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Cost-Benefit Analysis and Assessment of Quality of Care in patients with Hemophilia undergoing treatment at National Rural Health Mission in Maharashtra, India



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ABSTRACT

Background: Hemophilia is a genetic disorder with high health care burden. In India, most patients with hemophilia seek care through self-purchasing factor concentrate and incur huge out-of-pocket (OOP) expenditure. In March 2013, the government of India launched a pilot hematology program through the National Rural Health Mission for providing free treatment services to patients with hemophilia in the state of Maharashtra. Objectives: To estimate the benefit-cost ratio of the program from a patient perspective, to estimate reduction in OOP expenditure of the patients and their families, and to assess the quality of care delivered and the barriers to access care among patients with hemophilia. Methods: This cross-sectional study evaluated the intervention of free treatment to patients with hemophilia at four district civil hospitals of Maharashtra. The study sample included 232 people with hemophilia (193 with hemophilia A, 31 with hemophilia B, 6 with von Willebrand disease, and 2 others) under four study arms over a 1-year study period. Cost-benefit analysis was performed for patients undergoing treatment at government hospitals and through nongovernmental organizations. **Results:** The benefit-cost ratio for the government program was 1.89. There was reduction in OOP expenditure by 21% per patient annually for the families. About 98% patients were highly satisfied with the services, whereas a major barrier to access was difficulty in commuting during active bleeding episodes. **Conclusions:** The government intervention through the National Rural Health Mission was cost-beneficial to the patients with hemophilia. It helped in reducing the OOP expenditure by 21%.

Keywords: complementary and alternative medicine (CAM), costbenefit analysis, hemophilia, India, National Rural Health Mission (NRHM), out-of-pocket expenditure.

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Introduction

Bleeding disorders reportedly affect 1 in 1000 individuals globally [1]. The most prevalent bleeding disorders are hemophilia A and B [2-4] and von Willebrand disease [5,6]. Hemophilia A and B are coagulation disorders caused by a deficiency of clotting factors VIII and IX, respectively. The coagulation factor level in the body and the genotype of the patient determine the frequency of bleeding [3,7,8]. Patients frequently suffer from bleeding internally, mostly in joints, muscles, and the brain. Each bleeding episode causes immobilization and severe pain and can result in permanent disability. About 70% of all bleeding disorders are found in patients with severe hemophilia A. The hemorrhagic episodes of hemophilia are treated by replacement therapy, by infusing clotting factor VIII for hemophilia A or clotting factor IX for hemophilia B. In India, cryoprecipitate or fresh frozen plasma is used. The use of clotting factor concentrate is the preferred treatment option. Clotting factor concentrate is an orphan drug [7–10], and its high cost places the drug out of reach of most Indian patients. Because of the high treatment costs, families are unable to purchase clotting factor concentrates and hence patients with hemophilia in India receive suboptimal treatment [11]. In a few cases, because of the limited availability of clotting factor concentrate, any major hemorrhagic episode, such as intracranial bleed, may result in death if left untreated [12].

The lack of sufficient treatment product for pain relief, for life-threatening hemorrhagic episodes, and for the prevention of disability results in orthopedic morbidity, premature mortality, and extensive out-of-pocket (OOP) expenditure. The quality of life and the well-being of patients and family members are significantly affected because of the disease [11,12]. A study conducted in Pune, Maharashtra, to estimate the OOP expenditure of a person with hemophilia concluded that expenditure on treatment ranged from 1.5% to 12% of the monthly income of the family. The study, however, reported that only one in four

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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bleeding episodes was treated with factor concentrate. If all the bleeding episodes were treated with a factor concentrate, then the yearly cost of treatment would be 21 to 314 times of the monthly income [12]. In addition, this study found that nearly 70% of households experienced catastrophic expenditure in treating hemophilia. Given the high health care burden associated with hemophilia in India, it is imperative that the government of India plans a public health intervention that helps in reducing the OOP expenditure of the families of the patients and facilitates in seeking treatment and care. In 2013, the National Rural Health Mission (NRHM) in Maharashtra and the Maharashtra State Blood Transfusion Council launched an ambitious pilot project in four districts of Maharashtra: Thane, Satara, Nashik, and Amravati. The program was launched to provide financial assistance and quality health services to patients suffering from hemophilia. Through these districts it also aimed to cater to the nearby satellite towns and cities by bringing them under its ambit. It is understood that on the basis of the final results of this project, which is currently underway in the aforementioned districts, the state government plans to extend it across the state to enable all patients to enjoy the benefits of this scheme. Under this scheme, the state government has set up special day care centers in the selected districts and installed early detection tools aimed at helping the patients in timely detection of the disease [13-15].

Maharashtra is the first state in the country to launch such a program targeted to the service of thousands of patients suffering from this lifelong chronic blood disorder, the treatment of which is often too costly for patients. With the help of this state intervention, it has been possible to reach out to many patients who have not been able to afford the available treatment because of the huge cost associated with the same and also because they are usually out of reach [13-16]. Treatment options for patients with hemophilia in Maharashtra have traditionally involved self-purchasing of the factor concentrate from a nongovernmental organization (NGO) or society, but they are very expensive. Those who are unable to afford the cost undergo alternative medicine treatment. There is increased usage of alternative medicine among hemophilic patients in Maharashtra [17]. Since March 2013, after the launch of the NRHM program for free care for hemophilia in Maharashtra, patients have started seeking treatment at government civil hospitals in the four districts of Thane, Nashik, Satara, and Amravati.

The first objective of the study was to estimate the benefit-cost ratio (BCR) of the government-funded program from a patient perspective. The second objective was to assess the beneficial impact of the program in patients with hemophilia and their families in terms of reducing their OOP expenditure. The third objective was to compare the cost of treatment incurred by patients in self-financed care while seeking treatment from an NGO or using complementary and alternative medicine (CAM) with those incurred on patients availing treatment at

government hospitals. The final objective was to assess the quality of care and barriers to access among hemophilic patients treated in government hospitals.

Methods

This was a cross-sectional study in which quantitative research methodology was used to achieve the proposed objectives. The study was conducted in the state of Maharashtra, India, in 2014. Data were collected in April, May, September, and October 2014 from the four districts of Thane, Nashik, Satara, and Amravati. The total study sample included 232 patients with hemophilia (193 with hemophilia A, 31 with hemophilia B, 6 with von Willebrand disease, 1 with factor II deficiency, and 1 with factor XIII deficiency). Purposive sampling was done because the disease under study was rare and genetic in nature, and patients were interviewed face to face with a structured interview schedule under four study arms as shown in Fig. 1.

Study arm 1 had 35 patients who had undergone treatment at an NGO (hemophilia chapter), study arm 2 had 77 patients who had exclusively undergone treatment at a civil hospital, study arm 3 had 52 patients who had undergone CAM treatment (mainly homeopathy), and study arm 4 had 68 patients who underwent treatment at both a civil hospital and an NGO during the 1-year study period. Patients in study arms 1 and 2 formed the cohorts for objective 1, whereas those in study arms 2 and 4 formed the cohort for objective 2. Objective 3 was evaluated by all the four study arms. For objective 4, 145 patients who underwent treatment at a government hospital were considered and a Likert scale was used to obtain responses on quality of care and barriers to access care. These questions on the interview schedule were pilot-tested before the onset of the study.

Hemophilic patients diagnosed with hemophilia A or B or with any other factor deficiency (severe, mild, or moderate) and patients with von Willebrand disease who had undergone treatment in an outpatient department in civil hospitals or in private care/CAM treatment were considered for study. Consequently, patients who underwent treatment in an inpatient department or for intracranial bleeds were excluded because these patients require more intensive treatment than do patients in outpatient departments. Patients with hemophilia with inhibitor-positive status were not considered for the study because they have to be treated with products more expensive than factor concentrate. The cost calculation for all the four study arms included direct costs of factor concentrate, cost of getting case paper issued at the civil hospital, cost of infusing the factor concentrate privately by a nurse/doctor, and cost of homeopathic treatment as applicable for the given arm. Indirect cost was calculated by taking into account the cost of transport, the loss of wage of patients and caregivers, and in case of nonworking caregivers, especially mothers, loss of time of mothers in caregiving was considered and converted to monetary value. Benefits were measured in

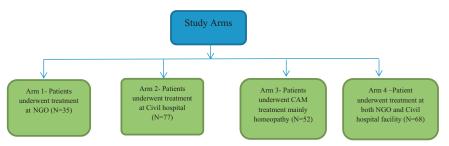


Fig. 1 - Study arms in the research. CAM, complementary and alternative medicine; NGO, nongovernmental organization.

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