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Gaze deviation and paresis score (GPS) sufficiently predicts emergent large vessel occluding strokes

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Running title: GPS for ELVO in AIS patients

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ABSTRACT

Background: The prognosis of patients with acute ischemic stroke (AIS) essentially depends on both prompt diagnosis and appropriate treatment. Endovascular stroke therapy (EST) proved to be highly efficient in the treatment of emergent large vessel occluding (ELVO) strokes in the anterior circulation. To achieve a timely diagnosis, a robust combination of few and simple signs to identify ELVOs in AIS patients applicable by paramedics in the prehospital triage is worthwhile.

Methods: This retrospective single-center study included 904 AIS patients (324 ELVO, 580 non-ELVO) admitted between 2010 and 2015 in a tertiary stroke center. We re-evaluated two symptoms based on NIHSS items, gaze deviation and hemiparesis of the limbs ("Gaze deviation and Paresis Score, GPS") for the pre-hospital prediction of ELVO.

Results: A positive GPS AIS in patients predicted ELVO with a sensitivity of 0.89, specificity = 0.97, positive predictive value (PPV) = 0.95, negative predictive value (NPV) = 0.94 and diagnostic odds ratio (DOR) = 34.25 (CI: 20.75 - 56.53). The positive Likelihood-ratio (LR+) was 29.67, the negative Likelihood ratio (LR-) 0.11. NIHSS of patients with positive GPS (gaze palsy NIHSS ≥ 0 , Motor arm NIHSS ≥ 2 and Motor leg NIHSS ≥ 2) was markedly higher compared to negative GPS patients ($p < 0.001$).

Conclusions: The GPS proved to be similarly accurate in detecting ELVO in the anterior circulation of AIS patients and even more specific than other published clinical scores. Its simplicity and clarity might enable non-neurological medical staff to identify ELVO AIS patients with high certainty in a preclinical setting.

Key words: Acute ischemic stroke, AIS, ELVO, EST, gaze deviation, hemiparesis, NIHSS

BACKGROUND

For decades, stroke has remained one of the leading causes of death and disability in the world [1-3]. Reperfusion modalities using systemic thrombolysis (intravenous tissue plasminogen activator [tPA]) and endovascular stroke therapy (EST) are the only established treatment options for acute ischemic stroke (AIS) [4-6]. The latter has become essential in the treatment of large vessel occlusions (ELVO) of the anterior circulation [7]. Both approaches depend profoundly on early initiation after onset of symptoms to ensure the best possible outcome [5]. While intravenous thrombolysis has been made widely available, EST requires specialized interdisciplinary expertise and technical equipment in comprehensive stroke centers (CSC) [8, 9]. The initial transport of AIS patients with ELVO to a non-EST center and subsequent secondary transfer to a center with EST expertise yields worse outcomes than direct referrals, even when longer distances were required [9-11]. To minimize delays, reliable prehospital identification of ELVOs in AIS patients would be required. Numerous prehospital stroke scales, including the Cincinnati Prehospital Stroke Severity (CPSS) scale, Field Assessment Stroke Triage for Emergency Destination (FAST-ED), and Prehospital Acute Stroke Severity scale (PASS), exist to identify the presence ELVO in AIS patients [12-14]. These recently published scales utilize simplifications of 3 and more items from the National Institutes of Health Stroke Scale (NIHSS) to optimize prediction of ELVO [15]. However, their application require a degree of (neurological) expertise and most of them have not yet undergone paramedic validation studies. In particular, screenings comprising several NIHSS items and a graduated evaluation of each item may hamper the appliance of the prehospital stroke scales for non-physicians in an emergency situation. Since gaze deviation and hemiparesis are both commonly observed in ELVO AIS patients[16], we analyzed the accuracy of the gaze

deviation and paresis score (GPS) as a prehospital predictor for the presence of ELVO in a retrospective study.

METHODS

Study population: A retrospective observational cohort analysis of patients presenting with acute ischemic stroke (AIS) in the Department of Neurology, RWTH Aachen University, tertiary university stroke center, was conducted. The analysis was based on a prospective stroke registry of all consecutive patients of the RWTH University Hospital Aachen (Germany) Tertiary Stroke Center [17]. A total of 1211 AIS patients receiving any kind of acute reperfusion therapy between January 2010 and May 2015 were identified. The available clinical documentation and the individual National Institutes of Health Stroke Scale (NIHSS [18]) at presentation were reviewed (Fig. 1A). The included ELVOs were located in the internal carotid arteria (ICA) (9.3%), terminal ICA (26.2%) and middle cerebral artery (MCA) (M1 (45.7%) and proximal M2 level (M1/2) (16.1%)). Patients with the following characteristics were excluded: missing diagnostical angiography by CT or MR (n=28), AIS in the posterior circulation (n=139), intubation at the time of diagnostics (n=103), miscellaneous (4 children, 1 oncological patient and 1 patient with cerebral venous sinus thrombosis) and in the clinical course confirmed stroke mimics (n=17) (seizure (n=9), migraine (n=4), vestibular neuronitis (n=2), Lyme disease (n=1), syndrome of delirium (n=1)) as well as missing or incomplete documentation (n=16) (Figure 1A).

Data: Baseline characteristics were collected from the patients' medical records. This included demographic characteristics (age, sex), stroke severity (NIHSS [18]), disability at admission (mRS [19]) and medical history which comprised risk factors for cerebrovascular complications, prophylactic use of antiplatelet or anticoagulant medication, International Normalized Ratio (INR) and serum glucose at admission, ischemic stroke classification (adapted from TOAST [20]), days of hospitalization,

number of patients admitted to the stroke unit and stroke-specific complications (pneumonia, re-stroke during hospital stay, decompressive craniectomy). Also, the number of patients receiving intravenous recombinant tissue plasminogen activator (IVRTPA) or endovascular stroke treatment (EST) solely or in combination with IVRTPA.

Test design: Considering the typical symptoms of AIS following ELVO and our intention to establish a test that can also be performed by non-medical personnel, we selected the NIHSS-items gaze deviation (NIHSS ≥ 1) and hemiparesis (NIHSS-Motor Arm and Motor leg (left and/or right ≥ 2)) as a prehospital test to predict ELVO in AIS patients. GPS was compared to the following previously published tests, that were also based on only NIHSS criteria: PASS [12], FAST-ED [13] and CPSS [14]. The following proposed cut-off values of the single tests were used: PASS: ≥ 2 ; FAST-ED: ≥ 4 ; CPSS: ≥ 2 .

Statistics: All statistical tests were performed using JMP(R), Version 10. SAS Institute Inc., Cary, NC, USA, 1989–2007. Residuals were analysed for normal distribution using the Shapiro-Wilk normality test and variance homogeneity was tested using the Bartlett test. Intergroup differences were tested by Mann-Whitney U test when applicable. Cross tables were used to evaluate sensitivity, specificity, positive and negative predictive value, diagnostic odds ratio (DOR) [21] and likelihood ratios. Data were expressed in patient numbers, mean value and standard deviation. Median, interquartile range, and percentage were given in brackets when applicable. The level of significance was set as $p < 0.05$. The numbers of included patients are given in the figures.

RESULTS

To assess the predictive power of the gaze deviation and hemiparesis score (GPS) as a prehospital test to identify ELVOs in AIS patients, we included a total of 904 (74.7%) AIS patients (male sex: 53%; median age, 72.3 years; IQR, 63.3 – 82.3 years). Baseline characteristics of the AIS patients are indicated in table 1. Within the study population, 324 AIS patients comprised the group of ELVO patients (154 male) and 580 the group of non-ELVO patients (325 male) (Fig. 1A). The median NIHSS of the examined population was 10 (IQR: 5-15).

Overall, AIS patients with ELVO exhibited significantly higher NIHSS compared to non-ELVO patients (median \pm SD; 16 ± 3.8 vs. 6 ± 4.6 , $p < 0.001$) (Fig. 1B). Among the 904 AIS patients, 302 presented a positive GPS (gaze palsy NIHSS ≥ 0 , Motor arm NIHSS ≥ 2 and Motor leg NIHSS ≥ 2). In total 288 of the AIS patients (95%) tested positive for GPS were in the ELVO group and 565 AIS patients (94%) tested negative for GPS were in the non-ELVO group (Fig. 2A).

The majority of ELVO were found in the terminal ICA (23.9%) and the M1 segment of the middle cerebral artery (39.4%). The NIHSS of GPS positive AIS patients (median 17, IQR: 14 - 19) was significantly higher compared to the negative cohort (median 6, IQR: 4 - 11, $p < 0.001$) (Fig. 2B). Similarly, mRS on admission was significantly higher in this group (positive GPS median: 5 vs. negative GPS median: 4; $p < 0.001$). GPS positive AIS patients had a longer hospital stay compared to negative tested patients (median: 15 vs. 8 days, $p < 0.001$) and were more likely to develop pneumonia[22].

Using crosstab calculation, we determined a sensitivity of 89%, a specificity of 97%, a positive predictive value (PPV) of 95%, a negative predictive value (NPV) of 94% and a Diagnostic odds ratio [21] (DOR) of 34.3 for a positive GPS in ELVO AIS patients. While the positive Likelihood-ratio (LR+) was 29.67, the negative Likelihood ratio (LR-

) was 0.11 (Table 2). Predictive values of the other scores (PASS, CPSS, FAST ED) are summarized in table 2.

DISCUSSION

We developed a simple and rapid prehospital score using two symptoms based on the NIHSS items, gaze palsy and hemiparesis (gaze deviation and paresis score- GPS), to reliably diagnose ELVO in the anterior circulation of AIS patients. Within the AIS study cohort, ELVOs were identified using GPS with a sensitivity of 89% and a specificity of 97%. AIS patients with ELVO identified by GPS revealed severe deficits (median NIHSS 17) compared to the negative tested patients (median NIHSS 6) (Fig. 1B). The median NIHSS of the 15 GPS positive non-ELVO patients (false positive) was 13, while the remaining 565 non-ELVO patients exhibited a median NIHSS of 6. This indicates that severe neurological impairments in non-ELVO patients might also be identified by the GPS in the prehospital setting.

In comparison to other prehospital ELVO triage scales such as CPSSS, FAST-ED, or PASS, which also utilize simplifications of NIHSS items to identify ELVOs, GPS exhibited a sensitivity of about 90%, revealed similar good negative but better positive predictive values and a better diagnostic odds ratio. The specificity of GPS even exceeded the other scales (Table 2). The high specificity especially ensures that only a small number of non-ELVO patients will risk potential delays in receiving IVRTPA by being directly transported to a more distant comprehensive stroke center. Turc and colleagues [23] demonstrated that by optimizing the cutoffs to obtain less than 10% false negative test results, the current simple predictive scales over-diagnosed ELVO from 46% up to 100%. Although the number of false positives can be reduced with increasing NIHSS items and corresponding complexity, implementation in the preclinical setting and by non-neurologically trained personnel becomes more difficult. Most of the NIHSS derived prehospital ELVO scales are comprised of at least 3 different assessments, some with gradations [13, 24] or patients have to gain a

minimum of points [12, 14]. Yet they yielded no superiority in direct comparison with one another in a meta-analysis [25]. Furthermore, the complexity of some of the previous ELVO scales would require paramedics to score as accurately as neurologists[9]. This is reflected in the paramedics validations of RACE (The Rapid Arterial Occlusion Scale) and LAMS (Los Angeles Motor Scale), where the paramedics, despite training, scored with significantly lower accuracy compared to specificities for ELVO identification assessed by physicians [24, 26, 27]. Thus, we focused on two symptoms of NIHSS items only to facilitate a simple and rapid identification of ELVOs in the prehospital setting by medical personnel without neurovascular expertise. The combination of these two prominent clinical symptoms after AIS as predictive ELVO triage is highly suitable, since gaze deviation occurs mainly after major infarctions with affection of several brain regions and hemiparesis of both arm and leg (NIHSS ≥ 2) as a sign of lacunar/cortical dysfunction can be easily identified even by staff not highly specialized in neurology [28-31]. Accordingly, the PASS study showed that abnormal gaze comprising gaze palsy and gaze deviation, alone accounted for identifying more than half of all the patients with verified occlusion on CTA or MRA with a high specificity. Furthermore, gaze deviation has been suggested as a predictor of short-term mortality and disability after stroke and has even been independently associated with the presence of ELVO in the anterior circulation by some authors recently [16, 30, 32].

Due to the high accuracy in the identification of ELVO in anterior circulation and its simplicity, GPS seems to be a very promising candidate for a prehospital test. However, some limitations of this study should be addressed. In our retrospective study, all patients had a confirmed AIS receiving intravenous tPA or EST. An application of GPS in an unselected patient cohort with suspicion of stroke would presumably lead to misclassification of stroke mimics and hemorrhagic strokes,

whereby the latter would certainly also benefit from early care in a comprehensive stroke center with advanced diagnostic imaging and neurocritical care. Furthermore, ELVOs in posterior circulation were not considered in our study and GPS was performed by experienced doctors at the time of admission to hospital. Therefore, it is necessary to test the practicability and validity of the GPS in terms of its speed, simplicity, interrater reliability and accuracy compared to previous prehospital scales in external data sets first. Subsequently, the test should be applied in the prehospital setting by neurologists and non-neurological medical personnel. This requires further prospective randomized trials, which could also provide information about the benefit of prehospital scores that identify patients with ELVO who are likely to respond to EST and their clinical outcomes. A timely care of ELVO patients in comprehensive stroke centers is not questioned, but whether a drip- and-ship versus mother-ship approach based on a prehospital ELVO score should be applied, has not been sufficiently investigated to date. Mohamad et al. demonstrated that when a preclinical protocol is established time delay reaching the CSC as well as in-hospital delay is not significant[10]. From our point of view a "drip-and-ship" policy described by Weber et al.[33] is only applicable in regions with high concentration of primary stroke center (PSC) and nearby CSC. Care of AIS needs to be adapted to local circumstances. In rural areas, a triage of direct transport to an EST center may be necessary and greatly facilitated by easy to use clinical scores such as GPS to identify LVO. The ongoing SWIFT DIRECT will provide further information on this issue.

List of Abbreviations:

AIS = acute ischemic stroke; CSC = comprehensive stroke centers; CPSS = Cincinnati Prehospital Stroke Severity Scale; DOR = Diagnostic Odds Ratio; EST = endovascular stroke therapy; ELVO = Emergent large vessel occlusion; FAST-ED = Field Assessment Stroke Triage for Emergency Destination; ICA = Internal carotid artery; INR = International normalized ratio; IQR = Interquartile range; IVRTPA = Intravenous recombinant tissue plasminogen activator; LR- = Negative Likelihood-ratio; LR+ = Positive Likelihood-ratio; MCA = Middle cerebral artery; mRS = Modified Rankin Scale; NIHSS = NIH Stroke Scale; PASS = Prehospital Acute Severity Scale; PSC = Primary stroke center; RACE = Rapid Arterial Occlusion Evaluation Scale; TOAST = Trial of Org 10172 in Acute Stroke Treatment

Declarations

Ethics Approval and Consent to Participate

This retrospective observational cohort analysis was approved by the local institutional ethics committee of the Medical Faculty, RWTH Aachen University, Aachen, Germany (EK 335/15) in accordance to the Declaration of Helsinki and the Guideline for Good Clinical Practice. All participants signed informed consent.

Consent for publication

This study does not include images or other personal or clinical details of participants that compromise anonymity. With their consent to participate, all patients have also signed a written consent to publish their data anonymously.

Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request

Competing interests

The authors declare no competing interests.

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Authors' contributions

Conceptualization: PH, JB, AR; methodology: PH, JB, AR; investigation/experiments: JB, PH; validation: KS, ON; formal analysis: MW, JBS; visualization: PH, AK, GW; resources: JBS; original draft preparation: PH, JB, AR; review and editing: PH, JB, AR, ON, KS, JBS, MW; supervision: AR;. All authors have read and approved the manuscript

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Figures and Tables

Table 1. Baseline characteristics of the study population

NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale; TOAST, Trial of ORG 10172 in Acute Stroke Treatment; SD, standard deviation; IQR, interquartile range; EST, endovascular therapy; IVRTPA, intravenous tissue plasminogen activator.

Table 2. GPS in comparison with other predictive scores.

GPS compared with other predictive tests including PASS, CPSS, FAST-ED and RACE in AIS patients. DOR: diagnostic odds ratio; PPV: Positive predictive Value; NPV: Negative predictive Value; LR+: positive likelihood ratio; LR-: negative likelihood ratio.

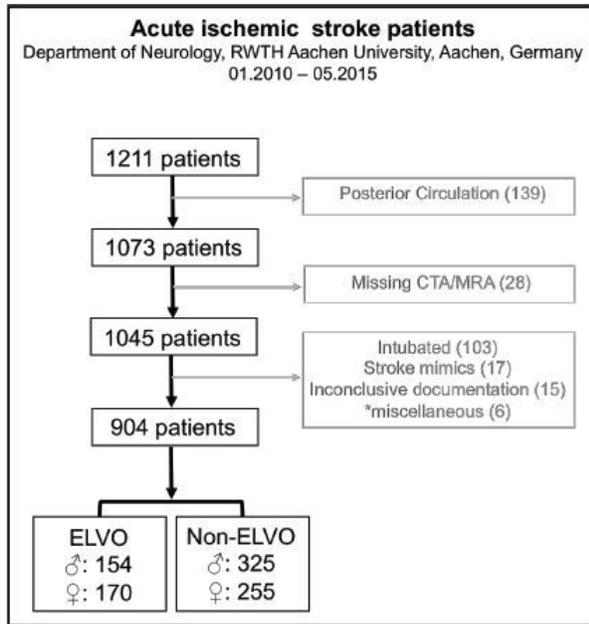
Figure 1. Increased NIHSS in ELVO patients compared to non-ELVO patients

(A) Flowchart of the study population. A total of 904 AIS patients (324 ELVO, 580 non-ELVO) between 2010 and 2015 from the RWTH Aachen University stroke registry. *miscellaneous: 4 children, 1 oncological patient and 1 patient with cerebral venous sinus thrombosis **(B)** NIHSS of AIS patients with or without ELVO in the anterior circulation is given. Mann-Whitney U test (ELVO vs. non-ELVO, * $p < 0.0001$).

Figure 2. Accuracy of GPS in prediction of ELVO in AIS patients. (A) GPS positive (ELVO/non-ELVO; 288/15) and negative (ELVO/non-ELVO; 37/565) AIS patients are shown. **(B)** Whisker-blot highlighting the impact of GPS on NIHSS of AIS patients. Mann-Whitney U test (ELVO vs. non-ELVO; * $p < 0.0001$).

Figures

A



B

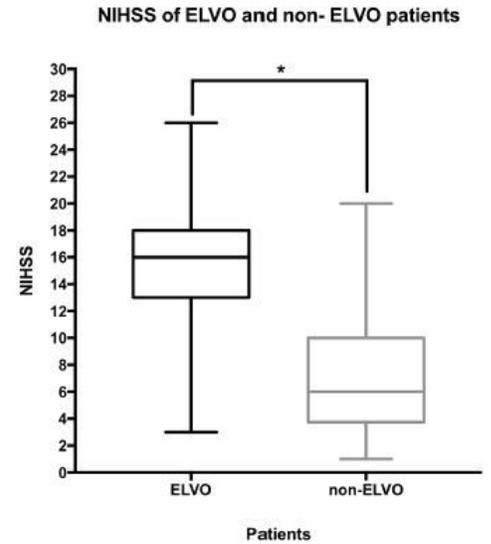
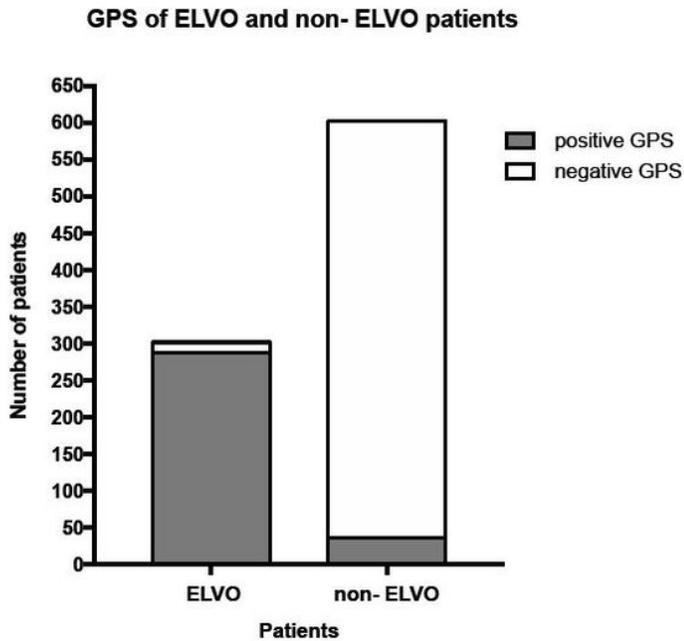
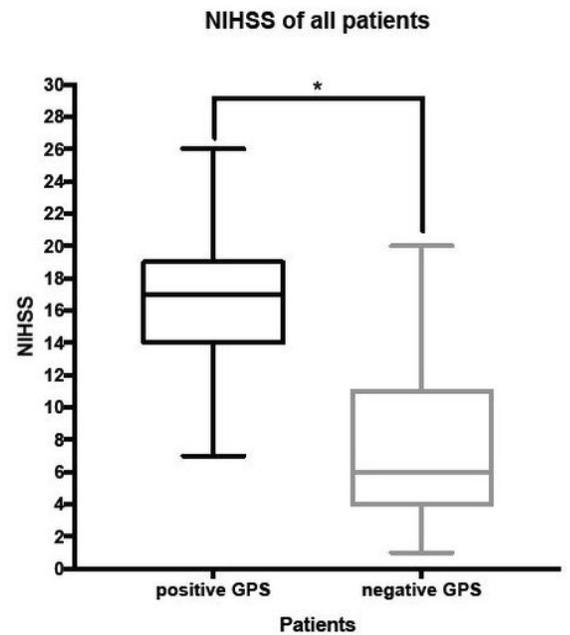


Figure 1

Increased NIHSS in ELVO patients compared to non-ELVO patients (A) Flowchart of the study population. A total of 904 AIS patients (324 ELVO, 580 non-ELVO) between 2010 and 2015 from the RWTH Aachen University stroke registry. *miscellaneous: 4 children, 1 oncological patient and 1 patient with cerebral venous sinus thrombosis (B) NIHSS of AIS patients with or without ELVO in the anterior circulation is given. Mann-Whitney U test (ELVO vs. non-ELVO, * $p < 0.0001$).

A**B****Figure 2**

Accuracy of GPS in prediction of ELVO in AIS patients. (A) GPS positive (ELVO/non-ELVO; 288/15) and negative (ELVO/non-ELVO; 37/565) AIS patients are shown. (B) Whisker-blot highlighting the impact of GPS on NIHSS of AIS patients. Mann-Whitney U test (ELVO vs. non-ELVO; * $p < 0.0001$).

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