

## A Novel Sleep Assist Device Prevents Gastroesophageal Reflux: A Randomized Controlled Trial

◆ ACG/AstraZeneca Fellow Award

Erik Person, MD, MS,<sup>1</sup> Janice Freeman, RN,<sup>1</sup> Christopher Rife, MD,<sup>1</sup> Aaron Clark, BSME,<sup>2</sup> Donald Castell, MD, MACG<sup>1</sup>  
 1. Medical University of South Carolina, Charleston, SC; 2. Amenity Health, Inc., San Diego, CA.

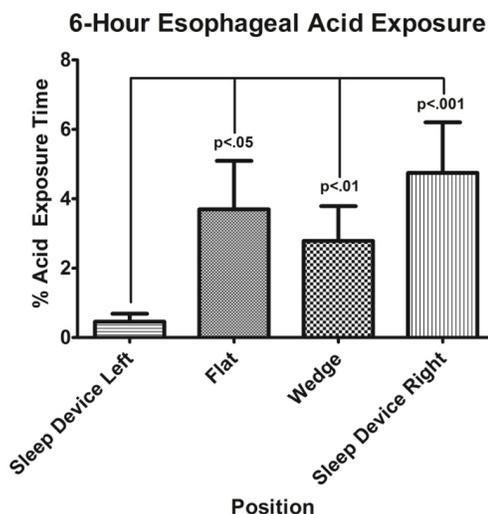
**Purpose:** Previous studies show that sleeping with the head of bed elevated or on a wedge reduces gastroesophageal reflux (GER). In addition, while recumbent, left side down reduces GER compared to right side down and supine. We performed a randomized controlled trial evaluating a sleep device (SD) consisting of a two-piece inclined base and body pillow (MedCline, Amenity Health, Inc., San Diego, CA) that maintains a patient in lateral position while elevating the head and torso. We hypothesized that sleeping in a fixed position on the left side with the head and torso elevated would significantly reduce recumbent GER.

**Methods:** This was a single institution, randomized controlled trial involving 20 healthy volunteers, each subject having 4 impedance-pH tests 6 hours in length. After placement of a reflux probe subjects returned home and ate a standardized meal (1350 kcal, 58g fat). Each subject then lay down in one of 4 randomly assigned positions: SD right side down (SD-R), SD left side down (SD-L), standard wedge any position (W), and flat any position (F). A wireless position monitor documented position during each study. Number of reflux episodes (RE) and esophageal acid exposure (EAE) was blindly calculated for 6 hour periods. Position monitor data was used to compare assigned position to actual position.

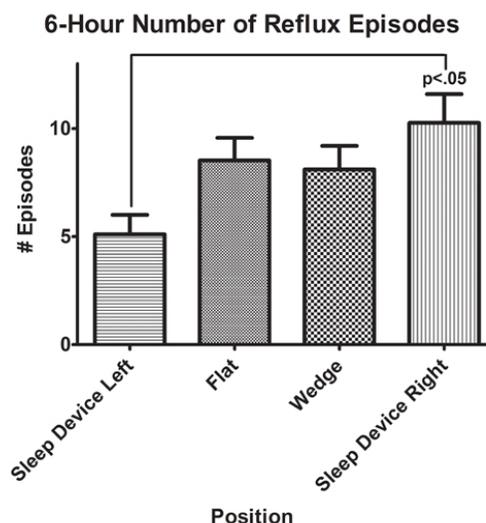
**Results:** Significantly less EAE over 6 hrs occurred sleeping SD-L compared to sleeping W (mean 0.46% v. 3.59%,  $p < .01$ ), SD-R (mean 0.46% v. 4.59%,  $p < .001$ ), and F (mean 0.46% v. 3.46%,  $p < .05$ ). RE over 6 hrs were significantly less SD-L than SD-R (mean 5.55 vs. 13.23,  $p < .05$ ). Patients assigned to SD-L on average spent 83% of first 2 hrs and 61% of 6 hrs in assigned position. Those assigned to SD-R spent 72% of first 2 hrs and 53% of 6 hrs in assigned position. Over 6 hrs, patients sleeping on W and F averaged significantly more time supine than R or L ( $p < .05$ ).

**Conclusion:** The sleep device maintains recumbent horizontal position effectively. Lying left side down, it dramatically reduces recumbent esophageal acid exposure. As in previous studies, right side down position gives the worst results, even with aid of the sleep device.

1A: 6 Hour Esophageal Acid Exposure



1B: 6 Hour Number Of Reflux Episodes



1A: 6 hour mean esophageal acid exposure (EAE) by position. SD-L exhibited significantly less EAE than any other position.

1B: 6 hour mean number of reflux episodes (RE) by position.