

## BRITISH CARDIAC SOCIETY

# Complications of diagnostic cardiac catheterisation: results from 34 041 patients in the United Kingdom confidential enquiry into cardiac catheter complications

David de Bono on behalf of the Joint Audit Committee of the British Cardiac Society and Royal College of Physicians of London

## Abstract

**Objectives**—To evaluate the frequency and nature of complications in patients undergoing diagnostic cardiac catheterisation and to assess the feasibility of a voluntary cooperative audit system.

**Methods**—27 centres enrolled patients over a two year period. Each centre voluntarily reported numbers of patients catheterised every month. Complications were reported as they occurred. Feedback was provided in the form of newsletters and reports.

**Results**—39 795 procedures were registered, of which 33 776 were diagnostic catheterisations in adults or adolescents, 1265 were paediatric catheter studies in patients under the age of 12 years, and 4754 were coronary angioplasties or balloon dilatation of valves. 83.3% of diagnostic catheter studies in adults were left heart studies with coronary arteriography. The overall complication rate for diagnostic studies was 0.80%, mortality rate 0.12%, emergency surgical intervention rate 0.08%. Complication rates varied between centres, but there was no correlation with case load. Different patterns of complication were associated with different technical approaches.

**Conclusions**—Complication rates of diagnostic catheterisation are low but neither negligible nor irreducible. Voluntary audit of this kind has limitations, but it is useful and inexpensive.

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Diagnostic cardiac catheterisation has been an integral part of cardiological practice for nearly three generations of cardiologists. Although diagnostic catheterisation has been largely superseded by non-invasive techniques for the evaluation of valvar disease and ventricular function, coronary angiography remains an invaluable, and some would argue indispensable, part of the assessment of patients with ischaemic heart disease. No technique which involves inserting catheters into the heart or great vessels can ever be entirely free from risk: this risk has compo-

nents which depend on the patient, on the technique used, and on the operator. Operator dependent risk can be reduced by training, but the range of possible hazards is so wide that it is unrealistic to expect trainees to have encountered all of them. Experience from other fields including surgery and aviation indicates that continuing feedback is important in maintaining and improving skill throughout the operator's working life, and that dispassionate identification and analysis of untoward events are important parts of this process. Continuing audit of catheter laboratory procedures was pioneered in the United States by the Society for Cardiac Angiography (now the Society for Cardiac Angiography and Intervention).<sup>1,2</sup> In Germany, there is a statutory requirement for catheter laboratory audit. In the United Kingdom annual audit of cardiac surgery<sup>3</sup> and coronary angioplasty<sup>4</sup> is now established on a voluntary basis. Audit results from individual United Kingdom units have been published.<sup>5</sup> The object of the present study was to extend the concept of multi-centre voluntary cooperative audit to diagnostic cardiac catheterisation. The project, the confidential enquiry into cardiac catheter complications (CECCC), was supported by the Joint Audit committee of the British Cardiac Society and the Royal College of Physicians of London.

## Methods

Five centres were initially invited to participate in a six month pilot study. Subsequently, an open invitation to participate was issued through the British Cardiac Society newsletter, and by writing to centres known to be performing diagnostic angiography. Twenty five centres are currently participating: two centres contributed initial data but subsequently dropped out.

Centres were asked to identify a "link person", usually a catheter laboratory nurse or manager, to be responsible for local data collection. Each month the link person sends a single-sheet form to the coordinating centre listing the number of procedures performed, categorised by type of procedure.

A complication is defined as "Any untoward event which jeopardises the patient's

## The British Cardiac Society and Royal College of Physicians of London

Correspondence to:  
Prof D de Bono,  
Department of Cardiology,  
University of Leicester,  
Leicester LE3 9QP.

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## Appendix 1

Centres participating in, or which had participated in, CECCC at 31 December 1992:

Grobby Road Hospital,  
Leicester  
Wythenshawe Hospital,  
Manchester  
St George's Hospital,  
London  
King's College Hospital,  
London  
John Radcliffe Hospital,  
Oxford  
BUPA Hospital, Leicester  
The London Chest Hospital  
Norfolk and Norwich  
Hospital  
Mayday University Hospital,  
London  
The Royal London Hospital  
Victoria Hospital, Blackpool  
Cardiothoracic Centre,  
Broadgreen Hospital,  
Liverpool  
Dudley Road Hospital,  
Birmingham  
Maidstone Hospital  
Queens Medical Centre,  
Nottingham  
St Bartholomew's Hospital,  
London  
Queen Elizabeth Hospital  
Birmingham  
University Hospital of  
Wales, Cardiff  
Leeds General Infirmary  
Papworth Hospital,  
Huntingdon  
Hospital for Sick Children,  
Great Ormond Street,  
London  
Bristol Children's Hospital  
Royal Postgraduate Medical  
School, Hammersmith  
Hospital, London  
Westminster Hospital,  
London  
Edinburgh Royal Infirmary  
Airedale Hospital, Keighley  
Conquest Hospital, St  
Leonards on Sea

Table 1 Types of procedure by centre

Centre	ADC (n)	LCA%	L no C%	RLCA%	RL no C%	R%	Paed (n)	PTCA/V (n)	Total (n)
1	3626	77.0	1.2	20.0	0.9	0.85	385	716	4731
2	4133	79.0	6.4	8.1	2.0	4.0	5	514	4652
3	1144	82.2	1.9	10.9	0.6	4.0	16	111	1271
4	2977	93.3	0.2	6.0	0.0	0.45	0	579	3556
5	3257	94.0	0.2	4.5	0.4	0.9	160	471	3888
6	1430	87.6	1.1	9.9	0.5	0.8	0	150	1580
7	3064	78.3	0.1	20.4	0.1	0.9	43	488	3595
8	1218	86.7	2.3	8.3	0.9	1.7	0	102	1320
9	1470	75.1	1.0	21.1	1.4	1.7	0	236	1706
10	3789	83.5	1.3	14.0	0.1	0.9	109	584	4482
11	1417	86.4	1.6	7.8	0.0	3.9	0	152	1569
12	1208	79.4	1.6	12.3	5.1	1.4	38	114	1360
13	1029	91.3	0.6	5.8	1.0	1.0	0	219	1248
14*	4014	79.4	0.3	9.3	8.7	2.1	505	318	4837
Total (n)	33776	-	-	-	-	-	1265	4754	39795

ADC, adult diagnostic catheterisations; LCA, left heart and coronary arteries; L no C, left heart no coronary arteries; RLCA, right and left heart and coronaries; RL no C, right and left heart no coronaries; R, right heart only; Paed, paediatric; PTCA/V, angioplasty and valve dilatation.

\*Pooled data from all centres registering fewer than 1000 patients.

life or prolongs the planned hospital stay". There is no specific time limit, but there has to be a definite or probable link between the catheter procedure itself and the complication. Thus the death of a patient while awaiting surgery for an acute post-infarct ventricular septal defect would *not* be regarded as a catheter complication, even though it occurred shortly after the catheter study, whereas late death from renal failure resulting from cholesterol embolism at the time of catheterisation would be counted, even if separated from the study by some days or weeks. Several examples are provided in the initial "information pack" sent to centres.

Complications are reported as they occur by filling in a simple form with a verbal description of the complication, date, type of procedure, and status of the operator and sending the form to the coordinating centre. The identity of the patient is not revealed to the coordinating centre, but is coded to prevent double entry and to enable reporting centres to identify their own patients for internal audit. Follow up reports are sent if needed.

All reports are scrutinised by one observer to ensure compliance with the guidelines before being entered on the database. The observer also classifies complications into groups according to the most likely primary aetiology. The groups used are arrhythmias, vascular access complications, ischaemia (where there was evidence of severe and persisting myocardial ischaemia as a complication of the catheter procedure), coronary dissection, haemodynamic collapse, cerebrovascular accident (including transient

ischaemic attack), inter or trans myocardial injection, and allergy. Occasionally one patient has complications which fall into two or more groups.

Feedback to reporting centres is provided in the form of newsletters and reports. Reports list activity in the individual centre and compare complication rates in that centre with pooled complication rates from other centres. The activity listing provides an opportunity for checking that returns have been correctly submitted and entered.

For the purpose of this paper, returns from centres registering fewer than 1000 patients have been pooled to preserve anonymity. These are not necessarily small centres, but may have joined the project relatively late. Confidence intervals have been calculated assuming a Poisson distribution for complications.

## Results

Participating centres (appendix 1) included teaching hospitals, regional cardiac centres, district general hospitals, a private clinic, and two specialist paediatric centres.

Between 1 August 1990 and 31 July 1991 39 795 patients were logged by the coordinating centre. Of these, 33 776 were adults or adolescents undergoing diagnostic catheterisation, 1265 were paediatric patients under the age of 12 years, and 4754 were patients undergoing coronary angioplasty or balloon dilatation of a valve. 295 complications were registered, and there were 40 procedure related deaths. For the purposes of the present report, complications related to angioplasty were excluded.

Table 1 shows numbers of procedures in the 13 centres which registered over 1000 patients and in the pooled group of centres which registered under 1000 patients per centre. Left heart catheterisation with coronary angiography accounted for 83.3% of adult diagnostic procedures.

Table 2 shows complication rates and mortality for different types of diagnostic procedure. The overall complication rate was 0.80% (95% confidence interval 0.70 to 0.90), mortality was 0.12% (0.08 to 0.16),

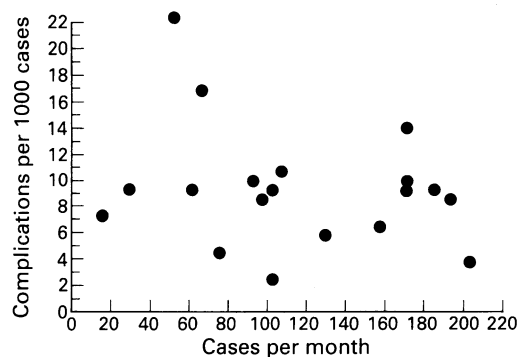
Table 2 Complication rates by type of procedure (pooled data from all centres)

Procedure type	Procedures (n)	Complications (%) (95% CI)	Mortality (%) (95% CI)
All adult diagnostic:	33 776	0.80 (0.70 to 0.90)	0.12 (0.08 to 0.16)
Left heart and coronaries	28 369	0.91 (0.79 to 1.02)	0.12 (0.07 to 0.16)
Left heart no coronaries	528	1.89 (0.69 to 3.09)	0
Left and right and coronaries	3936	0.53 (0.30 to 0.76)	0.08 (0 to 0.17)
Left and right, no coronaries	598	1.71 (0.28 to 2.05)	0
Right heart only	589	0.16 (0 to 0.62)	0
All left heart	33 637	0.88 (0.77 to 0.98)	0.11 (0.07 to 0.15)
All right heart	5123	0.64 (0.42 to 0.86)	0.06 (0 to 0.13)
Paediatric catheters	1265	0.32 (0 to 0.63)	0.16 (0 to 0.38)

Table 3 Complication rates per centre for adult diagnostic catheterisation

Centre	Procedures (n)	Complication rate (%) (95% CI)	Mortality (%) (95% CI)
1	3626	0.92 (0.64 to 1.19)	0.22 (0.08 to 0.41)
2	4133	1.47 (1.12 to 1.80)	0.1 (0 to 0.19)
3	1144	0.95 (0.40 to 1.50)	0.17 (0 to 0.41)
4	2977	0.67 (0.34 to 0.94)	0.07 (0 to 0.16)
5	3257	0.5 (0.27 to 0.73)	0.03 (0 to 0.09)
6	1430	0.98 (0.48 to 1.47)	0
7	3064	0.35 (0.15 to 0.55)	0.13 (0 to 0.26)
8	1218	0.98 (0.43 to 1.52)	0.08 (0 to 0.24)
9	1470	0.88 (0.43 to 1.33)	0.06 (0 to 0.18)
10	3789	0.88 (0.60 to 1.16)	0.10 (0 to 0.20)
11	1417	0.49 (0.14 to 0.89)	0.13 (0 to 0.32)
12	1208	0.40 (0.03 to 0.76)	0.16 (0 to 0.38)
13	1029	1.06 (0.48 to 1.64)	0
14*	4014	1.07 (0.74 to 1.40)	0.22 (0.07 to 0.37)
Total	33776	0.80 (0.70 to 0.90)	0.12 (0.08 to 0.16)

\*Pooled data from all centres registering fewer than 1000 patients.



Complication rates per 1000 cases plotted against caseload in cases per month for 19 centres for which data are available for 12 months or longer.

Table 4 Complications by type

Type	No	Deaths	Emergency cardiac surgery
<b>Arrhythmia:</b>			
Ventricular fibrillation	63		
Ventricular Tachycardia	14		
Asystole	10		
Vasovagal	8		
Total	95	1	0
<b>Vascular:</b>			
Femoral approach	37		
Brachial approach	37		
Total	74	1	0
<b>Myocardial ischaemia:</b>			
Leading to surgery	(29)	(8)	(29)
No surgery	(34)	(19)	(10)
Total	63	27	29
<b>Dissection:</b>			
Causing ischaemia*	14	(2)	9
Asymptomatic	6	1	3
<b>Haemodynamic collapse</b>			
	22	7	2
<b>Cerebrovascular/transient</b>			
	21	3	0
<b>Ischaemic attack</b>			
<b>Intramyocardial injection</b>			
	2	0	0
<b>Allergy</b>			
	6	0	0

\*Patients with ischaemic symptoms caused by coronary dissection are also counted under "ischaemia".

Some patients may have had more than one complication—for example, a vascular complication and ischaemia. Deaths have however been attributed to a single cause.

and emergency cardiac surgery rate 0.08% (0.05 to 0.11).

Table 3 lists morbidity and mortality rates by centre for adult diagnostic catheter patients for all centres registering over 1000 cases. Results from centres registering fewer than 1000 cases have been pooled.

Table 4 gives numbers of patients with different types of complications. Table 5 lists the incidence of different types of complication in individual centres.

The figure shows the relation between complication rate and caseload for 19 centres for which data are available for 12 months or longer.

## Discussion

Overall complication rates for the present study are of a similar order to those reported by the Society for Cardiac Angiography and Intervention.<sup>2</sup> In the American study, mortality (0.11%) was almost identical to the British rate; the total complication rate was slightly higher at 1.7%, but a substantial proportion of this (0.37%) was attributable to contrast reactions, which probably reflect a greater usage of ionic contrast medium in the United States. Detailed comparisons between different studies, and indeed between different centres in the same study, must be made with great caution because of possible differences in case mix and in reporting criteria.

The overwhelming predominance of left heart catheterisation with coronary angiography makes it possible to assess its complication rate with some precision; on the other

Table 5 Types of complication in individual centres (Rates per 1000 patients)

Centre	Arrh	Vasc	Isch	Haem	Diss	CVA	Iminj	Allergy
1	3	0.7	2	0.2	1.2	1.2	0.2	0
2	3.4	6.8	2.4	0.7	1.2	0.7	0.5	0
3	1.7	6.0	3.4	0	0.9	0	0	0
4	4.7	1.0	0.3	0	0.3	0.3	0	0
5	2.6	0.9	0.6	0.3	0.3	0.9	0	0
6	3.5	2.1	0	0	0	2.1	0.7	0
7	1.0	0	1.6	0.6	0	0	0	0.3
8	0.8	0.8	3.3	0	0	0	0.8	2.5
9	6.8	0	0	0.7	0	0	0.7	0
10	3.8	1.3	1.5	1.8	0.3	0.5	0	0.2
11	0.7	2.1	0.7	1.4	0	0	0	0
12	1.6	0	1.6	0.8	0.8	0	0	0
13	3.9	1.9	1.9	1.9	0	0	0	0.1
14*	2.0	4.4	1.5	0.7	0.4	1.3	0	0
Total	3.0	0.7	2.0	0.2	1.2	1.2	0.2	0.05

\*Composite of centres registering <1000 patients.

Arrh, arrhythmia; Vasc, vascular complication; Haem, haemodynamic complication; Diss, coronary dissection; CVA, cerebrovascular accident/transient ischaemic attack; Iminj, intramyocardial injection of contrast.

hand the confidence intervals for complication rates associated with other types of procedure remain relatively wide even in a study of this size.

There is little evidence of any correlation between either the complication or mortality rate and the workload of individual centres. Cardiac catheterisation is largely dependent on the skill and competence of the operator, and data on the complication rates associated with individual operators were not collected in this study. It is possible that all catheter studies in some small centres are performed by one experienced individual; conversely many catheter studies in larger centres are performed by operators in training. Since we did not collect data on the numbers of procedures performed by staff of different seniority, it is not possible to correlate the complication rate with operator experience.

Closer examination of different types of complication may make it possible to identify potentially avoidable causes. Arrhythmias were the commonest complication, and the most frequent serious arrhythmia was ventricular fibrillation associated with inadvertent selective injection of the conus branch of the right coronary artery. This complication is largely avoidable. Bradycardia or heart block were relatively uncommon, perhaps as a result of the widespread use of non-ionic contrast media. Few deaths resulted from arrhythmias, reflecting the high standards of resuscitation in most catheter laboratories.

Many of the "vascular" complications reported were associated with the use of the brachial approach; they were usually amenable to surgical repair and did not produce long-term morbidity. Since the monthly returns did not provide data about the proportion of studies done by the brachial and femoral routes their relative morbidity cannot be assessed here. Future returns will request this information.

Transient anginal symptoms at the time of cardiac catheterisation for ischaemic heart disease are common and do not come within the definition of "complication" used in this study. Severe and progressive myocardial ischaemia starting during or shortly after the catheter study was, however, an important cause of morbidity and mortality and a need for emergency surgery. In some cases it was possible to attribute this to a specific cause, such as dissection of the coronary ostium by the catheter or coronary thromboembolism. Both these complications might be avoided by better technique. Where ischaemia was recognised in the catheter laboratory and the patient was transferred for immediate surgery the survival rate seemed to be better than when ischaemia was recognised only after the patient had returned to the ward.

Haemodynamic complications were defined as sudden deteriorations in haemodynamic state without obvious myocardial ischaemia. They tended to occur in elderly, sick patients with valvar heart disease, such as severe aortic stenosis. Clearly the decision to

perform catheter studies in such patients has to take account of whether adequate information can be obtained from non-invasive studies.

Cerebrovascular accidents, transient ischaemic attacks, or amaurosis fugax were considered together. These are uncommon complications, but potentially important because of their major impact on quality of life. Overall incidence was 0.06%, but if transient ischaemic attacks are excluded the incidence of death or permanent neurological damage was 0.02%. Possible causes include atherothromboembolism from the ascending aorta, dissection of the neck vessels, or thromboembolism from the catheters or guide wire. There seems to be some evidence of "clustering" in that two centres contributed some 40% of all cases, but this could be an artefact of the case mix.

The method of data collection used in the present study did not permit identification of potential "high risk" patients such as the elderly or those with diabetes; questionnaires used from January 1993 are being modified to facilitate collection of such data.

## Conclusions

The rates for morbidity, mortality, and emergency surgical intervention after diagnostic cardiac catheterisation in the centres contributing to the study are low, but these are not grounds for complacency. Detailed analysis of the reported complications suggests that in nearly half there were some avoidable factors, either in terms of patient selection or of technique. Despite their limitations, voluntary audit schemes of this type may contribute to raising standards and increasing safety.

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- 1 Ward Kennedy J, the registry committee of the Society for Cardiac Angiography and Interventions. Symposium on catheterization complications: complications associated with cardiac catheterization and angiography. *Cathet Cardiovasc Diagn* 1982;8:5-11.
- 2 Noto TJ, Johnson LW, Krone R, Weaver WF, Clark DA, Kramer JR, Vetrovec GW and the Registry Committee of the Society for Cardiac Angiography and Interventions. Cardiac catheterization 1990: a report of the Registry of the Society for Cardiac Angiography and Interventions (SCA&I). *Cathet Cardiovasc Diagn* 1991; 24:75-83.
- 3 English TAH, Bailey AR, Dark JF, Williams WG. The UK cardiac surgical register, 1977-82. *BMJ* 1984;289: 1205-8.
- 4 Hubner PJB Cardiac interventional procedures in the United Kingdom during 1990. *Br Heart J* 1992;48: 434-6.
- 5 Stewart JT, Gray HH, Ward DE, Pumphrey CW, Redwood DR, Parker DJ. Major complications of coronary arteriography: the role of cardiac surgery. *Br Heart J* 1990;63:74-7.