Prosthetic Venous Valve Challenges
Until Now

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Nothing To Disclose

CVI: C4-6 Disease
Prevalence DEEP Vein Reflux

Mix of primary valve reflux and post-thrombotic venous obstruction at different levels of the venous tree (calf to the inferior vena cava) – focus most critical site of disease from detailed preoperative analysis

Therapy (Realized & Potential)

Surgical Valve Repair
Implantable Valves
Compression Stockings (SOX)

To control lower limb venous hypertension in patients with deep venous reflux, correction of deep axial reflux proximal to the calf/ankle area in at least one location is required

Robert Kistner, MD

External repair of primary valve reflux in the femoral vein is simpler, faster, and safer than internal repair, but its durability is less. The results approximate 50% to 65% competence for 4 years with freedom from recurrent ulcer and disability.
The valve is made of processed small intestinal submucosa (SIS – a collagen skeleton with growth factors) stretched over a square metal frame with a slit cut to form the valve opening. The valve is relatively resistant to thrombosis and becomes repopulated with recipient endothelial cells (deployed in the external jugular vein of sheep). Although patency and competency of this valve was 88%, tilting led to valve malfunction or occlusion in three animals. Subsequent modifications have been designed to ensure centering of the valve, improve valve hemodynamics, and prevent cusp thickening.

First-generation venous valve

tilting

First-generation venous valve and radiographic image of the front-loaded valve inside the delivery sheath (arrows).

Second-generation venous valve

Explanted specimen shows smooth incorporation of the bioprosthetic valve into the vein wall in sheep jugular vein at 6 weeks.

Transplanting a valve from one jugular vein to another jugular vein percutaneously

Intact vein with its competent valve inside a stent

They demonstrate at 3 months intact, flexible, non-thickened valve leaflets that were competent by venography.
Retention of an Autologous Endothelial Layer on a Bioprosthetic Valve

To examine the role of an autologous endothelial monolayer in the reduction of intimal hyperplasia formation

Needed to ensure the retention of EOCs under venous flow conditions (1 to 2 dynes/cm² wall shear stress)

Endothelial monolayers seeded on SIS were retained under loading and delivery, in vitro flow, and ex vivo flow.

EOCs are a promising cell source for autologous endothelialization of bioprosthetic valves

Jones CM, Pavcnik D. J Vasc Interv Radiol. 2012 May; 23(5): 697–703

Dotter Institute regarding the status of artificial vein valves

They had implanted some in Korea and Europe, and the efficacy was limited to about 3 months.

They then fibrosed or thrombosed.

No FDA approval.

Now, they are working with the stem cell people to create a biological layer.

No major breakthroughs.

Tim Liem, MD
Vascular Surgery
OHSC

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Neovalve

The 32 patients with post-thrombotic syndrome & resistant ulcers


Creation of Vein Valves out of the Intimal Layer with a Catheter Based Dissection Technique

Conclusion:

Percutaneous valve is an unmet need in a small subset patients with advanced venous disease with deep axial venous incompetence (primary or secondary)

Stay tuned

Thank you!