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ORIGINAL ARTICLE

Evaluation of 30-day morbidity and mortality of laparoscopic cholecystectomy: a multicenter prospective observational Indian Association of Gastrointestinal Endoscopic Surgeons (IAGES) Study

Vinaykumar B. Thapar[1] · Pinky M. Thapar[2] · Ramen Goel[3] · Ramesh Agarwalla[4] · Prashant H. Salvi[2] · Amrit M. Nasta[3] · Kamal Mahawar[5] on behalf of IAGES Research Collaborative Group

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Abstract

Background Laparoscopic cholecystectomy (LC) is the standard of care for benign gallstone disease. There are no robust Indian data on the 30-day morbidity and mortality of this procedure. A prospective multicentre observational study was conducted by the Indian Association of Gastro-Intestinal Endo Surgeons (IAGES) to assess the 30-day morbidity and mortality of LC in India.

Materials and methods Participating surgeons were invited to submit data on all consecutive LCs for benign diseases performed between 09/12/2020 and 08/03/2021 in adults. Primary outcome measures were 30-day morbidity and mortality. Univariate and multivariate analyses were performed to identify variables significantly associated with primary outcomes.

Results A total of 293 surgeons from 125 centres submitted data on 6666 patients. Of these, 71.7% ($n=4780$) were elective. A total LC was carried out in 95% ($n=6331$). Laparoscopic subtotal cholecystectomy was performed in 1.9% ($n=126$) and the procedure were converted to open in 1.4% of patients. Bile duct injury was seen in 0.3% ($n=20$). Overall, 30-day morbidity and mortality were 11.1% ($n=743$) and 0.2% ($n=14$), respectively. Nature of practice, ischemic heart disease, emergency surgery, postoperative intensive care, and postoperative hospital stay were independently associated with 30-day mortality. Age, weight, body mass index, duration of symptoms, nature of the practice, history of Coronavirus Disease-2019, previous major abdominal surgery, acute cholecystitis, use of electrosurgical or ultrasonic or bipolar energy for cystic artery control; use of polymer clips for cystic duct control; conversion to open surgery, subtotal cholecystectomy, simultaneous common bile duct exploration, mucocele, gangrenous gall bladder, dense adhesions, intraoperative cholangiogram, and use of drain were independently associated with 30-day morbidity.

Conclusion LC has 30-day morbidity of 11.1%, 30-day mortality of 0.2%, conversion to open rate of 1.4%, and bile duct injury rate of 0.3% in India.

Keywords Laparoscopic cholecystectomy · Morbidity · Mortality · Bile duct injury · Clavien–Dindo score

Gallstone disease is a common clinical condition with rising prevalence [1]. Laparoscopic cholecystectomy (LC), the standard of care for gallstone disease and other benign gallbladder pathologies, is one of the most commonly performed surgical procedures worldwide [2]. A systematic review and meta-analysis [3] published in 2018 reported morbidity, bile duct injury, and mortality rates of this procedure at around 1.6–5.3%, 0.32–0.52%, and 0.08–0.15% respectively. This analysis, however, included data published over several decades and cannot be used to indicate the current safety profile of this procedure.

Although there are some single-centre retrospective studies from India reporting on the 30-day safety of LC [4], there is no large, prospective, multicentre study. Such data

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✉ Pinky M. Thapar
pinkythapar71@gmail.com

1 Dr L. H. Hiranandani Hospital, Mumbai, India

2 Jupiter Hospital, Eastern Express Highway, Thane 400601, India

3 Wockhardt Hospital, Mumbai, India

4 Fortis Hospital, Kolkata, India

5 South Tyneside and Sunderland NHS Foundation Trust, Sunderland, UK

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are needed for benchmarking, quality improvement, and informed patient consent. Even globally, there are very few large, prospective studies on 30-day morbidity and mortality of LC that use a validated method of capturing complications such as Clavien–Dindo grade [5]. Most studies on this topic are either retrospective (based on national registry data) or do not use a robust method of capturing complications [6–8].

This means there is globally an acute need for contemporary, prospective, multicentre, robust data on 30-day morbidity and mortality of LC. Because of these reasons, the Indian Association of Gastro-Intestinal Endo Surgeons (IAGES) decided to perform a prospective multicentre observational cohort study to evaluate the 30-day morbidity and mortality of LC in India.

Material and methods

Design

This was a multicentre, prospective, observational, cohort study. Google forms soliciting surgeons' participation were circulated via social media and IAGES membership communication channels.

Patient eligibility

Participating surgeons submitted data on all consecutive LC performed by them between 09/12/2020 and 08/03/2021 in adult patients for benign gallbladder pathologies. 30-day follow-up data were collected for each patient.

Regulatory approval and data collection

Ethics committee permission was obtained at the leading primary Institute: (IRB: JLHL/IEC/2020), and the study was registered with the Clinical trial of Research of India (Registration number CTRI/2020/11/029448). Contributing Surgeons took part in a Zoom® meeting held to describe the study design and data capturing required for the study. Individual centres were recommended to follow local regulations and obtain additional permissions as needed. Anonymised patient data were collected using a Microsoft Excel® database as approved by the core team. Individual datasheets were carefully examined for errors, and any doubts were clarified with collaborators. Data were then pooled and analysed.

Inclusion and exclusion criteria

Inclusion criteria:

1. Age ≥ 18 years
2. LC as a primary procedure for benign symptomatic gallbladder disease
3. LC for benign gallbladder disease performed with other procedures like hernia surgery, appendectomy, and hysterectomy was included in the study (but not the removal of a normal gallbladder as part of other surgery like Whipple's).
4. Procedure performed in a centre in India

Exclusion criteria

1. Patients undergoing cholecystectomy for malignancy
2. Operations performed outside the study period
3. Planned open cholecystectomy

Primary outcome

30-day morbidity and mortality of patients undergoing LC in India.

Secondary outcome

1. To assess procedure-specific complication rates such as bleeding, bile leak, bowel injury, bile duct injury, and conversion to open surgery.
2. To study the effect of a range of patient-specific, surgeon-specific, and facility-specific variables on 30-day morbidity and mortality.

Statistical analysis

Data were analysed using IBM SPSS version 26 and Jamovi version 1.8.4. Normality was tested using Kolmogorov Smirnoff test. A value of < 0.05 was considered statistically significant. Descriptive statistics were applied to numerical variables. Data were represented as mean ± SD (standard deviation) or median and IQR (interquartile range) as appropriate. Frequencies were compared using the Chi-Square test or Fisher's exact test as appropriate and means were compared using the t test. Binomial logistic regressions were carried out with 30-day morbidity (all Clavien-Dindo grades) or 30-day mortality as dependent variables to test if variables were independently associated with dependent outcomes. No attempt was made to develop a predictive model.

Results

Basic demographics

A total of 293 surgeons from 125 institutes contributed data on 6666 patients. Of these, 68.4% ($n = 4544$) were females with a mean age of 45.5 ± 14.8 years. The mean body mass

index (BMI) was 26.08 ± 4.76 kg/m^2. Approximately 43.1% of patients suffered from at least one other co-morbidity. Nearly 3.8% (n = 255) patients had a history of Coronavirus Disease-2019 (COVID-19) infection and 17.6% (n = 1174) of patients had undergone a previous open or laparoscopic major intraabdominal surgery. Most (78.3%) surgeons had > 10 years' experience in laparoscopy; 12.3% had 6 to 10 years experience; 7.4% had 1–5 years experience; and 2.0% had < 1 year experience in laparoscopy. Data on 30-day morbidity and mortality were available for all the patients giving us a 100% follow-up in this study.

Indications, investigations, and prior ERCP/cholecystostomy

Majority (71.7%; n = 4780) of the procedures were elective. The indication for surgery was biliary colic in 65.4% and acute cholecystitis in 17.3%. A preoperative Ultrasound scan was performed on all the patients in this study. Ultrasound findings of increased wall thickness; impacted stone at neck; and pericholecystic fluid were seen in 30.9% (n = 2061), 11.3% (n = 756), and 16% (n = 1066), respectively. Magnetic resonance cholangiopancreatography (MRCP) was performed in 14% (n = 932) while a Computerised Tomography (CT) abdomen was carried out in 6.3% (n = 419). Approximately 7% (n = 463) patients had undergone a preoperative Endoscopic Retrograde Cholangio-Pancreatogram (ERCP) and 0.7% (n = 46) patients had a prior percutaneous cholecystostomy.

Surgical approach, important findings, and operating time

A total laparoscopic cholecystectomy was performed in 95% (n = 6331) of the patients while laparoscopic subtotal cholecystectomy was performed in 1.9% (n = 126). Conversion to open cholecystectomy was needed in 1.4% of patients (n = 96). A simultaneous laparoscopic common bile duct exploration was performed in 1.2% (n = 79) of patients. An additional procedure like appendectomy, hysterectomy, ureteric stone removal, or hernia repair was carried out in 0.5% (n = 34) patients. An intraoperative cholangiogram was performed in 1.4% (n = 95) patients. Cystic artery was controlled using titanium clips in 83.1% (n = 5537), polymer clips in 5.4% (n = 360), electrosurgical energy in 5.4% (n = 360), ultrasonic /bipolar energy in 3.7% (n = 252), and by ligation in 2.2% (n = 151). Cystic duct was controlled by titanium clips in 81.3% (n = 5412), polymer clips in 10.8% (n = 721), ligation in 4.3% (n = 292), and transfixation in 3.3% (n = 225). Mucocele, empyema, gangrene, and perforation were noted in 8.1% (n = 540), 8.7% (n = 581), 3.3% (n = 222) and 3.4% (n = 228), respectively. A "frozen" Calot's triangle was encountered in 11.2% (n = 745). An intraabdominal drain was used in 29.3% (n = 1955). The mean duration of surgery was 53 ± 36 min, and the mean duration of postoperative stay was 1.85 ± 1.41 days.

Histopathology

Histopathology revealed chronic cholecystitis in 70.7% (n = 4177), acute cholecystitis in 20.1% (n = 1338), and xanthogranulomatous cholecystitis in 1.4% (n = 101). In approximately 0.5% (n = 30) patients, histology revealed an incidental malignancy.

Readmission/reintervention

Approximately 0.9% (n = 58) patients needed to be readmitted during the study period. Additional endoscopic, radiological, and surgical procedure were needed in 0.4% (n = 27), 0.5% (n = 35), and 0.3% (n = 19), respectively.

30-day morbidity and mortality

A 30-day Morbidity was reported in 11.1% (n = 743) and 14 (0.2%) patients died during the 30 days. Most of the complications were Clavien–Dindo grade I (2.8%) or grade II (7.2%). Grade III (0.9%), grade IV (0.2%), and grade V (0.2%) complications were less common (Table 1). Bleeding was encountered in 1.5% (n = 103), and it needed blood transfusion in 0.7% (n = 44). A bowel injury occurred in 0.1% (n = 4), and bile duct injury was seen in 0.3% (n = 20). Bile leak and intraabdominal collections were reported in 0.9% (n = 58) and 0.8% (n = 56), respectively. Wound and chest infections were noticed in 1.5% (n = 98) and 0.4% (n = 27), respectively. One patient each developed deep venous thrombosis and pulmonary embolism. Five patients (0.1%) had a myocardial infarction and 15 patients (0.2%) had a stroke. Approximately 8.5% (n = 568) needed intensive care postoperatively (Table 1).

Several variables were significantly associated with 30-day morbidity on univariate analysis (Tables 2 and 3). On binomial, logistic regression, only age, weight, BMI, duration of symptoms, nature of surgeon practice, history of COVID-19, previous major abdominal surgery, acute cholecystitis (vs biliary colic), use of unipolar electrosurgical energy or ultrasonic/bipolar energy for cystic artery control (vs titanium clips); use of polymer clips for cystic duct control (vs titanium clips); conversion to open surgery, subtotal cholecystectomy, simultaneous common bile duct exploration (vs laparoscopic cholecystectomy), mucocele, gangrenous gallbladder, dense adhesions, intraoperative cholangiogram, and use of abdominal drain were independently associated with 30-day morbidity (Table 4).

Similarly, many variables were associated with 30-day mortality on univariate analysis (Tables 5 and 6). But on

Table 1 Details of complications (a) and Clavien–Dindo Score (b)

(a) Complications	Number (6666)	Percentage of total cases
Bleeding	103	1.5
Blood transfusion required	44	0.7
Bowel injury	4	0.1
Bile duct injury	20	0.30
Bile leak	58	0.9
Intra-abdominal collection	56	0.8
Wound infection	98	1.5
Chest infection	27	0.4
DVT	1	0.01
Pulmonary embolism	1	0.01
Myocardial Infarct	5	0.1
Stroke	15	0.2
(b) Clavien–Dindo grade of Complications	Number	Percentage of total cases
No complication	5910	88.7
Grade I	195	2.8
Grade II	480	7.2
Grade III	58	0.9
Grade IV	10	0.2
Grade V	13	0.2

Table 2 Univariate analysis continuous variables: 30-day morbidity

	Mean ± SD in those with 30-day morbidity	Mean ± SD in those without 30-day morbidity	*p* value	95% Confidence Intervals	
				Lower	Upper
Age (years)	49.93 ± 15.34	44.97 ± 14.59	< .001	3.850	6.07
Weight (kg)	69.65 ± 14.37	65.59 ± 12.44	< .001	3.098	5.02
BMI	26.88 ± 5.60	25.96 ± 4.63	< .001	0.564	1.28
Duration of symptoms	77.91 ± 184.10	130.47 ± 255.15	< .001	− 71.327	− 33.80
Duration of surgery	65.36 ± 45.33	52.23 ± 35.26	< .001	10.369	15.89
Postoperative duration of stay	2.68 ± 3.56	1.80 ± 1.09	< .001	0.764	1.00

binomial, logistic regression only nature of surgeon practice, ischemic heart disease, emergency surgery, postoperative ICU stay, and postoperative duration of stay were independently associated with 30-day mortality (Table 7).

Discussion

This large prospective, multicentre study of 30-day morbidity and mortality of LC in India conducted under the auspices of the Indian Association of Gastrointestinal Endoscopic Surgeons revealed 30-day morbidity of 11.1%, 30-day mortality of 0.2%, conversion to open surgery rate of 1.4%, and bile duct injury rate of 0.3%.

In comparison, Pucher et al. in their meta-analysis of 505,292 patients reported a conversion rate, BDI, morbidity, and mortality rates of 4.2–6.2%, 0.32–0.52%, 1.6–5.3%, and 0.08–0.14%, respectively [3]. But this meta-analysis included data from 150 studies performed over several decades, and authors admitted that data quality and reporting were heterogeneous with significant "reporting bias". In comparison, ours is a prospective study with 100.0% follow-up. Moreover, because this meta-analysis included data from studies over a prolonged period, it cannot represent the contemporary picture. The Chole-S study is probably the only similar study in the literature [8]. It is a national (United Kingdom), prospective study on a similar number of patients. The 30-day morbidity rate in that study of 10.8%

Table 3 Univariate analysis categorical variables: 30-day morbidity

Variable	Category 1	Category 2	Morbidity		OR	95% Confidence Interval		*p* value
			Cat 1/yes %	Cat 2/yes %		Lower	Upper	Pearson Chi-Square
Gender	Male	Female	14.5%	10.0%	1.534	1.313	1.792	< 0.001*
Age	Age > 65 years	Age < 65 years	17.6%	10.5%	1.813	1.486	2.213	< 0.001*
Obesity	Obese	Non Obese	13.9%	10.9%	1.328	1.098	1.605	0.003*
DM	Yes	No	15.3%	10.5%	1.534	1.284	1.832	< 0.001*
HTN	Yes	No	14.7%	10.3%	1.504	1.277	1.771	< 0.001*
IHD	Yes	No	21.8%	10.9%	2.283	1.712	3.046	< 0.001*
CLD	Yes	No	19.3%	11.3%	1.874	0.966	3.633	0.059
CKD	Yes	No	21.7%	11.3%	2.185	1.227	3.892	0.006*
COPD	Yes	No	16.6%	11.3%	1.564	1.020	2.399	0.039*
Past H/o covid-19 infection	Yes	No	20.0%	11.0%	2.014	1.467	2.764	< 0.001*
Previous major abdominal surgery	Yes	No	8.6%	12.0%	0.692	0.555	0.861	< 0.001*
US findings increased wall thickness	Yes	No	16.5%	9.1%	1.986	1.703	2.316	< 0.001*
US findings impacted stone	Yes	No	18.3%	10.1%	1.999	1.673	2.389	< 0.001*
Pre-operative ERCP	Yes	No	18.0%	10.9%	1.795	1.399	2.303	< 0.001*
Prior Percutaneous cholecystostomy	Yes	No	28.3%	11.3%	3.102	1.625	5.920	< 0.001*
Shrunken contracted GB	Yes	No	17.3%	10.8%	1.719	1.364	2.166	< 0.001*
Gangrenous GB	Yes	No	34.2%	10.6%	4.391	3.291	5.858	< 0.001*
Empyema GB	Yes	No	26.5%	9.9%	3.267	2.668	4.000	< 0.001*
Perforated GB	Yes	No	30.3%	10.7%	3.615	2.696	4.848	< 0.001*
Dense adhesions	Yes	No	20.0%	8.5%	2.699	2.310	3.154	< 0.001*
Frozen calots	Yes	No	24.4%	9.7%	2.994	2.481	3.613	< 0.001*
Private hospital/government hospital	Private hospital	Government Hospital	11.4%	12.0%	0.940	0.752	1.177	0.591
Both government and private hospitals/ government hospital	Government and private hospital	Government hospital	9.7%	12.0%	0.786	0.528	1.170	0.234
Operating surgeons Experience in laparoscopy	1–5 years	< 1 year	11.6%	6.0%	2.059	0.957	4.430	0.060
Operating surgeons Experience in laparoscopy	6–10 years	< 1 year	10.9%	6.0%	1.919	0.910	4.049	0.082
Operating surgeons Experience in laparoscopy	> 10 years	< 1 year	11.6%	6.0%	2.066	1.006	4.242	0.044*
Lap to open cholecystectomy/lap cholecystectomy	Lap to open cholecystectomy	Lap cholecystectomy	46.9%	9.9%	8.069	5.359	12.150	< 0.001*
Subtotal cholecystectomy/lap Cholecystectomy	Subtotal cholecystectomy	Lap cholecystecomy	37.3%	9.9%	5.441	3.756	7.880	< 0.001*
Lap cholecystectomy with other procedures/lap cholecystectomy	Lap cholecystectomy with other porcedures	Lap cholecystecomy	28.6%	9.9%	3.658	2.037	6.570	< 0.001*

Table 3 (continued)

Variable	Category 1	Category 2	Morbidity		OR	95% Confidence Interval		*p* value
			Cat 1/yes %	Cat 2/yes %		Lower	Upper	Pearson Chi-Square
Lap cholecystectomy with CBD exploration/lap cholecystectomy	Lap cholecystectomy with CBD exploration	Lap cholecystecomy	37.2%	9.9%	5.412	3.394	8.630	< 0.001*
Urgent surgery/elective surgery	Urgent surgery (within 48 h)	Elective	17.3%	10.3%	1.832	1.375	2.442	< 0.001*
Emergency surgery/elective surgery	Emergency surgery (48 h to 14 days)	Elective surgery	13.5%	10.3%	1.370	1.152	1.631	< 0.001*
Cystic artery control	Titanium clip	Ultrasonic or advanced bipolar	11.4%	6.7%	1.771	1.075	2.918	0.023
Cystic artery control	Titanium clip	Polymer clip	11.4%	7.8%	1.519	1.024	2.254	0.036
Cystic artery control	Titanium clip	Electrosurgical energy	11.4%	10.8%	1.055	0.749	1.486	0.761
Cystic artery control	Titanium clip	Ligation	11.4%	29.1%	0.312	0.217	0.447	< 0.001*
Cystic duct control	Titanium clip	Polymer clip	10.6%	6.9%	1.589	1.177	2.145	0.002*
Cystic duct control	Titanium clip	Ligation	10.6%	18.8%	0.510	0.376	0.693	< 0.001*
Cystic duct control	Titanium clip	Transfixation suture	10.6%	33.3%	0.237	0.177	0.317	< 0.001*

DM diabetes mellitus, *HTN* hypertension, *IHD* ischemic heart disease, *COPD* chronic obstructive pulmonary disease, *CKD* chronic kidney disease, *CLD* chronic liver disease, *US* ultrasonography, *ERCP* endoscopic retrograde cholangiopancreatography, *GB* Gallbladder, *CBD* common Bile Duct, Lap: laparoscopic

*Significant values

seems comparable to our 11.1%. Similarly, the 30-day mortality rate in that study was 0.12% compared to 0.2% in our study. Even that study was published six years ago.

In this study, we focussed on LC and not on the planned open procedure as LC has now become the standard of care for benign gallbladder disease even in developing countries such as India and the authors cannot think of any situation where they would "plan" to do an open cholecystectomy from the outset. Indeed, even though we had mentioned "planned" open cholecystectomy as an exclusion criterion for this study to avoid any confusion, none of our collaborators performed any planned open cholecystectomy during the study period.

Age was independently associated with 30-day morbidity in our study. Similar results have been noticed by other authors [9, 10]. This is probably due to increased frailty, presence of co-morbidities, higher use of antiplatelet and anticoagulants, and difficult local anatomy due to recurrent attacks and previous surgeries in these patients. Similarly, obesity, which was independently associated with 30-day morbidity in our study was associated with a higher risk of conversion to open surgery and bile duct injury in previous studies too [10–12]. This may be due to technical difficulties and obesity-associated co-morbidities. We found ischemic heart disease (IHD) to be independently associated with 30-day mortality. Others have also shown heart disease to be associated with a prolonged hospital stay, increased risk of readmissions, and resource utilisation in patients undergoing LC [13].

History of COVID-19 was noted in 3.8% of the patients and was independently associated with 30-day morbidity in our study. The countrywide lockdown for COVID-19 ended in India on 31st May 2020 and the gradual process of unlocking started on 1st June 2020. In most hospitals, elective surgeries had resumed by the case enrolment period of December 2020 to March 2021. This is further confirmed by the majority (71.7%; $n = 4780$) of the procedures being elective in our study. However, it is possible that the presentation of patients in this study was delayed due to the pandemic and this may have impacted the morbidity and mortality. But given that there is no robust pre-pandemic data on the outcomes of LC from India, one cannot be certain of that. Similarly, we are unable to deduce if patients with higher co-morbidity were excluded during the study period given the lack of pre-pandemic multicentre Indian data on this group of patients.

Acute cholecystitis and intraoperative findings of mucocele, gangrene, and dense adhesions were independently associated with 30-day morbidity in this study. These findings are unsurprising and others have also found acute cholecystitis to be associated with longer operating times, higher conversion rates, morbidity, and mortality [11, 12].

Table 4 Binomial logistic regression—30-day morbidity [AIC 3881, R^2 (McF) 0.190, p value of model < 0.001]

Predictor	Estimate	SE	Z	p	Odds ratio	95% Confidence Interval	
						Lower	Upper
Intercept	− 4.05285	0.48206	− 8.4074	< .001*	0.0174	0.00675	0.0447
Age	0.01144	0.00352	3.2481	0.001*	1.0115	1.00455	1.0185
Weight	0.03002	0.00682	4.3989	< .001*	1.0305	1.01678	1.0443
BMI	− 0.03555	0.01780	− 1.9970	0.046*	0.9651	0.93199	0.9993
Duration of symptoms	− 0.00119	3.04e−4	− 3.9049	< .001*	0.9988	0.99822	0.9994
Surgeon practice							
Private hospital–government hospital	− 0.28601	0.13865	− 2.0629	0.039*	0.7513	0.57249	0.9858
Both govt and private–government hospital	− 0.79743	0.25269	− 3.1558	0.002*	0.4505	0.27453	0.7392
Gender							
Male–female	− 0.16709	0.11460	− 1.4581	0.145	0.8461	0.67590	1.0592
DM							
Yes–no	− 0.07311	0.11841	− 0.6174	0.537	0.9295	0.73698	1.1723
HTN							
Yes–no	− 0.14870	0.11347	− 1.3105	0.190	0.8618	0.68998	1.0765
IHD							
Yes–no	0.35593	0.19030	1.8703	0.061	1.4275	0.98309	2.0728
CLD							
Yes–no	− 0.14326	0.38113	− 0.3759	0.707	0.8665	0.41055	1.8290
CKD							
Yes–no	0.20125	0.35102	0.5733	0.566	1.2229	0.61463	2.4333
COPD							
Yes–no	0.11666	0.25216	0.4626	0.644	1.1237	0.68553	1.8421
Past h/o COVID							
Yes–no	0.62448	0.18636	3.3509	< .001*	1.8673	1.29591	2.6906
Previous major abdominal surgery							
Yes–no	− 0.36689	0.12667	− 2.8963	0.004*	0.6929	0.54055	0.8881
Diagnosis							
Acute cholecystitis–biliary colic	0.67505	0.13527	4.9905	< .001*	1.9641	1.50671	2.5604
Pancreatitis–biliary colic	0.15453	0.26191	0.5900	0.555	1.1671	0.69852	1.9501
Polyp–biliary colic	0.88963	0.39634	2.2446	0.025*	2.4342	1.11942	5.2934
Others–biliary colic	2.04229	0.11271	18.1202	< .001*	7.7083	6.18045	9.6138
Increased wall thickness on US							
Yes–no	0.00611	0.11644	0.0525	0.958	1.0061	0.80083	1.2641
Pericholecystic fluid on US							
Yes–no	0.20057	0.14395	1.3933	0.164	1.2221	0.92167	1.6205
Impacted stone on US							
Yes–no	0.07443	0.12373	0.6016	0.547	1.0773	0.84530	1.3729
Previous ERCP							
Yes–no	0.10832	0.16251	0.6665	0.505	1.1144	0.81042	1.5324
Previous percutaneous cholecystostomy							
Yes–no	0.33744	0.41095	0.8211	0.412	1.4014	0.62625	3.1358
Nature of surgery							
Emergency–elective	0.07091	0.11866	0.5976	0.550	1.0735	0.85073	1.3546
Urgent–elective	− 0.06495	0.19173	− 0.3387	0.735	0.9371	0.64356	1.3646
Surgeon experience of laparoscopy							
1–5 years–	0.52640	0.41707	1.2622	0.207	1.6928	0.74749	3.8337
6 to 10 years–	− 0.01100	0.40744	− 0.0270	0.978	0.9891	0.44505	2.1980

Table 4 (continued)

Predictor	Estimate	SE	*Z*	*p*	Odds ratio	95% Confidence Interval	
						Lower	Upper
> 10 years–	0.02620	0.39310	0.0666	0.947	1.0265	0.47508	2.2181
Cystic artery control							
Ligation–titanium clips	0.05558	0.32568	0.1707	0.864	1.0572	0.55837	2.0015
Cauterisation–titanium clips	− 0.81572	0.22652	− 3.6011	< .001*	0.4423	0.28374	0.6895
Polymer clips–titanium clips	− 0.10719	0.28425	− 0.3771	0.706	0.8984	0.51462	1.5682
Ultrasonic/advanced bipolar–titanium clips	− 1.07139	0.29938	− 3.5787	< .001*	0.3425	0.19049	0.6159
Cystic duct control							
Polymer clips–titanium clips	− 0.82115	0.21222	− 3.8694	< .001*	0.4399	0.29023	0.6668
Ligated–titanium clips	− 0.28965	0.22941	− 1.2626	0.207	0.7485	0.47746	1.1735
Transfixed–titanium clips	0.37282	0.22138	1.6841	0.092	1.4518	0.94075	2.2405
Procedure type							
Lap cholecystectomy with CBD exploration–lap cholecystectomy	1.10305	0.30739	3.5884	< .001*	3.0133	1.64967	5.5043
Lap to open cholecystectomy–lap cholecystectomy	1.65039	0.31264	5.2789	< .001*	5.2090	2.82252	9.6132
Others–lap cholecystectomy	0.98993	0.36980	2.6769	0.007*	2.6910	1.30360	5.5552
Subtotal cholecystectomy–lap cholecystectomy	1.02102	0.26221	3.8939	< .001*	2.7760	1.66047	4.6411
Mucocoele							
Yes–no	− 0.47669	0.17458	− 2.7306	0.006*	0.6208	0.44093	0.8741
Shrunken GallBladder							
Yes–no	− 0.09830	0.15761	− 0.6237	0.533	0.9064	0.66550	1.2344
Gangrenous GallBladder							
Yes–no	0.52741	0.20589	2.5616	0.010*	1.6945	1.13188	2.5369
Empyema GallBladder							
Yes–no	0.17092	0.14841	1.1517	0.249	1.1864	0.88696	1.5869
Perforated GallBladder							
Yes–no	0.07668	0.19711	0.3890	0.697	1.0797	0.73371	1.5888
Dense adhesions							
Yes–no	0.39898	0.11598	3.4402	< .001*	1.4903	1.18729	1.8707
Frozen Calot's triangle							
Yes–no	0.23835	0.14570	1.6359	0.102	1.2692	0.95388	1.6886
Duration of surgery	− 0.00304	0.00131	− 2.3198	0.020*	0.9970	0.99441	0.9995
Intraoperative cholangiogram							
Yes–no	0.96646	0.28769	3.3593	< .001*	2.6286	1.49570	4.6197
Abdominal drain							
Yes–no	0.43712	0.11298	3.8691	< .001*	1.5482	1.24072	1.9320

Estimates represent the log odds of "30-day Morbidity = Morbidity" vs. "30-day Morbidity = No morbidity"

DM diabetes mellitus, *HTN* hypertension, *IHD* ischemic heart disease, *COPD* chronic obstructive pulmonary disease, *CKD* chronic kidney disease, *CLD* chronic liver disease, *US* ultrasonography, *ERCP* endoscopic retrograde cholangiopancreatography, *GB* Gallbladder, *CBD* common Bile Duct, *Lap* laparoscopic

* Significant values

Emergency surgery, postoperative ICU stay, and prolonged hospital stay were also found to be independently associated with 30-day mortality in this study. Similar results have also been seen in other studies [11, 12, 14]. Emergency surgery for acute cholecystitis is associated with longer operating times, higher conversion rates, higher bile leak rates, and longer hospital stay [14]. At the same time, early laparoscopic cholecystectomy has shown to be safer than delayed surgery for acute cholecystitis in a recent Cochrane review [15]. There is no contradiction between the two observations as though at higher risk than patients without acute cholecystitis, early LC is still safer in this population than delayed LC.

Table 5 Univariate analysis continuous variables: 30-day mortality

	Mean ± SD in those with 30-day mortality	Mean ± SD in those without 30-day mortality	*p*	Mean diff	SE diff	95% Confidence Intervals	
						Lower.	Upper
Age	62.43 ± 13.34	45.50 ± 14.74	< .001	− 16.92	3.944	− 24.66	− 9.193
Weight	73.74 ± 13.37	66.03 ± 12.74	0.024	− 7.71	3.408	− 14.39	− 1.030
BMI	28.09 ± 5.05	26.06 ± 4.75	0.112	− 2.02	1.272	− 4.52	0.469
Duration of symptoms	56.86 ± 100.03	124.62 ± 48.84	0.308	67.77	66.520	− 62.63	198.168
Duration of surgery	92.93 ± 51.63	53.64 ± 36.70	< .001	− 39.28	9.829	− 58.55	− 20.018
Postop duration of stay	7.21 ± 7.91	1.89 ± 1.55	< .001	− 5.33	0.425	− 6.16	− 4.494

The method of controlling cystic duct and artery was independently associated with 30-day morbidity in this study. Somewhat counterintuitively, the use of more secure locking polymer clips for cystic duct closure was associated with higher morbidity than the use of titanium clips. Similarly, the use of electrosurgical energy, ultrasonic energy, and advanced bipolar for cystic artery was associated with higher morbidity. These findings are probably due to selection bias as surgeons might have used these methods to control cystic duct and artery in more difficult cases. In a recently published review, the authors did not find any significant difference in outcomes between the different methods used to control the cystic duct [16]. There is probably hence a need for randomised studies to understand this better. Similarly, an Intraoperative cholangiogram was associated with higher 30-day morbidity—once again probably due to its selective use in difficult cases as only 1.5% of patients in this study underwent an intraoperative cholangiogram. This is probably also the explanation for drains being associated with higher morbidity.

Laparoscopy converted to open cholecystectomy, subtotal cholecystectomy, and simultaneous common bile duct explorations were all independently associated with 30-day morbidity in our study. These findings are unsurprising and have been confirmed by previous authors [17, 18].

A total of 34 patients in our study underwent additional surgeries such as hernia repair, appendectomy, ureteric stone removal, or hysterectomy. These combined surgeries offer the benefit of two procedures in single anaesthesia and hospital admission [19]. However, this advantage may come at a cost. We found that combining another procedure with LC was associated with higher 30-day morbidity on univariate analysis. More focussed studies need to examine this issue in more detail in the future.

Somewhat counterintuitively, we observed a lower risk of 30-day morbidity and mortality in the hands of surgeons with < 1 year of experience. This difference was not significant, and there can be several explanations for this observation—such as low numbers ($n = 134$) or that surgery was taken over by more experienced surgeons if found to be difficult intraoperatively as surgeons in this category would typically be trainees.

Limitations and strengths

The biggest weakness of this study is the self-reporting of complications. However, the authors believe anonymised data collection and pooling before analysis would have encouraged collaborators to submit accurate data as there was no personal incentive to underreport complications. And the morbidity and mortality rates in this study seem similar to what authors see in their institutions perhaps suggesting complications were fully reported. Other possible concerns could be regarding the inclusion of all consecutive cases during the study period. Though we repeatedly reminded our collaborators to include all consecutive cases during the study period to get rid of selection bias, we cannot be certain of this.

The study included surgeons practising in different setups (government hospitals as well as small and large private hospitals) with wide variation in health care facilities. The surgeons' expertise and training differed too as did the patient population thus leading to heterogenicity of data. Also, since ours was a multicentre study, the preoperative workup, and postoperative care, and overall quality of care would have varied from one institution to the other. But it was important for obtaining an estimate of the true picture of 30-day morbidity and mortality of LC in India. Although it was not our purpose to publish individual centre outcomes to preserve anonymity, surgeons in these centres should be able to compare their data to the pooled national data reported in this study and drive local quality improvement projects.

Table 6 Univariate analysis categorical variables: 30-day mortality

Variable	Category 1	Category 2	Morbidity		OR	95% Confidence Interval		*p* value
			Cat 1%	Cat 2%		Lower	Upper	Fisher's Exact Test
Gender	Male	Female	0.4%	0.1%	2.898	1.004	8.363	0.047*
Age 65	> 65 years	< 65 years	1.0%	0.1%	9.680	3.350	27.968	< 0.001*
Obesity (obese/non obese)	Obese	Non obese	0.4%	0.2%	2.765	0.925	8.267	0.070
DM	Yes	No	0.6%	0.1%	4.399	1.540	12.565	0.008*
HTN	Yes	No	0.5%	0.1%	4.039	1.399	11.657	0.010*
IHD	Yes	No	2.0%	0.1%	16.633	5.733	48.255	< 0.001*
CLD	Yes	No	1.8%	0.2%	9.060	1.165	70.443	0.113
CKD	Yes	No	2.9%	0.2%	16.381	3.596	74.609	0.009*
COPD	Yes	No	0.6%	0.2%	3.203	0.416	24.638	0.284
Past Ho covid infection	Yes	No	0.4%	0.2%	1.938	0.252	14.869	0.421
Previous major abdominal surgery	Yes	No	0.3%	0.2%	1.277	0.356	4.583	0.724
US findings increased wall thickness	Yes	No	0.5%	0.1%	5.608	1.757	17.902	0.002*
US findings impacted stone	Yes	No	0.6%	0.1%	3.957	1.370	11.426	0.016*
Preop ERCP	Yes	No	0.4%	0.2%	2.218	0.495	9.938	0.257
Prior percutaneous cholecystostomy	Yes	No	4.3%	0.2%	25.030	5.442	115.135	0.004*
Shrunken contracted GB	Yes	No	0.5%	0.2%	2.910	0.810	10.461	0.113
Gangrenous GB	Yes	No	2.7%	0.1%	22.347	7.687	64.965	< 0.001*
Empyema GB	Yes	No	0.7%	0.2%	4.211	1.317	13.470	0.028*
Perforated GB	Yes	No	2.2%	0.1%	16.016	5.324	48.180	< 0.001*
Dense adhesions	Yes	No	0.6%	0.1%	7.542	2.362	24.080	< 0.001*
Frozen calots triangle	Yes	No	1.1%	0.1%	10.701	3.703	30.926	< 0.001*
Private/government	Private	Government	0.2%	0.4%	0.564	0.157	2.026	0.419
Both government and private/government	Both Government and private	Government	0.0%	0.4%	1.004	1.000	1.008	0.556
Operating surgeons Experience in laparoscopy	1–5 years	< 1 year	0.0%	0.0%				1.000
Operating surgeons Experience in laparoscopy	6–10 yeaS	< 1 year	0.4%	0.0%				1.000
Operating surgeons experience in laparoscopy	> 10 years	< 1 year	0.2%	0.0%				1.000
Lap to open cholecystectomy/lap cholecystectomy	Lap to open cholecystectomy	Lap cholecystectomy	2.1%	0.2%	12.18	2.664	55.726	0.016*
Subtotal cholecystectomy/lap cholecystectomy	Subtotal cholecystectomy	Lap cholecystectomy	0.8%	0.2%	4.581	0.587	35.755	0.211
Lap cholecystectomy with other procedures/ lap cholecystectomy	Lap cholecystectomy with other procdures	Lap cholecystecomy	0.0%	0.2%				1.000
Lap cholecystectomy with CBD exploration/ lap Cholecystectomy	Lap cholecystectomy with CBD exploration	Lap cholecystecomy	0.0%	0.2%				1.000
Urgent/elective	Urgent	Elective	0.5%	0.1%	5.276	1.020	27.290	0.083*

Table 6 (continued)

Variable	Category 1	Category 2	Morbidity		OR	95% Confidence Interval		*p* value
			Cat 1%	Cat 2%		Lower	Upper	Fisher's Exact Test
Emergency/elective	Emergency	Elective	0.5%	0.1%	4.413	1.398	13.923	0.012*
Cystic artery control	Titanium clip	Ultrasonic/advanced bipolar	0.1%	0.0%	0.999	0.998	1.000	1.000
Cystic artery control	Titanium clip	Polymer clip	0.1%	0.6%	0.259	0.055	1.226	0.121
Cystic artery control	Titanium clip	Electrosurgical energy	0.1%	0.3%	0.520	0.065	4.171	0.433
Cystic artery control by	Titanium clip	Ligation	0.1%	1.3%	0.108	0.023	0.513	0.027*
Cystic duct control by	Titanium clip	Polymer clip	0.1%	0.4%	0.310	0.080	1.201	0.103
Cystic duct control by	Titanium clip	Ligation	0.1%	0.3%	0.377	0.046	3.073	0.343
Cystic duct control by	Titanium clip	transfixation	0.1%	1.3%	0.096	0.025	0.373	0.006*

DM diabetes mellitus, *HTN* hypertension, *IHD* ischemic heart disease, *COPD* chronic obstructive pulmonary disease, *CKD* chronic kidney disease, *CLD* chronic liver disease, *US* ultrasonography, *ERCP* endoscopic retrograde cholangiopancreatography, *GB*gallbladder, *CBD* common bile duct, *Lap* laparoscopic

*Significant values

The use of Clavien–Dindo scoring has its limitations as it does not tell us anything about the nature of complications. To overcome this, we have also reported individual complications. Another potential weakness of our study is the 30-day follow-up. We would, therefore, not have been able to capture morbidity and mortality occurring after that period. The use of a 90-day follow-up [20] could overcome this weakness. At the same time, 30-day morbidity and mortality are widely used as surrogates for surgical safety in the academic literature.

At the same time, there are few prospective, contemporary, multicentre national studies on LC on such a large number of patients making this study a valuable addition to the surgical literature on this topic. It is also the first large experience from India with patients operated across the entire spectrum of Indian hospitals allowing us to obtain close to a true estimate of the safety of LC in India and also test for independent associations of variables with 30-day morbidity and mortality. Our use of validated CD grade of complications for capturing 30-day morbidity, 100% follow-up rate, and careful, manual checking of data are other factors worth highlighting.

Conclusion

This multicentre, prospective study of 6666 patients undergoing LC in 125 centres found a 30-day morbidity and mortality rate of 11.1% and 0.2%, respectively. Factors independently associated with 30-day mortality were the nature of surgeon practice, ischemic heart disease, emergency surgery, postoperative ICU stay, and postoperative duration of stay. Age, body weight, BMI, duration of symptoms, nature of surgeon practice, history of COVID-19, previous major abdominal surgery, acute cholecystitis (vs biliary colic), use of electrosurgical energy or ultrasonic/ advanced bipolar energy for cystic artery control (vs titanium clips); use of polymer clips for cystic duct control (vs titanium clips); conversion to open surgery, subtotal cholecystectomy, simultaneous common bile duct exploration (vs laparoscopic cholecystectomy), mucocele, gangrenous gallbladder, dense adhesions, intraoperative cholangiogram, and use of abdominal drain were independently associated with 30-day morbidity. Our results show that morbidity and mortality following LC in Indian hospitals are comparable to that in other large series reported from other parts of the world. We also encourage more surgeons from other Indian hospitals to participate in similar collaborative studies.

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Table 7 Binomial logistic regression—30-day mortality [AIC 180, R^2 (McF) 0.605, p value of model < 0.001]

Predictor	Estimate	SE	Z	p	Odds ratio	95% Confidence Interval	
						Lower	Upper
Intercept	− 31.2030	8762.09046	− 0.003	0.997	2.81e−14	0.00000	Inf
Surgeon practice							
Private hospital–government hospital	− 2.56233	1.17080	− 2.188	0.029*	0.0771	0.00777	0.765
Both govt and private–government hospital	− 24.7373	3652.51261	− 0.006	0.995	1.81e−11	0.00000	Inf
Age	0.05225	0.03882	1.3459	0.178	1.0536	0.97645	1.137
Gender							
Male–female	− 0.62868	1.27027	− 0.494	0.621	0.5333	0.04423	6.430
Weight	0.04001	0.06056	0.6606	0.509	1.0408	0.92433	1.172
BMI	0.07594	0.14834	0.5119	0.609	1.0789	0.80670	1.443
DM							
Yes–no	0.34934	1.04012	0.3358	0.737	1.4181	0.18466	10.891
HTN							
Yes–no	− 2.24639	1.27472	− 1.762	0.078	0.1058	0.00870	1.287
IHD							
Yes–no	3.03137	1.26442	2.3974	0.017*	20.7255	1.73871	247.049
CLD							
Yes–no	2.94347	1.66741	1.7653	0.078	18.9817	0.72283	498.463
CKD							
Yes–no	1.86858	1.50162	1.2443	0.213	6.4791	0.34145	122.940
COPD							
Yes–no	− 0.82162	1.81506	− 0.452	0.651	0.4397	0.01254	15.423
Past h/o COVID							
Yes–no	− 1.31443	1.76473	− 0.744	0.456	0.2686	0.00845	8.537
Previous major abdominal surgery							
Yes–no	0.12033	1.05336	0.1142	0.909	1.1279	0.14310	8.889
Duration of symptoms	0.00112	0.00173	0.6488	0.516	1.0011	0.99774	1.005
Diagnosis							
Acute cholecystitis–biliary colic	− 2.29084	1.53087	− 1.496	0.135	0.1012	0.00504	2.033
Pancreatitis–Biliary colic	− 36.2340	4544.55434	− 0.0079	0.994	1.84e−16	0.00000	Inf
Polyp–Biliary colic	− 17.4889	11,771.91414	− 0.001	0.999	2.54e0−8	0.00000	Inf
Others–Biliary colic	1.79435	1.17776	1.5235	0.128	6.0156	0.59809	60.504
Increased wall thickness on US							
Yes–no	− 0.30060	1.14809	− 0.261	0.793	0.7404	0.07802	7.026
Pericholecystic fluid on US							
Yes–no	0.01482	1.39197	0.0106	0.992	1.0149	0.06631	15.534
Impacted stone on US							
Yes–no	1.12385	1.22132	0.9201	0.357	3.0767	0.28086	33.703
Previous ERCP							
Yes–no	− 1.42167	1.43658	− 0.989	0.322	0.2413	0.01445	4.031
Previous percutaneous cholecystostomy							
Yes–no	0.54028	2.14183	0.2522	0.801	1.7165	0.02579	114.226
Nature of surgery							
Emergency–elective	2.58551	1.20623	2.1434	0.032*	13.2700	1.24775	141.129
Urgent–elective	0.56157	1.64754	0.3408	0.733	1.7534	0.06942	44.287
Procedure type							
Lap cholecystectomy with CBD exploration–lap cholecystectomy	− 19.3653	10,645.24608	− 0.001	0.999	3.89e0−9	0.00000	Inf
Lap to open cholecystectomy–lap cholecystectomy	0.77964	2.09117	0.3728	0.709	2.1807	0.03619	131.403

Table 7 (continued)

Predictor	Estimate	SE	*Z*	*p*	Odds ratio	95% Confidence Interval	
						Lower	Upper
Others–lap cholecystectomy	− 18.2073	13,727.94819	− 0.001	0.999	1.24e0−8	0.00000	Inf
Subtotal cholecystectomy–Lap cholecystectomy	1.51952	1.90413	0.798	0.425	4.5700	0.10943	190.862
Surgeon experience of laparoscopy							
1–5 years–	− 3.79909	9430.82053	− 4.0e−4	1.000	0.0224	0.00000	Inf
6 to 10 years–	15.18161	8762.08994	0.0017	0.999	3.92e0 + 6	0.00000	Inf
> 10 years–	15.53521	8762.08988	0.0017	0.999	5.58e0 + 6	0.00000	Inf
Mucocoele							
Yes–no	− 18.9640	3249.91880	− 0.005	0.995	5.81e0−9	0.00000	Inf
Shrunken GallBladder							
Yes–no	0.24080	1.16570	0.2065	0.836	1.2723	0.12952	12.498
Gangrenous GallBladder							
Yes–no	1.44576	1.61118	0.8973	0.370	4.2451	0.18049	99.844
Empyema GallBladder							
Yes–no	− 3.24204	1.78221	− 1.819	0.069	0.0391	0.00119	1.285
Perforated GallBladder							
Yes–no	− 0.17550	1.16795	− 0.150	0.881	0.8390	0.08504	8.278
Dense adhesions							
Yes–no	− 0.54254	1.15088	− 0.471	0.637	0.5813	0.06092	5.546
Frozen Calot's triangle							
Yes–no	1.91558	1.35164	1.4172	0.156	6.7909	0.48018	96.039
Cystic artery control							
Ligation–titanium Clips	0.83385	2.36895	0.3519	0.725	2.3022	0.02217	239.104
Cauterisation–titanium Clips	0.25942	1.58411	0.1637	0.870	1.2962	0.05811	28.911
Polymer clips–titanium clips	− 0.53489	1.80804	− 0.295	0.767	0.5857	0.01693	20.263
Ultrasonic/advanced bipolar–titanium clips	− 20.2786	5659.45980	− 0.003	0.997	1.56e0−9	0.00000	Inf
Cystic duct control							
Polymer clips–titanium clips	1.74338	1.46757	1.1879	0.235	5.7166	0.32206	101.471
Ligated–titanium clips	− 1.05000	2.18243	− 0.481	0.630	0.3499	0.00486	25.216
Transfixed–titanium clips	2.24815	1.65824	1.3557	0.175	9.4702	0.36717	244.260
Duration of surgery	− 0.01803	0.01291	− 1.396	0.163	0.9821	0.95760	1.007
Intraoperative cholangiogram							
Yes–no	− 19.1267	8181.62244	− 0.002	0.998	4.94e0−9	0.00000	Inf
Abdominal drain							
Yes–no	1.53118	1.39567	1.0971	0.273	4.6236	0.29991	71.282
ICU stay							
Yes–no	3.05561	1.11558	2.7390	0.006*	21.2341	2.38478	189.068
Postoperative duration of stay	0.46316	0.13248	3.4959	< .001*	1.5891	1.22568	2.060

Estimates represent the log odds of "30-day Mortality = Yes" vs. "30-day Mortality = No"

DM diabetes mellitus, *HTN* hypertension, *IHD* ischemic heart disease, *COPD* chronic obstructive pulmonary disease, *CKD* chronic kidney disease, *CLD* chronic liver disease, *US* ultrasonography, *ERCP* endoscopic retrograde cholangiopancreatography, *GB*gallbladder, *CBD* common bile duct, *Lap* laparoscopic

* Significant values

Dr. Solanki Rashesh, Dr. Sonar Sanjay, and Dr. Suthar Ketankumar for taking part in the study. **Collaborative Author list:** A Karthik, Agarwal Lakshman, Agarwal Amit, Agarwalla Rishabh, Aggarwal Manas, Ahuja Anmol, AK Varadaraj, Akhtar Murtaza, Alinger Temsula, AnnaReddy Dinakar Reddy, Ayyar Srinivas, Badgoti Rambabu, Bagree Rajendra, Baig Sarfaraz, Baijal Manish, Bains Lovenish, Bairwa Banwari lal, Bali Rajandeep, Ballal Rajesh, Bandlur Sharath, Bansal Somendra, Bahadur Akshay, Bhagwat Sonali , Bhalla Bhavneet, Bhatt Jatin, Bhattacharjee Siddhartha, Bhojwani Rajesh, Bisht S D, Boddipalli Arjun, Bodra Pankaj, Borgaonkar Vijay, Boruah Prashanta, Brahma Rocket Chandra, Champawat Chitra, Chandak Kanhaiyya , Chandrasekar Sakthivel, Chatterjee Bitan, Chatterjee Shamita, Chaudhuri Tamonas, Chauhan Vikram, Chinnathambi Madeswaran, Chopra Shreya, Choudary Aditya, Choudhury Sourav, Choudhury Supriya, Chowbey Pradeep, Chowdhury A H, Dalal Ashwani, Dalal Usha, Dalvi Abhay, Das Chitta, Das Gunabhi Ram, Das Jayanta kumar, Datta Arupabha, Datta Rupjyoti, Deka Kunal, Dey Ashish, Dey Sumanta, Dhawan Monika, Doctor Nilesh, Donepudi B.Poornima, Dubey Sanjay, Easwaramoorthy S, Ekka Nishith, Eppa Vimalakar Reddy, Geyfane Naima, Goel Amitabh, Goel Apoorv, Goel Deep, Gowtham Thakut, Goyal Pankaj, Gupta Achal, Gupta Rajkumar, Gupta Rahul, Gupta Shalu, Gupta Shardool, HM Lokesh, Hamdani Nisar, Haridas Sarath, Hazarika Bhaskar, Heer Vikas, Hiremath Srikantaiah, I Hariharasaran, Ibrarullah Mohammad, Islam Chaidul, Islam Samsul, Ismail Mohammed, Jain Amit, Jain Mohit, Jain Parakash, Jain Sumita, Jathar Advait, Jassi Nikita, Jankar Samrat, Jeese James, Jindal Yashpaul, Joshi Abhijit, Joshi Praveen, Joy Rejana, K Pooja, K Prasad, K Anirudhan, Kalikar Vishakha, Kondeti Adityakalyan, Kamat Manmohan, Kapoor Abhimanyu, Kashmira Mayank, Katta Rohan, Kaur Jaspreet, Khan Hosni, Khanduri Archana, Khanna Ajay, Khandelwal RG, khanna Subhash, Khanna Shashi, Khiangte Elbert, Khullar Rajesh, Khuroo Suhail, kishore Shashank, Konwar Uttam, Kothari Shyam, Kothari Chaitanya Prakash, Kulkarni Jyotsna, Kumar Anil, Kumar Bhartendu, Kumar Durgesh, Kumar Jitendra, Kumar Shashidhar, Kumar Saurabh, Kumar Kshitiz, Kumar Puneet, Kumaran Ranjith, Kynjing Hampher, Lakshman Krishnaswamy, Lakshmi Suchitra, Lakshmi Kona, Lakshmikantha Nishanth, Lal Pawan, Lalhruaizela Samuel, Lepcha Alfred, Litake Manjusha, Lobo Lancelot, Lohiya Sushil, Longkume Temsutoshi, M MuniReddy, M Vijaykumar, Madhu Sivakumar, Mahadik Deepak, Malhotra Manan Singh, Mallipudi BV Prasad, Malviya Nishant Kumar, Mandal Suman, Manek Parth, Manglik Shresth, Mohd Faiz, Mathur Alok, Medappil Noushif, Meher Sadananda, Mehrotra Magan, Mehta Diksha, Meenakshisundaram Senthil, MG Prakash, Mishra Lalan, Mishra Subhash, Mithi Taher, Mittal Tarun, Mittal kushal, Madan Rajan, Modi Abhiram, Momin Erbaz, Mohan Rajashekar, Mulpuri Ramya, Muqueem Khalid, Murchite Sheetal A, Mushtaque Majid, N Dileep, Nagakumar Nikhil, Naik N Ramprasanna, Naik Madhavi, Nagar Anand, Nandakumar Govind, Nara Bharat Kumar, Nath Barun, Nayak Darshan, Nayak Manjunath, Niranjan Rohit, Ninan Oommen Ashok, Om Prabha, Panchauli Aashutosh, Paramashivaiah Niranjan, Pahari Hirak, Parikh Chirag, Patankar Roy, Patel Rakeshkumar, Patel Danesh, Patel Deepak, Patel Tejas, Patani Tanmaye, Paul Soumen, Paul Pratik, Poddar Anshuman, Porwal Pankaj, Prakash Anand, Prasad Arun, Priya Pallawi, Priyadarshan Gaurav, Puri Puneet, R Durai, R Santhosh, Rahate Prashant, Rahman Mohsinur, Rajgopal Mahesh, Ramesh B S, Rangad Gordon, Rao Prashanth, Rashid Arshad, Ray Sandip, Ray Udipta, Rege Sameer, Rengan Shyam, Rupavath Rajendar, S Anand, S ArunKumar, S DineshKumar, S Viswanath, Shah Amit, Sahadevan Sajeesh, Sangade Vishal, Saraswat Anurag, Sarkar Sauradeep, Sarwal Ankush, Saha Snehasish, Shah Harsh, Shah Shrenik, Sharma Anil, Sharma Abadhesh, Sharma Meenakshi, Sharma Varsha, Shellagi Nikhil, Sheth Harsh, Shetty Pravin, Shetty Sanjeev Vikram, Shrimal Ankur, Shrinivasan Pranav, Singh Arvind, Singh Abhishek, Singh Abhiyutthan, Singh Chandrapal, Singh Charan, Singh Gurbhaij, Singh Gurbachan, Singh Saurav , Singh Harmanmeet, Singh Shailendra Pal, Sinha Nawneet Kumar, Somani Aalok, Soni Vandana, Srivastava Sanjai, Surapaneni Sushama , Suryawanshi Pravin, Tantia Om, Tauheed Fahad, Thangavelu Ashwin, Thota Anuroop, Tiwari Abhishek, Tiwary Satyendra K, Tripathi Pradeep, Umapathi Lohith, Varshney Peeyush, Vashistha Ashish, Vats Ravindra, Verma Ram Kumar, Verma Arunima, Vyas Soumil, Wani Ajaz, Wani Sachin, Yadav Amit, Yadav Anand Kumar, Yerraguntla Raghu, Yaseen Mohammed.

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