

INTRODUCTION

Calciphylaxis or calcific uremic arteriolopathy is a rare disease characterized by ischemic cutaneous ulcerations and necrosis of skin, subcutaneous fat and visceral organs due to calcification. Sodium thiosulfate (STS) has been used to treat calciphylaxis in end-stage renal disease (ESRD). Though the mechanism of action involves mobilization of calcium, the effect on markers of mineral bone disease (MBD) has not been explored. We examined markers of MBD in a large population of dialysis patients treated with STS.

METHODOLOGY

- A retrospective analysis of 203 dialysis patients treated with STS from 01/01/09 to 12/31/09 was completed at a large US dialysis organization. Patient demographics are described in Table 1.
- Changes in calcium (Ca), phosphorus (P), parathyroid hormone (PTH) and IV activated vitamin D (IV D) dose were examined before and after initiation of STS treatment using repeated measures general linear models.
- Change in % of patients treated with cinacalcet was assessed using Cochran's Q.
- Patients were divided into 3 groups based upon the number of consecutive months of STS treatment (1, 2, or 3).

RESULTS

Table 1. STS-treated Calciphylaxis Patient Demographics

Mean ± SD	STS-treated patients	DaVita
N	203	123,521
Age (yr)	58.2 ± 12.8	60.8 ± 15.2
% Female	75.9%	44.2%
% Caucasian	53.2%	38.5%
<i>Race and Ethnicity</i>		
% African American	37.4%	36.7%
% Hispanic	5.9%	16.1%
% Asian, Pacific Islander	0.5%	4.2%
% Native American	0.5%	1.4%
% Other	2.5%	3.1%
% Diabetic (primary ESRD cause only)	41.4%	43.9%
<i>Vintage</i>		
≤6 months	19.2%	11.8%
7-12 months	4.9%	10.6%
>1-2 years	12.8%	17.8%
>2-5 years	28.6%	33.9%
>5-10 years	23.6%	19.4%
>10 years	10.8%	6.5%
BMI	30.9 ± 9.3	28.0 ± 7.2

Table 2. MDB Parameters in STS Patients

Months of STS Treatment	Month -2 (before STS)	Month -1 (before STS)	Month 1	Month 2	Month 3	Month 4	p-value
1 Month (n=203)							
Ca (mg/dL)	8.9±0.9	8.8±0.8	8.9±0.9	8.9±1.0			0.81
P (mg/dL)	6.2±2.1	6.0±2.1	5.5±1.8	5.5±2.0			<0.01
PTH (pg/mL)	549.5±714.4	505.4±585.2	422.4±459.5	424.0±587.1			<0.01
IV D (mcg)	5.7±4.1	5.7±4.0	5.2±3.6	4.7±3.4			0.55
Cinacalcet (% on)	30.5%	34.5%	34.0%	25.6%			0.05
2 Month (n=68)							
Ca (mg/dL)	9.0±0.7	8.9±0.6	8.9±0.8	8.9±0.8	9.0±0.7		0.64
P (mg/dL)	5.7±1.7	5.4±1.8	5.2±1.8	5.1±1.7	5.4±2.1		0.11
PTH (pg)	578.0±1035.9	485.0±737.1	457.9±563.6	403.6±672.3	575.3±1158.7		0.38
IV D (mcg)	5.5±4.6	4.9±4.2	4.8±3.8	4.1±3.1	4.1±3.2		0.97
Cinacalcet (% on)	32.4	35.3	41.2	35.3	32.3		0.21
3 Month (n=42)							
Ca (mg/dL)	8.9±0.7	8.9±0.6	8.9±0.7	8.9±0.8	8.9±0.8	9.0±0.7	0.95
P (mg/dL)	5.7±1.6	5.4±1.9	5.4±1.8	5.2±1.9	5.6±2.1	5.6±1.7	0.21
PTH (pg/mL)	423.4±679.2	343.6±353.5	302.9±382.2	415.0±860.7	414.5±619.7	478.7±706	0.04
IV D (mcg)	5.5±4.8	5.3±4.6	4.8±4.0	3.9±2.7	4.3±3.2	4.4±3.1	0.40
Cinacalcet (% on)	40.5	38.1	42.9	33.5	35.7	38.5	0.50

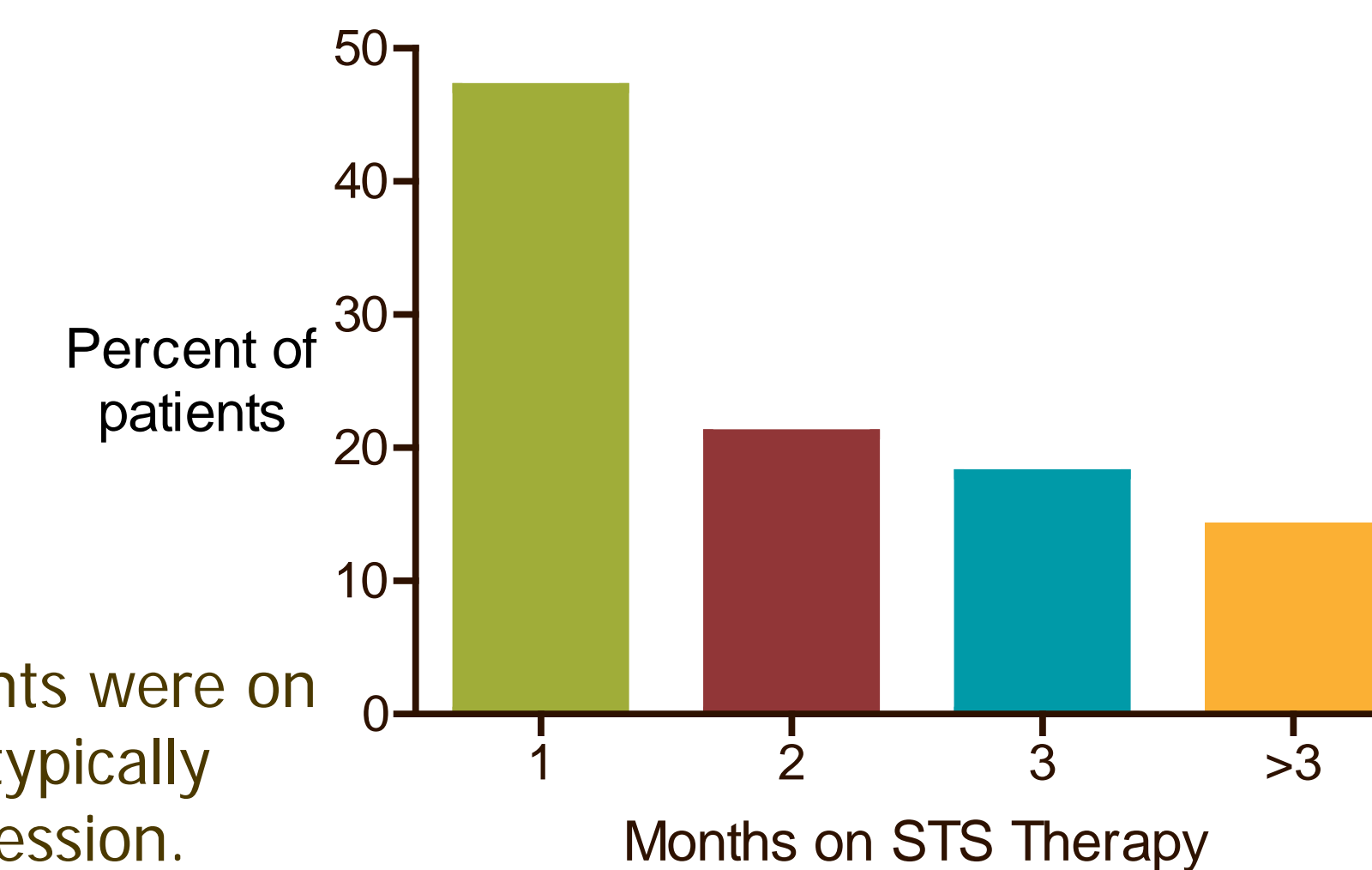


Figure 1. Months patients were on STS Therapy. Patients typically received 1 STS dose/ session.

SUMMARY of RESULTS

- The majority of patients (86%) received ≤3 months of STS therapy (Figure 1).
- STS treatment was associated with reductions in P, PTH, and cinacalcet use in the first 2 mo following initial treatment (Table 2).
- Serum Ca and IV vitamin D dose showed no change.

KEY LEARNINGS

- ✓ This is the largest case series of ESRD patients receiving STS treatment for presumptive calciphylaxis.
- ✓ Results suggest STS transiently improves MBD markers, but improvements aren't maintained over time.
- ✓ A randomized controlled trial is needed to determine the benefit of STS on intermediate and terminal outcomes.

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