



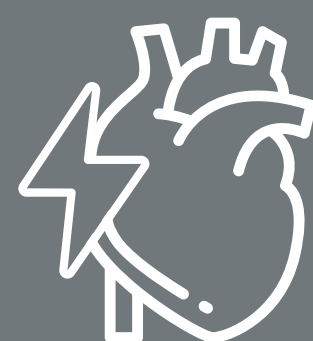
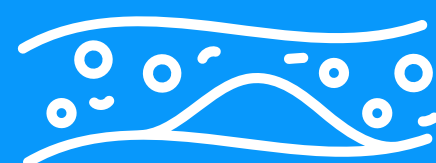
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MERIT Study

Weight Loss and Metabolic
Outcomes with Endoscopic
Sleeve Gastropasty (ESG)

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ESG is one of the procedures that is part of
Endura Weight Loss Solutions from Boston Scientific.

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Foreword

In this document, we present the results of the MERIT
(Multicentre ESG Randomised Interventional Trial).

**All data shown are derived from this study and are intended
to inform on metabolic outcomes following ESG.**

Findings should be interpreted in the context of the limited
number of patients presenting with this comorbidity; further data
are required to support definitive conclusions.



Introduction

The **MERIT (Multicentre ESG Randomised Interventional Trial)** was a prospective, multicentre, randomised clinical trial conducted at nine US centres enrolling adults aged 21 – 65 years with class 1 or class 2 obesity.

Participants were randomly assigned to Endoscopic Sleeve Gastroplasty (ESG) plus moderate-intensity lifestyle modification or to lifestyle modification alone for 52 weeks. Patients in the primary ESG group were followed for 104 weeks, and eligible control patients could cross over to ESG after the 52-week assessment.

The primary endpoint was percentage excess weight loss (EWL) at 52 weeks, and secondary endpoints included changes in metabolic comorbidities. A total of 209 participants were randomised: 85 to ESG and 124 to control.

The paper describes obesity as a risk factor for important chronic diseases, including type 2 diabetes, heart disease, fatty liver disease.

It also stated that the effect of ESG on obesity pathophysiology has been shown to go beyond mechanical restriction, affecting satiation and metabolic dysregulation pathways.

Within this framework, MERIT assessed not only weight loss, but also changes in metabolic comorbidities.

Key Results at 52 Weeks



Study Overview

At 52 weeks, mean excess weight loss was **49.2 %** with ESG versus **3.2 %** with lifestyle modification alone, and mean total body weight loss was **13.6 %** versus **0.8 %**, respectively.

At the same timepoint, **41 of 51 patients (80 %)** in the primary ESG group improved in at least one metabolic comorbidity and **6 of 51 (12 %)** worsened, compared with **28 of 62 (45 %)** improving and **31 of 62 (50 %)** worsening in the control group.

The paper’s findings are that **ESG resulted in significant weight loss with important improvements in metabolic comorbidities.**

At a Glance

Weight loss and overall metabolic impact at 52 weeks

Outcome	Primary ESG	Lifestyle modification alone
Mean % EWL	49.2 %	3.2 %
Mean % TBWL	13.6 %	0.8 %
Improved at least 1 metabolic comorbidity	41/51 (80 %)	28/62 (45 %)
Worsened at least 1 metabolic comorbidity	6/51 (12 %)	31/62 (50 %)

Impact on Key Metabolic Comorbidities



Type 2 Diabetes

Description of the comorbidity in the RCT

In this RCT **type 2 diabetes** was listed as comorbidity whenever that patient was under prescription of medication for the treatment of T2DM with any HbA1c, or no medication but an HbA1c greater than 7 at the screening visit. **Improvement** was defined as a decrease in medication, or a decrease in HbA1c of at least 0.5 %. **Worsening** was defined as an increase in medication, or an increase in HbA1c of at least 0.5 %.

Incidence in the study

The 52-week diabetes analysis included **40/187 patients (21.4 %)** overall.

Results with ESG

At 52 weeks, ESG resulted in significant improvement in diabetes-related parameters compared with lifestyle modification alone. In the randomised primary ESG group, diabetes clinically improved in **12 of 13 patients (92 %) who were available at the time of the follow up for this analysis**, and none **0 of 13 (0 %)** worsened. In the supplementary change-from-baseline analysis among participants stratified as diabetic at enrollment, primary ESG was associated with reductions in fasting glucose, fasting insulin, HOMA-IR, and HbA1c.

Results versus lifestyle modification alone

Compared with lifestyle modification alone, ESG showed a markedly more favorable outcome. In the control group, diabetes clinically improved in **4 of 27 patients (15 %)**

who were available at the time of the follow up for this analysis, while **12 of 27 (44 %)** worsened.

In the supplementary biomarker analysis for participants stratified as diabetic at enrollment, HbA1c changed by **-0.87** with primary ESG versus **+0.39** with lifestyle modification alone; fasting glucose changed by **-21.50 mg/dL** versus **+16.48 mg/dL**; fasting insulin by **-6.62 mIU/L** versus **+2.40 mIU/L**; and HOMA-IR by **-3.08** versus **+1.35**.

Among participants with baseline HbA1c greater than 7, HbA1c changed by **-1.77** with ESG versus **+0.16** with lifestyle modification alone.

52-week diabetes outcomes in MERIT

Outcome	Primary ESG	Lifestyle modification alone	p value
Clinical improvement	12/13 (92 %)	4/27 (15 %)	<0.0001
Clinical worsening	0/13 (0 %)	12/27 (44 %)	0.0041
HbA1c change in diabetics	-0.87	+0.39	0.0002
HbA1c change in subgroup with baseline HbA1c > 7	-1.77	+0.16	0.0006
Fasting glucose change in diabetics (mg/dL)	-21.50	+16.48	0.0081
Fasting insulin change in diabetics (mIU/L)	-6.62	+2.40	0.023
HOMA-IR change in diabetics	-3.08	+1.35	0.014

Source: MERIT Table 2 and Supplementary Table S9. In Supplementary Table S9, the diabetes biomarker rows were calculated in participants stratified as diabetic at enrollment. Negative values indicate a decrease from baseline.

Impact on Key Metabolic Comorbidities



Hypertension

Description of the comorbidity

Hypertension was listed as comorbidity whenever that patient was under prescription of medication for hypertension, **or** no medication but consistent high blood pressure measurements over several early visits, with high blood pressure defined as greater than 140/90. **Improvement** was defined as a decrease in medication, or a decrease in systolic blood pressure of at least 10 mm Hg. **Worsening** was defined as an increase in medication, or an increase in systolic blood pressure of at least 10 mm Hg.

Incidence in the study

The 52-week hypertension analysis included **84/187 patients (44.9 %)** overall.

Results with ESG

MERIT reports a significant clinical improvement in hypertension status with ESG. In the randomised primary ESG group, hypertension improved in **24 of 36 patients (67 %) who were available at the time of the follow up for this analysis**, while **2 of 36 (6 %)** worsened. In the supplementary change-from-baseline analysis, primary ESG was associated with a mean change of **-5.16 mm Hg** in systolic blood pressure and **-3.31 mm Hg** in diastolic blood pressure.

Results versus lifestyle modification alone

Compared with lifestyle modification alone, ESG showed better clinical hypertension outcomes. In the control group, hypertension improved in **19 of 48 patients (40 %) who were available at the time of the follow up for this analysis**, while **11 of 48 (23 %)** worsened. In the supplementary analysis, mean systolic blood pressure changed by **-0.72 mm Hg** with lifestyle modification alone versus **-5.16 mm Hg** with ESG, and mean diastolic blood pressure changed by **+0.06 mm Hg** versus **-3.31 mm Hg**.

The categorical clinical outcomes favored ESG significantly, while the continuous blood pressure changes in Supplementary Table S9 were numerically greater with ESG but did not reach statistical significance.

52-week hypertension outcomes in MERIT

Outcome	Primary ESG	Lifestyle modification alone	p value
Clinical improvement	24/36 (67 %)	19/48 (40 %)	0.014
Clinical worsening	2/36 (6 %)	11/48 (23 %)	0.029
Systolic BP change (mm Hg)	-5.16	-0.72	0.10
Diastolic BP change (mm Hg)	-3.31	+0.06	0.088

Source: MERIT Table 2 and Supplementary Table S9. Negative values indicate a decrease from baseline.

Impact on Key Metabolic Comorbidities



Hyperlipidaemia

Description of the comorbidity

Hyperlipidaemia was listed as comorbidity whenever that patient was under prescription of medication for hyperlipidaemia, **or** no medication but LDL of at least 190 at screening, **or** no medication but triglycerides of at least 200 at screening. **Improvement** was defined as a decrease in medication, or a decrease in LDL of at least 10%. **Worsening** was defined as an increase in medication, or an increase in LDL of at least 10 %.

Incidence in the study

The 52-week hyperlipidaemia analysis included **40/187 patients (21.4 %)** overall.

Results with ESG

Hyperlipidaemia outcomes were more mixed than the diabetes, hypertension, and metabolic syndrome results. In the randomised primary ESG group, **6 of 15 patients (40 %) who were available at the time of the follow up for this analysis** improved and **4 of 15 (27 %) worsened**. In the supplementary lipid analysis, primary ESG was associated with a mean **increase in HDL of 5.91 mg/dL** and a mean **decrease in triglycerides of 9.71 mg/dL**. Mean LDL changed by **-0.75 mg/dL** and total cholesterol by **+3.38 mg/dL**. MERIT also notes that hyperlipidaemia accounted for most of the worsening comorbidities observed in the ESG group, rather than diabetes or hypertension.

Results versus lifestyle modification alone

Compared with lifestyle modification alone, the categorical rates of hyperlipidaemia improvement and worsening were similar between groups, but some individual lipid parameters favored ESG. In the control group, **8 of 25 patients (32 %) who were available at the time of the follow up for this analysis** improved and **7 of 25 (28 %) worsened**. In the supplementary analysis, HDL changed by **-2.49 mg/dL** with lifestyle modification alone versus **+5.91 mg/dL** with ESG, and triglycerides changed by **+6.09 mg/dL** versus **-9.71 mg/dL**.

Differences in total cholesterol and LDL were not statistically significant in the supplementary analysis.

52-week hyperlipidaemia outcomes in MERIT

Outcome	Primary ESG	Lifestyle modification alone	p value
Clinical improvement	6/15 (40 %)	8/25 (32 %)	0.61
Clinical worsening	4/15 (27 %)	7/25 (28 %)	0.93
Total cholesterol change (mg/dL)	+3.38	-6.11	0.10
HDL change (mg/dL)	+5.91	-2.49	0.0005
LDL change (mg/dL)	-0.75	-3.71	0.522
Triglyceride change (mg/dL)	-9.71	+6.09	0.026

Source: MERIT Table 2 and Supplementary Table S9. Negative values indicate a decrease from baseline.

Impact on Key Metabolic Comorbidities



Metabolic Syndrome

Description of the comorbidity

In the supplementary appendix, **metabolic syndrome** was defined as meeting at least **3 of 5 criteria**: increased waist circumference, elevated triglycerides, low HDL, increased blood pressure, and impaired fasting blood glucose. **Improvement** was defined as a reduction in the number of criteria, or a clinically significant decrease in at least one criterion present at screening. **Worsening** was defined as an increase in the number of criteria, or a clinically significant increase in at least one criterion present at screening.

Incidence in the study

The 52-week metabolic syndrome analysis included **58/187 patients (31.0 %)** overall.

Results with ESG

Metabolic syndrome showed one of the clearest benefits with ESG in MERIT. In the randomised primary ESG group, metabolic syndrome improved in **24 of 29 patients (83 %)** who were available at the time of the follow up for this analysis, and **none** worsened.

MERIT also reports that, compared with the control group, patients in the ESG group had HDL increase, triglyceride decrease, and improvement in waist-to-hip ratio. In the supplementary analysis, waist-to-hip ratio changed by **-3.15 %** with primary ESG.

Results versus lifestyle modification alone

Compared with lifestyle modification alone, ESG showed substantially better metabolic syndrome outcomes. In the control group, metabolic syndrome improved in **10 of 29 patients (35 %)** who were available at the time of the follow up for this analysis, while **11 of 29 (38 %)** worsened.

In the supplementary analysis, waist-to-hip ratio changed by **-0.36 %** with lifestyle modification alone versus **-3.15 %** with ESG.

52-week metabolic syndrome outcomes in MERIT

Outcome	Primary ESG	Lifestyle modification alone	p value
Clinical improvement	24/29 (83 %)	10/29 (35 %)	0.0002
Clinical worsening	0/29 (0 %)	11/29 (38 %)	0.0002
Waist-to-hip ratio change (%)	-3.15	-0.36	0.024

Source: MERIT Table 2 and Supplementary Table S9. Negative values indicate a decrease from baseline.



Closing Remarks

Taken together, MERIT showed that ESG plus lifestyle modification was associated with **clinically meaningful weight loss and with improvements in obesity-related metabolic comorbidities**, particularly **type 2 diabetes, hypertension, and metabolic syndrome**, compared with lifestyle modification alone.

The paper also states that ESG induced **clinically meaningful weight loss with improvements in metabolic syndrome, type 2 diabetes, and hypertension**, and should be considered a synergistic weight loss intervention for patients with class 1 or class 2 obesity.



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