An automated method for analyzing adherence to therapeutic guidelines: Application in Diabetes

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Abstract. Background: Physicians’ adherence to guidelines can be used for measuring prescribing appropriateness. We present a simple approach allowing the automation of this process. Design: The drug therapy is described in terms of treatment type, pharmacotherapeutic classes, international non proprietary names (INN) and doses. A rule-based engine implementing the guideline generates recommendations for each patient record. These are automatically compared with prescriptions of the same patient in three levels of detail. Participants: Ambulatory patients admitted for the follow-up of their type 2 diabetes between June 2003 and September 2004 in a university hospital in France. Results: For 574 patient records included in the study, physicians agreed with the guideline recommendations over the choice of type of treatment in 473 cases (82%). When agreement over pharmacotherapeutic class of drugs was also taken into account, the adherence ratio decreased to 448 cases (78%). Finally, when the dosage of each drug was taken into account, the adherence ratio dropped to 396 cases (69%). Adherence ratios were also dependent on the type of treatment at admission: low for patients on oral tritherapy, and on diet and exercise. The results also highlighted inertia of physicians for beginning drug therapy and the underuse of biguanides. Conclusions: The proposed method provides an automatable way of measuring the appropriateness of treatment choice, which can be used for chronic diseases.

Keywords: assessment-evaluation, compliance, quality management, data analysis-extraction, evidence based guidelines, decision support, prescribing appropriateness, diabetes mellitus, therapeutic strategy.

Introduction

Assessing the quality of drug prescriptions is an important issue for which indicators of the appropriateness have been developed [1,2,3]. Some of these indicators are based on
the contents of summaries of product characteristics (SmPC). They can be used to assess the safety of prescriptions, based on the number of contraindications, drug interactions, dosage problems, etc. However, the assessment of the appropriateness of treatment choice goes beyond the SmPCs and requires comparison with recommendations from clinical guidelines [4]. For instance, antihypertensive drugs of various pharmacotherapeutic classes may have the same indication (hypertension) in SmPCs, but the choice of a specific class is generally based on the knowledge found in clinical guidelines (e.g., ACE inhibitors they may be preferred in diabetic patients).

Numerous studies have shown controversial results regarding adherence to guidelines even for a single disease [5,6,7], and the overall adherence is known to be mediocre [8,9]. It remains unclear whether the differences in adherence ratios result from differences in practices, in methods used to measure adherence, or both [10,11].

In this article, we present a simple method for quantifying the adherence to a therapeutic guideline and for easily analyzing the situations in which recommendations are not followed by physicians. This method is applied to type 2 diabetic patient data.

1. Materials and Methods

1.1. The description of treatments

We described the therapeutic prescriptions of physicians in terms of “type of treatment”. For example, the types of treatment for diabetes include diet and exercise (i.e. zero drug therapy), oral monotherapy, bitherapy, tritherapy, and insulin therapy. Each drug in a prescription is linked to some “pharmacotherapeutic class”, “international non proprietary name (INN)”, and “dose” (see Figure 1).

1.2. French clinical guidelines for the management of type 2 diabetes

We used the official guideline of the French National Authority for Health (FNAH) for the management of type 2 diabetes [12]. It was the national reference standard evidence-based guideline at the time of the study, and was widely available to physicians in electronic and paper forms. The guideline proposes a step-by-step therapeutic strategy by dedicating a section for each type of treatment.
Recommendations are provided by their grades of evidence. The goal of treatment is to maintain HbA1C inferior or equal to 6.5%. If this goal is not obtained within a step, the guideline recommends increasing the dose; if not possible: replacing the drug with one from a more efficient class; and if this is not possible: passing to the subsequent type of treatment. Specific recommendations are given for the obese, the elderly, and the patients with renal insufficiency.

1.3. Patient data

We used a database of electronic records of ambulatory patients admitted for the follow up of their type 2 diabetes to the endocrinology department of Avicenne university hospital of Bobigny, France. The patients came to the hospital for periodic control of their diabetes or because of its deregulation. They passed a few hours in the hospital during which they had a laboratory exam and a visit by a physician. During the consultations, physicians did not have access to patient specific recommendations but they could use the guideline as a whole in paper form. All admissions from June 2003 to September 2004 were included. The database contains demographc, anthropometric, clinical, laboratory and therapeutic information. Parameters used by the guideline include age, body mass index, creatinine clearance, ketonuria, and therapeutic history.

1.4. Measuring the adherence

We checked firstly if the type of treatment prescribed by the physician was the same as the one recommended by the guideline. For those prescriptions that fulfilled this condition, we verified if the pharmaco therapeutic classes of drugs were also the same as recommended by the guideline. Based on the anatomial therapeutic chemical (ATC) classification [13], for type 2 diabetes these classes include biguanides (A10BA), sulfonamides (A10BB and A10BC), alphaglucosidase inhibitors (A10BF), and the insulin family (A10A). Two classes; namely thiazolidinediones (A10BG) and other blood glucose lowering drugs (A10BX) are not represented in the studied version of the guideline. Finally, in prescriptions that conformed to the guideline in both type and classes, we checked whether physicians followed the guideline in making the same drug dose intervals (low, moderate, high). We did not check prescriptions for conformity in INN names because this level is not represented in the studied guideline.

1.5. Computer methods

We developed a computer system in Visual Basic® programming language with four major components (see Figure 2). The first two components analyze and abstract prescription data that are entered by physicians. Another component implements the guideline in a rule-based engine which generates the type of treatment, and class and dose of each drug. Experts verified the results generated by this component for about 25% of cases (selected randomly) in order to be sure of their exactness. The fourth component calculates the agreement between two formalized therapies: one resulting from the abstraction of prescription, and the other generated by the third component. They are calculated in three levels of type, class, and dose. In cases for which the rule-based engine cannot generate a treatment due to a lack of knowledge in the guideline, the comparison engine considers the prescription as conformable.
2. Results

Thirteen patient records containing thiazolidinediones and other glucose lowering drugs were excluded because the guideline lacked recommendations for these classes. A total of 574 patient records were included in the study and were analyzed by the computer system. The mean age of patients was 59.9 (SD = 11.4) years, the mean body mass index was 29.0 (sd = 6.0) kg/m², the mean Hb\textsubscript{A1C} ratio was 7.9 (SD = 1.7) percent and the mean duration of diabetes since its onset was 11.4 (SD=9.2) years.

2.1. How consistently do physicians follow the guideline?

The type of treatment conformed to the guideline in 473 (82%) cases, with a range of 11 to 96 percent, depending on the type of treatment at admission. These values decrease when the class and dose are also taken into account (see Table 1).

Table 1. Agreement between prescriptions and recommendations for each group of patients with the same type of treatment at admission

<table>
<thead>
<tr>
<th>Type of treatment at admission</th>
<th>Agreement between prescriptions and recommendations at discharge at three levels</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type only n (% in row)</td>
<td>Type and class n (% in row)</td>
</tr>
<tr>
<td>Diet and exercise</td>
<td>18 (62)</td>
<td>18 (62)</td>
</tr>
<tr>
<td>Oral monotherapy</td>
<td>127 (86)</td>
<td>117 (79)</td>
</tr>
<tr>
<td>Oral bitherapy</td>
<td>119 (82)</td>
<td>112 (77)</td>
</tr>
<tr>
<td>Oral tritherapy</td>
<td>4 (11)</td>
<td>4 (11)</td>
</tr>
<tr>
<td>Insulin alone or combined with oral therapy</td>
<td>205 (96)</td>
<td>197 (92)</td>
</tr>
<tr>
<td>Total</td>
<td>473 (82)</td>
<td>448 (78)</td>
</tr>
</tbody>
</table>
Table 2. For each group of patients with the same type of treatment at admission, the choices of physician are compared with those of the guideline. Ph: physician's prescription; GL: guideline.

<table>
<thead>
<tr>
<th>Type of treatment at discharge</th>
<th>Prescribed and recommended types of treatment at discharge</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diet and exercise</td>
<td>Oral monotherapy</td>
</tr>
<tr>
<td></td>
<td>Ph</td>
<td>GL</td>
</tr>
<tr>
<td>Diet and exercise</td>
<td>28</td>
<td>19</td>
</tr>
<tr>
<td>Oral monotherapy</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Oral bitherapy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Oral tritherapy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Insulin alone or combined with oral therapy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>29</td>
<td>19</td>
</tr>
</tbody>
</table>

2.2. What do physicians do when they do not follow the guideline?

 Physicians were less likely to start a monotherapy for patients on diet and exercise. This is shown by the fact that among 29 patients on diet and exercise only one is discharged with monotherapy versus 10 patients for the guideline (see Table 2). Further comparisons showed that physicians were less likely to change the class of a monotherapy from sulfamides or alphaglucosidase inhibitors to biguanides.

3. Discussion and conclusion

We proposed a method of measuring the appropriateness of treatment choice by use of a therapeutic guideline. We computerized our method and demonstrated it for a database of type 2 diabetic patients.

Like many other guidelines, our guideline did not contain recommendations for a number of items such as new pharmacotherapeutic classes. Although at the moment of study, HAS released a new version of the guideline, we preferred working with the previous one in order to be sure of physician awareness at the moment of prescriptions. We considered prescriptions conformed to the guideline in situations where the latter does not provide recommendations. Although this convention is quite common in measuring the adherence, it does not literally mean that physician followed the guideline. It would be useful to ask physicians on the reasons of non-adherence. We did not do so because our goal was to analyze the agreement only by use of patient records, in a way that the procedure could be automated.

We used the types of treatments, the pharmacotherapeutic class, and the dose of medications as principal levels of detail in drug therapy and we based our comparisons on these levels. The type of treatment is unspecific to diabetes. In a variety of conditions, such as hypertension and dyslipidemia, patients are treated with non-pharmacological, mono-, bi- and tritherapy. In other conditions, such as asthma, heart
failure and chronic infectious diseases, the therapeutic strategy often comprises several drug regimens, which may be considered as types of treatment. Pharmacotherapeutic class and dose are known concepts in therapeutics and can be applied to all pharmacological treatments.

Existing approaches for measuring adherence to guidelines are often based on physician surveys, patient records, guideline impacts, and multi-level explicit criteria [14,15,16]. Our method seems to be less comprehensive than methods based on explicit criteria, because it does not measure the adherence to all features of guidelines, such as diagnostics. However, it was not among our objectives to propose a comprehensive tool for measuring the adherence to guidelines.

Our method can be used both as a tool for assessing the appropriateness of choice of treatment, and as an educational aid for physicians. We are actually trying to combine this technique with data mining techniques in order to find decision-making pathways of medical experts.

References