

- Title** Assessment of the clinical value of the STAR™ radiofrequency ablation system intended to treat vertebral metastasis.
- Agency** Comité d'Évaluation et de Diffusion des Innovations Technologiques (CEDIT)
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- Reference** Link to the complete report on the CEDIT web site:
<http://alpha-recherche.aphp.fr/wp-content/blogs.dir/85/files/2015/05/SpineStar-avis-CEDIT.pdf>

Aim

To assess the clinical value of the STAR™ radiofrequency ablation system (company D-FINE), intended to treat vertebral metastasis.

Conclusions and results

Technical aspects: STAR device combines a bipolar directional flexible probe comprising two thermocouples measuring per-process temperature, with an RF generator - and monitoring unit. According to the manufacturer, these features allow to consider the safe destruction of vertebral metastases near heat-sensitive structures such as the spinal cord.

Medical aspects: vertebral metastases are common and patients can benefit, besides the background treatment, from surgical, radiotherapy or interventional treatment (without a formal consensus on the choice of a specific therapy). Radiofrequency ablation, often associated with vertebroplasty, is a common modality for interventional treatment, but sometimes contraindicated by the proximity of the nervous system. The STAR system has been assessed in three studies realized by the device development team. These studies showed the feasibility of the intervention and suggested its efficacy and safety, but do not allow comparisons with other competing technologies. The experts consulted agree on the usefulness of this device for lesions near the spinal cord. The target population is likely to be small.

Economic aspects: the monitor-generator (list price € 7,800) would initially be made available by the manufacturer. Disposable kits are announced at a list price of € 3,195. The French CCAM list of reimbursed procedures contains the item (LHFH001) corresponding to this intervention, at a price of € 209. No economic evaluation is available for this device.

Organizational aspects: the procedure itself does not present a major organizational impact: low budget impact given the small target population and professional skills currently available at the AP-HP. However this issue highlights the lack of a strong consensus on the methods of management of spinal metastases, and the influence of local practices in the therapeutic choice.

Recommendations

In patients for whom radiofrequency ablation is indicated but for which this procedure would be contraindicated by the proximity of the nervous system, the STAR™ device could be a useful alternative. Despite the high cost of the device and the procedure, the scarcity of indications suggests a low budgetary impact. Therefore, the CEDIT recommends that the STAR™ device be made available to radiology and interventional neuroradiology departments of AP-HP having experience in the management of vertebral metastases.

Methods

Literature review of the very limited material available: no comparative studies and all studies generated by the system development team.

Further research/reviews required

The CEDIT also calls for a clinical study whose methodology and objectives remain to be established.

Written by

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