Intracoronary β-Irradiation with Liquid Rhenium-188 to Prevent Restenosis Following Pure Balloon Angioplasty: Results from the TRIPPER-1 Study

Chi-Ling Hang, MD, FACC; Morgan Fu, MD; Bor-Tsung Hsieh[1], PhD; Stephen Wan Leung[2], MD; Chiung-Jen Wu, MD; Gann Ting[1], PhD

Background: Patients who receive percutaneous transluminal coronary angioplasty (PTCA) are often haunted by restenosis of the target vessel within 6 months. Intracoronary irradiation has been shown to alter the luminal narrowing response after balloon angioplasty.

Methods: The Taiwan Radiation in Prevention of Post-Pure Balloon Angioplasty Restenosis-I (TRIPPER-I) study evaluated the feasibility, safety, and 6-month angiographic restenosis with intracoronary irradiation after pure balloon angioplasty (POBA) of de novo and post-POBA restenotic lesions in native coronary arteries using a self-centering β-emitter rhenium-188 (Re-188)-filled balloon.

Results: Forty patients received 14 Gy at a 0.5-mm tissue depth with a Re-188 solution-filled perfusion balloon catheter, and 25 control patients received 5-min inflation with a perfusion balloon catheter. There were no procedural complications or in-hospital or 30-day major adverse cardiac events. Six-month angiographic follow-up was performed on 39 Re-188 (97.5%) and 25 control patients (100%). The restenosis rate was 49% in the Re-188 and 56% in the control groups ($p = 0.62$). The composite end-points of death, myocardial infarction, and target-vessel revascularization were 40% in the Re-188 group and 36% in the control group ($p = 0.80$).

Conclusions: Catheter-based radiotherapy after POBA of de novo and post-POBA restenotic lesions with a Re-188-filled balloon is feasible but was ineffective in reducing target lesion restenosis with a dose of 14 Gy delivered at a 0.5-mm tissue depth in this study.

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Key words: **angioplasty, restenosis, coronary artery disease, brachytherapy.**

The success of percutaneous transluminal coronary angioplasty (PTCA) is hindered by late restenosis, which ranges from 30% to 50% within the first 6 months of the initial procedure.[1-3] Efforts to prevent restenosis using a variety of pharmacological and/or mechanical interventions have largely

From the Section of Cardiology, Department of Internal Medicine, Chang Gung Memorial Hospital, Kaohsiung; [1]Institute of Nuclear Energy Research, Taoyuan; [2]Department of Radiation Oncology, Chang Gung Memorial Hospital, Kaohsiung.
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Address for reprints: Dr. Stephen Wan Leung, Department of Radiation Oncology, Yuan's General Hospital. 136, Swei Road Section 4, Kaohsiung, Taiwan, R.O.C. Tel.: 886-7-3351121 ext. 1651; Fax: 886-7-3319997

been unsuccessful in humans.[4-6] Animal studies using iridium-192, a β-emitting source, and various β-emitting sources have been shown to reduce restenosis.[7-10] The first reported study of intracoronary brachytherapy by Condado et al. and the first randomized intracoronary brachytherapy trial, the Scripps Coronary Radiation Trial to Inhibit Proliferation Post Stenting (SCRIPPS) demonstrated substantial reduction in the rate of restenosis in patients who received catheter-based radiation using iridium-192.[11,12] However, this isotope has serious limitations for use in human coronary arteries because it is deeply penetrating and is not effectively shielded by standard lead aprons. The potential need to add shielding to the catheterization suite or to transfer the patient to a radiation oncology facility for treatment presents significant problems. In contrast, β-emitters have favorable characteristics in terms of permitting delivery of the dose to the required depth in tissue (2 to 3 mm), with little dose measured further than 1 cm from the source. The Beta Energy Restenosis Trial (BERT) feasibility study employed a non-centering solid form of strontium-90/yttrium-90 to deliver intracoronary beta-radiation.[13] The BERT study has shown results comparable to γ-radiation studies. However, deviation of the position of a catheter-based β-source by as little as 0.5 mm from the center can lead to significant differences in dose distributions. Thus, filling a PTCA balloon dilatation catheter with a liquid form of β-emitters to provide accurate source positioning and uniform treatment to the vessel wall is a promising option. Among the β-emitters, rhenium-188 (Re-188), unlike yttrium-90, strontium-90, or phosphoros-32, is not a bone-seeking compound. Re-188 can be chelated to a chemical form and rapidly cleared by the kidneys and has a biological half-life of approximately 1-3 hours. Makkar et al. reported reductions in 30-day angiographic stenosis, area stenosis, and intimal area in a porcine model using a Re-188-filled balloon which delivered 14 Gy at a tissue depth of 0.5 mm.[14] Thus, we conducted this study to determine the effect of 14 Gy of β-radiation using a Re-188 filled balloon at a tissue depth of 0.5 mm on the 6-month angiographic restenosis rate after pure balloon angioplasty (POBA). The secondary objectives were to evaluate the safety and feasibility of the procedure.

METHODS

Study design

This was a prospective, non-randomized, single-center study approved by the Ethics Committee of our institution and Ministry of Health authorities. The Re-188 isotope was produced at the Institute of Nuclear Energy Research and delivered once every 1-2 weeks to our hospital for intracoronary brachytherapy. Patient enrollment to either the radiation or control group was dependent on the availability of the Re-188. There was no attempt to match the control group with the irradiation group. Between August 1999 and August 2000, 40 study and 25 control patients were enrolled in the study. At the time of registration, patients were evaluated by a radiation oncologist and interventional cardiologist. Risks and benefits were discussed with the patients. Patients willing to provide written informed consent were enrolled in the study. The criteria for enrollment were an age of 50 years or older, clinically indicated balloon angioplasty of a native coronary artery (either de novo or post-POBA restenotic lesions), target lesion with a reference vessel of between 2.5 and 3.5 mm in diameter, and lesion length ≤25 mm. Patients were excluded if the POBA procedure was not successful, the final angiographic residual stenosis was greater than 30% by on-line quantitative coronary analysis (QCA), a stent had been implanted, there was angiographic evidence of a thrombus in the target lesion, or the patient was pre-menopausal, had previous thoracic therapeutic radiation, advanced renal failure (creatinine greater than 3.0 mg/dl), left ventricular ejection fraction < 25%, evolving myocardial infarction within 72 hours, or had used thrombolytic or GpIIb/IIIa inhibitors within the previous 48 hours. At 1 and 6 months after the procedure, telephone contact with the patient, an outpatient visit, or chart check was employed to record the recurrent ischemic symptoms, death, target vessel myocardial infarction, or requirement for revascularization of the treated vessel. All patients were admitted to the hospital at around 6 months post-procedure for repeat coronary angiography.

The primary end point of the study was the angiographic restenosis rate at 6 months after the procedure. The secondary end points were the following major adverse cardiac events: death, myocar-

dial infarction, coronary artery bypass surgery, and percutanoeus intervention in the target vessel.

Procedure

Patients were pretreated with 100 mg/day aspirin. An intravenous or intracoronary bolus of 10,000 IU heparin was administered prior to the placement of a 0.014-inch guidewire into the target coronary artery. POBA balloon sizes were chosen by visual estimation or QCA of the reference vessel diameters. Gradual increments of the POBA balloon pressures or sizes were made to achieve a less than 30% residual stenosis by on-line QCA. The involved lesion was successfully treated if the residual stenosis was less than 30% according to on-line QCA. After the successful POBA, media-to-media measurements at the index study were obtained by intravascular ultrasonography (IVUS) to determine the radiation dose. The IVUS study was only intended for vessel sizing, not for determination of the adequacy of the POBA. No further intervention was performed for an unsatisfactory post-POBA result, such as dissection or small minimal luminal diameter (MLD), according to the IVUS study. Irradiation and control procedures were carried out after successful POBA without stenting or use of any other devices. A Lifestream perfusion balloon dilatation catheter (Advanced Cardiovascular Systems, Santa Clara, CA) was used in both the Re-188 and control groups to deliver the irradiation and diluted contrast, respectively. The size of the perfusion balloon for the delivery of the Re-188 isotope was within ± 0.5 mm of the reference vessel diameter by IVUS. The balloon was prepared by applying negative pressure with an empty 10-ml syringe via a 3-way valve. The Re-188-filled leaded glass syringe was connected to the balloon by the 3-way valve. The entire proximal balloon inflation structure was then embedded in a Lucite shield. The balloon was positioned to cover the target lesion and match the approximate position of the previous angioplasty balloon. A tiny amount of Re-188 solution (without contrast) was injected into the 10-ml empty syringe on the other side of the 3-way valve in order to eliminate the small amount of air present in the system. The balloon was manually inflated with the Re-188 solution at an approximate inflation pressure of 3 atm. Cineangiograms were taken with contrast injections to verify the position and full expansion of the balloon (Fig. 1). The irradiation did not cover the precise length of the vessel exposed to barotrauma from the POBA balloon plus a proximal and distal edge zone. After irradiation, the balloon catheter, guidewire, 10-ml syringe, 3-way valve, and the Re-188-filled syringe were placed in a plastic bag and immediately placed into a lead-shielded container for decay.

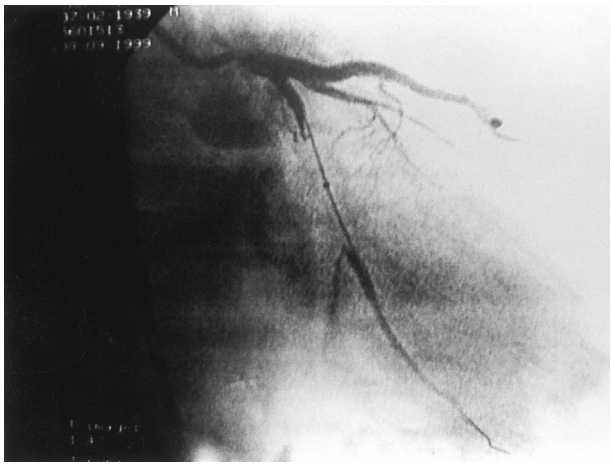

Fig. 1 Radiation treatment perfusion balloon catheter in place with contrast appearing distal to the fully expanded balloon.

Radiation source and dosimetry

Re-188 has a maximum transition energy of 2.13 MV, mean beta ray energy of 0.77 MV, and physical half-life of 17 hours. The carrier-free liquid Re-188 was obtained as sodium perrhenate prior to use by elution of a tungsten-188/Re-188 generator and was concentrated to 50-209 mCi/ml.

Media-to-media measurements of the vessel size at different sites of the target vessel, approximately 5 mm proximal and distal to the lesion, and at the lesion, were obtained by IVUS after successful POBA with the use of a 3.2-Fr. catheter. The vessel size data, the length and nominal size of the perfusion balloon catheter, and the activity of the Re-188 were used to calculate the irradiation (dwell) times to deliver 14 Gy to a tissue depth of 0.5 mm. This corresponded to a dose of 28 Gy at the surface of the balloon. The computer treatment-planning program was provided by Columbia University (New York, NY, USA).

Quantitative coronary angiography

Angiographic measurements were done with the on-line image system of a Philips 5000 catheterization laboratory machine. Image calibration was performed with a contrast-filled catheter. The external diameter of the catheter was used as the calibration standard. Coronary MLD and the degree of stenosis (percentage of the diameter) were measured from coronary end-diastolic-matched frames in the single worst view obtained before dilation, at the end of the procedure, and during follow-up angiography 6 months later (or earlier if there were recurrent symptoms). Restenosis was defined as the presence of stenosis of more than 50% of the luminal diameter by on-line QCA at follow-up in a vessel with less than 30% residual stenosis immediately after POBA.

Statistical analysis

Statistical analyses of frequency counts were performed with the use of chi-square test or Fisher's exact test for small samples, and the means were compared using the 2-sample *t*-test. All tests were 2-sided. Values were reported as the mean±SD. Differences were considered statistically significant at $p<0.05$.

RESULTS

Between August 1999 and August 2000, 65 patients were enrolled in the study; 40 were assigned to the Re-188 group and 25 to the control group. Baseline clinical and angiographic characteristics were similar between the 2 groups (Tables 1, 2). In the Re-188 group, the prescribed dose of 14 Gy at a 0.5-mm tissue depth was successfully delivered to all patients with Re-188 via a Lifestream perfusion dilatation balloon catheter. The average specific activity of the Re-188 was 108.7±45.0 (range, 50-209) mCi/ml. The mean dwell time for the irradiated group was 440±214s, while the dwell time for the control group was 300s. The treatment was given in a single inflation cycle in all patients. No adverse effects of delivering the radiation were observed. All patients were maintained on 100 mg/day aspirin indefinitely; none of them took clopidogrel or ticlopidine in addition to aspirin after the procedure. There were no deaths, myocardial infarctions, or reinterventions by the 30-day follow-up.

The baseline, post-procedure, and 6-month

Table 1. Baseline Clinical Characteristics of Patients*

	Re-188	Control	*p*
No. of patients	40	25	
Male, n (%)	31 (77)	19 (76)	0.56
Age (year)	62.4±7.0	63.2±6.9	0.65
Diabetes mellitus, n (%)	9 (23)	6 (24)	0.56
Hypertension, n (%)	26 (65)	14 (56)	0.60
Smoker, n (%)	9 (23)	10 (40)	0.17
Cholesterol > 200 mg%, n (%)	22 (55)	14 (56)	0.94
Triglyceride > 200 mg%, n (%)	8 (20)	5 (20)	0.57
Left ventricular ejection fraction (%)	63.6±14.3	68.9±15.4	0.31
Previous myocardial infarction, n (%)	17 (42.5)	6 (24)	0.18
Stable angina, n (%)	17 (42.5)	5 (20)	0.11
Unstable angina, n (%)	21 (52.5)	17 (68)	0.30
**Recent myocardial infarction, n (%)	2 (5)	3 (12)	0.37

*Plus-minus values are the means±SD; differences were considered statistically significant at $p<0.05$. **Recent myocardial infarction was defined as myocardial infarction occurring between 3 and 7 days.

Table 2. Baseline Angiographic Characteristics*

	Re-188	Control	*p*
No. of lesions	40	25	
De novo lesions, n (%)	33 (82.5)	20 (80)	0.29
Post-POBA restenotic lesions, n (%)	7 (17.5)	5 (20)	0.52
Multivessel disease, n (%)	35 (87.5)	18 (72)	0.19
Three-vessel disease, n (%)	21 (52.5)	13 (52)	0.59
Two-vessel disease, n (%)	14 (35)	5 (20)	0.27
Left anterior descending artery, n (%)	14 (35)	10 (40)	0.79
Left circumflex artery, n (%)	22 (55)	9 (36)	0.20
Right coronary artery, n (%)	4 (10)	6 (24)	0.17
Lesion length (mm)	13.8±4.5	12.2±4.7	0.30

*Plus-minus values are the mean±SD; differences were considered statistically significant at $p<0.05$.

QCA results showed that the post-procedure reference vessel diameter (Re-188 vs. the control; 2.89±0.31 vs. 3.13±0.45 mm; $p=0.01$) and MLD (Re-188 vs. control; 2.32±0.31 vs. 2.58±0.44 mm; $p=0.01$) of the Re-188 group were significantly smaller than the control group (Tables 3, 4). Angiographic follow-up data were obtained at 6 months in all patients in the control group (100%) and 39 of the 40 patients

Table 3. Baseline and Post-procedure Quantitative Angiographic Results*

	Re-188	Control	*p*
No. of lesions	40	25	
Before the procedure			
Reference diameter (mm)	2.80±0.33	2.98±0.46	0.07
Average MLD (mm)	0.67±0.27	0.59±0.26	0.27
Percent diameter stenosis	76±6	80±7	0.04
After the procedure			
Reference diameter (mm)	2.89±0.31	3.13±0.45	0.01
Average MLD (mm)	2.32±0.31	2.58±0.44	0.01
Percent diameter stenosis	21±6	16±8	0.13

*Plus-minus values are the mean±SD; differences were considered statistically significant at $p<0.05$.

Table 4. Six-month Quantitative Angiographic Results*

	Re-188	Control	*p*
No. of lesions	39	25	
At 6 months			
Reference diameter (mm)	2.98±0.49	3.03±0.52	0.73
Average MLD (mm)	1.43±0.89	1.45±0.73	0.92
Percent diameter stenosis	52±29	53±22	0.93
Intralesional restenosis only, n (%)	18 (46)	14 (56)	0.60
Intralesional and marginal restenosis, n (%)	19 (49)	14 (56)	0.62
Total occlusion, n (%)	3 (7.7)	1 (4)	0.49

*Plus-minus values are the mean±SD; differences were considered statistically significant at $p<0.05$.

in the Re-188 group (97.5%). One patient in the Re-188 group refused follow-up angiography and remained asymptomatic 18 months after the procedure. The mean time to angiographic follow-up was 5.8±2.0 months in the Re-188 group and 6.4±1.9 months in the control group. On the follow-up angiographic examination, there was total occlusion of the vessel in 3 of 39 patients who had had irradiation and 1 of 25 control patients (7.7% vs. 4%, $p=0.55$). Of the 3 patients in the irradiated group with an occlusion, 2 presented with unstable angina (at 2 and 4 months after the procedure, respectively). One patient in the irradiated group and 1 patient in the control group had silent total occlusions of the target vessel, which were discovered at the 6-month angiographic examination. Angiographic restenosis either within the lesion or at its marginal segment (5 mm beyond the approximate proximal or distal location of the previous angioplasty balloon) was observed in 49% of patients in the Re-188 group, compared with 56% of those in the control group ($p=0.57$). Restenosis limited to the marginal segment only occurred in 1 patient in the Re-188 group; 97% of the instances of restenosis in the Re-188 group were due to renarrowing of the target lesion.

Subgroup analyses with reference vessel diameters of < 3.0 mm and ≥ 3.0 mm, and de novo and post-POBA restenotic lesions were performed (Table 5). The Re-188 group had significantly more vessels with a reference vessel diameter < 3.0 mm (Table 5). Six-month target lesion angiographic restenosis occurred in 11 of the 24 lesions (46%) with a reference diameter < 3.0 mm in the Re-188 group, and 6 of the 8 lesions (75%) with a reference diameter < 3.0 mm in the control group ($p=0.23$). In the de novo lesions, the 6-month angiographic restenosis rates of the Re-188 and control groups were 47% (15 of 32 lesions) and 50% (10 of 20 lesions), respectively. In the post-POBA restenotic lesions, the 6-month angiographic restenosis rates of the Re-188 and control group were 57% (4 of 7 lesions) and 80% (4 of 5 lesions), respectively ($p=0.58$).

Table 5. Subgroups Analysis

	Re-188	Control	*p*
No. of lesions	39	25	
No. of lesions with a reference diameter < 3.0 mm	24 (62%)	8 (32%)	0.04
Six-month angiographic restenosis	46% (11/24)	75% (6/8)	0.23
No. of lesions with a reference diameter ≥ 3.0 mm	15 (38%)	17 (68%)	0.04
Six-month angiographic restenosis	53% (8/15)	47% (8/17)	0.50
No. of de novo lesions	32 (82%)	20 (80%)	0.54
Six-month angiographic restenosis	47% (15/32)	50% (10/20)	0.53
No. of post-POBA restenotic lesions	7 (18%)	5 (20%)	0.54
Six-month angiographic restenosis	57% (4/7)	80% (4/5)	0.58

*Differences were considered statistically significant at $p<0.05$.

Clinical events

Clinical follow-up data were obtained for all patients at a mean of 12.3±3.8 months in the Re-188 group and 12.6±3.1 months in the control group

(Table 6). One patient in the Re-188 group sustained a myocardial infarction on day 46. Angiographic examination showed a tight stenosis at the target lesion. The patient was then treated with stent implantation. Two patients in the Re-188 group, who had total occlusion of the vessel, subsequently underwent bypass surgery. There were no other myocardial infarctions, bypass surgeries, or deaths. Twelve patients in the Re-188 group underwent a percutaneous coronary intervention of the target lesion (7 received stent implantation and 5 underwent POBA) at the 6-month follow-up visit. One patient had a percutaneous intervention of the target vessel 8 months later. In this patient, the stenotic lesion was at the marginal segment of the previous lesion, and it was surmised that the new lesion site had probably been traumatized by the inflated balloon during the POBA procedure. Target vessel revascularization was required in 15 of the 40 patients in the Re-188 group (37.5%) and 9 of the 25 patients in the control group (36%). The number of patients who reached the composite clinical end points did not significantly differ between the Re-188 and control groups (40% vs. 36%, $p = 0.80$).

Table 6. Clinical Events at 6-month Follow-up*

	Re-188	Control	*p*
No. of patients	40	25	
Six-month angiographic follow-up	39 (97.5%)	25 (100%)	
Myocardial infarction, n (%)	1 (2.5)	0	0.43
Bypass surgery, n (%)	2 (5)	0	0.26
Death, n (%)	0	0	1.0
Repeat PTCA of target vessel, n (%)	13 (32.5)	9 (36)	0.79
Target vessel revascularization, n (%)	15 (37.5)	9 (36)	0.56
Composite clinical end point, n (%)	16 (40)	9 (36)	0.80

*Differences were considered statistically significant at $p < 0.05$.

DISCUSSION

The TRIPPER-I was a study of radiotherapy using a self-centering β-emitter Re-188 solution-filled balloon in patients undergoing POBA of the native coronary artery (either de novo or post-POBA restenotic lesions) without stent implantation. Randomization in this study was impossible due to the limited supply of the Re-188 isotope. Hence, a contemporaneous control group was collected. The study demonstrates that intracoronary irradiation with 14 Gy at a 0.5-mm tissue depth delivered by a Re-188 solution filled balloon was ineffective in reducing 6-month target lesion restenosis and the composite end-points of death, myocardial infarction, and target-vessel revascularization. The main cause of restenosis after irradiation in this study was intralesional stenosis. In contrast, edge stenosis was the main cause (61%) of restenosis after irradiation in the ECRIS-1 trial conducted by Hoeher et al. using the same isotope (Re-188) delivered at 15 Gy at a 0.5-mm tissue depth.[15] In that study, 68% of their patients underwent stent implantation, and the restenosis rate was significantly higher in the irradiated group as compared to the control group. The low intralesional restenosis rate might have been due to the effect of the stent itself. The lack of an effect might be attributed to the low irradiation dose used in both our TRIPPER-1 study and the EndoCoronary Rhenium Irradiation Study (ECRIS)-1 trial. In the ECRIS-2 trial, the irradiation dose was increased to 22.5 Gy at a 0.5-mm tissue depth delivered by a balloon > 10 mm longer than the segment traumatized by the preceding angioplasty to avoid a geographic miss. The interim analysis revealed a marked reduction in the restenosis rate.[15]

Data from animal studies and clinical trials show a wide therapeutic window and a minimum therapeutic dose. In order to deliver the optimal dosimetry, the target cells and treatment dose have to be determined. The intended target cells for irradiation in intravascular brachytherapy are not clearly identified. Smooth muscle cells originating from the adventitia and progenitor cells originating from the media have been suggested to play a role in the restenosis process.[16-18] Nevertheless, the media will be treated when the adventitia is targeted. However, multiple factors like the dose gradient of the isotopes, the location and volume of the residual plaque, and the presence of calcification or stenting have to be taken into account to determine the treatment dose. Based on animal studies, treatment doses of different isotopes using various delivery systems have been prescribed in clinical trials. The predetermined effective dose was not effective in our trial due to the fact that the over-stretched normal

coronary artery of the porcine model differs from heavy plaque-loaded lesions (mean percent of stenosis was 80%±6%) of the coronary arteries in our patients. The presence of plaque or calcium in the vessel walls might lead to the attenuation or absorption of the dose causing treatment under-dosing. Although it is ideal to have a uniform dose delivered to the vessel wall, the eccentricity of the residual plaque in the vessel wall might render the various centering devices ineffective in providing true centering.

Smaller vessels have been associated with a high rate of restenosis. In our trial, lesions with a reference vessel diameter < 3.0 and ≥ 3.0 mm in the Re-188 group had 46% and 53% restenosis rates, respectively. Lesions with a reference vessel diameter of < 3.0 mm in the placebo group had a 75% (6 of 8 lesions) restenosis rate compared with 46% (11 of 24 lesions) in the Re-188 group (a 39% reduction; $p=0.23$). Although, the difference in the restenosis rate in vessels of < 3.0 mm in diameter was not statistically significant, the decrease in the restenosis rate as compared to the control group might have been due to the closer proximity of the intended target for irradiation in smaller vessels.

Several randomized clinical trials focused on in-stent restenosis using iridium-192 and showed a remarkable reduction in the restenosis rate.[12,19,20] Recently, the US FDA approved 2 devices for the delivery of intracoronary radiation after effective percutaneous intervention of in-stent restenosis. Ongoing randomized clinical trials of intracoronary brachytherapy for de novo and restenotic lesions not previously stented and not stented during the procedure might expand the currently approved indications.

Animal studies have shown that radiation can induce thrombosis.[21,22] Intracoronary brachytherapy for patients with in-stent restenosis is associated with a high rate of late total occlusion (> 30 days after the procedure).[23] This phenomenon is more pronounced after restenting. In our study, 3 of 39 (7.7%) Re-188 patients had late total occlusion, 2 of whom suffered unstable angina and 1 of whom had a silent occlusion. There was only 1 silent late occlusion among the 25 patients (4%) in the placebo group. This was not statistically significant. However, adjunct antiplatelet therapy with ticlopidine or clopidogrel in patients receiving intracoronary brachytherapy after POBA might be needed to prevent this potentially disastrous complication.

Study limitations

The patient population in this study was small. Although it was a placebo-controlled study, it was not randomized. Trends were seen but not were significant by the tests employed. This could indicate a true lack of difference, an insufficiently large sample tested, or another variable of difference between the 2 groups. The study was limited to 6-month follow-up. Further follow-up is required to ensure that the safety of the procedure observed is maintained over time.

Conclusions

Catheter-based radiotherapy after POBA of de novo or post-POBA restenotic lesions with a Re-188-filled balloon is feasible, but was ineffective in reducing target lesion restenosis with a dose of 14 Gy delivered at a 0.5-mm tissue depth in this study.

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施行線液態銪-188照射以防止經血管氣球擴張術後之冠狀動脈再狹窄: TRIPPER-1 研究的結果

洪志凌 傅懋洋 謝柏滄[1] 梁 雲[2] 吳炯仁 丁 幹[1]

背 景： 接受經皮冠狀動脈血管形成術的患者，常因六個月內標的血管再狹窄而困擾。氣球擴張術後施行冠狀動脈放射線照射已顯示能改變血管再狹窄的反應。

方 法： 台灣以放射線照射防止經皮冠狀動脈氣球擴張術後之再狹窄研究-I (TRIPPER-I Study), 評估接受冠狀動脈氣球擴張術後使用自我置中貝它放射同位素液態銪-188灌注氣球治療的安全性與可行性及經六個月後血管的再狹窄率。

結 果： 40病患接受液態銪-188填充入灌流氣球導管14格雷照射於0.5厘深的管壁組織，而有25安慰劑對照組病患接受灌流氣球導管在病灶維持5分鐘的膨脹時間。治療過程中並無併發症。住院中及30天的追蹤並無主要不良心臟事故。39位銪-188組和25位控制組的病患接受六個月後血管的照相，檢查率分別爲97.5%和100%。六個月後血管的再狹窄率銪-188組爲49%，控制組爲56% ($p=0.62$)。死亡，心肌梗塞，標的病灶再治療率的混合終點，銪-188組爲40%，控制組爲36% ($p=0.80$)。

結 論： 新的或再狹窄的冠狀動脈病灶接受經冠狀動脈氣球擴張術後施行貝它放射線液態銪-188照射是可行的，但本研究未顯示14格雷照射於0.5厘深的管壁組織能有效防止經血管氣球擴張術後冠狀動脈再狹窄。

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關鍵字： 血管整形術，再狹窄，冠狀動脈病變，進階放射治療。

長庚紀念醫院 高雄院區 心臟內科；[1]原子能委員會核能研究所；[2]長庚紀念醫院 高雄院區 放射腫瘤科
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索取抽印本處：梁 雲醫師，阮綜合醫院 放射腫瘤科。高雄市四維路四段136號。Tel.: (07)3351121轉1651; Fax: (07) 3319997