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Comparison of three risk factor-based screening tools for the identification of prediabetes

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Abstract

Objective—To compare risk factor-based screening tools for identifying prediabetes

Methods—Participants in an employer-based wellness program received A1C testing during a regularly scheduled appointment, and prediabetes risk factor information was collected. Likelihood of having prediabetes and need for laboratory testing was determined based on three risk factor-based screening tools, the *Prediabetes Screening Test* (PST), *Prediabetes Risk Test* (PRT), and 2016 American Diabetes Association guidelines (ADA2016). Screening tool results were compared to A1C. The predictive ability of the PST, PRT, and ADA2016 were compared using logistic regression. Results were validated with data from a secondary population.

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Results—Of the three risk factor-based tools examined, the PRT demonstrated the best combination of sensitivity and specificity for identifying prediabetes. From July 2016 – March 2017, 740 beneficiaries of an employer-sponsored wellness program had their A1C tested and provided risk factor information. Population prevalence of prediabetes was 9.3%. Analysis of a second, independent population with a prediabetes prevalence over 50% of confirmed PRT's superiority despite differences in calculated sensitivity and specificity for each population.

Conclusion—PRT predicts prediabetes better than PST or ADA2016, and should be used preferentially.

BACKGROUND

More than one-third of American adults have prediabetes. Only approximately 12% of those affected are aware of their prediabetes. Adults 65 years of age or older are most at-risk, with nearly half of the population having prediabetes.[1] Impaired glucose regulation identified by an A1C of 5.7-6.4%, fasting plasma glucose (FPG) of 100-125 mg/dL, or 2-hour plasma glucose after a 75-gram oral glucose tolerance test (OGTT) of 140-199 mg/dL typifies this condition.[2] Early awareness may have significant implication, as prediabetes precedes the onset of type 2 diabetes (T2D) and, without intervention, an estimated 17% of individuals with prediabetes will develop T2D within 5 years and 70% will have T2D within 10 years.[3] Having prediabetes not only increases the risk for T2D, it is also associated with an increased risk for cardiovascular disease.[4]

National efforts to improve the identification and intervention for prediabetes have recently been endorsed by the nation's leading health organizations through avenues including a national marketing campaign that encourages individuals to learn about their prediabetes risk and to receive blood sugar testing.[5] The HealthyPeople2030 initiative has proposed an objective (D-2030-09) to decrease the number of adults with undiagnosed prediabetes.[6] The impact of improved prediabetes identification has been demonstrated by results from the 2011-2016 National Diabetes Education Program National Diabetes Survey (NNDS). Survey results reveal an increase in awareness of personal risk for T2D from 2011 to 2016 and that a diagnosis of prediabetes had a significant positive impact on improving this awareness, likelihood of receiving risk-reduction counseling, and probability that the individual would engage in risk-reducing behaviors.[7]

The national growth of diabetes prevention programs may be linked to the Center for Disease Control's (CDC) recent finding that the rate of new diabetes diagnoses is on the decline and that the total number of diabetes cases has stabilized within the last decade.[8] While recent efforts have made a significant positive impact, there remains a large population of patients that remain naïve to their risk and whom need to be reached.

Pharmacists are uniquely positioned to improve the identification of patients with prediabetes and to provide intervention.[9] Efficient identification of at-risk patients is important for the development of cost-effective prevention services. There are several risk factor-based tools used to identify individuals that should receive blood sugar testing including those provided by the American Diabetes Association (ADA) and the CDC.[2,10,11] Risk factors include age, gender, body mass index (BMI), activity level, race/ethnicity,

family history of diabetes, personal history of gestational diabetes or polycystic ovarian syndrome, and having hypertension, cardiovascular disease, or dyslipidemia.[2] Using varying combinations and weighting of these risk factors, the tools identify individuals most likely to have prediabetes or undiagnosed diabetes. Previous studies have demonstrated that these tools have a poor to moderate combination of sensitivity and specificity, leading to a large proportion of false positive results.[12] Despite this, the CDC's *Prediabetes Screening Test* (PST) and the ADA's *Prediabetes Risk Test* (PRT) are recommended by current screening guidelines and National Diabetes Prevention Program (NDPP) guidance materials to identify individuals who are at high risk for having prediabetes and should receive confirmatory laboratory testing.[2,9,13] The PST and PRT are scored based on the inclusion and weighting of specific risk factors, whereas the ADA2016 includes a broader list of known diabetes risk factors without a weighting system.[2] A comparison of the risk factors included and scoring systems is found in Table 1. Determination of the screening tool with the best predictive ability to guide testing would help to control testing costs and improve the financial feasibility of developing a screening and prevention service.

OBJECTIVE

The purpose of this report was to compare the ability of the currently recommended risk factor-based screening tools to predict prediabetes in a sample of participants in an employer-sponsored wellness program.

METHODS

This research was approved by the Institutional Review Board of Auburn University and was conducted from July 2016 to March 2017. The Auburn University Pharmaceutical Care Center (AUPCC) is a pharmacist-led ambulatory care clinic that provides services to university employees, their dependents, and the local community. All patients reporting to clinic for a regularly-scheduled biometric screening appointment were invited to have their A1C measured via the A1C Now Plus® point-of-care device (POC) using a finger stick blood sample as described previously.[14] Risk factor information was collected from the appointment findings and intake paperwork. Collected risk factor information was utilized to determine whether laboratory testing was recommended using each of the three screening tools and compared to A1C results. A1C was assessed as normal (less than 5.7%), prediabetes-range (5.7-6.4%), and suggestive of diabetes (>6.4%). The predictive ability of the risk factor-based screening tools, the PRT, PST, and the ADA2016, to correctly identify individuals with prediabetes were compared.[2,10,11] Owing to the low population prevalence of prediabetes, results were confirmed utilizing an independent data set from a primary care practice in rural Alabama.[15] Non-pregnant adult patients (age ≥ 19 years) without a previous diagnosis of diabetes were eligible to participate.

Statistical Analyses.

Sensitivity and specificity were calculated for each of the risk-factor-based algorithms as well as their corresponding 95% confidence intervals. Confidence intervals were based upon the normality approximation without a continuity correction. To estimate the predictive ability of each the algorithms to identify prediabetes, odds ratios were estimated for each

along with their corresponding 95% confidence interval using logistic regression. Finally, to compare sensitivity and specificity across algorithms, pairwise tests for differences in receiver operator curves were conducted. All statistical analyses and statistical graphs were conducted or developed using SAS 9.4 or R 3.3.2.

RESULTS

During the study period, 740 patients met inclusion criteria and consented to participate. This population has been described previously.[14] The population was an average of 45.0 ± 11.5 years of age, 55.7% female, 81.2% Caucasian, and 61.8% overweight or obese (27.5 ± 6.06). Sixty-nine individuals had an A1C in the prediabetes range (5.7-6.4%), suggesting prediabetes (9.3%). Seven participants had an A1C greater than 6.4%, suggestive of undiagnosed diabetes (1.0%). Participants with a normal A1C differed significantly from those with a prediabetes range A1C based on risk factors including age (44.4 ± 11.5 and 50.6 ± 10.4, respectively, $p<0.001$) , sex (46.8% male and 30.4%, respectively, $p<0.01$), race/ethnicity (84.3% Caucasian and 58.0%, respectively, $p<0.001$), BMI (27.1 ± 5.8 kg/m^2 and 31.3 ±7.1, respectively, $p<0.001$), A1C (5.1% ± 0.3 and 5.9% ± 0.2, respectively, $p<0.001$), high-density lipoprotein (HDL) (55.1 ± 17.2 mg/dL and 50.8 ± 14.1, respectively, $p<0.05$), inactivity (43.1% and 63.8%, respectively, $p<0.01$), and having hypertension (14.6% and 29.0% respectively, $p<0.001$).

The three risk factor-based tools identified different populations of participants that should receive blood sugar testing. According to ADA2016 criteria, 71.8% of the population should receive laboratory analysis compared to 45.1% and 30.8% for the PST and PRT, respectively. Sensitivity and specificity of the PST were estimated to be 85.7 (95% CI: 77.5 to 93.9) and 46.4 (95% CI: 42.6 to 50.2); sensitivity and specificity of the PRT were estimated to be 81.4 (95% CI: 72.3 to 90.5) and 70.2 (95% CI: 66.7 to 73.6). For the ADA2016, the sensitivity and specificity were estimated to be 94.3 (95% CI: 88.8 to 93.9) and 30.0 (95% CI: 26.4 to 33.4). In a logistic regression, PST produced an Odds Ratio of 3.29 (95% CI: 1.92, 5.66); PRT produced an Odds Ratio of 5.55 (95% CI: 3.27, 9.40); ADA2016 recommendations produced an Odds Ratio of 7.05 (95% CI: 2.54, 19.62). Test of Receiver Operator curves indicated significant statistical difference in screening characteristics for ADA2016 and PRT (PRT superior, $p = 0.0042$). (Table 2) Three individuals identified to have a prediabetes-level A1C were not recommended to receive testing via any of the three tools tested.

In a comparative family practice population, there were 155 patients with normal A1C, 121 with prediabetes, and 57 with undiagnosed diabetes. This population has been described previously.[15] For the sake of analyses and calculating sensitivity and specificity, only individuals with normal and prediabetes-level A1C were used. When comparing sensitivity and specificity among tests, PRT was superior to the PST ($p = 0.0006$) and ADA2016 ($p = 0.0004$). There was no statistical difference between PST and ADA2016 ($p = 0.9312$). (Table 2) This demonstrates that the PST superiority found in the subject population may extend to populations with significantly higher prevalence of prediabetes.

DISCUSSION

To determine the most efficient risk factor-based tool for identifying individuals that should receive blood sugar testing to determine glycemic status, three of the recommended algorithms were compared. This study demonstrates that the PRT had a superior combination of sensitivity and specificity for identifying A1C-confirmed prediabetes compared to the ADA2016 and PST, despite low specificity. Given the low prevalence of prediabetes in the subject population, the algorithms were tested in an independent population of family care patients and confirmed that the PRT was superior. It is important to note that the predictive values themselves varied between the two populations. Developing identification methods with enhanced specificity would greatly improve the economic feasibility of building a prediabetes identification program. False-positive screening results not only increase the cost to identify a true case of prediabetes, but may also have a negative impact on patient perception of their risk for developing prediabetes and T2D and could decrease willingness to receive blood sugar testing in a subsequent year. This must be balanced with the occurrence of false negative results which would leave untested a population of patients with elevated blood sugar and at risk for complications. Early identification and intervention for individuals with prediabetes and undiagnosed diabetes is integral to reducing morbidity and mortality in this population. In our population, frequent patient contact may allow for future identification of true cases of prediabetes, though a delay in diagnosis comes with increased health risk and is not ideal.[16] Differences in sensitivity and specificity between the two populations is hypothesized to be due to significant differences in average age, BMI, and prediabetes prevalence. We intend to investigate avenues for improving the sensitivity, specificity, and consistency of these measures across diverse populations.

Deployment of an enhanced prediabetes identification initiative in U.S. pharmacy practices could improve the reach of current identification methods by taking advantage of the broad and diverse population serviced by pharmacists. These practices could also offer education and prevention services to further increase their impact.[9,14] Demonstration of cost-effective methods for identifying patients with prediabetes in pharmacy practices around the country has the potential to substantially grow current national diabetes prevention efforts. This is particularly important in resource-limited settings such as community screenings and health fairs and indigent care clinics.

Limitations.

A limitation of this study is the testing of only three of the available risk factor-based screening methods. These tools were chosen based on their regular use in practice for identification of candidates for participation in the NDPP.[13] A second limitation includes low diversity in the subject population. This may decrease generalizability to more diverse patient populations. The limitation of having a low prevalence of prediabetes in our subject population was addressed by validation in an independent family practice population with a prevalence that more closely reflects the national average.

CONCLUSION

Of the ADA's *Prediabetes Risk Test* (PRT), the CDC's *Prediabetes Screening Test* (PST), and the 2016 ADA screening guidelines, the PRT was found to have the best combination of sensitivity and specificity for correctly identifying prediabetes. Despite this, the specificity of the PRT was low. Development of a tool with an improved combination of sensitivity and specificity could decrease program costs in a comprehensive diabetes prevention program.

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Key Points

Background

1. The CDC has published guidance for community pharmacists for developing diabetes prevention services in the community pharmacy setting.
2. Use of either the *Prediabetes Screening Test* (PST) or *Prediabetes Risk Test* (PRT) is recommended for identification of individuals that should receive laboratory testing for prediabetes and participated in the Diabetes Prevention Program.
3. Laboratory confirmation of prediabetes is required for enrollment of Medicare beneficiaries in the Medicare Diabetes Prevention Program (MDPP).

Findings

1. Of the PST, PRT, and the American Diabetes Association's Standards of Medical Care in Diabetes – 2016 screening criteria, the PRT demonstrated the best combination of sensitivity and specificity for identifying prediabetes.
2. Use of the PRT to guide laboratory testing would result in the lowest rate of false positives, thereby limiting the number of individuals without prediabetes that receive testing.

Table 1.

A comparison of a sample of risk factor-based prediabetes screening tools.

Tool	Prediabetes Screening Test (PST)[10]	Prediabetes Risk Test (PRT)[11]	2016 ADA Guidelines[2]
Scoring Interpretation	3-8 points = low risk ≥9 points = high risk Test patients with a score of ≥9 points	Test patients with a score of ≥5 points	Test patients aged ≥ 45 years or BMI ≥ 25 kg/m^2 (23 kg/m^2 if of Asian descent) with one additional risk factor
Included Risk Factors and Weighting	1 point each: Giving birth to a baby weighing > 9 pounds Having a sibling with diabetes Having a parent with diabetes	1 point each: Age 40-49 years BMI = 25-29.9 kg/m2 Family history of diabetes Inactivity History of GDM Male sex Hypertension	Inactivity Having a parent or sibling with diabetes Hypertension GDM or giving birth to a baby weighing >9 pounds Being of a high risk ethnicity[a] Polycystic ovarian syndrome (PCOS) HDL < 35 Triglycerides > 250 Having cardiovascular disease
	5 points each: Having a parent with diabetes Age 45-64 years, BMI ≥ 27 kg/m2 Inactivity	2 points each: Age 50-59 years BMI = 30-39.9 kg/m2	
	9 points each: Age ≥ 65 years	3 points each: Age ≥ 60 years BMI ≥ 40 kg/m2	

BMI = body mass index; GDM = gestational diabetes mellitus; ADA = American Diabetes Association; HDL = high density lipoprotein

[a]High risk ethnicity: African American, Latino, Native American, Asian, Pacific Islander

ADA = American Diabetes Association; HDL = high-density lipoprotein; CVD = cardiovascular disease

Table 2.

Predictive ability of three risk-factor-based screening tools. Sensitivity, specificity, and odds ratio for the prediction of prediabetes of the *Prediabetes Risk Test* (PRT), the *Prediabetes Screening Test* (PST), and the American Diabetes Association Standards of Medical Care – 2016 recommendations (ADA2016).

	Sensitivity with 95% Confidence Interval	**Specificity with 95% Confidence Interval**	**Odds Ratio for Prediction of Pre-diabetes**
Employer-based screening population			
PRT	81.4 (72.3, 90.5)	70.2 (66.7, 73.6).	5.55 (3.27, 9.40)
PST	85.7 (77.5, 93.9)	46.4 (42.6, 50.2)	3.29 (1.92, 5.66)
ADA2016	94.3 (88.8, 93.9)	30.0 (26.4, 33.4)	7.05 (2.54, 19.62)
Family practice population			
PRT	58.6 (49.9,67.5)	71.6 (64.5,78.7)	3.58 (2.17,5.92)
PST	62.8 (54.2,71.4)	47.1 (39.2,55.0)	1.50 (0.93,2.44)
ADA2016	90.0 (84.8,95.4)	19.4 (13.1,25.6)	2.18 (1.06,4.47)

PRT = prediabetes risk test; PST = prediabetes screening test; ADA2016 = American Diabetes Association's Standards in Medical Care in Diabetes -2016 recommendations