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Does ERCP position matter? A randomized controlled trial comparing efficacy and complications of left lateral versus prone position (POSITION study)

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ABSTRACT

Background and study aims Endoscopic retrograde cholangiopancreatography (ERCP) is traditionally performed with patients in the prone position (PP). However, this poses a potentially increased risk of anesthetic complications. An alternative is the left lateral (LL) decubitus position, which is commonly used for endoscopic procedures. Our aim was to compare cannulation rate, time, and outcomes in ERCP performed in LL versus PP.

Patients and methods We conducted a non-inferiority, prospective, randomized control trial with 1:1 randomization to either LL or PP position. Patients >18 years of age with native papillae requiring a therapeutic ERCP were recruited between March 2017 and November 2018 in a single tertiary center.

Results A total of 253 patients were randomized; 132 to LL (52.2%) and 121 to PP (47.8%). Cannulation rates were 97.0% in LL vs 99.2% in PP (difference −2.2% (one-sided 95% CI: −5% to 0.6%). Median time to biliary cannulation was 03:50 minutes in LL vs 02:57 minutes in PP ($P=0.62$). Pancreatitis rates were 2.3% in LL vs 5.8% in PP ($P=0.20$). There were significantly lower radiation doses used in PP (0.23 mGy/m^2 in LL vs 0.16 mGy/m^2 in PP, $P=0.008$) without a difference in fluoroscopy times.

Conclusions Our analysis comparing LL to PP during ERCP shows comparable procedural and anesthetic outcomes, with significantly lower radiation exposure when performed in PP. We conclude that ERCP undertaken in the LL position is not inferior to PP, except for higher radiation exposure, and should be considered as a safe alternate position for patients undergoing ERCP.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely utilized procedure in the treatment of pancreatobiliary disorders. Despite advances in technique and equipment, ERCP complications continue to occur and can be significant. A summary of 21 prospective studies involving 16,855 patients between 1987 and 2003 found that 1,154 patients (6.9 %) experienced specific complications with 55 deaths (0.33 %) [1].

Many studies have investigated risk factors for post-ERCP complications. Appropriate patient selection and awareness of higher-risk patient factors is paramount. Previous studies, including Williams et al. (2007), [2] found that one of the most relevant factors relating to ERCP outcomes was ease of cannulation.

After an initial trial of the left lateral (LL) decubitus position, ERCP since has been traditionally performed with patients in the prone position (PP) [3]. This position has been reported to improve visualization of the ampulla of Vater [3,4] and subsequently optimize position for papillary engagement and biliary cannulation. This potentially reduces cannulation time, need for a precut sphincterotomy, and/or patient repositioning. PP also permits improved radiographic imaging of biliary anatomy, thereby reducing the risk of pancreatic duct (PD) cannulations [5,6]. However, there is hesitancy by anesthetic staff at our center due to limited airway access and with fears of PP potentially increasing the risk of cardiopulmonary complications, although the limited data available suggest a small non-statistically significant increase in risk compared to LL [6].

LL is the most common position for upper and lower endoscopy; however, it is often not considered for ERCP. There are few data comparing LL with PP during ERCP and subsequent success and complication rates. In a retrospective study of 629 patients comparing LL and supine positions who underwent ERCP, success and complication rates were equivalent; however, procedural difficulty was significantly higher in the supine group [5]. Currently, ERCP established practice is to place patients in PP as this is thought to be advantageous from a procedural aspect due to the imaging characteristics and ampullary position. ERCP can be associated with significant complications and there are few data comparing the success and complication rates of LL versus PP. Our aim was to evaluate the success and ease of ERCP performed in LL versus the traditional PP, and compare procedural and patient outcomes. Our hypothesis was that LL would be non-inferior to PP for ERCP.

Patients and methods

Participants

The study was conducted at a single tertiary referral center by four experienced and accredited endoscopists between March 2017 and November 2018. The annual ERCP volume at this center is >600 a year with all attending endoscopists personally performing at least 75 cases annually. All four attending endoscopists have over 10 years post-fellowship experience and are accredited to perform ERCP procedures (https://secure.gesa.org.au/certification/List). A single skilled endoscopy fellow was involved in the study with direct supervision for all ERCP procedures. All patients over the age of 18 years with native ampullae requiring a therapeutic ERCP were considered for recruitment. Patients received verbal and written informed consent prior to the procedure. The study was approved by the Monash Health Research Committee and was registered in the Australian and New Zealand Clinical Trials Registry (ACTRN12615000219583) prior to recruitment.

Typically, sedation is given with propofol under anesthetic control at our institution. General anesthesia is performed at the discretion of the anesthetist. The type of sedation used in all study participants was not dictated by study protocol but decided upon by the anesthetist immediately prior to the ERCP, independent of the outcome of randomization.

The equipment used in the study is detailed in Supplementary ▶ **Table 1**. Post-ERCP prophylaxis (PEP) was used at the discretion of the endoscopist and included pre-procedure rectal indomethacin, intravenous fluids and/or pancreatic stent insertion.

Outcomes of interest

The primary endpoint was success rate of biliary cannulation and the study was powered for this endpoint. We also compared time to biliary cannulation as an important associated endpoint to be evaluated between the two study groups. Secondary endpoints included post-ERCP pancreatitis rates, cardiorespiratory and procedural complications, number of cannulation attempts, radiation exposure and fluoroscopy time. Post-ERCP pancreatitis was graded as per classifications highlighted in the American Society of Gastrointestinal Endoscopy guidelines [7–9]. Cardiac complications were defined by a change in heart rate of 25 % above or below baseline, or an overt cardiac event. Respiratory complications were defined as oxygen saturations below 90 %, and further classified as: 1) mild if no reversal was required and the patient was managed with oxygen, jaw support or stimulation; 2) moderate if a reversal agent was required; or 3) severe if the procedure was interrupted.

Baseline demographic data including age, gender, height, weight, and body mass index (BMI) were collected. The presence of a duodenal diverticulum, ampullae characteristics, and need for general anesthesia were also noted to compare baseline patient factors. Other parameters evaluated included PD cannulations, pancreatic stent insertion, indomethacin use, need for patient repositioning, rates of precut needle-knife sphincterotomy, immediate complications, delayed complications (within 7 days), repeat ERCPs and anesthetic and antispasmodic drug requirements.

Study design

We conducted a non-inferiority, randomized controlled trial (RCT) of patients with a native papilla requiring an ERCP. Patients were randomized 1:1 into either the LL arm or the PP arm of the study by secure envelope in batches of 50. The procedure was then conducted as per usual standards and was completed as necessary for best patient care.

If the fellow was unsuccessful with five attempts at ampullary engagement, then a highly-experienced endoscopist

▶ **Table 1** Baseline demographics.

	Left Lateral (n = 132)	Prone (n = 121)	*P* value
Age			
▪ Mean (± SD)	66.7 (17.4)	65.43 (18.23)	0.48
Gender, n (%)			
▪ Male	64 (48.5)	55 (44.6)	0.54
▪ Female	68 (51.5)	66 (55.4)	
Mean height, cms (± SD)	168 (± 0.1)	166 (± 0.1)	0.203
Mean weight, kg (± SD)	74.26 (± 16.08)	78.83 (± 17.98)	0.039
Body mass index (± SD)	26.34 (± 4.89)	28.83 (± 5.56)	**0.001**
ASA score, mean (range)	3 (1–4)	2 (1–4)	0.12
Presence of obstructive sleep apnea, n (%)	3 (2.3)	0	0.25
Endotracheal tube pre-procedure, n (%)	9 (6.8)	8 (6.6)	1.00
Laryngeal mask pre-procedure, n (%)	1 (0.8)	2 (1.7)	0.61
Indication, n (%)			
▪ Choledocholithiasis	88 (66.7)	93 (76.9)	0.07
▪ Benign stricture	3 (2.3)	1 (0.8)	0.62
▪ Malignant stricture	27 (20.5)	10 (8.3)	**0.006**
▪ Bile leak	6 (4.6)	3 (2.5)	0.50
▪ Other	8 (6.1)	13 (10.7)	0.18
Diverticulum, n (%)	32 (24.2)	28 (23.1)	0.88
Abnormal ampulla, n (%)	11 (8.3)	11 (9.1)	1.00
Fellow-attempted cases, n (%)	94 (71.2)	91 (75.2)	0.48

SD, standard deviation; ASA, American Society of Anesthesiologists.

would attempt cannulation for 5 minutes, after which, patients could be crossed over to the alternate position, if it was deemed that persistence in the original position would be unsuccessful. With intention-to-treat, all patients were analyzed in their original assigned groups.

Inclusion criteria

All patients > 18 years of age requiring a therapeutic ERCP were offered enrolment.

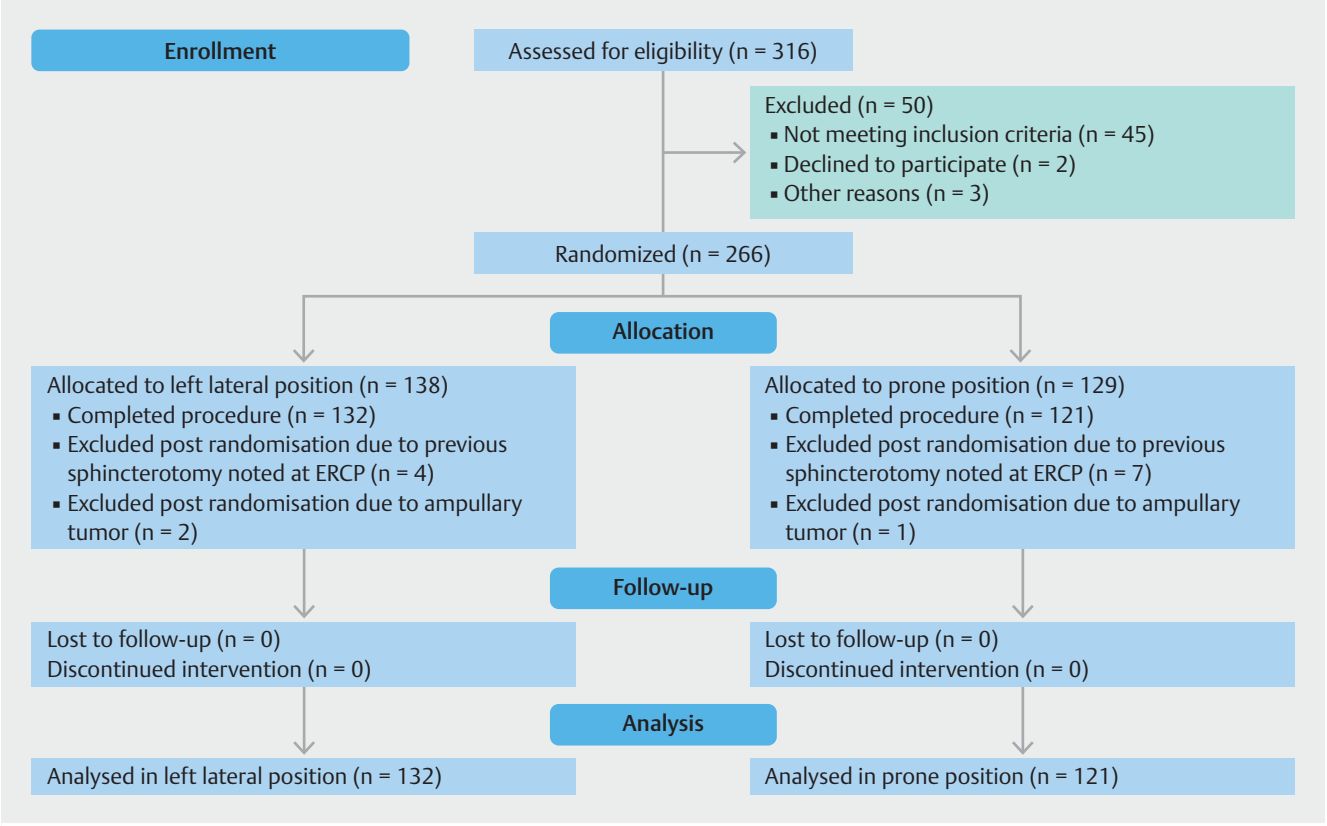
Exclusion criteria

These included patients with a previous sphincterotomy or ampullary lesion/tumor, critically unwell patients or those in the Intensive Care Unit, patients unable to lie in the required positions due to physical limitations, pregnant patients, patients unable to provide informed consent or those getting an endoscopic ultrasound immediately prior to ERCP to prevent confounders to the cardiopulmonary complications due to the extended anesthetic time and higher medication doses.

Patients were allowed to withdraw from the study at any time with no adverse effects on their medical care.

Statistical methods

The primary endpoint was time to cannulation as this was expected to have a greater dynamic range and thus better discrimination between the groups. However, to power the study, we chose a more conventional metric with an established standard, which was successful biliary cannulation. The sample size was calculated assuming a 94 % biliary cannulation success rate in the control group and a non-inferiority margin of 10 %. To be adequately powered with 90 % power at a one-sided alpha of 5%, 97 patients were required in each group. An intention-to-treat (ITT) analysis was used to compare efficacy for successful biliary cannulation with non-inferiority established if the lower confidence limit for the difference in effect was above –10 %. Comparisons of outcomes between treatment groups were made using the Student's t-test for normally distributed continuous variables, Wilcoxon rank-sum test for non-normally distributed continuous variables, and chi-square or Fisher's exact test as appropriate for categorical variables. A two-sided $P < 0.05$ indicated statistical significance. Statistical analyses were



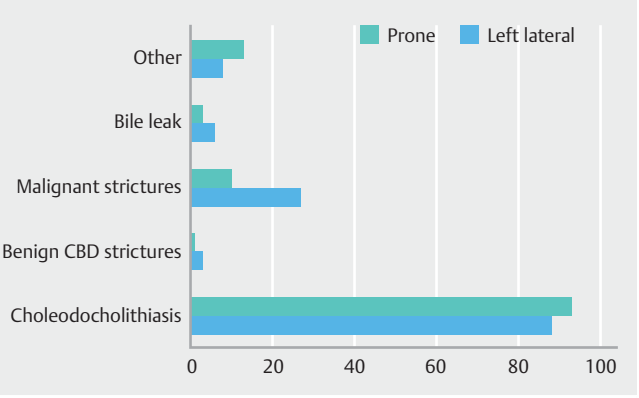
▶ **Fig. 1** Consort diagram.

performed with Stata software version 14 (StataCorp, Texas, United States).

Results

A total of 316 patients were considered for enrolment, of whom 266 were randomized. The CONSORT diagram in ▶ **Fig. 1** illustrates the patient flow from study commencement until completion. The final study cohort consisted of 253 patients, of whom 135 were women (53.4 %) with a mean age of 65.8 years [range 21–98 years]. A total of 132 patients were randomized to LL (52.2 %) and 121 to PP (47.8 %). Procedural indications (▶ **Fig. 2**) predominantly included choledocholithiasis (71.5 %, n = 181) and malignant strictures (14.6 %, n = 37). Other indications included benign strictures, bile leaks, Sphincter of Oddi dysfunction, Mirizzi's syndrome and ampullary stenosis. Across the cohort, the ERCP success rate was 97.2 %, with three median cannulation attempts at the ampulla. Post-ERCP pancreatitis rates were 3.95 %. Major bleeding occurred in one patient and respiratory complications in 3.95 % of patients.

▶ **Table 1** highlights the baseline demographics between groups. At baseline both groups were well matched. Age, gender, mean heights and weights were equivalent (P = ns between groups) with a sole statistical difference in the BMI (26.34 in LL vs 28.83 in PP, P = 0.001). There was no difference in rates of obstructive sleep apnea at baseline (P = 0.25) and physical status as graded by the American Society of Anesthesiologists (ASA)



▶ **Fig. 2** Indications for ERCP.

score (P = 0.12). There were comparable numbers of cases requiring endotracheal tubes pre-procedure (9 in LL vs 8 in PP, P = 1.00) and laryngeal masks (1 vs 2 respectively, P = 0.61). There was a significantly higher number of patients with malignant obstruction in the LL group compared to PP (27 vs 10, P = 0.006). Of these, 22 (81.5 %) malignant strictures in the LL group were distal biliary strictures (cholangiocarcinoma or pancreatic head lesions) as compared to eight (80 %) in the PP group, with a comparable percentage of hilar strictures in both groups (P = 1.00). On subgroup analysis of the malignant

▶ **Table 2** Intention to treat analysis of primary efficacy endpoint.

Full analysis set	Treatment group		Total
	Left lateral	Prone position	
Number of patients randomized	132	121	253
Number of patients included in Intention to treat analysis	132	121	253
Successful biliary cannulation, n (%)	128 (97)	120 (99.2)	248 (98)
Difference between treatment groups (one-sided 95 % confidence interval)	–2.2 % [–5 % to 0.6 %]		

▶ **Table 3** Procedure-related outcomes between groups

	Left lateral (n = 132)	Prone (n = 121)	*P* value
Cannulation attempts			
▪ Median (IQR)	3 (1–6)	2 (2–7)	0.55
Number of PD cannulations			
▪ Median (IQR)	0 (0–1)	0 (0–1)	0.35
Time to cannulation, min: sec			
▪ Median (IQR)	03:50 (01:32 – 07:15)	02:57 (01:25 – 07:34)	0.62
Needle-knife, n (%)	13 (9.8)	14 (11.6)	0.69
Pancreatic stent, n (%)	8 (6.1)	10 (8.3)	0.63
Indomethacin, n (%)	23 (17.4)	22 (18.2)	1.00
Need to reposition, n (%)	6 (5.0)	2 (1.7)	0.29
Total procedure time, min: sec			
▪ Median (IQR)	21:00 (13.46 – 31.00)	20:35 (13.45 – 28.50)	0.35
Repeat ERCP, n (%)	17 (12.9)	12 (9.9)	0.56

IQR, interquartile range; PD, pancreatic duct; ERCP endoscopic retrograde cholangiopancreatography.

stricture patients, there was no difference in successful biliary cannulation ($P = 1.00$) or time to cannulation between groups ($P = 0.21$). Similarly, an analysis of the non-malignant patients found no difference in successful biliary cannulation ($P = 1.00$) or time to cannulation between groups ($P = 0.71$).

ITT analysis of the primary efficacy endpoint (▶ **Table 2**) showed that successful biliary cannulation was 99.2 % in PP and 97.0 % in LL. The difference between groups was –2.2 % with a one-sided 95 % confidence interval of –5.0 % to 0.6 %, suggesting non-inferiority between groups.

There was no statistical difference in successful cannulation rates between endoscopists (range 95.89–100 %, $P = 0.76$). There was also no statistical difference in the proportion of procedures performed by each endoscopist in either position ($P = 0.75$) and no difference in complication rates.

▶ **Table 3** shows the outcomes between groups. The time to biliary cannulation, although numerically longer in LL, was not statistically different when compared to PP (3:50 minutes vs 2:57, $P = 0.62$), and total length of the ERCP remained almost identical at 21:00 minutes in LL as compared to 20:35 minutes in PP ($P = 0.56$). Median cannulation attempts at the ampulla of Vater were similar at three in LL versus two in PP ($P = 0.55$ as were rates of PD cannulations (median 0 in both groups, $P = 0.35$). Six patients in the LL group required repositioning to optimize biliary cannulation as compared to two in the PP group; however, this was non-significant ($P = 0.29$). Rates of needle-knife sphincterotomies, indomethacin use, and pancreatic stent insertions were similar across groups.

When comparing long- and short-wire technique using consultant practices as a surrogate for analysis, there were no differences found in the technique used and primary endpoints. Rates of successful biliary cannulation with long-wire technique in 162 patients were 98.8 % as compared to 96.6 % in 86 patients with short-wire ($P = 0.35$). Similarly, time to cannulation was non-significant with a median of 04:24 seconds (IQR 01:30–07:42) with long-wire versus 02:55 secs (IQR 01:30–06:30) with short-wire ($P = 0.47$).

There were no significant differences in immediate or delayed procedure-related complications between groups (▶ **Table 4**). In particular, the rates of pancreatitis were non-signifi-

▶ **Table 4** Complication rates between groups.

	Left lateral (n = 132)	Prone (n = 121)	*P* value
Post-ERCP pancreatitis, n (%)	3 (2.3)	7 (5.8)	0.20
Immediate complications, n (%)	2 (1.5)	2 (1.7)	1.00
Major bleeding	1 (0.8)	0	1.00
Minor bleeding	0	1 (0.8)	0.48
Perforation	1 (0.8)	0	1.00
Significant post-ERCP pain	0	1 (0.8)	0.48
Delayed complications, n (%)	10 (7.6)	7 (5.78)	0.62
Minor bleeding	1 (0.8)	2 (1.7)	0.61
Cholangitis	6 (4.5)	4 (3.3)	0.75
Other	3 (2.3)	1 (0.8)	0.62

ERCP, endoscopic retrograde cholangiopancreatography.

▶ **Table 5** Cardiorespiratory and anesthetic-related outcomes between groups.

	Left lateral (n = 132)	Prone (n = 121)	*P* value
Cardiorespiratory events, n (%)	8 (6.1)	8 (6.6)	1.00
▪ Mild respiratory	5 (3.8)	4 (3.3)	1.00
▪ Severe respiratory	0	1	0.48
▪ Tachycardia	0	1	0.48
▪ Bradycardia	3 (2.3)	2 (1.6)	1.00
Propofol dose, median (IQR)	380 (255–500)	300 (235–465)	0.14
Antispasmodic need, n (%)	40 (30.3)	32 (26.4)	0.58
Glucagon, n (%)	27 (20.5)	18 (14.9)	0.25
Buscopan, n (%)	16 (12.1)	16 (13.2)	0.85
ETT during procedure, n (%)	2 (1.5)	1 (0.8)	1.00

ETT, endotracheal tube.

cant when comparing between groups (3 in LL and 7 in PP, P = 0.20). None of these occurred in patients with malignant biliary obstruction. These are low in comparison to previously published literature on post-ERCP outcomes. The proportion of patients receiving PEP was comparable between groups; eight pancreatic stent insertions in LL group versus 10 in PP (P = 0.63), and 23 patients in LL receiving rectal indomethacin compared to 22 in PP (P = 1.00). Total complications were also comparable with 15 complications in the LL group and 16 in the PP group (P = 0.70). There were no procedure-related deaths in our cohort. One patient died during the work-up of for pancreatic malignancy and elected palliative care over study follow-up.

There was no significant difference in cardiorespiratory complications. There were five respiratory complications in both groups and five cardiac complications, as shown in ▶ **Table 5**. The majority of these were mild oxygen desaturations, which were easily reversed with oxygen and stimulation. Only one patient in the PP group had severe hypoxia due to laryngospasm and required intubation. Median total propofol doses appeared lower in the PP group but were non-significant (380 mg in LL vs 300 in PP, 0.14) and did not correlate with total length of procedure. Anti-spasmodic requirements were similar across groups as well (P = 0.58). Three patients in total required intubation during the procedure, two in LL and one in PP as mentioned above (P = 1.00).

▶ **Table 6** shows the radiation-related outcomes in both groups. We found significantly lower radiation doses in PP (0.23 mGy/m^2 in LL vs 0.16 mGy/m^2 in PP, P = 0.008); however, without a difference in median fluoroscopy times (1:46 minutes vs 1:38 minutes, P = 0.38). Given the higher rate of malignant

▶ **Table 6** Radiation-related outcomes between groups.

	Left lateral (n = 132)	Prone (n = 121)	*P* value
Radiation dose (mGy)			
▪ Median (IQR)	13.65 (6.84–21.6)	9.52 (5.32–17)	**0.03**
Radiation dose (mGy/m^2)			
▪ Median (IQR)	0.23 (0.12–0.38)	0.16 (0.08–0.28)	**0.008**
Total fluoroscopy time, min: sec			
▪ Median (IQR)	01:46 (1:04–2.54)	01:38 (1.04–2.38)	0.38

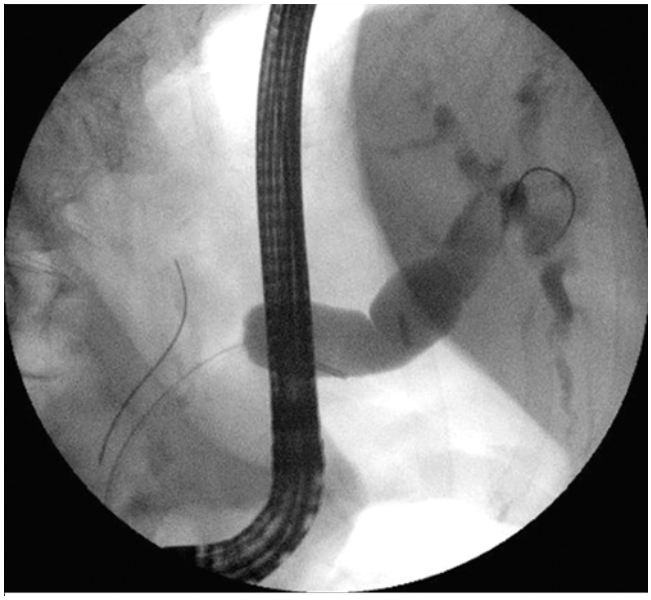
IQR, interquartile range.

strictures in the LL group as a potential confounder, a subgroup analysis was performed in non-malignant patients only, which supported the lower radiation doses in PP (0.20 mGy/m^2 in LL vs 0.16 mGy/m^2 in PP, $P = 0.027$), without a difference in median fluoroscopy times (1:40 minutes (1:04–2:33) in LL vs 1:38 minutes (1:04–2:24) in PP, $P = 0.59$).

Discussion

ERCP is traditionally performed with patients in PP with minimal data available about the feasibility or benefits/pitfalls of alternate patient positions. PP is often the default position adopted by endoscopists, given its perceived benefits, which include improved ampullary position, fluoroscopic delineation of the pancreaticobiliary anatomy, and more experience and familiarity. However, despite these preferences, there are few data available about the practical benefits of patient positioning, from an operator and patient perspective. Two studies in the last decade have largely focused on comparing supine versus PP for ERCP [5, 10]. These have shown no difference in success rates and complications in either position. A retrospective study by Ferreira et al showed similar success rates but greater procedural difficulty in the supine group without respiratory complications.

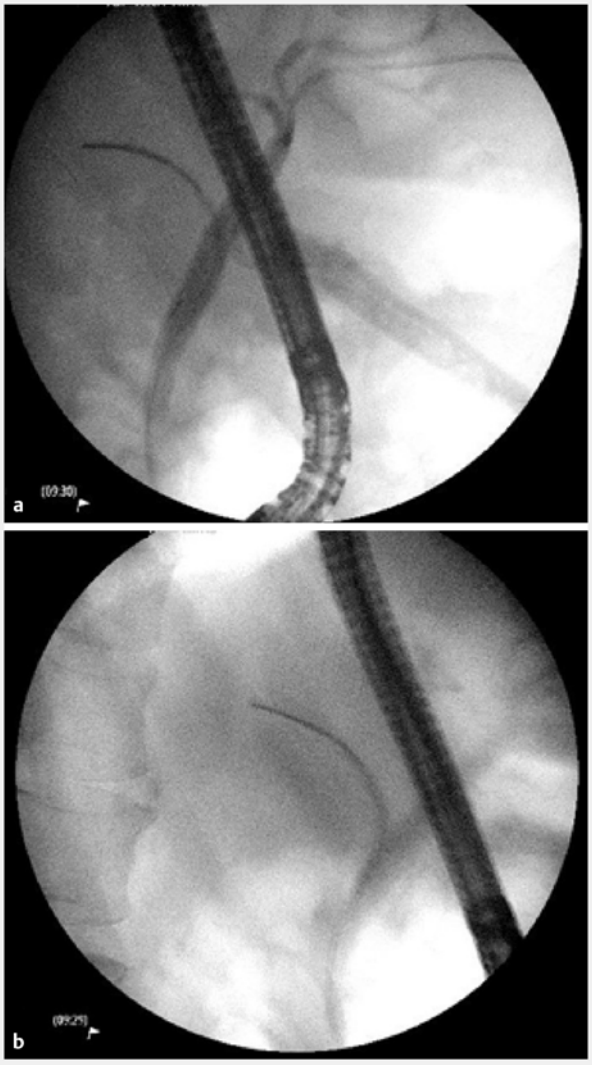
PP is known to be a difficult procedure in pregnant patients, obese patients, patients with drain tubes in-situ, the elderly, and those with rheumatological issues. In addition, PP theoretically poses an increased risk of anesthetic complications through poorer access for patients in need of respiratory support and intubation. An alternative position is LL, which is the most common position for all other endoscopic procedures. In comparison to PP, this position theoretically would be safer, easier, and more comfortable for patients. The biggest potential issues with LL are: 1) the difficulty with anatomical delineation of the biliary and pancreatic ductal systems; and 2) the ampullary position at endoscopy. ▶ **Fig. 3** shows fluoroscopic images of an ERCP performed in PP with a clear distinction between the courses of the pancreatic and bile duct, as shown with the trajectories of their respective wires. ▶ **Fig. 4a** and ▶ **Fig. 4b** show the loss of that distinction with an appreciable length of overlapping wires prior to their altered courses in the distal



▶ **Fig. 3** Distinct bile duct and pancreatic duct wire cannulations in prone position.

pancreas and proximal bile duct, respectively. These issues potentially increase the risk of inadvertent PD cannulation, and therefore, pancreatitis. One previous RCT comparing LL with PP in 62 patients [6] showed no difference in success and complication rates, although LL resulted in higher PD cannulations without an increase in pancreatitis [6]. Therefore, they cautioned against this approach. However, given the convenience and potential benefits of LL to both patients and proceduralists, we felt that this was worth exploring in a larger study. Our RCT aimed to address the potential procedural, patient, and anesthetic benefits and limitations of LL and prove its non-inferiority to the standard PP.

This study consisted of 253 patients over 20 months at a single tertiary referral center. Both groups were well-matched at baseline. with a marginal female predominance. We noted a significantly higher BMI in the PP group, which should pose a higher theoretical anesthetic risk; however, no such difference was noted between groups. There was only one patient in the



▶ **Fig. 4** Overlapping distal portion of **a** bile and **b** pancreatic ducts in left lateral position.

study (BMI 36, PP group) who experienced severe hypoxia due to laryngospasm and required intubation. It is possible her BMI put her at a higher anesthetic risk; however, it is unclear whether her position contributed to this event. All other cardiorespiratory and anesthetic outcomes were non-significant between both groups with no trends suggestive of adverse outcomes in the higher BMI group. Choledocholithiasis and malignant strictures were the most common indications for ERCP. At baseline, there was a discrepancy between the number of patients with malignant strictures in the LL group as compared to the PP group. On subgroup analysis, this discrepancy did not result in a difference in the primary outcomes, suggesting that patient position does not affect cannulation rates or time to cannulation in patients with malignant obstruction. In practice, patients with malignant strictures have often proven to be more difficult cannulations and have higher rates of unsuccessful ERCPs. It is reported that 5 % to 10 % of ERCPs performed for malignant indications fail due to the difficult anatomy or inability to cannulate the duct [11].

International standards and guidelines suggest a biliary cannulation rate ≥ 90 % [12, 13]. The overall rates shown in our study are on par with these standards, and when divided between the two groups, cannulation rates remain above this benchmark. Previous literature has reported cannulations rates of approximately 70 % to 90 % in the supine position, 90 % to 100 % in the PP, and 90 % to 96 % in the LL position; however, some of these are based on smaller-scale retrospective studies [5, 10, 11, 14, 15].

Median cannulation attempts often reflect more difficult cannulation. We found no difference between groups in this parameter, suggesting that LL does not increase the difficulty in successful cannulation. Similarly, there was no difference in the rates of PD cannulations, which can be considered a surrogate marker for difficult cannulation. As suggested by Sundaralingam et al, persistent ampullary trauma through repeated cannulation attempts and reluctance to escalate to early needle-knife sphincterotomy are independent risk factors for post-ERCP pancreatitis [16]. This finding is of significance as our study shows that LL does not increase the number of ampullary attempts, thereby not increasing the chance of ampullary trauma, risk of pancreatitis, and failed biliary cannulation.

The time to successful biliary cannulation was another outcome of interest as this can suggest a more difficult procedure. Historically it is thought and shown that PP provides the more stable and optimal duodenoscope position for ampullary engagement and successful biliary cannulation. Park et al, have shown no difference in cannulation time comparing LL and PP; however, there appeared to be a trend toward longer time to cannulation in PP ($P = 0.17$) [6]. In our study, there was a trend toward a longer time to biliary cannulation in LL (approximately 50 seconds); however, this was not significant when compared to PP ($P = 0.62$).

In our cohort, the complications are comparable to the reported adverse events and complications associated with ERCP [12]. In addition, no significant differences were found between groups with low rates of cholangitis, bleeding, and a single episode of significant post-ERCP pain requiring an overnight stay. The rates of pancreatitis, which occurred exclusively in patients with non-malignant disease, were not different between groups, suggesting that despite the fluoroscopic challenge with overlapping ducts, LL does not increase the risk of clinically significant inadvertent PD cannulations and pancreatitis episodes. The lower rate of pancreatitis in the LL group may be partly explained by the higher incidence of malignant obstruction. It has been shown that malignant obstruction appears protective against pancreatitis, especially in the presence of pancreatic adenocarcinoma and pancreatic ductal obstruction [17, 18]. Of the three patients in the PP group who developed pancreatitis, one required a needle-knife sphincterotomy, another developed pancreatitis despite indomethacin and a prophylactic pancreatic stent after three cannulations, and the third had a prophylactic pancreatic stent inserted on the second PD cannulation. PEP is not routine at our institution and is often administered on a case-by-case basis at endoscopist dis-

cretion. This ad hoc practice is different than in a recent US survey, which reported higher PEP prophylactic use. In that study, 59.7 % of respondents reported rectal nonsteroidal anti-inflammatory drug use in high-risk patients only and 40.1 % reported use for prevention of PEP in average-risk patients [19]. Of the respondents, 72 % also reported pancreatic stent insertion in high-risk patients only, with use specifically for PEP in ≤ 25 % of ERCPs [19].

Overall, no significant differences in cardiorespiratory complications or procedural medication dosages were found between groups. The respiratory complications were minor involving jaw support and higher-flow oxygen for reversal, and only three patients required intubation during the procedure: two in the LL group and one in the PP group. The low rates of respiratory complications and intubation episodes suggest that contrary to clinical concerns, there is no increase in anesthetic or airway risk for patients lying in PP for their ERCP. It is also noted that median propofol doses were similar between groups, which is in keeping with comparable length of procedures.

One of our secondary outcomes included radiation doses and fluoroscopy times. Radiation doses are absorbed through tissue. With greater tissue planes, often a higher setting is required for penetration and sharper images (as would be needed in LL fluoroscopy) [20]. It is, therefore, assumed that PP would result in less radiation than LL. It has also been shown that longer procedure and fluoroscopy times result in greater radiation exposure [20, 21], and those with malignancy obstruction, have greater fluoroscopy times and radiation doses [22]. Angsuwatcharakon et al, when assessing ocular radiation exposure to personnel, showed a one-third lower ocular radiation exposure when ERCP was performed in the PP position as compared to LL [23]. Similarly, our study showed significantly lower radiation doses were required in PP as compared to LL ($P = 0.008$); however, there was no difference in fluoroscopy times ($P = 0.38$). In addition, we factored in the higher rate of malignant strictures in the LL group and on analysis of the non-malignant patients only, the findings are replicated with a significantly lower radiation dose in PP ($P = 0.027$) with no difference in fluoroscopy times ($P = 0.59$). This suggests that perhaps the greater tissue plane present with patients in the LL position results in a greater radiation dose per procedure. This may represent an issue for patients who may be exposed to regular radiation due to underlying comorbidities or those requiring multiple ERCPs and is also relevant for procedural and anesthetic staff to minimize the cumulative radiation exposure over time.

One limitation of this study was its single network nature in which endoscopists are comfortable in performing ERCP in both LL and PP routinely. Although we aimed to perform a non-inferiority study, a multicenter study with more endoscopists and a higher number of cases may potentially show a difference between the two groups and superiority of one position over the other.

Conclusions

Our prospective RCT comparing LL to PP during ERCP shows comparable outcomes, including rates of biliary cannulation, pancreatitis, and cardiorespiratory complications. There was a statistically significantly lower radiation exposure in the PP position, likely due to a smaller area of penetration for radiation.

This study shows that ERCP undertaken in the LL position is not inferior to PP in terms of procedure and technical outcomes and can be considered a valid and safe alternative ERCP position for patients. The higher radiation exposure in this LL position may be significant for patients expected to require multiple ERCPs, particularly pediatric patients, but is also relevant for staff and their long-term exposure to radiation. A long-term follow-up study may be required to show clinical significance to procedure staff.

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Competing interests

The authors declare that they have no conflicts of interest.

Clinical trial

Australian and New Zealand Clinical Trials Registry
ACTRN12615000219583
TRIAL REGISTRATION: Single centre, prospective, randomized controlled trial. Conducted at Monash Health https://monashhealth.org/

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