Nasal EPAP as a Major OSA Therapeutic Option in a Clinical Sleep Center Setting

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BACKGROUND

PROVENT® Sleep Apnea Therapy (Ventus Medical, Inc) is a novel therapeutic device for the treatment of OSAHS.

Research has validated its efficacy (Berry, *Sleep*. 2011 Apr 1;34(4):479-85.); however, its optimal role in the management of OSAHS as part of a clinical practice based sleep center requires further exploration.

Fontana Sleep Disorders Center (Kaiser Permanente/SCPMG) is a high volume sleep center and has been clinically prescribing Provent as an alternative to CPAP therapy since 2009.

METHODS

KP Fontana Sleep Center Workflow:

- Portable monitoring with Embletta (Embla Systems®) is standard diagnostic testing modality
- CPAP is first-line therapy for OSAHS
- Provent is offered to patients intolerant of CPAP despite troubleshooting and ineligible for positional therapy.

Provent Clinical Pathway (*see Figure 1*):

1. Clinic Education – Patients accepting initiating Provent trial are scheduled for a 20 minute Clinic Education session with RT case manager (includes practice applying Provent, watching Provent video).
2. Home Acclimation – 5 to 10 day sample pack provided for home use
3. Provent Post-Test – PSG with Provent after Home Acclimation to assess response to Provent (almost all tested with Embletta)
4. Responders (AHI ↓ 50% and ≤15) are offered Provent Therapy
5. Almost all trials were performed with Provent Standard Resistance

Retrospective Analysis to evaluate Provent:

1. Workflow process
2. Efficacy
3. Patient acceptance
4. Profile responders and non-responders

AHI event is defined by apnea or hypopnea with flow decrease ≥30% and ≥4% oxygen desaturation

RESULTS

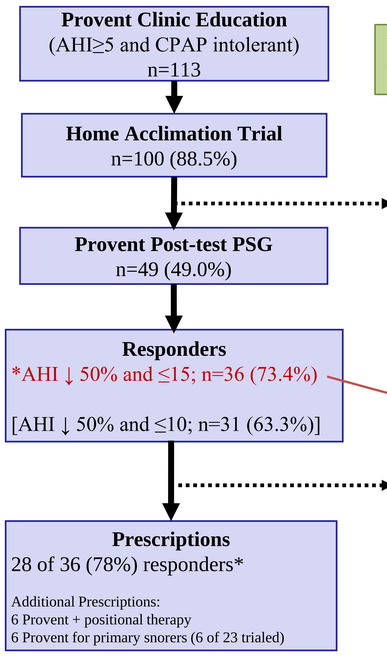

Figure 1: KP Provent Clinical Pathway

Reason Post-test Declined (Non-Post Test Population)	Patient Count
Total	**51**
Didn't keep appointment	10
Suboptimal subjective response	5
Discomfort (most common: congestion, pressure)	20
Cost	2
Other	14

Stratified Response Rate:
Mild – 75% (15/20)
Mod – 67% (8/12)
Sev – 76% (13/17)

Reason Provent Prescription Declined	Patient Count
Total	**8**
Lost to follow-up	1
Preferred CPAP	1
Cost	2
Unknown	4

Baseline Characteristics

	Post-test Population (N = 49)		Non-post-test Population (N = 51)		
	Mean	**(SD)**	**Mean**	**(SD)**	**P-value**
Home acclimation days	**5.5**	(1.8)	**5.5**	(1.2)	1.00
AHI	**23.8**	(17.4)	**27.3**	(22.3)	0.38
Supine AHI	**37.2**	(29.8)	**33.9**	(30.1)	0.65
Non-supine AHI	**12.4**	(10.6)	**23.5**	(21.9)	0.01
% time supine	**45.1%**	(31.5%)	**32.1%**	(30.3%)	0.08
ODI	**21.5**	(13.0)	**30.5**	(19.0)	0.03
T90%	**14.5%**	(17.9%)	**14.0%**	(17.3%)	0.91
Minimum saturation	**79.9%**	(7.4%)	**78.5%**	(9.1%)	0.45
Optimal CPAP pressure	**11.0**	(2.0)	**10.4**	(2.1)	0.26
Epworth (baseline)	**8.7**	(5.3)	**9.2**	(5.2)	0.77
Height (inches)	**68.1**	(3.8)	**67.7**	(4.0)	0.60
Weight (pounds)	**216.7**	(50.1)	**229.2**	(43.6)	0.20
BMI	**33.1**	(8.7)	**35.4**	(7.7)	0.17
Age	**56.9**	(12.3)	**57.4**	(13.3)	0.86
Sex	**14 F**	35 M	**18 F**	33 M	0.52

Efficacy

N = 49	Baseline		Provent		
	Mean	**SD**	**Mean**	**SD**	**P-value**
AHI	**23.8**	(17.4)	**8.0**	(9.1)	<0.01
Supine AHI	**37.2**	(29.8)	**18.6**	(23.3)	<0.01
Non-supine AHI	**12.4**	(10.6)	**2.9**	(3.3)	<0.01
% time supine	**45.1%**	(31.5%)	**42.0%**	(31.4%)	0.66
ODI	**21.5**	(13.0)	**11.3**	(9.8)	<0.01
T90%	**14.5%**	(17.9%)	**9.4%**	(16.2%)	0.20
Minimum saturation	**79.9%**	(7.4%)	**82.8%**	(5.6%)	0.04

Profile of Responders/Non-Responders: Efficacy (Post-Test PSG)

	Responders (N = 36)		Non-Responders (N = 13)		
	Mean	**SD**	**Mean**	**SD**	**P-value**
Post-AHI	**4.4**	(4.4)	**18.5**	(11.3)	<0.01
Post-supine AHI	**11.7**	(18.5)	**36.8**	(25.6)	0.01
Post-non-supine AHI	**2.3**	(3.2)	**4.4**	(3.2)	0.10
Post-% time supine	**36.4%**	(28.0%)	**56.7%**	(36.3%)	0.10
Post-ODI	**8.3**	(7.0)	**19.4**	(12.0)	0.01
Post-T90%	**8.9%**	(17.3%)	**10.7%**	(13.4%)	0.72
Post-minimum saturation	**83.8%**	(4.8%)	**80.3%**	(6.9%)	0.12
Δ in AHI (Median)	**84.6%**	**(12.3%)**	**28.7%**	**(43.6%)**	**<0.01**

Profile of Responders/Non-Responders: Baseline PSG & Demographic Data

	Responders (N = 36)		Non-Responders (N = 13)		
	Mean	**SD**	**Mean**	**SD**	**P-value**
Home acclimation days	**5.6**	(2.0)	**5.3**	(1.2)	0.63
AHI	**24.2**	(19.2)	**22.8**	(11.2)	0.77
Supine AHI	**37.9**	(32.6)	**35.3**	(22.4)	0.79
Non-supine AHI	**12.6**	(12.0)	**11.8**	(5.9)	0.79
% time supine	**40.4%**	(30.5%)	**55.7%**	(32.6%)	0.19
ODI	**21.6**	(14.5)	**21.1**	(6.5)	0.89
T90%	**13.8%**	(15.6%)	**16.3%**	(23.9%)	0.77
Minimum saturation	**79.9%**	(7.8%)	**79.8%**	(6.6%)	0.95
Optimal CPAP pressure	**10.8**	(1.6)	**11.3**	(2.7)	0.63
Epworth (baseline)	**7.8**	(6.1)	**10.1**	(3.8)	0.33
Height	**67.5**	(3.7)	**69.8**	(3.4)	0.06
Weight	**218.8**	(53.8)	**210.9**	(39.9)	0.60
BMI	**34.1**	(9.5)	**30.4**	(4.9)	0.10
Age	**56.3**	(12.6)	**58.8**	(11.8)	0.53
Sex	**14 F**	22 M	**0 F**	13 M	0.01

SUMMARY

- Efficacy is excellent for mild to severe OSAHS (in patients returning for Post-Test PSG evaluation with Provent).
- In responders, there is near normalization of OSA indices.
- In responders, there is high acceptance of Provent and conversion rate to Provent prescription.
- Largest drop-off on the Provent Clinical Pathway is returns for the Post-Test PSG.
- Profile of responders/non-responders does not reveal overt predictive characteristic, except all women with Post-test PSG responded to Provent.

CONCLUSIONS

Provent is a major therapeutic option for CPAP intolerant patients that can be successfully integrated into a clinical practice-based sleep center.

Follow-up and compliance assessment in patients prescribed Provent needs to be further assessed.

PROVENT® Sleep Apnea Therapy