Predictive Risk Factors for Restenosis after Remote Superficial Femoral Artery Endarterectomy

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\section*{KEYWORDS}
Remote endarterectomy; Superficial femoral artery; Restenosis; Atherosclerosis; Predictive value; Arterial occlusive disease

\section*{Abstract}
\textbf{Objectives:} Restenosis following remote superficial femoral artery endarterectomy (RSFAE) remains a challenging problem. The determinants predicting failure are lacking. This study investigated patient characteristics with predictive value for restenosis during the first year after RSFAE.

\textbf{Design:} A prospective cohort study.

\textbf{Materials and methods:} A total of 90 patients post-RSFAE were studied for the occurrence of restenosis (peak systolic velocity ratio $\geq 2.5$) in the first 12 months postoperatively. At baseline, clinical parameters were recorded. Vessel size was measured on the basis of plaque perimeter in the culprit lesion and lumen diameter on perioperative digital subtraction angiography.

\textbf{Results:} In 57 patients (63\%), a restenotic lesion was diagnosed within 12 months following surgery. Patients with longer time interval between start of ischaemic walking complaints and RSFAE revealed a significantly higher incidence of restenosis (hazard ratio (HR) = 1.3 (1.05--1.52) per 4 years). Small plaque perimeter and small superficial femoral artery (SFA) diameter on angiography were significantly associated with restenosis (HR = 0.54 (0.34--0.88) per 10 mm and HR = 0.46 (0.27--0.78) per 1.5 mm, respectively). In multivariate analysis, age, duration of ischaemic walking complaints and lumen diameter were independently associated with increased risk of restenosis after RSFAE.

\textbf{Conclusions:} This study provides evidence that age, vessel size and duration of ischaemic walking complaints before RSFAE are predictive values for restenosis after RSFAE.

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Remote superficial femoral artery endarterectomy (RSFAE) is established as a minimally invasive treatment option for long occlusions, defined as TransAtlantic Inter-Society Consensus (TASC) C and D lesions of the superficial femoral artery (SFA). RSFAE has comparable primary-assisted and secondary patency rates to prosthetic supragenicular bypass surgery. Besides, hospital stay is shorter and consequences of possible re-obstructions are less severe in patients treated with RSFAE. A drawback of RSFAE is the restenosis rate in the first year postoperatively caused by neo-intimal hyperplasia, with more than 80% of all restenoses occurring in the first year after surgery. Restenosis within the first year has been associated with a higher risk for occlusion. The restenotic lesions are equally distributed in the endarterectomised SFA, including the distal part of the SFA with the stented transection zone.

The determinants predicting failure after RSFAE are lacking. The general risk factors for cardiovascular disease are not successful in discriminating the risk for restenosis. The extent and severity of the treated lesion and technical considerations are determinants of failure after percutaneous interventions or bypass surgery. However, these clinical characteristics have not yet been proven to be of value for predicting restenosis after RSFAE. The objective of this study was to investigate patient characteristics that have a predictive value for restenosis during the first year after RSFAE.

Materials and Methods

Study population

All patients in the current study were included in the Athero-Express Biobank, an ongoing vascular biobank with a longitudinal study design that has been described previously. Dissected femoral plaques, obtained by endarterectomy in two participating Dutch teaching hospitals, were collected and examined histopathologically. In addition, clinical baseline characteristics of all included patients were obtained. The medical ethics boards of both participating hospitals approved the study, and all patients provided written informed consent.

In both hospitals, patients suffering from SFA obstructions were treated by use of the same protocol. Patients without improvement or worsening of their complaints after supervised exercise, and patients with critical ischaemia primarily, were discussed in a multidisciplinary meeting. If the patients did have a suitable greater saphenous vein (>3 mm), TASC C lesions, assessed as too complicated for percutaneous intervention, and TASC D lesions were treated with a venous supragenicular bypass. If the patients with extensive TASC C and TASC D SFA lesions did lack a suitable greater saphenous vein, they were treated primarily with RSFAE. Only when RSFAE failed that patients received a prosthetic supragenicular bypass.

A total of 90 consecutive patients who underwent RSFAE between February 2003 and October 2007 were selected. All patients underwent unilateral RSFAE with or without an additional open endarterectomy of the common femoral artery. All patients presented with intermittent claudication, critical ischaemia or tissue loss (Rutherford category 3–5) due to long-segment occlusion (TASC C and D lesions) of the SFA.

At baseline, clinical preoperative, perioperative and postoperative parameters were obtained from the Athero-Express medical database. Missing data were obtained from medical files or referral letters. The preoperative evaluation included a magnetic resonance angiography (MRA).

RSFAE technique

This minimally invasive debulking technique has been described previously. In summary, the SFA is exposed through a small groin incision. After anticoagulation with heparin, the proximal SFA is clamped, and a longitudinal arteriotomy is made in the proximal SFA. The intima core is dissected, between the lamina elastica interna and the circular fibres of the media, using the Vollmar dissector (Vollmar Dissector, Aesculap, San Francisco, CA, USA), until it reaches the distal limit of the atheroma in the SFA. The Vollmar dissector is then exchanged for the Mollring Cutter (LeMaitre Vascutek, San Jose, CA, USA). This device can transect and remove the entire desobstructed intimal core, all under fluoroscopic guidance. After the SFA is debulked, the distal transaction zone is secured by a stent and a completion angiography is performed to check the patency of the SFA and outflow arteries.

Atherosclerotic plaque

The excised plaques were directly transferred to the laboratory, processed and examined as described previously. The atherosclerotic lesions were dissected into 5-mm segments, and the segment with the greatest plaque area was defined as the disease-causing lesion. This segment was fixed in formaldehyde 4%, decalcified for 1 week in ethylenediaminetetraacetic acid and embedded in paraffin. The segments adjacent to the causative lesion were snap-frozen in liquid nitrogen and stored at −80 °C for future analysis.

Arterial size

Cross sections of the elastin von Gieson staining of the harvested atherosclerotic plaques were captured by digital image microscopy (AnalySiS version 3.2, Soft Imaging GmbH, Munster, Germany), and the perimeter of the plaque was measured in each cross section by tracing the internal elastic lamina (Fig. 1). As the studied femoral atherosclerotic plaques are dissected between the internal elastic lamina and the circular fibres of the media, we assumed that the perimeter of the dissected atherosclerotic plaque (the perimeter of the internal elastic lamina) is a measure of preoperative artery size.

The diameter of the arterial lumen was also measured on angiography performed at the end of the procedure as a measure for residual lumen size. All angiographies were stored in an electronic database, and all patients received an aSpire™ stent (LeMaitre Vascular, San Jose, CA, USA) to secure the transaction zone in the distal SFA. The distance between two nitinol frames of the double-helix
configuration of the aSpire® stent is a standard distance. This distance between the two nitinol frames at four helices of one aSpire® stent was measured and averaged and used for calibration. Next, the SFA lumen diameter was measured at three standardised levels: 1, 3 and 5 cm proximal of the stent in the distal SFA. The measurement outcomes at the three fixed points were then averaged. An interventional radiologist supervised the execution of all angiographic measurements and measurements were performed with the computer systems of our radiologists (Picture Archiving and Communications System (PACS) from Agfa-Gevaert Group).

Follow-up

Restenosis after initially successful RSFAE most often occurs in the first year postoperatively. These restenotic lesions have to be treated at an early stage to maintain patency whether symptomatic or not. Follow-up, including history, physical examination and duplex ultrasound scanning, was scheduled at 3, 6 and 12 months and annually thereafter. Duplex ultrasound scanning to detect restenotic lesions was performed according to protocol. The entire common femoral artery, the proximal profunda femoral artery, the entire SFA (from origin till popliteal artery, including distal stent) and the entire popliteal artery were scanned in every patient. Obstructions are classified on the base of the peak systolic velocity (PSV) within the obstruction (numerator of the PSV ratio) and distally of the obstruction (denominator of the PSV ratio). If the stenotic lesion is at the distal end of the artery, the PSV of the denominator will be measured proximal to the lesion. A stenosis of 50% is considered if the PSV ratio is 2.5. We considered a restenotic lesion if there was a lumen reduction of 50% or more (PSV ratio ≥ 2.5). Additional MRA may be performed in case of restenosis at the preference of the treating vascular surgeon.

Data analysis

Statistical analysis was performed with SPSS version 15.0 software (SPSS Inc, Chicago, IL, USA). In univariate analysis, the association between baseline data and restenosis was tested for significance with the Cox regression analysis. Hazard ratios (HRs) were calculated. The 95% confidence intervals (CIs) not containing 1 or values of \( P < 0.05 \) were considered statistically significant. To test independency of the univariate variables, multivariate Cox regression analysis (with backward exclusion of non-significant variables using likelihood ratio test) was performed. Variables showing an association with restenosis \( (P < 0.1) \) in univariate analysis were included in the multivariate analysis. Furthermore, age, sex and operation indication were always included in the multivariate analysis models.

Results

The study included 90 consecutive patients (74% men) undergoing unilateral RSFAE between February 2003 and October 2007. The baseline patient characteristics are summarised in Table 1. Mean patient age was 67 years. In 72 patients (80%), Rutherford category 3 was the indication for operation. The median duration of ischaemic walking complaints due to SFA occlusion before surgery was 56 months (range: 4–303 months).

A restenotic lesion was diagnosed in 57 patients (63%) within 12 months after RSFAE, including one patient with an early restenosis (<30 days). Of the 57 patients with restenosis, 47 (82%) were symptomatic. Thirty-four patients (72%) had Claudication complaints (Rutherford category 2 or 3); eight (17%) presented with critical leg ischaemia (Rutherford category 4) and three (6%) had tissue loss (Rutherford category 5). In addition, two patients (4%) were re-admitted with acute critical leg ischaemia.

Twenty patients were asymptomatic or had Rutherford class 2 ischaemia and were treated conservatively. Twenty-four patients were treated with percutaneous transluminal angioplasty (PTA), 11 patients received a bypass graft and two patients underwent an open re-endarterectomy of the common femoral artery/proximal SFA with proximal patch plasty.

In univariate analysis, gender was associated with restenosis. A restenotic lesion was found in 19 of 23 women (83%) and in 38 of 67 men (57%) within 12 months \( (P = 0.001; \text{ Table 1}) \).
Patients with longer time interval between the start of ischaemic complaints and RSFAE revealed higher incidence of restenosis. The median duration of ischaemic walking complaints before surgery was 65 months (range: 3–303 months) for patients with restenosis and 28 months (range: 3–248 months) in patients without restenosis (Fig. 2). The risk of restenosis increased with 30% (HR: 1.3 (95% CI: 1.05–1.52)) per 4 years of ischaemic walking complaints (P = 0.012; Table 1).

Histopathological analysis of the excised atherosclerotic plaques revealed that all femoral arteries were totally occluded at the time of RSFAE and the atherosclerotic plaque was dissected between intima and media as a circular core (Fig. 1).

A small perimeter of the plaque was significantly associated with restenosis. The median plaque perimeters were 16.9 ± 4.9 mm in patients with restenosis and 20.2 ± 4.7 mm in those without restenosis (P = 0.01; Table 2). Patients with a plaque perimeter smaller than the median (<17.6 mm) had a significantly higher risk of restenosis than patients with a larger perimeter (Fig. 3). The risk of restenosis decreased by 46% per 10-mm increase of plaque perimeter (HR: 0.54 (95% CI: 0.34–0.88); P = 0.01).

Consistent with the results of the plaque perimeter, the median diameters of the SFA lumen, as measured on

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Clinical characteristicsa.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
<td>All patients (n = 90)</td>
</tr>
<tr>
<td>Age, mean (range), years</td>
<td>67 (50–84)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>67 (74)</td>
</tr>
<tr>
<td>Female</td>
<td>23 (26)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>39 (43)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>59 (66)</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>27 (30)</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>63 (70)</td>
</tr>
<tr>
<td>Body mass index, mean (range)</td>
<td>26 (17–35)</td>
</tr>
<tr>
<td>Statin use</td>
<td>73 (81)</td>
</tr>
<tr>
<td>Acetylsalicylic acid use</td>
<td>75 (83)</td>
</tr>
<tr>
<td>Clopidogrel use</td>
<td>24 (27)</td>
</tr>
<tr>
<td>Clinical presentationc</td>
<td></td>
</tr>
<tr>
<td>Rutherford class III</td>
<td>72 (80)</td>
</tr>
<tr>
<td>Rutherford class IV</td>
<td>12 (13)</td>
</tr>
<tr>
<td>Rutherford class V</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Duration of ischaemic walking complaints, median (range), months</td>
<td>56 (4–303)</td>
</tr>
<tr>
<td>Patent runoff arteries</td>
<td></td>
</tr>
<tr>
<td>1 Artery</td>
<td>9 (10)</td>
</tr>
<tr>
<td>2 Arteries</td>
<td>32 (36)</td>
</tr>
<tr>
<td>3 Arteries</td>
<td>47 (52)</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (2)</td>
</tr>
</tbody>
</table>

*P < 0.05.

a Data are presented as No.(%) unless otherwise indicated.
b Cox regression analysis.
c Comparison of Rutherford class III and IV vs. reference.

Figure 2 Restenosis in relation to duration of ischaemic walking complaints. Patients with longer duration of ischaemic walking complaints (>median) due to superficial femoral artery occlusion revealed a significantly (P = 0.01) higher incidence of restenosis in the first 12 months postoperatively than patients with shorter duration of ischaemic walking complaints (<median).
perioperative angiography, were significantly smaller in patients with restenosis (5.6 mm) compared with patients without restenosis (6.4 mm; Table 2). The risk of restenosis decreases by 54% per 1.5-mm increase of lumen diameter as measured on the perioperative angiography (HR: 0.46 (95% CI: 0.27–0.78); P < 0.004).

**Multivariate analysis**

As sex, time interval between ischaemic complaints and RSFAE, plaque perimeter and lumen diameter on perioperative angiography were associated with 1-year restenosis, these variables were consequently entered in multivariate Cox hazard regression analysis. Age and operation indication (Rutherford category) were always included in the multivariate analysis models. In multivariate analysis, age (HR: 1.61 (95% CI: 1.03–2.53); P = 0.04), duration of ischaemic walking complaints (HR: 1.29 (95% CI: 1.03–1.62); P = 0.03) and lumen diameter (HR: 0.37 (95% CI: 0.19–0.72); P < 0.01) were independently associated with increased risk of restenosis after RSFAE (Table 3).

**Discussion**

Restenosis is a drawback in the first year after RSFAE; thus far, predictive clinical variables for restenosis are not available. This study shows that SFA diameter, age and interval between occurrence of ischaemic walking complaints and the RSFAE procedure are predictive for restenosis after RSFAE. These findings may have an effect in clinical practice. RSFAE should be reconsidered in older patients, in patients with a long history of ischaemic complaints and in patients with small SFA diameter. Follow-up and treatment of restenosis may need to be more aggressive for these subgroups.

A recently published randomised trial, comparing RSFAE and supragenicular bypass surgery for long occlusions of the SFA, concluded that venous bypass is superior to RSFAE. However, RSFAE has comparable secondary patency rates (61%) to prosthetic bypass grafts (63%), with the advantage of avoiding prosthetic material and shorter hospital stay. The difference between the RSFAE patency rates

**Table 2** Peri-operative results.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All patients (n = 90)</th>
<th>Restenosis (n = 33)</th>
<th>No restenosis (95% CI)</th>
<th>Hazard ratio&lt;sup&gt;a&lt;/sup&gt;</th>
<th>P-value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, mean (range), minutes</td>
<td>124 (70–190)</td>
<td>121 (70–187)</td>
<td>129 (70–190)</td>
<td>0.80 (0.62–1.05)</td>
<td>0.10</td>
</tr>
<tr>
<td>Blood loss, mean (range), ml</td>
<td>246 (50–1200)</td>
<td>228 (50–500)</td>
<td>280 (50–1200)</td>
<td>0.68 (0.43–1.07)</td>
<td>0.96</td>
</tr>
<tr>
<td>Length of dissected intima core, median (SD), cm</td>
<td>27 (5.6)</td>
<td>25 (6)</td>
<td>28 (4)</td>
<td>0.97 (0.92–1.02)</td>
<td>0.24</td>
</tr>
<tr>
<td>Lumen diameter on perioperative angiography, median (SD), mm</td>
<td>5.7 (1.0)</td>
<td>5.6 (0.9)</td>
<td>6.4 (1.0)</td>
<td>0.46 (0.27–0.78)</td>
<td>0.004*</td>
</tr>
<tr>
<td>Perimeter of the plaque, median (SD), mm</td>
<td>17.6 (5.1)</td>
<td>16.9 (4.9)</td>
<td>20.2 (4.7)</td>
<td>0.54 (0.34–0.88)</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

<sup>a</sup>P < 0.05.

<sup>a</sup>Cox regression analysis.

**Table 3** Multivariate cox regression analysis.<sup>a</sup>

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Hazard ratio (95% CI)</th>
<th>P-value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, per 10 years</td>
<td>1.61 (1.03–2.53)</td>
<td>0.04*</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>–</td>
<td>ns</td>
</tr>
<tr>
<td>Female</td>
<td>–</td>
<td></td>
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<tr>
<td>Clinical presentation</td>
<td></td>
<td></td>
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<tr>
<td>Rutherford class III</td>
<td></td>
<td>ns</td>
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<tr>
<td>Rutherford class IV</td>
<td></td>
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<tr>
<td>Rutherford class V-VI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of ischaemic walking complaints, per 4 years</td>
<td>1.29 (1.03–1.62)</td>
<td>0.03*</td>
</tr>
<tr>
<td>Perimeter of the plaque, per 10 mm</td>
<td>–</td>
<td>ns</td>
</tr>
<tr>
<td>Lumen diameter, per 1.5 mm</td>
<td>0.37 (0.19–0.72)</td>
<td>&lt;0.01*</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; ns, not significant (removed from the multivariate model based on likelihood ratio).

<sup>a</sup>P < 0.05.

<sup>a</sup>Cox regression analysis with backward exclusion of non-significant variables using likelihood ratio test.
restenosis is that we wanted to determine both the whole/tomatic patients without re-intervention) with described in literature.

The reason to focus on all patients (including asymptomatic patients without re-intervention) with ≥50% restenosis is that we wanted to determine both the whole spectrum of patients with significant lumen reduction after RSFAE and which factors influence restenosis.

In research considering peripheral artery disease, little is known about arterial size in relation to restenosis, although a recent study of bypass surgery showed an increase of graft restenosis as graft diameter diminished. In cardiology, vessel size is well established as an important determinant of an adverse outcome after re-vascularisation. It is biologically plausible that a reduction in luminal diameter by a constant amount of neo-intimal hyperplasia results in a proportionally higher grade of restenosis in small vessels compared with large ones. Re-vascularisation results in arterial injury, initiating a proliferative vascular cascade that causes smooth muscle cell proliferation and migration, resulting in neo-intimal hyperplasia. The amount of neo-intimal hyperplasia is largely independent of vessel size, and, thus, late luminal loss, an angiographic measure of neo-intimal hyperplasia, is similar across a wide range of vessel diameters. Accordingly, small vessels are more prone to restenosis than larger ones because they are less able to accommodate neo-intimal tissue without compromising blood flow.

This study found that gender was not an independent predictive variable for restenosis, although in univariate analysis women showed significantly more restenosis than men. Published reports indicate that gender differences in the risk of restenosis can be explained by the physical size of the patient. Although coronary artery diameter is highly related to body size, women have smaller coronary arteries than men after accounting for differences in body size. These findings further support the hypothesis that smaller coronary arteries explain higher perioperative mortality with coronary artery bypass grafting and poorer outcomes with other treatments for coronary disease in women and smaller people.

In univariate analysis, age seemed to have no relation with restenosis. However, in the multivariate model, age seemed to be an independent predictor for restenosis. The current way statistical analysis is performed can make this happen. Usually, only variables showing a relation in the univariate analysis (typically $P < 0.1$) are included in the multivariate analysis. However, these variables could also be related with each other (confounding). Therefore, multivariate analysis will discriminate whether these variables are dependent or independent of each other. We stated that we always included age (and gender, and operation indication) in the multivariate analysis.

In univariate analysis, age seemed to be confused to the null (i.e., showed no relation). However, age was an independent variable in the multivariate analysis. This can only be explained if age has been associated with the other independent variables or a combination of them. In our study, the ‘older’ patients cannot be compared with the ‘younger’ patients in relation to the other predictive variables.

We can only speculate about the predictive value of the duration of ischaemic complaints due to SFA occlusion for restenosis. In most cases, the SFA is occluded for a long period and will be fibrous. Fibrous plaques have previously been associated with arterial shrinkage resulting in smaller vessel size. Our results suggest that longer occlusion time and subsequent arterial fibrotic shrinkage may result in a smaller residual lumen after intervention, which makes the artery more prone to develop restenosis.

This study may have important implications for the care and treatment of patients with arterial obstructive disease in the SFA. Structured exercise and medical treatment constitute the initial approach to the treatment of intermittent claudication. Failure to respond to this would lead to limb re-vascularisation. Accordingly, most patients undergo operation after a long period of ischaemic complaints. The median duration of ischaemic walking complaints in our study was 56 months before surgery. As explained previously, a likely assumption is that the occluded fibrous femoral artery will shrink over time. Subsequently, patients with longer duration of ischaemic complaints will have smaller arteries with a higher restenosis rate. Therefore, our findings lead to a recommendation of a more aggressive treatment strategy in a subgroup of patients. The major challenge, however, is to identify the subgroup of patients who would benefit from this aggressive treatment; consequently, a longitudinal study is required to support this concept.

The known factors influencing outcomes after percutaneous intervention include the extent of the disease, use of a stent, amount of calcification and the runoff below the knee. The factors influencing the outcome of bypass surgery focus on the quality of the bypass (graft diameter, graft length and type of bypass) instead of the extent and severity of the lesion. Similar to percutaneous interventions, bypass surgery for tissue loss has worse outcomes compared with bypass for claudication. The reason for this is not fully understood and is not simply explained by inflow and outflow levels, because distal origin grafts as well as pedal bypass grafts have durable results. In this study, runoff, TASC classification and operation indication were not associated with restenosis after RSFAE. It is notable that recent reports concerning RSFAE also show no relation between these variables and restenosis.

Our study has several potential limitations. Our data are prospectively obtained but are retrospectively analysed. The findings of this study have to be confirmed in a larger randomised study. Our findings are based on a relatively small patient group, and confirmation in a larger cohort is required.

This study is the first of its kind to provide clinical characteristics that are predictive for RSFAE restenosis in the first year. Clinicians should reconsider RSFAE in older patients, patients with a longer history of ischaemic
complaints and in patients with small SFA diameter. Follow-up and treatment of restenosis may need to be more aggressive for these subgroups.

Conclusion

This study provides evidence that age, vessel size and duration of ischaemic walking complaints before RSFAE are predictive values for restenosis after RSFAE.

Conflict of Interest/Funding

The authors state that there is no conflict of interest.

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