

B. Meier

Cardiology,
Swiss Cardiovascular Center Bern,
University Hospital, Bern

The balloon, the mainstay to stay for coronary angioplasty

Historical development

Percutaneous transluminal coronary angioplasty (PTCA) is to be used synonymous with percutaneous coronary intervention (PCI). It includes balloon treatment and all other catheter based coronary revascularisation techniques. It is a derivative of peripheral catheter angioplasty introduced by Dotter and Judkins [1]. Grüntzig succeeded to refine this procedure by using a polyvinylchloride balloon [2]. Porstmann had failed with his earlier idea of a caged latex balloon [3].

PTCA was not at the beginning of interventional cardiology but it is its most important representative. Interventional cardiology commenced with a wire pulmonary valvuloplasty performed by Rubio-Alvarez in Mexico in 1951 and published in 1953 [4]. Rashkind followed with balloon septostomy in the United States in 1966 [5]. In 1967 Porstmann first closed a patent ductus arteriosus interventionally [6].

The father of PTCA [7], Andreas Roland Grüntzig, was born on June 25, 1939 in Dresden, Germany. He was never to remember his father who died during the Second World War. The mother raised the two sons to become doctors in spite of the socialist regime having planned for them to be manual workers. She crossed these plans and the border to West Germany before the wall went up in 1957. Grüntzig studied medicine in Heidelberg. He underwent further training in surgery and epi-

demiology in Germany and England. In 1969 he moved to the University Hospital of Zurich, Switzerland, to train under Hegglin. Upon arrival, a change of plans was imposed because Hegglin had passed away. Grüntzig became a fellow of the newly founded division of angi-ology of Bollinger. At Zeitler's angiology clinic in Germany, Grüntzig familiarised himself with the peripheral angioplasty method of Dotter. Together with his wife and friends, Grüntzig modified the Dotter technique to what it basically has remained to the current date [2].

First attempts in coronary arteries of corpses were judged as complete failures by the consulted pathologist. So was the first dog experiment with a coronary artery stenosis artificially produced by the cardiac surgeon Turina. Notwithstanding, Grüntzig banked on the experience of several hundred successful peripheral balloon angioplasty procedures and embarked on clinical coronary angioplasty in 1976 with a prototype balloon catheter manufactured by Schneider Medintag, a small technical firm in Zurich.

It was awfully difficult to find a suitable patient, as coronary angiography was carried out but late in the disease process at that time in Switzerland. On March 22, 1976 a first attempt was virtually forced upon Grüntzig by peers caring for a terminally ill patient with triple vessel coronary artery disease and poor ventricular function. The patient had addi-

Correspondence:

Prof. Dr. med. Bernhard Meier

Chefarzt

Schweizer Herz- und Gefässzentrum Bern

Universitätsklinik, Inselspital

CH-3010 Bern

e-mail: bernhard.meier@insel.ch

tional multi-organ problems and was deemed inoperable. Grüntzig had to access the heart through the arm and was not able to place the crude prototype of a guiding catheter available. The patient succumbed to his condition a few days later [8]. In March 1977 the first intra-operative balloon angioplasty procedures were performed in San Francisco by Grüntzig, Myler and Hanna. They were successful.

In September 1977, after spending two weeks in San Francisco without finding a suitable patient for a first PTCA procedure, Grüntzig returned back to Zurich to be presented with the case of an age mate of his (38 years old) with a first episode of chest pain and an isolated stenosis of the proximal left anterior descending coronary artery. In an era before internal review boards or consent forms had crossed the atlantic ocean, Grüntzig plainly explained the hitherto untried possibility of obviating bypass surgery to the patient who agreed without hesitation. Even the prospect of a possible emergency operation in case of problems could not deter the patient because he had already accepted the fact that surgery was inevitable.

As the resident in charge of this patient, I was an attentive witness to this historical conversation.

The intervention took place on September 16, 1977 and was a splendid success lasting up to the current day. Roughly 10 people witnessed the intervention. I noticed a couple of cardiac surgeons wearing faces difficult to interpret. The readied coronary perfusion pump, standard in the dog experiments, was not used as the patient tolerated the first balloon inflation well. It was not going to be used ever in elective cases. The only minor complication was a transient right bundle branch block [9].

Failures and complications did occur in subsequent patients. Yet, the method was launched for a journey of unparalleled success. Up to the current day, the balloon has remained the mainstay of non-surgical coronary artery revascularisation. The only addition of note was the coronary stent, first implanted by Puel [10] in Toulouse, France, on March 28, 1986, a few months after Grüntzig's untimely death in a crash as pilot of his own plane (October 27, 1985).

Current role of PTCA

Much in contrast to the common opinion that the impressive development of catheter technology has widened the indications for coronary angioplasty significantly, the indications have indeed stayed more or less the same. It still holds true that this method works best for early coronary artery disease. Applying it to diffuse disease, the risk of complications and recurrences overshadows the possible technical success. From the beginning, Grüntzig urged the community of cardiologists and family practitioners to subject the patients early to a coronary angiogram. This plea was honored increasingly which was the main driving force behind the phenomenal expansion of the procedure. Early diagnostic studies yield a high percentage of situations favourable for PTCA. The initial estimate of Grüntzig that about 15% of patients in need of coronary revascularization could be offered PTCA was revised drastically by this more aggressive behaviour of physicians towards early angiographic assessment of suspected coronary artery disease. Currently this figure is somewhere between 50 to 75%.

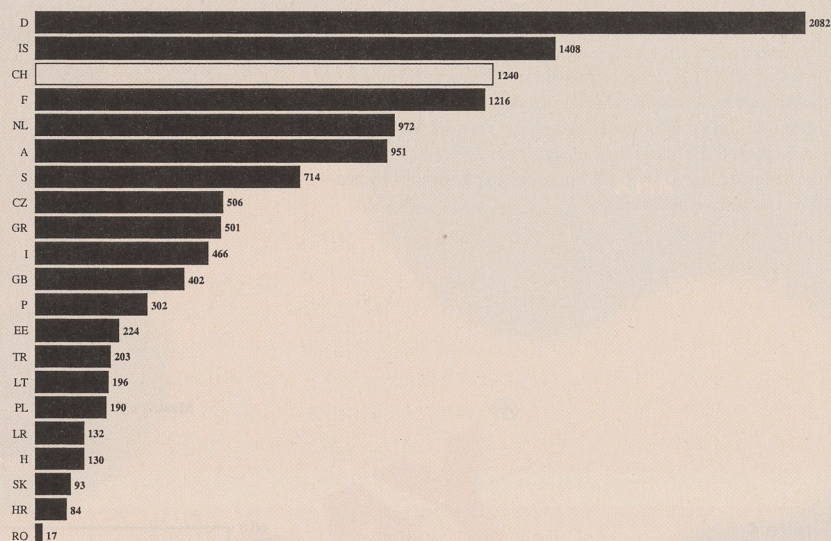
In late 1980 Grüntzig moved to the United States to practice at Emory University in Atlanta, USA, until his death. With him moved the primary focus of PTCA. Currently, Ameri-

cans contribute roughly half of the worldwide numbers of PTCA procedures estimated at more than 1 million per year. The economical importance of PTCA can be appreciated by calculating a cash flow of roughly CHF 10 000 per intervention and multiplying this with 1 million per year. This does not include investments in scientific and lay publications, training activities, professional and associated tourism, and expenditures for and revenues from professionals working in the field.

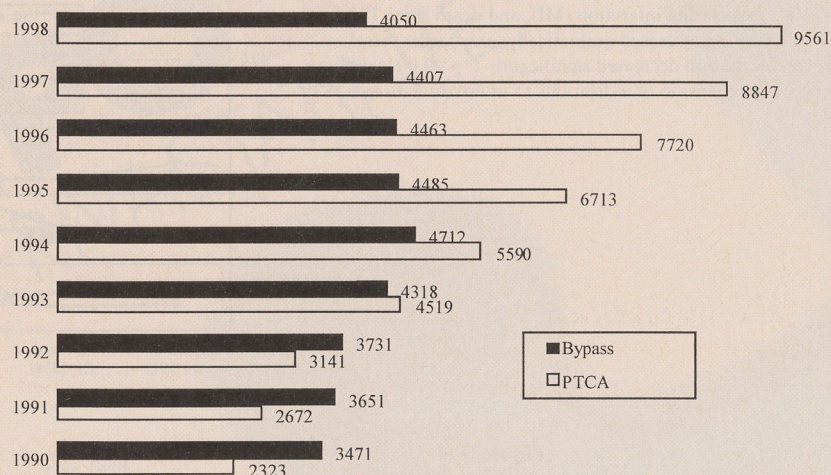
Currently about 2000 PTCAs per million inhabitants and year are performed in the United States and some leading European countries such as Germany (fig. 1). In urban areas with an elderly population, this figure may be considerably higher. Today a diagnostic coronary angiography will yield no significant disease, single vessel disease, double vessel disease, or triple vessel disease in about a quarter each. Two thirds of the patients will undergo PTCA, one fifth bypass surgery and only one out of 7 patients will be prescribed medical treatment alone [11]. Looking at single vessel disease specifically, PTCA will be recommended to roughly 90%. This figure drops to 30% in case of triple vessel disease. PTCA is rarely offered to patients with all the main vessels affected as these patients benefit more from coronary

Figure 1

Average number of PTCA procedures per 1 million of population in a selection of European countries in 1997. Abbreviations according to official car stickers.

**Figure 2**

Evolution of coronary bypass surgery and PTCA procedures in Switzerland since 1990. PTCA gained a clear dominance with some impact on the absolute figures of surgery in recent years.



artery bypass surgery. Thus, PTCA has remained a complement to bypass surgery rather than becoming a substitute which explains that the absolute numbers of bypass surgery have continuously grown worldwide albeit at a

much lower pace than those of PTCA. In Switzerland bypass surgery figures have levelled off and even given in slightly in recent years (fig. 2) [12].

Alternatives to balloon angioplasty

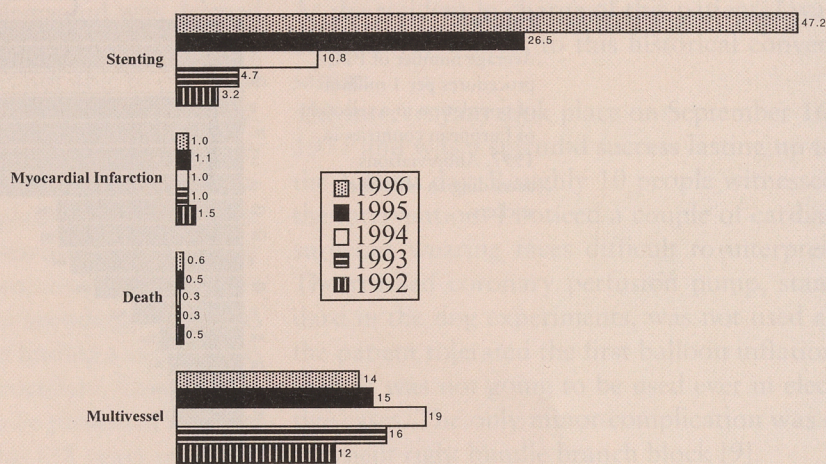
Of the numerous so-called new devices popping up in the eighties only the stent has improved the potential of PTCA. Surprisingly, its main virtue turned out not to be the reduction of acute complications for which it was initially introduced but the reduction of recurrence. Figure 3 displays on the basis of the example of the European Registry that the increasing use of stents has not reduced the occurrence of major cardiac events in spite of the fact that the indications have not expanded (constant figures of multivessel procedures). A Canadian survey [13] depicted in figure 4 corroborates this and points out that the only demonstrable beneficial impact of the stent was a reduction

of reinterventions. Although the stent is a true savior in case of impending or established acute occlusion, the overuse of stents observed today introduces about as many acute problems – if not more – than it prevents.

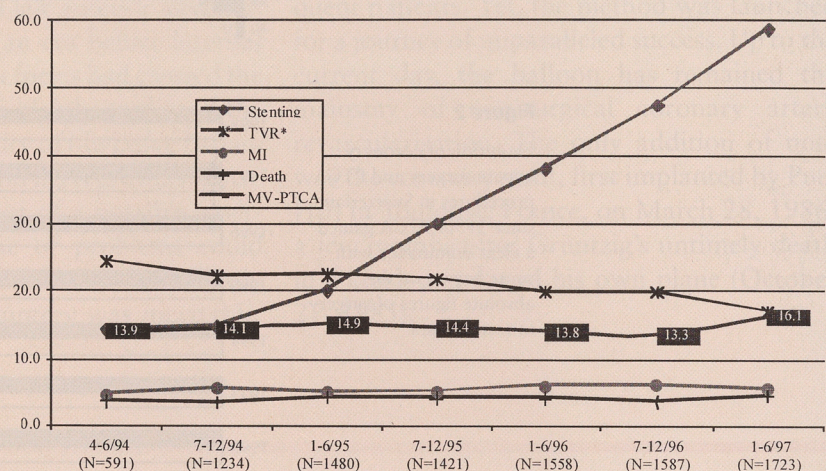
The easy application of the stent and its appeal of safety and durability have led to a current use of stents in about 80% of cases worldwide. Considering that before stents, 70% of patients had neither a complication nor a recurrence with balloon angioplasty alone, the current stenting rate has to be considered exaggerated. Other methods, in particular directional and rotational atherectomy or laser ablation, never gained a significant market share and further

Figure 3

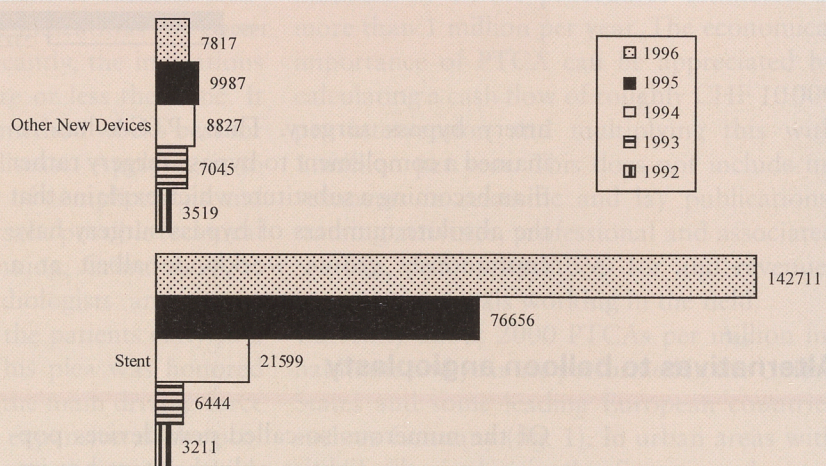
Evolution of stenting and major acute cardiac adverse events (in % of all PTCA procedures) since 1992 according to the European Registry. Multivessel denotes angioplasty on more than one major vessel in a single session. While stenting increased dramatically, no significant reduction in complications occurred without apparent expansion of indications to multivessel disease.

**Figure 4**

Canadian field study on the evolution (in % of all PTCA procedures) of stenting, target vessel revascularisation (TVR), myocardial infarction (MI), and death since 1994. While stenting increased dramatically, only target vessel revascularisation decreased significantly (*p < 0.001) without apparent expansion of indications to multivessel disease [13].

**Figure 5**

Evolution of absolute numbers of PTCA procedures with the use of stents or other so-called new devices since 1992 according to the European Registry.



decreased in importance as disappointing results in randomised studies emerged (fig. 5 and 6).

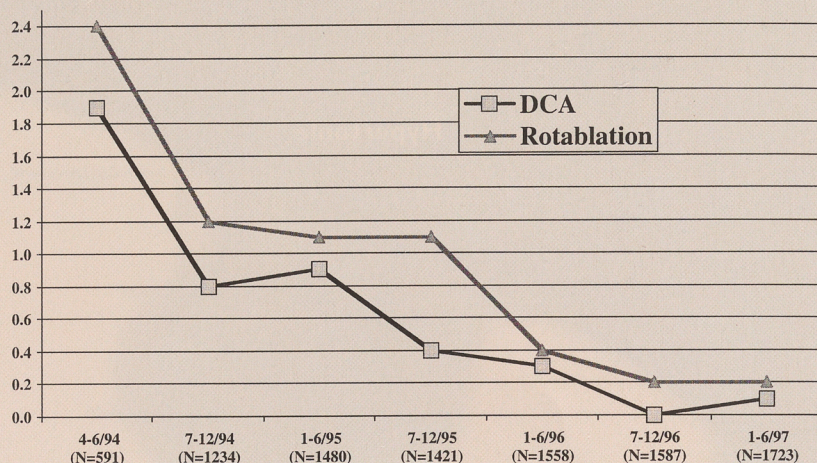
Some niche indications such as long calcified lesions in small arteries or balloon resistant tough stenoses for the rotablator or ostial lesions for directional atherectomy are maintained at some centres. Long in-stent restenoses have been tackled with rotablation or ablative laser to no avail. Other new devices to mechanically lyse thrombi have not found regular users, either. Emboli catchers are currently

investigated as are different modes of applying radiotherapy to curb restenosis (brachytherapy).

The stent has put a term to the 20-year controversy whether surgical stand-by has to be organised for every PTCA intervention. Even before the widespread application of stents, it became increasingly clear that less than 1% of PTCA cases really benefited from emergency surgery although acute occlusions occurred in about 7%. About half of these acute closures were clinically insignificant because of collat-

Figure 6

Canadian field study on the use of new devices other than stent (in % of all PTCA procedures) since 1994. In contrast to the steeply increasing use of stenting to about 60% during this time period, the use of directional (DCA) or rotational coronary atherectomy (rotablation) decreased to almost naught without ever having gained a significant market share [13].



erals or prior infarction in the pertinent myocardial territory. Of the remaining patients, the area was only rarely large enough to warrant emergency surgery which at best salvaged some of the muscle in jeopardy. The dreaded complications of emergency bypass surgery during myocardial infarction were generally a worse deal than the conservative treatment of the infarction induced by the failed PTCA attempt.

About half of these acute complications can nowadays be remedied or prevented with stent implantation. Many centres have been operating successfully for years without cardiac surgery under the same roof or even in the same city. This is not an ideal situation but it is acceptable [14].

Limitations of PTCA

A number of shortcomings of PTCA persist. There are limits to the amount of contrast medium, X-ray exposure, or compliance of the awake patient. The risks cumulate in long procedures involving several vessels. This explains why the percentage of multivessel PTCA in one session has remained below 20% in most western countries (fig. 3 and 4). An additional factor is the accumulated risk of restenosis which even nowadays has to be

calculated based on an individual risk of about 20% per lesion.

Chronic total occlusions still resist PTCA attempts in about 30% of cases and are the most important reason not to offer PTCA [15]. In non-occluded vessels, however, the risk of failure can be projected below 5%; if a lot of time and all the technical possibilities are invested without cost consideration even below 3%.

Prerequisites for PTCA

A modern catheterisation laboratory with digital image enhancement is the backbone of a successful procedure. A second unit should be available in case of technical failure. A complete stock of guiding catheters, guide wires, balloon catheters, and stents have to be maintained as well as a small but specific pharmacy with drugs effective in these interventions such as modern antiplatelet agents [16]. The laboratory must be able to function as a coronary care unit with all means for resuscitation being portable. Other devices such as atherectomy catheters, lasers, intravascular ultrasound equipment, pressure and flow measuring wires, angiography fiberscopes, or percutaneous by-

pass equipment are optional but frequently available in high volume centres.

The key factor for quality of any laboratory is the personnel. At least the main operator must have been trained according to general guidelines [16, 17] and should have passed a 1-year dedicated fellowship at a reputable teaching institution. A second experienced operator, able to work independently, should be in the house. The technical personnel should have profound knowledge and large experience to make swift and professional use of all techniques and installations in case of need. Regular morbidity and mortality rounds and case discussions should be selfunderstood. A comprehensive

data bank has to be maintained by professionals. A structured educational programme for medical doctors and auxiliary personnel including review of cases, journal clubs, and participation in theoretical and practical courses is essential and should be an integral part of the daily work.

Future perspectives

The age-adjusted prevalence of coronary artery disease has been significantly reduced in the United States over the past 20 years. Nevertheless, an increase in coronary revascularisation procedures has to be expected as the population ages and the overall prevalence of the disease increases [18]. PTCA offers professional satisfaction, prestige among peers, and substantial welfare. Catheterisation laboratories abound in the western world. Hence, a further increase in the numbers of PTCA per

population has to be anticipated. This evolution may be slowed, brought to a halt, or even reversed only by control through third-party payers or by rationing. Both are contrary to the medical profession and can only be imposed by politicians.

PTCA can be used to its best, when it is applied frugally. This means that the balloon should be the mainstay of the procedure, complemented by a stent in at the most 70% of cases. This yields optimal results and allows to let the largest number of potential patients benefit from the procedure with a limited budget. There is no need to treat a recurrent lesion any different than the initial lesion except that in desperate cases brachytherapy may be considered. Beyond the stent, this is the only method with a sufficiently reliable track record to reduce restenosis. However, the brachytherapy data are not consistent enough as of yet to render brachytherapy a mandatory addendum even in these cases.

References

- Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction: description of a new technique and a preliminary report of its application. *Circulation* 1964;3: 654-70.
- Grüntzig A, Hopff H. Perkutane Rekanalisation chronischer arterieller Verschlüsse mit einem neuen Dilatationskatheter. *Dtsch Med Wochenschr* 1974;99:2502-5.
- Porstmann W. Ein neuer Korsett-Ballonkatheter zur transluminalen Rekanalisation nach Dotter unter besonderer Berücksichtigung von Obliterationen an den Beckenarterien. *Rad Diagn* 1973;14:239-44.
- Rubio-Alvarez V, Larson RL, Soni J. Valvulotomias intracardiacas por medio de un cateter. *Arch Inst Cardiol Mex* 1953;23:183-92.
- Rashkind WJ, Miller WW. Creation of an atrial septal defect without thoracotomy. *JAMA* 1966;196:991-2.
- Porstmann W, Wierny L, Warnke H. Der Verschluss des Ductus arteriosus persistens ohne Thorakotomie. *Thoraxchirurgie* 1967;15:199-203.
- Grüntzig A. Transluminal dilatation of coronary artery stenosis. *Lancet* 1978;1:263.
- Meier B. Balloon angioplasty. In: Topol EJ, ed. *Comprehensive Cardiovascular Medicine*. Philadelphia: Lippincott-Raven Publishers; 1998. p. 2251-83.
- Hurst JW. The first coronary angioplasty as described by Andreas Gruentzig. *Am J Cardiol* 1986;57:185-6.
- Puel J, Joffre F, Rousseau H, Guermonprez B, Lancelin B, Valeix B, et al. Endo-prothèses coronariennes auto-expansives dans la prévention des resténoses après angioplastie transluminale. *Arch Mal Cœur* 1987;8:1311-2.
- Delacrétaz E, Meier B. Use of coronary angioplasty, bypass surgery, and conservative therapy for treatment of coronary artery disease over the past decade. *Eur Heart J* 1998;19: 1042-6.
- Roffi M, Arbeitsgruppe PTCA und Fibrinolyse der Schweizerischen Gesellschaft für Kardiologie. Herzeingriffe in der Schweiz 1998. *Kardiovask Med* 2000;3:89-103.
- Rankin M, Spinelli JJ, Carere RG, Ricci DR, Penn IM, Hilton JD, et al. Improved clinical outcome after widespread use of coronary-artery stenting in Canada. *N Engl J Med* 1999; 341:1957-65.
- Meier B. Surgical cover for angioplasty: Switzerland. *Br Heart J* 1994;72:506-8.
- Delacrétaz E, Meier B. Therapeutic strategy with total coronary artery occlusions. *Am J Cardiol* 1997;79:185-7.
- Meier B, Bonzel T, Fabian J, Heyndrickx G, Morice MC, Mühlberger V, et al., for the study group Clinical Issues, working group Coronary Circulation of the European Society of Cardiology. Recommendations for training and quality control in coronary angioplasty. *Eur Heart J* 1996;17:1477-81.
- Pepine CJ, Allen HD, Bashore TM, Brinker JA, Cohn LH, Dillon JC, et al. ACC/AHA guidelines for cardiac catheterization and cardiac catheterization laboratories. American College of Cardiology/American Heart Association Ad Hoc Task Force on Cardiac Catheterization. *Circulation* 1991;84: 2213-47.
- Levin PJ, Sassouni C. The potential world market for cardiovascular and medical devices. *J Invas Cardiol* 1997;9: 138-43.