

REVIEW ARTICLE

# Reporting of complications after laparoscopic cholecystectomy: a systematic review

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## Abstract

**Background:** Consistent measurement and reporting of outcomes, including adequately defined complications, is important for the evaluation of surgical care and the appraisal of new surgical techniques. The range of complications reported after LC has not been evaluated. This study aimed to identify the range of complications currently reported for laparoscopic cholecystectomy (LC), and the adequacy of their definitions.

**Methods:** MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials were searched for prospective studies reporting clinical outcomes of LC, between 2013 and 2016.

**Results:** In total 233 studies were included, reporting 967 complications, of which 204 (21%) were defined. One hundred and twenty-two studies (52%) did not provide definitions for any of the complications reported. Conversion to open cholecystectomy was the most commonly reported complication, reported in 135 (58%) studies, followed by bile leak in 89 (38%) and bile duct injury in 75 (32%). Mortality was reported in 89 studies (38%).

**Conclusion:** Considerable variation was identified between studies in the choice of measures used to evaluate the complications of LC, and in their definitions. A standardised set of core outcomes of LC should be developed for use in clinical trials and in evaluating the performance of surgical units.

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## Introduction

Gallstone disease is a common and costly health condition, affecting approximately 20 million people and resulting in 1.8 million ambulatory care visits per year in the United States (U.S.).<sup>1,2</sup> Cholecystectomy is the most common elective abdominal surgery in the U.S. with an estimated 750,000 operations performed annually, the vast majority of which are laparoscopic.<sup>3</sup>

The objectives of laparoscopic cholecystectomy (LC) are disability-free survival with relief of symptoms, and their assessment via patient-reported outcome (PRO) measures (PROMs) is gaining prominence.<sup>4</sup> Complications following LC impact negatively on these desired outcomes, and should also be reported.<sup>5</sup> These range from superficial surgical site infection, through major causes of serious morbidity, such as bile duct injury (BDI),<sup>6–8</sup> to death.

However, for complications reported in research and audit to be properly understood, they need to be clearly defined, either within the report, or by reference to previous publications that contain adequate definitions. Consistency in the reporting of complications is necessary for valid comparisons to be made between studies or between surgical units, for monitoring performance over time, and for the amalgamation of data in meta-analyses.<sup>9</sup>

Previous systematic reviews have identified substantial variation in the reporting and definition of complications following oesophagectomy and colorectal resection,<sup>9,10</sup> but none have reviewed the range, adequacy and consistency of the measurement and reporting of complications for LC. The identification of a small number of clearly defined complications for universal use in the evaluation of the quality of LC could facilitate more

consistent investigation of outcomes following LC, and also allow for benchmarking or monitoring of the performance of surgical care.<sup>3,11,12</sup> Recent trends towards the public reporting of surgical outcomes data make the latter application particularly important.<sup>13–16</sup>

This systematic review of the literature aimed to identify the range of complications measured and reported for LC, and the consistency of the definitions of the measures reported. The objectives of the reviewed studies were considered to inform the interpretation of any differences identified in the complications selected for reporting.

## Methods

### Data sources and search strategy

OVID Medline, EMBASE, and the Cochrane Central Register of Controlled Trials were searched using terms for ‘laparoscopic cholecystectomy’ and ‘randomised controlled trials or prospective studies’. MeSH terms for the search string are provided in [Supplementary Table 1](#). The search was limited to papers published in English between 1 January 2013 and 31 December 2016. Definitions for terms used in this review are provided in [Supplementary Table 2](#).

Prospective studies reporting clinical outcomes of LC were eligible for inclusion in this study. Retrospective analyses of prospectively collected data were included as these studies typically define complications prior to data collection.

A complication was defined as any undesired outcome reported after LC, with the exclusion of hematological, biochemical, physiological, or patient-reported outcomes.<sup>10</sup> Length of hospital stay, re-intervention and re-admission to hospital were also examined, as these may indirectly reflect the occurrence of complications. Conference abstracts, review papers, and studies reporting outcomes of LC in paediatric patients or for gallbladder carcinoma were excluded. Where multiple papers were published for the same cohort of patients, the first published study was selected.

Studies reporting the outcomes of combined procedures were excluded. Studies reporting outcomes of LC, after previous surgery or pre-operative endoscopic treatment, were included, provided outcomes of LC were reported separately.

### Data extraction

The titles and abstracts of all identified articles were screened independently by two reviewers (HA and CW), and a list of papers for full-text evaluation developed; discrepancies were resolved by discussion.

The identified articles were then reviewed by a single reviewer (HA), and data extracted into an electronic spreadsheet. A random sample of 25 articles also underwent independent data extraction by a second reviewer (CW), and a Cohen’s kappa agreement value was calculated to determine accuracy of data extraction.

### Study details

The following details were recorded for each study: year of publication, authors, title, journal, design (prospective observational study or randomised controlled trial), number of centres, number of surgeons, and number of LC. Retrieval of data from prospectively maintained multi-centre databases was also recorded. The indication for LC was recorded, as was the timing of the operation (acute, elective or early versus delayed). Study objectives were grouped into the following categories: comparison of surgical techniques, comparison of non-surgical interventions, evaluation of the rates of a specific outcome, evaluation of the outcomes of LC in a specific patient group, and presentation of a case series.

### Operative details

Details regarding the operative technique of LC were recorded, including the number of trocars and duration of operation.

Intra-operative blood loss and perforation of the gallbladder were considered technical outcomes. Reporting of intra-operative blood loss was classified as complete if the volume of intra-operative blood loss was provided and partially complete if intra-operative bleeding was described without giving specific volumes.

The reporting of length of stay, readmission, and re-intervention rates was examined. Studies were assessed for the provision of a defined time-period for the measurement of re-admission and re-intervention rates.

### Complications other than mortality

All complications of LC reported by studies were extracted and the papers examined for definitions. Where studies reported data from prospectively maintained multi-centre databases, such as the American College of Surgeons National Surgical Quality Improvement Program (NSQIP),<sup>17</sup> these registries were examined for definitions.

Each study was categorized as follows: no complications defined; 1–25% of reported complications defined; 26–50% defined; 51–75% defined; and >75% of complications defined. The number of unique definitions for each commonly reported complication was recorded. Definitions were considered unique on the basis of differences in content or phrasing.

Studies were examined for specification of primary or secondary outcomes. Where complications were considered as primary endpoints, the provision of definitions for these was examined.

Grading of complications by severity was also examined. The studies were also assessed as to whether a formal, validated severity rating scale such as the Clavien-Dindo classification had been used.<sup>18</sup>

Studies were examined for either risk adjustment of outcomes or provision of the American Society of Anesthesiologists (ASA) physical status classification system or Charlson Comorbidity Index (CCI) of the participants.<sup>19,20</sup>

**Table 1** Summary of included studies, selected operative details and outcome measures other than specific complications<sup>a</sup>

	All (n = 233)	RCT (n = 125)	Prospective observational (n = 82)	Database (n = 24)
Indication for laparoscopic cholecystectomy:				
Specified	198 (85%)	114 (91%)	68 (83%)	14
Not specified	35 (15%)	11 (9%)	14 (17%)	10
Operative technique <sup>b</sup> :				
Four-port or standard	110 (47%)	74 (59%)	35 (43%)	1
Three port	27 (12%)	17 (14%)	10 (12%)	0
Single-port	57 (24%)	36 (29%)	20 (24%)	1
Not specified	89 (38%)	35 (28%)	29 (35%)	23
Operative timing:				
Acute	23 (10%)	11 (9%)	9 (11%)	3
Elective	129 (55%)	81 (65%)	42 (51%)	5
Both	33 (14%)	7 (6%)	17 (21%)	9
Early/delayed	15 (6%)	11 (9%)	3 (4%)	0
Not specified	33 (14%)	15 (12%)	11 (13%)	7
Gallbladder perforation reported:				
Yes	44 (19%)	32 (26%)	8 (10%)	3
No	180 (77%)	85 (68%)	73 (89%)	21
Excluded	9 (4%)	8 (6%)	1 (1%)	0
Intra-operative blood loss reported:				
Yes	45 (19%)	33 (26%)	12 (15%)	0
Partial	58 (25%)	35 (28%)	19 (23%)	3
No	130 (56%)	57 (46%)	51 (62%)	21
Operating time reported:				
Yes	175 (75%)	108 (86%)	59 (72%)	8
No	58 (25%)	17 (14%)	23 (28%)	16
Length of Stay (L.O.S) reported:				
Yes	180 (77%)	105 (84%)	56 (68%)	18
No	53 (23%)	20 (16%)	26 (32%)	6
ICU L.O.S/admissions reported:				
Yes	13 (6%)	4 (3%)	8 (10%)	1
No	218 (94%)	119 (95%)	74 (90%)	23
Excluded	2 (1%)	2 (2%)	0 (0%)	0
Rates of readmission reported:				
Yes	53 (23%)	29 (23%)	19 (23%)	5
No	180 (77%)	96 (77%)	63 (77%)	19
If readmission reported, was a time frame reported: (n = 53)				
Yes	25 (47%)	12	8	5
No	28 (53%)	17	11	0
Rates of re-Intervention reported:				
Yes	99 (42%)	49 (39%)	39 (48%)	11
No	132 (57%)	74 (59%)	43 (52%)	13
Excluded	2 (1%)	2 (2%)	0 (0%)	0

**Table 1** (continued)

	All (n = 233)	RCT (n = 125)	Prospective observational (n = 82)	Database (n = 24)
If re-intervention reported, was a time frame reported: (n = 99)				
Yes	17 (17%)	5	9	3
No	82 (83%)	44	30	8

<sup>a</sup> Studies with dual study design (n = 2) are not included in this table.

<sup>b</sup> Studies reporting multiple operative techniques (such as conventional LC and single-incision LC) were counted in multiple categories.

Where applicable, blinding was assessed. Details on the time frame over which complications were measured, and on duration of follow-up, were recorded.

### Mortality

All measures used to report death were extracted and examined for provision of a definition. Definitions were classed as complete or partially complete on the basis of the provision of a time frame and place of death.<sup>9</sup>

### Results

The search identified 2480 articles, which were reduced to 357 after excluding duplicates and screening titles and abstracts (Supplementary Fig. 1).<sup>69</sup> The Cohen's kappa for agreement with the second reviewer was >99%.

The full texts of these 357 articles were reviewed and 233 were deemed eligible for inclusion, including 125 randomised controlled trials, 106 prospective observational studies, and two papers with dual study designs. Of the prospective studies, 24 reported outcomes from 13 unique prospectively maintained multi-centre databases. In these 233 papers, outcomes were reported for a total of 5,420,181 LC. Study details are shown in Table 1.

In 97 studies (42%) the objective was to compare the outcomes of different surgical techniques for LC. A further 46 articles (20%) evaluated the outcomes of non-surgical interventions in LC cohorts. Twenty-one papers (9%) aimed to evaluate the incidence of, or risk factors for, a particular outcome after LC. Fifteen papers (6%) presented a case series of LC, 10 of which described a novel technique. A further fifteen papers (6%) compared the outcomes of LC in different populations. Thirty-nine papers (17%) could not be classified into these categories. A specific study hypothesis was provided in 47 studies (20%).

### Operative details

Outcomes of four-port or conventional LC were reported in 110 studies (47%), compared to 57 studies (24%) which reported outcomes of single incision LC. Operative details about the laparoscopic approach (number of ports) were absent in 89 studies (38%). Reporting of blood loss and gallbladder perforation is

**Table 2** Summary of reporting of complications other than mortality<sup>a</sup>

	All (n = 233)	RCT (n = 125)	Prospective observational (n = 82)	Database (n = 24)
Defined/total complications reported	204/976 (21%)	90/552 (16%)	55/329 (17%)	57/91
Proportion of complications defined:				
No complications defined	122 (52%)	71 (57%)	45 (55%)	5
0–25% of complications defined	29 (12%)	18 (14%)	10 (12%)	1
26–50% of complications defined	31 (13%)	18 (14%)	11 (13%)	2
51–75% of complications defined	9 (4%)	2 (2%)	5 (6%)	1
76–100% of complications defined	25 (11%)	10 (8%)	6 (7%)	9
No complications reported	17 (17%)	6 (5%)	5 (6%)	9
Total morbidity rate provided:				
Yes	132 (57%)	73 (58%)	46 (56%)	11
No	101 (43%)	52 (42%)	36 (44%)	13
If total morbidity was reported, was this defined? (n = 132)				
Yes	20 (15%)	9 (12%)	7	4
No	112 (85%)	64 (88%)	39	7
BDI reported:				
Yes	75 (32%)	40 (32%)	31 (38%)	4
No	156 (67%)	83 (66%)	51 (62%)	20
Excluded	2 (1%)	2 (2%)	0 (0%)	0
Bile leak reported:				
Yes	89 (38%)	54 (43%)	33 (40%)	2
No	143 (61%)	71 (57%)	48 (59%)	22
Excluded	1 (0%)	0 (0%)	1 (1%)	0
Conversion to open reported:				
Yes	135 (58%)	76 (61%)	49 (60%)	9
No	65 (28%)	27 (22%)	25 (30%)	13
Excluded	33 (14%)	22 (18%)	8 (10%)	2
Wound infection reported:				
Yes	118 (51%)	75 (60%)	34 (41%)	8
No	115 (49%)	50 (40%)	48 (59%)	16
Hernia reported:				
Yes	50 (21%)	30 (24%)	19 (23%)	1
No	182 (78%)	94 (75%)	63 (77%)	23
Excluded	1 (0%)	1 (1%)	0 (0%)	0
Retained stones reported:				
Yes	49 (21%)	27 (22%)	19 (23%)	1 (4%)
No	184 (79%)	98 (78%)	63 (77%)	23 (96%)
Grading of complications by severity:				
Yes (formal severity rating scale)	26 (11%)	15 (12%)	9 (11%)	2
Yes (categorization only)	59 (25%)	36 (29%)	17 (21%)	6
No	148 (64%)	74 (59%)	56 (68%)	16
Adjustments made for pre-operative risk:				
Yes	175 (75%)	125 (100%)	25 (30%)	23
No (ASA/CCI given)	23 (10%)	0 (0%)	23 (28%)	0
No (ASA/CCI not given)	35 (15%)	0 (0%)	34 (41%)	1

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Table 2 (continued)

	All (n = 233)	RCT (n = 125)	Prospective observational (n = 82)	Database (n = 24)
Personnel assessing presence of complications reported:				
Yes (Blinded)	14 (6%)	14 (11%)	0 (0%)	0
Yes (Not blinded)	27 (12%)	8 (6%)	7 (9%)	11
Yes (Independent)	9 (4%)	8 (6%)	0 (0%)	1
No	183 (79%)	95 (76%)	75 (91%)	12
Time frame for assessment of complications given:				
Yes	122 (52%)	68 (54%)	32 (39%)	20
No	111 (48%)	57 (46%)	50 (61%)	4
Follow up time given:				
Yes	132 (57%)	84 (67%)	43 (52%)	4
No	101 (43%)	41 (33%)	39 (48%)	20

<sup>a</sup> Studies with dual study design (n = 2) are not included in this table.

shown in Table 1. Length of hospital stay was reported in 180 studies (77%). Rates of re-admission and re-intervention were reported in 53 (23%) and 99 (42%) studies respectively.

### Complications other than mortality

Of the 233 included studies, 216 (93%) reported rates of at least one complication (Table 2). Seventeen studies (7%) did not report any complications, but were eligible for inclusion because they reported other clinical outcomes (length of stay, mortality, re-admission, or re-intervention rates).

A total of 976 complications were reported, of which 204 (21%) were defined. In RCTs, 90/552 (16%) of complications were defined, compared to 55/329 (17%) in prospective observational studies and 57/91 (63%) in database studies. One-hundred and twenty-two studies (52%) did not define any

complications. A total of 108 complications were specified as primary endpoints in 42 studies (18%). Definitions were provided for forty-eight (44%) of these complications. An overall complication rate was reported by 132 studies (57%), of which 20 (15%) offered a definition for this outcome measure.

Bile leak was reported in 89 studies (38%) and defined in 15 (6%). BDI was reported in 75 studies (32%) and defined in 13 (6%), using 10 different definitions (Table 3). Hernia was reported in 50 studies (21%) and defined in 15 (6%). Wound infection was reported in 118 (51%) and defined in 24 (10%), using 16 different definitions (Table 4). Conversion to open cholecystectomy was the most commonly reported outcome, reported in 135 studies (58%) and defined in 11 (5%). Rates of retained gallstones (spilled stones, common bile duct stones, or remnants in the gallbladder or cystic stump) were reported in 49 (21%) studies.

Table 3 Definitions of bile duct injury

Study Authors	Reported incidence	Definitions
Viste <i>et al.</i> <sup>32</sup> , Stanisic <i>et al.</i> <sup>33</sup> , Zhao <i>et al.</i> <sup>34</sup>	0.27–0.67%	According to Strasberg classification. <sup>23</sup>
Vuong <i>et al.</i> <sup>35</sup>	0.02%	Unintended transection of the CBD, common hepatic duct, or right hepatic duct, Strasberg classification E1–E5, and requiring biliary reconstruction within one year of cholecystectomy. <sup>23</sup>
Mustafa <i>et al.</i> <sup>36</sup>	5.24%	Diagnosis of bile duct injury was made when there was intraoperative bile leak, presence of bile in subhepatic drain or post-operative jaundice (bilirubin > 3 mg/dl) measured at 2nd and 7th days after surgery.
Pekolj <i>et al.</i> <sup>37</sup>	0.19%	Intraoperative diagnosis of BDI was made by either direct view (bile leak or duct transection) or abnormal IOC findings. Strasberg also given. <sup>23</sup>
Worth <i>et al.</i> <sup>38</sup>	0.11%	Requiring an operative intervention, rather than endoscopic or percutaneous therapy.
Ruiz-Tovar <i>et al.</i> <sup>39</sup>	1.00%	Intra-operatively detected.
Nielsen <i>et al.</i> <sup>40</sup> , Rothman <i>et al.</i> <sup>41</sup>	0.13–0.22%	Requiring surgical reconstruction.
Van Dam <i>et al.</i> <sup>42</sup>	3.33%	ERCP documented, Strasberg also given. <sup>23</sup>
Lucarelli <i>et al.</i> <sup>43</sup>	3.33%	ERCP documented.
Parikh <i>et al.</i> <sup>44</sup>	2.00%	Requiring operative intervention, interventional radiology or hospital admission until resolution of symptoms.

**Table 4** Definitions of wound infection<sup>a</sup>

Author	Reported incidence	Definition
Fahrner <i>et al.</i> <sup>45</sup> , Comajuncosas <i>et al.</i> <sup>46</sup> , Wakasugi <i>et al.</i> <sup>47</sup> , Comajuncosas <i>et al.</i> <sup>48</sup> , Bogdanic <i>et al.</i> <sup>49</sup> , Parikh <i>et al.</i> <sup>44</sup>	0.82%–16.2%	As per Centre for Disease Control and Prevention. <sup>25</sup>
Passos <i>et al.</i> <sup>50</sup>	2.00%	Typical signs of local or systemic infection as: axillary temperature >37.8, tachycardia, asthenia, accompanied by local pain or purulent collection on the surgical site, or signs of inflammation in the wound with no purulent secretion with microbiological confirmation, even without signs of systemic infection.
Matsui <i>et al.</i> <sup>51</sup>	1.64%	Pus discharge from the surgical wound requiring open discharge.
Simorov <i>et al.</i> <sup>52</sup> , Cox <i>et al.</i> <sup>53</sup> , Rao <i>et al.</i> <sup>54</sup>	0.07–0.66%	As per NSQIP <sup>17</sup> .
Naqvi <i>et al.</i> <sup>55</sup>	4.29%	Body temperature higher than 38 °C twice a day (excluding the first postoperative day) and/or a culture positivity of pathogens from infectious sites such as the wound site.
Darzi <i>et al.</i> <sup>56</sup>	1.86%	Purulent drainage from the surgical sites.
Karaca <i>et al.</i> <sup>57</sup>	1.56%	Fever (fever of >38 °C twice a day at postoperative first day) and purulent discharge from the incision site.
Kim <i>et al.</i> <sup>58</sup> , Kim <i>et al.</i> <sup>59</sup>	1.96–3.63%	Any complications of the trocar sites, with erythema or tenderness that required opening, drainage or antibiotic therapy (hematoma or seroma was not included).
Zhao <i>et al.</i> <sup>60</sup> , Luna <i>et al.</i> <sup>61</sup>	3.57–7.50%	Using either physical examination or standard diagnostic testing.
Saad <i>et al.</i> <sup>62</sup>	4.76%	Requiring outpatient medical treatment (wound opening, cleansing or antibiotics).
Shamim <sup>63</sup>	1.29%	Port-site pain.
Sista <i>et al.</i> <sup>64</sup>	13.04%	Infections were considered grade I in the case of erythema, indurations, and pain; grade II as grade I but with serous fluid; grade III, in the presence of contaminated fluid in less than half the wound; grade IV as grade III but contaminated fluid was in more than half the wound.
Majid <i>et al.</i> <sup>65</sup>	1.88%	Skin or subcutaneous infection requiring antibiotics.
Mirani <i>et al.</i> <sup>66</sup>	4.84%	Stitch abscess, erythema, discharge.
Ruangsin <i>et al.</i> <sup>67</sup>	2.34%	Purulent discharge from the surgical site, with or without positive culture or signs of inflammation, but not including a normal serosanguinous discharge from the wound.
Armañanzas <i>et al.</i> <sup>68</sup>	3.77%	The presence of pain, heat, redness, swelling, and purulent discharge at the surgical incision and/or positive culture.

<sup>a</sup> Includes definitions of the terms 'wound infection', 'surgical site infection' and 'superficial surgical site infection' but does not include definitions for 'deep wound infection' or 'organ space infection'.

Grading of complications by severity was performed in 85 studies (36%). Formal severity rating scales were used by 26 studies (11%), whilst the remaining 59 studies (25%) graded complications by categorization only. The Clavien-Dindo classification system was used in 24 studies (10%).

Subgroup analysis of complication reporting by study aim is given in the Appendix (Supplementary Table 3).

### Mortality

Mortality was reported in 89 studies (38%). Nine studies (4%) reported mortality using more than one measure. Complete definitions for mortality were provided for 4 metrics (4%).

### Discussion

Considerable variation was identified in the complications reported after LC and in their definitions (if present at all). Many of the 976 complications identified were only reported in single studies. Conversion to open technique was the commonest, reported in 58% of studies. Definitions of complications were often not provided, and when they were, these definitions varied between studies. Although formal scales for grading complications have been successfully applied to LC,<sup>21</sup> only 26 studies (11%) used these.

BDI is a significant cause of morbidity and mortality, and is thus important in evaluating and comparing techniques for

cholecystectomy.<sup>22</sup> BDI was reported in only 75 studies (32%), possibly because its incidence is low (typically less than 0.5%<sup>24</sup>). BDI was defined in 10 different ways in 13 studies (6%). The well-established Strasberg classification of biliary injury<sup>23</sup> was only used to define BDI in 6 studies (3%).

The present review differs from most reports of complications after other surgical procedures in that LC is a lower risk procedure than those usually studied, so serious complications are typically less frequent. Nevertheless, the variation seen in this study is consistent with reports of previous investigators. For example, Blencowe *et al.* examined the reporting of complications after oesophagectomy and found that over 60% of studies failed to define any of the complications reported.<sup>9</sup> A review of colorectal cancer surgery identified similar heterogeneity in clinical and patient-reported outcomes.<sup>10</sup> Sixteen different definitions for wound infection were provided by studies in the current review, despite the existence of the CDC classification<sup>25</sup> for wound infection, while Bruce *et al.*<sup>26</sup> identified 41 separate definitions of wound infection from a systematic review of 90 papers.

The reporting of outcomes, including complications, is particularly important for LC given the emergence of several new techniques, such as single incision LC and natural orifice trans-luminal endoscopic surgery.<sup>27,28</sup> Consistent measurement and reporting of outcomes is necessary to robustly evaluate these techniques and to compare them with conventional LC. There is a strong case for developing a consensus on a core set of outcome measures to use in clinical trials and in evaluating services or individual surgeons who carry out LC. This set of measures should reflect the desired outcomes of the surgery as well as a selection of its complications. It would then be reasonable to expect that the same small set of standardized outcome measures would be included in every clinical trial of LC.<sup>29</sup> Core outcomes sets have been successfully developed for use in colorectal cancer surgery and oesophagectomy.<sup>9,10</sup> On the basis of the present review, potential candidates for a core set of complications for LC include BDI (defined and graded as per the Strasberg classification<sup>23</sup>), wound infection (defined as per the CDC guidelines<sup>25</sup>), and bile leak (defined and graded as described by Koch *et al.*<sup>30</sup>). Conversion to conventional open cholecystectomy should be included, noting that readiness to take this step in a timely fashion may arguably be seen as evidence of good practice. The rate of subtotal cholecystectomy should also be reported, given recent trends favoring this technique.<sup>31</sup>

Serious complications occur too infrequently after LC to be useful in identifying differences between practitioners or units. Length of stay, readmission rates and re-intervention rates are more commonly reported after LC and indirectly reflect complications or adverse events. Thus, these may be particularly useful components of a core outcome set for LC. Given that LCs are usually performed to alleviate symptoms of gallstone disease, measures capture positive outcomes of surgery, such as PROs, should also be included.

The outcomes of particular interest in any given study depend upon that study's aims or hypotheses. For example, wound infection would be important in studies comparing antibiotic regimens for LC whether it was included in a core outcome set or not. Thus certain outcomes might be used in some studies in addition to a core outcome set, but standardized definitions should still be expected.

There are several limitations to the current study. The search was limited to studies published between 2013 and 2016 and the reporting of outcomes from earlier studies were not assessed. Retrospective studies, except where they related to prospectively collected databases, were excluded, which may have introduced some bias to analysis. Outcome reporting for trans-vaginal or robotic cholecystectomy was not assessed. This review aimed to identify the full range of complications and other clinical outcomes currently reported after LC, so studies were included regardless of their objectives or hypotheses. This could be expected to have contributed to the heterogeneity of outcomes identified in this review. Nonetheless, subgroup analysis demonstrated that a wide range of complications were reported, regardless of the study aim. Finally, the reporting of PROs was beyond the scope of this review, although these may be useful measures for LC and should be evaluated in future work.<sup>4</sup>

In conclusion, this review has identified considerable variation between studies in the choice of measures used to evaluate the complications of LC, and in their definitions. This variation limits the ability of researchers and clinicians to compare the results of different studies involving LC. A standardised set of core outcomes (including complications) of LC should be developed for use in clinical trials and in evaluating the performance of surgeons and surgical units.

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#### Conflict of interest declaration

None declared.

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#### Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.hpb.2018.03.004>.