Patient Perceptions of a New Nasal Mask – Results of a Clinical Trial

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Introduction. Some of the primary factors that influence compliance with positive airway pressure (PAP) therapy are mask fit and comfort. With this in mind, we sought to determine the impressions of experienced PAP therapy users on the fit and comfort of a new nasal mask prototype. (Twilight Mask, Invacare Corp., Elyria, OH). This mask uses a clear polycarbonate shell, dual walled silicone cushion and adjustable forehead support.

Method. IRB approval for studies involving human subjects was obtained. PAP therapy patients that met inclusion criteria were recruited, after informed consent, from a database of patients seen at the sleep center. 23 of 26 recruited patients completed the study, 2 were dropped due to failure to appear for follow-up appointments, and 1 was dropped due to inability to tolerate a nasal mask (a full-face mask was required). Each participant was using PAP therapy ranging from 3 months to 4 years (mean 1.85 ± 1.32 years). Mean nightly PAP use was 6.62 ± 1.02 hours. Participants came to the sleep center where they completed a pre-trial questionnaire gauging perceptions of their current nasal mask and were then fitted with the prototype mask. The mask size used resulted in a 92 percentile fitting, based on width, depth, height and length of the nasal anatomy. After receiving instruction on adjustment and cleaning, participants took the mask home and used it for a 2-3 week period. At the end of the trial period, participants returned to the sleep center and completed a post-trial questionnaire about the study mask. Questions were designed to allow responses along a weighted continuum, allowing for analysis of the responses. These questions required the participant to compare the study mask to their current mask, and were focused on the silicone seal, vertical and horizontal fit, the exhalation exhaust ports, swivels, ease of assembly, forehead pads and headgear. Responses were grouped in three categories: 1) inferior, 2) same as, and 3) superior. For questions in which the majority of responses were in the "same as" category, the criteria being evaluated was considered to be similar to that offered by other masks. When the majority of responses were not in the "same as" category then the "same as" responses were dropped and the inferior and superior responses were compared.

Results. Although no single mask type was normally used by all of the participants in the study, several common features of this prototype began to emerge. 78% (14 of 18) rated the comfort of the trial mask to be better than that of their current mask. Similarly, 70% (16 of 23) rated the fit and overall presence of leakage to be better than that of their current mask. Also, 59% (10 of 17) found the mask to be quieter, and 93% (13 of 14) identified that the main tubing swivel was better than their mask. However, 2 of the 23 participants indicated that they experienced unintended disengagement of the main tubing swivel, and 48% (11 of 23) identified that they could feel exhaust gas blowing on them or their bed partner. When asked if they would choose to continue using the trial mask if the inequities with the prototype were corrected, 65% (15 of 23) identified that they would continue use.

Conclusion. This prototype mask seems to meet the comfort and fit requirements of a large portion of PAP users. With correction of the identified deficiencies, this nasal mask should become a valuable tool to aid in the promotion of patient compliance.

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