Update on autologous donation and transfusions

M.A. POPOVSKY

Current Status

A major development in transfusion medicine during the 1980s was the widespread use of autologous blood for routine transfusion. In many situations, the use of autologous blood transfusion became a standard of care.[1,2] In some states, laws dictate that the option of autologous blood must be discussed with potential blood recipients before elective surgery. Although some blood bankers had for many years espoused, at least in principle, the use of autologous blood, the real impetus was the recognition of HIV as a threat to the safety of the blood supply.[2] An anxious public frequently has been the standard bearer on this issue, serving as the catalyst for change within the healthcare community. This pressure resulted in a commitment to identify and deliver alternatives to allogeneic blood transfusions. An additional impetus was the growing awareness by the clinicians and the public of other complications of transfusion, specifically viral hepatitis.

As a consequence of these pressures, preoperative autologous donations (PADs) increased dramatically throughout the 1980s and into the 1990s. Years of experience with high-volume PADs and autologous blood transfusion now enable us to analyze the risks as well as the benefits and compare those with the risks and benefits of allogeneic blood transfusion. The benefits of PADs that are most frequently cited are elimination of pathogenic viruses, reactions to foreign antigens, and alloimmunization.

In 1982, there were 18,737 PADs, according to data from the American Association of Blood Banks (AABB). (It should be noted that these data are incomplete but are the best available.) By 1991, this number had increased to 745,000.[3] However, since 1993 this number has declined. In a study of transfusion practice in more than 150 New England hospitals, the New England Region of the American Red Cross found that autologous blood transfusions peaked in 1993 (28,862 total combined for the states of Massachusetts, Maine, Vermont, and New Hampshire) and declined over the subsequent 4 years to 23,180, a decrease of 17.8 percent.

There are probably several reasons for the decline in autologous blood donation and transfusions. The first relates to the vastly increased safety of the blood supply. With risks for HIV transmission at less than 1 per 600,000 units transfused and for viral hepatitis at less than 1 in 100,000, it is likely that both clinicians and the public have increased confidence in the safety of the blood transfused. Recent public opinion surveys would support this view. This has probably resulted in less interest on the part of physicians and their patients in PADs. Another factor is the high discard rate associated with PADs, which results in high costs for hospitals. Data collected by Popovsky and co-workers in Massachusetts from that state's 115 transfusion services shows that 48 percent of autologous blood collections were transfused as either allogeneic blood or were discarded.[4] Therefore, many autologous blood donations were requested for surgical procedures for which there is little, if any, likelihood of transfusion. Examples of this practice include PADs for routine hysterectomy, uncomplicated cholecystectomy, tubal ligation, and uncomplicated pregnancy. In the latter case, only 1–2 percent of collected units are actually transfused to the mother.[5] With increasing cost pressures on hospitals, blood banks and hospital transfusion committees began to more systematically and objectively evaluate the need for autologous blood units. Using standard surgical blood orders modified for autologous use, demand for autologous blood units has diminished.[6]

Cost Effectiveness

A series of studies examining the cost-effectiveness of PADs have been published recently. Etchason and colleagues used a decision analysis model to assess the

effectiveness of PADs.[7] Their data were based on 1992 transfusion practices in southern California. Their measure of weighing effectiveness was dollars per quality adjusted life year (QALY). For most accepted medical surgical interventions, the QALY is less than $50,000. These investigators evaluated four surgical procedures: total hip replacement, coronary artery bypass graft (CABG), hysterectomy, and transurethral prostatectomy (TURP). They found that PAD was associated with additional per unit costs that ranged from $68 for total hip replacement to $4,783 for TURP. Even more impressive were the calculations for the dollars per QALY, which ranged from $235,000 for total hip replacement, to $494,000 for CABG, to $1,358,000 for abdominal hysterectomy. The authors concluded that autologous blood transfusion was not justified by the cost. Because the authors based their analysis on transfusion risk estimates of 1 per 150,000 for HIV and 1992 transfusion practices, these findings would be even more striking (less cost effective) if 1997 data were used. Since 1992, clinicians have accepted greater levels of anemia before transfusing their patients.

Birkmeyer et al.[8] conducted a second study that used decision analysis. Again, dollars per QALY were used as a measure of cost effectiveness. These authors found that for both CABG and orthopedic surgery procedures, the cost effectiveness was directly linked to the likelihood of transfusion. Thus, with bilateral hip or revision arthroplasty, the cost per QALY was $40,241. For unilateral hip arthroplasty, they calculated the cost per QALY between $373,000 and $740,000. Thus, PAD was seen as a cost-ineffective transfusion modality.

Not all investigators share this view. Another group has drawn contradictory conclusions. Blumberg and coworkers compared the cost consequences of autologous and allogeneic blood transfusions.[9] They evaluated the incremental hospital costs per unit transfused in hip replacement surgery. The authors found that for donors of autologous blood, the mean total charges were $7,200 more for recipients of both autologous and allogeneic blood transfusions compared with recipients of autologous transfusion only ($p = .0001$). In a cohort of patients receiving identical amounts of either allogeneic or autologous blood, total hospital charges were a mean of $4,500 greater for allogeneic recipients ($p = .0001$). The authors concluded that allogeneic transfusions were associated with incremental hospital costs of $1,000–$1,500 per unit transfused when compared with costs for similar patients receiving no transfusions or 1–5 autologous blood units. It is important to note that the contradictory conclusion about the economic benefit of PADs is based on a cost, rather than cost-effectiveness, analysis.

Despite the cost pressures on hospitals, many patients remain willing to pay additional out-of-pocket charges to obtain PAD services. In a recent study, Lee et al.[10] found that despite education about the low risk of allogeneic blood transfusion, the dread of allogeneic blood and willingness to pay for PADs are substantial. In a survey of 647 patients making PADs, these authors found the median population willingness to pay for PADs correlated with their level of dread, perceived risk of requiring a blood transfusion, and income level ($p < .05$). Many patients were willing to pay as much as $1,200–$1,900 for PADs. This study suggests that despite decreasing risk to the allogeneic blood supply, unfavorable cost-effectiveness studies, and pressures to reduce costs in the healthcare system, PADs will remain an important transfusion option into the foreseeable future.

Adverse Outcomes

Throughout the 1980s and into the early 1990s, numerous studies examined the questions of safety of PADs. These studies evaluated the incidence of donor reactions, emphasizing medically high-risk donors (e.g., those with cardiovascular disease). These studies concluded that PAD is not significantly less safe than blood donation in the healthy population. These conclusions also applied to the so-called high-risk donor. In one study, the authors found that the antecedent medical history (including a history of cardiovascular disease) was a poor predictor of reactions.[11] A limitation of all these studies are that they are retrospective, uncontrolled, and involve relatively small populations for analysis.

However, one uncontrolled study demonstrated potentially significant hemodynamic changes in patients and donors with a history of cardiovascular disease. In a study of 123 patients with major cardiovascular disease in which there was close monitoring of blood pressure, heart rate, cardiac output, lead II cardiography, and pulse oxymetry, Speiss et al.[12] found systolic and diastolic hypotension, orthostatic hypotension, and arrhythmias (including premature ventricular contractions). These changes were seen in 3.1–22 percent of the patients. Because of the lack of controls or other types of autologous blood donors, these data are difficult to interpret.

Using a large, recently developed data base, Popovsky and colleagues examined the occurrence of very severe outcomes (VSOs) in patients undergoing PAD.[13] The authors defined a VSO as one requiring hospitalization.

Evaluating more than 4 million donations in 1993–1994, the authors found that the rate for a VSO in an autologous blood donor was 12 times that seen in allogeneic blood donors. The incidence of VSO in autologous blood donors was 1 per 16,783 donations versus 1 per 198,119 ($p < .001$). The most common VSOs were angina (66.7% of all VSOs) and tetany (12.1%). Contrary to previous studies that suggested that there are fewer donor reactions in older donors, these investigators found that VSOs were most likely in donors younger than 60 years of age. Eleven of 13 VSOs occurred in such donors. The mean hospital stay was 1.9 days. The authors concluded that the VSO is an infrequent complication of all types of blood donation, but its occurrence may be associated with significant morbidity and cost. In Germany, Singbartl et al.[14] studied 28,000 orthopedic patients making 132,093 PADs. Using three-lead ECG and noninvasive blood pressure monitoring, as well as replacement therapy by crystalloids or colloids, these authors investigated adverse events (AEs). They found that severe AEs were observed in 1 per 9,414 patients (0.011%) or 1 in 44,000 units of blood donated. Fatal events occurred in 1 in 14,122 patients (1 in 66,000 autologous blood units donated). The fatal events observed were pulmonary embolism and severe asthma attack. These authors concluded that PADs may be associated with serious risk, but it was difficult to conclude that these risks were precipitated by the autologous blood donations. These data support the findings of the American Red Cross Study.[13] On balance, these studies support the conclusion of earlier studies regarding the overall safety of PADs, but they underscore the fact that AEs may occur.

Another underexplored topic is adverse transfusion reactions to autologous blood. Autologous therapy is the safest form of transfusion; therefore, transfusion reactions involving an immune response are not to be expected. A recent study by Domen found that 15 of 967 transfusion reactions (1.6%) at a large teaching hospital were associated with PADs.[15] He found that 25 percent of these reactions were of the febrile, nonhemolytic type and another 20 percent were allergic. Most significant was the occurrence of an acute hemolytic reaction due to an ABO mismatch. The author concluded that transfusion reactions are associated with autologous blood, that they can be severe, and that all such reactions must be investigated.

Management of Autologous Blood Donation

Once an autologous blood donation is collected, a complex system of logistics is called into play to ensure that the unit arrives safely at the patient's bedside or in the operating room at the time it is needed. A recent Canadian study suggests that these logistics are not always well managed. Using a detailed questionnaire that was sent to 31 hospitals served by the Canadian Red Cross of Quebec, Goldman and colleagues studied deviation reports and calculated error rates.[16] They found that 113 errors occurred for 16,783 units collected, for a disturbingly high rate of 1 in 149 units collected. In their analysis of the errors, they found that 10 percent were associated with allogeneic blood units being transfused instead of autologous blood units; 25 percent were units arriving late for surgery; 23 percent were units sent to the wrong hospital; 13 percent had labeling problems; and 7 percent were involved with transportation or storage problems. These authors concluded that errors are not an infrequent event with autologous blood donations.

These data are corroborated by a 1992 College of American Pathologists survey that found that 34 of 3,852 institutions (0.8%) reported one or more instances of issuing an autologous blood unit to the wrong patient.[17] A 1995 AABB survey indicated that 22 of 1,829 respondents (1.2%) reported an erroneous transfusion of one or more autologous blood units to someone other than the intended recipient.[18] These data underscore the lack of fail-safe systems associated with the procurement and transfusion of autologous blood units.

In conclusion, autologous blood transfusion remains an important part of perioperative hemotherapy. It appears that its usage is diminishing as a result of a variety of factors. For the vast majority of patients or donors, PAD is safe. However, severe reactions and outcomes may result from the donation. Because systems involved in the procurement and distribution of PADs are complex and often cumbersome, errors can and do occur. Finally, it would appear that some autologous blood units are associated with a reaction in the intended recipient.

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Mark A. Popovsky, MD, Chief Executive Officer and Chief Medical Officer, American Red Cross Blood Services, New England Region, 180 Rustcraft Road, Dedham, MA 02026, and Associate Clinical Professor of Pathology, Harvard Medical School, Boston, MA.

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