HISTORY OF MEDICINE

Thirty Years of Balloon Dilations
A. R. Grüntzig and Percutaneous Balloon Angioplasty

Jerie P.

SUMMARY

Percutaneous transluminal coronary angioplasty – PTCA – will forever be linked with the name of A. Güntzig. Building on the work of Charles Dotter and Malvin Judkins, he developed a novel technique of revascularization and established a new speciality – interventional cardiology. The aim of this article is to sum up the most important data on Grüntzig's revolutionary work. Andreas Roland Grüntzig was born on 25th June 1939 in Dresden, Germany. In 1957 he received his B. A. in Leipzig (German Democratic Republic). In 1958, Andreas migrated to the German Federal Republic, received another B. A. in Heidelberg, and was enrolled at the Medical School in Heidelberg, from which he graduated in 1964. In 1969 he moved to Zurich, Switzerland, to the University Hospital, Dept. of Angiology. He soon recognized the potential of recanalizing partially occluded lower limb arteries using the Dotter-Judkins catheter, but was also aware of its risks. In 1972/73 he developed his balloon catheter and performed the first femoral angioplasty on 12th February 1974, and on 23rd January 1975 the first angioplasty using his new double-lumen catheter. The first experimental coronaroplasty in a dog followed on 24th September 1975. He presented his results with balloon catheters on 15th November 1976 in Miami. After a further period of arduous experimental research – still manufacturing the catheters with his small crew in the kitchen – he dilated a stenosed coronary artery in a 37-year-old man on 16th September 1977 in Zurich, with immediate relief of symptoms. The results of PTCA in the first five patients were published in Lancet on 14th February 1978; the coronarography in the first patient, performed on 10th April 2000, revealed normal patency of the dilated site (Prof. B. Meier, Bern). However, the news, published in Zurich in 1978, was received with some distrust and Grüntzig was unable – in spite of Professor A. Senning's support - to obtain resources to expand his research program and clinical activities. In September 1980 he accepted the Chair of Medicine (Cardiology) and Radiology, with the additional title of Director of the Dept. of Interventional Cardiology at Emory University in Atlanta, Georgia. Prof. Hurst gave him half of his office suite at Emory and later further facilities to expand his program. Here, at Emory, Grüntzig gave 10 angioplasty courses and, by 1985, performed 5,000 PTCAs with Dr. S. King and Dr. J. Douglas. Before reaching the peak of his scientific carrier, he died in a flying accident together with his second wife Margareth Ann, near Forsythe, Monroe County, Georgia, on 27th October 1985. His work was appreciated in tributes from U.S, U.K., Switzerland and Germany, by many international awards and honors. Numerous interventional laboratories in the world carry A. R. Grüntzig's name.

Key words: balloon angioplasty, balloon catheter, PTCA – historical aspects, A. R. Grüntzig, interventional cardiology, Å. Senning.

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Thirty years ago, in February 1974, Andreas Grüntzig used a balloon catheter for the first time to dilate an arterial occlusion, and in September 1977 he performed the first transluminal coronary angioplasty. And 25 years ago, in summer 1979, PTCA was recognized worldwide as a new, feasible treatment option for coronary bed stenoses and occlusions; the *NEJM* editorial of July 12, 1979 presents a summary of Grüntzig's most important results in the first 50 patients who underwent balloon dilation in Zurich (1). The editorial also contains an assessment of the data collected by U.S. centers – of altogether 259 patients registered worldwide at the time – and then, in the presence of professional stakeholders and the National Heart, Lung and Blood Institute (NHLBI) formulates the official position. Despite the dispassionateness of its conclusion, emphasizing the need of further verification of the new technique, its (hitherto merely) research nature and the need of further targeted monitoring (register), the tone of the summary is unequivocally favorable: Grüntzig's results "*evidently prove that in carefully selected and prepared patients, and in the hands of an experienced team, it is possible to use balloon angioplasty to successfully dilate a tight coronary stenosis and secure the immediate enhancement of coronary perfusion, thus improving cardiac output. The adjustment persists for six months or more; PTCA can therefore responsibly be considered a new technique.*" And so a new therapeutic era started and foundations were laid for a new specialization – invasive cardiology. The editorial also mentions that in 1974 A. Grüntzig, together with his colleagues, finished the development of the balloon catheter and wrote the first summary of his experience with percutaneous recanalization of chronic arterial occlusions in the lower limbs (2).

Thus, 2004 is the year of the thirtieth anniversary of the introduction of balloon dilation as a treatment of arterial occlusions, a technique now considered a routine intervention.

The historical aspect may have been made less interesting by the matter-of-course manner in which PTCA has been accepted. It also seems that former colleagues needed a certain interval to pass before they decided to remind others (3, 4) of the great obstacles Grüntzig had to overcome, and of the perseverance required to finish the project. Were it not for this steadfast enthusiasm and clearly defined goal, and the assistance of a number of dedicated colleagues, the balloon dilation technique would have been discovered much later. This was a unique creative process in the history of medical research, one that has much in common with Borel's discovery and the development of cyclosporin (5). Without Borel and some of his laboratory colleagues and clinicians in the U.S., cyclosporin would never have entered the phase of clinical trials. Both these large

projects, which brought about a revolutionary step forward in medicine, took place on Swiss soil; however, Grüntzig, like J. F. Borel, was not Swiss.

Andreas Roland Grüntzig (Fig. 1) was of German descent; he was born on 25th June 1939 in Dresden. His father was killed in the war. The mother and her two sons emigrated to Argentina. Several years later, however, she returned with her sons, and Andreas completed his secondary school and graduated in Leipzig. According to normal practice in the German Democratic Republic of those days he was supposed to become an apprentice mason. Thus, in 1958, the Grüntzigs left the country once again to settle in West Germany, and Andreas started studying medicine in Heidelberg, where he graduated in 1964. He did his training in Mannheim, Hannover and Ludwigshafen. In 1967 he spent some time in London as a research fellow at several university institutes and later, after returning to Germany, continued his work in Heidelberg. He also spent six months in Darmstadt where, at a clinical conference, he heard Eberhard Zeitler lecture on Dotter's method of peripheral vascular recanalization (3). The American radiologist Charles Dotter probed an occluded femoral artery, penetrating - probably unintentionally – with the catheter through the occlusion, after which he noticed that the vessel remained patent. He correctly recognized the significance of this finding, on which he then based the therapeutic concept described and published in 1964 together with the surgeon Judkins (6). This definitely opened a new chapter in the history of vascular surgery. His technique of fitting a wider catheter over the guide spread, especially in the U.S., while in Germany it was introduced by Professor Zeitler in Engelskirchen (7). Grüntzig visited him there to learn about his method, arriving from Zurich where he had been working since 1969, first at the angiology department headed by Alfred Bollinger and later at Joseph Wellauer's radiology department.

Grüntzig became very excited by Dotter's method and when, in 1971, Professor Zeitler came to Lucerne to speak at a congress Grüntzig invited him to Zurich to demonstrate the intervention. Zeitler agreed; Grüntzig selected a patient with an a. femoralis superior occlusion, presented him at an interdisciplinary seminar where it was decided after a stormy discussion that the intervention could take place. Professor Zeitler came, performed the intervention, everything was fine at first, but then a piece of plaque broke off and embolized in the popliteal artery, which, of course, led to some malicious remarks on the part of some of the observers. Grüntzig administered dextran, warmed the leg slowly and within three hours the state of the patient was stabilized. It was not the best of starts, however, and the number of opponents swelled. Grüntzig, nonetheless, received the backing of the then Head of the Clinic of Internal Medicine, Professor Walter Siegenthaler, and another intervention was performed on December 15, 1971; the recanalization was successful, although another small embolization occurred. Surgeons then had to suture a spurious aneurysm the size of a walnut, which formed in the inguinal area. The surgeons, of course, spoke up against any further interventions, but Professor Åke Senning (Fig. 2), the Head of Cardiosurgery at that time, was adamantly in favor of continuing (3). During the following two years a total number of 42 recanalizations were performed, during which Grüntzig recognized the stumbling block of this method: relatively often the shunting of the catheter caused embolization and, due to the width of the catheter, also led to subsequent inguinal bleeding, which had to be sutured surgically. Grüntzig's conclusion was simple: the catheter needs to be narrower and the force applied to achieve

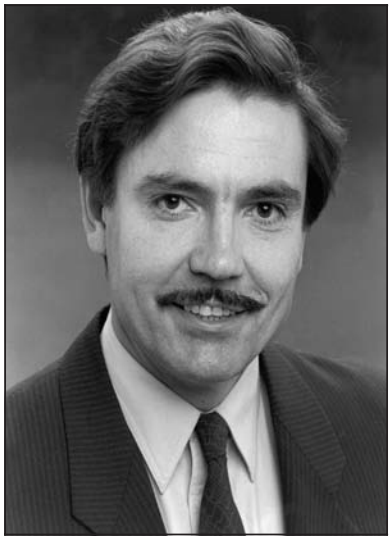

Figure 1. Andreas R. Grüntzig

recanalization must be exerted in the direction from the center of the vessel towards its walls, not by longitudinal shunting. Also, the part of the catheter used for dilation must adapt in form to the vessel being dilated, i.e. it ought to be something like an inflatable balloon. The concept was clear then, but its technical execution turned out to be extremely difficult. Grüntzig acquired various types of catheters and ordered all the flexible material that was available. The applicability of the constructed balloons to artificial stenoses was then tried out in domestic conditions, in the kitchen (Fig. 3). The result was always the same – the balloon dilated in the direction of the smallest resistance, i.e. longitudinally, both in front of the stenosis and behind it, like sand in an egg timer. Other routes were sought. Different types of techniques were tested both on animals and cadavers in collaboration with cardiologist M. Turina and pathologists H. L. Leue and J. Schneider, including laser and milling, but to no avail. On top of that, none of the specialized companies was willing to cooperate in the project that appeared to be a lost cause (3).

In 1973, Dr. Grüntzig moved to the Cardiology Department of Professor Rutishauser, who was favorably inclined towards his project, as many joint publications from that period prove (8). The question was how to reshape the part of the catheter used for dilation and to find a suitable material. Grüntzig kept thinking of a fire hose – when empty, it could be coiled; when full, it expanded, but dilation was restricted by its coating. Collaborating with a bandage producing company, Grüntzig's group succeeded in taking another step forward: a wax balloon of the appropriate shape could be coated with a braiding of fine wire, the wax then melted to leave a surface "skin" of a constant shape when inflated. The flexible balloons could then be inserted into this skin. And, at this moment, Grüntzig contacted Dr. Heinrich Hoff, Emeritus Professor of Technology (ETH) in Zurich, and an expert on polyamides, who knew that long-chain polymer molecules could be streamlined by stretching (*Reckung*), making it possible to shape certain sections of thin polyvinyl chloride tubes that remained stable even under later exposure to high pressure. This was a very promising finding. Mr. Kienast of Gummi Maag AG then helped to select the material and provided Grüntzig with several types of PVC tubes. The working group, consisting of Dr. Grüntzig and his first wife Michaela, and of Mrs. M. Schlumpf and her husband Walter, used the kitchen to produce balloon segments attached

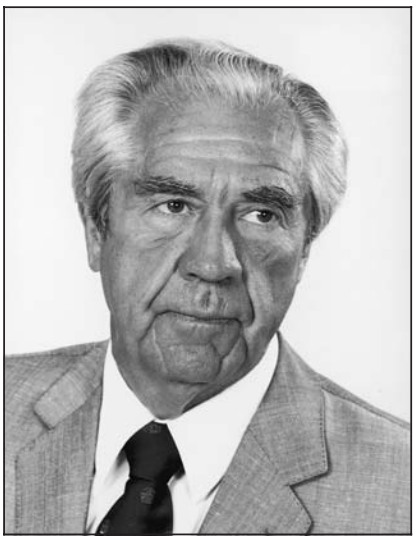

Figure 2. Prof. Åke Senning

Figure 3. Working desk in the Grüntzig's kitchen

Figure 4. Mrs. Schlumpf at work

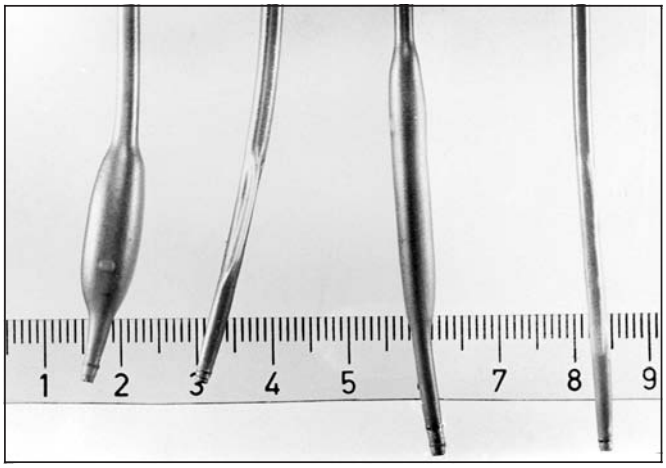

Figure 5. First two homemade double balloon catheters

to catheters (Fig. 4, 5). The balloons made did not change their shapes even when exposed to a pressure of 5 to 8 atmospheres.

The first successful dilation using a home-made balloon catheter was performed on 12th February 1974. It was followed by further interventions – the balloons were tailor-made, according to the size of the stenosis. The same year, the methodology and results of the first 15 patients were described by Grüntzig and Hopff in Deutsche Medizinische Wochenschrift (2). The simple catheter, however, was not yet perfect because it was necessary to control the achieved effect using contrast media. Once again, nobody was interested in developing and manufacturing a two-way catheter, so Grüntzig's team, with the assistance of Mr. Helmuth Schmid, an expert working for a small medical technology company, took up the challenge. Mr. Schmid, using a miniature plane of his own design, carved a longitudinal groove into the external wall of the primary catheter, which could hold a PVC catheter with balloon. Less than a year later, on 23rd January 1975, the first dilation using a two-way balloon catheter – still made in the family kitchen – was performed. Mr. Schmid tried to persuade his boss to take up the production of catheters. He failed and, in the end, was dismissed. Grüntzig continued to dilate, using catheters made in the kitchen sink. A year and a half later, two companies, Cook and Schneider, started producing catheters for the dilation of femoral and iliac arteries according to the Grüntzig's model (3).

Balloon recanalization of peripheral arteries was more than just a technical progress: it showed that a parietal thrombus could be pressed down against the wall of the vessel without causing the thrombus to crumble and embolize. Dilation of coronary stenosis, which had been on Grüntzig's mind from the very beginning, started becoming a feasible option. Experiments on dogs followed – the first experimental coronary angioplasty was performed on 24th September 1975. On 15th November 1976, he presented his results at a conference of the American Society of Cardiology in Miami and was approached on this occasion by Professors Richard K. Myler and Simon Sterzer from the U.S., and by Professor Martin Kaltenbach from Frankfurt, who expressed their wish to cooperate. In May 1977, Grüntzig received an invitation to San Francisco to demonstrate his angioplasty technique. The discussion with American cardiologists and surgeons strengthened his resolve to dilate coronary arteries too, as soon as a suitable patient with the right indication could be found (3, 9).

FIRST PATIENT

In September 1977, a 37 year-old patient with severe angina pectoris was referred for coronarography. There was a proximal stenosis of the left coronary artery immediately above the division of the wide diagonal branch. The patient was informed of his options and decided to have an angioplasty, in spite of the fact that he had been informed that he would be the first patient to have such an intervention. It was his consent which

proved conclusive in the end, because the position of most Zurich clinicians was unfavorable. It was Professor Senning who stepped in once again during the clinical conference stating: "Do it; if anything goes wrong, I'll operate!" The theatre was made ready and Senning stood by with his whole team. The intervention was performed in the catheterization laboratory in the early afternoon on Friday, 16th September 1977. Judkins' guiding catheter was introduced in the ordinary manner on the right side, while the left femoral artery was also probed to be able to perfuse the occluded coronary artery in the distal section with oxygenated blood should the need arise. In the end, this was not necessary. The catheter was introduced without difficulty and the stenosis was dilated without depression of the ST segment, extrasystoles or fibrillation; the patient was asymptomatic. Since coronary pressure was slightly enhanced after the first recanalization, Grüntzig dilated a second time - without any complications. After the second intervention, the affected segment was patent; the only problem was that it seemed that the proximal part of the dividing diagonal branch seemed constricted as well. Grüntzig therefore dilated once again; it was probably not an anatomical constriction. Again, there were no complications, except for a RBBB, which disappeared after 4 hours. The following course was uneventful and coronography proved a significant reduction of the earlier stenosis (10, 11). The patient presented after that for the first time with some problems as late as April 2000, when he had a full examination, during which normal patency of the site of the intervention was found on coronography (12). The report case my and the coronarogram of this patient have become a part of basic literature (13).

The successful outcome of the intervention, its smooth course and the good status of the patient afterwards surprised all present and the "intervention team" started preparing a party to celebrate. Without telling Grüntzig, the delighted patient called the editors of one of the large dailies and, of course, a reporter appeared on site almost immediately. Fortunately, he also wanted to speak to Dr. Grüntzig himself and the latter managed to convince the journalist that it was necessary to postpone the announcement until there was more experience, the patient dismissed from hospital, and the results published in relevant medical journals. The reporter kept his word and did not write about the breakthrough until February 1978, after Lancet had published the report on the first five patients (11).

Obviously, the outcome of the first coronary dilations aroused interest all over the world, and prospective followers started arriving in Zurich. This became such a burden for Grüntzig, hindering him in his work, that he decided to broadcast live interventions at the teaching hospital. He was aware of the risk, but he had mastered the technique well and was confident enough. Several courses took place and all had a high attendance rate (4).

EXPANSION OF PTCA

In spite of the convincing outcome of the first dilations and the enormous interest shown by specialists, the cardiologists in Zurich, and Switzerland and Europe as such, remained skeptical. As of August 1980, only 819 PTCA interventions were recorded worldwide, most of them in America. In Zurich, 171 interventions were performed, 69 in Frankfurtu a/M. In 1986, however, the numbers were 130,000 PTCA in the U.S., 400,000 by 1995, and, in 1996, more than one million – actually double the number of CABGs (13).

In the former Czechoslovakia, the first successful PTCA was performed on 21st January 1981 in Krč (A. Belán), and by 1993 more than 1,000 patients had undergone coronary angioplasty at IKEM alone (14). In Switzerland, the number of PTCAs was 1,773 in 1987, ten years later it was 8,679, and in 1999 almost 10,000 (15). PTCA acceptance was therefore much higher in America than in Europe or in Switzerland. And although there had been no early deaths among Grüntzig's first 50 patients, and no embolizations, and of his 170 dilations done in Zurich 133 were primarily successful, Zurich did not provide Grüntzig with adequate "space" or resources. There were not enough beds, the waiting list became longer and longer and there was no effort to find a solution. It was not only that there was a shortage of staff: there was also lack of will and effort to deal with the matter. The secretary of the clinic, for instance, was forbidden to answer letters concerning angioplasties and was told that Dr. Grüntzig should deal with them in his free time or during weekends. That was out of the question in the circumstance of growing numbers of everyday operations. Moreover, there was little space and equipment for the growing amount of everyday work and ongoing research. Grüntzig was not provided with anything, nor promised anything (3). So, when offered Professorship at Emory University Medical School in Atlanta, with the understanding that he would head the intervention cardiology department, he decided to take up the offer and, in September 1980, left for the United States. There he found total support – collaboration with Professors W. Hurst and Spencer King guaranteed practically unlimited possibilities. Prof. Hurst ceded almost half of his hospital offices adjacent to the catheterization lab to him, which meant they could discuss the patients at any time and deal with ordinary administrative issues. Andreas Grüntzig was 19 years younger than Professor Hurst, and his relation with the head of the clinic – to use his own words – was that of a son towards his father. The sincerity of the relationship is reflected in Hurst's speech made on the occasion of the Grüntzigs' tragic death as well as in articles on PTCA included in Hurst's book (9, 13). And, especially, in everything Hurst did for his new colleague: The moment Grüntzig's work team expanded, he made new office space available, and, in 1984, allotted new rooms on another floor to them, which meant that the working area increased twofold (Fig. 6). Grüntzig had three laboratories; one was experimental and two were used for coronary angioplasty. In 1985, the number of coronary angioplasties, performed in conjunction with Dr. Spencer King and Dr. John Douglas, reached 5,000. It would be wrong, however, to document Grüntzig's merits only on the basis of figures. Grüntzig was an extraordinarily dexterous man, he was hard-working, and also responsible and prudent. He had courage, but never took unnecessary risk; he empathized with the patients. *"He always aimed forward, albeit by taking small, cautious steps,"* as Willis Hurst wrote (9). He never claimed anything that he could not support by facts and his own experience, and he asked others to multiply and disseminate his work. That is why he put so much emphasis on education and training, and why his teaching skills were so much appreciated.

UNFISHED PLANS

Grüntzig had far-reaching plans and was working hard to make them come true. He could not finish his work. He died at the age of 46, together with his second wife Margareth Ann, piloting a plane which crashed during a storm over Monroe County, Georgia, on 27th October 1985.

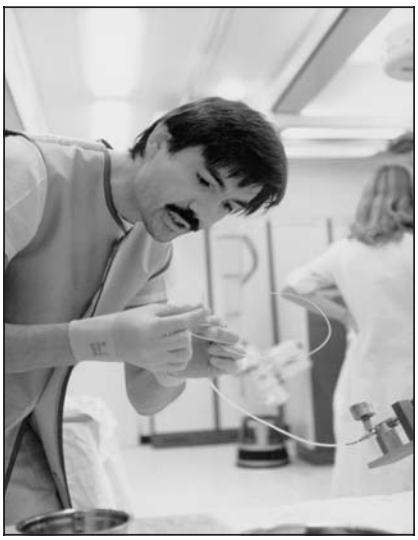

Figure 6. Dr. Grüntzig in the laboratory

The A. Grüntzig Cardiovascular Center was founded at the University in Atlanta, where he had taught, as well as a foundation bearing his name. A number of other laboratories and funds bear his name, as well as a Zurich research center. His contribution to intervention cardiology has been enormous, especially in America, and the anniversary of the introduction of balloon angioplasty is remembered both in the country of his origin as well as on the continent where he had worked for more than 20 years; questions are usually posed on such occasions - both in medical journals (4) and other periodicals (16) – as to the reasons why Switzerland, Germany, and namely Zurich, failed to treat Grüntzig with the necessary understanding when he worked there, and why Zurich University did not use his success to promote its own renown. There may, of course, be many objective reasons. Resources are scarce, for instance, and always have been – but in Switzerland money is always available when necessary. The same applies to "space" and staff. The crux of the problem was, as usual, in the unbalance between Grüntzig's personality and the contemporary context. Grüntzig's specific way of working, shaped by his life experience, was marked by spontaneity, activity, imagination and the ability to improvise. The Swiss are known for their conservative ways based on lengthy considerations of all real and unreal circumstances and their possible (or impossible) consequences; they are incapable of improvisation and, in fact, consider it to be an expression of dilettantism. In the eyes of his contemporaries, Dr. Grüntzig's approach was not only risky, but also premature. For instance, there were no available data on the consequences of temporary coronary occlusion in man, nor on the results of experiments on dogs – as performed at ÚCHOK in Prague by J. Hammer, Z. Píša et al. (17) – also not much was known about the earlier pioneering work of V. Ganz (18). The comparison of experimental results and clinical experience was therefore not possible, and a thorough correlation of clinical and autopsy findings of patients during and after acute MI was also absent. Seeing the situation from this point of view, the hesitant attitude of the then heads of clinics is easier to understand. A sober assessment would conclude that any first application of a new treatment method is, in fact, a risk-bearing experiment. Grüntzig introduced something which arrived a bit too soon for contemporary European medicine; it was a time when we had only just started evaluating our experience with Dotter's method (19).

As for Zurich, the situation at the clinic was marked, amongst other things, by the fact that Professor Rutishauser left for Geneva in April 1976 and the new Head of the Cardiology Department was Professor Hanspeter Krayenbühl, who had little sympathy for Grüntzig. Grüntzig's only remaining supporter was Professor Senning. Å. Senning was a brilliant diagnostician and surgeon and an internationally recognized heart surgery pioneer (20). He, too, was not Swiss and could not therefore have any say in domestic personnel policy.

Summing up the contemporary state of cardiology, and taking into account the fact that at the time of his first PTCA Grüntzig was not even 40, it is no wonder that Europe, and especially Switzerland, were unable to find the right place for him. And, summing up the results of interventional cardiology from the time of its introduction, the obvious conclusion is that Atlanta was the ideal place for him to work and promote PTCA. Professor Hurst, with whom Grüntzig shared a number of common activities, had adopted, even before their meeting, P. D. White's concept of clinical cardiology and had been inspired by P. Wood (13). Therefore, since the beginning of Professor Hurst's career, he had cherished an exceptional relationship with European cardiology - and continues to declare his allegiance to its tradition until this day (13). The obituary which Hurst wrote on the occasion of Grüntzig's demise contains an excerpt from a letter written by Ignacio Chavez to Diego Rivera, in which the former describes his idea for the frescoes to be installed in the entrance lobby of the National Institute of Cardiology in Mexico City: *"The men who forged cardiology are of the most varied nationalities: Belgians and Frenchmen, Italians and Germans – Englishmen and Czechs, Spaniards and Americans – both of the Saxon and Latin worlds – Greco-Romans and Austrians, Dutchmen and Japanese. This single fact marks the spirit which should be imprinted upon the picture. And it is this spirit of universality which you should embody in the two great frescoes."*

To which Hurst adds: "Chavez and Grüntzig never met, but I believe Grüntzig exhibited what Chavez had in mind. What Chavez could have told Rivera was: "He had what I am speaking about. Capture Grüntzig's spirit in your frescoes." (9).

The oldest figures in the frescoes are Galen and Vesalius; after that Harvey and J. E. Purkyně, Škoda and Rokitanski; of the Germans - L. Aschoff, W. His and W. Frankel next to Withering. The youngest are W. K. Roentgen and Paul D. White - A. R. Grüntzig would be in the best of companies!

Together with those who immediately preceded him and those who were his contemporaries he opened a new therapeutic era in cardiology. Intervention cardiology was born in conjunction with a new nosologic entity – restenosis (4). Its treatment is a new chapter in the modern history of cardiovascular therapy - a new chapter involving the future.

Abbreviations

B. A. – Bachelor of Arts
ETH – Eidgenosische Technische Hochschule
IKEM – Institute of Clinical and Experimental Medicine (Prague)
NHLBI – National Heart, Lung and Blood Institute
NZZ – Neue Zürcher Zeitung
PTCA – percutaneous transluminal coronary angioplasty
PTCI – percutaneous transluminal coronary intervention

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