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Preoperative autologous blood donation: a therapy that needs to be scientifically evaluated

Don du sang autologue avant intervention : Une thérapie qui doit être scientifiquement validée

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Abstract

The aim of preoperative autologous blood donation (PABD) is to reduce both the risk of transfusion transmitted disease and the need of blood from donors. One advantage of PABD is to prevent transfusion-transmitted disease namely viral infections such as HIV or hepatitis virus or emerging virus. Actually, the very low residual risk of allogeneic transfusion does not argue for PABD. On the other hand, the risk of bacterial contamination must be taken in account for both autologous and homologous transfusion (HT). A meta-analysis showed that ABD reduces the exposure to HT (OR: 0.17). Clinical studies evidenced that patients who predonated autologous blood were more likely to receive any blood transfusions (autologous and/or allogeneic) than those who did not (OR: 3.31). More, the reduction of exposure to allogeneic transfusion may be questioned in view of prescription bias. Additionally, PABD is poorly cost-effective. It leads to significant blood wastage while in most studies about half of the units are discarded. In conclusion PABD is a therapy that has not been sufficiently evaluated. The interest of this therapy remains to be demonstrated.

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Résumé

La transfusion autologue programmée (TAP) a deux objectifs : la sécurité et l'épargne de sang homologue. La première justification de l'utilisation de la TAP est l'élimination du risque d'infection transfusionnelle par agents transmissibles, viraux : agents des hépatites, VIH ou virus émergents. Le risque résiduel actuel, réduit par la sélection des donneurs, la déleucocytation et l'introduction du dépistage génomique viral en qualification des dons justifie difficilement à lui seul la TA. Par contre doit être pris en compte le problème du risque bactérien en transfusion, au moins égal en transfusion homologue (TH) et autologue (TA). La réduction attendue du risque immuno-hématologique de la transfusion n'est peut-être pas non plus un critère majeur de décision. L'épargne de sang homologue réalisée par la TAP est un argument important, retrouvé dans plusieurs études. Une méta-analyse montre une réduction de l'exposition au sang homologue chez les patients ayant suivi un protocole de TAD (OR = 0,17). Ceci doit être mis en balance avec l'augmentation du risque d'exposition à la transfusion (TH + TA) retrouvée chez les patients en TAP (OR : 3,31). La réduction des TH peut, elle-même, être remise en question par l'analyse des critères de prescription qui seraient différents selon que le patient a effectué ou non un don autologue pré-opératoire. Une étude contrôlée récente effectuée en orthopédie ne retrouve d'ailleurs pas cette réduction de l'exposition à la transfusion. Enfin, les études économiques semblent montrer un surcoût lié en partie au taux de non-utilisation des produits prélevés homologues. En conclusion, la TAP est actuellement une thérapeutique insuffisamment évaluée et dont l'intérêt réel reste à démontrer.

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1. Introduction

During the 1980s, due to the increasing problem of transfusion-transmitted disease (TTD), the procedures of preoperative autologous blood donation (PABD) were recommended. However, the threshold of 10% of all transfusions [1] that was defined for PABD has never been reached. Moreover, in the last years, a dramatic decrease in indications of PABD was observed, mainly due to the many advances that occurred in all the stages of transfusion as well as the overall reduction of transfusion requirements [2].

2. PABD and TTD

The risk of TTD was the main justification of PABD. It concerns virus, bacteria, parasites and non-conventional agents. The risk of virus linked TTD has been dramatically decreased both by exclusion of at risk donors and progress in qualification of blood donation (QBD), namely the introduction of nuclear acid testing (NAT). In the literature, the risk for HIV transmission is estimated at 1 for 1,900,000, for HCV at 1 for 1,600,000 [3]. These estimations have been confirmed in France after NAT introduction [4]. The main residual risk concerns HBV estimated in France at 1 pour 450,000. Yet, one should consider two parameters that has to be taken in account: first the general increase of patients immunized by anti-HBV vaccination, second the true clinical risk of receiving units with significant HBV viremia: while acute B hepatitis occurs in 35% of recipients, the risk of chronic disease concerns 10% of patients. Thus, transfusion linked chronic B hepatitis might be estimated at 1 for 5,000,000. The other viral risks are within the same ranges: 1 for 1,000,000 to 1 for 5 to 7,000,000 for blood derived products after de leukocytation. [5,6]. In France it has been decided that NAT will not be applied for PABD. Thus units coming from PABD are the only products present in the circuit of distribution that have not been tested by NAT.

Bacterial risk is now one of the major problems in transfusion. It may result of bacteremia in donor: the main risk concerns *Yersinia enterocolitica*. Its frequency is estimated at 1 for 65,000 to 1 for 1,000,000 [5,6]. The risk of bacterial contamination of blood units is probably the same for homologous transfusion (HT) as for autologous transfusion (AT). More, considering that the risk of bacterial proliferation increase with the duration of conservation, the question of an increase in bacterial risk for PABD has to be considered: median duration of conservation is longer for AT (at least 3 weeks). This increase has not been evidenced in clinical studies. This question also concerns cutaneous bacteria introduced by venipuncture during blood collection.

We have no comparative data on the bacterial risk of HT versus AT. In the OSTHEO study, the rate of infection after hip or knee surgery was higher in HT patients (13%) than in AT patients (4%) [7]. A similar difference has been found in a clinical study [8]: 7% of infections among patients that received HT versus 4% in AT and 3% in non-transfused patients. These data coming from open studies must be discussed: PABD procedures include a systematic detection of latent in-

fection, while patients in bad condition, likely to be at risk of post surgical infection are generally excluded of PABD. In conclusion in the absence of true randomized control study one should consider that the bacterial risk of AT or HT are at least similar.

The risk of parasite transmission in France is represented by malaria. The exclusion of donors that traveled recently (4 months) in endemic zone of malaria and the systematic detection of plasmodium for blood samples issued of donors that traveled in endemic zone in the last 2 years has probably eliminated this risk in our country.

The risk of transmission of non-conventional agents (prions) by whole blood transfusion has been recently highlighted. Actually no case of transmission has been described after de leukocytated blood unit transfusion.

3. Hemolytic reactions

One of the main advantages of PABD is the prevention of hemolytic reactions induced by undiagnosed anti-erythrocytes alloantibodies. The frequency of such accidents has been considerably reduced by good medical practice applied to transfusion and hemovigilance network in hospitals. Actually, the main risk concerns acute hemolytic reactions caused by ABO incompatibility as a result of administrative error. The risk is estimated at 1 for 250,000 to 1 for 1,000,000. In 2001 the *Agence Française de Sécurité Sanitaire et des Produits de Santé* (<http://agmed.sante.gouv.fr/pdf-5hmv2001.pdf>) reported 17 immediate ABO accidents for 2,380,256 units distributed. The risk of administrative error is similar for HT and AT. Between 1994 and 2001, 197 acute hemolytic reactions caused by ABO incompatibility were reported: 11 were due to PABD. It has been demonstrated [9] that PABD leads to an increase in total transfusion (HT + AT) received by the patients. Considering that the risk of administrative errors increase with the number of units transfused, we cannot exclude the possibility that PABD leads to an increase in acute hemolytic reactions caused by ABO incompatibility.

Finally 8–25% of patients will receive HT despite PABD [10,11]. For all of them remains the risk of hemolytic reaction caused by undiagnosed anti-erythrocyte antibodies.

4. Other risks secondary to transfusion

Immunosuppressive effect: the reality of HT induced immunosuppression is still a matter of debate [12]. This effect might be due to the presence of homologous leukocytes or soluble components coming from these cells. If this hypothesis is confirmed, systematic de leukocytation introduced in France in 1988 abolished the so called immunosuppressive effect of HT. A randomized study [13] had found an increase in disease free survival among patients that did not receive transfusion during surgery for colorectal cancer as compared to transfused one. In this study, the risk of relapse was identical after HT or AT.

The risk of pulmonary edema caused by fluid overload is estimated at 3–4% [7]. It increases with the number of units

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