Review Paper

Assessing Safety of Blood Donation by people Diagnosed with Diabetes, Hypertension, Malaria and Cancer

ABSTRACT

Diabetes, hypertension, malaria and cancer have become common health problems to human society. Cases of blood transfusion-transmitted malaria, hypertension, cancer and safety of blood donation by diabetic people have been described around the world and highlighted in some studies. Diabetes is generally associated with complications and people with diabetes usually take different medications and may already have anaemia secondary to renal impairment, B12 deficiency. As for the recipient safety, a blood from a person with hyperglycaemia but otherwise healthy i.e. satisfy blood donation safety standards (does not have HIV, Hep B or C) would be quite safe to receive as the extra glucose would simply be regulated and utilised by the recipient's body. Diabetic people when they donate blood may become, hypotensive or hypoglycemic. Hypoglycemia is as bad as hyperglycemia and could be fatal and hence, generally it is not desired that diabetics give blood donations. Diabetic patients taking bovine or porcine insulins may develop antibodies and it is not recommended that the antibody contaminated blood be given to any other person. A person with hypertension can donate blood, as long as the blood pressure is normal at the time of blood donation and there's no fluctuation. Acceptable blood pressure rate for blood donation is below 180 systolic (first number) and below 100 diastolic (second number) at the time of donation. Malaria is also readily transmitted by blood transfusion through donations collected from asymptomatic, parasitaemic donors. The parasite is released into the bloodstream during its lifecycle and will therefore be present in blood donated by infected individuals.The presence of total anti-Plasmodium spp. antibodies in the bloodstream of individuals many years after exposure, with no history of malaria in the meantime, is important to highlight. Regarding donors with cancer Blood donations should not be taken from people with recently active malignancies, except in the case of basal cell carcinoma or cervical carcinoma in situ.

Keywords: *Blood Transfusion, Diabetes Mellitus, Hypertension, Malaria and Cancer*

1. INTRODUCTION

Diabetes has become endemic to human society, and over 400 million people live with this syndrome across the world. It is natural that there will be questions regarding the safety of blood donation in persons with diabetes, as well as about the viability of blood taken from them. There may be further questions about the safety of blood component transfusion in persons with diabetes. Unfortunately, strong evidence based knowledge for any of these questions is lacking. (Nilotpal Chowdhury 2017). There is no evidence that raised baseline blood pressure, treated hypertension or low blood pressure are predictive of increased adverse reactions to blood donation, although the level of evidence is limited. In addition, there is no evidence of harm to recipients of blood from donors taking anti-hypertensive medication. Individuals whose blood pressure is well-controlled by medication and meet other donor selection criteria can be accepted as blood donors. Donors who have recently started taking anti-hypertensive medication or for whom the dose of anti-hypertensive medication has been adjusted, should be deferred for a period of 28 days after the blood pressure has been stabilized (Nilotpal Chowdhury 2017).

Cases of transfusion-transmitted malaria have been described around the world and highlighted in some studies. Semi-immune individuals are more likely to transmit malaria as they may be asymptomatic. Some countries allow blood donations only based on epidemiological criteria while others reinforce their criteria with serological tests. However, little is known about the longevity of anti-*Plasmodium* spp. antibodies and its meaning in blood donation (Singh G et al 2010, Candolfi E 2005).

Acceptance criteria for prospective donors with a past history of treated solid tumours vary widely. Some BTS accept donors who are disease-free for a specified period, while others permanently defer on the basis that there is a theoretical possibility of transfusion-transmission of tumour cells or of oncogenic viruses, although these policies are currently under review.

A large retrospective cohort study of cancer incidence among patients who received blood from donors deemed to have a subclinical cancer at the time of donation (diagnosed with cancer within five years of the donation) showed no excess risk of cancer among recipients of blood from pre-cancerous donors compared with recipients of blood from non-cancerous donors. However, the transmission of donor melanoma by organ transplantation has been reported. Transfusion-transmitted cancers have never been convincingly demonstrated, but most BTS

continue to take a precautionary approach and do not accept blood from people who have had a malignancy as many malignancies spread through the blood stream and by invading surrounding tissues. Blood donations should not be taken from people with recently active malignancies, except in the case of basal cell carcinoma or cervical carcinoma in situ.

2. Blood donation by diabetic people

Are persons with diabetes eligible to donate blood? In general, if well controlled, persons with diabetes can do so safely. The guidelines of the National AIDS Control Organization (NACO) advise that prospective donors be screened for any serious illness, primarily to safeguard donors. Patient advisories by the American Diabetes Association clearly mention that statements as persons with diabetes cannot donate blood are a myth. However, opinion varies about whether all persons with diabetes are eligible for donation. The World Health Organization (WHO) British and European Guidelines have only included persons with diabetes well controlled on diet or oral medications as eligible donors, while the American Red Cross Society has deemed even persons well controlled on insulin as eligible. It should also be noted that persons with diabetes who had injected bovine insulin sourced from the UK after 1980 are not eligible for donation even under the American Red Cross guidelines (Nilotpal Chowdhury, 2017).

Modern diabetes care, however, does not use animal insulin, and only recombinant human insulin and insulin analogues are available today. The published evidence of the safety of blood donation in insulin dependent diabetes is scant. One published study which gives the donor reaction rate in type 1 diabetic autologous blood donors showed a donor reaction rate of 4.8% as compared to 2.7 % for normal donors. Therefore, it is advisable to avoid blood donation by individuals with type 1 diabetes, as per the WHO criteria, until further studies clearly demonstrate safety. Even for type 2 diabetes, published evidence about the safety of blood donation is sparse. Though the WHO, British and European guidelines have included non-insulin requiring persons with type 2 diabetes as eligible donors, a systematic review found no data relating to blood donor safety in type 2 diabetes controlled on oral hypoglycaemic agents. Few studies have observed that repeated blood donations may increase insulin sensitivity both in persons with type 2 diabetes as well as non-diabetics. Therefore, blood donation may have the potential to prevent the development of diabetes in normal persons by preventing iron overload. This, however, needs confirmation through well-designed studies.

Type 2 DM can donate safely for Type 1 it is clinically unsafe and if should be done for any reason you need to do that after being sure that the patient is at optimal conditions for donating blood + a blood glucose and clinical follow up for at least 8-12 hours after donation (speaking about Type 1 DM)(Nilotpal Chowdhury, 2017).

Those with Type 2 diabetes need not be excluded if they are on diet alone, metformin alone or th ialodinediones or insulin to control their blood glucose. One should be cautious with those on sulphonylureas as residual concentrations of these in the blood might cause hypoglycae mia in the recipient however this is a theoretical possibility and no evidence to suggest that this would be a serious risk. It is likely that the risk (if any) from suphonylureas would only exist for a few hours following ingestion.
It is suggested that for the sulphonylurea gliclazide, plasma concentrations around 1.5 mg/l cause hypoglycaemic effects. It is estimated that a unit of whole blood from a donor taking gliclazide is likely to contain 10- to 100-fold less than a single daily therapeutic dose, and is very unlikely to produce hypoglycaemia. It is recommend that individuals with non-insulin dependent diabetes should be accepted as whole blood or component donors, provided that treatment is stable (i.e. not altered within the past 4 weeks) and the donor is well, with no history suggestive of cardiovascular or cerebrovascular, disease, renal impairment or peripheral vascular disease(UK Blood Transfusion Services' Forum2005)

What are the transfusion guidelines for persons with diabetes? By and large, the only potential problem is that blood bag solutions contain a small amount of glucose (approximately 2.5 g of dextrose monohydrate in 100 ml of Citrate Phosphate Dextrose (CPD) solution; one blood bag of 450 ml contains about 69 ml of CPD), and therefore, in serious conditions, when a large number of transfusions have to be given, the patient needs to be closely monitored.The long term effect of one-time transfusion on glycaemic control has not been studied. In the short term, HbA1C may be lowered due to mixing of normal red blood cells (RBCs) with RBCs of the person with diabetes. HbA1C has been deemed an unreliable marker for glycaemic control in diabetic blood recipients even in autologous donors (Nilotpal Chowdhury,2017).

In the United States, the Food and Drug Administration does not have any regulatory restrictions against diabetics donating blood other than if the individual has received bovine source insulin since 1980. The concern here is not the diabetes but rather the bovine spongiform encephalopathy. As bovine source insulins were not widely available in the US, the diabetic would have had to specifically import it from Europe. (Of note, the FDA regulations require that is the donor answers that they are not certain whether they received bovine source insulin, they are deferred. Many donors answer "I do not know" and are therefore deferred when in reality they have not been exposed as it was not available in the US.) Donors may mistake this deferral as being due to their having diabetes. Here is the FDA guidance (Mayo Foundation for Medical Education and Research).

The only instance where diabetes would have a negative effect on blood product and therefore an adverse effect on the patient would be in the rare instances where we collect granulocytes. If the donor had poor glucose control, this could impair neutrophil function. Since granulocyte donors are usually stimulated with corticosteroids, which would worsen glucose control, diabetics are deferred from granulocyte donation at my institution so this is not an issue.

However diabetes is generally associated with complications and people with diabetes usually take different medications and may already have anaemia secondary to renal impairment, B12 deficiency . As for the recipient safety, a blood from a person with hyperglycaemia but otherwise healthy i.e. satisfy blood donation safety standards (does not have HIV, Hep B or C) would be quite safe to receive as the extra glucose would simply be regulated and utilised by the recipient's body.

Diabetic people when they donate blood may become, hypotensive or hypoglycemic. Hypoglycemia is as bad as hyperglycemia and could be fatal and hence, generally it is not desired that diabetics give blood donations. Diabetic patients taking bovine or porcine insulins may develop antibodies and it is not recommended that the antibody contaminated blood be given to any other person. Each country and each hospital may have its own rules and regulations which are quite strict. There is indeed no necessity to have a uniform policy for a generally objectionable practice.. In those urgent life-saving circumstances, if the blood from normal healthy volunteers is absolutely not available, then perhaps blood from carefully drawn from diabetics may be transfused under supervision of hospital authorities. Diabetic patients are

actually apparently likely to benefit from donating blood/ blood letting, , in view of the fact that about 10% of Americans and 25% of the Irish, are carriers fro hemochromatosis, a hereditary iron overload disease and excess iron appears to induce insulin resistance, and many people in the Western world particularly, eat lots of red meat, (Loyola University Medical Center http://www.biomedcentral.com/1741-7015/10/54).

3. Blood donation by hypertensive people

'A 2002 study of 72,059 whole blood donations at the American Red Cross (ARC) showed no statistical association between low pre-donation systolic or diastolic blood pressure and adverse reaction. In addition, ARC reviewed pre-donation blood pressure on all donors with adverse reactions that resulted in hospitalization from January 1999 to December 2002. This review showed no over-representation of low blood pressure or antihypertensive use in those donors.

'Health Canada's decision (to accept donors taking antihypertensive medication) is based on the fact that there is no known link between reactions from giving blood and the use of medication to control high blood pressure. Donors who take anti hypertensive medication are no more at risk than other donors. (UK Blood Transfusion Services' Forum2005).

It would be medically safe to accept donations from donors on antihypertensive medication other than diuretics. None of the anti-hypertensive agents in regular use should compromise a patient's ability to compensate for a 1 unit donation.' Regardin g possible direct toxicity to the recipient, his view was that 'that unit of blood will have very little active drug in it by the time it reaches the recipient.'

It would not be unreasonable to consider allowing blood donation in patients with stable cardiovascular disease or those taking cardioactive medications, provided that they do not suffer from symptoms of postural hypotension generally(UK Blood Transfusion Services' Forum2005).

They have not suffered any adverse effects of raised blood pressure (BP) such as heart disease (angina, heart attack or heart failure), stroke, transient ischaemic attack (TIA or mini-stroke), or peripheral vascular disease (intermittent claudication,gangrene). They are taking only a Beta(ß)-blocker and/or diuretic as their treatment for the raised BP. The list below shows the proper and

trade names of allowed drugs. It is important to note that this list is not exclusive and that these drugs may be used to treat other conditions such as heart failure and abnormal heart rhythms (arrhythmia); both of which would mean the donor must not donate. Other medication should be assessed independently. Treatment is stable and this requires:That the donor is well and not having any problems with feeling faint, fainting or Giddines (UK Blood Transfusion Services' Forum2005)

There is no evidence that raised baseline blood pressure, treated hypertension or low blood pressure are predictive of increased adverse reactions to blood donation, although the level of evidence is limited. In addition, there is no evidence of harm to recipients of blood from donors taking anti-hypertensive medication. Individuals whose blood pressure is well-controlled by medication and meet other donor selection criteria can be accepted as blood donors. Donors who have recently started taking anti-hypertensive medication or for whom the dose of anti-hypertensive medication has been adjusted, should be deferred for a period of 28 days after the blood pressure has been stabilized.

A person with hypertension can donate blood, as long as the blood pressure is normal at the time of blood donation and there's no fluctuation. Acceptable blood pressure rate for blood donation is below 180 systolic (first number) and below 100 diastolic (second number) at the time of donation. Even though, the donor is on regular medications, one must understand that medications for high blood pressure do not disqualify you from donating blood. Provided, you don't have side effects related to your medication. Also, the person shouldn't be suffering from other co-morbid diseases associated with hypertension. People who have fluctuating blood pressure with irregular treatment must stay away from donating

Routine ambulatory BP monitoring may identify a large number of individuals with white-coat hypertension and a smaller but significant number of individuals with masked hypertension, ensuring adequate protection of potential donors and accurate assessment of donor risk. Differences in baseline characteristics are small and are not clinically useful in distinguishing individuals with masked hypertension from individuals with sustained normotension or individuals with white-coat hypertension from individuals with sustained hypertension,

demonstrating the importance of ambulatory BP monitoring in this population (RoutiElizabeth S. Ommen et al 2007)

4. Blood donation by people with malaria

A number of Chinese workers also travel as laborers to Africa, where many countries are endemic for malaria; this trend has further increased the number of potential malaria-infected donors in China. No autochthonous cases of malaria have been reported in the Jiangsu province since 1998 sporadic cases of imported malaria, mostly from Africa and Southeast Asia, have been reported in recent years. This has led to an increase in the proportion of blood donors at risk for malaria. In August 2013, a transfusion-transmitted malaria (TTM) case caused by *P. falciparum* was reported in Jiangsu Province Blood Center for the first time. The blood donor was a worker who recently returned from Kenya and once had malaria. He later admitted to concealing his medical history in order to know whether he had recovered enough to donate blood. Malaria antibodies were detected in 2.13% of the 704 plasma samples studied. The prevalence of malaria antibodies was not significantly correlated with gender, occupation and frequency of donation, but it increased with age. No *Plasmodium* was observed in red blood cells and no *Plasmodium* DNA was detected in any of the antibody-positive samples. (Hong Lin et al 2017, Nguyen ML et al 2013 and Dubey A et al 2012).

The study prevalence of malaria antibodies was no higher than expected, even in donors from regions where malaria is endemic. Additionally, parasitemia was not detected even once, and none tested positive for *Plasmodium* DNA in the PCR assay. The number of blood donors is estimated to be less than 1% of the total national population. Donor deferral will further reduce repeat donations and universal serological screening is impossible. In this study, follow-up investigations were not conducted, and none of the donors was deferred. Hence, the deferral of malaria-risk donors still relies on the deferral guidelines, and, for a long time, this has been the only method to prevent TTM in China. Donors may give inaccurate information intentionally or unintentionally because they misunderstand the questions or are unaware or have forgotten that they have previously had contact with malaria(Hong Lin et al 2017, Nguyen ML et al 2013 and Dubey A et al 2012).

Some factors that may influence the longevity of total anti-*Plasmodium* spp. antibodies over time were identified: (a) had been born in endemic areas and (b) previous history of malaria. On the other hand, living in endemic areas during childhood does not seem to be related to the longevity of total anti-*Plasmodium* spp. antibodies, as well as the number of travels to endemic areas or the length of time spent in endemic areas, for the population studied. Although the length of time since the last stay in endemic areas was not statistically significant, the presence of total anti-*Plasmodium* spp. antibodies in the bloodstream of individuals many years after exposure, with no history of malaria in the meantime, is important to highlight (Daniela Portugal-Calisto et al 2016).

Asymptomatic malaria parasitaemia and anemia were observed to be higher among commercial blood donors than voluntary donors. Malaria parasite infected blood transfused to a non–immune individual is associated with fatal outcomes. Mandatory screening of blood donors for malaria parasite is advocated to curb transfusion transmitted malaria and associated squeal. Voluntary donation of blood should be encouraged. When malaria is transmitted through blood transfusion to a non-immune recipient, it can be rapidly fatal. Although, reports shows that a good number of recipients of blood transfusion living in malaria-endemic areas in sub- Saharan Africa are semi-immune to malaria , the degree of protection that this immunity confers against transfusion-transmitted malaria is unknown. Malaria due to *Plasmodium falciparum* can be acquired even with transfusion of a small number of infected red blood cells . Children and pregnant women, who form the bulk of recipients of blood in sub-Saharan Africa, are more likely to be immunologically compromised , thus exposing them to complications of transfusion-transmitted malaria. Hemoglobin assessment is an important criterion for blood donor selection. This is critical for the safety of blood donor and recipient. A number of African studies have reported that low hemoglobin concentration is frequent in most blood donors. This has great implication for the rate of recovery of patients transfused with blood(Bankole Henry OLADEINDE et al 2014).

Malaria is also readily transmitted by blood transfusion through donations collected from asymptomatic, parasitaemic donors. The parasite is released into the bloodstream during its

lifecycle and will therefore be present in blood donated by infected individuals. The parasites are stable in plasma and whole blood for at least 18 days when stored at +4°C and for extended periods in a frozen state criteria to exclude collecting blood from individuals with current or past history of malarial infection and at risk of transmitting malaria through transfusion, should be based on local epidemiological evidence and endemicity of the infection (World Health Organization; 2012).

Malaria is transmitted by the bite of mosquitoes found in certain countries and may be transmitted to patients through blood transfusion. Blood donations are not tested for malaria because there is no sensitive blood test available for malaria. If you have traveled or lived in a malaria-risk country, it requires a waiting period before you can donate blood. Wait 3 years after completing treatment for malaria,wait 12 months after returning from a trip to an area where malaria is found,wait 3 years after living more than 5 years in a country or countries where malaria is found. An additional waiting period of 3 years may be required if you have traveled to an area where malaria is found if you have not lived a consecutive 3 years in a country or countries where malaria is not found. If you have traveled outside of the United States and Canada, your travel destinations will be reviewed at the time of donation (American Red cross, Medications and Vaccinations).

4. Blood donation by people with Cancer

Acceptance criteria for prospective donors with a past history of treated solid tumours vary widely. Some BTS accept donors who are disease-free for a specified period,while others permanently defer on the basis that there is a theoretical possibility of transfusion-transmission of tumour cells or of oncogenic viruses.

A large retrospective cohort study of cancer incidence among patients who received blood from donors deemed to have a subclinical cancer at the time of donation (diagnosed with cancer within five years of the donation) showed no excess risk of cancer among recipients of blood from pre-cancerous donors compared with recipients of blood from non-cancerous donors. However, the transmission of donor melanoma by organ transplantation has been reported . Transfusion-transmitted cancers have never been convincingly demonstrated, but most BTS

continue to take a precautionary approach and do not accept blood from people who have had a malignancy as many malignancies spread through the blood stream and by invading surrounding tissues. Blood donations should not be taken from people with recently active malignancies, except in the case of basal cell carcinoma or cervical carcinoma in situ (World Health Organization 2012).

A recent literature review concluded that that there is now ample evidence to consider accepting selected donors with a history of malignant disease (except for those where there are specific safety concerns, such as hematological malignancy and melanoma) on the basis of a minimum (suggested 5-year) interval after the completion of successful curative treatment. Healthy adults with a remote history of treated malignant conditions from which they can be regarded as cured may be able to donate under certain well-monitored circumstances. Further studies in this field are indicated.

- For individuals with a past history of solid malignant tumour, BTS may consider acceptance if 5 years or more since completion of successful curative treatment.
- Individuals with a history of "in situ" malignant disease such as basal cell carcinoma or cervical carcinoma in situ, if regularly monitored and considered successfully treated and in good health.
- Individuals with a current diagnosis of malignancy. Individuals with past history of solid malignant tumour if less than 5 years since completion of treatment. Individuals with a history of malignant melanoma and Individuals with current or past haematological malignancy, including: Leukaemia: i.e. lymphoproliferative and myeloproliferative disorders-Lymphomas, Clonal haematological disorders such as: Polycythaemia rubra vera and essential thrombocythaemia ,Paroxysmal nocturnal haemoglobinuria and Myelodysplastic syndromes(World Health Organization 2012).

Conclusions

It is advisable to avoid blood donation by individuals with type 1 diabetes, as per the WHO criteria, until further studies clearly demonstrate safety. Even for type 2 diabetes, published evidence about the safety of blood donation is sparse. A person with hypertension can donate blood, as long as the blood pressure is normal at the time of blood donation and there's no fluctuation. Acceptable blood pressure rate for blood donation is below 180 systolic (first number) and below 100 diastolic (second number) at the time of donation. Malaria is also readily transmitted by blood transfusion through donations collected from asymptomatic, parasitaemic donors. The parasite is released into the bloodstream during its lifecycle and will therefore be present in blood donated by infected individuals.The presence of total anti-*Plasmodium* spp. antibodies in the bloodstream of individuals many years after exposure, with no history of malaria in the meantime, is important to highlight. Regarding donors with cancer Blood donations should not be taken from people with recently active malignancies, except in the case of basal cell carcinoma or cervical carcinoma in situ.

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