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A Tribute to PCI: Celebrating 40 Years and Counting!

By Amy Newell

For many in the cardiovascular specialty, it seems hard to believe it has been nearly 40 years since percutaneous transluminal balloon angioplasty (PTCA) aka percutaneous coronary intervention (PCI), was first performed on a human patient by Dr. Andreas Gruentzig in Zurich, Switzerland in September of 1977. And yet, four decades later, industry experts are still refining and perfecting this amazing procedure that continues to save millions of lives across the world.

Dr. Gruentzig, considered a pioneer in his time, had also paved the way for the many exciting scientific advances that followed, allowing interventional cardiologists the ability to treat coronary artery disease in a safe and minimally-invasive setting. His vision — from refining 'plain old balloon angioplasty' (POBA) procedures to thoughts of utilizing lasers or even a scaffold device to prop open a blockage within the coronary artery, was only the beginning of a true interventional cardiology evolution (Figure 1).

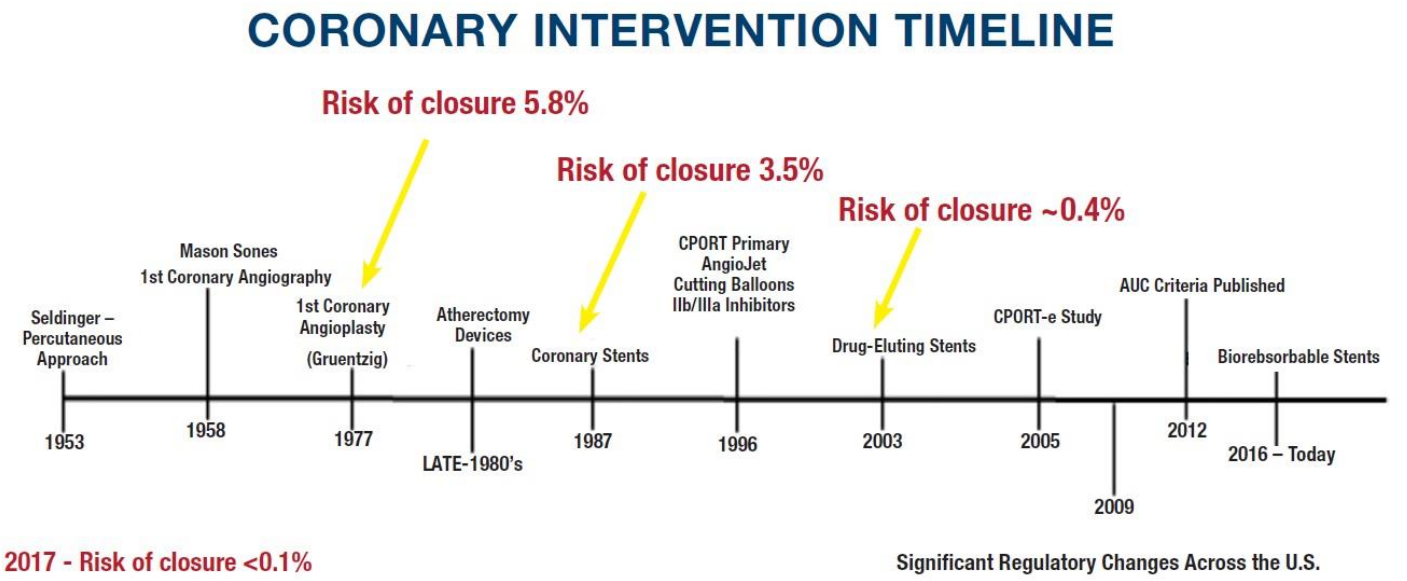

Figure 1. A snapshot timeline of remarkable milestones related to coronary interventions. *(Data source: American College of Cardiology)*

Procedure Advances

Given the evolution of science, the early adoption of coronary (or in some cases biliary) stents being implanted into the coronary anatomy represented efforts to offer patients a less-invasive option to treat their coronary artery disease, in particular, a "blocked artery." During the early days of angioplasty, in many tertiary or open heart surgical programs, cardiothoracic surgeons would be *waiting in the wings* with an open heart surgical suite ready to treat those patients, who perhaps, did not respond as expected from the less-invasive angioplasty procedure. This approach offered a unique collaboration between the interventional cardiologist and cardio-thoracic surgeon, perhaps the earliest adoption of what is often referenced as a ***heart team approach,*** which Corazon recommends today. In fact, continued focus and recommendations from the national societal guidelines specific to PCI programs without onsite open heart surgery believe a collaborative setting is best. Corazon believes ALL PCI programs should be held to the same standards…*especially* those without open heart surgery on-site.

Over the past decades, the medical community of cardiology and interventional cardiology has been witness to many clinical trials across the globe (and in the United States) that seek to prove the efficacy and safety of angioplasty. In particular at hospitals that do not offer onsite open heart surgery, where a surgical suite is not available down the hall. The purpose of these clinical trials was to compare both clinical outcomes that specifically looked at Major Adverse Cardiac Events (M.A.C.E) of patients 30 days from their angioplasty to one full year, as well the fiscal costs associated with the patient care incurred during their length of stay.

Improving Access

Corazon has worked, and continues to do so, with dozens of community-based hospitals across the United States from the early planning or feasibility analysis, through implementation and accreditation of this life saving service of PCI. These studies have found that angioplasty services at a hospital without on-site open heart surgery actually had comparable or better clinical/quality outcomes than those hospitals having open heart surgery on-site. Financially speaking, a cardiovascular service line that tightly manages its patients most appropriately post procedure and before discharge is best able to reap the clinical and financial benefits of these diligent efforts.

Forty years after its initiation and despite the clinical trials that prove otherwise, the governing bodies of many states choose to maintain sometimes strict regulations for angioplasty programs at hospitals not offering onsite open heart surgery. Be it for political or even selfish programmatic reasons, state leaders and/or physicians who have not quite caught-up to the current societal guideline recommendations are negatively impacting the progression of PCI access. In any case, ensuring that programs offering angioplasty without onsite open heart surgery will meet, or in many circumstance exceed, national societal recommendations is enough to verify the program is a viable one.

These guidelines offer very pointed recommendations of processes that should be in place prior to any program considering expansion to offer advanced cardiac care – with OHs or without. In fact, these very guidelines have afforded patients in many markets the ability to stay "at home" for their advanced cardiac care needs. So, essentially, patients who now have access to expanded cardiac care within their communities may otherwise have had to incur unnecessary burdens seeking treatment, or worse, have suffered a life-altering or life-ending cardiac event.

Other Factors

Equipment - Aside from the opportunities for program expansion, and condensed for the purpose of this tribute, many other factors have greatly impacted the evolution of angioplasty. For example, in the early to mid-1990s, the inception of the "bare metal stent" (BMS); then in the early 2000s, the "drug eluting stent" (DES), which offered another option with its own level of benefit and risk. Consider too the evolution from developing cine film to the continued refinement of digital imaging technology, and how this technology continues to evolve.

Benchmarks - For years, and even in the 1970s, many countries were ahead of the curve when it came to treating patients having an ST Elevation Myocardial Infarction (STEMI), aka "heart attack" (i.e., the DANAMI and PAMI trials). For decades, hospitals and EMS services have believed that **"time is muscle."** In fact, the American Heart Association and American College of Cardiology (AHA/ACC) have put a national benchmark of < 90 minutes "door to balloon" or "door to reperfusion" in efforts to reverse the potential myocardial damage that can occur in those patients having an active cardiac event.

In the years prior to Primary PCI, for AMI the options were limited to fibrinolytic therapy, and this too has evolved from the 60 minute benchmark to a 30 minute benchmark. Today there are clinical circumstances where a patient may be given this treatment first and then referred onto a PCI. we must too recognize the advancement of pre-hospital providers now having the technology to transmit (from in the field) the ever-critical 12-lead ECG, thus affording the opportunity to activate the interventional cardiologist as well the cardiac catheterization laboratory team before the patient even arrives at the hospital. And certainly, this activation takes great collaboration and trust to bring to fruition, though Corazon recommends that PCI-capable facilities implement this approach, as such a process brings the best opportunity for fast, effective, and appropriate PCI when immediately necessary.

Regulatory Impacts

So as the evolution of cardiac science continues to evolve, so does greater scrutiny of what is considered "appropriate" selection of patients in need of a coronary intervention. In 2005, the inception of the earliest evidence of appropriate use criteria (AUC) emerged, still leaving a rather large area of interpretation, especially for those patients with coronary artery disease but without an active heart attack!

As the years and even decades pass and science evolves, as does the regulatory focus, whether at the state or national level, relative to angioplasty services at hospitals without on-site open heart surgery. Corazon has been intimately involved at the regulatory level in many states across the country offering clinical, operational, and financial advice, while also providing program-specific accreditation for cath labs or PCI services.

Due to the more widespread adoption of various advances, PCI program competition is on the rise in regions all over the country. With this expansion of PCI availability, whether at site with or without OHS, the value of accreditation is increasing…not only to show program quality, but also to serve as a differentiator for patients who have a choice of hospitals for their PCI or other CCL procedure.

As a named accrediting body in both Michigan and Pennsylvania, as well an approved third party verifier in the State of Georgia, Corazon holds programs not only clinically accountable, but offers an exceptional continuous quality improvement (CQI) program ensuring the highest level quality of patient care outcomes are being employed and maintained. Corazon offers ongoing quality program oversight and should a program fall below a defined benchmark, we are able to quickly engage and reinforce "best practice" and "evidence-based" recommendations, also providing the necessary education and tools to maintain and exceed expectations year after year.

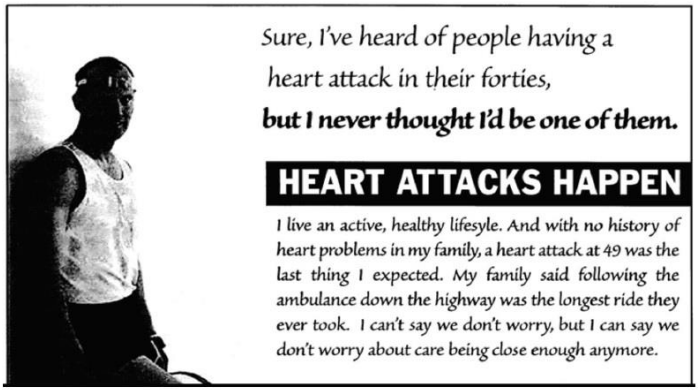

Figure 2. A sample marketing tool used during the implementation of a PCI program in a small community hospital.

The Future and Anticipated Changes

For many years and even today in 2017, the argument continues around the relationship between volume and quality. Consider if you will, that the current open heart surgical centers across the country do NOT maintain an "open" CVOR in the unlikely event a patient having an angioplasty is in need of a more invasive treatment for their coronary artery disease. However, strong partnerships and open communication with OHS-capable tertiary centers are key to the success of the "heart team" approach. Corazon firmly believes, and given the low percentage of patients who would be in need of an urgent or emergent transfer, that quarterly test drills (per societal recommendations) be facilitated and documented in effort to maintain a "best practice" approach to patient care.

In our experience over the past decade, we have seen a decline in PCI volumes due to several factors, which also equates to a decline in individual operator volumes. It is essential that program quality outcomes be closely monitored, and focus be kept on continued quality improvement (CQI) in order to represent the direct involvement with physicians and hospital administration in efforts to sustain and exhibit stellar patient outcomes, regardless of decreasing volumes.

In conclusion, thinking about how far PCI has come since 1977, the current direction and what the future holds for interventional cardiology is yet undetermined. What would Andreas Gruentzig think about angioplasty 40 years later in 2017 given all of the regulatory restrictions and guideline revisions that directly impact the decisions in treating patients with coronary artery disease? Would he approve of all of the politics that has manifested its way into cardiovascular science? Regardless of the PCI situation in individual states, Corazon believes that the healthcare industry should seek to provide best practice care for all patients; therefore the outcome for a patient in a rural community should be the same as a resident of a large city – giving access to the best care should be the goal, not considering any other agendas. Indeed, the patient will most benefit when PCI is offered appropriately and effectively with a qualified team.

Amy Newell is a Vice President at Corazon, Inc., a national leader in strategic program development for the heart, vascular, neuro, and orthopedic specialties. Corazon offers a full continuum of consulting, software solution, recruitment, and interim management services for hospitals, health systems and practices of all sizes across the country and in Canada. To learn more, visit www.corazoninc.com or call 412-364-8200. To reach the author, email anewell@corazoninc.com.