

Prevalence, incidence, and residual risk of HIV among blood donors in Sfax (Tunisia)

Prévalence, incidence et risque résiduel du VIH chez les donneurs de sang à Sfax (Tunisie)

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ABSTRACT

Background and aim: Blood transfusion is not without risk, particularly the infectious risk related to the Human Immunodeficiency Virus (HIV). The objective of our study is to report the evolution of HIV indicators in blood donors (BDs) at the regional blood transfusion center of Sfax (Tunisia).

Methods: This was a retrospective descriptive study including both replacement and voluntary BDs collected from mobile and fixed donation units over a 10-year period (January 2014–December 2023). Combined screening for HIV antigens and antibodies was carried out by ELISA, with confirmation of positive results by Western blot. Prevalence and seroconversions according to age group, gender, and donation type were analyzed using the Hémos II G3.8 software by GPI. Incidence and residual risk were calculated using the Schreiber mathematical model.

Results: Forty-seven BDs were confirmed to be HIV-positive, with a male predominance (87.23%). The overall HIV prevalence was 0.16‰, with a peak of 0.4‰. During the study period, 21 seroconversions were recorded. The incidence was 9.38 per 100,000 person-years, and increased from 33.28 per 100,000 person-years in 2014-2015 to 97.22 per 100,000 person-years in 2022-2023. The residual risk was 0.46 per 100,000 donations.

Conclusion: Prevention is the key pillar in reducing the residual risk of HIV transmission through transfusions. It is based on improved HIV awareness in the general population and rigorous BDs selection.

Keywords: blood donors, HIV, prevalence, incidence, residual risk

RÉSUMÉ

Contexte et objectif : La transfusion sanguine n'est pas dénuée de risque en particulier le risque infectieux vis-à-vis du virus de l'immunodéficience humaine (VIH).

Le but de notre étude est de rapporter l'évolution des indicateurs du VIH chez les donneurs de sang (DDS) au centre régional de transfusion sanguine de Sfax (Tunisie)

Méthodes : Il s'agit d'une étude rétrospective et descriptive qui a concerné les DDS de compensation et volontaires prélevés aux cabines mobiles et fixes sur 10 années (Janvier 2014-Décembre 2023). Le dépistage combiné des antigènes et anticorps anti-VIH a été fait par ELISA et la confirmation des positifs par Western blot. Les prévalences et les séroconversions selon la tranche d'âge, le sexe et le type de don ont été édités par le logiciel Hémos II G3.8 de GPI. L'incidence et le risque résiduel (RR) ont été calculés selon le modèle mathématique de Schreiber.

Résultats : Quarante-sept DDS ont été confirmés porteurs du VIH avec une prédominance masculine (87,23%). La prévalence globale du VIH a été de (0,16‰) avec un pic estimé à 0,4‰. Durant la période d'étude, 21 séroconversions ont été recensées. L'incidence était de 9,38/100000 personne-années et elle est passée de 33,28 pour 100 000 personne-années en 2014-2015 à 97,22 pour 100 000 personne-années en 2022-2023. Le risque résiduel était de 0,46 pour 100 000 dons.

Conclusion : La prévention est le pilier essentiel pour réduire le risque résiduel de transmission du VIH par les transfusions. Elle se base sur une meilleure sensibilisation au VIH dans la population générale et sur une rigueur dans la sélection des DDS.

Mots clés : donneur de sang, VIH, prévalence, incidence, risque résiduel

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INTRODUCTION

Despite major advances in the identification and screening of infectious agents over the last few decades, the residual risk (RR) of transfusion-transmitted infections (TTIs), particularly HIV, persists. This risk is variable between countries, depending on the prevalence of the disease and the screening test used. Tunisia is considered a low-prevalence country for HIV infection, with an estimated rate of 0.015% in 2021 and a stable epidemic within the population (1). The selection of blood donors (BDs) and the progressive improvement of screening tests for HIV detection have reduced the risk of HIV TTIs. Mathematical models can be used to estimate the residual risk (RR) of TTIs, which is defined as the probability of accepting an infected donation from a donor whose infection is not detectable by screening tests (2). The objective of our study is to report the evolution of HIV indicators (prevalence, incidence) in BDs and to estimate the RR of HIV transmission in the region of Sfax (Tunisia).

METHODS

In our study, we used ELISA for HIV screening. The kits used in our study were the fourth generation ELISA from different firms (Murex, Bio-Rad, Génedia, Abia, Wantai). Serology was interpreted according to the optical density value. All initially positive samples were retested in duplicate. Repeated reactive samples were submitted to confirmatory testing with Western blot (WB). The number of BDs and their characteristics according to age, sex, type, nationality, serological results, seroconversions, and intervals between donations were published by GPI's Haematos II G3.8 software.

The prevalence is the proportion of infections identified at a specified point in time or over a specified period in a defined population. Prevalence of HIV was calculated as follows:

$$\text{Prevalence (\%)} = \frac{\text{number of HIV positive donors}}{\text{total number of donors}} \times 1000$$

The incidence was calculated among repeat donors as follows:

$$\text{Incidence} = \frac{\text{incident cases number}}{\text{number of person - years}}$$

The incident cases were the HIV seroconverted BDs and the number of person-years (PY) was calculated by summing the intervals in days between the first and last donation made by each regular blood donor during the study period, divided by 365. The incidence was calculated for 2-year intervals for the period from 2014 to 2023. For the RR, it was evaluated using the incidence rate and the window period, proposed by Schreiber (3,4). The RR was calculated for 2-year intervals for the period from 2014 to 2023.

$$\text{Residual risk} = \frac{\text{incidence rate} \times \text{the duration of the window period}}{365}$$

The window period was 18 days for the HIV ELISA (5). For statistical analysis, we used the bivariate correlation test, applying them to the prevalence rates, incidence rates and residual risks obtained during the 10 years of study. We assumed a level of statistical significance of 0.05. Data management was carried out on a spreadsheet of Microsoft Excel®, and the statistical analysis was performed using the Statistical Package for Social Sciences (SPSS®), 2020 version.

RESULTS

During the study period, 285 147 BDs made at least one blood donation. Their age ranged from 18 to 70 years and the sex ratio was 5.1. Forty-seven BDs who contracted HIV were confirmed by a positive Western blot (Table 1).

Table 1. Sociodemographic characteristics of blood donors tested for HIV

	Total of blood donors (%)	HIV- positive blood donors (%)
Gender		
Male	238 721 (83.72)	41 (87.23)
Female	46 426 (16.28)	6 (12.76)
Age groups		
18-20 years	8 556 (3)	2 (4.25)
21-30 years	78 482 (27.53)	8 (17.02)
31-40 years	95 638 (33.53)	17 (36.17)
41-50 years	67 488 (23.67)	18 (38.29)
≥ 50 years	34 983 (12.27)	2 (4.25)
Geographical origin		
Tunisia	235 222 (82.49)	38 (80.85)
Other countries	49 925 (17.51)	9 (19.14)
Type of donors		
Voluntary	26 605 (9.33)	3 (6.38)
Replacement	258 542 (90.67)	44 (93.62)
Number of donations		
One donation	230 564 (80.85)	26 (55.31)
≥ 2 donations	54 583 (19.15)	21 (44.68)
Total	285 147 (100)	47 (100)

Among the 38 Tunisians with HIV, 31 were from Sfax and the others from other governorates (Gafsa, Kef, Kebili).

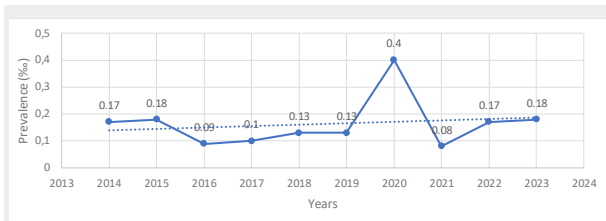
The prevalence of HIV

During the study period, the overall HIV prevalence rate among blood donors was 0.16 ‰. It increased from 0.17‰ in 2014 to 0.18‰ in 2023, with a peak (0.4‰) observed in 2020 (Table 2).

Table 2. Prevalence of HIV by years

Years	Number of blood donors	HIV-positive donors	Prevalence (‰)
2014	33 643	6	0.17
2015	32 432	6	0.18
2016	30 113	3	0.09
2017	28 682	3	0.10
2018	28 845	4	0.13
2019	29 411	4	0.13
2020	22 297	9	0.40
2021	24 084	2	0.08
2022	28 108	5	0.17
2023	27 532	5	0.18
Total	285 147	47	0.16

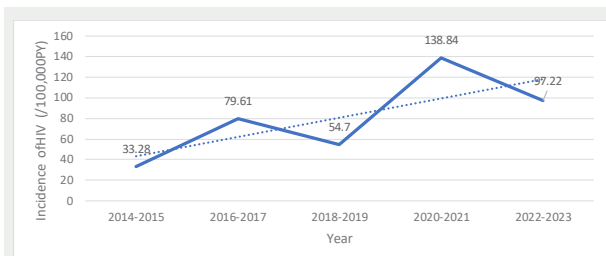
The chronological trend in HIV prevalence rates among BDs was stable over the years ($Rho=0.122$; $p=0.736$) (Figure1).


Figure 1. The evolution of the HIV prevalence by years

The incidence of HIV

A total of 21 HIV-positive repeat donors were HIV seroconverted (incident cases) between 2014 and 2023. The average incidence of HIV during the 10-year study period was 9.38/100,000 PY and increased from 33.28/100,000 PY in 2014-2015 to 97.22/100,000 PY in 2022-2023, with two peaks in 2016-2017 (79.61/100,000 PY) and in 2020-2021 (138.84/100,000 PY).

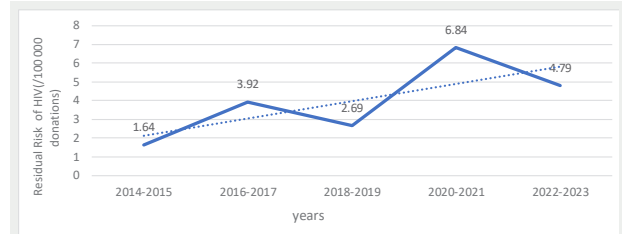
We observed a chronological upward trend in the incidence rate over the years ($Rho = 0.718$; $p = 0.019$) (Figure2).


Figure 2. The evolution of HIV incidence

The residual risk of HIV

Based on the incidence rate window period model, the overall RR of HIV transmission was estimated at 0.46/100,000 donations over the study period. Over

a 2-year period, this RR increased from 1.64/100,000 donations in 2014-2015 to 4.79/100,000 donations in 2022-2023, with 2 peaks in 2016-2017 (3.92/100,000 donations) and 2020-2021 (6.84/100,000 donations). We noted a chronological upward trend in the RR of HIV infection among BDs over the years ($Rho=0.718$; $p=0.019$) (Figure 3).


Figure 3. The evolution of HIV residual risk

Discussion

This study provides an updated overview of HIV infection among BDs in Tunisia over a long observation period. We found a low overall HIV prevalence (0.16‰) with a marked male predominance (87.23%), along with a clear increase in incidence over time, particularly from 2020 onwards. Twenty-one seroconversions were identified, resulting in an incidence of 9.38 per 100,000 PY and a RR of 0.46 per 100,000 donations.

In this context, reducing the risk of TTIs represents a critical component of transfusion safety. Appropriate selection of BDs can reduce the risk of TTIs by up to 90% (5). Therefore, each donor undergoes a pre-donation medical interview. However, the effectiveness of this interview depends on both the donor's understanding of the questions and the honesty of their responses (5). A lack of cooperation from donors, due to a lack of trust in the doctor or external pressures (replacement donation), explains why some BDs exhibiting high-risk behaviors for infectious agent transmission may bypass the selection process. The pre-donation medical interview also helps to minimize the wastage of expensive reagent kits, which is of significant importance for developing countries such as Tunisia.

The male predominance among HIV-positive individuals has already been reported in the literature and in different regions of the world (Italy, Brazil, the USA, China, Serbia, Pakistan, Burkina Faso) (4,6,7-13). There are even published studies reporting that all HIV infections were found in male BDs (14,15). These results are consistent with those of our study, where the majority of infected BDs (87.23%) were male. This situation can be attributed to the direct impact of male predominance within the BD population, influenced by sociocultural characteristics, making men the ideal candidates for blood donation. Additionally, certain risk behaviors observed in men in our society, such as engaging in multiple sexual relationships and high-risk sexual practices, such as men who have sex with men (MSM), contribute to this trend. Indeed, MSM represent the population with the highest HIV prevalence in the Western world, with increasing incidence in

many countries (15). Furthermore, gynecological and obstetric factors, such as menstrual cycles, pregnancy, and breastfeeding, can discourage many women from donating blood, thus reinforcing this male predominance (9,16).

In contrast to many studies reporting higher HIV prevalence among younger donors (6,9,13,14,17), our HIV-positive donor population was older, with a mean age of 37 years and a peak in the 41-50 age group. This difference may be explained by sociocultural, economic, and healthcare-related disparities between countries. The decline in prevalence after 50 years of age likely reflects reduced social exposure, health-related donor deferral, and premature mortality among individuals infected earlier in life. Nevertheless, the increasing risk of HIV infection among young people remains a concern for blood safety (17–21).

The variation in HIV prevalence according to geographical origin has been reported in the literature (9,18,19). In our study, we found that the majority of HIV-positive BDs were Tunisian nationals from the region of Sfax. This is explained by the fact that the HIV epidemic in Tunisia is geographically concentrated in coastal regions (22), and most BDs at the regional blood transfusion center were from Sfax.

Blood donation in Tunisia is voluntary, anonymous, and unpaid. However, we distinguish between replacement donors and voluntary donors who donate blood without being obliged to do so for a specific person. Voluntary donation is associated with a lower risk of infection transmission, although this hypothesis is sometimes controversial. For voluntary donors, the primary motivation for donating is altruism. Furthermore, according to the study by Gonzalez et al., the motivation for voluntary donation may be free serological screening tests. Indeed, in Brazil, HIV seroprevalence was significantly higher among voluntary donors, which was attributed to the desire for quick and free HIV screening (23). For replacement donors, the compulsion to donate blood and the possibility of concealing high-risk behaviors explain the higher rates of infectious markers in the replacement donor category compared to voluntary donors (12,24–26). This aligns with the results found in our study, as 93.62% of HIV-positive BDs were replacement donors.

Several studies conducted in different countries with different socioeconomic levels (the USA, China, Burkina Faso, Iran, Lithuania) have reported that the majority of infected blood donations come from first-time BDs (8–10,13,21,27). Indeed, according to Niazkar et al., first-time BDs may have different motivations for donating blood (free screening), which encourages them to conceal factors that pose a risk of TTIs (21). On the other hand, most HIV-positive donors in Serbia and Spain were regular donors (6,28). In our study, 55.31% of HIV-positive cases were identified among first-time donors, supporting the effectiveness of donor database computerization in excluding previously identified high-risk donors while highlighting the vulnerability associated with first-time donation.

In our study, the overall prevalence of HIV infection

among BDs was low (0.16%), similar to the findings of the Serbian study (6). This prevalence is lower than that reported in Africa, notably in Ethiopia (24) and Burkina Faso (13), but higher than that found in Europe (Spain (29) and in the USA (9)).

The analysis in our study showed a stable rate between 2014 and 2019, with a significant increase in 2020, the year the COVID-19 pandemic began. The COVID-19 pandemic had a serious impact on blood donation. It led to a crisis in the availability of blood products with a decrease in the number of BDs. However, its effect on HIV prevalence was variable across studies. Indeed, a study conducted in Shenzhen (China) showed that COVID-19 had no significant effect on HIV prevalence among BDs (10). A study conducted in Japan showed a significant decrease in the incidence of certain sexually transmitted infections, indicating a decrease in sexual activity. This incidence rebounded after the end of lockdowns. However, it remains to be proven whether this incidence truly decreased or if diagnoses were simply reduced (30,31).

During the study period, 21 HIV seroconversions were found, including 11 from 2020 onwards. The incidence rate of HIV infection among BDs was 9.38 per 100,000 PY. The increase in incidence over time, particularly in the last four years, may be explained by both donor database computerization (implemented since 2008) and a genuine rise in HIV incidence in the general population. Estimating the transfusion risk has become an essential indicator for assessing transfusion safety (32). The RR can be attributed to several factors, including technical errors, undetected viral variants, and donations collected during the serological window period before detectable biomarkers appear (33). The most direct and reliable way to estimate the RR of transfusion-transmitted infections is to prospectively follow the recipients of blood products to evaluate the number of seroconversions. When the risk is low, the number of recipients required to obtain precise estimates is very high. This difficulty can be bypassed by mathematical models based on BDs. In this study, we used the mathematical method proposed by Schreiber (4).

The RR observed in our study was higher than that reported in Spain (29), Italy (4), and the USA (9), but lower than that reported in African countries such as Burkina Faso (13). These disparities likely reflect differences in HIV seroprevalence, incidence, and screening strategies between developed and developing countries. In developed settings, screening methods based on viral genome detection enable earlier identification of infection, whereas in countries such as Tunisia, ELISA-based testing is predominantly used, potentially prolonging the serological window period and contributing to the observed differences.

In recent years, many researchers have focused on HIV prevalence based on positive nucleic acid testing or WB results (34,35) since a positive ELISA result is not enough to indicate that a BD is infected. In our study, the confirmatory test used is WB, as in other studies conducted in China (10) and Serbia (6).

CONCLUSION

Prevention of HIV transmission through blood transfusion relies on several strategies. The rigorous selection of BDs with a thorough medical interview in a trusting environment with a medical examination is essential to exclude BDs at risk of viral infections. Education and information for BDs also play a crucial role in the pre-donation selection process. Finally, the proper use of blood is another aspect of ensuring transfusion safety. Excessive or inappropriate use exposes patients to serious risks and wastage of blood products.

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