C.I. di Metodologia clinica

Modulo 5.

I metodi per la sintesi e la comunicazione delle informazioni sulla salute

Come valutare la qualità delle informazioni biomediche?

Diabetes Care 29:498–503, 2006

Clinical Care/Education/Nutrition

ORIGINAL ARTICLE

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

OBJECTIVE. The purpose of this study was to assess the prevalence of cardiorenal risk factors, their management in a routine clinical setting, and the actual achievement of international guideline targets in a large cohort of type 2 diabetic patients with diabetic nephropathy.

Lo studio è osservazionale o sperimentale?

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

Diabetes Care 29:498–503, 2006

RESEARCH DESIGN AND METHODS

Come? This was a multicenter cross-sectional study.

Dove? The study group covered 21 outpatient clinics in Campania, Italy, caring for diabetic patients.

Twenty-one outpatient clinics in the Campania region of Italy (a geographic area characterized by a homogeneous prevalence of type 2 diabetes) were randomly chosen among all the regional clinics.

Quando? All consecutive subjects seen at the centers during a 6-month period from November 2002 to May 2003

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

Diabetes Care 29:498–503, 2006

RESEARCH DESIGN AND METHODS

Chi? Eligible patients were type 2 diabetic subjects with diabetic nephropathy who had regularly received outpatient care in the participating centers for at least 1 year.

Inclusion criteria were type 2 diabetes, age ≥40 years, therapy with diet and/or oral hypoglycemic agents during the first 3 years of diagnosis of diabetes, persistent albumin excretion rate …..

Exclusion criteria were diagnosis of the diabetes at <30 years of age …

28,550 diabetic patients were screened; 847 (348 male and 449 female) patients were recruited.

Metodologia clinica 5.2

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

Diabetes Care 29:498–503, 2006

RESEARCH DESIGN AND METHODS

Che cosa?

Blood pressure monitoring as a mean of three measurements taken in a sitting position after 10 min of rest and with current drug regimens.

Daily salt intake (grams per day) was calculated by dividing 24-h urinary sodium excretion by 17. Patients were defined as ex-smokers if they had ceased smoking for 6 months.

Laboratory tests were performed at each investigative site. All the laboratories checked internal quality and participated in a control program for external quality by sending random blood and urine samples to a central laboratory

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

Diabetes Care 29:498–503, 2006

Table 1—*Clinical characteristics and laboratory parameters of the participants*

Age (years)	65.7 ± 8.7
Men (%)	47
BMI (kg/m^2)	29.3 ± 4.9
Systolic blood pressure (mmHg)	136.7 ± 13.5
Diastolic blood pressure (mmHg)	78.6 ± 6.8
Duration of hypertension (years)	8.5 ± 6.7
Cigarette smoking (%)	23.6
At least one cardiovascular event (%)	23.0
Left ventricular hypertension (%)	30.9
Hospitalization in the last year (%)	21.8
Family history for cardiovascular event (%)	27.7

348/847 = 41%

Data are means ± SD unless otherwise indicated. Cardiovascular event includes acute myocardial infarction, transient ischemic attack, or stroke.

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

Diabetes Care 29:498–503, 2006

Table 1—*Clinical characteristics and laboratory parameters of the participants*

A1C (%)	7.5 ± 1.3
Serum creatinine (mg/dl)	1.2 ± 0.6
Total cholesterol (mg/dl)	196.5 ± 40
LDL cholesterol (mg/dl)	118.6 ± 34.9
HDL cholesterol (mg/dl)	47.5 ± 11.8
Triglycerides (mg/dl)	151.6 ± 77.5
Serum uric acid (mg/dl)	5.2 ± 1.4
Hemoglobin (g/dl)	13.2 ± 1.4
Micro-/macroalbuminuric (*n*)	749/98
GFR (ml/min per 1.73 m^2)	72.7 ± 24.7
Urinary sodium excretion (mmol/day)	169.8 ± 78.7

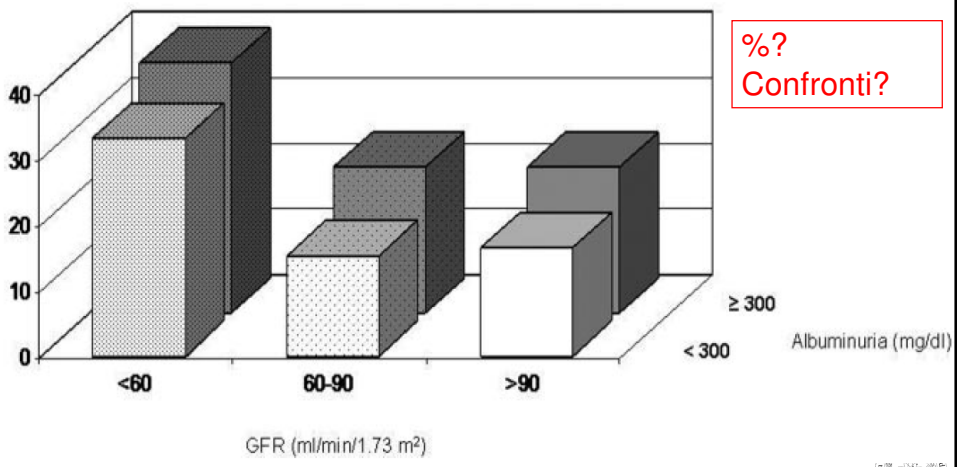
odds

Data are means ± SD unless otherwise indicated. Cardiovascular event includes acute myocardial infarction, transient ischemic attack, or stroke

Cardiovascular Risk Factors and Disease Management in Type 2 Diabetic Patients With Diabetic Nephropathy

Diabetes Care 29:498–503, 2006

Figure 1—*Prevalence of anemic patients according to World Health Organization criteria in the patients after grouping for renal function and level of albuminuria.*



%?
Confronti?

Metodologia clinica 5.2

AJH 2004; 18:1300–1305

Increased Sodium Intake Correlates With Greater Use of Antihypertensive Agents by Subjects With Chronic Kidney Disease

OBJECTIVE. The aim of this study was to assess the sodium balance in a CKD clinic and its effect on BP management.

METHODS. We retrospectively reviewed charts from June 1998 through to June 2003

Because of the retrospective nature of this study, BP measurements were not performed under a rigorous study protocol

Table 1. Demographic data of study subjects

	GFR <30 mL/min	GFR <15 mL/min
N	141	77
Age (y)	65.0 ± 1.2	66.9 ± 1.8
Male:Female	93:48	50:27
Etiology of renal failure		
Diabetes mellitus	44 (31.2%)	23 (29.9%)
Hypertension	45 (31.9%)	29 (37.7%)
Glomerulonephritis	14 (9.9%)	8 (10.4%)
Polycystic kidney disease	6 (4.3%)	4 (5.2%)
Unknown	19 (13.5%)	5 (6.5%)
Reflux	4 (2.8%)	2 (2.6%)
Other	9 (6.4%)	6 (7.8%)
Glomerular filtration rate (mL/min)	16.4 ± 0.67	10.6 ± 0.32
Normalized protein catabolic rate (g/kg/day)	0.85 ± 0.02	0.77 ± 0.02
24-hour urine sodium (mmol)	145.7 ± 4.7	124.7 ± 5.4
Systolic blood pressure (mm Hg)	141.7 ± 1.1	142.8 ± 2.7
Diastolic blood pressure (mm Hg)	75.1 ± 1.0	74.4 ± 1.4
Number of patients using diuretics	88 (69%)	51 (74%)

GFR = glomerular filtration rate. Values are mean ± standard error

DOI: 10.2169/internalmedicine.46.6056

INTERNAL MEDICINE

□ ORIGINAL ARTICLE □

The Association between Microalbuminuria and Metabolic Syndrome in the General Population in Japan: The Takahata Study

The aim of the present study was to determine the association between microalbuminuria and the components of the metabolic syndrome in the general population in Japan.

The metabolic syndrome, a multifactorial disorder, is characterized by abdominal obesity, hypertriglyceridemia, low high-density lipoprotein (HDL) cholesterol level, high blood pressure and high fasting glucose level.

DOI: 10.2169/internalmedicine.46.6056

The survey population in this study is the general population aged from 40 to 87 years in Takahata town. This region has a resident population of 15,222 adults over the age of 40 years (males: 7,109, females: 8,113). From June through November 2004, 1,055 males and 1,346 females (total, 2,401) took part in the program and agreed to join the study.

Systolic and diastolic blood pressures were determined by using a mercury manometer in a sitting position after at least 5 minutes rest. Measurement was performed twice, with the mean value used for statistical analysis.

The Association between Microalbuminuria and Metabolic Syndrome in the General Population in Japan: The Takahata Study

DOI: 10.2169/internalmedicine.46.6056

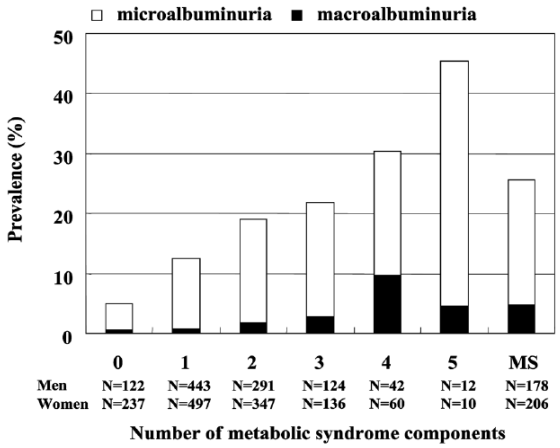


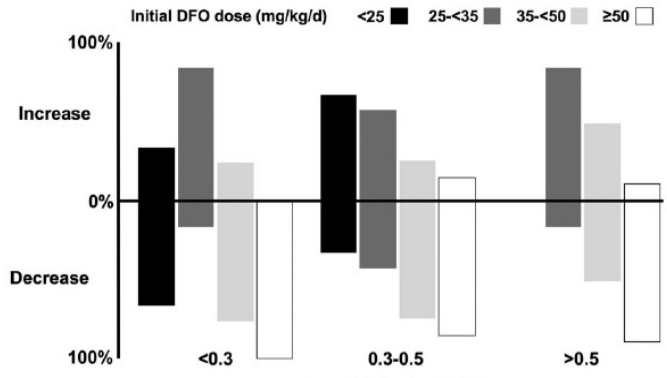
Figure 1. Prevalence of microalbuminuria according to the number of metabolic syndrome components. MS, metabolic syndrom.

Qual è la prevalenza di microalbuminuria nei pazienti con sindrome metabolica (MS)?

There was a significant positive correlation between the number of components present and the corresponding prevalence of microalbuminuria ($p<0.001$).

Effect of transfusional iron intake on response to chelation therapy in β-thalassemia major

BLOOD, 15 JANUARY 2008 • VOLUME 111, NUMBER 2



Total patients, n	3	6	17	16	3	28	68	76	0	6	31	19
Decrease in LIC, n	2	1	13	16	1	12	51	65	-	1	16	17
Decrease in LIC, %	67	17	76	100	33	43	75	86	-	17	52	89

Figure 2. Proportion of patients with increased or decreased liver iron concentration (LIC), according to iron intake and DFO dose. As with patients

AIM

To investigate the influence of transfusional iron intake on the outcome of iron chelation therapy in thalassemia major.

Endocrine Effects of Adjuvant Letrozole + Triptorelin Compared With Tamoxifen + Triptorelin in Premenopausal Patients With Early Breast Cancer

DOI: 10.1200/JCO.2007.13.5319

Table 1. Baseline Characteristics of Patients

Characteristic	Tamoxifen + Triptorelin (n = 30)		Letrozole + Triptorelin (n = 51)	
	Median	Range	Median	Range
Age, years	44	30-53	44	28-53
17-β-estradiol, pg/mL	12.4	< 5-157.8	14.0	< 5-775.5
FSH, mU/mL	63.9	3.7-117.7	59.2	3.3-125.9
LH, mU/mL	39.5	4.3-62.2	33.4	1.1-112.4
Progesterone, ng/mL	0.36	0.1-8.6	0.4	< 0.03-13.8
Testosterone, ng/mL	0.15	< 0.02-0.7	0.21	< 0.02-0.85
Androstenedione, ng/mL	1.02	0.08-49.1	1.16	0.4-5.6
DHEA-S, μg/dL	129.8	7.8-363.1	156.2	29.0-337.9
Cortisol, μg/dL	11.9	0.4-24.8	10.4	2.7-30.4
ACTH, pg/mL	17.0	5.2-377.4	19.0	2.2-215.6
Aldosterone, pg/mL	113.35	27.1-828.7	66.4	151.1-382.1

Endocrine Effects of Adjuvant Letrozole Compared With Tamoxifen in Hormone-Responsive Postmenopausal Patients With Early Breast Cancer: The HOBOE Trial

DOI: 10.1200/JCO.2008.18.6213

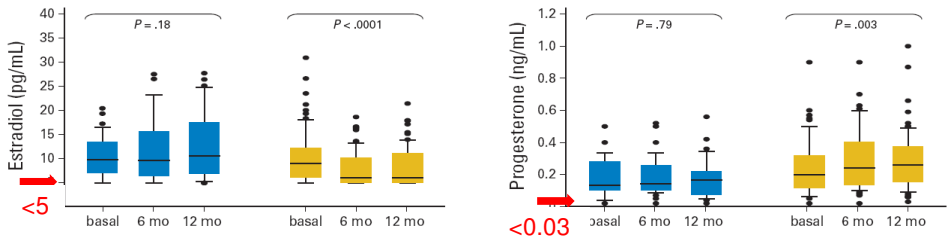


Fig 2. Graphical representation of distribution of hormones by treatment group (tamoxifen [blue] *vs* letrozole [yellow]) at baseline, 6 months, and 12 months among patients with all values available. Box plots show (from up to down): higher outliers (dots), 95 degrees percentile (line), 75 degrees percentile (upper side of the box), median (line within the box), 25 degrees percentile (lower side of the box), 5 degrees percentile (line), lower outliers (dots). P values for change over time are calculated by the Friedman analysis of variance test.

Haematologica 2005; 90:1309-1314

Thalassemia Major • Research Paper

Combined therapy with deferiprone and desferrioxamine in thalassemia major

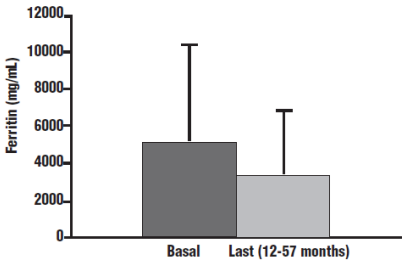


Figure 2. Mean ferritin levels in patients on combination therapy.

Statistical methods

A paired t-test was performed to examine the changes in serum ferritin and ALT levels between baseline and last results

Ferritin decreased from 5243±2345 to 3439±2446 ng/mL, $p<0.001$).

Combined therapy with deferiprone and desferrioxamine in thalassemia major

Haematologica 2005; 90:1309-1314

Design and Methods. We used combined therapy with desferrioxamine and deferiprone to treat 79 patients

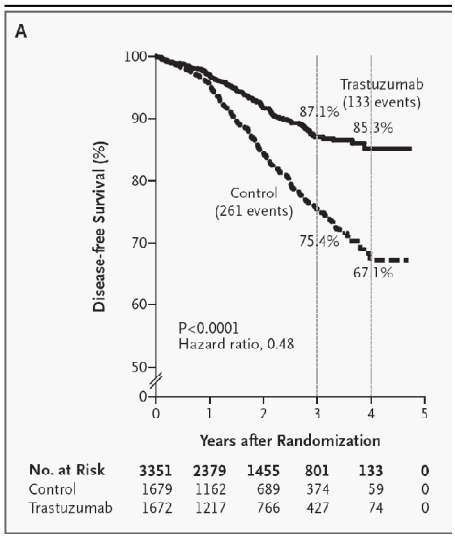
Results. The efficacy of combined therapy was evaluated in 64 patients treated for at least 12 months.

Withdrawals

Thirty-four patients dropped out of the study after 1-38 months of treatment. Thirteen patients (13%) withdrew because of adverse events, … eight patients withdrew because of a medical decision, … 13 patients withdrew voluntarily.

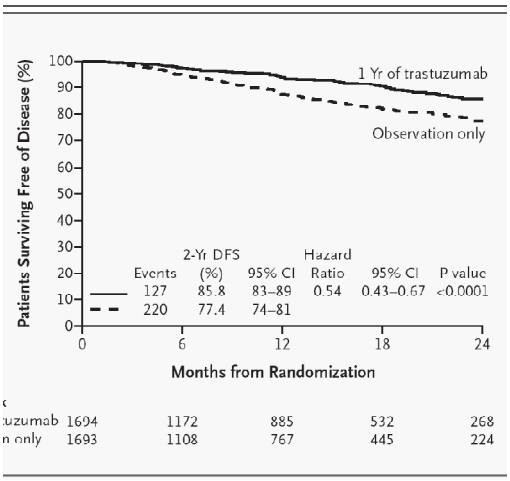
Trastuzumab plus Adjuvant Chemotherapy for Operable HER2-Positive Breast Cancer

N Engl J Med 2005;353:1673-84.

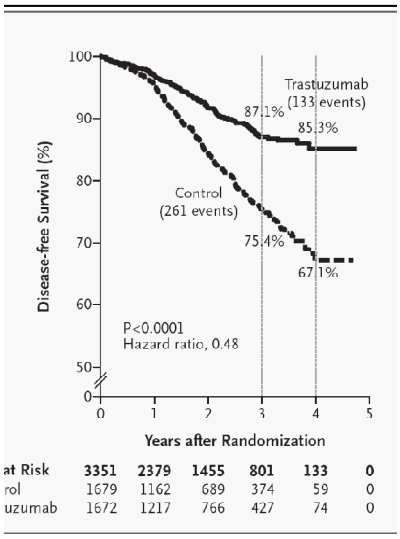


Trastuzumab after Adjuvant Chemotherapy in HER2-Positive Breast Cancer

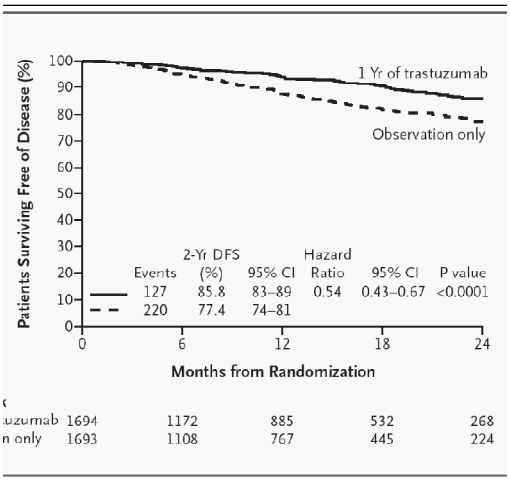
N Engl J Med 2005;353:1659-72.



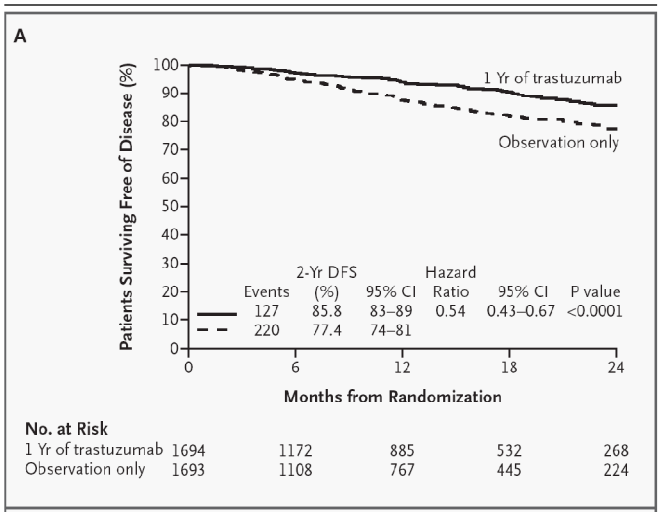
N Engl J Med 2005;353:1673-84.



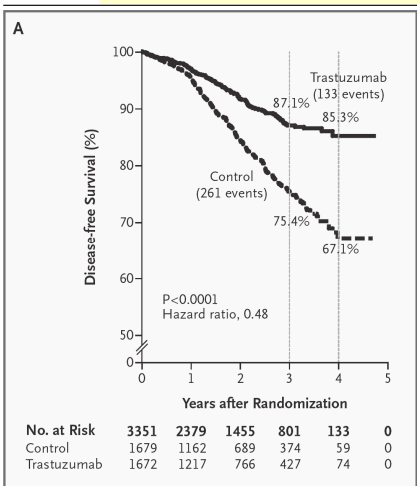
N Engl J Med 2005;353:1659-72.



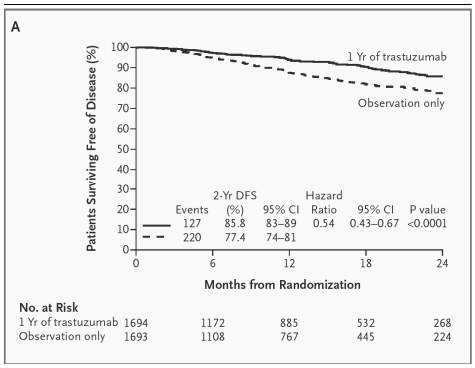
Uguali o diverse?



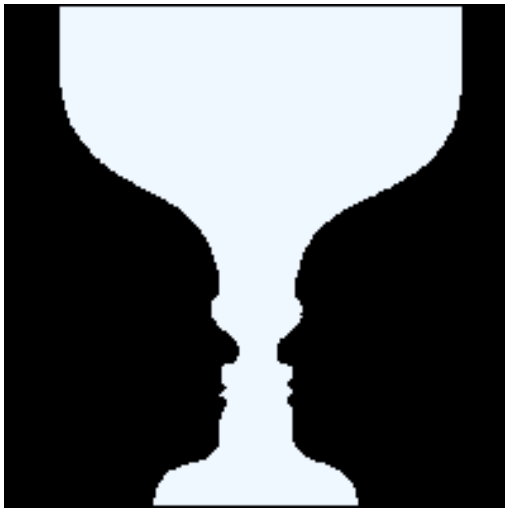
Uguali o diverse?



NSABP/NCCTG,
NEJM 2005; 353: 1673-84

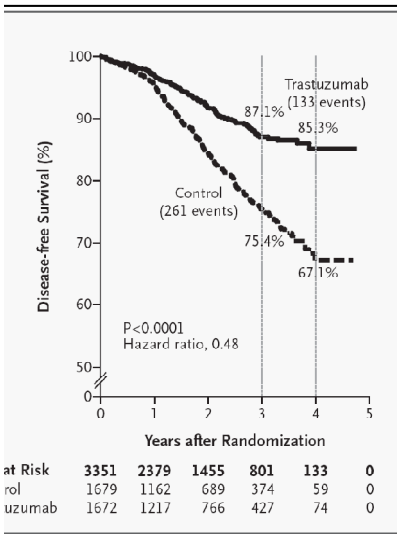


HERA trial,
NEJM 2005; 353: 1659-72

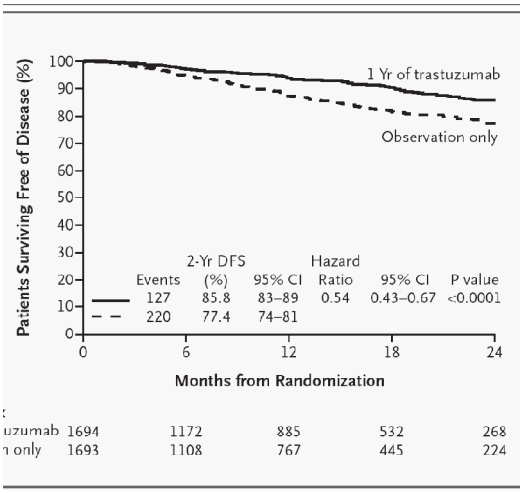


Un bicchiere o due profili?

N Engl J Med 2005;353:1673-84.



N Engl J Med 2005;353:1659-72.



Uguali o diverse?

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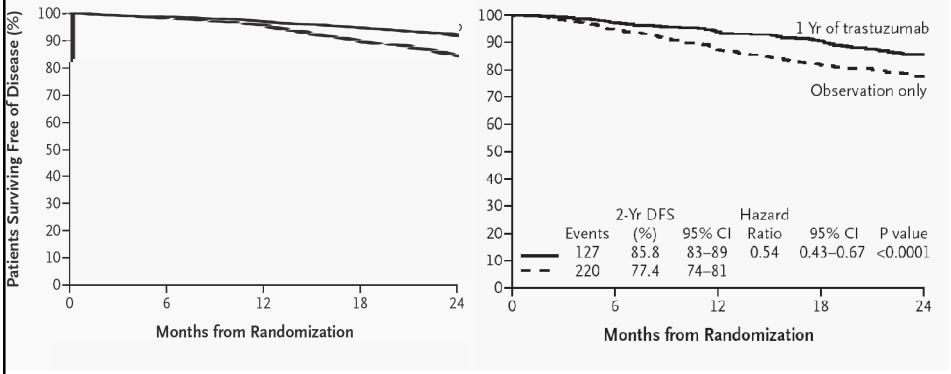

Uguali o diverse?

Metodologia clinica 5.2