

Leucorreducción universal de productos sanguíneos

Revisión Sistemática de la
Literatura y Evaluación
Económica

Universal leukorreduction.
A systematic review of the
literature and an economic
assessment. Executive summary

Leucorreducción universal de productos sanguíneos

Revisión Sistemática de la
Literatura y Evaluación
Económica

Universal leukorreduction.
A systematic review of the
literature and an economic
assessment. *Executive summary*

Aguado Romeo, María José

Leucorreducción universal de productos sanguíneos. Revisión Sistemática de la Literatura y Evaluación Económica/ María José Aguado Romeo, Román Villegas Portero, Sergio Márquez Peláez, Belén Corbacho Martín, José Antonio Navarro Caballero. Sevilla: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía; Madrid: Ministerio de Sanidad y Consumo, 2007

91 p. 24 cm.- (Informes, Estudios e Investigación; AETSA Nº 2006/35)

1. Transfusión Sanguínea 2. Transfusión de Componentes Sanguíneos 3. Procedimientos de Reducción del Leucocitos 4. Citaféresis 5. Plaquetoféresis 6. Transfusión de Leucocitos I. Villegas Portero, Román II. Márquez Peláez, Sergio III. Corbacho Martín, Belén IV. Navarro Caballero, José Antonio V. Andalucía. Agencia de Evaluación de Tecnologías Sanitarias. VI España. Ministerio de Sanidad y Consumo VII. Serie

Autores: María José Aguado Romeo, Román Villegas Portero, Sergio Márquez Peláez, Belén Corbacho Martín, José Antonio Navarro Caballero.

(La revisión sistemática ha sido responsabilidad de MJAR y RVP. La evaluación económica la han realizado SMP, BCM y JANC)

Dirección técnica:

Agencia de Evaluación de Tecnologías Sanitarias de Andalucía

Este documento se ha realizado en el marco de colaboración previsto en el Plan de Calidad para el Sistema Nacional de Salud, al amparo del convenio de colaboración suscrito por el Instituto de Salud Carlos III, organismo autónomo del Ministerio de Sanidad y Consumo, y la Fundación Progreso y Salud de Andalucía

Edita:

Agencia de Evaluación de Tecnologías Sanitarias de Andalucía

Avda. de la Innovación s/n

Edificio Denta Sevilla, 2ª planta

41020 Sevilla

España – Spain

© de la presente edición: Ministerio de Sanidad y Consumo.

© de los contenidos: Consejería de Salud – JUNTA DE ANDALUCÍA

ISBN: 978-84-932545-8-2

NIPO: 354-07-0711-7

Depósito Legal: SE-5452/07

Imprime: Tecnographic, S.L.

Este documento puede ser reproducido en todo o en parte, por cualquier medio, siempre que se cite explícitamente su procedencia

Leucorreducción universal de productos sanguíneos

Revisión Sistemática de la
Literatura y Evaluación
Económica

Universal leukorreduction.
A systematic review of the
literature and an economic
assessment. *Executive summary*



MINISTERIO
DE SANIDAD
Y CONSUMO



Ministerio de Sanidad y Consumo

AIE Agencia de Evaluación
de Tecnologías Sanitarias



Executive summary

Title: Universal leukorreduction. A systematic review of the literature and an economic assessment.

Authors: María José Aguado Romeo, Román Villegas Portero, Sergio Márquez Peláez, Belén Corbacho Martín, José Antonio Navarro Caballero

BACKGROUND: The presence of leukocytes in blood components is the cause of certain adverse reactions associated with blood transfusion. Universal leukorreduction (ULR) involves striving to remove leukocytes in all blood derivatives to below certain safety levels ($1-5 \times 10^6$ per unit) in all transfusions for any type of patient.

The “mad cows' disease” epidemic of the 1990s in the United Kingdom, which was linked to human-variant Creutzfeldt-Jakob disease, led the public health authorities to adopt the precautionary principle, based on the balance of risks of transmission through blood, and adopt ULR in 1998.

A decade after the epidemic, in light of the knowledge gained, there is still great controversy concerning the effectiveness of ULR. This systematic review seeks to collate the scientific evidence published since the introduction of ULR, and determine whether pre-storage leukorreduction by filtration of all blood components is effective in averting adverse reactions caused by leukocytes in blood derivatives in all transfusion patients, and whether it provides benefits over the removal of the leukocytic layer and/or selective leukorreduction.

OBJECTIVES: To assess the efficacy of universal leukorreduction of cellular components (erythrocyte and platelet concentrates) in terms of reducing the rate of complications related to allogeneic leukocyte transfusion, compared with leukocytic layer removal and/or selective leukorreduction or other techniques; and to estimate the economic impact of a potential change in strategy.

METHODS: Systematic review in the reference databases MEDLINE and EMBASE [1998 to June 2006], Cochrane Library, International Network of Agencies for Health Technology Assessment, Euroscan, and the Spanish medical index, Índice Médico Español. Included are clinical trials and systematic reviews on the efficacy of ULR in reducing adverse reactions related to the presence of leukocytes in blood derivatives. The critical analysis was made following SIGN guidelines and applying Spain's CASPe

critical appraisal skills programme and the Jadad trial quality scale. In the absence of clinical trials, observational studies were included. An estimate was made of the economic impact of limiting the use of leukorreduction to those patients for whom it would be expressly indicated (selective leukorreduction, LRS), comparing the costs of both options, based on the number of blood bags used nationally and their cost (since no other costs were found to be associated with the change in strategy), together with the number of patients for whom LRS would be indicated.

RESULTS: Of the 319 articles found, 18 high-quality clinical trials (CASPe 10-11; Jadad 4-5) and 5 observational studies were chosen.

- Non-haemolytic febrile transfusion reactions were assessed in 2 clinical trials, but not as the main aim of the study, so the 5 observational studies were considered. They conclude that ULR helps to reduce, but not eliminate adverse reactions.
- Alloimmunization versus erythrocyte concentrates was assessed in only one clinical trial and does not describe benefits in favour of ULR. There were no studies comparing alloimmunization versus platelets.
- Transfusion-related immunomodulation in surgical patients is studied in 7 clinical trials which did not find a clear reduction in the number of infections, in the recurrence of tumoural diseases, in the length of hospital stays, or in the mortality of transfused patients having undergone ULR, compared with patients who undergo other forms of leucodepletion.
- The transmission or activation of cytomegalovirus by blood derivatives is assessed in 3 clinical trials. ULR does not offer benefits over other previously-used methods of prophylaxis of infection from blood derivatives.
- No studies were found that demonstrate the transmission of prion diseases.
- The economic impact of a change in strategy from performing universal to selective leukorreduction nationally, would result in a fall in the costs of purchasing blood derivative bags of between 27,564,590 and 29,095,956 euros per year.

CONCLUSIONS: There is no new scientific evidence to justify performing ULR, nor advantages over leukorreduction using other methods, such as removal of the leukocyte layer and/or selective leukorreduction.

RECOMMENDATIONS: There appears to be a need for reconsidering whether it is necessary to continue with universal leukorreduction or to abandon it and direct all technical and economic efforts toward improving other aspects of transfusion medicine and to incorporate emerging technologies.