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ORIGINAL RESEARCH

Safety and Efficacy of Polyvinyl Alcohol Granules in Treating Type II and III Coronary Artery Perforation

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Objective: The success rate of polyvinyl alcohol (PAV) granules in the treatment of coronary artery perforation (CAP) was investigated to determine their safety and efficacy.

Methods: Forty patients with II and III coronary artery perforations during percutaneous coronary intervention were divided into two groups. One group was only occluded by low pressure balloons (balloon occlusion group), and the other one was occluded with PVA granules during low-pressure balloon dilatation (PVA granules embolization group). Retrospective analysis of clinical data was used to compare the success rate and safety of various methods.

Results: The balloon embolization group had 16 cases (88.9%) of coronary perforation type II and 2 cases (11.1%) of coronary perforation type III. The PVA granules embolization group had 20 cases (90.9%) of coronary perforation type II and 2 cases (9.1%) of coronary perforation type III. Of the 18 patients in the balloon occlusion group, 13 were immediately occluded, with a success rate of 72.2%, while the remaining 5 required embolization or covered stents. 6 of the 18 patients had pericardial effusion, and two of them underwent pericardiocentesis. Among the 22 patients in the PVA granules embolization group, 21 were immediately blocked, with a 95.5% success rate, while the other was occluded by a covered stent. The results revealed that the success rate of transcatheter closure in the PVA granules embolization group was significantly higher than that in the balloon embolization group, and the risk of pericardial effusion and pericardiocentesis in the PVA granules embolization group was significantly lower than that in the balloon embolization group.

Conclusion: In comparison to the simple use of low-pressure balloon occlusion, the use of PAV granules in the treatment of II, III coronary artery perforation has a high success rate and safety, and is a viable method for treating coronary artery perforation.

Keywords: percutaneous coronary intervention, coronary artery perforation, polyvinyl alcohol granules

Introduction

Coronary artery perforation is a rare but severe complication of percutaneous coronary intervention. CAP can occur in blood vessels of different sizes, mostly in branches and endings. It can be obvious blood leakage or local bleeding, or small leaks that are not easily detected in peripheral blood vessels. The specific manifestations include coronary ventricular leakage, pericardial tamponade, coronary arteriovenous leakage, etc. In severe cases, coronary artery perforation can cause contrast medium or blood to leak out of the blood vessel through the tear, resulting in pericardial effusion and pericardial tamponade, which may necessitate emergency pericardiocentesis or surgery. According to a large number of literature reports, the incidence of coronary artery perforation ranges between 0.1% and 3%.[1,2] Especially with the emergence of new instruments and more patients with chronic total occlusion (CTO) undergoing PCI surgery, the incidence of coronary artery perforation has significantly increased, up to 27.6%.[3] The high-risk factors for CAP include women, hypertension, and advanced age, history of coronary artery bypass grafting, and complex coronary artery disease Changes (such as chronic complete occlusion, bifurcation, severe tortuosity, etc). Angular or calcified lesions, etc. The

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cause of CAP is the guide wire Perforation (commonly seen through lesions using superhard, hydrophilic, and super smooth guide wires) When mistakenly entering a false lumen or penetrating small blood vessel branches, plaque circumcision surgery Balloon or stent models are too large, there are too many stents, etc. To reduce the risk of coronary artery perforation, careful preoperative evaluation and gentle use of intraoperative instruments are critical. After a coronary artery perforation, the surgeon's calm and composed response is even more important. Currently, the methods for treating coronary artery perforation are as follows: suspending or correcting anticoagulation therapy, balloon dilatation similar to vascular diameter for a long time and at low pressure, and transfusion of gelatin sponge, PVA granules, spring coils, and covered stents via microcatheters. Some patients still require emergency pericardiocentesis and surgery to repair the rupture. The purpose of this study was to evaluate the success rate and safety of PAV granules embolization in patients with II and III coronary artery perforation.

Methods

Study Population

Between June 2012 and June 2022, 40 patients with coronary heart disease who had coronary artery perforation during PCI were collected from the Department of Cardiology at Nanjing Hospital, which is affiliated with Nanjing Medical University. Of the 40 patients, 26 were male and 14 were female, with an average age of 56.7 ±9.8 years.

Among the 40 patients, there were 22 cases of unstable angina pectoris, 13 cases of stable angina pectoris, and 5 cases of ischemic cardiomyopathy, as well as 23 cases of hypertension, 12 cases of diabetes, 16 cases of hyperlipidemia, 10 cases of cerebral infarction, 5 cases of peripheral vascular disease, and 18 cases of overweight, 14 cases of smoking, 8 cases of alcohol consumption. Coronary perforation occurred in the anterior descending branch (n=19), right coronary artery (n=14), and circumflex branch (n=7). In 36 cases, perforation was caused by a guide wire, while in 6 cases, balloon dilatation was the cause. According to the standard sign of Ellis,[4] coronary perforation can be classified into three types: (I) Type I: Under X-ray, the contrast medium revealed a mushroom or ulcer protruding outside the blood vessel, confined to the coronary artery adventitia with no leakage. (II) Type II: Under X-ray, the contrast medium could be seen leaking into the myocardium or pericardium, but no jet leakage was observed. (III): Type III: X-rays show that the contrast medium leaked into the pericardium, pericardium, or coronary vein from the coronary artery rupture (diameter > 1mm). There are two subtypes of type III. Type III A: contrast medium leaks into the pericardium, while type III B: contrast medium leaks into the Cardiac ventricular cavity or other parts. Inclusion criteria: Type II and III CAP occurred during PCI and Patients treated with PVA granules embolization. Exclusion criteria: Type I CAP or not collected CAP patients treated with PVA.

Operation Method

Before surgery, all patients were given oral aspirin 100mg/d, clopidogrel 75mg/d or ticagrelor 180mg/d, and Atto vastatin 20mg/d. They were also given β-blockers, antihypertensive medicines, and hypoglycemic drugs according on their clinical circumstances. One day before the operation, an oral loading dose of 300mg aspirin, 300mg clopidogrel, or 180mg ticagrelor was administered. Heparin sodium 100~120U/kg was injected intravenously during the operation, and the activated clotting time was maintained at 250 ~ 350s.

All patients underwent routine coronary angiography through the right radial artery, and percutaneous coronary intervention was performed once the indication for interventional therapy was met. If a coronary perforation occurs while using an interventional guide wire or balloon dilatation, different treatments will be administered based on the type of coronary perforation. If a coronary perforation occurs while using an interventional guide wire or balloon dilatation, different treatments will be administered based on the type of coronary perforation. The patients with Ellis type I were admitted to the CHD intensive care unit for observation and continuous bedside monitoring of cardiac B-ultrasounds. If there were signs of pericardial tamponade, pericardial puncture and drainage were performed quickly using bedside B-ultrasound or X-ray fluoroscopy of the catheterization chamber. In patients with an Ellis classification of II or III, a balloon proportional to the diameter of the vessel was placed at the perforation of the coronary artery with 6–8atm for 10–15 minutes. During the balloon emptying process, another guide wire is prepared to direct the microcatheter (Terumo

Corporation, Japan) to the coronary perforation. Two bottles of 100mg PAV-150 (The diameter of polyvinyl alcohol granules is 100–350um) granules and PAV-350 (The diameter of polyvinyl alcohol granules is 330–560um) granules were simultaneously added to a 10mL suspension of contrast agent (The concentration of contrast medium is 30–40%) and normal saline. The suspension was thoroughly mixed with a 2mL screw syringe, and 1–2mL of it was extracted and slowly injected through a microcatheter. Simultaneously, the proximal balloon of the perforated coronary artery is expanded to keep PAV granules from returning to the proximal vessels. Finally, angiography determines the blocking effect of PAV granules. If the result is not satisfactory, it can be repeated several times. Patient's hemodynamic changes and whether pericardial tamponade occurs are observed. If the hemodynamic changes are obvious, pericardiocentesis should be performed immediately (Figure 1).

Postoperative Treatment and Follow-Up

All patients received main and secondary preventive medication for coronary heart disease, including daily oral administration of aspirin 100mg, clopidogrel 75mg, or ticagrelor 180mg, as well as statins and β-receptor blockers. The patients were followed for one month, three months, six months, and twelve months, respectively. The follow-up included target vessel revascularization, as well as the incidence of MACE and all-cause mortality.

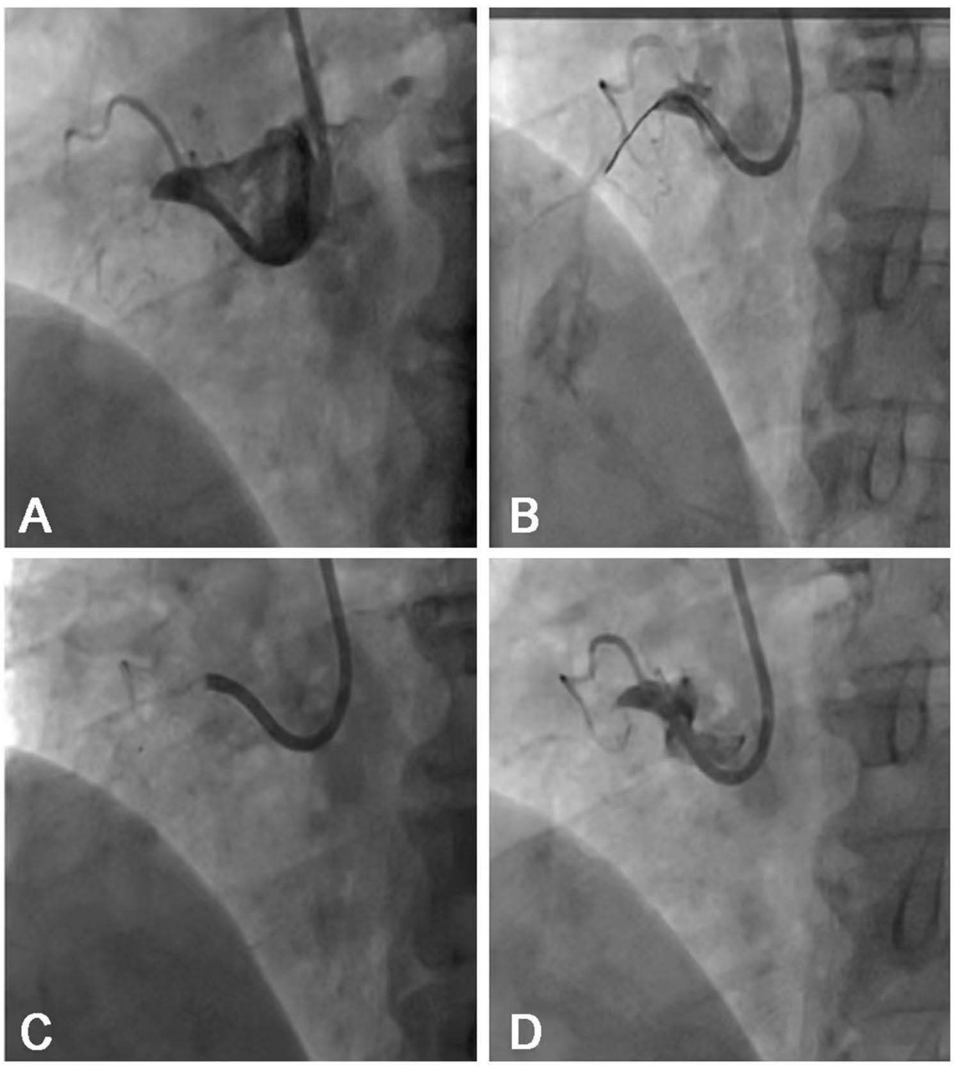

Figure 1 Coronary angiography. (**A**) Coronary angiography demonstrated complete occlusion of the proximal end of the RCA; (**B**) Coronary angiography showed a type II coronary perforation; (**C**) The red arrow shows PAV granules injected into the microcatheter for embolization; (**D**) Coronary angiography reexamination revealed that the PAV granules were successfully blocked.

Statistical Analysis

The data were analysed using SPSS22.0 statistical software. Data is expressed as $\bar{x} \pm s$ for measurements, *t*-tests for group comparisons, percentages for counting, and χ^2 tests for group comparisons. P value < 0.05 was considered statistically significant.

Results

Of the forty patients, twenty-six (65.0%) were men and fourteen (35.0%) were women. There were twelve men in the balloon embolization group and fourteen in the PVA granules embolization group. The balloon embolization group had 16 cases (88.9%) of coronary perforation type II and 2 cases (11.1%) of coronary perforation type III. The PVA granules embolization group had 20 cases (90.9%) of coronary perforation type II and 2 cases (9.1%) of coronary perforation type III. The findings revealed no significant difference between the two groups in terms of baseline clinical data such as gender, age, risk factors for coronary heart disease, and Coronary perforation classification (Table 1).

In the balloon embolization group, 13 patients were successfully occluded immediately after using the balloon (72.2% success rate), but coronary angiography of the remaining 5 patients revealed contrast media leakage even after low-pressure balloon expansion and occlusion for 2–3 times. Three of the five patients were successfully embolised with polyvinyl alcohol granules, while the remaining two were urgently implanted with covered stents due to polyvinyl alcohol granules embolisation failure. Because of the unstable hemodynamics during the operation, the bedside B-ultrasound revealed a significant amount of pericardial effusion, which gradually stabilised following pericardiocentesis. In the PVA granules embolization group, 21 patients (95.5%) were successfully occluded with polyvinyl alcohol granules immediately. One patient with type IIIA CAP underwent emergency stent implantation and pericardiocentesis after polyvinyl alcohol granules embolisation failed. There were significant differences between the two groups (P<0.05) (Table 2). All patients were safely released following surgery. There were no major adverse events reported over the follow-up period of one month to one year. At present, polyethylene glycol particles are one of the materials used to seal coronary artery perforation, and the technology and process are very mature. Our center uses polyethylene glycol particles to seal coronary artery perforation with an immediate success rate of 95.5%. Our innovation is to mix polyethylene glycol particles with different diameters, and mixing two different diameter particles can produce complementary effects, making

Table 1 Baseline Characteristics of Patients in This Study

	Balloon Embolization Group	PVA Granules Embolization Group	T/χ2	P
Sample (n)	18	22	–	–
Age (year)	58.3±9.8	58.3±10.5	0.28	0.68
Male (n)	12 (66.7%)	14 (63.7%)	0.04	0.86
Hypertension (%)	10 (55.6%)	13 (59.1%)	0.05	0.78
Diabetes (%)	5(27.8%)	7(31.8%)	0.01	0.95
Stable angina (%)	6(33.3%)	7(31.8%)	0.005	0.97
LVEF(%)	52.1±6.5	51.3±6.3	0.31	0.64
LDL-cholesterol (mg/dl)	145.5±16.5	143.6±13.2	0.75	0.45
Type II perforation (%)	16(88.9%)	20(90.9%)	0.045	0.84

Table 2 Comparison of Intraoperative Parameters Between the Two Groups

	Balloon Embolization	PVA Granules Embolization	T/ χ^2	P
Successful occlusion of coronary artery perforation (%)	13 (72.2%)	21 (95.5%)	3.96	0.035
Pericardial effusion (%)	6 (33.3%)	1 (0.045%)	5.68	0.015

its internal structure more complex. Tighter structure, greatly reduced liquidity, increased adhesion, and can be tightened. Tightly fitting onto the coronary artery rupture increases the success rate of occlusion.

Discussion

Coronary perforation is a rare but potentially fatal complication of percutaneous coronary interventions. Although interventional instruments and techniques have advanced dramatically in recent years, coronary perforation has not been significantly reduced during PCI. Paying close attention to coronary perforation is critical for prevention and treatment in order to improve PCI safety. The first step in preventing and treating coronary artery perforation is to reduce the risk of it occurring. The risk factors for coronary artery perforation are: (I) Clinical risk factors: advanced age, female gender, acute myocardial infarction, heart failure, chronic renal insufficiency, and a history of coronary artery bypass surgery. (II) Instrument operating factors: ultra-slippery and hard guide wires were chosen to enter the interlayer or into the distal end or branch to continue pushing through; Balloon: the ratio of vascular diameter to balloon diameter ≥ 1.3; stent was too large; rotary grinding, rotary cutting, laser ablation device; temporary cardiac pacemaker. (III) Vascular pathological factors: occlusive lesions, angular lesions, severe tortuosity, bifurcation lesions, severe calcification and long lesions. (IV) Drug factors: Antiplatelet drugs and anticoagulants are commonly used during the perioperative period of PCI, but they raise the risk of vascular rupture and bleeding. The routine use of GPIIb/IIIa receptor antagonists is not recommended for CTO lesions.

Second, early detection is critical for both preventing and treating coronary perforation. The features of coronary perforation are as follows: (I) Imaging features: abnormal guide wire, large head end swing, the sudden disappearance of resistance of the guide wire or balloon after passing through the lesion, new contrast extravasation or pericardial or myocardial contrast retention on coronary angiography, and cardiac tamponade on X-ray fluoroscopy (The heartbeat was significantly weaker or disappeared in the positive foot position or right anterior oblique 30° projection). (II) Clinical characteristics: Patients who experience chest tightness, irritability, nausea, bradycardia, tachycardia, or hypotension during or after PCI should be evaluated for pericardial tamponade. Bedside B-ultrasound can confirm the presence of cardiac tamponade while also providing pericardial effusion volume, tear location information, and guiding pericardial puncture.[5,6]

Because the risk of coronary artery perforation is extremely high, coronary artery perforation is mainly prevented. Preventive measures for coronary artery perforation include: (I) Read the angiographic results carefully, defining the course of blood vessels and assessing the risk of surgery. CTO lesions should be treated with contralateral radiography rather than blind balloon dilation. (II) When using medium hardness or hydrophilic coated guide wire, it should be operated gently, while the multi-body should project the direction of the guide wire, change it to the ordinary working guide wire after passing through the lesion, and pay attention to the position of the guide wire's end. (III) When choosing balloon or stent, the ratio of vascular diameter to balloon diameter should not be too high, and blind dilatation should be avoided. (IV) To avoid high pressure dilatation, highly calcified lesions should be thoroughly pretreated with a rotary grinding or cutting balloon prior to stent implantation. Similarly, when using the rotary grinding technique to pretreat plaques in tortuous vascular segments, extreme caution is advised. (V) Stop using low molecular weight heparin 12 hours before the operation, avoid cross-heparin application, and try to use familiar instruments and techniques.

The need to control coronary artery extravasation and maintain hemodynamics drives the selection of coronary artery perforation management strategies. Currently, the general management of coronary artery perforation is as follows: (I) Continuous low-pressure balloon dilation and closure: Continuous low-pressure balloon dilatation typically employs semi-compliant balloons with the same diameter as perforated vessels at the perforation site, or proximal dilatation with low pressure (usually 6–8atm). This method is simple and effective, but long-term occlusion can cause ST segment elevation, decreased blood pressure, and an increased risk of arrhythmia, and even if occlusion is repeated for an extended period of time, 20–40% of patients are found to be ineffective. In this study, 18 patients were treated with low pressure balloon dilatation; 13 were successfully blocked right away, 5 failed, and the failure rate was 27.8%, which was consistent with the report. (II) Film-covered support plugging: When balloon compression and embolisation are ineffective for an extended period of time, covered stents can be used; however, commercial covered stents are not always available in most cardiac catheterization rooms in China, and covered stents are not appropriate for larger branches of blood vessels near perforation. At the same time, covered stents have low passability and a high rate of long-term adverse events such as in-stent thrombosis and restenosis. (III) Embolism: Embolisation is the most widely used treatment for distal vascular perforation. Thrombin, coil, suture,[7] autologous tissue,[8] gelatin sponge, and polyvinyl alcohol granules are some of the most commonly used embolic materials today. Polyvinyl alcohol granules have easy deformation, biocompatibility, hydrophilicity, and non-absorption properties, so they are frequently used for peripheral artery intervention, such as bronchial artery occlusion during hemoptysis or uterine artery occlusion during uterine leiomyoma, but they have rarely been reported to block coronary artery perforation.

In this study, polyvinyl alcohol granules were used to block coronary artery perforation. The findings revealed that 21 of the 22 patients were successfully occluded, with an immediate success rate of 95.5%. The success rate of type II CAP embolization treatment is 100%. Occlusion failed in one patient with type IIIA coronary artery perforation. Type IIIA coronary artery perforation increases the risk of cardiac tamponade, circulatory collapse, and hospital death, and the rupture is typically larger and with high blood pressure, making it more difficult to block. At the same time, due to the critical condition and short rescue time, the frequency of embolisation is restricted. In the 18 balloon occlusion cases, two patients with type IIIA CAP failed and were occluded with covered stents. As a result, it is recommended that type III coronary perforation be treated as soon as possible with a covered stent and pericardiocentesis.

Polyvinyl alcohol granules are commonly used in the chemical industry. Polyvinyl alcohol granules have expanded their applications to include food and medicine, where they are suitable for embolisation of various vascular solid organ tumours and arterial hemorrhagic lesions. Polyvinyl alcohol granules are expandable, compressible, and highly absorbent. It is insoluble in water and is made by cross-linking polyvinyl alcohol foam and formaldehyde, then drying, crushing, and sieving. Once it comes into contact with a water-based liquid, the volume will increase by 20%, and the biological compatibility is excellent. It exhibits mild cytotoxicity (grade I), no sensitization, a hemolysis rate of ≤ 5%, no systemic acute toxicity, no intradermal irritation, no subchronic toxicity, and no genotoxicity. Compared with spring coils, Polyvinyl alcohol granules particles do not leave foreign objects in the body, are more convenient to transport compared to autologous fat, and have a more definite therapeutic effect compared to thrombin. Our centre uses PVA granules to seal coronary perforations, which has the following advantages: (I) In comparison to balloon closure of coronary perforation, PVA granule closure of coronary perforation significantly increased the success rate, and even after successful balloon closure of coronary perforation, we observed subsequent pericardial tamponade. Although pericardial puncture was not required, patients' hospital stays were prolonged; however, this phenomenon was not observed in the PVA granules embolization group. As a result, even if the balloon is successfully used to seal a coronary artery perforation, it can be combined with PVA granules. (II) PAV granules can be precisely delivered to the site of coronary artery perforation using a microcatheter, and the injection procedure is simple and easy to control. It is appropriate for patients with type II CAP and some patients with type III CAP. (III) Because of the precise location, polyvinyl alcohol granules can be used to avoid embolisation of branch vessels. When compared to covered stents, it can reduce the risk of myocardial infarction during PCI. (IV) After successful embolisation with polyvinyl alcohol granules, protamine neutralisation and heparin can be avoid being used. Furthermore, there is no need to discontinue antiplatelet medications following surgery, lowering the risk of intraoperative and postoperative thrombosis. (V) Although embolisation with polyvinyl alcohol granules is costly, when compared to the risk of pericardiocentesis and emergency thoracotomy, the overall cost will be significantly lower, reducing patients' ideological and economic burden. (VI) PAV particles themselves have no pharmacological effects, no exclusivity, compared to local thrombin injection. It has more advantages and avoids the risk of thrombosis in the proximal segment of the vascular perforation caused by improper local thrombin injection operation. (VII) Compared to simple large and small particles, mixing pastes can form internal structures. Tighter structure, greatly reduced liquidity, increased adhesion, and can be tightened tightly fitted to the coronary artery rupture, reducing perforation bleeding time. At the same time, it is not easy to shift to the distal end and there is less reflux to the main trunk, thereby reducing the risk of related coronary artery branches and main trunk embolism.

Polyvinyl alcohol granules come in a variety of specifications, including PAV-150 (The diameter of polyvinyl alcohol granules is 100–350um), PAV-350 (The diameter of polyvinyl alcohol granules is 330–560um), and PAV-560 granules (The diameter of polyvinyl alcohol granules is 560–710um), which are commonly used in clinics. Based on previous experience with polyvinyl alcohol granules in peripheral arteries[9] and gelatin sponge granules,[10] we chose a suspension made of PAV-150 and PAV-350 granules. The coronary microcirculatory system is made up of external anterior arterioles (200–500 μm), intramyocardial arterioles (<200 μm), and capillaries (5–8 μm). Compared to simple large and small granules, the suspension can cover all microvessel diameters, allowing them to be closely attached to the coronary artery rupture and reducing perforation bleeding.

Study Limitations

This study suggests that polyvinyl alcohol embolic granules are effective in the treatment of CAP in the short term, and the prognosis for patients with successful CAP occlusion is favourable. Because coronary artery perforation is a rare complication in coronary intervention treatment, the incidence rate in our center is less than 1%, and a large part is type I coronary artery perforation, so the sample size is small. This retrospective study has a short follow-up time, and there may be some bias in data collection, so the medium- and long-term efficacy and safety of polyvinyl alcohol embolic granules in the treatment of CAP require further investigation.

Conclusions

In comparison to the simple use of low-pressure balloon occlusion, the use of a mixture of large and small polyethylene glycol particles with different diameters in the treatment of II, III coronary artery perforation has a high success rate and safety, and is a viable method for treating coronary artery perforation.

Ethical Statement

The guidelines outlined in the Declaration of Helsinki were followed in the study, and the study was approved by the ethic committee of Nanjing First hospital (20180517). Informed consent was obtained from the study participants.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

All authors declare no conflicts of interest in this work.

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