Clinical Utilization of the Coronary Pressure Wires

Ramón López-Palop, Eduardo Pinar, Íñigo Lozano, Pilar Carrillo, Rocío Cortés, Francisco Picó and Mariano Valdés

Servicio de Cardiología. Hospital Universitario Virgen de la Arrixaca. Murcia.

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Introduction. Earlier studies have established the value of coronary pressure wires for diagnosing and monitoring the treatment of patients with coronary artery disease. In this study we demonstrated their usefulness in the daily clinical practice of a catheterization laboratory.

Material and methods. A retrospective study of the use of pressure wires in our laboratory between October 1998 and November 2000. The pressure wire was inserted whenever the interventional cardiologist considered it to be indicated. In all cases, pressures were recorded with a Waveguide Cardiometrics 0.014 guide (Endosonics) and hyperemia was induced by intracoronary adenosine.

Results. Two hundred fifty-three lesions were studied in 190 patients. Indications were functional evaluation of lesions of intermediate severity for 82% (9% intrastent restenoses); guidance of balloon PTCA for 5%; and fulfillment of a research protocol for 13%. Twenty-six percent of lesions considered to be of moderate severity based on angiography were treated as a consequence of the pressures measured by the wire. A decision to begin or continue a procedure was based on wire pressures in 24% and intervention was avoided in 60%. No major complications attributable to the wire were observed. A lesion was dissected in one patient (0.5%) but it was treated without consequences. Twenty pressure wires (11%) failed to work properly during the procedure, fourteen of them (7%) before insertion. The wire could not be advanced across the lesion in one case.

Conclusions. The pressure wire is useful in the daily clinical practice of a catheterization laboratory. Its most common indication is the evaluation of lesions of intermediate or unknown severity, and use is associated with few complications.

Key words: *Coronary angioplasty. Methods. Coronary circulation. Blood pressure.*

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Correspondencia: Dr. R. López Palop.
Ricardo Gil, 20, 3.º dcha. 30002 Murcia.Spain.
E-mail: mlopezs@meditex.es

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Utilización habitual de la guía de presión intracoronaria. Experiencia de un centro

Introducción. Estudios previos han establecido el valor de la guía de presión en el diagnóstico y optimización del tratamiento de la enfermedad coronaria. En este trabajo mostramos su utilización como herramienta integrada en la actividad cotidiana de un laboratorio de hemodinámica.

Material y métodos. Estudio retrospectivo sobre el empleo de la guía de presión en un solo centro entre octubre de 1998 y noviembre de 2000. El empleo de la guía de presión quedó a criterio del intervencionista. Se utilizaron en todos los procedimientos adenosina intracoronaria y la guía Waveguire Cardiometrics 0,014 de Endosonics®.

Resultados. Se estudiaron 253 lesiones en 190 pacientes. Las indicaciones fueron: en el 82% valoración de estenosis angiográficamente moderadas; en el 5% optimización de la ACTP con balón, y en el 13% protocolos de investigación. El 26% de las lesiones moderadas angiográficamente fueron tratadas a consecuencia del resultado de la guía. En un 24% de las lesiones la guía condicionó el inicio o continuación de la intervención, y en un 60% la evitó. No se observaron complicaciones mayores debidas al uso de la guía, aunque en un paciente se produjo una disección coronaria finalmente sin secuelas. Veinte guías (11%) disfuncionaron durante el procedimiento y 14 (7%) antes de ser introducidas en el paciente. No se consiguió pasar la lesión en un caso.

Conclusiones. La guía de presión es una herramienta integrable en la práctica habitual de un laboratorio de hemodinámica. Su indicación más frecuente es la valoración de lesiones de gravedad intermedia, y se asocia a un número mínimo de complicaciones.

Palabras clave: *Angioplastia coronaria. Métodos.*

ABBREVIATIONS

PTCA: percutaneous transluminal coronary angioplasty
FFR: fractional flow reserve
ACT: activated clotting time (coagulation time)
AMI: acute myocardial infarction

Enfermedad coronaria. Presión arterial.

INTRODUCTION

Technical advances in recent years have made new diagnostic and therapeutic devices available in the hemodynamics laboratory. The use of intracoronary echography has made it possible to obtain better knowledge of the morphology of the arteriosclerotic plaque and the mechanisms involved in its development and treatment. Intracoronary pressure guide wires and Doppler have improved the functional assessment of coronary arteriosclerotic disease, enabling coronary stenosis to be more rationally managed than with morphological data alone.[1,2] In the case of the pressure guide wire, a parameter, fractional flow reserve (FFR), has been established with a value (0.75) representing a specific cutoff point for determining the functional meaning of a coronary lesion.[3-6] This allows decisions to be made regarding the revascularization of lesions with inconclusive angiographic findings,[7,8] and the determination of the prognosis of coronary lesions treated by balloon angioplasty alone or using a stent.[9-11] The fractional flow reserve has been shown to correlate well with noninvasive tests for the detection of ischemia.[12-14] The latest guidelines for clinical practice in interventionist cardiology published by the Spanish Society of Cardiology establish the use of pressure guide wires as class IIa procedures for the determination of the severity of lesions and optimization of angioplasty results. This supports the inclusion of this device as a routine tool in the hemodynamics laboratory.[15]

Our center has used the intracoronary pressure guide wire since October 1998. In the present study we describe our experience with the use of this device, studying its value in reaching decisions regarding revascularization and coronary interventionist procedures, as well as complications associated with the use of the device.

MATERIAL AND METHODS

Patients

Between 1 October 1998 and 31 October 2000, 5693 procedures were carried out at our center, 1991 of which were coronary interventional procedures. Our hemodynamics laboratory has been equipped with pressure guide wire equipment since October 1998, and has been used up to October 2000 in 190 procedures. The use of this device in each procedure, like the decisions made using values obtained with it, depend on the criterion of the hemodynamics specialist performing the intervention, the clinical manifestations of the patient, and the angiographic findings of coronariography. No particular protocol exists in our center for the use of pressure guide wire procedures or actions taken.

Technique

The pressure guide wire used in our laboratory is the Cardiometrics® 0.014 intracoronary guide wire of Endosonics. Whether performed for diagnostic purposes or in the course of a coronary intervention, in all procedures the patient was heparinized until a clotting time (activated clotting time, ACT) of more than 300 was obtained. A 6-French or 7-French catheter was used and the guide wire was calibrated before it was introduced in the catheter. In the coronary ostium, the pressures obtained in the catheter guide and pressure guide wire were systematically equalized. Two recordings were made in all studies of baseline pressures and at least another two after reaching maximum hyperemia. Maximum hyperemia was induced with intracoronary adenosine at a dose of 20 to 200 µg, generally more than 50 µg. FFR, obtained automatically on the console of the pressure guide wire, was defined as the ratio between the pressure distal to the lesion (recorded by the pressure sensor located on the guide wire at the point of union between its most radiopaque part and the rest) and the pressure proximal to the lesion (obtained from the pressure line connected to the catheter guide wire and corresponding to the pressure at the distal end of this catheter).

In all interventions, after the measurements were made the pressure guide wire was slowly withdrawn to a segment of the coronary artery proximal to the zone of study in order to confirm the correct operation of the device without losing its calibration during measurements. In the interventionist procedures, the pressure guide wire was used as an intracoronary guide wire and was not systematically exchanged for a conventional guide.

Lesions in the ostium of the left common coronary trunk were not studied in any case. In the study of lesions of the left common coronary trunk, which did not affect the ostium angiographically, it was confirmed that catheterization did not disturb the pressure curve recorded in the aorta.

Data collection and statistical analysis

The indications for the use of a pressure guide wire, clinical and angiographic results, and data of each patient were collected from the records on interventions kept in our hemodynamics laboratory and from the medical records of patients. Digital anatomic quantification of the lesions was carried out *a posteriori* using the Inturis Cardioview 4.00 program and the quantitative analysis package Inturis CIVP version 3.3 of Phillips.

Lesions were considered significant when the fractional flow reserve was less than 0.75, whereas values of at least 0.90 were required to consider

TABLE 1. **Characteristics of the study population**

	Number	Percentage
Procedures	190	
Age (mean±SD)	61±10	
Male sex	147	77
Indication for the procedure		
Unstable angina	121	64
Stable angina	21	11
Post-AMI	29	15
Acute MI	4	2
Ventricular dysfunction	11	6
Valve disease	4	2
Ventricular function		
Normal	136	71
Slight depression	20	11
Moderate depression	21	11
Severe depression	13	7
Test of ischemia		
Not made	89	47
Negative	5	3
Inconclusive/indeterminate	15	10
Positive	77	40
Previous AMI	78	41
No. of vessels (mean±SD)	1.3±0.9	Multivess
patients	84	45
Indication for pressure guide wire		
Assessment of severity	156	82
Optimization of result	10	5
Investigation	24	13

SD indicates standard deviation; AMI, acute myocardial infarction.

TABLE 2. **Characteristics of the lesions studied by pressure guide wire**

	All lesions (%) n=253	Inconclusive stenoses (%) n=182 (72)
Vessel		
Common coronary trunk	7 (3)	7 (4)
Anterior descending coronary artery	148 (58)	110 (60)
Circumflex coronary	37 (15)	29 (16)
Right coronary	59 (23)	34 (19)
Saphenous graft	2 (1)	2 (1)
Type of lesion		
A	3 (1)	2 (1)
B1	76 (30)	59 (32)
B2	147 (58)	97 (53)
C	28 (11)	4 (3)
De novo	224 (89)	161 (88)
Restenosis	5 (2)	19 (10)
Intrastent restenosis	22 (9)	2 (1)
Indication for pressure guide wire		
Assessment of severity	182 (72)	
Optimization of result	39 (15)	
Investigation	32 (13)	
Quantitative analysis*		
Reference diameter	2.9±0.5	2.9±0.6
Percentage stenosis	63±19	54±12
Length	10.3±7.7	10±7.2

*Mean±standard deviation.

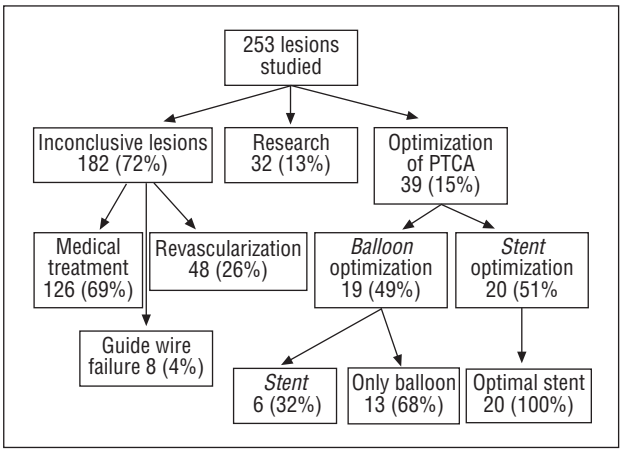

Fig. 1. Distribution of indications for using the pressure guide wire and later management in accordance with results.

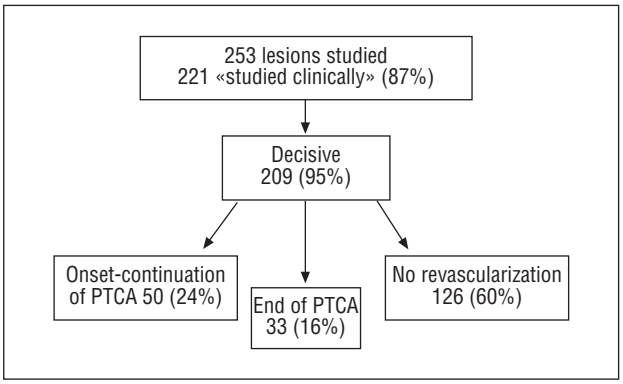

Fig. 2. Therapeutic attitude considered overall, in view of the results obtained with the pressure guide wire.

optimal the results of balloon angioplasty and at least 0.94 for stents.

To analyze the possible prolongation of intervention time due to the use of the pressure guide wire, we studied the mean imaging-guidance time recorded by the radiographic equipment and the mean amount of contrast consumed in the procedures. For this purpose, procedures in which a single lesion was studied with a pressure guide wire without being treated were compared with single-vessel angioplasty procedures and diagnostic procedures.

Quantitative variables were expressed as the mean and standard deviation. Qualitative variables were expressed as absolute values and percentages. Quantitative variables were compared with the Student t test.

RESULTS

From 1 October 1998 to 31 October 2000, 190 pressure guide wire procedures were carried out at our center, which was 9.5% of the total of 1991 interventionist procedures and 5% of the total of 3702 diagnostic procedures performed between the same dates. Two hundred fifty-three lesions were studied with the pressure guide wire (1.3 lesions per procedure). The baseline characteristics of the population and the indication for coronariography are shown in Table 1.

The initial indication for the use of the pressure guide wire (Table 2) was the assessment of the functional importance of a stenosis of angiographically inconclusive severity in 156 cases (82%), optimization of the result of coronary angioplasty in 10 (5%), and the collection of data for investigational protocols in 24 (13%). Once the use of the pressure guide wire was decided on, independently of the initial indication, it was used to optimize the lesion if the decision was made to treat it and to optimize any other lesions treated in the same procedure.

In 182 lesions (72%), the indication for the use of the pressure guide wire was the determination of the functional importance of a stenosis that had been considered angiographically borderline by the hemodynamics specialist. In 126 of these lesions (69%), the result of the pressure guide wire study conditioned the decision to not treat the lesion. In 39 lesions (15%) the pressure guide wire was used to optimize the result of coronary angioplasty, in 20 lesions to assess the good functional result of the stent implanted, and in 19 balloon angioplasties to decide whether or not to implant a stent. In 6 of these 19 lesions (32%), the result obtained with the pressure guide wire motivated treatment of the lesion with a stent (Figure 1).

Overall analysis of the use of the pressure guide wire (Figure 2) indicated that the data obtained by the device were decisive for action in 95% of the lesions studied for clinical purposes (excluding investigational use). In 126 lesions (60%), the decision to not

TABLE 3. **Time of imaging-guidance and volume of contrast used, according to the type of procedure**

	Diagnosis	Single lesion pressure guide wire	P*	Single-lesion PTCA	P**
Imaging-guidance time (min)	2.5±1	8.5±5	<.005	17.6±20	<.005
Volume of contrast (mL	75±15	160±99	.02	258±134	<.005

*Value of P for comparison of the diagnostic pressure guide wire.**Value of P for comparison of single-lesion pressure guide wire-PTCA. PTCA indicates percutaneous transluminal coronary angioplasty.

revascularize the lesion was based on the results obtained with the pressure guide wire. The other characteristics of the procedures are shown in Table 2.

Complications and problems with use of the device

Only one minor complication attributable to the use of the pressure guide wire occurred. In case 156, the worsening of the series of an image compatible with minimal ulceration or spontaneous dissection within the context of stenosis quantified as 53% of diameter, with appearance of a type B dissection that was treated with a stent without other consequences.

In one case (a lesion of inconclusive severity in the first oblique marginal branch of the circumflex artery that was sharply angled at its origin), the pressure guide wire could not be advanced through the artery.

No patient had contraindications for the use of intracoronary adenosine and none of the patients with an indication for pressure guide wire study was treated with methylxanthines. No complications secondary to the use of intracoronary adenosine were observed, with the exception of transitory episodes of complete, asymptomatic atrioventricular block that disappeared either spontaneously or by making the patient cough.

Twenty pressure guide wires (11%) functioned incorrectly (no signal or impossible to calibrate) during the procedure and had to be substituted. Fourteen of them (7%) functioned incorrectly before being introduced in the patient. Eight lesions (4%) were not studied with the pressure guide wire due to guide wire failure. The percentage of pressure guide wire dysfunction decreased progressively after the first months of use and after technical improvements in the guide wire connector. In the last year, only 6% of the guides failed, 2% before introduction in the patient.

The procedures in which a single lesion was studied with a pressure guide wire but did not have to be treated required a significantly longer mean imaging-guidance time than needed for diagnostic coronariography, and a significantly shorter mean imaging-guidance time than single-vessel stent angioplasty in our center. The volume of contrast required was also intermediate between that used in diagnostic procedures and that needed for single-vessel angioplasty (Table 3).

DISCUSSION

In this study we report the 2-year experience of our center with the use of the pressure guide wire as a tool integrated in the routine activity of the hemodynamics laboratory.

Technical development has made newer and better-designed tools available for coronary interventionist procedures. Sometimes, the complexity of the devices, their cost, their limited field of application, or the scant yield of relevant information in an interventionist procedure mean that new devices are used only for research in few hemodynamics laboratories, or in sporadic cases with unusual presentations or evolution. In this study the pressure guide wire was used in 10% of the interventionist procedures in our laboratory, with a clinical indication (not motivated by research protocols) in 87% of cases.

The two indications catalogued as IIa in the recent Guidelines for Clinical Practice in Interventionist Cardiology published by the Sociedad Española de Cardiología[15] (assessment of the severity of lesions and optimization of interventionist procedures) were the main reasons for using a pressure guide wire in our series. Of these two indications, assessment of the severity of angiographically inconclusive lesions was the main indication in our center, whereas the optimization of interventionist procedures represented only 5% of all the procedures carried out with a pressure guide wire. This is probably because of the almost systematic use of stents in our laboratory and the scant number of balloon angioplasties alone, in which optimization is considered indicated.

Several reasons have motivated the widespread use of the pressure guide wire technique in our center to establish the severity of coronary lesions: *a)* the contribution of purely anatomical functional data to the morphological data obtained by angiography and intracoronary echography; *b)* the good correlation reported in the literature with noninvasive tests of ischemia;[12-14] *c)* the easy interpretation of results due to the existence of a precise cutoff point (0.75) that is not affected by the presence of microvascular coronary artery disease, and *d)* the fact that it is a technique that the hemodynamics specialist can perform, which avoids delay and postponement of decisions. The course of action to be taken in a patient can be decided on without performing a new catheterization.

In our experience, this point adds special value to the pressure guide wire because the device provides objective information on which base the treatment of patients with inconclusive lesions and ischemia tests that are either inconclusive or have not been made by the clinician. Often, the physician did not consider action indicated before coronariography was carried out.

In comparison with intracoronary echography, two recent studies[16,17] have tried to establish the minimum cross-sectional area determined by intracoronary echography, corresponding to the limit of 0.75 used with the pressure guide wire to determine the functional significance of a lesion. Although the authors obtained a good correlation between the two devices in both studies, in daily practice intracoronary echography always involves introducing an echography catheter in the coronary artery, in addition to the guide wire, which

is why it prolongs the procedure and favors the appearance of complications.

The hemodynamics specialist responsible for the intervention based his or her decision on the data obtained with the pressure guide wire procedure in 209 of 221 lesions (95%) studied for a clinical indication, not including research protocols. In the other 12 cases (all of them assessments of the severity of angiographically inconclusive lesions), in spite of the result of the pressure guide wire procedure (FFR>0,75), the decision was made to treat the lesion based on its morphological characteristics, for instance because of the presence of images suggestive of spontaneous dissection, possible intraluminal thrombus, ect. (Figure 2).

Current use of the pressure guide wire procedure is based on the conclusions obtained in studies of patients with stable angina. The suitability of extending its use to patients with acute coronary syndromes and the validity of the cutoff point of 0.75 in the lesions of these patients have not been fully demonstrated. In our opinion, the use of the pressure guide wire procedure and decisions based on data obtained with this study are another element that must be combined with the clinical context of the patient, morphology of the lesion (angiographic, or echographic if intracoronary echography is considered necessary), and the results of noninvasive ischemia detection tests. This affirmation, which is applicable (we believe) to all studies made with pressure guide wires, is still more important in patients with unstable coronary syndromes. In these patients, in spite of the possible limitations of the technique, the dynamic character of the lesions can condition a prognosis that is independent of the functional importance of the obstruction present.

The low number of complications observed, 0.5% (one case, which was inconsequential for the patient), was slightly lower than has been reported by other studies using intracoronary echography.[18,19] This has favored the increased use of the device in our laboratory. The practical absence of complications is motivated, in our opinion, by two reasons: *a)* the characteristics of the device itself, which is an intracoronary guide, that, although not as well developed as the intracoronary guides generally used in interventionist procedures, is sufficiently manageable to reach most of the lesions susceptible to study, and *b)* the most frequent type of indication in which it is used, lesions that are not severe angiographically and treated lesions to be optimized. Also, the selection of lesions (main vessels of a certain caliber, ect.) may have contributed to the fact that it was not possible to access the lesion to be studied with the guide in only one case.

Another important aspect is the number of guide wires that, in our experience, do not function correctly during use. This is a circumstance associated with a delay in the procedure and a greater cost of the procedure if the guide wire malfunctions during use. In the most recent months of the study, 6% of the pressure guide wires could not be used to complete the procedure for which they were destined. Except in cases in which the pressure guide wire functioned incorrectly or did not function (2%) because the package had been opened, it was exceptional that the pressure guide wire malfunctioned before the severity of the inconclusive lesion had been assessed. During angioplasty, when indicated, malfunction could occur when the balloon or stent was exchanged.

In an era in which a large amount of time is invested in procedures and attention must be given to how procedures are scheduled in the workday, the duration of procedures involving new devices must be considered. In our series, the use of the pressure guide wire was associated with a significant prolongation of procedures with respect to diagnostic studies, as indicated by the two indirect parameters used to measure the duration of the procedure (imaging-guidance time and amount of contrast used). Although significant statistically, we considered that a 5-minute prolongation of the procedure in relation to a single-vessel interventionist procedure is not relevant in the daily activity of a hemodynamics laboratory. Our assessment that the delay occasioned by use of the guide wire was short was confirmed by the fact that the procedure required only half of the mean time required for single-vessel angioplasty.

LIMITATIONS

In the present study, we described the activity in our center with the intracoronary pressure guide wire from the time this device was acquired by our laboratory until October 2000. The indication for its use and mode of use were decided by the interventionist responsible for each case, following protocols described in the literature,[2] rather than in accordance with a method especially designed for this study. It is difficult to know how often the decision was made to not make a pressure guide wire study in angiographically moderate stenoses, due to the morphological characteristics of the lesion or the patient´s clinical context. This circumstance is especially important in patients with unstable coronary syndromes, in which it is logical to assume that only the most stable lesions and patients were included for performing pressure guide wire interventions, and that it was not carried out in unstable patients regardless of the existence of lesions of inconclusive angiographic severity. It is not possible and it was not the aim of this study to establish new indications or uses for the pressure guide wire, but to describe its applicability and results in routine practice in accordance with the

indications described.[15]

The doses of adenosine used, which were higher than those recommended in the literature, were not used after studies of dose-response curves. These doses were used empirically by each interventionist, who attempted to attain maximum hyperemia safely, compensating for possible variations in the real dose of adenosine introduced in the coronary artery due to differences in the cannulation of the coronary ostia in each specific case.

Although intracoronary adenosine has been considered as effective as intravenous adenosine for achieving maximum hyperemia, the use of intracoronary route of administration in our laboratory could be considered a limitation to the results obtained in certain cases, especially those in which the lesion studied was located in the left common coronary artery trunk.

CONCLUSIONS

In our experience, the pressure guide wire is a useful tool that can be integrated in the daily work of a hemodynamics laboratory. Its main clinical uses, given the current acceptance of the use of stents, resides in the assessment of lesions of unclear severity. The use of the pressure guide wire is associated with the appearance of practically no complications and with a significant, although small, prolongation of the procedures. However, it provides information for agile and effective decision-making based on functional data that complement the morphological data obtained during angiography.

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