# BASIC RESEARCH FOR CLINICIANS

# An Introduction to Evidence-Based Practice for Cardiologists: Finding, Utilising and Planning to Conduct Research to Inform Practice

Carole Fogg, MSc, Donah Zachariah, MBBS, MRCP, Christian Markham, PhD, Heather MacKenzie, PhD, Rebecca Stores, PhD, Paul R Kalra, MD, *Portsmouth, Hampshire, UK* 

#### ABSTRACT

This article introduces the concept of evidence-based practice (EBP), with a focus on cardiology. It describes some of the components of EBP, including literature search and review, and how these also relate to establishing an original research question. (J Clin Prev Cardiol 2012;1(3):144-51)

Key Words: Evidence-based practice, research question, literature review, critical appraisal.

# What is Evidence Based Practice and Why is it Important?

Evidence based practice (EBP) was first described in 1996 in an editorial as 'the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients, integrating individual clinical expertise with the best available external clinical evidence from systematic research' (1). A more recent definition highlights the limitations of availability of research in some areas, and also the important role of the patient in decisions about their own care, describing EBP as 'an approach to decision making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits the patient best' (2). In lay terms, it is the use of best research evidence to treat patients; taking into account their own preferences, values and expectations, as well as practitioner expertise (Figure 1).

Corresponding Author: Carole Fogg, MSc. School of Health Science and Social Work, University of Portsmouth, Queen Alexandra Hospital, Cosham, Portsmouth Hospitals NHS Trust, Portsmouth, Hampshire, UK

Email: Carole.Fogg@port.ac.uk



Figure 1. EBP Venn Diagram

The use of previous experiences in patient management goes back in history, but perhaps the most pertinent hint of evidence based practice as it is known today was a retrospective study by Dr. Pierre Louis in 1836 that showed the practice of bloodletting hastened death (3). Illness in those times was thought to be a consequence of contamination, and opening a vein and letting the toxin run out was believed to be an effective remedy (even George Washington was a victim to this and apparently had 2.4 litres of blood drained from him a few hours before his demise) (4). This conclusion was based on data analysis from large numbers of patients and undoubtedly sent shock waves across the medical community. It was nevertheless instrumental in sounding the death knell to this practice.

The dramatic reductions in cardiovascular deaths by the end of the 20th century and the greater than 50%

From: School of Health Science and Social Work, University of Portsmouth, Portsmouth, Hampshire, UK, (C.F., C.M., H.M., R.S.), Queen Alexandra Hospital, Cosham, Portsmouth Hospitals NHS Trust, Portsmouth, Hampshire, UK (C.F., D.Z., P.R.K.)

reduction in age-adjusted mortality from coronary artery disease in the Western world alone in the last two decades (5) are ample proof of the impact of evidence based therapies. From the use of aspirin and statins post-myocardial infarction to the use of angiotensin converting enzyme inhibitors and beta blockers in heart failure, almost every therapy in cardiology is supported by a large evidence base. This is mainly driven by large scale randomized double blind multi-centre trials, often recruiting many thousands of patients. Treatments offered may involve medical therapy, interventional procedures or a combination. State of the art technologies involving percutaneous coronary angioplasty, pacemaker and defibrillator implantation and intra-cardiac ablations of arrhythmias have all seen phenomenal developments in the last decade and modalities such as rotablation, laser, 3D and cryo technology are now available to make these treatments even more effective. None of these services are by any means inexpensive and in addition to equipment costs require specialised personnel training and an amalgamation of several services to allow for smooth delivery of care. It is imperative that each new technology is subject to robust evaluation prior to wide scale introduction into clinical practice.

This availability of a strong armamentarium of investigational and interventional tools can potentially complicate decision making and therefore makes it a necessity for the cardiologist to have a good knowledge of the existing evidence base. With widespread access to the Cochrane library, various medical search engines and the internet in general, EBP is becoming increasingly integral to daily patient care.

EBP is as important to the patient as it is to the clinician. It helps patients make informed decisions, quantifies risks of procedures and treatments and predicts outcomes based on previous studies. It identifies the gaps in knowledge and helps direct new research towards filling these. It is an essential tool in health economics and defines the cost effectiveness of treatments available.

However, there remains a disparity in practice across the world between 'what we know' and 'what we do'. The reasons for these are multifactorial and range from poor accessibility to the knowledge base, differences in attitudes (including an unshakable belief that an individual's practice is always correct), and absence of clear recommendations to disparities in health care funding and delivery across the world. The aim of this paper is to instil in the reader the need to seek out what evidence is available to improve day to day patient care as well as create a yearning to contribute to the existing gaps in our vast knowledge base with some initial guidance towards this goal.

# Why and How Do We Generate Evidence?

Evidence is the reason we have for believing; it is the justification we give for our actions (6) and in the case of applied healthcare, it is the body of facts and experiences available to clinicians during the decision making process. Healthcare decisions have impact at the level of the individual, group and society and consequently some commentators argue that, at the very least, there is a moral obligation on clinicians and healthcare workers to utilise the best available evidence in their decisions (7). Evidence comes in numerous forms, each with different contributions to healthcare decision making and therefore an understanding of its nature can help establish which pieces of evidence should influence a decision.

Personal experience is a form of evidence, but as psychologists have shown, experiences are biased according to subjective interpretations and therefore do not always form the best justification for pursuing an action or decision (8). In the case of healthcare decisions, such as those involving very complex or rare cases, experience may be all that is available. However, in many cases other forms of evidence are available, and clinical experience can be much enhanced and challenged by research evidence. Evidence derived from research provides justifications based on systematic observations and evaluations (9). Depending on the type of research design, these observations and subsequent analysis will be subjective or objective, but they should still be more systematic, representative and valid than individual experience alone.

The need for evidence can arise in different situations, for example:

- In clinical scenarios that are complex and involve challenges beyond the scope of routine daily practice
- Giving patients reliable, individualised information regarding the disease prognosis or clarifying the relative risks and benefits of proposed treatments

- Financial justification for the implementation of new therapies/ technology in the health care setting
- Service development with a view to improving current practice based on new research evidence available
- Self advancement in an area of special interest

Whatever the impetus for requiring evidence, once the need to gather evidence has been identified, a clinical question needs to be formulated, which can also be modified into a research question if adequate evidence cannot be found. Question formulation can take time, and if the question is intended to be a topic for original research, careful consideration is required to settle upon what is realistic with the resources available and whether additional funding is required. Note that questions regarding common, expensive to treat conditions which are associated with a high morbidity or mortality are those most likely to be of interest to funders, either to perform a systematic review of existing evidence, or to investigate the question through a well-defined research project.

The initial steps of the EBP cycle are also important in preparing a potential research project, and there are some key processes that a practitioner should be familiar with. We will now describe some of the key steps in the EBP cycle and how they relate to preparing for research (Figure 2).

### Formulating an Answerable Question

A vital stage in the evidence gathering process therefore is to invest time at the outset formulating a clear and answerable clinical question. It is important to be clear



Figure 2. EBP Cycle

in your own mind what question you are intending your research findings to answer. In addition, having a clear question will help you search for previous research efficiently and effectively to discover what work has already been done in your chosen area.

It is useful to first consider what type of question you are asking. This will help to decide what research design and techniques you should make use of. The most common types of research question are: effectiveness questions (which usually evaluate methods of treatment); causal (which determine the cause of a disease or condition); incidence or prevalence (which determine population incidence or prevalence of a disease or characteristics of a disease); screening (where a specific screening programme is evaluated); diagnostic (where different types of tests are evaluated); prognosis (which estimate the likely progress of a condition); cost effectiveness (where the economics of health care is evaluated) and psychosocial (where knowledge, attitude and behaviour patterns are studied).

The acronym PICO or PECO is often used to highlight the most important aspects of an answerable research question. This helps you break down your question into different components. P stands for 'population', I stands for 'intervention' and E for 'exposure', C for 'comparison' and O for outcome.

Table 1 shows how the following question can be broken down in to the PICO format: "What is the effectiveness of antiplatelet agents compared to anticoagulant therapy on death and/or major thromboembolic events in adults with heart failure who are in sinus rhythm?"

Depending on the topic, it may not always be appropriate to specify an intervention, but population and outcomes can usually be identified. For complex problems, it may be necessary to map out a series of component parts and ask a succession of questions.

For those asking questions about people's experiences, knowledge, attitudes, behaviour or decision making, the following adaptation of the standard PICO format may be more useful. In the adapted PICO (Qualitative) (10), the P stands for people or perspective (for example, in adolescents with congenital heart disease), the I stands for Issue (for example, major depressive symptoms), the C stands for context or setting (for example, attending a local service) and the Outcome for opinions or attitudes (for example, of living with depression).

Research questions take many different forms. It is important to avoid making the question too general, too vague or too ambitious. It should be relevant and

#### Table 1.

Components of a research question.

Component	Key step	Example
Population	How would I precisely describe a group of similar patients?	Adults with heart failure who are in sinus rhythm
Intervention / Exposure The test, treatment, process of care, service, environmental agent or other exposure	<ul><li>I = What is the main action (intervention) I am considering?</li><li>E = Exposure occurs when the patient comes into contact with something and it is usually naturally occurring</li></ul>	Antiplatelet agents
Comparison or alternative	What is/are the other options?	Anticoagulant therapy
Outcome What do I/the patients want or not want to happen?		Effectiveness (measured by death and/or thromboembolic events).

built on what research has already been conducted. Most research projects have modest aims and are not earth shattering in nature but contribute valuable information to what is already known on a particular topic.

### Searching for Available Evidence Relating to the Question

Once the clinical question has been defined it is important to search the existing evidence to ensure this area of research has not already been evaluated in precisely the same format, or is not ongoing. Reviewing existing evidence can also provide a perspective on the scale of the problem in question, as well as identify what is known on the topic and enable you to identify the 'gap' in current knowledge. A thorough literature review will also give an idea of the type of research methods used in similar research, for example the research design and commonly used outcome measures, as well as some of the limitations identified by the authors, which may help in the planning of your research.

Relevant information can come in many formats – there are many thousands of journal publications each year, in addition to guidelines, reports, theses and monographs which may be less publicly available. Journal publications may be restricted by subscription, but international initiatives exist to promote wider access – for example the World Health Organisation HINARI partnership with major publishers enables institutions in more than 100 developing countries, areas and territories to gain access to one of the world's largest collections of biomedical and health literature (http://www.who.int/hinari/en/). With so much data available it may be difficult to know where to start.

Searching for systematic reviews in the chosen area is a good starting point; if there have been several studies on the topic of interest these may have already been located, reviewed and summarised. The Cochrane Library (11) allows the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effects (DARE) to be searched. These reviews often provide recommendations for future research and may help in adapting the research question.

If there are no systematic reviews available, or the reviews are inconclusive, a search for randomised controlled trials and/or other study designs is a sensible next step. This can be done using a large medical referencing database such as MEDLINE, EMBASE (which has more pharmacology-related and European journals) (12), or CINAHL, which has a focus on nursing and allied health studies. The TRIP database is an alternative clinical search tool which incorporates primary research, systematic reviews and guidelines, and is designed to allow health professionals to rapidly identify the highest quality clinical evidence for clinical practice TRIP (http://www.tripdatabase.com/). Each search engine has specific instructions on how to search. Generally, the research question can be used to identify key words from the population, intervention or outcome which can be combined to generate more relevant results.

Indexed articles include descriptive terms which describe the PICO components, known as Medical Subject Headings (MESH) in MEDLINE and Subjects (SU) in EMBASE –can assist in keeping a consistent search between databases, and permits a clear description of the search methodology in the literature review. Use of truncation symbols and wildcards to aid your search will be explained on the website, for example hypotens\* will search for both terms 'hypotension' and 'hypotensive', or 'o?dema' to search for both 'oedema' and 'odema'. In addition, using Boolean operators (AND, OR and NOT) to combine key words and synonyms into a search strategy can be useful to increase the specificity of the search (12). For example, 'hypotension' OR 'hypotensive' would retrieve articles with either term; 'obesity' AND ('heart failure' OR 'oedema') enables you to combine both diagnoses and symptoms of a condition in the same population. Literature searching is a skill which requires practice, and library services staff should be able to assist.

Using the example given in Table 1, you might construct a search as follows:

Searching is an iterative process; you may need to broaden or narrow your search strategy depending upon how many search results your draft search strategy returns. In areas which have been very widely researched, a broad search strategy may return an unmanageable number of articles. Conversely, in those not widely researched, a narrow search strategy may not adequately capture the literature.

If the literature search reveals that there are no studies which address the clinical question, then consider checking trial registries. Useful websites include Trials Central (Trials Central) http://www.trialscentral. org/, the EU Clinical Trials Register https://www. clinicaltrialsregister.eu/, the World Health Organisation (WHO) clinical trials registry platform http://www. who.int/ictrp/en/ and the US National Institute of Health http://clinicaltrials.gov/ If a trial is registered it may

#### Table 2.

Example of relating a question to a search strategy.

Search 1	Population	Adults with heart failure who are in sinus rhythm	Identify synonyms (also consider using wildcards/truncation and, if they exist, appropriate MeSH terms) for the following terms (i) adults (ii) heart failure and (iii) sinus rhythm, and combine as follows: (adults OR synonym 1 OR synonym 2) AND (heart failure OR synonym 1) AND (sinus rhythm OR synonym 1)
Search 2	Intervention / Exposure	Antiplatelet agents	Identify synonyms (also consider using wildcards/truncation and, if they exist, appropriate MeSH terms) for 'antiplatelet agents'
Search 3 (optional depending on how many search results you obtain)	Comparison or alternative	Anticoagulant therapy	Identify synonyms (also consider using wildcards/truncation and, if they exist, appropriate MeSH terms) for 'anticoagulant therapy'
Search 4 (again optional, as this may be too specific)	Outcome	Death and/or thromboembolic events	Identify synonyms (also consider using wildcards/truncation and, if they exist, appropriate MeSH terms) for 'death' and 'thromboembolic events' combined as follows: (death OR synonym 1 OR synonym 2) OR (thromboembolic events OR synonym 1)
Combine all searches as follows: Search 1 AND Search 2 AND Search 3 AND Search 4			

be that the researchers have published their protocols– the International committee of medical journal editors (ICJME) encourages authors to publish their research protocols to: facilitate transparency in enabling readers to compare what was originally intended with what was actually done, enable systematic reviewers to identify potential publication bias, and enable funders and researchers to see which studies are underway and hence reduce duplication of research effort (13).

## Critically Appraise the Evidence for its Validity, Impact and Applicability

After retrieving relevant literature, the next step is to ascertain whether the results and conclusions of these articles are valid and useful. This can be done by using a structured approach to critique the methodology and assess the risk of bias and the potential roles of chance and confounding in affecting their study results. This would also build a better understanding and justification of the research approach in question. Useful advice on how to critique literature is given by the Critical Appraisal Skills Programme, which provides useful tools aimed at critiquing all types of research, from qualitative to quantitative frameworks (14), and the British Medical Journal series on how to read a paper (15).

Each type of study design requires a different approach to critical appraisal (16). Appraisal of all studies, however, has some common features. The description of the sampling of participants and their characteristics should be clearly described to enable clinicians to assess the generalisability of the study results in relation to their clinical population of interest. For example, a study of the risk factors for myocardial infarction which excludes diabetic patients will give very different results to one which is inclusive. The study design chosen should be appropriate for the hypothesis or research question asked. For example, a research question aimed at exploring the barriers to adherence of statins in an elderly population may require a mixed-methods approach to gain both qualitative data from the patients to understand why they may not take the medicines in the way in which they have been prescribed, in addition to numerical (quantitative) outcomes measuring doses administered and/or changes in lipid profiles. The data collected should be relevant to the research question and the study design selected. For example, a safety study looking at the cardiac risk of a new anti-diabetic drug should be focused on ascertainment of cardiac events in a large population, rather than the reported effectiveness of the medication. The risk of introducing bias into the study for example at participant selection, data collection and analysis stage – should be addressed in the study design, and the discussion should highlight any limitations of the study due to bias. For example, collection of blood pressure measurements in a trial of a new antihypertensive by practitioners who have knowledge of which treatment the patient is on constitutes unblinded outcome data collection, and this could lead to observer bias - i.e. systematically higher or lower values recorded according to the patients' treatment group.

Critical appraisal can be time consuming to begin with, but once familiarity with the terminology and key characteristics of different study designs has been established, it can be made more fun by sharing the learning journey with a group of colleagues – for example by setting up a journal club. A suggested format would be for the lead appraiser to present approximately 10 slides to describe the basics of the paper, and then highlight key issues for discussion and appraisal. It is important for all members to read the paper before the session, and useful to invite participants of varying backgrounds – for example staff with research interests as well as pure clinicians, different cadres of staff, biomedical scientists and colleagues with some knowledge of statistics.

#### **Research and Audit**

So far we have focussed on the numerous sources of evidence available to inform evidence based decision making, and clinical research has been discussed in some detail. Another area closely allied to research and clinical care is audit. Clinical audits are a systematic approach to monitoring and ultimately improving care provided by a service or individual. They can include a number of methods, depending on the overall aim of the audit, including statistics, organisational and information management (17). What they all involve, though, is a process of identifying a clinical issue, setting a clinical standard and then collecting data on actual events to evaluate if standards are being met. Figure 3 illustrates the principles and process of audit.

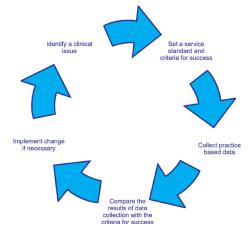


Figure 3. Clinical audit

As illustrated above, clinical audits shed light on the outcomes obtained from using evidence that has been reached by research. Unlike research which generates new knowledge regarding healthcare, clinical audits provide evidence about whether a service is meeting a predetermined criteria and as such are central to Clinical Governance. The UK National Research Ethics Service (NRES) has published useful guidance on distinguishing audit from research (18). Indeed, within the UK, it is mandatory for all Doctors to participate in clinical audits as part of a process of local, regional or national monitoring in order to provide a source of evidence for the effectiveness of care (17).

It may be that from doing a detailed search for the evidence base, the clinician identifies an area that needs further research and feels inclined to pursue this. We shall be discussing the methodical steps involved in conducting research in later articles but for now it is sufficient to understand the distinction between two key research methodologies: qualitative and quantitative. Although both designs involve the systematic collection and analysis of data, qualitative research embraces subjectivity. Qualitative research provides evidence that can be robust and insightful, particularly in situations of new enquiry and where the experience and perception of healthcare and its provision is the area of interest. It seeks to answer questions about the 'what', 'how' or 'why?' of a phenomenon by using appropriate data collection methods such as interviews, observations and group discussions (19). An example is given by the qualitative exploration of patients' understanding of their heart failure and necessary treatments, which can then inform clinicians how to communicate more effectively in order to reduce anxiety and promote greater adherence to treatments (20), whilst exploration of patient preferences can inform health care strategies, for example examining self-care strategies used for sleep by a sample of patients with heart disease identify areas for intervention across the patient group (21), Quantitative designs have grown from a different philosophy and aim to minimise subjectivity and maximise objective evidence. Quantitative studies aim to measure specific quantifiable outcomes in order to describe or compare groups of patients in a numerical manner, often with a form of statistical hypothesis testing. Quantitative research equally provides robust evidence, and is more commonly encountered, because it is the choice of design in epidemiology and medicine, particularly the evaluation of new interventions. Despite these distinctions each design can lead to credible evidence that is of value to patients, clinicians and policy makers alike. Indeed, it is becoming naive to view these two paradigms in isolation because increasingly healthcare research involves combining the methods to complement each other in providing a richer source of evidence for decision makers in their pursuit of healthier and happier patients (22). It is suggested a multimethod approach in cardiovascular research programs will strengthen knowledge development by enhancing understanding of the complex issues related to cardiovascular health and illness for persons and their families (23).

#### Conclusions

In summary, clinical medicine and in particular cardiology is today enriched with a huge evidence base which would answer most clinical questions. A focussed search for the available evidence based on the steps outlined in the preceding paragraphs would often lead to a systematic conclusion that would aid decision making for the individual patient. The application of this evidence, however, needs further analysis of outcomes and adjustment of practice by a reflective practitioner, as per the last two stages of the EBP cycle. It may be pointed out however that occasionally, there may be problems with the applicability of evidence based data to the patient in question. For example, many trials in cardiology have recruited subjects who are much younger, more often male and have few co-morbidities as compared with an unselected cohort of patients with the specific disease. We are increasingly seeing older and frailer patients who do not quite fulfil the inclusion/ exclusion criteria of the relevant study and forming clinical decisions in such patients requires a small leap of faith such that it in reality becomes 'evidence informed practice'. While decisions here would rely perhaps more on clinical expertise and patient choice, it is still heavily guided by what evidence is available and importantly, it highlights the need to generate more evidence. Hence further research ideas are born and the cycle continues.

#### **Acknowedgements**

The authors would like to thank Dr Ann Dewey, Dr Sally Kilburn and Dr Amy Drahota for reviewing this manuscript and useful suggestions.

#### References

- 1. Haynes RB, Sackett DL, Gray JM, Cook DJ, Guyatt GH. Transferring evidence from research into practice: 1. The role of clinical care research evidence in clinical decisions. *ACP J Club* 1996; 125(3): A14-16
- Muir Gray JA. Evidence-based health care: how to make health policy and management decisions. Churchill Livingstone, London; 1997
- Louis PCA. Researches on the effects of blood-letting in some inflammatory diseases, and on the influence of tartarised antimony and vesication in pneumonitis. *Americal Journal of Medical Sciences* 1836; 18: 102-11
- 4. Morens DM. Death of a president NEJM 1999: 341 (24) :1845-9
- Ford ES, Ajani UA, Croft JB, Critchley JA, Labarthe DR, Kottke TE, Giles WH, Capewell S. Explaining the decrease in US deaths from coronary artery disease, 1980-2000. *NEJM* 2007: 356(23):2388-98
- 6. Dawkins, R. The magic of reality. Bantam Press, London; 2011
- Dawes, M., Davies, P., Gray, A., Mant, Jonathan, Sears, K. and Snowball, R. Evidence Based Practice: A primer for Healthcare professionals. Elsevier, Kidlington;2004
- Solms, M. and Turnbull, O. The brain and the inner world: An introduction to the neuroscience of subjective experience. Karnac Books, London; 2002.
- 9. Lindsay, B . Understanding Research and Evidence Based Practice. Reflect Press, Exeter; 2007.
- 10. Aveyard H, Sharp P. A Beginner's Guide to Evidence Based Practice in Health and Social Care. McGraw Hill. 2009
- Cochrane Collaboration (2010) 'The Cochrane Library', [online], available: http://www.thecochranelibrary.com/view/0/index.html [accessed June 2012]
- Moore A, McQuay H. Bandolier's Little Book of Making Sense of the Medical Evidence. Oxford University Press. 2006, pp. 10, 11

- 13. International committee of medical journal editors (ICJME) www. icmje.org Accessed June 2012.
- Solutions for Public Health (2010) 'Critical Appraisal Skills Programme', [online], available: http://www.sph.nhs.uk/what-we-do/public-healthworkforce/resources/critical-appraisals-skills-programme [accessed June 2012]
- British Medical Journal (2011) 'How to Read a Paper', [online], available: http://resources.bmj.com/bmj/readers/how-to-read-a-paper/ [accessed July 2011]
- 16. Heneghan C, Badenoch D. Evidence-based Medicine Toolkit 2nd Edition. Blackwell Publishing, Oxford. 2006
- Scrivener, R., Morrel, C., Baker, R., Redsell, S., Shaw, E., Stevenson, K., Pink, D. and Bromwich N. Principle for best practice in clinical audit (National Institute for Clinical Excellence). Radcliffe Medical Prress, Abingdon; 2002.
- National Research Ethics Service (online): http://www.nres.nhs.uk/ applications/guidance/research-guidance/?entryid62=66984 Accessed June 2012.
- 19. Green J, Thorogood N. Qualitative Methods for Health Research , 2nd Edition. Sage Publications, London. 2009
- Rogers A, Addington-Hall JM, McCoy ASM, Edmonds PM, Abery A, Coats AJS, Simon J, Gibbs R. 2002 A qualitative study of chronic heart failure patients' understanding of their symptoms and drug therapy. *Eur J Heart Fail* 2002; 4 (3): 283-287
- 21. Johansson A, Karlsson J, Brodje K, Edell-Gustafsson U. Self-care strategies to facilitate sleep in patients with heart disease--a qualitative study. *Int J Nurs Pract.* 2012; Feb;18(1):44-51.
- 22. Bowling, A. Research methods in health. Open University Press, Maidenhead; 2009.
- 23. Young, JE, Jillings CR. Qualitative methods add quality to cardiovascular science. *Can J Cardiol*. 2000; Jun;16(6):793-7.