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Original Article

Clinical and economic implications of a clinical pathway for laparoscopic cholecystectomy in Northwest China: a propensity score-matched cohort study

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Abstract: Background: China is undergoing a revolution to curb widespread overtreatment and overcharge in the healthcare system, especially in rural areas. Clinical pathways are standardized patient care plans developed for specific procedures that aim to improve the quality and effectiveness of healthcare. Laparoscopic cholecystectomy is an ideal procedure to assess the effectiveness of clinical pathways owing to its standardized procedure and predictable clinical course. Methods: A total of 2,031 patients who underwent laparoscopic cholecystectomy at four hospitals across northwest rural China from 2005 to 2007 were enrolled. The cohort included 1,156 (56.9%) patients who were intervened with clinical pathways (CP group) and 875 (43.1%) patients who received usual care without intervention (non-CP group). Data regarding patient clinical characteristics, duration of operation and hospital stay, and medical costs were collected and compared. Results: Patients in the CP group had a shorter operation time than those in the non-CP group (31.15 ± 4.83 min vs. 23.99 ± 4.55 min, $P < 0.001$). The median length of hospital stay was shorter in the CP group than in the non-CP group (1.16 ± 0.25 days vs. 1.49 ± 0.31 days, $P < 0.001$). The median total costs were lower in the CP group compared to the non-CP group (RMB 2,394.41 ± 167.41 vs. 3,073.80 ± 198.95, $P < 0.001$). There were no significant differences in the overall postoperative complications or 30-day re-admission rates of patients. Conclusion: The implementation of a clinical pathway in laparoscopic cholecystectomy in rural China improved patient outcome and resulted in substantial cost savings, with no reduction in the overall postoperative complications or 30-day readmission rate. Our study suggests that clinical pathway is very effective in promoting the quality and affordability of care in rural China.

Keywords: Clinical pathway, laparoscopic cholecystectomy, patient outcome, propensity score, public care reform, rural China

Introduction

Inefficiency and low quality of health services are common in rural China. The existing fee-for-service method allowed doctors to purchase medications to prescribe to patients and earn a markup on each prescription [1]. The government allowed hospitals to earn markups of 15-30 percent on some services charged to patients or health insurers, such as tests, imaging, and the dispensing of drugs. As a result, treatments trended toward high margin services, and overtreatment of patients became a serious concern [2]. Reforming public hospitals in China to curb widespread overtreatment and improve the quality and affordability of care has been a great challenge [2]. To ensure access to basic care, the government continued tight controls over the amount that publicly owned hospitals and clinics could charge for routine visits and services such as surgeries, standard diagnostic tests, and routine pharmaceuticals.

One of the most popular methods of meeting this challenge is clinical pathways [3, 4]. Clinical pathways are a methodology for mutual decision making and organization of care for a well-defined group of patients during a well-defined period, with an aim to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources. The clinical pathways are developed by multi-professional teams [5].

In October 2005, the Ministry of Health of China signed two national clinical experts to provide technical assistance to two hospitals on the development of evidence-based clinical pathways in northwest China. The ministry hoped to "popularize the management of clinical pathways and appropriate hospital compensation mechanisms, and provide policy recommendations to policy makers on controlling the unreasonable rise in medical costs [6]".

Although clinical pathways have been implemented in several hospitals in the United States, several systematic reviews of the many uncontrolled and few mostly small, randomized, controlled trials have not supported this widespread use. These reviews conclude that evidence for reducing the length of stay and hospital costs is weak because of the preponderance of retrospective studies that use historical controls and do not adjust for risk or secular trends. Moreover, the use of clinical pathways may also possess risks [7].

We studied an unselected, population-based cohort of patients undergoing laparoscopic cholecystectomy who were intervened with or without clinical pathways.

Our hypothesis was that clinical pathways are more effective than routine care in treating patients by laparoscopic cholecystectomy and that the pathways should enhance patient care while optimizing resource utilization, and should improve patient outcomes at discharge.

We also aimed to improve the quality of care delivered at rural public hospitals by changing the provider behavior through the implementation of clinical pathways, and to measure the true impact of clinical pathways.

Methods

Design, setting, and participants

The Institutional Review Board of Xiangya Hospital of Central South University approved this study. All participants provided written informed consent.

Patients undergoing laparoscopic cholecystectomy are ideal candidates for the systemization of clinical pathway, as it is a standardized, common, and elective procedure, and most patients have a predictable clinical course [8]. Because benign gall bladder disease is a common condition with high prevalence in rural China, it had high incidence rates among the local population and was listed in the local disease registry, provided the hospitals had the technical competency to treat the patients.

The four hospitals included in the pilot study represented all the county-level hospitals in China, because these pilot hospitals were located in relatively poorer and less developed inland provinces. They included 180-260-bedded hospitals serving a population of 500,000-1000,000 in northwest China, including Inner Mongolia.

The hospital selection was made based on the comparability of the history, geography, patient population, transportation, same economic marketplace, local gross domestic product by industry tier, local economic growth rate during the 3-5 years preceding the study, number of hospital beds, number of physicians and nurses, hospital revenue, number and distribution of healthcare institutions in the area, and other factors [6].

Two hospitals were assigned to the clinical pathways (CP) group and the other two hospitals were assigned to usual care group (non-CP). The mean bed count of the hospitals assigned to the CP and non-CP groups was 230 and 210, respectively.

The clinical and administrative staff at each hospital was asked to confirm whether the hospital had a clinical pathway or other specific initiatives to improve the efficiency of any of the study procedures. Surgeons from one study hospital were not attached to any of the other hospitals included in the study.

All patients from a study hospital were operated on by the same two expert laparoscopic cholecystectomy surgeons.

Clinical pathways program interventions

The clinical pathways program was implemented in October 2005. Each hospital was assigned one methodological leader by quality control departments, who monitored all new patients for their eligibility to enroll in the study. The quality control departments consisted of the chief medical officer, clinical department chairmen, and senior administrators who identified the strategic goals and oversaw efforts to achieve them.

A team of two national clinical experts worked closely with local clinical experts to modify clinical pathways so as to reflect local conditions and needs. Each team comprised 7 to 10 members; all teams used a combination of data from outside benchmarking, internal chart review, process flow diagramming, and financial reports. They collected information about similar pathways developed at other hospitals, and information from journals and the internet about what constituted the best clinical practice. The pathways contained information required for clinical decision making (including management algorithms) and evidence-based guidelines; such information was developed into checklists for the entire continuum of care, including care for each day of stay in the hospital, perioperative treatment, and discharge planning. This information was designed in such a way that it could be easily completed by the staff and incorporated into the admission medical record of the patients. As a final step, a consensus meeting with all project participants was held to agree on a final clinical pathway version. Prior to the definite implementation, all staff members were educated on how to work with the clinical pathways. After implementation, the teams met at least once a month, and continuous efforts were made to further develop and improve the clinical pathways based on the suggestions of the staff members. Clinical and quality control departments received quarterly feedback on the rates of pathway compliance and achievement of pathway goals.

Data were prospectively collected by local staff, both in the CP and non-CP groups.

Main outcome measures

The clinical characteristics analyzed included patient age, race, sex, race/ethnicity, surgical indication, and whether the benign gall bladder disease was an indication for laparoscopic cholecystectomy, including cholecystolithiasis, gallbladder polyp and adenomyomatosis.

Perioperative complications, length of hospital stay, overall hospitalization cost, median operating time, and re-admission rates (defined as any emergency re-admission in the 30 days after initial hospital discharge) were assessed.

Perioperative complications included biliary leak, bile duct injury, acute biliary pancreatitis, residual common bile duct stones, abdominal abscess, and abdominal wall hematoma complications. Data regarding the hospital costs were captured through the recorded actual cost variables in multiplying the total hospital charges. The data included an itemized log of all items that were billed to a patient during the hospitalization. The costs were adjusted for inflation using the consumer price index and reported in 2007 RMB.

The designated time of discharge was Day 2 after the procedure. Outpatient follow-up appointments were scheduled within 7 days of discharge.

Statistical analysis

To minimize selection bias, a propensity score-matched cohort was created by attempting to match each patient from the CP group with a patient from the non-CP group (a 1:1 match). For each patient, a propensity score was generated from logistic regression models that included all clinical and demographic characteristics of interest [9]. The probabilities from these models were used to generate a propensity score ranging from 0 to 1 for each patient. A nearest neighbor-matching algorithm with a "greedy" heuristic was used to match patients on the basis of the logit of their propensity score. Based on the resulting propensity score, matched groups (1 CP:1 non-CP) were generated using a matching algorithm with a caliper of 0.005 [10]. A patient from the CP group was randomly selected and matched with the "nearest" patient from the non-CP group. This 0.005 caliper ensures the removal of approximately 90% of the bias in estimates of effects due to differences in covariate distributions between the intervention and control groups [11]. Using the matched pairs, paired t-tests were performed. All analyses were performed with SAS version 9.2 (SAS Institute). All statistical tests were 2-sided. $P < 0.05$ was considered statistically significant.

Results

A total of 2,031 patients who underwent laparoscopic cholecystectomy at four hospitals

Table 1. Characteristics of patients in the CP and non-CP groups before (n = 2,031) and after (n = 1,250) propensity score matching

	Total patients (n = 2,031)			Propensity-matched patients (n = 1,250)		
	non-CP (n = 875)	CP (n = 1156)	*P*	non-CP (n = 625)	CP (n = 625)	*P*
Age (yrs)	51.82 ± 12.26	48.50 ± 13.12	0.000	51.67 ± 11.95	52.01 ± 12.94	0.632
Gender			0.458			0.817
M	364 (41.6%)	462 (40.0%)		247 (39.5%)	251 (40.2%)	
F	511 (58.4%)	694 (60.0%)		378 (60.5%)	374 (59.8%)	
Ethnicity			0.000			0.320
Han	729 (83.3%)	981 (84.9%)		550 (88.0%)	533 (85.3%)	
Mongolian	62 (7.1%)	139 (12.0%)		55 (8.8%)	64 (10.2%)	
Other	84 (9.6%)	36 (3.1%)		20 (3.2%)	28 (4.5%)	
Body mass index (kg/m^2)	27.35 ± 5.67	28.89 ± 4.52	0.000	28.54 ± 5.21	28.85 ± 4.61	0.270
ASA grade			0.497			0.092
II	545 (62.3%)	715 (61.9%)		388 (62.1%)	395 (63.2%)	
III	305 (34.9%)	403 (34.9%)		222 (35.5%)	205 (32.8%)	
IV	24 (2.7%)	32 (2.8%)		15 (2.4%)	20 (3.2%)	
V	1 (0.1%)	6 (0.5%)		0 (0%)	5 (0.8%)	
Disease			0.000			.795
Cholecystolithiasis	398 (45.5%)	583 (50.4%)		294 (47.0%)	285 (45.6%)	
Gallbladder polyp	383 (43.8%)	465 (40.2%)		269 (43.1%)	276 (44.2%)	
Adenomyomatosis	94 (10.7%)	108 (9.3%)		62 (9.9%)	64 (10.2%)	

Table 2. Outcomes among patients in the CP and non-CP groups before (n = 2,031) and after (n = 1,250) propensity score matching

	Total patients (n = 2,031)			Propensity score-matched patients (n = 1,250)		
	non-CP (n = 875)	CP (n = 1,156)	*P*	non-CP (n = 625)	CP (n = 625)	*P*
Median operating time (min)	30.05 ± 5.23	23.01 ± 4.70	0.000	31.15 ± 4.83	23.99 ± 4.55	0.000
Median hospital duration (d)	1.46 ± 0.30	1.08 ± 0.25	0.000	1.49 ± 0.31	1.16 ± 0.25	0.000
Re-admissions (% of total)	1.6	1.2	0.000	1.6	1.1	0.000

across northwest rural China from 2005 to 2007 were identified and recruited. Among these, clinical pathways were used for 1,156 patients (CP group; 56.9%), while the remaining 875 patients (non-CP group; 43.1%) received usual care. Patient and hospital baseline characteristics are summarized in **Table 1**. The characteristics of patients in both the groups showed several important differences. Patients in the CP group were more likely younger (mean age 48.50 ± 13.12 years), had a significantly higher body mass index (28.89 ± 4.52 kg/m^2), and were Mongolian (n = 139 [12.0%]). The three most common indications for laparoscopic cholecystectomy were cholecystolithiasis (n = 981 [48.3%]), gallbladder polyp (n = 848 [41.8%]), and adenomyomatosis (n = 202 [9.9%]).

After propensity score matching, patient distributions were closely balanced between the groups. By one-to-one propensity score matching, 625 pairs of patients from CP and non-CP groups were selected.

Table 2 describes the duration of operation (min), length of stay (days), and the average total and itemized costs in the CP and non-CP groups before (n = 2,031) and after (n = 1,250) propensity score matching. The median duration of operation in the non-CP group was significantly greater than that in the CP group (31.15 ± 4.83 min vs. 23.99 ± 4.55 min, *P* <

Table 3. Postoperative complications among patients from the CP and non-CP groups before (n = 2,031) and after (n = 1,250) propensity score matching

	Total patients (n = 2,031)			Propensity score-matched patients (n = 1,250)				
	non-CP (n = 14)	CP (n = 14)	*P*	non-CP (n = 10)	CP (n = 7)	*P*	95% CI	HR
Biliary leak	3 (0.3%)	1 (0.1%)	0.197	2 (0.3%)	1 (0.2%)	0.563	0.181-22.15	2.00
Bile duct injury	1 (0.1%)	1 (0.1%)	0.843	0 (0%)	1 (0.2%)	0.317	0.998-1.01	1.00
Acute biliary pancreatitis	1 (0.1%)	2 (0.2%)	0.733	0 (0%)	1 (0.2%)	0.317		
Residual CBD stones	3 (0.6%)	10 (0.9%)	0.144	3 (0.5%)	4 (0.6%)	0.705	0.167-3.36	0.749
Abdominal abscess	6 (0.7%)	0	0.005	5 (0.8%)	0	0.025	0.985-0.999	0.992
Re-admissions (% of total)	1.6	1.2	0.457	1.6	1.1	0.464	0.543-3.80	1.44

Table 4. Total and itemized average costs/patient in the CP and non-CP groups before (n = 2,031) and after (n = 1,250) propensity score matching

	Total patients (n = 2,031)			Propensity score-matched patients (n = 1,250)		
	non-CP (n = 875)	CP (n = 1,156)	*P*	non-CP (n = 625)	CP (n = 625)	*P*
Total costs	3027.21 ± 216.43	2354.14 ± 156.72	0.000	3073.80 ± 198.95	2394.41 ± 167.41	0.000
Itemized costs						
Perioperative examinations	673.08 ± 33.72	505.85 ± 15.44	0.000	680.19 ± 31.19	508.33 ± 17.61	0.000
Room and board	102.68 ± 25.44	65.73 ± 18.92	0.000	108.11 ± 23.42	70.32 ± 19.59	0.000
Operative	1085.80 ± 67.572	1011.07 ± 90.50	0.000	1100.50 ± 62.02	1030.56 ± 102.65	0.000
Medications						
Anesthesia	593.42 ± 33.057	412.56 ± 22.43	0.000	600.50 ± 30.47	420.50 ± 20.46	0.000
All other meds	141.81 ± 16.52	113.00 ± 15.52	0.000	145.36 ± 15.21	115.80 ± 17.34	0.000
Other	76.90 ± 8.07	45.90 ± 13.68	0.000	78.64 ± 7.39	46.14 ± 16.34	0.000
Disposable instruments	353.52 ± 33.24	199.41 ± 13.72	0.000	360.50 ± 30.50	201.76 ± 14.66	0.000

0.001). The median length of hospital stay was lesser in the CP group than in the non-CP group (1.16 ± 0.25 days vs. 1.49 ± 0.31 days, $P < 0.001$). The median total costs were higher in the non-CP group than in the CP group (RMB 3,073.80 ± 198.95 vs. 2,394.41 ± 167.41, $P < 0.001$). In addition, the itemized average hospital costs were all higher in the non-CP group than in the CP group (**Table 4**).

Table 3 demonstrates the postoperative complications and 30-day re-admission rates in the CP and non-CP groups.

The propensity score-matched analysis of all patients showed no significant differences between the CP and non-CP groups in the overall postoperative complications such as biliary leak (0.2% vs. 0.3%, $P = 0.563$; RR, 2.00; 95% CI, 0.181-22.15), bile duct injury (0% vs. 0.2%, $P = 0.317$; RR, 1.0; 95% CI, 0.998-1.01), acute biliary pancreatitis (0% vs. 0.2%, $P = 0.317$; RR, 1.0; 95% CI, 0.998-1.01), residual CBD stones (0.5% vs. 0.6%, $P = 0.705$; RR, 0.749; 95% CI, 0.167-3.36), abdominal abscess (0.8% vs. 0%, $P = 0.025$; RR, 0.992; 95% CI, 0.985-0.999), and 30-day re-admission rates (1.6% vs. 1.1%, $P = 0.464$; RR, 1.44; 95% CI, 0.543-3.80).

Discussion

A well-designed, structured, and multidisciplinary clinical pathway optimizes and systematizes the sequencing and timing of medical intervention, and reduces unnecessary variations for a particular diagnosis or procedure [12, 13]. Clinical pathways can also help in postoperative recovery by outlining of assessment, pain management, standardization of orders, mobilization, and discharge planning [14]. Surgical procedures are particularly suited to the critical pathway model because of the relative predictability of postoperative care. In this study, the implementation of a clinical pathway program in patients who underwent laparoscopic cholecystectomy in rural China resulted in reduced operation time, shorter hospital stay, and substantial cost savings compared with patients who received no such intervention. Meanwhile, there was no significant difference in the overall postoperative complications or 30-day re-admission rate in patients who underwent clinical pathway intervention compared with patients who received usual care. Taken together, our results strongly suggest that the use of clinical pathways for laparoscopic cholecystectomy in rural China improved the quality and affordability of care.

Despite the increasing popularity of clinical pathways, few evidence-based, large scale, and controlled studies focusing on them have been conducted. The effectiveness, and even the constituent, of clinical pathways still vary and are even contradictory [7, 15]. A recent systematic review found no randomized trials supporting the use of critical pathways for surgical procedures [7, 16]. Most of these observational studies are uncontrolled before-after comparisons of a single pathway or a small group of pathways [7]. Most importantly, many previous studies did not account for the ongoing trends in clinical practice toward shorter hospital stay even without clinical pathway intervention. Thus, the impact of clinical pathways on reducing the length of hospital stay might be overestimated [15, 16]. In addition, it is difficult to measure certain benefits that occur in the development and implementation period of clinical pathway programs without very large sample sizes, which is only possible with a few procedures in large institutions. The results of clinical pathway intervention may differ substantially for illnesses of different severities or observable factors, owing to the effect of treatment-selection bias and potential confounding factors in the observational study [15].

We performed a large-scale, population-based, and propensity score-matched analysis to study the effectiveness of clinical pathways in an attempt to overcome the abovementioned issues. Our propensity-matched patient cohort was evaluated to ensure a balance between the CP and the non-CP group regarding potential confounding factors. Propensity scores are a statistical technique to reduce the selection bias in observational studies [17-19]. Selection bias arises when certain types of patients are more or less likely to receive treatment owing to possible confounding factors or indications. By one-to-one propensity score matching, 625 pairs of CP and non-CP patients were selected and analyzed. With a matching algorithm with a caliper of 0.005, approximately 90% of the bias was removed in estimating the effects due to differences in covariate distributions between the CP and non-CP groups.

Our study has two limitations. First, the propensity score method, despite its advantages discussed above, is still subject to biases from unobserved differences or residue confounding factors. Second, our cost data is based on direct hospital costs incurred for the procedure, and some perioperative or societal expenses may not have been captured.

In conclusion, our study provides a framework for the development and implementation of clinical pathways that could be used by other hospitals, especially public hospitals from northeast rural China, with modifications to meet their local conditions and needs. Our data supports that evidence-based clinical pathways should be developed and advocated in medical reforms in China as tools for continuous medical education and quick dissemination of best clinical practice.

Disclosure of conflict of interest

None.

Authors' contribution

MR participated in the design of the study and performed statistical analysis. GL conceived the study, participated in its design and coordination, and helped to draft the manuscript. All authors read and approved the final manuscript.

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