5-27-2021

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ARTICLE IN PRESS
CARREV-02365; No of Pages 6
Cardiovascular Revascularization Medicine xxx (xxxx) xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Trends and outcomes of utilization of thrombectomy during primary percutaneous coronary intervention

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ARTICLE INFO

Article history:
Received 2 May 2021
Received in revised form 23 May 2021
Accepted 24 May 2021
Available online xxxx

Keywords:
STEMI
Primary PCI
Thrombectomy
Stroke

ABSTRACT

Background: To describe the national trends and outcomes of contemporary thrombectomy use for primary percutaneous coronary intervention (PCI) from 2016 to 2018.
Methods: We queried the Nationwide Readmission Database (NRD) from January 2016 to December 2018 to identify patients who underwent primary PCI and thrombectomy. We conducted a multivariate regression analysis to identify variables associated with in-hospital mortality and stroke in patients undergoing primary PCI and those who underwent thrombectomy.
Results: We identified 409,910 total hospitalizations who underwent primary PCI. Thrombectomy was used in 62,446 records (15.2%) with no change in the trend over the study period (p trend = 0.52). Thrombectomy was more utilized in patients who had more cardiogenic shock and use of mechanical circulatory devices. The overall incidence of in-hospital mortality and stroke were 5.6% and 1.1%, respectively. The incidence of in-hospital mortality (6.7% vs. 5.4%, $p < 0.001$) and strokes (1.3% vs. 1.0%, $p < 0.001$) were higher in the thrombectomy group. On multivariable regression analysis adjusting for high-risk features, thrombectomy was not independently associated with in-hospital mortality [1.036, 95% CI (0.993–1.080), $p = 0.100$], but was associated with a higher risk of stroke [OR 1.186, 95% CI (1.097–1.283), $p < 0.001$].
Conclusion: During primary PCI, thrombectomy was used in 1 of 6 cases, and its use has been stable over 2016–2018. The use of thrombectomy was associated with a higher risk of stroke, but not in-hospital death.

1. Introduction

The presence of large thrombus burden in patients presenting with ST-elevation myocardial infarction (STEMI) remains a challenge in contemporary interventional cardiology practice. Patients with large thrombus burden undergoing primary percutaneous coronary intervention (PCI) experience higher rates of distal embolization, slow- or no-reflow with resultant clinical deterioration, and worse in-hospital and long-term outcomes [1].

There are multiple pharmacological and mechanical measures to deal with large thrombus burden. Thrombus aspiration (thrombectomy) mechanically removes the thrombus using different tools (manual or mechanical). In theory, thrombectomy works by reducing distal embolization and improving microvascular perfusion leading to improved outcomes by avoiding the no-reflow phenomenon [2]. Initial studies have shown improved outcomes (cardiac death and non-fatal MI) with thrombus aspiration [3,4], but has been challenged by multiple randomized controlled trials (RCTs) demonstrating no clinical benefit of routine use of thrombectomy with possible signals for harm due to increased risk of stroke [5,6,7].

Abbreviations: PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

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https://doi.org/10.1016/j.carrev.2021.05.021
1553-8389/

Despite the recent guidelines downgrading routine use of thrombectomy during PCI to class IIb or III [8,9], thrombectomy remains a useful strategy for treating high-risk lesions with large thrombus burden [10]. Secemsky et al. investigated the National Cardiovascular Data Registry (NCDR) CathPCI registry and showed the decline in manual thrombectomy use from 2011 to 2016 [11]. We performed a comprehensive analysis of the Nationwide Readmissions Database (NRD) to describe the national trends and outcomes of thrombectomy use during primary PCI between 2016 and 2018.

2. Methods

2.1. Data source

We used the Nationwide Readmissions Database (NRD), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality to obtain our cohort. The NRD contains discharge data from 28 geographically dispersed States, accounting for 60% of the total U.S. resident population and 58.2% of all U.S. hospitalizations. We identified our cohort, procedures, and outcomes using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD 10 CM) and procedure (ICD 10-PCS) codes along with ICD-10 clinical classification codes (CCS). The codes used are summarized in Table S1.

2.2. Study population

We identified our cohort using the ICD 10 codes for thrombectomy during primary PCI for years 2016 to 2018 (Table S1). Patient and hospital-level variables provided by HCUP NRD were used to identify demographics and baseline characteristics. The Elixhauser method was used to assess comorbidities [12]. The rest of the comorbidities were identified using appropriate ICD 10 CM codes (Table S1). We excluded patients with missing data on in-hospital mortality. The NRD is a publicly available database with de-identified hospitalization records; therefore, institutional review board approval was not required.

2.3. Outcomes

The primary outcomes of our study were in-hospital mortality and stroke. Secondary outcomes included vascular complications, renal complications, discharge to a nursing facility, length of hospital stay, and the cost of the index hospitalization.

2.4. Statistical analysis

All analyses were conducted using the appropriate weighting, stratifying, and clustering samples following HCUP regulations [13,14]. Given the lack of essential variables that would be required for adequate matching (e.g., lesion complexity, thrombus burden, etc.), we did not perform propensity-score matching. Categorical variables are displayed as numbers and percentages and compared with Pearson's chi-square or Fisher's exact tests. Continuous variables are summarized as medians and interquartile range (IQR) (25th and 75th percentiles) and compared with the Mann-Whitney *U* test. All *p*-values are 2-sided with a significance threshold<0.05. The trend analysis was performed using the linear regression method.

We performed multivariable regression analysis to identify variables associated with in-hospital mortality and stroke in patients undergoing primary PCI. We included all variables considered significant based on background knowledge using the "Enter" method. We then performed multivariable regression analysis to identify variables associated with in-hospital mortality and stroke in the cohort of patients who underwent thrombectomy. We included annual hospital thrombectomy volume as a variable in the regression analysis for the thrombectomy cohort. Statistical analysis was performed using IBM SPSS Statistics for Windows (version 25.0. Armonk, NY: IBM Corp).

3. Results

3.1. Patients and hospitals characteristics

We identified 409,910 total weighted hospitalizations who underwent primary PCI for STEMI after excluding patients with missing data on in-hospital mortality (Fig. S1). Thrombectomy was used in 62,446 records (15.2%). Over the study period, there was no significant change in the trends of thrombectomy use (15% in the first quarter of 2016 and 14.6% in the last quarter of 2018), $p = 0.524$ (Fig. 1). The total annual hospital volume of thrombectomy was highly variable, with a median annual volume of 38 procedures [IQR 21–68]. High-volume thrombectomy hospitals were defined as those hospitals performing procedures above the 90th percentile of volumes (≥110 thrombectomy procedures a year) (Fig. S2).

Baseline characteristics of the included patients are shown in Table S2. The median patient age was 62 (IQR 54–71) years, and 28.8% were women. Of these patients, about 39.6% presented with anterior STEMI. PCI of bifurcation lesions occurred in 3.1%, and multivessel PCI in 15.4%. Impella was used in 2.3% and intra-aortic balloon pump (IABP) was used in 7.1% of cases. Intravascular imaging was used in 6.1% of cases.

Patients who underwent thrombectomy were younger (61 vs. 62 years, $p < 0.001$) and less likely to be female (25.7% vs. 29.3%, $p < 0.001$). Thrombectomy was more utilized in patients with atrial fibrillation or flutter (13.4% vs. 11.8%, $p < 0.001$), chronic total occlusion (9.3% vs. 8.2%, $p < 0.001$), congestive heart failure (1.5% vs. 1.4%, $p < 0.001$), prior myocardial infarction (13.5% vs. 12.1%, $p < 0.001$), acute stent thrombosis (7.6% vs. 2.4%, $p < 0.001$), and bifurcation lesions (3.4% vs. 3%, $p < 0.001$) (Table S2). Mechanical circulatory devices [Impella, IABP, and extracorporeal membrane oxygenation (ECMO)] were more reported in patients who underwent thrombectomy (Table 1). Thrombectomy was less utilized in patients presenting with anterior STEMI (38% vs. 39.9%, $p < 0.001$) and multivessel PCI (13.6% vs. 15.7%, $p < 0.001$).

3.2. Outcomes

Study outcomes are summarized in Table 1. The overall incidence of in-hospital mortality and stroke were 5.6% and 1.1%. The incidence of in-hospital mortality (6.7% vs. 5.4%, $p < 0.001$) and stroke (1.3% vs. 1.0%, $p < 0.001$) were higher in the thrombectomy group.

The risk of ischemic stroke, hemorrhagic stroke, and combined ischemic and hemorrhagic strokes were 0.9%, 0.3%, and 0.1%, respectively. All subtypes of strokes were higher in the thrombectomy group. Patients who underwent thrombectomy had a higher incidence of cardiogenic shock, cardiac arrest, ventricular tachycardia, and complete atrioventricular block. The length of stay was longer, and the cost of index hospitalization was higher in patients who underwent thrombectomy (Table 1).

On multivariable regression analysis adjusting for all high-risk features in Table S3, there was no association between thrombectomy and in-hospital mortality [1.036, 95% CI (0.993–1.080), $p = 0.100$]. However, thrombectomy was associated with a higher risk of stroke [OR 1.186, 95% CI (1.097–1.283), $p < 0.001$].

On multivariate regression analysis within the cohort of patients who underwent thrombectomy, thrombectomy performed at a higher-volume hospital (above the 90th percentile in thrombectomy volume) was associated with lower incidence of all-cause mortality [OR 0.816, 95% CI (0.716–0.929), $p = 0.002$], and was not associated with an increased risk of stroke [OR 1.046, 95% CI (0.835–1.311), $p = 0.694$].

The summary of the study results is shown in Fig. 2.

4. Discussion

The main findings of the study can be summarized as follows: 1) Over the years 2016–2018, thrombectomy was used in 15.2% of

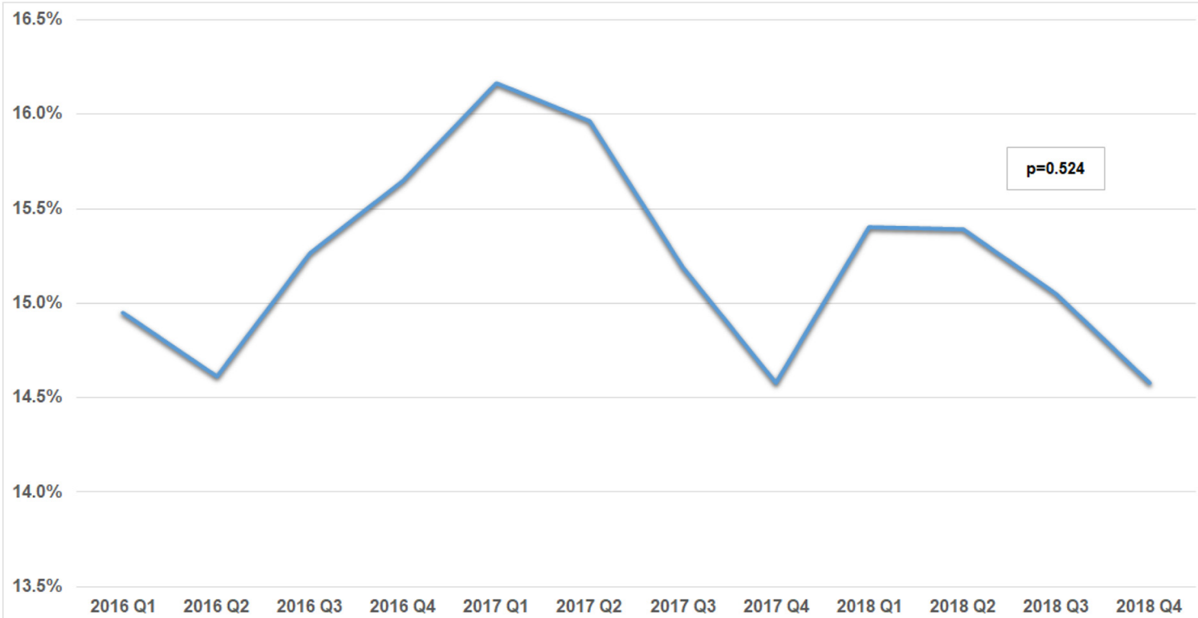

Fig. 1. Trends of thrombectomy use during primary percutaneous coronary intervention in the Nationwide Readmissions Database.

cases during primary PCI, and the trend has been stable, 2) Patients who had thrombectomy were higher risk with a higher incidence of cardiogenic shock, cardiac arrest, and use of mechanical circulatory support devices, 3) patients who received thrombectomy had a higher incidence of death and stroke, 4) after adjusting for high risk features, thrombectomy was not independently associated with a higher risk of death but associated with a higher risk of stroke, and 5) within the cohort of patients who underwent thrombectomy, thrombectomy at high-volume centers was associated with a lower incidence of in-hospital mortality and was not associated with an increased risk of stroke.

Thrombus aspiration during primary PCI remains one of the controversial treatment modalities in interventional cardiology. Previous studies have shown a controversial impact on the long-term outcomes, including major adverse events (MACE) and cardiac death [3,4,5,6,7]. These studies have been heterogeneous in multiple aspects, including

Table 1
Summary of the study outcomes.

	Overall (409,910)	Thrombectomy ($n = 62{,}446$)	No thrombectomy ($n = 347{,}464$)	P-value
In-hospital mortality, n (%)	22,889 (5.6%)	4022 (6.7%)	18,867 (5.4%)	<0.001
Discharge to a facility, n (%)	26,076 (6.4%)	4104 (6.6%)	21,972 (6.3%)	0.010
Neurological complications				
All strokes, n (%)	4427 (1.1%)	818 (1.3%)	3690 (1%)	<0.001
Ischemic stroke, n (%)	3523 (0.9%)	631 (1%)	2892 (0.8%)	<0.001
Hemorrhagic stroke, n (%)	1120 (0.3%)	242 (0.4%)	877 (0.3%)	<0.001
Mixed (ischemic and hemorrhagic strokes), n (%)	216 (0.1%)	55 (0.1%)	161 (<0.1%)	<0.001
Transient ischemic attack, n (%)	634 (0.2%)	97 (0.2%)	537 (0.2%)	0.960
Cardiac complications				
In-hospital CABG, n (%)	9252 (2.3%)	1361 (2.2%)	7891 (2.3%)	0.160
Tamponade, n (%)	1055 (0.3%)	158 (0.3%)	898 (0.3%)	0.830
Cardiogenic shock, n (%)	51,617 (12.6%)	10,227 (16.4%)	41,390 (11.9%)	<0.001
Cardiac arrest, n (%)	45,110 (11%)	7934 (12.7%)	37,176 (10.7%)	<0.001
Coronary perforation, n (%)	1145 (0.3%)	202 (0.3%)	943 (0.3%)	0.020
Coronary dissection n (%)	4575 (1.1%)	663 (1.1%)	3912 (1.1%)	0.170
Ventricular tachycardia, n (%)	52,321 (12.8%)	9600 (15.4%)	42,721 (12.3%)	<0.001
Complete atrioventricular block, n (%)	12,366 (3%)	2708 (4.3%)	9658 (2.8%)	<0.001
Impella, n (%)	9565 (2.3%)	1962 (3.1%)	7603 (2.2%)	<0.001
ECMO, n (%)	158 (<0.1%)	37 (0.1%)	121 (0%)	<0.001
Intra-aortic balloon, n (%)	29,252 (7.1%)	6185 (9.9%)	23,067 (6.6%)	<0.001
Renal complications				
Acute kidney injury requiring hemodialysis, n (%)	4043 (1%)	691 (1.1%)	3353 (1%)	<0.001
Vascular complications				
Vascular complications requiring surgery, n (%)	100 (0%)	16 (0%)	84 (0%)	0.780
Vascular complication, n (%)	357 (0.1%)	57 (0.1%)	301 (0.1%)	0.720
Postprocedural bleeding, n (%)	4988 (1.2%)	822 (1.3%)	4166 (1.2%)	0.001
Length of stay and cost				
LOS, (median, IQR and mean ± SD) (days)	3 (2–4)	3 (2–4)	2 (2–4)	<0.001
Cost, median (IQR) (dollars)	21,124 (16,116-30,320)	23,141 (17,413-34,049)	20,794 (15,926-29,703)	<0.001

IQR: interquartile range; MI: Myocardial infarction; CABG: Coronary artery bypass graft; LOS: length of stay; OR: odds ratio; CI: confidence interval; SD: standard deviation, ECMO: extracorporeal membrane oxygenation.

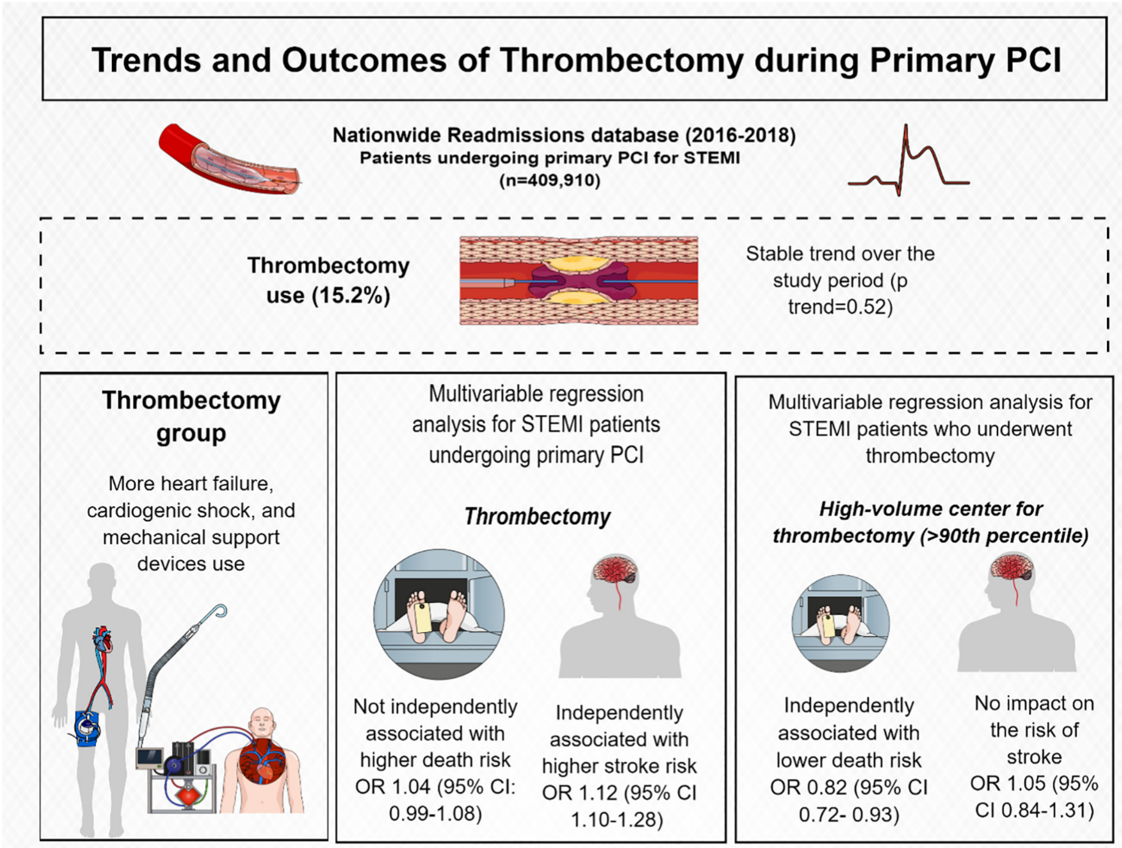

Fig. 2. Summary of the study results.

the types of thrombectomy devices used and thrombus burden reporting. As recent RCTs showed no benefit in long-term outcomes, routine thrombectomy recommendations have been incrementally downgraded to class III in both American and European guidelines [8,9]. However, room was given for thrombectomy use in patients with large residual thrombus burden after initial ballooning (Class IIb).

In our study, despite the guidelines' recommendations, thrombectomy was used in nearly 1 of 6 primary PCI cases from 2016 to 2018, with a stable trend over the three years. Our study showed a higher rate of using thrombectomy (15%) compared with the NCDR CathPCI database (<5%) [11]. This is likely due to the differences in the databases with the NRD capturing >50% of the hospitals in the United States, including those not reporting to the NCDR CathPCI. The high use of thrombectomy in our study can be interpreted in multiple ways. First, there is a general acceptance that thrombectomy should not be routinely used, reflected in the relatively small percentage of its use (15.2%). Second, this also reflects that interventional cardiologists apply their clinical judgment and selectively use thrombectomy in higher thrombus burden or bailout situations. Our analysis showed that patients who underwent thrombectomy had a higher incidence of adverse outcomes, including cardiogenic shock, cardiac arrest, ventricular tachycardia, stroke, and in-hospital death. These features might reflect the use of thrombectomy in patients with higher-risk features, including higher thrombus burden, late presentation, and hypercoagulable states like cancer and diabetes. Previous studies have shown that massive intracoronary thrombus has been reported in 16.4% of patients with acute coronary syndromes [15], which corresponds to the rate of use of thrombectomy in our real-world study.

The most feared complication of thrombectomy use is the occurrence of stroke, demonstrated in the TOTAL study, which showed a higher risk of stroke during 1-year follow-up after routine thrombectomy [7]. A substudy of the TOTAL trial showed that the difference in stroke was apparent within the first 48 h after the procedure (0.3% versus 0.1%) [16]. The primary proposed mechanism of stroke is when the thrombus is not fully aspirated or withdrawn intact into the guide catheter, leading to further thrombus fragmentation, and shedding into the bloodstream. This is more likely to occur with a high thrombus burden and if the suction could not be maintained on the thrombectomy catheter [17]. Other mechanisms, including excess manipulation of the guide catheter or increased platelet reactivity after thrombectomy, are less likely to explain the higher stroke risk with thrombectomy [18]. In our study, with multivariate regression analysis adjusting for higher-risk features, thrombectomy remained associated with a higher risk of Stroke. Our contemporary cohort should reflect the improved operators' experience with thrombectomy devices and the caution to maintain suction throughout the thrombectomy procedure until the device is out of the body. However, the risk of stroke with thrombectomy remains real and consistent with previous RCTs. There is a possibility that the occurrence of stroke is independent of the technique and could be related to other factors (e.g., excessive antithrombotic therapies with high thrombus burden leading to more hemorrhagic strokes). The higher risk of hemorrhagic stroke with manual thrombectomy has been previously shown in a substudy of the TOTAL trial [16].

Within patients who underwent thrombectomy, our study showed that performing thrombectomy in high-volume centers was associated with a lower risk of death without an increased risk of stroke. Better outcomes with thrombectomy in high-volume sites could be related to the presence of high-volume operators. Other technical aspects of the manual thrombectomy might also explain why high-volume centers might have better outcomes. Deep guide catheter engagement during manual thrombectomy might prevent dragging the thrombus into the aortic flow and stroke. Less experienced operators are less likely to perform deep guide catheter engagement. Application of continuous mechanical aspiration during thrombectomy procedure might also prevent the release of thrombus fragments into the aortic blood flow. The Indigo System CAT RX mechanical thrombectomy applies continuous vacuum suction compared to manual suction. The powerful suction may overcome the main Achilles heel of manual thrombectomy which is diminished aspiration force as fluid fills in the syringe, leading to potential systemic embolization and increased stroke risk [7]. The initial experience with the Indigo CAT RX system was reported on 59 patients. It showed a TIMI III flow in 93.2% of patients with a median aspiration time of 35 s and zero stroke incidences [19]. Multiple studies using different mechanical thrombectomy devices did not demonstrate benefit of mechanical thrombectomy during primary PCI. However, the Indigo CAT RX system might be different given its superior suction power [20]. The prospective, multicenter U.S. (CHEETAH) study (NCT03957473) would provide more information on mechanical thrombectomy's safety and efficacy in patients with a high-thrombus burden.

Despite the current controversy, thrombectomy remains a practical tool during primary PCI. A recent patient-level meta-analysis demonstrated that routine thrombectomy did not improve clinical outcomes. Still, there was a trend towards reduced cardiac death in the high thrombus burden group, but at the expense of increased stroke risk [21]. The most recent 2018 European guidelines on myocardial revascularization acknowledged the absence of data on thrombectomy's current benefits, labeling the topic as a knowledge gap requiring more studies, especially with the newer mechanical thrombectomy devices available [22]. The Indigo CAT RX system might not be reflected on our data as it was approved in April 2018. However, our results still emphasize the need to confirm the safety of thrombectomy in contemporary practice and encourage further randomized trials.

4.1. Limitations

Our study has limitations. First, our study is a retrospective observational study with its inherent limitation of selection bias. Second, given the administrative database structure of NRD, the study is subject to coding errors. Our study depends on discharge diagnosis codes, which may underestimate non-fatal events and less severe strokes. Third, it is not possible to determine if the strokes reported in the study were adjudicated by a neurologist or confirmed with brain imaging. Finally, long-term outcomes, including long-term major adverse events, cardiac death, or stroke, could not be assessed.

4.2. Conclusions

During primary PCI, thrombectomy was used in 1 of 6 cases, and its use has been stable over 2016–2018. The use of thrombectomy was associated with a higher risk of stroke, but not in-hospital death.

Funding

None.

CRediT authorship contribution statement

Michael Megaly: conceptualization, Development or design of methodology, statistical analysis, writing the initial draft.

Magi Zordok: Data curation, development or design of methodology

Amgad Mentias: Data curation

Yashasvi Chugh: Data curation

Rupinder S Buttar: Data curation

Mir B. Basir: critical review, commentary, and revision.

M Nicholas Burke: critical review, commentary, and revision.

Dimitrios Karmpaliotis: critical review, commentary, and revision.

Lorenzo Azzalini: critical review, commentary, and revision.

Khaldoon Alaswad: critical review, commentary, and revision.

Emmanouil S. Brilakis: Conceptualization oversight and leadership responsibility for the research activity planning and execution. Critical review, commentary, and revision.

Declaration of competing interest

Khaldoon Alaswad: consulting/speaker honoraria from Boston Scientific, Cardiovascular Systems Inc., Abbott Vascular, Teleflex.

Mir Basir: Consulting/Speaker Abbott Vascular, Abiomed, Cardiovascular Systems, Chiesi, Zoll.

Emmanouil Brilakis: consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Amgen, Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), ControlRad, CSI, Ebix, Elsevier, GE Healthcare, InfraRedx, Medtronic, Siemens, and Teleflex; research support from Regeneron and Siemens. Shareholder: MHI Ventures.

Farouc Jaffer: sponsored research grants from Siemens, Canon, Shockwave, and Teleflex; consulting agreements with Boston Scientific, Siemens, Biotronik, and Magenta Medical; equity interest, Intravascular Imaging. Massachusetts General Hospital has patent licensing arrangements with Canon, Terumo, and Spectrawave; Dr. Jaffer has a right to receive licensing royalties.

All other authors have nothing to disclose.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2021.05.021.

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