

Feasibility of pre-operative autologous blood donation in Indian patients with elective orthopaedic surgery

Karan Saluja, Neelam Marwaha, Beenu Thakral, Vijay Goni*, R.R. Sharma & G.D. Puri**

*Departments of Transfusion Medicine, *Orthopaedics & **Anaesthesia, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, India*

Received November 24, 2005

Background & objectives: Pre-operative autologous blood donation (PABD) in elective orthopaedic surgeries is a well known procedure in the West. We initiated this programme at a tertiary care hospital in north India to study its feasibility in Indian patients.

Methods: In a prospective case-control study, 144 patients undergoing primary total hip or knee replacement, inter-vertebral discectomy, mal-union and non-union reconstruction were educated and motivated to pre-donate. Patients fulfilling the inclusion criteria and making autologous donation formed the PABD group (n=22). Patients eligible for PABD, but unwilling to participate; age, sex, pre-operative haemoglobin and operative procedure matched acted as controls (n=27). Unit(s) collected was processed like an allogeneic unit. Unit(s) found reactive for infectious markers or not utilized was discarded. Mean blood losses, transfusion trigger, allogeneic exposure and wastage between the two groups were compared.

Results: Of the 144 patients motivated, 40 per cent of the eligible subjects pre-deposited. The main motivational factor was fear of getting infection from someone's blood. Cardiac events and anaemia prevented 61.8 per cent patients to participate. Of the 50 units ordered, autologous units with a mean of 1.4 units/patient contributed 62 per cent. For total hip and total knee replacement (THR and TKR), autologous units met 76.2 and 80 per cent respectively of the total blood requirement. A significant decrease in the allogeneic exposure was observed between PABD and control group (18.2 vs 66.7%); 32.3 per cent of the autologous units were discarded.

Interpretation & conclusion: Comprehensive PABD programme may be an effective method for reducing the need for allogeneic transfusion in patients undergoing joint replacement surgeries in our country, where transfusion transmitted infections due to high percentage of replacement donations and lack of sensitive assays for testing are still a cause for concern.

Key words Elective orthopaedic surgery - pre-operative autologous blood donation

Transfusion of blood and blood components is associated with an inherent risk of transfusion transmitted infections (TTI). Fortunately, due to stringent donor screening, sensitive ELISA testing and introduction of nucleic acid testing (NAT) the risk of TTI has decreased considerably in the developed countries. The risk per unit transfused of HIV is 1:1,900,000 whereas hepatitis C and B virus (HCV and HBV) transmission risk is 1:1,600,000 and 1:63,000 respectively¹. However, such data are lacking in developing countries because of non-uniformity in screening procedures despite mandatory testing by law, financial constraints of the government in introducing NAT, lack of trained personnel and look back policy. According to WHO statistics on blood safety, 43 per cent (13 million units) of donated blood in the developing countries is not screened for all relevant TTIs. Thus, 80 per cent of the world's population in developing countries has access to only 20 per cent of the world's safe blood supply². Moreover, in India only 52 per cent of the total blood collection is from voluntary donors as compared to 100 per cent in the West. Thus 48 per cent of the country's blood collection is from replacement or relative donors who donate under pressure and stress³. Hence, autologous blood donation would provide a safe alternative for patients in specific conditions.

Pre-operative autologous blood donation (PABD) in elective orthopaedic surgeries is a well known procedure in the West but on the contrary, in India it is still in infancy due to ignorance among patients and physicians. We initiated this programme in elective orthopaedic surgery at a tertiary care hospital in north India to assess its feasibility in Indian patients.

Material & Methods

A prospective case-control study was conducted from July 2002 to October 2003 at the Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, after approval from the

Institutional Ethics Committee. During this period, all patients undergoing elective orthopaedic surgeries like primary total hip replacement (THR), primary total knee replacement (TKR), inter-vertebral discectomy, mal-union and non-union reconstruction were educated and motivated to participate in the PABD programme. The educational material was circulated in the form of posters, pamphlets and through verbal communication with patients and surgeons.

Apart from normal donor screening, the additional inclusion criteria for the PABD programme were (i) baseline haemoglobin >11 g/dl or haematocrit >34 per cent; (ii) controlled hypertension on one drug only; and (iii) controlled diabetes mellitus on oral hypoglycaemic. Patients with uncontrolled hypertension, history of angina, myocardial infarction (MI), severe or unstable cardiac disease, aortic stenosis, insulin dependent diabetes mellitus (IDDM), infection or conditions predisposing to bacteraemia, any chronic hepatic or renal disorder were excluded. After a written informed consent, patients who donated their own blood prior to surgery formed the PABD group. Age, sex, pre-operative haemoglobin and operative procedure matched patients who were eligible for pre-operative donation, but unwilling to participate constituted the control group for comparison. All eligible, willing patient-donors were prescribed sustained release ferrous sulphate tablets in a dosage of 200 mg thrice daily at their selection for PABD and were advised to continue the same till two months after the surgery as has been suggested by Guinea *et al*⁴. A minimum of one week interval was taken between start of iron therapy and the first PABD donation by a patient.

Autologous blood donation schedule: The blood was collected according to Morse formula⁵ (10% of the estimated blood volume) at a time in 450 ml CPDA₁ plastic blood bag (Terumo Penpol Limited, Chennai, India). Blood from patients requiring single unit was collected any time between 4-10 days prior to their

surgery whereas blood from patients requiring multiple units (2-4 units) was collected at weekly intervals for a single unit each time. The last unit was collected 72 h prior to the proposed date of surgery.

Processing of autologous units: The units were stored at $4 \pm 2^\circ\text{C}$ for a maximum period of 35 days on a separate shelf to avoid mix up with other units in the inventory. Unit(s) not utilized during the specified time was discarded and no crossover were made to the homologous pool. All units collected was ABO and Rh grouped, screened for irregular antibodies and mandatory tests (HBsAg, anti-HCV, anti-HIV I&II, malarial parasite and VDRL test for syphilis) as per Indian Drugs and Cosmetic Act 1940, Rules 1945 (amendment June 2001)⁶. Any unit found reactive for any of the above tests was discarded to ensure procedure uniformity to that of an allogeneic unit and the surgeon concerned was informed of the same.

In order to avoid errors, the following check strategies were made: (i) Separate fluorescent green

labels showing patient's identification were used in triplicate. The first one was pasted on the autologous unit, second pasted on the blood requisition form and last on the patient's record file. (ii) Separate issue forms were given for autologous and allogeneic unit(s) of blood. Autologous units were issued prior to allogeneic ones.

Transfusion of autologous units: The amount of blood loss (intra-operative and post-operative) and the post-operative Hb were the deciding factors for transfusion. Hb of < 9 g/dl was decided by surgeons as transfusion trigger. Hospital stay was defined as the period from the day of surgery to the day of discharge from the hospital. The percentage of autologous blood utilization and the allogeneic blood exposure between the two groups were compared. The wastage of the autologous units was also calculated.

Statistical analysis was done using Wilcoxon Rank sum test and unpaired 't' test, wherever appropriate, while comparing similar parameters between the two groups.

Results

A total of 144 adult patients who were to undergo elective orthopaedic surgery were assessed for autologous blood donation. Fifty five (51M/4F) out of 144 (94M/50F) were eligible as per inclusion criteria but only 40 per cent (22/55) consented for PABD, and 27 of the remaining 33 eligible patients acted as controls. Cardiac events and anaemia prevented 61.8 per cent (89/144) patients to participate. Anaemia (Hb < 11.0 g/dl) was seen in 47 per cent (68/144) of which females were significantly more anaemic as compared to males [28.3 vs 18.7% ($P < 0.05$)].

The mean age of patients in both the groups for various procedures was comparable (Table I). The mean Hb (g/dl) values prior to autologous donation and pre-operatively was 14.4 and 12.1 for THR; 14.5 and 12.1 for TKR; 15.5 and 13.8 for

Table I. Patient characteristics of pre-operative autologous blood donation (PABD) and control groups

Characteristics	PABD group (n=22)	Control group (n=27)
Age (yr) mean \pm SD (range)	38.1 \pm 15.1 (20 - 66)	42.96 \pm 13.1 (20 - 67)
Male : Female ratio:	1 : 0	1 : 0
Weight (kg) mean \pm SD (range)	72.18 \pm 11.1 (50 - 94)	75.19 \pm 10.2 (56 - 96)
<i>Type of procedure:</i>		
U/L primary THR	12	15
U/L primary TKR	3	4
Inter-vertebral discectomy for PIVD	1	2
Nailing/plating of non- union or mal-union	6	6
U/L, Unilateral; THR, total hip replacement; TKR, total knee replacement; PIVD, prolapsed inter-vertebral disc		

discectomy; 13.4 and 11.9 for nailing/plating respectively in the PABD group. In the control group, mean pre-operative Hb (g/dl) for the above procedures were 12.4, 12.2, 13.2 and 12.3 respectively. No significant difference in the mean pre-operative Hb was observed between the two groups. Only one patient developed anaemia by pre-depositing one autologous unit (11 g/dl to 9.7 g/dl).

According to the Maximum Surgical Blood Ordering Schedule (MSBOS) of our Institute 3-4, 2-3, 2 and 1 units were requested for unilateral primary THR, unilateral primary TKR, inter-vertebral discectomy and nailing/plating for non-union/mal-union respectively. No significant difference in blood ordering pattern was observed between the two groups. The blood ordering per procedure, mean number of units deposited per patient, autologous unit utilization and allogeneic transfusion in the PABD group is shown in Table II. Fifty units were ordered, out of which 62 per cent (31/50) were pre-deposited. The mean number of units pre-deposited per patient was 1.4 (1 to 1.67). The reasons for less number of units collected in PABD group as compared to the number requested were due to the following reasons: HBsAg reactivity

(n=1), anaemia (n=1) and nine patients were enrolled later in their collection schedule and were not willing to postpone their surgery dates.

The mean blood losses (ml) in PABD vs. control group for various procedures [THR (733.3 vs. 826.7); TKR (566.7 vs 518.8); discectomy (175 vs 300); nailing/plating (142.5 vs 168.8)] were comparable. The mean transfusion trigger (Hb) for PABD group (8.39 ± 0.6 g/dl) was comparable to control group (8.12 ± 0.78 g/dl) and thus patients with PABD were not over-transfused. The transfusion rate per patient in PABD vs. control group for THR [1.7 (21/12) vs 1.8 (27/15)] and TKR [1.67 (5/3) vs 1.5 (6/4)] was comparable. A significant decrease in the mean duration of hospital stay (days) was observed between PABD and control group for THR (31.6 ± 5.7 vs. 39.5 ± 4.7) and TKR (16.7 ± 1.5 vs. 24.5 ± 3.4) surgeries respectively.

Of the 31 pre-deposited units, 21 (67.7%) were transfused. Maximum and minimum utilization of 83.3 per cent (20/24) and 16.7 per cent (1/6) of these autologous units was observed for joint replacement surgeries and nailing/plating procedures respectively. A highly significant decrease of allogeneic blood

Table II. Blood ordering pattern, pre-deposit per patient, autologous unit utilization and allogeneic transfusion in study group (n=22)

Type of procedure	Units ordered (per patient)	Units pre-deposited (% collected)	Units pre-deposited per patient (mean)	Units transfused (% utilized)	Allogeneic units transfused/total requirement (%)	Autologous units transfused/total requirement (%)
U/L primary THR (n=12)	36 (3)	20 (55.5)	1.67	16 (80)	5/21 (23.8)	16/21 (76.2)
U/L primary TKR (n=3)	6 (2)	4 (66.7)	1.33	4 (100)	1/5 (20)	4/5 (80)
Inter-vertebral discectomy for PIVD (n=1)	2 (2)	1 (50)	1	0	0	-
Nailing/plating of non-union or mal-union (n=6)	6 (1)	6 (100)	1	1 (16.7)	0	1/1 (100)
Total	50 (2.27)	31 (62)	1.4	21 (67.7)	6/27 (22.2)	21/27 (77.8)

U/L, Unilateral; THR, total hip replacement; TKR, total knee replacement; PIVD, prolapsed inter-vertebral disc

Table III. Allogeneic exposure (%) in PABD vs control groups

Type of procedure	Allogeneic exposure (%)	
	PABD group (n = 22)	Control group (n = 27)
U/L primary THR	3/12** (25)	14/15 (93.3)
U/L primary TKR	1/3* (33.3)	3/4 (75)
Inter-vertebral discectomy for PIVD	-	1/2 (50)
Nailing/plating of non-union or mal-union	-	-
Total	4/22+ (18.2)	18/27 (66.7)

U/L, unilateral; THR, total hip replacement; TKR, total knee replacement; PIVD, prolapsed inter-vertebral disc
*P**<0.05, **<0.01, +<0.001 compared to control group

exposure was seen between PABD and control group (18.2 vs 66.7%) (Table III). This decrease was primarily observed in patients undergoing joint replacement surgeries [26.7% (4/15) in PABD vs 89.5 per cent (17/19) in control group]. In patients with THR, autologous transfusion was sufficient in nine cases. In the remaining three patients, one patient was given allogeneic units only on account of his HBsAg reactivity and the other two patients were transfused one allogeneic unit in addition to autologous ones. In patients with TKR, autologous units were sufficient for two patients, but one donor-patient required an additional allogeneic unit.

Overall 32.3 per cent (10/31) of the autologous units were not utilized. The maximum wastage was seen in one unit collection (50%) and for inter-vertebral discectomy and nailing/plating procedures [85.7% (6/7)]. This is reflected by a high cross-match to transfusion (CT) ratio for these latter surgeries (7:1 and 10:1) as compared to joint replacement surgeries (1.2:1 and 1.7:1) in PABD and control group respectively. One autologous donor-patient (32/M) had a mild vasovagal reaction ten minutes post-

donation. No transfusion reaction was observed in PABD group as against four (3 febrile non-haemolytic transfusion reaction, 1 allergic) reactions in the control group.

Discussion

Donor-patient reasons for participation in a PABD programme vary from country to country. In one of an early study from UK by Howard *et al*⁷, 59 per cent of the eligible patients actually pre-donated, other studies found only 5 and 8 per cent of the eligible patients pre-donated prior to their scheduled joint replacement surgeries^{8,9}. In the present study, 40 per cent of the eligible patients participated in PABD programme. This percentage is higher than that found in a study from western India, where 13.5 and 14.5 per cent patients participated in PABD for orthopaedic surgeries during two consecutive years¹⁰. The fear of getting infection from someone else's blood (100%) and surgeon's recommendation (77%) were the motivational factors for patients to pre-donate in our study. This is in contrast to western studies where only 20-53 per cent of autologous donors cited fear of infection from transfusion as their primary motivational factor to donate^{11,12}. Therefore in the West, now there is a decline in the percentage of the eligible patients who actually pre-donate due to better availability of more sensitive and specific screening tests for TTI, high cost of autologous blood units and inconvenience for the patients to travel long distances to blood centers for pre-donation. This is in contrast to the scenario in the developing countries where this practice has not gained momentum due to lack of sensitization among surgeons and ignorance among patients. NAT testing at present may not be feasible in our country, thus autologous blood donation may be a useful and safe alternative in certain surgeries.

Anaemia was the main hindering factor that prevented 47 per cent of our patients to participate and significantly so in females. Anaemia has a high

prevalence (35-64%) in female population in our country^{13,14}. Studies on PABD also suggest that female patient selection should be done with caution as PABD induced iatrogenic anaemia is found more commonly in women as compared to men (36 vs 4%) resulting in a higher allogeneic exposure¹⁵. In the present study, none of the eligible female patient participated, whereas one male patient developed iatrogenic anaemia. PABD studies using erythropoietin (EPO) have been conducted in the West with good results¹⁶ but due to its high cost, there is scarcity of data on this issue from our country.

The mean age of patients undergoing PABD for THR in our study was 39 yr which is in contrast to 60-65 yr cited in the western literature^{9,17}. The underlying medical condition in the old age (cardiovascular events or IDDM) prevented them to enroll in our PABD programme.

Significant blood losses during the joint replacement surgeries make peri-operative blood management an issue of primary concern for surgeons. Though there is no consensus to decide a cut-off value as a transfusion trigger for red cells, it is recommended that transfusion should be given only when the Hb is < 7 g/dl¹⁸. A blood conservative strategy by Billote *et al*¹⁹, using Hb 7 g/dl as a transfusion trigger for both PABD and control group, found no allogeneic blood requirement in either group. However, at our institute, Hb <9 g/dl is taken as a guide for transfusion by the surgeons.

Autologous blood though providing the benefit of avoiding allogeneic exposure is itself associated with the concern of over-transfusion. Thus, not only collection efficiency needs to be increased, efforts should be directed at its rational utilization. In our study, 83.3 per cent utilization of autologous blood was seen in joint replacement surgeries which is comparable to other studies^{9,10,19}. In our study, a significant decrease in allogeneic exposure was

observed in PABD as compared to the control group. Allogeneic exposure in autologous patient-donor undergoing joint replacement surgeries have varied from 8-17 per cent in various studies^{20,21} with 26.7 per cent observed in the present study. Thus allogeneic exposure in these patients can further be reduced if they are educated and motivated for collection of the desired number of autologous units and measures taken to prevent the development of iatrogenic anaemia.

In recent years, interest in the use of autologous blood donation has declined. The main reasons attributed were high wastage due to inappropriate patient selection for PABD, negligible risk of TTI by allogeneic exposure and high cost of an autologous unit²². The overall wastage of autologous units in the present study was 32.3 per cent. The discard rate of the autologous units in elective orthopaedic surgeries shows a wide variation from 6.9-56 per cent^{21,23}. In our study, 83.3 per cent of autologous units for the nailing/plating surgeries were wasted as compared to 16.7 per cent for joint replacement surgeries. A low CT ratio was observed for joint replacement surgeries in both PABD and control groups. Thus ineffective patient selection for one unit autologous donation was mainly responsible for the above wastage.

In our study, a significant difference in the length of hospital stay was observed between PABD and control group recipients undergoing joint replacement surgeries. Further investigations are required before benefit other than safety from TTI can be attributed to autologous transfusion.

Thus, the present study although conducted on a small number of patients suggests that a comprehensive programme of pre-deposit autologous blood for transfusion is an effective method for reducing the need for allogeneic transfusion and thus avoids the attendant complications associated with it in patients

undergoing joint replacement surgeries. Such a programme was well tolerated by our patients and easily managed by the staff. The main difficulty in implementing this programme was in females and older patients. In such patients pre-donation with administration of EPO, haemodilution or blood salvage (intra-operative and post-operative) needs to be studied. It also emphasizes the need for proper organization, planning and communication between surgeons and transfusion specialists for its implementation. This is of particular significance in developing countries like India where TTI due to high percentage of replacement donations and lack of NAT testing are still a cause for concern and acute shortages of blood and its components occurs frequently.

References

1. Brecher ME. *American Association of Blood Banks, Technical Manual*, 14th ed. Bethesda: American Association of Blood Banks; 2002 p. 662.
2. World Health Organization, Blood Transfusion Service. *Global database on blood safety from 1998-1999*. Geneva, WHO/BTS, 2001, Summary report.
3. Voluntary blood donation collection: Indian scenario. New Delhi: National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India; 2004.
4. Guinea JM, Lafuente P, Mendizabal A, Pereda A, Sainz Arroniz MR, Perez Clausell C. Results of pre-operative autotransfusion with ferrous ascorbate prophylaxis in orthopedic surgery patients. *Sangre (Barc)* 1996; 41 : 25-8.
5. Morse M, Carsello DE, Schultz FW. Blood volume of normal children. *Am J Physiol* 1947; 151 : 448-58.
6. Malik V. *Drugs and Cosmetic Act, 1940*, 16th ed. New Delhi: Eastern Book Company; 2003 p. 279-303.
7. Howard MR, Chapman CE, Dunstan JA, Mitchell C, Lloyd HL. Regional transfusion center pre-operative blood donation program: the first two years. *BMJ* 1992; 305 : 1470-3.
8. Toy PT, Strauss RG, Stehling LC, Sears R, Price TH, Rossi EC, *et al*. Pre-deposited autologous blood for elective surgery: A national multicenter study. *N Engl J Med* 1987; 316 : 517-20.
9. Feagan BG, Wong CJ, Lau CY, Wheeler SL, Sue-A-Quan G, Kirkley A. Transfusion practice in elective orthopaedic surgery. *Transf Med* 2001; 11 : 87-95.
10. Khodaiji SJ, Agarwala S, Mehrotra M, Deshpande AS. Autologous blood transfusion in orthopaedic surgery - A practical alternative. *Indian J Orthop* 1999; 33 : 195-9.
11. Domen RE, Ribicki LA, Hoeltge GA. An analysis of autologous blood donor motivational factors. *Vox Sang* 1995; 69 : 110-3.
12. Lee SJ, Liljas B, Churchill WH, Popovsky MA, Stowell CP, Cannon ME, *et al*. Perceptions and preferences of autologous blood donors. *Transfusion* 1998; 38 : 757-63.
13. *Nutritional anemia: Report of a WHO scientific group. Technical report series no. 405*. Geneva: World Health Organization; 1968.
14. *Nutritional anemia: Report of a WHO scientific group. Technical report series no. 580*. Geneva: World Health Organization; 1975.
15. Sher JD, Callum JL, Hall GA, Fuller K. Pre-operative autologous blood donations (PAD) in women: Are we doing more harm than good? *Transfusion* 1998; 38 : 67S.
16. Bezwada HP, Nazarian DG, Henry DH, Booth RE Jr. Pre-operative use of recombinant human erythropoietin before total joint arthroplasty. *J Bone Joint Surg Am* 2003; 85 : 1795-800.
17. Thomson JD, Callaghan JJ, Savory CG, Stanton RP, Pierce RN. Prior deposition of autologous blood in elective orthopaedic surgery. *J Bone Joint Surg Am* 1987; 69 : 320-4.
18. Practice Guidelines for Blood Component Therapy: A report by the American Society of Anesthesiologists Task Force on Blood Component Therapy. *Anesthesiology* 1996; 84 : 732-47.
19. Billote DB, Glisson SN, Green D, Wixson RL. A prospective, randomized study of pre-operative autologous donation for hip replacement surgery. *J Bone Joint Surg Am* 2002; 84 : 1299-304.

20. Sculco TP, Gallina J. Blood management experience: Relationship between autologous blood donation and transfusion in orthopaedic surgery. *Orthopaedics* 1992; 22 (Suppl 1) : S129-34.
21. Hatzidakis AM, Mendlick RM, McKillip T, Reddy RL, Garvin KL. Preoperative autologous donation for total joint arthroplasty. An analysis of risk factors for allogeneic transfusion. *J Bone Joint Surg Am* 2000; 82 : 89-100.
22. Brecher ME, Goodnough LT. The rise and fall of pre-operative autologous blood donation. *Transfusion* 2001; 41 : 1459-62.
23. Goodnough LT, Rudnick S, Price TH, Ballas SK, Collins ML, Crowley JP, *et al.* Increased pre-operative collection of autologous blood with recombinant human erythropoietin therapy. *N Engl J Med* 1989; 321 : 1163-8.

Reprint requests: Dr Neelam Marwaha, Professor & Head, Department of Transfusion Medicine
Post Graduate Institute of Medical Education & Research, Chandigarh 160012, India
e-mail: karansalujal1975@yahoo.com; neelam2918@yahoo.com