation (0.6% of pre-path vs. 0.3% of post-path; OR 0.398; 95% CI 0.196-1.808) within 30 days after discharge than the pre-path period (Table 2).

Table 2. Legend: Clinical outcomes among patients treated with pre-path versus post-path.

	Pre-path (n=2931)	Post-path (n=5551)	Multivariable model Adjusted OR (95% CI)	
	n (%)	n (%)		*p*
Complications during the hospital stay				
Reoperation	20 (0.7)	18 (0.3)	0.570 (0.293 to 1.110)	.098
SSI	12 (0.4)	30 (0.5)	1.545 (0.767 to 3.110)	.223
Wound	13 (0.4)	8 (0.1)	0.413 (0.165 to 1.038)	.060
Bleeding	7 (0.2)	6 (0.1)	0.537 (0.173 to 1.670)	.283
Hematoma	10 (0.3)	15 (0.3)	1.076 (0.469 to 2.469)	.864
Seroma	1 (0.0)	6 (0.1)	3.716 (0.423 to 32.066)	.237
Anemia	0 (0.0)	2 (0.0)	.	.
Arrhythmia	0 (0.0)	0 (0.0)	.	.
Complication within 30 days after discharge				
Readmission	324 (11.1)	135 (2.4)	0.238 (0.193 to 0.294)	〈 .001
Reoperation	17 (0.6)	15 (0.3)	0.398 (0.196 to 0.808)	.011
ER visit	56 (1.9)	96 (1.7)	0.874 (0.619 to 1.233)	.443

ER= Emergency Room; SSI= Surgical Site Infection; RR= Relative Risk
Adjusted for age, stage, operation type
Pre-path=reference group

Cost Outcomes

After adjusting for inflation rates and RVS, the model demonstrated savings of $146 per patient in the post-path for total costs, and $537 per patient for patient out-of-pocket costs (p=.001, Table 3). In the segmented regression model of total cost changes, decrements of −443.49 USD in the BCS group (p〈.001) and -442.25 USD in the TM group (p〈.001) were observed immediately after the intervention (Figure 3). Increasing trends in total costs after the intervention were found; however, the difference was not statistically significant (Supplementary Table). In terms of out-of-pocket cost, decrements of −136.53 USD in the BCS group (p〈.001) and -151.37 USD in the TM group (p〈.001) were observed after the immediate intervention (Figure 3). However, a significant decreasing trend after the intervention was observed only in the BCS group (p〈.001).

Table 3. Legend: Health care cost among patients treated with pre-path versus post-path.

	Pre-path (n=2931)		Post-path (n=5551)		Incremental Difference		
Adjusted	Mean ($)	SD	Mean ($)	SD	PostPath+	95% CI	*p*
Total cost	4,462	2,173	4,316	1,077	- 146	-229 to -62	〈 .001
Patient out-of-pocket cost	1,612	1,876	1,075	740	- 537	-607 to -466	〈 .001

Cost data are presented in US$
Adjusted data applied to the inflation rate from 2015 to 2019 and government medical policy changes (relative value score) in 2018 and 2019.
Pre-path=reference group

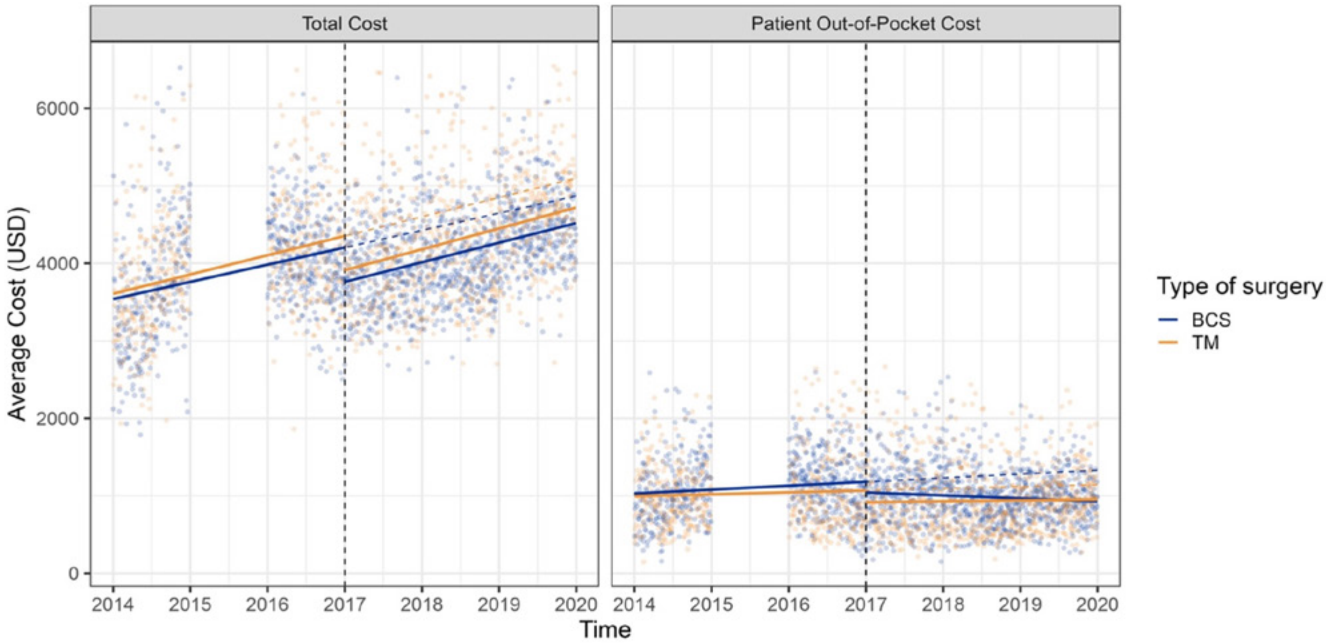

Figure 3. Legend : Changes in levels and trends of total cost (left) and out-of-pocket cost (right) from 2014 to 2020.

Ⅳ. Discussion

This study demonstrated that the post-pathway period had fewer patient complications during hospitalization and after discharge than the pre-pathway period. Additionally, we found that CP implementation significantly reduced both hospital administration and patients' medical service fees.

The CPs implementation significantly reduced hospital LOS and the incidence of patient complications, readmission, and reoperation rates. Previous studies have demonstrated that the use of CPs decreases readmission rates, wound infections, and several common surgical procedures, including pancreatectomy and laparoscopic gastrectomy [16,17]. However, previous observational studies relying on a small number of pre- and post-intervention measurements are prone to bias, as they do not account for pre-existing underlying short- and long-term trends [18]. Conversely, the ITS analysis we used was more robust as it controlled for these issues by longitudinally tracking outcomes before and after the intervention. The ITS is considered one of the best designs for establishing causality when randomized controlled trials (RCTs) are neither feasible nor ethical [19]. Thus, our study provides strong evidence of the benefits of CPs on clinical outcomes. Practice-based standard clinical guidelines and management protocols to improve the quality of care for patients with cancer can reduce risks by providing useful options in critical situations [8]. These findings suggest that CPs can be effectively implemented for patients who have undergone breast cancer surgery, while maintaining or improving the quality of care and cost control. It is worth noting that the number of patients with breast cancer has been growing rapidly, with a compound annual growth rate (CAGR) of 8% since 2000, which is 1.6 times higher than that of all patients with cancer [20]. Appropriate risk management is necessary when treating patients with limited medical resources. Thus, the implementation of CPs should be considered to improve the safety and affordability of cancer care [8,21].

In terms of cost outcomes, this study found meaningful results indicating that CPs can reduce out-of-pocket costs for patients while maintaining or improving the quality of clinical outcomes. Additionally, CPs implementation significantly reduced hospital administration fees and fees for patients receiving medical services. Our data demonstrated that the implementation of CPs significantly reduced the financial burden on patients. Previous studies have demonstrated that the use of CPs reduces healthcare costs by reducing hospital stays for several common surgical procedures, including prostate, stomach, thyroid, and breast cancer [4,16,17,22,23]. In a recent breast cancer regimen pathway study, the main finding was that treatment regimens were associated with cost savings without compromising the quality of care, as evidenced by comparable rates of hospitalization, ER visits, and reduced use of supportive drugs [8]. The consistent development and expansion of CPs is expected to support the clinical field by presenting a standardized protocol, not cost control, from the perspective of the government, which minimizes blind spots in medical welfare and rationally organizes and executes the medical budget. Therefore, CPs are expected to serve as appropriate tools for realizing value-based healthcare.

By devising mechanisms to contain costs and minimize resource utilization while maintaining or improving the quality of cancer patient care, CPs have been widely used by various medical institutions because they are relatively easy to implement and involve a wide range of stakeholders. The original concept of the pathway was initially used in construction and engineering work environments to provide an outline of a given job and its timely completion [24].

This study has some limitations that should be considered when interpreting the findings. First, we did not evaluate changes in patient satisfaction. Further studies on patient satisfaction, using patient-reported outcomes (PROs) should be conducted. Second, this study was performed using single-center data; thus, the results may be limited in terms of the representativeness and generalizability of the study population. However, the breast cancer center at the SMC treats approximately 13.7% of cancer cases nationwide every year as of 2019 [20]. Moreover, as of 2019, the annual number of breast cancer surgeries was approximately 2,900, the highest in Korea as a single center. Third, the correlation analysis between short-term clinical outcomes and costs can be both advantageous and a limitation. Finally, in terms of unplanned clinical encounters after discharge, not every patient was observed, which may imply uncertainty in determining the effect of the established clinical pathway. However, our patients were informed that they should contact our hospital first if they had any clinical issues within 30 days of discharge. Thus, the possible bias may not have been large.

In conclusion, well-designed standard protocols for patients with breast cancer demonstrate an example of high-value care because of the reduced cost without compromising the quality of care by reducing complications, reoperation, and readmission rates. The essential goal of CPs implementation is to reduce the economic burden on patients by optimizing the use of medical resources while maintaining or improving clinical outcomes through a standardized care process.

Ⅴ. References

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Supplementary Table 1. Legend: segmented regression model coefficients in length of hospital stay.

	BCS group			TM group		
	Coefficients	SE	*p*	Coefficients	SE	*p*
Length of Hospital Stay						
Intercept	5.198	0.116	〈 .001	7.545	0.131	〈 .001
Time	-0.001	0.001	.204	-0.001	0.001	.012
Intervention	0.043	0.144	.767	0.251	0.193	.192
Time since intervention	-0.001	0.001	.002	-0.001	0.001	.207

SE=Standard Error

Supplementary Table 2. Legend: segmented regression model coefficients in total cost and out-of-pocket cost.

	BCS group			TM group		
	Coefficients	SE	*p*	Coefficients	SE	*p*
Total Cost						
Intercept	3538.458	50.555	〈 .001	3606.682	57.318	〈 .001
Time	0.607	0.072	〈 .001	0.680	0.087	〈 .001
Intervention	-443.493	63.136	〈 .001	-442.259	82.346	〈 .001
Time since intervention	0.086	0.100	.392	0.059	0.125	.634
Out-of-pocket Cost						
Intercept	1029.825	30.425	〈 .001	996.309	36.127	〈 .001
Time	0.138	0.044	.002	0.067	0.055	.223
Intervention	-136.537	37.912	〈 .001	-151.377	51.645	.003
Time since intervention	-0.243	0.060	〈 .001	-0.034	0.078	.659

SE=Standard Error