




DISCLOSURES

- Dr. Ravikumar is the founder of Sun Scientific, Inc.

AGENDA



- Background
- Overview of a Novel Hemostatic Device - HemoWrap
- Clinical Applications
- Clinical Evidence
 - Safety and Efficacy Study - Emory Health
 - Usability Study - Azura Vascular
- Conclusion

HEMOWRAP OVERVIEW



Key Features

- Manual inflation to desired pressure
- Transparent bladder for visualization
- Unique bladder design for local compression at the needle site without tourniquet effect thus avoiding access thrombosis
- Can be used in any part of the arm
- Saves time for clinical team members
- Eliminates need for sutures, suture related issues




An FDA registered device was designed to improve safety, efficacy and clinician and patient experience when achieving post-decannulation hemostasis.

Life Science Solutions

Clinical Applications

1. Post-Hemodialysis
2. Post-Intervention in Vascular Access
3. Tibial Access for Vascular Intervention
4. Radial Access for Cardiac Intervention



Proper cannulation and decannulation techniques are important for achieving hemostasis and preventing complications from bleeding.

Life Science Solutions



SUN SCIENTIFIC

hemo wrap™

CLINICAL TRIAL
Emory University School of Medicine

Safety and Efficacy of a Novel Compression Hemostatic Device for Vascular Access: A Quality Improvement Study

Mohamed Modar Abidjan, Rodella Broxton-Key, Forest Rawls and Vandana D. Niyyar

Presented at: American Society of Nephrology in 2023

CRITERIA/OUTCOMES

Inclusion Criteria:
Patients who had HD with either AVF or AVG

Primary Efficacy Outcome:
Achieving post decannulation hemostasis within 15 minutes

Safety Outcome:

- Prolonged bleeding (> 15 minutes)
- Access thrombosis
- Local infection

Patient Satisfaction Survey: Likert scale measurement

RESULTS

166 HD sessions using the Hemowrap in 28 patients

Table 1. Incidence Rate of Complications

No. of patients	Total No. (average per patient) of HD sessions performed using the device	No. of prolonged bleeding >15 min per patient	No. of access thrombosis	No. of local infection	Average patient satisfaction (1-5)
28	166 (5.8 per patient)	1 (0.03%)	0 (0%)	0 (0%)	4.6

Conclusion: "This novel device was safe and effective in achieving post-cannulation hemostasis and was preferred to manual compression by patients at our center."

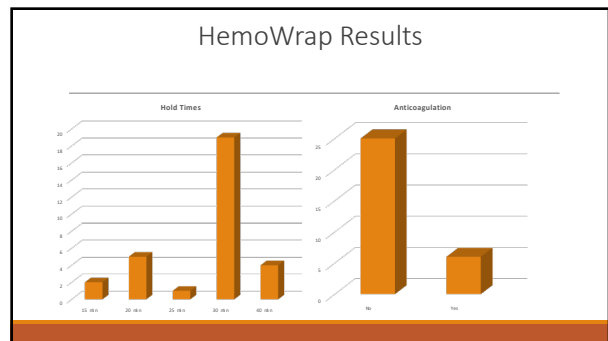
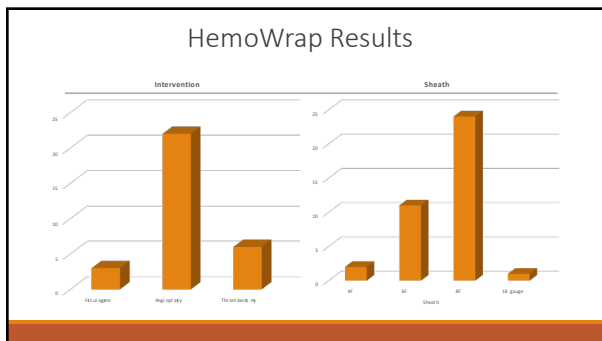
CLINICAL TRIAL
AZURA VASCULAR

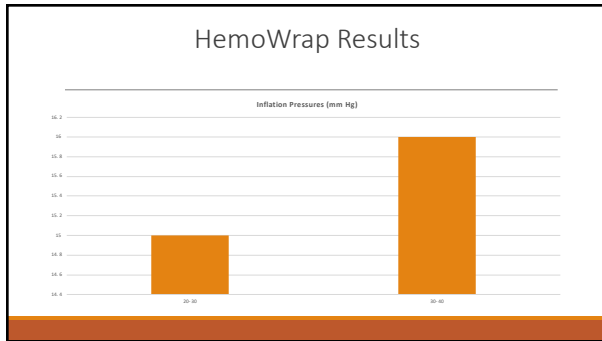
30 patient usability study

Access Type: Right (20), Left (10)

Access Side: Left (25), Right (10)

Access Location: Upper arm (25), Forearm (10)





HemoWrap Results – Azura Vascular

- Immediate post op bleeding - 1
- 48 – 72 hour post op bleeding – None
- 48 – 72 hour post op infection – None
- 48 – 72 hour pseudoaneurysm – None
- 48 – 72 hour thrombosis – 1 (Fistula)
- 30 day thrombosis – 3 (2 Fistula & 1 Graft)

HemoWrap Results – Westchester Vascular

CLINICAL TRIAL
WESTCHESTER VASCULAR

200 patient case series (since 2020)

Vascular Access Intervention

- AV Fistula
- AV Graft
- Pseudoaneurysm

Outcomes: Immediate and 1 week post-operative

- No episodes of thrombosis
- No Bleeding
- No post-op infection

Pedal Access

CASE SERIES

SUNRISE VASCULAR – 100 PATIENTS
WESTCHESTER VASCULAR – 50 PATIENTS

Procedure:

- Apply at end of case and have patient move to recovery room where they can eat, drink and recover comfortably
- After 12 minutes, remove wrap and perform ultrasound of access site

Results:

- No failures of hemostasis and no access site occlusions

Dr. Ash Sastry: "It has been game changing for the patient experience and workflow in our practice."

STUDY CONCLUSIONS

Azura Vascular Access – 30 patient usability study

Functioned as expected with minimal post-operative bleeding and complications

Emory Healthcare – Quality Improvement study to evaluate Safety and Efficacy in 166 hemodialysis sessions

"This novel device was safe and effective in achieving post-cannulation hemostasis and was preferred to manual compression by patients at our center."


Sunrise Vascular – 100 patient pedal access

"It has been game changing for the patient experience and workflow in our practice."


CONCLUSION

The HemoWrap has been shown


- to be safe and effective at achieving post decannulation hemostasis
- to have excellent patient satisfaction
- to be easy to use with minimal training
- it may help avoid suture related complications such as skin necrosis and subsequent infection
- to save clinician time



Improved Care



Better Patient Experience



Cost Savings & Clinical Efficiencies