Status of Intravascular Brachytherapy (IVB) in 2016

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In the 1990s, coronary artery stents were welcomed by doctors and patients alike, offering a less invasive, cheaper alternative to bypass surgery, and an option more effective than angioplasty on its own.

Since then, about 1 million stents have been implanted each year in the United States.
Before intravascular brachytherapy, 30 to 40% of patients receiving bare metal coronary artery stents returned to the cardiac catheterization lab within 4 to 6 months with in-stent restenosis (re-narrowing).

Intravascular brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 60 Nath, Ravinder; Amols, Howard; Coffey, Charles; Duggan, Dennis; Jani, Shirish; Li, Zuofeng; Schell, Michael; Soares, Christopher; Whiting, James; Cole, Patricia E.; Crocker, Ian; Schwartz, Robert Medical Physics, Volume 26, Issue 2, February 1999, pp.119-152
Disease Progression to ISR

Normal Coronary Artery
Disease Progression to ISR

Normal Coronary Artery

Stenosis
Disease Progression to ISR

Normal Coronary Artery

Stenosis

Percutaneous Coronary Transluminal Angioplasty (PTCA)
Disease Progression to ISR

Patent Vessel post PTCA
Disease Progression to ISR

Re-stenosis
Disease Progression to ISR

Stenting
Disease Progression to ISR

Patent Vessel Post Stent
Disease Progression to ISR

In-Stent Restenosis
Disease Progression to ISR

In-stent Restenosis
Porcine Artery
Mechanisms of Restenosis

- Recoil after PTCA balloon injury
- Arterial Remodeling
- Hyperplasia
- Stents address recoil and remodeling, but not hyperplasia
- Intravascular brachytherapy was applied to inhibit hyperplasia
IVB Case Images

Right Coronary Artery
IVB Case Images

Right Coronary Artery

In-stent Restenosis
IVB Case Images

Right Coronary Artery

PTCA Balloon
IVB Case Images

Right Coronary Artery, Post PCTA

Beta-Cath 3.5F System
B-Rail Delivery Catheter
Indicator of Source Train Wire Markers
IVB Case Images

Beta-Cath 3.5F System
30mm Jacketed Radiation Source Train

Right Coronary Artery, Post PCTA
Intravascular brachytherapy is the application of ionizing radiation from a radioactive source to the inside of a blood vessel for medical therapeutic purposes.

IVB reduced restenosis and repeat coronary interventions inside failed stents by 40% at 8 months.

IVB studies yielded the most profound treatment effect ever seen in interventional cardiology....before drug eluting stents.
In the first year of US sales, Novoste Corporation revenue was 87 million USD.
At peak, Novoste Corporation was selling approximately 100 catheters per day.
Estimate more than 115,000 patients were treated with the Novoste Beta-Cath System alone.
In 2003 – 2004 time period, drug eluting stents were introduced in the United States.

The use of drug eluting stents to treat failed stents became the clinically preferred alternative to intravascular brachytherapy.

Two of the three IVB suppliers ceased production, leaving only Novoste Corp. with the Beta-Cath System.

What changed?

- The number of sites using the Novoste Beta-Cath System decreased from 400+ worldwide to fewer than 30, solely in the United States.
- Catheter sales reached a low point in 2010.
Demand for IVB is Growing

Increase from 2010
Where is IVB used today in 2016?

Abbott Northwestern, Minneapolis, MN
Alexian Brothers Medical Center, Chicago, IL
Allegheny General, Pittsburgh, PA
Augusta University Hospital, Augusta, GA
Beaumont Hospital, Royal Oak (Detroit), MI
Brigham & Womens, Boston, MA
Christ Hospital, Cincinnati, OH
Cleveland Clinic, Cleveland, OH
Froedtert / Medical College of W, Milwaukee, WI
Maine Medical, Portland, ME
Mercy Medical, Des Moines, IA
Mount Sinai Hospital, NYC
Munson Medical, Traverse City, MI
New York Presbyterian - Columbia University NYC
NorthShore University Hospital, Manhassett, NY
Ochsner Foundation, New Orleans, LA
Oklahoma Heart Hospitals (North & South), Oklahoma City, OK
Scripps Hospital, La Jolla CA
The Methodist Hospital, Houston, TX
Thomas Jefferson University Hospital, Philadelphia, PA
University of Washington Medical Center, Seattle WA
University Wisconsin Hospital, Madison, WI
Washington Hospital Center, Washington, D.C.
Future IVB challenges?

The Novoste Beta-Cath System was proven safe and effective for the treatment of native coronary artery in-stent restenosis in vessels ranging from 2.7 to 4.0mm diameter.

Patients in 2016 are presenting with complex disease: multiple layers of failed stents, smaller diameter stents, very distal disease, non-native bypass grafts, bifurcated lesions, and long lesions.

New geometrical/anatomical challenges require advances in design and new studies!