




Predictive factors for recurrent suicide attempts: Evidence from the ACTION-J study

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Abstract

Aim: Risk factors for attempted suicide have been widely studied. However, there is limited evidence on predictive factors for suicide reattempts. We aimed to identify these in suicide attempters admitted to emergency departments.

Methods: This is the second analysis from a randomized controlled multicenter trial, ACTION-J. Patient characteristics were extracted from baseline demographic data and clinical data of participants. Predictive factors for a recurrent suicide attempt in each gender were examined using Cox proportional hazards regression analysis. Dependent variables were months from trial entry to the first reattempt. Independent variables were characteristics regarded as potential predictive factors.

Results: The study included 914 adults (400 men and 514 women). A visit to a psychiatrist within a month of the suicide attempt was significantly associated with reattempts in men (hazard ratio [HR] 2.49, 95% confidence interval [CI] 1.21–5.25). Substance-related disorders (HR 3.65, 95% CI 1.16–7.9.60), drinking alcohol less than once per month (HR 0.42, 95% CI 0.17–0.88), previous suicide attempts (HR 2.28, 95% CI 1.40–3.87), and taking a drug overdose for the first suicide attempt (HR 1.82, 95% CI 1.14–3.01) were significantly associated with reattempts in women.

Conclusion: Our data highlight the importance of visits to a psychiatrist a short time before the first suicide attempt in men and substance-related disorder, previous suicide attempts, and drug overdose in the first suicide attempt in women as predictive factors for future suicide reattempts.

KEYWORDS

ACTION-J, emergency medicine, predictive factors, substance-related disorder, suicide reattempt

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INTRODUCTION

Suicide is both a tragic individual issue and a critical public health issue all over the world. A report by the World Health Organization¹ found that it was the cause of more than 800,000 deaths worldwide and the second most important cause of death among young people. Many researchers have therefore tried to identify risk factors associated with suicide to develop effective suicide prevention strategies.

There are gender differences in suicide. Men are more likely to die by suicide than women, but women are more likely to attempt it.²⁻⁴ Previous studies have shown many individual risk factors for suicide, including a previous suicide attempt,^{5,6} mental health problems,^{7,8} abuse of alcohol and other substances,⁹ job or financial loss,¹⁰ hopelessness,^{11,12} chronic pain and illness,¹³ and family history of suicide.¹⁴ Previous suicide attempts are the strongest predictor of later suicide.^{15,16}

Risk factors for attempted suicide have been studied in more detail because attempters are more likely than suicides to visit medical departments, and their characteristics can therefore be studied. The main risk factors for attempted suicide are previous suicide attempts, alcohol and drug abuse, mental health problems, previous psychiatric inpatient treatment, self-discharge before evaluation, personality disorder, unemployment, frequent change of address, hostility, and living alone.² A population-based case-control study found that the number of visits of suicide attempters to emergency departments was associated with future risk of suicide.¹⁷ Indeed, suicide attempters were nearly 12 times more likely to report ongoing suicidal ideation in the emergency department than nonattempters.¹⁸ Predicting risk factors for reattempts of suicide among attempters presenting at emergency departments is therefore critical.

Previous studies suggested that many attempters might share clinical and sociodemographic factors that could explain the recurrence of suicidal behavior. The significant risk factors for suicide repetition are being female, young, in socioeconomic difficulties, with higher severity of psychiatric symptoms, and comorbidity.¹⁹⁻²⁴ Most of these studies were retrospective comparisons of characteristics between single and multiple attempters, and therefore could not directly predict future reattempts.

Recent studies therefore began to examine predictive risk factors for suicide reattempts by using prospective cohort and survival analysis. These studies have used various samples and settings, such as those presenting with alcohol disorders in emergency departments,²⁵ attempters in primary care clinics,²⁶ and adolescents in psychiatric hospitals.²⁷ A few studies have examined predictive risk factors of suicide reattempts in attempters admitted to emergency departments. These include an observational study by telephone among 1241 attempters after admission,²⁸ a multicenter prospective cohort study among 324 attempters admitted to the emergency department,²⁹ a cohort study for 291 attempters admitted to the emergency department in a primary care hospital,³⁰ and a prospective study about gender differences among 273 attempters admitted

to psychiatric emergency units.³¹ The follow-up periods varied from 2 months to 5 years, and the results were sometimes contradictory because of limitations including sample size, bias in the data, and collection methods.

From 2006 to 2011, we conducted a study comparing assertive case management with enhanced usual care for people with mental health problems who had attempted suicide and were admitted to the emergency departments in general hospitals in Japan (ACTION-J).³² This multicenter, randomized controlled trial provided an opportunity to create a database of detailed clinical information and suicide reattempts in 914 suicide attempters over 5 years during the prospective study period.

We therefore collected attributes and clinical datasets of suicide attempters from the database of the ACTION-J study and carried out secondary analyses to examine associations between each characteristic and time from trial entry to the first suicide reattempt to identify strict predictive factors for suicide reattempts in each gender.

METHODS

Participants

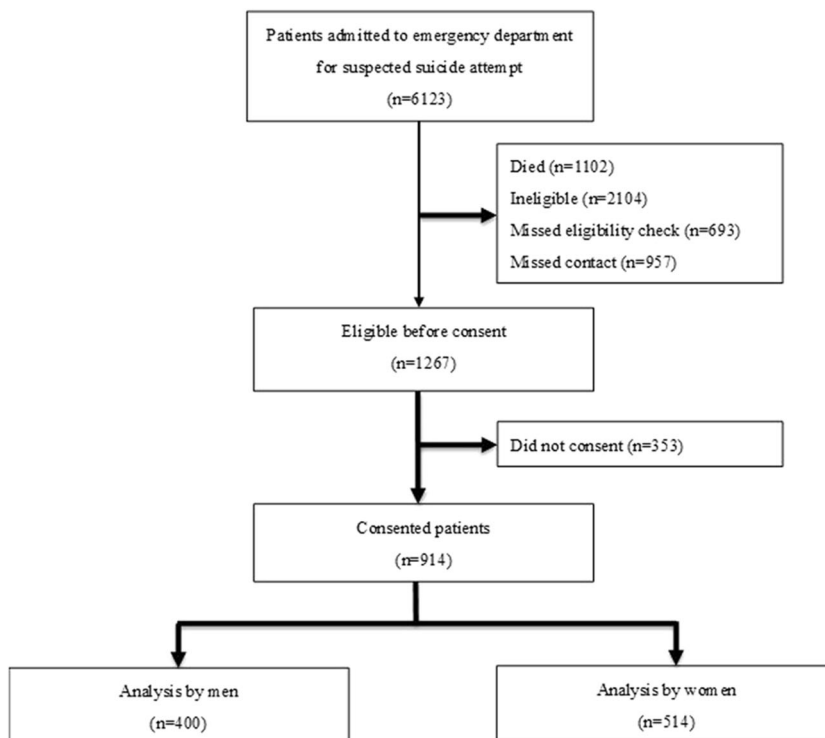
The participants in this study were adults aged 20 years and above who had attempted suicide and were admitted to emergency departments for critical care. They all had a primary diagnosis of an Axis I psychiatric disorder (*DSM-IV-TR*) and participated in the ACTION-J study. Suicide attempt was defined as self-poisoning (overdose) or self-injury carried out with apparent suicidal intent.³³ Suicidal intention was confirmed at least twice in each patient by psychiatrists in the emergency department using the Suicide Intent Scale.³² Figure 1 shows the patient flow indicating the progress of all participants through the study.

Procedure of the study

ACTION-J was a multicenter, randomized controlled trial conducted in emergency and psychiatric departments at 17 general hospitals in Japan from 2006 to 2011. Details of the case management and results of the original trial, including the survival curve, have been previously published.³² We carried out secondary analyses of data from the ACTION-J study to examine associations between each characteristic and time from trial entry to the first suicide reattempt to identify strict predictive factors for suicide reattempts.

Baseline characteristics were obtained from each participant when they had been physically stabilized, and alertness and consciousness confirmed by psychosocial assessments. Characteristics included attributes, assessment of the social, psychological, and motivational factors specific to the self-harm event and an assessment of mental health, social risks, and needs as recommended by UK national clinical practice guidelines.³⁴ After baseline evaluation, participants were randomly assigned to receive either assertive case

FIGURE 1 Patient flow indicating the progress of all participants through the study



management or enhanced usual care. Interventions were provided until the end of the follow-up period (at least 18 months and up to 5 years). The primary outcome of the study is the incidence of the first suicide reattempts during the follow-up period, which are identified by the on-site research staff at the participating hospital and confirmed by the event review committee with the evaluation criterion in the event definitions and event review procedures.³⁵ Since the study focused on time from the first attempt to the repetition of suicide attempts, definition of "suicide reattempts" did not matter whether outcome was expressed as attempted suicide or died by suicide.

Statistical analysis of this study

Patient characteristics were extracted from baseline demographic data and clinical data of participants. The characteristics were gender (men or women), age (older than 65 years or other), primary psychiatric diagnosis (mood disorder, substance-related disorder, schizophrenia or other psychotic disorder, adjustment disorder, or other), alcohol consumption (none, drinking two to four times per month, two to three times per week, or four or more times per week), visited a psychiatrist before the suicide attempt (none, before 1 month, or over 3 months), education (less than high school, high school, or more than high school), employment status (employed, unemployed, home keeping, retired, student, or not specified), marital status (married, single, divorced, or widowed), lives with partner or family (yes or no), existence of advisors (none, family, or others), previous suicide attempts (none, one or two, or three or more), and

method of attempted suicide in this attempt (drug overdose, poison, gas, laceration, jumping from a high place, intentional traffic-related injury, hanging, or other). We described a survival curve for the first reattempt by Kaplan–Meier method.

Predictive factors for recurrent suicide attempts were examined for each gender using Cox proportional hazards regression analysis. Dependent variables were months from entering the trial to the first reattempt. Independent variables were each characteristic regarded as a potentially prognostic factor. Categories were grouped when the sample size was too small for analysis. Hazard ratios (HRs) and 95% confidence intervals (CIs) were calculated. A P-value of <0.05 was considered significant.

Statistical analyses used SAS 9.4 (SAS Institute Inc.) and JMP 10.0.2 (SAS Institute Inc.).

RESULTS

Characteristics of participants

Eligible participants included 914 adults (400 men and 514 women). The characteristics of the participants at baseline are summarized in Table 1. Several characteristics varied by gender. A higher proportion of men had a substance-related disorder, showed high-frequency drinking (four or more times per week), had not visited a psychiatrist before the suicide attempt, had high levels of education (beyond high school), were employed, single, living with partner or family, had no adviser or previous suicide attempts, and used a more usually fatal method of suicide in this attempt (gas, laceration, jumping, intentional

TABLE 1 Distribution of characteristics at baseline (n = 914)

	Men (n = 400)	Women (n = 514)
Age in years, mean (SD)	44.4 (14.6)	40.8 (15.0)
Older than 65 years, n (%)	46 (11.5)	40 (7.7)
Primary psychiatric diagnosis, n (%)		
Substance-related disorder	34 (8.5)	11 (2.1)
Schizophrenia or other psychotic disorder	70 (17.5)	109 (21.2)
Mood disorder	192 (48.0)	234 (45.5)
Adjustment disorder	83 (20.8)	108 (21.1)
Other	21 (5.2)	52 (10.1)
Alcohol consumption, n (%)		
Do not drink	139 (34.8)	268 (52.3)
Drink	38 (9.5)	65 (12.7)
Two to four times per month	44 (11.0)	46 (9.0)
Two to three times per week	36 (9.0)	45 (8.8)
Four or more times per week	142 (35.6)	88 (17.2)
Visited a psychiatrist before the suicide attempt, n (%)		
None	174 (43.5)	92 (17.9)
Before 1 month	167 (41.8)	350 (68.1)
Over 3 months	59 (14.8)	72 (14.0)
Education, n (%)		
Less than high school	94 (23.5)	129 (25.1)
High school	205 (51.3)	261 (50.8)
Beyond high school	101 (25.3)	124 (24.1)
Employment status, n (%)		
Employed	200 (50.0)	170 (33.1)
Unemployed	16 (4.0)	20 (3.9)
Home keeping	0 (0.0)	119 (23.2)
Retired	23 (5.8)	4 (6.8)
Student	8 (2.0)	15 (2.9)
Not specified	153 (38.3)	185 (36.1)
Marital status, n (%)		
Married	159 (39.8)	216 (42.0)
Single	178 (44.5)	174 (33.9)
Divorced	54 (13.5)	101 (19.7)
Widowed	9 (2.3)	23 (4.5)
Lives with partner or family, n (%)	111 (27.8)	86 (16.7)
Advisors, n (%)		
None	142 (35.5)	85 (16.5)
Family	136 (34.0)	245 (47.7)

TABLE 1 (Continued)

	Men (n = 400)	Women (n = 514)
Other	186 (46.5)	342 (66.5)
Previous suicide attempts, n (%)		
None	255 (63.8)	209 (40.7)
One or two times	96 (24.0)	160 (31.1)
Three or more times	49 (12.3)	145 (28.2)
Method of the present suicide attempt, n (%)		
Drug overdose	144 (36.0)	301 (58.2)
Poison	49 (13.3)	51 (11.0)
Gas	45 (11.3)	12 (3.3)
Laceration	70 (14.0)	42 (8.1)
Jumping from a high place	10 (2.5)	6 (1.2)
Intentional traffic-related injury	39 (9.8)	74 (14.4)
Hanging	32 (8.0)	14 (2.7)
Other	11 (2.8)	14 (2.7)
Intervention group, n (%)	197 (49.3)	263 (51.2)

traffic-related injury, or hanging). There was a higher proportion of women who did not drink alcohol, had visited a psychiatrist within a month of their suicide attempt, did not work, were divorced or widowed, had advisors, had attempted suicide three or more times, or had taken a drug overdose in this suicide attempt. The gender balance in the intervention and control groups was not significantly different because of the randomization procedure used in the original study.

First suicide reattempts

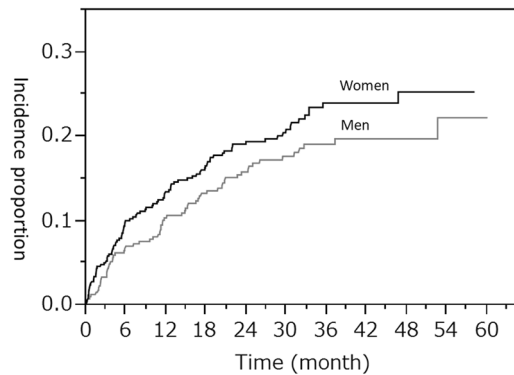
Table 2 shows information about the first reattempt, grouped by gender. In total, 67 (16.8%) of the first reattempts in men occurred during the observation period and the mean (standard deviation [SD]) time to them was 44.9 (0.87) months. In women, 100 (19.5%) of the first reattempts occurred during the observation period and the mean (SD) time to them was 38.6 (0.73) months. The survival curve for the first reattempt by gender is shown in Figure 2.

Predictive factors for reattempts in men

Table 3 shows results of Cox analysis in men. In the univariate analysis, significant factors were each 10-year increase in age (HR 0.79, 95% CI 0.66–0.95), visiting a psychiatrist in the month before the suicide attempt (HR 2.91, 95% CI 1.67–5.35), not being married (HR 1.75, 95% CI 1.04–3.04), one or more previous suicide attempts

TABLE 2 Time to the first reattempt by gender

Groups	Number (%) of reattempts	Mean (months)	SD
Men	67 (16.8)	44.9	0.87
Women	100 (19.5)	38.6	0.73
Total	167 (18.3)	43.9	0.61

**FIGURE 2** Survival curve for the first reattempt by gender

(HR 1.75, 95% CI 1.08–2.84), and taking a drug overdose in this suicide attempt (HR 2.42, 95% CI 1.50–3.94). However, only visiting a psychiatrist in the month before the suicide attempt remained significant in the multivariate analysis (HR 2.49, 95% CI 1.21–5.25).

Predictive factors for reattempts in women

Table 4 shows results of the Cox analysis in women. Significant factors in the univariate analysis were each 10-year increase in age (HR 0.82, 95% CI 0.71–0.95), substance-related disorders (HR 3.25, 95% CI 1.12–7.44), drinking alcohol less than once per month (HR 0.52, 95% CI 0.22–1.07), visiting a psychiatrist within 1 month of (HR 3.73, 95% CI 1.77–9.60) and more than 3 months before (HR 2.78, 95% CI 1.09–7.92) the suicide attempt, not being married (HR 1.57, 95% CI 1.03–2.40), previous suicide attempts (HR 2.81, 95% CI 1.78–4.61), and using a drug overdose in this suicide attempt (HR 2.13, 95% CI 1.38–3.40). Of these, substance-related disorders (HR 3.65, 95% CI 1.16–7.9.60), drinking alcohol less than once per month (HR 0.42, 95% CI 0.17–0.88), previous suicide attempts (HR 2.28, 95% CI 1.40–3.87), and taking a drug overdose in this suicide attempt (HR 1.82, 95% CI 1.14–3.01) remained significant in the multivariate analysis.

DISCUSSION

Over the 5-year study period, 16.8% of men and 19.5% of women who attempted suicide once also reattempted. The predictive factors for reattempting were having visited a psychiatrist within the month before the first suicide attempt in men and substance-related disorders, previous

suicide attempts, and a drug overdose in the first suicide attempt in women. Many studies have tried to find predictive factors for suicide reattempts. Most have been retrospective and compared characteristics for repeated and single attempters. A few prospective studies have followed attempters to another suicide attempt as a cohort or used survival analysis.^{26,28,30,31} These studies took place in clinics and psychiatric hospitals, used a registry, review of medical records or telephone interviews, and usually failed to follow up all participants. The strengths of our study were that this was a secondary analysis from a strictly planned randomized controlled trial in emergency departments, all suicide attempts were confirmed by face-to-face interviews and a masked event review committee, and all participants completed the follow-up during the study. The data were therefore robust and could be analyzed by gender.

Most of the previous cohort studies reported that over 20% of suicide attempters reattempted suicide during the follow-up period.^{36–38} This study was a secondary analysis of data from the ACTION-J study in which half the participants received assertive case management. The percentage of reattempts in our study might therefore be lower than in previous studies.

We found significant gender differences in the predictive risk factors for reattempting suicide. Sawa et al.³⁰ also found gender differences in risk factors among 291 suicide reattempters. The main factors in their study were drug overdose, past psychiatric history, and the timing of the suicide attempt in men (suicide attempts were more likely in summer), and past psychiatric history and multiple diagnoses in women. These results are different from ours, perhaps because they reviewed medical records from a single hospital. However, both studies suggest that there are important gender differences in risk factors for suicide reattempts.

Predictive factors for women identified in our study included substance-related disorders, previous suicide attempts, and drug overdoses. Previous studies have also found these were independent risk factors for suicide attempts.^{3,4,39} Prospective studies using multivariate survival analysis have provided similar results, but with an additional influence of personality disorders. Parra-Urbe et al.²⁸ found three predictive risk factors for suicide reattempts among 1241 suicide attempters in an observational study of a telephone management program. These were being younger, having cluster B personality disorders, and having alcohol use disorders. Irigoyen et al.²⁶ followed 371 suicide attempters and found three predictive risk factors including a cluster B personality disorder, good treatment compliance, and at least one previous suicide attempt before the index event. Substance use disorders had the highest hazard ratio among Axis I diagnosis in their study. Our study only included participants with Axis I primary diagnoses. Personality disorders are Axis II disorders, so might have been pre-excluded as risk factors, which would explain this discrepancy. Our results, coupled with those of previous studies, suggest that women attempting suicide who have personality or addiction problems may be more likely to reattempt using a drug overdose.

In men, visiting a psychiatrist in the month before the first suicide attempt was the only significant predictive factor for reattempting. This

TABLE 3 Predictive factors for a first suicide reattempt in men

	Univariate		Multivariate	
	HR (95%CI)	p-Value	HR (95%CI)	p-Value
Age				
Per 10 year increased	0.79 (0.66–0.95)	0.0099	0.82 (0.65–1.02)	0.0722
Primary psychiatric diagnosis				
Mood disorder	Reference			
Substance-related disorder	2.08 (0.96–4.15)	0.0617	2.17 (0.94–4.65)	0.0684
Schizophrenia or other psychotic disorder	1.29 (0.65–2.44)	0.4546	0.99 (0.47–1.98)	0.9765
Adjustment disorder	1.06 (0.52–2.04)	0.8651	1.37 (0.64–2.78)	0.4054
Other	1.26 (0.37–3.23)	0.6738	0.78 (0.22–2.11)	0.6488
Alcohol consumption				
Do not drink	Reference			
Under once per month	0.82 (0.31–1.85)	0.6483	0.76 (0.27–1.80)	0.5501
Two to four times per month	0.99 (0.42–2.08)	0.9739	0.80 (0.33–1.78)	0.60190
Two to three times per week	0.98 (0.37–2.22)	0.9642	0.99 (0.36–2.37)	0.9876
Four or more times per week	0.70 (0.39–1.25)	0.2287	0.97 (0.51–1.82)	0.9171
Visited a psychiatrist before the suicide attempt				
None	Reference			
Before 1 month	2.91 (1.67–5.35)	0.0001	2.49 (1.21–5.25)	0.0131
Over 3 months	1.72 (0.75–3.73)	0.1923	1.22 (0.49–2.91)	0.6671
Education				
Less than high school	1.05 (0.56–1.87)	0.8849	0.92 (0.46–1.73)	0.7867
High school	Reference			
Beyond high school	1.11 (0.61–1.94)	0.7338	1.23 (0.66–2.22)	0.5149
Employment status				
Employed	Reference			
Other	1.35 (0.83–2.20)	0.2242	1.13 (0.65–1.97)	0.6609
Marital status				
Married	Reference			
Other	1.75 (1.04–3.04)	0.0335	1.23 (0.66–2.37)	0.5132
Lives with partner or family	1.42 (0.84–2.34)	0.1865	1.50 (0.83–2.63)	0.1735
Advisors				
No	Reference			
Family	0.69 (0.39–1.17)	0.1714	0.62 (0.34–1.08)	0.0933
Other	0.92 (0.56–1.49)	0.7927	0.70 (0.42–1.17)	0.1712
Previous suicide attempts				
None	Reference			
One or more times	1.75 (1.08–2.84)	0.0227	1.15 (0.67–2.00)	0.6086
Method of the present suicide attempt				
Drug overdose	2.42 (1.50–3.94)	0.0003	1.69 (0.98–2.94)	0.0615
Other	Reference			

TABLE 4 Predictive factors for a first suicide reattempt in women

	Univariate		Multivariate	
	HR (95%CI)	p-Value	HR (95%CI)	p-Value
Age				
Per 10 year Increased	0.82 (0.71–0.95)	0.0061	1.02 (0.85–1.22)	0.7977
Primary psychiatric diagnosis				
Mood disorder	Reference			
Substance-related disorder	3.25 (1.12–7.44)	0.0321	3.65 (1.16–9.60)	0.0295
Schizophrenia or other psychotic disorder	0.85 (0.48–1.45)	0.5435	0.92 (0.51–1.60)	0.7710
Adjustment disorder	0.80 (0.44–1.83)	0.4337	0.95 (0.51–1.69)	0.8631
Other	1.74 (0.96–3.02)	0.0690	1.66 (0.89–2.95)	0.1078
Alcohol consumption				
Do not drink	Reference			
Under once per month	0.52 (0.22–1.07)	0.0791	0.42 (0.17–0.88)	0.01950
Two to four times per month	1.49 (0.76–2.70)	0.2342	1.12 (0.55–2.13)	0.7415
Two to three times per week	1.27 (0.61–2.39)	0.5044	0.96 (0.44–1.89)	0.9050
Four or more times per week	1.25 (0.73–2.06)	0.4123	1.14 (0.65–1.93)	0.6473
Visited a psychiatrist before the suicide attempt				
None	Reference			
Before 1 month	3.73 (1.77–9.60)	0.0002	2.26 (0.98–6.15)	0.0556
Over 3 month	2.78 (1.09–7.92)	0.0305	2.13 (0.79–6.35)	0.1353
Education				
Less than high school	0.86 (0.52–1.39)	0.5503	0.79 (0.46–1.32)	0.3697
High school	Reference			
Beyond high school	0.97 (0.59–1.54)	0.8945	1.11 (0.67–1.78)	0.6805
Employment status				
Employed	Reference			
Other	0.78 (0.53–1.19)	0.2514	0.68 (0.44–1.08)	0.1023
Marital status				
Married	Reference			
Other	1.57 (1.03–2.40)	0.0300	1.59 (0.97–2.63)	0.0645
Lives with partner or family	1.12 (0.65–1.82)	0.6733		0.4808
Advisors				
No	Reference			
Family	1.21 (0.82–1.79)	0.3464	1.45 (0.96–2.20)	0.0806
Other	1.39 (0.91–2.20)	0.1356	1.25 (0.79–2.04)	0.3451
Previous suicide attempts				
None	Reference			
One or more times	2.81 (1.78–4.61)	<.0001	2.28 (1.40–3.87)	0.0008
Method of the present suicide attempt				
Drug overdose	2.13 (1.38–3.40)	0.0005	1.82 (1.14–3.01)	0.0125
Other	Reference			

result is similar to that in a Spanish study, which found that psychiatric treatment before the suicide attempt was the only factor associated with repeated suicide attempts.⁴⁰ Substance-related disorders also had a high HR in our study, although it was not significant. A qualitative study asking why patients did not report suicide ideation at a healthcare visit before a suicide attempt found that reasons included heavy episodic drinking at the time of the suicide attempt and fear of the outcome of disclosure, including stigma, overreaction, and loss of autonomy.⁴¹ Clinicians should pay particular attention to male suicidal attempters who visited a psychiatrist shortly before their first suicide attempt, and be aware that they have a relatively high possibility of future reattempts. Men are less likely to report suicide ideation and behaviors to others, and more likely to complete suicide than women.⁴²

This study had a number of limitations. Some of the risk and protective factors found in previous studies could not be included, such as family history of suicide, details of prescriptions, past history of mental health problems, social resources, and comorbidity of Axis II mental health problems. Early-life (during age 0–15 years) and recent (in the last 6 months) life events before the index admission are also important to evaluate.⁴³ Detailed psychopathology such as hopelessness, depression, and suicide ideation were not evaluated using psychometric scales in this study. This was a secondary analysis of the ACTION-J study, and the main purpose of that study was to confirm the effects of a case management intervention so the participants' risk factors were controlled in the intervention group. Further prospective cohort studies that include these indicators are needed to confirm our results.

CONCLUSIONS

Our data highlight the importance of visits to a psychiatrist a short time before the first suicide attempt in men and substance-related disorders, previous suicide attempts, and taking a drug overdose in the first suicide attempt in women as predictive factors for future suicide reattempts. When suicide attempters visit an emergency department with these characteristics, clinicians should follow up to prevent reattempts.

AUTHOR CONTRIBUTIONS

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Furthermore, each author certifies that this material or similar material has not been and will not be submitted to or published in any other publication before its appearance in *Psychiatry and Clinical Neuroscience Reports*.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article are subject to the restrictions. Data usage for secondary purpose is required to be approved by the ACTION-J group. Requests to access these datasets should be directed to the last author.

ETHICS APPROVAL STATEMENT

The study protocol was approved by the Central Research Ethics Committee of the study sponsor (Japan Foundation for Neuroscience and Mental Health, Tokyo, Japan) and the local ethics committees of all participating hospitals. This study is registered at ClinicalTrials.gov (NCT00736918) and UMIN-CTR (C000000444).

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