Cover sheet

Title

Routine abdominal drainage in uncomplicated laparoscopic cholecystectomy

Reviewers

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Dates

Date edited: 12/01/2007
Date of last substantive update: 12/01/2007
Date of last minor update: 26/09/2006
Date next stage expected / /
Protocol first published: Issue 2, 2006
Review first published:

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Contribution of reviewers

K Gurusamy is the lead reviewer and identified the studies for inclusion; extracted the data for some studies and wrote the review. K Samraj independently identified studies for inclusion, extracted the data for all the studies and helped with discussion. P Mullerat extracted data for some studies. Prof BR Davidson critically commented on the review and suggested improvements.

Internal sources of support

None

External sources of support

None

What's new

Dates

Date review re-formatted: / /
Date new studies sought but none found: / /
Date new studies found but not yet included/excluded: / /
Date new studies found and included/excluded: 30/04/2006
Date reviewers' conclusions section amended: / /
Date comment/criticism added: / /
Date response to comment/criticisms added: / /

Text of review

Synopsis

Laparoscopic cholecystectomy is the currently preferred method of treatment of symptomatic gallstones. Drain use after laparoscopic cholecystectomy is controversial. This review found out the drain use after laparoscopic cholecystectomy decreases early post-operative pain but increases wound infection and delays discharge from hospital. Currently there is no evidence to support the use of drain after laparoscopic cholecystectomy.

Abstract

Background

Laparoscopic cholecystectomy is the main method of treatment of symptomatic gallstones. Drains are used after laparoscopic cholecystectomy to prevent abdominal collections. However, drain use may increase infective complications and delays discharge.

Objectives

The aim is to assess the advantages and disadvantages of routine abdominal drainage in uncomplicated laparoscopic cholecystectomy.

Search strategy

We searched The Cochrane Hepato-Biliary Group Controlled Trials Register, The Cochrane Central

Register of Controlled Trials in The Cochrane Library, MEDLINE, EMBASE, and Science Citation Index Expanded until April 2006.

Selection criteria

We included all randomised clinical trials (RCT) comparing drainage with no drainage after laparoscopic cholecystectomy. RCT comparing one type of drain with another were also reviewed.

Data collection & analysis

We collected the data on the characteristics, methodological quality, mortality, abdominal collections, pain, nausea, vomiting and hospital stay from each trial. We analysed the data with both the fixed-effect and the random-effects model using RevMan Analysis. For each outcome we calculated the odds ratio (OR) with 95% confidence intervals (CI) based on intention-to-treat analysis.

Main results

We analysed five trials involving 591 patients randomised to drain (281) or no drain (310). We also reviewed one trial with 41 patients randomised to suction drain (22) and closed passive drain (19). The only study which reported on abdominal collections requiring intervention reported no abdominal collections requiring intervention in either group. Wound infection was higher in those with a drain (Risk difference -0.03 (95% CI 0.00, 0.06)). Drainage was associated with lower shoulder, abdominal pain and nausea but this was not statistically significant. Hospital stay was longer in the drain group.

Reviewers' conclusions

(1) Drain use after elective laparoscopic cholecystectomy reduces early post-operative pain but increases wound infection rates and delays hospital discharge.
(2) Currently, there is no evidence to support the use of drain after laparoscopic cholecystectomy.

Background

About 10% to 15% of the adult population in the United States have gallstones (NIH 1992). Only 1% to 4% of people with gallstones become symptomatic in a year (NIH 1992). More than half a million cholecystectomies are performed per year in the United States alone (NIH 1992). Laparoscopic cholecystectomy, which was introduced in 1987, is now the preferred method of cholecystectomy (NIH 1992; Fullarton 1994; Bakken 2004).

Routine drainage after laparoscopic cholecystectomy is an issue of considerable debate. In the era of open cholecystectomy, the value of surgical drainage was not resolved. However, a pooled analysis of 1920 patients showed no significant difference in the complication rate between the drained and non-drained group (Lewis 1990). A recent Cochrane review found that drain use after open cholecystectomy in not beneficial and increases the wound infection rate and the incidence of chest complications.

Surgeons have routinely drained after laparoscopic cholecystectomy because of the fear of collection of bile or blood requiring open procedures (Hawasli 1992). Another reason for draining is fto allow CO_2 insufflated during laparoscopy to escape via the drain site, thereby decreasing the shoulder pain (Alexander 1987; Hawasli 1992; Fredman 1994;Jorgensen 1995; Abbott 2001). A higher proportion of patients with nausea and vomiting has also been noted (Nursal 2003) and these complications are less in gasless laparoscopic cholecystectomy (Lindgren 1995; Koivusalo 1996).

Studies have shown higher wound infection rate in the drain group (Thiebe 1994). Studies have also reported a longer hospital stay in the drained group (Nomdedeu 1997; Satinský 2003). Also, none of the patients in the drain group could be discharged the same day (Hawasli 1994).

Some studies have shown that the infection rate (Hawasli 1994) and the re-operation rate (Satinsky 2003) were not significantly different irrespective of whether drain was used or not after laparoscopic cholecystetomy.

Surgical drains may either be open or closed. An open drain is when an artificial conduit is left in the wound to allow drainage of fluids to the exterior (eg, corrugated drain; Penrose drain; Yeates drain). Closed drains may either be suction drains (eg, Redon drain) or passive (gravity-assisted) drains (eg, Robinson drain).

We have not been able to identify any meta-analyses or systematic reviews comparing routine abdominal drainage versus no abdominal drainage in uncomplicated laparoscopic cholecystectomy.

Objectives

To assess the benefits and harms of routine abdominal drainage in uncomplicated laparoscopic cholecystectomy.

Criteria for considering studies for this review

Types of studies

Only randomised clinical trials (irrespective of language, blinding, or publication status) were considered for this review.

Quasi-randomised studies (where the method of allocating participants to a treatment are not strictly random, eg, date of birth, hospital record number, alternation) and case control studies were excluded.

Types of participants

Patients who have undergone uncomplicated laparoscopic cholecystectomy. We did not include patients with complicated laparoscopic cholecystectomy as these will be a different group of patients.

Types of interventions

We included only trials comparing abdominal drainage and no drainage in laparoscopic cholecystectomy (irrespective of the type of the drain; timing of surgery; size and the number of ports; or abdominal lift or open or closed method of induction of pneumoperitoneum).

Trials comparing two types of drains were also included in this review.

Co-interventions were allowed provided they are used equally in the intervention arms.

Types of outcome measures

Primary outcomes

(1) Mortality at maximal follow-up.

(2) Additional procedures for subhepatic collection
(a) Open procedure.
(b) Radiological drainage requiring insertion of drain.
(c) Radiological drainage requiring percutaneous aspiration.

Secondary outcomes
(3) Wound infection (as reported by authors).
(4) Respiratory complications (mainly chest infections).
(5) Hospital stay.
(6) Same day discharge
(7) Abdominal pain (measured using any validated scale).
(8) Shoulder pain (measured using any validated scale).
(9) Nausea (at times reported by authors)
(10) Vomiting (at times reported by authors)

Search strategy for identification of studies

We searched *The Cochrane Hepato-Biliary Group Controlled Trials Register*, *The Cochrane Central Register of Controlled Trials (CENTRAL)* in *The Cochrane Library*, *MEDLINE, EMBASE*, and *Science Citation Index Expanded* (Royle 2003). We have given the search strategies in Table 01 with the time span for the searches.

We also searched the references of the identified trials to identify further relevant trials.

Methods of the review

Trial selection and extraction of data
We did not apply any language or publication status restrictions. Two authors (KG and KS), independent of each other, identified the trials for inclusion. We also included the list of excluded studies with the reasons for the exclusion.

Two sets of authors (KG and KS or KS and PM) independently extracted the data mentioned above.

The authors assessed the methodological quality of the trials independently, without masking of the trial names. Any unclear or missing information were sought by contacting the authors of the individual trials (for recent trials). There was no doubt whether the trials share the same patients. (Comment: In the protocol we told them that we will contact the authors if there was any doubt whether the report was duplicated. In the update, we may need to contact the authors for this).

We resolved all differences in opinion through discussion.

Assessment of methodological quality
We followed the instructions given in the Cochrane Reviewer's Handbook (Higgins 2005).

Due to the risk of biased overestimation of intervention effects in randomised trials with inadequate methodological quality (Schulz 1995; Moher 1998; Kjaergard 2001), we looked at the influence of methodological quality of the trials on the results by evaluating the reported randomisation and follow-up procedures in each trial. If information was not available in the published trial, we contacted the authors in order to assess the trials correctly. We assessed generation of allocation sequence, allocation concealment, and follow-up.

Generation of the allocation sequence

- Adequate, if the allocation sequence was generated by a computer or random number table. Drawing of lots, tossing of a coin, shuffling of cards, or throwing dice will be considered as adequate if a person who was not otherwise involved in the recruitment of participants performed the procedure.
- Unclear, if the trial was described as randomised, but the method used for the allocation sequence generation was not described.
- Inadequate, if a system involving dates, names, or admittance numbers were used for the allocation of patients. These studies are known as quasi-randomised and were excluded from the review.

Allocation concealment

- Adequate, if the allocation of patients involved a central independent unit, on-site locked computer, or sealed envelopes.
- Unclear, if the trial was described as randomised, but the method used to conceal the allocation was not described.
- Inadequate, if the allocation sequence was known to the investigators who assigned participants (such studies were excluded).

Blinding was not assessed since we expect that there will be no double-blind trials. However, we will record whether any of the outcomes were assessed by a blinded observer or blinded assessor.

Follow-up

- Adequate, if the numbers and reasons for dropouts and withdrawals in all intervention groups were described or if it was specified that there were no dropouts or withdrawals.
- Unclear, if the report gave the impression that there had been no dropouts or withdrawals, but this was not specifically stated.
- Inadequate, if the number or reasons for dropouts and withdrawals were not described.

Statistical methods

We performed the meta-analyses using the software package Revman 2003 and the recommendations of The Cochrane Collaboration (Higgins 2005).

For dichotomous variables, we calculated the odds ratio with 95% confidence interval. For continuous variables, we calculated the standardized mean difference (SMD) with 95% confidence intervals in order to take into account the different scales used for the measurement of these variables. We used the random-effects model (DerSimonian 1986) and the fixed-effect model (DeMets 1987). We have reported the results of both the models to demonstrate transparency in arriving at conclusions. We explored heterogeneity by chi-squared test with significance set at P value 0.10, and measure the quantity of heterogeneity by I^2 (Higgins 2002).

We adopted the 'available case analysis' (Higgins 2005). We performed the analysis based on an intention-to-treat basis (Newell 1992). We also intended to perform a sensitivity analysis with and without empirical continuity correction factors as suggested by Sweeting et al (Sweeting 2004) in case we find 'zero-event' trials in outcomes that were statistically significant. We have also reported the risk difference because of its immunity to 'zero-event' trials. For the risk difference, we have reported the fixed-effect model if there was no heterogeneity (I^2<25%) and the random-effects model if there was heterogeneity (I^2 = 25% or above).

Subgroup analysis

We intended to perform the following subgroup analyses:

- trials with high- versus trials with low methodological quality.
- drainage in emergency compared to elective laparoscopic cholecystectomy.
- open compared to closed drains.
- suction compared to passive drains.
- trials that use routine antibiotic prophylaxis compared to those that do not use routine antibiotic prophylaxis.

For the subgroup analysis, we followed the policy followed for risk difference regarding usage of fixed-effect or the random-effects model.

The trials included under each outcome were few and so we did not perform any subgroup analysis other than the subgroup analysis of including only studies of high methodological quality.

Bias exploration
We used a funnel plot to explore publication bias (Egger 1997; Macaskill 2001). We were unable to determine asymmetry in funnel plot of trial size against treatment effect by visual inspection or by the linear regression approach described by Egger et al (Egger 1997) because of the few trials included in this review.

Description of studies

We identified a total of 201 references through electronic searches of The Cochrane Hepato-Biliary Group Controlled Trials Register and The Cochrane Central Register of Controlled Trials in The Cochrane Library (n =20), MEDLINE (n = 34), EMBASE (n = 105), and Science Citation Index Expanded (n = 42). We excluded 49 duplicates and 140 clearly irrelevant references through reading abstracts. Twelve references were retrieved for further assessment. No references were identified through scanning reference lists of the identified randomised trials. We excluded five references for the reasons listed under the table 'Characteristics of excluded studies'. We identified two reports of the same study (Nomdedeu 1997). In total, six randomised trials described in seven publications fulfilled the inclusion criteria. All the six were completed trials and could provide data for the analyses (Hawasli 1994; Thiebe 1994; Jorgensen 1995; Nomdedeu 1997; Nursal 2003; Thiebe 1994). Five trials ((Hawasli 1994; Thiebe 1994; Nomdedeu 1997; Nursal 2003; Thiebe 1994) compared drain with no drain in laparoscopic cholecystectomy. One trial (Jorgensen 1995) compared suction drainage and closed passive drain. Details including the timing of randomisation and the inclusion and exclusion criteria used in the trials are shown in the table 'Characteristics of included studies'.

Drain versus 'No drain'
In the five trials, a total of 591 patients were randomised to drain (281) and no drain (310). The percentage of females was 71.5%. The mean age was 52 years. One study (Thiebe 1994) could not provide data on females or age.

Suction drain versus closed passive drain.
The only study included under this category (Jorgensen 1995) randomised 41 patients (females - 63.4%) to suction drain (22 - median age 64.5 years) and closed passive drain (19 - median age 61 years).

Methodological quality of included studies

Drain versus 'No drain'
Only two (Nomdedeu 1997; Capitanich 2005) of the five trials (40%) had adequate allocation concealment and are considered to be of high methodological quality. The rest of the trials are considered to be of poor methodological quality. Three studies (Hawasli 1994; Nomdedeu 1997; Capitanich 2005) had adequate generation of randomisation (60%). All the trials had adequate follow-up. None of the studies reported

sample-size calculations. None reported 'intention-to-treat analysis'. One trial (Capitanich 2005) reported that the randomisation was performed after removal of gallbladder and did not report any drop-out or cross-over (to the other group). One trial (Nomdedeu 1997) reported that the surgeons were blinded to the group until the removal of gallbladder and did not report any drop-out or cross-over. One study (Hawasli 1994) did not report the time of randomisation but did not report any cross-over or drop-out. One study (Nursal 2003) withdrew 16 patients from the analysis because of conversion to open cholecystectomy (7), violation of anaesthetic protocol (8) and loss to follow-up (1). Another study had 6 cross-over from 'no drain' group to drain group and 3 cross-over from drain group to 'no drain' group and used a per-protocol analysis. If randomisation is performed after the removal of gallbladder, the post-randomisation exclusions and cross-overs can be avoided and the bias arising from difference in the treatment (for example - meticulous haemostasis in 'no drain' group only) can be decreased. One study (Nursal 2003) reported blinding of patients.

Suction drain versus closed passive drain
The only study (Jorgensen 1995) included under this category had adequate random sequence generation and adequate follow-up. The allocation concealment was unclear and so this study is also of low methodological quality. This study also did not contain sample-size calculation or intention-to-treat analysis. This study reported blinding of patients. The randomisation was performed after the removal of gallbladder.

Results

The results are reported in the format Odds Ratio [95% Confidence Intervals].
Drain versus 'No drain'

Mortality at maximal follow-up
None of the included studies reported any deaths in either group.

Total abdominal collections
The drain group had higher total abdominal collections than the 'no drain' group (OR 15.13 [95% CI 6.68, 34.29]). However, on adopting the random-effects model, the difference became non-significant. The results did not change by calculating the risk difference.

Abdominal collections requiring intervention
The only study which reported on this outcome (Capitanich 2005) did not report any abdominal collection requiring drainage.

Infected abdominal collections
There was no statistically significant difference between the two groups in this outcome (OR 3.41 [0.14, 84.53]).

Wound infection
The wound infection rate in the drain group (3.3%) compared to nil in the 'no drain' group (0%). Although the odd's ratio did not demonstrate a significant difference between the groups (OR 15.38 [0.86, 275.74]), the risk difference demonstrated a statistically significant difference between the groups (Risk Difference 0.03 [0.00, 0.06]).

Chest complications
There was no statistically significant difference between the two groups in this outcome (OR 0.83 [0.24, 2.85]). The results did not change by adopting the random-effects model and by calculating the risk difference.

Nausea
The number of people who developed nausea was lower in the drain group than the 'no drain' group at 0-6 hours OR (0.74 [0.27, 2.00]); 7-12 hours OR (0.50 [0.13, 1.89]); 13-24 hours OR (0.35 [0.06, 1.95]); >24 hours(OR 0.22 [0.05, 0.90]) and when the overall number of people who suffered from nausea until discharge was taken into account (OR 0.61 [0.26, 1.47]). However, this achieved statistical significance only for >24 hours. The number of people who required anti-emetic (OR 0.65 [0.24, 1.77]) and the amount of anti-emetic used (Standardized mean difference SMD -0.28 [-0.76, 0.19]) was also less in the drain group than the 'no drain' group. However, these were also not statistically significant.

Vomiting
A trend similar to the one noticed for nausea was not noticed for vomiting. At certain post-operative periods, there was higher incidence of vomiting in the drain group and at other post-operative periods, it was lower than the 'no drain' group. There was no vomiting reported in either group after 24 hours. Another study (Nomdedeu 1997) which was included in the review but could not be included for meta-analysis because of the lack of the number of people who vomited (in each group) in the report. This study did not specify the time of measurement of vomiting.

Shoulder pain
In the first 12 hours and the second 12 hours, the shoulder pain tended to be lower in the drain group than the 'no drain' group (OR 0.75 [0.18, 3.06]; 0.73 [0.36, 1.45] respectively). However, after 24 hours, the drain group tended to have more pain than the 'no drain' group (OR 1.50 [0.23, 9.61]). These differences were not statistically significant.

Abdominal pain
The abdominal pain was lower in the drain group than the 'no drain' group in the first 12 hours. The difference was not statistically significant when the number of people who had abdominal pain was concerned (OR 0.39 [0.09, 1.64]) but was statistically significant when the severity of the pain was calculated (SMD -0.55 [-1.03, -0.07]). For the time period 13-24 hours, the number of people with abdominal pain was lower in the drain group than the 'no drain' group (OR 0.49 [0.26, 0.93]). The results did not change on adopting the random-effects model or by calculating the risk difference. Abdominal pain was less in the drain group than the 'no drain' group even after 24 hours. However, this difference was not statistically significant OR (0.84 [0.32, 2.19]). One study (Hawasli 1994), which reported the mean pain score in the two groups could not be included because the standard deviation was not available. In this trial, the abdominal pain was lower in the drain group (statistically not significant) (Table 02).

Pain (Site unspecified)
Some studies measured the pain without explaining whether this pain was in the abdomen or in the shoulder. In the first 12 hours, the pain was statistically significantly more severe in the drain group than the 'no drain' group (SMD 0.55 [0.13, 0.97]). There was no significant difference in the number of people complaining of pain (OR 1.03[0.06,17.16]). During the next 12 hours, the number of people who reported pain was higher in the drain group (OR 1.42[0.62, 3.21]), but the severity of pain was less severe in the drain group than the 'no drain' group (SMD -0.18[-0.59,0.23]). This difference is not statistically significant. The number of people who reported pain was higher in the drain group than 'no drain' group after 24 hours (OR 1.91[0.90,4.05]). The trial by Thiebe et al (Thiebe 1994) could not be included for the meta-analysis of mean pain scores because the mean and standard deviation of the pain scores was not stated. The time of measurement of mean scores of pain were not specified but the mean pain scores were statistically significantly higher in the drain group then the 'no drain' group (Table 02).

Analgesic requirement
There was no statistically significant difference in the requirement of non-steroidal anti-inflammatory drugs (SMD -0.12 [-0.40, 0.15]) or opiate analgesia (SMD OR 0.17 [-0.31, 0.64]) or in the number of people requiring opiate analgesia (SMD 1.72 [0.38, 7.85]). The results did not change on calculating the risk

difference. the study by Thiebe et al (Thiebe 1994) which could not be included in the meta-analysis found a statistically higher analgesic requirement in the drain group than the 'no drain' group (Table 02).

Hospital stay
Nearly one-third of patients in the 'no drain' group (11/35) could be sent home on the day of surgery in comparison to none (0/33) in the drain group (OR 0.03 [0.00, 0.57]). The overall hospital stay in the different studies is tabulated in the Table 03. All the three studies reporting on the hospital stay (Hawasli 1994; Thiebe 1994; Nomdedeu 1997) show a lower hospital stay in the 'no drain' group than the drain group.

Subgroup analyses
The only outcomes suitable for meta-analysis from the two studies with high methodological quality (Nomdedeu 1997; Capitanich 2005) were abdominal collections (Capitanich 2005) and pain (Nomdedeu 1997; Capitanich 2005) (Comparison 3). There was no difference in the total abdominal collections between the two groups. No patient in either group developed infected abdominal collection or collections requiring any intervention. There was no difference in the analgesic requirement or pain scores between the groups. The hospital stay was statistically significantly lower in the 'no drain' group (Table 03).

We did not perform any other sub-group analysis because of the small number of studies included under each of the outcomes.

Funnel plot
We did not use a funnel plot because of the small number of studies included under each of the important outcomes.

Suction drain versus closed passive drain
The only study (Jorgensen 1995) that compared different types of drains compared the two groups using median pain scores. The value of the median scores were also not given. This study found that the abdominal pain was statistically significantly lower in the suction group than passive drain group in the morning of the first post-operative day (POD). There was no difference in the abdominal pain between the two groups after this. The shoulder pain was statistically significantly lower in the suction group than the passive drain group at all times of measurement till the third POD except the morning of the first POD. There was no statistically significant difference in the wound pain between the groups at any time.

Discussion

This study has shown no significant advantage of using a drain after laparoscopic cholecystectomy. One of the main reasons of using a drain after laparoscopic cholecystectomy is to prevent intra-abdominal collections. The total number of abdominal collections was higher in the drain group compared to the 'no drain' group when the fixed-effect model was used to combine the two studies reporting this outcome. This is mainly because of one study (Thiebe 1994) where 58/131(44%) of drain group developed collections compared to 6/148 (4.1%) in the 'no drain' group. However, the definition of abdominal collection is not stated. Some abdominal collections may be infected or may need drainage when they are clinically significant. Other abdominal collections may not be clinically significant. In this trial, routine ultrasound was performed on the fourth post-operative day and the clinical significance of these collections are questionable as the authors state that there was only one infected collection and did not state whether any of these collections required drainage. By adopting the random-effects model, there is no statistically significant difference between the two groups for the total number of collections. A sensitivity analysis excluding this study (Thiebe 1994) was performed. This demonstrated that there was no statistically significant difference between the two groups in the total number of collections. The abdominal collections may be of no clinical significance. The only study (Capitanich 2005), which mentioned about the treatment of the abdominal collections reported that there were no abdominal collections that required any

intervention. There was no statistically significant difference between the groups in the rate of infected abdominal collections (0.6% drain group vs 0% 'no drain' group).

The wound infection was lower in the 'no drain' group than the drain group (as demonstrated by the risk difference). This may be because of the presence of foreign body. In the only study (Thiebe 1994) which contributed to the meta-analysis, prophylactic antibiotic was not used. There was no statistically significant difference between the groups in the rate of chest complications.

The reason for post-laparoscopy pain is thought to be due to peritoneal irritation caused by carbonic acid and creation of space between diaphragm and liver leading to loss of suction support of heavy liver (Alexander 1987). There is no clear evidence that post-operative drainage reduces pain following laparoscopic cholecystectomy. Although early post-operative shoulder pain was decreased in the drain group, this was not significant and reversed in the later post-operative period. This would not suggest that drainage of residual Co2 or peritoneal fluid is of value in reducing the pain of laparoscopic cholecystectomy.

There was a trend of lower nausea rate in the drain group compared to 'no drain' group. It is difficult to assess the significance of this finding when vomiting did not follow any trend.

Hospital stay was reported to be lower in the 'no drain' group in all the three studies which reported on this outcome (Table 03). In one study none of the 33 patients (who underwent surgery in the morning session) in the drain group could be discharged the same day while 11 of the 35 patients (31.4%) in the 'no drain' group who underwent surgery in the morning session could be discharged on the same day (Hawasli 1994). Recent studies have shown that day-case laparoscopic cholecystectomy is safe with low rates of re-admissions (Leeder 2004; Johansson 2006). However, the insertion of drain can delay the discharge and thus decrease any saving in costs of day case laparoscopic cholecystectomy.

In the absence of a clear benefit of drain use after laparoscopic cholecystectomy, we do not attach much importance to comparison of suction drain and closed passive drain. However, this study (Jorgensen 1995) is useful to determine the type of drain that can be used in future trials involving drains in laparoscopic cholecystectomy. This study found that suction drains are more effective in reduction of pain than passive drains in elective laparoscopic cholecystectomy.

The limitations of this review include the lack of RCTs with high methodological quality (only two of the studies are of high methodological quality) and heterogeneity in the measurement of outcomes resulting in inclusion of only one or two studies for most of the outcomes. Because of this heterogeneity, we were unable to perform any subgroup analyses. Recently, in a Cochrane review, the first two authors of this review found that laparoscopic cholecystectomy is safe during acute cholecystitis (Gurusamy 2006). Only one of the included studies (Nursal 2003) included patients with cholecystitis (3 patients) . It is not clear how many patients had acute cholecystitis. The other trials exlcuded patients with acute cholecystitis. Thus the conclusions of this review are applicable to elective laparoscopic cholecystectomy only.

In another Cochrane review in editorial process, the first two authors of this review, found that drain use in open cholecystectomy increased the wound infection and chest complications without offering any significant benefits. It is interesting to note that drain use after laparoscopic cholecystectomy also increases the wound infection although there is no increase in the chest complications.

Reviewers' conclusions

Implications for practice

(1) Drain use after elective laparoscopic cholecystectomy increases wound infection rates and delays hospital discharge.
(2) Currently, there is no evidence to support the use of drains after laparoscopic cholecystectomy.

Implications for research

(1) Further randomised clinical trials are needed to compare drain use in laparoscopic cholecystectomy performed for acute cholecystitis.
(2) The future trials should adapt blinded assessments of outcome measures whenever possible (The assessor can be blinded to all the important outcome measures stated if adequate efforts are taken). It is even possible to blind the health-care providers in the case of a trial of drain use in laparoscopic cholecystectomy as this is an unique situation where one of the small ports can be used as an exit for drains. Thus, after the surgeon inserts the drains in all patients, a third party either pulls out the drain outside the port, shortens the drain and fixes the end to the skin with a tape after blocking the tip with a bead (to ensure that suction can be applied at the other end) or leaves the end of the drain in the peritoneal cavity and connects the drain to the suction. This way, the patients are also blinded to the groups. Thus, this is a rare instance, where adequate blinding is possible in assessment of interventions in surgery.
(3) Trials need to be conducted and reported according to the CONSORT Statement (www.consort-statement.org).

Acknowledgements

(1) To Dr Martyn Parker, author of more than 15 Cochrane reviews, who inspired me to write Cochrane reviews.
(2) To The Cochrane Hepato-Biliary Group for the support that they have provided.
(3) To Z Yu, who contributed to the background section.

Potential conflict of interest

None known.

Characteristics of included studies

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Capitanich 2005	Randomised clinical trial Generation of the allocation sequence: random number table. Allocation concealment: sealed envelope	Country: Argentina. Number randomised: 93. Mean age: 52.4 years. Females: 55. Inclusion criteria: Elective laparoscopic cholecystectomy. Exclusion criteria: 1. Emergency cholecystectomy. 2. Jaundice. 3. Injury	Participants were randomly assigned to two groups. Time of randomisation: After removal of gallbladder. Group 1: Closed passive open drain (n=40)	The main outcome measures were pain at different times (8 hours, 16 hours, 24 hours)	The authors replied to the questions related to generation of allocation sequence and the allocation concealment.	A

	technique. Follow-up: adequate. Intention-to-treat analysis: no. Sample size calculation: no.	to cystic artery. 4. Choledocholithiasis. 5. Sclerotic gallbladder.	Group 2: No drain (n = 53). Co-interventions: Drain brought through: port Antibiotic use: Not stated. Duration of drain: Not stated.			
Hawasli 1994	Randomised clinical trial Generation of the allocation sequence: adequate (computer generated). Allocation concealment: unclear. Follow-up: adequate. Intention-to-treat analysis: no. Sample size calculation: no.	Country: United States of America. Number randomised: 100. Mean age: 52 years Females: 79. Inclusion criteria: Elective laparoscopic cholecystectomy. Exclusion criteria: 1. Acute cholecystitis. 2. Required cholangiogram, 3. Complicated procedure.	Participants were randomly assigned to two groups. Time of randomisation: Not stated. Group 1: Suction drain (n=50) Group 2: No drain (n =50). Co-interventions: Drain brought through: port. Antibiotic use: Not stated. Duration of drain: Not stated.	The main outcome measures were wound infection, same day discharge, abdominal pain, (number and severity), shoulder pain (number) and nausea.	No attempts were made to contact the author as the study was more than 10 years ago.	B
Jorgensen 1995	Randomised clinical trial Generation of the allocation sequence: adequate (number lottery). Allocation concealment: unclear. Follow-up: adequate. Intention-to-treat analysis: no.	Country: Australia. Number randomised: 41. Median age: 64.5 and 61 years in the treatment and control arms. Females: 26. Inclusion criteria: Elective laparoscopic cholecystectomy. Exclusion criteria: 1. Refusal of consent. 2. Age less than 18 years. 3. Inability to	Participants were randomly assigned to two groups. Time of randomisation: After removal of gallbladder. Group 1: Suction drain (n=22) Group 2: Passive closed drain (n =19). Co-interventions:	The main outcome measures were abdominal pain, shoulder pain and wound pain.	No attempts were made to contact the author as the study was more than 10 years ago. Patients were blinded to the group to which they belonged to.	B

	Sample size calculation: no.	understand and hence inaccurately fill out the research questionnaire. 4. Performance of an additional procedure. 5. Surgical indication for operative intra-abdominal suction drainage (not stated what these are).	Drain brought through: port. Antibiotic use: Not stated. Duration of drain: Removed on 1st Post-operative day.			
Nomdedeu 1997	Randomised clinical trial Generation of the allocation sequence: Random table. Allocation concealment: Held by third party. Follow-up: adequate. Intention-to-treat analysis: no. Sample size calculation: no.	Country: Spain. Number randomised: 50. Mean age: 54 years. Females: 35. Inclusion criteria: Symptomatic gallstones. Exclusion criteria: 1. Cholecystitis 2. Coagulopathy 3. Abnormal cholangiogram 4. Conversion to open cholecystectomy 5. Biliary colic 6. GB rupture during surgery 7. Liver disease	Participants were randomly assigned to two groups. Time of randomisation: Not stated but the surgeons did not know the group until the end of the surgery. Group 1: Suction drain (n=25) Group 2: No drain (n =25). Co-interventions: Drain brought through: port. Antibiotic use: Yes. Duration of drain: <50ml	The main outcome measures were abdominal collections and hospital stay.	The author was contacted over telephone and he answered on the generation of random sequence and allocation concealment.	A
Nursal 2003	Randomised clinical trial Generation of the allocation sequence: unclear. Allocation concealment: unclear. Follow-up: adequate. Intention-to-	Country: Turkey. Number randomised: 69. Mean age: 50 years. Females: 54. Inclusion criteria: 1. ASA grade I and II 2. Gallstones with or without acute cholecystitis. Exclusion criteria: 1. Patients who were converted to	Participants were randomly assigned to two groups. Time of randomisation: Not stated. Group 1: Suction drain (n=35) Group 2: No drain (n =34).	The main outcome measures were abdominal pain, shoulder pain, chest complications, analgesic requirement and antiemetic requirement.	Attempts were made to contact the author. But no reply was received. Patients were blinded to the group to which they belonged to.	B

	treat analysis: no. Sample size calculation: no.	open surgery 2. Refused laparoscopic cholecystectomy 3. Refused to give informed consent 4. Given medications other than the standard anesthesia protocol	Co-interventions: Drain brought through: separate wound. Antibiotic use: Yes. Duration of drain: 24 hours			
Thiebe 1994	Randomised clinical trial Generation of the allocation sequence: unclear. Allocation concealment: unclear. Follow-up: adequate. Intention-to-treat analysis: no. Sample size calculation: no.	Country: Germany. Number randomised: 279. Mean age: Not stated. Females: Not stated. Inclusion criteria: Laparoscopic cholecystectomy. Exclusion criteria: 1. Patients who were converted to open surgery. 2. Liver bed bleeding 3. Acute cholecystitis	Participants were randomly assigned to two groups. Time of randomisation: Not stated. Group 1: Passive closed drain (n=131) Group 2: No drain (n =148). Co-interventions: Drain brought through: separate wound. Antibiotic use: Yes. Duration of drain: 24 hours	The main outcome measures were abdominal collections, chest infection, other chest complications, pain, analgesic requirements and hospital stay.	No attempts were made to contact the author as the study was more than 10 years ago.	B

Characteristics of excluded studies

Study	Reason for exclusion
Abbott 2001	Performed in other laparoscopic procedures and not in laparoscopic cholecystectomy
Alexander 1987	Performed in other laparoscopic procedures and not in laparoscopic cholecystectomy
Mrsic 1997	Not a randomized clinical trial
Tsimoyiannis 1998	Some patients who were randomised were replaced by other new patients who were allocated to the same group as the patients originally included.
Tsimoyiannis 1998b	In this study where the main outcome measures were pain, nausea and vomiting, the drain group received other interventions such as intraperitoneal normal saline or bupivacaine instillation.

References to studies

References to included studies

Capitanich 2005 {published and unpublished data}

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** indicates the primary reference for the study*

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Comparisons and data

01 Drain versus 'No drain' (Fixed-effect model)

01.01 Total abdominal collections

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	1	39	1	52
Thiebe 1994	58	131	6	148

01.02 Abdominal collections requiring re-operation

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

01.03 Abdominal collections requiring drain insertion

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

01.04 Abdominal collections requiring percutaneous drainage

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

01.05 Infected abdominal collections

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53
Thiebe 1994	1	131	0	148

01.06 Wound infection

Study ID	Drain n	Drain N	No drain n	No drain N

Hawasli 1994	0	50	0	50
Thiebe 1994	6	131	0	148

01.07 Chest complications

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	3	34	5	33
Thiebe 1994	2	131	1	148

01.08 Nausea (0-6 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	11	35	13	34

01.09 Nausea (7-12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	4	35	7	34

01.10 Nausea (13-24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	2	35	5	34

01.11 Nausea (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	3	34	10	33

01.12 Nausea (until discharge)

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	12	50	17	50

01.13 Vomiting (0-6 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	2	35	2	34

01.14 Vomiting (7-12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	5	35	2	34

01.15 Vomiting (13-24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	1	35	2	34

01.16 Vomiting (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	0	34	0	33

01.17 Number requiring anti-emetic

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	10	35	13	34

01.18 Anti-emetic requirement

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Nursal 2003	35	3.42	5.91	34	5.58	8.94

01.19 Shoulder pain (0 -12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	4	35	5	34

01.20 Shoulder pain (13 -24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	15	50	22	50
Nursal 2003	6	35	4	34

01.21 Shoulder pain (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	3	34	2	33

01.22 Abdominal pain (0 - 12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	33	35	30	34

01.23 Abdominal pain (0-12 hours)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Nursal 2003	35	31.62	19.12	34	43.85	24.72

01.24 Abdominal pain (13 -24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	15	50	22	50
Nursal 2003	20	35	26	34

01.25 Abdominal pain (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	15	34	16	33

01.26 Pain (site unspecified) (0 -12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	34	35	33	34

01.27 Pain (site unspecified) (0-12 hours)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Capitanich 2005	40	3.92	2.01	53	2.53	2.83

01.28 Pain (site unspecified) (13 -24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	28	35	31	34
Thiebe 1994	11	131	4	148

01.29 Pain (site unspecified) (13-24 hours)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Capitanich 2005	40	1.14	1.21	53	1.41	1.67

01.30 Pain (site unspecified) (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	20	34	18	33
Thiebe 1994	10	131	3	148

01.31 Analgesic requirement (Non-steroidal anti-inflammatory)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Capitanich 2005	40	1.68	0.94	53	2.15	1.21
Nomdedeu 1997	25	3.70	1.82	25	3.50	2.54
Nursal 2003	35	79.71	36.09	34	75.88	34.65

01.32 Analgesic requirement (opiates)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Nursal 2003	35	7.14	17.75	34	4.41	14.39

01.33 Number needing opiate analgesia

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	5	35	3	34

01.34 Same day discharge

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	0	33	11	35

02 Drain versus 'No drain' (Risk difference)

02.01 Total abdominal collections

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	1	39	1	52
Thiebe 1994	58	131	6	148

02.02 Abdominal collections requiring re-operation

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

02.03 Abdominal collections requiring drain insertion

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

02.04 Abdominal collections requiring percutaneous drainage

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

02.05 Infected abdominal collections

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53
Thiebe 1994	1	131	0	148

02.06 Wound infection

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	0	50	0	50
Thiebe 1994	6	131	0	148

02.07 Chest complications

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	3	34	5	33
Thiebe 1994	2	131	1	148

02.08 Nausea (0-6 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	11	35	13	34

02.09 Nausea (7-12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	4	35	7	34

02.10 Nausea (13-24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	2	35	5	34

02.11 Nausea (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	3	34	10	33

02.12 Nausea (until discharge)

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	12	50	17	50

02.13 Vomiting (0-6 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	2	35	2	34

02.14 Vomiting (7-12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	5	35	2	34

02.15 Vomiting (13-24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	1	35	2	34

02.16 Vomiting (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	0	34	0	33

02.17 Number requiring anti-emetic

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	10	35	13	34

02.18 Shoulder pain (0 -12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	4	35	5	34

02.19 Shoulder pain (13 -24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	15	50	22	50
Nursal 2003	6	35	4	34

02.20 Shoulder pain (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	3	34	2	33

02.21 Abdominal pain (0 - 12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	33	35	30	34

02.22 Abdominal pain (13 -24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	15	50	22	50
Nursal 2003	20	35	26	34

02.23 Abdominal pain (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	15	34	16	33

02.24 Pain (site unspecified) (0 -12 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	34	35	33	34

02.25 Pain (site unspecified) (13 -24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	28	35	31	34
Thiebe 1994	11	131	4	148

02.26 Pain (site unspecified) (>24 hours)

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	20	34	18	33
Thiebe 1994	10	131	3	148

02.27 Number needing opiate analgesia

Study ID	Drain n	Drain N	No drain n	No drain N
Nursal 2003	5	35	3	34

02.28 Same day discharge

Study ID	Drain n	Drain N	No drain n	No drain N
Hawasli 1994	0	33	11	35

03 Drain versus 'No drain' (High methodological quality)

03.01 Total abdominal collections

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	1	39	1	52

03.02 Abdominal collections requiring re-operation

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

03.03 Abdominal collections requiring drain insertion

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

03.04 Abdominal collections requiring percutaneous drainage

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

03.05 Infected abdominal collections

Study ID	Drain n	Drain N	No drain n	No drain N
Capitanich 2005	0	40	0	53

03.06 Pain (site unspecified) (0-12 hours)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Capitanich 2005	40	3.92	2.01	53	2.53	2.83

03.07 Pain (site unspecified) (13-24 hours)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Capitanich 2005	40	1.14	1.21	53	1.41	1.67

03.08 Analgesic requirement (Non-steroidal anti-inflammatory)

Study ID	Drain N	Drain Mean	Drain SD	No drain N	No drain Mean	No drain SD
Capitanich 2005	40	1.68	0.94	53	2.15	1.21
Nomdedeu 1997	25	3.70	1.82	25	3.50	2.54

Additional tables

01 Search strategies for identification of studies

Database	Period	Search strategy used
The Cochrane Hepato-Biliary Group Controlled Trials Register	Issue 2, 2006	(laparoscop* OR celioscop* OR coelioscop* OR abdominoscop* OR peritoneoscop*) AND (cholecystecto* OR colecystecto*) AND drain*
The Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library	Issue 2, 2006	#1 laparoscop$ or celioscop$ or coelioscop$ or abdominoscop$ or peritoneoscop$ in All Fields in all products #2 cholecystecto* or colecystecto* in All Fields in all products #3 MeSH descriptor Cholecystectomy, Laparoscopic explode all trees in MeSH products #4 MeSH descriptor Drainage explode all trees in MeSH products #5 drain* in All Fields in all products #6 ((#1 AND #2) OR #3) AND (#4 OR #5)
Pubmed	January 1987 to 30/04/06	((((laparoscop* or celioscop* or coelioscop* or abdominoscop* or peritoneoscop*) AND (cholecystecto* or colecystecto*)) OR "Cholecystectomy, Laparoscopic"[MeSH]) AND ("Drainage"[MeSH] OR drain*)) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR ("clinical trial" [tw]) OR ((singl* [tw] OR doubl* [tw] OR trebl* [tw] OR tripl* [tw]) AND (mask* [tw] OR blind* [tw])) OR (placebos [mh] OR placebo* [tw] OR random* [tw] OR research design [mh:noexp]) NOT (animals [mh] NOT human [mh])) AND ("1987"[PDAT] : "3000"[PDAT])
		1 laparoscop$ OR celioscop$ OR coelioscop$ OR abdominoscop$ OR peritoneoscop$ 2 cholecystect$ OR colecystect$ 3 1 AND 2 4 LAPAROSCOPIC-SURGERY#.DE. OR LAPAROSCOPY#.W..DE. 5 CHOLECYSTECTOMY#.W..DE. 6 4 AND 5 7 3 OR 6 8 drain$ OR SURGICAL-DRAINAGE#.DE. OR DRAIN#.W..DE. 9 7 AND 8 10 RANDOMIZED-CONTROLLED-TRIAL#.DE. OR

EMBASE	January 1987 to 30/04/06	RANDOMIZATION#.W..DE. OR CONTROLLED-STUDY#.DE. OR MULTICENTER-STUDY#.DE. OR PHASE-3-CLINICAL-TRIAL#.DE. OR PHASE-4-CLINICAL-TRIAL#.DE. OR DOUBLE-BLIND-PROCEDURE#.DE. OR SINGLE-BLIND-PROCEDURE#.DE. 11 RANDOM$ OR CROSSOVER$ OR CROSS-OVER OR CROSS ADJ OVER OR FACTORIAL$ OR PLACEBO$ OR VOLUNTEER$ 12 (SINGLE OR DOUBLE OR TREBLE OR TRIPLE) NEAR (BLIND OR MASK) 13 10 OR 11 OR 12 14 13 AND HUMAN=YES 15 9 AND 14
Science Citation Index Expanded (http://portal.isiknowledge.com/portal.cgi?DestApp=WOS&Func=Frame)	1987 to to 30/04/06	#1 TS=(laparoscop* OR celioscop* OR coelioscop* OR abdominoscop* OR peritoneoscop*) #2 TS=(cholecystecto* OR colecystecto*) #3 TS=drain* #4 TS=(random* OR blind* OR placebo* OR meta-analysis) #5 #1 AND #2 AND #3 AND #4

02 Pain (studies not included in meta-analysis)

Study	Site	Time of measurement	Measure	Drain	No drain	Statist significance
Hawasli 1994	Abdomen	<23 hours	Pain score - Mean	2.24	2.46	Not significant
Hawasli 1994	Abdomen	>23 hours	Pain score - Mean	1.70	1.86	Not significant
Thiebe 1994	Not stated	Not stated	Pain score - Mean	Not stated	Not stated	Significantly lower in the 'no drain' group
Thiebe 1994	Not stated	Not stated	Analgesic requirement - Mean	Not stated	Not stated	Significantly lower in the 'no drain' group

03 Hospital stay in days

Study	Drain	No drain	Measure	Statis significance
Capitanich 2005	Not stated	Not stated	Not applicable	Not applicable

Hawasli 1994	all patients discharged on next day	11/35 patients, who underwent surgery in the morning session were discharged the same day. The remaining 24 patients from morning session and all patients from the afternoon session were discharged by next day.	Not applicable	Not applicable
Nomdedeu 1997	3.16	2.68	Median	Statistically significant
Nursal 2003	Not stated	Not stated	Not applicable	Not applicable
Thiebe 1994	7.7	6.0	Mean	Not stated

Notes

Unpublished CRG notes

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Published notes

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