Table 1. Primary and Secondary Outcomes at 3 Years

Parameter	Medical therapy n=40	Bypass n=48	Sleeve n=49	p[1]	p[2]
Primary Outcome					
HbA1C ≤6%	5%	37.5%	24.5%	<0.001	0.012
HbA1C ≤6%, no medications	0%	35.4%	20.4%	<0.001	0.002
Secondary outcomes					
HbA1C ≤7%	40%	64.6%	65.3%	0.02	0.02
Change in FPG, mg/dL	-6	-85.5	-46	0.001	0.006
Relapse of glycemic control at 3 years	80%	23.8%	50%	0.03	0.34
% change in high-density lipoprotein	+4.6	+34.7%	+35.0	<0.001	<0.001
% change in triglycerides	-21.5	-45.9	-31.5	0.01	0.01
% change in CIMT	0.048	0.013	0.017	0.36	0.49

CIMT=carotid intima media thickness; FPG=fasting plasma glucose; 1gastric bypass versus medical therapy; 2sleeve gastrectomy versus medical therapy.

Both types of bariatric surgery similarly and significantly decreased HbA1C at multiple time points throughout the 3-year trial (Table 2).

Table 2. Change in HbA1C

	Value at Visit, Average (Median)				
Treatment	Baseline	Month 6	Month 12	Month 24	Month 36
Medical therapy	9.0 (8.5)	7.1 (6.8)	7.5 (6.9)	7.7 (7.3)	8.4 (7.6)
Gastric bypass	9.3 (9.2)*	6.3 (6.2)*	6.3 (6.1)*	6.5 (6.4)*	6.7 (6.6)*
Sleeve gastrectomy	9.5 (8.9)*	6.7 (6.4)*	6.6 (6.4)*	6.8 (6.8)*	7.0 (6.6)*

*p<0.001 compared with MT at the same time point; the bariatric surgeries were not significantly different from each other.

Gastric bypass and sleeve gastrectomy also rapidly and significantly decreased BMI, and maintained the decrease over 3 years, compared with the modest reduction achieved with MT alone (p<0.001 for both), with gastric bypass proving significantly superior to sleeve gastrectomy from 6 months onward (p=0.006; Table 3).

Table 3. Change in BMI

	Value at Visit, kg/m^2				
Treatment	Baseline	Month 6	Month 12	Month 24	Month 36
Medical therapy	36.4	34.6	34.2	35.0	34.8
Gastric bypass	37.1	28.2	26.7	27.3	27.9
Sleeve gastrectomy	36.1	28.3	27.1	27.9	29.3

Adverse events were infrequent and similar between the study arms, with the exception of gastrointestinal complications, which occurred in 13 of 50 (26%) bypass patients.

The findings support bariatric surgery as a treatment option for moderately-to-severely obese patients with uncontrolled T2DM to improve glycemic control in the near-term. Longer follow-up of clinical results and larger experience in routine clinical practice will provide further insight into the durability of efficacy and the prognosis associated with adverse events with each of these bariatric surgery procedures.

Single-Center Study Finds Bivalirudin Associated With Increased Ischemic Risk in Primary PCI for STEMI (HEAT PPCI)

Written by Muriel Cunningham

Adeel Shahzad, PhD, Liverpool Heart and Chest Hospital, Liverpool, United Kingdom (UK), presented results from the How Effective Are Antithrombotic Therapies in Primary Percutaneous Coronary Intervention trial [HEAT PPCI; NCT01519518]. All patients with ST-segment elevation myocardial infarction presenting at a single UK center were randomized to open-label treatment with heparin (70 units/kg body weight preprocedure) or bivalirudin (bolus of 0.75 mg/kg followed by 1.75 mg/kg/hour infusion during the procedure) on top of preprocedure dual antiplatelet therapy. The glycoprotein IIb/IIIa inhibitor, abciximab, was available for "bailout" from ischemic complications in both groups. Patients were excluded if they had active bleeding at presentation; administration of oral antiplatelet therapy was contraindicated, had a known intolerance or contraindication to the study medications, or had previously enrolled in the study.

The study protocol received full UK ethics approval and both drugs were administered according to the approved labeling. The ancillary benefit of this consent approach was to improve generalizability of the study results by allowing for enrollment of subjects that would not typically be included. The primary efficacy endpoint was major adverse cardiac events (MACE) at 28 days. Major bleeds, defined as Type 3 to 5 per the Bleeding Academic Research Consortium definitions, was the primary safety endpoint. A clinical events committee blinded to treatment assignment adjudicated key clinical events.

Over a 22-month period, 1917 patients presented for emergency angiography and 1829 eligible patients were randomized. Only seventeen patients did not give informed consent after the acute intervention. Of those randomized, 905 were in the bivalirudin analysis and 907 were analyzed from the heparin group. The demographic characteristics were similar between the two treatment groups. The median age was ~63 years, ~27% were female, and >95% were Caucasian. Approximately 12% of patients had a previous MI. Procedural details are presented in Table 1.

Table 1. Procedural Information

Characteristic	Bivalirudin (%)	Heparin (%)
P2Y12 use		
Any	99.6	99.5
Clopidogrel	11.8	10.0
Prasugrel	27.3	27.6
Ticagrelor	61.2	62.7
GPI use	13.5	15.5
Radial arterial access	80.3	82.0
PCI performed	83.0	81.6
Thrombectomy	59.1	57.6
Single vessel treatment	93.2	90.3
Any stent implant	92.8	92.2
Drug-eluting stent implantation	79.8	79.9
TIMI III flow post-PCI	93.3	92.7

GPI=glycoprotein IIb/IIIa inhibitor; PCI=percutaneous coronary intervention.

Event rates by treatment group are presented in Table 2. For the primary efficacy outcome, MACE was 8.7% (n=79) in the bivalirudin group compared with 5.7% (n=52) in heparin-treated patients, resulting in an absolute risk difference of 3.0% and a relative risk ratio (RRR) of 1.52 (95% CI, 1.1 to 2.1; p=0.01). The risk of stent thrombosis was higher with bivalirudin (3.4% [n=24] vs 0.9% [n=6], RRR, 3.91; 95% CI, 1.6 to 9.5; p=0.001). Safety was similar between the two groups for the primary safety outcome of major bleeds. Thirty-two bivalirudin-treated patients (3.5%) had a major bleed compared with 28 patients receiving heparin (3.1%; RR, 1.15; 95% CI, 0.7 to 1.9; p=0.59).

Table 2. Efficacy and Safety Outcomes

Event	Bivalirudin n (%)	Heparinn (%)
Any MACE	79 (8.7)	52 (5.7)
Death	46 (5.1)	39 (4.3)
Cerebrovascular event	15 (1.6)	11 (1.2)
Reinfarction	24 (2.7)	8 (0.9)
TLR	24 (2.7)	6 (0.7)
Stent thrombosis	24 (3.4)	6 (0.9)
Definite	23 (3.3)	6 (0.9)
Probable	1 (0.1)	0
Acute	20 (2.9)	6 (0.9)
Subacute	4 (0.6)	0
Major bleed	32 (3.5)	28 (3.1)
Minor bleed	83 (9.2)	98 (10.8)
Major or minor bleed	113 (12.5)	122 (13.5)

MACE=major adverse cardiac event; TLR=target lesion revascularization.

Although the trial was large, it was conducted at a single center and with open-label therapy. Dr. Shahzad noted that the large sample size and unselected population with multiple operators made this a "real world" trial. The investigators believe that the potential impact of the open-label design, which has been utilized in other trials, was mitigated by complete follow-up (no loss to follow-up), a primary outcome of overt clinical events, and adjudication by independent blinded clinicians.