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Optimizing common bile duct stone management: Single-stage laparoscopic exploration versus two-stage ERCP and cholecystectomy

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Ethics Committee Approval
The study was approved by the Sohag University Ethics Committee in January 2016. All participants provided verbal and written informed consent. Written informed consent for publication of intraoperative images was obtained from all patients.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Concomitant gallbladder and common bile duct (CBD) stones can be managed with a single-stage operative pathway, including laparoscopic CBD exploration (LCBDE) and laparoscopic cholecystectomy (LC), or with a two-stage strategy using preoperative endoscopic retrograde cholangiopancreatography (ERCP) followed by LC during the same admission. In this randomized controlled trial, we compared these strategies in terms of perioperative safety, overall effectiveness, and patient recovery experience.

Methods: A total of 200 patients with gallstones and CBD stones were enrolled between January 2016 and December 2024 and randomized using sealed opaque envelopes to Group I, single-stage LCBDE + LC (n = 100), or Group II, two-stage ERCP + LC (n = 100). The primary outcome was successful CBD stone clearance and gallbladder removal using the assigned approach without conversion. Secondary outcomes included postoperative pain, complications, hospital stay, retained CBD stones, and patient satisfaction. Data were analyzed using SPSS version 26, and statistical significance was defined as a two-tailed *P*-value <0.050.

Results: Baseline demographic characteristics were similar between groups. Mean CBD diameter and stone size were larger in Group I than in Group II [13.18 (2.01) mm vs. 10.94 (2.46) mm, P <0.001; and 6.29 (1.47) mm vs. 5.65 (1.69) mm, P = 0.005, respectively]. Mean operative time was comparable [138.3 (20.4) min vs. 140.85 (43.98) min, P = 0.600]. Intraoperative complication and conversion rates were low and comparable. Postoperative direct bilirubin levels were slightly higher in Group I [1.01 (0.08) mg/dL vs. 0.83 (0.06) mg/dL, P = 0.030]. Early pain scores at 24 h favored Group I [5.34 (1.02) vs. 6.30 (1.02), P <0.001], whereas day 3 pain scores were similar. Retained CBD stones were rare [3% vs. 0%, P = 0.246]. Hospital stay, overall complications, and patient satisfaction were comparable between groups.

Conclusion: Single-stage LCBDE + LC was as safe and effective as two-stage ERCP + LC and was associated with better early pain control and potential resource advantages through single-session treatment. Both strategies remain viable options, and the preferred approach should be guided by patient anatomy, local expertise, available resources, and institutional logistics.

Keywords: common bile duct stones, gallstones, laparoscopic cholecystectomy, endoscopic retrograde cholangiopancreatography, single-stage surgery, patient outcomes

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Introduction

Gallstones accompanied by common bile duct (CBD) stones are found in approximately 10-15% of patients undergoing cholecystectomy and continue to pose a practical challenge for biliary surgeons. Two main management strategies are commonly practiced: a single-stage operative route in which laparoscopic common bile duct exploration is performed together with laparoscopic cholecystectomy (LCBDE + LC), and a two-stage pathway involving preoperative endoscopic retrograde cholangiopancreatography (ERCP) followed by LC. Systematic reviews and randomized trials report broadly comparable overall success and safety for the two strategies, but important trade-offs exist, notably the risk of post-ERCP pancreatitis with ERCP-first strategies versus bile leakage and ductal injury risk after transcholedochal exploration. Outcomes are strongly influenced by case selection, stone burden, duct anatomy, and local operator expertise [1-9].

Randomized trials and meta-analyses also suggest that single-stage approaches may reduce the need for multiple procedures and, in some systems, shorten the total hospital stay and lower cumulative resource use when surgical expertise and instrumentation, such as choledochoscopy, are available [2-8]. However, heterogeneity in trial methods, variable experience with LCBDE, and differing health system logistics limit the generalizability of the evidence [10-16]. Additional meta-analytic and comparative reports have reached similar conclusions [17, 18].

Given the relative paucity of randomized, patient-centered data from our region and the need to examine both clinical and patient-reported endpoints, we conducted a randomized trial at a tertiary university center to compare single-stage LCBDE + LC with two-stage ERCP + LC with respect to intraoperative and postoperative outcomes, retained stones, pain, and patient satisfaction.

Materials and methods

Study design and setting

This randomized controlled trial was conducted at the Department of General Surgery, Sohag University Hospital, from January 2016 to December 2024. Ethical approval was granted by the Sohag University Ethics Committee in January 2016, before patient enrollment. All procedures were performed in accordance with the principles of the Declaration of Helsinki.

Participants

Eligible participants were men and women 16 to 70 years of age with gallbladder stones confirmed by imaging and radiologic or clinical evidence of CBD stones. Patients were excluded if they had acute cholecystitis, acute pancreatitis, uncorrectable coagulopathy, end-stage renal or severe cardiac disease, liver cirrhosis, intrahepatic biliary pathology, hepatic mass, hepatic abscess, hepatic neoplasm, recurrent choledocholithiasis, or malignant biliary or pancreatic tumors.

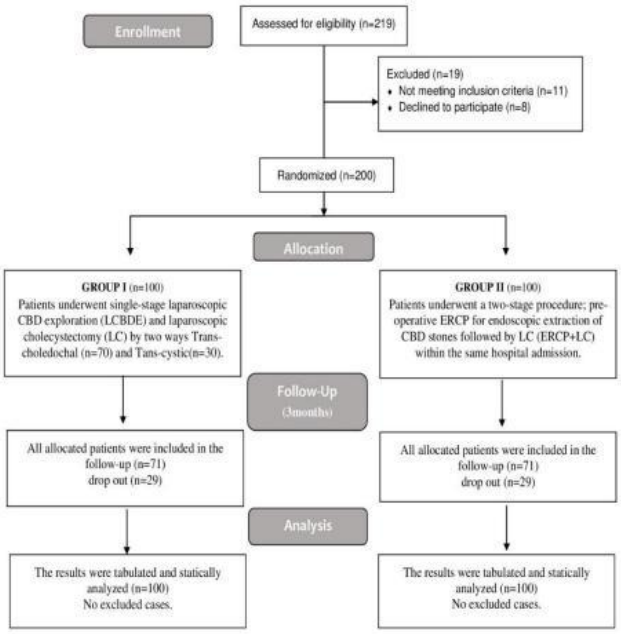
Sample size and power

A total of 200 patients, with 100 patients in each group, were included. The sample size was determined pragmatically based on the hospital annual case volume and provided approximately 80% power to detect a clinically relevant 15% difference in the primary outcome at an alpha level of 0.05.

Randomization and allocation

Eligible patients were randomized in a 1:1 ratio to Group I, single-stage LCBDE + LC (n = 100), or Group II, two-stage ERCP + LC during the same admission (n = 100). Randomization followed a computer-generated sequence prepared by an independent statistician who had no role in patient recruitment or data evaluation. The allocation sequence was concealed in sequentially numbered sealed opaque envelopes prepared by the study coordinator. The operating team opened envelopes sequentially immediately before the procedure to maintain allocation concealment. Neither the enrolling investigator nor the outcome assessor had access to the randomization list before allocation. Participant enrollment, allocation, follow-up, and analysis are summarized in Figure 1.

Figure 1. CONSORT flowchart of enrolled patients.



Preoperative assessment and imaging

All patients underwent clinical evaluation, baseline laboratory testing including liver function tests, and magnetic resonance cholangiopancreatography (MRCP) to determine CBD diameter, stone number, stone size, and stone location. Demographic and comorbidity data were recorded.

Interventions

Patients in Group I underwent single-stage laparoscopic common bile duct exploration followed by laparoscopic cholecystectomy, with exploration performed through either the transcystic or transcholedochal approach (Figures 2-4). Patients in Group II underwent ERCP with endoscopic sphincterotomy and stone extraction, followed by LC during the same admission (Figures 5-7). All LCBDE procedures were performed by surgeons experienced in laparoscopic biliary surgery, each with experience of more than 50 cases, while ERCP procedures were performed by senior endoscopists with more than five years of experience in therapeutic biliary interventions.

Figure 2. A: Introduction of the choledochoscope; B: visualization of a CBD stone.

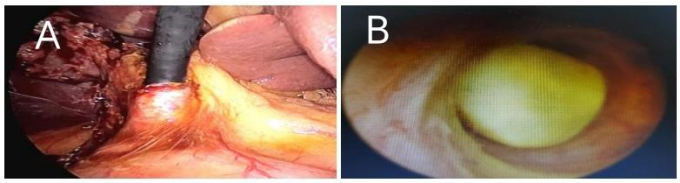


Figure 3. A: Stone extraction by flushing with saline; B: stone extraction with a Dormia basket.

Figure 4. A: Primary closure of the CBD; B: T-tube insertion.

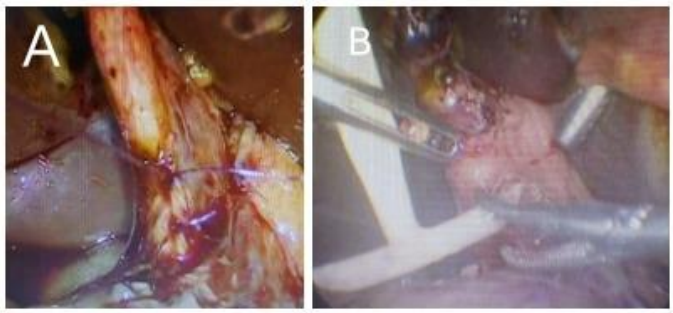


Figure 5. A: ERCP showing multiple CBD stones; B: endoscopic sphincterotomy.

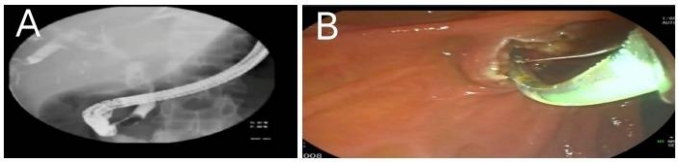


Figure 6. A: Stone extraction by basket; B: extraction of multiple stones by balloon.

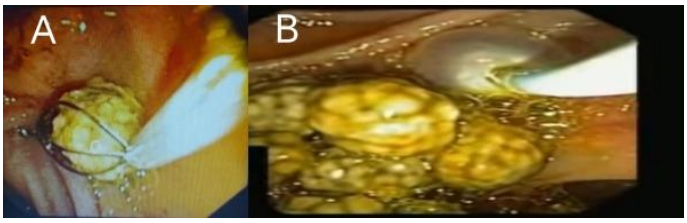
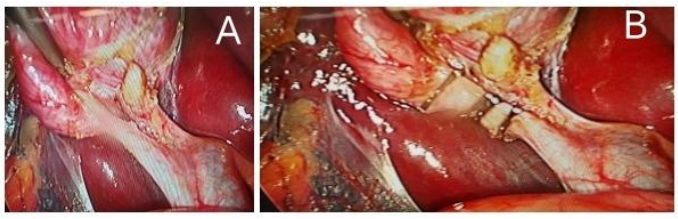


Figure 7. Laparoscopic cholecystectomy.



Outcome measures

The primary outcome was successful removal of both CBD stones and the gallbladder using the intended approach without conversion. Secondary outcomes included operative time, intraoperative and postoperative complications, conversion rate, postoperative pain assessed using the visual analog scale (VAS) on postoperative days 1 and 3, length of hospital stay, retained CBD stones, and patient satisfaction scores. Retained CBD stones were defined as stones undetected intraoperatively but diagnosed within six months postoperatively by ultrasonography or MRCP. Follow-up imaging was routinely obtained at 3 and 6 months after surgery or earlier in patients who developed recurrent symptoms. To estimate resource utilization, the number of anesthesia sessions and the total duration of hospital stay were recorded for each patient.

Statistical analysis

Statistical analysis was performed using SPSS software, version 26. The distribution of continuous data was examined for normality using the Shapiro-Wilk test. Parametric data were summarized as mean (SD) and compared using the unpaired Student t-test. Nonparametric variables were summarized as median (IQR). Categorical variables were compared using the chi-square test or Fisher exact test, as appropriate. A prespecified multivariable analysis was not performed; therefore, potential confounding by baseline differences, particularly the larger CBD diameter in Group I, cannot be fully excluded. Statistical significance was set at P <0.050. The study could not be prospectively registered because of institutional restrictions; however, the design and reporting followed CONSORT recommendations.

Results

Patient population

A total of 200 patients with concomitant gallbladder and CBD stones were enrolled and randomly assigned to two groups, with 100 patients in each group. All randomized patients were included in the final analysis according to the intention-to-treat principle (Figure 1).

Baseline characteristics

Baseline demographic characteristics were comparable between the two groups, except for CBD diameter and stone size (Table 1). Mean age was 43.16 (12.66) years in Group I and 41.52 (9.54) years in Group II (P = 0.302). Female patients accounted for 58% and 68% of Groups I and II, respectively (P = 0.143). The prevalence of comorbid conditions was similar between the groups, including diabetes mellitus and hypertension (Table 1).

Table 1. Demographic and preoperative data (n = 200).

Variable	Group I (n = 100)	Group II (n = 100)	*P*-value
Age (years), mean (SD)	43.16 (12.66)	41.52 (9.54)	0.302
Range (years)	19-68	18-68	NA
Male sex, n (%)	42 (42%)	32 (32%)	0.143
Female sex, n (%)	58 (58%)	68 (68%)	0.143
Preoperative jaundice, n (%)	88 (88%)	86 (86%)	0.674
Total bilirubin (mg/dL), mean (SD)	2.80 (0.36)	2.75 (0.56)	0.820
Direct bilirubin (mg/dL), mean (SD)	2.33 (0.28)	2.24 (0.49)	0.641
Diabetes mellitus, n (%)	21 (21%)	12 (12%)	0.219
Hypertension, n (%)	9 (9%)	15 (15%)	0.345
No comorbidity, n (%)	62 (62%)	62 (62%)	1.000

SD: standard deviation, n: number, %: percent, NA: not applicable.

Preoperative assessment

Clinical jaundice was present in 88% and 86% of patients in Groups I and II, respectively (P = 0.674). Preoperative laboratory parameters were comparable, including total bilirubin [2.80 (0.36) mg/dL vs. 2.75 (0.56) mg/dL, P = 0.820] and direct bilirubin [2.33 (0.28) mg/dL vs. 2.24 (0.49) mg/dL, P = 0.641]. MRCP revealed a significantly larger mean CBD diameter in Group I than in Group II [13.18 (2.01) mm vs. 10.94 (2.46) mm, P <0.001]. Mean stone size was also larger in the single-stage group [6.29 (1.47) mm vs. 5.65 (1.69) mm, P = 0.005]. The number and anatomical distribution of stones were comparable between the groups (Table 2).

Table 2. MRCP findings.

Variable	Group I (n = 100)	Group II (n = 100)	*P*-value
CBD diameter (mm), mean (SD)	13.18 (2.01)	10.94 (2.46)	<0.001*
Range (mm)	10-23	8-17	NA
Single stone, n (%)	92 (92%)	90 (90%)	0.621
Multiple stones, n (%)	8 (8%)	10 (10%)	0.621
Stone size (mm), mean (SD)	6.29 (1.47)	5.65 (1.69)	0.005*
Proximal site, n (%)	18 (18%)	28 (28%)	0.178
Distal site, n (%)	74 (74%)	62 (62%)	0.178
Both sites, n (%)	8 (8%)	10 (10%)	0.178

MRCP: magnetic resonance cholangiopancreatography, CBD: common bile duct, SD: standard deviation, mm: millimeter, n: number, %: percent, NA: not applicable. *P <0.050 was considered statistically significant.

Intraoperative findings

Mean operative time did not differ significantly between the two strategies [138.3 (20.4) min in Group I vs. 140.85 (43.98) min in Group II, P = 0.600]. Intraoperative bleeding occurred in 4% of patients in Group I and 3% in Group II (P = 0.542). No biliary or duodenal injury was observed. Conversion to open surgery was required in three patients in each group (3% vs. 3%, P = 1.000) (Table 3).

Postoperative outcomes

Postoperative jaundice occurred in 4% of patients in Group I and 10% of patients in Group II (P = 0.096). Although total bilirubin levels decreased postoperatively in both groups, early postoperative direct bilirubin was statistically higher in Group I [1.01 (0.08) mg/dL vs. 0.83 (0.06) mg/dL, P = 0.030]; however, the absolute difference was clinically minimal. Wound infection occurred in 3% of patients in each group. Postoperative pancreatitis developed in two patients in Group I and three patients in Group II (P = 0.732). Minor bile leakage was observed in two patients (2%) in Group I, with no cases in Group II (P = 0.532). Retained CBD stones were detected in three patients (3%) in the single-stage group, whereas no retained stones were identified in the two-stage group (P = 0.246) (Table 3).

Hospital stay and patient-reported outcomes

Mean length of hospital stay was comparable between the groups [6.8 (2.08) days in Group I vs. 7.18 (2.28) days in Group II, P = 0.219]. At 24 h postoperatively, pain scores assessed using the VAS were significantly lower in Group I [5.34 (1.02) vs. 6.30 (1.02), P <0.001], whereas pain scores were similar between the groups on postoperative day 3 [1.42 (0.39) vs. 1.52 (0.56), P = 0.468]. Overall patient satisfaction was high and did not differ significantly between the two strategies (78% vs. 75%, P = 0.843). No in-hospital mortality was observed (Table 3).

Table 3. Operative and postoperative outcomes.

Variable	Group I (n = 100)	Group II (n = 100)	*P*-value
Operative time (min), mean (SD)	138.3 (20.4)	140.85 (43.98)	0.600
Range (min)	105-180	90-360	NA
Intraoperative bleeding, n (%)	4 (4%)	3 (3%)	0.542
Biliary injury, n (%)	0 (0%)	0 (0%)	NA
Conversion to open surgery, n (%)	3 (3%)	3 (3%)	1.000
Postoperative jaundice, n (%)	4 (4%)	10 (10%)	0.096
Postoperative total bilirubin (mg/dL), mean (SD)	1.39 (0.13)	1.23 (0.21)	0.063
Postoperative direct bilirubin (mg/dL), mean (SD)	1.01 (0.08)	0.83 (0.06)	0.030*
Wound infection, n (%)	3 (3%)	3 (3%)	1.000
Pancreatitis, n (%)	2 (2%)	3 (3%)	0.732
Bile leakage, n (%)	2 (2%)	0 (0%)	0.532
VAS at 24 h, mean (SD)	5.34 (1.02)	6.30 (1.02)	<0.001*
VAS on day 3, mean (SD)	1.42 (0.39)	1.52 (0.56)	0.468
Hospital stay (days), mean (SD)	6.8 (2.08)	7.18 (2.28)	0.219
Retained CBD stones, n (%)	3 (3%)	0 (0%)	0.246
Very satisfied, n (%)	78 (78%)	75 (75%)	0.843

Min: minutes, CBD: common bile duct, SD: standard deviation, VAS: visual analog scale, n: number, %: percent, NA: not applicable. *P <0.050 was considered statistically significant.

Exploratory analysis and resource utilization

After adjustment for baseline CBD diameter and stone size in an exploratory post-hoc analysis, no statistically significant differences were observed in clearance or conversion rates. Stone clearance was achieved in 97% of patients in Group I (95% CI, 93-99%) and 98% of patients in Group II (95% CI, 94-100%). The single-stage approach required one anesthesia session and fewer procedural exposures, reflecting its potential advantages in resource utilization. Follow-up beyond six months was unavailable for approximately 30% of patients, limiting the assessment of long-term recurrence and late complications.

Discussion

The management of concomitant gallbladder and CBD stones remains controversial. Single-stage LCBDE with cholecystectomy offers definitive treatment during a single hospital admission, whereas a two-stage strategy using preoperative ERCP followed by LC remains widely adopted because of endoscopic availability and procedural familiarity [2, 3, 19]. Randomized trials and meta-analyses have demonstrated comparable safety and ductal clearance between these approaches, while emphasizing distinct trade-offs, including post-ERCP pancreatitis, bile leakage after choledochotomy, and differences in resource utilization and hospital stay [1, 5-8]. This randomized trial contributes region-specific evidence from a tertiary university center and incorporates prospectively collected patient-centered outcomes.

Baseline biochemical parameters, including the presence of jaundice and serum bilirubin levels, were similar between the groups, consistent with previous randomized studies reporting comparable preintervention profiles [2-4, 11]. In contrast, preoperative MRCP revealed a significantly larger CBD diameter and slightly larger stone size in the single-stage group. These anatomical differences are clinically relevant because duct diameter and stone burden influence operative strategy, technical complexity, and the choice between transcystic and transcholedochal approaches. Prior observational studies and systematic reviews have identified these factors as key determinants of procedural difficulty and outcomes [7, 12, 14, 15].

Operative duration did not differ meaningfully between the two strategies in our cohort. This finding aligns with prior studies reporting comparable overall procedural times, as the longer operative component of a single-stage approach may be offset by eliminating a separate ERCP session, resulting in similar cumulative resource utilization [2, 3, 5-7]. Intraoperative complications and conversion rates were low and comparable between the groups, supporting the safety of both approaches when performed by experienced surgical and endoscopic teams [2, 4, 5, 11].

Postoperative complication rates were low in both arms, with no evident difference in pancreatitis or bile leakage. This is consistent with pooled evidence suggesting that ERCP carries a higher risk of pancreatitis, whereas choledochotomy-based approaches may increase the risk of bile leakage, with absolute risks strongly influenced by technique and operator experience [7, 8]. Although early postoperative direct bilirubin levels were modestly higher in the single-stage group, the absolute difference was small and of limited clinical relevance, likely reflecting

transient ductal edema or manipulation, as bilirubin levels declined in both groups.

Early postoperative pain scores favored the single-stage approach at 24 h, with convergence by postoperative day 3. This observation supports the hypothesis that avoiding a second invasive procedure may reduce early postoperative discomfort. Patient satisfaction was high and comparable between groups, indicating that overall procedural success and convenience were likely important drivers of patient-reported outcomes [3, 5, 6]. Retained CBD stones were infrequent, occurring in a small proportion of patients in the single-stage group and in none of the patients in the two-stage group. Previous meta-analyses have reported slightly higher immediate clearance rates with ERCP in some settings, particularly where routine choledochoscopy is unavailable; however, centers with established LCBDE expertise often achieve comparable clearance rates [1, 7-9].

Although a formal cost-effectiveness analysis was beyond the scope of this study, the single-stage approach consolidated management into a single anesthesia exposure and hospital admission, suggesting potential advantages in resource utilization. Health-economic evaluations in different healthcare systems have reported reduced cumulative costs with single-session strategies, although these findings vary depending on local infrastructure, reimbursement models, and the availability of expertise [16, 19, 20].

Despite randomized allocation, baseline imbalances in CBD diameter and stone size were observed between the groups. This may reflect chance variation or subtle referral and triage factors and represents a potential source of residual confounding, particularly regarding technical difficulty and the risk of retained stones. Although overall outcomes remained comparable, these imbalances should be considered when interpreting the results. Future multicenter trials incorporating stratified randomization by duct diameter and stone burden, as well as multivariable adjustment, are warranted to further validate these findings.

Limitations

As a single-center randomized trial, this study has several limitations. The relatively small number of uncommon complications limited the statistical power to detect small differences in effect. In addition, prespecified multivariable adjustment for baseline imbalances was not performed; therefore, residual confounding, particularly due to the larger CBD diameter in Group I, cannot be completely excluded. Finally, the lack of long-term follow-up and the absence of a formal cost-effectiveness analysis restricted the evaluation of late recurrence and economic outcomes.

Future directions

Future research should focus on multicenter randomized trials with stratified randomization according to CBD diameter and stone size, combined with standardized intraoperative clearance protocols. Incorporating formal health-economic evaluations and extended follow-up would allow a more robust assessment of recurrence rates and overall cost-effectiveness. Comparative evaluation of transcystic versus transcholedochal LCBDE and laparoscopic-endoscopic rendezvous approaches may further refine procedural selection. Integrating such evidence into regional surgical pathways could optimize care delivery and resource utilization.

Conclusion

Single-stage LCBDE + LC and two-stage ERCP + LC demonstrated comparable short-term safety and efficacy. The single-stage approach reduced early postoperative pain and avoided the need for a second procedure in many cases. The optimal management approach should consider patient anatomy, available surgical and endoscopic expertise, and patient preferences regarding single-session versus staged care. Broader multicenter trials, including economic evaluations, are needed to refine evidence-based decision-making.

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