Original Article

Complications related to blood donation: A multicenter study of the prevalence and influencing factors in voluntary blood donation camps in Karnataka, India

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Abstract:

Introduction: Complications associated with blood donation significantly lower odds of subsequent donations. The aim of the study is to assess the prevalence of complications related to blood donation, identify the influencing factors, and come up with suggestions for minimizing discomfort to donors and making outdoor voluntary blood donation camps safer. **Materials and Methods:** This study covered 181 blood donation camps organized by Sankalp India Foundation where 16 blood banks participated from 01-04-2011 to 01-08-2014 in Karnataka. Uniform protocols for donor selection, predonation preparation, counseling, postdonation care, and refreshments were used. The postdonation complications were recorded on a form immediately, after they were observed. **Results:** We observed 995 (3.2%) complications in 30,928 whole blood donations. Of these 884 (2.86%) mild, 77 (0.25%) moderate, and 5 (0.02%) severe complications were observed. Local symptoms (blood outside vessels, pain, and allergy) contributed 1.0%, and generalized symptoms (vasovagal reaction) contributed 2.2% to all the complications. **Conclusion:** We observed 322 complications for every 10,000 donations. Since 27 out of every 10000 experience moderate and severe complication, the readiness to manage complications is crucial. Women donors, young donors, and donors with a lower weight are at a significantly greater risk of experiencing complications, highlighting the need for specific guidelines for the management of higher risk donor groups. Complications varied significantly between various blood banks. Predonation hydration was effective in limiting complications with generalized symptoms. We recommend a robust donor hemovigilance program for voluntary blood donation for monitoring complications and enable assessment of effectiveness and implementation of appropriate interventions.

Key words:

Blood donation, blood donation camps, blood donors, blood safety, complications, hematoma, hemovigilance, India, vasovagal syncope, voluntary blood donation

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Introduction

According to WHO, the safest blood donors are voluntary, non-remunerated and from low-risk populations. WHO has set the goal for all countries to obtain all blood supplies from voluntary unpaid donors by 2020.[1] The National Blood Policy, 2007[2] in the India States — "the practice of replacement donors shall be gradually phased out in a time-bound programme to achieve 100% voluntary non-remunerated blood donation programme." Sankalp India Foundation is an organization working for the cause of achieving 100% voluntary blood donation by means of organizing regular blood donation camps in India. The success of repeat voluntary blood donation camps depends upon the retention of donors. A previous study by Newman[3] has shown that donor reaction had the most negative impact on the blood donor return rate (85% reduction). One study concluded that "having an adverse reaction leads to significantly lower odds of subsequent donation irrespective of previous donation history."[4] Another study showed that higher rate of reactions was associated with a significantly lower likelihood of repeat donation.[5] Sankalp India Foundation undertook a study of the complications related to

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blood donation for all the blood donation camps it organizes. The aim of the study was to assess the prevalence of complications related to blood donation, identify influencing factors, and come up with suggestions for minimizing discomfort to donors and making blood donation camps safer.

Studies have shown the rate of adverse events/reactions to vary from 0.59% to 33%.[6-8] However, this may be because of the lack of a common standard to define the adverse event and the difference in the donor selection criteria. A previous single center study done in North India showed overall reaction rate of 2.5%[9] for replacement as well as voluntary blood donors. Results of other single center studies in India concluded upon the rate of reactions varying between 0.6-2.33%.[10,11] The present study focuses on voluntary blood donation in outdoor blood donation camps and includes the participation of 16 blood banks in Karnataka.

Materials and Methods

This study was conducted across 181 blood donation camps organized by Sankalp India Foundation where a total of 16 different blood banks came to collect blood from 1, April 2011 to 1, August 2014. "Standard for Surveillance of Complications Related to Blood Donation" by the "working group on Complications Related to Blood Donation" of the International Society of Blood Transfusion — working party on hemovigilance was chosen as the reference document to define a postdonation complication.[12]

At the beginning of the study, all the blood banks that were scheduled to come for blood donation camps were given a copy of the standard. A training program was organized to enable proper understanding of the identification, classification, management, and recording of complications for the blood bank medical officers and the camp in charge volunteers. A form was designed and printed to capture complications. Postdonation complications were recorded in this form immediately after they were observed or reported during the camps, and the same were systematically recorded on a software system.

In each of the blood donation camps where this study was conducted, significant emphasis was given to strict adherence to the standard protocol for donor selection, bleeding, and resting as laid out by the Drugs and Cosmetics Act, Ministry of Health and Family Welfare, Government of India and the recommendations of National AIDS Control Organization (NACO).[2,13,14] The camps were organized only in the cool environment by using air conditioning or by providing fans. Each donor was given proper predonation counseling, and adequate care was taken to ensure that they were well rested, had something substantial to eat during the four hours prior to donation, were not under any kind of medication and did not smoke during the 2 h prior to donation. Hemoglobin test by copper sulfate method was done for each donor. An extensive donor form containing all criteria as detailed in the recommendations of the Drugs and Cosmetics Act and NACO guidelines[2,13,14] were utilized across all camps. The form included columns for indicating any history of discomfort in previous donations. All the donations were carried out on beds while the donors lay flat. Donors were also given minimum 5 min of rest after donation. Donors were kept at the camp venue for another 5-10 min postdonation and were given a juice and packet of biscuits while trained volunteers looked for signs of discomfort. Each donor was provided with a card which had the emergency numbers to be contacted in case of any postdonation complication. Points of contact in the organizations where the camps happened were also requested to inform about any complications which come to their notice after the team left the venue. However, no feedback call was made to donors to confirm, if they had delayed complications or not.

Periodically, the number of complications that were being recorded was captured and analyzed using a dedicated software system built for the purpose of study and the outcome shared with the blood banks in an attempt to promote better care and management of donation and prevent complications in blood donation camps. After every camp, the blood banks were provided with a written feedback indicating the number of complications and the type of complications so as to enable immediate assessment of the possible reasons and facilitate preventive steps in subsequent camps.

Since large numbers of vasovagal complications were being observed, predonation hydration was considered. Studies indicated that hydration before blood donation reduces chances of adverse events.[15,16] With the intent to minimize complications, all donors were requested to have two cups of water before donating blood starting April 2013. As a result, 16,504 donors were given predonation hydration. The occurrence of vasovagal complications before and after this change was compared separately to observe the efficacy this change in reducing complications.

Of the 366 camps, 18 camps (5%) were excluded from the study because either the medical officer/camp incharge was unaware of the process of filling complication assessment forms or the forms were lost.

Results

A total of 995 (3.2%) complications were observed in the 30,928 whole blood donations that happened in the study period. Of these, 884 (2.86%) complications were mild, 77 (0.25%) complications were moderate, while 5 (0.02%) were severe. For the remaining 29 (0.09%) complications, the severity was not captured. All severe complications and 90% of the moderate complications were associated with generalized symptoms. Arm related injuries contributed to 10% of the moderate complications associated with the donor not being able to perform normal activities and/or discomfort lasting more than a week after donation. Figure 1 shows the rate of complications based on the severity.

Type of complication

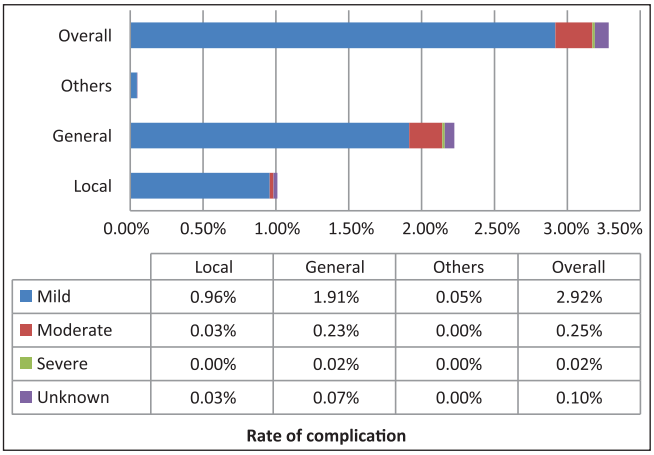
A total of 306 (1.0%) complications with local symptoms (blood outside vessels, pain, and allergy) and 674 (2.2%) of complications with generalized symptoms (vasovagal reaction) were observed. Immediate vasovagal reaction (1.53%) was the most common complication both for men and women followed by delayed vasovagal (0.51%) reaction and hematoma (0.22%). Total of 15 (0.05%) complications were attributed to other or unknown symptoms. Figure 2 shows the rate of complications based on the type of complication.

Gender

Women donors experienced about 4 times as many complications with generalized symptoms (women: 6.50%, men: 1.74% overall: 2.14%) and twice as many complications with localized symptoms (women: 1.71%, men: 0.92%, overall: 1.01%) as their male counterparts. The frequency of postdonation complications was observed to be 3 times higher for women (8.7%) compared to men (2.8%).

Age

The higher rate of complication was also observed for younger donors with 4.6% of the donors below the age of 20 experiencing one of the complications. The rate of complications steadily declined with age both for male and for female donors, and a strong correlation(r = 0.97) was seen between the age of the donor and the probability of complication. Younger female donors showed the highest rate of complications at about 10%. The average age of the donors was 28.2 years (standard deviation [SD]: 5.5) while the average age of donors who experienced reactions was 27.6 years (SD: 8.4) that for donors who had vasovagal reactions was 26.9 (SD: 4.8) years. Figure 3 shows the variation of complications with donor's age for male and female donors.



	Local	General	Others	Overall
Mild	0.96%	1.91%	0.05%	2.92%
Moderate	0.03%	0.23%	0.00%	0.25%
Severe	0.00%	0.02%	0.00%	0.02%
Unknown	0.03%	0.07%	0.00%	0.10%

Figure 1: Comparison of the category and severity of complications

Weight

The rate of complications also showed a relationship with the weight of donors, with 5% of donors weighing <55 kg experiencing a complication. There was a steady decline in the rate of complications as donors weight increased. Women had a significantly higher rate of complication between the weight of 45-50 kg (12.4%) and 51-55 kg (9.4%). Strong correlation was observed between weight and complications for women(r = –0.67) and overall donor pool(r = –0.95) while the correlation in case of male donor alone was weaker (r = –0.34). The average weight of donors was 73.1 kg (SD: 11.3) while the average weight of donors who experienced reactions was 69.8 kg (SD: 10.8) while that for donors who had vasovagal reactions was 68.2 kg (SD: 10.0). Figure 4 shows the variation of complications with donor's weight for male and female donors.

Type of organization for camp

Blood donation camps organized in colleges and educational institutions also noted a higher rate of complication (3.9% in 14 camps), corporate blood donation camps had a rate of complication of 3.3% (in 304 camps), and public camps has a complication rate of 2.8% (12 camps).

Blood bank team

We studied the relationship of blood bank teams with the rate of complications for the six teams which collected more than 5% of the total blood units collected during the study period. The variation between the team with minimum complication rate and maximum complication rate was as much as 2 times for complications with generalized symptoms, 2.5 times for complications with localized symptoms and 1.6 times for the all complications put together. Figure 5 shows variation in the rate of complications with blood banks.

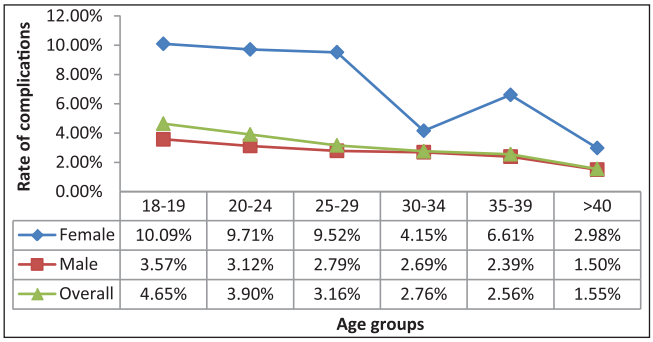
Predonation hydration

The contribution of vasovagal reactions to the overall rate of complications dropped from 78% to 62% when predonation hydration was introduced. Figure 6 shows variation in the contribution of vasovagal reactions to overall reactions before and after predonation hydration.

Rate of complications based upon the type and severtity of complications.

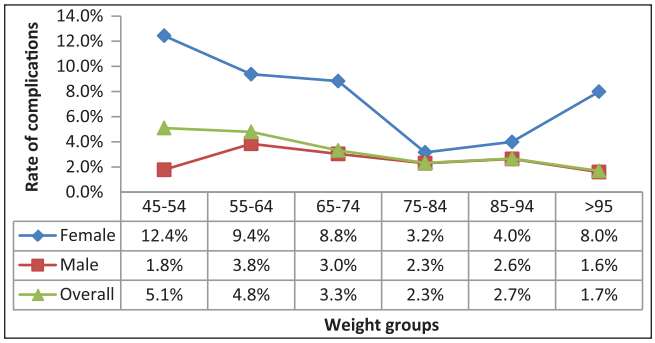
	Severity-wise				Gender-wise		Overall
Type	**Mild**	**Moderate**	**Severe**	**Unknown**	**Female**	**Male**	**Overall**
Immediate VVR	1.34% (n=415)	0.13% (n=41)	0.01% (n=3)	0.05% (n=15)	4.80% (n=104)	1.26% (n=362)	1.53% (n=474)
Immediate VVR with injury	0.01% (n=3)	0.00% (n=0)	0.00% (n=0)	0.00% (n=0)	0.09% (n=2)	0.00% (n=1)	0.01% (n=3)
Delayed VVR	0.48% (n=150)	0.09% (n=27)	0.01% (n=2)	0.02% (n=5)	1.61% (n=35)	0.47% (n=135)	0.59% (n=184)
Delayed VVR with injury	0.00% (n=1)	0.00% (n=)	0.00% (n=)	0.00% (n=0)	0.00% (n=)	0.00% (n=1)	0.00% (n=1)
Generalised Symptoms	**1.84% (n=569)**	**0.22% (n=68)**	**0.02% (n=5)**	**0.06% (n=20)**	**6.50% (n=141)**	**1.74% (n=499)**	**2.14% (n=662)**
Nerve irritation	0.01% (n=2)	0.00% (n=0)	0.00% (n=0)	0.00% (n=0)	0.00% (n=)	0.01% (n=2)	0.01% (n=2)
Tendon injury	0.00% (n=1)	0.00% (n=0)	0.00% (n=0)	0.00% (n=0)	0.00% (n=)	0.00% (n=)	0.00% (n=1)
Haematoma	0.19% (n=60)	0.02% (n=5)	0.00% (n=0)	0.01% (n=4)	0.51% (n=11)	0.20% (n=57)	0.22% (n=69)
Painful arm	0.16% (n=49)	0.01% (n=3)	0.00% (n=0)	0.00% (n=1)	0.28% (n=6)	0.15% (n=44)	0.17% (n=53)
Delayed bleeding	0.59% (n=184)	0.00% (n=0)	0.00% (n=0)	0.01% (n=3)	0.92% (n=20)	0.56% (n=162)	0.60% (n=187)
Localised Symptoms	**0.96% (n=296)**	**0.03% (n=8)**	**0.00% (n=0)**	**0.03% (n=8)**	**1.71% (n=37)**	**0.92% (n=265)**	**1.01% (n=312)**
Other	0.04% (n=13)	0.00% (n=0)	0.00% (n=0)	0.00% (n=1)	0.05% (n=1)	0.04% (n=11)	0.05% (n=14)
Allergy (local)	0.01% (n=2)	0.00% (n=0)	0.00% (n=0)	0.00% (n=0)	0.05% (n=1)	0.00% (n=)	0.01% (n=2)
Thrombophlebitis	0.02% (n=5)	0.00% (n=0)	0.00% (n=0)	0.00% (n=0)	0.09% (n=2)	0.01% (n=3)	0.02% (n=5)
Others	**0.06% (n=20)**	**0.00% (n=0)**	**0.00% (n=0)**	**0.00% (n=1)**	**0.18% (n=4)**	**0.05% (n=14)**	**0.07% (n=21)**
Overall	**2.86% (n=885)**	**0.25% (n=76)**	**0.02% (n=5)**	**0.09% (n=29)**	**8.39% (n=182)**	**2.71% (n=778)**	**3.22% (n=995)**

Figure 2: Rate of complications based on the type and severity of complications



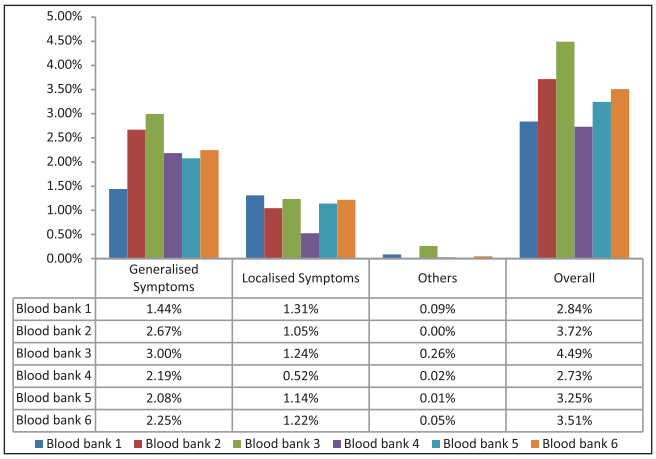
	18-19	20-24	25-29	30-34	35-39	>40
Female	10.09%	9.71%	9.52%	4.15%	6.61%	2.98%
Male	3.57%	3.12%	2.79%	2.69%	2.39%	1.50%
Overall	4.65%	3.90%	3.16%	2.76%	2.56%	1.55%

Figure 3: Variation of rate of complications with donor's age



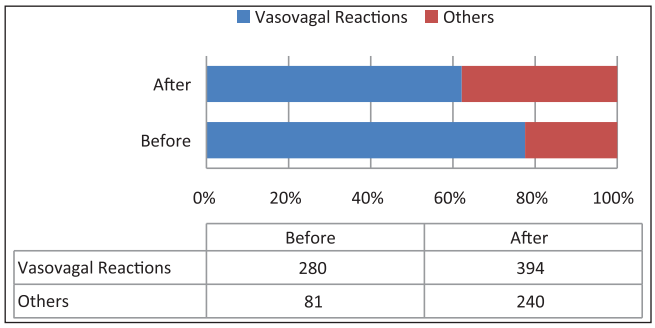
	45-54	55-64	65-74	75-84	85-94	>95
Female	12.4%	9.4%	8.8%	3.2%	4.0%	8.0%
Male	1.8%	3.8%	3.0%	2.3%	2.6%	1.6%
Overall	5.1%	4.8%	3.3%	2.3%	2.7%	1.7%

Figure 4: Variation of rate of complications with donor's weight



	Generalised Symptoms	Localised Symptoms	Others	Overall
Blood bank 1	1.44%	1.31%	0.09%	2.84%
Blood bank 2	2.67%	1.05%	0.00%	3.72%
Blood bank 3	3.00%	1.24%	0.26%	4.49%
Blood bank 4	2.19%	0.52%	0.02%	2.73%
Blood bank 5	2.08%	1.14%	0.01%	3.25%
Blood bank 6	2.25%	1.22%	0.05%	3.51%

Figure 5: Variation of rate of complications with blood banks



	Before	After
Vasovagal Reactions	280	394
Others	81	240

Figure 6: Impact of predonation hydration

Discussion

In our study, the overall rate of complications was 3.2%. This is in agreement with some studies[9,11] which reported 2.3-2.5%, higher than some other studies[8,10] which reported 0.6-0.8% and lesser than several other[3,7,17,18] studies which reported more than 7% complications. The significant differences in the definitions and the mechanism for identification of the complication may explain the variations. The studies are showing that the lower rate of reactions relied upon the medical teams to identify and document complications at the time of donation, thus limiting their observation to immediate complications only. The studies which reported a higher rate of complications typically involved calling the blood donor after few days of donation and included symptoms like feeling weak which was not part of the criteria we used to define complications. We believe that the process of informing each donor on how they can seek help in case they feel discomfort after leaving the venue enabled us to identify the delayed complications and explain the slightly higher rate of complications as compared to other studies in similar setup. We found that 1 in 400 donors experienced a moderate adverse event while 1 in 5000 donors experienced a severe event. The management of the severe complications in our camps included calling external medical consultants for help, oxygen, and IV administration. Moderate complications also demanded the prolonged involvement of the medical officer and other staff members. The normal procedure of phlebotomy was halted and the donor was given immediate care and attention. In four cases, the donors were hospitalized. The management of moderate and severe complications demands specific expertise and clear roles of the various members of the blood bank team. It also requires teams to be prepared with emergency medicines and equipment necessary to manage an adverse event in the limited settings of outdoor voluntary blood donation camps. Investing in training and preparedness of the blood bank teams to handle various scenarios associate with severe complications appears to be essential.

We observed that women donors were at a significantly higher risk of complications compared to their male counterparts which are in agreement with earlier studies.[9,18-21] Also, the rate of complications decreasing with increasing age and weight are in agreement with the earlier findings.[6,9,19-24] While the study establishes that younger donors, women donors, and donors with lower weight are at a greater risk of complications, the fact remains that the country is still facing shortage of blood and enabling all eligible donors to donate blood safely is of utmost importance. The way ahead seems to be adoption and implementation of specific guidelines for managing donors who are at greater risk of complications.

We organized 92% blood donation camps in corporate setup (where most donors are above the age of 24 years). Only 1% of the donors in our blood donation camps were below the age of 20 years where the overall rate of complications was highest. Since, the contribution of blood donation camps in colleges (where donors are typically 17-21-year-old) are higher in the most places in India, we believe the higher rate of complications could be expected for a more accurately representative donor population.

The high variation in the rate of complications between the various blood bank teams indicates the role of blood bank team specific factors. We believe that experience and skill of staff,

variations in donor selection criteria, proficiency in donor counseling and reassuring, general soft skills of staff may be contributing to the variation. The fact that there are team specific factors which influence complications indicates that complications could be limited by adoption of best practices associated with complication prevention, specific training, and skill building of the teams.

There are pressing problems related to the knowledge and attitude of the medical teams toward postdonation complications. The absence of national standards mandated by law in the country has contributed to the absence of skill to systematically identify and manage complications. The task of convincing the medical officers to acknowledge the occurrence of postdonation complications was found to be significantly challenging. Often complications of mild severity were seen as a routine event by the medical staff and resistance to acknowledge and document the complication was observed. A quick reference card with the definitions of complications as per the standard[12] was included in the stationary being made available to blood bank medical officers to ensure that there is no dispute over which complications should be recorded as part of the study. Another challenge was faced in the process of identification and capturing of arm injuries which were observed immediately postdonation when often, the phlebotomists tried to manage the situation by themselves and were reluctant to bring it to the notice of the camp incharge medical officer and volunteer. The camp incharge volunteer from Sankalp India Foundation insisted upon proper recording of complications by the staff. The confusion over the definitions and scope of complications is also evident in the various studies that have been done on the subject within the country.[9-11] There appears to be an urgent need for national guidelines on definitions, prevention and management of postdonation complications which would then pave the way for uniform training and skill building.

Predonation hydration was found to be very effective in limiting the number of vasovagal complications which is in agreement with prior findings.[15,16]

The regular monitoring of the rate of reactions and the regular feedback to the blood banks helped identify patterns of the abnormally high rate of adverse events associated with particular medical teams. Periodic feedback in this regard helped control complication rates with the teams exercising greater caution while selecting, counseling, bleeding and taking care of donors.

While we came across several factors including proficiency level of the phlebotomist, blood pressure of the donor prior to donation, the number of times the donor has donated blood, as factors related to complications, the weakness of our study is that we were unable to capture enough data to firmly establish these relationships. More work needs to be done to understand why some blood banks show lower complication rates than the others including the role of experience and skill of staff, variations in donor selection criteria, proficiency level in donor counseling and reassuring and general soft skills of staff. Since the capturing of delayed reactions depends upon the self-reporting by the donors, we believe that some delayed complications may have gone unreported.

The process of calling donors a day after the complication was reported was much appreciated by the donors. Proper advice was given to such donors through telephone calls and follow-up was repeated until the donor recovered. In cases of delayed moderate and serious complications, the donor was examined by physicians and advised appropriately. In our opinion, reassuring and counseling the donor a day after the camp enabled forging better relationship not only with the donor but also with the organization where the camps were conducted.

Our study was instrumental in the proper assessment of the extent of postdonation complications and enabled setting up a systematic mechanism for proper identification, documentation, intervention, and follow-up. As a direct outcome of the study, we are convinced that routine monitoring of postdonation complications and their management is essential to donor's safety and in the best interest of voluntary blood donation. Thus, we are firmly committed to monitor complications in the all blood donation camps.

Conclusion

For every 10,000 blood donations, our study observed 322 donors experienced complications in outdoor blood donation camps. Two-third of all complications were associated with generalized symptoms, and the remaining one-third were associated with localized symptoms. Since 27 out of every 10,000 blood donors experience a moderate or severe complication, the specific preparedness to manage such complications in every blood donation camp is crucial.

Our study identified that woman donors, young donors and donors with a lower weight are at a significantly greater risk of experiencing a complication. Our findings highlight the need for specific guidelines for management of women donors and young blood donors.

We found predonation hydration to be an effective mechanism to limit the complications with generalized symptoms.

Our study was only able to analyze limited number of predisposition factors and more work is needed to study the relationship of complications with proficiency and experience level of the phlebotomist, measuring blood pressure of the donor prior to donation, the number of times the donor has donated blood, role of applied muscle tension, etc.

The higher rate of complications is known to be associated with a significantly lower likelihood of repeat donation. There appears to be a need for an urgent review of the strategies and interventions which can prevent complications. In order to make progress with the voluntary blood donation movement, and in the best interest of donors safety we recommend a robust donor hemovigilance program with standardized definitions, complication prevention strategies, and complication management guidelines.

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Conflicts of interest

There are no conflicts of interest.

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