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Update of proton radiation therapy indications in oncology

English summary

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This is the English summary of the guidance entitled Mise à jour des indications de la protonthérapie en oncologie published in May 2017.

The complete version of this guidance (in French) is available on the website of INESSS in the *Publications* section.

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SUMMARY

Radiotherapy based on photon irradiation, or photon therapy (P*h*T), is an effective treatment modality for several types of cancer. However, it has the disadvantage of affecting healthy tissues surrounding the tumour, which increases the risk of complications, especially if the tumour is close to a vital organ.

Proton therapy (P*r*T) can be proposed as an alternative for certain tumours that are difficult to treat with P*h*T and in pediatrics. P*r*T destroys cancer cells and spares adjacent healthy tissues to a greater degree. Unlike photons, protons release almost all of their energy within the tumour. Therefore, the residual dose to organs outside the target volume is very low. These properties are especially advantageous in children, who are more susceptible to the adverse effects of radiation. However, this technology is expensive. It is therefore reserved for a limited number of patients.

Several professional associations and assessment agencies have proposed a list of indications, including the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS), which, in 2010, identified 5 clinical situations that could justify the use of P*r*T:

- Intraocular melanomas;
- Skull base and spinal chordomas;
- Skull base chondrosarcomas;
- Tumours whose treatment with PhT could damage adjacent tissues, namely, certain meningiomas or intracranial tumours and spinal or paraspinal soft-tissue or bone sarcomas;
- Pediatric tumours (ependymomas, craniopharyngiomas, primary neuroectodermal tumours, Ewing's sarcoma, pineal gland tumours, lymphomas, rhabdomyosarcomas, retinoblastomas and others).

P*r*T is not available in Québec. There is a centre in Vancouver that specializes in the treatment of ocular tumours, and worldwide, there are more than 60 facilities. Québec patients in whom P*r*T is indicated are treated in the United States after their case is evaluated by an expert committee of the Régie de l'assurance maladie du Québec (RAMQ). Since 2010, 76 patients have been treated with P*r*T, at a cost of more than $15 million to the RAMQ.

Since the cost of a P*r*T treatment has doubled in the past 5 years, the Direction générale de cancérologie asked INESSS to update the clinical indications for P*r*T and to then estimate the annual number of patients who might be treated with this modality.

This information brief summarizes the recent evidence from assessment reports and systematic reviews comparing the efficacy and safety of P*r*T with those of P*h*T in the treatment of several types of cancer. Although they are of fairly good quality, the synthesis documents considered include studies that vary widely in terms of their designs, the types of tumours, the clinical indicators examined, the P*h*T and P*r*T

techniques used, and the types of analyses. Furthermore, the methodological biases inherent in retrospective studies and non-controlled prospective studies limit the scope of the conclusions. As well, the most relevant clinical indicators are not systematically reported in all the studies. For all these reasons, it is difficult to rule on the net health benefit of P*r*T in comparison to P*h*T.

Indeed, the evidence does not provide any proof in favour of P*r*T for the indications recognized by most organizations and experts worldwide, with the exception of ocular cancer, pediatric cancers and central nervous system cancers. Furthermore, the level of evidence is weak for the potential indications, which are presently not recognized in Québec. The recommendations in several countries differ with regard to hepatocellular carcinoma, non-small-cell lung cancer, prostate cancer and other clinical situations, such as re-irradiation. However, esophageal and breast cancers are not indications recognized in current practice.

In conclusion, since the quality of the existing data is inadequate, it is presently not relevant to propose treatment with PrT for:

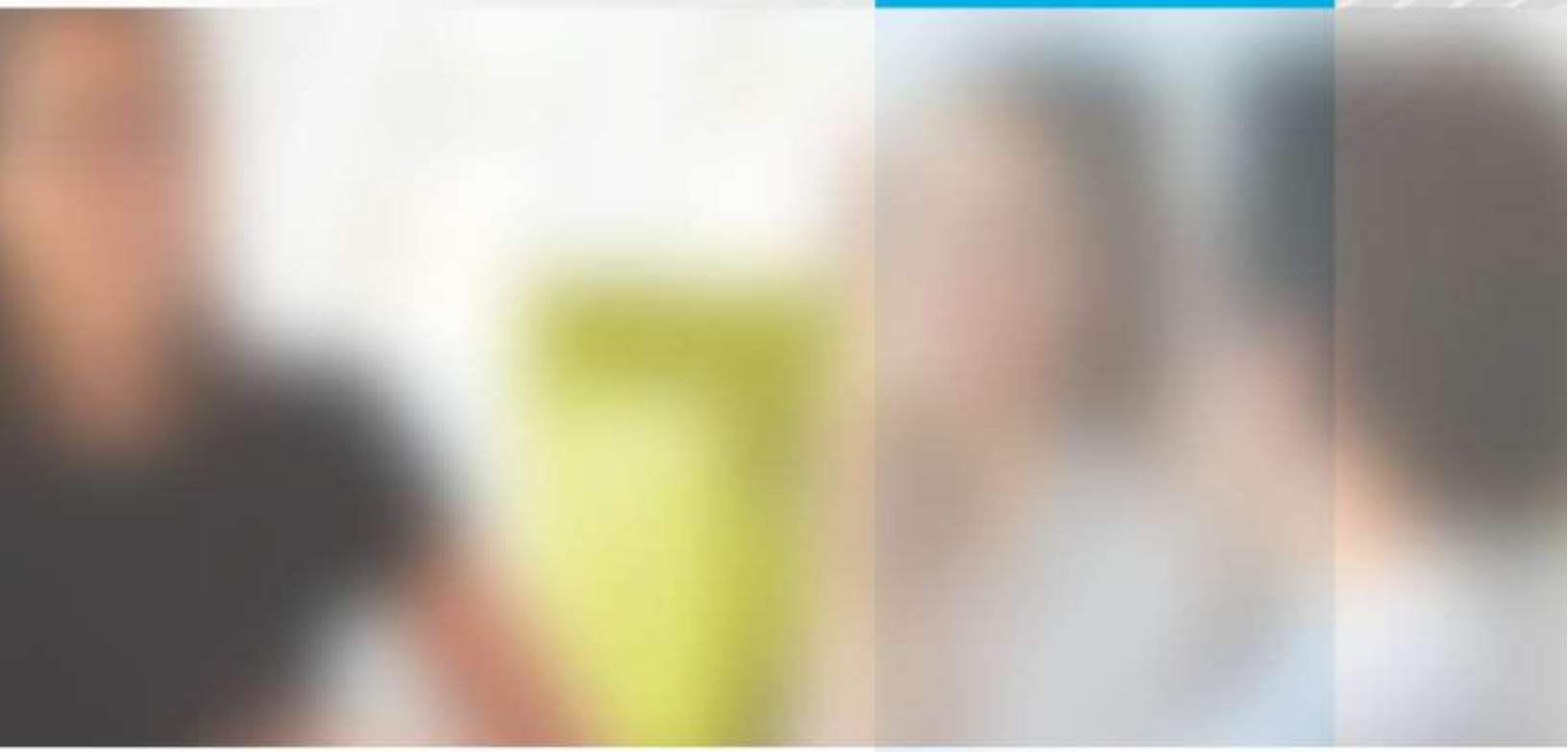
- Non-small-cell lung cancer;
- Hepatocellular carcinoma;
- Prostate cancer;
- Esophageal cancer;
- Breast cancer;
- Re-irradiation cases.

For the indications recognized in Québec, the following principles should be applied when evaluating treatment requests:

- P*r*T should confer to the patient a significant benefit over the latest P*h*T techniques available in Québec, such as image-guided radiotherapy (IGRT), volumetric-modulated arc therapy (VMAT), 4-dimensional radiotherapy or radiosurgery.
- Approved P*r*T treatments should:
  - be curative in intent;
  - be for patients with a good performance score (0 to 2);
  - be for patients with a life expectancy greater than 5 years.
- The patient's ability and willingness to travel should be taken into consideration.
- Whether P*r*T is to be used as first- or second-line treatment, all cases involving patients likely to receive PrT should be discussed within a committee specializing in cancer diagnosis and treatment.
- Every request for P*r*T treatment should be submitted to the Comité provincial de protonthérapie by a radiation oncologist who has evaluated the patient concerned.

Research in the area of P*r*T is growing rapidly, which suggests that the clinical indications for this treatment modality might be broadened in the more or less long term. Within the next 3 years, the current phase III studies will provide new efficacy and safety

data for better assessing the actual role of P*r*T in the treatment of several types of cancer.



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