Original article

Assessment of side effects of venesection (phlebotomy) procedure in Iraqi patients presenting with erythrocytosis: single center experience

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Background: Venesection or phlebotomy is generally considered to be a safe method, but occasionally adverse effects of varying severity may occur during or at the end of the procedure.

Objectives: The aim of the study was to estimate the frequency and type of adverse events occurring during venesection and to assess the practices which would help to minimize them.

Materials and methods: This is prospective single-center study was conducted from October 2011 to November 2012 at the emergency unit of the national center of hematology in Baghdad. All phlebotomies procedures made at the center were analyzed. All adverse events occurring during or at the end of procedure were registered by using a standardized questionnaire.

Results: Overall 3 adverse events were reported in relation to 960 venesections done, resulting in an overall adverse event rate of 0.3125%, that is, an incidence of 1 in every 320 venesections. One adverse effect was presyncopal symptoms of mild intensity, and the other two that observed were extravasation at site of puncture.

Conclusions: Only 0.3% of phlebotomies were complicated by adverse events which were very mild and easily managed. Our study confirms the fact that venesection procedure is a very safe method which could be made even more event-free by following certain friendly, reassuring and competent practices.

Key words: side effects, venesections, erythrocytosis

Introduction

Despite that great knowledge about venesection procedure and its safety in regards to patients, still there are rare cases in which serious adverse event happened as nerve injury or profound vasovagal shocks and soft tissue infections. Medical personnel's (doctors and nurses) who do venesection should be aware about the anatomical landmarks of target sites and have enough idea about the of pathophysiology of these adverse events to

avoiding them, and to be capable to treat them properly. Injury to peripheral nerves is one of the serious complications of which medical staff should take the utmost attention. It may lead permanent motor and/or sensory nerve damage. Selection of proper vein and careful procedure of venipuncture are essential. Vasovagal shock is quite common complication causing hypotension, pallor and infrequently syncope. Infections, particularly those by blood-borne pathogen, are rare but carry grave consequences. other side effects which occur less frequently include Hematoma at site of puncture, allergy, hyperventilation, air embolism, anemia and thrombosis. Finally, medical staff should know that close communication with patients undergoing venesection is crucial and efforts to advise them about risk of these side effects are becoming increasingly important in the current medical environment.[1]

Erythrocytosis, an increase of the red blood cell count above the threshold value of 6,000,000/μL, with a corresponding rise in the hematocrit (Hct) to over 50%, leads to a increase in the total red blood cell mass. Erythrocytosis is usually secondary to various conditions such as cardiac disorders (particularly congenital), lung diseases [in particular chronic obstructive pulmonary disease (COPD) and emphysema], tumors that produce erythropoietin, renal cysts, smoking, residence at high altitude, post-hematopoietic cell transplant, and endocrine disorders (with adrenocortical dysfunction). Patients with erythrocytosis have a high risk of severe thrombo-embolic events, which are directly related to the clear increase in blood viscosity [2]

From a therapeutic point of view, venesection (phlebotomy) is the most commonly used, cheapest and practical form of treatment for erythrocytosis and polycythemia, with the use of specific drugs such as busulphan and hydroxyurea [3]

The aim of this study was to estimate the frequency and type of adverse events of venesection occurring in persons presenting with erythrocytosis at the national center of hematology in Baghdad and to assess the practices which would help to minimize them.

Materials and methods

This is a prospective, single-center study of all adverse reactions related to all the consecutive venesections done between October 2011 and November 2012. All venesections were collected using a 16 gauge needle inserted into a vein in the antecubital area. Strict asepsis was maintained by cleaning the site of venipuncture sequentially using betadine and alcohol. The minimum hematocrit required for venesection was 45 and the lowest acceptable hemoglobin concentration was set at 15 g/dL. For venesection 350 to 450 mL of whole blood were collected from donors aged more than 18 years. As part of our study we assessed certain practices which could help to minimize the adverse incidents associated with venesection. The periods between two consecutive treatments were dictated by the hematocrit (Hct): patients underwent phlebotomy when the Hct rose to 50±1%. The aim was to bring the Hct to below 45% and maintain it at about this value for as long as possible. Full blood counts were performed 48 h after the

treatment and systematically repeated every 15-30 days in order to follow the trend in Hct over time. When the Hct reached about 50% or above, a new therapeutic procedure was performed. Besides being prescribed specific drugs, the patients were advised to increase their intake of fluids, stop smoking, limit food intake. It is always advisable to provide a friendly, warm and comfortable atmosphere for the donor and to engage particularly anxious donors in conversation during the donation, in order to distract their attention. It is also very important to react swiftly to initial complaints of giddiness, light headedness, pallor by the donor by stopping the procedure immediately and raising the legs of the donor (anti-shock position) as pallor, sweating, agitation are harbingers of a severe vasovagal reaction which could be prevented by taking corrective measures right at the onset of symptoms.

The classification scheme employed for recording the adverse events was suggested by the American Red Cross Hemovigilance Program that classifies complications into defined categories with severity ratings (minor/major) for certain types of reaction (4,5). Presyncopal symptoms include pallor, sweating or light-headedness without loss of consciousness. Syncopal types of complications are classified as minor if there is a transient loss of consciousness lasting less than one minute, while prolonged loss of consciousness for more than a minute or complicated by loss of bowel/bladder control, seizures or convulsions is said to be a major syncopal complication. Local adverse events include hematomas which can be small (<25.8 mm2) or large (>25.8 mm2), bruises, infiltration, allergic reactions, and a tingling/burning sensation.

Results

This study included a total of 960 venesections for whole blood (350 mL/450 mL) during the study period of which 943 were made by males and 17 by females aged between 18 and 65 years old. The age groups most represented were those between 30 and 40 years old (23 patients) and between 40 and 50 years old (31 patients).table 1

The venesections were made by 794 as first-time venesections and 166 repeated donors. Overall 3 adverse events were reported in relation to 960 venesections done, resulting in an overall adverse event rate of 0.3125%, that is, an incidence of 1 in every 320 venesections. One adverse effect was presyncopal symptoms of mild intensity, and the other two that observed were extravasation at site of puncture of all venesections; none necessitated hospitalization of the donor. The frequency distribution of the various types of adverse reactions that occurred in donors during the study period is presented in Table 2.

Table 1: distribution of age in the studied persons

Age(years)	Number	Present
15-25	84	8.75
26-35	204	21.25
36-45	387	40.31
46-55	175	18.22
56-65	67	6.97
>66	43	4.47

Table 2 - Frequency of various types of adverse reactions occurring in erythrocytosis persons

Type of adverse reaction	Number affected	Percentage
presyncopal complications	1	0.001
Syncopal complications		
Minor	0	0
Major	0	0
Hematoma	2	0.002
Numbness/tingling	0	0

Discussion

Hematology centers have a dual responsibility to offer sufficient supply of blood components to the community they serve and to ensure the safety and well-being of their donor's weather they are come to donation or to do venesection due to erythrocytosis. The most common systemic and venesection-related complications are presyncope and small hematomas. The importance of these minor complications, nonetheless, lies predominantly in the observation that any complication, even a minor one, decreases the likelihood of adherence to therapy [6]Although whole blood donation is considered to be safe, reports in the medical literature about the frequency of adverse events during donations show broad heterogeneity [7,8]

The aim of this study was to assess the frequency of various types of adverse reactions associated with venesection and to assess the measures that would help prevent or reduce the occurrence of these side effects. Donation-related adverse events were recorded according to standardized criteria as suggested by The American Red Cross Hemovigilance Program [4]. In our study, 0.3% percent of all venesections were complicated by an adverse event. This is similar to that found in various studies conducted all over the world in which the rate of adverse events associated with donations ranged from 0.3% to 3.8% [5,6,7-11]. Presyncopal symptoms, which include giddiness, sweating or light-headedness without loss of consciousness, accounted for approximately 33% of all adverse events. This is in contrast to the results of a study conducted by Crocco *et al*. in 2009, who found that vasovagal reactions of mild intensity constituted 71% of all adverse incidents reported.[9]

As regards local reactions, hematomas were found to be the most common adverse event 67%. Local reactions are mainly caused by blood donation-related neurological needle injuries which are commonly experienced by the donors after the donation in the form of hematomas, numbness/tingling, excessive or radiating pain, loss of arm/hand strength. The time to recover from these complications can range from less than 3 days to more than 6 months [12]. Since these complications are mostly experienced by the donor sometime after venesection and we recorded only adverse events occurring during the donation period and stay in the emergency unit, the rate of local adverse incidents observed in our study was not recorded. Like other studies, we found no incidence of severe reactions (major syncopal reactions with no episodes necessitating hospitalization of the donor or administration of intravenous fluids. It is worth noting that the maximum volume of blood withdrawn during venesection (350 to 450 mL) represents only about 10% of the total blood volume in a subject weighing 70 kg. Since at least 800-1,500 mL of blood, i.e. 15-20% of the total blood volume would have to be lost in order to be in at least class I risk of hypovolemia, erythrocytosis patients are unlikely to experience severe vasovagal reactions [13]. As part of our study we also assessed certain practices which could help to minimize the adverse incidents associated with venesections. It is always advisable to provide a friendly, warm and comfortable atmosphere for the persons who want to do venesection and to engage particularly anxious one in conversation during the procedure, in order to distract their attention. It is also very important to react positively to initial complaints of giddiness, lightheadedness, or pallor by the patients by stopping the procedure immediately and raising the legs of patient (anti-shock position) as pallor, sweating, agitation are early signs of a severe vasovagal reaction which could be prevented by taking correct measures right at the onset of symptoms.

In conclusion only 0.3% of whole blood venesections were complicated by adverse events and one of these events were presyncopal symptoms. Thus our study confirms the fact that venesection is a very safe procedure with no major complications.

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