

## Audit Evaluating Pharmacological Therapies used to treat Raynaud's Phenomenon in the Rheumatology Department, Freeman Hospital, Newcastle upon Tyne

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### Background

Raynaud's phenomenon (RP) is a clinical syndrome most commonly primary in nature and relatively benign. However, RP can be the first presentation of a variety of underlying diseases, including systemic sclerosis (SSc): a rare, multi-organ autoimmune connective tissue disease. If severe, RP can result in digital ulceration (DU) and significant morbidity. Treatments available include phosphodiesterase-5 inhibitors (PDE5i), intravenous prostanoids and endothelin-receptor antagonists (ERAs), as approved by NHS England's clinical commissioning policy.<sup>1</sup>

### Aim

To evaluate the use and effectiveness of PDE5i, IV epoprostenol and ERAs for the treatment of RP/DUs within the Department of Rheumatology, Newcastle upon Tyne.

### Methods

Patients were identified at random from a departmental database of current drug prescriptions for RP patients. A detailed structured questionnaire was formulated and posted. Patient demographics (age, sex, smoking status, occupational status), underlying diagnoses and duration of RP, current and previous pharmacological treatments, improvement to DU with treatment and quality of life data were collected. Current treatments were categorised as: sildenafil alone, epoprostenol alone, sildenafil + epoprostenol, bosentan + sildenafil, and triple therapy (bosentan, sildenafil and epoprostenol).

### Results

44 of 72 (61%) questionnaires were returned. Of the total population: male to female ratio was 1:3, mean age was 64 years and age range 30-87. Distribution of patient-reported diagnoses was: 64% primary RP, 43% limited cutaneous (lc)SSc, 32% MCTD, 25% diffuse cutaneous (dc)SSc and 11% other diagnoses. 33 patients reported more than one diagnosis.

	All patients	Sildenafil only	Epoprostenol only	Sildenafil + epoprostenol	Bosentan + sildenafil	Triple Therapy
Patient numbers (n)	44	21	8	10	4	1
Mean duration of RP (years)	16.2	13.7	16.1	14.8	34	12
Functional improvement reported with treatment (n)	21	7	6	6	2	0
Pain score (% improvement)	23.0 %	29%	16%	34%	9%	0%
Current features of low mood (n)	19	8	3	5	2	1
% reduction mean number of DUs with treatment	71%	50%	100%	100%	63%	56%
% reduction mean duration of DU with treatment	98%	36%	100%	98%	0%	Unanswered
Summer DU before versus after treatment (n)	16 vs 6	5 vs 3	3 vs 0	4 vs 1	3 vs 2	1 vs 0
Antibiotics for DU before versus after treatment (n)	11 vs 4	3 vs 2	2 vs 1	2 vs 0	3 vs 2	1 vs 0
Admission for DU before versus after treatment (n)	9 vs 6	2 vs 0	1 vs 1	2 vs 2	3 vs 3	1 vs 0

**Table 1: Summary of study findings, comparing treatment categories**

### Conclusions

A definite improvement in symptoms and function was reported in more than 50% of patients. Table 1 summarises the key findings from this study, predominantly focusing on the reported effectiveness of treatment. The greatest reduction in pain was demonstrated with dual epoprostenol and sildenafil treatment (90% primary RP), however, epoprostenol treatment alone gave the greatest improvement in activity levels and number/duration of DU (63% primary RP). The number of patients receiving bosentan is small. Patients prescribed bosentan generally have more severe disease of greater duration at therapy initiation, possibly explaining lower response rates. This study provides the basis for further discussion and possibly further study for optimal use of currently available RP treatments.

## References

1. Clinical Commissioning Policy: Sildenafil and bosentan for the treatment of digital ulceration in systemic sclerosis. NHS England. 2015