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Stents, Timing and Shades of Electiveness

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In 2007, Grines et al. published a science advisory from the American Heart Association (AHA), American College of Cardiology (ACC), Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians that stresses the importance of 12 months of dual antiplatelet therapy after placement of a drug-eluting stent and educating patients and health care providers about hazards of premature discontinuation. It also recommends postponing elective surgery for one year, and if surgery cannot be deferred, considering the continuation of aspirin during the perioperative period in high-risk patients with drug-eluting stents [1].

AHA/ACC guidelines were revised in 2007 for patients with Drug Eluting Stent (DES) undergoing noncardiac surgery to recommend the following: (1) elective surgeries be delayed until 1 year of dual antiplatelet therapy has been completed, and (2) if the surgery is urgent, perform the surgery without ceasing antiplatelet therapy. At the time of the recommendation in 2007, the supporting evidence for delaying elective surgery for recent DES insertion was based on limited information from nonrandomized studies (ACC/AHA level of evidence, B) and very limited information from case studies or expert opinion on continuing aspirin therapy for surgeries within 1 year (ACC/AHA level of evidence, C) [2].

The Task Force for preoperative cardiac risk assessment and perioperative cardiac management in non-cardiac surgery of the European Society of Cardiology and European Society of Anaesthesiology published their guidelines for pre-operative cardiac risk assessment and perioperative cardiac management in non-cardiac surgery in 2009 [3], and the Cardiac Society of Australia and New Zealand [4] published their Guidelines for the management of antiplatelet therapy in patients with coronary stents undergoing non-cardiac surgery in 2010. Both of these guidelines [3,4] supported the ACC/AHA recommendation that elective surgery should be delayed for at least a year after DES insertions.

Hollis and colleagues performed a systematic review and found that the current literature supports a significant decrease in Major Advance Cardiac Events (MACE) when surgery is performed 1 year after DES placement; however, the level of evidence is weak [5]. Larger studies are needed to determine the safe interval for surgery after stent placement.

Dr. Hawn's group performed a systematic literature review of MACE associated with noncardiac surgery in patients with DES. Not surprisingly, only 28 of 358 (8%) studies met the inclusion criteria. Overall, MACE rates decreased as the time to surgery increased and varied from 0% to 18% for surgeries performed within 1 year compared with 0% to 12% for surgery more than 1 year after a stent. The literature showed limited evidence for a protective effect of continuing perioperative dual antiplatelet therapy on MACE rates. Although published data support a significant decrease in MACE when surgery is delayed for over 1 year, the level of evidence is weak (i.e., level C evidence) [6].

It appears that overall these guidelines have been somewhat effective in delaying elective surgery after DES insertion. From 2000 to 2010, 126,773 stent procedures were followed by 25,977 (20.5%) noncardiac operations within 24 months. Overall, 11.8% of the Bare Metal Stent (BMS) surgery cohort had early surgery (less than 6 weeks) compared with 46.7% of the DES surgery cohort, which had early surgery (less than 12 months). The incidence of surgery differed significantly by stent type (BMS 24.1% vs. DES 17.5%, $p<0.001$) and in relation to guideline release (pre- 24.6% vs. postguideline 13.1%, $p<0.001$). Higher complexity operations (work relative value units) were more likely to occur in the early period for both BMS ($p<0.0001$) and DES ($p<0.003$). After guideline release, the incidence of surgery within 12 months decreased from 16.7% to 10.0% ($p<0.0001$) [7]. Hawn et al. found evidence that guidelines recommending delaying surgery appear to be effective in decreasing the incidence of early surgery; however, early surgery is still a frequent occurrence [7].

However, their reasonably strong influence on clinician practice may have gone "too far", since currently some clinicians will not allow even minor elective surgery to be performed on dual antiplatelet therapy 11.9 months after DES insertion. Over the past 5-7 years a small amount of support may be gradually growing that appears to be "chipping away" at the "12 month mark" and potentially may "open the door" for at least certain surgeries to be done on dual antiplatelet therapy less than 12 months after DES insertion.

In 2006, the recommendation of a French Task Force on perioperative management of antiplatelet agents in patients with coronary stent; stated to "delay elective surgery for 6 months to 1 year after insertion of a DES" [8]. In 2012, Douketis et al. published "Perioperative management of antithrombotic therapy", In: Antithrombotic Therapy and Prevention of Thrombosis in the 9th edition of the American College of Chest Physicians Evidence-Based Clinical Practice Guidelines [9]; which stated that in patients with a coronary stent who require surgery, they recommended deferring surgery >6 weeks after bare-metal stent placement and >6 months after drug-eluting stent placement instead of undertaking surgery within these time periods (Evidence Grade 1C); in patients requiring surgery within 6 weeks of bare-metal stent placement or within 6 months of drug-eluting stent placement, we suggest continuing antiplatelet therapy perioperatively instead of stopping therapy 7 to 10 days before surgery (Evidence Grade 2C) [9].

Berger and colleagues found that more than 4% of patients required a major surgical procedure in the year after placement of a DES [10]. If a DES was placed before the need for a surgical procedure was recognized, it has been recommended that at least 1 year be allowed to elapse after the DES was implanted before surgery is performed and that dual antiplatelet therapy be continued perioperatively whenever

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the surgery can be safely performed during such therapy [11,12]. Berger et al. concluded that major noncardiac surgery appears to be safer than was believed when performed months after receipt of a DES and likely is safer than when surgery is performed within 2 months after bare metal stent placement [10] In the modern stent era, the frequency of major noncardiac surgery in the year after DES placement is nearly 5%, occurring in approximately 0.5% of patients per month after the first 2 months placement [10].

In the Evaluation of Drug-Eluting Stents and Ischemic Events (EVENT) minor surgery (defined as procedures not requiring a major surgical incision) was performed in 164 (2.0%) of 8,323 patients <1 year after stenting, as follows: pacemaker/defibrillator implantation (46%), eye surgery (17%), orthopedic (9%), dermatologic (8%), endovascular (6%), and gastrointestinal procedures (5%) [13]. Only 1 (0.6%, 95% CI 0.0%-3.4%) of 164 patients had an event (stent thrombosis causing myocardial infarction) during the first week after minor surgery; this rate was slightly higher than the background rate of ischemic events in the study population (exact mid P=0.01) [13]. Minor surgery does not generally lead to a significant inflammatory response and therefore conceivable may be less apt to lead to stent thrombosis.

Wijeysundera and colleagues used linked registry data and population-based administrative health care databases to conduct a cohort study of 8,116 patients (≥ 40 years of age) who underwent major elective noncardiac surgery in Ontario, Canada between 2003 and 2009, and received coronary stents within 10 years before surgery. Approximately 34% (n=2725) underwent stent insertion within 2 years before surgery, of whom 905 (33%) received drug-eluting stents. For comparison, they assembled a separate cohort of 341,350 surgical patients who had not undergone coronary revascularization. The primary outcome was 30-day major adverse cardiac events (mortality, readmission for acute coronary syndrome, or repeat coronary revascularization). The overall rate of 30-day events in patients with coronary stents was 2.1% (n=170). When the interval between stent insertion and surgery was <45 days, event rates were high for bare-metal (6.7%) and drug-eluting (20.0%) stents. When the interval was 45 to 180 days, the event rate for bare-metal stents was 2.6%, approaching that of intermediate-risk nonrevascularized individuals. For drug-eluting stents, the event rate was 1.2% once the interval exceeded 180 days, approaching that of intermediate-risk nonrevascularized individuals. They concluded that the earliest optimal time for elective surgery is 46 to 180 days after bare-metal stent implantation or >180 days after drug-eluting stent implantation [14].

Traditionally, surgery has been categorized into three classes: elective, urgent and emergent. However, the elective category may be too vast and it may be advantageous as well as more precise to subdivide this class into multiple classes. Elective cases that have no medical basis (e.g. cosmetic surgery) [so-called "purely elective"] may be referred to as "ultra-elective". Elective cases that have medical basis but in terms of timing can wait for months without any difference whatsoever may be referred to as "elective". Elective cases that have medical basis, however, in terms of timing can wait a few months but should not wait for more than that; --- (since the patient's condition may become worse if surgery is delayed for many months or perhaps the surgery will likely be significantly more difficult to perform if there is a wait of several months); --- may be referred to as "semi-elective". Finally, elective cases that have medical basis and can wait a few days to weeks but should not wait longer; may be referred to as non-elective non-urgent.

Thus, in 2013 and beyond, the author proposes that patients who have had a drug-eluting stent over 6 months ago and are scheduled to have "elective" minor surgery, semi-elective minor surgery, or non-elective non-urgent surgery; should continue their dual antiplatelet therapy and have their surgery (provided that the risk of clinically significant bleeding does not greatly outweigh the risk of stent thrombosis) without the need to delay surgery for over a year.

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