Beneficial effects of long-term testosterone therapy with testosterone undecanoate injections (TU) in hypogonadal men with cardiovascular disease (CVD) in an observational registry study

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Background:

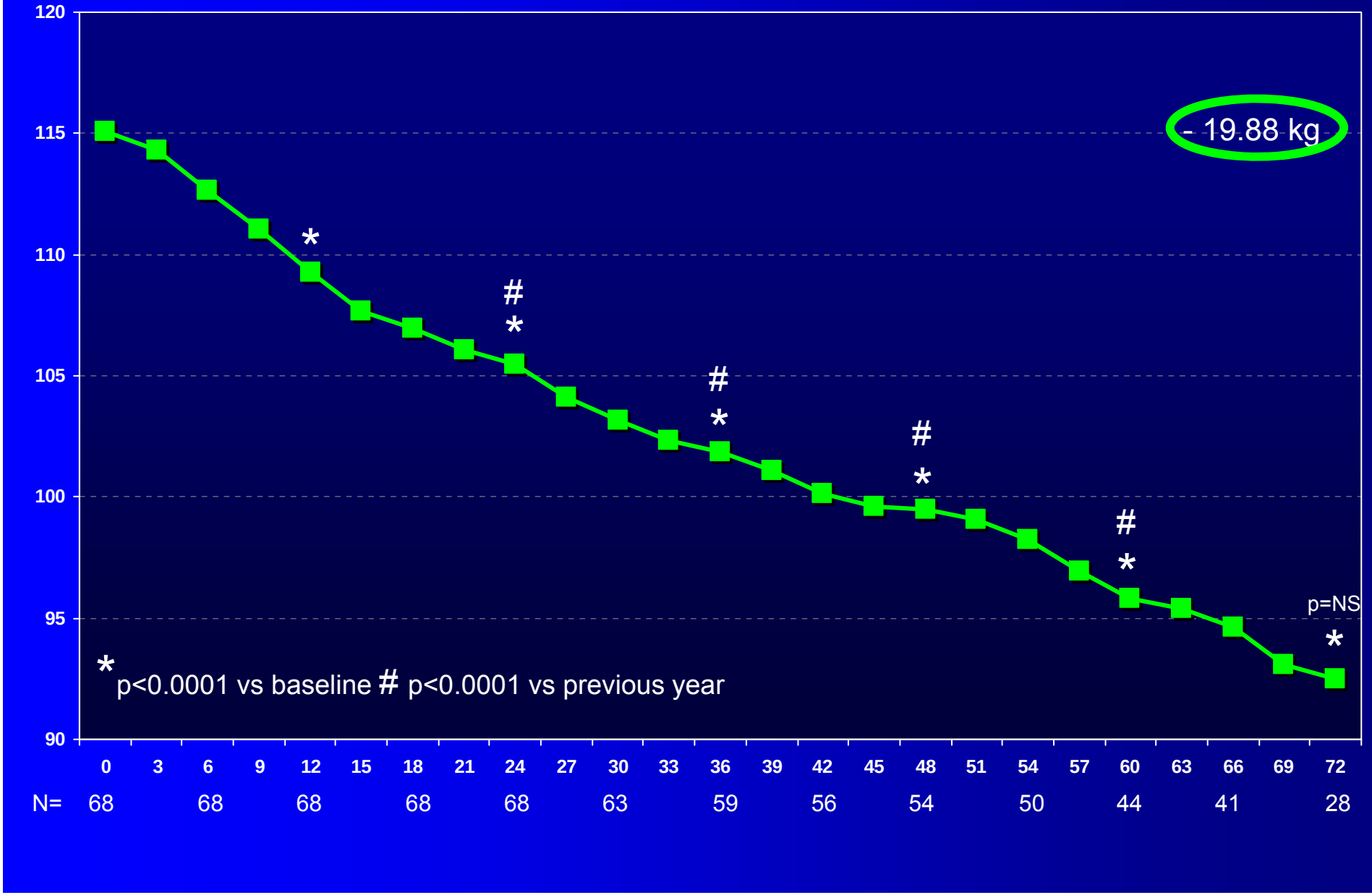
Hypogonadism is associated with cardiometabolic risk. Several studies suggest that hypogonadism increases the risk of all-cause and cardiovascular mortality. While some short-term studies have been performed in men with CVD, there are no data on long-term effects of testosterone replacement therapy (TRT) in men with CVD.

Methods:

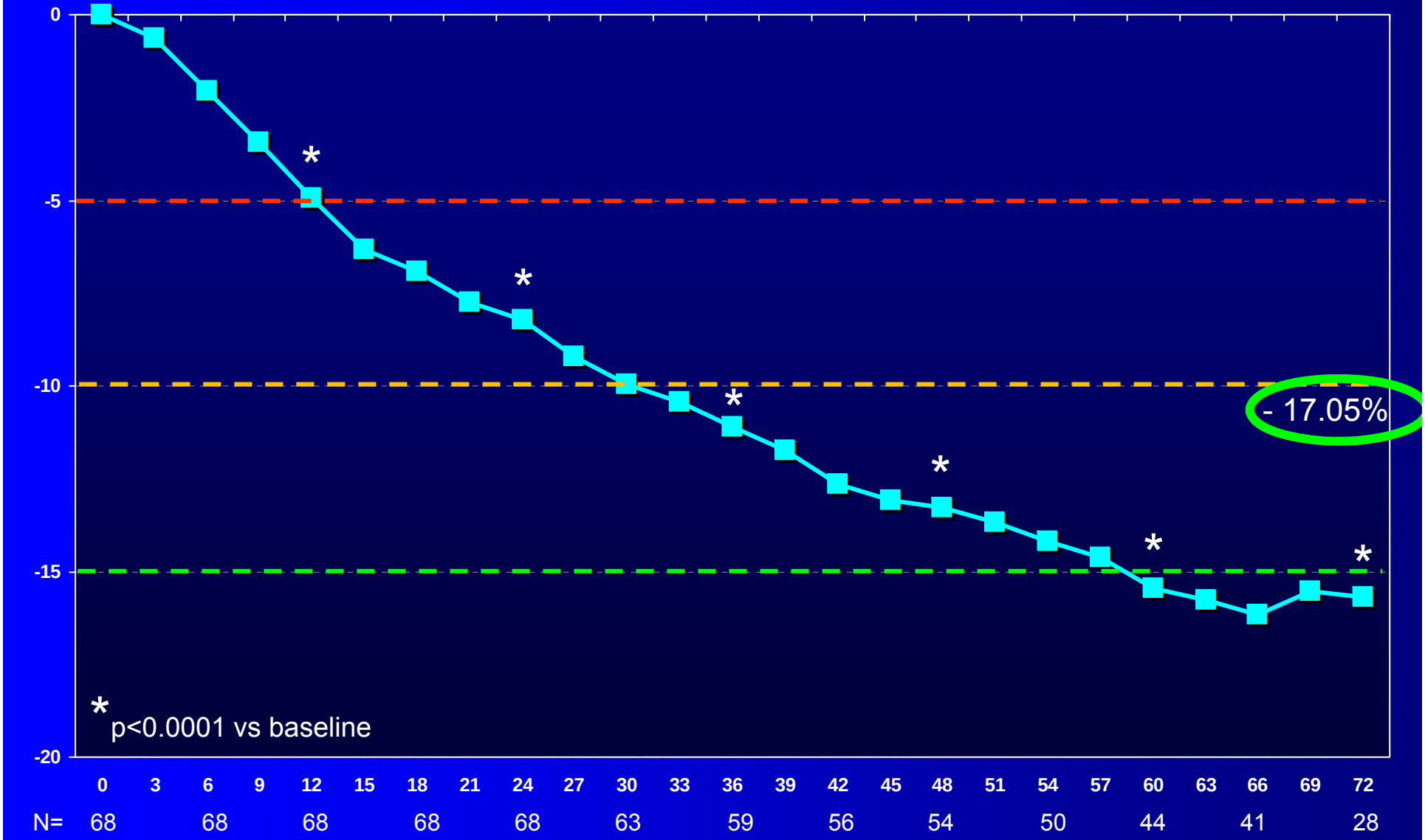
In a prospective, cumulative, observational registry study from a single urologist's office, 300 men with testosterone ≤12.1 nmol/L received TU injections for up to 6 years. In this subgroup analysis, 68 men with a previous diagnosis of coronary artery disease (CAD; n=40) and/or a history of myocardial infarction (MI; n=40) and/or Stroke (n=6) were analyzed.

Mean age was 60.76±4.94 years. 68 men were included for 2 years, 59 for 3 years, 54 for 4 years, 44 for 5 years, and 28 for 6 years. Declining numbers reflect the nature of the registry (patients are included after receiving 1 year of TRT) but not drop-out rates.

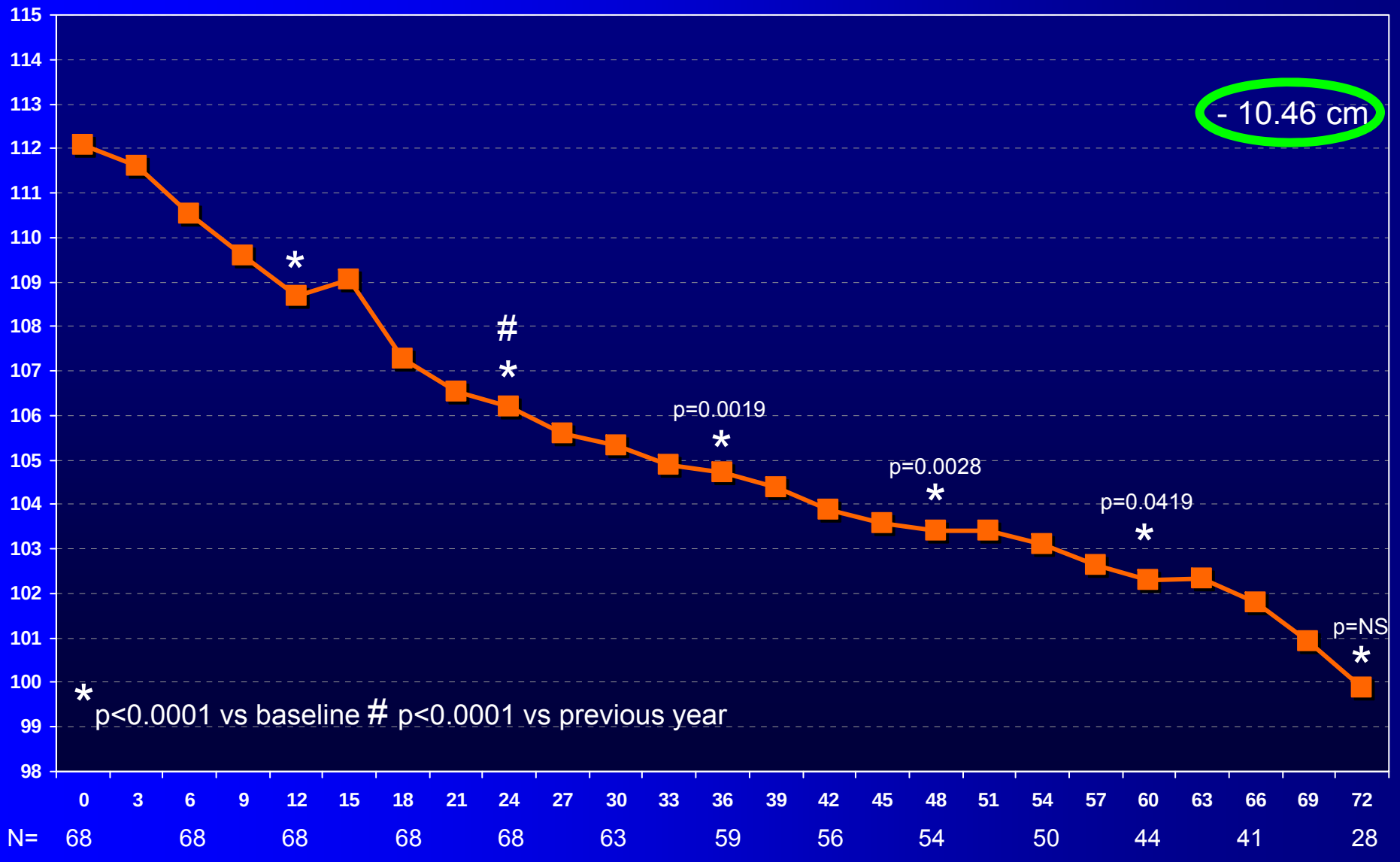
Body Weight (kg)



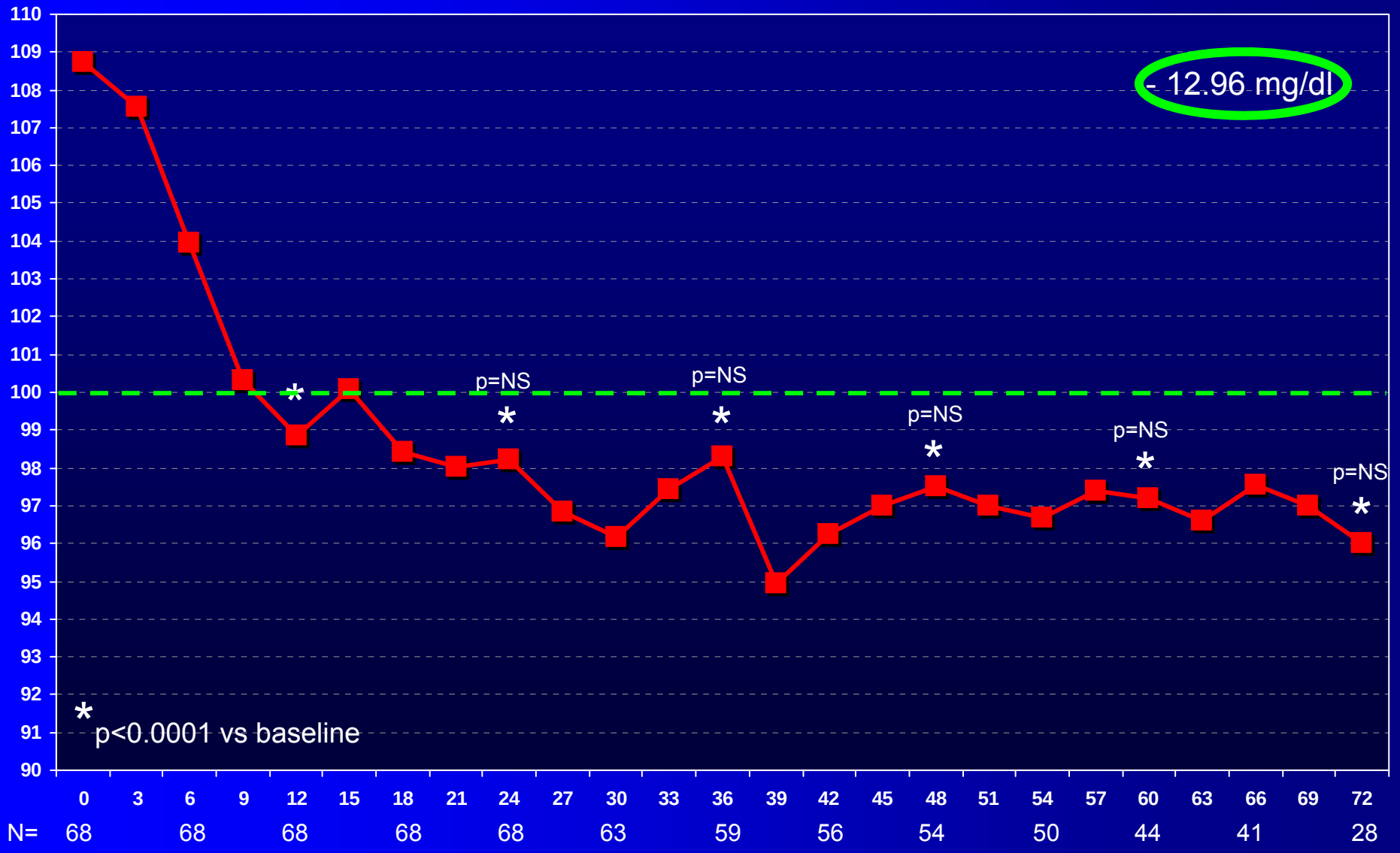
Weight Change (% from Baseline)

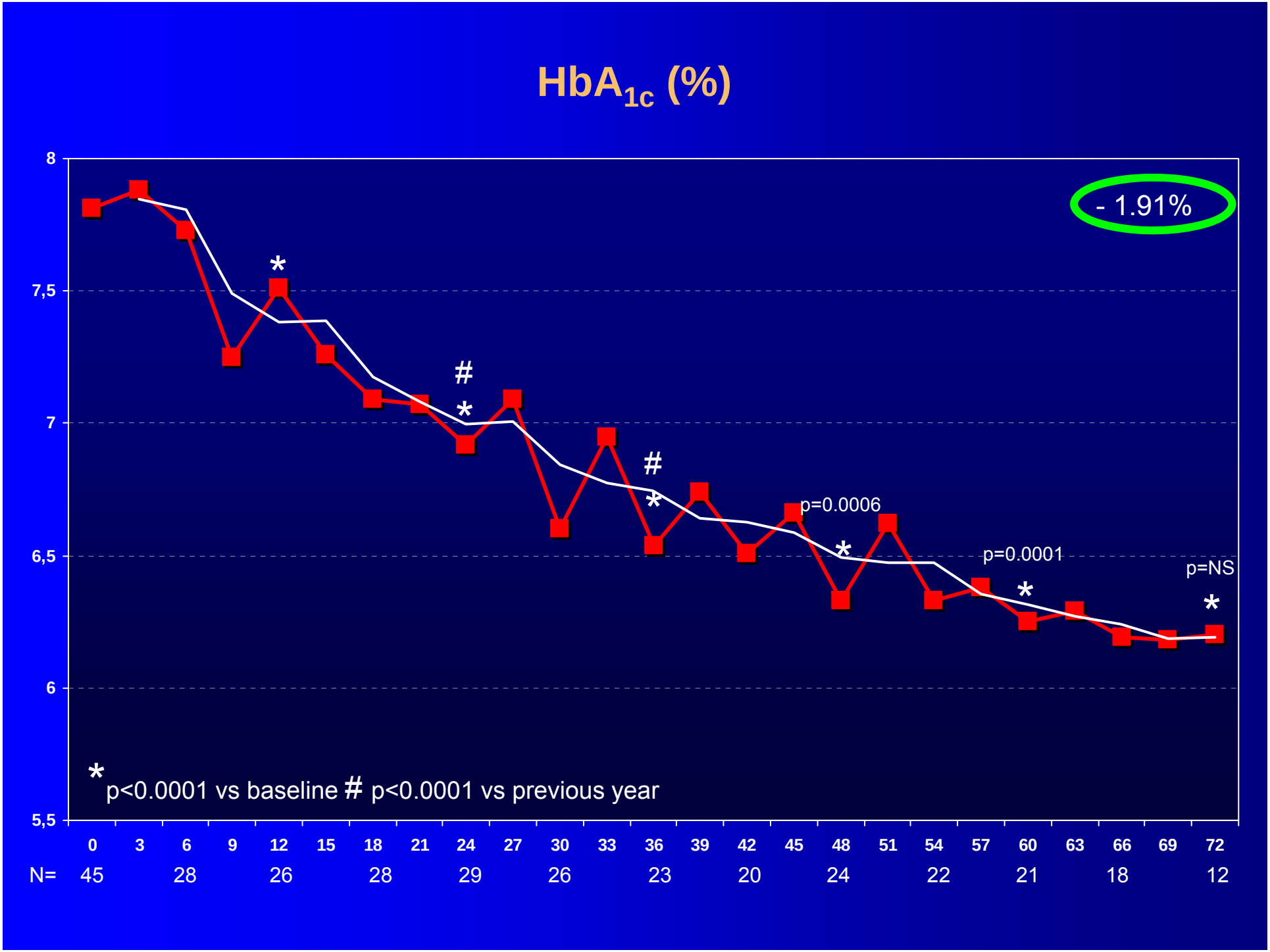


Waist Circumference (cm)

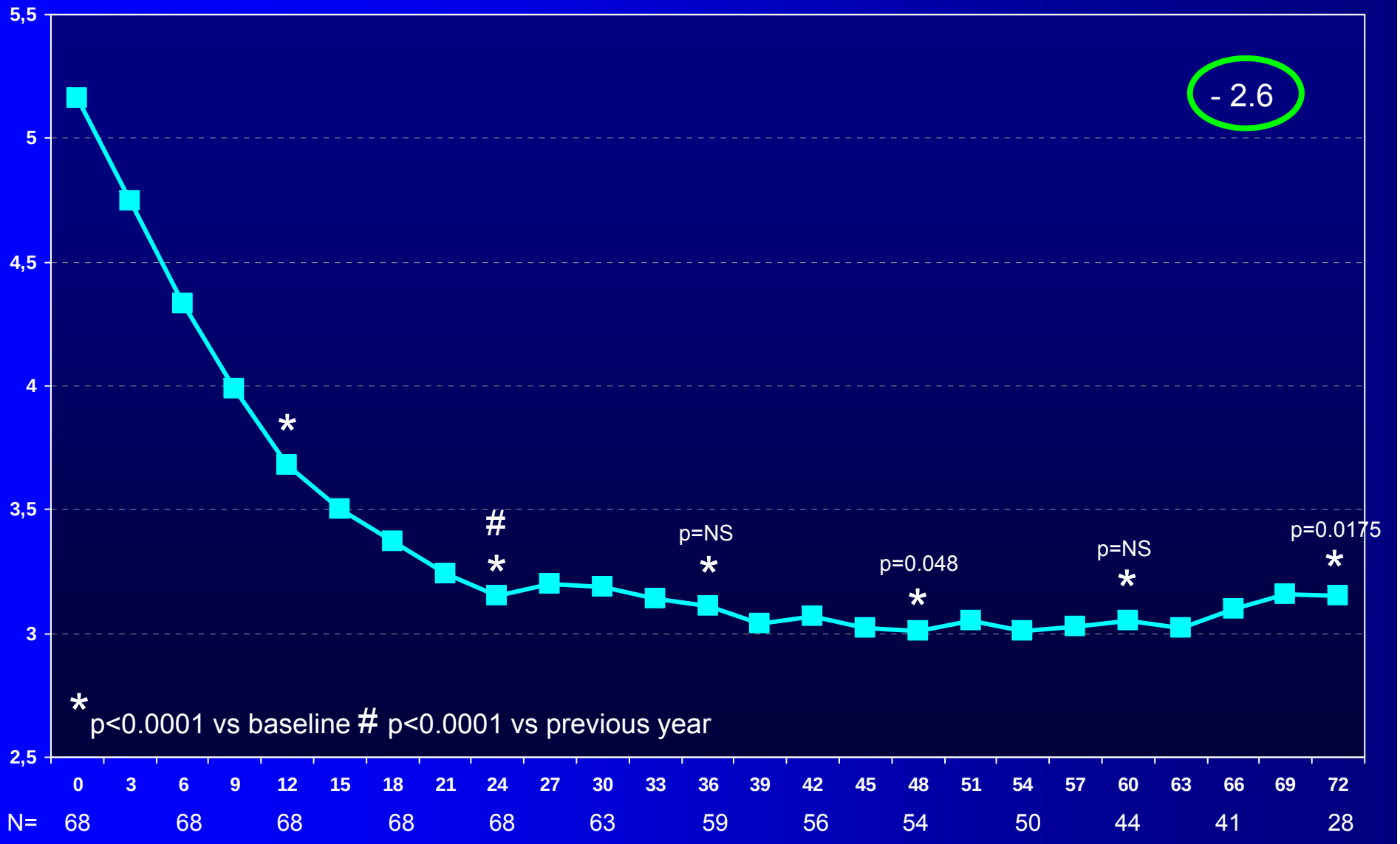


Fasting Glucose (mg/dl)

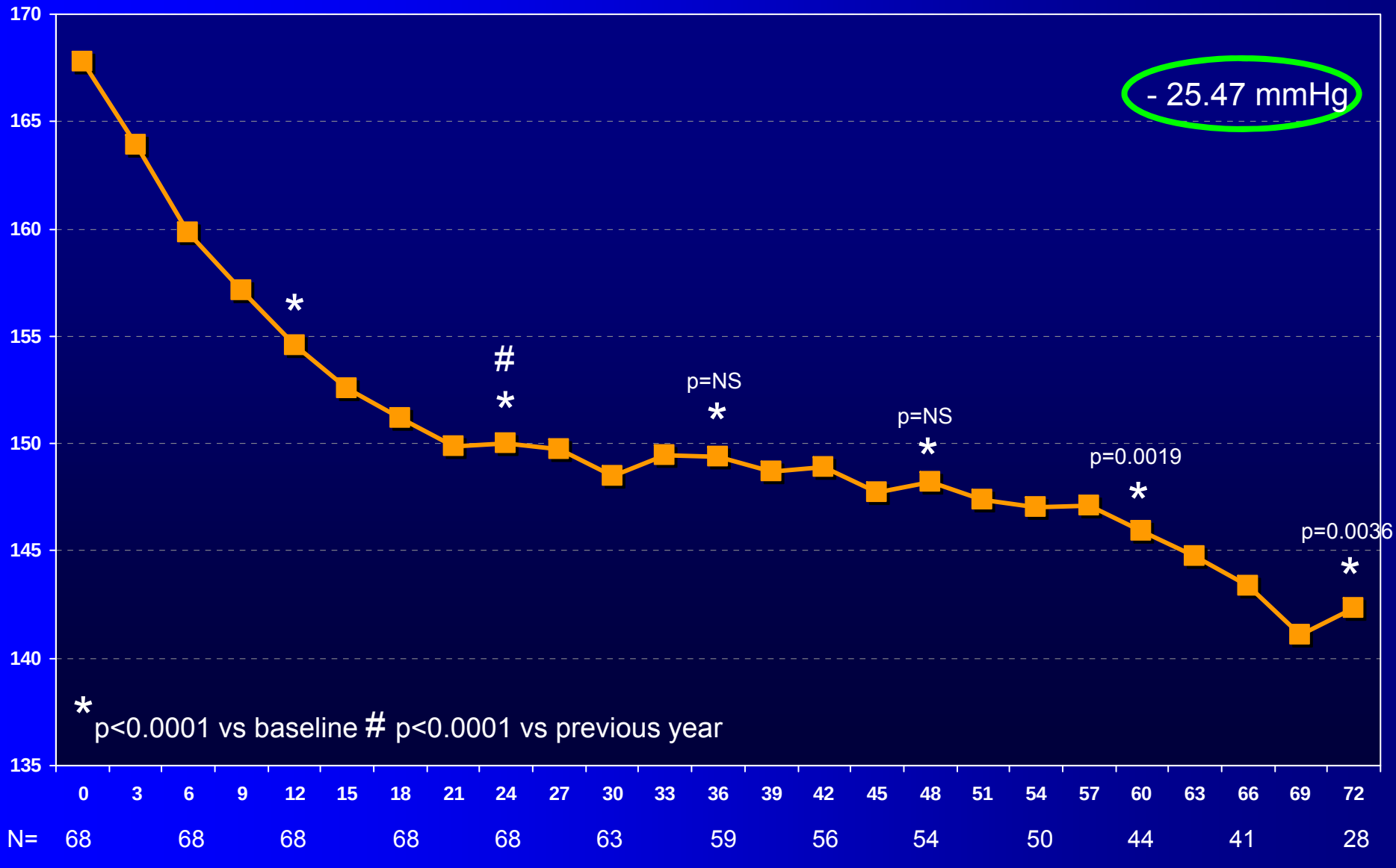



HbA1c (%)
8
7,5
7
6,5
6
5,5
- 1.91%
*
#
*
#
*
p=0.0006
*
p=0.0001
*
p=NS
*
* p<0.0001 vs baseline # p<0.0001 vs previous year
0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45 48 51 54 57 60 63 66 69 72
N= 45 28 26 28 29 26 23 20 24 22 21 18 12

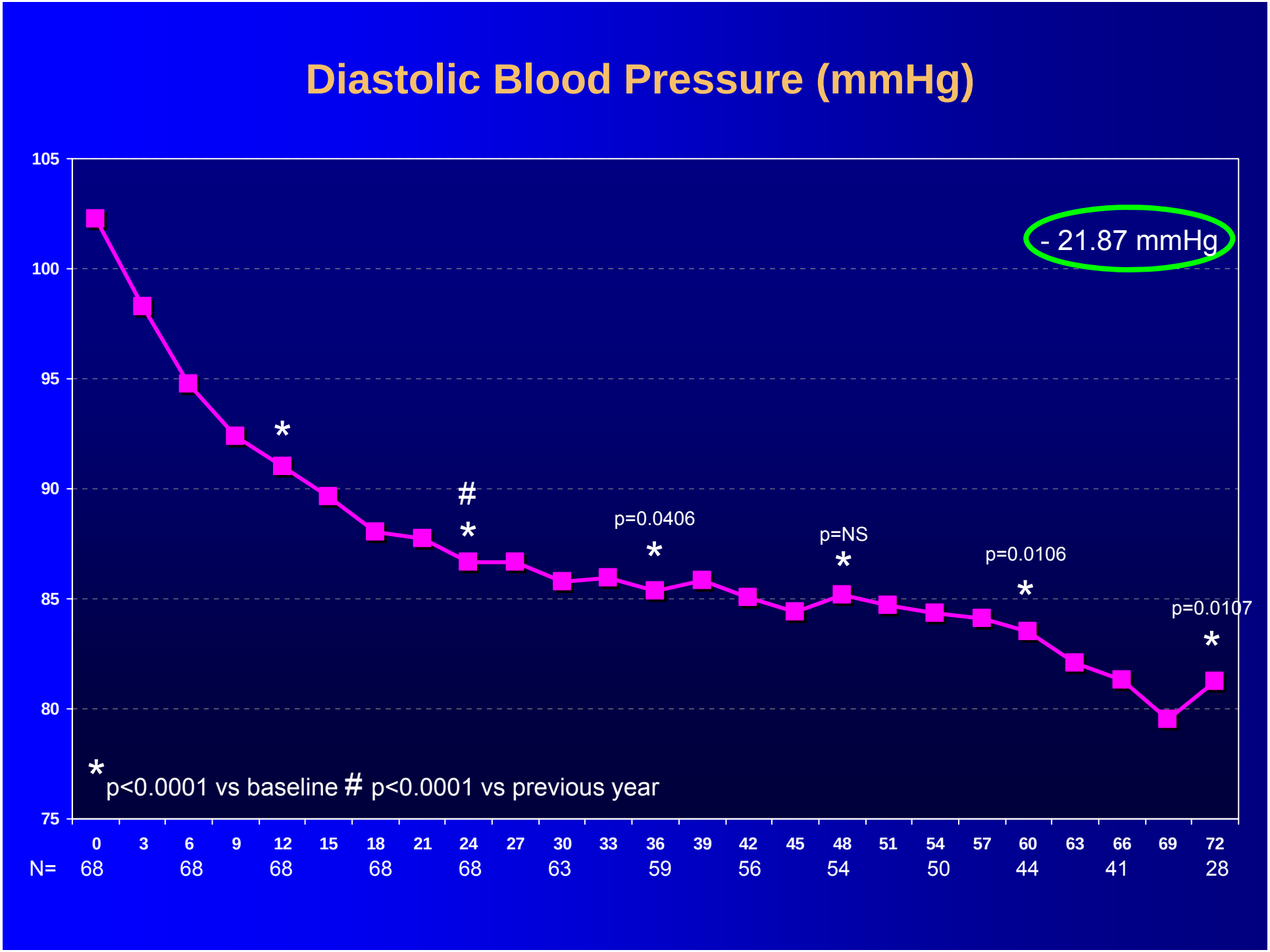
Total Cholesterol : HDL Ratio



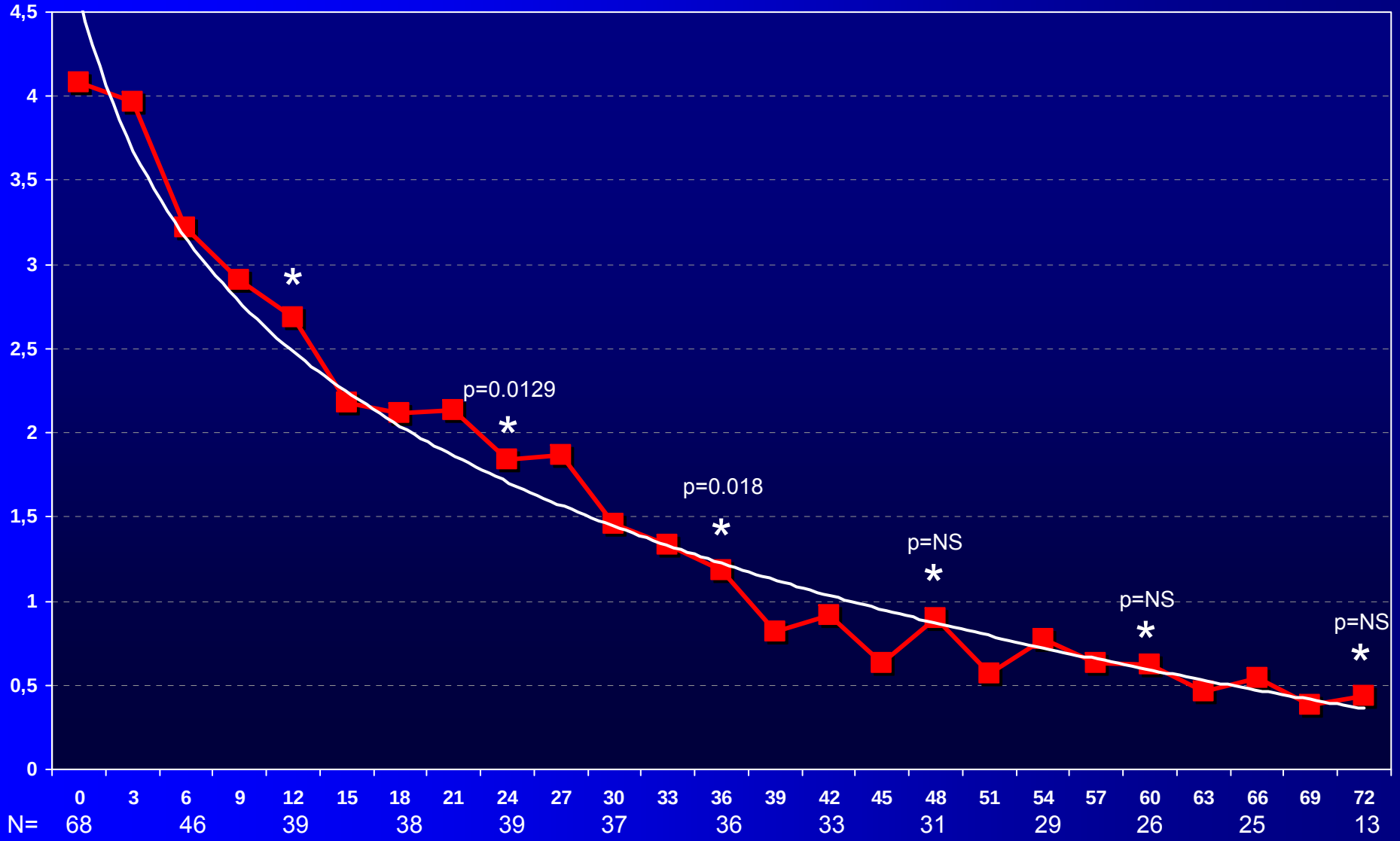
Systolic Blood Pressure (mmHg)



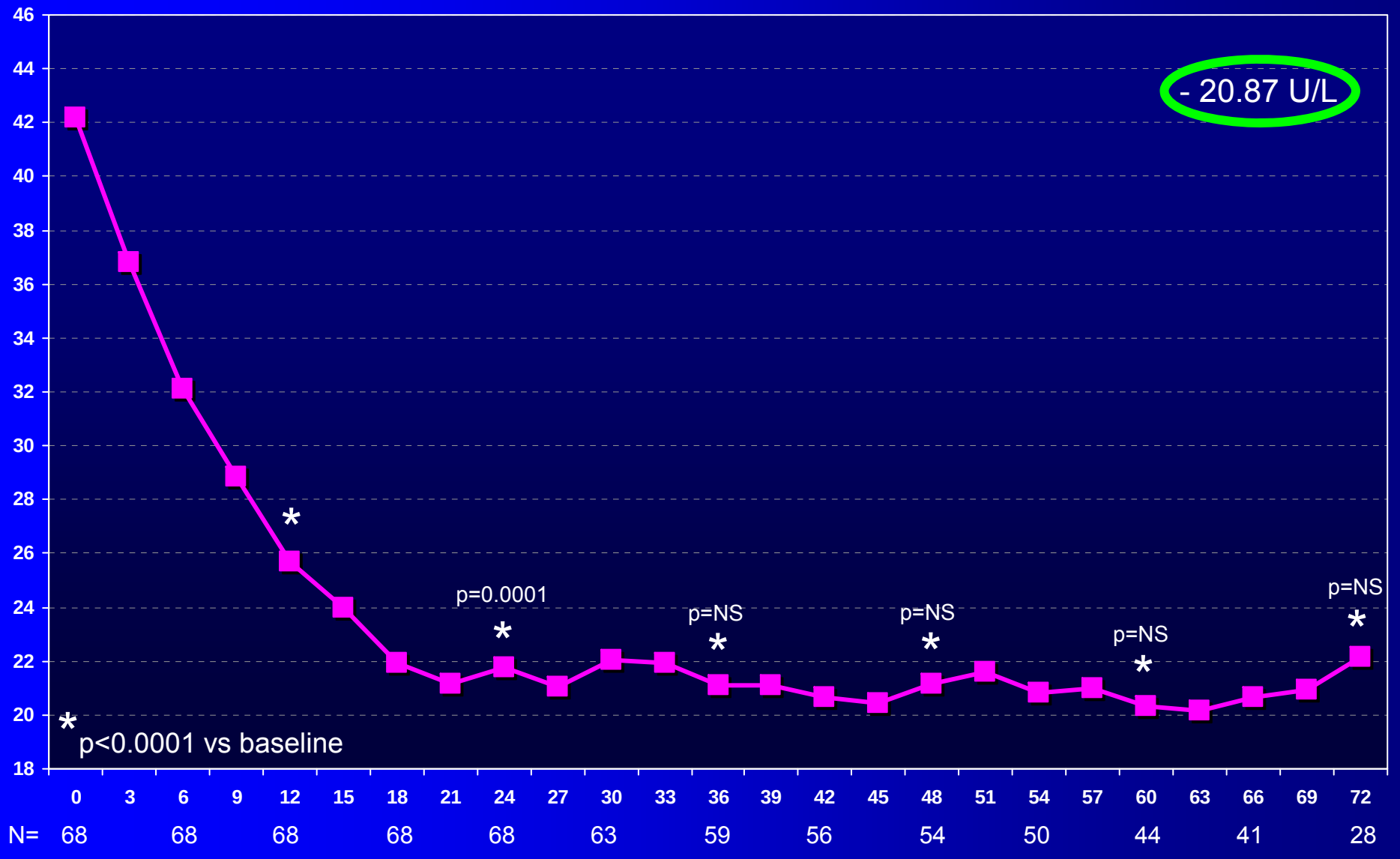
Diastolic Blood Pressure (mmHg)



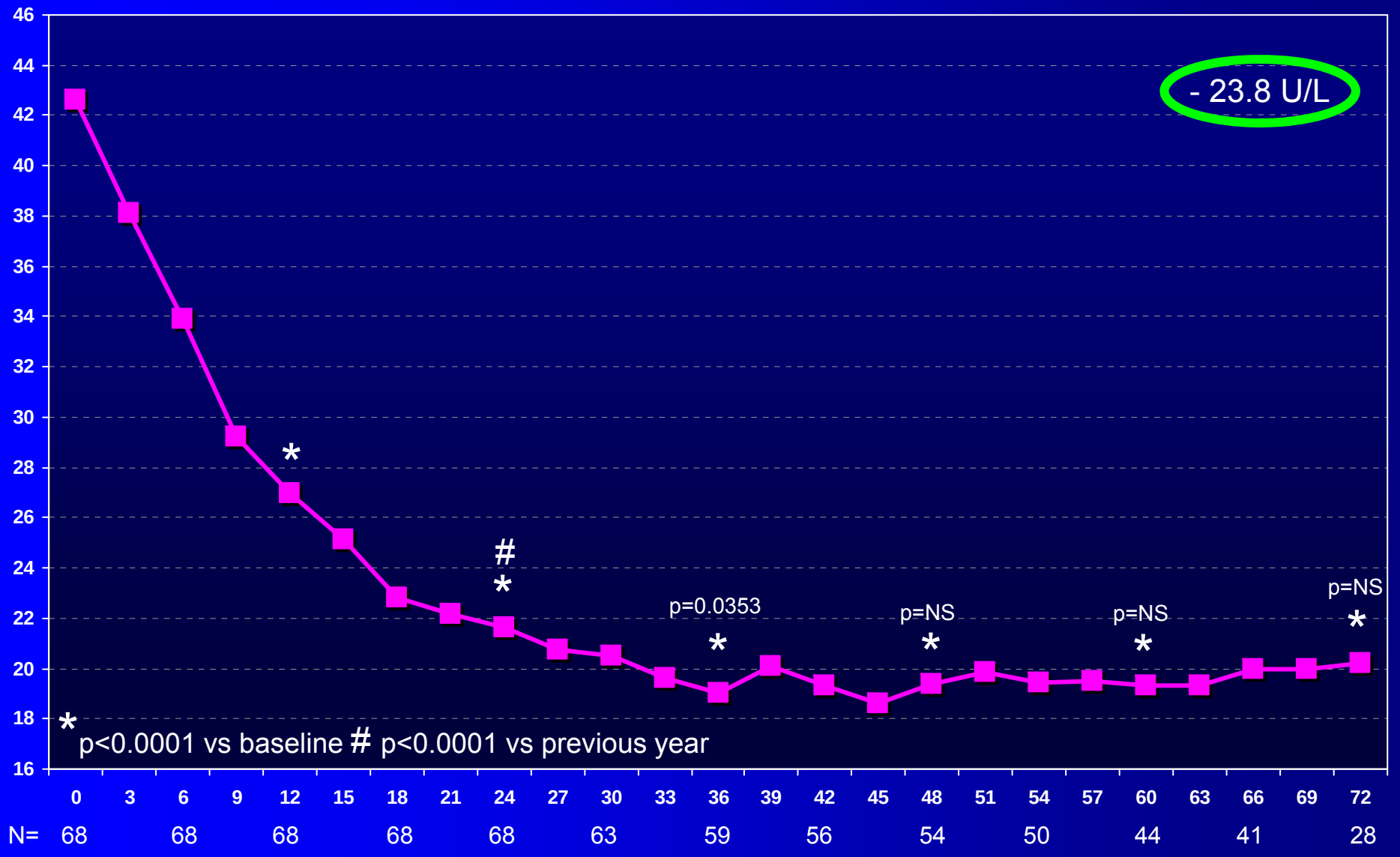
C-Reactive Protein (CRP, mg/L)



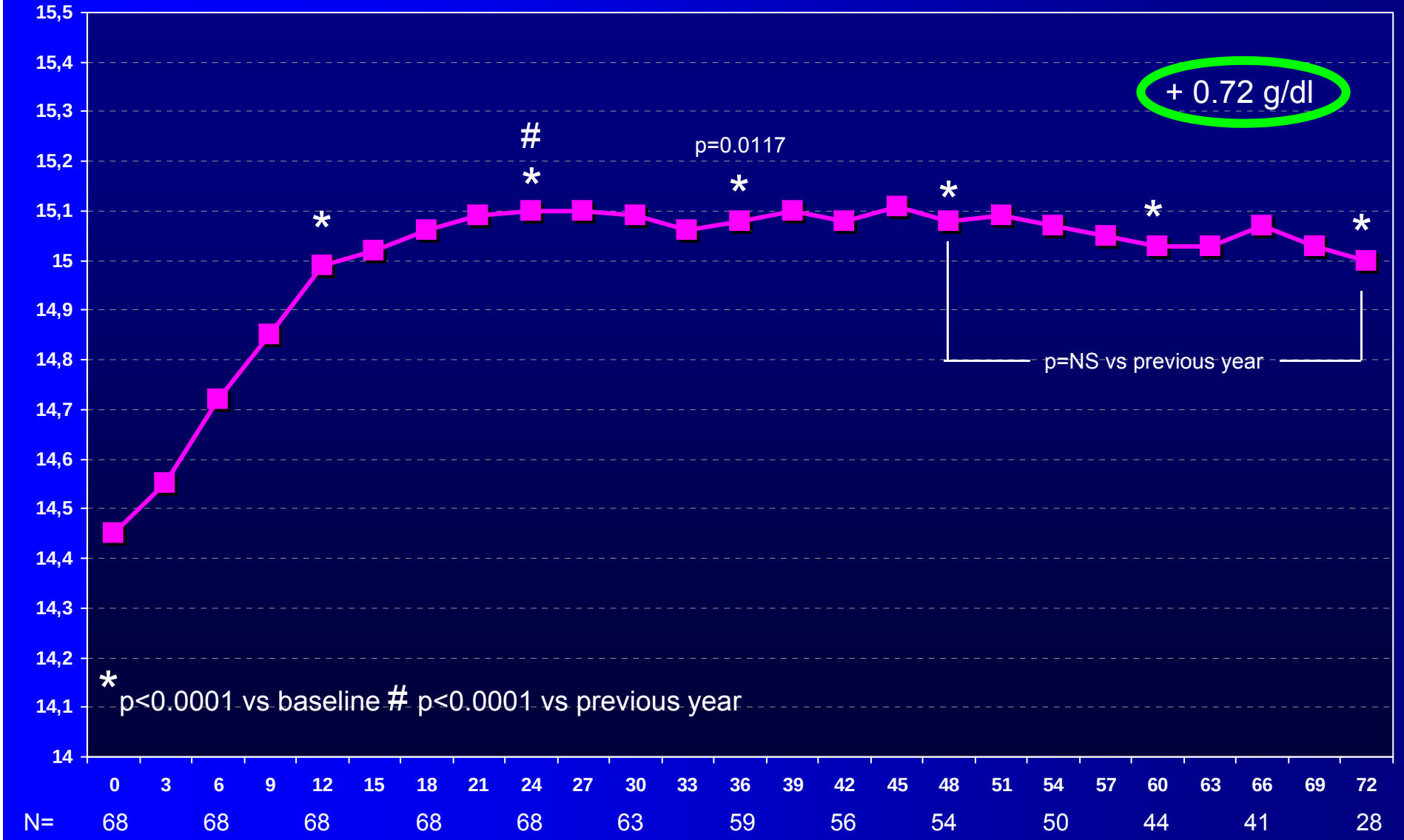
Aspartate Transaminase (AST, U/L; formerly GOT)



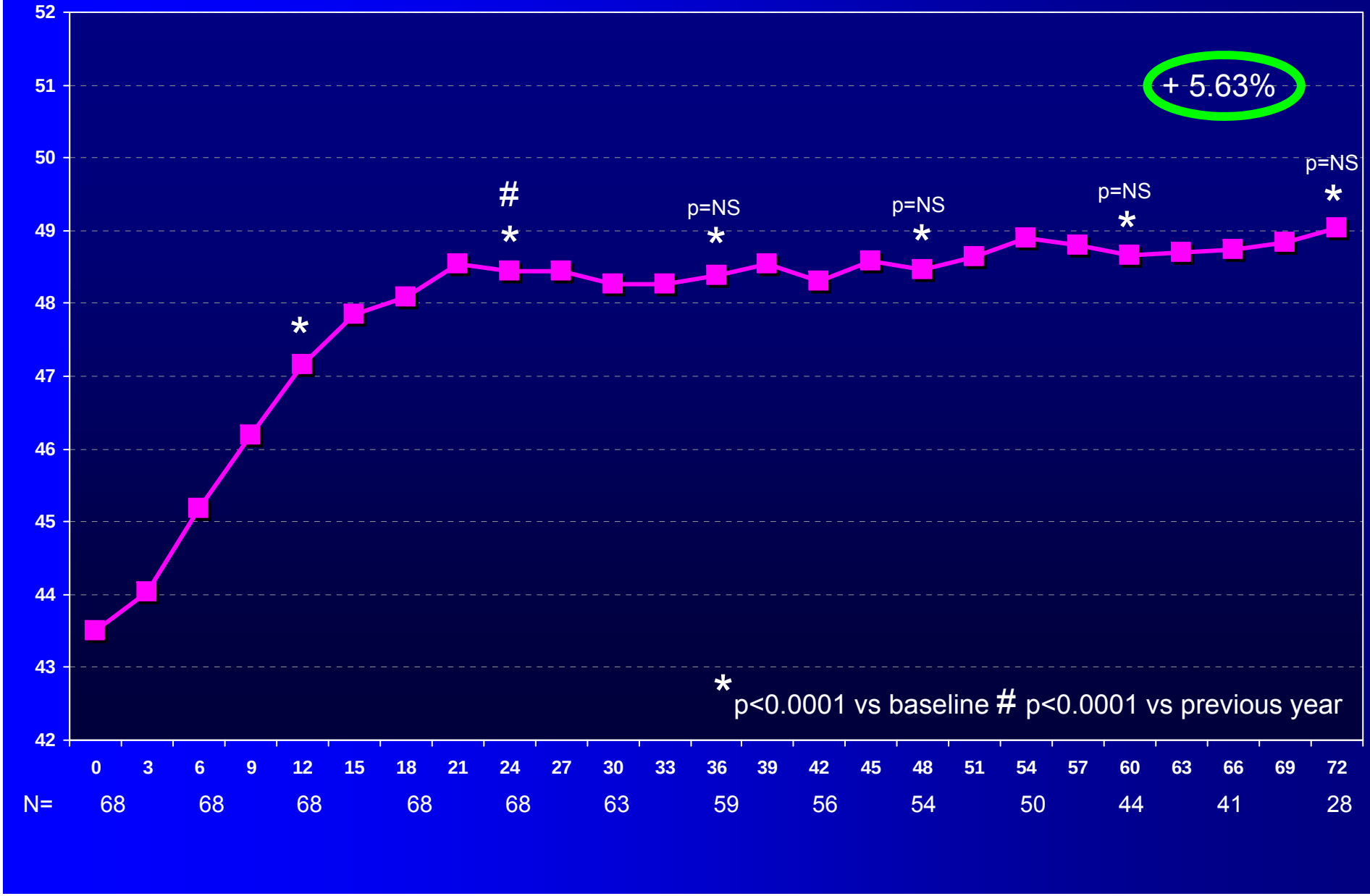
Alanine Transaminase (ALT, U/L; formerly GPT)



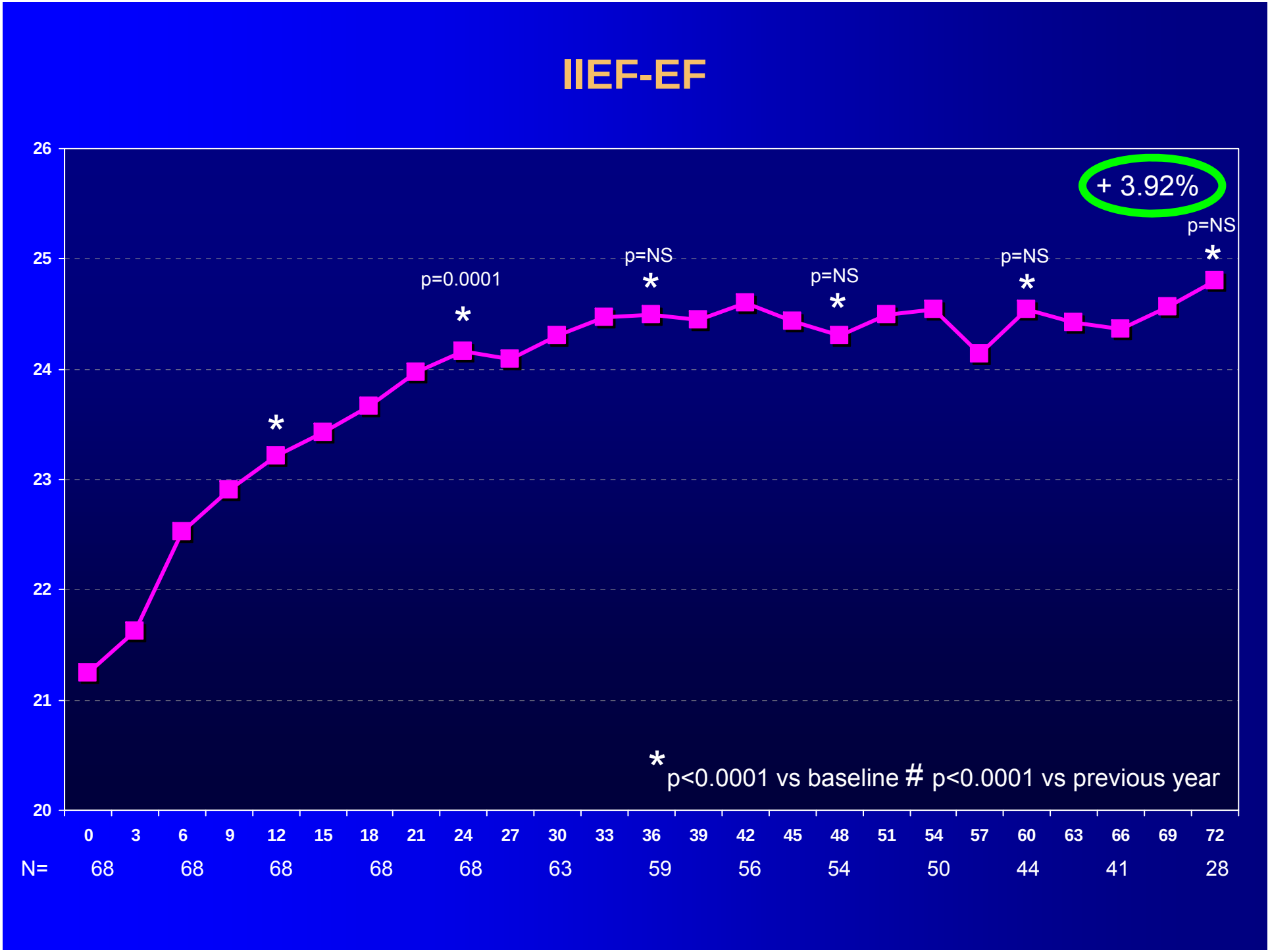
Haemoglobin (g/dl)



Haematocrit (%)



IIEF-EF


26
25
24
23
22
21
20
+ 3.92%
p=NS
p=NS
p=NS
p=0.0001
p=NS
*
* p<0.0001 vs baseline # p<0.0001 vs previous year
0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45 48 51 54 57 60 63 66 69 72
N= 68 68 68 68 68 63 59 56 54 50 44 41 28

The minimum number of injections was 9, maximum 26.

No patient suffered a major adverse cardiovascular event (MACE).

No patient was diagnosed with prostate cancer.

No patient missed a single injection.

No patient dropped out.

Conclusion:

Correcting hypogonadism by TRT in hypogonadal men with CVD resulted in significant and sustained improvements of cardiometabolic risk factors. TRT in hypogonadal men with CVD was well tolerated. No major cardiovascular events occurred. The adherence to TRT was excellent.