Closed versus open approach in laparoscopic colorectal surgery (Protocol)

Magaji BA, Roslani AC, Chee Wei L, Moy FM, Buckley BS

This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2010, Issue 12

http://www.thecochranelibrary.com
# Table of Contents

1. Header ................................................................................................................................. 1  
2. Abstract ................................................................................................................................. 1  
3. Background ............................................................................................................................ 2  
4. Objectives .............................................................................................................................. 2  
5. Methods ................................................................................................................................. 2  
6. Acknowledgements ............................................................................................................... 3  
7. References ............................................................................................................................. 4  
8. Appendices ............................................................................................................................. 4  
9. What’s New ........................................................................................................................... 7  
10. History ................................................................................................................................ 7  
11. Contributions of Authors ..................................................................................................... 7  
12. Declarations of Interest ........................................................................................................ 7  
13. Sources of Support ............................................................................................................... 7  
14. Notes .................................................................................................................................. 8
Closed versus open approach in laparoscopic colorectal surgery

Bello Arkilla Magaji\textsuperscript{1}, April Camilla Roslani\textsuperscript{2}, Law Chee Wei\textsuperscript{2}, Foong Ming Moy\textsuperscript{3}, Brian S Buckley\textsuperscript{4}

\textsuperscript{1}Julius Centre University of Malaya, Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia. \textsuperscript{2}Department of Surgery, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia. \textsuperscript{3}Julius Centre University of Malaya, Social and Preventive Medicine, University of Malaya, Kuala Lumpur, Malaysia. \textsuperscript{4}Department of General Practice, National University of Ireland, Galway, Ireland

Contact address: Bello Arkilla Magaji, Julius Centre University of Malaya, Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Kuala Lumpur, Wilayah Persekutuan, 50603, Malaysia. drmagaji@siswa.um.edu.my, mbarkilla@hotmail.com.

Editorial group: Cochrane Colorectal Cancer Group.

Publication status and date: Edited (no change to conclusions), published in Issue 12, 2010.

Citation: Magaji BA, Roslani AC, Chee Wei L, Moy FM, Buckley BS. Closed versus open approach in laparoscopic colorectal surgery. Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD003547. DOI: 10.1002/14651858.CD003547.pub2.

Copyright © 2010 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

\textbf{A B S T R A C T}

This is the protocol for a review and there is no abstract. The objectives are as follows:

The aim of this review is to compare the ‘closed’ and ‘open’ approaches of creating pneumoperitoneum in laparoscopic colorectal surgery in terms of major and minor complications and other patient and procedure related outcomes.
BACKGROUND

Laparoscopy was originally developed in gynaecology, today is widely used in abdominal and pelvic surgery (Ledger 2009). Laparoscopic operations in large bowel diseases are now a standard part of the colorectal surgeons armamentarium.

The first step in a laparoscopic procedure is to provide enough intraabdominal space to ensure an adequate view. Air or gas, is insufflated into the abdominal cavity to separate the abdominal wall from the visceral organs (Jansen 2004). This artificial state is called ‘pneumoperitoneum’ or, if carbon dioxide is used, ‘capnoperitoneum’. There are two common techniques to create a pneumoperitoneum or capnoperitoneum.

After skin incision the 'closed' technique uses the Veress needle for gas insufflation (to establish a pneumoperitoneum) followed by blind insertion of the first trocar. The Veress needle is a sharp, thin needle which is always inserted blindly (Jansen 2004). The danger of the Veress needle lies in the possibility of puncturing intraabdominal or even retro-abdominal organs, especially gut or blood vessels. Alternatively, the pneumoperitoneum can be accomplished by using the open (Hasson) technique (Hasson 1971). During the 'open' technique all layers of the abdominal wall are incised until the peritoneum (ideally at midline) can be opened. The first blunt ('Hasson') trocar is then inserted under direct vision followed by gas insufflation to create the pneumoperitoneum. Needle and trocar insertion can lead to trauma to intraabdominal organs. Although the overall incidence of complications related to trocar insertion for gastrointestinal laparoscopic surgery has not been critically assessed (Mayol 1997), some authors cited the incidence of major complications is estimated to range between 0.05 and 0.3% (Phillips 2001). Closed technique account for one third to half of all major complication (Seifman 2003). In spite of the potential complications resulting from blind insertion of the Veress needle or the first trocar, the closed technique remains a popular method of establishing a pneumoperitoneum (Rohatgi 2004). However, with the continuing growth of laparoscopic colorectal surgery, the controversy concerning the best technique to insert the first trocar increases (Bridgewater 1999; Bonjer 1997). The contradictory trial results, the variation of surgical practice, and the ongoing discussion in literature make it necessary to clarify this issue.

OBJECTIVES

The aim of this review is to compare the 'closed' and 'open' approaches of creating pneumoperitoneum in laparoscopic colorectal surgery in terms of major and minor complications and other patient and procedure related outcomes.

METHODS

Closed versus open approach in laparoscopic colorectal surgery (Protocol)

Copyright © 2010 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
The aim of this search strategy is to identify all relevant studies for inclusion in this review.

**Electronic databases**
Search strategy will be designed in accordance with Cochrane Colorectal Cancer Group methods and guidance. Relevant trials will be identified by searching the Cochrane Central Register of Controlled Trials in the Cochrane Library, Medline and Embase. No language or other limitations will be imposed. Search terms are included in Appendix 1.

**Searching other sources**
Reference lists of included studies and previous reviews will be checked for additional studies.

### Data collection and analysis

**Selection of studies**
The titles and abstracts included in the initial search results will be scanned by two independent reviewers (BAM and ACR) to identify trials that may meet the inclusion criteria. The full text reports of potentially eligible studies will be accessed by two reviewers and inclusion criteria will be applied independently. Another reviewer (MFM) will act as the arbiter and resolve any difference of opinion. Papers in languages other than English will be assessed by native speakers for eligibility and subsequently for data extraction. Excluded studies and reasons for exclusion will be detailed in a 'Characteristics of Excluded Studies' table.

**Data extraction and management**
Data will be extracted by two reviewers (BAM and MFM) independently using standard form containing pre-specified outcomes. Where data from the study is not provided, the author(S) will be contacted requesting further information. Included trial data will be processed as described in the Cochrane Handbook for Interventions. Differences will be resolved by discussion among the two reviewers and if necessary will be referred to a third reviewer for arbitration.

**Assessment of risk of bias**
The risk of bias in eligible studies will be assessed independently by two reviewers using the Cochrane risk of bias assessment tool (Appendix 2). Factors considered will include quality of random allocation and concealment (where appropriate), description of drop-outs, withdrawals, and missing data, blinding during intervention and at outcome assessment (where appropriate), selective reporting and other sources of bias. Primary analysis will include only studies judged to be at low or unclear risk of bias. Sensitivity analysis will be conducted to assess the effect on results of the inclusion of studies at high risk of bias.

**Measures of Treatment effect**
we shall report risk ratios for dichotomous data and mean differences for 95% confidence intervals for continuous data. A fixed effect model will be used in data analysis unless there is evidence of heterogeneity, in which case a random effects model will be used.

**Missing data**
Where possible, if sufficient data are included in trial reports, authors will be contacted and missing data requested.

**Assessment of heterogeneity**
Where excessive heterogeneity is evident through visual inspection of forest plots, the test for heterogeneity and I-squared (I2) will be used to consider the influence on meta-analysis of heterogeneity between studies.

**Assessment of reporting bias**
Funnel plots will be generated to assess reporting bias if enough studies are identified to allow this.

**Data synthesis**
Included data will be processed as described in the Cochrane Handbook. If quantitative data synthesis are not appropriate because of the nature of reported data or because of evident heterogeneity, a narrative review of the evidence will be presented.

**Subgroup analysis**
Where adequate data are reported, subgroup analysis will considered to show differences in outcomes between subgroups defined by criteria such as age, gender, race, co-morbidity, concurrent treatment for co-morbidities, different types of surgical operations and different types of anaesthetic procedures.

**Sensitivity analysis**
If the data allow, sensitivity analysis may be performed to assess the effect of possible bias associated with individual trials on the outcome of meta-analysis.

### Acknowledgements

The authors would like to thank Dr Henning K and other members of the CCCG editorial boards for all their valuable comments on the protocol. We would also like to acknowledge Marija Barbatiskovic the CCCG trials search co-coordinator, for her assistance in developing the search strategies and initial search.
REFERENCES

Additional references

Bonjer 1997

Bridgewater 1999

Hasson 1971

Jansen 2004

Ledger 2009

Mayol 1997

Philips 2001

Rohatgi 2004

Seifman 2003

* Indicates the major publication for the study

APPENDICES

Appendix 1. Search Strategies

Search strategy the Cochrane Library
#1 MeSH descriptor Laparoscopy explode all trees
#2 (laparascop*)
#3 MeSH descriptor Pneumoperitoneum explode all trees
#4 (pneumoperitoneum*)
#5 (#1 OR #2 OR #3 OR #4)
#6 MeSH descriptor Needles explode all trees
#7 (veress needle*) or (verress needle*) or (veres needle*) or (trocar*) or (troc* or (throc*) or (throc* or (needle*))
#8 (#6 OR #7)
#9 MeSH descriptor Colorectal Surgery explode all trees
#10 (colorect*) or (colon*) or (rect*)
#11 (surger*) #12 (#10 AND #11)
#13 (#9 OR #12)
#14 (#5 AND #8 AND #13)

Search strategy for Medline
#1 exp Laparoscopy/
#2 laparoscopy*.mp.
#3 exp Pneumoperitoneum/
Search strategy for EMBASE

#1 exp LAPAROSCOPY/
#2 laparoscop*.mp.
#3 exp PNEUMOPERITONEUM/
#4 pneumoperitoneum*.mp.
#5 1 or 2 or 3 or 4
#6 exp needle/
#7 (veress needle* or verres needle* or veres needle* or trocar* or trokar* or throcar* or needle*).mp.
#8 6 or 7
#9 exp Colorectal Surgery/
#10 exp Colon/su [Surgery]
#11 exp Rectum/su [Surgery]
#12 (colorect* or colon* or rect*).mp.
#13 surger*.mp.
#14 12 and 13
#15 9 or 10 or 11 or 14
#16 5 and 8 and 15
#17 randomized controlled trial.pt.
#18 controlled clinical trial.pt.
#19 randomized.ab.
#20 placebo.ab.
#21 clinical trial.sh.
#22 randomly.ab.
#23 trial.ti.
#24 17 or 18 or 19 or 20 or 21 or 22 or 23
#25 humans.sh.
#26 24 and 25
#27 16 and 26
Appendix 2. Assessment of risk of bias tool

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
<th>Review authors’ judgments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence generation</td>
<td>Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.</td>
<td>Was the allocation sequence adequately generated? Yes/ No/ Unclear</td>
</tr>
<tr>
<td>Allocation of concealment</td>
<td>Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.</td>
<td>Was allocation adequately concealed? Yes/ No/ Unclear</td>
</tr>
<tr>
<td>Blinding of participants, personnel and outcome assessors (assessment should be made for each main outcome or class of outcomes)</td>
<td>Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.</td>
<td>Was knowledge of the allocated intervention adequately prevented during the study? Yes/ No/ Unclear</td>
</tr>
<tr>
<td>Incomplete outcome data. Assessment should be made for each main outcome or class of outcomes</td>
<td>Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.</td>
<td>Were incomplete outcome data adequately addressed? Yes/ No/ Unclear</td>
</tr>
<tr>
<td>Selective outcome reporting</td>
<td>State how the possibility of selective outcome reporting was examined by the review authors, and what was found.</td>
<td>Are reports of the study free of suggestion of selective outcome reporting? Yes/ No/ Unclear</td>
</tr>
<tr>
<td>Other sources of bias</td>
<td>State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were</td>
<td>Was the study apparently free of other problems that could put it at a high risk of bias? Yes/ No/ Unclear</td>
</tr>
</tbody>
</table>

#27 22 or 19 or 23 or 25 or 18 or 24 or 20 or 17 or 26 or 21
#28 “human*”.ti,ab.
#29 (animal* or nonhuman*).ti,ab.
#30 29 and 28
#31 29 not 30
#32 27 not 31
#33 16 and 32
prespecified in the review’s protocol, responses should be provided for each question/entry.

**WHAT'S NEW**

Last assessed as up-to-date: 31 October 2010.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 November 2010</td>
<td>Amended</td>
<td>Updated Protocol for review by the editorial board</td>
</tr>
<tr>
<td>27 October 2008</td>
<td>Amended</td>
<td>Converted to new review format.</td>
</tr>
</tbody>
</table>

**HISTORY**

Protocol first published: Issue 2, 2002

**CONTRIBUTIONS OF AUTHORS**

The principal author (BAM) initiated and planned the review. All authors (BAM, MFM, BB, LCW, and ACR) were involved in writing the protocol. The principal author (BAM) developed the search strategy in association with Marija Barbateskovic of the CCCG.

**DECLARATIONS OF INTEREST**

None known

**SOURCES OF SUPPORT**

**Internal sources**

- University of Malaya, Malaysia.
- Usmanu Danfodiyo University Sokoto, Nigeria.
- Sokoto State Government Overseas Doctors Training Programme, Nigeria.
External sources

- E. Not specified.

NOTES

Reason for withdrawal is that the protocol is out-of-date, and that the authors haven’t indicated any progress for fulfilling the review.