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Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: a meta-analysis of randomised control trials

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Abstract
Aims: To use meta-analytic techniques to compare perioperative and short term post-operative outcomes for patients undergoing cholecystectomy via the laparoscopic or mini-open approach.
Methods: Randomised control trials published between 1992 and 2005, cited in the literature of elective laparoscopic (LC) versus mini-open cholecystectomy (MoC) for symptomatic gallstone disease were included. End points evaluated were adverse events, operative and functional outcomes. A random effects meta-analytical model was used and between-study heterogeneity assessed. Subgroup analysis was performed to evaluate the difference in results for study size and quality and data reported from 2000.
Results: Nine randomised studies of 2032 patients were included in the analysis. There was considerable variation in the size and type of incision used for MoC in the studies. There was a significantly longer operating time for the LC group, by 14.14 minutes (95% CI 2.08, 26.19; $p < 0.0001$). Length of stay was reduced in the LC group by 0.37 days (95% CI −0.53, −0.21; $p < 0.0001$), with no significant heterogeneity for either outcome. For all other operative and post-operative outcomes, there was no significant difference between the two groups.
Conclusion: MoC appeared to have similar outcomes compared to LC, however LC did reduce the length of hospital stay. MoC is a viable and safe option for healthcare providers without the financial resources for laparoscopic equipment and appropriately trained surgical teams.

Key words: Cholecystectomy — Laparoscopy — Mini-laparotomy — Randomised trial — Meta-analysis

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Laparoscopic cholecystectomy (LC) has become readily acceptable as the treatment of choice for symptomatic gallstone pathology [1]. It has been shown to have better outcomes compared to the traditional open technique [2]. Although well established in developed countries, a recent cost analysis has shown that LC will only gain economic feasibility over conventional cholecystectomy in less developed health care systems when costs of laparoscopic equipment are reduced and personnel earnings increase sufficiently [3]. A meta-analysis including data from more than 90,000 patients has demonstrated wide variability in the data gathered but generally lower morbidity, despite higher bile duct injury rates, for LC compared to open surgery [4].

Small incision or mini-open cholecystectomy (MoC) has been evaluated as an alternative to LC due to the cost of the equipment, staff and learning curves needed for the latter. Small capital costs for surgical procedures are particularly essential for surgical units with reduced financial resources and yet high volume of patients. A recent study from a rural surgical unit has even assessed the feasibility and usefulness of MoC as a day case procedure, with positive results [5]. There have been several randomized control trials comparing LC versus MoC [6–14], however, currently these data have not been pooled for evaluation of overall outcomes.

The aim of the present study was to use meta-analytical techniques to compare operative and post-operative outcomes from randomised studies of LC versus MoC in patients undergoing elective cholecystectomy for symptomatic gallstone disease.

Methods

Study selection

A Medline (using Pubmed as the search engine), Embase, Ovid, Cochrane database and Google^{TM} Scholar search was performed on all studies between 1992 and 2005 for randomised trials comparing elective laparoscopic cholecystectomy (LC) and small incision or mini-open technique (MoC) surgery for symptomatic gallstone disease. The following Mesh search headings were used: "Cholecystectomy", "laparoscopic cholecystectomy", "laparoscopy", "mini-laparotomy", "mini-open cholecystectomy", "gallstones / biliary disease / *pathology / *surgery", "gallstone / *pathology / surgery", "randomised study", and "treatment outcome". The "related articles" function was used in Pubmed to broaden the search, and all titles, abstracts, studies, and citations scanned were reviewed. References of the articles acquired in full were also reviewed. No language restrictions were made. The latest date for this search was 9th May 2006.

Data extraction

Two reviewers (SP and PG) independently extracted the following from each study: first author, year of publication, study population characteristics, study design, inclusion and exclusion criteria, matching criteria, number of subjects operated on with each technique, male to female ratio, conversion rates and outcomes of interest.

Inclusion criteria

In order to be included in the analysis, studies had to: (1) Compare laparoscopic and mini-open techniques in patients undergoing elective cholecystectomy for symptomatic gallstone disease. (2) Report on at least one of the outcome measures mentioned below. (3) Clearly document technique as "laparoscopic" or "min-open". (4) Clearly report the indications for surgery. When two studies were reported by the same institution and/or authors, they were included only if there was no overlap between the results of the studies. Otherwise, the larger, higher quality studies were included in the analysis.

Exclusion criteria

Studies were excluded from the analysis if: (1) The outcomes of interest were not reported for the two techniques. (2) It was impossible to extrapolate or calculate the necessary data from the published results. (3) There was considerable overlap between authors, centres or patient cohorts evaluated in the published literature.

Outcomes of interest and definitions

The following outcomes were used to compare the laparoscopic surgery (LC) group compared with the mini-open surgery (MoC) group:

1. *Operative outcomes* included blood loss, operative time and conversion to open procedure.
2. *Adverse events* included abdominal complications (wound infections, haematoma, bile leak, common bile duct strictures, jaundice, incisional/port site hernias, urinary retention and urinary tract infections) and extra-abdominal complications (pulmonary complications, thromboembolism and cardiac complications).
3. *Functional outcomes* included length of hospital stay, sick leave, the need for readmission and the need for reoperation.

Mini-open cholecystectomy had to be clearly defined as a less invasive procedure compared to the traditional open cholecystectomy and described in the included studies.

Statistical Analysis

Meta-analysis was performed in line with recommendations from the Cochrane Collaboration and the Quality of Reporting of Meta-analyses (QUORUM) guidelines [15]. Statistical analysis for dichotomous variables was carried out using the odds ratio as the summary statistic. This ratio represents the odds of an adverse event occurring in the LC group compared with the MoC group.

The Mantel-Haenszel method was used to combine the odds ratio for the outcomes of interest using a "random effect" meta-analytical technique. In a random effect model it is assumed that there is variation between studies and the calculated odds ratio thus has a more conservative value [16]. In surgical research, meta-analysis using the random effect model is preferable particularly because patients that are operated on in different centres have varying risk profiles and selection criteria for each surgical technique. Yates' correction was used for those studies that contained a zero in one cell for the number of events of interest in one of the two groups [17, 18]. These "zero cells" created problems with the computation of ratio measure and its standard error of the treatment effect. This was resolved by adding the value 0.5 in each cell of the 2×2 table for the study in question, and if there were no events for both the LC and MoC groups the study was discarded from the meta-analysis. For continuous variables such as operative time or length of stay, statistical analysis was carried out using the weighted mean difference (WMD) as the summary statistic [16].

The quality of the studies was assessed by using the Jadad Score [19, 20]. Studies achieving three or more points (from a maximum of five) were considered as being of high quality**.** Subgroup analysis was performed by considering studies with greater than 100 patients, high quality studies only, studies published in or since 2000.

Three strategies were employed to quantitatively assess heterogeneity. First, data was re-analysed using both random and fixed effect models. Second, graphical exploration with funnel plots was used to evaluate publication bias [21, 22]. Thirdly subgroup analysis was undertaken using the subgroups described above. Analysis was conducted by using Review Manager Version 4.2 (The Cochrane Collaboration®, Software Update, Oxford).

Results

Eligible studies (Figure 1)

One hundred and twenty four reports were identified using the above search keywords. Title and abstract examination resulted in the exclusion of 103 studies (36 case series, 14 letters, 12 reviews, 3 robotic studies, 13 studies on traditional open cholecystectomy and 25 studies on other laparoscopic procedures). This resulted in 21 studies for evaluation in full, of which a further 7 were excluded (5 studies with significant potential for overlapping cohorts and therefore only the largest, highest quality study was included (i.e. 4 studies excluded), 2 studies that only reported outcomes on respiratory function and one study where the data was not extractable). This resulted in 14 comparative studies evaluated [6–14, 23–27], of these 9 were randomised control trials [6–14], including 2032 patients and were therefore included in the meta-analysis. The study characteristics of these 9 trials are shown in Table 1.

Study characteristics (Table 1)

Each study fulfilled the inclusion and exclusion criteria and only randomised elective surgical case data was used. All the studies except two [8, 13] utilised some form of matching criteria. All the studies except one [6] reported on the conversion rates in both the LC and MoC groups. Although all the studies explicitly stated that the comparison was between LC and MoC, the exact definitions for the latter were variable. Six of the studies used the measured length of the subcostal skin incision as their definition for MoC [7, 10–14]. However this ranged from "3–5 cm" [7] to "5–10 cm" [11, 13]. One study used a high transverse sub-xiphoid incision where "the length of the incision was tailored to the individual patient and kept to the minimum necessary to allow safe and adequate access to the gallbladder" [9].

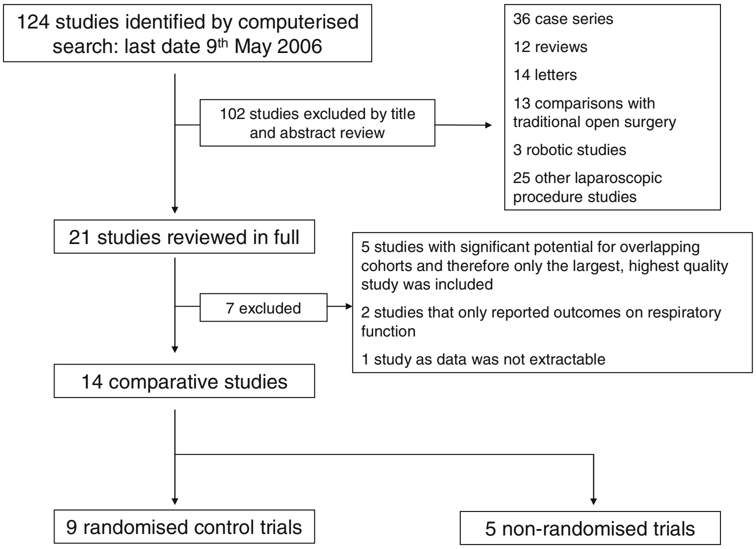

Fig. 1. Flow chart for literature search

Table 1. Study Characteristics

Author (Reference)	Year	Country of origin	Design	Total Patients	Conversions LC	Conversions MoC	Jadad score (1–5)
Barkun et al. [6]	1992	Canada	RCT	62	–	–	3
Harju et al. [7]	2005	Finland	RCT	157	4	2	2
Kunz et al. [8]	1993	Germany	RCT	77	0	0	2
Majeed et al. [9]	1996	United Kingdom	RCT	200	20	22	5
McGinn et al. [10]	1995	United Kingdom	RCT	310	20	6	3
McMahon et al. [11]	1994	United Kingdom	RCT	299	15	14	3
Secco et al. [12]	2002	Italy	RCT	172	5	4	2
Shrivastava et al. [13]	2001	India	RCT	99	0	1	2
Ros et al. [14]	2001	Sweden	RCT	724	69	101	3

RCT = randomised control trial; LC = laparoscopic cholecystectomy group; MoC = mini-open cholecystectomy group

One study varied the length of the subcostal incision according to the depth of the incision from skin to cystic duct [8]. One study described the use of a small transverse incision in the right upper quadrant used by 6 surgeons in the study and a small midline incision used by one surgeon [6]. Four studies reported how many port sites were used [7, 10–12], of these 3 used 4 ports sites [7, 11, 12] and one used 3–4 port sites [10].

Results from overall meta-analysis (Table 2, figures 2a and 2b)

Results from the overall meta-analysis are outlined in table 2 and illustrated as a forest plot in figures 2a and 2b. Using random effects modelling, the overall results demonstrated that there was a significantly longer operating time for the LC group by 14.14 minutes (95% CI 2.08, 26.19; $p < 0.0001$) with no significant heterogeneity. Length of stay was reduced in the LC group (WMD −0.37days, 95% CI −0.53, −0.21; $p < 0.0001$) with no significant heterogeneity. For all other operative and post-operative outcomes, there was no significant difference between the two groups. Overall, only the results for conversion rate, abdominal complications and duration of sick leave demonstrated significant heterogeneity ($p = 0.02$, $p = 0.006$ and $p = 0.009$ respectively).

Results from subgroup analysis (Table 3)

Subgroup analysis for studies with more than 150 patients and a Jadad score or 3 or more continued to demonstrate that operative time was significantly longer in the LC group by 18.69 (95% CI 13.08, 24.30; $p < 0.0001$) and 16.65 (95% CI 13.39, 19.91; $p < 0.0001$) minutes respectively, with no significant heterogeneity. When studies published from the year 2000 were analysed separately, there was no significant difference in operative time (WMD = −1.95 95% CI −3.04, −0.85; $p = 0.20$). This effect may be explained by the fact that the more recent publications included surgeons and teams performing laparoscopic cases at a higher point in the learning curve as LC had become more routine surgical cases. This latter subgroup of more recent studies also maintained a significantly reduced length of stay (WMD = −0.40 95%CI −0.47,

Table 2. Results of overall meta-analysis

Outcome of Interest	No of studies	No of Patients	OR/WMD(*)	95% CI	*p*-value	HG Chi-square	HG *p* -value
Operative Outcomes							
Operative time	6	1541	14.14*	2.08, 26.19	**< 0.0001**	173.64	0.44
Conversion Rate	7	1970	1.12	0.64, 1.95	0.69	15.60	**0.02**
Post-operative complications							
Abdominal Complications	9	2032	0.77	0.36, 1.63	0.20	21.32	**0.006**
Extra-Abdominal Complications	7	1870	0.64	0.37, 1.09	0.10	8.56	0.20
Hernias	3	1195	1.77	0.29, 10.93	0.54	1.64	0.44
Bile leak	4	844	0.36	0.05, 2.42	0.29	7.09	0.07
CBD Stricture	2	376	0.31	0.03, 3.04	0.32	0.00	0.97
Bleeding	3	660	2.51	0.45, 13.89	0.29	2.94	0.23
Jaundice	3	548	2.40	0.35, 16.43	0.37	2.34	0.31
Pulmonary Complications	5	1510	0.77	0.37, 1.61	0.49	3.09	0.54
Chest Infection	3	587	0.47	0.10, 2.10	0.32	2.15	0.34
Kidney/UTI	3	1180	0.38	0.13, 1.10	0.08	0.70	0.71
Urinary Retention	3	741	0.46	0.19, 1.08	0.07	0.33	0.85
Thromboembolism/DVT	2	1008	1.43	0.09, 22.79	0.80	1.57	0.21
Cardiac complications	3	1307	0.44	0.09, 2.20	0.32	2.09	0.35
Wound Infection	8	1955	0.78	0.35, 1.72	0.53	11.61	0.11
Wound Haematoma	2	471	4.76	0.54, 42.22	0.16	0.14	0.71
Post Op Recovery							
Length of Stay	4	1180	-0.37*	−0.53, −0.21	**< 0.0001**	3.29	0.35
Sick Leave	4	1143	-0.22	−0.50, 0.06	0.12	11.61	**0.009**
Readmission	2	461	1.55	0.41, 5.80	0.52	0.05	0.82
Reoperation	6	1604	0.78	0.36, 1.73	0.55	3.84	0.57

No = number; OR = odds ratio; WMD = weighted mean difference; HG = heterogeneity

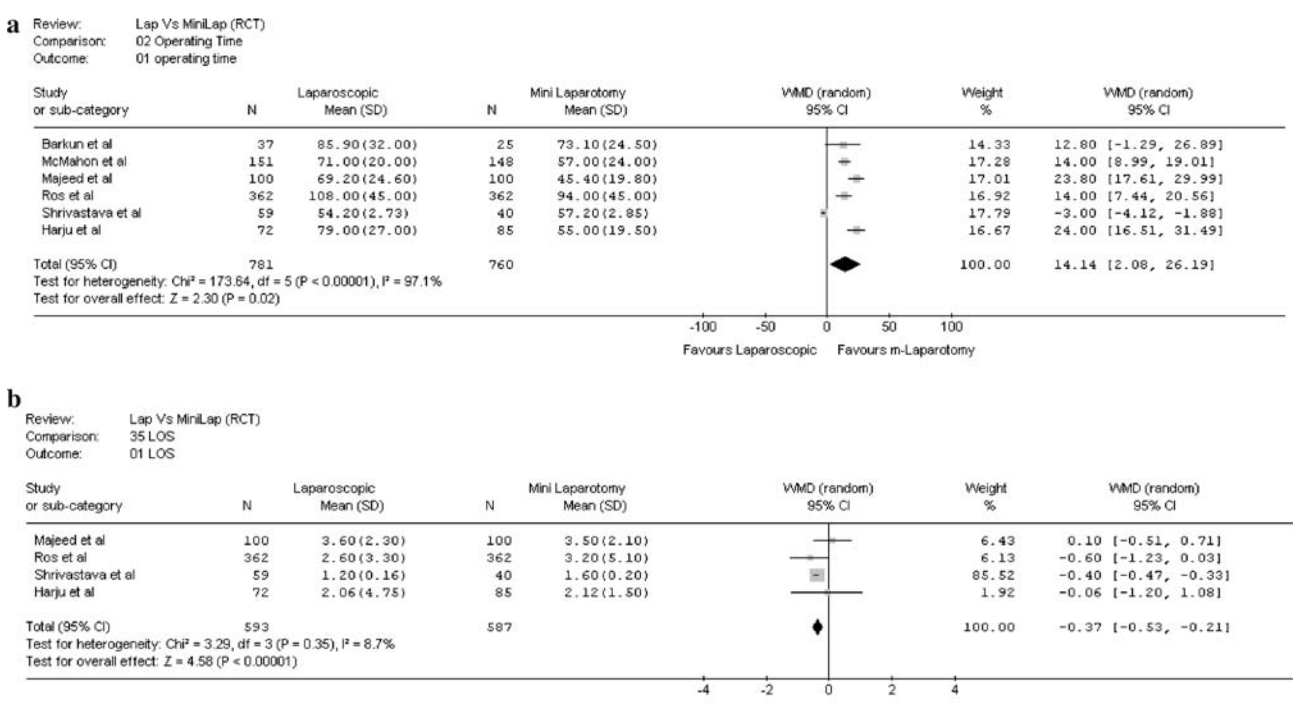

Fig. 2 a. Forest plot for length of stay. **b**: Forest plot for operating time. SD = standard deviation; WMD = weighted mean difference; CI = confidence interval; df = degrees of freedom; LOS = length of stay; m-laparotomy = mini laparotomy.

−0.33; $p < 0.0001$) and demonstrated reduced sick leave (WMD = −0.30 95%CI −0.44, −0.17; $p < 0.0001$) with no heterogeneity. However there was no significant difference in the length of stay or amount of sick leave needed in the other two subgroups assessed.

Discussion

The present meta-analysis has illustrated how short-term adverse events are comparable following cholecystectomy performed either by a laparoscopic or mini-

Table 3. Results of subgroup analysis

Outcome of Interest	No of studies	No of Patients	OR/WMD(*)	95% CI	*p*-value	HG Chi-square	HG *p*-value
Studies > 150 patients							
Operative time	4	1380	18.69	13.08, 24.30	**< 0.0001**	9.71	**0.02**
Abdominal Complications	6	1794	1.19	0.72, 1.95	0.50	6.44	0.27
Extra-Abdominal Complications	6	1793	0.65	0.36, 1.16	0.15	8.34	0.14
Length of Stay	3	1081	−0.22	−0.69, 0.26	0.37	2.55	0.28
Sick Leave	3	1081	−0.14	−0.44, 0.16	0.37	9.09	**0.01**
Studies published in or since 2000							
Operative time	3	980	−1.95	−3.04, −0.85	0.20	72.21	**< 0.0001**
Abdominal Complications	4	1152	0.51	0.32, 0.82	**0.006**	13.20	**0.004**
Extra-Abdominal Complications	3	1052	0.68	0.28, 1.65	0.40	4.19	0.12
Length of Stay	3	980	−0.40	−0.47, −0.33	**< 0.0001**	0.73	0.69
Sick Leave	2	881	−0.30	−0.44, −0.17	**< 0.0001**	0.52	0.47
Studies quality score ≥ *3*							
Operative time	4	1285	16.65	13.39, 19.91	**< 0.0001**	7.11	0.07
Abdominal Complications	5	1527	1.09	0.74, 1.62	0.66	6.55	0.16
Extra-Abdominal Complications	4	1465	1.55	0.31, 0.98	0.04	3.88	0.27
Length of Stay	2	924	−0.25	−0.93, 0.44	0.48	2.46	0.12
Sick Leave	3	986	−0.24	−0.63, 0.16	0.24	11.54	**0.003**

No = number; OR = odds ratio; WMD = weighted mean difference; HG = heterogeneity

open approach. MoC offers a small but statistically significant benefit in the duration of surgery while laparoscopic patients are discharged from hospital on average 0.37 days sooner. While the effects of such differences in length of stay and duration of surgery are unlikely to be clinically significant for individual patients, in the context of a hospital or the wider healthcare system they may have important implications.

Advantages of the present study include the aggregation of a large volume of clinical data (on 2,032 patients) from randomised controlled trials. The appropriate pooling of data is highlighted by the fact that heterogeneity between studies was found to be statistically significant for only three of the 21 outcomes considered on overall meta-analysis, and for none of those outcomes where significant differences between the laparoscopic and mini-laparotomy groups were shown.

The major limitation of this study lies in the accurate definition of 'mini-laparotomy' used by the analysed studies. Reported lengths of incision varied from 3–10 cm [11, 13] and it is therefore surprising that a greater degree of heterogeneity between studies was not observed. Other authors have recently highlighted this problem, suggesting that incisions which require some degree of division of the rectus muscle should be considered conversion to a 'conventional laparotomy' [7]. The inability to perform meta-analysis of the costs of surgery and post-operative analgesic requirements as well cosmetic and quality of life outcomes, due to inconsistencies in the way that these outcomes were reported, also limit the conclusions that can be drawn.

Cholecystectomy is quoted as the most commonly performed abdominal operation in the United States, with 500,000 procedures annually [28]. Ultrasonographic studies have suggested the prevalence of gallstones to vary across the world at 10–12% in Europeans, 3–4% in Asians and around 5.2–10% in African populations [29]. There has been a steady shift away from open cholecystectomy following the introduction of LC, with the proportion of procedures performed laparoscopically having risen from 0–63% in Scotland between 1990 and 1993 [30]. Despite this it has been suggested that the incision length for open cholecystectomy had been falling at the time when LC became routine, to some extent stifling the development and evaluation of MoC [9]. The introduction of LC is associated with a substantial increase in operating theatre costs due to the purchase price of the laparoscopic equipment [30] as well as the costs of training surgical and theatre staff [9]. In contrast, MoC requires no extra instrumentation and appears to be a skill which can be acquired by surgical trainees without a marked learning curve [7]. Measures can be taken to limit the start-up costs of laparoscopic surgery [31], and some authors have argued that lower overall costs compared even to the mini-laparotomy technique, taking into account the societal costs of lost work-days, are eventually achievable [13]. However, to achieve these reduced costs, some studies have relied on data suggesting that mini-open cholecystectomy is associated with significantly higher rates of bile duct injury and wound infection, neither of which were reflected by the results of the present study or a previous meta-analysis comparing laparoscopic with open cholecystectomy [4]. Differences in convalescence periods were small in the present analysis, as were the benefits in terms of length of stay towards the laparoscopic group. It has been calculated that to equalise hospital costs between LC and MoC, the laparoscopic procedure would need to demonstrate a length of post-operative stay of more than three days less then MoC [30], an effect which is unlikely to be shown, not least in the context of a recent report which showed day-case mini-laparotomy cholecystectomy to be achievable in more than 78% of patients [5].

The results of the present study are suggestive that patients treated in units in developing countries where the start-up costs of minimally invasive surgery are considered prohibitive are not disadvantaged. Although the method of presentation of cost data from the analysed randomised studies precluded meta-analysis, individual studies have consistently shown hospital costs to be cheaper for the mini-laparotomy approach [11, 12, 27, 30], even when the costs of disposable equipment used in the laparoscopic procedure are discounted [11]. The suggestion that LC leads to lower overall costs to society, due to a more rapid return to work, has not been substantiated by the present study. Using sick-leave as a marker of the time taken to return to normal activities, there was no significant difference between the study groups on overall analysis, as well as subgroups of larger studies, and those of higher overall quality. It is only in the subgroup of studies published in or since 2000 that a statistically significant reduction in the duration of sick-leave was shown, perhaps reflecting a more aggressive post-operative policy in recent years, although the clinical relevance of a 0.30 day reduction in the time until return to work for the average patient is debatable. While it could be argued that in overall health economics terms, small benefits for individuals become significant when multiplied by the size of the population at risk. The higher incidences of gallstones appear to occur in European populations where relatively fewer financial constraints and differences in patient expectation might have a greater impact on the decision to offer LC, while in areas where minimising hospital costs is of paramount concern, MoC may be considered the optimal strategy [25].

The issues of cosmesis and quality of life have been relatively poorly addressed by existing studies. Two studies have suggested that overall the quality of life following both procedures is similar, although for those undergoing LC the post-operative improvement appears to be more rapid, equalising by around 12 weeks [6, 11]. Ros et al. reported cosmetic and quality of life data at 1 year following surgery for their trial patients [32] noting no significant differences in pain, analgesic requirements or cosmetic result between the treatment groups. In another 1 year follow-up paper, McMahon et al. [33] reported that the only significant difference in outcomes between the two treatment arms was a significantly higher rate of reported heartburn in the mini-laparotomy group.

While small benefits in the length of stay and return to normal activities may be associated with LC versus MoC, these may be offset by the shorter operating time associated with the open approach. While at approximately 14 minutes per patient overall, the effects for individual patients are not likely to be significant, in the context of a full day list of cholecystectomies such a time-saving could be responsible for an extra case per day being completed, representing a more efficient use of operating theatre time.

While this study has shown comparable outcomes between MoC and LC, there is little doubt that there is a perception that laparoscopy represents a lower magnitude of risk than open surgery. Such bias can be dangerous and lead to a lower threshold for surgical intervention in patients with borderline indications. A resultant increase in the volume of cases performed laparoscopically can lead to a paradoxical increase in healthcare costs, even if the costs of individual procedures are lower. The potential for such a trend has been a contentious issue in relation to other laparoscopic procedures, such as anti-reflux surgery [34].

In conclusion, this meta-analysis has shown how the adverse event profile for mini-laparotomy cholecystectomy is equivalent to that following laparoscopic cholecystectomy. It has not been possible to meta-analyse comparative data concerning cost, cosmesis or quality of life and these should be addressed by future studies. While laparoscopic cholecystectomy may be considered to represent the standard of care in first-world medicine, the present meta-analysis suggests that for those healthcare systems where the costs of setting up and maintaining a laparoscopic service are seen as prohibitive, or in those patients in whom laparoscopy is contra-indicated, mini-laparotomy cholecystectomy offers an effective alternative, with similar patient outcomes.

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