Invivo measurement accuracy assessment of the EndoFLIP system
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Introduction

The EndoFLIP system (Crospon, Galway, Ireland) is a new imaging technology for measuring the cross sectional area of hollow organs in vivo. To date no data has been published on the measurement accuracy of the system. We sought to demonstrate the in vivo accuracy of the system against an alternative measurement standard.
Methods and Procedures

Patients being fitted with a gastric band were measured using two methods (a) using an EndoFLIP EF-325 balloon catheter and (b) using the same balloon filled with gastrograffin, and measured using fluoroscopy. The balloon was filled with gastrograffin to the same volume of inflation as that used for the EndoFLIP measurement. The band was then inflated to different volumes to provide a series of test cases for each patient.

The EF-325 catheter has an 8cm long image field and provides 16 diameter measurements 5mm apart. The EndoFLIP system was used to inflate the catheter balloon with 30mL of a calibrated diluted saline solution. The catheter was deployed transorally and positioned so as to locate the band stoma centrally within the balloon. The minimum diameter of the band stoma was noted from the EndoFLIP system.
Methods and Procedures (continued)

A GE OEC 9800 Plus fluoroscopic imaging system was used as the reference measurement technique. The fluoroscopic images were printed out and boundary points of the band stoma in each image marked by a trained radiology technician, and thereafter measured using a vernier calipers. Marker bands on the catheter shaft were measured and used to scale the fluoroscopic image.

20 patients were enrolled in the study. Both Allergan LapBand APS (small) and APL (large) models were used. One patient data set was excluded due to difficulties in placing the reference catheter. 190 EndoFLIP reference measurement pairs in total were available for analysis from the remaining 19 patients, representing, on average, 10 band size adjustments per patient.
Results

The average subject age was 42 years [20-64], average subject weight was 221.3 lb [172-299], and the average Body Mass Index (BMI) for the cohort was 35.2 [26.9-44.3]. 65% of the subjects were female. 65% of the bands used were APS models.

A paired-t test of the differences between both techniques was conducted. The test showed that the mean difference between the techniques was -0.33mm with a 95% CI of -0.72 to 0.05mm.
Conclusion

Whereas the accuracy of the reference measurement method is less than that afforded by in vitro bench testing using static dimension standards, it is believed that the above results provide satisfactory evidence of agreement between using the EndoFLIP measurement system, versus using fluoroscopic measurements with an EndoFLIP catheter balloon filled with gastrograftin.