Bare Metal Stents – RIP?

Dr. Morton Kern, with contributions from Drs. Malcolm Bell, Rochester, Minnesota; Sam Butman, Scottsdale, Arizona; Mauricio Cohen, Miami, Florida; Larry Dean, Seattle, Washington; Kirk Garratt, Newport, Delaware; Allen Jeremias, Long Island, New York; Aaron Kaplan, Dartmouth, New Hampshire; Dean Kereiakes, Cincinnati, Ohio; Ajay Kirtane, New York, New York; Neal Kleiman, Houston, Texas; Mitch Krucoff, Raleigh, North Carolina; Bernie Meier, Bern, Switzerland; Jeffrey Moses, New York, New York; Steve Ramee, New Orleans, Louisiana; Sunil Rao, New York City, New York; David Rizik, Scottsdale, Arizona; Will Suh, Riverside, California; Jon Tobis, Los Angeles, California; Peter Ver Lee, Bangor, Maine; Bonnie Weiner, Worcester, Massachusetts

For at least a decade, we have been in a drug-eluting stent (DES) era. Almost all studies point to superiority of DES over bare metal stents with regard to restenosis, but past controversies included the incidence of thrombosis and short duration of dual antiplatelet therapy (DAPT) with DES. At this time, I believe the issues are settled in favor of DES. While most do agree, Peter Ver Lee, Bangor, Maine, asks our experts about keeping BMS in their lab.

His question: "Mort, forgive me for asking a question that may have already been answered in this forum. Are bare metal stents ever needed in a typical cath lab's inventory? I can't remember the last time I put one in a coronary artery. With the emergence of 3-month and now 1-month DAPT regimens in high bleeding risk (HBR) patients, I can't think of a need to ever implant a BMS for percutaneous coronary intervention (PCI). Is there a downside of getting rid of them completely?"

Mort Kern, Long Beach, California: We don't use BMS anymore. Short DAPT seems effective and well tolerated. I don't think we stock them in our lab anymore either. Let's see what others say.

Malcolm Bell, Rochester, Minnesota: Great question. Current DES are better and safer than BMS and now we have bigger DES options on the shelf. I can't recall when we last used one (BMS). Interestingly, we still occasionally get asked to place one in a HBR patient or one with need for very short DAPT. We educate them [the requestor] and always place a DES.

David Rizik, Scottsdale, Arizona: BMS — Rest in Peace.

Sam Butman, Scottsdale, Arizona: I agree with the "requiem for BMS." This conversation should serve as a good resource for any labs still stocking BMS.

Larry Dean, Seattle, Washington: We took them out of our labs a few years ago.

Aaron Kaplan, Dartmouth, New Hampshire: I cannot see an indication for BMS. I do believe that we need to make sure our referral doctors understand the current state-of-the-art [is DES] and reassure them on this point.

Jeffrey Moses, New York, New York: Since DES are at least as safe and more efficacious in randomized clinical trials (RCTs), it is hard to justify their use. It would be interesting to know if BMS are still manufactured.

Dean Kereiakes, Cincinnati, Ohio: I thought this issue was dead, but there remain some clinical cardiologists and primary care physicians (PCPs) who still cling to "the myths of the BMS"[1] and short DAPT. We took BMS off the shelf several years ago. To quote Bernard Chevalier, "The BMS should disappear from the therapeutic armamentarium of the interventional cardiologist." [BMS are] Less safe and less efficacious than new generation DES.

Kirk Garratt, Newport, Delaware: BMS served us well, but that's history. I'm curious if anybody's using novel non DES products like the PzF-nanocoated Cobra stent (CeloNova Biosciences). Don Cutlip and colleagues showed very good results — no stent thrombosis after 5 years — in a modest number of nonrandomized patients with 30-day DAPT. Target lesion revascularization (TLR) rates are

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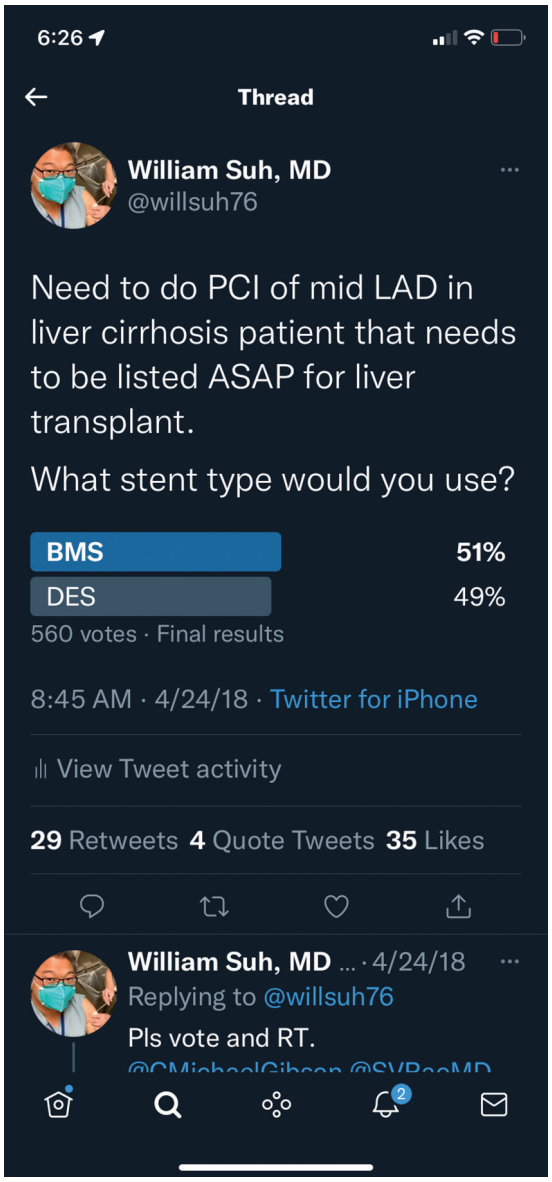
—Sam Butman, MD



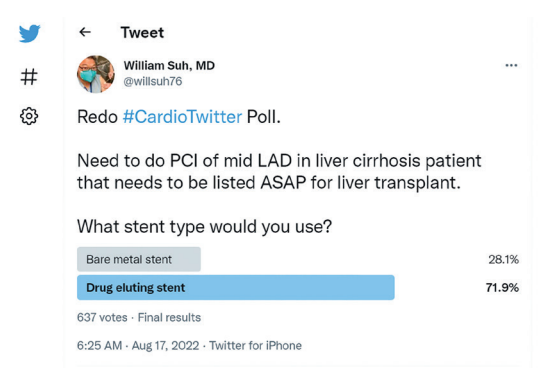


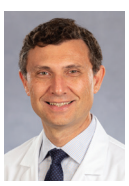
Figure 1A-B. (A) @WillSuh76's Twitter poll in 2018. Shortened link: https://tinyurl.com/WillSuh76CLD

(B) @WillSuh76's redo Twitter poll for 2022. Shortened link: https://tinyurl.com/WillSuh76CLD2

similar to first gen DES, but not as good as current DES, and less expensive. Does a product like that have value today?

Will Suh, Riverside, California: I did this Twitter poll in 2018 (Figure 1A) about type of stent in pre liver transplant patient. Fifty-one percent picked BMS. BMS still has a small role in special populations? Anybody have data on short DAPT in liver patients?

Jon Tobis, Los Angeles, California: This is an important point, Aaron [Kaplan]. The surgeons are still under the impression that they will have to wait a year after PCI with DES before their procedure can be done. This makes a big difference in treatment strategies. We had a patient with aortic stenosis (AS), coronary artery disease (CAD), and rectal carcinoma. The surgeon was surprised to learn that DAPT could be stopped after 1-2 months, and this will influence the treatment plan. This change in approach needs to be publicized to the general physician community.



Mauricio Cohen, Miami, Florida: BMS were removed from the shelves 2 years ago at University of Miami.

Steve Ramee, New Orleans, Louisiana: While I agree with my esteemed colleagues about the benefit of DES versus BMS, I'm not sure in situations where elective surgery is needed within six weeks that BMS are not still a good choice. This review by Antonio Colombo summarizes this position.[2] Furthermore, the current literature seems to support more RCTs regarding duration of DAPT after DES before a conclusion can be made.

Ajay Kirtane, New York, New York: I'm glad someone else said it… the reality is that I haven't personally put in a BMS in years, but we don't really have enough data to feel absolutely comfortable sending patients with fresh stents to a (pro-thrombotic) surgical procedure so early. I made this point as well in an editorial note titled "Is There Any Current Role for Bare-Metal Coronary Stents?" in the same issue of *JAMA Cardiology* that Dean [Kereiakes] referenced earlier.[3]

"There are still very rarely occurring clinical scenarios (eg, active severe bleeding, need for expedited surgical procedures, or incontrovertible evidence of an inability to take medications for a month) that may require DAPT durations even shorter than 1 month. Whether percutaneous coronary intervention is indicated at all in these scenarios is always a legitimate question, but for the very short term (until newer DES data and/or device approvals emerge), I personally would grant a respite to the extremely rare case of BMS implantation that might occur in these extreme scenarios."

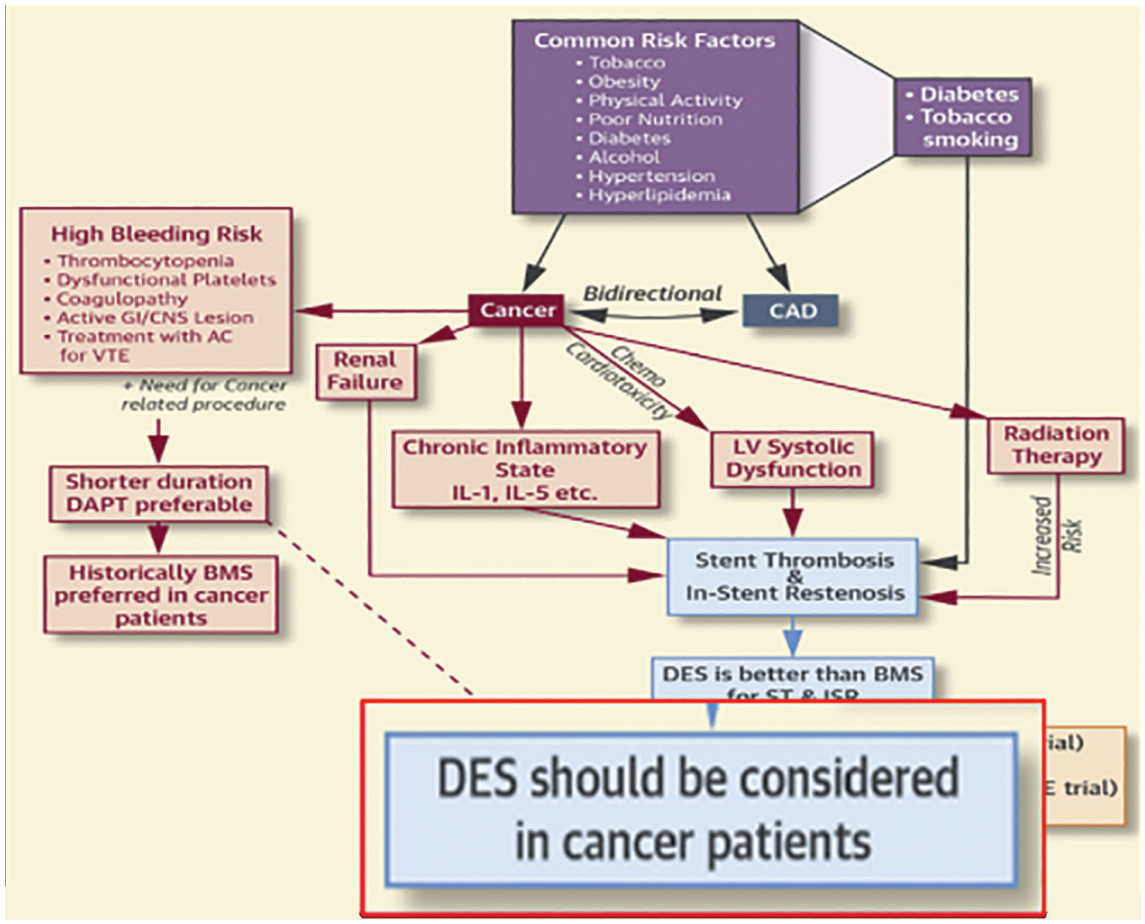


Figure 2. Cancer and coronary artery disease: Impact on stent choice.

Reprinted with permission from Ganatra S, Sharma A, Levy MS. Re-evaluating the safety of drug-eluting stents in cancer patients. JACC Cardiovasc Interv. 2017 Nov 27; 10(22): 2334-2337. doi: 10.1016/j.jcin.2017.06.068

Bonnie Weiner, Worcester, Massachusetts: Steve [Ramee] makes an excellent point. We have always known and recent publications support the fact that patients are not as compliant with meds as we think (or they tell us) they are. There are patients that we know up front are not going to be compliant and particularly in larger vessels, the benefit of a BMS may still outweigh the risk of restenosis and thrombosis, making it a reasonable thing to consider. If they are not on the shelf, that option goes away.

Will Suh, Riverside, California: As requested, here's a redo of the Twitter poll for 2022 (Figure 1B). The poll in 2018 was 560 votes, 51% BMS and 49% DES. Poll yesterday [August 2022] was 637 votes, 28% BMS and 72% DES. To Dr. Weiner's point, my colleague had a ST-elevation myocardial infarction (STEMI) patient who was a homeless man. The culprit lesion was a 4 mm vessel. Due to compliance concerns, a bare metal stent was placed. We still have bare metal stents on our shelves so that the option is there if needed.

Kirk Garratt, Newport, Delaware: Interesting data, Will [Suh], thanks for sharing. The case is interesting: homeless man, 4 mm vessel, assume TIMI-3 flow at the end. If the patient isn't diabetic and the lesion isn't too long, the restenosis benefit is small for a DES, but I don't think the thrombotic risk with 30-day DAPT is higher for 3rd gen DES than BMS in this setting. Of course, we don't know if there's a difference if he takes NO antiplatelet therapy, which seems a risk with this patient.

Also, I'm with Dean [Kereiakes] and I'll add something that won't be popular. I don't think we need any more trials about it (new products excepted). We've studied stents in HBR patients enough to be confident that any difference between BMS and current DES (other than restenosis-related events) has to be small. If we're still debating which is better after years of study, it's because any true difference must be very small. I feel I've got enough data already to make the call on this one.

Sunil Rao, New York, New York: Large vessels like this were studied in the NORSTENT trial that randomized patients to BMS versus DES. While there was no difference in death or MI between the two strategies, the rate of repeat revascularization and more importantly, stent thrombosis, was significantly lower in the DES group.

Neal Kleiman, Houston, Texas: I can't recall the last time I've seen one [BMS] used, and I can't think of a good reason to use one, or of a single piece of contemporary data suggesting a benefit.

Mitch Krucoff, Raleigh, North Carolina: We don't use BMS at all anymore. Urban et al's study, LEADERS FREE (LF), and our USA study LFII showed superior safety as well as efficacy in the high bleeding risk cohorts that were the main use globally until these reports. So, in fact, you could argue that use of BMS in lieu of contemporary DES could be seen as doing harm.

Allen Jeremias, Long Island, New York: To my reading, the literature regarding the safety of short DAPT for current generation DES is very favorable for the high bleeding risk patient population, but I do not believe that this can be extrapolated to the surgical population (especially with cancer). The stress, inflammation, etc., that is induced by surgery can pose a significant thrombotic risk for patients with recent PCI. We recently had a case of a thrombosed left main artery/left anterior descending coronary artery stent 5 weeks post implant during a laparoscopic cholecystectomy (patient was even bridged with cangrelor). Not that using a BMS would help in any way with this issue.

Dean Kereiakes, Cincinnati, Ohio: The issue regarding patients with cancer has been addressed (see Figure 2). I don't know of a single scenario where BMS should be the choice over new generation DES.

Bernie Meier, Bern, Switzerland: Our community had misinterpreted the data from the beginning. The warning in 2006 about higher thrombogenicity of the early generation DES only pertained to the later phase, ie, 9 months or later. In the early phase, particularly in the first days and weeks, already the early generation DES had a lower risk for thrombosis and therefore, less need for DAPT, than BMS. The increased risk of DES for the later phase, 9 or more months after implantation, was corrected with later generation DES. Personally, I stopped using DES in 2006. [*MK:* Always out front, some might say contrarian.]

The Bottom Line

BMS are rarely used. Most labs stopped stocking them. There may be rare cases where a BMS has important benefits over DES, but these cases do not justify stocking more than a few stents. I must agree with David Rizik's comment: "BMS-RIP." ■

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— Sunil Rao, MD

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