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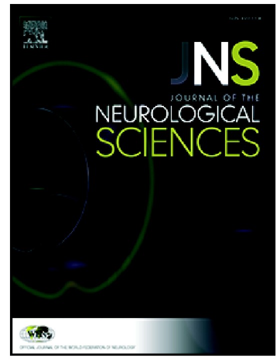

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Risk Profile of Decompressive Hemicraniectomy for Malignant Stroke after Revascularization Treatment

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ABSTRACT

Objective

Revascularization by pharmacological and/or endovascular treatment is an effective therapy for acute ischemic stroke caused by artery occlusion. In the context of malignant middle cerebral artery infarction (MMI), decompressive hemicraniectomy (DHC) can be life-saving. However, its effectiveness and safety after revascularization have not been thoroughly assessed. This retrospective study aimed to determine the risk profile of pre-surgical revascularization treatment (RT) for subsequent DHC.

Methods

A total of 152 consecutive patients treated by DHC after MMI were identified between 2012-2015. After elimination of cases with previous stroke and cases pre-treated with antiplatelets or anticoagulants (increased postoperative bleeding), twenty-four out of fifty patients (n=24/50, 48%) received pre-surgical revascularization treatment by intravenous thrombolysis (TL), mechanical thrombectomy (MT) or a combination of both. Demographic data was compared alongside perioperative, postoperative complications (intra-/extracerebral hemorrhage, revision surgery due to hemorrhage or infection, and overall mortality) and economic parameters.

Results

Comparing patients with and without prior RT, there was no statistically significant difference in duration of surgery (RT: 83 [57 - 116] min *vs.* no-RT: 96 [69 - 119] min, p=0.308), intraoperative blood loss (RT: 300 [225 - 375] ml *vs.* no-RT: 300 [250 - 400] ml, p=0.763), intraoperative transfusion requirement (RT: 12.5% *vs.* no-RT: 26.9%, p=0.294), or need for volume substitution (RT: 1300 [1200 - 1400] ml *vs.* no-RT: 1200 [1100 - 1400] ml, p=0.359). The rate of postoperative complications was also comparable in both groups, including intra-/extracerebral hemorrhage, revision due to hemorrhage or infections, and mortality (p=0.814, p=0.520, p=0.697, and p=0.769). Health economic parameters were not affected (ventilation time: RT: 309 [12 - 527] hrs. *vs.* no-RT: 444 [171 - 605] hrs., p=0.120, length of stay: RT: 23 [13 - 32] days *vs.* no-RT: 28 [19 - 41], p=0.156, and stay costs: RT: 27768 [13044 - 60248] € *vs.* no-RT: 35422 [21225-49585] €, p=0.312).

Conclusion

DHC for patients with MMI who previously received revascularization therapy appears to be safe and not associated with a higher complication rate or increased health economic burden.

INTRODUCTION

Middle cerebral artery occlusion occurs in up to 10% of all stroke patients. For numerous years, intravenous thrombolysis (TL) with recombinant tissue plasminogen activator (rtPA) has been the gold standard for the treatment of acute ischemic stroke [1]. Prognosis of patients with acute ischemic stroke and large vessel occlusion improved considerably with the introduction of endovascular mechanical thrombectomy (MT) [2]. Several clinical trials have demonstrated that a significant reduction in mortality and improved outcomes can be achieved by mechanical thrombectomy [3].

Despite recanalization therapy, numerous patients still develop a malignant cerebral infarction occupying more than 50% of the MCA territory (MMI, malignant middle cerebral artery infarction), which is characterized by mortality rates of up to 80% [3]. According to current evidence, decompressive hemicraniectomy (DHC) combined with the best medical treatment reduces the case fatality rate after MMI by 50-75% [4]. Several studies indicate that DHC can be a life-saving treatment and that early DHC has a significant impact on prognosis [5, 6]. Furthermore, delays in diagnosis or in the decision for surgical intervention have a significantly negative effect on mortality and overall clinical outcome [5].

Decompressive surgery can relieve increased intracranial pressure and resolve brain tissue shifts that occur secondary to space-occupying brain swelling [7], even though it does not directly alleviate the damage caused by the stroke itself [3]. Nevertheless, DHC indirectly increases cerebral perfusion in the ischemic penumbra and optimizes collateral perfusion via leptomeningeal vessels [8], possibly increasing the volume of salvaged brain tissue. It remains unclear whether prior revascularization treatment (RT) increases the risk of hemorrhagic complications after DHC due to the applied thrombolytic or antiaggregant agents. Hemorrhagic transformation of the revascularized tissue has been described to be mediated by the sudden pressure release achieved by DHC [9]. The present study aimed to assess peri-/postoperative complications and the safety profile of DHC in patients with and without prior RT.

MATERIAL AND METHODS

Patients enrolled in the present study suffered malignant middle cerebral artery infarction (MMI) and underwent DHC to relieve anticipated midline-shift and intracranial pressure. Included cases were treated at the departments of neurosurgery, neurology, and neuroradiology of the University Hospital RWTH Aachen between 05/2012 and 05/2015. This time frame was chosen to parallel the implementation of a modified posterior question-mark incision for DHC at our institution [10]. Recorded demographic and clinical data included: age, gender, BMI, arterial hypertension (HTN), Glasgow Coma Scale (GCS), National Institutes of Health Stroke Scale (NIHSS) at admission, and ASA score (ASA-classification defined by the American Society of Anesthesiologists). Ischemic stroke was diagnosed clinically and confirmed in standard computed tomography (CT) complemented by perfusion CT (CTP) and CT angiography (CTA). Imaging data were obtained and analyzed by an experienced neuroradiologist in accordance with existing institutional standards. Stroke management and endovascular thrombectomy were performed as reported previously [11, 12]. Mechanical thrombectomy with stent retrievers under continuous distal aspiration and flow arrest in the internal carotid arteries in the so-called SAVE- and SOLUMBRA-Techniques was performed in all cases. The details of the thrombectomy techniques are beyond this article's scope and have been described elsewhere [13, 14].

Exclusion criteria were: age < 18 years, pregnancy, intracerebral hemorrhage, preexisting neurological disorders, and preexisting coagulation disorders. As patients with preexisting neurological deficits can influence the overall outcome, we excluded patients with previous ischemic stroke. Besides, due to increased postoperative bleeding, we excluded patients treated with oral antiplatelets or anticoagulants.

Pre-surgical revascularization was classified as either intravenous thrombolysis (TL) treated with weight-adapted recombinant tissue plasminogen activator (rtPA), mechanical thrombectomy (MT) or a combination of both treatments (TL+MT).

All patients received postoperative surgical silicone drain subgalealy for one or two days (Robdrain®, 12 CH., outer diameter 4mm, length 100cm, B. Braun Melsungen AG, Melsungen, Germany).

Recorded perioperative parameters included the duration of surgery (min), intraoperative blood loss (ml), transfusion requirements (number of packed red blood cells), volume substitution (ml) and intraoperative urine output (ml). Postoperative complications such as intra-/extracerebral hemorrhage, need for surgical revisions due to hemorrhage or infections (cerebral or wound), and mortality were noted. Hematomas with relevant space occupation on imaging were considered for surgical evacuation on an individual basis. In case of evacuation of cerebral abscess, affected patients received antibiotic therapy (vancomycin and meropenem). After the antibiotic sensitivity testing has been approved, the antibiosis will be then adjusted.

Health economic factors such as the length of ventilation (days) and length and cost of stay (based on the German diagnosis related group system, DRG) were also documented.

Long-term clinical outcome was determined by the Glasgow Outcome Scale (GOS) after 3 months, assessed during follow-up examinations and dichotomized into favorable (GOS_{4-5}) and unfavorable (GOS_{1-3}) outcome. All additional data were extracted from the comprehensive database of our local hospital information systems (MEDICO V22.10, Siemens AG).

Statistical analysis

Two-sided Student t-test was used for the comparison of quantitative parameters after normality testing (Shapiro-Wilk and/or Kolmogorow-Smirnow test). Non-parametric continuous data were tested via the Mann-Whitney-U-test. All continuous variables are summarized as means ± standard deviations (SD) for normally distributed data or as median and [1st quartile - 3rd quartile] for nonparametric data. Categorical data are presented as absolute frequencies (n) and percentages (%) and compared via chi-square or Fisher exact testing. Differences between more than two groups were compared by ANOVA for normally distributed or Kruskal Wallis test for non-parametric data, with a Bonferroni post-hoc correction for multiple comparisons. We identified variables that may influence long-term outcome using the univariate logistic regression model. Factors showing a p-value equal to or less than 0.05 were included into the multivariate logistic regression model. A p-value below 0.05 was considered statistically significant. Results are reported as p-values, odds ratios and corresponding 95% confidence intervals (CI). All analyses were performed using IBM® SPSS® Statistics V22.0 (IBM, Chicago, Illinois, USA).

RESULTS

Patient characteristics and risk profile in all patients

A total of 152 patients treated by DHC after MMI were identified within the inclusion time frame. Due to previous ischemic stroke or prior treatment with blood thinning drugs, 102 patients were excluded. This resulted in inclusion of a total of 50 consecutive cases with a mean age of 50.7±10.7 yrs. of whom 22 (44%) were female. A flowchart depicting patient enrollment is shown in **Fig 1.**

Characteristics and risk profile in patients with and without revascularization therapy

Twenty-four cases (48%) received revascularization treatment (RT). These patients were divided into cases having received only intravenous thrombolysis (TL: n=13), only mechanical thrombectomy (MT: n=4), or a combination of both (TL+MT: n=7). Baseline characteristics, peri- and postoperative parameters of patients with or without prior RT are depicted in **Tab. 1 & Tab. 2**.

The median time between TL and surgery was 27 [21-45.5] hrs. The following outcome parameters did not differ between the groups; perioperative risks: duration of surgery (DHC, p=0.308), intraoperative blood loss (p=0.763), transfusion requirement (p=0.294), volume substitution (p=0.359) and intraoperative urine output (p=0.339). Postoperative risks were also comparable between the groups, including intra/extracerebral hemorrhages, ventilation time, and need for revisions. Patients receiving thrombolysis therapy had a shorter ventilation time, and length of ICU stay, but these differences did not reach statistical significance (p=0.120, p=0.156). The costs of in-hospital treatment were also comparable between the groups (p=0.312). A total of 7 patients (14%) died and the mortality rate was comparable between both groups (no-RT: n=4 deaths (15.4%) *vs.* RT: n=3 deaths (12.5%), p=0.769).

In the subgroup analysis of the classified revascularization modality, neither TL or MT nor the combination of both significantly influenced the rate of intra-/extracerebral hemorrhage (p=0.764). Peri- and postoperative risks were also comparable (**Suppl. Tab. 1**).

Effect of variables on long-term clinical outcome

Seven cases (14%) were lost to follow-up resulting in missing outcome after three-months. From the evaluated variables, the following were associated with a favorable clinical outcome (GOS_{4-5}): lower NIHSS (p=0.039), patients receiving only TL (p=0.004) and patients with shorter ventilation time (p=0.043). A trend toward more favorable outcome was observed in patients with a better physical condition (ASA), right-sided infarction and fewer required transfusions (p=0.085, p=0.081, p=0.098).

Correspondingly, the multifactorial analysis yielded TL treatment as an independent predictor for an increased rate of good clinical outcomes (p=0.022), while lower NIHSS showed only a trend (p=0.076) (**Suppl. Tab. 2)**.

DISCUSSION

Decompressive hemicraniectomy (DHC) reduces mortality and improves outcome after malignant cerebral infarction. Still, early in-hospital morbidity and mortality remain high, especially in the elderly population [15, 16]. Data on the risk profile after DHC when performed following thrombolysis remain sparse, but there is some evidence that prior revascularization treatment (RT) results in a higher risk profile and increased hospital costs [17]. The major concern of surgeons is that RT or antiplatelet pretreatment could increase the risk of relevant hemorrhagic complications such as intracerebral bleeding or space-occupying subdural hematoma, resulting in poorer clinical outcome. With regard to antiplatelet pretreatment, increased postoperative bleeding complications after DHC have been documented by a previous study [18]. To isolate the effects of RT in the present study, we excluded patients receiving antiplatelet pretreatment. In our series, initial RT did not cause relevant additional risk of complications of DHC compared to DHC without prior RT.

Recombinant tissue plasminogen activator (rtPA) increases local fibrinolysis by transforming plasminogen to plasmin. Despite the short half-life of rtPA, its effect may last up to 24-48 hours [19]. The safest time point to perform DHC after intravenous thrombolysis (TL) remains unknown, and cannot be extrapolated from our data. Thus, while it might seem prudent to suspend DHC for the first 24-36 h after TL, the longer waiting time could also reduce the benefits of DHC as suggested previously [20]. DHC performed more than 48 hours after onset of the symptoms does not appear to be superior compared to best medical treatment [21]. With a median of 27 hours between TL and surgery, we are well within this recommended time frame.

Clinically relevant cerebral hemorrhage is the most severe complication after thrombolytic treatment [22]. Here, we divided revascularization treatment (RT) in the context of DHC into intravenous thrombolysis (TL), mechanical thrombectomy (MT) or a combination of both treatments. Hemorrhagic intra/extracerebral complications post DHC occurred in 16.7% of patients with prior rtPA administration. In the subgroup without thrombolysis, cerebral bleedings occurred in 19.2% of cases. Neither TL or MT nor a combination of both affected the rate of hemorrhages. Previous studies have suggested that DHC after thrombolytic treatment is safe [23, 24]. Our findings support the assumption that rtPA does not contribute to additional hemorrhagic events in patients after DHC, and suggest that the observed postoperative hemorrhages either occurred spontaneously or were triggered by DHC.

Our findings are not only in line with previous studies reporting that TL does not increase the risk of poor clinical outcomes after DHC [18, 24, 25], but actually indicate that TL could be an independent predictor for a favorable outcome. TL could possibly increase cerebral perfusion of the ischemic penumbra and optimize collateral perfusion via leptomeningeal vessels, which might be reinforced by DHC [8]. Prior TL in patients receiving mechanical thrombectomy (MT) may enhance survival without additional risk of symptomatic hemorrhagic transformation [26].

The use of MT in acute stroke patients continuously increased during the last years, which has led to a decrease in the rates of decompressive hemicraniectomy (DHC) [27-29]. We documented sixteen patients with thrombectomy prior to DHC, of which seven patients were treated with both, MT and TL in the absence of antiplatelet treatment. It has been reported that MT prior to DHC is safe [30] and our findings support this assumption.

In the present study, the DHC mortality rate was 14% for the reported fifty patients, which is in line with previous studies [4, 9].

In addition, we evaluated relevant health economic factors and found that patients who received prior revascularization treatment had a shorter ventilation time and length of ICU stay; with an according reduction in costs. These effects did not reach the level of statistical significance, but may still be relevant from an economic point of view. Patients with shorter ventilation time experienced a better clinical outcome, which is consistent with the literature as well [31].

Obviously, our study is limited due to the retrospective nature of the design and the relatively small sample size. Our results do not readily allow extrapolation to other centers. Although being a straightforward and life-saving procedure, DHC is associated with relevant short- and long-term complications. We evaluated whether prior revascularization treatment contributes to procedure-specific and clinically relevant complications. In this small series, peri- and postoperative risks of patients with DHC were similar in those receiving RT compared to those who did not receive RT prior to DHC.

CONCLUSION

We provide first evidence about risk profile of DHC after revascularization treatment in patients without previous stroke or pre-treatment with antiplatelets/anticoagulants. This study suggests that DHC after intravenous thrombolysis and / or mechanical thrombectomy for treatment of malignant middle cerebral artery infarctions is safe and not associated with an increase in peri- or postoperative risk. Further studies with more patients and randomized designs are necessary to confirm our findings, not only with regard to outcome but also from an economic perspective.

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Competing interests

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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Authors contributions:

Conceived, designed and performed the experiments: MA GAS WA. First Drafting of the manuscript and illustrations: MA. Data acquisition: MA TS WA. Analyzed and interpretation of data: MA HC MV AR GAS WA. Critical review of the manuscript: MV HC MAB JS GAS. The final manuscript was critically revised and approved by all authors.

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Table 1. Baseline characteristics of patients with and without revascularization treatment
ASA, classification of physical status defined by the American Society of Anesthesiologists; BMI, Body Mass Index; **DHC; decompressive hemicraniectomy**; GCS, Glasgow Coma Scale; **ICH; intracerebral hemorrhage**; TL, intravenous thrombolysis; NIHSS, National Institutes of Health Stroke Scale; RT, revascularization treatment; MT mechanical thrombectomy

	all	**No RT**	**RT**	**p-value**
total – n (%)	50	26 (52)	24 (48)	
age, yrs.	50.7±10.7	49.4±9.2	52.1±12.2	0.373
gender – n (%) male : female	28 (56):22 (44)	14 (53.8):12 (46.2)	14 (58.3):10 (41.7)	0.749
BMI – median [$q_1 – q_3$]	27 [23-29.5]	27 [23.8-33.3]	26 [23-29]	0.335
arterial hypertension - n (%)	28 (56)	14 (53.8)	14 (58.3)	0.749
diabetes mellitus type 2 - n (%)	15 (30)	6 (23.1)	9 (37.5)	0.266
GCS – median [$q_1 – q_3$]	10 [9 - 12]	10 [9 - 12]	11 [9-12]	0.913
NIHSS – median [$q_1 – q_3$]	25 [20 - 25]	25 [20 - 30]	23.5 [20-25]	0.150
ASA- n (%) 1 2 3 4 5 6 missing	 1 (2.1) 6 (12.5) 30 (62.5) 8 (16.7) 3 (6.3) 0 2 (4)	 0 1 (4.2) 16 (66.7) 4 (16.7) 3 (12.5) 0 2 (7.7)	 1 (4.2) 5 (20.8) 14 (58.3) 4 (16.7) 0 0 0	0.147
infarct side - n (%) left : right	24 (48) : 26 (52)	13 (50) : 13(50)	11 (45.8) : 13 (54.2)	0.768
RT - n (%) TL only MT only TL + MT	 13 (26) 4 (8) 7 (14)	-	 13 (26) 4 (8) 7 (14)	-
RT with ICH **DHC due to ICH**	**4 (8)** **2 (4)**	-	**4 (8)** **2 (4)**	-

Table 2. Characteristics in patients with and without revascularization treatment
ICH, intracerebral hemorrhage; RT, revascularization treatment; **q_1, first quartile; q_3, third quartile**

parameter	**n (%) median [q_1 – q_3]**			**p-value**
	all	**no RT**	**RT**	
total	50	26 (52%)	24 (48%)	
perioperative risks				
duration of surgery, min	90 [62 - 118]	96 [69 - 119]	83 [57 - 116]	0.308
blood loss, ml	300 [250 - 400]	300 [250 - 400]	300 [225 - 375]	0.763
transfusion required	10 (20)	7 (26.9)	3 (12.5)	0.294
volume substitution, ml	1200 [1100 - 1400]	1200 [1100 - 1400]	1300 [1200 - 1400]	0.359
urine output, ml	600 [500 - 800]	600 [500 - 700]	700 [500 - 1200]	0.339
postoperative risks				
intra-/extracerebral hemorrhage	9 (18)	5 (19.2)	4 (16.7)	0.814
ICH	4 (8)	2 (7.7)	2 (8.3)	
subdural hemorrhage	5 (10)	3 (11.5)	2 (8.3)	
revision due to hemorrhage	1/9 (11.1)	1/9 (11.1)	0	0.520
ICH	0	0	0	
subdural hemorrhage	1	0	0	
revisions others	7 (14)	3 (11.5)	4 (16.7)	0.697
wound infection	4 (8)	2 (7.7)	3 (12.5)	
cerebral abscess	3 (6)	1 (3.8)	2 (8.3)	
mortality	7 (14)	4 (15.4)	3 (12.5)	0.769
economic parameters				
ventilation time, hrs.	352 [67 - 563]	444 [171 - 605]	309 [12 - 527]	0.120
length of stay, days	26 [15 - 33]	28 [19 - 41]	23 [13 - 32]	0.156
cost of stay, €	31590 [16117 - 56124]	35422 [21225 - 49585]	27768 [13044 - 60248]	0.312

Highlights

- Revascularization treatment (RT) is an effective therapy for acute ischemic stroke.
- For malignant middle cerebral artery infarction, decompressive hemicraniectomy (DHC) can be life-saving.
- We determined the risk profile of pre-surgical revascularization treatment for subsequent DHC.
- DHC after RT appears to be safe and is not associated with a higher complication rate.

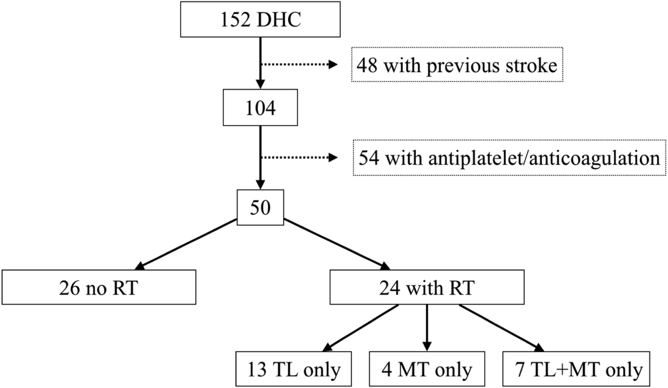
152 DHC
48 with previous stroke
104
54 with antiplatelet/anticoagulation
50
26 no RT
24 with RT
13 TL only
4 MT only
7 TL+MT only

Figure 1