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Residual Risk of HIV in African Transfusional Setting: Systematic Review and Meta-Analysis

Christian Mangala[1,2*], Joseph Fokam[1,3,4], Denis Maulot Bangola[1,2], Mireille Moundanga[2] and Thérèse Nkoa[1,4]

[1]Catholic University of Central Africa, Cameroon.
[2]National Public Health Laboratory, Gabon.
[3]Chantal Biya International Reference Center, Cameroon.
[4]University of Yaoundé 1, Cameroon.

Authors' contributions

This work was carried out in collaboration among all authors. Author CM designed the study and designed it together with author JF. General supervision was carried out by author TN. Author CM wrote the article. All authors read and approved the final manuscript.

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ABSTRACT

Context: The residual risk of HIV transmission is still a real problem into the transfusional settings of limited resources countries. Blood banks of African countries confront the risk of transmitting HIV to recipients. The objective of this study is to estimate the residual risk of HIV in African transfusion settings and to compare this residual risk with that of other countries in the South (developping countries).

Methods: This study resulted of a systematic review with meta-analysis of data from several comprehensive studies carried out between 2011 and 2017 whose purpose was focused on the residual risk of HIV transmission through blood transfusion. The studies on the residual risk were systematically searched in the different databases (PubMed, Medline and Google Scholar). The eligibility criteria were based on published studies which had blood donors as participants, looking at the residual risk of HIV in developing countries and the technique was based on the search for antibodies-P24 Antigen of the HIV or on nucleic acid (RNA) testing. Studies carried out before 2011

**Corresponding author: Email: imohu2004@yahoo.fr;*

and after 2017 were excluded. Studies in rich countries were also excluded. The Cochrane tool was used to assess the risk of bias.
Results: A total of 327,278 seronegative donors (for 12 eligible studies) were admitted for this study, i.e. 75.5% of men and 24.5% of women. The median age of all donors was 30.4 years. For studies carried out in the Africa zone (Burkina Faso, Ivory Coast, Nigeria, Democratic Republic of Congo, Tanzania and Zimbabwe), 327,278 donors were initially seronegative, of which 626 were found to be positive. Indeed, out of 742 incident cases in this study from African countries and other countries of the South, 84.4% of positive donors came from African studies and 15.6% of positive donors came from other countries of the South in this study. The residual risk (RR) of HIV in Africa has been estimated at 13 per 1,000,000 donations, with an incidence rate (IR) of 21.5 per 100,000 person-years. And in the other countries of the South (Brazil, Croatia, India, Iran, Malaysia and Pakistan), the RR of HIV has been estimated at 0.6 per 1,000,000 donations, or an incidence rate of 1.1 per 100,000 person-years.
Conclusion: The residual risk of HIV in the transfusion environment is still high and still persists in blood banks in southern countries in general and in Africa in particular.

Keywords: HIV ; blood transfusion; residual risk; Africa.

1. INTRODUCTION

The risk of viral transmission associated with donating blood remains a real concern for transfusion safety. Transfusion transmitted infections (TTIs) still threaten donation safety in blood banks. He is imperious to improve screening strategies at all the transfusion chain in order to provide recipients with labile blood products (LBP) devoid of any viral threat that could have severe consequences on the state of health of recipient patients [1,2,3].

However in developed countries, the risk of transmission has been reduced over the past decade thanks to the implementation of strategies aimed at improving blood safety [4]. In the USA, the introduction of techniques detecting nucleic acid (NAT) in blood banks have significantly reduced the residual risk of human immunodeficiency virus (HIV) which is now 1 in 2.3 million donations [5].

In developing countries with the exception of African countries, the residual risk is also a problem which negatively impacts blood safety. But this situation of residual risk is not too alarming as some of these countries have strengthened their blood bank screening strategies by implementing nucleic acid testing in their various blood banks. For example, Brazil, where the residual risk has decreased considerably after the implementation of the nucleic acid test [6,7,8].

In Africa, the residual risk of HIV transmission in transfusional setting has an impact on the quality of blood donation, promoting important transmission of HIV from donor to recipient patient blood transfusion is responsible for 5% to 10% of HIV infections in Sub-Saharan Africa [9]. These resource-limited countries are faced with this problem because they are still unable to obtain techniques based on the research of nucleic acid, but also because of a low coverage of 4th generation screening tests (Ab / AgP24) in blood banks [10,11,12].

To the example, in the countries of Central Africa where the residual risk of HIV transmission is permanent given its endemic situation and also these limited resources which cannot cover all blood banks for 4th generation screening techniques (screening for both the antibody and the P24 antigen), which puts them at high risk of transmitting the virus to blood recipients [13].

It is necessary to further investigate the genetic diversity of HIV in order to improve the different screening strategies for the virus in blood banks in countries with high endemicity because the genetic diversity of the virus can have an impact on the risk of virus transmission in transfusional setting. This may improve the virus-free blood supply in endemic and resource-limited countries [14,15].

The objective of this study is to estimate the residual risk of HIV in transfusional settings in Africa and to compare this residual risk of HIV with that of other countries in the South**.**

2. METHODS

2.1 Study Design

This study resulted of a systematic review with meta-analysis of summary data from several

studies which focused on the residual risk of HIV in transfusion settings in Africa. Indeed, we used a meta-analysis based on data retrieved from full articles and abstracts. These were obtained by the reading the full article or the abstract setting out the most important data for the realization of this study. All relevant studies reporting data on the residual risk of HIV in African transfusion settings and other developing countries published between January 1, 2011 and December 31, 2017 have been identified.

2.2 Research Strategy

Studies on the residual risk of HIV in transfusion settings in African countries and other countries in the South were systematically searched for in the various databases, namely PubMed, Medline, Google Scholar and we have manually searched major transfusion journals. This data search was done after the realization several bibliographic search equations such as : « HIV OR residual risk OR blood donors OR seronegative OR positive NAT », « HIV OR risk of transmission OR blood donors» and « Residual risk OR HIV OR blood transfusion OR negative Ac-AgP24 OR positive Ac-AgP24 ».

2.3 Selection Criteria

Preferred reporting elements for systematic reviews and meta-analysis (PRISMA) of the 2020 guidelines served as a template for this review's report [16]. Abstracts, titles and full articles were independently reviewed by two people from the research team for inclusion in the review. But in the event of disagreement between the two researchers, a third researcher was consulted in order to settle this situation. Of the one thousand eight hundred and sixteen (1,816) studies (full articles and abstracts) which were retrieved from the differents databases, twelve (12) studies met the eligibility criteria, namely the published studies with blood donors as participants, focusing on the residual risk of HIV and the methodology based on the search for antibodies-antigen P24 or on the search for nucleic acid (RNA of the virus). On the other hand, for non-inclusion criteria, one thousand eight hundred four (1,804) articles were excluded for various reasons such as studies lasting more than 10 years, not including all the key words, non-coherent and non-exploitable results, and other reasons not allowing to associate these studies with our meta-analysis study. Studies with a small size (< 100 participants) were excluded (Fig. 1).

2.4 The Quality of the Studies Included

The methodological quality of the included studies was assessed using the 9-point scoring system developed by Stanifer et al [17]. The sample size, the representativeness of the participants and the sample size of the study were assessed by these scoring criteria. If the score was between 1-3; 4-6 or 7-9 then the quality of the studies was considered to be low, medium or high, respectively.

2.5 Data Abstraction

Studies carried out in African countries have been separated from studies carried out in other developing countries. Data extraction was done independently for statistical comparison purposes. And if there was a difference of opinion between the two people responsible for the extraction, a third person was invited to resolve the ambiguity in order to reach a consensus. All data from eligible studies were extracted. Among these data, there was the number of donors, their serological status a priori, seronegative donors at the first donation and seropositive at the second donation, the number of donors positive for the nucleic acid test (NAT) or PCR from the first donation. But also the socio-demographic data were extracted. Then all abstractions and calculations were checked by all members of the research team. But on the other hand, for the studies for which the data were not obtained or well calculated, they were simply excluded from our study.

2.6 Impact of Serological Tests on the Residual Risk

The simultaneous search for the two biomarkers (antibody and P24 antigen) would considerably reduce the residual risk of HIV transmission. Which would not be the case for the detection of anti-HIV antibodies only. When the infection is very recent about two weeks after exposure, only the P24 antigen would be detectable by serological tests. Antibody has been shown to be the marker that persists throughout infection, yet combining it with P24 antigen would significantly reduce the residual risk of infection. Which would improve a virus-free blood supply. But this did not exclude that these combined tests also have limitations in terms of virus

detection because with a viral load of less than 107 copies / ml or in the presence of viral variants not taken into account by the test (during the preparation of the test by the manufacturer) but circulating in the population could explain the non-detection of the virus during screening [18,19,20].

2.7 Impact of Molecular Tests on Residual Risk

New technology for screening donated blood has been used in blood banks in high-income countries to test for virus nucleic acid (RNA). This test would contribute to the reduction of the immunological window period but also to seroconversion. This test would improve the quality of the blood donation and significantly reduced the residual risk of transmission of HIV from donor to recipient patient. The routine introduction of this test in transfusional setting in countries with limited resources would improve the supply and safety of the blood donation. Nucleic acid detection tests (NAT, PCR) being very efficient compared to serological tests which would be less efficient during the window period and seroconversion [21,22,23].

2.8 Profile of Residual HIV Risk

The residual risk in the context of this study was the risk of transmission of HIV from donor to recipient during the window period despite taking into account measures of donor selection and biomarker screening. The donor had the status : Ac-AgP24 negative at the first donation and Ac-AgP24 positive at the second donation or even Ac-AgP24 negative but NAT or PCR positive on the first donation only. Residual risk could have a direct impact on the incidence of HIV in recipients of donated blood. And therefore, a recipient who was HIV negative before the transfusion will be assigned a new HIV naïve status.

2.9 Impact of HIV Genetic Diversity on Residual Risk

The genetic diversity of HIV would to greatly contribute to the increase in the residual risk in transfusional setting. With a very low viral load (undetectable) and in presence of significant viral variability in the donor population, they would not facilitate detection of the virus when screening the blood donation by serological tests. These different links would further show the implication of genetic diversity on the residual risk of HIV in transfusional setting and especially in countries limited resources to high endemicity. The serological tests currently used would have limitations in terms of the detection of the various variants of HIV-1. These tests do not detect all variants of HIV-1 and especially in endemic countries, where this becomes a real problem in terms of blood safety. And to overcome this difficulty, screening using TAN or PCR tests in a transfusional setting is necessary [24,25,26].

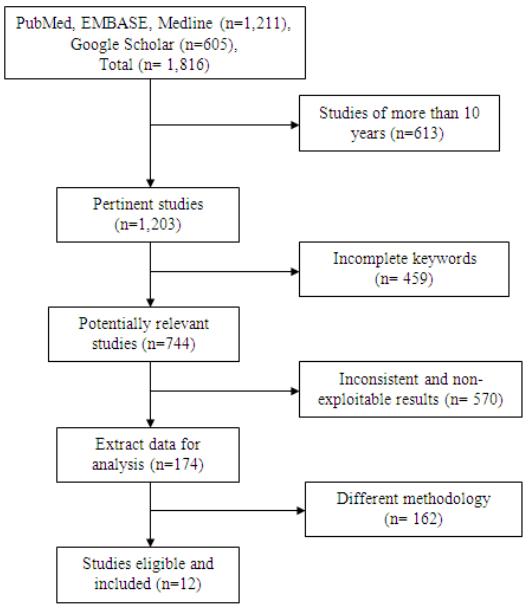

Fig. 1. Flow Diagram for the selection of studies

2.10 Statistical Analysis

We used a meta-analysis to summarize the data on the residual risk of HIV in African transfusion settings and in transfusion settings from other developing countries. The study-specific estimates were pooled using the random-effect meta-analysis model in order to obtain a global and synthetic estimate of the residual risk of HIV in the transfusion environment of these two groups (African countries and others). developing countries). Inter-rater agreement for study inclusion and data extraction was assessed using Cohen's kappa (κ) coefficient. All eligible studies reporting the residual risk of HIV in blood donors or providing ample data were used to estimate the residual risk. The residual risks (RR) of each eligible study were determined by Schreiber's method (RR = Incidence Rate (IR) x Duration of Serological Window (DSW) / 365) [27]. The duration of the window period was 22 days. The IRs of each study were calculated by dividing the number of incident cases during the study period by the total number of person-years (PY). Person-year is calculated by multiplying the study population by the duration of the study. Likewise for the percentages of male and female donors were calculated. The statistical cutoff was defined as $P \leq .05$.

3. RESULTS

The documentary search allowed us to find 1,816 articles, of which 12 were declared eligible and included in this systematic review study (Fig. 1). A total of 327,278 HIV-negative African donors were admitted for this study, 75.5% were of men and 24.5% of women. The median age of all donors was 30.4 years. This donor population consisted of 92% of regular donors who made at least two donations during the study period and 8% of new voluntary donors (Table 1). For studies carried out in the Africa zone (Burkina Faso, Democratic Republic of Congo (DRC), Nigeria, Ivory Coast, Tanzania and Zimbabwe), 327,278 donors were initially seronegative of which 626 donors have tested positive, i.e. 1 positive donor with the NAT at the first donation and 625 positive donors with Ab-antigen P24 test at the second donation (Table 2). And in the area of other southern countries (Brazil, Croatia, India, Iran, Malaysia and Pakistan), 2,484,136 donors were initially seronegative, of which 116 donors have tested positive, i.e. 94 positive donors with the NAT at the first donation and 22 positive donors with the Ab- AgP24 test at the second donation (Table 2).

In fact, out of 742 incident cases for all the studies, 84.4% of the positive donors came from African studies while 15.6% of the positive donors came from the other southern countries of this study. The residual risk (RR) of HIV in Africa has been estimated at 13 per 1,000,000 donations, with an incidence rate (IR) of 21.5 per 100,000 person-years (Table 3). And in the other countries of the South, the RR has been estimated at 0.6 per 1,000,000 donations, with an incidence rate of 1.1 per 100,000 person-years (Table 4).

4. DISCUSSION

Our meta-analysis study looked at the residual risk of HIV transmission through transfusion in blood banks in several southern countries (African and non-African) in order to show that the residual risk of HIV transmission is still news in these blood banks and to compare this risk between African countries and the rest of the South. After using the results of different studies eligible for this study, it emerged that male

Table 1. Socio-demographic data of African donors

Socio-demographic characteristics	N	%	Total
Sex			
Male	247,095	75.5	
Female	80,183	24.5	327,278
Médian Age (years)	30.4		
Status of donor			
Regular			
	301,096	92	327,278
New volunteers			
	26,182	8	

*N: Nimber **%** : Percentage*

Table 2. Summary of data extracted from all included studies from African and other developing countries

					Serological Test		Molecular Test	
Author	**Year**	**Origin**	**Type of study**	**Study duration**	**Ab-AgP24 negative (1st donation)**	**Ab-AgP24 positive (2nd donation)**	**PCR/NAT negative**	**PCR/NAT positive**
Lefrere et al	2011	Ivory Coast	cohort	3 years (2003-2005)	42,799	83	NA	NA
Mapako et al	2016	Zimbabwe	Longitudinal	10 years(2002-2011)	276,776	471	NA	NA
Japhet et al	2016	Nigeria	Cohort	1 year (J-Dec2008)	169	10	NA	NA
Kabinda Maotela et al	2014	DR Congo	Cohort	3 years (2010-2012)	2,986	8	NA	NA
Nagalo et al	2012	Burkina faso	Retrospective cohort	1year (J-Dec2009)	3,996	53	NA	NA
Nyale et al	2011	Tanzania	Cross-sectional	1year (J-Dec2010)	552		551	1
Safic Stanic et al	2017	Croatia	cross-sectional	4 years(2013-2016)	481,389		481,388	1
Kumar et al	2015	India	cross-sectional	1 year (J-Déc2013)	509		489	20
Kupek et al	2014	Brazil	cross-sectional	7 years (2007-2013)	23,798		23,730	68
Saber et al	2016	Iran	Cohort	6 years (2005-2010)	1,207,155	22	NA	NA
Chow et al	2016	Malaysia	cross-sectional	2 years (2013-2014)	729,981		729,977	4
Moiz et al	2014	Pakistan	cross-sectional	1 year (J-Dec2012)	41,304		41,303	1

NAT : Nucleic Acid Test ; Ab : Antibody ; Ag,P24 : Antigen P24 ; NA : Not Achieved

Table 3. Incidence rate and residual risk of HIV transmission by transfusion in African countries

African countries	Study duration	PY	Number of incident cases	IR per 100,000 per person-Year	RR per 1million of donation
Burkina Faso	1 year (Jan-Dec2009)	3,996	53	1,326.3	799.4
Nigeria	1 year (Jan-Dec2008)	169	10	5917.2	3566.5
Ivory Coast	3 years (2003-2005)	128397	83	64.4	39
Tanzania	1 year (Jan-Dec2010)	552	1	181.2	109.2
DR of Congo	3 years (2010-2012)	8,958	8	89.3	53.8
Zimbabwe	10 years (2002-2011)	2,767,760	471	17	10.3

RR : Residual Risk ; IR : Incidence Rate ; PY : Person-Year

Table 4. Incidence rate and Residual risk of HIV transmission by transfusion in other countries of South

Other developing Countries	Study duration	PY	Number of incident cases	IR per 100,000 per person-year	RR per 1 million of donation
Brazil	7 years (2007-2013)	166,586	68	40.8	24.6
Croatia	4 years (2013-2016)	1,925,556	1	0.05	0.03
India	1 year (Jan-Dec2013)	509	20	3929.3	2368.3
Iran	6 years (2005-2010)	7,242,930	22	0.3	0.2
Malaysia	2 years (2013-2014)	1,459,962	4	0.3	0.2
Pakistan	1 year (Jan-Dec2012)	41,304	1	2.4	1.5

IR : Incidence Rate ; RR : Residual Risk PY : Person-Year

donors were more representative than female donors, 75.5% and 24.5% respectively. And the median age was 30.4 years old. This could be explained by an important male participation in the blood donation process in African countries and by a participation in the blood donation process by younger people. Studies carried out in some African countries such as Ethiopia, Eritrea, the Democratic Republic of Congo (DRC), Malawi and Nigeria showed that the youngest and the men were the ones who would greatly contribute to the donation process blood in Africa [28,29,30,31,32]. Regarding the residual risk of HIV transmission in african transfusional settings, it was estimated at 13 per 1,000,000 donations as well as the incidence rate which was 21.5 per 100,000 person-years. These results showed that the residual risk of HIV in african countries was high. And this could be explained by a low coverage of 4th generation screening tests or by the absence of techniques to test for viral nucleic acid (RNA) in plasma in the vast majority of blood banks on the African continent. But also these data could be due to the different donor selection strategies put in place in blood banks that hardly meet the requirements dictated by the World Health Organization (WHO) in order to eliminate a large acceptable number of donors at risk. Some studies have shown that the residual risk of HIV was present and high in some blood banks in these low-resource countries [33,34,35,36]. In other resource-limited countries in the rest of the world, the

residual risk for all countries was 0.6 per 1,000,000 of donations and with an incidence rate of 1.1 per 100,000 person-years. These results showed that the residual risk in these low-resource countries was not very high. This could be explained by the fact that these countries have taken matters into their own hands by devoting more resources to blood safety despite their current weak economic situation. Their concern being to protect their population against contamination by transfusion transmissible infections. In addition, despite their economic situation, some of these countries have stepped up their screening strategy on the search for the viral genome using NAT [37,38,39,40]. By comparing the two residual risks of African countries and that of other countries in the rest of the world with low resources, the finding gave a picture where the difference between the two residual risks of these regions was significant. This difference of residual risk of HIV showed that blood banks in African countries would have a higher residual risk of HIV than those in other countries, even with low resources (13 per 1,000,000 donations compared to 0.6 per 1,000,000 donations). And this could be explained by the measures put in place for the detection of the virus where the rest of the low-resource countries would already use techniques based on research of viral genome (NAT) while African countries would use techniques based on screening tests of the anti-HIV antibody alone or combined with the P24 antigen. Previous studies carried out in some countries on the gap between detection based on testing for antibodies or P24 antigen and detection based on testing for HIV RNA (NAT) have also shown this considerable gap between results obtained from both types of screening strategies. Consequently, donation screening strategies have a impact on the residual risk in transfusional setting [7,41,42]. The residual risk in an African transfusional setting is very high compared to developed countries. This is due on the one hand to economic reasons because developed countries use techniques based on viral nucleic acid (RNA) research in their blood banks, which is not the case for African countries which do not. do not have the financial means to obtain this technology. And on the other hand, this gap also emanates from the health policies put in place by the leaders of these African countries which have no significant impact because they do not meet the structural and health needs of blood banks [43,44].

The limits of the study were more centered on the quality of the studies especially at the level of the different techniques used and of certain studies which were not accessible but of good quality.

5. CONCLUSION

The residual risk of HIV still persists in blood banks in resource-limited countries, especially those on the African continent. Our study has shown that this risk is high depending on the screening strategies put in place for the detection of virus markers during the screening of the blood donation. Ultimately, African countries must make a lot of efforts to make all major blood banks available for viral genome detection tests (such as NAT) and to small blood banks 4th generation screening tests (Antibodies- P24 antigen) in order to significantly reduce the residual risk of HIV, which would ensure a blood supply devoid of any viral agent.

** The residual risk of infections transmissible by transfusion (HIV, hepatitis B and C, syphilis) depends very much on the screening strategy used in each blood bank.

*** The residual risk of HIV in blood banks in African countries is higher than in blood banks in other developing countries in the rest of the world. The speed of HIV transmission (incidence rate) in African transfusional setting is greater, thus promoting the transmission of HIV to the recipient of the blood donation.

*** This study presents a grim picture on the quality of blood safety in the various blood banks in African countries.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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