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Comparative evaluation of two resorbable microparticles in a porcine kidney model: angiographic and pathologic outcomes

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PURPOSE

This study aimed to compare the safety and efficacy of two resorbable microparticles in a porcine kidney model, focusing on recanalization and tissue injury outcomes over a 7-day follow-up period.

METHODS

This exploratory proof-of-concept study included 10 pigs, each undergoing embolization of the upper polar arteries in both kidneys, resulting in 20 treated kidneys (10 per group). Angiographic evaluations were performed on all 20 treated kidneys (10 per group) across the 10 animals at immediate, 2-hour, 1-day, and 7-day post-embolization time points. Histopathologic evaluations were performed on 5 animals per group (5 kidneys per group). The primary endpoint was complete angiographic recanalization at 7 days. Secondary endpoints included early recanalization at 2 hours and 1 day and histopathologic tissue injury. In Group A, the right upper polar artery was embolized with spherical gelatin microparticles (Nexsphere-F®), whereas in Group B, the left upper polar artery was embolized with irregular microparticles (KIPZA®). Approximately 5–10 mL of microparticle suspension was injected per kidney; the mean embolization time per kidney was 30 ± 5 minutes.

RESULTS

At 2 hours post-embolization, complete recanalization was observed in all Nexsphere-F kidneys and in 9 of 10 KIPZA kidneys; 1 KIPZA kidney showed partial recanalization. Full recanalization was observed in all kidneys by day 7. Histopathologic evaluation (5 kidneys per group) revealed no residual emboli or parenchymal infarction in Group A. In Group B, minimal microparticle residue and focal infarction (mean infarcted area 2.78% ± 1.33%) were observed, along with endothelial proliferation in arcuate and interlobular arteries.

CONCLUSION

In this exploratory pilot study, embolization with both Nexsphere-F and KIPZA microparticles resulted in early recanalization and minimal tissue injury. These proof-of-concept findings suggest that both microparticles may be suitable for temporary embolization when organ preservation is paramount, although larger powered studies with disease models and longer follow-up are needed.

CLINICAL SIGNIFICANCE

These preliminary data support the potential of resorbable microparticles for temporary embolization, emphasizing their use in scenarios requiring parenchymal preservation and underscoring the need for further research.

KEYWORDS

Microparticles, organ preservation, angiography, embolization, therapeutic, embolic agent

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Transarterial embolization (TAE) is a cornerstone technique in interventional radiology, widely used to manage hemorrhage, target tumor vasculature, and treat vascular disorders.[1-5] Permanent embolic agents, such as polyvinyl alcohol particles and tris-acryl microparticles, have been the standard for achieving sustained occlusion.[6] However, their pro-

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longed presence can cause ischemic injury to non-target tissues, particularly in sensitive regions, such as the kidneys, liver, or reproductive organs, where ischemia may impair function or limit future therapeutic options.[7] These limitations highlight the need for temporary embolization agents that provide effective occlusion while minimizing long-term tissue damage.

Resorbable microparticles have recently emerged as promising alternatives for TAE, offering controlled, temporary occlusion with predictable degradation.[8-11] These agents have shown therapeutic benefits across diverse applications. For example, resorbable microparticles have been used in uterine artery embolization to treat fibroids while preserving fertility.[11] In genicular artery embolization for osteoarthritis, temporary occlusion reduces inflammation without causing permanent vascular damage.[9] Additionally, in transarterial chemoembolization for liver tumors, resorbable microparticles enhance chemotherapy delivery and reduce surrounding tissue injury by aligning with drug pharmacokinetics.[10]

Despite their growing use, the unique characteristics of resorbable microparticles, such as composition and morphology, remain underexplored. These features influence their safety, efficacy, and suitability for different clinical contexts. Detailed evaluations are essential to optimize their use for temporary embolization, particularly in organ-preserving interventions.

In this study, we compare the angiographic and histopathological outcomes of two distinct resorbable microparticles, Nexsphere-F (Nextbiomedical, Incheon, Republic of Korea) and KIPZA (Engain, Hwaseong, Republic of Korea), in a porcine kidney model. The findings provide insights into their potential applications and limitations for temporary embolization, addressing the critical need for informed selection of embolic agents in clinical settings requiring organ preservation.

Main points

- Embolization with Nexsphere-F and KIPZA resorbable microparticles in porcine kidneys demonstrated early recanalization, minimal inflammatory reaction, and no significant tissue injury.
- Effective, safe, and temporary vascular occlusion with minimal tissue injury is possible with both microparticles.
- Our findings suggest that Nexsphere-F and KIPZA resorbable microparticles are suitable for temporary embolization applications, in which preservation of the organ parenchyma is essential.

Methods

Animal model

This study was approved by the Institutional Animal Care and Use Committee of Seoul National University Bundang Hospital (protocol number: BA-2007-301-085, date: 30.01.2025) and was conducted in compliance with the Animal Research: Reporting of *In Vivo* Experiments 2.0 guidelines to ensure ethical and accurate reporting of animal research.[12] Ten male farm pigs (30–40 kg) were housed under standard conditions with free access to food and water and received veterinary oversight throughout the study.

This investigation was an exploratory proof-of-concept study; therefore, no formal sample size calculation was performed. Ten pigs were selected to allow bilateral within-animal comparisons, and the findings should be interpreted as hypothesis-generating. Following embolization, the animals were monitored for welfare, analgesia, and post-procedural complications. Analgesia was provided via intramuscular ketoprofen (3 mg/kg) as needed. The animals were evaluated hourly for appetite, behavior, and signs of distress by veterinary staff using predefined welfare assessment criteria. On day 7, after the final angiography and under deep anesthesia, the animals were humanely euthanized by intravenous potassium chloride injection.

Renal arteriography and embolization

All procedures were performed by a board-certified interventional radiologist. On the day of the experiment, the animals were pretreated with an injection of atropine (Jeil Pharmaceutical, Seoul, Republic of Korea) 0.05 mg/kg and the antibiotic 'Baytril (Bayer, Leverkusen, Germany) 5 mg/kg, and then anesthesia was induced with intramuscular injections of Zoletil 50 (Virbac, Carros, France) 5 mg/kg and Rompun (Bayer, Leverkusen, Germany) 2 mg/kg. After induction, the animals were transferred to the laboratory, and tracheal intubation was performed. Respiratory anesthesia was maintained at 5–10 mL/kg/min with FORANE (JW Pharmaceutical, Seoul, Republic of Korea) and O_2 in a ratio of 1-1.5 using a Primus respiratory anesthesia machine (Drager, Lübeck, Germany). The pigs were positioned supine in a dedicated angiography suite (Axiom Artis Zee, Siemens, Forchheim, Germany). Right femoral artery access was obtained through ultrasound-guided puncture, followed by insertion of a 5-F angiographic guide catheter (Davis, Cook Medical, Bloomington, IN, USA) and a 1.7-F microcatheter (Progreat Lambda, Terumo, Tokyo, Japan). Bilateral renal and upper polar angiograms were then performed.

Each animal underwent embolization of the upper polar arteries in both kidneys. For procedural consistency, the right upper polar artery was embolized with resorbable gelatin microparticles (100–300 μm; Nexsphere-F®, Nextbiomedical, Incheon, Republic of Korea), and the left upper polar artery was embolized with resorbable microparticles of the same size range (100–300 μm; KIPZA®, Engain, Hwaseong, Republic of Korea). Follow-up angiography was performed immediately and at 2 hours, 1 day, and 7 days post-embolization to assess recanalization. After the final angiography on day 7, 5 of the 10 pigs were randomly selected for histopathologic evaluation to minimize animal sacrifice while enabling robust comparative analysis; these animals were euthanized under deep anesthesia, and both treated renal segments were harvested for pathologic analysis (5 kidneys per group) (Figure 1).

Nexsphere-F® consists of uniform spherical gelatin-based microparticles (100–300 μm) with smooth surfaces, whereas KIPZA® comprises irregularly shaped gelatin-based microparticles (100–300 μm) with rough surfaces. All microparticles were prepared by hydration with 2 mL of normal saline, followed by the addition of approximately 8 mL of contrast medium and thorough mixing. Subsequently, 5–10 mL of the suspension was injected per kidney until near stasis was achieved. The mean procedure time per kidney (from catheter placement to completion of embolization) was 30 ± 5 minutes.

Angiographic recanalization was graded by two independent interventional radiologists using a modified Thrombolysis in Myocardial Infarction (TIMI) scale (0: no perfusion; 1: minimal perfusion; 2: partial recanalization; 3: complete recanalization). Reviewers were blinded to group allocation; disagreements were resolved by consensus.

Endpoints

The primary endpoint was complete angiographic recanalization at 7 days post-embolization. Secondary endpoints included early angiographic recanalization at 2 hours and 1 day and histopathologic parameters, including the presence of residual micropar-

ticles, infarcted area percentage, inflammatory cell infiltration, and endothelial proliferation.

Histopathological analysis

To minimize bias, kidney specimens from each pig were sent to an independent laboratory (HLB BioStep, Incheon, Republic of Korea) for blinded analysis. Each kidney was bisected longitudinally and transversely sectioned to produce 12 slides per specimen. The pathological evaluation focused on parenchymal infarction and inflammatory cell infiltration, and the infarcted area was quantified as a percentage of the total cross-sectional area using ImageJ software (Bethesda, Maryland, USA). Prior to histological processing, each kidney was visually inspected for surface discoloration and textural changes as indicators of infarction. Tissue samples were stained with hematoxylin and eosin to detect residual embolic agents, lymphocyte and macrophage infiltration, and reactive endothelial cell proliferation.

The histopathologic assessment was independently performed by two board-certified pathologists blinded to group allocation. They quantified infarcted tissue and inflammation and noted endothelial proliferation.

Statistical analysis

Because this was an exploratory pilot study without a formal sample size calculation, statistical analyses were descriptive and hypothesis-generating. Inter-rater reliability for histopathologic assessments was evaluated using Cohen's κ statistic.

Given the exploratory pilot design and small sample size, the analyses were primarily descriptive, focusing on effect sizes and paired comparisons without prespecified hypothesis testing. The normality of continuous variables was evaluated using the Shapiro–Wilk test. Paired comparisons (right vs. left kidney) used paired t-tests for normally distributed outcomes and Wilcoxon signed-rank tests otherwise to generate exploratory *P* values; however, these should be interpreted cautiously and without strict significance thresholds.

Results

Angiographic evaluation

Pre-embolization angiography showed no significant variations in the renal vasculature of any pig. Immediately after embolization, angiography confirmed complete occlusion of the arteries supplying the embolized upper poles of the kidneys. At the 2-hour follow-up, restored blood flow and full parenchymal staining were observed in the right kidneys of all animals treated with Nexsphere-F (TIMI 3) (Figure 2). Among the left kidneys treated with KIPZA, partial recanalization (TIMI 2) was observed in 1 animal, whereas the remaining animals showed complete recanalization (TIMI 3) at this time point (Figure 3). Follow-up angiograms at 1 and 7 days post-embolization revealed full recanalization with restored parenchymal staining in all pigs.

Qualitative and quantitative histopathological analysis

On day 7, after bilateral renal angiography, all animals were sacrificed, and the kidneys were harvested. Gross examination revealed no significant abnormalities in the kidneys treated with either product. Histological evaluation revealed no residual emboli and no lymphocyte or macrophage infiltration in the Nexsphere-F group, with no evidence of parenchymal infarction. The inter-rater reliability for assessing parenchymal infarction and endothelial proliferation was excellent (Cohen's κ: 0.92).

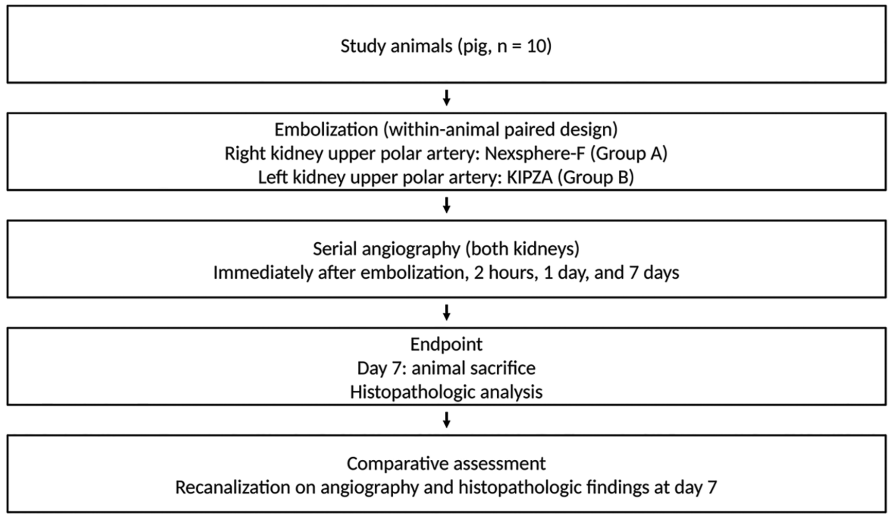


Figure 1. Flowchart of experimental procedure. The flowchart illustrates the embolization procedure performed on the upper polar artery in both groups.

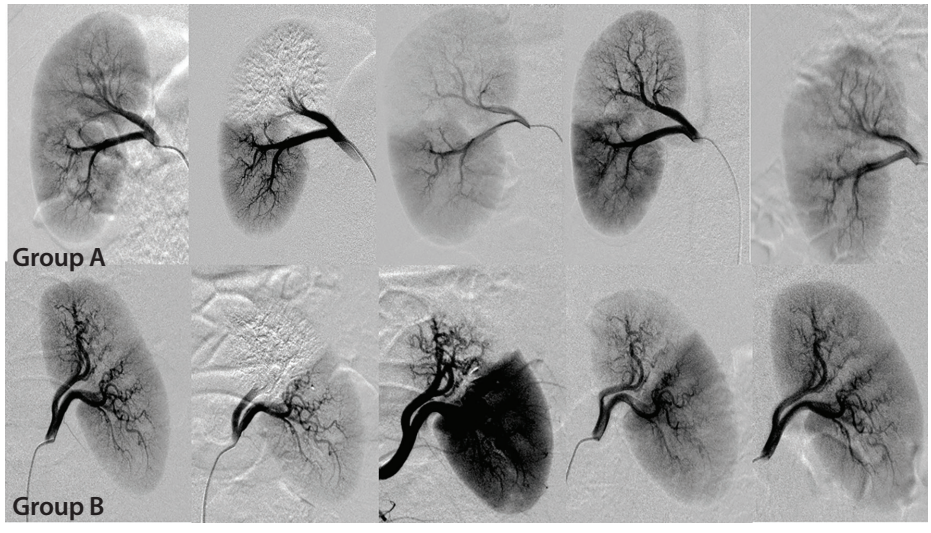


Figure 2. Baseline and follow-up angiography post-embolization of Groups A and B. Serial angiographic images display blood flow in treated renal segments at baseline, immediately post-embolization, 2 hours post-embolization, 1 day post-embolization, and 7 days post-embolization (arranged chronologically from left to right). The top row (Group **A**) and bottom row (Group **B**) represent representative cases chosen to illustrate typical recanalization patterns; all animals demonstrated similar findings. Full recanalization with restored perfusion was observed at the 2-hour mark and maintained through day 7 in Group A. Partial recanalization was observed at 2 hours post-embolization in Group B, with flow fully restored by day 7.

In the KIPZA group, 1 kidney (1/5) exhibited minimal microparticle residue in the dorsal glomerulus and interlobular arteries, along with multifocal lymphocyte infiltration in a single lobule. Additionally, endothelial cell proliferation in the arcuate and interlobular arteries was observed in all kidneys in the KIPZA group, as shown in Table 1. A focal infarction area was observed in 3 of the 5 kidneys in the KIPZA group (60%). The mean infarction percentage area was 2.78% ± 1.33% (95% confidence interval: 1.2%–4.3%), whereas no infarctions were observed in Group A. Although the sample size precludes definitive statistical comparison, this effect size suggests a difference in tissue response between the two microparticles (Figure 4).

Discussion

In this study, we evaluated the angiographic and histopathologic characteristics of two resorbable microparticles—Nexsphere-F and KIPZA—in a porcine kidney model, focusing on their potential for controlled, temporary embolization. Both microparticle types demonstrated favorable safety profiles, with full recanalization of embolized vessels and minimal tissue injury observed by day 7 post-embolization. Because this was an exploratory pilot study, our findings should be interpreted descriptively rather than as definitive comparative efficacy. The

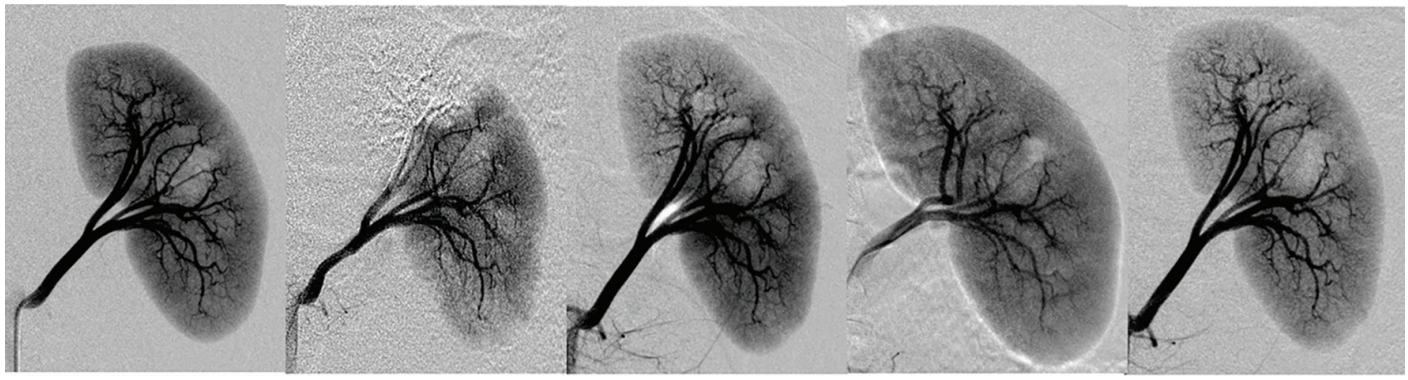


Figure 3. Baseline and follow-up angiography post-embolization in an additional representative case of Group B. Serial angiographic images display blood flow in treated renal segments at baseline, immediately post-embolization, 2 hours post-embolization, 1 day post-embolization, and 7 days post-embolization (arranged chronologically from left to right). This case was selected to represent the typical angiographic response in Group B; all other Group B animals exhibited similar recanalization patterns with full restoration by day 7.

Table 1. Histopathologic evaluation of two groups

	Right kidney upper pole (Nexsphere-F)			Left kidney upper pole (KIPZA)		
Individual number	Residual emboli in renal vessels	Lymphocyte/ macrophage infiltration	Endothelial cell proliferation	Residual emboli in renal vessels	Lymphocyte/ macrophage infiltration	Endothelial cell proliferation
1	No (0/12)	No (0/12)	No (0/12)	No (0/12)	Yes (12/12)	Yes (9/12)
2	No (0/12)	No (0/12)	No (0/12)	No (0/12)	Yes (3/12)	Yes (1/12)
3	No (0/12)	No (0/12)	No (0/12)	Yes (2/12)	Yes (2/12)	Yes (5/12)
4	No (0/12)	No (0/12)	No (0/12)	No (0/12)	Yes (9/12)	Yes (3/12)
5	No (0/12)	No (0/12)	No (0/12)	No (0/12)	Yes (12/12)	Yes (2/12)

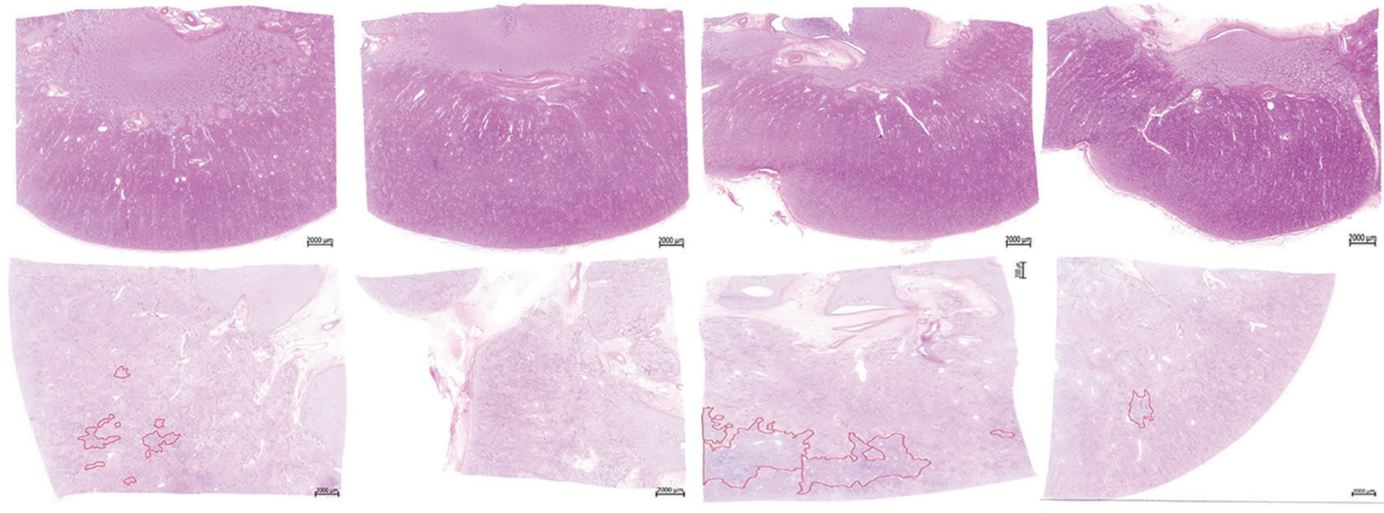


Figure 4. Infarction area analysis in both groups. Quantitative analysis of infarcted tissue in the right kidney (top row) and left kidney (bottom row) post-embolization. Red-shaded areas indicate areas of infarction.

observed effect sizes highlight trends that warrant further investigation in larger, powered studies. Our claims regarding organ preservation reflect structural observations only; functional renal outcomes were not assessed, so organ preservation must be interpreted cautiously.

Resorbable microparticles have shown promising applications in settings that require temporary vascular occlusion. For instance, Han et al.[11] demonstrated the effectiveness of resorbable microparticles in uterine artery embolization, achieving outcomes comparable with those of permanent agents while preserving options for future interventions due to recanalization. In addition, Verret et al.[13] reported transient uterine artery occlusion using a resorbable embolization microparticle in a sheep model. Similarly, Min et al.[9] reported effective pain relief in osteoarthritis using resorbable microparticles for genicular artery occlusion, minimizing long-term tissue damage. Wang and Rao[10] highlighted their alignment with chemotherapy in transarterial chemoembolization for liver tumors, enhancing therapeutic effects while reducing liver injury.

Despite these advances, detailed *in vivo* characterization of resorbable microparticles is limited, particularly in differentiating their effects across diverse clinical contexts that require specific properties. Factors such as particle shape and surface structure influence microparticle behavior and outcomes. Laurent et al.[14] observed that irregular microparticles penetrate more distally within vascular networks, promoting more durable occlusions due to enhanced deformation and thrombotic retention. Another study reported that irregularly shaped particles tend to aggregate and occlude vessels larger than their own diameter, unlike spherical embolics with smooth surfaces.[15] This aligns with the present findings, as differences between Nexsphere-F and KIPZA highlight how microparticle morphology impacts recanalization. These findings may have implications for real-world embolization practice: agents with rapid recanalization may be preferable for temporary hemostasis or fertility-preserving interventions, whereas KIPZA may be more suitable when temporary but relatively more durable occlusion is desired, particularly in embolization of relatively high-flow vascular channels, such as transarterial microembolization for shoulder pain.

In this study, serial angiography post-embolization showed complete recanalization and restored parenchymal enhancement in all individuals of Group A by 2 hours, likely owing to its rapid hydrolytic degradation and smooth, spherical structure, which promotes efficient resorption and timely recanalization. In contrast, 1 animal in Group B showed partial recanalization with reduced parenchymal enhancement at the 2-hour follow-up, with full restoration by day 7. Rapid recanalization may be desirable in contexts where quick restoration of perfusion is critical (e.g., fertility-sparing uterine artery embolization); however, in situations requiring durable occlusion, such early recanalization could indicate insufficient durability of the embolic material. The irregular shape of KIPZA likely enhances deep penetration, aggregation, and thrombotic occlusion, leading to a delayed recanalization response.[6,14,16]

Histopathologic analysis supported these angiographic findings, showing no ischemic damage or inflammatory cell infiltration in Group A. The fast resorption of Nexsphere-F was not associated with any structural alteration of the arterial walls. Conversely, Group B exhibited minimal ischemia (2.78% ± 1.33%) and endothelial cell proliferation in the arcuate and interlobular arteries, likely due to KIPZA's irregular surface, which promotes platelet adhesion and more durable thrombosis.[6,14,17,18] In this context, the endothelial proliferation observed in Group B may represent a reparative response to transient ischemia rather than pathologic neointimal formation; however, further mechanistic studies are needed to clarify this finding.

This study contributes to the literature by comparing the differential effects of Nexsphere-F and KIPZA *in vivo*. Although both achieved full recanalization, KIPZA's irregular shape may be beneficial for temporary embolization in high-flow areas or lesions with multiple connections where more durable occlusion is needed. Nexsphere-F's uniform spherical shape appears more suitable for end organs or tissues vulnerable to ischemia. These findings underscore the impact of microparticle morphology on embolization outcomes, highlighting the importance of selecting embolic agents based on specific clinical needs.

This study had several limitations. It was an exploratory pilot study with a small sample size (angiography n = 10, histopathology n = 5 per group) and no formal power calculation. The healthy porcine model lacks underlying disease and functional endpoints (e.g., serum creatinine) to assess renal function. Therefore, conclusions regarding organ preservation are limited to structural findings rather than functional outcomes. The follow-up duration was limited to 7 days, preventing evaluation of long-term outcomes or delayed recanalization. Furthermore, extrapolation of these results to human pathology should be undertaken with caution.

In this exploratory pilot study, both Nexsphere-F and KIPZA demonstrated temporary vascular occlusion with early recanalization and minimal structural tissue injury in a porcine kidney model. However, the observed differences in recanalization pattern and histopathologic response should be interpreted descriptively rather than as evidence of definitive comparative efficacy. Rapid recanalization may be advantageous in clinical settings requiring temporary embolization and parenchymal preservation, although its implications for embolic durability depend on the intended therapeutic use. Because organ preservation in this study was assessed only by structural findings in a healthy animal model over short-term follow-up, larger studies with functional endpoints, disease models, and longer observation are needed.

Footnotes

Conflict of interest disclosure

J.H.L. received a donation of experimental microparticles from Nextbiomedical Co., Ltd. and Engain Co., Ltd., the manufacturers of the microparticles studied. All other authors declare no conflicts of interest related to this work.

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