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The herniation WFNS scale improves prediction of outcome in poor-grade aneurysmal subarachnoid haemorrhage patients

Andreas Raabe, MD	Department of Neurosurgery, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland	Andreas.raabe@insel.ch
Jürgen Beck, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	j.beck@uniklinik-freiburg.de
Johannes Goldberg, MD	Department of Neurosurgery, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland	Johannes.goldberg@insel.ch
Werner J. Z´Graggen, MD	Department of Neurosurgery, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland	werner.zgraggen@insel.ch
Mattia Branca, PhD	CTU Bern, University of Bern, Bern, Switzerland	mattia.branca@ctu.unibe.ch
Serge Marbacher, MD	Department of Neurosurgery, Kantonsspital Aarau, Aarau 5000, Switzerland	Serge.marbacher@ksa.ch
Donato D'Alonzo, MD	Department of Neurosurgery, Kantonsspital Aarau, Aarau 5000, Switzerland	donato.dalonzo@ksa.ch
Javier Fandino, MD	Department of Neurosurgery, Kantonsspital Aarau, Aarau 5000, Switzerland	praxisfandino@hin.ch
Martin N. Stienen, MD	Department of Neurosurgery, University Hospital Zürich Switzerland	mnstienen@gmail.com
Marian C. Neidert, MD	Department of Neurosurgery, University Hospital Zürich Switzerland	marian.neidert@kssg.ch
Jan-Karl Burkhardt, MD	Department of Neurosurgery, University Hospital Zürich Switzerland	jankarl.burkhardt@gmail.com

	Department of Neurosurgery, Hospital of the University of Pennsylvania, Penn Medicine, Philadelphia, PA, USA	
Luca Regli, MD	Department of Neurosurgery, University Hospital Zürich Switzerland	luca.regli@usz.ch
Martin Hlavica, MD	Department of Neurosurgery, Kantonsspital St. Gallen Switzerland	martin.hlavica@insel.ch
Martin Seule, MD	Department of Neurosurgery, Kantonsspital St. Gallen Switzerland	Martin.Seule@kssg.ch
Michel Roethlisberger, MD	Department of Neurosurgery, University Hospital Basel Switzerland	Michel.Roethlisberger@usb.ch
Raphael Guzman, MD	Department of Neurosurgery, University Hospital Basel Switzerland	Raphael.Guzman@usb.ch
Daniel Walter Zumofen, MD	Department of Surgery, Neurology, and Radiology Maimonides Medical Center SUNY Downstate University Brooklyn NY USA	DZumofen@maimonidesmed.org
Rodolfo Maduri, MD	Avaton Surgical Group, Swiss Medical Network, Clinique de Genolier, Switzerland	rmaduri@genolier.net
Roy Thomas Daniel, MD	Department of Neurosurgery, University Hospital Lausanne Switzerland	Roy.daniel@chuv.ch
Amir El Rahal, MD	Department of Neurosurgery, University Hospital Geneva, Faculty of Medicine Switzerland	amir.elrahal@uniklinik-freiburg.de
Marco V. Corniola, MD	Department of Neurosurgery, University	marco.corniola@hcuge.ch

	Hospital Geneva, Switzerland	
Philippe Bijlenga, MD	Department of Neurosurgery, University Hospital Geneva, Switzerland	philippe.bijlenga@hcuge.ch
Karl Schaller, MD	Department of Neurosurgery, University Hospital Geneva, Switzerland	karl.schaller@hcuge.ch
Roland Rölz, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	Roland.roelz@uniklinik-freiburg.de
Christian Scheiwe, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	Christian.scheiwe@uniklinik-freiburg.de
Mukesch Shah, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	Mukesch.shah@uniklinik-freiburg.de
Dieter Henrik Heiland, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	dieter.henrik.heiland@uniklinik-freiburg.de
Oliver Schnell, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	Oliver.schnell@uniklinik-freiburg.de
Christian Fung, MD	Department of Neurosurgery, Faculty of Medicine, Medical Center, University of Freiburg, Germany	Christian.fung@uniklinik-freiburg.de

Corresponding author

Christian Fung

Department of Neurosurgery

Faculty of Medicine, Medical Center

University of Freiburg

Germany

Email: Christian.fung@uniklinik-freiburg.de

Telephone: +49 761 270 50010

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Abstract

Background and Purpose

Favourable outcomes are seen in up to 50% of patients with World Federation of Neurosurgical Societies (WFNS) grade V aneurysmal subarachnoid haemorrhage (aSAH). Therefore, the usefulness of the current WFNS grading system for identifying the worst scenarios for clinical studies and for making treatment decisions is limited. We previously modified the WFNS scale by requiring "positive" signs of brainstem dysfunction to assign grade V. This study aimed to validate the new herniation WFNS grading system in an independent prospective cohort.

Methods

We conducted an international prospective multicentre study in poor-grade aSAH patients comparing the WFNS classification with a modified version – the herniation WFNS scale (hWFNS). Here, only patients that showed "positive" signs of brainstem dysfunction (posturing, anisocoric or bilateral dilated pupils) were assigned hWFNS grade V. Outcome was assessed by modified Rankin Scale (mRS) score 6 months after haemorrhage. The primary endpoint was the difference in specificity of the WFNS and hWFNS grading with respect to poor outcomes (mRS 4-6).

Results

Of the 250 patients included, 237 reached the primary endpoint. Comparing the WFNS and hWFNS scale after neurological resuscitation, the specificity to predict poor outcome increased from 0·19 (WFNS) to 0·93 (hWFNS) (McNemar, $p<0·001$) whereas the sensitivity decreased from 0·88 to 0·37 ($p<0·001$), and the positive predictive value from 61·9 to 88·3 (weighted generalized score statistic, $p<0·001$). For mortality, the specificity increased from 0·19 to 0·93 (McNemar, $p<0·001$), and the positive predictive value from 52.5 to 86.7 (weighted generalized score statistic, $p<0·001$).

Conclusions

The identification of objective "positive" signs of brainstem dysfunction significantly improves the specificity and positive predictive value with respect to poor outcome in grade V patients. Therefore, a simple modification – presence of brainstem signs is required for grade V – should be added to the WFNS classification.

Registration

Registration-URL: https://clinicaltrials.gov; Unique identifier: NCT02304328

Non-standard Abbreviations and Acronyms

WFNS World Federation of Neurosurgical Societies

aSAH aneurysmal subarachnoid haemorrhage

hWFNS herniation World Federation of Neurosurgical Societies

mRS modified Rankin Scale

GCS Glasgow Coma Scale

PPV positive predictive value

Introduction

In 1988, the current World Federation of Neurosurgical Societies (WFNS) classification was introduced to grade the severity of aneurysmal subarachnoid haemorrhage (aSAH) and to allow prognostic predictions.[1] It is based on the Glasgow coma scale (GCS) score and the presence or absence of major neurological deficits.[1] Despite the wide acceptance of the WFNS scale, it has some inherent limitations.[2] With progressive brainstem dysfunction, i.e. higher WFNS grades (corresponding to lower GCS grades), the classification switches from "positive" signs, such as withdrawal to pain (GCS 6), flexion (GCS 5), and extension posturing (GCS 4) to a "negative" sign – no motor response – to assign a GCS score of 3.

In comatose, intubated, and ventilated poor-grade patients, sedation, muscle relaxation, or insufficient pain stimuli may mimic a missing motor response and lead to assignment of a false GCS score of 3, which is a considerable confounder in the GCS and WFNS scales. This is demonstrated by a rate of favourable outcomes of 24%–50% of aggressively treated grade V patients.[3-6] Owing to the considerable proportion of WFNS grade V patients with favourable outcomes, this grade does not allow futility to be predicted and cannot be used to limit treatment.[7]

Various studies have reported on the impact on outcome of aSAH patients in whom signs of brainstem dysfunction were identified.[8-12] Using a simple modification of the WFNS scale, we have previously shown an improvement in the prediction of mortality and poor outcomes in a retrospective cohort study.[13] This modification is based on the pathophysiology of brainstem dysfunction, which is the underlying event in patients with GCS grades 3–5. As herniation progresses from flexion (GCS 5) to extension posturing (GCS 4), any further deterioration must inevitably be pathophysiologically associated with positive clinical signs of herniation

progression. Thus, instead of using “no motor response”, we only graded patients as GCS 3 when they also showed additional pupillary signs of herniation, such as mydriasis.

To further evaluate and validate our previous finding of a significantly better poor-grade scoring, we performed the prospective multicentre observational study “Impact of Herniation on WFNS Grading and Outcome in Spontaneous Subarachnoid Hemorrhage – a SWISS SOS Observational Trial“. Specifically, we sought to compare the specificity and positive predictive value (PPV) of this new herniation WFNS (hWFNS) scale for predicting poor outcome and mortality with the classic WFNS scale.

Methods

The data supporting the findings of this study are available from the corresponding author upon request.

Study design

This international prospective observational study included patients being screened in seven Swiss and one German neurosurgical department between December 2015 and November 2019. Inclusion criteria were i) spontaneous SAH, ii) age ≥ 18 years, iii) GCS ≤ 12, iv) consent of the patient or the patient´s next of kin. Exclusion criteria were i) SAH due to any other cause or structural abnormality (arterio-venous malformation, dural arterio-venous fistula, cavernous malformation, dissection, tumour or trauma) of the brain, and ii) foreseeable difficulties during follow-up.

We compared the grading of WFNS grade IV and V patients to a modified grading system – the hWFNS scale. According to the original WFNS scale, a GCS score of 3–6 corresponds to WFNS V and a GCS score of 7–12 corresponds to WFNS IV.[1] For the new hWFNS grade V,

we included only patients with positive signs of brainstem dysfunction.[13] Patients with a GCS score of 6–12 or with no motor response but otherwise intact brainstem function were graded hWFNS Grade IV (Table 1). Thus, a patient graded as GCS 3 (no motor response) but with 3-mm symmetrical pupils and prompt reaction to light was assigned hWFNS Grade IV instead of WFNS grade V.[13] Patients were examined after neurological resuscitation. All initial assessments (WFNS, hWFNS) were performed by clinicians throughout their daily routine to reflect the current standard of grading. All follow-up investigations were performed by an independent trained investigator or study nurses blinded to the clinical course. Modified Rankin Scale (mRS) was assessed during a structured telephone interview 6 months ± 14 days post ictus.[14] Data were entered into a REDCap database, which was hosted by the Clinical Trial Unit of the University of Bern. The study was approved by each local ethics committee and was registered (NCT02304328). The reporting of this study is according to the TRIPOD guideline.

Clinical management

SAH was confirmed by either computed tomography, magnetic resonance imaging, or lumbar puncture. Patients were treated according to current guidelines, which included early angiography and transfer to an intensive care unit.[15,16] First-line treatment included neurological resuscitation (insertion of external cerebrospinal fluid drainage in case of hydrocephalus, treatment of seizure, and general intensive care measures). Aggressive treatment of poor-grade patients was at the discretion of the treating surgeon and was based on parameters like clinical presentation, age, pretreatment morbidities, and the patient's expressed wishes.

Outcome measures

The primary endpoint was the difference in specificity of the WFNS and hWFNS grading with respect to poor outcome at 6 months after initial haemorrhage. Poor outcome was defined as

mRS 4–6, where 0 indicates no symptoms and 6 signifies death. The secondary endpoint was the effect of the new scale on prediction of mortality.

Statistical analysis

The statistical analysis was performed using R, version 3.6.1, through the R studio interface. The descriptive statistics for baseline characteristics, procedural information (therapy and radiology), and follow-up details are shown using frequencies and percentages for categorical variables and mean (± SD) or median (interquartile range) for continuous variables. No group comparison was performed for this different information.

To analyse the primary outcome of this study, we based the hypotheses on our earlier retrospective study in which we calculated a specificity and sensitivity for poor outcome for the existing WFNS scale of 0·63 and 0·70, respectively.[13] For the hWFNS scale the values were 0·85 and 0·58, respectively. This gives ratios of truly negative and truly positive rates of 1·35 and 0·82. Probabilities for a positive and negative score in the same patient with the two scales were estimated to be 0·53 and 0·43, respectively. The prevalence of a poor outcome was 0·61 in this study. With a two-sided alpha of 0·025 (0·05 divided by two for multiple testing, because specificity and sensitivity are both tested) we calculated a minimum sample size of 233. To increase the probability of enrolling enough patients with a poor outcome, we increased the sample size to 250 (probability (phi): 0·90; assuming a binomial distribution).

This study tested the null hypothesis that the ratio of the true negative rates (specificity) of the hWFNS and WFNS scales is 1·35; i.e., the new scale will identify 35% more patients as truly negative (favourable outcome) than the old scale. In addition, and because of the negative correlation between specificity and sensitivity, we also tested to make certain that the ratio of the true positive rate (sensitivity) is not below 0·82; i.e., the new scale will not identify more than 18% less patients as truly positive (poor outcome).

To analyse the results of the primary outcome, sensitivity, specificity, and PPVs for the post-neurological resuscitation status were obtained to compare the two different grading systems – WFNS and hWFNS. The results of the two grading systems were compared using McNemar's test (specificity and/or sensitivity), while the PPVs were compared using (weighted) generalized score statistics. The same approach was applied to analyse the mortality prediction of the two different grading systems, with sensitivity, specificity, and PPV.

Results

Between December 2015 and November 2019, we included 250 patients (mean age 61·2 years, 64% female) in the study. Patients were enrolled at the departments of neurosurgery in eight hospitals in Switzerland and Germany: Aarau, Basel, Bern, Freiburg im Breisgau, Geneva, Lausanne, St. Gallen, and Zürich. Recruitment rate per department is displayed in the supplemental material. Thirteen patients had to be excluded (nine withdrew consent, three were lost to follow-up, and one had angio-negative SAH), leaving 237 patients to reach the primary endpoint. One hundred and ninety patients (86%) were intubated and ventilated at the time of initial clinical assessment. After neurological resuscitation, 40 patients (16%) were classified as WFNS grade IV and 210 (84%) WFNS grade V compared to 190 (76%) hWFNS grade IV and 60 (24%) hWFNS grade V. The hWFNS grading reduced the grade V group to 28% of its original (WFNS) size ($p<0.001$), inverting the proportions of grade IV and V patients in the respective groups.

Primary and secondary endpoints

Two hundred and thirty-seven patients reached the primary endpoint, i.e., mRS after 6 months. The mRS after 6 months with respect to WFNS and hWFNS grading is displayed in Table 2 and figure 1. Comparing the post-resuscitation WFNS with hWFNS, the specificity to predict

poor outcome increased from 0·19 to 0·93 (p<0·001), whereas the sensitivity decreased from 0·88 to 0·37 (p<0·001). The PPV for poor outcome increased from 61·9 to 88·3 (p<0·001) (Table 2).

Mortality after 6 months with respect to WFNS and hWFNS grading is presented in Table 2 and figure 1. Comparing post-resuscitation WFNS and hWFNS grading, the specificity for prediction of mortality increased from 0·19 to 0·93 (p<0·001), whereas the sensitivity decreased from 0·89 to 0·44 (p<0·001). The PPV for mortality increased from 52.5 to 86·7 (p<0·001).

Withdrawal of care

In the WFNS V group 106 patients (87.8%) died and in the hWFNS V group 52 patients (90.4%) died. The percentage of patients from whom the care was withdrawn was equal in both groups, 87.8% for the WFNS and 90.4% for the hWFNS group.

Discussion

The results of this prospective multicentre observational trial confirm that the incorporation of simple signs of brainstem dysfunction into the current WFNS scale significantly improves the prediction of poor outcomes at 6 months after aSAH. This holds true for outcome dichotomized into favourable (mRS 0–3) and poor (mRS 4–6) as well as mortality. Applying the hWFNS scale significantly decreases the overall number of patients being assigned to grade V to only 28% of the size of the grade V groups when using the original WFNS classification. Thus, by making the presence of positive brainstem signs mandatory, it is likely that it would capture the truly severely affected patients and reduce the probability of patients being falsely assigned to grade V.

Given that up to 50% of WFNS grade V patients show a favourable outcome, various authors have proposed variations of the WFNS grading to improve outcome prediction.[8-12,17] According to the initial report of the World Federation of Neurological Surgeons Committee the most important predictor of death and disability was the level of consciousness.[1] Therefore, the more precisely the level of consciousness can be described, the more precise should be the outcome prediction based on the WFNS scale. Since the WFNS scale is based on the GCS score, shortcomings of the GCS score translate into WFNS grading. The major shortcomings of the GCS score are i) the difficulty in assessing verbal response in intubated patients, ii) a "missing sign"— no motor response — to allocate the worst grade, and iii) the lack of attention paid to abnormal brainstem reflexes and signs of herniation.[13,18,19] Consequently, "positive" signs of progressive brainstem dysfunction including flexor and extensor posturing (motor score) and pupil status are the key features of the hWFNS scale. In fact, Teasdale and Jennett stated that they had never recommended using the GCS alone, either as a means of monitoring coma, to assess the severity of brain damage, or to predict outcome.[20] In an early investigation these authors had already emphasized that pupil reactions correlate with responsiveness and herniation status.[21] Thus, clinical assessment in these patients is challenging even for experienced examiners. By limiting grade V to "positive" signs, we have shown that the hWFNS scale is more robust than the original WFNS grade V.

To achieve wide acceptance, a prognostic scale should be i) simple and easy to use while avoiding too many variables and complex arithmetic,[12] ii) it should define appropriate breakpoints if the prognostic scale is based on compression of another system,[22] and iii) the prognostic scale should have a significant correlation with outcome and significant differences in outcome between grades.[23] Signs of brainstem dysfunction can be easily incorporated into the current WFNS grading system to create a clearer distinction between the two poorest WFNS

grades and to predict outcome of the worst-affected patients better than is possible with the current WFNS grading.

The results of this prospective study may have major implications for clinical decision making as well as for clinical studies; in particular, the differentiation between the worst grades may have an impact on whether treatment is initiated or halted.

Limitations of the study

Our study was performed in Switzerland (98% of patients) and Germany with a rather homogeneous care and a more international center selection would have provided a more robust information about the value of the hWFNS modifications. Also, unlike others, we have not included comorbidities or therapeutic maneuvers into the hWFNS scale. Omitting additional information might limit the prognostic information of the hWFNS scale.

Conclusion

The hWFNS scale improves outcome prediction for poor-grade aSAH patients by incorporating signs of brainstem dysfunction into the current WFNS grading. The authors therefore recommend that this simple modification should be added to the current WFNS scale.

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Disclosure

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Supplemental Materials

Expanded Results

Checklist

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Table 1. Grading of poor-grade patients after subarachnoid haemorrhage

	WFNS	Herniation-modified WFNS
IV	GCS 7–12	GCS 6–12 including “false” GCS 3 gradings where patients show no motor response but have otherwise normal pupillary response and no other sign of brainstem dysfunction
V	GCS 3–6	GCS 4–5 Or signs of brainstem dysfunction other than posturing, confirming deep coma and a “true” GCS 3 score

GCS, Glasgow coma scale; WFNS, World Federation of Neurosurgical Societies.

Table 2. Outcome 6 months after initial hemorrhage

	mRS					mortality				
	0–3	4–6	PPV	Sensitivity (95% CI)	Specificity (95% CI)	Alive	Dead	PPV	Sensitivity (95% CI)	Specificity (95% CI)
WFNS										
Grade IV	18	17 (49%)		0.88 (0.82–0.93)	0.19 (0.12–0.28)	22	13 (37%)		0.89 (0.82–0.94)	0.19 (0.12–0.27)
Grade V	77	125 (62%)	61.9			96	106 (52%)	52.5		
hWFNS										
Grade IV	88	89 (50%)		0.37 (0.29–0.46)	0.93 (0.85–0.97)	110	67 (38%)		0.44 (0.35–0.53)	0.93 (0.87–0.97)
Grade V	7	53 (88%)	88.3			8	52 (87%)	86.7		

PPV, positive predictive value; CI, confidence intervals; WFNS, World Federation of Neurosurgical Societies.

Figure 1. Sankey diagrams displaying outcome dichotomized in mRS 0-3 vs. mRS 4-6 and for mortality

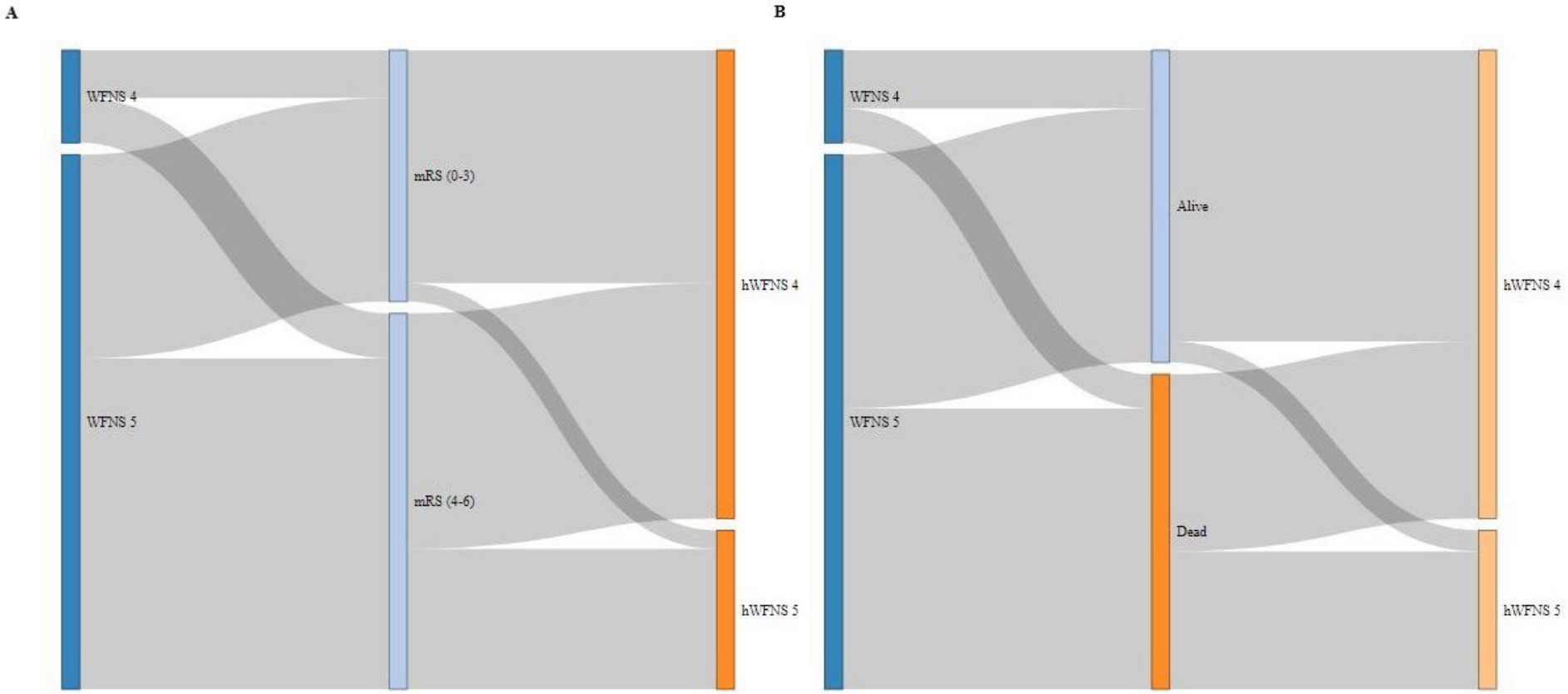

Figure 1 legend: Sankey diagrams of the current WFNS scale and the herniation WFNS scale with respect to poor outcome (mRS 0-3 vs. 4-6) and mortality. Note the reduction of patients being assigned to hWFNS grade 5 and the few patients being assigned hWFNS grade 5 and present a good outcome and are still alive at follow up, respectively.