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

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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 Data reception and cleaning

See section below.

3 METHODS

The data procedures, design and analysis methods used in this report are fully described in the annex document **SAP-2023-003-JG-v01**.

This analysis was performed using statistical software R version 4.2.1.

4 RESULTS

4.1 Study population and follow up

There were 226 participants included in the analysis. The epidemiological profile of the study participant can be described as having average (SD) 50 (12) years old, with 76% females (Table 1). Most (45%) participants were caucasian.

Most prevalent comorbidities include hypertension (64%), GERD (47%) and Dyslipidemia (43%). Other comorbidities can be seen in Table 1.

Table 1 Study participants demographic characteristics and occurrence of comorbidities.

Characteristic	Overall, N = 226 ¹	Pharmacological, N = 174	Surgery, N = 37	Both, N = 15
Demographic				
Age, Mean (SD)	50 (12)	50 (12)	48 (12)	58 (12)
Unknown	107	98	0	9
Gender, n (%)				
Female	91 (76%)	57 (75%)	31 (84%)	3 (50%)
Male	28 (24%)	19 (25%)	6 (16%)	3 (50%)
Unknown	107	98	0	9
Race, n (%)				
Black	25 (24%)	16 (25%)	8 (23%)	1 (17%)
Caucasian	46 (43%)	30 (46%)	13 (37%)	3 (50%)
Hispanic	35 (33%)	19 (29%)	14 (40%)	2 (33%)
Unknown	120	109	2	9
Comorbidities				
Hypertension, n (%)	63 (64%)	32 (54%)	27 (77%)	4 (100%)
Unknown	128	115	2	11
Diabetes, n (%)	31 (31%)	22 (36%)	8 (24%)	1 (25%)
Unknown	127	113	3	11
Dyslipidemia, n (%)	42 (43%)	26 (44%)	13 (37%)	3 (75%)
Unknown	128	115	2	11
GERD, n (%)	45 (47%)	13 (23%)	29 (83%)	3 (75%)

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Unknown	130	117	2	11
Obstructive sleep apnea, n (%)	24 (24%)	9 (15%)	13 (37%)	2 (50%)
Unknown	128	115	2	11
Coronary artery disease, n (%)				
No	89 (92%)	57 (98%)	30 (86%)	2 (50%)
Possible esrd	1 (1.0%)	0 (0%)	1 (2.9%)	0 (0%)
Yes	7 (7.2%)	1 (1.7%)	4 (11%)	2 (50%)
Unknown	129	116	2	11
Tobacco, n (%)	6 (6.1%)	5 (8.5%)	0 (0%)	1 (25%)
Unknown	128	115	2	11
Chronic lung disease, n (%)	11 (22%)	11 (22%)	0 (NA%)	0 (NA%)
Unknown	177	125	37	15
Steroid use, n (%)	17 (35%)	17 (35%)	0 (NA%)	0 (NA%)
Unknown	177	125	37	15
Cancer, n (%)	1 (2.0%)	1 (2.0%)	0 (NA%)	0 (NA%)
Unknown	177	125	37	15
Alcohol, n (%)	46 (47%)	33 (56%)	10 (29%)	3 (75%)
Unknown	128	115	2	11
Anxiety, n (%)	25 (26%)	15 (25%)	9 (26%)	1 (25%)
Unknown	128	115	2	11
Depression, n (%)	18 (19%)	11 (19%)	6 (18%)	1 (25%)
Unknown	129	115	3	11
*Mean (SD); n (%)				

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Figure 1 shows the distribution densities for all outcomes in the study, when considering only the comparator groups. BMI appears to differ between both interventions after follow-up, as their modes are not on a similar location in their respective horizontal axes. The surgery group appears to experience a slightly higher decrease in BMI when compared to the pharmacological group, on average.

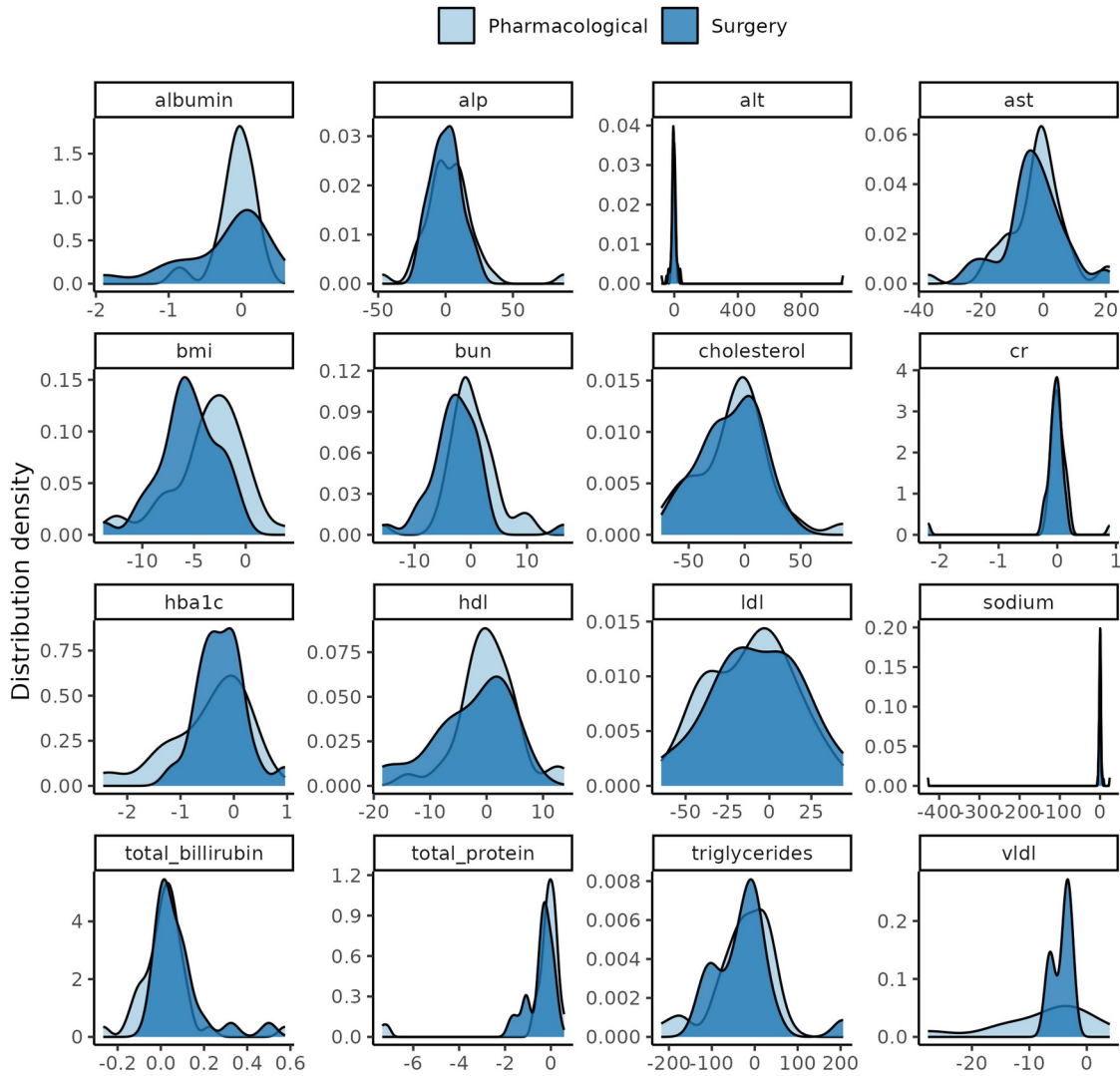


Figure 1 Distribution densities of all outcomes in the study population.

Most laboratory blood tests have similar averages, except for BUN where the group that received bariatric surgery appears to have a slightly lower average change when compared to the pharmacological intervention group.

4.2 Average change in outcomes at follow-up

When considering only the groups that received only a single intervention, the comparative effect between interventions on BMI can be seen in Table 2.

On average participants receiving the surgical intervention experienced 1.9 kg/m² smaller BMI than those that received the pharmacological treatment (95% CI: 0.58 to 3.3 kg/m², p=0.006). This means that the effect of surgical intervention is significantly smaller than the comparator, all other factors constant.

Table 2 Change in outcomes measured between baseline and follow-up.

Characteristic	Pharmacological, N = 174	Surgery, N = 37	Difference ¹	95% CI ^{1,2}	p-value ¹
BMI, Mean (SD)	-3.6 (3.5)	-5.5 (2.9)	1.9	0.58 to 3.3	0.006
Unknown	120	3			
Cholesterol, Mean (SD)	-9 (33)	-12 (27)	3.1	-14 to 20	0.711
Unknown	142	17			
Triglycerides, Mean (SD)	-28 (66)	-23 (73)	-5.1	-46 to 36	0.802
Unknown	142	17			
LDL, Mean (SD)	-12 (25)	-8 (27)	-3.9	-19 to 12	0.614
Unknown	142	18			
HDL, Mean (SD)	0.4 (5.3)	-2.6 (6.8)	3.0	-0.66 to 6.6	0.106
Unknown	142	17			
VLDL, Mean (SD)	-8 (9)	-4 (2)	-3.2	-9.9 to 3.5	0.316
Unknown	164	34			
HbA1c, Mean (SD)	-0.47 (0.75)	-0.23 (0.45)	-0.24	-0.56 to 0.08	0.132
Unknown	140	15			
Sodium, Mean (SD)	-9.61 (68.00)	0.04 (1.90)	-9.6	-31 to 12	0.375
Unknown	134	3			
BUN, Mean (SD)	0.1 (4.5)	-2.5 (5.0)	2.6	0.34 to 4.8	0.025
Unknown	134	3			
Cr., Mean (SD)	0.03 (0.17)	-0.09 (0.39)	0.12	-0.02 to 0.26	0.098
Unknown	134	3			
ALP, Mean (SD)	3 (20)	0 (11)	3.0	-5.0 to 11	0.460
Unknown	133	15			
AST, Mean (SD)	-2 (10)	-3 (9)	0.53	-4.5 to 5.6	0.834
Unknown	133	14			
ALT, Mean (SD)	23 (168)	-4 (12)	27	-26 to 80	0.316
Unknown	133	14			
Total bilirubin, Mean (SD)	0.02 (0.13)	0.08 (0.12)	-0.06	-0.12 to 0.01	0.089
Unknown	134	14			

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Albumin, Mean (SD)	-0.07 (0.26)	-0.24 (0.65)	0.18	-0.19 to 0.54	0.326
Unknown	140	22			
Total protein, Mean (SD)	-0.42 (1.59)	-0.43 (0.55)	0.01	-0.54 to 0.56	0.966
Unknown	133	15			
¹ Welch Two Sample t-test ² CI = Confidence Interval					

In this sample most laboratory blood tests do not appear different between interventions after follow-up (Table 2). The average BUN effect of receiving just the surgical intervention instead of just a pharmacological treatment was 2.6 smaller (95% CI: 0.34 to 4.8, $p=0.025$). This means that the effect of surgical intervention is significantly smaller than the comparator, all other factors constant.

All other blood tests produced similar results between interventions (Table 2, Figure 1).

5 OBSERVATIONS AND LIMITATIONS

Comparison between single-treatment and double-treatment groups

This is a simple methodology and the methods used in this analysis are not sufficiently sophisticated to disentangle the relationship between treatments when both single and double treatments were administered to participants. In order to assess the comparative effect of one procedure and the other in the presence of a complex study design, a suitable methodology should be chosen as stated below.

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).

6 CONCLUSIONS

Although the average BMI reduced in both treatment groups after follow-up, it was decreased significantly faster in the surgical group.

Most blood tests produced comparable results after followup. Only the BUN test showed a significant decrease when using surgical treatment instead of pharmacological treatment.

7 REFERENCES

- **SAP-2023-003-JG-v01** – Analytical Plan for Effect of surgical and pharmacological interventions in BMI reduction: retrospective cohort
- 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>).
- Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM; RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. *PLoS Med.* 2015 Oct 6;12(10):e1001885 (<https://doi.org/10.1371/journal.pmed.1001885>).

8 APPENDIX

8.1 Exploratory data analysis

Table A1 Alternative version of Table 2 (descriptive version, with all three intervention groups).

Characteristic	Overall, N = 226 [†]	Pharmacological, N = 174	Surgery, N = 37	Both, N = 15
BMI, Mean (SD)	-4.5 (3.5)	-3.6 (3.5)	-5.5 (2.9)	-8.0 (4.8)
Unknown	134	120	3	11
Cholesterol, Mean (SD)	-11 (31)	-9 (33)	-12 (27)	-27 (33)
Unknown	171	142	17	12
Triglycerides, Mean (SD)	-29 (67)	-28 (66)	-23 (73)	-65 (45)
Unknown	171	142	17	12
LDL, Mean (SD)	-10 (26)	-12 (25)	-8 (27)	-15 (36)
Unknown	172	142	18	12
HDL, Mean (SD)	-0.9 (6.0)	0.4 (5.3)	-2.6 (6.8)	-2.8 (6.3)
Unknown	171	142	17	12
VLDL, Mean (SD)	-6.8 (7.7)	-7.6 (9.0)	-4.4 (1.8)	-6.4 (NA)
Unknown	212	164	34	14
HbA1c, Mean (SD)	-0.37 (0.64)	-0.47 (0.75)	-0.23 (0.45)	-0.28 (0.25)
Unknown	167	140	15	12
Sodium, Mean (SD)	-5.00 (48.96)	-9.61 (68.00)	0.04 (1.90)	-0.84 (0.45)
Unknown	149	134	3	12
BUN, Mean (SD)	-1.1 (4.8)	0.1 (4.5)	-2.5 (5.0)	-2.3 (0.9)
Unknown	149	134	3	12
Cr., Mean (SD)	-0.03 (0.29)	0.03 (0.17)	-0.09 (0.39)	-0.14 (0.13)
Unknown	149	134	3	12
ALP, Mean (SD)	3 (17)	3 (20)	0 (11)	8 (3)
Unknown	160	133	15	12
AST, Mean (SD)	-3 (10)	-2 (10)	-3 (9)	-4 (4)
Unknown	159	133	14	12
ALT, Mean (SD)	12 (131)	23 (168)	-4 (12)	-5 (9)
Unknown	159	133	14	12
Total bilirubin, Mean (SD)	0.05 (0.13)	0.02 (0.13)	0.08 (0.12)	0.16 (0.16)
Unknown	160	134	14	12
Albumin, Mean (SD)	-0.13 (0.42)	-0.07 (0.26)	-0.24 (0.65)	-0.34 (0.48)
Unknown	175	140	22	13

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Total protein, Mean (SD)	-0.41 (1.29)	-0.42 (1.59)	-0.43 (0.55)	-0.12 (0.21)
Unknown	160	133	15	12
Mean (SD)				

8.2 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/>

8.3 Analytical dataset

Table A1 is a simplified structure of the analytical dataset showing the study outcomes while omitting demographic variables and comorbidities.

Table A1 Analytical dataset structure

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

Due to confidentiality the data-set used in this analysis cannot be shared online in the public version of this report.