Carotid Revascularization
20 Years From Now

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In 2036, if we are all still alive…

This is where we will be spending our time!
These guys will be in a communal cell (as opposed to solitary confinement for me and Bill Gray!!)
The only one amongst us who will be out of jail will be....
...and why will we be there???

...because we are all “criminals” – and have been called such by some of our esteemed colleagues

And what is our crime??

...treating carotid artery stenosis!

And those who stent (as opposed to CEA)...they get to be “lifers”!
And, by the way…

Every carotid artery will look…

Pristine…!!!

And because of “new and improved” medical treatment, there won’t be any strokes or TIA’s
That is, if you believe certain individuals…

Whose brain is Dr. Abbott holding?
We are definitely coming to the *Crossroads in Rx for Carotid Artery*

“When you come to a fork in the road, take it.” - Yogi Berra
Back to reality

Well, like it or not, this is still gonna happen…

So how are we gonna deal with it in 2036?
Carotids now and in 20 years.

“It ain’t over till it’s over.”

-Yogi Berra
Predictions – risk and incidence

- Prevention with meds, diet & lifestyle modification will continue to improve for a while but will **plateau**... severe symptomatic (and asymptomatic) stenosis will definitely still occur and require treatment.

- Better agents to prevent plaque formation, carotid artery athero, and atheroembolic stroke will be developed.
  - Statins, antihypertensives, anti-thrombotics and anti-platelet agents
- CREST 2 will provide info about potential for optimized medical Rx (intervent)
- Generalizability will remain in question
Predictions – identification of “at-risk” lesion

- Imaging will progress
  - new techniques such as plaque imaging with fluorescent antibodies to define “plaque at risk” or high risk plaque for rupture, progression, or embolization
  - Predictive models and protocols will be utilized (based on imaging studies and evidence-based correlation between stroke/TIA and imaging findings)
What will Equipment be like? Will Filters continue to be used?

Ref: WLGore Website
Alternatives for embolic protection will increase.

Proximal Occlusion

ASPIRATION
A-V SHUNT
Profi – DW MRI lesions (embolic brain burden)
Procedural Selection: Transcervical Approach With Flow Reversal will play increased role (w/perc access)

Blood flow is reversed from the common carotid artery

Shorter delivery system and wires for simplified setup and delivery

Dynamic Flow Controller Hi / Low / Off

Blood flow is returned to femoral vein

Embolic filter (200µ)
# Carotid Mesh Stent Designs

<table>
<thead>
<tr>
<th>Design</th>
<th>Gore</th>
<th>Terumo Roadsaver</th>
<th>CGuard™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aperture Size</td>
<td>500µ</td>
<td>375-500µ</td>
<td>150-180µ</td>
</tr>
<tr>
<td>Materials</td>
<td>PTFE mesh (Heparin coated) on nitinol stent</td>
<td>nitinol on nitinol</td>
<td>PET MicroNet™ on nitinol stent</td>
</tr>
<tr>
<td>(Min Guide Sheath/ Min Guide Cath)</td>
<td>5F/7F</td>
<td>5F/7F</td>
<td>6F/8F</td>
</tr>
<tr>
<td>Details</td>
<td>• Launched SCAFFOLD trial in Sept 2013</td>
<td>• Data on first 11 pts presented at LINC (Max Amor, MD)</td>
<td>• Initial placements promising</td>
</tr>
<tr>
<td></td>
<td>• PI: Bill Gray, MD</td>
<td>• Flexibility, plaque coverage and ability to conform to any anatomy mentioned as key benefits</td>
<td>• 11 of 11 KOL’s (LINC) felt our aperture size a benefit over larger</td>
</tr>
<tr>
<td></td>
<td>• Target 351 pts</td>
<td>• Easy to recross (tapered ends)</td>
<td>• Data on MGuard MicroNet a “plus” for CGuard</td>
</tr>
<tr>
<td></td>
<td>• Has enrolled 100 pts. FDA has stopped trial requesting 6 mo F/U on these 100 before proceeding</td>
<td></td>
<td>• Ability to dilate MicroNet at external bifurcation a potential benefit</td>
</tr>
</tbody>
</table>
Late Embolization – will be addressed

No stent or current EPS protects against late embolization

<table>
<thead>
<tr>
<th>Stent name</th>
<th>All events</th>
<th>Post-procedural events</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-act</td>
<td>1.9%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Nexstent</td>
<td>3.3%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Wallstent</td>
<td>2.3%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Precise</td>
<td>4.1%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Protégé</td>
<td>3.0%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Acculink</td>
<td>4.2%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Exponent</td>
<td>11.8%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>2.83%</td>
</tr>
</tbody>
</table>

Bosiers et al. *Eur J Vasc Endovasc Surg* 2007;33
MicroNet™ Technology

The MicroNet™ is a bio-stable mesh woven from a single strand of 20μm Polyethylene Terephthalate (PET). The MicroNet™ is designed to trap and seal thrombus and plaque against the vessel wall, preventing embolization. The MicroNet™ is sutured to both the distal and proximal crowns of the stent platform.

Advantages of technology:
• Flexible structure
• Does not promote thrombosis
• Minimal foreign body reaction
• Does not alter procedure
• Optimal pore size
CGuard™ Case Study

Thrombus-containing
34 days post Stroke with Lytic Tx

CGuard™ 8.0x30mm, postdilated φ4.5mm/18atm

Piotr Musialek
Washington DC
September 15, 2014
• Initial data for double filtration using the Paladin balloon demonstrated excellent safety and technical success

• Majority of the particles captured in the PALADIN filter are less than 100 microns

• Double filtration appears to reduce the incidence and volume of new ischemic DW MRI lesions

• Double filtration may help to reduce the problem of minor stroke during CAS

• This hypothesis needs to be studied further
Predictions – Equipment and techniques

- Advances will occur
  - Stents – covered stents will dominate…
  - EPD – Proximal protection will be preferred, perhaps in combination with distal
  - Direct carotid access will be more routine, a la Silk Road, but purely percutaneous with good closure available
The C2R CAS Registry (C2R) will promote completion of enrollment in the CREST-2 trial, but will also reinvigorate CAS and train new operators.
Predictions – Payment, Operators, and Quality

• CMS will approve CAS for asymptomatics, but there will be “strings attached”.

• Requirements for operators will be driven by payers and health care systems…who will demand that operators be high volume/high quality…

• Payment systems will have changed dramatically…this will now be about keeping the patient healthy and out of hospital.
• The rancor will have gone away long ago…with the current leadership yielding to a cadre of vascular specialists who work in teams to achieve optimal results.
The right therapy will be delivered for the right patient substrate.
Working together to come up with solutions that are optimal for the patient.

L ICA s/p CEA

R ICA s/p Stent
ECVD Guidelines 2011 - Recommendations will change...not sure exactly in which direction

<table>
<thead>
<tr>
<th></th>
<th>Symptomatic patients</th>
<th>Symptomatic patients</th>
<th>Asymptomatic patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stenosis</strong></td>
<td>50-69% stenosis</td>
<td>70-99% stenosis</td>
<td>70-99% stenosis</td>
</tr>
<tr>
<td><strong>CEA</strong></td>
<td>Class I LOE: B</td>
<td>Class I LOE: A</td>
<td>Class IIa LOE: A</td>
</tr>
<tr>
<td><strong>Stent</strong></td>
<td>Class I LOE: B</td>
<td>Class I LOE: B</td>
<td>Class IIb LOE: B</td>
</tr>
</tbody>
</table>
Perspectives of the Interventionalist

What *should* happen…but shouldn’t take 20 y 

Differences between CEA and CAS outcomes…no longer lie in the procedure choice, but rather:

- Operator
- Case selection
- Equipment and technique

Level I evidence and guidelines will support offering CAS as (covered) option

Operators will get appropriate training, experience, and judgement

Playing field will be level
“The future ain't what it used to be.”

-Yogi Berra
Attend live, online

Visit our booth!

www.VIVAPhysicians.org