



BMJ Open Ten-year trends of clinical outcomes after percutaneous coronary intervention: a Korean nationwide longitudinal cohort study

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ABSTRACT

Objectives Mortality following percutaneous coronary intervention (PCI) is a key quality measurement in clinical practice. This study investigated the 10-year trends of mortality following PCI in an unselected nationwide cohort.

Design Retrospective cohort study.

Setting A nationwide study in South Korea.

Participants PCI claim data from 2006 to 2015 of the National Health Insurance Service and the Statistics of Korea.

Measures 1-year cardiovascular or non-cardiovascular death.

Results In total, 437 436 patients were included. The annual number of PCI cases increased from 32 098 to 51 990 over the decade studied ($p<0.001$). Patients were divided into quartile subgroups according to an estimated adjusted probability for predicting 1-year all-cause death. The proportion of patients in the high-risk quartiles increased whereas those in the low-risk quartiles decreased ($p<0.001$). The 1-year cumulative incidence rate of all-cause death did not change in the population with risk scores in the 1st (0.9% to 0.8%) and 2nd (1.3% to 1.3%) quartiles, whereas it increased in the population with risk scores in the 3rd (3.4% to 5.1%) and 4th (15.5% to 19.4%) quartiles ($p<0.001$). Compared with year 2006, the mean survival time in year 2015 was shorter by 0, 3.3 and 12.4 days in patients with risk scores in the 1st or 2nd, 3rd and 4th quartiles, respectively. These findings were also consistent for cardiovascular or non-cardiovascular deaths.

Conclusion The number, proportion and the overall risk of patients with a high risk for mortality after PCI increased over the decade in Korea.

INTRODUCTION

Percutaneous coronary intervention (PCI) is the most common procedure for revascularisation of coronary artery disease. Substantial advancements in the management of obstructive coronary artery disease have been made with PCI over the last decades.¹ Primary PCI is a well-established and recommended treatment for acute myocardial infarction (AMI). Advances and innovations in technology have led to the expansion of indications for PCI

Strengths and limitations of this study

- Almost all percutaneous coronary interventions (PCI) performed in a nation for 10 years were included with 100% 1-year follow-up rate, which virtually eliminated selection bias.
- This study is a good real-world example that shows the increasing number of high-risk patients in a country with ageing population.
- The results of this study do not reflect the changes in the outcome of patients with coronary artery disease, because only patients who underwent PCI but not patients who were treated by optimal medical therapy without PCI were investigated.
- Advances in optimal medical therapy or applying optimal medical therapy instead of PCI might result in apparently higher risk of PCI, which was not covered in this study.

to include complex coronary artery disease, such as left main disease, multivessel disease and chronic total occlusion.^{2 3}

The clinical circumstances associated with PCI have changed in the contemporary era. The incidence rates of AMI have decreased as a result of improvement in the management for primary or secondary prevention of coronary artery disease.⁴ Among AMI types, the prevalence of non-ST-elevation myocardial infarction (NSTEMI) is increasing compared with that of ST-elevation myocardial infarction (STEMI).^{5 6} Moreover, PCI is increasingly being used in high-risk patients, including elderly patients, cardiogenic shock with the use of mechanical circulatory support devices and patients with multiple clinical comorbidities.⁷⁻⁹

The mortality rate following PCI is a key quality measure in clinical practice. If the mortality rate changes over time, it is necessary to investigate the extent to which the changes are related to the patient-specific baseline risk. Therefore, it is important to access the trends related to clinical outcome

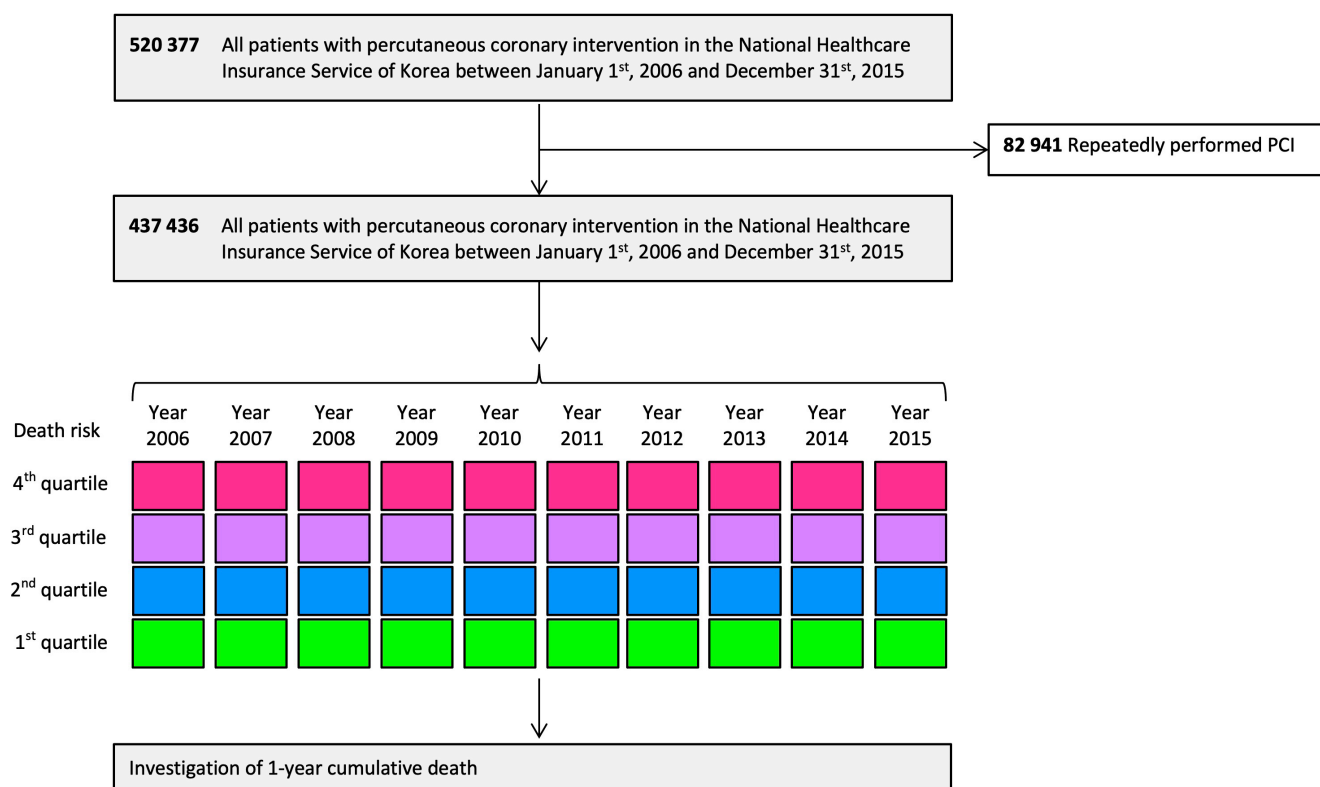


Figure 1 Study flow. To assess the impact of baseline comorbidities on the risk of 1-year death, trends in the change of 1-year death risk were investigated according to the cohort year and quartiles of estimated adjusted probability of 1-year death. PCI, percutaneous coronary intervention.

as well as the clinical characteristics based on real-world data. These changes in trends may influence the interpretation of the clinical outcomes of PCI in randomised clinical trials as well as in registry studies.

This study aimed to investigate 10-year trends of the mortality rate after PCI in the context of changing clinical comorbidities using real-world data from a nationwide whole PCI registry.

METHODS

Study population

This study was a retrospective cohort analysis of administrative claims data from the National Healthcare Insurance Service, which is a unique healthcare insurance system that is mandatory for almost all residents in the Republic of Korea. Data on all individual claims for PCI using stents between January 2006 and December 2015 were retrieved. Repeated PCI for the same patient was regarded as revascularisation, not the index PCI. The medical service claims, diagnostic codes of the 10th Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) and death records issued between January 2004 and December 2016 were also retrieved to assess baseline clinical characteristics and clinical events after PCI.

All results are reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines.

Study definitions and endpoints

The index PCI date was the first date of PCI. Cardiogenic shock was defined in cases where claims related to the following were used: resuscitation, endotracheal intubation, mechanical ventilation and use of haemodynamic support devices including intra-aortic balloon counterpulsation or extracorporeal membrane oxygenation. Cardiovascular or non-cardiovascular death was defined based on ICD-10 codes used in the death certificate records retrieved from the Statistics of Korea. Other definitions of clinical characteristics based on ICD-10 codes are listed in the online supplemental data. No patient was lost to follow-up with respect to death. The primary outcome was all-cause death within 1 year.

Statistical analysis

The entire cohort was divided into 10 subcohorts according to the calendar year of the index PCI. Trends of annual changes in baseline clinical characteristics were investigated using Cochran-Armitage test.

The cumulative incidence of 1-year death was evaluated using Kaplan-Meier curves for each year cohort. Hence, the rate of death rapidly decreased over time, the 1-year death risk of each year cohort was compared using

Table 1 Baseline clinical and procedural characteristics

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	P value for trend
n	32 098	35 831	38 915	40 946	44 119	46 098	47 721	48 370	51 348	51 990	
Male gender	21 110 (65.8)	23 461 (65.5)	25 333 (65.1)	27 209 (66.5)	29 564 (67.0)	31 181 (67.6)	32 610 (68.3)	33 225 (68.7)	35 632 (69.4)	36 656 (70.5)	<0.001
Age	62.3±10.9	62.6±11.0	63.0±11.1	63.3±11.1	63.7±11.3	64.0±11.3	64.2±11.4	64.3±11.6	64.5±11.6	64.7±11.6	<0.001
Age ≥69	9798 (30.5)	11 635 (32.5)	13 206 (33.9)	14 546 (35.5)	16 336 (37.0)	17 571 (38.1)	18 852 (39.5)	19 415 (40.1)	20 688 (40.3)	21 082 (40.6)	<0.001
Hypertension	23 576 (73.5)	26 162 (73.0)	28 406 (73.0)	29 875 (73.0)	31 947 (72.4)	32 695 (70.9)	33 507 (70.2)	33 804 (69.9)	35 905 (69.9)	36 377 (70.0)	<0.001
Diabetes	13 309 (41.5)	15 112 (42.2)	16 496 (42.4)	17 840 (43.6)	19 421 (44.0)	20 733 (45.0)	21 337 (44.7)	21 996 (45.5)	23 597 (46.0)	24 594 (47.3)	<0.001
Dyslipidaemia	16 183 (50.4)	18 425 (51.4)	20 773 (53.4)	22 870 (55.9)	25 608 (58.0)	27 421 (59.5)	28 406 (59.5)	29 665 (61.3)	32 933 (64.1)	35 004 (67.3)	<0.001
Stroke	913 (2.8)	1190 (3.3)	1365 (3.5)	1520 (3.7)	1721 (3.9)	1930 (4.2)	2015 (4.2)	1928 (4.0)	2005 (3.9)	2017 (3.9)	<0.001
CKD	1235 (3.8)	1475 (4.1)	1723 (4.4)	1859 (4.5)	2083 (4.7)	2357 (5.1)	2668 (5.6)	2897 (6.0)	3249 (6.3)	3641 (7.0)	<0.001
Dialysis	543 (1.7)	642 (1.8)	734 (1.9)	836 (2.0)	816 (1.8)	981 (2.1)	1038 (2.2)	1107 (2.3)	1245 (2.4)	1374 (2.6)	<0.001
Cancer	896 (2.8)	1029 (2.9)	1353 (3.5)	1607 (3.9)	1880 (4.3)	1854 (4.0)	1926 (4.0)	1930 (4.0)	2162 (4.2)	2395 (4.6)	<0.001
Previous MI	4891 (15.2)	4966 (13.9)	4736 (12.2)	4719 (11.5)	5074 (11.5)	4805 (10.4)	4521 (9.5)	4535 (9.4)	4759 (9.3)	5419 (10.4)	<0.001
Heart failure	2494 (7.8)	2783 (7.8)	2800 (7.2)	2844 (6.9)	2962 (6.7)	3369 (7.3)	3552 (7.4)	3581 (7.4)	3829 (7.5)	3941 (7.6)	<0.001
Shock	1361 (4.2)	1639 (4.6)	2022 (5.2)	2036 (5.0)	2391 (5.4)	2418 (5.2)	2691 (5.6)	2752 (5.7)	2881 (5.6)	3021 (5.8)	<0.001
Diagnosis											
Angina	18 974 (59.1)	21 981 (61.3)	24 580 (63.2)	26 174 (63.9)	28 648 (64.9)	30 017 (65.1)	30 503 (63.9)	30 101 (62.2)	31 676 (61.7)	31 455 (60.5)	
NSTEMI	4645 (14.5)	5015 (14.0)	5357 (13.8)	6112 (14.9)	6738 (15.3)	8061 (17.5)	9011 (18.9)	10 447 (21.6)	11 874 (23.1)	12 446 (23.9)	<0.001
STEMI	8479 (26.4)	8835 (24.7)	8978 (23.1)	8660 (21.1)	8733 (19.8)	8020 (17.4)	8207 (17.2)	7822 (16.2)	7798 (15.2)	8089 (15.6)	
Stent											
DES	30 099 (93.8)	33 713 (94.1)	36 513 (93.8)	38 777 (94.7)	42 476 (96.3)	44 943 (97.5)	46 795 (98.1)	47 545 (98.3)	50 617 (98.6)	51 440 (98.9)	<0.001
BMS	2655 (8.3)	2593 (7.2)	2854 (7.3)	2443 (6.0)	1861 (4.2)	1300 (2.8)	1058 (2.2)	934 (1.9)	815 (1.6)	630 (1.2)	<0.001
POBA	1054 (3.3)	1110 (3.1)	1215 (3.1)	1236 (3.0)	1350 (3.1)	1356 (2.9)	1387 (2.9)	1503 (3.1)	1576 (3.1)	1566 (3.0)	0.16
Stents (n)	1.12±0.35	1.14±0.37	1.16±0.39	1.14±0.37	1.13±0.36	1.12±0.35	1.10±0.31	1.09±0.31	1.10±0.31	1.11±0.35	<0.001

Data are expressed as n (%) or mean±SD.

BMS, bare metal stent; CKD, chronic kidney disease; DES, drug-eluting stent; MI, myocardial infarction; NSTEMI, non-ST-elevation myocardial infarction; POBA, plain old balloon angioplasty; STEMI, ST-elevation myocardial infarction.

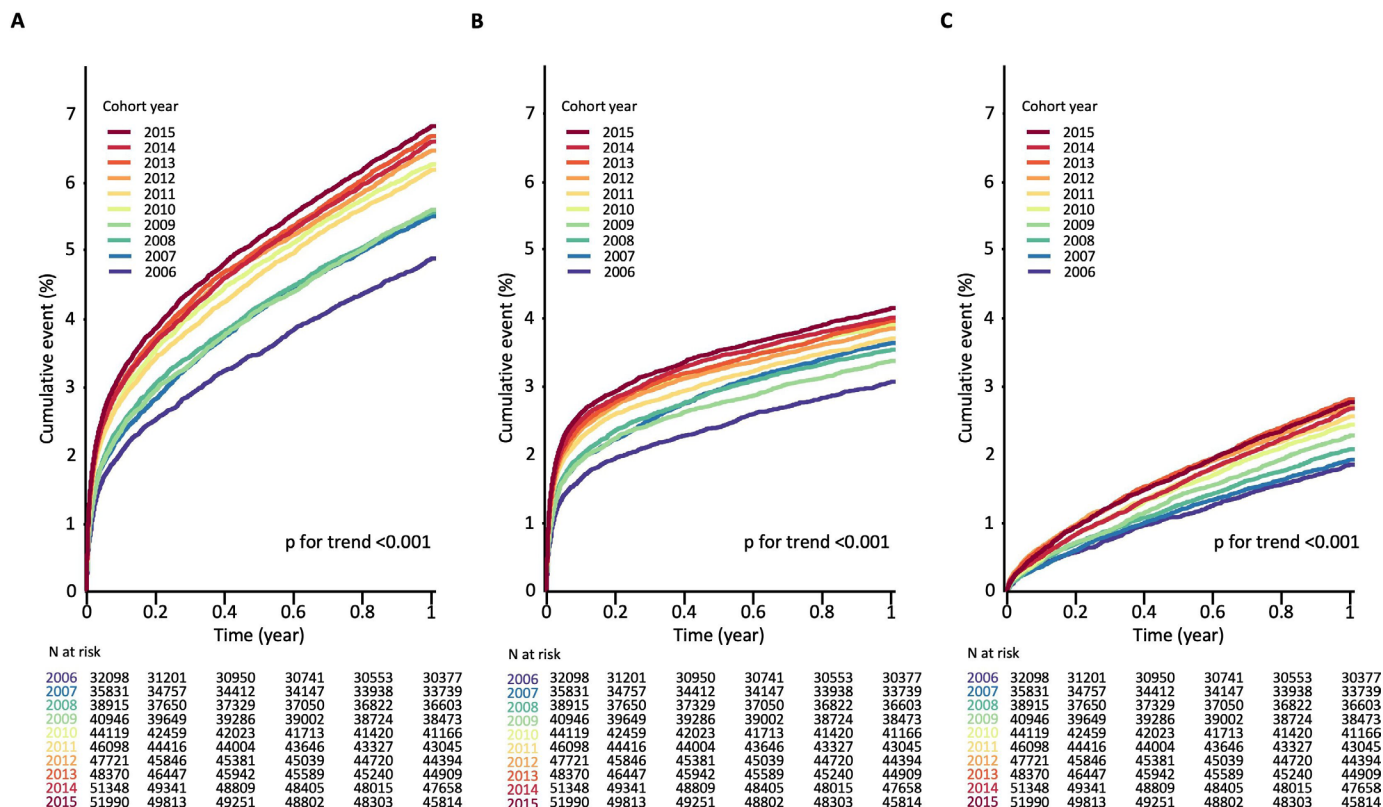


Figure 2 Kaplan-Meier plots for the cumulative incidence of 1-year death: entire cohort. The unadjusted cumulative incidence of 1-year (A) all-cause death, (B) cardiovascular death, and (C) non-cardiovascular death consistently increased over the decade.

restrictive mean survival time (RMST) as well as Cox proportional hazards model. In brief, RMST represents the area under the survival curve and can be interpreted as ‘life expectancy’ in the predefined follow-up period. Unlike the Cox model, RMST is statistically valid even when the HR varies according to the distribution of time to event. The ratio of restrictive mean time lost is comparable to the HR in the Cox model. The difference of RMST approximates absolute effect sizes that are not available from the Cox model.¹⁰ Restrictive cubic spline plots were also shown to summarise the trends of annual changes of cumulative incidence of death.¹¹

To assess the impact of baseline clinical comorbidities on the risk of 1-year death, an estimated adjusted probability of all-cause death for 1-year death was established by generalised linear model using representative clinical parameters including age, sex, hypertension, diabetes, hyperlipidaemia, chronic kidney disease, stroke, cancer, myocardial infarction (MI) and cardiogenic shock. Age was treated as a dichotomous parameter of ≥ 69 or < 69 years, which was the optimal cut-off for 1-year death risk based on Youden’s J statistic (c -statistics=0.725). The estimated adjusted probability of 1-year death was derived from 191 909 patients in the year 2006–2010 cohorts, and was validated in 245 227 patients in the year 2011–2015 cohorts. This model showed a good predictive performance in both the derivation cohort (c -statistics=0.840,

95% CI 0.836 to 0.844) and validation cohort (c -statistics=0.849, 95% CI 0.846 to 0.852) (online supplemental figure 1).

Each year, cohort was divided into the 1st quartile (the lowest risk), 2nd quartile (low risk), 3rd quartile (high risk) and 4th quartile (the highest risk) subgroups according to the estimated adjusted probability of 1-year death quartiles. The cumulative incidence of death was evaluated using Kaplan-Meier curves for the subgroups. The 1-year death risk of each subcohort was compared using RMST or Cox proportional hazards model, with the first year cohort as a reference.

Statistical significance in the survival analyses was defined by two-sided p value < 0.05 . All analyses were performed using SAS V.9.4 (SAS Institute) and R V.4.0 (R Foundation for Statistical Computing).

RESULTS

Baseline clinical characteristics

A total of 520 377 PCI cases were identified between January 2006 and December 2015. After exclusion of 82 941 PCI cases that were repeatedly performed for the same patient, 437 436 PCI cases were enrolled in the analysis (figure 1).

The number of annual PCI cases increased consistently from 32 098 in 2006 to 51 990 in 2015. There were

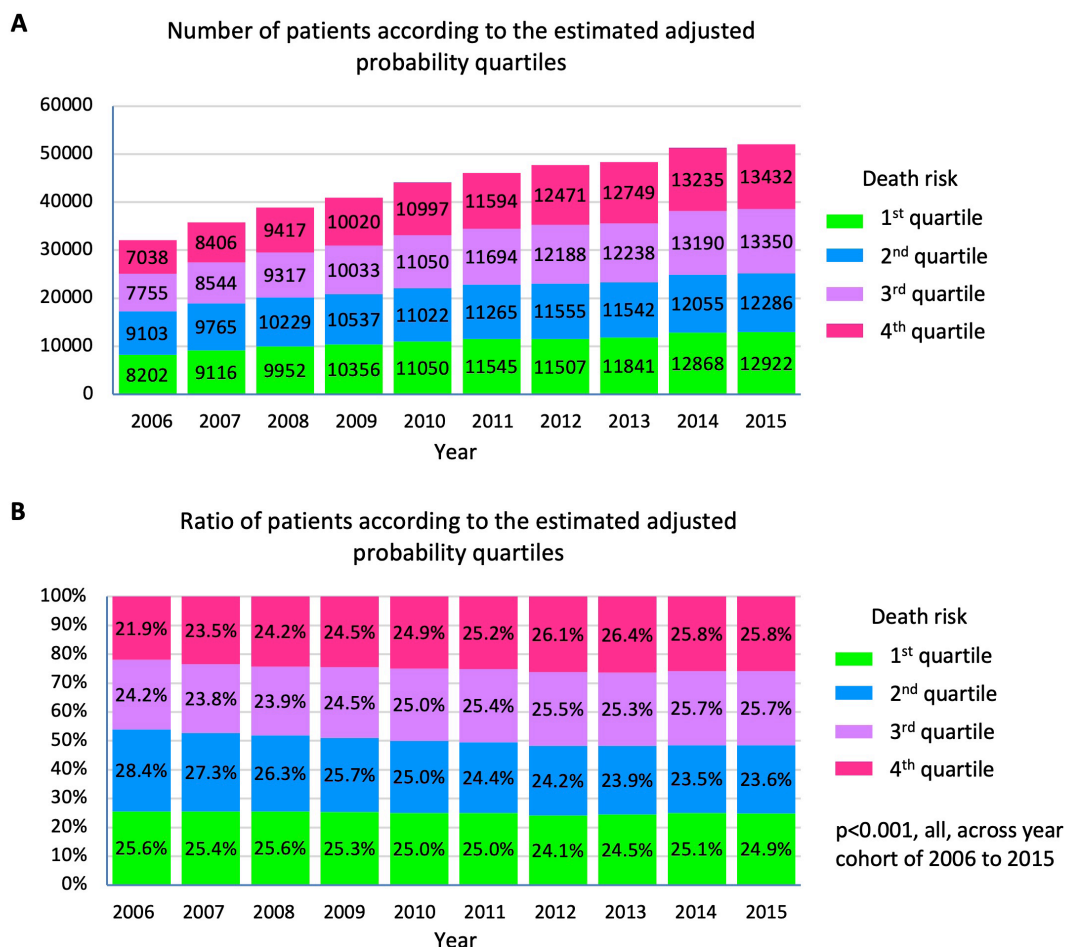


Figure 3 Ten-year trends of the changes in clinical characteristics based on the estimated adjusted probability of 1-year death quartiles. Patients were grouped into four categories according to the quartiles of estimated adjusted probability of 1-year death risk (online supplemental figure 1). (A) From 2006 to 2015, the number of patients undergoing PCI increased from 2006 to 2015. (B) In the same period, the proportion of patients with lower estimated adjusted probability of 1-year death (1st or 2nd quartile) decreased, whereas that of patients with higher estimated adjusted probability of 1-year death (3rd and 4th quartiles) increased.

trends of significant changes in the proportions of older and male patients and frequency of clinical comorbidities over the decade from 2006 to 2015. The mean age increased from 62.3±10.9 to 64.7±11.6 years. The proportion of men increased from 65.8% to 70.5%. The proportion of STEMI decreased from 26.4% to 15.6% whereas that of NSTEMI increased from 14.5% to 23.9%. The frequencies of comorbidities including diabetes, hyperlipidaemia, history of stroke, chronic kidney disease, dialysis and cancer also increased significantly (p<0.001, all) (table 1).

Trends of the annual risk of death

The unadjusted cumulative incidence of 1-year all-cause death consistently increased over the decade from 4.9% in 2006 to 6.8% in 2015. The unadjusted cumulative incidence of 1-year cardiovascular death and non-cardiovascular death also increased from 3.1% to 4.1% and 1.8% to 2.7%, respectively (p<0.001, all) (figure 2) (online supplemental figure 2). The increasing trends of the cumulative incidence of 1-year all-cause death were

consistent in subgroup analyses according to clinical characteristics (online supplemental figure 3).

To assess the changes in the clinical characteristics of the death risk, patients were classified into four groups according to the estimated adjusted probability of 1-year death quartiles (online supplemental figure 1). From 2006 to 2015, the proportion of patients with risk scores in the 1st or 2nd quartile decreased (25.6% to 24.9% and 28.4% to 23.6%, respectively; p<0.001, all), whereas that of patients with risk scores in the 3rd and 4th quartiles increased (24.2% to 25.7% and 21.9% to 25.8%, respectively; p<0.001, all) (figure 3).

From 2006 to 2015, the cumulative incidence of 1-year all-cause death did not change significantly in patients with risk in the 1st or 2nd quartile (0.9% to 0.8% and 1.3% to 1.3%, respectively; p value for trend >0.05, all), but it increased in patients with risk in the 3rd or 4th quartile (3.8% to 5.1% and 15.5% to 19.4%, respectively; p value for trend <0.001, all). The cumulative incidence of 1-year cardiovascular death (risk in the 1st quartile, 0.5% to 0.5%; 2nd quartile, 0.7% to 0.6%; 3rd quartile,

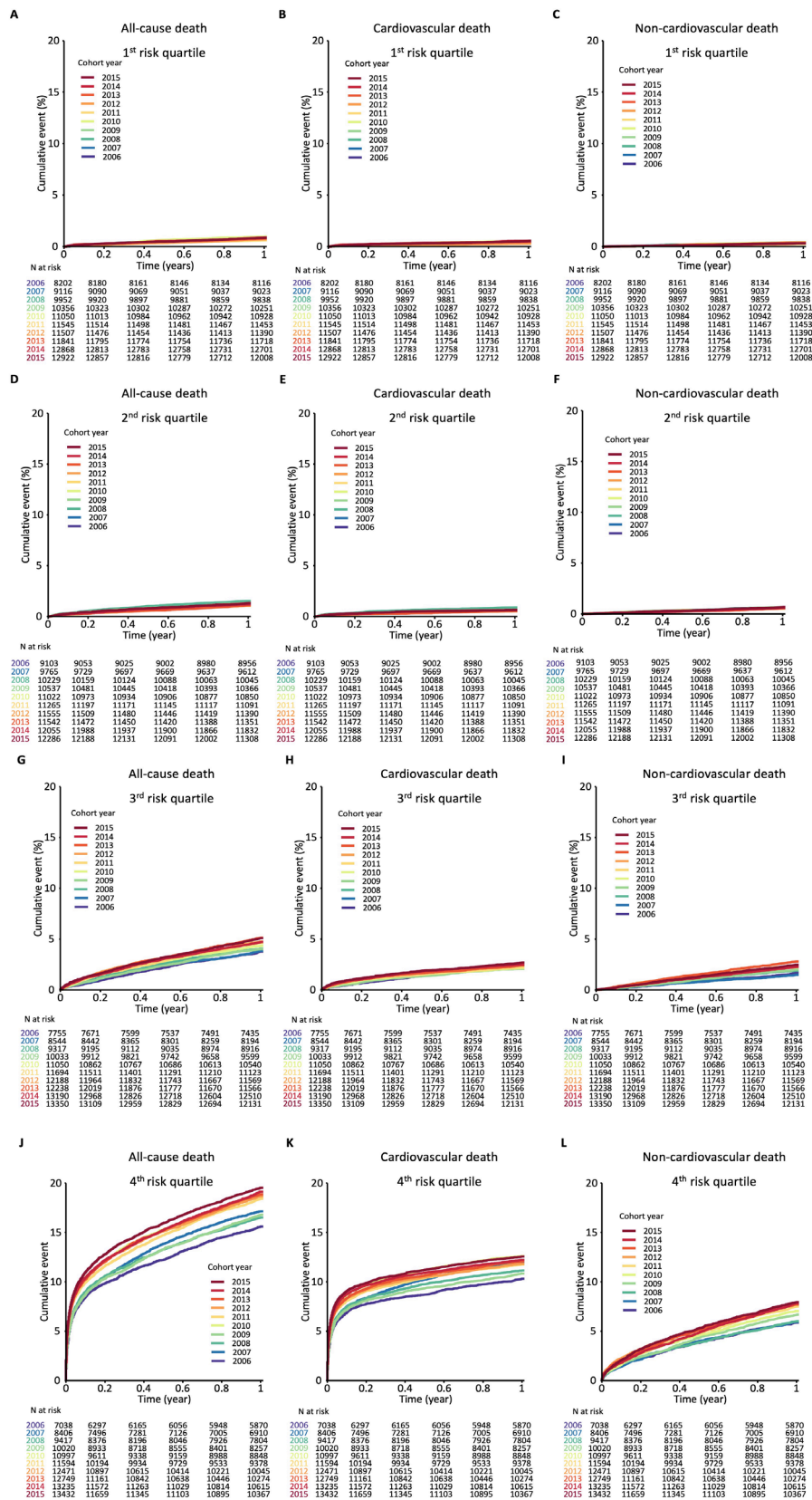


Figure 4 Kaplan–Meier plots for the cumulative incidence of 1-year death: subgroups according to estimated adjusted probability of 1-year death quartiles. From 2006 to 2015, the cumulative incidence of 1-year all-cause, cardiovascular and non-cardiovascular deaths did not change in patients with lower estimated adjusted probability of 1-year death (1st or 2nd quartile) but increased in patients with higher estimated adjusted probability of 1-year death (3rd or 4th quartile) (3.8% to 5.1% and 15.5% to 19.4%, respectively; p value for trend <0.001, all). These changes in the trends of the 1-year death risk are summarised in the restrictive cubic spline curves in online supplemental figure 4.

2.1% to 2.7%; 4th quartile, 10.1% to 12.3%) and non-cardiovascular death (risk in the 1st quartile, 0.3% to 0.3%; 2nd quartile, 0.6% to 0.7%; 3rd quartile, 1.6% to 2.4%; 4th quartile, 5.4% to 7.1%) also showed consistent findings (figure 4) (online supplemental table 1). These changes in the trends of the 1-year death risk are summarised in the restrictive cubic spline curves (online supplemental figure 4).

In the RMST analysis, the loss of survival time in 2015 compared with 2006 was 0 day in patients with risk in the 1st or 2nd quartile, whereas it was 3.3 days in patients with risk in the 3rd quartile, and 12.4 days in patients with risk in the 4th quartile (online supplemental table 2).

DISCUSSION

This study had three major findings. First, there was an overall 62.0% increase in the index PCI volume in Korea from 2006 to 2015. Second, the proportion of patients with clinical comorbidities increased. Third, the 1-year death risk did not change in patients with lower risk, whereas it increased in patients with higher risk and consequently resulted in an overall increase in 1-year death risk of PCI. These results were derived from a nationwide whole registry that included almost all PCI cases performed in the Republic of Korea.

The 1.6-fold increase in the number of PCI cases for the studied decade was mainly driven by 1.7-fold increase in angina and 2.7-fold increase in NSTEMI, whereas the number of STEMI cases was stationary throughout the decade. The relatively increased number of angina or NSTEMI cases compared with that of STEMI was presumed to be the result of increasing age and clinical comorbidities in the population, which would increase the burden of atherosclerotic coronary artery disease.¹² As Korea is one of the world's fastest ageing countries, the increasing trend of angina or NSTEMI incidence is expected to continue for the time being.¹³

Our study revealed a small but consistent increase in the risk after PCI, which is consistent with the findings of other large or nationwide studies.^{14–18} Although speculative, reasons for this phenomenon may include a preference for conservative medical therapy based on the clinical trials reporting comparable effectiveness of optimal medical management for stable coronary artery disease, improved efficacy of medical therapy and widespread application of appropriate use criteria.^{19–22} The relative risk of patients undergoing PCI may increase because patients with lower risk are treated with optimal medical therapy. Advances in technology and accumulation of experience might also contribute to expanding the indications for complex procedures or high-risk patients.

In this study, cardiovascular death and non-cardiovascular death accounted for 61.0% and 39.0% of all causes of death, respectively. Prior studies reported highly variable rates for cardiovascular or non-cardiovascular death after PCI from 40% to 92%.^{18 23–25} Cardiovascular death may dominate the reason for mortality in the short term, but

their prevalence decreases in the long term follow as the incidence of malignancy and non-cardiovascular diseases increase.

Limitations

The results are based on the retrospective analysis of administrative data and need to be interpreted as descriptive findings. The source data were administrative claims and death records, and did not include patient-reported outcomes. Cardiovascular death was defined using ICD-10 codes in death certificates. Jurisdiction of the undetermined cause of death, which was reportedly found to be up to 25%, might have affected the proportion of cardiovascular deaths.²³ The relative timing of cardiovascular and non-cardiovascular deaths may change according to the follow-up period.²⁴ This study did not include coronary artery bypass surgery, which accounted for 4.9%–8.1% of all coronary revascularisation procedures during the study period.²⁶ MI was defined by the administrative claim of 'acute myocardial infarction', which was submitted by the diagnosis of attending physicians. The definition of MI is evolving constantly. The latest 4th definition of MI has been introduced in 2018 after the inclusion period of this study.²⁷ Non-fatal clinical events including MI, stent thrombosis, revascularisation or bleeding were not assessed because data related to laboratory tests, cardiac biomarkers, electrocardiography or coronary angiography were not available in the administrative database. Despite the potential importance, metrics for medications, sophisticated analysis of procedural details and non-laboratory-based risk factors including obesity, smoking, mental health and socioeconomic status were not investigated.²⁸ The results were derived from the data related to clinical practice in Korean hospitals and need to be compared with those in non-Korean or non-Asian settings as significant differences in PCI procedural characteristics and mortality have been reported between Japan and the USA.¹⁶

CONCLUSIONS

In this real-world nationwide data analysis study, the number, proportion and overall 1-year death risk of high-risk patients increased over the studied decade in Korea. Interpretation and understanding of these changes in real-world clinical practice may be crucial to the translation of clinical evidence to real-world practice.

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Contributors JMC and J-HC conceived the study and are responsible for the overall content as guarantor. JMC and J-HC collected and analysed the data. S-HL provided oversight of data collection and overview of data registry. JMC, S-HL and J-HC led the statistical analysis and generated the tables and figures. JMC and J-HC drafted the manuscript. All authors reviewed, modified and approved the final manuscript. All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. JMC is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval The Samsung Medical Center Institutional Review Board approved this study and determined that this study did not require informed consent given that the analysis focused on the quality reporting of aggregated results from a deidentified large database and did not involve human participants.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The data set used in this study is held by the National Healthcare Insurance Service (NHIS) of Korea and is available from the website (<http://nhiss.nhis.or.kr>) for researchers who meet the criteria for access to confidential data. Submission of study proposal, which is reviewed by NHIS review committee, and an ethics approval from affiliated institutional review board are required.

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