

The safety of blood donation by elderly blood donors

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Vox Sanguinis

Background Due to the ageing population, blood donation by the elderly is necessary to maintain blood supply. We initiated a prospective study, to assess whether there is an increased risk of donor reactions in elderly donors.

Study Design and Methods In this prospective study, regular donors aged from 66 to 68 and 69 to 71 years were invited to continue blood donation on mobile collection sites of the German Red Cross Blood Service West. A control group (50–52 years) was established. Admission of donors in all groups followed the German national guidelines for blood donation. Donor deferrals and all kinds of donor reactions during donation (on-site) and in the 48 h following donation (off-site) were monitored.

Results A total of 64 260 valid cases were entered in the study. Donor deferrals increased with age from 1·12% in the control group up to 8·74 in female donors aged 69–71 years. Adverse reactions to blood donation were rare with an overall reaction rate of 0·63% (0·05% on-site; 0·58% off-site). Off-site reactions significantly decreased with increasing age. The relative risk (RR) for adverse reactions in elderly donors compared to the control group (50–52 years) was slightly increased for on-site reactions in the 69- to 71-year-old donors (RR 1·0309; 95% CI 1·0292–1·0325). In all other comparisons, the RR for adverse reactions was distinctively lower in elderly donors (RR 0·3785 – 0·7778).

Conclusions Our data confirm that elderly regular blood donors may safely continue blood donation at least to the age of 71. Based on these data, we increased the upper age limit.

Key words: adverse effects, age limit, aged, blood donation, blood donors, safety.

Received: 1 December 2010,
revised 23 February 2011,
accepted 23 February 2011,
published online 3 May 2011

Introduction

Increasing life expectancies and decreasing birth rates are leading to an ageing population. Consequently, the pool of young and healthy blood donors decreases, whereas at the same time, the demand for blood components – mostly transfused to older patients – increases [1]. This development may lead to a significant shortage of blood and blood components in the near future [2,3].

One way to respond to this problem could be to change the upper age limit for blood donors. However, there are hardly data to corroborate the definition of upper age limits

for blood donation [4]. Only few studies were published that indicate that blood donation by elderly donors seems not to result in higher rates of adverse events [5–8]. Upper age limits still vary considerably not only between different countries but even between different blood donation services within one country, e.g. in the USA from 59 years to ‘no upper limit’ [7]. Authorities and decision makers are not sure about the assessment of the obviously increasing risk of diseases and particularly cardiovascular complications in elderly blood donors. Due to different regulations and donor populations in Europe, data from the United States may not be transferred unrestricted to other continents.

The upper age limit for blood donors in Germany was increased from 65 to 68 years for repeat donors in 1996 [9], and since 2005, blood donors older than 68 years may be allowed to continue blood donation at the physicians’

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assessment [10]. However, sound medical data to support admission of elderly donors, particularly with respect to an indisputable increase in cardiovascular diseases with increasing age [11] did not yet exist. Therefore, we initiated this first large prospective study to assess whether there is an increased risk of reactions in elderly donors, particularly beyond the age of 68. The study was performed at the German Red Cross Blood Service West (GRCBS-West) which is located in the western part of Germany, an area with 23 million inhabitants. GRCBS-West collects about one million blood donations annually.

Materials and methods

At the GRCBS-West, all adverse acute reactions occurring during blood donation and at the donation site as well as off-site reactions reported by blood donors are registered according to a standard operating procedure (SOP) on a standard form and entered into a database for statistical analysis.

Starting in 2006, regular donors aged from 69 to 71 years were invited to continue blood donation on mobile collection sites of the GRCBS-West.

In addition, data from donors aged 66–68 years (representing the increase in the upper age limit in 1996) and from donors aged 50–52 years (control group) were collected. The study protocol was approved by the ethics committee of the Medical Association of the province of North Rhine.

Repeat donors in the age group of 50–52 years were selected as control group for the following reasons:

- (1) The rate of donation reactions seems to be dependent from donation frequency [6], and according to our data, the donation frequency of elderly donors was expected to be in the range of the age group 50–52.
- (2) There is a well-known higher incidence of donor reactions in younger blood donors [6,12], and there might be an increase in elderly donors. Integrating younger donors or elderly donors (e.g. by selecting 60- to 65-year-old donors) in the control group might have resulted in bias in the statistical analysis.
- (3) Reaction rates might decrease with increasing numbers of previous donations due to a long-lasting 'selection process'. Thus, a control group with extensive experience in blood donation was selected, since elderly blood donors are assumed to be experienced blood donors, too.

Admission of donors in all groups followed the German national guidelines for blood donation [10]. Haemoglobin level was checked before each blood donation from capillary blood using a photometric device (HaemoCue Hb 301; HaemoCue GmbH, Großostheim, Germany). First-time donors (i.e. blood donors with no previous record of blood donation at the GRCBS-West) were not entered in the study.

All donations were performed on mobile blood drives and according to the standard operating procedures of the GRCBS-West. The total volume of each blood donation was 500 ml and additional 40 ml for laboratory tests. Donor deferrals and all kinds of donor reactions during donation and at the donation site (on-site) were monitored and documented on a standard form. In addition, all donors were given a questionnaire asking for well-being and donor reactions in the 48 h following donation (off-site) with instructions to return it to the study office in a prepaid envelope. Biometric parameters of the donors which might have an influence on reaction rates or deferrals were documented. All data were collected in the study office and entered in statistical software by a trained secretary.

Statistical methods

The study was designed as a prospective three-arm non-inferiority study comparing two groups of elderly blood donors aged 66–68 years and 69–71 years to a control group aged 50–52 years. The calculation of the sample size was based on the known ratio of donor reactions (0·21%) registered in the routine quality monitoring system of the GRCBS-West in 2005. Assuming that an increase in adverse reactions of maximal 0·2% in the elderly donors (age groups 66–68 and 69–71) compared to the control group (50–52) would be acceptable, a sample size of 15 694 donations in each group was calculated to provide statistical power of 90%. The relative risk (RR) of donor reactions (on-site, off-site and total) of the two groups of older blood donors (66–68 years; 69–71 years) was calculated against the control group (50–52 years). Differences between factors that might influence the occurrence of donor reactions (e.g. weight) or deferrals (e.g. haemoglobin, blood pressure) were calculated with the *t*-test and the Chi-square test. Statistical analysis was performed, using the software SPSS/PC+ (SPSS Inc, Chicago, IL, USA).

Donor reactions were classified as mild, moderate or severe following a modified version of the definitions published by the Canadian Blood Services [6] and others [7,13] including not only systemic reactions but also donor injuries and continued medical treatment.

Mild reactions included bruising, painful phlebotomy, re-bleeding, local allergic reactions and systemic symptoms (without loss of consciousness) of pallor, diaphoresis, sweating, nausea, hyperventilation, weakness and fainting that resolved within 15 min.

Moderate reactions included haematoma, massive re-bleeding, arterial puncture, a loss of consciousness for less than 30 s, and/or bradycardia and hypotension with a full recovery within 30 min.

Severe reactions comprised chest pain, loss of consciousness for more than 30 s and/or convulsions, vomiting,

incontinence or tetany, and a reaction where the duration of recovery lasted more than 30 min. Any reactions or injuries requiring intravenous fluids, medication or further medical treatment by another physician than the responsible physician of the blood donation service (outside medical care) were classified as severe.

Results

Donors were recruited from September 2006 to December 2009. Data from 64 260 blood donations (age group 50–52: 21 574; age group 66–68: 20 015; age group 69–71: 22 671) were included in the study. Male donors outnumbered female donors in all age groups, ranging from 2·1-fold (50–52) to 3·6-fold (69–71). Table 1 illustrates the distribution of female and male donors in the three age groups.

Systolic and diastolic blood pressure significantly increased in men and women with increasing age, whereas the pulse rate only slightly increased. The body weight of female donors was nearly identical in all age groups (72·8–73·5 kg), whereas the weight of male donors significantly decreased with age from 89·9 kg in age group 50–52 to 84·9 kg in age group 69–71 ($P < 0·001$). Venous haemoglobin level (Hb) proved to be identical in all female donor groups (143·7–143·9 g/l). In male donors of the age group 50–52, Hb was slightly higher (153·9 g/l) compared to older donors (age group 66–68: 152·5 g/l; age group 69–71: 152·6 g/l).

All age groups consisted of particularly dedicated blood donors with an average annual whole-blood donation frequency ranging from 2·9 ($\pm 0·9$) to 3·5 ($\pm 0·8$). The mean number of previous blood donations increased with age from 43·8 \pm 29·7 in the 50–52 group to 74·4 \pm 35·5 in the 69–71 group.

Cumulative on-site and off-site reactions to blood donation were rare with an overall reaction rate of 0·63%. The majority of the reactions in our study was reported by means of a questionnaire and occurred off-site in the 48 h following blood donation. Only 0·05% (30 of 64 260) of the donors had an adverse reaction on-site, whereas the number of off-site reactions was ten times higher (0·58%; 373 of 64 260). The higher rate of off-site reactions is largely

the result of symptoms with delayed onset such as mild haematomas and fatigue. The rate of adverse reactions generally decreased with increasing age of the donors. Off-site reactions significantly decreased with increasing age. In contrast, the lowest number of on-site reactions (5/20 014; 0·025%) was registered in the 66– to 68-year age group. The occurrence of on-site reactions in the 69– to 71-year age group (13/22 672; 0·057%) was almost identical to the control group of the 50– to 52-year-old donors (12/21 574; 0·056%). In general, adverse reactions were predominantly mild and more frequent in women than in men. Details are displayed in Table 2.

Donor deferrals were higher in women than in men and increased significantly ($P < 0·001$ Chi square test) with age from 1·12% to 2·18% and to 6·56% in male donors and from 1·81% to 3·17% and to 8·74% in female donors. The number of rejected donors in the 69– to 71-year age group was 2·9-fold that of the 66– to 68-year age group and 5·3-fold that of the control group. A more detailed analysis of the donor deferrals (Table 3) revealed that apart from the increase in donor deferrals, the pattern of reasons for donor deferrals changed with increasing age. While low haemoglobin accounted for more than 50% of all deferrals in younger donors, in the elderly donors only 35·5% were rejected due to low haemoglobin. On the other hand, elderly donors were more often deferred due to high blood pressure, surgery or endoscopy and manifestations of cardiac and malignant diseases. In addition, elderly donors had to be deferred due to various reasons like missing documents, bad venous status or simply because elder donors wanted to give blood ignoring pre-existing deferrals.

The RR for adverse donor reactions in elderly donors compared to the control group was calculated as follows: RR is equal to the risk among elderly donors divided by the risk among the control group. When RR is $>1·0$, the risk of adverse reaction is increased in the elderly donors; when RR is $<1·0$, the risk of adverse reactions is decreased. The calculation of the RR for adverse donor reactions in elderly donors compared to the control group (50–52 years) showed that there was only a slightly increased risk for on-site adverse reactions in the 69– to 71-year-old donors (RR 1·0309; 95% CI 1·0292–1·0325). In all other comparisons, the RR for adverse reactions was distinctively lower in elderly donors (RR 0·3785–0·7778) (Fig. 1).

Table 1 Donors by sex and age group

Age group (years)	Total	Male (M)	Female (F)	M : F
50–52	21 574	14 631	6943	2·1
66–68	20 015	15 284	4731	3·2
69–71	22 671	17 753	4918	3·6
Total	64 260	47 668	16592	2·9

Discussion

Older donors substantially contribute to the pool of donated blood. Many of them have undergone extended typing for various red cell antigens during their long-lasting career as blood donors, and the risk of acquiring transfusion relevant viral diseases is lower in older repeat donors. They constitute the cohort with the highest annually number of blood

Table 2 Donor reaction rates (%) adjusted for age group and sex

Mild (n = 16)			Moderate (n = 4)			Severe (n = 10)			
Female	Male	F + M	Female	Male	F + M	Female	Male	F + M	Total
On-site reactions (%)									
<i>Age group</i>									
50–52	0·058	0·027	0·037	0·000	0·000	0·000	0·043	0·007	0·019
66–68	0·021 ^a	0·013 ^a	0·015 ^a	0·000 ^a	0·000 ^a	0·000 ^a	0·021 ^a	0·007 ^a	0·010 ^a
69–71	0·063 ^a	0·011 ^a	0·022 ^a	0·041 ^a	0·011 ^a	0·018 ^a	0·041 ^a	0·011 ^a	0·018 ^a
Total									0·05
Mild (n = 310)			Moderate (n = 47)			Severe (n = 16)			
Female	Male	F + M	Female	Male	F + M	Female	Male	F + M	Total
Off-site reactions within 48 h after blood donation (%)									
<i>Age group</i>									
50–52	1·53	0·28	0·68	0·23	0·05	0·11	0·04	0·01	0·02
66–68	1·40 ^a	0·27 ^a	0·53 ^a	0·23 ^a	0·03 ^a	0·08 ^a	0·04 ^a	0·01 ^a	0·02 ^a
69–71	0·59 ^c	0·15 ^b	0·25 ^c	0·04 ^d	0·03 ^a	0·03 ^d	0·06 ^a	0·02 ^a	0·03 ^a
Total									0·58
Mild (n = 326)			Moderate (n = 51)			Severe (n = 26)			
Female	Male	F + M	Female	Male	F + M	Female	Male	F + M	Total
Total (on-site and off-site) %									
<i>Age group</i>									
50–52	1·58	0·31	0·72	0·23	0·05	0·11	0·09	0·02	0·04
66–68	1·42 ^a	0·28 ^a	0·55 ^a	0·23 ^a	0·03 ^a	0·08 ^a	0·06 ^a	0·02 ^a	0·03 ^a
69–71	0·65 ^c	0·16 ^d	0·27 ^c	0·08 ^a	0·04 ^a	0·05 ^b	0·10 ^a	0·03 ^a	0·05 ^a
Total									0·63

^aNot significant vs. control group (χ^2 test).^b $P < 0·05$ vs. control group.^c $P < 0·001$ vs. control group.^d $P < 0·01$ vs. control group.

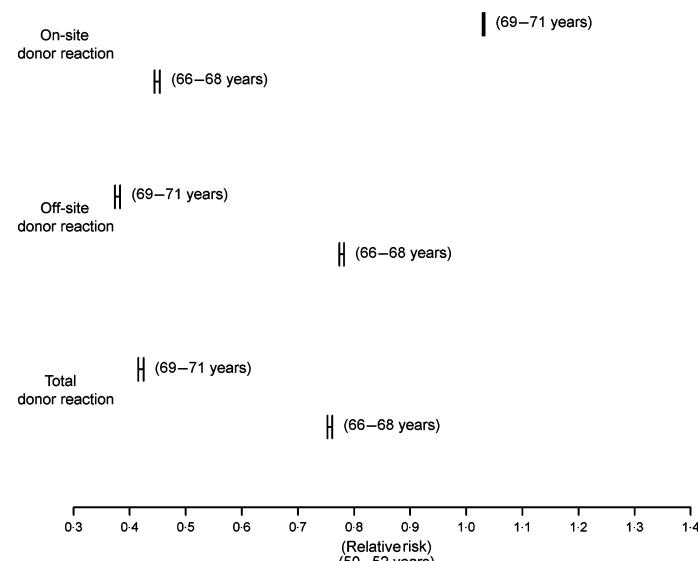
donations per donor [2]. Thus, it seems reasonable to extend the period of time a donor is allowed to donate blood by increasing the upper age limit for blood donation. However, the question whether the existing age criteria of blood donation could be changed was discussed controversially already 25 years ago in an international forum [14]. Some Canadian and US blood donations meanwhile have increased the upper age limits for blood donation and published no increased risk for older blood donors in retrospective studies. However, since donor populations as well as selection criteria and procedures vary considerably, these data should not be transferred easily to other donor populations in different continents. The need to ensure adequate blood supplies must not result in a higher risk for the blood donor, a healthy person who volunteers for non-remunerated blood donation, just to help other people. Moreover, severe adverse reactions, e.g. injuries, caused by loss of consciousness in elderly donors may not only have serious consequences for the donor but inflict also a publicity risk

for the blood donation service. Thus, any decision about changing the criteria for blood donor acceptance has to be scrutinized relative to donor safety. Since the upper age limit in Germany has been based merely on expert hypothesis because scientific data about our donor population did not exist, we initiated this first prospective study to obtain sufficient data to make a sound decision about the RR of increasing the upper age limit for blood donation.

There is little doubt that the incidence of diseases, particularly cardiovascular diseases, increases with age [11]. Donor deferrals by the attending physician due to heart diseases increased 6·7-times in the elderly. The individual assessment and decision of the attending physician may have had significant influence on donor reaction rates since blood donors with a higher risk for adverse reactions to blood donation were not allowed to give blood. Otherwise, the reaction rates might have been higher. Therefore, increasing incidence of diseases in older blood donors as demonstrated by significantly increasing donor deferral

Table 3 Donor deferrals by reason and age group

Donor deferrals	Age group (years)					
	50–52		66–68		69–71	
	% of donations ^a	% of deferrals ^b	% of donations ^a	% of deferrals ^b	% of donations ^a	% of deferrals ^b
Metabolic diseases, autoimmune diseases, allergy	0·014	1·06	0·10 ^c	0·42	0·058 ^d	0·83
Pulmonary diseases	0·005	0·35	0·010 ^c	0·42	0·027 ^c	0·38
Blood pressure	0·109	8·16	0·183 ^c	7·58	0·944 ^f	13·41
Diseases of the skin, skeleton, kidney and the nerves	0·005	0·35	0·025 ^c	1·05	0·094 ^f	1·34
Diseases of the heart	0·024	1·77	0·122	5·05	0·358 ^f	5·09
Haematologic diseases	0·005	0·35	0·010 ^c	0·42	0·013 ^c	0·19
Diseases of the vascular system	0·005	0·35	0·015 ^c	0·63	0·049 ^e	0·70
Low haemoglobin	0·699	52·13	1·249	51·79	2·496 ^f	35·47
Infectious diseases	0·095	7·09	0·117 ^c	4·84	0·264 ^f	3·75
Risk for infectious diseases and travel	0·038	2·84	0·041 ^c	1·68	0·210 ^f	2·99
Drugs	0·062	4·61	0·117 ^c	4·84	0·349 ^f	4·96
Surgery and endoscopy	0·128	9·57	0·274 ^e	11·37	0·863 ^f	12·27
Malignant diseases	0·00	0·00	0·020 ^d	0·84	0·121 ^f	1·72
Donor situation (fear, missing documents, venous status, lack of time, etc.)	0·133	9·93	0·178 ^c	7·37	0·796 ^f	11·32
Pre-existing deferral	0·019	1·42	0·041 ^c	1·68	0·389 ^f	5·53

^a% of donors that were deferred or rejected for defined reasons, adjusted for age group.^b% of deferrals with respect to the total number of deferrals in the age group.^cNot significant vs. control group (χ^2 test).^d $P < 0·05$ vs. control group.^e $P < 0·01$ vs. control group.^f $P < 0·001$ vs. control group.**Fig. 1** Relative risk of adverse donor reactions (on-site/off-site) in elderly blood donors aged 66–68 years and 69–71 years compared to a control group (50–52 years).

rates due to medical reasons in our study emphasize that decisions about upper age limits should be backed by large prospective studies.

Additional physician approval by the donors family physician as performed in a study on elderly blood donors previously performed in Canada [7] was not done in our study.

Thus, there is no bias due to pre-selection of the older donors by the family physician in our study. The results of our study can be transferred to the standard blood donation procedure in Germany without any additional requirements for older blood donors. This is of special interest, since as reported by Pindyck *et al.*, [8] the extra effort and expense resulting from additional consultation of a family practitioner to obtain physician approval for blood donation has resulted in most elderly donors to quit donating.

The data of our study show that whole-blood donation is safe in older blood donors. The total reaction rates of 0·66% (66–68 years) and 0·37% (69–71 years) are remarkably low compared to published data [12,13,15], particularly when taking into account that even off-site reactions were registered. A comparison of the rate of off-site reactions to the published literature is difficult. Data about adverse effects of blood donation occurring after leaving the site of blood donation are registered only in few studies and vary considerably due to the way of reporting (e.g. donor self-reports vs. post-donation interviews, open-ended questions vs. specific questions) [16]. Off-site reactions constituted the majority of the registered reactions in our study and were predominantly mild or moderate. Severe off-site reactions were very rare events. The delayed onset of off-site reactions is due to the nature of these reactions – predominantly haematomas, fatigue and weakness.

It is well known that the highest rates of adverse reactions to blood donation are seen in first-time donors and particularly in young donors <20 years [17,18]. Published data point to a decrease in adverse reactions with increasing age which seems to remain stable at a lower level for donors beyond the age of 60 [6,19,20]. This may be due to a lifelong selection and ‘self-deferral’ of blood donors experiencing adverse reactions in the past resulting in a very healthy group of older repeat donors. This assumption is supported by the high average number of blood donations given by the elder blood donors in our study. Our data are in line with the results of a retrospective Canadian study on the safety of blood donation by elderly blood donors up to the age of 71 years [6] and with the American Red Cross haemovigilance data [19].

Our study was very well accepted by our older blood donors. Most of them were happy that they could continue with blood donation. As stated by Goldman *et al.* [7], the deferral of otherwise healthy blood donors solely due to an arbitrary age limit may generate substantial donor dissatisfaction; however, donor deferrals due to clear medical reasons by the attending physician were accepted very well by our donors. The very broad acceptance of the increased age limit by the donor population resulted in various letters of thanks from committed donors.

Our data confirm the safety of blood donation by elderly blood donors at least if the donors are repeat donors and admission to blood donation is given by the attending physician. Based on these data, we increased the upper age limit for blood donors. From January 2010 on, we informed our older blood donors that the upper age limit for blood donors was increased and we actively invited repeat blood donors until the age of 71 years. After their 72nd birthday, blood donors are no longer invited, but repeat donors are allowed to give blood according to the physician’s decision. Since repeat donors beyond the age of 68 previously were generally lost as donors, even in the light of the increased deferral rates in this elderly donor group, each donor above 68 who continues to donate is an additional donor and there are no special operational costs for these donors beside the fact that they receive an invitation letter to donate blood. Today, 1 year after increasing the upper age limit, 3·6% of our blood donations are from donors older than 68 years.

Data of this prospective study sufficiently supply evidence for a safe increase in the upper age limit for our repeat blood donors at least to the age of 71. However, since all the donors examined in our study were regular repeat donors, many of them donated more than 50 times in their lifetime and the conclusion of our study must not be transferred to the safety of blood donation by elderly first-time donors. Data of first-time donors, generated in 2010 *after* the end of this study, demonstrated that the risk of adverse reactions in *first-time donors* constantly decreased from 3·64% in 18- to 20-year-old donors to a nadir of 1·69% in 41- to 50-year-old donors but then increased again to 1·78% (51–60 years) and 2·25% in donors beyond the age of 60. Thus, before increasing the upper age limit for first-time donors, controlled studies should be performed.

Acknowledgements

We would like to thank Mrs Anke Mohlfeld for excellent assistance in collecting and coding data and entering all data into the study data base, Detlef Kühnel, Petra Weischer, Barbara Spier, Ulrike Möller and Jutta Hettinger for coordinating the study in the blood donation centres and all physicians who took part in the study looking after our blood donors on the mobile blood donation sites.

Conflict of interest

The authors declare that they have no conflict of interest relevant to the manuscript submitted.

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