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PROCEDURAL CHARACTERISTICS AND CANNULATION DIFFICULTY DURING ERCP FOR CHOLEDOCHOLITHIASIS: EXPERIENCE FROM A TERTIARY CARE CENTER

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ABSTRACT

Background: Difficult biliary cannulation is a major determinant of procedural complexity and adverse events during endoscopic retrograde cholangiopancreatography (ERCP); however, Indian tertiary-center data on its frequency and associated features are limited. We describe the procedural characteristics and cannulation difficulty in patients undergoing ERCP for choledocholithiasis.

Methods: We analyzed the ERCP arm of a prospective comparative study at the Department of Surgery, Jawaharlal Nehru Medical College, Aligarh Muslim University (May 2024–May 2026). Cannulation difficulty (endoscopist-recorded), number of attempts, papilla morphology, sphincterotomy, stenting, procedure duration, post-ERCP pancreatitis (PEP), and hospital stay were also recorded. Patients with and without difficult cannulation were compared using exploratory analyses.

Results: Twenty-nine patients (21 women; mean age 41.5 ± 15.8 years) were included. Difficult cannulation occurred in 14 (48.3%) and multiple attempts in 12 (41.4%). The papilla was normal in 22 (75.9%), bulging in five, and flat in two. Sphincterotomy was performed in 24 (82.8%); the mean procedure time was 57.7 ± 11.7 min. PEP occurred in two patients (6.9%), both with difficult cannulation. Multiple stones (71.4% vs 20.0%, p = 0.009) and higher alkaline phosphatase (466 vs 293 IU/L, p = 0.012) were more frequent with difficult cannulation, and the bile duct tended to be narrower (9.8 vs 11.5 mm, p = 0.053). No perforation, bleeding, cholangitis, or death occurred.

Conclusions: Nearly half of the ERCPs for choledocholithiasis involved difficult cannulation, clustering with multiple stones, and a less dilated duct. Standardized definitions, anticipation of difficulty, early rescue techniques, and PEP prophylaxis merit prospective evaluation.

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INTRODUCTION

Choledocholithiasis complicates a substantial minority of symptomatic gallstone diseases and can present with biliary pain, obstructive jaundice, cholangitis, or pancreatitis. Endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and stone extraction remains the first-line therapy in most guidelines [1–3] and, because laparoscopic bile duct exploration expertise is concentrated in a few tertiary centers, is the usual first approach in much of Indian practice. Its therapeutic success depends on a step that is easily taken for granted: selective deep cannulation of the common bile duct (CBD). Cannulation is the point at which most avoidable harm is done. Repeated contact with the papilla, inadvertent pancreatic duct cannulation, and contrast injection into the pancreatic duct contribute to papillary edema and post-ERCP pancreatitis (PEP), the most frequent serious complication of the procedure [4–6]. The European Society of Gastrointestinal Endoscopy (ESGE) defines difficult cannulation as more than five contacts with the papilla, more than five minutes of cannulation effort after the papilla is visualized, or more than one unintended pancreatic duct cannulation or opacification, and recommends early recourse to rescue techniques such as double-guidewire cannulation or precut sphincterotomy rather than persistent attempts [4]. Difficult cannulation has repeatedly been identified as an independent risk factor for ERCP-related complications [5,6]. Papillary anatomy, duct calibre, stone burden, and operator experience are

plausible determinants of the difficulty of duct entry; however, the relative importance of each is unclear, and published cohorts differ in how difficulty is defined. Reports from India have concentrated mainly on stone clearance and overall complication rates, often as part of comparisons with surgical bile duct exploration [7,8]. Less attention has been paid to the cannulation step itself, even though ERCP is the default first-line option, and training units must manage difficult papillae as part of routine service.

Therefore, we analyzed the ERCP arm of a prospective comparative study of laparoscopic common bile duct exploration (LCBDE) and ERCP at a tertiary teaching hospital in northern India. Our aims were to describe the procedural characteristics of ERCP for choledocholithiasis in this setting, to estimate how often cannulation was difficult, and to explore which patient, stone, and papillary features were associated with difficulty and with PEP. The comparison with LCBDE is reported separately.

2. MATERIALS AND METHODS

2.1 Study design and setting

This article reports the ERCP arm of a prospective comparative study conducted in the Department of Surgery, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, India, between May 2024 and May 2026. The parent study compared LCBDE with ERCP in patients with choledocholithiasis; the outcomes of the LCBDE arm and between-arm comparison are reported elsewhere. The analysis presented here is a descriptive, single-arm evaluation with an exploratory internal comparison and has not been designed to test a pre-specified hypothesis.

2.2 Participants

Patients older than 14 years with symptomatic primary, secondary, or recurrent choledocholithiasis, diagnosed based on clinical features, liver biochemistry, and imaging, were eligible for the parent study if they provided written informed consent. Patients who did not provide consent and those younger than 14 years were excluded. For this analysis, all patients who underwent ERCP in the parent study were included.

2.3 Data collection

Data were prospectively recorded on a structured proforma. Demographic and clinical variables included age, sex, presenting symptoms, and previous pancreatitis. Laboratory data included serum bilirubin and alkaline phosphatase (ALP) levels. Imaging variables included the maximum stone diameter (mm), number of stones (single or multiple), and CBD diameter (mm). Procedural variables included papilla morphology (normal, bulging, or flat), number of cannulation attempts (single or multiple), endoscopist's assessment of whether cannulation was difficult, use of a guidewire, sphincterotomy, biliary stent placement, procedure duration (duodenoscope insertion to withdrawal), ductal clearance, post-procedure complaints, serum amylase and lipase levels, hospital stay, and outcome. Difficult cannulation was recorded by the operating endoscopist at the end of the procedure; a time- or contact-based definition was not applied prospectively. Multiple attempts denoted more than one cannulation attempt.

2.4 ERCP technique

ERCP was performed in a dedicated endoscopy suite with digital fluoroscopy using an Olympus TJF-Q150 side-viewing duodenoscope. Patients received conscious sedation (intravenous midazolam and fentanyl) or propofol-based monitored anesthesia care at the discretion of the anesthesiologist and were positioned prone or in the left lateral position. Selective biliary cannulation was attempted with a pull-type sphincterotome preloaded with a 0.035-inch hydrophilic guidewire directed towards the 11 o'clock position of the papillary orifice. Cannulation was confirmed by bile aspiration and fluoroscopic demonstration of the wire passing towards the hilum. When standard cannulation failed after three attempts, precut access sphincterotomy or a double-guidewire technique could be used at the endoscopist's discretion.

After cholangiography, sphincterotomy was performed using a blended current. Stones were removed using a Dormia basket or extraction balloon, and mechanical lithotripsy was available for large or impacted stones. A 7–10 Fr plastic biliary stent was placed when clearance was incomplete. Ductal clearance was assessed on a completion cholangiogram. Patients were observed in the recovery area for at least two hours, and serum amylase was measured two to four hours after the procedure.

2.5 Outcomes

The primary outcome was the proportion of procedures with difficult cannulation. Secondary outcomes were the proportion requiring multiple attempts, papilla morphology, sphincterotomy and stenting rates, procedure duration, ductal clearance, PEP, other complications, post-procedure pain, and length of hospital stay. PEP was defined according to the Cotton consensus criteria [9]. Patients were followed up at 2 weeks, 4 weeks, and 3 months with clinical review, liver biochemistry, abdominal ultrasonography, and magnetic resonance cholangiopancreatography when residual stones were suspected.

2.6 Statistical analysis

Data were analyzed with IBM SPSS Statistics version 26.0. Continuous variables are presented as mean ± standard deviation (SD) and, where useful, median; categorical variables as counts and percentages, with exact (Clopper–Pearson) 95% confidence intervals for key proportions. Patients with and without difficult cannulation were compared using the Mann–Whitney U test for continuous variables and Fisher's exact test for categorical variables. Because of the small sample, no multivariable modelling was attempted. All tests were two-sided with $p < 0.05$ considered statistically significant; no correction for multiple comparisons was applied, and all between-group comparisons are exploratory.

2.7 Ethics

The study was approved by the Institutional Ethics Committee of Jawaharlal Nehru Medical College, Aligarh Muslim University, and written informed consent was obtained from all the participants.

3. RESULTS

3.1 Patient and disease characteristics

Twenty-nine patients underwent ERCP. The mean age was 41.5 ± 15.8 years (range, 18–78), and 21 (72.4%) were women. All patients presented with abdominal pain, and 11 (37.9%) had jaundice. One patient (3.4%) had a history of pancreatitis. The mean total bilirubin was 1.70 ± 1.15 mg/dL and the mean ALP was 376.4 ± 224.4 IU/L. The mean maximum stone diameter was 7.3 ± 3.3 mm (range, 3–18

mm); only three patients (10.3%) had a stone of ≥ 10 mm. Thirteen patients (44.8%) had multiple stones, and the mean CBD diameter was 10.7 ± 2.1 mm (range, 8–14 mm) (Table 1).

3.2 Procedural characteristics

A guidewire was used in all 29 procedures. The papilla was normal in 22 patients (75.9%), bulging in five (17.2%), and flat in two (6.9%). Difficult cannulation was recorded in 14 patients (48.3%; 95% CI 29.4–67.5%), and 12 patients (41.4%; 95% CI 23.5–61.1%) needed multiple attempts. Ten of the 14 difficult procedures involved multiple attempts, compared with two of 15 procedures not classified as difficult (p = 0.003), indicating good but imperfect agreement between the two measures. Biliary access was achieved in allpatients. Sphincterotomy was performed in 24 patients (82.8%), and a biliary stent was placed in 23 (79.3%). The mean procedure time was 57.7 ± 11.7 min (range 38–78; recorded in 27 patients). Ductal clearance was recorded at the index procedure in all patients, and residual stones were detected on follow-up imaging in two patients (6.9%).

3.3 Cannulation difficulty

Compared with patients who did not experience difficulty during cannulation, those with difficult cannulation had more stones (10/14, 71.4% vs 3/15, 20.0%; p = 0.009) and higher ALP (466.1 ± 186.2 vs 292.7 ± 230.0 IU/L; p = 0.012) (Table 2). The CBD was narrower in the difficult group (9.8 ± 1.7 vs 11.5 ± 2.1 mm; p = 0.053), and a CBD diameter of ≥ 12 mm was present in 2/14 (14.3%) versus 8/15 (53.3%) patients (p = 0.050). Abnormal papilla morphology (bulging or flat) was recorded in 5/14 (35.7%) of the difficult group and 2/15 (13.3%) of the others (p = 0.215); both patients with a flat papilla had difficult cannulation. Men accounted for 6/14 (42.9%) of difficult and 2/15 (13.3%) of non-difficult procedures (p = 0.109). Age, maximum stone diameter, total bilirubin, and the presence of jaundice did not differ materially between the groups. Sphincterotomy (92.9% vs 73.3%) and stenting (85.7% vs 73.3%) were numerically more frequent after difficult cannulation without reaching significance.

Procedure time was longer when more than one attempt was required (64.7 ± 11.1 vs 53.6 ± 10.3 min; p = 0.022). The difference in procedure time based on cannulation difficulty was in the same direction (62.4 ± 11.4 vs 53.9 ± 10.8 min; p = 0.091), but procedure time was missing for two patients, both in the difficult group.

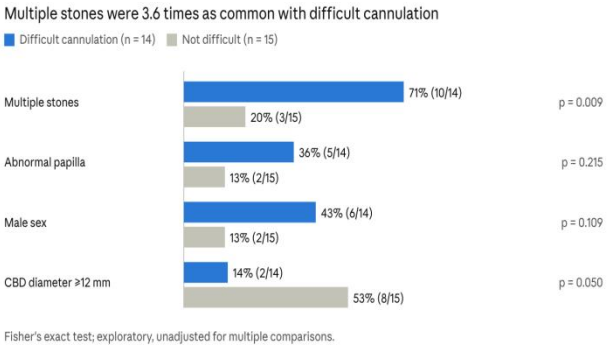

Figure 01: Patient and stone features based on cannulation difficulty.

ERCP master chart, n = 29 (14 difficult, 15 not difficult)

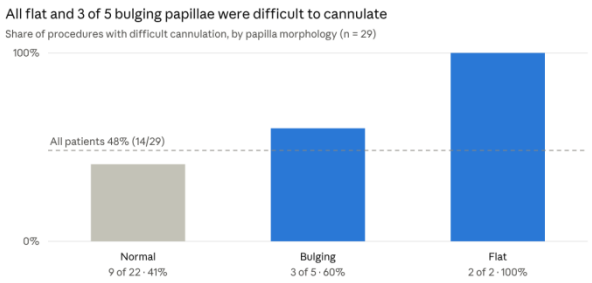

Figure 02: Proportion of difficult cannulations by papilla morphology

ERCP master chart, n = 29

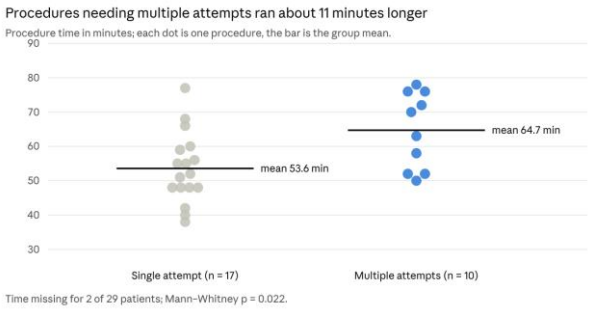

Figure 03: Procedure time by number of cannulation attempts

ERCP master chart, 27 of 29 procedures with recorded time

3.4 Complications and hospital stay

PEP developed in two patients (6.9%; 95% CI 0.8–22.8%). Both were women (aged 21 and 50 years), both had difficult cannulation with multiple attempts, and both underwent sphincterotomy and stenting; one had a flat papilla and a 14-mm stone in a 14-mm duct. Post-procedure serum amylase values were 1078 and 514 U/L, and serum lipase values were 13,780 and 17,856 U/L. Median serum amylase and lipase in the cohort were 56 and 90 U/L, respectively. Both patients recovered and were discharged after four and three days, respectively. The association between PEP and difficult cannulation (2/14 vs. 0/15; p = 0.224) or multiple attempts (2/12 vs 0/17; p = 0.163) was not statistically significant, reflecting the small number of events. Seven patients (24.1%) reported post-procedure pain. There was no perforation, hemorrhage, or cholangitis, and no patient died. The mean hospital stay was 1.62 ± 0.73 days, and was 3.5 days in patients with PEP compared with 1.5 days in the remainder. All patients were discharged.

Table 01: Clinical and procedural characteristics of patients undergoing ERCP (n = 29)

Characteristic	Value
Age, years, mean ± SD (range)	41.5 ± 15.8 (18–78)
Female sex, n (%)	21 (72.4)
Jaundice, n (%)	11 (37.9)
Total bilirubin, mg/dL, mean ± SD	1.70 ± 1.15
Alkaline phosphatase, IU/L, mean ± SD	376.4 ± 224.4
Maximum stone diameter, mm, mean ± SD (range)	7.3 ± 3.3 (3–18)
Multiple stones, n (%)	13 (44.8)
CBD diameter, mm, mean ± SD (range)	10.7 ± 2.1 (8–14)
Papilla: normal / bulging / flat, n (%)	22 (75.9) / 5 (17.2) / 2 (6.9)

Characteristic	Value
Guidewire-assisted cannulation, n (%)	29 (100)
Difficult cannulation, n (%)	14 (48.3)
Multiple cannulation attempts, n (%)	12 (41.4)
Sphincterotomy, n (%)	24 (82.8)
Biliary stent placement, n (%)	23 (79.3)
Procedure time, min, mean ± SD (n = 27)	57.7 ± 11.7
Post-ERCP pancreatitis, n (%)	2 (6.9)
Residual stones on follow-up, n (%)	2 (6.9)
Hospital stay, days, mean ± SD	1.62 ± 0.73

Table 02: Comparison of patients with and without difficult cannulation

Variable	Difficult (n = 14)	Not difficult (n = 15)	p value
Age, years	44.3 ± 17.3	38.8 ± 14.2	0.471
Male sex, n (%)	6 (42.9)	2 (13.3)	0.109
Jaundice, n (%)	4 (28.6)	7 (46.7)	0.450
Total bilirubin, mg/dL	1.41 ± 1.03	1.98 ± 1.21	0.174
Alkaline phosphatase, IU/L	466.1 ± 186.2	292.7 ± 230.0	0.012
Stone diameter, mm	7.4 ± 4.1	7.2 ± 2.4	0.480
Multiple stones, n (%)	10 (71.4)	3 (20.0)	0.009
CBD diameter, mm	9.8 ± 1.7	11.5 ± 2.1	0.053
Abnormal papilla (bulging or flat), n (%)	5 (35.7)	2 (13.3)	0.215
Multiple attempts, n (%)	10 (71.4)	2 (13.3)	0.003
Sphincterotomy, n (%)	13 (92.9)	11 (73.3)	0.330
Biliary stent, n (%)	12 (85.7)	11 (73.3)	0.651
Procedure time, min*	62.4 ± 11.4	53.9 ± 10.8	0.091
Post-ERCP pancreatitis, n (%)	2 (14.3)	0 (0)	0.224
Hospital stay, days	1.7 ± 0.9	1.5 ± 0.5	0.845

Values are expressed as the mean ± standard deviation (SD), unless otherwise stated. p values: Mann–Whitney U test (continuous) or Fisher's exact test (categorical).

4. DISCUSSION

In this prospective cohort of 29 patients undergoing ERCP for choledocholithiasis at a tertiary teaching hospital, cannulation was judged difficult in nearly half of the procedures and required more than one attempt in approximately two-fifths. Difficult cannulation clustered with multiple stones, tended to occur in narrower ducts, and was accompanied by episodes of post-ERCP pancreatitis. Nevertheless, biliary access was obtained in every patient, with no perforation, bleeding, cholangitis, or death, which is consistent with the low mortality reported for ERCP in experienced centers. The proportion of difficult cannulation we report should be read against how difficulty was defined. The ESGE definition is explicit and time- and contact-based [4]; ours was the endoscopist's overall impression at the end of the procedure, which is likely to be more inclusive and may conflate difficulty entering the duct with difficulty clearing it. This may partly explain why multiple stones, rather than papillary features, emerged as the strongest correlate. Even so, the fact that 10 of 14 difficult procedures involved multiple attempts, and that procedure time was approximately 11 minutes longer when more than one attempt was needed, suggests that the label captured real additional effort. Practical definitions that can be recorded in routine reports, such as the number of papillary contacts and minutes to cannulation, would make the results from different centers comparable and should be built into endoscopy documentation in training units.

Papillary morphology was normal in three of the four patients. Although the association was not statistically significant, five of the seven patients with bulging or flat papillae had difficult cannulation, and both flat papillae did, which fits the clinical impression that atypical papillary anatomy makes axis alignment harder. The study was too small to quantify this, and we did not record periampullary diverticula or papilla size, both of which have been associated with difficult access.

A less dilated duct was more frequent among difficult cannulations, although the difference did not reach conventional significance. This finding is plausible, since a smaller duct leaves less room for the wire and catheter to find the axis, and it is relevant because difficult cannulation is itself a recognized risk factor for PEP [5,6]. We caution against over-reading it: the p value was borderline, the comparison was one of many, and mean duct diameter in both groups lay within a range that most endoscopists would not regard as small. In our view, the higher ALP in the difficult group is more likely to be a chance finding or a marker of stone burden than a cause of difficulty, particularly as bilirubin and the frequency of jaundice were not higher.

The association with multiple stones has more than one possible explanation:multiple stones may be accompanied by distal impaction and papillary edema, which make selective cannulation more difficult, or they may simply prolong the procedure and thereby affect the endoscopist's overall judgement of difficulty. Predictors of failure to clear the duct at index ERCP have been examined prospectively [10], and a recent North Indian series focused on the management of difficult stones [8]. A comparative study from Northeast India reported an index procedure clearance rate of 72.2% for ERCP [7]. In our cohort, ductal clearance was recorded at the index procedure in all patients, although residual stones were identified on follow-up in two patients, a pattern that argues for routine completion cholangiography and a low threshold for interval imaging.

Post-ERCP pancreatitis occurred in 6.9% of patients, a proportion with a wide confidence interval (0.8–22.8%) because of the small sample size, but similar in magnitude to the 7.2% reported in a recent Turkish study that also identified sphincterotomy, basket use, and repeated cannulation attempts as predictors of complications [11]. Both of our cases had allrecognized procedural risk markers: difficult cannulation, multiple attempts, and sphincterotomy. Both were women, one only 21 years old, and female sex and younger age are recognized patient-related risk factors for PEP [5]. The clinical consequence was a stay that was approximately two days longer than average. In the multivariate analysis of Cotton et al., difficult

cannulation was an independent predictor of complications [6], and the present data are consistent with this conclusion, although with two events we cannot make any claim about the strength of the association.

Several implications follow. First, an endoscopist who anticipates difficulty from multiple stones, an atypical papilla, or a non-dilated duct should plan the strategy before the first pass, limit the number of attempts, and move early to a rescue technique, using double-guidewire cannulation or precut sphincterotomy in line with ESGE guidance [4]. Second, PEP prophylaxis should not be left to chance when cannulation is difficult: ESGE guidance recommends routine rectal non-steroidal anti-inflammatory drugs and peri-procedural hydration in the absence of contraindications, and pancreatic stenting in selected high-risk cases [4,5]. We did not systematically capture these measures in the dataset analyzed here, which we regard as a gap to be closed in a prospective audit rather than as evidence of how they were applied. Third, patients with large, impacted, or multiple stones, particularly where cannulation has failed or stone clearance remains incomplete, may be better served by mechanical lithotripsy [12] or by a surgical route, and our parent study found that LCBDE achieved clearance in patients with larger stones and more obstruction than those in the ERCP arm.

In the parent study, ERCP was associated with a shorter hospital stay than LCBDE (1.6 vs 4.3 days) and no bile leak or wound infection, whereas pancreatitis occurred only after ERCP. The present analysis adds that the price of this efficiency is paid largely at the papilla: when cannulation was easy, no patient developed pancreatitis, and when it was difficult, the stay and the risk of an adverse event rose. For units that offer both modalities, anticipated difficulty at the papilla may therefore be a legitimate factor in choosing the route, alongside stone burden, patient fitness, and local expertise.

The high stenting rate deserves further comment. A biliary stent was placed in just under four-fifths of the patients, a proportion higher than expected if stones were cleared at the index procedure in every patient. The dataset does not record the indication for each stent, and we cannot say how many stents were placed because clearance was incomplete, how many were placed as drainage after difficult extraction, and how many were placed as routine practice. This is a practical question for audit in our unit, since stents carry the cost of a second procedure and their own complications.

4.1 Strengths and limitations

The strengths of the present study are prospective data collection, systematic recording of papilla morphology and cannulation attempts, and a clearly described technique. The limitations are substantial. The sample is small and from a single centre, so confidence intervals are wide and the analysis could not adjust for confounding; a multivariable model would be unstable with 14 events. Difficult cannulation was not defined by objective criteria, so misclassification is likely, and our estimate is not directly comparable to studies using the ESGE criteria. We did not record operator experience, trainee involvement, time to cannulation, unintended pancreatic duct cannulation, precut or double-guidewire use, periampullary diverticula, or the indication for stenting, and the measures used for PEP prophylaxis were not captured. Fifteen comparisons were made without correction; therefore, one or two nominally significant results, in particular the ALP difference, may be due to chance, and the two missing procedure times fell in the difficult group. The ERCP arm of the parent study had smaller stones (mean 7.3 mm) and lower bilirubin than the LCBDE arm; therefore, these findings probably underestimate the difficulty of ERCP in complex stone disease. Follow-up was limited to three months. These results should therefore be regarded as hypothesis-generating.

5. CONCLUSION

In this single-center cohort, ERCP for choledocholithiasis was technically successful and safe; however, cannulation was difficult in nearly half of the procedures, more often with multiple stones and possibly in less dilated ducts, and both cases of post-ERCP pancreatitis occurred after difficult cannulation. Standardized, objective recording of cannulation difficulty, early use of rescue techniques, and routine PEP prophylaxis should be adopted and audited, and larger multicenter prospective studies are needed to identify predictors of difficult cannulation in Indian practice.

6. Ethics approval and consent:

The study was approved by the Institutional Ethics Committee of Jawaharlal Nehru Medical College, Aligarh Muslim University [approval reference number and date to be inserted]. Written informed consent was obtained from all the participants.

7. FUNDING

None.

8. CONFLICTS OF INTEREST

None declared.

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