

# Preventing Inadvertent Foreign Body Injection in Angiography

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See also the editorial by Nikolic in this issue.

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**Background:** Inadvertent injection of foreign material during angiography, particularly neuroangiography, should be avoided to reduce the risk of embolic complications. Woven gauze and cotton fabrics have been identified as sources of inadvertent foreign body embolization.

**Purpose:** To find the source of particles that contaminate injections on an angiography table and to identify measures for their reduction.

**Materials and Methods:** The number and size of particles on an angiographic supply table at a tertiary stroke center were analyzed by using the Coulter principle in September 2019. Seven conditions (saline directly drawn from its bag, from a small metal cup, from a small plastic cup, from a large plastic bowl, from a large plastic bowl with a guidewire and its sheath, from a large plastic bowl with a stack of woven gauze, and from a large plastic bowl with a large cotton towel) were tested at different time intervals (0, 30, and 60 minutes). Each container was filled with saline, and particle count was analyzed immediately after unpackaging, after rinsing with saline, and after introduction of foreign material; *t* tests were used for statistical comparisons.

**Results:** Freshly unpacked basins can be contaminated with many submillimetric particles (range, 4.4–25.1 particles per milliliter on average, depending on basin). Cotton towels and woven gauze placed in rinsed basins resulted in a significant increase in particles (from 1.5 particles per milliliter  $\pm$  0.4 [standard deviation] to 64.4 particles per milliliter  $\pm$  4.1 and 257.1 particles per milliliter  $\pm$  11.6, respectively;  $P < .001$ ). Rinsing basins with saline significantly reduced the number of particles ( $P \leq .03$ ). Drawing saline directly from bags through intravenous lines yielded the lowest number of particles (0.1 particles per milliliter).

**Conclusion:** To decrease the risk for foreign body embolization, it is best to rinse all basins before use, draw saline and contrast agents directly from the respective bags and bottles through intravenous lines, and avoid cotton towels and woven gauze in basins and on the angiography table altogether whenever possible.

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Cerebral angiography is a common tool in the clinical routine of neurovascular centers. Because of its invasiveness, great care must be taken to prevent complications, particularly cerebral embolism (1). For instance, current standards for cerebral angiography include the continuous flushing of catheters with heparinized saline or the use of air filters (2).

Inadvertent foreign body embolization was identified as a complication of cerebral angiography in 1949, but to our knowledge, only a few studies have dealt with this subject since that time (3–7). Vinters et al (5) in 1983 and Shannon et al (6) in 2006 identified cotton fibers as an important source of emboli during diagnostic angiography. Despite these findings, few attempts have been made to approach this issue systematically and to reduce the risk of inadvertent foreign body embolization by improving the angiographic work environment (7). The focus remains on devices rather than on the angiographic environment: Medical device manufacturers are required to follow strict

regulations to ensure their devices are biocompatible and free of thromboembolic material.

However, the terms *biocompatible* and *sterile* do not necessarily imply that devices on the angiography table are free of potentially embolic material (7). For instance, depending on type and manufacturer, woven gauze may not necessarily be produced in clean rooms, but rather in ordinary factories without specific measures to reduce particles; the gauze may then be shipped, sterilized, and packed without eliminating particles that may have arisen during production or shipping. The same unpacked gauze is then put into angiography sets, which again may contaminate the entire angiography set with particles (Fig 1). Even though woven gauze and cotton fabrics have been identified as sources of inadvertent foreign body embolization, it is still common practice to place woven gauze and towels in saline basins and to draw the same saline for neuroangiographic injections. These micro- and macroscopic particles from packaging or gauze can be inadvertently introduced into

## Summary

The angiographic work environment can be contaminated with many particles; rinsing basins can reduce the number of particles.

## Key Results

- Sterilized basins in angiographic sets can be contaminated with many mainly submillimetric particles (range, 4.4–25.1 particles per milliliter on average, depending on basin).
- When placed in basins, cotton towels and woven gauze resulted in a significant increase in particles (from 1.5 particles per milliliter  $\pm$  0.4 [standard deviation] to 64.4 particles per milliliter  $\pm$  4.1 and 257.1 particles per milliliter  $\pm$  11.6, respectively;  $P < .001$ ).
- Rinsing basins with saline significantly decreased the number of particles ( $P = .03$  to  $P < .001$ , depending on basin).

the patient's vasculature and may cause serious clinical complications, such as inflammation or thrombosis (7).

The aim of this study was to find the source of particles on an angiography table and to identify measures for their reduction.

## Materials and Methods

### Experiments

A standard diagnostic angiography supply table with sterile draping and various sterile basins was prepared in a sterile field at the New England Center for Stroke Research to simulate a realistic clinical setup. For particle analysis, three types of new sterile containers were filled with saline (0.9% sodium chloride solution; Baxter): (a) large plastic bowls for storing wires or catheters, (b) small plastic cups, and (c) small metal cups, typically used for saline or contrast agents (Fig 2). All plastic containers were wrapped in fabric, as provided by the vendor that supplies our sterilized angiography sets (Kimal), and all metal cups were wrapped in plastic bags (Fig 1). These containers were chosen to address the impact of container size (small vs large surface area) and material (plastic vs metal) on particle contamination. For particle analysis, each container was filled with the typical amount of saline: 150 mL in the metal cup, 400 mL in the small plastic cup, and 1000 mL in the large plastic bowl. To analyze particles that originated from packaging and to analyze the impact of rinsing the containers with saline after unpacking, particles in each container were assessed (a) immediately after unpacking and (b) immediately after the containers were rinsed with saline ( $t_0$ ). The impact of foreign material on particle load in the containers was then investigated by analyzing the particles after placing (a) a guidewire with its sheath (0.035-inch standard angled guidewire; Terumo) as well as (b) a stack of woven gauze (Dermacea Gauze, Medtronic) and (c) a large cotton towel (Medline Industries), both often used to clean or weigh down catheters and wires, in rinsed large plastic bowls. The impact of time was also investigated by setting up all experiments (small metal cup, small plastic cup, large plastic bowl, large plastic bowl with a guidewire and its sheath, large plastic bowl with a stack of woven gauze, and large plastic bowl with a large cotton towel) and analyzing the saline after 30 minutes ( $t_{30}$ ) and 60 minutes ( $t_{60}$ ) without further manipulation but

exposed to room air in our angiography suite, which does not have any specific operating room–graded air circulation. Time points of 30 and 60 minutes were chosen to search for evidence of additional airborne particle contamination over time during short- and medium-length angiographic examinations. As a control, saline that was drawn directly from a bag using an intravenous line was analyzed (Fig 3).

### Measurements

For particle analysis, each container was filled with saline, which was then collected entirely at certain time points (described earlier). After saline collection, the fluid was sampled to measure particulates 8–1000  $\mu\text{m}$  in size by using the Coulter principle (Multisizer 4 Coulter Counter; Beckman Coulter). The number and Feret diameter of the foreign bodies were recorded, and particles smaller than 20  $\mu\text{m}$  were excluded from further analysis to reduce the impact of artifacts, such as air bubbles. The results of particulate analysis with small- and large-aperture detectors were grouped into two categories based on fragment diameter: small particles less than 200  $\mu\text{m}$  and large particles greater than 200  $\mu\text{m}$ . Every experiment was conducted three times in total using three separate sets of containers of the same type per condition, resulting in three measurements per condition and time point (eg, three large plastic containers with a cotton towel measured after 30 minutes). The large plastic containers were reused and rinsed thoroughly with more than 1 L of saline between the experiments. More than three sets were used to allow for parallel measurements. For material handling, we used powder-free latex gloves that were rinsed between each experiment. The analyzing beaker used for particle count was thoroughly rinsed after each reading to avoid contamination.

### Statistical Analysis

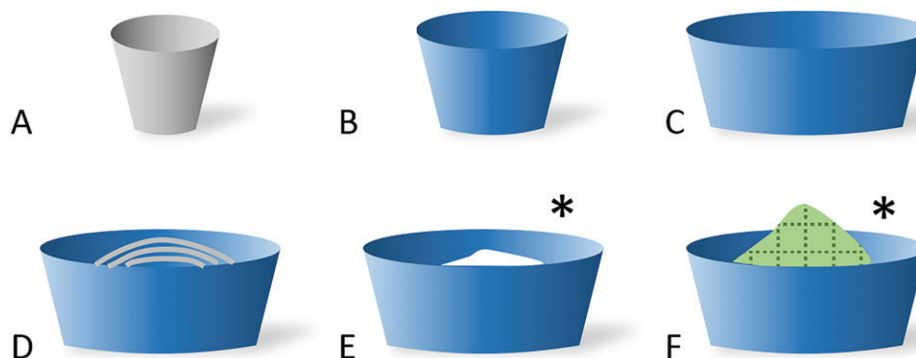
Particle sizes are indicated as the weighted average of mean diameters, because our measurement method indicates the number of particles and average sizes per measurement. Given the small number of measurements per experiment, we used Student  $t$  tests and paired  $t$  tests for comparisons and indicated particle numbers as mean  $\pm$  standard deviation, regardless of data distribution and variances (8). With the exception of the first experimental step, in which rinsing was the actual experimental intervention, our experiments were not strictly longitudinal. We used multiple containers to facilitate parallel measurements and we collected and analyzed all the fluid in each container to avoid a sampling bias. In conclusion, comparison of total particle numbers (sum of small and large particles) before and after rinsing was performed by using paired tests, and we used independent tests for the all other comparisons.  $P$  values with  $\alpha < .05$  were considered to indicate a significant difference. All statistical analyses were performed with software (SPSS, version 25; IBM).

## Results

The results are summarized in the Table and Figures 4 and 5. The vast majority of particles (99.9%, 59.5 small particles per milliliter vs 0.1 large particles per milliliter) were small ( $<200 \mu\text{m}$ ).



**Figure 1:** Photographs of, A, a metal cup in its packaging; B, an unpacked angiography set (label is blurred); and, C, a freshly unpacked angiography set with two plastic containers (arrows). D, A close-up photograph of the bottom of a plastic container shows a long fiber (thick arrow) and macroscopic particles (arrows in enlarged details with twofold omagnification).



**Figure 2:** Schematic illustration of our experimental setups. A, Small metal cup; B, small plastic cup; C, large plastic bowl; D, large plastic bowl with guidewire and its sheath; E, large plastic bowl with stack of woven gauze; F, large plastic bowl with large cotton towel. All containers were filled with saline, which was then analyzed for particles. The control experiment with saline directly drawn from its bag is not shown, but its principle can be found in Figure 3. \* Placing a stack of woven gauze and a cotton towel in the bowl resulted in a significant increase in the number of particles ( $P < .001$ ).



**Figure 3:** Schematic illustration of setup for drawing saline and contrast agent directly from their respective containers through intravenous lines. Saline bag and bottle of contrast agent are connected to three-way valves via intravenous lines. A saline three-way valve directs saline toward other three-way valves only. Turning contrast agent valve allows switching between drawing saline or contrast agent. Thus, a syringe can be filled with only saline, only a contrast agent, or a mixture of both. The number of particles was close to zero (0.1 particle per milliliter, on average) but not zero. Because we expected the saline bag to be free of particles, we hypothesized that measured particles originated from tubing or beaker.

The saline bag, which served as the control, yielded an average of 0.1 particles per milliliter when fluid was directly introduced from the bag into the analyzing beaker.

The metal cup, after unpacking, yielded a significantly higher number of particles than the control (mean, 4.4 particles per milliliter  $\pm$  1.8;  $P = .02$ ). Rinsing significantly decreased the number of particles (mean, 0.4 particles per milliliter  $\pm$  0.2;  $P = .02$ ). The number of particles after rinsing did not differ significantly from the control ( $P = .07$ ). The number of particles immediately after rinsing and after 30 minutes (mean, 0.7 particles per milliliter  $\pm$  0.8;  $P = .48$ ) as well as between 30 minutes and 60 minutes (mean, 3.2 particles per milliliter  $\pm$  3.4,  $P = .28$ ) did not differ significantly.

The plastic cup, after unpacking, yielded significantly more particles than the control (mean, 25.1 particles per milliliter  $\pm$  1.1;  $P < .001$ ) and the metal cup ( $P < .001$ ). Rinsing resulted in a significant decrease in particles in the plastic cup (mean, 2.8 particles per milliliter  $\pm$  1.4;  $P < .001$ ). The number of particles after rinsing was significantly higher than in the control ( $P = .03$ ). The number of particles immediately after rinsing and after 30 minutes (mean, 0.9 particles per milliliter  $\pm$  0.2;  $P = .08$ ) as well as between 30 minutes and 60 minutes (mean, 1.3 particles per milliliter  $\pm$  1.0;  $P = .54$ ) did not differ significantly.

The large plastic bowl, after unpacking, yielded significantly more particles than the control (mean, 21.5 particles per milliliter  $\pm$  10.2;  $P = .02$ ) and the metal cup ( $P = .046$ ) but not the plastic cup ( $P = .58$ ) after unpacking. Rinsing significantly decreased the number of particles (mean, 1.5 particles per milliliter  $\pm$  0.4;  $P = .03$ ). The number of particles after rinsing was significantly higher than in the control ( $P = .004$ ). The number of particles immediately after rinsing and after 30 minutes (mean, 3.4 particles per milliliter  $\pm$  2.3;  $P = .22$ ) as well as between 30 minutes and 60 minutes (mean, 2.5 particles per milliliter  $\pm$  1.7;  $P = .59$ ) did not differ significantly.

A large plastic bowl with a guidewire and its sheath yielded significantly more particles than a rinsed large plastic bowl (mean, 5.0 particles per milliliter  $\pm$  1.2;  $P = .01$ ). The number of particles after 30 minutes was significantly higher compared with immediately after placing the guidewire and its sheath into the bowl (mean, 7.8 particles per milliliter  $\pm$  0.6;  $P = .02$ ) and did not differ significantly between 30 minutes and 60 minutes (mean, 7.4 particles per milliliter  $\pm$  0.6;  $P = .40$ ).

A large plastic bowl with a stack of woven gauze yielded more than 100 times more particles than a rinsed large plastic bowl (mean, 257.1 particles per milliliter  $\pm$  11.6;  $P < .001$ ). The number of particles immediately after placement of the stack of woven gauze and after 30 minutes (mean, 308.5 particles per milliliter  $\pm$  36.4;  $P = .08$ ) as well as between 30 minutes and 60 minutes (mean, 315.0 particles per milliliter  $\pm$  7.3;  $P = .78$ ) did not differ significantly.

A large plastic bowl with a cotton towel yielded three times more particles than a rinsed large plastic bowl (mean, 64.4 particles/mL  $\pm$  4.1;  $P < .001$ ). The number of particles 30 minutes after rinsing was significantly higher compared with that immediately after placement of the cotton towel (mean, 146.9 particles/mL  $\pm$  10.4;  $P < .001$ ) and did not differ significantly between 30 and 60 minutes (mean, 129.7 particles/mL  $\pm$  7.9;  $P = .07$ ).

The stack of woven gauze resulted in significantly more particles than the cotton towel at any time point ( $P < .001$  at t0,  $P = .002$  at t30, and  $P < .001$  at t60).

## Discussion

Our key findings included that freshly unpacked sterile containers can be contaminated with a considerable number of mainly microscopic, and to a smaller extent, macroscopic particles and that rinsing basins with saline significantly decreased the number of particles.

Plastic containers, which were wrapped in fabric and contained gauze in their packaging, yielded more particles than

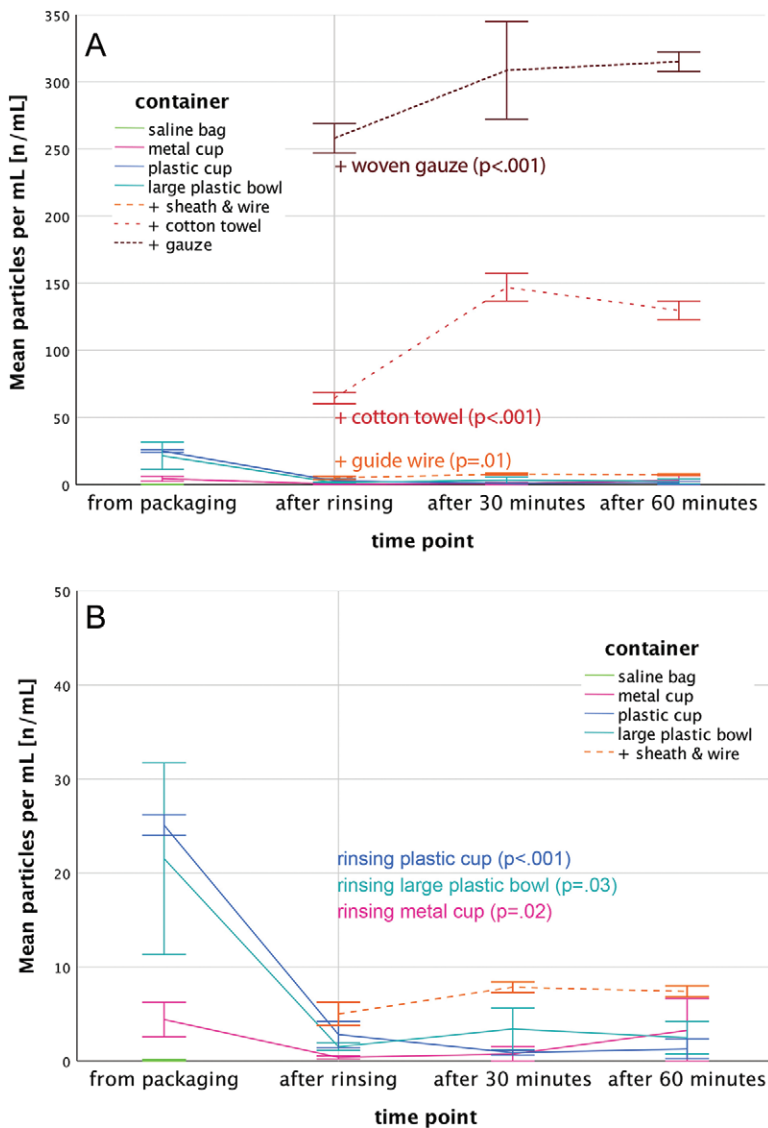
**Number of Particles per Milliliter and Average of Mean Particle Size in Various Experiments with Use of Different Materials**

Basin and Setting	No. of Small Particles (<200 $\mu\text{m}$ ) per Milliliter	No. of Large Particles ( $\geq 200 \mu\text{m}$ ) per Milliliter	Weighted Average of Mean Particle Size ( $\mu\text{m}$ )	<i>P</i> Value
Saline bag, directly through intravenous lines	0.1 $\pm$ 0.1	0 $\pm$ 0	35.4	...
<b>Metal cup</b>				
After unpacking	4.4 $\pm$ 1.8	0 $\pm$ 0	43.2	...
After unpacking vs after rinsing	...	...	...	.02
After rinsing	0.4 $\pm$ 0.2	0 $\pm$ 0	40.2	...
After rinsing vs after 30 minutes	...	...	...	.48
After 30 minutes	0.7 $\pm$ 0.8	0.01 $\pm$ 0.02	41.6	...
After 30 minutes vs after 60 minutes	...	...	...	.28
After 60 minutes	3.2 $\pm$ 3.4	0.01 $\pm$ 0.01	35.5	...
<b>Plastic cup</b>				
After unpacking	25.1 $\pm$ 1.1	0.01 $\pm$ 0.02	25.0	...
After unpacking vs after rinsing	...	...	...	<.001
After rinsing	2.8 $\pm$ 1.4	0 $\pm$ 0	32.7	...
After rinsing vs after 30 minutes	...	...	...	.08
After 30 minutes	0.9 $\pm$ 0.2	0 $\pm$ 0	43.6	...
After 30 minutes vs after 60 minutes	...	...	...	.54
After 60 minutes	1.3 $\pm$ 1.0	0 $\pm$ 0	32.4	...
<b>Large plastic bowl</b>				
After unpacking	21.5 $\pm$ 10.2	0.03 $\pm$ 0.03	41.7	...
After unpacking vs after rinsing	...	...	...	.03
After rinsing	1.5 $\pm$ 0.4	0.01 $\pm$ 0.02	43.8	...
After rinsing vs after 30 minutes	...	...	...	.22
After 30 minutes	3.4 $\pm$ 2.3	0.05 $\pm$ 0.05	40.9	...
After 30 minutes vs after 60 minutes	...	...	...	.59
After 60 minutes	2.5 $\pm$ 1.7	0 $\pm$ 0.01	31.5	...
<b>Rinsed large plastic bowl and guidewire and its sheath</b>				
Immediately after placement	5.0 $\pm$ 1.2	0.02 $\pm$ 0.02	29.7	...
Immediately after placement vs after 30 minutes	...	...	...	.02
After 30 minutes	7.8 $\pm$ 0.6	0.03 $\pm$ 0.02	27.9	...
After 30 minutes vs after 60 minutes	...	...	...	.40
After 60 minutes	7.4 $\pm$ 0.6	0.01 $\pm$ 0.02	15.4	...
<b>Rinsed large plastic bowl and woven gauze</b>				
Immediately after placement	257.1 $\pm$ 11.6	0.9 $\pm$ 0.8	34.2	...
Immediately after placement vs after 30 minutes	...	...	...	.08
After 30 minutes	308.5 $\pm$ 36.4	0.1 $\pm$ 0.03	35.2	...
After 30 minutes vs after 60 minutes	...	...	...	.78
After 60 minutes	315.0 $\pm$ 7.3	0.06 $\pm$ 0.03	28.4	...
<b>Rinsed large plastic bowl and cotton towel</b>				
Immediately after placement	64.4 $\pm$ 4.1	0 $\pm$ 0.01	28.9	...
Immediately after placement vs after 30 minutes	...	...	...	<.001
After 30 minutes	146.9 $\pm$ 10.4	0.03 $\pm$ 0.02	29.6	...
After 30 minutes vs after 60 minutes	...	...	...	.07
After 60 minutes	129.6 $\pm$ 7.0	0.02 $\pm$ 0.01	28.7	...

Note.—Except where indicated, data are mean  $\pm$  standard deviation. *P* values are for comparison of overall numbers of particles.

metal cups, which were wrapped in plastic bags. This implies that these particles originated from production and packaging. Even placement of a guidewire and its sheath in the large plastic bowl resulted in a minimal but significant increase in the number of particles. Although definitive proof is missing, our results suggest that these particles originated from the packaging of the

wire or the wire case. Notably, our sample was too small and not representative enough to draw definitive conclusions that can be generalized. Nonetheless, the consistent results with small standard deviations imply that particle contamination is not due to single outliers, but rather is a systematic issue. This is not surprising, as sterilization by means of autoclaving or radiation does not



**Figure 4:** Graphs depict the number of particles (mean  $\pm$  standard deviation). A, All experiments. B, Detailed view of A, highlights the range between 0 and 50 particles per milliliter. Connecting lines have been added for better readability, but our experiments were not strictly linear. Rinsing significantly reduced the number of particles ( $P \leq .03$ , depending on container). Placing woven gauze or a cotton towel into rinsed containers significantly increased the number of particles ( $P < .001$ ) (Table).

eliminate (dust) particles that may have gotten into the containers within the packaging.

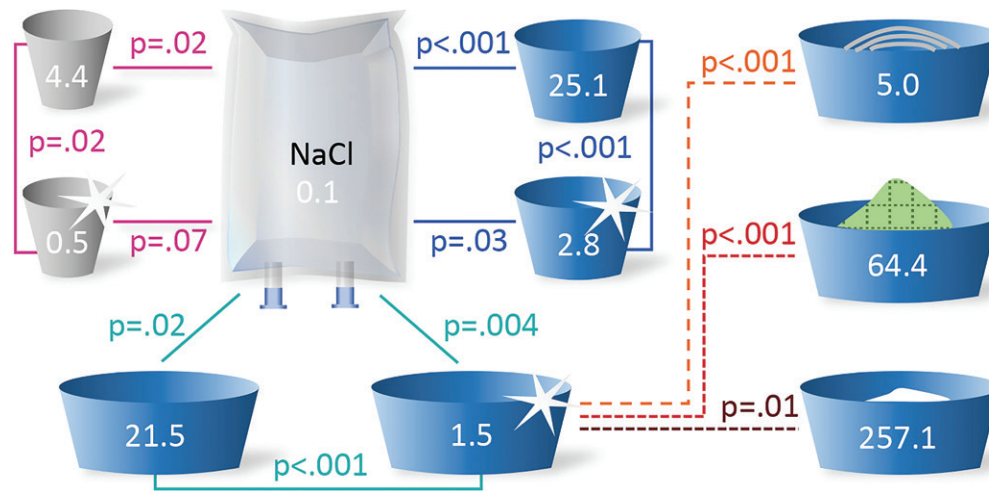
Our experiments also revealed that cotton towels and woven gauze placed in basins were major sources of foreign bodies. This is in line with results by Laird et al (7), who showed that particle contamination depended on the type of gauze, with standard woven gauze being associated with a high number of particles. Placing towels and woven gauze into basins resulted in an immediate increase in the number of particles in our experiments. Thus, the common practice of placing towels and woven gauze into basins to clean or weigh down angiographic material and to draw saline from these basins should be avoided. Instead, it is advised to draw saline and contrast material directly from the respective bags and bottles by means

of intravenous lines—a small and cost-efficient effort as an additional precaution.

The number of particles in the containers filled with saline, without any foreign material, did not differ significantly over time, implying that particles in the air do not contribute significantly to the number of particles. This was the case with all container types, which implies that neither the size of a container (small vs large surface) nor its material (plastic vs metal) has an impact on particle contamination from air. However, the fact that particles in the air do not contribute to the particle load does not mean that the number of particles during angiography does not increase over time. Yunis et al (9) showed that particles on outdated powdered latex gloves contaminate the work environment, emphasizing that many overlooked factors can contribute to setup contamination.

Although our results show that particle contamination during neuroangiography is a real issue, the question remains whether these foreign bodies are clinically relevant. Foreign body distribution within fluid containers may not be uniform. One could argue that the majority of particles are small and likely to be located on the surface of the fluids. Consequently, the overall risk for injecting foreign bodies is small if fluids are drawn from underneath the surface. Moreover, neurologic deficits due to inadvertent foreign body embolization appear to be relatively rare and unlikely, given the small size of the particles. However, manipulating saline with hands or syringes keeps the fluid and particles in motion, which increases the risk for drawing them into a syringe. Also, even though particles may be too small to result in visible infarction at 1.5- or 3.0-T MRI, even the occlusion of tiny vessels can impair neurologic outcome (10,11). Even though the vast majority of injected particles have no apparent harmful effects, a single particle may be enough to harm a patient, although this is unlikely (11). It is important to consider that only particles larger than 20  $\mu\text{m}$  were accounted for in our experiments, whereas capillaries in the human

brain have a typical diameter of 5  $\mu\text{m}$ . This means that every single particle injected into cerebral vessels is bound to remain in the brain and will lead to occlusion of intracerebral vessels. Data in the literature suggest that foreign body embolization is in fact not rare but is an underestimated complication in diagnostic and therapeutic cerebral angiography. In the largest analyses to date, Shannon et al (6) and Vinters et al (5) reported rates of foreign body embolization as high as 5% (three of 61 resected arteriovenous malformations) and 4% (three of 84 resected arteriovenous malformations), respectively. Such high numbers may appear surprising because they surpass common complication rates of approximately 1% (1). This is mainly because these numbers are derived from histologic examinations including microscopically small fibers that are



**Figure 5:** Schematic illustration of results. Number of particles indicated as mean number of particles per milliliter on containers. Saline (middle), metal cups (left), plastic cups (right), and large plastic bowls (bottom) are shown. Filled large plastic bowls on the far right with guidewire and its sheath on top, a large cotton towel in the middle, and a stack of woven gauze on the bottom. \* = rinsed containers.

not likely to result in clinically apparent complications, such as stroke or inflammation. In fact, Shannon et al (6) reported that none of the patients developed symptoms even though all the foreign material was associated with a brisk inflammatory and endothelial response. However, if something appears to be clinically inapparent, it does not mean that it is in fact irrelevant. Small infarctions attributed to clot embolization during catheterization may be the result of foreign body embolization, particularly because the vast majority of studies dealing with procedure-related infarction do not specifically investigate the source of emboli. Accordingly, inadvertent foreign material injection should always be considered in the differential diagnosis when postangiographic adverse events arise. Even though they seem to occur only very rarely, adverse events secondary to foreign body embolization have also been reported in cardiology or body interventional radiology (12,13).

Although postprocedural complications due to foreign material injection can be thought of as acute processes, some studies have shown that they can also lead to long-term sequelae. A study by Whelan et al (14) showed an 11.8% starch contamination and an 8.8% textile fiber contamination at long-term follow-up in 34 pigs after coronary artery stent placement. The investigators concluded that although contaminating factors may seem harmless, they may contribute to delayed wound healing and fibrosis and, by extension, subacute thrombosis of stented arteries. These changes might be difficult to identify and thus might be overlooked.

A major limitation of this study was the lack of in vivo experiments with histologic studies, which would validate our findings. However, given that the negative impact of foreign body embolization has already been shown in previous studies, the clinical implications of these in vitro experiments ought to be considered valid. Additional limitations were the limited number of experiments and small sample sizes. Quantitative and qualitative analyses involving all production steps in various facilities and during a longer period would be needed to reliably

identify the source of particles. Hence, it is conceivable that our initially measured contamination of containers may have been related to a specific production batch and may not be reproducible in another. However, because an experiment that involves all possible combinations of containers, fluids, and foreign material is almost impossible to conduct, it was decided to focus on the most common settings in a simple but valid in vitro experiment. Consequently, despite its limitations, our study serves as an exploratory study that generates hypotheses for future research.

In summary, the experiments imply that the angiographic work environment can be contaminated with a considerable number of particles. We therefore recommend the following steps: (a) containers on the angiography table should be carefully rinsed before being filled with saline; (b) towels and woven gauze should not be placed in saline basins; and (c) saline and contrast material should not be drawn from containers on the angiography table but directly from the respective bags and bottles using intravenous lines.

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