

Table 3—Scoring and classification of APAP devices.

Device	Treatment Efficacy	Scoring Accuracy	Central Mechanism Detection	Snoring Detection	Patient Profile
D1	95%	67%	N	N	O
D2	81%	47%	N	Y	O, S
D3	100%	93%	N	N	O
D4	97%	N/A	N	N	O
D5	24%	99%	Y	Y	O, C, S
D6	94%	95%	N	N	O
D7*	84%	83%	Y	Y	O, C, S
D8	85%	91%	Y	Y	O, C, S
D9*	84%	94%	N	N	O
D10	96%	97%	N	N	O
D11*	57%	97%	Y	Y	O, C, S

Results were averaged over 2 tests (or 3 if * is indicated). Treatment of efficacy and scoring accuracy in the table were derived from the results of the long general scenario, in which snoring, “obstructive pressure peak” and cardiac oscillations were not simulated. Treatment efficacy, normalized as $TE = 1 - \text{residual obstructive AHI} / 38.6$, in which 38.6 is the bench-simulated obstructive AHI in the long general scenario; Scoring accuracy, normalized as $= 1 - |\Delta \text{Residual total AHI}|$, in which $\Delta \text{Residual total AHI} = (\text{AHI report} - \text{AHI bench}) / \text{AHI bench} \times 100\%$; N/A, non applicable since the device data is not available for D4; N, negative; Y, positive. O, obstructive SDB profile; S, snoring; C, central SDB profile; D1, iCH Auto; D2, RESmart Auto; D3, iSleep20i; D4, Floton Auto; D5, SleepCube Auto; D6, ICON+; D7, PR1 Remstar Auto; D8, S9 AutoSet; D9, DreamStar Auto; D10, Transcend Auto; D11, SOMNOBalance-e.

profiles. D1, D3, D4, D6, and D10 showed a treatment efficacy > 90% (Table 3). In addition, D3, D5, D6, D8, D9, D10, and D11 showed an accuracy of device-reported AHI > 90% (Table 3). However, the inability of central-mechanism detection should be highlighted for the following devices: D1, D2, D3, D4, D6, D9, and D10. These devices should be used with cautions in patients with coexisting central SDB events.

Limitation of the Study

On the current bench, the obstructive SDB patterns were characterized by the mechanical properties of the upper airway. Compared to the clinical trials, the variety of specific airflow patterns was limited, and the critical closing pressure for the upper airway (6 cm H₂O) was positive as observed, particularly in severe obstructive patients. Also, the reported device performance only relies on the simulated patient’s condition, i.e., the general scenarios, which were created to more closely simulate clinical variations within sleep-stage distribution.

CONCLUSIONS

This study using reproducible and standardized SDB events evidenced large differences between all APAP devices in performance and treatment efficacy. Both bench studies and clinical evaluations are necessary to test the devices in full range of patients’ spectrum of diseases and should be implemented in the registration of devices.

ABBREVIATIONS

AHI, apnea-hypopnea index
 APAP, auto-titrating positive airway pressure
 OSA, obstructive sleep apnea
 CPAP, continuous positive airway pressure
 SDB, sleep-disordered breathing

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