Cochrane Hepato-Biliary

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IN THIS ISSUE

The numbering is a continuation from Vol. 19, Issue 1, 2015.

PUBLICATIONS IN THE COCHRANE LIBRARY (THE CLIB). ISSUE 5 OF 2015 THROUGH ISSUE 10 OF 2015

NEW REVIEWS

187. Endoscopic injection of cyanoacrylate glue versus other endoscopic procedures for acute bleeding gastric varices in people with portal hypertension. Ríos Castellanos E, Seron P, Gisbert JP, Bonfill Cosp X.

UPDATED REVIEWS

72. Antifibrinolytic amino acids for upper gastrointestinal bleeding in people with acute or chronic liver disease. Martí-Carvajal AJ, Solà I.

73. Vitamin K for upper gastrointestinal bleeding in people with acute or chronic liver diseases. Martí-Carvajal AJ, Solà I.

74. Branched-chain amino acids for people with hepatic encephalopathy. Gluud LL, Dam G, Les I, Córdoba J, Marchesini G, Borre M, Aagaard NK, Vilstrup H.

NEW PROTOCOLS

308. Beta-blockers alone or with isosorbide mono-nitrate for primary prevention of bleeding in adults with cirrhosis and gastro-oesophageal varices. Kimer N, Naver AV, Thiele M, Krag A, Gluud LL.

309. Surgical portosystemic shunts versus devascularisation procedures for variceal bleeding due to hepatosplenic schistosomiasis. Ede CJ, Brand M.

310. Combination of magnetic resonance cholangiopancreatography and conventional magnetic resonance imaging for the diagnosis of

bile duct stenosis. Cavalcanti Neto AJ, Lustosa SAS, Casazza G, Reis C, Gomes MP, Do Carmo ACF, D'Ippolito G, Matos D.
311. Gemcitabine-based chemotherapy for advanced biliary tract carcinomas. Abdel-Rahman OM, Elsayed Z.
312. Interferon alpha versus any other drug for chronic hepatitis D. Abbas Z, Ali SS, Shazi L.
313. Banding ligation versus sclerotherapy for primary prophylaxis of oesophageal varices in children. Gana JC, Cifuentes LI, Cerda J, Villarroel del Pino LA, Peña A, Torres-Robles R.
314. Molecular and antigen detection tests for leptospirosis. Yang B, de Vries SG, Visser BJ, Nagel IM, Goris M, Leeflang MMG, Grobusch MP, Hartskeerl RA.
315. Surgical portosystemic shunts versus transjugular intrahepatic portosystemic shunt for variceal haemorrhage. Brand M, Prodehl L.

NEW REGISTERED TITLES

493. Diagnostic test accuracy of transabdominal ultrasound or endoscopic ultrasound for diagnosis of gallbladder polyps. Wennmacker SZ, Lamberts M, Gurusamy KS, Drenth JPH, van Laarhoven CJHM.
494. Direct-acting antivirals for chronic hepatitis C. Jakobsen JC, Gluud C.
495. Direct-acting antivirals for chronic hepatitis C: a network meta-analysis. Jakobsen JC, Gluud C.
496. Total serum bile acids or serum bile acid profile for the diagnosis of intrahepatic cholestasis of pregnancy. Manzotti C, Casazza G, Stimac T, Nikolova D, Gluud C.
497. Magnetic resonance imaging performed with gadoxetate disodium for the diagnosis of hepatocellular carcinoma in people with or without cirrhosis. Thomas H, Vu K-N, Amre D, Tang A, McInnes M, Wolfson T, Roy C, Sirlin C.

PAST EVENTS

THE INTERNATIONAL LIVER CONGRESS™ 2015 APRIL 22 TO 26 -- VIENNA, AUSTRIA -- THE COCHRANE HEPATO-BILIARY GROUP MEETING AND STAND AT THE EXHIBITION

During the congress, the CHBG ran its 36 bi-annual meeting on April 23, at room Schubert 6, Reed Messe.
We thank all people who delivered presentations or attended the meeting, or the exhibition stand.

WORKING VISIT

From August 22 to August 28, 2015, Christian Gluud, Goran Bjelakovic, and Dimitrinka Nikolova were on a working visit in Palermo, Italy to work together with Rosanna Simonetti (the host) and Giovanni Perricone on a review with a title: "Plasma expanders for people with cirrhosis and large ascites treated with abdominal paracentesis". The team work allowed discussion of review issues, and in this way, to bring it much quicker to completion.

BI-ANNUAL CHBG WEB-BASED AND FACE-TO-FACE EDITORS' MEETING

On August 27, we also had a bi-annual CHBG web-based and face-to-face editors' meeting that started at 4 pm. We would like to acknowledge the hospitality of Giovanni Merlino, Luigi Galvano, Gaetano Ferraro, and Francesco Agnese who made us feel at home at the beautiful Villa Magnisi, at Ordine dei Medici Chirurghi e degli Odontoiatri della Provincia di Palermo (Via Rosario da Partanna 22, Palermo 90100, Italy) during the afternoon visit of 27 of August. We would also like to extend our special thanks to Rosa Simonetti for an excellent organization and hospitality.

Luigi Pagliaro, our former CHBG editor, was invited to attend the editors' meeting, as Luigi Pagliaro, despite his retirement, is still interested in the work of The CHBG. Luigi Pagliaro talked about his personal views on evidence-based medicine. This talk is now 'waiting publication article' and can be found at www.sciencedirect.com/science/article/pii/S1590865815006167. We strongly recommend it to you, and Luigi Pagliaro will be most happy to receive

comments on it.
Gennaro D'Amico, from Italy, and Davor Stimac, from Croatia, were also present to our 'face-to face editors' meeting.
Among the items discussed during the meeting were prioritisation of topics for systematic reviews and their preparation; core outcomes for the different types of hepatitis; involving young physicians in review preparation; outdated reviews; and the 37th Cochrane Hepato-Biliary Group meeting, an affiliate Event at the 2015 Liver Meeting® in San Francisco, US.

CORE OUTCOMES FOR CHRONIC HEPATITIS B AND CHRONIC HEPATITIS C VIRUS INFECTIONS

For years core outcomes have been discussed, also within The CHBG. We acknowledge that it is difficult to find common ground on which all feel comfortable. However, focusing on the patients interests, the Editorial Team has reached some agreement on the following core outcomes for chronic hepatitis B and C infection. We need to consider the type of outcomes and their number. To ensure a clear message, which the clinical community can react on, the number of outcomes should not be high. We still welcome suggestions for improvement **before 1st of December 2015**.

CORE OUTCOMES FOR CHRONIC HEPATITIS B VIRUS INFECTION

Primary outcomes

- All-cause mortality or hepatitis B-related morbidity (number of participants who developed cirrhosis, ascites, variceal bleeding, hepato-renal syndrome, hepatocellular carcinoma, or hepatic encephalopathy and who have not died). These outcomes will be tested as a composite outcome as well as individually (mortality or morbidity). Such composite outcomes need to be interpreted with caution, especially if the components are influenced differently by the intervention.
- Health-related quality of life (any valid assessment scale, filled out by the participant).
- Serious adverse events, that is, any untoward medical occurrence that results in death, is life threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect (The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (ICH-GCP 1997)).

Secondary outcomes

- Mortality due to hepatitis B-related liver disease.
- Non-serious adverse events. Any untoward medical occurrence in a participant or clinical investigation participant that does not meet the above criteria for a serious adverse event is defined as a non-serious adverse event.
- Number of participants without histological improvement.
- Number of participants with detectable HBsAg in serum or plasma.
- Number of participants with detectable HBV DNA in serum or plasma.

Exploratory outcomes

- Number of participants with detectable HBeAg in serum or plasma (this outcome is only relevant for HBeAg-positive participants).
- Number of participants without HBeAg seroconversion in serum or plasma (this outcome is only relevant for HBeAg-positive participants).
- Number of participants without normalisation of transaminases.

CORE OUTCOMES FOR CHRONIC HEPATITIS C VIRUS INFECTION

Primary outcomes

- All-cause mortality or hepatitis C-related morbidity (number of participants who developed cirrhosis, ascites, variceal bleeding, hepato-renal syndrome, hepatocellular carcinoma, or hepatic encephalopathy and who have not died). These outcomes will be tested as a composite outcome as well as individually (mortality or morbidity). Such composite outcomes need to be interpreted with caution, especially if the components are influenced differently by the intervention.
- Health-related quality of life (any valid assessment scale, filled out by the participant).
- Serious adverse events, that is, any untoward medical occurrence that results in death, is life threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect (The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (ICH-GCP 1997)).

Secondary outcomes

- Mortality due to hepatitis C-related liver disease.
- Non-serious adverse events. Any untoward medical occurrence in a participant or clinical investigation participant that does not meet the above criteria for a serious adverse event is defined as a non-serious adverse events.
- Number of participants without histological improvement.
- Failure of virological response: number of participants without sustained virological response, i.e., number of participants with detectable hepatitis C virus RNA (i.e., above lower limit of detection) in the serum by a sensitive PCR-based essay or by a transcription-mediated amplification testing 12 and 24 weeks after end of treatment.

Exploratory outcomes

- Number of participants without normalisation of transaminases.

References:

- International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use. ICH harmonised tripartite guideline. Guideline for good clinical practice CFR & ICH Guidelines. Vol. 1. Pennsylvania, USA: Barnett International/PAREXEL, 1997.

Information in general on core outcome sets can be found on http://www.comet-initiative.org/

Core outcomes for hepatitis A, D, and E will also be suggested by CHBG editors by the end of the year, and these outcomes will be presented on the CHBG website (hbg.cochrane.org).

THE 23RD COCHRANE COLLOQUIUM, VIENNA, AUSTRIA OCTOBER 3 TO 7, 2015

Cochrane colloquia provide an annual forum where Cochrane staff come together to share ideas and information, hold important meetings, and learn.

The colloquium theme was: "Filtering the information overload for better decisions".

A wide and varied program of plenaries, special sessions, research, and workshops were run. The social and cultural programme was interesting, and all events were well attended.

COLLOQUIUM HIGHLIGHTS

COCHRANE STEERING GROUP ANNOUNCES MAIN DECISIONS FROM MEETING IN VIENNA

From early 2016, the Cochrane Steering Group decided the following:

1. All Cochrane Protocols will be available Open Access via the Cochrane Library.
2. All Cochrane Reviews will be automatically deposited in PubMed Central 12 months after publication.

3. Will explore the provision of a limited number of vouchers for discounted 'Gold' Open Access to Cochrane's funding agencies; which means that funders can get immediate Open Access for a selected number of Cochrane Reviews at a discounted rate.

http://community.cochrane.org/news/tags/authors/cochrane-steering-group-announces-main-decisions-meeting-vienna

REBRANDING OF COCHRANE AND ITS GROUPS

'The Cochrane Collaboration' is now 'Cochrane'. The look of the logo is updated. Some Cochrane groups have modified their names, but The Cochrane Hepato-Biliary Group has not. We continue to be The CHBG!

DEVELOPING PLAIN LANGUAGE SUMMARIES FOR DIAGNOSTIC TEST ACCURACY (DTA) REVIEWS

A plain language summary (PLS) is a stand-alone summary of the systematic review. The results of DTA reviews are more complex, and their results may not be that understandable for a non-specialist, such as consumers. Currently, Cochrane is working on a project investigating how results and other review information is best described in a plain language so that guidelines for a PLS become available.

SYSTEMATIC REVIEWS OF PROGNOSTIC STUDIES

The Cochrane Prognosis Methods Group is responsible for the development of guidelines and methods for systematic reviews of prognostic studies. So far, there are three protocols published in the Cochrane Database for Systematic Reviews. The CHBG is also considering registration of such reviews sometimes during 2016 or as soon as guidelines are drafted. However, we can obtain a protocol template, search strategy guidelines, and critical appraisal and meta-analytical guidance form the conveners of the group. If you are interested, please contact us.

TRIAL SEQUENTIAL ANALYSIS – A STATISTICAL METHOD FOR META-ANALYSES

Each meta-analysis is linked with statistical problems connected with type I errors and type II errors, and these errors, known as multiplicity, increase with each update of the meta-analysis. Misleading results can be produced. Trial Sequential Analysis (TSA), developed by researchers at The Copenhagen Trial Unit, Centre for Clinical Intervention Research at Rigshospitalet in Copenhagen, Denmark, is a method that The CHBG as well as other Cochrane groups have been using during the past seven years.

A TSA workshop was run at the 2015 Cochrane colloquium in Vienna, and there have been ardent advocates for it, but also people who were not convinced that TSA would help. Cochrane has started working on a project that aims at identifying statistical methods that the review groups can use, when sparse data are present or when repetitive analyses are conducted.

DIAGNOSIS: THE PATHWAY OF A DIAGNOSTIC TEST FROM BENCH TO BEDSIDE

This basic residential course was planned to be run in September 20 to 23, 2015 at Palazzo Feltrinelli Gargnano, Lago di Garda, Italy, but due to insufficient number of applicants, the course had to be cancelled. We do hope to be able to organize a diagnostic test course in 2016.

New possibilities will be looked after in order to run a shorter, less expensive course in Milan in the early 2016. It was suggested that the course combined diagnostic test accuracy with therapeutic accuracy.

FUTURE EVENTS

37TH CHBG MEETING DURING THE LIVER® MEETING, SAN FRANCISCO, CA, USA. NOVEMBER 13 TO NOVEMBER 17, 2015

The 37th bi-annual Cochrane Hepato-Biliary Group (CHBG) meeting, affiliate event at The Liver Meeting®, will be run November 16th, 2015, from

6:30pm to 8:00pm, in room "Sierra E", on the 5th floor, at the Marriott Marquis, 780 Mission Street, San Francisco, CA, USA.
The program is distributed with this newsletter.

CHBG EXHIBITION STAND DURING THE LIVER® MEETING, SAN FRANCISCO, CA, USA. NOVEMBER 13 TO NOVEMBER 17, 2015. BOOTH NO. 633

CHBG exhibitions have become the meeting place for editorial staff to meet with CHBG collaborators in person and discuss work, provide technical help, advice, or just say 'hallo'. We will be happy to see as many of you as possible.

38TH CHBG MEETING DURING THE LIVER® CONGRESS™, BARCELONA, SPAIN.

The International Liver Congress™ 2016 will take place from 13 to 17 April, 2016 at the Fira Barcelona Gran Via, Barcelona, Spain.

A joint workshop, EASL – CHBG, will be run Wednesday **13 April 2016**, from 08:00 to 11:00 in Hall 8.0-F8 of Fira Barcelona.

Description:
Based on four systematic reviews of interventions for different liver conditions (chronic hepatitis C; hospitalized liver patients; primary biliary cirrhosis; and hepatic encephalopathy) the harms and benefits of different interventions for these conditions will be evaluated in Cochrane Hepato-Biliary systematic reviews with meta-analysis, Trial Sequential Analysis, and network meta-analysis. Furthermore, non-invasive diagnostic tests for oesophageal varices will be assessed in a Cochrane Hepato-Biliary diagnostic accuracy test review. The learning objectives are to understand the powers and weaknesses of systematic reviewing outperforming even large single randomised clinical trials.

Chair: Christian Gluud (Denmark), Cecilia Rodrigues (Portugal).

Presentations:

08:00 - 08:05 Welcome. Speaker: Christian Gluud (DK), Cecilia Rodrigues (PT).

08:05 - 08:35 Direct acting antivirals: do they work beyond sustained virological response in chronic hepatitis C patients? Speaker: Ronald L. Koretz (US).

08:35 - 09:05 The effects of nutrition to hospitalized liver patients – a systematic review. Speaker: Joshua Rose-Hansen Feinberg (DK).

09:05 - 09:30 Ursodeoxycholic acid for primary biliary cirrhosis – a systematic review. Speaker: Jelena S. Rudic (Republic of Serbia).

10:00 - 10:30 Non-invasive diagnostic tests for oesophageal varices – a systematic review. Speaker: Agostino Colli (I).

10:30 - 11:00 Nonabsorbable disaccharides for hepatic encephalopathy – a systematic review. Speaker: Lise Lotte Gluud (DK).

For further information, please visit
http://ilc-congress.eu/ilc-2016-barcelona

The CHBG will also have a booth. More details will follow in the next 2016 CHBG Newsletter as well as on The CHBG website [hbg.cochrane.org].

VISITORS

Chavdar S Pavlov, from Russia, visited the Editorial Team Office of The CHBG in Copenhagen, Denmark from 7 to 17 of April, 2015. Chavdar Pavlov worked on updating the protocols of two intervention reviews with titles: S-adenosyl-L-methionine for alcoholic liver disease and Glucocorticosteroids for people with alcoholic hepatitis before the reviews are updated.

Maoling Wei, from China, visited the Editorial Team Office of The CHBG in Copenhagen, Denmark on 22 and 23 of June 2015. The purpose of Maoling Wei's visit was to learn more about CHBG editorial work and explore possibilities for collaboration in the field of clinical trials conductance. CHBG is hosted by The Copenhagen Trial Unit.

Volume 18, Issue 2

Karl Heinz Weiss and **Kilian Friedrich**, from Germany, visited the Editorial Team Office of The CHBG in Copenhagen, Denmark on 22 and 23 of September 2015. The purpose of their visit was to discuss the update of the Transarterial (chemo)embolisation for unresectable hepatocellular carcinoma review together with Janus Christian Jakobsen and Christian Gluud. The two guests were also introduced to Trial Sequential Analysis and Cochrane methodology.

Cristina Manzotti, from Italy, came to the Editorial Team Office of The CHBG in Copenhagen, Denmark September 20, 2015 to work on the diagnostic test accuracy review "Total serum bile acids or serum bile acid profile for the diagnosis of intrahepatic cholestasis of pregnancy". Cristina Manzotti has also submitted the protocol for peer reviewing. She is expected to have drafted the review during her three months-stay.

THE CHBG WEBSITE

The CHBG website [hbg.cochrane.org] has now a new look following the Cochrane re-brand initiative. More work on it is to be done towards the end of the year.
Authors of CHBG reviews and contributors are requested to check for relevant 'Information for authors' on [hbg.cochrane.org], in addition to the [cochrane.org] website.

THE COCHRANE EDITORIAL AND PUBLISHING POLICY RESOURCE

Review authors are advised to read carefully the information provided at www.cochrane.org/editorial-and-publishing-policy-resource and encompassing permissions to reuse material from Cochrane sources, reprints of Cochrane Reviews, correspondence, dissemination, and impact, feedback, dissemination, translation and alike.
Cochrane review authors are not allowed to send manuscripts of their Cochrane reviews for publication in paper journals without obtained permissions to do so, from the Cochrane Editorial Unit. Please read the Cochrane co-publication policy on these issues.

The Cochrane Hepato-Biliary Group (The CHBG) Newsletter is written, edited, and published in electronic and paper format by Dimitrinka Nikolova and Christian Gluud at The CHBG Editorial Office in Copenhagen, Denmark.

It is issued twice a year and is also distributed for free world-wide to all people on The CHBG members' list who have contributed, are contributing, or have shown interest in the work of The CHBG or in this CHBG Newsletter.

The purpose with The CHBG Newsletter is to inform its readers about activities of The CHBG.

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THE COCHRANE HEPATO-BILIARY GROUP

BI-ANNUAL MEETING PROGRAMME

THE CHBG

The 37th bi-annual Cochrane Hepato-Biliary Group (The CHBG) meeting, affiliate event* at The Liver Meeting®, will be run

November **16th, 2015, from 6:30pm to 8:00pm**, in room "**Sierra E**", on the **5th** floor,

at the **Marriott Marquis**, 780 Mission Street, San Francisco, CA, USA.

You are kindly invited to participate in the meeting while attending The Liver Meeting® 2015/the 66th AASLD Annual Meeting.

There is no registration fee.

Chair: Christian Gluud (DK).

6:30pm to 6:35pm	Welcome and program introduction.	C Gluud (DK).
6:35pm to 6:55pm	Endoscopic ultrasound versus magnetic resonance cholangiopancreatography for common bile duct stones. A Cochrane systematic review.	Giljaca V (HR), Gurusamy KS (UK), Takwoingi Y (UK), Higgie D (UK), Poropat G (HR), Štimac D (HR), Davidson BR (UK).
6:55pm to 7:15pm	Nutritional support for liver disease. A Cochrane systematic review.	Koretz RL (US), Avenell A (UK), Lipman TO (US).
7:15pm to 7:35pm	Plasma expanders for people with cirrhosis and large ascites treated with abdominal paracentesis. A Cochrane systematic review.	Simonetti RG (I), Perricone G (I), Nikolova D (DK), Bjelakovic G (RS), Gluud C (DK).
7:35pm to 7:55pm	Is a sustained virologic response in hepatitis C really a cure?	Koretz RL (US).
7:55pm to 8:00pm	Questions and closing remarks.	All.

*This is not an official event of the American Association for the Study of Liver Diseases.

Improving healthcare decision-making globally, through systematic reviews of the effects of healthcare interventions, published in *The Cochrane Library*.

The CHBG website: hbg.cochrane.org