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Comparison of Three Auto-adjusting Positive Pressure Devices in Patients with Sleep Apnoea

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Abstract

Background: Auto-adjustable continuous positive airway pressure (APAP) devices are an emerging treatment alternative to fixed pressure CPAP therapy for obstructive sleep apnoea syndrome (OSAS). They have been engineered to automatically adjust pressure to the optimal level on a continuous basis. However, not all APAP technologies use the same algorithm. We compared three different APAP devices (Autoset Spirit, Breas PV 10i, and RemStar Auto) in a randomised crossover trial in patients already established on fixed pressure CPAP therapy. Outcome measures were compliance, quality of life and side effects.

Methods: 27 middle aged patients (25 male) diagnosed previously with severe OSAS (apnoea/hypopnoea index (AHI) 48 [29;76] median[interquartile range]), established on CPAP therapy for more than 3 years, were randomised for 4 weeks to each APAP device.

Results: Average pressure and patient compliance were significantly lower on the Breas PV10i device compared to the other APAP devices. The devices were similar in terms of quality of life, daytime sleepiness and upper airway side effects, but patients evaluated them significantly different in terms of device features, sleep quality and pressure comfort with the Breas PV10i being the least popular.

Conclusion: APAP devices differ in pressure delivery and patient compliance in OSAS patients.

Key words: Obstructive sleep apnoea syndrome, CPAP therapy, APAP therapy, compliance, quality of life

Word count (abstract): 198

Introduction

Obstructive Sleep Apnoea Syndrome (OSAS) is a common and potentially serious disorder, affecting around 4% of adults (1). It is characterised by repeated episodes of apnoea during sleep, up to several hundred times per night, which lead to hypoxia, sleep fragmentation and excessive daytime sleepiness with associated risk of serious sequelae such as road traffic accidents and significant cardiovascular morbidity and mortality (2-4). Nasal continuous positive airway pressure (nCPAP) is the current therapy of choice, particularly in moderate and severe cases. It has shown to improve quality of life, to reduce the risk of road traffic and occupational accidents and to decrease cardiovascular morbidity and mortality (5 - 8).

In recent years, auto-adjustable positive airway pressure (APAP) devices have been developed to improve patient comfort and compliance. APAP devices are designed to continuously adjust the applied pressure to the optimal level throughout the night, according to an algorithm, and therefore minimise the average overnight pressure requirements of patients with OSAS (9,10). The effectiveness of APAP in reducing the apnoea/hypopnoea index (AHI) as well as the improvement in symptoms is similar to fixed pressure CPAP therapy (11-13). At present, there is insufficient evidence of benefits of APAP devices over traditional CPAP treatment to justify their routine use in clinical practice (14). Particularly, the role of APAP in increasing patient compliance remains unsolved. Moreover, it is unknown if the different device algorithms have a comparable effect on patient comfort and compliance.

This study was designed to compare the effect of three APAP devices on compliance, quality of life and side effects of treatment in patients with OSAS, who were already established on fixed pressure CPAP therapy.

Methods

Subject details

Patients were recruited from the patient population attending the Respiratory Sleep Disorders Unit at St Vincent's University Hospital Dublin, Ireland. Patients were eligible to participate if they had a confirmed diagnosis of OSAS and were already established on fixed pressure CPAP therapy, using a nasal mask with a device that downloaded time-coded compliance data. Patients diagnosed with a malignant or psychiatric disease, or on regular narcotics, sedatives or psychoactive medications were excluded. The study protocol was approved by the St. Vincent's University Hospital Ethics Committee. Each subject gave written informed consent. Consecutive patients who fulfilled the inclusion criteria were invited to participate.

Baseline characteristics of the subjects are described in Table 1. Patients had been commenced on fixed pressure therapy for 53[37;85] months (median[interquartile range]) prior to the start of the study. The following CPAP devices were in use at that time: Sullivan Elite V (ResMed Ltd., Australia) [9 patients], Respironics Aria Lx (Respironics Inc., USA) [13 patients], RemStar Pro (Respironics Inc., USA) [4 patients] and Fisher & Paykel HC221 (Fisher & Paykel Healthcare, New Zealand) [1 patient]. Each patient was given a 4-week trial at home of three APAP devices; Autoset Spirit (ResMed Ltd., Australia), Breas PV10i (Breas Medical, Sweden) and RemStar Auto (Respironics Inc., USA), set between 4-16cm H_20, in a randomised crossover trial. The trial was fully blinded to the investigator performing the analysis as this person was not involved in the immediate patient contact and they were also blinded to the randomisation. It was not possible to fully blind the patients because of the different appearances of the devices. However, patients were not informed about the different technologies used in the APAP devices, they were simply told that these were newer treatment machines. The patients used the same nasal mask throughout the trial. The devices

were assigned to patients in random order by an independent person not involved in the study design, protocol or analysis. At the end of each APAP trial period patients were evaluated by an experienced sleep technician and physician and asked to complete the Epworth Sleepiness Scale (ESS) (15), a questionnaire about physical and mental health (Short Form 36 Health Survey [SF-36]) (16) and an in-house evaluation questionnaire specifically addressing device features, sleep quality and side effects (Appendix 1). Time coded compliance data from the fixed pressure CPAP device at the start of the trial and from the APAP devices at the end of each 4-week trial were downloaded. At the end of the study patients were asked to place the 4 devices (3 APAP and CPAP) in order of preference and to give reasons for their first preference.

APAP technologies

The three devices all use flow signal analysis as the basis for their algorithms, but in a different manner to each other. The Autoset Spirit reviews the shape of the inspiratory flow curve on a breath-by-breath basis. A normal unobstructed breath displays a smooth rounded curve shape, but as the upper airway narrows, flattening of the curve occurs, altering the shape. The degree of flattening determines the response of the device.

The Breas PV10i creates a model of the patients breathing signal, which is then compared several times per second to a grid containing 64 pre-stored templates of normal and abnormal respiration events. The template closest to the patient model will determine the response of this unit.

The RemStar Auto compares the inspiratory flow shape of each breath to a rolling patient database, which has been derived from the previous 2-3 minutes of breath shapes. Two pressure tests are then performed one which reduces pressure until the airway begins to collapse and the other one where pressure is increased until there is no further improvement

in the flow shape. A therapy mode is then entered providing a constant ideal pressure until the next change in respiration occurs.

All three devices also have a safety feature, which will increase pressure rapidly in the presence of an unexpected abnormal event.

Statistical analysis

Subject baseline characteristics and downloaded device parameters are expressed as median [interquartile range] or mean ± standard deviation depending of distribution and comparisons were made using the paired t-test or Wilcoxon Signed Rank test for paired samples. A significance level of $p<0.05$ was considered significant. Statistical analysis was performed using a commercial software package (SPSS Version 11, Chicago, IL).

Results

Subjects

27 consecutive patients who met the inclusion criteria were recruited. No subject refused participation and none were lost during the study. Patients were predominately male (2 females), obese and had previously been diagnosed with severe OSAS disease as indicated by the median AHI of 48[29;76] and an ESS of 15[9;19] (Table 1) and compatible clinical signs.

Compliance and treatment pressure

After each 4-week treatment period the devices were downloaded for evaluation of compliance and applied pressure. The mean applied pressure was significantly lower on all three APAP devices when compared to CPAP with the lowest mean pressure of 5.8 cmH_20 recorded on the Breas PV10i. Overall, compliance was acceptable (>70% nights used and >4

hours/night used) on CPAP and on the RemStar Auto and the Autoset Spirit, but was significantly lower on the Breas PV 10i (Table 2).

Quality of life and subjective sleepiness

Analysis of the SF-36 quality of life questionnaire showed no significant differences between the three APAP devices or between the APAP devices and those values obtained on fixed CPAP therapy in all domains. Subjective sleepiness was evaluated by the ESS. Initially, ESS was reduced by fixed pressure CPAP therapy from a pre-treatment diagnostic baseline of 15[9;19] to 5[3;11] ($p=0.002$), but there was no further significant change after treatment with any of the three APAP devices.

Patient evaluation of the three APAP devices

All subjects evaluated the devices after each treatment period in terms of device features, sleep quality and side effects (figures 1,2,3). Overall, all three APAP devices were equally easy to use. The Autoset Spirit was the least preferable machine in terms of size and noise, whereas the RemStar Auto represented the best device features by the evaluation (figure 1). The Breas PV 10i provided significantly poorer sleep quality in comparison to the other two APAP devices, which were similar in this aspect (figure 2). All three devices were similar in causing nasal and upper airways side effects. Pressure discomfort was reported most frequently by using the Breas PV 10i (figure 3).

Patient preference

14 (52%) of patients preferred an auto-adjusting device over the fixed pressure device at the end of the trial with 13 (48%) choosing to remain on the original CPAP device. Six patients who preferred the APAP devices chose the RemStar Auto, five chose the Autoset

Spirit and three chose the Breas PV10i. 56% of patients said that "ease of use" was the main reason for selecting the machine of choice, with 22% listing "the noise of device" as the second reason. No patient selected "value for money" as a reason for end preference.

Discussion

Auto-adjusting positive airway pressure devices are an emerging treatment alternative to fixed pressure CPAP therapy. Several randomised studies have shown that APAP therapy is effective in lowering the AHI and improving subjective sleepiness (11-13). However, only limited data are available comparing different APAP devices in terms of objective and subjective effectiveness. Various authors have suggested that the efficacy of different APAP devices in improving objective sleep parameters varies (17-19). In a randomised crossover trial of 12 CPAP naïve patients, 3 different APAP devices and fixed CPAP were used each for one night. All three APAP devices produced a significant reduction in the AHI, but there was considerable difference in the efficacy of the devices, as only two of the APAP devices reduced the AHI to the optimal treatment level of <5 events/hr (17). Similarly, Pevernagie et al. compared the AutoSet device (ResMed) and the SOMNOsmart system (Weinmann) in a split-night protocol and detected small but significant differences in polysomnography parameters in favour of the AutoSet (18). However, this study compared a titration device with a treatment device and therefore the different settings might have contributed to the variation in results obtained.

The present study is the first report comparing three different APAP devices in terms of delivered pressure profile, patient compliance, quality of life and side effects in patients already established on fixed CPAP therapy. Although all three APAP devices studied use the flow signal to determine the required pressure the actual different algorithms account for a significant difference in delivered pressure and subsequently for differences in subjective

outcome parameters and compliance. No previous study has compared these same three devices. However, in comparing different APAP devices similar observations of efficacy and pressure profiles have been obtained. Farre et al. assessed 5 different APAP devices in a bench study utilising a breathing waveform generator and concluded that the responses of the devices to apnoeas, hypopnoeas, flow limitation and snoring were considerably different (20). Hertegonne et al. came to a similar conclusion in a patient population (21). They compared comfort parameters and pressure profiles of the AutoSet (Resmed) and the SOMNOsmart (Weinmann) in a split-night crossover protocol and detected significant differences in these.

Only one other trial to date has compared different APAP technologies in a patient group over a longer treatment period. Senn et al. evaluated 29 CPAP-naïve patients with OSAS and compared fixed CPAP and two APAP technologies, each for one month in a crossover design (22). This study did not find any significant differences between the two APAP devices in terms of symptoms, AHI, mean applied pressure or compliance. At the end of the trial, 72% of patients had no preference for either APAP or CPAP, with 4 (14%) choosing APAP and 4 choosing CPAP. These results differed from our study where 52% preferred APAP and 48% CPAP. However, similar to our results they too found that details in size, weight and noise level during use were the most frequently cited reasons for end preference. Furthermore, our study evaluated a group of patients already established on fixed CPAP. We selected such patients because they are familiar and compliant with this type of treatment process and local airway pathology such as oedema and inflammation is likely to have already subsided with CPAP therapy. Also, these patients are established on their mask system and could therefore more accurately evaluate the different APAP technologies without the inevitable limitations associated with CPAP naïve patients.

However, we recognise that, since patients were already established on CPAP, there may have been a bias towards CPAP over APAP in this study. Some previous reports have

indicated a preference towards APAP in treatment naïve patients (23,24), others have not reported such a preference (25,26). However, the present study design was specifically chosen to directly compare these 3 APAP devices, an objective that would have been more difficult in treatment naïve patients. There are only limited data on APAP therapy in patients with mild OSAS although a preliminary report from our unit indicates no consistent preference for APAP over CPAP therapy in patients with mild disease (27).

Another potential limitation of our study is the inclusion of only two female subjects. This distribution does not allow a conclusion about gender differences. However, these gender frequencies represent the distribution of severe OSAS in our unit and separate studies investigating APAP evaluation in women should be performed specifically targeting this question.

We found that the Breas PV 10i resulted in a significant lower pressure profile, but poorer sleep quality, more complaints of pressure discomfort and lowest compliance rates were also observed with this device. Furthermore, it was the least popular choice among patients preferring APAP devices at the end of the study. Unfortunately, an evaluation of the AHI data is not available on this machine making it impossible to propose ineffective treatment response as a cause of its negative impact. Both the RemStar Auto and the Autoset Spirit reduced the AHI to <5 events/hour (data not shown) but given the significant lower pressure with the Breas PV10i the same efficacy may have not been achieved. This could have led to impairment in sleep quality with subsequent lower compliance.

Interestingly, none of the APAP devices led to a change in quality of life as assessed by the SF-36 or in daytime sleepiness indicating that APAP treatment does not provide additional benefits in these domains. This is of clinical importance as it indicates that patients already established on fixed pressure CPAP therapy will not gain further benefit by switching to an APAP device.

We conclude from our findings that the different APAP algorithms create pressure profiles that are not equally effective in terms of compliance, sleep quality and side effects in patients established on CPAP therapy. A routine switching from fixed pressure CPAP to APAP treatment cannot be recommended but if a patient wishes to try APAP treatment the specific device needs to be carefully assessed to assure treatment effectiveness. Furthermore, the data do not support the routine prescription of APAP as initial therapy for severe OSAS and the authors recommend that, at present, APAP therapy be reserved for patients having difficulty with standard CPAP, or in selected patients where there is objective evidence of APAP superiority such as those requiring high fixed pressure levels with CPAP (28).

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Parameter	Patient Population (n=27)
Sex	25 males
Age (years)	53 [48;67]
BMI† (kg/m^2)	36.2 [31.3;38.6]
Diagnostic AHI‡	48 [29;76]
Diagnostic ESS§	15 [9;19]
Mean Fixed Pressure CPAP (cmH_2O)	10 [8;12]
Mean Prior CPAP Treatment Time (months)	53[37;85]

Table 1: Baseline characteristics (data presented as median [interquartile range]; † = body mass index; ‡ = apnoea/hypopnoea index; § = Epworth Sleepiness Score)

Parameter	CPAP	RemStar Auto	Autoset Spirit	Breas Pv10i
% Nights used	100[94;100]	100[79;100]	96[42;100]	59[17;93]*
Mean hours per night	6.6[5.9;7.9]	7.1[5.3;8.1]	6.8[5.9;8.0]	5.0[3.8;5.6]*
Mean Pressure	10 [8;12]	7.3 [6.0;9.1]^†	8.0[7.2;10.4]^	5.3[4.5;6.8]*
Maximum Pressure	10 [8;12]	13.4[9.4;16.0]^	12.2[10.2;13.4]	10.2[7.2;12.4]

Table 2: Compliance and Treatment Pressure (data presented as median [interquartile range]; * = $p<0.01$ to CPAP, RemStar Auto and Autoset Spirit; ^ = $p<0.01$ to CPAP; † = $p<0.05$ to AutoSet Spirit)

Legend-Figures

Figure 1

Subjective evaluation of device features of 3 Auto devices. *Bars represent mean values and standard deviation; ∗ = p<0.001 to Breas Pv 10i and RemStar Auto; † = p<0.05 to RemStar Auto*

Figure 2

Subjective evaluation of sleep quality on 3 Auto devices. *Bars represent mean values and standard deviation; § = p<0.05 to Autoset Spirit and RemStar Auto*

Figure 3

Subjective evaluation of treatment side effects of 3 Auto devices. *Bars represent mean values and standard deviation; § = p<0.05 to Autoset Spirit and RemStar Auto; # = p<0.05 to RemStar Auto*

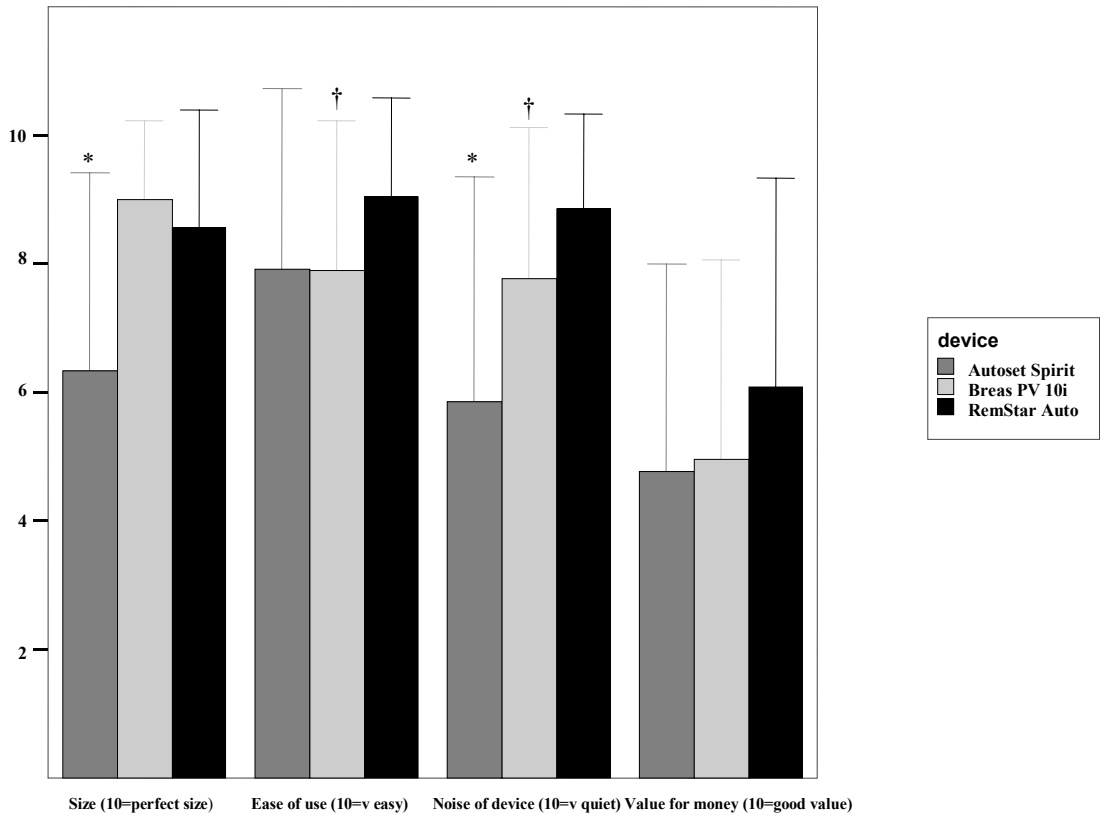
10
8
6
4
2
*
†
*
†
Size (10=perfect size)
Ease of use (10=v easy)
Noise of device (10=v quiet)
Value for money (10=good value)
device
Autoset Spirit
Breas PV 10i
RemStar Auto

Figure 1

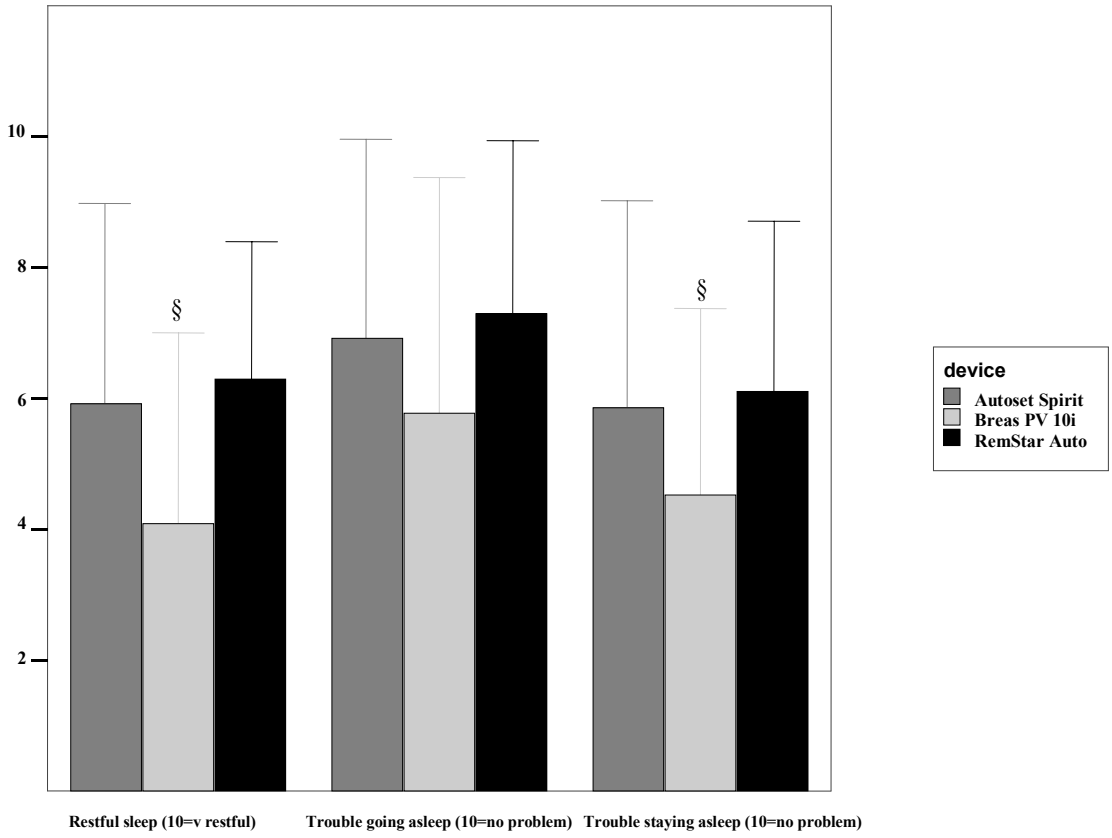
10
8
6
4
2
§
§
Restful sleep (10=v restful)
Trouble going asleep (10=no problem)
Trouble staying asleep (10=no problem)
device
Autoset Spirit
Breas PV 10i
RemStar Auto

Figure 2

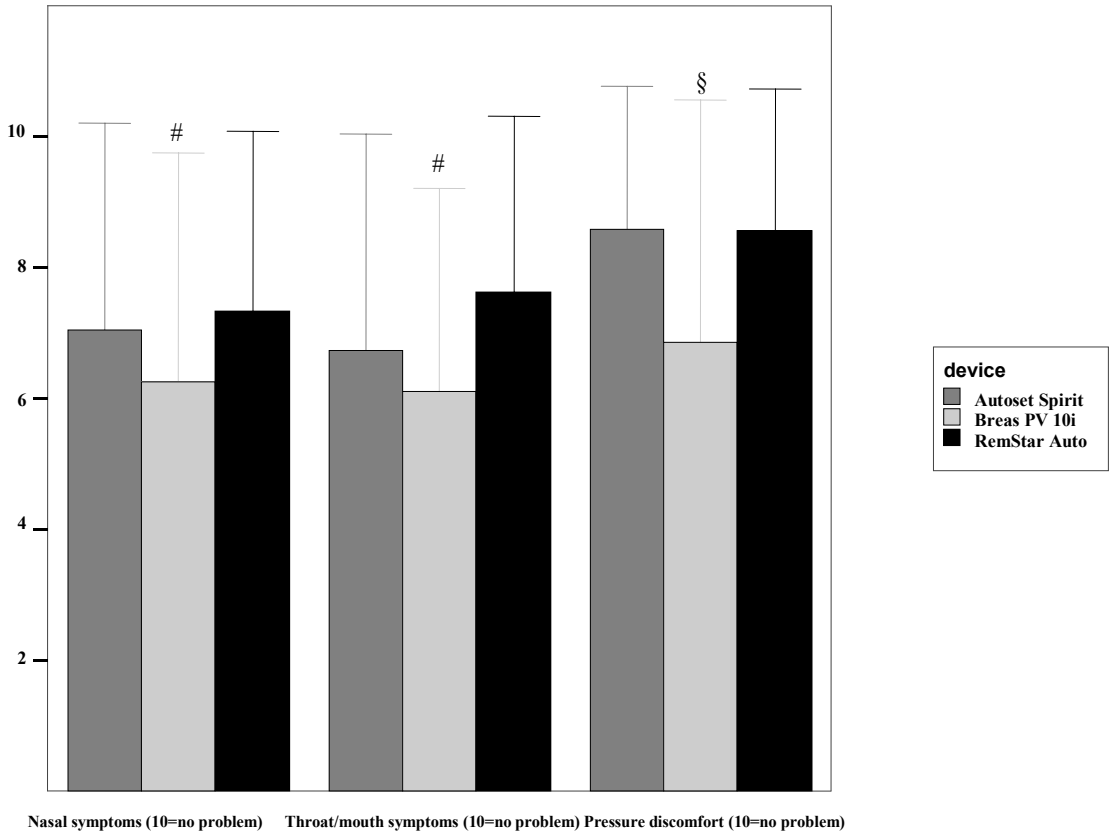
10
8
6
4
2
#
#
§
Nasal symptoms (10=no problem)
Throat/mouth symptoms (10=no problem)
Pressure discomfort (10=no problem)
device
Autoset Spirit
Breas PV 10i
RemStar Auto

Figure 3

Appendix 1

EVALUATION REPORT

NAME: DATE:

HOSP. NO: DEVICE:

The answers to these questions are graded on a scale of 1 to 10 where 1 indicates a strongly negative response and 10 a strongly positive response.

Please complete this questionnaire by circling the number between 1-10 that best reflects your opinion.

A. WHAT DO YOU THINK ABOUT THE SIZE OF THE DEVICE?

1 2 3 4 5 6 7 8 9 10

(1 = too bulky) (10 = perfect size)

B. DO YOU FIND THE DEVICE EASY TO USE?

1 2 3 4 5 6 7 8 9 10

(1 = too difficult) (10 = very easy)

C. IS THE DEVICE VERY NOISY?

1 2 3 4 5 6 7 8 9 10

(1 = too loud) (10 = very quiet)

D. WHAT ABOUT THE COST OF THE DEVICE?

1 2 3 4 5 6 7 8 9 10

(1 = too expensive) (10 = excellent value)

E. WHAT IS YOUR OVERALL IMPRESSION OF THE DEVICE?

1 2 3 4 5 6 7 8 9 10

(1 = not impressed at all) (10 = very impressed)

F. HOW RESTFUL WAS YOUR SLEEP?

1 2 3 4 5 6 7 8 9 10

(1 = not restful at all) (10 = very restful)

G. HOW MUCH TROUBLE DID YOU HAVE GETTING TO SLEEP?

1 2 3 4 5 6 7 8 9 10

(1 = a lot of trouble) (10 = no trouble at all)

H. DID YOU HAVE TROUBLE STAYING ASLEEP DURING THE NIGHT?

1 2 3 4 5 6 7 8 9 10

(1 = a lot of trouble) (10 = no trouble at all)

I. ARE YOU HAVING PROBLEMS WITH A BLOCKED, RUNNY OR STINGING NOSE?

1 2 3 4 5 6 7 8 9 10

(1 = a lot of problems) (10 = no problems at all)

J. DID YOU HAVE A SORE OR DRY MOUTH OR THROAT?

1 2 3 4 5 6 7 8 9 10

(1 = very much so) (10 = not at all)

K. HOW MUCH DISCOMFORT DID YOU GET FROM THE PRESSURE?

1 2 3 4 5 6 7 8 9 10

(1 = a lot of discomfort) (10 = none at all)