



ROLE OF DRAIN PLACEMENT AFTER UNCOMPLICATED LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Background: Laparoscopic cholecystectomy is the standard of care for symptomatic gallstone disease, yet many surgeons continue to place a subhepatic drain after uncomplicated procedures despite accumulating evidence questioning the practice. This study evaluated whether routine drain placement after uncomplicated laparoscopic cholecystectomy confers any measurable benefit.

Methods: In this prospective randomized controlled study, 100 patients undergoing elective laparoscopic cholecystectomy for symptomatic cholelithiasis were randomized after completion of an uncomplicated procedure to a drain group (n = 50; closed suction subhepatic drain removed at 24 hours) or a no-drain group (n = 50). The primary endpoints were postoperative pain (visual analogue scale, VAS) and length of hospital stay. Secondary endpoints included shoulder tip pain, nausea and vomiting, subhepatic collection on ultrasonography, wound infection, analgesic requirement and time to ambulation; safety endpoints were bile leak, haemorrhage and reintervention. Analysis followed the intention-to-treat principle, with effect sizes reported as mean differences (MD) and relative risks with 95% confidence intervals (CI).

Results: The groups were comparable at baseline. Pain was greater in the drain group at 6 hours (5.8 ± 1.2 vs 4.6 ± 1.1 ; MD 1.2, 95% CI 0.75 to 1.65; Cohen's d = 1.04; $p < 0.001$) and 24 hours (4.1 ± 1.0 vs 3.2 ± 0.9 ; MD 0.9, 95% CI 0.53 to 1.27; $p < 0.001$). Drained patients required more analgesic doses (MD 1.1, 95% CI 0.71 to 1.49; $p < 0.001$), ambulated later (MD 2.3 hours, 95% CI 1.36 to 3.24; $p < 0.001$) and stayed longer (2.7 ± 0.8 vs 1.9 ± 0.6 days; MD 0.8, 95% CI 0.52 to 1.08; $p < 0.001$). Subhepatic collection (10% vs 14%; risk difference -4.0%, 95% CI -16.7 to 8.7), wound infection, shoulder tip pain and emetic symptoms did not differ significantly. There were no bile leaks, haemorrhages or reinterventions.

Conclusion: Routine drainage after uncomplicated laparoscopic cholecystectomy did not reduce complications but increased pain, analgesic use and hospital stay. Routine drainage appears unnecessary in uncomplicated cases and should be reserved for selective intraoperative indications.

Keywords: Laparoscopic Cholecystectomy, Abdominal Drainage, Subhepatic Drain, Postoperative Pain, Randomized Controlled Trial.

INTRODUCTION

Since its introduction in the late 1980s, laparoscopic cholecystectomy has replaced the open approach as the gold standard treatment for symptomatic cholelithiasis,

offering less postoperative pain, shorter hospitalization, earlier return to activity and better cosmesis [1]. It is now among the most frequently performed general surgical operations worldwide, and much of its appeal rests on the promise of rapid, uneventful recovery.

The practice of placing a prophylactic abdominal drain after cholecystectomy predates the laparoscopic era and was historically justified on two grounds: early detection and controlled egress of bile leak or haemorrhage from the gallbladder bed, and evacuation of serosanguineous fluid that might otherwise become infected [2,3]. With the



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transition to laparoscopy, a third rationale emerged — that a subhepatic drain might vent residual carbon dioxide and thereby reduce shoulder tip pain attributed to diaphragmatic irritation [4].

These theoretical benefits have been increasingly challenged. Drains are not innocuous: they are foreign bodies that may act as conduits for retrograde infection, cause discomfort at the exit site, restrict early mobilization and prolong hospital stay [2,5]. Randomized trials in elective, uncomplicated laparoscopic cholecystectomy have repeatedly failed to demonstrate an advantage for routine drainage [5-9], and the Cochrane systematic review by Gurusamy and colleagues concluded that there was no convincing evidence to support the practice, while noting an association with increased wound infection and delayed discharge [2]. Subsequent meta-analyses, including a trial sequential analysis of 16 randomized trials, have reached the same conclusion and reported that pain 24 hours after surgery is consistently worse in drained patients [10-13]. The question continues to attract systematic evaluation in recent literature [14]. Despite this body of evidence, routine drain placement remains common in many surgical units, particularly in training institutions, where it is often perceived as a medicolegally 'safer' habit. Local practice patterns, case mix and resource considerations differ between settings, and unit-level data can be persuasive in changing entrenched habits. The present study was therefore undertaken to compare postoperative outcomes between patients with and without a subhepatic drain following elective, uncomplicated laparoscopic cholecystectomy, with the hypothesis that omission of the drain would not increase complications and would improve early recovery parameters.

MATERIALS AND METHODS

Study design and setting

This prospective randomized controlled study was conducted in the Department of General Surgery at Government Medical College, Mahbubnagar, Telangana, India.

over a period of 18 months from January 2025 to June 2026. The protocol was approved by the Institutional Ethics Committee and written informed consent was obtained from all participants.

Participants

Patients aged 18 to 65 years undergoing elective laparoscopic cholecystectomy for symptomatic cholelithiasis, with American Society of Anesthesiologists (ASA) physical status I or II, were eligible. Exclusion criteria were acute cholecystitis or empyema at surgery, choledocholithiasis or deranged liver function, previous upper abdominal surgery, coagulopathy, pregnancy, conversion to open cholecystectomy, and any intraoperative event mandating drainage in the operating surgeon's

judgement (significant bleeding, bile spillage with stone loss, doubtful haemostasis or suspicion of duct injury). Patients meeting an exclusion event intraoperatively were withdrawn before randomization.

Randomization and intervention

Randomization was performed only after the cholecystectomy had been completed and confirmed to be uncomplicated, using a computer-generated random number sequence with allocation concealed in sequentially numbered opaque sealed envelopes opened in the operating room. In the drain group, a 16-Fr closed suction drain was placed in the subhepatic space through the lateral 5-mm port and removed at 24 hours if output was serous and less than 30 mL. In the no-drain group, no drain was placed. The radiologist performing follow-up ultrasonography was blinded to allocation; ward outcome assessors were not involved in the surgery, although complete blinding of patients and ward staff was not feasible owing to the visible drain.

Surgical technique and perioperative care

All procedures were performed under general anaesthesia using a standard four-port technique with carbon dioxide pneumoperitoneum maintained at 12 mmHg. The gallbladder was dissected using electrocautery after achieving the critical view of safety, and haemostasis of the liver bed was confirmed. Residual gas was evacuated by manual compression before port closure. Postoperative analgesia was standardized to intravenous diclofenac 75 mg twelve-hourly on the day of surgery, followed by oral diclofenac on demand; additional doses were recorded. Oral fluids were started at 6 hours and patients were encouraged to ambulate as tolerated. Discharge criteria were adequate oral intake, independent ambulation, pain controlled on oral analgesics and absence of fever or wound concern.

Endpoints

Primary endpoints: postoperative pain measured on a 10-cm visual analogue scale (VAS) at 6, 24 and 48 hours, and length of hospital stay.

Secondary endpoints: shoulder tip pain, postoperative nausea and vomiting within 24 hours, subhepatic fluid collection on abdominal ultrasonography at 48 hours performed by a blinded radiologist, surgical site infection within 30 days (Centers for Disease Control and Prevention criteria), total analgesic doses administered, and time to unassisted ambulation.

Safety endpoints: bile leak, postoperative haemorrhage, reintervention (radiological or surgical) and 30-day mortality.

Sample size and statistical analysis

Assuming a clinically meaningful difference of 1.0 in mean 24-hour VAS score with a standard deviation of 1.5, a two-sided alpha of 0.05 and power of 90%, 48 patients per group were required;

50 per group were enrolled to allow for attrition. All analyses followed the intention-to-treat principle. Continuous variables are presented as mean $\pm$ standard deviation and compared using the unpaired Student's t-test, with effect sizes expressed as mean differences (MD) with 95% confidence intervals (CI) and Cohen's d. Categorical variables are presented as frequencies and percentages and compared using the chi-square test or Fisher's exact test, with effect sizes expressed as relative risks (RR) and absolute risk differences (RD) with 95% CI. Pre-specified subgroup analyses of the 24-hour VAS difference were performed by age, sex, body mass index and operative time, with tests for interaction. A p value below 0.05 was considered

statistically significant. Analyses were performed using [statistical software, version].

RESULTS

Of 126 patients assessed for eligibility, 26 were excluded (15 not meeting inclusion criteria, 6 declined participation, and 5 developed an intraoperative indication for drainage before randomization). One hundred patients were randomized, 50 to each group; there were no losses to follow-up and all randomized patients were analysed in their allocated groups (Figure 1). The groups were well matched for demographic, clinical and operative characteristics (Table 1).

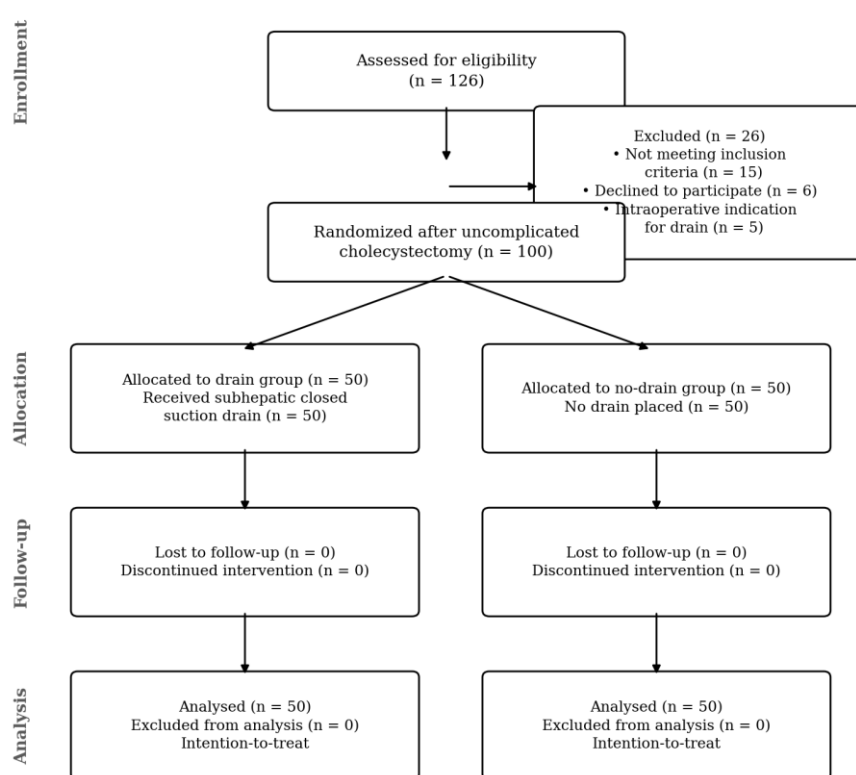


Figure 1. CONSORT flow diagram of participant enrolment, allocation, follow-up and analysis.

Table 1. Baseline and operative characteristics (simulated data)

Variable	Drain group (n = 50)	No-drain group (n = 50)	p value
Age, years (mean $\pm$ SD)	42.6 $\pm$ 11.8	43.9 $\pm$ 12.4	0.592
Female sex, n (%)	36 (72%)	34 (68%)	0.663
Body mass index, kg/m ² (mean $\pm$ SD)	26.4 $\pm$ 3.1	26.9 $\pm$ 3.4	0.443
ASA grade I / II, n	31 / 19	29 / 21	0.685
Diabetes mellitus, n (%)	8 (16%)	10 (20%)	0.603
Hypertension, n (%)	11 (22%)	9 (18%)	0.617

Current smoker, n (%)	7 (14%)	8 (16%)	0.779
≥2 previous episodes of biliary colic, n (%)	28 (56%)	26 (52%)	0.688
Gallbladder wall thickness, mm (mean ± SD)	2.9 ± 0.6	3.0 ± 0.7	0.446
Largest stone size, mm (mean ± SD)	11.2 ± 4.8	10.6 ± 4.5	0.520
Operative time, minutes (mean ± SD)	48.2 ± 10.5	46.7 ± 11.2	0.490
Estimated blood loss, mL (mean ± SD)	22.5 ± 9.8	21.1 ± 8.9	0.457

Pain scores were significantly higher in the drain group at 6 and 24 hours, with large effect sizes; by 48 hours the difference had narrowed and was no longer statistically significant (Table 2, Figure 2).

Patients with a drain required more analgesic doses, ambulated later and had a longer hospital stay; the distribution of hospital stay is shown in Figure 3.

Table 2. Postoperative pain and recovery parameters (simulated data)

Parameter	Drain group (n = 50)	No-drain group (n = 50)	MD (95% CI)	Cohen's d	p value
VAS at 6 h (mean ± SD)	5.8 ± 1.2	4.6 ± 1.1	1.2 (0.75 to 1.65)	1.04	< 0.001
VAS at 24 h (mean ± SD)	4.1 ± 1.0	3.2 ± 0.9	0.9 (0.53 to 1.27)	0.95	< 0.001
VAS at 48 h (mean ± SD)	2.6 ± 0.8	2.3 ± 0.9	0.3 (−0.03 to 0.63)	0.35	0.081
Analgesic doses, n (mean ± SD)	4.2 ± 1.1	3.1 ± 0.9	1.1 (0.71 to 1.49)	1.09	< 0.001
Time to ambulation, h (mean ± SD)	10.4 ± 2.6	8.1 ± 2.2	2.3 (1.36 to 3.24)	0.96	< 0.001
Hospital stay, days (mean ± SD)	2.7 ± 0.8	1.9 ± 0.6	0.8 (0.52 to 1.08)	1.13	< 0.001

MD: mean difference (drain minus no-drain); CI: confidence interval; VAS: visual analogue scale.

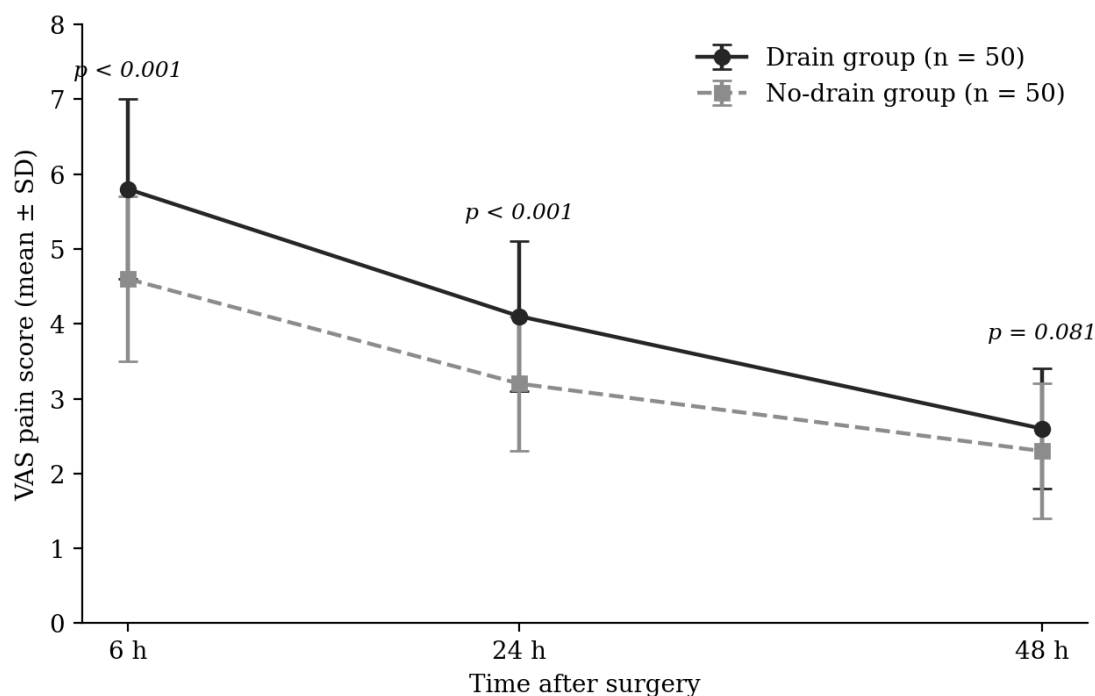


Figure 2. Mean visual analogue scale (VAS) pain scores ($\pm$ SD) at 6, 24 and 48 hours after surgery in the drain and no-drain groups.

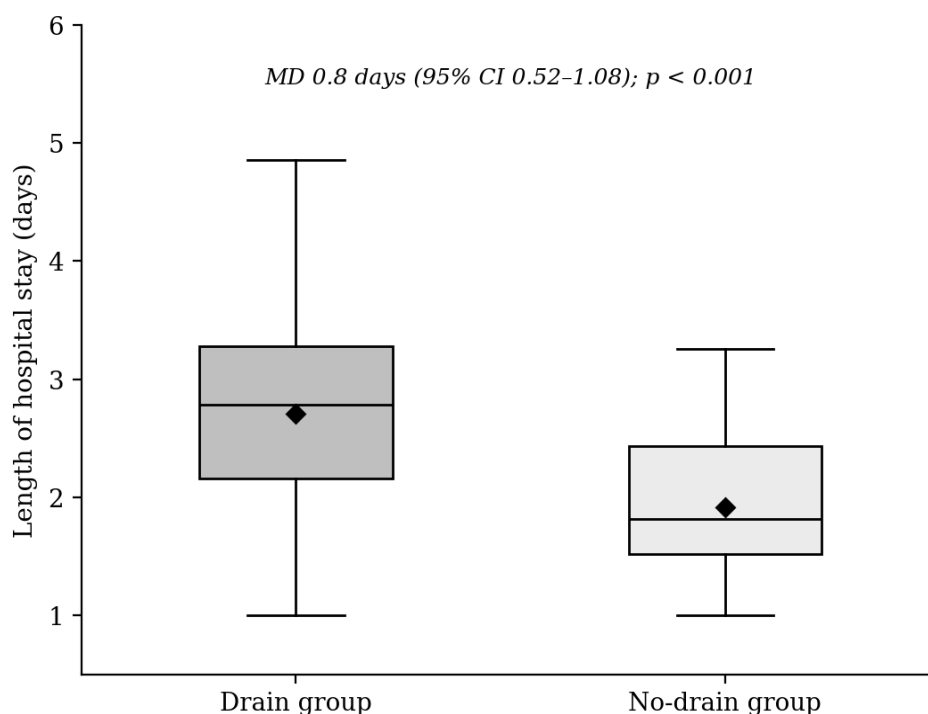


Figure 3. Box plot of length of hospital stay by study group. Boxes show median and interquartile range; whiskers show range; diamonds show means. MD: mean difference; CI: confidence interval.

Morbidity outcomes are summarized in Table 3 and Figure 4. Small subhepatic collections were identified on 48-hour ultrasonography with similar frequency in both groups; all measured less than 30 mL, none was symptomatic and none required aspiration or reoperation. Surgical site infections

were superficial and resolved with dressing care and oral antibiotics. Shoulder tip pain and postoperative nausea and vomiting occurred at comparable rates, indicating no measurable benefit from carbon dioxide venting through the drain. The confidence intervals around all relative risks crossed unity.

There was no bile leak, no postoperative haemorrhage, no reintervention and no mortality in either group.

Table 3. Postoperative morbidity (simulated data)

Outcome	Drain group (n = 50)	No-drain group (n = 50)	RR (95% CI)	RD, % (95% CI)	P value
Shoulder tip pain, n (%)	9 (18%)	7 (14%)	1.29 (0.52 to 3.19)	4.0 (−10.3 to 18.3)	0.585
Nausea/vomiting within 24 h, n (%)	12 (24%)	9 (18%)	1.33 (0.62 to 2.88)	6.0 (−9.9 to 21.9)	0.461
Subhepatic collection at 48 h, n (%)	5 (10%)	7 (14%)	0.71 (0.24 to 2.10)	−4.0 (−16.7 to 8.7)	0.538
Surgical site infection, n (%)	3 (6%)	1 (2%)	3.00 (0.32 to 27.9)	4.0 (−3.6 to 11.6)	0.617
Bile leak, n (%)	0	0	—	0.0	—
Reintervention, n (%)	0	0	—	0.0	—

RR: relative risk; RD: absolute risk difference (drain minus no-drain); CI: confidence interval. p values by chi-square or Fisher's exact test.

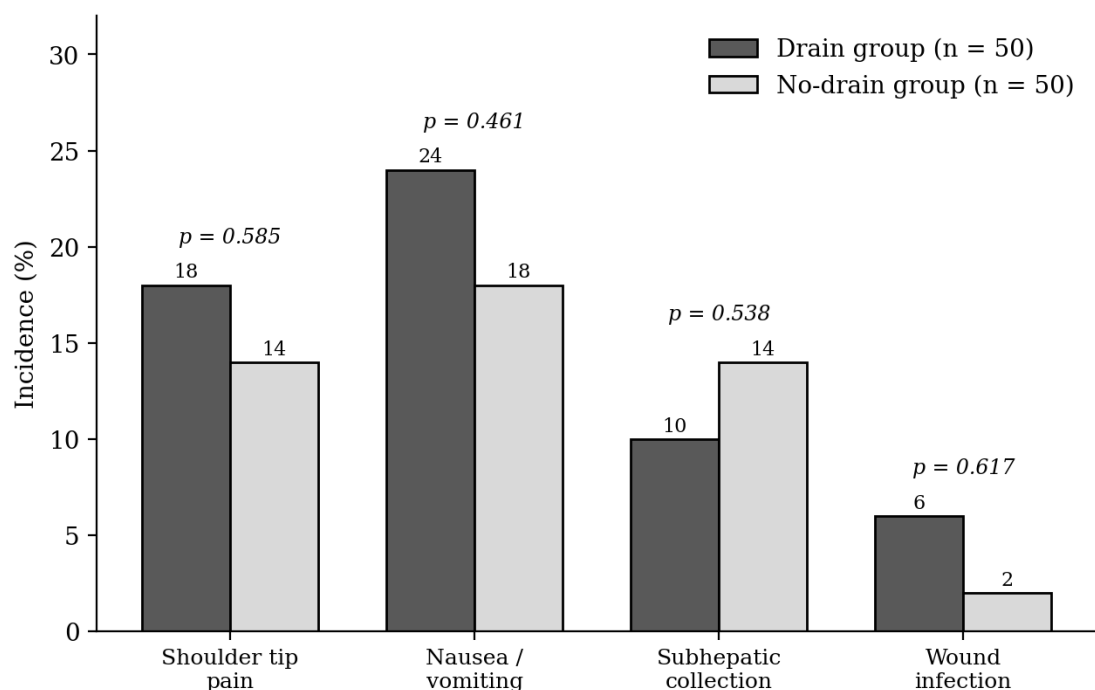


Figure 4. Incidence of postoperative morbidity by study group. None of the differences reached statistical significance.

Pre-specified subgroup analyses showed that the excess 24-hour pain associated with drainage was consistent across strata of age, sex, body mass index

and operative time, with no significant interactions (Table 4).

Table 4. Subgroup analysis of the 24-hour VAS difference (simulated data)

Subgroup	n (drain / no-drain)	MD in 24-h VAS (95% CI)	Interaction p
Age < 45 years	27 / 26	0.8 (0.3 to 1.3)	
Age ≥ 45 years	23 / 24	1.0 (0.5 to 1.5)	0.58

Female	36 / 34	0.9 (0.5 to 1.3)	
Male	14 / 16	0.9 (0.2 to 1.6)	0.97
BMI < 27 kg/m ²	29 / 26	0.8 (0.3 to 1.3)	
BMI ≥ 27 kg/m ²	21 / 24	1.0 (0.5 to 1.5)	0.55
Operative time < 50 min	28 / 30	0.8 (0.4 to 1.2)	
Operative time ≥ 50 min	22 / 20	1.1 (0.5 to 1.7)	0.42

MD: mean difference (drain minus no-drain); CI: confidence interval; BMI: body mass index.

DISCUSSION

In this randomized study of elective, uncomplicated laparoscopic cholecystectomy, routine subhepatic drainage provided no detectable clinical benefit. Drained patients experienced more early postoperative pain — a difference of about one full VAS point at 6 and 24 hours, with effect sizes around one standard deviation — consumed more analgesics, mobilized later and stayed nearly a day longer in hospital, while rates of subhepatic collection, wound infection, shoulder tip pain and emetic symptoms were statistically indistinguishable between groups. No patient in either arm developed a complication that a drain could plausibly have prevented or mitigated.

These findings are concordant with the wider literature. The Cochrane review of randomized trials found no evidence that drains reduce complications after uncomplicated laparoscopic cholecystectomy and observed a trend toward more wound infections and longer hospitalization in drained patients [2]. Individual trials by Tzovaras et al. [6], Georgiou et al. [7] and the multicentre study of Picchio et al. [8] similarly found no advantage, and El-Labban et al. reported higher pain scores with drainage [9]. Meta-analyses pooling these and other trials have consistently concluded that routine drainage is unjustified in the elective, uncomplicated setting [10-12]; notably, a systematic review with trial sequential analysis of 16 trials and 2,398 participants reported that 24-hour pain was significantly worse with a drain (pooled mean difference 1.31, 95% CI 0.96 to 1.65) — closely mirroring the direction and magnitude observed here — with no compensating reduction in intra-abdominal fluid, wound infection, nausea or mortality [13]. The broader principle that prophylactic drainage after uncomplicated gastrointestinal surgery lacks an evidence base was articulated by Petrowsky and colleagues two decades ago [3].

The mechanism by which drains worsen early recovery is intuitive. The drain traverses the abdominal wall, causing somatic pain at the exit site with every movement, which discourages ambulation and deep breathing; its presence also creates a psychological tether to the bed, and its care

adds nursing steps that can delay discharge. The hypothesis that a subhepatic drain vents residual carbon dioxide and thereby relieves shoulder tip pain was not supported here, in keeping with the trial of Nursal et al., which found drainage ineffective against post-laparoscopic nausea, vomiting and pain [4], and with Uchiyama et al., who identified benefit only in selected, more complex gallbladder pathology [5].

The similar incidence of small, clinically silent subhepatic collections in both groups is noteworthy. Minor fluid in the gallbladder fossa is a normal postoperative finding that is resorbed spontaneously; a drain neither prevents its formation nor is required for its resolution, and reliance on a drain to 'signal' a bile leak is misplaced because drains are readily blocked by omentum or clot and a dry drain does not exclude a leak [2,8]. Clinical vigilance and liberal use of ultrasonography remain the appropriate surveillance strategy.

Healthcare economic implications

Routine drainage carries a cost dimension that is rarely quantified but is directly relevant to high-volume public hospitals. Each drain adds the cost of the device itself, daily dressing materials, nursing time for output charting and drain care, and — most importantly — the incremental bed occupancy implied by the additional 0.8 days of hospital stay observed in this study. Multiplied across the hundreds of laparoscopic cholecystectomies performed annually in a teaching institution, the avoidable expenditure and bed-days are substantial. Although a formal cost-effectiveness analysis was not performed, the direction of every cost component favours the no-drain strategy, since no offsetting benefit in complication detection or prevention was demonstrated.

Relevance to enhanced recovery pathways

The findings also align with the principles of enhanced recovery after surgery (ERAS), which emphasize multimodal strategies to attenuate the surgical stress response and specifically discourage tubes, drains and catheters that impede early mobilization and feeding without proven benefit [15]. Omitting the drain removes one of the last routine obstacles to managing uncomplicated laparoscopic cholecystectomy as a short-stay or day-

care procedure, and units seeking to implement ERAS-consistent pathways may find drain omission one of the simplest and highest-yield changes available.

Quality of life considerations

Beyond measurable endpoints, a drain plausibly affects patient comfort, sleep quality, ease of movement and overall satisfaction during the first postoperative day — domains this study did not formally capture. Patient-reported outcome measures and validated quality-of-life instruments were not employed, and future trials incorporating such measures, together with prospective cost analysis, would complete the case for or against routine drainage from the patient's perspective.

None of this argues against selective drainage. When cholecystectomy is complicated — severe acute cholecystitis, empyema, difficult dissection with imperfect haemostasis, or concern about the cystic duct closure — a drain may still be a reasonable adjunct, and such patients were deliberately excluded from this trial. The message of the present data is narrower and practical: in the straightforward elective case that constitutes the majority of laparoscopic cholecystectomies, the drain adds discomfort and cost without adding safety.

Strengths

Strengths of this study include its prospective randomized design with computer-generated sequence and allocation concealment using sealed opaque envelopes; randomization performed only after the procedure was confirmed uncomplicated, eliminating confounding by intraoperative severity; standardized surgical technique, analgesic protocol and discharge criteria across both arms; objective ultrasonographic assessment of subhepatic collections by a radiologist blinded to allocation; complete follow-up with no attrition; and reporting of effect sizes with confidence intervals alongside p values, in line with CONSORT recommendations.

Limitations

This was a single-centre study, and the sample size was powered for pain outcomes rather than for rare complications such as bile leak, so small differences in infrequent events cannot be excluded. Patients and ward assessors could not be blinded to the presence of a visible drain, which may have influenced subjective pain reporting and discharge decisions; only the radiologist was blinded. Pain is inherently subjective despite the use of a validated scale. No formal cost analysis was undertaken, quality-of-life and patient-reported outcomes were not measured, and follow-up was limited to 30 days. Multicentre studies with larger cohorts would be required to confirm equivalence for rare morbidity.

CONCLUSION

Routine placement of a subhepatic drain after elective, uncomplicated laparoscopic cholecystectomy conferred no benefit in terms of complications, shoulder tip pain or emetic symptoms, and was associated with greater early postoperative pain, higher analgesic requirement, delayed ambulation and longer hospital stay, with consistent effects across all examined subgroups. Routine drainage should be abandoned in uncomplicated cases and reserved for specific intraoperative indications at the surgeon's discretion.

Author Contributions (Credit Taxonomy)

Prathap Chouhan M: Conceptualization, Methodology, Investigation, Data curation, Formal analysis, Writing – original draft. Bangi Sunil Kumar: Supervision, Validation, Writing – review & editing. Kanishka Reddy: Formal analysis, Investigation, Visualization, Writing – review & editing. Mohammed Mujtaba: Investigation, Resources, Project administration, Writing – review & editing. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

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