

Aug 20, 2018

Presentation of clinical epidemiology study result



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Contents

- Research question
- Steps of data analysis.
- Presentation of analyzed data.
- Implications of results.

What is research question?

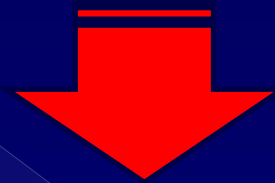
- ✓ The research question sets out what you hope to learn about the topic.
- ✓ This question, together with your approach, will guide and structure the choice of data to be collected and analyzed.

<http://www.socscidiss.bham.ac.uk/research-question.html>

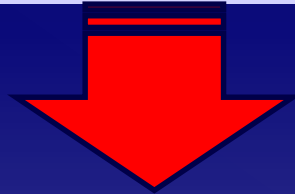
http://twp.duke.edu/uploads/media_items/research-questions.original.pdf



Research Question



Hypothesis



Specific Aim

Guidelines highlight some of the features of good questions

- Relevant.
- Manageable in terms of research and in terms of your own academic abilities.
- Substantial and with original dimensions.
- Consistent with the requirements of the assessment.
- Clear and simple.
- Interesting.



- **Relevant:** Arising from issues raised in literature and/or practice, the question will be of academic and intellectual interest.
- **Manageable:** You must be able to access your sources of data (be they documents or people), and to give a full and nuanced answer to your question.

- **Substantial and original:** The question should showcase your imaginative abilities, however far it may be couched in existing literature.
- **Fit for assessment:** Remember, you must satisfy the learning outcomes of your course. Your question must be open to assessment, as well as interesting.

- **Clear and simple:** A clear and simple research question will become more complex as your research progresses.
- **Interesting:** Make your question interesting, but try to avoid questions which are convenient or flashy.

Steps of clinical epidemiology

Descriptive study

(To know distribution and characteristics)



Analytic study

(To know associations)



Intervention study

(To know effectiveness)

Descriptive study

- **Checking distribution and characteristics of the participants:** To know the distribution and characteristics may lead adequate advanced analysis.
- **Checking errors:** Data errors may be corrected before main analysis.

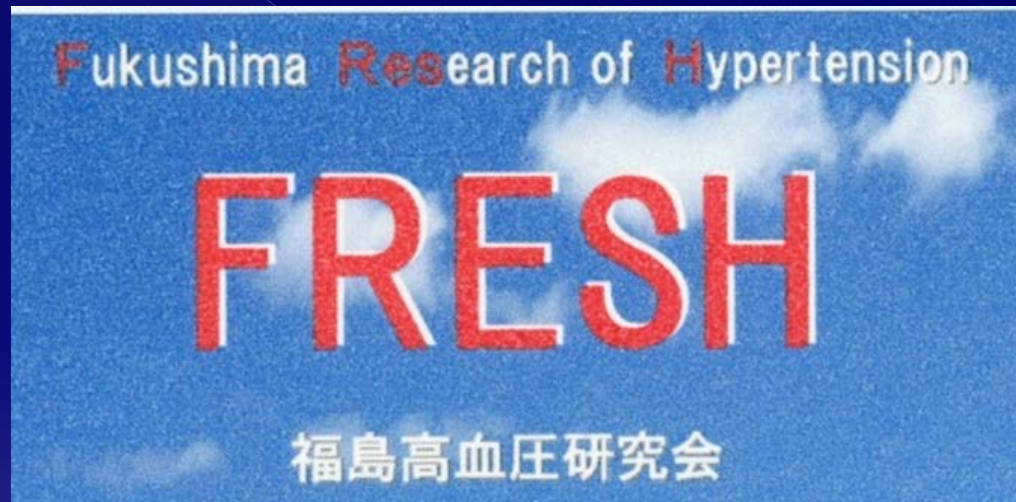
Analytic study

- **Estimating associations:** To know associations between outcome and factors.
- **Exploring associated factors:** To explore factors associated with outcome.

How to interpret the clinical study results?



Example of clinical study



Background

Hypertension is a well-known risk factor of atherosclerotic disease. In Japan, hypertension is recommended to be treated according to the Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2004).

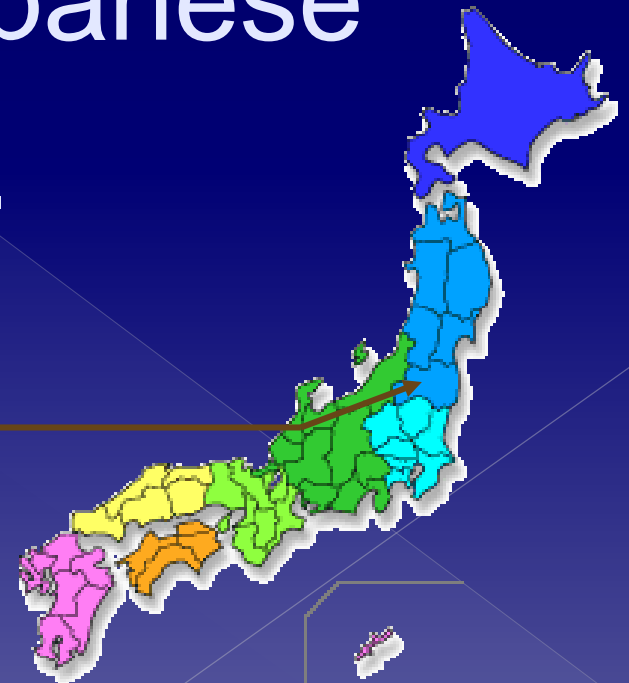


Community-based evaluations of the achievement of blood pressure control among hypertensive patients are few.

Aim

To assess the achievement toward treatment goals (JSH2004) among Japanese hypertensive patients.

Fukushima prefecture



Methods

Research Design

Observational Cohort Study
(from July 2006 to May 2007)

Subjects

Subjects were 3,358 registered hypertensive patients.

1. Received hypertensive medication for at least three months.
2. Visited the registered doctors during the baseline-survey period (July 2006).

Research Variables in Baseline Survey

Basic characteristics

Family histories

Health behaviors

(Smoking, Alcohol)

Anthropometries

(Height, Weight, Waist
circumference)

Metabolic disorders

Diabetes Mellitus

Dyslipidemia

**Achievement
toward
hypertension
treatment goal**

Organ damages and
Cardiovascular diseases

Brain

Heart

Kidney

Blood vessel

Hypertensive retinopathy

Diabetic retinopathy

Blood pressure

Systolic blood pressure

Diastolic blood pressure

Instruction of home blood pressure
measurement

Duration of hypertension

Results

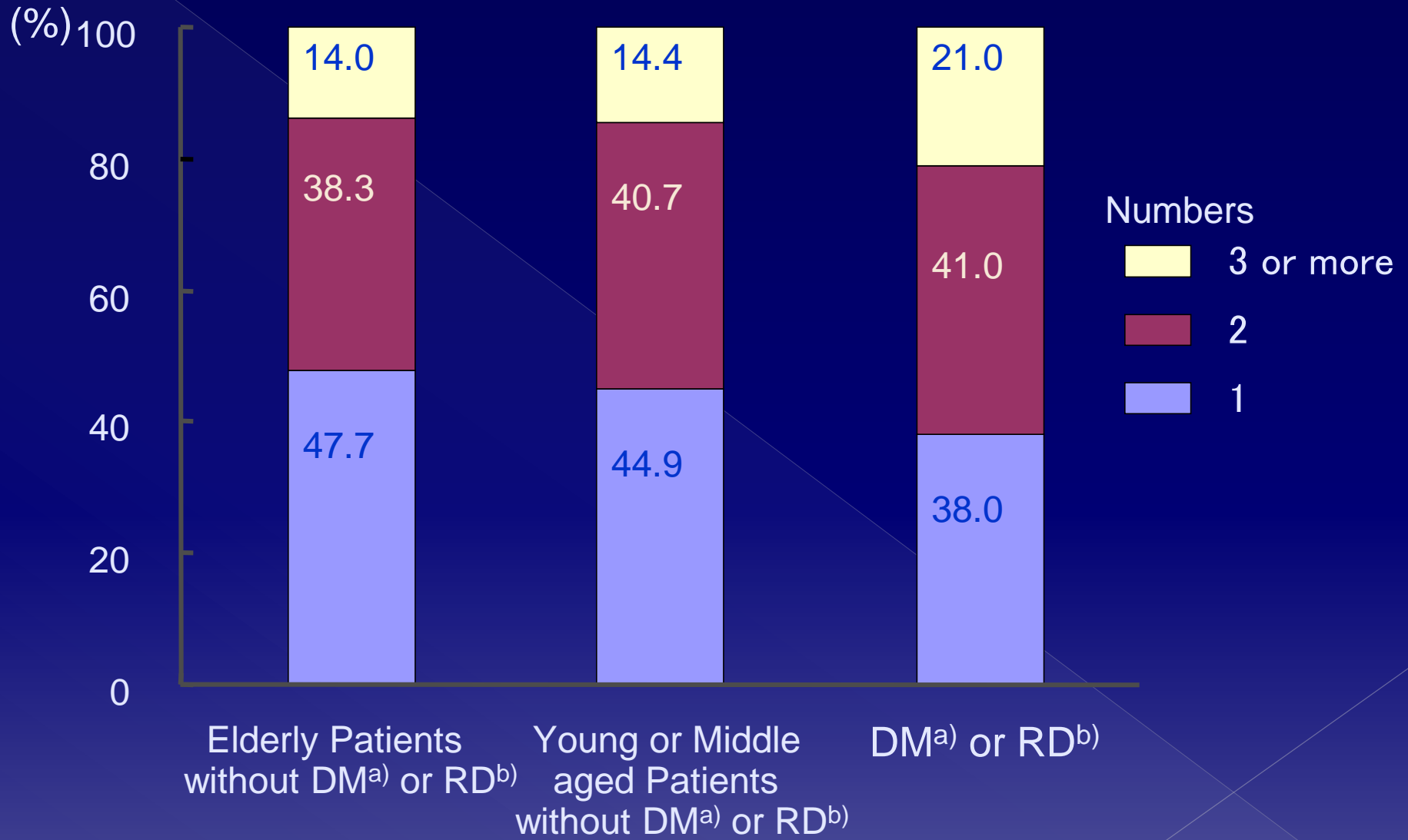
Table 1-1. Characteristics of hypertensive patients at baseline

Variables	<i>Median (min, max) or N (%)</i>
Age (years)	71 (24, 99)
Sex (Male)	1524 (46.1)
Anthropometric measurements	
Body mass index (BMI)	24.3 (13.2, 45.4)
Waist circumference (cm)	
Male	87.6 (59.0, 126.0)
Female	85.0 (53.0, 134.0)
Family histories	
Hypertension (yes)	1805 (55.2)
Stroke (yes)	902 (27.6)
Diabetes mellitus (yes)	589 (18.0)
Heart disease (yes)	499 (15.3)
Dyslipidemia (yes)	132 (4.0)
Kidney disease (yes)	123 (3.8)
Premature cardiovascular disease (yes)	47 (1.4)

Table 1-2. Characteristics of hypertensive patients at baseline

Variables	Median (min, max) or N (%)
Alcohol consumption (Everyday)	705 (21.7)
Current smoking (yes)	392 (12.1)
Hypertension related factors	
Systolic blood pressure (mmHg)	134 (82, 212)
Diastolic blood pressure (mmHg)	76 (36, 124)
Instruction of home blood pressure measurement (yes)	1969 (59.6)
Duration of hypertension treatment (years)	8.0 (0.5, 60.0)
Metabolic disorders	
Diabetes mellitus (yes)	1050 (31.7)
Dyslipidemia (yes)	1484 (44.8)
Organ damage/ cardiovascular disease	
Heart (yes)	713 (21.5)
Brain (yes)	445 (13.4)
Kidney (yes)	368 (11.1)
Blood vessel (yes)	249 (7.5)
Hypertensive retinopathy (yes)	150 (4.5)
Diabetic retinopathy (yes)	176 (5.3)

Figure 1. Numbers of antihypertensive drug used



a)DM; Diabetes mellitus, b)RD; Renal disease

Table3. Achievement rates of target blood pressure levels

	Target blood pressure level (mmHg)	Achievement rate(%)
Elderly patients without DM ^{a)} or RD ^{b)} (n=1518)	<140/90	1002 (66.0)
Young or middle aged patients without DM ^{a)} or RD ^{b)} (n=583)	<130/85	177 (30.4)
Patients with DM ^{a)} or RD ^{b)} (n=1212)	<130/80	324 (26.7)

a)DM; Diabetes mellitus, b)RD; Renal disease

Table.4-1 Association of blood pressure achievement failure in elderly patients without DM^{a)} or RD^{b)} (multivariate logistic regression analyses)

Variables	Odds Ratio	95% Confidence Interval	
Waist circumference (cm) ^{c)}	1.26	1.01-1.57	*
Number of antihypertensive drug used			
1	1.00(Reference)		
2	1.15	0.91-1.46	
≥3	1.96	1.42-2.71	*

*<0.05, **<0.01 a)Diabetes mellitus, b)Renal disease
c) 85 or higher for Men, 90 or higher for Women

Table.4-2 Association of blood pressure achievement failure in young and middle aged patients without DM^{a)} or RD^{b)} (multivariate logistic regression analyses)

Variables	Odds Ratio	95% Confidence Interval	
Body mass index (BMI) 25 or higher	1.74	1.19-2.56	*
Family history of hypertension (yes)	1.67	1.14-2.45	*
Organ damage/ cardiovascular disease			
Brain (yes)	0.33	0.16-0.68	*
Hypertensive retinopathy (yes)	0.33	0.12-0.91	*

* <0.05, ** <0.01 a) Diabetes mellitus, b) Renal disease

Table.4-3 Association of blood pressure achievement failure in patients with DM^{a)} or RD^{b)} (multivariate logistic regression analyses)

Variables	Odds Ratio	95% Confidence Interval	
Body mass index (BMI) 25 or higher	1.34	1.03-1.75	*
Family history of diabetes mellitus (yes)	1.40	1.04-1.87	*
Dyslipidemia (yes)	1.41	1.08-1.84	*
Organ damage/ cardiovascular disease			
Brain (yes)	0.62	0.44-0.87	*
Blood vessel (yes)	0.48	0.33-0.70	*

*<0.05, **<0.01 a)Diabetes mellitus, b)Renal disease

1. Let's summarize the obtained results.
2. How do you interpret the results?
3. How do you utilize the results in your actual clinical setting?

2nd Fukushima Research of Hypertension (FRESH)

Achievement status toward goal blood pressure levels and healthy lifestyles

Research Variables in Baseline Survey

Basic characteristics
Family histories
Health behaviors
(Smoking, Alcohol)
Anthropometries
(Height, Weight, Waist
circumference)

**Achievement
toward
hypertension
treatment goal**

Metabolic disorders
Diabetes Mellitus
Dyslipidemia

Organ damages and
Cardiovascular diseases

Blood pressure
Systolic blood pressure
Diastolic blood pressure
Instruction of home blood pressure
measurement
Duration of hypertension

Healthy lifestyle characteristics
Alcohol consumption (non-daily)
Smoking behavior (non-smoker)
Exercise frequency ($2 \geq$ /week)
Body mass index (18.5-24.9)
Sleep hours (6-9)
Breakfast (every morning)
Snack between meals (no)

Results

Table 1-1. Characteristics of hypertensive patients

Variables	<i>Median (min, max) or N (%)</i>
Age (years)	74 (26, 94)
Sex (Male)	519 (41.1)
Anthropometric measurements	
Body mass index (BMI)	24.1 (14.4, 45.6)
Waist circumference (cm)	
Male	88.0 (44.2, 128.0)
Female	85.5 (56.0, 136.0)
Family histories	
Hypertension (yes)	756 (59.8)
Stroke (yes)	336 (26.6)
Diabetes mellitus (yes)	206 (16.3)
Heart disease (yes)	191 (15.1)
Dyslipidemia (yes)	48 (3.8)
Kidney disease (yes)	46 (3.6)
Premature cardiovascular disease (yes)	18 (1.4)

Table 1-2. Characteristics of hypertensive patients

Variables	<i>Median (min, max) or N (%)</i>
Healthy lifestyle characteristics	
Alcohol consumption (non-daily drinker)	1031 (81.7)
Smoking behavior (non-smoker)	1140 (90.6)
Exercise frequency (2 times or more per week)	649 (51.6)
Body mass index (18.5-24.9)	702 (55.8)
Sleep hours (6-9)	1032 (82.1)
Breakfast (every morning)	1232 (97.7)
Snack between meals (no)	626 (50.6)
Total number of healthy lifestyles ^{a)}	
Male	5 (1, 7)
Female	5 (2, 7)
Total number of healthy lifestyles (0-3)	88 (7.3)
Total number of healthy lifestyles (6-7)	452 (37.3)

a) Total number of healthy lifestyles was calculated by totaling items listed in Breslow's seven health practices associated with mortality.

Table 1-3. Characteristics of hypertensive patients

Variables	<i>Median (min, max) or N (%)</i>
Hypertension-related factors	
Systolic blood pressure (mmHg)	132 (90, 190)
Diastolic blood pressure (mmHg)	74 (40, 106)
Instruction on home blood pressure measurement (yes)	758 (60.0)
Duration of hypertension treatment (years)	11 (2.5, 52)
Metabolic disorders	
Diabetes mellitus	346 (27.4)
Dyslipidemia	532 (42.2)

Table 1-4. Characteristics of hypertensive patients

Variables	<i>Median (min, max) or N (%)</i>
Organ damage/ cardiovascular disease	
Heart	209 (16.5)
Brain	164 (13.0)
Kidney	98 (7.8)
Peripheral Vascular Disease	118 (9.3)
Hypertensive retinopathy	38 (3.0)
Diabetic retinopathy	62 (4.9)
Mental status	
Well being (less than 13)	202 (16.4)
Medical regimen adherence (good)	1238 (98.1)

Table 2. Median of blood pressures and success rates toward target blood pressure levels

	Target BP (mmHg)	Median (Min, Max) of BP (mmHg)	Success rates [N (%)]
Young or middle-aged patients without diabetes mellitus or chronic kidney disease (n=167)	<130/85	132(105, 178) / 80(50, 101)	53 (31.7)
Elderly patients without diabetes mellitus or chronic kidney disease (n=494)	<140/90	134(101, 190) / 74(40, 103)	337 (68.2)
Patients with diabetes mellitus, chronic kidney disease or had myocardial infarction (n=519)	<130/80	131(90, 180) / 72(40, 106)	198 (37.4)
Patients with cerebrovascular disorders (n=84)	<140/90	130(94, 170) / 73.5(41, 100)	60 (71.4)

Table3-1. Factors associated with therapeutic failures among male participants (multivariate logistic regression analyses)

	Multivariate					
	Model 1 ^{c)}			Model 2 ^{d)}		
	OR ^{a)}	95% CI ^{b)}	<i>P</i>	OR ^{a)}	95% CI ^{b)}	<i>P</i>
Anthropometric measurements						
Body mass index (BMI) (Under 18.5/25 or over)	1.83	1.26-2.65	**	—	—	—
Duration of hypertension treatment (11 years or longer)	0.59	0.41-0.86	**	0.62	0.43-0.90	*
Healthy lifestyle characteristics						
Smoking behavior (current smoker)	1.75	1.07-2.89	*	—	—	—
Snack between meals (yes)	0.64	0.43-0.95	*	—	—	—
Total number of healthy lifestyles (0-3)	Reference			Reference		
(4-5)	—	—	—	0.59	0.32-1.09	
(6-7)	—	—	—	0.37	0.19-0.70	**

a)Odds ratio, b)95% confidence interval, c)Model 1 was adjusted for body mass index, duration of hypertension treatment, alcoholic consumption, smoking behavior, and taking snack between meals. d) Model 2 was adjusted for the duration of hypertension treatment and total number of healthy lifestyles.

* $P < 0.05$, ** $P < 0.01$

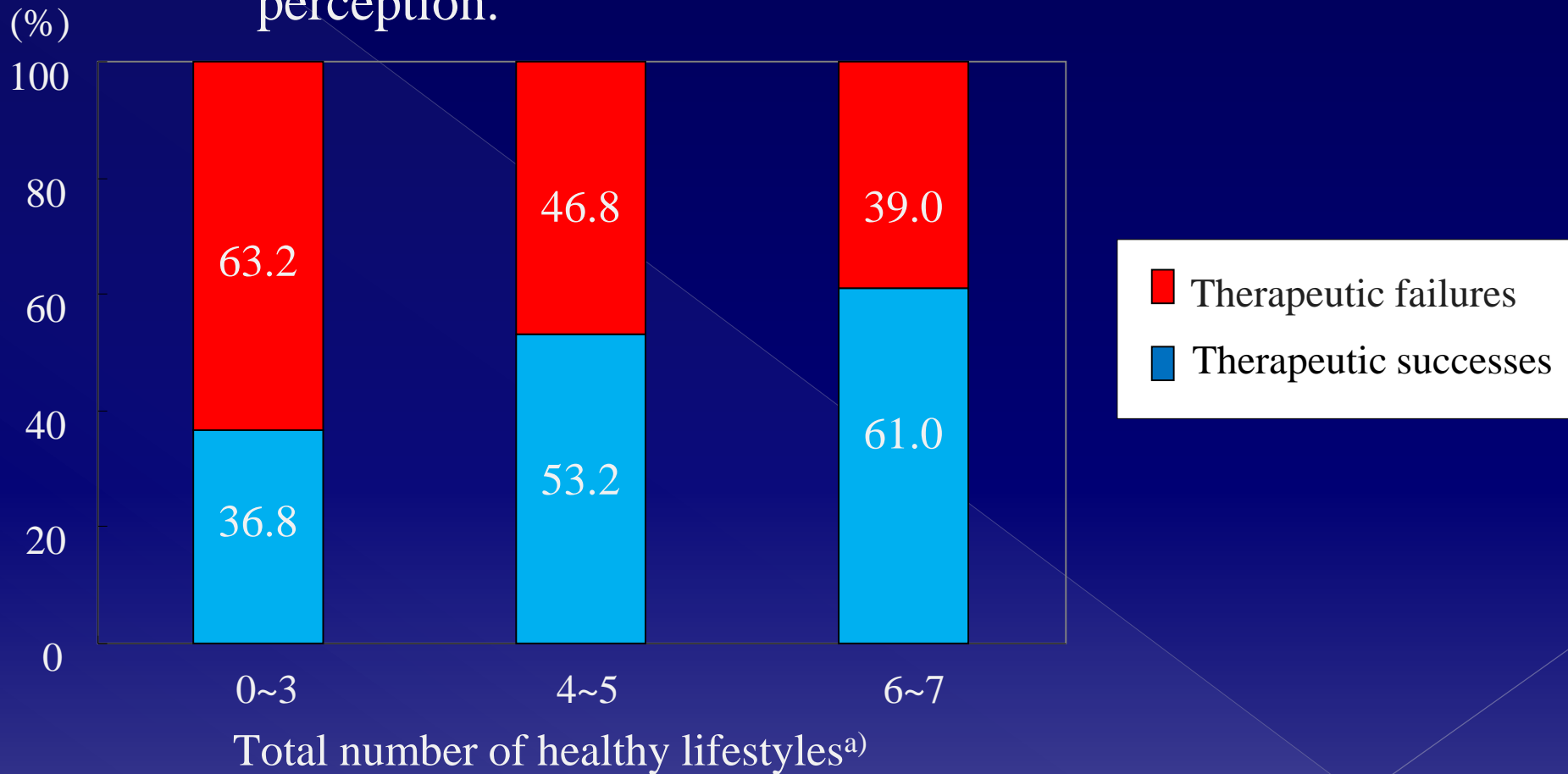
Table3-2. Factors associated with therapeutic failures among female participants(multivariate logistic regression analyses)

	Multivariate					
	Model 1 ^{c)}			Model 2 ^{d)}		
	OR ^{a)}	95% CI ^{b)}	<i>P</i>	OR ^{a)}	95% CI ^{b)}	<i>P</i>
Anthropometric measurements						
Body mass index (BMI) (Under 18.5/25 or over)	1.50	1.07-2.10	*	—	—	—
Family histories (present)						
Diabetes mellitus	1.57	1.04-2.37	*	1.62	1.08-2.44	*
Healthy lifestyle characteristics						
Total number of healthy lifestyles (0-3)	Reference			Reference		
(4-5)	—	—	—	0.42	0.19-0.93	*
(6-7)	—	—	—	0.32	0.14-0.73	**

a)Odds ratio, b)95% confidence interval, c)Model 1 was adjusted for body mass index, duration of hypertension treatment, alcoholic consumption, smoking behavior, and taking snack between meals. d) Model 2 was adjusted for the duration of hypertension treatment and total number of healthy lifestyles.

* $P < 0.05$, ** $P < 0.01$

Figure 3. An association between healthy lifestyles and therapeutic failures toward target blood pressure levels among hypertensive patients with good blood pressure control perception.



a) Healthy lifestyles include smoking behaviour (non-smoker), drinking behaviour (no daily), exercise frequency (2 times or more per week), body mass index (Under 18.5/25 or over), sleep hours (6-9), breakfast (every morning), and snack between meals (no). These items are listed in Breslow's seven health practices associated with mortality (Belloc & Breslow 1972)

1. Let's summarize the obtained results.
2. How do you interpret the results?
3. How do you utilize the results in your actual clinical setting?