Summary

I have been solicited by the organizers not to present a final solution to the problem, but to comment on controversial issues.

For the indications for aorto-coronary bypass, consensus has been reached by most medical men that angina pectoris and, in selected patients, prognostic considerations are important. Controversy starts when we ask how much angina or what pattern of clinical and angiographic risk factors are required for the operative indication.

It remains to be seen, whether other forms of mechanical revascularisation, such as balloon dilatation can replace surgery in large numbers of patients, who are presently treated by aorto-coronary bypass.

An effort has been made by physicians to make greater use of cost–benefit analysis estimates in their medical decisions, and to provide policy makers with this information.

The number of aorto-coronary bypass operations in European countries varies considerably. The trend of these figures, however, is rising throughout Europe and therefore my personal answer to the crucial question in the title is: *expand*.

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What will be the requirements for acute interventional procedures in Europe?

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The needs and the requirements are changing with such a pace that it is almost impossible to foresee what is going to happen within 5 years or even within 2 years. An inventory of interventional cardiac catheterization procedures (Table 1) shows that no. 1 is still percutaneous transluminal coronary angioplasty carried out by means of a balloon, a laser or by spark erosion[1,2]. These last two techniques are really to drill craters into atherosclerotic plaques. We believe that transluminal angioscopy will be necessary to keep the side-effects of these two powerful tools under control[3].

Transluminal coronary recanalization and angioplasty in acute myocardial infarction, although extensively applied, is still under clinical investigation[4,5]. New techniques such as transluminal atherectomy have been recently introduced and tested in human beings, but only on peripheral vessels[6]. For more than 10 years investigators have tried to supply the ischaemic myocardium with oxygenated blood through the coronary sinus[7]. Pulsatile retroperfusion of coronary sinus with oxygenated blood has been attempted in a few patients with unstable angina or during angioplasty. Intermittent coronary sinus occlusion seems to be another possible approach. Several percutaneous left ventricular assist devices are still under development; the most commonly used is intra-aortic balloon counterpulsation.

In 1984/1985 in Europe percutaneous balloon valvuloplasty began to be applied to acquired valvular disease. Congenital pulmonary stenosis was already an established indication when French cardiologists started to dilate calcified aortic valves

Table 1 Inventory of interventional cardiac catheterization procedures

1 Percutaneous transluminal coronary angioplasty (balloon–laser–spark erosion)
2 Transluminal angioscopy
3 Transluminal coronary recanalisation and angioplasty in acute M.I. (with or without lysis)
4 Transluminal atherectomy (Simpson)
5 Pressure controlled intermittent occlusion (PICSO) or pulsatile retro perfusion of coronary sinus (SRP)
6 Percutaneous left ventricular assist device
7 Percutaneous balloon valvuloplasty (aortic, pulmonary, mitral valve)
8 Transluminal dilatation of aortic coarctation and other vascular congenital defects
9 Laser catheter valvulotomy
10 Transarterial lasermyoplasty for hypertrophic cardiomyopathy
11 Balloon atrial septostomy and closure of atrial septal defect
12 Transvasal closure of patent ductus
13 Pacemaker implantation
14 Electrical or laser transcatheter ablation of accessory and reentry pathways

and rheumatic mitral valves[8]. Within two years they have collected more than 500 cases. Transluminal dilation of aortic coarctation and other vascular congential defects are currently performed in many institutions in Europe. Unfortunately, there are no formal registries for any of these interventions. Some experimental valvulotomies have been carried out with a laser catheter[9]. Along the same line, transarterial lasermyoplasty for hypertrophic cardiomyopathy has been tried. Balloon atrial septostomy and closure of atrial septal defects have been undertaken for some time as well as the transvasal closure of a patent ductus which has been an East German speciality for more than 20 years. Pacemaker implantation was certainly one of the oldest interventional procedures in the catheterization laboratory and electrical or laser transcatheter ablation of accessory and reentry pathways has opened new avenues of treatment. This list is not complete, but it illustrates very well the therapeutic potential of an interventional catherization laboratory.

European needs in coronary angioplasty

Coronary angioplasty is now being performed in large numbers of patients. Over the last three years more than 7746 procedures have been performed in the Netherlands. In 1986 alone, 3508 PTCAs were done in a country which has a population of 14·4 million. The Netherlands is a technically and socially advanced country and it is daring to extrapolate these figures to the entire European Community, but it is the only way to get an approximate idea of the theoretical needs for PTCA in Europe. With a total population of 380 millions of inhabitants, we should have done 67 000 PTCA in 1985.

These extrapolated figures are hardly credible, but according to the report of the Task Force on angioplasty[10], the total number of PTCA procedure performed in the U.S.A. in 1985 was 64 000 for a population of 247 millions inhabitants (the PTCA ratio between the Netherlands and the U.S.A. was 1·7).

REQUIREMENT IN X-RAY EQUIPMENT

It is clear that any type of X-ray equipment which does not allow a hemiaxial view of the heart such as a cradle bed, should be considered as an inappropriate type of equipment to perform coronary angioplasty. On the other hand, a biplane rotational system which allows simultaneous orthogonal views is a superfluous luxury. Of course it is nice to visualize coronary arteries in biplane and to push a guidewire during angioplasty on the control of a biplane fluoroscopy, but it is not a necessity. The cost of the X-ray equipment with a monoplane unit is about DM 1 400 000; a biplane unit will cost DM 2 650 000.

This does not include the costs of the imaging equipment which includes a video image processor for image enhancement, a video disc for instant automatic replay, extra video monitors for optimal perception and pathfinding reference through reference images and finally, a video recorder for automatic storage and replay, altogether 150 000 DM.

The costs of the monitoring equipment which includes ECG, pressure and flow as well as computer facilities might easily amount up to 320 000 DM. Taking into account all these items of technical equipment, it is not surprising to see that the room size of an interventional catheterization laboratory in 1986 needs to be almost twice as big as that for the diagnostic laboratory in 1968 (43 m^2 in 1976 versus 70 m^2 in 1986). The question is still open whether this interventional laboratory should be also an operating theatre with all the technical facilities required by the anaesthesiologists and by the surgeons.

The X-ray, imaging and monitoring equipment has a lifetime of about 8 years. If one treats 500

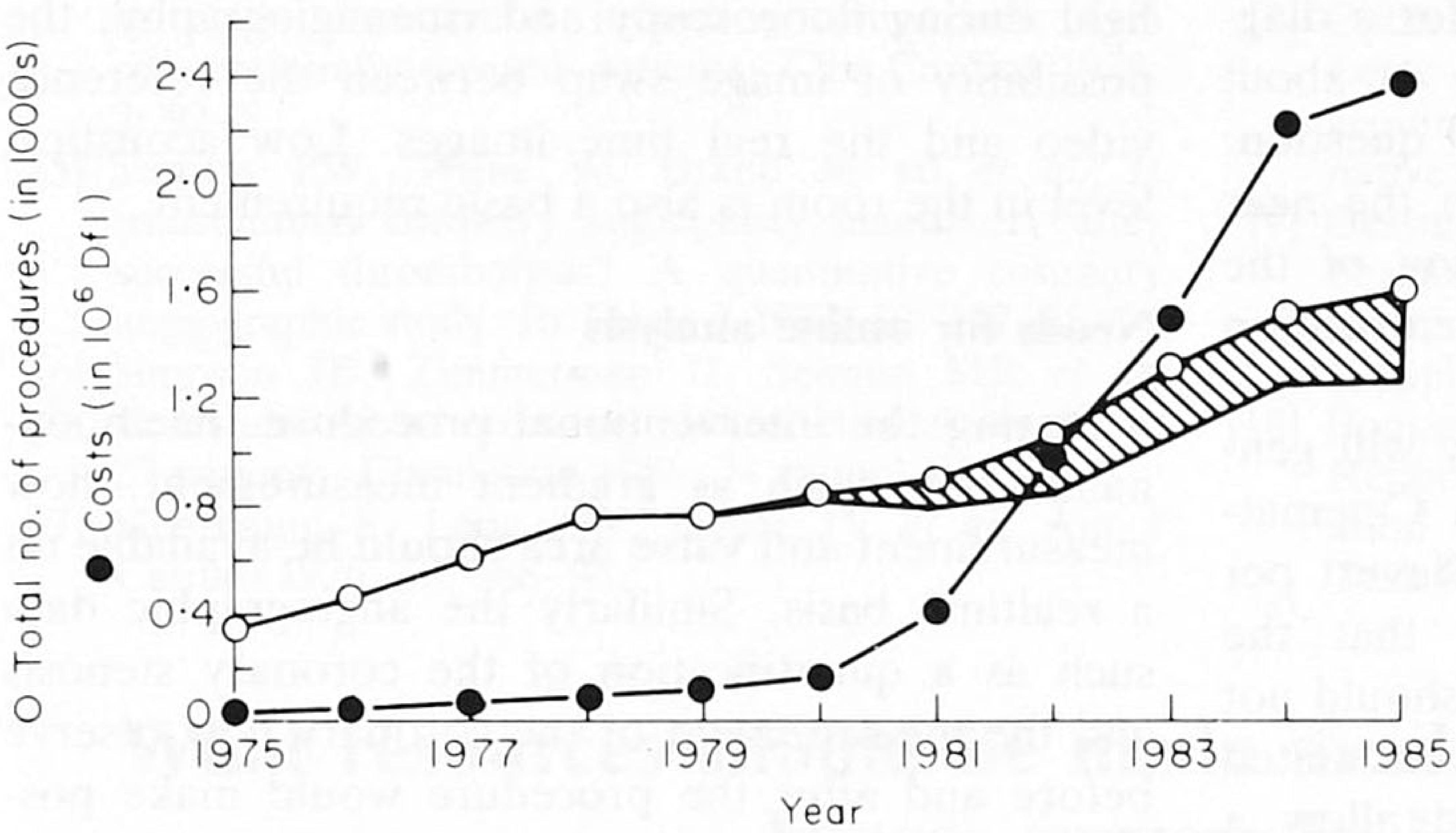

Figure 1 Number of procedures and costs of disposable material. The shaded area corresponds to the total number of interventional catheterizations.

patients per year over a period of 8 years the initial investment per patient will be DM 520 for a monoplane unit and DM 840 for a biplane unit.

Figure 1 shows the increase in the total number of procedures performed at the Thoraxcenter over the last 10 years. The scale on the vertical axis has to be multiplied by 1000. The shaded area on the figures corresponds to the total number of interventional catheterizations which represent 20% of our daily activities. The third curve on the diagram shows the dramatic increase in the costs of the disposable material. Until 1980 our laboratory was essentially diagnostic; a multiple use Sones positrol catheter was our main tool. Today, a standard angioplasty balloon catheter costs about Dfl 1200, a high-tech balloon is Dfl 1800. In 1979 the cost of disposable materials per procedure was Dfl 150, within 4 years the cost per procedure has increased by a factor of 10. The current cost per procedure including the interventional and diagnostic procedures is Dfl 1500 per procedure.

We must ask ourselves whether this cost inflation due to interventional procedures is justified. In 1984 the cost control system of the Thoraxcenter calculated the respective costs of a bypass operation and of a PTCA procedure. The cost of a bypass operation including the operating theatre costs, the costs of the 2 days spent in the post-operative unit as well as the 10 days on the ward amount up to Dfl 24 690 or ECU 10 155. On the other hand the PTCA costs included the catheterization laboratory costs as well as the 2 days spent on the ward after the procedure, the total costs amount up to Dfl 9560 or ECU 3943. Based on these figures, the cost ratio of bypass surgery versus PTCA was 2·6. A survey of 10 hospitals in the U.S.A. reveals that the cost ratios in that country vary between 5·4 and 2. This cost ratio is of course dependent on the primary success rate and on the recurrence rate of 30%, but PTCA is still significantly cheaper than bypass surgery.

Another direct consequence of the advent of interventional catheterization has been the increasing number of acutely ill patients who have to be treated as an emergency outside of normal working hours. In 1986, this represents 15% of the total number of procedures performed in the catheterization laboratory. During an emergency procedure, interventional or diagnostic, 1 nurse and 1 technician have to be present. In compensation for the work done outside of normal working hours they get days off. Between 1979 and 1985 the total number of days off has increased from 110 to 444 days for a team of 6 nurses and 6 technicians. These 444 days correspond to 2 years of full-time work for a technician and for a nurse. In other words, if the catheterization laboratory gets involved with emergency interventional procedures, an expansion of this team will be necessary.

Radiation exposure: a limiting factor?

Another direct consequence of the introduction of interventional procedures is the tremendous increase in the total fluoroscopy time in our catheterization laboratory. For 1984/1985 the total fluoroscopy time amounted to 28 000 minutes which correspond to 467 hours of continuous fluoroscopy, that is to say 90 days of fluoroscopy. The average fluoroscopy time for an interventional procedure is around 25 minutes, while for a diagnostic procedure the fluoroscopy time is about 10–15 minutes. This raises the following question: will the radiation exposure constitute in the near future a limiting factor to the expansion of the interventional activities in the catheterization laboratory?

With standard equipment, fluoroscopy will generate 0·4 to 0·9 milli Sievert per second. Cinematography will generate 0·2 to 0·6 milli Sievert per frame. Taking into account the fact that the radiation exposure of the thyroid gland should not exceed 3 Sievert per year, it has been calculated that the maximal personal dose would allow a single operator to perform 15 interventions per week.

Some additional means of radiation reduction are now available on standard equipment such as an optimal tv chain and image intensifier, an X-ray beam with automatic collimation, a correct field size on image intensifier, a carbon fibre scattered radiation grid, a carbon fibre table top, a correct tube filter and so on. All this results in a 50% dosage reduction, a lower X-ray tube loading with a smaller focal spot and an improved quality of the picture. The maximal personal dose then allows an operator to perform 30 interventions per week.

An additional radiation reduction can be achieved using extra equipment such as a video image processor. During fluoroscopy, filtering and the last image hold technique will considerably reduce the duration of a fluoroscopy examination. During cinematography gapfilling and the selection of reference images will improve the visual perception of the operator and make frequent cinefilming unnecessary. Pathfinding by reference monitor, automated video replay after cine using a video disc and automatic and instant storage of the image with a video recorder will finally result in a 75% dosage reduction in X-ray. So that finally the maximal personal dose will allow the operator to perform 60 interventions per week. In other words, the radiation exposure during interventional procedure in a technically updated catheterization laboratory does not constitute a limiting factor to the expansion of the interventional activities in the laboratory.

Of course this implies appropriate personal protection against radiation exposure by using special procedure aprons, eye glasses, thyroid protection and extra shielding of the X-ray tube. Finally the optimal perception of the operators requires the following measures: automatic cut off of surgical light during fluoroscopy and cineangiography, the possibility of image swap between the reference video and the real time images. Low acoustical level in the room is also a basic requirement.

Needs for online analysis

During the interventional procedure, haemodynamic data such as gradient measurement, flow measurement and valve area should be available on a realtime basis. Similarly the angiographic data such as a quantification of the coronary stenosis and the measurement of the coronary flow reserve before and after the procedure would make possible the immediate assessment of the results of the procedure. In this context, the angiographic analysis from cinefilm can be obtained at low cost and high resolution but has the major disadvantage of being offline. In contrast, digital angiography analysis permits an online assessment of the results of the procedure, but is currently relatively expensive and has low resolution. Therefore, for the time being, simultaneous cineangiography is still essential for practical reasons.

Conclusion

In summary, the ratio interventional catheterization/surgery will certainly increase in the near future. An interventional catheterization laboratory requires specific equipment, siting and organizational structure. From now on industry should plan integrated systems, dedicated to effective interventional coronary angiography. Finally, hospital management and public health care officials should realize that increasing therapeutic activities will take place in an interventional catheterization laboratory and based upon the current cost/benefit ratio they should foresee and provide for future needs.

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What resources should be made available for coronary artery bypass surgery in Europe

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Introduction

Any attempt to answer the question of what resources should be made available for coronary artery bypass surgery requires an analysis of the need for such surgery and just as important, the distribution of those resources to ensure optimal delivery of care to patients suffering from coronary artery disease in its various presentations including chronic stable angina, unstable angina and myocardial infarction. The advent of thrombolysis in the management of myocardial infarction and possibly unstable angina will have an effect on surgical practice, but that is not defined at the present time.

It is important to recognise that resources needed include buildings and equipment, adequate recurrent financial provision to use those resources and appropriate medical and other trained staff. Furthermore, it must be recognised that centres must be large enough to provide a continuous 24 hour service to deal with urgent and emergency cases. Research has an important role in such centres to ensure that current strategies are developed and evaluated and new ideas allowed to emerge. Furthermore the overall environment must be designed to provide professional job satisfaction. This may mean that fewer larger centres are required, leading to a policy of expanding existing centres rather than creating new ones. ones.

Estimate of the need for coronary artery surgery

Throughout Europe the amount of coronary artery surgery continues to expand, but nowhere has it reached the levels attained in the USA where the best estimates suggest that at the current time approximately 900 coronary artery bypass grafts per million of the population are being undertaken with a further 500–600 per million angioplasties, to give a total number of procedures for coronary artery disease approaching 1500 per million per year. In Europe the best statistics have been collected in the United Kingdom, the Netherlands and the Federal Republic of Germany.

In the United Kingdom the register of all cardiac operations undertaken in the National Health Service units has been kept since 1977[1] and in 1985[2] a total 11 783 operations were undertaken for ischaemic heart disease of which 10 667 were isolated coronary artery bypass procedures. Although these totals do not account for operations done in private hospitals, they do include overseas patients done in National Health Service units and it seems likely that the total procedures done on U.K. resident patients is not significantly different from this total. This represents at 10 667 operations, a rate of 189 procedures per million of the population. The corresponding figures for the register for 1977 were 2297 procedures (41 cases per million) and in 1982 were 5866 (104 cases per million).

In the Federal Republic of Germany the register of cardiac surgery for 1985[3] shows that 12 346 isolated coronary artery bypass grafts were undertaken for a rate of 202 cases per million population. In the Netherlands[4] the Health Council issued a report in 1984 reviewing the current workloads and projected workload in 1990. As far