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Title: Mechanical complications in ST-elevation myocardial infarction: the impact of pre-hospital delay

Running title: Mechanical complications in STEMI

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1. Introduction

Mechanical complications (MC) in the setting of ST-elevation Myocardial Infarction (STEMI) include free wall rupture (FWR), papillary muscle rupture (PMR) and ventricular septal rupture (VSR). These are rare, but disastrous complications, with a poor prognosis which did not improve over the last two decades¹⁻³. Reperfusion therapy, however, and in particular primary percutaneous coronary intervention (PCI), has led to a decrease in the frequency of these MC, as compared to the pre-reperfusion era^{1,4,5}. The main risk factors for MC occurrence in the setting of STEMI include older age and female sex^{4,6-9}.

MC risk is classically considered to increase with the duration of myocardial ischemia, but differs according to the type of MC¹⁰⁻¹². Most of available data, however, come from past reports, the majority of which predate the era of myocardial reperfusion. Moreover, the incidence, at the present time, of MC according to pre-hospital delay remains unknown.

We thus conducted an analysis on a large, contemporary, nationwide STEMI population in order to determine the global and individual rates of each type of mechanical complications according to pre-hospital delay.

2. Material and methods

2.1. Population

The present analysis was performed on data from the MODIF registry, which was initially designed to assess the management and prognosis of ST-elevation myocardial infarction in France during the COVID-19 outbreak. The detailed design of this survey has already been published¹³. In summary, MODIF is a retrospective, observational, multicenter nationwide study which included 65 public and private interventional cardiology centers in metropolitan France and La Réunion (French island in the Indian Ocean), initiated by the *French Society of Cardiology* and endorsed by the Coronary Atheroma and Interventional Cardiology Group “*Groupe Atherome Coronaire et Cardiologie*” (GACI) (**Supplementary Table 1**). This study included all consecutive patients with STEMI – as defined by the European Society of Cardiology¹⁴ – presenting within 48 hours after symptoms onset and referred for urgent revascularization to the heart catheterization laboratory over two periods: from March, 1st to May, 31st 2019 and from March 1st to May, 31st 2020. Patients with delayed presentation and criteria of revascularization were included in the analysis. The MODIF survey was declared to the French data protection committee (Commission Nationale Informatique et Liberté, MR0617050520), was registered on the clinical trial website ClinicalTrials.Gov (NCT04357314) and was conducted in accordance with the Declaration of Helsinki. The authors had full access to and take full responsibility for the integrity of the data.

2.2. Data collection

Data were collected by local investigators in an electronic case report form via REDCap software (Research Electronic Data Capture, Vanderbilt University) hosted by a secured server from the French Institute of Health and Medical Research at the Paris Cardiovascular Research Center.

Patient demographics including age, body mass index (BMI) and sex were obtained. Cardiovascular risk factors and past medical history were also collected. Delays between symptoms onset and first medical contact, PCI (percutaneous coronary intervention), and in-hospital complications were recorded. MC were classified into three categories: free wall rupture (FWR), papillary muscle rupture (PMR) and

ventricular septal rupture (VSR). Patients were allocated to four groups according to the duration of the pre-hospital delay: 0 to 12 hours, 12 to 24 hours, 24 to 36 hours and 36 to 48 hours. Since the present registry only included patients referred for urgent revascularization, we considered as pre-hospital delay the delay between symptom onset and arrival to the catheterization laboratory, as it corresponded to the patient's hospital admission in this context.

During the 2020 phase of recruitment, corresponding to the first peak of COVID-19 pandemic in France, patients were classified as being infected by COVID-19 if they had a positive test result on reverse transcriptase polymerase chain reaction.

2.3. Outcomes

The primary objective of the present study was to describe the global and individual rates of the three types of MC, based on the delay between symptoms onset and hospitalization. Mechanical complications were classified into three groups : free wall rupture (FWR), papillary muscle rupture (PMR) and ventricular septal rupture (VSR) and defined by echocardiography¹⁴.

The secondary objective was to describe the clinical and paraclinical characteristics of the patients who presented with MC, as compared to patients who remained unaffected by MC.

2.4. Statistical analyses

Statistical analysis was performed on STATA statistical software, release 14.1 (Stata Corporation, College Station, Texas, USA). Continuous variables were summarized as means and standard deviations for normal distributions, and as medians and interquartile ranges when distributions were not normally distributed. Categorical variables are presented as proportions. In univariate analysis, categorical variables were compared with *Chi²-test* (or *Fischer's exact test* when necessary). *Student's t test* or *ANOVA* were used to compare the distribution of continuous normally distributed data according to categorical variables. *Mann-Whitney* and *Kruskal-Wallis tests* were used to compare ranges of continuous non-normally distributed variables according to categorical variables. A p-value < 0.05 was considered as statistically significant.

Characteristics independently related to MC occurrence were initially assessed by determining a crude OR by a logistic regression, and then a model adding all variables associated with a p-value < 0.20 in univariate analysis was built to obtain a complete model. Afterwards, a backward procedure was applied in order to assess the variables that were significantly and independently associated with MC occurrence ($p < 0.05$).

3. Results

A population of 6306 STEMI patients were enrolled over the whole duration – six months in total – of the study. One hundred twenty-one patients (1.9%) were excluded because of missing data, 6185 patients were thus included in the final analysis. Mean age was 64.1 years, and 75.7% of patients were males. Eighty-three patients (1.34%) presented with MC (32 patients in 2019 and 51 patients in 2020). Among these 83 patients, 44 (0.71%) experienced a FWR, 17 (0.27%) a PMR, and 22 (0.36%) a VSR (**Figure 1**). Each of the four groups, determined by a pre-hospital admission delay of 0 to 12 hours, 12 to 24 hours, 24 to 36 hours and 36 to 48 hours, included 4733 patients, 561 patients, 242 patients, and 651 patients, respectively.

3.1. Primary endpoint

The global rate of MC significantly increased with pre-hospital delay, with a value of 0.82%, 1.43%, 1.24% and 5.07% obtained for delays of 0 to 12 hours, 12 to 24 hours, 24 to 36 hours and 36 to 48 hours, respectively ($p < 0.001$). The same tendency, although not statistically significant, was observed for the three types of MC ($p = 0.16$) (**Figure 2**).

3.2. Secondary endpoint

Patients presenting with MC were significantly older (71.4 (+/-13.8) vs 64 (+/-13.5) years old, $p < 0.001$), and more frequently female (43.4 vs 24%, $p < 0.001$). Cardiovascular risk factors did not differ among patients with MC and without MC, except for family history of coronary artery disease (CAD), less frequent among patients who experienced MC (8.5% vs 18.6%, $p = 0.02$). No difference was observed regarding prior comorbidities, the mode of arrival and cardiac arrest at admission among patients with MC and those who did not present mechanical complications. The delay between symptoms onset and first medical contact was significantly longer among patients with MC: 801 [210 – 3406] vs 135 [60 – 369] min, $p < 0.001$. As a result, the delay between symptoms onset and cardiac catheterization (*i.e.*, pre-hospital delay) was also significantly longer among patients with MC (1111 [320 – 2880] vs 254 [145

– 660] min, $p < 0.001$). The presence of MC was not related to the location of the culprit lesion, as observed during the coronary angiography procedure, however, patients with MC were more likely to present a flow TIMI 0 or 1 in the culprit vessel (87.2% vs 66.2%, $p < 0.001$). Following the coronary angiography procedure, patients who experienced MC were more likely to be treated without PCI (27.7% vs 10.1%, $p < 0.001$), and to be sent to surgery when possible. Regarding laboratory investigations, patients with MC had a poorer renal function (68 [49 – 92] vs 88 [70 – 105] ml/min/m² GFR, $p < 0.001$), and a higher troponin elevation (253 [92 – 735] vs 58 [10 – 300] x URL, $p < 0.001$). Inflammation was also more important among patients with MC, with a higher CRP level (42 [7 – 114] vs 4 [2 – 11.5] mg/l, $p < 0.001$). On transthoracic echocardiography, a lower level of left ventricular ejection fraction (LVEF) was observed among patients presenting with MC: 42% (+/-14) vs 49% (+/-11). Left ventricular aneurysm and left ventricular thrombus were also more frequent among patients with MC: 4.8% vs 0.4% and 3.6% vs 1.3%, respectively. Finally, in-hospital complications were more likely to occur in patients with MC. In-hospital cardiac arrest, cardiogenic shock, and death were significantly more frequent among patients with MC with rates of 28.9% vs 5.4%, 39.8% vs 6.4%, and 47% vs 5.2%, respectively, $p < 0.001$ for all. The median length of stay did not differ between patients with or without mechanical complications with a value of 5 days in both groups. However, in the MC group, the length of stay was highly variable between deceased patients - who had a short length of stay with a median of 2 days - and patients who survived, whose length of stay was longer with a median of 14 days. A detailed comparison of patient characteristics, prior and during hospitalization, according to MC occurrence is presented in **Table 1**.

In multivariate analysis, factors independently related to the presence of MC were: age, female sex, COVID-19 infection, absence of dyslipidemia, pre-hospital delay, initial TIMI flow of 0 or 1 in the culprit vessel, and absence of revascularization during coronary angiography. (**Table 2**).

The comparison of the 3 types of MC showed no significant differences regarding clinical, paraclinical features and presentation, except for the presence of a culprit lesion on the circumflex artery, statistically more frequent in case of PMR. The other difference was the COVID-19 infection, more frequent in patients that presented a VSR ($p = 0.02$). A tendency for longer pre-hospital delay was observed in case

of PMR and VSR ($p=0.14$ for symptoms onset to first medical contact and $p=0.1$ for symptoms onset to cardiac catheterization). A detailed comparison of patient characteristics according to the three types of mechanical complication is presented in **Supplementary Table 2**.

4. Discussion

The present study included 6185 STEMI patients recruited in 65 French interventional cardiology centers over two three-month periods in 2019 and 2020. Among these patients, 83 (1.34%) presented with a mechanical complication of their myocardial infarction: 44 (0.71%) experienced a free wall rupture, 17 (0.27%) a papillary muscle rupture and 22 (0.36%) a ventricular septal rupture. The incidence of MC significantly increased with the delay between symptoms onset and cardiac catheterization, from 0.82% within 0 to 12 hours to 5.07% within 36 to 48 hours of pre-hospital delay.

As compared to recent series, which estimated the incidence of post AMI MC to be comprised between 0.27 to 0.91%^{1,2}, we observed a higher rate of MC of 1.34% in our cohort. This difference may be explained by the fact that the recruitment of half of our cohort was performed during the first wave of the COVID-19 pandemic in France. This period was associated with a strong decrease in hospitalizations for acute coronary syndrome^{15,16} and with a longer delay between symptoms onset and first medical contact and hospitalization¹³, as patients feared to be hospitalized in the context of COVID-19 outbreak. These longer delays contributed to a higher incidence of MC, as demonstrated in a previous study based on the same registry¹³.

In our cohort, the prognosis of patients presenting with MC was poor: in-hospital global mortality rate was 47%, with no differences according to the type of MC (44.2% for FWR, 47.1% for PMR and 54.6% for VSR, $p = 0.71$). These data are in line with recent studies derived from nationwide databases created in other countries, which reported in-hospital mortality rates ranging from 42.4% in the United States of America to 59.5% in Spain, but did not report any data regarding pre-hospital delay^{2,17}. Similarly, we observed that FWR was the most frequent MC in the setting of STEMI, as usually reported in other registries⁹. In our cohort, pre-hospital delay was independently related to the occurrence of MC (**Table 2**): patients presenting with a 36 to 48 hours delay exhibited a 5 times higher risk for MC than patients presenting within 12 hours after symptoms onset. Compared to previous surveys assessing the relationship between pre-treatment delay and occurrence of MC¹⁸, our study, based on a contemporary cohort, provides a more precise description of this relationship, and describes the incidence rate of MC for every 12-hour interval from symptoms onset.

In addition, our multivariate analysis showed a significant relationship between an initial TIMI flow 0 or 1 in the culprit artery and occurrence of a MC. This relation is consistent with the fact that the preservation of an antegrade TIMI flow is known to be associated with a reduction of the infarct size^{19,20} and with better clinical outcomes²¹. However, the observation of a higher probability of MC in the absence of angioplasty with stent insertion (Table 2) is probably related to the fact that the detection of MC occurred, in most cases, prior or during the coronary angiography procedure: patients were then referred for surgery – which remains the treatment of choice of MC – and thus did not undergo PCI in this context of MC.

Interestingly, in our study, COVID-19 infection was independently related to the occurrence of MC. So far, the COVID-19 pandemic in ACS patients, was described as being associated with longer delays and poorer prognosis¹⁶ – in particular with more cases of cardiogenic shock²². Here, this observation cannot be explained by longer delays, as pre-hospital delay is included in the model. One could hypothesize that inflammation and larger thrombus burden²³ associated with COVID-19 infection could promote MC occurrence. However, it should be underlined that in our study, only 3 patients with a COVID-19 infection presented a MC, which precludes definitive conclusion. This observation needs to be confirmed on larger cohorts.

Limitations

The main limitation of this study is the fact that it was conducted retrospectively, generating potential bias in data collection. However, this bias appears to be limited in the present analysis, as MC are usually clearly documented in medical reports. Another limitation is the absence of patients admitted above 48 hours following symptoms onset in the MODIF registry, preventing the calculation of the incidence of MC above this delay. Moreover, follow-up data were not available, it was thus not possible to study the mid- and long-term prognosis of patients who experienced MC. Finally, the registry only included STEMI patients, preventing the study of MC occurrence in non-STEMI settings.

5. Conclusion

Among patients presenting with STEMI within 48 hours following symptoms onset, the rate of mechanical complications increased with the delay between symptom onset and hospitalization. A significant increase is observed above a 36-hour delay. Moreover, COVID-19 infection could promote MC complication in STEMI patients, independently of pre-hospital delay.

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Tables

	All (n=6185)	No mechanical complications (n=6102)	Mechanical complications (n=83)	p-value
Demographics				
Male sex, n (%)	4683/6185 (75.7)	4636/6102 (76)	47/83 (56.6)	<0.001
Age (years), mean (SD) (n= 6182)	64.1 (13.5)	64 (13.5)	71.4 (13.8)	<0.001
BMI (kg/m ²), mean (SD) (n= 5854)	26.8 (5.7)	26.8 (5.8)	25.6 (4.2)	0.06
Cardiovascular risk factors				
Active tobacco, n (%)	2404/5941 (40.5)	2381/5865 (40.6)	23/76 (30.3)	0.07
Diabetes, n (%)	1189/6177 (19.3)	1174/6095 (19.3)	15/82 (18.3)	0.83
Hypertension, n (%)	2787/6176 (45.1)	2749/6094 (45.1)	38/82 (46.3)	0.82
Dyslipidaemia, n (%)	2099/6166 (34.0)	2079/6084 (34.2)	20/82 (24.4)	0.06
Family history of CAD, n (%)	1142/6170 (18.5)	1135/6088 (18.6)	7/82 (8.5)	0.02
Prior comorbidities				
PAD, n (%)	259/6174 (4.2)	253/6092 (4.2)	6/82 (7.3)	0.15
Stroke, n (%)	258/6175 (4.2)	256/6093 (4.2)	2/82 (2.4)	0.42
Previous CAD, n (%)	868/6176 (14.1)	857/6094 (14.1)	11/82 (13.4)	0.87
Presentation				
COVID-19 infection	55/6185 (0.9)	52/6102 (0.9)	3/83 (3.6)	<0.001
Pre-hospital cardiac arrest, n (%)	452/6178 (7.3)	443/6095 (7.3)	9/83 (10.8)	0.21
Mode of arrival				
				0.17
French SAMU (Mobile Urgent Medical Aid), n (%)	3888/6184 (62.9)	3844/6101 (63)	44/83 (53)	
Emergency ward, n (%)	2107/6184 (34.1)	2071/6101 (34)	36/83 (43.4)	
In-hospital transfer, n (%)	189/6184 (3.1)	186/6101 (3.1)	3/83 (3.6)	
Delays				

Time between onset of symptoms and first medical contact (min), median [IQR] (n=5907)	136 [60 - 388]	135 [60 - 369]	801 [210 - 3406]	<0.001
Time between first medical contact and cardiac catheterization (min), median [IQR] (n= 5930)	85 [54 - 163]	85 [54 - 162]	96 [60 - 255]	0.13
Time between onset of symptoms and cardiac catheterization (min), median [IQR] (n=6185)	254 [145 - 660]	254 [145 - 660]	1111 [320 - 2880]	<0.001
Length of stay (days), median [IQR] (n= 5861)	5 [3 - 7]	5 [3 - 7]	5 [1 - 16]	0.86
Angiographic findings				
Culprit lesion				
Left Main Coronary Artery	86/6185 (1.4)	86/6102 (1.4)	0/83 (0)	0.27
Left Anterior Descendant Artery	1979/6185 (32.0)	1953/6102 (32.0)	26/83 (31.3)	0.89
Diagonal branch	217/6185 (3.5)	215/6102 (3.5)	2/83 (2.4)	0.58
Circumflex Artery	641/6185 (10.4)	633/6102 (10.4)	8/83 (9.6)	0.82
Marginal branch	316/6185 (5.1)	313/6102 (5.1)	3/83 (3.6)	0.53
Right Coronary Artery	1776/6185 (28.7)	1745/6102 (28.6)	31/83 (37.4)	0.08
Other	114/6185 (1.8)	114/6102 (1.9)	0/83 (0)	0.21
Initial TIMI flow in culprit vessel				<0.001
0 or 1	4031/6066 (66.5)	3963/5988 (66.2)	68/78 (87.2)	
2 or 3	2035/6066 (33.5)	2025/5988 (33.8)	10/78 (12.8)	
Reperfusion therapy				
Thrombolytic therapy, n (%)	248/6180 (4.0)	247/6097 (4.1)	1/83 (1.2)	0.14
Treatment during angiography				<0.001
PCI with stent, n (%)	5194/6185 (84)	5146/6102 (84.3)	48/83 (57.8)	
PCI with balloon alone, n (%)	224/6185 (3.6)	215/6102 (3.5)	9/83 (10.9)	
No PCI, n (%)	639/6185 (10.3)	616 /6102 (10.1)	23/83 (27.7)	

Admission laboratory testing				
Leucocytes (G/L), median [IQR] (n= 5863)	11 [8.75 - 13.91]	10.9 [8.7 - 13.9]	13.9 [11.2 - 17.3]	<0.001
Hemoglobin (g/dL), median [IQR] (n= 5882)	14.1 [13.0 - 15.2]	14.1 [13.0 - 15.2]	13.5 [11.9 - 14.8]	<0.001
GFR (mL/min/m ²), mean (SD) (n= 5896)	87 [69 - 105]	88 [70 - 105]	68 [49 - 92]	<0.001
CRP (mg/L), median [IQR] (n= 5078)	4 [2 - 12]	4 [2 - 11.5]	42 [7 - 114]	<0.001
Troponin elevation (xURL), median [IQR] (n= 5185)	59 [10 - 302]	58 [10 - 300]	253 [92 - 735]	<0.001
Echocardiographic characteristics				
LVEF (%), mean (SD) (n= 5826)	49 (11)	49 (11)	42 (14)	<0.001
Impaired LVEF (%), n (%)	2346/5826 (40.3)	2300/5757 (40.0)	46/69 (66.7)	<0.001
LV aneurysm, n (%)	28/6185 (0.5)	24/6102 (0.4)	4/83 (4.8)	<0.001
Intraventricular thrombus, n (%)	81/6185 (1.3)	78/6102 (1.3)	3/83 (3.6)	<0.001
In-hospital complications, n (%)				
In-hospital cardiac arrest, n (%)	355/6185 (5.7)	331/6102 (5.4)	24/83 (28.9)	<0.001
VT/VF, n (%)	270/6185 (4.4)	263/6102 (4.3)	7/83 (8.4)	0.07
Cardiogenic shock, n (%)	424/6185 (6.9)	391/6102 (6.4)	33/83 (39.8)	<0.001
Death, n (%)	359/6185 (5.8)	320/6102 (5.2)	39/83 (47.0)	<0.001

SD: Standard Deviation; BMI: Body Mass Index; CAD: Coronary Artery Disease; PAD: Peripheral Artery Disease; IQR: Inter Quartile Range; PCI: Percutaneous Coronary Intervention; GFR: Glomerular Filtration Rate; CRP: C-Reactive Protein; URL: Upper Reference Limit; LVEF: Left Ventricular Ejection Fraction; LV: Left Ventricle; VT/VF: Ventricular Tachycardia / Ventricular Fibrillation

Table 1: Patient characteristics according to the occurrence of mechanical complications

variable	Univariate		Multivariate	
	OR (95% CI)	p value	OR (95% CI)	p value
Female sex	2.42 [1.56 - 3.75]	<0.001	1.96 [1.22 - 3.15]	0.005
Age (for one more year)	1.04 [1.02 - 1.06]	<0.001	1.03 [1.01 - 1.05]	<0.001
BMI (for one more kg/m ²)	0.94 [0.89 - 0.99]	0.03	-	-
Dyslipidemia	0.94 [0.89 - 0.99]	0.06	0.56 [0.33 - 0.94]	0.03
Family history of CAD	0.40 [0.18 - 0.88]	0.02	-	-
PAD	1.82 [0.78 - 4.22]	0.16	-	-
COVID-19 infection	4.36 [1.33 - 14.26]	0.02	4.35 [1.21 - 15.55]	0.02
Mode of arrival				
French SAMU network	1	ref	-	-
Emergency ward	1.51 [0.97 - 2.36]	0.07	-	-
In-hospital transfert	1.41 [0.43 - 4.58]	0.56	-	-
Time between onset of symptoms and cardiac catheterization				
0 to 12 hours	1	ref	1	ref
12 to 24 hours	1.74 [0.80 - 3.74]	0.15	1.46 [0.67 - 3.18]	0.33
24 to 36 hours	1.51 [0.46 - 4.92]	0.49	1.27 [0.38 - 4.23]	0.69
36 to 48 hours	6.42 [4.01 - 10.29]	<0.001	4.52 [2.69 - 7.60]	<0.001
Initial TIMI flow in culprit vessel				
2 or 3	1	ref	1	ref
0 or 1	3.47 [1.78 - 6.76]	<0.001	3.63 [1.97 - 6.70]	<0.001
Treatment during angiography				
PCI with stent, n(%)	1	ref	1	ref
PCI with ballon alone, n(%)	4.48 [2.17 - 9.26]	<0.001	3.81 [1.80 - 8.07]	0.001
No PCI, n(%)	4.00 [2.41 - 6.62]	<0.001	3.24 [1.82 - 5.76]	0.001

Table 2: Patient characteristics related to the occurrence of mechanical complications

Figures legend

Figure 1: Flow chart diagram of study population

Figure 2: Rate of mechanical complications according to pre-hospital delay

Figures

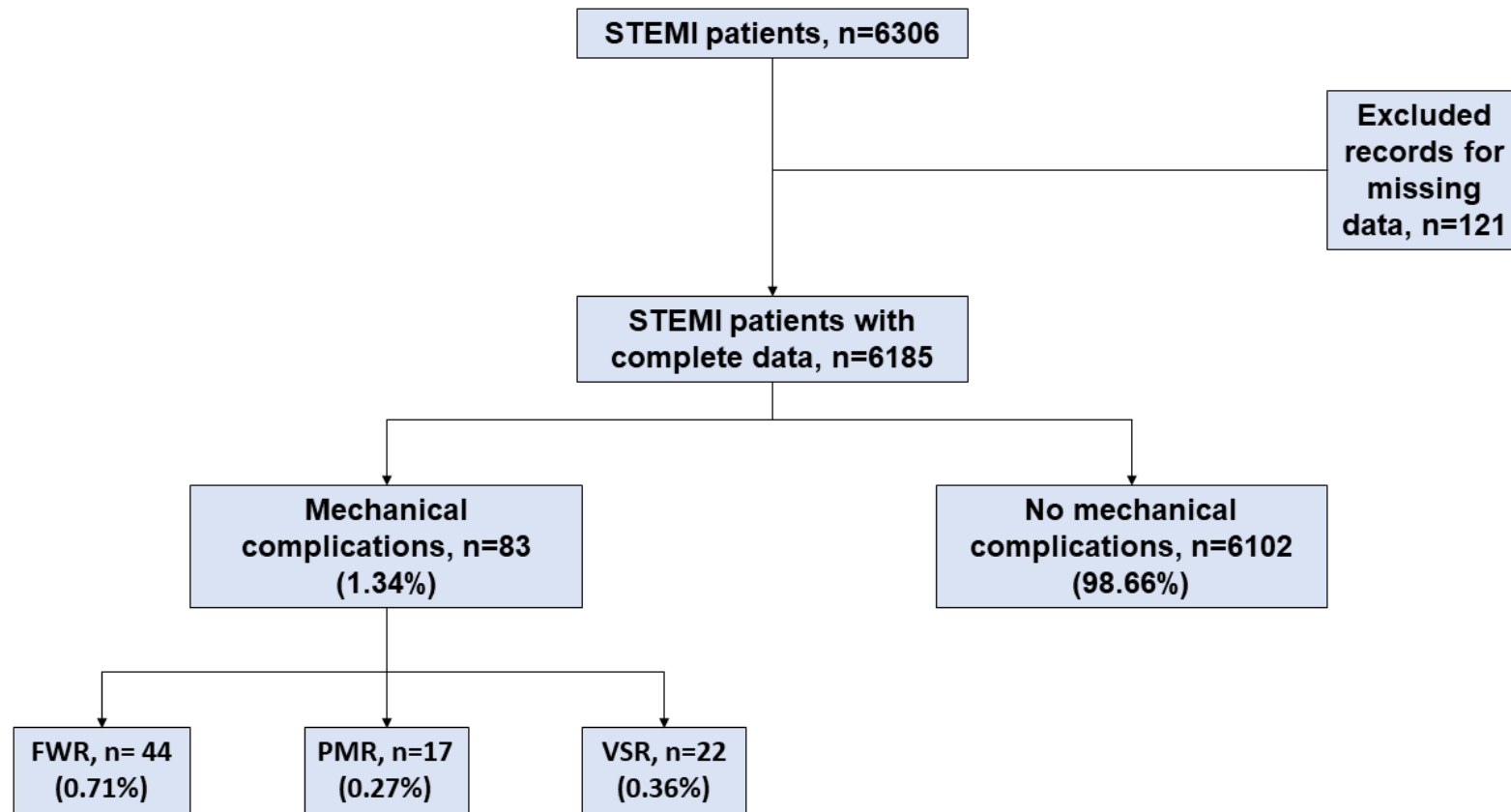


Figure 1

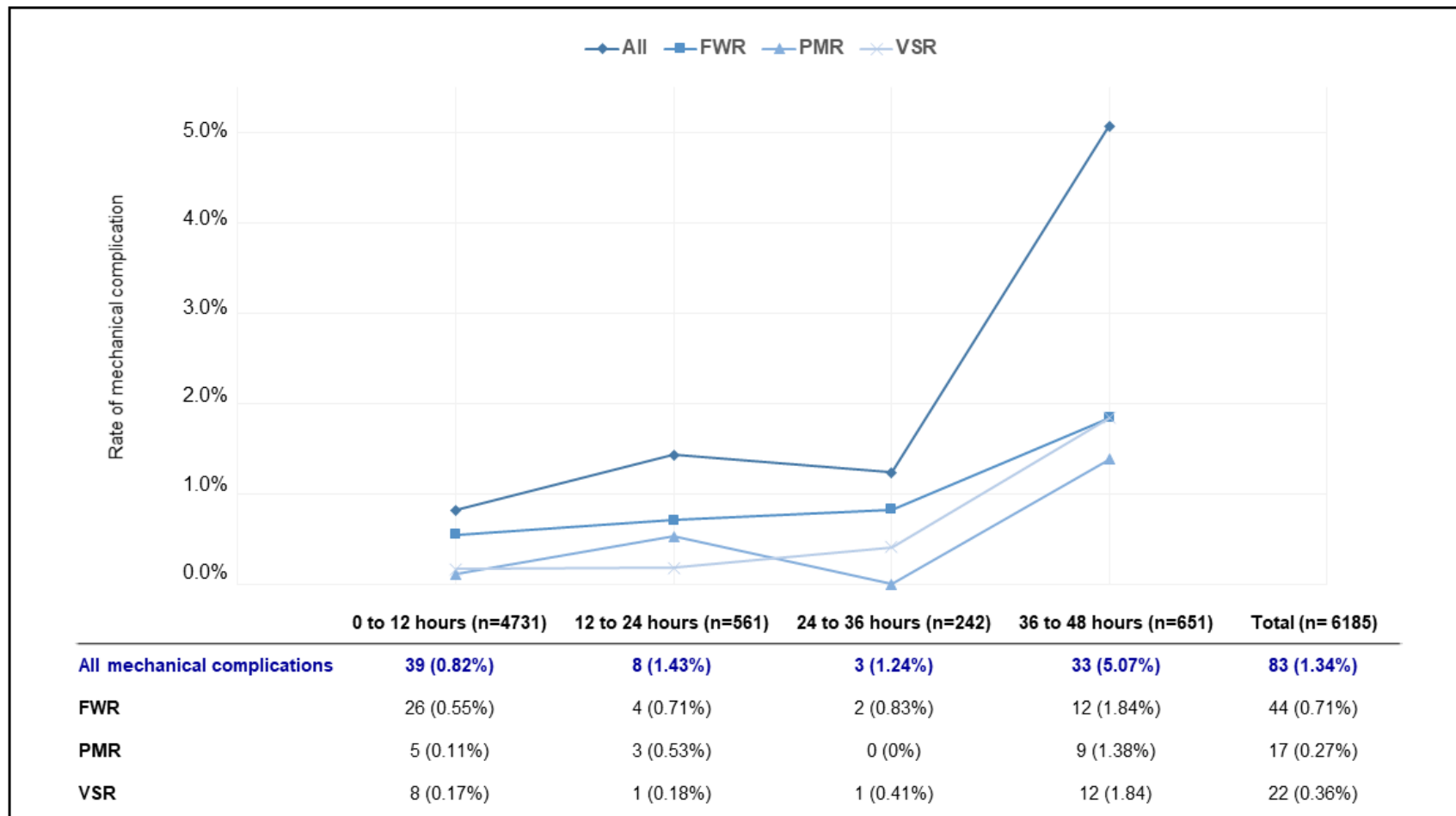
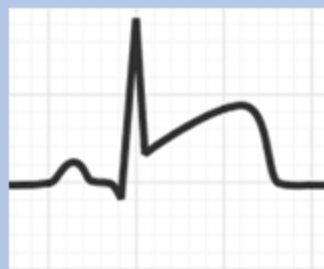


Figure 2

6185 patients presenting with STEMI

In 65 public and private French centers



Admission within 48 hours after symptoms onset



83 patients presenting with Mechanical Complications



44 (0.71%)
Free Wall Rupture



22 (0.36%)
Ventricular Septal Rupture



17 (0.27%)
Papillary Muscle Rupture

Delay	Rate of MC
0 to 12H	0.82%
12 to 24H	1.43%
24 to 36H	1.24%
36 to 48H	5.07%

$P < 0.001$

Mechanical Complication rate in STEMI patients increases with pre-hospital delay, in particular over 36 hours