Multicentre validation of the Geneva Risk Score for hospitalised medical patients at risk of venous thromboembolism

Explicit ASsessment of Thromboembolic RIsk and Prophylaxis for Medical PATients in SwitzErland (ESTIMATE)

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Summary

There is a need to validate risk assessment tools for hospitalised medical patients at risk of venous thromboembolism (VTE). We investigated whether a predefined cut-off of the Geneva Risk Score, as compared to the Padua Prediction Score, accurately distinguishes low-risk from high-risk patients regardless of the use of thromboprophylaxis. In the multicentre, prospective Explicit ASsessment of Thromboembolic Risk and Prophylaxis for Medical PATients in SwitzErland (ESTIMATE) cohort study, 1,478 hospitalised medical patients were enrolled of whom 637 (43%) did not receive thromboprophylaxis. The primary endpoint was symptomatic VTE or VTE-related death at 90 days. The study is registered at ClinicalTrials.gov, number NCT01277536. According to the Geneva Risk Score, the cumulative rate of the primary endpoint was 3.2% (95% confidence interval [CI] 2.2–4.6%) in 962 high-risk vs 0.6% (95% CI 0.2–1.9%) in 516 low-risk patients (p=0.002); among patients without prophylaxis, it was 3.5% vs 0.8% (p=0.029), respectively. In comparison, the Padua Prediction Score yielded a cumulative rate of the primary endpoint of 3.5% (95% CI 2.3–5.3%) in 714 high-risk vs 1.1% (95% CI 0.6–2.3%) in 764 low-risk patients (p=0.002); among patients without prophylaxis, it was 3.2% vs 1.5% (p=0.130), respectively. Negative likelihood ratio was 0.28 (95% CI 0.10–0.83) for the Geneva Risk Score and 0.51 (95% CI 0.28–0.93) for the Padua Prediction Score. In conclusion, among hospitalised medical patients, the Geneva Risk Score predicted VTE and VTE-related mortality and compared favourably with the Padua Prediction Score, particularly for its accuracy to identify low-risk patients who do not require thromboprophylaxis.

Keywords

Venous thromboembolism, internal medicine, risk assessment, thromboprophylaxis, validation studies

Introduction

In six large EU countries, the annual incidence of venous thromboembolism (VTE) exceeds 1 million cases (1), and at least half of such events occur in hospitalised patients (2). VTE may be responsible for 5 to 10% of all in-hospital deaths (2).

In acutely ill medical patients judged to have a high risk of VTE, pharmacological thromboprophylaxis halved the rate of symptomatic VTE in comparison to placebo (3–7). Various risk assessment models (RAMs) have been developed for identifying hospitalised medical patients at increased risk of VTE (8–11). Although the implementation of such tools may improve the adherence to guidelines (12, 13), the adequacy of prophylaxis in hospitalised medical patients remains haphazard (14–19). The inadequacy of thromboprophylaxis prescription may partly be explained by the fact that the majority of RAMs have not been prospectively validated in a multicenter setting (20).

The Padua Prediction Score (21) incorporates 15 risk factors within 11 items, and is one of the few RAMs which has been recently validated in hospitalised medical patients from a single centre. The VTE event rate at 90 days was 11.0% in high-risk patients without thromboprophylaxis as compared to 0.3% in low-risk patients of
whom the majority did not receive thromboprophylaxis (hazard ratio [HR] 32.0; 95% confidence interval [CI] 4.1–251.0).

The Geneva Risk Score was generated by incorporating inclusion criteria of randomised, controlled VTE prevention trials (3-5) and recommendations from the American College of Chest Physicians consensus guidelines (22). In a retrospective validation study, a score of 3 score points was identified as the best cut-off for separating low-risk from high-risk patients (8).

The aim of the present study was to conduct a multicentre, prospective clinical validation of the Geneva Risk Score for predicting the occurrence of symptomatic VTE events at 90 days among consecutive hospitalised medical patients, regardless of the use of thromboprophylaxis. We also compared its predictive performance to the Padua Prediction Score applied to our dataset.

Methods

Patients

In the Explicit ASsessment of Thromboembolic RIsk and Prophy-laxis for Medical PATients in SwitzErland (ESTIMATE) non-interventional, prospective cohort study, three academic and five non-academic acute care hospitals in Switzerland enrolled 1,478 consecutive acutely ill medical patients between December 2010 and November 2011. The mean duration of patient enrolment per center was 3 ± 1 months. Inclusion criteria were age ≥18 years and admission to a medical ward with a minimum stay of >24 hours (h). Exclusion criteria were anticoagulant treatment or indication for therapeutic anticoagulation upon hospital admission, and inability to provide an informed consent. The study period included the duration of hospitalisation and 90-day follow-up after hospital admission. Eligible patients were enrolled on the day of hospital discharge. In accordance with local regulations, the study was approved by the Ethics Committee of the Internal Medicine and General Medicine Departments at the University Hospitals Geneva and by the local ethics committees of all participating hospitals. Informed consent was effectively provided by all included patients who survived until hospital discharge and it was waived in patients who died during the hospital stay. The study did not issue recommendations for the use of any VTE risk assessment tool or the use of thromboprophylaxis. The study is registered at ClinicalTrials.gov, number NCT01277536.

Data and definitions

Data were collected by physician-investigators or dedicated study coordinators and entered in a standardised electronic case report form. All patients had complete follow-up for the duration of hospitalisation, and 1,461 (99%) patients had complete 90-day follow-up data (Figure 1).

The Geneva Risk Score was calculated after patient discharge, from data at hospital admission. Two points were allocated to cardiac failure, respiratory failure, recent stroke (<3 months), recent myocardial infarction (<4 weeks), acute infectious disease (includ-
ing sepsis), acute rheumatic disease, active cancer, myeloproliferative syndrome, nephrotic syndrome, prior VTE, and known hypercoagulable state; one point was allocated to immobilisation (complete bed rest or inability to walk for >30 minutes [min] per day) for >3 days, recent travel >6 h, age >60 years, body mass index [BMI] >30 kg/m², chronic venous insufficiency, pregnancy, hormonal therapy, and dehydration (assessed subjectively by the treating physician) (19). Subsequently, patients were classified as having a high (Geneva Risk Score ≥3) or low (Geneva Risk Score <3) risk of VTE.

We also applied to our data the Padua Prediction Score, published while this study was ongoing: three points were allocated to active cancer, previous VTE, reduced mobility, already known thrombophilic condition; two points to recent trauma and/or surgery, and one point to elderly age ≥70 years, heart and/or respiratory failure, acute myocardial infarction or ischaemic stroke, acute infection and/or rheumatologic disorder, obesity (BMI ≥30 kg/m²), and ongoing hormonal treatment (21). Patients were classified as having a high (Padua Prediction Score ≥4) or low (Padua Prediction Score <4) risk of VTE.

The primary endpoint was a composite of symptomatic VTE and VTE-related death at 90 days. Dedicated scientific collaborators interviewed all enrolled patients by telephone at the end of the 90-day study period. Family physicians were interviewed and asked to provide documentation if patients were not accessible, reported VTE or bleeding complications, or had died.

An independent clinical event adjudication committee, the members of which were unaware of the calculated score results, reviewed clinical and imaging documentation of all patients who had suspected symptomatic VTE or had died. Each event was independently evaluated by two adjudicators and classified according to predefined criteria. In case of disagreement, final adjudication was performed by the chairman of the adjudication committee. PE had to be objectively confirmed by contrast-enhanced computer tomography, ventilation perfusion scan or conventional pulmonary angiography, and deep-vein thrombosis by compression ultrasound or venography; VTE-related death was defined as death following VTE, confirmed by autopsy or an imaging test, or death in which VTE was considered a likely contributor to the fatal outcome. Fatal bleeding complications following anticoagulation treatment for acute VTE were also adjudicated as VTE-related death.

Table 1: Patient characteristics according to individual components of the Geneva Risk Score and the Padua Prediction Score at hospital admission.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Geneva Risk Score</th>
<th>Padua Prediction Score</th>
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</thead>
<tbody>
<tr>
<td>Low Risk* N = 516</td>
<td>High Risk* N = 962</td>
<td>Low Risk† N = 764</td>
</tr>
<tr>
<td>High Risk† N = 714</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt;60, n (%)</td>
<td>225 (43.6)</td>
<td>735 (76.4)</td>
</tr>
<tr>
<td>Age ≥70, n (%)</td>
<td>157 (30.4)</td>
<td>494 (51.4)</td>
</tr>
<tr>
<td>Immobilisation‡, n (%)</td>
<td>148 (28.7)</td>
<td>403 (41.9)</td>
</tr>
<tr>
<td>Acute infection/sepsis, n (%)</td>
<td>41 (8.0)</td>
<td>403 (41.9)</td>
</tr>
<tr>
<td>Active malignancy, n (%)</td>
<td>25 (4.8)</td>
<td>351 (36.5)</td>
</tr>
<tr>
<td>Respiratory failure, n (%)</td>
<td>12 (2.3)</td>
<td>341 (35.5)</td>
</tr>
<tr>
<td>Obesity (BMI ≥30), n (%)</td>
<td>39 (7.6)</td>
<td>180 (18.7)</td>
</tr>
<tr>
<td>Cardiac failure, n (%)</td>
<td>5 (1.0)</td>
<td>172 (17.9)</td>
</tr>
<tr>
<td>Dehydration, n (%)</td>
<td>18 (3.5)</td>
<td>150 (15.6)</td>
</tr>
<tr>
<td>Prior VTE, n (%)</td>
<td>1 (0.2)</td>
<td>120 (12.5)</td>
</tr>
<tr>
<td>Chronic venous insufficiency, n (%)</td>
<td>12 (2.3)</td>
<td>85 (8.8)</td>
</tr>
<tr>
<td>Recent trauma or surgery ≤1 month, n (%)</td>
<td>32 (6.2)</td>
<td>62 (6.4)</td>
</tr>
<tr>
<td>Hormonal therapy§, n (%)</td>
<td>13 (2.5)</td>
<td>56 (5.8)</td>
</tr>
<tr>
<td>Acute inflammatory/rheumatic disease, n (%)</td>
<td>4 (0.8)</td>
<td>56 (5.8)</td>
</tr>
<tr>
<td>Recent travel for &gt;6 h, n (%)</td>
<td>12 (2.3)</td>
<td>38 (4.0)</td>
</tr>
<tr>
<td>Recent myocardial infarction &lt;4 wks, n (%)</td>
<td>6 (1.2)</td>
<td>26 (2.7)</td>
</tr>
<tr>
<td>Myeloproliferative syndrome, n (%)</td>
<td>0 (0.0)</td>
<td>31 (3.2)</td>
</tr>
<tr>
<td>Recent stroke &lt;3 months, n (%)</td>
<td>1 (0.2)</td>
<td>30 (3.1)</td>
</tr>
<tr>
<td>Nephrotic syndrome, n (%)</td>
<td>3 (0.6)</td>
<td>21 (2.2)</td>
</tr>
<tr>
<td>Known thrombophilia, n (%)</td>
<td>1 (0.2)</td>
<td>8 (0.8)</td>
</tr>
<tr>
<td>Pregnancy, n (%)</td>
<td>1 (0.2)</td>
<td>2 (0.2)</td>
</tr>
</tbody>
</table>

* defined as: low risk = Geneva Risk Score <3, high risk = Geneva Risk Score ≥3. † defined as: low risk = Padua Prediction Score <4, high risk = Padua Prediction Score ≥4. ‡ defined as complete bed rest or inability to walk for >30 min per day for >3 days. § contraceptive or substitutive.
Statistical analysis

We assumed that half of the patients hospitalised for an acute medical illness would have a Geneva risk score ≥3 of whom 50% would receive in-hospital thromboprophylaxis (15, 16, 23, 24). We estimated the mean (95% CI) rate of symptomatic VTE at three months after hospital admission to be 7.0% (4.3-10.3%) in high-risk patients and 0.3% (0.1-1.0%) in low-risk patients (21). For sample size calculation, a conservative approach was used by selecting the lower bound of the 95% CI of the three-month symptomatic VTE rate in high-risk patients and the higher bound of the 95% CI of the three-month symptomatic VTE rate in low-risk patients. To show a difference between the estimated proportions of events of 4.3% and 1.0% with type-I-error of 0.05 (two-sided) and power of 80%, a minimum sample of 430 patients per risk group was calculated.

Outcome data were presented as cumulative failure rates, and the time course for the occurrence of adverse clinical outcome was graphically depicted as Kaplan-Meier curves. Group comparisons for outcome data were performed by the log-rank test.

Univariate Cox regression analyses reporting HR with 95% CIs was conducted to explore whether the Geneva Risk Score and the Padua Prediction Score were associated with the occurrence of adverse clinical outcome. Subsequently, bivariate Cox regression analysis was used to evaluate whether both scores independently predicted adverse clinical outcome after adjustment for the use of prophylaxis.

Negative likelihood ratio, sensitivity, specificity, positive and negative predictive values were calculated for the pre-specified cut-offs of both scores. All reported p-values are two-tailed. Data were analysed using the STATA 10 software (STATACorp LP, College Station, TX, USA).

Results

Patient characteristics

Overall, 2,820 patients were screened of whom 2,298 (81%) were eligible. The reasons for exclusion are summarised in Figure 1. Among the 1,478 enrolled patients, the mean age was 65 ± 17 years, 700 (47%) were female, and the median (interquartile range [IQR]) duration of hospital stay was 8 (5-14) days. The most frequent reasons for hospital admission were acute non-pulmonary infection or sepsis (15%), malignancy (13%), cardiovascular disease (11%), and pneumonia (9%).

According to the Geneva Risk Score, 962 (65%) patients were at high risk and 516 (35%) were at low risk. According to the Padua Prediction Score, 714 (48%) patients were at high risk and 764 (52%) were at low risk. Age >60 years, immobilisation for more than three days, acute infection or sepsis, active malignancy, respiratory failure, obesity, dehydration, cardiac failure, and prior VTE were frequently present (Table 1). In contrast, nephrotic syndrome, known thrombophilia, and pregnancy were rare conditions.

In comparison to patients with Geneva Risk Score <3, patients with Geneva Risk Score ≥3 more often had severe renal dysfunction with a glomerular filtration rate below 30 ml/min (11% vs 6%; p=0.001) and thrombocytopenia of less than 100 G/l (11% vs 5%; p<0.001).

VTE prophylaxis

Upon hospital admission, 88 (6%) patients had a contraindication to pharmacological prophylaxis. Overall, in-hospital thromboprophylaxis was administered in 841 (57%) patients; 596 (62%) with Geneva Risk Score ≥3 vs 245 (48%) with Geneva Risk Score <3 (p<0.001), and 436 (61%) with Padua Prediction Score ≥4 vs 405 (53%) with Padua Prediction Score <4 (p=0.002). The median (IQR) duration of thromboprophylaxis was 7 (4-12) days; 8 (5-14) in patients with Geneva Risk Score ≥3 and 5 (3-9) in patients with Geneva Risk Score <3 (p<0.001). Among patients with thromboprophylaxis, pharmacological measures were used in 834 (99%) patients and mechanical in 75 (9%).

Among the 962 patients with Geneva Risk Score ≥3, patients with prophylaxis more frequently had acute infection or sepsis (48% vs 32%; p<0.001) and acute cardiac failure (13% vs 8%; p=0.013), more often were admitted to the intensive care unit (11% vs 6%; P=0.002), and were hospitalised for a longer period of time (median 10, IQR 7-16 days vs median 8, IQR 5-15 days; p<0.001) than those without prophylaxis.

<table>
<thead>
<tr>
<th></th>
<th>Total N = 1,478</th>
<th>Low Risk* N = 516</th>
<th>High Risk* N = 962</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic VTE or VTE-related mortality†, n (%)</td>
<td>30 (2.3)</td>
<td>3 (0.6)</td>
<td>27 (3.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>VTE-related mortality, n (%)</td>
<td>18 (1.3)</td>
<td>0 (0.0)</td>
<td>18 (2.1)</td>
<td>0.002</td>
</tr>
<tr>
<td>Non-fatal PE, n (%)</td>
<td>7 (0.5)</td>
<td>3 (0.6)</td>
<td>4 (0.5)</td>
<td>0.95</td>
</tr>
<tr>
<td>Symptomatic DVT, n (%)</td>
<td>11 (0.9)</td>
<td>1 (0.2)</td>
<td>10 (1.3)</td>
<td>0.034</td>
</tr>
<tr>
<td>Bleeding requiring medical attention, n (%)</td>
<td>69 (4.8)</td>
<td>23 (4.5)</td>
<td>46 (5.0)</td>
<td>0.58</td>
</tr>
</tbody>
</table>

* defined as: low risk = Geneva risk score <3, high risk = Geneva risk score ≥3. † some patients had a sequential combination of symptomatic DVT, non-fatal PE, and VTE-related mortality. VTE venous thromboembolism; PE pulmonary embolism; DVT deep-vein thrombosis.

Table 2: Cumulative rates of clinical outcomes at 90-days according to the Geneva Risk Score.
Clinical outcomes according to the Geneva Risk Score

Overall, the primary endpoint occurred in 30 (2.3%) patients. The primary endpoint occurred in 3.2% (95% CI 2.2-4.6%) high-risk vs 0.6% (95% CI 0.2-1.9%) low-risk patients (p=0.002) (▶Table 2, ▶Figure 2). The rate of the primary endpoint increased stepwise with increasing Geneva Risk Score (p<0.001) (▶Figure 3). Among patients with thromboprophylaxis, the rate of the primary endpoint was 3.0% in high-risk vs 0.4% in low-risk patients (p=0.027); among patients without prophylaxis, it was 3.5% vs 0.8% (p=0.029), respectively. Rates of the primary endpoint according to individual components of the risk scores items are summarised in ▶Table 3.

The cumulative VTE-related mortality at 90 days was 1.3%; 2.1% in high-risk vs 0% in low-risk patients (p=0.001). Among patients with thromboprophylaxis, the rate of VTE-related mortality at 90 days was 2.2% in high-risk vs 0% in low-risk patients (p=0.022); among patients without prophylaxis, it was 1.8% vs 0% in (p=0.030), respectively.

The 90-day rate of bleeding requiring medical attention was 4.8%; 5.0% in high-risk vs 4.5% in low-risk patients (p=0.58). Among patients with thromboprophylaxis, the rate of bleeding requiring medical attention at 90 days was 3.4% in high-risk vs 4.6% in low-risk patients (p=0.33).

Clinical outcomes according to the Padua Prediction Score

The primary endpoint occurred in 3.5% (95% CI 2.3-5.3%) high-risk vs 1.1% (95% CI 0.6-2.3%) low-risk patients (p=0.002) (▶Figure 2). The rate of the primary endpoint increased with increasing Padua Prediction Score (p<0.001) (▶Figure 3). Among patients
with thromboprophylaxis, the rate of the primary endpoint was 3.7% in high-risk vs 0.8% in low-risk patients (p=0.006); among patients without prophylaxis, it was 3.2% vs 1.5% (p=0.130), respectively.

### Characteristics of the Geneva Risk Score and the Padua Prediction Score

A Geneva Risk Score ≥3 was univariately associated with the primary endpoint (HR 5.30, 95% CI 1.61-17.48; p=0.006); it also predicted the occurrence of the primary endpoint (HR 3.33, 95% CI 1.48-7.50; p=0.004) when adjusted for the use of thromboprophylaxis. Negative likelihood ratio, sensitivity, specificity, NPVs and PPVs for the predefined Padua Prediction Score cut-off of 4 points were 0.51 (95% CI 0.28-0.93), 73.3% (95% CI 54.1-87.7%), 51.9% (95% CI 49.3-54.5%), 98.9% (95% CI 97.9-99.5%), and 3.1% (95% CI 2.0-4.7%), respectively.

### Discussion

In the ESTIMATE study population, a Geneva Risk Score of ≥3 points and a Padua Prediction Score of ≥4 points were strongly associated with the composite endpoint of symptomatic VTE or VTE-related death at 90 days. The Geneva Risk Score significantly predicted events in both patients with and without thromboprophylaxis. In addition to testing the Geneva Risk Score, ESTIMATE
is the first study to test the Padua Prediction Score in a multicenter setting. However, further validation and comparison of both scores in a multinational setting is warranted.

Appropriate derivation and validation of a VTE risk score would theoretically require assessment of VTE events in consecutive hospitalised medical patients without the use of thromboprophylaxis. However, such a study will likely never be performed because it is nowadays unethical to withhold thromboprophylaxis from patients judged to have an increased risk of VTE. In clinical practice, thromboprophylaxis among hospitalised medical patients is used inconsistently (13-15), and ESTIMATE confirmed that both, underuse in high-risk patients and overuse in low-risk patients, occur frequently. Therefore, it was important to validate the risk scores in both patients with and without thromboprophylaxis.

To the best of our knowledge, ESTIMATE is the first study confirming that a VTE risk score predicts VTE events among hospitalised medical patients, regardless of the use of thromboprophylaxis. It is likely that both evaluated risk scores would have predicted VTE events even if thromboprophylaxis had been entirely withheld in the present study.

Because the use of thromboprophylaxis was not randomised, confounding factors, such as severity of patient illness, may have influenced the physicians' decision to use prophylaxis in our study. Indeed, high-risk patients with prophylaxis more frequently had severe illness and were hospitalised for a longer period of time than those without prophylaxis. Observational studies like ESTIMATE are unable to assess efficacy and safety of prophylaxis, and any differences noted are likely to be due to bias and confounding.

Since the incidence of in-patient symptomatic VTE is relatively low, the cost-benefit of thromboprophylaxis in hospitalised medical patients has been challenged, stressing the importance of developing risk assessment tools for the identification of candidates who do not need thromboprophylaxis (25). ESTIMATE confirms a low overall incidence of VTE during hospitalisation and the follow-up period of 90 days (2.3%).

The present study has limitations. First, the Geneva Risk Score was not derived from a population at risk but was inferred from explicit criteria used in previous randomised controlled trials on thromboprophylaxis. In addition, the weighting of individual items was arbitrary. However, the stepwise increase in VTE events with higher scores results suggests that the weighting of individual items was appropriate (see Figure 3). Some of the score items, for example, nephrotic syndrome, known thrombophilia, or pregnancy were infrequent in ESTIMATE, and it is not surprising that no VTE events were observed in the presence of these risk factors. The Padua Prediction Score (15 variables in 11 items) and the Geneva Risk Score (19 variables in 19 items) are complex, and their simplification may be the topic of future evaluation.

Such a multicentre study would require a large sample size for assessing the risk of VTE for individual items that are less common among hospitalised medical patients. Second, patients who accepted to be included in the ESTIMATE study represented 64% of the eligible patients, which may raise the issue of potential, although moderate, selection bias and result generalisability. Comparatively, only 53% of eligible patients were included in the validation study of the Padua Prediction Score (21). It is likely that patients who died were over represented in ESTIMATE because informed consent was waived in those patients. Among high-risk patients, the observed event rate was lower than expected (3.5% vs 7.0%) possibly due to selection bias introduced by the informed consent procedure which may also explain the younger age of the ESTIMATE patients as compared to previous studies (3-5, 21). Third, the minimum hospital stay in our study was >24 h which reflects clinical practice but may be considered short as most randomised controlled studies examined patients with at least three days in hospital (3-5). Finally, assessment of VTE events after hospital discharge relied on reporting of patients and their primary care physicians, leaving the possibility that the VTE event rate was underestimated.

In conclusion, the Geneva Risk Score can help physicians assess the risk of VTE in acutely ill medical patients, similarly to the Padua Prediction Score. Improving physicians’ compliance with the use of such tools remains a challenge (12, 13). The availability of validated scores may motivate physicians to use them systematically, thereby improving the adequacy of thromboprophylaxis in the future.

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What is known about this topic?

- In acutely ill medical patients judged to have a high risk of venous thromboembolism (VTE), pharmacological thromboprophylaxis halved the rate of symptomatic VTE in comparison to placebo.
- There is a need to validate risk assessment tools for identification of hospitalised medical patients at risk of VTE.

What does this paper add?

- The Geneva Risk Score predicted VTE and VTE-related mortality and compared favourably with the Padua Prediction Score, particularly for its accuracy to identify low-risk patients who do not require thromboprophylaxis.
- The availability of validated risk assessment tools in a multicenter setting will help to improve the adequacy of thromboprophylaxis for acutely ill medical patients in the future.
Conflicts of interest
Dr. Spirk is an employee of Sanofi-Aventis (Suisse) SA, Vernier, Switzerland. No other conflict of interest was reported from the authors regarding the content of this manuscript.

References