The dawn of a new era in the struggle against sudden cardiac death

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The year 2009 is important for Dutch cardiology. It marks not only the 75th anniversary of the Netherlands Society of Cardiology, but also the starting of ICD therapy, 25 years ago. The first ICD implant in the Netherlands was carried out in Utrecht by the cardiac surgeon Dr Penn with the technical assistance of Mr Seah Nisam in April 1984. The patient was referred from Maastricht by Professor Wellens. Referral was needed since Maastricht had no cardiac surgery department at that time. The patient was resuscitated from ventricular fibrillation (VF) due to coronary artery disease with left ventricular (LV) ejection fraction of 17% and appeared to be refractory to six antiarrhythmic drug regimens. Because of the very poor LV function, map-guided surgery was not an option and the patient was considered to be candidate for ICD therapy. Since at that time epicardial patch electrodes were required for shock delivery, sternotomy was needed for appropriate patch positioning. This explains why cardiac surgeons were involved in ICD implantation.

ICD therapy was still at an experimental stage. The device could only recognise VF or ventricular tachycardia (VT) followed by shock delivery, automatically. The name of the device was not ICD, but AICD or automatic implantable cardioverter defibrillator. The University Hospital Utrecht became partner in a multicentre study to obtain FDA approval in the USA in 1985. In total four ICD implants in 1994 and two in 1995 were performed, all in resuscitated patients with myocardial infarction. Early ICD therapy was in line with the development of other innovative antiarrhythmic therapeutic strategies in Utrecht in the early 1980s, including arrhythmia surgery and catheter ablation (first His bundle ablation in 1983). Four years

before the first ICD implantation in Utrecht the first human ICD implant in the world was in Baltimore.¹ The device was developed by Dr Michel Mirowski (figure 1) with Dr Morton Mower and others. Thus, the story of the ICD in the struggle against sudden cardiac death starts with the history of Mirowski (1924-1990) and his device development.

Mirowski was born in 1924 in Warsaw, Poland. Because of his Jewish ancestry he fled his homeland in 1939, at the beginning of World War II, at the age of 15, and travelled east to Russia, ahead of the German army. After the war he returned to Poland to find that none of his family had survived. He studied medicine in Lyon, France and went to Israel after graduating in 1953. In 1966 the mentor of Dr Mirowski, named Dr Heller, started with episodes of VT necessitating frequent hospitalisations. Shortly afterwards he died suddenly. This event triggered Dr Mirowski to the challenge to build a small implantable device that could detect VF automatically, and to deliver a high energy shock to defibrillate. In 1968 he emigrated to Baltimore (USA) to start animal experiments. The first results were published in 1970,² but were not well received by the medical community, including a very critical editorial. The widespread scepticism about the device prevented Mirowski from obtaining appropriate funding. Nevertheless, by 1975 the first small device was implanted in a dog and the effectiveness of the ICD was demonstrated in a movie. The first human implant was on 4 February 1980 at Johns Hopkins University Hospital in Baltimore. In the experimental phase of ICD therapy (1980-1985) the devices were produced by the company *Intec-Medrad*, brought by CPI/Lilly in 1985.

Back to the Netherlands, in 1984 we expected difficulties with insurance companies, since the devices were not FDA approved. Remarkably, payment problems were absent initially, but this changed rapidly because of the high costs. Even after FDA approval in 1985 insurance companies refused to accept the new therapy. We had to prove that results primarily obtained in the USA were also applicable in the Netherlands. Years of struggle started. Several patient

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Figure 1. Photograph taken at the Cardiotim meeting in Nice, September 1989. Seated at the right is Dr Michel Mirowski, one year before his death. Sitting next to him is Dr Helmut Klein, followed by Mr Guido Neels. Standing from left to right are Mr Bill Hawkins, Dr Morton Mower, Dr Karl-Heinz Kuck, Dr Sam Levy, the author, and Mr Seah Nisam, who technically accompanied all AICD implants in Europe during these first years (By courtesy of Mr Seah Nisam).

letters ended by mentioning the two alternatives: Either the patient remained permanently admitted in the monitoring area or CCU, or alternatively will receive an ICD implant and can be discharged from hospital. Some patients had to stay for up to two months in the hospital to obtain acceptance from the insurance company!

Because of absence of appropriate studies, limited device availability and costs, a combination of stringent criteria for implantation were used in these early years:

1) At least one episode requiring resuscitation, 2) fail-

ure of drug therapy, 3) not a candidate for arrhythmia surgery or revascularisation. In addition, death from nonarrhythmic causes was not expected within one year, and recurrent episodes requiring shocks should be limited because of psychological impact.^{3,4}

Since, even in the late 1980s, ICD therapy was associated with very difficult acceptance by insurance companies and also low acceptance in the medical community because of strong belief in drug therapy, a cost-effectiveness study of ICD as first choice therapy versus drugs as first choice was initiated in 1989. The results of this first randomised ICD trial, showing favourable effects of ICD as treatment of choice, were published in 1995.⁵ Shortly afterwards other randomised trials followed, confirming ICD superiority above pharmacological treatment. The ICD became well accepted, but it was a long struggle to reach this point. Let me end with Mirowski's famous words: 'The bumps in the road are not bumps, they are the road'. ■

References

- 1 Mirowski M, Reid PR, Mower MM, Watkins L, Gott VL, Schauble JR, et al. Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings. *N Engl J Med* 1980;**360**:322-4.
- 2 Mirowski M, Mower MM, Staewen WS, Tabatznik B, Mendeloff AI. Standby automatic defibrillator. An approach to prevention of sudden coronary death. *Arch Intern Med* 1970;**126**:158-61.
- 3 Freericks MP, Hauer RNW, Hitchcock JF, Penn OCKM, Meursing BTJ, Robles de Medina EO. Eerste Nederlandse ervaringen met de implanteerbare automatische defibrillator. *Ned Tijdschr Geneesk* 1987;**131**:951-4.
- 4 Wever EFD, Hauer RNW, Bakker PFA, Robles de Medina EO. Automatic implantable cardioverter defibrillator: new avenue in prevention of sudden cardiac death. *Neth J Cardiol* 1991;**4**: 227-33.
- 5 Wever EFD, Hauer RNW, van Capelle FJL, Tijssen JGP, Crijns HJGM, Algra A, et al. Randomized study of implantable defibrillator as first-choice therapy versus conventional strategy in post infarct sudden death survivors. *Circulation*, 1995;**91**:2195-203.