The effect of education in preventing recurrent vasovagal syncope

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The effect of education in preventing recurrent vasovagal syncope

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Jin Ho Kim

<TABLE OF CONTENTS>

LIST OF FIGURES

LIST OF TABLES

<ABSTRACT>

The effect of education in preventing recurrent vasovagal syncope

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Although vasovagal syncope is a common type of syncope, its treatment has not been well established. We evaluated the long-term efficacy of education in preventing recurrent vasovagal syncope compared with drug treatment. We retrospectively investigated a total of 422 patients who were diagnosed with vasovagal syncope from June 2007 to October 2009. Group 1 (n=213, 50.5%) was treated with education alone. Group 2 (n=209, 49.5%) received education plus medication; β-blockers (n=132, 63%), midodrine (n=71, 34%), and selective serotonin reuptake inhibitors (n=6, 3%). All patients were educated about lying down at the onset of prodromal symptoms, avoiding triggering events, and modifying their lifestyle. Patients were regularly followed up at an outpatient clinic or by phone for 2.43 ± 0.03 years. During follow-up, the frequency of syncopal episodes per year (n/year) following treatment reduced

from 1.66 ± 1.11 to 0.06 ± 0.37 in group 1, and from 1.50 ± 1.18 to 0.07 ± 0.23 in group 2. In multiple logistic regression analysis in matched groups according to propensity score, young age < 35 years (odds ratio [OR] 2.18, 95 confidence interval [CI] 1.03-4.64, p=0.042), and frequent previous syncopal episodes/year > 2.08 (OR 2.11, CI 1.26-4.22, p=0.034) remained significant as independent predictors associated with increased risk for recurrent vasovagal syncope, but treatment type was not related to recurrent vasovagal syncope. In conclusion, medication as a treatment for recurrent vasovagal syncope are not more effective than education.

Key Words**:** education; vasovagal syncope; head-up tilt test

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I. INTRODUCTION

Syncope is defined as a transient loss of consciousness, caused by transient global cerebral hypoperfusion and systemic hypotension.[1, 2] Vasovagal syncope is the most common type of syncope, with a mean prevalence of 24% in the general population.[3] Even though the prognosis of vasovagal syncope is generally benign and is not associated with an increase in cardiovascular morbidity or mortality,[4] the recurrence rate of vasovagal syncope is as high as 21.6%,[4] and a syncopal episodes may reduce quality of life or even be fatal in certain situations, such as driving. Accordingly, preventive therapeutic attempts to reduce recurrent vasovagal syncope could be important in patients who are at high risk of fatal accidents or who experience psychological distress and reduced quality of life.

However, therapeutic strategies to prevent recurrent vasovagal syncope have not yet been well established and it is still controversial whether conventional pharmacological agents used widely in clinical practice are effective for treatment. Although recent guidelines recommend education as a first-line treatment for

vasovagal syncope,[2] there is a lack of convincing data to support the effectiveness of intensive education as a therapeutic option. In addition, the long-term outcomes of vasovagal syncope treated with intensive education or conventional medical treatment in real clinical practice have not yet been investigated. Therefore, we assessed the long-term efficacy of intensive education for recurrent vasovagal syncope in real clinical practice in comparison to current conventional medical therapy.

II. MATERIALS AND METHODS

1. Patients

We surveyed the Clinical Database Registry System of Yonsei University Medical Center from June 2007 to October 2009. A total of 1151 subjects underwent head-up tilt tests (HUT). From a cohort of subjects who underwent HUT, we selected those (n=737**,** 64%) who had ≥ 1 syncopal episode and showed positive results for the HUT. A history of syncopal episodes was identified by medical records if episodes were triggered by prolonged upright position or emotional stress and were accompanied by typical symptoms such as faintness, lightheadedness, blurred vision, nausea/vomiting, or abdominal discomfort/pain. A positive response for HUT was defined as follows; when syncope or presyncope was induced in the presence of significantly decreased blood pressure, bradycardia, or both.[5, 6] We excluded subjects (n = 114) with 1) any bradycardia; sinus bradycardia (<50 bpm), sinus pause > 3 sec, Mobitz type II atroiventricular (AV) block or complete AV block, 2) previous cardiac surgery, 3) atrial fibrillation, 4) implanted pacemakers, 5) neurologic deficits, 6) life-threatening arrhythmias (ventricular tachycardia or ventricular fibrillation), or 7) malignancies. We classified accident severity during syncope according to trauma severity as follows; grade 1, no traumatic lesion; grade 2, slight contusion; and grade 3, severe damage demanding surgical treatment. We classified vasovagal syncope into three

types; mixed, cardioinhibitory, and vasodepressor, according to heart rate and blood pressure during HUT.[7]

The head-up tilt test was performed with a protocol using a total of 4 phases as follows: 1) supine pre-tilt phase during which the patient is supine for 10 minutes; 2) passive tilting phase with tilt angle of 70° for 30 minutes; 3) intravenous infusion of isoproterenol phase with incremental doses for a total of 15 minutes for each step (1ug/min) until the full dose was reached (5ug/min), and 4) passive tilting phase with tilt angle of 70° with intravenous infusion of isoproterenol for 10 minutes.[8]

2. Management and Follow-up

When diagnosed with vasovagal syncope based on historical features and positive results in HUT, subjects were treated with education alone or with conventional medical treatment combined with education, according to the preferences of physicians who specialized in clinical cardiac electrophysiology. According to treatment types, we divided the subjects into two groups; group 1, which received education alone and group 2, which received medication plus education. All patients were provided with an explanation of the mechanisms of vasovagal syncope and were educated about lying down at the onset of symptoms, avoidance of triggering events, adequate water intake, and lifestyle modifications. Medication that may induce hypotension was modified or discontinued. For patients treated with education alone, repetitive explanation and educational sessions were given until the patients ensured their understanding of the natural course of syncope, mechanisms, and instructions.

During a mean follow-up of 2.4 years, 422 of 623 subjects were interviewed by telephone or regularly visited an outpatient clinic, and 201 of 623 were not followed up or refused the survey. Finally, data from 422 subjects were analyzed in the current

study, as shown in Figure 1. The subjects were asked for 1) the number of recurrent vasovagal syncopal episodes following individual treatments including education alone or conventional medication and 2) compliance for medication prescribed for vasovagal syncope. Recurrent vasovagal syncope was defined as ≥ 1 syncopal episode during the follow-up period after treatment.

Figure 1

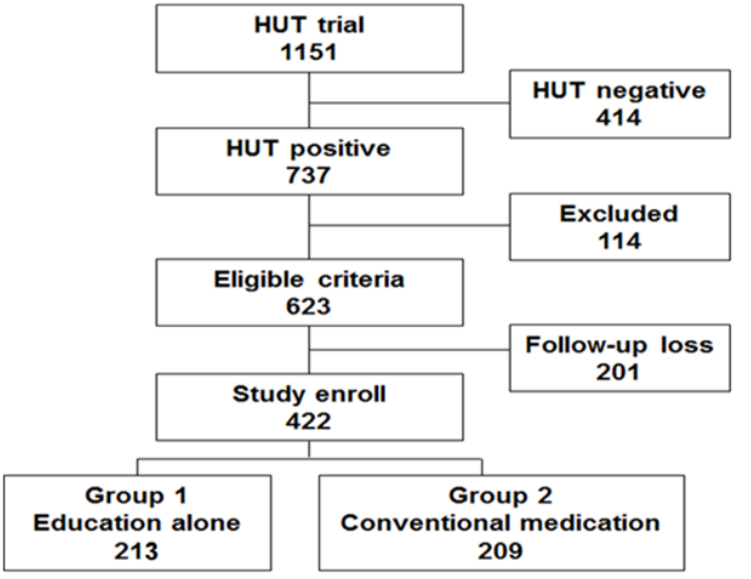

Figure 1. Flow diagram and number of patients (HUT, head-up tilt test).

3. Statistical Analysis

All continuous data are described as the mean ± standard deviation and categorical variables are described as proportions. We used the Student *t*-test for group comparisons and the chi-square test for categorical variables. A multiple logistic

regression was constructed to determine whether treatment type was associated with reduced syncopal episodes, entering other variables with values of $p < 0.1$. The prognostic values of variables related to the decreased syncope episodes were estimated using propensity scores. The SPSS R plug-in (SPSS R Essentials) 20 package (SPSS Inc., Chicago, IL, USA) and R version 2.12.0 (R Development Core Team, Vienna, Austria) were used. Values of $p < 0.05$ were considered statistically significant.

III. RESULTS

1. Baseline characteristics of patients

The baseline characteristics of subjects receiving education alone (group 1: n=213, 50.5%) and conventional medication (group 2: n=209, 49.5%) are described in Table 1. Group 2 was composed of patients who were prescribed β-blockers (n=132, 63%), midodrine (n=71, 34%), and selective serotonin reuptake inhibitors (n=6, 3%). The patients receiving conventional medication were significantly older, and had significantly higher prevalences of histories of hypertension, coronary artery disease and cerebrovascular accident, compared with those receiving education alone. There were no significant differences in sex, history of diabetes mellitus or heart failure between the groups. Furthermore, accident severity, vasovagal syncope type, and the number of previous syncopal episodes prior to treatment were similar between the education alone group and conventional medication group. Historical features of prodromal symptoms are presented in Table 2. Historical features of the patients with education alone were not different from those of patients with medication.

Table 1. Baseline characteristics of patients

	Group 1 Education alone (n=213, 50.5%)	Group 2 Conventional medication (n=209, 49.5%)	*p*-value
Age (yrs)	37.73 ± 16.12	46.94 ± 19.31	0.001
Age < 35	112 (52.6%)	70 (33.5%)	0.001
Male	98 (46.0%)	90 (43.1%)	0.543
Hypertension	12 (5.6%)	62 (29.7%)	0.001
Diabetes mellitus	11 (5.2%)	18 (8.6%)	0.162
Coronary artery disease	3 (1.4%)	17 (8.1%)	0.001
Cerebrovascular accident	1 (0.5%)	12 (5.7%)	0.002
Heart failure	2 (0.9%)	3 (1.4%)	0.637
Accident severity grade 3	11 (5.2%)	16 (7.7%)	0.296
Vasovagal syncope type			0.327
Mixed	198 (93.0%)	187 (89.5%)	
Vasodepressor	9 (4.2%)	16 (7.7%)	
Cardioinhibitory	6 (2.8%)	6 (2.9%)	
Follow-up duration	823.72 ± 319.86	871.88 ± 281.43	0.869
Syncopal episodes per year prior to treatment (n/year)	1.59 ± 1.08	1.60 ± 1.52	0.108

Table 2. Historical features of prodromal symptoms

	Group 1 Education alone (n=213, 50.5%)	Group 2 Conventional medication (n=209, 49.5%)	*p*-value
Dizziness	204 (96.2%)	193 (92.3%)	0.088
Gastrointestinal discomfort	99 (46.7%)	101 (48.3%)	0.738
Visual disturbance	73 (34.4%)	59 (28.2%)	0.170
Chest discomfort	44 (20.8%)	50 (23.9%)	0.435
Palpitation	51 (24.1%)	53 (25.4%)	0.757
Sweating	16 (7.5%)	27 (12.9%)	0.069
Amnesia	9 (4.2%)	8 (3.8%)	0.828
General weakness	24 (11.3%)	24 (11.5%)	0.958
Pallor	22 (10.4%)	33 (15.8%)	0.099

2. Syncope recurrence during follow-up

During a mean follow-up of 29 ± 10 months, 41 of 422 patients (9.7%) had recurrent vasovagal syncopal episodes after treatment with education alone or medication. The frequency of syncopal episodes per year (n/year) following treatment decreased from 1.66 ± 1.11 to 0.06 ± 0.37 in group 1, and from 1.50 ± 1.18 to 0.07 ± 0.23 in group 2 ($p < 0.001$, Figure 2).

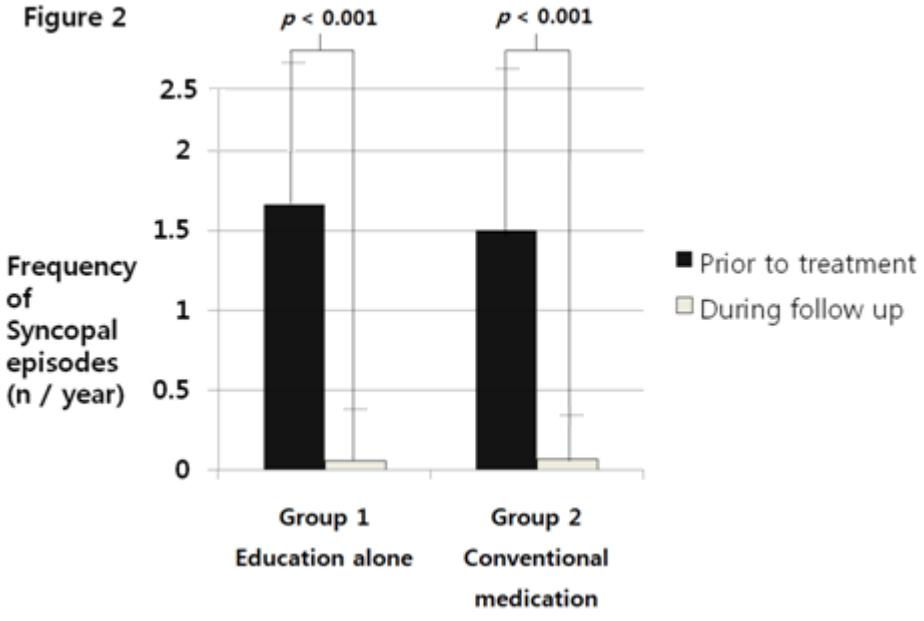

Figure 2. Syncopal episodes per year (n/year) before and after treatment in the education alone group and conventional medication group.

3. Independent predictor associated with recurrence of vasovagal syncope

The patients with recurrent syncope were younger, had significantly more previous syncopal episodes, and severer accidents prior to treatment. As treated by categorical variables, young age < 35 years, frequent previous syncopal episodes per year > 2.08, and higher incidence of severe accident (grade 3) were associated with recurrent syncope. However, treatment type was not associated with syncopal episodes prior to and following treatment. Other confounding variables including sex, hypertension, diabetes mellitus, coronary artery disease, cerebrovascular disease, heart failure, vasovagal syncope type according to heart rate and blood pressure response, and historical features not

related to recurrent vasovagal syncopal episodes following treatment. In multiple logistic regression analysis, young age < 35 years, frequent previous syncopal episodes per year > 2.08, and higher incidence of severe accidents (grade 3) remained significant independent predictors associated with increased risk for recurrent vasovagal syncope.

Treatment type was not related to decreased incidence of recurrent vasovagal syncopal episodes. To control selection bias in determining the effect of treatment type on recurrent syncope, age, sex, history of hypertension, diabetes mellitus, cerebrovascular accident, coronary artery disease, congestive heart failure, previous syncopal episodes per year, and accident severity during syncope were matched between the two groups according to propensity score (see Table 3). After multiple logistic regression analysis in the matched group by propensity score, treatment type was not related to decreased incidence of recurrent syncope, and young age < 35 years, and frequent previous syncopal episodes per year > 2.08 remained significant independent predictors associated with increased risk for recurrent vasovagal syncope (Figure 3).

Table 3. Baseline characteristics in matched groups according to propensity score

	Group 1 Education alone (n=154)	Group 2 Conventional medication (n=154)	*p*-value
Age (yrs)	38.22 ± 16.63	40.95 ± 18.12	0.169
Age < 35	81 (26.3%)	70 (22.7%)	0.210
Male	61 (19.8%)	60 (19.5%)	0.907
Hypertension	12 (3.9%)	12 (3.9%)	1.000
Diabetes mellitus	7 (2.3%)	7 (2.3%)	1.000
Coronary artery disease	3 (1.0%)	5 (1.6%)	0.474
Cerebrovascular accident	1 (0.3%)	2(0.6%)	0.562
Heart failure	1 (0.3%)	1 (0.3%)	1.000
Accident severity grade 3	9 (2.9%)	8 (2.6%)	0.803
Vasovagal syncope type			0.618
Mixed	142 (92.2%)	137 (89.0%)	
Vasodepressor	8 (5.2%)	11 (7.1%)	
Cardioinhibitory	4 (2.6%)	6 (3.9%)	
Follow-up duration	810.21 ± 294.14	813.82 ± 268.21	0.989

Syncopal episodes per year prior to treatment (n/year)	1.57 ± 0.89	1.58 ± 0.26	0.477

Figure 3

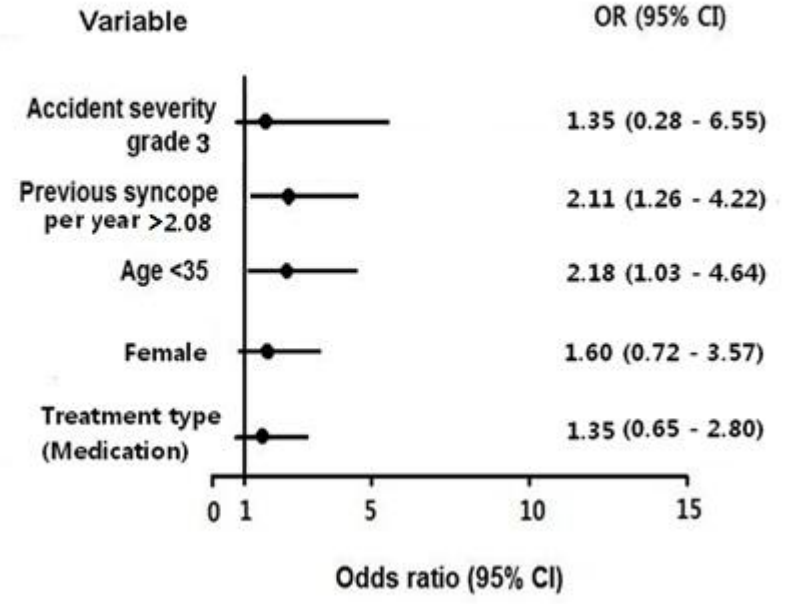

Figure 3. **.** Multiple logistic regression analysis in matched groups according to propensity score.

4. Subgroup analysis

Next, we performed further subgroup analysis to determine the relationship between treatment type and recurrent syncope. In each subgroup with young age < 35, multiple co-morbidities and accident severity grade 3, there was no statistical significance between treatment type and recurrent syncope (Table 4). The multiple co-morbidities group was composed of ≥ 1 of the following diseases: hypertension, diabetes mellitus, coronary artery disease, cerebrovascular accident, and heart failure.

Table 4. Subgroup analysis to determine the relationship between treatment type and syncope recurrence

	Odds ratio	95% CI	*p*-value
Entire cohort	1.671	0.84 – 3.35	0.145
Multiple co-morbidities	1.618	0.18 – 14.60	0.668
Young age < 35 years	2.094	0.88 – 4.97	0.094
Accident severity grade 3	0.615	0.10 – 3.82	0.602

* Multiple co-morbidities group was composed with ≥ 1 of the following diseases; hypertension, diabetes mellitus, coronary artery disease, cerebrovascular accident, heart failure.

IV. DISCUSSION

We found that the efficacy of education was not different from that of conventional medical therapy for preventing the recurrence of vasovagal syncope during long-term follow-up.

To date, numerous randomized or observational clinical studies of treatment for recurrent vasovagal syncope have focused on the effectiveness of pharmacological agents. The β-blockers that are widely used for vasovagal syncope patients in clinical practice have not been proven to be effective in randomized controlled trials,[9-12] although a multicenter, double-blind, randomized controlled trial (Prevention Of Syncope Trial [POST]) indicated a weak trend of β-blockers being effective in an older age group.[13] Midodrine, a potent alpha-1 receptor agonist, showed beneficial results in several small randomized controlled trials.[14-16] In addition, several medications such as selective serotonin reuptake inhibitors,[12, 17] anticholinergics,[18] angiotensin converting enzyme inhibitors,[19] and theophylline[20] have been investigated in small clinical trials or observational studies, and have shown modest beneficial effects.

However, medications prescribed to prevent recurrent vasovagal syncope, including β-blockers, midodrine, or selective serotonin reuptake inhibitors, may have some limitations in real clinical practice, because their side effects are potentially harmful. Midodrine has side effects such as supine systolic hypertension, urinary frequency or urgency, worsening of angina, and cerebrovascular disease.[21] β-Blockers and selective serotonin reuptake inhibitors have side effects such as bradycardia, fatigue, and headache.[9, 17, 21] Our data show that 33% (69 of 209) of patients who had taken medication stopped medication arbitrarily without their doctors' instructions, showing poor drug compliance. A previous study demonstrated that up to 25% of older patients who were taking midodrine stopped medication within a year.[21]

Moreover, the long-term efficacy of pharmacological intervention in vasovagal syncope has been not investigated well. The observational or follow-up periods of most clinical studies that demonstrated modest or substantial beneficial effects for some medications, but not β-blockers, are limited to a maximum of 12 months.[14, 15, 22] And in some studies related to midodrine and selective serotonin reuptake inhibitors such as paroxetin with follow-up durations of 21.9 and 25 months, the numbers of enrolled patients were limited to just 23 and 68 patients, respectively.[16, 17] Ultimately, the prescription of pharmacological agents as initial treatment for vasovagal syncope may be unnecessary.

The current clinical guidelines, including those of the European Society of Cardiology, suggest education and reassurance regarding the benign natural course of vasovagal syncope as an initial treatment.[2] However, the efficacy of education as a therapeutic modality for vasovagal syncope is uncertain, and besides, long-term outcomes with education have not yet been investigated. In the current study, we highlight that intensive education as an initial treatment for vasovagal syncope is more effective than conventional medication treatments widely used in clinical practice. Additionally, we demonstrate that recurrent syncope following treatment is associated with young age and frequent previous syncopal episodes. In particular, patients with high risk of recurrent vasovagal syncope should be provided with intensive education. Further studies of management of vasovagal syncope refractory to education or conventional medical treatment are needed.

This study has several limitations. First, we did not show purely beneficial effects of education in vasovagal syncope compared with no treatment, as discussed above. It would not be possible to treat patients without providing any advice or assurance in clinical practice. Second, accurate comparisons among individual drugs were not possible because we did not have equal numbers of patients in the sample for each drug. Nevertheless, this observational study reflects real clinical practice, in which

patients with vasovagal syncope had low compliance for medication prescribed, irrespective of drug type. Third, the incidence of recurrent vasovagal syncope following treatment was low, compared with the findings of other clinical studies. This finding may be due to the small number of the patients with multiple syncopal episodes in our study sample.

V. CONCLUSION

Medication as a treatment for recurrent vasovagal syncope are not more effective than education during long-term follow up. And young age < 35 years and frequent previous syncopal episodes per year > 2.08 were significant independent predictors associated with increased risk for recurrent vasovagal syncope.

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ABSTRACT(IN KOREAN)

미주신경성 실신 예방에 대한 교육의 효과

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김 진 호

미주신경성 실신은 실신의 흔한 형태이지만, 그것에 대한 치료는 현재까지 명확하게 정립되지 못하고 있다. 본 연구의 목적은 재발성 미주신경성 실신을 방지하기 위해 약물과 비교하여 교육의 장기적인 효과를 밝히는 데에 있다. 2007년 6월부터 2009년 10월사이에 미주신경성 실신으로 진단받은 422명의 환자를 대상으로 연구를 진행하였으며, 전체 환자 군을 교육만 한 환자 군(Group 1, n=213, 50.5%)과 교육과 약물치료를 병합한 환자 군(Group 2, n=209, 49.5%) 으로 나누었다. 모든 환자는 전조 증상이 발생 즉시 바로 누울 것, 유발 인자 등 피할 것, 그리고 생활 습관 교정 등을 교육받았다. 환자들은 약 2.4년 동안 유선연락 또는 외래 방문을 통해 정기적으로 추적 관찰하였다. 추적관찰 기간 동안, 치료 후 연간 실신 빈도(횟수/

년) 는 교육만 한 환자 군에서는 1.66 ± 1.11에서 0.06 ± 0.37로 감소되었고, 교육과 약물 병합한 환자 군에서는 1.50 ± 1.18에서 0.07 ± 0.23로 감소되었다. 성향 점수에 따라 짝지은 집단 간 로지스틱 분석에서, 35세 미만의 젊은 연령(OR 2.18, 95% CI 1.03-4.64, p=0.042)과 치료 전의 2.08회/년 초과의 빈번한 실신 횟수 (OR 2.11, CI 1.26-4.22, p=0.034) 가 재발성 미주신경성 실신의 위험도를 증가시키는 독립적인 인자로 의미가 있었으나, 치료형태는 이와 관련이 없는 것으로 나타났다. 결론적으로, 미주신경성 실신에 대한 치료로서 약물 치료는 교육 보다 효과적이지 못하다.

핵심되는 말 : 교육; 미주신경성 실신; 기립경 검사