Eur Spine J (2004) 13 (Suppl. 1) : S34–S39
DOI 10.1007/s00586-004-0726-0

ORIGINAL ARTICLE

Predeposit autologous donation in spinal surgery: a multicentre study

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Received: 11 March 2004
Accepted: 2 April 2004
Published online: 6 July 2004

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Abstract *Background.* Allogeneic blood transfusions (ABT) are often necessary in elective spine surgery because of perioperative blood loss. Preoperative autologous blood donation (PABD) has emerged as the principal means to avoid or reduce the need for ABT. Consequently, a multicentre study was conducted to determine the yield and efficacy of PABD in spine surgery and the possible role of recombinant human erythropoietin (EPO) in facilitating PABD.
Methods. We retrospectively reviewed the hospital charts and blood bank records from all consecutive spine surgery patients who were referred for PABD. Data were obtained from two A-category hospital blood banks and one general hospital. Although we collected data from 1994, the analytic study period was from the last quarter of 1995 to December 2003. Fifty-four (7%) out of 763 patients referred for PABD were rejected, and medical records were available for 680 patients who were grouped into spinal fusion (556; 82%) and scoliosis surgery (124;18%). EPO was administered to 120 patients (17.6%). From 1999 to 2003, PABD steadily increased from 60 to 209 patients per year.
Results. Overall, 92% of the patients were able to complete PABD, 71% were transfused, and almost 80% avoided ABT. PABD was more effective in fusions (86%) than in scoliosis (47%). Blood wastage was 38%, ranging from 18% for scoliosis to 42% for fusions. EPO allowed the results in the anaemic patients to be improved.
Conclusions. Therefore, despite the limitations of this retrospective study, we feel that PABD is an excellent alternative to ABT in spine surgery. However, the effectiveness of PABD may be enhanced if associated with other blood-saving techniques.

Keywords Autotransfusion · Predeposit autologous donation · Scoliosis · Spinal surgery · Erytropoeitin

Introduction

Allogeneic blood transfusions (ABT) are often necessary in elective spine surgery because of perioperative blood loss. However, ABTs are not a risk-free therapy as they carry the potential risk of viral disease transmission, bacterial contamination, incompatibility reactions or transfusion-related immunomodulation (TRIM) [4]. The TRIM effect has been particularly implicated in the increased postoperative infection rate observed in patients who received ABT [6, 25, 26, 27, 28].

Autologous blood transfusion (AUT) techniques have emerged as the principal means to avoid or reduce the need for ABT. These techniques involve the collection and reinfusion of the patient's own blood by using preoperative autologous blood donation (PABD), preoperative acute normovolaemic haemodilution, intraoperative sal-

vage of blood from the surgical field, or postoperative blood salvage, by which drained blood is collected and re-infused within the first 6–8 postoperative hours [18].

However, in order to minimise blood loss and further reduce the need for ABT, several other factors need to be considered, such as preoperative correction of anaemia and withdrawal of coagulation disturbing drugs, the use of controlled hypotensive anaesthesia, a meticulous surgical haemostasis and a sound clinical judgement in deciding when transfusion is required [18].

In addition to clearly reducing most of the ABT-related side effects, AUT has several other advantages; namely, it can be used for patients with rare blood groups, multiple allo-antibodies or religious objections to allogeneic transfusion [18], and helps to preserve the stocks of allogeneic blood, which are becoming increasingly scarce.

For all these reasons, AUT techniques are becoming popular, with PABD being the most used form of autologous blood replacement. Programmes for its use have become standard, especially in association with major orthopaedic procedures such as total joint replacement and spinal surgery. In Europe, the success of these programmes has been well documented in total joint replacement [19], but there is not much information regarding the use of PABD in spine surgery [18, 20].

Consequently, a retrospective multicentre study was conducted to determine: (1) the yield and efficacy [14] related to a PABD programme for patients (including children and teenagers) undergoing posterior spinal fusion or corrective surgery for scoliosis; (2) the possible role of adjuvant treatment with recombinant human erythropoietin (EPO) in facilitating PABD and reducing the exposure to ABT; and (3) to assess the evolution of PABD use in our area over the last ten years.

Patients and methods

Study design

We conducted a retrospective review of hospital charts and blood bank records from all consecutive patients who were referred to the blood banks before undergoing elective surgery for a variety of spine disorders, including channel stenosis, degenerative spondylolisthesis, idiopathic scoliosis and neuromuscular scoliosis.

Data were obtained from two A-category blood banks (more than 15,000 donations per year): Sant Pau i Creu Roja Hospital (HSP, Barcelona), which also serves another six institutions (El Pilar, FIATC, Asepeyo, Dexeus, Teknon and Hospital del Mar), and University Hospital Miguel Servet (HUMS, Zaragoza). We also included data from elective spine surgery at Hospital de la Esperanza (HESP, Barcelona), in which orthopaedic surgery represents 50% of the total surgical activity. Although we collected data from 1994, the analytic study period was from the last quarter of 1995 to December 2003.

Surgical procedures

All surgical procedures included instrumented vertebral fusion, and a spondylodesis with allogeneic or autologous bone from the iliac crest was added to the instrumentation. All anticoagulant and nonsteroidal antiinflammatory medications were discontinued at least 1 week before surgery. Normovolaemic haemodilution, perioperative blood salvage or antifibrinolytic drugs were not used in any patients.

Transfusion criteria were not predefined. 70.5% of the surgery was for fusions and 29.5% was for scoliosis. Some 68% of all the scoliosis surgery was performed at one centre (HUMS), although 29% of this surgery was for patients from another centre (HSP); at the third centre, this pathology only affected up to 1% of the PABD patients (p <0.001).

PABD schedule

All patients scheduled for surgery were asked to preoperatively donate at least two units of autologous blood. In accordance with Spanish and European regulations, requested PABD units were drawn once a week during 2–5 weeks prior to surgery, stored in citrate-phosphate-dextrose-adenine solution or in adenine-dextrose-saline-mannitol, and used within 5 or 7 weeks respectively.

Some patients were unable to donate blood for a variety of reasons, including geographic limitations, patient refusal, bad venous access for phlebotomy, insufficient time before surgery, low weight, and pre-existing medical limitations (e.g. viral hepatitis, coronary artery disease, cerebrovascular disease, uncontrolled hypertension, severe anaemia).

Patients with previous Hb≤130 g/l (who were asked to donate ≥3 autologous units) received EPO since 2000: 600 U/kg bw sc at the time of each donation and on the day of surgery (HUMS), or 600 U/kg bw sc twice a week (HSP, HESP), with a maximum of six doses.

Demographic and clinical data

General patient demographics, including age, weight, gender, number of PABD units requested, donated, transfused and wasted, and allogeneic units transfused were determined from blood bank records by the centres. Baseline haemoglobin was defined as the level obtained before PABD, whereas preoperative haemoglobin was defined as the level obtained after donation of the last autologous unit. PABD success was defined as the requested to donated unit ratio, PABD adjustment or yield was defined as the donated to transfused unit ratio, and PABD effectiveness was defined as the percentage of patients who avoided exposure to ABT [11].

Data analysis

Data from the small clinical centres were analysed together with those of their reference hospital (HSP) to avoid dispersion, so we analysed three groups of patients: HUMS (n =400), HESP (n =187) and HSP (n =132). We also analysed the evolution of PABD by years, and determined the statistical significance of variations in patients' characteristics and outcomes. Statistical univariant analysis included the Student's t -test for numeric variables and the Pearson's Chi square test for string variables. Differences were considered to be statistically significant at p <0.05.

Results

We reviewed the blood bank charts of 763 patients referred for PABD from nine different clinics and hospitals between 1994 and 2003. Fifty-four patients (7%) were not allowed to participate in the PABD programme. The causes of rejection were anaemia (14), lack of time (12),

Table 1 Some demographic and clinical characteristics of the patients who entered the PABD programme, and their distribution by centres (*HUMS* University Hospital Miguel Servet, Zaragoza, *HSP* Sant Pau i Creu Roja Hospital, Clinica El Pilar, Clínica FIATC, Clínica Asepeyo, Clínica Dexeus, Clínica Teknon, and Hospital del Mar, Barcelona, *HESP* Hospital de la Esperanza, Barcelona, *Hb previous* Hb at admission to the PABD programme, *+EPO* patients receiving EPO to facilitate PABD, *M* male, *F* female). Data are the incidence, the percentage, or the mean±standard deviation

Hospital	Number n (%)	Gender M/F	Age (years)	Weight (kg)	Hb previous (g/L)	Diagnostics		+EPO n (%)
						Fusions	Scoliosis	
HUMS	400 (55.6)	193/207	39±16	65±20	143±15	312 (78.0)	88 (22.0)	50 (12.9)
HESP	187 (26.0)	71/116	53±14	73±13	140±14	185 (98.9)	2 (1.1)	40 (23.1)
HSP + others	132 (18.4)	54/78	38±17	70±17	139±13	93 (70.5)	39 (29.5)	30 (22.7)
P (inter-centres)		<0.05	<0.05	<0.05	<0.05	<0.05	<0.001	<0.001

Table 2 Results of the PABD programme for the total series and according to the type of surgery. *PABD success*: ratio between requested to donated units, *PABD effectiveness*: percentage of patients who avoided exposure to ABT, *PABD adjustment*: ratio between donated and transfused units, *P*: level of statistical significance between types of surgery

	Patients n (%)	PABD success (%)	Transfused patients (%)	PABD effectiveness (%)	PABD adjustment (%)	Patients with EPO (%)
Total series	680 (100)	91.8	71.1	78.8	50.9	17.6
Vertebral fusions	556 (81.8)	91.7	65.9	85.7	46.5	13.6
Scoliosis	124 (18.2)	92.1	94.7	47.8	70.8	38.5
P	<0.0001	NS	<0.0001	<0.0001	<0.0001	<0.0001

positive serologies (8), cardiopathy (5), other comorbidities (8), bad venous access (5), and patient refusal (2). The surgical indications for the remaining 719 patients were grouped into 590 cases of spinal fusion (82%) and 129 cases of scoliosis (18%), with most of the scoliosis being treated at two centres (88 at HUMS and 26 at HSP). The male/female ratio was 0.79, with this rate varying among centres. EPO was administered to 120 patients (17.6%), but this varied from 11.9% to 23.1% among the centres (p <0.001) (Table 1).

Six hundred and eighty out of 719 PABD patients (556 fusions and 124 cases of scoliosis) had medical records available and were included in the analysis. As shown in Table 2, 91.7% of the patients completed the PABD programme, without any differences regarding the type of pathology or medical centre. More than 70% of the patients were transfused with at least their own blood. However, although the overall transfusion rate varied from 50% to 100% among the centres (p <0.001), the overall PABD effectiveness in avoiding exposure to ABT was 78.8%. This effectiveness varied from 47.8% for scoliosis to 85.7% for vertebral fusions (p <0.0001). However, PABD adjustment was achieved in only 51% of the patients who entered the programme. The PABD adjustment varied from 0% to 100% among the centres (p <0.001), and from 46.5% to 70.8% for vertebral fusions and scoliosis, respectively (p <0.0001). Overall, 1,632 PABD units were drawn and 1,032 units were transfused, with a wastage of 0.86 units per patient (95% CI 0.77–0.94; range 0–3 units).

As expected, detailed data analysis as a function of the type of surgery revealed significant differences (p <0.05) in both demographical and clinical parameters, with scoliosis patients (n =124) being younger, having lower weight and previous Hb, and needing more blood reposition than fusion patients (n =556) (Table 3). Patients who received EPO (introduced in 2000 as an adjuvant to facilitate PABD), were also younger, had lower weight and previous Hb (≤130 g/L), and were asked to donate more units than patients who did not receive EPO (p <0.05) (Table 4). However, there were no significant differences between groups in the number of donated units to the number of transfused autologous or allogeneic units, regardless of whether or not they received EPO during PABD (Table 4).

Finally, we analysed pooled data from the nine centres regarding the evolution of PABD use during the study pe-

Table 3 Some demographic and clinical data of the patients who entered the PABD programme, classified according to the type of surgery. All data are the mean±standard deviation (*Hb previous* haemoglobin before PABD, *U* blood units, *U/pt* units per patient, *auto* autologous blood, *allo* allogeneic blood)

	Fusion (n =556)	Scoliosis (n=120)	*P*
Age (years)	47±14	20±10	<0.05
Weight (kg)	72±17	56±12	<0.05
Hb previous (g/L)	143±14	135±12	<0.05
Requested units (U/pt)	2.54±0.60	2.95±0.68	<0.05
Donated units (U/pt)	2.33±0.76	2.72±0.91	<0.05
Transfusion auto (U/pt)	1.36±1.13	2.23±1.15	<0.05
Transfusion allo (U/pt)	0.34±1.67	1.38±1.67	<0.05
Total transfusion (U/pt)	1.69±1.69	3.61±2.11	<0.05

Table 4 Some demographic and clinical data of the patients who entered the PABD programme, classified according to whether adjuvant treatment with EPO was used or not. All data are the mean±standard deviation (*Hb previous* haemoglobin before PABD, *U* blood units, *U/pt* units per patient, *auto* autologous blood, *allo* allogeneic blood)

	EPO (124)	No EPO (556)	P
Age (years)	37±20	44±16	<0.05
Weight (kg)	62±15	71±17	<0.05
Hb previous (g/L)	128±11	145±13	<0.05
Requested units (U/pt)	2.77±0.64	2.61±0.58	<0.05
Donated units (U/pt)	2.49±0.97	2.38±0.76	NS
Transfusion auto (U/pt)	1.72±1.24	1.47±1.16	NS
Transfusion allo (U/pt)	0.66±1.38	0.50±1.20	NS
Total transfusion (U/pt)	2.38±2.13	1.96±1.85	NS

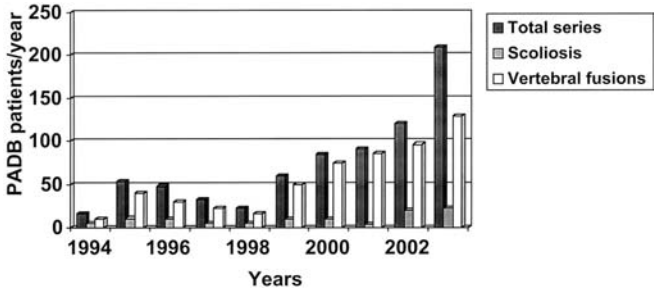

Fig. 1 Pooled data from the nine medical centres included in this study, regarding the evolution of the use of PABD by patients undergoing spine surgery over the last ten years (1994–2003)

riod. As depicted in Fig. 1, from 1994 to 1998, the use of PABD programmes was not a common practice in these centres (with a mean of 32 patients included per year). However, from 1999 to 2003, PABD use steadily increased from 60 patients in 1999 to 209 patients in 2003.

Discussion

Since the AIDS epidemic of the early 1980s, a paradigm of blood safety in established blood delivery systems has evolved which proposes the "safety tripod": appropriate donor selection, screening tests for pathogens and pathogen reduction [5]. With the increasing burden of "zero risk" in public and political perception, it is difficult to question the immutability of this paradigm, but in practice these measures have obviously increased the number of deferred donors and the number of discarded blood units. In addition, the progressively aging population is reducing the number of altruist donors, although there is an increasing demand for blood to meet transfusion requirements of surgical procedures (orthopaedic, cardiac, cancer) [15]. The low birth rate in most European countries will be a further problem in the near future. As a consequence, allogeneic blood has become so scarce that orthopaedic surgery delays have occurred in Spain as well as in Europe [19].

On the other hand, there are several other deleterious ABT side effects through storage-dependent mechanisms, errors in blood administration, and immunosupression

Table 5 Results obtained in several international studies regarding the use of PABD in spine surgery (*P* prospective, *R* retrospective, *IBS* intraoperative blood salvage, *FS* fibrin sealant, *EC* electrocauterious, *ABT* allogeneic blood tranfusion, *NA* not assessed)

Author (reference no.)	Study period	Type of study	Patients (total)	Additional methods	Diagnostics	Efficacy (%)	Wastage (%)	ABT (%)	Donated (U/pt)
Ridgeway et al. [18]	Jan 1998–Dec 2001	R	27 (45)	IBS	Scoliosis	92.6	5.2	7.4 (88.9)[a]	3.6
Lo et al. [11]	2002	R	77	No	Scoliosis	88	6.5	12	NA
Murray et al. [16]	1989–1994	R	164 (243)	No	Idiopathic scoliosis	91	NA	<10	NA
Moran et al. [13]	Jan1989–Jan 1993	P	116 (147)	FS, EC, adrenalin	Scoliosis, kyphosis	89	NA	11 (60)	3
Oga et al. [17]	1992	-	101	No	Scoliosis, others	90 96.2	NA	<10	NA
Johnson et al. [9]	1989	-	63	IBS	-	98.4	54	1. 6	NA
Cha et al. [4]	1996–1998	R	129 (191)	No	Laminectomy, fusions	82.2	77 28 16	0 (12) 16 (55) [a] 37 (78) [a]	2.2
Goodnough et al. [8]	July1985–June 1988	R	150 (595)	No	Elective spine	87	NA	13 (26)	2.4 3.0
Seltzer et al. [22]	3.5 years	R	174 (224)	IBS	Revision, fusion, fixation	99	4	7	96

[a] $P < 0.05$

which are not included in the "safety tripod". In fact, there is increasing evidence that TRIM effects of ABT may be responsible for at least a 10% higher rate of postoperative infection in transfused patients, with longer hospital stays [6, 25, 27, 28]. Several studies and clinical observations suggest that AUT might be clinically and immunologically less detrimental than ABT [26].

For all these reasons, the interest in alternatives to ABT has particularly grown for elective surgery. One alternative that currently accounts for over 5% of the blood donated in the United States and some countries in Europe is AUT, obtained primarily by PABD. However, Brecher and Goodnough recently wrote in Transfusion that the global interest in PABD is decreasing, but we feel that this statement should not be applied universally [2, 3]. Although PABD is underused in most European Union (EU) countries, there are several reasons to believe that the use of PABD and other blood saving strategies is rising in Europe and will rise further in the near future [15]. Our data showing a steady increase of PABD use over the last years (Fig. 1) seem to support this view.

With regard to spine surgery, PABD (which is considered as the "gold standard" in AUT) can not only be safely and effectively used in adults (e.g. vertebral fusions) but also in adolescents (e.g. scoliosis surgery) (Table 5) [4, 8, 9, 11, 13, 17, 18, 19, 22]. Data from our series showed that PABD avoided exposure to ABT in almost 80% of the patients, even though PABD was far more effective in fusions (85.7%) than in scoliosis (47.8%) (Table 2). However, the patients who underwent surgery for scoliosis had lower body weight and previous Hb levels together with higher perioperative blood loss, and consequently needed a higher volume of blood reposition [1, 7, 12, 30]. All this led these patients to have an increased ABT rate, despite the fact that more PABD units were available (Table 3) although the amount of AUT transfused correlated negatively with the amount of ABT [12]. Thus, these data clearly indicate the need to associate other blood saving methods (e.g. perioperative blood salvage, haemostatic drugs or EPO) with PABD in scoliosis [4, 7, 9, 11, 12, 13, 16, 17, 18, 21, 22, 29].

PABD wastage is a serious problem because up to half of the blood collected may be discarded, and this wastage leads to PABD costs that are higher than those for ABT [29]. Data from the OSTHEO study (a multinational survey conducted in Europe on lower limb arthroplasty) are promising in this regard since 87% of the autologous units collected were actually transfused [1, 9]. In our series, PABD adjustment varied among the centres (p <0.001) and from 46.5% to 70.8% for vertebral fusion and scoliosis, respectively (p <0.0001) (Table 2). According to data shown in Table 3, the overall blood discard rate was 37%, with rates ranging from 18% in scoliosis to 42% in vertebral fusions. However, we feel that wastage in the later surgery can be reduced by adjusting the number of units collected to each hospital's transfusion experience, or each surgical team's or patient's characteristics, and not to general surgical blood-ordering schedules [7]. This strategy, together with periodical audits of PABD use, should avoid over-collection, prevent excessively decreased postoperative haemoglobin levels, reduce administrative errors, and improve cost-effectiveness [15, 24].

In the clinical setting of spine surgery, adjuvant treatment with EPO might facilitate the collection of the requested PABD units and result in higher perioperative haemoglobin levels and a further reduction in the exposure to ABT. In our series, 120 patients (38.5% scoliosis) with previous Hb≤130 g/l received EPO (4.13 doses per patient). As shown in Table 4, despite their lower Hb levels (128±11 g/L) they were able to donate autologous blood and avoid ABT to the same extent as those patients who did not receive EPO (Hb=145±13 g/L) – whilst blood wastage was lower in the EPO group (30.9% vs. 38.2% for EPO and non EPO groups, respectively). Therefore, our results are partially in agreement with those of previous studies involving patients with similar surgical pathologies [10, 17, 23].

Conclusions

Autologous transfusion is one of several techniques used to reduce the need for allogeneic transfusion and is most widely used in elective surgery, obtained primarily by PABD. However, the implementation of PABD programmes requires careful organisation, a guarantee that the surgery will proceed at the right date, as the donated blood has a caducity of 5 or 7 weeks, and excellent communication between the surgeons, anaesthetists, haematologists and blood bank personnel.

We have shown that this multidisciplinary collaboration is possible in three different organization models. First, a blood bank inside a tertiary hospital; second, a blood bank with one special section exclusively dedicated to autotransfusion which obtains and supplies autologous blood to several hospitals and clinics; and third, a general hospital half dedicated to orthopaedic surgery with a dynamic and involved transfusion committee that controls all transfusions.

Overall, in our series PABD avoided exposure to ABT in almost 80% of the patients, although there were significant differences between those who underwent scoliosis surgery (47.8%) and those who underwent vertebral fusions (85.7%), with a blood wastage acceptable in the former (18%) and perhaps too high in the latter (41%). In addition, adjuvant treatment with EPO facilitated completion of PABD in moderately anaemic patients.

Despite the limitations of this retrospective study without comparisons to a control group, we feel that PABD is an excellent alternative to ABT in spine surgery. The effectiveness of spine surgery may be enhanced if an individualized approach is taken into account, considering

both the patient's likelihood of requiring ABT and the risks and benefits of PABD for that individual, and also associating ABT with other AUT modalities or other blood saving techniques, such as antifibrinolytic drugs, fibrin sealant, controlled hypotension, autologous platelets, etc.

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