Medical Device Industry Perspective

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Why Are We Here?

• Growing need to bring healthcare costs under control with “specific” focus on high profile, high cost cardiology areas

• Hospitals need to become more cost efficient, with specific focus on delivering improved quality outcomes

• Bleeding and access site complications continue to contribute to LOS, adverse outcomes and excess costs

• Vascular complications are twice as likely to occur as the next leading complication-renal failure\(^1\)

• Femoral access has been a traditionally trained procedure, but perhaps it is time to rethink and move towards recognized alternative approaches

\(^1\)Kugelmass A, et. al. *AJC* 2006
Is It Just About Bleeding?

- Complications attributed to vascular access have the most lasting and meaningful impact to patients.
- The periprocedural management of a femoral PCI patient has a direct and significant impact to the healthcare professional and patient.
- Socioeconomic impact to the patient, family and caregiver is currently not well appreciated or measured.
- Education and training of the HCP in procedural techniques has been traditionally product related/focused.
Current Device Industry Assessment

- Device solutions in the US have been universally focused on femoral access for over 40 years.
- Product development has been primarily directed at the therapy spectrum over the past 25 years.
- Attitudes and approaches to vascular access have remained relatively unchanged for the better part of three decades.
- Currently, radial access requires a small subset of tools and techniques to realize the advantages gained for all stakeholders.
Considerations for TREATTT

- Devices utilized in the trial should have an indication for use for radial access
- “Patent” hemostasis should be encouraged and measured to reduce potentiality and occurrence of radial occlusion
- Hydrophylllic introducers and recognized pharmacotherapy should be encouraged to reduce occurrence of radial spasm
- Patient preference and experience should be measured
- Site selection should give consideration to quantifying and correlating physician’s radial experience/outcomes

1Sudhir Rathore, et al., *Impact of Length and Hydrophilic Coating of the Introducer Sheath on Radial Artery Spasm During Transradial Coronary Intervention; J. Am. Coll. Cardiol. Intv. 2010;3;475-483*
What Does The Future Hold

• Changing healthcare climate and patient preference mandates a need for change

• Access site complications being considered as “never” events

• Future device focus towards transradial procedures could produce a paradigm shift towards new and improved procedural methodologies