ORIGINAL ARTICLE

A ten-year hemovigilance report in the regional blood transfusion center of Sfax (Tunisia)

Bilan de dix ans d'hémovigilance au centre régional de transfusion sanguine de Sfax (Tunisie)

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Abstract

Objectives: In Tunisia, despite hemovigilance regulations since 2007, transfusion adverse events (TAEs) remain underreported. Here, we analyze and evaluate the reported TAEs over ten years in the blood transfusion center of Sfax (Tunisia).

Methods: This is a ten-year (2012-2021) descriptive and exhaustive report on TAE from the second largest blood center in Tunisia, where around 56,000 labile blood products are issued annually.

Results: Four-hundred-sixty-four TAEs were reported. The median age of the patients was 38 years (1 month to 94 years). The sex ratio was 0.68. The overall TAE annual incidence per issued labile blood product was 0.77‰ and ranged from 0.47 to 1.43‰. The most common TAE was a febrile non-hemolytic reaction (31.7%), followed by an allergic reaction (21.6%). The severity degree was informed in 433 cases (93.3%). Grade 1 severity was the most common (80.8%), followed by grades 3, 2 and 4 (10.6%, 1.3% and 0.6%, respectively). Packed red blood cells were the most implicated labile blood product (81.5%). Standard platelet concentrates and fresh frozen plasma accounted for 6.5% and 5% of the total adverse transfusion reactions, respectively.

Conclusion: The TAE incidence in our study seems to be underestimated compared to worldwide reported TAEs. The analysis of reported TAEs in our context illustrates the insufficiency of the regulation's implementation alone.

Key words: hemovigilance, adverse transfusion reaction, declaration, transfusion safet

Résumé

Objectifs: En Tunisie, malgré la réglementation de l'hémovigilance depuis 2007, les effets indésirables receveurs restent méconnus et sous-déclarés. Dans ce cadre, nous avons analysé et évaluer ces effets déclarés sur une période de 10 ans au centre régional de transfusion sanguine de Sfax (Tunisie).

Méthodes: Notre étude est descriptive et exhaustive sur 10 ans d'étude (2012-2021), portant sur les effets indésirables receveurs (EIR) déclarés au deuxième centre tunisien, avec une production annuelle estimée à 56 000 produits sanguins labiles.

Résultats: Nous avons colligé 464 EIR déclarés. La médiane d'âge des patients était de 38 ans (1 mois-94 ans). Le sex-ratio était à 0,68. L'incidence moyenne des EIR était de de 0,77‰ PSL cédés, elle variait de 0,47 à 1,43‰. L'effet indésirable le plus fréquent était la réaction fébrile non hémolytique (31,7% des cas) suivie par la réaction allergique (21,6% des cas). Les degrés de sévérité ont été précisés dans 433 cas (93,3%). Le grade de gravité 1 était le plus fréquent (80,8% des cas) suivi par les grades 3,2 et 4 (respectivement 10,6% ,1,3% et 0,6% des cas). Les concentrés de globules rouges étaient les plus incriminés (81,5% des cas). Les concentrés plaquettaires standards et les plasmas frais congelés étaient à l'origine de 6,5% et 5% des effets indésirables receveurs respectivement.

Conclusion: En comparaison avec EIR déclarés dans différentes régions du monde, les nôtres semblent être sous-estimés. L'analyse des EIR rapportés dans notre contexte illustre l'insuffisance de mise en œuvre seulement de la réglementation.

Mots clés: hémovigilance, effet indésirable receveur, déclaration, sécurité transfusionnelle

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Introduction

The labile blood product (LBP) consumption increases due to the aging of the population and the development of medical and surgical procedures. However, despite its life-saving potential, blood transfusion has inherent risks. Inspired by the French hemovigilance model, a pioneer in the field since 1993, Tunisia implemented hemovigilance regulation in February 2007, as outlined in the 24/2007 circular (1). It aimed to systematically report and collect transfusion adverse events (TAEs) and related data.

Each TAE, whether occurring immediately or delayed, requires the completion of a transfusion incident form (TIF), which is tracked locally, regionally, and nationally. Physicians and transfusion staff initiate a thorough investigation to ascertain the underlying cause of the TAE to manage and prevent its recurrence, thus contributing to ongoing transfusion safety. At a regional or national level, the hemovigilance reporting process also serves as a tool for the epidemiological surveillance, assessment, and controlling of TAEs. The precise tracking and analysis of TAE cases are the key to the success of the hemovigilance system. This is not always granted in our country, where previously reported TAEs seem to be underestimated despite the existing regulations.

This study aims to conduct a comprehensive analysis of TAEs to determine and assess their incidence and types.

Methods

This is a descriptive, exhaustive, and analytical investigation of all the TAEs reported to the Sfax Blood Center Hemovigilance Unit over 10 years, from January 2012 to December 2021. Sfax City is the second-largest Tunisian city, with one million inhabitants. Sfax Blood Center, the unique provider of transfusion services for Sfax City and its region's healthcare facilities, issues over 55k LBPs annually.

The city and its regions have various first-, second-, and third-line medical, surgical, and obstetrical healthcare facilities except for bone marrow, liver, and cardiac allografts. Those are hosted across two university hospitals, three regional hospitals, twelve private clinics, and eleven hemodialysis centers. Patients receive transfusions in accordance with Tunisian regulations. All issued packed red blood cells are cross-matched using either a tube or a gel-centrifugation. Almost all issued packed red blood cells (PRBC) are ABO RH1 isogroup or compatible and phenotyped in the RH-KEL system. Broad phenotyping is mandatory for the antigen(s) against which the patient is alloimmunized. No universal leukoreduction is available, nor are Human Leukocyte Antigen (HLA) compatibility tests. Leukoreduction is applied on PBRC and/or platelets concentrated (PC) before 48 hours of life on demand – whenever primary or secondary HLA-immunization prevention is indicated. The Sfax Blood Center applies other LBP transformations on demand (irradiated, washed, fractionated, etc.). A 24/7 medical on-call service ensures advice on transfusions and support whenever TAEs are reported. For each TAE, the regulation requires the transfusing physician to fill out the TIF form and evaluate the TAE imputability ("doubtful", "possible", "probable", or "certain") and the grade (Grade 1: Absence of immediate or long-term life-threatening condition (e.g., chills, hyperthermia, urticarial); Grade 2: Long-term morbidity (e.g., viral disease, malaria); Grade 3: Immediate life- threatening condition (e.g., shock, respiratory distress) and Grade 4: Death). Then submit it to the hemovigilance correspondent. It comes with blood samples and the involved LBP bag. The hemovigilance correspondent initiates and coordinates a collaborative, comprehensive, and etiological investigation as guided by the transfusing physician report. Such an investigation is based on clinical patient features, relevant laboratory tests carried out on the patient pre- and post-transfusion blood samples, and the involved LBP whenever available and applicable. The laboratory investigation might be the LBP bag physical check, an immunohematology, a cellular immunology, and/or a microbiology investigation. The immunohematology laboratory of Sfax Blood Transfusion Center performs the usual immunohematology tests ABO-RH1 and RH-KEL group retyping, irregular anti-erythrocyte antibodies gel screening, and identification, direct anti-globulin test, indirect anti-globulin compatibility test tube and gel recheck, ultimate bedside tests recheck, etc. The immunology department of Sfax University Hospital performs the anti-HLA screening by means of lymphocytotoxicity or Luminex technology when indicated. Moreover, the microbiology department of Sfax University Hospital performs the LBP direct examination and culture in addition to patient blood culture. The hemovigilance correspondent issues a conclusion on the nature of the TAE, ensures the management and prevention recommendations, if applicable, and finally fills out the dedicated traceability registry.

In order to assess the reported TAE in Sfax City, Tunisia, we extracted data from tractability registry records and the related TIFs. We double-entered and analyzed extracted data on an Excel file (Office 2016, Windows) and the statistical package for social sciences, 20th version (SPSS.20). We performed the Pearson test to check the correlation between two quantitative variables. Statistical significance was set at $p < 0.05$.

Results

Over ten years, 464 TAEs were reported, resulting in an overall annual incidence of 0.77‰ of issued LBPs. Over the years, the annual incidence has increased significantly from 0.66 to 1.43‰ (p=0.049) issued LBPs (Figure 1).

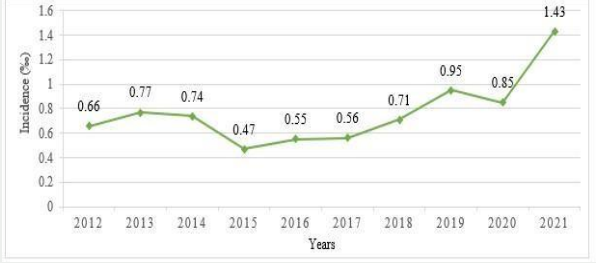

Figure 1. Evolution of the annual incidence of transfusion adverse events

The reported TAEs occurred after apheresis PC, PRBC, standard PC, fresh frozen plasma (FFP) and two LBP transfusions (Table 1).

Table 1. Incidence of the transfusion adverse events by type of labile blood product

Labile blood product		Apheresis platelet concentrates	Packed red blood cells	Standard platelet concentrates	Fresh frozen plasma	Association of LBP*	Not specified
Issued; N=		1 671	283 177	172 984	152 252	-	-
TAE*	N=	3	378	30	25	16	12
	Incidence (‰ LBP)	1.8	1.33	0.17	0.16	-	-

* TAE: transfusion adverse events
* LBP: labile blood product

The patients' median age was 38 years (range: from 1 month to 94 years) with a sex ratio of 0.68. Patient medical history was completed in 427 cases (92%). Previous transfusion history was reported in 267 cases (57.5%), of which 58 (21.7%) had previous TAEs. Obstetric, surgical, and other medical histories were reported in 22.6%, 5.6%, and 6.3%, respectively. The patients' diagnosis was provided on 418 (90.1%) TIFs and the most frequent diagnosis was cancer, with 91 cases (19.6 %) (Table 2).

Table 2. Distribution of transfusion adverse events according to pathology

Pathology	Number	Percentage (%)
Cancers	91	19.6
Benign hematopathy	51	11
Surgical pathology	27	5.8
Chronic renal failure	27	5.8
Hemorrhage (digestive/ gynecological)	43	9.3
Other	179	38.6
Not specified	46	9.9
Total	464	100

Concerning the type of TAEs, the most prevalent reported one was febrile non-hemolytic reaction (FNHTR), reported in 147 cases (31.7%). Allergic reactions were reported in 100 cases (21.6%). In 107 cases (23.1%), the investigations did not yield any results. PRBC ABO incompatibility was reported in 9 cases (2.2%). Investigations showed a non-conformity in patient identification within transfusion (6 cases), pre-transfusion sample identification (1 case), and blood group transcription (2 cases). One case of FFP ABO incompatibility was reported after post-partum massive hemorrhage. The immunological incompatibility other than ABO was confirmed in 13 cases (2.8%) or an association of anti-RH3+ anti-KEL1 (3 cases), anti-RH 4 + anti-FY1 (1 case), anti-public (3 cases), anti-RH 3 (2 cases), anti-JK2 (1 case), anti-MNS1 (1 case), anti-RH5 (1 case), and anti-MNS4 (1 case). The transfusion-related lung injury (TRALI) was reported in 5 cases (1.1%). Other TAE were: non-immunological hemolysis (27 cases or 5.8% related to massive transfusion, cardiac valve, cold chain non-conformity, severe septic shock), transfusion-associated circulatory overload (2 cases or 0.4%), delayed hemolytic post-transfusion in a sickle cell patient (1 case or 0.2%), and an anxiety attack (1 case or 0.2%). The severity degree was informed in 433 cases (93.3%). Grade 1 severity was the most common (80.8%), followed by grades 3, 2, and 4 (10.6%, 1.3%, and 0.6%, respectively). The imputability was reported in 258 cases (55.6%) categorized as "doubtful" in 4.7% of cases, "possible" in 15.9% of cases, "probable" in 20.5%, and "certain" in 14.5% of cases (Table 3).

Table 3. Distribution of transfusion adverse events based on the grade and the imputability

		Non-hemolytic febrile reaction	Allergic reaction	Pathology related reaction	Incompatibilityin systems other than ABO	ABO incompatibility	TRALI	Inconclusive investigation	Other	Total
Number (%)		147 (31.7%)	100 (21.6%)	51 (11%)	13 (2.8%)	10 (2.2%)	5 (1.1%)	107 (23.1%)	31 (6.7%)	464 (100%)
Grade	Grade 1	136	77	27	10	6	1	92	26	375
	Grade 2	0	1	2	0	0	0	2	1	6
	Grade 3	4	18	5	2	2	4	10	4	49
	Grade 4	0	0	0	0	0	0	3	0	3
	Not specified	7	4	17	1	2	0	0	0	31
Imputability	doubtful	5	2	5	1	0	0	6	3	22
	Possible	29	14	6	1	0	3	14	7	74
	Probable	22	26	4	4	0	2	26	11	95
	Certain	19	26	4	1	6	0	10	1	67
	Not specified	72	32	32	6	4	0	51	9	206

The majority of reported TAEs originated from the Hedi Chaker University Hospital (50.43%) and the Pediatrics Department, which accounted for 56 cases (12.1%) (Table 4).

Table 4. Distribution of adverse transfusion events according to hospital department

Department	Number	Percentage (%)
Pediatric	56	12.1
Hematology	53	11.4
Gynecology and obstetrics	49	10.6
General surgery	35	7.5
Medical intensive care	25	5.4
Gastroenterology	24	5.2
Nephrology	20	4.3
Surgical intensive care	19	4.1
Orthopedic surgery	17	3.7
Pulmonology	14	3.0
Urology	12	2.6
Other	64	13.8
Not specified	76	16.3
Total	464	100

Discussion

The median TAE incidence observed during the decade-long study period stood at 0.77‰ distributed labile blood products. The incidence of TAEs ranged from 0.7 to 213‰ in various countries (developed and emerging countries) and exhibited disparities even within the confines of the same country (2–18). The TAE incidence recorded in our study is lower than what has been reported in studies conducted both internationally and even within Tunisia (Tunis) (13).

Several factors may help elucidate this discrepancy:

- The underreporting of certain non-severe TAEs, such as FNHTR and allergic reactions, which might be considered minor incidents
- Apprehension of potential repercussions or sanctions, potentially deterring healthcare professionals from reporting TAEs
- Insufficient awareness regarding certain types of TAEs, such as TRALI
- Limited recognition among nursing professionals regarding the obligation to report TAEs
- Insufficient collaboration and communication between transfusion services and the regional blood transfusion center
- Variations in ease of reporting across different countries, where some regions facilitate reporting through the use of software (France) (11)
- The possible ambiguity and/or inconsistency in establishing a direct link between transfusion and a TAE in all instances

However, the incidence is increasing significantly, as efforts to raise awareness and provide training have been made since 2018. Regarding gender distribution, studies conducted in various countries have revealed disparities. For instance, studies in Morocco (64.8%), Pakistan (54.3%), Zimbabwe (61.6%), and Indonesia (52.8%) showed a predominance of women experiencing TAEs (9,14,19,20). In India, the prevalence of female TAE cases ranged from 59.4% to 80% (2–5), while male cases accounted for 54.3% to 65.8% (21,22). According to the results of our study, TAEs were more frequently observed in women (sex ratio: 0.68). This predominance in women may be attributed to their higher transfusion needs and the prevalence of gynecological and obstetrical pathologies (2).

Regarding patient age, the study conducted by Mahjoub et al. reported an average patient age of 51.2 years (13). Similarly, a study in Bangalore (India) revealed an average age of 40.9 years among TAE cases (4). Another study, published in 2020, encompassing TAEs reported in a multi-organ transplant center in South India, reported that 94.3% of TAE occurred in adults, with a median age of 50 years (23). In our study, the median age was 38 years, ranging from as young as 1 month to as old as 94 years old. Notably, some studies have reported higher TAE rates in children compared to adults, except in cases involving alloimmunization (24–26). These variations may be attributed to the physiological differences between pediatric and adult populations, as well as the specific demographics of the study populations (24). Concerning the distribution of TAEs based on recipient history, our study found that 57.5% of the patients had a history of previous transfusions. Our findings align with studies carried out in India and China, where 77.98% and 52.38% of patients were identified as multi-transfused individuals (21,27).

In terms of obstetrical history, 22.6% of patients in our study had prior pregnancies. This is consistent with the study conducted by Marwaha et al., which reported a history of pregnancy in 75% of their patient population (21). The vulnerability of multi-transfused patients and women with a history of pregnancies to develop TAEs could be attributed to alloimmunizations.

In France, FNHTR constituted the majority of immediate TAEs, accounting for 21.1% of cases, according to the 20th National Hemovigilance Report (11). Similarly, in the United States, FNHTR was reported in 46% of cases (12). In India, several studies have consistently identified FNHTR as the most frequent TAE, with incidence rates ranging from 51.4% to 73% (2,4,5).

These results closely align with our study, where FNHTR was the most prevalent type of TAE, occurring in 31.7% of cases. Variations in the incidence of FNHTR across different studies could be attributed to various factors, such as the administration of antipyretic premedication before the transfusion, the universal leukoreduction in some countries, and the potential underreporting of other TAE types.

If we compare the results found in our study with those in the literature, the incidence of allergic reactions found is among the lowest incidence (8,11,12,16,28,29). The high consumption of PRBCs and the under-reporting of platelet-related TAE may explain these results. This underscores the importance of making clinicians aware of the need to report allergic TAEs so that appropriate preventive measures can be taken, such as premedication or deplasmatization of transfused LBPs in cases of severe allergic reactions.

In our study, hemolytic accidents due to ABO and other systems incompatibilities were observed in 2.2% and 2.8% of cases respectively. In France, the incidence of

accidents due to immunological incompatibility was 4.5% in 2022 (11) and was estimated at 1/19 000 for the ABO incompatibility in New York (30). The rate of incidence of the immunologic incompatibility accidents reported in our study and in other studies could be explained by the application of current regulations aimed at ensuring recipient safety. The ultimate bedside test, which is compulsory in our country before any PRBC transfusion, could have reduced or even eliminated the ABO errors, but only if carried out correctly. In this context, a Tunisian study evaluating the theoretical knowledge and practical attitudes of healthcare staff regarding blood transfusion showed that 53.6% of staff verified the concordance between the recipient's identity and the identity mentioned on the grouping documents before the transfusion, 19.9% of staff verified the concordance between the blood products and their delivery cards, 12.2% of staff verified the quality of the blood product, and only 7.7% of staff verified the ultimate bedside test (31). Accidents due to ABO incompatibility in our series were the result of human error. These results are in line with the literature. Indeed, a review of the literature published in 2018 showed that hemolytic accidents in the ABO system occur almost exclusively as a result of human error (32). According to data reported by SHOT, ABO incompatibilities were most often the result of misidentification of the patient at the time of collection or administration of the LBP to another recipient (33). The incompatibility in systems other than ABO was often the result of the presence of one or more alloantibodies not identified before the transfusion in multi-transfused patients with a high risk of alloimmunization such as thalassemia and sickle cell disease (16,34). The prevention of these accidents is based on phenotyping, pre-transfusion crossmatching, and irregular anti-erythrocyte screening. This highlights the importance of immune-hematological monitoring of multi-transfused patients and its impact on requests for LBP. Another often overlooked and under-diagnosed TAE clinically manifested by hemolysis is delayed post-transfusion hyperhemolysis. It was observed in 0.2% in our study. It is a potentially fatal complication, mainly described in patients with sickle cell disease. Its diagnosis must be made rapidly since additional transfusions increase hemolysis. Its incidence in sickle cell disease was between 4% and 11% of cases(25). TRALI is one of the main causes of transfusion-related morbidity and it is responsible for a mortality rate of 10% and the need for mechanical ventilation in 70-90% of patients (35). In our study, 5 cases of TRALI were observed. The TRALI prevention is based on deferring multiparous women from donating blood. This measure reduced the TRALI rate by 80% in the United States (36). However, the leukodepletion and the exclusion of multiparous women from blood donation is not always possible in our country where the majority of donors are family donors. The assessment of TAE severity has been a focal point of numerous studies.

In Tunis, for instance, 78% of the 120 collected TAE cases were classified as grade 1 (13). In France, reports were classified as follows: grade 1 in 92% of cases, grade 2 in 6.4%, grade 3 in 1.6%, and grade 4 in 0.1% (11). In our study, TAEs were classified as grade 1 in 80.8% of cases and grade 2 in 1.3%. Grades 3 and 4 accounted for 10.6% and 0.6%, respectively. The prevailing majority of TAEs were of severity grade 1, consistent with findings reported in the existing literature. However, based on the reports, typically communicated via telephone, some pre-transfusion incidents, not covered by the TIF (clotted bags), might warrant the inclusion of a "zero" grade to acknowledge certain isolated malfunctions that often go unnoticed due to their lack of repercussions on the recipient. Furthermore, the reevaluation of the severity grades by the hemovigilance correspondent could help to clarify the correct severity grade of TAEs, as, for example, grade 2 was mentioned in 1.3% of cases; however, no viral seroconversions or parasitic transmissions were detected in the study population.

Concerning the imputability, in France and according to the national hemovigilance report, the imputability was "probable" in 30.9% of TAE cases and "certain" in 30.9%. Moreover, an "unevaluable" imputability category was noted in some cases (11). In the United States and China, TAE imputability cases were classified as "certain" in 46% and 43.8% of all incidents, respectively (12,18). In Tunisia, the imputability of TAEs was from 1 to 4 using TIFs.

Clinicians determine the imputability degrees based on clinical signs, biological tests, and the patient's clinical context. In our series, imputability was categorized as "doubtful" in 4.7%, "possible" in 15.9%, "probable" in 20.5%, and "certain" in 14.5% of cases. The predominance of "probable" imputability in our study may be associated with several factors including the absence of well-defined criteria for categorizing TAEs based on imputability levels and the report of a TAE when a clear link to a transfusion has been established, while other cases with uncertain associations may be overlooked. In 44.4% of cases, no information about imputability was provided. This underscores the challenges some clinicians face in establishing a direct link between the clinical manifestations and the LBP.

For the department, many publications have explored the pattern of TAE reporting across different hospital departments. In 2021, in a Turkish study, the surgery department reported a TAE occurrence in 0.46% of cases, followed by the hematology-oncology departments with 0.21% of cases (16). In an Indian study, it was shown that 61.9% of TAEs were reported by gynecology-obstetrics departments, with general medicine and surgery departments accounting for 23.8% and 14.29% of cases, respectively (2). A study from Burkina Faso spanning six years (2010-2015) showed that pediatrics departments reported the majority of the TAEs (37.2%) (37). This is consistent with the results found in our study, where a significant proportion of TAEs were reported by pediatric departments (12.1%).

Conclusion

Our study successfully addressed the issue of underreporting TAEs, revealing an incidence rate of 0.77‰ among distributed blood components. This

finding highlights the need for enhanced training of healthcare professionals and stronger inter-institutional collaboration to enhance the overall quality of transfusion safety.

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