
# Come presentare i dati di uno studio clinico

## Metodologia degli studi clinici in diabetologia



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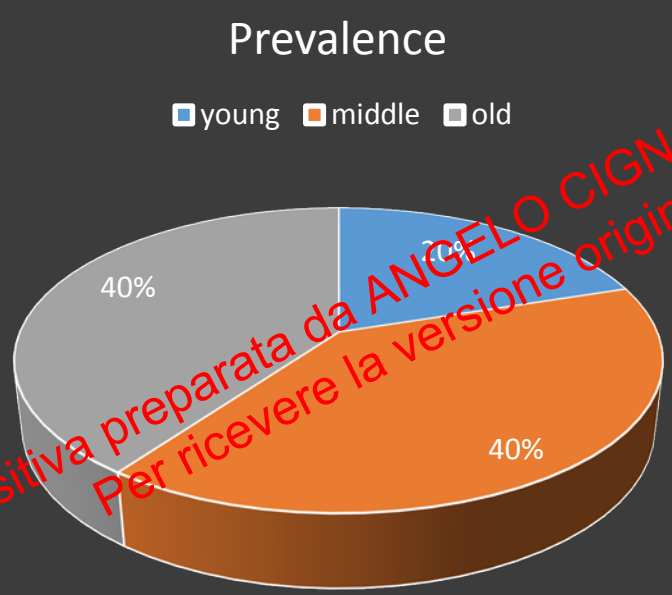
SID ACADEMY
Bologna, 20 marzo 2018


# DATA

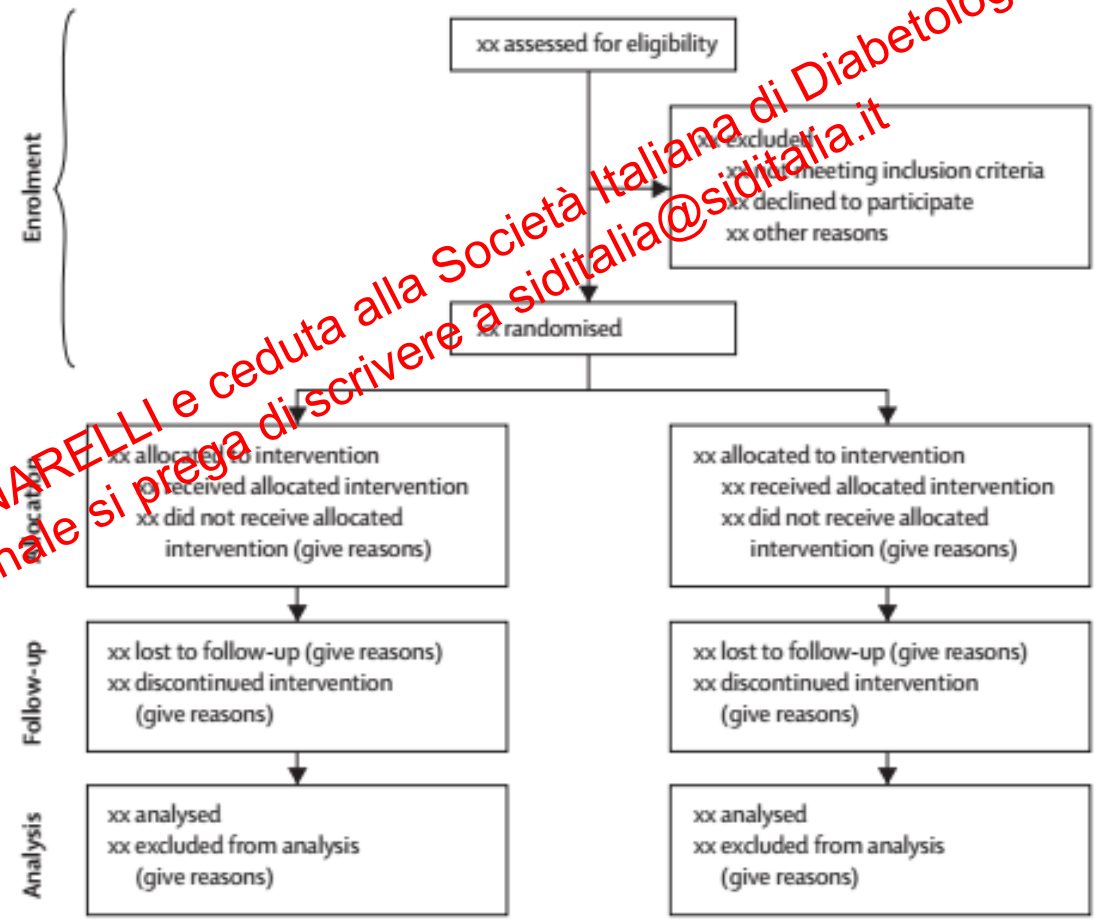



# CONSORT 2010 STATEMENT

## GUIDELINES FOR REPORTING PARALLEL GROUP RANDOMISED TRIALS

- We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.
- http://www.consort-statement.org

# Flow diagram of the progress through the phases of a parallel randomised trial of two groups



# CONSORT 2010 checklist of information to include when reporting a randomized trial

| Section/topic | Item number | Checklist item |
|---|---|---|
| **Title and abstract** | | |
| | 1a | Identification as a randomised trial in the title |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[21,31]) |
| **Introduction** | | |
| Background and objectives | 2a | Scientific background and explanation of rationale |
| | 2b | Specific objectives or hypotheses |
| **Methods** | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |
| Participants | 4a | Eligibility criteria for participants |
| | 4b | Settings and locations where the data were collected |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |
| Outcomes | 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons |
| Sample size | 7a | How sample size was determined |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines |

# CONSORT 2010 checklist of information to include when reporting a randomized trial

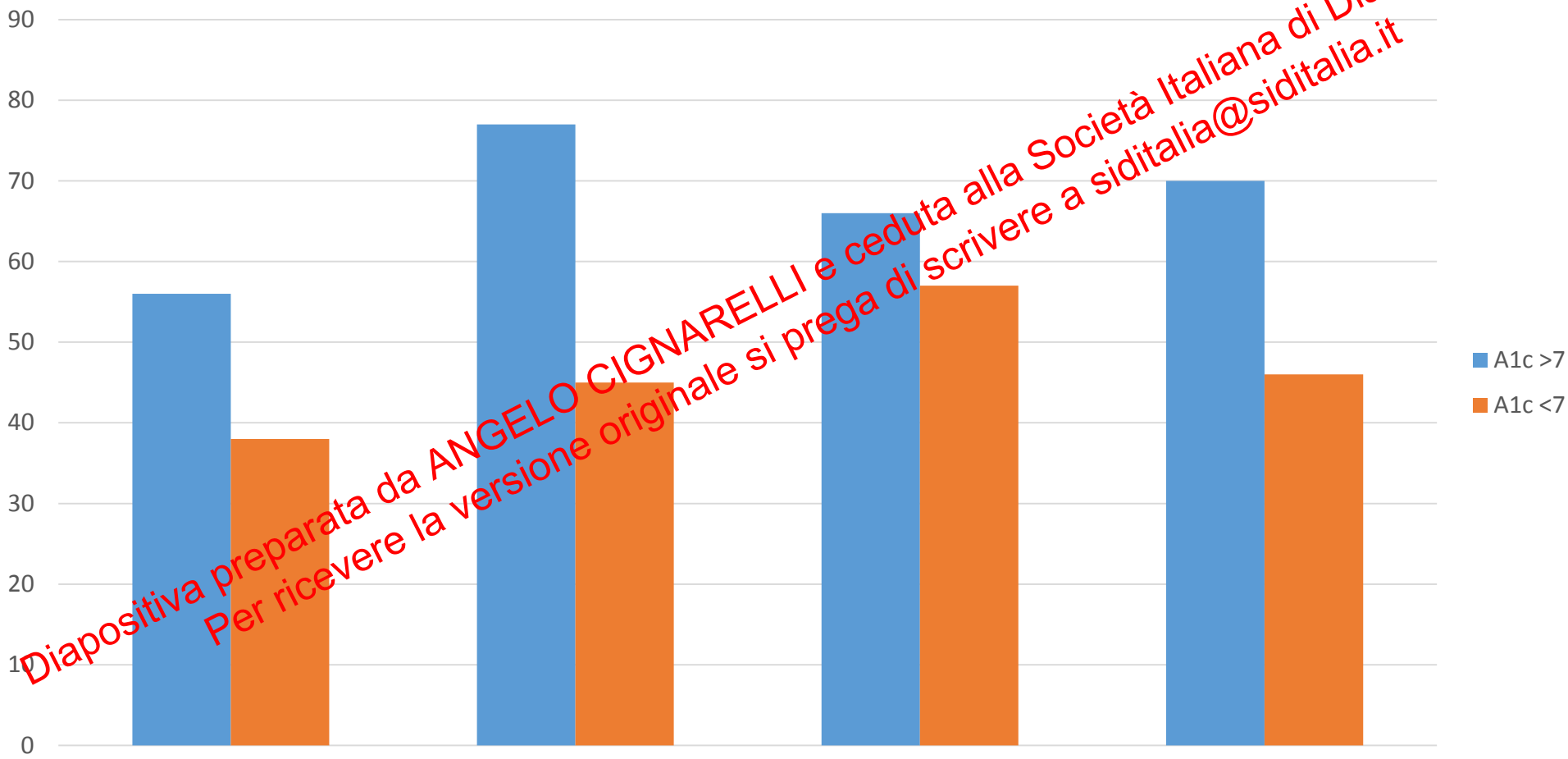
| | | |
|---|---|---|
| **Randomisation** | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |
| | 11b | If relevant, description of the similarity of interventions |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |
| **Results** | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |
| | 14b | Why the trial ended or was stopped |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI) |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[28]) |

# CONSORT 2010 checklist of information to include when reporting a randomized trial

| | | |
|---|---|---|
| **Discussion** | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |
| **Other information** | | |
| Registration | 23 | Registration number and name of trial registry |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |

# Do you present yourself like this?

# So why would you present your data like this?



# Effective presentation

For all communication formats it is important to ensure that there is:

- Consistency
  - Font, Colors, Punctuation, Terminology, Line/ Paragraph Spacing
- An appropriate amount of information
  - Less is more
- Appropriate content and format for audience
  - Scientific community, Journalist, Politicians

# Summarizing data

- Tables
  - Simplest way to summarize data
  - Data is presented as absolute numbers or percentages
- Charts and graphs
  - Visual representation of data
  - Usually data is presented using percentages

# Points to remember

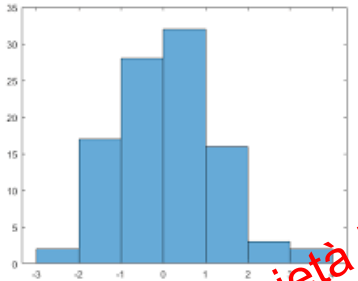
- Ensure graphic has a title
- Label the components of your graphic
- Indicate source of data with date
- Provide number of observations (n=xx) as a reference point
- Add footnote if more information is needed

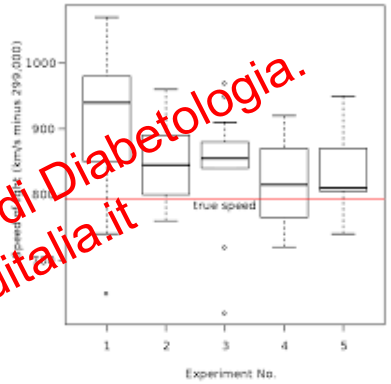
# Tips for Presenting Data in PowerPoint

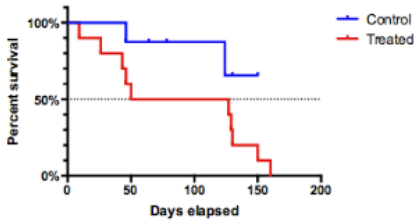
- All text should be readable
- Use sans serif fonts
  - Gill Sans (sans serif)
  - Times New Roman (serif)
- Keep slides simple
- Limit animations and special effects
- Use high contrast text and backgrounds

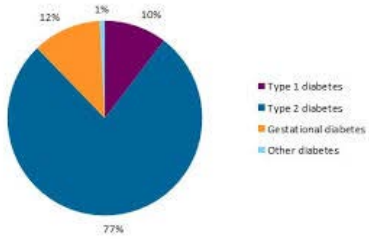
# How to present data

- Tables
- Continue → boxplot → http://shiny.chemgrid.org/boxplotr/
- N, frequency → histogram → excel
- % → pie → excel
- Survival curves → line plot → excel





# Tables

| | Dulaglutide 1·5 mg (n=142) | Dulaglutide 0·75 mg (n=141) | Placebo (n=140) |
|---|---|---|---|
| Sex | | | |
| Men | 77 (54%) | 69 (49%) | 66 (47%) |
| Women | 65 (46%) | 72 (51%) | 74 (53%) |
| Mean age (years) | 56·17 (9·26) | 58·55 (9·14) | 57·10 (9·59) |
| Aged ≥65 years | 23 (16%) | 44 (31%) | 31 (22%) |
| Race | | | |
| American Indian or Alaska Native | 1 (1%) | 2 (1%) | 4 (3%) |
| Asian | 0 | 1 (1%) | 0 |
| Black or African American | 3 (2%) | 3 (2%) | 6 (4%) |
| Multiple | 11 (8%) | 8 (6%) | 6 (4%) |
| White | 127 (89%) | 127 (90%) | 124 (89%) |
| Ethnic origin | | | |
| Hispanic or Latino | 51 (36%) | 44 (31%) | 44 (31%) |
| Not Hispanic or Latino | 90 (63%) | 97 (69%) | 94 (67%) |
| Not reported | 1 (1%) | 0 | 2 (1%) |
| Bodyweight (kg) | 92·87 (19·73) | 91·07 (20·99) | 90·50 (19·47) |
| BMI (kg/m²) | 32·87 (5·56) | 32·77 (6·27) | 32·39 (4·98) |



*Ludvik B et al. Lancet Diabetes Endocrinol. 2018 Feb 23. pii: S2213-8587(18)30023-8*

# Tables

**Table 1. Primary Outcomes.***

| Outcome | Degludec (N=3818) | | Glargine (N=3819) | | Hazard Ratio (95% CI) | P Value |
|---|---|---|---|---|---|---|
| | Patients | Event Rate | Patients | Event Rate | | |
| | *no. (%)* | *no./100 patient-yr* | *no. (%)* | *no./100 patient-yr* | | |
| Primary composite cardiovascular outcome | 325 (8.5) | 4.29 | 356 (9.3) | 4.71 | 0.91 (0.78–1.06) | <0.001† |
| Expanded composite cardiovascular outcome‡ | 386 (10.1) | 5.10 | 419 (11.0) | 5.54 | 0.92 (0.80–1.05) | 0.22 |
| Component outcomes | | | | | | |
| Death from any cause | 202 (5.3) | 2.67 | 221 (5.8) | 2.92 | 0.91 (0.76–1.11) | 0.35 |
| Noncardiovascular death | 66 (1.7) | 0.87 | 79 (2.1) | 1.05 | 0.84 (0.60–1.16) | 0.28 |
| Cardiovascular death | 136 (3.6) | 1.80 | 142 (3.7) | 1.88 | 0.96 (0.76–1.21) | 0.71 |
| Cardiovascular death excluding undetermined cause of death | 97 (2.5) | 1.28 | 106 (2.8) | 1.40 | 0.91 (0.69–1.20) | 0.52 |
| Nonfatal myocardial infarction | 144 (3.8) | 2.27 | 169 (4.4) | 2.47 | 0.85 (0.68–1.06) | 0.15 |
| Nonfatal stroke | 71 (1.9) | 0.98 | 79 (2.1) | 1.16 | 0.90 (0.65–1.23) | 0.50 |
| Unstable angina leading to hospitalization | 71 (1.9) | 1.04 | 74 (1.9) | 1.10 | 0.95 (0.68–1.31) | 0.74 |

* The primary composite outcome was analyzed with the use of a Cox proportional-hazards regression model with treatment group as a factor in the intention-to-treat population with testing for noninferiority. All P values are two-sided unless otherwise stated.
† This one-sided P value confirmed noninferiority. The two-sided P value testing for a significant between-group difference was 0.21.
‡ The expanded composite cardiovascular outcome (a secondary outcome) consisted of the primary composite outcome plus unstable angina leading to hospitalization.

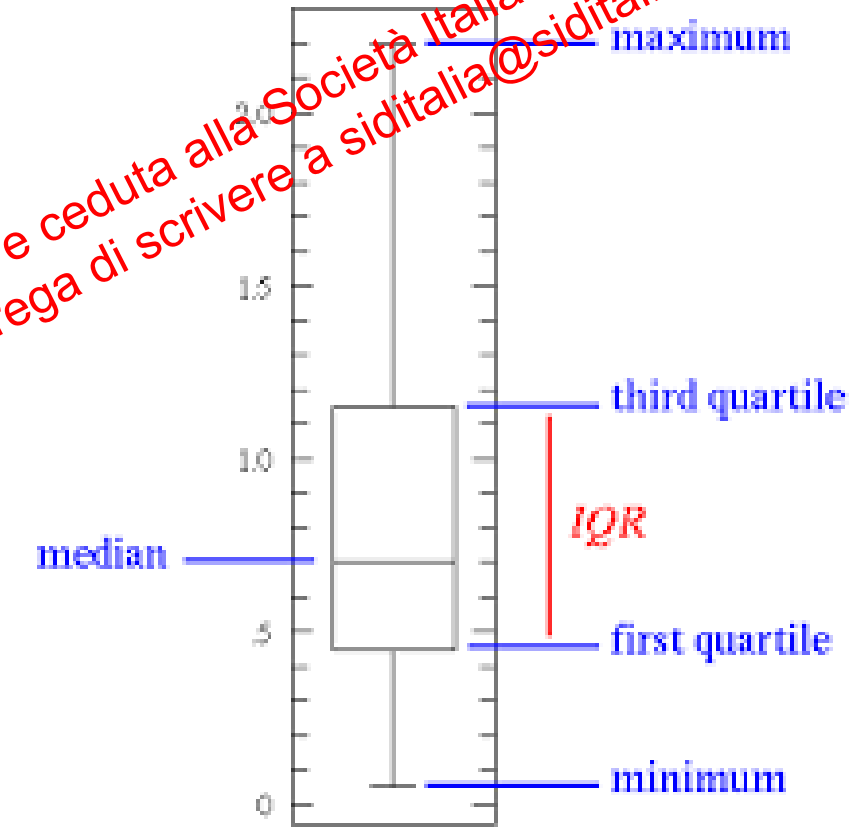


N Engl J Med. 2017 Sep 28;377(13):1228-1239.

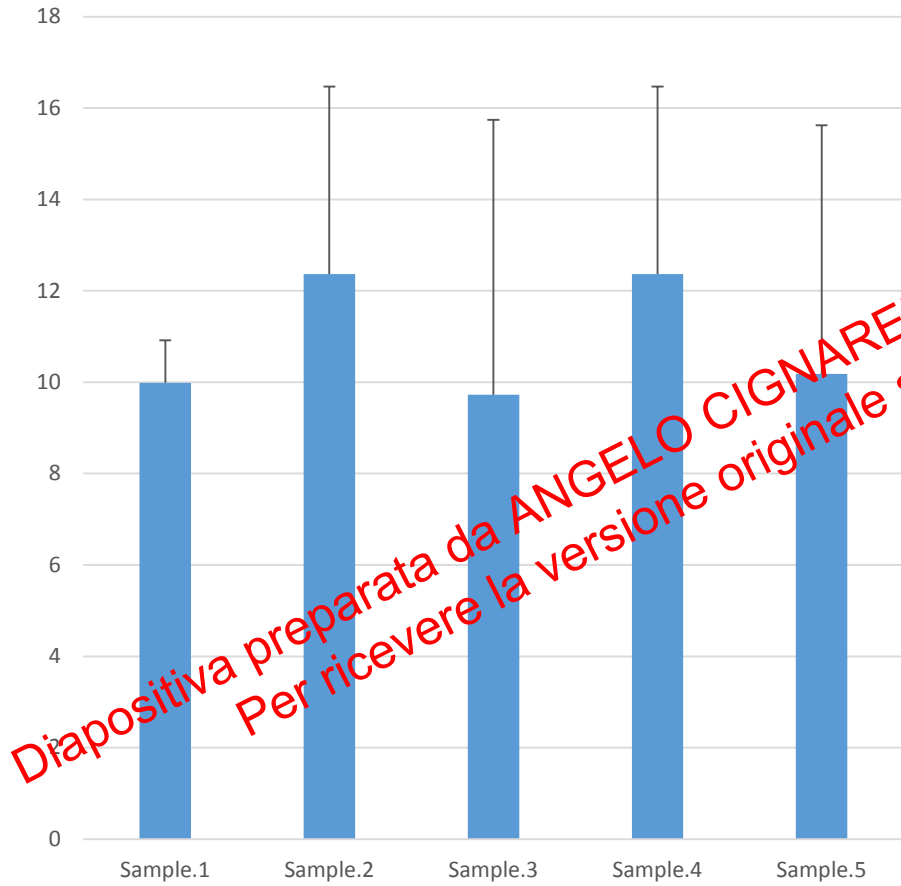
# Continue variables


HISTOGRAM

BOXPLOT



# Visual display of continuous variables

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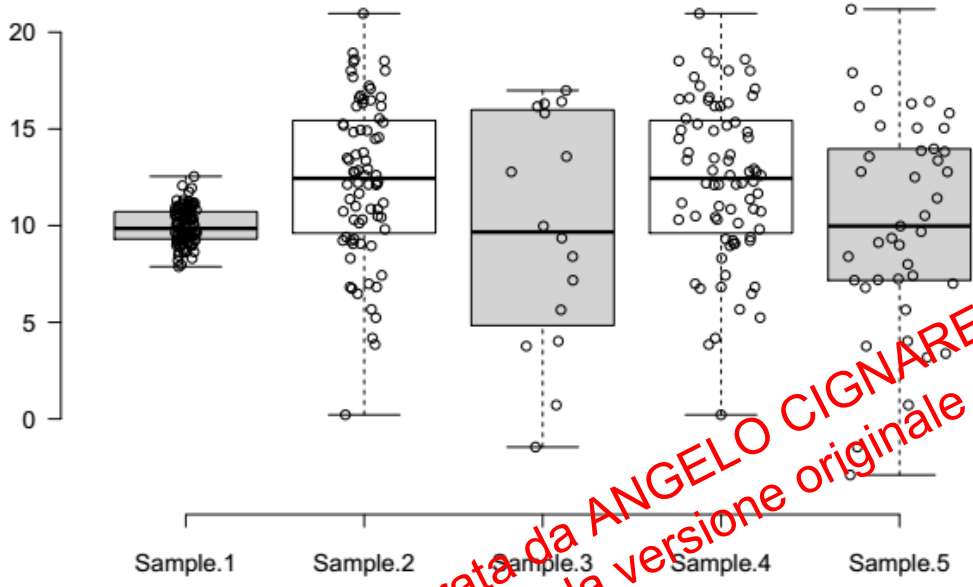
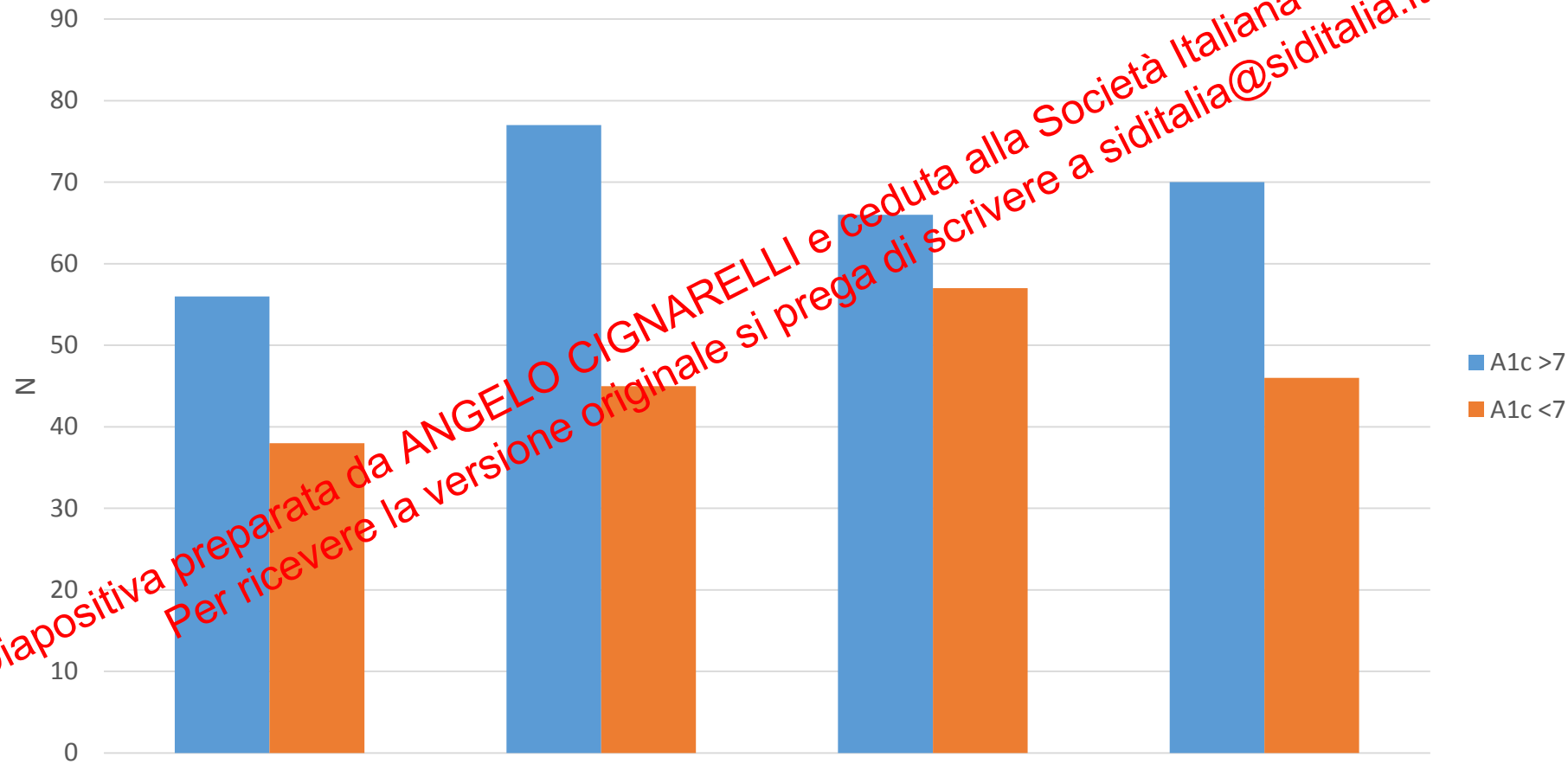


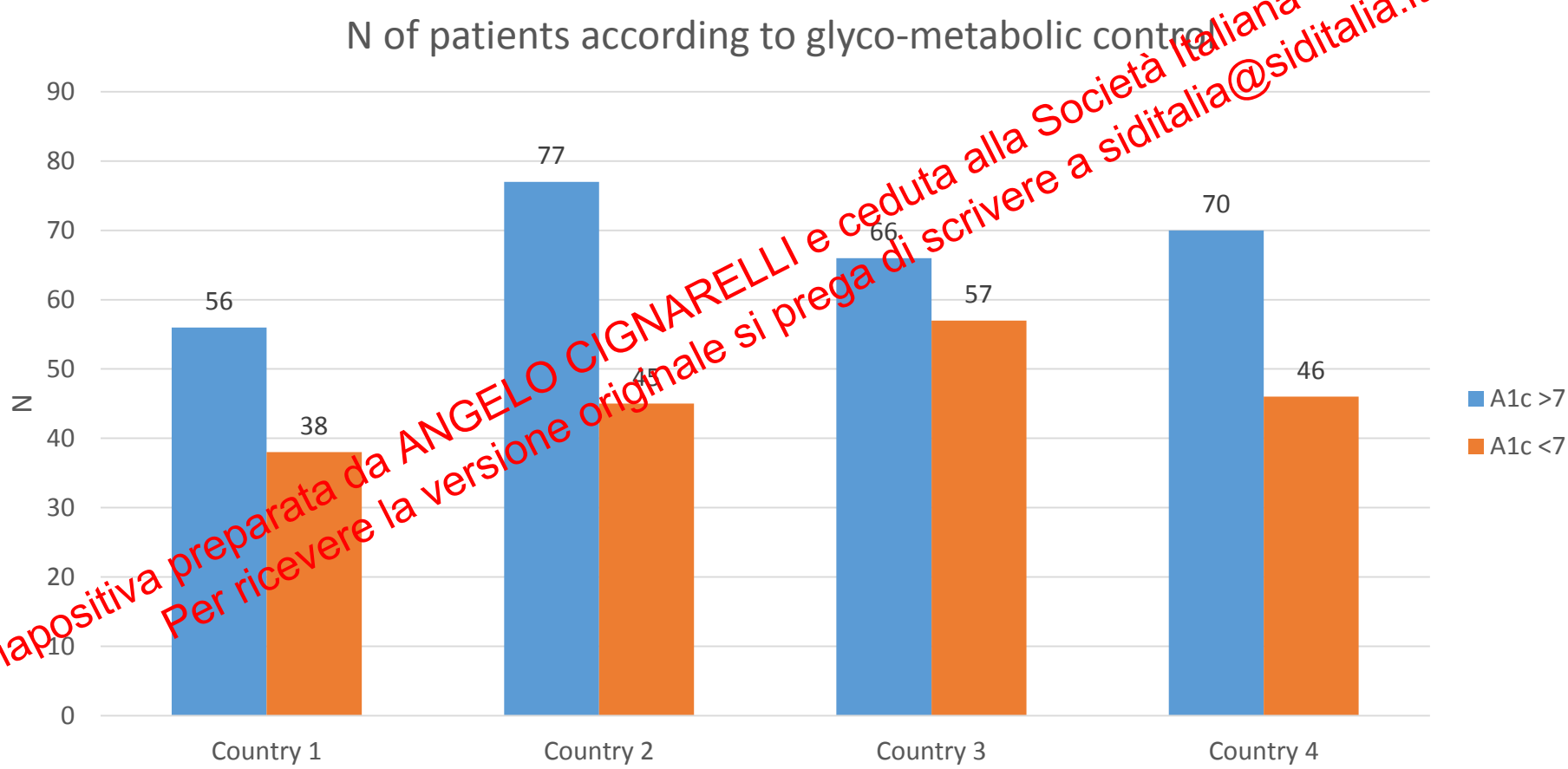

| | Sample. 1 | Sample. 2 | Sample. 3 | Sample. 4 | Sample. 5 |
|---|---|---|---|---|---|
| Upper whisker | 12.55 | 20.97 | 16.99 | 20.97 | 21.19 |
| 3rd quartile | 10.72 | 15.44 | 15.99 | 15.44 | 13.97 |
| Median | 9.85 | 12.44 | 9.67 | 12.44 | 9.98 |
| 1st quartile | 9.31 | 9.61 | 4.83 | 9.61 | 7.17 |
| Lower whisker | 7.87 | 3.85 | -1.45 | 3.85 | -2.90 |



# Histogram

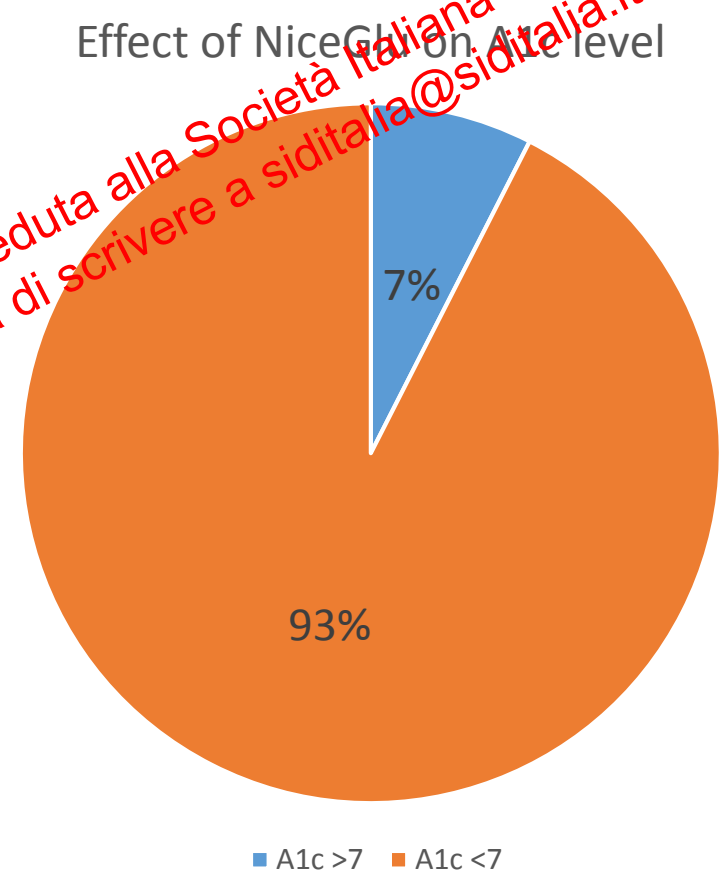


# Histogram



# CREATING GOOD CHARTS

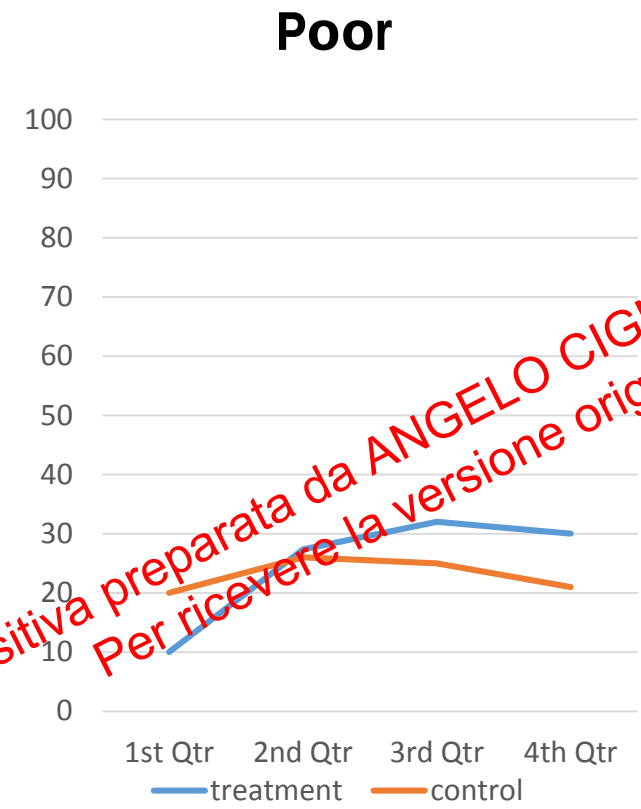
- Good charts should focus on getting your message across, rather than creating fancy, and distracting, images.
- **Remember:** Do not use graphs just for the sake of it.

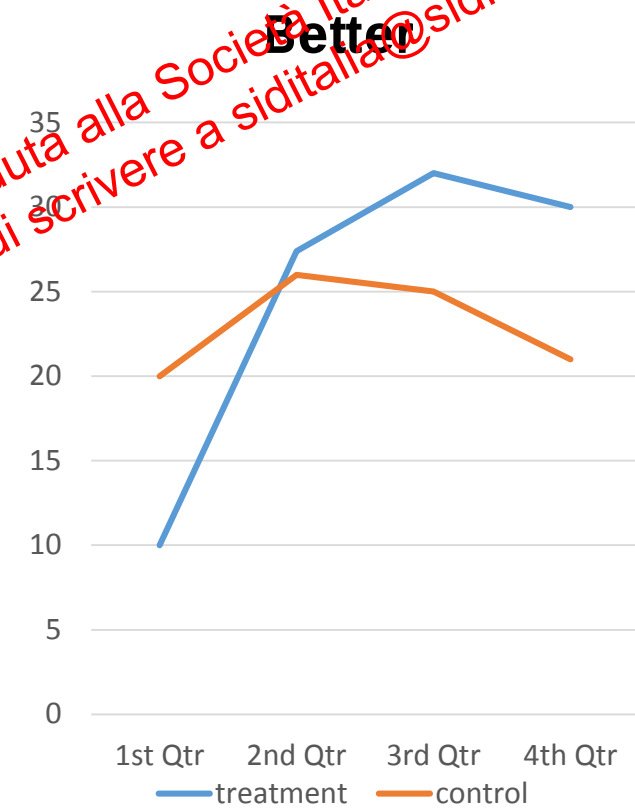




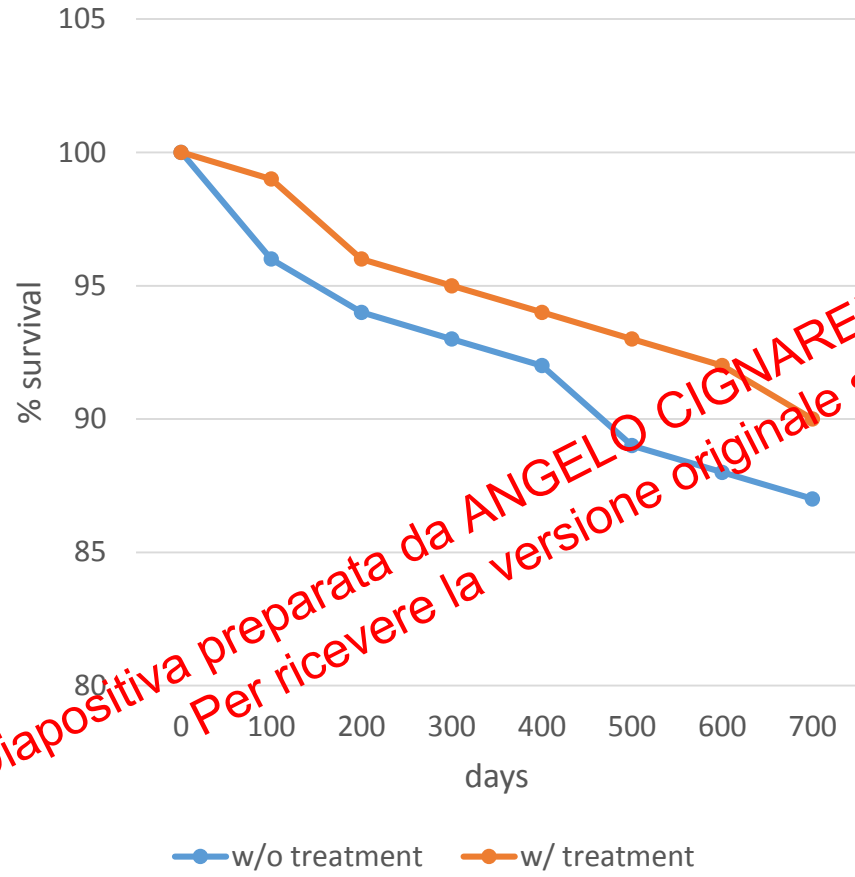

***in some cases simply expressing the data as 'x/n (y%)' is sufficient.***

# Visual Display of Same Data



# EFFECTS OF CHANGES IN FAT, FISH, AND FIBRE INTAKES ON DEATH AND MYOCARDIAL REINFARCTION: DIET AND REINFARCTION TRIAL (DART)






Riduzione della mortalità

↓ 29%

*Burr et al. Volume 334, Issue 8666, 30 September 1989, Pages 757-761*

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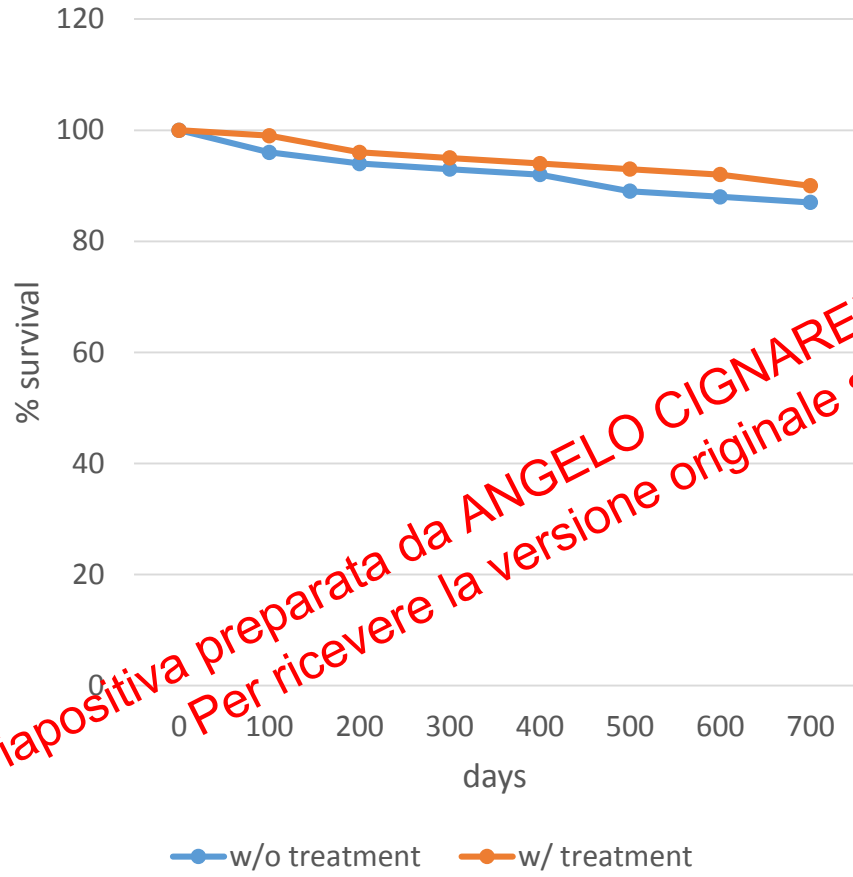


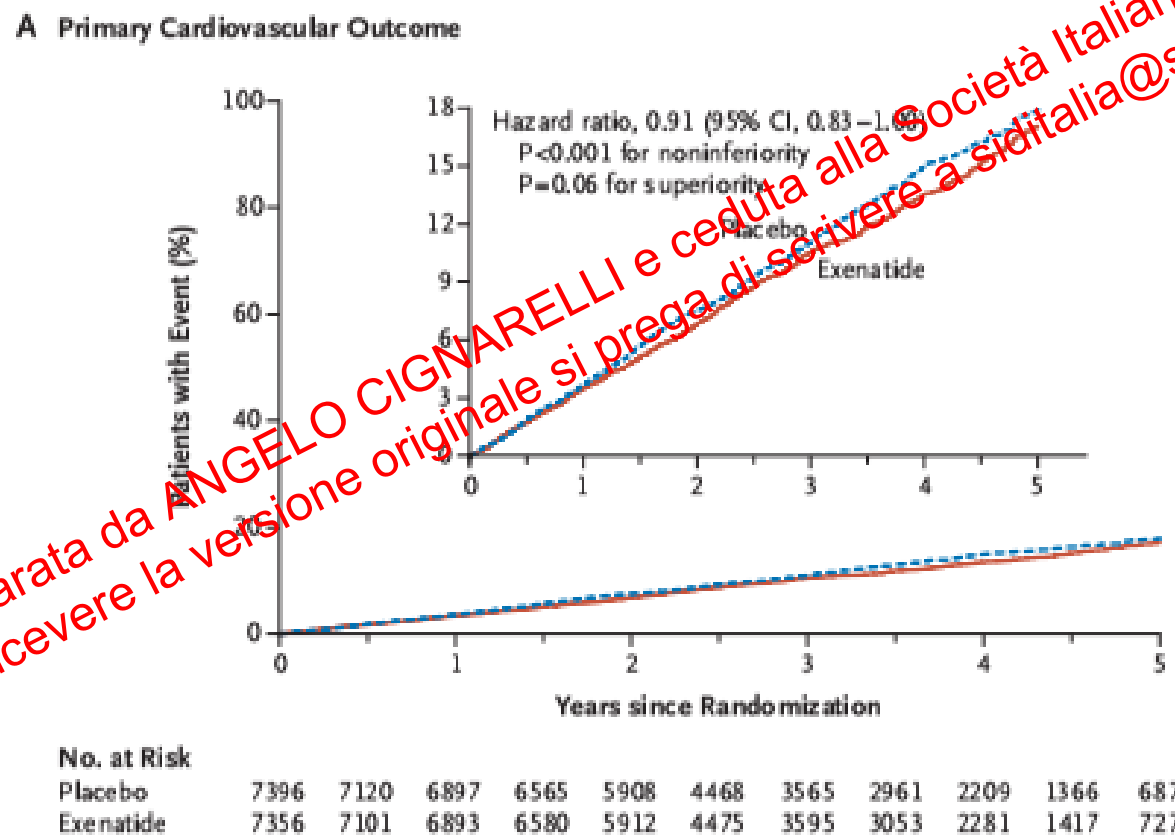



- Mortalità dal 12,8% al 9,3%
- ARR: 3,5%
- NNT: 29

*Burr et al. Volume 334, Issue 8666, 30 September 1989, Pages 757-761*

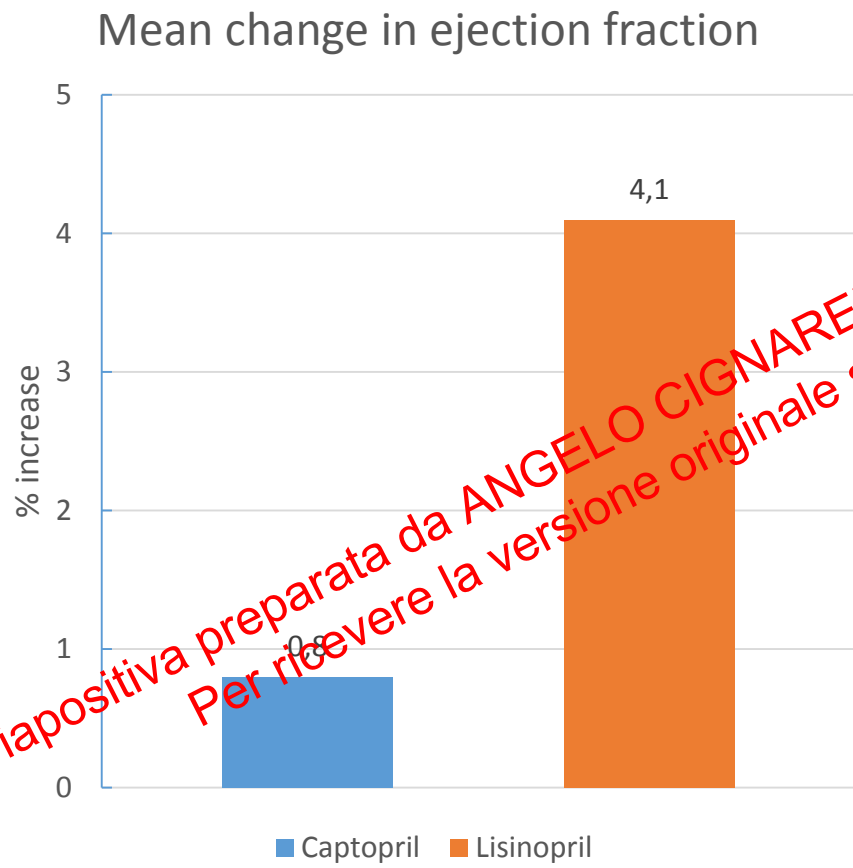
# Effects of Once-Weekly Exenatide on Cardiovascular Outcomes in Type 2 Diabetes

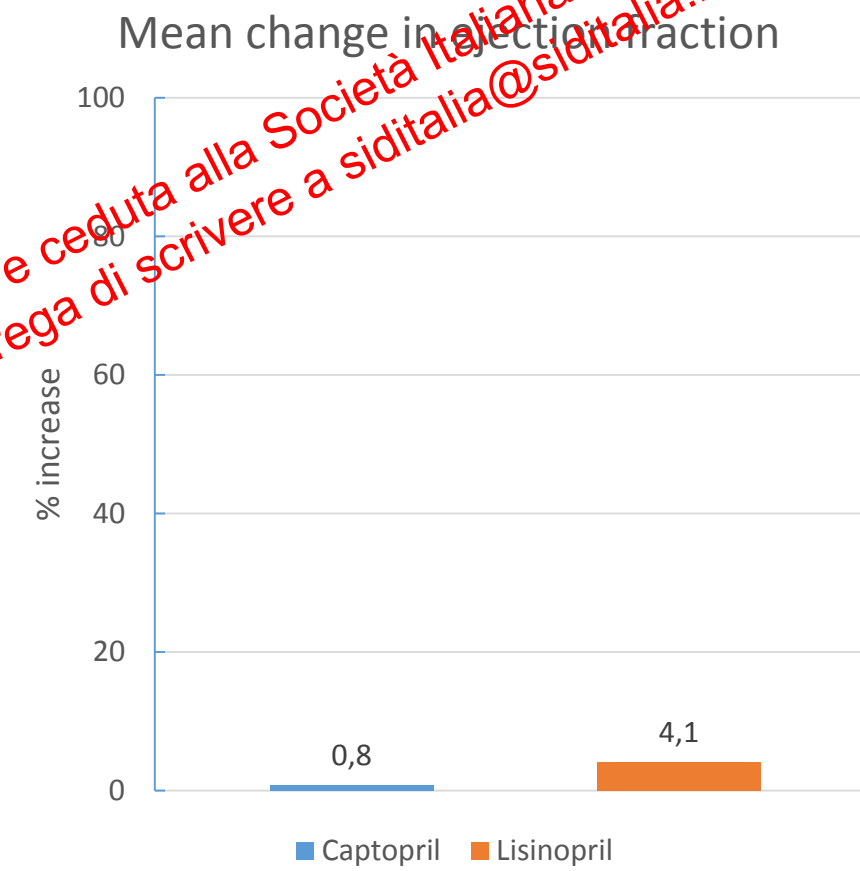





*Holman R.R., Bethel M.A., Mentz R.J., et al. | N Engl J Med 2017; 377:1228-1239*

# Short- and long-acting angiotensin-converting enzyme inhibitors: A randomized trial of lisinopril versus captopril in the treatment of congestive heart failure






*Giles et al. J Am Coll Cardiol. 1989 May;13(6):1240-7.*

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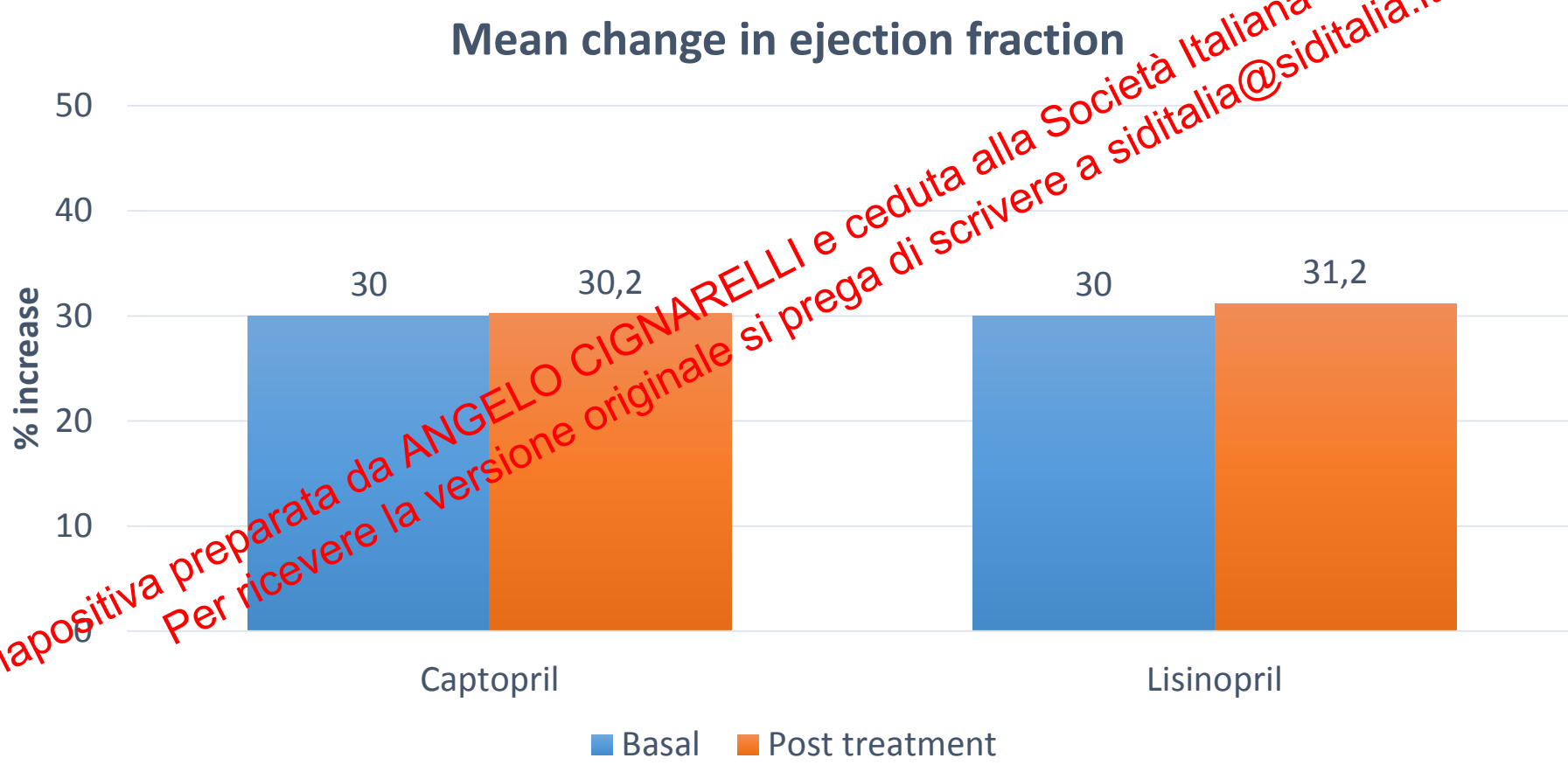
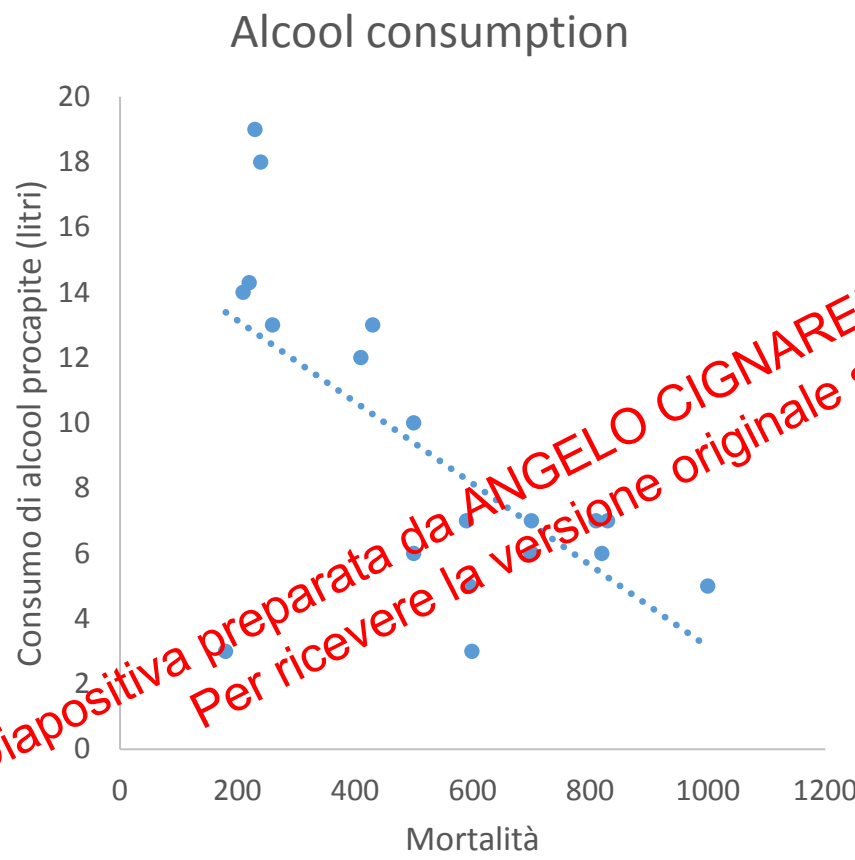
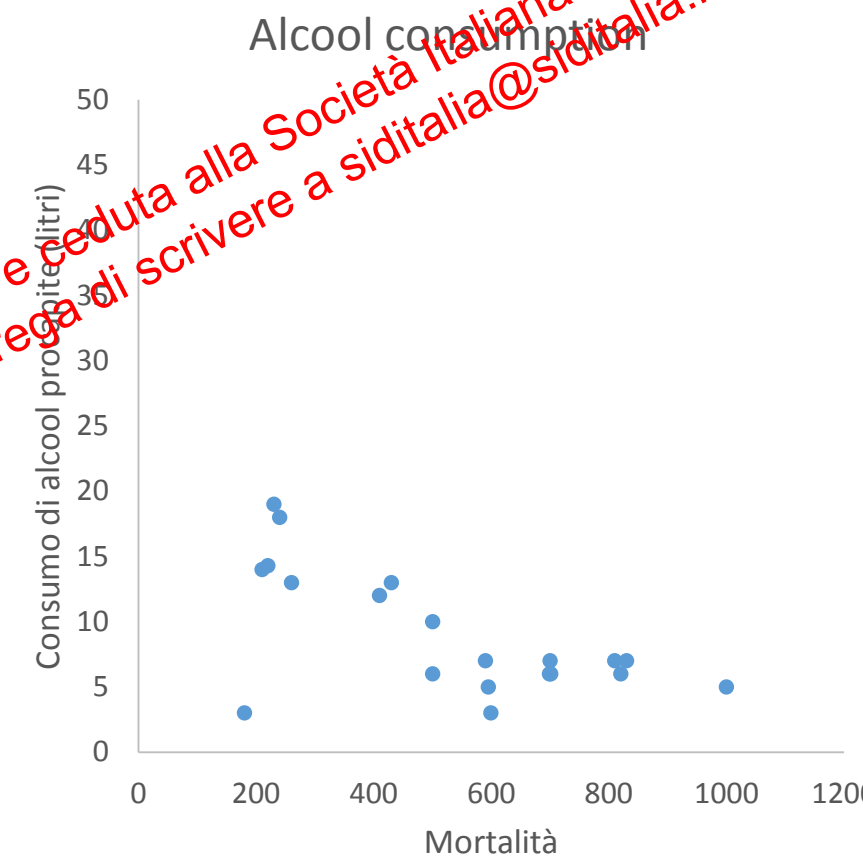





*Adapted from Giles et al. J Am Coll Cardiol. 1989 May;13(6):1240-7.*

# The relationship of alcohol consumption to atherosclerotic heart disease

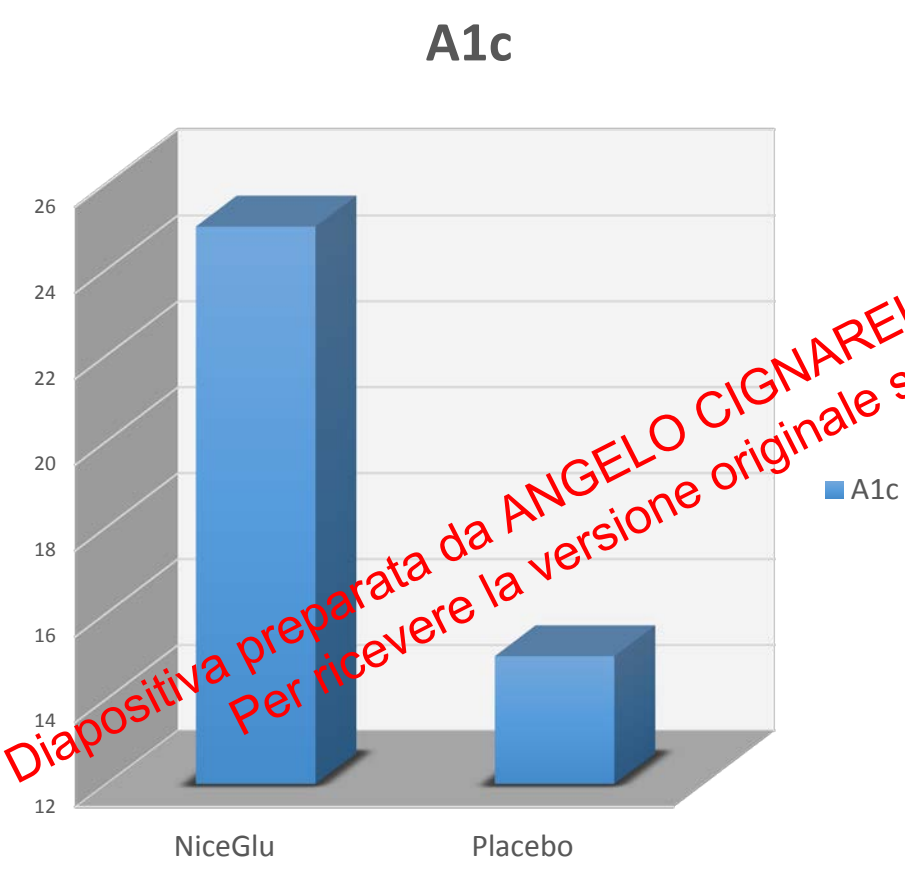


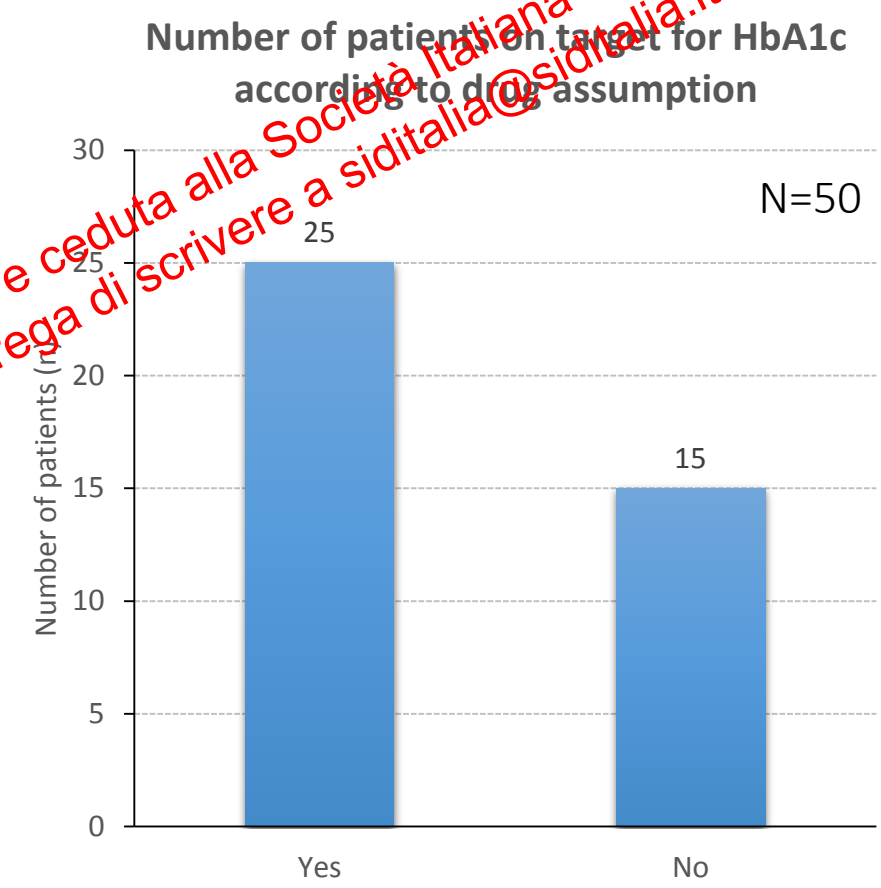






*LaPorte RE, Cresanta JL, Kuller LH. Prev Med. 1980 Jan;9(1):22-40.*

# What's wrong here?



# Summary

- Considerare se sia realmente necessario rappresentare graficamente I dati
- Considerare quale tipo di grafico possa trasferire il messaggio nella maniera più chiara possibile
- Accertarsi che il grafico non alteri il significato dei risultati
- Evitare di ingombrare




*Thank you for your attention*