

# Complications related to blood donation: a population-based study

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## Vox Sanguinis

**Background** Population-based data on the rate and outcome of complications related to blood donation are sparse.

**Study Design and Methods** Data from a survey conducted in 2003 in Aarhus County, Denmark, were used to assess the overall rate of donor complications. Additional nationwide data on moderate and severe donor complications were obtained from the Danish Register of Complications Related to Blood Donation, with records of all moderate and severe donor complications in Denmark occurring during the period 1997–2003.

**Results** In the regional survey, we identified 340 complications of any type among 41 274 donations, corresponding to a rate of 824/100 000 donations [95% confidence interval (CI): 741–916]. All complications were either needle injuries or vasovagal reactions. In the nationwide register, a total of 752 moderate and severe complications were recorded among 2 575 264 donations, corresponding to a rate of 29/100 000 donations (95% CI: 27–31). The rates of complications leading to long-term morbidity or disablement (> 5% loss of working capacity) were 5/100 000 donations (95% CI: 4.2–5.9) and 2.3/100 000 donations (95% CI: 1.8–2.9), respectively.

**Conclusion** The risk of complications related to blood donation is low. However, attention towards donor complications is warranted, given the non-negligible rate of complications resulting in long-term morbidity and disablement.

**Key words:** blood donor, complications related to blood donation, needle injury, vasovagal reaction.

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## Introduction

The donation of blood involves insertion of a needle into a blood vessel of the arm followed by a loss of 10% of the total blood volume within a few minutes. Worldwide this procedure is performed daily thousands of times, predominantly without complications, except for mild transient discomfort [1]. However, complications do occur and include both needle injuries and vasovagal reactions [2,3]. Although most

complications are transient, needle injuries in particular may cause long-lasting or even permanent disability [4,5].

Despite complication rates of blood donation being relatively low compared to complication rates of other invasive procedures (e.g. reported rates of nerve irritation and nerve injuries range from 16/100 000 to 23/100 000 donations) [2,3,5], donor complications are an important problem not only for the donors but also for the transfusion medicine in general, as some complications may negatively affect donor recruitment and retention [6]. Data on donor complications are sparse and primarily from a few American centres [2,3,5,7]. Furthermore, as existing studies primarily focused on complications registered during the donation, the extent of long-term complications may not be fully appreciated. For example, incidence of nerve injury (sensory changes) found

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by a postdonation interview is as high as 900/100 000 donations or 0.9%, indicating that complications recorded solely during the donation underestimate the actual complication frequency [8]. We examined the rates, types and outcomes of complications related to blood donation in a population-based study with long-term follow-up.

## Materials and methods

### Study populations

The tax-financed transfusion service in Denmark operates on a regional basis, with each region having its central transfusion centre and satellite blood banks. All blood donors must fulfil a set of safety criteria set by the national guidelines of transfusion medicine and defined by The Danish Society of Clinical Immunology. These guidelines also set standards for the blood donation. The safety criteria ensure protection of both the donor and the recipient. Blood donors must be 18 to 65 years old and in good health. The health status is determined by a questionnaire.

We studied two populations of Danish volunteer blood donors. First, we used the data from the regional survey, which comprised donors from Aarhus County, Denmark, who provided a total of 41 274 donations from March to December, 2003. Second, we accessed data, from 1997 to 2003, from the Danish Register of Complications Related to Blood Donation, which covers all donors in Denmark who provided a total of 2 575 264 whole-blood donations during this period.

### Definitions of donor complications

A donor-related complication was defined as symptoms occurring during or just after the donation. If the donor returned later with complaints, the symptoms were first considered as donor related after a clinical evaluation by a nurse or a physician with education and experience in blood donation. The localization, onset and nature of symptoms were all included in the decision of a possible relation between the donation and the symptoms.

The complications in this study were categorized into three groups: mild, moderate and severe. If the symptoms disappeared within 7 days from the phlebotomy or did not require immediate medical attention the complication was categorized as mild. The remaining complications were all reported to the Danish Register of Complications Related to Blood Donation and were complications where symptoms persisted 7 days after the phlebotomy or complications requiring immediate medical attention. These complications were categorized as moderate and if the donor had symptoms at least 1 year after the phlebotomy (complications with long-term morbidity), the complication was then categorized as severe.

Disablement was defined as any complication leading to a reduction in the working capacity of > 5%. The degree of disablement was determined by the Public Patients-Insurance Fund on the basis of an evaluation by a physician and was quantified according to the nature and extent of the injury and the inconvenience it caused to the donor's life. A disablement of 5% makes one eligible for an economic compensation. The Public Patient-Insurance Fund acts according to the Danish Patient Insurance Act, which states that any injury caused by a blood donation entitles economical compensation unless the injury, on preponderance of evidence, had another cause. Compensation will be determined in accordance with the provisions of the Danish Liability for Damages Act.

All donor-related complications were classified as injury of a vessel (haematoma or arterial puncture), injury of a nerve, or vasovagal reaction.

Haematoma was defined as a localized collection of blood under the skin accompanied by swelling with or without skin discoloration, but without symptoms of a nerve injury by a needle.

Nerve injury was defined as an injury of a nerve directly by a needle or indirectly by a haematoma (via pressure on adjacent structures). The signs and symptoms included sensory changes (numbness, tingling), excessive burning or radiating pain in the arm, or loss of arm or hand strength. Unlike a nerve injury caused by a haematoma, a direct nerve injury becomes instantly manifest by symptoms during insertion of the needle. Nerve injury can be temporary, but may also become complicated by permanent residual focal numbness, pain in the arm for many years, or permanent disability.

Vasovagal reactions were defined by subjective symptoms like discomfort, weakness, dizziness and objective symptoms like sweating, pallor and hyperventilation. They were categorized into reactions with or without loss of consciousness. The reactions could be of immediate or delayed type (i.e. symptoms occurring after the donor left the blood bank but within 24 h).

### Data sources

#### *Regional survey*

The transfusion service in Aarhus County consists of the central transfusion service located in the city of Aarhus and five satellite blood banks. All complications irrespective of severity occurring in the county were registered from March to December, 2003. This registration was done using a detailed standardized form and the registered data included type of complication, symptoms and time of the symptom's onset. To ensure that all reports were registered, we did not discriminate between the reports. The registration was primarily based on the subjective symptoms reported by the donor in relation to the phlebotomy. Donors with complications

requiring immediate medical attention, complications were symptoms persisted 7 days or more after the phlebotomy or complications, which were reported for the first time more than 7 days after the phlebotomy, were initially examined by a physician or nurse with education and experience in blood donation. These complications were then reported to the Danish Register of Complications Related to Blood Donation on a standardized claim form which included both subjective and objective symptoms. All complications not reported to the Danish Register of Complications Related to Blood Donation were considered mild.

#### *Danish Register of Complications Related to Blood Donation*

This nationwide register, maintained by the national blood donor organization in Denmark (BiD), tracks all moderate and severe complications (as categorized above) related to blood donation. BiD follows up each donor by regular telephone contact. The first contact is made 1 week after receiving the claim form and then whenever necessary. Unless the donor, when contacted, reports that the symptoms have disappeared, BiD will pass the claim form on to the Public Patient-Insurance Fund as soon as the donor have been evaluated and treated by an independent physician. If the symptoms have disappeared or the donor is not available for follow-up, the case is closed. The follow-up is carried out in collaboration with the blood bank physician or nurse who ensures that the donor is evaluated and treated by an independent specialist in neurology, rheumatology or orthopaedic surgery depending on the complication. The health statement from the independent specialist and the claim form function as legal documents for the Public Patient-Insurance Fund, which is the body that decides claims for compensation in the case of personal injury. The Public Patient-Insurance Fund makes use of medical consultants when evaluating the claims. The decision is made when the medical consultants

evaluate that the symptoms are in a steady state or there is no longer benefit from therapy. BiD has a function as a secretariat and maintains close cooperation with the Public Patient-Insurance Fund. The registration to BiD can be done several months or even years after the donation, but the donor is only entitled to economical compensation if the Public Patient-Insurance Fund is notified within 5 years of the date the donor became or would have become aware of the injury.

#### Statistical analysis

We created contingency tables on all study variables. The rates of all complications, moderate and severe complications, and complications with long-term morbidity or disablement were calculated as the number of respective complications divided by the total number of donations. The analyses were done using SAS software, version 8-02 (SAS Institute Inc., Cary, NC, USA).

#### Results

In the regional survey, we identified 340 complications among 41 274 donations. The overall rate of complications was 824/100 000 donations [95% confidence interval (CI): 741–916] (Table 1), and the rate of moderate and severe complications was 29/100 000 donations (95% CI: 17–51) (Table 2).

A similar rate of moderate and severe complications was found in the Danish Register of Complications Related to Blood Donation. There were 752 moderate and severe complications among 2 575 264 donations or a rate of 29/100 000 donations (95% CI: 27–31) (Table 2). The nationwide rate of complications with long-term morbidity was 5/100 000 donations (95% CI: 4.2–5.9), whereas the rate of complications leading to disablement was 2.3/100 000 (95% CI: 1.8–2.9) (Table 3).

	Number <sup>a</sup>	%	Rate <sup>b</sup>
Needle injuries			
Injury of a vessel (haematoma)	113	33	274 (228–329)
Injury of a vessel (arterial puncture)	1	0	2 (0.5–1.4)
Injury of a nerve	29 (8)	9	70 (49–101)
Total	143 (8)	42	346 (294–408)
Vasovagal reactions			
Vasovagal reaction	165 (3)	49	400 (343–465)
Vasovagal reaction with loss of consciousness	32 (1)	9	78 (55–109)
Total	197 (4)	58	478 (415–549)
Total (needle injuries and vasovagal reactions)	340 (12)	100	824 (741–916)

**Table 1** Complications related to blood donation. Data from a regional survey in the county of Aarhus, Denmark (41 274 donations)

<sup>a</sup>Number in parenthesis indicates number of complications reported to the Danish Register of Complications Related to Blood Donation. All other complications were considered mild.

<sup>b</sup>Number per 100 000 donations (95% CI).

**Table 2** Moderate and severe complications related to blood donation. Data from a regional survey from Aarhus County and the Danish Register of Complications Related to Blood Donation

	Regional survey <sup>a</sup>			National register <sup>b</sup>		
	Number	%	Rate <sup>c</sup>	Number	%	Rate <sup>c</sup>
Needle injuries	8	67	19 (10–38)	559	74	22 (20–24)
Vasovagal reactions	4	33	10 (4–25)	193	26	7 (7–9)
Total	12	100	29 (17–51)	752	100	29 (27–31)

<sup>a</sup>Based on 41 274 donations.

<sup>b</sup>Based on 2 575 264 donations.

<sup>c</sup>Number per 100 000 donations (95% CI).

**Table 3** Outcome of complications related to blood donation. Data from the Danish Register of Complications Related to Blood Donation (2 575 264 donations)

	Long-term morbidity <sup>a</sup>			Disablement <sup>b</sup>		
	Number	%	Rate <sup>c</sup>	Number	%	Rate <sup>c</sup>
Needle injuries	121	95	4.7 (4.0–5.6)	56	97	2.2 (1.7–2.9)
Vasovagal reactions	5	3	0.2 (0.07–0.4)	2	3	0.08 (0.0–0.3)
Total	126	100	5.0 (4.2–5.9)	58	100	2.3 (1.8–2.9)

<sup>a</sup>Symptoms 1 year after the donation.

<sup>b</sup>More than 5% reduction in working capacity.

<sup>c</sup>Number per 100 000 donations (95% CI).

**Table 4** Description of donors with long-term morbidity

Donors with long-term morbidity	
Symptoms	Number
Pain in the arm when using it	39
Radiating pain down the forearm or fingers	
Pain in the arm and shoulder	
Sensory changes in either the arm, hand or fingers	9
Pain in the arm or elbow and sensory changes in the forearm or fingers	17
Headache due to vasovagal reaction (accident)	2
Distortion of lower extremities due to vasovagal reaction (accident)	1
Total	68

Sixty-eight donors had long-term morbidity without disablement. In 65 of them, the complication was due to needle injury, and among remaining three donors it was due to vasovagal reaction (Table 4). Fifty-eight donors suffered disablement, caused in 56 of them by a needle injury and in two of them, by a vasovagal reaction (Table 5). In 52 of the cases, the degree of disablement was deemed to be 5%. Four donors had disablement of 8%, one donor of 12%, and one donor of 15%. The donors with 5% disablement mainly had daily pain when moving the arm/hand. Sixty-two per cent of the donors with long-term morbidity and/or disablement

**Table 5** Description of donors with long-term morbidity and disablement

Donors with long-term morbidity and disablement	
Symptoms	Number
Constant pain in the arm	10
Pain in the arm when using it	9
Paraesthesia in the arm and diminished function of the elbow	1
Pain in the arm and paraesthesia in the ulnar fingers	15
Pain in the arm and paraesthesia in the hand	2
Pain in the arm and paraesthesia in the arm	10
Pain in the elbow and radiating pain in the fingers	2
Pain in the elbow and radiating pain in forearm	2
Pain in the elbow and radiating pain in the shoulder	1
Diminished force in the fingers	1
Diminished function of the shoulder and pain in the arm when using it	3
Traffic accidents: broken bone and teeth damage due to delayed vasovagal reaction with loss of consciousness	1
Brain contusion due to vasovagal reaction, loss of consciousness and accident	1
Total	58

sought medical care outside the blood bank. The donor with 15% disablement felt the first symptoms 1 week after the donation as pain at the venipuncture site. The pain spread into the entire arm within weeks, in the shoulder as a

constant pain, and in the arm as a pain that occurred when the arm was moved. The donor also got diminished strength in the hand and impaired function of the shoulder and elbow joint.

The complications registered in both the regional survey and the Danish Register of Complications related to Blood Donation could be tentatively classified into needle injuries (to a vessel or a nerve) and vasovagal reactions.

### Needle injuries

Local complications caused by insertion of the needle, including mild, moderate and severe ones, occurred with a rate of 346/100 000 donations (95% CI: 294–408) (Table 1). Most of the complications were vessel injuries with haematoma (274/100 000 donations, 95% CI: 228–329). Arterial puncture occurred with a rate of merely 2/100 000 donations (95% CI: 0.5–1.4). The remainder consisted of nerve injuries (70/100 000 donations, 95% CI: 49–101). The haematoma developed either at venipuncture (58%) or during the bleeding (42%). In 13 donors timing were not specified. The nerve injuries with symptoms of pain occurred at venipuncture (24%), during the bleeding (24%) or after the donation (17%). The remaining (34%) experienced paraesthesia during or after the donation.

Almost all complications with long-term morbidity (4.7/100 000 donations, 95% CI: 4.0–5.6) or disablement (2.2/100 000 donations, 95% CI: 1.7–2.9) were caused by needle injury (Table 3).

### Vasovagal reactions

Complications related to vasovagal reactions occurred with a rate of 478/100 000 donations (95% CI: 415–549) (Table 1). Most of the complications were vasovagal reactions without loss of consciousness (400/100 000 donations, 95% CI: 343–465), while some experienced loss of consciousness (78/100 000 donations, 95% CI: 55–109). Immediate vasovagal reaction occurred in 165 donors of which 13% lost their consciousness. Delayed vasovagal reaction occurred in 19 donors of which 31% lost their consciousness. The characteristics of the remaining 13 vasovagal reactions were not specified. Accidents with a severe outcome occurred in five of the 32 donors who lost their consciousness (one very severe car accident).

### Discussion

Our study indicates that nerve injury that leads to permanent injury or some degree of disablement may be more frequent than previous believed, but the rate of complications leading to severe disablement in our study was consistent with previous reports [5,9].

The main strengths of our study are the large sample size, the population-based design, and the availability of prospectively collected data with complete follow-up. The study found a high degree of agreement between the regional and the nationwide data, suggesting that the data from the regional survey are representative of the entire country. The main limitation of this study is the lack of detailed data on donors' demographics and the circumstances of the donations. This precluded identification of potential risk factors associated with donor complications (e.g. age, phlebotomists' experience etc.). Furthermore, the registration of donor complications in Denmark is based on an on-site registration and late-developing complications are therefore only identified if the donor returns with a complaint. Thus, late events could be under-reported, in particular, mild complications, such as mild vasovagal reactions. In contrast, the registration of moderate and severe complications is more likely to have been complete.

Comparison among international data on blood donation-related complications is difficult, because the classification of complications and the quantification of severity vary substantially. The creation of an international consensus on a common classification is in progress and is done by the International Society of Blood Transfusion and the European Haemovigilance Network. A common classification will improve the possibility of direct comparisons, and thereby will hopefully facilitate further studies and initiatives within this area.

We found the overall rate of complications related to blood donation to be low, even when considering all mild complications. A similar rate has previously been reported by Caffrey *et al.*, who also included all cases, irrespective of severity [10]. We found that the most common types of complications were vasovagal reactions and haematomas. The rate of vasovagal reactions found in this study was lower than reported in other studies, whereas the rate of vasovagal reactions complicated by a loss of consciousness was slightly higher than in previous reports [2,3,7,11,12]. The pattern may be explained by the possible under-reporting of late complications, in particular mild vasovagal reactions.

When all categories of nerve injuries were considered, the rate was slightly higher than previously reported; however, considering the most severe cases of disablement the rate was consistent with previous reports [5,9]. A substantial number of donors experienced long-term morbidity in our study. The rate appeared higher than those reported previously [2]. Most donors with long-term morbidity had complaints of arm pain when they were moving it, and some also had radiating pain or sensory changes extending to the forearm, hand or fingers. Some of these donors were eventually deemed disabled due to a donation-related complication. The degree of disablement in general did not greatly exceed the 5% threshold and was probably not severe. Still, the symptoms were interfering with the donors' daily activities and therefore cannot be considered negligible.

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## References

- 1 Goodnough LT, Brecher ME, Kanter MH, AuBuchon JP: Transfusion medicine. First of two parts – blood transfusion. *N Engl J Med* 1999; 340:438–447
- 2 Newman BH: Blood donor complications after whole-blood donation. *Curr Opin Hematol* 2004; 11:339–345
- 3 Newman BH: Donor reactions and injuries from whole blood donation. *Transfus Med Rev* 1997; 11:64–75
- 4 Horowitz SH: What happens when cutaneous nerves are injured during venipuncture? *Muscle Nerve* 2005; 31:415–417
- 5 Newman BH, Waxman DA: Blood donation-related neurologic needle injury: evaluation of 2 years' worth of data from a large blood center. *Transfusion* 1996; 36:213–215
- 6 France CR, France JL, Roussos M, Ditto B: Mild reactions to blood donation predict a decreased likelihood of donor return. *Transfus Apher Sci* 2004; 30:17–22
- 7 Trouern-Trend JJ, Cable RG, Badon SJ, Newman BH, Popovsky MA: A case-controlled multicenter study of vasovagal reactions in blood donors: influence of sex, age, donation status, weight, blood pressure, and pulse. *Transfusion* 1999; 39:316–320
- 8 Newman BH, Pichette S, Pichette D, Dzaka E: Adverse effects in blood donors after whole-blood donation: a study of 1000 blood donors interviewed 3 weeks after whole-blood donation. *Transfusion* 2003; 43:598–603
- 9 Horowitz SH: Venipuncture-induced Nerve Injury: a review. *J Neuropathic Pain Symptom Palliation* 2005; 1:109–114
- 10 Caffrey EA, Butler M, Bissell L, Bowden M, Fry R: Establishing a national adverse event reporting system for blood donors – a prospective study of 1.8 million attendances in England and North Wales. *Vox Sang* 2005; 89(Suppl. 1):114
- 11 Newman BH: Vasovagal reaction rates and body weight: findings in high- and low-risk populations. *Transfusion* 2003; 43:1084–1088
- 12 Newman BH: Vasovagal reactions in high school students: findings relative to race, risk factor synergism, female sex, and non-high school participants. *Transfusion* 2002; 42:1557–1560