Preoperative Autologous Blood Donation (PABD)

September 2000

Executive Summary

Since the mid 1980s, when concerns over the safety of the U.S. blood supply arose, preoperative autologous blood donation (PABD) has been utilized by patients undergoing elective surgery for which blood transfusion was anticipated. However, the risk of acquiring blood-borne disease from allogeneic transfusion has been substantially minimized in recent years by thorough screening of blood donors and extensive testing of all allogeneic blood. The current risk of transmitting HIV through allogeneic transfusion is approximately 1 in 676,000.

Physician recommendation is the major motivating factor for autologous donation. However, studies suggest that while PABD decreases, it does not eliminate, the need for allogeneic transfusion. PABD increases the likelihood of any transfusion and is not entirely without medical risks. The medical risks include vasovagal reactions, cardiac complications, anemia, possible administration of the wrong blood (that is, blood than than the autologous donor's blood) and bacterial and viral infection.

Only about two-thirds of the autologous blood units collected are actually utilized, and the cost per life-year-saved is higher than the cost of accepted medical and surgical interventions. Therefore, in view of the safety of the U.S. blood supply today, PABD has been shown not to be cost-effective.

Conclusions

Studies suggest that while PABD decreases, it does not totally eliminate, the need for allogeneic transfusion for elective surgery. However, it does greatly increase the likelihood of any transfusion and is not entirely without medical risks.

Medical risks associated with autologous donation, from dizziness to anemia to the possibility of angina (and even cardiac arrest), should be considered when high-risk patients are referred for preoperative autologous collection.

It is possible that the wrong blood, either allogeneic blood or another patient's autologous blood, may be given to the PABD donor or another patient. Only about two-thirds of all autologous blood units collected are actually used, and the cost per life-year-saved is higher than the benchmark cost for most medical and surgical interventions.

As the safety of the American blood supply continues to improve, the possible clinical benefit of autologous blood donation becomes diminished.

Recommendations

PABD should be discontinued as a routine medical practice due to the current high degree of safety of the U.S. blood bank supply, as well as due to the inherent medical risks associated with PABD. This recommendation becomes of even increasing clinical importance since new blood bank testing procedures, and new means of treating and handling allogeneic blood units, are being developed and implemented on an ongoing basis.

Blood transfusion requires the informed consent of patients, and the medical risks and benefits of both autologous and allogeneic blood transfusion need to be discussed in detail by physicians prior to elective surgery. It is important during such discussions to reserve the encouragement of PABD for patients who, in the physician's professional opinion, have a real and obvious medical
requirement for electing PABD.

Allogeneic blood units should be transfused whenever clinically appropriate.

Physicians should discuss the medical risks and costs associated with PABD in detail with their patients before encouraging the use of PABD.

Background

Major blood loss during surgical procedures can be managed by transfusion of blood donated by the patient himself (autologous transfusion), by the intraoperative collection and filtration of the patient's blood, or by blood donated by someone other than the patient (allogeneic transfusion). Allogeneic transfusion has been associated with a risk for the recipient developing a variety of immune, hemolytic and allergic reactions, and for acquiring serious blood-borne diseases. Autologous blood donation has been proven to decrease the incidence of allogeneic transfusions and the associated risk of disease transmission. Patient and physician concerns over the medical risks of allogeneic transfusion during the mid-1980s led to the increased practice of preoperative autologous blood donation (PABD); that is, the collection of a patient's own blood during a 4 to 6 week period prior to surgery to be used for his/her own peri-operative transfusion needs. 1-8

However, the risk of acquiring blood-borne disease from allogeneic transfusion has been dramatically minimized in recent years by stringent, standardized screening of potential blood donors and testing of their blood. 9-11 Each unit of allogeneic blood is tested for HIV 1 & 2 (antibody and antigen), hepatitis C and B, as well as hepatitis B antigen, syphilis, and human T-lymphotropic virus (HTLV) 1 and 2.3,4 The current risk of transmitting HIV through allogeneic transfusion has been estimated to be 1 in 676,000.8,25 Nearly all people infected with HIV through blood transfusions received those transfusions before 1985, the year HIV testing began for all donated blood.25 Each unit is also classified by blood group and Rh factor.9 The number of autologous collections peaked in 1992 at an estimated 1.1 million units, which represented approximately 8% of total blood donations for that year.9,12,13 Since 1992, there has been a continuing decline in autologous blood donation. 9,12,14,15 An estimated 0.64 million units of autologous whole blood were collected nationally in 1997 which represented about 5% of the total annual collections.12

U.S. blood banks are continuing to find ways to improve the safety of the blood supply. Three new technologies will further reduce transfusion-transmitted infection risks and potentially eliminate transfusion-related reactions. Nucleic acid amplification testing (NAT) began in the spring of 1999. NAT detects genomic HIV and Hepatitis C virus (HCV) RNA sequences. It has been estimated that NAT could reduce the infectious detection window for HIV from the current 16 days to 10 days and the window for hepatitis C could be decreased from 70 to 90 days to just 10 to 30 days.9 Other technologies currently under development include: (1) viral inactivation, which prevents transmission of lipid envelope-containing viruses by plasma and plasma derivatives; and (2) leukocyte reduction filtration, which removes white blood cells before cytokine production and leukocyte fragmentation to lower the rates of febrile reactions.26

Despite the safety of the U.S. blood supply, physician recommendation continues to be the primary motivating factor for autologous donation. In a clinic survey, 110 patients who had donated autologous blood were asked why they opted for PABD. Only twenty percent of the patients surveyed cited fear of infection from allogeneic blood, but 68% said they elected PABD based on their physicians' recommendation.3

PABD Risks

Studies suggest that while PABD decreases, it does not totally eliminate, the need for allogeneic transfusion. Furthermore, it greatly increases the likelihood of any transfusion and is not entirely without medical risks. 6-8,13,16-18

Vasovagal Reactions and Cardiac Complications

The act of autologous donation, which is generally considered safe, has particular risks for older patients or patients with preexisting heart conditions. A study reviewed the incidence of complications associated with allogeneic and autologous donation. For volunteers who donate
allogeneic blood there was one serious complication per approximately 200,000 donations, while in the autologous group there was 1 for every 16,783 donations. The study defined a serious complication as an incident associated with the blood donation which required hospitalization. The most common complications were vasovagal symptoms, but 12% had angina sufficient to require hospitalization.10

Vasovagal reactions most frequently involve pallor, dizziness or lightheadedness, and/or profuse perspiration associated with transient hypotension, hyperventilation and/or bradycardia, although on rare occasions, such reactions may involve loss of consciousness with or without seizure activity. The donation of blood reduces the overall volume of blood in the vessels which can lead to a transient reduction in blood pressure, and which then generally results in mild vasovagal reactions.2,3,16 Vasovagal reactions occur during or immediately after PABD in 2% to 5% of all patients.4,16,18

Cardiac complications may occur during or shortly after the donation of blood, particularly in patients with preexisting cardiovascular disease. These complications may range in severity from the onset of angina to cardiac arrest. In a cohort of 1526 cardiovascular patients, cardiac complications occurred during the collection of 42 of 2647 autologous units (that is, 2.8% of patients involving 16% of the blood units). These complications were mild in 23 cases, moderate in 7 cases, and severe in 12 cases.3

Anemia
Blood collection visits are usually scheduled at intervals of one week but may be as frequent as every 2 to 3 days. The last blood collection is generally no sooner than 72 hours before scheduled surgery. When a patient donates blood preoperatively, it is expected that he or she will produce additional red blood cells between the time of blood donation(s) and the day of the surgery. However, there is little stimulus for reticulocytosis until the patient's hematocrit drops below 30%. Since most guidelines for preoperative donation require hematocrit to be in the upper 30's in order to donate, the hematocrit seldom decreases sufficiently to produce a hematopoietic response that will generate additional red blood cells. Therefore, it has been found that most patients who donate blood preoperatively are relatively anemic on the day of surgery and, as a result of their PABD, have an increased chance of requiring at least the transfusion of their autologous blood if not additional allogeneic blood.4,10,16,19

This was demonstrated in a study that included 263 patients undergoing elective total abdominal hysterectomy during 1993 and 1994. The 143 patients who donated an average of two units of blood presented on the day of surgery with a hematocrit of 35%, while the 120 patients who did not donate preoperatively had a preoperative hematocrit of 40%. Eighteen percent, that is approximately 26 of the 143 patients in the autologous group required a blood transfusion, and two of these patients required allogeneic blood. In the group that did not pre-donate, only 1 out of the 120 patients received a transfusion.10

In patients undergoing elective hip surgery, PABD provided the peri-operative transfusion requirements in most cases. However, it did not eliminate the need for allogeneic transfusion in 8% to 22% of the cases. In studies involving patients undergoing elective hip surgery with and without PABD, PABD patients had a greater need for any transfusion (79% to 84%) than did patients undergoing hip surgery without pre-donation of autologous blood (46% to 54%). Reasons cited for the inability to avoid allogeneic transfusion in some patients, and the greater transfusion frequency overall in patients undergoing PABD, included the fact that stored autologous blood units sometimes contain sub-optimal levels of red blood cells and the fact that patients donating one or more units of autologous blood may be anemic at the time of surgery. In fact, the risk of exposure to allogeneic transfusion was greater with the presence of preoperative anemia and increased proportionately with the severity of anemia, as determined by preoperative hemoglobin values.5,7,8,16-18

Handling
While standard blood donation is permitted only by healthy subjects who have been carefully screened for the presence of a variety of infectious diseases, PABD may be undertaken in patients with complex medical histories or whose blood contains antigens for serious infections. This necessitates segregated processing and storage of autologous blood (and therefore, additional costs).4

http://www.health.state.mn.us/htac/pabd.htm
6/16/2009
It is possible that the wrong blood, either allogeneic blood or another patient's autologous blood, may be given to the PABD donor or to another patient.\textsuperscript{3,4} The risk that autologous blood may erroneously be given to the wrong patient is estimated to be 1 in 30,000 to 1 in 50,000.\textsuperscript{4} In a study conducted by the New York State Department of Health, this occurred 4 out of 189,101 autologous blood units collected (a risk of 1 in 47,275), and 3 patients received allogeneic blood when autologous blood was available (a risk of 1 in 63,033).\textsuperscript{3}

Since autologous donors may not meet the same medical criteria as allogeneic donors and since autologous blood may not be tested for blood-borne diseases, especially when it is collected and transfused in the same medical facility, administration of autologous blood to the wrong person is associated with an even greater medical risk than allogeneic transfusion.\textsuperscript{3}

Storage

Since even a patient's own blood has the same clerical risks and bacterial contamination risks of allogeneic blood, this adds additional risks to the patient who elected PABD.\textsuperscript{10} During donation or storage, blood may become bacterially contaminated, resulting in transfusion reactions.\textsuperscript{3} While the actual incidence of bacterial contamination is not known, there appears to be no reason for it to be greater for autologous blood than for allogeneic blood.\textsuperscript{3}

Refrigerated whole blood units or packed red blood cells can be stored no longer than 35 and 42 days, respectively, after collection and must be discarded thereafter. At the end of its shelf-life, whole blood has lower free hemoglobin levels than red blood cells alone (45 mg/dL versus 170 mg/dL, respectively) and lower coagulation factors than fresh-frozen plasma (20% versus 80% to 95%, respectively).\textsuperscript{3,16,17,20,21}

Cost

The discard rate of autologous blood donation is one of the variables that affects the cost effectiveness of this practice since autologous blood, which is not necessarily screened for blood born pathogens or donor risk factors, cannot be transfused to another patient and must be discarded if not given to the PABD patient. The discard rate of autologous blood collected ranged from 5% to 38% in studies reviewed, but has been reported to be as high as 50% at some medical centers.\textsuperscript{5,6,13,17,18} The 0.64 million units of autologous blood collected in 1997 generated a cost to the consumer of approximately $103 million. However, only 0.42 million units of the autologous blood were actually transfused, which indicates that 0.22 million units of autologous blood were discarded. The economic impact of this wastage to the consumer in 1997 was estimated to be about $36 million.\textsuperscript{12}

Decision analysis is used to demonstrate the relative benefit obtained from the commitment of health care resources to a particular medical intervention. Because the health effect of an intervention is best stated in terms that allow comparison across various therapies, the phrase "dollars per life-year-saved", which represents the cost in dollars to extend the life of a patient for one year, is a commonly used measure.\textsuperscript{1} Recent published studies have estimated the cost effectiveness of autologous blood donation in terms of dollars per life-year-saved for various surgical procedures.\textsuperscript{10} PABD can increase the cost in terms of dollars per life-year-saved of a surgical procedure by a factor of 2-3 times more expense to 7-10 times more expense depending on the procedure. For example, a coronary artery bypass with PABD cost approximately $500,000 dollars per life-year-saved whereas surgical treatment of left main disease without PABD cost approximately $6,000 dollars per life-year-saved. To put these costs per life-year-saved figures in perspective, most medical and surgical interventions typically cost less than $50,000 per life-year-saved, which is used as a benchmark.\textsuperscript{1}

Other decision analyses models have considered the immunomodulatory effect of allogeneic transfusion on the rate of postoperative infection and suggest the PABD is cost-effective.\textsuperscript{22,23} Some models also suggest the cost of PABD could be significantly lowered by reducing the amount of autologous blood wastage, limiting and standardizing handling, and/or holding autologous blood donors responsible for the additional costs of collecting and storing their blood.\textsuperscript{3,24} Another potential method of reducing autologous blood wastage would be to divert unused autologous blood to the general blood supply (so called, "crossover use"). However, due to the procedural differences between autologous and allogeneic blood donation with respect to the donor's medical status and the requirements for collecting, labeling, screening and storing donated blood, the crossover scheme may add additional costs.
blood, crossover use of autologous blood is not currently endorsed by the American Medical Association's Council on Scientific Affairs.6

**Conclusions**

Studies suggest that while PABD decreases, it does not totally eliminate, the need for allogeneic transfusion for elective surgery. However, it does greatly increases the likelihood of any transfusion and is not entirely without medical risks.

Medical risks associated with autologous donation, from dizziness to anemia to the possibility of angina (and even cardiac arrest), should be considered when high-risk patients are referred for preoperative autologous collection.

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Only about two-thirds of all autologous blood units collected are actually used, and the cost per life-year-saved is higher than the benchmark cost for most medical and surgical interventions.

As the safety of the American blood supply continues to improve, the possible clinical benefit of autologous blood donation becomes diminished.

**Recommendations**

PABD should be discontinued as a routine medical practice due to the current high degree of safety of the U.S. blood bank supply, as well as due to the inherent medical risks associated with PABD. This recommendation becomes of even increasing clinical importance since new blood bank testing procedures, and new means of treating and handling allogeneic blood units, are being developed and implemented on an ongoing basis.

Blood transfusion requires the informed consent of patients, and the medical risks and benefits of both autologous and allogeneic blood transfusion need to be discussed in detail by physicians prior to elective surgery. It is important during such discussions to reserve the encouragement of PABD for patients who, in the physician's professional opinion, have a real and obvious medical requirement for electing PABD.

Allogeneic blood units should be transfused whenever clinically appropriate.

Physicians should discuss the medical risks and costs associated with PABD in detail with their patients before encouraging the use of PABD.

**Appendix I: Studies Assessing the Efficacy of PABD in Elective Hip Surgery**

Key: FFP, fresh frozen plasma; NS, not significant; PABD, preoperative autologous blood donation; pHb, preoperative hemoglobin level; pHCT, pre-operative hematocrit; PHA, partial hip arthroplasty; PHR, partial hip replacement; PKR, partial knee arthroplasty; RBC, red blood cells; rEPO, recombinant erythropoietin; THA, total hip arthroplasty; THR, total hip replacement; TKA, total knee arthroplasty; TKR, total knee replacement.

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<td>Sculco and Gallina (1999)</td>
<td>Hospital for Special Surgery, New York, NY</td>
<td>THA with (n=529) or without (n=113) PABD</td>
<td>Transfusion frequency: 84% and 52% in PABD and non-PABD groups; 84% and 100% in patients with uni- and bilateral THA (no P values provided).</td>
<td>In patients undergoing elective THA, PABD provides most peri-operative blood needs but results in an increased need for transfusion, as compared with THA without PABD.</td>
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<td>Mean pHb: 12.4 g/dl for both PABD and non-PABD groups undergoing THA.</td>
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http://www.health.state.mn.us/htac/pabd.htm
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<td>Gandini et al. (1999)</td>
<td>1073 elderly subjects (aged, 65 to &gt; 80 years) undergoing elective surgery, including 410 undergoing PHR or THA</td>
<td>Prospective, controlled design.</td>
<td>Exposure to peri-operative blood loss was associated with pHb of 14 or more, 13-13.9, 12-12.9, 11-11.9, and &lt;11, respectively. PABD does not completely eliminate possible exposure to allogeneic blood, particularly in patients with low pHb and is associated with wastage of autologous blood.</td>
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<td>Van der Weyden et al. (1993)</td>
<td>108 subjects undergoing elective THR (n=70) or TKR (n=38).</td>
<td>Prospective design.</td>
<td>PABD in all patients. In patients undergoing elective THR, PABD provides most peri-operative blood needs but does not completely eliminate possible exposure to allogeneic blood and is associated with some wastage of autologous blood.</td>
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<td>Graham et al. (1999)</td>
<td>73 subjects undergoing elective PTHA or TKRA (n=41) or elective PKA/TKA (n=32).</td>
<td>Prospective, controlled design.</td>
<td>PABD in all patients. In patients undergoing elective THR, PABD provides most peri-operative blood needs but does not completely eliminate possible exposure to allogeneic blood and is associated with some wastage of autologous blood.</td>
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<td>Bernstein et al. (1999)</td>
<td>493 subjects undergoing THA (n=123), TKA (n=182), laminectomy (n=33), hysterectomy and myomectomy (n=83), radical retropubic prostatectomy (n=95), or nephrectomy and lymph node resection (n=10).</td>
<td>Prospective, controlled design.</td>
<td>PABD in all patients. Overutilization of PABD and wastage of autologous blood can be reduced by restricting PABD to surgical procedures involving large blood loss, such as THA, and by limiting the amount of blood collected to the average amount of blood transfused for such procedures.</td>
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**Preoperative Autologous Blood Donation (PABD)**

- S42 medically stable subjects undergoing elective uni- or bilateral THA.
- PABD protocol not specified.
- Exposure to allogeneic blood in patients with PABD: 8% overall; 3.9%, 4.3%, 16.2%, 12.5%, and 16.8% for pHb of 14 or more, 13-13.9, 12-12.9, 11-11.9, and <11, respectively.
- Discarded autologous blood: 38% and 34% in patients with uni- and bilateral THA (average, 1 unit of blood per person).
- PABD does not completely eliminate possible exposure to allogeneic blood, particularly in patients with low pHb and is associated with wastage of autologous blood.
- Limitations: Retrospective design.
Appendix II: Public Comment

JUL. 13, 2000 4:16PM

Memorial Blood
Centers of Minnesota

MEMO

TO: Tania L. Hughes

FROM: Jed B, Godin MD

CC: HTAC

DATE: 07/13/00

RE: Pre-Operative Autologous Blood Donation Report

Global Comments

I appreciate the thorough and well reviewed topic. As we discussed, the major objection is that the procedure is not particularly cost effective and prone to waste. While I agree wholeheartedly with the conclusions, I think it needs to be put into context that many of the FDA mandated requirements for Blood Banks and Transfusion Services are not cost effective. I enclose a slide from a recent meeting about NAT testing summarizing the apparent cost/QALY for many of the procedures we do. I would like to point out that the most cost inefficient component now being heavily marketed is solvent-detergent plasma, which you allude to on p5 lines 9-10. Do you see any internal inconsistency about largely condemning the process of autologous blood donation, which is many fold more cost effective than this component?

Minor Picky comment

Lines 13-14 on p 2 make no sense - Allogeneic blood should be used in situations like when

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Nydegger (1996)
University Hospital, Berne, Switzerland

62 subjects undergoing elective hip surgery (type not specified).

PABD with rEPO at 100 (n=19) or 200 (n=22) IU/kg or placebo (n=21) on each blood donation day beginning 30 days before surgery with weekly donations until 9 days before surgery (4 blood donations).

Blood separated into RBC and FFP units.

Iron supplement for all patients.

Mean units donated in placebo, 100/rEPO, 200/rEPO groups: 4, 4, and 3.95 (NS between groups).

Mean pHb in placebo, 100/rEPO, and 200/rEPO groups: 12.3, 12.8, and 14 g/dl (P<.05 between placebo and 200/rEPO groups).

All FFP units used in all groups.

Autologous RBC units discarded in placebo, 100/rEPO, and 200/rEPO groups. 10%, 14%, and 26%

Exposure to allogeneic blood in placebo, 100/rEPO, and 200/rEPO groups. 9.5%, 0%, and 0%

In patients undergoing elective hip surgery, the addition of rEPO to a PABD program improves pHb and reduces exposure to allogeneic blood, as compared to PABD alone.

Prospective, randomized, placebo-controlled, double-blind design.

Limitations: Small study sample; P values not provided for most parameters; no control group without PABD.
allogeneic blood is refused... I suspect you mean Autologous blood should ... but even then, I'm not sure that you can say, we don't recommend using it, but hey use it whenever it is indicated.

Lund, Jan

To: http://www.health.state.mn.us/htac


-----Original Message-----

From: Lund, Jan
Sent: Friday, July 28, 2000 2:10 PM
To: http://www.health.state.mn.us/htac/index.htm
Subject: Pre-operative Autologous Blood Donation- Physician Report Draft.

I reviewed the article as well as my Assistant Medical Director and Public Relations Manager.

Page 3, lines 7-8, and page 4, lines 34-35, suggest "Prior to the introduction of Nucleic Acid Testing, the national average risk of HIV exposure through allogeneic transfusion was estimated to be 1 in 676,000, with a lower risk associated with blood collected in the Midwestern United States."

Page 4, lines 2 and page 9, lines 2: suggest, "PABD should be discouraged as a routine medical practice...

Page 4, lines 13-14 and page 9, lines 13-14: Typo? Should state "Autologous blood units should be transfused whenever..."

Page 7, lines 25-26: suggests, "...which is not necessarily screened for blood borne pathogens or donor risk factors."

Page 3, line 15: questioning Only about two thirds of autologous blood units collected are actually utilized.

Page 3, line 31: "...the possible clinical benefits of autologous blood donation..." What about the possible psychological benefits of autologous blood donation?? No where In the article does it talk about the psychological benefits perceived or not.

Page 9, line 2: "PABD should be discontinued (by when and how?) as a routine (in what way Is it a 'routine' now?)..."

I was reading an article that come over the news wire concerning _Public Concern about the Safety of the Blood Supply_. According to the survey of 502 adults, conducted by the Survey Research Center of the Institute for Social Research at the University of Michigan, Inc., 84 percent of Americans are concerned about the safety of blood transfusions today. Only eight percent of respondents would elect to receive blood from the current supply, while an overwhelming 83 percent would prefer autologous or directed donations. Perhaps the most striking finding was that over half of patient respondents would pay $100 - $1000 more, on top of the current cost of about $100/unit of blood, to eliminate the risk of receiving infection from transfusion.

Let me know if you have any questions. Thanks for letting me read and review this article. If any questions, call me at 651-291-4637.

Sincerely,

Jan Lund
Operations Supervisor
North Central Blood Services
References


For questions about this page, please contact our Health Policy, Information and Compliance Monitoring Division: hpsc@health.state.mn.us

See also > Health Policy, Information and Compliance Monitoring Division Home