Incidence and Long-Term Follow-Up of Silent Cerebral Lesions After Pulmonary Vein Isolation Using a Remote Robotic Navigation System as Compared With Manual Ablation

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Background—The incidence of silent cerebral lesions (SCL) after atrial fibrillation (AF) ablation is highly variable, depending on the technology used. Recently, an increased risk for SCL has been described for a novel, nonirrigated ablation tool using multielectrode phased radiofrequency (PVAC). The aim of this prospective study was to evaluate the incidence and long-term follow-up of SCL in patients undergoing robotically assisted pulmonary vein isolation (RA-PVI) as compared with manual PVI.

Methods and Results—Circumferential PVI using irrigated radiofrequency current was performed on 70 patients (41 patients with paroxysmal AF, 59%). Fifty patients underwent RA-PVI and 20 patients underwent a manual approach. Cerebral MRI was performed the day before and the day after the ablation procedure; follow-up MRI was performed on 9 of 12 (75%) patients after a follow-up period of 21 months. SCLs were found in 12 of 70 (17%) patients in this study; the incidence of SCLs was similar in patients undergoing RA-PVI as compared with manually ablated patients (n=9, 18% versus n=3, 15%; probability value=1.0). In 1 patient undergoing manual PVI (1%), an SCL with asymptomatic subarachnoid hemorrhage was detected; the bleeding completely resolved within 1 month. Transient ischemic attack occurred in 1 (1%) patient 2 days after manual PVI. After a median follow-up period of 21 months, no residual SCLs were detected.

Conclusions—The incidence of SCL using the robotic navigation system was 18% in this study. Incidence and size of SCL appears to be similar after RA-PVI as compared with manual PVI. Repeat MRI showed no residual SCLs at long-term follow-up. (Circ Arrhythm Electrophysiol. 2012;5:15-21.)

Key Words: robotic navigation ■ pulmonary vein isolation ■ silent cerebral lesion ■ cerebral MRI

Pulmonary vein isolation (PVI) has been established as a treatment option for patients with symptomatic atrial fibrillation (AF).1-3

Editorial see p 2

Clinical Perspective on p 21

This prospective pilot study is the first to compare the incidence, size, and long-term course of SCL in patients undergoing RNS-assisted PVI with a manual control group.

Patients
Overall, 70 consecutive patients (female, n=26; 37%) with paroxysmal AF (PAF; n=41, 59%) or persistent AF were included in this prospective pilot study. Fifty patients (PAF in 29 patients, 58%) underwent circumferential PVI (CPVI) using the RNS and were compared with a control group of 20 consecutive patients (PAF in 12 patients, 60%) undergoing manually performed ablation.

Exclusion criteria were age <18 years and >80 years, severe valve disease, acute coronary syndrome in the last 3 months, previous transient ischemic attack (TIA) or stroke, left atrial (LA) thrombus, or spontaneous echo contrast in the LA appendage (LAA).

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15
or any contraindication to MRI. LA thrombus and spontaneous echo contrast were excluded by transesophageal echocardiography the day before the ablation procedure.

Physical examination and careful neurological assessment were conducted on all patients before and after the ablation procedure. Oral anticoagulation therapy was discontinued 5 days before ablation and replaced by weight-adjusted low-molecular-weight heparin.

Enoxaparin in a weight-adjusted dose (1 mg/kg) twice daily was started immediately after sheath removal until international normalized ratio >2 or equivalent. Phenprocoumon was started 48 hours after the ablation procedure.

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript as written.

Pulmonary Vein Isolation

After written informed consent, all patients underwent ablation while under deep sedation using midazolam and fentanyl.

After having placed a coronary sinus catheter through the left subclavian vein, access for either 2 conventional transseptal sheaths (SL 0, length 63 cm, St Jude Medical, manual ablation group) or 1 conventional transseptal sheath and the Artisan sheath (AS, RNS group) was performed at the right femoral vein. Before the first transseptal puncture a heparin bolus of 3000 IE was administered intravenously. After the first transseptal puncture was performed, a conventional transseptal sheath (St Jude Medical SL0) was advanced into the LA. Thereafter, a second heparin bolus of 5000 IE was administered, and, after having removed the first transseptal sheath out of the LA with the guide wire left in the left superior pulmonary vein, either a second conventional transseptal sheath (manual approach) or the artisan sheath was introduced into the LA across the same puncture site as described previously.8 In a final step, the first transseptal sheath was advanced again into the LA over the guide wire. Activated clotting time (ACT) levels were measured every 30 minutes with a target ACT of 250–350 seconds according to current recommendations.9 Additional heparin boluses were administered to maintain the ACT levels above 250 seconds. The conventional transseptal sheaths were flushed with normal saline infusion with a flow rate of 150 mL/h. The inner and outer sheaths of the artisan sheath were flushed with saline infusion (infusion of inner sheath warmed to 43°C to prevent bubble formation).

Selective angiography of the pulmonary veins was performed in 3 projections (posterior-anterior, left anterior oblique 30°, and right anterior oblique 30°) to define the pulmonary vein (PV) ostia. Electroanatomic mapping was performed using the Ensite NavX system (St Jude Medical, St Paul, MN). For mapping and radiofrequency current ablation, a 3.5-mm irrigated-tip ablation catheter (Cool path ns, St Jude Medical) was used.

For CPVI, a circumferential ablation line was deployed around the ipsilateral PV ostia. Irrigated radiofrequency ablation was performed 0.5–1 cm proximal to the angiographically defined PV ostia. Power was limited in both patient groups to 20 W at the posterior wall and 30 W at the anterior aspect of the LA, with an irrigation rate of 150 mL/h. The inner and outer sheaths of the artisan sheath were flushed with saline infusion (infusion of inner sheath warmed to 43°C to prevent bubble formation).

Cerebral MRI

MRI was performed before and after the ablation procedure, using a 1.5-T MRI scanner (Signa Excite HD, GE Medical Systems, Milwaukee, WI). In 9 of 12 (75%) patients with SCL, follow-up MRI was performed after a median follow-up period of 21 months (19–22 months). The imaging protocol before the procedure consisted of a T2-weighted gradient echo sequence, a fluid-attenuated inversion recovery sequence (FLAIR, inversion time 2200 ms), a T1-weighted spin-echo sequence, axial and sagittal T2-weighted fast spin-echo sequences, and a diffusion-weighted single-shot echo-planar sequence (DWI, diffusion gradient b-values of 0, 500, and 1000 s/mm²). In addition, apparent diffusion coefficient maps were calculated for every patient. After the ablation procedure, the imaging protocol included the same DWI, FLAIR, and T1-weighted spin-echo sequences as obtained before the intervention. Acute SCL on the postablation MRI was defined as a focal hyperintense area in the diffusion-weighted images with corresponding hypointensity in the apparent diffusion coefficient map. All SCLs were analyzed for size and localization of the lesions. All MRIs were interpreted independently by 2 certified radiologists in a blinded manner.

Statistical Analysis

Continuous data are expressed as mean±SD or median with first and third quartiles (Q1-Q3). Categorical variables are summarized with absolute and relative frequencies.

The data were compared between the ablation groups and the patients with and without SCL. Continuous data were analyzed using the Student t test or Wilcoxon Mann-Whitney test, and categorical data were analyzed using χ² analysis or Fisher exact test where appropriate. A probability value <0.05 was considered statistically significant.

All analyses were performed using the statistical software SAS software-version 9.2 (Copyright 2002–2008 by SAS Institute Inc, Cary, NC).

Results

Baseline Neurological Assessment Was Normal in All Patients

CHADS₂ score was 0 in 22 patients (31%), 1 in 39 patients (56%), and 2 in 9 patients (13%). There were no significant differences regarding the baseline characteristics, including the CHADS₂ score, LA diameter, LA appendage flow velocity, or procedure-related details of patients undergoing PVI using a manual approach versus a robotically assisted approach (Table 1).

Ablation Results

CPVI was successfully performed on all (n=70) patients. Additionally, LA isthmus ablation was performed in 2 patients (4%) of the RA group for perimital flutter.

Mean levels of activated clotting time (ACT) were 278.9±35.3 seconds; minimum ACT levels, 231.5 (203–250) seconds; and maximum ACT levels, 327±39.7 seconds. There were no significant differences regarding the ACT levels between manually ablated patients compared with patients with robotically assisted PVI or patients with SCL compared with patients without SCL (Table 1 and Table 2).

Incidence of Silent Cerebral Ischemia

No recent SCL was found at baseline MRI; in 12 of 70 (17%) patients, SCL was found the day after the ablation procedure (Figure 1).

CHADS² score was similar in patients with and without SCL (median, 1 [0.5—1] versus median 1 [0—1]; P=0.86).

There were no significant differences regarding the baseline characteristics, LA diameter, LA appendage flow velocity, ACT levels, or procedure related details in patients with or without SCL (Table 2).
In patients with SCL detected on cerebral MRI after the ablation procedure, electric cardioversion was not performed more frequently than in patients without SCL (n = 11005/7 [58%] versus n = 23 [40%], P = 0.23). The number of electric cardioversions during the ablation procedure also did not differ significantly (see Table 2).

The localization and distribution of the SCL are displayed in Table 3. The incidence of SCL was similar in the RN group compared with the manual ablation group (n = 9, 18% versus n = 3, 15%; probability value = 1.0). Multiple SCLs were seen in 2 patients of the RNS group. Neither the overall incidence nor the median size of the cerebral lesions differed significantly between the manual ablation group and the robotic ablation group (Table 1). One patient (1%) had a TIA 2 days after manual PVI. He presented with a left-sided hemiparesis that completely recovered without significant sequelae within 24 hours. Interestingly, no SCL was detected 1 day after the ablation procedure.

In another patient undergoing manual-CPVI, SCL as well as asymptomatic intracerebral bleeding (subarachnoid hemorrhage) of the right-sided frontal and parietal region were detected by MRI the day after the ablation procedure (Figure 2). Repeat MRI within 2 days showed a reduction of the extent of the hemorrhage, and no further signs of intracerebral bleeding were detected 1 month later in repeat MRI. The patient remained asymptomatic during follow-up.

Follow-Up MRI
Cerebral MRI was repeated in 9 of 12 (75%) patients after a median follow-up period of 21 (19—22) months (2 patients of the manual group and 7 patients of the robotic group); 1 patient died during the follow-up period and 2 patients refused to undergo further cerebral MRIs. No patient demonstrated residual SCLs or any glial scar formation on follow-up MRI. In the robotic group, one patient who sustained a left-sided parietal SCL after the procedure, presented with TIA and a transient paresis of the right arm 7 months after the ablation procedure. Emergency cerebral MRI showed no new cerebral lesions and no remnant of the formerly described SCL.

Table 1. Characteristics of Patients With Manually Versus Robotically Assisted PVI

<table>
<thead>
<tr>
<th></th>
<th>Patients With Manually Performed Ablation (n=20)</th>
<th>Patients With RNS-Assisted Ablation (n=50)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>66.5 (58–69.5)</td>
<td>60 (56–68)</td>
<td>0.14</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>5 (25%)</td>
<td>21 (42%)</td>
<td>0.18</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>26.9 (25.3–28.9)</td>
<td>26.7 (24.9–29.7)</td>
<td>0.72</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>15 (75)</td>
<td>31 (62)</td>
<td>0.30</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>0 (5)</td>
<td>(14)</td>
<td>0.29</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>2 (10)</td>
<td>4 (8)</td>
<td>0.79</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>5 (25)</td>
<td>16 (32)</td>
<td>0.56</td>
</tr>
<tr>
<td>Creatinine level, mg/dL</td>
<td>1.0 (0.85–1.1)</td>
<td>1.0 (0.9–1.1)</td>
<td>0.93</td>
</tr>
<tr>
<td>GFR, mL/min</td>
<td>78 (66–99)</td>
<td>73 (61–87)</td>
<td>0.44</td>
</tr>
<tr>
<td>CHADS2 score</td>
<td>1 (0.5–1)</td>
<td>1 (0–1)</td>
<td>0.47</td>
</tr>
<tr>
<td>Left atrial diameter, mm</td>
<td>47.5 (41–55)</td>
<td>47.5 (41–51)</td>
<td>0.58</td>
</tr>
<tr>
<td>Decreased LAA flow velocity,* n (%)</td>
<td>5 (25)</td>
<td>5 (10)</td>
<td>0.14</td>
</tr>
<tr>
<td>Cardioversion during procedure, n (%)</td>
<td>9 (45)</td>
<td>21 (42)</td>
<td>0.82</td>
</tr>
<tr>
<td>Cardioversions, n</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0.67</td>
</tr>
<tr>
<td>Minimum ACT levels, s</td>
<td>226 (188.5–242.5)</td>
<td>233.5 (207–259)</td>
<td>0.25</td>
</tr>
<tr>
<td>Mean ACT levels, s</td>
<td>267.5±40.5</td>
<td>285.5±32.3</td>
<td>0.09</td>
</tr>
<tr>
<td>Maximum ACT levels, s</td>
<td>308.5±42.3</td>
<td>331.5±38.2</td>
<td>0.15</td>
</tr>
<tr>
<td>Incidence of silent cerebral ischemia, n (%)</td>
<td>3 (15)</td>
<td>9 (18)</td>
<td>1.0</td>
</tr>
<tr>
<td>Cerebral lesions, n</td>
<td>1 (1–1)</td>
<td>1 (1–1)</td>
<td>0.48</td>
</tr>
<tr>
<td>Mean size of silent cerebral ischemia, mm</td>
<td>3 (3–4)</td>
<td>4 (3–4)</td>
<td>0.38</td>
</tr>
<tr>
<td>Maximum size of SCL, mm</td>
<td>3 (3–4)</td>
<td>4 (3–4)</td>
<td>0.32</td>
</tr>
<tr>
<td>Left ventricular ejection fraction (%)</td>
<td>65 (60–65)</td>
<td>65 (62–65)</td>
<td>0.87</td>
</tr>
<tr>
<td>Paroxysmal AF, n (%)</td>
<td>12 (60)</td>
<td>29 (58)</td>
<td>0.88</td>
</tr>
<tr>
<td>Persistent AF, n (%)</td>
<td>8 (40)</td>
<td>21 (42)</td>
<td>0.88</td>
</tr>
<tr>
<td>Overall procedure time, min</td>
<td>255 (225–325)</td>
<td>257.5 (210–290)</td>
<td>0.31</td>
</tr>
<tr>
<td>Fluoroscopy time, min</td>
<td>17.1 (13, 2–20, 5)</td>
<td>16.4 (12, 1–22, 3)</td>
<td>0.67</td>
</tr>
<tr>
<td>Overall energy delivery, W</td>
<td>93 003 (77 139–103 121)</td>
<td>86 953 (76 024–111 552)</td>
<td>0.82</td>
</tr>
<tr>
<td>Ablation of mitral isthmus line, n (%)</td>
<td>0 (0)</td>
<td>2 (4)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Continuous data are expressed as mean±SD or median (Q1–Q3).

PVI indicates pulmonary vein isolation; RNS, robotic navigation system; GFR, glomerular filtration rate; LAA, left atrial appendage; ACT, activated clotting time; SCL, silent cerebral lesions; AF, atrial fibrillation.

*Decreased LAA velocity defined as flow velocity <0.5 m/s.
Discussion

This is the first prospective study describing the incidence and long-term results of silent cerebral lesions after robotic AF ablation as compared with manual AF ablation.

The main findings of the present study are

(1) The incidence and size of silent cerebral lesions using RNS was similar compared with manual ablation.

(2) No residual SCLs or any scar formation were seen in repeat MRI after a median follow-up period of 21 (19—22) months.

(3) Silent cerebral lesions did not predict subsequent procedure-related TIA.

Incidence and Risk Factors for Silent Cerebral Ischemia

Silent cerebral ischemia occurring during catheter ablation has been described previously and is dependent on energy source, ablation site, and the extent of the ablation.4,6,7,10,11

The influence of different ablation tools on the incidence of SCL during PVI, ranging from 5.6% when using cryoenergy up to 38.9% when nonirrigated duty-cycled radiofrequency ablation (PVAC) is used, has been recently demonstrated.6,7,12

There are several potential additional risk factors leading to an increased incidence of silent cerebral lesions during PVI, including air embolism, microthrombembolism caused by popping, charring at the catheter tip,13 or gaseous steam formation during radiofrequency ablation.14–16 Previous studies have identified electric or pharmacological cardioversion as 1 of the most important factors for SCL during PVI.5 In this study, the incidence of SCL was 17%, but cardioversion or the number of cardioversions was not associated with an increased number of SCL.

For electric cardioversion, it has been suggested that mechanical trauma or the restored atrial contractility after AF termination may dislodge LA microthrombi, causing cerebral embolism.5 Because gaseous steam formation during the ablation procedure may play a major role in the formation of SCL during PVI, intraprocedural cardioversion might be of less importance for the occurrence of SCL.15,16

Anticoagulation Regimen and Prevention of Intracardiac Thrombus Formation

Because the mechanism of SCL after PVI is not completely understood, the impact of ACT levels on the incidence of SCL still remains debatable.
In general, lower ACT levels are associated with a higher risk for thromboembolic events during LA catheter ablation\(^{17,18}\) and therefore should be kept between 250–350 seconds, as recommended by the Venice chart.\(^9\) Further, ACT levels have been shown to be an independent risk factor for the incidence of SCL during PVI.\(^5\) However, in the present study, no significant differences in ACT levels were seen between patients with or without SCL during the procedure. First, this might occur because all patients in this study had a narrow ACT range of 250—350, with most being around 300 seconds, and, second, a significant number of these SCLs may not result from actual thrombus formation but rather occur as the result of transient gas formation at the time of ablation, which is not affected by ACT levels.\(^{15}\)

In addition to SCL, asymptomatic subarachnoid hemorrhage was seen in 1 patient of the manual ablation group (patient 1). This illustrates the difficulty in defining ACT levels, which are both safe and effective.

### Table 3. SCL Characteristics in Patients With Manually or Robotically Performed Ablation

<table>
<thead>
<tr>
<th>Localization</th>
<th>No. of Lesions</th>
<th>Maximum Lesion Size, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation performed manually</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 1 Left, central</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Patient 2 Left, parietal</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient 3 Right, central</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Ablation performed with RNS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 1 Left, parietal</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Patient 2 Left, parietal</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient 3 Left, parietal</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Patient 4 Right, frontal</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Patient 5 Left, frontal; left central</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Left parietooccipital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right occipital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 6 Left, frontal</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Patient 7 Right, parietal</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Right, periventricular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 8 Right, central</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Patient 9 Left, frontal</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

SCL indicates silent cerebral lesions; RNS, robotic navigation system.

Manually Performed Ablation Versus RNS-Assisted Ablation

To the best of our knowledge, no data exist about the incidence of SCL after robotic AF ablation as compared with a manual approach. Using robotic navigation may affect the risk for SCL for the following reasons: a larger sheath (14F) is advanced into the LA,\(^8\) additional flushing of the inner and outer robotic sheath is required,\(^{19,20}\) and the tip-to-tissue contact may be enhanced using robotic navigation, thereby potentially increasing the risk of charring, thrombus formation, or gaseous steam formation caused by tissue overheating.\(^{13,15,16}\)

Tissue overheating causing increased steam formation might be 1 of the major reasons why irrigated catheters still produce SCL as irrigation cools the catheter tip but not the tissue. However, in this study, the potentially more powerful tool (ie, RNS) with a supposed increased tip-to-tissue contact did not result in a higher incidence of SCL.

Clinical Implication and Long-Term Course of SCL

The clinical relevance of SCL is still under debate. After PVI, adverse neuropsychological changes in verbal memory have been found but were not directly associated with ischemic brain lesions on cerebral MRI.\(^{21}\) Data regarding the long-term course of SCL are sparse. Recently Deneke et al\(^{22}\) could demonstrate that 94% of asymptomatic cerebral lesions ob-
served acutely after AF ablation procedures healed without scarring at follow-up; only larger SCLs with more than 10 mm in size showed the potential for glial scar formation. In the present study, all SCLs were smaller than 10 mm in size (Table 3), and follow-up MRI, which was performed on patients with SCL after a median follow-up-period of 21 (19—22) months revealed no residual SCLs or scar formation in any of the patients; these findings, which are in line with the findings reported by Deneke et al, probably indicate that SCLs after PVI might be transient cellular membrane disruption/dysfunction due to largely gas emboli, which then resolves.

Moreover, this study shows that confirmation of SCL does not necessarily predict subsequent procedure-related TIA or stroke because 1 patient without detected SCL after the procedure had a TIA 2 days after the ablation.

Study Limitations
This study is a prospective but nonrandomized trial. However, there were no significant differences in the baseline characteristics between those patients undergoing RNS or having conventional ablation and the incidence of SCL. This study was intended to be a pilot study, providing preliminary data on the incidence of SCL using RNS and thus contributing important information pertinent to the ongoing debate about SCLs and new ablation tools. The results therefore must be interpreted by taking note of the fact that the sample size was small and therefore lacked statistical power to detect associations.

Because the exact mechanism of SCL still remains unclear, the use of intracardiac ultrasound may have helped to rule out thrombus formation at the transseptal sheath or to detect bubbles or gaseous steam formation. One of the major limitations is the fact that follow-up MRI was performed only in 75% of the patients with SCL after a median follow-up period of 21 (19—22) months. Follow-up MRIs will be of major importance in future studies to clarify the time course and clinical relevance of SCL.

Conclusions
The incidence of SCL using the RNS was 18% in this study. In contrast to other novel ablation tools, incidence and size of SCL appear to be similar after RA-PVI as compared with manual PVI. No residuals of SCL or glial scar formation were seen in repeat MRI after a median follow-up period of 21 months.

Disclosures
None.

References


**CLINICAL PERSPECTIVE**

Although their exact mechanism and their clinical relevance are not completely understood, attention has turned to silent cerebral lesions (SCL) detected on cerebral MRI after pulmonary vein isolation. In addition, it has been shown that different ablation tools result in a variable incidence of SCL. The use of a remote robotic navigation system (RNS) may enhance tip-to-tissue contact resulting in tissue damage or microbubble formation during ablation. The current study reports on the incidence of SCLs after pulmonary vein isolation, using the RNS as compared with manual ablation. It was found that the incidence of SCLs was similar between the RNS (18%) and manual groups (15%). One patient without documented SCL had a transitory ischemic attack during the postoperative period. Subsequent MRI in those patients with SCL revealed no residual lesions during long-term follow-up of 21 months. Additional studies on the long-term consequences of SCLs are needed.
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