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Evaluation of Textbook Outcome as a Composite Quality Measure of Elective Laparoscopic Cholecystectomy

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Abstract

IMPORTANCE A textbook outcome (TO) is a composite quality measure that incorporates multiple perioperative events to reflect the most desirable outcome. The use of TO increases the event rate, captures more outcomes to reflect patient experience, and can be used as a benchmark for quality improvement.

OBJECTIVES To introduce the concept of TO to elective laparoscopic cholecystectomy (LC), propose the TO criteria, and identify characteristics associated with TO failure.

DESIGN, SETTING, AND PARTICIPANTS This retrospective cohort study was performed at 3 surgical units in a single health board in the United Kingdom. Participants included all patients undergoing elective LC between January 1, 2015, and January 1, 2020. Data were analyzed from January 1, 2015, to January 1, 2020.

MAIN OUTCOMES AND MEASURES The TO criteria were defined based on review of existing TO metrics in the literature for other surgical procedures. A TO was defined as an unremarkable elective LC without conversion to open cholecystectomy, subtotal cholecystectomy, intraoperative complication, postoperative complications (Clavien-Dindo classification ≥2), postoperative imaging, postoperative intervention, prolonged length of stay (>2 days), readmission within 100 days, or mortality. The rate of TOs was reported. Reasons for TO failure were reported, and preoperative characteristics were compared between TO and TO failure groups using both univariate analysis and multivariable logistic regressions.

RESULTS A total of 2166 patients underwent elective LC (median age, 54 [range, 13-92] years; 1579 [72.9%] female). One thousand eight hundred fifty-one patients (85.5%) achieved a TO with an unremarkable perioperative course. Reasons for TO failure (315 patients [14.5%]) included conversion to open procedure (25 [7.9%]), subtotal cholecystectomy (59 [18.7%]), intraoperative complications (40 [12.7%]), postoperative complications (Clavien-Dindo classification \geq 2; 92 [29.2%]), postoperative imaging (182 [57.8%]), postoperative intervention (57 [18.1%]), prolonged length of stay (>2 days; 142 [45.1%]), readmission (130 [41.3%]), and mortality (1 [0.3%]). Variables associated with TO failure included increasing American Society of Anesthesiologists score (odds ratio [OR], 2.55 [95 Cl, 1.69-3.85]; P < .001), increasing number of prior biliary-related admissions (OR, 2.68 [95% Cl, 1.36-5.27]; P = .004), acute cholecystitis (OR, 1.42 [95% Cl, 1.08-1.85]; P = .01), preoperative endoscopic retrograde cholangiopancreatography (OR, 2.07 [95% Cl, 1.46-2.92]; P < .001), and preoperative cholecystostomy (OR, 3.22 [95% Cl, 1.54-6.76]; P = .002).

CONCLUSIONS AND RELEVANCE These findings suggest that applying the concept of TO to elective LC provides a benchmark to identify suboptimal patterns of care and enables institutions to identify strategies for quality improvement.

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Key Points

Question Can the concept of textbook outcome (TO) be applied to elective laparoscopic cholecystectomy (LC), and if so, what are the TO criteria and the characteristics associated with TO failure?

Findings In this cohort study of 2166 participants undergoing elective LC, 1851 (85.5%) achieved a TO with an unremarkable perioperative course. Predisposing factors and those contributing to TO failure were identified.

Meaning These findings suggest that applying the concept of TO to elective LC provides a benchmark to enable institutions to identify strategies for quality improvement.

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Introduction

Textbook outcome (TO) is a composite quality measure that incorporates multiple perioperative outcomes to reflect the most desirable outcome. It is a multidimensional indicator that considers many aspects of morbidity (eg, complications, prolonged admission, further intervention, and readmission) and incorporates multiple facets of patient care. Reliance on single outcomes with low event rates does not reflect the perioperative course accurately and does not incite improvements in quality of care.¹⁻⁴

To date a TO has not been described after elective LC. Although bile duct injury is the most emphasized complication, it is infrequent and does not capture the extent of perioperative morbidity when used as an outcome measure. Even referring to overall complication rates (eg, through the Clavien-Dindo classification) will fail to acknowledge the extent of postoperative problems such as prolonged length of stay and readmission.

Reporting a TO will acknowledge all adverse perioperative outcomes, giving a better impression of quality of care as a metric of assessment.⁵⁻¹¹ A TO metric will provide a holistic perspective on outcomes better aligned with patient experiences and improve transparency of reporting vs single-outcome metrics. It may also highlight variation in outcomes between centers and provide a benchmark standard of care.¹²⁻¹⁷ The aims of this cohort study were to propose the TO criteria after elective LC and to identify reasons for TO failure and individual patient factors predisposing to failure.

Methods

Population Cohort

All patients who underwent elective LC in 1 health board in the United Kingdom (consisting of 1 tertiary referral center and 2 satellite units) between January 1, 2015, and January 1, 2020, were included in this retrospective cohort study. The health board covers a defined geographical region with a stable population of approximately 493 000 people. Indications for elective LC included all symptomatic biliary pathology (eg, biliary colic, cholecystitis, gallstone pancreatitis). Ethical approval was granted by the Caldicott Guardian and the regional information governance service, which waived the need for informed consent for deidentified retrospective data. This study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Emergency cholecystectomies, which were excluded, were defined as any cholecystectomy performed during an acute admission, whereas elective cholecystectomies were strictly those performed on an outpatient basis, whether or not they were performed as an interval procedure. Planned open cholecystectomies and planned bile duct explorations were excluded in the analysis because both are likely to have a different expected perioperative course (**Figure 1**).

Data Collection

Data were collected retrospectively from multiple databases using a deterministic records-linkage method. Patients were tracked between databases using a unique 10-digit patient identifier. These



databases were used to obtain information relating to both previous gallstone-related admissions and the operative admission and included baseline demographic and operative data. Details of any perioperative adverse outcomes (eg, complications, imaging, or intervention) were recorded. Total length of stay (LOS) was recorded for all patients. Records of those patients who were readmitted under surgical care within 100 days of their operation were scrutinized for details of any further complications, imaging, or intervention.

Defining TO

The literature was reviewed and TO was defined as an elective LC performed in the absence of conversion to open cholecystectomy, subtotal cholecystectomy, intraoperative complication, postoperative complication (Clavien-Dindo classification \geq 2), postoperative imaging or intervention, prolonged postoperative LOS, readmission, or mortality. An LOS greater than 2 postoperative days was regarded as prolonged because this LOS was associated with the other perioperative adverse outcomes.

Reasons for TO Failure and Predisposing Factors

The overall rate of TO was calculated, and the perioperative outcomes contributing to failure were reported. The associations between adverse perioperative outcomes were found to identify interconnected aspects of these outcomes. By determining these associations, surgical units can begin to identify suboptimal patterns of care.

Statistical Analysis

Data were analyzed from January 1, 2015, to January 1, 2020. Factors associated with achieving TO were determined using univariate and multivariable analysis. Factors included in the analysis included age (<40, 40-59, and \geq 60 years), American Society of Anesthesiologists (ASA) score (1, 2, or \geq 3), diagnosis (biliary colic, cholecystitis, biliary pancreatitis), radiological findings (wall thickening [\geq 4 mm], pericholecystic fluid), number of previous biliary admissions and preoperative interventions (endoscopic retrograde cholangiopancreatography [ERCP], cholecystostomy). In the multivariable logistic regression, a top-down approach was used, eliminating the most insignificant variables remain. Multicollinearity between all variables were determined using Pearson correlation coefficients (*r* values), and collinearity coefficients greater than 0.25 were reported. All statistical tests were conducted using the STATA IC, version 16.1, statistical software package (StataCorp LLC). One-sided *P* < .05 was considered statistically significant.

Results

Background

During the 5-year period, 2166 elective cholecystectomies were performed. The median age of the cohort was 54 (range, 13-92) years. The cohort was predominantly female (1579 [72.9%] vs 587 [27.1%] male), and the median ASA score was 2 (range, 1-4) (**Table 1**).

Overall, 4 patients had bile duct injuries (0.2%), only 1 of which was a complete transection of the bile duct (0.05%). In the entire study cohort, postoperative intervention was required in 57 patients and included ERCP (n = 30), laparoscopy (n = 15), laparotomy (n = 10), and radiologically guided drainage (n = 5). The indications for return to operating theater were collections (n = 9), bile leak (n = 8), bowel perforations (n = 3), hemorrhage (n = 2), bowel obstruction (n = 2), and oncologic resection secondary to gallbladder cancer (n = 1). The radiologically guided drainages were performed for intra-abdominal collections (n = 5).

One hundred eighty-two patients underwent postoperative imaging, of whom 178 (97.8%) had symptoms or worsening clinical signs. One hundred thirty patients (6.0%) were readmitted during the 100-day follow-up period (total of 158 admissions; median time from admission, 9 [range, 0-97] days; median length of admission, 2 [range, 1-70] days). The most common causes for readmission

included collections, retained stone, and wound infections. One patient died during the 100-day follow-up period (morality rate, 0.05%) owing to unexpected disseminated malignant disease.

TO and Its Contributors

A total of 1851 patients (85.5%) had a TO for elective LC with an unremarkable perioperative and postoperative course without subtotal cholecystecomy, conversion to open cholecystecomy, complication, prolonged LOS, postoperative imaging or intervention, readmission, or mortality (Table 1). Perioperative outcomes and reasons for TO failure (315 [14.5%]) are reported in **Table 2**. As demonstrated, the most frequent contributors toward TO failure were postoperative imaging (59 [57.8%]), prolonged LOS (142 [45.1%]), readmission (130 [41.3%]), and postoperative complication (92 [29.2%]). The associations between adverse outcomes are demonstrated in **Figure 2** to identify interconnected aspects of outcomes and further interpret quality of care.

Risk Factors for TO Failure

In the univariate analysis, patients not achieving TO were more likely to be older (median age, 58 [range, 18-91] vs 53 [range, 13-86] years), to be male (113 of 315 [35.9%] vs 474 of 1851 [25.6%]), to have an ASA score of at least 2 (245 of 315 [77.8%] vs 1195 of 1851 [64.5%]), and to have had cholecystitis (146 of 315 [46.3%] vs 538 of 1851 [29.1%]) (Table 1). Patients not achieving TO also were more likely to have had at least 2 previous biliary-related admissions (59 of 315 [18.7%] vs 130

	Patient group ^a			
Characteristic	All (N = 2166)	TO achieved (n = 1851)	TO not achieved (n = 315)	– P value
Age, median (range), y	54 (13-92)	53 (13-86)	58 (18-91)	<.001
Sex, %				
Male	587 (27.1)	474 (25.6)	113 (35.9)	. 001
Female	1579 (72.9)	1377 (74.4)	202 (64.1)	<.001
ASA score				
1	726 (33.5)	656 (35.4)	70 (22.2)	
2	1227 (56.6)	1036 (56.0)	191 (60.6)	<.001
≥3	213 (9.8)	159 (8.6)	54 (17.1)	
Indication				
Biliary colic	1262 (58.3)	1133 (61.2)	129 (41.0)	<.001
Cholecystitis	703 (32.4)	557 (30.1)	146 (46.3)	<.001
Gallstone pancreatitis	91 (4.2)	76 (4.1)	15 (4.8)	.29
Other (eg, biliary dyskinesia, polyps)	110 (5.1)	85 (4.6)	25 (7.9)	.01
Imaging				
US of abdomen	2086 (96.3)	1792 (96.8)	294 (93.3)	.003
MRCP	647 (29.9)	516 (27.9)	131 (41.6)	<.001
CT of abdomen and/or pelvis	306 (14.1)	216 (11.7)	90 (28.6)	<.001
Preoperative radiological findings				
Thickened gallbladder wall	666 (30.7)	528 (28.5)	138 (43.8)	<.001
Pericholecystic fluid	276 (12.7)	223 (12.0)	53 (16.8)	.02
Common bile duct stones	158 (7.3)	101 (5.5)	57 (18.1)	<.001
Preoperative ERCP	178 (8.2)	110 (5.9)	68 (21.6)	<.001
Preoperative cholecystostomy	32 (1.5)	13 (0.7)	19 (6.0)	<.001
No. of previous biliary-related admissions				
1	762 (35.2)	637 (34.4)	125 (39.7)	
2	139 (6.4)	97 (5.2)	42 (13.3)	<.001
≥3	50 (2.3)	33 (1.8)	17 (5.4)	
Previous abandoned cholecystectomy	19 (0.9)	9 (0.5)	10 (3.2)	<.001

Abbreviations: ASA, American Society of Anesthesiologists; CT, computed tomography; ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography; TO, textbook outcome;

US, ultrasonography.

^a Unless otherwise indicated, data are expressed as No. (%) of patients. Percentages have been rounded and may not total 100.

of 1851 [7.0%]) and to have undergone a preoperative ERCP (68 of 315 [21.6%] vs 110 of 1851 [5.9%]), cholecystostomy (19 of 315 [6.0%] vs 13 of 1851 [0.7%]), or previous abandoned elective LC (10 of 315 [3.2%] vs 9 of 1851 [0.5%]) (Table 1).

In the multivariable analysis, the following variables were positively associated with failure to achieve TO: ASA score of at least 2 (odds ratio [OR], 1.57 [95% CI, 1.17-2.12]; P = .003), at least 2 previous admissions (OR, 1.80 [95% CI, 1.18-2.76]; P = .007), cholecystitis (OR, 1.42 [95% CI, 1.08-1.85]; P = .01), preoperative ERCP (OR, 2.07 [95% CI, 1.46-2.92]; P < .001), and cholecystostomy (OR, 3.22 [95% CI, 1.54-6.76]; P = .002) (**Table 3**). Of all variables considered for inclusion in the final model, we identified significant collinearity ($r \ge 0.25$) between previous cholecystitis and both thickened wall (r = 0.81) and pericholecystic fluid (r = 0.51).

Table 2. Perioperative Data for Patients Undergoing Elective Laparoscopic Cholecystectomy

	No. (%) of patients		
Outcome	All (N = 2166)	Contribution to TO failure (n = 315)	Single contributor to TO (n = 315)
Converted to open cholecystectomy	25 (1.2)	25 (7.9)	4 (1.3)
Subtotal cholecystectomy	59 (2.7)	59 (18.7)	8 (2.5)
Intraoperative complications	40 (1.8)	40 (12.7)	12 (3.8)
Postoperative complications (Clavien-Dindo classification ≥2)	92 (4.2)	92 (29.2)	4 (1.3)
Postoperative imaging	182 (8.4)	182 (57.8)	46 (14.6)
Postoperative intervention	57 (2.6)	57 (18.1)	0
Prolonged LOS (>2 d)	142 (6.5)	142 (45.1)	31 (9.8)
Readmission	130 (6.0)	130 (41.3)	23 (7.3)
Mortality	1 (0.05)	1 (0.3)	0

Abbreviations: LOS, length of stay; TO, textbook outcome.

<10% 10%-25% 26%-50% >50%

Figure 2. Proportion of Patients With Adverse Outcome 2 Among Those With Adverse Outcome 1

							L			
		Adverse outcome 1, %								
		Conversion to open procedure	Subtotal cholecystectomy	Intraoperative complication	Postoperative complication	Prolonged LOS	Postoperative imaging	Postoperative intervention	Readmission	Mortality
	Conversion to open procedure		14	18	10	15	5	12	5	100
outcome 2, %	Subtotal cholecystectomy	32		23	24	35	13	26	10	0
	Intraoperative complication	32	15		18	19	10	21	8	0
	Postoperative complication	28	37	43		43	47	86	44	0
	Prolonged LOS	88	83	68	66		36	61	27	100
Adverse	Postoperative imaging	36	39	45	92	46		88	26	0
	Postoperative intervention	36	25	30	53	25	27		28	0
	Readmission	28	22	28	62	25	19	63		100
	Mortality	0	0	0	0	1	0	0	1	

LOS indicates length of stay.

Discussion

The concept of the TO was first described by Kolfschoten et al,¹⁸ who reported this composite outcome measure in patients undergoing colonic resection for cancer. However, this approach has since been extended to noncancer surgery (aortic aneurysm repair, liver transplant).^{19,20} Definitions of TO typically include freedom from perioperative morbidity, early mortality, readmission, and procedure-specific variables such as margin status and lymph node yield.^{18,20-26} Single complication indicators such as bile duct injuries after LC have a low event rate and therefore do not represent the multidimensional approach of the surgical process. Furthermore, acknowledging complication rates in general will not reflect all the perioperative problems that a patient may face. The use of TO increases the event rate and captures more outcomes to reflect patient experience. To our knowledge, this study is the first to apply TO to elective LC, propose the TO criteria as a performance assessment tool, and report risk factors for TO failure.

The proposed TO criteria is a perioperative course not affected by conversion to open cholecystectomy, subtotal cholecystectomy, intraoperative complication, postoperative complication (Clavien-Dindo classification \geq 2), postoperative imaging or intervention, prolonged postoperative LOS (>2 days), readmission, or mortality. Textbook outcome was achieved in most patients (85.5%), and the most frequent contributors toward TO failure were postoperative imaging (57.8%), prolonged LOS (45.1%), readmission (41.3%), and postoperative complication (29.2%). Although TO rates have not been reported before, the rates of the reported adverse outcomes are broadly consistent with those reported by both the CholeS group and a single surgeon series.²⁷

Processes of care represent the actual care delivered to a patient and play a fundamental role in hospital quality assessment. Measuring and reporting process measures can be facilitated by establishing a clear definition of the population or procedure being studied (denominator) and what represents a success or a failure (numerator). Finally, process measures can be used as clinical quality indictors to facilitate more proactive quality improvement. It has been argued that there must be a direct link to a defined outcome for a process measure to be valid, and as such, proposing TO helps to facilitate this process.^{4,25}

Benchmarks are a fundamental part of the quality improvement process to which institutions refer and compare their outcomes. Setting benchmarks through the format of TO can provide an internationally recognized standard of care to improve assessment of individual hospital performance and assist with quality improvement activity. These benchmarks should continuously evolve over time to drive progressive quality improvement.^{4,18,20} As demonstrated, this study sets the criteria for this benchmark and should be regarded as a stepping stone to the establishment of internationally recognized benchmark rates.²⁰ As the concept of TO becomes more widely disseminated, definitions proposed at the institutional level may motivate revision of data captured in databases to facilitate both validation and revision of this metric, and comparison of outcomes across institutions.

Table 3. Multivariable Logistic Regression of Variables Associated With Not Achieving TO						
Independent variable for outcome of TO failure	OR (95% CI) [SE]	Z	P value			
ASA score						
2	1.57 (1.17-2.12) [0.24]	2.99	.003			
≥3	2.55 (1.69-3.85) [0.53]	4.49	<.001			
No. of previous admissions						
2	1.80 (1.18-2.76) [0.39]	2.72	.007			
≥3	2.68 (1.36-5.27) [0.93]	2.85	.004			
Cholecystitis	1.42 (1.08-1.85) [0.19]	2.55	.01			
ERCP	2.07 (1.46-2.92) [0.37]	4.12	<.001			
Cholecystostomy	3.22 (1.54-6.76) [1.21]	3.10	.002			

Abbreviations: ASA, American Society of Anesthesiologists; ERCP, endoscopic retrograde cholangiopancreatography; OR, odds ratio; TO, textbook outcome.

A significant strength of TO is its multidimensional perspective as a composite quality of care indicator. Just as TO criteria after oncologic surgery include multiple outcomes (eg, resection margins, nodal harvest, and survival rates), TO after elective LC incorporates all adverse outcomes that would deviate from an unremarkable outcome. This approach can identify various suboptimal patterns of perioperative care to guide quality improvement, which is not possible when depending on single infrequent outcomes.^{20,24} For example, in the present cohort, prolonged LOS and readmission were among the most frequent reasons for TO failure and interconnected aspects between outcomes are reported. Quality improvement processes to reduce these rates with reference to internationally accepted benchmarks would help improve outcomes.

It has been demonstrated that the patient consent process before LC is often inadequate. The concept of TO may be useful in helping obtain informed preoperative consent.¹²⁻¹⁷ Traditionally, precholecystectomy discussion has focused heavily on bile duct injury, which, given its potentially catastrophic consequences, will always remain a cornerstone of the consent process. Although individual complications may portend differential implications for long-term prognosis, understanding of the multitude of immediate outcomes may be particularly important to patients and their view of the health care experience.²³ Reference to textbook outcome rates during a consultation provides a multidimensional account of the quality of the perioperative care that is better aligned with patient experience compared with any single metric.^{1-3,21,22,28-30} This study reports a significant proportion of patients who do not achieve TO (14.5%) and its contributors. Outlining the perioperative course in this way provides a more comprehensive and representative picture than quoting infrequent outcomes. Of course, acknowledging patient risk factors for TO failure will help surgeons appreciate patient variation and guide an individualized consent process. In the present study, an ASA score of at least 2, at least 2 previous biliary-related emergency admissions, previous cholecystitis, preoperative ERCP, and cholecystostomy were associated with TO failure.

Elective LC is an extremely common operation consuming large amounts of surgical and financial resources.³¹ Applying TO rates to cholecystectomy will also help guide those bodies responsible for funding and organizing health services. Many elective LCs will be straightforward procedures with no follow-up required. Determining that 14.5% of patients undergoing elective LC need ongoing surgical care will inform appropriate resource allocation and health care organization.

When considering factors to be included in this TO model, several potential options were appraised but ultimately rejected. Conventional wisdom would suggest that an intraoperative critical view of safety should be achieved during every elective LC. Although obtaining a critical view might be regarded as normal practice, there are other methods of safely performing a cholecystectomy. Indeed, some evidence suggests that a critical view is obtained much less than commonly assumed.³² Therefore we believed it was inappropriate to include this as a TO objective. Other variables related to the quality of surgery may be considered, such as prolonged operative time, intraoperative bile spillage, blood loss, or postoperative pain. Although these variables have been found to be associated with varied patient outcomes, it might be difficult to obtain accurate measurements, and these parameters might not necessarily imply lower surgical quality.²⁵

Relief of biliary symptoms may initially appear a logical criterion to include; however, such symptoms can be variable, unpredictable, and subjective. Some patients may also develop new issues such as postcholecystectomy pain or diarrhea. Although developing such symptoms is troublesome, these are not markers of the quality of the operation; hence, they were not considered as TO criteria. These patient-related outcomes should be considered in a global outcome measure that assesses quality of life after elective LC.

Limitations

The present study has limitations. First, the cohort is from a single health board and is unlikely to be representative of nationwide or international data. Nevertheless, the aim was not to set the internationally accepted benchmark rates, but instead to introduce the concept of TO for elective LC

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and to demonstrate the advantages of TO as a quality improvement metric. Multicenter cohort studies should be conducted to establish accepted TO benchmarks rates to drive quality improvement. Second, further limitation is the standardization of terms. Although most constituents of the TO criteria are self-explanatory, the definition of subtotal cholecystectomy is open to interpretation, and there are multiple variations in surgical technique. As such, accuracy of reporting of subtotal cholecystectomy is likely to vary more than the other outcome measures. Similarly, the accepted inclusion criteria may vary by expect opinion. For example, an expert may only consider Clavien-Dindo classification of at least 3 a severe enough complication to define TO failure vs Clavien-Dindo classification of at least 2. However, the criteria in this study have all been used in previous TO research after other operations and increase the credibility of the criteria used herein.⁴ One may argue that the application of TO to elective LC is not a worthy endeavor, given the high rate of TO achievement. However, the frequency of elective LC, particularly in Western populations, means that the procedure incurs great cost and results in high absolute morbidity, and thus the importance of maximizing TO is vital.³³⁻³⁶ Last, if TO would be implemented as a part of a nationwide audit, defensive strategies such as strict patient selection in certain centers could emerge. This emphasizes that TO should always be used in addition to the other quality indicators. Textbook outcomes are not designed to replace single-quality indicators, but as an additional tool. In this sense, patientreported outcome measures will gain significance in future quality programs.³⁷

Conclusions

In this cohort study, we introduce the concept of TO after elective LC, propose the TO criteria, and identify reasons for TO failure. Our findings suggest that the use of TO increases the event rate, captures more aspects of patient care and experience, and provides a multidimensional view of patient outcomes. These outcomes should help better assessment of the quality of care provided and drive quality improvement.

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Author Contributions: Mr Lucocq had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

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