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ORIGINAL ARTICLE

End-digit preference in general practice: A comparison of the conventional auscultatory and electronic oscillometric methods

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Abstract

Introduction. In clinical practice, end-digit preference is a common feature of blood pressure (BP) measurements. A wider use of electronic BP measuring machines could decrease this observer-linked artefact. The purpose of this analysis was to investigate the frequency of end-digit preference and to evaluate the impact of this observer bias on the assessment of the BP control induced in a large group of hypertensive patients treated with a calcium-channel blocker in whom BP was measured either with an automatic device or with a conventional sphygmomanometer. *Methods*. Five hundred and four physicians participated in the study and 2199 patients were included. Treatment with lercanidipine was introduced at a dosage of 10 mg and titration to 20 mg was optional according to the physician's decision. BP was assessed at 4 and 8 weeks. To measure BP, physicians could use either a standard mercury sphygmomanometer or a pre-defined validated semi-automatic device (Microlife Average Mode, BP 3AC1-1, Microlife Corporation, Berneck, Switzerland) but they had to use the same method throughout the study. Physicians had to transcribe all BP measurements onto case report forms. *Results*. Very marked digit preferences were observed for both the conventional and the automatic measurements, being most prominent for the digit "0" (52% and 25%, respectively) followed by a preference for the digit "5" (19% and 15%). The use of the semi-automatic device reduces to a certain extent the frequency of the bias but the problem remains if physicians have to transfer the BP values onto case report forms. The end-digit preference has a major impact on the evaluation of a treatment effect and on the assessment of the percentage of patients achieving target BP in a population. *Conclusion*. These results confirm that end-digit preference remains a serious bias in clinical practice. This bias has important consequences when evaluating the efficacy of a new antihypertensive drug. There is a need for training programmes and quality controls in clinical practice. The development of automatic systems with a direct transfer of BP values from the measuring device to the clinical chart or to the case report form should be encouraged.

Key Words: *Calcium antagonists, hypertension, lercanidipine, mercury sphygmomanometer, Microlife*

Introduction

Blood pressure (BP) measurement is one of the most frequent procedures performed in clinical practice. The protocols for measuring BP are well described and standardized (1). However, several artefacts can affect the determination of BP, such as, for example, the cuff size, the position of the arm and body, and the stress linked to the measurement itself (2). One very common cause of inaccuracy of the BP methodology is the observer preference for terminal digits and single numbers. Indeed, terminal digit preference in BP measurement has been reported as a frequent bias in both clinical and research settings (3–7). This observer bias may have a major impact on therapeutic decisions, on the evaluation of therapeutic strategies as well as on hypertension management in populations (4,6,8).

It has been suggested that a wider use of electronic BP measuring machines could decrease this observer-linked artefact and improve BP management in clinical practice (9,10). However, very few studies have investigated this hypothesis in a large population of physicians. The purpose of this analysis was

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to investigate the frequency of end-digit preference and to evaluate the impact of this observer bias on the assessment of the BP control induced by a third-generation calcium-channel blocker in a large group of hypertensive patients treated in general practice (11). According to the protocol, physicians were allowed to use either the conventional method using a mercury sphygmomanometer or a semi-automatic device depending on their preference, but they had to keep to the same method throughout the study period and to transfer the BP data manually on case report forms. Our results demonstrate that in these conditions, digit preference is common with both methods and that it has a major impact on the assessment of BP control in a large group of patients.

Patients and methods

The primary objective of this non-interventional, observational study conducted in general practice in Switzerland was to evaluate the clinical efficacy and safety of lercanidipine as "first-line treatment" in newly diagnosed patients and as "add-on" or "substitution" in patients with insufficient BP control or adverse events. The study design and results on clinical efficacy and safety have been published previously (11).

To measure BP, physicians could use either a standard mercury sphygmomanometer or a defined automatic device but they had to use the same method throughout the study. As a standard semi-automatic device for BP measurement, the Microlife Average Mode (MAM BP 3AC1-1, Microlife Corporation, Berneck, Switzerland) was chosen, since this device was validated according to European Society of Hypertension (12). The MAM device measures the brachial BP by oscillometry. The cuff is inflated automatically by an electric pump system and deflated by an active electronic control valve system. Two sizes of cuffs (standard-sized and large) were offered to ensure an optimal fit. The BP was measured three times and the mean brachial BP, heart rate, time and date were displayed on an LCD display. Data can be stored and printed or transferred to a personal computer via specific software. However, in this investigation the systolic (SBP) and diastolic BP (DBP) values shown on LCD display had to be transcribed by the physician to a paper case report form. Participating physicians filled in a baseline visit case report form for every patient, indicated the BP measurement of their choice, and recorded the SBP and DBP at baseline and after 4 and 8 weeks of treatment.

Data management

Anonymous data were collected by fax transmission, and routine data quality checks were performed prior to entering the data on a SAS database. Digit preference and proportion of patients with "normalized BP" were assessed for all patients who had a baseline and a subsequent documentation. Results were presented for all patients, the two populations "conventional" and "automatic" measurements, as well as for the two subpopulations "non-diabetic patients" and "patients with diabetes".

Definition of therapeutic targets

In order to assess the impact of digit preferences on the percentage of patients with a normalized BP, the two following target limits were defined for the statistical analysis: SBP $\leqslant$ 140 mmHg and DBP $\leqslant$ 90 mmHg vs SBP < 140 mmHg and DBP < 90 mmHg for non-diabetic patients, and SBP $\leqslant$ 130 mmHg and DBP $\leqslant$ 80 mmHg vs SBP < 130 mmHg and DBP < 80 mmHg for diabetic patients. Prior to the study, physicians were informed of the target BP for diabetics and non-diabetics, and reduction of BP to target levels was recommended but not defined as endpoint of the study.

Statistical analysis

The statistical analysis was performed using descriptive statistics. The analysis of the digit preference was done using the distribution of end-digits and an estimation of the deviation from a normal distribution according to which each digit should represent 10% of the values. A two-sided binomial test on all BP measurements was performed to assess whether the proportional representation of all digits was significantly different from the expected mean of 10%, for both the "conventional" and "automatic" measurements. The percentage of controlled patients in the various groups of patients according to the different cut-offs was calculated based on the χ^2 test.

Results

Patient population

A total of 504 physicians participated in this investigation. Of the 2199 included patients, a total of 1963 completed this observational study (89.3%). A total of 50 patients (2.3%) were classified by physicians as "lost to follow-up". The patients population consisted of 54% females and 46% males with a mean age (±SD) of the 64 years (±18 years). The effect of lercanidipine on BP control has been published previously (11).

Digit preference

A total of 6713 averages of three BP measurements derived from a total population of 2199 patients were collected during the study: 2580 (38%) were performed with the semi-automatic device. As shown in Figure 1, very pronounced digit preferences were observed for both "conventional" and "semi-automatic" measurements, being most prominent for the digit "0" (52% and 25%, respectively) followed by a preference for the digit "5" (19% and 15%). The frequencies for the even digits were clearly higher compared with the odd digits (except digit "5") with the overall lowest representation for the digits "1" and "9". As a consequence of the relatively high preference of the digit "5", the frequency for the adjacent digits "4" and "6" were lower compared with the other even digits "2 and "8". The pattern of digit frequencies revealed the following pattern: "0" > > "5" > "2"≈"8" > "4"≈ "6" > > "3"≈"7" > "1"≈"9"). The magnitude of the digit preference with the "conventional" methods was about twofold compared with automatic measurements. The pattern of digit preferences was very similar for both SBP and DBP, and for each of the visits (Figures 1 and 2). The shown digit preferences in total and at each of the three visits were statistically significant compared with the

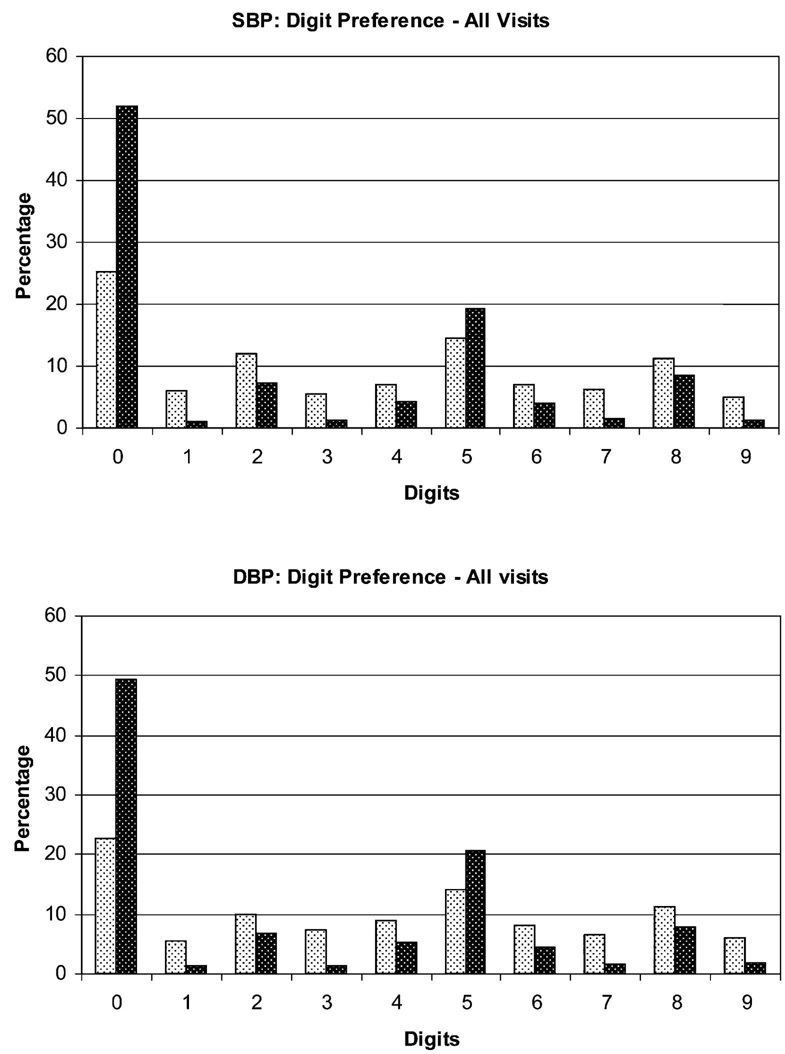

Figure 1. Distribution of digit preferences for systolic (SBP) and diastolic (DBP) blood pressures for automatic (bright bars) and conventional BP measurements (dark bars). All visits (V1, V2 and V3; Microlife Average Mode n=2580 and conventional n=4133). The probability of each digit to represent 10% of all values was rejected (two-sided binomial test) resulting in significant ($p \leqslant 0.05$) preferences of some digits for both automatic and conventional BP measurements.

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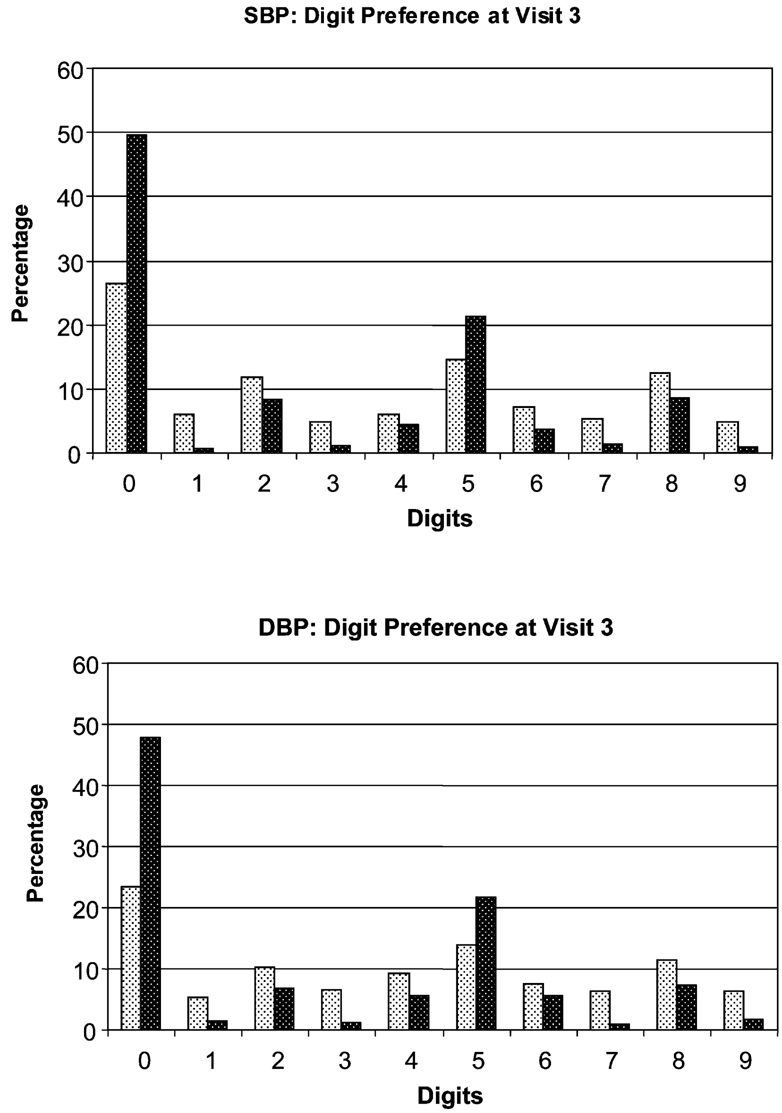

Figure 2. Digit preference with automatic measurements (bright columns) or conventional measurements (dark columns) at visit 3 after 8 weeks of therapy. The probability of each digit to represent 10% of all values was rejected (two-sided binomial test) resulting in significant ($p \leq 0.05$) preferences for all systolic (SBP) and diastolic (DBP) digits in both automatic and conventional blood pressure measurements, except DBP digits 2, 4 and 8.

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assumed equal distribution for both, SBP and DBP, except for the digits "2", "4" and "8" for the DBP at visit 3.

As a result of the treatment, BP was significantly reduced from baseline to week 8, and a clear shift from higher BP values at baseline to lower values at visit 2 and 3 was observed. However, the pattern of digit preferences remained unchanged.

Effect of the digit preference on the response rate

The overall response rate defined as a decrease in SBP≥10 mmHg and DBP≥5 mmHg was 71.8%. The proportion of patients with "normalized BP" was markedly higher in the non-diabetic subpopulation compared with the diabetic subpopulation. The proportion of patients with a "normalized BP" varies markedly when the limits for normalization were set at "equal to or less than" or "less than" the target values. Indeed, the percentage of patients on target in the non-diabetic subpopulation was 62.7% and 54.9% using conventional and automatic BP measurements, respectively, when setting target limits to SBP ≤ 140 mmHg and DBP ≤ 90 mmHg and dropped to 41.3% and 43.6% when the target limits of SBP and DBP were set at < 140 mmHg and < 90 mmHg. Similarly, the percentage of patients with normalized BP in the diabetic

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subpopulation were 17.9% and 10.3% using conventional and semi-automatic BP measurements, respectively, when defining target limits of SBP ⩽ 130 mmHg and DBP ⩽ 80 mmHg and dropped to 7.5% and 6.4% when the target limits of SBP < 130 mmHg and DBP < 80 mmHg were applied.

Interestingly, when target BPs were set at ⩽ 140/90 mmHg or ⩽ 130/80 mmHg for diabetics, the percentage of patients achieving target BP was significantly greater with the conventional method (χ^2 test; $p < 0.0001$) than with the semi-automatic device whatever the population. However, this difference disappeared when the corresponding target limits were set at < 140/90 and < 130/80 mmHg.

Discussion

Taken together, these data demonstrate that end-digit preference remains a major and frequent bias in clinical practice. This bias is more pronounced when physicians measure BP with the conventional auscultatory method and a mercury column. The use of semi-automatic devices reduces to a certain extent the frequency of the bias but the problem remains if physicians have to transfer the BP values on case report forms. Our data also confirm that the end-digit preference has a major impact on the evaluation of a treatment effect and on the assessment of the percentage of patients achieving target BP in a population.

Theoretically, in the absence of any bias, the 0 to 9 digits should be represented equally when BP is measured frequently on a large group of patients. The first observation of our study is that end-digits are definitively not equally distributed in clinical practice and that there is a clear preference for the 0 and 5 values. Moreover, even digits appear to be more commonly represented than odd digits. This latter finding may be explained by the fact that mercury columns are generally graduated by 2 mmHg. In addition, digits that are close to the 0 and 5 such as 4 and 6 or 1 and 9 or are clearly under-represented. This observation is in line with several previous publications indicating that last digit preference is a common issue when BP is measured by patients as well as nurses and physicians (4–6,13,14). This problem is present in general practice, in specialized hypertension clinics and large therapeutic trials (7,13,14).

Some previous studies have suggested that the use of semi-automatic devices enables the reduction of the importance of this bias (9,10). In our study, we indeed found a better distribution of end-digits among BP values obtained with the automatic device. Nevertheless, the end-digit preference remained. This may due to the fact that physicians had to transfer the BP values on a case report form and this transfer was apparently associated with an unconscious trend to use 0 and 5 rather than the measured end-digit. Thus, whenever possible, data transfer should be avoided when automatic devices are used in order to maintain a high quality of the data set. In many studies, the protocol recommended obtaining three BP values and calculating the mean of these measurements. To a certain degree, this approach reduces the end-digit preference, although it tends to displace the digit distribution from the 0 and 5 to the 2, 3, 6 and 7 digits. Since BP measurement is one of the most common procedure in clinical practice, a better education of physicians using training programmes and quality control activities is certainly another approach that should be implemented to reduce this bias (15).

Interestingly, physicians who care for individual patients often consider this problem irrelevant. Yet, studies have suggested that end-digit preference may have an impact on the probability of receiving an active prescription for an antihypertensive medication (4). Thus, end-digit preference may have considerable implications for decisions about treatment for patients. More importantly, the end-digit preference clearly has an impact on the assessment of the antihypertensive efficacy of a drug (8,16,17). This is illustrated once more in the present study with an almost 20% lower percentage of patients achieving the target BP depending on whether the target is set at ⩽ 140/90 mmHg or < 140/90 mmHg. At last, the bias linked to the end-digit preference may have a major influence on the assessment of the quality of BP control in populations. In recent years, several large surveys have demonstrated that BP control is rather poor in many develop countries (18). The real figures may actually be much worst if one takes into account a 10–20% overestimation due to the end-digit preference.

In conclusion, the results of the present analysis based on a large group of Swiss physicians in clinical practice clearly demonstrate that end-digit preference remains a serious bias in clinical practice. This bias has several important consequences particularly when evaluating the efficacy of a new antihypertensive drug. Our study was not originally designed to investigate this specific issue. Therefore, it suffers from some limitations: firstly, this is not a randomized blinded study and the study protocol was certainly not optimal; secondly, we could not discriminate between rounding up and rounding down. Our data nevertheless confirm the need for training programmes and quality controls in clinical practice. They also emphasize the importance of developing semi-automatic systems with a direct transfer of BP values from the measuring device to the clinical chart or to the case report form in order to avoid any interference of the observer, be it a patient, a nurse or a physician, with the measured parameter. In drug studies, automatic devices should be preferred, possibly with memory and data transfer to a computer, and the data should be analysed by independent evaluation committees.

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