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A study on the concordance between different blood pressure measurement devices among inmates of a correction centre

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ABSTRACT

Objective: To evaluate the reliability and assess the differences between blood pressure readings obtained with different measuring devices (mercury sphygmomanometer, aneroid sphygmomanometer and digital sphygmomanometer) among inmates of a correction centre. With the results obtained, we saw that there was a similarity in readings with the mercury and digital sphygmomanometers, with differences of means that were higher when these two devices were compared than with the aneroid sphygmomanometer.

Kay Words: Sphygmomanometers, prison

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INTRODUCTION

In our place of work, we have been constantly using two types of sphygmomanometer to determine blood pressure: the aneroid and mercury sphygmomanometer.

The growing use of automatic and semi-automatic devices in care practice has led us to try to introduce them into our work, but before doing so, we wanted to assess the advantages and disadvantages connected with using a particular measuring device; we were interested in assessing whether there were any differences between blood pressure readings made with three different devices (mercury, aneroid, and digital sphygmomanometer) among inmates of a correction centre.

To conduct this study, we reviewed the publications of the previous four years (2001-2004) using the bibliographical databases on the Internet, such as Index Medicus (MEDLINE) and the Índex de Enfermería (CUIDEN).

There are very few studies on this topic and those we did find basically compare the differences between observers and between measuring devices[1-3].

Other studies were aimed at validating particular devices based on the criteria proposed by the Working Group on Blood Pressure Monitoring of the European Hypertension Society[4].

In all these studies, the reference group has been the population of particular primary health care centres and hospitals, and so we decided to carry out a more thorough search for a study of similar characteristics conducted in a correction centre, but we found none.

The penitentiary population has particular characteristics that distinguish it from the general population. The fact that we found no recent or older publication on this type of study, together with our curiosity in knowing whether there were differences in measurement depending on the type of device used, makes this study of particular interest for healthcare staff that work with this type of population.

And so our **main objective** with this study is**:**

- To evaluate the reliability and assess the differences between blood pressure readings obtained with different measuring devices (mercury sphygmomanometer, aneroid sphygmomanometer and digital sphygmomanometer) among inmates of a correction centre.

Secondary objectives are:
- To determine the degree of agreement in readings taken by 2 observers (Inter-observer Concordance).
- To compare the accuracy between a semi-automatic device and 2 manual devices.

MATERIAL AND METHOD

Type of Design: a transversal descriptive observational study of concordance with quantitative measurements.

Study population: the study was conducted on inmates of a correction centre with 521 inmates at the beginning of the study.

No inclusion or exclusion criteria were established.

With regard to feasibility criteria, we decided to work with a representative sample of the study population, and so we carried out a simple random sampling of the reference population, by obtaining random numbers. From an alphabetical list of the whole population of the centre, we began selecting candidates for the sample chosen by random numbers.

Sample and calculation of the size: for the calculation of the sample size, we started from a standard deviation of the mean of blood pressure readings of 16.7 mmHg (pilot study) and we aimed to estimate with a level of confidence of 95% and an absolute precision or error of ±4%.

We carried out the calculation automatically using the !NMD macro (V2002.02.16 © A.Bonillo, JM. Doménech & R.Granero)[7] for SPSS 11.5 by introducing the standard deviation, the level of confidence and the precision we wanted. We obtained a sample of 134 subjects.

In case any subject of the sample was unwilling to participate, or did not present himself for the taking of a blood pressure reading, we decided to estimate the possibility that 5% were abandonments or refusals; thus, we applied a correction formula to calculate the sample size in the event of losses or abandonments.

Correction for non-replies, losses or abandonments:

$Na = N [1/(1-R)]$ $Na = 134 [1/(1-0.05)]$; **Na = 141**

Na = Sample size with number of subjects adjusted for possible losses.
N = Sample size for finite populations.
R = Expected loss percentage.

After the calculations were made, the sample consisted of a total of 141 subjects.

The characteristics of the population of a penitentiary centre present certain advantages, including the accessibility and availability of the subjects at any time. Because of this, on the day before the taking of the blood pressure readings, we decided to meet the sampling subjects, and we told each one that he had been selected for this study, how he had been selected, and what the taking of the blood pressure reading consisted of. They were asked to take part in the study and for their authorised consent, and they were assured of confidentiality and use of the data obtained under Act 15/1999 of 13th December, concerning Personal Data Protection, as well as under articles 4.2.b, 211.2 and 211.3 of current Penitentiary Regulations.

As soon as they agreed to take part in the study, they were notified of the time and place of the reading with the following observations:

- They were to present themselves with clothing that was easy to remove in order to have access to the arm on which the reading was to be taken (preferably a short-sleeved t-shirt).
- They were not to smoke or drink coffee within 30 minutes prior to the reading.
- They were not to do physical exercise or eat heavy meals within an hour prior to the visit.
- They were to urinate before the reading.

Sources of information (Observers): These consisted of three professionals trained in the technique according to the established protocol. The first two, whom we shall refer to as OBS1 and OBS2, took 2 readings (one with the mercury sphygmomanometer and the other with the aneroid sphygmomanometer) from each of the sample subjects.

The readings were registered blind, so that each observer noted his readings independently without the other knowing the results, since we needed to study the inter-observer variability.

With regard to the digital sphygmomanometer, it takes readings automatically, so we did not need to determine the Inter-observer variation: one reading was enough.

Finally, a third professional (OBS3) was responsible for taking readings with the digital sphygmomanometer, once the first two observers had taken theirs. He also recorded data for date of birth and sex, and assigned them a correlative numerical identification.

Monitoring and procedure: the study was conducted over one month, and monitoring was established for the whole sample. 705 blood pressure readings were recorded (five for each subject).

As there was a large number of readings to take each day, we decided to split them up, so that readings were taken over 14 working days (Monday to Friday, at the same time and under the same conditions). Each day, 10 subjects were called, except the last day when 11 were called to complete the 141 subjects of the sample.

An office was set up next to a waiting room. The reading recording procedure was as follows:

- First, the ten patients for the day came into the office one after the other, so that ***OBS1*** took a reading from subject 1 with the mercury sphygmomanometer. ***OBS2*** took a reading from subject 1 with the aneroid sphygmomanometer, and ***OBS3*** took a reading from subject 1 with the digital sphygmomanometer and recorded the date of birth and sex, and assigned an identification number. This was repeated with each subject until subject 10.
- Secondly, there was a change of instruments and a second reading was taken, so that ***OBS1*** took a reading from subject 1 with the aneroid sphygmomanometer. ***OBS2*** took a reading from subject 1 with the mercury sphygmomanometer. ***OBS3*** did not take a reading.

This procedure was repeated in the same way over the 14 days planned for the completion of the entire sample.

Measuring instruments: for this study we used:

- 3 sphygmomanometers correctly calibrated and validated:
  - — One mercury sphygmomanometer (Riester Diplomat Presamater).
  - — One aneroid sphygmomanometer (Riester Minimus III).
  - — One digital sphygmomanometer (OMROM M4-I).
- 2 stethoscopes (3M Littmann).
- 3 cuffs 12 x 23 cm. (For normal-sized arms).
- 3 cuffs 15 x 31 cm. (For obese persons).

Each pressure cuff had the right connection for each type of sphygmomanometer.

The sphygmomanometers and the cuffs were brand new at the start of the study, so that the connections and tubes were in perfect condition.

Data gathered: For the data-gathering, each observer had a separate sheet to record the subject's identification number, which was assigned correlatively, with boxes to note down the systolic and diastolic arterial pressure, and the type of sphygmomanometer used. The data-collection sheet of observer 3 was somewhat different to the others, as it recorded the date of birth, name (coded with the first two letters of the 1st surname, the next two letters of the 2nd surname and the first two letters of the forename), and sex.

Variables: these were classified thus:

- Universal descriptive variables:
  - — ***Sex*** = a qualitative nominal dichotomous variable, or binary variable, coded (0= Feminine; 1= Masculine).
  - — ***Decimal age (completed years)*** = a continuous quantitative variable obtained from the difference between the date of the beginning of the study and the date of birth, maintaining the decimals so that it would not be a truncated variable.
- Variables for measuring the study factors:
  - — ***Observer*** = nominal qualitative variable (OBS1, OBS2, OBS3).
  - — ***Device*** = nominal qualitative variable (Mercury, Aneroid, Digital).
  - — ***PAS (Systolic Arterial Pressure)*** = continuous quantitative variable, measured in mmHg.
  - — ***PAD (Diastolic Arterial Pressure)*** = continuous quantitative variable, measured in mmHg.
- Other variables of interest:
  - — ***Id*** = Identification of the subject. A discrete quantitative variable with a range of values between 1 and 141.
  - — ***Date of birth*** = discrete quantitative variable, measured in day, month and year.

A database was set up using ACCESS-2000 limiting the entry of certain types of data in order to sift out errors. Each observer entered the data he had collected and then he checked again in order to reduce the possibility of having made any error.

With this program we had a resource from which data could be exported to international systems of various statistical analysis programs.

Once the database had been completed, the data were exported to a PA_CONTROLES.SAV data file for processing with the SPSS 11.5 statistics program.

Once the data had been exported, and prior to any calculation process, we carried out a new data **sifting process** to check their quality using two types of technique:

- Ranking tests.
- Distribution of "missing" or unknown values of all the variables using the MVA (Missing Value Analysis) procedure included in version 11.5 of SPSS.

Statistical analysis: the analysis was carried out using SPSS 11.5.

One: a descriptive analysis of the universal variables (sex and age) of the sample was carried out.

Two: a study was conducted of the distribution of the blood pressure readings taken with the various devices in order to provide a visual comparison, by means of a Box-Plot, of possible differences and anomalies between them (Figure I).

Three: an Inter-observer concordance study was carried out to determine the coefficients of intra-class correlation by device between observers. These coefficients were suitable for the study of concordance between quantitative readings.

Four: a study of concordance between devices was conducted, again using the intra-class correlation coefficients.

Five: we conducted a difference of means study based on the Bland and Altman method. In order to carry out this type of determination, one of the principal conditions is that the differences must be modelled in terms of a normal distribution, and so we determined it by applying the Kolmogorov-Smirnov and Shapiro-Wilk tests, both of which gave us a statistical significance of P>0.05. This confirmed that they were distributed in terms of a normal modelling.

Six: We determined the comparison of accuracy between an automatic device (digital sphygmomanometer) and two manual devices (mercury sphygmomanometer and aneroid sphygmomanometer) using the Passing-Bablok[8] method, which consists of carrying out a non-parametric estimation of the regression line which, because of its robustness, is considered the method of choice in the comparison of different devices. This test is based on the coefficients of the lines of regression (a and b), the trust intervals, significance tests for **a** (H_0: ?=0) and **b** (H_0: ?=1), and the linearity test based on the CUSUM coefficient.

RESULTS

There was no loss or abandonment among the 141 subjects obtained by the sampling.

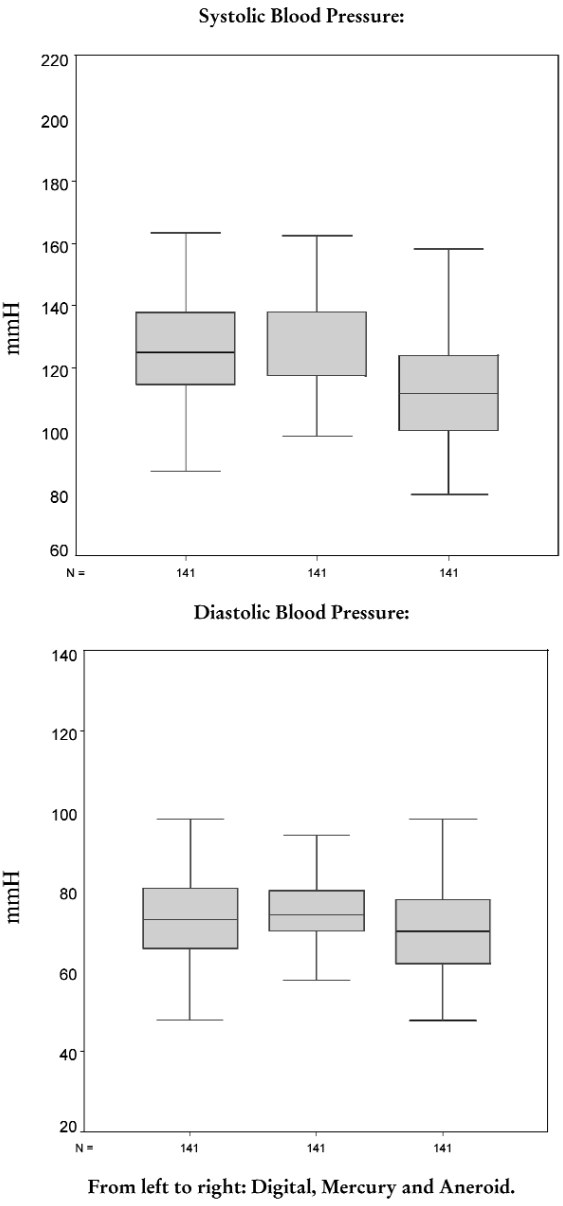


Fig. I. Distributions of blood pressure readings by device.

The study sample was made up of 28 women (19.9%), and 113 males (80.1%).

The average age was 33.00 years with a CI of 95% (31.45 – 34.56), with 50% of the ages situated between 24.40 and 40.10 years, with an IQR of 15.70 years.

The degree of concordance between observers OBS1/OBS2 for systolic blood pressure was ICCc = 0.94 CI 95% (0.92 – 0.95) for the mercury device and ICCc = 0.89 CI 95% (0.74 – 0.86) for the aneroid device.

The degree of concordance between observers OBS1/OBS2 for diastolic blood pressure was ICCc = 0.82 CI 95% (0.75 – 0.87) with the mercury device and ICCc = 0.64 IC 95% (0.51 – 0.74) for the aneroid device.

The degree of concordance between devices was practically the same between the combination of the two devices (Table I).

The Bland and Altman method, or method based on the difference of means between devices, showed us that the differences of means between devices for systolic readings were generally higher when comparing Mercury-Aneroid and Digital-Aneroid; there were practically no differences when comparing Mercury-Digital. The same occurred with the differences of means for diastolic readings between the various combinations of devices (Table II).

The Passing-Bablok method was used to compare the digital to the mercury device and then to the aneroid device; there were no differences of either a constant or a proportional type (Figures II and III).

OBS	APARATOS:	PAS		PAD	
		ICCc	IC 95%	ICCc	IC 95%
OBS 1	Aneroid – Mercury.	0.8366	0.7721 – 0.8829	0.6847	0.5603 – 0.7739
	Aneroid – Digital.	0.8365	0.7719 – 0.8827	0.6921	0.5706 – 0.7793
	Mercury – Digital.	0.8114	0.7370 – 0.8648	0.6717	0.5422 – 0.7646
OBS 2	Aneroid – Mercury.	0.7923	0.7104 – 0.8511	0.4077	0.1740 – 0.5753
	Aneroid – Digital.	0.7590	0.6639 – 0.8272	0.5042	0.3085 – 0.6445
	Mercury – Digital.	0.8364	0.7719 – 0.8827	0.7495	0.6507 – 0.8204

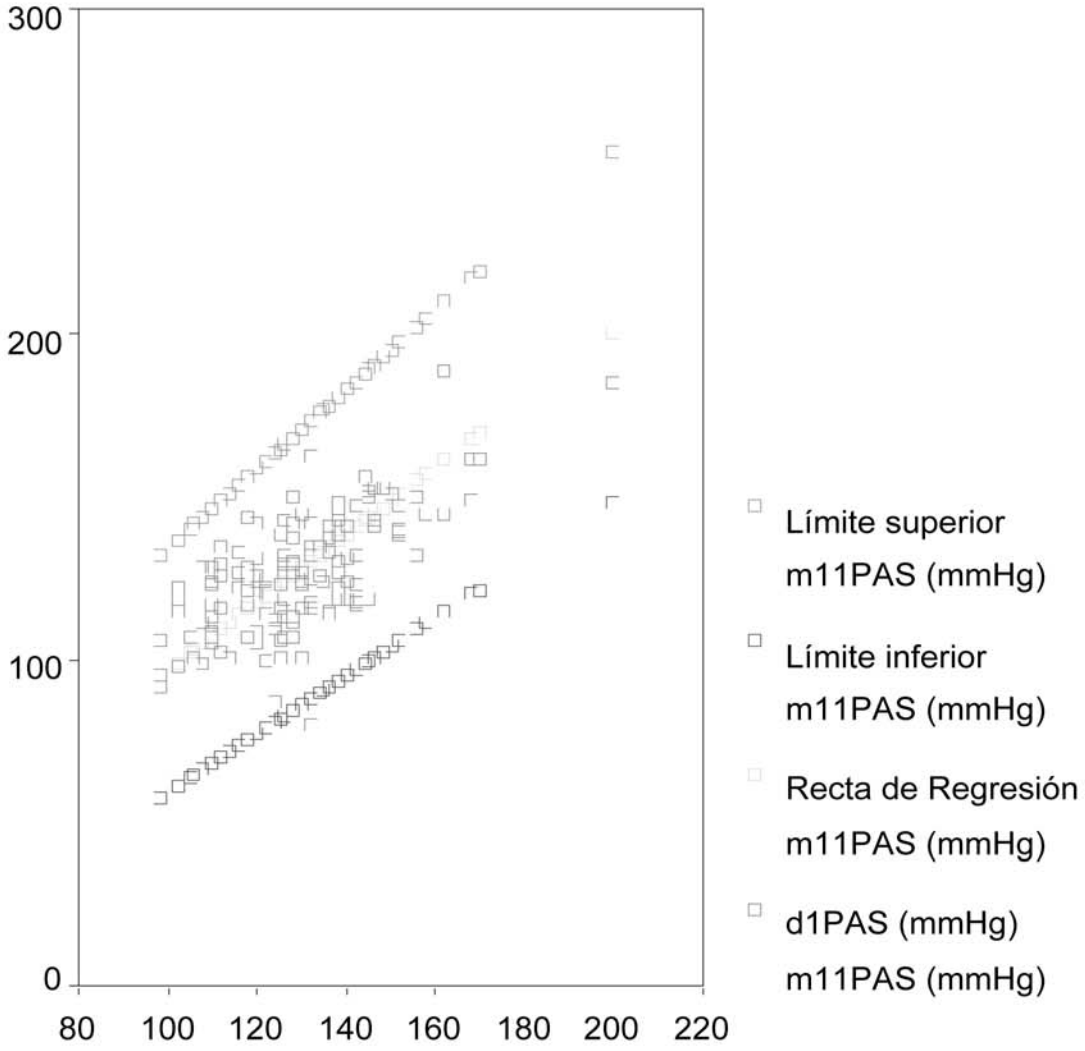
Table I. Degree of concordance between the various measuring devices.

The Intra-class Correlation Coefficient values range between 0 (no concordance) and 1 (absolute concordance). There is a certain consensus about accepting the following criterion (Fleiss, 1986)

ICCc Value	Concordance
<40	Low
0.41 – 0.75	Fair-Good
0.76 – 1.00	Very Good

		PAS (mmHg)				PAD (mmHg)			
		Dif. Means	Des. Típica	Dif. CI at 95%	Bilateral Sig.	Dif. Means	Des. Típica	Dif. CI at 95%	Bilateral Sig.
OBS 1	Mercury-Aneroid	16.0	12.5	13.9-18.1	0.0001	4.8	11	2.9-6.6	0.0001
	Digital-Aneroid	13.3	13.1	11.1-15.5	0.001	3.3	12.2	1.3-5.3	0.002
	Mercury-Digital	2.7	13.7	0.4-4.9	0.021	1.5	11.1	- 0.4-3.3	0.116
OBS 2	Mercury-Aneroid	10.3	12.1	8.3-12.3	0.0001	5.7	12.9	3.5-7.8	0.0001
	Digital-Aneroid	10.8	14.2	8.5-13.2	0.0001	4.6	13.5	2.4-6.9	0.0001
	Mercury-Digital	0.57	12.4	- 1.5- 2.6	0.589	1.02	10.3	- 0.7-2.7	0.241

Table II. Method for the difference of means btween devices (bland and altman).



STATISTICS	Mercury	Digital
Cases	141	
Mean	128.9929	126.2908
Minimum	98.0000	80.0000
Maximum	200.0000	189.0000
Stand. dev.	16.4887	17.8987

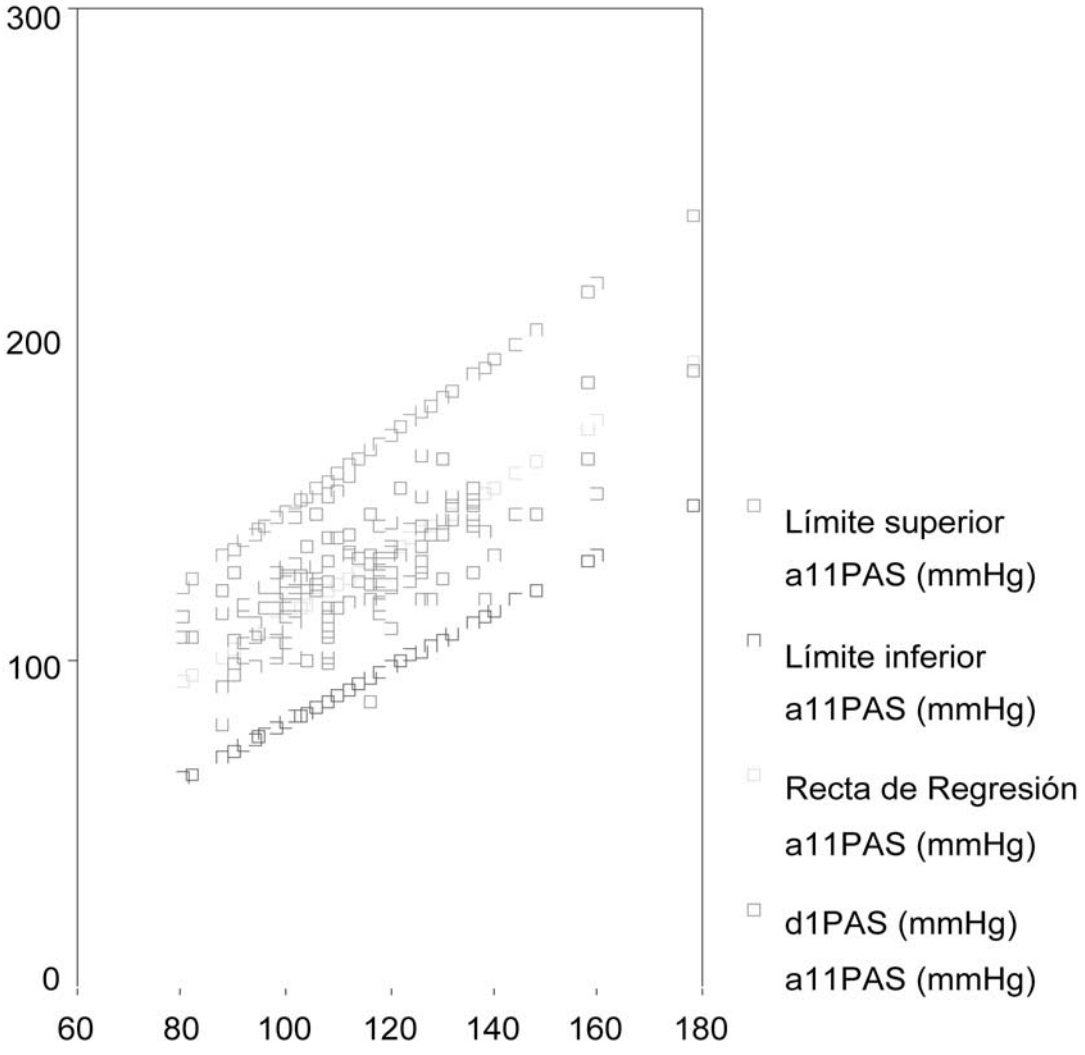
REGRESSION EQUATION

Digital = -6.464286 + 1.035714 * Mercury

Constant = -6.464286 (CI95%: -28.875000 to 12.371429)
Gradient = 1.035714 (CI95%: .885714 to 1.218750)

LINEARITY (CUSUM linearity deviation test):
0.1< P < 0.20 (Not Significant)

Fig. II. Passing-Bablok Regression (Digital - Mercury)



STATISTICS	Aneroid	Digital
Cases	141	
Mean	112.9929	126.2908
Minimum	80.0000	80.0000
Maximum	178.0000	189.0000
Stand. Dev.	17.1020	17.8987

REGRESSION EQUATION
Digital = 13.000000 + 1.000000 * Aneroid

Constant= 13.000000 (CI95%: -5.210526 to 29.857143)
Gradient= 1.000000 (CI95%: .857143 to 1.157895)

LINEARITY (CUSUM linearity deviation test):
P> 0.20 (Not Significant)

Figura III: Passing-Bablok Regression (Digital-Aneroid).

DISCUSSION

With the results obtained, we saw that there was a similarity in readings with the mercury and digital sphygmomanometers, with differences of means that were higher when these two devices were compared than with the aneroid sphygmomanometer.

The statistical procedures used were the most suitable for carrying out this type of study and are similar to those used in other published works[1-6]. We complemented the study with an uncommon procedure that is used in laboratory studies to detect systematic errors in values obtained with method "Y" as against a comparative reference method "X"; this highly robust method is the Passing and Bablok method.

The (random) sample selection procedure provided us with a suitable representativity of the reference population. In addition, the taking of blood pressure readings independently, without either of the two observers knowing the readings taken by the other, and the exchange of devices between observers minimised any potential bias that might have occurred.

The double-sifting process carried out improved the quality of the data.

The distribution of blood pressure readings with the different devices (Figure I) show the similarity between the digital and mercury devices for systolic pressure, with slightly lower values for the aneroid device.

According to the results of the intra-class correlation coefficients, the degree of agreement between observers (according to the Fleiss criterion) was highly satisfactory for systolic blood pressure readings, from the mercury as well as the aneroid devices, although slightly lower for the aneroid device. The degree of agreement between observers for diastolic blood pressure readings was satisfactory, and again, slightly lower for the aneroid as against the mercury device.

The degree of agreement between devices was particularly the same between the various combinations, with lower intra-class correlation coefficients for diastolic readings; this might be due to the fact that this coefficient was affected by the variability of the values observed, in that if the scores are homogeneous, the intra-class correlation coefficient tends to be low, so that it is, in fact, a statistical artefact. These figures agree with those published in some of the quoted articles[2].

One of the great limitations in this study is the fact that the sample was made up of young persons, which suggests that the variability of the blood pressure readings should not be very high, since age is one of the conditioning factors in this area (the greater the age, the higher the figures).

It would have been interesting to have had a sample with greater variability which would have enabled us to make the same comparisons but between different strata.

Typically in our work, blood pressure readings have usually been taken with the mercury and aneroid sphygmomanometer, to detect hypertension and its consequences as a cardiovascular risk factor, as well as to establish the diagnosis and discover how it has been controlled under pharmacological treatment. In spite of this, there are clear limitations because of the difficulty in estimating fluctuations in a variable that is constantly changing.

Recent years have seen the appearance of new semi-automatic and automatic devices that are more exact, enabling readings to be taken safely and reliably when carried out in standardised conditions. To this should be added the European Community Regulations[9] which advocate the progressive abandonment of clinical instruments that contain mercury, and this makes the introduction of this type of device into our daily work a necessity.

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