Material y Métodos

Pacientes y Métodos

Material y Métodos

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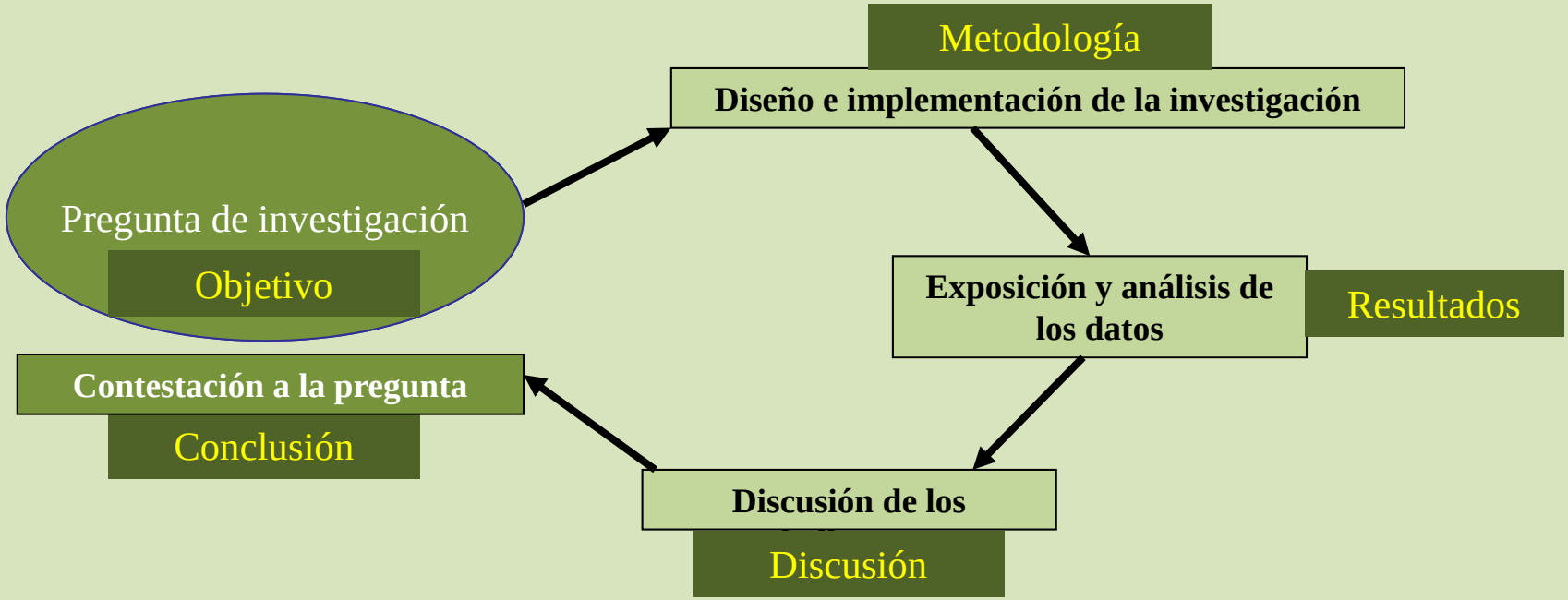
¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

Todo gira alrededor de la pregunta planteada en la investigación…



Estructura del manuscrito

- ***Titulo // página del titulo***
- ***Resumen***
- ***Introducción // Objetivo***
- ***Material y métodos // Pacientes y métodos***
- ***Resultados***
- ***Discusión***
- ***Bibliografía***
- ***Tablas y/o figuras***

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

- Debe dar “validez” al estudio
- Emplear sub-apartados para organizar la sección si fuese necesario
- Facilitar los suficentes datos como para que el estudio pudiera ser reproducido por otros:
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    d) Intervención
    e) Mediciones (primarias y secundarias)
    f) Metodología utilizada para “medir”
    g) Forma de registrar datos
    h) Análisis de los datos (estadística)
- Detallar los procedimientos referentes a la aprovación por Comités Éticos y de Consentimiento informado por parte de pacientes.
- Redactar en pretérito.
- **¡¡ Sin resultados !!**

Material y Métodos

Pacientes y Métodos

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- Redactar en pretérito.
- **¡¡ Sin resultados !!**

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS	**ICMJE:** International Committee of Medical Journal Editors	http://www.icmje.org/
Council of Science Editors	**CSE:** Council of Science Editors	http://www.councilscienceeditors.org/
WAME world association of medical editors	**WAME:** World Association of Medical Editors	http://www.wame.org/
COPE COMMITTEE ON PUBLICATION ETHICS	**COPE:** Committee on Publication Ethics	http://publicationethics.org/
ORI research integrity	**ORI:** Office forResearch Integrity	http://ori.dhhs.gov/

CONSORT CONSORT TRANSPARENT REPORTING OF TRIALS	**CONSORT** Statement: Transparent reporting of trials	http://www.consort-statement.org/
STROBE Statement Strengthening the reporting of observational studies in epidemiology	**STROBE** Statement: Strengthening the reporting of observational studies in epidemiology	http://www.strobe-statement.org/
SQUIRE	**SQUIRE:** Standards for Quality Improvement Reporting Excellence	http://www.squire-statement.org/
STARD	**STARD** Statement: STAndards for the Reporting of Diagnostic accuracy studies	http://www.stard-statement.org/
	STREGA: STrengthening the REporting of Genetic Associations	http://www.medicine.uottawa.ca/public-health-genomics/web/eng/strega.html

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

http://www.strobe-statement.org/index.php?id=strobe-home

STROBE Statement—Items to be included when reporting observational studies in a conference abstract

Item	Recommendation
Title	Indicate the study's design with a commonly used term in the title (e.g cohort, case-control, cross sectional)
Authors	Contact details for the corresponding author
Study design	Description of the study design (e.g cohort, case-control, cross sectional)
Objective	Specific objectives or hypothesis
Methods	
Setting	Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes (e.g., prevalence at age 18, 1998-2007).
Participants	*Cohort study*—Give the most important eligibility criteria, and the most important sources and methods of selection of participants. Describe briefly the methods of follow-up *Case-control study*—Give the major eligibility criteria, and the major sources and methods of case ascertainment and control selection *Cross-sectional study*—Give the eligibility criteria, and the major sources and methods of selection of participants
	Cohort study—For matched studies, give matching and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	Clearly define primary outcome for this report.
Statistical methods	Describe statistical methods, including those used to control for confounding
Results	
Participants	Report Number of participants at the beginning and end of the study
Main results	Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals
Conclusions	General interpretation of study results

The STROBE statement-checklist of items that should be included in reports of observational studies

STROBE Statement
Strengthening the reporting of observational studies in epidemiology

http://www.strobe-statement.org/index.php?id=available-checklists

Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

CONSORT TRANSPARENT REPORTING of TRIALS

http://www.consort-statement.org/home/

K.F. Schulz et al. / Journal of Clinical Epidemiology 63 (2010) 834e840 835

CONSORT 2010 checklist of information to include when reporting a randomised trial*

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 pre-specified 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
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

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

- Debe dar “validez” al estudio
- Facilitar los suficentes datos como para que el estudio pudiera ser reproducido por otros:
  - a) Diseño
  - b) Entorno (t… …ón
  - c) Sujetos es… …ó
  - d) Intervenci…
  - e) Medicione…
  - f) Metodolog…
  - g) Forma de …
  - h) Análisis de…
- Emplear sub-apart… …cción si fuese necesario
- Detallar los procedimientos referentes a la aprovación por Comités Éticos y de Consentimiento informado por parte de pacientes.
- Redactar en pretérito.
- ¡¡ **Sin resultados !!**

Tipo de estudio

- **Observacional:**
  - **tranversal**
  - **longitudinal**
  - **serie de casos**
  - **cohortes**
  - **casos y controles**
- **Intervención controlada**
  - **centros**
  - **aleatorización**
  - **placebo controlado**
- **Cualitativo**

Study design	4	Present key elements of study design early in the paper
		Description of trial design (such as parallel, factorial) including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Examples of Trial Design

This page contains Examples of CONSORT item 3a - Description of trial design (such as parallel, factorial) including allocation ratio.

You can submit your own Examples here.

Read more explanation of CONSORT item 3a

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

"This was a multicenter, stratified (6 to 11 years and 12 to 17 years of age, with imbalanced randomisation [2:1]), double-blind, placebo-controlled, parallel-group study conducted in the United States (41 sites)."		
Blumer JL, Findling RL et al	Controlled clinical trial of zolpidem for the treatment of insomnia associated with attention-deficit/hyperactivity disorder in children 6 to 17 years of age.	Pediatrics 2009;123:e770-e776.

Material y Métodos

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  d) Intervenci…
  e) Mediciones (primarias y sec…
  f) Metodología utilizada para “medir”
  g) Forma de registrar datos
  h) Análisis de los datos (estadística)
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- Redactar en pretérito.
- ¡¡ **Sin resultados !!**

- **temporal**
- **espacial**
- **asistencial**

Setting 5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	

Examples of Study Settings

This page contains examples of CONSORT Item 4b - Study Settings.

Read more explanation of CONSORT Item 4b.

You can submit your own Examples here.

http://www.consort-statement.org/home/

CONSORT
TRANSPARENT REPORTING of TRIALS

The study took place at the antiretroviral therapy clinic of Queen Elizabeth Central Hospital in Blantyre, Malawi, from January 2006 to April 2007. Blantyre is the major commercial city of Malawi, with a population of 1 000 000 and an estimated HIV prevalence of 27% in adults in 2004.		
Ndekha MJ, van Oosterhout JJ, Zijlstra EE, Manary M, Saloojee H, Manary MJ.	Supplementary feeding with either ready-to-use fortified spread or corn-soy blend in wasted adults starting antiretroviral therapy in Malawi: randomised, investigator blinded, controlled trial.	BMJ 2009;338:1867-75.

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

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  c) Sujetos estudiados
  d) Mediciones (primaria
  e) Metodología utilizada
  f) Forma de registrar d
  g) Análisis de los datos
- Emplear sub-apartados par
- Detallar los procedimientos
  Consentimiento informado p
- Redactar en pretérito.
- **¡¡ Sin resultados !!**

- **Criterios de inclusión**
  - **edad**
  - **sexo**
  - **raza**
  - **características clínicas**
  - **… etcétera …**
- **Criterios de exclusión**
  - **edad**
  - **sexo**
  - **raza**
  - **características clínicas**
  - **… etcétera …**
- Distribución en grupos
- Aleatorización

(a) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
(b) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case

Eligibility criteria for participants
Settings and locations where the data were collected

Examples of Participants

This page contains examples of CONSORT Item 4a - Participants.

You can submit your own Examples here.

Read more explanation of CONSORT Item 4a.

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

Eligible participants were all adults aged 18 or over with HIV who met the eligibility criteria for antiretroviral therapy according to the Malawian national HIV treatment guidelines (WHO clinical stage III or IV or any WHO stage with a CD4 count <250/mm3) and who were starting treatment with a BMI <18.5. Exclusion criteria were pregnancy and lactation or participation in another supplementary feeding programme.		
Ndekha MJ, van Oosterhout JJ, Zijlstra EE, Manary M, Saloojee H, Manary MJ.	Supplementary feeding with either ready-to-use fortified spread or corn-soy blend in wasted adults starting antiretroviral therapy in Malawi: randomised, investigator blinded, controlled trial.	BMJ 2009;338:1867-75.

Material y Métodos

Pacientes y Métodos

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  e) Mediciones (primarias y secu
  f) Metodología utilizada para “
  g) Forma de registrar datos
  h) Análisis de los datos (estadí

¿ … ?

- **Modalidad**
- **Dosis**
- **Intervalo horario**
- **Duración**
- **Asignación a grupos**

The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

- Emplear sub-apartados para organizar la sección si fuese necesario
- Detallar los procedimientos referentes a la aprovación por Comités Éticos y de Consentimiento informado por parte de pacientes.
- Redactar en pretérito.
- **¡¡ Sin resultados !!**

Examples of Interventions

This page contains examples of CONSORT Item 5 - Interventions.

You can submit your own Examples here.

Read more explanation of CONSORT Item 5.

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

In POISE, patients received the first dose of the study drug (ie, oral extended-release metoprolol 100 mg or matching placebo) 2-4 h before surgery. Study drug administration required a heart rate of 50 bpm or more and a systolic blood pressure of 100 mm Hg or greater; these haemodynamics were checked before each administration. If, at any time during the first 6 h after surgery, heart rate was 80 bpm or more and systolic blood pressure was 100 mm Hg or higher, patients received their first postoperative dose (extended-release metoprolol 100 mg or matched placebo) orally. If the study drug was not given during the first 6 h, patients received their first postoperative dose at 6 h after surgery. 12 h after the first postoperative dose, patients started taking oral extended-release metoprolol 200 mg or placebo every day for 30 days. If a patient's heart rate was consistently below 45 bpm or their systolic blood pressure dropped below 100 mm Hg, study drug was withheld until their heart rate or systolic blood pressure recovered; the study drug was then restarted at 100 mg once daily. Patients whose heart rate was consistently 45-49 bpm and systolic blood pressure exceeded 100 mm Hg delayed taking the study drug for 12 h.		
Devereaux PJ, Yang H, Yusuf S, Guyatt G, Leslie K, Villar JC, et al.	Effects of extended-release metoprolol succinate in patients undergoing non-cardiac surgery (POISE trial): a randomised controlled trial.	Lancet 2008;371:1839-47.

Patients were randomly assigned to receive a custom-made neoprene splint to be worn at night or to usual care. The splint was a rigid rest orthosis recommended for use only at night. It covered the base of the thumb and the thenar eminence but not the wrist (Figure 1). Splints were made by 3 trained occupational therapists, who adjusted the splint for each patient so that the first web could be opened and the thumb placed in opposition with the first long finger. Patients were encouraged to contact the occupational therapist if they felt that the splint needed adjustment, pain increased while wearing the splint, or they had adverse effects (such as skin erosion). Because no treatment can be considered the gold standard in this situation, patients in the control and intervention groups received usual care at the discretion of their physician (general practitioner or rheumatologist). We decided not to use a placebo because, to our knowledge, no placebo for splinting has achieved successful blinding of patients, as recommended.		
Rannou F, Dimet J, Boutron I, Baron G, Fayad F, Macé Y, et al.	Splint for base-of-thumb osteoarthritis: a randomized trial.	Ann Intern Med 2009;150:661-9.

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

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  f) Forma de reg
  g) Análisis de lo
- Emplear sub-apartad
- Detallar los procedim s y de Consentimiento informado por parte de pacientes.
- Redactar en pretérito.
- **¡¡ Sin resultados !!**

Mediciones Primarias
- las necesarias para dar respuesta al objetivo principal

Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable

Mediciones secundarias
- las necesarias para dar respuesta al objetivo secundario

Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Otras medidas
- cualquiera potencialmente “confusora” o “influyente” sobre las primarias o secundarias

Examples of Outcomes

This page contains examples of CONSORT Item 6a - Outcomes.

You can submit your own Examples here.

Read more explanation of CONSORT Item 6a.

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

The primary endpoint with respect to efficacy in psoriasis was the proportion of patients achieving a 75% improvement in psoriasis activity from baseline to 12 weeks as measured by the PASI [psoriasis area and severity index] Additional analyses were done on the percentage change in PASI scores and improvement in target psoriasis lesions.		
Mease PJ, Goffe BS, Metz J, VanderStoep A, Finck B, Burge DJ.	Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomised trial.	Lancet. 2000;356:385-90.

The original primary endpoint was all-cause mortality, but, during a masked analysis, the data and safety monitoring board noted that overall mortality was lower than had been predicted and that the study could not be completed with the sample size and power originally planned. The steering committee therefore decided to adopt co-primary endpoints of all-cause mortality (the original primary endpoint), together with all-cause mortality or cardiovascular hospital admissions (the first prespecified secondary endpoint).		
Dargie HJ.	Effect of carvedilol on outcome after myocardial infarction in patients with left-ventricular dysfunction: the CAPRICORN randomised trial.	Lancet 2001;357:1385-90.

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

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  f) Metodología utilizada para “medir”
  g) Forma de registrar datos
  h) Análisis de los datos (estadística)
- Emplear sub-apartados para organizar la sección si fuese necesario
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- Redactar en pretérito.
- ¡¡ **Sin resultados !!**

- **Tipos de variables**
- **Categorizaciones**
- **Personas que registran**
- **Bases de datos**

For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

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  e) Mediciones (primarias y secundar
  f) Metodología utilizada para “medir”
  g) Forma de registrar datos
  h) Análisis de los datos (estadística)
- Emplear sub
- Detallar los p
  Consentimie
- Redactar en
- ¡¡ **Sin resultados !!**

(*a*) Describe all statistical methods, including those used to control for confounding
(*b*) Describe any methods used to examine subgroups and interactions
(*c*) Explain how missing data were addressed
(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed
Case-control study—If applicable, explain how matching of cases and controls was addressed
Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy
(*e*) Describe any sensitivity analyses

- **Metodologías estadística básica**
- **Metodología estadística analítica**
- **Criterios de interpretación**
  - **p.ej. “intención de tratar”,**
  - **“tratamiento observado”,**
  - **“pérdidas = fallo”,**
  - **“arrastre de datos”**
  - **…etcétera ..**

Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
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

http://www.consort-statement.org/home/

CONSORT
TRANSPARENT REPORTING of TRIALS

Examples of Statistical Methods

This page contains examples of CONSORT Item 12a - Statistical Methods.

You can submit your own Examples here.

Read more explanation of CONSORT Item 12a

The primary endpoint was change in bodyweight during the 20 weeks of the study in the intention-to-treat population ... Secondary efficacy endpoints included change in waist circumference, systolic and diastolic blood pressure, prevalence of metabolic syndrome ... We used an analysis of covariance (ANCOVA) for the primary endpoint and for secondary endpoints waist circumference, blood pressure, and patient-reported outcome scores; this was supplemented by a repeated measures analysis. The ANCOVA model included treatment, country, and sex as fixed effects, and bodyweight at randomisation as covariate. We aimed to assess whether data provided evidence of superiority of each liraglutide dose to placebo (primary objective) and to orlistat (secondary objective.

Astrup A, Rössner S, Van Gaal L, Rissanen A, Niskanen L, Al HM, et al.	Effects of liraglutide in the treatment of obesity: a randomised, double-blind, placebo-controlled study.	Lancet 2009;374:1606-16.

Examples of Blinding

This page contains examples of CONSORT Item 11a - Blinding.

You can submit your own Examples here.

Read more explanation of CONSORT Item 11a.

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

Whereas patients and physicians allocated to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation.		
Smith SA, Shah ND, Bryant SC, Christianson TJ, Bjornsen SS, Giesler PD, et al.	Chronic care model and shared care in diabetes: randomized trial of an electronic decision support system.	Mayo Clin Proc 2008;83:747-57.

Blinding and equipoise were strictly maintained by emphasising to intervention staff and participants that each diet adheres to healthy principles, and each is advocated by certain experts to be superior for long-term weight-loss. Except for the interventionists (dieticians and behavioural psychologists), investigators and staff were kept blind to diet assignment of the participants. The trial adhered to established procedures to maintain separation between staff that take outcome measurements and staff that deliver the intervention. Staff members who obtained outcome measurements were not informed of the diet group assignment. Intervention staff, dieticians and behavioural psychologists who delivered the intervention did not take outcome measurements. All investigators, staff, and participants were kept masked to outcome measurements and trial results.		
Sacks FM, Bray GA, Carey VJ, Smith SR, Ryan DH, Anton SD, et al.	Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates.	N Engl J Med 2009;360:859-73.

Examples of Randomisation Implementation

Read more explanation of CONSORT Item 10.

This page contains examples of CONSORT Item 10 - Randomisation Implementation.

You can submit your own Examples here.

Determination of whether a patient would be treated by streptomycin and bed-rest (S case) or by bed-rest alone (C case) was made by reference to a statistical series based on random sampling numbers drawn up for each sex at each centre by Professor Bradford Hill; the details of the series were unknown to any of the investigators or to the co-ordinator ... After acceptance of a patient by the panel, and before admission to the streptomycin centre, the appropriate numbered envelope was opened at the central office; the card inside told if the patient was to be an S or a C case, and this information was then given to the medical officer of the centre.

Not stated	Streptomycin treatment of pulmonary tuberculosis: a Medical Research Council investigation.	BMJ 1948;2:769-82.

Details of the allocated group were given on coloured cards contained in sequentially numbered, opaque, sealed envelopes. These were prepared at the NPEU and kept in an agreed location on each ward. Randomisation took place at the end of the 2nd stage of labour when the midwife considered a vaginal birth was imminent. To enter a women into the study, the midwife opened the next consecutively numbered envelope.

McCandlish R, Bowler U, van Asten H, Berridge G, Winter C, Sames L, et al.	A randomised controlled trial of care of the perineum during second stage of normal labour.	Br J Obstet Gynaecol 1998;105:1262-72.

Block randomisation was by a computer generated random number list prepared by an investigator with no clinical involvement in the trial. We stratified by admission for an oncology related procedure. After the research nurse had obtained the patient's consent, she telephoned a contact who was independent of the recruitment process for allocation consignment.

Webster J, Clarke S, Paterson D, Hutton A, van Dyk S, Gale C, et al.	Routine care of peripheral intravenous catheters versus clinically indicated replacement: randomised controlled trial.	BMJ 2008;337:a339.

http://www.consort-statement.org/home/

CONSORT
TRANSPARENT REPORTING of TRIALS

Material y Métodos

Pacientes y Métodos

¿ Cómo se planificó evaluar la pregunta de investigación planteada en el estudio ?

- Debe dar “validez” al estudio
- Facilitar los suficentes datos como para que el estudio pudiera ser reproducido por otros:
    a) Diseño
    b) Entorno (temporal, espacial y asistencial)
    c) Sujetos estudiados (criterios de inclusión y de exclusión)
    d) Intervención
    e) Mediciones (primarias y secundarias)
    f) Metodología utilizada para “medir”
    g) Forma de registrar datos
    h) Análisis de los datos (estadística)
- Emplear sub-apartados para organizar la sección si fuese necesario
- Detallar los procedimientos referentes a la aprovación por Comités Éticos y de Consentimiento informado por parte de pacientes.
- Redactar en pretérito.
- **¡¡ Sin resultados !!**

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STARD checklist for the reporting of studies of diagnostic accuracy.

First official version, January 2003.

STARD Statement

STAndards for the Reporting of Diagnostic accuracy studies

http://www.stard-statement.org/

METHODS		
Participants	3	Describe the study population: The inclusion and exclusion criteria, setting and locations where the data were collected.
	4	Describe participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the (evaluated) index tests or the (golden) reference standard?
	5	Describe participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in items 3 and 4? If not, specify how participants were further selected.
	6	Describe data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?
Test methods	7	Describe the reference standard and its rationale.
	8	Describe technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.
	9	Describe definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.
	10	Describe the number, training and expertise of the persons executing and reading the index tests and the reference standard.
	11	Describe whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.
Statistical methods	12	Describe methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).
	13	Describe methods for calculating test reproducibility, if done.

SQUIRE Guidelines (Standards for Quality Improvement Reporting Excellence)

Version 2.62 SHORT – 10/2/08

SQUIRE Standards for Quality Improvement Reporting Excellence

http://www.squire-statement.org/

Methods	*What did you do?*
7. Ethical issues	• Describes the ethical aspects of implementing and studying the improvement, and how ethical concerns were addressed
8. Setting	• Specifies how relevant context factors were identified and characterized
9. Planning the intervention	• Describes the intervention itself; why it was chosen; and what was to be done initially, and by whom
10. Planning the study of the intervention	• Describes plans for assessing how effectively the intervention was implemented; mechanisms by which intervention components were expected to cause changes; study design chosen; and efforts to maximize internal and external validity
11. Methods of evaluation	• Describes instruments used to assess effectiveness of implementation; contributions of intervention components and context factors to intervention effectiveness, primary and secondary outcomes; validation of instruments; methods for assuring data quality and adequacy
12. Analysis	• Describes qualitative and quantitative analytic methods; variability expected in implementing the intervention; expected change in outcomes; power of study to detect such effects; methods used to demonstrate effects of time as a variable

Sociedad de Medicina Interna de Madrid-Castilla La Mancha

Revista Clínica Española

XXXII CONGRESO NACIONAL DE LA SOCIEDAD ESPAÑOLA DE MEDICINA INTERNA

SEMI SOCIEDAD ESPAÑOLA DE MEDICINA INTERNA

26-28 Octubre 2011

Costa Meloneras

Palacio de Congresos Expomeloneras
Maspalomas, San Bartolomé de Tirajana
Gran Canaria, Las Palmas

Resultados

¿Qué datos se han encontrado en el estudio?

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- Diferenciar los resultados correspondientes a la “medición principal” de los de las “mediciones secundarias”.
- ¿Cuál es la mejor manera de presentar los datos: texto, tabla ó figura.
- Relaciona los resultados presentados con la metología utilizada para emplearla, pero no la describas nuevamente.
- **¡¡ No discutir los datos todavía !!**
- !!! Cuidado con términos como « significativo » y calificativos poco concretos de los datos (algunos – muchas – pocas – bastante)

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The STROBE statement-checklist of items that should be included in reports of observational studies

STROBE Statement
Strengthening the reporting of observational studies in epidemiology

http://www.strobe-statement.org/index.php?id=available-checklists

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

CONSORT TRANSPARENT REPORTING of TRIALS

http://www.consort-statement.org/home/

K.F. Schulz et al. / Journal of Clinical Epidemiology 63 (2010) 834e840 835

CONSORT 2010 checklist of information to include when reporting a randomised trial*

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% confidence interval)
	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 pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[28])

STARD checklist for the reporting of studies of diagnostic accuracy.

First official version, January 2003.

STARD Statement

STAndards for the Reporting of Diagnostic accuracy studies

http://www.stard-statement.org/

RESULTS		
Participants	14	Report when study was done, including beginning and ending dates of recruitment.
	15	Report clinical and demographic characteristics of the study population (e.g. age, sex, spectrum of presenting symptoms, co morbidity, current treatments, recruitment centers).
	16	Report the number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and/or the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended).
Test results	17	Report time interval from the index tests to the reference standard, and any treatment administered between.
	18	Report distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.
	19	Report a cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.
	20	Report any adverse events from performing the index tests or the reference standard.
Estimates	21	Report estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).
	22	Report how indeterminate results, missing responses and outliers of the index tests were handled.
	23	Report estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.
	24	Report estimates of test reproducibility, if done.

SQUIRE Guidelines (Standards for Quality Improvement Reporting Excellence)

Version 2.62 SHORT – 10/2/08

SQUIRE Standards for Quality Improvement Reporting Excellence

http://www.squire-statement.org/

Results	*What did you find?*
13. Outcomes	a) Nature of setting and improvement intervention • Characterizes elements of setting, and structures and patterns of care that provided the context; actual course of the intervention; degree of success in implementing the intervention; evolution of the initial plan, and lessons learned from that evolution b) Changes in care process and clinical outcomes associated with the intervention • Presents data on changes in care delivery process and patient outcomes; benefits, harms, unexpected results, problems, failures; evidence on strength of the association between outcomes and intervention/context factors; summary of missing data for intervention and outcomes

Fig 2. Flow diagram of a multicentre trial of fractional flow reserve versus angiography for guiding percutaneous coronary intervention (PCI) (adapted from Tonino et al(313)). The diagram includes detailed information on the excluded participants.

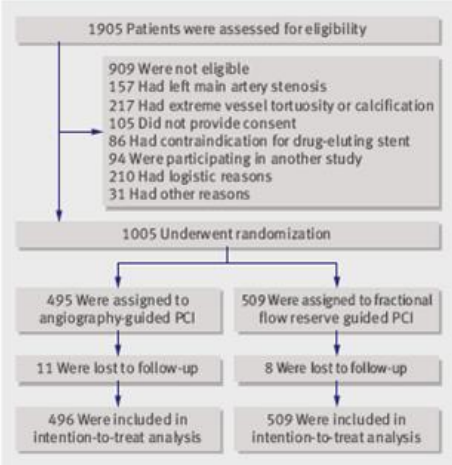
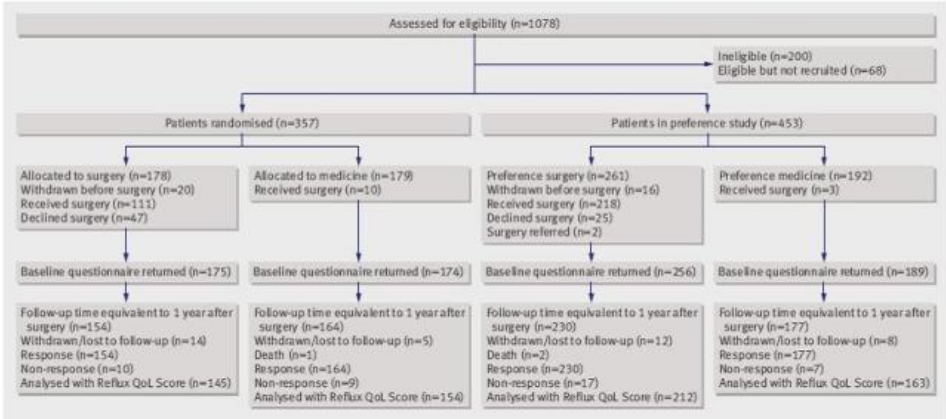


Fig 3. Flow diagram of minimal surgery compared with medical management for chronic gastro-oesophageal reflux disease (adapted from Grant et al(196)). The diagram shows a multicentre trial with a parallel non-randomised preference group.



Tonino PA, De Bruyne B et al	Fractional flow reserve versus angiography for guiding percutaneous coronary intervention.	N Engl J Med 2009;360:213-24.

http://www.consort-statement.org/home/

CONSORT
TRANSPARENT REPORTING of TRIALS

Examples of Baseline Data

This page contains examples of CONSORT Item 15 - Baseline Data.

You can submit your own Examples here.

Read more examples of CONSORT Item 15.

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

	Telmisartan (N=2954)	Placebo (N=2972)
Age (years)	66.9 (7.3)	66.9 (7.4)
Sex (female)	1280 (43.3%)	1267 (42.6%)
Smoking status:		
Current	293 (9.9%)	289 (9.7%)
Past	1273 (43.1%)	1283 (43.2%)
Ethnic origin:		
Asian	637 (21.6%)	624 (21.0%)
Arab	37 (1.3%)	40 (1.3%)
African	51 (1.7%)	55 (1.9%)
European	1801 (61.0%)	1820 (61.2%)
Native or Aboriginal	390 (13.2%)	393 (13.2%)
Other	38 (1.3%)	40 (1.3%)
Blood pressure (mm Hg)	140.7 (16.8/81.8) (10.1)	141.3 (16.4/82.0) (10.2)
Heart rate (beats per min)	68.8 (11.5)	68.8 (12.1)
Cholesterol (mmol/l):		
Total	5.09 (1.18)	5.08 (1.15)
LDL	3.02 (1.01)	3.03 (1.02)
HDL	1.27 (0.37)	1.28 (0.41)
Coronary artery disease	2211 (74.8%)	2207 (74.3%)
Myocardial infarction	1381 (46.8%)	1360 (45.8%)
Angina pectoris	1412 (47.8%)	1412 (47.5%)
Peripheral artery disease	349 (11.8%)	323 (10.9%)
Hypertension	2259 (76.5%)	2269 (76.3%)
Diabetes	1059 (35.8%)	1059 (35.6%)

*Data are means (SD) or numbers (%).

Yusuf S, Teo K, Anderson C, Pogue J, Dyal L, Copland I, et al.	Effects of the angiotensin-receptor blocker telmisartan on cardiovascular events in high-risk patients intolerant to angiotensin-converting enzyme inhibitors: a randomised controlled trial.	Lancet 2008;372:1174-83.

http://www.consort-statement.org/home/

CONSORT
TRANSPARENT REPORTING of TRIALS

Examples of Numbers Analysed

This page contains examples of CONSORT Item 16 - Numbers Analysed.

Read more explanation of CONSORT Item 16.

You can submit your own Examples here.

The primary analysis was intention-to-treat and involved all patients who were randomly assigned.		
Heit JA, Elliott CG, Trowbridge AA, Morrey BF, Gent M, Hirsh J.	Ardeparin sodium for extended out-of-hospital prophylaxis against venous thromboembolism after total hip or knee replacement. A randomized, double-blind, placebo-controlled trial.	Ann Intern Med. 2000;132:853-61.

One patient in the alendronate group was lost to follow up; thus data from 31 patients were available for the intention-to-treat analysis. Five patients were considered protocol violators … consequently 26 patients remained for the per-protocol analyses.		
Haderslev KV, Tjellesen L, Sorensen HA, Staun M.	Alendronate increases lumbar spine bone mineral density in patients with Crohn's disease.	Gastroenterology. 2000;119:639-46.

Examples of Outcomes and Estimation

This page contains examples of CONSORT Item 17a - Outcomes and Estimation.

You can submit your own Examples here.

Read more explanation of CONSORT Item 17a.

Table 5 - Example of reporting of summary results for each study group (binary outcomes)*

Endpoint	Number (%)		Risk difference (95% CI)
	Etanercept (n=30)	Placebo (n=30)	
Primary endpoint			
Achieved PsARC at 12 weeks	26 (87)	7 (23)	63% (44 to 83)
Secondary endpoint			
Proportion of patients meeting ACR criteria:			
ACR20	22 (73)	4 (13)	60% (40 to 80)
ACR50	15 (50)	1 (3)	47% (28 to 66)
ACR70	4 (13)	0 (0)	13% (1 to 26)

***See also example for item 6a.**
PsARC=psoriatic arthritis response criteria. ACR=American College of Rheumatology.

Mease PJ, Goffe BS, Metz J, VanderStoep A, Finck B, Burge DJ.	Etanercept in the treatment of psoriatic arthritis and psoriasis: a randomised trial.	Lancet. 2000;356:385-90.

Table 6- Example of reporting of summary results for each study group (continuous outcomes)

	Exercise therapy (n=65)		Control (n=66)		
	Baseline (mean (SD))	12 months (mean (SD))	Baseline (mean (SD))	12 months (mean (SD))	Adjusted difference* (95% CI) at 12 months
Function score (0-100)	**64.4 (13.9)**	**83.2 (14.8)**	**65.9 (15.2)**	**79.8 (17.5)**	**4.52 (-0.73 to 9.76)**
Pain at rest (0-100)	**4.14 (2.3)**	**1.43 (2.2)**	**4.03 (2.3)**	**2.61 (2.9)**	**-1.29 (-2.16 to -0.42)**
Pain on activity (0-100)	**6.32 (2.2)**	**2.57 (2.9)**	**5.97 (2.3)**	**3.54 (3.38)**	**-1.19 (-2.22 to -0.16)**

*** Function score adjusted for baseline, age, and duration of symptoms.**

van Linschoten R, van Middelkoop M, Berger MY, Heintjes EM, Verhaar JA, Willemsen SP, et al.	Supervised exercise therapy versus usual care for patellofemoral pain syndrome: an open label randomised controlled trial.	BMJ 2009;339:b4074.

Examples of Binary Outcomes

This page contains examples of CONSORT Item 17b - Binary Outcomes.

You can submit your own Examples here.

Read more explanation of CONSORT Item 17b.

http://www.consort-statement.org/home/

CONSORT TRANSPARENT REPORTING of TRIALS

The risk of oxygen dependence or death was reduced by 16% (95% CI 25% to 7%). The absolute difference was -6.3% (95% CI -9.9% to -2.7%); early administration to an estimated 16 babies would therefore prevent 1 baby dying or being long-term dependent on oxygen" (also see table 7).(242)

Table 7 - Example of reporting both absolute and relative effect sizes

(Adpated from table 3 of The OSIRIS Collaborative Group(242))

	Percentage (No)			
Primary outcome	**Early administration (n=1344)**	**Delayed selective administration (n=1346)**	**Risk ratio (95% CI)**	**Risk difference (95% CI)**
Death or oxygen dependence at "expected date of delivery"	31.9 (429)	38.2 (514)	0.84 (0.75 to 0.93)	-6.3 (-9.9 to -2.7)

The OSIRIS Collaborative Group.	Early versus delayed neonatal administration of a synthetic surfactant—the judgment of OSIRIS (open study of infants at high risk of or with respiratory insufficiency—the role of surfactant).	Lancet 1992;340:1363-9.

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Revista Clínica Española

XXXII CONGRESO NACIONAL DE LA SOCIEDAD ESPAÑOLA DE MEDICINA INTERNA

SEMI

26-28 Octubre 2011

Costa Meloneras

¿Que tipos distintos de información contiene esta frase?

Consecuencias de la suplementación con micronutrientes múltiples sobre la supervivencia de los niños infectados por VIH en Uganda: ensayo clínico, randomizado, con control placebo

Ndeezi G, Tylleskär T, Ndugwa CM, Tumwine JK. *Effect of multiple micronutrient supplementation on survival of HIV-infected children in Uganda: a randomized, controlled trial.* JIAS 2010; 13: 18

intervención

medición principal

pacientes

entorno

diseño

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- **intervención**
- **medición principal**
- **pacientes**
- **entorno**
- **diseño**

¡¡Se trata de un título!!

¿Podría indicarse suficiente información con mayor brevedad?

Efectos de la suplementación con micronutrientes múltiples sobre la supervivencia de los niños infectados por VIH.

TITULO: Enfermedad cardiovascular en pacientes con hipertensión arterial: diferencias por género en 100.000 historias clínicas.

Texto pre-editado

Resultados: … Las técnicas de detección de *Plasmodium* son la tinción de Field y examen microscópico, la prueba de detección rápida de antígeno de *Plasmodium* en sangre (test MALARIA NOW® (BINAX, Leti)), y la técnica de PCR disponible en el Centro Nacional de Majadahonda12 durante el período de estudio …

TITULO: Enfermedad cardiovascular en pacientes con hipertensión arterial: diferencias por género en 100.000 historias clínicas.

Texto pre-editado

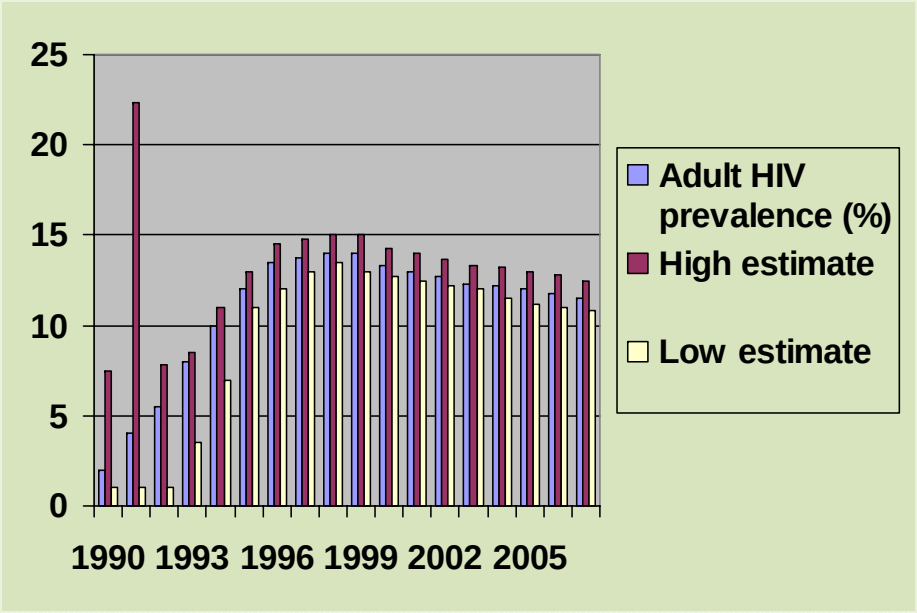
Resultados: … Las técnicas de detección de *Plasmodium* son la tinción de Field y examen microscópico, la prueba de detección rápida de antígeno de *Plasmodium* en sangre (test MALARIA NOW® (BINAX, Leti)), y la técnica de PCR disponible en el Centro Nacional de Majadahonda12 durante el período de estudio …

Texto editado

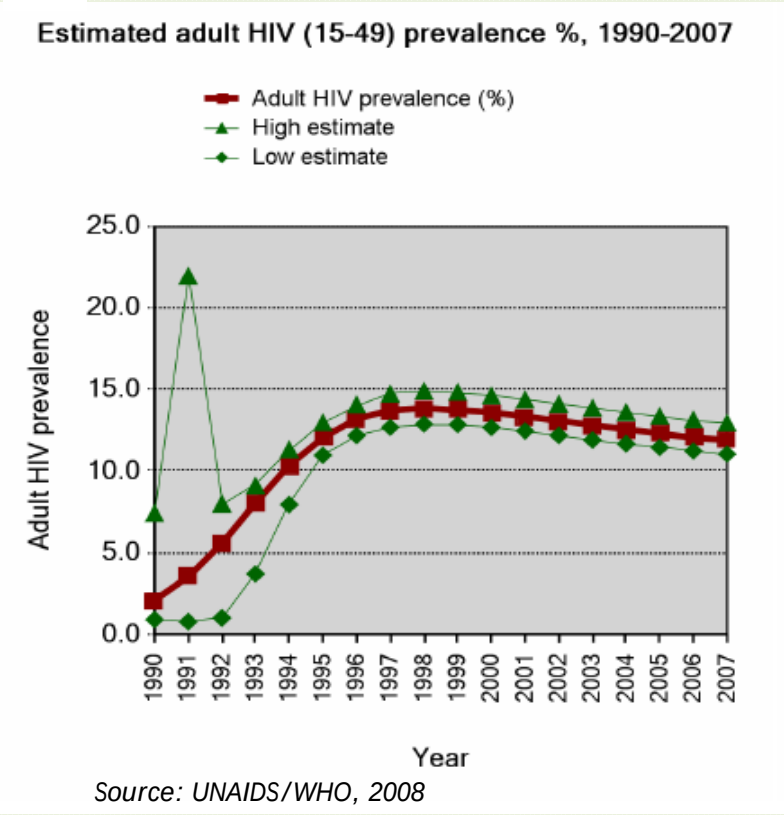
Resultados: … Las técnicas de detección de *Plasmodium* fueron la tinción de Field y el examen microscópico (considerado hasta la fecha como patrón de referencia con un umbral de detección (U) de 5-16 parásitos/mcl), la prueba de detección rápida de antígeno de *Plasmodium* en sangre (test MALARIA NOW® (BINAX, Leti), con sensibilidad global del 93,4% y especificidad del 96%, y U de 100 parásitos/mcl), y la técnica de PCR semi-nested multiplex (U de 0,02-1 parásitos/mcl) que puede detectar hasta un 12% más de infectados que la microscopía [17]. …

¿Cuál de estos gráficos es mejor para mostrar cambios a lo largo del tiempo?

A.



B.



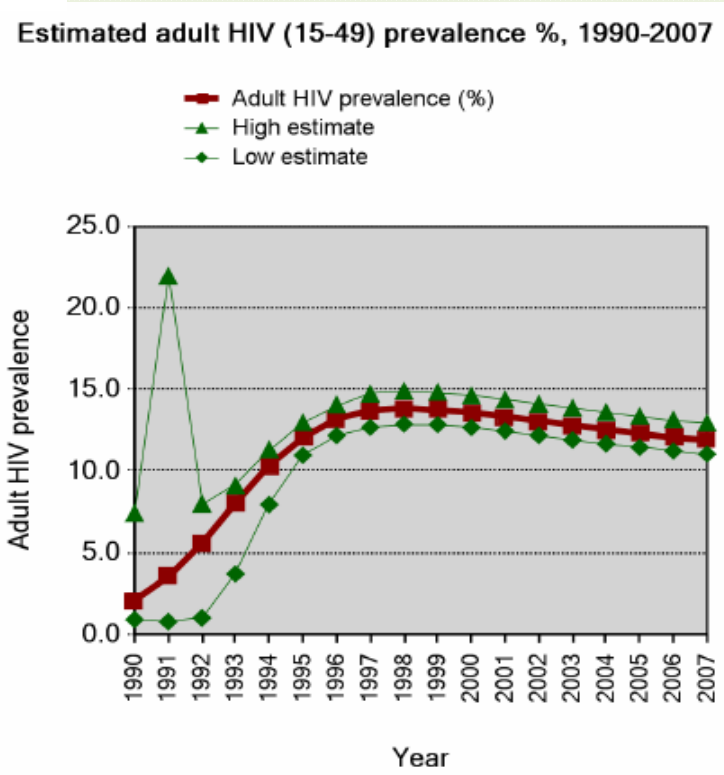
Source: UNAIDS/WHO, 2008

¿Cuál de estos gráficos es mejor para mostrar cambios a lo largo del tiempo?

Figuras diferentes para transmitir mejor mensajes diferentes

Una gráfica lineal transmite mejor los cambios de datos en el tiempo

B.

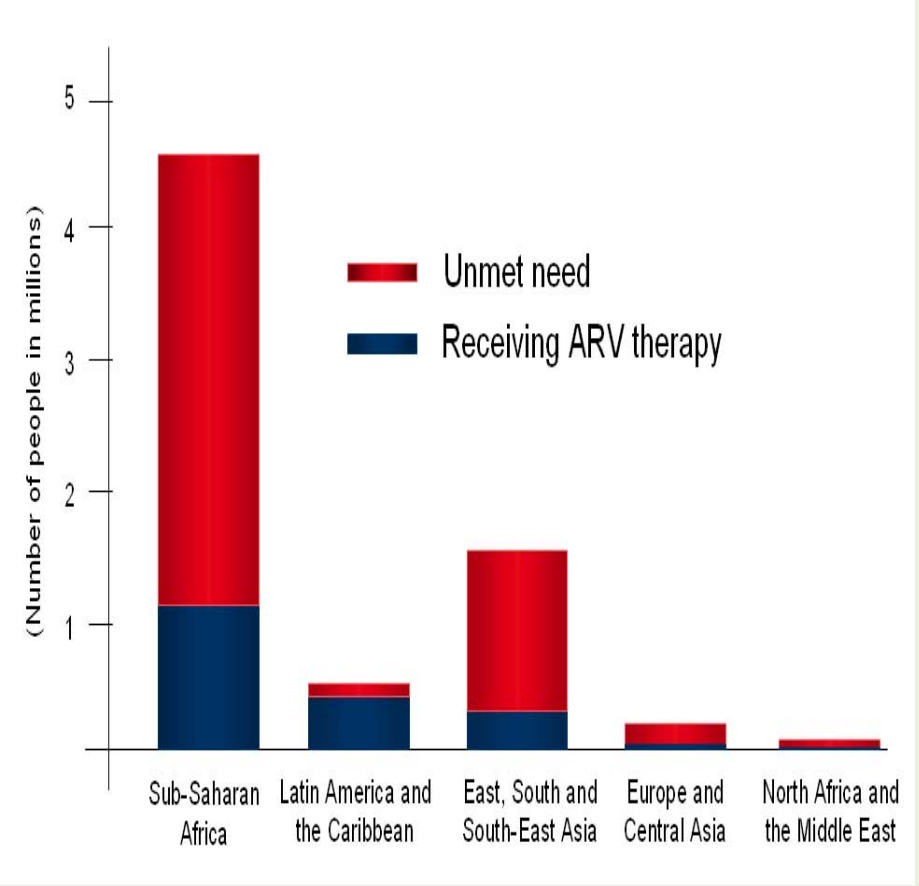


Source: UNAIDS/WHO, 2008

Figuras diferentes para transmitir mejor mensajes diferentes

Los gráficos de barras resultan preferibles para reflejar otros tipos de datos, por ejemplo los porcentajes

- ✓ **Utilizarlos únicamente cuando resulten de utilidad para transmitir ó hacer fácilmente comprensible algún tipo de información.**
- ✓ **Deben ser comprensibles sin tener que leer el texto acompañante**
- ✓ **Evitar solaparse con lo expresado en el texto**



Source: UNAIDS/WHO, 2006

TITULO: Enfermedad cardiovascular en pacientes con hipertensión arterial: diferencias por género en 100.000 historias clínicas.

Texto pre-editado

Resultados: De 92.079 historias, 19.501 (21,2%) tenían diagnóstico previo de ECV (23,9% en varones y 19,1% en mujeres). En estos hipertensos con ECV, los diagnósticos más frecuentes y su proporción en el varón y en la mujer fueron: la cardiopatía isquémica 35,6% (43,7 %/ 27,6%), la fibrilación auricular 29,5% (25%/33,9%), el ictus 24% (22 %/26,7%), la insuficiencia renal 15,7% (18,2 %/13,2%), la insuficiencia cardíaca 15,3% (10,4%/20,2%) y la enfermedad arterial periférica 7,5% (8,7%/6,4%) ($p<0,05$).

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TITULO: Tumores pardos e hiperparatiroidismo

Texto pre-editado

Resultados:… En la bioquímica destacaba un Ca_s de 13,1 mg/dl (rango normal 8.4 - 10.2 mg/dl), Pi de 1,9 mg/dl (rango normal 2.7 - 4.5 mg/dl), FA 591 U/L (rango normal 56 – 155 mg/dl) Mg 2,10 mEq/l (rango normal 1.3 – 2.1nmEq/l), PTH 1024 pg/ml (rango normal 10 – 60 pg/ml) ...

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TITULO: Hipopotasemia e insuficiencia renal prerrenal secundarias a adenoma velloso.

Texto pre-editado

Resultados:… El paciente acudía con una analítica donde los hallazgos más destacables eran una urea de 114, creatinina de 1,6 mg/dl, Na: 120 mmol/l, K: 2,5 mmol/l, ph: 7,49, bicarbonato: 34,1 mmol/l, exceso de base: 9,7 mmol/l, cloro: 101 mmol/l. El hierro era de 62 y la ferritina: 51. A nivel hematológico, presentaba una Hemoglobina de 7,3 g/l, VCM: 104, plaquetas: 700.000 y leucocitos: 5.990 con neutrofilia (80%). Los reticulocitos eran 68.600. Las hormonas tiroideas, vitamina B12 y ácido fólico fueron normales, al igual que los niveles de inmunoglobulinas. La VSG era de 33 mm. Se analizaron tres muestras de heces que resultaron positivas para SOH.
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Texto editado

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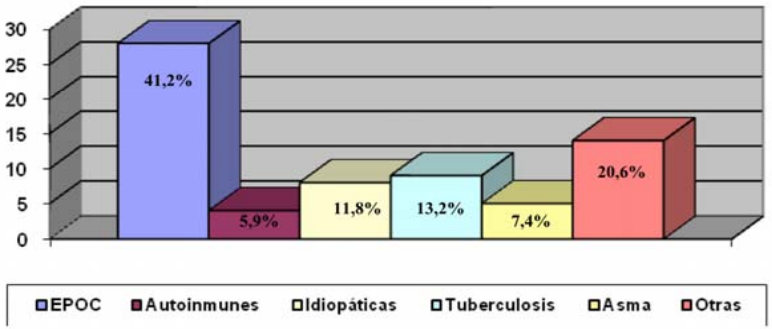
<u>Título</u>: ***Infección por micobacterias no tuberculosas en pacientes con bronquiectasias no causadas por fibrosis quística.***

¿Parece adecuada la expresión de los datos relativos a la etiología de las bronquiectasias de los pacientes incluidos en la serie?

FIGURA 1

Figura 1: Etiología de las BQ y frecuencia



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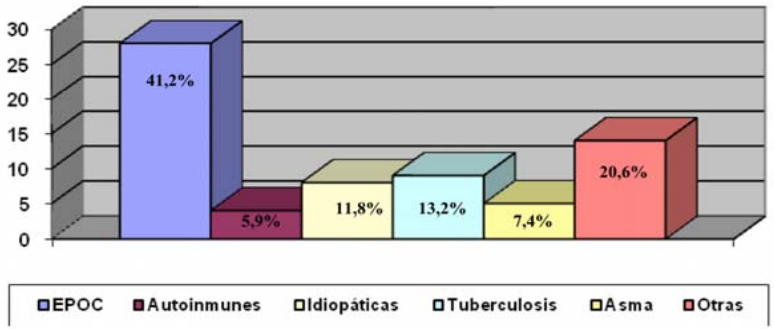


Tabla 1: Etiología de las bronquiectasias.

Etiología	número	%
EPOC	**28**	46,2
Tuberculosis	**9**	13,2
Asma	**5**	7,4
Autoinmunes	**4**	5,9
Otras [@]	**14**	20,6
Idiopáticas	**8**	11,8

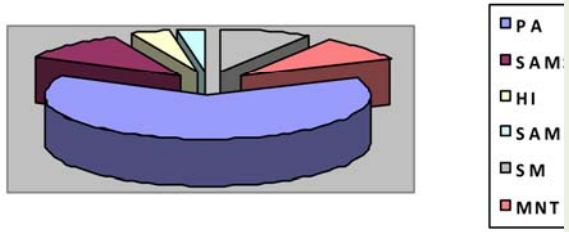
EPOC – Enfermedad Pulmonar Obstructiva Crónica

[@] (déficit de inmunoglobulina G, neumonías de repetición, neumonía necrotizante, linfoma MALT, post-sarampión, síndrome de Kartagener, y discinesia ciliar primaria)

Título: *Infección por micobacterias no tuberculosas en pacientes con bronquiectasias no causadas por fibrosis quística.*

¿Parece adecuada la expresión de los datos relativos a los aislamientos microbológicos ?

Figura 2: **AISLAMIENTO MICROBIOLÓGICO EN CULTIVO DE ESPUTO Y NÚMERO DE PACIENTES**



PA: *Pseudomonas aeruginosa 48 (70,6%);* SAMS: *Staphylococcus aureus meticilina sensible 8 (11,8%);* HI: *Haemophilus influenzae 2 (2,9%);* SAMR: *Staphylococcus aureus meticilina resistente 2 (2,9%);* SM: *Stenotrophomonas maltophilia 7 (10,3%);* MNT: micobacterias no tuberculosas 7 (10,3%).

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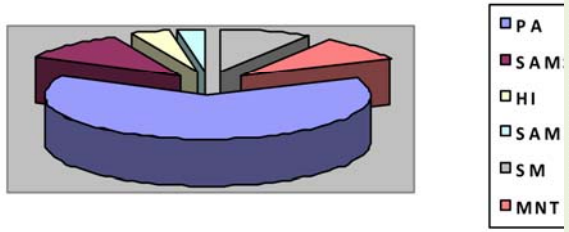

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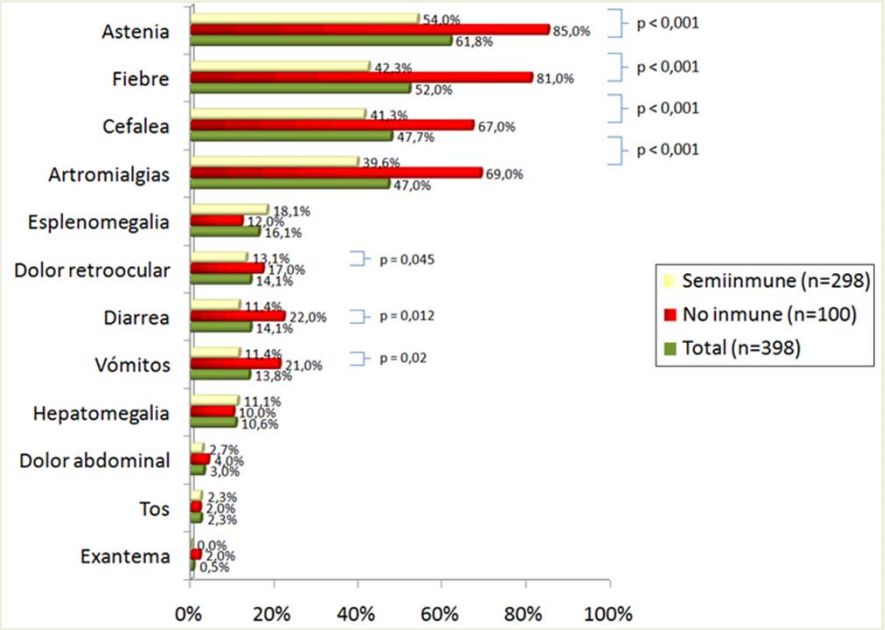
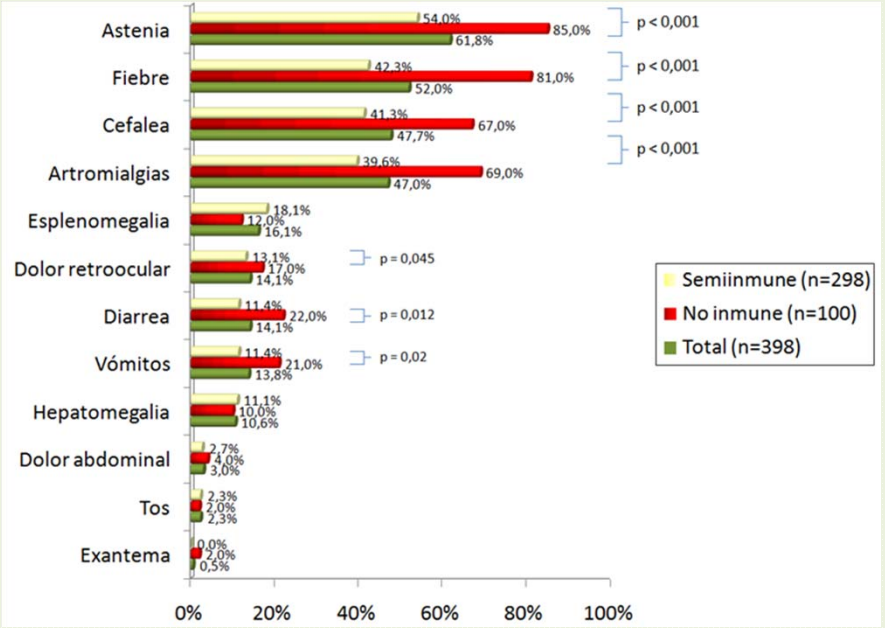
Los gérmenes aislados en esputo fueron *Pseudomonas aeruginosa en 48 ocasiones (70,6%), Staphylococcus aureus meticilin sensible en 8 (11,8%), Haemophilus influenzae en 2 (2,9%), Staphylococcus aureus meticilin resistente en 2 (2,9%), Stenotrophomonas maltophilia en 7 (10,3%) y* MNT en 7 (10,3%). En 7 pacientes se aisló más de un microorganismo (4 con *P. aeruginosas* más *S. aureus meticilin-resistente*, 1 con P. aeruginosa y S. aureus meticilin-sensible y 2 con *Pseudomonas aeruginosa* y *H. Influenzae)*.



Gráfica 2: ***Síntomas.*** En todos los casos (n=398) se obtuvieron datos referentes a la sintomatología.

datos en %	Semiinmune	No inmune	Total	*P*
Astenia	54,0	85,0	61,8	,001
Fiebre	42,3	81,0	52,0	,001
Cefalea	41,3	67,0	47,7	,001
Artromialgias	39,6	69,0	47,0	,001
Esplenomegalia	18,1	12,0	16,1	>,05
Dolor retroocular	13,1	12,0	16,1	,045
Diarrea	11,4	22,0	14,1	,012
Vómitos	11,4	21,0	13,8	,02
Hepatomegalia	11,1	10,0	10,6	>,05
Dolor abdominal	2,7	4,0	3,0	>,05
Tos	2,3	2,0	2,3	>,05
Exantema	0,0	2,0	0,5	>,05



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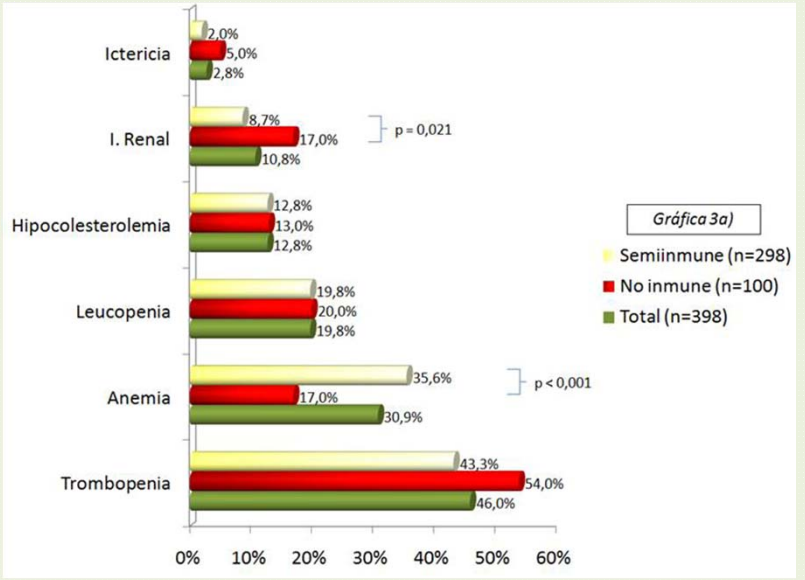
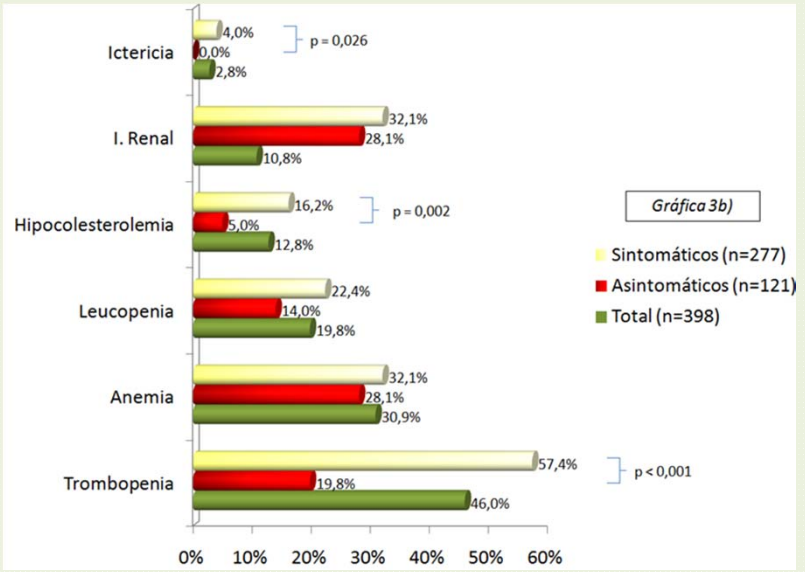
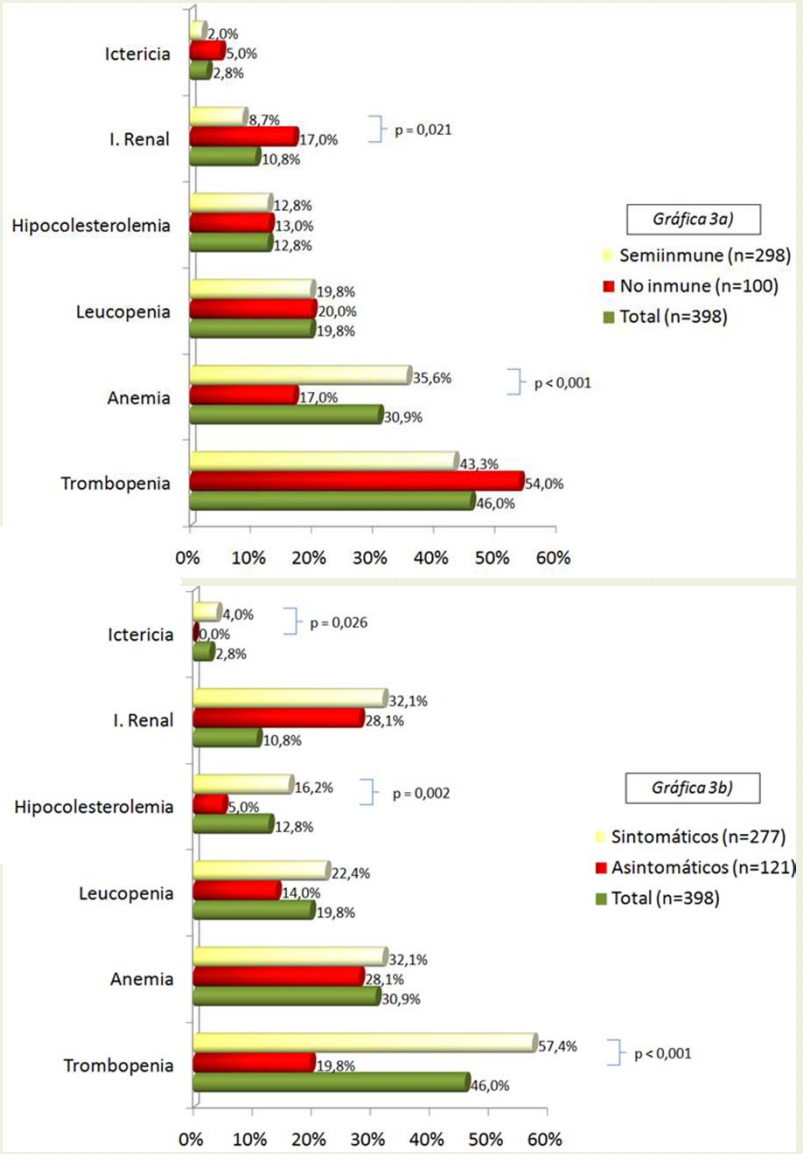




Gráfica 3. Alteraciones analíticas. En todos los casos (n=398) se obtuvieron datos analíticos. 3a) Porcentaje de casos de paludismo con alteraciones analíticas, en semiinmunes y en no inmunes. 3b) Porcentaje de casos de paludismo con alteraciones analíticas, en asintomáticos y en sintomáticos.

Gráfica 3. Alteraciones analíticas. En todos los casos (n=398) se obtuvieron datos analíticos.

	Semiinmune	No Inmune	Total	P	Sintomáticos	Asintomáticos	Total	P
Ictericia	2,0	5,0	2,8	ns	4,0	0,0	2,8	,026
Insuficiencia Renal	8,7	17,0	10,8	,021	32,1	28,1	10,8	ns
Hipocolesterolemia	12,8	13,0	12,8	ns	16,2	5,0	12,8	,002
Leucopenia	19,8	20,0	19,8	ns	22,4	14,0	19,8	ns
Anemia	35,6	17,0	30,9	,001	32,1	28,1	30,9	ns
Trobopenia	43,3	54,0	46,0	ns	57,4	19,8	46,0	,001



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