

WEIGHT LOSS AND IMPROVED QUALITY OF LIFE WITH A NOVEL, NON-SURGICAL ENDOSCOPIC TREATMENT FOR OBESITY: CLINICAL RESULTS FROM A 3- AND 6-MONTH STUDY

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BACKGROUND: The TransPyloric Shuttle® (TPS®) is a non-surgical device that is delivered endoscopically to the stomach to treat chronic obesity. The TPS is deployed into the stomach to mechanically form a large spherical bulb connected to a smaller cylindrical bulb by a flexible tether. The larger bulb prevents migration from the stomach, while the smaller bulb passes freely into the duodenum during peristalsis to enable self-positioning of the TPS across the pylorus. Once transpyloric, the larger bulb engages the pylorus directly to form an intermittent seal designed to delay gastric emptying, enhance satiety, and enable a reduction in caloric intake.

METHODS: Patients enrolled in a prospective, open-label, non-randomized single center study in Sydney, Australia. Subjects were serially assigned to three-month and six-month treatment cohorts. Change in excess weight and weight-specific quality of life were evaluated as part of this study. The Impact of Weight on Quality of Life-Lite (IWQoL-Lite) Questionnaire was administered at baseline and end of treatment to assess the effect of obesity on an individual in five domains: Physical Function (PF), Self-Esteem (SE), Sexual Life (SL), Public Distress (PD), Work (W), and Overall (O). Higher scores are positive, indicating that obesity has less impact on emotional and physical well-being.

RESULTS: TPS delivery and removal procedures were successfully performed in outpatient endoscopic settings using a standard gastric overtube for access and esophageal protection. Deployment and retrieval times for the device were typically less than 15 minutes (10.3 ± 3.9 and 12.9 ± 6.4 , respectively). Devices were removed 1-2 weeks prior to completion of the planned treatment period in two subjects due to the development of symptomatic gastric ulcerations. Baseline mean body mass index (BMI) across the twenty subjects was $36.0 \text{ kg/m}^2 \pm 5.4 \text{ kg/m}^2$. At device removal, mean BMI reductions were $3.1 \text{ kg/m}^2 \pm 1.7 \text{ kg/m}^2$ and $5.6 \text{ kg/m}^2 \pm 2.1 \text{ kg/m}^2$ in the three and six-month cohorts respectively. This equated to a percent EWL of $31.3\% \pm 15.7\%$ at three months and $50.0\% \pm 26.4\%$ at six months. Crosby, et al (2004) determined that a 7.7 to 12-point increase in the IWQoL-Lite scores represented a meaningful improvement in weight-related quality of life. After treatment, three-month patients IWQoL-Lite mean scores improved by 17.4 ± 15.7 , 32.9 ± 23.7 , 21.8 ± 24.4 , 11.3 ± 21.0 , 16.3 ± 18.4 , and 20.4 ± 14.2 for PF, SE, SL, PD, W, and O scores, respectively. Six-month patients IWQoL-Lite mean scores improved by 26.3 ± 26.0 , 34.8 ± 25.5 , 29.1 ± 26.6 , 8.9 ± 19.8 , 6.8 ± 15.3 , and 23.2 ± 20.5 for PF, SE, SL, PD, W, and O scores, respectively.

CONCLUSION: Obesity represents a major health concern facing our population today. In addition to increased health risk, obesity often carries with it a significant and negative impact on an individual's quality of life (QoL). The present study demonstrated substantial weight loss in 20 subjects using an experimental, non-surgical device therapy. Treatment with the TPS was safe, well-tolerated and resulted in meaningful improvements in weight-related QoL measures that reached statistical significance ($p < 0.05$) in four of the five domains of the IWQoL-Lite (PF, SE, SL, and O) after three and six-month periods.