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| Title | Serum Alpha-Fetoprotein (AFP) and/or Ultrasound (US) for Hepatocellular Carcinoma (HCC) Screening |
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Aim

To review evidence on the efficacy/effectiveness and cost-effectiveness of using serum AFP and/or US for HCC detection in the high-risk group in Ministry of Health (MOH) facilities

Conclusions and results

There was good level evidence on effectiveness (mortality and survival rate) to demonstrate the benefits in screening for HCC using serum AFP and/or US in a high-risk group. There was also good level evidence which indicated that the combination of serum AFP and US is the most suitable method to be used for HCC detection, particularly for HCC related with chronic liver infection due to Hepatitis B virus (HBV). In addition, the recommended cut-off level of serum AFP was ≥ 20.0 ng/mL, as evidence showed that there was an optimal balance between sensitivity and specificity in detecting HCC at this cutoff level.

From the cost-effectiveness perspective, most of the studies in the review indicated that 12-months screening interval using serum AFP plus US was as cost-effective as the 6-months interval using serum AFP alone. Hence, the screening interval of 6 to 12 months was a reasonable cost-effective strategy for surveillance of HCC.

In the Malaysian context, the fees charged by MOH hospitals for serum AFP is approximately RM35.00 per test, while US varied from RM17.00 to RM100.00 per imaging. Ultrasound machines cost about RM 30,000 and range up to RM 600,000 (USD\$10,000 to USD\$200,000). The price depends largely on the level of complexity of the machine.

Recommendations

Based on this review, screening for HCC using serum AFP and/or US in the high-risk group can be established as part of the Malaysian National Cancer Control Programme. The decision to enter a patient into a screening programme is determined by the level of risk for HCC and hence, surveillance is recommended for the following groups of patients:

- i. Hepatitis B carriers:
 - Asian males ≥ 40 years
 - Asian females ≥ 50 years
- ii. All cirrhotic hepatitis B regardless of age
- iii. Family history of HCC

- iv. Liver cirrhosis

- Hepatitis C
- Alcoholic cirrhosis
- Genetic hemochromatosis
- Primary biliary cirrhosis

Methods

The following electronic databases were searched: MEDLINE (1950 March 2012), EBM Reviews-Cochrane Database of Systematic Reviews (2005 to May 2012), EBM Reviews-Cochrane Central Register of Controlled Trials (1st Quarter 2012), EBM Reviews-HTA Databases (1st Quarter 2012), EBM Reviews-Cochrane Methodology Register (1st Quarter 2012), EBM Reviews-ACP Journal Club (1991 to May 2012), EBM Reviews-NHS Economic Evaluation Database (1st Quarter 2012) via OVID, PubMed, INAHTA database, HTA database and US FDA database. The last search was run on 10 May 2012. No limits were applied to the search. The search strategy is detailed in Appendix 4. Additional articles were identified from reviewing the bibliographies of retrieved articles and hand-searching of journals. A general search engine was used to obtain additional web-based information.

Further research/reviews required

Before commencing the screening programme for HCC detection, it should be noted that currently in Malaysia, serum AFP tests are conducted at laboratory hospitals with immunoassay facilities (MOH state hospitals and hospitals with specialists) amounting to 36 MOH hospitals (personal communication with Head of Chemical Pathology Activities, MOH). Meanwhile, US examination of the liver is conducted in 39 MOH hospitals with radiologist (personal communication with Head of Radiology Service, MOH).

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