

Comparison of Clinically Used Embolic Agents with GPX in Domestic Swine

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Disclosure

Speaker name:

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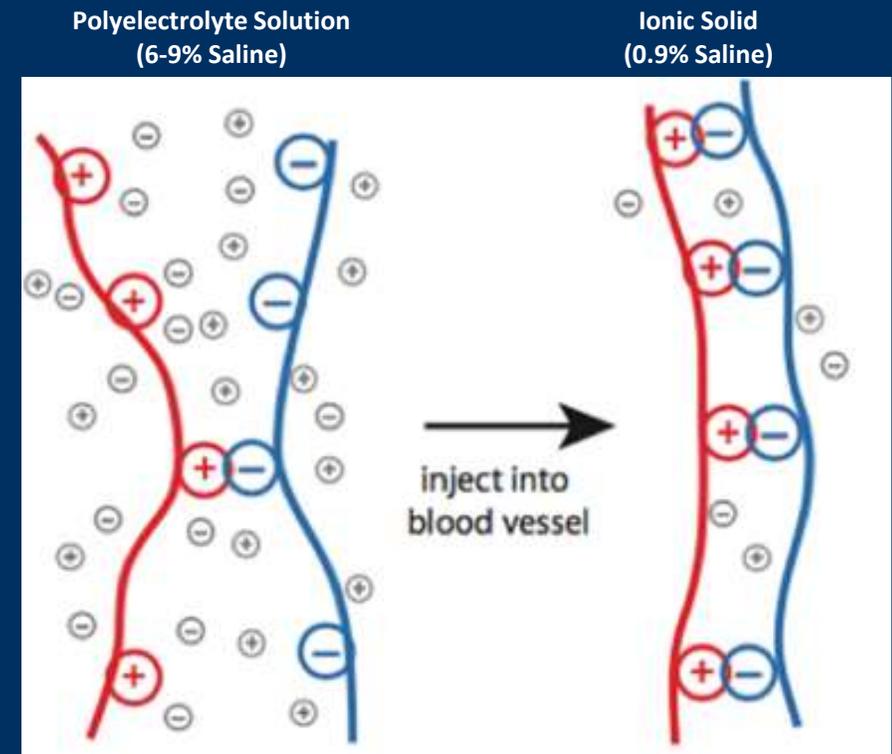
I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

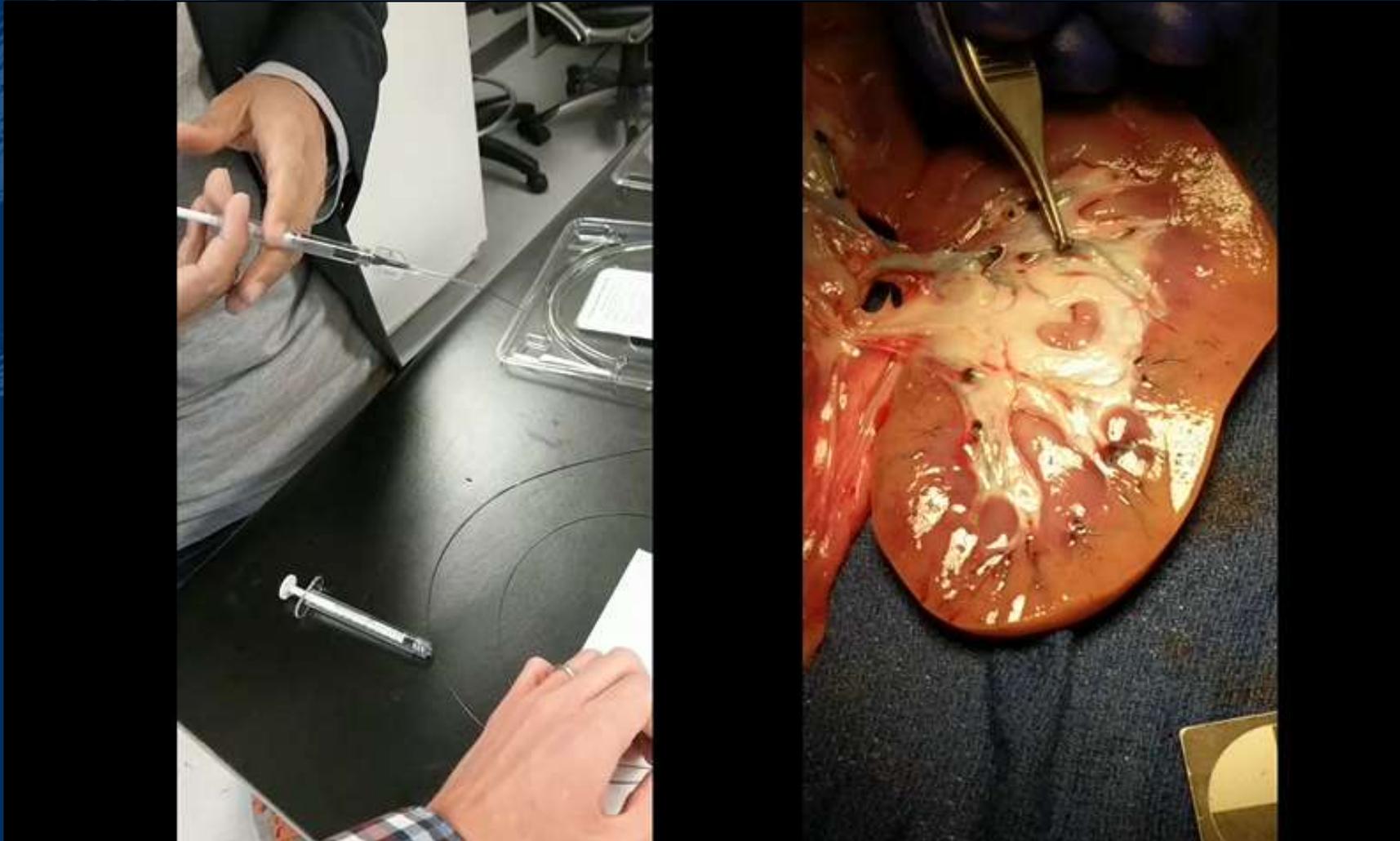
Introduction to GPX

- GPX: polymer-based technology consisting of a polycation, polyanion, and tantalum (radiopacity) premixed in a syringe
- The oppositely charged polymers remain dissolved in water at high salt concentrations, resulting in a flowable liquid
- The interaction strength between the oppositely charged polymers increases as GPX is injected into the blood stream and salt dissipates, forming a gel-like solid
- Viscosity is determined by polymer concentration and can be tailored for a variety of applications
 - Low viscosity for deep embolization and use with small ID microcatheters
 - High viscosity for occluding larger vessels and proximal occlusion with larger microcatheters



General Principle:
GPX solidifies upon injection into the blood vessel in response to decreased NaCl concentration

Introduction to GPX

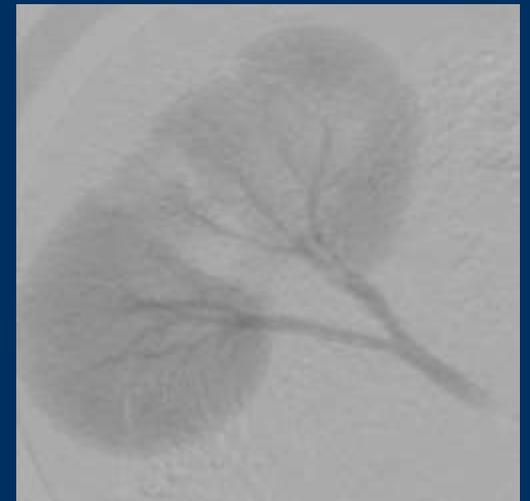


Study Design: Kidney Embolization

n=10 swine

Objectives

- Evaluate occlusion with low viscosity GPX
 - Acute follow-up
 - 30 day follow-up
 - 90 day follow-up
- Examine handling characteristics including:
 - Material characteristics
 - Handling attributes
 - Catheter entrapment
 - Reflux
 - Distal penetration
- Compare with clinical controls
 - Coils
 - NBCA
 - Onyx
 - PVA



Handling and Usage Survey Results (n=2)

- Usage surveys were performed immediately after the initial embolization and acute angiogram
- All liquids rated similar in Ability to Occlude (Not statistically significant), Accuracy of Delivery, and Radiographic Visualization
- Compared to other liquids, GPX Achieved higher scores (statistically significant) in Ease of Preparation, Ease of delivery, and Overall Ease of Use.

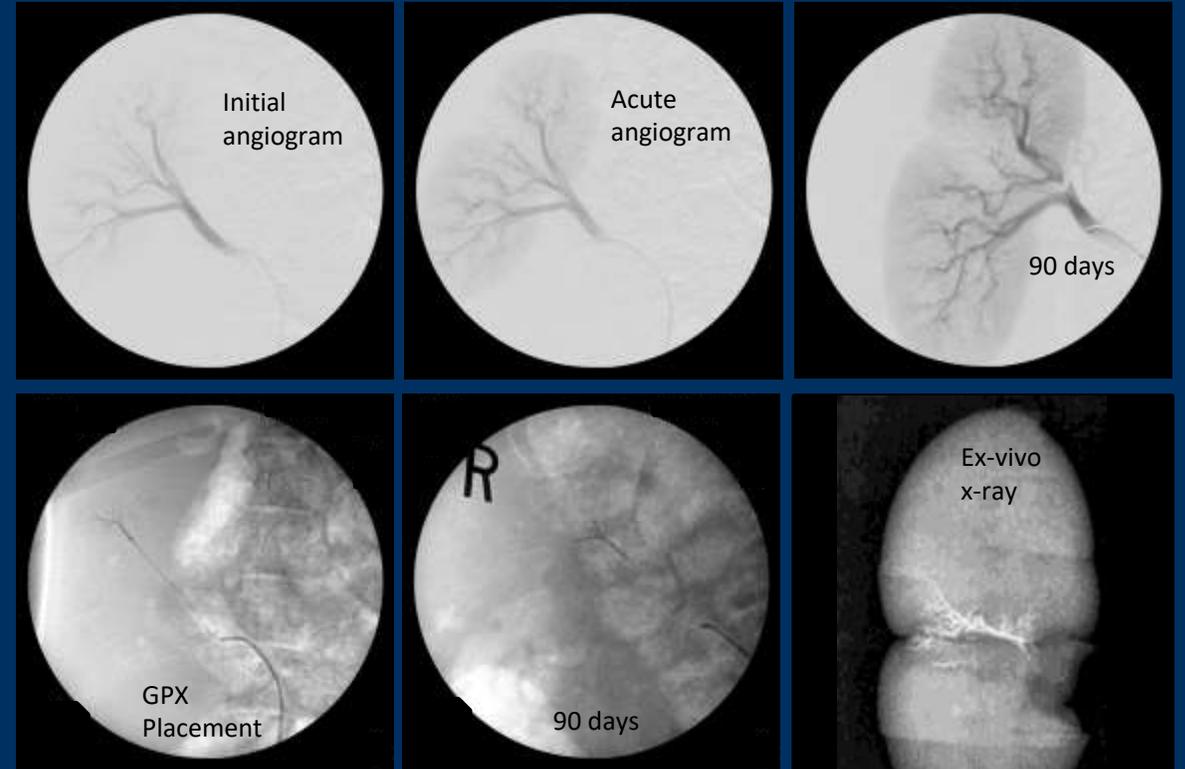
Agent	Ease of Preparation	Ease of Delivery	Accuracy of Delivery	Ability to Occlude Target Vasculature	Overall Ease of Use	Visualization after Delivery
Coils	4.33 (0.82)	3.83 (1.17)	4.67 (0.52)	4.33 (0.82)	4.17 (0.75)	4.83 (0.41)
GPX	4.82 (0.60)	4.82 (0.40)	4.64 (0.67)	5.00 (0.00)	4.55 (0.69)	4.73 (0.47)
NBCA	2.43 (0.79)	3.86 (0.69)	4.29 (0.49)	5.00 (0.00)	3.00 (0.58)	4.29 (1.11)
Onyx	3.00 (0.71)	3.40 (1.14)	4.20 (0.45)	4.80 (0.45)	3.20 (0.84)	4.20 (0.84)
PVA	3.57 (1.13)	3.57 (1.13)	2.86 (0.69)	3.93 (1.02)	3.21 (0.91)	1.00 (0.58)

Values= Average (Standard Deviation)
Scale: 1=Very Unacceptable; 2= Unacceptable; 3=Neutral; 4= Acceptable; 5=Very Acceptable

Porcine Kidney Embolization

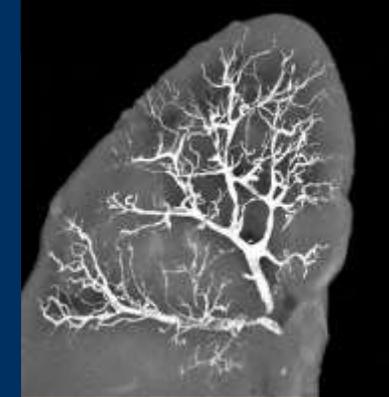
Results

- No adverse effects seen on the animals from any of the devices
 - Blood chemistry
 - Clinical signs
- GPX Produced Stable Occlusions at 30 and 90 days
 - 12/12 sites remained occluded at follow-up
 - No migration or off target embolization
- Partial to full recanalization seen with other devices:
 - Coils (5/6)
 - PVA (5/6)
 - Onyx (2/5)
 - NBCA (1/7)



Conclusions

- In porcine renal and hepatic arteries, GPX produces stable occlusions at 30 and 90 days
 - May provide an advantage in terms of low recanalization, but further studies are needed
- Additional pilot studies have been successful in:
 - Portal vein
 - Use in conjunction with a single coil
 - Porcine rete mirabile (AV malformations)
 - Rabbit aneurysms
- Based on the results of these studies, GPX displays promise in a variety of embolization situations
- Further characterization will continue to examine technique and scenarios of use



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