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ORIGINAL ARTICLE

A mixed-methods study to define Textbook Outcome for the treatment of patients with uncomplicated symptomatic gallstone disease with hospital variation analyses in Dutch trial data

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Abstract

Background: International consensus on the ideal outcome for treatment of uncomplicated symptomatic gallstone disease is absent. This mixed-method study defined a Textbook Outcome (TO) for this large group of patients.

Methods: First, expert meetings were organised with stakeholders to design the survey and identify possible outcomes. To reach consensus, results from expert meetings were converted in a survey for clinicians and for patients. During the final expert meeting, clinicians and patients discussed survey outcomes and a definitive TO was formulated. Subsequently, TO-rate and hospital variation were analysed in Dutch hospital data from patients with uncomplicated gallstone disease.

Results: First expert meetings returned 32 outcomes. Outcomes were distributed in a survey among 830 clinicians from 81 countries and 645 Dutch patients. Consensus-based TO was defined as no more biliary colic, no biliary and surgical complications, and the absence or reduction of abdominal pain. Analysis of individual patient data showed that TO was achieved in 64.2% (1002/1561). Adjusted-TO rates showed modest variation between hospitals (56.6-74.9%).

Conclusion: TO for treatment of uncomplicated gallstone disease was defined as no more biliary colic, no biliary and surgical complications, and absence or reduction of abdominal pain.TO may optimise consistent outcome reporting in care and guidelines for treating uncomplicated gallstone disease.

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Informed consent: Written informed consent was obtained from all participants.

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Introduction

Approximately, 5–25% of the Western population has gallstones.[1] The majority of patients with gallstones remain asymptomatic.[2,3] Only 20% of patients will develop typical episodes of a biliary colic, defined by the ROME III criteria.[4] Current international guidelines advise laparoscopic cholecystectomy (LC) to treat persistent symptomatic gallstone disease, while non-operative management is appropriate in patients with a single or infrequent biliary colic.[5,6] LC for uncomplicated gallstone disease is a safe procedure with an associated risk of severe complications (i.e. bile duct injury) of less than 2%.[7] However, up to 40% of patients suffer from persistent abdominal pain one year after LC, possibly due to imprecise patient selection for surgery.[8] Persistent symptoms compromise the affecting quality of life, and put a considerable burden on healthcare systems' expenses.[9]

Quality and outcome assessment is important in high volume surgical procedures.[10,11] However, the outcomes of treatment are commonly expressed as single indicators such as morbidity, mortality or readmission-rates, while patient-reported outcomes are less likely to be incorporated.[12] A composite endpoint that includes all relevant outcomes offers a better reflection of overall quality of treatment. Textbook outcome (TO) is an emerging composite outcome that includes all relevant treatment results that reflect a desirable treatment outcome.[13] A TO has been defined for several surgical procedures, but rarely for the management of gastrointestinal diseases such as gallstones.[14–16] International consensus on the definition of a specific TO for uncomplicated gallstone disease facilitates comparing relevant treatment outcomes between hospitals and in research.

The main objective of this mixed method study was to define TO for treatment of patients with uncomplicated gallstone disease, based on consensus in expert meetings and an international survey. Secondly, this study determines the TO-rate and the variation in TO-rate between hospitals in the Netherlands on basis of available prospectively generated patient data.

Methods

Study design

This study has a mixed methods approach, combining qualitative and quantitative methods to define a consensus-based definition of TO for treatment of patients with uncomplicated gallstone disease. As treatment may be managed through surgery (LC) or conservatively, the TO encompasses both treatment options. A flowchart of the steps of the study is shown in Fig. 1. First, two expert meetings were organized to identify all possible outcomes of treatment in patients with uncomplicated symptomatic gallstone disease. Only health related outcomes (e.g. pain reduction, complications, treatment satisfaction) were included. These outcomes were used for the design of the surveys. Subsequently, two surveys were developed to assess which of the outcomes were considered ideal outcomes: one survey for gastroenterologists and surgeons, which was distributed internationally and one survey for Dutch patients with a history of gallstone disease. Third, during a final expert meeting, the results from the survey were discussed by clinicians and patients to reach consensus on the definition of TO. In this step the final definition of TO was established. For the secondary aim, we benchmarked the established definition of TO using data from two Dutch multicentre trials, and compared the rate of TO between participating hospitals (step 4, Fig. 1). We followed the Standards for Quality Improvement Reporting Excellence (SQUIRE) guideline.[17] Patients and public were involved in the expert meeting and dissemination of the survey.

Final definition of Textbook Outcome

The primary endpoint is a consensus-based definition of TO for treatment of patients with uncomplicated gallstone disease. An agreement rate of >80% per surveyed outcome was considered as consensus and resulted in the item being included in the definition of TO.[18]

Expert meetings

In a first round, two expert meetings were organized (October 2021). The participants were nine gastrointestinal surgeons, two gastroenterologists, one methodologist (FA), and two patients with a history of symptomatic gallstone disease. The aim of these expert meetings was to list all possible outcomes for the design of the survey on operative and non-operative treatment for uncomplicated symptomatic gallstone disease. Participants were asked to think of both positive and negative outcomes, with or without undergoing surgery.

Survey among clinicians

To determine ideal outcomes for the definition of TO, an international survey with all possible outcomes from the first expert meetings was distributed among clinicians. The survey included 22 questions about possibly important outcomes after treatment such as abdominal pain and symptoms, satisfaction, complications (biliary and surgical), and de novo complaints after treatment (survey in Appendix I). Questions were scored on a 5-point Likert scale, ranging from strongly disagree to strongly agree. Additional questions on the respondents' occupation (surgeon or gastroenterologist), and resident in training or not in training were also part of the survey.

To disseminate the survey, we approached an international group of collaborating experts in the field of gastrointestinal surgery and gastroenterology. These experts were asked to disseminate the survey among colleagues through multiple channels including social media. We identified experts through a systematic literature search and contacted corresponding authors of studies on outcomes of LC published in the last 10 years. Dutch collaborating experts of the study group were local investigators of two prospective trials. The Dutch Society for

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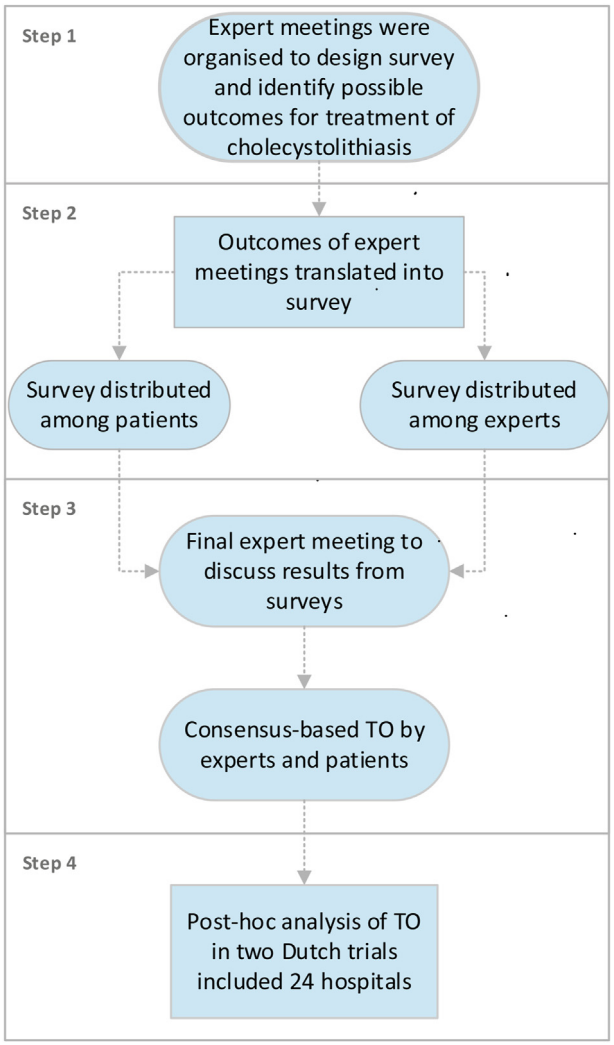

Figure 1 Flowchart of study steps This mixed method included four steps: Step 1: Expert meetings with experts and patients with history of gallstone disease, Step 2: (Inter)national survey among experts and patients, Step 3: Final expert meeting to discuss results from surveys and consensus-based TO by experts and patients, Step 4: Assessment of the TO-rate in Dutch trial data

Gastrointestinal Surgery (NVGIC), the Dutch Society for Gastroenterology (NVGE), the Association of Upper Gastrointestinal Surgery of Great Britain and Ireland (AUGIS), and the International Hepato-Pancreato-Biliary Association (IHPBA) distributed the survey among their members via direct e-mail and online. Additionally, the survey was distributed via social media including WhatsApp, Twitter, LinkedIn. As confirmation of expertise, surgeons were subsequently asked if the "critical view of safety" could be identified on a photo, and gastroenterologists were asked if the pylorus was visible on a photo taken during an upper gastrointestinal tract endoscopy. The survey was open between December 2021 and March 2022. Incomplete survey responses and responses with incorrect answers on confirmation of expertise were excluded from the analysis.

Survey among patients

In addition, to determine ideal outcomes for the definition of TO according to patients, a survey was conducted among patients with abdominal symptoms and gallstones who participated in recent multicentre Dutch trials (SECURE-trial, NTR4022), SUCCESS-trial (NTR7069), and PERFECT-trial (NTR7307)).[8,19,20] Patients who provided written consent to be contacted for future research were contacted by e-mail. The patient survey was based on the outcomes of the expert meetings and comprised 18 questions (survey in Appendix II). The questions were about possibly important treatment outcomes such as abdominal pain and symptoms, and complications (biliary and surgical complications). The survey was written in plain language and checked for easy reading Questions were scored on a 5-point Likert scale, ranging from strongly disagree to strongly agree. The survey was open between January 2022 and March 2022. Incomplete survey responses were excluded from analysis.

Consensus meeting and determination of TO-rates

In a final round (September 2022), two expert meetings were organized, and the same experts as the first round of expert meetings were involved. The aim of this final expert meeting was to reach consensus between clinicians and patients on the definition of the TO. The outcomes of both surveys among clinicians and patients were compared and discussed. Based on the agreement rate (consensus rate of >80% per surveys), items were selected and a TO was formulated. Final definition of a TO was defined during this last meeting.

Previous Dutch trials

Assessment of the TO-rate in real data was performed for all patients included in the SECURE and SUCCESS-trial.[8,19] In these studies, all patients aged 18–95 years old, referred to a surgical outpatient clinic for abdominal pain with ultrasound proven gallstone disease and/or sludge were eligible for inclusion. For the SECURE-trial, patients were included in 24 hospitals between February 2014 and April 2017. For the SUCCESS-trial, patients were included in 7 hospitals between October 2017 and June 2019. Six hospitals participated in both studies at different moments. In total, 1067 patients were included in the SECURE-trial and 494 patients in the SUCCESS-trial.[8,19]

In both studies, included patients received questionnaires after the first outpatient clinic visit (baseline) and at 6 months of follow-up. Patient characteristics (age, sex, BMI, history of abdominal surgery, smoking and use of alcohol) were registered

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at baseline. The study questionnaires consisted of the Izbicki Pain Score (IPS) and questions on abdominal symptoms.[21] The IPS consists of four questions regarding frequency of pain, use of pain medication, disease-related inability to work and intensity of pain based on a Visual Analog Scale (VAS-score, 0 = no pain and 10 = worst imaginable pain). After six months of follow-up, individual patients' medical records were examined for recurrence of biliary colic with hospitalization, biliary complications, and surgical complications. Surgical complications were classified in accordance with the Clavien-Dindo classification. Bile duct injuries were classified as minor or major.[22,23]

Statistical analyses

To describe the trial data, categorical variables were reported as counts with percentages and continuous variables as median values with corresponding Interquartile Ranges (IQR). Absence of pain was defined as a VAS $\leq$4 and clinically relevant pain reduction as a reduction of at least 4 points on the VAS pain score after 6 months (baseline VAS pain score minus 6-month VAS pain score, ΔVAS>4). TO was achieved if a patient met all selected criteria for a TO at six months of follow-up (Box 1).[13]

Hospital variation in TO-rates were analysed. To avoid small sample variation, hospitals with less than 30 included patients were excluded from these analyses. TO-rates per hospital were adjusted for patient characteristics (case-mix adjusted (standardized) TO-rate per hospital). The calculation of the case-mix-adjusted TO per 100 gallstone patients consisted of 3 steps: first, crude TO-percentages were calculated (observed rates). Second, a logistic regression with TO as outcome and age, sex, and BMI >25 kg/m^2 as covariates was performed to assess the expected TO-rate per hospital; third, the observed TO-rate per 100 patients was divided by the expected TO-rate per 100 patients and multiplied by the national average of TO.

To express the amount of variation, histograms were drafted and the factor difference between high and low hospitals was calculated. Subsequently, the mean of the case-mix-adjusted TO-rates of the three highest hospitals was divided by the mean of the case-mix-adjusted TO-rates of the three lowest hospitals. We consider a factor score of more than 2.0 as a modest and relevant variation. Factor scores were calculated between hospitals. A funnel plot was constructed to detect outliers and to distinguish systematic variation from random variation. Data analysis was performed using SPSS, version 27.0 (IBM) and R version 4.1.3.

Results

Outcomes of expert meetings

In total, fifteen different experts (surgeons, gastroenterologists, methodologist and patients with a history of gallstone disease) participated in two expert meetings (Table 1, Step 1). Expert meetings resulted in 32 different important clinical outcomes for treatment of uncomplicated gallstone disease. The 32 different outcomes were subdivided into eleven subgroups (Table 1, Step 2). The eleven outcome subgroups included biliary complications, surgical complications, morbidity and mortality, abdominal pain and symptoms, satisfaction, daily activities, food intolerance, de novo symptoms, referral, new diagnostics, treatment and treatment costs. Outcomes of expert meetings were translated into surveys and disseminated among clinicians and patients. An overview of the first expert meetings and survey responses is shown in Table 1 and Table 2.

Box 1. Textbook outcome for treatment of patients with uncomplicated gallstone disease.

Composite Textbook Outcome for treatment of uncomplicated gallstone disease:

No recurrent biliary colic with hospitalization
and
Absence or reduction of abdominal pain
and
Absence of biliary complications
and
Absence of surgical complications

Survey for clinicians

Between December 2021 and March 2022, 830 clinicians responded to the survey. The survey was completed by 603 clinicians (72.6%) from 81 countries.(Table 2) Three percent of the responders (n = 26) incorrectly answered the question to test their expertise and were excluded from the analysis. An agreement rate of >80% per surveyed item was achieved in five outcomes: no recurrent biliary colic with hospitalization (90% agreement rate), absence of abdominal pain after treatment (88%), no surgical complications (86%), patient is satisfied (85%), no biliary complications (81%).

Survey for patients

Between January 2022 and March 2022, 1653 patients received a digital invitation for the survey, of whom 645 opened the survey. The survey was completed by 490 patients (75.9%). (Table 2) An agreement rate of >80% per surveyed item was achieved in eight outcomes: no recurrent biliary colic with hospitalization (94%), impairment of daily activities (93%), good physical health (89%), good night's sleep (87%), absence of food intolerance (86%), absence of abdominal pain after treatment (84%), no biliary complications (83%), pain reduction after treatment (82%).

Consensus-based TO

In a final expert meeting, a consensus based TO was established based on outcomes of the surveys. Outcomes considered to be not

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Table 1 Participants and outcomes of expert meeting sessions and international survey participants

Step 1. Expert meeting sessions participants[1]			
Participants	Total	Session 1	Session 2
Gastrointestinal surgeon, n	9	5	4
Gastroenterologist, n	2	1	1
Methodologist, n	1	1	1
Patient with history of gallstone disease, n	2	1	1
Step 2. Complications and outcomes reported in expert meetings and subsequently included in the survey[2]			
Biliary related	Cholecystitis Biliary pancreatitis Choledocholithiasis Cholangitis Icterus Post-ERCP complication Mirizzi-syndrome		
Surgery related	Surgical related complications like wound infection Bile duct injury and bile leakage Bile duct stenosis		
Morbidity and Mortality	Hospital admission ICU admission Deceased		
Abdominal pain and symptoms	Absence or reduction of abdominal pain Absence of biliary colic No recurrent biliary colic with hospitalization No improvement of abdominal pain after cholecystectomy Spontaneous recovery of abdominal pain without treatment		
Satisfaction	Satisfied patient after treatment		
Daily activities	Hindrance due to abdominal complaints during daily activities (i.e., work, sleep, and hobbies)		
Food intolerance	Normal food habits pre and post cholecystectomy Diet with or without biliary colic		
De novo symptoms	No bloating No diarrhoea Normal defecation No weight-gain		
Referral	No new referral for persistent abdominal complaints		
New diagnostic and treatment	Upper GI-endoscopy tract endoscopy ERCP		
Treatment costs	No extra healthcare costs Reduction of healthcare costs		
Step 3. Response of (inter)national survey			
	Clinicians	Patients	
Total respondents, n	830	645	
Completed, n (%)	603 (72.6)	490 (75.9)	
Countries	81	1	
Age, median (IQR)	43.0 (36.0–53.0)	56.0 (45.0–64.0)	
Surgeons/Gastroenterologists, n (%)	781 (94)/49 (6)		

Abbreviations: Endoscopic Retrograde Cholangiopancreatography (ERCP), Intensive care unit (ICU), Gastrointestinal (GI), Interquartile Ranges (IQR).

directly affected by treatment for symptomatic gallstone disease (such as good physical health) were discarded after discussion with participating patients. The definitive TO for treatment of patients with uncomplicated gallstone disease was defined as follows: no recurrent biliary colic with hospitalization, absence or relief of abdominal pain after treatment, absence of biliary complications (i.e., acute cholecystitis, biliary pancreatitis, choledocholithiasis and cholangitis), and absence of surgical complications (i.e. bile duct injury and bile leakage) regardless the duration of follow-up. The consensus based TO is shown in Box 1.

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Table 2 Agreement rate of items from surveys in which consensus was reached in clinicians and patients with a history of uncomplicated gallstone disease

Reported outcome	Agreement rate among 603 clinicians	Reported outcome	Agreement rate among 490 patients
No recurrent biliary colic with hospitalization[a]	90%	No recurrent biliary colic with hospitalization[a]	94%
Absence of abdominal pain[a]	88%	No hindrance in daily activities	93%
No surgical complications[a]	86%	Good physical health	89%
Patient is satisfied	85%	Good night's sleep	87%
No biliary complications[a]	81%	Absence of food intolerance	86%
		Absence of abdominal pain[a]	84%
		No biliary complications[a]	83%
		Pain reduction[a]	82%

An agreement rate of 80% per item was considered as consensus.
[a] Outcome item was selected as criteria for composite TO.

TO-rate and hospital variation

Hospital variation in TO-rates were analysed in the trial data of two Dutch trials.[8,19] Overall, TO was achieved in 64.2% of patients (1002/1561). Patients who underwent LC reached TO more often compared to patients with conservative treatment (76.1% vs. 64.1%, $P < .001$).

The main cause of not reaching a TO was persistent abdominal pain, reported by 365 of the 1561 patients (23.4%). A biliary complication occurred in 108 patients (6.9%); recurrent biliary colic resulting in hospital admission in 47 patients (3.0%), other biliary complications (i.e. cholecystitis, biliary pancreatitis) in 61 patients (3.9%). A surgical complication occurred in 13.7% of patients (154/1124); bile duct injury in 1.1% of patients (12/1124), of which four were major bile duct injury (0.4%). The overall rate of TO and the contribution of individual criteria in reaching a TO are shown in Fig. 2 and Appendix (Tables 3 and 4).

Eight of the 24 participating hospitals were excluded because of less than 30 included patients, leaving 1432 patients from 16 hospitals for the variation analyses (91.7%, 1432/1561). There were 14 general hospitals and two academic hospitals. TO was achieved in 63.8% of patients (914/1432) in 16 hospitals and thus comparable with the proportion of TO (64.2%) in the total population of 24 hospitals. The histogram (Fig. 3) with unadjusted TO-rates shows modest variation between hospitals, ranging from 56.6% to 75.6%. Standardized TO-rates ranged from 56.6% to 74.9%. The calculated factor score was 1.26. The funnel plot shows there were no systematic outliers (see Fig. 4).

Discussion

This study reports an international consensus-based definition of TO for the treatment of patients with uncomplicated gallstone disease. TO in these patients was defined as no recurrent biliary colic with hospitalization, absence or reduction of abdominal pain, absence of biliary complications and absence of surgical complications. Post-hoc analysis of Dutch trial data showed that 64% of patients treated for uncomplicated gallstone disease reached a TO with modest outcome variation between hospitals and without any true outliers.

The multidimensional indicator TO is a novel but emerging measure for the quality of medical treatment outcomes.[14,15] Surgical treatments with high impact have been evaluated based on the TO strategy. In relation to the TO defined in the present study, experiences of clinicians, as well as patients, were considered. TO for patients with gallstones is a composite measure of patient-reported outcomes and biliary and surgical complications. The reported complication rates in the analysed patient series are low and consistent with the literature.[1,24] Although surgery is associated with a higher TO rate than conservative management (76.1% vs. 64.1%, $P < .001$), improved patient selection for surgery remains critical as the most modifiable factor contributing TO is the reduction of persisting abdominal pain after cholecystectomy. Persisting pain may be explained by the fact that 30% of patients with gallstone disease fulfil the criteria for FGID (i.e. functional dyspepsia and irritable bowel syndrome) and underlying FGID negatively impact the outcome of cholecystectomy.[20] Moreover, the indication for cholecystectomy for uncomplicated gallstone disease varies among clinicians and guidelines.[25] There is no (international) consensus on the best criteria to select patients resulting in preference-sensitive care in cholecystectomy practices.[26] The selection of patients for cholecystectomy is challenging and the ROME III criteria fail to serve as diagnostic tool to deselect patients for cholecystectomy.[8] Recently, our study group developed a clinical decision tool to predict the probability of pain reduction after cholecystectomy. This validated model may aid surgeons and patients in deciding whether an operation will contribute to pain-relief and improve selection. A tool which may lead to higher TO-rates.[19] A formal three-round Delphi

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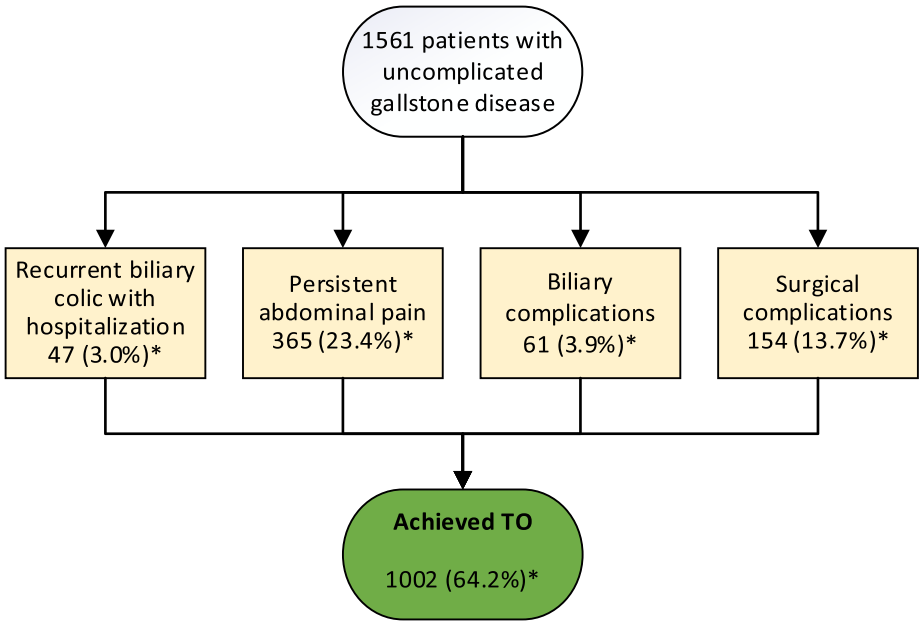

Figure 2 **Contribution of selected criteria in achieving Textbook Outcome** * Textbook Outcome (TO) for treatment of patients was defined as no recurrent of biliary colic with hospitalization, absence or reduction of abdominal pain, absence of biliary complications, and absence of surgical complications. TO was determined in 1561 patients from 24 hospitals

survey recently led to a core outcome set for symptomatic gallstone disease. The developed set corroborates with the present outcome set that includes quality of life, patient satisfaction, postoperative pain, and surgical complications yet does not precisely define included outcomes.[27] A potential pitfall of a Delphi round is the selective recruitment and sustained participation of stakeholders. International dissemination via social media and a survey among patients may reflect values from more different stakeholders and perspectives from other national healthcare systems. The added value of the present TO is a specific definition of outcomes and validation in a large group of international clinicians and patients. Compared to the core outcome set, the current TO is applied in clinical data, illustrating the potential application to optimize consistent outcome reporting in care, clinical trials and guidelines for patients with symptomatic gallstones. A recent retrospective analysis from the UK assessed a different TO definition for LC in 2166 patients and reported a TO rate of 85%.[28] TO was defined as an unremarkable surgical procedure without post-operative complications, leaving out patient-reported outcomes. Our expert meeting agreed that a

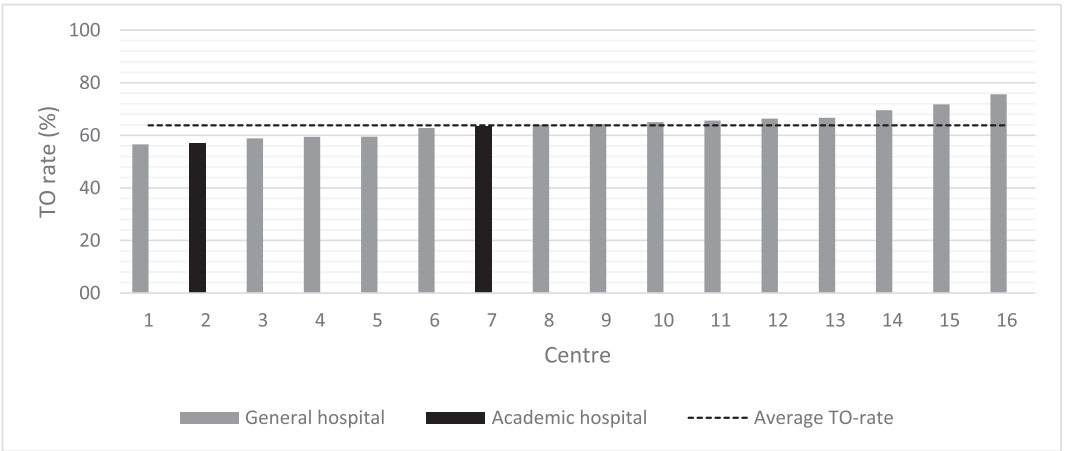

Figure 3 **Histogram with unadjusted TO-rates between hospitals** Eight of the 24 participating hospitals were excluded because of less than 30 included patients, leaving 1432 patients from 16 hospitals for the variation analyses. Average TO-rate was 63.8% (914/1432). Unadjusted TO-rate ranging from 56.6% to 75.6%

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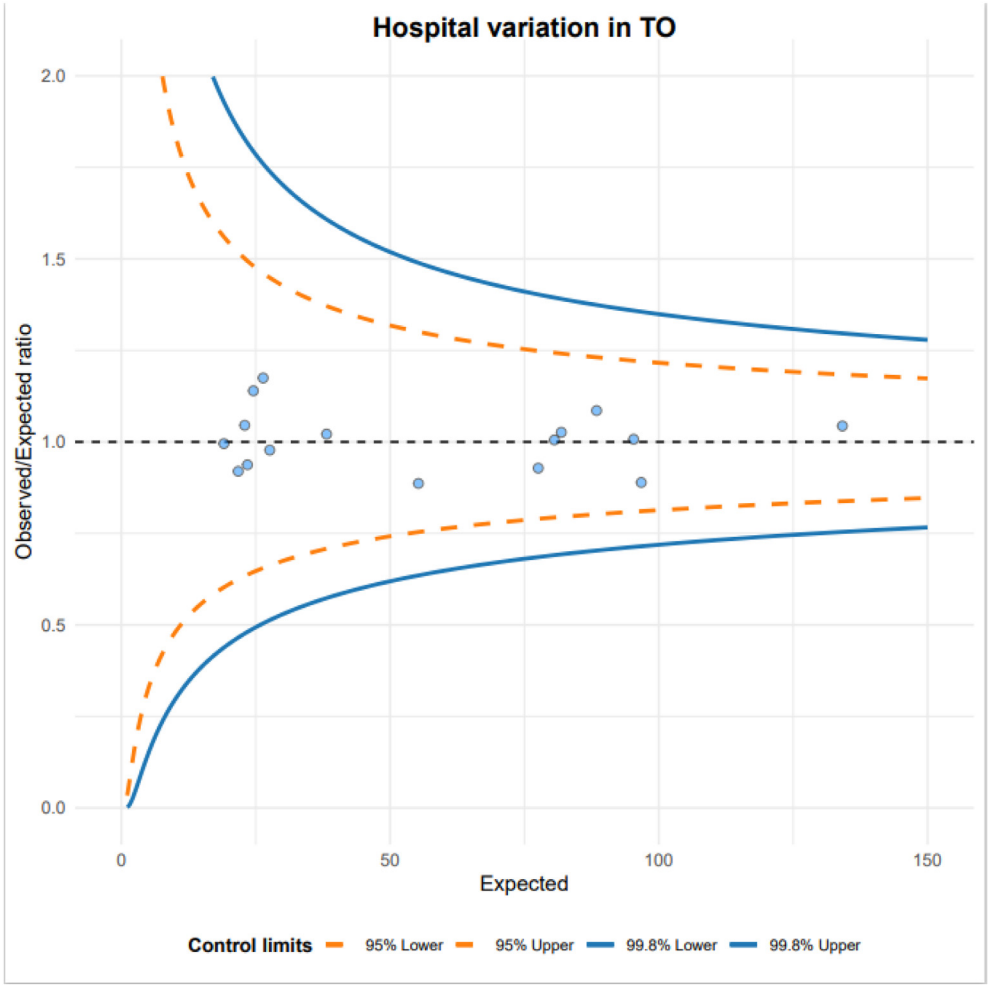

Figure 4 Funnel plot of between-hospital variation in Textbook Outcome after treatment for gallstone disease during 2014–2019
*Observed/Expected ratio: observed number of Textbook Outcome patients divided by expected number of Textbook Outcome patients. ** Expected number of patients achieving TO, based on population characteristics (age, BMI and gender)

surgically focused definition shows insufficient equality of the most important stakeholder, the patient.

This study has strengths and limitations. To define TO, comprehensive methods were used in which both clinicians and patients were involved. The composed surveys were distributed by colleagues, and national and international associations. The established collaborative group was able to reach clinicians from 81 countries from all continents, which provides a support base for future implementation of this TO in clinical practice. In addition, an assessment of TO in Dutch trial data was performed to provide valuable insight into the impact of specific factors in reaching a TO.

This study has several limitations. For instance, no formal Delphi method was performed to reach consensus. This was considered but not achieved during the initiation phase of the project due to practical considerations. Regardless, the adopted method provided possibilities for regular feedback during different stages of the study (i.e. during expert meetings, within the survey and during the final consensus meetings). Furthermore, patient reported outcome measures may not always be suitable for a TO as not all outcomes relevant to patients were included in the definitive TO. For example, 87% of patients indicated that a good night's sleep should be in the TO. During the final expert meetings, outcomes such as sleep were discussed, and it was determined that they were too non-specific for gallstone disease and depended on too many other factors. Cardiopulmonary complications are relevant outcomes for elderly patients, but this was not separately reported. Although patients with uncomplicated gallstone disease in the present series are relatively young (mean age 50) and healthy (85% ASA I), cardiopulmonary complications are more prevalent in an older population, more prone to complicated gallstone diseases such as cholecystitis and choledocholithiasis. Finally, neither the expert meeting members nor the experts defined a time period within which TO should be achieved. In the present

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analysis TO rate was assessed at six months follow-up, but the need for longer follow-up is for discussion.

The reported between-hospital variation in TO-rate shows that measuring TO for patients with gallstones is a feasible, transparent and is an informative way to assess quality assurance. The present international collaboration and global survey to define TO for patients with gallstones may serve as a basis for an international benchmark in future gastrointestinal care. This benchmark addresses the need to include patient-reported outcomes in quality assessments. Implementation of TO in local services will not primarily drive clinicians to reduce biliary and surgical complications but mainly to better select patients for cholecystectomy and reduce the number of patients with postoperative abdominal pain.

In conclusion, TO for treatment of patients with symptomatic gallstones is defined with input from patients, surgeons and gastroenterologists. Variation between hospitals in TO-rate is modest, and failure to achieve a TO in gallstone patients is primarily due to persistent abdominal pain. These findings both illustrate the need to better select patients for either conservative or operative treatment.

Author contribution

Thunnissen and Comes contributed substantially to the conception, design, acquisition, analysis, and interpretation of data for the work, and drafted the manuscript, approved the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Latenstein, Stommel, van Laarhoven, Drenth, Lantinga contributed substantially to the acquisition of data and interpreted the data for the work, revised the manuscript critically for important intellectual content, approved the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

De Reuver, Atsma contributed substantially to the conception and design of the work, interpreted the data for the work, revised the manuscript critically for important intellectual content, approved the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Thunnissen and Comes had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

International collaborators are experts in the field of gastrointestinal surgery and gastroenterology and contributed in the dissemination of the survey, support the conclusions and approved the final version of the manuscript before submission. Patients participating in the expert meetings are listed as collaborators.

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Patient and public involvement

Patients were involved during different study phases, in the design of the survey for patients and interpreted the data for the work.

Provenance and peer review

Not commissioned; internally peer reviewed.

Conflicts of interest

Dr Drenth reports grants from Gilead outside the submitted work, paid to the Radboud University Medical Center.

Appendix

Table 3 Baseline characteristics of patients included for Textbook Outcome (TO) analysis in Dutch trial data

	Total (N = 1561)	TO (N = 1002)	No TO (N = 559)	*P*
Sex, female n (%)	1143 (73.2)	728 (72.7)	415 (74.2)	0.498
Age, median (IQR)	50 (38.0–60.0)	50.0 (39.0–60.0)	49.0 (38.0–60.0)	0.143
BMI, median (IQR)	27.5 (24.7–31.4)	27.4 (24.6–31.2)	28.0 (24.8–31.9)	0.074
History of abdominal surgery, yes (%)	590 (37.8)	363 (36.2)	227 (40.6)	0.087
Biliary colic, yes (%)	1046 (67.0)	699 (69.8)	347 (62.1)	0.002
Treatment at 6 months				
Laparoscopic cholecystectomy, yes (%)	1124 (72.0)	763 (76.1)	361 (64.6)	<0.001

BMI missing for 1 patient (0.064%)Biliary colic in accordance with the ROME-criteria (severe pain attacks, located in the right upper quadrant or epigastrium, lasting for at least 15–30 min).

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Table 4 Patient outcomes of individual criteria of the Textbook Outcome (TO)

Selected criteria for TO	Total (N = 1561)
No recurrent biliary colic with hospitalization, n (%)[b]	1514 (97.0)
Recurrent biliary colic with hospitalization, n (%)	47 (3.0)
Absence or reduction of abdominal pain, n (%)[a,b]	1196 (76.6)
Persisting abdominal pain, n (%)	365 (23.4)
No biliary complications, n (%)[b]	1500 (96.1)
Biliary complication, n (%)	61 (3.9)
Cholecystitis, n (%)	21 (1.3)
Choledocholithiasis, n (%)	32 (2.0)
Cholangitis, n (%)	0
Biliary pancreatitis, n (%)	8 (0.5)
No surgical complication, n (%)[b]	970/1124 (86.3)
Surgical complication, n (%)	154 (13.7)
Bile duct injury[c]	
Minor injury, n (%)	8 (0.5)
Major injury, n (%)	4 (0.3)
Conservative therapy, n (%)	437 (27.9)
Composite Textbook Outcome rate, n (%)[b]	1002 (64.2)

[a] Absence or reduction of abdominal pain was defined as VAS $\leq$4 or reduction VAS pain score $\geq$4 points.
[b] For the TO, the following criteria were selected: no recurrent of biliary colic with hospitalization, absence or reduction of abdominal pain at six months of follow-up, absence of biliary complications, and absence of surgical complications. TO was achieved in 1002 of 1561 patients.
[c] Bile duct injury is classified in minor or major injury (Bergman JJ. et al. Gut 1996).[23]

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpb.2023.05.005.

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