CHBG NEWSLETTER

The Cochrane Hepato-Biliary Group (CHBG)

Volume 8, Issue 1 March 2004

IN THIS ISSUE

THE CHBG TURNS 8!

The CHBG - The Cochrane Hepato-Biliary Group (or The Continuously Hardworking Biasreducing Group) – turns eight years this spring. There is ample room to congratulate the members of the Group for a very good job done so far.

We have now registered about 190 titles for systematic Cochrane reviews. Of these, 100 have turned into published protocols. And of these, 36 have turned into published reviews. And we are presently peer reviewing another 16 reviews! On top of this, we have published another 59 paper journal articles. Several of these have been in highly esteemed journals like *American Journal of Gastroenterology*, *Gastroenterology*, *JAMA*, and *BMJ*.

We have also built up a large research library – *The CHBG Controlled Trials Register*. It now contains more than 16,000 references. Out of those, more than 8,000 references are on randomised clinical trials. Each year, about 600 new references appear on trials on interventions for patients with hepatic or biliary diseases.

My thanks go to the increasing group of dedicated reviewers conducting the protocols and reviews. They are the core producers of our main products! My thanks also go to the growing group of highly professional group of peer reviewers. My thanks go to the hardworking handsearchers who are sifting through a growing number of journals. My thanks go to Johnny Boesen, the new CHBG consumer. My thanks go to translators who help our reviewers extract data from non-English language article. My thanks go to the three part time assistants who assist us in building up *The CHBG Controlled Trials Register*. My thanks go to the Editors of The CHBG, who all do a large unpaid job of securing the quality of our protocols and reviews. Last, but not least my thanks go to the Editorial Team Office staff here in Copenhagen, Dimitrinka Nikolova, Sarah Frederiksen, Ninna Frydendall, Nader Salasshahri, and Styrbjørn Birch.

Although we have been very successful, we need to realize that a job as tremendous as the whole Cochrane Collaboration has been able to accomplish until now lies ahead of us. With 8,000 identified trial reports, probably another 4,000 unidentified back in time, plus the 6,000 that are expected to be published over the next ten years, we probably have to perform about 1,800 systematic reviews (i.e., 18,000 trials divided by 10, the median number of references to included trials per review)! These reviews must be continuously updated. And we must handsearch, say, about 250 paper journals retrospectively as well as prospectively. So we need extra resources, extra reviewers, extra peer reviewers, extra handsearchers, extra consumers, etc. We also need to establish co-publication agreements with journals like *Journal of Hepatology* and *Hepatology*. If you know someone that could help in all these tasks, please do not hesitate to contact us here in Copenhagen.

Christian Gluud,
Co-ordinating editor

UPDATE ON ACHIEVEMENTS: WHAT IS ON THE CLIB, ISSUE 1 AND 2, 2004?

NEW REVIEWS (continuation)

32. Artificial and bioartificial support systems for liver failure. Liu JP, Gluud LL, Als-Nielsen B, and Gluud C.
33. Colchicine for primary biliary cirrhosis. Gong Y and Gluud C.
34. Glucocorticosteroids for viral hepatitis C. Brok J, Mellerup MT, Krogsgaard K, and Gluud C.
35. Nonabsorbable disaccharides for hepatic encephalopathy. Als-Nielsen B, Gluud LL, and Gluud C.

SUBSTANTIVELY UPDATED REVIEWS

1. Benzodiazepine receptor antagonists for hepatic encephalopathy. Als-Nielsen B, Gluud LL, and Gluud C
2. Radiofrequency thermal ablation versus other interventions for hepatocellular carcinoma. Galandi D and Antes G.

WITHDRAWN REVIEWS

1. Vaccines for preventing hepatitis B in health-care workers. Jefferson T, Demicheli V, Deeks J, MacMillan A, Sassi F, and Pratt M.

NEW PROTOCOLS (continuation)

80. Beta-blockers for cirrhotic patients with oesophageal varices that have never bled. Chen W, Nikolova D, Frederiksen SL, and Gluud C.
81. Beta-blockers for prevention of oesophageal variceal rebleeding in cirrhotic patients. Chen W, Frederiksen SL, Nikolova D, and Gluud C.
82. Chemotherapy for gallbladder cancer. Pandey M and Krishnan Nair C.
83. Immunosuppressive drugs for autoimmune hepatitis. Efsen E, Gluud LL, and Schlichting P.
84. Medicinal herbs for acute hepatitis B. Liu YX, Pang CK, and Liu JP.
85. Medicinal herbs for cholelithiasis. Tao G, Ling T, Shuli J, and Yiping W.
86. D-penicillamine for primary biliary cirrhosis. Gong Y, Frederiksen SL, and Gluud C.

87. Hepatitis B prophylaxis for newborns of hepatitis B surface antigen-positive mothers. Lee C, Gong Y, Brok J, Boxall EH, and Gluud C.
88. Laparoscopic, small-incision, or open cholecystectomy for patients with symptomatic cholecystolithiasis. Keus E, van Laarhoven C, van der Tweel I, and Gooszen HG.
89. Transcatheter arterial embolisation and chemoembolisation for hepatocellular carcinoma. Oliveri RS and Gluud C.
90. Vitamin K for upper gastrointestinal bleeding in patients with liver diseases. Martí-Carvajal AJ and Martí-Peña AJ.
91. Antibiotic prophylaxis for bacterial infections in cirrhotic patients with ascites. Sahar T, Brezis M, and Soares-Weiser K.

SUBSTANTIVELY UPDATED PROTOCOLS
1. D-penicillamine for primary sclerosing cholangitis. Frederiksen SL and Chen W.

WITHDRAWN PROTOCOLS (continuation)
3. Antibiotic prophylaxis for bacterial infections in cirrhotic patients with ascites. Bernard B, Grangé JD, Nguyen Khac E, Regimbeau C, Amiot X, Opolon P, and Poynard T.
4. Laparoscopic versus small-incision or open operation for cholecystectomy. Jørgensen T, and Laugesen H.
5. Transcatheter arterial chemoembolization for hepatocellular carcinoma. Büchner-Steudel P, Patzies A, Behl S, and Fleig WE.
6. Vaccines for preventing hepatitis B in high-risk newborn infants. Boxall EH, Jefferson TO, Pratt M, Buttery J, and El-Shukri N.

NEW REGISTERED TITLES (continuation)
169. Alpha 2-adrenergic agonists for primary and secondary prevention of portal hypertension-induced gastrointestinal bleeding in cirrhotic patients. The CHBG.
170. Angiotensin II receptor antagonists for primary and secondary prevention of portal hypertension-induced gastrointestinal bleeding in cirrhotic patients. The CHBG.
171. Antioxidant supplements for non-alcoholic fatty liver disease and/or steatohepatitis. Lirussi F, et al., Italy.
172. Azathioprine for primary biliary cirrhosis. Gong Y, et al., Denmark.
173. Bile acids for non-alcoholic fatty liver disease and/or steatohepatitis. Orlando R, et al., Italy.
174. Chlorambucil for primary biliary cirrhosis. Gong Y, et al., Denmark.
175. Cryotherapy for hepatocellular carcinoma. The CHBG.
176. Cyclosporin A for primary biliary cirrhosis. Gong Y, et al., Denmark.
177. Diuretics for primary and secondary prevention of portal hypertension-induced gastrointestinal bleeding in cirrhotic patients. The CHBG.
178. Doxorubicin for hepatocellular carcinoma. The CHBG.
179. Drugs improving insulin resistance for non-alcoholic fatty liver disease and/or steatohepatitis. Angelico F, et al., Italy.
180. Gene therapy for hepatocellular carcinoma. The CHBG.
181. Immunosuppressants for primary biliary cirrhosis. Gong Y, et al., Denmark.
182. Octreotide for hepatocellular carcinoma. The CHBG.
183. Probiotics for non-alcoholic fatty liver disease and/or steatohepatitis. Lirussi F, et al., Italy.
184. Radiotherapy for hepatocellular carcinoma. Thephamongkhol K, et al., Thailand.
185. Seretonin S2 receptor antagonists for primary and secondary prevention of portal hypertension-induced gastrointestinal bleeding in cirrhotic patients. The CHBG.
186. Surgical resection for hepatocellular carcinoma. The CHBG.

'The CHBG' in this case means that an application for obtaining a grant to perform these systematic reviews, from a funding organization in Denmark, is sent out. Should we be successful in getting money, then the planned mutual project between The Chinese Cochrane Centre – Shanghai Branch and staff at the Editorial Base could start.
Looking for funding to support Ph.D. projects is an inseparable thing of our work. We encourage people to look for support from governmental institutions or other not for profit organizations.

REVIEWS IN EDITORIAL PROCESS

1. Antibiotics for cholangitis and/or cholecystitis. Kukuruzovic RH and Elliott EJ.
2. Antioxidant supplements for preventing gastrointestinal cancers. Bjelakovic G, Nikolova D, Simonetti RG, and Gluud C.
3. Bile acids for liver transplanted patients. Chen W and Gluud C.
4. Comparison of medicinal herbs for chronic hepatitis B virus infection. Liu JP, Liu YX, Lin H, and Gluud C.
5. Dopaminergic agonists for hepatic encephalopathy. Als-Nielsen B, Gluud LL, and Gluud C.
6. D-penicillamine for primary sclerosing cholangitis. Frederiksen SL and Chen W.
7. D-penicillamine treatment of primary biliary cirrhosis. Gong Y, Frederiksen SL, and Gluud C.
8. Glucocorticosteroids for primary sclerosing cholangitis. Chen W and Gluud C.
9. Hepatitis B vaccination for patients with chronic renal failure. Schroth RJ, Hitchon CA, Uhanova J, Noreddin A, Taback SP, Moffatt MEK, and Zacharias JM.
10. Methotrexate for primary biliary cirrhosis. Gong Y and Gluud C.
11. Milk thistle for alcoholic and/or hepatitis B or C liver diseases. Rambaldi A, Jacobs BP, Iaquinto G, and Gluud C.
12. Portosystemic shunts versus endoscopic therapy for variceal rebleeding in patients with cirrhosis. Khan S, Tudur Smith C, Williamson P, and Sutton R.
13. Surgical versus endoscopic treatment of bile duct stones. Martin D, Vernon DR, Jobling J, and Toouli J.
14. Tamoxifen for hepatocellular carcinoma. Nowak A, Findlay M, Culjak G, and Stockler M.
15. TIPS versus paracentesis for cirrhotic patients with refractory ascites. Saab S, Nieto JM, Ly D, and Runyon BA.
16. Vaccines for preventing hepatitis A. Tiberti D and Demicheli V.

UPDATES OF REVIEWS UNDERWAY

1. Neoadjuvant and adjuvant therapy for operable hepatocellular carcinoma. Samuel M, et al.
2. Vaccines for preventing hepatitis B in health-care workers. Chen W, Deeks JJ, and Gluud C.

ABANDONED REVIEWS IN NEED TO BE UPDATED

Should you wish to work on any of these, please contact us.

1. Antibiotics for leptospirosis.
2. Antibiotics for preventing leptospirosis.

PROTOCOLS IN EDITORIAL PROCESS

1. Antiviral therapy for chronic hepatitis C in patients with human immunodeficiency virus. Iorio A, Francisci D, Luchetta ML, Kjaer MS, and Gluud LL.
2. Bicyclol for chronic hepatitis C. Yang XY, Wu TX, and Liu GJ.
3. Endoscopic balloon sphincter dilation (sphincteroplasty) versus sphincterotomy for common bile duct stones. Weinberg B, Lo S, and Shindy W.
4. Hepatitis B immune globulin for prevention of posttransplantation hepatitis B. Hong Z, Gao RN, and Zou S.
5. Human recombinant activated factor VII for upper gastrointestinal bleeding in patients with liver diseases. Martí-Carvajal AJ, and Marti-Carvajal P.
6. Metronidazole with or without image-guided percutaneous procedure for uncomplicated amoebic liver abscess
7. S-adenosyl-L-methionine for viral hepatitis. Hu G, Duan J, and Liu K.

ABANDONED PROTOCOLS

Should you wish to work on this review, please contact us.

1. Vaccines for leptospirosis.

PROTOCOLS OR REVIEWS THAT SEEM FORGOTTEN BY THE AUTHORS

1. Preoperative biliary drainage for obstructive jaundice. McCall J, et al. (USA)
2. Prophylactic endoscopic sclerotherapy for oesophageal varices. Fardy J, et al. (Canada)

PAST EVENTS

3rd WORKSHOP ON COCHRANE EDITING, COPENHAGEN - DENMARK

In The CHBG Newsletter [Vol. 7 Issue 2 (October 2003) p. 3], we wrote at large about the international workshop held on 18 and 19 of September, but it slipped our mind to write that the workshop was organized and sponsored by The Nordic Cochrane Centre, led by Peter Gøtzsche, Copenhagen, Denmark. We apologize

for this omission and extend our thanks again to Peter and his staff. We are looking forward to similar workshops in the year 2004. The workshops are run in English.

11th COCHRANE COLLOQUIUM
The 11th Cochrane Colloquium was held from 26 to 31 of October 2003 in Barcelona, Spain. It was very successful and we urge members of The CHBG to join future Cochrane Colloquia.

16TH CHBG MEETING DURING THE AASLD MEETING
It was held on 27 of November 2003 in Boston, USA. About 20 people were present. We would like to thank all the people who attended the meeting and the presenters who worked hard.

FUTURE EVENTS

17th CHBG BI-ANNUAL MEETING DURING THE EASL MEETING, BERLIN - GERMANY
The CHBG will hold its 17th meeting on 14 of April, Wednesday, from 9:30 to 12:00 o'clock in hall 6. The final programme for The CHBG is sent out with this Newsletter. The CHBG will also have a stand at the EASL exhibition. Both events are kindly sponsored by EASL and we extend our thanks. We will be happy to see you there!

TRAIN THE TRAINERS IV, CRETE - GREECE
The workshop is devised and organized by the World Gastroenterology Organisation//World Organisation for Digestive Endoscopy (OMGE/OMED) Education and Training Committee, under the guidance of James Toouli, Australia. Following the success of the previous three workshops, it will be run from 19 to 23 of April 2004 in Crete, Greece. Christian Gluud is one of the tutors. For more information, http://www.omge.org/.

DIGESTIVE DISEASE WEEK (DDW), NEW ORLEANS - USA
The DDW meeting will be held from 15 to 21 of May 2004. For more information, http://www.ddw.org/. The symposium that this year will be presided by The Cochrane Upper-Gastrointestinal and Pancreatic Diseases Group will be on 17 of May from 2:15 p.m. to 3:45 p.m. (confirmed in DDW Daily News). Please contact the information desk as to which room it will be held in.

12th COCHRANE COLLOQUIUM, OTTAWA - CANADA
The 12th Cochrane Colloquium will be held from 2 to 6 of October 2004 in Ottawa, Canada. For more information, http://www.colloquium.info/. Please visit the web site for some important dates.

18th CHBG BI-ANNUAL MEETING DURING THE AASLD MEETING, BOSTON, MA - USA
The AASLD meeting will be run from 29 of October to 2 of November 2004 in Boston. The date for The CHBG meeting will be scheduled after the summer.

VISITS

Chuanfang Lee, Ass. Prof., pharmacist from Taiwan, and a member of The CHBG since October 2003, came on 31 of January 2004. He has overtaken the work on an abandoned protocol on hepatitis B prophylaxis for newborns of hepatitis B surface antigen-positive mothers and together with his co-reviewers, though the short time, he managed to rewrite and submit a new protocol for publication. His plan is to finalize the review before going back home in July 2004. We wish him good luck!

Andrea Rambaldi, Italy, came to The CHBG office on 9 of February 2004 and worked for five days on his review on milk thistle for alcoholic and/or hepatitis B or C liver diseases.

Serena Orando and *Flavio Lirussi*, Italy, are new members of The CHBG. They came to The CHBG office on 3 of March and worked for four days on antioxidant supplements for non-alcoholic fatty liver disease and/or steatohepatitis. They were so kind as to share their experience from their visit by sending us the letter below. We thank them most heartily.

A LETTER FROM PADOVA

The idea of a thorough and exhausting reading of the 230 pages of the famous 'Reviewers' Handbook' provided by The Cochrane Collaboration was really frightening. Even its

electronic version would have not made the task easier… .

Thus, Serena - a sixth-year medical student at the University of Padova, Italy -, and myself - a researcher working at the same University - thought that we could attend a sort of "crash course" in systematic reviews just in one of the very European temples in this field: the Rigshospitalet of Copenhagen.

The good relations I had maintained over the years with Christian Gluud, the scientist responsible for The Cochrane Hepato-Biliary Group in the Danish capital, made the project feasible. Christian was contacted and immediately agreed on our proposal: Serena and I would go to Copenhagen and would be taught by him and Dimitrinka, the Coordinator of the Group, how to write a protocol and how to evaluate trials for the systematic review.

A low-cost flight took us to Copenhagen, where we spent three working days and part of the weekend. Over this time, we managed to produce a protocol on a nowadays-hot topic not only in the field of hepato-biliary disorders but also of metabolic diseases: non-alcoholic fatty liver disease. We also searched the net for the articles to be reviewed, and even started the reviewing process. Needless to say, Christian's and his team's (about fifteen people in the Copenhagen Trial Unit department) kind but professional attitude towards us surely contributed to the accomplishment of our goal.

If I then look at the social side of our expedition to Hamlet's country, I can only say that exploring every evening the palatable tastes of a different cuisine - the typical Danish one or the ethnic ones -, made the whole stay even more enjoyable.

In conclusion, I believe that our move represented an original and more dynamic approach to the world of systematic reviews. We thoroughly recommend it especially to people who, like us, are somewhat newcomers in this particular field of research. After all, the setting appears "adequate", the mission is quite "clear" and "unblinded" and the people up there have all the "intention-to-help" you writing a review, but also enjoying "wonderful Copenhagen".

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CHBG CONSUMER

In December 2003 I accepted to become a consumer of The CHBG. I am working to make the public aware that information about medicine may be biased and defective and that the laws must be changed so consumers get full information about efficacy and adverse effects of medicine. Some of my tasks are to read and comment on the reviews to be published from a consumer point of view: Is the review understandable for the consumer and does it give useful advice on what treatment to choose?

Johnny Boesen,
www.bedremedicin.dk

ASSESSMENT OF METHODOLOGICAL QUALITY

In The CHBG Module on Issue 1, 2004 of The Cochrane Library we published an update of the components to be used by reviewers when assessing the methodological quality of the studies relevant for the review. This information is more elaborative than the one given in The Cochrane Reviewers' Handbook. Below is a copy of the published text.

The quality of the included trials is assessed independently in all reviews using assessment criteria defined in the protocol. Eventual differences in the quality assessment of trials are resolved in discussion in order to reach consensus.

Methodological quality and intervention effects

Methodological studies indicate that trials with unclear or inadequate methodological quality may be biased (1-6). Such bias may lead to overestimation of intervention benefits. The most important quality components are generation of the allocation sequence, allocation concealment, and blinding (1-9). Attrition bias may also lead to exaggerated estimates of intervention effects (4).

Trials with adequate randomisation, blinding, and follow up generate the most valid results. Unfortunately, such trials are often not available for meta-analyses. Of 370 drug trials, 28% reported adequate generation of the allocation sequence, 22% reported adequate allocation concealment, and 63% were double blind (6). Accordingly, only 4% were adequate regarding all components. Subgroup analyses are therefore important to evaluate the influence of unclear or inadequate methodological quality.

Based on the recommendations in the Cochrane Reviewers' Handbook (7) and methodological studies (1-3;59, we suggest that systematic reviewers use the following definitions in the assessment of methodological quality. Please note that specific circumstances may sometimes necessitate changes in the definitions or make additional quality components important.

Generation of the allocation sequence
The procedure used to create a random sequence ensuring that each participant has a known, unpredictable, and usually equal chance of being assigned to intervention groups. The allocation sequence generation can be classified as
(1) Adequate, if the allocation sequence was generated by a computer or random number table. Drawing of lots, tossing of a coin, shuffling of cards, or throwing dice may also be considered as adequate if a person who was not otherwise involved in the recruitment of participants performed the procedure.
(2) Unclear, if the trial was described as randomised, but the method used for the allocation sequence generation was not described.
(3) Inadequate, if a system involving dates, names, or admittance numbers were used for the allocation of patients. Such studies are known as quasi-randomised studies and should usually be excluded from systematic Reviews because they are associated with a considerable risk of bias (8;9).

Allocation concealment
The procedure used to conceal the allocation sequence from the investigators who assign participants to the intervention groups. The allocation concealment can be classified as
(1) Adequate, if the allocation of patients involved a central independent unit, on-site locked computer, identically appearing numbered drug bottles or containers prepared by an independent pharmacist or investigator, or sealed envelopes. Envelopes should be serially numbered, sealed, and opaque. However, this information is rarely provided, indicating an increased risk of bias. In that case, sealed envelopes may constitute an intermediate category between adequate and unclear.
(2) Unclear, if the trial was described as randomised, but the method used to conceal the allocation was not described.
(3) Inadequate, if the allocation sequence was known to the investigators who assigned participants or if the study was quasi-randomised.

Blinding (or masking)
The procedure used to keep trial participants, health care providers, and outcome assessors unaware of the intervention to which participants were assigned. Judicial assessors of outcomes, data analysts, data safety monitoring committee members, and manuscript writers can also be blinded. In some cases, evaluation of whether outcome assessors were blinded may be sufficient (5). This primarily concerns trials on surgery or other procedures. In drug trials, blinding of patients and health care providers is usually possible. Blinding can then be classified as
(1) Adequate, if the trial was described as double blind and the method of blinding involved identical placebo or active drugs.
(2) Unclear, if the trial was described as double blind, but the method of blinding was not described.
(3) Not performed, if the trial was not double blind.

Follow-up
The purpose of randomisation is to generate comparable intervention groups. This baseline equivalence may be disrupted if participants are lost to follow up. To evaluate the risk of such attrition bias, we suggest that reviewers extract the number and reasons for dropouts and withdrawals. Extraction of this information may be difficult due to unclear reporting. It may therefore sometimes be relevant to extract the adequacy of follow-up

reports. The reported follow-up can be classified as
(1) Adequate, if the numbers and reasons for dropouts and withdrawals in all intervention groups were described or if it was specified that there were no dropouts or withdrawals.
(2) Unclear, if the report gave the impression that there had been no dropouts or withdrawals, but this was not specifically stated.
(3) Inadequate, if the number or reasons for dropouts and withdrawals were not described.

References

1. Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA 1995;273:408-12.
2. Moher D, Pham B, Jones A, Cook DJ, Jadad AR, Moher M, et al. Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? Lancet 1998;352:609-13.
3. Kjaergard LL, Villumsen J, Gluud C. Reported methodologic quality and discrepancies between large and small randomized trials in meta-analyses. Ann Intern Med 2001;135:982-9.
4. Jüni P, Altman D, Egger M. Assessing the quality of controlled clinical trials. BMJ 2001;323:42-6.
5. Egger M, Jüni P, Bartlett C, Holenstein F, Sterne J. How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? Empirical study. Health Technol Assess 2003;7:1-76.
6. Als-Nielsen B, Chen W, Gluud C, Kjaergard LL. Association of funding and conclusions in randomized drug trials: a reflection of treatment effect or adverse events? JAMA 2003;290:921-8.
7. Alderson P, Green S, Higgins JPT, editors. Cochrane Reviewers' Handbook 4.2.1 [updated December 2003]. In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd
8. Kunz R, Vist G, Oxman A. Randomisation to protect against selection bias in healthcare trials. In: The Cochrane Library 2003, Issue 4.
9. Kjaergard LL, Liu JP, Als-Nielsen B, Gluud C. Artificial and bioartificial support systems for acute and acute-on-chronic liver failure: a systematic review. JAMA 2003;289:217-22.

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