INAHTA Brief 2017/003

Title Stereotactic Radiation Therapy for Liver Tumours

Agency HAS (French National Authority for Health - Haute Autorité de Santé)
5 avenue du Stade de France – F 93218 La Plaine Cedex, France
Tel.: +33 (0)1 55 93 70 00 – Fax: +33 (0)1 55 93 74 35, contact.seap@has-santé.fr, www.has-sante.fr

Reference ISBN number: 978-2-11-151438-6, link to full report in French: http://www.has-sante.fr/portail/jcms/c_2565031/fr/radiotherapie-en-conditions-stereotaxiques-des-tumeurs-hepatiques-rapport-d-evaluation-technologique

Aim

The purpose of this report was to analyse the efficacy and safety data of Stereotactic Body Radiation Therapy (SBRT) in patients with inoperable primary (hepatocellular carcinoma (HCC) and metastatic liver tumours (LM), to define the indications and the place of SBRT in the therapeutic strategy with the aim of its inclusion in the CCAM (French National list of reimbursement).

Conclusions and results

The key points that arose from this assessment are the following:

- The results are preliminary and the literature is inconclusive about safety and efficacy;
- There are no standardised guidelines for: the indications, the eligibility criteria, the treatment protocols or the place of SBRT in the therapeutic strategy;
- SBRT is a technique that requires great rigorous radioprotection and quality assurance procedures; the professionals and National institutions concerned recommend that SBRT only be performed in centres with sufficient resources, specific expertise and an organisation which guarantees that the quality assurance procedures will be respected.

Recommendations

HAS believes it is premature to recommend SBRT for the routine treatment of liver tumours and its reimbursement by the National Health Insurance (Assurance Maladie). .
HAS recommends its use in the strict context of clinical research by centres with sufficient resources, specific expertise and an organisation which guarantees that the quality assurance procedures will be respected.

Methods

The literature search strategy prioritized randomised comparative studies and systematic reviews; If these were not available then non-randomised controlled trials, prospective studies were to be used and finally retrospective studies and case series were to be used.
The assessment of SRBT for liver tumours was based on the critical analysis of clinical data from:

- Three prospective case series, five retrospective case series, four health technology evaluation reports and 11 good practice recommendations, for primary liver tumours (HCC)
- One prospective case series, five retrospective case series, four health technology evaluation reports and one good practice recommendation for liver metastasis.

The results of this analysis were supplemented by a consultation with ten stakeholders (CNPCVD[1], CNPHGE[2], CPRF[3], SFCO[4], CNPOM[5], ASN[6], IRSN[7], SFPM[8], SFRO[9], SFRP[10]), which were interviewed via a questionnaire about aspects related to clinical aspects (ten questions) and radioprotection (four questions).

The whole report has been reviewed by the National Commission for the Assessment of Medical Devices and Health Technologies and then validated by the HAS Board.

Written by

Nadia Zeghari-Squalli, HAS (French National Authority for Health - Haute Autorité de santé), France.

[1] Conseil national professionnel de chirurgie viscérale et digestive [National Professional Council of Visceral and Digestive Surgery].

[2] Conseil national professionnel d'hépato-gastro-entérologie [National Professional Council of Hepatogastroenterology].

[3] Conseil professionnel de la radiologie française [French Professional Council on Radiology].

[4] Société française de chirurgie oncologique [French Society of Surgical Oncology].

[5] Conseil national professionnel d'oncologie médicale [National Professional Council of Medical Oncology].

[6] Autorité de sureté nucléaire [Authority for Nuclear Safety].

[7] Institut de radioprotection et de sûreté nucléaire [French Institute for Radiological Protection and Nuclear Safety].

[8] Société française de physique médicale [French Society of Medical Physics].

[9] Société française de radiothérapie oncologique [French Society of Oncological Radiation Therapy].

[10] Société française de radioprotection [French Society for Radiological Protection].