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Clinical epidemiology study ~ Actual procedures ~



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Contents

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

What is a 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>

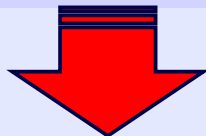
http://twp.duke.edu/uploads/media_items/research-questions.original.pdf



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:** Knowing the distribution and characteristics leads to adequate further analytic analysis.
- **Checking errors:** Data errors must be corrected before main analysis.

Analytic study

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

An example of a research question

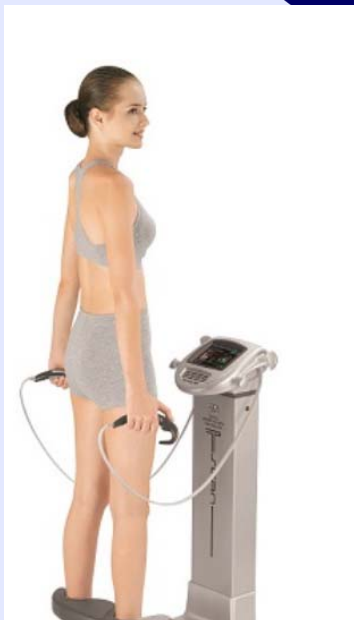


The association between waist circumference and lifestyle related disorders has been reported already.



However, there are few studies examining the association between **actual visceral fat mass** and **lifestyle-related disorders**.

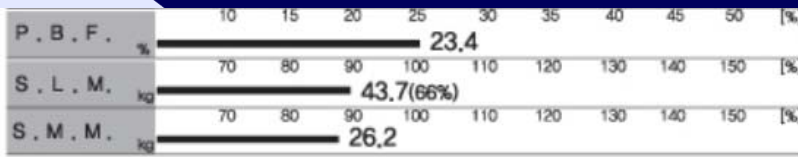
Automated bioelectrical impedance analysis (BIA)



 X-SCAN PLUS

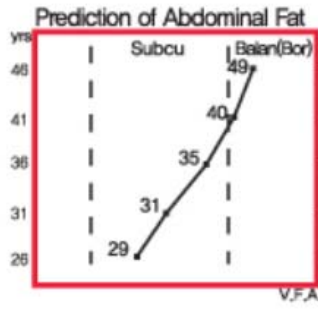
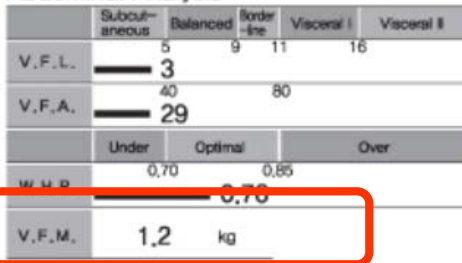
<http://www.sowamedical.com/>

Summary report



Protein : 9.7 kg (9.2 ~ 10.5)
Mineral : 3.5 kg (3.6 ~ 3.9)
B.C.M. : 30.4 kg (29.2 ~ 31.0)
B.M.R. : 1306 kcal
T.E.E. : 2011 kcal
A.M.B. : 26 yrs
Total score 80/100
Phase Angle(PA.): 5.3°

4 Abdominal Analysis



10 Study

Impedance (320Ω)

Freq	1K	5K	50K	250K	550K
RA,Imp.	338	338	314	262	260
LA,Imp.	332	323	308	263	243
Trunk	22	67	42	67	72
RL,Imp.	252	243	229	183	164
LL,Imp.	256	256	235	182	181

5 Target to Control

	Measured data	Under		Optimal		Over	Control
		1st	2nd	1st	2nd	1st	
M. B. F.	14.4		13.2		19.7		-2.0
S. L. M. kg	43.7		45.5		54.9		-1.8
Weight kg	61.6		59.2		72.3		-4.2

11 Systolic Lt 125 mmHg / Rt 111 mmHg
 Diastolic Lt 65 mmHg / Rt 69 mmHg
 Pulse 76 bpm
 The difference of your inter-arm pressure
 Svstolic 14mmHg. Diastolic 04mmHg

<http://jawon.com/japanese/bca/x-scanplus950kr.html>

Let's make a research question and discuss how to analyze the data.



A research question

To clarify the association between visceral fat mass and lifestyle-related disorders, and estimate an appropriate cutoff value for visceral fat mass that associates with an increased risk of developing lifestyle-related disorders.

What is the first step to analyze the clinical data?



- **Establish the inclusion and exclusion criteria**
- **Checking distribution and characteristics of the participants**
- **Checking errors**

Inclusion and exclusion criteria

Inclusion criteria; Completed voluntary medical check-ups, and had their amounts of visceral fat measured using a BIA automated body composition analyzer.

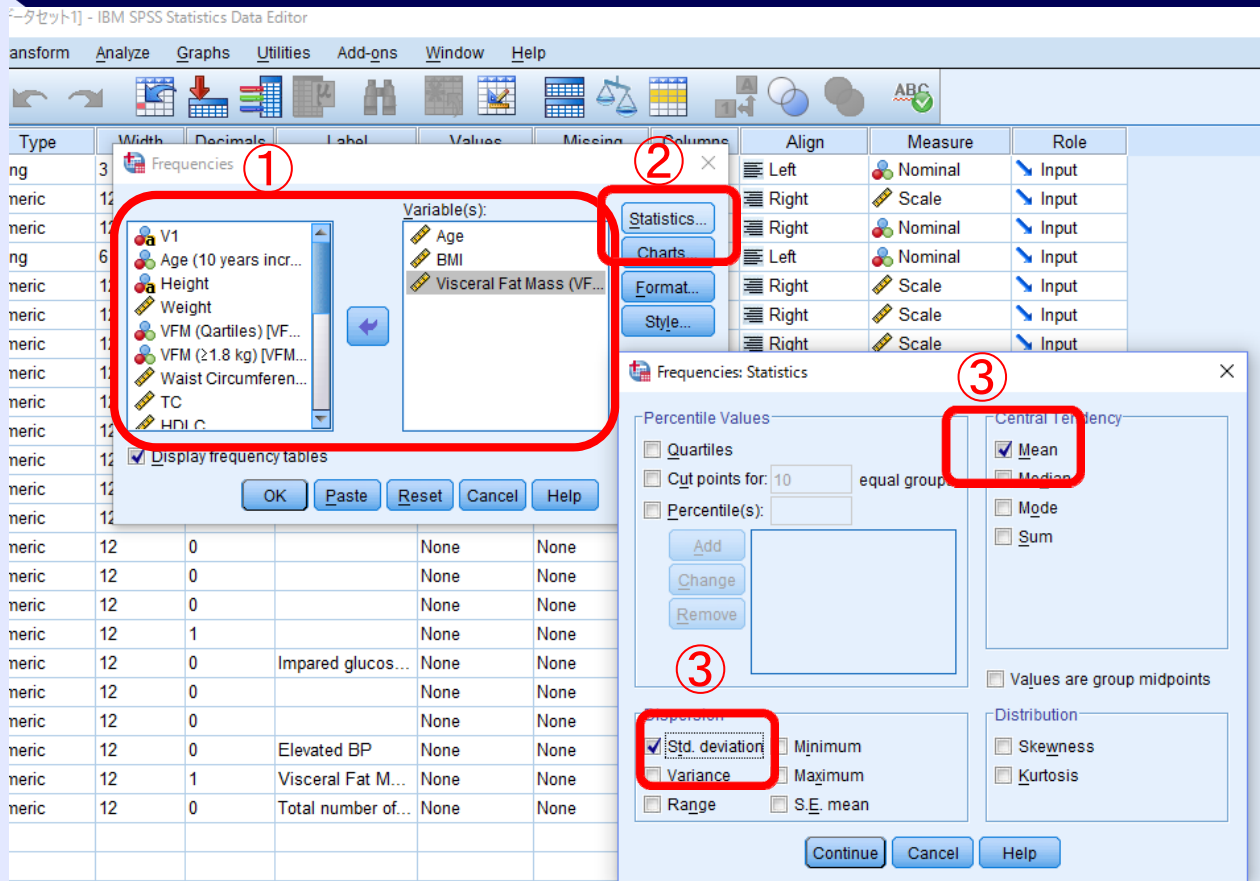
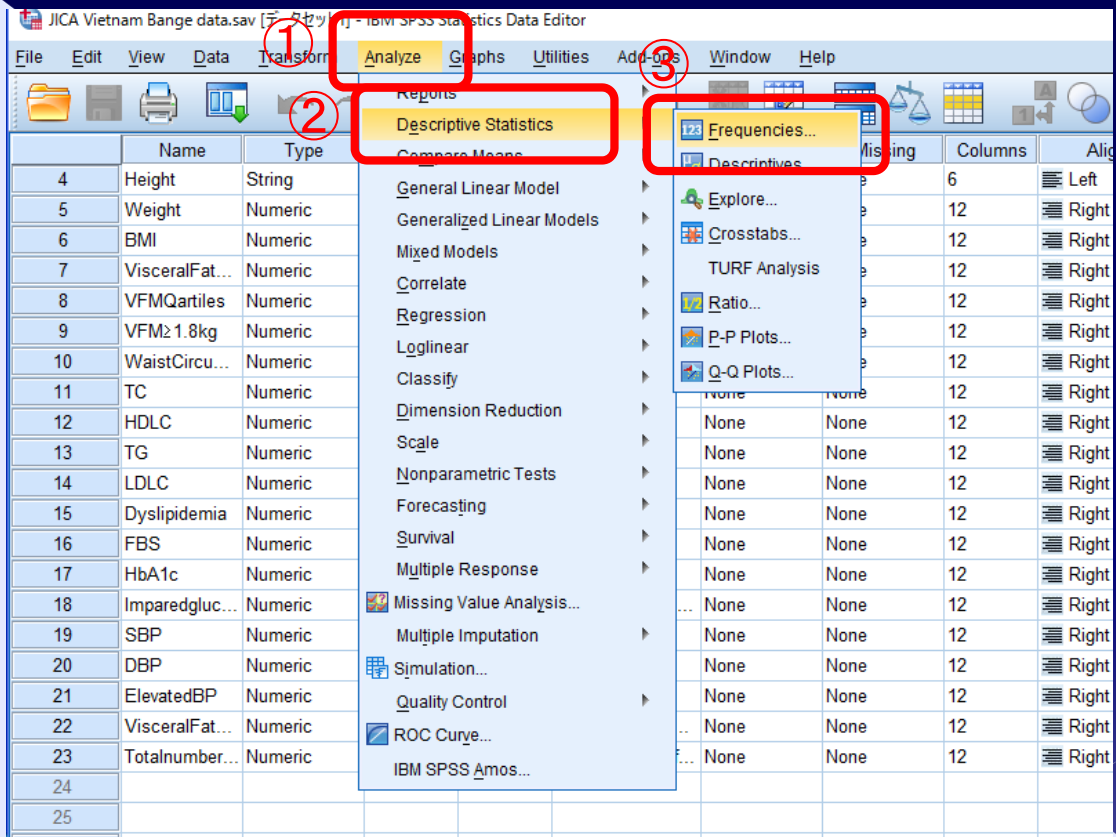
Exclusion criteria; Use of medications for hypertension, dyslipidemia, or diabetes mellitus, and/or past history of cardiovascular disease or cerebrovascular disease.

How to present distribution and characteristics?

- The first Table (Table 1) usually shows distribution and characteristics.
- As representative values, **mean (standard deviation)** for parametric data, **median (minimum, maximum)** for non-parametric data, **percentage** for categorical data are usually used.

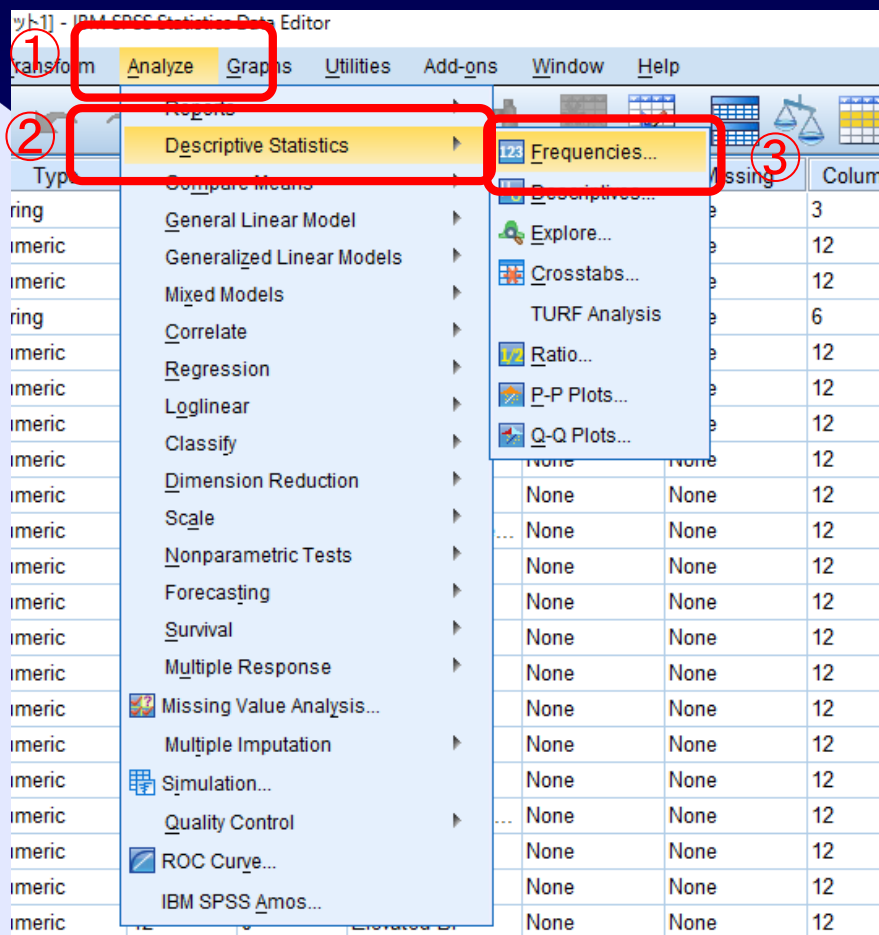
Let's calculate **mean (standard deviation)** for the items below.

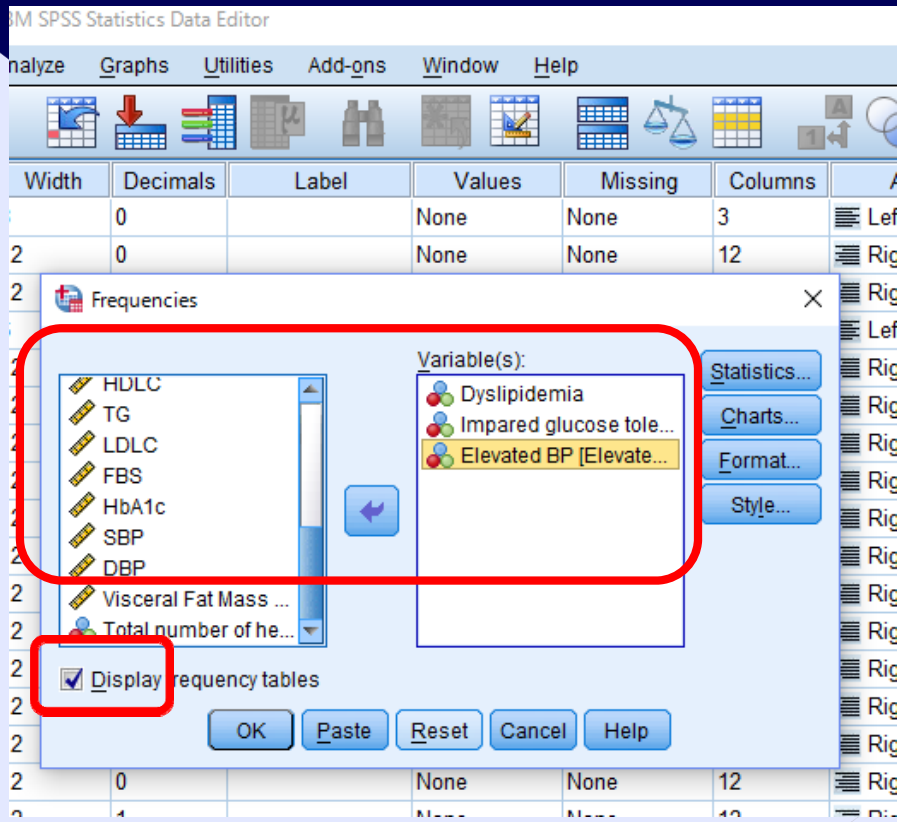
Age, BMI, Waist circumference (WC), Visceral fat mass (VFM), Lipid profiles (LDL-C, HDL-C, TG), Blood pressures, HbA1c.



Let's calculate **percentage** for the items below.

High blood pressure
Dyslipidemia
Impaired glucose tolerance





Let's make a table for basic characteristics.

Table . Basic characteristics (N=422)

	Number (%) or Mean (Standard deviation)
Age (years)	56.0 (8.8)
Anthropometric measurements	
Body mass index (BMI) (kg/m ²)	
Waist circumference (WC) (cm)	
Visceral fat mass (kg)	
Blood pressure-related factors	
Systolic blood pressure (mmHg)	
Diastolic blood pressure (mmHg)	
High blood pressure	
Lipid-related items	
High-density lipoprotein cholesterol (HDL-C) (mg/dL)	
Low-density lipoprotein cholesterol (LDL-C) (mg/dL)	
Triglycerides (TG) (mg/dL)	
Dyslipidemia	
Glucose-related items	
Hemoglobin A1c (HbA1c) (%)	
Impaired glucose tolerance	

Let's discuss following questions.

1. Which lifestyle related disorders is the most frequent?
2. What kind of intervention will be effective?

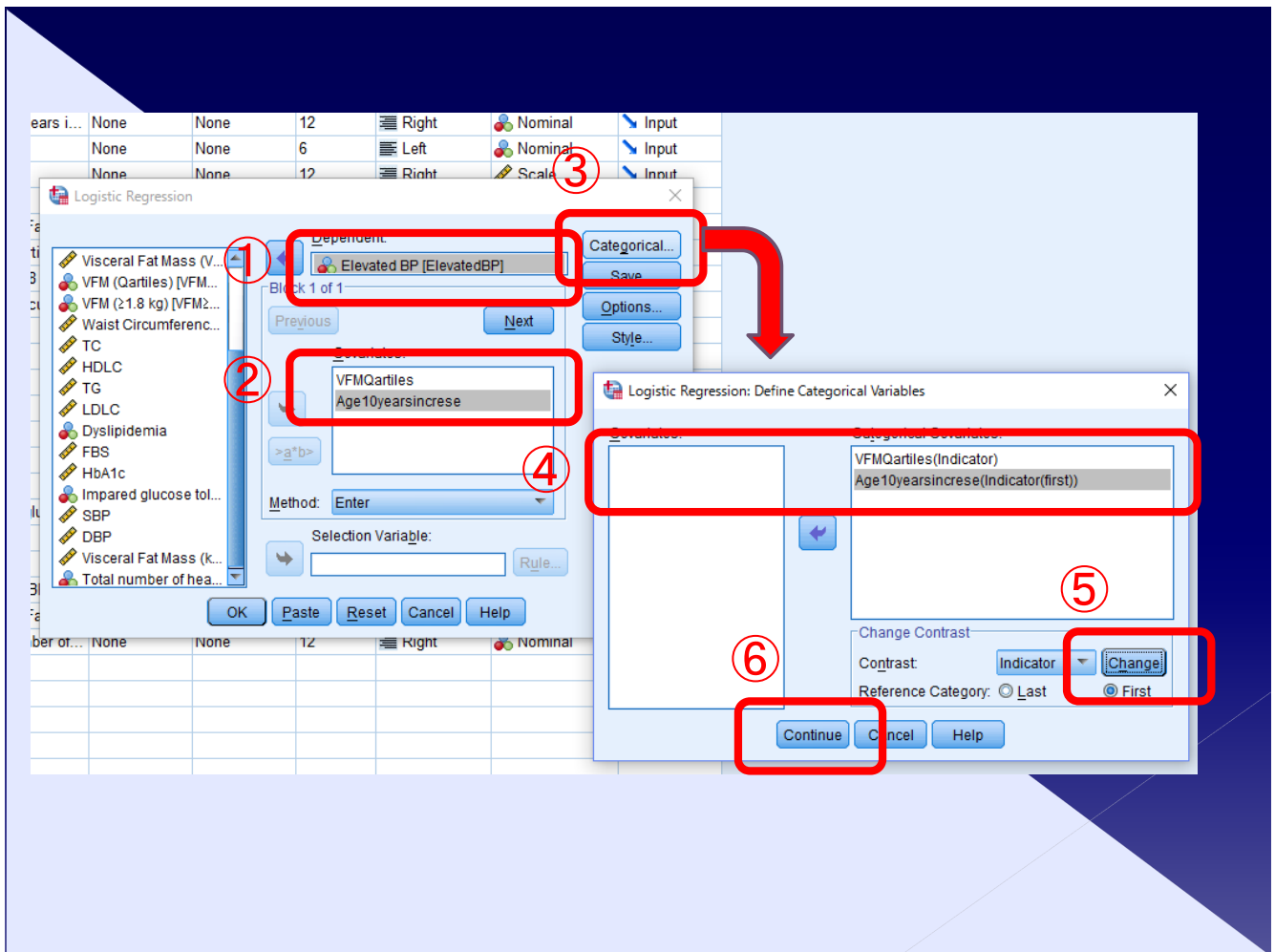
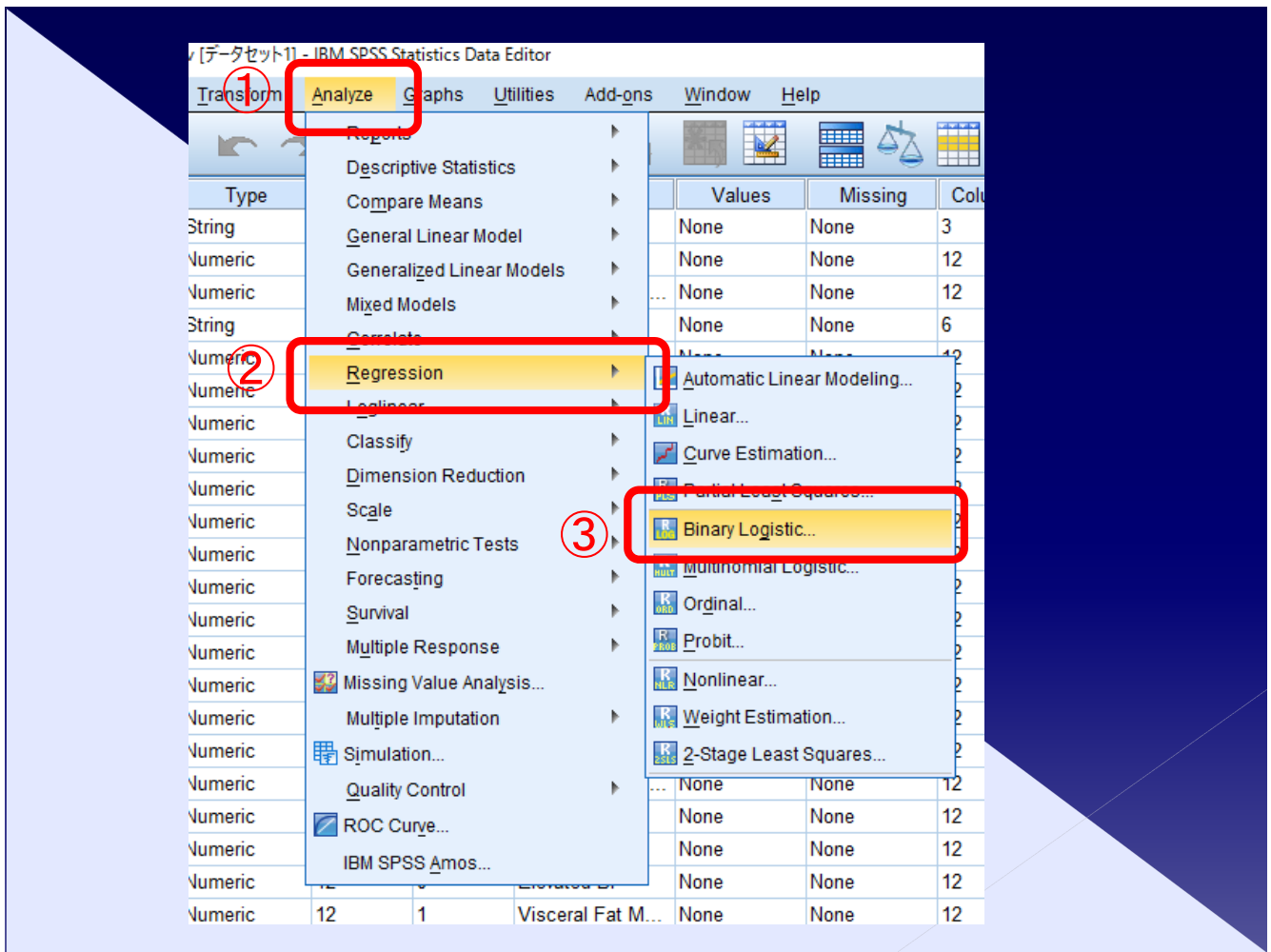
How to present analytic study data?

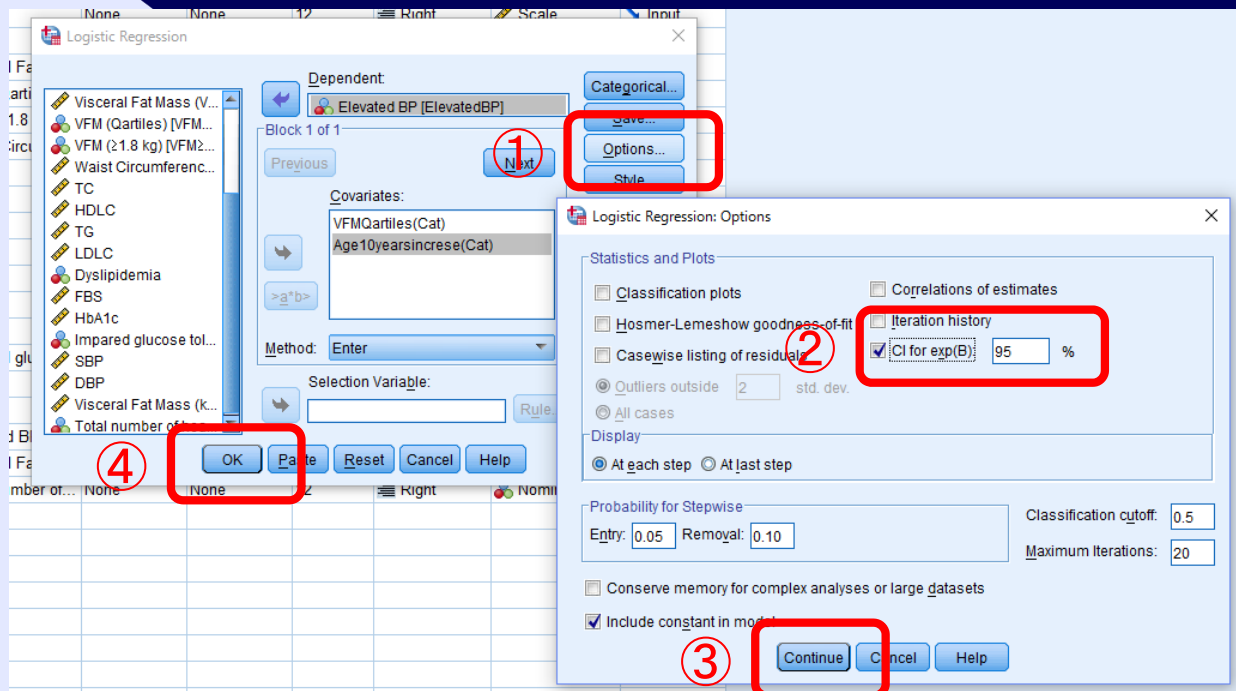


www.brandwithin.com

Let's conduct Logistic regression analysis

- Bivariate regression analysis; adjusting for age (10-year increase)





Variables in the Equation

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for EXP(B)	
							Lower	Upper
Step 1 ^a								
Age10yearsincrease			3.992	3	.262			
Age10yearsincrease(1)	.160	.576	.078	1	.781	1.174	.380	3.631
Age10yearsincrease(2)	.310	.522	.352	1	.553	1.363	.490	3.789
Age10yearsincrease(3)	.648	.529	1.501	1	.221	1.911	.678	5.386
VFMQartiles			11.363	3	.010			
VFMQartiles(1)	.066	.311	.045	1	.833	1.068	.581	1.964
VFMQartiles(2)	.612	.301	4.139	1	.042	1.844	1.023	3.326
VFMQartiles(3)	.804	.307	6.862	1	.009	2.233	1.224	4.075
Constant	-1.260	.543	5.398	1	.020	.284		

a. Variable(s) entered on step 1: Age10yearsincrease, VFMQartiles.

↑
Odds ratio

Table . Odds Ratios for Lifestyle-Related Disorders According to Visceral Fat Mass (Logistic Regression Analysis)

Visceral Fat Mass (kg)	Bivariate ^{a)}			Multivariate						
	OR ^{b)}	95% CI ^{c)}	P	Model 1 ^{d)}			Model 2 ^{e)}			
				OR ^{b)}	95% CI ^{c)}	P	OR ^{b)}	95% CI ^{c)}	P	
Elevated blood pressure										
Q1≤1.2	Reference			Reference			Reference			
1.2<Q2≤1.8	1.07	0.58-1.96	0.83							
1.8<Q3≤2.5	1.84	1.02-3.33	0.04							
2.5<Q4	2.23	1.22-4.08	<0.01							
Dyslipidemia										
Q1≤1.2	Reference			Reference			Reference			
1.2<Q2≤1.8										
1.8<Q3≤2.5										
2.5<Q4										
Glucose tolerance impairment										
Q1≤1.2	Reference			Reference			Reference			
1.2<Q2≤1.8										
1.8<Q3≤2.5										
2.5<Q4										

Let's conduct multiple Logistic regression analysis.

1. Which are the adjusting factors?

Let's interpret the results.

Which is the most appropriate cutoff of VFM for lifestyle related disorders?

(1.2, 1.8, or 2.5 kg)

Let's make a **Receiver operating characteristics curve (ROC curve)** and estimate the appropriate **cut off values** of BMI and WC for visceral fat mass (≥ 1.8 kg)

Analyze Graphs Utilities Add-ons Window Help

Reports
Descriptive Statistics
Compare Means
General Linear Model
Generalized Linear Models
Mixed Models
Correlate
Regression
Loglinear
Classify
Dimension Reduction
Scale
Nonparametric Tests
Forecasting
Survival
Multiple Response
Missing Value Analysis...
Multiple Imputation
Simulation...
Quality Control
ROC Curve... ②

ROC Curve

Test Variable: BMI ③

State Variable: VFM (≥1.8 kg) [VFM>1.8kg] ④
Value of State Variable: 1 ⑤

Display
 ROC Curve ⑥
 With diagonal reference line
 Standard error and confidence interval
 Coordinate points of the ROC Curve

OK Cancel Help

Values	Missing	Columns	Align	Measure
None	None	3	Left	Nominal

None	None	12	Right	Scale
None	None	12	Right	Scale
None	None	12	Right	Nominal



Association between lifestyle-related disorders and visceral fat mass in Japanese males: a hospital based cross-sectional study

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Junichi Yatabe · Scott M. Williams ·
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