CHBG NEWSLETTER

The Cochrane Hepato-Biliary Group (CHBG)

Volume 8, Issue 2 **October 2004**

IN THIS ISSUE

CHBG REVIEWS AND PROTOCOLS IN THE CLIB ISSUE 3 AND 4, 2004

The numbering is a continuation from vol.8 iss.1.2004

NEW REVIEWS

36. Glucocorticosteroids for primary sclerosing cholangitis. Chen W and Gluud C.
37. Hepatitis B vaccination for patients with chronic renal failure. Schroth RJ, Hitchon CA, Uhanova J, Noreddin A, Taback SP, Moffatt MEK, and Zacharias JM.
38. TIPS versus paracentesis for cirrhotic patients with refractory ascites. Saab S, Nieto JM, Ly D, and Runyon BA.
39. Tamoxifen for hepatocellular carcinoma. Nowak A, Findlay M, Culjak G, and Stockler M.
40. Antioxidant supplements for preventing gastrointestinal cancers. Bjelakovic G, Nikolova D, Simonetti RG, and Gluud C.
41. D-penicillamine for primary biliary cirrhosis. Gong Y, Frederiksen SL, and Gluud C.
42. Dopaminergic agonists for hepatic encephalopathy. Als-Nielsen B, Gluud LL, and Gluud C.

NEW PROTOCOLS

92. Antiviral therapy for chronic hepatitis C in patients with human immunodeficiency virus. Iorio A, Francisci D, Luchetta ML, Kjaer MS, and Gluud LL.
93. Endoscopic balloon sphincter dilation (sphincteroplasty) versus sphincterotomy for common bile duct stones. Weinberg BM, Shindy W, and Lo S.
94. Human recombinant activated factor VII for upper gastrointestinal bleeding in patients with liver diseases. Martí-Carvajal AJ and Martí-Carvajal P.
95. Metronidazole with or without image-guided percutaneous procedure for uncomplicated amoebic liver abscess. Labio E, Destura R, Alejandria MM, and Daez MLO.
96. Antioxidant supplements for nonalcoholic fatty liver disease and/or steatohepatitis. Lirussi F, Orando

S, Orlando R, and Angelico F.
97. Bicyclol for chronic hepatitis C. Yang XY, Wu TX, and Liu GJ.
98. Hepatitis B immune globulin for prevention of posttransplantation hepatitis B. Hong Z, Gao RN, and Zou S.

NEW REGISTERED TITLES
187. Chelating agents for Wilson's disease. Efsen E et al, Denmark.
188. Interleukins for chronic hepatitis C. Chen W et al, Canada.
189. Non-steroidal antiinflammatory drugs for chronic hepatitis C. Chen W et al, Canada.
190. Lamivudine for hepatitis B virus carriers planned to receive immunosuppressive treatment. Fraser A et al, Israel.
191. Lamivudine and hepatitis B immune globulin for preventing hepatitis B recurrence after liver transplantation. Katz L et al, Israel.
192. Vasopressin analogues for acquired coagulation disorders in patients with liver disease. Marti-Carvajal Arturo et al, Venezuela.
193. Adefovir dipivoxil for chronic hepatitis B. Simjee Ahmed E et al, South Africa.
194. Phlebotomy for hereditary haemochromatosis. Milic S et al, Croatia.
195. Acupuncture for chronic hepatitis B virus infection. Liu J et al, Norway.

REVIEWS STILL IN EDITORIAL PROCESS
In the previous issue of The CHBG Newsletter we listed 16 reviews that were undergoing editorial evaluation. Out of these 16, seven reached publication status. Some of the remaining nine reviews still stay with the authors and the danger exists that the information included may get outdated. The review 'Comparison of medicinal herbs for chronic hepatitis B virus infection' by Liu JP, Liu YX, Lin H, and Gluud C, is omitted from the list below since the editorial opinion was that it had to be split into multiple separate reviews.

- Antibiotics for cholangitis and/or cholecystitis. Kukuruzovic RH and Elliott EJ.
- Bile acids for liver transplanted patients. Chen W and Gluud C.
- D-penicillamine for primary sclerosing cholangitis. Frederiksen SL and Chen W.
- Methotrexate for primary biliary cirrhosis. Gong Y and Gluud C.
- Milk thistle for alcoholic and/or hepatitis B or C virus liver diseases. Rambaldi A, Jacobs BP, Iaquinto G, and Gluud C.
- Portosystemic shunts versus endoscopic therapy for variceal rebleeding in patients with cirrhosis. Khan S, Tudur Smith C, Williamson P, and Sutton R.
- Surgical versus endoscopic treatment of bile duct stones. Martin D, Vernon DR, Jobling J, and Toouli J.
- Vaccines for preventing hepatitis A. Tiberti D and Demicheli V.

NEW REVIEWS IN EDITORIAL PROCESS
- Glucocorticosteroids for primary biliary cirrhosis. Prince M, Christensen E, and Gluud C.
- Bicyclol for chronic hepatitis B. Wu T, Hao B, and Liu G.
- Immunoglobulin for preventing hepatitis A. Liu JP, Yang M, and Du XM.
- Beta-interferon for chronic hepatitis B. Saconato H, Albuquerque ABM L, Gabriel FGS, and Atallah AN.
- Vitamin K for upper gastrointestinal bleeding in patients with liver diseases. Martí-Carvajal AJ and Martí-Peña AJ.
- Percutaneous needle aspiration with or without albendazole for uncomlicated hepatic hydatid cyst. Nasseri-Moghaddam S, Abrishami A, and Malekzadeh R.

We expect these reviews to be published in Issue 1 or 2 of The Clib, 2005.

UPDATES OF REVIEWS FOR CLIB ISSUE 1, 2005
The following updates on earlier published reviews have been submitted by the authors for a new evaluation by either peer reviewers or editors.

- Colchicine for alcoholic and non-alcoholic liver fibrosis and cirrhosis. Rambaldi A and Gluud C.
- Ribavirin plus interferon versus interferon for chronic hepatitis C by Brok J, Gluud C, and Gluud LL, is an update of a split review published with the title 'Ribavirin with or without alpha interferon for chronic hepatitis C'.
- Somatostatin analogues for acute bleeding oesophageal varices. Gøtzsche PC and Hróbjartsson A.
- Neoadjuvant and adjuvant therapy for operable hepatocellular carcinoma. Chan ES-Y, Chow PK-H, Machin D, Soo K-C, and Samuel M.

PROTOCOLS IN EDITORIAL PROCESS
- Elective surgery for benign liver tumours. Colli A, Fraquelli M, Massironi S, Colucci A, Paggi S, and

Conte D.

- Ø Cyclosporin versus tacrolimus as primary immunosuppressant after liver transplantation. Haddad EM, McAlister VC, Renouf E, Malthaner R, Kjaer MS, and Gluud LL.
- Ø Drugs improving insulin resistance for nonalcoholic fatty liver disease and/or non-alcoholic steatohepatitis. Angelico F, Alessandri C, Burattin M, Del Ben M, Orando S, and Lirussi F.
- Ø Probiotics for nonalcoholic fatty liver disease and/or steatohepatitis. Lirussi F, Mastropasqua E, Orando S, and Orlando R.
- Ø Terlipressin for hepatorenal syndrome. Kjaer MS, Gluud LL, Taastroem A, and Christensen E.
- Ø Bile acids for non-alcoholic fatty liver disease and/or steatohepatitis. Orlando R, Orando S, and Lirussi F.
- Ø Acupuncture for chronic hepatitis B virus infection. Liu JP and Wang J.
- Ø Lamivudine for preventing reactivation of hepatitis B infection in patients planned to undergo immunosuppressive therapy. Katz LHAIM, Fraser A, Leibovici L, and Tur-kaspa R.
- Ø Antacids for preventing esophageal variceal bleeding and rebleeding in cirrhotic patients. Zhao P, Qiong W, and Yiping W.

We expect these protocols to be published in Issue 1 or 2 of The Clib, 2005.

PAST EVENTS

17TH CHBG BI-ANNUAL MEETING DURING THE EASL MEETING – BERLIN, GERMANY

The CHBG held its 17th meeting 14 of April 2004. Up to 80 people attended it. The CHBG stand at the EASL exhibition was also well visited. New members were recruited.

TRAIN THE TRAINERS – CRETE, GREECE

The workshop was run from 19 to 23 of April 2004 in Crete. It is organised for the fourth time by Organisation Mondiale de Gastro-Entérologie (OMGE) and Organisation Mondiale D'Endoscopie Digestive (OMED) Education and Training Committee, under the elegant guidance of James Toouli, Australia. Christian Gluud was a faculty member on all the workshops.

DIGESTIVE DISEASE WEEK (DDW) -NEW ORLEANS, USA

The DDW meeting was held from 15 to 21 of May 2004. The Cochrane Upper-Gastrointestinal and Pancreatic Diseases Group presided this year a symposium on 17 of May. Below we have made a summary based on what Henning K Andersen, The Colorectal Cancer Group (CCCG), and Iris Gordon, The Upper-Gastrointestinal and Pancreatic Diseases Group (UGPD) (both Review Group Coordinators) wrote us about the past event:

INAUGURAL COCHRANE SYMPOSIUM AT THE AGA/DDW MEETING MAY 15-20, NEW ORLEANS, A GREAT SUCCESS

Since 2001, The Colorectal Cancer Group and The Upper-Gastrointestinal and Pancreatic Diseases Group have been manning a display booth at the annual Digestive Diseases Week (DDW) meeting of the American Gastroenterology Association (AGA). There, among other things, they made demonstrations on The Cochrane Library and have also advertised for The Cochrane Hepato-Biliary Group. The DDW is the largest gathering of gastroenterologists in the world, and it usually attracts around 15,000 delegates. Growing recognition of The Cochrane Collaboration work and interest in the activities made the editors of the gastrointestinal diseases groups approach the AGA to suggest a dedicated session at the 2004 event. This was accepted as part of the core conference programme. On Monday 17th May the Cochrane Symposium was held at the AGA-meeting in New Orleans. The UGPD group arranged the symposium. Its theme was "Managing Dyspepsia". In four talks, chaired by the group's co-ordinating editor - David Forman - and AGA member Nick Talley, Cochrane authors spoke about dyspepsia, meta-analyses, methodological problems, as well as Cochrane history. Well over 400 delegates attended this symposium. The exhibition booth was also extremely busy and it is reasonable to assume that several new reviews were founded in New Orleans. The work of The Cochrane Collaboration is now becoming established in the US gastroenterological community. The AGA/DDW Cochrane Symposium has come to stay, and in 2005 The Colorectal Cancer Group will arrange it in Chicago. The theme will be "The surgical gastrointestinal patient - an evidence-based approach". A preliminary programme is available upon request through The CHBG editorial office. The CHBG will take the lead for a meeting in 2006.

THE DANISH ASSOCIATION FOR THE STUDY OF THE LIVER (DASL) MEETING –COPENHAGEN, DENMARK

DASL organised a meeting on 21 September 2004 at which the results from a project 'Getting research into practice' were presented. This project started in the

year 2000 and finished in 2004. CHBG reviews were used as a base for the questionnaire survey performed by the Danish Institute for Health Services Research. The objective of the study was to evaluate the agreement between clinical practice and evidence found in CHBG reviews. The finding was that still there was a considerable gap between research evidence and clinical practice for some interventions.

12TH COCHRANE COLLOQUIUM - OTTAWA, CANADA

The 12th Cochrane Colloquium was held from 2 to 6 of October 2004 in Ottawa, Canada. Presentations given during the colloquium and other related materials will be posted October 20, 2004 on the web site of The Canadian Cochrane centre http://cochrane.mcmaster.ca/. Members of The CHBG contributed to the colloquium with:

Oral presentations

1. Methodological quality and treatment effects in randomised trials: a review of six empirical studies. Als-Nielsen B et al.
2. Multivariate modeling for meta-epidemiological assessment of the association between trial quality and apparent treatment effects in randomised clinical trials. Siersma V et al.

Posters

3. Are trial size and reported methodological quality associated with treatment effects? Observational study of 523 randomised trials. Als-Nilesen B et al.
4. Testing the success of blinding in randomised clinical trials. Hrobjartsson A et al.
5. The size of the gap between research evidence and clinical practice: questionnaire survey on treatment of patients with liver disease. Gluud LL et al.
6. Comparison of The Cochrane Neonatal Group Systematic Reviews and Danish Guidelines for newborns. Brok J et al.
7. A combined database for meta-epidemiological research: characteristics of included trials. Wood L et al.
8. Trends in reported allocation concealment in RCTs included in systematic reviews. Wood L et al.

There were training workshops for everyone. A great attention was given to the new information management system (IMS). The new IMS will be built around a central system accessible via the Internet. It will contain contact details, reviews, studies, review group topics lists, and other information. Staff at editorial bases of Collaborative Review Groups and other Cochrane entities will use a standard Internet browser to access the system. Reviewers will continue to prepare and maintain reviews as they do today in a new version of RevMan (RevMan 5) that links with the central system. Reviewers with poor access to the Internet, however, can continue exchange their reviews with co-reviewers and their editorial base in the same way as they do today. The overall advantage of the new IMS being Internet-based is that the data will no longer be spread and duplicated across several small PC-based systems. Other advantages include a central back-up of all information in the system; an archive of reviews that can be accessed when needed; preparation and maintenance of reviews can be tracked, and some editorial processes can be supported by automatic routines; data can be accessed from any computer on the Internet (with the appropriate access rights); and users will not be limited to the Windows platform. The new IMS will use open document formats for information exchange. This is in line with the way in which more and more non-commercial organisations organise their work. Having an open format for reviews, for instance, will mean that the structure of a review will be published in detail and, on the basis of this definition, it will be possible for software developers to produce other review-writing software. Reviews will be checked against the specification before they are accepted for inclusion in the central review database. While The Cochrane Collaboration as a whole will only be able to support its own software, RevMan, there may be good reasons for some reviewers to use other available software, for instance review writing software that works on a Macintosh or UNIX platform.

FUTURE EVENTS

18 TH CHBG BI-ANNUAL MEETING DURING THE AASLD 2003 MEETING - BOSTON, USA

The AASLD meeting will be run from 29 of October to 2 of November 2004. The CHBG meeting will be at 7 p.m. on 1 of November 2004. The programme is sent out with this Newsletter.

THE 3RD ASIA PACIFIC EVIDENCE-BASED MEDICINE CONFERENCE - HONG KONG, CHINA

This conference will be run from 26 to 28 of November 2004. Yan Gong, a Ph.D. student and a CHBG reviewer, presently working at The Editorial Team Office in Copenhagen, will make an oral presentation: ‘D-penicillamine for primary biliary cirrhosis: a systematic review of randomised clinical trials’.

THE 40TH ANNUAL EASL 2005 MEETING - PARIS, FRANCE

It will be run from 13 to 17 of April 2005. The CHBG will have a meeting and an exhibition, as well as will explore the possibility of training reviewers in preparation of systematic reviews. More information will be published in Issue 1 of The CHBG Newsletter 2005. Please note that the deadline for submission of abstracts is 16 of November 2004. Abstract form will be available on the EASL web site from October 2004. The early registration is until 10 of February 2004.

VISITS

Chuanfang Lee, Ass. Prof., pharmacist from Taiwan, and as we wrote in the previous Newsletter, working on an abandoned protocol on hepatitis B prophylaxis for newborns of hepatitis B surface antigen-positive mothers, is now back in Taiwan. He managed to publish an update of the protocol and almost finalised the review, which within short time will be sent out for peer reviewing. We wish to express our thanks.

Jianpin Liu,UK, during his vacation, chose to come to Copenhagen in August in order to work on the review 'Immunoglobulin for preventing hepatitis A'.

Andrea Rambaldi, Italy, stayed for a week in September at the Editorial Team office and worked on an update of a systematic review, entitled 'Colchicine for alcoholic and non-alcoholic liver fibrosis and cirrhosis'. He also worked on a paper version of the review 'Milk thistle for alcoholic and/or hepatitis B or C virus liver diseases'.

PUBLISHED ELSEWHERE

Due to the limited space we cannot inform our readers in details about new reports or policies of The Cochrane Collaboration or the working activities within entities. That is why we can only recommend that you visit regularly The Cochrane Collaboration website to follow the development http://www.cochrane.org/index0.htm.

We would like to highlight the following publications:

- Cochrane reviews of diagnostic test accuracy. A progress report by Jon Deeks, et al.

and

- 'The Cochrane Collaboration supports prospective registration of clinical trials'.

Both are available from:
http://www.cochrane.org/newslett/ccnews31-lowres.pdf

COCHRANE TRAINING WORKSHOPS

At the web address:
http://www.cochrane.org/cochrane/workshop.htm you will find information on Cochrane workshops throughout the world.

CO-PUBLICATION AGREEMENTS FOR PUBLISHING COCHRANE REVIEWS

Co-publication agreements have been made with a number of journals. However, we list primarily those relevant for gastroenterology topics:

American Journal of Gastroenterology
British Journal of Surgery
British Medical Journal
BMJ Publishing Group's specialist journals (all)
Cancer Treatment Review
Colorectal Disease
Diseases of Colon and Rectum
Health Education Journal
Human Reproduction
JAMA
Journal of Health Services Research and Policy
Journal of Neurology, Neurosurgery and Psychiatry
Journal of Rheumatology
Journal of Wound, Ostomy and Continence Nursing
Lancet
South African Medical Journal.

THE NEW REPRODUCTIVE HEALTH LIBRARY

The best example of Cochrane in practice is online at www.rhlibrary.com and presently you can view it at no charge. The Reproductive Health Library (RHL) includes the full text of systematic reviews produced by The Cochrane Collaboration, with commentaries on implications for practice, as well as The Lancet series on randomised controlled trials, videos on evidence-based techniques, a training course and much more.

The RHL is put together by The Department of Reproductive Health and Research of The World Health Organization and published annually in English and Spanish by Update Software, both Online and on CD-ROM. The RHL is available Online and on CD-ROM from only £47 (GBP). You may order it online or contact Update Software (sales@update.co.uk) for details. There is no charge for access in low-income countries!

HOW TO WRITE THE 'STATISTICAL METHODS' SECTION IN COCHRANE REVIEWS

Gong Y, Als-Nielsen B, Brok J, Gluud LL, Gluud C

Before you start writing the 'statistical methods' section in a protocol for a Cochrane review, you need to consider thoroughly which methods would be most appropriate with regard to your specific question. You should consult The Cochrane Reviewers' Handbook[1] where you will find a thorough presentation of most of the statistical methods used in meta-analysis.

Overall, the writing of 'statistical methods' in a review is not fixed and should be changed according to the need and characteristics of every unique systematic review. Below, you will find a very brief introduction on how to write the statistical methods section including some examples.

You need to specify the main software used in the review. This is of course The Review Manager Analyses or among friends (a slowly, but steadily growing number) RevMan Analyses: *'We will use the software package RevMan Analyses 1.0.2 provided by The Cochrane Collaboration.'* Any additional software could also be mentioned here.

You should specify the summary statistics for the kind of data you plan to analyse in your review (eg, relative risk for dichotomous data and weighted mean difference for continuous data). You should decide whether you want to use a fixed effect model or a random effects model. You should consult the Handbook to be updated on this issue. Currently, many reviewers apply both a fixed and a random effects model. In case of discrepancies, both results are reported, otherwise only one of the results is reported. An example of wording:

'For dichotomous variables, we will calculate the relative risks with 95% confidence interval. We will use a random effects model[2] and a fixed effect model.[3] In case of discrepancy between the two models (eg, one giving a significant intervention effect the other no significant intervention effect) we will report both results, otherwise we will report only the results from the fixed model.'

Heterogeneity between trials should always be explored by considering the methodological quality of trials, clinical setting, patients involved, and the intervention. Subgroup analyses, sensitivity analyses, or meta-regression may be appropriate. It is important to define the subgroup analyses at the protocol stage and follow them in the review stage. (If you need to do post hoc subgroup analyses, you should specify the reason sufficiently in the review and interpret the results with great caution.) An example of wording:

The Chi-square test for heterogeneity was used to provide an indication of between-study heterogeneity. In addition, the degree of heterogeneity observed in the results was quantified using the I-squared statistic,[4] which can be interpreted as the percentage of variation observed between the studies attributable to between-study differences rather than sampling error(chance). We will perform a subgroup analysis in order to compare the intervention effect in trials with high methodological quality (ie, trials with adequate generation of the allocation sequence, allocation concealment, and blinding) to that of trials with low methodological quality (ie, trials not having one or more adequate component).[5,6,7]

It is difficult to handle trials with missing data (dropout/withdrawals).[8] We recommend that you always seek to perform intention-to-treat analysis. You can include missing data by including the last reported observed response or by considering them as treatment failures or treatment successes. Further, you could do extreme case analyses where you consider the dropouts as failures in the experimental group and as success in the control group and vice versa. You need to consider what would be most appropriate to assume for your unique review (eg, in a trial on flu vaccination, it would properly not be appropriate to consider dropouts as dead).

An example of wording of each of the situations mentioned above:

Intention-to-treat analyses
Regarding the primary outcome measure we will include patients with incomplete or missing data in the sensitivity analyses by imputing them according to the following scenarios.[8]

- *Carry forward analysis: if patients had missing outcome data, we used the last reported observed response ('carry forward') in the nominator and included all randomised participants in the denominator.*
- *Poor outcome analysis: assuming that dropouts/participants lost from both the experimental and control arms had the primary outcome including all randomised participants in the denominator.*
- *Good outcome analysis: assuming that none of the dropouts/participants lost from the experimental and control arms had the primary outcome including all randomised participants in the denominator.*
- *Extreme case favouring the experimental intervention: none of the dropouts/participants lost from the experimental arm, but all dropouts/participants lost from the control group had the primary outcome including all randomised participants in the denominator.*
- *Extreme case analysis favouring control: all dropouts/participants lost from the experimental arm, but none from the control arm had the primary outcomes including all randomised participants in the denominator.*

It would be too excessive to mention and do all types of intention-to-treat analyses for all outcomes considered in your review. Even for your primary outcome it may be appropriate to perform only some of the scenarios.

You may also choose to ignore the missing data and perform per-protocol analyses as sensitivity analyses.

Per protocol analyses
Complete patients' course analysis: data on only those, whose results are known, using as denominator the total number of patients who completed the trial. (Interpretation of such per protocol analyses will be cautious as they may be biased.)

We recommend to those who want to include crossover trials in their systematic reviews the analytical methods described by Elbourne et al 2002.[9]

Publication bias and other biases can be explored by visual estimation of funnel plots and different statistical methods. The results of these methods vary with the magnitude of the treatment effect, the distribution of study size, and whether a one- or two-tailed test is used.[10] Therefore, several methods should be explored. We can briefly describe the plans as follows.

Funnel plot on the primary outcome will be used to provide a visual assessment of whether treatment estimates are associated with study size. We will use two tests to assess funnel plot asymmetry, adjusted rank correlation test[11] and regression asymmetry test.[12]

References:

1. Alderson P, Green S, Higgins JPT, editors. Cochrane Reviewers' Handbook 4.2.1[updated December 2003]. In: The Cochrane Library, Issue 1, 2004. Oxford: Chichester, UK: John Wiley & Sons, Ltd.
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The Cochrane Hepato-Biliary Group (CHBG) Newsletter is written, edited, and published in electronic and paper format by staff at the CHBG Editorial Base in Copenhagen, Denmark. It is issued twice a year and we distribute it for free world-wide to all people on The CHBG list who either have contributed, are contributing, or show interest in the work of The CHBG. The purpose is to inform CHBG members and other interested parties about activities within The CHBG.

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