DOI 10.4149/BLL_2024_45

Bratisl Med J 2024; 125 (5):
305–310

CLINICAL STUDY

Estimation of prognosis in patients after decompressive craniectomy after malignant hemispheric infarction: multifactorial scoring scale

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ABSTRACT

BACKGROUND: Patient's age is considered to be one of the most relevant factors in selecting surgical candidates for decompressive hemicraniectomy after malignant hemispheric infarction. However, questions about surgical indication in older patients, patients with consciousness disorder or patients with large infarctions remain unanswered.

OBJECTIVE: Our aim was to design a multifactorial scoring scale based on a combination of patient-specific factors in order to optimize the assessment of prognosis in patients after hemicraniectomy malignant strokes.

METHODS: In this prospective observational study with a one-year follow-up, we assessed clinical and imaging data of patients who underwent decompressive hemicraniectomy due to malignant brain infarction. Barthel index was used as a single outcome measure to distinguish favorable vs. unfavorable outcomes. Associations between multiple variables and clinical outcome were assessed. Subsequently, a design of a predictive scoring system was proposed.

RESULTS: Age of the patient, preoperative level of consciousness, midline shift, and volume of infarction showed a significant association with postoperative Barthel index. According to the identified factors, a multifactorial prognostic scoring system was introduced, aimed to distinguish between favorable and unfavorable outcomes. Using ROC analysis, it has achieved an AUC of 0.74 (95%CI 0.58–0.89, p=0.01)

CONCLUSIONS: Prediction of postoperative outcome should be based on multiple variables. Our scale, based on the clinical and imaging data, can be used during decision-making to estimate potential benefit of decompressive craniectomy in patients after malignant brain infarction *(Tab. 5, Fig. 1, Ref. 32)*. Text in PDF *www.elis.sk*

KEY WORDS: decompressive hemicraniectomy, malignant hemispheric infarction, indication, outcome, prediction.

Abbreviations: ACA = anterior cerebral artery, AUC = area under curve, ASPECTS = Alabama Stroke Program Early Computed Tomography Score, BI = Barthel Index, CS = collateral score, DHC = decompressive hemicraniectomy, GCS = Glasgow Coma Scale, ICA = internal carotid artery, ICH = intracranial hypertension, ICP = intracranial pressure, MCA = middle cerebral artery, MHI = malignant hemispheric infarction, mRS = modified Rankin Scale, NA = not analyzed, NIHSS = National Institutes of Health Stroke Scale, PCA = posterior cerebral artery, RCT = randomized control trial, ROC = receiver operating characteristic, r = Spearman's correlation coefficient, SD = standard deviation of the mean, tau-b = Kendall's rank correlation coefficient

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Introduction

Life-threatening brain edema occurs in 1–10% of patients with a supratentorial infarct. The prognosis of these infarctions is poor, with case fatality rates of nearly 80%. No medical treatment has been proven effective (1). Apart from primary ischemic brain damage, the cause of high mortality and morbidity often stems from the development of secondary brain damage. This is caused by cytotoxic edema and subsequent intracranial hypertension (ICH) (2). The brain edema develops within 24–72 hours after an ischemic stroke and can cause secondary infarctions through external vascular compression, potentially leading to a fatal brainstem compression (3).

Decompressive hemicraniectomy (DHC) has been established as an effective treatment modality for malignant hemispheric infarction (MHI) (4, 5). DHC The treatment of sequels of malignant hemispheric infarctions by means of DHC was analyzed in form of pooled analysis of three randomized studies (1). The pooled risk reduction in overall survival in the surgically treated patients younger than 60 years, irrespective of the severity of the disability, was 51% (1). Over the last decade, the DHC in patients with MHI has been established in the common clinical practice principle as a life-saving procedure.

However, the specific postoperative disability of survivors after DHC after MHI brings many medical, ethical, social, legal and financial questions related to surgical indication. Optimal selection of candidates for DHC after MHI who would benefit from surgery still remains a subject of interest. The associations of many patient-specific factors with the postoperative outcome has been studied recently (4, 6–10). There are also several computed algorithms designed to improve the decision-making process of indication for DHC (11). It is evident that using single cut-off thresholds to offer a DHC for MHI, may it be age, or any other relevant factor might neither predict postoperative outcome precisely nor consider the role of other relevant factors together.

We hypothesized that designing a scoring scale based on a combination of patient´s relevant factors may better predict which patient will benefit from surgical treatment.

Methods

A prospective single-center observational trial of consecutively treated patients with malignant middle cerebral artery (MCA) infarction was conducted over the period of 2006–2012 at the Department of Neurosurgery of the Landesklinikum Wiener Neustadt. This observational cohort study adheres to the STROBE guidelines (12). Inclusion criteria are summarized in Table 1. An informed consent was obtained from each patient (or their guardian) before their inclusion in the study. No patients underwent thrombectomy, patients after previously administered thrombolysis were included. Following the defined indicating criteria for surgery, a standard unilateral DHC with expansive duraplasty was performed and followed by a standard postoperative management as indicated depending on the clinical course of individual patients. Selected series of perioperative demographic, clinical and radiological parameters, where associations with the clinical outcome were anticipated, were recorded on admission, perioperatively and at one year follow-up clinical check. These included patients': age, sex, preoperative level of consciousness described using Glasgow Coma Scale (GCS), timing of the surgery from the onset of symptoms (quantified in days), affected vascular territory (partial vs. complete territory of the middle cerebral artery vs combined territory of the middle and anterior or posterior cerebral artery), laterality and volume of the infarction, preoperative midline shift (measured at the level of foramen of Monro). Imaging measurements were based on preoperative CT studies. Volume of infarction was measured using manually acquired 3-D volumetric analysis based on CT scans after demarking of the infarction area (13, 14). The one-year post operation follow-up interviews were conducted either in person or via telephone with the patients themselves or their caregivers. The Barthel index (BI) at one-year postoperative follow-up was used as a single outcome measure (15, 16). A score of 60 points on the BI was set as a reference cutting point between favorable ($BI \geq 60$) and unfavorable ($BI<60$) clinical outcomes. In statistical analysis, continuous variables were summarized using mean and median values with standard deviations calculated. Bivariate associations between BI and continuous variables were assessed using Kendall's rank correlation coefficient tau-b. Robust linear regression (Theil-Sen estimator) was used to find a regression line presented in scatter plots. The Mann–Whitney U test was used to find relationships between BI and dichotomous variables. A multifactorial scoring system was then proposed, using identified significant parameters. Firstly, they were analyzed using the ROC method to determine optimal cut-off values. If necessary, an interval of ±1SD was used with a concordance to the cut-off value. p-values less than 0.05 were considered statistically significant; all presented p-values are two-sided. Performance of the prognostic score in distinguishing between favorable and unfavorable outcomes was assessed using the ROC curve. Statistical analysis was performed using the statistical software StatsDirect 3.0.90. (http://www.statsdirect.com. United Kingdom: StatsDirect Ltd., 2008) and IBM SPSS (25.0; Chicago, United States, 2017).

Results

Indication criteria and successful follow-up were met in 40 patients. On average, DHC was performed after 1.66±1.36 days. Previous thrombolysis was administered in 9 patients. Partial middle cerebral artery infarction occurred in 7 patients, a complete one in 19 patients; in 14 patients there was an involvement of anterior or posterior cerebral artery territory as well. Full cohort characteristics

Tab. 1. Eligibility criteria for surgical treatment in our cohort.

INCLUSION CRITERIA	EXCLUSION CRITERIA
CT or MR documented infarction involving more than 50% of the vascular territory of the MCA with or without accompanying same-hemisphere infarction of the ACA and/or PCA territories	Hemispheric infarction (vascular territories of ACA, MCA and PCA) and/or presence of contralateral infarction
Neuroradiological signs of increasing brain oedema with compression of the basal cisterns as well as compression of brain sulci and subarachnoid space	Signs of brain stem compression with a mydriatic pupil
Presence of clinical signs of infarction and their progressive deterioration	Significant severe comorbidity with life expectancy less than 3 years
No age limitation	Hemorrhagic transformation of the infarction
	Systemic hemorrhagic disorder
	Contraindication to general anesthesia

Tab. 2. Characteristics of the patient cohort (n=40), relevance of the parameters to patient's outcome: * represents significant variables associated with BI at 1-year postoperative follow-up in bivariate analysis.

VARIABLE			mean	SD	median	relevance to BI
Sex	male	23				p=0.70, 95%CI=–20–30
	female	17				
Age (years)			56.28	11.01	55	***tau-b=–0.32 p=0.006**
Volume of infarction (ml)			375.5	176.11	352	***tau-b=–0.26 p=0.04**
Laterality of the infarction	dominant	18				p=0.60, 95%CI=–35–15
	non-dominant	22				
Preoperative midline shift (mm)			4.98	5.39	3.0	***tau-b=-0.24 p=0.03**
Preoperative GCS			11.23	2.38	12	***tau-b=0.34 p=0.01**
Timing of DHC (days)			1.66	1.36	1.0	tau-b=–0.06, p=0.63
BI at 1-year postoperative	all (n=40)		41.63	36.47	40	
	surviving (=28)		59.46	28.65	62.5	NA

are summarized in Table 2. At 1-year postoperative follow-up, we have recorded a mortality rate of 30% (12 patients of 40) and average BI of the survivors reaching 59.46±28.65. The analysis of potential predictive factors for the development of a classification score is described below and also summarized in Table 2.

Individual variables

The factor of patients' age has shown a significant association with the clinical outcome (Kendall's rank correlation coefficient tau-b= –0.32, p=0.006) and in the multivariate analysis, it acted as a single significant independent predictor r= –0.43 p=0.005. ROC curve analysis determined the age of 65 years as a most appropriate cut-off point for classification between favorable and unfavorable outcomes. The variable of patients' preoperative level of consciousness was also associated with the clinical outcome (tau-b=0.34, p=0.01). All of the patients with preoperative GCS≤8 had an unfavorable outcome (BI≥60 in 0/3 (0%) patients) and died. ROC curve analysis did not provide a satisfactory cut-off point regarding GCS and patients' outcome. The association between the volume of infarction and clinical outcome was significant (tau-b=-0.26, p=0.04). According to the ROC curve analysis, a cut-off value of 376ml was proposed. Infarctions with volume of <200 ml were mostly caused by partial ischemia in the territory of the MCA. In this group, most of the patients had a favorable outcome (BI≥60 in (80%) patients). Midline shift described on the preoperative CT (tau-b= -0.24, p=0.03) was significantly associated with clinical outcome. The proposed cut-off value according to the ROC curve analysis was determined to be 5.6mm. The association between the timing of surgery and the clinical outcome was not significant (tau-b=-0.06, p=0.63). There was no significant association between laterality of the infarction (dominant vs. non-dominant hemisphere) and the clinical outcome (p=0.60, 95%CI= –35–15). There was also no significant association between patients' sex and clinical outcome (p=0.70, 95%CI= –20–30).

Development of the prognostic scoring system

We included a combination of variables identified as significant in our statistical analysis. Incorporating the identified significant risk factors, specifically age, preoperative GCS, midline shift and volume of the infarction, a multifactorial scoring system was designed, evaluating individual variables in subgroups by assigning points. Based on a cut-off value of 65 years, patients' ages were further divided into subgroups according to the ±1SD interval (11 years, approximated to 10), considering the distribution of patients in each subgroup. This resulted in the creation of age subgroups as follows: ≤54, 55–64, 65–74, and ≥75 years."

These subgroups were awarded values of 0–3 points. Such sorting was not possible according to the preoperative level of GCS, and we have therefore used the value of 8 points as a cut-off, assigning 1 point to patients with GCS 8-3. Similarly, 1 point was awarded to patients with preoperative midline shift of ≥5 respecting a determined cut-off value of 5.6 (approximated to 5 points). Awarding patients with midline shifts exceeding 10mm a score of 2 points (according to SD) did not improve the performance of our scoring system. As for the infarction's volume, ROC curve analysis determined a cut-off value of 376ml, which we have approximated to 380ml. Respecting the approximated value of ±1SD (176 ml), final classification according to volumetric findings determined volume subgroups as follows: ≤200ml, 200–379 ml, 380-549 ml, and ≥550ml, with each subgroup being awarded a value of 0-3 points, respectively. Utilizing these 4 variables, a scoring system ranging from 0 to 8 points was created (Tab. 3).

Tab. 3. Calculation of the multifactorial prognostic score.

VARIABLE		POINTS
age (years)	≤54	0
	55–64	1
	65–74	2
	≥75	3
Preoperative GCS	15–9	0
	8–3	1
volume of infarction (ml)	≤199	0
	200–379	1
	380–549	2
	≥550	3
Preoperative midline shift (mm)	<5	0
	≥5	1
TOTAL SCORE	0–8	

Tab. 4. Use of the proposed multifactorial score in our cohort: Distribution of patients amongst values and associated rates of unfavorable (BI<60) outcome.

SCORE	number of patients in our cohort	rate of unfavorable outcome (%)
0	1	0
1	10	30
2	5	60
3	13	61,5
4	4	75
5	4	75
6	2	100
7	1	100
8	0	NA

Performance of the multifactorial scoring system

Using the described scoring system in our group, a single patient achieved a score of 0, also representing 0% rate of unfavorable outcome. Ten patients achieved a score of 1 (30% rate of unfavorable outcome), 5 patients were awarded a score of 2 (60% rate of unfavorable outcome), 13 patients scored 3 points (61.5% rate of unfavorable outcome), 4 patients were distributed in subgroups scoring 4 and 5 points (75% rate of unfavorable outcome), 2 patients achieved a score of 6, and one patient scored 7 points (both subgroups having a 100% rate of unfavorable outcome). No patient in our group achieved a score of 8. ROC curve analysis of our scoring system in classification between favorable and unfavorable outcomes (according to BI with the cut-off value of 60) determined its AUC of 0.74, 95%CI 0.58–0.89, standard error rate of 0.08, p=0.01 (Fig. 1). Possible alternative scoring systems, utilizing single cut-off values for volume (380ml), age (65 years) or 0–1–2-point classification in midline shift exceeding 5 and 10mm, respectively, did not outperform the proposed scoring system.

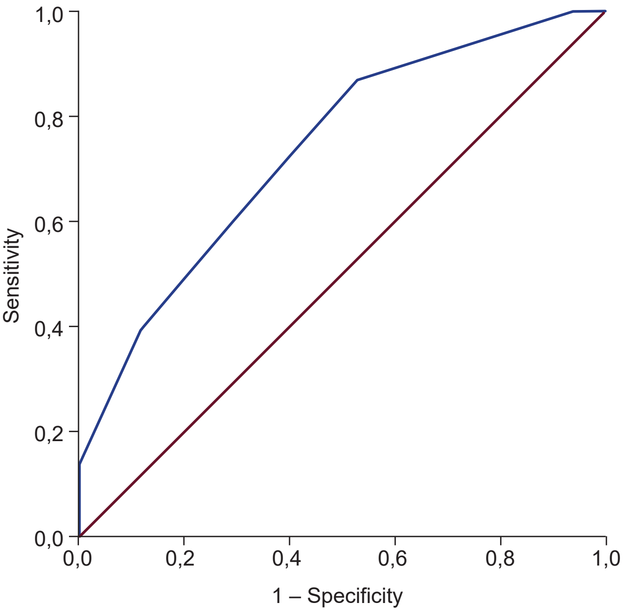

Fig. 1. ROC curve characteristics of the proposed scoring system (AUC=0.74, 95%CI 0.58–0.89, p=0.01, standard error 0.08).

Discussion

The association between age of the patient, as the most relevant and independent factor, and clinical outcome was confirmed in our patient population and is in accord with previously published findings (17–26). As well as with results of DESTINY II (6, 27) that demonstrated benefits of DHC, especially mortality reduction also in patients 61–82 years old. However, there was a substantial number of patients with unfavorable clinical outcomes (mRS 4 and 5). These results were not considered to be surprising since age as a single factor has been shown as an independent predictor of the postoperative outcome in MHI previously (28, 29).

Our patient population also demonstrated that the volume of infarction relates to affected vascular territory and is associated with the clinical outcome. This result is also in accord with published findings showing that infarction in more than one vascular territory is an unfavorable factor with an impact on survival (23–25). Hecht et al (7) reported on 96 patients (aged under and over 60 years) undergoing DHC for MHI. They found that not only the age (p=0.004) but also the volume of infarction (p=0.015) predicted a favorable outcome with mRS of 3 or less at 12 months postoperatively. They also found that the infarction volume threshold for prediction of an unfavorable outcome in their cohort was 270 cm^3.

An association between preoperative level of consciousness and clinical outcome was demonstrated in this work. It is in accord with published findings that a lower preoperative level of consciousness has a negative impact on the functional outcome (17, 21, 23).

Since the discussion regarding timing of surgery (ultra-early operation <24 hours, early operation <48 hours or an operation after 48 hours after the onset of symptoms) remains ongoing, we looked at these data and did not confirm an association between the timing of surgery and clinical outcome. The benefits of ultra-early operation, probably only with the exclusion of patients with a rapid deterioration of consciousness resulting from a progressing brain edema, have not been shown to be sufficient to operate routinely within 24 hours in all patients. Although some studies described lower mortality and better clinical outcome in patients who were operated early in comparison to the outcome of patients operated after clinical deterioration (30–32), a systematic review by Gupta et al. (22) did not confirm these findings. Similarly, the results of Vahedi's pooled analysis of three European trials comparing the clinical outcome of patients operated up to and after 24 hours from the beginning of symptoms did not show any difference in functional outcome (1). On the other hand, recent studies (9, 10) reported that DHC performed even later than48 hours after stroke did not significantly increase the risk of an unfavorable outcome. Looking at our data and the literature, we cannot make any clear evidence-based recommendation at this time as to the timing of surgery. However, in the absence of other conclusive data, and considering the findings reported from randomized control trials and pathophysiological background, early DHC <48 hours seems to be most appropriate (27).

There is a number of patients who presently do not meet the standard indication criteria for surgery, however, who might achieve favorable clinical outcomes in case of surgery. The clinical outcome of our patient´s population also supports this argument. To date and to the best of our knowledge, there is no clear consensus as to whether and when we offer DHC for MHI to elderly patients (especially to those aged over 60 years) (21, 25), those with larger strokes or to patients in a poor level of consciousness.

The need for a multifactorial tool that predicts the overall outcome was, amongst others, recognized by the researchers (8) who proposed a prediction scoring system for development of malignant brain edema and its progression after MHI. Their scoring scale is based on a combination of multiple well established stroke scoring systems (NIHSS, ASPECTS, CS). As they reported, both edema progression and the functional outcomes were strongly associated with their scoring system. This study is on the natural course of edema development, however, did not consider effects of specific treatments on the clinical outcome.

In our study we developed a multifactorial scoring scale that addresses these points. Based on our findings a surgical treatment would be strongly recommended in the subgroup of patients achieving 0–1 point; The operation as an option would generally also be recommended to patients scoring 2–3 points on our scale, however, with an associated higher percentage of unfavorable outcomes. Patients scoring higher values would be expected to have a poor outcome, especially patients achieving scores of 6–8.

The proposed scoring scale defines a combination of multiple relevant factors and could provide assistance to the clinicians when deciding about indication of DHI in patients with a malignant stroke, or in discussion with patients' relatives regarding the overall perspective. The predicted outcome should be critically reserved for a subgroup of patients with MHI in a situation when DHI is being considered, thus quantifying the potential benefit of the surgical treatment during the decision-making.

Limitations

The number of patients included in the study was relatively small for an exact evaluation of the predictive role of all the parameters, as well as for evaluation of the independent predictive roles of the volume of infarction and preoperative level of consciousness using multivariate analysis. Also, the scoring scale was not tested on a different patient´s population, and therefore an external validation would be recommended. Finally, we acknowledge that exact volumetric measurement of the infarction [ml] on preoperative CT can be demanding, especially in rapidly deteriorating patients with infarction areas being not yet exactly demarked. However, for the purpose of calculating a patient's score in our population it was consistently possible to divide patients into the defined subgroups.

Conclusions

A combination of predictive factors of age, midline shift, volume of infarction and level of consciousness in a scoring scale identifies patients who would most benefit from decompressive hemicraniectomy after a malignant hemispheric infarction. Rational recommendations for surgical treatment could be made with assistance of the proposed scoring system.

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Received July 10, 2023.
Accepted December 15, 2023.