Predictive value of the Essen Stroke Risk Score and Ankle Brachial Index in Acute Ischemic Stroke Patients from 85 German Stroke Units

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Key words: Ischemic stroke – secondary prevention – risk prediction – peripheral arterial disease – ankle brachial index.

Abstract

Background. Risk stratification can contribute to individualized, optimal secondary prevention in patients with cerebrovascular disease. 

Objective. To prospectively investigate the prediction of the Essen Stroke Risk Score (ESRS) and a pathological ankle brachial index (ABI) in consecutive patients hospitalized with acute ischemic stroke or TIA in 85 neurological stroke units throughout Germany.

Methods. 852 patients were prospectively documented on standardized case report forms including assessment of ESRS and ABI. After 17.5 months, recurrent cerebrovascular events, functional outcome or death could be assessed in 729 patients predominantly via central telephone interview.

Results. After discharge from the documenting hospital, recurrent stroke occurred in 41 patients (5.6%) and recurrent TIA in 15 patients (2.1%). 52 patients (7.1%) had died, 33 (4.5%) from cardiovascular causes. Patients with an ESRS \( \geq 3 \) (vs. <3) had a significantly higher risk of recurrent stroke or cardiovascular death (9.7% vs. 5.1%, odds ratio [OR] 2.00, 95% confidence interval [CI] 1.08-3.70) and a higher recurrent stroke risk (6.9% vs. 3.7%, OR 1.93; 95% CI 0.95-3.94). Patients with an ABI \( \leq 0.9 \) (vs. >0.9) had a significantly higher risk of recurrent stroke or cardiovascular death (10.4% vs. 5.5%, OR 2.00, 95% CI 1.12-3.56) and a higher recurrent stroke risk (6.6% vs. 4.6%, OR 1.47, 95% CI 0.76-2.83).

Conclusion. Our prospective follow-up study shows a significantly higher rate of recurrent stroke or cardiovascular death and a clear trend for a higher rate of recurrent stroke in patients with acute cerebrovascular events classified as high-risk by an ESRS \( \geq 3 \) or a pathological ABI.
Due to the aging populations, the incidence of ischemic stroke (IS) is increasing in industrialized countries with a significant burden from an individual as well as a public health perspective.[1] In contrast to the incidence of first-ever stroke which is still expected to rise due to an increasing life expectancy,[2] the rate of recurrent stroke is more susceptible to medical treatment or preventive measures and therefore could be effectively reduced.[3, 4] While predictive models have already proven their usefulness in patients with myocardial infarction and atrial fibrillation, they are still hardly used in treatment decisions following IS or transient ischemic attack (TIA).

Validated scores exist for the prediction of first stroke,[5, 6] as well as for prediction of recurrent (cerebro)vascular events.[7-9] Recently, the Essen Stroke Risk Score (ESRS,[10]) was derived from the data subset of 6,433 cerebrovascular patients in the large-scale Clopidogrel versus Aspirin in Patients at Risk of Ischaemic Events (CAPRIE) trial.[11] On a linear 10-point scale, the ESRS as presented in table 1 predicts short-term (1-year) risk of recurrent stroke. Low risk category (score 0-2) and the higher risk category (score ≥3) can easily be distinguished. Because the ESRS so far has been developed and validated only in populations from randomized controlled trials with strict inclusion and exclusion criteria, we performed a prospective validation in the Systemic Risk Score Evaluation in Ischemic Stroke Patients (SCALA) study on IS and TIA patients routinely admitted to certified German stroke units.[12] At baseline, we also assessed the ankle brachial index (ABI) which is an easy-to-use, inexpensive and reliable tool to identify patients with high atherosclerotic burden and thus high cardiovascular risk. Among trained investigators, test-retest reliability of the ABI is excellent, and a series of large-scale epidemiological studies have shown a strong correlation between low ABI scores and (cardiovascular) mortality.[13, 14] Current guidelines of the American Heart Association thus recommend the ABI for screening of asymptomatic patients to identify and treat an increased risk of coronary artery disease and stroke.[15] Similarly, a strong association could be demonstrated between a low ABI and an increased incidence of ischemic stroke although sensitivity was low.[13, 16-18] However, only one study so far has assessed the prognostic value of the ABI in patients with acute cerebrovascular events.[19] The aims of the present longitudinal study therefore were to validate the prediction of the ESRS with the established cut-off ≥3 for high risk patients and to investigate the prediction of a pathological ABI for future cerebrovascular events and vascular death in patients after an acute IS or TIA.

Methods
This prospective, observational cohort study (acronym Systemic Risk Score Evaluation in Ischemic Stroke Patients, SCALA) was conducted in 85 certified German neurological stroke units each of which documented 10 consecutive patients with acute IS or TIA on standardized case report forms during a period between 07/2005 to 10/2005. Methods and results of baseline data collection have been described previously.[12] In short, the following exclusion criteria were applied: primary cerebral hemorrhage, intubation, and refusal or inability to provide informed consent. Patients were treated according to best current knowledge and management was not delayed nor altered by participation in this study. Patients provided written informed consent for study participation. The study was approved by the Ethics Committee of the University of Essen and conducted according to the national data protection legislation. The ESRS is a simple sum score calculated as follows: 2 points for age >75, each one point for age ≥65-75, arterial hypertension, diabetes mellitus, previous myocardial infarction (MI),
other cardiovascular disease (except MI and atrial fibrillation), peripheral arterial
disease (PAD), current or past (<5 years) smoking, and previous transient ischemic
attack (TIA) or ischemic stroke in addition to qualifying event. The ABI was obtained
after a 5 min rest in supine position from systolic blood pressure readings by Doppler
sonography at the ankle (posterior and anterior tibial artery) and at the brachial artery.
The highest systolic blood pressure in each leg was then divided by the average systolic
pressure in both arms (unless there was a discrepancy of ≥10mmHg between the two
arms).
A central follow-up interview via telephone (N=649) or written questionnaire (N=80)
could be performed in 729 participants after 17.5 (SD 0.88) months. No follow-up could
be obtained in 123 patients (14.4%) either because they did not consent to follow-up
(N=112) or were reportedly alive but could not be reached (N=11). Follow-up included
screening for recurrent cerebrovascular events and assessment of functional disability
scales (Barthel Index, modified Rankin Scale) or cause of death. In case of a recurrent
cerebrovascular event or death, confirmation was sought form the family physician,
treating hospital or local death registries. Only events after discharge from the
documenting hospital were considered.

Statistics
Categorical variables are presented as percentages and continuous variables as mean
with standard deviation (SD) and/or median and quartiles. Chi-square test and Fisher’s
exact test as appropriate were used for comparison of categorical variables. Wilcoxon
rank sum score was used for comparison of non-normally distributed variables. If any
variable was not available for all patients, only valid cases were reported. We calculated
the time of event-free survival by Kaplan-Meier (KM) estimates. To evaluate the
performance of the ESRS and the ABI, we calculated the the area under the curve
(AUC) by c-statistic and calibration chi-square (survival modified Hosmer-Lemeshow).
An AUC of 0.5 indicates no discrimination, and an AUC of 1.0 indicates perfect
discrimination. Analyses were done with SAS version 8.2 and SPSS version 14.0.2.

Results
The 85 centers listed in the appendix consecutively included 852 patients with a mean
age of 67.1 years (SD 12.4) and a diagnosis of IS in 82.9%, and TIA in 17.1 %. Most
index events (89.7%) had occurred within the last 7 days prior to study inclusion. Stroke
etiology was classified as large artery disease in 26.0%, small vessel disease in 27.2%,
cardioembolic in 23.9% and other or undetermined etiology in 22.9% of patients. Other
baseline characteristics have been reported previously.[12] A follow up after 17.5 (SD
0.88) months could be obtained in 729 patients (85.6%), 17.4% with TIA and 82.6%
with IS. Compared to patients with follow-up, those without follow-up were
significantly older (p=0.043), more often had a pathological ABI (66.7% vs. 52.8%;
p<0.005) and had more severe baseline stroke severity on the NIH-SS (mean 6.96 vs.
4.96; p=0.012) but were not significantly different with regard to their overall ESRS
sum score (table 1).
Table 1. Baseline characteristics on the Essen Stroke Risk Score (ESRS) of patients with and without follow-up

<table>
<thead>
<tr>
<th>Risk factor (points allocated)</th>
<th>With follow-up (N=729)</th>
<th>Without follow-up (N=123)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 65–75 years, % (1 point)</td>
<td>35.9</td>
<td>33.3</td>
</tr>
<tr>
<td>Age &gt;75 years, % (2 points)</td>
<td>26.0</td>
<td>36.6*</td>
</tr>
<tr>
<td>Arterial hypertension, % (1 point)</td>
<td>70.4</td>
<td>73.8</td>
</tr>
<tr>
<td>Diabetes mellitus, % (1 point)</td>
<td>26.9</td>
<td>22.8</td>
</tr>
<tr>
<td>Previous myocardial infarction (MI), % (1 point)</td>
<td>17.1</td>
<td>19.7</td>
</tr>
<tr>
<td>Other cardiovascular disease (except MI and atrial fibrillation), % (1 point)</td>
<td>36.8</td>
<td>30.1</td>
</tr>
<tr>
<td>Peripheral arterial disease (PAD), % (1 point)</td>
<td>10.3</td>
<td>10.6</td>
</tr>
<tr>
<td>Smoker, % (1 point)</td>
<td>24.9</td>
<td>23.9</td>
</tr>
<tr>
<td>Previous Transient Ischemic Attack (TIA) or ischemic stroke in addition to qualifying event, % (1 point)</td>
<td>25.4</td>
<td>30.1</td>
</tr>
<tr>
<td>Mean ESRS sum score</td>
<td><strong>2.96</strong></td>
<td><strong>3.06</strong></td>
</tr>
</tbody>
</table>

*significant at p<0.05

A recurrent fatal or non-fatal stroke was reported by or in 41 patients (5.6%) and a recurrent TIA by 15 patients (2.1%). Confirmation of these events by the family practitioner or treating hospital could be obtained in 37 and 11 patients, respectively. One event occurred during carotid endarterectomy which together with endovascular stenting was performed in 32 patients. A recurrent stroke or cardiovascular death occurred in 60 patients. Overall 52 patients (7.1%) had died during follow-up (7 because of the initial stroke, 12 because of a recurrent stroke, 5 because of myocardial infarction, 9 because of other cardiovascular events, 13 because of other causes and 6 due to an unknown cause). Of 677 surviving patients, 179 patients (26.4%) had not regained functional independence (modified Rankin Scale, mRS >2), 85 patients (12.6%) were largely independent (mRS 2), 398 patients (58.8%) reported no or only minor disability (mRS <2) and no information on functional outcome was available in 15 patients (2.2%). Surviving patients with a recurrent stroke had a significantly worse functional status on follow-up (median mRS 4) compared to event-free patients (median mRS 1). No antithrombotic medication at follow-up was reported by 44 patients (6.5%), 287 patients (42.4%) were on aspirin, 148 (21.9%) were on phenprocoumon or warfarin (7 with additional aspirin), 107 (15.8%) on clopidogrel (12 with additional aspirin), 52 (7.7%) on aspirin/dipyridamol, 2 (0.3%) on heparin and 8 (1.2%) on various study medications (medication not further specified in 29 patients). Complete information for calculation of the ESRS was available in 700 patients and for the ABI in 692 patients.
Recurrent stroke occurred in 11 (3.7%) of 296 patients with ESRS <3 (or 17 / 5.7% including TIA) compared to 28 (6.9%) (or 35 / 8.7% including TIA) of 404 patients with ESRS ≥3 (odds ratio for stroke 1.93, 95% confidence interval [CI] 0.95-3.94). The survival proportion free of recurrent stroke stratified by the ESRS is displayed in figure 1. The AUC assessed by c-statistics was 0.56 (not significant). The risk of the combined vascular endpoint recurrent stroke or cardiovascular death was significantly higher in patients with ESRS ≥3 (39 events / 9.7%) compared to patients with ESRS <3 (15 events / 5.1%; OR 2.00, CI 1.08-3.70; p=0.031). Stratified KM-estimates are displayed in figure 2. The AUC assessed by c-statistics was 0.61 (CI 0.54-0.69, p=0.006).

Recurrent stroke occurred in 16 (4.6%) of 346 patients with ABI >0.9 (or 20 / 5.8% including TIA) compared to 23 (6.6%) (or 32 / 9.2% including TIA) of 346 patients with ABI ≤0.9 (OR for stroke 1.47, CI 0.76-2.83) which was mainly due to the high stroke risk of 7.6% in 170 patients with an ABI <0.6. The survival proportion free of recurrent stroke stratified by the ABI is displayed in figure 3. The AUC assessed by c-statistics was 0.56 (not significant). The risk of the combined vascular endpoint was significantly higher in patients with ABI ≤0.9 (36 events / 10.4%) compared to patients with ABI >0.9 (19 events / 5.5%; OR odds ratio 2.00, CI 1.12-3.56; p=0.024). Stratified KM-estimates are displayed in figure 4. The AUC assessed by c-statistics was 0.61 (CI 0.53-0.69, p=0.006). The correlation between the ESRS and ABI in patients with follow-up was low (r=0.166, p<0.001). The combination of a high risk on both ESRS and ABI did not result in an improved risk prediction for stroke (6.7% versus 5.2%; OR 1.31, CI 0.67-2.54; p=0.482) nor for the combined vascular endpoint (10.8% versus 6.3%; OR 1.79, CI 1.02-3.15; p=0.048).

No significant differences or relevant trends in the risk of recurrent stroke were found for different stroke etiologies according to the TOAST classification (figure 5).

**Discussion**

Our study evaluates the ESRS and the ABI for identification of patients at high risk for stroke or cardiovascular death after a preceding cerebrovascular ischemic event. Only few prognostic instruments for the identification of cerebrovascular patients at high risk have been prospectively validated so far and are rarely used in clinical routine. We prospectively assessed the ESRS and ABI in consecutive patients with acute TIA or IS admitted to a large number of acute stroke units covering all geographic areas in Germany. Patients were included consecutively provided they could give informed consent, representing about 80-90% of unselected patients admitted to German stroke units. Thus, with the exception of severely aphasic and severely ill patients, the population in our study can be regarded as representative for acute stroke units. While both scoring instruments (ABI and ESRS) are simple to apply, their combination did not improve overall prediction, which may be due to their low correlation (Pearson correlation coefficient 0.21)[12] or the low event rates during follow-up resulting in a wide CI. Similarly, stratification by type of stroke according to the TOAST criteria in our study did not show any clear trend in risk of recurrent stroke and therefore would not add any predictive accuracy.

Our study on ESRS and ABI in cerebrovascular patients has three major limitations: We did not assess and therefore were unable to consider recurrent cerebrovascular events or cardiovascular death during the acute hospital stay, resulting in lower event rates than expected from other hospital-based studies. Due to the low number of stroke events during follow-up, we failed to demonstrate statistically significant differences between
high-risk and low-risk patients for the endpoint of recurrent stroke, although clear trends for higher stroke recurrence were seen in patients with ESRS ≥3 or ABI <0.6. Statistically significant differences were found for the combined vascular endpoint with higher event rates in patients with ESRS ≥3 or ABI ≤0.9. Unfortunately, the number of endpoint events was insufficient to provide meaningful risk stratifications of smaller ESRS or ABI categories and confidence intervals remain wide for the KM estimates which can explain the delayed segregation of the KM curves. A higher follow-up percentage than 85.6% would have been unlikely to change our results because most patients without follow-up simply did not provide informed consent for follow-up and citizen registries were consulted before any patients was considered lost. Furthermore, the rates of recurrent stroke in the high- and low-risk strata of the ESRS were very similar to the CAPRIE data set initially used for model development,[10] and the ESPS-2 data used for its retrospective validation,[20] and therefore confirm its predictive value in consecutive patients treated with modern prevention strategies in acute stroke units. Both retrospective analyses of CAPRIE and ESPS2 could also show a steady increase in the risk of stroke with increasing ESRS sum score and an amplified (although non significant) benefit of clopidogrel or aspirin plus dipyridamole over aspirin in patients with ESRS ≥3. Second, atrial fibrillation (AF) was not investigated as an independent predictor nor included upon development of the ESRS. However, AF has not been identified as an independent risk factor in other follow-up studies either,[7, 8] and the risk of stroke recurrence in patients with a cardioembolic stroke etiology (most of which had atrial fibrillation) was not significantly different from other etiologies. On the other hand, we did not exclude patients with cardioembolic stroke etiology. Although exclusion of patients with non-atherothrombotic stroke might result in a better prediction of the ESRS and ABI, we aimed to demonstrate the general applicability of the two instruments without additional diagnostic work-up to exclude cardioembolic etiologies.

Finally, the prediction of the ESRS was based solely on clinical variables, while the ABI assesses generalized atherosclerosis only which is responsible for less than half of all strokes. In comparison, another clinical scoring system, developed by Hankey et al. predicting various vascular events (stroke, coronary events, vascular death) at 1 and 5 years later found an AUC value of 0.65 upon external validation in the UK–TIA cohort.[21] Likewise, the SPI-II found an AUC of 0.63 for prediction of stroke or death within 2 years in independent research populations.[7] Both scores therefore have comparable predictive accuracy compared to our scores for the combined endpoint recurrent stroke/cardiovascular death. Neither one of these scales however has been prospectively validated for prediction of stroke in a non-research population. We could not compare the predictive accuracy between these scales and the ESRS in our study-population because not all variables from the other scales had been prospectively documented and the number of outcome events would have been too small to detect any statistically significant differences. As previously reported, an important finding in our study was the high prevalence of pathological ABI values in more than half of all patients which can be attributed to the inclusion of consecutive patients with acute ischemic events as well as to a more comprehensive definition of pathological ABI values (<0.9 vs. >0.9) in our trial.[12] Although prediction of stroke could be improved by dichotomizing the ABI at 0.6, all patients with a low ABI should be considered at high risk for any cardiovascular event including death.[19]
In conclusion, the ESRS is convenient to use, targets a distinctly important clinical outcome and is reasonably accurate for clinical stratification of high-risk patients. Both the ESRS and ABI seem suitable for routine application to increase awareness of recurrent stroke risk in cerebrovascular patients. Whether patients at high risk according to the ABI or ESRS benefit from intensified medical prevention strategies is difficult to assess because of the high number of endpoints needed. Because of its potential for optimizing secondary prevention strategies this question is of major relevance to public health decisions and should be assessed in future secondary prevention trials. In addition, high-risk patients may constitute the ideal target population for clinical trials of more aggressive medical prevention strategies which may also imply a higher associated risk. Moreover, by including only patients at higher risk of recurrent stroke, future trials could achieve the necessary number of endpoint events with fewer patients or within shorter follow-up periods.

Acknowledgments
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References


Figure Legends

Figure 1: Survival free of recurrent stroke during follow-up in patients with Essen Stroke Risk Score (ESRS) <3 versus ≥3 (N=700)

Figure 2: Survival free of recurrent stroke or cardiovascular death during follow-up in patients with Essen Stroke Risk Score (ESRS) <3 versus ≥3 (N=700)

Figure 3: Survival free of recurrent stroke during follow-up in patients with Ankle Brachial Index (ABI) >0.9 vs. 0.6-0.9 and <0.6 (N=692)

Figure 4: Survival free of recurrent stroke or cardiovascular death during follow-up in patients with Ankle Brachial Index (ABI) >0.9 vs. 0.6-0.9 and <0.6 (N=692)

Figure 5: Survival free of recurrent stroke during follow-up stratified by etiology (large artery atherosclerosis=laa, N = 178 ; cardiac embolism=ce, N= 163; small vessel disease=svd, N= 209; other/undetermined=o/u, N= 160)
Appendix: List of participating centers
Adelmann M. Klinikum Weilmünster
Arnold G. Städtisches Krankenhaus Sindelfingen
Bauer B. Dietrich-Bonhoeffer Klinik Neubrandenburg
Berlit P. Alfried Krupp Krankenhaus Essen
Berrouschot J. Kreiskrankenhaus Altenburg
Bitsch A. Ruppiner Kliniken GmbH Neuruppin
Bittermann H.-J. Klinik und Reha-Zentrum Wahlburg
Brüderl W. Schwarzwaldbaar Klinikum GmbH Villingen-Schwenningen
Buchner H. Knappschafts-Krankenhaus Recklinghausen
Dichgans M. Klinikum der Universität München
Dommasch D. Evangelisches Krankenhaus Bielefeld
Erbguth F. Klinikum Süd Nürnberg
Eue S. Klinikum Bernburg (Saale)
Ferbert A. Klinikum Kassel
Finke E. Evangelisches Krankenhaus Unna
Gahn G. Universitätsklinikum Dresden
Gerhard H. Kath. Krankenhaus Philippusstift Essen
Glahn J. Klinikum Minden
Greil H. Evangelisches Krankenhaus Duisburg-Nord Duisburg
Grond M. Kreiskrankenhaus Haus Hüttenal Siegen
Haan J. Krankenhaus St. Franziskus Mönchengladbach
Haas W. Unfallkrankenhaus Berlin
Haberl R.L. Städtisches Krankenhaus Harlaching München
Hammann G.F. Dr.-Horst-Schmidt-Kliniken Wiesbaden
Handrup R. St. Johannes-Krankenhaus Troisdorf
Hansen H.-C. Friedrich-Ebert-Krankenhaus Neumünster
Haupt W. Hephata-Klinik Schwalmstadt
Heinen M. Medizinisches Zentrum Aachen Würselen
Hennerici M.G. Klinikum Mannheim
Hetzel A. Universitätsklinikum Freiburg im Breisgau
Hoffmann F. Städt. Krankenhaus Martha-Maria Halle (Saale)
Horn M. Klinikum Bad Hersfeld
Huber R. Rehabilitationskrankenhaus Ulm
Ickenstein G. Helios-Klinikum Müllheim
Janzen R.W.C. Krankenhaus Nordwest Frankfurt am Main
Jauß M. Klinikum der Justus-Liebig-Universität Gießen
Jörg J. Helios-Klinikum Barmen Wuppertal
Klingelhöfer J. Klinikum Chemnitz
Köhler W. Sächs. Krankenhaus Hubertusburg Wermsdorf
Könnecke H.-C. Evangelisches Krankenhaus Berlin
Körner C.-F. Kreiskrankenhaus Eschwege
Lohner H. Klinikum Rosenheim
Mast H. Berufsgenossenschaftliche Kliniken Halle (Saale)
Masuhr F. Charité Campus Mitte Berlin
Matz D. Evangelisches Krankenhaus Lippstadt
Menger H. St. Marien-Hospital Borken
Motzek-Noé T. Klinikum Passau
Mühler J. Leopoldina-Krankenhaus Schweinfurt
Müller S. Eichsfeld Klinikum Worbis
Neukäter W. Evang. Krankenhaus Wesel
Ochs G. Klinikum Ingolstadt
Oellmann H.-D. St. Barbara-Hospital Gladbeck
Poremba M. Caritas-Krankenhaus Bad Mergentheim
Rimpau W. Park-Klinik Weißensee Berlin
Ringelstein E.B. Universitätsklinikum Münster
Rollnik J.D. Neurologische Klinik Hessisch Oldendorf
Rooschütz H.-D. Zentrum für Psychiatrie Winnenden
Rosenkranz M. Universitätsklinikum Eppendorf Hamburg
Ruf H. St. Johannes-Hospital Hagen
Schad M. Christophsbad Göppingen
Schlachetzki F. Bezirksklinikum Regensburg
Schneider R. Klinikum Aschaffenburg
Schröder K. Krankenhaus d. Barmherzigen Brüder Trier
Schütz H. Städt. Kliniken Ffm.-Höchst Frankfurt am Main
Schwartz A. Klinikum Hannover Nordstadt
Skodda S. Knappschaftskrankenhaus Bochum
Steinke W. Marien-Hospital Düsseldorf
Stock A. Klinikum Fulda
Thomsen A. Fürst-Stirum-Klinik Bruchsal
Töpper R.F. Allgemeines Krankenhaus Harburg Hamburg
Treib J. Westpfalz-Klinikum Kaiserslautern
Vette T. Sächsisches Krankenhaus Schkeuditz
Vogel P. Allgem. Krankenhaus St. Georg Hamburg
Weimar C. Universitätsklinikum Essen
Weißenborn K. Medizinische Hochschule Hannover
Wessels H.-J. Ev. Bathildiskrankenhaus Bad Pyrmont
Widder B. Bezirkskrankenhaus Günzburg
Wiesenfeldt J. Verbundkrankenhaus Bernkastel/Wittlich
Wilmsen H. St. Augustinus-Krankenhaus Düren
Witte O-W. Universitätsklinikum Jena
月后事件自由率

- ABI > 0.9
- ABI 0.6-0.9
- ABI < 0.6

事件率 [%]

月后入院
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