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Original article

Seroprevalency of transfusion-transmitted infections in first-time volunteer and replacement donors in Tunisia

Séroprévalence des infections transmissibles par transfusion chez les donneurs de sang volontaires et de compensation en Tunisie

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Abstract

Background. – Replacement donors are considered as having a major risk of transmission of infections to recipients mainly by the World Health Organisation.
Study design and methods. – Seroprevalency of HBV, HCV, HIV and syphilis were determined in 19,783 whole blood donations collected in the Tunisian National Blood Transfusion Centre during the year 2010 (12,968 [65.55%] replacement donations and 6815 [34.44%] voluntary blood donations). For HBV, HCV and syphilis, we performed a univariate analysis to determine whether age, sex and type of donation were risk factors, then multivariate logistic regression, to see if these factors were independent.
Results. – Mean age of donors was 30.1 years (replacement donors 34.5 years, first time non-remunerated donors 34.5 years, $P < 0.001$). The predominant age group was 30–39 years (35.51%) in replacement donors and 20–29 years (54.15%) in first time non-remunerated donors. Male gender was significantly predominant (73.00% men vs 27.00% women, $P < 10^{-6}$). There were significantly more men among replacement donors (82.27% vs 55.38%, $P < 10^{-3}$). There were more women in the age groups 18–19 and 20–29 years. Only one HIV seropositive donation was noted in a male first time non-remunerated donor aged 18. Replacement type of donation, male sex and age were three independent risk factors for the HBs Ag carriage. For anti-HCV antibodies and TPHA, only replacement type of donation and age were found out to be risk factors and only age was independent.
Conclusion. – In Tunisia, replacement blood donors were at higher risk of infection transmission, but only for hepatitis B.

Keywords: Blood donors; Volunteer donors; Replacement donors; Transfusion-transmitted disease; Hepatitis; HIV; Syphilis

Résumé

But de l'étude. – Les donneurs de compensation sont considérés à plus haut risque de transmission d'infections notamment par l'Organisation mondiale de la santé.
Sujets et méthodes. – Les séroprévalences de l'HBV, l'HCV, le VIH et la syphilis ont été déterminées chez 19 783 dons de sang total, collectés au Centre national de transfusion sanguine durant l'année 2010 (12 968 [65,55 %] dons de compensation et 6815 [34,44 %] dons volontaires). Pour l'HBV, l'HCV et la syphilis, on a effectué une analyse univariée pour déterminer si l'âge, le sexe et le type de don étaient des facteurs de risque suivie d'une étude multivariée en régression logistique pour voir si ces facteurs étaient indépendants.
Résultats. – L'âge moyen des donneurs était de 30,1 ans (donneurs de compensation 34,5 ans, donneurs volontaires 34,5 ans, $p < 0{,}001$). Le groupe d'âge prédominant était 30–39 ans (35,51 %) chez les donneurs de compensation et 20–29 ans (54,15 %) chez les donneurs volontaires. Le sexe masculin était significativement prédominant (73,00 % hommes vs 27,00 % femmes, $p < 10^{-6}$). Il y avait significativement plus d'hommes parmi les donneurs de compensation (82,27 % vs 55,38 %, $p < 10^{-3}$). Les femmes étaient plus nombreuses dans les groupes d'âge 18–19 et 20–29 ans. Un

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seul don VIH positif a été noté chez un donneur volontaire, un homme âgé de 18 ans. Le type don de compensation, le sexe masculin et l'âge étaient trois facteurs de risque indépendants de portage de l'Ag HBs. Pour les anticorps anti-HCV et le TPHA, uniquement le type don de compensation et l'âge étaient des facteurs de risque et seul l'âge était indépendant.
Conclusion. – En Tunisie, les donneurs de compensation étaient à risque plus élevé uniquement pour l'hépatite virale B.

Mots clés : Donneurs de sang ; Donneurs volontaires ; Donneurs de compensation ; Infections transmises par transfusion ; Hépatite ; VIH ; Syphilis

1. Abbreviations

RD	replacement donors
FTNRD	first time non-remunerated donorse
CNTS	National center of blood transfusion
WHO	World Health Organisation

2. Introduction

Blood transfusion is a crucial therapeutic means in every health system. Satisfying the needs of blood products and ensuring blood safety, especially infectious safety, remain major challenges for blood transfusion establishments.

In Tunisia, like in many other countries, we still rely on family or replacement blood donors (RD), family members or friends, who donate blood to replace the one that has been transfused to a relative. They contribute seriously to the blood supply in this country as they represent 60% of blood donors. The World Health Organisation (WHO) recommends excluding this type of blood donors as they present a major risk of transmitting infections [1].

In order to check this data, we determined the seroprevalency of HBV, HCV, HIV and syphilis in replacement and first time non-remunerated (FTNRD) Tunisian blood donors; then, we conducted a statistical study to see if age and sex were involved with any significant difference between the two types of donors.

3. Materials and methods

3.1. Study design and population

It is a retrospective study including 19,783 whole blood donations collected in the Tunisian national blood transfusion centre (CNTS) during the year 2010. A total of 12,968 (65.55%) replacement blood donations collected between January and June 2010 at fixed site at the CNTS and 6815 (34.44%) voluntary blood donations collected between January and December 2010 at mobile collections from first time non-remunerated donors (FTNRD) (27,789 blood donations provided by donors having donated earlier have been excluded from the study).

Age, sex and results of screening tests for HBV, HCV, HIV and syphilis were collected from the centre written records.

3.2. Infectious disease testing

Tests for serological markers of the viral agents were performed by commercial kits:

- monolisa HBs Ag ULTRA (BIO-RAD, France) for the detection of the hepatitis B surface antigen (HBs Ag);
- HCV Murex Ag/Ab combination (Abbot Murex), detecting hepatitis C virus antibody (anti-HCV) and the capsid antigen;
- genscreen ULTRA HIV Ag-Ab Assay (BIO-RAD, France), detecting the p24 antigen and antibodies for HIV-1 and HIV-2.

Syphilitic antibodies were screened by the Treponema pallidum hemagglutination assay (TPHA Biomaghreb).

3.3. Statistical analysis

Prevalencies were calculated for 100 donors with the Epitable program of the EPI INFO software Version 6.04 d. with confidence intervals at 95% of confidence (Fleiss quadratic method). The search for carriage risk factors was performed using SPSS for Windows version 11.5 in univariate analysis and in multivariate analysis.

Risk factors searched for were: type of donor (replacement/FTNRD), gender of donor (male/female), age of donor (classified in four age groups: 18–19, 20–29, 30–39, ≥ 40 years).

For the univariate study, we calculated the odds ratio (for the age groups, the lowest odds ratio was considered as reference) and then we conducted a multivariate logistic regression using backward stepwise method. Multivariate analysis identified factors related independently of others to carriage.

The significance level for all comparisons was set at 0.05.

4. Results

4.1. Demographic characteristics of blood donors

Mean age of all the donors was 30.1 years. Replacement donors were significantly older than FTNRD (mean age: RD 34.5 years, FTNRD 34.5 years, $P < 0.001$), the predominant age group was 30–39 years (35.51%) followed by 20–29 years (33.71%) in RD and 20–29 years (54.15%) followed by 18–19 (39.14%) years in FTNRD (Fig. 1).

In all blood donors, male gender was significantly predominant (73.00% men vs 27.00% women, $P < 10^{-6}$). There was significantly more men among RD than among FTNRD (82.27% men in RD vs 55.38% men in FTNRD, $P < 10^{-3}$).

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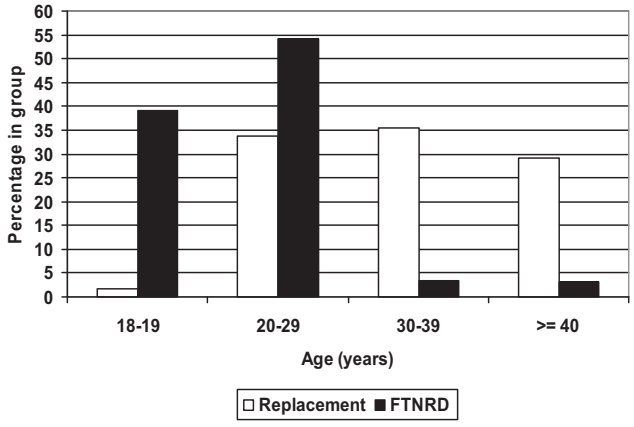

Fig. 1. Distribution of donors according to age groups and type of donation.

Women were more numerous in the age groups 18–19 and 20–29 years (Fig. 2).

4.2. *Seroprevalency of transfusion-transmissible infections in replacement and FTNR donors*

Only one HIV seropositive donation was noted in a male FTNR donor aged 18.

For HBV, HCV and syphilis, we performed first a univariate analysis to determine whether age, sex and type of donation were risk factors, then multivariate logistic regression, to see if these factors were independent.

Replacement type of donation, male sex and age were three risk factors for the HBs Ag carriage. For anti-HCV antibodies and TPHA, only the replacement type of donation and the age were found out to be risk factors (Table 1).

According to the multivariate study, replacement type of donation, male sex and age were found as independent risk factors for the carriage of the HBs Ag. However, only age was an independent risk factor for the anti-HCV and TPHA.

Replacement type of donation was therefore an independent risk factor only for the HBs Ag (Table 2).

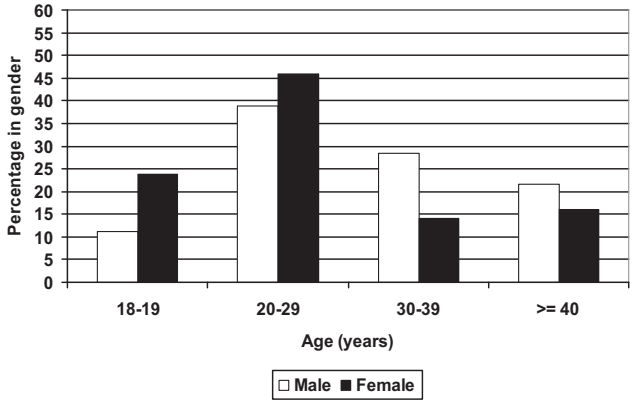

Fig. 2. Distribution of donors according to age groups and sex.

5. Discussion

Blood donation in Tunisia is voluntary, anonymous and unpaid. However, we distinguish:

- replacement or family donors: donors who donate blood to compensate for the one that should be transfused to a relative or a friend;
- volunteer donors: donors who donate blood without being compelled to do so for someone special. We distinguish in this group:
  - regular volunteer donors: who attend regularly (at least once per year) transfusion centres or blood banks to donate,
  - occasional donors: who donate blood less regularly,
  - new volunteer donors: who donate for the first time.

In Tunisia, 50% of donors are replacement donors and thus contribute significantly to the blood products supply in this country.

WHO recommends countries to abandon this type of donors who would be providers of infection risk compared to volunteer donors [1]. However, in the literature, the results of the comparison of the prevalency of transfusion-transmissible infections in these two types of donors are highly disparate and do not conclude in a unanimous way to a higher risk among replacement donors [2].

Several hypotheses have been advanced to explain the higher risk in RD. In unpaid blood donors, the main motivation to make a donation is altruism, however, some have explained the higher risk of transmission of infection in RD by the pressure that makes them hide risk behaviours, so they escape the exclusion during the pre-donation medical screening. In a Greek study based on a questionnaire to identify motivators and reluctance to donate blood, 5.3% of donors admitted having hidden data during pre-donation medical screening. A total of 3.4% of them were volunteer donors and 7.1% were RD ($P < 0.001$). Eighty percent of these have admitted that they had this behaviour to be sure that the blood needs of their parents are insured [3]. Others have suggested the possibility that some RD may be paid donors submitted by the patient's family members as RD [4]. In volunteer donors, the main motivation to make a donation is altruism [5–8], which makes them safer donors. Nevertheless, a Brazilian study showed that this is not always the case: VD motivation may be looking for free serological tests screenings [9]. In Brazil, HIV seroprevalency was significantly higher in VD [10] and it has been shown that the cause would be seeking for free HIV testing with faster results [9]. It should be noted that in Tunisia there is a centre for free and anonymous HIV screening; however its role in limiting this behaviour in blood donors still needs to be evaluated.

Comparing the seroprevalency of transfusion-transmissible, infections in RD and VD were the subject of numerous studies worldwide [4,11–20] and the results were different depending on the serological marker studied and countries. Many studies have been criticized for having found a higher seroprevalency in RD compared to VD without taking into consideration the

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status of the donor: new VD or regular VD (regular VD can skew the results as they had serological tests earlier) nor the heterogeneity of age and sex of the two donor groups compared [2,12]. These factors are all selection bias. For two comparable groups, donors should be at their first donation, adjusted for age and sex and with confirmed positive serology.

Voluntary donations included in this study come from donors who donate for the first time (this information has been taken from the donor during the medical selection, and that cannot be verified in the computerized data since there is no unique identifier for each donor). On the other hand, we know that replacement donors are rarely regular donors. We can therefore consider for the two groups studied that a donation corresponds to a new donor.

Our results showed a statistically significant male predominance in all blood donors (men 73%, women 27%, $P < 10^{-6}$). This result has been widely found in other studies where blood donors were more frequently male [13,21,22]. Males were significantly more common among RD (male 82.27%, female 17.73%, $P < 0.001$) but not in VD (male 55.38%, female 44.62%). Male predominance among RD was found in other studies [3] and may be due to cultural reasons: in case of need for blood donation by a family member, it is rather the men who are volunteer. Voluntary donors in our study were collected in the mobile site, and therefore it is the blood centre that "goes to them" which could explain the lack of significant difference between the two sexes.

Women were more numerous in the age groups 18–19 and 20–29 years. This result can be explained by a greater interest among young women in blood donation probably as a sign of emancipation.

Replacement donors were significantly older than FTNRD (mean age: RD 34.5 years, FTNRD 34.5 years, $P < 0.001$), the predominant age group was 30–39 years (35.51%) followed by 20–29 years (33.71%) in RD and 20–29 years (54.15%) followed by 18–19 (39.14%) years in FTNRD.

In the United States, Europe and India, it was shown that VD belonged to younger age groups [21,23,24]. In this study, many VD were recruited from high schools, universities, colleges and vocational training centres, which may partly explain their young age. We can also speculate that the Tunisian youth are more motivated by voluntary donation. In both sexes, group age 20–29 years was predominant, it included 38.82% of male donors and 45.99% of female donors.

5.1. Seroprevalency of transfusion-transmissible infections in RD and VD

Only one HIV positive donation was noted in a volunteer donor, which is consistent with the national epidemiological data on this virus.

The seroprevalency of HBV, HCV and syphilis were significantly higher in replacement donors as compared to voluntary donors (Table 1).

Table 1
Are the type of donation, age and male gender risk factors for HBV, HCV and syphilis carriage?

Characteristics	HBs Ag		Anti-HCV Ab		TPHA	
	Prevalence % (95% CI)	OR (95% CI) & *P* value	Prevalence % (95% CI)	OR (95% CI) & *P* value	Prevalence % (95% CI)	OR (95% CI) & *P* value
Overall (n = 19,783)	1.46 (1.30–1.64)	-	0.37 (0.29–0.47)	-	0.13 (0.09–0.20)	-
Type						
Replacement (*n* = 12,968)	1.80 (1.60–2.06)	2.4 (1.8–3.2)	0.50 (0.39–0.64)	3.8 (1.9–7.6)	0.18 (0.12–0.27)	4.2 (1.3–14.0)
FTNRD (*n* = 6815)	0.77 (0.58–1.02)	*P* < 0.001	0.13 (0.06–0.26)	*P* < 0.001	0.04 (0.01–0.14)	*P* = 0.08
Gender						
Male (*n* = 14,443)	1.66 (1.46–1.89)	1.9 (1.4–2.6)	0.40 (0.31–0.53)	1.5 (0.8–2.6)	0.14 (0.09–0.22)	1.3 (0.5–3.2)
Female (*n* = 5340)	0.89 (0.67–1.20)	*P* < 0.001	0.28 (0.16–0.47)	*P* = 0.19	0.11 (0.04–0.25)	*P* = 0.58
Age group (years)						
18–19 (*n* = 2888)	0.65 (0.40–1.04)	1 (reference)	0.03 (0.00–0.23)	1 (reference)	0.00 (0.00–0.16)	1 (reference)
20–29 (*n* = 8062)	1.07 (0.87–1.33)	1.6 (1.0–2.7)	0.26 (0.16–0.40)	7.5 (1.0–56.1)	0.06 (0.02–0.15)	Undefined
30–39 (*n* = 4841)	1.83 (1.48–2.26)	2.8 (1.7–4.7)	0.39 (0.24–0.62)	11.4 (1.5–85.0)	0.10 (0.03–0.25)	Undefined
≥ 40 (*n* = 3992)	2.35 (1.91–2.88)	3.6 (2.2–6.0)	0.82 (0.57–1.17)	24.1 (3.3–176.1)	0.42 (0.25–0.69)	Undefined

Table 2
Multivariate analysis in logistic regression: last step.

	HBs Ag	Anti-HCV Ac	TPHA
	Adjusted OR (95% CI) & *P* value	Adjusted OR (95% CI) & *P* value	Adjusted OR (95% CI) & *P* value
Type	1.5 (1.0–2.1)	1.9 (0.9–4.1)	1.1 (0.3–4.2)
	P = 0.035	*P* = 0.11	*P* = 0.87
Gender	1.5 (1.1–2.1)	Not in the model	Not in the model
	P = 0.01	-	-
Age group	1.4 (1.2–1.6)	1.7 (1.3–2.3)	2.9 (1.7–5.1)
	P < 0.001	*P* < 0.001	*P* < 0.001

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Statistical analysis showed that age, male sex and replacement donor type were independent risk factors for carrying the HBs Ag (Tables 1 and 2). In the literature, the male sex is a known risk factor for carriage of HBsAg [25,26] and other serological markers of HBV [27,28], it can be explained by a higher frequency of risk behaviours in men. In a study of 9486 Tunisian volunteers, male sex rises significantly the risk of anti-HBc and HBs Ag positivity and chronic HBV infection [26]. Age is logically a risk factor of carrying the HBsAg. Indeed, one subject is more likely to have HBV that he is older and HBs Ag persists long after the infection. This result is found in other studies [4,25].

Tunisia is a country of medium endemicity for HBV [29]. The study of risk factors in the Tunisian population showed that the presence of a family member infected with HBV, increases the risk of positivity of HBs Ag, anti-HBc Ab and chronic infection virus. A hypothesis arises then: the fact that members of the same family volunteer to make a donation to a parent and since this virus has an average endemicity in Tunisia, may explain the fact that replacement donor type is an independent risk factor of HBs Ag carriage in blood donors.

In univariate analysis, age and replacement donor type were found out to be risk factors for carrying anti-HCV Ab. In multivariate analysis, only age was an independent risk factor. Tunisia has a low endemicity for HCV [30,31]. Age was found out to increase the risk of carrying anti-HCV in the general population of Tunisia [9]. Male sex was not a risk factor and this is consistent with the results of a study [30] that found no difference in the prevalence of HCV in the general population according to sex.

The same study [30] found no significant difference between the prevalency of HCV patients in family contact with the virus seropositive members, and that in the entire study population.

Another Tunisian study conducted among a highly endemic area of HCV in a general population [31] shows that only antecedents of intravenous injections or invasive procedures were significantly associated with risk of HCV seropositivity. Risk factors are essentially iatrogenic.

Finally for TPHA, in univariate analysis, age and replacement donor type were found out to be risk factors for carrying this marker. In multivariate analysis, only age was an independent risk factor. It is expected that age is a risk factor independent of the positive TPHA; given that this marker is a serological scar with any person entering in contact with *T. pallidun* bacteria, whether this sickness evolves or is cured and that the older one gets, one more may catch this infection.

In conclusion, replacement donors were blood donors at risk as stipulated by WHO, but only for hepatitis B in Tunisia. Further studies need to be done in order to see if this result is related to the endemicity of the HBV virus in this country.

Policy to have 100% voluntary donors has to be adopted to improve transfusion safety. However, the total exclusion of replacement donors (who represent 50% of donors) would affect self-sufficiency. Thus, means of recruitment and retention of volunteer donors should be put in place.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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