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Incomplete revascularization in the drug eluting stent era permits meaningful long-term (12-78 months) outcomes in patients ≥ 75 years with acute coronary syndrome

Jie Chen, Qiao Xue, Jing Bai, Lei Gao, Jin-Wen Tian, Ke Li, Qiang Xu, Yan-Hua Li, Yu Wang

Institute of Geriatric Cardiology, Chinese PLA General Hospital, 28 Fuxing Road, 100853 Beijing, China

Abstract

Objective To compare long-term prognosis between complete revascularization (CR) and incomplete revascularization (IR) in elderly patients with acute coronary syndrome (ACS) who underwent percutaneous coronary intervention (PCI). **Methods** We prospectively enrolled patients ≥ 75 years with ACS and multi-lesion disease between January 2005 and December 2010 at our center (Institute of Geriatric Cardiology, Chinese PLA General Hospital). Baseline clinical characteristics, PCI parameters and long-term (12 to 78 months) outcomes including main adverse cardiac and cerebral events (MACCE) were compared between CR and IR groups. We used the Kaplan-Meier curve to describe the survival rates, and variables reported to be associated with prognosis were included in Cox regression. **Results** Of the 502 patients, 230 patients obtained CR, and the other 272 patients underwent IR. Higher SYNTAX score was an independent predictor of IR [Odds ratio (OR): 1.141, 95% confidence interval (95% CI): 1.066–1.221, $P = 0.000$]. A total of 429 patients (85.5%) were followed with a duration ranging from 12 months to 78 months. There were no significant differences in cumulative survival rates and event free survival rates between the two groups, even for patients with multi-vessel disease. Older age (OR: 1.079, 95% CI: 1.007–1.157, $P = 0.032$), prior myocardial infarction (OR: 1.440, 95% CI: 1.268–2.723, $P = 0.001$) and hypertension (OR: 1. 653, 95% CI: 1.010–2.734, $P = 0.050$) were significant independent predictors of long-term MACCE. **Conclusions** Given that both clinical and coronary lesion characteristics are much more complex in patients ≥75 years with ACS and multi-lesion disease, IR may be an option allowing low risk hospital results and meaningful long-term (12 to 78 months) outcomes.

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Keywords: Elderly patients; Percutaneous Coronary Intervention; Incomplete Revascularization; Long-term Prognosis

1 Introduction

Revascularization of all diseased coronary lesions, complete revascularization (CR) with either percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG), is considered superior to incomplete revascularization (IR), having a potential long-term benefit and a lower rate of re-intervention.[1–3] However, in high-risk patients, such as patients with severe coronary disease or with complex clinical co-morbidities, IR is a reasonable intervention to reduce perioperative mortality and morbidity. Generally, as a surgical strategy, IR may negatively affect long-term outcomes, but it may be the ideal treatment strategy in some high-risk patients such as those who are elderly and in a critical situation.[4–6] As a coronary stenting strategy, IR plays a controversial role in the long-term. In the bare metal stent era, IR might be associated with higher risk of long-term mortality in patients with multi-vessel disease.[7] But in drug-eluting stent era, some studies argue that angiographic CR seems not to improve long-term clinical outcomes.[8,9] Consequently, we doubt the necessity of CR in complex cases, and we hypothesized that IR may permit meaningful long-term results in selected high risk patients with severe and multiple coronary artery disease and complex clinical co-morbidities.

Elderly patients ≥ 75 years comprise a steadily growing population of PCI in the Western World and China.[10–13] Multi-vessel disease, complex lesions and other co-morbid conditions are more likely to occur in elderly patients, so CR can not be always achieved. The extent of planned revascularization is often a critical determination of treatment strategy. Some studies indicate that in elderly patients CR might improve the prognosis (≤ 1 year) and reduce the

Correspondence to: Yu Wang, PhD, Chinese PLA General Hospital, 28 Fuxing Road, 100853 Beijing, China. E-mail: wangyuheart@yahoo.com.cn
Telephone: +86-10-55499037 **Fax:** +86-10-55499037
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incidence of cardiac events.[14–16] However, others suggested that CR neither significantly influences the rate of repeat revascularizations, nor 12 month total events in octogenarians.[17] Slower atherosclerotic development in elderly patients may also result in different long-term prognosis for the younger patient.[15] So far, limited data have been shown to compare the long-term (≥ 1 year) outcomes in elderly patients ≥ 75 years with complete or IR prospectively, especially for Chinese population.

The purpose of our study was to assess the long-term outcomes of CR versus IR with drug-eluting stent implantation in elderly patients (≥ 75 years) who were confirmed as acute coronary syndrome (ACS) and multi-lesion disease. Also we aimed to identify whether long-term adverse outcomes are directly due to IR, or preoperative conditions of the patients.

2 Methods

2.1 Study population and data collection

We prospectively screened all the consecutive patients aged ≥ 75 years at our center (Institute of Geriatric Cardiology, Chinese PLA General Hospital) from January 2005 to December 2010 presenting with ACS and multiple-lesion disease and undergoing stenting. All the patients who met the inclusive criteria were assigned to two groups according to clinical decision treatment: CR and IR. This clinical decision was based on: (1) hemodynamic stability; (2) possibility of identifying the culprit vessel; (3) the clinical feasibility of complete percutaneous revascularization; and (4) referring preference of the physician and patients.[18] Exclusion criteria included: (1) patients failed to be treated with stents; (2) patients must use bare-metal stents; and (3) patients who were expected to die within 12 months for other reasons. The patients in CR group failed to obtain CR were allocated to IR group. The study protocol was shown in Figure 1.

Culprit vessel was defined by reviewing each patient's data, such as angiographic report, electrocardiogram (ECG), echocardiogram, or non-invasive ischemia tests.[18] Baseline clinical and procedural materials with in-hospital outcomes were collected in a hospital database. Follow-up examinations, which were conducted in 2010 and 2011, included interviews by telephone, or in the outpatient clinic. If re-admission occurred, the participant's hospital records were also abstracted. Any adverse event was confirmed by hospital documents. The investigation was in accordance with the Declaration of Helsinki.

The study protocol was reviewed and approved by the ethnical committees of the Chinese PLA General Hospital. All participants gave their informed consent before they were recruited. All investigators were trained to be eligible by test at the Institute of Geriatric Cardiology, Chinese PLA General Hospital (Beijing, China).

2.2 Stent implantation procedure

All of the procedures were performed with a standard technique via the femoral access. Before the procedure, all patients received aspirin 300 mg and 300 mg clopidogrel, and thereafter, 100 mg aspirin plus 75mg clopidogrel. A dose of 75–100 u/kg unit of unfractionated heparin was administered after sheath insertion. According to the American

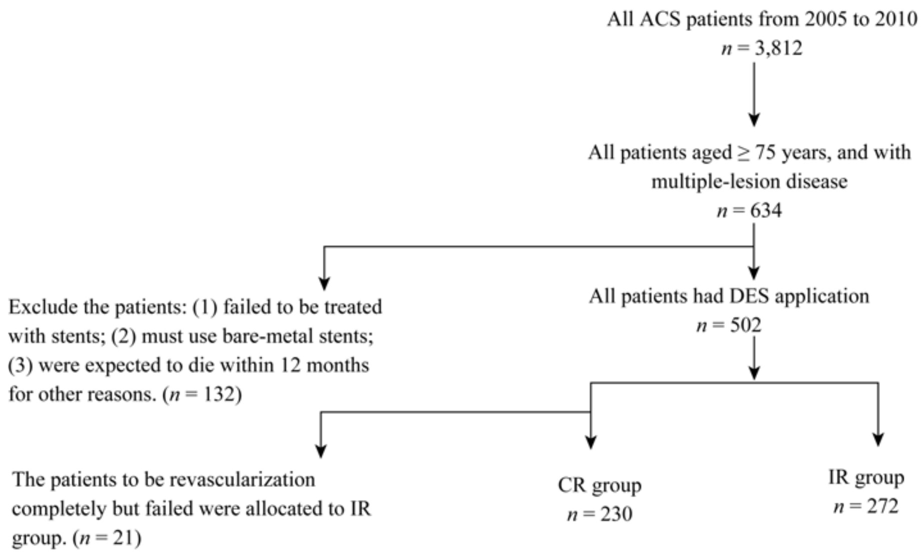

Figure 1. Flow chart of the study protocol. ACS: acute coronary syndrome; CR: complete revascularization; DES: drug eluting stent; IR: incomplete revascularization.

Heart Association/American College of Cardiology (AHA/ ACC) Guidelines of coronary angiography,[19] we applied PHILIPH Allura Xper FD 20 digital subtraction angiography system (Holand) and Judkin's method. Drug eluting stents were employed for all the enrolled patients. Two skilled cardiologists assessed the angiographic data according to our research standard and used SYNTAX Scores to evaluate the lesions, which were calculated by SYNTAX-score-calculator-202.

2.3 Definitions

ACS: ST-elevation myocardial infarction, non-ST-elevation myocardial infarction and unstable angina; CR: Successful treatment of all the vessels (diameter ≥ 2.0 mm) with critically stenotic lesion (diameter stenosis ≥ 70% at visual estimation); IR: Not all significant lesions, but at least one was successfully treated; Multi-lesion disease: at least two lesions present with visual stenosis ≥ 70%, and two separated lesions were defined as lesions at a distance of more than three reference artery diameters.

Multi-vessel disease: at least two main coronary arteries presented with visual stenosis ≥ 70% on coronary angiography findings; Main Adverse Coronary Cerebral Events (MACCE): Cardiac death, non-fatal acute myocardial infarction, target lesion/target vessel revascularization and cerebral artery events; Procedure success: Residual stenosis was less than 20% in the target lesion in the post-stent angiographic evaluation without the occurrence of myocardial infarction, urgent coronary artery bypass graft surgery or death; Vascular complications: The occurrence of pseudoaneurysm, bleeding or hematoma at the access site requiring vascular repair or external compression.[20] Main bleeding complications: Gastrointestinal, neurologic or any other significant bleeding other than that of the access site.[20]

In patients undergoing staged procedures, target lesions from both procedures were grouped together to avoid misclassification.

2.4 Statistical analysis

Categorical data are presented as percentages and compared by chi-square or Fisher exact analysis when necessary. Continuous variables are presented as mean ± SD and compared by Student's *t* test. A multivariable logistic regression model was applied including all the potential confounding variables in Table 1 and 2.

Survival analysis was performed with the Kaplan-Meier method for each group and compared with log-rank test. Multivariate analysis of predictors of adverse events during the follow-up period was performed with the Cox proportional hazards model. The hazard ratio (HR) and 95% CI for each variable were expressed.

We used the SPSS 17.0 statistical software package to do the statistical analysis. All calculated *P* values are two-sided and $P < 0.05$ was considered statistically significant.

3 Results

3.1 Baseline characteristics

A total of 502 patients ≥ 75 years with ACS who underwent stenting procedures from 2005 to 2010 were screened. The mean age was 78.5 ± 3.2 years, with a range from 75 to 94 years. A total of 230 (45.8%) patients underwent CR and 272 (54.2%) IR. All the patients were treated solely with drug eluting stents. The baseline characteristics are presented and compared in Table 1. IR patients had a higher prevalence of hypertension, diabetes, dyslipidemia, cerebral vascular disease and previous bypass surgery, and they were more likely to present with non-ST Segment Myocardial Infarction (NSTEMI), STEMI, severe heart failure and higher SYNTAX scores.

Multivariate analysis revealed the following independent predictors of IR: SYNTAX score [Odd Ratio (OR): 1.141, 95% Confidence Interval (CI): 1.066–1.221, P = 0.000], single vessel disease (OR: 0.491, 95% CI: 0.252–0.959, P = 0.037) and non-diabetes (OR: 0.034, 95% CI: 0.014–0.083, P = 0.000).

3.2 PCI characteristics and in-hospital outcomes

The angiographic and procedural characteristics were summarized in Table 2. There were no statistically significant differences between the two groups, such as the number of target vessels, reference diameter, and staged stenting. The in-hospital outcomes, including procedure success, vascular complications and main bleeding complications, were also similar. However, the patients who received IR were more likely to have a higher risk of in-hospital death (2.9% *vs*. 1.3%, P = 0.000).

3.3 Long-term (12–78 months) clinical follow-up outcomes

The follow-up time ranged from 12 months to 78 months with a median of 35.7 ± 21.9 months for IR patients and 36.6 ± 21.8 months for CR patients. Of the 429 (85.5%) patients followed clinically, 47 patients died, which gave a follow-up mortality rate of 11.0%, including 31 (7.2%) cardiac deaths, two (0.5%) strokes and 14 (3.3%) deaths of multiple organ dysfunction. Table 3 indicates that deaths from all causes in the long term (12–78 months) seemed to be

Table 1. Baseline clinical characteristics.

	CR, *n* = 230	IR, *n* = 272	*P* Value
Age (yrs)	78.4 ± 3.2	78.7 ± 3.2	0.269
75–79	168 (49.9)	169 (50.1)	
≥ 80	62 (37.6)	103 (62.4)	
Male	145 (63.0)	174 (64.0)	0.830
Co-morbidities			
Hypertension	165 (71.7)	225 (82.7)	0.003
Diabetes	64 (27.8)	118 (43.4)	< 0.001
Dyslipidemia	102 (44.3)	155 (57.0)	0.005
Current Smoking	47 (20.4)	75 (27.6)	0.063
Chronic bronchial disease	23 (10.0)	35 (12.9)	0.317
Cerebral vascular disease	41 (17.8)	75 (27.6)	0.010
Prior myocardial infarction	39 (17.0)	63 (23.2)	0.085
Previous PCI	28 (12.2)	39 (14.3)	0.477
Previous Bypass Surgery	10 (4.3)	35 (12.9)	0.001
Indications			
Unstable Angina	171 (74.3)	163 (59.9)	0.001
NSTEMI	19 (8.3)	44 (16.2)	0.008
STEMI	30 (13.0)	58 (21.3)	0.015
Heart failure III-IV	21 (9.1)	39 (14.3)	0.007
EF	59.9 ± 9.1 (197)	63.3 ± 11.4 (247)	0.664
eGFR (L/min per 1.73 m^2)	84.4 ± 25.6	67.7 ± 29.4	0.043
Significant disease			
Single vessel	135 (58.7)	14 (5.1)	
Two vessels	79 (34.3)	98 (36.0)	< 0.001
Three vessels	16 (7.0)	160 (58.9)	
SYNTAX Score	13.7 ± 9.7	28.6 ± 15.0	< 0.001
< 22	189 (82.2)	106 (39.0)	
22–31	31 (13.5)	76 (27.9)	< 0.001
≥ 32	10 (4.3)	90 (33.3)	

Data are presented as mean ± SD or *n* (%). CR: complete revascularization; EF: ejection fraction; eGFR: estimated glomerular filtration rate calculated by MDRD equation (the Modification of Diet in Renal Disease equation); Heart failure III-IV: New York Heart Classification; IR: incomplete revascularization; NSTEMI: non-ST segment elevated myocardial infarction; STEMI: ST segment elevated myocardial infarction.

higher in IR group, but the difference has no statistical significance. There were no significant differences in the overall MACCE (20.4% *vs*. 14.9%, *P* = 0.141), including cardiac death, non-fatal acute myocardial infarction, target vessel revascularization and cerebral vascular disease. The IR patients did not present with higher rates of angina recurrence and readmission.

Figure 2 shows there were no significant differences in cumulative survival rate (log rank *P* value = 0.051) and event free survival rate (log rank *P* value = 0.162) between CR and IR group. With respect to selected multi-vessel disease subgroup of 225 patients, Figure 3 indicates the cumulative survival rate (log rank *P* value = 0.448) and event free survival rate (log rank *P* value = 0.724) were also similar between CR and IR group.

3.3 Multivariable modeling for independent predictors of long-term MACCE and cardiac death

The significant independent predictors of MACCE included older age (OR: 1. 079; 95% CI: 1.007–1.157; *P* = 0.032), history of prior myocardial infarction (OR: 1.440; 95% CI: 1.268–2.723; *P* = 0.001) and hypertension (OR: 1. 653; 95% CI: 1.010–2.734; *P* = 0.050). Older age (OR: 1.478; 95% CI: 1.260–2.881; *P* = 0.018) and history of prior myocardial infarction (OR: 1.113; 95% CI: 1.026–1.208; *P* = 0.010) were also significant predictors of cardiac death.

Table 2. PCI characteristics and in-hospital outcomes.

	CR, *n* = 230	IR, *n* = 272	*P* Value
Target vessels			
LAD	129 (56.1)	128 (47.1)	0.054
LCX	89 (38.7)	101 (37.1)	0.719
RCA	99 (43.0)	132 (48.5)	0.219
LM	12 (5.2)	24 (8.8)	0.119
Reference diameter (mm)	2.8 ± 0.4	2.8 ± 0.4	0.706
Lesion length (mm)	19.4 ± 9.8	19.3 ± 9.5	0.619
Number of stents	2.1 ± 1.3	2.1 ± 1.1	0.534
Pre-stenting stenosis (%)	71.9 ± 12.7	72.3 ± 13.3	0.817
Post-stenting stenosis (%)	16.8 ± 6.6	16.8 ± 6.8	0.672
Procedure success rate	217 (94.3)	257 (94.5)	1.000
Vascular complications	18 (7.8)	20 (7.3)	0.786
Main bleeding	8 (3.4)	9 (3.3)	0.569
Death in hospital	3 (1.3)	8 (2.9)	0.000*
Staged stenting	35 (15.2)	31 (11.4)	0.121
IABP use	7 (3.0)	9 (3.3)	0.643
Gp II b/IIIa inhibitor use	47 (20.4)	62 (22.8)	0.420

Data are presented as mean ± SD or *n* (%). CR: complete revascularization; IABP: Intra Aortic Balloon Pump; IR: incomplete revascularization; LAD: left anterior descending; LCX: left circumflex; LM: left main; RCA: right coronary artery.

Table 3. Long-term (12–78 months) clinical follow-up outcomes.

	CR, *n* = 194	IR, *n* = 235	*P* Value
Death of all causes	15 (7.7)	32 (13.6)	0.050
MACCE	29 (14.9)	48 (20.4)	0.141
Cardiac death	9 (4.6)	22 (9.4)	0.126
Non-fatal AMI	5 (2.6)	3 (1.3)	0.322
Target vessel revascularization	11 (5.7)	13 (5.5)	0.951
Cerebral vascular disease	16 (8.2)	15 (6.4)	0.458
Angina recurrence within 6 months	98 (50.5)	124 (52.8)	0.642
Readmission	59 (30.4)	68 (28.9)	0.739

Data are presented as *n* (%). AMI: acute myocardial infarction; CR: complete revascularization; IR: incomplete revascularization; MACCE: main adverse cardiac and cerebral events.

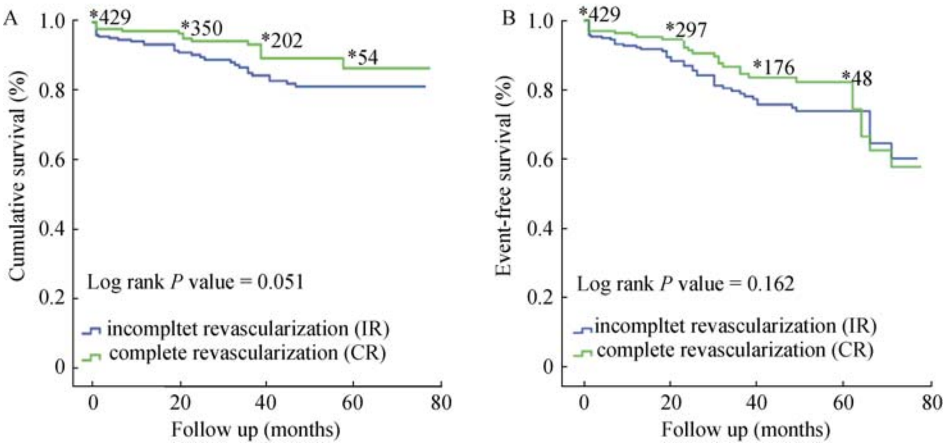

Figure 2. Kaplan-Meier survival curves of patients undergoing CR and IR. (A): cumulative survival; (B): event-free survival.

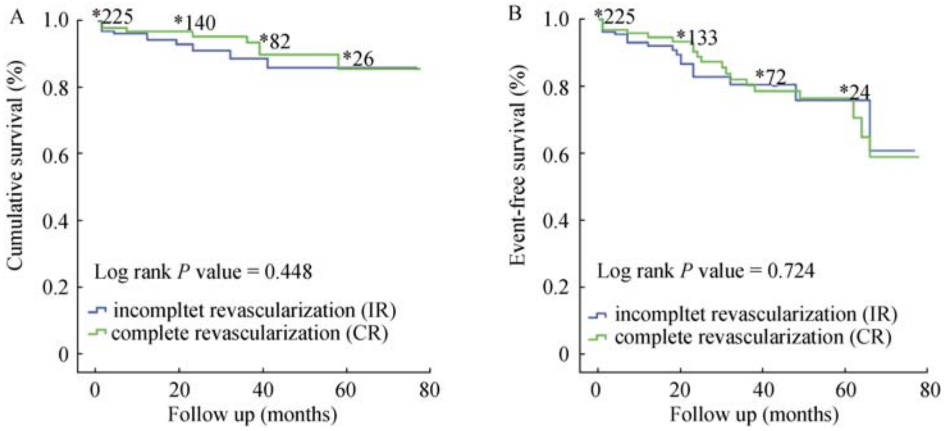

Figure 3. Kaplan-Meier survival curves of patients with multi-vessel disease undergoing CR and IR. A: cumulative survival; B: event-free survival.

4 Discussion

Along with the development of instruments and techniques related to PCI, elderly patients present a growing proportion of patients treated with PCI in the real world. In these high-risk patients, the benefit of CR by PCI is controversial.[21,22]

A number of reasons may explain why we observed a higher prevalence of IR in elderly patients. One main possibility is that complex clinical conditions and severe coronary lesions not only bring more difficulty to PCI, but also increase mortality.[23,24] According to a report from American College of Cardiology National Cardiovascular Database Registry, contributing factors are independently associated with the performance of single-vessel rather than multi-vessel PCI involved the presentation of NSTEMI or total occlusion and being older.[25,26] Our population shares the similar characteristics in elderly patients in previous studies, including more clinical co-morbidities, a higher prevalence of ACS, multiple vessel disease and complex lesions, especially in the patients who underwent IR. Our results demonstrate that older age, a history of prior myocardial infarction, and a higher SYNTAX Score are predictors for higher in-hospital mortality in the IR group, which indicates that the higher the risk, the worse the outcomes, irrespective of the completeness of revascularization.

Previous studies have noted that octogenarians to be completely revascularized undertook much higher risk, such as acute or sub-acute thrombosis, sudden death or bleeding.[16,27,28] In our research, the PCI characteristics and complications were similar between the CR and IR groups. Our results showed that there was no significant difference in cumulative survival and event free survival between the CR and IR groups. A previous study also reported that procedural success rates were significantly higher in single-vessel PCI, while rates of morbidity, bleeding, renal failure and nonfatal cardiogenic shock were similar, which indicated that in patients with multi-vessel disease, the in-hospital outcome of multi-vessel PCI appears to be at least as successful as single-vessel PCI.[29]

Investigators revealed the results of PCI in 356 patients aged ≥ 80 years among which 48% obtained CR. There were no differences in acute and 12 months total events between completely or incompletely revascularized subjects.[17] Frequent use of glycoprotein IIb/IIIa inhibitors may improve the immediate and mid-term clinical outcomes, irrespective of the completeness of revascularization obtained. However, elderly patients (>75) were significantly less often treated with GP IIb/IIIa antagonists.[30] In our experience, IR does not increase long-term mortality and MACCE, and angina presentations could be relieved as well. At the same time, vascular complications and main bleeding complications are acceptable in the two groups. One in five of the enrolled participants were treated with GP IIb/IIIa antagonists. Finally, similar to previous data,[15,30-33] we identified that advanced age and history of multi-vessel disease were independent predictors of long-term MACCE and cardiac mortality. Previous studies indicated that aging might exacerbate myocardial ischemia / reperfusion injury in humans and rats, which may significantly decrease cardiac function. Furthermore, the elderly with hypertension were expected to have more risk of MACCE.[34]

In conclusion, this study represents the relatively substantial experience of a single tertiary center in China, and the results remain to be further validated by multi-center investigations. The enrolled patients do not have the same follow-up period in this interim study, but we plan to continue with the follow-up results of the whole cohort at three and five years hereafter. Although both the clinical and coronary disease characteristics are much more complex, the elderly patients underwent IR could achieve the same successful long-term outcomes.

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