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Treatment of Diabetic Foot Ulcers

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Abbreviations: DFU: Diabetic Foot Ulcer; IWGDF: International Working Group of the Diabetic Foot; LLA: Lower Limb Amputation

Opinion

Diabetic wound is the most common cause of non-traumatic lower extremity amputation, and response to traditional interventions is poor in many patients. The lifetime risk of developing an ulcer among diabetics is 25%, and recurrent wounds are common after healing. Stigmatization, social isolation, unemployment, and depression are some of the negative consequence of Diabetic Foot Ulcer (DFU) on the quality of life of diabetics. DFU adds a substantial economic burden to afflicted patients and health systems, primarily attributable to frequent hospitalization, medication, surgical procedures, amputation, prosthesis, rehabilitation, and loss of productivity.

Fran Game points out key issues that put into context advances on Research and Development (R&D) of medical solutions for DFU [1]. This comment and systematic reviews by the International Working Group of the Diabetic Foot (IWGDF) suggest that attention should also be paid to more critical issues of the DFU's global situation. First, R&D productivity on DFU has been low for a long time, and most treatments have been focused to low-grade, neuropathic ulcers, excluding high-grade ulcers, which are more likely to progress to amputation. A comparison of clinical trial data between 2012 and 2017 revealed a reduction in the amount of molecules under investigation by 26, according to a manually curated database.

Second, a relevant solution to treat advanced DFU has been developed in a country without resources to meet requirements of major regulatory agencies (FDA-EMA) [2]. This treatment has saved 3 600 people per year from Lower Limb Amputation (LLA) in Cuba from 2006, and would save more in the other countries, in case of regulatory approval. Health authorities from Turkey, Slovakia, Ukraine, Georgia, Belarus, Kazakhstan, Russia, and other countries have granted approval, after clinical trials, due diligence, and inspection in situ of manufacturing facilities and quality system, as a rational alternative to LLA [3].

On one hand, this medicine has been created in a developing country, but it is not available for DFU patients in developed nations, because obtaining regulatory approval would require unaffordable investments [4-6]. On the other, this medicine has been approved for commercialization in more than 20 countries, including several European territories, and one member of the European Union. A direct conclusion could be that patients from nations with the highest regulatory standards will probably have not access to innovative medicines created in developing countries, although being manufactured in compliance with current Good Manufacturing Practices [7-9]. Other innovative medicines developed in Cuba have been facing this challenge for more than 10 years, and a remarkable pipeline of more than 20 R&D biomedical projects point to that [10]. Therefore, it is not difficult to forecast a similar situation in other developing countries with less economic hindrances.

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