The Platinum Ball A New Embolic Material

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Summary

Polyvinyl alcohol (PVA) particles have been widely used as an embolic material for endovascular treatment of vascular enriched tumors, especially for meningiomas. However, there are disadvantages with their use due to the fact that they are radiolucent, with a very irregular shape and a tendency for self-adhesion. With alternative organic liquids there is also a possibility of toxicity.

We have therefore developed a new embolic material, platinum balls, which feature radio-opacity, a relatively well-defined oval shape, multi-pitted and indented surfaces on electron microscopy and a lower tendency for self-adhesion. Based on positive findings in experimental studies, embolization of meningiomas was conducted with platinum balls in 27 patients and the results compared with findings for a matched group previously treated with PVA particles. Total volume of blood transfused during surgery was comparable in the two cases, although a tendency for lower values was noted with the platinum balls, and outcome was equally positive.

Introduction

Polyvinyl alcohol (PVA) particles¹⁻⁹ and liquid materials such as N-butyl cyanoacrylate (NB-CA)¹⁰⁻¹⁵ EVAL/DMSO¹⁶, Onyx¹⁷, and EVAL/E-

thanol¹⁸ are widely used as embolic materials for treatment of arteriovenous malformations or tumors. However, with such embolic materials made from organic molecules, we need to take into account possible toxicity. We have developed "the platinum ball", which is made from almost pure (99.9%) platinum as an inorganic, non-degenerative and harmless material for human use. After prior experimental studies, it was employed for embolization of meningiomas and the results compared to findings with the previously applied PVA particles in our institution.

Material and Methods

Animal Experimental Studies

The diameters of the "platinum balls" ranged from 150 to 250 μ m (average: 200 μ m), each being oval, and porous with irregular surfaces under electron microscopy (see Electron Microscope: figure 1). Mongrel dogs (13-20 kg) were catheterized with a 6Fr. Envoy guiding catheter (Cordis-Johnson & Johnson, Miami Lakes, FL) under general anesthesia and a Fast-Tracker-18MX (Boston Scientific, Fremont, CA) was manipulated into the right internal carotid arteries over a Dacher-14 (Boston Scientific), or flow-guided Magic STD catheter (Balt, Montmorency, France). Platinum balls and a contrast medium mixture were prepared

Figure 1 A) Electron micrograph (x 500) showing a "Platinum ball" with a roughly oval shape and irregular surfaces. B) Electron micrograph (x 1500) showing a "Platinum ball" with multiple crevices and holes.

and well mixed, immediately introduced into a 1ml syringe and injected through the microcatheter under digital subtraction angiography. Brains were investigated for spread after fixation in formalin for 48 hours.

Clinical Studies

Until July 1998, polyvinyl alcohol particles ranging from 150-250 microns in diameter had been used as the embolic material for meningiomas. Since August 1999, platinum balls ranging from 150-250 microns have been employed in their place. A total of 27 consecutive meningioma cases were embolized using "platinum balls" after providing informed consent. Their mean age was 53.3 years.

The locations of the meningiomas were in the convexity in eight, the skull base in twelve, the parasagittal area in six, and the falx in one. A 6F sheath was inserted into the femoral artery followed by a 6F Envoy guiding catheter introduced into external carotid system.

Tumor vessels were catheterized superselectively with a microcatheter (Excelsior SL 10, Excel 14, Excelsior-18, Boston Scientific), under local anesthesia. After provocative testing

using xylocaine 30 mg in each feeding artery, embolization using platinum balls was performed.

In all cases, histo-pathological examination was performed. In addition 67 cases of meningiomas previously embolized by PVA particles were retrospectively examined and 27 were selected who are well matched with the patients receiving platinum balls with regard to age, sex, maximum lesion size, location and period until surgery (table 1). We then compared differences in embolization outcome between the two groups with regard to total volume of blood which needed to be transfused during surgery.

Results

Animal Experimental Study

Platinum balls became deposited in containers on standing, but after stirring well in the contrast medium could be smoothly injected through Magic STD catheters with a small inner diameter of 0.0125 inch. With small amounts of platinum balls, obstruction of microcatheters was not encountered. Pathological findings showed occlusion of similar sized arterioles by platinum balls (figure 2A).

Figure 2 A) Patho-physiological finding showing an arteriole ($150\mu\text{ m}$) occluded by standard sized platinum balls. B) Patho-physiological findings for a human meningioma case ten days after embolization showing an arteriole ($150\mu\text{ m}$) occluded by platinum balls with no giant cell reaction.

Clinical Study

In all 27 cases, intra-tumoral embolization using platinum balls could be successfully performed without complications (figure 3). Post-procedural skull XP (figure 4) and plain CT scans (figure 5) demonstrated sand like enhancement of whole meningiomas resulting from wide spreading of platinum balls. Pathological findings were essentially the same as in the animal experimental study (figure 2B), the vascular beds of tumors being occluded with platinum balls. Thrombus formation was recognized around platinum balls, but giant cell reactions were not present, either in intravascular spaces or vascular walls, regardless of the length after embolization. Platinum ball group and PVA group were well matched in regard to age, sex, size of tumor, duration until surgery after embolization (table 1).

In the 27 matched PVA group, there were no significant differences in lesion location and statistical analysis revealed no significant difference in total volume of blood transfused during surgery, although this tended to be lower in the platinum ball group.

Discussion

Vascular enriched tumors supplied by external carotid arteries are appropriate targets for treatment by embolization. For this purpose, particle emboli are more common than liquid emboli because of the spread characteristics and PVA particles have been widely adopted for tumor embolization since their clinical introduction in 1952. Porstmann et Al.⁶ introduced PVA as suitable for embolic material for human organ because of biologically inert. In different from Gelfoam

Figure 3 Left external carotid angiograms before (A) and after (B) embolization

powder, PVA is expected for progressive thrombosis because of non-absorbable material. Long-term obstruction of vessels by PVA has been reported to be from a few months⁹ to several years¹⁷. PVA will establish progressive

thrombosis and fibrosis³. Some authors¹ reported to be a strong inflammation, vascular degeneration and necrosis induced by PVA such as silk, but the other many authors^{6,7} reported histo-pathological findings in subacute

Figure 4 Plain skull XP scan showing scattered platinum balls well visualized.

Figure 5 Plain computed tomogram showing sand like enhancement of an entire meningioma resulting from wide-spread distribution of platinum balls.

stage showing a loss of inner layer until internal elastic membrane and infiltration of inflammation cells into the middle layer and mild foreign body reaction around PVA particle. Although PVA is easy to handle, its toxicity is undeniable. Hence irregular shape resulted in high coefficient of friction^{8,9}, PVA has the difficulty to reach to target vessels with matched size, which may bring an incomplete occlusion. Furthermore, catheter may become to stiff resulting from its coherent tendency. Radio-lucency is also disadvantage of PVA particles.

Recently, Konishi et Al.¹⁹ reported mixture of biosphere (BS) particle (made of acrylic copolymer; Bio Sphere Medical, MA) with tantalum powder. BS particle has shown to be an ideal embolic material because it is easy to handle, non-absorbable and spherical shape, but lack of radio-opacity. They recommend to use it mixed with tantalum powder.

We developed platinum ball, which is well defined under fluoroscopy because of an excellent radio-opacity and 99.9% platinum has been already established as a safety inert material for human organ. Oval shape with less coherent tendency enables an easy injection from small microcatheter. Oval shape of the platinum ball different from PVA can reach to tumor vessels with matched size. On the other hand, platinum ball has multi-hole surface on an electron microscope, which may make pro-

gressive thrombosis. Patho-physiological findings showed few foreign body reaction around platinum ball, which shows a harmless for human body. Excellent radio-opacity which well defined under fluoroscopy is also excellent as an embolic material.

The size of platinum ball was decided between 150 and 250 micron because small size less than 100 micron may occlude vasa nervosum. Over 50 cases with meningiomas for pre-operative embolization used by platinum ball, we confirmed its usefulness as embolic material, but long-term follow-up after embolization and further cases will be needed to define it.

Conclusions

Platinum balls have advantages compared with PVA particles, being less toxic because of their pure platinum nature and eliciting only limited foreign body reactions on histopathological findings. Furthermore they are radio-opaque with low self-adhesion, which facilitates injection and definition by real time fluoroscopy. The oval morphology and porosity allow occlusion of vessels with progressive thrombosis and platinum balls here were found to reduce intra-operative bleeding in vascular enriched meningiomas to the same if not a greater extent than PVA particles. To further define utility, additional cases and longer term follow-up are now needed.

Table 1 Summary of details for the two groups of matched patients treated with platinum balls and PVA particles.

	Platinum Ball	PVA
Number	27	27
Age (mean±SD)	53.3±8.0	53.5±7.7
Sex (male: female)	12:15	12:15
Size of tumor (mean±SD, cm ³)	67.5±53.2	63.7±66.8
Location		
– Convexity	8	9
– Falx	1	1
– Parasagittal	6	7
– Skull base	12	10
– Tentorial	0	0
Duration from emb. to surg.	9.8±13.9	9.3±13.5
Vol. for blood transfusion (ml)	392±604	941±1565

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