50 years of CRM Device Therapy
Past, Present and Future

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Cardiac Pacing

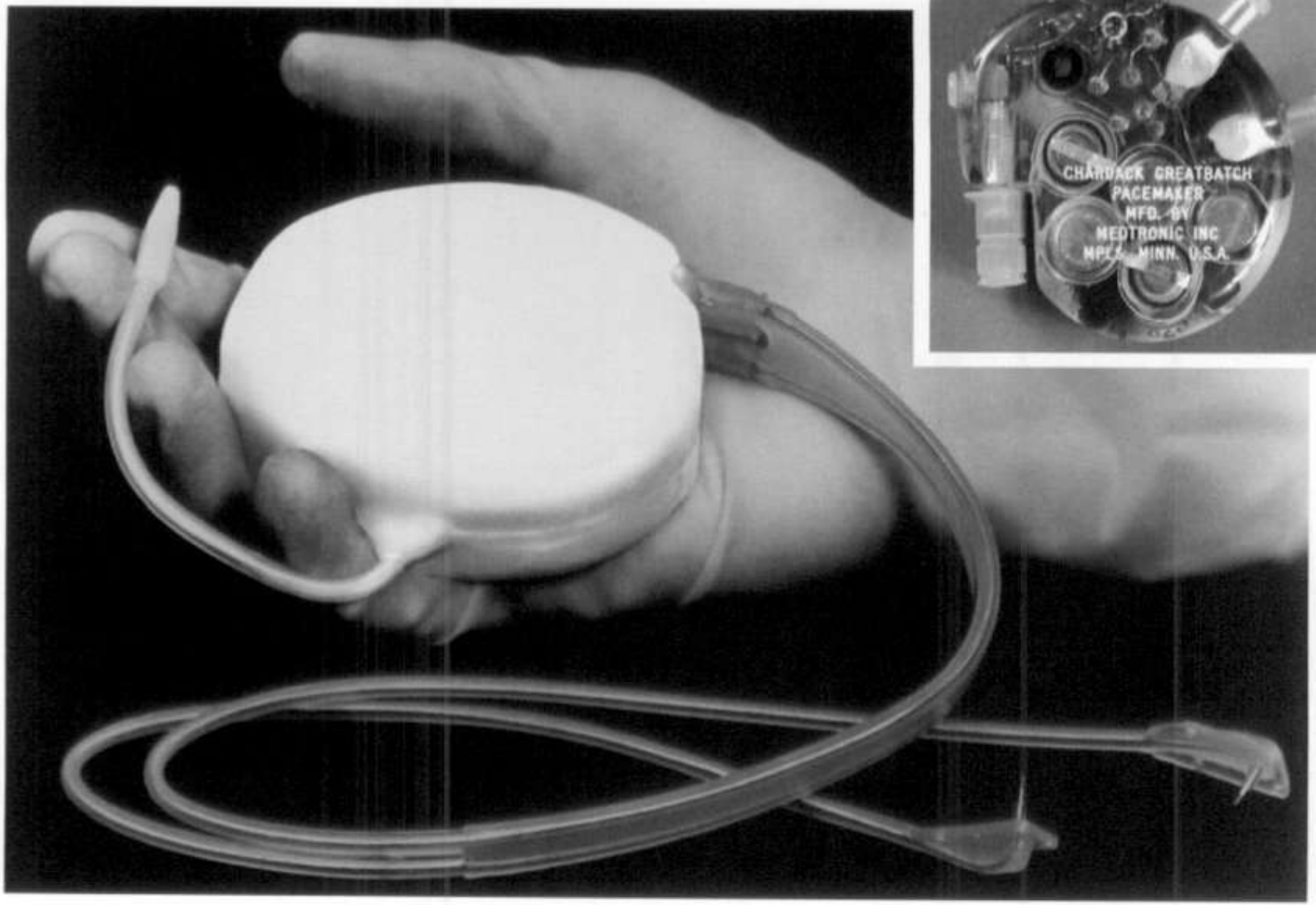
The Past

First implant 1958 Sweden
Dual Chamber pacing (VAT) 1962 US
Transvenous VDD pacing Europe/US 1976
DDD pacing 1978 Germany
Large clinical trials in Pacing 1980s–2005 Europe/US
~ 500,000 Pacemaker Implants/Year
Pacing for heart failure 1994 France
Large clinical trials of Resynch Europe/US 2001-pres

Earl Bakken's garage

Earl Bakken in his garage

Chardack-Greatbatch implantable pacemakers c 1960



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The Future

Which areas will develop?

Any areas which will contract?

What are the threats to pacing?

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AV Block

Sinus Node Disease

Carotid Sinus Syndrome

are all diseases occurring in older age

The population is ageing in the West which will later occur in developing countries

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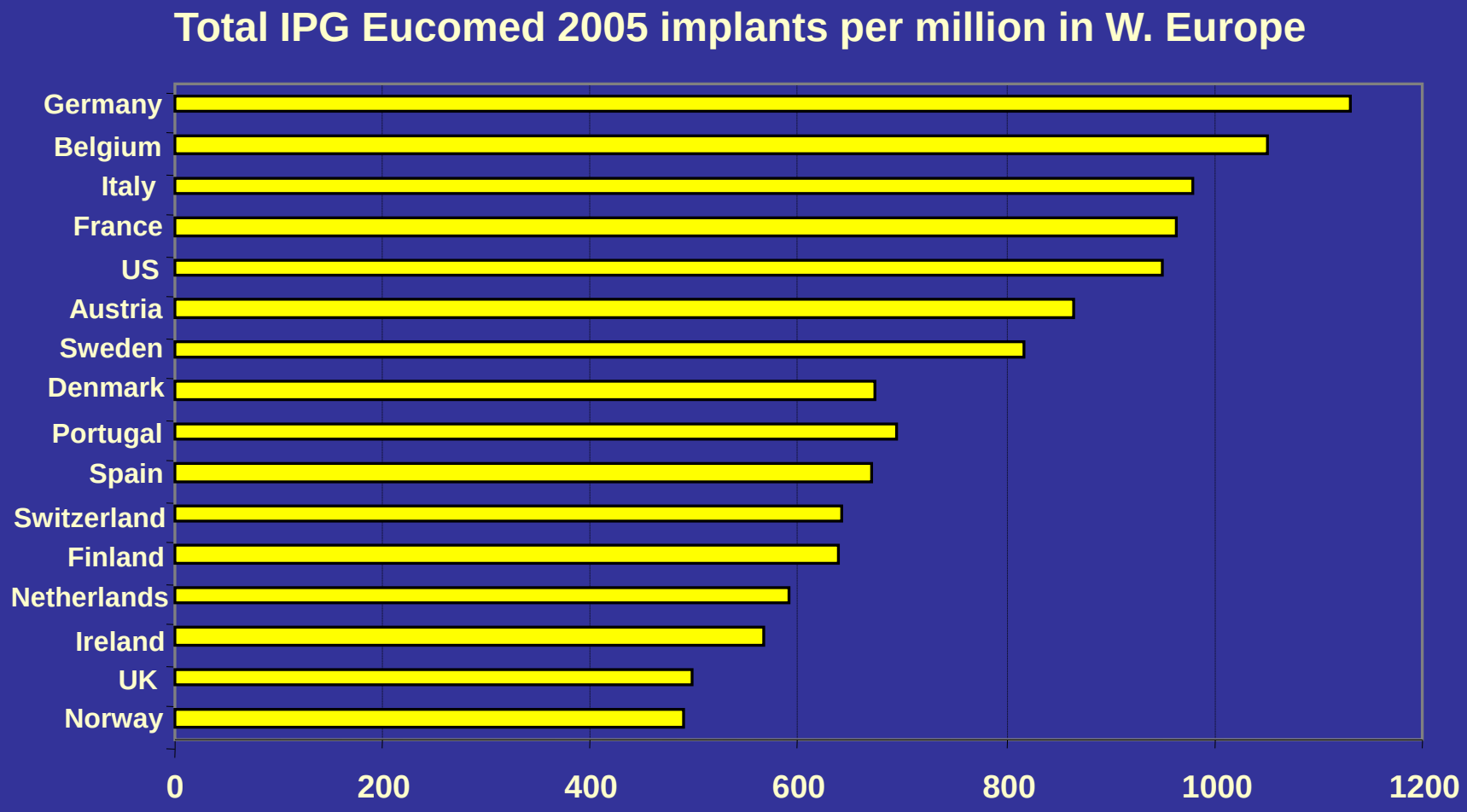
Reaching patients with conditions which will benefit from pacing is still far from complete

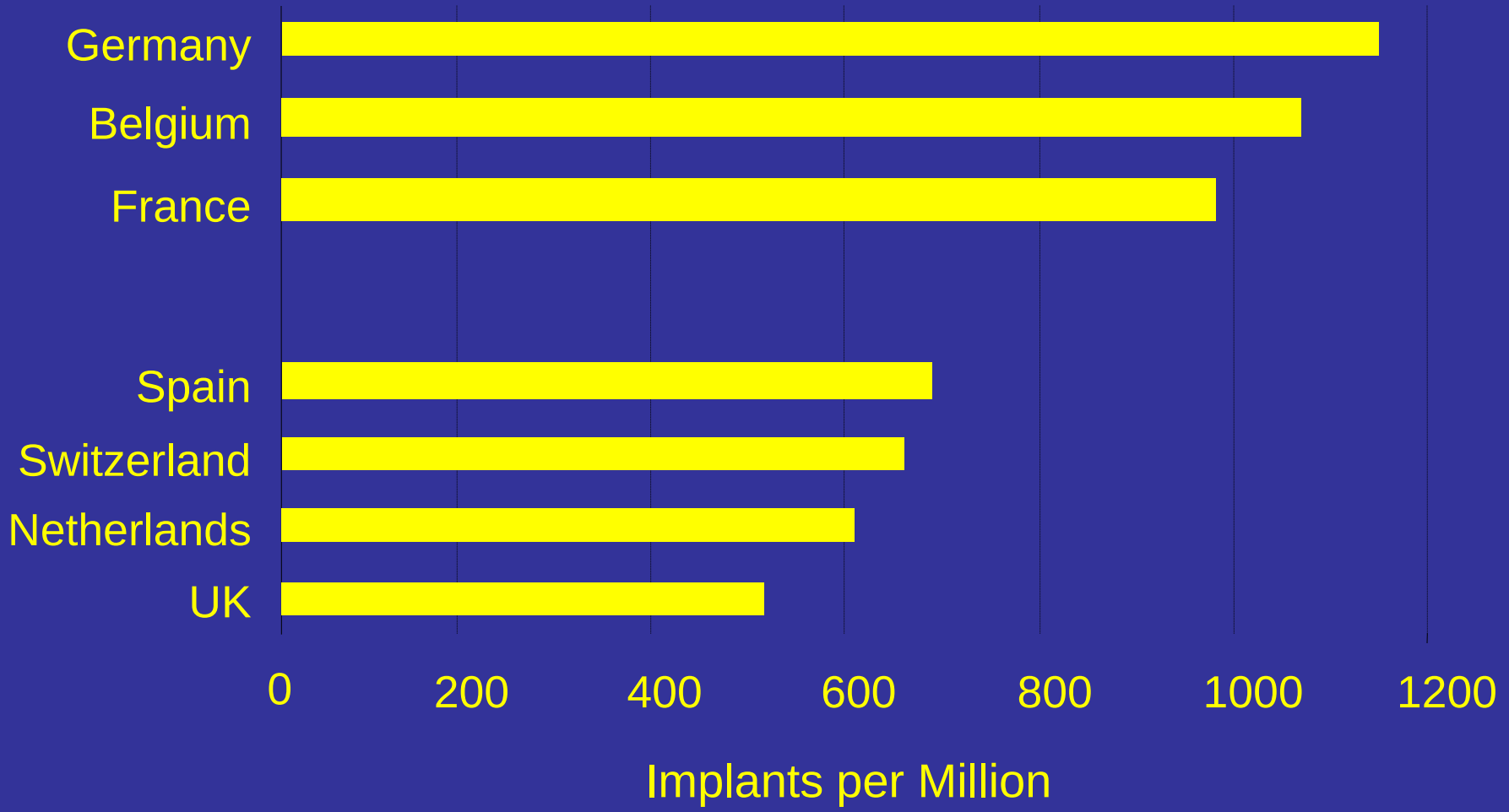
In Europe obvious examples are UK, Spain, Portugal and Switzerland

Many Western populations appear to be under-paced



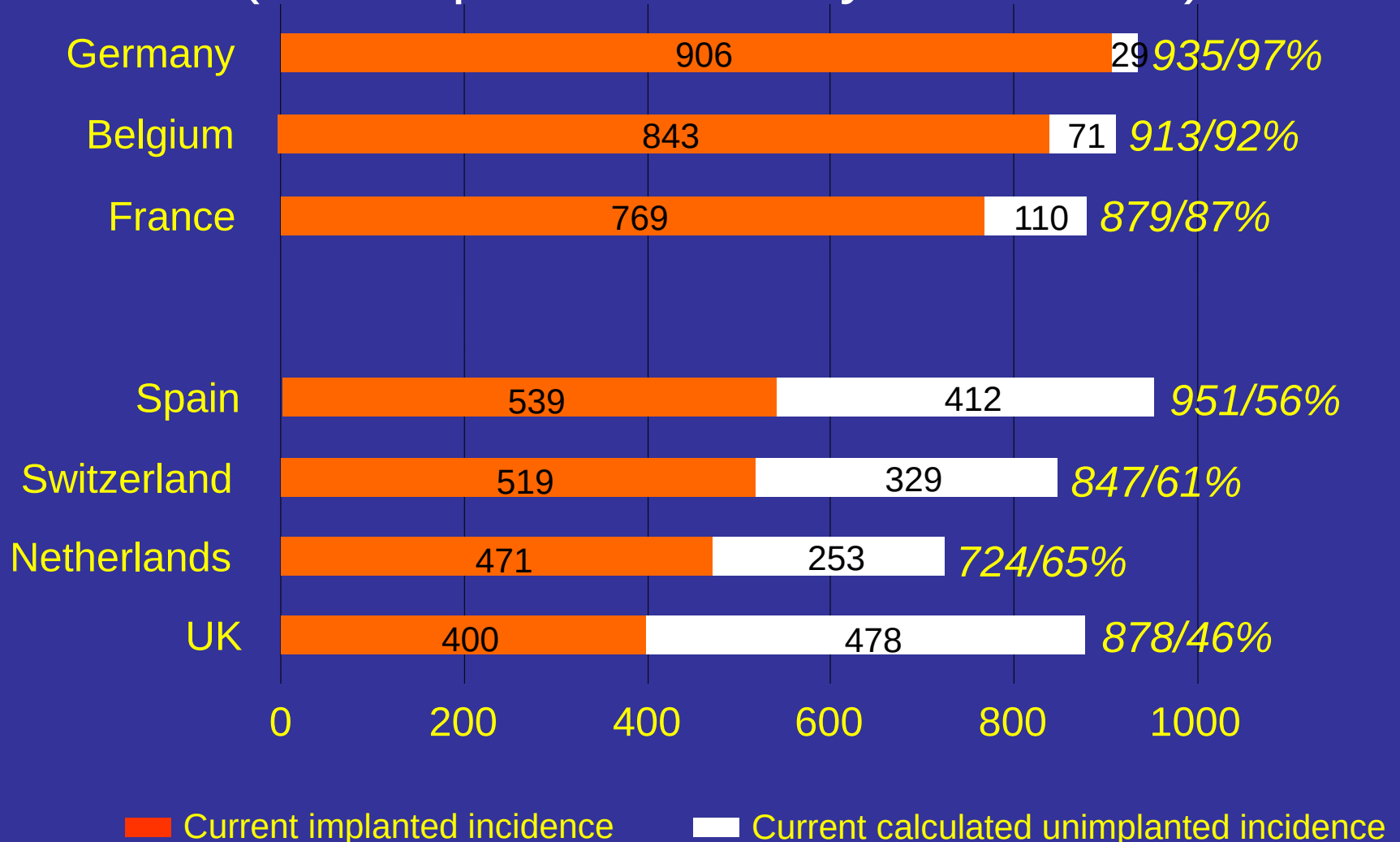
These data include replacements which are estimated at 20%

High implant rates vs. low implant rates

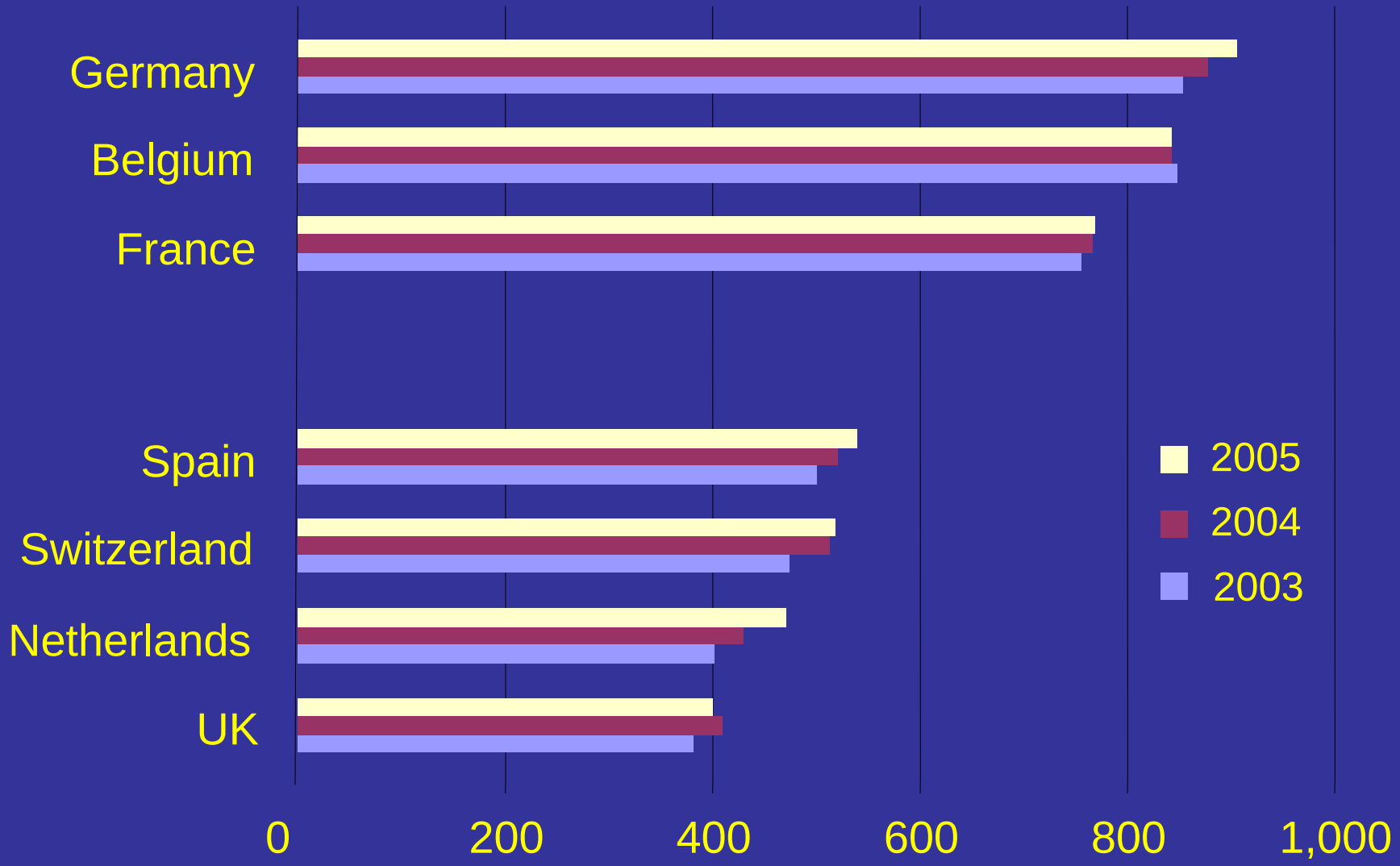


Implants per million vs. calculated incidence per million

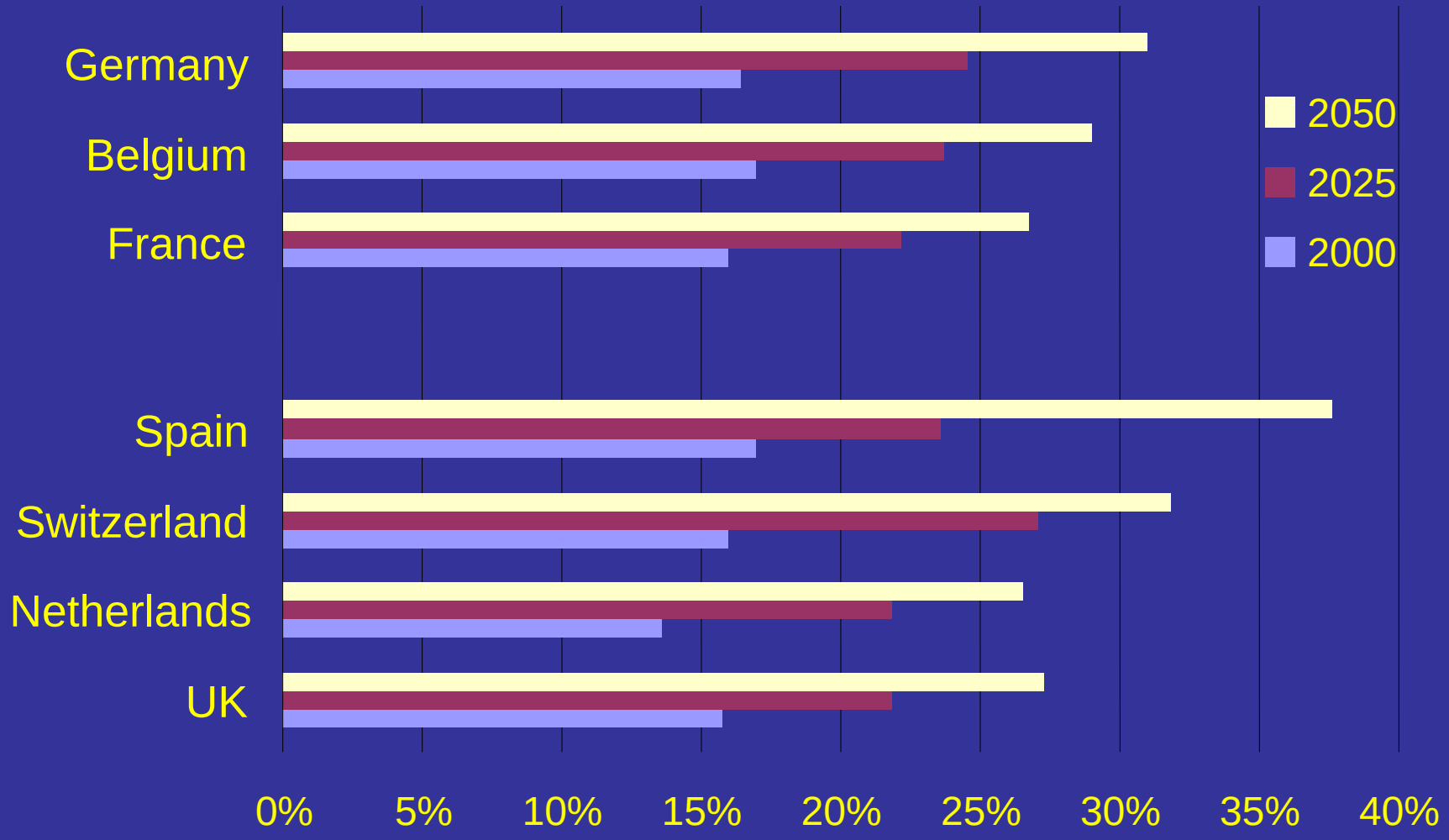
(new implants now only considered)



Implants per million 2003-2005



% of total population aged 65+ across Western Europe, Year 2000 to 2050 – UN data



Low-implant rates compared with calculated need

- Possible explanations
  - Different populations – based on age
  - Lack of diagnosis
  - Lack of application of appropriate technology in diagnosis and treatment
- Why?
  - Underdeveloped medical system
  - Insufficient numbers of cardiologists
  - Poor training
  - Hostility to referrals
  - Lack of facilities
  - Uneducated patient population

Conclusion: we may think we are implanting enough pacemakers in W. Europe, but we are, in many cases, not doing this

How to overcome?

- More cardiologists
- Better training of doctors at all levels (family doctor and up)
- Better continuing education at all levels
- Better facilities
- Better use of appropriate technology
- More patient education

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Carotid Sinus Syndrome

Still greatly underdiagnosed

Not investigated by most physicians

Two estimates in early 1980s of the Incidence 35-40 new cases/million/year

Almost certainly more than this: EP community needs to refocus

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Population is increasingly becoming obese

Obesity is strongly associated with Sleep Apnoea

Sleep Apnoea probably causes

- Arrhythmias esp. Sinus Node Disease
- Hypertension

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Sleep Apnoea can be addressed in many ways

1. Detection

2. Better treatment of complicating arrhythmias

3. Better treatments of the condition itself

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Neurally Mediated Syncope – Recent Events

Trials of pacing for VVS initially favourable

Failed to demonstrate benefit when all patients received a pacemaker randomized to ‘ON’ or ‘OFF’

Why?

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The answer does not lie in placebo effect rather in inappropriate patient selection

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Potential for pacing in VVS

Story begins with VASIS and ISSUE 1

1. European selection for trials has typically been of patients >15 years older than N America

2. ISSUE 1 demonstrated that tilt testing does not reliably reveal asystole in contrast to use of ILRs

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Pacing in VVS

ISSUE 2, a registry, has suggested that

In patients of mean age 63
registration of asystole in a spontaneous attack will result in successful subsequent use of pacing

ISSUE 3,a RCT, is anticipated to prove this.
Recruitment now complete. 73 patients randomized to pacemaker ON or OFF

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Pacing in VVS

The emerging message is that VVS in older patients is a disease, perhaps caused by a degenerative process in autonomic control and quite different from the VVS phenomenon in young people. Being so may be amenable to successful pacing therapy

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Pacing in VVS

In an ageing population the need for pacing could be 50 new cases per/million/year.

Emphasis on NMS both CSS and VVS could add 10-20% increase in pacemaker use

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Developing areas in developed countries

Better application of therapy in SND/AVB +NMS pacing

900-1000 implants/m/y → 1100
400-600 implants/m/y → 1100

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Developing areas in underdeveloped countries

Potential is enormous to approach that in the West but finances lacking.

To this end

- Older pacer models to be maintained
- New simpler models omitting sophisticated options of limited benefit
- Implant without the use of X-ray fluoroscopy
- Hub and spoke
- Self-help plus outside help

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Areas which will contract

1. Long term less ischaemic disease so less AV Block but patients will live longer and be exposed to other causes of AV Block

2. AV Junctional ablation is now rarely practised

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Threats to technology of cardiac pacing

Stem cell therapy

A. Ways presently difficult to conceive

B. Source of ventricular depolarisation

Problem is coordination of ‘new’ pacemaker with:

A. Patient’s autonomic control system

B. With other cell sources

e.g. A-V sequence

Resynchronisation of ventricles

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Threats to technology of cardiac pacing

Bio-electric power sources

Not really a threat because if successful will still need aspects of pacing technology

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Threats to delivery of pacing therapy

Healthcare systems and bodies such as NICE

New therapy will have to be justified by clinical trial

New therapy will have to demonstrate cost-effectiveness

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Better pacing

Avoidance of ventricular stimulation
except when necessary implying
minimization of ventricular pacing by algorithm

HIS bundle pacing,possibly alternative stimulation sites including LV via coronary sinus or direct into LV

Avoid causing heart failure

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Better pacing

Using sensors to optimize the benefit from pacing

Using sensors to warn when patient's condition is deteriorating and other measures are required

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Better pacing

Home monitoring to permit adaptation of the system to the patient and be able to anticipate future problems

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Better pacing

Better resynchronization

Multiple ventricular sites

Solve problem of non-responders to CRT

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Could cardiac desynchronization by pacing have value?

1. Hypertrophic Cardiomyopathy
2. Hypertension
3. VVS

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Major challenges in Cardiology are:

1. Prevention of hypertrophy

2. Prevention of fibrotic areas (scars)
   Primary angioplasty
   Stem cell therapy

3. Prevention of calcification in the heart. Pacing susceptible tissue in absolute refractory period may have preventative value

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Conclusions

State of pacing is healthy and offers improved health

Pacing will grow not contract: much work needs to be done

Pacing will become more patient-friendly

May be further applications of stimulation technology