ORIGINAL RESEARCH

Equal performance of aspiration and stent retriever thrombectomy in daily stroke treatment

Marie Louise Elisabeth Bernsen,1 Robert-Jan Berend Goldhoorn,2 Robert J van Oostenbrugge,2 Wim H van Zwam,3 Maarten Uyttenboogaart,4,5 Yvo B W E M Roos,6 Jeannette Hofmeijer,7 Jasper M Martens,1 on behalf of the MR CLEAN Registry investigators

ABSTRACT

Background Mechanical thrombectomy with stent retrievers has proved to be safe and effective in endovascular treatment of acute ischemic stroke. Direct aspiration has shown revascularization rates comparable to those of stent retrievers in the recent ASTER and COMPASS trials. However, the efficacy of aspiration in routine clinical practice has not yet been shown.

Objective To show that aspiration has clinical and technical outcomes equal to those of stent retriever thrombectomy in daily clinical practice.

Methods We analysed data of patients with a large vessel occlusion of the anterior circulation registered in the Dutch MR CLEAN Registry between March 2014 and June 2016. Primary outcome was functional outcome measured with the modified Rankin Scale (mRS) score. Secondary outcomes were reperfusion grade, periprocedural complication rate, and procedure duration. Association of treatment technique with functional outcome was estimated with univariable and multivariable ordinal logistic regression analysis and expressed as a common OR (cOR) for a shift towards better outcome on the mRS.

Results As first-line treatment, 207 of 1175 patients (17.6%) were treated with direct aspiration, and 968 (82.4%) by a stent retriever. We observed no differences in functional outcome (adjusted cOR=1.020 (95% CI 0.68 to 1.52)) and periprocedural complications. Successful reperfusion (extended Thrombolysis in Cerebral Infarction ≥2b) was similar. Duration of the procedure was shorter with aspiration (57 min (IQR 35–73) vs 70 min (IQR 47–95), p<0.0001).

Conclusion Direct aspiration shows clinical outcomes equal to those of stent retriever thrombectomy in our large multicenter real-life cohort. We found no difference in complication rates and shorter procedure times for aspiration.

INTRODUCTION

Various recent randomized clinical trials have shown that endovascular treatment (EVT) is safe and effective for patients with acute ischemic stroke with large vessel occlusion of the anterior circulation.1–8 In the vast majority of patients in the interventional arms of these trials, thrombectomy was performed with latest generation thrombectomy devices, so-called stent retrievers.

Use of the alternative technique of contact aspiration thrombectomy as first-line treatment has long been debated. Early generation aspiration devices had several difficulties, many of which have been overcome by the newer generations of large-bore flexible catheters.9–11

Proposed advantages of aspiration include usability, less injury to the vessel wall, shorter procedure times, and lower cost.12–14

Case series and retrospective single-centre data have shown acceptable results.15 The recently published results of the ASTER trial showed similar revascularization rates for both techniques. ASTER was designed to show superiority of aspiration over stent retriever, but failed to do so. Clinical outcome, assessed as a secondary endpoint, was similar for both techniques.16 The recently announced but yet to be published results of the COMPASS trial report comparable clinical outcome for both techniques.

The purpose of our study was to compare first-line strategy of direct aspiration with stent retriever thrombectomy for functional outcome, reperfusion grade, complication rate, and duration of intervention procedure in patients with a proximal arterial occlusion in the anterior circulation in routine clinical practice.

METHODS

Design

We analysed differences between groups of patients who were included in the MR CLEAN Registry.17 The MR CLEAN Registry is a prospective, observational study in all centres that perform EVT in the Netherlands. In this registry, which started following the conclusion of the MR CLEAN trial on March 16, 2014, all patients undergoing EVT (defined as entry into the angiography suite and arterial puncture) are registered. Data on patient characteristics, intervention procedure, complications, reperfusion grade, and clinical outcome are recorded. Data of patients included up to June 15, 2016 are processed and used in this analysis. Sixteen centres participated in the MR CLEAN trial and are considered MR CLEAN centres. Two other centres started performing EVT later on, but their patients were not included in this study. The MR CLEAN Registry was approved by the medical ethics committee.

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Ischemic Stroke

Figure 1  Flow of patients through this study. DSA, digital subtraction angiography; EVT, endovascular treatment; MR CLEAN, Multicentre Randomized CLinical trial of Endovascular treatment for Acute ischemic stroke in the Netherlands.

Patients
We included patients who underwent first-line treatment with direct aspiration or a stent retriever. Patients treated with intra-arterial thrombolysis only, or with a MERCI device or other modality, were excluded. Inclusion criteria for this study are age ≥18 years, intracranial proximal arterial occlusion in the anterior circulation (intracranial carotid artery (ICA, ICA-T) or middle (M1/M2) or anterior (A1/A2) cerebral artery) demonstrated by CT angiography (CTA), and arterial puncture within 6.5 hours of symptom onset.17

Outcome measures
The primary outcome measure was functional outcome measured by the modified Rankin Scale (mRS) score at 90 days, ranging from 0 (no symptoms) to 6 (dead). Secondary outcomes were reperfusion grade according to the extended Thrombolysis in Cerebral Infarction (eTICI) scale score at end of the intervention procedure, complication rate, and time to reperfusion. As a measure of distal embolization, we also used the eTICI score, which ranges from 0 (no antegrade reperfusion of the occluded vascular territory) to 3 (complete antegrade reperfusion). The eTICI score includes grade 2c (slow flow in a few distal cortical vessels or presence of small distal cortical emboli, corresponding to 90–99% reperfusion). To reach an eTICI score of ≥2b, complete digital subtraction angiography (DSA) runs, including anteroposterior and lateral views after EVT, were mandatory. If a lateral view was missing, 2a was the highest possible score. Successful reperfusion was defined as eTICI 2b–3.

Relevant imaging datasets (baseline non-contrast CT, baseline CTA, interventional DSA, and follow-up imaging, if applicable) were collected, anonymized, stored in an imaging database (XNAT; NRG, St Louis, Missouri, USA), and subsequently analysed by an imaging core laboratory. Observers were blinded to all clinical findings, with the exception of clinical assessment of lesion location in the case of baseline non-contrast CT. In separate sessions, the core laboratory evaluated the Alberta Stroke Program Early CT score (ASPECTs) on baseline CT, eTICI on DSA, and the presence of intracranial haemorrhage on follow-up CT.

Complications that occurred during intervention, hospital admittance, or in the 3-month follow-up period were registered and evaluated by the serious adverse event committee. Medical records were searched for complications to prevent under-reporting. These included intracranial haemorrhage, progression of ischemic stroke (resulting in a decline of at least four points on the National Institutes of Health Stroke Scale (NIHSS)), new ischemic stroke, extracranial haemorrhage, and death.
Intracranial haemorrhage on follow-up imaging was classified according to the Heidelberg criteria\(^{18}\) and was considered symptomatic if the patient had died or had deteriorated neurologically (a decline of at least four points on the NIHSS), and the haemorrhage was related to the clinical deterioration (according to Heidelberg criteria). Symptomatic intracranial haemorrhage (sICH) was assessed by the serious adverse event committee after evaluation of medical reports and imaging assessment.

### Treatment

Patients were treated according to national guidelines for treatment of acute ischemic stroke, including intravenous thrombolysis if indicated.\(^{17}\) Choice of clot retriever method was left to the attending physician. Direct aspiration was defined as aspiration with a syringe or mechanical pump on a large-bore catheter near the occluding clot.

Anesthetic management varied depending on local protocols. In most centres patients were treated primarily with local anesthetics only. In two hospitals, general anesthesia was applied to almost all patients. In two centres general anesthesia and local anesthesia were equally used.

### Statistical analyses

Baseline characteristics are presented in a descriptive way as mean and SD, median and IQR, or frequency (%), and compared between patients who underwent first treatment with aspiration versus stent retriever thrombectomy. Differences between the groups were tested with Pearson’s \(\chi^2\) test in cases of ordinal/nominal variables. All datasets with continuous variables were checked for normality of distribution using a normal probability plot and the Kolmogorov-Smirnov test. For comparison of continuous variables, we used the unpaired t-test combined with Levene’s test to check for homogeneity. If the distribution was not normal, we used the Mann-Whitney U test. The level of significance was set at a p value < 0.05.

Multivariable ordinal regression analyses were performed to identify factors predictive for clinical outcome (mRS) at 3 months. Potential factors that were included in this analysis

### Table 1  Baseline characteristics of patients treated with aspiration or stent retriever

| Characteristics | Aspiration (n=207) | Stent retriever (n=968) | P values |
|-----------------|-------------------|------------------------|---------|
| **Demographics** |                   |                        |         |
| Age, median (IQR) | 68.50 (54–77) | 69 (57–78) | 0.50   |
| Male, n (%) | 112 (54) | 516 (53) | 0.89   |
| NIHSS baseline, median (IQR) | 16 (12–21) | 16 (12–19) | 0.59   |
| Pre-stroke mRS, n (%) | 0.02 |
| 0 | 119 (59) | 663 (70) |         |
| 1 | 29 (14) | 116 (12) |          |
| 2 | 24 (12) | 64 (7) |           |
| >2 | 29 (14) | 110 (12) |           |
| **Medical history, n (%)** |                   |                        |         |
| Previous stroke | 31 (15) | 162 (17) | 0.62   |
| Myocardial infarction | 37 (19) | 151 (16) | 0.39   |
| Peripheral arterial disease | 17 (9) | 85 (9) | 0.99   |
| Atrial fibrillation | 38 (19) | 224 (23) | 0.21   |
| **Cardiovascular risk factors, n (%)** |                   |                        |         |
| Hypertension | 99 (48) | 495 (52) | 0.33   |
| Hypercholesterolemia | 67 (34) | 279 (30) | 0.32   |
| Diabetes mellitus | 27 (13) | 168 (18) | 0.15   |
| Smoking | 47 (23) | 226 (24) | 0.97   |
| Medication, n (%) |                   |                        |         |
| Antiplaetel use | 77 (38) | 313 (33) | 0.19   |
| Coumadin | 20 (10) | 137 (14) | 0.10   |
| Statin | 68 (34) | 346 (37) | 0.46   |
| **Stroke characteristics, n (%)** |                   |                        |         |
| IVT | 156 (75) | 741 (77) | 0.73   |
| Level of occlusion, n (%) | 0.02 |
| ICA intracranial | 51 (25) | 272 (28) |         |
| M1 proximal | 51 (25) | 246 (26) |          |
| M1 distal | 56 (29) | 309 (33) |          |
| M2 | 29 (15) | 96 (10) |            |
| M3 | 3 (2) | 6 (1) |            |
| A1 | 0 (0) | 2 (0.2) |            |
| A2 | 1 (0.5) | 1 (0.1) |            |
| ASPECTS subgroups, n (%) | 0.91 |
| 0–4 | 12 (6) | 64 (7) |         |
| 5–7 | 50 (25) | 235 (25) |         |
| 8–10 | 137 (69) | 633 (68) |         |

**Continued**
Figure 2  Distribution of scores on the modified Rankin Scale (mRS) for the aspiration and stent retriever groups. There is no statistically significant difference between the groups in the overall distribution of scores in an analysis with univariable ordinal regression. There was no significant shift in the mRS distribution in favour of the aspiration strategy, with a common OR (cOR) for a one-point improvement of score on the mRS of 0.962 (95% CI 0.725 to 1.276). Results after adjustment for age, intervention centre, collaterals, time to groin, National Institutes of Health Stroke Scale score at baseline, general anesthesia, and pre-stroke mRS score in an analysis with multivariable regression are essentially the same (adjusted cOR 1.020 (95% CI 0.68 to 1.52)).

were determined based on (1) any (clinical) significant group difference in the comparison of baseline characteristics and (2) factors known to influence outcome, such as baseline NIHSS score and pre-stroke mRS score. Relations were expressed as odds ratios with corresponding 95% confidence intervals. We conducted a correlation analysis, calculating the Spearman ρ on the independent variables before performing the ordinal regression analyses to prevent misinterpretation of the results caused by multicollinearity.

Missing values
Missing NIHSS scores were retrospectively scored with a standardized score chart based on information from the reported neurological examination. If successful reperfusion was not achieved during EVT, the time of last contrast bolus injection was used as a proxy for time of duration of the procedure. Any mRS score of 0 to 5 assessed within 30 days was considered not valid and treated as missing. These values were therefore replaced by mRS scores derived from multiple imputation. All descriptive analyses include all patients without imputation of the data. In order to make unbiased estimates of associations between intervention and outcome, multiple imputation was performed with the following variables: age, sex, baseline NIHSS score, diabetes mellitus, previous myocardial infarction, previous stroke, pre-stroke mRS score, atrial fibrillation, intravenous thrombolysis before EVT, systolic blood pressure, baseline ASPECTS, occlusion segment, CTA collateral status, time from symptom onset to start of EVT, time from symptom onset to successful reperfusion, eTICI score at the end of the intervention, and NIHSS score after 24-48 hours.

All analyses were performed with SPSS 24 for Macintosh.

RESULTS
In the MR CLEAN registry, 1628 patients have been registered between March 16, 2014 and June 15, 2016. For this analysis, 453 patients were excluded. Most of these (201) underwent catheterization only and no thrombectomy was performed, either because the target occlusion resolved, or owing to distal migration of the clot. Another 45 underwent primary treatment other than by aspiration or stent retriever and were also excluded; in 67 patients, it was unclear which treatment method was used. The remaining 1175 patients were included, of whom 968 were initially treated with stent retriever and 207 with aspiration (figure 1).

One of the 16 intervention centres used aspiration as first-line strategy in most of the cases. In 12 centres a stent retriever was the main first-line treatment modality. Three centres used both methods equally as the initial approach (Supplementary file Table 3).

Baseline characteristics
Pre-stroke mRS score was higher in the aspiration group, and patients in the aspiration group more often underwent general anesthesia (54% vs 24%, p<0.05). Level of occlusion differed significantly; patients in the aspiration group had a more distal occlusion site. Balloon guiding was used less in the aspiration group. The distribution of other baseline characteristics was similar in both groups (table 1).

Functional outcome
There was no significant difference in the distribution of the mRS score between the treatment groups, with a common odds ratio (cOR) for a shift of at least one-point improvement on the mRS after treatment with aspiration first of 0.962 (95% CI 0.73 to 1.28). Adjustment for age, intervention centre, collateral status, time from onset to groin, general anesthesia, pre-stroke mRS score, and baseline NIHSS score did not change this significantly (adjusted cOR 1.020 (95% CI 0.68 to 1.52)), (figure 2).

Technical outcome
Successful reperfusion (eTICI ≥2b) was achieved slightly more often, although not significantly, in the aspiration group than in the stent retriever group (63% vs 56%; p=0.06)(supplementary file). Duration of the endovascular procedure was shorter in the aspiration group: median 57 min (IQR 35–73) versus median 70 min (IQR 47–95, p<0.0001, table 2).
First-line strategy only

Single-pass successful reperfusion was achieved in 108 patients (52%) with aspiration and in 458 (47%) with stent retriever thrombectomy (p=0.53). If successful reperfusion was achieved after a single pass, the median time of EVT was 40 (IQR 30–60) min with aspiration versus 52 (IQR 35–75) min with stent retriever (p<0.001).

Single-pass successful reperfusion rate was highest for a proximal M1 occlusion (70% with aspiration vs 59% with stent retriever, p=0.13) and lowest in the case of an intracranial ICA occlusion (31% with aspiration vs 30% with stent retriever p=0.18).

Fifteen patients (3%) had a periprocedural sICH after single pass with stent retriever versus 1 (0.9%) with aspiration (p=0.15).

Additional treatment

An additional attempt after first-line strategy was performed in 45 patients (22%) in the aspiration group, and 248 (26%) in the stent retriever group (figure 1). In the stent retriever group, 107 patients (11%) were converted to aspiration, of whom 52% achieved successful reperfusion. In the aspiration group 35 patients (17%) were converted to stent retriever treatment, in which 15 patients (43%) achieved successful reperfusion. For the second, third, and fourth attempts, either aspiration or stent retriever were used, without differences between the groups. After these additional attempts, 26/45 (58%) patients achieved successful reperfusion in the aspiration group and 114/248 (46%) in the stent retriever group (p=0.15).

DISCUSSION

This study shows that in routine clinical practice similar technical and clinical results are achieved when EVT is performed by direct aspiration or stent retriever as first approach in patients with acute ischemic stroke due to large vessel occlusive stroke of the anterior circulation. The results of this large patient cohort are in line with those of earlier studies comparing the technical outcomes of these thrombectomy techniques and adds important results on clinical outcome.11 12 14 16 20 Compared with randomized controlled trials our results more closely reflect the use of both techniques in daily clinical practice, with patient selection according to current clinical guidelines. Both techniques were performed by experienced interventionists, minimalizing a learning curve effect.

Results of our study show equal reperfusion rates with a single pass of aspiration compared with a stent retriever. However, aspiration required shorter procedure times than thrombectomy by stent retriever. Consequently, the time from onset of symptoms to reperfusion was shorter in patients treated with aspiration. This finding is in line with the ASTER trial and reported but as of yet unpublished results of the COMPASS trial.

Although favourable clinical outcome is strongly associated with time to reperfusion,21 we did not observe a significant difference in functional outcome between patients treated with aspiration or stent retriever. The latter may be related to several factors: first, general anesthesia was more often applied in the aspiration than in the stent retriever group (aspiration 54% vs stent retriever 24%), whereas local anesthesia was the most commonly used method in the stent retriever group (aspiration 31% vs stent retriever 61%). The effect of the type of anesthesia on outcome remains unclear. Although studies comparing general anesthesia and conscious sedation in EVT showed equivalence, data comparing these two methods with local anesthesia

### Safety

Safety sICH was seen in 18 patients (9%) in the aspiration group versus 55 (6%) in the stent retriever group (p=0.14). Mortality did not differ significantly between the two groups (27% in the aspiration group vs 26% in the stent retriever group (p=0.93), table 2).

Clinically significant new infarction occurred in five patients (2%) in the aspiration group versus 16 (2%) in the stent retriever group (p=0.64). Distal embolization rates seemed the same in both groups, as reperfusion rates (especially eTICI 2b and 2c scores) were the same.

### Table 2 Outcomes, complications

|                          | Aspiration (n=207) | Stent retriever (n=968) | P value |
|--------------------------|--------------------|-------------------------|---------|
| Duration of procedure (min), median (IQR) | 56.5 (35–73) | 70 (47–95) | <0.0001 |
| ER first hospital to reperfusion, (min)/last contrast bolus, median (IQR) | 164 (137–232) | 196 (151–245) | <0.0001 |
| SAE, any, n (%) | 85 (41) | 414 (43) | 0.71 |
| Intracranial haemorrhage total, n (%) | 18 (9) | 54 (6) | 0.14 |
| sICH periprocedural | 16 (30) | | |
| sICH after 24 hours | 9 (50) | 30 (56) | |
| sICH after 48 hours | 3 (17) | 2 (4) | |
| sICH at discharge | 1 (6) | 4 (7) | |
| sICH at follow-up | 0 (0) | 2 (4) | |
| Post EVT eTICI, n (%) | | | 0.03 |
| 0 | 28 (14) | 128 (13) | |
| 1 | 1 (1) | 44 (5) | |
| 2a | 46 (22) | 250 (26) | |
| 2b | 33 (16) | 174 (18) | |
| 2c | 24 (12) | 85 (9) | |
| 3 | 70 (35) | 271 (29) | |
| Successful reperfusion (eTICI 2b–3), n (%) | 127 (63) | 530 (56) | 0.06 |
| NIHSS 12–48 hours, median (IQR) | 12 (4–18) | 11 (4–17) | 0.60 |
| mRS 3 months’ follow-up, n (%) | | | 0.72 |
| 0 | 9 (5) | 47 (5) | |
| 1 | 19 (11) | 113 (13) | |
| 2 | 41 (23) | 175 (20) | |
| >2 | 111 (62) | 560 (63) | |
| Stroke progression resulting in neurodeterioration/death, n (%) | 17 (8) | 101 (10) | 0.40 |
| New ischemic stroke resulting in neurodeterioration/death, n (%) | 5 (2) | 16 (2) | 0.64 |
| Mortality, n (%) | 56 (27) | 256 (26) | 0.93 |
| Mortality within 7 days | 27 (13) | 137 (14) | 0.76 |
| Mortality within 1 month | 45 (22) | 213 (22) | 1.00 |

Missing values: time onset to reperfusion: 35 (0.3%); time duration of procedure: 80 (7%); moment of sICH: 1; post EVT eTICI: 21 (2%); NIHSS 12–48 hours: 119 (10%); mRS 3 months’ follow-up: 100 (9%).

ER, emergency room; eTICI, extended Thrombolysis in Cerebral Infarction; EVT, endovascular treatment; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; SAE, serious adverse events; sICH, symptomatic intracranial haemorrhage.
only are lacking.\textsuperscript{22–23} Differences in general anesthesia use are probably related to preferences of individual centres.

Second, the pre-stroke mRS score was higher in the aspiration than the stent retriever group. However, for both of the above-mentioned factors adjustment was applied in our analysis. Probably, the time difference between the two procedures may be too short and the groups too small to provide significant differences in functional recovery. In the stent retriever group, 107 patients (11%) were converted to aspiration, of whom 52% achieved successful reperfusion. In the aspiration group, 35 patients (17%) were converted to stent retriever treatment, with 15 patients (43%) achieving successful reperfusion. This indicates that conversion to the aspiration strategy may be advantageous, if first attempts with a stent retriever fail and vice versa.

The number of second passes for both techniques is in line with other studies.\textsuperscript{16,20}

Safety
Intracranial haemorrhage may be caused by reperfusion injury or by device-induced vessel damage. The latter may be caused by manipulation of the intracranial vasculature with any thrombectomy device.\textsuperscript{13} We found no difference in the occurrence of intracranial bleeding between the groups.

A matter of concern in mechanical thrombectomy is the periprocedural thrombus fragmentation, leading to the spread of emboli in a previously unaffected arterial territory.\textsuperscript{26} We observed no differences in clinically relevant infarction in another territory between the treatment groups. In addition, reperfusion rates were similar, especially cTICI 2b and 2c scores, indicating that both techniques probably induced same rates of thrombus fragmentation. This is in accordance with other studies.\textsuperscript{16,27}

Limitations
This study is not a randomized clinical trial, but both groups had similar baseline characteristics and with this study design the results represent daily clinical practice in a large real-life cohort. In this multicentre observational study not every centre used the same treatment protocols—for example, anesthetic management and choice of treatment modality varied. Significant differences in baseline characteristics (pre-stroke mRS score, use of general anesthesia, balloon guidng use, site of occlusion) seem to be less favourable for aspiration than stent retriever in our cohort, based on the current state of knowledge.

Procedures in which the final lateral DSA is missing were given a maximum cTICI score of 2a, which may lead to under-reporting of successful reperfusion. However, we assume that this occurred at a similar frequency in both groups and thus would not have influenced our results.

The combined treatment of stent retriever and aspiration could not be analysed separately; in this analysis it is considered a stent retriever approach.

CONCLUSION
The results of this large multicenter real-life cohort study showed no difference in safety and outcome between direct aspiration and stent retriever thrombectomy as first-line treatment strategy in patients with acute stroke with a large vessel occlusion. Both approaches are equally effective in endovascular treatment of acute ischemic stroke. This study confirms in a real-life population the results previously reported in randomized trials.

Author affiliations
\textsuperscript{1}Department of Radiology, Rijnstate Hospital, Arnhem, The Netherlands
\textsuperscript{2}Department of Neurology, Cardiovascular Research Institute Maastricht (CARIM), Maastricht University Medical Centre, Maastricht, The Netherlands
\textsuperscript{3}Department of Radiology, Cardiovascular Research Institute Maastricht (CARIM), Maastricht University Medical Centre, Maastricht, The Netherlands
\textsuperscript{4}Department of Neurology, University Medical Centre Groningen, University of Groningen, Groningen, The Netherlands
\textsuperscript{5}Department of Radiology, University Medical Centre Groningen, University of Groningen, Groningen, The Netherlands
\textsuperscript{6}Department of Neurology, Academic Medical Centre, Amsterdam, The Netherlands
\textsuperscript{7}Department of Neurology, Rijnstate Hospital, Arnhem, The Netherlands

Collaborators The collaborator details can be found in the online supplementary file.

Contributors MLEB wrote the statistical analysis plan, designed the first draft, conducted the statistical analysis, and revised the draft paper. R-JBG, JMM, and JH participated in study design, data collection, data analysis, interpretation, and writing of the manuscript. R-JBG, JH, JMM, WHvZ, RvdW, and MU revised the draft paper. The study coordinators, local investigators, and members of the executive, imaging, and complication committees collected the data. All authors critically reviewed the manuscript and approved the final version.

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