THE METHODOLOGY OF BLOOD PRESSURE RECORDING

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Introduction

Blood pressure is a continuous physiological variable. The heart beats approximately 110,000 times in 24 h and each beat generates a systolic and a diastolic pressure. While directional changes over each 24 h period can be defined (Millar Craig, Bishop & Raftery, 1978), no two beats generate exactly the same pressures; beat-to-beat pressure variation appears to be a random process influenced by an almost infinite number of variables (Goldberg, 1977). Minute to minute variation also appears to be a random process, with changes in physical activity exerting a strong directional influence. Direct comparability is not seen in pressure samples of less than 3 h and even then underlying circadian rhythms have a pronounced influence. It is plainly inconceivable that any random measurement of blood pressure should be representative of any patient's 'blood pressure'; it cannot represent anything more than the blood pressure generated by the heart of that individual under the prevailing conditions (Figure 1).

It is therefore of paramount importance that the clinical pharmacologist who intends to study the effects of drugs on blood pressure in human subjects should define quite precisely the objects of his investigation before choosing a method of measurement. The methodology required to measure the size of a drug effect on the blood pressure response to severe exercise would not necessarily be suitable for determining the size of an effect on blood pressure during deep sleep.

Most studies of blood pressure are concerned with the effects of drugs on relatively high pressures, as defined by arbitrary clinical criteria (Pickering, 1974). The object of therapy in these patients is to reduce the risk of cardiovascular complications, so it would seem logical to use the same measuring methods as those which were used to define the risks. Unfortunately, in these basic studies (Actuarial Society, 1941; Metropolitan Life Insurance Co., 1961; Kannel & Dawber, 1974), the blood pressure measurements were random one-off events, and the methods used were always indirect and never standardized. It is inconceivable that such a crude measurement could be a sensitive indicator of risk and the only factor which makes such figures reliable is the large numbers of subjects involved. No-one could conceive including such large numbers of subjects in a trial examination of a drug without crippling expense. What methods, therefore, should the clinical pharmacologist use and what are the significant parameters of blood pressure that he should extract from his small numbers of patients? Is average pressure more significant than pulse pressure? Is a measure of variation more important than absolute levels? There are, unfortunately, no ready answers to these questions, but they cannot be ignored.

Available methods

Two methodologies of measurement are available to the investigator; direct and indirect. The direct methods are highly-developed, of known and precise accuracy, and yield large quantities of data; the indirect methods are poorly developed, of dubious accuracy, and yield only small quantities of data. Clearly the direct methods are most suitable for scientific studies of blood pressure and yet they are seldom used. The reason for this is their essentially invasive nature; the incredible naivety displayed by generations of clinical cardiologists in interpreting direct pressure measurements made in patients subjected to cardiac catheterization in specialized laboratories full of strange equipment, and medical personnel in full surgical plumage, has led many scientists to doubt the significance of all invasive measurements. The equipment required has restricted measurement to the laboratory, and long-term studies have been hampered by the fear of serious complications. Fortunately, these objections to the direct methods of recording blood pressure have now been largely overcome, but almost all published studies of the effects of drugs on blood pressure have been performed using one or other of the indirect methods of measurements.

Indirect measurement of blood pressure

All indirect methods are firmly based upon the occluding-cuff technique devised by workers such as Hill & Barnard (1897), Riva–Rocci (1896), and Korotkoff (1905), and which has altered very little since their time. In summary, a cuff containing an inflatable rubber bag is wrapped around the arm. The bag is then inflated by means of a one-way hand pump
until the radial arterial pulse disappears. A valve on the pump is then partially released, and the pressure within the bag allowed to fall. The bag is connected to a mercury-in-glass manometer which expresses the pressure in terms of mm Hg. The pressure corresponding to the first appearance of a pulse in the brachial artery below the cuff (detected by any means) is taken as a measure of the systolic pressure (Figure 2). Korotkoff (1905) detected reappearance of a pulse in the collapsed brachial artery as a succession of sounds accompanying each heart beat and appreciated by means of a stethoscope applied to the artery below the cuff. He defined different kinds of sound appearing as the pressure fell from phase I (initial sound-sharp and of high frequency) to phase IV (disappearance of high frequency leaving only low-frequency noise—'muffling'), and phase V (cessation of noise). Many investigations have been conducted into the genesis of Korotkoff sounds and these were summarized by Burton (1953) as follows:

The walls of the artery below the inflated cuff fall together to form a flat ribbon. As the cuff pressure falls a systolic pulse will eventually succeed in penetrating the length of the cuff, and temporarily distend the artery below. The transverse section of the artery will expand to an ovoid and flow will be highly turbulent, vibrating the tissues around, and then collapsing again (Figure 2). Many comparisons of direct and indirect measurements agree that the first Korotkoff sound (which may be equated with the first appearance of ‘flutter’ in the collapsed arterial wall, detected by any means) is a sensitive indicator of systolic pressure.

As the pressure continues to fall, each successive pulse which penetrates the cuff adds to the volume of blood in the system below, until a point is reached at which the collapsed segment remains distended between beats but flow remains turbulent. In theory the critical opening pressure of the artery has been exceeded in diastole and this must be equal to diastolic blood pressure. The failure to collapse between beats should lead to a loss of high frequency components with the next systolic expansion—thus there is a clear theoretical link between diastolic pressure and phase IV (muffling). As the cuff pressure continues to fall, a point is reached at which the artery remains fully distended, flow becomes laminar, and the succeeding systolic pulse produces no significant vibration of surrounding tissues; the Korotkoff sounds disappear (phase V). There has been considerable controversy over the years about which of these two points should be taken as diastolic pressure—phase IV or phase V—and even official recommendations have been known to differ (Burton, 1967). Physiological studies