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The Relationship Between Gelatin Sponge Preparation Methods and the Incidence of Intrauterine Synechia Following Uterine Artery Embolization for Postpartum Hemorrhage

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Abstract

Purpose To evaluate the relationship between gelatin sponge preparation methods and the incidence of intrauterine synechia following uterine artery embolization (UAE) for postpartum hemorrhage (PPH).

Materials and Methods In a retrospective monocentric study, we used data from 20 consecutive UAE procedures (19 patients) for PPH, performed in 2007–2016, in which gelatin sponge had been used. The gelatin sponge was processed either into a slurry by pumping it back and forth about 10 times through two syringes connected to a three-way stopcock or into pledgets using a scalpel and small scissors to obtain pieces approximately 2 × 2 × 2 mm in size. Patient information was obtained from medical records, and the data were compared between patients treated with the slurry (n = 7) or pledgets (n = 13) forms. Due to the lack of follow-up data and hysterectomy after UAE, the sample size was 6 and 12 because 1 patient with 2 procedures was excluded.

Results The rate of intrauterine synechia was significantly higher in the slurry group (5/6, 83.3%) than that in the pledgets group (0/12, 0%; $P < 0.001$). In contrast, there were no significant differences in population characteristics, such as the incidence of placenta accreta, non-placental diseases, and severity of shock (DIC score, shock index, or blood loss) between the groups.

Conclusions Although non-randomization and small sample size were the two main limitations, our observations suggest that UAE using gelatin sponge slurry may be associated with a high incidence of intrauterine synechia compared to UAE using pledgets.

Keywords Uterine arterial embolization · Intrauterine synechia · Postpartum hemorrhage · Gelatin sponge preparation methods · Pledgets · Slurry

Introduction

Postpartum hemorrhage (PPH) is commonly defined as blood loss of more than 500 ml after vaginal delivery or that of more than 1000 ml after cesarean section [1]. PPH is initially controlled using conservative methods such as uterine massage and administration of uterotonic agents, after which hemostatic hysterectomy may be performed in case of persistent bleeding, resulting in the loss of fertility. In contrast to a hysterectomy, uterine artery embolization (UAE) was first reported as a treatment for PPH in 1979 [2] and not only it is highly successful with success rates of over 90% [3–5], but it also has the advantage of being a rapid and repeatable procedure that does not require

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general anesthesia. However, although UAE can potentially preserve fertility, it may lead to ischemic complications such as intrauterine synechia that are associated with reproductive problems including infertility and unsuccessful pregnancies [6].

Gelatin sponge is a frequently used embolic agent during UAE, and the two widely used methods of preparing the gelatin sponge are the fluid "slurry" form made by pumping it through two syringes attached on a three-way stopcock and the handmade "pledgets" form, which are small pieces (approximately 2 × 2 × 2 mm in size) cut using a scalpel and small scissors (Fig. 1). The slurry preparation can be rapidly produced, which may be essential in emergency cases, but this method carries a higher risk of generating smaller particles (≤ 500 μm) compared to the pledgets method [7]. Interestingly, although some reports speculate that these small-sized embolic agents (≤ 500 μm) are related to ischemic complications such as intrauterine synechia [8] and uterine necrosis [9–14], Pellerin et al. [15] have reported that the slurry form was safe and effective. Several studies have reported that UAE with the pledgets form also leads to intrauterine synechia [8, 16, 17] and uterine necrosis [18, 19]. Although these studies are descriptive, none of them directly compare the relationship between the gelatin sponge preparation methods and the incidence of ischemic

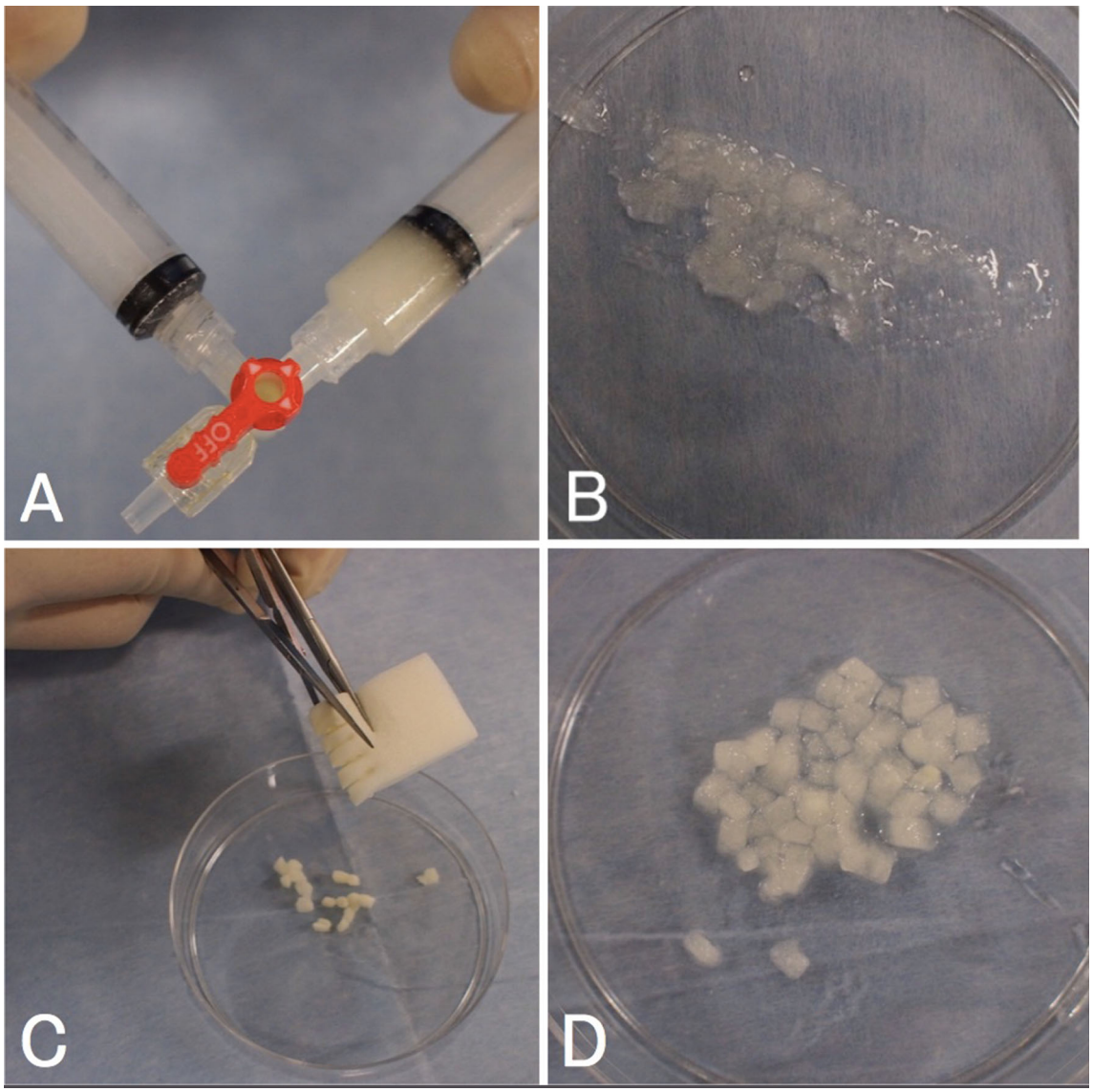

Fig. 1 Preparation of slurry (**A** and **B**) or pledgets forms (**C** and **D**). In the slurry form, the Spongel sheet was divided into a few pieces and inserted into a 2.5-ml syringe. Another syringe filled with contrast agent was connected to a three-way stopcock, and syringes were pumped back and forth about 10 times. In the pledgets form, the Spongel sheet was cut into cubes, approximately 2 × 2 × 2 mm in size, using a scalpel and small scissors

complications after UAE. Therefore, the aim of this study was to evaluate the relationship between the two gelatin sponge preparation methods and the incidence of intrauterine synechia following UAE.

Materials and Methods

Subjects

This retrospective study was approved by our institutional review board. Written informed consent was obtained from all patients included in this study. We have received no grants specifically related to this study. We first identified 36 patients who underwent 38 UAE procedures between 2007 and 2016 at our institute. Among these, 17 patients (18 procedures) were excluded because UAE was performed to correct hemorrhage associated with uterine cervical carcinoma (8 patients and 9 procedures) or bleeding after dilation and curettage (3 patients and 3 procedures). Thus, a total of 20 UAE procedures using gelatin sponge for primary and secondary PPH were performed on 19 patients (mean age, 31.3 ± 6.3 years) and were included in this study. Clinical data for the 20 procedures are listed in Table 1. One patient underwent two UAE procedures (embolized once each time with slurry and pledgets, respectively) for recurrent PPH. Medical records were reviewed to collect the following data: patient age, parity, history of cesarean section/dilatation and curettage, type of delivery, cause of PPH, vital signs, laboratory data, disseminated intravascular coagulation (DIC) score [20], and estimated blood loss.

Follow-Up Method After UAE

After UAE, obstetricians examined the size of the uterus and the thickness of the endometrium using transvaginal ultrasound (TVUS), once a month, for an average follow-up period of 21.8 ± 20.4 months. Follow-up visits were discontinued when regular menstruation was confirmed, and no abnormality was observed on TVUS. Cases with suspected intrauterine synechia on follow-up were further investigated using hysteroscopy or magnetic resonance imaging (MRI), and ovarian function was assessed using hormonal profiles of follicle stimulating hormone (FSH), luteinizing hormone (LH), and estradiol (E2) in only 5 patients. We also compared subsequent pregnancy and/or childbirth and menstrual disorder incidence after UAE between both groups. In cases that were lost to follow-up or after referral to another hospital, 3 patients were contacted by telephone to inquire about the results of secondary follow-up examinations.

Embolization Technique

All patients were initially treated using conservative methods such as uterine massage, packing gauze, and administration of oxytocin (Atonin-O, ASKA Pharmaceutical Co., Tokyo, Japan), and UAE was considered only after these treatments had failed to control hemorrhage and if the patients' vital signs were relatively stable (i.e., a systolic blood pressure of 100 mmHg or above). However, if patients' vital signs were not stable (i.e., a systolic blood pressure below 60 mmHg), a hysterectomy was performed immediately. UAE was performed by two well-experienced interventional radiologists. The first and second interventional radiologists who have 12- and 8-year experience, respectively, performed the procedures. The embolization procedure used is as follows. Right femoral artery catheterization was routinely performed under local anesthesia (1% lidocaine) using the Seldinger technique, a 5Fr. vascular sheath was inserted, and embolization was performed using standard 4–5 Fr. catheters. In all patients, the shepherd hook-shaped catheter (OKUNO No.9, Medikit, Tokyo, Japan) was used to catheterize the internal iliac and the uterine arteries. A coaxial microcatheter (2.7/2.9 Fr. Progreat, Terumo, Tokyo, Japan) was used in 15 procedures at the discretion of the radiologist performing the procedure. Absorbable gelatin sponges (Spongel, Astellas Pharma, Tokyo, Japan or Serescue, Nippon Kayaku, Tokyo, Japan) were used as embolic agents in 19 procedures and 1 procedure, respectively. Serescue is composed of the same material as Spongel. Spongel sheets (2.5 × 5 × 1 cm; width × length × thickness) or Serescue sheet (2.5 × 2.5 × 1 cm; width × length × thickness) were processed according to one of the two following methods, as shown in Fig. 1. A gelatin sponge slurry was predominantly used during the period 2007–2008. However, because obstetricians observed the occurrence of intrauterine synechia after UAE with gelatin sponge slurry in several cases, the use was discontinued from 2009, and pledgets were predominantly used during the period 2009–2016, except in emergency cases. Average amount of gelatin sponge was 2.3 ± 1.0 sheets in the slurry group and 1.6 ± 1.0 sheets in the pledgets group. Porous gelatin sponge (2-mm Gelpart, Nippon Kayaku, Tokyo, Japan) was also added at a ratio of one to four (slurry to pledgets form) in 5 procedures at the discretion of the radiologist performing the procedure. We did not use other embolic agents like a polyvinyl alcohol (PVA) that are not covered by the health insurance in Japan, or metallic coils. Embolization of the bilateral uterine arteries was performed in all surgeries except one. Embolization of the anterior divisions of the internal iliac arteries was performed in three procedures only when the uterine artery could not be catheterized quickly because of cannulation

Table 1 Clinical data of procedures undergoing UAE (n = 20)

	Slurry (n = 7)	Missing	Pledgets (n = 13)	Missing	P value
Median age [25, 75 percentile]	30 [27, 33]		33 [30, 36]		0.211
Past history					
Pregnancy history	1 (14.3%)		5 (38.4%)		0.354
Cesarean section	0 (0.0%)	1	1 (7.7%)		1.00
Induced abortion	0 (0.0%)	1	1 (7.7%)	3	1.00
Type of delivery					0.0694
Transvaginal	6 (85.7%)		8 (61.5%)		
Vacuum extraction	1 (14.3%)		0 (0.0%)		
Cesarean section	0 (0.0%)		5 (38.4%)		
Cause of PPH					0.329
Placental disease	6 (85.7%)		7 (53.8%)		
Placenta accrete	6 (85.7%)		3 (23.0%)		
Retained placenta	0 (0.0%)		4 (30.7%)		
Non-placental disease	1 (14.3%)		6 (46.1%)		
Uncontrolled hemorrhage after CS	0 (0.0%)		4 (30.8%)		
Uterine atony	0 (0.0%)		2 (15.3%)		
Uterine inversion	1 (14.3%)		0 (0.0%)		
Vital signs					
Systolic blood pressure (mmHg)	91.5 [83.3, 120]	1	92.0 [84.0, 105.0]		1.00
Pulse rate (beats/min)	113 [92, 139]	1	106 [94, 126]		0.579
Shock index	1.34 [0.80, 1.72]	1	1.23 [0.91, 1.29]		0.639
Laboratory data					
Hemoglobin (g/dl)	8.2 [6.3, 8.8]		6.7 [5.8, 8.5]		0.938
Hematocrit (%)	24.2 [19.4, 26.8]		20.7 [17.9, 25.8]		0.938
Platelet ($\times 10^3$/mm^3)	155 [121, 225]		138 [76, 197]		0.643
Creatinine (mg/dl)	0.53 [0.51, 0.58]		0.51 [0.43, 0.55]		0.275
FDP (μg/ml)	8.00 [5.95, 11.4]		22.8 [4.80, 42.9]		0.393
Antithrombin III (%)	69 [42, 73]	1	68 [45, 80]		0.639
DIC score	4 [3, 7]		6 [4, 7]		0.536
Median estimated blood loss (ml)	2600 [1285, 5400]		2965 [2219, 3567]	1	0.536

UAE uterine artery embolization, *CS* cesarean section, *DIC* disseminated intravascular coagulation, *FDP* fibrin and fibrinogen degradation product

difficulties or lack of adequate skill. Embolization was stopped with the disappearance of placental staining and extravasation. If these signs were not visible, embolization was terminated only after angiographic documentation of minimal or absent antegrade flow into the uterine arteries. At the end of the procedure, an abdominal and pelvic aortogram was performed using a pigtail catheter placed at the level of the renal arteries to verify the absence of hemorrhage from other arteries such as the ovarian artery.

Statistical Analysis

All statistical analyses were performed using the SPSS 22.0 software package (IBM Corp., Armonk, NY). The relationship between gelatin sponge preparation methods and each patient parameter was evaluated using the Fisher's exact test and the Mann–Whitney U test. A two-sided P value of less than 0.05 was considered statistically significant.

Results

Of the 20 procedures included in our study, 7 were UAE with slurry and 13 were with the pledgets form; thus, procedures were classified into slurry or pledgets groups, respectively. No perioperative complications occurred in any of the procedures. Information on procedural parameters and complications is provided in Table 2. The flowchart used for follow-up on intrauterine synechia after

Table 2 Data on procedural parameters, subsequent pregnancy/childbirth, and complications

	Slurry (n = 7)	Missing	Pledgets (n = 13)	Missing	P value
Details of UAE					
Bilateral uterine arteries	7 (100%)		9 (69.2%)		0.249
Unilateral uterine artery	0		1 (7.6%)		
Bilateral beyond uterine artery	0		2 (15.3%)		
Unilateral beyond uterine artery and unilateral uterine artery	0		1 (7.6%)		
Amount of gelatin sponge (sheets)	2.0 [1.8, 2.8]	4	1.5 [0.75, 2.3]	7	0.381
Microcatheter use	3 (42.9%)		12 (92.3%)		0.0307
Gelpart use	1 (14.3%)	1	4 (30.7%)	4	0.613
Procedure time (min)	108 [49.0, 136]		99.0 [93.0, 137]		0.485
Period of hospital stay (days)	10 [8.5, 13]		8.0 [5.0, 12]		0.393
Subsequent pregnancy/childbirth					
Pregnancy	2 (33.3%)		3 (33.3%)		1.00
Childbirth	2 (33.3%)		2 (22.2%)		1.00
Late complication					
Intrauterine synechia	5 (83.3%)	1	0 (0.0%)	1	< 0.001
Reason for the visit	5				
Amenorrhea	2				
Regular visits	1				
Recommended for examine	2				
How to diagnosis	4				
Hysteroscopy	1				
MRI	5 (83.3%)				
Menstrual disorder					
Amenorrhea	2		2 (16.7%)		0.0128
Hypomenorrhea	2		1		
Menorrhagia	0		1		
Oligomenorrhea	1		0		

UAE uterine artery embolization, *MRI* magnetic resonance imaging

UAE is shown in Fig. 2. All 20 UAE procedures achieved hemorrhage control on angiographic and gynecological examination at least once, although one patient in the pledgets group needed a hysterectomy owing to recurrent hemorrhage. Data from one procedure in the slurry group were excluded due to lack of follow-up data. Thus, final sample sizes were 6 and 12 patients, respectively, as 1 patient with 2 procedures was excluded.

Primary follow-up using TVUS was conducted once a month until regular menstruation was confirmed in 13 patients, 2 from the slurry group and 11 from the pledgets group. TVUS was not performed in 5 of the 18 patients during primary follow-up because they either dropped out early or underwent only short-term follow-up; such patients underwent secondary follow-up. Finally, 5 patients in the slurry group and 1 patient in the pledgets group were suspected to be suffering from intrauterine synechia based on TVUS findings; a hysteroscopy was performed in 5 patients, and 1 patient underwent MRI on request. Thus, 5/18 (27.8%) patients had intrauterine synechia (Fig. 3). Further, 3 out of 5 patients with intrauterine synechia underwent hormonal profile assessment and were found to have normal ovarian function. The average period between UAE and the diagnosis of intrauterine synechia was 30.8 ± 11.2 months. Intrauterine synechia after UAE in the slurry group occurred in 5 patients (5/6; 83.3%), whereas there was no incidence of intrauterine synechia in the pledgets group (0%); the incidence of intrauterine synechia between the two preparation methods was significantly different ($P < 0.001$). Except for microcatheter use ($P = 0.0307$), no other patient or procedure parameters were significantly different between the groups (Table 2). In our study, menstrual disorders after UAE occurred in 5 patients in the slurry group (5/6; 83.3%) and in 2 patients in the pledgets group (2/12; 16.7%), respectively. Significant differences were observed between the groups in terms of menstrual disorders ($P = 0.0128$; Table 2). Two patients in the slurry group had two pregnancies with two term

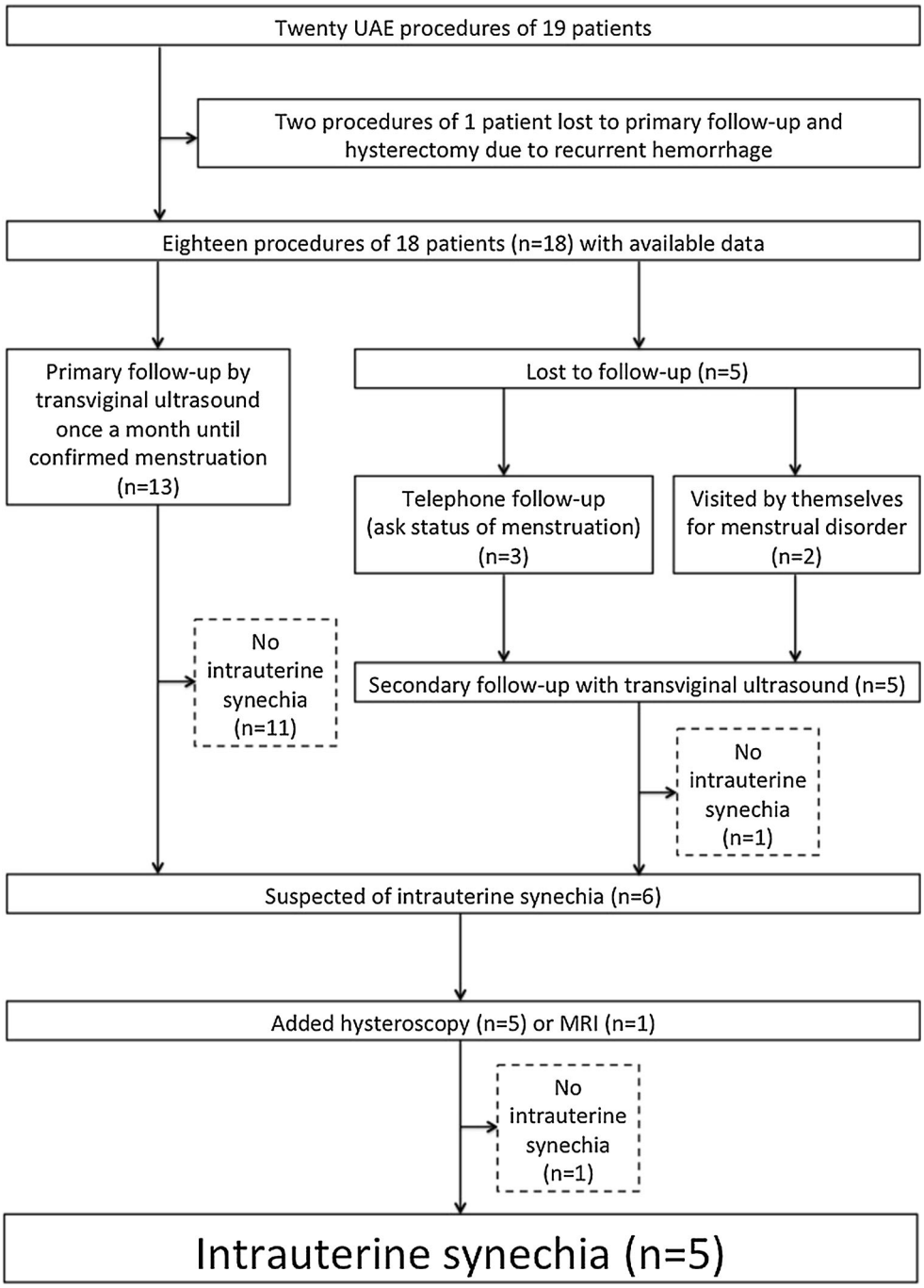

Fig. 2 Flowchart of follow-up for intrauterine synechia after uterine arterial embolization

deliveries, and three patients had four pregnancies in the pledgets group with two term deliveries, one ectopic pregnancy, and one miscarriage (Table 2).

Discussion

The relationship between gelatin sponge preparation methods and the incidence of late complications such as intrauterine synechia remains unknown. To the best of our knowledge, no studies have directly compared the two preparation methods. Thus, the results of our study, which demonstrate that the incidence of intrauterine synechia after UAE, leads to reproductive problems including infertility and unsuccessful pregnancies, is significantly higher if the slurry form is used, are significant. The other procedural parameters (details of UAE and Gelpart use, except for microcatheter use) and all patient characteristics (median age, past history, type of delivery, cause of PPH, vital signs, laboratory data, DIC score, and median

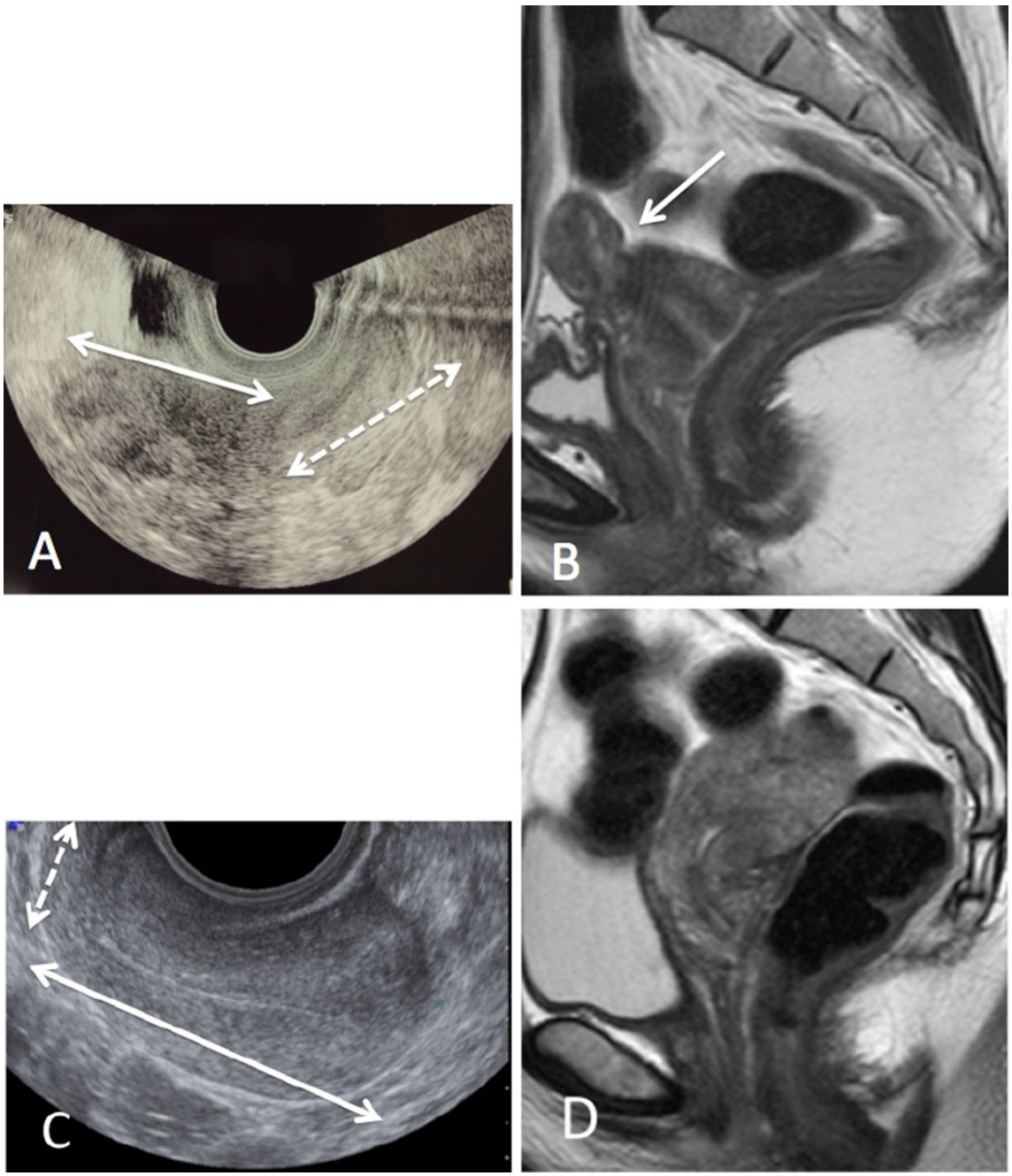

Fig. 3 Evaluation of intrauterine synechia: **A**, **B** 31-year-old female underwent uterine arterial embolization using slurry form (Spongel) for placenta accreta. **A** Two years later, transvaginal ultrasonography shows that uterine body (solid lines) had atrophied to about the same size as the uterine cervix (dotted lines). **B** T2-weighted image (sagittal view) after two years shows uterine atrophy and adhesions within the uterine cavity (arrow). **C**, **D** 31-year-old female underwent uterine arterial embolization using pledgets form (Spongel) for retained placenta. **C** Seven months later, transvaginal ultrasonography shows that the size of uterine body (solid lines) is obviously much larger than the uterine cervix (dotted lines). **D** T2-weighted image (sagittal view) after two months shows normal appearance

estimated blood loss) were not significantly different between the two groups.

Previous reports have suggested that the small size of embolic agents is related to ischemic complications such as intrauterine synechia and uterine necrosis, even though the embolic agents used differ among these reports. Uterine necrosis after embolization with PVA particles (diameters of 45–150 μm [12], 150–250 and 300–600 μm [13], and 200–500 μm [14]) has been reported. Gelatin sponge has also been frequently used as an embolic agent in UAE, and

there are several reports on the incidence of intrauterine synechia [8, 16, 17] and uterine necrosis [9–11, 18, 19] after the use of gelatin sponge for embolization. These include pledgets [8, 16–19], gelatin sponge powder [8], gelatin sponge powder with pledgets [9], slurry with or without pledgets [10], and slurry with or without coils and PVA (500–700 μm) [11]. However, no studies have directly compared the relationship between the type of gelatin sponge used for embolization and the incidence of ischemic complications.

Coulange et al. [21] suggested complete embolization as one of the mechanisms to explain the onset of uterine necrosis, wherein the use of the slurry form that is too fine and too emulsified leads to these fine particles traveling to distal vessels and reaching the collateral vessels, including the utero-ovarian and the cervico-vaginal arteries, and blocking flow through them as well. Pelage et al. [22] recommended the use of relatively large absorbable gelatin sponge particles (> 1 mm) to prevent occlusion of collateral flow in the uterus. We speculate that in comparison with the pledgets form, the slurry form, which has particles of size ≤ 500 μm [7], might compromise collateral supply to the uterus and, thereby, cause intrauterine synechia.

We compared the rates of incidence for intrauterine synechia with embolic agent used from published studies (Table 3) and found that the rate of intrauterine synechia reported here (27.8%) is much higher compared with that reported in other studies. However, after categorization according to embolic agent size, we found that the rate of intrauterine synechia incidence was comparable between this study and that of Gaia et al. [8], implying that the slurry form may be a crucial factor that affects intrauterine synechia incidence.

Ischemic complications after embolization using small-sized embolic agents have also been reported in conditions other than UAE. An experimental study by Sonomura et al. [23] reported that canine hepatic artery embolization using Gelfoam powder of sizes < 200 μm and 200–500 μm induced bile duct necrosis and that powder of size < 200 μm caused pancreatic necrosis, while gelatin sponge particles of size > 500 μm did not cause any complications. In human clinical cases, bile duct necrosis [24] and gallbladder infarction [25] have been reportedly caused by gelatin powder and Gelfoam powder use, apart from spinal cord infarction [26, 27] and cerebral infarction [28, 29] after bronchial artery embolization using PVA (size, 300–500 μm) [26], microspheres (300–500 μm and 500–700 μm) [28], and the slurry form of gelatin [27, 29].

There are two main limitations to our study. First, true randomization between the slurry and the pledgets group was not possible because these groups were formed at different time points. Next, the small sample size did not permit for multivariate analyses. Although the preparation method of gelatin sponge was the only significant

Table 3 Comparison of the incidence of intrauterine synechia after uterine artery embolization among published studies

	Success rate of UAE (%)	Total rate of intrauterine synechia (%)	Embolic agent/brand (rate of intrauterine synechia)				
			Small sized (< 500 μm)	Medium sized (500–2000 μm)		Others	
Gaia et al. [8][a]	111/113 (98.1%)	6/107 (5.6%)	Gelatin powder/ Curaspon (2/3, 66.7%)	Pledgets form/ Curaspon (3 patients)	Inert microparticles (700–1200 μm)/ Bland is not reported (1 patient)		
Fiori et al. [16]	54/55 (98.2%)	1/33 (3.0%)		Pledgets form/Bland is not reported (1/33, 3.0%)			
Sentilhes et al. [17][b]	93/100 (93.0%)	8/68 (11.8%)		Pledgets form/Gelfoam (5/48, 10.4%)		[c]Inert microparticles/ embosphere (4/39, 10.3%)	Coils/fibered steel (cook) and fibered platinum (target therapeutics) (1/11, 9.1%)
Our study	19/20 (95.0%)	5/18 (27.8%)	Slurry form/ Spongel (5/6, 83.3%)	Pledgets form/Spongel and Serescue (0/12, 0.0%)			

[a]The percentage of intrauterine synechia in the pledgets form and inert microparticles was not reported

[b]Total percentages exceed 100 because different embolic agents were used for the same woman

[c]The size of embosphere was not reported

difference in our data set, cesarean section, induced abortion [6], and placental accreta [17] are also risk factors for intrauterine synechia. Accordingly, these parameters may contain bias. Furthermore, we could not increase sample size because the data show that the slurry form had an obviously higher complication rate. Second, all patients did not undergo hysteroscopy for intrauterine synechia as the TVUS is a noninvasive and cost-effective imaging modality. Shalev et al. [30] have reported a sensitivity of 80% for TVUS in the diagnosis of intrauterine synechia. Therefore, TVUS may be useful as screening test for intrauterine synechia. Third, microcatheter use demonstrated a significant difference between the slurry and the pledgets group in our study. Katsumori et al. [7] have reported no significant difference in particle size distribution before and after passage through a microcatheter for the pledgets form, and, based on our results, we also speculate that microcatheter use was less relevant with respect to the incidence of intrauterine synechia. Finally, as we only evaluated uterine synechia as a marker of fertility, further studies are needed to evaluate fertility, as fertility is related to many other factors such as aging and ovarian reserve.

In conclusion, UAE performed using the slurry form may be associated with a higher incidence of intrauterine synechia compared to the pledgets form. Our observations suggest that the slurry form may need to be avoided when performing UAE.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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