Extracorporeal photopheresis

Main indications and implementation parameters

English summary

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

Équipe de projet

Auteurs
Christian Jossart, Ph. D.
Richard Le Blanc, M.D.

Coordination scientifique
Khalil Moqadem, Ph. D.

Conseiller scientifique
Gilles Pineau, M.D.

Recherche d'information scientifique
Caroline Dion, M.B.S.I

Soutien documentaire
Micheline Paquin, tech. doc.

SUMMARY

Extracorporeal photopheresis (ECP) is a cell therapy technique consisting in removing mononuclear cells from the patient's blood by apheresis, exposing them *ex vivo* to ultraviolet light in the presence of a photoactivatable substrate and then reinjecting them into the patient. This procedure triggers an immune reaction that modulates the number and function of T lymphocytes and other immune system cells, hence the clinical effect. ECP can be considered a form of immunomodulatory therapy, whose beneficial effects in patients with cutaneous T-cell lymphomas (CTCLs) have been reported since 1987. Since then, other diseases associated with T lymphocyte dysfunctions have been the subject of clinical studies of ECP. In 2015, the three main indications were CTCLs, graft-versus-host disease (GVHD) in the context of allogenic hematopoietic stem cell transplantation (HSCT), and solid-organ transplant rejection.

Since ECP is a highly specialized medical procedure, the Ministère de la Santé et des Services sociaux (MSSS) authorized, in 2010, the creation of a Québec ECP program. The program was set up jointly by Hôpital Maisonneuve-Rosemont (HMR) and the McGill University Health Centre (MUHC). Subsequently, other Quebec hospitals informed the MSSS of their desire to offer ECP as well. In order to reply to these requests objectively, the Direction générale de cancérologie (DGC) asked, in January 2014, the Institut national d'excellence en santé et en services sociaux (INESSS) to examine the scientific evidence regarding the efficacy, safety, and organizational and economic aspects of ECP as it pertains to the three main indications for this treatment modality.

A literature search was therefore conducted in databases and on health technology assessment (HTA) agency websites for relevant articles and reports published up to May 2015. In the end, of the total of 947 documents identified, 52 were selected. The level of evidence of the studies on the efficacy of ECP in the treatment of CTCLs, GVHD and solid-organ transplant rejection was limited. In effect, there were a few modestly sized randomized clinical trials, but most of the selected studies were uncontrolled and retrospective. As a result, the indications for ECP are presently recognized by consensus.

ECP is indicated in the treatment of two CTCLs, namely, mycosis fungoides (MF) and Sezary syndrome (SS), as first- or second-line therapy, depending on the stage of the disease. ECP is also indicated in the second-line treatment of the chronic or acute form of GVHD that is refractory to first-line immunosuppressive therapies and in cases of intolerance to immunosuppressive therapies. In the case of recurrent or refractory cardiac transplant rejection, ECP is indicated as second-line therapy, as an adjunct to the standard immunosuppressive therapies. However, there is no consensus regarding this indication. As well, recent practice guidelines support the view that ECP is indicated as second-line therapy for treating chronic lung transplant dysfunction (bronchiolitis obliterans [BO] syndrome).

All the studies and guidelines examined are unanimous that ECP is safe, both in the pediatric and adult population. The reported adverse effects are usually limited. Most often, they are associated with the use of a venous catheter (infection, thrombosis), blood volume (hypotension, tachycardia), cytopenias (anemia, thrombocytopenia) or electrolyte disturbances (hypocalcemia). Serious or long-term complications are rare. EPC should be performed by a specialized apheresis team trained in this technique, and ECP sessions involving pediatric patients should be performed by an experienced team at a specialized facility with a pediatrics unit.

ECP is an expensive therapeutic modality. In most countries, its implementation is limited to highly specialized centres, where there is good expertise in this technique, and the requirement for patients to travel to such facilities is a factor limiting their access to care. Consequently, before setting up an ECP unit, consideration should first be given to the number of patients that would be served, the high operating costs, expertise in the technique, the level of specialization of designated centres, and the distance patients would have to travel to access these highly specialized resources.