HAIFU®MODUL-JC FOCUSED ULTRASOUND TUMOR THERAPEUTIC SYSTEM-AN UPDATE
Executive Summary

[Adapted from the report by Ku Nurhasni Ku Abd Rahim]

Review Group Membership

MaHTAS Reviewer:
Ku Nurhasni Ku Abd Rahim
Datin Dr. Rugayah Bakri

External Reviewer:
Dr. Gerard Lim Chin Chye

Disclaimer:
Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It is subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

For further information please contact:

Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya.

Tel: 603 8883 1246

Fax: 603 8883 1230

Available at the following website:
http://www.moh.gov.my

2013

Introduction

High-intensity focused ultrasound which is also known as focused ultrasound ablation or focused ultrasound surgery is a hyperthermia therapy that uses temperature to treat disease. It uses ultrasound at high intensity and ultrasound beam is being focused at a specific target area to destroy cells. Typically, high-intensity focused ultrasound (HIFU) procedures are performed in conjunction with an imaging guidance namely magnetic resonance imaging (MRI) or diagnostic sonography as the imaging procedure enables the treatment planning and targeting before applying the ablative levels of ultrasound energy.

Objective/Aim

To assess the new evidence from 2011 onwards on the efficacy/effectiveness, safety and cost/cost effectiveness of Haifu® Model-JC Focused Ultrasound Tumor Therapeutic System for treatment of solid tumor.

Results and Conclusions

From the systematic search conducted in the available scientific databases and other websites, there was no retrievable systematic review or randomized controlled trial on Haifu® Model-JC Focused Ultrasound Tumor Therapeutic System for treatment of solid tumor. However, there were 8 literatures consisting of non-randomized single arm trials, case series, cohort study and case report on the efficacy/effectiveness and safety of Haifu® Model-JC Focused Ultrasound Tumor Therapeutic System for treatment of patients with hepatocellular carcinoma, advanced pancreatic cancer and uterine fibroids which were included in this review. No recent evidence was retrieved on other types of solid tumor.

In conclusion, there were limited fair level of evidence from recent publications retrieved from the available scientific databases on the efficacy/effectiveness and safety of Haifu® Model-JC Focused Ultrasound Tumor Therapeutic System for the treatment of hepatocellular carcinoma, advanced pancreatic cancer and uterine fibroid. Further research such as randomized controlled trial is warranted to provide high quality of evidence before it can be used as standard treatment for solid tumor.

Complications related to skin which were also reported in earlier technology review report were the most commonly reported complication from the available evidence. Other complications namely body temperature increase, abnormal cardiac rhythm, injuries of sternal vertebrae and vertebrae lumbales, acute cholecystitis, nausea, ileus, anorexia and abdominal pain, transient pancreatitis,sacrococcyx pain, hip pain, radiating pain in the lower limbs, pancreatic fistula and gastrointestinal tract bleeding due to gastric ulcer have also been reported in the literature. Thus, it is important for the clinicians to monitor the adverse events during and after the HIFU treatment.

The cost-effectiveness of Haifu® Model-JC Focused Ultrasound Tumor Therapeutic System for treatment of solid tumor cannot be determined as there were no local economic studies retrieved from the scientific databases.

Methods

Scientific electronic databases were searched through OVID interface which include MEDLINE(R) In-process and other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials-December 2012. EBM Reviews – Database of Abstracts of

Review of Effects (4th Quarter 2012), EBM Reviews - Cochrane database of systematic reviews - 2005 to November 2012 , EBM Reviews – Cochrane Methodology Register 3rd Quarter 2012, EBM Reviews - Health Technology Assessment - 4th Quarter 2012 , NHS economic evaluation database - 4th Quarter 2012, Pubmed and USFDA website.

Last search was done on 16th January 2013 and there was no limitation during the search. Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and evidence graded according to the US / Canadian Preventive Services Task Force