Laparoscopic cholecystectomy 2004

Summary Recommendations

Notes on PROSPECT recommendations

Recommendations are graded according to the overall level of evidence (LoE) on which the recommendations are based, which is determined by the quality and source of evidence: (Appendix A: Levels of evidence and grades of recommendation).

PROSPECT provides clinicians with supporting arguments for and against the use of various interventions in postoperative pain based on published evidence and expert opinion. Clinicians must make judgements based upon the clinical circumstances and local regulations. At all times, local prescribing information for the drugs referred to must be consulted.

Summary recommendations

Pre-, intra- and postoperative interventions have been evaluated for the management of postoperative pain following laparoscopic cholecystectomy. Unless otherwise stated, ‘pre-operative’ refers to interventions applied before surgical incision, ‘intra-operative’ refers to interventions applied after incision and before wound closure, ‘postoperative’ refers to interventions applied at or after wound closure.

The following peri-operative interventions for laparoscopic cholecystectomy have been reviewed:

PRE-OPERATIVE

PRE-OPERATIVE RECOMMENDED	*NOT RECOMMENDED*
SYSTEMIC ANALGESIA **Corticosteroid** • dexamethasone (Grade B for analgesic effects; Grade A for anti-emetic effects) **COX-2-selective inhibitors** • (Grade B) **Gabapentinoids** • gabapentin (Grade B)	**SYSTEMIC ANALGESIA** **Alpha-2-adrenergic receptor agonists** • clonidine (Grade D) **Conventional NSAIDs** • (Grade B) **IV LA** • (Grade D) **NMDA antagonist** • dextromethorphan (Grade D) • ketamine (Grade D) • magnesium (Grade B) **Strong opioids** • strong opioids (Grade B) **Weak opioids** • tramadol (Grade B) **Paracetamol** • (Grade B)
REGIONAL ANALGESIA **LA wound infiltration** • long-acting LA wound infiltration (Grade A) for reducing wound pain but not shoulder pain	**REGIONAL ANALGESIA** **Paravertebral block** • (Grade D) **Spinal LA + strong opioid**

PRE-OPERATIVE RECOMMENDED	*NOT RECOMMENDED*
	• (Grade D)
Epidural analgesia • in high-risk pulmonary patients (Grade D)	**Epidural analgesia** • except in high-risk pulmonary patients (Grade D)
	OTHER INTERVENTIONS
	Oral carbohydrate • (Grade D)

INTRA-OPERATIVE

INTRA-OPERATIVE RECOMMENDED	*NOT RECOMMENDED*
SYSTEMIC ANALGESIA	**SYSTEMIC ANALGESIA**
Conventional NSAIDs • at end of surgery (Grade D)	**NMDA antagonist** • dextromethorphan (Grade D) • ketamine infusion (Grade D) • magnesium infusion (Grade B)
COX-2-selective inhibitors • (Grade D)	**Strong opioids** • longer-acting strong opioids (Grade B)
Short-acting strong opioids • as part of the anaesthetic technique (Grade D)	

INTRA-OPERATIVE RECOMMENDED	*NOT RECOMMENDED*
REGIONAL ANALGESIA **LA wound infiltration** • long-acting LA wound infiltration (Grade A) for reducing wound pain but not shoulder pain **IP LA** • IP LA (Grade A) for reducing wound pain but not shoulder pain **Combined LA wound infiltration/IP LA** • (Grade A; dose needs monitoring for toxicity Grade D)	**REGIONAL ANALGESIA** **Epinephrine as part of LA solution** • (Grade B) **Intraperitoneal strong opioid** • (Grade D) **Interpleural LA** • (Grade B) **Interpleural strong opioid** • (Grade B)
ANAESTHETIC TECHNIQUES **General anaesthesia** **Combined epidural/general anaesthesia** • for high-risk pulmonary patients (Grade D)	**ANAESTHETIC TECHNIQUES** **Combined epidural/general anaesthesia** • for routine anaesthesia (Grade D)
OPERATIVE TECHNIQUES **Low-pressure CO_2** • (Grade A) **Saline lavage, followed by suction** • (Grade A)	**OPERATIVE TECHNIQUES** **Gasless laparoscopic cholecystectomy** • (Grade A) **Humidified and warmed CO_2 pneumoperitoneum** • (Grade D and A, respectively) **N_2O pneumoperitoneum** • (Grade D) **Helium pneumoperitoneum** • (Grade B) **Smaller total size of trocar incision** • (Grade D)

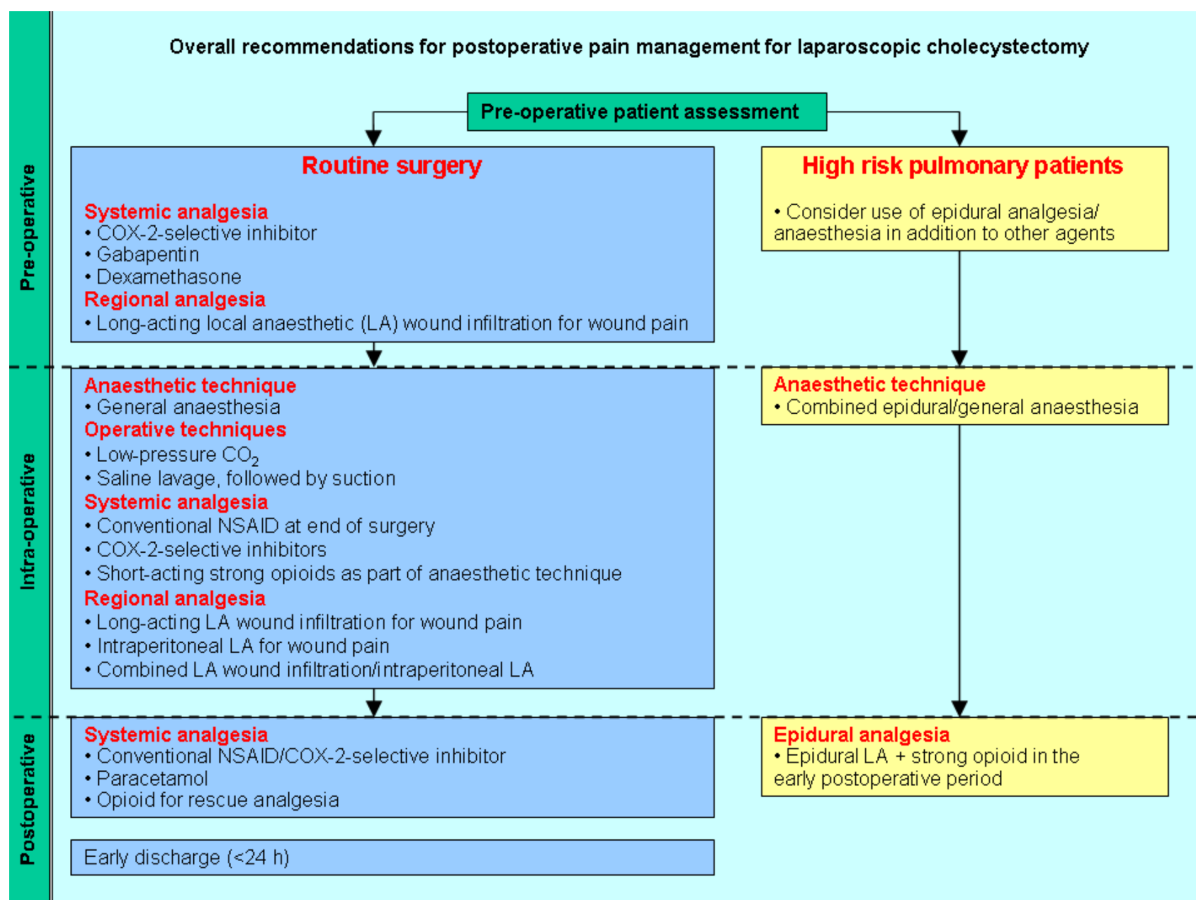
INTRA-OPERATIVE RECOMMENDED	*NOT RECOMMENDED*
	Radially expanding trocars • (Grade D) **Subhepatic drain** • (Grade D) **Aspiration of pneumoperitoneum gas** • (Grade D)

POSTOPERATIVE

POSTOPERATIVE RECOMMENDED	*NOT RECOMMENDED*
SYSTEMIC ANALGESIA **Conventional NSAIDs** • (Grade A) **COX-2-selective inhibitors** • (Grade A) **Strong opioids** • for high-intensity pain in addition to other agents (Grade D) **Weak opioids** • for rescue analgesia with medium-to-low-intensity pain in addition to other agents (Grade D) **Paracetamol** • (Grade A)	**SYSTEMIC ANALGESIA** **NMDA antagonist** • ketamine (Grade D) • magnesium (Grade B) **Strong opioids** • for routine analgesia (Grade B) **Weak opioids** • for routine analgesia (Grade B)
	REGIONAL ANALGESIA **PCA IP LA** • (Grade D)
EPIDURAL ANALGESIA **Epidural analgesia** • for high-risk pulmonary patients (Grade D)	**EPIDURAL ANALGESIA** **Epidural strong opioid + LA** • for routine analgesia (Grade D)
PATIENT MANAGEMENT **Early discharge** • (Grade D)	

Overall Recommendations: Pain Management for Laparoscopic cholecystectomy

PROSPECT overall recommendations for postoperative pain management following laparoscopic cholecystectomy:



Not recommended for Laparoscopic Cholecystectomy

Not recommended: Pre-operative

Systemic analgesia
- Clonidine
- Conventional NSAIDs
- Dextromethorphan
- IV local anaesthetic (LA) infusion
- Ketamine bolus
- Magnesium
- Strong opioids
- Tramadol
- Paracetamol

Regional analgesia
- Long-acting LA wound infiltration
- Epinephrine as part of the LA solution for wound infiltration
- Bilateral paravertebral block
- Spinal LA + strong opioid
- Epidural analgesia except in high risk pulmonary patients

Other interventions
- Pre-operative oral carbohydrate

Not recommended: Intra-operative

Systemic analgesia
- Dextromethorphan
- Ketamine infusion
- Magnesium infusion
- Longer-acting strong opioids (instead of short-acting strong opioids as part of the anaesthetic technique)

Regional analgesia
- Epinephrine as part of the LA solution for wound infiltration or intraperitoneal analgesia
- Intraperitoneal strong opioid
- Interpleural LA or strong opioid

Anaesthetic techniques
- Combined epidural/general anaesthesia except in high risk pulmonary patients

Operative techniques
- Gasless laparoscopic cholecystectomy
- Humidified and warmed CO_2 pneumoperitoneum
- N_2O pneumoperitoneum
- Helium pneumoperitoneum
- Smaller size of trocar incision
- Radially expanding trocars
- Subhepatic drain
- Aspiration of pneumoperitoneum gas

Not recommended: Postoperative

Systemic analgesia
- Ketamine infusion
- Magnesium infusion
- Strong opioids for routine analgesia
- Weak opioids for routine analgesia

Regional analgesia
- PCA intraperitoneal LA
- Epidural analgesia except in high risk pulmonary patients

Evidence review process

Details of systematic literature review

Literature search

- Systematic review of the literature from 1966–October 2005 using MEDLINE and EmBASE, following the protocol of the Cochrane Collaboration (Appendix B: Laparoscopic Cholecystectomy Update 2006 Search Terms)
- Inclusion of randomised studies in English, assessing analgesic interventions in laparoscopic cholecystectomy in adults, and reporting pain on a linear analogue scale
- Identification of 289 studies of peri-operative interventions for postoperative pain following laparoscopic cholecystectomy
- 121 studies included (Appendix C: Laparoscopic Cholecystectomy Update 2006 Included References)
- 169 studies excluded (Appendix D: Laparoscopic Cholecystectomy Update 2006 Excluded References)
- The most common reason for exclusion was that the study did not report pain scores (47 studies) (Appendix E: Laparoscopic Cholecystectomy Update 2006 Reasons for Exclusion)

Appendix

A. Levels of evidence and grades of recommendation

From 2006 onwards, the **prospect** methodology has been refined to take more account of the quality of the evidence on which the recommendations are based. The way in which the quality of studies determines the level of evidence, and thereby determines the grade of recommendation, is summarised below. Development of the **prospect** methodology has been an ongoing process, and previous experience indicated the need for these changes, to help clarify the basis for the recommendations.

Sources of evidence in PROSPECT

The evidence for **prospect** is derived from three separate sources, and this evidence is taken into consideration by the **prospect** Working Group to determine the **prospect** recommendations:

- Procedure-specific evidence derived from the systematic reviews of the literature
- Transferable evidence from comparable procedures, or from other relevant sources, identified by the members of the **prospect** Working Group
- Current practice – a commentary on the interventions from the members of the **prospect** Working Group
- Practical **prospect** recommendations are based on all the information **Study quality assessment**

All cited studies are assessed for quality of reporting of methodology and results (assessment performed by the medical writing team and the **prospect** Subgroup):

1. Statistical analyses and patient follow-up assessment: indicates whether statistical analyses were reported, and whether patient follow-up was greater or lesser than 80%.

2. Allocation concealment assessment: indicates whether there was adequate prevention of foreknowledge of treatment assignment by those involved in recruitment (A adequate, B unclear, C inadequate, D not used). Empirical research has shown that trials with inadequate or unclear allocation concealment report significantly greater estimates of treatment effect than those trials in which concealment was adequate (Chalmers 1983, Schulz 1995, Moher 1998). Allocation concealment was found to be more important for preventing bias than other aspects of study quality, such as generation of the allocation sequence and double-blinding (Chalmers 1983, Schulz 1995, Moher 1998, Higgins JPT, Green S, editors, 2005; http://www.cochrane.org/resources/handbook/hbook.htm (accessed 31st May 2005): Section 6.3.)

3. Numerical scores (total 1–5) for study quality: assigned using the method proposed by Jadad et al 1996, to indicate whether a study reports appropriate randomisation, double-blinding and statements of possible withdrawals. Empirical research found that low-quality trials were associated with an increased estimate of treatment benefit than high-quality trials (Moher 1998)

4. Additional study quality assessment: including an assessment of how closely the study report meets the requirements of the CONSORT statement (Moher 2005) (additional assessment performed by the **prospect** Subgroup)

Grading of recommendations based on overall level of evidence

The recommendations are graded according to the overall level of evidence, which is determined by the quality of studies cited, the consistency of evidence and the source of evidence (as indicated in the table below).

Relationship between quality and source of evidence, levels of evidence and grades of recommendation in PROSPECT

<table>
<tr><th></th><th colspan="5">Study quality assessments</th><th>Level of Evidence (LoE)</th><th colspan="2">Grade of recommendation (based on overall LoE, considering balance of clinical practice information and evidence)</th></tr>
<tr><th>Study type</th><th>Statistical analyses and patient follow-up assessment</th><th></th><th>Allocation concealment</th><th>Jadad scores</th><th>Additional assessment of overall study quality required to judge LoE</th><th></th><th>Procedure-specific</th><th>Transferable</th></tr>
<tr><td>Systematic review with homogeneous results</td><td>N/A</td><td></td><td>N/A</td><td>N/A</td><td>N/A</td><td>1</td><td>A</td><td>B</td></tr>
<tr><td rowspan="5">Randomised controlled trial (RCT)</td><td rowspan="5">Statistics reported and >80% follow-up</td><td rowspan="5">AND</td><td>A</td><td>(1-5)</td><td>N/A</td><td rowspan="5">1</td><td rowspan="5">A
(based on two or more studies or a single large, well-designed study)</td><td rowspan="5">B</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>B</td><td>(3-5)</td><td>N/A</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>B</td><td>(1-2)</td><td>Yes</td></tr>
<tr><td rowspan="5">RCT</td><td rowspan="5">Statistics not reported or questionable or <80% follow-up</td><td rowspan="5">AND/ OR</td><td>B</td><td>(1-2)</td><td>Yes</td><td rowspan="5">2</td><td rowspan="5">B
(or extrapolation from one procedure-specific LoE 1 study)</td><td rowspan="5">C</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>C</td><td>(1-5)</td><td>N/A</td></tr>
<tr><td colspan="3">OR</td></tr>
<tr><td>D</td><td>(1-5)</td><td>N/A</td></tr>
<tr><td>Non-systematic review, cohort study, case study;
(e.g. some adverse effects evidence)</td><td>N/A</td><td></td><td colspan="3">N/A</td><td>3</td><td colspan="2">C</td></tr>
<tr><td>Clinical practice information (expert opinion); inconsistent evidence</td><td>N/A</td><td></td><td colspan="3">N/A</td><td>4</td><td colspan="2">D</td></tr>
</table>

B. Laparoscopic Cholecystectomy Update 2006 Search Terms

Limits: Title/Abstract, 1966 to October 2005

(pain OR analgesi* OR anaesthe* OR anesthe* OR vas OR "visual analog*" OR vrs OR mcgill OR epidural OR neuraxial OR intrathecal OR spinal OR caudal OR interpleural OR “peripheral nerve” OR “peripheral block” OR intercostal OR “nerve block” OR NSAID OR COX-2 OR paracetamol OR acetaminophen OR gabapentin OR pregabalin OR clonidine OR opioid OR ketamine OR corticosteroid) AND (laparoscop* OR endoscop*) AND (cholecystectomy OR “gall bladder”)

C. Laparoscopic Cholecystectomy Update 2006 Included References

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E. Laparoscopic Cholecystectomy Update 2006 Reasons for Exclusion

Study	***REASONS FOR EXCLUSION***
1. Acil 2004	Pain scores not presented
2. Agarwal 2003	No VAS pain assessment
3. Agarwal 2004	Propofol-induced pain not postop-pain
4. Agnifili 1993	Compares lap chole against open procedure
5. Akca 2004	Combined lap chole and groin hernia repair groups
6. Argiriadou 2002	No VAS pain assessment
7. Assalia 1993	No VAS pain assessment + open cholecystectomy
8. Assalia 1997	No VAS pain assessment + open cholecystectomy
9. Awad 2002	No VAS pain assessment
10. Barkun 1992	Compares lap chole against mini-lap chole procedure
11. Barkun 1993	Duplicates data in Barkun 1992
12. Berberoglu 1998	No VAS pain assessment
13. Berggren 1994	No VAS pain assessment
14. Berven 1995	RCT - status unclear + no VAS pain assessment
15. Bhoyrul 2000	Combined procedures
16. Bisgaard 2002	Not a comparative study
17. Biswas 2003	No VAS pain assessment
18. Boldt 1998	Not RCT
19. Brackman 2002	No VAS pain assessment + cost savings study
20. Buanes 1993	Not RCT

21. Buanes 1996	Not RCT
22. Byrne 1994	Compares lap chole against open procedure
23. Campbell 2000	No VAS pain assessment
24. Camus 1995	No VAS pain assessment
25. Cason 1996	Not RCT
26. Cete 1996	Conventional cholecystectomy
27. Chan 1994	Not RCT
28. Chan 1995	Not RCT
29. Chen 1995	Not RCT
30. Chok 2004	Not RCT
31. Chow 1997	Retrospective
32. Colak 2004	Compares use vs. re-use of disposable instruments
33. Collier 1993	Not RCT
34. Cox 1992	Retrospective
35. Croce 1999	Not laparoscopic cholecystectomy (duodenal ulcers)
36. Cunniffe 1998	Mixed laparoscopic procedures
37. Dahl 1994	Minilaparotomy cholecystectomy
38. Davides 1999	Not RCT
39. Dill 2000	Not RCT
40. Eberhart 1999a	No VAS pain assessment
41. Eberhart 1999b	Compares antiemetics not analgesics
42. Ehsan-ul-Haq 2004	No pain assessment
43. Eldar 1997	Not RCT

44. Ell 1990	Piezoelectric lithotripsy
45. Fiorillo 1996	Not RCT
46. Frank 1990	Conventional cholecystectomy
47. Frenette 1991	Conventional cholecystectomy
48. Fujii 2000	No pain assessment
49. Fujii 2004	No pain assessment; nausea and vomiting study
50. Gan 2004b	Used Joshi 2004 data, but tested hypothesis that reducing opioid consumption reduced opioid-related side effects
51. Gharaibeh 2000	No VAS pain assessment
52. Gillberg 1993	Gynaecological laparoscopy
53. Golder 1998	No VAS pain assessment specified. Comparison of operative techniques
54. Gurmarnik 1996	No VAS pain assessment
55. Habib 2004	No VAS pain assessment
56. Hakanson 1989	Conventional cholecystectomy
57. Hanaoka 2004	No VAS pain assessment
58. Hasaniya 2001	No VAS pain assessment
59. Helmy 1999	No VAS pain assessment
60. Hendolin 2000	Compares lap chole against open procedure
61. Hong 2003b	Physiological study, no pain assessment
62. Hong 2003a	Gynaecological laparoscopy
63. Horattas 2004	No VAS pain assessment
64. Hsieh 2003	Acute cholecystitis, no VAS assessment

65. Huang 1990	Conventional cholecystectomy
66. Inan 2004	Not RCT
67. Jallali 2004	No VAS pain assessment + not relevant (investigating closure techniques)
68. Jelicic 1993	Conventional cholecystectomy
69. Jensen 2002	Laparotomy
70. Jensen 2004	Used Joshi 2004 data, but investigated the relationship between several predictors and patient satisfaction
71. Johansson 2005	Compares lap chole vs. open procedure
72. Joris 1992	Not RCT
73. Joris 1998	Gastroplasty
74. Karayiannakis 1997	Compares lap chole vs. open procedure
75. Kenady 1992	Conventional cholecystectomy
76. Khan 1997	No VAS pain assessment
77. Khan 2002	No VAS pain assessment
78. Kimberley 1996	Not RCT
79. Kitano 1993	No VAS pain assessment
80. Klockgether-Radke 1996	No VAS pain assessment
81. Koivuranta 1996	No VAS pain assessment
82. Koivusalo 1996	No VAS pain assessment
83. Koivusalo 1997	No VAS pain assessment
84. Koivusalo 2000	Review paper

85. Kolla 2004	Statistical analysis of pain outcomes unclear
86. Kristiansson 1999	Not RCT
87. Kum 1994	Not RCT
88. Lai 1998	No VAS pain assessment
89. Larsen 2002	Only abstract in English
90. Laurito 1991	Conventional cholecystectomy
91. Le Blanc-Louvry 2000	Compares lap chole vs. open procedure
92. Lee 1990	Conventional cholecystectomy
93. Lee 2005	Not RCT
94. Lindgren 1997	No VAS pain assessment
95. Los 1995	No VAS pain assessment
96. Lysak 1994	Gynaecological laparoscopy
97. Madsen 1992	Not RCT
98. Maidatsi 1998	Conventional cholecystectomy
99. Majeed 1996	No VAS pain assessment
100. McCrory 2002	Review paper
101. McGinn 1995	No VAS pain assessment
102. McLaughlin 1994	Gynaecological laparoscopy
103. McMahon 1994a	Compares lap chole vs. mini-lap chole
104. McMahon 1994b	Compares lap chole vs. mini-lap chole
105. Mealy 1992	Not RCT
106. Morino 1998	No VAS pain assessment + Study about hepatic function
107. Mrsic 1997	RCT-status unclear

108. Murrell 1996	Not just lap chole
109. Naguib 1996	Compares antiemetics not analgesics
110. Naude 1996	No VAS pain assessment + Study about hormone changes
	Compares antiemetics not analgesics
	Combined procedures Study cited before June 2002, included in initial analysis
111. O'Dwyer 1992	No VAS pain assessment
112. Ortega 1995	Appendectomy
113. Ortega 1996	Compares lap chole vs. open procedure
114. Oxorn 1989	Conventional cholecystectomy
115. Ozkocak 2002	Only abstract in English
116. Paolucci 1995	No VAS pain assessment
117. Paventi 2001	Compares antiemetics not analgesics
118. Perry 1993	Gynaecological laparoscopy
119. Power 1990	Conventional cholecystectomy
120. Quaynor 2002	No VAS pain assessment
121. Rademaker 1991	Conventional cholecystectomy
122. Raeder 1998	VAS pain scores not recorded
123. Roberts-Thomson 1994	Conventional cholecystectomy
124. Ros 2004	No VAS pain assessment
125. Rosenblum 1991	Gynaecological laparoscopy
126. Ross 1989	Conventional cholecystectomy

127. Sarli 2001	Combined procedures
128. Sarli 2001	Not RCT
129. Schmitz 1997	Conventional cholecystectomy vs. minicholecystectomy
130. Schroeder 1990	Conventional cholecystectomy
131. Schulze 1988	Conventional cholecystectomy
132. Schwenk 2002	Not a comparison of treatment modalities
133. Scott 1989	Conventional cholecystectomy
134. Shah 1986	Conventional cholecystectomy
135. Smith 1993	Procedures other than laparoscopic cholecystectomy
136. Smythe 1993	No VAS pain assessment. Unclear if any patients received laparoscopic cholecystectomy
137. So 2002	Compares antiemetics not analgesics
138. Song 2000	No VAS pain assessment
139. Squirrell 1998	Comparison of operative procedures not pain relief after laparoscopic cholecystectomy
140. Steffen 1997	Only abstract in English
141. Steinbrook 1998	Compares antiemetics not analgesics
142. Sternlo 1992	Conventional cholecystectomy
143. Striebel 1993	Conventional cholecystectomy
144. Stromskag 1991	Conventional cholecystectomy
145. Tarnow 1998	Conventional cholecystectomy
146. Taylor 1992	No pain assessment included
147. Trondsen 1993	Compares lap chole vs. open procedure

148. Ure 1994	Not RCT
149. Uzunkoy 1999	Duplicates Uzunkoy 2001
150. Van Delden 2002	No VAS pain assessment + Dose-response study
151. van Raay 1992	Conventional cholecystectomy
152. Varrassi 1994	Conventional cholecystectomy
153. Verborgh 1994	Conventional cholecystectomy
154. Vetrhus 2004	Combined laparoscopic + open cholecystectomy
155. Vetrhus 2004	No VAS pain assessment + not relevant (risk assessment study)
156. Vieira 2004	Only abstract in English
157. Wajima 1998	Conventional cholecystectomy
158. Wallin 1988	Conventional cholecystectomy
159. Wang 2002	Nausea and vomiting study comparing anti-emetic regimens
160. Wani 2000	Conventional cholecystectomy vs. minicholecystectomy
161. Weinbroum 2001	No sub-analysis of laparoscopic cholecystectomy patients
162. Westerling 1997	Minilaparotomy
163. Witjes 1992	Conventional cholecystectomy
164. Yang 2004	No VAS pain assessment
165. Yotsui 2001	Not double-blinded. No pain assessment
166. Yu 2003	No VAS pain assessment
167. Zhao 2004	Health outcomes analysis of Joshi 2004 data