Assessment of prostanoids (Iloprost, Alprostadil) efficacy in treatment of ulcers in patients with systemic sclerosis.

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Background

The prostanoids are currently regarded as the most effective agents in treatment of ischemic lesions in patients with rheumatic diseases. However, the efficacy of Alprostadil is underexplored, especially in comparison with Iloprost.

Objectives

To evaluate the efficacy of Alprostadil (Vazaprostan®) and Iloprost (Ilomedin®) in treatment of digital ulcers in SSc pts using modern assessment tools (questionnaires and designated forms) of digital ulcers.

Materials and methods

This 1 year study included 42 patients with systemic scleroderma (SSc) aged > 18y, having digital ulcers. Standard evaluation procedures and questionnaire to assess therapy, as well as scales and questionnaires for assessment of digital ulcers were used at baseline and after 12 months. The therapeutic regimens were as follows: Alprostadil at 20 mg/kg i/v drip rate infusion during 10 days, 1 course in 6mo (totally 2 courses). Iloprost at 20 mg/kg i/v via infusion pump during 5 days each 3 months (totally 2 courses).
The following questionnaires/forms to evaluate the therapy of digital ulcers were used: 1/ VAS for pain assessment, 2/ SSc-HAQ, 3/ Cochin hand function scale, 4/ the total hand pain score, 5/ global patient's assessment of ulcers, 6/ global physician's assessment of ulcers, 7/ patient's evaluation of changes in ulcers, 8/ physician's evaluation of changes in ulcers 9/ number of digital ulcers.
The patients were evaluated after the drug infusion and 1 year later. Clinical and demographic characteristics of patients treated with vasoactive drugs are presented in Table 1.

Table 1. *Clinical and demographic characteristics of patients with digital ulcers*

	Ilomedin®	Vazaprostan®
N	22	20
Females(%)	100	90
Age	46,7 (± 9.9)	41.9 (±12.9)
Diffuse SSc(%)	36.4	14.3
SSc duration(yy)	13.9	10.8
N of ulcers (baseline)	3.3 (± 2.2)	1.7 (± 1.03)

*Mean ±SD

Results: The results obtained show improvement of ischemic lesions in both groups. The comparison of results speaks in favor of Vasoprostan vs Ilomedin in terms of significant pain reduction, Table 2.

Table 2 *Comparative characteristics of scores and values from different assessment tools in groups treated with Vasoprostan and Ilomedin (post-treatment).*

	Ilomedin®	Vazaprostan®
HAQ-SSc	1.49	1.18
HAQ	1.22	1.18
Cochin score	16.38	22
VAS	46.61 *	27.12 *
Physicians Global assessment	3.8	3.5
Patients Global assessment	4.61	3.75
Ulcers N	3.07	1.16

* $p<0.05$

Conclusion

Conclusion: It should be noted that certain degree of positive dynamics in healing of ulcers was established by practically all assessment tools. VAS looks like the most sensitive tool in evaluation of pain. Of importance is the fact, that despite marked ischemic lesions and digital ulcers, the Cochin score reflecting hand functional capacity did not exceed average values at baseline and did not change significantly post-treatment.

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