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The effects of economic sanctions on disease specific clinical outcomes of patients with thalassemia and hemophilia in Iran

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ABSTRACT

Background: The sanctions applied by both the USA and the EU against Iran do not formally ban the exports of medicines; in practice, however, patients are experiencing great difficulty in securing the treatment. This article documents the impact of international sanctions on patients with thalassemia and hemophilia in southern Iran.
Methods: This survey examined the specific effects of external sanctions on the access of patients to their treatment between 2009 and 2012 from the point of view of patients with thalassemia ($n = 69$) and congenital coagulation disorders ($n = 40$) as well as related physicians ($n = 20$). Also, clinical manifestation and laboratory data of patients were compared in the same period.
Results: Access to deferoxamine and Exjade as iron chelators in patients with thalasseamia, respectively, declined by almost 70% and half over this period. In addition, access to lyophilized coagulation factor VIII concentrate in hemophilia A dramatically dropped from 96.7% in 2009 to 3.3% in 2012. The clinical results showed a significant deterioration of arthropathy ($P < 0.001$) in hemophiliac patients and a significant increase in serum ferritin levels in thalassemia patients ($P = 0.036$).
Conclusion: Sanctions had significant effect on public health on patients with thalassemia and hemophilia.

1. Introduction

Sanctions and embargos are political tools that are generally designed to affect trade and economic activities of the target country to coerce a change in the state's policies. However, these can have an effect not only on the political and economic domains, but also on wider social aspects including the public health. Previous reports have indicated that the effects of sanctions may be most prominent on the general public, especially on the poor, ordinary people and patients, with a direct and adverse impact on the population's health and well-being [1,2]. Many countries such as Iran, Syria, Iraq, Cuba, and Libya have been affected by international sanctions as a coercive foreign policy tool over the past few decades [3,4].

The European Union in accordance with the US (United States) has enforced sanctions against Iran since Feb 27, 2007followed by the most important one in 2010 whereby 10 individuals and 104 companies were further added as a direct result of Iran's nuclear program [5]. However, Iranian banks were not sanctioned by the EU totally and SWIFT system has remained open for Iranian banks that were not sanctioned [6]. Several reports by the United Nations (UN), academia, non-governmental organizations [NGOs], and patient advocacy groups have addressed the potential adverse effects of sanctions on general population and specifically on the availability of medications in Iran [7,8]. The impacts of sanctions on Iranian

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pharmaceutical markets have been evaluated in recent papers. They stated that sanctions have resulted in development of major difficulties for importing of not only finished products and pharmaceutical raw materials but also medical equipment needed in hospitals [4,9,10]. Moreover, there are many reports of sanction-related deaths in Iran due to drug supply shortage in patients with cancer, hemophilia, and complex diseases [4,11]. In order to establish approaches and policies to protect the vulnerable populations, it is crucial to systematically measure the impact of embargos on the population's health [12].

Iran, a country of more than 75 million people, has a large population of thalassemia and congenital bleeding disorders with considerable burden on the health care system. Optimal care of these chronic diseases requires availability of specialized and disease-specific medical supplies and medications which are often quite expensive. As a result, these patients are amongst the most vulnerable to the possible shortage of medications and medical supplies.

This study was carried out to systematically measure the effect of economic sanctions on the availability of the standard of care and disease-related clinical outcomes in patients with thalassemia and hemophilia.

2. Methods

2.1. Patients

This questionnaire-based and chart review study was conducted in the Hematology Research Center of Namazee Hospital and was approved by the Research Ethics Board of Hemophilia Research Center. All patients signed a consent form upon entry to the study. The Hematology Research Center of Namazee Hospital is a tertiary care center for the management of patients with hematologic disorders and is one of the largest centers caring for patients with thalassemia and congenital bleeding disorders in Iran. In our center we follow more than 2000 beta thalassemia patients and 390 patients with hemophilia A and B. For the purpose of the study, 69 thalassemia and 40 hemophilia patients were randomly selected. Inclusion criteria were willingness to participate in study for all patients. Moreover, for thalassemia group, we considered beta-thalasemia major patients who were on regular red blood cell transfusion and iron chelation at the start of the study. Thalassemia patients who received bone marrow transplant during the study period were excluded. For hemophilia group, only patients with severe hemophilia-A or hemophilia-B (defined as less than 1% factor activity) were enrolled. All hemophilia patients have been receiving factor replacement, cryoprecipitate or fresh frozen plasma (FFP) therapy (episodic or prophylactic). In addition, we have assessed the experience of 20 specialists who were directly involved in the care of these patients, again comparing availability of the products in 2009 compared with 2012.

2.2. Study design

Disease-specific questionnaires for the subjective assessment of the experience of patients with transfusion-dependant beta-thalassemia, and patients with severe hemophilia A and hemophilia B were designed. Questionnaires were completed in the presence of trained research personnel. These questionnaires evaluated the changes in the availability, affordability and the usage of the disease-specific medications over past years, including the possible change of treatments to cheaper second-line alternatives. Similarly, a questionnaire was sent to the 20 health care professionals who were involved in the care of these patients. The evaluated medications included: two domestic manufactured products deferiperone (Avesina Company) and deferasirox, (Osveral by Osveh Company), original products deferoxamine and Exjade (Novartis Company) for thalassemia patients and specific coagulation factor VIII, (CSL, Biotest and Baxter) and IX (Biotest) concentrates FFP, or cryoprecipitate for patients with hemophilia A or B.

Next, patients' medical records were reviewed in detail for the assessment of the clinical outcomes in our patients in three time points: 2006 and 2009 (before the sanctions, to establish the baseline trend) and in 2012 (after the sanctions; to determine possible changes). In addition to patients' demographics (age, sex, disease diagnosis and severity) collected data included: the mean annual numbers of joint and extra-articular hemorrhages, total units of factors per body weight per year (μ/kg/yr) used for each patient and their indications (prophylaxis vs. episodic), total high-titer inhibitor formation events in each year, and deterioration of arthropathy as measured by the Haemophilia Joint Health Score (HJHS) for hemophilia group and the number of pRBC transfusions per person per year and average serum ferritin levels in individual patients in each year for thalassemia patients. Although ferritin may not be the most accurate measure of tissue iron overload in thalassemia patients, it is a reasonable screening marker for follow-up. Ferriscan and T2* MRI assessment of tissue iron overload is not widely available in our center and so was not used for analysis of data. It should be mentioned that all related laboratory tests were performed in a comprehensive reference laboratory and the kits and instruments were not changed during 2006–2012.

2.3. Statistical analysis

Using the statistical software SPSS v. 17, the changes of clinical outcomes (HJHS and number of bleeding in hemophilia patients, as well as average serum ferritin levels in thalassemia patients) within the three time periods, 2006 to 2009, 2009 to 2012, and 2006 to 2012 were evaluated using student *t*-test (or Wilcoxon rank sum test if there was not a normal distribution of variables). Association of the viewpoints of patients and physicians toward the effect of sanctions on the availability of medicines with demographic variables of the patients were evaluated by student t test and Chi-square test. A *P*-value of less than 0.05 was considered as statistically significant.

3. Results

Demographics and clinical characteristics of the participants (72.7% female and 27.3% male) are shown in Table 1.

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