

Therapy of Snoring and Obstructive Sleep Apnea Using the Velumount® Palatal Device

Kurt Tschopp Esther Genoveva Thomaser Cristina Staub

ENT Clinic, Cantonal Hospital, Liestal, Switzerland

Key Words

Velumount · Snoring · Obstructive sleep apnea syndrome · Conservative treatment · Retropalatal obstruction · Upper airway manometry

Abstract

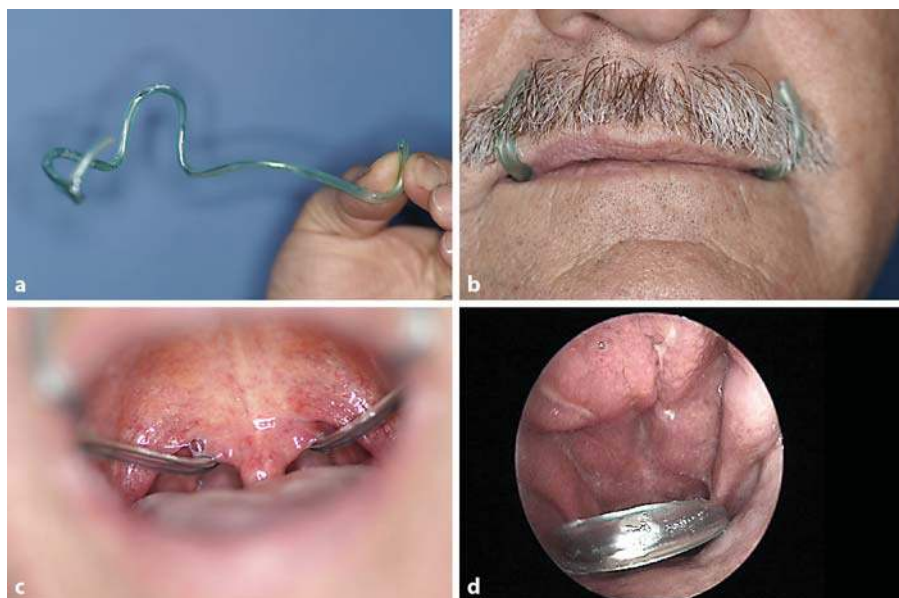
Objectives: The aim of the present study is to investigate the efficacy of the Velumount® device. **Methods:** In a prospective cohort study 40 patients were examined with and without Velumount. The apnea-hypopnea index and average esophageal pressure were measured using nocturnal manometry of the upper airways, combined with respiratory polygraphy. The snoring index (1–10) and daytime sleepiness using the Epworth Sleepiness Scale were assessed by means of a questionnaire. **Results:** Using Velumount the snoring index was reduced from on average 8.4 (SD ± 1.3) to 3.7 (SD ± 2.5), the Epworth Sleepiness Scale score from on average 7.9 (SD ± 4.4) to 3.8 (SD ± 3.4) and esophageal pressure from on average 14.8 cm H₂O (SD ± 6.7) to 11.2 cm H₂O (SD ± 6.4). In patients (n = 25) with obstructive sleep apnea, the average apnea-hypopnea index was 24.3 (SD ± 10.1) without and 13.6 (SD ± 12.2) with Velumount. All changes were highly significant. **Conclusions:** The Velumount device is effective for the treatment of snoring and obstructive sleep apnea. The effect is similar to that reported from uvulopalatopharyngoplasty.

Copyright © 2009 S. Karger AG, Basel

Introduction

The Velumount® device was developed and patented by A. Wyss in Bern, Switzerland, for the treatment of snoring and obstructive sleep apnea syndrome (OSAS). It has a unique history. Arthur Wyss himself suffered from snoring and obstructive sleep apnea. He had an uvulopalatopharyngoplasty (UPPP) without success and tolerated continuous positive airway pressure (CPAP) therapy poorly; therefore he was looking for alternative treatment options. He initially introduced a suction catheter into his nose, drew it out through his mouth using tweezers and fixed it in front of the upper lip, thus applying a velotraction. Sleeping with this mount, A. Wyss' wife noted that the snoring was dramatically reduced and she did not observe apneas anymore. A. Wyss slept for over half a year with the self-applied velotraction before he tried to find a more comfortable and professional solution. In this way the device, which is now known as the Velumount method, was invented.

The study was performed at the ENT Clinic, Cantonal Hospital, Liestal, Switzerland. The paper was presented on June 5, 2008, at the 95th annual congress of the Swiss Society of Otorhinolaryngology in Zug, Switzerland.



Color version available online

Fig. 1. **a** Velumount device. **b** Velumount is stabilized by the lips. **c** Intraoral view. **d** Velumount seen from nasendoscopy.

Velumount in its present form is a plasticized wire which is introduced through the mouth and advances the soft palate by stenting the retropalatal space (fig. 1a). The device is held and fixed by the lips (fig. 1b). The wire lies behind the lips laterally on both sides of the alveolar process and crosses medially in the retromolar region (fig. 1c). Then it passes to the retropalatal space in the form of a slightly anteriorly benched bow, thus stenting and advancing the soft palate (fig. 1d). Speaking and drinking is possible wearing the Velumount device. However, a slight rhinophonia may be noticed in some patients. Drinking small sips of water or similar liquids is possible and appreciated in case of a dry mouth when waking up during the night.

The Velumount device has to be carefully adjusted to the shape of the soft palate in each patient. The upward bent retropalatal part of the device needs particularly careful fitting. Side effects such as irritation and foreign body sensation are increased if this part of the device is bent too strongly. However, the efficacy is compromised if the bending is too weak. Moreover, the plasticized wire is available in several degrees of rigidity. This is necessary in order to meet different muscular tones of individual soft palates. Most patients need 2–3 sessions for definite fitting of the device. Careful adjusting of the Velumount cannot be overestimated.

In Switzerland, more than 5,000 people have received the Velumount device so far. The aim of the present study is to evaluate its efficacy in snoring and OSAS.

Methods

From May 2007 to July 2008, 40 patients were evaluated at the Cantonal Hospital of Liestal. Only patients who regularly used the Velumount device for at least 4 weeks before testing were included in the study. Regular use was defined as at least 5 nights per week.

All patients had a careful ENT examination and a nocturnal manometry of the upper airways, combined with respiratory polygraphy (ApneaGraph®) with and without the Velumount device. The ApneaGraph system uses a naso-pharyngo-esophageal probe. The pressure gradient between ambient pressure and the pressure just below the soft palate and the pressure gradient between the probe immediately below the soft palate and that in the esophagus are measured by means of 2 manometers (1 below the soft palate and 1 in the upper third of the esophagus). There are 2 thermistors for measuring the airflow in the nasopharynx and in the oropharynx. Thus the apnea-hypopnea index (AHI), distribution of obstructions as retropalatal ('upper') and retrolingual ('lower') events and esophageal pressure (Pes) are assessed. The mean Pes is measured during 5 episodes of mostly undisturbed respiration. The registration time is 6 h. A good correspondence between AHI obtained by upper airway manometry and polysomnography has been demonstrated [1]. OSAS was defined as AHI >10/h.

Daytime sleepiness was assessed using the Epworth Sleepiness Scale (ESS). Snoring was estimated by means of a visual analogue scale (1–10, 1 meaning no snoring and 10 meaning very intensive snoring).

The criteria for treatment success were defined as follows: (1) AHI: fulfillment of the Sher criteria, that is an AHI ≤20/h under treatment and a ≥50% reduction with respect to AHI before treatment [2]; (2) snoring: snoring index ≤3 as socially not disturbing snoring, and (3) Pes: normalization, e.g. a Pes ≤10 cm H₂O.

Table 1. The motivation for trying the Velumount device in snorers (n = 15) and OSAS patients (n = 25)

	Snorers	OSAS patients
Reduction of snoring	11	12
Reduction of daytime sleepiness	2	2
Worry about apneas	2	7
Wish to avoid CPAP therapy	0	17
Wish to avoid an operation	2	5

Fig. 2. Distribution of severity of OSAS, based on AHI values, before and with Velumount.

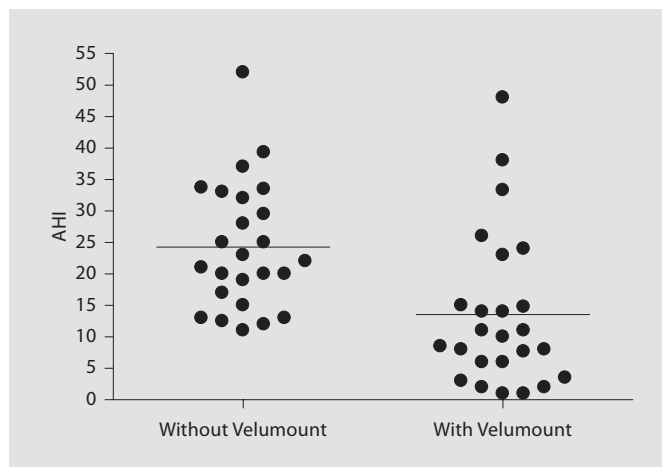


Table 2. The effect of Velumount device on snoring, AHI, ESS and Pes

	Collective	Without Velumount	With Velumount	Wilcoxon test
Snoring index (1–10)	n = 40 (all)	8.4 ± 1.3	3.7 ± 2.5	p < 0.001
ESS	n = 40 (all)	7.9 ± 4.4	3.8 ± 3.4	p < 0.001
Pes, cm H ₂ O	n = 40 (all)	14.8 ± 6.7	11.2 ± 6.4	p < 0.001
AHI	n = 25 (only OSA)	24.3 ± 10.1	13.6 ± 12.2	p < 0.001

Regarding AHI only OSA patients (AHI >10/h) are included. Figures are means ± SD.

The patients were routinely asked about side effects. The sleep quality of the patient and the bed partner were assessed as very good, good, medium and poor using a questionnaire, and the number 1, 2, 3 and 4 was attributed to each sleep quality, respectively.

Program GraphPad InStat 3 was applied for statistical evaluation. The Wilcoxon test was used for comparison of means and Spearman rank correlation for correlational analyses. The level of significance was defined as p < 0.05.

Results

Twenty-nine men and 11 women were included in the study. The average age was 57.5 years (SD ±11.9). The mean body mass index (BMI) was 28.0 (SD ±3.6) and 28.0 (SD ±3.5) without and with Velumount, respectively. The time between the examination with and without Velumount was, on average, 20 days (range = 1–112).

In 18 cases the previous therapy was nocturnal CPAP ventilation, which was abandoned by the patients, in 7

cases unsuccessful uvulopalatopharyngoplasty (UPPP) and in 3 cases mandibular advancement splints.

The subjects' major complaints were snoring (36/40), daytime sleepiness (16/40) and worry about observed apneas (18/40). Fifteen patients were simple snorers and 25 fulfilled the criteria of OSAS with an initial AHI of >10/h before treatment. The motivation for Velumount is indicated in table 1. Reduction of snoring and the hope to avoid CPAP therapy were the most important reasons. The relatively low number of patients who indicated that they wanted to avoid an operation in the snorer group may be explained by the fact that 4/15 already had previously undergone unsuccessful UPPP.

The results are shown in table 2. AHI, ESS, Pes and snoring index were significantly improved using Velumount. Regarding AHI only patients with OSAS were evaluated (n = 25), and a response rate of 60% (15/25) was found according to the Sher criteria. The distribution of severity of OSAS, based on AHI values, before and with Velumount is depicted in figure 2. The success rate re-

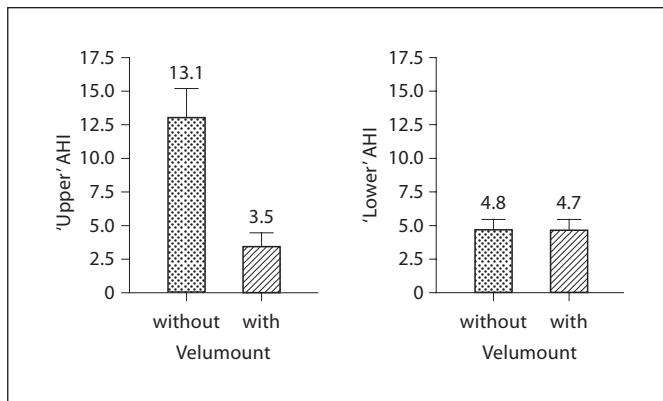


Fig. 3. 'Upper' (retropalatal) and 'lower' (retrolingual) AHI with and without Velumount ($n = 25$ OSA patients). The improvement in upper AHI is significant (Wilcoxon test: $p < 0.001$). The lower AHI is not changed with Velumount (Wilcoxon test: $p = 0.77$). The standard deviation is marked by bars.

garding snoring (defined as snoring index < 3) was 65% (26/40). Pes was elevated (defined as Pes > 10 cm H₂O) in 77.5% (31/40) and normalized using Velumount in 45.2% (14/31).

The distribution of retropalatal ('upper') and retrolingual ('lower') obstructions is obtained in nocturnal upper airway manometry. Without Velumount 67.8% (SD ± 25) upper obstructions and 32.2% (SD ± 26) lower obstructions were found. With Velumount upper obstructions were significantly reduced to a mean of 26.2% (SD ± 26), and hereby the amount of lower obstructions increased to a mean of 73.8% (SD ± 28). An upper and a lower AHI may be calculated using the distribution of upper and lower obstructions. Velumount significantly improved upper AHI, but not lower AHI (fig. 3). On the contrary, a shift from predominantly upper obstructions to lower obstructions was observed in some cases using Velumount. The upper AHI without Velumount was correlated with the improvement in the total AHI with Velumount (Spearman $r = 0.46$; $p = 0.004$), the improvement in the upper AHI with Velumount (Spearman $r = 0.41$; $p = 0.01$), but not with the change in lower AHI with Velumount (Spearman $r = 0.29$; $p = 0.07$). Thus, upper AHI without Velumount had a predictive value for success with the device.

Looking at the subgroup of the 7 patients who underwent unsuccessful UPPP before Velumount, 3 met the OSAS criteria and 4 were simple snorers. In the OSAS patients, AHI before and with Velumount was on average 12.2/h and 1.7/h, respectively. All 3 patients were re-

sponders according to the Sher criteria. The snoring index was reduced in all 7 patients from 8.4 without Velumount to 3.3 with Velumount. The responder rate with respect to snoring was 57% (4/7). Apparently previous UPPP did not hamper the success of Velumount.

Side effects, such as foreign body sensation, were reported in 19 cases, increased gag reflex in 6 cases and hypersalivation, pain and episodes of slight bleeding in 1 case, respectively. Due to habituation the patients coped rather well with the undesired effects and tolerated the Velumount device insofar as they regularly used it. The patients used Velumount on average 6.4 days/week (SD ± 1). The average duration of sleep was 7.1 h (SD ± 0.8 h), and all patients indicated that they used the device during the whole sleeping time. However, it should be kept in mind that only patients who regularly used and therefore tolerated Velumount well were included in the study.

The sleep quality of the patient and the bed partner were assessed as poor (4), medium (3), good (2) and very good (1). Without Velumount mean sleep quality of the patients was 2.7 (SD ± 0.8) and with Velumount 1.8 (SD ± 0.4). The sleep quality of the bed partners was 3.3 (SD ± 0.6) without Velumount and 2.0 (SD ± 0.7) with Velumount. The improvement in sleep quality using Velumount was significant for patients as well as for bed partners (Wilcoxon test: $p < 0.0001$).

Discussion

In the literature, only 1 retrospective case-control study concerning the efficacy of Velumount which has been performed by pneumologists [3] exists so far. In this study, a significant reduction of snoring and the desaturation index was also found. However, improvement in the desaturation index was judged as not being relevant because of a mean weight reduction of 3 kg in the patient collective between the examination with and without Velumount. The time interval between the examinations was not specified in the article but was obviously larger than in our study with a mean of only 20 days and no change in BMI. However, the observation of significant weight loss using Velumount is interesting and may indicate reduced daytime sleepiness and increased physical activity using the palatal device. This is noteworthy because under CPAP therapy no decrease in BMI was observed [4]. On the contrary, an increase in BMI was even found in women and primarily nonobese patients after 1 year of CPAP therapy. In the pneumologists' study, 44% (19/39) did not tolerate the Velumount device.

In the present analysis, no assessment of the acceptance of Velumount can be made due to the study design. The main purpose of the present study was to evaluate the efficacy of the device. Therefore, only patients who regularly used Velumount were examined. Regular use of course implies good tolerance of the device. However, the question of acceptance of Velumount is important and has to be investigated in a further study because the device is worthless unless regularly used. Wearing Velumount needs a habituation process, which is certainly not managed by all patients. However, it should be kept in mind that acceptance of Velumount also depends on careful fitting of the device.

In the present study, a definite efficacy of Velumount could be demonstrated regarding the improvement in snoring and OSAS. The snoring index, AHI, ESS scores and Pes were significantly reduced. A reduction of snoring was observed by most patients and of course particularly appreciated by the bed partners. However, the reduction of snoring intensity is definitely not sufficient as an evaluation of therapeutic success in OSA patients and may be deceptive. In OSA patients, control of the therapeutic effect is mandatory by means of respiratory polygraphy. In some cases even a shift from predominantly retro-palatal to more retrolingual obstructions was observed using Velumount.

Velumount only reduced apneas and hypopneas due to retro-palatal obstructions, as is to be expected from its site of application. Retrolingual collapse of the upper airway is not prevented by Velumount. Nocturnal upper airway manometry is useful for patient selection because the distribution of 'upper' and 'lower' obstructions is assessed. Only patients with predominantly upper (retro-palatal) obstructions will profit from the application of the Velumount device.

In our study, only mild and moderate degrees of OSA were investigated. It is well known that in severe OSA retrolingual obstruction is frequently present [5]. Therefore, Velumount may be recommended only for mild to moderate OSA. CPAP remains the therapy of choice for severe OSA. Further studies are necessary to evaluate Velumount versus CPAP in a controlled clinical trial. However, it should be kept in mind that in our study 18 patients had previous CPAP therapy which was not tolerated. These patients thus had untreated OSA before Velumount, and a response rate of 60% applying Sher's criteria is noteworthy.

The long-term success rate after UPPP for snoring is about 70% and for OSA it is 50–60% using Sher's criteria [6]. The results with Velumount are similar. Therefore, Velumount is a valuable alternative to UPPP for patients who prefer conservative treatment.

Conclusion

The Velumount palatal device is a new treatment option for simple snoring and OSA with predominantly retro-palatal obstruction. Its success rate is similar to that of UPPP. Velumount is a valuable therapeutic option for otolaryngologists counseling patients for snoring and mild to moderate OSA.

Acknowledgements

The authors wish to thank A. Wyss, Velumount GmbH, for his cooperation in motivating patients for the study and Dr. Fabian Schauer for data collection and statistical analysis.

References

- 1 Tvinnereim M, Cole P, Haight JS, Hoffstein V: Diagnostic airway pressure recording in sleep apnea syndrome. *Acta Otolaryngol* 1995;115:449–454.
- 2 Sher AE, Schechtmann KB, Piccirillo JF: The efficiency of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep* 1996;19:156–177.
- 3 Strobel W: The Velumount® device to treat obstructive sleep apnea: does it work? *Swiss Med Wkly* 2008;138(suppl):29.
- 4 Redenius R, Murphy C, O'Neill E, Al-Hamwi M, Zallek SN: Does CPAP lead to change in BMI? *J Clin Sleep Med* 2008;15:205–209.
- 5 Shepard J, Thawley SE: Localisation of upper airway collapse during sleep in patients with obstructive sleep apnea. *Am Rev Respir Dis* 1990;141:1350–1355.
- 6 Hörmann K, Verse T: *Surgery of Sleep-Disordered Breathing*. Berlin, Springer, 2005.