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Do patient-related blood donors represent a threat to the safety of the blood supply?

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Background and Objectives. Patient-related blood donors contribute to a significant proportion of the blood units collected in hospital-based blood banks. However, there is some concern on the safety of this kind of donation because of the possible existence of incentives for the donor to conceal deferrable risk factors, thus increasing the risk of donation within the window-period of transfusion-transmitted infections. We tested the hypothesis that if patient-related blood donors are less safe than community ones, the former would display both a higher prevalence of viral markers and a predominance of undisclosed risk-factors with low social acceptability.

Design and Methods. Comparison of virus reactivity rates against hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV), and the associated risk-factors, between patient-related and community donors who donated whole blood in our center during a five-year period.

Results. During the period under study 72,226 donors gave 149,944 whole blood units, of which 22,888 (15.3%) were provided by patient-related donors. There were 273 confirmed virus-reactive donations (15 anti-HIV, 148 anti-HCV and 110 HBsAg). The adjusted prevalence of virus reactivity was 19 (95% CI: 11-35) times higher in first-time donors than in repeat donors, 3.5 (95% CI: 2.3-4.1) times higher in donors ≥ 30 years old than in younger ones, and 2.5 (95% CI: 1.9-3.2) times higher in patient-related donors than in community donors. With regard to deferrable risk-factors not disclosed at the time of donation, there was no significant difference between patient-related and community donors in the frequency of people who denied any risk-factor or who admitted intravenous drug use or high-risk sex. Past household contact with individuals having liver disease was significantly more frequent in patient-related donors than in community ones.

Interpretation and Conclusions. Our results do not support the hypothesis that patient-related donors represent an increased risk of window-period donation because they conceal deferrable risk factors more frequently than community donors.

Key words: blood donors, transfusion-transmitted infections.

Since the early 1980s studies of the blood supply in the US have shown a narrowing margin between supply and demand.[1] Some analysts have even predicted that, in the absence of timely and adequate interventions, a critical blood shortage will occur in the coming years.[2] Although not so publicized as in the US, there are reasons to believe that the adequacy of the blood supply is also under threat in Europe. Population aging –more marked in Europe than in the US-, a growing list of donor deferral criteria, and changes in the population lifestyle and, perhaps, also in the scale of values may be contributing to a progressive inadequacy of the blood supply. Beside other measures aimed at preventing future blood shortages, such as a close monitoring of the blood supply and studies on the determinants of blood donation and transfusion, care must be taken before expanding the current list of deferral criteria with new, scientifically unsound additions.

Donor recruitment among patients' relatives and friends has been a traditional source of allogeneic blood supply in hospital-based blood banks. Taken as a source of motivated blood donors rather than as a way to restore inventories or to provide directed donations, these patient-related donors should not be different from those recruited in the community. However, it has recently been argued that patient-related donors are less safe than community-recruited ones. Provided that patient-related donors go through the same qualification

process as community donors do, the only scientific basis for an increased risk associated with this kind of donation would be the existence of incentives to not disclose behavioral or medical history risk-factors that would preclude donation acceptance. Peer pressure and the relative lack of anonymity associated with patient-related donations might induce the prospective donor to conceal personal behavior that would be the basis for deferral. False statements at the pre-donation interview, mainly in response to sensitive questions on personal behaviors, are not rare among blood donors, and may allow blood collection within the window period of transfusion-transmitted infections.[3,4] Therefore, any condition encouraging inaccurate answers at the pre-donation interview may represent a threat to the safety of the blood supply.

We formulated the hypothesis that if patient-related blood donors are less safe than community-recruited ones, the former would display both a higher prevalence of viral markers and a different profile of undisclosed risk-factors, with a predominance of those with lowest social acceptability. In order to test this hypothesis we compared the prevalence of viral markers, and the associated risk-factors, between patient-related and community-recruited donors who gave whole blood at our center within the past five years.

Design and Methods

The Hospital Clinic Blood Bank is located in a large metropolitan area (2.2 million inhabitants) and supplies blood components to one 711-bed tertiary care university hospital, one 146-bed general and obstetrics hospital, and one 369-bed children's hospital. Blood is collected at a fixed facility in the hospital and through external blood drives. As in many other hospital-based blood banks, patient-related donations have been a traditional source of allogeneic blood supply in our center. The families contacted are those of patients preferentially selected because they had received large quantities of blood components, had had a favorable outcome, and their transfusions were probably perceived as a life-saving therapy. Examples include cases of liver transplant, hematologic malignancies, gastrointestinal hemorrhage, cardiac surgery, or multiple traumatisms. Patient's relatives are contacted by a trained social worker who talks to them about the peculiarities of blood transfusion and donation, and are invited to donate and/or forward the message to friends and relatives. The rationale is that family members and friends of a recently transfused patient would be more conscious of the importance of donating blood. Patient-related blood donors go through the same qualification process as community donors do.

In Spain, the state and regional health authorities regulate the basic requirements of the donor qualification process. Local blood bank medical directors may add supplemental donor deferral criteria or screening tests if they are considered pertinent. With regard to protecting the blood recipient from transfusion-transmitted viral diseases, prospective donors receive educational material and explanations, and are asked about the deferral criteria listed in Table 1. They should also fill in and sign a questionnaire stating that they do not have any of the listed conditions. Among other assays, every blood donation is tested by ELISA for anti-HIV 1+2, anti-HCV (3rd generation), and HBsAg. In our center, repeatedly reactive donations are submitted to a confirmatory test for anti-HIV by Western-blot (Bioblot HIV-1 plus, Biokit SA, Barcelona, Spain), anti-HCV by RIBA (Chiron RIBA HCV 3.0, Emerville, CA, USA) or HBsAg by a neutralization assay (Ortho Antibody to HBsAg ELISA Confirmatory test; Ortho Diagnostic Systems Inc, Raritan, NJ, USA). Donors with a confirmed positive result are notified by registered letter that an abnormality was found in the post-donation laboratory testing, and are invited to come back to the blood bank for further information and counseling. During the period under study every virus-reactive donor who came back was interviewed and counseled by one of the authors (DT). Medical re-interviews are performed according to an established protocol, and include questions on potential risk factors for the corresponding viral infection. A new blood sample is taken for serologic and other laboratory tests, and donors are offered the possibility of receiving further medical care or follow-up at the hepatology or infectious diseases unit of our hospital.

We retrieved the data corresponding to every whole blood donation collected from June 1st, 1996 to May 31st, 2001 from the computer files of our blood bank. Data included the donor unique identification number, donation unique identification number, donor's sex and birth date, date of donation, whether the donation was patient-related or not, place of donation (blood bank or blood drive), and results of the screening tests.

Statistical analyses were performed with the SPSS (v10, SPSS Inc, Chicago, USA). Cross-tabulated data were analyzed by the χ^2 test (with continuity correction when pertinent), and by calculating relative risks and their 95% confidence intervals (CI). For the binary logistic regression analysis,

Table 1. Deferral criteria for protecting a blood recipient against transfusion-transmitted viral infections.

AIDS diagnosis or positive anti-HIV test ever
IDU[1] ever
Prostitution ever
Congenital bleeding disease and treatment with coagulation factor concentrates ever
Sex with a partner included in any one of the above categories, past year
Non-protected sex with more than one partner, past year
History of syphilis or gonorrhea, past year
History of blood transfusion, past year[2]
History of hepatitis after the 12th birthday
Positive HBsAg test ever
Household residing or sexual contact with an individual having hepatitis or HBsAg, past year[2]
Tattoos, past year[2]
Acupuncture with non-sterilized material, past year[2]
Surgical procedure or invasive instrumental exploration, past year[3]

[1]IDU: intravenous drug use; [2]increased from 6 to 12 months in April 1997; [3]invasive instrumental exploration included in April 2000.

Table 2. Characteristics of patient-related blood donations and those given by community donors.

	Patient-related	*Community-recruited*	*Statistics*	*p*
Frequency of donation				
First-time	18,768 (82%)	53,487(42%)	χ^2=12367	< 0.0001
Repeat	4,120 (18%)	73,569 (58%)		
Age at donation				
Median	36	27	t=64	< 0.0001
1st, 3rd quartiles	28, 47	21, 41		
≥ 30 years	15,775 (69%)	56,193 (44%)	χ^2=4738	< 0.0001
< 30 years	7,113 (31%)	70,863 (56%)		
Sex				
Male	12,854 (56%)	74,277 (58%)	χ^2=42	< 0.0001
Female	10,034 (44%)	52,779 (42%)		
Virus-reactivity				
Any	147 (0.6%)	126 (0.1%)	χ^2=311	< 0.0001
None	22,741 (99.4%)	126,930 (99.9%)		

the dependent variable was codified as 0 (non virus-reactive) or 1 (virus-reactive). Independent variables included sex (0: female, 1: male), kind of donation (0: community-recruited; 1: patient-related), frequency of donation (0: repeat; 1: first-time); and age, which was dichotomized by its median value (0: younger than 30 years; 1: 30 years or greater). Codified as stated above, the adjusted odds ratio for each (0,1) variable in the logistic model can be obtained by exponentiating the β coefficient corresponding to that variable.[5] All four independent variables were forced to remain in the logistic model.

Since history of prior donation at other blood centers is provided by the donor but is not easily verifiable, for the purpose of this analysis the donor's first donation registered at our center during the period under study was considered as a first-time donation.

Results

During the five-year period under study, 72,226 donors gave 149,944 whole blood units in our blood bank. The median age at the time of donation was 29 years, with first and third quartiles being 22 and 42 years, respectively; 58% of the donors were males. Patient-related donations amounted to 22,888 whole blood units, which accounted for 15.3% of all blood collections. Table 2 shows the main donor characteristics according to whether the donation was patient-related or given by a community donor.

There were 273 confirmed virus-reactive donations, which included 15 for anti-HIV, 148 for anti-HCV, and 110 for HBsAg. As can be seen in Table 3, reactivity for any of these virus was significantly more frequent in first-time donors, in those ≥ 30 years old, and in patient-related donors. Since this last group included a significantly higher proportion of first-time donors and older people (Table 2), we included all these variables in a logistic regression model in order to ascertain the independent odds ratio of virus-reactivity associated with family-related donations. After adjustment for the effect of the other covariates, the relative prevalence of virus-reactivity in patient-related donors was 2.5 (95% CI: 1.9–3.2) times higher than in community-recruited donors (Table 3). As shown in this table, first-time donation and age ≥ 30 years were the main independent predictors of a confirmed reactivity for any of the tested viruses.

Table 4 shows the exposure risk-factors disclosed by confirmed virus-reactive donors when they were re-interviewed after knowing the serologic results. There were no significant differences between patient-related and community donors in the proportions of people who did not respond to the notification letter, or who either denied any risk-factor or admitted a high-risk sexual behavior or having ever used intravenous drugs. On the contrary, past household contact with patients having hepatitis or chronic liver disease was significantly more frequent in patient-related donors than in community-recruited ones. There were 11 sero-

Table 3. Association of blood donor characteristics with prevalence of transmissible diseases markers.

	VNR	VR				URP of	ARP of
		HBsAg	HCV	HIV	Total	VR (95% CI)	VR (95% CI)
Sex							
Male	86967	79	73	12	164	1.1 (0.9-1.3)	1.2 (0.9-1.5)
Female	62704	31	75	3	109		
Age							
≥ 30	71760	79	121	8	208	3.5 (2.7-4.4)	3.1 (2.3-4.1)
< 30	77911	31	27	7	65		
Donation frequency							
First-time	71994	104	147	10	261	23.4 (14.4-38.0)	19.1 (10.6-34.5)
Repeat	77677	6	1	5	12		
Kind of donation							
Patient-related	22741	60	82	5	147	6.5 (5.3-7.9)	2.5 (1.9-3.2)
Community	126930	50	66	10	126		
Total	149671	110	148	15	273		

VNR: virus non-reactive; VR: virus reactive; URP: unadjusted relative prevalence; ARP: adjusted relative prevalence.

conversions among 30,229 donors who gave two or more donations during the period under study, including five seroconversions for anti-HIV, five for HBsAg, and one for anti-HCV. All the seroconversions were found in community-recruited donors.

In order to evaluate the contribution of patient-related donors to the pool of repeat donors, we analyzed the proportion of them who came to donate at least twice during the period under study, and compared it to that found in community donors. For the purpose of this analysis we excluded donors who gave their first donation within the last 12 months of the study. Among 16,214 patient-related donors, 3,025 (11%) came back to donate at least once, and 3.7% gave three or more donations. Among 46,310 community-recruited donors, these percentages were 55.9% and 34.8%, respectively.

Discussion

Blood collected after the donor has become infectious for a transmissible disease, but before the infective agent can be detected by the routine blood bank laboratory screening is the primary reason for the persistence of a residual risk of transfusion-transmitted viral infections.[6] Besides testing all donated blood with sensitive laboratory assays, the deferral of prospective donors who disclose infection risk-factors at the time of donation is the main safety tool at the disposal of blood banks to avoid collecting window period donations. Therefore, individuals who do not respond accurately to questions about their behavior or medical history at the pre-donation interview represent a potential threat to the safety of the blood supply. It is generally assumed that, in the absence of incentives other than altruism, and granted that adequate educational material has been provided, blood donors should have no reason to lie about their behavior or medical history. However, studies have shown that a proportion of blood donors do not respond accurately to sensitive questions asked at the pre-donation interview.[3,4] Test-seeking and

Table 4. Exposure risk factors disclosed by virus-reactive blood donors, according to whether the donation was patient-related or given by a community donor.[1]

Exposure risk factor	Kind of donation								Patient-related (total) versus community donors (total)
	Patient-related				Community-recruited				
	HBsAg	HCV	HIV	Total	HBsAg	HCV	HIV	Total	p
Did not come back	11	18	0	29	4	16	1	21	> 0.1
Unknown	12	13	1	26	18	12	3	33	0.08
Past surgery	17	18	0	35	15	14	0	29	> 0.1
Past dental manipulation	3	0	0	3	1	1	0	2	> 0.1
Acupuncture or tattooing	3	5	0	8	6	3	1	10	> 0.1
Past household contact with individuals having hepatitis or chronic liver disease	15	17	0	32	8	5	0	13	0.01
Transfusion	3	14	0	17	1	15	0	16	> 0.1
High-risk sex	1	2	4	7	6	1	5	12	> 0.1
IDU[2] ever	0	2	0	2	0	0	0	0	> 0.1
Other	1	1	0	2	0	1	0	1	> 0.1
Total cases	60	82	5	147	50	66	10	126	

[1]Some donors had more than one risk-factor; [2]IDU: intravenous drug use.

pressure by peers are the most frequent incentives for not disclosing personal behavior that can lead to donation deferral. Volunteer blood donation offers a confidential and non-stigmatizing way to obtain testing for HIV and other transmissible diseases, and it also provides the opportunity for serial testing for individuals who have ongoing high-risk behaviors. Studies conducted in the US, Canada and Norway found that 2%-7% of unselected blood donors admitted to having donated blood in order to obtain the results of transmissible diseases tests.[7,8] Among blood donors found to be anti-HIV reactive, 14% to 50% admitted test-seeking as the main motivation for blood donation.[7] Test-seeking is more frequent in younger donors, in those who donate for the first-time, and in those with deferrable risk-factors within the year preceding blood donation.[7]

While there is no reason to believe that test-seeking is more frequent in patient-related donors than in community-recruited ones, there is cause to wonder whether the former may have other incentives to give inaccurate answers at the pre-donation interview. Since friends and relatives usually know that the putative donor has come to the blood bank, the patient-related donor may be motivated to conceal personal behavior that would preclude donation, thereby giving rise to embarrassing questions from peers and relatives. If this were the case, a higher rate of infectious diseases markers would be expected in accepted donations from patient-related donors, as well as a predominance of exposure risk–factors with low social acceptability, such as high-risk sex or intravenous drug use (IDU). Our results show that the prevalence of transmissible disease markers was higher in patient-related donors than in community-recruited ones. After adjustment for other covariates influencing the rate of viral markers, the relative prevalence of reactivity against HCV, HBV or HIV was 2.5 (95% CI: 1.9-3.2) times higher in patient-related donations than in community recruited ones. However, analysis of the exposure risk-factors failed to show any significant difference between both groups of donors in the rates of individuals who did not come back to the medical interview, or who either denied any known risk-factor or admitted a history of IDU or high-risk sex. The only significant difference between both groups was the history of past household contact with patients having hepatitis or chronic liver disease, which accounted for most of the higher prevalence of hepatitis viral markers in patient-related donors. This may be a characteristic of this kind of donation in our blood center, where some patient-related donors are recruited among sons or brothers of patients transfused because of complications of liver disease, and who may have shared with the patient the same exposure factors in the past. It is worth noting that hepatitis virus infections acquired sometime ago are easily detected by the routine laboratory screening of blood donors, and do not bear an increased risk of window-period donation. There is, however, a small risk of HBV transmission by donors in whom HBsAg serum levels could have decreased below the detection threshold of screening assays.[9]

It should be noted that taking the first donation registered during the period under study as the first one ever given by the donor may have biased the relative prevalence of virus reactivity against patient-related donors. Since first-time donations were more frequent among the latter, and strongly correlated with virus-reactivity, unaccounted repeat donors among those recruited from the community may have precluded a full adjustment of the relative prevalence of virus reactivity. Therefore, a fraction of the higher prevalence found in patient-related donors may be due to the higher frequency of first-time donors in this group, even after statistical adjustment.

Despite the fact that patient-related donors gave less than 16% of all the whole blood collected in our center, and that they rarely came to donate again, their replacement with community donors would not be easy in this era of narrowing margin between blood supply and demand. In addition, since community donors are on average a decade younger than patient-related ones, enhanced recruitment among this young population might increase the proportion of test-seekers and of those with undisclosed, recent deferrable risk-factors.[7] For instance, studies conducted in the US have shown that blanket removal of older donors (because of concern about Creutzfeldt-Jakob disease transmission) would increase the risk of HBV, HCV, and HIV transmission.[10] Therefore, allocating efforts to retain qualified patient-related donors in the pool of repeat donors seems a more reasonable strategy for hospital-based blood banks.

Our study was conducted in a single institution, so results may have been influenced by local factors such as demographic or epidemiologic characteristics of the donor population or specific practices in donor recruitment, and therefore they may not be generalized to other hospital-based blood banks. In addition, there is no recent publication addressing the issue of patient-related donations

that allows comparisons to be established. However, studies on directed donations conducted in the late 1980s in the US showed that donors recruited by patients were not different from community donors with regard to the prevalence of the infectious diseases markers tested for at that time.[11] Our patient-related donors were recruited after the patient had been transfused, so they were not under the psychological pressure of directed donors. However both kinds of donors are comparable regarding the relative lack of anonymity that surrounds the donation process.

On the other hand, the rates of virus-reactivity found in our study among first-time and repeat donors are within the ranges of those reported from a large multicenter European study.[12] With regard to the exposure risk-factors disclosed by HIV-reactive donors, our results are comparable with those found in two recent studies conducted in France[13] and the US,[14] in which high-risk sex was the most frequent risk-factor disclosed by these donors. It is worth noting that in both studies, around 40% of HIV-reactive donors had no identifiable risk-factor, a proportion somewhat higher than that found in our anti-HIV reactive donors. Prior studies conducted in Western Europe,[15-17] Canada,[18] Australia[19] and the US[20] have shown that IDU, prior transfusion and having had sex with IDUs are the main epidemiologic determinants of HCV-reactivity in blood donors. As in our case, a history of chronic liver disease in close relatives, or of prior surgery or percutaneous procedures,[21,22] was also a frequent finding in HCV-reactive blood donors. In comparison with results of these studies, a history of IDU was rare among our prospective donors with HCV antibodies, since it was elicited in only two out of 148 HCV-positive donors. IDUs pose a particular threat to the safety of the blood supply. In several regions of the world, including France,[17,23] Italy[24,25] and Spain,[26,27] IDUs frequently harbor HCV genotypes other than 1,[7,23-31] and antibodies elicited against these phenotypes react poorly in some of the enzyme immunoassays used for the routine screening of blood donors.[32] Furthermore, some IDUs have a very delayed seroconversion after HCV infection, and HCV RNA levels may be below the detection limit of mini-pool NAT during the long pre-seroconversion period.[33]

In conclusion, the present analysis does not support the hypothesis that patient-related donors represent a threat to the safety of the blood supply because of the existence of incentives to conceal deferrable risk factors. These donations may represent a significant proportion of the blood units collected in hospital-based blood banks, and their replacement with community-recruited donations may be difficult in the short-run, and may give rise to risks higher than those the strategy is intended to prevent.

Contributions and Acknowledgments

AP was responsible for the conception of this study, data analysis, and drafting the article. CS and DT were responsible for the laboratory tests, and contributed to the study's design, data interpretation, and drafting the article. DT performed the medical interviews of virus-reactive donors. BR contributed to data retrieval and analysis, and critically reviewed the article. All authors have given final approval of the version to be published.

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Disclosures

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Peer Review Outcomes

Manuscript processing

This manuscript was peer-reviewed by two external referees and by Professor Paolo Rebulla, who acted as an Associate Editor. The final decision to accept this paper for publication was taken jointly by Professor Rebulla and the Editors. Manuscript received January 4, 2002; accepted February 12, 2002.

What is already known on this topic

It has been hypothesized that patient-related blood donors, being highly motivated to give blood, might conceal risk factors for blood-borne infections, so representing a threat to the safety of the blood supply.

What this study adds

This study indicates that patient-related donations constitute a substantial proportion of blood collected in Spain. In addition, it shows that the prevalence of HIV, HBV and HCV markers and the frequency of risk factors for blood borne infections do not differ between patient-related and community donors.

Potential implications for clinical practice

Patient related donors should be considered as a safe resource in the geographic area that was examined in this study.

Paolo Rebulla, Associate Editor