

Title	Conformational intensity-modulated radiation therapy in anal canal cancer
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Aim

This report aims to assess clinical effectiveness and safety of conformational intensity-modulated radiotherapy (IMRT) for the treatment of anal canal cancer in view of its reimbursement by National Health Insurance, the comparator being three-dimensional conformational 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 anal cancer;
- a practice that has established itself in France. According to the survey report of the national radiation therapy observatory, it is, with cervical cancer, the 3rd most common indication after, respectively, prostate cancer and upper aerodigestive tract cancer.

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

- mature centres in terms of: experience, sufficient resources, specific expertise for the professionals concerned (radiation therapists, physicists, dosimetrists, etc.) 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 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 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 treatment of anal canal cancers with IMRT involves, compared with 3D-CRT, a treatment 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 INCA, 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 conformational intensity-modulated radiation therapy in anal canal 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 this, non-randomised comparative studies and prospective studies and finally retrospective studies and cases series were included.

The assessment of IMRT in anal canal cancer was based on the critical analysis of clinical data resulting from: 1 prospective case series, 10 retrospective case series including 4 with historical control, and 4 clinical practice guidelines. The results of this analysis were discussed by a panel of multidisciplinary experts (6 radiotherapists, 2 medical oncologists, 2 radio-physicists, 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, the ASN¹, IRSN², SFPM³, SFRO⁴ and SFRP⁵)

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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

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