Received Date : 09-Dec-2016

Revised Date : 06-Mar-2017

Accepted Date : 06-Mar-2017

Article type : Clinical Investigation

Efficacy and Safety of Mechanical Thrombectomy in Older Patients with Acute Ischemic Stroke

Fabrizio Sallustio MD^{1,2}, Giacomo Koch PhD^{1,2}, Caterina Motta MD^{1,2}, Marina Diomedi MD¹, Fana Alemseged^{1,3}, Vittoria Carla D'Agostino MD¹, Simone Napolitano MD¹, Domenico Samà MD¹, Alessandro Davoli MD¹, Daniel Konda MD⁴, Daniele Morosetti MD⁴, Enrico Pampana MD⁴, Roberto Floris MD⁴, Roberto Gandini MD⁴

¹ Comprehensive Stroke Center, Department of Neuroscience, University of Tor Vergata, Rome, Italy

² Neurorehabilitation Unit, Santa Lucia Foundation, Rome, Italy

³ Department of Medicine and Neurology, Royal Melbourne Hospital, University of Melbourne, Parkville, Australia

⁴ Interventional Radiology and Neuroradiology, University of Tor Vergata, Rome, Italy

Abstract word count: 248

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/jgs.14909](https://doi.org/10.1111/jgs.14909)

25 **Text word count: 2113**

26 **Number of figures: 0**

27 **Number of tables: 4**

28 **Number of references: 25**

29 **Number of supplementary files: 2**

30 **Running title:** Endovascular stroke treatment in the elderly

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34 **Correspondence to:**

35 Fabrizio Sallustio,

36 Stroke Unit, Policlinico Tor Vergata, Viale Oxford 81, 00133, Rome, Italy

37 Phone/fax number: +390620903423; E-mail: fsall75@gmail.com

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Abstract

Background: only a minority of elderly patients have been enrolled so far in large randomized controlled trials evaluating the efficacy of intravenous thrombolysis and/or endovascular acute stroke treatment. We evaluated safety and efficacy of endovascular therapy in elderly patients treated for acute ischemic stroke.

Methods: 219 patients were divided into two groups based on their age: over 80 (N=62) and under 80 years (N=157). Baseline and procedural characteristics, safety outcomes such as intracranial haemorrhage (ICH) and mortality and efficacy outcomes such as successful reperfusion and 3-month good clinical outcome were compared between the two groups. Multivariable analysis was performed to identify predictors of clinical outcome.

Results: Intravenous thrombolysis was more frequent and onset-to-reperfusion time was shorter in the over 80 group (67.7% vs 52.8%, $p=0.04$; 318.7 ± 128.7 vs 282 ± 53.5 , $p=0.02$) whereas no differences were found between groups in terms of successful reperfusion (69% vs 63%, $p=0.4$), good clinical outcome (30.6% vs 34.3, $p=0.6$), any and symptomatic ICH (37% vs 37.5%, $p=1.00$; 11% vs 14%, $p=0.6$) and mortality (40.3% vs 29.2%, $p=0.1$). Multivariable analysis revealed that in the older group onset National Institute of Health Stroke Scale (NIHSS) and 24 hours clinical improvement (OR, 0.65; 95% CI, 0.44 to 0.96;

74 p=0.03; OR, 141.13; 95% CI, 2.96 to 6720.7; p=0.01) were independent predictors of 3
 75 month functional independence.

76 **Conclusions:** our findings seem to suggest that endovascular treatment for stroke in
 77 selected elderly patients could be safe and effective. Major determinants of outcome in this
 78 subgroup are presentation NIHSS and 24 hours clinical improvement.

79
 80 **Keywords:** elderly, ischemic stroke; mechanical thrombectomy; outcome.

81 INTRODUCTION

82 Due to aging of population and the increasing incidence and prevalence of ischemic stroke
 83 with age [1-2], the burden of stroke care is growing dramatically. A lot of skepticism toward
 84 treatment of elderly stroke patients in the last decades has led to the inclusion of a limited
 85 number of patients in randomized controlled trials (RCTs) [3]. The Third International
 86 Stroke Trial (IST-3) has been the largest RCT providing evidence for benefit of intravenous
 87 thrombolysis (IVT) for patients older than 80 years.[4] In a metaanalysis including 6 RCTs,
 88 benefit of IVT within 3 hour-time window was demonstrated for both younger and older
 89 patients [5]. Similar hesitation has been noticed in recent endovascular stroke trials, in
 90 which the median age of recruited stroke patients was 68 years [6]. In a recent meta-
 91 analysis of data collected from five large RCTs , only 15% of overall 1287 patients, were
 92 included in subgroup analysis restricted to elderly patients (≥80 years) and superiority of
 93 intervention over control group was claimed [6]. One of the main reasons for this
 94 skepticism has been the fear of complications, such as intracranial hemorrhage (ICH),
 95 higher in-hospital mortality and lower likelihood of being discharged home with lower
 96 functional independence at 3 months compared to younger patients [7-8]. This fear is
 97 supported by studies showing increased risk of bleeding or symptomatic ICH in elderly
 98 patients after IVT [9-10]. However, this trend is changing in the last years, as revealed by
 99 the latest IST-3 trial in which more than 50% of recruited patients were older than 80 years
 100 and those older than 90 years represented 7% of both active and control group. The aim of
 101 the present study was therefore to assess safety and efficacy of endovascular therapy by
 102 evaluating determinants of successful outcome in elderly patients with acute ischemic
 103 stroke.

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106 **METHODS**

107 Patients with anterior circulation acute ischemic stroke were collected from our prospective
 108 endovascular stroke registry (started in August 2009). Patients were selected based on
 109 following criteria: 1. CT-angiography (CTA) documentation of occlusion of middle cerebral
 110 artery (M1 or M2 segment), or anterior cerebral artery (A1 or A2 segment), or terminal
 111 internal carotid artery, or more than one of previous vessels in combination, or proximal
 112 internal carotid artery in combination to an intracranial vessel, confirmed on conventional
 113 angiography; 2. onset to groin puncture within 5 hours from symptom onset; 3. National
 114 Institute of Health Stroke Scale (NIHSS) ≥ 10 ; 4. pre-stroke modified Rankin Scale (mRS)
 115 ≤ 2 ; 5. available 3 month follow-up. Patients were divided into two groups based on their
 116 age: over 80 (≥ 80) and under 80 (≤ 79). Baseline characteristics included in the analysis
 117 were: age, gender, NIHSS, rate of tandem lesion, history of hypertension, diabetes,
 118 smoking, atrial fibrillation, Alberta Stroke Program Early CT score (ASPECTS) on non-
 119 contrast CT,[11] collaterals adequacy on pretreatment CTA. Collaterals were defined using
 120 a scale from 0 to 3 derived from the Prolyse in Acute Cerebral Thromboembolism
 121 (PROACT) II trial (0: no collaterals; 1: collaterals to the periphery of ischemia; 2: collaterals
 122 filling 50%-100% of ischemic area; 3: collaterals filling 100% of ischemic area).[12]
 123 Thereafter collateral score was dichotomized in poor (0-1) and good (2-3). The validity of
 124 this dichotomization in terms of functional outcome has been already shown.[13] Based on
 125 current guidelines IVT was administered within 4,5 hours after stroke onset at a full dose
 126 (0.9 mg/kg, 10% as a bolus and the remaining in 1 hour infusion)[10] and continued during
 127 endovascular procedure.[14] As procedural variables we adopted: use of intravenous
 128 heparin during the procedure, onset to groin puncture time, onset to reperfusion time and
 129 groin to reperfusion time, type of device used for thrombectomy. Outcome measures
 130 included successful reperfusion defined, according to the Thrombolysis in Cerebral
 131 Infarction (TICI) grading, as a score ≥ 2 , [15] ASPECTS on 24 hour non -contrast CT,
 132 haemorrhagic complications defined according to the European Cooperative Acute Stroke
 133 Study criteria (no haemorrhage, haemorrhagic infarction-1, haemorrhagic infarction-2,
 134 parenchymal haematoma-1, parenchymal haematoma-2), [16] symptomatic ICH (sICH)
 135 defined as an haemorrhage associated with an increase of at least 4 points in the NIHSS,
 136 24 hour clinical improvement defined as a reduction of at least 4 points in the NIHSS, 3
 137 month functional independence defined according to the mRS as a score ≤ 2 , and global

mortality. Due to higher number of comorbidities, usually observed in the elderly, we differentiated mortality due to neurological deterioration for malignant stroke or hemorrhagic transformation of the ischemic lesion from mortality occurred for other causes (pneumonia, sepsis, myocardial infarction). The study was approved by local ethical committee. Informed consent was obtained from all patients or their relatives.

Statistical Analysis

All data were initially entered into an EXCEL database (Microsoft, Redmond, Washington – United States) and the analysis was performed using the Stata/IC version 13 (StataCorp 2013, College Station, TX, USA). Descriptive statistics consisted of means±standard deviation (SD) or medians with interquartile range (IQR) for parameters with gaussian distributions (after confirmation with histograms and the Kolmogorov-Smirnov test) or frequencies (%) as appropriate. Comparison of continuous variables was performed by means of Student's t-test or Mann-Whitney U test. Comparison of categorical variables was performed by means of Fisher's exact test. Variables with a univariate p value <0.01 were further tested for the prediction of good outcome (mRS) and symptomatic ICH in different multivariate logistic regression analyses. A p value of < 0.05 was considered statistically significant for all analyses.

RESULTS

Of 254 patients treated with thrombectomy between august 2009 and June 2016, 219 fulfilled selection criteria and were included in the analysis. Of 35 patients excluded two were lost at follow-up and 33 had an onset-to-groin puncture time of more than 5 hours with a mean value of 351 minutes (range:305-605 min). Of 219 selected patients 157 were in the under 80 years old and 62 in the over 80 years old group. Table 1 shows baseline characteristics and demographics of the two groups. Patients in the older group were more frequently affected by atrial fibrillation and hypertension and significantly differed for gender. As shown in table 2, they were more frequently treated with IVT, intravenous heparin and conscious sedation during the procedure and were more quickly reperfused compared to the younger group.

When evaluating safety and efficacy endpoints in the univariate analysis (table 3) we found higher 24 hours ASPECTS in the older group, indicating smaller infarct size, whereas no

differences were found in the rate of hemorrhagic complications nor in 3 month clinical outcome nor in global mortality and mortality secondary to neurological deterioration. Furthermore we analysed all potential factors associated to 3 month functional clinical outcome in the elderly and younger groups. In both groups lower onset NIHSS, higher baseline and 24 hour ASPECTS, good collateral flow and 24 hour clinical improvement were associated with functional independence at 3 month follow-up. Functional outcome was associated with baseline glycemia and sICH rate only in the under 80 group and with a shorter groin-to-reperfusion time only in the elderly group (Supplementary Table S1). In the multivariate analysis, factors associated with 3 month functional independence were 24 hour clinical improvement and number of device passages in the under 80 years group (OR, 7.59; 95% CI, 1.9 to 28.8; $p=0.003$; OR, 0.48; 95% CI, 0.29 to 0.78; $p=0.004$) (Supplementary Table S2), onset NIHSS and 24 hours clinical improvement in the over 80 years group (OR, 0.65; 95% CI, 0.44 to 0.96; $p=0.03$; OR, 141.13; 95% CI, 2.96 to 6720.7; $p=0.01$) (Table 4).

DISCUSSION

In this single-center experience, endovascular treatment resulted in a similar rate of functional independence in elderly and relatively younger patients (30.6% vs 34.3%). The rate of favourable outcome obtained in the older patients in our study was comparable to the one of the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN) trial [17]. Global mortality was comparable to the one observed in previous studies [18], although tended to be higher in the older group. Moreover, mortality due to non neurological causes tended to be higher in the older group suggesting the role of preexisting comorbidities in affecting clinical outcome in the elderly. In addition, it is noteworthy to underline that hypertension, the most important risk factor for stroke, and atrial fibrillation, the most frequent cause of cardioembolic stroke, were more frequent in the elderly as already described [2].

Despite a more frequent use of IVT (a finding in countertrend to the above-mentioned skepticism) and intravenous heparin during procedure in the over 80 group, similar rates of ICH including the most serious parenchymal hemathoma type 2 were observed in the two groups [16]. This finding is in line with a metanalysis of IVT RCTs data reporting how the increased risk of ICH is irrespective of age [19] and with a recent metanalysis of five

201 endovascular stroke trials showing no differences in risk of parenchymal hematoma and
 202 sICH between populations with the highest common odds ratio for 3 month mRS 0-2
 203 favouring intervention in the subgroup analysis of elderly patients [6].

204 Our elderly patients were treated more frequently without general anesthesia, likely to
 205 reduce risk of overall complications in a population already affected by other comorbidities
 206 and with an increased risk of stroke-associated pneumonia [20-21]. Moreover, elderly
 207 patients showed shorter reperfusion times. Although avoiding general anesthesia could
 208 have speeded up reperfusion times, it has to be noted that in elderly reperfusion was
 209 achieved with a lower number of device passages. Nevertheless, we cannot say if this was
 210 an effect or a cause of shorter reperfusion times since it lies outside the purpose of this
 211 study.

212 The over 80 group had higher 24 hour ASPECTS, indicating a smaller infarct size than the
 213 under 80 group after treatment: this could be due, in our opinion, to both shorter
 214 reperfusion times and to a more frequent use of IVT with consequent more efficient
 215 preservation of ischemic penumbra resulting in a limitation of infarct burden.

216 Our multivariate analysis indicates onset NIHSS and 24 hour clinical improvement as the
 217 sole independent predictors of good outcome in aged stroke patients whereas 24 hour
 218 clinical improvement and the number of device passages were independent predictors in
 219 the under 80 years old group. Although 24 hour clinical improvement was predictive of
 220 functional outcome in both groups, odds ratio for elderly was much higher than for younger
 221 patients. This finding suggests that for those aged patients showing remarkable clinical
 222 improvement in the early period after procedure, all efforts should be made to prevent or
 223 treat post-stroke complications which are known to strongly affect short, intermediate and
 224 long-term morbidity and mortality [8, 22]. Our analysis revealed also onset NIHSS as a
 225 predictor of outcome in elderly but not in younger population. Onset NIHSS is a well-
 226 known and accurate predictor of outcome since it is related to infarct size and to the ability
 227 of collaterals to sustain ischemic penumbra which is known to be worse in elderly [23-24].
 228 Despite this, shorter times needed for reperfusion could have offset this assumption and
 229 could explain the high rate of 3-month functional independence and the surprising higher
 230 24 hour ASPECTS observed in the older group. Particular attention to onset NIHSS and
 231 baseline ASPECTS could be, therefore, of great value for proper patients selection, but
 232 speed of endovascular procedure seems to be of grounded relevance in achieving
 233 reperfusion and good clinical outcome in this subgroup.

The main limitation of our study is its retrospective nature and the relatively small number of patients in the elderly group. The strict selection criteria could have led to misleading results, limiting the generalizability of conclusions. However, these criteria were chosen in order to adhere, as much as possible, to updated guidelines and current real practice. Moreover, only 4 patients out of excluded 35, were older than 80 likely not affecting the results (of them 2 died and 2 were independent at 3 month follow-up). Furthermore the 7 year-period analyzed includes the use of first-generation devices and different levels of interventionalists' skill secondary to an expected learning curve over the years [25]. All this could have affect outcome measures such as successful reperfusion and good clinical outcome. However, to our knowledge, this is one of the largest single-center controlled study of endovascular treatment in elderly acute ischemic stroke patients.

In conclusion, this study seems to suggest that endovascular treatment for large vessel occlusion stroke in the elderly could be safe and effective. Major determinants of outcome in this subgroup of patients are presentation NIHSS and 24 hour clinical improvement. Further studies in larger series are warranted to confirm our results and to evaluate safety and efficacy of endovascular treatment also in ultra-elderly patients.

ACKNOWLEDGMENTS

Conflict of interest: The authors have no conflicts in the cover letter as well as in the manuscript

Author's Contributions

Fabrizio Sallustio: conception and design, acquisition of data, analysis and interpretation of data; drafting the article; final approval of the version to be published.

Giacomo Koch: analysis and interpretation of data; revising the article critically for important intellectual content; final approval of the version to be published.

- 263 **Caterina Motta:** conception and design, analysis and interpretation of data; drafting the
264 article; final approval of the version to be published.
- 265 **Marina Diomedi:** analysis and interpretation of data; revising the article critically for
266 important intellectual content; final approval of the version to be published.
- 267 **Fana Alemseged:** revising the article critically for important intellectual content; English
268 editing; final approval of the version to be published.
- 269 **Vittoria Carla D'Agostino:** acquisition of data; revising the article critically for important
270 intellectual content; final approval of the version to be published.
- 271 **Simone Napolitano:** acquisition of data; revising the article critically for important
272 intellectual content; final approval of the version to be published.
- 273 **Domenico Samà:** acquisition of data; revising the article critically for important intellectual
274 content; final approval of the version to be published.
- 275 **Alessandro Davoli:** acquisition of data; drafting the article; final approval of the version to
276 be published.
- 277 **Daniel Konda:** acquisition of data; revising the article critically for important intellectual
278 content; final approval of the version to be published.
- 279 **Daniele Morosetti:** acquisition of data; revising the article critically for important
280 intellectual content; final approval of the version to be published.
- 281 **Enrico Pampana:** acquisition of data, analysis and interpretation of data; revising the
282 article critically for important intellectual content; final approval of the version to be
283 published.
- 284 **Roberto Floris:** analysis and interpretation of data; revising the article critically for
285 important intellectual content; final approval of the version to be published.
- 286 **Roberto Gandini:** conception and design, acquisition of data, analysis and interpretation
287 of data; revising the article critically for important intellectual content; final approval of the
288 version to be published.
- 289
- 290 **Sponsor's Role:** this manuscript has no sponsor.

Funding Statement: this work was supported by the Italian Ministry of Health (RF-2013-02358679).

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LEGENDS

Supplementary Table S1: Univariate analysis of outcome predictors in the two groups

Supplementary Table S2: Multivariate analysis of outcome predictors in patients aged < 80 years

Table 1. Demographics and baseline characteristics

	Under 80 (n=157)	Over 80 (n=62)	p
<i>Age, years (mean±SD)</i>	64.5±10.7	84.9±4.2	<0.001
<i>Gender (male) (%)</i>	81(51.5)	13(20.9)	0.001
<i>Hypertension (%)</i>	115(73.2)	54(87)	0.03
<i>Diabetes (%)</i>	27(17.1)	11(17.7)	0.7

<i>Atrial Fibrillation (%)</i>	57(36.3)	41(66)	<0.001
<i>Smoking (%)</i>	33(21)	0	<0.001
<i>Baseline glycemia (mean±SD)</i>	134±61.3	135±34	0.9
<i>Baseline NIHSS (mean±SD)</i>	18±3.1	18±4.2	0.7
<i>Baseline SBP (mean±SD)</i>	145.5±28.1	147±23	0.6
<i>Baseline DBP (mean±SD)</i>	82±14.4	79±14.8	0.2
<i>Baseline ASPECTS (mean±SD)</i>	7.3±2.2	7.9±2.1	0.06
<i>MCA occlusion (%)</i>	88(56)	43(69.3)	0.09
<i>Terminal ICA (%)</i>	1(0.6)	1(1.6)	0.4
<i>T occlusion^a (%)</i>	4(2.5)	0	0.5
<i>Tandem occlusion (%)</i>	64(40.7)	18(29)	0.1
<i>Good collaterals (%)</i>	87(55.4)	35(56.4)	0.7

NIHSS= National Institute of Health Stroke Scale; SBP: systolic blood pressure; DBP= diastolic blood pressure; ASPECTS= Alberta Stroke Program Early CT Score; MCA= middle cerebral artery; ICA= internal carotid artery; T occlusion= combined occlusion of terminal ICA, MCA and ACA

Table 2. Procedural characteristics

	Under 80 (n=157)	Over 80 (n=62)	p
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<i>I.V. Thrombolysis (%)</i>	83(52.8)	42(67.7)	0.04
<i>I.V. Heparin (%)</i>	44(28)	27(43.5)	0.03
<i>General Anesthesia (%)</i>	93(59.2)	21(33.8)	<0.001
<i>Stent retriever use (%)</i>	45(28.6)	8(13)	0.01
<i>Thromboaspiration device use (%)</i>	77(49)	39(63)	0.07
<i>Rescue device use (%)</i>	42(26.7)	19(30.6)	0.6
<i>Onset-groin puncture time (mean±SD)</i>	239.7±117.7	219±52.5	0.1
<i>Onset-reperfusion time (mean±SD)</i>	318.7±128.7	282±53.5	0.02
<i>Groin-reperfusion time (mean±SD)</i>	78.5±60.7	60±28.5	0.009
<i>Device attempts (mean±SD)</i>	2.8±2	2.1±1.3	0.01

Table 3. Safety and efficacy outcomes

	Under 80 (n=157)	Over 80 (n=62)	p
<i>Successful reperfusion (%)</i>	99(63)	43(69)	0.4
<i>24 hs follow-up ASPECTS (mean±SD)</i>	3.5±2.5	5±2.7	<0.001
<i>Any ICH (%)</i>	59(37.5)	23(37)	1.000
SAH	2(3.3)	2(8.6)	0.3
HI-1	6(10.1)	3(13)	0.7
HI-2	6(10.1)	3(13)	0.7
PH-1	22(37.2)	4(17.3)	0.1
PH-2	23(38.9)	11(47.8)	0.6
<i>Symptomatic ICH (%)</i>	22(14)	7(11)	0.6
<i>mRS≤2 (%)</i>	54(34.3)	19(30.6)	0.6
<i>mRS≤3 (%)</i>	74(47.1)	21(33.8)	0.09
<i>Global mortality (%)</i>	46(29.2)	25(40.3)	0.1
<i>Mortality due to neurological deterioration</i>	33(21)	9(14.5)	0.3

ASPECTS= Alberta Stroke Program Early CT Score; ICH= Intracranial haemorrhage;
 SAH= Subarachnoid haemorrhage; HI= Hemorrhagic Infarction; PH= Parenchymal
 haematoma; mRS= modified Rankin Scale

Table 4. Multivariable regression model: independent predictors of three months good outcome in patients aged >80 years.

	OR	SE	95% CI	p
Onset NIHSS	0.65	0.13	0.44 – 0.96	0.033
Groin-to-reperfusion time	0.98	0.02	0.94 – 1.01	0.344
24 hs NIHSS improvement	141.13	278.19	2.96 – 6720	0.012
Baseline ASPECTS	1.28	0.45	0.64 – 2.54	0.469
24 hs follow-up ASPECTS	1.08	0.39	0.53 – 2.19	0.831
Good collateral flow	4.22	5.41	0.34 – 52.14	0.261

NIHSS: National Institutes of Health Stroke Scale; ASPECTS: Alberta Stroke Program Early CT Score; OR: odds ratio; SE: standard error; CI: confidence intervals.

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Author/s:

Sallustio, F;Koch, G;Motta, C;Diomedi, M;Alemseged, F;D'Agostino, VC;Napolitano, S;Sama, D;Davoli, A;Konda, D;Morosetti, D;Pampana, E;Floris, R;Gandini, R

Title:

Efficacy and Safety of Mechanical Thrombectomy in Older Adults with Acute Ischemic Stroke

Date:

2017-08-01

Citation:

Sallustio, F., Koch, G., Motta, C., Diomedi, M., Alemseged, F., D'Agostino, V. C., Napolitano, S., Sama, D., Davoli, A., Konda, D., Morosetti, D., Pampana, E., Floris, R. & Gandini, R. (2017). Efficacy and Safety of Mechanical Thrombectomy in Older Adults with Acute Ischemic Stroke. JOURNAL OF THE AMERICAN GERIATRICS SOCIETY, 65 (8), pp.1816-1820. <https://doi.org/10.1111/jgs.14909>.

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