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## The current status of autologous blood transfusion in Japan – The importance of pre-deposit autologous blood donation program and the needs to achieve patient blood management



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### ABSTRACT

**Background:** Autologous blood transfusion (ABT) is currently considered the safest transfusion, since the risks of allogeneic immunological reaction and viral transmission are theoretically null. Although its use has declined in Western countries in the recent decade, it has been progressively expanded in Japan. With the widening of the concept of patient blood management (PBM), which aims to prevent the harmful adverse effects of the exposure to allogeneic blood, the importance of the ABT has once again gained interest.

**Study design and methods:** Here, we retrospectively analyzed the cases pre-depositing autologous blood for an elective surgery in the period of January 2000 to December 2010 in our hospital, where a pre-deposit autologous blood donation (PAD) program has been established in 2006, in an attempt to analyze the improvements achieved, and the problems remaining to achieve patient blood management.

**Results:** The PAD program contributed for the further improvement of ABT, and the number of participating patients increased, especially in the period 2002–2003, when the idea of PAD program implementation came out. By simple extrapolation of the ABT data to allogeneic blood, ABT was found to be superior in terms of cost-effectiveness. However, problems such as the high wastage rate, and the inappropriate transfusion triggers remain to be solved.

**Conclusion:** ABT plays the central role in PBM, but to achieve the real PBM, there is need to indicate ABT appropriately, according to the individual needs, and use it adequately, without discarding. Our present data reflect the present status of the ABT performance in Japan, and will serve as the basis for the development of strategies to achieve safe and appropriate performance of ABT, and consequently, achieve PBM.

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### 1. Introduction

Recently, the patient blood management (PBM) or blood conservation, which aims to fully evaluate the patient's condition to assess for factors predictive of preoperative

and postoperative anemia and the need for transfusion, in an attempt to prevent the harmful adverse effects of the exposure to allogeneic blood [1–7] have gained especial interest. ABT is an important approach to achieve PBM [8]. Although, theoretically, autologous blood has low risk of immune-mediated adverse events, and has been shown to be superior to the pre-storage leukoreduced allogeneic one in terms of the risk of transfusion-related immunomodulation [9], the risk of adverse effects caused by soluble

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factors, such as cytokines and chemokines, accumulating during the storage period, still remain. Whereas many studies, including randomized controlled trials, have shown that autologous blood is not superior to allogeneic one in terms of transfusion-related immunomodulation (TRIM) [10–12] the use of ABT has been suggested as an alternative to prevent TRIM [13].

In the United States, hospital-based autologous whole blood donation programs were implemented in the 1980s, at the time there was a great threat related to transfusion-transmitted disease, especially with the advent of the HIV infection [14]. Although these programs continued into the 1990s, it has progressively declined in the 2000s [14], when a significant decline in the risk of transfusion-associated disease was achieved, and reports have shown that PAD might increase the performance of transfusion, including the autologous one [14]. More recently, however, with the increasing interest in the PBM, in which ABT plays the central role, it seems that interest is increasing.

In Japan, however, the situation is completely different due to the different circumstances, such as the social features, the governmental incentives, and the historical background of transfusion medicine. Instead of the increasing safety of allogeneic blood, after the tragic incidents that have led many people to be infected by HCV or HIV, there is a tendency of the Japanese population to opt for the own blood in the process of informed consent. It is a consensus in Japan that patients have the right of “informed choice”, i.e., based on the information provided by the doctors, they can choose which transfusion to receive. And the surgeons also believe that it is the best alternative. Also, based on the fact that the Japanese society is a super-graying society, bearing the risk of blood shortage in the near future, the Japanese government strongly encourages ABT. In this context, for more than 20 years ABT is largely performed in Japan. Although considered the safest transfusion, in most institutions dealing with ABT in Japan, the pre-deposit autologous blood donation program (PADP) is not established, thus the real safety of ABT remains to be confirmed. Also, the concept of patient blood management is not generalized in Japan, therefore, autologous blood may be over-collected and over-transfused.

Here, we present the data on the ABT performance during 10 years in a large university hospital in Japan, where a hospital-based PAD program was established, and show the improvements achieved, the cost-effectiveness of ABT compared to the allogeneic one, and discuss the problems remaining, and the future challenges for the achievement of safety and appropriateness of ABT in the context of PBM.

## 2. Methods

### 2.1. Patients

Patients pre-depositing autologous blood for elective surgery in the period between January 2000 and December 2010 were retrospectively analyzed. All patients received informed consent on blood transfusion, and have opted for the use of pre-deposited autologous blood.

### 2.2. Improvements achieved

The pre-deposit autologous blood donation (PAD) program was created in January 2006, as part of the Department of General Medicine, after 3 years of careful planning. After the implementation of the PAD program, the roles of surgeons and transfusionists were clearly defined. Presently, the surgeons only appoint a consultation of the PAD program, and the transfusionist consults the patient, and after providing the necessary information, obtains the informed consent of autologous blood collection, and schedules the collection. Additionally, the transfusionist investigates on the presence of anemia, and takes the appropriate measures for the prevention or treatment. According to the “Guidelines of the pre-deposit ABT” of the Japanese Society of Autologous Blood Transfusion, the minimum Hb level necessary for autologous blood donation is 11.0 g/dl. The use of erythropoietin is covered by the Japanese universal health insurance in case more than 800 mL of autologous blood is collected.

The achievements of the establishment of the PAD program in the performance of ABT was evaluated by the following parameters: (1) the number of patients receiving autologous blood collection and transfusion, (2) the amount of autologous blood collection and transfusion, (3) the autologous transfusion rate, which represents the percentage of patients in elective surgery who receive only autologous blood, among the transfused patients, (4) the allogeneic transfusion avoidance rate, which represents the percentage of patients who pre-donated and were transfused only autologous blood, without exposure to allogeneic blood, (5) the changes in the autologous blood preservation methods, and (6) the rate of autologous blood wastage.

### 2.3. The cost-effectiveness of ABT

The cost-effectiveness of ABT was calculated as the gross profit to the hospital dependent on the performance of ABT, and compared to the profit that would be obtained in case the same amount of allogeneic blood was used.

For the calculation of the profits, the incomes and outcomes shown in Tables 1 and 2, for autologous and allogeneic blood, respectively, were applied. The income of ABT, shown in Table 1, includes the outpatient medical fee, which is charged to the patient in each hospital visit for PAD, the costs of Ringer lactate and the iron preparation infusion, which is given after each blood collection, and the autologous transfusion fee, giving a total of 565.25 dollars per 2 units (400 mL). The hemogram test performed before each blood collection is included in the outpatient medical fee. The blood group typing of the patient needs to be performed at least twice, as stipulated in the Guideline for Transfusion Practice, released by the Ministry of Health, Labor and Welfare of Japan. In our service, the infusion of Ringer lactate is a routine after the blood collection, and iron infusion is indicated for the prevention of PAD-associated anemia. PAD-associated anemia, if not appropriately prevented or treated, may result in allogeneic blood exposure. The cost of the erythropoietin was not included in the calculation, since it is not indicated to most patients.

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