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ORIGINAL ARTICLE

Endovascular Stroke Treatment on Single-Plane vs. Bi-Plane Angiography Suites

Technical Considerations and Evaluation of Treatment Success

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Abstract

Introduction Endovascular stroke therapy is mostly available in comprehensive stroke centers with state of the art bi-plane angiography suites. The aim of the present study was to analyze if it is justifiable to treat patients with alternative x-ray machines in the case of capacity constraints, or if it is mandatory to refer patients in such cases. Secondly, we wanted to draw conclusions for the feasibility of different logistic approaches in stroke treatment, such as a "helistroke" concept.

Methods This was a retrospective dual center analysis of all patients treated on a single-plane angiography suite between 2009 and 2017. A propensity scored matching analysis at a 1:3 ratio was performed with patients treated on a bi-plane angiography suite to receive homogeneous groups.

Results A total of 42 patients were treated on a single-plane angiography suite and were compared to 126 patients treated on a bi-plane angiography suite. No significant differences in technical parameters, procedure times, recanalization success and complications could be detected. Also, there was no difference in the clinical outcome between the two groups. The only significant difference was the higher amount of radiation dose used on the bi-plane angiography machines to achieve the final results (205,660 mGy × cm^2 vs. 114,565 mGy × cm^2; $p < 0.001$).

Discussion In an era of an ever-changing stroke infrastructure and an increasing demand in thrombectomy procedures, it is feasible and safe for experienced neurointerventionalists to perform endovascular stroke procedures on single-plane angiography units.

Keywords Stroke · Endovascular treatment · Single-plane · Bi-plane · Angiography suite

Introduction

Despite the fact that based on the present evidence [1–5], national and international guidelines recommend extended time windows for mechanical thrombectomy (MT) in patients with emergent large vessel occlusions (ELVO) even beyond the time window for the intravenous administration of recombinant tissue plasminogen activator (i. v. rtPA) [6, 7], the clinical benefit of MT is highly time dependent [8–10]. While early recanalization within the first 150 min from symptom onset until successful reperfusion led to functional independence in approximately 90% in a subgroup analysis of the SWIFT PRIME data, the probability decreased by 10–20% for every hour of further delay [11];

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therefore, aiming at functional independence, patients suffering from ELVO must be treated as soon as possible.

Since both the endovascular techniques for MT and even more the convincing proof of efficacy in ELVO are comparatively recent, the demand for this highly effective therapeutic procedure cannot be sufficiently met. In fact, MT is almost exclusively available in large comprehensive stroke centers (CSC), which might be a disadvantage for rural areas with primary stroke centers (PSC) not capable of performing endovascular techniques; therefore, we face important challenges regarding the provision of prompt and universal access to MT for all patients. Different approaches have been proposed in the past including drip 'n ship, mothership, and helistroke concepts [12–14]. While the first two are aimed at the transportation of stroke patients to the next available CSC, the latter follows the opposite approach. As could be shown in the past, secondary transfers (drip 'n ship) are more time-consuming compared to mothership treatment, prolonging the time from symptom onset to recanalization [15]. On the other hand, not all patients need to be transported to a CSC following the mothership concept, as not all patients are eligible for MT. Thus, mothership treatment has the disadvantage of potentially prolonging the time from symptom onset until i. v. rtPA, which might have negative sequelae in cases of distal occlusions that are not treatable with MT [12].

The helistroke concept has been recently introduced as a possible alternative [14]. Here, the interventionalist is transported to the patient and not vice versa. The advantage is a relevant gain of time, depending on the infrastructure. This approach might be particularly interesting in rural areas with only PSC and might help to significantly improve the treatment of patients suffering from an ELVO in such areas. On the other hand, a possible disadvantage might be the less sophisticated local angiography suites, different local physicians and paramedical personnel as well as possibly substandard post-care in PSC stroke units [16–18]. This raises the question if the time advantage outweighs the potential disadvantages.

Due to capacity constraints, such as ongoing cerebrovascular interventions or technical malfunctions, there were repeated necessities over the last years in our two CSCs to switch from the bi-plane state of the art neuroangiographic units to different sites, such as in-house single-plane radiological angiography machines, cardiological catheter laboratories, or fluoroscopy units. On the basis of this, we wanted to find out if it is justifiable to treat patients in a CSC at alternative x-ray machines in the case of capacity constraints, or if it is mandatory to refer such patients to a different CSC for MT. On the other hand, we wanted to draw conclusions for the feasibility of helistroke approaches as such suboptimal localities might be comparable to the sites that can be expected when performing helistroke interventions in different localities.

We therefore evaluated technical parameters, such as success rates, time parameters and complications of the interventions and compared them to standard MT procedures, performed in our bi-plane neurointerventional angiography suites.

Material and Methods

For the present case control study we performed a retrospective analysis of a prospectively collected database including all consecutive stroke patients treated by endovascular measures in two university hospitals. We identified all consecutive patients treated on a single-plane angiography unit from 1 January 2009 until 20 August 2017. A propensity score-matched analysis including the age and occlusion site with a ratio of 1:3 to patients treated on a bi-plane angiography suite was performed. Written consent was waived by the local ethics committee due to the retrospective design of the present study.

Intervention

Patients were eligible for MT if computed tomography angiography (CTA) confirmed occlusion of the proximal or distal part of the internal cerebral artery (ICA), the proximal middle cerebral artery (MCA) or the basilar artery (BA). The neurological deficit had to be considerable. In individual cases, due to the occlusion pattern and the clinical situation (e.g. fluctuating clinical symptoms and current arterial hypertension), the individual case decision for endovascular therapy was made, even with low National Institute of Health Stroke Scale (NIHSS) values. The initial Alberta Stroke Program Early CT Score (ASPECTS) had to be >5, in cases of BA occlusion a complete infarction of the brain stem was an exclusion criterion. Groin puncture needed to be achieved within 6 h after symptom onset in anterior circulation stroke but in the posterior circulation no time window was applied. No age or perfusion selection was applied. In all patients, a femoral artery access was established and either stent retriever-based or pure aspiration recanalization of the occluded vessel was performed.

Angiography Suites

The MT was performed either on a bi-plane angiography machine (n = 126; Siemens Axiom Artis, Siemens, Erlangen, Germany, Department of Neuroradiology Center 2 or Philips AlluraXper FD 20/10 cm, Philips, Best, The Netherlands, Department of Neuroradiology Center 1) or were performed on 6 different Philips single-plane machines: Al-

luraXper FD 27 cm (Department of Radiology Center 1, $n = 28$), another AlluraXper FD 27 cm (Department of Radiology Center 1, $n = 7$), another AlluxaXper FD 27 cm (Department of Radiology Center 2, $n = 5$), MultiDiagnost ELEVA (Department of Radiology Center 1, $n = 2$), MultiDiagnost 4 FD 20 cm (Department of Radiology Center 1, $n = 1$) and Allura Xper FD 15 cm, coronary angiography (Department of Cardiology Center 1, $n = 1$). In all cases, the interventionalist and the nurse were formally instructed in the operation of the system, but not experienced in its use. For all interventions the dose area product, the fluoroscopy time as well as the amount of contrast agent used was documented.

Outcome Analysis

The neurological deficits prior to the intervention and on the day of discharge were evaluated using the NIHSS and the modified Rankin scale (mRS) by experienced stroke neurologists. Substantial neurological improvement was defined as either NIHSS at discharge ≤ 1 or a difference between the NIHSS on admission and discharge ≥ 8. Furthermore, the delta NIHSS was calculated as the difference between NIHSS on admission and at discharge. Reperfusion was graded using the original Thrombolysis In Cerebral Infarction (oTICI) scale [19]. Successful reperfusion was defined as oTICI 2b/3. All documented images of the procedure were analyzed by two experienced interventional neuroradiologists (BF, CM) and the number of passes needed to achieve recanalization or until the procedure was terminated was documented. Additionally, the complications rates were analyzed. Both readers investigated the postinterventional imaging in combination with the medical charts for the rate of symptomatic intracranial hemorrhage.

Statistical Analysis

We performed a propensity score-matched analysis comparing patients treated on a single-plane angiography machine to patients treated on a bi-plane angiography unit in a 1:3 ratio with age and occlusion site as co-variates with nearest neighbor matching logistic regression analysis with a caliper of 0.2 (SPSS 24, IBM, Armonk, NY, USA & R 3.3.3). Baseline variables were compared before and after matching to check for reduction of bias. Baseline, technical and outcome parameters between two groups were compared using Mann-Whitney U-test or Fisher's exact test depending on the type of variables analyzed.

Data are generally displayed as n (%) or median, if not indicated otherwise. Statistical significance was assumed at $p < 0.05$.

Results

A total of 42 patients were treated using single-plane angiography. These patients were matched in a 1:3 ratio with 126 patients treated on a bi-plane angiography unit, resulting in a total of 168 analyzed patients in the present study. After propensity score matching a homogeneous distribution without significant differences between the baseline parameters including sex, age, initial NIHSS, initial mRS, administration of i. v. rtPA or site of vessel occlusion between the two groups could be detected (Table 1). In the analysis of the procedure details, the type of angiography suite did not result in significant differences regarding procedure time, the number of maneuvers needed, the final reperfusion results or the rate of successful recanalization (Fig. 1 and 2; Table 2). Also, there was no difference in the rate of procedure-related complications or the rate of symptomatic intracranial hemorrhage. (Table 2). The only significant difference was the amount of radiation applied: treatment on a bi-plane angiography suite resulted in signif-

Table 1 Patient characteristics

	Bi-plane angio ($n = 126$)	Single-plane angio ($n = 42$)	p-value
Sex	51% female	48% female	0.912
Mean age (years min; max)	73 (23; 91)	74 (43; 88)	0.886
Occlusion			0.921
Proximal ICA	10%	10%	
Distal ICA	30%	31%	
MCA	40%	40%	
BA	20%	19%	
NIHSS on admission (min; max)	15 (1; 35)	14 (1; 28)	0.714
mRS on admission (min; max)	5 (1; 5)	5 (1; 5)	0.46
i. v. rtPA	56%	61%	0.474

ICA internal carotid artery, *MCA* middle cerebral artery, *BA* basilar artery, *NIHSS* National Institute of Health Stroke Scale, *mRS* modified Rankin scale, *rtPA* recombinant tissue plasminogen activator

Table 2 Procedure description

	Bi-plane angio (n = 126)	Single-plane angio (n = 42)	p-value
Groin to recanalization	66 ± 53 min	60 ± 39pmin	0.539
Symptom onset to recanalization	310 ± 142 min	267 ± 95 min	0.118
Number of passes (min; max)	2 (1; 13)	2 (1; 12)	0.918
DAP	205660 mGy × cm^2	114565 mGy × cm^2	**<0.001**
Fluoroscopy time	34 ± 24 min	30 ± 20 min	0.360
Volume of contrast agent	156 ± 75 ml	161 ± 69 ml	0.188
oTICI			0.326
0	12%	14%	
1	2%	0%	
2a	9%	5%	
2b	37%	19%	
3	40%	62%	
Successful recanalization	77%	81%	0.594
Number of complications (%)	10 (7.9%)	3 (7.1%)	0.898
Symptomatic hemorrhage	1%	2%	0.821

DAP dose area product, *oTICI* thrombolysis in cerebral infarction score

Table 3 Clinical results

	Bi-plane angio (n = 126)	Single-plane angio (n = 42)	p-value
NIHSS at discharge (min; max)	8 (0; 42)	4 (0; 42)	0.236
mRS at discharge (min; max)	4 (0; 6)	3 (0; 6)	0.350
Median delta NIHSS (95% CI)	5 (2–10)	8 (3–11)	0.192
Substantial neurological improvement (%)	37%	50%	0.148

NIHSS National Institute of Health Stroke Scale, *mRS* modified Rankin scale, *rtPA* recombinant tissue plasminogen activator

icantly higher radiation exposure, compared to the single-plane angiography suite (205,660 mGy × cm^2 vs. 114,565 mGy × cm^2; $p < 0.001$). In concordance with the procedure data, no statistically significant differences in the clinical results, neither expressed by the NIHSS nor the mRS, could be detected between MT on single vs. bi-plane angiography suites (Table 3).

Discussion

Following the ground-breaking publication of five randomized trials proving its safety and efficacy, MT has dramatically changed the treatment of patients with ELVO. The frequency and demand for this new treatment method has been ever increasing, reflected by a doubling of cases in hospitals in the USA capable of performing MT from 2013 to 2016 [20]. This increasing demand requires new organizational structures to ensure good care for all patients suffering from ELVOs. One possible approach could be increasing the numbers of CSC offering endovascular procedures; however, this does not seem to be a feasible approach since the number of well-trained neurointerventionalists is still too low and low numbers of endovascular procedures per CSC might negatively affect the interventionalists' experience. This could endanger the quality of MTs in such institutions. Alternatively, the current approach is to transfer patients from PSCs to CSCs for thrombectomy (drip 'n ship concept); however, these relocations are often time-consuming, especially in sparsely populated rural regions. For this reason, a new concept has emerged, transporting the interventionalist instead of the patient either by car or by helicopters to cover longer distances [14]. This new approach, which has already been implemented or is in the planning stage is expected to save a considerable amount of time resulting in an improvement in patient outcome; however, there are a number of factors that may potentially hamper the patients' benefit with this concept: the care situation of patients on site after the procedure may not be ideal, as there is not much experience in the peripheral hospitals with the treatment of severely affected stroke patients but one of the main concerns in such a treatment concept are the technical conditions on site, since most peripheral hospitals only have single-plane angiography units. Since thrombectomy is a highly complex procedure in filigree vessels in the brain, a potentially restricted visibility and navigability, as it is to be expected on a single-plane system, is a possible substantial restriction.

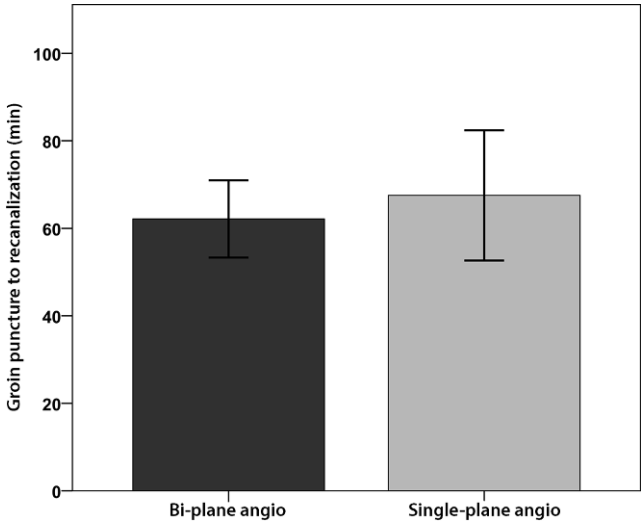

Fig. 1 Bar chart showing the average procedure time in the thrombectomy cases performed on the different types of angiography suites. There was no statistical significant difference ($p = 0.539$)

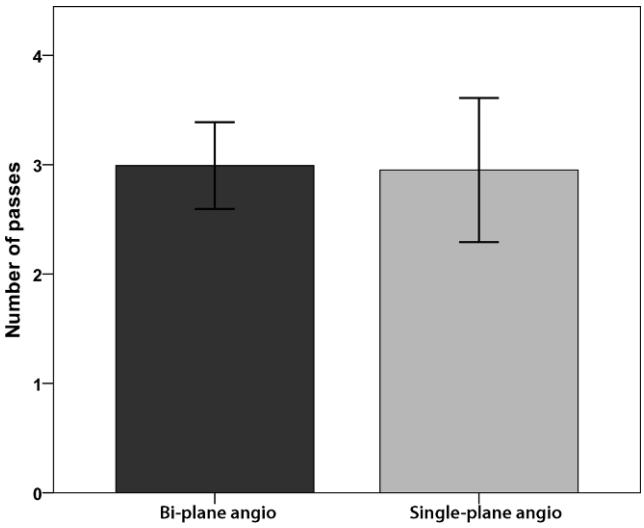

Fig. 2 Bar charts indicating the number of maneuvers needed to achieve the final angiographic result. There was no statistical significant difference regarding the type of angiography suite ($p = 0.918$)

Another consequence of the increased demand in thrombectomy procedures is the steadily increasing number of procedures in the CSCs themselves. With an ever-increasing number of cases, the probability that a technical defect in the existing bi-plane system is present or that two cases require MT at the same time increases; however, most CSCs have only one or a maximum of two bi-plane angiography systems available. In these cases, therefore, single-plane systems would also have to be used instead.

The two possible scenarios described above, both already part of reality in daily health care, were the reasons for us to analyze if acute stroke treatment can be performed in single-plane angiography suites. To the best of our knowledge, this is the first time this question has been thoroughly analyzed.

In addition to the many factors that influence the clinical outcome, two are of particular importance: the success of the reperfusion and the time from symptom onset to reperfusion. Successful recanalization was achieved in 71% of the patients in the randomized trials [21]. This successful recanalization rate is of great importance as it could be shown that there is a clear correlation between the stent retriever-based recanalization rate and the clinical outcome [22]. In the MRCLEAN trial, successful recanalization could be achieved in 59% of the patients, resulting in a good clinical outcome in 33%; in EXTEND-IA 86% of the patients could be successfully recanalized resulting in an increase in good clinical outcome to 71% [4, 5]. In our series, successful recanalization was achieved in 80% of the patients, irrespective of the angiography unit used for MT. This shows that even in a less than perfect technical environment, such as a single-plane angiography suit, a skilled and experienced neurointerventionalist can achieve the same technical success in acute stroke treatment.

The other determining factor is the time from symptom onset to recanalization. In the randomized trials this time delay was approximately 285 min [21]. In our study, with 310 and 267 min for bi-plane and single-plane angiography suites respectively, we were in the same range as the published series and there was no significant difference regarding the time from symptom onset to recanalization as well as the procedure times between the different angiography suites.

A third potential drawback of using a single-plane angiography suit might be safety issues. Neurointerventionalists are mostly used to bi-plane views for navigating the intracranial vessels. Thus, the lack of a second plane might potentially increase the risk of complications, such as vessel perforation and subsequent intracranial hemorrhage. This might especially be true in the thrombectomy setting, as the target vessels cannot be visualized due to the blocking clot; however, our data indicate that there is no increased risk of hemorrhage by performing thrombectomy procedures on a single-plane machine. On the contrast, with 1–2% our rate of symptomatic intracranial hemorrhages is below the published series [21].

Transferring our findings to the helistroke concept, one can assume that the positive effects gained by decreased time measures are not foiled by a technically worse result, an extended procedure time or an increased complication rate caused by the use of single-plane angiography units. In the helistroke concept one advantage compared to the setting analyzed in the present work could be that the previously trained PSC could already prepare the basic material before the neurointerventionalist finally arrives. Only dedicated neurointerventional devices would then be needed to

be transported. In contrast, in our study there were no preceding preparations of the material and all materials had to be transferred. On the other hand, there was potential access to special devices if necessary as the patients were treated in-house. In helistroke interventions the interventionalist has to bring along all potentially needed devices. In limited cases this might downgrade the quality of the medical treatment, especially in cases of acute complications.

We could find a significantly higher amount of radiation applied on bi-plane units compared to single-plane units. This can probably mainly be explained by the use of biplanar fluoroscopy. Even though the mostly elderly patients will most likely not suffer from any negative sequelae from the high radiation dose and this furthermore is negligible in the setting of an acute stroke, our data show that a great deal of attention should be paid to radiation protection measures in the future and that fluoroscopy should only be applied in the plane of interest at the moment.

Finally, we have to point out that the experience of the individual neurointerventionalist plays a major role when performing MT under suboptimal conditions. Our results cannot be applied to scenarios with less experienced interventionalists, especially non-neurointerventionalists.

The present study is not without limitations. First it is a retrospective study with all inherent potential biases. By applying a propensity-score matched analysis, we tried to correct for most of those methodological limitations resulting in a relatively homogeneous cohort regarding the relevant baseline parameters. Furthermore, the number of patients treated on a single-plane angiography suite is small which was met by the application of a propensity-score matched analysis in a 1:3 ratio and thus substantially enhancing the statistical power. The thrombectomy procedures in our series were performed by 6 different neurointerventionalists, all of them with an experience of more than 30 cases per year. So, despite the number of different operators, due to the high experience of each interventionalist the group of operators can be seen as homogeneous.

Conclusion

In the present study, we were able to show that MT can also be performed on single-plane angiography systems without sacrificing technical success or patient safety if performed by highly experienced, dedicated neurointerventionalists. This might have implications for future efforts to improve the infrastructure for the treatment of stroke patients, e. g. by implementing helistroke concepts for rural areas.

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Conflict of interest B. Friedrich, C. Maegerlein, D. Lobsien, S. Mönch, M. Berndt, D. Hedderich, S. Wunderlich, D. Michalski, M. Lehm, T. Boeckh-Behrens, C. Zimmer and K. Kreiser declare that they have no competing interests.

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