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ORIGINAL RESEARCH

# Six Sigma and Statistical Process Control in Clinical Pathway Management: An Evaluation Using Coefficient of Variation, Control Charts, and Process Performance Index

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**Background:** With the increasing emphasis on cost control and quality improvement under the Diagnosis-Related Groups (DRG) payment system, clinical pathway management has become a crucial strategy for hospitals. However, systematic, quantitative tools to assess its implementation and impact remain limited. This study explores the application value of Six Sigma-related metrics in clinical pathway management using the example of cholecystectomy for gallbladder polyps.

**Methods:** Hospitalization costs and length of stay were used as evaluation indicators. Six Sigma-related parameters, including the coefficient of variation, Statistical Process Control (SPC) control charts, and process performance indices, were employed to assess the differences before and after the implementation of the clinical pathway.

**Results:** After implementation of the clinical pathway, the average total cost significantly decreased from ¥10,509±1457 to ¥9998.4 ±1370.7 ($P < 0.001$), and the mean LOS reduced from 4.64±1.47 to 3.90 ± 1.08 days ($P < 0.001$). Process stability improved markedly, with the CV for cost and LOS dropping from 0.139 to 0.137 and 0.317 to 0.278, respectively. The Ppk for total cost rose from 0.46 to 0.67, corresponding to a reduction in the expected defective rate from 82,101.71 to 21,779.86 Parts Per Million (PPM). SPC control charts demonstrated narrowed control limits and enhanced process precision, indicating that clinical variability was effectively suppressed.

**Conclusion:** Integrating Six Sigma into clinical pathway management provides a robust approach to enhance healthcare delivery under Diagnosis-Related Group(DRG) constraints. Hospital administrators can leverage Statistical Process Control charts for real-time monitoring and train staff in Six Sigma to improve care consistency, while policymakers can establish healthcare-specific process performance benchmarks to advance quality and payment reforms. This method bridges industrial quality control with healthcare, offering scalable benefits for system efficiency and equity.

**Keywords:** six sigma, statistical process control, process performance index, clinical pathway coefficient of variation, gallbladder polyps

## Introduction

With the increasing length of hospital stays and the growing financial burden on patients, the issues of "difficult and expensive medical care in China" have become more pronounced. To address these challenges, the implementation of the Diagnosis-Related Groups (DRG) payment system has gradually become a key direction healthcare payment reform in china.[1–5] This system requires hospitals to classify inpatients into several disease groups based on the similarity of their disease types and resource consumption. The payment standard for each disease group is determined by the length of stay and resource consumption recorded in the medical records, combined with cost driver analysis, to establish a bundled prepayment standard. This prepayment model, based on hard budget constraints, forces hospitals to improve diagnostic and treatment efficiency while ensuring medical quality, thereby optimizing resource allocation and achieving both cost control and service quality improvement. However, under this payment model, hospitals face not only the challenge of effectively controlling costs but

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also how to provide high-quality medical services within a limited budget. Therefore, balancing cost control and service quality under the DRG system has become a critical issue in current hospital management.[6,7]

Clinical pathways are a standardized clinical care management model designed to adapt to prepayment systems. Their core lies in the collaboration of multidisciplinary teams to manage patients from admission to discharge according to a predefined optimal treatment plan. This management approach not only ensures continuous improvement in medical quality but also effectively controls the length of hospital stays under resource constraints.[8–11] However, despite their widespread adoption, a notable research gap persists: there is currently no comprehensive indicator system for systematically monitoring and evaluating the implementation and standardization of clinical pathways, limiting the ability to quantitatively assess their impact on cost control and quality outcomes under DRG constraints. Existing literature predominantly focuses on qualitative outcomes or simple comparisons of mean values. There remains a critical research gap in the application of comprehensive quantitative frameworks—specifically Statistical Process Control (SPC) and process performance metrics—to evaluate the stability and consistency of clinical pathway implementation. Most current studies fail to address process variability, which is essential for sustainable quality improvement and accurate resource forecasting under the DRG system. To fill this gap, this study takes gallbladder polyps as the research subject and innovatively introduces Six Sigma methods, including the coefficient of variation, Statistical Process Control (SPC), and Ppk, to evaluate the effectiveness of clinical pathway implementation and its role in cost control. Widely utilized in industrial settings to reduce variability and enhance process quality, these Six Sigma methodologies provide a robust, data-driven approach that remains underutilized in healthcare, offering a novel framework to bridge this evaluation gap. Through these quantitative analysis methods, this study not only provides data support for the accurate assessment of gallbladder polyp treatment costs but also offers a theoretical basis for further optimizing the quality control and hospital stay management of clinical pathways, contributing to the broader advancement of healthcare quality management under resource-limited settings.

# Materials and Methods

## Study Subjects

This study selected gallbladder polyp surgery cases before the implementation of the clinical pathway (from January 2020 to June 2022) as the control group and cases after the implementation of the clinical pathway (from July 2022 to December 2024) as the study group. All included patients had a DRG code of HS10B (Laparoscopic Cholecystectomy without Common Bile Duct Exploration) and a surgery code of 51.2300 (Laparoscopic Cholecystectomy). Patients with comorbidities were excluded to ensure the homogeneity of the study subjects. During the study period, the surgical team, clinical protocols (outside the tested pathway), and hospital reimbursement policies remained stable, minimizing potential external influences on the outcomes.

A total of 284 patients were initially identified in the control group, of which 274 were included after applying exclusion criteria (96.5% inclusion rate). In the study group, 211 patients were identified, with 201 included (95.3% inclusion rate). This sample size was deemed sufficient to detect significant differences in hospitalization costs and length of stay based on a power calculation assuming a 10% reduction in costs ($\alpha = 0.05$, power = 0.80). The sample inclusion is shown in Figure 1.

## Implementation of Clinical Pathways

The clinical pathway for gallbladder polyp surgery was developed by a multidisciplinary team to standardize care from admission to discharge. Integrated into the hospital's HIS, it enabled providers to follow evidence-based orders across diagnostic, preoperative, and postoperative phases. Regular staff training and real-time monitoring ensured adherence, minimized variability, and supported continuous improvement.

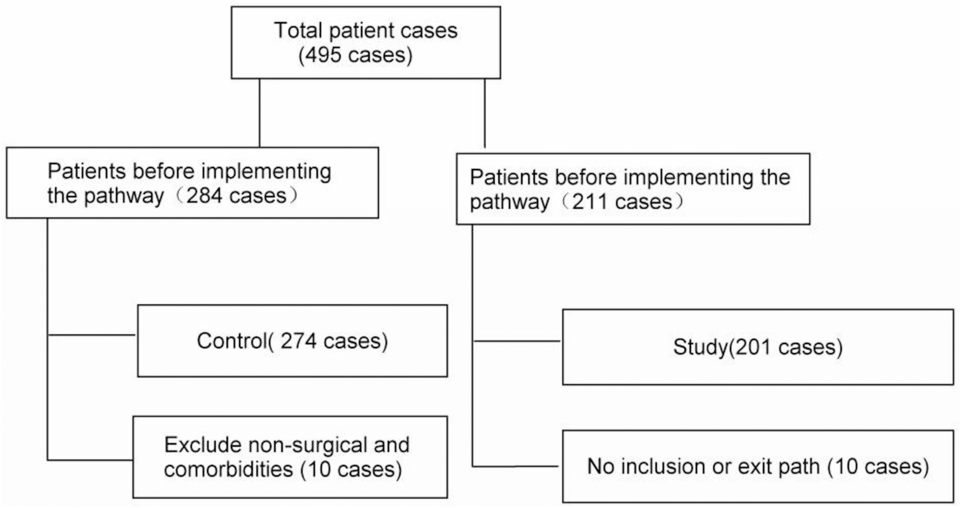


**Figure 1** Flowchart of the patient enrollment process in the study.

## Evaluation Indicators

Hospitalization days and length of stay were selected as evaluation indicators. Six Sigma-related parameters, including the Coefficient of Variation (CV), Statistical Process Control (SPC) charts, and Process Performance Index(Ppk), were employed to assess differences before and after the implementation of the clinical pathway. The formulas used are as follows:

$$CV = \overline{X}/\sigma \tag{1}$$

(1) Coefficient of Variation (CV), where σ is the standard deviation and $\overline{X}$ is the mean.

$$Ppk = (USL - \overline{X})/3\sigma \tag{2}$$

(2) Process Performance Index (Ppk), where USL represents the Upper Specification Limit, $\overline{X}$ is the process mean, and σ is the standard deviation.

## Statistical Analysis and Six Sigma Methods

Data were analyzed using Minitab 21.0 software. Count data (eg, gender, case numbers) were assessed with the $\chi^2$-test. Measurement data were tested for normality; normally distributed data were compared using the *t*-test, while non-normal data used the rank-sum test ($\alpha = 0.05$).

This study applied Six Sigma method (CV, SPC, and Ppk) to evaluate the clinical pathway's effectiveness for gallbladder polyp surgery. CV assessed data dispersion in hospitalization days, length of stay, and costs before and after pathway implementation to measure consistency changes. SPC monitored indicator trends for real-time process control. Xbar-R charts (subgroups of five) were used for costs, with pre-pathway control limits (Xbar ± $3\sigma/\sqrt{n}$; R ± 3σ_R) and Western Electric rules[12] (eg, points beyond 3σ) identifying out-of-control points. U charts were used for length of stay, defining defects as stays exceeding 4 days, with limits U ± 3 $\sqrt{(U/n}$, where U is the average defect rate. Stability was confirmed by no out-of-control signals. Ppk was calculated in Minitab 21.0 using formula (2), with USL at ¥12,592 for costs (2023 medical insurance benchmark). Non-normal cost data were normalized via Johnson transformation. Ppk reflecting long-term capability, was evaluated descriptively, as its sample-based nature and lack of standard significance tests in quality control precluded statistical testing.

# Results

## Baseline Patient Characteristics

In this study, 96.5% of the control group cases were included before the implementation of the clinical pathway, and 95.3% of the study group cases were included after implementation, with no statistically significant difference between

the two groups (P > 0.05). Additionally, the control group consisted of 105 males and 169 females, while the study group consisted of 91 males and 110 females, with no significant difference in gender ratio (P > 0.05). In terms of age, the average age of the clinical pathway group was 48.0 years, compared to 48.6 years in the control group, with no statistically significant difference (P > 0.05). See Table 1.

## Hospitalization Costs

This study compared the differences in total medical costs between the study group and the control group before and after the implementation of the clinical pathway. The results showed that after the implementation of the clinical pathway, the median total cost in the study group was ¥10,039, significantly lower than the ¥10,323 in the control group before pathway implementation (P < 0.05). Additionally, the mean and standard deviation of total costs before and after pathway implementation were ¥10,509 ± 1457 and ¥9998.4 ± 1370.7, respectively. The coefficient of variation (CV) decreased slightly from 0.139 before pathway implementation to 0.137, indicating improved precision in total medical costs. See Table 1.

Using five patient samples as a subgroup, this study constructed an Xbar-R control chart. The results showed that before the implementation of the clinical pathway, several out-of-control points appeared on the range control chart, indicating significant variability in the treatment process. After pathway implementation, the average and standard deviation of the post-pathway data were used as control limits for re-evaluation, showing an increase in the number of out-of-control points before pathway implementation, further indicating greater variability in costs before pathway implementation. See Figure 2.

Since the total Hospitalization costs did not follow a normal distribution, Johnson transformation was applied to construct a capability analysis for costs. The upper control limit (UCL) for costs was set at ¥12,592, based on the 2023 local medical insurance payment benchmark points. The results showed that the Ppk for controlling hospitalization costs improved from 0.46 before pathway implementation to 0.67 after implementation, with the expected defective parts per million (PPM) decreasing from 82,101.71 to 21,779.86. See Table 1 and Figure 3.

## Length of Stay

This study compared the differences in hospitalization days between the control group and the study group before and after the implementation of the clinical pathway. The results showed that after pathway implementation, the median hospitalization days in the study group decreased from 4 (4–5) days to 4 (3–4) days (P < 0.05). The mean and standard

**Table 1** Comparison Between the Control Group and the Study Group

| Variable | Control Group | Study Group | Statistic | P-value |
|---|---|---|---|---|
| Case Inclusion% | 96.5% (274/284) | 95.3% (201/211) | 0.463 | 0.496 |
| Age(years) | 48.6 ± 11.8 | 48.0 ± 13.6 | 0.486 | 0.627 |
| Gender | 38.3% (105/169) | 45.3% (91/110) | 2.312 | 0.128 |
| Total cost | | | | |
| P50 (P25-P75) | 10,323.0 (9481.0–16,703.0) | 10,039.0 (8876.7–13,290.9) | 92,749 | P < 0.001 |
| $\overline{X}$±SD | 10,509 ± 1457 | 9998.4± 1370.7 | 5.7 | P < 0.001* |
| CV | 0.139 | 0.137 | - | - |
| Ppk | 0.46 | 0.67 | - | - |
| Expected PPM | 82,101.71 | 21,779.86 | - | - |
| Length of Stay | | | | |
| P50 (P25-P75) | 4 (4–5) | 4 (3–4) | 73,737.5 | P < 0.001 |
| $\overline{X}$ ± SD | 4.64 ± 1.47 | 3.90 ± 1.08 | - | - |
| CV | 0.317 | 0.278 | - | - |
| Major Postoperative Complications% | 0.0% (0/274) | 0.0% (0/201) | - | - |
| Reoperation % | 0.0% (0/274) | 0.0% (0/201) | - | - |
| 30-day readmission% | 0.0% (0/274) | 0.0% (0/201) | - | - |

**Notes**: *t-test after Johnson transformation. Costs and hospitalization days were non-normally distributed, so the rank-sum test was used. - Not applicable.

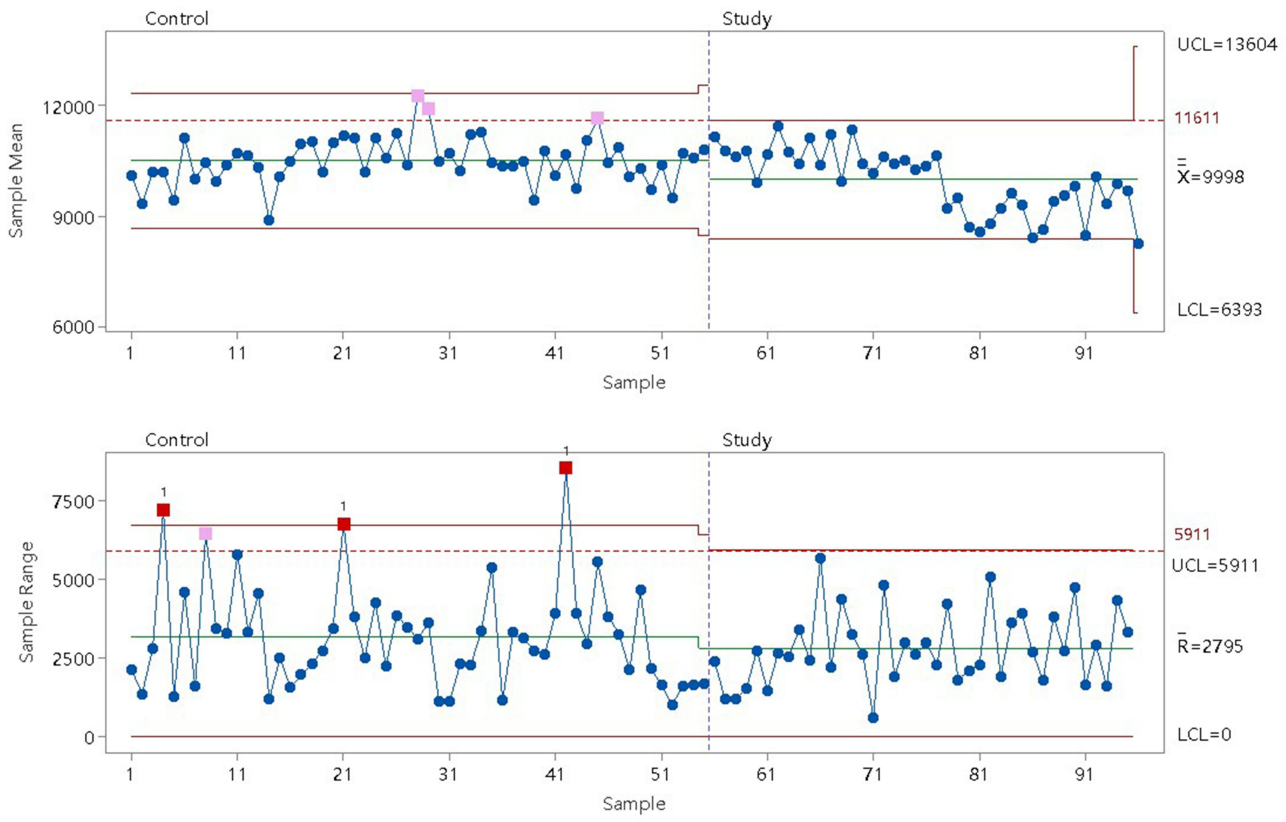


**Figure 2** Xbar-R control chart of total hospitalization cost (subgroup size = 5). The dashed line marks the clinical pathway implementation point. Red dots indicate out of control. Light red dots: Uncontrolled cases that occur based on the mean and standard deviation after implementing the clinical pathway as control lines.

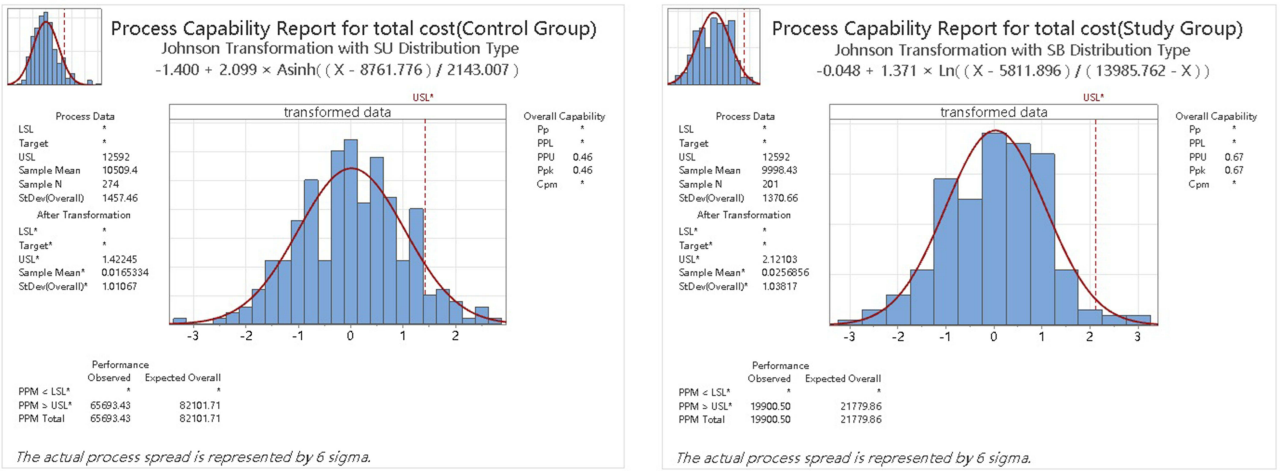


**Figure 3** Process capability analysis of total hospitalization costs before (Control) and after (Study) clinical pathway implementation. Johnson transformation was applied to address non-normal distribution. The charts display the process spread and distribution fit relative to the defined control limits, with Ppk used to assess cost control performance. The red dotted line denotes the Upper Specification Limit (USL); asterisks (*) on the USL, Pp, and PPL indicate values calculated on the Johnson-transformed scale due to non-normal data; meanwhile, other asterisks (*) indicate that certain indices are not calculated because no Lower Specification Limit (LSL) was defined for this analysis.


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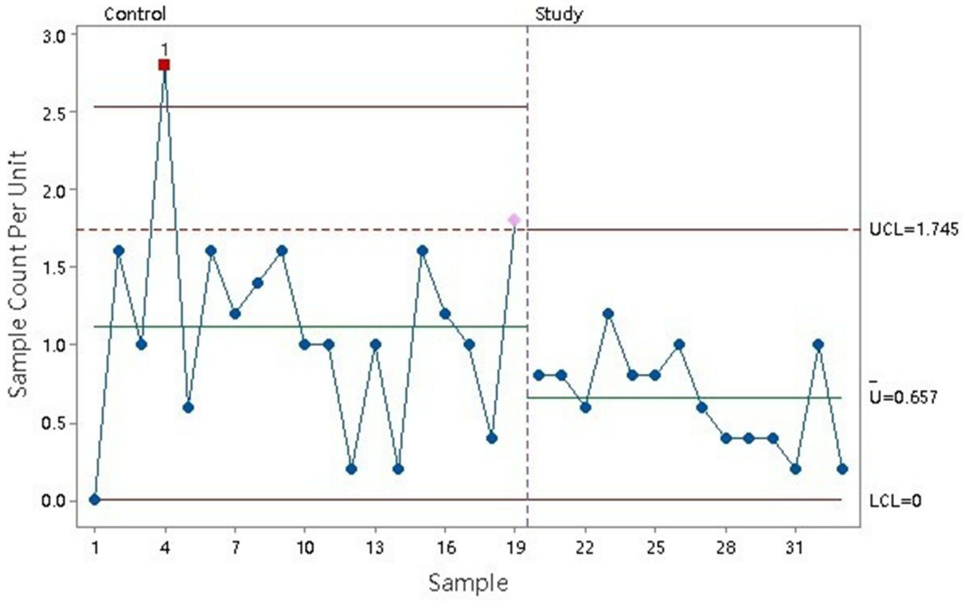


**Figure 4** U control chart for hospitalization days using a subgroup size of five and a defect criterion of hospitalization exceeding 4 days. The dashed line marks the clinical pathway implementation point. Red dots indicate out of control; Light red dots: Uncontrolled cases that occur based on the mean and standard deviation after implementing the clinical pathway as control lines.

deviation of hospitalization days decreased from 4.64 ± 1.47 days in the control group to 3.90 ± 1.08 days in the study group. The coefficient of variation (CV) decreased from 0.317 before pathway implementation to 0.218, indicating that hospitalization days became more concentrated around 3 days after pathway implementation. See Table 1.

Using hospitalization days exceeding 4 days as a defect and five patient samples as a subgroup, a U control chart was constructed. The U control chart showed one out-of-control point before pathway implementation. When the post-pathway mean and standard deviation were used as control limits, the number of out-of-control points before pathway implementation increased further. See Figure 4.

## Postoperative Complications

No Major complications (such as bile duct injury, post-cholecystectomy hemorrhage, or severe infection), reoperation and 30-day readmission were observed in either group before or after the implementation of the clinical pathway. See Table 1.

# Discussion

## Statement of Principal Findings

In the fields of industry and manufacturing, a mature quality control and improvement mechanism has long been established by implementing statistical process control and evaluating process capabilities.[12,13] The core goal of this mechanism is to identify, monitor and reduce the factors that cause variation in a specific industrial process or system. Although the medical field has gradually drawn on these management concepts, especially the DMAIC (define, measure, analyze, improve, control) method,[14–16] the application research of evaluation parameters (such as control chart, coefficient of variation, process capability index, etc.) in Six Sigma in the medical and health industry is still limited. This study applied these tools to clinical pathway management and yielded promising outcomes.

Considering that our hospital has mature experience in the implementation of clinical pathways, and some clinical pathways have undergone multiple versions of iteration and optimization, there may be some differences in diagnosis and treatment. The clinical pathway of cholecystectomy for gallbladder polyps was newly built in July 2020 and has not been revised. Therefore, in this study, we chose the clinical pathway of laparoscopic treatment of gallbladder polyps with DRG code HS10B (laparoscopic cholecystectomy without exploration of common bile duct) and surgical code 51.2300 (laparoscopic cholecystectomy) for analysis. This path is the standard diagnosis and treatment path for cholecystectomy

of gallbladder polyps and has sufficient case data, which provides a reliable basis for subsequent analysis. Through the analysis of this unrevised standard path, the application effect of Six Sigma related parameters in this field can be more accurately evaluated.

In this study, the average hospitalization cost and length of stay of patients decreased significantly before and after the implementation of the treatment path for cholecystectomy of gallbladder polyps. At the same time, the coefficient of variation of hospitalization cost and length of stay also decreased. However, the coefficient of variation of length of stay decreased significantly, while that of hospitalization cost decreased relatively little. These results show that: 1) the implementation of clinical pathways effectively reduces the input of medical resources for the same disease. This change reflects the effectiveness of clinical pathways in standardizing the treatment process and reducing unnecessary diagnosis and treatment operations. 2) The decrease of the coefficient of variation indicates that after the implementation of clinical pathways, the precision of hospitalization cost and length of stay is improved, showing that the consistency and predictability of medical services is enhanced. 3) The small decrease of the coefficient of variation of hospitalization cost may be related to the large proportion of diagnosis and treatment costs in surgical treatment-based diseases. Therefore, the overall variability of hospitalization costs decreases relatively little. 4) The significant decrease of the coefficient of variation of length of stay is closely related to the strict standardized management of patients' hospitalization process. The clinical pathway clearly stipulates daily diagnostic and treatment steps, reducing individual differences and achieving standardization of hospitalization days.

These findings align with previous studies that have applied Six Sigma and SPC in healthcare settings. For instance, Improta et al[15] used Six Sigma to reduce preoperative hospital stay lengths for patients undergoing surgery at an Italian hospital, reporting a decrease from 4.36 to 3.58 days, similar to our reduction from 4.64 to 3.90 days after clinical pathway (CP) implementation. Likewise, Scala et al[16] applied a Lean Six Sigma approach to femur fracture patients, achieving a significant reduction in length of stay and improved process stability. However, unlike our study, which focused on both cost and length of stay with Six Sigma analysis, these studies primarily targeted operational efficiency without extensively evaluating cost variability. Our Ppk improvement (from 0.46 to 0.67 for costs) is modest compared to industrial benchmarks (eg, Ppk > 1.67 for Six Sigma level[17]), reflecting the inherent complexity of healthcare processes versus manufacturing, a distinction also noted by Ortíz-Barrios et al[18] in their application of Six Sigma to shortening the appointment lead-time in Gynecobstetrics Departments.

Although the cost data of patients before and after the implementation of clinical pathways are non-normally distributed, according to the law of large numbers,[19] the mean and mean difference of their values conform to the normal distribution. Therefore, this study chose to use the Xbar-R control chart to analyze the cost data. For the length of stay of patients, as discrete counting data, we set 4 days as the defect item, and constructed a U control chart. In the control chart analysis of cost and length of stay, it was observed that after the implementation of clinical pathways, the mean and standard deviation of patients' cost and length of stay decreased, indicating significant improvements. In addition, the control chart showed better precision, reflecting enhanced standardization. Specifically, the fluctuation of cost and length of stay is reduced and falls within a more stable range, demonstrating the role of clinical pathways in improving consistency in diagnosis and treatment.

## Strengths and Limitations

This study is a post-hoc quality analysis, aiming to evaluate the change of results after the implementation of clinical pathways. However, it is worth noting that once implementation stabilizes, SPC technology can be used to monitor and continuously analyze processes in real time. Therefore, SPC not only helps optimize outcomes but also supports ongoing quality assurance.

In the industrial field, process capability indices include Capability index (Cp) and Ppk. Cp reflects short-term potential capability under controlled conditions, while Ppk reflects long-term performance. Due to high variation in medical data, Cp is less suitable; thus, we used Ppk. While Ppk > 1.67 is considered excellent in industry,[17] our Ppk of 0.67 reflects improved but still suboptimal control. The difference is attributed to healthcare's complexity, patients' conditions, complications, and individual variability all influence costs.

The design of clinical pathways may vary in detail, which can affect cost stability. This highlights the need for further improvement, particularly in enhancing standardization and individualization. However, several limitations should be acknowledged. Selection bias may result from excluding patients with complications or comorbidities, potentially leading to an overestimation of pathway effectiveness. Data variability—such as unrecorded deviations from the pathway or differences in surgeon performance—may have influenced the outcomes, although staff training was implemented to reduce such variation. In addition, external factors, including changes in hospital policies or patient demographics during the study period, were not controlled due to the single-center, retrospective design. These limitations align with challenges noted in prior Six Sigma healthcare studies, such as Niemeijer et al,[20] which also faced issues with generalizability due to reliance on single-site data.

### Interpretation within the Context of the Wider Literature

Future research could expand Six Sigma and SPC applications to other medical procedures, such as orthopedic surgeries or chronic disease management, to test their versatility across diverse clinical pathways. Multi-center studies with larger, more heterogeneous samples could enhance generalizability and refine Ppk benchmarks specific to healthcare. Additionally, integrating real-time SPC monitoring into hospital information systems could enable proactive quality control, a direction also suggested by Che et al[14] for nursing optimization. Considering that this study is only a single-center observation with a relatively limited sample size, the external generalizability of the target value setting may be limited. Therefore, future multi-center studies will further verify these findings under the support of more extensive clinical data. In multi-center research, based on large-scale clinical data, combined with different diagnostic related group (DRGs) grouping, establishing more accurate and adaptive process performance indicators will help to more scientifically evaluate the implementation effect of clinical pathways. This will contribute to improved pathway quality and efficient resource utilization.

### Implications for Policy, Practice and Research

Integrating Six Sigma and SPC into routine clinical management under DRG constraints can support performance evaluation and optimization. Hospital administrators may use control charts for real-time tracking, while training in Six Sigma methods may improve consistency. Policymakers should consider developing healthcare-specific Ppk benchmarks to guide reforms and align incentives.

## Conclusion

Integrating Six Sigma into clinical pathway management offers a powerful approach to improve healthcare under DRG constraints. Hospital administrators can use SPC charts for real-time process monitoring and train staff in Six Sigma to enhance care consistency. Policymakers should develop healthcare-specific Ppk benchmarks to support quality and payment reforms. This method bridges industrial quality control with healthcare, promising scalable benefits for system efficiency and equity.

## Data Sharing Statement

The datasets generated and/or analyzed during the current study are not publicly available due to hospital policy and patient confidentiality restrictions, but are available from the corresponding author upon reasonable request.

## Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of Ruian People's Hospital (Approval No. M2025002). All procedures were conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to their inclusion in the study.

## Consent for Publication

Not applicable, as no identifiable personal data of participants are included in this manuscript.

## Acknowledgments

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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors declare no competing financial or commercial interests in this work.

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