



CHBG NEWSLETTER

Cochrane Hepato-Biliary Group (CHBG)

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THE COCHRANE HEPATO-BILIARY GROUP - SIX FRUITFUL YEARS!

Since the registration of The CHBG within The Cochrane Collaboration in 1996, The CHBG has registered a total of 137 titles for systematic Reviews. Of these, 71 have turned into protocols, which have been published at

The Cochrane Library. This corresponds to one published protocol per month during the period The CHBG has been in action! In addition to this achievement, we have extra 11 protocols presently undergoing editorial processing.

Of the 71 protocols, 26 have been turned into published systematic Reviews on The Cochrane Library (CLib) Issue 4, 2002. This corresponds to about one published Review per 2.8 months we have been in action. Further 24 systematic Reviews are presently undergoing editorial processing and we hope to have all these published in The Cochrane Library during 2003. If this can be accomplished, this will improve our production to about one review per 1.7 months – or about seven reviews per year.

By searching paper journals, abstract books, and electronic databases, we have now a database storing 6,931 randomised clinical trials, 476 controlled clinical trials, 710 'second opinion ought to be sought studies', 244 meta-analyses, 2,711 observational studies, 684 letters, 1,772 reviews, 630 miscellaneous studies, and 73 consensus reports.

In addition, CHBG Editors and reviewers have during this period published around 30 abstracts at international meetings and 45 articles published in paper journals related to the work of The CHBG.

We have also achieved increasing attention from international scientific organisations,

primarily, European Association of the Liver Diseases (EASL), the World Organization of Gastroenterology (OMGE), and the World Organization of Digestive Endoscopy (OMED). Further, our double-publication agreements with LIVER and the American Journal of Gastroenterology have been very important to increase the visibility of The CHBG. These organisations and journals are thanked for the collaboration.

We find ourselves that this is fairly good for a six-year old research group, in which we all have had a lot to learn. These accomplishments could not have been produced without support from our sponsors, which during the years primarily have been the following: The Copenhagen Hospital Corporation; The Copenhagen Trial Unit; The Danish Medical Research Council; The 1991 Pharmacy Foundation; The Copenhagen Hospital Corporation's Medical Research Council; The Danish Council for Development Research, Denmark; The Fund of 1870; and The Danish Institute for Health Technology Assessment. We wish to take the opportunity to thank these sponsors.

However, we should all be aware of the fact that there are several Cochrane Collaborative Review Groups that are doing much better than The CHBG regarding quantity and maybe quality. And more importantly, the task ahead is immense. As a rule of thumb, there are about six randomised clinical trials per Cochrane Review - and with 7,000 randomised clinical trials identified and the

present production of 500 new randomised clinical trials per year within hepato-biliary diseases, The CHBG must conduct about 1,500 to 2,000 systematic Reviews before the hepato-biliary area is covered! On top of this comes the work with keeping the Reviews up-to date. This is a task, which can be compared to what the whole Cochrane Collaboration has been able to produce until now! It may seem a bit scaring. However, there may be light in the tunnel. The importance of systematic reviews for getting research implemented in clinical practice is increasingly being recognised. In Australia they are contemplating of doing at least one systematic Review part of the education to become a specialist. The ideology is simple. How can you be a specialist if you are not able to critically read, understand, and analyse summaries of evidence?

So, for the future we need the support from private and public funds as well as non-governmental and governmental organisations - and all the good research brains we can get! During the coming years we will continue our efforts to get AASLD and IASL more interested in our work as well as co-publication agreements with other specialists journals.

Anyone who can help in these efforts is welcome on board!

Below, is a list of the protocols and Reviews presently on The CLib:

CHBG Protocols published in Issue 4, 2002:

- Alpha-foetoprotein and/or liver ultrasonography for liver cancer screening in hepatitis B carriers, Wun Yuk Tsan, et al., China.
- Alpha-interferon for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Anabolic-androgenic steroids for alcoholic liver disease, Andrea Rambaldi, et al., Italy.
- Antibiotic prophylaxis for bacterial infections in cirrhotic patients with ascites, Brigitte Bernard, et al., France.
- Antibiotics for cholangitis, Renata Kukuruzovic et al., Australia.
- Artificial and bioartificial support systems for liver failure, Jianping Liu, et al., China.
- Beta-interferon for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Bile acids for primary sclerosing cholangitis, Wendong Chen, et al., Denmark.
- Bile acids for viral hepatitis, Wendong Chen, et al., Denmark.
- Branched-chain amino acids for hepatic encephalopathy, Christian Gluud, et al., Denmark.
- Cholecystectomy for gallbladder dyskinesia, James Tooouli, et al., Australia.

- Dopaminergic agents for hepatic encephalopathy, Bodil Als-Nielsen, et al., Denmark.
- Emergency sclerotherapy or band ligation combined with vasoactive drugs for bleeding esophageal varices in cirrhosis, Gennaro D'Amico, et al., Italy.
- Endoscopic interventions for unresectable cholangiocarcinoma, Regina Imada, et al., Brazil.
- Foscarnet for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Gamma-interferon for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Glucocorticosteroids for viral hepatitis C, Martin Thyge Møllerup, et al., Denmark.
- Glucocorticosteroids for viral hepatitis B, Martin Thyge Møllerup, et al., Denmark.
- Glucocorticosteroids for alcoholic hepatitis, Humberto Saconato, et al., Brazil.
- Glucocorticosteroids for primary biliary cirrhosis, Martin Prince, et al., UK.
- Hepatitis B vaccination for patients with chronic renal failure, James M. Zacharias, et al., Canada.
- Interferon for hepatocellular carcinoma, Rosa Simonetti, et al., Italy.
- Lamivudine for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Laparoscopic versus small incision or open operation for cholecystectomy, Torben T. Jørgensen, et al., Denmark.
- Levamisole for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Medicinal herbs versus medicinal herbs for chronic hepatitis B virus infection, Jianping Liu, et al., China.
- Milk thistle for alcoholic and/or hepatitis B or C liver diseases, Andrea Rambaldi, et al., Italy.
- Nonabsorbable disaccharides for hepatic encephalopathy, Bodil Als-Nielsen, et al., Denmark.
- Organic nitrates for prevention of esophageal varices bleeding and rebleeding, Liu Tianshu, et al., China.
- Percutaneous ethanol injection or percutaneous acetic acid injection for hepatocellular carcinoma, Petra Büchner-Steudel, et al., Germany.
- Percutaneous needle aspiration with or without oral albendazole for uncomplicated hepatic hydatid cysts, Siavosh Nasser Moghaddam, et al., Iran.
- Shunts versus endoscopic therapy for long-term management of variceal haemorrhage, Saboor A. Khan, et al., UK.
- Surgical portosystemic shunts versus transjugular intrahepatic portosystemic shunt for variceal haemorrhage, Saboor A. Khan, et al., UK.
- Surgical versus endoscopic treatment of bile duct stones, David Vernon, et al., Australia.
- Surgical versus medical treatment of refractory ascites, Sammy Saab, et al., USA.
- Systemic chemotherapy for inoperable hepatocellular carcinoma, Pierce K.H. Chow, et al., Singapore.
- Tamoxifen for hepatocellular carcinoma, Martin R. Stockler, et al., Australia.
- Thymosin alpha1 for chronic hepatitis B, Humberto Saconato, et al., Brazil.
- Total portosystemic shunt versus shunts preserving portal venous hepatic perfusion for variceal haemorrhage, Saboor A. Khan, et al., UK.
- Transcatheter arterial chemoembolization for hepatocellular carcinoma, Petra Büchner-Steudel, et al., Germany.
- Vaccines for leptospirosis, Fábio Guidugli, et al., Brazil.
- Vaccines for preventing hepatitis B in newborn infants, Elizabeth H. Boxall, et al., UK.
- Vaccines for preventing hepatitis B in high-risk newborn infants, Elizabeth H. Boxall, et al., UK.
- Vaccines for preventing hepatitis A, Vittorio Demicheli, et al., Italy.
- Weight reduction for non-alcoholic fatty liver, Rex Wang, et al., USA.

CHBG Reviews published in Issue 4, 2002:

- Antibiotic prophylaxis for cirrhotic patients with gastrointestinal bleeding, Karla Soares-Weiser, et al., Israel.
- Antibiotics for leptospirosis, Fábio Guidugli, et al., Brazil.

- Antibiotics for preventing leptospirosis, Fábio Guidugli, et al., Brazil.
- Antibiotics for spontaneous bacterial peritonitis in cirrhotics, Karla Soares-Weiser, et al., Israel.
- Benzodiazepine receptor antagonists for acute and chronic hepatic encephalopathy, Bodil Als-Nielsen, et al., Denmark.
- Chinese medicinal herbs for asymptomatic carriers of hepatitis B virus infection, Jianping Liu, et al., China.
- Chinese medicinal herbs for chronic hepatitis B, Jianping Liu, et al., China.
- Colchicine for alcoholic and non-alcoholic liver fibrosis and cirrhosis, Andrea Rambaldi, et al., Italy.
- Emergency sclerotherapy versus medical interventions for bleeding oesophageal varices in cirrhotic patients, Gennaro D'Amico, et al., Italy.
- Interferon for acute hepatitis C, Robert P. Myers, et al., France.
- Interferon for interferon naive patients with chronic hepatitis C, Robert P. Myers, et al., France.
- Interferon for interferon nonresponding and relapsing patients with chronic hepatitis C, Robert P. Myers, et al., France.
- Interventions for paracetamol (acetaminophen) overdoses, Jesper Brok, et al., Denmark.
- Medicinal herbs for hepatitis C virus infection, Jianping Liu, et al., China.
- Neoadjuvant and adjuvant therapy for operable hepatocellular carcinoma, Edwin Shih-Yen Chan, et al., Singapore.
- Propylthiouracil for alcoholic liver disease, Andrea Rambaldi, et al., Italy.
- Radiofrequency thermal ablation versus other interventions for hepatocellular carcinoma, Daniel Galandi, et al., Germany.
- Ribavirin with or without alpha interferon for chronic hepatitis C, Lise Lotte Kjaergard, et al., Denmark.
- S-adenosyl-L-methionine for alcoholic liver diseases, Andrea Rambaldi, et al., Italy.
- Sequential combination of glucocorticosteroids and alfa interferon versus alfa interferon alone for HBeAg-positive chronic hepatitis B, Martin Thyge Møllerup, et al., Denmark.
- Somatostatin analogues for acute bleeding oesophageal varices, Peter C. Gøtzsche, Denmark.
- Sphincterotomy for biliary sphincter of Oddi dysfunction, Alexander AG Craig, Australia.
- Terlipressin for acute esophageal variceal hemorrhage, George Ioannou, et al., USA.
- Ursodeoxycholic acid for primary biliary cirrhosis, Christian Gluud, et al., Denmark.
- Ursodeoxycholic acid and/or antibiotics for prevention of biliary stent occlusion, Daniel Galandi, et al., Germany.
- Vaccines for preventing hepatitis B in health-care workers, Tom T. Jefferson, et al., UK.

You may find abstracts of any of the published Cochrane Reviews on The CLib web site <<http://www.update-software.com/Cochrane/abstract.htm>>. You may also browse or search Cochrane Reviews for free.

I thank editors, authors, peer reviewers, commentators, handsearchers, and last but not least the Editorial Team staff here in Copenhagen for all the work that has been performed. There is more out there for all of us.

Christian Gluud, Coordinating Editor

The Submission deadline for The CLib Issue 1, 2003 is November 20, 2002

In order to be sure that your peer reviewed, amended protocol or Review can meet the date for publication on The CLib, you have to submit it to The CHBG Editorial Team Office at least two weeks in advance.

INFORMATION WORTH TO BE REGULARLY CHECKED

For information on the Cochrane Collaboration, see: www.cochrane.de

For consumer information see: www.cochraneconsumer.com

For little gems from The Cochrane Library, see:
http://www.nelh.nhs.uk/cochrane_gems/archives.asp

For basic principles applying to the construction of search profiles for use on Internet search engines or on any on-line database searches, see: **http://www.frame-uk.demon.co.uk/guide/search_basics.htm**
For access to an international database of ongoing randomised clinical trials in all areas of healthcare see: **<http://www.controlled-trials.com/mrct/>**

For access to the core library for evidence-based practice publications see:
<http://www.shef.ac.uk/~scharr/ir/core.html>

NEWS FROM UPDATE SOFTWARE

Update Software has introduced a new electronic document delivery system that will allow people to purchase individual copies of Cochrane Reviews even if they do not subscribe to The CLib.

After searching or browsing the abstracts of the reviews online at <http://www.update-software.com/abstracts/mainindex.htm> you can select and purchase individual copies of Cochrane Reviews in PDF format. Once you have browsed the abstracts and found a Review that you would like to purchase, simply click the 'Order full review' link in the top right hand corner of the abstract and you will automatically be connected to an online order form for purchasing the Review. If you are a first time user of the system you must first enter some basic contact details and register for a unique username and password, which you will need to enter each time you purchase a new Review or set of Reviews.

Each full Cochrane Review costs £10 and payment is made online via a secure credit card payment site. As soon as the credit card transaction has been approved, a PDF copy of the requested Review will automatically be sent to your registered email address. To view and print out the document you will need to have Adobe Acrobat Reader installed on your computer. A link to enable you to download this free software is available from the

Review order page if you do not already have it installed on your machine.

However, The National Electronic Library for Health (NeLH) have reached the final stages of contract negotiation with the Cochrane Collaboration, Update Software, and BMJ Publications on free and unrestricted access to CLib and Clinical Evidence for patients, the public and NHS staff in England via the NeLH website. So access will be available via NeLH very shortly.

EDITORIAL MESSAGES

Sarah Louise Frederiksen, the Trials Search Coordinator, is back from maternity leave and has resumed her duties, consisting primarily of handsearching relevant journals and coordinating the handsearch activities, performing searches to expand further The Cochrane Hepato-Biliary Group Controlled Trials Register and submitting it for publication on The CLib as well as performing searches for the reviewers and helping them with development of the search strategies.

Ninna Frydendal, assisting the CHBG and the Copenhagen Trial Unit full time, has turned 78 years old August 11, 2002. We do not think that any of the Cochrane entities may compete with having such a treasure as Ninna, who, to name some of the tasks, with ease downloads MEDLINE and EMBASE citations, enters citations manually in a ProCite database, enters MEDLINE accession numbers of references in RevMan, maintains a CHBG membership list in a Lotus Notes database, makes labels, and files correspondence. Here we also have to mention the enormous help she is giving us within the Copenhagen Trial Unit as it concerns randomisation of patients and the related tasks. We wish her many years ahead, years full of joy and good health! Thank you, Ninna!

CALENDAR OF EVENTS

Past events

The 13th CHBG biannual meeting during The 2002 EASL meeting in April in Madrid, Spain

This meeting was cancelled due to the inconvenience of the allotted time. We would,

however, like to thank Luigi Pagliaro, CHBG Editor and Rosa Simonetti, CHBG Associate Editor, Italy, for their efforts in working out the programme for the meeting we thought would take place. The CHBG had but a stand at the EASL exhibition from 18.04 - 22.04.2002, and new members of the CHBG were recruited. We thank all who visited the stand and inquired about the CHBG activities and contribution to The CLib as well as expressed their interest in participating in the work of The CHBG.

Train-the-Trainers II Workshop in April 2002 in Crete

James Toouli, CHBG Editor, was directing this EMGE/OMED sponsored event. Two leading representatives from 20 nations' gastroenterology societies were flown into Crete to participate in this three-day workshop on evidence-based learning, evidence-based medicine, and The Cochrane Collaboration. Christian Gluud, was one of the trainers. Again this year the workshop became a great success. The work with the 2003 Workshop has already begun.

The 10th Cochrane Colloquium, Stavanger, Norway, 31 July – 3 August 2002

Ronald Koretz, Christian Gluud, Lise Lotte Kjaergard, Jianping Liu, Dimitrinka Nikolova, Sarah Louise Frederiksen, and Wendong Chen attended the colloquium. We found that the meetings and the workshops were well selected and well organised. From the plenary sessions, we all had the chance to learn about helping to inform healthcare policy, grading evidence within Cochrane reviews, and improving the quality of Cochrane reviews. In addition, the visions for achievements of the Collaboration by the 20th Colloquium were discussed.

Wendong Chen, our guest reviewer from China says: "Stavanger is a beautiful and quiet town in Norway; well known for its beautiful mountains, large rocks, and fjords. But this time this is not what I would most remember from a new place; what I will carry in my memory is my first attendance at a Cochrane Colloquium. As a systematic reviewer, I feel confident on how to perform systematic reviews, but I have had no idea

what position the Review in the whole Cochrane programme had. The opening ceremony was simple and meaningful. I realised how important the work I had been doing was and how great the forthcoming challenges were. We all know that in the health-care sector, there are still a lot of interventions waiting to be systematically evaluated. There are still a lot of professional health-care workers who have not yet realised the importance of the Cochrane work that is being performed. I was deeply touched by the contribution of so many people with strong beliefs and motivations to develop better evidence for the health care products and bring them out to the people around the world."

Allen C., et al. from The Cochrane Collaboration Secretariat reported their results from a survey on the international distribution of activity within 49 Collaborative Review Groups. The data they report are conspicuous. Around November 2001 there were 7,727 Cochrane contributors from 78 countries. Fifty-five per cent were reviewers and out of them eight per cent came from low/middle income countries. They also gave the order of countries with most contributors. It is UK, USA, Australia, Canada, The Netherlands, Italy, Denmark, New Zealand, Germany, and Spain. Compared with a year ago the increase in the number of contributors was 42 per cent!

Another great news was the fact that The CLib is going to have a new vendor. The final decision is going to be taken by the steering Group in 2002 or early next year. This may have consequences for the way Cochrane Reviews are distributed around the world.

The greatest news was also the saddest. Sir Iain Chalmers – the man who was pivotal to the build-up of The Cochrane Collaboration – left his position as director of The UK Cochrane Centre. He will now devote his time to other research questions like the history of randomised clinical trials and the further build-up of The Campbell Collaboration (named after Donald Campbell, an American psychologist and thinker). The Campbell Organisation is a sibling organisation to the

Cochrane Collaboration which is being formed to prepare, maintain and promote the accessibility of systematic reviews in areas such as education, criminal justice, social policy, and social care. For information <<http://www.campbellcollaboration.org/>>.

Cochrane Editing Workshop, 12-14 September 2002 in Copenhagen

The aim is to teach people involved in Cochrane work how to improve the quality of Cochrane Reviews. It has been previously shown that systematic Cochrane Reviews had higher quality and were less biased than systematic reviews published in high-profile paper journals, but improvement is always possible (Quality of Cochrane reviews: assessment of sample from 1998. Olsen O. et al. BMJ 2001;323:829-32). Peter Gøtzsche, The Nordic Cochrane Centre, had arranged the workshop and Drummond Rennie, JAMA Editor, Jos Kleijnen, NHS Centre for Reviews and Dissemination, University of York, UK, and Christian Gluud were among the trainers. We can recommend this workshop to Editors as well as systematic reviewers.

Visits to The CHBG Editorial Office Reviewers

Andrea Rambaldi, a CHBG reviewer from Italy, came twice to Copenhagen in June and August and stayed both times for a week to work on his fifth systematic Review entitled 'Milk thistle for alcoholic and/or hepatitis B or C liver diseases'.

Wendong Chen, a CHBG reviewer from China, has prolonged his period of stay until May 2003. In total, he authors seven Reviews and is a co-author of one.

High-ranking delegation from China

Sixteen representatives from the Ministry of Health, The Chinese Cochrane Centre, and from eleven provinces in China were guests of The Copenhagen Trial Unit (CTU) and The CHBG in August. They participated in an eight-days intensive course 'Evidence-based medicine and evidence-based clinical practice' arranged by The CTU and The CHBG. The three Danish Cochrane Collaborative Review Groups and The Nordic Cochrane Centre presented talks on methodology of clinical

trials; preparation of Cochrane Systematic Reviews; The Cochrane Library and searches on its databases; and The Cochrane Collaboration's structure. At The Danish Institute for Health Services Research (DSI) participants were taught on evidence-based standards in quality assurance; and use of cost-effectiveness analyses in the Danish health care system. At The CTU they were introduced to how to design, perform, and organise the data management of randomised clinical trials; and what Good Clinical Practice is and what are the Standard Operating Procedures for clinical research. The course further included inter-active lectures, course notes, demonstrations, and excursions to The Danish Ministry of the Interior and Health; The Danish National Board of Health; The Danish Centre for Evaluation and Health Technology Assessment; The Danish Medicine Agency; The Danish Institute for Rational Pharmacotherapy; and The University of Copenhagen. The participants have acquired a good understanding of the application of evidence-based medicine into clinical practice, and The Ministry of Health already plans seminars on evidence-based medicine during 2003 in China.

Future events

The 14th CHBG biannual meeting during The 2002 AASLD meeting in Boston, USA

The CHBG will hold its 14th biannual meeting on 4th November 2002 in Boston, USA. The programme is sent with this Newsletter.

The 15th CHBG biannual meeting during The 2003 EASL meeting in Istanbul, Turkey

The CHBG will hold its 15th biannual meeting from 09:00 to 12:15 on 28 March 2002 (pre-meeting activities) in Istanbul, Turkey. The CHBG is also given a space for a stand at the EASL exhibition 29.03.03 – 02.04.03. For more information about EASL, please see http://www.easl.ch/easl2003/pre_meeting.htm.

Anybody interested is most welcome to any of the meetings.

HELP FOR REVIEWERS

How do subgroup and sensitivity analyses differ?

Sensitivity analyses and subgroup analyses overlap to some extent, but there are differences between them.

A sensitivity analysis is any analysis that answers the question 'Are my results robust to...[decision]?' They tend to refer to testing assumptions made in the reviewing process, to see how robust the results are to arbitrary decisions. For instance, fixed effects versus random effects, different ways of handling missing data, the effects of including low quality studies, seeing whether the results are sensitive to the exclusion of one particular study. Often, various versions of the analysis are compared to the 'main' analysis to look for differences.

Subgroup analyses, on the other hand, tend to relate to the underlying clinical question.

Groups of studies or groups of patients within studies are compared to each other (not to the main analysis). There should be pre-specified hypotheses that different sets of patients will respond in different ways.

However, subgroup analyses and sensitivity analyses overlap. A subgroup analysis could be used to answer the 'Are my results robust to...[decision]?' question, and thus be a form of sensitivity analysis. Sometimes a question can be made into a subgroup analysis or a sensitivity analysis depending on how it is worded. For example 'Are the results different for different drugs?' is a subgroup analysis, whereas 'Are the results for the different drugs similar enough for a combined estimate over all drugs to be a sensible measure?' could be a sensitivity analysis. It all depends how you word it.

The Cochrane Hepato-Biliary Newsletter is prepared, 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 distributed free of charge by The CHBG worldwide to all people on The CHBG list who either have contributed, are contributing, or show interest in the work of the Group. The purpose is to inform CHBG members and other interested parties about activities within The CHBG.

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