inadequate or limited by side effect. Cannabidiol-CBD, is the major non-psychoactive component of the Cannabis sativa, recent studies on its effectiveness as an anxiolytic, anti-inflammatory, and antipsychotic drug showed promising results, in the setting of chronic pain too.

Objectives: We evaluated the efficacy of CBD drop in pain management in a cohort of SSc patients using standard rating scale VAS, PSQI and HAQ. We further assessed the safety profile and the potential use as opioid-sparing.

Methods: From January to November 2019 we consecutively enrolled 31 SSc patients (FM 26/5, mean age 53.0±14.3SD-years) referred to our Scleroderma Unit. All patients satisfied the EULAR/ACR SSc classification criteria. All cases were complicated by painful DUs resistant to analgesics and pain was classified as severe, according to WHO guidelines. CBD drops consist of cannabis sativa seed in olive oil, 10% CBD, laboratory-tested to confirm a tetrahydrocannabinol-THC level<0.3%. The CBD oil was administered sublingually twice-a-day. All patients started with CBD drops twice-a-day, and progressively increased to the maximum dosage of 6 drops twice-a-day (from 27.6g to 55.2g dose/day). All patients continued local/systemic treatments for SSc: 24/31 subjects performed calcium-channel blockers, 31/31 prednisone infusion, 24/31 anti-endothelin drugs. All subjects were provided with a daily diary to record self-evaluation of pain using VAS, PSQI, hours of sleep per night, use of other analgesics, eventual side effects. HAQ-DI was also administered. These indicators were assessed baseline and during follow-up. Safety of CBD was evaluated by patient’s records of side effects. All data were analyzed by paired t-test. This investigation was a monocentric, prospective study. Ethical approval was obtained from the Competent Ethics Committee (protocol n. 282/15) and all participants gave written consent.

Results: CBD was administered for a mean period of 5.9±3.2SD-months. After the first month, VAS decreased from 54.8±8.7SD to 54.7±9.4SD (p<0.001), PSQI decreased from 4.27±2.9SD to 4.42±1.09SD (p<0.001), total hours of sleep increased from 2.56±1.28SD to 5.67±0.85SD (p<0.001). The additional analgesic therapy was necessary in 22/31 patients: 6/22 only paracetamol, 12/22 paracetamol-oxycodone reducing the dosage of oxycodone at the minimum, 2/22 oxycodone 20 mg twice-a-day, 2/22 need fentanyl transdermal patch. After 3 months, VAS further reduced to 40.9±12.9SD, PSQI decreased to 3.1±1.45SD, the mean total hours of sleep per night was 6.10±0.79SD and the HAQ-DI decreased from 2.19±0.67SD (baseline) to 0.79±0.46SD at the last patients’ evaluation. At the end of the observation, 18/31 patients (58%) showed DUs healing. We also interestingly reported improvement of dysphagia and appetite in 70%, and an improvement in constipation related to opioids in 48%. No patients experienced severe side effects in particular no psychoactive aspects. Mild side effects, namely dry mouth was referred by 9/31 (29%), mild abdominal pain and changes in appetite by 10/31 (32%). No interaction with other drugs was observed.

Conclusion: Our study suggests that oral CBD is effective and safe in maintaining analgesia in SSc patients with DUs. Furthermore, CBD could be helpful in opioids tapering and to treat dysphagia, even if these observations need focused investigations. In conclusion, CBD might be a useful tool to manage chronic pain in SSc-DUs. These data provide compelling rationale for further research investigations. In conclusion, CBD might be a useful tool to manage chronic pain opioids tapering and to treat dysphagia, even if these observations need focused investigations.

Disclosure of Interests: None declared

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Figure 1. Survival of 85 Olmsted County residents with SSc compared with expected survival rates from Minnesota lifetables (observed: solid line, expected: dashed line).

Disclosure of Interests: None declared

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Background: Systemic sclerosis (SSc) is a complex immune-mediated disease with heterogeneous manifestations, which is characterized by vasculopathy and fibrosis of the skin and visceral organs. Mortality associated with SSc exceeds that of other rheumatic diseases, though population-based studies assessing mortality rates from Minnesota lifetables (observed: solid line, expected: dashed line).

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Background: Sarcopenia can be age associated (primary form) or secondary to chronic disorders, including rheumatic inflammatory disorders. Systemic sclerosis (SSc) is a chronic autoimmune rheumatic disease characterized by widespread vasculopathy, progressive fibrosis of the skin and other internal organs, such as lungs, kidneys, gastrointestinal tract, cardiovascular system. Different from the other chronic rheumatic inflammatory (scleroderma) disorders, sarcopenia has not been well evaluated in SSc patients.