

# **The appropriateness of coronary revascularization in Spain.**

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## **Abstract**

In Spain, 456 PTCA per million population were performed in 1997, with wide variations among regions. The rate in the Basque Country was 831 PTCA per million, whereas the rates in the regions of Valencia and Andalusia were considerably lower. In the 10 regions that make up the Insalud, which are governed by a single health authority, the rate was 561 PTCA per million population.

The CABG rate in Spain was 236 per million population in 1997. The same as for PTCA, wide variations can be seen among regions. The Basque Country was again the region with the highest rate of coronary surgeries, with 408 CABG procedures per million population. The regions of Andalusia and Valencia had the lowest rates. In the 10 regions of the Insalud, 238 CABGs were performed per million population.

Overall, the use of coronary revascularization techniques in Spain has grown in recent years. In 1997 slightly over 18,000 PTCA were performed, which represents a 23% increase over the previous year, and a 50% increase with respect to 1995. The increase in CABG has been more moderate. In 1997 about 9,000 procedures were performed, double that of 1990. In view of the variability among regions and the increase in the use of both of these coronary revascularization techniques, questions arise about how appropriately they are being used.

To answer these kinds of questions, we designed a research project whose objectives were to identify the proportion of coronary revascularization procedures -- PTCA and CABG -- that were performed in Spain for appropriate, uncertain and inappropriate reasons.

Applying the RAND appropriateness method, we developed appropriateness criteria for coronary revascularization, PTCA and CABG in Spain. The list of indications for this project was developed by two Spanish interventional cardiologists and two researchers who were experienced in the RAND method. The final list consisted of 1826 indications.

The synthesis of the evidence was prepared by two physicians with training in clinical research methodology, supervised by an epidemiologist with expertise in literature reviews.

Subsequently, a panel of 10 experts, made up of non-interventional cardiologists, interventional cardiologists and cardiac surgeons, rated the appropriateness of the 1826 indications in the list. The panel rated the indications in two rounds, following the modified Delphi method. In the first round, there was no interaction among panelists. In the second round, the panelists met in Madrid for a day and a half to discuss their ratings. During the meeting, some changes were suggested to the structure of the chapters in the list of indications, and all the indications were rated again.

The criteria produced were published in the Journal of Spanish Cardiology for prospective use.

We also carried out a retrospective study to measure the appropriateness of coronary revascularization procedures in Spain. In this presentation I will focus on the results of the retrospective study.

The study population consisted of 18,091 PTCA and 9,065 CABG procedures carried out in Spain in 1997. The population was stratified by type of center -- public or private -- and by annual volume of interventions, which was categorized as low, medium or high. In the case of PTCA "low" was defined as 50 to 249 interventions per year; "medium" was 250 to 399, and "high" was 400 or more

interventions. For CABG, “low” was considered to be 50 to 99 procedures, “medium” was 100 to 199, and “high” was 200 or more.

For both PTCA and CABG, we excluded centers that performed fewer than 50 procedures per year. These centers were excluded from the study because we believed that such a small number of interventions could compromise the feasibility of the study and would reduce the efficiency of the sampling design, since they represented less than 3% of all interventions.

The sample design was two-stage stratified random sampling, by clusters. The first stage units were the centers, throughout the whole country, in which coronary revascularization procedures were performed in 1997. The second stage units were the procedures.

The sample was made up of 1,959 PTCA procedures and 1,819 CABG procedures. As a result of the sampling design, 16 coronary intervention units were selected for PTCA and 16 cardiac surgery units for CABG. Within each stratum, the sample was self-weighted and the probability of selection of each cluster was proportional to the size of the cluster.

The PTCA sample was made up of 11 public hospital units (3 low volume, 3 medium volume and 5 high volume) and 5 private units (3 low volume, 1 medium volume and 1 high volume). The CABG sample was made up of 11 public units (1 low volume, 5 medium volume and 5 high volume) and 5 private units (2 low volume, 1 medium volume and 2 high volume). All the units selected agreed to participate in the study. The study guaranteed the anonymity of both physicians and patients, as well as the confidentiality of the center.

Before doing the field work, we carried out a pilot study to confirm the sample size and validate the data collection form. The information needed to classify each patient in the list of indications was obtained from the clinical records, which were abstracted on the data collection form by a medical resident in each unit. The pilot study also served to test the training session for the data abstractors. Finally, we also measured the level of inter-observer reliability in the pilot phase of the project.

The data were collected by medical residents in each hospital unit, all of whom had attended a training session. The data collection took place between July 1998 and January 1999. To assure that data were entered correctly, double data entry was performed independently by different researchers.

When the information necessary to classify the patient in the list of indications was incomplete, whatever assumptions were made always favored appropriateness. Thus, the possible biases in the results of this study act in favor of the physician; that is, in favor of the appropriateness of the procedure. For example, if no data were available on the medical therapy received by the patient, it was assumed that they had received optimal treatment. With this bias, we can be sure that we are not overestimating the percentage of inappropriate and uncertain use, nor underestimating appropriate use.

This slide shows the proportion of interventions that were found to be appropriate, uncertain, and inappropriate for each procedure and for revascularization in general, together with the corresponding 95% confidence intervals. The confidence intervals were calculated correcting for the design effect, thus they are wider than they would be if simple random sampling had been used.

About 46% of the PTCAs and 79% of the CABGs were performed for appropriate reasons. Overall, 64% of all revascularization procedures were found to be appropriate.

About 31% of the PTCAs were uncertain, and 12% of the CABGs. Overall, 21% of revascularization procedures were uncertain.

A total of 22% of the PTCA procedures were performed for inappropriate reasons. One percent of these would not have been inappropriate if the alternative procedure -- CABG -- had been performed. A total of 8.5% of the CABGs were found to be inappropriate, but most of them -- 7% -- would not

have been so classified if the alternative procedure -- PTCA -- had been performed. Overall, 15% of the coronary revascularization procedures performed in 1997 were found to be inappropriate.

To estimate the appropriateness of coronary revascularization procedures in Spain, we extrapolated the study results to the entire population of revascularized patients in 1997. Of the 26,905 coronary revascularization procedures carried out in Spain in that year, 8,294 PTCAs and 7,136 CABGs were appropriate. Overall, 17,336 revascularizations were appropriate. In some cases, the decision to revascularize the patient was appropriate, but the procedure chosen was not. For this reason, the number of appropriate coronary revascularizations is larger than the sum of the two individual procedures.

Our results showed that the number of uncertain procedures was 5,591 for PTCA, 1,090 for CABG and 5,601 for all revascularizations.

The total number of revascularization procedures performed for inappropriate reasons was 3,967. Of these, 3,824 were PTCAs and 143 were CABG surgeries. A small number of the inappropriate PTCA interventions – just 187 of 4,011 – would not have been inappropriate if CABG had been performed. However, most of the inappropriate CABG interventions – 640 of 783 – would not have been so classified if PTCA had been performed on those patients.

In conclusion, we have applied the appropriateness method to estimate the appropriateness and overuse of coronary revascularization procedures in Spain.

At least 15% of coronary revascularization procedures performed in Spain in 1997 were inappropriate, which represents some 4,000 procedures.

The selective elimination of inappropriate procedures would make it possible to free resources to provide effective services to persons who need them and who do not have access to appropriate care.