United States Data for the Bolton Relay® Thoracic Stent-Graft

The Relay thoracic stent-graft with Plus delivery system (Bolton Medical, Inc., Sunrise, FL) received United States Food and Drug Administration approval in September 2012, but it has been used in Europe and other international markets since 2005. The United States pivotal study included 120 endovascular patients at 30 hospitals. The study was expanded to include a continued access arm. The clinical data presented here are updated through February 2013 and include both phase II and continued access figures.

DEMOGRAPHICS. There were 133 patients treated with Relay, including both the clinical trial and continued access data (Table 1). A surgical control arm was required in the clinical trial, consisting of 60 patients.

Most notable in the Relay arm was a very large percentage of older patients—46.6% of patients were over 75 and 26.3% were 80 years or older, which is double the 11.7% of octogenarians included in the surgical group. No surgical patients were over the age of 84. There was an approximately even amount of men and women, and the majority of patients were Caucasian.

CLINICAL UTILITIES. The procedure times were quite similar to surgical control groups in other clinical trials, with the endovascular arm being far superior in almost every metric (Table 2). The Relay arm had a mean and standard deviation (SD) of 2.3±1.2 (range, 0.1–6.2 hours) versus the surgery arm's SD of 4.6±2.3 (1.4–14.1 hours).

Blood loss, ICU time, and hospital stay were all more favorable in the Relay arm.

RELAY OPERATIVE DATA. Implants were successful in 96.7% of patients (128 of 132; one subject did not have a completed case report). Four subjects' procedures were aborted, all related to anatomical challenges. There were no operative conversions to open repair.

EARLY OUTCOMES. Mortality within 30 days was 5.3%. The surgical arm had higher rates of stroke, paralysis/paraplegia, myocardial infarction, procedural bleeding, renal failure, respiratory failure, wound complications, and mortality.

LATE OUTCOMES. Mean follow-up was 30 months and outcomes were CEC-adjudicated (Table 3). The Relay arm had substantially lower rates of procedural bleeding, renal failure, respiratory failure, wound complications, all-cause mortality, and aneurysm-related mortality than the surgical control.

EFFECTIVENESS. There was no site-reported incidence of stent-graft migration, lumen occlusion, or aneurysm rupture. One patient required conversion to open repair during follow up. Throughout all follow-ups, there was a 6.0% overall incidence of endoleak; type I endoleak was in 4.5% (6/133) and type III, 2.3% (3/133).

Table 1. Demographics

	Relay (n = 133)	Surgical (n = 60)
Mean Age (Range)	72.8 (28–91)	70.0 (35–84)
18–64	15.8% (21/133)	20% (12/60)
65–74	37.6% (50/133)	40% (24/60)
75–79	20.3% (27/133)	28.3% (17/60)
80–84	16.5% (22/133)	11.7% (7/60)
≥ 85	9.8% (13/133)	0% (0/60)
Gender		
Male	52.6% (70/133)	68.3% (41/60)
Female	47.4% (63/133)	31.7% (19/60)
Race		
Caucasian	85.7% (114/133)	83.3% (50/60)
African American	6.8% (9/133)	10% (6/60)
Other	7.5% (10/133)	6.7% (2/60)

Table 2. Clinical Utilities

Parameter	Relay (m±SD, range)	Surgical (m±SD, range)
n Procedure Time (hours)	132 2.3±1.2 (0.1–6.2)	56 4.6±2.3 (1.4–14.1)
n Blood Loss (ml)	130 217±377 (0–4000)	31 2347±2647 (0–12,000)
n ICU Time (hours)	127 56±51 (0–257)	42 191±190 (24–745)
n Hospital Stay (days)	127 5.2±4.1 (1–30)	56 13±10 (3–45)

Table 3. Early and Overall Outcomes

Early safety outcomes		
Adverse Events	Relay (n = 133)	Surgical (n = 60)
Stroke	4.5% (6/133)	6.7% (4/60)
Paralysis/Paraplegia	1.5% (2/133)	3.3% (2/60)
MI	1.5% (2/133)	1.7% (1/60)
Procedural Bleeding	6.0% (8/133)	28.3% (17/60)
Renal Failure	1.5% (2/133)	5.0% (3/60)
Respiratory Failure	5.3% (7/133)	18.3% (11/60)
Wound Complications	5.3% (7/133)	6.7% (4/60)
Mortality	5.3% (7/133)	10.0% (6/60)
Overall effectiveness outcomes		
Major device-related adverse events	9/133 (6.8%)	
Any endoleak	8/133 (6.0%)	
Type I	6/133 (4.5%)	
Type III	3/133 (2.3%)	
Type IV	0/133 (0%)	
Stent migration	0/133 (0%)	
Lumen occlusion	0/133 (0%)	
Aneurysm rupture	0/133 (0%)	
Deployment failure/conversion to surgical repair	1/133 (0.8%)	