The impact of an individualized risk-adjusted approach on hypertension treatment in primary care

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INTRODUCTION

Elevated blood pressure (BP) is a leading risk factor for premature death, stroke, and heart disease worldwide. A broad armament of evidence-based treatment options as well as guidelines providing the latest evidence on how to use these different treatment options exist. Nevertheless, there is suspicion that a considerable proportion of patients diagnosed with hypertension worldwide do not receive appropriate treatment. Different studies have found a substantial gap between guideline recommendations and the actual treatment of hypertension in patients. This gap is often referred to as the evidence-performance gap (EPG). Approximately 60% or more patients with hypertension worldwide, especially patients treated in primary care settings, might be affected by the EPG. These previous studies used the BP threshold of 140/90 mm Hg as a single criterion for appropriate treatment. Consequently, all patients with a BP ≥140/90 mm Hg without treatment, disregarding their overall cardiovascular risk (CVR), were defined as being affected by the EPG.

Because comorbidities and other CVR factors in addition to hypertension are frequent in real-life patients, especially in the primary care setting, the integration of comorbidities and CVR factors into the assessment is important. Recent studies support the recommendation to shift focus from rigid BP thresholds to patients’ overall CVR to facilitate an individualized risk-adjusted assessment whenever deciding on hypertension treatment. A possible explanation for the EPG is that primary care physicians (PCPs) adapt guideline recommendations to the needs of their real-life patients, a finding that has been shown in diabetes management. Thus, EPGs might rather be explained by an individualized risk-adjusted assessment than by low adherence to guidelines.

The latest guidelines of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC) published in 2013 recommend taking cardiovascular risk factors into account when assessing treatment for patients with hypertension. The authors hypothesize that this approach will reduce the proportion of patients receiving inappropriate treatment. In this cross-sectional study using electronic medical records of Swiss primary care patients, the authors estimate the proportion of patients receiving inappropriate treatment using two approaches: (1) based on a blood pressure threshold of 140/90 mm Hg; and (2) based on cardiovascular risk factors. A total of 22,434 patients with hypertension were identified. Based on these approaches, 72.7% and 44.6% of patients, respectively, qualified for drug treatment. In addition, 23.0% and 10.8% of patients, respectively, received inappropriate treatment. Application of the 2013 ESH/ESC guidelines reduced the proportion of patients receiving inappropriate treatment by 50%. This shows the major impact of risk adjustment and highlights the need for a patient-centered approach in hypertension treatment.
friability into account. At present, the 2013 ESH/ESC guidelines are the clinical standard for the management of patients with hypertension in Europe.

However, the proportion of patients with hypertension who qualify for treatment according to these guidelines remains unknown, as it is true for the proportion of patients affected by the EPG.

We hypothesize that the risk-adjusted approach will result in a smaller proportion of patients who qualify for treatment; thus, the EPG will decrease.

2 | METHODS

This cross-sectional study used data collected from electronic medical records of primary care patients with hypertension registered between January 2009 and August 2015. We estimated the proportion of patients qualifying for treatment according to two different approaches and assessed whether PCPs had prescribed treatment or not. The primary outcome of the study was the proportion of patients who did not receive treatment although recommended by guidelines. By definition, these patients were considered as being affected by an EPG. The secondary outcome was the difference between the EPG estimations obtained by the two approaches.

First, patients were stratified according to the BP threshold of 140/90 mm Hg, subsequently referred to as "standardized BP approach." Second, patients were stratified to CVR categories according to BP levels and additional CVR factors as recommended in the 2013 ESH/ESC guidelines, subsequently referred to as "risk-adjusted approach."24

2.1 | Data collection

Medical record data were extracted from the database of the Family Medicine ICPC-Research Using Electronic Medical Records (FIRE) project. FIRE is an ongoing research project of the Institute of Primary Care at the University and University Hospital of Zurich, Switzerland, involving PCPs in the German-speaking part of Switzerland. PCPs voluntarily provide standardized, anonymized medical record data of all patient encounters in daily practice. Data include patients’ demographics, vital signs, diagnostic codes using the second version of the International Classification of Primary Care (ICPC-2),25-28 laboratory values, and data on medication using the Anatomical Therapeutic Chemical Classification System (ATC).27 Further details on the FIRE database and its validation are provided elsewhere.21,28

2.2 | Patients

All patients registered in the FIRE database between January 2009 and August 2015 were assessed for the eligibility criterion hypertension.

The definition of hypertension was based on the occurrence of at least one of the following criteria (which were searched for in the following hierarchically order):

- more than two BP measurements ≥140/90 mm Hg or
- at least one recorded ICPC-2 coding (K85 "elevated blood pressure," K86 "hypertension uncomplicated," K87 "hypertension complicated") or
- at least two prescriptions for antihypertensive drugs according to ATC coding as validated by Lamers and colleagues29 (C02 "antihypertensives," C03A "low-ceiling diuretics, thiazides," C03EA01 "hydrochlorothiazide and potassium-sparing agents," C07 "beta-blocking agents," C08 "calcium channel blockers," C09A "ACE inhibitors, plain," C09B "ACE inhibitors, combinations") and ATC coding of angiotensin II receptor antagonists (C09C "angiotensin II antagonists, plain," C09D "angiotensin II antagonists, combinations").

Patients who had fewer than two BP measurements (regardless of the measured value [this was possible as eligible patients had to meet only one and not all three inclusion criteria to be eligible]), fewer than two PCP consultations, were younger than 18 years, or pregnant were excluded.

Patients’ individual observation period was defined using an inclusion and an end date. The first visit date on which a patient met one of the three inclusion criteria was used as the inclusion date. The end date was the date of the latest visit a BP measurement was made. ICPC-2 codes were used if they occurred only once, as these codes were based on best medical practice by participating PCPs who did the coding by themselves. ATC codes were used if they occurred at least twice to avoid prescription errors. We used the latest available data for changing parameters (e.g., laboratory data or demographic data such as weight) going backward starting at the end date.

2.3 | Baseline characteristics

The following baseline characteristics of included patients were assessed based on medical record entries: “age,” “antihypertensive drugs,” “concomitant nonantihypertensive drugs,” “concomitant chronic diseases,” “BP measurements,” “risk factors,” and “asymptomatic organ damage.” Patients’ chronic comorbidities were assessed based on the ICPC-2 classification as recommended by O’Halloran and colleagues30 and based on PCGs.29

2.4 | Stratification according to BP levels (standardized BP approach)

We established five hypertension grade groups: normal (systolic BP [SBP] ≤129 mm Hg and diastolic BP [DBP] ≤84 mm Hg), high normal (SBP 130–139 mm Hg, DBP 85–89 mm Hg), grade 1 (SBP 140–159 mm Hg, DBP 90–99 mm Hg), grade 2 (SBP 160–179 mm Hg, DBP 100–109 mm Hg), and grade 3 (SBP ≥180 mm Hg, DBP ≥110 mm Hg).24

Patients were stratified to these groups based on the mean value of all recorded BP measurements. As recommended by the 2013 ESC/ESH guidelines, stratification to a specific hypertension grade group was based on the higher level, regardless of whether it was SBP or DBP. If two BP measurements were available from the same visit, we used the mean of the two available values.
2.5 | Stratification according to CVR categories (risk-adjusted approach)

As recommended by the 2013 ESH/ESC guidelines, we established eight CVR categories: average, low, low-moderate, moderate, moderate-high, high, high-very high, and very high depending on the patients’ hypertension grade group and number of existing risk factors, asymptomatic organ damage, and established diseases (see Figure 1 for details). Therefore, we searched each patient’s latest medical record for ICPC-2 diagnoses, medication lists/ATC codes, and laboratory results (Table 1).

2.6 | Treatment criteria

All patients stratified to hypertension grade ≥1 group qualified for drug treatment according to the standardized BP approach.

All patients with hypertension grade ≥1 group with a CVR category of at least “high” qualified for drug treatment according to the risk-adjusted approach.

Exceptions within the risk-adjusted approach apply to young patients with isolated systolic hypertension (ISH) and elderly patients. In the context of ISH, patients 30 years or younger were determined as “young.”

We therefore decided to consider patients 30 years and younger with a mean SBP level of >140 mm Hg and a mean DBP level of <90 mm Hg as patients affected by ISH. In regard to age, neither the 2013 ESH/ESC guideline nor general medical literature defines exact thresholds for “elderly.” Thus, we did not set an exact age threshold and stratified patients affected by the EPG according to age (Figure 4).

In order to assess possible changes in clinical practice over the observation period of 6 years, we performed a sensitivity analysis comparing patients within the first 3 years with patients within the last 3 years. Because eligible patients could be found anytime between January 1, 2009, and December 31, 2015, and the duration of patients’ observation period was subject to change, patients included in the first as well as the last years were not included in this sensitivity analysis.

2.7 | Statistical analysis

Continuous variables are presented as means and standard deviations (SDs) and categorial data as frequencies and percentages. We used Wald’s interval to calculate the confidence interval (CI). Data analysis was performed using R statistics software (version 3.2.0; R Foundation, Vienna, Austria).
RESULTS

Until August 2015, 264,641 primary care patients were registered in the FIRE database. All patients were assessed for the eligibility criterion hypertension and 48,602 were defined as eligible. Of these, 20,236 patients were excluded because they had fewer than two BP measurements available, 312 patients had fewer than two PCP consultations, 5,613 patients were younger than 18 years, and seven patients were pregnant. Data on the remaining 22,434 patients with hypertension were included in the analysis (Figure 2).

The average age of included patients was 66.4 years and 50.7% were male. The average observation period for the individual patient was 2.7 years. During observation, on average 9.7 BP measurements per patient were performed, corresponding to an average of 3.7 BP measurements per patient per year. In addition to hypertension, patients had a mean of 4.8 concomitant chronic diseases and took 5.9 concomitant nonantihypertensive drugs. Detailed baseline characteristics are shown in Table 2.

3.1 | Standardized BP approach

Based on the BP threshold of 140/90 mm Hg, 72.7% (95% CI, 72.0–73.4) of all patients qualified for drug treatment. About 49.7% (95% CI, 48.8–50.1) received a drug as recommended, while 23.0% (95% CI, 21.8–24.1) received no drugs although they qualified for treatment. The latter were therefore identified as being affected by the EPG (Figure 3).

3.2 | Risk-adjusted approach

Based on the CVR categories, 44.6% (95% CI, 43.6–45.6) of all patients qualified for drug treatment. A total of 33.9% (95% CI, 32.8–34.9) received a drug as recommended, while 10.8% (95% CI, 9.5–12.0) received no drugs although they qualified for treatment. The latter were therefore identified as being affected by the EPG (Figure 3).

3.3 | Difference between approaches

The proportion of patients affected by the EPG differed by 12.2% (95% CI, 10.9–13.4) depending on the approach used.

3.4 | Further analysis

The stratification of all patients to the eight different CVR categories showed that 53.2% (11,941/22,434) of all patients were assigned to the moderate-high or to a lower CVR category. Accordingly, 46.8% (10,493/22,434) were assigned to higher CVR categories, but only

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### TABLE 1 Definition of risk factors, asymptomatic organ damage, and established disease

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Male sex</th>
<th>Male sex</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>Male sex and age ≥55 y or female sex and age ≥65 y (age assessed on date of study inclusion)</td>
<td>Male sex and age ≥55 y or female sex and age ≥65 y (age assessed on date of study inclusion)</td>
</tr>
<tr>
<td><strong>Dyslipidemia</strong></td>
<td>Use of lipid-lowering medication (ATC C10) or ICPC-2 code (lipid disorder) or cholesterol &gt;4.9 mmol/L or low-density lipoprotein &gt;3.0 mmol/L or triglycerides &gt;1.7 mmol/L, or male sex and high-density lipoprotein &lt;1.0 mmol/L or female sex and high-density lipoprotein &lt;1.2 mmol/L</td>
<td>Use of lipid-lowering medication (ATC C10) or ICPC-2 code (lipid disorder) or cholesterol &gt;4.9 mmol/L or low-density lipoprotein &gt;3.0 mmol/L or triglycerides &gt;1.7 mmol/L, or male sex and high-density lipoprotein &lt;1.0 mmol/L or female sex and high-density lipoprotein &lt;1.2 mmol/L</td>
</tr>
<tr>
<td><strong>Obesity</strong></td>
<td>ICPC-2 code (obesity) or BMI ≥30</td>
<td>ICPC-2 code (obesity) or BMI ≥30</td>
</tr>
<tr>
<td><strong>Elevated fasting glucose</strong></td>
<td>Fasting glucose level between 5.6 mmol/L and 6.9 mmol/L</td>
<td>Fasting glucose level between 5.6 mmol/L and 6.9 mmol/L</td>
</tr>
</tbody>
</table>

**Asymptomatic organ damage**

| Pulse pressure | Difference between systolic and diastolic blood pressure ≥60 mm Hg and age ≥65 y (age assessed on date of study inclusion) | Difference between systolic and diastolic blood pressure ≥60 mm Hg and age ≥65 y (age assessed on date of study inclusion) |
| **Chronic kidney disease Grade 3** | Glomerular filtration rate between 30 mL/min/1.73 m² and 60 mL/min/1.73 m² according to CKD-EPI formula | Glomerular filtration rate between 30 mL/min/1.73 m² according to CKD-EPI formula |

**Established disease**

| Chronic kidney disease Grade 4 | Glomerular filtration rate <30 mL/min/1.73 m² according to CKD-EPI formula | Glomerular filtration rate <30 mL/min/1.73 m² according to CKD-EPI formula |
| **Diabetes** | Use of antidiabetic medication (ATC A10A, A10B, A10X) or ICPC-2 code (diabetes insulin dependent, diabetes not insulin dependent) or at least two fasting blood sugar measurements ≥7.0 mmol/L or glycated hemoglobin ≥6.5% | Use of antidiabetic medication (ATC A10A, A10B, A10X) or ICPC-2 code (diabetes insulin dependent, diabetes not insulin dependent) or at least two fasting blood sugar measurements ≥7.0 mmol/L or glycated hemoglobin ≥6.5% |
| **Cardiovascular disease** | Use of cardiac medication (ATC C01) or ICPC-2 code (ischemic heart disease with angina, acute myocardial infarction, ischemic heart disease with/without angina, heart failure, atrial fibrillation/flutter, paroxysmal tachycardia, transient cerebral ischemia, stroke/cerebrovascular accident, cerebrovascular disease, arteriosclerosis/PVD, retinopathy) | Use of cardiac medication (ATC C01) or ICPC-2 code (ischemic heart disease with angina, acute myocardial infarction, ischemic heart disease with/without angina, heart failure, atrial fibrillation/flutter, paroxysmal tachycardia, transient cerebral ischemia, stroke/cerebrovascular accident, cerebrovascular disease, arteriosclerosis/PVD, retinopathy) |

*Chronic Kidney Disease Epidemiology collaboration equation (CKD-EPI): glomerular filtration rate (GFR)=141 × min(Scr/K, 1) × max(Scr/K, 1) 1.209 × 0.993 0.329 if female and 0.9 if male; α= −0.329 if female and −0.411 if male; min=the minimum of K or 1; max=the maximum of K or 1; Scr=serum creatinine (mg/dL).28 Abbreviations: ATC, Anatomical Therapeutic Chemical Classification System; BMI, body mass index; ICPC-2, second version of the International Classification of Primary Care; PVD, peripheral vascular disease.
8.1% (1816/22434) were assigned to the “very high” CVR category. Results of stratification of patients to different CVR categories are shown in Figure 1.

The age stratification of all 2416 patients affected by the risk-adjusted EPG approach showed that 11.1% (266/2416) of these patients were 60 years or younger, while 88.9% (2150/2416) were older than 60 years (Figure 4).

Among patients younger than 60 years, three patients were identified as being affected by ISH.

Sensitivity analysis splitting the 6-year observation period into two periods of 3 years each showed no relevant difference in clinical practice concerning our main outcome of “appropriateness of hypertension treatment.”

**FIGURE 2**  Inclusion flowchart. ATC, Anatomical Therapeutic Chemical Classification System; BP, blood pressure; FIRE, Family Medicine ICPC-Research Using Electronic Medical Records; ICPC-2, second version of the International Classification of Primary Care

4 | DISCUSSION

In this study, we applied two different approaches to data of patients with hypertension treated in Swiss primary care to evaluate the proportion of patients who qualify for treatment and are affected by the EPG. That way, we were able to demonstrate the actual impact of individualized risk adjustment compared with assessment based on a rigid BP threshold.

Using the standardized BP approach, the proportion of patients with hypertension who qualified for drug treatment was 72.7% compared with 44.6% using the risk-adjusted approach, resulting in a difference of 28.1%. The proportion of patients identified as being
affected by the EPG decreased from 23.0% using the standardized BP approach to 10.8% using the risk-adjusted approach, resulting in a difference of 12.2%.

Our results using the standardized BP approach are comparable to previous studies that only used the standardized BP approach and neglected patients’ individual CVR factors. Some of these studies described a decrease of the EPG over time but attributed it to reasons such as a healthier lifestyle, increase of drug treatment, or higher awareness of hypertension.10,11,13,14,37,38

Scheltens and colleagues12 were the first and only authors who used a more individualized approach estimating the EPG in hypertension management based on the Framingham risk function. However, they applied this approach only to a small (n=292) and special subgroup of patients with hypertension who were free from cardiovascular disease and had an average age of 38 years. Moreover, this approach was based on a number of assessment criteria that is currently considered outdated.12

Recently, Navar-Boggan and colleagues39 demonstrated that the introduction of a new guideline for hypertension management in the United States significantly changed the proportion of patients who qualified for treatment. Applying the 2013 ESH/ESC guidelines, we are now the first to use a risk-adjusted approach. This risk-adjusted approach reduced the EPG by more than 50%. A more detailed analysis of the proportion of patients (10.8%) affected by the EPG using the risk-adjusted approach showed that the majority (88.9%) of patients was older than 60 years when stratified by age. Unfortunately, specifications of terms concerning age such as “elderly” are vague and differ considerably depending on the source.24,32–35,40 Therefore, we refrained from using a clear age threshold when assessing appropriateness of treatment. Nevertheless, one should keep in mind that the observed EPG might further decrease depending on the definition of “elderly.”

In addition to age, but partially associated with age, there are other factors such as patient frailty, orthostatic hypotension, vertigo, social circumstances, individual compliance, and preferences, as well as comorbidities and preexisting polypharmacy, that might influence the decision process. One faces the challenge of balancing advantages and disadvantages of additional treatment based on these factors. Obviously, additional treatment as well as concomitant chronic disease will complicate the decision.41 In this study, patients had a mean of 4.8 concomitant chronic diseases and received 5.9 concomitant drugs. These circumstances emphasize that more effective studies in primary care are needed in order to define the evidence base of treatment, since patients with multimorbid disease with concomitant polypharmacy are often excluded from guideline-influencing randomized controlled trials. For example, one of the latest studies on the topic of BP management excluded patients affected by dementia, diabetes, history of stroke, and those living in a nursing home who are commonly found in the primary care setting.42 This study among patients with high CVR targeting an SBP of <120 mm Hg, as compared with <140 mm Hg, resulted in lower rates of fatal and nonfatal major cardiovascular events and death from any cause, although
the intensive-treatment group experienced significantly higher rates of some adverse events.42,43 These results, supported by data from a large meta-analysis, will influence future guidelines and stress the importance of risk adjustment and patient-centeredness.44

### 4.1 Strengths und limitations

In our dataset, the prevalence of hypertension is seemingly low compared with other studies in the primary care setting.9,10,14,21,45-47 This is explained by exclusion of patients who had fewer than two encounters with their PCP and/or fewer than two BP measurements. This decision was taken because we aimed to specifically analyze PCPs’ treatment performance, as it is unlikely that PCPs have an influence on patients’ hypertension treatment without regular contact. Leaving these patients within our analysis, the prevalence of patients with hypertension would have been 18.4%, and thus similar to other studies in this setting. Nevertheless, our analysis is still based on data of 22 434 patients.

Our data were extracted from routinely collected data from medical records. Therefore, they are subject to the usual limitations of routine data.48,49 We assessed patients’ CVR profile according to the 2013 ESH/ESC guidelines, but some variables (ie, smoking, abdominal obesity, family history for premature cardiovascular diseases, and indicators for asymptomatic organ damage) were limited or not available in our dataset. However, PCPs base their daily decisions on the same variables as we did when extracting data from their medical records. Thus, these data are the best available proxy to measure the actual medical care situation of primary care patients with hypertension to date. A prospective study in this setting would be a disruption of daily practice and prone to the Hawthorne effect.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Included Patients (n=22 434)</th>
<th>Mean</th>
<th>Standard Deviation</th>
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<td>Cardiovascular disease</td>
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DBP, diastolic blood pressure; SBP, systolic blood pressure.

¹Data calculated only among patients with antihypertensive drugs (n=13 506, 60.2% of 22 434).
²Data calculated only among patients where laboratory data were available (n=328, 1.5% of 22 434).
³Data calculated only among patients where laboratory data were available (n=12 426, 55.4% of 22 434).
This study of patients with hypertension in Swiss primary care is of international value because hypertension treatment is an eminent problem in health systems worldwide and the majority of patients with hypertension are treated in this setting. Most likely, our data cannot be generalized to other care settings, but countries with an equal health system should take these results as a suggestion to revisit previous EPG estimations. Switzerland serves as a good example of an industrialized country with an insurance-based healthcare system with a fee-for-service reimbursement and mostly free choice of doctors—a model that can also be found in other countries, eg, Austria, France, Germany, and parts of the United States. The estimation of the actual risk-adjusted EPG in Swiss primary care will thus allow an extrapolation of the EPG in these countries.

5 | CONCLUSIONS

Application of the risk-adjusted approach as recommended by the 2013 ESH/ESC guidelines reduced the EPG by more than 50%. This demonstrates the major impact of risk adjustment and highlights the need for a patient-centered approach in the treatment of hypertension.

ACKNOWLEDGMENT

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DISCLOSURES

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REFERENCES


