SYNDROME OF SENILE ASTHENIA IN PATIENTS WITH ACUTE CORONARY SYNDROME CAN DETERMINE THE RESULT OF INVASIVE TREATMENT

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Abstract

The objective of the work was to evaluate the significance of senile frailty syndrome in patients with acute coronary syndrome (ACS) older than 75 years.This work presents an analysis of the data from ORACUL II multicenter observational study (Exacerbation of Coronary Heart Disease: Logi-Probabilistic Ways of Course Prediction for Optimization of Treatment). In total, 415 patients (271 women (65.3%) and 144 men (34.7%) of senile age (75 years and older) were included). The average age was 80.78 ± 4.503 years (from 75 to 99 years). ACS patients without ST elevation were 255 (68.9%) and ACS patients with ST

elevation -160 (31.1%). 395 (95.2%) had a history of hypertension, 348 (83.9%) had IHD, 176 (42.4%) had myocardial infarction, 44 (10.6%) had previous revascularization procedures. Senile frailty was diagnosed using the questionnaire "Age is not a hindrance." Frailty syndrome was detected in 53 patients (12.8%), pre-frailty in 252 patients (60.7%), signs of senile asthenia were absent in 110 patients (26.5%).Patients with senile frailty had a lower body mass index, lower glomerular filtration rate, lower hemoglobin level, and higher troponin level. They had more frequent syncope and valvular heart disease in history, more often they had severe heart failure. These patients more frequently suffered from constipation. In the Kaplan-Meier analysis, it was shown that in patients without senile frailty or with pre-frailty, percutaneous coronary intervention (PCI) is effective. In contrast to patients without asthenia, for whom PCI was effective, in persons with early asthenia, PCI did not significantly affect the risk of overall mortality; this factor turned out to be independent. Thus, the presence of senile asthenia should be considered when planning the treatment of patients with acute coronary syndrome.

Keywords: acute coronary syndrome, senile age, frailty, coronary revascularization, mortality

The management of elderly patients is a difficult task for a doctor of any specialty, including a cardiologist. In elderly and senile patients, as a rule, there is a burdened comorbid background, the sensitivity of the receptor apparatus changes, the activity of the main enzyme systems decreases, the bioavailability of drugs decreases and their distribution decreases. All these features affect the course of diseases and the effectiveness of their treatment.Changes in the body that occur in the elderly and senile age constitute the syndrome of senile frailty, which implies a deterioration in the health of the patient in the elderly and senile age, which reflects the need for care. Fried et al. [1] identified senile frailty as a syndrome that includes weight loss (sarcopenia), dynamometric reduction in hand strength, pronounced weakness and increased fatigue, reduced movement speed,

and significant reduction in physical activity. If there are three or more symptoms, the syndrome of senile frailty is diagnosed, but in the presence of one or two of them, senile preasthenia (pre-frailty) is diagnosed. Diagnosis of senile frailty syndrome requires special geriatric examination using a large number of questionnaires and scales, which is difficult to implement in routine clinical practice, especially in a situation of acute illness requiring emergency care. For screening the presence of senile frailty in domestic practice, a simple questionnaire “Age is not a hindrance” was proposed, consisting of 7 questions [2]. This method of detecting senile frailty syndrome was used in our work, the objective of which was to evaluate the significance of senile frailty syndrome in patients with acute coronary syndrome (ACS).

Clinical characteristics of patients and methods of study

This work presents an analysis of the data from ORACUL II multicenter observational study (Exacerbation of Coronary Heart Disease: Logi-Probabilistic Ways of Course Prediction for Optimization of Treatment), which included 1502 patients with ACS, with and without elevation of the ST segment, who had the indication for conducting percutaneous coronary interventions (PCI) in this hospitalization, regardless of whether PCI was performed or not. In the ORACUL II study, patient recruitment was conducted in 2014-2017 in 4 centers of Moscow, Kazan, Astrakhan and Krasnodar. The study protocol ORACUL II was described by us earlier [3].

415 patients (271 women (65.3%) and 144 men (34.7%) of senile age (75 years and older) were included in the present analysis. The average age was 80.78 ± 4.503 years (from 75 to 99 years). The studied group included 255 ACS patients without ST elevation were (68.9%) and 160 ACS patients with ST elevation (31.1%). 395 (95.2%) patients had a history of hypertension, 348 (83.9%) had IHD, 176 (42.4%) had myocardial infarction, 44 (10.6%) had previous revascularization procedures. 139 (33.5%) patients suffered from atrial fibrillation, 36 (8.7%) had a history of conduction disturbances, and 14 (3.4%)

had cardiac pacemaker implanted. 295 (71.1%) had a history of CHF, 73 (17.6%) had a history of stroke, 100 (24.1%) had diabetes, 124 (29.9%) had peripheral atherosclerosis.

In the course of observation, a total mortality (death from all causes), and a total endpoint of "coronary outcome" (death from MI + repeated ACS) were recorded by telephone contact. An assessment of the presence of adverse outcomes was conducted on the 25th, 90th, 180th and 360th day from the time of the development of ACS. Also, all cases of bleeding were recorded during the observation. The severity of bleeding was assessed according to the BARC scale.

The syndrome of senile asthenia (frailty) (SSA) was assessed by the screening questionnaire "Age is not a hindrance." In the presence of 1-2 points, "pre-frailty" was diagnosed, in the presence of 3 points or more, frailty was diagnosed [2].

For all patients, the risks of atherothrombotic events were assessed on the GRACE [4] and RECORD [5] scales and the risks of bleeding were accessed on the CRUSADE scale [6] and the ORACUL scale developed by us.

Statistical analysis

For statistical data processing, the standard software package IBM SPSS Statistics Version 22 was used. The normality of the distribution of quantitative traits was checked by the Shapiro-Wilk method. To describe the traits with a normal distribution, an average value was used with an indication of the standard deviation. Discrete values were compared using the Pearson and/or Fisher $\chi 2$ test. Comparison of quantitative traits that obey the normal distribution was carried out using Student's τ-test, and the traits which did not comply with the normal distribution were compared using the non-parametric Mann–Whitney test. The analysis of survival and factors influencing it was carried out by the Kaplan-Meyer method using the LogRank statistical test. Multivariate analysis was performed by binary logistic regression. For all types of analysis, the differences were considered statistically significant at $p < 0.05$.

Study results

The distribution of points on the scale of “Age is not a hindrance” is presented in table 1.

Thus, SSA can be detected in 53 patients (12.8%), pre-frailty can be diagnosed in 252 patients (60.7%), signs of senile asthenia were absent in 110 patients (26.5%). Comparisons were made of the main clinical characteristics, comorbidities in patients without asthenia, with preasthenia and SSA (Table 2.). Patients with senile frailty had a lower body mass index and lower glomerular filtration rate (GFR). They had more frequent syncope and valvular heart disease in history. These patients more frequently suffered from constipation. When hospitalized due to an index event, their hemoglobin level was lower. The level of troponin in patients with preasthenia and asthenia was higher. Patients with senile asthenia often had severe heart failure upon admission (4 on Killip scale). Patients with senile asthenia less often undergo PCI during index hospitalization (Table 2). When analyzing drug therapy, there were no significant differences in prescribing the main groups of drugs (antiplatelet agents, ACE inhibitors, sartans, beta-blockers, calcium antagonists, diuretics, statins, nitrates, hypoglycemic drugs).

Patients conducted an assessment of the risk of adverse outcomes on the GRACE and Record scales, as well as the assessment of hemorrhagic risks on the CRUSADE and ORACUL scales. The risk on the GRACE and RECORD scales corresponded to a high one, but for the GRACE scale there were no significant differences in risk between groups of patients without asthenia and with preasthenia and asthenia. For the RECORD scale, patients with senile asthenia had a significantly higher number of points. For the risk of bleeding - there were no significant differences in the risk assessment on the CRUSADE scale. When assessing on the ORACUL scale, it turned out that patients with SSA have a significantly higher number of points.

When analyzing the risks of adverse outcomes from the observation results, it turned out that patients with SSA have a higher level of coronary and total

mortality for 1 year of observation and a significantly larger number of coronary events during this observation period (Fig. 1). The frequency of deaths in the hospital was also somewhat higher in these patients, but no significant differences were recorded. When analyzing the frequency of bleeding, it turned out that the frequency of significant and large bleeding during index hospitalization did not differ significantly, and the frequency of large bleeding for 1 year of observation was significantly higher in patients with SSA.

A regression analysis was performed to assess the independence of the association of SSAs with the risk of total mortality. The data of univariate and multivariate regression analysis are presented in Table 3.

Independently associated with the risk of adverse outcome were the presence of aortic stenosis in patients, increased troponin and the presence of heart failure of 4 FC according to Killip in an index episode of ACS and conducting PCI during index hospitalization.

The effectiveness of revascularization procedures (PCI) was analyzed depending on the presence of syndrome of senile asthenia in patients. The efficacy of PCI was considered in relation to the risk of total mortality (primary endpoint). In the analysis of Kaplan Meier, performed in the strata depending on the presence of SSA, it was shown that in patients without SSA, or with pre-asthenia, PCI is effective. In patients with SSA, conducting PCI did not significantly affect the risk of total mortality (Figure 3), p (for interaction) = 0.001,χ^2 =11.798.

To assess the independence of the association of SSA with the efficacy of PCI, to reduce overall mortality, a multivariate regression analysis was conducted (Table 4). The factors independently associated with a decrease in mortality in patients with PCI in elderly patients were diabetes, aortic stenosis, severe heart failure during an index event, and senile frailty syndrome.

Discussion

In our study, the proportion of patients with PAS was 12.8%, proportion of patients with pre-frailty was 60.7%. The number of patients with SSA strongly depends on the method of assessing frailty syndrome. So in the group of patients with ACS over the age of 75 years in the ICON-1 study, the proportion of patients with senile frailty was 39%, with pre-frailty - 27.5%. Evaluation of senile frailty was carried out according to the FRAIL-HEART scale [7]. In the same study, the association of senile frailty with age, the presence of peripheral atherosclerosis, heart failure 4 FC according to Killip at admission and a decrease in hemoglobin level were shown, as in our study. In the Spanish registry among patients older than 80 years, the frequency of senile frailty syndrome was about 20%, while the examined group was slightly older than in our study [8]. The lowest incidence of senile frailty syndrome was demonstrated in the TRYLOGY study (4.7%). According to a meta-analysis of data available in the literature published in 2018, the median frequency of detecting frailty syndrome among patients with ACS of ages of age was 31.5% [9]

The association between senile frailty syndrome and the risk of adverse outcomes has been shown repeatedly in various studies. So in the ICON-1 study among patients with MI over 75, senile frailty was independently associated with the risk of mortality and recurrent episodes of ACS, along with a GRACE, CRUSADE score, impaired kidney function, revascularization during index hospitalization and recommendation of double antithrombotic therapy at discharge [10]. Also, senile frailty was an independent risk factor for overall mortality in patients with ACS over the age of 80 in a study at the University Hospital of Toulouse. Senile frailty was rated on the Edmonton scale. The prevalence of senile frailty was about 20%, and the risk of total mortality increased with its presence by 1.5 fold [11]. In the American registry of patients with ACS over 65, senile frailty and comorbidity index were independent predictors of overall mortality and increased the diagnostic value of the standard risk assessment scales in the elderly patients [12]. It should be noted that none of the studies available in the literature consider

the factor of the presence of aortic stenosis in patients as a risk factor for adverse outcomes. We have previously shown an association of aortic stenosis with an unfavorable outcome in ACS [13]. This association should be of particular interest in the elderly due to an increase in the frequency of detection of this disease among the older age groups. In our group among patients with senile age, its prevalence was 14%. The presented analysis shows an increase in the frequency of aortic stenosis with an increase in the number of points on the scale "Age is not a hindrance." Among patients with diagnosed frailty syndrome, the rate of aortic stenosis was more than 20%. In a multivariate analysis, aortic stenosis proved to be an independent predictor of total mortality, along with the presence of severe heart failure of 4 FC on the Killip scale and increased troponin levels upon admission during an index episode of ACS. Senile frailty syndrome, the age of patients, the presence of diabetes and peripheral atherosclerosis have lost an independent association with the prognosis in a multivariate analysis.

In patients with the syndrome of senile frailty, there was no decrease in mortality when performing PCI. There are almost no similar studies in the literature. Our data correlate in part with the results of a study of R Murali-Krishnan et al. at the University of Sheffield, who showed that conducting PCI in patients over 65 years old with senile frailty is associated with an increase in the length of hospitalization and an increase in the risk of total mortality regardless of age, sex and concomitant diseases [14].

The association of senile frailty (asthenia) syndrome with the risk of bleeding has been previously analyzed in the framework of the ACTION register. An association of the risk of bleeding with an increase in the number of points on the scale of Rockwood et al was shown. In this study, it was shown that the association of the risk of bleeding and the severity of senile frailty are particularly closely related in patients who have undergone revascularization [15]. In our study, among patients with senile age, in the presence of SSA, the risk of major bleeding was also higher.

Thus, we have shown that patients with the syndrome of senile frailty after suffering ACS have a higher risk of death and coronary events, as well as higher risk of bleeding. Patients with SSA have a more unfavorable background of associated diseases. In our study, the association of senile frailty with high mortality was less significant than the association of high mortality and aortic stenosis. The frequency of this heart disease increases with age, and in our group, this defect was significantly more common in patients with SSA than without it. From a practical point of view, it may be interesting to reduce the effectiveness of PCI as a saving measure in patients with SSA. This association has maintained its independence in conducting multivariate regression analysis, however, specially designed studies are needed to confirm the identified trend.

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Table 1. Distribution of points on the “Age is not a hindrance” scale in the examined group

Number of points on the “Age is not a hindrance” scale	Number of patients	Share of patients, %
.00	110	26.5
1.00	151	36.4
2.00	101	24.3
3.00	42	10.1
4.00	9	2.2
5.00	2	,5

Table 2. Clinical characterization of patients with ACS, depending on the presence of SSA in the ORACUL II study

Parameter	*Patients without SSA (n=110)*	*Patients with preasthenia (n=252)*	*Patients with SSA (n=53)*	*p*
Men / Women (n, %)	38(34.5%)/72(65.4%)	90(35.7%)/162(64.3%)	16(30.2%)/37(69.8%)	0.498
Age at inclusion, years	79.96±4.102	80.94±4.668	81.68±4.314	0.138
BMI, kg/m^2	**27.7±4.15**	**27.9±5.41**	**26.3±4.59**	**0.048**
GFR, ml/min/1.73 m^2	**39.15±6.496**	**40.40±10.301**	**42.95±8.956**	**0.026**
Troponin at admission	**44.11±199.332**	**235.27±126.474**	**323.98±803.602**	**0.041**
Hemoglobin at admission	**129.00±13.765**	**127.48±18.220**	**118.04±19.062**	**0.001**
SBP at admission	148.99±33.417	144.37±27.751	144.85±32.368	0.554
HR at admission	78.93±21.819	80.24±20.230	78.82±26.463	0.886
HF 2-4 according to Killip at admission	25(24.3%)	77(32.5%)	77(32.5%)	0.076
HF 4 according to Killip at admission	**3(2.9%)**	**8(3.4%)**	**7(14.0%)**	**0.003**
EST ACS/NEST ACS, (n, %)	66(60%)/44(40%)	158(62.7%)/94(37.3%)	31(58.5)/22(41.5%)	0.531
IHD in anamnesis, (n, %)	91(82.7%)	213(84.5%)	44(83.0%)	0.728
MI in anamnesis, (n, %)	45(41.3%)	110(43.7%)	21(39.6%)	0.824
PCI in anamnesis	12(11.0%)	29(11.5%)	3(5.7%)	0.450
AH in anamnesis, (n, %)	104(95.4%)	242(96.0%)	49(92.5%)	0.084
Valvular heart disease in	16(14.7%)	54(21.4%)	18(34.0%)	0.332

anamnesis				
Aortic stenosis	**13(13.4%)**	**37(15.9%)**	**9(21.9%)**	**0.034**
Syncope in anamnesis, (n, %)	**8(7.3%)**	**42(16.7%)**	**7(13.2%)**	**0.046**
AF in anamnesis, (n, %)	34(31.2%)	84(33.3%)	21(39.6%)	0.875
Blockade of CA and AV nodes	9(8.3%)	23(9.1%)	4(7.5%)	0.139
Stroke in anamnesis, (n, %)	15(13.8%)	45(17.9%)	13(24.5%)	0.383
CCF before the present hospitalization, (n, %)	75(68.8%)	174(69.0%)	46(86.8%)	0.062
Atherosclerosis of peripheral arteries, (n, %)	31(28.7%)	74(29.4%)	19(35.8%)	0.211
Diabetes mellitus, (n, %)	22(20.2%)	65(25.8%)	13(24.5%)	0.081
Smoking at the moment of inclusion, (n, %) Smoking in the past, n(%)	5(4.5%) 19(17.3%)	7(2.8%) 45(17.9%)	2(3.8%) 6(11.3%)	0.147 0.078
COPD	5 (4.5%)	10 (4.0%)	3 (5.7%)	0.651
Bronchial asthma	7 (6.4%)	7 (2.8%)	1 (1.9%)	0.339
Hepatic diseases	6(5.5%)	12(4.8%)	3(5.7%)	0.135
Renal diseases	36(33.0%)	122(48.4%)	31(58.5%)	0.062
Diseases of thyroid gland	15(13.8%)	32(12.7%)	11(20.8%)	0.125
Constipations	**35 (31.8%)**	**82 (32.5%)**	**29 (54.7%)**	**0.003**
Ulcer of stomach and duodenum	9 (8.2%)	30 (11.9%)	7 (13.2%)	0.143
PCI at index hospitalization, (n, %)	**56(50.9%)**	**109(43.3%)**	**15(28.3%)**	**0.019**
GRACE scale	148.±20.95	150.±22.79	148.2±17.62	0.734
CRUSADE scale	46.5±10.60	45.2±11.16	47.4±12.90	0.645
Record Scale	2.47±0.786	2.41±0.879	2.85±0.963	**0.01**
ORACUL scale	79.1±35.22	80.6±37.03	96.7±50.13	**0.047**

BMI - body mass index
GFR - glomerular filtration rate
SBP - systolic blood pressure
HR - heart rate
HF - heart failure
EST ACS - ST segment elevation acute coronary syndrome
NEST ACS – non-ST segment elevation acute coronary syndrome
IHD – ischemic heart disease
MI – myocardial infarction
PCI - percutaneous coronary intervention
AH - arterial hypertension
AF - atrial fibrillation

Table 3. Factors independently associated with adverse outcome in elderly patients with ACS.

Factors	Total mortality			
	Univariate analysis		*Multivariant analysis*	
	OR [CI95%]	*p*	*OR [CI95%]*	*p*
Age	1.063[1.02-1.108]	0.003	1.302[0.544-3.117]	0.553
HF 4 according to Killip	1.908[1.576-2.311]	0.001	2.133[1.083-4.200]	0.028
Peripheral atherosclerosis	1.284[1.011-1.631]	0.041	1.725[0.872-3.412]	0.117
History of chronic heart failure	1.75[1.07-2.863]	0.026	1.028[0.698-1.514]	0.887
DM	1.625[1.055-2.502]	0.028	1.266[0.609-2.633]	0.528
Aortic stenosis	2.384[1.396-4.070]	0.003	2.858[1.270-6.431]	0.011
TOC	1.394[1.001-1.94]	0.049	1.044[0.973-1.120]	0.231
Hb below 100 g/l	2.675[1.457-4.90]9	0.001	1.422[0.437-4.627]	0.559
Troponin increase	1.751[1.401-2.189]	0.001	1.643[1.205-2.003]	0.022
PCI at primary hospitalization	0.385[0.232-0.641]	<0.0001	0.502[0.259-0.974]	0.042

HF - heart failure
SSA - syndrome of senile asthenia
CCF - chronic heart failure
DM – diabetes mellitus
PCI - percutaneous coronary intervention

Table 4. Factors independently associated with the efficacy of PCI in elderly patients.

Factors	Efficacy of PCI in decrease of total mortality			
	Univariate analysis		*Multivariant analysis*	
	OR [CI95%]	*p*	*OR [CI95%]*	*p*
Age	1.045[1.007-1.083]	0.046	1.014[0.952-1.081]	0.660
HF 4 according to Killip at admission	2.547[1.572-4.126]	0.0001	2.659[1.536-4.605]	0.001
Diabetes mellitus	1.608[1.003-2.558]	0.044	1.823[1.092-2.624]	0.038
Aortic stenosis	2.138[1.232-3.708]	0.007	1.599[1.142-2.038]	0.015
TOC	1.487[1.020-2.168]	0.039	1.807[1.074-2.559]	0.043
Creatinine clearance below 30 ml/min	0.486[0.146-0.826]	0.049	0.674[0.257-1.763]	0.421

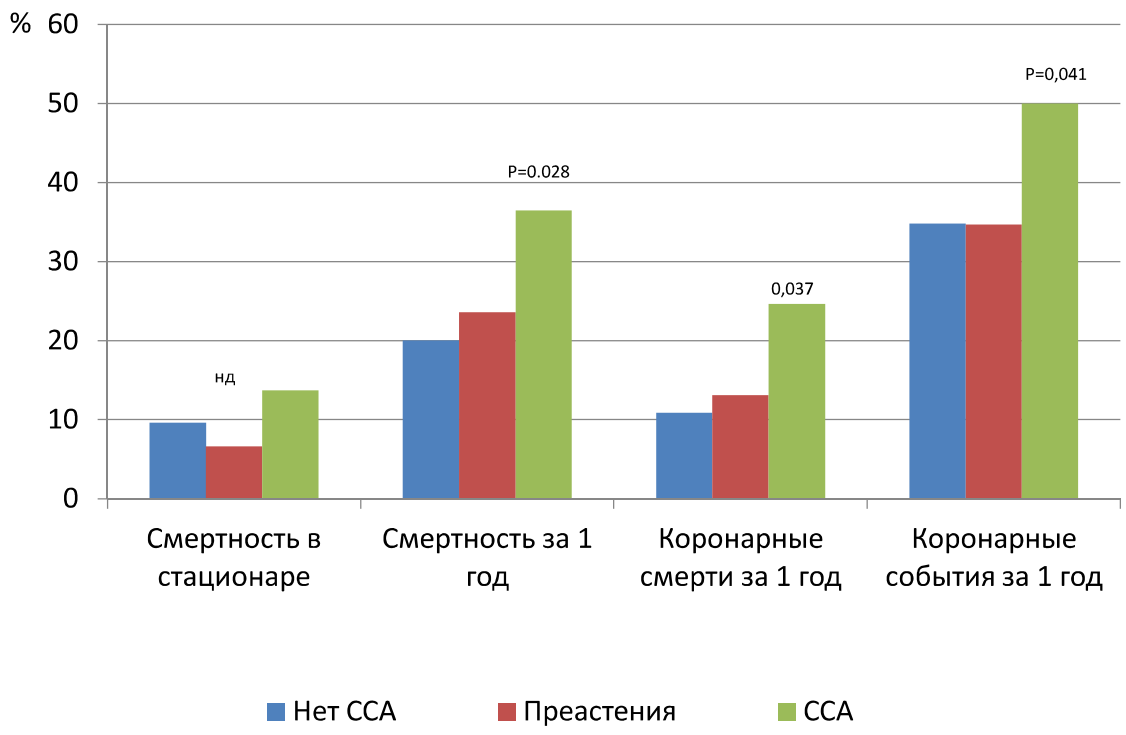

Figure 1. Frequency of adverse events in 1 year of observation

Смертность в стационаре	Hospital mortality
Смертность за 1 год	Mortality in 1 year
Коронарные смерти за 1 год	Coronary deaths in 1 year
Коронарные события за 1 год	Coronary events in 1 year
Нет ССА	No SSA
Преастения	Preasthenia
ССА	SSA

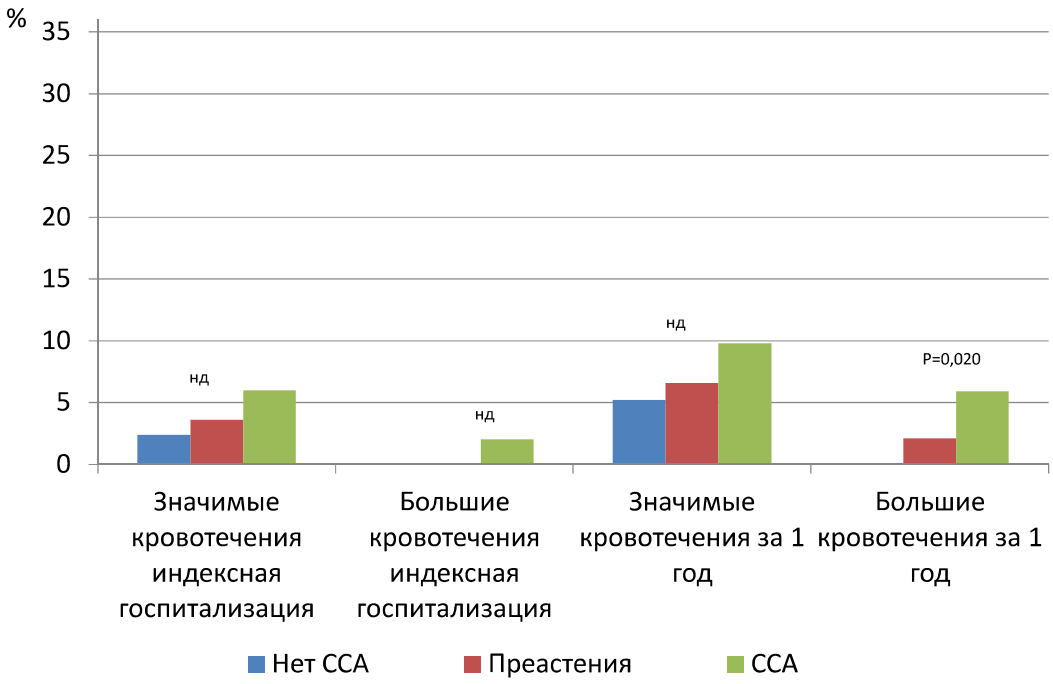

Figure 2. Frequency of bleeding in 1 year of observation

Значимые кровотечения индексная госпитализация	Significant bleedings index hospitalization
Большие кровотечения индексная госпитализация	Massive bleedings index hospitalization
Значимые кровотечения за 1 год	Significant bleedings in 1 year
Большие кровотечения за 1 год	Massive bleedings in 1 year
Нет ССА	No SSA
Преастения	Preasthenia
ССА	SSA

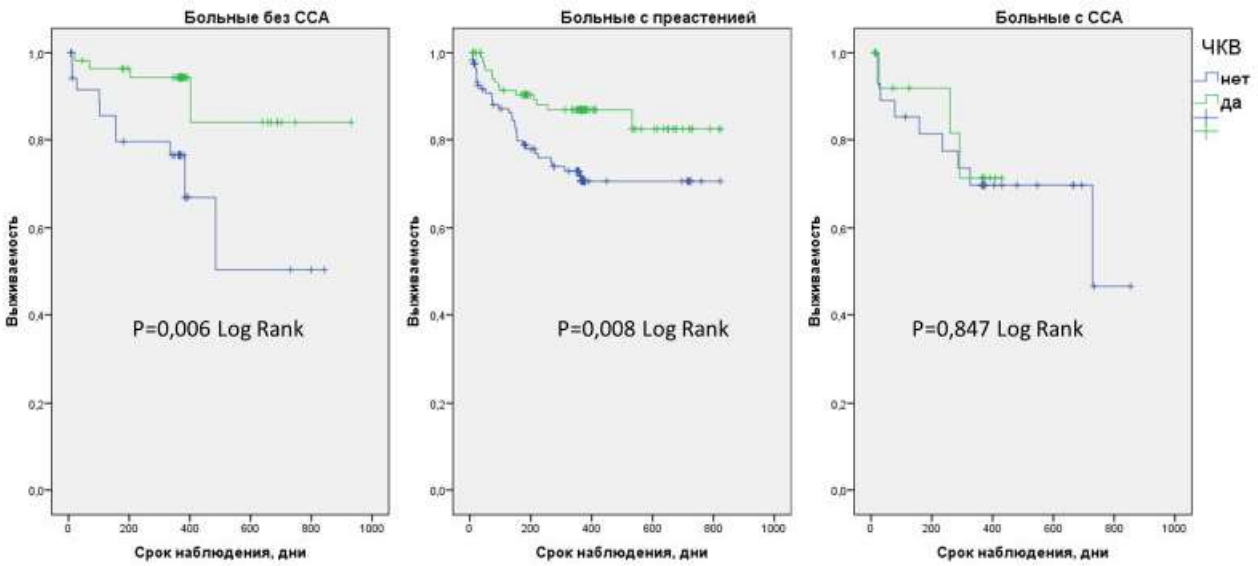

Figure 3. Efficacy of PCI in elderly patients depending on the presence of syndrome of senile asthenia

Больные без ССА	Patients without SSA
Больные с преастенией	Patients with preasthenia
Больные с ССА	Patients with SSA
Выживаемость	Survival
Срок наблюдения, дни	Period of observation, days
ЧКВ	PCI
Да	Yes
Нет	No