Conclusion: There have been few reports evaluating the usefulness of a heat pad for RP. The wrist mounted disposable heat pad was thought to be a heating method having the potential to achieve high levels of usability and practicality on CTD patients presenting with RP. Given that the heat pad alleviated RP or caused sites other than where the pad was mounted to be felt warm even though it did not directly heat the hands and fingers, the pad seemed to have usefulness attributed to the heating of the wrist. Although the heat pad seems to be an excellent method for addressing RP in patients' daily lives, we hope that this heat pad will be evaluated on a larger number of patients with the addition of objective indices.

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TOFACITINIB IN THE TREATMENT OF SKIN AND MUSCULOSKELETAL INVOLVEMENT IN ADULT PATIENTS WITH EARLY SYSTEMIC SCLEROSIS, EVALUATED BY ULTRASOUND

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Background: The whole management of systemic sclerosis (SSc) remains to be defined while trials mainly focus on the treatment of different organ involvement and disease-modifying treatments are still not available.

Objectives: To assess the safety and efficacy of tofacitinib (TOF) treatment on skin and musculoskeletal involvement as compared to methotrexate (MTX) treatment in patients with early SSc.

Methods: In this 52-week, prospective, investigator-initiated, open-label, single-centre study, 66 patients with SSc were enrolled. Thirty-three patients received 5mg of oral TOF twice a day; and thirty-three received 7.5-10mg of MTX weekly. The primary outcome measures were: skin fibrosis improvement at week 26, assessed by the reduction in skin thickness - evaluated by the modified Rodnan skin score (mRSS) and the ultrasound (US) measured skin thickness; improvement in the musculoskeletal involvement, assessed by the reduction in the joint and tendon score (US10SSc score); and adverse events from baseline to week 26. The dynamics in the outcome measures within each group were examined through Wilcoxon tests and between-group comparisons were performed through Mann-Whitney U and Chi-square tests.

Results: At baseline, both groups of patients had similar median scores with no significant differences on all measures: mRSS ($p = 0.589$), US measured skin thickness ($p = 0.822$), and US10SSc score ($p = 0.918$). At week 26, significant differences were observed between the two treatment groups as the TOF treated patients showed a greater reduction in mRSS and musculoskeletal manifestations. In the TOF group, the median mRSS score decreased by 50% from 24 to 12 (IQR = 7.50) versus a smaller decrease of 8.70% in the MTX group, from 23 to 21 (IQR = 8.00), $p < 0.001$. The median US measured skin thickness in the TOF treated patients decreased by 12.87% from 1.71 to 1.49 (IQR = 0.31) versus a decrease of 4.73%, from 1.69 to 1.61 (IQR = 0.52)

in the MTX group, $p = 0.040$. The US10SSc median score in the TOF group decreased by 56.25% from 16 to 7 (IQR = 6.50) versus a decrease of 12.5% in MTX group from 16 to 14 (IQR = 10.50), $p < 0.001$. There was no significant difference between the groups in the number of adverse events from baseline to week 26. No cases of herpes zoster and deep vein thrombosis were observed in the TOF group.

Conclusion: The data show that in early SSc TOF may lead to a significant improvement of skin thickness, measured with the mRSS and US, and of the musculoskeletal involvement, measured by the US10SSc score. TOF has also shown a satisfactory safety profile.

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Figure 1. Panel A - Dynamics in mRSS between baseline and week 26 in the MTX group; **Panel B** - Dynamics in mRSS between baseline and week 26 in the TOF group.

Figure 2. Panel A - Dynamics in skin thickness between baseline and week 26 in the MTX group; **Panel B** - Dynamics in skin thickness between baseline and week 26 in the TOF group.

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