Perioperative blood salvage

HAS, Saint-Denis La Plaine, France
Authors: Roselyne Delaveyne MD, Nathalie Préaubert MSc, MPH

Perioperative blood salvage (PBS) is a blood-saving method used during surgery involving substantial blood loss. It avoids the use of allogenic blood by collecting and then reinfusing the patient’s own blood. Blood is collected from the operative site or postoperative wound. Two types of system (single-use medical devices (SUD)) are available in France for PBS: a system with filtration, concentration and washing, and a system without washing.

Aims
- To assess the efficacy and safety of PBS systems and their anticipated benefit.
- To propose a CCAM\(^1\) status for the technique and a legal status for the blood product in order to identify the appropriate vigilance systems.

Results
(i) Quality of the blood product: washed and unwashed red blood cells obtained by PBS are viable and their oxygen transport capacity is preserved.
(ii) Efficacy of PBS: the volume of allogenic blood transfused is reduced by 20−87% when using PBS. Efficacy depends on the type of surgery and increases with the amount of blood lost. Data on the impact of PBS on length of hospital stay and reduction in postoperative bleeding are contradictory.
(iii) Risks related to PBS: contamination of blood product storage packs has been reported but it has not caused infection in patients. Fatal gas embolism has been reported. In all cases, it has been related to non-compliance with procedures for use.
(iv) Status and vigilance system: in the current CCAM, PBS is defined as a "complementary professional procedure" always associated with a surgical procedure. It is never an "isolated procedure". Health professionals' expectations with regard to the status of the technique and the restrictions imposed by vigilance systems and legal authorisations were reviewed.
(v) Regulatory aspects: PBS is covered by a circular (Jan. 1997) which states Good Practice but does not mention the schedule for biological controls, standards, nor blood product specifications.

HAS conclusions
- PBS with washed blood should remain a CCAM professional procedure. The committee deciding on state reimbursement for procedures (CHAP\(^2\)) has to decide whether it will be "a procedure linked to a surgical procedure", an "isolated procedure", or a "full-scale procedure".
- PBS with unwashed blood should not retain complementary status but should be included in the CCAM with the reservation that its place in postoperative blood saving after surgery has not yet been clarified.
- PBS blood product cannot be included under health products nor under labile blood products, and does not necessitate a specific status.
- The vigilance systems associated with the procedure and the PBS product are: medical device vigilance for incidents related to SUD, and the nosocomial infection notification

\(^1\) CCAM = Classification Commune des Actes Médicaux (= Common Classification of Medical Procedures)
\(^2\) CHAP = Commission de Hiérarchisation des Actes Professionnels – replaces the Nomenclature Committee in deciding whether the cost of specific professional procedures should be reimbursed by the French Health Insurance system.
system and/or system for reporting care-related adverse events for incidents related to PBS blood products.

**Methods**

HAS searched the following databases: MEDLINE, EMBASE, PASCAL, the Cochrane Library, National Guidelines Clearinghouse, HTA Database, French public health database (1996-2005) as well as websites of professional societies, lists of literature references at the end of articles, and manufacturers’ technical brochures. Studies were selected on the basis of level of evidence and design quality. The critical literature review was validated by a group of institutional representatives (n = 12), a working group (n = 15) and peer reviewers (n = 19).

**Looking ahead**

The working group identified the following needs:
- standardisation of practice (indications, contraindications, procedures for use by type of PBS and surgery)
- setting up of quality control procedures (type, technique, threshold values, frequency)
- establishing the contribution of PBS to strategies for blood-saving during surgery in 2006.