

Road Safety Research Report No. 67

**Expert Consensus Workshop:
Driving Safety and Cardiac
Ischaemia, 7–8 July 2005**

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ABBREVIATIONS

bpm	beats per minute
CAA	Civil Aviation Authority
CABG	coronary artery bypass graft
CAD	coronary artery disease
CASS	Coronary Artery Surgery Study
COPD	chronic obstructive pulmonary disease
DfT	Department for Transport
DMG	Drivers Medical Group
DSE	dobutamine stress echocardiography
DTS	Duke Treadmill Score
DVLA	Driver and Vehicle Licensing Agency
EASA	European Aviation Safety Agency
ECG	electrocardiogram
ICAO	International Civil Aviation Organisation
IHD	ischaemic heart disease
IVUS	intravascular ultrasound
JAA	Joint Aviation Authorities
LBBB	left bundle branch block
LGV	large goods vehicle
LVEF	left ventricular ejection fraction
MET	metabolic equivalent
MPS	myocardial perfusion scintigraphy
PCI	percutaneous coronary intervention
PCV	passenger carrying vehicle
RNA-EF	radionuclide angiography ejection fraction
RBBB	right bundle branch block
SPECT	Single Photon Emission Computed Tomography

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1 INTRODUCTION

The Expert Consensus Workshop, Driving Safety and Cardiac Ischaemia, was organised to evaluate the currently available assessment tools that determine the most accurate and reliable prognostic indicators of a high cardiovascular event rate while driving, for Group 2 drivers with a history or evidence of established cardiovascular disease. The estimated level of risk of a cardiovascular event is used in making decisions on whether to grant, renew or revoke Group 2 licences on medical grounds. The Driver and Vehicle Licensing Agency (DVLA) has a commitment to continuous improvement in customer care, to ensure up-to-date and objective medical criteria, and to avoid unjustified discrimination. The scientific workshop was convened by the Department for Transport (DfT) to draw on the best medical expertise available in reviewing current practice.

1.1 Prognostic tests

Prognostic tests are used to determine whether a driver is at a high (unacceptable) annual risk or at a lower, acceptable annual risk of experiencing a cardiovascular event while driving. A high risk is defined as a recurrent cardiovascular event rate of more than 2% per annum; an acceptable risk is defined as an annual event rate of 2% or lower. The 2% cut-off is the established level of acceptable risk for a cardiovascular or other sudden disabling event occurring in the next year used by the DVLA in setting its medical standards for Group 2 drivers. Group 2 drivers are those holding one or more of the following licences:

- large goods vehicle (LGV);
- passenger carrying vehicle (PCV);
- C1 (medium goods); or
- D1 (minibus).

Current evaluation tools include the exercise-tolerance test, myocardial perfusion scans and stress echocardiography. Angiograms are not commissioned by the DVLA, but are considered when submitted.

1.2 Aims and structure of the Expert Workshop

The aims of the Workshop were to examine a number of protocol issues, such as:

- the value of symptom-limited exercise testing rather than the standard nine-minute treadmill test used by the DVLA;
- the appropriate interval between revascularisation procedures and exercise-tolerance tests; and

- the procedure to be undertaken when licence holders or applicants are unable to complete the standard exercise-tolerance test for non-cardiac reasons (such as lower-limb pain or disability).

The suitability of stress echocardiography and myocardial perfusion scintigraphy (MPS) in determining cases where exercise-tolerance test results are equivocal was reviewed, as was the role of coronary angiography in providing additional prognostic evidence. Cost–benefit issues were also considered. The Workshop also discussed how to respond to applicants and licence holders who undertake unsolicited medical tests that generate results that conflict with the DVLA test results. Another discussion point was whether other coronary artery disease risk factors, such as age and smoking, should be taken into consideration in decisions about who should undergo exercise-tolerance testing.

The Workshop was divided into two parts: a formal review of relevant research evidence; and an open discussion to address current testing protocols and decision making. It also included a review of current practice by the Civil Aviation Authority (CAA) in granting pilots' licences and whether there are any lessons to be drawn from the higher medical standards – based on lower levels of acceptable risk – used in aviation.

Workshop participants included leading cardiologists in the UK, members of the DVLA Cardiac Expert Panel, and medical officers from the DVLA, CAA and DfT. The event was managed by an independent organisation, the At Work Partnership, which was also responsible for writing and editing the workshop proceedings.

2 EXPERT PRESENTATIONS: OPENING REMARKS

In his introduction to the Expert Consensus Workshop, Dr Tim Carter, Chief Medical Adviser at the DfT, explained that there was a need not just to examine current evidence on the standard prognostic tests, but also to determine the appropriate way to handle results from tests not specifically required by the DVLA but which the licence holder or applicant has nevertheless submitted in support of their application.

Dr Major, Senior Medical Adviser at the DVLA, asked whether, before giving her opening presentation, participants wished to comment on either the ‘DVLA position paper on ischaemic heart disease and driving in the context of licensing’ (Appendix 1) or the *At a Glance Guide to the Current Medical Standards of Fitness to Drive* (DVLA, 2005) with respect to the various cardiovascular conditions considered a bar to Group 2 entitlement (Chapter 2 on cardiovascular disorders is reproduced in Appendix 2). The *At a Glance Guide* is available freely to all general practitioners, consultants and the public on the DVLA website (www.dvla.gov.uk).

There was a short discussion on the appropriateness of the current 2% per annum cardiovascular event risk threshold and whether, given recent advances in the treatment of cardiovascular disease, the limit was too restrictive. It was agreed that what constituted an acceptable risk was an issue for much wider discussion, beyond the remit of the Expert Consensus Workshop.

2.1 Reference

Driver and Vehicle Licensing Agency (DVLA) (2005) *At a Glance Guide to the Current Medical Standards of Fitness to Drive*. Swansea: DVLA. www.dvla.gov.uk/at_a_glance/content.htm

3 ISCHAEMIC HEART DISEASE AND DRIVING IN THE CONTEXT OF GROUP 2 LICENSING

Heather Major

Dr Major reviewed the role of the Driver and Vehicle Licensing Agency (DVLA), the legislative framework of licensing, concepts of medical impairment and risk, and the current cardiac assessment process with its advantages and disadvantages.

3.1 Medical standards

The role of medical licensing standards is to try to minimise a foreseeable significant excess risk to road safety. Medical standards are administered through the Drivers Medical Group (DMG), which, in turn, has links to other statutory, advocacy and advisory bodies. The advisory bodies include the Secretary of State for Transport's Honorary Medical Advisory Panels, comprising specialists in each of several different disease areas, including cardiology. Each Panel's advice, and its legislative basis, are published in the DVLA's *At a Glance Guide to the Current Medical Standards of Fitness to Drive* (DVLA, 2005), which is revised and published twice yearly on the DVLA website.

There are 41 million driving licence holders, including an increasing number of people over the age of 70 years. Of this total, approximately 1.7 million have Group 2 entitlement, of which over 600,000 are lorry LGV drivers. Group 2 drivers' licences expire initially at the age of 45 years, and are then renewable every five years until the age of 65, and annually thereafter. A medical examination is required on first issue and for relicensing.

The medical standards required for licensing are based on the risk, nature and impact of medical impairment, and on the vehicle-associated risk. For the medical risks, standards are based on either a 20% per annum (Group 1) or a 2% per annum (Group 2) risk of a sudden disabling event. The medical standards for vehicle-associated risk for Group 2 drivers are higher than those for Group 1 drivers (ordinary car licence holders) due to:

- longer periods of exposure to driving;
- the larger weight of the vehicle and/or greater number of passengers;
- the higher rate of fatal accidents involving Group 2 compared with Group 1 vehicles (Government figures for 1999 show that the fatal injury rates per vehicle kilometres were: 1.0 deaths per million vehicle kilometres for cars; 2.2 for HGVs; and 2.8 for buses/coaches); and
- the pressure of work schedules in Group 2 driving.

3.2 Legislation

Driving licence legislation is based on the Second EC Directive on the Driving Licence (91/439/EEC), the Road Traffic Act 1988 (sections 92–94 and amendments), and the Motor Vehicles (Driving Licences) Regulations 1999 and subsequent amendments. The Road Traffic Act requires drivers or applicants to notify and declare to the DVLA any medical condition that may affect driving, and the Act gives the DVLA powers to investigate, and to issue, refuse or revoke licences. The Act also specifies the duration of licences, and gives licence holders and applicants the right of appeal. The definition of ‘reasonable grounds’ for a medical enquiry is that the licence holder may suffer from a relevant or prospective disability.

However, the DVLA’s powers to investigate and withhold licences are limited by other relevant legislation, such as the:

- Human Rights Act 1998;
- Data Protection Act 1998;
- Disability Discrimination Act 1995; and
- Freedom of Information Act 2000.

Under the Human Rights Act, the holding of a driving licence is considered a qualified right, interference with which is justified only if it has its basis in law and is necessary in a democratic society, i.e. it fulfils a pressing social need, pursues a legitimate aim and is proportionate to the aims being pursued, such as crime prevention or the protection of public health or order.

3.3 Types of impairment relevant to driving fitness

For the purposes of licensing, the Road Traffic Act specifies various prescribed disabilities, including the liability to sudden attacks of disabling giddiness or fainting, such as those which, as Dr Major pointed out, may occur during cardiac ischaemia. The types of impairment relevant to driving fitness therefore includes sudden incapacity, including heart attack, the tolerable risk of which has been established at 20% or less per annum for Group 1 drivers and 2% or less per annum for those in Group 2. These levels are based on a number of years’ experience applying the same percentages to sudden incapacity from seizures. The most appropriate method of quantification of risk remains the subject of ongoing debate.

3.4 Current method of assessing ischaemic heart disease by the DVLA

Dr Major outlined the current process of assessment of ‘cardiac’ cases, which applies only to Group 2 drivers. This requires notification to the DVLA of a medical

condition, either by letter or telephone, or by completing a D4 medical report form. The individual's consent to a medical enquiry must then be obtained. The available medical reports are then viewed, cardiological (and where relevant neurological) opinion sought and relevant examinations undertaken, and a functional investigation performed – all at the DVLA's expense.

Cardiovascular conditions requiring investigation include:

- angina;
- myocardial infarction;
- acute coronary syndrome;
- coronary intervention (such as angioplasty and coronary artery bypass graft);
- symptomatic peripheral arterial disease; and
- cerebrovascular disease (i.e. stroke or transient ischaemic attack).

The cardiac standards, summarised in Chapter 2 of the *At a Glance Guide* (see Appendix 2), require freedom from coronary ischaemic symptoms, no residual neurological deficit and completion of three stages of the standard Bruce exercise electrocardiogram (ECG) test, conducted as specified on a treadmill, or equivalent exercise conducted on bicycle ergometer.

Functional assessment options are myocardial perfusion study and stress echocardiography. Coronary angiography may provide additional evidence, but it is not specifically commissioned by the DVLA. Dr Major explained that approximately 8,000 Group 2 cardiac cases are assessed by exercise testing annually, costing £150–300 per case. Of these, approximately 100 cases need further, much more expensive, investigations, such as myocardial perfusion study.

3.5 Benefits and disadvantages of the current assessment tools for licensing purposes

The Bruce exercise ECG has both benefits and disadvantages. The benefits include:

- wide and generally ready availability;
- relative lack of expense;
- reproducibility;
- good face validity;
- good predictive value; and
- low risk.

However, patients may be unable to complete the required nine minutes on the treadmill for reasons other than cardiac disease (such as lower-limb joint pain). Trace interpretation is not always straightforward, for example in patients with left bundle branch block (LBBB). Some patients may be unable to use the treadmill because they are significantly overweight or otherwise unfit. Consequently, the results may be subject to inappropriate interpretation or they may be inconclusive.

Alternatively, myocardial perfusion study overcomes adverse mobility problems, may be more sensitive and/or accurate in identifying reversible ischaemia, and has reasonably good evidence to support its prognostic value. However, myocardial perfusion study is much less widely available than exercise ECG testing, it is expensive, with costs varying considerably between centres, and it lacks an agreed standard methodological and reporting protocol. Myocardial perfusion study is also claimed to carry some radiation risk and to produce false-positive results (Groves *et al.*, 2004).

Stress echocardiography has both advantages and disadvantages, and it has not yet been established whether or not it has an important role to play in DVLA medical enquiries.

3.6 Key problems

The key problems for the DVLA are as follows:

- Which evaluation tool takes precedence in terms of predictive value?
- How can the false-positive and false-negative results from exercise ECG be identified?
- How should functional tests be interpreted against the anatomical evidence from angiography?
- Assessments are repeated every three years – should this frequency be changed?

Dr Major presented some anonymised examples of real casework problems where the results of a standard exercise ECG conflicted with consultant opinion, other functional assessments or angiography. Dr Major also emphasised that the numbers and costs of assessing Group 2 cardiac cases are increasing steadily – there were 5,631 cardiac investigation letters recorded from September 2003 to March 2004, compared with 6,188 investigation letters recorded from September 2004 to March 2005 (excludes direct referrals from medical advisers). Unfavourable licensing decisions may be challenged in court, while unduly lenient decisions may pose a risk to public road safety.

The Cardiac Panel and the DVLA wished to reach a consensus view of the experts attending the Workshop on the prognostic value of the currently available assessment tools in mainstream clinical practice. The consensus view should be

based on sound, referenced evidence and will lead to confirmation of the most cost-effective and scientifically robust best practice for the DVLA's assessment of cardiac cases. The aim, Dr Major added, would be to help the DVLA screen individuals who are already at some risk in order to divide individuals into high- and low-risk cohorts.

3.7 Panel discussion

It was agreed that exercise test results in the same individual might differ when conducted several months apart or in different ambient temperatures. The subsequent results are open to interpretation unless an objective measure, such as the Duke Treadmill Score, is used. The panel also agreed that a negative result required individuals to have completed the full nine minutes without significant ST-segment change. It was also pointed out that exercise testing may not have the same validity as a means of identifying coronary ischaemia or to predict risk in patients following coronary artery bypass graft. Bundle branch block also makes test interpretation difficult.

3.8 References

Driver and Vehicle Licensing Agency (DVLA) (2005) *At a Glance Guide to the Current Medical Standards of Fitness to Drive*. Swansea: DVLA. www.dvla.gov.uk/at_a_glance/content.htm

Groves, A. M., Kayani, I., Syed, R., Gacinovic, S., Nagabushan, N. and Ell, P. J. (2004) Myocardial perfusion scintigraphy: patients' perception of benefit and risk. *Nucl Med Commun*, 25, 1219–22.

4 THE ABILITY TO PREDICT FUTURE CARDIAC EVENTS BASED ON THE EXERCISE ECG IN PATIENTS WITH KNOWN CORONARY ARTERY DISEASE

Hugh McIntyre

Dr McIntyre declared that while he is not an ardent supporter of the Duke Treadmill Score (DTS), it may provide an objective assessment of risk that is defensible in a UK court of law because it demonstrates that the exercise test protocol has been followed. The exercise-tolerance test, he continued, is both diagnostic and prognostic. It is the prognostic aspect of the exercise test that is of most relevance with respect to fitness to drive. The Group 2 definition of fitness to drive – a risk of a disabling event of 2% or less per annum – may be assumed to equate to a cardiovascular event rate of 2% or less per annum which, in turn, equates to a total mortality of 1% or less per annum. This is the background mortality for a general population aged around 60 years.

4.1 Limitations and strengths

The limitations of the exercise-tolerance test include the diffuse literature that supports it, with most directed at diagnostic discrimination in suspected coronary artery disease (CAD) and its ability to predict an anatomically observable lesion. Where prognosis is reviewed, this usually does not distinguish between all-cause survival and cardiac survival – neither does it record sudden death nor discriminate between symptomatic and asymptomatic individuals. When including prior CAD, the literature often does not define the exact diagnosis or the duration of the condition.

The strengths of the exercise-tolerance test as a prognostic test are that it addresses a relevant biological effect, requires functional assessment during stress, is performed to a standardised protocol and is widely available. However, the question remains as to whether the exercise-tolerance test is fit for its intended purpose: to readily identify people with prior CAD who have a low likelihood of disabling events.

4.2 Unit of measurement: the metabolic equivalent

The unit of measurement, the metabolic equivalent (MET), used in the exercise-tolerance test is defined as one unit of oxygen uptake in a sitting, resting position, and equals 3.5 ml O₂/min/kg. Thus, the measured VO₂ in ml O₂/min/kg divided by 3.5 equals the number of METs associated with a particular activity. Activities using more than nine METs include such actions as participating in heavy labour, playing

squash, and running at 6–7 mph. The standard Bruce protocol (used by physicians the world over to test cardiovascular function) comprises seven graded stages, each three-minutes long. Completion of stage III (a total of nine minutes) equates to 10.5 METs.

4.3 Exercise-tolerance testing in individuals with a history of CAD

An early study investigating the prognostic importance of exercise-tolerance testing in medically treated patients with CAD involved the Coronary Artery Surgery Study (CASS) registry. A total of 4,083 patients underwent exercise testing and angiography, and were followed for five years (the study was limited to patients with symptoms). Patients who could exercise to at least stage III of the standard Bruce protocol with no ST changes were defined as a low-risk group, with an estimated annual mortality of less than 1% (Weiner *et al.*, 1984). This study established the importance of functional status as a determinant of prognosis in patients with proven CAD.

The study sought to identify those at high risk – and who should have surgery – and included several variables, including the severity of symptoms, number of stenoses, number of vessels involved, as well as exercise-tolerance test variables. For the exercise-tolerance test, the authors found that an ability to reach stage V of the test in 572 patients with three-vessel disease and good left ventricular function predicted 100% survival at four years. By contrast, those able to reach only stage I/II had a 53% survival at four years.

In 1987, a group from Duke University, Durham, North Carolina, USA, reported on the prognostic ability of exercise-tolerance testing in 2,842 symptomatic inpatients with known or suspected CAD who underwent both exercise testing and coronary angiography within six weeks (Mark *et al.*, 1987). The patients – limited to those with symptoms – were divided randomly into a training group, used to develop the predictive model, and a validation group. Follow-up was five years (10% were followed up for more than 10 years). Multivariate analysis identified ST deviation, angina during the test and exercise capacity as independent prognostic variables. From these findings, the authors devised the DTS, which is defined as follows:

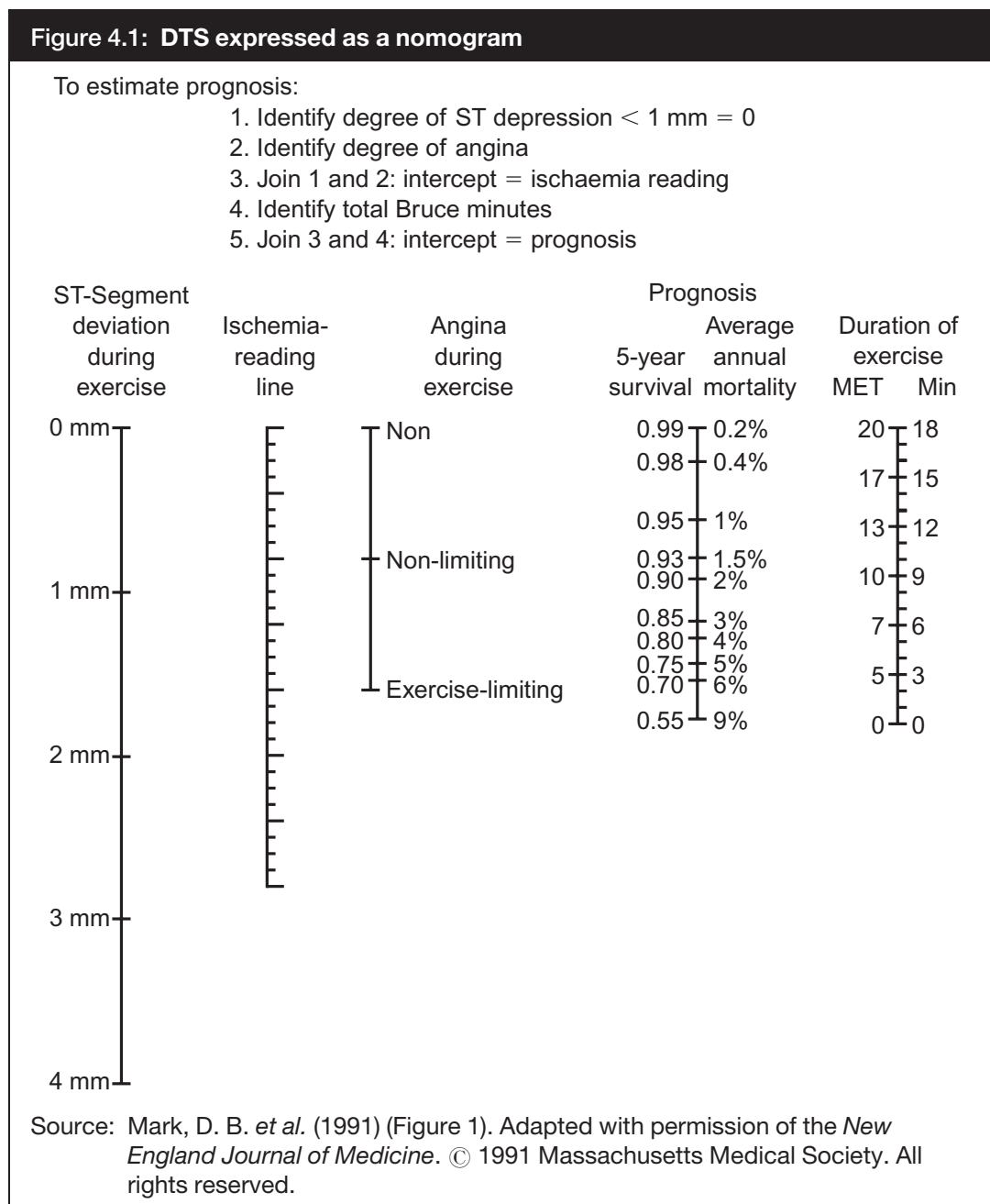
$$\text{DTS} = (\text{exercise time}) - (5 \times \text{amount of ST-segment deviation in mm}) \\ - (4 \times \text{exercise angina index}^*)$$

Low-risk patients are defined as those with a DTS greater than 5. In the study, this group – which comprised 34% of the total patients – had an average cardiovascular mortality rate of 0.5%. In 49 patients with three-vessel disease and a DTS greater

* The exercise angina index has a value of 0 if there is no angina, 1 if exercise angina occurs, and 2 if angina is the reason for the patient stopping exercising.

than 7, five-year survival was 93%. The DTS was subsequently applied to symptomatic outpatients referred for non-invasive testing: four-year cardiovascular survival was 99% for those scoring 5 or more, which is superior to that of the background population (Mark *et al.*, 1991).

The investigators developed a nomogram from their original data to allow prognosis stratification (Figure 4.1).



This indicates that, for example, an individual exercising for the full nine minutes with less than 1 mm ST-segment depression and no angina (DTS: 9) has an average annual cardiac mortality risk of less than 1% (Figure 4.2).

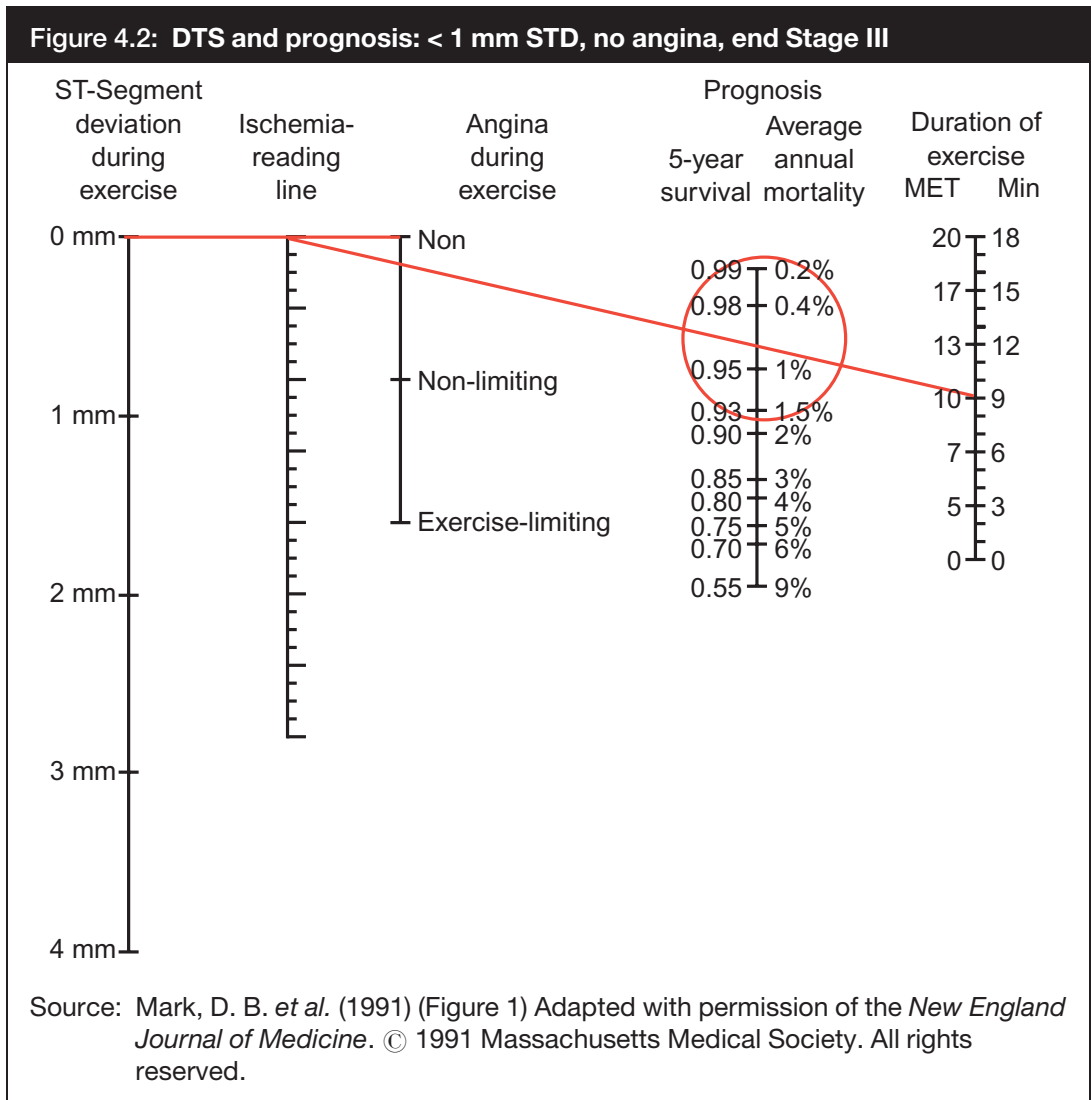
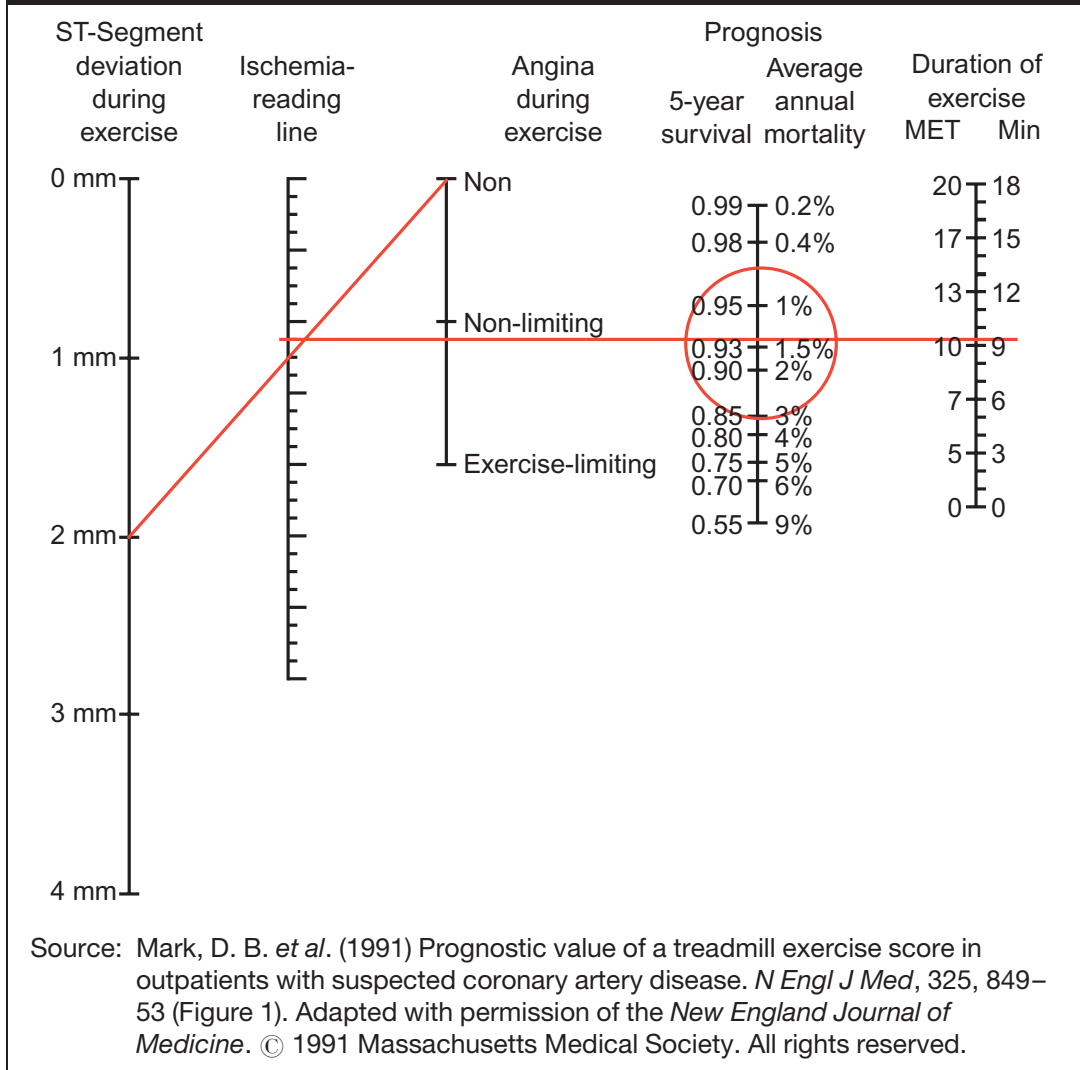


Figure 4.3 illustrates the current DfT standard (2 mm ST-segment depression, end stage III (DTS: 1), equating to an annual cardiovascular mortality risk of 1.5%.

Figure 4.3: DTS and prognosis: 2 mm STD, no angina, end stage III (the current DfT standard)



4.4 Exercise-tolerance testing and mortality in asymptomatic individuals with CAD

The DTS is useful in that it predicts prognosis by summing ST-segment changes, symptoms and exercise capacity. However, it overemphasises the cardiac prognosis (although this may not, in itself, be a limitation) and overestimates the total risk since the scoring system was derived from patient populations that excluded asymptomatic individuals. In addition, intervention thresholds are lower today than 15 years ago, casting doubt on the current applicability of the results.

A more recent study of 6,213 consecutive men (mean age 59 years for all subjects), referred for symptom-limited treadmill testing, evaluated the role of overall exercise capacity in providing independent prognostic information in apparently healthy people (Myers *et al.*, 2002). The cohort was divided into two groups: those with

either an abnormal exercise test and/or a history of CAD ($n = 3,679$; mean age 61.5 years) and those with normal exercise tolerance and no CAD history ($n = 2,534$; mean age 55.5 years). Mean follow-up was 6.2 years. After adjustment for age, the peak exercise capacity, measured in METs, was the strongest prognostic indicator of the risk of all-cause mortality among both normal subjects and those with cardiovascular disease. The average mortality of the total cohort was 2.6% per annum: 288 of the 2,534 normal subjects had died (approximate annual mortality rate = 1.8%), compared with 968 of the 3,679 cardiovascular subjects (approximate annual mortality rate = 4.3%). The ability to complete eight METs or more was associated with an overall mortality of approximately 1.3% per annum. However, the decline in survival accelerated after 3.5 to 4 years.

These findings indicate that exercise capacity alone predicts prognosis in stable patients with pre-existing cardiovascular disease, irrespective of exercise-induced angina or ST-segment depression. The use of beta blockade does not affect the results. They also suggest, however, the need to re-test at relatively short intervals. The limitations of the study include the omission from the report of the time to event, and the possibility of overestimating risk since the cardiovascular group included patients with ST-segment depression and exercise angina. The study population also excluded women.

4.5 Exercise testing and prognosis after myocardial infarction

In the GISSI-2 thrombolysis study (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico), 6,296 patients underwent symptom-limited bicycle ergometry at an average of 28 days after myocardial infarction (Villella *et al.*, 1995). The test was judged positive for residual ischaemia if there was typical angina or ST depression (horizontal or down-sloping) of greater than 1 mm. A negative test identified a cohort with a six-month cardiovascular mortality of 0.9%, and the ability to complete approximately seven METs of exercise predicted a six-month total mortality of 0.8%. Only exercise-induced angina predicted re-infarction (2.1%).

The DANAMI study (Danish Acute Myocardial Infarction study, 1997–2001) was designed to compare primary angioplasty with fibrinolysis in 1,462 patients with ST elevation of 4 mm or more; 590 patients underwent fibrinolysis and 575 percutaneous coronary intervention (PCI) (Valeur *et al.*, 2005). A total of 1,164 patients performed a bicycle exercise test a median of six days following myocardial infarction. Follow-up was for 3.1 years. Exercise test interpretation was based on intention to treat. Of those in the exercise cohort, 6.1% died and 5.9% suffered re-infarction.

Of the variables studied, multivariate analysis found that exercise testing (METs) alone predicted death in both the PCI and thrombolysis groups (Valeur *et al.*, 2005). The total mortality was approximately 3% at one year in those capable of

performing any exercise testing whatsoever. The ability to complete at least eight METs of exercise was significantly associated with a reduced likelihood of death or re-infarction at one year (approximately 1% per annum over three years), and a combined incidence of death and non-fatal myocardial infarction in the post-acute phase of less than 2%.

The limitations of this study include its early (pre-discharge) use of exercise-tolerance testing and the finding that, in multivariate analysis, death, exercise capacity and ST-segment depression remain predictive only for the thrombolysis group. An accompanying editorial suggested that 'exercise capacity seems to be the best single exercise variable for identifying patients at low-risk for cardiac death post-MI' (Borjesson and Dellborg, 2005).

4.6 Exercise testing post revascularisation

The joint American College of Cardiology and American Heart Association guidelines state: 'Exercise testing in an asymptomatic patient who has undergone successful CABG [coronary artery bypass graft] is not predictive of subsequent events when the test is performed within the first few years after the procedure' (Gibbons *et al.*, 2002). For elective PCI, evaluation has been for the identification of restenosis over a one-month to six-month follow-up.

A recent study compared the DTS, peak exercise radionuclide angiography ejection fraction (RNA-EF) and Single Photon Emission Computed Tomography (SPECT) perfusion imaging, performed as a single test, in the prediction of death and non-fatal myocardial infarction in high-risk CAD patients (Liao *et al.*, 2005). The study was based on 997 patients, with follow-up at four years. The DTS was as effective as RNA-EF in predicting all-cause and cardiovascular mortality. SPECT (summed stress score) added discriminatory value by identifying low-risk patients (99% cardiac survival at five years) among those with intermediate risk by the DTS. (See also Hachamovich *et al.*, 1996; Gibbons *et al.*, 1999.)

4.7 Heart rate profile

Historically, chronotropic incompetence has been defined as an inability to achieve 85% of maximal predicted heart rate (maximum predicted heart rate = 220 – age in years). In a study of 2,428 patients, heart rate recovery of less than 12 bpm after two minutes predicted all-cause mortality (Cole *et al.*, 2000). In 5,713 asymptomatic-employed men, followed for 23 years following standardised graded bicycle testing (Jouven *et al.*, 2005), the relative risk for sudden death from myocardial infarction was:

- 3.92 for resting heart rates of greater than 75 bpm;
- 6.18 for an increase in heart rate during exercise of less than 89 bpm; and
- 2.2 for a decrease of less than 25 bpm in the first minute of recovery.

Heart rate profile has considerable prognostic potential because of the importance of sudden death as a potential cause of road accidents.

4.8 Conclusion

Exercise-tolerance testing consistently identifies a cohort of patients with known CAD at low-risk of an event. The discriminatory ability of the test is less than 1% per annum for total mortality, and less than 2% for death and myocardial infarction in patients with known CAD able to complete stage III of the standard Bruce protocol with no chest pain and no ST-segment depression below 1 mm. For new or recurrent events, and following PCI or CABG, there remains a question of the optimal time for testing: six weeks or three months? However, the available evidence supports retesting at no more than three years, as is current practice.

4.9 Panel discussion

There was some discussion about the prognostic versus diagnostic value of ischaemia identified during the exercise-tolerance test. The current criteria for granting/renewing a Group 2 licence require an exercise level of 9–10 METs plus electrocardiographic evidence of a lack of ischaemia; the latter can hinge on the opinion of the cardiologist.

The question was raised whether the DVLA, like the Civil Aviation Authority (CAA), should require symptom-limited exercise testing rather than the completion of stage III of the standard Bruce protocol. However, it was also pointed out that an individual might well exercise for nine minutes without chest pain and yet still have a 2 mm ST-segment depression, giving him a DTS of –1. Conversely, the individual could have an ST-segment depression of 1.8 mm and be granted a licence even though a cardiologist would identify the presence of significant ischaemia. This appeared to be a cause for concern in some cases. Nevertheless, where opinions conflicted, the existing algorithm (see Appendix 3) already required the driver/applicant to undergo further testing.

Some participants felt that symptom-limited testing – up to the end of stage V on the Bruce protocol, if necessary – was prognostically more reliable than the presence or absence of ST-segment depression. Others pointed out that it was possible to exercise for as long as 14–15 minutes despite a 2 mm ST-segment depression and that a requirement for a symptom-limited exercise-tolerance test might deter some community cardiologists from using it. Conversely, the DTS based on stage III of the standard protocol was an objective measure that they could

defend in court. There also remains the question of whether exercise-tolerance testing is relevant in people who have undergone CABG or PCI. (This was considered in more detail in the open discussion at the end of the meeting – see section 11.3)

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5 ELECTROCARDIOGRAM AS A PROGNOSTIC TOOL IN ISCHAEMIC HEART DISEASE

John Camm

The electrocardiogram (ECG) contains a large amount of prognostic information. However, there is uncertainty about what this information predicts. Although the prediction of mortality is fairly straightforward, there is nothing in the literature to indicate that ECGs can predict sudden death or a disabling cardiac symptom relevant to road safety. These issues were explored in detail.

5.1 Heart rate

Although heart rate can be derived from the ECG, the scale of risk it predicts is modest. Even with resting heart rates above 90 bpm, mortality from coronary artery disease (CAD) is only 8/1,000 per annum, or just less than 1% per annum. Conversely, heart rate is an important risk stratifier; in the Framingham population, for example, the older the patient, the more important heart rate is as a predictor of sudden death (Levy *et al.*, 1989).

Heart rate is also a more powerful risk stratifier than the QT interval. Results from the Coronary Artery Surgery Study (CASS) registry confirm the long-term prognostic value of heart rate in CAD. In a recently published paper, cumulative 15-year survival was shown to decline as resting heart rate at baseline increased – those with a resting heart rate of 83 bpm or more at the start of the study period had a higher risk both of total mortality and cardiovascular mortality (Diaz *et al.*, 2005). The time to first cardiovascular re-hospitalisation was also compared for patients with resting heart rates of 77–82 bpm and 83 bpm or more at baseline with patients with resting heart rates below 63 bpm. The risk was significantly elevated in both comparisons (odds ratios for time to first re-hospitalisation were 1.11 and 1.14, respectively; $p < 0.001$).

Moreover, in the GISSI-2 study (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico), mortality was directly related to heart rate independent of other risk factors. A resting heart rate on admission of more than 100 bpm was associated with an in-hospital mortality of 23.4%, compared with 7.1% in those with a heart rate of between 60 bpm and 80 bpm (Zuanetti *et al.*, 1996). An admission heart rate of more than 100 bpm was also the most important predictor for mortality six months after discharge (risk ratio = 4.54).

Other studies have shown that with a one-year follow-up, heart rates of greater than 89 bpm are associated with a 10% mortality, compared with just 1% mortality for those with a heart rate below 70 bpm (Hjalmarson *et al.*, 1990; Palatini *et al.*, 1999).

Another ECG sign, atrial fibrillation, also predicts mortality with a risk 1.5–2.0 times that associated with sinus rhythm (Benjamin *et al.*, 1998; Wyse *et al.*, 2002).

5.2 ECG abnormalities

An assessment of the relative odds of coronary heart disease by ECG abnormality has indicated ischaemia and myocardial infarction to be the most powerful predictors, ahead of left ventricular hypertrophy, intraventricular conduction disturbance and supraventricular ectopic beats (Whincup *et al.*, 1995). ECG markers for cardiovascular events include left ventricular hypertrophy with an ejection fraction below 40%, non-sustained ventricular tachycardia and premature ventricular contractions.

Professor Camm reported that, despite these findings, none of these indicators greatly helps in determining a person's entitlement to drive. In this context, the prediction of sudden cardiac death is much more important, and, of the ECG variables assessed, several have been found to be positively, but relatively weakly associated (for example, bundle branch block) (Kreger *et al.*, 1987; Baldasseroni *et al.*, 2002)

Other studies have found various ECG parameters to predict overall cardiovascular death (De Bacquer *et al.*, 1998; Engel *et al.*, 2004; Kannel *et al.*, 1987; Kannel 1987; Richardson *et al.*, 2005; Beckerman *et al.*, 2005). In some of these studies, however, patients had an underlying diagnosis of congestive heart failure and so might already have been barred because they had an ejection fraction below 40%.

5.3 Myocardial Damage Score

The Myocardial Damage Score (and a number of other scoring systems) is a composite total that combines several different ECG abnormalities into one score (van Domburg *et al.*, 1998; Dekker *et al.*, 1995(a); Dekker *et al.*, 1995(b); Kannel and Abbot, 1984; Jones *et al.*, 1990; Pedoe, 1978; Ostor *et al.*, 1981; Culen *et al.*, 1982; Menotti and Seccareccia, 1997; Tervahauta *et al.*, 1996; Reunanen *et al.*, 1983). This has been found to be of substantial value, identifying both high-risk and low-risk groups with 35% and 3% mortality, respectively, at 10 years. However, in spite of its relative predictive power, the Myocardial Damage Score is not used in clinical medicine and is not useful in the prediction of syncope or sudden death; its potential value in the assessment of driving entitlement has not been evaluated but it is not expected to be useful.

5.4 Panel discussion

It was agreed that the use of the resting ECG alone would not advance the assessment of ischaemic heart disease and driving entitlement since, while very

useful for the diagnosis of arrhythmia, it should not be used as a prognostic tool. However, a resting ECG might be useful in patients with an equivocal exercise ECG.

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6 MYOCARDIAL PERFUSION SCINTIGRAPHY

S. Richard Underwood

6.1 Techniques

Myocardial perfusion scintigraphy (MPS) is a reproducible and robust technique for studying myocardial perfusion, and the routine use of Single Photon Emission Computed Tomography (SPECT) gives a three-dimensional image of tracer uptake throughout the myocardium. Thallium-201 is still used widely as a tracer but technetium-99m labelled radiopharmaceuticals, such as MIBI and tetrofosmin, give higher-quality images and allow electrocardiogram (ECG) gated acquisition, providing simultaneous assessment of myocardial perfusion, viability and function.

6.2 Diagnosis of coronary artery disease

MPS can detect perfusion inhomogeneities caused by haemodynamically significant coronary artery stenosis. Pharmacological stress or exercise can produce these inhomogeneities so that individuals who are, for example, overly obese can be assessed without the need for maximal dynamic exercise. Typical sensitivity and specificity for diagnosing coronary artery disease (CAD) are 91% and 89%, respectively (Maddahi, 1996), which are both significantly higher than for exercise ECG (Gianrossi *et al.*, 1989).

When using MPS to assess the extent and depth of ischaemia, it is usual to use a segmented model to quantify the proportion of the left ventricle involved. The nine-segment model fits the usual coronary territories while the 17-segment model, used in the US, corresponds to the fields assessed using echocardiography, magnetic resonance or computerised tomography. Each segment of the left ventricle is assessed for ischaemia severity and, by adding scores for each segment to a summed score, both the extent and severity of ischaemia are combined in a single measure. Scores of 4, 3, 2, 1 and 0 represent normal perfusion (100–70%), mild ischaemia (70–50%), moderate ischaemia (50–30%), severe ischaemia (30–10%) and absent perfusion (10–0%), respectively. Multiple prognostic studies show that a normal perfusion study carries a very low risk of major cardiac events (less than 1% per annum) for up to five years. The current Group 2 licensing threshold of more than 2% would correspond to moderate ischaemia in about one of nine, or two of seventeen segments, or involvement of about 10% of the left ventricle.

Intervention for minor degrees of ischaemia, below this 10% limit, appears to have no effect on outcome, whereas revascularisation in patients with greater amounts of ischaemia reduces events compared with medical therapy. The selection of this 10% limit would, therefore, be an additional and useful cut-off to indicate patients at low risk.

6.3 Cost-effectiveness and service provision

The direct cost of MPS per patient is approximately £300, assuming a high throughput of 3,000 patients per annum. It rises to approximately £500 per patient for a lower throughput of around 1,000 patients per annum. Private-sector prices are higher: £500–850 per patient. Although these costs are higher than those of an exercise ECG (which is around £70 per patient), they compare favourably with those for coronary angiography (£1,100 per patient). Moreover, MPS is highly cost-effective, providing a 33% saving over two years compared with other techniques when CAD was absent (Underwood *et al.*, 1999) and was recently approved by the National Institute for Clinical Excellence (NICE) for the diagnosis and management of angina and myocardial infarction.

6.4 Conclusion

MPS is a widely available, simple, robust and stable technology with accepted and validated procedures. MPS is effective for the diagnosis, management and prognosis of patients with CAD, and provides a cost-effective method for assessing ischaemia in applicants for Group 2 licensing.

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7 Myocardial perfusion scintigraphy for risk stratification

Mark Harbinson

There is much to recommend the use of myocardial perfusion scintigraphy (MPS) to determine prognosis in ischaemic heart disease (IHD). Left ventricular function and perfusion data are the strongest predictors of IHD events. Perfusion data alone predict myocardial infarction, acute coronary syndrome and death. These data are at least as good as angiography in predicting prognosis. MPS using Single Photon Emission Computed Tomography (SPECT) is the most researched and best validated prognostic test for IHD, and gated MPS scans allow accurate measurement of left ventricular ejection fraction in a single test.

7.1 Prognostic markers

The prognostic markers used in MPS are the extent, depth and distribution of inducible perfusion defects, lung uptake of tracer, stress-induced chamber dilatation and left ventricular function parameters. A 'normal' SPECT carries a benign prognosis with an average event rate of 0.7% per annum. The average event rate is only slightly worse (0.8% per annum) in individuals with normal SPECT scans but with known or suspected IHD. Conversely, a significantly abnormal scan is associated with a subsequent annual event rate of 5.5%.

The combination of both the severity and extent of ischaemia to stratify event rates provides a highly powerful prognostic indicator. For example, among 5,183 patients (with and without coronary artery disease (CAD)) followed up for 642 days, the MPS scan strongly predicted the rate of both death and myocardial infarction among those receiving medical treatment alone (Hachamovitch *et al.*, 1998). In another clinical series, of 10,627 patients undergoing SPECT and followed for a mean of 1.9 years, the mortality increased with the per cent of ischaemia in those receiving medical therapy. The mortality in the revascularisation group was lower for patients with moderate or severe ischaemia but not for those with mild ischaemia (Hachamovitch *et al.*, 2003). This study showed that while there was no benefit from revascularisation in low-risk groups, revascularisation is helpful when the ischaemic burden is greater than 10%.

The identification and measurement of ischaemia does not provide all the information needed for accurate prognosis. Ejection fraction and cardiac volumes, obtained from electrocardiogram (ECG) gated data, are also important. For example, mortality increases with left ventricular end-diastolic volume, reduced left ventricular ejection fraction, and increased left ventricular end-systolic volume.

Although gating mainly allows mortality prediction, it also improves study accuracy by providing the simultaneous assessment of regional and global function.

7.2 Implications for licensing

Measures showing reduced left ventricular function predict death, and reversible defects predict both death and myocardial infarction. Prognosis worsens with the number, extent, and depth of defects. However, an individual interpretation is required to take account of all the available data. A normal SPECT, on the other hand, has a very low event rate regardless of pre-test predictions.

There is an interaction between ischaemia and ventricular function, and they should be viewed in light of each other. Studies have shown that if left ventricular function is normal – which should be the case for Group 2 licence holders – then the degree of ischaemia becomes the dominant marker for prognosis. In the context of licensing, an event rate of less than 2% per year can be anticipated if less than 10% of the left ventricular mass shows ischaemia.

Research shows that invasive treatment (coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI)) does not seem to reduce the risk in patients with less than 10% of the ventricle ischaemic, but does have an effect on prognosis in patients with more extensive ischaemia (Hachamovitch *et al.*, 2003). While the data are retrospective, these findings give support to the 10% threshold argument. On the other hand, if the left ventricular function is abnormal, then the event rate is high even if there is very little ischaemia. Patients with abnormal left ventricular function should be excluded automatically from holding a Group 2 licence; however, left ventricular function may not always be measured routinely. There is, therefore, an argument for ECG gating all studies, as left ventricular function is then obtained routinely.

For the purposes of licensing risk assessment, it should be noted that left ventricular ejection fraction and end-systolic volume mainly predict death: an ejection fraction below 45% and an end-systolic volume greater than 70 ml are associated with an adverse mortality. Conversely, ischaemia greater than 10% mainly predicts myocardial infarction. MPS findings suggest, therefore, that for an individual to have an annual risk of major events of less than 2%, he or she should have normal ventricular function and a burden of ischaemia of moderate depth involving no more than 10% of the left ventricular mass.

7.3 Panel discussion

Although MPS is an accurate technique, service provision is patchy and different units use different isotopes; gating cannot be used with thallium, for example, which limits its general applicability. Nevertheless, prognostic data are available for all the

available tracers and all produce equally valid results. However, reporting is variable and efforts are in hand to address issues of quality control.

According to one recently published study, MPS activity in the UK remains low, and ‘tends to be provided as a low volume service with unacceptably long waiting times and a lack of involvement by cardiologists’ (Kelion *et al.*, 2005). The finding is based on a postal questionnaire of 207 nuclear medicine departments in the UK carried out in 2000 (61% response). Just over half (52%) of departments performed MPS. The median number of studies performed was 256, with an estimated rate of 1,200 per million population.

Approximately 80 facilities in the UK could offer MPS but only about 20 of these are doing enough scans to ensure a sufficiently high standard for licensing purposes.

In the meantime, the panel agreed that the Driver and Vehicle Licensing Agency (DVLA) should specify the protocol and (as Civil Aviation Authority (CAA) practice) continue referring equivocal cases to the Secretary of State for Transport’s Honorary Medical Advisory Panel for further assessment. It was also suggested that facilities interested in carrying out MPS for licensing purposes could submit tenders to the DVLA, in which they would have to detail costs and provide evidence of competence. It was clear, however, that MPS is not suitable for use as a first-line test, and should be reserved for individuals with equivocal or abnormal exercise ECGs and those who are unable to undertake exercise ECGs.

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8 WHAT DOES STRESS ECHOCARDIOGRAPHY TELL US ABOUT THE PROBABILITY OF A FUTURE CARDIAC EVENT?

Denis Pellerin

There are several reasons to support the use of stress echocardiography as a prognostic tool for licensing purposes. Stress echocardiography has a strong clinical evidence base – controlled trials involving more than 30,000 patients have been carried out – while the recent and considerable advances in image acquisition and quality have addressed earlier problems with the technique. Advances in analysis and interpretation, including side-by-side digital display, the introduction of standard interpretative criteria and the possibility of quantitative analysis, have all enhanced the utility of stress echo as a prognostic tool (Hoffman *et al.*, 2002; Pellerin and Brecker, 2002).

8.1 Pre-test likelihood of coronary artery disease

The pre-test likelihood of coronary artery disease (CAD) depends on several factors, including age, sex, the presence of angina or diabetes, a history of coronary events and the presence of heart failure (Pryor *et al.*, 1983; Diamond *et al.*, 1979). Stress testing with imaging is most appropriate for individuals with intermediate cardiac risk factors according to current guidelines (Eagle *et al.*, 1996). Drivers with intermediate cardiac risk factors are also those whose Group 2 entitlement is most likely to need further investigation.

8.2 Protocols

Although there are a number of different stress echocardiography protocols, the most frequently used are the exercise stress echocardiography using treadmill, bicycle or supine bicycle and, for those who cannot exercise maximally, the dobutamine stress echo. A full echocardiographic study is performed before the stress test, including assessment of global and regional left ventricular function, diastolic left ventricular function, detection of valve disease and pericardial effusion. Five views are recorded at each stage and records are taken of the heart rate and blood pressure response, exercise duration and any ST-segment depression. New or worsening regional wall motion abnormalities are identified and characterised, and mitral regurgitation at rest and peak stress is documented. A semi-quantitative analysis using conventional echocardiography allows calculation of the regional wall motion score index based on endocardial motion and wall thickening. In addition to conventional exercise treadmill test parameters, stress echocardiography data include the detection of myocardial ischaemia, the extent of ischaemia and the coronary artery territory involved.

8.3 Outcome

Several studies have shown a benign outcome after a normal stress echocardiography, with an annual mortality of less than 1% (McCully *et al.*, 1998; Marwick *et al.*, 2001; Elhendy *et al.*, 2001; Sicari *et al.*, 2003). The outcome of 1,325, 5,375 and 7,333 patients referred for stress echocardiography has been reported with a follow-up of 3, 10 and 16 years, respectively. Annual mortality was 0.9%, less than 1% and 0.7%, respectively, in these three cohorts of patients. Moreover, in two head-to-head studies comparing stress echo and stress myocardial perfusion studies, the outcomes for normal scans were identical (Geleijnse *et al.*, 1997; Olmos *et al.*, 1998). Conversely, a positive stress echogram carries a 10–30% risk of a future spontaneous or perioperative event. It also adds incrementally and independently to the information available from clinical data and left ventricular ejection fraction at rest (Marwick *et al.*, 2001).

The extent of stress echocardiography abnormalities (normal, single-vessel disease and multi-vessel disease) can be used to sub-stratify the risk of patients identified as intermediate risk by the Duke Treadmill Score (DTS) (Marwick *et al.*, 2001; Marwick *et al.*, 2003) and to predict future mortality (Marwick *et al.*, 2001). Differences in event-free survival at three years were markedly smaller among patients who were risk-stratified by the DTS than among patients who were risk-stratified by exercise stress echocardiography. In a report of 5,798 patients, there were no significant differences in the ability of stress echocardiography to predict outcome between males and females, although cardiac events occurred more frequently in men. In patients with diabetes, the extent of myocardial ischaemia detected by stress echocardiography is associated with increasing cardiac events and reduced survival at five years (Elhendy *et al.*, 2001). Although diabetic patients with a negative scan have a very low risk initially, this begins to increase after three years of follow-up, indicating the need for repeat tests at this interval. The detection of silent ischaemia should be performed in asymptomatic patients with diabetes if they are older than 60 years, have had diagnosed diabetes for more than 10 years, have two other risk factors for CAD, or any complication of diabetes mellitus.

8.4 Outcome after acute myocardial infarction and revascularisation

Stress echocardiography can also predict the recovery of function after acute myocardial infarction by discriminating between stunned and necrotic myocardium. Stress echocardiography identifies the absence of contractile reserve, which indicates a poor prognosis, and predicts future cardiac events (Carlos *et al.*, 1997). The technique can also predict outcome after revascularisation; there is an 11-fold reduction in mortality in patients who undergo revascularisation following induced ischaemia identified on stress echocardiography (Severi *et al.*, 1994). However, patients who undergo revascularisation following a normal stress echocardiography

do not benefit from the procedure; indeed, a three-fold (albeit non-significant) increase in mortality has been reported in such patients (Picano *et al.*, 1993).

8.5 Risk stratification before major vascular surgery

In a study conducted in eight centres in the Netherlands, Belgium and Italy, risk scores were assigned to patients scheduled for major vascular surgery, of which 27% were receiving beta-blocker therapy (Boersma *et al.*, 2001). Risk scores were assigned by giving one point for each of several characteristics, including age, current angina, prior myocardial infarction, congestive heart failure and diabetes. Patients with a score of 0, 1 and 2, and who are treated by beta-blocker therapy, have a low risk (<1%) of perioperative events and do not require any further tests. Patients with a score of 3 or higher should undergo stress echocardiography. Patients with a negative stress echocardiography, and who are treated by beta-blocker therapy, have a risk of 2%. Patients with induced ischaemia in four or fewer myocardial segments, and who are treated with beta-blocker therapy, have a risk of 2.8%. Patients with a positive stress echocardiographic study in more than four segments should undergo a coronary angiogram as the occurrence of cardiac complications is high, 33–36%, and could not be reduced by beta-blocker therapy. This group of patients would benefit from coronary revascularisation.

8.6 Cost-effectiveness of strategies based on exercise echocardiography and exercise electrocardiogram

In a recent analysis of 7,656 patients, exercise ECG identified more patients as low risk and fewer as intermediate and high-risk than exercise echocardiography (Marwick *et al.*, 2003). Exercise echocardiography was associated with a greater incremental life expectancy and a lower use of additional diagnostic procedures than exercise ECG, especially in low-risk patients. Finally, using decision analysis, exercise echocardiography was found to be more cost-effective than exercise ECG.

8.7 Advantages and limitations

The prognostic content of stress echocardiography – in terms of event-free survival – is similar to that of myocardial perfusion study using thallium Single Photon Emission Computed Tomography (SPECT). Moreover, most of the disadvantages of stress echocardiography, such as its operator dependence, need for specific training and the problems due to the translational and rotational movement of the heart in the chest, apply to all imaging techniques. In addition, many of these drawbacks have been addressed in the past five years, leading to an improvement in the accuracy and prognostic value of recent imaging modalities. Furthermore, recent ultrasound imaging modalities, including contrast echocardiography, tissue Doppler and deformation imaging, have reduced observer variability. Stress echocardiography is less expensive, the test duration is markedly shorter, and there is no radiation. In

addition, stress echocardiography enables the detection of valve disease and pericardial effusion as well as left ventricular cavity size and function. The total cost is reduced even further as the majority of patients have an echocardiogram at rest as part of the diagnostic evaluation, which is part of the stress echocardiogram study.

8.8 Indications for stress echocardiography in the evaluation of entitlement for a Group 2 driving licence

Individuals for whom stress echocardiography could provide additional prognostic information include those who:

- have a suspicious false-positive exercise-tolerance test;
- have poor functional capacity (exercise capability below 4 METs);
- are unable to exercise;
- have ECG abnormalities at rest;
- have hypertensive heart disease;
- have suffered a myocardial infarction;
- are female;
- are asymptomatic males with three or more risk factors for CAD; and
- are asymptomatic patients with diabetes and:
 - are older than 60 years;
 - have had diagnosed diabetes for more than 10 years;
 - have two other risk factors for CAD; and
 - have any complication of diabetes.

8.9 Conclusion

Although prognostic information derived from stress echocardiography is similar to that obtained from myocardial perfusion study, few units can offer both. Thus, the best imaging modality is that for which there is local expertise.

8.10 Panel discussion

It was emphasised that, when patients are able to exercise maximally, they should undergo exercise rather than dobutamine stress echocardiography (DSE). However, most individuals prefer the latter because it requires less effort. It was also noted that the cost of stress echocardiography is approximately £100–200 lower than for scintigraphy. Stress echocardiography is available in approximately 40 hospitals in the UK. The technique is not equipment-dependent and the only limiting factor is the training and expertise of the operator. There was a suggestion that stress echocardiography might be better than myocardial perfusion study in complicated

cases as stress echocardiography has markedly better spatial resolution and enables an independent assessment of coronary artery territories.

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9 CAN WE USE CORONARY ANGIOGRAPHY TO PREDICT EVENTS?

David Smith

9.1 Inherent problems of the technique

Coronary arteries follow a tortuous course that changes with the beating of the heart. X-ray contrast angiography would, on the face of it, appear totally unsuited to their analysis since it produces two-dimensional images of a three-dimensional structure, compresses the data onto a single plane, creates imaging, geometric and motion artefacts, and uses potentially dangerous ionising radiation. Most importantly, the technique produces images of the contrast medium used and not of the walls of the coronary arteries themselves, the morphology only being inferred by the distortion of the contrast. Many of the technical problems have been surmounted with modern X-ray technology using pulsed dosing and digital flat-plate technology, resulting in relatively accurate undistorted images of the luminal column of contrast. These can provide an accurate measure of luminal diameter. Nevertheless, while arterial stenoses can be identified, the technique does not provide analysis of the biochemical constituents or the stability of the atherosclerotic plaque. Instability and the subsequent rupture of the plaque results in acute coronary syndromes, which can be disabling. Contrast angiography seems unsuited to detect these events.

9.2 Experimental alternatives to contrast angiography

A relatively new method that is claimed to predict plaque rupture uses a thermography catheter to detect cellular infiltrates in living atherosclerotic plaques. To achieve this, the method claims to identify increased local temperatures within the plaque, compared with the normal coronary artery (Stefanadis *et al.*, 1999). However, other investigators have failed to reproduce these findings.

Another new, also highly experimental, technique is intravascular elastography/palpography, which uses intravascular ultrasound to detect the density and elasticity of tissue within the arterial wall, translating this into a 'virtual histology' of the atheromatous coronary artery. Other investigators have examined the vulnerability of the coronary artery bed using various markers, including those of inflammation (Buffon *et al.*, 2002), the metabolic syndrome, blood hypercoagulability and platelet activation/aggregation.

9.3 Angiographic prediction of cardiac events

It is often quoted that the degree of stenosis noted on coronary angiography cannot predict cardiac events because most myocardial infarctions are due to subcritical

lesions and most acute coronary syndromes occur at sites of mild stenosis (Ambrose *et al.*, 1988; Little *et al.*, 1988; Giroud *et al.*, 1992; Moise *et al.*, 1984; Webster *et al.*, 1990; Hackett *et al.*, 1989). This seems at odds with other studies that suggest that the more stenosed an artery, the more likely it is to occlude. Alderman and colleagues showed that initial stenosis severity does predict coronary occlusion at five years (Alderman *et al.*, 1993). Research led by Abizaid showed that luminal diameter assessed on intravascular ultrasound (IVUS) predicted adverse cardiac events (Abizaid *et al.*, 1999), and Qiao and colleagues showed that patients dying of acute myocardial infarction had occlusion at the site of severe stenoses (Qiao and Fishbein, 1991).

How are these two views reconciled? The apparent conundrum is explained by the fact that, although there are far fewer severe lesions than there are mild lesions, it is the severe lesions that carry the higher risk of occlusion and thus of adverse coronary events.

Improved predictive power can be achieved by combining angiographic results with clinical predictors, such as smoking and gender (Moise *et al.*, 1984). A study of the morphology of left anterior descending coronary arteries in the Coronary Artery Surgery Study (CASS) registry angiograms revealed various morphological and other variables as predictors of increased risk of infarction. Univariate analysis revealed that luminal roughness and lesion length were highly correlated with the future risk of infarction. Multivariate analysis revealed that stenosis greater than 50%, lesion roughness and smoking were significantly significant predictors of anterior myocardial infarction (Ellis *et al.*, 1989).

Lesion geometry may also be useful. A retrospective analysis was carried out on patients with acute myocardial infarction who had undergone coronary angiography within the preceding 36 months (Ledru *et al.*, 1999). All lesions with a luminal diameter reduction of 10–95% at baseline were studied on subsequent angiograms. Both symmetry index and outflow angles were found to be independent predictors of acute myocardial infarction. Lesions with a luminal diameter reduction of 40–70% were not associated with excess risk from occlusion. Stenosis severity only predicted infarctions occurring within one year after angiography. In moderately severe stenoses (40–70% luminal diameter reduction), symmetry index and outflow angles predicted lesions remaining free of occlusion and infarction at three-year follow-up.

In a study in Minnesota, USA, patients with unstable angina admitted to hospital over a seven-year period, 1985–92, and who underwent early angiography, were stratified into low-, medium- and high-risk groups according to the Agency for Health Care Policy and Research criteria (Mathew *et al.*, 2001). Normal and mild coronary disease (lesions of less than 50% occlusion) correlated significantly with low-risk patients. Significant one-, two- or three-vessel coronary disease (lesions more than 70% stenosis), and left main stem vessel disease, all correlated with high-

risk patients. Moderate coronary disease (50–70% lesions) showed no risk-group correlation.

Combining angiography with the electrocardiogram (ECG) can also improve its predictive power, as shown in a study of acute myocardial infarction survivors followed for 46 months (Puđu *et al.*, 1983). Poor left ventricular function and multi-vessel disease predicted death but a prolonged QT_c predicted the mode of death. In patients with a prolonged QT_c (greater than 440 ms), 61% of subjects suffered a sudden death. Significantly greater than those with QT_c < 440 ms. The authors of a later study, however, concluded that exercise testing, radionuclide angiography and coronary angiography two months after an episode of uncomplicated myocardial infarction do not help to identify patients who will suffer a new coronary event (Fubini *et al.*, 1992). In contrast, the results of a long-term (15-year) prospective study in young myocardial infarction survivors has shown that the time to next event is predicted by the extent of angiographic disease (one, two or three vessels) (Awad-Elkarim *et al.*, 2003). The time to next event is also significantly predicted by exercise duration, with patients who could exercise for 15 minutes or more showing delayed first event compared with patients who could only exercise for less than 15 minutes. Furthermore, medium-term favourable survival was followed by significant deterioration after nine years. These findings support the use of risk stratification, combining angiography with non-invasive testing.

9.4 Conclusions

Coronary angiography identifies the extent and severity of coronary disease. Both increasing extent of disease – one-, two- or three-vessel disease – and increasing severity of lesion stenosis can predict potentially disabling coronary events, but the latter only applies to stenoses of 70% or more.

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10 LICENSING AND THE PREDICTION OF FUTURE CARDIAC EVENTS: LESSONS FROM AVIATION

Michael Joy

10.1 The aviation regulatory environment

The medical standards for aviation are laid down by international statute in Annex 1 (personnel licensing) to the *Convention on International Civil Aviation* (International Civil Aviation Organisation (ICAO), 2001). All nations are signatories to the Convention and are required to maintain or improve the promulgated standards. The standards for cardiology contain fewer than 300 words and are interpreted in the *ICAO Manual of civil aviation medicine* (ICAO, 1985). In 1992, some European nations, as the Joint Aviation Authorities (JAA), converged their interpretation of the ICAO Standard. This process of convergence was permitted by the so-called waiver clause – ‘subject to accredited medical conclusion’ under ICAO 1.2.4.8. This will be replaced by the European Aviation Safety Agency (EASA), the requirements of which will be legally binding. The UK has made a significant contribution to the development of the regulatory process in aviation and operates in an environment in which there is no appeal against the final decision of the Chief Medical Officer. Thus, the UK system is, as far as is possible, non-adversarial.

10.2 The aviation operational environment

In the single-crew environment the mission is critically dependent on the personal performance and the good health of the pilot. Little or no increase in actuarial risk is likely to be tolerable. This implies that the predicted cardiovascular event rate – which reaches 1% per annum (approximately one event per million hours) at age 70 years – is likely to be associated with a similar accident rate in single-crew aircraft. Partly for this reason, public transport operations are not permitted after age 65 years. There is an exponential increase in the likelihood of an accident from cardiovascular cause with increasing pilot age in single-crew operations. In the multi-crew environment, the accident rate due to cardiovascular causes should be of the order of the square of the individual risk, or one accident per 10^{12} hours. This is not achievable in practice.

Routine medical review, including a resting electrocardiogram (ECG), is at a frequency related to age and licence type. It is carried out by an authorised medical examiner. Medical declaration of intercurrent illness is required after 21 days and for any initially disqualifying cause, i.e. myocardial infarction. Recreational pilots may hold a National Private Pilot’s Licence and are assessed by their general practitioner.

10.3 Medical/cardiological contributions to aviation accidents and licence refusal

Human error contributes to 80% of all airline accidents. The accident rate for Class I pilots (flying with a co-pilot) decreases with increasing age and this is a good reason to maintain flying status if possible. A Royal Air Force review of 1,000 fatal aircraft accidents over the period 1957–96 demonstrated that medical cause was implicated in 47 incidents and cardiological cause in 22 (2.2%) (Cullen *et al.*, 1997). This was an eclectic group and included both civil and military aircraft as well as gliders and micro-light aircraft. The different levels of operation are not directly comparable, but four commercial accidents were contributable to cardiovascular cause, three of them single-crew incidents.

Each year between 50 and 60 of the 18,500 UK professional pilot's licences are revoked; fewer than 20 from cardiovascular cause. Neurological/psychological illness comes in second place, overall. There has been a trend towards a reduction in cardiovascular revocation mirroring the decline in circulatory disease in the population as a whole over the past 20 years.

Coronary artery disease (CAD) is the primary cardiovascular cause of refusal of Class I licence renewal. Atrial and ventricular rhythm disturbance, valvular heart disease, cardiomyopathy, the ion channelopathies and cerebrovascular accident/transient ischaemic attack are also encountered. Total cardiovascular mortality, including ischaemic heart disease (IHD) mortality, increases exponentially after about age 50 years and, thus, whilst pilots become safer with age they are more prone to cardiovascular incapacitation. These competing trends need to be taken into account when assessing fitness to fly.

10.4 Methodology of medical regulation

The management and regulation of risk in the aviation industry has been the subject of several UK and European workshops (Joy, 1999), with the publication of more than 100 papers in which the declared objective was to make licence decision-making more precise, objective and fair. CAD was a major focus of these discussions. The methodology of medical regulation is founded on the need to assure public and personal safety, and to determine the **acceptable probability** of an event. It must also protect the rights of the licence holder and be defensible as 'reasonable'. Finally, although no system of mass transportation has to be completely safe – and the controlling legislation does not require it to be so – it must be 'safe enough' (Chaplin, 1988).

10.5 Risk definition and estimation

When estimating risk, 'incapacitation' of the pilot needs definition. Pilot incapacitation is not limited to the total loss of awareness and even if subtle, or partial,

can lead to serious misjudgement, leading to loss of control and a fatal accident. This applies almost exclusively to the single-crew situation and not necessarily to a Group 2 driver who usually has enough warning to pull over. In multi-crew airline operations, pilots are required to be trained for the eventuality of incapacitation of his/her colleague. Nevertheless, whilst safety may be impaired, good training will all but remove the risk of an adverse outcome. The concept of risk needs definition.

The measurements of **absolute risk** require a numerator, a denominator and a time base (Tunstall-Pedoe, 1984). Risk can therefore be expressed as the number of events per 1,000,000 hours, or events per year (or other time interval). It can also be expressed as fatal accidents per 1,000,000 hours. (Given that there are 8,760 hours in a year, a year can be conveniently rounded up to 10,000 hours.) Risk may also be expressed in relative terms by comparing two rates of event. **Relative risk** may identify a safer airline and may help in regulatory decision-making by defining intervention points. The relative risk of cardiovascular event is increased five-fold by the presence of three or more major cardiac risk factors, but only three-fifths of subsequent events will occur in those in the top quintile of risk. Increased relative vascular risk alone should not be employed to deny certification in asymptomatic aircrew. But further investigation may be justified.

The **population-attributable risk** is the increase in risk across a whole population, attributable both to the risk associated with the presence of the factor and also its prevalence. The removal of individuals with relatively high or higher risk is likely to have a smaller effect than might be imagined. If one-third of the population carry a risk factor and an event occurs in one-third of them over a defined period, only one in nine of the whole population will be affected. Removal of the affected population will therefore be costly, unproductive and potentially unsafe.

Hypertension is very common and is the most powerful and prevalent of all the cardiovascular risk factors, apart from age. Both the absolute and relative risk of both systolic and diastolic hypertension increases with age. The risk of sudden cardiac death also increases with age. A study in the Netherlands involving 2,758,000 initially asymptomatic male patients aged 35–65 years found that of the 1% presenting with cardiac symptoms, 13% presented with sudden death, two-fifths each presenting with stable angina or fatal or non-fatal myocardial infarction. Of those who were to die within the first 28 days following their heart attack (about one-third of the total), 50% will do so within the first 15 minutes after experiencing symptoms. In the case of the single-crew pilot, this is very likely to lead to a fatal outcome for those on board.

10.6 Acceptable risk: the ‘1% rule’

The ‘1% rule’ was a statistical attempt nearly 20 years ago to define a cut-off point beyond which the risk of a medical event in a pilot engaged in a multi-crew operation was felt to be excessive. One interpretation is as follows:

In the Western world, both crude mortality and the cardiovascular mortality in a 65–70-year-old man is approximately 1% per annum. As explained above, a 1% risk of an event per annum may be expressed as approximately one event in 1,000,000 hours. Pilot performance may be critical for 10% – and even less now – of a flight of average duration (originally, average flight duration was 60 minutes but this has increased significantly). It has also been demonstrated in simulated flight that there is a 1% chance of an accident in the event of incapacitation during a critical phase of flight. Thus, the chance of an accident due to such an event is:

$$1/10^6 \times 1/10^1 \times 1/10^2 = 1/10^9 \text{ hours}$$

This matches the industry target for an unpredicted fatal catastrophe at 1/1,000,000,000 ($1/10^9$) hours.

A cardiovascular mortality of 1% per annum will carry a co-morbidity of approximately 3–4% in terms of new ischaemic events (angina and non-fatal myocardial infarction), with a 0.5% risk of stroke. Not all events are incapacitating and some of those who die will have been excluded from certification by pre-morbid events. The ‘1% rule’ is therefore composite and relates to predicted events, including mortality, which will increase with age. It factors the removal of those at excess risk of potentially fatal and non-fatal incapacitating events. Recent reconsideration, however, following developments in the diagnosis and management of CAD as well as in the aviation industry, has suggested that a 2% target might be more appropriate (Mitchell and Evans, 2004).

The ‘1% rule’ is best applied to those conditions with the largest datasets, such as CAD, with mortality as a surrogate marker for non-fatal events. It is not easily applicable to capricious conditions with intermittent symptoms, such as atrial fibrillation.

10.7 Class 1/2 certification requirements

A pilot with CAD (following myocardial infarction, coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)) is grounded for six months. To be eligible for recertification, he or she must be asymptomatic and not be receiving anti-anginal medication. An angiogram must be available for staging the disease and exercise to Stage IV of the Bruce protocol must be completed without ECG evidence of myocardial ischaemia. An echocardiogram must show no wall motion abnormality and the ejection fraction must be greater than 50% (using Simpson’s rule). Individuals who have undergone angioplasty must also undergo a stress myocardial perfusion scintigram at six months. This must show no evidence of a reversible defect (and thus myocardial ischaemia). Class I pilots are limited to multi-crew operations and are not permitted to undertake single-crew professional operations.

There are strict angiographic requirements. There must be less than 50% narrowing in any major untreated vessel/bypass graft/stented vessel (excluding the left main stem and left anterior descending vessel, which must be less than 30%), unless infarct related. More than two stenoses of 30–50% are unacceptable. The angiogram must be reviewed by the CAA Medical Advisory Panel in borderline cases and the pilot must undertake reduction of his/her cardiovascular risk profile. Follow-up is annual, with exercise electrocardiography and review at five years – at this time a further MPS scan is needed in those who have undergone PCI, with discretion for others with known coronary syndromes. All the intervention trials have demonstrated that, for patients undergoing CABG or stenting, the mortality/morbidity rate is highest in the first six months and declines thereafter, although in the case of PCI it continues to drift upwards. A pilot's licence cannot be granted or renewed, therefore, for at least six months following such interventions. The delay to re-issuance of a Group 2 driver's licence is at least six weeks and is predicated upon satisfactory exercise ECG performance.

As a concluding point, it should be noted that even in the multi-crew environment – which is inherently safer than the single-pilot situation – a high level of fitness should be demanded and maintained.

10.8 References

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11 DISCUSSION AND CONSENSUS

Having heard the various research reviews, the Expert Workshop participants reconvened to discuss the relevance of currently available tests in the prognosis of cardiovascular event risk and their applicability to Driver and Vehicle Licensing Agency (DVLA) medical standards for Group 2 drivers. The meeting discussed the current risk criteria, possible additional risk factors (such as age and smoking), and drew a consensus on the utility of emerging techniques in licensing decisions, particularly where individuals were unable to complete the exercise tolerance tests. The discussion included a consideration on the suitable time interval between revascularisation procedures and exercise-tolerance tests and the appropriate responses to unsolicited medical reports that conflict with the DVLA test results.

11.1 The role of the exercise-tolerance test

It was agreed by the participants that the exercise-tolerance test should remain the entry point for the investigation of ischaemic heart disease in Group 2 driving licence holders/applicants. However, there was some debate about whether to include individuals at increased risk of coronary artery disease (CAD) who were currently asymptomatic. These would include people aged over 50 years, or who had hypertension or diabetes or who smoked.

It was suggested that once an individual was deemed to be at a greater than 2% annual risk of an event when assessed by recent European Society of Cardiology criteria (Conroy *et al.*, 2003), he or she should immediately be subject to the same testing algorithm as those with established CAD. However, this suggestion ultimately was rejected because of the potentially large numbers needing assessment to prevent only a small number of accidents. It is estimated that of the 250,000 accidents notified annually in the UK, only 250 are due to medical causes, of which only 25 to 75 are due to cardiac events (and most of these occur in Group 1 rather than Group 2 drivers). Furthermore, a significant proportion of the cardiac events in at-risk, but currently asymptomatic, individuals are neither sudden nor disabling and are, therefore, of less relevance to road safety. It was also argued that including asymptomatic people in the testing algorithm would increase the numbers requiring further investigation.

The discussion raised the question about the need for an exercise electrocardiogram (ECG) at the five-year review. However, it was stated that this might reveal abnormalities requiring further medical testing – again, an impractical proposition given the large numbers involved. It was also agreed to maintain the current nine-minute/10.5 metabolic equivalents (METs) exercise-tolerance test rather than changing to symptom-limited testing, as used by the Civil Aviation Authority (CAA).

If the nine-minute treadmill test cannot be achieved for any reason – or is equivocal – then a functional test will be needed that includes a measurement of the left ventricular ejection fraction (LVEF). The LVEF is of major prognostic importance in people unable to complete the standard protocol (particularly people who have failed an exercise-tolerance test, for example, because of dyspnoea). Thus for individuals unable to complete Stage III of the Bruce Protocol, either stress echocardiography or myocardial perfusion scintigraphy (MPS) would be an appropriate alternative. Both techniques allow measurement of the ejection fraction and procedure guidelines are already available for MPS to ensure adequate standards.

11.2 Conduct and reporting of exercise-tolerance tests

Participants noted that some consultants appeared to terminate the exercise-tolerance test too early, having assumed that the individual had been adequately stressed and that heart rate measurements indicated that to continue would be unsafe. This approach is adequate diagnostically but not prognostically. Nevertheless, the existing guidelines to technicians conducting unsupervised tests state that the heart rate must not exceed 85% of the predicted maximum. Although, a consultant should ideally be present – in which case, greater stress could be allowed – in practice, this may not always happen. The panel noted, therefore, that consultants should be advised that if the full nine minutes is not completed then other investigations (MPS or stress echo) might be required unless the failure clearly reflects a cardiac cause.

Failure to complete an exercise-tolerance test can lead to other issues, not all of which are directly related to licensing. An applicant who is referred for, but fails to complete, an exercise test – for example because of claudication (leg pain on exercise) – might not be under the care of a cardiologist and there may be no recorded suspicion of CAD. In such cases, the clinician supervising the test should advise the patient and his/her GP that further investigation is merited. Other problematic cases were discussed that illustrated the need, when reporting the results, for consultants to distinguish between diagnostic and prognostic information. This highlights the need for the DVLA to specify its requirements in more detail.

11.3 Assessment following coronary artery bypass graft or percutaneous coronary intervention

Concern was expressed about the utility of exercise testing following revascularisation procedures. American Heart Association guidelines (Gibbons *et al.*, 2002) suggest that it is not particularly useful to undergo exercise testing within two years of the procedure, but this is based on diagnostic rather than prognostic considerations. It was suggested that while revascularisation did not invalidate

exercise testing, a six-week postoperative test was too early and a three-month wait might be more appropriate. There was, however, some controversy over the time interval and whether or not different criteria should be applied depending on the nature of the medical intervention.

Some participants felt that the current six-week delay was adequate in all cases, while others wished to distinguish between coronary artery bypass graft (CABG) – for which they said a delay of three months would be appropriate – and percutaneous coronary intervention (PCI), where a six-week interval would be sufficient. Conversely, it was pointed out that the event rate was higher after PCI than it was after CABG, supporting the argument for a longer time interval after PCI than after CABG. Practically, however, applicants are likely to seek relicensing earlier after PCI than CABG and so a three-month delay for the latter was unlikely to be problematic.

Doubt was also expressed about whether exercise testing is useful after CABG, even three months postoperatively. Although small studies have shown that exercise test results provide useful prognostic information after CABG, others have shown rapid graft occlusion after the procedure, albeit at a much lower rate than after angioplasty. One suggestion was that the frequency of retesting should be increased after about six years and then again after 10 years. This might apply to approximately one-third of the 8,000 cases reviewed annually by the DVLA (although, in terms of event rate, it is not possible to distinguish between individuals who have had CABG and those who have had other procedures). There is also evidence that more frequent testing might be needed earlier since the mortality rate following these procedures begins to increase considerably after three to four years (Myers *et al.*, 2002).

Participants were unable to agree absolutely on whether or not the delay before exercise testing should be longer for CABG than for other coronary revascularisation procedures; however, a common position was found. Some participants continued to feel that the interval should be longer after CABG because of the difficulty in analysing the results – mainly because, after the procedure, ECG changes are unrelated to ischaemia and ST changes and pain are absent. Other participants suggested that to change the current rules might confuse licence applicants and be difficult to justify in terms of the low absolute number of events in these individuals. Additionally, there is no alternative to exercise testing in this population because the numbers involved prohibit the use of MPS or stress echo. However, some Workshop members noted that the costs of stress echo and exercise testing were similar and either would be cheaper than one MPS study. If the stress echo result were positive, then the licence would be refused and the DVLA would incur no additional expense (if the applicant wished to undergo further testing at a later date, then it would be at his or her own expense). A particular advantage of these second-line tests is that they allow measurement of ejection fraction and so can also confirm or exclude

ventricular dysfunction in individuals who have failed to complete the exercise test because of dyspnoea.

Finally, it was agreed to leave the current six-week interval unchanged for PCI but to extend it to three months for CABG. It was suggested that testing for both CABG and PCI patients should be repeated at three and six years, and thereafter at yearly intervals.

11.4 Age as a disbaring condition

There was a short discussion amongst participants about whether licences should be withheld automatically from Group 2 licence holders or applicants older than 70 years, regardless of a negative CAD history. It was emphasised, however, that although this approach could be defended, it might also constitute unfair discrimination on grounds of age and so could be challenged in the UK courts. In addition, there are a large number of Group 2 drivers in this category: approximately 2,000 bus licences are held by individuals over the age of 75 years. It was suggested that elderly, yet apparently healthy, drivers might be required to undergo an exercise-tolerance test.

A paper by Tauqir Goraya and colleagues (Goraya *et al.*, 2000) provides some useful information on the prognostic value of treadmill exercise testing in elderly patients. The research established that workload remains the most important variable, with prognostic effect of the same magnitude in both elderly (65 years and over) and younger people. The ability to complete 85% of predicted exercise capacity for age without chest pain predicted a cardiac-event-free survival of about 92% to 93% at five years in patients aged 65 years or over.

11.5 Conflicting unsolicited reports

The Workshop considered how the DVLA should address unsolicited medical reports that conflicted with its own test reports. Examples have included a favourable thallium scan used to counter an unfavourable exercise test, or vice versa. Currently, the thallium scan would take precedence, but the question was raised as to whether a marginal pass on an exercise-tolerance test would pose a more difficult dilemma where there was an abnormal coronary angiogram. Participants agreed that this would depend on the angiogram itself: a 70% diameter stenosis would indicate clearly an unfavourable prognosis, and an angiogram showing minimal distal disease would overrule a marginal exercise test with minimal ST depression. However, angiography had been omitted from the DVLA's algorithm (Appendix 3) for equivocal exercise test results because it is regarded as an investigation and not a functional assessment.

A problem is created where some drivers or applicants with equivocal exercise test results, who have not undergone unsolicited tests, may be at a disadvantage compared with those with identical exercise test results but who have had additional

tests and submitted the results to the DVLA. It was agreed that individuals with an equivocal exercise test and no additional unsolicited investigations should undergo further testing using either MPS or stress echo.

11.6 Diabetes and dialysis

Group 2 drivers with diabetes or who are undergoing dialysis might require more frequent exercise testing because of their increased risk of cardiovascular events. There was no further discussion on these issues.

11.7 Risk factor management

In line with the guidelines for sleep apnoea and diabetes, advice about risk factor management might be added to the *At a Glance Guide to the Current Medical Standards of Fitness to Drive* (DVLA, 2005) for ischaemic heart disease.

11.8 References

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12 KEY RECOMMENDATIONS

- The Expert Workshop discussed the relevance of currently available tests in the prognosis of cardiovascular event risk and their applicability to Driver and Vehicle Licensing Agency (DVLA) medical standards for Group 2 drivers.
- It discussed current risk criteria, possible additional risk factors – for example, age and smoking – and drew a consensus on the utility of emerging techniques in licensing decisions, particularly where individuals are unable to complete exercise tolerance tests.
- The exercise-tolerance test should remain the entry point for the investigation of ischaemic heart disease in Group 2 driving licence holders/applicants.
- The Expert Workshop rejected a suggestion to test, in addition to those with established coronary artery disease (CAD), all **asymptomatic** individuals deemed to be at a greater than 2% annual risk of a cardiovascular event – huge numbers of tests would be required to prevent very few accidents.
- It was also agreed to maintain the current nine-minute/10.5 metabolic equivalents (METs) exercise-tolerance test rather than changing to symptom-limited testing.
- Where individuals are unable to complete the standard nine-minute treadmill test, for whatever reason – or where the test is equivocal – either stress echocardiography or myocardial perfusion scintigraphy (MPS) would be appropriate alternatives.
- Existing guidelines to technicians conducting unsupervised tests state that the heart rate must not exceed 85% of the predicted maximum. On occasions where consultants are not present during the test, they should be advised that if the full nine minutes are not completed then other investigations (e.g. MPS or stress echo) might be required unless the failure clearly reflects a cardiac cause.
- When reporting the results, consultants should distinguish between diagnostic and prognostic information.
- American Heart Association guidelines suggest that exercise testing is not particularly valuable within two years of a revascularisation procedure, but this is based on diagnostic rather than prognostic considerations. Revascularisation does not invalidate exercise testing for licensing purposes, but should not be conducted until three months after a coronary artery bypass unchanged graft. The current six-week interval for percutaneous coronary intervention does not need to be changed.
- The Expert Workshop rejected a suggestion to withhold Group 2 licences automatically from holders or applicants aged older than 70 years, regardless of a negative CAD history.

- The Expert Workshop advised that where DVLA receives unsolicited medical reports to counteract unfavourable decisions based on DVLA tests, the DVLA would need to be consider the quality of the evidence – a favourable thallium scan would take precedence over an exercise test, but a marginal pass on an exercise-tolerance test would pose more of a dilemma if there was an abnormal coronary angiogram.
- Drivers or applicants with equivocal exercise test results, but who have not undergone unsolicited tests, could be at a disadvantage compared with others who have had additional tests and submitted the results to the DVLA. In order to counteract this disadvantage, such drivers should undergo further testing using either MPS or stress echo.
- The Expert Workshop suggested that advice about risk factor management be added to the *At a Glance Guide to the Current Medical Standards of Fitness to Drive* for ischaemic heart disease.

13 GLOSSARY

Angiography (coronary angiography) is performed to detect obstructions in the coronary arteries. It uses a contrast material or dye introduced into the heart or arteries supplying the heart by a catheter inserted into a blood vessel. The contrast material is detected by X-ray imaging. The images are called angiograms.

Bruce exercise ECG test – a standard procedure with a range of cardiovascular purposes, including the diagnosis of angina, risk stratification of Myocardial infarction, evaluation of exercise tolerance and cardiac function, assessing the treatment of arrhythmia, and the physical assessment of people in safety critical jobs. The individual uses an exercise treadmill while connected to an electrocardiogram (ECG) machine and, in the Standard Bruce Protocol, undergoes up to seven three-minute exercise stages. The Driver and Vehicle Licensing Agency (DVLA) test for Group 2 drivers considered at risk of a cardiovascular event requires completion of stage III of the Bruce Protocol, which equates to an exercise level of 10.5 **metabolic equivalents (METs)** off cardioactive medication.

Cardiovascular event rate – the likelihood of a cardiovascular event occurring at some point over a 12-month period, expressed as a per cent per annum. A high risk is defined as a recurrent cardiovascular event rate of 2% or more per annum; a low risk is defined as an annual event rate of less than 2%. The 2% cut-off is the established level of acceptable risk per annum for a cardiovascular event while driving used by the DVLA in setting its medical standards for Group 2 drivers.

Duke Treadmill Score – a quantitative expression of cardiac risk derived from the exercise ECG. The score incorporates **ST depression** and time on the treadmill.

ECG-gating – technique whereby the ECG wave is split into 16 or 32 frames per R-R interval. At the end of the scan there may be more than 1,000 heartbeats' worth of information accumulated into one simulated heartbeat/cycle. This sequence is then viewed to assess heart wall motion. Regions of interest are then drawn around the heart in diastole and systole. The difference between the two stages provides the ejection fraction.

Echocardiography uses ultrasound to produce images of the heart, with the 'echoes' converted into visual images on a video monitor.

Functional capacity – variously defined as an individual's capacity to perform daily activities and, more specifically, as the capacity to sustain performance in response to broadly defined aerobic work demands. Functional capacity is typically expressed in METs.

Metabolic equivalent (MET) – a measure of the level of exercise. One MET is

equivalent to the energy expended at rest, or 3.5 ml O₂ per kg body mass per minute. One MET is equivalent to getting dressed and walking around the house; 4 METs is equivalent to light housework or climbing the stairs; and 10 METs is equivalent to heavy labour or playing strenuous sport, such as football. Anyone unable to meet 4 METs during normal daily activities is considered to have poor functional capacity and is at increased cardiovascular risk.

Myocardial perfusion scintigraphy (MPS) – uses radioactive tracers, such as thallium-201 or technetium-99m MIBI or tetrofosmin, to image a combination of myocardial perfusion and viability. It requires the intravenous injection of small amounts of the tracer at rest and during exercise (a standard exercise ECG test is used, with the tracer injected at peak exercise). The tracer accumulates into viable myocardium in proportion to perfusion and its distribution within the myocardium is detected using a gamma camera (**Single Photon Emission Computed Tomography (SPECT)** imaging is the most common). The stress and rest studies therefore show myocardial perfusion at rest and during stress; a stress defect that improves at rest indicates stress-induced perfusion abnormality while a fixed defect in stress and rest images indicates infarction. Cardiovascular stress can also be induced pharmacologically (for example using adenosine or dobutamine). Myocardial perfusion scintigraphy (MPS) is particularly useful in the diagnosis and management of angina and myocardial infarction.

QT interval – a measure of the time between the start of the Q wave and the end of the T wave in the ECG. It represents the total duration of electrical activity of the ventricles.

Single Photon Emission Computed Tomography (SPECT) – is a nuclear medicine acquisition technique used to generate three-dimensional images of radioactive tracer activity (tracers include technetium-99m and thallium-201). SPECT can be used to image myocardial perfusion and viability, and is the common method of image acquisition in **MPS**.

ST segment (or S-T segment) – is a defined part of an ECG trace that follows immediately after the QRS complex and merges into the T wave.

ST-segment depression – a drop in the ST segment of the ECG that can be indicative of, among others, myocardial ischaemia, myocardial infarction, ventricular hypertrophy and left bundle branch block. The shape of the ECG curve is used in the diagnosis.

Stress echocardiography uses standard **echocardiography** to record images of the heart before and after exercise. Exercise can be mimicked by injecting dobutamine to increase the heart rate and workload. The technique is used to monitor for reduced blood flow to the heart – and, therefore, whether the heart is receiving sufficient oxygen during exercise.

APPENDIX 1

DVLA Position Paper on ischaemic heart disease and driving in the context of licensing

Dr H. G. Major

Background

The Driver and Vehicle Licensing Agency (DVLA) is an Executive Agency of the Department for Transport (DfT). One of its core functions is the promotion of road safety. In this, the Drivers Medical Group (DMG) contributes significantly by the application of the medical licensing regulations and standards, the purpose of which is to minimise the foreseeable excess risk of road accidents attributable to a medical condition in the driver.

There are some 16 medical advisers in DMG supported by about 300 clerical staff. Together they handle over 500,000 medical cases annually across a range of medical conditions. The group works closely with policy colleagues and with the DfT research department in support of an active programme of research into various aspects of medical fitness to drive. This Workshop forms part of that programme of studies.

DMG also has close association with the Secretary of State's six expert Medical Advisory Panels and for which its medical advisers provide the secretariat support. The Panels (focusing on alcohol and drug misuse, psychiatry, cardiology, vision, diabetes and neurology) are chaired by subject experts, with between six and twelve expert clinical members and two lay members each. The Panels advise the DVLA on the appropriate medical licensing standards based on available medical evidence and the perception of the risk to road safety. The standards are published in the *At a Glance Guide to the Current Medical Standards of Fitness to Drive*, available on the DVLA website (www.dvla.gov.uk – a copy of the relevant chapter is reproduced in Appendix 2).

Legislative framework

Medical licensing policy in the UK is underpinned by EC and national legislation, principally the second EC Directive on driver licensing, the Road Traffic Act 1988 and the Motor Vehicle (Driving Licences) Regulations 1999. These define the concept of prescribed, relevant and prospective disabilities, and define the different driver licensing categories: Group 1 or ordinary car licence; Group 2, including buses (categories D/D1); and lorries (categories C/C1). Higher medical licensing standards apply to Group 2 drivers because of the 'vocational' element of their work and the concomitant increased potential risks to road safety. These include: high

mileage, working long hours, shift work, scheduling demands, the size and weight of the vehicles, the carriage of potentially toxic or inflammable loads and, with buses, the number of passengers carried.

In addition to licensing regulations, other important legislation includes the Human Rights Act 1998 and the Disability Discrimination Act 1995. These must be borne in mind when setting the standards to ensure an equitable balance is achieved between an individual's right to drive and public road safety. Such a balance must be particularly well evidenced in sensitive areas, such as older drivers or those for whom driving is a basis for employment. In this context, and fundamental to the Workshop, the licensing standards for lorry and bus drivers with cardiac conditions are relevant.

Concept of risk

In viewing risk, the concept of 'significant excess risk' applies. For medical conditions in which the risk of impairment is from sudden and disabling collapse, actuarial figures may be available and may be helpful in assessment of that risk relevant to driving. Other types of impairment contribute to driving risk in different ways, for example:

- progressive cognitive impairment, as in dementia;
- fluctuating impairment, as in multiple sclerosis;
- intermittent impairment, for example insulin-treated diabetes; and
- static impairment, for example limb loss.

As the major risk in cardiac conditions is of a sudden and disabling event (sudden death, myocardial infarction, acute coronary syndrome, dysrhythmia), an 'actuarial' approach is generally appropriate. For licensing purposes, acceptable event rates of less than 2% per annum apply for vocational (Group 2) drivers and less than 20% per annum for Group 1 drivers have been agreed. The figures are derived from actuarial data on epilepsy recurrence risks and have been extrapolated to apply to cardiac mortality data.

This Workshop aims to evaluate the currently available **assessment tools** (exercise-tolerance test, myocardial perfusion scintigraphy (MPS), angiograms, etc.) to determine the most accurate and reliable prognostic indicators of high (at least 2% per annum recurrent cardiovascular event rate) or low (below 2% per annum event rate) for those Group 2 drivers with a history or evidence of established cardiovascular disease.

The debate continues on the methodologies of risk measurement and whether, for example, an assessment of absolute risk, residual risk, lifetime or 10-year risk, etc., is most appropriate. An understanding of whether that risk increases or decreases

with time is also necessary, as this may well vary between conditions and between different types of impairment. The modification of risk factors may also be possible in some circumstances. These factors will need to be considered by the Workshop in understanding and evaluating the cited evidence.

Current method of assessing ischaemic heart disease by the DVLA

Medical case enquiries within the DVLA are commenced on receipt of information from the Group 2 driver or licence applicant that he or she may have a relevant medical condition. The patient's (driver's) consent is obtained in order to permit access to their medical records to confirm the history which may be of angina, myocardial infarction, acute coronary syndrome, of symptomatic peripheral arterial disease, or of other vascular event, for example stroke. (In the latter case, an assessment of full neurological recovery is first required before any cardiac assessment is considered.)

The recommended procedure is then for all such Group 2 drivers to undertake an exercise-tolerance test using the standard Bruce protocol (detailed in Appendix 3) as the basic assessment tool to evaluate their ability to meet the Group 2 licensing standard. Currently, some 8,000 plus exercise tests are arranged by the DVLA annually, the cost of which, at about £300 each, falls to the Agency. A majority of drivers can be assessed as fit or unfit to hold Group 2 entitlement on this basis.

For a steadily increasing proportion of drivers, however, the outcome is equivocal either because of difficulties in interpretation of the tracing, for example left bundle branch block (LBBB), or because of the patient's inability to complete nine minutes on the treadmill. A number of different factors may be responsible for this, including general levels of unfitness and limb disability which limits walking or dyspnoea caused by chronic obstructive pulmonary disease (COPD); excessive weight precluding the use of the treadmill is an occasional cause.

Until recently, such patients may have undergone **coronary angiography** – if also clinically indicated – or attempts were made to use **Duke's Treadmill Score**. (Angiography has never been commissioned by the Agency but results have sometimes been submitted as evidence of a favourable prognosis in an individual case, where there have been adverse or equivocal exercise test results.) However, uncertainty over the comparable predictive values of the different techniques persisted and, latterly, some form of **MPS** is recommended as an alternative indicator of functional cardiac performance. Last year over 100 MPS scans were requested by the DVLA at costs varying between £200 and £1,000 each. There is, as yet, no agreed DVLA preferred protocol, and assessments have included gated and ungated scans, those using thallium or technetium, and those using different pharmacological stimuli. As the licensing demands increase so the need for

standardisation and consistency becomes an increasingly urgent imperative to allow us to compare the predictive values of the most cost-effective scintigraphy method against those of exercise testing.

Benefits and disadvantages of current assessment tools for licensing purposes

Exercise test

- **Benefits:** widely available, relatively cheap and generally few(er) delays in obtaining appointments. It is generally reproducible and has good face validity for the licence holder. Belief that meeting the current criteria (nine minutes of the standard Bruce Protocol, symptom free with less than 2 mm ST-segment depression, etc.) equates to less than 2% per annum risk of cardiac event.
- **Disadvantages:** may be difficult to interpret the tracing in, for example, those with baseline changes or with LBBB. Mobility problems, severe weight problems, respiratory disease may be limiting. 'False-positives' and 'false-negative' results occur.

Myocardial perfusion scintigraphy

- **Benefits:** may be more accurate in predicting prognosis; overcome mobility problems.
- **Disadvantages:** expensive, less readily available with less standardisation of methodology and reporting protocols; significant waiting list in some areas; suggestion of increased patient risk from radiation effect (?) and still some false-positive results.

Other tools

Coronary Angiography is invasive with an associated, albeit small, mortality risk. It is not, therefore requested de novo by the DVLA. It is also expensive and limited in availability to specialist cardiac centres. It is not a test of function and there are uncertainties how the total distribution and load of atheroma compare with functional assessments of risk. Newer concepts of 'the vulnerable plaque' and new intravascular ultrasound techniques may advance this understanding in the future.

Stress echocardiograms – the Agency has little experience of this technique but understands it to be generally cheaper than myoview scans. We are not familiar with its prognostic value.

Summary

The DVLA assesses over 8,000 bus and lorry drivers annually who have a history of established ischaemic cardiovascular disease. Increasing numbers of drivers require a prognostic risk assessment other than that offered by the standard treadmill exercise-tolerance test. Whilst proposing to continue using the exercise test as the screening tool of choice, we need to identify the most cost-effective and robust method as a safe and reliable alternative. The Cardiac Panel and the Agency are anxious to reach a consensus view on the prognostic value of the tools currently available in mainstream cardiological practice based on sound, referenced evidence.

APPENDIX 2

Cardiovascular disorders – current medical standards on fitness to drive

Reproduced from Chapter 2 of the *At a Glance Guide to the Current Medical Standards of Fitness to Drive*, Swansea: DVLA, February 2005. © Crown copyright.

NB A Left Ventricular Ejection Fraction of < 0.4 is considered a bar to Group 2 Entitlement.

	GROUP 1 ENTITLEMENT ODL - CAR, M/CYCLE	GROUP 2 ENTITLEMENT VOC – LGV/PCV
ANGINA	<p>Driving must cease when symptoms occur at rest or at the wheel.</p> <p>Driving may recommence when satisfactory symptom control is achieved.</p> <p>DVLA need not be notified.</p>	<p>Refusal or revocation with continuing symptoms (treated and/or untreated)</p> <p>Re-licensing may be permitted when free from angina for at least 6/52, provided that the exercise/functional test requirements can be met and there is no other disqualifying condition</p>
ANGIOPLASTY (elective)	<p>Driving must cease for at least 1/52.</p> <p>Driving may recommence thereafter provided there is no other disqualifying condition.</p> <p>DVLA need not be notified.</p>	<p>Disqualifies from driving for at least 6/52.</p> <p>Re/licensing may be permitted thereafter provided that the exercise/functional test requirements can be met and there is no other disqualifying condition.</p>
CABG	<p>Driving must cease for at least 4/52.</p> <p>Driving may recommence thereafter provided there is no other disqualifying condition.</p> <p>DVLA need not be notified.</p>	<p>Disqualifies from driving for at least 3 months.</p> <p>Re/licensing may be permitted thereafter provided that the exercise/functional test requirements can be met on a test carried out no sooner than 3 months post operatively and there is no other disqualifying condition. In addition the LVEF must be equal to or exceed 40%.</p>
LEFT VENTRICULAR ASSIST DEVICES	<p>DVLA should be notified.</p> <p>Driving should cease on insertion. (Re-) licensing will be considered on an individual basis 6 months after insertion.</p>	<p>Permanently bars</p>

<p>ACUTE CORONARY SYNDROMES (ACS) including MYOCARDIAL INFARCTION</p>	<p>ACS is defined for Group 1 licence holders to include only those with the presence of ALL of the following criteria:</p> <ul style="list-style-type: none"> ● Persistent or recurrent cardiac pain ● Cardiac troponin release positive ● Electrocardiographic changes <p>After MI, driving must cease for at least 4 weeks. Driving may recommence thereafter providing there is no other disqualifying condition.</p> <p>After a non ST elevation MI, driving may recommence 1 week after successful angioplasty, if there is no other disqualifying condition.</p> <p>DVLA need not be notified.</p>	<p>ACS is defined for Group 2 licence holders to include all acute coronary syndromes. These are all considered relevant and disqualify from driving for at least 6 weeks.</p> <p>Re/licensing may be permitted thereafter provided that the exercise/functional test requirements can be met and there is no other disqualifying condition.</p>
<p>CAROTID ARTERY STENOSIS (see also neurological section)</p>	<p>DVLA need not be notified</p>	<p>If the level of stenosis is severe enough to warrant intervention, the exercise/functional test requirement must be met.</p>
<p>PERIPHERAL ARTERIAL DISEASE</p>	<p>Driving may continue unless other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Re/licensing may be permitted provided that:</p> <ul style="list-style-type: none"> ● there is no symptomatic myocardial ischaemia ● the exercise test requirements can be met and <p>When exercise testing cannot be completed to the required level, other functional testing or specialist cardiological opinion may be required.</p>
<p>ASCENDING/ DESCENDING THORACIC and ABDOMINAL AORTIC ANEURYSM</p>	<p>DVLA should be notified of any aneurysm that reaches 6 cm or greater in diameter, despite treatment. Licensing will be permitted subject to annual review.</p> <p>Driving may be continued after satisfactory medical (blood pressure control) or surgical treatment, with no evidence of further enlargement, unless other disqualifying condition.</p> <p>An aortic diameter of 6.5 cm or greater disqualifies from driving</p>	<p>Disqualifies from driving if the aortic diameter is >5.5cm. Driving may continue after satisfactory medical or surgical treatment, unless other disqualifying condition.</p> <p>NB Exercise/functional test requirement will apply for abdominal aortic aneurysm</p>

<p>ARRHYTHMIA Sinoatrial disease Significant atrio-ventricular conduction defect Atrial flutter/fibrillation Narrow or broad complex tachycardia</p> <p>(See also following Sections Pacemakers are considered separately)</p> <p>NB: Transient Arrhythmias occurring during acute coronary syndromes do not require assessment under this Section.</p>	<p>Driving must cease if the arrhythmia has caused or is likely to cause incapacity.</p> <p>Driving may be permitted when underlying cause has been identified and controlled for at least 4/52.</p> <p>DVLA need not be notified unless there are distracting/disabling symptoms.</p>	<p>Disqualifies from driving if the arrhythmia has caused or is likely to cause incapacity.</p> <p>Driving may be permitted when the arrhythmia is controlled for at least 3/12, provided that the LV ejection fraction is satisfactory (ie LVEF is \geq or >0.4), and there is no other disqualifying condition.</p>
<p>PACEMAKER IMPLANT Includes box change</p>	<p>Driving must cease for at least 1/52.</p> <p>Driving may be permitted thereafter provided there is no other disqualifying condition.</p>	<p>Disqualifies from driving for 6/52.</p> <p>Re/licensing may be permitted thereafter provided that there is no other disqualifying condition.</p>
<p>SUCCESSFUL CATHETER ABLATION</p>	<p>Driving must cease for at least 1/52.</p> <p>Driving may be permitted thereafter provided there is no other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from driving for 6/52.</p> <p>Re/licensing may be permitted thereafter provided that there is no other disqualifying condition.</p>
<p>UNPACED CONGENITAL COMPLETE HEART BLOCK</p>	<p>May drive if asymptomatic.</p>	<p>Bars whether symptomatic or asymptomatic.</p>
<p>ATRIAL DEFIBRILLATOR Physician/patient activated</p>	<p>Driving may continue provided there is no other disqualifying condition. See ICD Section</p>	<p>Re/licensing may be permitted provided that the arrhythmia section is met and there is no other disqualifying condition.</p>
<p>ATRIAL DEFIBRILLATOR Automatic</p>	<p>Driving may continue provided there is no other disqualifying condition. See ICD Section</p>	<p>Permanently bars</p>
<p>ECG ABNORMALITY Suspected myocardial infarction</p>	<p>Driving may continue unless other disqualifying condition</p>	<p>Re/licensing may be permitted provided that there is no other disqualifying condition and the functional test requirements can be met</p>
<p>Left Bundle Branch Block</p>	<p>Driving may continue unless other disqualifying condition.</p>	<p>Re/licensing may be permitted provided that there is no other disqualifying condition and the exercise test requirements can be met.</p>
<p>PRE-EXCITATION</p>	<p>Driving may continue unless other disqualifying condition.</p>	<p>May be ignored unless associated with an arrhythmia (See Arrhythmia Section) or other disqualifying condition.</p>

<p>IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) implanted for ventricular arrhythmia which caused incapacity</p>	<p>Patients should notify DVLA following initial ICD implantation and should not drive for:</p> <ol style="list-style-type: none"> 1) A period of 6 months after the first implant 2) A further 6 months after any shock therapy and/or symptomatic antitachycardia pacing (see 3a below). 3) A period of 2 years if any therapy following device implantation has been accompanied by incapacity (whether caused by the device or arrhythmia). <p>3a) If therapy was delivered due to an inappropriate cause, i.e. atrial fibrillation or programming issues, then driving may resume 1 month after this has been completely controlled to the satisfaction of the cardiologist, in which case DVLA will need to be notified.</p> <p>3b) If the incapacitating shock was appropriate (i.e. for sustained VT or VF) and new therapy has been introduced to prevent recurrence, driving may resume after 6 months in the absence of further symptomatic therapy.</p> <p>For 2 and 3 if the patient has been re-licensed prior to the event the DVLA should be notified.</p> <ol style="list-style-type: none"> 4) A period of 1 month off driving must occur following any revision of the electrodes or alteration of anti-arrhythmic drug treatment. 5) A period of 1 week off driving is required after a defibrillator box change. <p>Resumption of driving requires that;</p> <ol style="list-style-type: none"> 1) The device is subject to regular review with interrogation. 2) There is no other disqualifying condition. 	<p>Permanently bars</p>
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<p>IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) implanted for ventricular arrhythmia which did not cause incapacity</p>	<p>If the patient presents with a non-disqualifying cardiac event, i.e. haemodynamically stable non-ncapacitating ventricular tachycardia, the patient can drive after one month if all of the conditions below are met and DVLA need not be notified.</p> <p>1) LVEF greater than 35%</p> <p>2) No fast VT induced on electrophysiological study (RR<250 msec)</p> <p>3) Any induced VT could be pace-terminated by the ICD twice, without acceleration, during the post implanation study.</p> <p>If all these criteria cannot be met then these patients cannot drive for 6 months and DVLA needs to be notified.</p> <p>In addition, should the ICD subsequently deliver ATP and/or shock therapy (except during normal clinical testing) then the usual criteria apply and DVLA should be notified</p>	<p>Permanently bars</p>
<p>PROPHYLACTIC ICD IMPLANT</p>	<p>Asymptomatic individuals with high risk of significant arrhythmia.</p> <p>One month off driving. DVLA need not be notified.</p> <p>However, should the ICD subsequently deliver ATP and/or shock therapy (except during normal clinical testing) then the usual criteria apply and DVLA should be notified.</p>	<p>Permanently bars</p>
<p>ARRHYTHMOGENIC RIGHT VENTRICULAR DYSPLASIA (ARVD) AND ALLIED DISORDERS</p> <p>(See also arrhythmia, pacemaker and ICD sections)</p>	<p>Asymptomatic - Driving may continue.</p> <p>DVLA need not be notified.</p>	<p>Asymptomatic - Driving must cease but may be permitted following Specialist electrophysiological assessment provided that there is no other disqualifying condition.</p>
	<p>Symptomatic - Driving must cease if an arrhythmia has caused or is likely to cause incapacity. Re/licensing may be permitted when arrhythmia is controlled and there is no other disqualifying condition.</p>	<p>Symptomatic - permanently bars</p>

<p>SYNCOPE</p> <p>NB Cough Syncope see Chapter 7</p>	<p>See section entitled "Loss of Consciousness" (Chapter 1)</p>	<p>See section entitled "Loss of Consciousness" (Chapter 1)</p>
<p>HYPERTENSION</p>	<p>Driving may continue unless treatment causes unacceptable side effects.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from driving if resting BP consistently 180 mm Hg systolic or more and/or 100 mm Hg diastolic or more.</p> <p>Re/licensing may be permitted when controlled provided that treatment does not cause side effects which may interfere with driving.</p>
<p>CHRONIC AORTIC DISSECTION</p>	<p>Driving may continue after satisfactory medical (blood pressure control) or surgical treatment, unless other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Re/licensing may be permitted if ALL of the following apply:</p> <ul style="list-style-type: none"> • maximum transverse diameter of the aorta, including false lumen/thrombosed segment, does not exceed 5.5cm • there is complete thrombosis of the false lumen • BP is well controlled* <p>NOTE "well controlled" refers to clinical, NOT DVLA, standard of control.</p>
<p>MARFAN'S SYNDROME</p>	<p>DVLA need not be notified unless there is aneurysm q.v.</p>	<p>Re/licensing permitted subject to: the requirements for aneurysm being met (q.v.) satisfactory medical treatment annual cardiac review to include aortic root measurement NOTE that aortic root replacement will debar.</p>
<p>HYPERTROPHIC (OBSTRUCTIVE) HARDIOMYOPATHY (H.(O)C.M) (See also arrhythmia, pacemaker and ICD sections)</p>	<p>Driving may continue provided no other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from driving if symptomatic.</p> <p>Re/licensing may be permitted if no more than one of the following criteria are not met and there is no other disqualifying condition.</p> <ol style="list-style-type: none"> 1) There is no family history of sudden premature death from presumed HCM. 2) The cardiologist can confirm that the HCM is anatomically mild. 3) No serious abnormality of heart rhythm has been demonstrated i.e. ventricular tachy-arrhythmia excluding isolated ventricular pre excitation beats. 4) Hypotension does not occur during the completion of 9 minutes of exercise testing.

<p>DILATED CARDIOMYOPATHY</p> <p>(See also arrhythmia, pacemaker, I.C.D and heart failure sections)</p>	<p>Driving may continue provided no other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from driving if symptomatic.</p> <p>Re/licensing may be permitted provided that there is no other disqualifying condition.</p>
<p>HEART OR HEART LUNG TRANSPLANT</p>	<p>Driving may continue provided no other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from driving if symptomatic.</p> <p>Re/licensing may be permitted provided that the exercise/functional test requirement can be met, the LV function remains good (ie LVEF is = or >0.4) and there is no other disqualifying condition.</p>
<p>HEART VALVE DISEASE (to include surgery, ie replacement and/or repair)</p>	<p>Driving may continue provided no other disqualifying condition.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from Driving:</p> <p>1) whilst symptomatic. 2) For 12 months after cerebral embolism following which Specialist assessment is required to determine licensing fitness.</p> <p>Re/licensing may be permitted provided that there is no other disqualifying condition.</p>
<p>HEART FAILURE</p>	<p>Driving may continue provided there are no symptoms that may distract the driver's attention.</p> <p>DVLA need not be notified</p>	<p>Disqualifies from driving if symptomatic.</p> <p>Re/licensing may be permitted provided that the LV ejection fraction is good (ie LVEF is =or >0.4), the exercise/functional test requirements can be met and there is no other disqualifying condition.</p>
<p>CONGENITAL HEART DISEASE</p>	<p>Driving may continue provided there is no other disqualifying condition. On first application/identification report of a recent (within 2 years) examination/assessment by an appropriate consultant may be required before a licence is issued.</p> <p>Certain conditions will require the issue of a medical review licence for 1, 2 or 3 years.</p>	<p>Disqualifies from driving when complex or severe disorder(s) is(are) present.</p> <p>On first application/identification a recent examination /assessment by an appropriate consultant will be required before a licence is issued. Those with minor disease and others who have had successful repair of defects or relief of valvular problems, fistulae etc may be licensed provided that there is no other disqualifying condition.</p> <p>Certain conditions will require the issue of a medical review licence for 1, 2 or 3 years.</p>

APPENDIX

(A) - Group 1 And 2 Entitlements

MEDICATION

If drug treatment for any cardiovascular condition is required, any adverse effect which may affect driver performance will disqualify.

(B) - GROUP 2 ENTITLEMENT ONLY

ISCHAEMIC HEART DISEASE etc.

LICENCE DURATION

An applicant or driver who has, after cardiac assessment, been permitted to hold either LGV or PCV licence will usually be issued with a short term licence (maximum duration 3 years) renewable on receipt of satisfactory medical reports.

EXERCISE TESTING

NB A Left Ventricular Ejection Fraction of < 0.4 is considered a bar to Group 2 Entitlement.

Exercise evaluation shall be performed on a bicycle* or treadmill. Drivers should be able to complete 3 stages of the Bruce protocol or equivalent safely, without anti-anginal** medication for 48 hours and should remain free from signs of cardiovascular dysfunction, viz. angina pectoris, syncope, hypotension, sustained ventricular tachycardia, and/or electrocardiographic ST segment shift which accredited medical opinion interprets as being indicative of myocardial ischaemia (usually $>2\text{mm}$ horizontal or down-sloping) during exercise or the recovery period. In the presence of established coronary heart disease exercise evaluation shall be required at regular intervals not to exceed 3 years.

Any of these medicines which are prescribed specifically for the control of hypertension If the cause of the chest pain is in doubt, an exercise test should be carried out as above. Those with a locomotor disorder who cannot comply will require perfusion scan/stress echocardiography or specialist cardiologist opinion.

* cycling for ten minutes with 20 watt increments/minute to a total of 200W

** Anti-anginal medication refers to the use of nitrates, B-blockers, Nicorandil and calcium antagonists, prescribed for anti-anginal purposes or for other reasons such as cardio-protection.

STRESS MYOCARDIAL PERFUSION SCANNING/STRESS ECHOCARDIOGRAPHY

The standard requires that no more than 10% of the myocardium is affected by reversible ischaemic change AND in addition the LVEF must be demonstrated to be 40% or greater.

Please note that the same requirements for the cessation of anti-anginal medication apply.

CORONARY ANGIOGRAPHY

The functional implication of coronary heart disease is considered to be more predictive for licensing purposes than the anatomical findings. For this reason the Exercise Tolerance Test and, where necessary, the stress myocardial perfusion scan, are the investigations of relevance for licensing purposes and it is the normal requirement that the standard of one or other of these must be met. Angiography is therefore not commissioned for (re-) licensing purposes. Where there remains conflict between the outcome of a functional test and the results of any recent angiography that may have been submitted, cases can be considered individually. However, (re-) licensing will not normally be considered unless the coronary angiograms are unobstructed and the left ventricular ejection fraction is = or > than 40% or greater.

‘Predictive’ refers to the risk of an infarct within 1 year. Grafts are assumed to be included as ‘coronary arteries’.

APPENDIX 3

Investigation of ischaemic heart disease – algorithm

