

Clinical Cardiology

Critical analysis of the latest clinical research in cardiovascular medicine [ALERT]

ABSTRACT & COMMENTARY

DAPT Trial Adds Both Clarity and Confusion to the Debate Over Optimal Duration of Dual Antiplatelet Therapy

By Jeffrey Zimmet, MD, PhD

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Dr. Zimmet reports no financial relationships relevant to this field of study.

SOURCE: Mauri L, et al. Twelve or 30 months of dual antiplatelet therapy after drug-eluting stents. *N Engl J Med* 2014;371:2155-2166.

Dual antiplatelet therapy (DAPT) following coronary stenting is essential for the prevention of stent thrombosis, which can occur due to a response to the vascular scaffold, as well as to the local inflammation that occurs after angioplasty. DAPT after drug-eluting stent (DES) implantation is currently recommended for at least 12 months in the United States and for 6 months in Europe. Concern over very late stent thrombosis (occurring later than 1 year) with DES prompted a collaborative effort between the FDA and device and pharmaceutical manufacturers to study the efficacy of DAPT beyond 1 year in these patients.

The DAPT trial, whose results were published in the *New England Journal of Medicine* following a presentation at the American Heart Association meeting in November, enrolled patients following treatment with drug-eluting and bare metal stents. There were 22,866 patients who received DES initially registered. From that number, more than half dropped out before 1 year. Some of these were not eligible because they had experienced ischemic or bleeding events or had demonstrated nonadherence to therapy. Others withdrew consent or were otherwise unable to be randomized. In the end, 9961 patients underwent randomization at 12 months to receive either continued thienopyridine or placebo for up to 33 months. More than 95%

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of these patients were included in clinical follow up at 30 months.

During the period from randomization at 12 months to analysis at 30 months, patients receiving continued thienopyridine showed a significantly lower incidence of both stent thrombosis (0.4% vs 1.4%, $P < 0.001$) and major adverse cardiovascular and cerebrovascular events (4.3% vs 5.9%, $P < 0.001$). Among MACCE events, myocardial infarction (MI), in particular, was lower in the continued thienopyridine group. MI not related to stent thrombosis accounted for just over half of this benefit, presumably indicating an advantage in preventing events distant from the stented region. As might be expected, these benefits came at the cost of higher rates of moderate and severe bleeding (2.5% vs 1.6%; hazard ratio [HR], 1.61; 95% confidence interval [CI], 1.21 to 2.16; $P = 0.001$), although severe and fatal bleeding (by GUSTO and BARC criteria) were not significantly increased. All-cause mortality was slightly higher in the continued DAPT group (2.0% vs 1.5%; HR, 1.36; $P = 0.05$), with non-cardiovascular death accounting for the difference. Interestingly, bleeding-related deaths were not the sole contributor; cancer-related deaths were significantly greater (31 vs 14, $P = 0.02$) in the group receiving continued thienopyridines. The authors concluded that treatment beyond 1 year with dual antiplatelet therapy has measurable benefits in terms of ischemic outcomes, but at the expense of higher rates of bleeding.

■ COMMENTARY

Back in 2006, the interventional cardiology world was shaken by data suggesting increased rates of late and very late stent thrombosis with first-generation DES. The current post-percutaneous coronary intervention (PCI) antiplatelet recommendations, as well as the DAPT trial itself, were born of these concerns. However, over the past several years, multiple studies with second- and third-generation DES have focused on the shorter end of the time scale, comparing 12 months of thienopyridine to 6-, 3-, or even 1-month durations. The majority of these smaller and shorter-term studies

have shown non-inferiority of the shorter durations of therapy. Although the European Society of Cardiology guidelines currently recommend 6 months of treatment post-stent, Abbott's Xience DES has had CE Mark labeling for at least 3 months since 2012, and Medtronic updated its European labeling for the Resolute Integrity stent to state that "patients who interrupt or discontinue DAPT medication one month or more after stent implantation are considered at low risk...."

What then are we to make of these results, and how will they change practice? In an accompanying editorial, Dr. Antonio Colombo wisely argues that the time course following DES implantation should be divided into an early "mandatory" period and a later "possibly beneficial" phase. A bevy of smaller studies (PRODIGY, RESET, OPTIMIZE, and, most recently, ISAR-SAFE) have focused on the "mandatory" period, and have, for the most part, shown that low-risk patients do not show an undue hazard from shorter durations of thienopyridine. The DAPT study focuses on the later, possibly beneficial, period, and does so with a rigorous study design and large sample size. The results show convincingly that there is a small but real benefit to longer-term therapy in terms of preventing both thrombosis of the stented segment and acute coronary syndromes involving other vessels.

In examining the results, we should ask ourselves: Who were the patients in this trial and how do they compare with our patient population? The DAPT trial evaluated patients who were relatively adherent and had already completed a year of thienopyridine without adverse events. In many ways, this focuses on patients who were already in a relatively low-risk category. Patients who had ischemic events in the first year post-PCI were not evaluated, but one might reasonably expect an even higher benefit to longer-term therapy in such patients.

It should be pointed out that the newer non-thienopyridine agent, ticagrelor, was not included in the DAPT study. Also at issue is the apparent differential response

among the different stent types in the study. For example, the difference between thienopyridine and placebo groups was most marked with the older paclitaxel-eluting stents, and was less striking with more contemporary stent platforms.

As with many issues in medicine, an individualized approach is needed when evaluating the duration of antiplatelet therapy for any particular patient.

Tailored therapy that compares bleeding risk with known risk factors for MI and stent thrombosis is likely to be the best tactic, and this requires intimate knowledge of the each patient's risk profile and stent anatomy. Patients with low propensity for bleeding, who are at higher risk of ischemic complications, including patients with acute coronary syndrome with multiple or complex stents, now have data to support longer-term therapy. ■

ABSTRACT & COMMENTARY

Paradoxical Low-flow, Low-gradient AS

By Michael H. Crawford, MD, Editor

SOURCE: Clavel MA, et al. Paradoxical low-flow, low-gradient aortic stenosis despite preserved left ventricular ejection fraction: New insights from weights of operatively excised aortic valves. *Eur Heart J* 2014;35:2655-2662.

Low-flow, low-gradient aortic stenosis (AS) is usually associated with reduced left ventricular (LV) performance. When LV systolic function is normal, it has been labelled “paradoxical.” Such patients have considerable concentric LV hypertrophy and a restrictive physiology with a normal LV ejection fraction (EF) but low stroke volume. The prognosis of these patients compared to those with similar severity of AS but normal stroke volume is unclear from the literature, raising the questions of whether AS severity can be determined accurately. Thus, these investigators from Quebec, Canada, hypothesized that aortic valve weight after excision at surgery would be a surrogate for AS severity, and sought to compare it in the paradoxical low-flow, low-gradient (PLF-LG) patients vs AS patients with normal flow and high gradients (NF-HG). They studied two groups: 250 patients with severe AS (valve area ≤ 1.0 cm² and index ≤ 0.6 , $n = 33$) and either paradoxical AS or high-flow, high-gradient AS ($n = 105$) undergoing surgical aortic valve (AV) replacement, and 150 patients with moderate-to-severe AS with NF-HG undergoing AV replacement during coronary bypass surgery. The latter group was used to define a valve weight cutoff for severe AS using echo Doppler as the standard.

Baseline data showed that PLF-LG patients had more dyslipidemia and coronary artery disease. PLF-LG patients had smaller LVs with lower mass than NF-HG patients. Interestingly, BNP levels and AV area were not different between these two AS groups. There were more patients with bicuspid valves in the NF-HG group (42% vs 15%, $P = 0.003$). AV weight was higher in the NF-HG group

compared to the PLF-LG group ($P = 0.02$), but when dichotomized by sex, the difference was not significant in women. Using the established AV weigh cutoff from the 150 patients with moderate-to-severe AS undergoing coronary artery bypass grafting (CABG) plus AV replacement, severe AS was present in 70% of the PLF-LG group and 86% of the NF-HG patients. This finding was also only significant in men. The authors concluded that a majority of patients with PLF-LG AS have severe stenosis as defined by valve weight after surgery, and the valve gradient may underestimate stenosis severity in such patients.

■ COMMENTARY

This is a novel approach to studying patients with low-flow, low-gradient AS. A major issue in studying these patients is determining the gold standard for measuring AS severity. Many studies in the area suffer from measurement errors, failure to take body size into consideration, and lack of a more in-depth analysis of orifice area. They chose the weight of the aortic valve excised at surgery as compared to a comprehensive Doppler-echo evaluation to establish a weight cutoff for severe AS in patients with moderate-to-severe AS undergoing CABG and AV replacement. They then applied this cutoff to selected patients presumed to have severe AS who had an isolated AV replacement by surgery. The patients selected were divided into two groups: NF-HG and PLF-LG, the latter being paradoxical because their left ventricular ejection fraction (LVEF) was normal. More than 80% of the NF-HG patients of either sex had severe AS by valve weight and 65-80% of PLF-LG patients, depending on sex, had severe AS. These findings validate their selection criteria for surgery,

but, more importantly, highlight the fact that patients with normal LVEFs with low-flow, low-gradient AS on echo often have severe AS and benefit from valve replacement.

How do we identify the PLF-LG patients who have severe AS? The authors suggest a multimodality approach. Clinically, these patients often have considerable hypertrophy with small cavity sizes, normal LVEF, but reduced longitudinal function and high valve-arterial impedance. The first step is a

comprehensive echo-Doppler approach to quantifying AV area, which could include dobutamine stress testing to identify pseudo AS and transesophageal echo to measure orifice area. If there is still uncertainty, a CT scan to quantify AV calcium content could be helpful. In this study, brain natriuretic peptide was not particularly useful. Also, in this study, only echo-Doppler AV area at rest was used to clinically characterize the patients and make surgical decisions. So this multimodality approach has not been prospectively tested. ■

ABSTRACT & COMMENTARY

Carotid Artery Stenting Bested by Endarterectomy in Asymptomatic Patients

By Jeffrey Zimmet, MD, PhD

SOURCE: Choi JC, et al. Early outcomes after carotid artery stenting compared with endarterectomy for asymptomatic carotid stenosis. *Stroke* 2014 Nov 25. pii: STROKEAHA.114.006209. [Epub ahead of print]

Although carotid artery stenting (CAS) is a less invasive means of carotid revascularization, multiple trials have demonstrated an increased risk of post-procedural stroke in patients with symptomatic carotid stenosis, as compared to carotid endarterectomy (CEA). Because of the lower annual stroke hazard associated with asymptomatic severe carotid stenosis (approximately 2%), carotid revascularization is recommended by current guidelines only in selected patients and when the procedural risk of morbidity and mortality is estimated to be less than 3%. Randomized clinical trial data comparing CAS to CEA for asymptomatic patients are lacking. Nevertheless, the application of CAS to this population in the United States has been growing steadily over the past decade.

Using retrospective data from the University Health System Consortium (UHC)'s clinical database, Dr. Anthony Kim and colleagues from the University of California, San Francisco department of neurology analyzed rates of in-hospital death and postoperative stroke following CEA and CAS performed on asymptomatic patients. For the study period from January 2010 to December 2012, the authors identified 17,716 patients with asymptomatic carotid stenosis treated with CEA and 3962 treated with CAS at 186 University Health System Consortium hospitals. Compared with CEA patients, those patients treated with CAS were more likely to be younger and black, and to have high-risk comorbidities, including coronary artery disease, peripheral artery disease, chronic

kidney disease, and heart failure. Balancing this out, however, was a lower likelihood of having hypertension, hyperlipidemia, and smoking. Just 61% of patients in the CAS group and 59% in the CEA group were considered high risk for CEA by standard definitions (age > 80, history of coronary artery disease, congestive heart failure, or chronic lung disease).

In the unadjusted analysis, CAS patients compared with CEA patients were more likely to develop in-hospital death or postoperative stroke (4.0% vs 1.5%; $P < 0.001$). After logistic regression analysis adjusting for age, race, sex, and multiple comorbidities, the odds of stroke or death after CAS remained significantly higher than after CEA (odds ratio 2.5; 95% confidence interval, 2.1-3.1; $P < 0.001$). Similar results were obtained using propensity score matching. Other expected benefits of the less-invasive procedure did not materialize, as the postoperative myocardial infarction (MI) rate and early readmission for MI rate was not significantly different between the two groups.

Analysis of hospital-level and physician-level information yielded several interesting results. At the physician level, a link between higher operator volumes and improved outcomes was seen with CEA but not with CAS. Low annual procedure volumes for CAS may be partly responsible for this observation; median annual procedure volumes were only 1.5 for CAS, as compared with 3 for CEA. While rates of in-hospital death and postoperative

stroke were < 3% for all specialties performing CEA, adverse event rates for CAS were > 3% for most specialties (vascular surgeons, neurosurgeons, radiologists, general surgeons, and neurologists), with the exception of cardiologists, who composed 22.8% of the total group and had an adverse event rate of 2.6%.

Hospitals for which CAS composed a greater proportion of carotid revascularization procedures had greater odds of inducing postoperative stroke or in-hospital death than those where CAS was less common, even after adjustment for patient-level variables.

The authors argue that “widespread prophylactic use of CAS for asymptomatic carotid stenosis is not justified without additional evidence of clear benefit, and provide further justification for additional randomized clinical trial data for this indication.”

■ COMMENTARY

Currently in the United States, more than 90% of carotid revascularization procedures are performed in asymptomatic patients. The proportion of

asymptomatic patients in the United States treated by CAS has increased from 3% in 1998 to 13% in 2008, and, further, to more than 18% in this analysis. This steady increase has been in spite of the lack of high-level evidence supporting the use of CAS in this population.

In the current study, CAS, as compared with CEA, was associated with more than a two-fold higher rate of in-hospital death and stroke, even after adjustment with several methods to adjust for confounding. In each group, the death/stroke rates exceeded the commonly accepted 3% threshold to justify any intervention. At the very least, randomized clinical trials are warranted to fully explore this question and to inform future practice.

The low per-physician and per-hospital annual CAS procedure volumes were a surprising and somewhat disturbing aspect of this study. Whether practitioners who perform only one or two procedures annually should continue to do so is questionable, especially in the already-controversial asymptomatic population. ■

ABSTRACT & COMMENTARY

Alcohol Septal Ablation vs Surgical Myectomy for HOCM

By Michael H. Crawford, MD, Editor

SOURCES: Steggerda RC, et al. Periprocedural complications and long-term outcome after alcohol septal ablation versus surgical myectomy in hypertrophic obstructive cardiomyopathy: A single-center experience. *JACC Cardiovasc Interv* 2014;7(11):1227-1234; Geske JB, et al. Myectomy versus alcohol septal ablation: Experience remains key. *JACC Cardiovasc Interv* 2014;7:1235-1236.

Symptomatic left ventricular outflow tract (LVOT) obstruction is common in patients with hypertrophic obstructive cardiomyopathy (HOCM), and medical therapy does not always relieve the symptoms. In such cases, septal reduction therapies are indicated, and both alcohol septal ablation (ASA) and surgical myectomy have been proven to reduce symptoms effectively. However, there is controversy concerning the post-procedure complications and long-term success of both procedures. Thus, these investigators from the Netherlands analyzed their single center experience from 1981 through 2009. ASA was introduced in 2000, and from then on, after a discussion of the potential risks and benefits of both procedures, patients were offered a choice of which they

preferred. The primary endpoint was all-cause mortality during a maximum follow-up of 11 years for both procedures. Several secondary clinical endpoints were also assessed, including cardiac death, which included deaths of unknown cause. ASA was employed in 161 patients and myectomy in 102. Baseline characteristics were similar, but myectomy patients were more likely to have CAD and ASA patients had thicker LV walls. The 30-day post-procedure severe complications (death, stroke, cardiac arrest) were not significantly different between procedures, but the total complication rate was higher after myectomy (28% vs 14%, $P = 0.004$), which remained true when only the patients done after 2000 are considered. Long-term (median 9 years) follow-up in 99% of the patients showed

that yearly all-cause mortality was similar (1.5 ASA, 2.2 myectomy, $P = \text{NS}$), as was cardiac mortality (0.7 ASA vs 1.4 myectomy, $P = \text{NS}$). In the 13 patients with implantable cardioverter defibrillators (ICDs), no appropriate shocks were observed. Also, symptoms, rehospitalization for heart failure, stroke, and myocardial infarction were not different. In the 92% with a late echocardiograms (mean 4 years), provoked LVOT gradients were higher in the ASA patients (19 vs 10 mmHg, $P < 0.001$). The authors concluded that survival and clinical outcomes were similar in ASA and myectomy patients.

■ COMMENTARY

As this study shows, less invasive procedures have great appeal for patients. Once ASA was introduced, it quickly became the predominant procedure when patients were offered a choice. What this experience shows is that this choice was reasonable given the excellent short- and long-term results with ASA. It is not surprising that a percutaneous procedure would have less periprocedural complications, but there has been fear that the induction of a septal MI would lead to long-term ventricular arrhythmias and an increase in late sudden death. This was not observed in this study, and in the patients with ICDs, there was no difference in appropriate shocks during follow up. Another critique of ASA was that the need for a pacemaker afterward would be higher. This also was not observed; 11% of ASA patients and 9% of myectomy patients needed a pacemaker ($P = \text{NS}$).

The strengths of this study are the long follow up and the completeness of the follow-up data. Weaknesses include the retrospective, observational design and

that myectomies were done over a longer time period. However, the groups were well-matched, and when the study was censored at year 2000 forward (start of ASA), the results were the same.

The current American College of Cardiology/American Heart Association guidelines recommend myectomy as the procedure of choice and ASA as an alternative for those who cannot, or will not, have myectomy. These data would support both as reasonable first-line therapy. One caveat is that ASA cannot be done in all patients due to variations in septal perforator coronary anatomy. Some patients don't have one large septal perforator supplying the largest superior portion of the septum. Presumably, myectomy can be done in almost everyone. Some patients are not candidates for either procedure due to more diffuse septal hypertrophy, resulting in more of a cavity obliteration physiology with more diastolic heart failure.

Another issue is what to do with the patients with concomitant CAD. In this study, most of these patients had myectomy with bypass surgery. However, a percutaneous coronary procedure could be feasible in many patients, but there is little experience with this approach currently. In the final analysis, the choice of procedure is complicated, and medical issues as well as patient preference should be considered in the decision. This study provides reassurance that either decision is likely to lead to a good outcome. Finally, the editorial accompanying this paper by two Mayo Clinic cardiologists suggests that the infrequent HPCM patient who would benefit from septal reduction therapy should probably be sent to a center experienced with these procedures. ■

ABSTRACT & COMMENTARY

Can Intracardiac Echo Be Used As a Substitute for Transesophageal Echo Prior to Atrial Fibrillation Ablation?

By Edward P. Gerstenfeld, MD

Professor of Medicine, Chief, Cardiac Electrophysiology, University of California, San Francisco

Dr. Gerstenfeld does research for Biosense Webster, Medtronic, and Rhythmia Medical.

SOURCE: Anter E, et al. Comparison of intracardiac echocardiography and transesophageal echocardiography for imaging of the right and left atrial appendages. *Heart Rhythm* 2014;11:1890-1897.

Transesophageal echocardiography (TEE) is commonly performed prior to atrial

fibrillation (AF) ablation to exclude left atrial appendage thrombus. The purpose of this

study was to compare TEE and intracardiac echocardiography (ICE) for assessing left atrial appendage (LAA) anatomy and thrombus. This study was a prospective, blinded study that enrolled 71 patients referred for ablation of AF. TEE and ICE were performed simultaneously to assess for thrombi, spontaneous echo contrast, and LAA dimensions. Imaging of the LAA was achieved in all 71 patients using ICE but in only in 69 patients using TEE because of inability to intubate the esophagus. A total of four thrombi were diagnosed (three LAA, one renin-angiotensin-aldosterone). All were detected by ICE but only one by TEE. Diagnostic imaging of the LAA was achieved in 71 patients (100%) with ICE and in 62 patients (87.3%) with TEE ($P < .002$). Spontaneous echo contrast was more commonly diagnosed with ICE ($P < .01$). There was strong correlation between TEE and ICE for LAA length ($r = 0.71$), width ($r = 0.94$), and area ($r = 0.88$). Image quality with ICE was highest from the pulmonary artery and lowest from the right atrium. The authors concluded that ICE imaging is a viable alternative to TEE for visualization of the LAA during catheter ablation procedures.

■ COMMENTARY

The AF ablation guidelines recommend TEE prior to AF ablation in patients who have not been therapeutically anticoagulated for 3 weeks prior to the procedure. However, a TEE is commonly performed in many centers, even when patients have been anticoagulated prior to the procedure. This is because ablation of persistent AF seems to carry a higher stroke risk and because catheters will often be manipulated inside the left atrial appendage. Performing a TEE adds time, cost, and possible additional complications to the ablation procedure. The costs are felt to be justified by the reduction in stroke risk; however, many studies have found the incidence of thrombi detected prior to AF ablation to be exceedingly low. ICE is an alternative imaging modality that is typically used during AF ablation procedures in some centers to guide transeptal puncture and catheter positioning. ICE can view the LAA from several

locations: the right atrium, the right ventricular outflow tract, and the pulmonary artery, which lies adjacent to the LAA. In this study, the authors prospectively compared ICE and TEE for LAA imaging and the presence of thrombus. Interestingly, diagnostic imaging of the LAA was achieved in all patients using ICE but only 87% using TEE. ICE was also superior to TEE for detecting LAA thrombi (as stated above, TEE missed three of four thrombi).

The findings, though in a small group of patients, are provocative. One might question the expertise of the authors using TEE, given successful esophageal intubation in only 87% and absence of visualized thrombus in three of four cases. The GE Vivid E9 echocardiography machine was used for TEEs, and I know echocardiographers at our institution do feel that the image quality does vary by manufacturer. However, the authors have significant experience performing TEEs, including the senior author who first brought the use of TEEs for excluding LAA thrombus to the mainstream. Nevertheless, it is possible that since an alternative imaging modality was available, the authors were less aggressive in trying to intubate the esophagus in difficult patients. It should also be noted that the authors were experienced in the use of ICE, and that diagnostic views were typically obtained from the pulmonary artery (PA). Although no complications were reported in this manuscript, advancing the ICE probe through the right ventricular (RV) to the PA does add some risk, and can be challenging in patients with RV enlargement or pulmonary hypertension.

Nevertheless, the paper does support the use of ICE for LAA screening in low-risk patients undergoing AF ablation. This could save significant time and cost prior to AF ablation at centers where ICE is used routinely for AF ablation. Additional experience with larger numbers of patients will be needed, however, before ICE can be recommended as an alternative screening modality to TEE for patients undergoing AF ablation. ■

Pharmacology Watch and Clinical Briefs in Primary Care Available Online

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CME QUESTIONS

1. **A small study comparing intracardiac echocardiography (ICE) to transesophageal echocardiography for left atrial thrombus detection showed:**
 - A. more thrombus detection with ICE.
 - B. more complications with ICE.
 - C. more spontaneous contrast detection with ICE.
 - D. A and C
2. **Surgical carotid endarterectomy (CEA) compared to carotid artery stenting (CAS) showed:**
 - A. lower stroke risk with CEA.
 - B. lower hospital mortality with CAS.
 - C. CAS adverse events were lowest when done by cardiologists.
 - D. CAS results are related to an operator's number of cases.
3. **Extending dual antiplatelet therapy for up to 30 months:**
 - A. reduces stent thrombosis events.
 - B. reduces subsequent myocardial infarctions.
 - C. increases the bleeding risk.
 - D. All of the above
4. **In patients with low-flow, low-gradient, but a normal LVEF, what percentage have severe AS by valve weight?**
 - A. 25%
 - B. 50%
 - C. 70% *
 - D. 90%
5. **Alcohol septal ablation for symptomatic hypertrophic obstructive cardiomyopathy, as compared to surgical myectomy, results in:**
 - A. more major 30-day complications.
 - B. better symptom reduction.
 - C. lower all-cause mortality.
 - D. higher left ventricular outflow tract gradients.

CME OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- discuss the most current information related to cardiac illness and the treatment of cardiac disease;
- explain the advantages and disadvantages, as well as possible complications of interventions to treat cardiac illness;
- discuss the advantages, disadvantages, and cost-effectiveness of new and traditional diagnostic tests in the treatment of cardiac illness; and
- discuss current data regarding outpatient care of cardiac patients.

Clinical Cardiology

Critical analysis of the latest clinical research in cardiovascular medicine [ALERT]

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