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Title Intracoronary Brachytherapy

Agency CEDIT, Committee for Evaluation and Diffusion of Innovative Technologies
Assistance Publique Hôpitaux de Paris
3, avenue Victoria, 75100 Paris RP, France; tel: +33 3 40 27 31 09, fax:+33 1 40 27 55 65,
info.cedit@sap.ap-hop-paris.fr, http://cedit.ap-hop-paris.fr

Reference CEDIT Report (in French) 01.09/Ra1/01/Recommendation 01.09/Re1/02.

Aim

CEDIT was consulted by Professor Beaufils and Dr. Henry (Cardiology Department, Lariboisière Hospital) in association with Professor Maylin and Dr. Gozy (Radiotherapy Department, Saint-Louis Hospital) for an evaluation of intracoronary brachytherapy. This technique is used in cases of coronary restenosis following angioplasty and more generally as an adjuvant therapy for coronary atherosclerosis associated with angioplasty.

Intracoronary brachytherapy involves temporary insertion of a radiation source into the lumen of a vessel to be treated. Under optimal safety conditions for the operator, a radiation source, delivered by a radioactive source train, is inserted via the distal end of a catheter and then removed at the end of treatment. The procedure is conducted with radioscopic control. The equipment most widely used is the *GALILEO™ Intravascular Radiotherapy System* manufactured by GUIDANT and *Beta-Cath®* from NOVOSTE. Both are _-radiation systems used only in intracoronary brachytherapy.

Results

Abundant data have been presented over the last 5 years on intracoronary brachytherapy. Our bibliographical search highlighted eight studies based on randomized treatment trials. They conclude that the arterial lumen in treated patients is favorably influenced by irradiation. Thus, a stenosis of over 50% during followup is far less frequent in treated groups than in control groups. However, it must be noted that for a non-negligible number of patients, data on control examinations are not available and followup modalities are rarely described.

The surplus cost of an intracoronary brachytherapy procedure as part of angioplasty is estimated at between 3800 EUR and 4600 EUR. This surplus cost includes equipment costs, consumables (the single-use catheter accounts for 90% of the overall surplus cost), and staffing costs. In light of results of randomized studies comparing brachytherapy to a placebo in the case of a first-time in-stent restenosis, our cost-effectiveness approach does not suggest that this surplus cost is offset by a significant reduction in clinical incidents.

Recommendations

CEDIT is of the opinion that intracoronary brachytherapy has yet to be sufficiently evaluated. Since followup periods are not lengthy enough, its long-term effects are not fully known.

CEDIT emphasizes that the current development of coated stents, a promising technology, could well provide an alternative to intracoronary brachytherapy. However, followup information on the medium and long-term effects of such stents is insufficient, and their indications are yet to be clearly established.

CEDIT recommends that only one center of the AP-HP be designated for treatment with intracoronary brachytherapy for patients showing an in-stent restenosis.

Methods

A literature search was conducted; five databases were scanned: MEDLINE, EMBASE, Pascal, BIOSIS and Current Contents. Seven experts were interviewed on the innovative character and on the medical benefit of this technology.

Written by Catherine Edlinger, Sandrine Baffert, Jean-Philippe Perrin, Elisabeth Féry-Lemonnier, CEDIT, France