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Digital pressure with Laser Doppler Flowmetry is better than Photoplethysmography to characterize peripheral arterial disease of the upper limbs in end-stage renal disease patients.

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## Running title: Digital pressure with Laser Doppler Flowmetry is better than

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### **HIGHLIGHTS**

- There is no consensual definition of peripheral arterial disease of the upper limbs. Doppler ultrasound may not be the optimal technique to correctly evaluate it. Finger systolic blood pressure is a useful tool, which must be carried out for a quantitative evaluation.
- Peripheral arterial disease of the upper limbs in patients with end-stage renal disease is probably underestimated. Doppler ultrasound detected a high rate of upper limb arterial disease but may not be the optimal technique to correctly evaluate it. Microcirculation methods have to be added for a quantitative evaluation and particularly before creation of an arteriovenous fistula for haemodialysis access in order to avoid ischaemic issues (pain, necrosis, and digital ulcers). But there is a poor correlation coefficient of 0.493 (p < 0.001) between laser Doppler flowmetry and photoplethysmography.</li>
- Laser Doppler flowmetry seems to be better in detecting peripheral arterial disease, as compared to photoplethysmography, which tends to overestimate the raw values.

#### Abstract :

**Objective:** There is no consensual definition of significant peripheral arterial disease of the upper limbs. Patients with end-stage renal disease are usually explored with Doppler ultrasound, which seems insufficient to characterize and quantify the arterial disease in this anatomic site. Candidates for haemodialysis access tend to be increasingly older and have polyvascular disease, and a better assessment of the vascular status of their upper limbs with finger systolic blood pressure is necessary. Photoplethysmography is simple and currently used in practice, but laser Doppler flowmetry may be more sensitive for low values. Our objective is to investigate additional information in the digit assessment over the ultrasound assessment of the upper limbs of patients awaiting haemodialysis and compare digital pressure values taken by photoplethysmography and laser Doppler.

**Methods:** All included patients with end-stage renal disease scheduled for haemodialysis access received a prospective evaluation of their upper limbs with a clinical examination of the hands, an arterial upper limb Doppler ultrasound, and finger systolic blood pressure using photoplethysmography and laser Doppler flowmetry. Significant upper limb arterial disease was defined by a finger systolic blood pressure below 60 mmHg or a finger brachial pressure index below 0.7.

**<u>Results</u>**: Twenty-four patients were included in the study. In all, 41.7% of patients (n = 10) had parietal calcifications to the antebrachial arteries on Doppler ultrasound, 8.3% of patients (n = 2) had bilateral finger systolic blood pressure values below 60 mmHg with laser Doppler flowmetry (but not confirmed with photoplethysmography), and 16.6% of patients (n = 4) had a finger brachial pressure index below 0.7 on both laser Doppler flowmetry and photoplethysmography. While there was an agreement between these two methods, higher values were recorded with photoplethysmography. The Pearson coefficient was 0.493 for the

median of basal digital pressures in absolute values and 0.489 for finger brachial pressure index (p < 0.001).

<u>Conclusion</u>: Our study confirms the need to evaluate significant upper limb arterial disease in patients with end-stage renal disease not only with Doppler ultrasound but also with an evaluation of the finger systolic blood pressure. The correlation of the finger systolic blood pressure values using laser Doppler flowmetry and photoplethysmography was poor, which was probably due to an overestimation of the pressures with photoplethysmography. Despite the absence of a gold standard, we suggest that Laser Doppler flowmetry should be used rather than photoplethysmography to better characterize significant peripheral arterial disease of the upper limbs in patients with end-stage renal disease, particularly before creation of a new haemodialysis access.

Protocol Record on clinical trial 38RC19.285

**Key-words:** Peripheral arterial disease of the upper limbs; Laser Doppler Flowmetry; Photoplethysmography; Finger systolic blood pressure; End Stage Renal Disease; Renal Replacement Therapy

## List of Abbreviations:

AVF : arteriovenous fistula HAIDI : haemodialysis access-induced distal ischaemia LDF : laser Doppler flowmetry FSBP: finger systolic blood pressure PPG: photoplethysmography ESRD: end-stage renal disease CRF: case report form FBPI: finger brachial pressure index

#### **Introduction :**

One of the most widely used methods of renal replacement therapy is haemodialysis. It requires the creation of an arteriovenous fistula (AVF) in one of the upper limbs. Creation of a vascular access needs an adequate arterial flow to allow for dialysis adequacy and exposes patients to the occurrence of complications (Stone PA et al, 2012), including steal syndrome or haemodialysis access-induced distal ischaemia (HAIDI), which is relatively uncommon (around 5%) (Scheltinga MR et al, 2009). Doppler ultrasound is the current tool to assess vascular evaluation but may not be the optimal technique to correctly evaluate arterial disease of the upper limbs. There is in fact no consensual definition of peripheral arterial disease of the upper limbs. Toe systolic blood pressure measurement is the reference technique for the hemodynamic evaluation of severe peripheral arterial disease of the lower limbs, and its methodology is well described (De Graaff et al., 2000; Beinder et al, 1992). Laser Doppler flowmetry (LDF) is also the best tool, with excellent repeatability and better sensitivity for the measurement of low pressures (Ubbink et al., 2004). The measurement of finger systolic blood pressure (FSBP) in the diagnosis of HAIDI is determined with very good accuracy (Schanzer A, et al., 2006). The guidelines for the management of HAIDI state that digital blood pressure should be measured to confirm the diagnosis when uncertain (Beathard GA et al.. 2019). Its measurement until recently in the literature was always with photoplethysmography (PPG) (Odland et al., 1991; Lazarides et al., 1998; Schanzer et al., 2006; Goff et al., 2000). Although both techniques are practically used for digital pressure measurement of vascular approaches for haemodialysis, only PPG has been evaluated in the medical literature (Schanzer A, et al., 2006; Papasavas PK, et al., 2003; Modaghegh M-HS et al, 2015). Our objective in this study is to investigate additional information in the digit arterial assessment over the ultrasound assessment of the upper limbs of patients awaiting haemodialysis who tend to be older (over 65) and have polyvascular disease due to hypertension and diabetes in the majority. The second objective was to compare arterial digital pressure values with both PPG and LDF.

#### **Methods**

#### **Population**

All patients with end-stage renal disease (ESRD) waiting for creation of an AVF after a decision by a nephrologist on a pre-dialysis assessment between 1 May 2019 and 30 August 2019 were included. Each patient was able to sign for non-oppositional involvement at the time of their consultation (clinical trial 38RC19.285). They had to be 18 years old or older and affiliated with the Social Security system. The only exclusion criterion was patient opposition to participate in the study or withdrawal during the study.

#### Data features

Each patient received a medical exam with precise medical history enquiry, including a check of cardiovascular risk factors (tobacco abuse, hypertension, diabetes mellitus, dyslipidaemia, age, and gender), history of cerebrovascular disease, coronary artery disease, peripheral arterial disease of the lower limbs, and aetiology of their ESRD. A clinical examination of the hands was made with pulses and the Allen manoeuvre. Haemoglobin, glycated haemoglobin, LDL cholesterol, HDL cholesterol and creatinine clearance were measured. Medical treatment in progress at the time of inclusion was documented. All of these data were collected in a case report form (CRF). Systolic blood pressure was measured in both arms when possible (i.e., in the absence of a patent AVF). The diameter, patency of the arteries of the upper limbs and presence of calcifications were collected during a Doppler ultrasound. Digital pressures using LDF and PPG were performed. Significant upper limb arterial disease was defined by a FSBP threshold below 60 mmHg or a finger brachial pressure index (FBPI) below 0.7. The FBPI was defined as the ratio between the FSBP and ipsilateral brachial systolic pressure.

#### **Techniques**

Evaluation and quantification of peripheral arterial disease in upper limbs was carried out during vascular cartography in order to create the AVF, using B-mode ultrasound (in transverse and longitudinal sections), colour Doppler, and pulsed Doppler. Doppler ultrasound exams were performed using a 50 mm opening with a 12-5 Hz and 9-5 Hz linear Philips probe and a 22.4 mm opening with a 8-5 Hz microconvex Phillips probe. Images were obtained using Philips IU 22 and Philips Affiniti 70 (Philips-France, Suresnes). Each patient received investigation of the patency and the diameter of the axillary, brachial, radial, and ulnar arteries on each side. The presence of calcifications and the compressibility of the antebrachial arteries were also noted.

All patients had digital arterial pressure values measured with both techniques. The patient was under a heated blanket. Standardized methodology for digital pressure measurement was used and carried out on each finger, except the thumb. The FSBP was recorded with LDF (Periflux System 5000; Perimed, Järfälla, Sweden) (Blaise S et al, 2020) and PPG (SysToe: Atys Médical, Soucieu-en-Jarrest, France) on eight fingers, all but the thumbs. After the patient had rested for 15 minutes in a room with a comfortable temperature between 20°C and 25°C according to the season, an appropriately sized cuff was fitted on the second phalanx (Figure 1). After the pulp of the finger had been emptied by gentle manual compression, the cuff was inflated up to a suprasystolic pressure (200 mmHg), followed by slow deflation to allow researchers to detect the reappearance of the flow and the corresponding value from the digital blood pressure. All fingers, then the two middle fingers, then the two ring fingers and then the two little fingers. Then the measurements were taken with the PPG. More precisely, for laser Doppler measurements, the values were defined by the baseline upward

deflection and the very beginning of the slope. For PPG values, the flow recovery values were considered when a signal reappeared.

The FSBP value for a given finger was the median value of three measurements with LDF and two measurements with PPG. The main objective was to describe the arteries of the upper limbs with Doppler ultrasound. Significant arterial disease was defined with values of FSBP lower than 60 mmHg with both LDF and PPG or FBPI below 0.70.

#### **Statistical analysis**

Qualitative and quantitative variables were analysed using means or medians, percentages and standard deviations. Normality was assessed by the Shapiro test. A Pearson correlation test was used to establish the correlation between the measures of each method with a p < 0.001. The Bland and Altman concordance assessment method (Bland JM et al., 2003) was used to assess the concordance between the measurements of the two digital pressure techniques. Statistical analysis was performed with SAS system software version 9.2 (SAS France, Brie Comte Robert). For the firsty objective, i.e. the characterization of the peripheral vascular status of the upper limbs of patients awaiting haemodialysis, we recorded the data for all available patients over the study period. This objective, i.e. to compare digital pressure values taken by both photoplethysmography and laser Doppler, a 0,05 two-sided test of the null hypothesis that the Pearson correlation coefficient equals 0 had 80% power to detect a correlation of 0,55 in the enrolled 24 patients (nQuery Advisor® 7.0).

#### **Results**

A total of 24 patients were included in the study, with a median age of 71.5 (+/-19.6) years (range 27 to 91 years) and a majority of males (n = 18, 75%). Almost all patients were

hypertensive (95.6%) and almost half were diabetic (43.4%). The characteristics of the population have been listed in Table 1.

Ten patients (41.6%) had parietal calcifications to the antebrachial arteries on Doppler ultrasound and nine patients (37.5%) had incompressible antebrachial arteries. Only one patient presented with atherosclerotic stenosis in the axillary and brachial axis. The ultrasound features of upper limb arterial disease are listed in Table 2. Two patients (P12 and P22) presented with low FSBP values (< 60 mmHg) with LDF in both hands, which was not found with PPG (Figure 2). Four patients (P9, P10, P12, and P22) had a FSBP below 0.70, measured with LDF (Figure 3a). With PPG (Figure 3b), four patients also had a low FBPI (P1, P9, P20, and P22), two of which were identical with the LDF measurements (P9 and P22).

We noticed a poor correlation between both methods with a Pearson coefficient at 0.493 for the medians of the FSBP and 0.489 for the FBPI (p < 0.001). We also found average agreement between both measurement methods using the Bland-Altman diagram (Figure 4 and 5).

#### **Discussion**

We present, for the first time, the evaluation of upper limb arterial disease in patients with ESRD awaiting creation of an AVF using Doppler ultrasound coupled with LDF and PPG FSBP measurements. Despite the limits of the small cohort, we found a high proportion of upper limb arterial disease in patients with ESRD. Microcirculatory assessment is essential to establish the diagnosis of significant peripheral arterial disease with insufficient data provided by Doppler ultrasound alone. There is a lack of consensus in medical societies concerning the definition of arteriopathy at the level of the upper limbs. There is no gold standard for defining the best examination to explore the digital arterial microcirculation. Nevertheless, the

analysis and determination of FSBP have been carried out in the literature, mainly in the context of HAIDI in patients already carrying an AVF (Beathard GA et al., 2019). However, the measurement techniques were different, not codified and exclusively made with PPG. (Odland et al., 1991; Lazarides et al., 1998; Schanzer et al., 2006; Goff et al., 2000). FSBP measurement has shown promising applications in other diseases, such as systemic sclerosis (Hirai et al., 1978; Herrick et al., 1998; Blaise S et al, 2020), where arterial insufficiency of the distal upper limbs is of crucial clinical relevance.

The few studies comparing LDF and PPG were performed on the foot (de Graaff JC et al., 2000; Ubbink et al., 2004). The designs of studies comparing these two techniques remains heterogeneous. The repeatability of LDF and PPG is good, except in low pressure values (de Graaff JC et al., 2000; Widmer et al., 2012). LDF on the lower limbs has a better sensitivity for the measurement of low pressures (de Graaff JC et al., 2000; Ubbink et al., 2004), which is of special interest in patients with severe arterial insufficiency (Widmer et al., 2012; Høyer et al., 2014).

The methods used to measure FSBP are not yet standardized, especially in upper limbs. Certain methodological parameters have shown their great importance. FSPB with LDF has an excellent repeatability whatever the site of phalanx, but measurements performed on the second phalanx have a better sensitivity for the prediction of digital ulcers in patients with systemic sclerosis (Blaise S et al., 2020). A pressure gradient between the proximal and distal phalanx sites was observed; hence, the interest of making measurements as distal as possible to detect arterial disease (Blaise S et al., 2020).

We considered in our study a threshold of 60 mmHg for FSBP and 0.70 for FBPI to define the diagnosis of significant arterial disease by using the thresholds proposed in the literature for HAIDI with PPG (Odland MD et al., 1991; Schanzer A et al., 2006).

In our cohort, LDF detected two patients with a FSPB below 60 mmHg, whereas PPG failed to detect any patients with a FSBP below 60 mmHg.

These results are inconsistent with the Doppler ultrasound characteristics for one of these patients. Although the first patient had the lowest FSBP (Figure 1, P12), the ultrasound examination showed no features compatible with upper limb arterial disease. In contrast, the second patient (Figure 2, P22) had arterial calcifications and thrombosis of one of his radial arteries.

These results led us to suggest that digital arterial disease could remain unnoticed before the creation of an AVF when Doppler ultrasound is used alone. FSBP data (raw values) and correlation diagrams (Figure 4) suggest that PPG tends to overestimate the raw values. The question which is not yet elucidated is the threshold value of FSBP corresponding to significant arterial disease using PPG and/or LDF.

The proportion of patients with significant upper limb arterial disease was larger when analysing FBPI data rather than FSBP data. Four patients (16.6%) showed a FBPI < 0.70 with LDF (Figure 2a; P9, P10, P12, and P22). However, the brachial systolic blood pressure seemed to have a significant impact in our population, which was overwhelmingly hypertensive. It cannot be excluded that hypertension may induce false positives when expressing results of the FBPI. Thus, it is undoubtedly necessary to use the two criteria, FSBP and FBPI, to formally establish peripheral arterial disease in the upper limbs.

Thus, it seems difficult to formally establish digital arterial disease in patients using only the DBI criterion < 0.70, without the criterion of digital pressures < 60 mmHg (P9 and P10) by LDF and PPG, despite the ultrasound evidence of antebrachial arterial disease in these patients.

Analysing PPG and FBPI data in two patients (Figure 2b; P9 and P22 with FBPI < 0.70), both with antebrachial calcifications, it is likely that the results of one of them (P9) are overestimated due to hypertension, which is consistent with the LDF results.

It is also important to note that two patients can be falsely considered as carriers of significant arterial disease. These patients had a FBPI below 0.70 with PPG (Figure 3b, P1 and P20) but only on the fifth finger of one hand, but neither of them had a FSBP below 60 mmHg. These patients had a very high brachial systolic pressure. This point also raises the question of the choice of the number of fingers involved in the diagnosis of arterial disease, with possible false positives in patients due to the criteria of only one finger. For the diagnosis of arteriopathy, it would be legitimate to retain the lowest digital pressure at a single finger. Indeed, low values are not always present on all fingers (Figure 2). For example, in two patients with FSBP < 60 mmHg with LDF, one patient only had this result at the index fingers of both hands (Figure 2, P22) and one patient had this result on all the left fingers and only on two right fingers (Figure 1, P12).

The correlation of the FSBP values using LDF and PPG was poor and disappointing, which was confirmed with the Bland-Altman diagram (Figure 5) and with low Pearson coefficients (0.493 for FSBP and 0.489 for FBPI) (p < 0.001). The assumptions are that PPG tends to overestimate the measurements, with a lack of correlation between the two methods in extreme values. Two patients presented with very significant differences between the raw FSBP values with LDF and PPG (Figure 5), leading to a possible interpretation bias. For one of the patients, arterial flow could not be stopped during inflation of the cuff at the level of the phalanx, inducing difficult interpretation.

These results raise the question of the place of PPG as a screening tool if it overestimates certain values. The risk is clearly the underestimation of peripheral arterial disease. Some patients have shown that LDF could detect pressures below 60 mmHg, whereas PPG has not

13

done so. Therefore, LDF appears to be more sensitive, as has already been demonstrated in the literature at the level of the lower limbs (de Graaff JC et al., 2000; Ubbink et al., 2004). The explanation could be the difference of the techniques in terms of signal collection between LDF and PPG. Indeed, the arterial systolic pressure is detected with LDF with the measurement of the capillary flow via the emission of laser light carried by an optic fibre probe. Light strikes moving blood cells, which changes the wavelength (Doppler effect). Diffusion is detected by a sensor, while PPG is based on a difference of erythrocytes in the underlying tissue, which is a phenomenon subject to more potential artefacts. LDF is able to detect very small blood cell movements and is very sensitive to the detection of the resumption of microcirculatory blood flow in the toes, as opposed to the more coarse detection of blood filling by PPG (de Graaff JC et al., 2000). Standardized Doppler laser flux assessments define a different "biological zero" greater than the "zero" value, reflecting the great sensitivity of the technique. Therefore, it is very unlikely that the laser would underestimate pressure values.

LDF requires significant equipment (monitor, multiple cuffs and Doppler probes) and is time consuming. The equipment configuration conditions require that the measurement process take place in a dedicated room at a controlled temperature (as usually recommended for microcirculatory examinations), unlike PPG which is portable and easy to use. The LDF probe is easier to apply on the fingers, especially if small-sized, thanks to adhesive strips. PPG requires a cuff to attach the sensor. All of these arguments could argue in favour of greater sensitivity for LDF. The convenience of use of PPG undoubtedly explains the number of studies using this tool, especially in patients with AVFs. Nevertheless, the number of studies should not make up for the lack of data on reproducibility, repeatability and reproducibility.

Whatever the method, this study highlights the very likely underestimation of peripheral upper limb arterial disease in patients with ESRD. Our study shows that the choice of technique used can change the conclusions. At this stage, there is always no gold standard for defining the best examination to explore the digital arterial microcirculation but we suggest the use of LDF because of its better sensitivity, especially with low values or the both technics LDF and PPG to avoid to avoid false high values.

Screening appears to be necessary at an early stage and probably before the creation of an AVF is performed. The number of publications concerning macro and microcirculatory arterial assessment, and in particular in ESRD patients, is low or even non-existent with laser Doppler. It therefore seems important to warn about possible false overestimates in plethysmography, especially in cases of clinical discordance.

When the patient already has an AVF, the prospects could be to suggest a systematic microcirculatory evaluation in case of the appearance of clinical signs of HAIDI. Digital arterial pressure values could be a functional indicator, in addition to the clinical stage of HAIDI, to help nephrologists and vascular surgeons to discuss a surgical procedure on the fistula in order to refine the functional prognosis.

Another longer term perspective could be to evaluate more systematically in microcirculation the values of digital arterial pressures in patients at high risk of upper limb arteriopathy (ESRD patients just before the creation of an AVF) in order to possibly recuse these patients at very high risk of the occurrence of HAIDI.

#### **Conclusion**

Our small cohort of patients with ESRD, prior to AVF creation, showed a high rate of Doppler ultrasound arterial calcifications, reflecting a high incidence of upper limb arterial disease. The study confirmed that, despite the effort to standardize the Doppler ultrasound data and process, assessment of FSBP seems to be not only essential to establish the diagnosis of digital arterial disease but also to define its severity. At this stage, there is always no gold standard for defining the best examination to explore the digital arterial microcirculation.LDF seems to be a better tool compared to PPG, which tended to overestimate raw values. It also suggests that raw values with FSBP should be used rather than FBPI (risk of bias due to hypertension). Further prospective studies will be needed to define the frequency of significant upper limb arterial disease and define the threshold of severe arteriopathy. One of the long-term objectives is to better screen patients at risk of being assessed for HAIDI before the creation of an AVF creation with the aim to prevent ischaemic issues (pain, necrosis, and digital ulcers).

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#### **Perspectives**

Our study suggest that microcirculation methods have to be added for a quantitative evaluation and particularly before creation of an arteriovenous fistula for haemodialysis access. The study confirmed that, despite the effort to standardize the Doppler ultrasound data and process, assessment of FSBP seems to be not only essential to establish the diagnosis of digital arterial disease but also to define its severity. LDF was a better tool compared to PPG, which tended to overestimate raw values. It also suggests that raw values with FSBP should be used rather than FBPI (risk of bias due to hypertension). Further prospective studies will be needed to define the frequency of significant upper limb arterial disease and define the threshold of severe arteriopathy. One of the long-term objectives is to better screen patients at risk of being assessed for HAIDI before the creation of an AVF creation with the aim to prevent ischaemic issues (pain, necrosis, and digital ulcers).

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Table 1: Demographic table (n=24) Results expressed in number (percentage)

Variable	N = 24
Median age (years)	71.5 ± 19.6
Male	18 (75%)
Female	6 (25%)
BMI (kg/m <sup>2</sup> )	$27.5 \pm 6.2$
Non smoker	11 (45.8%)
Former smoker	11 (45.8%)
Current smoker	2 (8.3%)
Hypertension	22* (95.6%)
Hyperlipidemia	5* (21.7%)
Diabetes mellitus	
No	13* (56.5%)
Yes	10* (43.4%)
> 10 years	9 (90%)
< 10 years	1 (10%)
Congestive heart failure	6 (25%)
Coronary artery disease	10 (41.6%)
Stroke	4 (16.6%)
Myocardial infarction	10 (41.6%)
Peripheral Occlusive Arterial Disease	5 (20.8%)
Asymptomatic	4 (80%)
Symptomatic	1 (20%)
Aetiology of renal failure	
Hypertension	11 (45.8%)
Diabetes metillus	9 (37.5%)
Polycystic kidney disease	1 (4.1%)
Vasculitis	0
Glomerulonephritis	0
Other	8 (33.3%)
* Data for 23 patients	

Table 2 Doppler-US characteristics of upper limbs

Variable	N = 24
Calcifications	10 (41.6)
Incompressibility of ante-brachial arteries	9 (37.5)
Calcifications et incompressibility	7 (29.1)
Occluded ante-brachial artery (Allen +)	3 (12.5)
Arterial stenosis	1 (4.1)

#### FIGURE LEGENDS

Figure 1: Successive positioning of the laser Doppler and plethysmography probes on the pulps of all fingers (except the thumb). The patient was under a heated blanket (1a). All fingers were studied successively and bilaterally with LDF measurements of the two index fingers, then the two middle fingers, then the two ring fingers and then the two little fingers (1b). Then the measurements were taken with the PPG (1c). The details of the probe positions are shown here without the heating blanket for better visibility.

Figure 2. Representing values of FSBP on the right hand and the left hand with LDF (a) and PPG (b). In ordinate, FSBP in mmHg. In absciss, IF;MF;RF;LF representing in order the index finger, the middle finger, the ring finger, the little finger on each hand. Each patient is representing with a specific color.

Figure 3. Representing values of FBPI on the right hand and the left hand with LDF (a) and PPG (b). In ordinate, basal digital pressure in mmHg. In absciss, IF;MF;RF;LF representing in order the index finger, the middle finger, the ring finger, the little finger on each hand.

Figure 4. Representing the correlation between medians values (in mmHG) and averages of values (in mmHG) of FSBP (left) of each finger excluding thumbs and values of FBPI (right) with LDF (absciss) and PPG (Ordinate).

Figure 5. Diagram of Bland-Altman: difference between pressure values (in mmHg) measured with PPG and LDF against the means of both methods. 95% limits of agreement (dotted lines) of the differences are presented as horizontal lines.









