

Experiences in the nationwide program for the integral care of the patient with diabetic foot ulcer using Heberprot-P

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ABSTRACT

Experiences in the nationwide program for the integral care of the patient with diabetic foot ulcer using Heberprot-P. The Cuban product Heberprot-P is indicated for the treatment of complex diabetic foot ulcers (DFU). After its registration in 2006, the product was included into the Cuban List of Medicines and a nationwide program for the integral care of the DFU patient began. To date Heberprot-P is available in more than 85 Cuban health institutions and more than 3 800 diabetic patients with ulcers in their feet have received the benefits of this unique product. An integral program has been established for the attention of the patient with DFU, including the advanced technology of Heberprot-P. This program relies on the closely linked and coordinated interaction between the primary and secondary levels of health, in which prevention and therapy merge each other. The Ministry of Public Health of Cuba has established impact indicators in order to control and assess the performance of the program.

Keywords: Heberprot-P, Diabetic foot ulcer, Primary Health Care

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RESUMEN

Experiencias en la extensión nacional del Programa de atención integral al paciente con úlcera del pie diabético y el empleo del Heberprot-P. El novedoso producto cubano Heberprot-P está indicado para el tratamiento de las úlceras complicadas del pie diabético (UPD). Una vez aprobado su registro sanitario, pasó a formar parte del Cuadro Básico de Medicamentos de Cuba, y se inició el proceso de extensión nacional. Más de 3800 pacientes diabéticos con úlceras en sus pies en Cuba han recibido las bondades de este medicamento, que se administra en más de 85 instituciones de salud del país. Se ha establecido un Programa de atención integral al paciente con úlcera del pie diabético que incluye el uso del Heberprot-P. Este programa está organizado sobre la base del trabajo coordinado del nivel primario y secundario de salud, en el que se funden el papel preventivo y terapéutico de la atención al paciente diabético. El Ministerio e Salud Pública cubano ha establecido indicadores de impacto para medir y controlar el desarrollo de este programa.

Palabras clave: Heberprot-P, úlcera de pie diabético, Atención Primaria de Salud

Introduction

At present diabetes mellitus is a serious health problem and within it, the diabetic foot ulcer (DFU) is one of its major complications. Global prevalence is estimated in 285 million people and this number will increase in the incoming years [1]. In Cuba, the average rate of dispensed patients having diabetes mellitus is 40.4 per 1 000 inhabitants, representing an estimate of 450 000 diabetics [2].

Heberprot-P was registered in Cuba in June 2006, and was included into the Cuban List of Medicines in April, 2007. It is a worldwide unique product of its kind, a result of the Cuban biotechnology, developed by the Center for Genetic Engineering and Biotechnology, together with the National Institute of Angiology and Vascular Surgery (NIAVS) and other institutions from the Cuban Ministry of Public Health (MINSAP). Heberprot-P is indicated, as well as other

conventional therapies, for the treatment of neuropathic and ischemic ulcers from the diabetic foot, to stimulate a useful granulation tissue formation, so as to allow the closure by second intention or by skin graft, as it has been demonstrated in various clinical trials [3-5].

Among its properties and advantages it stimulates granulation and accelerates re-epithelization in DFU and reduces the time for healing of these lesions, contributing thereby to reduce the number and extension of surgical debridements and the risk of amputation.

From June 30th 2007, a nationwide program for the integral care of the DFU patient began at the secondary and tertiary levels of health, in particular in the Angiology Services of hospitals and the NIAVS. In 2009 the program was extended also, as a pilot trial,

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to the primary level of health (PLH) in selected Cuban polyclinics.

The safety and efficacy of Heberprot-P have been demonstrated in more than 15 000 treated patients in Cuba and in other countries such as Venezuela, Algeria, Argentina, Libya, and the Dominican Republic among others.

The experience of its use in the Cuban health system is supported by the implementation of nationwide program for the integral care of the DFU patient with the use of Heberprot-P, through a methodological protocol agreed by consensus.

Results upon the implementation of the nationwide program using Heberprot-P

The extension process of Heberprot-P in the Cuban public health system is developed under a post-marketing phase IV study (intensive pharmaco-surveillance), conducted by the Center for the Development of Pharmaco-epidemiology [6-8].

This Cuban drug is applied in more than 85 health institutions (hospitals and polyclinics), distributed all over the provinces of the country. At present, all Cuban hospitals having the service of Angiology apply the therapy for the treatment of the DFU with this novel product.

To date, 3 853 patients with DFU have been included within the nationwide Program of Heberprot-P in Cuba. This number is having a steady increase and all the Cuban DFU patients should continuous receiving the benefits of the product. Figure 1 shows the patient inclusion per year to the intensive pharmaco-surveillance system from June 2007 to July 2010.

Heberprot-P has been indicated to patients with neuro-infectious and ischemic ulcers. Most of them having lesions with grades 3, 4 and 5 within the Wagner's classification [9, 10]. Results upon product administration have demonstrated its efficacy and safety (see results of Dr. Isis Year in this number).

The process of Heberprot-P's spread as part of the Program for the integral care of the DFU patient has increased since June 2007, but results yet do not correspond to the amount of patients that potentially could be treated.

The diabetic patient must be treated in an integral manner considering the possible complications, cha-

racteristic of this kind of disease; for instance, the diabetic foot ulcer.

How the Program for the integral care of the DFU patient is structured, in particular, those requiring treatment with Heberprot-P in Cuba.

Program for the integral care of the patient with diabetic foot ulcer in Cuba with the use of Heberprot-P

Objectives of the Program for integral care of the DFU patient with the use of Heberprot-P

- Increase accessibility to the treatment with Heberprot-P; that is, to the majority of patients with DFU that require the treatment in Cuba.
- Supply of the product in all health services where DFU patients may arrive. A practical behavior agreed by consensus by the NIAVS has been established to treat the patient with DFU in all Angiology services from hospitals, polyclinics and in all diabetic care centers (National Health System, MINSAP; Figure 2).
- Control of diabetic patients and with DFU throughout medical offices, identification through surveillance in the communities and the existence of a documented register in the medical offices of all health areas.
- Implement the integral care of the DFU patient. The patient must be treated in an integral manner and be remitted to other specialties, according to the type of complication. These specialties can be Ophthalmology, Nephrology, Cardiology, and Angiology, which have specialized care in the treatment of complex and advanced ulcers of the diabetic foot with the use of Heberprot-P.
- Implement the flow of patients with DFU to be assisted and/or remitted from the primary health care to the secondary health care (hospitals), according to the type of complication of the lesion.
- Systematic training of health personnel in charge of the integral care of the DFU patient, in diabetes and treatment with Heberprot-P (angiologists, integral general physicians, nurses, podiatrists, nutritionists, educators and others).

The integral care of the DFU patient with the use of Heberprot-P forms part of the objectives of the National Health System in all levels of medical care to the population, including from the primary level (medical offices, polyclinics and diabetic care centers) to the secondary level (Angiology services of all hospitals), and the tertiary level of health (NIAVS).

The health management of the provinces and municipalities establish an effective interaction among all levels of health, so that the patient with DFU can reach specialized care through any level. To avoid limitations in the proper care of this type of patient, all Cuban health personnel involved in the activity must know where to assist and/or remit the patients, according to the severity of their lesions or the level of metabolic decompensation.

The success of this Program depends on the coordinated interaction between the primary (medical offices, polyclinics and diabetic care centers) and secondary levels of health (Angiology services of all hospitals).

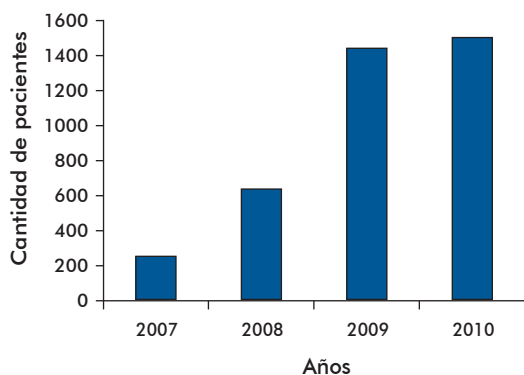


Figure 1. Behavior of the patient's inclusion process to the nationwide Program from June 2007 to July 2010.

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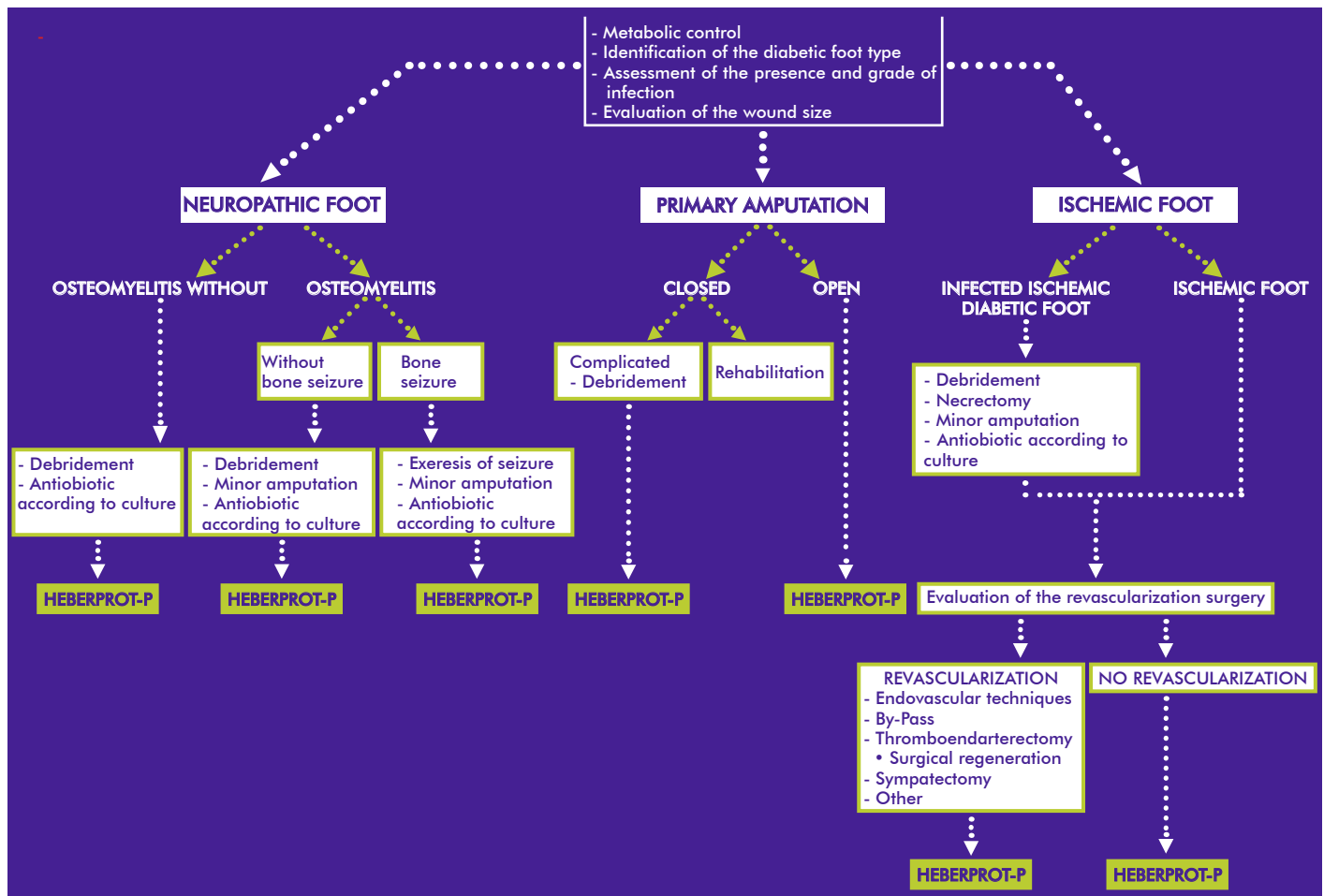


Figure 2. Practical behavior for the treatment of the diabetic foot ulcer with the use of Heberprot-P. Consensus from the NIAVS.

Secondary health care in Angiology services from hospitals

Inclusion criteria of patients to be assisted in the Angiology services from hospitals

End-stages diabetic foot patients will be assisted in these highly specialized clinical sites:

- Patients to high risk of suffering an amputation. They usually have more complicated ulcers, grades 3, 4 and 5 of the Wagner's classification.
- Patients with acute local infections.
- Decompensate patients with additional risk factors.

According to the evaluation of the specialist the treatment to this kind of patient might or might not include hospitalization.

Behavior to evaluate this kind of patient

- It is mandatory that the patient be evaluated by the endocrinologist or the diabetes specialist in the hospital or the polyclinic, respectively.
- The patient must be evaluated and assisted in an integral manner, not only his foot or lesion, but also considering other complications and risk factors to be sent to other specialties.
- As result of the proper care a rapid and positive evolution in the majority of patients is expected

between the first 48 and 72 hours.

- The metabolic control and the control of local infection are key elements contributing to reduce the level of complication of the lesion.

Duties of the angiologist

1. Perform the general medical examination to the patient together with the endocrinologist.
2. Treat in an integral manner the patient, taking into account all possible complications of this kind of patient (related areas: cardiology, nephrology, stomatology, etc.).
3. Define those cases for hospital admission and those for hospital ambulatory care and ambulatory primary health care.
4. Define the surgical procedure to each patient with the use of Heberprot-P.
5. Conduct the treatment with Heberprot-P following strictly the established practical behavior for the care of patients with this complication.
6. Define the fulfillment of treatment and when to discharge each patient.
7. Coordinate the remission of patient once discharged from hospital to be treated in ambulatory regime, or to be directly treated in the polyclinic, the medical office and/or the diabetic care center.

8. Attend as teaching institution in the training of specialists in general integral medicine, nursing, podiatry and/or nurses and podiatrists.
9. Coordinate and attend in the teaching of diabetic patients and relatives on the treatment of people with diabetes.
10. Keep a close interaction with all the primary health care.

Duties of endocrinologist

1. Establish metabolic control of patient as part of the integral care.
2. Integral care of patient taking into account all possible complications.
3. Diagnose all additional complications in the patient and send him to the required specialties (cardiology, nephrology, stomatology, among others). Once the general condition of the patient improves, with a clear positive evolution of his lesion, with previous evaluation by the specialist and in coordination with the primary health care, the patient could be sent to his community's care area and treated in ambulatory regime.

Primary health care (medical offices, polyclinics and diabetic care centers)

In this level, the physician of the consultation area for the diabetic integral care (qualified in diabetes and in diabetic foot), together with his team, formed by a nurse, a dietitian and a health educator, fulfill a rectorship function. The main objective in the primary health care is to prevent by protecting diabetic patients from developing foot ulcers through the control and the educational action. Despite the preventive action, within the Program it has been established that patients having less complicated ulcers can be assisted in this level of health.

Inclusion criteria of patients to be assisted in the primary health care

1. Patients with ulcers grades 1 and 2 of the Wagner's classification with the previous evaluation of the angiologist.
2. Patients coming from the Angiology service that can be assisted in the primary health care and continuous the follow-up at this level of health care.

Duties in the integral care of the patient with DFU in the primary health care

1. Carry out the control of the diabetic patients' database in their health care area and the systematic follow-up.
2. Organize and perform the active surveillance in the communities and medical offices for early detection of diabetic patients and with DFU, who must be remitted to the consultations for the integral care of the diabetic patient and/or specialized services.
3. Perform the physical and medical examination of patients arriving to the polyclinic or medical office to diagnose the type of diabetes and/or DFU.

4. Send decompensate patients and/or with complex DFU, requiring hospitalization and/or surgical procedures, to the Angiology service or specialized consultation at the hospital level.
5. Perform ambulatory treatment to patients with DFU arriving to consultation or remitted from the hospital Angiology services.
6. Send the patient to the specialist if any suspicion of complication during treatment arises.
7. Perform an educational action with the diabetic patient and his relatives in the diabetic integral care consultations and medical offices, in terms of proper diet, care of his feet, correct shoes wear and/or suitable insoles.
8. Maintain the training of health personnel in contact with patients requiring treatment in coordination with the Angiology services.

Impact indicators of the Program for the integral care of the patient with DFU with the use of Heberprot-P

In order to quantify the suitable functioning of the Program for the integral care of the patient with DFU with the use of Heberprot-P, the Cuban Ministry of Health proposed an assessment system measured through impact indicators. Figures will correspond to the period 2010-2011. They are shown below:

1. Proportion of cases with DFU treated with Heberprot-P. Measure criterion: 80% of the cases.
2. Correct register, file elaboration and follow-up by angiologists of all treated cases with Heberprot-P.
3. Incorporation of the Heberprot-P use into the surgical procedure usually followed by angiologists.
4. Proportion of consultations for the integral care of diabetic (health areas) where conditions for the treatment with Heberprot-P were created for those patients requiring such treatment. Measure criterion: 50%.
5. Amputation index per complications of the DFU. Measure criterion: 5%.
6. Control with insulin 100% of DFU patients treated with Heberprot-P.

Conclusions

The introduction of Heberprot-P into the Cuban health system has contributed to solve an unmet medical need as the healing of advanced diabetic foot ulcers. This Cuban product has become a novel technology for the treatment of this severe disorder that in many patients ends in amputation of their low-extremities.

The use of this drug is part of the Program for the integral care of the patient with DFU, established by the Ministry of Public Health of Cuba. The success of this Program relies on the closely linked and coordinated interaction between the primary and secondary levels of health.