Original Article

# Safety of conservative management for non-stenotic culprit lesions in STEMI patients treated with a two-step reperfusion strategy: a SUPER-MIMI sub-study

**Marc Bonnet[1]^, Stephanie Marliere[2], Victor Mathieu[3], Allan Tronchi[3], Nicolas Delarche[4], Mohamed Abdellaoui[5], Olivier Dubreuil[6], Ziad Boueri[7], Mohamed Chettibi[8], Geraud Souteyrand[9], Chloé Durier[10], Frederic Bouisset[11], Loic Belle[3]**

[1]Département de Cardiologie, Hôpital Universitaire de la Croix Rousse, Lyon, France; [2]Département de Cardiologie, Hopital Universitaire, Grenoble, France; [3]Département de Cardiologie, Centre Hospitalier Annecy Genevois, Metz-Tessy, France; [4]Département de Cardiologie, Centre Hospitalier de Pau, Pau, France; [5]Département de Cardiologie, Groupe Hospitalier Mutualiste, Grenoble, France; [6]Département de Cardiologie, Centre Hospitalier Saint Joseph-Saint Luc, Lyon, France; [7]Département de Cardiologie, Centre Hospitalier de Bastia, Bastia, France; [8]Département de Cardiologie, Hôpital Universitaire, Bilda, Algerie; [9]Département de Cardiologie, Hôpital Universitaire, Clermont Ferrand, France; [10]Département de Cardiologie, Centre Hospitalier Argenteuil, Argenteuil, France; [11]Département de Cardiologie, Hopital Universitaire, Toulouse, France

*Contributions:* (I) Conception and design: L Belle, M Bonnet; (II) Administrative support: All authors; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: L Belle, M Bonnet; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

*Correspondence to:* Loic Belle. Department of Cardiology, Hospital Annecy Genevois, 1 Avenue de l'Hopital, 74370 Metz-Tessy, France.
Email: loic.belle@wanadoo.fr.

**Background:** In the observational SUPER-MIMI study, a minimalist immediate mechanical intervention (MIMI) technique—which involves restoring blood flow in the acute phase and postponing stenting—was shown to be safe and effective among patients with a high thrombotic burden after ST-segment elevation myocardial infarction (STEMI). We aim to assess whether a non-stenting strategy after a SUPER-MIMI strategy was safe at 4-year follow-up in patients enrolled in the SUPER-MIMI study who were not stented.

**Methods:** This prospective cohort study assessed the long-term outcomes of a subgroup of patients included in the SUPER-MIMI study.

**Results:** Among the 155 patients enrolled in the SUPER-MIMI study, 57 patients (36.8%) benefited from a conservative management (without stenting or balloon angioplasty) and were included in the current substudy. The mean duration of follow-up was 4.1±1.0 years. Four patients (7.0%) presented definite culprit lesion re-thrombosis, all of which occurred in the right coronary artery. The re-thrombosis rate appeared to be higher among patients with larger vessels: 2.9%, 8.3%, and 28.6% in arteries with diameters of 3–<4, 4–<5, and ≥5 mm, respectively. The overall rate of target lesion revascularization was 10.5%. There was one cardiac death and three rehospitalizations for heart failure. Overall, 82.5% of patients remained event free at a mean of 4.1±1.0 years.

**Conclusions:** Conservative management of non-stenotic culprit lesions after a SUPER-MIMI strategy was associated with a high rate of re-thrombosis, particularly in patients with large coronary arteries.

**Keywords:** Acute coronary syndromes; ST-segment elevation myocardial infarction (STEMI); minimalist immediate mechanical intervention (MIMI) technique

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^ ORCID: 0000-0003-1847-1583.

## Introduction

Culprit lesion stenting is the evidence-based standard of care in patients with acute myocardial infarction undergoing primary percutaneous coronary intervention (PCI) (1,2). To prevent no-reflow, the minimalist immediate mechanical intervention (MIMI) technique—which involves restoring Thrombolysis In Myocardial Infarction (TIMI) 3 flow in the acute phase and postponing stenting—has been investigated (3-5). Although this strategy does not improve outcomes in non-selected patients with ST-segment elevation myocardial infarction (STEMI), it may be effective in specific subgroups (6). It also allows for a better assessment of the underlying culprit lesion, particularly in case of high thrombus burden (7,8).

The SUPER-MIMI strategy—which consists of restoring TIMI 3 flow with thin tools and postponing a second angiogram for ≥7 days—has been proven to be safe (8,9) and is commonly used in culprit lesions with a high thrombus burden. With a longer delay between the two procedures, this strategy allows for a better thrombus dissolution over time on antiplatelet therapy and may provide a safer condition in which to implant the stent. In the SUPER-MIMI study (8), 1.3% of patients had reinfarction of the infarct-related artery between the first and the second procedures, both of whom were not treated with glycoprotein IIb/IIIa inhibitors. In the SUPER-MIMI study, 36.8% of STEMI patients were managed without stent implantation or balloon angioplasty (8). These patients had complete thrombus dissolution without any significant residual stenosis (<50%) after the second angiogram.

Recent studies have suggested that systematic stenting of the infarct-related artery might not be necessary in the absence of significant residual stenosis (9-12). In a single-centre retrospective study, Souteyrand *et al.* (10) reported excellent outcomes with this strategy. Among 46 patients with an acute coronary syndrome (ACS) with non-vulnerable plaque [as assessed by optical coherence tomography (OCT)] managed without stenting after a MIMI strategy, no cardiac deaths or myocardial infarctions occurred after a mean follow-up of 1 year (10). Another OCT study demonstrated that an ACS secondary to plaque erosion could be safely managed conservatively (11,12). Such conservative treatment of the infarct-related artery could prevent acute and long-term complications associated with stenting, such as distal embolization, stent thrombosis, and restenosis (13). However, the long-term follow-up and safety of this conservative strategy are not well documented.

We therefore aimed to assess the long-term safety of PCI without stent implantation in patients with STEMI managed with a SUPER-MIMI strategy in the absence of significant residual stenosis on the second angiography. The current manuscript reports the long-term follow-up of the patients managed without stenting in the SUPER-MIMI study. We present the following article in accordance with the STROBE reporting checklist (available at https://cdt.amegroups.com/article/view/10.21037/cdt-21-631/rc).

## Methods

### *SUPER-MIMI study design*

The study design of the SUPER-MIMI study has previously been described (8). Briefly, SUPER-MIMI was a prospective, observational trial conducted between January 2014 and April 2015 in 14 French centres. Between January 2014 and April 2015, 155 patients were enrolled in the SUPER-MIMI study. It included adults (≥18 years) who met the following three criteria at first angiography: STEMI intended for primary, rescue, or routine PCI <48 hours after successful pharmacological or spontaneous reperfusion; restoration of an optimal epicardial flow in the culprit artery (either spontaneously or after minimal coronary manipulation using the thinnest tool/device); and a sufficiently important thrombotic burden for the operator to opt for delaying reassessment for ≥7 days. The main exclusion criteria were pre-hospital cardiac arrest, life expectancy <30 days, and indication for revascularization by coronary artery bypass grafting at the time of first coronary angiography (8).

### *The SUPER-MIMI strategy*

Reperfusion of the infarct-related artery was attempted by means of prehospital fibrinolysis, guidewire recanalization, thrombus aspiration, and small-diameter balloon angioplasty. If optimal reperfusion was achieved—defined by a TIMI 3 flow—no additional angioplasties were performed during the acute phase. All non-stented patients underwent a subsequent delayed angiogram, ≥7 days after the first (8). In the SUPER-MIMI study, there were no guidelines on how to manage the patient during the second procedure. As such, the decision to stent or manage the culprit lesion conservatively during the second angiogram was at the discretion of the operator.

 

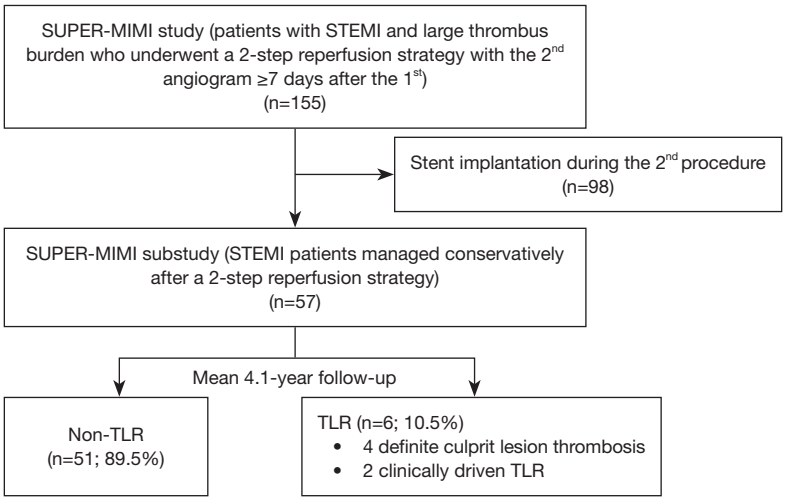


**Figure 1** Study flow diagram. STEMI, ST-segment elevation myocardial infarction; TLR, target lesion revascularization.

### *SUPER-MIMI substudy*

The SUPER-MIMI substudy includes the 57 of 155 patients (36.8%) in the SUPER-MIMI study who were managed conservatively without stent implantation during the second procedure.

All patients provided written informed consent to participate in the substudy. An information sheet was given to the patient or their relatives. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The regulatory authorizations have been done on the Commission nationale de l'informatique et des libertés (number 2215079) and on the Health data hub National repertory (number I41102009192019).

Follow-up involved screening for major adverse cardiac events (death, recurrence of myocardial infarction, or need for surgical or percutaneous revascularization) and functional assessment (recurrence of angina). The primary endpoint was a composite of definite or probable new thrombosis of the culprit lesion [defined by analogy to the definitions of definite and probable stent thrombosis proposed by the Academic Research Consortium recommendations (14)]. The secondary endpoints were the rates of: definite culprit lesion thrombosis or clinically driven (urgent and non-urgent) target lesion revascularization (TLR), death (cardiac, non-cardiac, unknown cause), and rehospitalization for heart failure.

Clinical outcomes since the index procedure have been collected from cardiologists and/or by conducting telephone surveys with the patients. The referring centre was in charge of the survey. In the event that a new angiogram was required, it was reviewed by two independent operators who were not involved in the study. They independently quantified the degree of stenosis in the culprit artery, the presence and location of the thrombus, and the TIMI flow grade. They then compared these to the index angiogram.

### *Statistical analyses*

Continuous variables are summarized as means and standard deviations (SDs). Categorical variables are presented as frequencies and percentages. Statistical analyses were performed using SPSS software.

## Results

### *Patients and baseline characteristics*

The study flow chart is shown in *Figure 1*. This substudy cohort included 57 STEMI patients who were managed conservatively after a two-step reperfusion strategy. None of the patients were lost to follow-up, which ended in May 2020 after a mean follow-up of 4.1±1.0 years.

The substudy population included mainly male patients (84.2%) and the mean age was 53.8±14.4 years (*Table 1*). Many (64.9%) were active smokers and only 8.8% had diabetes mellitus. The majority of patients (80.7%) had single-vessel disease and there was a low rate of coronary or cerebrovascular history (3.5%). The majority of patients presented with Killip 1 STEMI (84.2%).

 

**Table 1** Baseline patient characteristics

| Characteristics | Value |
|---|---|
| Patients | 57 |
| Age (years) | 53.8±14.4 |
| <50 years | 28 (49.1%) |
| 50–70 years | 21 (36.8%) |
| >70 years | 8 (14.0%) |
| Male | 48 (84.2%) |
| Cardiovascular risk factors | |
| Smoking | 37 (64.9%) |
| Dyslipidaemia | 13 (22.8%) |
| Hypertension | 13 (22.8%) |
| Obesity | 12 (21.1%) |
| Family history of coronary artery disease | 9 (15.8%) |
| Diabetes mellitus | 5 (8.8%) |
| Medical history | |
| Myocardial infarction | 3 (5.3%) |
| PCI | 2 (3.5%) |
| Stroke | 2 (3.5%) |
| Coronary artery bypass grafting | 0 |
| Presentation | |
| Killip 1 | 48 (84.2%) |
| Killip 2 | 2 (3.5%) |
| Killip 4 | 1 (1.8%) |
| Unknown | 6 (10.5%) |
| Culprit lesion location | |
| Right coronary artery | 28 (49.1%) |
| LAD artery | 24 (42.1%) |
| Proximal LAD artery | 19 (33.3%) |
| Mid LAD artery | 5 (8.8%) |
| Circumflex artery | 5 (8.8%) |
| Other lesion(s) | |
| Multi-vessel disease (>70% stenosis) | 11 (19.3%) |
| Left main coronary artery | 6 (10.5%) |

Values are expressed as mean ± SD or n (%). PCI, percutaneous coronary intervention; LAD, left anterior descending; SD, standard deviation.

**Table 2** Procedural characteristics

| Characteristics | Value |
|---|---|
| Patients | 57 |
| Initial procedure | |
| Reperfusion strategy | |
| Primary PCI | 47 (82.5%) |
| PCI after reperfusion | 6 (10.5%) |
| Rescue PCI | 4 (7.0%) |
| Procedural characteristics | |
| Thromboaspiration | 36 (63.2%) |
| Glycoprotein IIb/IIIa inhibitors use between the two procedures | 29 (50.9%) |
| Second procedure | |
| Time interval between the two procedures (days) | 11.5±6.9 |
| TIMI flow | |
| Grade 2 | 1 (1.8%) |
| Grade 3 | 56 (98.2%) |
| Artery diameter (mm) | 3.8±1.0 |
| ≥4 mm | 19 (33.3%) |
| Lesion length (mm) | 7.5±6.6 |
| Bifurcation | 10 (17.5%) |
| Ectatic/aneurysmal target segment | 7 (12.3%) |
| Residual stenosis (%) | 21.3±17.8 |
| 30–50% | 23 (40.4%) |
| <30% | 34 (59.6%) |
| Treatment | |
| Aspirin | 57 (100.0%) |
| Dual antiplatelet therapy | 57 (100.0%) |
| Ticagrelor | 28 (49.1%) |
| Prasugrel | 21 (36.8%) |
| Clopidogrel | 8 (14.0%) |

Values are expressed as n (%) or mean ± SD. PCI, percutaneous coronary intervention; SD, standard deviation; TIMI, Thrombolysis In Myocardial Infarction.

**Table 3** Characteristics of the four patients with culprit lesion re-thrombosis

| Patient | Thrombosis time interval[a] | Event type | Culprit lesion characteristics[b] | | | | Antiplatelet therapy |
|---|---|---|---|---|---|---|---|
| | | | Localization | DRS (%) | Length (mm) | RVD[c] (mm) | |
| 1 | 38 days | Definite thrombosis | Distal RCA | 10 | 0 | 7 (ectatic) | Aspirin + clopidogrel |
| 2 | 2 years | Definite thrombosis | Distal RCA | 40 | 16 | 7 (ectatic) | Aspirin |
| 3 | 3.5 years | Definite thrombosis (previously stented mid-RCA, first year) | Mid RCA (previously stented) | 30 | 6 | 3.5 | Aspirin |
| 4 | 3.8 years | Definite thrombosis | Mid RCA | 30 | 7 | 4 | Aspirin |

[a], Time interval from first angiogram. [b], Culprit lesion characteristics on the control angiogram. [c], Diameter of the normal segment proximal to the culprit lesion. DRS, diameter residual stenosis; RCA, right coronary artery; RVD, reference vessel diameter.

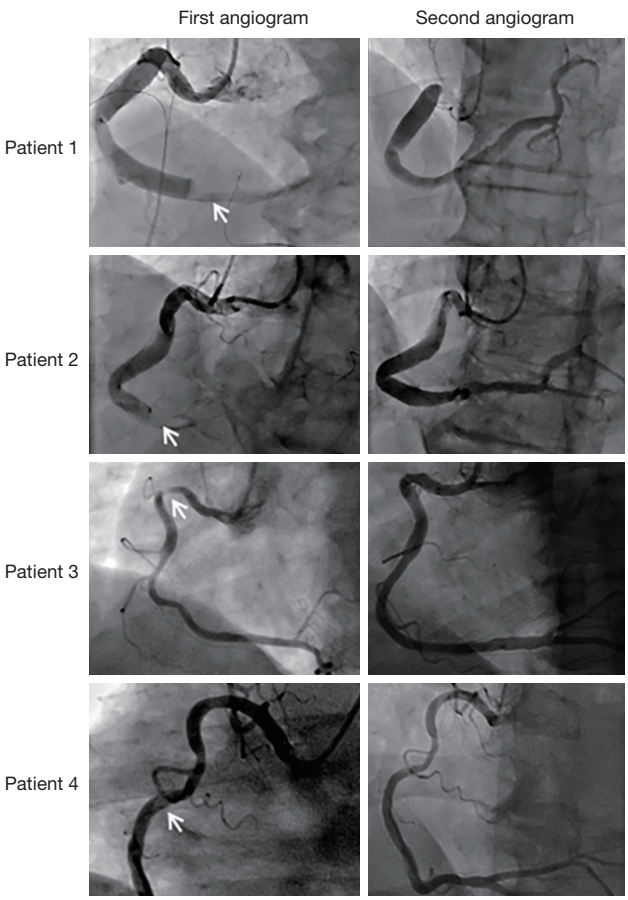


**Figure 2** Angiograms of culprit lesions that ultimately re-thrombosed. The left column displays the first angiogram (acute phase) and the right column, the second angiogram. The white arrows indicate thrombi.

### *Culprit lesion characteristics*

The culprit lesion diameter residual stenoses (DRS) during the second angiogram were all below 50% (*Table 2*). In contrast to patients who were managed conservatively, patients who were stented in the SUPER-MIMI study had more significant residual stenosis with 71.4% of the culprit lesion DRS above 50%.

### *Procedural characteristics*

Most patients underwent primary PCI (82.5%) (*Table 2*). Thromboaspiration was performed in 63.2% of patients and 50.9% benefited from glycoprotein IIb/IIIa inhibitor administration. The mean time between the two procedures was 11.5±6.9 days. All 57 patients were initially treated with dual antiplatelet therapy after the second procedure.

### *Clinical outcomes*

The primary endpoint (definite or probable new thrombosis of the culprit lesion) was met in four patients (7.0%), with all four patients having definite culprit lesion thrombosis. One culprit lesion thrombosis occurred during the first year, one occurred at 2 years, and two occurred at 4 years. One of them occurred on a previously stented artery (stent thrombosis managed with a SUPER-MIMI strategy) while the other three occurred on native non-stented right coronary arteries. *Table 3* presents the characteristics of the four patients with culprit lesion re-thrombosis, all of which occurred in right coronary arteries (RCAs). *Figure 2*

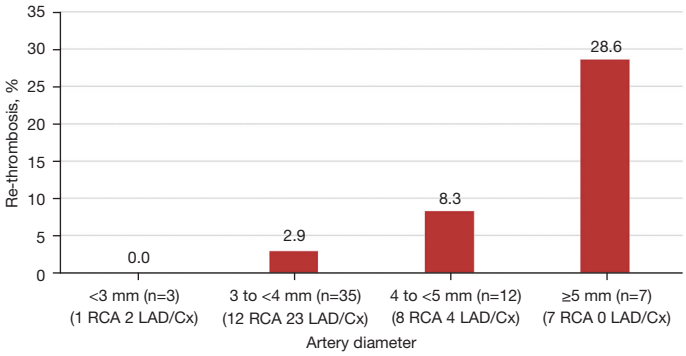


**Figure 3** The rate of culprit lesion re-thrombosis increased with increasing artery diameter (assessed on quantitative coronary angiography analysis). Cx, circumflex; LAD, left anterior descending; RCA, right coronary artery.

shows the first and control angiograms of the culprit lesion that ultimately re-thrombosed. The rate of culprit lesion re-thrombosis increased with increasing diameter of the affected artery (*Figure 3*). Of note, the mean diameter of the RCAs was larger than that of the left anterior descending or circumflex arteries (4.21±1.20 *vs.* 3.46±0.45 mm; P=0.004).

The first secondary endpoint was met in six patients (10.5%): four definite culprit lesion re-thrombosis and two clinically driven target lesion revascularization (one urgent and one non urgent) (*Figure 1*). Three patients were re-hospitalized for heart failure and there was one death (sudden cardiac death, unexplained, 51 days after inclusion).

The overall rate of the combined primary and secondary endpoints was 17.5% (six TLR, one cardiac death, and three rehospitalizations for heart failure), meaning that 82.5% of patients remained free of these events after a mean follow-up of 4.1±1.0 years.

## Discussion

In our selected population of STEMI patients—those with a large thrombus burden who benefited from a two-step reperfusion strategy with a second angiogram after the seventh day—a conservative management without stent implantation in case of culprit lesion without significant residual stenosis was associated with an unexpectedly high rate of definite culprit lesion re-thrombosis (7.0% at 4 years).

Our culprit lesion re-thrombosis rate is higher than those reported in other conservative management studies guided with OCT imaging (10,11). In a single-centre retrospective study, Souteyrand *et al.* (10) reported excellent outcomes. Among 46 patients with ACS with non-vulnerable plaque (as assessed by OCT) managed without a stent after a MIMI strategy, no re-thrombosis occurred after 1 year of follow-up (10). In the EROSION study (11), all patients were free from culprit lesion re-thrombosis after a mean follow-up of 4.8 years. In these two studies, all patients were free from death and myocardial infarction.

The baseline characteristics of our cohort are consistent with other populations of STEMI patients who have been managed conservatively, which have consistently included younger patients with higher rates of smoking and lower rates of diabetes and hypertension (9,10,15) compared with a general population with ACS (16,17). The high rate of non-stenotic culprit lesions among younger patients with myocardial infarction might be explained by a different underlying mechanism in these patients, with a higher prevalence of erosive lesions that usually display relatively minor luminal narrowing (10). In a histopathological study, smoking history has also been reported as a prominent risk factor among younger patients with coronary thrombosis; and hypertension and diabetes were more prevalent in stable coronary artery disease (18).

Two aspects should be discussed to explain the higher rate of re-thrombosis in our cohort: the anatomical characteristics and selection of culprit lesions eligible for conservative management. Firstly, when examining the anatomical characteristics, we noticed that the culprit coronary arteries in our cohort were very large, likely because patients with such anatomy are more prone to develop a higher thrombus burden and benefit from a SUPER-MIMI strategy. In our study, the mean reference vessel diameter was 3.82 mm, compared to 3.18 mm in the EROSION study (19) and 3.48 mm in the study by Souteyrand *et al.* (10) Also, the rate of ectatic/aneurysmal culprit lesion was 12.3% in our cohort, whereas the rate among patients with non-selected acute myocardial infarction is around 3% (20). When looking at the culprit

 

coronary arteries that presented new thromboses, two characteristics were noteworthy. First, the thrombosis rate seemed to be higher in large coronary arteries with re-thrombosis rates of 8.3% in coronary arteries of 4 to <5 mm and 28.6% for those >5 mm. Second, all re-thromboses occurred in right coronary arteries, which had a larger mean diameter than the left anterior descending and circumflex arteries (4.21 *vs.* 3.45 mm; P=0.004). We could hypothesized that altered flow characteristics in large segments could predispose to culprit lesion re-thrombosis. Also, endothelial cells that are exposed to low and/or directional varying wall shear stress are known to display a pro-inflammatory state (21). Low shear stress is recognized as one element of plaque vulnerability in non-culprit high-risk plaques (22). Coronary artery ectasia has also been shown to be associated with enhanced thrombogenicity and inflammatory reactions, such as activation of tumor necrosis factor-α and interleukin-1β (23). Only one small study has investigated STEMI patients with very large or ectatic/aneurysmal coronary arteries (20). This study reported a higher event rate in patients with coronary ectasia presenting with acute myocardial infarction, with 28% having a major adverse cardiac event during 49-month follow-up versus 8% among patients without coronary ectasia (20). Further, patients who achieved a time in therapeutic range ≥60% with warfarin exhibited a lower occurrence of MACE than those with <60% or without anticoagulation therapy (20). The proper management in this setting therefore remains to be defined. Stent implantation does not seem to be a viable option due to mechanical issues, and undersizing and malapposition might increase the risk of re-thrombosis. A dedicated antithrombotic regimen with a prolonged and more aggressive antiplatelet therapy and/or an association with oral anticoagulant therapy is a compelling option. However our sample of patient is too small to draw definite conclusion about the effect of coronary artery dilation or ectasia. Further prospective randomized studies are warranted to confirm this observation and to define the optimal management of STEMI on ectatic coronary arteries.

Secondly, we wish to discuss the selection of culprit lesions eligible for conservative management. To date, the criteria to guide the decision to treat a STEMI culprit lesion conservatively have not been defined. Some authors have studied the role of OCT analysis in this setting (10,11,19). Due to its superior spatial resolution, OCT imaging provides additional valuable information on the underlying mechanism of the thrombotic event (namely plaque rupture or erosion) (24,25). As previously discussed, a few studies have suggested that plaque erosion or "non-vulnerable plaque rupture" ["a vulnerable plaque rupture being" defined by Souteyrand *et al.* (10) as a mobile plaque in continuity with the coronary wall; with evidence of plaque prolapse into the lumen; and a maximal plaque length exceeding one third of the arterial diameter] could safely be managed conservatively in the absence of significant residual stenosis when associated with dual antiplatelet therapy with a low rate of new thrombosis and target lesion failure (12,19,26). However, whether OCT could help guide treatment decisions in these patient remains uncertain and, to date, there are no formal OCT criteria to predict the risk of re-thrombosis. To our knowledge, no study has compared OCT and angiography-alone analyses to guide the conservative management of STEMI patients with non-stenotic culprit lesions. As coronary imaging was not systematically used to guide our management, our cohort should encompass plaque erosion as well as ruptured plaque. Furthermore, OCT imaging might be uninterpretable in ectatic coronary arteries. Further randomized controlled studies are needed to assess the influence of OCT in guiding treatment decisions in these patients and to define criteria to assess the risk of re-thrombosis of these non-stenotic culprit lesions. In the meantime, conservative management should not be the default strategy in patients with non-stenotic culprit lesions after a STEMI. Rather, each individual should be assessed on a case-by-case basis. The role of fractional flow reserve measurement could also be debated in this setting, but this was not investigated in our cohort.

### *Limitations*

This was a non-randomized prospective design with a small sample and a selected population. The main limitation is the lack of comparison with STEMI patients managed by stenting. Also, our population was highly selected, as we only included patients with STEMI with a large thrombotic burden managed with a SUPER-MIMI strategy. Thus, our results cannot be extended to all patients admitted for STEMI.

Our conservative management was mainly based on angiographic criteria alone, which is not accurate to determine the haemodynamic impact of a stenosis. Moreover, the decision to treat conservatively was at the operator's discretion and no criteria were defined "à priori". Thus, we are not able to provide any consistent angiographic criteria. Fractional flow reserve and OCT, as

 

discussed above, could help to select culprit lesions at low risk of re-occlusion. Further studies are needed to define criteria and provide a more tailored approach.

## Conclusions

The present study shows that conservative management of non-stenotic culprit lesions in patients who presented with a STEMI and were managed with an initial two-step reperfusion strategy was associated with a high rate of culprit lesion re-thrombosis (7.0%). Randomized controlled studies are warranted to define angiographic and/or OCT criteria that could be used to assess the risk of re-thrombosis of non-stenotic culprit lesions treated conservatively.

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## Footnote

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*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at https://cdt.amegroups.com/article/view/10.21037/cdt-21-631/coif). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All patients provided written informed consent to participate in the substudy. An information sheet was given to the patient or their relatives. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The regulatory authorizations have been done on the Commission nationale de l'informatique et des libertés (number 2215079) and on the Health data hub National repertory (number I41102009192019).



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