ORIGINAL ARTICLE

MEDICATION ADHERENCE AND ITS IMPACT ON THE AVERAGE LIFE EXPECTANCY AFTER ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION: THE RESULTS OF THE UKRAINIAN STIMUL REGISTRY

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ABSTRACT

The aim: The present study aimed to evaluate the adherence to medications prior and within a two-year period after ST-segment elevation myocardial infarction (STEMI) and to estimate its impact on the average lifespan of patients after STEMI.

Materials and methods: 1,103 patients with STEMI were enrolled in the prospective Ukrainian STIMUL registry with 24-month follow-up. The relationship between adherence to medical treatment and average lifespan was evaluated.

Results: The majority of prior STEMI patients were characterized with high and very high cardiovascular risk. The rate of revascularization was 29.9% (21.5% pPCI, 8.4% fibrinolytic therapy). The main reason for the low level of pPCI was late hospitalization and the inaccessibility of pPCI. This contributed greatly to in-hospital mortality (11.3%). Adherence to all medications progressively decreased ($p < 0.001$) within 24 months after STEMI. Permanent use of acetylsalicylic acid (ASA) and statins during the two-year follow-up was associated with 7.0% of the mortalities, whereas non-adherence to medications was related to a 15% risk of death (OR 4.2; 95% CI 0.2–0.9; $p < 0.05$). The average life expectancy with regular use of ASA and statins within 24 months after STEMI was 62.3 ± 1.1 years (95% CI 60.1–64.4; $p < 0.05$) and 61.2 ± 0.9 years with non-regular use of ASA and statins (95% CI 59.4–62.9; $p < 0.05$).

Conclusions: Adherence to evidence-based medicines was low in the STIMUL population both prior and after STEMI. This worsened cardiovascular prognosis and reduced average lifespan by one year within the following two years after STEMI.

KEY WORDS: ST-segment elevation myocardial infarction, STEMI, Ukraine, medication adherence, prevention, registry

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INTRODUCTION

Secondary prevention of cardiovascular diseases is strongly recommended by international guidelines [1–2]. However, several trials have shown that adherence to therapy recommended at discharge from hospital dramatically decreases among patients after acute coronary syndromes (ACS) [3–8]. To date limited data about medication adherence and ST-segment elevation myocardial infarction (STEMI) treatment in Ukraine are available.

THE AIM

The general objective of the present study was to evaluate the adherence to medications prior and within a two-year period after STEMI in STIMUL (ST-segment elevation Myocardial Infarctions in Ukraine and its Lethality) registry patients and to estimate the impact of adherence on the average lifespan of patients after STEMI.

MATERIALS AND METHODS

Details of the prospective STIMUL survey have been described previously [9]. In brief, 1,103 patients with STEMI [2] were enrolled to the registry. This study analysed a whole range of data on patients with STEMI who were admitted to three cardiology departments of the central regions of Ukraine. Informed consent was obtained from all patients at the time of enrolment. All patients with confirmed STEMI at discharge from hospital entered two-year follow-up observation with clinical assessment after 6, 12, and 24 months. The recommended post-STEMI management analysed in the present study included statins, dual antiplatelet therapy (DAPT – acetylsalicylic acid, continuously, and P2Y12 inhibitors during the first year); angiotensin-converting enzyme inhibitors (ACE-I), or angiotensin receptor blockers (ARB) in the case of ACE-I intolerance and beta-blockers. The primary end-points were cardiovascular death and non-fatal myocardial infarction.

STATISTICAL ANALYSIS

All analyses were performed using SAS software (SAS Institute Inc., Cary, NC, USA). All tests were considered statistically significant if $p < 0.05$. The use of medications was assessed as a proportion of patients who took medications to the total number of patients at the end of each follow-up period. Adherence was considered high when the number of medications was ≥ 80.0% when compared with the number of medications at discharge. The relationship between adherence and average lifespan was evaluated by the cross-tabulation analysis based on the Pearson's χ^2 (chi-squared) test. The association between two variables was calculated by the phi and Cramer's V coefficients. The Kaplan-Meier curves were constructed to graphically present crude survival estimates, with a log-rank test for the equality of survivor functions used to assess group differences.

RESULTS

BASELINE DATA AND TREATMENT BEFORE STEMI

The baseline characteristics of all patients included in the study are presented in Table I. In addition, 34.5% of the patients had a high risk of in-hospital mortality according to their GRACE score. 11.9% and 19.5% of the patients, respectively, had high and very high bleeding risk as assessed by the CRUSADE score. According to the baseline data, the STIMUL population was characterized by high or very high cardiovascular risk. However, only a few of them reported regular use of medicines prior to STEMI. The frequency of regular use of medications among patients prior to STEMI is presented in Table II. The antiplatelet therapy was used in 57.0% and 54.5% of the individuals with a history of MI and stroke, respectively. Among patients with high blood pressure at admission, 78.0% (n = 659) of the patients were aware that they had hypertension. Hypotensive therapy was used in 51.0% (n = 431) of the individuals, but only in 35.4% of the individuals on a regular basis (n = 299). Half of the patients with hypertension were treated with monotherapy. As a result, only 7.5% of them achieved target levels of blood pressure. Statins were predominantly used in patients who experienced cardiovascular events (ACS or stroke). Lipid targets were achieved only in 5.5% of patients. The main reasons for statin discontinuation or dose reduction were: a fear of side effects or perceived side-effects (25.6%) based on negative media coverage, advice from friends or family members, or lack of clinicians' guidance; the absence of clinical symptoms of dyslipidaemia making it easy to forget to take statins (forgetfulness) (18.3%), and the cost of statins (8.3%). 47.9% of patients did not take statins because of a lack of medical appointments/medical control. The main reasons for the discontinuation or episodic use of blood pressure lowering therapy were forgetfulness (22.0%), the fear of: side effects (21.6%), taking too many drugs at the same time (3.0%) and damage caused by long-lasting medication use (5.6%).

IN-HOSPITAL TREATMENT

The median time from symptom onset to hospital admission was 5.1 ± 0.3 hours. 59.8% (n = 660) of the patients were admitted to cardiology units. However, only a half of them (51.4%, 339 patients) were hospitalized in interventional units and 73.4% (n = 237) of the patients admitted to interventional units underwent primary percutaneous coronary intervention (pPCI). Fibrinolytic therapy was performed in 8.4% (n = 93) of the cases. Therefore, in the entire cohort, only 29.9% of the study population underwent reperfusion therapy. The major reasons for the non-performance of reperfusion therapy were late arrival (40.5%) and unavailability of catheterization laboratories (31.4%). Additional reasons were contraindications (7.4%), uncertain diagnosis (6.3%), patient refusal (6.1%).

In-hospital mortality rate was 11.3% (125 cases) in the STIMUL cohort and 7.0% (23 cases) among patients who underwent coronary reperfusion.

Finally, 872 (79.1%) patients were discharged from hospital with STEMI. They were included in a further two-year follow-up.

As shown in Table III, at discharge, the majority of the STIMUL population received recommendations to take the main cardiovascular medications, except for P2Y12 inhibitors. A lower level of recommendation to take P2Y12 inhibitors was related with a patient's high bleeding risk at admission.

TREATMENT DURING FOLLOW-UP AFTER ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

Post-discharge events were followed for 636 (72.9%) patients for six months, 480 (55.1%) patients for 12 months, and 278 (31.9%) patients for 24 months. During the first six months after STEMI, 64 patients (7.3%) had died and 8.0% of the patients had experienced a non-fatal myocardial infarction. After 12 months, 140 patients (16.1%) had died and 15.6% had a non-fatal myocardial infarction. After 24 months, 169 patients (19.4%) had died and 21.9% had a non-fatal myocardial infarction.

The adherence to medical treatment recommended at discharge from hospital progressively decreased ($p<0.001$) during the 24-month follow-up period (Table IV). After 24 months, regular use of ASA decreased by 35.2%, statins by 80.5%, beta-blockers by 38.1%, and ACE-I by 43.9% ($p < 0.001$), when compare with the recommendations of the clinicians at discharge from hospital.

DAPT adherence was 21.4% during the six-month follow-up period and 16.3% during the first 12 months after STEMI. The main reasons for DAPT discontinuation were the fear of side effects in 26.4% of the cases (n = 106), price in 22.4% of the cases (n = 90), and forgetfulness due to the lack of noticeable benefits in 18.4% of the cases (n = 74).

At the end of 24-month follow-up, further reduction of ASA, statin, ACE-I/ARB and beta-blockers adherence was observed (Table IV). The main reasons for medication discontinuation were similar as in the prior myocardial

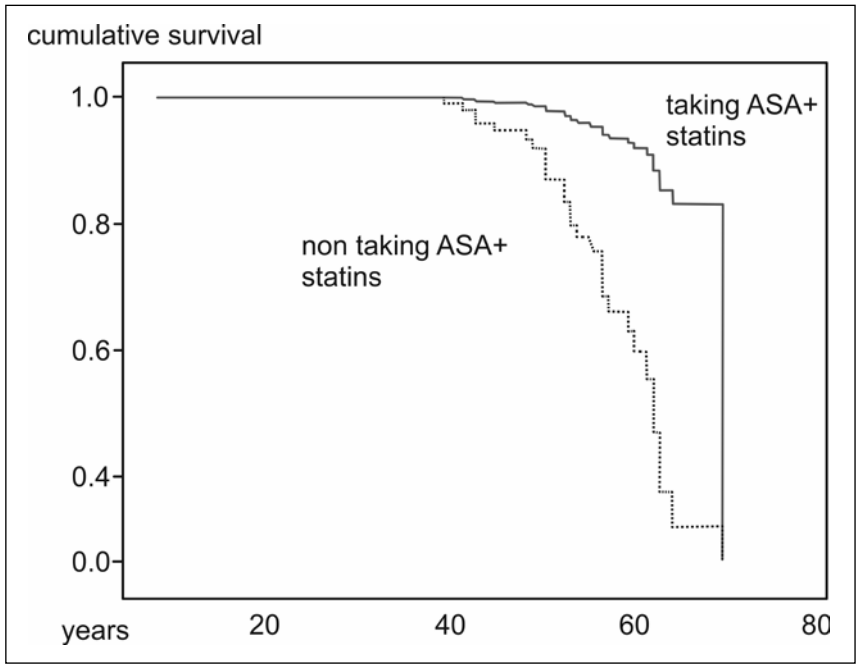

Fig. 1. Average life expectancy among patients taking and without taking acetylsalicylic acid (ASA) plus statin therapy within two-year follow-up after ST-segment elevation myocardial infarction.

Table I. Baseline, demographic and clinical characteristics of STIMUL registry population.

Characteristic	N	[%]
Age, years	63.4 ± 11.5	
Male gender	819	74.3%
Hypertension	845	76.6%
Hyperlipidemia (defined as total cholesterol ≥ 4.5 mmol/l)	565	50.7%
Body mass index (BMI) > 30 kg/m2	353	32.0%
Family history of coronary artery disease	351	31.8%
Diabetes mellitus	275	24.9%
Current smoker	300	27.2%
Past smoker	354	32.1%
Prior angina	380	34.5%
Prior myocardial infarction	267	24.2%
Prior percutaneous coronary intervention	23	2.1%
Prior coronary bypass graft surgery	3	0.3%
Prior heart failure	251	22.8%
Prior stroke/transient ischemic attack	72	6.5%
Prior renal failure	19	1.7%
Heart rate, mean bpm	83.4 ± 2.6	
Systolic blood pressure, mmHg	138.6 ± 3.6	
Killip class, ≥ II cardiogenic shock	262 39	23.8% 3.5%

infarction period: fear of side effects, especially in case of ASA (15.7%) and statins (18.4%), and forgetting to take the medication.

As shown in Table V, significant correlations were determined between two-year death risk and complete cessation of medications (ASA and statins) within 24 months after STEMI ($p<0.05$) or ASA discontinuation ($p<0.05$). We did not find any correlation between statin discontinuation and two-year death risk after STEMI ($p<0.05$) because of the small cohort of patients (n = 27) still using statins after the two-year period.

The continual use of ASA and statins for two years after STEMI was associated with a 7.0% mortality rate, while discontinuation of antiplatelet and lipid-lowering therapy

led to a 15.0% mortality rate during the two-year follow-up (Table VI). Therefore, the risk of two-year death in the case of discontinuation of the abovementioned treatment increased four times (OR 4.2; 95% CI 0.2–0.9; p<0.05). Among the patients with regular ASA intake, the rate of two-year death was 6.5%. Meanwhile, the cessation of the regular use of ASA was associated with a 15.5% mortality rate. As a result, the discontinuation of ASA during the first two years after STEMI increased the mortality risk three times (OR 3.8; 95% CI 0.2–0.9; p<0.05).

Regular statin intake was associated with a 6.9% mortality rate, whereas statin discontinuation increased this risk to 14.9%. Therefore, the two-year death risk in the case of the discontinuation of lipid-lowering therapy increased by four times (OR 4.2; 95% CI 0.1–0.9; p>0.05). However, the risk appears to be not significant statistically because of the small number of patients using statin treatment after two years.

The impact of adherence to treatment on average lifespan during the two-year follow-up period after STEMI is presented in Figure 1 and Table VII.

To conclude, the average lifespan in the case of regular use of antithrombotic and lipid-lowering therapy during the first two years after STEMI was 62.3 ± 1.1 years (95% CI 60.1–64.4; p<0.05) and 61.2 ± 0.9 years in the case of discontinuation of the recommended treatment (95% CI 59.4–62.9; p<0.05). Therefore, regular use of ASA and statins during the 24 months after STEMI prolonged lifespan by one year.

Table II. Treatment before admission to hospital.

Medication	N	[%]
ASA	295	26.8%
P2Y12 inhibitors	9	0.8%
Beta-blockers	195	17.7%
ACE-I/ARB	290	26.3%
Statins	113	10.2%

Table III. Treatment among the STIMUL population at discharge from hospital.

Medication	N	[%]
ASA	815	93.5%
P2Y12 inhibitors	674	77.3%
Beta-blockers	837	96.0%
ACE-I/ARB	778	89.2%
Statins	837	96.0%

ACE-I – angiotensin-converting enzyme inhibitor, ARB – angiotensin receptor blocker, ASA – acetylsalicylic acid

DISCUSSION

The results of our study indicate the poor level of cardiac prevention in the STIMUL registry population of Ukrainian patients before STEMI. In the present study, we observed a low and irregular rate of use of statin and hypotensive therapy prior to STEMI. This resulted in the non-achievement of target lipid and blood pressure goals and substantially increased the risk of adverse cardiovascular outcomes. The results of the STIMUL registry are much worse than those obtained in the EUROASPIRE V survey [10].

In our study, the rate of reperfusion therapy in Ukrainian patients with STEMI was dramatically low. Late hospitalization was the main barrier to invasive reperfusion treatment and had a great impact on in-hospital mortality. The importance of time in the management of STEMI was shown to directly affect both mortality and morbidity [11]. General in-hospital mortality in the STIMUL registry population was high (11.3%), when compared with international registries: 4.6% in the GRACE registry [12]; 4.0% in the second Euro Heart Survey on acute coronary syndromes [13] or 5.9% in the Polish PL-ACS registry

Table IV. Treatment among the STIMUL population at discharge from hospital and during the 6month, 12-month, and 24-month follow-up period after ST-segment elevation myocardial infarction.

Medication, %	at discharge	after 6 months	after 12 months	after 24 months
ASA	93.5%	73.3%	64.2%	58.3%
P2Y12 inhibitors	77.3%	21.4%	16.3%	–
ACE-I/ARB	96.0%	78.0%	63.3%	58.0%
Beta-blockers	89.2%	64.1%	53.1%	45.3%
Statins	96.0%	36.3%	24.2%	15.5%

ACE-I – angiotensin-converting enzyme inhibitor, ARB – angiotensin receptor blocker, ASA – acetylsalicylic acid

Table V. The impact of persistence on two-year death among STIMUL patients after ST-segment elevation myocardial infarction.

24-month medicine intake	Pearson's X^2	Degrees of freedom	p	Cramér's V	p Cramér's V	φ	p
ASA	5.9	1	< 0.05	0.2	< 0.05	–0.2	< 0.05
Statins	1.4	1	> 0.05	0.1	> 0.05	–0.1	> 0.05
ASA + statins	7.7	1	< 0.05	0.1	< 0.05	–0.1	< 0.05

ASA – acetylsalicylic acid

Table VI. Prognostic factors for two-year death risk after ST-segment elevation myocardial infarction in STIMUL population.

Variables		Two-year risk of death				OR	95% CI		p
		Yes		No			low	high	
		N	[%]	N	[%]				
ASA	Take	10	6.5%	145	93.6%	3.8	0.2	0.9	< 0.05
	No	19	15.5%	145	84.6%				
Statins	Take	2	6.9%	27	93.1%	4.2	0.1	1.9	> 0.05
	No	37	14.9%	212	85.1%				
ASA + statins	Take	11	7.0%	147	93.0%	4.2	0.2	0.9	< 0.05
	No	18	15.0%	102	85.0%				

ASA – acetylsalicylic acid

Table VII. Average lifespan among patients with different adherence to treatment within the first two years after ST-segment elevation myocardial infarction.

Adherence to medication	Average lifespan	SD	95% CI		p
			low	high	
ASA and statin adherence	62.3	1.1	60.1	64.4	< 0.05
ASA adherence	62.2	1.1	60.1	64.4	< 0.05
ASA and statin non-adherence	61.2	0.9	59.4	62.9	< 0.05

[14]. Another problem that should be emphasized when discussing the low pPCI rate in the STIMUL population is limited access to PCI procedures at the time of registry due to the lack of an organized PCI network in Ukraine. Kämpfer et al. have shown significant differences in the number of pPCI procedures for ACS in 2010 between three different socioeconomic environments [15]. In Switzerland and Poland, coronary interventions were the first choice therapy, whereas in Ukraine 30% of patients with ACS received fibrinolysis therapy and pPCI was not performed at all, as it was unavailable at this time in the study centre in Ukraine. Our results also correspond with the Euro Heart Survey 2009 Snapshot where, in comparison to western European countries, the use of pPCI for STEMI treatment in eastern European countries was low (23%), and 44% of patients called within 12 hours of symptom onset did not receive reperfusion therapy. Similarly to the our data, the low rate of reperfusion therapy resulted in a high in-hospital mortality rate (10.1%) [16].

During the first two years after STEMI, adherence to treatment of all medications recommended at the moment of discharge from hospital progressively decreased ($p<0.001$). These results correspond with data obtained by other researchers [17–23].

Data from the STIMUL registry revealed a high frequency of ASA administration at discharge. The rate of clopidogrel administration was lower, and this can be partially explained by the low rate of pPCI procedures and the high bleeding risk among the registry cohort. In the Ukrainian registry, adherence to DAPT was 16.3% at the end of the 12-month follow-up after STEMI. Despite strong evidence for a significant correlation between adherence with respect to antiplatelet and statin therapy and a decrease in mortality for patients with ACS, a reduction in adherence to DAPT and statins in patients after myocardial infarction has been commonly described [3-4, 6, 17-19, 21–22, 24]. Jackevicius et al. reported 44% of unfilled ASA prescriptions and almost 70% of unfilled prescriptions for medication other than ASA in 120 days for acute coronary syndrome [24]. According to Moalem et al., 6.5% of patients discontinued DAPT due to non-compliance at the end of a year [4]. Similar results have been shown in the international GRACE registry [19, 21], where only one third of the patients took clopidogrel after 6-month observation.

Adherence to therapy with statins decreased during the two-year follow-up period by almost 80%. In another observational study undertaken in one Ukrainian clinical centre, the rate of statin discontinuation after ACS was lower (about 64% during 3.5-year follow-up), but still higher than in western European countries or United States clinical centres [15]. In a large prospective multicentre cohort of patients with ACS, the discontinuation rate for statins was 6.7% and the main reason for discontinuation was the presence of side effects [23]. Low adherence to statins in the STIMUL population absolutely cannot be explained by the presence of side effects [6, 20]. The most common reasons for statin cessation in the Ukrainian registry were: the fear of side effects or the perceived side effects, a low disease awareness, and a lack of motivation or medical guidance. Our results correspond with the results obtained in the nationwide study in Denmark, where early statin discontinuation was significantly associated with negative statin-related news stories [25].

Among the Ukrainian population of STEMI patients, the frequency of ACE-I/ARB and beta-blocker use remained low after two years. Despite the high prevalence of hypertension among the STIMUL patients prior ACS, only 26.3% and

17.7% of the patients used these medicines regularly. After STEMI adherence to ACEI/ARB and beta-blockers decreased with time from the time of discharge and was 58.0% and 45.3%, respectively at two-year follow-up. It is a much lower rate than the current data from the EUROASPIRE V survey [10], where in the population with confirmed coronary artery disease 81% of the population were on beta-blockers and 75% were on ACE-I/ ARBs. The major reasons for discontinuation or dose reduction of blood pressure were fear of side effects, lack of self-motivation based on low disease awareness. It correspond with the results obtained by Khan et al., where strong myths responsible for the fear of antihypertensive medication use as well as for the poor acceptance of hypertension as a main risk factor of ACS and stroke have been described [26].

In our registry, we observed a high mortality rate and a high risk of recurrent myocardial infarction in a two-year period. The risk was the highest during the first year after STEMI. The high risk for adverse incidents was contributed by the low rate of reperfusion therapy and the discontinuation of evidence-based treatment with antiplatelets and statins. Discontinuation of treatment with ASA in the two-year observation period increased the risk of death three times, whereas discontinuation of both ASA and statin therapy increased the risk of death four times. In multivariable analysis, Ho et al. reported lower one-year survival after the discontinuation of both ASA and statins [27]. In our registry regular use of ASA and statins for 24 months after STEMI prolonged average lifespan by one year. This corresponds with the results of Rodriguez et al. [6].

CONCLUSIONS

1. The population of Ukrainian patients in the STIMUL registry was predominantly at a high and very high cardiovascular risk before STEMI with a poor level of cardiac prevention.
2. The level of reperfusion therapy among patients with STEMI was low, due to late hospitalization and limited access to primary PCI. This had a great impact on inhospital death. The frequency of recommendation of evidence-based therapy was high at discharge from hospital.
3. In a real-life setting, adherence to medications for secondary prevention after STEMI was low to moderate in Ukraine. The cessation of ASA and lipid-lowering therapy in two-year follow-up after STEMI led to a reduction of average lifespan by one year.
4. Our study revealed the immense need of improvement of cardiac care for patients at high and very high cardiovascular risk in Ukraine by increasing accessibility to invasive reperfusion procedures in ACS and specialist healthcare, by implementing national educational programs about the symptoms of ACS. This is required to decrease both in-hospital and long-term mortality of patients with STEMI. Currently, according to the Ukrainian Ministry of Health reports, the total number of catheterization laboratories (Cath Labs) is 42 whereas the population of Ukraine is over 44 million (1 Cath Lab for 1,048,000 people) [28]. In Switzerland it is 1 Cath Lab for 230,000 people and in Poland, a country neighbouring Ukraine, with a population of 37.97 million it is 1 Cath Lab for 239,000 people.

LIMITATIONS OF THE STUDY

Our study has several limitations that need to be addressed. Extrapolation of local results to the whole country needs to be performed with caution. The PCI results, in-hospital and general mortality since 2013 for STEMI in Ukraine could have changed. In regards to follow-up data, the reliability of the data with regards to medication is somewhat compromised by the fact that two-year follow-up was limited to 31.9% (278) of the patients of the whole registry cohort who entered the follow-up period at the time of discharge from hospital.

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The Authors declare no conflict of interest.

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