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Do coronary stent policies affect the cost-effectiveness of percutaneous coronary intervention among patients with acute coronary syndrome in Shanghai? A retrospective cohort study based on real-world and propensity score-matched data

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ABSTRACT

Objectives This study aimed to assess whether the national centralised volume-based procurement policy and the Shanghai government's supportive measures (coronary stent policies) implemented in Shanghai, China, on 20 January 2021 affected the cost-effectiveness of percutaneous coronary intervention (PCI) in patients with acute coronary syndrome (ACS) in the year after surgery.

Design A retrospective cohort study based on real-world data and propensity score (PS)-matched data was conducted to compare the cost-effectiveness of PCI before and after policy implementation.

Patients and setting Patients with ACS who had undergone first-time PCI over 1 year previously in hospitals in Shanghai and were discharged between 1 March 2019 and 30 April 2022 were included in the study.

Outcome measures In the present study, cost was defined as total direct medical expenses, and effectiveness was defined as the prevention of major adverse cardiac events (MACEs). Incremental cost-effectiveness ratios (ICERs) were used to measure the cost-effectiveness of PCI in patients with ACS 1 year after surgery.

Results The study included 31 760 patients. According to real-world and PS-matched data, the implementation of coronary stent policies in Shanghai reduced the total medical cost of patients with ACS 1 year after PCI by 24.39% (p<0.0001) and 22.26% (p<0.0001), respectively. The ICERs were ¥−1131.72 and ¥−842.00 thousand per MACE avoided, respectively. The ICERs were robust to parameter uncertainty, and there was a substantial chance for policy implementation to improve the cost-effectiveness of PCI among patients with ACS in the short term.

Conclusions The implementation of coronary stent policies has improved the cost-effectiveness of PCI for patients with ACS in the short term. The long-term impact of coronary stent policies on the cost-effectiveness of PCI in patients with ACS or other coronary heart diseases should be assessed in the future.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Based on propensity score (PS)-matched data, the cost-effectiveness of percutaneous coronary intervention before and after policy implementation was compared while controlling for influencing factors (such as demographic and clinical characteristics) to some extent.
- ⇒ Although 12 medicines prescribed at outpatient visits were included in the multilevel logistic model for the probability of major adverse cardiac events (MACEs) and in the general linear model for total medical costs, the dosage of these medicines and the duration of their use were not considered in the models.
- ⇒ Although PS matching was used to balance the baseline characteristics of patients with acute coronary syndrome in the postpolicy and prepolicy cohorts, there might still be some unmeasured confounders that could have affected MACE occurrence and total medical costs.
- ⇒ Generalising the study results to other regions of China or other countries should be done with caution.

INTRODUCTION

Coronary heart disease (CHD) is the most common type of heart disease and a leading cause of death globally.[1] In 2019, the mortality rate of CHD in China was 121.59/100 000 for urban residents and 130.14/100 000 for rural residents, with a continuous upwards trend.[2] Because most patients diagnosed with CHD will undergo percutaneous coronary intervention (PCI) for coronary artery revascularisation,[3] the total number of PCIs was 915 256 in 2018, which was a prevalence of 651 PCIs per million residents and an average number of 1.46 stents per patient with CHD in China.[4] The substantial number of PCIs performed combined with the high cost of the stents used for PCI are a heavy economic burden worldwide.[5–7]

In December 2020, the central government of China issued a national centralised volume-based procurement (VBP) policy for coronary stents to reduce stent prices. The Chinese government announced that 10 types of coronary stents were selected for VBP, and the prices for these bid-winning coronary stents decreased from more than ¥10 thousand to less than ¥1 thousand. Furthermore, the cost of these coronary stents would be covered under basic medical insurance according to the bid-winning prices with a possible copayment.[8] All of these coronary stent policies were implemented in Shanghai beginning 20 January 2021. Our previous study showed that the implementation of coronary stent policies in Shanghai reduced the inpatient care costs for patients with CHD who underwent PCI in hospitals by approximately ¥400 million per year, and the proportion of patients with CHD who had undergone PCI using at least one bid-winning coronary stent increased from 54.35% to 84.10%.[8 9] However, a lack of evidence that coronary stent policies improve cost-effectiveness in patients who undergo PCI might cause concerns about balancing the safety and cost of PCI.

The aim of this study was to assess whether the implementation of coronary stent policies in Shanghai improved the cost-effectiveness of PCI in patients with acute coronary syndrome (ACS) 1 year after PCI. We selected patients with ACS to evaluate the effect of coronary stent policies on the cost-effectiveness of PCI because PCI is the preferred means of coronary revascularisation for these patients based on international guidelines.[5]

METHODS

Data source

We conducted a retrospective cohort study, and all study data were obtained from the Shanghai Statistics Center for Health. This centre houses all of the data related to inpatient, outpatient and emergency care; medical records, including information on inpatient admissions and medical histories; and databases that detail prescriptions, medical expenses and population-based deaths.

Inclusion and exclusion criteria

The patients included in the study were those with a first diagnosis of ACS who (1) had undergone PCI but not in the previous year ('first-time PCI' hereafter) in hospitals in Shanghai; (2) were Shanghai residents and discharged between 1 March 2019 and 30 April 2022; and (3) had undergone their first-time PCI more than 1 year prior. These inclusion criteria allowed us to identify patients who had undergone PCI in both the postpolicy and prepolicy periods and to obtain their medical data for the first year after PCI. In addition, we included more patients in the prepolicy cohort using a longer range of discharge dates to obtain more relevant data in the prepolicy period.

Patients who did not have any outpatient visits for cardiovascular disease (CVD) in the first year after PCI were excluded from the study. This exclusion criterion allowed us to collect information about the costs and outcomes of patients in 1 year after PCI (online supplemental figure S1).

Cost-effectiveness analyses

In this study, cost was defined as total direct medical expenses, including initial inpatient care expenses (involving first-time PCI), outpatient care expenses during the year after PCI, and readmission expenses for CVD after PCI, and was analysed using Chinese yuan. Effectiveness was defined as the prevention of major adverse cardiac events (MACEs). MACEs referred to death from any cause, coronary artery revascularisation, non-fatal myocardial infarction with no revascularisation (MI) and coronary artery restenosis or stent thrombosis.

The included patients were divided into a postpolicy cohort and a prepolicy cohort. Using a 1-year decision tree, the incremental cost-effectiveness ratio (ICER) for the postpolicy period relative to the prepolicy period was calculated by dividing the incremental cost by the incremental gain in the prevention of MACEs a year after PCI. To assess the effect of the policy implementation, a cost-effectiveness assessment was performed from the perspective of the healthcare system focused on the overall effect of the policy implementation; the effect of the policy implementation on the cost-effectiveness of PCI in subgroups of ACS patients was not estimated.

Deterministic sensitivity analyses (DSAs) and probabilistic sensitivity analyses (PSAs) were performed to test the robustness of the ICERs to parameter uncertainty. In one-way DSAs with 5000 samples, the minimum and maximum ranges for all parameters were ±30% of the probability or ±30% of the average total medical cost for each event. In the PSAs, 5000 Monte Carlo simulations were completed, using beta distributions for the probability and gamma distributions for the cost. Cost-effectiveness was defined as a willingness-to-pay (WTP) threshold of ¥160.0 thousand per MACE avoided because the gross domestic product per capita in Shanghai in 2019, 2020 and 2021 was ¥153.3, ¥156.8 and ¥173.6 thousand, respectively. An acceptance curve with a WTP ranging from ¥0 to ¥600 thousand was plotted.

No discount was used for cost and effectiveness in this study. Compared with those in the previous year, the consumer price indices overall and for healthcare in Shanghai were 101.7 and 101.2 in 2020 and 101.2 and 98.9 in 2021, respectively. In addition, the price of coronary stents dropped dramatically after the implementation of coronary stent policies on 20 January 2021.

For clarity, the ICERs and the WTP threshold ranges in Monte Carlo simulations are also presented in US$ in the Discussion section, based on the US dollars to renminbi exchange rate of 6.53 on 1 January 2021.

Statistical analyses

In the present study, the χ^2 test was used to compare categorical variables before and after the implementation of coronary stent policies, the Wilcoxon Z test was used for cost variables, Student's t-test was used for the continuous variable of age. Missing data were not filled.

To analyse whether the implementation of coronary stent policies affected the probability of MACEs and total medical costs during the year after PCI, we used a multilevel logistic model and a general linear regression model (GLM) to control for the random effect of medical institutions and fixed effects of demographic characteristics (age, sex, medical insurance coverage); clinical characteristics (medical history, admissions to various types of hospitals, New York Heart Association (NYHA) or Killip functional classification, and number of coronary stents implanted); and 12 medicines used in outpatient care in the year after PCI, including anticoagulant and antiplatelet drugs (aspirin, clopidogrel, ticagrelor), nitrates (nicorandil, isosorbide dinitrate), beta-blockers (metoprolol), angiotensin receptor-enkephalinase inhibitors (sacubitril/valsartan), angina attack preventive drugs (trimetazidine dihydrochloride), cholesterol absorption inhibitors (ezetimibe) and statins (atorvastatin, rosuvastatin, pravastatin sodium). These 12 medicines were the most frequently prescribed to ACS patients at outpatient visits after PCI accounting for 73.49% of the total prescriptions. Dual antiplatelet therapy is the standard-of-care treatment for patients undergoing PCI to prevent stent thrombosis.[10] The Chinese guidelines for CVD prevention (2017) also recommended the use of aspirin plus clopidogrel for at least 12 months after PCI and the use of ticagrelor or prasugrel as alternative medicines for patients who cannot tolerate clopidogrel or who have shown clear evidence of clopidogrel resistance.[11] However, there were no ACS patients who used prasugrel after PCI in our study; therefore, this medication was not included in the analyses. We used outpatient medication as a fixed factor in the models because it may affect MACE occurrence and total medical costs in the year after PCI.[3 12] In the GLM, the response variable was the log-transform of total medical costs in the year after PCI because cost was not normally distributed.

The empty models of the multilevel logistic model for MACE probability and multilevel GLM for total medical costs showed that the intraclass correlation coefficients (ICCs) were 0.318 and 0.122, respectively; the t values were 4.21 and 429.19, respectively; and all p values were <0.0001, which indicated the appropriateness of using multilevel models.

Propensity score analyses

Regarding possible bias related to patient background, the propensity score (PS) was used to reduce the differences in patient background between the postpolicy and prepolicy cohorts as much as possible.

The fixed effects of demographic and clinical characteristics that significantly influenced MACE probability at 1 year and total medical costs during the year after PCI were included in the PS model to generate the PS-matched postpolicy and prepolicy cohorts. Age and level of the admission hospital were also included in the PS model to control for patient background and quality of PCI.

PSs were derived using a logistic regression model that included demographic characteristics (sex, age, medical insurance coverage) and clinical characteristics (diabetes, hypertension, previous coronary artery bypass grafting (CABG), level of the admission hospital, severity of heart function). In this study, an NYHA or Killip functional classification of IV was defined as severe heart malfunction. In addition, in PS matching, the logit of the PS was used as the 'distance' to compare the postpolicy and prepolicy cohorts, the 1:1 matching method (greedy matching) was applied, and a calliper width of 0.25 was specified. In the PS model, sex and medical history of diabetes, hypertension and CABG were requested for exact matching.

PS matching created 4098 patient pairs in the postpolicy and prepolicy cohorts. After PS matching, cost-effectiveness analyses with DSAs and PSAs were conducted on PS-matched data using the same procedures as those used for real-world data.

SAS 9.4 software (SAS Institute Inc., Cary, NC, USA) and TreeAge 2021 R2.1 software (TreeAge Software, Inc., Williamstown, MA, USA) were used for the statistical analyses and cost-effectiveness analyses, respectively.

Patient and public involvement

None.

RESULTS

Characteristics of patients with ACS

The total number of patients with ACS who had undergone PCI was 31 760 from 19 secondary hospitals and 38 tertiary hospitals in Shanghai. Analyses of real-world data by Student's t-test or the χ^2 tests, revealed statistically significant differences in most patient demographic characteristics between the postpolicy and prepolicy cohorts, including age (65.03±11.61 vs 65.52±11.52 years, p<0.0001), medical insurance coverage (88.34% vs 89.16%, p=0.0356) and proportions of previous medical conditions (all p values were <0.05) (diabetes (30.98% vs 32.97%), hypertension (58.68% vs 63.44%), hyperlipidaemia (30.53% vs 33.53%), stroke (0.90% vs 1.16%), chronic kidney disease (9.40% vs 10.50%), chronic obstructive pulmonary disease (2.79% vs 3.35%), previous MI (7.19% vs 8.90%) and previous CABG (2.94% vs 4.40)). However, there was no significant difference in the diagnostic classification of ACS (unstable angina pectoris (43.79% vs 42.55%), non-ST-segment elevation MI (22.87% vs 23.49%), ST-segment elevation MI (33.02% vs 33.58%), or undetermined (0.32% vs 0.38%)) (p=0.2026) or proportion of male patients (75.55% vs 75.60%, p=0.9038) (online supplemental table S1).

There were also statistically significant differences in clinical characteristics between the two cohorts, including level of the admission hospital (88.89% vs 91.26% at tertiary hospitals) and NYHA or Killip functional classification (60.59% vs 55.68% at classification of I). All p values were <0.0001 for the χ^2 tests (online supplemental table S1).

In addition, there was no significant difference between the two cohorts for aspirin use (69.64% vs 69.10%, p value=0.3459) in outpatient care 1 year after PCI, while there were significant differences in the use of clopidogrel (52.23% vs 53.76%, p=0.0135), ticagrelor (44.95% vs 49.89%, p<0.0001) and other medications (p<0.05) (online supplemental table S1).

Moreover, the proportion of patients with ACS who had three or more coronary stents implanted during PCI was greater in the postpolicy cohort than in the prepolicy cohort (6.27% vs 4.39%), and the proportion of patients with ACS who had undergone PCI with at least one bid-winning stent was 86.52% in the postpolicy cohort but only 55.67% in the prepolicy cohort. In the ACS patients who underwent first-time PCI, all the bid-winning stents implanted were drug-eluting or drug-coating stents, while the bid-nonwinning stents included drug-eluting, drug-coating and biodegradable stents. Bare metal stents were not used in any of the patients.

After using PS matching to generate PS-matched postpolicy and prepolicy cohorts, the two PS-matched cohorts were the same in sex ratio; history of diabetes, hypertension and CABG; and severity of heart function. There were no significant differences in age or the proportion of patients with medical insurance (t value was −0.05 for age; χ^2 was 0.05 for age and 0.01 for the proportion of patients with medical insurance; all p values >0.05) (online supplemental table S2).

Probability of MACEs and total medical costs for each event during the year after PCI

Analyses using real-world data revealed that patients with ACS in the postpolicy cohort had a greater probability of being MACE-free and a lower probability of revascularisation during the year after PCI than did those in the prepolicy cohort (0.8167 vs 0.7992 and 0.1623 vs 0.1766, respectively). The analyses using PS-matched data had similar results. The probabilities of MACE-free survival and revascularisation during the year after PCI in the PS-matched postpolicy and prepolicy cohorts were 0.8184 versus 0.7967 and 0.1596 versus 0.1803, respectively (table 1).

Analyses using real-world data showed that patients with ACS in the postpolicy cohort had much lower average total medical costs for each MI, revascularisation, death and MACE-free event in the year after PCI (¥86 768.20, ¥98 764.88, ¥111 610.76 and ¥53 260.80, respectively) than did those in the prepolicy cohort (¥102 291.26, ¥134 962.50, ¥172 267.88 and ¥68 435.20, respectively). However, the analyses using PS-matched data showed that only the average total medical costs for each revascularisation and MACE-free event the year after PCI significantly differed between the two PS-matched cohorts (table 2).

The implementation of coronary stent policies in Shanghai reduced the total medical costs by ¥19 810.32 (24.39% reduction, p<0.0001) on average for each patient with ACS in the year after PCI according to real-world data and ¥18 277.16 (22.26% reduction, p<0.0001) on average according to PS-matched data (table 2).

Table 1 Probability of each event 1 year after percutaneous coronary intervention in the postpolicy and prepolicy cohorts

		Postpolicy (i=1)			Prepolicy (i=2)				
	Events	n	Probability (P)	Range	n	Probability (P)	Range	χ^2	P value
Based on real-world data									
j=1	Restenosis or stent thrombosis	14	0.0016	0.0011–0.0021	31	0.0014	0.0010–0.0018	0.18	0.6741
j=2	MI	150	0.0167	0.0117–0.0217	453	0.0199	0.0139–0.0259	3.53	0.0602
j=3	Revascularisation	1458	0.1623	0.1136–0.2110	4023	0.1766	0.1236–0.2296	9.31	0.0023
j=4	Death	24	0.0027	0.0019–0.0035	67	0.0029	0.0020–0.0038	0.17	0.6845
j=5	MACE-free	7336	0.8167	$1-P_{11}-P_{12}-P_{13}-P_{14}$	18 204	0.7992	$1-P_{21}-P_{22}-P_{23}-P_{24}$	12.60	0.0004
Based on PS-matched data									
j=1	Restenosis or stent thrombosis	5	0.0012	0.0008–0.0016	5	0.0012	0.0008–0.0016	0.00	1.0000
j=2	MI	68	0.0166	0.0116–0.0216	72	0.0176	0.0123–0.0229	0.12	0.7331
j=3	Revascularisation	654	0.1596	0.1117–0.2075	739	0.1803	0.1262–0.2344	6.25	0.0124
j=4	Death	17	0.0041	0.0029–0.0053	17	0.0041	0.0029–0.0053	0.00	1.0000
j=5	MACE-free	3354	0.8184	$1-P_{11}-P_{12}-P_{13}-P_{14}$	3265	0.7967	$1-P_{21}-P_{22}-P_{23}-P_{24}$	6.22	0.0126

*Pij: i represents postpolicy or prepolicy implementation, j represents events.
MACE, major adverse cardiac event; MI, myocardial infarction; PS, propensity score.

Table 2 Total medical cost of each event 1 year after percutaneous coronary intervention in the postpolicy and prepolicy cohorts

		Postpolicy (i=1)				Prepolicy (i=2)					
	Events	Mean	SD	Median	Range	Mean	SD	Median	Range	$Z_{Wilcoxon}$	P value
Based on real-world data											
j=1	Restenosis or stent thrombosis	94 746.90	36 658.98	92 731.62	66 322.83–123170.97	122 707.51	48 118.43	109 075.38	85 895.26–159519.76	–1.85	0.0642
j=2	MI	86 768.20	38 109.32	80 036.36	60 737.74–112798.66	102 291.26	51 984.81	89 903.96	71 603.88–132978.64	–3.46	0.0005
j=3	Revascularisation	98 764.88	41 737.79	89 145.12	69 135.42–128394.34	134 962.50	54 692.45	124 579.64	94 473.75–175451.25	–27.32	<0.0001
j=4	Death	111 610.73	94 319.85	87 808.14	78 127.51–145093.95	172 267.88	144 780.86	128 075.02	120587.52–223948.24	–2.87	0.0041
j=5	MACE-free	53 260.80	27 459.54	46 094.89	37 282.56–69 239.04	68 435.20	31 058.39	60 096.14	47 904.64–88 965.76	–46.77	<0.0001
	Total	61 427.38	35 316.45	51 724.53	–	81 237.70	45 747.81	67 707.17	–	–46.39	<0.0001
Based on PS-matched data											
j=1	Restenosis or stent thrombosis	104 484.78	47 154.35	92 906.70	73 139.35–135830.21	116 492.42	45 621.90	116 455.51	81 544.69–151440.15	–0.21	0.8345
j=2	MI	91 473.95	39 862.41	82 634.67	64 031.77–118916.14	98 732.74	43 019.46	91 385.84	69 112.92–128352.56	–0.87	0.3870
j=3	Revascularisation	103 489.66	41 408.98	92 720.56	72 442.76–134536.56	136 092.33	64 281.86	124 432.21	95 264.63–176920.03	–13.88	<0.0001
j=4	Death	131 494.93	103 555.04	91 141.06	92 046.45–170943.41	223 020.02	232 709.80	137 136.39	156114.01–289926.03	–1.24	0.2150
j=5	MACE-free	55 121.08	28 245.33	47 585.52	38 584.76–71 657.40	68 723.26	30 610.28	60 239.93	48 106.28–89 340.24	23.74	<0.0001
	Total	63 820.50	36 648.64	53 589.38	–	82 097.66	49 935.32	68 430.76	–	–23.50	<0.0001

MACE, major adverse cardiac event; MI, myocardial infarction; PS, propensity score.

Factors influencing the MACE-free probability and total medical costs

Using the multilevel logistic model and GLM to control for the random effect of medical institution and fixed effects of demographic characteristics, clinical characteristics and outpatient medications, the results showed that the implementation of coronary stent policies significantly reduced the probability of MACEs (OR=0.808, 95% CI 0.704 to 0.928) and total medical costs during the year after PCI (table 3). The adjusted total medical cost for patients with ACS during the year after PCI was ¥62 874.75 on average in the postpolicy cohort, which was much lower than that in the prepolicy cohort (¥84 178.94).

In addition, after controlling for other factors, including sex; medical insurance coverage; medical history of diabetes, hypertension or previous CABG; NYHA or Killip functional classification; and number of coronary stents implanted, the policy implementation influenced the probability of MACEs and/or total medical costs in the year after PCI (table 3).

Cost-effectiveness and sensitivity analyses

For real-world data and PS-matched data, the ICERs for postpolicy relative to prepolicy were ¥–1131.72 and ¥–842.00 thousand per MACE saved, respectively, with ‘dominant’ positions (table 4).

A tornado diagram demonstrated that when the ranges of all parameters were defined as ±30% of the probability or average total medical costs for each event and 5000 samples were used, the ranges of ICERs for postpolicy relative to prepolicy were all less than 0, regardless of whether real-world data or PS-matched data were used (online supplemental figure S2).

When Monte Carlo simulations with 5000 samples were conducted with a WTP threshold of ¥160 thousand per MACE prevented, the probabilities that the implementation of coronary stent policies improved the cost-effectiveness of PCI in patients with ACS were 75% and 74%, respectively, for real-world data and PS-matched data (online supplemental figure S3). When the WTP threshold was increased to ¥480 thousand per MACE prevented, the probabilities reached to 80% (figure 1). Cost-effectiveness scatterplots are presented in online supplemental figure S4.

DISCUSSION

Cost reduction after the implementation of coronary stent policies

Based on real-world and PS-matched data, the implementation of coronary stent policies in Shanghai reduced the total medical costs of patients with ACS 1 year after PCI by 24.39% and 22.26%, respectively, similar to how the daily cost of generic cardiovascular drugs decreased by 24.24% in Shanghai after the implementation of a national centralised VBP policy for drugs.[13] Using a multilevel GLM to control for the random effect of medical institution and other fixed effects of demographic characteristics, clinical characteristics and outpatient medications during the year after PCI, the policy implementation was found to reduce the adjusted total medical costs by 25.31% for patients with ACS the year after PCI.

Although the difference-in-differences approach could not be applied in this type of study, an interrupted time series model in our previous Shanghai study revealed that there was a large, instantaneous decrease (¥–9142.12; 95% CI ¥–7926.98 to ¥–10 357.26; approximately US$–1400 (95% CI US$1214 to US$1586)) in average inpatient cost after stent policy implementation in patients with CHD (39.12% of whom underwent PCI). This decrease is not easily explained by any reasons other than stent policy implementation.[9] In this study, the cost reduction may be attributed not only to the large decrease in the price of bid-winning stents and the substantial increase in the proportion of patients using at least one bid-winning stent (from 55.67% before the policy implementation to 86.52% after the policy implementation) but also to the decrease in the price of bid-nonwinning stents because of the spillover effect. The national centralised VBP policy for coronary stents achieved negotiation power for stent prices and combined government supportive measures in Shanghai, and the cost reduction relieved some of the economic burden for patients with ACS who underwent PCI, possibly increasing the accessibility of PCI.

Cost-effectiveness of PCI improved by policy implementation

Although the implementation of coronary stent policies reduced the cost of PCI, the impact of the policy implementation on the safety and cost-effectiveness of PCI deserves attention. Using real-world data, this study revealed that the probability of revascularisation in ACS patients during the year after PCI was slightly lower after the policy was implemented than before (0.1623 vs 0.1766). There were no significant differences in the probabilities of other MACEs before or after policy implementation. Using a multilevel logistic model to control for the random effect of medical institution and other fixed effects, policy implementation reduced the probability of MACEs among patients with ACS in the year after PCI by approximately 20% (OR=0.808).

Based on real-world data and PS-matched data, the study revealed that the ICERs for postpolicy relative to prepolicy were ¥–1131.72 and ¥–842.00 thousand (approximately US$–173 and US$–129 thousand) per MACE prevented, respectively, with ‘dominant’ positions. Based on real-world data and PS-matched data, sensitivity analyses (DSA and PSA) demonstrated the robustness of the ICERs to parameter uncertainty. When Monte Carlo simulations were performed with 5000 samples and at a WTP threshold from ¥160 to ¥600 thousand (approximately from US$25 to US$92 thousand) per MACE prevented, the probabilities that the implementation of coronary stent policies improved the cost-effectiveness of PCI in patients with ACS ranged from 75% and 74% to more than 80%. There is a substantial chance that the implementation of coronary stent policies will improve

Table 3 Multilevel logistic model for MACE probability and general linear regression model for total medical costs 1 year after PCI (n=6375)*

Fixed effects	Probability of MACEs							Logarithmic value of total medical cost			
	Estimate	SD	T value	P value	OR	95% CI		Estimate	SD	T value	P value
Intercept	−1.6723	0.2136	−7.83	<0.0001				11.0183	0.0565	195.14	<0.0001
Policy implementation (1: yes, 0: no)	−0.2130	0.0704	−3.03	0.0025	0.808	0.704	0.928	−0.2918	0.0115	−25.30	<0.0001
Tertiary hospital (1: yes, 0: no)	−0.0411	0.1772	−0.23	0.8177	0.960	0.671	1.373	−0.0267	0.0616	−0.43	0.6674
Age, years (reference: <60)											
60–	0.0431	0.0840	0.51	0.6080	1.044	0.886	1.231	0.0235	0.0138	1.70	0.0883
70–	−0.0900	0.0929	−0.97	0.3324	0.914	0.762	1.096	0.0259	0.0150	1.72	0.0856
Male (1: yes, 0: no)	0.2706	0.0837	3.24	0.0012	1.311	1.113	1.544	0.0540	0.0130	4.16	<0.0001
No medical insurance (1: yes, 0: no)	0.0626	0.1092	0.57	0.5663	1.065	0.859	1.319	−0.0922	0.0176	−5.24	<0.0001
Medical history											
Diabetes (1: yes, 0: no)	0.2582	0.0753	3.43	0.0006	1.295	1.117	1.501	0.0639	0.0124	5.13	<0.0001
Hypertension (1: yes, 0: no)	0.2026	0.0800	2.53	0.0113	1.225	1.047	1.432	0.0481	0.0129	3.72	0.0002
Hyperlipidaemia (1: yes, 0: no)	−0.0907	0.0810	−1.12	0.2626	0.913	0.779	1.070	0.0030	0.0132	0.23	0.8184
Stroke (1: yes, 0: no)	−0.0558	0.3430	−0.16	0.8708	0.946	0.483	1.853	0.0168	0.0531	0.32	0.7520
Chronic kidney disease (1: yes, 0: no)	−0.0244	0.1160	−0.21	0.8334	0.976	0.777	1.225	0.0014	0.0188	0.08	0.9391
Chronic obstructive pulmonary disease (1: yes, 0: no)	−0.2996	0.2037	−1.47	0.1414	0.741	0.497	1.105	−0.0346	0.0306	−1.13	0.2590
MI (1: yes, 0: no)	−0.0894	0.1370	−0.65	0.5142	0.915	0.699	1.196	0.0016	0.0219	0.07	0.9421
CABG (1: yes, 0: no)	−0.5286	0.2345	−2.25	0.0242	0.589	0.372	0.933	−0.1034	0.0329	−3.15	0.0017
NYHA or Killip functional classification (reference: I)											
IV (1: yes, 0: no)	0.3182	0.1910	1.67	0.1004	1.375	0.939	2.013	0.2695	0.0341	7.89	<0.0001
II or III (1: yes, 0: no)	−0.1968	0.0765	−2.57	0.0124	0.821	0.705	0.957	0.0237	0.0123	1.93	0.0581
Number of coronary stents implanted (reference: 1)											
2 (1: yes, 0: no)	0.1021	0.0812	1.26	0.2089	1.107	0.944	1.299	0.2165	0.0135	16.09	<0.0001
3 (1: yes, 0: no)	−0.0115	0.1659	−0.07	0.9449	0.989	0.714	1.369	0.3360	0.0266	12.64	<0.0001
4 or more (1: yes, 0: no)	0.3497	0.3376	1.04	0.3004	1.419	0.732	2.750	0.4488	0.0593	7.57	<0.0001
−2 res log likelihood	30 366.15							7077.43			
Generalised χ^2/DF	1.00							0.17			

*In the models, the response variable was MACE occurrence (1: yes, 0: no) or the logarithmic value of total medical cost (yuan); the random effect of medical institution and the fixed effect of outpatient medicines used within 1 year after PCI were controlled.
CABG, coronary artery bypass grafting; MACE, major adverse cardiac event; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.

Table 4 ICER for postpolicy relative to prepolicy in acute coronary syndrome patients 1 year after percutaneous coronary intervention

Implementation of coronary stent policies	Total medical cost (thousand ¥)	Incremental cost (thousand ¥)	Number of MACEs prevented	Incremental effectiveness (number of MACEs prevented)	ICER
Based on real-world data					
Postpolicy	6 142 960.83	–1 980 514.44	81 670	1750	–1131.72
Prepolicy	8 123 475.28		79 920		
Based on PS-matched data					
Postpolicy	6 381 653.22	–1 827 147.76	81 850	2170	–842.00
Prepolicy	8 208 800.99		79 680		

ICER, incremental cost-effectiveness ratio; MACEs, major adverse cardiac events; PS, propensity score.

the cost-effectiveness of PCI in patients with ACS in the short term.

Complementary way to conduct cost-effectiveness analyses

In our study, the use of complementary data makes the study findings more meaningful. Considering that real-world data on all ACS patient subgroups with different known or unknown risks are available, the cost-effectiveness analyses in this study provide real-world evidence to decision makers (including policy makers and clinical decision makers) about whether policy implementation affects the costs and health outcomes of PCI and the extent of cost-effectiveness. Because the impact of the national centralised VBP policy on the cost-effectiveness of drugs or coronary stents has not been well addressed previously in China,[13–16] the findings of this study enrich the knowledge of the impact of the national centralised VBP policy in the real world. The positive findings of the study also provide evidence that the national centralised VBP policy can probably be extended to other implanted devices in China as well as to other countries. Using PS-matched data, the backgrounds of the ACS patients were controlled to some extent, making the sampled postpolicy and prepolicy patient populations more comparable. This may be crucial from a scientific view.

Limitations

The effects of coronary stent policies on the cost-effectiveness of PCI in ACS patients are influenced by various factors.[15 17–19] This study has several limitations. First, data on cardiac function and the number of coronary stents implanted were not successfully extracted for some ACS patients. This caused a reduction in the sample size in the PS matching model and therefore might have led to selection bias in the PS-matched data. Second, although 12 medications prescribed at outpatient visits were included in the multilevel logistic model and GLM, the dosage of these medications and the duration of their use were not considered in the models, which were too complex to conduct such analyses. Third, the COVID-19 pandemic may have limited the attainability of PCI due to the overwhelmed health services, delayed patients from seeking medical care and extended the time for reperfusion, which are linked to a greater risk of adverse events and death.[20] In this study, the COVID-19 pandemic obviously affected medical care in Shanghai

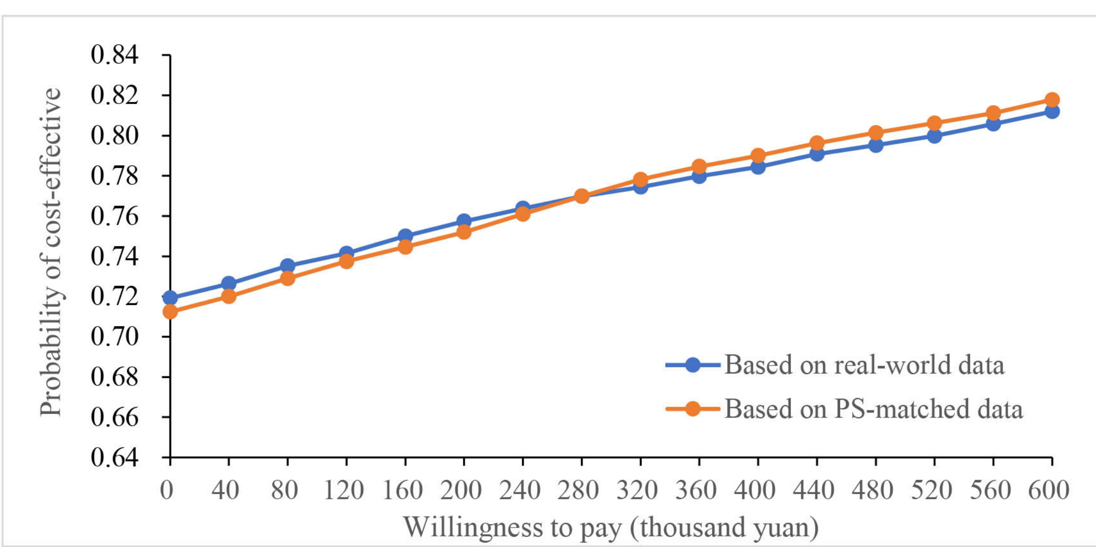

Figure 1 Cost-effectiveness acceptability curve (postpolicy vs prepolicy).

only in April and May of 2022, when the city was almost shut down (not including hospitals), affecting only the postpolicy cohort. However, within 1 year after their first PCI, ACS patients with severe conditions (such as coronary artery restenosis, coronary stent thrombosis and MI) generally sought medical care through emergency departments or outpatient departments and inpatient departments thereafter, even in April and May of 2022 in Shanghai. Furthermore, all ACS patients in the postpolicy and prepolicy cohorts were more than 6 months after their first PCI in April 2022. Our previous study showed that the majority of MACEs that occurred within 1 year after PCI in ACS patients occurred within 60 days after PCI. Using the same study data as we did in this study, the adjusted and unadjusted probability trends of MACE-free survival between the two cohorts were parallel and smooth from 61 to 360 days after PCI. There was no indication that the COVID-19 pandemic significantly affected the medical care of ACS patients in Shanghai in April to May of 2022.[21] Considering that the main reduction in MACEs was observed for coronary artery revascularisation between the two cohorts and that the number of deaths included those who died at hospitals and at home, the COVID-19 pandemic might have limited the ability of the study to confirm these findings. Fourth, although we used a PS to balance the baseline characteristics of patients with ACS between the postpolicy and prepolicy cohorts, there might be some unmeasured confounders that could have affected MACE occurrence and total medical costs (such as vascular access site for PCI, time of PCI admission, physician's experience, and type and complexity of the lesion[22 23]). Fifth, the effect of coronary stent policies on the cost-effectiveness of PCI in patients with ACS was retrospectively assessed only at 1 year after PCI in Shanghai. Generalising the study results to other regions of China or other countries should be performed with caution. The long-term impact of coronary stent policies on the cost-effectiveness of PCI in patients with ACS or other CHDs should be investigated in the future.

Conclusions

This study based on real-world data and PS-matched data revealed that the implementation of coronary stent policies in Shanghai reduced the medical costs for patients with ACS during the year after PCI and has a substantial chance (more than 74%) of increasing the cost-effectiveness of PCI in patients with ACS 1 year after PCI. The positive findings of this study suggest that the national centralised VBP policy can probably be extended to other implanted devices in China as well as to other countries. However, the long-term impact of coronary stent policies on the cost-effectiveness of PCI in patients with ACS or other CHDs should be addressed in the future.

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Contributors DX, DL and ZS conceived and designed the study; ZS and YW extracted data; DL and DX conducted data analyses and interpreted the data; DL drafted the manuscript; and DX, DL, YW and ZS revised the manuscript. DX is the guarantor who accepts full responsibility for the finished work and the conduct of the study, had access to the data, and controlled the decision to publish.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and the study plan was submitted to the institutional review board (IRB) of the School of Public Health, Fudan University, and the study was approved by the IRB (IRB#2022-01-0937 and IRB#2022-01-0937-s). The requirement for informed consent from patients was waived by the IRB.

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