SingHealth
Defining Tomorrow's Medicine

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UEN No. 200002698Z

CIRB Ref: **2013/145/D**

26 February 2015

Dr Chew Min Hoe
Department of Colorectal Surgery
Singapore General Hospital

Dear Dr Chew

RENEWAL OF SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL

Protocol Title: A retrospective evaluation of laparoscopic versus open colorectal surgery - a comparison of outcomes

We are pleased to inform you that the SingHealth CIRB D has reviewed and approved the renewal of IRB approval for the study to be conducted in Singapore General Hospital.

Please note that annual IRB renewal is required and the review is based on the Study Status Report submitted. It is the Principal Investigator's responsibility to submit a Study Status Report for the study at least one month before the expiry date of the study for renewal of IRB approval. This approval is valid till **25 February 2016**.

The document reviewed is:

a) Study Status Report dated 10 February 2015

The SingHealth CIRB operates in accordance with the ICH/ Singapore Guideline for Good Clinical Practices, and with the applicable regulatory requirement(s).

Yours sincerely,

Dr Steve Yang
Chairman
SingHealth Centralised Institutional Review Board D

cc: Institution Representative, SGH
Head, Department of Colorectal Surgery, SGH

submit to CIRB on 25 FEB 2013

CIRB & DSRB APPLICATION FORM

SingHealth

National Healthcare Group

OFFICIAL USE ONLY	
Doc Name : CIRB & DSRB Application Form	
Doc Number : 205-001	
Doc Version : 8.0	Date : 27 Mar 2012

I. Basic Information

Protocol Title:

A retrospective evaluation of laparoscopic versus open colorectal surgery- a comparison of outcomes.

Protocol Number (if available) and Current Version Date (if available):

Text Field

Study Team Members:

Note: For a multi-centre study, please appoint a Site Principal Investigator (PI) for each Institution in addition to the PI (who will also be the corresponding PI for the multi-centre study). All investigators who have a responsibility for the consent process or direct data collection for this study should be listed below. Multiple copies of this page may be submitted as necessary. Additional copies of this page can be downloaded at www.b2bresearch.nhg.com.sg or http://research.singhealth.com.sg

Title	Full Name	Study Role	Institution/Department
Dr	Chew Min Hoe	Principal Investigator	Department of Colorectal Surgery
Dr	Angela Renayanti Dharmawan	Co-Investigator	Department of Colorectal Surgery
A/Prof	Tang Choong Leong	Co-Investigator	Department of Colorectal Surgery
Choose	Text Field	Choose from list	Text Field
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Study Sponsor:

If Other/Pharmaceutical Company, please specify name: Text Field

Note: If this Study is initiated by Industry / commercial entities, please attach Annex D.

Nature of Project:	Phase of Clinical Trial:
Clinical Research (Retrospective Review)	Text Field

Research May Involve:

- ☐ Pregnant Women, Foetuses or Neonates *(Attach Annex F)*
- ☐ Children (Age <21 yrs) *(Attach Annex G)*
- ☐ Prisoners *(Attach Annex H)*
- ☐ Cognitively Impaired Persons – Please specify type: _____
- ☒ Outpatients
- ☒ Inpatients
- ☐ Healthy Volunteers

Research Participants Will Be:

☐ Paid - $_____ ☒ Not paid ☐ Not charged for trial procedures

Has this proposal been rejected by any IRB /CIRB /DSRB?

DSRB SGH

☒ No ☐ Yes If yes, please provide details for the rejection: _____

Study Site details:

☒ Single-Centre Study ☐ Multi-Centre Study:- No. of local sites: _____ No. of overseas sites: _____

SingHealth Study site:	☐ CGH	☐ KKH	☐ NCC	☐ NDC	☐ NHC	☐ NNI
	☒ SGH	☐ SHP	☐ SNEC	☐ IMU		

This Application is submitted to:

SingHealth	☐ CIRB A	☐ CIRB B	☐ CIRB C	☒ CIRB D	☐ CIRB E
NHG DSRB:	☐ Domain-A	☐ Domain-B	☐ Domain-C	☐ Domain-D	☐ Domain-E

Is this a US FDA IND / IDE study?

☒ No ☐ Yes ☐ IND Study. Please provide the IND number: _____

☐ IDE Study. Please provide the IDE number: _____

Protocol Administrators

Protocol Administrators are persons who are responsible for administrative matters related to the Study. They can be the Study Coordinators, Research Nurses or Clinical Research Associates, and need not be part of the Study Team. While the PI remains the primary contact person, the CIRB/DSRB may contact the Protocol Administrators for clarification of administrative matters related to the Study. You may list up to 3 Protocol Administrators. This section is optional but PI's are encouraged to nominate at least one Protocol Administrator.

Full Name:	Text Field		
Institution:	Text Field	*Position Held:*	Text Field
Department:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:	____________	*Date:*	Text Field

Full Name:	Text Field		
Institution:	Text Field	*Position Held:*	Text Field
Department:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:	____________	*Date:*	Text Field

Full Name:	Text Field		
Institution:	Text Field	*Position Held:*	Text Field
Department:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:	____________	*Date:*	Text Field

II. Declaration of the Principal Investigator

For a Multi-centre study, the PI and each Site PI must sign this page. Please submit multiple copies of this page. Additional copies of this page can be downloaded at www.b2bresearch.nhg.com.sg or http://research.singhealth.com.sg

The information provided in this form is correct.

a. I will not initiate this study until I receive written notification of CIRB/ DSRB approval and regulatory authority approval (if applicable).

b. I will not initiate any change in protocol without prior written approval from CIRB/ DSRB except when it is necessary to reduce or eliminate immediate risk to the Study Participant. Thereafter, I will submit the proposed amendment to the CIRB/ DSRB and other relevant authority for approval.

c. I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that may occur in the course of this study.

d. I will maintain all relevant documents and recognize that the CIRB/ DSRB staff and regulatory authorities may inspect these records.

e. I understand that failure to comply with all applicable regulations, institutional and CIRB/ DSRB policies and requirements may result in the suspension or termination of this study.

f. I declare that there are no conflicting interests for any of the research personnel participating in this research study. ***(Important: Should you or any of the research personnel have any conflicting interest in this research study, please complete Annex B – Conflict of Interest Declaration Form for each individual having the conflict)***

Remarks (if any):
Text Field

07/02/2013

Principal Investigator's Signature | *Date*

Full Name:	Dr Chew Min Hoe		
Institution:	SGH	*Position Held:*	Consultant
Department:	Department of Colorectal Surgery	*Email address:*	chew.min.hoe@sgh.com.sg
Telephone:	97569839	*Fax:*	62262009
Mailing Address:	SGH Department of Colorectal Surgery, Blk 7 Level 7, Outram Road, (S) 169608		

**All fields must be completed.*

III. Study Team Members' Endorsements

All investigators who have a responsibility for consent process or direct data collection for this study should be listed below. Multiple copies of this form may be submitted as necessary. All collaborators/co–investigators need not sign on the same form. Additional copies of this page can be downloaded at www.b2bresearch.nhg.com.sg. Note: For SingHealth Institutions: Co-investigators need not sign.

Full Name:	Dr Angela Renayanti Dharmawan	*Study Role:*	Co-Investigator
Institution:	SGH	*Department:*	Department of Colorectal Surgery
Position Held:	Medical Officer	*Email address:*	rena.dharmawan@gmail.com
Telephone:	92213743	*Fax:*	62262009
Signature:		*Date:*	13 Febuary 2013

Full Name:	Dr Chew Min Hoe	*Study Role:*	Principal Investigator
Institution:	SGH	*Department:*	Department of Colorectal Surgery
Position Held:	Consultant	*Email address:*	ustwo@singnet.com.sg
Telephone:	97569839	*Fax:*	62262009
Signature:		*Date:*	13 Febuary 2013

Full Name:	A/Prof Tang Choong Leong	*Study Role:*	Co-Investigator
Institution:	SGH	*Department:*	Department of Colorectal Surgery
Position Held:	Senior Consultant	*Email address:*	tang.choong.leong@sgh.com.sg
Telephone:		*Fax:*	62262009
Signature:		*Date:*	13 Febuary 2013

Full Name:	Text Field	*Study Role:*	Choose from list
Institution:	Text Field	*Department:*	Text Field
Position Held:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:		*Date:*	Text Field

Full Name:	Text Field	*Study Role:*	Choose from list
Institution:	Text Field	*Department:*	Text Field
Position Held:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:		*Date:*	Text Field

Full Name:	Text Field	*Study Role:*	Choose from list
Institution:	Text Field	*Department:*	Text Field
Position Held:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:		*Date:*	Text Field

Full Name:	Text Field	*Study Role:*	Choose from list
Institution:	Text Field	*Department:*	Text Field
Position Held:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:		*Date:*	Text Field

Full Name:	Text Field	*Study Role:*	Choose from list
Institution:	Text Field	*Department:*	Text Field
Position Held:	Text Field	*Email address:*	Text Field
Telephone:	Text Field	*Fax:*	Text Field
Signature:		*Date:*	Text Field

IV. Comments of Department Representative

**The Department Representative can be the Head / Chief / Research Head of the PI's Department. Should the Head or Chief be the PI or Co-Investigator, then their reporting officer should complete this Section. It is assumed that all Departments involved concur with the PI's Department Representative. The validity of this assumption rests solely on the PI. Should views differ, multiple declarations by the other Department Representatives may be submitted. Additional copies of this page can be downloaded at www.b2bresearch.nhg.com.sg or http://research.singhealth.com.sg*

1. Significance:	
Does the study address an important problem? Will the study affect concepts and methods that drive the field?	Yes / No
2. Approach:	
Is the conceptual framework adequately developed? Are the design, methods and analyses adequately developed and appropriate?	Yes / No
3. Innovation:	
Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods?	Yes / No
4. Principal Investigator:	
Is the Principal Investigator appropriately trained to conduct this study? Does the Principal Investigator have evidence of commitment (e.g. previous track record)?	Yes / No
5. Environment:	
Is the Principal Investigator's environment suited to conduct the study? Is there an adequate patient pool and are there adequate resources?	Yes / No
6. Budget:	
Are the projected costs appropriate (i.e. accurate)? Is the overall budget reasonable for the significance of the study?	Yes / No
7. Time:	
Does the Principal Investigator have adequate resources and time to conduct and complete the study?	Yes / No

Comments:

I acknowledge that this research is in keeping with standards set by the Principal Investigator's Department.

Department Representative's Signature

08/02/13
Date

Full Name: Dr Kam Min Hian
Position Held: Consultant
Institution: Singapore General Hospital
Department: Department of Colorectal Surgery

V. Declaration of the Institution Representative*

** The Institution Representative has been determined by your institution as the authority that declares whether your research is in keeping with the institution's research objectives, reputation and standards. The role of the Institution Representative is not to evaluate the scientific or ethical aspects of your study, although they may offer their comments.*

For a multi-centre study, a copy this section must be completed by each institution. Additional copies of this page can be downloaded at www.b2bresearch.nhg.com.sg or http://research.singhealth.com.sg
Note: For SingHealth Institutions, please refer to 'Application Form Instruction Sheet' for the list of Institution Representatives.

Comments:

I acknowledge that this research is in keeping with standards set by my Institution

Institution Representative's Signature *Date* 15/2/13.

Full Name:	Text Field
Position Held:	Text Field
Institution:	Text Field
Department:	Text Field

A/PROF LEE LAI HENG
Chairman
Division of Research
Singapore General Hospital

VI. Abstract of Research Proposal

In no more than 300 words, describe concisely the specific aims, hypotheses, methodology and approach of the application, indicating where appropriate the application's importance to science or medicine. The abstract must be self-contained so that it can serve as a succinct and accurate description of the application when separated from it. Please use lay terms. If this not possible, the technical and medical terms should be explained in simple language.

Laparoscopic approach to colorectal surgery has been gaining increasing popularity in the past decade and is accepted as an alternative to open surgery. Its advantages include superior perioperative short-term outcomes with shorter hospital stay, less narcotic and analgesic requirements, faster return of bowel function and lower morbidity. However, majority of these studies are non-randomised and limited by their small sample size. In addition, there is also a lack of data on the long term outcomes comparing laparoscopic and open surgery. Thus, the aim of our study is to compare the short and long term outcomes of laparoscopic versus open colorectal surgery in a single institution on a large scale.

VII. Research Details

Organize details of the research proposal under the following headings (in no more than 7 pages).

1. Specific Aims

State concisely and realistically what the research described in this application is intended to accomplish and/ or what hypothesis is to be tested.

Primary Aim: To evaluate outcomes of laparoscopic versus open colorectal surgery. This includes short term indicators such as conversion, morbidity and mortality and adequate oncologic clearance. Long term outcomes include cancer recurrence and survival, risk of adhesions and readmissions as well as incisional hernias.

2. Introduction

Briefly describe the background to the current proposal, critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill.

Laparoscopic approach to colorectal surgery has been gaining increasing popularity in the past decade and is accepted as an alternative to open surgery. The short-term peri-operative outcomes have been well studied and are shown to be superior in terms of shorter hospital stay, less narcotic and analgesic requirements, faster return of bowel function and lower morbidity. However, majority of these studies are non-randomized and limited by their small sample size, making their results difficult to interpret. In addition, there is a lack of information about the long-term outcomes in evaluating laparoscopic versus open colorectal surgery. These include overall survival, cancer recurrence, incisional hernias, re-operations for complications of initial surgery. Thus, our study aims to analyze a large sample size of patients and compare both the short and long term outcomes of laparoscopic versus open colorectal surgery in a single centered institution.

State concisely the importance of the research described in this application by relating the specific aims to the long term objectives.

See above

Relevant references (please submit copies of at least two relevant papers)

1. Evaluation of laparoscopic versus open colorectal surgery in elderly patients more than 70 years old: an evaluation of 727 patients. Tan WS et al. Int J Colorectal Dis, 2012 Jun; 27(6):773-80

2. Laparoscopic versus open right hemicolectomy: a comparison of short term outcomes. Tan WS et al. Int J Colorectal Dis. 2009 Nov;24(11):1333-9

3. Survival after laparoscopic surgery versius open surgery for colon cancer: long term outcome of a randomized clinical trial. The Colon Cancer Laparoscopic or Open Resection Study Group et al. Lancet Oncol, 2009 Jan; 10(1):44-52
4. Laparoscopic surgery vs Open surgery for colon cancer: short term outcomes of a randomized trial. Veldkamp R et al. Lancet Oncol, 2005 Jul; 6(7):477-84

3. Preliminary Studies / Progress Reports

Provide an account of the Principal Investigator's preliminary studies (if any) pertinent to the applications
NIL

4. Methodology

Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the project.
Medical records of all patients who underwent elective colorectal resections at the Department of Colorectal Surgery in Singapore General Hospital from January 2005 to December 2010 will be retrieved from a prospectively collected computer database. Consultant colorectal surgeons trained in both laparoscopic and open surgeries performed all operations. The choice of approach based on surgeon and patients' preference after informed consent was taken. Demographic data, operative details and post-operative recovery parameters will be collected and analyzed. Statistical analysis will be performed using the Statistical Package for Social Science (SPSS) and a p value of <0.05 will be considered statistically significant.

Describe the protocol(s) to be used. If the study is a drug trial, please include information of the study drug and any other drugs that will be used in the trial. Will placebo control be used? If so, please include completed Annex A.
NA

Include details on sample size calculation and the means by which data will be analysed and interpreted.
All patients who underwent elective colorectal resections at the Department of Colorectal Surgery in Singapore General Hospital from January 2005 to December 2010 will be included in this study. The estimated number of patient is about 2000.

List all trial related procedures. Please also describe the study participant visits (frequency and procedures involved).For studies with multiple visits, please attach study schedule.
NA

If the study involves the use of study drug / device, describe how you plan to ensure that investigators are trained in the management (receipt, storage, utilization, and disposal) of the study drug/ device.
NA

Please describe how you plan to ensure that the study drug / device would be used only by investigators, and only in study participants.
NA

If samples of body fluids or tissues are taken as part of this research, state the amount and frequency at which these samples are taken. Will these samples be stored? If so, please include completed Annex C.
NA

What are the anticipated benefits and risks to study participants in this research?
NA

Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.
NA

Will any part of the procedures be recorded on audiotape, film/ video, or other electronic medium?
Yes *No*
If 'Yes', what is the recording medium? Explain how the recorded information will be used? How long will the recording medium be retained and how will they be disposed of?
Text Field

5. Characteristics of Target Study Participants / Target Patient Data

If the target Study Participants include these vulnerable populations, please complete and attach the relevant Annexes to the Application Form:-

- ***Annex F:*** *Pregnant Women, Foetuses and Neonates*
- ***Annex G:*** *Children (Persons under the age of 21 years)*
- ***Annex H:*** *Prisoners*

If the study only involves the collection of tissue samples, please indicate the number of samples to be collected in lieu of recruitment numbers.

What is the number of Study Participants to be enrolled? Give a breakdown by institution for multi-center studies within Singapore.

Institution	Total Recruitment Number	No of Adult Males	No of Adult Females	No of Children (Persons under the age of 21 years)
Singapore General Hospital				
Choose from list				
Choose from list				
Choose from list				
Choose from list				
Choose from list				
Choose from list				
Choose from list				

If there are more sites, please fill up Additional Sheet for Characteristics of Target Study Participants. Additional copies of this section can be downloaded at www.b2bresearch.nhg.com.sg or http://research.singhealth.com.sg

Study Participants' Lower Age Limit: 21

Study Participants' Upper Age Limit: 99

Total number of Study Participants targeted for enrollment worldwide (for international studies): _____

Are there any recruitment restrictions based on race of the Participant?
☐ *Yes* ☒ *No*
If 'Yes', Please provide details:-
Text Field

List the Inclusion criteria
All patients who has undergone laparoscopic and open colorectal surgery

List the Exclusion criteria
None

Do the Study Participants have a dependent relationship with the researchers?
☒ *Yes* ☐ *No* ☐ *Not applicable*
If 'Yes', Please provide details:-
Patients of investigators will be included in the study population.

Will any vulnerable Study Participants (Pregnant Women, Foetuses & Neonates, Children (Persons under the age of 21 years), Prisoners) be recruited in this research study?
☐ *Yes* ☒ *No*
If 'Yes', please describe steps that will be taken to minimize the possibility of coercion or undue influence over the vulnerable Study Participants.
Text Field

6. Informed Consent Process and Consent Document

The PI is responsible for ensuring that all Study Participants give informed consent before enrolling into the study. Please submit a copy of the Consent Document. For guidelines on preparing a Participation Sheet and Consent Form compliant with Good Clinical Practice Guidelines please contact the CIRB/DSRB Secretariat. A Consent Form template can be downloaded at www.b2bresearch.nhg.com.sg or http://research.singhealth.com.sg
Please describe the consent procedure. Please specify the following:-

When will consent be taken?
Text Field

Where will consent be taken?
Text Field

Who will conduct the consent process?
Text Field

Do you anticipate a situation where obtaining informed consent from a potential Study Subject is not possible and informed consent will be taken from the legally acceptable representative (including spouse, parent, and guardian)?
Text Field

Describe provisions to protect the privacy interests of Study Subjects, where "privacy interests" refer to interests of individuals to be left alone, free from intrusion and comfort with the proposed settings
Text Field

Besides the Consent document, will any other materials or documents be used to explain the study to potential Study Subjects? (eg. scripts, handouts, brochures, videos, logs, etc)
Text Field

7. Recruitment Process

Explain the process of recruitment in detail. For example, state how the list of potential Study Participants will be

obtained. (e.g. whether from attending doctor who will refer potential subjects.)
Text Field

Will subjects be chosen from medical records? If so, how will you obtain names and NRIC numbers of Study Participants?
Text Field

Please submit a copy of any advertisements/posters that will be used.
Text Field

8. Data And Safety Monitoring Plan (DSMP)

If the research involves more than minimal risks to Study Participants, please provide details on the Data And Safety Monitoring Plan (DSMP) of the research.

Who performs the data and safety monitoring? If there is a Data Safety Monitoring Board (DSMB), please provide the charter of the DSMB.
Not Applicable

When and what safety data is monitored?
N.A.

When and how is data integrity monitored?
N.A.

What are the criteria for suspending the research?
Nil

How will the outcome of data and safety monitoring be communicated to other sites? (for multi-centre studies only)
Nil

9. Research Data Confidentiality

In general, to protect Study Participant's confidentiality, research data should be coded, and the links between the Participant's identifiers and the codes should be stored separately from the research data.

Will coded research data be sent to the sponsor, and no research database will be created in NHG/SingHealth?
☐ *Yes, If 'Yes', please skip this question and go to Section 10 – Timelines.*
☒ *No, If 'No', please answer the following questions:-*

Describe where the research data will be stored? (i.e.: network or Stand alone PC and the physical location)
Polyposis Registry in Stand Alone PC

Who will have access to the research data and how will access to the research data be controlled and monitored?
Principle Investigator and Co-investigators. The use of the data will be for data analysis and manuscript preparation. Data will be kept for 5 years before being discarded.

Are there any research data sharing agreements with individuals or entities outside the Institution, to release and share research data collected?
☒ *No*
☐ *Yes, If yes, please describe the agreement*
Text Field

Describe what will happen to the research data when the study is completed.
The data collected will be kept in the polyposis registry and form as part of a department audit.

Are there any other measures in place to protect the confidentiality of the research data?
The data will be secured by the polyposis registry co-ordinator

10. Timelines

What are the estimated start and end dates of the study?
Start Date: March 2013 End Date: March 2014

Indicate the duration of subject involvement in the research. Please also state the recruitment period.
Nil. The project is a retrospective study.

11. Financial Aspects

Who will be responsible for research related costs? For sponsored projects, list the costs that will be borne by the sponsor. For industry sponsored clinical trials, please complete Annex D.
Nil

Total amount of grant/fund: $ _____

If this study has a Grant Application, please answer the following questions.

a) *Has grant been awarded?*
   - ☐ *Pending approval*
   - ☐ *Yes. If 'Yes', please submit a copy of the grant approval letter.*

b) *Which grant exercise was this submitted to? (enter Grant Submission Deadline date)*
   Text Field

c) *For **approved grant applications** (including United States Department of Health and Human Services (DHHS) approved studies), please submit the protocol and consent document (if any) approved by the grant body.*

   Are the Protocol and Consent documents approved by the grant body, identical to the information that has been submitted in this application?
   - ☐ *Yes*
   - ☐ *No. If 'No', please provide details of the differences:*

   Text Field

Will the Study Participants receive any financial payment/incentive for participation?
☐ *Yes* ☒ *No*
If 'Yes', please elaborate.
Text Field

Who will be responsible for the payment and compensation of injury or illness arising from participation of subjects in the research project?
Not Applicable

Note:-
NHG: *For investigator-initiated studies – Contact your OBR/ CRU for more information on available NHG Clinical Trial Compensation Insurance Scheme.*
SingHealth: *Please contact your CIRB on how to word the Informed Consent Document.*

12. Application Checklist:	
Attached?	Document
Yes	Study Protocol *(latest version)*
Not Applicable	Approved Grant Application *(including DHHS approved Study Protocol and Sample Consent Form, if one exists)*
Not Applicable	Participant Information Sheet and Consent Form
Yes	Principal Investigator's CV
Not Applicable	Principal Investigator's SG GCP Certificate of Attendance *(Applicable only for clinical trials application)*
Yes	CITI Certificate (**NHG**: For PI only; **SingHealth**: For all investigators)
Not Applicable	Investigator Brochure
Not Applicable	Survey Forms/Questionnaires / Diary Card
Not Applicable	Data Collection Form
Not Applicable	Posters for Advertisement
Not Applicable	Letter of Invitation to Patients
Not Applicable	Letter to Doctors Requesting Referral
Yes	Relevant Publications
Not Applicable	Cheque payment for Industry Sponsored Trials
Not Applicable	Participant Payment Details +
Not Applicable	Participant Compensation Details +
Not Applicable	Financial Agreement
Not Applicable	Annex A – Placebo Usage
Not Applicable	Annex B – Conflict of Interest Declaration Form
Not Applicable	Annex C – Biological Materials Storage
Not Applicable	Annex D – Industry Sponsored Studies
Not Applicable	Annex E – Waiver of Informed Consent
Not Applicable	Annex F – Research involving Pregnant Women, Foetuses and Neonates
Not Applicable	Annex G – Research involving Children (*Persons under the age of 21 years old)*
Not Applicable	Annex H – Research involving Prisoners
No	Any other materials/documents? Please list here:- Text Field

+ If information is not included in the protocol / application form

~ End of Application Form ~

Int J C: orectal Dis
DOI 1(007/s00384-011-1375-5

ORI INAL ARTICLE

Ev: luation of laparoscopic versus open colorectal surgery in e derly patients more than 70 years old: an evaluation of 7 27 patients

Wah Siew Tan · Min Hoe Chew · Irene Ai Ling Lim · Kheng Hong Ng · Choong Leong Tang · Kong Weng Eu

Accepte : 15 November 2011

Abstr :t

Backg und With longer life expectancy, surgeons can expect to op te on older patients. Laparoscopic colorectal (LC) surge has been demonstrated to be superior to open surgery. Contr ersy persists, however, regarding benefits of LC in the elderl due to increase in operative time. The aim of our study was to ompare short-term outcomes of LC versus open colorectal (OC) surgery in elderly patients.

Mater ls and methods Patients ≥70 years old that underwent elective LC between 2005 and 2008 were compared with controls who underwent OC. Data was extracted from a prospe tively collected database.

Results Seven hundred and twenty-seven patients underwent colorectal resection in this study period (LC n=225, OC n=502). The laparoscopic arm was characterised by shorter incisions (LC 6.0 cm vs. OC 12.0 cm, p<0.001) but longer operating times (LC 125 min vs. OC 85 min, p< 0.001). Median use of narcotics and length of stay were significantly shorter in the laparoscopic group (LC 2 days vs. OC 3 days, p<0.001 and LC 6 days vs. OC 7 days, p< 0.001, respectively). There was no significant difference in median recovery of bowel function (LC 4 days vs. OC 4 days, p=0.14) and post-operative morbidity (p=0.725). Thirty-day mortality was significantly lower in the laparoscopic arm (LC 1.3% vs. OC 4.6%, p=0.03)

Conclusion This is the largest series from a single institution comparing LC and OC in elderly patients. In our series, LC in elderly patients was safe and not associated with a higher morbidity. LC was also associated with less narcotic use and shorter length of stay.

Keywords Laparoscopic · Colorectal surgery · Elderly · Colorectal cancer

W. S. T · M. H. Chew · K. H. Ng · C. L. Tang (✉) · K. W. Eu
Depart nt of Colorectal Surgery, Singapore General Hospital, Outram oad, Singapore 169608
e-mail: ng.choong.leong@sgh.com.sg

I. A. L im
Yong L o Lin School of Medicine,
Nationa University of Singapore,
1E Ken Ridge Road,
Singapo e 119228

Introduction

Laparoscopic colorectal (LC) surgery has been shown in many studies to be associated with superior perioperative outcomes when compared to open colorectal (OC) surgery. The advantages reported include less analgesic requirements, earlier return of bowel function, as well as shorter hospital stay [1, 2]. With longer life expectancy in populations the world over, surgeons can expect to operate more frequently on elderly patients. Elderly patients have a high incidence of colorectal disease and are more likely to have significant co-morbid conditions compared to younger patients. In addition, increasing age itself is also an important risk factor for post-operative morbidity and mortality [3]. In Singapore, the average life expectancy at birth has increased from 66.0 years in 1970 to 81.4 years in 2009 [4]. A similar trend is being seen in many other countries, highlighting the need for improved medical and surgical care knowledge for an ageing population.

It is recognised that post-operative complications in the elderly are higher. For patients aged 70 years and above, the 30-day mortality is about 6% and at least 20% develop one complication during hospitalisation. In addition, mortality risk increases 10% for every year after age 70 [5]. Perioperative outcomes in laparoscopic surgery for the elderly

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remain non-conclusive. In laparoscopic colectomies, post-operative outcomes were noted to be similar in both elderly and younger patients in some studies [6–8], while others, however, have shown superior outcomes in the LC group [9–15]. Studies examining laparoscopic surgery in both young and elderly patients have found that the benefits of laparoscopic surgery are more marked in elderly patients [16, 17]. Subset analysis of these studies, however, has shown that there is a significant higher risk of cardio-respiratory complications in elderly patients [5–7]. This may be attributed to a longer operating time with prolonged time under general anaesthesia and resultant post-operative atelectasis. In addition, the head-down tilt during laparoscopy and pneumoperitoneum may result in a significant reduction in stroke volume and cardiac outputs with a possible increased cardiac strain [18]. This majority of the studies were, however, non-randomised and limited by small numbers. In the only randomised trial to describe age-related post-operative morbidity [17], 45% of the study cohort was however aged less than 70 years and thus leaves the results difficult to interpret.

There has been no consistent definition of the age cut-off for elderly in the literature. However, several studies evaluating the risks of mortality after colorectal surgery have shown an increased mortality rate after surgery in patients aged more than 75 compared to patients aged less than 70 [19, 20]. We have thus used the age of 70 years as our cut-off, to evaluate the short-term outcomes of laparoscopic colorectal surgery versus open colorectal surgery in our institution.

Methods

Medical records of consecutive patients, aged 70 years and older, who underwent elective colorectal resections at the Department of Colorectal Surgery, Singapore General Hospital (SGH), from January 2005 to December 2008 were retrieved from a prospectively collected computer database. Both benign and malignant diseases were included in the study. This study was approved by the Institutional Review Board of SGH.

Pre-operatively, all patients received mechanical bowel preparation with 2 l of polyethylene glycol and prophylactic subcutaneous enoxaparin for deep vein thrombosis (DVT) prophylaxis the evening before surgery. Prophylactic antibiotics were administered at induction of anaesthesia. Consultant colorectal surgeons experienced in both open and laparoscopic approaches performed all the surgeries in our study. The choice of approach was left up to surgeon preference and to the patient after informed consent had been taken. In a full laparoscopic approach, complete bowel mobilisation, intracorporeal ligation of vessels was followed by distal bowel transaction intracorporeally after distal cytocidal washout was performed. A port wound is extended to deliver the specimen. For right and left hemicolectomies, anastomosis is performed extracorporeally with linear staples. For procedures requiring an anastomosis to the rectum, a circular stapled anastomosis is performed intracorporeally after re-establishment of pneumoperitoneum.

In our institution, we have defined conversion whereby during vascular ligation or colonic mobilisation, the laparoscopic procedure is aborted at the surgeon's discretion for reasons of patient's safety, equipment failure, tumour factors undiagnosed pre-operatively with anatomical uncertainty and invasion to surrounding organs, or the development of complications such as uncontrolled bleeding or injury of adjacent organs or structures such as ureters or small bowel. The abdominal incision is thus made earlier than planned. Patients who had conversion to open surgery were analysed on an intention to treat basis [21].

Post-operatively, all patients were managed according to a standardised protocol in a Coordinated Clinical Pathway (CCP) (Table 1). This included a structured rehabilitation programme involving physiotherapists, dieticians and nurse clinicians. Progress of diet is according to surgeon in charge and determined by restoration of bowel sounds, passage of flatus and stool. All patients received DVT prophylaxis and anti-embolic stockings during the entire duration of hospital stay. Patients were reviewed 2 weeks after discharge from hospital. In patients diagnosed with colorectal cancer, staging of disease after surgical resection was according to AJCC Cancer Staging Manual 7th edition [22], after review of the pathological specimen and investigations of distant metastases.

Demographic data such as age, gender, body mass index (BMI), co-morbidities (including history of cardiovascular accidents and acute myocardial infarcts, arrythmias, obstructive pulmonary disease, diabetes, hypertension and end-stage

Table 1 Coordinated clinical pathway

POD 1	IV morphine infusion or patient controlled analgesia
	Sips of water to small clear feeds
	Chest physiotherapy and limb exercises
	Sit up in bed
POD 2	Intravenous analgesia discontinued, oral analgesia commenced
	Small feeds
	Urinary catheter removed
	Chest physiotherapy
	Sit out of bed
POD 3	Feeds to diet of choice
	Exercise rehabilitation programme
	Ambulate by walking

renal failure) and Association of Anaesthesiologists (ASA) status were assessed. Operative details (operative time, incision length and peri-operative complications), recovery parameters (duration of narcotic usage, time to return of bowel function and length of stay) and details of resected specimen (pathology, number of lymph nodes, margins, and stage of cancer where appropriate) were also obtained and analysed.

Statistical analyses were performed using Statistical Package for Social Science (version 17.0; SPSS, Chicago, IL, USA). The chi-square test, Fisher's exact test and Mann–Whitney *U* test were used as appropriate. A *P* value of <0.05 was considered statistically significant.

Results

A total of 1,775 patients underwent elective colorectal resections in our institution during this 4-year period. Of these, 727 (41%) elderly patients, aged 70 years or more, were included in our study with 225 patients in the laparoscopic arm and 502 patients in the open arm. In total, there were 375 (52%) men and 352 (48%) women. The clinical and demographic data are summarised in Table 2. There were slightly more males in the LC group compared to the OC group (LC 58.6%, OC 51.6%). Otherwise, there were no significant differences between the two arms in terms of median age, median BMI, race and ASA status. The incidence of co-morbidities, including hypertension, diabetes mellitus, ischaemic heart disease, arrythmia, end-stage renal impairment on dialysis, chronic lung disease and history of cerebrovascular accidents (CVA) were also similar between both groups.

Twenty-seven patients in the LC group required conversion to open surgery, giving a conversion rate of 12%. Reasons for conversion included dense adhesions from previous surgery ($n=14$), tumour factors undiagnosed preoperatively such as invasion to surrounding organs or bulky tumour-causing anatomical uncertainty ($n=11$), the development of complications such as bleeding ($n=1$) and patient intolerance of pneumoperitoneum with excessively high airway pressures ($n=1$).

The majority of the patients had left-sided resections (Table 3). The median operative time was significantly longer in the LC group (125 vs. 85 min in the OC group, $p<0.001$). The median length of skin incision was significantly shorter in the LC group (6.0 vs. 12.0 cm, $p<0.001$). Most of the patients in both groups had skin crease incisions. Majority of the surgeries in both groups were performed for cancer and polyps (Table 4). Both groups had similar percentages of early (stages I and II) and advanced stage (stages III and IV) cancers. There were no significant differences between the two groups in terms of tumour size and number of lymph nodes removed. Both proximal and distal margins were adequate in both groups. Long-term oncological outcomes were not evaluated in this study.

The LC group was associated with superior outcomes in terms of post-operative recovery parameters (Table 5). The median number of days of narcotic use was significantly shorter (2 vs. 3 days, $p<0.001$). In addition, the median length of stay was also shorter (6 vs. 7 days, $p<0.001$).

Table 2. Demographic data of patients

Factor	Laparoscopic (%) ($n=225$)	Open (%) ($n=502$)	p valuc
Gender			$p=0.01$
Male	132 (58.6)	243 (48.4)	
Female	93 (41.3)	259 (51.6)	
Race			$p=0.931$ (NS)
Chinese	204 (90.7)	461(91.8)	
Non-Chinese	21 (9.3)	41 (8.2)	
Median age (range)	76 (70 to 90)	77 (70 to 95)	$p=0.862$ (NS)
Median BMI (range)	23.1 (16.1 to 31.1)	22.0 (17.3 to 27.3)	$p=0.305$ (NS)
ASA			$p=0.182$ (NS)
1	44 (19.6)	107 (21.3)	
2	137 (60.8)	277 (55.2)	
3	44 (19.6)	118 (23.5)	
Co-morbidities			
Diabetes mellitus	61 (27.1)	137 (27.3)	$p=0.96$ (NS)
Hypertension	144 (64.0)	302 (60.2)	$p=0.326$ (NS)
End-stage renal disease	2(0.9)	7 (1.4)	$p=0.569$ (NS)
Ischaemic heart disease/arrythmia	45 (20.0)	102 (20.3)	$p=0.921$ (NS)
Chronic lung disease	12 (5.3)	24 (4.8)	$p=0.741$ (NS)
Previous cerebrovascular accident	13 (5.8)	29 (5.8)	$p=1.000$ (NS)

Table 3 Operative data

	Laparoscopic n=225	Open n=502	p value
Surgery perfonned			p=0.066 (NS)
Right hemicolectomy/extended right hemicolectomy	41 (18.2)	136 (27.1)	
Left hemicolectomy	10 (4.4)	29 (5.8)	
High anterior resection	122 (54.2)	178 (35.5)	
Low anterior resection	16 (7.1)	55 (11.0)	
Ultra-low anterior resection	24 (10.6)	60 (12.0)	
Subtotal/total colectomy	2 (0.9)	10 (2.0)	
Abdominal–perineum reseetion	9 (4.0)	22 (4.4)	
Hartmann's procedure	1 (0.4)	8 (1.6)	
Right hemicolectomy+high anterior resection	1 (0.4)	4 (0.8)	
Median operative time (minutes)	125 (65 to 360)	85 (25 to 260)	<0.001
Type of incision			0.000
Skin crease	191 (84.9%)	329 (65.5%)	
Vertical	25 (11.1%)	173 (34.5%)	
None (laparoscopic APR)	9 (4.0%)	0	
Median length of incision (cm)	6.0	12.0	<0.001

However, there was no significant difference in median recovery of bowel function, with patients in both groups having bowel movement at a median of 4 days post-operative. Majority of patients in both groups were discharged to their own home. However, there was a significantly higher percentage of patients in the OC group who were discharged to inpatient rehabilitation (17.3% vs. 10.4% in the LC group, p=0.017).

The overall post-operative morbidity in both groups were comparable with 20.4% in the LC group and 20.9% in the OC group. Major morbidity was defined as follows: (1) Acute myocardial infarctions or cardiovascular accidents, (2) pneumonias or other respiratory compromise requiring intubation, (3) anastomotic leaks, (4) intestinal obstruction or bleeding requiring re-operation, (5) pulmonary embolism. Minor morbidity included arrythmias, pneumonias not requiring intubation, urinary tract infections, superficial wound infections, acute retention of urine and post-operative ileus which resolved without re-operation. The incidence of major morbidity was also similar in both groups at 9.3% and 10.2%, respectively. A significant overall proportion of post-operative morbidity was contributed

Table 4 Pathological data

	Laparoscopic	Open	p value
Pathology			p=0.05
Cancer (includes GIST, lymphoma, melanomas SCC anus)	188 (83)	453 (90)	
Divertieular	0	2 (1)	
Polyps	33 (15)	41 (8)	
Others[a]	4 (2)	6 (1)	
AJCC stage (adenoearcinomas only)	(n=186)	(n=447)	p=0.184 (NS)
I	48 (26)	67 (15)	
II	51 (27)	145 (32)	
III	58 (31)	146 (32)	
IV	29 (15)	89 (21)	
Mean diameter of tumour (cm)	4.1	4.5	p=0.62 (NS)
Mean number of lymph nodes removed	13	14	p=0.08 (NS)
Mean proximal margin (em)	8.3	11.3	p=0.003
Mean distal margin (cm)	6.2	6.8	0.31 (NS)

Values in parentheses are in percentages unless otherwise stated

[a] Two cases of benign strictures, one carcinoid tumour and one caecal ulcer operated via laparosopic surgery; two carcinoid tumours, one TB gut, three benign ulcers performed via open surgery

Table 5 Postoperative recovery parameters

	Laparoscopic	Open	p value
Median number of days of narcotic use	2 (1–5)	3 (1–6)	$p<0.001$
Median recovery of bowel function (days)	4 (2–10)	4 (2–10)	$p=0.230$ (NS)
Median length of hospital stay (days)	6 (3–109)	7 (3–116)	$p<0.001$
Discharge location	($n=222$)	($n=479$)	$p=0.017$
Back to own home or nursing home	199 (89.6)	396 (82.7)	
Inpatient rehabilitation	23 (10.4)	83 (17.3)	

by cardio-respiratory complications (Table 6). However, there was no significant difference in the incidence of cardio-respiratory complications when compared between both groups ($p=0.238$).

The 30-day mortality rate was however significantly higher in the OC group as compared to the LC group ($p=0.03$). All three patients who died in the LC group died of cardio-respiratory complications. More than 90% of the patients who died in the OC group died from cardio-respiratory causes (Table 7).

Discussion

Increased life expectancy has resulted in more elderly patients with surgically correctable disease. Previous studies have shown that colorectal surgery in elderly patients is generally well tolerated although pre-morbid cardio-pulmonary conditions do predispose to higher morbidity and mortality rates as compared to younger patients [6, 23]. Laparoscopic colorectal resection is fast becoming the gold standard of treatment for both malignant and benign colorectal lesions, with improved short-term and comparable long-term outcomes when compared to the open method [1, 2, 24]. Improved short-term outcomes after laparoscopy have been attributed to less post-operative pain, better pulmonary function and less stress response. These outcomes are particularly important in elderly patients who are at higher risk of post-operative morbidity and mortality. It would seem natural then that laparoscopic surgery should be the ideal surgical approach for elderly patients.

In our study, there was a conversion rate of 12%. This is comparable to figures available in the literature, ranging from 6.1% to 18.7% [17, 25–28]. The reasons for conversion in our series were mainly related to adhesions from previous surgery and advanced disease, with less than 1% of the patients requiring conversion due to intra-operative complications.

There have been concerns previously about the safety of laparoscopic colorectal surgery in elderly patients mainly related to longer operative time as well as physiological stresses associated with carbon dioxide pneumoperitoneum

Table 6 Post-operative complications and mortality

Factor	Laparoscopic	Open	p value
30-day mortality (overall $n=26$, 3.6%)	3 (1.3)	23 (4.6)	$p=0.03$
Post-operative complications: (overall $n=147$, 20.2%)	Major morbidity a) AMI, CVA, b) Pneumonias that require intubation, c) Leaks, d) I/O and bleeding that require laparotomy, e) Pulmonary embolism	Minor morbidity a) arrhythmias, b) Atelectasis/pneumonia/UTI, e) Wound infection, superficial d) ARU, d) ARU, e) Ileus, resolve spontaneously	
Major morbidity	21 (9.3)	51 (10.2)	$p=0.725$(NS)
Overall morbidity	$n=46$ (20.4)	$n=105$ (20.9)	
Cardiac/arrythmias/CVA (37%)	22 (9.8)	35 (7.0)	
Pneumonia/UTI (12%)	5 (2.2)	14 (2.8)	
Ileus (9%)	7 (3.1)	6 (1.2)	
Anastomotic leak/intra-abdominal abscess (10%)	2 (0.9)	13 (2.6)	(Overall leak rate—2.1%)
Wound infection (18%)	7 (3.1)	20 (4.0)	
Bleeding (6%)	1 (0.4)	8 (1.6)	
Urinary retention (6%)	2 (0.9)	8 (1.6)	
Pulmonary embolism (1%)	0	1 (0.2)	

Table 7 Causes of death

Cause	Number of patients (laparoseopic arm)	Number of patients (open arm)
AMI	2	10
CVA	1	3
Pneumonia	0	8
Sepsis due to leak	0	2

and steep head-down tilts required for the main duration of surgery. All these may potentially increase the risk of cardio-respiratory complications. However, our results do show that LC was associated with improved short-term outcomes, namely less narcotic use, shorter length of stay and lower discharges to inpatient rehabilitation. In addition, there was no increased risk of post-operative morbidity related to laparoscopic surgery. In particular, incidence of cardio-respiratory complications in our study was similar irrespective of whether the patient underwent open or laparoscopic surgery.

In the LC group, the overall morbidity of 20.4% is comparable to incidences of 14% to 51% quoted in the literature pertaining to colorectal surgery in elderly patients [6, 8, 10, 11, 13–16, 24, 28, 29]. Cardio-respiratory complications after surgery in elderly patients are a major cause of post-operative morbidity and mortality. In our study, 7.8% of patients suffered cardio-respiratory complications. This is comparable to rates of 6.7% to 14.4% quoted in the literature [6, 11, 13, 28]. Of note, incidence of cardio-respiratory complications was similar in both LC and OC groups but mortality rate from these complications was higher in the OC group.

Length of stay after surgery in elderly patients after laparoscopic colorectal surgery has been shown to be comparable to that of younger patients undergoing similar surgery. Although this is a crude measurement of post-operative recovery, we observed that the length of stay of 6 days in the LC group in our study compares favourably with that in other studies, ranging from 4.2 to 11 days [6, 10–14, 16, 28, 29]. Factors affecting length of stay include post-operative pain, mobility status of patient, post-operative morbidity and social support available for the patient. One of the reasons for early discharges despite the elderly age group is the coordinated clinical pathway. In our study, both arms of patients had pain control optimised with intravenous narcotics and reviews by the acute pain team led by an anaesthetist. Patients in both groups were also attended to, both pre-operatively and post-operatively, by physiotherapists. Patients were discharged when they had return of bowel function, were able to tolerate diet, had recovered from any post-operative complications and had started to ambulate with help. In addition, social support for elderly patients in Singapore is generally favourable as the majority of the elderly population tend to stay with their children who are their primary caregivers. We did however observe that patients in the OC group were still more likely to require inpatient rehabilitation prolonging their hospitalisation stay. This may reflect that the potentially reduced surgical stimulus of laparoscopic surgery does impact on the functional recovery of the elderly patient.

Our results thus suggest that laparoscopic colorectal surgery is safe in the elderly and that age should not be a deterrent to performing laparoscopic surgery. This concurs with previous studies performed, which showed that laparoscopic surgery in elderly patients was associated with shorter length of stay and less post-operative morbidity and mortality. These studies included mostly non-randomised studies, one single-centre randomised-controlled trial and one multi-centre randomised-controlled trial [6, 10–15, 17, 28]. In addition, Faiz et al. recently published a review of post-operative mortality after colorectal surgery in English NHS hospitals and concluded that although advancing age was an independent risk factor for post-operative death, laparoscopic colorectal surgery was associated with a lower risk of death than open surgery [9]. However, our study is the largest series to date comparing laparoscopic versus open colorectal surgery in elderly patients from a single institution (Table 8).

During the interpretation of our results, we are aware that there are several potential sources of bias in our study. Firstly, we included laparoscopic patients that were operated

Table 8 Previous studies comparing laparoscopic versus open surgery in elderly patients

Study	No. of patients (laparoscopic arm)	No. of patients (open arm)	Type of study	Age
Stewart et al. [13]	42	35	Randomised	>80
Stocchi et al. [14]	42	42	Non-randomised	>75
Senagore et al. [12]	50	123	Non-randomised	>70
Yamamoto et al. [8]	17	34	Non-randomised	>80
Vignali et al. [28]	61	61	Non-randomised	>80
Tei et al. [15]	78	51	Non-randomised	>71
Lian et al. [11]	97	97	Non-randomised	>80

on during our unit's learning curve but this did not affect any of the analysed outcomes. Secondly, this was not a randomised study and may thus be subject to selection bias inherent in non-randomised studies. To overcome this bias, we thus attempted to match the demographics of the patients in both groups, including median age, ASA status, incidence co-morbidities and BMI, which were similar. So although there was a higher proportion of males and a slightly lower incidence of cancers operated in the LC group, there were similar percentage of advanced tumours (stages III and IV) in both groups thus indicating that laparoscopic surgery was performed as frequently in more advanced tumours as in early stage tumours.

Studies evaluating the cost-effectiveness of laparoscopic colorectal surgery have generally concluded that despite costs related to increase in operating theatre time and increased number of consumables used, it is as cost-beneficial as compared to open colorectal surgery [30–32]. This is likely related to improved short-term outcomes such as shorter length of stay and lower pain scores. In elderly patients, it is likely that this cost-benefit ratio may be even more marked, as outcomes such as less need for inpatient rehabilitation and lower cardio-respiratory morbidity and mortality may also contribute. Further studies are required to evaluate this.

Conclusion

Our results suggest that laparoscopic colorectal surgery in elderly patients aged 70 years or older is feasible. It is associated with superior short-term outcomes, namely less narcotic use, shorter length of stay, reduced need for post-operative inpatient rehabilitation as well as lower mortality when compared to the open method. Hence, laparoscopic colorectal surgery should be performed in the elderly.

Disclosure The authors declare that they have no conflicts of interest.

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Laparoscopic surgery versus open surgery for colon cancer: short-term outcomes of a randomised trial

*The COlon cancer Laparoscopic or Open Resection Study Group**

Summary

Background The safety and short-term benefits of laparoscopic colectomy for cancer remain debatable. The multicentre COLOR (COlon cancer Laparoscopic or Open Resection) trial was done to assess the safety and benefit of laparoscopic resection compared with open resection for curative treatment of patients with cancer of the right or left colon.

Methods 627 patients were randomly assigned to laparoscopic surgery and 621 patients to open surgery. The primary endpoint was cancer-free survival 3 years after surgery. Secondary outcomes were short-term morbidity and mortality, number of positive resection margins, local recurrence, port-site or wound-site recurrence, metastasis, overall survival, and blood loss during surgery. Analysis was by intention to treat. Here, clinical characteristics, operative findings, and postoperative outcome are reported.

Findings Patients assigned laparoscopic resection had less blood loss compared with those assigned open resection (median 100 mL [range 0–2700] *vs* 175 mL [0–2000], $p<0·0001$), although laparoscopic surgery lasted 30 min longer than did open surgery ($p<0·0001$). Conversion to open surgery was needed for 91 (17%) patients undergoing the laparoscopic procedure. Radicality of resection as assessed by number of removed lymph nodes and length of resected oral and aboral bowel did not differ between groups. Laparoscopic colectomy was associated with earlier recovery of bowel function ($p<0.0001$), need for fewer analgesics, and with a shorter hospital stay ($p<0·0001$) compared with open colectomy. Morbidity and mortality 28 days after colectomy did not differ between groups.

Interpretation Laparoscopic surgery can be used for safe and radical resection of cancer in the right, left, and sigmoid colon.

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Introduction

Minimally invasive surgery reduces surgical trauma. Laparoscopic surgery restricts the extent of abdominal incisions, avoids manual traction and manipulation of abdominal tissue, and prevents undue blood loss, thus diminishing immune activation and catabolism as a response to surgery.[1,2] 15 years after Muehe first did laparoscopic cholecystectomy, minimally invasive surgery has become the preferred approach for treatment of symptomatic cholecystolithiasis, gastro-oesophageal reflux, and morbid obesity.[3–6] Although Jacobs and Verdeja[7] reported a case series on laparoscopic segmental colectomy in patients with sigmoid cancer in 1991, laparoscopic colectomy for cancer has not been readily accepted: the safety of the procedure has been questioned because of early reports of port-site metastases. Despite reduced morbidity and improved convalescence after laparoscopic operations for benign disorders such as gallbladder stones and reflux oesophagitis, surgeons have been sceptical about similar advantages of laparoscopic colectomy for cancer.

The European, multicentre COLOR (COlon cancer Laparoscopic or Open Resection) trial aimed to assess laparoscopic surgery as curative treatment for colon cancer by analysis of short-term outcome and of cancer-free survival 3 years after laparoscopic surgery or open surgery for colon cancer. Data for cancer-free survival will be reported later. Here, the short-term results of clinical characteristics, operative findings, and post-operative outcome are reported.

Methods

Patients

Between March 7, 1997, and March 6, 2003, all patients with colon cancer who presented to the 29 participating hospitals were screened for inclusion into the trial. Patients with one adenocarcinoma, localised in the caecum, ascending colon, descending colon, or sigmoid colon above the peritoneal deflection who were aged 18 years or older and who gave written informed consent were eligible. The number of eligible patients who were not randomised was not recorded. Exclusion criteria were: body-mass index (BMI) of more than 30 kg/m^2; adenocarcinoma of the transverse colon or splenic flexure; metastases in the liver or lungs; acute intestinal obstruction, multiple primary tumours of the colon; scheduled need for synchronous intra-abdominal surgery; preoperative evidence of invasion of adjacent structures, as assessed by CT, MRI, or ultrasonography; previous ipsilateral colon surgery; previous malignant disease (except those who had had curative treatment for basocellular carcinoma of the skin or in-situ carcinoma of the cervix); absolute contraindications to general anaesthesia; and a long-term pneumoperitoneum.

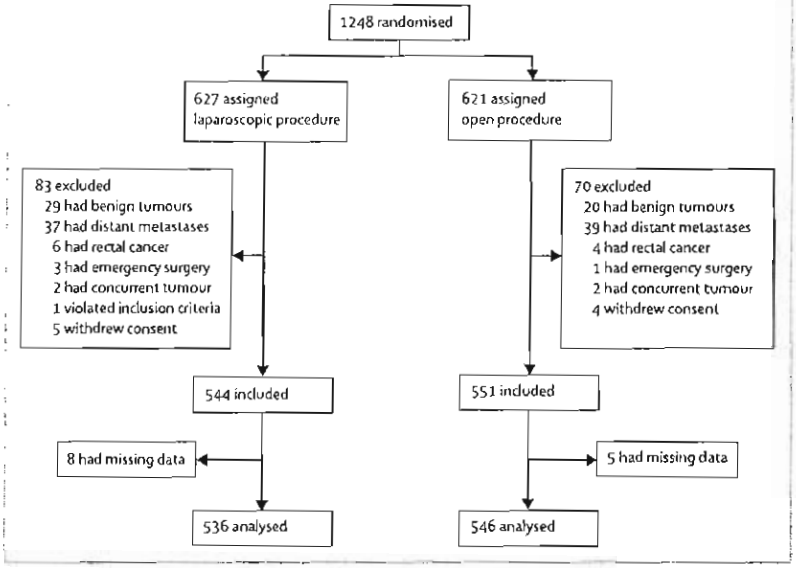

Figure 1: Trial profile

627 patients were randomly assigned to laparoscopic resection and 621 to open resection by use of computer-generated random numbers; randomisation was stratified according to participating centre and type of resection (ie, right hemicolectomy, left hemicolectomy, or sigmoidectomy). Patients were randomised by the trial coordinator (RV, who was succeeded by EK) at Erasmus University Medical Center, Rotterdam, Netherlands, and allocation was done by telephone or fax. Patients were not blinded to the procedure they were allocated because covering all possible open and laparoscopic incisions was thought too cumbersome.

	Laparoscopic colectomy (n=627)	Open colectomy (n=621)
Age (years)		
Median (range)	71 (27–92)	71 (31–95)
Sex		
Men	326 (52%)	336 (54%)
American Society of Anesthesiologists group		
I	164 (26%)	166 (27%)
II	353 (56%)	318 (51%)
III	92 (15%)	112 (18%)
IV	4 (1%)	5 (1%)
Missing data	14 (2%)	20 (3%)
Body-mass index (kg/m²)		
Median (range)	24·5 (12·1–37·1)	24·9 (14·5–40·5)
Previous abdominal surgery*		
No	386 (62%)	384 (62%)
Once	167 (27%)	163 (26%)
Twice	43 (7%)	49 (8%)
Three or more times	13 (2%)	9 (1%)
Missing data	20 (3%)	16 (3%)

*Does not total 100% because of rounding

Table 1: Baseline characteristics

Patients were excluded after randomisation only if metastasis was detected during surgery, microscopic examination of the resected sample showed no signs of malignant disease, other primary malignant disease was discovered before or during surgery, patients needed emergency surgery, or if patients withdrew consent. The trial coordinator supervised data gathering and provided progress data to the protocol committee and the monitoring committee. The ethics committees of every participating centre gave ethics approval for the trial.

Diagnosis of colon cancer was confirmed by barium-enema radiography or colonoscopy. Biopsy samples were taken for polyps, but not for macroscopically evident carcinomas. All patients underwent radiographic imaging of the liver and chest to exclude distant metastases. In patients with rectosigmoid carcinoma, lateral barium-enema radiography was done to determine the exact location of the tumour. Bowel preparation, prophylaxis with antibiotics, and prophylactic treatment for thrombosis were done in accordance with standards at the participating institution.

Open surgery and laparoscopic surgery had similar protocols; extent of resection was much the same for both procedures. Right hemicolectomy involved resection of the caecum, ascending colon, and hepatic flexure with preservation of the main and left branches of the middle colic artery. Left hemicolectomy involved resection of at least 5 cm above and 5 cm below the lesion. For sigmoidectomy, resection of the sigmoid 5 cm above and 5 cm below the lesion was done. During laparoscopic surgery, either the tumour and adjacent tissue or the extraction site was protected during removal of the affected bowel. For laparoscopy, all surgical teams had done at least 20 laparoscopically assisted colectomies. An unedited videotape of a laparoscopic colectomy was submitted before a centre participated in the trial to assess safe and thorough techniques. All open colectomies were done by surgical teams who had at least one staff member with credentials in colon surgery. The resected tumour was presented unfixed to a pathologist, who recorded the size of the tumour, involvement of circumferential and longitudinal margins, number of resected lymph nodes, number of positive lymph nodes, and TNM classification in accordance with standardised techniques;[8] pathologists were not informed of the mode of resection.

Patients allocated laparoscopic surgery were converted to open surgery before the first incision when the laparoscopic equipment malfunctioned or when the laparoscopic surgical team was absent. Analysis was by intention to treat—ie, patients who had preoperative conversion remained in the laparoscopic group for analysis. Case-record forms were collected by the coordinating centre in Rotterdam, Netherlands. Short-term morbidity and mortality was defined as 28-day or in-hospital morbidity and mortality.

Interim analyses were done by the data monitoring committee after the report of every 50th recurrence in the whole study population. The trial was to be stopped if there was a convincing difference ($p<0·001$) in recurrence between groups.

Postoperative care, including use of narcotics for the first 3 days after surgery, was done in accordance with standard practice of the surgeons at the participating centre. Adjuvant therapy before and after surgery was allowed at the physician's discretion.

Primary and secondary outcomes

The primary outcome of the trial was cancer-free survival 3 years after surgery, and will be reported elsewhere. Secondary outcomes were short-term morbidity and mortality, number of positive resection margins, local recurrence, port-site and wound-site recurrence, metastasis, overall survival, and blood loss during surgery. Blood loss, operating time, conversions, radicality of resections, morbidity, mortality, and hospital stay are the outcomes reported here. Cost analyses[9] and quality-of-life assessments (not yet reported) have been done separately for every country because health-care costs and measurement of quality of life vary widely among European countries.

Statistical analysis

At the design of the trial, power calculations were done to exclude a difference of 7·4% or more in 3-year disease-free survival with 95% confidence. Thus, 1200 patients were needed to obtain 80% power.

Percentage differences between groups were compared with the χ^2 test or Fisher's exact test; comparison of continuous data was done by use of the Mann-Whitney test. Assessment of the effects of centre on operation time, blood loss, hospital stay, and number of lymph nodes was done with ANOVA after logarithmic transformation of these outcomes to obtain approximate normal distributions, and interaction terms were used to assess whether treatment effect differed between centres. Treatment effects are therefore expressed as ratios of geometric means. Centres with fewer than 30 patients were grouped. Further exploratory analyses, allowing for random centre effects, were done to investigate whether the number of patients per centre affected outcomes; only centres that accrued at least ten patients were included in this analysis. The effects of procedure and study centre on the odds of positive against negative resection margins were analysed by use of exact logistic regression. Statistical analyses were done with SPSS version 5.11. $p=0·05$ (two-sided) was the limit of significance in all analyses.

Role of the funding source

The sponsor of the trial had no role in the study design; collection, analysis, or interpretation of data; or the writing of the report. The corresponding author had full access to all data in the study and had final responsibility to submit the paper for publication.

	Laparoscopic colectomy (n=536)	Open colectomy (n=546)	p
Intervention			
Right hemicolectomy	259 (48%)	253 (46%)	0·87
Left hemicolectomy	57 (11%)	56 (10%)	
Sigmoid resection	199 (37%)	212 (39%)	
Other	21 (4%)	25 (5%)	
Time in theatre (min)*			
Median (range)	202 (50–540)	170 (45–580)	<0·0001
Duration of surgery (skin to skin, min)†			
Median (range)	145 (45–420)	115 (40–355)	<0·0001
Blood loss (mL)‡			
Median (range)	100 (0–2700)	175 (0–2000)	<0·0001

*Data missing for 99 patients. †Time from first incision to skin closure; data missing for 68 patients. ‡Data missing for 69 patients.

Table 2: Operative data

Results

Figure 1 shows the trial profile. The trial was not stopped early. 11 patients allocated laparoscopic surgery underwent open surgery because of malfunctioning laparoscopic equipment (eight patients) or absence of a skilled laparoscopic surgeon (three patients). Table 1 shows baseline characteristics of participants.

Malignant disease was confirmed preoperatively by a biopsy sample in 827 (76%) of 1082 patients. To diagnose the tumour, 876 (81%) of 1082 patients had colonoscopy and 432 (40%) had barium-enema radiography. Imaging of the primary tumour with CT was done for 48 (4%) of

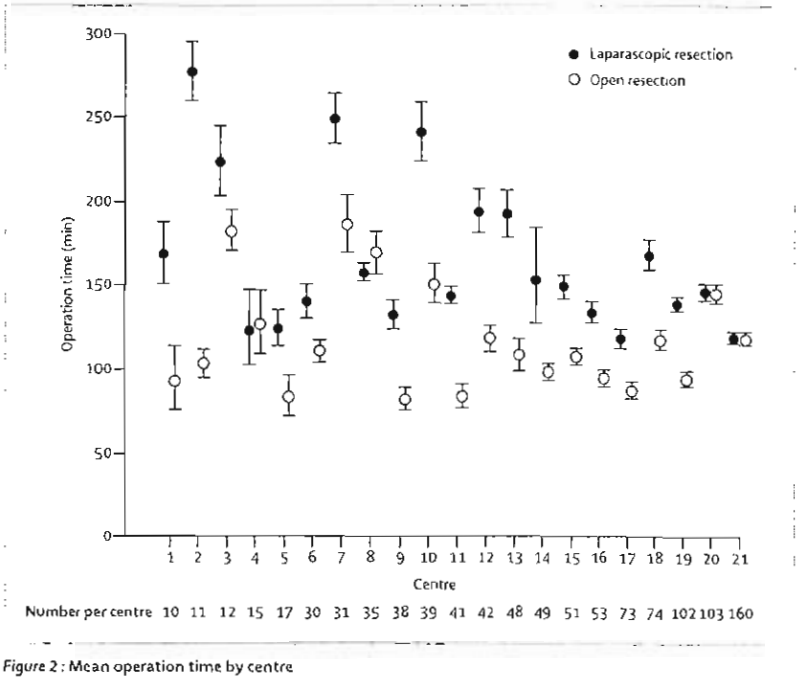

Figure 2: Mean operation time by centre
The 21 centres with at least ten patients are ranked according to number per centre. Vertical bars are SE.

Colonoscopic tattooing
Injection of India ink by use of a catheter, which is passed down a working channel in the colonscope, in the bowel wall surrounding the lesion. Blue ink is visualised on the serosal side of the bowel, allowing localisation of small lesions that are not readily visible.

1082 patients, and colonoscopic tattooing of the tumour for 37 (3%). In the laparoscopic group 21 tumours were tattooed: 15 in stage I disease, three in stage II, and three in stage III, of which four were in the right colon, five in the descending colon, and 12 in the sigmoid colon. In the open-surgery group, 16 tumours were tattooed: eight in stage I disease, six in stage II, and two in stage III, of which four were in the right colon, three in the descending colon, and nine in the sigmoid colon.

Screening for liver metastases before surgery was done by use of ultrasonography in 869 (80%) of 1082 patients, CT in 75 (7%), ultrasonography and CT in 123 (11%), and MRI combined with ultrasonography or with CT in four patients; 11 (<1%) patients did not have any such procedure and were assumed to have no liver metastases. Screening for pulmonary metastases before surgery was done with plain radiography of the chest in 1046 (97%) of 1082 patients, radiography and CT of the chest in 12 (1%), and chest CT in nine (1%); 15 (1%) patients had no procedure and were assumed to have no pulmonary metastasis. Use of imaging techniques did not differ between groups. The median time between randomisation and surgery was longer in the laparoscopic group than in the open-surgery group (6 days [range 1–85] *vs* 5 days [1–63]; p=0·02).

	Laparoscopic colectomy (n=536)	Open colectomy (n=546)	p
Tumour size (cm)*			
Median (range)	4·0 (0·4–17)	4·5 (0·8–17)	0·09
Resection margins†			
Positive	10 of 526 (2%)	10 of 538 (2%)	1·0
Aboral	1	1	
Oral	0	1	
Circumferential	9	8	
Negative	516 of 526 (98%)	528 of 538 (98%)	
Clinical T stage‡			
T1	41 of 528 (8%)	39 of 537 (7%)	0·95
T2	107 of 528 (20%)	105 of 537 (20%)	
T3	350 of 528 (66%)	359 of 537 (67%)	
T4	30 of 528 (6%)	34 of 537 (6%)	
Clinical N stage§¶			
N0	347 of 528 (66%)	364 of 539 (68%)	0·44
N1	125 of 528 (24%)	122 of 539 (23%)	
N2	45 of 528 (9%)	48 of 539 (9%)	
N3	11 of 528 (2%)	5 of 539 (1%)	
Tumour stage§¶			
I	129 of 528 (24%)	125 of 539 (23%)	0·60
II	218 of 528 (41%)	239 of 539 (44%)	
III	181 of 528 (34%)	175 of 539 (32%)	
Histology§¶			
Well differentiated	90 of 529 (17%)	86 of 538 (16%)	0·89
Well to moderately differentiated	28 of 529 (5%)	32 of 538 (6%)	
Moderately differentiated	321 of 529 (61%)	315 of 538 (59%)	
Moderately to poorly differentiated	13 of 529 (2%)	15 of 538 (3%)	
Poorly differentiated or undifferentiated	46 of 529 (9%)	55 of 538 (10%)	
Not specified	31 of 529 (6%)	35 of 538 (7%)	
Number of positive lymph nodes in resected sample‖			
Median (range)	10 (0–41)	10 (0–42)	0·35

*Data missing for 11 patients. †Data missing for 18 patients. ‡Data missing for 17 patients. §Data missing for 15 patients ¶Might not add to 100% because of rounding. ‖Data missing for 36 patients.

Table 3: Details of pathology report

Table 2 shows operative findings. Duration of surgery was longer for patients assigned laparoscopic resection than for those assigned open resection. ANOVA showed that the centre-adjusted ratio (laparoscopic/open) of geometric mean duration of surgery was 1·39 (95% CI 1·32–1·49), but this effect differed significantly between centres. Random-effects regression analysis showed that the difference in duration of surgery between groups decreased with increasing numbers of patients per centre, an effect that was significant for the laparoscopic group (p=0·027) but not for the open-resection group (figure 2). Furthermore, time spent in the operating theatre was shorter for patients assigned open surgery than for those assigned laparoscopic surgery (table 2). By use of ANOVA, the centre-adjusted ratio (laparoscopic/open) of geometric mean time spent in theatre was 1·27 (1·22–1·32, p<0·001), which differed significantly between centres (data not shown). Random-effects regression analysis showed that mean time spent in theatre for patients assigned laparoscopic resection dropped with increased number of patients per centre (p=0·032), whereas no such association was noted for those assigned open colectomy.

Blood loss during laparoscopic colectomy was significantly less than that during open colectomy (table 2). ANOVA showed a centre-adjusted ratio (open/laparoscopic) of geometric mean blood loss of 1·66 (1·37–2·00)—a treatment effect that did not differ significantly between centres (data not shown).

During laparoscopic colectomy, adhesions were more frequently classified as problematic than during open colectomy (26 patients [5%] *vs* 11 patients [2%], p=0·02). During surgery, 91 (17%) patients who were undergoing laparoscopic colectomy were converted to open surgery because of: fixation to, or invasion of, adjacent structures by the tumour (n=31); size of the tumour (n=8); extensive adhesions (n=10); inability to localise the tumour (n=8); bleeding (n=7); tumour in transverse colon or below promontory (n=5); bad vision (n=5); length of procedure (n=3); anatomical difficulties (n=3); macroscopic suspicious lymph nodes needing extensive resection (n=3); ischaemia of the distal colon (n=1); intra-abdominal abscess (n=1); urethral injury (n=1); two synchronous tumours (n=1); gaseous distention of the bowls after colonoscopy during surgery (n=1); resection of leiomyoma of the adnex (n=1); and unknown reasons (n=2).

Postoperative microscopic examination showed no differences between laparoscopically resected and openly resected samples. Stage distribution, size of the tumour, and histological type were much the same for both groups (table 3). Furthermore, groups did not differ in the number of positive resection margins (table 3), and centre did not modify this effect (data not shown). The common odds ratio for positive against negative resection margins was 1·01 (0·36–2·68, p=1·0). In patients assigned laparoscopic resection, positive

margins were recorded in four patients with T3 tumours and in six patients with T4 tumours. In patients assigned open resection, four patients with positive margins had T3 tumours and six had T4 tumours. Groups did not differ in the number of lymph nodes harvested during surgery (table 3). ANOVA showed a centre-adjusted ratio (open/laparoscopic) of geometric mean number of lymph nodes of 1·08 (0·98–1·17, p=0·106), which did not differ significantly between centres (data not shown).

After laparoscopic colectomy, patients tolerated an oral fluid intake of more than 1 L 1 day earlier than did patients assigned open surgery, and time to first bowel movement was shorter after laparoscopic surgery than after open surgery (table 4). Moreover, laparoscopic colectomy was associated with a lower need for opioid analgesics on days 2 and 3 after surgery, and for non-opioids on the first day after surgery than was open resection. Epidural analgesics were used less frequently in the laparoscopic group compared with the open-resection group for the first 3 days after surgery (table 4).

Overall morbidity was much the same after laparoscopic surgery and open surgery (table 4). Groups did not differ in the occurrence of pulmonary or cardiac events, anastomotic failure, wound or urinary-tract infections, bowel obstruction for more than 3 days after surgery, or postoperative bleeding. The number of deaths were similar after surgery for both groups (table 4).

Groups did not differ in the numbers of reinterventions done 28 days after surgery (table 4). In the laparoscopic group, 18 reinterventions were needed for anastomotic leakage and abdominal sepsis, five for wound infections and dehiscence, four for bowel obstruction lasting more than 3 days, five for bleeding, one for a ruptured inflammatory aneurysm, two for a perforated gastric ulcer, one for explorative laparotomy, and one for removal of a rectal adenoma. In the open-resection group, eight reinterventions were needed for anastomotic leakage, nine for wound infections and dehiscence, four for bowel obstruction lasting more than 3 days, three for bleeding, and one for an ischaemic bowel.

Postoperative hospital stay was 1 day shorter in the laparoscopic group than in the open-resection group (table 4). By use of ANOVA, the centre-adjusted ratio (open/laparoscopic) of geometric mean hospital stay was 1·16 (1·08–1·23), and this treatment effect did not differ significantly between centres.

	Laparoscopic colectomy (n=536)	Open colectomy (n=546)	Mean difference between groups (95% CI)	p
Fluid intake >1 L (days)*				
Mean (SD)	2·9 (1·9)	3·8 (3·4)	0·9 (0·6 to 1·2)	<0·0001
First bowel movement (days)†				
Mean (SD)	3·6 (1·7)	4·6 (3·0)	1·0 (0·7 to 1·3)	<0·0001
Hospital stay (days)‡				
Mean (SD)	8·2 (6·6)	9·3 (7·3)	1·1 (0·2 to 1·9)	<0·0001
Analgesic use				
Day 1				
Opiates	292 of 516 (57%)	313 of 526 (60%)	3 (−3 to 9)	0·37
Non-opiates	366 of 517 (71%)	335 of 526 (64%)	−7 (−13 to −1)	0·02
Epidural	111 of 517 (22%)	190 of 526 (36%)	14 (9 to 20)	<0·0001
Day 2				
Opiates	208 of 514 (41%)	256 of 524 (49%)	8 (2 to 14)	0·008
Non-opiates	421 of 514 (82%)	443 of 524 (85%)	3 (−2 to 7)	0·29
Epidural	95 of 514 (18%)	164 of 523 (31%)	13 (8 to 18)	<0·0001
Day 3				
Opiates	132 of 513 (26%)	191 of 524 (37%)	11 (5 to 16)	0·0003
Non-opiates	343 of 513 (67%)	368 of 526 (70%)	3 (−2 to 9)	0·27
Epidural	42 of 513 (8%)	83 of 524 (16%)	8 (4 to 12)	0·0002
Complications§				
Overall	111 of 535 (21%)	110 of 545 (20%)	−1 (−5 to 4)	0·88
Wound infection	20 of 535 (4%)	16 of 545 (3%)	−1 (−3 to 1)	0·57
Wound dehiscence	2 of 534 (<1%)	7 of 544 (1%)	0·6 (−0·2 to 2)	0·18
Pulmonary	8 of 535 (2%)	13 of 545 (2%)	0·9 (−1 to 3)	0·40
Cardiac	4 of 535 (1%)	9 of 545 (2%)	1 (−0·5 to 2)	0·28
Bleeding	13 of 534 (2%)	8 of 544 (2%)	−0·9 (−3 to 1)	0·36
Urinary-tract infection	12 of 535 (2%)	13 of 545 (2%)	0·2 (−2 to 2)	1·00
Anastomotic failure	15 of 535 (3%)	10 of 545 (2%)	−1 (−3 to 1)	0·39
Bowel obstruction >3 days	10 of 534 (2%)	15 of 544 (3%)	0·9 (−1 to 3)	0·45
Other	45 of 534 (8%)	40 of 544 (7%)	−1 (−4 to 2)	0·59
Reintervention	37 of 535 (7%)	25 of 545 (5%)	−2 (−5 to 0·4)	0·13
Death	6 of 535 (1%)	10 of 545 (2%)	0·7 (−0·7 to 2·2)	0·45

*Data missing for 64 patients. †Data missing for 54 patients. ‡Data missing for 11 patients. §Some patients had more than one complication.

Table 4: Postoperative recovery, morbidity, and mortality

Discussion

The short-term outcomes of the COLOR trial show that although duration of surgery for laparoscopic colectomy for colon cancer was longer than that of open colectomy, patients who underwent the laparoscopic procedure had less blood loss during surgery. Moreover, tumours resected by laparoscopy or by open surgery did not differ in stage, distribution, size, histology, number of positive resection margins, and number of positive lymph nodes. After surgery, patients allocated laparoscopic colectomy tolerated fluid intake and had a first bowel movement, earlier than did those allocated open colectomy. Patients assigned laparoscopic colectomy had a lower need for analgesics and epidurals in the 3 days after surgery than did those assigned open colectomy.

29 university hospitals and community hospitals in seven European countries participated in this trial, and the outcomes thus give an insight into laparoscopic colon surgery as done in Europe. Importantly, however, this trial started in 1997 when the laparoscopic technique of segmental colectomy was changing. In the past 8 years, new ways of vessel sealing, such as bipolar and ultrasonic forceps, have been introduced. These devices allow faster and more secure haemostasis than do conventional laparoscopic techniques such as clips and unipolar diathermia. Furthermore, a shortcoming of this trial is that patients were not blinded as to the procedure they were allocated, which could have affected subjective outcomes. Missing data for 13 of 1248 patients seems acceptable, given that the trial was multicentre.

In this trial, patients who underwent laparoscopic colectomy spent longer undergoing surgery than did those who had open colectomy, but needed fewer opioids on the second and third postoperative day than did those who had open surgery. By contrast, Joels and colleagues[10] associated use of opioids after open colectomy with operative time as a result of more extensive tissue manipulation and protracted incision of the abdominal wall. The findings reported here suggest that manipulation of tissues is a more important determinant of postoperative pain than is operative time, and are consistent with Weeks and co-workers'[11] trial, which recorded shorter postoperative use of parenteral analgesics after laparoscopic colectomy than after open colectomy ($p<0·001$).

Bowel obstruction after colectomy, as defined by postoperative day of fluid intake of more than 1 L and postoperative day of first bowel movement, was 1 day shorter in patients who had laparoscopic surgery than in those who had open surgery in the COLOR trial. Braga and colleagues[12] noted first bowel movement 1 day earlier after laparoscopic colectomy than after open colectomy, and animal studies[13] have shown that laparoscopic colectomy reduces postoperative atony of the small bowel, as measured by electromyographic activity, compared with open colectomy. Clinical manometric recordings[14] of motility at the splenic flexure of the colon have shown that colonic motility recovers earlier after laparoscopic colectomy than after open colectomy. Rapid rehabilitation protocols involving thoracic epidural local anaesthetic blockade, early mobilisation of the patient, and solid food on the first postoperative day have reduced bowel obstruction to 1–2 days.[15]

Findings reported here show that hospital stay after laparoscopic colectomy was 1 day shorter with laparoscopic colectomy than with open colectomy, and are consistent with the findings of Lacy and colleagues[16] and the Clinical Outcomes of Surgical Therapy (COST) study group.[17] However, Basse and co-workers[18] showed substantial reduction of hospital stay after open colectomy by use of transverse incisions combined with accelerated multimodal rehabilitation programmes. Further assessment of the effect of such rehabilitation programmes on the outcome of laparoscopic and open colectomy are needed.

Conversion of laparoscopic procedures to open surgery was needed in 19% of patients, mainly because of the presence of a large and invasive cancer. Size and infiltration of adjacent tissues by a tumour cannot be assessed accurately by either colonoscopy or barium enema. However, these imaging modalities are regarded as the standard of care in Europe. Only 5% of patients had a CT scan to image the primary tumour, and use of CT or MRI in patients with colon cancer may identify patients with bulky or invasive lesions, or lesions at the flexures or transverse colon, which are less amenable to laparoscopic removal.

Operating time varies with surgical experience, and gaining experience with laparoscopic colectomy can reduce the operating time to that with open colectomy. Although in this trial, laparoscopic colectomies lasted longer than did open procedures, operating time varied substantially between centres. Although total open surgical procedures done per centre was not recorded, the presence of a skilled colorectal surgeon during all open colectomies ensured appropriate and timely procedures. Reluctance to implement laparoscopic colectomy in surgical practice because of restraints on operating time therefore seems unsubstantiated.

Blood loss during laparoscopic colectomy was less than that during open colectomy in this study. Kiran and colleagues[19] assessed use of blood products (ie, packed cell or transfused red cells) in a case-matched study of patients undergoing laparoscopic colectomy or open colectomy, and reported that demand for blood transfusions during and after surgery was less in the laparoscopic group compared with the open-surgery group. Furthermore, the safety and effectiveness of laparoscopic surgery can be measured by the degree of resection and disease-free survival. In the COLOR trial, the extent of resection of the colon and mesocolon was much the same for both groups. These findings are consistent with other prospective trials[20,21] of laparoscopic resection versus open resection for colon cancer, and by a consensus conference.[22] Moreover, a median number of ten lymph nodes were removed during surgery in both groups. It has been suggested[23] that at least 12 lymph nodes should be removed to ensure radical resection. However, the number of removed lymph nodes recorded by the pathologist is a function of the scrutiny of the detection method. In this study, pathologists were not urged to do a more thorough search for lymph nodes than is done in practice. A consensus conference[22] that documented available data for laparoscopic versus open colectomy showed that both procedures commonly yield ten lymph nodes. Assessment of 5-year survival after laparoscopic colectomy for tumours in the left and right colon by Jacob and Salky[24] showed that the mean harvest of ten lymph nodes was much the same as that with open colectomy.

Patients with a BMI of more than 30 kg/m^2 were excluded from the COLOR trial because at the time of trial design obesity was regarded as a technical challenge to laparoscopic colectomy. Delaney and co-workers[25] studied patients with a BMI of more than 30 kg/m^2 who had either laparoscopic colectomy or open colectomy. The researchers found that operating times and morbidity did not differ between groups and that hospital stay was 2 days shorter after laparoscopic surgery than after open surgery. However, the conversion rate from laparoscopic surgery to open surgery was 30%. Leroy and colleagues[26] assessed outcome of laparoscopic colectomy in obese and non-

obese patients who had diverticular disease or colon cancer, and found that groups did not differ in operating times, radicality of resection, and morbidity. Moreover, none of the 23 patients with a BMI of more than 30 kg/m² needed conversion to open surgery in Leroy and colleagues' study.[16] Patients who are obese can thus benefit from laparoscopic surgery, and obesity should no longer be regarded as a contraindication to laparoscopic colectomy.

Elderly patients were not been excluded from the COLOR trial. Yamamoto[17] showed that surgical outcome after laparoscopic colectomy for patients 80–90 years old was much the same as for those 60 years or younger. Furthermore, Sklow and co-workers[18] reported faster recovery after laparoscopic colectomy than after open colectomy in patients older than 75 years despite a longer operating time compared with open surgery.

The improved short-term outcome after laparoscopic surgery compared with open surgery may be a consequence of reduced surgical trauma. Serum concentration of interleukin 6 is a commonly used measure of surgical trauma: Ozawa and colleagues[19] recorded lower concentrations of serum interleukin 6 after laparoscopic colectomy than after open colectomy, and Whelan and co-workers[10] showed that open colectomy was associated with significant suppression of the cell-mediated immune response whereas laparoscopic colectomy was not ($p<0\cdot007$).

In conclusion, the outcomes of studies on laparoscopic resection for colon cancer reflect experience of the past decade. During this period, laparoscopic surgical techniques have improved substantially as a result of growing experience and progressing technology that allows better video imaging, and safer and more efficient tissue ablation. Procedure times have dropped and undue tissue manipulation has decreased. The practice of open colectomy is changing too, with the implementation of rapid-recovery protocols. Further studies of the current surgical approaches for colon cancer are warranted to establish the optimum procedure for the individual patient with colon cancer.

Contributors

H J Bonjer was the principal investigator, and developed the protocol and helped write the report. E Haglind, J Jeekel, G Kazemier, and L Påhlman developed the protocol. W C J Hop did statistical analyses and helped write the report. R Veldkamp, E Kuhry, E Haglind, L Påhlman, M A Cuesta, S Msika, M Morino, A Lacy, and J Jeekel helped write the report.

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Conflict of interest

We declare no conflicts of interest.

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ORIGINAL ARTICLE

Laparoscopic versus open right hemicolectomy: a comparison of short-term outcomes

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Abstract
Background The laparoscopic approach is increasingly becoming the gold standard for colorectal resections. While laparoscopic surgery of the left colon and rectum has been evaluated in many studies, laparoscopic resection of the right colon has not been as widely examined. The aim of this study was to examine the short-term outcomes after laparoscopic right hemicolectomies and to determine if they were superior when compared with those after open resection.
Patients and methods Consecutive cases of laparoscopic right hemicolectomies performed between May 2005 and December 2007, in the Department of Colorectal Surgery, Singapore General Hospital, were compared with a matched series of patients who underwent open surgery.
Results From a total of 37 laparoscopic cases, 36 patients successfully underwent laparoscopic right hemicolectomies. There was one conversion, giving a conversion rate of 2.7%. These 37 patients were compared with 40 patients who underwent open right hemicolectomies. The laparoscopic arm was characterised by shorter length of incisions (5.7 vs. 11.2 cm, $p<0.001$) but longer operating times (110.8 vs. 71.6 min, $p<0.001$). Mean number of lymph nodes harvested and length of proximal and distal margins were similar in both groups. There were also no significant differences between the groups in terms of narcotic use, recovery of bowel function, length of stay, post-operative morbidity and 30-day mortality.
Conclusion Laparoscopic right hemicolectomies are as feasible and safe as the open technique. They confer improved cosmesis with smaller incisions but at the expense of longer operating time.

Keywords Right hemicolectomy · Laparoscopic · Colorectal · Conversion · Outcome

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Introduction

Laparoscopic colorectal resections have become increasingly accepted as the technique of choice in the treatment of colorectal diseases, with proven advantages such as less post-operative analgesic requirements, earlier return of bowel function and shorter hospital stay [1-6]. Numerous studies have also demonstrated that there has been no compromise in adequacy of oncological clearance as disease control and overall survival are comparable to open colectomies [1-5, 7-12]. However, the main bulk of the literature centres mainly on either an overall comparison of laparoscopic and open colorectal resections or solely on left-sided laparoscopic resections, with fewer publications comparing solely the outcomes of laparoscopic right hemicolectomies (LRH) with those performed via the open approach. The aim of our study was to evaluate short-term outcomes of LRH performed in our unit against a matched series of patients (matched for age, sex, ASA status and pathology) who underwent open right hemicolectomies (ORH) during the same period. The outcomes evaluated were 30-day mortality, peri-operative complications, duration of operation, length of incision, patient recovery and oncological clearance. We wanted to determine if these outcomes were indeed superior with the laparoscopic approach.

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Methods

This study was approved by the Institutional Review Board of Singapore General Hospital (SGH). Medical records of consecutive patients who had elective right hemicolectomies at the Department of Colorectal Surgery, SGH, from May 2005 to December 2007 were retrieved from a prospectively collected computer database. Both benign and malignant diseases were included in the study. Only patients who had colorectal resections were included in the study. Patients who underwent laparoscopic exploration or colonic diversion without resections were excluded.

In the event of colorectal cancer, pre-operative staging of disease was evaluated by plain chest radiographs, ultrasound and/or computed tomography of the abdomen and pelvis. Staging of disease was according to AJCC Cancer Staging Manual, 6th edition [13] after surgical resection with review of the pathological specimen and investigations of distant metastases.

Pre-operatively, all patients received prophylactic enoxaparin for deep vein thrombosis (DVT) prophylaxis and mechanical bowel preparation (polyethylene glycol 2 L) the evening before surgery. Prophylactic antibiotics were administered on induction of anaesthesia. All surgeries were performed by consultant colorectal surgeons experienced in both open and laparoscopic approaches. As this was a retrospective review of data, there was no strict selection criterion to determine if a patient qualified for the laparoscopic approach. The choice of approach was left up to surgeon preference and to the patient after informed consent had been taken.

LRH commenced after insertion of a camera port below the umbilieus and the use of two to three other ports, depending on the preference of the individual surgeon. Transection of the ileocolic and right colic vessels was performed intra-corporeally with either laparoscopic linear staples or with LigaSure Vessel Sealing System (Valleylab, Boulder, CO). Mobilisation of bowel from the ileum to the proximal transverse colon was performed via a medial to lateral approach. The specimen was extracted either through extension of the camera port wound or a limited right-sided transverse incision. Transection of bowel and creation of a functional end-to-end ileocolie anastomosis was completed extra-corporeally with linear staples.

Laparoscopic conversion was defined as incision made to perform any part of the procedure before the right colon was completely mobilised. Reasons for conversion included patient's safety, equipment failure, tumour factors undiagnosed pre-operatively with anatomical uncertainty and invasion to surrounding organs or the development of complications such as bleeding or visceral injury. In our unit, elective ORHs were performed either via a right transverse skin crease incision on the right flank or a short midline incision. Mobilisation of colon was performed using a lateral to medial approach. This was followed by division of vessels and the creation of a functional end-to-end anastomosis with linear staples.

Postoperatively, all patients were managed according to a standardised protocol in a coordinated clinical pathway (CCP; Table 1). This included post-operative chest and ambulatory physiotherapy, dietitian reviews as well as counselling on post-operative care of wounds by specialised colorectal nurse clinicians. Postoperative analgesia was administered via patient-controlled analgesia or continuous infusion of morphine. Advancement of diet post-operatively was carried out as suggested by the CCP. Deviation from CCP was made at surgeon's discretion. All patients received DVT prophylaxis and anti-embolic stockings during the entire duration of hospital stay. Patients were reviewed by their respective surgeons in the clinic 2 weeks after discharge from hospital.

Demographic data such as age, gender, body mass index (BMI) and co-morbidities were assessed. In addition, operative details (operative time, incision length and peri-operative complications), recovery parameters (duration of narcotic usage, time to first flatus and bowel movement, time to full diet and length of stay) and details of resected specimen (pathology, size of lesion, number of lymph nodes and stage of cancer where appropriate) were obtained and analysed.

All statistical analyses were performed using Statistical Package for Social Science (version 14.0; SPSS, Chicago, IL). The chi-square test, Fisher's exact test and Mann–Whitney U test were used where appropriate. All statistical tests were assessed at the conventional 0.05 level of significance.

Table 1 Coordinated clinical pathway

POD 1	IV morphine infusion or patient controlled analgesia
	Sips of water to small clear feeds
	Chest physiotherapy and limb exercises
	Sit up in bed
POD 2	Intravenous analgesia discontinued, oral analgesia commenced
	Small feeds
	Urinary catheter removed
	Chest physiotherapy
	Sit out of bed
POD 3	Feeds to Diet of Choice
	Exercise rehabilitation programme
	Ambulate by walking

Results

Thirty-seven patients underwent LRH during this 2.5-year period (May 2005 to December 2007). During the same period, 227 consecutive patients underwent elective ORH. Of these, 40 patients who were matched for age, gender, BMI, ASA status and pathology were selected to be in the control group. This matched group was chosen as the total group of 227 patients who underwent ORH was a disparate group, with a proportion of patients having recurrent or metachronous cancers. The matched group of 40 patients, thus, served as a better comparison group. The clinical and demographic data for the two groups are shown in Table 2. The majority in both groups were males (LRH 51%, ORH 55%) and the mean age was 67.5 years old (Range 37 to 87). Mean BMI was 23 in both groups and the majority of the patients were ASA 2 (LRH 54%, ORH 60%). The most common indications for surgery in both groups were cancer and polyps (LRH 81%, ORH 88%). More than 60% of the patients had stages II or III cancer. Eight patients (22%) in the LRH group had history of previous open abdominal or pelvic surgery compared to seven patients (18%) in the ORH group. The site of incisions was relatively similar between the two groups. In the LRH group, there were five right-sided abdominal incisions and three pfannestiel incisions compared to five and two, respectively, in the ORH group. Type of incisions made for previous operations are listed in Table 3. Patients in the two arms were not specifically matched for history of previous surgery.

The conversion rate in LRH was 2.7% (n=1). In the converted case, mobilisation of the colon commenced but revealed tumour adherence to the duodenum as well as to the superior mesenteric vein that was not apparent in the pre-operative computed tomographic scan. Conversion was made to complete the dissection safely. There was no history of previous abdominal or pelvic surgery in this patient.

Patients who underwent laparoscopic resection had significantly smaller incisions (5.6 vs. 11.2 cm, $p<0.01$) but required longer operating time (111 vs. 72 min, $p<0.01$). The incision length mentioned for the LRH group was the length of the incision used to extract the specimen. It did not include the cumulative length of all the trocar incisions. There were no significant differences in tumour size (LRH 3.9 cm vs. ORH 4.3 cm), number of lymph nodes harvested for cancer resections (LRH 18 nodes vs. ORH 15 nodes) as well as proximal and distal margin clearances (Table 4). Interestingly, post-operative recov-

Table 2 Clinical and demographic data of patients

Factor	LRH (%)	ORH (%)
Gender		
Male	19 (51)	22 (55)
Female	18 (49)	18 (45)
Mean Age (range)	68 (37 to 83)	67 (42 to 87)
Mean BMI (range)	23.5 (17.6 to 35.8)	22.9 (17.1 to 32.7)
ASA		
1	10 (27)	12 (30)
2	20 (54)	24 (60)
3	7 (19)	4 (10)
History of cardiac disease		
Yes	7 (19)	5 (13)
No	30 (81)	35 (88)
History of pulmonary disease		
Yes	1 (3)	1 (3)
No	36 (97)	39 (98)
Pathology		
Cancer	23 (62)	27 (68)
Diverticular Disease	5 (14)	3 (8)
Polyps	7 (19)	8 (20)
Others**	2(5)	2 (5)
AJCC stage	(n=23)	(n=27)
I	4 (17)	5 (19)
II	10 (43)	6 (22)
III	6 (26)	11(40)
IV	3 (13)	5 (19)

Values in parentheses are in percentages unless otherwise stated. **Two cases of Caecal ulcers operated via LRH; one case of Caecal lipoma and one case of Caecal Crohn's disease operated via ORH

Table 3 Patients with previous operations

Factor	LRH	ORH
Type of incisions		
Gridiron	4 appendectomies	2 appendectomies
Pfannestiel	1 myomectomy	1 caesarian section
	1 total hysterectomy	1 total hystereetomy
	1 caesarian section	
Right Subcostal	Nil	1 cholecystectomy
Right Loin	1 nephrectomy	Nil
Laparoscopic	1 tubal ligation 1 cholecystectomy	Nil
Right paramedian	Nil	1 appendectomy and cholecystectomy
Right Subcostal and Gridiron	Nil	1 appendectomy and cholecysteetomy
Nil	27	33

Table 4 Comparison between operative and pathological differences

Factor	LRH	ORH	*p* Value
Mean operative time(minutes)	111 (65 to 190)	72 (35 to 160)	<0.01
Type of incision			
Skin ercase	29 (78%)	22 (55%)	NA
Vertical	8 (22%)	18 (45%)	
Mean length of incision (cm)	5.6 (3–10)	11.2 (6–20)	<0.01
Mean diameter of tumour (cm)	3.9 (n=30)	4.3 (n=36)	0.772 (NS)
Mean number of lymph nodes removed	18 (n=23)	15 (n=27)	0.174 (NS)
Mean proximal margin (cm)	10.1 (n=30)	11.2 (n=36)	0.704 (NS)
Mean distal margin (cm)	8.6 (n=30)	8.7 (n=36)	0.852 (NS)
Mean length of lesion (em)	4.2 (n=30)	4.3 (n=36)	0.949 (NS)

NA not applicable *NS* not significant

Table 5 Postoperative recovery parameters and complications

Factor	LRH	ORH	*p* Value
Median duration of narcotic usage (days)	2	2	0.478 (NS)
Median timc to flatus (days)	2	2	0.199 (NS)
Median time to bowel movement (days)	3	3	0.233 (NS)
Median time to full diet (days)	4	4	0.328 (NS)
Median length of hospital stay (days)	5	5	0.481 (NS)
Peri and post-operative blood transfusions (n)	5 (14%)	8 (20%)	0.549 (NS)
Postoperative complications			0.251 (NS)
Superficial wound infection	2	1	
Intra-abdominal abscess	1	0	
Cardiac complication	1	1	
Rcspiratory complicarion	1	0	

NS not significant

ery was similar in patients who underwent LRH and ORH (Table 5). In particular, median duration of narcotics use, median time to passing flatus, median time to bowel movement and median time to restoration to full normal diet were similar for both groups. The median length of hospital stay was also similar at 5 days in both groups.

There was also no difference for peri-operative or post-operative blood transfusions in both groups (Table 5). Five patients (14%) in the LRH group and eight (20%) in the ORH group required peri-operative transfusions. All but two of these patients had pre-operative transfusions as they presented with anaemia secondary to a bleeding right-sided neoplasm. The last two patients had transfusions post-operatively when the haemoglobin level was noted to be low.

There was no significant difference between the two groups in terms of post-operative morbidity (Table 5). In the LRH group, two patients developed superficial infections of the wound through which the colon was extracted and were treated sufficiently with antibiotics and wound dressings. Other morbidities included an intra-abdominal abscess away from the anastomostic site possibly due to an infected hematoma, peri-operative acute myocardial infarction and respiratory failure secondary to pneumonia necessitating intubation. In the ORH group, the morbidities consisted of a superficial wound infection and acute myocardial infarction. All patients were treated conservatively and were discharged well. There were no anastomotic leaks or 30-day mortalities in both groups.

Discussion

Laparoscopic colonic resection is increasingly becoming the gold standard of management for both benign and malignant colonic lesions, with good oncologic clearance as well as comparable long term outcomes to open surgery [1-5, 7-12]. Laparoscopic resection of left-sided colonic and rectal lesions has been reported widely. However, in comparison, resection of the right colon via the laparoscopic approach has developed more slowly. There are two possible reasons for this. Firstly, laparoscopic resection of the right colon is commonly regarded as a laparoscopic-assisted procedure rather than a pure laparoscopic procedure, as bowel transection and anastomosis are both carried out extra-corporeally. The second reason is likely because of more complicated anatomy and requirement for more technical expertise in right-sided resections performed laparoscopically. This prompted us to review our results not only to evaluate the safety and feasibility of performing laparoscopic right hemicolectomies in our unit but also to determine if the short-term outcomes were superior to those after the open approach.

The reported rate of conversion for both left and right laparoscopic colorectal surgery varies from 5% to 41% [5, 6, 14, 15]. Conversion rates for right-sided laparoscopic resections range from to 0% to 18% [16-22]. In our series, conversion was performed in only one patient (2.7%), and this was done to complete mobilisation for a locally advanced cancer. We attribute the low conversion rate in our series to optimal patient selection and careful technique during colon mobilisa-

Table 6 Operative time (minutes)

Source	LRH	ORH	*p* Value
Leung et al (1999) [20]	191.8 (mean)	148.6 (mean)	<0.001
Baker et al (2004) [16]	107.2 (mean)	97.4 (mean)	0.155 (NS)
Zheng et al (2005) [18]	152.65 (mean)	147.25 (mean)	0.562 (NS)
Lohsiriwat et al (2007) [23]	207.7 (mean)	104.5 (mean)	<0.001
Tong et al (2007) [19]	165 (mean)	115 (mean)	<0.001
Braga et al (2007) [21]	131 (mean)	112 (mean)	0.01
Chung et al (2007) [22]	110 (median)	97.5 (median)	0.003
Ng et al (2008) [17]	187.5 (median)	145 (median)	0.034

NS not significant

Table 8 Time to bowel recovery (days)

Source	LRH	ORH	*p* Value
Zheng et al (2005) [18] (flatus)	2.24 (mean)	3.25 (mean)	0.012
Lohsiriwat et al (2007) [23] (bowel movement)	3.2 (mean)	3.7 (mean)	0.25 (NS)
Tong et al (2007) [19] (bowel movement)	4 (median)	4 (median)	NS
Chung et al (2007) [22] (flatus)	2 (median)	3 (median)	0.003
Ng et al (2008) [17] (bowel movement)	5 (median)	5 (median)	0.645 (NS)

NS not significant

tion. However, the conversion rate may increase as surgeons attempt LRH on larger and more advanced tumours.

In our LRH series, we have demonstrated equivalent results for the time taken to perform the procedure as well as adequacy of oncologic clearance against other reviews. While it is not surprising that a laparoscopic approach requires a significantly longer amount of time to perform due to the increased complexity of the procedure, the mean operative time of 111 min in our series for a LRH is comparable with reported operative times ranging from 107 to 208 min in other reviews [16-23]. In addition, the mean operative time of 72 min for an ORH in our study was shorter than that reported in other series [16-23] (Table 6). This would have contributed to the difference in operative time being significant. Previous concerns that the number of lymph nodes harvested could be compromised with the laparoscopic approach have been dispelled by numerous studies demonstrating this to be untrue [2, 3, 7]. Similarly, in our subset analysis of the patients who underwent surgery for cancer (23 LRH, 27 ORH), the mean number of lymph nodes harvested were equivalent at 18 and 15, respectively. Margins necessary for oncologic clearance were similar in both groups as well.

One interesting phenomenon in our series is the lack of differences in outcome between both groups. As in other reviews, parameters such as duration of narcotic usage, restoration of bowel function, time to resumption of normal diet and hospital stay were used to compare post-operative recovery. We feel, however, that this may not be adequate in assessing outcome. Firstly, all our post-operative patients are on a CCP. This multidisciplinary approach encourages early ambulation, improves social well-being, thus, hastening discharge and reduces hospital stay. In our unit, ORH patients, thus, have a much shorter length of stay (5 days) as compared to other reviews (range 7 to 18 days; Table 7). This CCP was used similarly for the LRH group, and we have comparable lengths of stay with other LRH reviews (Table 7). Length of stay, however, is influenced by multiple factors including the patient's social support at home and the patient's perception of recovery after a major surgery. Nonetheless, for significant improvements to reduce length of stay, mindsets of our medical personnel involved in post-operative recovery of these patients may

Table 7 Length of stay (days)

Source	LRH	ORH	*p* Value
Leung et al (1999) [20]	5 (median)	7 (median)	0.002
Baker et al (2004) [16]	9.9 (mean)	12.8 (mean)	0.073 (NS)
Zheng et al (2005) [18]	13.94 (mean)	18.25 (mean)	0.043
Lohsiriwat et al (2007) [23]	6.2 (mean)	7.1 (mean)	0.3 (NS)
Tong et al (2007) [19]	6 .0 (median)	7.0 (median)	<0.001
Braga et al (2007) [21]	5.4 (mean) 5 (median)	6.4 (mean) 5 (median)	0.002
Chung et al (2007) [22]	7 (median)	9 (median)	0.004
Ng et al (2008) [17]	7 (median)	9 (median)	0.251 (NS)

NS not significant

Table 9 Time to resuming normal diet (days)

Source	LRH	ORH	*p* Value
Leung et al. (1999) [20]	4 (median)	5 (median)	<0.001
Baker et al (2004) [16]	3.65 (mean)	4.42 (mean)	0.005
Zheng et al (2005) [18]	5.65 (mean)	7.30 (mean)	0.060 (NS)
Lohsiriwat et al (2007) [23]	3.9 (mean)	4.3 (mean)	0.39 (NS)
Tong et al (2007) [19]	3 (median)	4 (median)	<0.001
Braga et al (2007) [21]	2.1 (mean)	3.0 (mean)	0.0001
Chung et al (2007) [22]	3 (median)	3 (median)	0.001
Ng et al (2008) [17]	4 (median)	3 (median)	0.178 (NS)

NS not significant

need to be altered to gear patients with laparoscopic resection for shorter hospital stays.

In addition, we noticed that although the length of incision was significantly shorter in the LRH group, there was no difference in the duration of narcotic usage. One possible reason for this is the type of incision that we use for ORH. In some reviews, LRHs were associated with better pain control and less opioid analgesic usage as compared to ORHs [16, 18]. These open procedures were performed mainly with a midline incision in these studies. In our study, however, the majority of patients in the ORH group had limited transverse skin crease incisions. Numerous studies have found transverse incisions to be associated with less post-operative pain as well as improved pulmonary function as compared to a midline incision [24-28]. Our findings are similar to those reported by Lohsiriwat et al., in which transverse skin crease incisions were used for both open and laparoscopic cases [23].

There have been conflicting results with regard to recovery of bowel function after laparoscopic colectomy, with some studies showing earlier recovery of bowel function with laparoscopic colectomy [18, 22] and others not demonstrating any benefit [17, 19, 23] (Table 8). The difference in time to resumption of normal diet also varies between studies (Table 9). Firstly, assessment of bowel function is often very subjective and is based on restoration of bowel sounds and passage of flatus or stool. In addition, bowel function is also dependent on various factors including quantity of narcotics used, length and type of incision used as well as patient mobility. Progression to diet and rehabilitation, thus, have to be individualised. Lastly, improvements in restoration of bowel function in laparoscopic patients may have been due to treatment biases as many of these reviews were unblinded, and recovery decisions may have been influenced by the mode of operation performed.

Conclusion

We have demonstrated that laparoscopic right hemicolectomy can be performed with minimal complications and oncological clearance in terms of number of lymph nodes removed, and resection margins are comparable to the open method. The operative time required is about 30 min longer with the laparoscopic approach but short term outcomes are similar to that of open right hemicolectomies. There is also the advantage of a shorter incision and, thus, better cosmesis.

References

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3. Abraham NS, Young JM, Solomon MJ (2004) Meta-analysis of short-term outcomes after laparoscopic resection for colorectal cancer. Br J Surg 91:1111–24
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6. Veldkamp R, Kuhry E, Hop WC et al (2005) Laparoscopic surgery versus open surgery for colon cancer: short-term outcomes of a randomised trial. Lancet Oncol 6:477–84
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17. Ng SS, Lee JF, Yiu RY et al (2008) Emergency laparoscopic-assisted versus open right hemicolectomy for obstructing right-sided colonic carcinoma: a comparative study of short-term clinical outcomes. World J Surg 32:454–8
18. Zheng MH, Feng B, Lu AG et al (2005) Laparoscopic versus open right hemicolectomy with curative intent for colon carcinoma. World J Gastroenterol 11:323–6
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28. Proske JM, Zieren J, Muller JM (2005) Transverse versus midline incision for upper abdominal surgery. Surg Today 35:117–21

CURRICULUM VITAE

Chew Min Hoe

MBBS (S'PORE), MRCS(Ed), M Med (Surgery), FRCS(Ed)

A. PERSONAL DETAILS

Age	: 35
Date of Birth	: 11/11/1977
Address	: 121 Meyer Road, The Makena, #11-09, S(437932)

B. EDUCATION HISTORY

1984-1989	Nanyang Primary School	PSLE
1990-1993	The Chinese High School	GCE O-Levels
1994-1995	Raffles Junior College	GCE A- Levels
1996-2001	National University of Singapore	MBBS
Sep 2003	MRCS(Ed) MCQ 1	
May 2004	MRCS(Ed) MCQ 2	
Sep 2005	MRCS (Intercollegiate) MCQ 1&2	
Jan 2006	MRCS (Intercollegiate) Final Assessment	
May 2006	MMed (Surgery)	
Mar 2010	FRCS(Ed)	

Awarded Basic Specialist Trainee- Sept 04 (on completion of National Service)
Awarded Advanced Specialist Trainee- Nov' 06 (Completed April 2010)

C. TRAINING LOG

Houseofficer

a) Pediatrics (NUH)- May '01- Aug '01
b) General Surgery (SGH) – Sept '01- Dec'01
c) Medicine (SGH) – Jan '02 – Apr '02

Medical Officer

a) Cardiology (CGH) - May '02- Oct'02
b) General Surgery (SGH)- Sept '04 – April '05
c) Orthopedics (SGH)- - May '05 – Oct '05
d) Colorectal (SGH)- - Nov'05 – April '06
e) General Surgery (SGH)- May '06 – Oct '06

Registrar – commenced 1st November 2006 (Backdated May '06)

a) Colorectal (SGH) – Nov'06 – Oct '07
b) General Surgery (TTSH) Vascular and Upper GI: Nov'07 – Oct'08
c) General Surgery (SGH) HPB and Breast – Nov '08 – Oct'09
d) Colorectal (SGH) Research- Nov'09 to Apr '10

Associate consultant –1st August 2010 -30th April 2012

Consultant- 1st May 2012- current

HDMP fellowship- Royal Prince Alfred Hospital, Sydney, Australia : July 2011-Present

D. TEACHING APPOINTMENTS

a) Yong Loo Lin NUS School of Medicine
   a. Clinical Tutor-2006-2009
   b. Clinical Teacher-2009 to 2012
   c. Senior Clinical Lecturer- 2012 to present

b) Adjunct Assistant Professor Duke-NUS Graduate Medical School- October 2012- present

E. PRESENTATIONS

Local

a) Singhealth/NHG Combined Scientific Meeting November 2005
- Multimodal Treatment of Well-Differentiated Thyroid Cancers: A Single Institution Review over the last 14 years- *Oral and Poster*
- Significance of tumour volume measurements in tongue cancer: a proposed novel role in staging- *Oral and Poster*

b) SGH Annual Scientific Meeting 2006
- Multimodal Treatment of Well-Differentiated Thyroid Cancers: A Single Institution Review over the last 14 years
  - *Awarded 1st Runner-up Poster Presentation*

c) SGH Annual Scientific Meeting 2007
- A Prospective study assessing anal plug for containment of faecal soilage and incontinence- *Poster*
- Characteristics of Asian HNPCC defined by the Amsterdam criteria: Are we on the right track? – *Poster*

d) Singapore Colorectal Society Meeting 27th January 2007
- Colonic Stenting in Acute Intestinal Obstruction-*Video Presentation*
  - *Awarded Best Video*

e) 41st Singapore-Malaysia Congress of Medicine 2007

- Stage IV Colorectal Cancers in patients ≤50, a retrospective review of a national database – *Oral Presentation*

f) Asean Society of Colorectal Surgeons November 2007

- Evaluation of CEEA 34 for stapled hemorrhoidectomy: results of a prospective clinical trial and patient satisfaction- *Oral presentation*

g) GIHep Singapore July 2008

- Improved Survival in Sporadic Colorectal Cancer Patients Younger than 50 years old: an Analysis of 523 Patients from a Single Institution- *Oral presentation*
    - *Awarded 1st runner up Best Oral Presentation*

h) GIHep Singapore July 2009

- Improved Survival in Sporadic Colorectal Cancer Patients Younger than 50 years old: an Analysis of 523 Patients from a Single Institution- *Oral presentation*
    - *Awarded Best Oral Presentation*

i) Singhealth Duke-NUS Scientific Congress 2010

- 20 years of Familial Adenomatosis Polyposis syndromes in the Singapore Polyposis Registry-an analysis of outcomes –*Poster*

- Evaluation of laparoscopic versus open colorectal surgery in elderly patients more than 70 years old –*Poster*

- Critical analysis of mucin and signet ring cell as prognostic factors in an asian population of 2764 sporadic colorectal cancers –*Poster*

- Stage IV colorectal cancers: an analysis of factors predicting survival and outcome-*Poster*

    - *Awarded Best EBM Poster (Medical student category)*

Overseas

a) 10th Congress Asian Association of Endocrine Surgeons (12-15th March 2006) (Hong Kong)

- Multimodal Treatment of Well-Differentiated Thyroid Cancers: A Single Institution Review over the last 14 years -*Poster*

b) 20th World Congress of International Society for Digestive Surgery (ISDS) (29th Nov – 2nd Dec 2006) (Rome, Italy)

- Modified Stapled haemorrhoidectomy- The Eu Technique -*Video*

c) 11th Congress of Asian Federation of Coloproctology (20th- 22nd September 2007) (Tokyo, Japan)

- A Prospective study assessing anal plug for containment of faecal soilage and incontinence-*Poster*

d) The Edinburgh International Coloproctology Festival (30th-31st August 2010)

- Preliminary results of Mismatch repair deficiency screening via immunohistochemical staining in Young Asian Colorectal Cancers. -*Poster*

e) 18th United European Gastroenterology Week (UEGW) (23-27 October 2010) (Barcelona, Spain)

- 20 years of Familial Adenomatosis Polyposis syndromes in the Singapore Polyposis Registry-an analysis of outcomes –*Poster*

- Evaluation of laparoscopic versus open colorectal surgery in elderly patients more than 70 years old –*Poster*

f) European Society of colproctology Austria 2012

- Mismatch repair deficiency screening via immunohistochemistry staining in young asian colorectal cancers- *Oral poster*

F. TALKS

a) Taishan-Dongying-Beijing SGH Visit 13-16th September 2012- Updates on Colorectal Cancer surgery 2012 and Treatment of CRC

b) World Stoma Day Public Forum 22nd Sept 2012- Treatment of Colorectal Cancer

c) GP Forum 10th November 2012

G. PAPERS AND PUBLICATIONS

1) Case Report: A Problem Encapsulated- a rare case of Peritoneal Encapsulation and a review of the literature
Chew MH, SI Hadi, Chan G, Ong HS, Wong WK
Published Singapore Medical Journal Sept 2006; 47(9): 808-810

2) Significance of tumour volume measurements in tongue cancer: a proposed novel role in staging
Chew MH, Khoo JB, Chong VF, Tai BC, Soo KC, Lim DT
Published ANZ J Surg 2007; 77(8), 632-637

3) Modified stapled hemorrhoidectomy
Ng KH, Chew MH, Eu KW
Published ANZ J Surg 2008 May; 78(5):394-397.

4) Multimodal Treatment of Well-Differentiated Thyroid Cancers: A Single Institution Review over the last 14 years
Chew MH, Chan G, Siddiqui MM, Tai BC, Sivanandan R, Soo KC, Lim DT.
Published World Journal of Surgery 2008 Mar; 32(3):386-394

5) The use of CEEA 34 in stapled hemorrhoidectomy: suggested modifications in technique
Chew MH, Tan WS, Eu KW
Published World J Surg. 2008 Jun; 32(6):1160-1.

Published Correspondence World J Surg. 2009 Jan; 33(1):156.

6) Case Report: Adenocarcinoma of the anal transitional zone after double stapled ileal pouch-anal anastomosis for ulcerative colitis in an Asian
Chia CS, Chew MH, Ho KS, Eu KW
Published Colorectal Dis. 2008 Jul; 10(6):621-3.

7) Phenotypic characteristics of HNPCC by the Amsterdam criteria: An Asian perspective
Chew MH, Koh PK, Ng KH, Lim JF, Ho KS, Ooi BS, Tang CL, Eu KW
Published ANZ J Surg 2008 Jul; 78(7):556-560.

8) Letter to editor: Giant Pseudopolyposis in Crohn's disease mimicking malignancy
Chew MH, Goh MH, Ooi BS, Eu KW
Published Int J of Colorectal Dis 2008 Aug; 23(8):823-4.

9) A Prospective study assessing anal plug for containment of faecal soilage and incontinence
Chew MH, Quah HM, Ooi BS, Lim JF, Ho KS, Tang CL, Eu KW
Published Colorectal Dis. 2008 Sep;10(7):677-80. Epub 2007 Nov 12.

10) Letter to editor: Keloid formation post stapled haemorrhoidectomy causing anal stenosis: a rare complication
Chew MH, Chiow A, Tang CL
Published Techniques of Coloproctology 2008 Dec; 12(4):351-2

11) The evaluation of CEEA 34 for stapled hemorrhoidectomy: results of a prospective clinical trial and patient satisfaction
Chew MH, Kam MH, Lim JF, Ho KS, Ooi BS, Tang CL, Eu KW
Published American Journal of Surgery 2009 Jun; 197(6):695-701

12) Results from a colorectal cancer mass screening event utilizing Quantitative Fecal Occult Blood Test

Chew MH, Suzanah N, Lim JF, Ho KS, Ooi BS, Tang CL, Eu KW
Published Singapore Med J. 2009 Apr;50(4):348-53.

13) Gluteal Compartment Syndrome Following Abdominal Aortic Aneurysm Repair: A Case Report
Chew MH, Xu GG, Ho PW, Lee CW
Published Ann Vasc Surg. 2009 Jul-Aug;23(4):535.e15-20

14) Improved Survival in Sporadic Colorectal Cancer Patients Younger than 50 years old: an Analysis of 523 Patients from a Single Institution
Chew MH, Koh PK, Ng KH, Eu KW
Published Int J of Colorectal Dis 2009 Sep;24(9):1075-83

15) Laparoscopic versus open right hemicolectomy: a comparison of short term outcomes.
Tan WS, Chew MH, Ooi BS, Ng KH, Lim JF, Ho KS, Tang CL, Eu KW
Published Int J Colorectal Dis. 2009 Nov;24(11):1333-9.

16) An unconscious patient with a ruptured pseudoaneurysm: clues to suggest IVDA
Chew MH, Tan KK, Lee CW
Published ANZ J Surg. 2010 May;80(5):379

17) Prospective Randomized Study to evaluate the use of DERMABOND ProPen (2-octylcyanoacrylate) in the closure of abdominal wounds versus closure with skin staples in patients undergoing elective colectomy.
J Ong, Ho KS, Chew MH, Eu KW
Published Int J Colorectal Dis 2010 Jul; 25(7):899-905.

18) Letter to editor: Differentiating durian seed bezoar from gallstone ileus on computed tomography
Tan G, Pua U, Quek HH, Wansaicheong G, Chew MH
Published Ann Acad Med Singapore 2010 Sept; 39(9):745-746

19) Preliminary results of Mismatch repair deficiency screening via immunohistochemical staining in Young Asian Colorectal Cancers.
Koh PK, Chew MH, Tan YS, C Loi, Tang CL, Eu KW
Published in Proceedings of Singapore Healthcare 2010; 19(1):3-11

20) Correspondence: Systematic review and meta-analysis of the diagnostic and therapeutic role of water-soluble contrast agent in adhesive small bowel obstruction (Br J Surg 2010; 97; 470-478).
Yeo SA, Chew MH, Eu KW.
Published in Br J Surg. 2010 Jul 5;97(8):1311.

21) Critical analysis of mucin and signet ring cell as prognostic factors in an Asian cohort of 2764 sporadic colorectal cancers and a comparison of the literature.

Chew MH, Eugene Yeo, Nick Ng, Ng KH, Lim KH, Eu KW
Published Int J Colorectal Dis. 2010 Oct;25(10):1221-9. Epub 2010 Aug 5.

22) Redefining conversions in laparoscopic colectomy and its influence on outcomes: analysis of 418 cases from a single institution.
Chew MH, Ng KH, Eu KW
Published World J Surg. 2011 Jan;35(1):178-85.

23) Evaluation of current devices in Single Incision Laparoscopic Colorectal Surgery: a preliminary experience in 32 consecutive cases
Chew MH, Wong MTC, Lim YK, Ng KH, Eu KW
Published World J Surg 2011 Apr;35(4):873-80.

Published Correspondence World J Surg. 2011 Nov;35(11)2580-1

24) Retroperitoneal liposarcomas: the experience of a tertiary Asian center.
Lee SY, Goh BK, Teo MC, Chew MH, Chow PK, Wong WK, Ooi LL, Soo KC.
Published World J Surg Oncol. 2011 Feb 1;9(1):12.

25) 20 years of Familial Adenomatosis Polyposis syndromes in the Singapore Polyposis Registry: an analysis of outcomes
Chew MH, Quah HM, Teh KL ,Loi TT C, Tang CL, Eu KW
Published Singapore Med J. 2011 Apr;52(4):246-51.

26) Ischemic colitis due to a dissecting aneurysm of the superior rectal artery.
Liu HP, Chew MH, Ho KS, Tang CL
Published Tech Coloproctol. 2011 Jul 12

27) Stage IV colorectal cancers: an analysis of factors predicting outcome and survival in 728 cases
Chew MH, Teo JY, T Kadir, Koh PK, Eu KW, Tang CL
Published J Gastrointest Surg. 2012 Mar;16(3):603-12.

28) Prognostic variables in 1814 sporadic colon cancers: a review of experience from a single institution from 1999-2005
Chew MH, Yeo SA, Tang CL
Published in Proceedings of Singapore Healthcare 2011; 20(1):3-11

29) Evaluation of laparoscopic versus open surgery in elderly patients more than 70 years old: evaluation of 727 patients
Tan WS, Chew MH, Lim IAL, Ng KH, Tang CL, Eu KW
Published Int J Colorectal Dis.2012 Jun;27(6):773-80.

30) Close Shave margins do not increase rectal cancer recurrence after sphincter-saving surgery without neoadjuvant therapy
Lim JWM, Chew MH, Lim KH, Ng KH, Tang CL, Eu KW

Published Int J Colorectal Dis. 2012 Oct;27(10):1285-94. Epub 2012 Aug 24.

31) Conventional laparoscopic versus single-incision laparoscopic right hemicolectomy: a case cohort comparison of short-term outcomes in 149 consecutive cases
Chew MH, Chang MH, Tan WS, Wong TC, Tang CL
Published Surg Endosc. 2012 Jul 18. [Epub ahead of print]

32) Clinical, MRI and PET criteria used by surgeons to determine suitability for pelvic exenteration surgery for recurrent rectal cancers: A Delphi Study
Chew MH, Brown WE, Harrison JD, Myers E, Solomon M
Accepted for publication Dis Colon Rect Dec 2012

Pending Review:

Discovery of a new panel or serum methylated genes as diagnostic markers for early stage colorectal cancers
Liu YQ, Tham CK, Ong S, Lim JF, Chew MH, Eu KW, Tang CL

Management of 154 recurrent rectal cancer patients between 1999-2005- an analysis of outcomes
Goh MH, Chew MH, Koh PK, Eu KW, Tang CL

Young colorectal carcinoma patients do not have a poorer prognosis: a review of 2426 cases
Yeo SA, Chew MH, Ng KH, Tang CL

Traumatic colon and rectal injuries: experience in an urban Asian hospital
Tan WS, Chew MH, Yeo YT, Goh KTS, Vijayan A, Chiu MT

Clinical, MRI and PET criteria used by surgeons to determine suitability for pelvic exenteration surgery for recurrent rectal cancers: A Delphi Study
Chew MH, Brown WE, Harrison JD, Myers E, Solomon M

Mismatch Repair Deficiency screening via immunohistochemical staining in young colorectal cancers
Chew MH, Koh PK, Tan M, Loi C, Lim KH, Tang CL

Appraisal of the LIFT and BIOLIFT procedure: initial experience and short-term outcomes of 33 consecutive patients
Chew MH, Lee PJM, Koh CE, Chew HE

Articles written:

Training the Trainee: A Surgical Trainee's reflection: Chew MH, Kow A
Singapore Medical Association News. Vol 42 No.5 May 2010; 19-21

H. EXTRA-CURRICULAR ACTIVITIES AND EVENTS ORGNIASED

Marathons/Half Marathons/Races completed

- 2012 Army Half Marathon 2012 (September)
- 2012 Sydney Morning Herald Half Marathon 2012 (May)
- 2011 Sydney Blackmores Half Marathon 2011 (September)
- 2011 Mount Faber 10km Race (June)
- 2010 Army Half Marathon (September)
- 2008 Standard Chartered 42km Marathon (December)
- 2007 Army Half marathon (September)

2007

- SGH Colon Cancer Awareness Outreach Carnival May 19-20th 2007- Vice Chairman Organizing Committee
- SGH Colorectal Cancer Public Forum Toa Payoh HDB Hub May 26th 2007- Speaker
- Asean Society of Colorectal Surgeons (ASCS) 3rd International Scientific Congress 2007 Committee

2005, 2006

- SGH Junior Welfare Committee

2000

- NUS Zaam Dance Competition Finalist

1997

- King Edward Hall 41st Junior Common Room Committee Sports Secretary
- NTU Dance Competition 1st Runner-up
- Participated in Athletics, Basketball, Handball Inter Hall Games

1996, 1997

- Rag and Flag Chairman
- Best Float, Best Presentation and Overall Champion– 1997
- Best Float - 1996

1994, 1995

- Captain- RJC Track & Field Team
  - National Schools Team Champion 1994 and 1995
  - National Schools 1995 Triple Jump- Gold

- National Schools 1995 Long Jump- Bronze
- National Schools 1994 Triple Jump- Gold
- Caltex Junior Athletics Meet U17 Triple Jump Record Holder

- Represented Singapore in 1994 ASEAN School Track and Field Meet
- RJC Faculty of Medicine Chairman
- Group Leader-Freshman Orientation

1990-1993

- Captain- Chinese High Track & Field Team
- National Schools Team Champion 1990-1993
- National Schools 1992- Triple Jump and Long Jump Gold Medalists
- National Schools 1991- Triple Jump Silver Medalist
- Represented Singapore in Malaysian Junior Open Athletics Meet
- ECA Council Member 1993
- Student Council Member 1992

I. NATIONAL SERVICE

- Officer Cadet School 1996- disrupted
- 55th Medical Officer Conversion Course- Nov 2002- Feb 2003
- Medical Response Force
  - Platoon Commander(PC) Mar 2003- Oct 2003
  - Officer Commanding(OC) Nov 2003- June 2004
  - Developed Unit Training and Safety, Logistics and Operation doctrines
  - Involved in various security operations- IISS '03 &'04, Asian Aerospace'04, Dignitary visits , NDP '03 & '04
  - Commanded unit for SARS screening in Changi Airport 2003
- National Day Medical Operations Officer 2004
- 3 Combat Service Hospital (NS)
- Completed Advanced Medical Officer Course 2010

J. AWARDS

- Singapore Health Quality Service Award 2012- Gold
- NUS-YLL Dean's Award for Teaching Excellence (Academic Year 2009/2010)
- HMDP Fellowship Award (2011) –Royal Prince Alfred Hospital, Sydney, Australia

- Duke-NUS Graduate Medical School Singapore Appreciation Award 2012- Outstanding Educator (Surgical Clerkship)
- Singapore Health Quality Service Award 2010- Silver
- NUS Yong Loo Lin School of Medicine Best Tutor Award- 2010
- NUS Yong Loo Lin School of Medicine Best Tutor Award- 2009
- National IQC Assessment 2009-Silver Award
- Singhealth Registrar Award-September 2008
- Singhealth Registrar Award-August 2007
- Asian Hospital Management Awards 2007- Category : Community Service for SGH Colon Cancer Awareness Outreach Campaign
  Awarded 1st runner-up
- Letter of Commendation in recognition for National Day Parade Contribution 2004
- Certificate of Appreciation in recognition for National Day Parade Contribution 2003, 2004
- SARS Medal & Certificate of Appreciation by MINDEF- 2003
- Singapore Schools Sports Council National Colours Awards Certificate of Achievement in Track and Field- 1994
- Singapore West Zone School Sports Council Colours Awards- 1995, 1994, 1992
- Raffles Junior College Colours for Track And Field-1995
- Raffles Junior College Certificate of Appreciation, Chairman Medicine Faculty-1995
- Raffles Junior College School Advisory Committee ECA Scholarship- 1994

K. COURSES ATTENDED

- Advanced Trauma Life Support – Sep' 04, Nov'06
- Basic Cardiac Life Support –Jul '09
- Advanced Cardiac Life Support – Feb' 08

- Basic Surgical Skills Course – April' 05
- Fundamental Critical Care Support Course – Oct' 05
- Basic SPPS Course for Health Researchers– Nov' 05
- Basic Emergency Sonography for Trauma Course (TTSH) - Mar'07
- Singhealth Emerging Clinical Leadership Course – Aug '07
- Evidence Based Medicine (SGH, PGMI)- Oct'07
- Singhealth Emerging Clinical Leadership Course II-Mar'08
- Definitive Surgical Trauma Course- Apr'08
- Robotics laparoscopic course- NUH – Dec'09
- Laparoscopic colorectal surgery course, IRCAD Taiwan- Sept'10

Saturday, March 18, 2006

CITI Course Completion Record
for Min Hoe Chew

To whom it may concern:

On *3/18/2006*, *Min Hoe Chew* (username=dr10035h; Employee Number=) completed all *CITI Program* requirements for the *Basic CITI* Course in The Protection of Human Research Subjects.

Learner Institution: *Singapore Health Services Pte (SingHealth)*

Learner Group: *Biomedical Research Investigators and Key Personnel*

Learner Group Description:

Contact Information:

Gender: Male
Department: Surgery
Which course do you plan to take?: The Social & Behavioral AND Biomedical Courses
Role in human subjects research: Clinical Reseacher
Mailing Address:
Email: ustwo@singnet.com.sg
Office Phone: 6581230992
Home Phone:

The Required Modules for *Biomedical Research Investigators and Key Personnel* are:	**Date completed**
Introduction	03/18/06
History and Ethical Principles	03/18/06
Basic Institutional Review Board (IRB) Regulations and Review Process	03/18/06
Informed Consent	03/18/06
Social and Behavioral Research for Biomedical Researchers	03/18/06
Records-Based Research	03/18/06
Genetic Research in Human Populations	03/18/06
Research With Protected Populations - Vulnerable Subjects: An Overview	03/18/06
Vulnerable Subjects - Research with Prisoners	03/18/06

Vulnerable Subjects - Research Involving Minors	03/18/06
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	03/18/06
Group Harms: Research With Culturally or Medically Vulnerable Groups	03/18/06
HIPAA and Human Subjects Research	03/18/06
Conflicts of Interest in Research Involving Human Subjects	03/18/06
SingHealth	03/18/06

Additional optional modules completed:	**Date completed**

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

CITI Collaborative Institutional Training Initiative

CITI Health Information Privacy and Security (HIPS) Curriculum Completion Report
Printed on 2/5/2013

Learner: Angela Dharmawan (username: renadh)
Institution: National University of Singapore
Contact Information Department: Duke-NUS Graduate Medical School
Email: renadh@gmail.com

CITI Health Information Privacy and Security (HIPS): This course will satisfy the mandate for basic training in the HIPAA. In addition other modules on keeping your computers, passwords and electronic media safe and secure are included.

Stage 1. Basic Course Passed on 12/15/10 (Ref # 5350615)

Required Modules	Date Completed	Score
National University of Singapore	04/21/10	no quiz
Elective Modules	**Date Completed**	**Score**
Introduction	12/14/10	no quiz
About the Course	12/14/10	1/1 (100%)
Privacy Rules: Introduction to Federal and State Requirements*	12/14/10	9/10 (90%)
Privacy Rules: Clinicians*	12/14/10	8/8 (100%)
Privacy Rules and Research*	12/14/10	10/10 (100%)
Privacy Rules: Students and Instructors*	12/14/10	3/4 (75%)
Privacy Rules: Fundraisers*	12/14/10	4/5 (80%)
Privacy Rules: Marketers*	12/14/10	3/5 (60%)
Security Rules: Basics of Being Secure, Part 1*	12/15/10	no quiz
Security Rules: Basics of Being Secure, Part 2*	12/15/10	9/10 (90%)
Security Rules: Protecting your Computer*	12/15/10	7/8 (88%)
Security Rules: Picking and Protecting Passwords**	12/15/10	8/8 (100%)
Security Rules: Protecting your Portables*	12/15/10	7/7 (100%)
Security Rules: Protecting your identity*	12/15/10	6/7 (86%)
Security Rules: Safer Email-ing and IM-ing, Part 1*	12/15/10	no quiz
Security Rules: Safer Email-ing and IM-ing, Part 2*	12/15/10	16/16 (100%)
Security Rules: Safer Web Surfing*	12/15/10	8/8 (100%)
Security Rules: Introduction to Federal and State Requirements*	12/15/10	4/6 (67%)
Security Rules: Issues for Work/Workers Off-Site*	12/15/10	4/4 (100%)
Completing the Privacy and Security Course	12/15/10	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and

unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

Biomedical Research - Basic/Refresher Curriculum Completion Report
Printed on 2/5/2013

Learner: Angela Dharmawan (username: renadh)
Institution: Duke Medicine
Contact Information Phone: 919-360-7327
Email: renadh@gmail.com

Biomedical Research - Basic/Refresher: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

Stage 2. Refresher Course Passed on 06/28/12 (Ref # 6258350)

Elective Modules	Date Completed	Score
GCP Introduction	06/28/12	3/3 (100%)
Overview of New Drug Development	06/28/12	4/5 (80%)

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Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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Monday, August 8, 2005

CITI Course Completion Record for Choong-Leong Tang

To whom it may concern:

On *8/8/2005*, *Choong-Leong Tang* (username=dr04504g; Employee Number=1036219) completed all *CITI Program* requirements for the *Basic CITI* Course in The Protection of Human Research Subjects.

Learner Institution: *Singapore Health Services Pte (SingHealth)*

Learner Group: *Biomedical Research Investigators and Key Personnel*

Learner Group Description:

Contact Information:

Department: Colorectal Surgery

Which course do you plan to take?: Biomedical Investigator Course Only

Role in human subjects research: Clinical Reseacher

Mailing Address:

Singapore General Hospital
Outram Road
Singapore
Singapore
169608
Singapore

Email: gcstcl@sgh.com.sg

Office Phone: +65 6321-4677

The Required Modules for *Biomedical Research Investigators and Key Personnel* are:	Date completed
Introduction	03/14/05
	03/14/05

Basic Institutional Review Board (IRB) Regulations and Review Process	03/14/05
Informed Consent	03/14/05
Social and Behavioral Research for Biomedical Researchers	03/14/05
Records-Based Research	04/18/05
Genetic Research in Human Populations	06/19/05
Research With Protected Populations - Vulnerable Subjects: An Overview	08/08/05
Vulnerable Subjects- Research With Prisoners	08/08/05
Vulnerable Subjects- Research Involving Minors	08/08/05
Vulnerable Subjects- Research Involving Pregnant Women and Fetuses in Utero	08/08/05
Group Harms:Research With Culturally or Medically Vulnerable Groups	08/08/05
HIPAA and Human Subjects Research	08/08/05
Conflicts of Interest in Research Involving Human Subjects	08/08/05
SingHealth	08/08/05
Additional optional modules completed:	**Date completed**

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