

EVALUATION OF THE EFFECTIVENESS AND SECURITY OF THE USE OF DRESSINGS FOR INJURIES TISSUPOR® 3D EMBROIDERY IN PATIENTS WITH NEUROPATHIC DIABETIC FOOT ULCERS

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CONFORMATION OF THE CONTROL GROUP

Group	Medical unit	number of patients
CONTROL	HOSPITAL GENERAL REGIONAL CON MEDICINA FAMILIAR #1 in CUERNAVACA, MORELOS.	43
	women	15
	men	28

CONFORMATION OF THE INTERVENTION GROUP

GROUP	MEDICAL UNIT	NUMBER OF PATIENTS
INTERVENTION HGZ MF5	HOSPITAL GENERAL DE ZONA CON MEDICINA FAMILIAR #5, ZACATEPEC, MORELOS	35
	WOMEN	14
	MEN	21
INTERVENCION HGZ MF5A	HOSPITAL GENERAL DE ZONA CON MEDICINA FAMILIAR NUM. CINCO, ZACATEPEC, MORELOS	23
	WOMEN	13
	MEN	10
	TOTAL	58
	WOMEN	27
	MEN	31

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3 CONCLUSIONS

The entire population of the study were 101 subjects. 43 subjects in HGR MF1 Cuernavaca y 58 subjects in HGZ MF5 Zacatepec. 28 men, 15 women in HGR MF1 Cuernavaca, 31 men, and 27 women in HGZ MF5 Zacatepec.

The total number of ulcers were 143. From the patients of the Unit HGR MF1 Cuernavaca the number of ulcers were 52, from which 23 were Wagner 1 y 29 Wagner 2, while in Unit HGZ MF5 Zacatepec were 91, from which 57 were Wagner 1 y 34 were Wagner 2.

1,485 wound healing procedures were performed in all the patients. In the Unit of HGR MF1 Cuernavaca the average of wound healing procedure for patients with Wagner 1 and Wagner 2 classification was of 26.63 and 24.92 respectively, additionally to the non-assisted procedures. While for the patients treated in the Unit HGZ MF5 of Zacatepec with Tissupor 3d Embroidery dressing with Wagner 1 y Wagner 2 classification was of 11.0 and 11.72 wound healing procedure in average respectively.

In a generalized analysis with all the values and all the patients, while making the analysis of the difference of means according to the % of the reduction area, it was observed that of the Levene test the p-value is meaningful and it is assumed that different variances exist. Thus, the test statistic equals $t = -.860$ and the associated p-value equals 0.00. Therefore, there is a difference in both Units where the patients were treated, and the means are different to 95%. Likewise it was observed that there are gender differences in the response to the treatment in men ($p = 0.000$) (Stata 12.0).

These results allow us to conclude that the patients of HGZ MF5 Zacatepec treated with Tissupor 3d Embroidery dressing, have a better % of area of reduction compared with the patients of Cuernavaca, that received a conventional treatment; which is statistically significant, even with the losses in the follow up and the quitting patients ($< 30\%$). So that is relevant to take into account the treatment with Tissupor 3d Embroidery dressing to improve the prognostic of patients with diabetic foot and prevent amputations in the compromised limb. Consequently, it would be relevant to perform another investigation that measures the impact of the cost-benefit; since in this investigation it was possible to determine that the number of wound healing procedures diminishes in frequency in more than 50% of the patients treated in the Medical Unit of Zacatepec with the Tissupor 3d Embroidery dressing compared to the patients that received the conventional treatment in the Medical Unit in Cuernavaca. This has implications, not only in the substantial saving in wound healing materials, but in the need of prescribe treatment with multiple antibiotics, as in the case of the patients treated with the Tissupor 3d Embroidery dressing (Petruyte S, 2008), the use of antibiotics is generally spared, giving priority to the topical treatment. In addition to this, a reduction on the number of transfers of the patient for the wound healing procedure is observed; or that the ambulatory unit goes to make the procedure at the patient's home; generating a saving in hours- men of work, fuel and even on the wear of the primary taker, that attends the sick patient at home.

On the other hand, it was possible to observe from a clinical point of view, that in the group of patients treated in the Unit of HGZ MF5 Zacatepec classified in Wagner 1, and that received treatment with the dressing, presented a much faster evolution to cicatrization compared with the subjects of the Unit HGR MF1 of Cuernavaca who received the conventional treatment. This argued by the obtained results; for example: in 7 patients that were discharged by healing with Wagner 1 ulcers. In the case of the patients of the Unit HGR MF1 of Cuernavaca, it was observed that they present a much slower evolution towards cicatrization, and merit a closer follow-up because they can easily relapse. This depends essentially on the patient's rest. It was also found that the wounds are not easily infected. The wound healing procedure shouldn't be too energetic.

In relation to the patients with Wagner 2 classification, it was found that they could easily evolve to Wagner 3. In this sense, the key to success in these patients is the debridement. Likewise, the

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moisture keeps the wound in good condition. The healing procedures with debridement make that the wound evolve faster towards cicatrization. It was determined that holding a longer pressure over the wound rapidly evolves towards necrosis. Some evolve faster from the inflammatory stage to the proliferative stage. Within the same proliferative stage, it is quicker to evolve from the angiogenesis to the granulation, than from granulation to reepithelization. All of the above is largely determined by an optimal metabolic control.

In the cases treated in the Unit HGZ MF5 of Zacatepec with the use of the dressing, it was observed that in very small ulcers, it is difficult to fix the dressing, and this is accentuated by the use of inadequate footwear, increasing the risk of the dressing moving out of the ulcer, so it is important the use of diabetic footwear.

In summary, it is assumed that the diabetic foot in its more advanced stages (Wagner 2, 3 and 4) (Martínez de Jesús, et al, 2012) is one of the most severe complications for patients with DM2, because it generates functional dependency, and progressive and permanent disability (even early death) (International Diabetes Federation, 2014), with years of productive life lost, that has implications to the health system, the society and essentially to the family. This generates an important load for the main keeper that is usually the wife or husband, or the closer son or daughter. Because it's important to remember that chronic patients, require chronic cares, nevertheless through time, this support of the family network tends to deteriorate, this is why the innovations on the treatment of diabetic foot are the corner stone to keep the mobility of the patients with this kind of complex affections; in a time of limited resources, where chronic diseases and their complications have surpassed the Institutions (Wong R, et al, 2012)

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Table 1. Number of Wound healing procedures Number of Wound healing procedures per patient according to the Unit			
Unit Cuernavaca HGR MF1 (Average of Procedures per patient with conventional treatment/dressing)		Unit Zacatepec HGZ MF5 (Average of Procedures per patient with non-conventional treatment/dressing)	
Wagner 1	Wagner 2	Wagner 1	Wagner 2
26.63	24.92	11	11.72

Table 2. % of reduction area					
	Medical Units	N	Mean	Standard Deviation	Std. Error Mean
		Reduction Area (%)	CUERNAVACA	52	,120
	ZACATEPEC	91	,308	,3633	,0379

Table 3. % Area of Reduction. Test of independent samples										
		Levene test for the equality of variances		Test T for the equality of means						
		F	Sig.	t	df	Sig (2-tailed)	Mean difference	Std. error difference	95% Confidence interval of the difference	
Reduction area (%)	equal variances assumed	37,4285	,000	-3,470	146	,001	-,1877	,0541	Lower	Upper
		Equal variances not assumed			-3,860	145,824	,000	-,1877	,0486	-,2839

Date:

Signature: