Analytical Plan for Effect of surgical and pharmacological interventions in BMI reduction: retrospective cohort

DOCUMENT: SAP-2023-003-JG-v01

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2023-01-05

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Analytical Plan for Effect of surgical and pharmacological interventions in BMI reduction: retrospective cohort

Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- ALP:
- ALT:
- AST:
- BMI: body mass index
- BUN
- CI: confidence interval
- Cr.:
- HbA1c:
- HDL:
- LDL:
- SD: standard deviation
- VLDL:

2 CONTEXT

2.1 Objectives

1. To compare the change in BMI after two types of weight-loss interventions.
2. To compare the results of various laboratory blood tests after two types of weight-loss interventions.

2.2 Hypotheses

1. The average change in BMI after pharmacological intervention is different from that in bariatric surgery;
2. The average change in laboratory blood tests is different between interventions.

3 DATA

3.1 Raw data

The original data base had 94 variables collected on 226 observations. All outcomes were measured independently at two times: at baseline and at follow-up.

3.2 Analytical dataset

For each individual participant the BMI measurement at follow-up was subtracted from the baseline measurement This represents BMI change as negative numbers for BMI decrease and positive numbers for BMI increase. The same procedure was performed for all secondary outcomes.

After the cleaning process 36 variables were included in the analysis. The total number of observations excluded due to incompleteness and exclusion criteria will be reported in the analysis. Table 1 is a simplified structure of the analytical dataset showing the study outcomes while omitting demographic variables and comorbidities.

Table 1 *Analytical dataset structure after variable selection and cleaning.*

id	exposure	bmi	cholesterol	triglycerides	ldl	hdl	vldl	hba1c	sodium	bun	cr	alp	ast	alt	total_billirubin	albumin	total_protein
1																	
2																	
3																	
…																	
N																	

All variables in the analytical set were labeled according to the raw data provided and values were labeled according to the data dictionary for the preparation of production-quality results tables and figures.

4 STUDY PARAMETERS

4.1 Study design

Retrospective cohort, based on hospital records.

4.2 Inclusion and exclusion criteria

N/A

4.3 Exposures

Study participants were exposed to different weight-loss interventions: some were prescribed pharmacological treatment and some undergone bariatric surgery. A few participants received a combination of both treatments, but those will not be included in the analysis (see Observations).

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Obesity
2. (Specific measurement) BMI
3. (Specific metric) Change from baseline
4. (Method of aggregation) Mean

Primary outcome

Average change in BMI.

Secondary outcomes

Average change in laboratory diagnostic tests will be calculated for the following outcomes.

- Cholesterol
- Triglycerides
- LDL
- HDL
- VLDL
- HbA1c
- Sodium
- BUN
- Cr.
- ALP
- AST
- ALT
- Total billirubin
- Albumin
- Total protein

4.5 Covariates

This analysis will not evaluate covariates and will not control for bias or confounding.

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The epidemiological profile of the study participants will be described. Demographic (sex, age and BMI) and clinical variables will be described as mean (SD) or as counts and proportions (%), as appropriate. The distributions of participants' characteristics will be summarized in tables and visualized in exploratory plots.

5.1.2 Inferential analyses

All comparisons between groups will be performed as univariate analyses. Continuous variables will be compared between groups with the independent t test with the Welch correction.

5.1.3 Statistical modeling

N/A

5.1.4 Missing data

No missing data imputation will be performed. All evaluations will be performed as complete case analyses. Missing data counts and proportions will be reported in tables.

5.2 Significance and Confidence Intervals

All analyses will be performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed will be two-tailed.

5.3 Study size and Power

N/A

5.4 Statistical packages

This analysis will be performed using statistical software R version 4.2.1.

6 OBSERVATIONS AND LIMITATIONS

Not controlled for covariates

This analysis uses a univariate approach and as such its comparison between interventions lack the capacity to control for confounding due to age, sex, and

comorbidities. Future studies might employ a multivariate approach for a more in-depth exploration of the relationship between the variables under investigation.

Recommended reporting guideline

The adoption of the EQUATOR network (http://www.equator-network.org/) reporting guidelines have seen increasing adoption by scientific journals. All observational studies are recommended to be reported following the STROBE guideline (von Elm et al, 2014).

In particular when a retrospective study is conducted using hospital records, it is recommended that the RECORD extension of the STROBE guideline is considered (Benchimol et al, 2015).

7 REFERENCES

- **SAR-2023-003-JG-v01** – Effect of surgical and pharmacological interventions in BMI reduction: retrospective cohort
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- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Int J Surg. 2014 Dec;12(12):1495-9 (https://doi.org/10.1016/j.ijsu.2014.07.013).
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8 APPENDIX

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

8.1 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2023-003-JG/