Prospective Multicenter GPX® Embolic Device Clinical Trial Summary

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INTRODUCTION

The use of liquid embolic devices in peripheral applications continues to expand significantly, but device preparation can be burdensome and embolic delivery can be complicated and uncontrolled. The GPX Embolic Device is a novel, simple to prepare, easy to deliver, aqueous-based embolic agent that solidifies in situ through ionic bonds.

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 objective of this study was to evaluate safety and early indicators of performance for the GPX Embolic Device.

MATERIALS & METHODS

Enrollment consisted of 17 patients with diverse distal embolization needs, including renal angiomyolipoma, primary and secondary renal cell carcinoma, portal veins, pelvic sarcoma, and polycystic kidney embolizations (Refer to Table 1 for study demographics). No significant changes in embolization procedure or delivery microcatheter were required for embolization using the study device. The microcatheter used for study device delivery was chosen by each investigator based on preferences and/or anatomical determinants. Pre-and post-embolization angiograms were completed to confirm complete occlusion of the target region.

TABLE 1: STUDY DEMOGRAPHICS

SEX		AGE	
MALE	8 (47%)	MEAN/MEDIAN	54.3/58
FEMALE	9 (53%)	RANGE	22-85

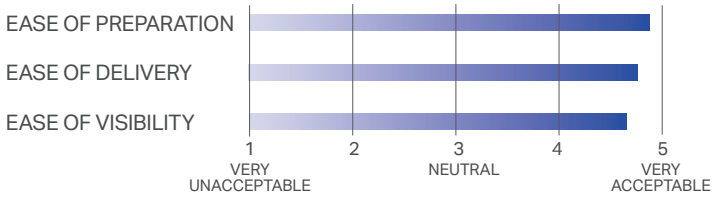
- Primary Endpoints:
  - Technical success (complete occlusion of target region at time of procedure).
  - Incidence of Device-Related Serious Adverse Events (SAEs).
  - Follow-up was performed at 30 days, with imaging included if dictated by standard of care.
- For each case, operators were asked to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

Scan this link to view trial results as published in the Journal of Vascular and Interventional Radiology.

RESULTS

- In all cases (100%), technical success was achieved 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.
  - Both patients with SAEs were undergoing treatment for osseous renal cell carcinomas metastasis, which is often a significantly painful procedure.
  - Adverse event rate was comparable to other feasibility trials in the space.
- Each patient completed a 30-day follow-up evaluation, and sites remained fully occluded in each case where imaging was available (6/17 patients (35.3%) had follow-up imaging with all sites deemed occluded (100%) and a mean of 30.2 days post-procedure).
- GPX Embolic Device scored very highly across all usability dimensions, averaging "Very Acceptable" for key aspects including Ease of Preparation, Delivery, and Visibility, with no responses lower than "Acceptable" for any of the dimensions studied (Graph 1).

GRAPH 1: KEY INVESTIGATOR USABILITY QUESTIONNAIRE RESULTS



CONCLUSIONS

- While limited by sample size, the study indicates that the 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.
- Investigators gave GPX Embolic Device high scores for simple preparation, radiographic visibility, and favorable control during delivery.

Continued on following page.

ILLUSTRATIVE CASES

Below are cases from the trial that highlight the utility, distal penetration, and durable nature of the GPX Embolic Device across a range of applications.

RENAL ANGIOMYOLIPOMA EMBOLIZATION

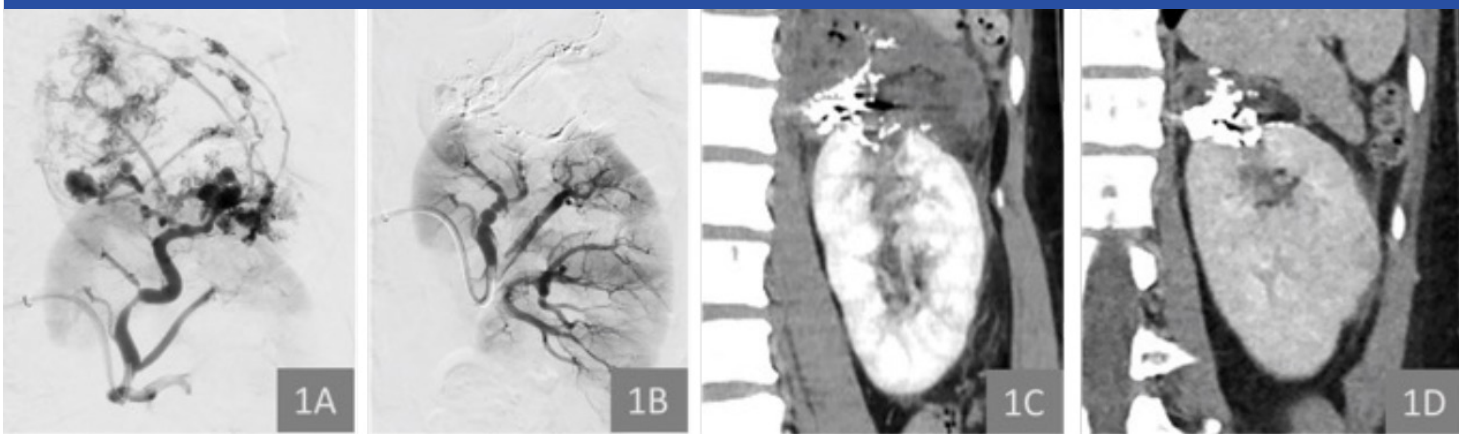


Figure 1A-D: *Embolization of Renal Angiomyolipoma (AML) Demonstrating Targeted Delivery and Post-Treatment Tumor Shrinkage. (A) Pre-embolization angiogram of AML treatment area. (B) Post-embolization DSA showing complete occlusion of target area with study material. (C) CT image of targeted region 5 days post-treatment. (D) CT image of targeted region 6 months post-treatment showing shrinkage of the AML. Note: The results in Figure 1D fall outside of the trial period.*

PELVIC SARCOMA EMBOLIZATION

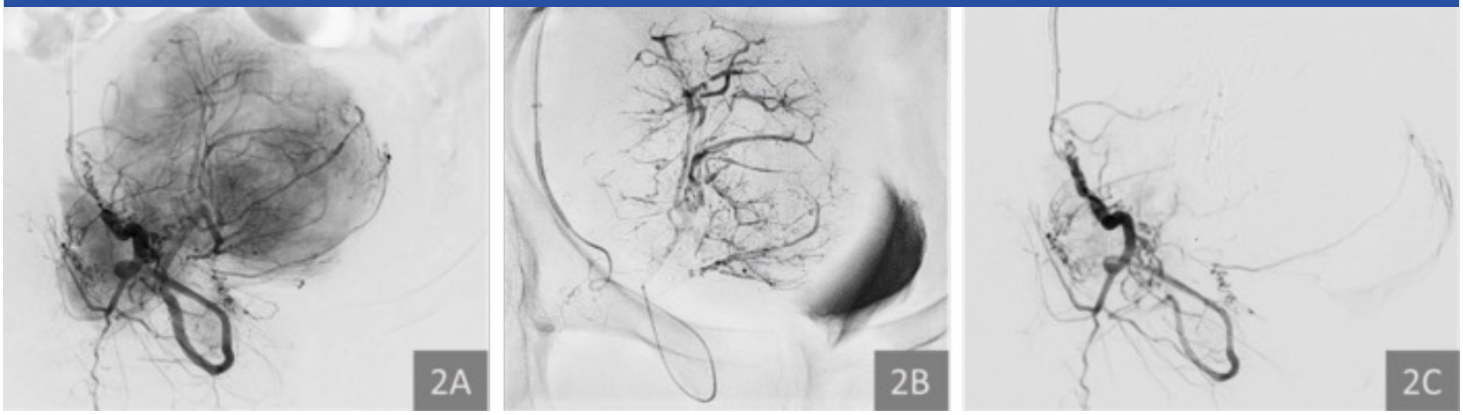


Figure 2A-C*: Distal Penetration in Embolization of Pelvic Sarcoma. (A) Pre-embolization angiogram of treatment area. (B) Post-embolization angiogram showing study material in target area. (C) Post-embolization DSA showing complete occlusion of target area with study material.*

PORTAL VEIN EMBOLIZATION

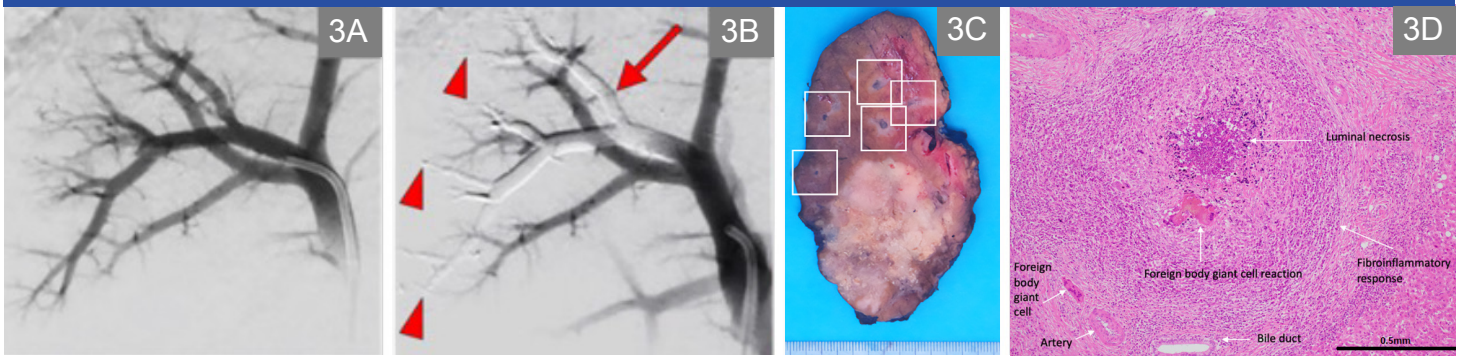


Figure 3A-D: *Distal Penetration of Study Device in Portal Vein Embolization. (A) Pre-embolization angiogram of treatment area. (B) Post-embolization DSA showing complete occlusion of target area with study material (target area denoted with red arrows). (C) Explanted tissue at 57 days post-embolization procedure showing vessels filled with embolic study material. (D) H&E pathology showing tissue response to embolization with the study material.*

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