

Title	Conformational intensity-modulated radiation therapy in cervical cancer
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Aim

This report aims to assess the clinical effectiveness and safety of conformational intensity-modulated radiotherapy (IMRT) for the treatment of cervical cancer, in view of reimbursement of IMRT by National Health Insurance, the comparator being conformational three-dimensional radiation therapy (3D-CRT).

Conclusions and results

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

- the strength of evidence of the literature is insufficient to draw conclusions the firm conviction of professionals of the value of this technique in cervical cancer
- a practice that has established itself in France with more than 1600 cases treated per year out of 3000 cases of cervical cancer

In view of these points, HAS believes that the implementation of IMRT treatment for cervical cancer requires:

- maturity of centres in terms of experience, sufficient resources, and specific expertise and organisation ensuring that quality assurance procedures are respected;
- informing patients of the available level of knowledge for this technology and their active involvement in collecting follow-up data in terms of recurrence and long-term toxicity;
- use of a national registry to systematically collect observational data of late toxicity and local relapse rates. These data could be collected and utilised as part of follow-up of patients treated with radiation therapy according to the certification criteria defined by INCA [French National Cancer Institute] and with regard to paragraph 3 of Article R. 6123-88 of the Public Health Code;
- identification of radiation-induced cancers which could be included in the implementation of the national health surveillance system.

Furthermore, HAS feels that it is necessary to collect clinical data (efficacy and toxicity):

- as part of a controlled comparative study: if the IMRT treatment protocols (total dose, dose per fraction,

treatment duration or treatment throughput) are unchanged compared with 3D-CRT.

- as part of controlled randomised studies : if the IMRT treatment of cervical cancers involves, compared with 3D-CRT, a modality that changes the total dose, dose per fraction, treatment duration, treatment throughput (i.e. hypofractionation):
- as part of a comparative analysis which could therefore be done by INCA¹, which coordinates the radiation therapy observatory; The absence of generalisation for IMRT at all the radiation therapy centres in France enables collecting efficacy and safety data in centres performing IMRT and 3D-CRT.

Recommendations

HAS approves the inclusion of intensity-modulated conformational radiation therapy in cervical cancer on the list of procedures and services as long as the considerations mentioned above are met.

Methods

The literature search strategy focused on randomised comparative studies and systematic reviews; failing that non-randomised comparative studies and prospective studies and finally retrospective studies and cases series were used.

Assessment of IMRT in cervical cancer was based on the critical analysis of clinical data from two prospective randomised studies, four prospective case series including one prospective cohort with historical control s, 8 retrospective cases series including two with historical control , , and five good practice recommendations. The results of this analysis were discussed by a panel of multidisciplinary experts (6 radiotherapists, 2 radio-physicists, 2 medical oncologists, 3 OB-GYNs, 2 digestive surgeons, 1 radiologist, and 2 representatives of patients' associations. Professional opinions were collected by stakeholder consultation (five institutions were concerned: ASN², IRSN³, SFPM⁴, SFRO⁵ and SFRP⁶)

¹ Institut National du Cancer

² Autorité de Sûreté Nucléaire [Authority for Nuclear Safety]

³ Institut de Radioprotection et de Sûreté Nucléaire [French Institute for Radiological Protection and Nuclear Safety]

⁴ Société française de physique médicale [French Society of Medical Physics]

⁵ Société française de radiothérapie oncologique [French Society of Oncological Radiation Therapy]

The whole report has been reviewed by the specialized appraisal committee Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (Commission on medical devices and health technologies) and was given final approval by the HAS board.

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⁶ Société française de radioprotection [French Society for Radiological Protection]