Complete Summary

GUIDELINE TITLE

Chronic hepatitis B infection.

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Chronic hepatitis B infection. Singapore: Singapore Ministry of Health; 2003 Mar. 30 p. [43 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chronic hepatitis B infection

GUIDELINE CATEGORY

Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide guidance on the primary prevention of hepatitis B infection through vaccination
- To provide guidance on the management of patients with chronic viral hepatitis B infection in terms of surveillance for hepatocellular carcinoma and treatment of chronic hepatitis B infection

TARGET POPULATION

- Patients of all ages in Singapore suspected or known to be in need of immunity from hepatitis B infection (Prevention; Screening)
- Patients of all ages in Singapore with chronic hepatitis B infection (Management; Treatment)

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention/Screening

1. Serological screening for hepatitis B surface (HBs) antigen and antibody (HBs Ag, anti-HBs IgG)
2. Hepatitis B vaccination
3. Hepatitis B immunoglobulin

Management/Treatment

1. Surveillance for hepatocellular carcinoma (HCC) in patients with chronic hepatitis B virus (HBV) infection using ultrasonography (U/S) and serum alpha-fetoprotein (s. AFP)
2. Surveillance of exacerbation of hepatitis B by checking serum alanine transaminase (ALT) levels
3. Individualized treatment of chronic hepatitis B with interferon–alpha, thymosin alpha-1, or lamivudine
4. Referral, as indicated, to gastroenterologists/hepatologists

MAJOR OUTCOMES CONSIDERED

- Herd immunity for hepatitis B infection
- Morbidity and mortality related to chronic hepatitis B infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials.

Level Ib: Evidence obtained from at least one randomised controlled trial.

Level IIa: Evidence obtained from at least one well-designed controlled study without randomisation.

Level IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies.

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations that follow are those from the guideline's executive summary; detailed recommendations can be found in the original guideline document. Each recommendation is rated based on the level of the evidence and the grades of recommendation. Definitions of the grades of the recommendations (A, B, C, Good Practice Points) and level of the evidence (Level I-Level IV) are presented at the end of the Major Recommendations field.

Hepatitis B Screening and Vaccination

A - Serological screening for hepatitis B surface (HBs) antigen and antibody (HBs Ag, anti-HBs IgG) should be done within 6 months pre-vaccination for all, except newborns (Alderman et al., 1998). Hepatitis B vaccinations, except for newborns, should be given at months 0, 1, and 6, and anti-HBs IgG should be checked within

3 months after the booster dose at month 6. For newborns, vaccinations are given at months 0, 1, and 5. Newborns of hepatitis B virus–infected mothers who are hepatitis B e antigen (HBeAg) positive should also be given hepatitis B immunoglobulin at birth. (Grade A, Level Ib)

Hepatocellular Carcinoma (HCC) Surveillance for Patients with Chronic Hepatitis B Virus (HBV) Infection

GPP - Patients should be told of the risks of hepatocellular carcinoma (HCC) associated with chronic hepatitis B infection and offered the option of hepatocellular carcinoma surveillance. For patients who are agreeable to surveillance, ultrasonography and serum alpha-fetoprotein should be done at regular intervals. Ultrasonography should be done at 6- and 12-monthly intervals for cirrhotic and non-cirrhotic patients, respectively. Patients' blood should be sampled for alpha-fetoprotein every 3 to 6 months and 6 to 12 months for cirrhotic and non-cirrhotic patients, respectively. (GPP)

Surveillance of Exacerbation of Hepatitis B

GPP - Patients with normal serum alanine transaminase (ALT) levels should have 6-monthly outpatient follow-up visits with repeat serum ALT done at each visit. Patients with elevated serum ALT levels should have more frequent follow-up visits, with repeat liver function tests carried out based on the physician-in-charge's discretion. (GPP)

Treatment of Chronic Hepatitis B

B - Viraemic patients (i.e., patients who are hepatitis B e antigen [HBeAg] positive and/or hepatitis B virus deoxyribonucleic acid [HBV DNA] positive) should be considered for treatment if the serum ALT is persistently (three or more readings) above twice the upper limit of normal. The three currently available choices of therapeutic agents are interferon–alpha, thymosin alpha-1, and lamivudine. Choice of the available therapeutic agents should be individualised, taking into consideration the contraindications for use in specific patients. (Grade A, Levels Ia & Ib)

Definitions:

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials.

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Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies.

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the assessment and management of chronic hepatitis B virus infection.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- High levels of hepatitis B vaccination in the community would help ensure a better herd immunity against hepatitis B virus infection.
- Timely treatment of chronic hepatitis B can prevent development of its associated complications. In addition, preliminary data suggest better therapeutic outcomes with early detection of hepatitis B-related hepatocellular carcinoma.

POTENTIAL HARMS

- Interferon–alpha: Hepatic decompensation may sometimes occur with interferon treatment. Treatment should be withdrawn promptly with the occurrence of jaundice.
- Lamivudine: After withdrawal from lamivudine, patients may develop marked elevation of serum alanine transaminase (s. ALT) with potential risk of hepatic decompensation associated with acute-on-chronic hepatitis B.

CONTRAINDICATIONS

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- Hepatitis B vaccination is contraindicated for those who are allergic to the hepatitis B vaccine or its preservative.
- Interferon-alpha is contraindicated in patients with decompensated liver disease and co-existing autoimmune diseases.

QUALIFYING STATEMENTS

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- These guidelines are not intended to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.
- The contents of the guideline document are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient in the light of the clinical data presented by the patient and the diagnostic and treatment options available.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The following are some suggested clinical audit parameters, based on recommendations in these guidelines:

- Proportion of patients (other than newborns) who received hepatitis B vaccination who had had serological screening for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis B surface antigen (anti-HBs IgG) done within 6 months pre-vaccination
- Proportion of newborns of hepatitis B e antigen (HBeAg) positive mothers who were given hepatitis B immunoglobulin at birth
- For patients with chronic hepatitis B virus infection, proportion of patients with normal serum alanine transaminase (ALT) levels who had 6-monthly outpatient follow-up visits with repeat serum ALT done at each visit

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar

GUIDELINE DEVELOPER(S)

Singapore Ministry of Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Singapore Ministry of Health

GUIDELINE COMMITTEE

Workgroup on Chronic Hepatitis B Infection

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Prof Ng Han Seong, Department of Gastroenterology, Singapore General Hospital (Co-Chairman); Dr Roland Chong, Roland Chong Gastroenterology & Medical Clinic (Co-Chairman); Dr Richard Guan, Mt Elizabeth Medical Centre; Dr Ivy Yap, Mt Elizabeth Medical Centre; Prof Fock Kwong Ming, Medical Board, Changi General Hospital; Prof Ng Keng Yeen, Department of Gastroenterology, Singapore General Hospital; Assoc Prof Lim Seng Ghee,

Department of Gastroenterology, National University Hospital; Dr Chow Wan Cheng, Department of Gastroenterology, Singapore General Hospital (Secretary)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Singapore Ministry of Health Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 28, 2003.

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