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Prospective validation of the Israeli Score for the prediction of common bile duct stones in patients with acute calculous cholecystitis

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Abstract

Background Existing guidelines for predicting common bile duct stones (CBDS) are not specific for acute calculous cholecystitis (ACC). This paper is a posthoc analysis of the S.P.Ri.M.A.C.C study aiming to prospectively validate on a large independent cohort of patients the Israeli Score (IS) in predicting CBDS in patients with ACC.

Methods The S.P.Ri.M.A.C.C. study is an observational multicenter prospective study endorsed by the World Society of Emergency Surgery (WSES). Between September 1st, 2021, and September 1st, 2022, 1201 participants were included. The Chi-Square test was used to compare categorical data. A Cochran-Armitage test was run to determine whether a linear trend existed between the IS and the presence of CBDS. To assess the accuracy of the prediction model, the receiver operating characteristic (ROC) curve was generated, and the area under the ROC curve (AUC) was calculated. Logistic regression was run to obtain Odds Ratio (OR). A two-tailed $p < 0.05$ was considered statistically significant.

Results The rate of CBDS was 1.8% in patients with an IS of 0, 4.2% in patients with an IS of 1, 24.5% in patients with 2 and 56.3% in patients with 3 ($p < 0.001$). The Cochran-Armitage test of trend showed a statistically significant linear trend, $p < 0.001$. Patients with an IS of 3 had 64.4 times (95% CI 24.8–166.9) higher odds of having associated CBDS than patients with an IS of 0. The AUC of the ROC curve of IS for the prediction of CBDS was 0.809 (95% CI 0.752–0.865, $p < 0.001$). By applying the highest cut-off point (3), the specificity reached 99%, while using the lowest cut-off value (0), the sensitivity reached 100%.

Conclusion The IS is a reliable tool to predict CBDS associated with ACC. The algorithm derived from the IS could optimize the management of patients with ACC.

Keywords Acute cholecystitis · Common bile duct stone · Choledocholithiasis

Gallstones are common in 10–15% of the general population, and 20–40% of these people are likely to experience complications [1]. 10–15% of patients with symptoms associated with gallstones present with acute calculous cholecystitis (ACC) as their initial clinical manifestation [1]. Common bile duct stones (CBDS), also known as choledocholithiasis, are present in 10% to 20% of patients with gallstones, with a lower incidence of 5% to 15% in instances of ACC [1].

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Endoscopic Retrograde CholangioPancreatography (ERCP) is very effective in diagnosing and treating biliary obstruction, but it entails risks of perforation, infection, anesthesia-related adverse events, in addition to a 15% risk of post-ERCP pancreatitis and a 1% to 2% risk of post-endoscopic sphincterotomy hemorrhage [2]. For this reason, ERCP should not be used for mere diagnostic purposes. Endoscopic ultrasound (EUS) or magnetic resonance cholangiopancreatography (MRCP) are used as very accurate, lower-risk options for second-level evaluation when the diagnosis is uncertain, allowing to select patients for ERCP. Second-level examinations, however, are expensive and not readily available and could delay surgical therapy for ACC patients, worsening their outcomes [3–6]. In light of the low prevalence of CBDS during ACC, the key challenge is choosing patients with a high risk of CBDS who would benefit from further diagnostic tests and CBDS removal before or during cholecystectomy. Usually, the presence of abnormal liver enzymes in patients with gallstones raises the suspicion of concomitant CBDS. Unfortunately, hepatocellular and cholestatic liver enzymes linked with the acute inflammatory disease are typically mildly elevated in ACC patients, which makes it more difficult to diagnose the associated CBDS. For this reason, blood examination alone could not be the only criterion for selecting patients deserving of second-level examinations.

However, existing guidelines performed suboptimally for predicting choledocholithiasis and the specific population of ACC was underrepresented [2, 7]. For these reasons in 2020 in Israel, Khoury et al. created a new simple score for CBDS prediction, specifically for patients with ACC [8]. The Israeli Score (IS) considered age, CBD width by ultrasound (US), and total bilirubin, and it was validated in a retrospective independent cohort of 105 patients.

The World Society of Emergency Surgery (WSES) prospective multicenter observational study known as the "Validation and comparison of Scores for Prediction of Risk for post-operative major Morbidity after cholecystectomy in Acute Calculous Cholecystitis" (S.P.Ri.M.A.C.C.) study was designed to compare and validate various scores for predicting postoperative complications in patients with ACC who are candidates for EC [9]. This current paper is a posthoc analysis of the S.P.Ri.M.A.C.C study aiming to prospectively validate on a large independent cohort of patients the IS in predicting associated CBDS in patients with ACC.

Methods

Ethical considerations

The S.P.Ri.M.A.C.C. study protocol was approved by the medical ethics committee of the trial's coordination site, the IRCCS San Matteo Hospital in Pavia, Italy. Secondary approval was given by all of the participating centres' regional ethics committees. Patients gave their verbal and written informed permission before enrollment. The trial was conducted following the Helsinki Declaration.

Study design

The S.P.Ri.M.A.C.C. study is an observational multicenter prospective study endorsed by the WSES. It aimed to prospectively validate the Chole-Risk score [10] in predicting postoperative complications in patients undergoing EC for ACC compared with other pre-operative risk prediction models.

Between September 1st, 2021, and September 1st, 2022, 1253 patients were enrolled from 79 locations across 19 different countries. NCT04995380 was assigned to the study on ClinicalTrial.gov. The full study protocol can be accessed via the study website https://sprimaccstudy.wixsite.com/website.

Present study is a retrospective study of prospectively collected data. 1201 participants with ACC were included in the analysis. 52 patients were excluded for lack of complete data regarding IS variables or the presence of associated CBDS. Patients received second-level examinations for CBDS detection according to local clinical practice. The goal of the study was to prospectively validate the IS in predicting CBDS.

The Israeli Score

The IS was developed using three preoperative variables: (a) age ≥ 70; (b) CBD width by ultrasound (US) ≥ 7 mm; (c) total bilirubin (within 24 h) ≥ 1.8 mg. Each variable can score either 0—if the condition is not assessed—or 1 for a positive variable: therefore, the overall score is composed of a maximum of 3 points (scale 0–3). If, during the US, the evaluation of the CBD width was not possible, the variable got a score of 0. Patients with lack of data regarding one or more IS variables were excluded.

Studied variables

The presence of associated CBDS was the primary objective of the study. EUS and MRCP were considered reliable methods for the diagnosis of CBDS, as recommended by the European Society of Gastrointestinal Endoscopy (ESGE) [11]. EUS has a sensitivity of 95–97% and a specificity of 87–97%, while MRCP has a sensitivity of 90–93% and a specificity of 92–96% [11]. However, not all patients received EUS or MRCP: patients were subjected to second-level examinations based on local clinical practice. For this reason, the primary endpoint included patients with CBDS

finding on EUS or MRCP or patients subjected to postoperative ERCP during hospitalization or within 30 days from discharge for reasons other than iatrogenic biliary tree injuries. Accordingly, all patients with clinically relevant CBDS should have been identified by one of the three methods. The IS values were calculated before EUS, MRCP or ERCP but they were not available to the endoscopists and radiologists who performed EUS, ERCP, and MRCP.

Participants

Elegible patients were identified after admission to the General Surgery ward. Consecutive patients fulfilling the following requirements were included: (1) be identified as having ACC following the Tokyo Guidelines; (2) be a candidate for EC during the index admission; (3) be over the age of 18; (4) be assessed for the likelihood of CBDS; (5) sign a written informed consent; and (6) be available for the follow-up.

Symptoms developed more than 10 days before cholecystectomy, concomitant cholangitis or pancreatitis, pregnancy or lactation, and acute cholecystitis unrelated to a gallstone cause were the exclusion criteria.

Sample size

Sample size to validate the diagnostic performance of the IS was calculated with the aim to obtain a minimum of 100 events and 100 nonevents [12–14]. Considering an incidence of 10% of CBDS associatedto ACC [1], the number of patients needed to reach 100 events was 1000 enrolled patients.

Statistical analysis

The Chi-Square test was used to compare categorical data. A Cochran-Armitage test of the trend was run to determine whether a linear trend existed between the IS and the presence of CBDS. The receiver operating characteristic (ROC) curve was generated to assess the accuracy of the analyzed prediction model, and the area under the ROC curve (AUC) was calculated. Logistic regression was run to obtain odd ratio (OR). A two-tailed $p < 0.05$ was considered statistically significant. SPSS version 26 was used for statistical analysis.

Reporting was in line with STARD 2015 guidelines [15] (Supplementary file 1).

Results

The validation cohort included 1201 patients with ACC. The characteristics of patients are reported in Table 1.

Among them, 134 patients (11.2%) had a CDB width ≥ 7 mm, 256 patients (21.3%) had total bilirubin ≥ 1.8 mg, and 385 patients (32.1%) were more than 70

Table 1 Patients characteristics

Characteristic	Mean ± SD median (IQR) or *N* (%)
Age	59.7 ± 17.0 61 (47–74)
Age ≥ 70	385 (32.1)
Gender	
Male	627 (52.8)
Female	561 (47.2)
ACC grade	
1	384 (32.0)
2	811 (67.5)
3	6 (0.5)
POSSUM physiological score	20.7 ± 6.4 19 (16–24)
	19 (16–24)
Total bilirubine ≥ 1.8 mg	256 (21.3)
CBD width ≥ 7 mm	134 (11.2)
IS	
0	625 (52.0)
1	405 (33.7)
2	143 (11.9)
3	28 (2.3)
Presence of CBDS on EUS or MRCP	71 (5.9)
Post-op ERCP within 30 days from discharge	7 (0.6)

ACC, Acute Calculous Cholecystitis; *CBD*, Common Bile Duct; *IS*, Israeli Score; *CBDS*, Common Bile Duct Stones; *EUS*, Endoscopic Ultrasound; *MRCP*, Magnetic Resonance CholangioPancreatography; *ERCP*, Endoscopic Retrograde CholangioPancreatography

years old. 71 (5.9%) patients had a diagnosis of associated CBDS after EUS or MRCP. 7 patients (0.6%) received postoperative ERCP during hospitalization or within 30 days from discharge for reasons other than iatrogenic biliary tree injuries. A total of 78 patients (6.5%) have met the primary outcome (Fig. 1).

Among included patients, 625 patients (52.0%) had an IS of 0, 405 patients (33.7%) of 1, 143 patients (11.9%) of 2, 28 patients (2,3%) of 3.

The rate of CBDS was 1.8% (11 patients) among patients with an IS of 0, 4.2% (17 patients) among patients with an IS of 1, 24.5% (35 patients) among patients with 2 and 53.6% (15 patients) among patients with 3 ($p < 0.001$), as shown in the following Fig. 2.

The Cochran-Armitage test of trend showed a statistically significant linear trend, $p < 0.001$, with a higher IS score associated with a higher proportion of patients with CBDS. The ORs of the IS derived from logistic regression are reported in Table 2. Patients with an IS of 3 had 64.4 times (95% CI 24.8–166.9) higher odds to have associated CBDS than patients with an IS of 0.

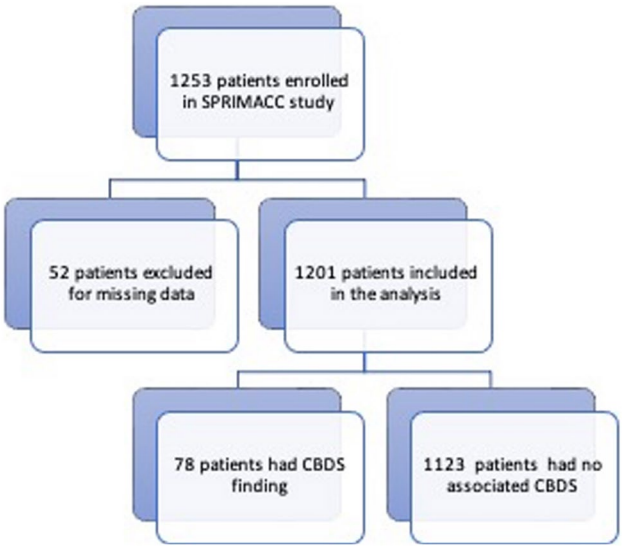

Fig. 1 Patients flow diagram

Table 2 The odd ratios (OR) of the Israeli Score values derived from logistic regression with 95% confidence interval (CI)

Israeli Score	B	*p* value	OR	95% CI
0	Ref	< 0.001	Ref	Ref
1	0.9	0.023	2.5	1.1–5.3
2	2.9	< 0.001	18.1	8.9–36.7
3	4.2	< 0.001	64.4	24.8–166.9

The AUC of the ROC curve of IS for the prediction of CBDS was 0.809 (95% CI 0.752–0.865, $p < 0.001$), as underlined in Fig. 3. The predictive values of IS are reported in Table 3. By applying the highest cut-off point—3—the specificity reached 99%, while using the lowest cut-off value—0—the sensitivity reached 100%. An IS of 0–1 has a sensitivity of 86% and a LR− of 0.3 in excluding the presence of CBDS, while an IS of 3 has a specificity of 99% and a LR+ of 19.0 in predicting the presence of CBDS.

Discussion

Preoperative risk stratification for CBDS is very useful in the management of patients with ACC. It allows clinicians to plan preoperative (EUS or MRCP) or intraoperative (intraoperative cholangiography, IOC, laparoscopic US, LUS) second-level examinations and preoperative (preoperative ERCP) or intraoperative (intraoperative ERCP or laparoscopic CBD exploration) CBDS removal. Recent studies found that intraoperative ERCP, during laparoscopic

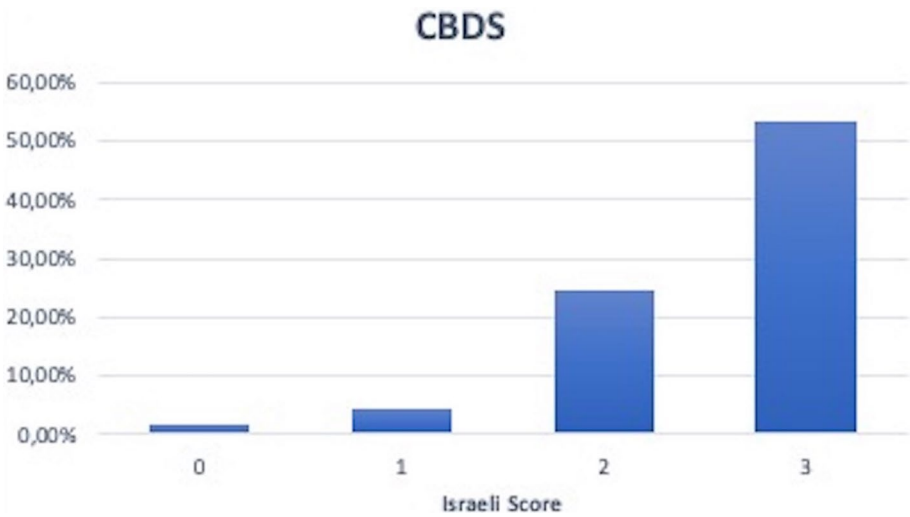

Fig. 2 Common bile duct stones prevalence according to the Israeli Score ($p < 0.001$) (*CBDS* Common bile duct stones, *IS* Israeli Score)

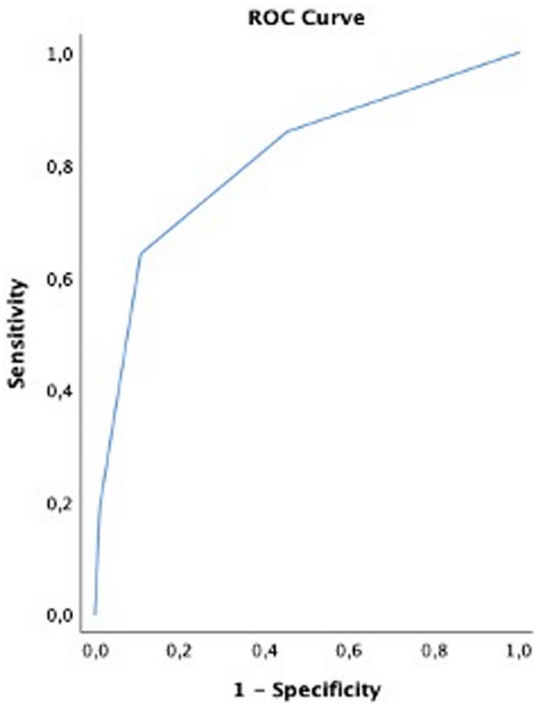

Fig. 3 Receiver operating characteristics (ROC) curve of Israeli Score in predicting common bile duct stones (AUC 0.839, 95% CI 0.786–0.892)

Table 3 Diagnostic accuracy of Israeli Score (*LR*+ positive likelihood ratio, *LR*− negative likelihood ratio)

Israeli Score	0	1	2	3
Sensitivity	100%	86%	64%	19%
Specificity	0%	55%	89%	99%
LR+	1.0	1.9	5.8	19.0
LR−	0.0	0.3	0.4	0.8

cholecystectomy is a safer approach for patients with cholecystocholedocholithiasis. It might make intubation easier, reduce the need for additional surgery to remove the stone, shorten hospital stays, reduce postoperative complications—including pancreatitis—and diminish stone residue [16]. However, ERCP is burdened with a non-negligible rate of complications and should be reserved for patients with a high level of suspicion of CBDS, possibly after less invasive second-level examinations [2].

Preoperative second-level examinations for CBDS are expensive, not readily available and could delay surgical therapy in patients with ACC. On the other hand, intraoperative second-level examinations for CBDS lengthen operating times and therefore costs, require different programming and organization of the operating room and can be technically more difficult or risky in patients with intense local inflammatory reactions such as those with ACC. For these reasons, in patients with ACC, in which a delay in surgical source control could worsen prognosis [3–6] and surgical intervention could be more difficult, a tool to select patients deserving of second-level examinations is necessary.

Unfortunately, in patients with ACC liver tests alone could not be reliable predictors for CBDS, due to the elevation of hepatocellular and cholestatic liver enzymes linked with the acute inflammatory disease [1]. Furthermore, existing risk prediction models for CBDS perform suboptimally and they are not specific for ACC [2, 7].

The WSES guidelines for ACC [1] endorsed the American Society for Gastrointestinal Endoscopy (ASGE) guidelines [17] as a valuable tool for the preoperative diagnosis and the management of CBDS, also associated with ACC. Still, they propose a modified and more cautious risk stratification. Patients with total serum bilirubin > 4 mg/dl or enlarged common bile duct diameter in the US with concomitant bilirubin level 1.8 to 4 mg/dl should be considered as moderate risk and should undergo second-level investigation such as EUS or MRCP, LUS, or IOC. Only patients with evidence of CBDS in the abdominal US should be considered at high risk of CBDS and should undergo diagnostic and therapeutic ERCP directly. However, also in the ASGE guidelines population, patients with ACC are underrepresented and data regarding clinical and laboratory diagnosis of CBDS in the setting of ACC are scarce [2, 7].

The IS is based on simple available clinical, laboratory, and radiological parameters that can predict CBDS specifically in patients hospitalized with ACC [8], but it lacks a prospective large-scale validation. In this study, we validate the IS in predicting CBDS in a prospective cohort of 1201 patients with ACC. By applying the highest cut-off point of the IS, 3, the specificity reached 99%, while using the lowest cut-off value, 0, the sensitivity reached 100%.

Based on these results, we propose the algorithm shown in Fig. 4 for the diagnosis and management of CBDS in patients with ACC. Patients with an IS of 0–1 are at low-risk for CBDS and they could be safely proposed for cholecystectomy. Patients with an IS of 3 are at high-risk for CBDS and should receive ERCP directly or intraoperative CBD exploration, according to local expertise. Patients with an IS of 2 should undergo second-level diagnostics: EUS, MRCP, LUS or IOC according to the local expertise.

Our research is based on a clear methodology, a robust statistics, and massive data from S.P.Ri.M.A.C.C. study. The algorithm we proposed could improve the clinical and organizational management of patients with ACC, optimizing the time from admission to surgery and the diagnostic processes and avoiding the prescription of unnecessary examinations and the related increase in costs and time. Furthermore, the IS have a good global applicability: the three included

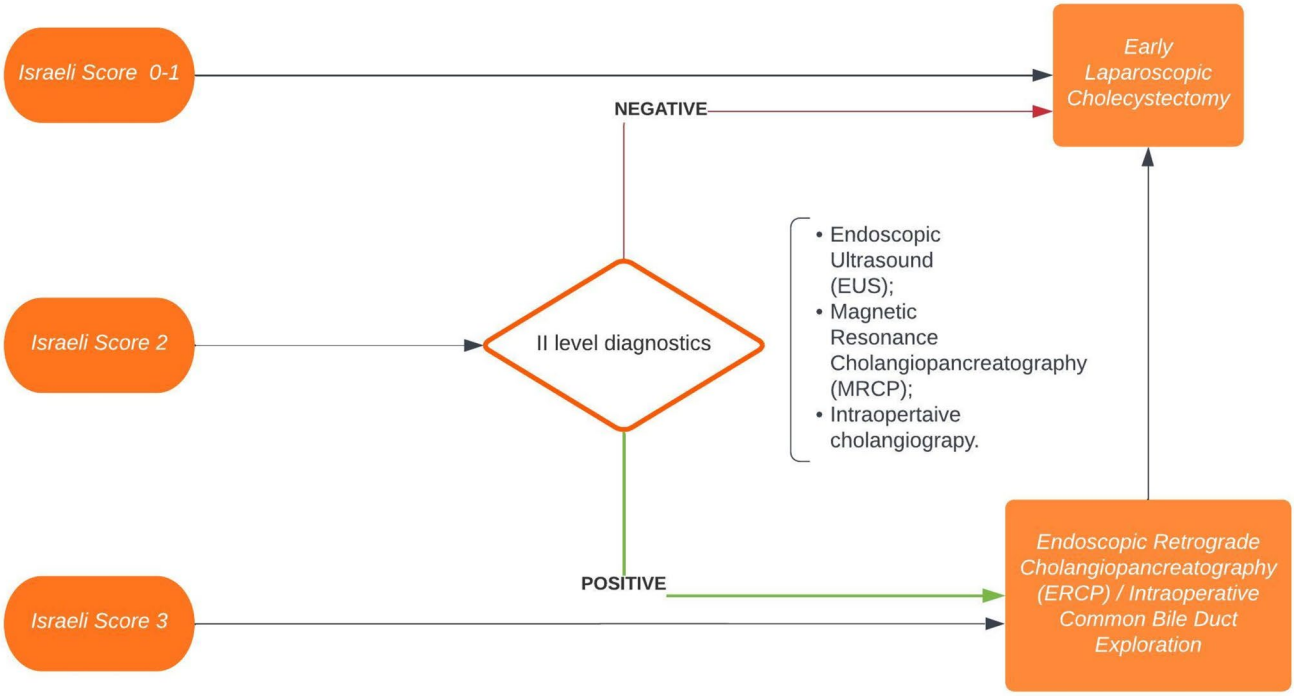

Fig. 4 Algorithm for the diagnosis and management of common bile duct stones in patients with acute calcolous cholecystitis

variables are easy to use and generally available everywhere cholecystectomy is performed. For these reasons, it would be advisable to include this tool in the next update of the WSES guidelines about ACC as a recommended score for stratification of CBDS risk, specific for patients with ACC.

Conclusion and limitations

There are some limitations to our study. First, not all included patients were subjected to second-level examinations, but patients were investigated for CBDS according to local clinical practice. For this reason, we included in the primary outcome also patients subjected to post-operative ERCP during hospitalization or within 30 days from discharge, for reasons other than biliary tree injuries. In this way, all patients with clinically relevant CBDS should have been identified by one of the three methods. However, if a small number of patients with CBDS could have been unrecognized, because they did not need a therapeutic procedure, their choledocolithiasis could be considered as not clinically relevant. Finally, although our study used type II research data, we believe that its prospective data collection and large sample size produced the highest-quality data currently available in the literature on this specific population. A future project could be to carry out a prospective study that compares the performance of the Israeli Score with that of ASGE and WSES Guidelines in predicting CBDS in patients with ACC.

In conclusion, the IS stands as a reliable and accurate tool to predict CBDS associated with ACC. The application of the algorithm derived from the IS could optimize the management of patients with ACC.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-023-10442-x.

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Data availability The datasets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author at reasonable request.

Declarations

Disclosures Paola Fugazzola, Enrico Cicuttin, Lorenzo Cobianchi, Francesca Dal Mas, Tommaso Dominioni, Simone Frassini, Matteo

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Ethical approval The study protocol was approved by the medical Ethics Board of the trial coordinating center at the IRCCS San Matteo Hospital, Pavia (Italy). Secondary approvals were obtained from all local ethics committees in the participating centers.

Informed consent Patients gave oral and written informed consent before inclusion.

Consent for publication Not applicable.

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