



APPLICATION FOR WSF SPECIAL WORKING GROUPS

Principal Investigator: Dr Michael Hughes

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Description of the project:

Digital ulcers (DUs) are a major cause of pain and disability in patients with systemic sclerosis (SSc).

Despite a range of available treatments, around one-third of patients are affected by DU refractory to the majority of treatments.

Indeed, DU have a significant impact on all aspects of patients' personal, social and family life including occupation.

Today, there is significant variation in clinician's management of DUs internationally, including wound bed management (e.g., debridement).

Moreover, the assessment of DU burden including clinical practice and trials has been challenging. However, promising advancements have been made including ulcer ultrasound, composite (e.g., DUCAS) and patient reported (e.g., SSiDU) outcome measures.

Hypothesis: Our community may optimise the treatment strategies concerning local wound bed management as well as the systemic therapy in order to improve quality of life of SSc patients.

Aim: provide a homogeneous and rational recommendations for the local and the systemic management of DU in practice.

Objectives:

1. To identify unmet needs of patients relating to SSc-DUs.
2. To develop WSF-supported recommendations relating to the local wound management and systemic treatment of SSc-DUs.
3. to support the development of novel methods to assess DUs including (but to limited) to patient reported outcome measures, definition,

composite outcome measures, and ultrasound.

Methods:

Step 1: Creation of an international task force (doctors, patients and nurses) as a WSF Working Group consisting of worldwide experts in SSc-DUs. The participating task force members are named below but will be further supplemented with additional EUSTAR, SCTC, Japanese, Chinese and Korean members to ensure representative geographical representation.

Step 2: Undertake an international survey of clinicians and patients with an interest in SSc-DUs to identify unmet needs and understand the differences in DU management. A web-based survey shall be developed to easily record the opinions of patients (including via patient-led organisations) and clinicians (including membership of EUSTAR and the SCTC).

Step 3a: Task force development of the guidelines. Dedicated systematic literature reviews (SLR) will be undertaken to support the development of the guidelines. These shall be presented to the Task force along with recommendations for guideline items for discussion including possible addition of new items. Online voting rounds will be used to decide on whether items should be accepted in the final guideline. An item will be immediately accepted if >75% of the task force members voted for it. For items where this is not achieved, the text will be amended and subjected to a second voting round, where a 67% majority will be required. For items not included after this, the text will be revised a third time and subject to a final voting round, which >50% is required to include. After this, each item, as agreed by the task force, will received an appropriate level of evidence and strength of recommendation based upon the SLRs. The level of agreement will be assessed using online voting on a 0-10 scale where 0 means no agreement and 10 full agreement.

As above, additional EUSTAR, SCTC, Japanese, Chinese, Korean members to ensure representative geographical representation. Experts in wound bed management (including debridement) will be recruited to the local wound management guideline.

Step 3b: identify potential collaborative projects and suitable external funding to develop novel methods to assess DUs within the Working Group.

Statistical approach: Descriptive statistics and appropriate statistical analyses will be used to report and describe the data.

Milestones (24 months – 01/2021 to 01/2023):

- January-February 2021: *Assemble task force for the DU Working Group.*
- February- May 2021: *task force survey, involvement of EUSTAR centres*
- May- October 21: *Wound bed treatment recommendations development*
- Late 2021- mid 22: *Systemic treatment recommendations development.*
- Middle 2021 to Late 2022: *Developing novel methods to assess DUs/collaborative research projects including funding applications.*
- January 2021 – Late 2022: *Search for funding and progressive setting of future research agendas.*

Importance to patients

Optimised approaches to the treatment and assessment of DUs will improve quality of life and function for this very challenging and painful manifestation of SSc.

Participants (in alphabetical order):

1. Professor Yannick Allanore (F)
2. Dr Murray Baron (CA)
3. Dr Francesco Boin (USA)
4. Professor Eun Bong Lee (K)
5. Dr Cosimo Bruni (I)
6. Dr Lorinda Chung (USA)
7. Professor Christopher Denton (UK)
8. Professor Oliver Distler (CH)
9. Professor Chingching Foocharoen (Thailand)
10. Dr Tracy Frech (USA)
11. Professor Dan Furst (USA)
12. Professor Dilia Giuggioli (I)
13. Professor Ariane Herrick (UK)
14. Dr Laura Hummers (USA)
15. Professor Dinesh Khanna (USA)
16. Professor Thomas Krieg (D)
17. Professor Masataka Kuwana (Jp)
18. Professor Eun Bong Lee (Ko)
19. Professor Meng Tao Li (China)

20. Professor Marco Matucci-Cerinic (I)
21. Dr Mandana Nikpour (AU)
22. Dr John Pauling (UK)
23. Prof Susana Proudman (AU)
24. Dr Shefali K Sharma (India)
25. Dr Kamal Solanki (NZ)
26. Dr Yossra Suliman (UAE)
27. Prof Hidetaka Yasuoka (Jp)
28. Dr Yukai Wang (China)

Still, to be identified: patients, nurses, dermatologists

Enlarged Task Force: EUSTAR, SCTC, Japanese, Chinese, Korean members

Detailed Budget:

- Online survey manager €2000
- Open access peer-reviewed publications to facilitate dissemination of knowledge (X2): €3000
- Administrative support: €500

Grand Total: 5500 (2750 x year)
