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Blood pressure variability and stroke outcome in patients with internal carotid artery occlusion

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ABSTRACT

Purpose: The aim of this study was to evaluate the relationship between arterial blood pressure (BP) variability during the acute phase and the 3-month outcome in ischemic stroke patients with internal carotid artery (ICA) occlusion.
Methods: At least 10 BP measurements during the first 48 h after stroke onset were obtained in 89 patients with ICA occlusion. BP profile was described using various parameters: average of recordings, maximum (max), minimum (min), difference between max and min (max − min), standard deviation (SD) and coefficient of variation (CV) for both systolic and diastolic BP. Outcome at 3 months was defined using the modified Rankin Scale (mRS) score corrected for baseline stroke severity.
Results: Fifty-five patients had a good and 34 a poor outcome. Max values, max − min, SD and CV of both systolic and diastolic BP resulted significantly higher in patients with poor outcome compared to those with good outcome ($p < 0.05$, multivariate adjusted model).
Conclusions: In a cohort of acute ischemic stroke patients with ipsilateral ICA occlusion BP variability, assessed in the acute phase, was associated with poor clinical outcome. These preliminary exploratory findings are worthy of further study to be conducted to confirm or confute the role of BP variability in predicting stroke outcome. In order to obtain more comprehensive information, it would also be appropriate to consider the possibility of acquiring data related to the pathophysiology of stroke and to cerebral hemodynamic changes.
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1. Introduction

An elevated blood pressure (BP), which often declines spontaneously, is seen on presentation in most patients with acute ischemic stroke [1,2].

Most studies, although not all, have found that high BP in the acute phase of stroke is associated with a poor outcome [3,4]. Observational and interventional studies of management of acute post-stroke hypertension yield conflicting results [5–7] and yet there is no reliable evidence to guide the management of BP during the acute phase of stroke.

Whether high BP in acute stroke is a physiological and protective reaction or a harmful generalized stress response and whether it should be lowered or not, remains an unsolved issue in acute stroke management [8].

In the lack of definitive evidence about the most appropriate approach, there is a general consensus to avoid BP reduction in the first hours after an ischemic stroke unless very critical levels are reached [9].

Previous research suggested that proper BP management in acute stroke may need to take into account the underlying etiology [10,11]. Consistently, while there is evidence about the negative impact of high BP in patients with lacunar stroke [12], some pathophysiological observations have suggested the possible detrimental effect of lowering BP in patients with persistent large-vessel occlusion [13].

Furthermore, recent observations suggested that fluctuations or "variability" of BP in the first hours after stroke onset may be more relevant for prognosis than high BP per se [11,14]. A precise definition of this last aspect could have implication for a better management especially during the acute phase.

The aim of this study was to investigate how different components of BP, including BP variability, assessed in acute ischemic stroke patients relate to a 3-month clinical outcome. For this investigation, we selected patients with internal carotid artery (ICA) occlusion, intrinsically more vulnerable to BP fluctuations and in which BP reduction may precipitate chronically impaired cerebral perfusion.

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2. Methods

We prospectively evaluated consecutive patients with acute ischemic stroke ipsilateral to an ICA occlusion.

The study was approved by the ethics committee of the Marche Polytechnic University. All participants and/or caregivers gave their informed written consent according to the Declaration of Helsinki.

Inclusion criteria were clinical and neuroimaging diagnosis of acute ischemic stroke in the presence of an ipsilateral ICA occlusion as evidenced by a Carotid Duplex ultrasound test performed within the first hours after admission to the hospital and defined as no detectable patent lumen at gray-scale ultrasound and no flow with spectral, power, and color Doppler ultrasound [15]. In each patient enrolled in the study the diagnosis of ICA occlusion was confirmed by repeating a Carotid Duplex ultrasound test within 24 h from the enrollment. In a subgroup of patients, a follow-up vascular imaging MR or CT angiography within 72 h from admission, according to the standard of care and independently from our study, was performed.

The only exclusion criterion was heart failure defined as the left ventricular ejection fraction below 50%.

This was an observational study and the study procedure did not interfere with the clinical management of any of the acute stroke patients enrolled. Each patient received the best standard care available at our institution and according to the current guidelines [9]. Specifically, with respect to the treatment of acute hypertension post-stroke, a treatment algorithm based on national guidelines has been followed in all cases [16].

In all patients, supine BP was measured in the non-paralyzed arm using a manually standard mercury sphygmomanometer every 4 h from the time of admission to the stroke unit until 48 h since the onset of the stroke.

The BP profile was described using various parameters for each systolic (SBP) and diastolic blood pressure (DBP) value: average of all recordings (mean), maximum (max), minimum (min), difference between max and min (max − min), standard deviation (SD) and coefficient of variation (CV) [10].

As per study protocol, we recorded the following variables: patients' demographics, stroke lesion hemispheric side, stroke subtype according to the Oxford Classification [17]: total anterior (TACS) or partial anterior circulation stroke (PACS), medications before stroke occurrence, vascular risk factors including history of prior stroke and heart disease, and stroke severity at baseline defined by the National Institute of Health Stroke Scale (NIHSS) [18] score.

The clinical outcome measure was assessed using the modified Rankin Scale (mRS) score at 3 months [19]. Two certified blinded assessors measured the mRS score in all subjects. We used a baseline severity-adjusted dichotomization to define functional outcome for improving study power [10,20,21]. Poor outcome was defined as a 3-month mRS score of 2 to 6 if the baseline NIHSS score was ≤7 points, a 3-month mRS score of 3 to 6 if the NIHSS score was 8 to 14 points, and a 3-month mRS score of 4 to 6 if the NIHSS score was ≥15 points.

Post-hoc power analysis showed, for a sample of 89 subjects in a MANOVA model with 12 response variables, two groups and an α set of 0.05, a power of 0.85 and an effect size (f^2) of 0.25. In order to identify the possible influence of BP variability in the acute phase on 3-month functional disability (mRS score), the dataset was subdivided into two different outcome groups including patients with good and poor outcome, respectively. Differences in baseline characteristics of the sample between the outcome groups were evaluated with chi-squared test for dichotomous variables and with *t*-test for independent samples for continuous variables. Ordinal variables were compared with the nonparametric median test.

The differences between the two outcome groups for average (mean), maximum (max), minimum (min), difference between max and min (max − min), standard deviation (SD) and coefficient of variation (CV) for both systolic BP (SBP) and diastolic BP (DBP) were analyzed with a *t*-test for independent samples. The difference among groups was also evaluated with a multivariate, unadjusted model. In order to predict functional outcome from baseline hemodynamic variables, the multivariate/adjusted model was set up to evaluate differences between outcome groups accounting for age, sex, hypertension, diabetes, smoking, dyslipidemia, side and ischemic lesion subtype according to the Oxford classification of stroke (TACS/PACS) [19]. We also performed a multivariate analysis to evaluate whether SBP variability was associated with the 3-month functional outcome independently of other BP components. For this analysis, only SBP indices (SBP max, mean, min, CV, max − min and SD) were included, adjusting for the same covariates used in the previous model.

In order to internally validate the outcome measure (mRS weighted by baseline NIHSS score) we also performed a multivariate model accounting of mRS score (binary: ≤2 for good outcome or >2 for poor outcome) at 3 months as outcome variable and baseline NIHSS score as covariate, maintaining all the covariates and risk factors used in the multivariate adjusted model. Statistical analysis was performed with the SPSS 13.0 package for Windows systems, and power analysis was performed with G*Power 3.1 for Windows systems.

3. Results

During the study period, 103 patients with acute ischemic stroke and ipsilateral ICA occlusion were considered for enrolment in the study. Four were excluded due to the presence of heart failure. Out of 99 included, 10 were lost at follow-up. In all subjects, the initial ultrasound-based diagnosis of ICA occlusion was confirmed by the second Carotid Duplex ultrasound test. Reliability of diagnostic ultrasound accuracy was further confirmed by the results of CT or MRI angiography performed in 54% of patients (36 and 12 patients respectively).

The final analysis included 89 patients. Time from stroke onset to admission to the hospital ranged from 7 to 9 h (mean: 8.1 ± 1.3 SD). None of these patients were treated with intravenous thrombolysis, all patients being admitted outside the approved treatment time window.

At least 10 BP measurements were taken for each patient during the first 48 h after stroke onset (41–37 h after enrolment). At 3 months fifty-five patients had a good outcome and 34 had a poor outcome. Comparisons of baseline characteristics between the two groups are reported in Table 1. No significant difference was found between the two groups, including median value of baseline NIHSS scores (9.5 vs. 8; $p = 0.222$, median test). Median NIHSS score resulted significantly different at the 3-month evaluation (3 vs. 8, $p < 0.001$, median test). Blood pressure measurements are reported in Table 2.

Student's *t*-test for independent samples and multivariate unadjusted model showed that values of mean DBP, SBP and DBP max values, max − min values, SD and CV of SBP and DBP were significantly higher in the poor outcome group compared to those with good outcome. Mean DBP was no longer significantly different, while the difference

Table 1
Comparisons of baseline characteristics according to a 3-month functional outcome based on mRS score corrected for entry NIHSS score.

Characteristics	Good outcome	Poor outcome	*p*
Age, years ± SD	67.25 ± 9.86	69.85 ± 8.39	0.205
Male	63.6%	58.8%	0.661
TACS	30.9%	35.3%	0.816
Side: right	50.9%	52.9%	0.999
Entry NIHSS (median)	8	9.5	0.222
Three-month NIHSS (median)	3	6	<0.001
Hypertension	65.5%	52.9%	0.270
Diabetes	30.9%	26.5%	0.811
Dyslipidemia	32.7%	35.3%	0.821
Smoking	25.5%	26.5%	0.999

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