

# UTILIZATION OF PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY FOR QUALITY ASSURANCE IN HEALTH CARE FROM 1983 TO 1996

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## Abstract

**Objectives:** To examine the distribution of interventional cardiac catheterization laboratories, their case load, the time trends, and the regional variation of percutaneous transluminal cutaneous angioplasty (PTCA) utilization in Italy.

**Methods:** Analysis of data was provided by the annual reports of the Italian Group of Studies and Interventional Cardiology over the period from 1983 to 1996.

**Results:** The number of PTCA facilities and their use steadily increased, mainly in the North. In 1996 the utilization rate was 34 per 100,000 population, but only 60% of labs performed 200 or more procedures.

**Conclusions:** Dramatic time trends and regional variations often took place without an epidemiology and technology assessment-based planning process.

**Keywords:** PTCA, Utilization, Regional variation

Percutaneous transluminal coronary angioplasty (PTCA), also known as balloon angioplasty, is an effective cardiac revascularization technology, introduced in 1977 by Andreas Gruntzig, that has shown a rapidly growing utilization.

It is relatively nontraumatic and can be repeated (8). The main disadvantages are its costs and the high restenosis rate. Restenosis occurs in approximately one-third of patients undergoing dilatation of partially stenosed blood vessels (4;6;12;15) and in approximately 60% of those undergoing dilatation of a totally occluded

The authors thank the Italian Group of Studies and Interventional Cardiology (GISE).

artery (1;14). It is also the main cause of revascularization operations, required by 30–60% of patients undergoing PTCA (20;21).

Several studies suggest an inverse association between the volume of PTCA procedures at a given center and unfavorable outcomes (9;16). These data confirm the guidelines for PTCA procedures drawn up by the the American College of Cardiology and the American Heart Association, which recommend a minimum annual volume of angioplastic interventions of 200.

To contribute to the planning process for interventional cardiology services in Italy, we analyzed the distribution of interventional cardiac catheterization laboratories, the utilization of PTCA, and the case load per lab per year for the period from 1983 through 1996.

## **METHODS**

Data for the period from 1983 to 1996 were extracted from the annual reports of the Italian Group of Hemodynamic Studies and Interventional Cardiology (GISE), which at present includes almost 100% of public and about 90% of private labs (13;17;18;19;23;24;25;26;27;28). The tradition of this register, its easy compilation, its regular publication, and the prestige of the GISE guarantee the careful collection of data.

However, it is important to point out that the reports focus on procedures, not on patients; hence, it is not possible to study the indications (and consequently the appropriateness) or the outcomes (and consequently the effectiveness), nor to know how many PTCAs are re-interventions on the same patients.

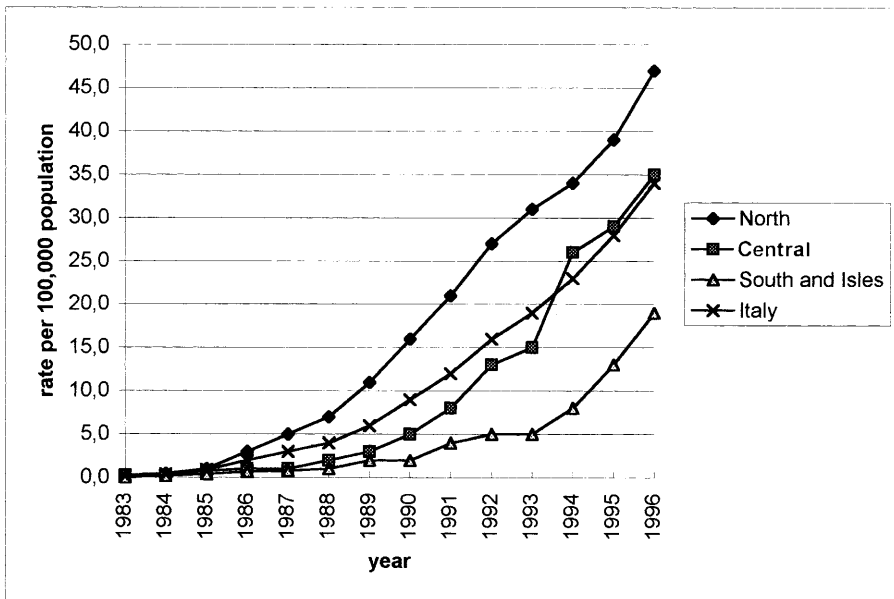
For each year, data were grouped in order to evaluate the situation of the three main regions of Italy (North, Central, South, and the Islands) and of Italy as a whole. The distribution of interventional cardiac catheterization laboratories and the number of PTCAs performed were examined. These numbers were translated into procedures per million inhabitants using the data from the 1991 Italian census.

Case load per lab and percentage of labs performing 200 or more angioplasties per year were also calculated: previous studies examining the relationship between the number of PTCAs performed at hospitals (volume) and adverse outcomes have shown that low-volume hospitals (< 201 PTCAs/year) have a significantly higher rate of adverse outcomes than high-volume hospitals (9;16). These findings are consistent with the recommendation of the American College of Cardiology and the American Heart Association for minimal annual volumes.

## **RESULTS**

From 1983 to 1996 the number of interventional cardiac catheterization laboratories in Italy underwent a sevenfold increase. In 1996 there were 70 (39 in the North, 14 in central Italy, and 17 in the South and Isles) with a rate of 1.3 labs per million population. During the same period the number of PTCAs per 100,000 inhabitants increased from 0.3 to 47 in the North, from 0.3 to 35 in central Italy, from 0 to 19 in the South and Isles, and from 0.2 to 34 at the national level (Figure 1). In addition, the average of case load per lab increased during this period from 12 to 311 in the North, from 7 to 210 in central Italy, from 0 to 156 in the South and Isles, and from 10 to 246 in the country as a whole.

On separate analysis of cardiac catheterization laboratories performing fewer than 200 PTCAs per year and those performing 200 or more per year, we found



year	North		Central		South and Isles		Italy	
	No.	rate*	No.	rate*	No.	rate*	No.	rate*
1983	71	0.3	29	0.3	0	0	100	0.2
1984	134	0.5	29	0.3	40	0.2	203	0.4
1985	362	1	83	0.8	93	0.4	538	0.9
1986	813	3	164	1	143	0.7	1,120	2
1987	1,275	5	163	1	162	0.8	1,600	3
1988	1,857	7	252	2	293	1	2,402	4
1989	2,819	11	338	3	353	2	3,510	6
1990	4,090	16	550	5	505	2	5,145	9
1991	5,288	21	826	8	778	4	6,892	12
1992	6,935	27	1,405	13	1,002	5	9,342	16
1993	7,943	31	1,683	15	940	5	10,566	19
1994	8,601	34	2,896	26	1,566	8	13,063	23
1995	9,942	39	3,154	29	2,651	13	15,747	28
1996	11,889	47	3,824	35	3,880	19	19,593	34

\*per 100,000 population

Figure 1. PTCA utilization rates in Italy, by geographical area, 1983–96.

that prior to 1988, no lab had a volume of procedures of 200 or more per year. In 1988 5% of labs in northern Italy had a case load of 200 or more per year, but this volume of activity per lab was not achieved until 1993 in central Italy, and only in 1994 in the South and Isles. In 1996, 60% of labs at the national level had a case load of 200 or more PTCA's per year, while in the northern, central, and southern regions this percentage was 59, 71, and 52, respectively (Figure 2).

## DISCUSSION AND CONCLUSIONS

Bearing in mind the approximate nature of the figures, owing to the limitations of the source, the number of PTCA procedures has undergone a marked increase in Italy over the last decade, as in many other countries (29). The magnitude of the

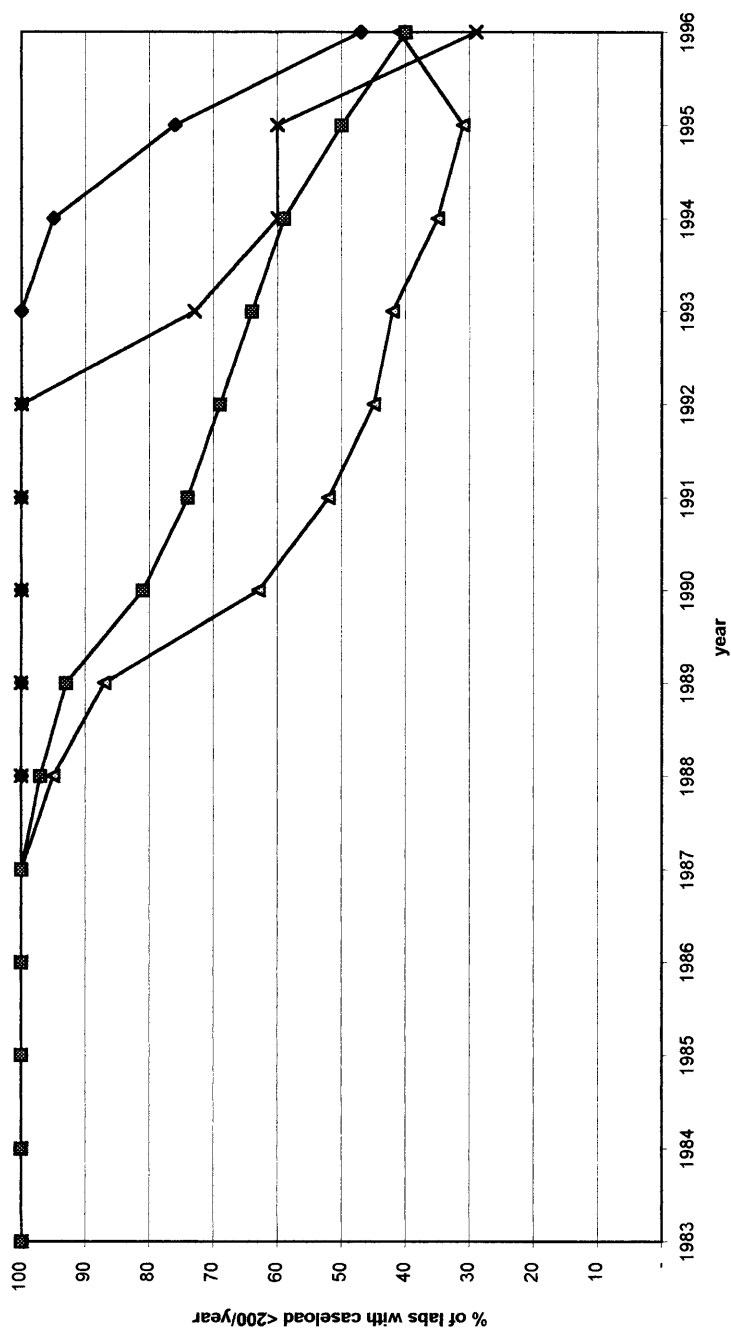


Figure 2. PTCA labs case loads in Italy, by geographical area, 1983–96.

phenomenon can be seen in a comparison of data available for 1990 in nine countries (2). The rate of nine PTCA procedures per 100,000 population in Italy is similar to rates recorded in Sweden (12.8/100,000), Germany (14.4/100,000 compared with 277.3/100,000 in 1989), and the United Kingdom (14.8/100,000). This rate is much lower than rates recorded in Japan (16.2/100,000), Australia (25.1/100,000), Canada (39/100,000), the Netherlands (48.8/100,000), Belgium (55/100,000), and the United States (84.7/100,000 in 1988).

In his comparison of PTCA usage in 14 different European nations, van den Brand (29) reported a mean increase of 600%, although there were marked differences between the various countries considered. With a view to explaining the variations in use, considerations were made for each country of the relationship between annual number of PTCAs and the death rate (standardized by age) for ischemic heart disease, gross domestic product (GDP) and health expenditure per capita, and number of cardiologists and interventional cardiac catheterization laboratories. On comparison of the volume of PTCA procedures and death rate for ischemic heart diseases, three clusters of nations emerged: one with a low death rate and low annual volume of PTCA procedures (Portugal, Italy, and Spain), one with a high death rate and low annual PTCA volume (Sweden, Norway, Finland, Denmark, United Kingdom), and one with an intermediate death rate and medium to high annual PTCA volume (France, Switzerland, Austria, Germany, the Netherlands, Belgium). While no relationship emerged on comparison of PTCA rate and GDP, and health expenditure and number of cardiologists, a direct relationship emerged between PTCA volume and number of laboratories per million population. Increasing utilization of PTCA procedures is therefore a widespread, quantified, but inadequately explained phenomenon.

It is not easy to interpret the decreasing gradient of utilization between the northern and southern regions. The most updated figures on mortality in Italy for myocardial infarction and other ischemic heart diseases go back to 1994 (22), and show rates that are variously distributed throughout the country: 144/100,000 population in the North; 149/100,000 in central Italy; and 101/100,000 in the South and Isles. Specific mortality rates alone, in the absence of epidemiologic data on morbidity, appropriateness, and outcomes, do not allow assessment of whether there is, for example, overuse in the North and underuse in the South. Moreover, it is not currently possible to evaluate accurately the underestimation of private centers, which are probably more widespread in the South.

A progressive increase in use is part of the natural history of the supply of all new medical procedures, including development of a case study to assess whether it would be appropriate to extend the service to all subjects for whom it is prescribed. Until the new technology proves to be preferable to available alternatives, such increase in use appears justified only in centers subjecting it to trial. It does not seem rational to increase the number of centers providing the technology. Such trials should systematically include studies on appropriateness, outcome, and cost assessment, together with an estimate of population needs.

In a study conducted in the state of New York (5), it emerged that the appropriateness of as many as 38% of PTCA procedures was uncertain and that 4% were totally inappropriate. Only a very limited number of studies on appropriateness have been conducted in Italy, although generally speaking there is no reason to believe that our standards differ completely from those of the United States.

Outcome assessment, like cost assessment, requires a long time to be complete, although it is easy to obtain an indirect indicator of outcomes in such data as annual

case load per laboratory. As we have seen, Italian data show that only 52% of laboratories in the South and Islands, 71% of those in central Italy, and 59% of those in the North have an annual PTCA volume greater than 200, which several sources consider to be the minimum work load in terms of both effectiveness and efficiency.

As concerns costs, it would be interesting to conduct an analysis from the point of view not only of the provider but also of the facility reimbursing the service (in Italy the National Health Service for public and subsidizes private services). Following the introduction in Italy of a system of hospital financing based on diagnosis-related group (DRG) tariffs for PTCA procedures, it would be worthwhile to assess whether the increase in DRG tariffs for PTCA procedures would be a financial incentive, as in the United States (7), to use this technique in place of coronary artery bypass grafting. A short hospital stay is generally required for coronary angioplasty. Restenosis, which is the most frequent complication, in many cases requiring revascularization surgery, tends to present after discharge from the hospital, for which reason bypass operations are reimbursed separately as new cases.

In Italy the data on which requirement estimates and interventional cardiac catheterization laboratory programming should be based are largely unavailable, and there are considerable regional differences in the availability and volume of laboratories offering PTCA procedures. At present, it does not appear to be strategically appropriate to establish new centers, in the name of a (badly interpreted) right to services, even in those regions where these services are less accessible. On the other hand, should there prove to be an increase in the demand for PTCA procedures, even following health policies able to reveal health demands presently hidden, such expansion may be warranted. In the meantime, supply should undoubtedly be adjusted through the development of existing laboratories, with a view to obtaining more efficient services, coupled with a volume of activity and expertise able to secure optimum outcomes. Moreover, benefits may be achieved by publicizing waiting times, and the outcomes of the centers, enhancing patients' free choice.

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