Final Results of the GPX Embolic Device Multi-Center Trial for Distal Applications

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CIO Symposium on Clinical Interventional Oncology

FLUIDX MEDICAL TECHNOLOGY

Introduction

- A prospective, multicenter feasibility clinical trial was conducted examining the use of the GPX® Embolic Device for distal applications within the peripheral vasculature.
- The primary objectives of this study were to evaluate safety and early indicators of performance for the GPX Embolic Device, a novel liquid embolic agent
- The GPX Embolic Device is a novel aqueous-based embolic agent that solidifies in situ through ionic bonds
- Preparation: Resuspend tantalum by pushing opposing syringe plungers back and forth at least 25 times within 60 seconds

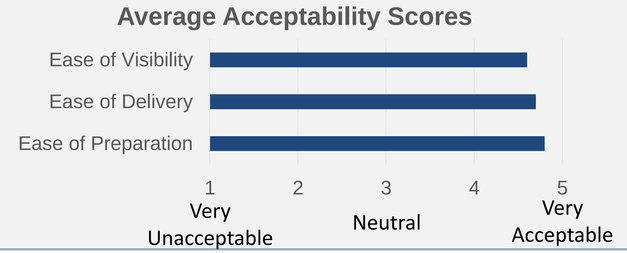
Materials & Methods

- Enrollment consisted of 17 subjects with diverse distal embolization needs
- Primary Endpoints:
  - Technical success (complete occlusion of target region at time of procedure)
  - Incidence of Device-Related Serious Adverse Events (SAEs)
- Follow-up was performed at 30 days, with imaging included if dictated by standard of care
- For each case, operators were asked to score several dimensions of their experience with the GPX Embolic Device including acceptability of preparation, delivery, and visibility

Rating Scale	1.0	2.0	3.0	4.0	5.0
Description	Very Unacceptable	Unacceptable	Neutral	Acceptable	Very Acceptable

Results

- Technical success was achieved in all cases with target regions fully occluded at the first angiogram (taken immediately after delivery)
- Excellent distal penetration into vessel beds was observed in all cases
- 15/17 patients (88.2%) were free from device related SAEs
  - 2 bone tumor patients experienced intraprocedural pain during delivery
- At the 30-day follow-up, patients reported good outcomes, and sites remained fully occluded with stable positioning of the embolic device in each case where imaging was available
- GPX was found to be very acceptable across all usability dimensions studied.



Sex		Age	
Male	8 (47%)	Mean/Median	54.3/58
Female	9 (53%)	Range	22-85
Type of Embolization			
Renal Angiomyolipoma (AML)			7
Primary Renal Cell Carcinoma (RCC)			2
Secondary RCC (Impacting Femur)			2
Portal Vein			4
Pelvic Tumor			1
Polycystic Kidney			1

Table 1: Study Demographics

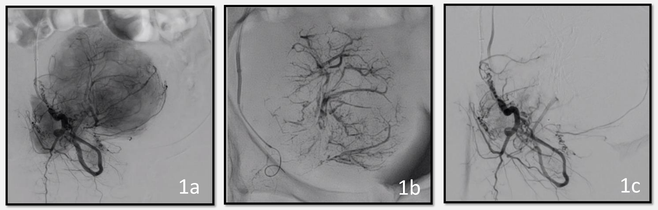


Figure 1: Pelvic Tumor Embolization
1a) Pre-embolization
1b) GPX placement
1c) Post-embolization DSA

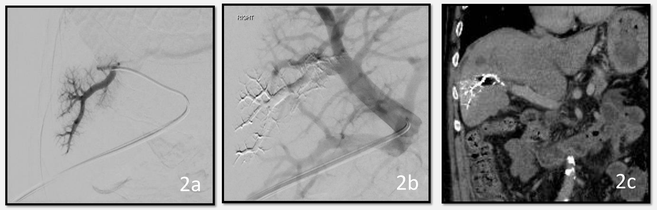


Figure 2: Portal Vein Embolization
2a) Pre-embolization
2b) Post-embolization DSA
2c) 9 Day CT showing occlusion

Conclusions

- GPX Embolic Device may provide safe and effective embolization for arterial or venous applications where distal penetration is desired
- 100% technical success with no instances of recanalization or migration observed
- Adverse event rate was comparable to other feasibility trials in the space
- Operators gave GPX Embolic Device high scores for simple preparation, radiographic visibility, and favorable control during delivery

The GPX® Embolic Device is under development and does not have marketing clearance or approval in any market at this time.