Correlation of Externally Applied Cricoid Pressure to Intraluminal Pressure*

CLINICAL STUDY SERIES

Correlation of Externally Applied Cricoid Pressure to Intraluminal Pressure*

AIMS

Determine the relationship between externally applied cricoid pressure and resulting intraluminal pressure at the UES.

Determine the effect of the Somna Therapeutics External Manometer on intraluminal pressure.

METHODS

• Seven (7) subjects with clinically established extraesophageal reflux and 7 healthy volunteers were studied.

• External pressure was applied manually and with the Reflux Band™ UES Assist Device at 10 to 50 mmHg in upright and supine positions.

• Intraluminal pressure measured 3 times with solid-state circumferential manometry catheter and externally with the Somna External Manometer.

• Both the nadir and the average UES pressure were determined.

• Measured intraluminal pressure with and without the Pressure Sensor in place.

RESULTS

• Fourteen (14) subjects reported a mean age (SD) of 59.2 (21) years old, a mean BMI (SD) of 28.9 (5.5) and a mean neck circumference (SD) of 14.7 (1.0)*.

• There were no adverse events or complications reported.

• Pressure applied by the Reflux Band™ was highly correlated to the intraluminal pressure at the UES (Figure 1).

• The externally applied manual pressure was highly correlated to the intraluminal pressure at the UES (Figure 2).

*Data on file.
RESULTS, continued

**RESULTS**

- The Reflux Band™, as well as manually applied pressure, were highly correlated for both the nadir and the average intraluminal pressure.
- Externally applied pressure for both the upright and supine positions for the Reflux Band™ and the manual technique were highly correlated to the intraluminal pressure (Figures 3 and 4).

**CONCLUSIONS**

- UES pressure increase is significantly correlated with external cricoid pressure irrespective of position, type of pressure application or measurement technique.
- Nadir luminal UES pressure is highly correlated with external cricoid pressure (p<0.0001).
- The Reflux Band™ applied pressure of 20 and 30 mmHg resulted in consistently correlated luminal UES pressure increase.
- External manual cricoid pressure of 20 and 30 mmHg resulted in correlated intraluminal UES pressure.
- The Pressure Sensor had no clinical affect on the intraluminal UES pressure.

NOTE: The Reflux Band™ was formerly known as the Reza Band®