ORCADES

A prospective cohort study of severe obstructive sleep apnoea patients receiving second line-treatment with a mandibular repositioning device (CadCam; Narval)

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AIMS

Mandibular repositioning devices (MRDs) are an alternative therapy for obstructive sleep apnoea (OSA) especially in patients noncompliant with continuous positive airway pressure (CPAP) therapy.

ORCADES is a French prospective multicentre observational cohort study providing long-term data (5 years' follow-up) on 360 OSA patients who refused or did not tolerate CPAP and were treated with a custom MRD. Baseline characteristics and results for the first patients treated are presented.

METHODS

OSA patients were screened by sleep physicians and referred to a dental specialist who fitted a custom MRD (CadCam; Narval) in eligible patients and did gradual mandibular advancement (MA) titration until the best benefit-risk ratio was achieved. Objective sleep data (polygraphy or polysomnography), symptoms, quality of life, side effects and compliance were evaluated. Treatment success was defined as a ≥50% decrease from baseline in the apnoea-hypopnoea index (AHI).

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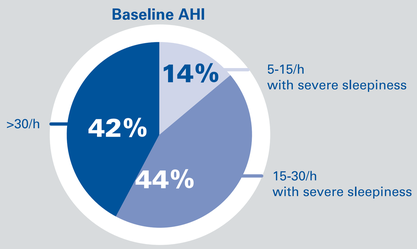
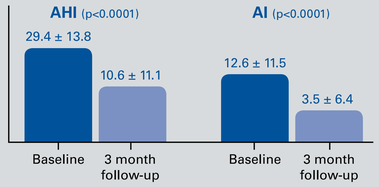
RESULTS

As at 31 January 2013, 232 patients had been treated with a MRD (71% male, age 53.2±11.9 years, body mass index 27.1±4.1 kg/m2; 21% of patients were obese, 31% had hypertension and 49.8% had previously been treated with CPAP).



59.4% of patients had an Epworth Sleepiness Scale (ESS) score >10.
79% of patients were daily snorers and 42% had severe snoring.The mean number of titration visits was 2.0±1.0, and the final mean MA was 7.3±2.2 mm (75% of maximum MA).
To date, 143 patients have had a 3-month assessment (Table 1). After this visit, 10% of patients needed additional MA and a new control recording to achieve optimal efficacy.

The rate of treatment success (defined as a ≥50% decrease in AHI) was 84%, irrespective of OSA severity or previous CPAP, and AHI was <10/h in 63.4% of patients.

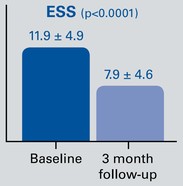


There was no change in mean central AI. The mean oxygen desaturation index was decreased significantly from 20.7±17.0 at baseline to 8.2±10.3 during MRD therapy (p<0.0001).

Efficacy of MRD therapy by patient subgroup (3-month follow-up)

	MRD Therapy					
	AHI, /h			Previous CPAP		
	>30 (n=67)	5-30 (n=75)	*p* value	Refusal (n=68)	Failure (n=74)	*p* value
Success rate, n (%)	56 (83.6)	63 (84)	NS	55 (80.9)	64 (86.5)	NS
AHI <10/h, n (%)	26 (38.8)	64 (85.3)	**<0.0001**	49 (72.1)	41 (55.4)	**0.040**
Change from baseline, mean (SD)						
BMI, kg/m2	-0.19 (0.99)	0.05 (1.15)	NS	-0.13 (1.29)	-0.01 (0.82)	NS
Waist size, cm	-0.15 (4.15)	0.06 (3.49)	NS	-0.21 (3.74)	0.11 (3.91)	NS
Neck size, cm	-0.07 (1.85)	-0.23 (1.38)	NS	-0.53 (1.71)	0.18 (1.49)	**0.045**
AHI, /h	-26.0 (12.5)	-12.6 (7.7)	**<0.0001**	-16.1 (11.9)	-21.5 (11.9)	**0.0085**
AI, /h	-13.1 (11.0)	-5.3 (5.5)	**<0.0001**	-6.6 (8.1)	-11.1 (9.9)	**0.0017**
HI, /h	-12.8 (11.6)	-7.5 (6.8)	**0.0016**	-9.4 (8.7)	-10.5 (10.6)	NS
cAI, /h	0.1 (1.6)	-0.1 (0.4)	NS	-0.1 (0.4)	0.1 (1.5)	NS
Dorsal AHI, /h	-29.7 (27.3)	-20.8 (14.8)	**0.0036**	-20.6 (23.6)	-28.7 (19.9)	NS
Average SpO2, %	0.6 (1.7)	-0.1 (1.5)	NS	0.1 (1.3)	0.4 (1.9)	NS
SpO2 min, %	3.6 (7.9	0.5 (14.7)	NS	1.5 (11.3)	2.4 (12.5)	NS
ODI, /h	-18.5 (16.8)	-6.7 (15.7)	**0.0001**	-10.6 (14.6)	-14.0 (19.7)	NS
ESS score	-3.4 (3.2)	-4.8 (4.8)	NS	-4.4 (4.2)	-3.8 (3.9)	NS

AHI: Apnoea-Hypopnoea Index ; AI: Apnoea Index ; CAI: Central Apnoea Index ; BMI: Body Mass Index ; CPAP: Continuous Positive Airway Pressure ; HI: Hypopnoea Index ; NS: Not Significant ; ODI: Oxygen Desaturation Index ; SpO2: oxygen saturation ; Success: ≥50% decrease in AHI.



Sleep study data showed that MRD treatment reduced the frequency and duration of snoring by 50% from baseline. Loud snoring disappeared in 90% of patients affected. Other OSA symptoms (nocturnal polyuria, libido disorders, mouth breathing and respiratory pauses) resolved completely during MRD therapy in >50% of patients.

Significant improvements were also seen in quality of life, fatigue score and sleep quality. Fewer than 5% of patients stopped treatment early for intolerance or side effects.

Compliance was excellent (mean MRD usage for 6.7 hours/night on a mean of 6.6 days/week).

CONCLUSION

Use of a customized MRD (CadCam; Narval) is an effective therapy especially for moderate-to-severe OSA that can be used for patients refusing or noncompliant with CPAP.