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Neuropad: Validation of a new indicator plaster as a screening tool in identifying patients at risk of foot ulceration – a multicenter study

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Sensory loss is considered as one of the most important factors predisposing to foot ulceration (FU). Small fiber neuropathy contributing to sensory loss and anhydrosis as a consequence of sweet glands denervation can facilitate the process of ulceration. Since a new indicator (Neuropad) changes its color if moisture is present, this study was undertaken to validate this plaster as a simple screening tool to identify high risk patients for FU in a large population.

Patients – Methods: 506 diabetic patients (type 2) were included (47,5% males) mean age $64,9 \pm 12,1$ and mean known duration of diabetes (yrs) $10,4 \pm 8,4$. All the patients underwent a detailed clinical examination (testing ankle and knee reflexes, sensory signs for pain, thermal, light touch and vibration perception). In all the patients this indicator (Neuropad) was applied in the planter surfaces and partial change and/or the stability of its color (Neuropad positive) were recorded.

Results: a) 190 (37,5%) patients were recorded as Neuropad positive (Group A) and the remain were classified as Group B-neuropad negative). b) Bivariate analysis: Group A compared to group B has longer duration of diabetes and were older ($12,11 \pm 8,41$ vs $10,44 \pm 7,7$ $p < 0,05$ and $64,9 \pm 10,47$ vs $62,42 \pm 10,73$ $p < 0,05$ respectively). More severe neuropathy was detected in Group A (Neuropathy disability score-NDS $5,8 \pm 4,18$ vs $1,92 \pm 1,32$ $p < 0,05$) c) Multivariate analysis: Neuropathy score for small fiber dysfunction (NDS_1), overall nerve dysfunction (small and large fiber – NDS were the most powerful variables - $p < 0,05$ - logistic regression stepwise model) for the neuropad positive results. d) Overall predictive value of the new indicator to identify neuropathic patients was 79,3%.

Conclusion: The present multicenter study clearly showed that the new indicator could be useful as a screening tool to detect patients at risk of foot ulceration.