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ORIGINAL ARTICLE

Assessment of a smartphone app (Capstesia) for measuring pulse pressure variation: agreement between two methods

A Cross-sectional study

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BACKGROUND Less invasive and noninvasive methods are emerging for haemodynamic monitoring. Among them is Capstesia, a smartphone app that, from photographs of a patient monitor showing invasive arterial pressure, estimates advanced haemodynamic variables after digitising and analysing the pressure curves.

OBJECTIVE The aim of this study was to compare the level of agreement between the analysis of the signals obtained from the patient monitor and a photograph of the same images using the Capstesia app.

DESIGN Cross-sectional study.

SETTING Araba University hospital (Txagorritxu), Vitoria-Gasteiz, Alava, Spain, from January to February 2015.

PATIENTS Twenty patients (229 images) who had an arterial catheter (radial or femoral artery) inserted for haemodynamic monitoring.

INTERVENTION Snapshots obtained from the patient monitor and a photograph of these same snapshots using the Capstesia application were assessed with the same software (MATLAB, Mathworks, Natick, Massachusetats, USA) for evaluating the level of concordance of the following variables: pulse pressure variation (PPV), cardiac output (CO) and maximum slope of the pressure curve (dP/dt). Comparison was made using interclass correlation coefficients with corresponding 95% confidence intervals, and Bland–Altman plots with the corresponding percentages of error.

MAIN OUTCOME MEASURES (PPV). Secondary outcome: CO and maximum slope of the pressure curve [dP/dt].

RESULTS The interclass correlation coefficients for PPV, CO and max dP/dt were 0.991 (95% confidence interval 0.988 to 0.993), 0.966 (95% confidence interval 0.956 to 0.974) and 0.962 (95% confidence interval 0.950 to 0.970), respectively. In the Bland–Altman analysis, bias and limits of agreement of PPV were (0.50% ± 1.42) resulting in a percentage of error of 20% for PPV. For CO they were 0.19 ± 0.341, with a 13.8% of error. Finally bias and limits of agreement for max dP/dt were 1.33 ± 77.71, resulting in an error of 14.20%

CONCLUSIONS Photograph of the screenshots obtained with the Capstesia app show a good concordance with analysis of the original screenshots. Either approach could be used to monitor the haemodynamic variables assessed.

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Introduction

In recent years, it has been shown that haemodynamic goal-directed therapy (GDT) in surgical patients reduces perioperative morbidity and even mortality in very high-risk patients.[1] A recent Cochrane systematic review based on 31 different studies including more than 5000 patients provided evidence that GDT for patients undergoing surgery reduces postoperative complications and hospital stay.[1,2] The therapy aims to improve oxygen delivery to the tissues through the administration of fluids and inotropic agents.[3]

There are numerous methods for advanced haemodynamic monitoring, from pulmonary artery catheterisation to more recent, minimally invasive approaches such as

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pulse pressure analysis, transpulmonary thermodilution, oesophageal Doppler monitoring, thoracic electrical impedance and echocardiography.[4,5] In recent years, digital innovations have also been introduced.[6] Among methods that analyse the pulse pressure waveform, a new way to provide variables for assisting GDT has emerged in the form of an application for smartphones, Capstesia (Galenic App, Vitoria-Gasteiz, Spain). From photographs of the screen of a patient monitor showing invasive arterial pressure, the app estimates advanced haemodynamic variables such as cardiac output (CO), pulse pressure variation (PPV), maximum slope of the pressure curve (max dP/dt) after digitizing and analysing the pressure curves. However its effectiveness has yet to be properly evaluated.

Since the appearance of mobile phone networks in the 1980s, their use has grown exponentially; the International Telecommunication Union reported more than 7 billion subscriptions in 2015.[7] Mobile phones are proving increasingly useful in the provision of primary care, as they improve access and provide flexible responses to the needs of users (clinicians, healthcare managers and the general population). Notably, 80% of phones are now latest generation devices (smartphones). Further, more than 85% of health professionals worldwide use this type of technology and 30 to 50% use medical apps in their clinical practice.[8]

None of the currently available noninvasive techniques for GDT meet all the characteristics to be considered ideal. Namely, noninvasive, accurate, continuous, cost-effective, reliable, reproducible, comfortable for patients and clinicians, and with minimal adverse effects.[9,10] Given this, we consider that it is necessary to explore alternatives, and hence we decided to assess a new tool for the measurement of advanced haemodynamic variables, the Capstesia app, and compare this with direct analysis from the monitor.

Material and methods

Ethical approval for this study (Ethical Committee N° 2014–091) was provided by the Ethical Committee of Araba University Hospital, Vitoria-Gasteiz (Alava), Spain, on 21 December 2014. All participants or their legal representatives gave written informed consent prior to inclusion.

We carried out a cross-sectional study to assess the level of agreement between two methods for recording and measuring PPV using the same software and the same algorithm analysis, in patients who had an arterial catheter (radial or femoral artery) inserted for haemodynamic monitoring in an ICU at Araba University Hospital (Txagorritxu), between 1 January and 28 February 2015. Patients with atrial fibrillation were excluded.

Patient haemodynamic variables were monitored using Dräger Infinity C700© monitors (Drager Medical, Lübeck, Germany), set at a speed of 25 mm s^{-1} and were recorded on a web server for later retrieval and analysis. The Dräger Infinity Gateway Suite, an interface linking external applications with a web server, allowing the exchange of all types of files, text, audio and video among others, via the web was used to manage the files. The recorded signals were reproduced in ''real time'' on a remote computer where 30-s sections were reproduced, this time being long enough to ensure the acquisition of three complete screen snapshots of patient monitoring data. Subsequently, a photograph of these screenshots was taken using the Capstesia app.

The two methods under comparison were the analysis of Screenshots obtained directly from the patient monitor (performed by one of the research team) and of photographs of these same screenshots using the Capstesia smartphone app (performed by another member of the team). The analyses were performed off-line with the same software in both cases. These two analyses were performed independently and the results were then subjected to statistical analysis by another independent member of the team.

Both the screen snapshot and the photographs of the screen snapshots taken using Capstesia were analysed using MATLAB software (version R2009a). In the case of Capstesia, the image was sent through the Internet to the server.

The smartphone used with Capstesia was a Samsung Galaxy SIII (Samsung Electronics, Suwon, South Korea) which has an 8 MP photo camera. Capture of the screen image was not standardised at a fixed distance and a tripod was not used to improve stability of the image. To mimic the use of the application by any doctor in a clinical setting, the photographs taken of the screen by the hand-held smartphone were made parallel to the screen, as suggested by the manufacturer, and captured the entire monitor screen. For the comparisons, a single photograph was made with the smartphone of each of the each of the monitor screen snapshots.

The primary endpoint was the PPV% across each complete screen calculated using the following formula: $PPV\% = 100\ x\ (PPmax - PPmin)/[(PPmax + PPmin)/2]$.

The following variables were also recorded: sex, Sequential Organ Failure Assessment score, the type of access (radial/femoral), CO (l min^{-2}) calculated with the following formula: CO = stroke volume × heart rate; and max dP/dt (mmHg s^{-1}), both over each complete screen. To assess CO, we used the values of SBP and DBP and the heart rate that appeared at the end of each screen snapshot.

Statistical analysis

The expected PPV% values were 9.50% using the standard method (direct analysis of signals from the patient monitor) and 8.5% using Capstesia (photograph of the

screen snapshot), and we decided to set the threshold for agreement of PPV% at ± 2.5%. Hence, for a statistical power of 80% and a 95% confidence level, we estimated that we required a sample of 235 images to assess the level of agreement between the two methods for measuring PPV. Further, we estimated that around 20 to 25 patients who met the selection criteria would be admitted to the unit during the study period. Therefore, aiming to obtain a sample size of at least 235 images, we made four 30-s recordings for each patient, with a gap of at least 5 min between recordings.

Qualitative variables were expressed as percentages and 95% confidence intervals, and quantitative variables as means ± SD or medians and interquartile ranges depending on whether the variables were normally distributed.

To assess the level of agreement between the methods, we used intraclass correlation coefficients (ICCs), considering values of 0.75 to indicate very good agreement,[11] Bland and Altman methodology (bias-mean difference between both techniques, the limits of agreements 95% condifence interval (calculated as bias ± 1.96*SD), and percentage of error [calculated as 1.96 SD of bias/(mean1 + mean2/2)*100)] between test and reference method, considering the two methods interchangeable when the percentage of error between them was less or equal to 30%.[12]

The overall level of concordance was assessed both over the full range of PPV% values and by range (PPV% of ≤10, >10 and <15, and ≥15%).

IBM SPSS (IBM Corporation, New York, USA) (version 22.0) was used for performing the analysis and α was set at 0.05.

Results

Of the 240 images initially taken, in 9 there were errors in digitisation of the screenshots and these were excluded from the analysis. In two others the images were lost during the recording process leaving 229 images in the final analysis (Fig. 1). The 20 patients had a mean age of 69.55 (± 10.13 years and a mean Sequential Organ Failure Assessment score of 7.55 ± 5.88. Of the 20 patients, 75% ($n = 15$) were ventilated mechanically, this being controlled ventilation in 14 cases. Radial artery access was used in 80% of the patients ($n = 16$).

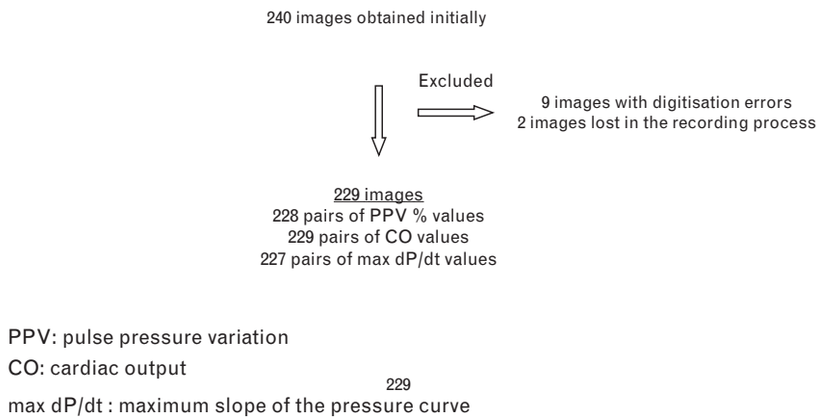
Data was not normally distributed for any of the variables analysed. The medians and interquartile ranges of each variable measured using each method can be seen in Table 1.

The analysis of the level of concordance between the methods is summarised in Table 2. In all cases, the ICCs were high, indicting a high or excellent level of agreement, and based on the Bland–Altman plot (Figs. 2–7), the mean of the differences between the results obtained with the two methods was small for PVV% (both overall and by ranges), for CO, and for max dP/dt. The error rate in all cases was less or equal than 20% except for values of PPV% less than 10% in which the error was higher, about 28%.

Discussion

Despite the recognised benefits of perioperative GDT the technology required has not been uniformly standardised.[13] Building on efforts to identify novel technologies for haemodynamic monitoring that are noninvasive, effective and safe, we have developed an application for smartphones (Capstesia), that can capture a photographic image of the arterial waveform from a screenshot of the patient monitor and subsequently by communicating with an off-line server, can provide values of PPV%, CO and max dP/dt. Our objective was to assess the degree of agreement between the analysis of the photograph taken from patient monitor and the direct analysis

Fig. 1



Flow diagram.

Table 1 Haemodynamic data

Haemodynamic data	*n*	Median	Interquartile range
Heart rate	228	87	22.75
SBP	228	124	29
DBP	228	58	14
$PPV\%_{smartphone}$	227	10.50	17.6
$PPV\%_{computer}$	227	10.08	16.7
$Cardiac\ output_{smartphone}$	228	5.04	1.44
$Cardiac\ output_{computer}$	228	4.83	1.51
maxdP/dt $_{smartphone}$	228	1063	342
maxdP/dt $_{computer}$	226	1076.50	272.25

maxdP/dt: maximum slope of the pressure curve; PPV, pulse pressure variation.

of the monitor screenshot with the same software. In the overall concordance analysis (using all the PPV% values), we obtained an ICC between the two methods of 0.991 (Table 2), which can be considered excellent,[11] indicating that either of the methods could be used.

Analysis of the Bland–Altman plot leads to a similar conclusion: the mean of the differences is small (0.50%), and the percentage of error is acceptable (20.01%), making the two methods interchangeable for the measurement of PPV%.[12] When we analysed by range of PPV% ($\leq$10, >10 and <15, $\geq$15%), the results were also similar. ICCs obtained in all the cases were greater than 0.75 (Table 2), indicating a high level of agreement,[11] and in all ranges of PPV% the percentage of error was less than or equal to 30%, making the two methods interchangeable.[12] With regards to CO and the maximum slope of the curve, results were also excellent, with ICCs of 0.966 and 0.962, respectively, and with a percentage of error about 14%.

Notably, we found clinically acceptable levels of agreement for low ($\leq$10%), moderate (10 to 15%) and high ($\geq$15%) values of PPV%. This indicates that the app is reliably independent of the magnitude of the variation, and can indicate to clinicians whether patients are responding to fluid therapy administered to increase their CO.[1] However, it is the intermediate range, considered a clinical grey area, where users require the greatest accuracy to guide treatment decisions, and for this range, we obtained the lowest ICC. Nevertheless, the ICC can still be regarded as a good result, being above 0.75, and its error percentage is acceptable (18.9%), so, we can consider the two methods interchangeable, even in this section of the PPV % range.

We should remember that the objective of this study was not to assess the accuracy or precision of the haemodynamic variables analysed, but rather to assess whether the Capstesia app (taking photographs of the monitor screenshots using smartphones, together with software and calculation algorithms,) is valid, from a clinical point of view, and whether the analysis of these photographs provides similar results to the traditional method of recording and analysis.

There are differences between the two methods that might be due to two main factors: first, we did not standardise the distance between the monitor screen and the smartphone when taking the hand held photographic images; instead we have reproduced normal clinical conditions. The absence of perfect parallelism between the monitor screen and smartphone can lead to distortions in perspective but the software can compensate for this. Second, the appearance of light reflections on the screen could also distort signal digitisation, although this phenomenon is easily verifiable by observing the scanned image.

The results obtained with the Samsung Galaxy SIII, could have been obtained with any other smartphone, provided it meets a minimum specification. The number of megapixels in the screens of smartphones marketed today are more than sufficient to meet the requirements of the Nyquist frequency for a medical signal, so this factor should not affect the outcome.[14]

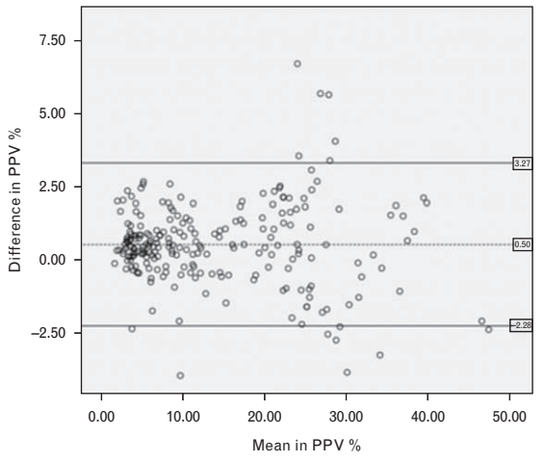
Each of the variables has been analysed by studying the pulse pressure waves displayed on a full screen of the monitor, at a standard speed of 25 mm s^{-1}, which in our case corresponded to 9 s. This would imply that if a patient's respiratory rate were to be slower than seven breaths per minute, the arterial pulse pressure waves studied would not correspond to a complete respiratory cycle, thus reducing the clinical validity of the PPV%

Table 2 Concordance between the methods (smartphone app vs. computer-based approach)

Values compared	Sample	ICC (95% CI)	Mean of the differences (%)	SD of the differences (%)	Limits of agreement (%)	Error percentage (1,96*SD/mean)
$PPV\%_{smartphone}$-$PPV\%_{computer}$	Full range of PPV% values	0.991 (0.988–0.993)	0.50	1.42	3.27;−2.28	20,01%
	PPV% $\leq$10%	0.929 (0.898–0.950)	0.56	0.85	2.23; −1.11	28,70%
	PPV% >10% and <15	0.769 (0.554–0.888)	−0.0052	1.16	2.27; −2.28	18,94%
	PPV% $\geq$15%	0.958 (0.936–0.972)	0.56	1.96	4.40; −3.28	15,10%
$CO_{smartphone}$-$CO_{computer}$	Full range of CO values	0.966 (0.956–0.974)	0.19	0.341	0.86; −0.48	13,8%
$maxdP/dt_{smartphone}$-$maxdP/dt_{computer}$	Full range of maxdP/dt values	0.962 (0.950–0.970)	1.33	77.71	153.64; −151	14,20%

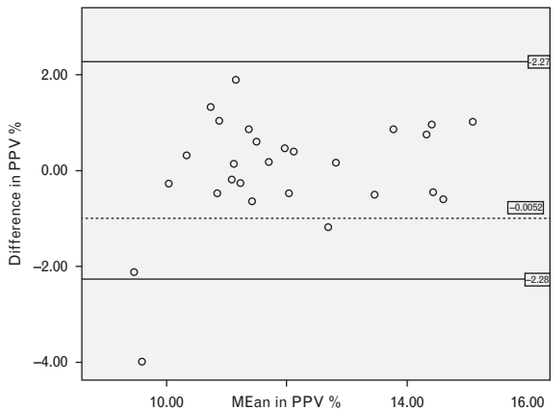
CO, cardiac output; maxdP/dt: maximum slope of the pressure curve; PPV, pulse pressure variation.

Fig. 2



Bland–Altman plot for the full range of PPV% values. CO, cardiac output; maxdP/dt: maximum slope of the pressure curve; PPV, pulse pressure variation.

Fig. 4



Bland–Altman plot for PPV% values >10 and <15%. PPV, pulse pressure variation

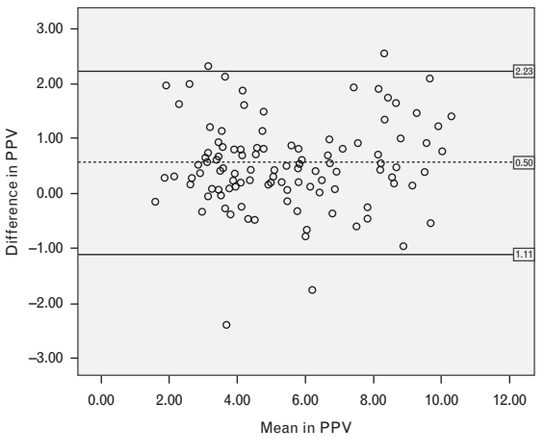
results. However, if we half the sweep speed of the monitor, to 12.5 mm s^{-1}, the arterial pulse pressure waves shown would extend over 15 to 20 s, depending on the type of monitor used, but in most cases this would then be sufficient to include at least 3 to 5 respiratory cycles, as recommended for analysis of PPV.[15]

The clinical validity of the Capstesia app should now be assessed in trials comparing its results with those of the standard technology, as has been done for PPV%. Because the correlation between the app and the standard method is acceptable it mean that the app could be put into use merely by implementing algorithms already validated. The method would even be applicable to the pulse plethysmograph wave, and allow the variation in the plethysmographic trace to be calculated , in a similar way to PPV%.[10]

To conclude, the present study demonstrates that the Capstesia app analysis based on data, extracted from a photograph of a monitor screen snapshot taken using a smartphone, has a sufficiently good level of agreement with the analysis of the screen snapshot itself. Thus it is possible to use either of the methods to monitor the haemodynamic variables under study.

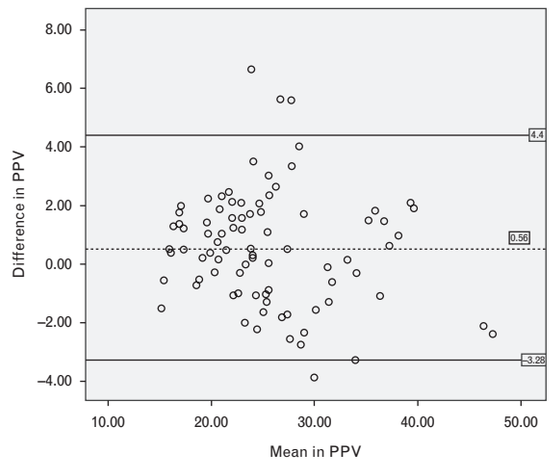
The novelty of the Capstesia app in advanced haemodynamic monitoring lies mainly in the concept it illustrates: the obtaining of haemodynamic data though analysis of a

Fig. 3



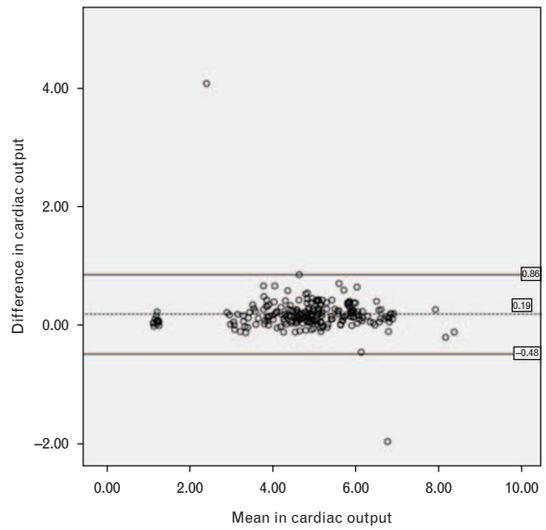
Bland–Altman plot for PPV values ≤10%. PPV, pulse pressure variation.

Fig. 5



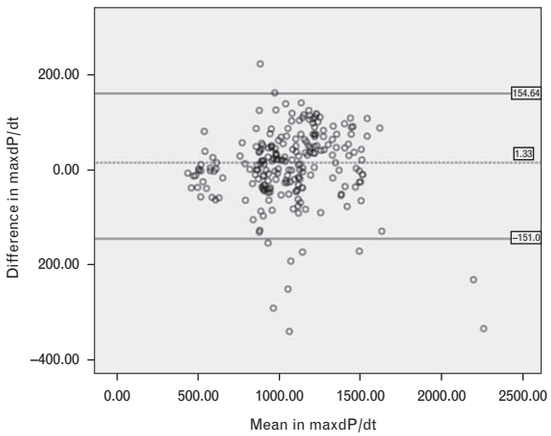
Bland–Altman plot for PPV values ≥15%. PPV, pulse pressure variation

Fig. 6



Bland–Altman plot for cardiac output.

Fig. 7



Bland–Altman plot for max dP/dt. maxdP/dt: maximum slope of the pressure curve.

photograph taken smartphone. It represents a simple and accessible option for directing GDT in our patients.

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Conflicts of interest: B B and C V are co-founders of Galenic App S.L., the company that has developed 'Capstesia App'.

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