# Methods of Reporting Research-Results and their Influence on Decision-Making by Cardiologists Prescribing Drugs for Primary and Secondary Prevention

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**Objectives.** To assess the influence of the form of presentation of the results of clinical trials on the quantitative perceptions of cardiologists regarding the efficacy of drugs for the primary and secondary prevention of coronary heart disease and their likelihood of prescribing them.

**Method.** We conducted a survey of 1,408 cardiologists in Spain who were randomly allocated of three questionnaires that used different measurements to evaluate the impact of published clinical trials.

**Results.** Five-hundred and fifty-nine questionnaires (40%) were suitable for analysis. On a scale of 0 to 10, the following mean efficacy estimates were obtained from questionnaire items that focused, respectively, on the results of clinical trials in terms of relative risk reduction, absolute risk reduction, and number needed to treat: primary prevention with statins: 6.79, 6.38 and 5.43; primary prevention with statins: 8.16, 7.76 and 7.54; secondary prevention with ACE inhibitors: 7.11, 7.81 and 7.19, and secondary prevention with beta-blockers: 7.22, 7.43 and 6.98. The likelihood that a drug treatment would be prescribed was not influenced very much by the form of presentation of the trial results.

**Conclusions.** Presenting the results of clinical trials in the form of relative risk reduction, as compared with presenting results in terms of absolute risk reduction or number needed to treat, led to overestimation of the efficacy of interventions without influencing the likelihood of prescribing a given drug therapy.

## Key words: Prevention. Clinical trials. Epidemiology.

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# La influencia de los métodos de presentación de los resultados en ensayos clínicos sobre la eficacia de una intervención y la intención de prescribir fármacos para la prevención cardiovascular

**Objetivos.** Evaluar la influencia de los métodos de presentación de los resultados sobre la percepción cuantitativa de la eficacia de fármacos utilizados en prevención primaria y secundaria de la enfermedad coronaria y la probabilidad de comenzar el tratamiento con dichos fármacos.

**Método.** Estudio realizado en 1.408 cardiólogos españoles a los que se asignó, de forma aleatoria, tres cuestionarios en los que se utilizaban diferentes medidas de efecto de ensayos clínicos publicados.

Resultados. Se pudo aplicar 559 cuestionarios (40%). A partir de las respuestas a los cuestionarios se estimó, en una escala del 0 al 10 (valor éste máximo de eficacia), la percepción de la eficacia media de diferentes fármacos utilizados en ensayos clínicos cuyos resultados fueron expresados en términos de reducción relativa del riesgo, reducción absoluta del riesgo y número necesario de pacientes a tratar para evitar un caso, respectivamente, obteniéndose: prevención primaria con estatinas: 6,79, 6,38 y 5,43; prevención primaria con aspirina: 6,84, 5,06 y 4,25; prevención secundaria con estatinas: 8,16, 7,76 y 7,54; prevención secundaria con inhibidores de la enzima conversiva de la angiotensina (IECA): 7,11, 7,81 y 7,19, y prevención secundaria con bloqueadores beta: 7,22, 7,43 y 6,98. Sin embargo, la probabilidad de iniciar el tratamiento con los fármacos considerados se vio poco influida debido a la forma de presentación de los resultados en los ensayos clínicos.

**Conclusiones.** La presentación de resultados en los ensayos clínicos en forma de reducción relativa del riesgo, en comparación con su presentación en forma de reducción absoluta del riesgo o número necesario de pacientes a tratar, dio lugar globalmente a una percepción de mayor eficacia de la intervención, sin influir, sin embargo, en la probabilidad de iniciar el tratamiento con los fármacos.

**Palabras clave:** *Prevención. Ensayos clínicos. Epidemiología.* 

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# **ABBREVIATIONS**

RRR: relative risk reduction ARR: absolute risk reduction NNT: number needed to treat

# INTRODUCTION

The way study results are presented can influence the perception of the value of the study and, as a consequence, clinical decisions. The interpretation of numerical data can vary depending on the way biomedical research results are presented. Random distribution clinical trials generally use relative risk reduction (RRR) to describe the effect of a particular treatment, a measurement that is independent of baseline patient risk and. therefore, is easy to extrapolate. Nevertheless, it is also clear that this measurement augments the effect of an intervention, particularly when there is a low incidence of episodes. For example, an RRR of 25% can be mean absolute episode rates of 30%, 15%, 5%, or 2%. The RRR clearly quantifies the effects of an intervention in a proportional manner, but does not quantify the magnitude of the effect on an absolute scale. An alternative method for presenting clinical data is absolute risk reduction (ARR), which establishes the underlying susceptibility of the patients and provides more complete information than the RRR. Nevertheless, contrary to the RRR, the ARR is difficult to document and incorporate in clinical practice since, if not converted, it tends to be expressed in decimal fractions. The reciprocal corresponding measurement, number of people who need to be treated to prevent an event (NNT), has the same advantages but is more useful than the ARR because it indicates to clinicians, in a definitive way, what the necessary inversion is to avoid an episode and also what the probability is that an effect will be clinically significant.<sup>1</sup> As opposed to the RRR, neither the ARR nor the NNT can extrapolate which patients have specific baseline risks. Different studies in the fields of primary care and internal medicine<sup>2-5</sup> have shown that the opinions of clinicians about pharmacological treatment are influenced by the predominant use of the RRR.

Our study was performed with the help of Spanish cardiologists who were randomly assigned 3 questionnaires with different measurements to assess the effect of an intervention (RRR, ARR or NNT) and to evaluate its influence on their perceptions of the degree of efficacy of the pharmacological treatment in the prevention of heart disease, as well as the probability of initiating said treatment in simulated patient cases. As a secondary objective, we evaluated the theoretical total and LDL cholesterol that they believed were recommended for patients with myocardial infarction, as well as the percentage of patients they thought could attain these levels.

# METHOD

All cardiologists who were members of the Sociedad Española de Cardiología (Spanish Society of Cardiology) were included in the study. Pediatric cardiologists and cardiovascular surgeons were excluded since they do not normally participate in the preventative treatment of heart disease. The data utilized in the 3 questionnaires dealing with treatment effects was taken from the WOSCOPS study,<sup>6</sup> Physicians' Health Study,8 a meta-analysis of beta-blockers after acute myocardial infarction,9 and SAVE,10 although the questionnaires did not reveal from which studies the data had been obtained. We created 3 types of guestionnaires (Appendix). Ouestionnaire A included the effects of treatment as reported by RRR; questionnaire B as reported by ARR, and questionnaire C as reported by NNT. The confidence intervals for the values considered were obtained from the original study or calculated by means of standard methods for categorical variables.<sup>11</sup> A summary of the results from each of the 5 studies was given (2 for primary prevention and 3 for secondary prevention), and we evaluated the perception of the pharmacological treatment's efficacy by a Likert scale with values from 0 (treatment that had no effect) to 10 points (treatment with the most beneficial effect) on which the respondent marked with an X the value they considered most appropriate. We also included simulated clinical cases based on each study, from which the cardiologists had to indicate the probability of using a specific medication on a Likert scale with values from 0 (very low probability of using the medication) to 10 points (very high probability of using the medication).

In addition, the 3 questionnaires all contained a question regarding the recommended levels of total and LDL cholesterol for patients with a history of acute myocardial infarction and the percentage of patients they though could achieve said cholesterol levels.

The cardiologists were chosen randomly from a table of random numbers to receive 1 of the 3 questionnaires. We did 3 mailings at 14-week intervals between May, 1998, and January, 1999, to 1408 clinical cardiologists.

Statistical analysis was performed with the SPSS-PC<sup>12</sup> information program. The characteristics of the 3 random groups of cardiologists were compared by the  $\chi^2$  test and variance analysis. We used the Kruskal-Wallis test to compare the scores obtained according to the method used to present the results. We defined a

TABLE 1. Characteristics	of the 3 groups that	at
responded		

	Presentation method			
Characteristics	RRR (n=209)	ARR (n=188)	NNT (n=162)	Ρ
Age (SD)	48 (9.4)	48 (9.5)	47 (9.5)	.5
Sex, % men	87	90	90	.5
Hospital practice, %	84.5	85	82	.7
Mean response time to the questionnaire (SD), days Time devoted to clinical	119 (96)	107 (94)	117 (97)	.4
practice (SD), %	49 (29)	50 (28)	49 (29)	.9

SD indicates standard deviation; n, group size; RRR, relative risk reduction; ARR, absolute risk reduction; NNT, number needed to treat (in order to prevent an episode).

statistically significant level as  $P \le .05$  bilaterally.

# RESULTS

Six hundred and fifty-eight questionnaires (46%) were returned; in these questionnaires, 99 replied that the questionnaires were not appropriate for their practice, leaving 559 questionnaires (40%) for analysis.

# Characteristics of the respondents

Table 1 shows the characteristics of the 3 groups that were surveyed. There were no differences between groups with respect to age, sex, type of hospital, amount of time taken to answer the questionnaire, or percentage of time devoted to clinical practice.

# Comparison of the scores from the 3 groups

Tables 2 and 3 show the comparison of the mean scores, on a scale from 0 to 10 points, of the 3 groups with respect to the efficacy level perceived and the probability of beginning treatment as a function of RRR, ARR, and NNT. Calculation of the mean efficacy level was assessed from the answers to the questionnaire as a function of the presentation method for the study results in terms of RRR, ARR, and NNT. We observed an absolute difference of 0.41 (RRR and AAR) and 1.36 (RRR and NNT), for primary prevention with statins; an absolute difference of 1.78 (RRR and AAR) and 2.59 (RRR and NNT) for primary prevention with aspirin; an absolute difference of 0.70 (RRR and AAR) and 0.62 (RRR and NNT) for secondary prevention with angiotensive converting enzyme inhibitors (ACEI); we observed practically no difference in the results for secondary prevention with statins or secondary prevention with beta-blockers. There was no difference between the groups with respect to the probability of initiating pharmacological treatment

# TABLE 2. Comparison of the level of efficacy perceived by cardiologists as a function of the different presentation methods (mean and standard deviation) of the study results

	RRR Mean (SD) (n=209)	ARR Mean (SD) (n=188)	NNT Mean (SD) (n=162)
Primary prevention	0.70 (1.00)	0.00 (0.10)	F 40 (0.04)
Of MI with statins	6.79 (1.83)	6.38 (2.18)	5.43 (2.34)
of IM with aspirin <sup>a,b,c</sup>	6.84 (2.18)	5.06 (2.58)	4.25 (2.52)
Secondary prevention	0.10 (1.00)	7 70 (1 04)	7 54 (0.00)
With Statins	8.16 (1.30)	7.76 (1.64)	7.54 (2.02)
with ACEI <sup>b,c</sup>	7.11 (1.74)	7.81 (1.64)	7.19 (2.04)
Secondary prevention with beta blockers	7.22 (1.72)	7.43 (1.72)	6.98 (1.93)

SD indicates standard deviation; n, group size; RRR, relative risk reduction; ARR, absolute risk reduction; NNT, number needed to treat (in order to prevent an episode).

\*P<.05 among the RRR-NNT groups.

<sup>b</sup>P<.05 among the ARR-NNT groups.

°P<.05 among the RRR-ARR groups.

# TABLE 3. Probability of initiating treatment as a function of the different presentation methods (mean and standard deviation) for the study results

	RRR Mean (SD) (n=209)	ARR Mean (SD) (n=188)	NNT Mean (SD) (n=162)
Primary prevention			
of MI with statins	7.09 (2.59)	6.94 (2.72)	7.16 (2.45)
Primary prevention			
of MI with aspirin*	3.20 (2.81)	2.49 (2.59)	2.63 (2.41)
Secondary prevention			
with statins	7.76 (2.14)	7.54 (2.29)	7.55 (2.43)
Secondary prevention			
with ACEI	8.39 (1.60)	8.69 (1.39)	8.60 (1.41)
Secondary prevention			
with beta-blockers	6.25 (2.90)	6.28 (2.91)	6.19 (2.72)

SD indicates standard deviation; n, group size; RRR, relative risk reduction; ARR, absolute risk reduction; NNT, number needed to treat (in order to prevent an episode).

\*P<.05 among the RRR-ARR groups.

except in the case of aspirin used for primary prevention of an acute myocardial infarction—scores were higher when the results were presented in terms of RRR.

On the topic of the recommended total and LDL

cholesterol levels for patients with a history of myocardial infarction, 90% of the cardiologists responded with a total cholesterol level of 200 mg/dL or lower, and 99% answered 130 mg/dL or lower for LDL cholesterol. On the topic of the percentage of patients the physicians believed could achieve said levels, 34% of the cardiologists thought that 80% to 100% of their patients could reach these levels, 55% thought 40% to 60% of their patients could achieve the levels, and 23% thought that only 20% or fewer of their patients could achieve these levels.

# DISCUSSION

In our study, we observed how the method of presenting the results of a study can result in different perceptions of the efficacy of the intervention studied, a finding that concurs with the findings of previous studies.<sup>1-4</sup> Nevertheless, since we used various clinical cases, our findings are more reliable than previous studies from a methodological point of view. We confirmed that using RRR can augment the perception of the efficacy of an intervention, resulting in overestimation of the results.

As opposed to other studies, we did not find differences in the probability of initiating treatment except in the case of aspirin for the primary prevention of myocardial infarction. We believe that the decision to initiate treatment extends beyond the perception of efficacy, and can be influenced by other factors. A possible explanation may be that our study population was made up of clinical cardiologists, and therefore was a more homogenous population than that studied in previous investigations, in which general practioners or internists were selected. It is also of note that the clinical studies used in our study to present the clinical cases are very well known, and have been widely disseminated in recent years among the cardiology community by means of articles in professional journals, medical meetings and symposia, and (as far as the medications in question are concerned) by the pharmaceutical companies. This fact may be the reason we rarely encountered a relationship between the way the study results were presented and the probability of initiating pharmacological treatment.

Another interesting finding of our study is that, overall, there is a slight tendency to use aspirin for primary prevention, and beta-blockers after myocardial infarction, in simulated clinical cases. The first finding may be due to the fear of adverse effects from the use of aspirin, especially with respect to hemorrhagic problems. The Physician's Health study certainly did not convince the medical community of the efficacy of this intervention, particularly given the British study results<sup>13</sup> did not confirm their findings. As a result, it is understandable that there is a low incidence of the use of aspirin in the case of an asymptomatic male patient

without risk factors. The second finding is consistent with the results from other studies that have shown that beta-blockers are clearly underused.<sup>14,15</sup> This finding may partially reflect the relatively conservative attitude in Spain with respect to the use of beta-blockers for this condition, which has been evident since publication of the results of the EUROASPIRE study, which in 1995 and 1996 examined secondary prevention of heart disease in 9 European countries, including Spain.<sup>16</sup> In that study, only 35% of Spanish heart patients used beta-blockers compared with 54% of patients in a combined population of 9 countries. Nevertheless, these results have improved in accordance with the results from the recently published EURO-ASPIRE II study,<sup>17</sup> in which 47% of Spanish heart patients and 63% of the total combined population used beta-blockers. The fact that 50% of clinical cardiologists think that only 50% of their patients could achieve cholesterol values recommended for secondary prevention, including when said levels are reasonably well known, reflects the opinion of the cardiologists with regard to the difficulty in implementing medical guidelines in clinical practice. Among the reasons for this point of view are a number of factors such as professional experience, noncompliance with treatment by patients, and the cost of treatment. Other authors<sup>18</sup> consider the lack of communication among specialists and primary care physicians to be an additional barrier. In a study that compared the differences in treatment continuity rates with hypolipemic medications among patients included in clinical trials and patients not included in clinical trials in 2 primary care centers,<sup>19</sup> substantially lower rates were found in actual medical practice.

# **Study Limitations**

Our results are restricted to the clinical settings presented in the study; the perception of the efficacy of an intervention and the likeliness to treat may have varied considerably if different clinical trials or different settings based on the same clinical studies had been used. For this reason, we cannot extrapolate our results to other studies with different clinical trials or different simulated cases, and we cannot easily compare our results with those from other studies.

Forty percent of cardiologists responded to the questionnaires, and although this is not an unusual percentage for a study conducted by mail, it could have produced a skew in the results. However, we believe such a skew is improbable since this was not a study of the cardiologists' knowledge but instead of their clinical perceptions; the profiles of the cardiologists who did not respond to the questionnaires should not differ in principal from those who did respond. Nevertheless, if the probability of less-informed cardiologists not responding to the questionnaires was

greater than that of more well-informed cardiologists, our results could be skewed in the sense of undervaluing the differences observed. It is also probable that the cardiologists who responded were more critical with respect to the efficacy of the medications than those who did not respond, and that their point of view with regard to a particular treatment would be more to the point than those who did not respond. Unfortunately, we did not have information about the cardiologists who did not respond with regard to their age, workplace, type of practice, and other characteristics, preventing comparison with those who did respond.

In conclusion, our study shows that there are differences in the perception of efficacy according to the method of measuring effect, although the decision to initiate pharmacological treatment for those in the simulated cases was independent of the method of presentation of the results from the clinical trials in the questionnaires. The use of ARR and NNT methods, rather than RRR methods, is advisable to describe the expected benefits of an intervention in individual patients for therapeutic recommendations that appear in scientific publications. Nevertheless, these variables should be only one element considered when a treatment decision is to be made; the physician's own experience and clinical judgment, and the quality of life and the patient's preferences should also be taken into account.

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# APPENDIX

# **QUESTIONNAIRE A**

#### Scenario number 1

According to the results of a primary prevention study, hypolipemic drugs cause a relative reduction in the risk of nonfatal infarction or coronary death in 31% of patients. This result is statistically significant, and the confidence interval varies from 17% to 45%. How would you interpret the results of this study with regard to the efficacy of hypolipemia drug treatment?



In light of these study results, would you pharmacologically treat a 55-year-old man without a history of cardiovascular disease or other risk factors and with a total cholesterol level of 290 mg/dL who has not been able to reduce his cholesterol with diet?



#### Scenario number 2

According to the results of another primary prevention study, acetylsalicylic acid produces a relative reduction in the risk of suffering a myocardial infarct of 44%. This result is statistically significant, and the confidence interval varies from 30% to 55%. How would you interpret the results of this study with regard to the efficacy of treatment with aspirin?



In light of these study results, would you treat a 58-year-old man without a clinical history of heart disease, with acetylsalicylic acid to prevent an AMI (it is assumed that he does not have aspirin intolerance)?



#### Scenario number 3

According to the results of a study of secondary prevention, hypolipemic medications produce a relative reduction in the risk of coronary death of 42% in patients that have suffered a coronary event.

This result is statistically significant. The confidence interval is between 27% and 54%. How would you interpret the results of this study with regard to the efficacy of treatment with hypolipemic drugs?



In light of these study results, would you treat a 60-year-old woman with a history of having suffered an AMI with a total cholesterol of 230 mg/dL and an LDL cholesterol of 140 mg/dL?



Scenario number 4

According to the results of another secondary prevention study, treatment with ACEI of patients who have suffered a myocardial infarct and have ventricular dysfunction produces a reduction in the relative risk of cardiovascular death of 21%. This result is significantly significant. The confidence interval is between 5% and 35%.

How would you interpret the results of this study with regard to the efficacy of treatment with ACEI?



In light of these study results, would you pharmacologically treat a 53-year-old man who had a week ago suffered a myocardial infarct who did not show clinical evidence of cardiac insufficiency and who had an ejection fraction of 30% on echocardiography?



#### Scenario number 5

According to the results of a meta-analysis, using beta-blockers after a myocardial infarct (including patients with a good prognosis and those with a poor prognosis) reduces the relative risk of death or reinfarct by 25%. This result is statistically significant. The confidence interval varies from 19% to 33%. How would you interpret the results of this study with regard to the efficacy of treatment with beta-blockers?



In light of these study results, would you use beta-blockers to pharmacologically treat a 55-year-old non-hypertensive woman who a week prior had an anterior myocardial infarction, without clinical complications, with a negative stress test, and an ejection fraction of 53% on echocardiography, and who did not have contraindications for treatment with beta-blockers?



#### **QUESTIONNAIRE B**

#### Scenario number 1

According to a study of primary prevention, hypolipimic medications prevented 24 cases of non-fatal myocardial infarct or cardiac death for every 1000 patients treated over 5 years. This result is statistically significant and the confidence interval varies from 11 to 34 per 1000 patients. How would you interpret the results of this study with regard to the efficacy of hypolipemic medication treatment?



In light of these study results, would you use hypolipemic medications to treat a 55-year-old man with no history of cardiovascular disease or other risk factors, and a total cholesterol of 290 mg/dL who had not been able to reduce his cholesterol with diet?



#### Scenario number 2

According to the results of another study of primary prevention, acetylsalicylic acid prevents 9 cases of myocardial infarct for every 1000 patients treated over a 5-year period. This result is statistically significant, and the confidence interval varies from 6 to 12 per 1000. How would you interpret the results of this study with regard to the efficacy of treatment?



In light of these study results, would you treat a 58-year-old man with no clinical data indicating heart disease with acetylsalicylic acid to prevent an AMI (assuming that he does not have aspirin intolerance)?



### Scenario number 3

According to the results from a study of secondary prevention, hypolipemic medications prevent 35 cases of death for every 1000 patients diagnosed with heart disease during 5 years of treatment. This result is statistically significant and the confidence interval varies from 20 to 50 per 1000.

How would you interpret the results of this study with regard to the efficacy of treatment?



# **QUESTIONNAIRE C**

#### Scenario number 1

According to the results of a study of primary prevention of 42 healthy patients during a 5-year period, it is necessary to use hyperlipemic drugs to prevent an infarct or death by heart disease. These results are statistically significant with a confidence interval that was between 29 and 91 patients over the 5-year period.

How would you interpret the results of this study with regard to the efficacy of hypolipemic treatment?



In light of these study results, would you, using hypolipemic drugs to pharmacologically treat a 55-year-old man, with no history of cardiovascular disease or other risk factors, a total cholesterol level of 290 mg/dL, who had not been able to reduce his cholesterol with diet?



#### Scenario number 2

According to the results of another study of primary prevention in 108 patients over 5 years, treatment with acetylsalicylic acid is necessary to avoid acute myocardial infarction. This result is statistically significant with a confidence interval between 83 and 166 patients. How would you interpret the results of this study with regard to the efficacy of the treatment?



In light of these study results, would you treat a 58-year-old man, without a history of heart disease with acetylsalicylic acid to prevent an AMI (assuming that he did not have aspirin intolerance)?



#### Scenario number 3

According to the results of a study of secondary prevention over a 5-year period of 28 patients diagnosed with heart disease, it is necessary to treat hypolipemia preventively to prevent 1 death due to heart disease. This result is statistically significant, and the confidence interval varied from 20 to 50 patients.

How would you interpret the results of this study with regard to the efficacy of hypolipemic treatment?



effect

beneficial effect

In light of these study results, would you use ACEI to pharmacologically treat a 53-year-old man who had suffered a myocardial infarct 1 week previously, without clinical evidence of cardiac insufficiency and with an ejection fraction of 30% on echocardiography?



#### Scenario number 5

According to the results of a meta-analysis study of the use of beta-blockers following a myocardial infarction (including patients with good and bad prognoses), the number of patients needed to treat over a 2-year period to prevent 1 case of re-infarct or death was 56. This result is statistically significant, and the confidence interval varied from 40 to 91 over 2 years, or from 80 to 182 over 1 year. How would you interpret the results of this study with regard to the efficacy of treatment with beta-blockers? It has no It has a very effect beneficial effect In light of these study results, would you use beta-blockers to pharmacologically treat a 55-year-old woman without hypertension who had suffered a myocardial infarction 1 week previously, with no clinical complications, with a negative stress test, and with an ejection fraction of 53% on echocardiography, if she had no contraindications for beta-blocker treatment? Not inclined Very inclined to treat to treat For the following 2 questions, please underline 1 of the options for total cholesterol and LDL cholesterol: To what level do you believe, in theory, total cholesterol and LDL cholesterol should be reduced in patients who have suffered an AMI? Total cholesterol:

180 mg/dL	200 mg/dL	220 mg/dL	240 mg/dL	
LDL cholesterol:				
100 mg/dL	120 mg/dL	130 mg/dL	160 mg/dL	

What percentage of patients who have suffered an AMI in your practice do you believe are capable of reducing their total and LDL cholesterol to the values that you indicated?

100% 80% 60% 40% 20% <20%