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Construction and Practice of Standardized Operating Procedures for Laparoscopic Cholecystectomy

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Abstract: The *Comprehensive Action Plan for Improving Medical Quality (2023–2025)* issued in May 2023 proposed that medical institutions should strengthen basic quality and safety management, enhance key process and behavior management, and ensure patient safety in healthcare. Improving medical quality and safety not only safeguards public health rights but also constitutes a core aspect of hospital management. Establishing standardized operational procedures is an effective measure for enhancing medical quality and safety. Since August 2018, Deyang People's Hospital has implemented a standardized laparoscopic cholecystectomy procedure through collaborative efforts between administrative departments and multiple clinical departments, effectively ensuring patient safety and therapeutic outcomes. This article systematically elaborates on the development and implementation of standardized laparoscopic cholecystectomy procedures for reference and sharing among peers.

Keywords: Laparoscopic cholecystectomy; Standard Operating Procedure (SOP); Postoperative complications; Management; Healthcare quality and safety; Day surgery

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1. Current status and challenges of laparoscopic cholecystectomy

Laparoscopic cholecystectomy (LC) is characterized by minimal invasiveness and rapid recovery, making it the "gold standard" for treating benign gallbladder lesions [1]. Although LC has been included in the scope of day surgery with strict inclusion and exclusion criteria, there remains a contradiction between short hospital stays and high healthcare quality [2,3].

1.1. Clinical level: "Volatility risk" in safety and quality

The incidence of complications following laparoscopic cholecystectomy has significantly decreased, but complications still occur in approximately 3.6–17% of cases [4]. Among various complications, biliary fistula (incidence rate 0.20%), intra-abdominal hemorrhage (incidence rate 0.16%), and bile duct injury (incidence rate 0.1–0.2%) are the most clinically critical types requiring vigilance [5]. Bile duct injury, due to its high repair difficulty and significant prognostic variability, not only increases hospitalization costs, prolongs recovery periods, and exacerbates patients' physical and psychological distress but also elevates the risk of medical disputes and markedly reduces patient satisfaction with healthcare services [6,7].

1.2. Management level: The "inefficiency bottleneck" in resources and collaboration

As a typical "high-efficiency intensive" day surgery, the entire treatment cycle of LC requires close collaboration among multiple departments and processes. Preoperative evaluation must be completed through coordinated efforts between the preoperative preparation center and auxiliary examination departments. However, the lack of standardized interdepartmental workflow coordination often leads to prolonged preoperative preparation periods, adversely affecting the turnover efficiency of day surgeries. Postoperatively, to further reduce hospitalization duration, the concept of accelerated recovery surgery (ERAS) must be systematically integrated into perioperative management. Yet, the absence of standardized cross-departmental collaboration mechanisms currently results in inconsistent implementation quality and execution consistency of ERAS measures during the perioperative period of LC. This inefficiency in collaboration ultimately hinders the effective balance between quality assurance and efficiency improvement in day surgeries.

1.3. Quality monitoring: Indicator deficiencies and inadequate improvement measures

Current medical institutions generally lack a systematic specialized quality monitoring indicator system for LC surgery, resulting in management-level difficulties in accurately identifying weak links in the diagnostic and treatment process (such as the standardization of gallbladder triangle dissection techniques and postoperative drainage tube care quality at critical junctures). A more prominent issue is that when abnormal increases in complication rates occur, management often simplistically attributes them to "individual physician operational errors" without conducting systematic root cause analysis (RCA) through root cause analysis methods. This superficial attribution pattern fails to identify fundamental causes such as process design deficiencies, inadequate physician training systems, or delayed equipment maintenance, ultimately leading to recurrent quality issues and stagnation in diagnostic and treatment process optimization efforts.

2. Systematic breakthrough: Construction pathway for standardized procedures of laparoscopic cholecystectomy

To address the aforementioned issues, the development of standardized operating procedures (SOPs) should adopt a "problem-oriented" approach, while integrating management mechanisms to establish a dual regulatory framework encompassing both clinical and administrative aspects.

2.1. Preoperative phase: Precision screening and process optimization

2.1.1. Quantitative access assessment criteria

The "LC Patient Admission Assessment Form" was developed, specifying 12 quantitative indicators: age ≤ 80 years (special cases requiring departmental discussion), ASA classification I–III, gallbladder wall thickness ≤ 5 mm (> 5 mm requiring difficulty assessment), bilirubin < 34 μmol/L, and EF value > 50%. This transitioned the assessment from "empirical judgment" to "standardized judgment." Additionally, supplementary criteria were established for diabetic and hypertensive patients (blood glucose 7.0–11.1 mmol/L, blood pressure ≤ 160/100 mmHg).

2.1.2. Optimization of pre-hospital processes

Our hospital has established an Admission Preparation Center adjacent to the admission department. Outpatient physicians issue appointment admission certificates and simultaneously provide standardized examination packages (including mandatory tests such as complete blood count and abdominal ultrasound). The Admission Preparation Center performs blood draws for patients and schedules additional examinations, thereby streamlining the patient appointment and examination process. Additionally, anesthesiologists conduct anesthesia evaluations for patients who complete examinations at the Admission Preparation Center. If abnormal test results are detected, the attending physician is promptly notified to further refine relevant examinations or arrange consultations, thereby reducing anesthesia risks. For patients who pass the evaluation, the Admission Preparation Center promptly notifies them of admission for surgery, shortening the preoperative cycle from 5 days to 2–3 days.

2.1.3. Standardized education and informed consent

Design preoperative education QR codes covering dietary guidelines (preoperative fasting and fluid restriction periods), medication management (timing for discontinuation of anticoagulants, cessation of hypoglycemic agents, and continuation of oral antihypertensive therapy), and surgical procedures; establish standardized Informed Consent Forms specifying the incidence rates and management measures for risks such as biliary leakage, hemorrhage, and trauma to prevent disputes. Implement a three-dimensional education approach combining QR codes, verbal explanations, and written documentation, with patients signing the Surgical Informed Consent Form.

2.2. Intraoperative phase: Standard operating procedures and team collaboration

2.2.1. Clarify indications for antibiotic use

Indications for antibiotic use: Prophylactic administration in patients with high-risk factors, including age > 70 years, diabetes mellitus, and hormone users. Drug selection: First-line agents: first-and second-generation cephalosporins. For β-lactam allergy: lincomycin or quinolone antibiotics. Timing of administration: Strictly within 30 minutes prior to surgery.

2.2.2. Standardized anesthesia

Antiemetic and sedative administration is performed prior to anesthesia induction, followed by anesthesia induction and maintenance. Anesthesia maintenance protocols include: (1) Intravenous inhalation combined anesthesia: 1–2% sevoflurane + 6 mg/kg/h propofol, with dosing adjusted based on patient blood pressure and heart rate. Sevoflurane is discontinued after cholecystectomy, and other maintenance medications are stopped during skin suturing. Endotracheal intubation is removed after the patient regains consciousness and resumes spontaneous breathing. (2) Total intravenous anesthesia: 6 mg/kg/h propofol (± /or) remifentanil 5–10 μg/kg/h, with dosing adjusted according to blood pressure and heart rate. Propofol is discontinued after cholecystectomy, and other maintenance medications are stopped during skin suturing. Endotracheal intubation is removed after the patient regains consciousness and resumes spontaneous breathing.

2.2.3. Standardization of intraoperative consumables usage

The puncture device should preferably be a domestically produced disposable puncture tool, with all puncture tools ideally being metallic. The distal end of the cystic duct should be clamped with a titanium clip. The proximal end of the cystic duct should be secured with two absorbable clips or two Hem-o-lok clips. The cystic artery should be clamped with one absorbable clip or two Hem-o-lok clips. In cases of severe oozing or significant bleeding, hemostatic materials should be used intraoperatively.

2.2.4. Standardization of intraoperative standard procedures (Figure 1)

This SOP serves as a critical control point, with the following steps: Fully expose the gallbladder triangle to reveal the cystic duct, common hepatic duct, and common bile duct, achieving 360° exposure of the cystic duct and gallbladder artery. Place two circumferential ligating clips proximal to the cystic duct and one titanium metal clip distally, followed by scissors dissection of the cystic duct. Apply one circumferential ligating clip proximal to the gallbladder artery and perform electrocoagulation dissection distally using a coagulation hook. Carefully dissect the gallbladder while monitoring for hemorrhage from the gallbladder bed. Prior to gallbladder extraction, place a sterile white gauze strip on the gallbladder bed. After gallbladder removal, inspect the white gauze strip for yellow discoloration to rule out biliary leakage from the vagal duct. Perform hemostasis by cauterizing the gallbladder bed as needed. Depending on intraoperative conditions, insert a standard plasma drainage tube for external drainage.

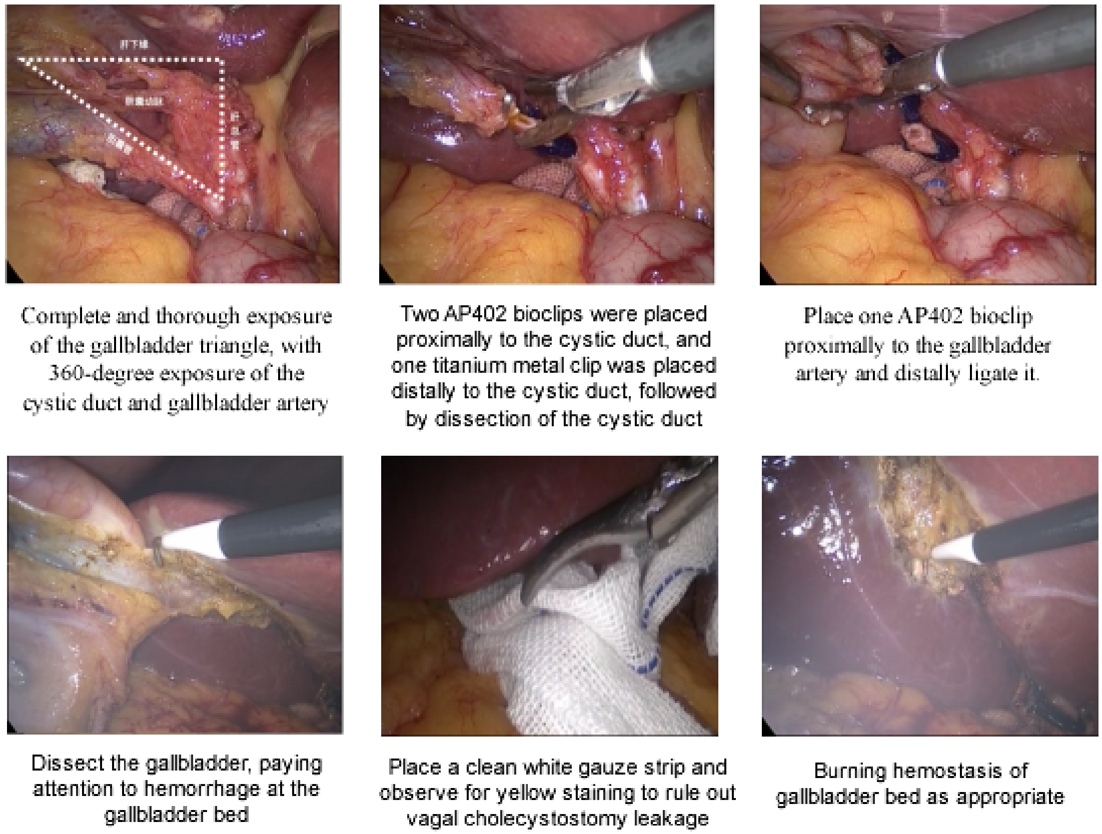

Figure 1. Standard operating procedure for laparoscopic cholecystectomy

2.3. Postoperative phase: Rehabilitation acceleration and risk warning

2.3.1. Standardized resuscitation and analgesia

The patient was transferred to the Post-Anesthesia Care Unit (PACU) after surgery. Nurses assessed consciousness and vital signs (blood pressure 100–140/60–90 mmHg, oxygen saturation > 95%) and pain scores (NRS < 4) based on the Resuscitation Assessment Form. Pain management followed a “stepwise protocol”: intravenous patient-controlled analgesia (PCA) with sufentanil 0.5–1 μg/kg was administered within the first 6 hours postoperatively, followed by oral ibuprofen after 6 hours to maintain pain scores below 3 on the NRS scale.

2.3.2. Graded discharge assessment

The design of the “Discharge Assessment Scale” (total score of 100 points, discharge is permitted with a score ≥ 80) includes indicators such as body temperature < 38°C, absence of abdominal pain and distension, and the ability to walk independently for 50 meters. Daytime LC patients must additionally meet the criteria of stable vital signs within 8 hours postoperatively and an NRS score < 3. This approach reduces the average hospital stay from 5–7 days to 2–3 days (conventional) or 1 day (daytime).

2.3.3. Full-cycle follow-up mechanism

Full-time nurses conducted telephone follow-ups on days 1, 3, and 7 post-discharge to assess pain levels, dietary intake, and symptoms of complications. Immediate emergency procedures were initiated upon detection of abnormalities. A follow-up ultrasound examination was scheduled one month postoperatively, which reduced the time to identify complications from 7 days to 1–3 days.

2.4. Management support: Collaboration and resource assurance

2.4.1. Collaboration among hospital functional departments

The implementation of SOPs involves multiple departments and specialties on one hand, and requires conceptual shifts in the lead surgeon's mindset to facilitate habitual changes on the other. This necessitates the participation and coordination of hospital administrative departments. To ensure efficient and thorough SOP implementation, adopting a "top-leader" initiative yields optimal results with minimal effort. Our hospital has accumulated relevant experience in implementing the Multidisciplinary Team (MDT) model during earlier phases. Leveraging the authority of the "top leader" to mobilize functional departments such as medical management, operational management, finance, as well as the day care center, operating rooms, and anesthesiology department, in collaboration with clinical units, is a shortcut to overcoming various obstacles in SOP implementation and ensuring its high-quality execution. From initial theoretical preparation to SOP formulation and subsequent implementation, all processes at our hospital were conducted under the direct leadership of the hospital president. Furthermore, the president regularly participates in post-SOP implementation data analysis, continuous improvement, and ongoing refinement of SOPs.

2.4.2. Performance evaluation based on reward and punishment model

First, hospitals strictly adhere to antibiotic usage guidelines for prescriptive prophylactic antibiotic administration prior to surgery. Violations are managed through a point deduction system analogous to driver's license penalties. Hospitals then implement performance incentives based on hospitalization duration: initial admission within 48 hours receives performance rewards, admission within 36 hours transitions to performance incentives, and admission within 24 hours ultimately qualifies for performance rewards. To achieve true day surgery implementation, rigorous control over patient admission workflows and interdepartmental coordination is essential, with the LC SOP process playing a pivotal role.

2.4.3. Dynamic quality monitoring

Establish 10 LC-specific KPIs: preoperative examination completion rate, intraoperative procedural compliance rate, complication incidence rate, and patient satisfaction rate. Monthly Quality Analysis Reports are generated to conduct root cause analysis for abnormal indicators (e.g., rising complication rates), with continuous process optimization through PDCA cycles. The initial concept of implementing SOPs was merely to standardize intraoperative procedures. During the early stages, relevant literature reviews and previous best practices were integrated to formulate the initial LC SOP. Continuous improvements were made by comparing summary data with baseline metrics and intraoperative observations, such as transitioning from initial push-type to embracing-style clamps, and adding a sterile white gauze strip to the gallbladder bed during gallbladder extraction. Standardized anesthesia medication protocols further reduced postoperative discomfort while ensuring safe extubation time. Through iterative summarization, continuous refinement, and sustained improvement, the ultimate goal of SOP implementation can be truly achieved.

3. Validation of outcomes: Multidimensional changes after standardized process implementation

Since the implementation of the LC standardized process in August 2018, our hospital has achieved significant results in three dimensions: clinical quality, operational efficiency, and patient experience, demonstrating the practical value of standardized processes.

3.1. Clinical quality: Dual improvement in safety and quality

Our hospital has implemented the gallbladder SOP since August 2018. Prior to SOP implementation, the number of LCs was 2,839 cases, while post-SOP implementation, the number increased to 5,322 cases. Before SOP implementation, there were 9 cases of biliary tract injury (0.32%), 9 cases of bile leakage (0.32%), and 6 cases of bleeding (0.21%). After SOP implementation, the incidence of biliary tract injury decreased to 3 cases (0.06%), bile leakage to 5 cases (0.09%), and bleeding to 2 cases (0.04%). The overall postoperative complication rate (0.19% vs 0.85%) and reoperation rate (0.04% vs 0.25%) after SOP implementation were significantly lower than pre-SOP levels, with statistically significant differences ($P < 0.05$). See **Table 1**. Literature reports indicate that the incidence of bile leakage after laparoscopic cholecystectomy is approximately 1.7%, primarily caused by residual cystic duct leakage and intraoperative biliary tract injury. Our hospital has observed a significant reduction in bile leakage after SOP implementation. The main reasons for this improvement include: first, adherence to SOP for 360° exposure of the cystic duct to avoid accidental clamping of intrahepatic and extrahepatic bile ducts; second, use of a double-clamping technique with a ring-shaped biological clip to minimize residual cystic duct leakage; and third, preoperative observation of white gauze strips for yellow discoloration to detect possible biliary leakage through the vagus duct. Intraoperative lacerations and electrocoagulation burns are the primary causes of biliary tract injury. The iatrogenic biliary tract injury rate in laparoscopic cholecystectomy ranges from 0.3% to 0.7%. The incidence of biliary tract injury before implementing the gallbladder SOP in our hospital was 0.32%, which is consistent with literature reports. After implementing the SOP, the incidence rate decreased to 0.06%, significantly reducing the occurrence of biliary tract injuries. This is attributed to adequate exposure of the gallbladder triangle, 360° exposure of the cystic duct and gallbladder artery. Following the implementation of the gallbladder SOP, the postoperative rates of biliary tract injuries, bile leakage, and hemorrhage were all reduced, thereby decreasing the need for reoperation.

Table 1. Incidence of postoperative complications after LC before and after SOP implementation

Group	Number of cases (*n*)	Biliary tract injury [*n*(%)]	Biliary fistula [*n* (%)]	Hemorrhage [*n* (%)]	Total complications [*n* (%)]	Reoperation rate [*n* (%)]
Before SOP implementation	2839	9 (0.32)	9 (0.32)	6 (0.21)	24 (0.85)	7 (0.25)
After SOP implementation	5322	3 (0.06)	5 (0.09)	2 (0.04)	10 (0.19)	2 (0.04)
Chi-square		5.452	3.424	1.124	6.424	14.9
P		0.015	0.049	0.285	0.012	0.001

3.2. Operational efficiency: Maximization of resource efficiency

The implementation of SOPs for gallbladder surgery significantly reduced average hospital stay duration and inpatient costs, with statistically significant differences ($P < 0.05$) (see **Table 2**). This further increased the day surgery rate for LC (see **Figure 2**). The SOPs encompass comprehensive preoperative, intraoperative, and postoperative management, with this study focusing on key control processes. Thorough preoperative preparation, standardized anesthesia protocols during surgery, and postoperative care all contribute to shorter hospital stays. Standardized intraoperative anesthesia and fixed surgical consumables are primary factors in reducing hospitalization costs, while the gradual decline in hospitalization expenses over the years is attributed to progressively shorter hospital stays. With LC now classified as a day surgery procedure, the SOP management has led to a year-on-year increase in day surgery rates (see **Figure 2**).

Table 2. Per capita hospitalization costs and average length of stay before and after implementation of SOP

Group	Number of cases (*n*)	Number of hospitalization days (d)	Hospitalization expenses (RMB)
Before SOP implementation	2839	9.58	15711
After SOP implementation	5322	2.24	15711
χ^2/t value		5.464	3.478
P		0.02	<0.01

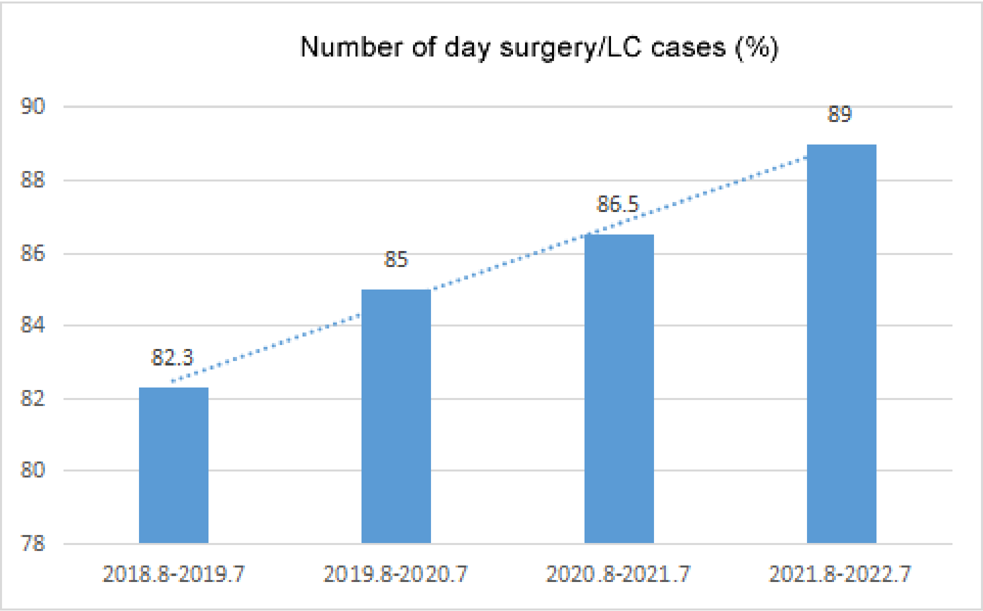

Figure 2. Trend chart of daytime LC procedure volume from 2018 to 2022

3.3. Patient experience: Dual improvement in satisfaction and word-of-mouth reputation

The implementation of gallbladder SOPs has improved patient experience by enabling multi-departmental collaboration in patient care, with clear medical procedures, shortened preoperative examination time, reduced preoperative waiting periods, comprehensive preoperative education, and timely postoperative follow-ups, thereby enhancing overall healthcare satisfaction.

4. Conclusion

The standardized transformation of laparoscopic cholecystectomy is essentially a revolution aimed at "replacing safety with standards, enhancing efficiency through standardized procedures, and creating value via regulation." It not only addresses the dual challenges in both clinical practice and management but also validates the core principle that "standardization is not a constraint but the foundation for higher-level innovation." In the future, with the integration of smart healthcare technologies (such as AI-based preoperative assessment), standardized procedures will be further refined, yet the fundamental commitment to being "patient-centered and quality-focused" remains unchanged. We anticipate that more hospitals will take LC surgery as a starting point to drive the transition of medical services from being "experience-driven" to "standard-driven," thereby contributing substantial practical efforts to the construction of a Healthy China.

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Disclosure statement

The authors declare no conflict of interest.

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