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Research Article

Evaluation of the Utility and Application of the Tardivo Algorithm to Predict of Amputation Risk of Diabetic Foot

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Abstract

Diabetes is a disease that affects about 422 million people in the world. It is associated with serious chronic complications, among which the diabetic foot stands out due to the rapidity with which it deteriorates the quality of life of these patients and can even lead to death.

Objective: To evaluate the usefulness of the application of the Tardivo Algorithm as a predict method for amputation risk in patients with diabetic foot.

Methods: The Tardivo Algorithm was designed to indicate the approximate risk of amputation in patients with diabetic foot injuries. Several parameters are used for their calculation, such as the staging of the lesions using the Wagner classification, the determination of peripheral arterial disease (using the ankle-arm index) and specifying the location of the ulcers. Based on their score system, we place patients in three categories: elevated amputation risk 12-32 points, moderate 8-11 and low 2-7 points.

Results: Twenty-four patients with mean age of 62 ± 9.8 years, were evaluated in the Diabetic Foot Sub-Unit during June to October 2015 and when using the Tardivo Algorithm, was found with a score of 12-32 points at 42% (n:10), a score of 8-11 to 25% (n:6) and a score of 2-7 to 33% (n:8) of the patients evaluated. Subsequently, in March 2016, 40% (n:4) of high risk patients were amputated, as were 17% (n:1) with medium risk.

Conclusion: The use of the Tardivo algorithm allowed us to make a prognosis of amputation risk and thus facilitate intensive treatment to prevent this serious complication.

Introduction

Diabetes is a chronic disease that occurs when the body cannot produce enough insulin or cannot use insulin efficiently, and is diagnosed by observing elevated blood glucose levels (hyperglycemia). Over time the constant levels of hyperglycemia cause damage to many tissues in the body, leading to the development of disabling and life-threatening health complications [1].

According to the most recent estimates of the World Health Organization (WHO), there are approximately 422 million adults with diabetes in the world and data from the International Diabetes Federation (IDF) there are about 318 million adults with glucose intolerance, which puts them at high risk of developing the disease in the future [1,2]. This number will continue to increase worldwide due to population size growth, urbanization, and high prevalence of obesity and sedentary lifestyle [3]. In Venezuela, the Ministerio del Poder Popular para la Salud (Ministry of Popular Power for Health) in its latest mortality yearbook, have pointed out that the diabetes was in the 5th place among the causes of death in the country [4].

Among the complications, Diabetic Foot (DF) stands out because it is considered one of the most feared conditions of diabetes, since it compromises the lower extremities and makes patients to be susceptible to possible amputations, decreasing their quality of life. It is a social, economic and psychological consequence for the patient and their family. For this reason, it is important to have a system that can predict in advance differences in the injuries of patients taking into account their level of complexity. It system should help, in such a way, that it is possible to discern the severity of the injuries, thus allowing the application of timely and effective treatments that favors the forecast of improvement of the same.

In a compilation of various studies concerning to the prediction of amputations in patients with DF, outstands the work of Tardivo and collaborators [5]. These authors have developed the "Tardivo Algorithm", which consists of a prognostic scale that allows assessment of diabetic foot based on three main factors: Staging of lesions using the Wagner classification, the presence of Peripheral Arterial Disease (PAD) using the Ankle-Arm Index (AAI) method as well as the location of ulcerations.

The Wagner's classification [6] for the application of this algorithm includes patients in grades I, II, III and IV (excluding grades 0 and V) by assigning the score corresponding to its grade (1 point to grade I, 2 points to grade II and so on).

The presence of PAD was detected by the AAI method and assigned a score of 1 to the absence of PAD and 2 to the presence of PAD, while for the location of the ulcers they set a score of 1 to the area of the toes, 2 to the foot, 3 to the midfoot and 4 to the heel area.

The final score is obtained by the product of the three factors (Wagner classification, PAD assessment and ulcer location) and may result in a score of 1 to 32. The higher the score obtained, the greater the probability of amputation for the patient with DF either a minor amputation (digital) or greater.

This work of biological-medical integration aims to evaluate the utility of the application of the Tardivo Algorithm as a predictor of risk of amputation in patients with DF. This is done with the aim of obtaining a prognosis of amputation risk and facilitating the accomplishment of an intensive treatment in such a way as to avoid amputation of the extremity of these patients.

Methods

A study was carried out in which 24 patients were selected through a probabilistic sampling in the consultation of the Sub-Unit of Diabetic Foot of the Department of Endocrinology and Metabolic Diseases in the Hospital Military "Dr. Carlos Arvelo" in the city of Caracas, in the period from June to October 2015 with a follow-up of the patients in March 2016 (5 months) after the initial evaluations.

Inclusion criteria incorporate adult patients between 25 and 85 years old male or female whose acceptance of the informed consent as well as a confirmed diagnosis of diabetes and diabetic foot syndrome in patients who were located in the Wagner classification between grades 1 and 4 without having suffered major amputations.

As for the exclusion criteria were those patients with total lower limb amputation, those with severe or terminal chronic renal and / or liver disease, patients with an acute decompensation of diabetes, affected by some malignant disease and individuals that will be in the rankings 0 and 5 of the Wagner classification.

Diabetic foot classification

Staging of lesions was performed using the Wagner classification (Figure 1).

Grade 0: Injury: Any, Characteristics: Foot at risk (deformity) Thick calluses, heads of metatarsals, Prominent, claw-shaped fingers, Bone deformities.

Figure 1: Wagner Classification.

Grade I: Injury: Surface ulcers, Characteristics: Destruction of the total thickness of the skin.

Grade II: Injury: Deep ulcers, Characteristics: It penetrates the oily skin, ligaments but without affecting the bone.

Grade III: Injury: Deep ulcer plus abscess (osteomyelitis). Characteristics: Extensive and deep, secretion, bad smell.

Grade IV: Injury: Localized gangrene. Characteristics: Necrosis of a part of the foot or fingers, heel or plant.

Grade V: Injury: Extensive gangrene. Characteristics: All affected foot, systemic effects.

For this study, patients belonging to the Wagner classification of grades (1, 2, 3 and 4) were included, assigning them the score associated with the respective grade.

PAD detection

It was performed using the Ankle-Arm Index method using a Nicolet Vascular Eco Doppler device, which presented an emission frequency of 5 MHz and a blood pressure monitor for manual blood pressure monitoring. Patients were placed in the supine position where they were kept at rest for 5 min prior to measurement.

The patient's arm was then taken and the zone that produced the most audible sound was searched with the Doppler transducer, and then the cuff pressure was increased by at least 20 mmHg above the patient's blood pressure and decreased to little pressure until sound became audible again, this value was scored and the procedure was repeated for the other arm and both patient's ankles. The maximum value of the arm and ankle was then selected and related to the following formula:

AAI= (Systolic pressure of the ankle)/ (Systolic pressure of the arm)

The value obtained was compared to the American Diabetes Association (ADA) rating table of PAD: normal (0.91-1.30), PAD: mild (0.90-0.70), moderate (0.69-0.4), severe (0.39), arterial calcification (> 1.3) [7].

The patients assessed were scored: 1 point for the absence of PAD and 2 points for those with PAD.

Location of ulcerations

Photographs of each patient's lesions were taken and the location of ulcerations in the foot (finger area, forefoot, and midfoot or heel area) was determined. And he was given the appropriate score depending on the location of the ulceration (Figure 2).

Figure 2: Location of ulceration. FF1 (Finger area): 1 point, FF2 (Fore foot): 2 point, HF3 (Mid foot): 3 point, HF4 (Heel area): 4 point.

Tardive algorithm

Scores corresponding to the three factors (Wagner classification, PAD, and location of ulcerations) were assigned to the patients using the algorithm proposed by Tardivo et al. (2015).

Based on the scores they use, for this study, patients were classified into three categories of amputation risk, the low level incorporated patients with 2 to 7 points, the mean level included those with 8 to 11 points and the elevated risk level was composed of patients with 12 to 32 points.

Subsequently, in March 2016 (5 months) after the initial evaluations, the patients were monitored in order to know the progression of their lesions and to identify the predictive value of the Tardivo algorithm.

Results

The age range of the patients evaluated was 43 - 79 years. The distribution of gender was equitable between women and men. In addition, the 63% of the patients evaluated presented a data of more than 10 years of evolution with diabetes. The 54% of patients said they did not follow any diet plan to control their diabetes. In addition, 79% of the patients evaluated indicated that they did not exercise because of their condition.

Using Wagner's classification, most patients were represented with grades III and IV both with 41, 7%, the rest were in grades I with 4.2% and II with 12.5%.

On the other hand, 54% of the patients had PAD (mild, moderate and arterial calcification), while the remaining 46% showed normal values and therefore absence of PAD.

After using the Tardivo Algorithm were found that 42% of patients had a high risk of amputation. Subsequently, in March 2016, after monitoring a patients, no were submitted to amputation surgeries those categorized with (low-risk), whereas 1 of the patients with (medium-risk) underwent an amputation procedure. And 4 of the patients of (high-risk) required processes amputation

In general, from the population sample, 25% of the patients after 5 months of treatment showed a recovery in lesions and were discharged clinic, meanwhile 54% although their lesions did not heal completely, showed an improvement over their initial state and finally 21% of the patients required minor or digital amputation surgeries.

Table 1: Demographic Characteristics.

Variables	Total (n: 24)		
Age (years) mean ± standard deviation	62 ± 9,76		
Gender, n (%)	Woman	12	50%
	Man	12	50%
Duration of Illness (years) mean ± standard deviation	14 ± 10,5		
Feed plan, n (%)	Yes	11	46%
	No	13	54%
Exercise, n (%)	Yes	5	21%
	No	19	79%

The amputations performed on the patients were as follows: 2 minor amputations (digitals), 1 trans-metatarsal amputation (5 fingers) and two major amputations of which 1 resulted in amputation of the foot and another amputation at the knee level.

Weeks after the evaluation of these results, one of the patients (the one who received amputation at knee level) died. This shows the severity of this disease and how the quality of life of the patients is reduced after having undergone a major amputation process.

Discussion

Diabetes is one of the greatest global health emergencies in the 21st century. It is a chronic disease that affects several organs of the body and every day increases the number of people who develop this condition. Among the complications, diabetic foot stands out because it is considered one of the most feared conditions of diabetes because it compromises the lower extremities and does patients susceptible to possible amputations, considerably decreasing their quality of life.

Diabetic foot syndrome is considered by WHO as the presence of ulceration, infection and / or gangrene of the foot associated with diabetic neuropathy and different degrees of peripheral vascular disease [8].

Proper care of diabetic foot ulcers requires a clear and descriptive injury classification system. This system should be used to guide clinicians towards the appropriate treatment for each injury, in addition to having some predictive capacity about the prognosis in each case [9].

The evaluated patients were equally distributed between women and men, so there was no evidence of predisposition in males, as observed in other related studies such as Al-Rubeaan et al. (2015), who found predominance of diabetic foot in male patients [10]. This may have been influenced by the size of the population sample used in this study (n: 24), so it is recommended to increase the number of patients for future studies.

In addition, the average age of the patients was 62 ± 9.76 years (range 43-79). Similar values were found in the study developed by Vera, Brito, Lares and collaborators (2012), the mean age of patients. They evaluated was 53.38 ± 13.01 years of which 73.8% presented more than 10 years of evolution with diabetes [11]. Similarly, the mean duration of the disease was 14 ± 10.5 years (range 1-40), where 63% had a history of more than 10 years of evolution with diabetes (as shown in Table 1).

It was found that 79% of the patients did not perform physical exercises and 54% did not follow a diet plan that facilitates them to maintain the care of their health. For this reason, it is recommended that diabetic patients make changes in their lifestyle and diet by incorporating healthy diets and maintenance of ideal body weight.

On the other hand, patients were staged according to Wagner's classification of lesions (as shown in Figure 3) where the patients were distributed in the different grades, most of them belonging to grades III and IV. The use of the Wagner classification was easy medical application in addition to being sensitive for the staging of the complexity of the severity of the lesions. It is fundamental a classification system that allows to differentiate the lesions of the patients taking into account the level of complexity of the same ones so as to be able to discern the severity of the lesions of the patients,

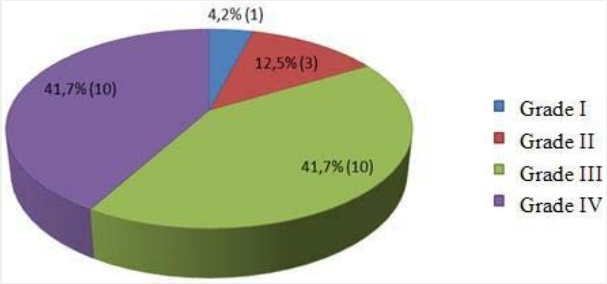

Figure 3: The status of diabetic foot injuries is represented using the Wagner classification method. Taking into account the presence of the lesion and its associated morphological characteristics, managing to group the patients in degrees I, II, III and IV.

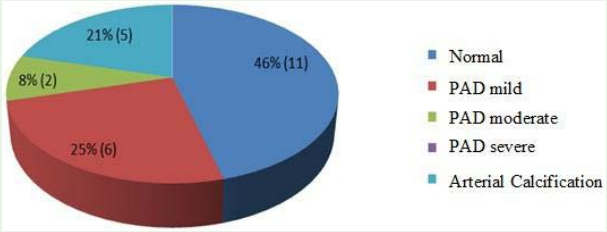

Figure 4: The assessment of peripheral arterial disease (PAD) was assessed using the ankle-brachial index (ABI) method using the reference values given by the American Diabetes Association (ADA) for the gradation of disease [normal (0.91-1.30), PAD mild (0.90-0.70), PAD moderate (0.69-0.4), PAD severe (0.39), arterial calcification (> 1.3)].

allowing the application of timely and effective treatments that favor the forecast of improvement of the same ones [9].

Peripheral Arterial Disease (PAD) is one of the fundamental pillars for the appearance of the diabetic foot, as it causes a decrease in blood flow to the limbs, which together with attenuation of pain perception, changes in pressure points and the existence of micro-traumatisms that go unnoticed may lead to the appearance of superficial lesions or ulcers [12]. In addition, involvement of the distal vessels of the limbs is typical and, together with microangiopathy and neuropathy, involve a poor response to infection and a specific scarring disorder, conditioning the risk of amputation up to 10 times higher than that of non-diabetic patients [13].

In this research the ABI method was used to evaluate the peripheral vascular function of the study group, the results are shown in Figure 4 where it is observed that 54% of the patients presented signs of disease (PAD) and its distribution was as follows: 25% were classified as mild PAD, 8% with moderate PAD, and 21% had arterial calcification, whereas 46% of the remaining patients did not present PAD.

The twenty-five percent (n:6) of the patients evaluated despite no symptoms such as intermittent claudication (numbness/cramping) or loss of sensory sensibility of the extremities were diagnosed with mild peripheral arterial disease, suggesting that the ankle-arm index method is efficient to detect the appearance of mild PAD even in its initial stages which favors the development of treatments that reduce the complications associated with this disease.

While those patients with moderate PAD are those at higher risk of progressing to a state of critical ischemia and therefore increase their chances of losing the lower limb, therefore these patients should be treated and initiate a therapy involving modification of their habits in order to reduce risk factors and thus reduce the risk of progression of this disease. And patients with arterial calcification showed pain in the muscle groups of their lower extremities, intermittent claudication, mild loss of sensation, and a decrease in the blood circulation of the legs, which was observed in the same aspect at the same time distinguish pallor and decrease in skin temperature compared to their upper limbs, revealing the presence of Mönckeberg's sclerosis.

In the study by Kannel and McLee (1970), it was found that less than 2% of patients with PAD required a greater amputation and in patients with claudication the best predictor of disease progression was AAI [14]. One of the elements that make the Ankle Arm Index (AAI) for the diagnosis of Peripheral Arterial Disease (PAD) especially interesting is the low variability in the same patient between two different moments, making it useful to assess the progression of the disease. Its transcendence surpasses the role of a diagnostic tool in arterial disease to become a prognostic tool for atherosclerotic patients [15,16].

The determination of PAD by the AAI method showed to be efficient in detecting the different degrees of this disease from its initial stages such as mild PAD to advanced states such as arterial calcification.

When applying the Tardivo Algorithm in order to know the risk of amputation of the patients evaluated the patients were classified into three categories of amputation risk, the low level incorporated patients with 2 to 7 points, the mean level included those with 8 to 11 points and the high level of risk was composed of patients with 12 to 32 points. These data are presented in Table 2; it is noteworthy that 42% (10) of the patients presented an elevated risk of amputation.

Subsequently, in March 2016, the patients in the study were followed up (5 months after the initial evaluations) in order to know the progression of their lesions. And it was found that 25% of the patients were discharged for clinical cure of the lesions, while the other 54% at the end of this study had not completely healed their lesions, however a considerable improvement was seen in them

Table 2: Distribution of patients according to the score obtained with the Tardivo Algorithm.

Risk	Score	Patients (n: 24)		Post evaluation (5 months)		
				Clinical cure	Injury improvement	Amputation
		n	%	n	n	n
Low	2-7	8	33	2	6	0
Medium	8-11	6	25	2	3	1
High	12-32	10	42	2	4	4

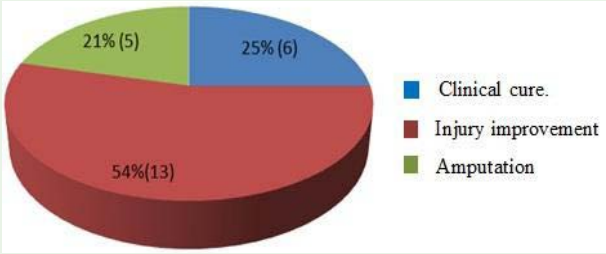

Figure 5: The condition of the diabetic foot injuries is evidenced after 5 months of treatment, most patients improved the state of their injuries, in other cases they healed completely and a small group was submitted to amputations in their lower extremities.

compared to their initial conditions and finally 21% of the remaining patients underwent amputation surgery, these data are observed in Figure 5.

The amputations that were performed were the following: two of them received a minor (digital) amputation; another patient was amputated with 5 fingers, while the remaining two underwent major surgery where one of them had an amputation of the foot and the other an amputation to the level of the knee.

Observing these results, we can say that the predictive value of the Tardivo algorithm was demonstrated since the patients who underwent amputation were in the medium or high risk category, whereas none of the patients in the mild category were amputated. It was also evidenced that the work performed in the diabetic foot sub-unit favored the patients to heal or improve the status of their injuries both for patients classified with the algorithm as mild, moderate or severe.

The results obtained during the accomplishment of this work show the importance of the early detection of treatable diseases and the recognition of other risk factors in patients with diabetes and diabetic foot injuries to improve the prognosis of cure of their injuries as well as their quality of lifetime. As otherwise the patient is at high risk of amputation which will greatly reduce their chances of recovery.

Conclusion

The Tardivo algorithm proved to be sensitive in the staging of severity of the diabetic foot lesions. It also demonstrated its predictive value of amputation processes.

The results suggest the importance of the evaluation of Peripheral arterial disease, the use of Wagner's classification and location of ulcers as part of an initial assessment and follow-up of the lesions of these patients.

It is recommended to incorporate the application of the Tardivo algorithm as a predictor of amputation risk in the diabetic foot sub-units thus performed intensive and timely treatments that favor the improvement of these injuries. In addition, the development of talks and awareness campaigns about this serious condition in the diabetic population must be increased.

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