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Exploring the Latest Advances in Tenecteplase in the Treatment of Acute ST-Segment Elevation Myocardial Infarction

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Abstract

Acute ST-segment elevation myocardial infarction (STEMI) is a life-threatening condition where rapid reperfusion therapy is critical for improving patient outcomes. As a next-generation targeted thrombolytic agent, tenecteplase optimizes the structure of tissue-type plasminogen activator (t-PA), significantly extending its half-life, enhancing specificity, and improving resistance to PAI-1. These modifications result in superior thrombolytic speed, safety, and efficacy. Clinical studies demonstrate that intravenous tenecteplase effectively improves cardiac function, increases vascular recanalization rates, and reduces myocardial damage and bleeding risks in STEMI patients, outperforming urokinase and streptokinase. Additionally, intracoronary tenecteplase combined with emergency PCI shows promising potential in patients with high thrombus burden, effectively reducing thrombotic load, optimizing microcirculatory perfusion, and maintaining a favorable safety profile. However, current research is predominantly limited to small-scale or single-center trials, highlighting the need for larger, multicenter studies to further validate its therapeutic benefits. While intracoronary tenecteplase has not been widely adopted internationally, China's domestically developed tenecteplase (Mingfule) has achieved positive clinical results. Future research should explore the broader potential of tenecteplase in STEMI treatment, particularly in combination therapies and personalized treatment strategies.

Keywords

Tenecteplase, Acute ST-Segment Elevation Myocardial Infarction, Thrombolytic Therapy, Percutaneous Coronary Intervention, Safety, Efficacy

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1. Introduction

Acute myocardial infarction (AMI) occurs due to thrombus formation on the basis of coronary atherosclerosis, leading to complete occlusion of the lumen, subsequent narrowing, and a series of pathophysiological changes that ultimately result in myocardial ischemia, hypoxia, and necrosis [1]. Acute ST-segment elevation myocardial infarction (STEMI) is a specific type of AMI characterized by significant ST-segment elevation on electrocardiograms. Although data extracted from large and diverse community populations demonstrate that significant shifts in public health policies prioritizing primary prevention strategies for coronary artery disease control/prevention, along with heightened awareness of coronary risk factors, have led to notable declines in the prevalence of myocardial infarction (post-2000) and the incidence of ST-segment elevation (over recent decades) [2]-[4]—specifically, the incidence of STEMI decreased from 121 to 77 per 100,000 between 1997 and 2005 [5]—it remains that over 3 million people still develop STEMI annually worldwide [6]-[9]. For STEMI patients, rapid reperfusion therapy is critical, as it not only reduces the infarct size but also significantly improves ventricular function and long-term prognosis [10]. Studies have shown that percutaneous coronary intervention (PCI) is highly effective in treating STEMI and is widely recommended by authoritative guidelines worldwide [11]-[15]. Thrombolytic therapy is currently the most effective treatment for thrombotic diseases and a major research focus in thrombosis management. It primarily achieves vascular recanalization by dissolving existing blood clots. In recent years, the combination of emergency PCI and intracoronary thrombolysis has gained increasing attention in STEMI treatment. Research indicates that this combined approach is an excellent therapeutic strategy, effectively reducing the risk of no-reflow and slow-flow phenomena in AMI patients with high thrombus burden [16] [17]. Currently, thrombolytic drugs for coronary artery recanalization can be categorized into two types: non-specific fibrinogen activators and specific fibrinogen activators [18]. Although thrombolytic agents such as SK (Streptokinase) and UK (Urokinase) have been widely used in clinical practice with proven efficacy, current thrombolytic drugs still suffer from limitations including high antigenicity, short half-life, low specificity, high cost, and adverse effects such as bleeding and allergic reactions. Therefore, developing more effective, safer, and cost-efficient thrombolytic agents holds significant importance for the treatment of thrombotic diseases. Tenecteplase, as a unique fibrinogen activator, has demonstrated remarkable clinical efficacy. Therefore, this study aims to synthesize existing research and systematically review the progress of tenecteplase in STEMI treatment, providing a theoretical foundation and direction for future investigations.

2. Comparison of Various Fibrinolytic Agents and the Unique Molecular Mechanism of Tenecteplase

Fibrinolytic agents can be classified into three generations based on their chronological development and therapeutic efficacy.

- First-generation thrombolytics, represented by SK (Streptokinase) and UK (Urokinase), exert indirect antithrombotic effects by activating plasminogen into plasmin. Due to their lack of fibrin specificity, these agents are prone to severe side effects such as bleeding [19]. However, their low cost ensures continued widespread clinical use "**Table 1**".
- Second-generation thrombolytics, exemplified by t-PA (tissue plasminogen activator) and Alteplase, preferentially activate plasminogen on thrombi. This enhances antithrombotic efficacy while reducing bleeding risks, offering superior fibrin specificity and thrombolytic effectiveness compared to first-generation agents [20] "**Table 1**".
- Third-generation thrombolytics are engineered through genetic modifications of earlier generations to improve fibrin specificity and prolong plasma half-life, thereby minimizing adverse effects and enhancing thrombolytic performance. Examples include: Monteplase: A mutant of t-PA where the 84th cysteine residue is site-specifically mutated to serine. Pamiteplase: A t-PA variant with the 273th arginine residue mutated to glutamic acid. Tenecteplase, a next-generation targeted thrombolytic agent, is an optimized version of tissue-type plasminogen activator (t-PA). It retains all five structural domains of t-PA but incorporates precise modifications at three specific sites involving six amino acids [21]-[23] "**Figure 1**" and "**Table 1**".

a) At position 103, asparagine replaces threonine, extending the half-life to over 20 minutes and enabling a single intravenous bolus injection of 5 - 10 seconds, significantly enhancing thrombolytic speed and convenience.

b) At position 117, glutamine replaces asparagine, increasing specificity by 10 - 14 times, reducing fibrinogen consumption, and improving safety.

c) At positions 296 - 299, four alanine residues replace lysine, histidine, and two arginine residues, boosting resistance to PAI-1 by 80-fold and greatly enhancing thrombolytic activity and therapeutic efficacy [24] [25].

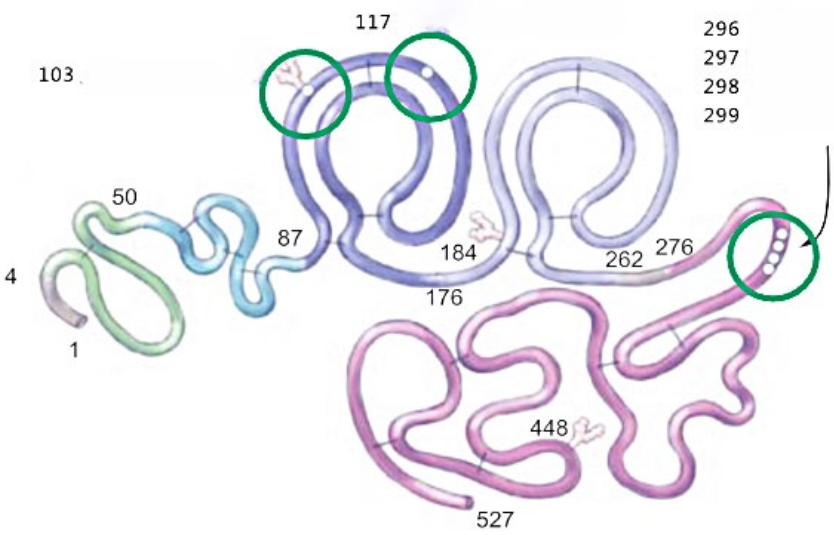

Figure 1. Schematic diagram of the three engineered modification sites in tenecteplase.

Although rapid advancements in genetic and enzyme engineering have ushered in a new era for thrombolytic therapy, these agents still face challenges such as persistent adverse effects linked to their indirect thrombolytic mechanisms and high production costs [26] [27].

Table 1. Comparison of various fibrinolytic agents.

Generation	Representative drug	Mechanism of action	Advantages	Limitations
1st Generation	Streptokinase (SK), Urokinase (UK)[a]	Non-specifically activates plasminogen→plasmin, indirectly dissolving thrombi	Low cost, widely used clinically	Lacks fibrin specificity, may cause bleeding side effects
2nd Generation	t-PA, Alteplase	Preferentially activates plasminogen on thrombi with enhanced fibrin specificity	Bleeding risk, reduced better thrombolytic efficacy than 1st generation	Requires frequent Short half-life administration
3rd Generation	Monteplase, Tenecteplase, Pamiteplase	Genetically modified: Improved fibrin specificity, prolonged half-life (e.g., Tenecteplase has 3 mutation sites)	Higher thrombolytic efficiency, fewer side effects	High production costs, inherent risks of indirect thrombolysis (e.g., systemic bleeding)

3. Safety and Efficacy of Tenecteplase

As a modern thrombolytic agent, the safety and efficacy of tenecteplase are critical issues in clinical medicine. Adverse effects of tenecteplase, including bleeding, allergic reactions, thromboembolic events, and arrhythmias, are similar to those of other thrombolytic agents. Bleeding, the most common complication of tenecteplase and other thrombolytic therapies, can occur at any site throughout the body, including puncture sites and surgical wounds. Intracranial hemorrhage requires particular vigilance due to its significant association with increased mortality. Data indicate that the incidence of symptomatic intracranial hemorrhage in patients treated with tenecteplase (2.9%) is comparable to that of alteplase (2.7%) [28]. The bleeding risk of tenecteplase further escalates when co-administered with anticoagulants or antiplatelet agents. Clinical studies report that thrombolytic agents like tenecteplase may trigger thromboembolic events and cholesterol crystal embolization. Additionally, ST-segment elevation myocardial infarction (STEMI) patients undergoing thrombolytic therapy may experience arrhythmias associated with tissue reperfusion. The ASSENT-4 trial demonstrated that compared to the PCI-only group, the tenecteplase-plus-PCI group exhibited higher rates of mortality, cardiogenic shock, congestive heart failure, and reinfarction requiring repeat revascularization [29]. However, despite these adverse effects, multiple studies have confirmed the safety profile of tenecteplase. For example, Benedict *et al.* [30] found in rabbit experiments that tenecteplase did not induce platelet aggregation, thereby maintaining vascular patency and significantly reducing bleeding risks. C. Michael *et al.* [16] demonstrated in a multicenter randomized controlled trial that low-dose tenecteplase as an adjunct to PCI in STEMI patients is both feasible and safe. Further, Wang Jianyuan *et al.* [31] found in clinical trials that tenecteplase

thrombolysis in STEMI patients achieved significant efficacy, promoted cardiac function recovery, and effectively controlled adverse reactions and vascular events. Comprehensive analysis indicates that tenecteplase exhibits outstanding therapeutic performance and holds great potential for clinical application.

4. Application of Tenecteplase in AMI

4.1. Intravenous Tenecteplase

STEMI, as an extreme form of acute coronary syndrome, requires immediate reperfusion therapy upon diagnosis. For patients within 12 hours of symptom onset, intravenous thrombolysis should be prioritized. A 2024 clinical study by He Yuansheng [32] showed that intravenous tenecteplase significantly improved cardiac function and vascular recanalization rates in early STEMI patients. Compared to other thrombolytics, tenecteplase demonstrates unique advantages. For example, Huang Yunxi *et al.* [33] found no significant difference in recanalization efficiency or complication rates between tenecteplase and alteplase, but tenecteplase acted faster and was superior in reducing myocardial damage and bleeding events. Similarly, Bawaskar *et al.* [34] compared tenecteplase with streptokinase in STEMI patients, showing that tenecteplase had better thrombolytic effects and lower mortality. A 2023 retrospective analysis by Zheng Chenxi *et al.* [35] confirmed that tenecteplase outperformed urokinase in coronary recanalization, myocardial protection, and safety.

4.2. Intracoronary Tenecteplase

While intravenous thrombolysis before PCI can achieve rapid reperfusion, it increases bleeding risks. Balancing safety and efficacy, the combination of emergency PCI and intracoronary thrombolysis has gained attention in STEMI treatment. This approach has been proven effective in reducing no-reflow and slow-flow phenomena in high-thrombus-burden AMI patients [16] [17]. Although intracoronary tenecteplase is not widely adopted internationally, China's domestically developed tenecteplase (Mingfule) has entered clinical use. Current Recommendation from the Chinese Expert Consensus: The Chinese Expert Consensus on Microcirculation Protection Strategies for Emergency Percutaneous Coronary Intervention (PCI) in Patients with ST-Segment Elevation Myocardial Infarction (STEMI) recommends an intracoronary thrombolysis dosage of 4 - 8 mg Tenecteplase. Studies, such as those by He Lingyun [36] and Wang Hui [37], show that intracoronary tenecteplase combined with PCI improves outcomes in high-thrombus-burden patients, enhancing cardiac function, reducing myocardial damage, and lowering adverse event rates without increasing bleeding risks. The application of intracoronary tenecteplase in STEMI also exhibits individualized variability "**Table 2**". Studies suggest that intracoronary thrombolysis may play a role in the current primary percutaneous coronary intervention (PPCI) era, particularly in younger STEMI patients, those with massive thrombus burden, and those presenting relatively early after chest pain onset, potentially avoiding unnecessary stent

implantation and its associated complications [38]. Similarly, for STEMI patients with high thrombus burden and failed manual aspiration, low-dose intracoronary thrombolysis has been shown to be safe, effectively reducing thrombotic load to improve epicardial blood flow and myocardial reperfusion [39].

Table 2. Summary of research on the individualized application of intracoronary tenecteplase in STEMI.

Time	Number of patients	Patient type	TNK dosage and administration	Clinical efficacy
2020	40 TNK 20 Placebo 20	Age ≥ 18 years, ischemic chest pain lasting ≥ 20 minutes but < 6 hours, Angiographically confirmed STEMI with TIMI Bow grade 0 - 1, Scheduled for primary PCI within guideline- recommended timeframe	Pre-stent implantation 4mg (intracoronary bolus) Post-stent implantation: Additional 4 mg (intracoronary bolus)	Intracoronary Tenecteplase (TNK) Administration Significantly Reduces Thrombotic Burden Post-PCI with Demonstrated Safety
2018	9	High Thrombus Burden	1/5 Intracoronary injection 4/5 intravenous injection	TIME Flow Grade Myocardial Blush Grade ST-Segment Resolution
2014	30	TIMI Thrombus Grade 4 - 5 with Failed Thrombectomy	TNK 1/3 of standard Slow intravenous push ever 4 - 5 minutes	Reduces thrombus burden, thereby improving both epicardial Mood flow and myocardial reperfusion
2012	1	STEMI with Faded Primary PCI	40 mg (8000˚C)	Thrombus dissolution with restoration of TIMI flow
2005	34	Intracoronary Thrombotic Complications During PCI (Angiographically confirmed new progressing thrombus, no-Reflow phenomenon, distal embolization)	initial dove: 5 mg (intracoronary bolus) Repeat dosing: If coronary angiography shows persistent thrombus and/or no flow improvement (TIMI 51), administer additional 5 mg boluses Maximum total dose: 25 mg	Thrombus dissolution with TIMI flow improvement in 91% of patients Intracoronary TNK demonstrated safety and favorable tolerability
2005	85 TNK 24 1-PA 61	STEMI Patients with Failed Primary Recanalization of Chronic Total Occlusion	0.5 mg/h, 8 h	A procedural success rate of 5% - 47% was achieved. Intracoronary administration of fibrin-specific thrombolytics during PCI may represent a valuable and safe therapeutic option for STEMI patients with chronic total occlusion.

However, there remains an extreme paucity of high-quality evidence-based medical evidence in this area, with current conclusions largely reliant on small single-center studies that carry multiple limitations: Limited sample sizes (typically n < 100) result in insufficient statistical power to detect clinically meaningful differences, particularly reducing reliability in assessing rare adverse events. Selection bias is common, as participants are often recruited from a single geographic region or

institution, compromising the external validity of findings and limiting generalizability to broader populations. Clinical translation challenges: Conclusions from such studies require validation through multicenter trials. Direct extrapolation to diverse populations may lead to clinical decision-making errors. For example, single-center studies reporting bleeding rates as low as 1.2% for novel thrombolytics may deviate from real-world data (e.g., multicenter studies showing 3.5%). Thus, there is a critical need for larger-scale, multicenter randomized trials to establish robust evidence guiding optimal intracoronary thrombolytic strategies.

5. Current Research Status

Tenecteplase plays a vital role in STEMI treatment globally. While intracoronary tenecteplase is not widely used internationally, China's Mingfule (tenecteplase) has been clinically applied since 2015. Although molecularly similar to foreign TNK, differences exist in strain selection and production processes. Clinical trials confirm the benefits of intracoronary tenecteplase in PCI-treated STEMI patients, highlighting its potential as an emerging intervention.

6. Summary and Outlook

In summary, as a next-generation thrombolytic, tenecteplase demonstrates excellent safety and efficacy, making it a promising candidate for clinical adoption. In STEMI patients, tenecteplase improves cardiac function, enhances recanalization rates, and reduces adverse events. Its superiority over other thrombolytics further underscores its value. Studies have confirmed that tenecteplase exhibits individualized variability in its application across different ST-segment elevation myocardial infarction (STEMI) cases. Furthermore, tenecteplase can be combined with other thrombolytic agents to yield differential effects; however, research in this area remains limited. Thus, tenecteplase warrants further exploration in STEMI treatment.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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