Original Article

Validation of Community Based Assessment Checklist for Diabetes Mellitus in tertiary care setting, Himachal Pradesh, India.

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Abstract:

Background: Government of India has developed a Community Based Assessment Checklist (CBAC) as a screening tool for Hypertension, Diabetes, and Cancers (Oral, Breast, Cervix). The objective was to assess the validity of the CBAC checklist for type-2 DM at a suggested cut off score of four. **Methods**: Cross-sectional study was carried out in the central laboratory of medical college in the northern state of India. Total 120 already known cases of DM or had Fasting Blood Glucose (FBG) of ≥126 gm/dl and 120 individuals with FBG of ≤126 gm/dl, considered as negative for type-2 DM, were recruited. Simultaneously, CBAC checklist was administered to all the 240 participants. **Results**: High risk CBAC score (≥4) was present in 27.5% patients with diabetes and 12.5% without diabetes (p=0.004). Risk criteria of ≥4 had a diagnostic accuracy of 80.5% (Sensitivity: 42.9%; Specificity: 87.5%) with positive and negative predictive value of 37.5% and 89.7% respectively. Area under curve based on Receiver Operator Characteristic (AUC-ROC) curve was observed to be 0.62 (95% CI: 0.55-0.69) (p=0.001). **Conclusion**: Questionnaire based CBAC risk assessment criteria as a screening tool for blood sugar assessment had poor sensitivity, good specificity and poor discriminatory ability.

Key Words: Validation, **Community Based Assessment Checklist, Diabetes Mellitus**

Introduction

In India, the rising prevalence of Diabetes Mellitus (DM) as a physiological risk factor for vascular diseases has resulted the birth of National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). It has envisaged preventive strategies like opportunistic screening at a health facility, capacity building for management of non-communicable diseases, and health promotion.[1] Early detection and treatment for Diabetes Mellitus (DM) is an effective preventive strategy for DM implemented as a comprehensive approach in a primary health care settings.[2] Though laboratory and clinical assessment are required for diagnosis but it also requires an institutional settings. So, an interviewer administered questionnaire, Community Based Assessment Checklist (CBAC), has been developed under NPCDCS for early detection of Diabetes, hypertension and stroke.[3] Although, DM can be detected by a blood glucose assessment which is a laboratory based procedure. But, CBAC tool helps the village level health workers to screen the probable cases of DM who can be further assessed for DM by blood glucose levels at nearby health facilities. CBAC intends to work as a community based screening tool with a maximum score of ten. NPCDCS recommends individuals with a score of more than four for blood sugar assessment in the laboratory for establishing the diagnosis of DM.[3] Literature review did not find any evidence in support its use in mentioned diseases and in favour of suggested cut off CBAC score of 4 as screening criteria for blood sugar assessment. Therefore, present exercise was carried out to assess its validity of CBAC's screening criteria for blood sugar assessment to diagnose DM.

Methodology:

The study was conducted at Dr. Rajendra Prasad Government Medical College and Hospital (Dr. RPGMC), Kangra, Himachal

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Received: 04.06.2018 **Accepted:17.10.2018**

Pradesh from 8th September to 15th November, 2016. Sample size of 240 (120 diseased and 120 non-diseased) was estimated with expected sensitivity and specificity of 90.0% and 85.0% respectively, with 12.0% disease prevalence, 5.0% precision and at 95% confidence interval (CI).[4] Patients of more than 30 years of age and were recommended for fasting blood glucose (FBG) by the treating physician were contacted in the forenoon at a central laboratory of a medical college. After obtaining an informed consent, patients were recruited consecutively. Patients with known case of DM were considered as diseased along with FBS value of ≥126 mg/dl. Patients had no history of DM and FBS value <126 mg/dl were considered as non-diseased. Patients less than 30 years of age, antenatal cases and patients on drugs like corticosteroids β-blockers, thiazide diuretics, niacin, pentamidine and atypical antipsychotics which are the causes of secondary hyperglycaemia were excluded from the study. Findings of the study are applicable to the individuals to be screened for DM.

Laboratory technician (LT) assessed all recruited patients with CBAC checklist which has five questions and one anthropometric assessment with a maximum score of 10. Each patient was assessed and his/her total score was calculated based on subset score. (Table: 1) Waist circumference was measured in centimetre (Cm) with non stretching measuring tape at the midpoint between the lower costal margin and the top of the iliac crest. A venous blood sample was taken from each participant and blood sugar level was measured using XL-300.[5]Both treating physician and LT were unaware about the study.

The mean and proportions were compared using an unpaired student't' test and chi-square test respectively at 5.0% level of significance and exact p values are reported. Area under curve (AUC) with 95.0% CI was calculated for Receiver Operator Characteristic (ROC) curve to assess the discriminatory ability of the CBAC score using logistic regression; presence of DM as dependent and age, physical activity, and family history of DM were independent variables. As suggested, and AUC-ROC of 0.7-0.8 was considered as acceptable, <0.7 as poor and >0.8 as excellent.[6]

Results:

Total 120 patients with and 120 without DM were recruited in the study with a significant difference (p=0.000) for mean age between patients with diabetes (56.5±9.0) and without diabetes (49.7±12.9). Gender distribution was similar as there were 47.5% males with diabetes and 38.3% without diabetes (p=0.151). Most (82.5%) of patients with DM gave the history for regular intake of medicines. Family history of DM was present in 26.7% patients with diabetes and in 11.7% without diabetes (p=0.003). Use of smoking or smokeless tobacco was observed statistically similar (p=0.514) in patients with diabetes (10.8%) and without diabetes (15.8%), and there was no difference (p=0.542) for daily alcohol consumption which was 10.8% in patients with diabetes and 8.3% in without diabetes. Patients replied that they were carrying out physical activity in the form of exercise, mostly brisk walking and was significantly more (p=0.024) among patients with diabetes (81.7%) than without diabetes (69.2%). Patients with diabetes stated that they were carrying out exercise for an average of 33.4±22.5 minutes in a typical/usual day which is significantly more (p=0.001) compared to patients without diabetes, where it was for average of 33.0±21.5 minutes. Patients with and without disease were observed with statistically similar (p=0.190) waist circumference (Diabetes:

Table 1: Community Based Assessment Checklist (CBAC) for screening of Hypertension, Diabetes, and common cancers (Oral, Breast, Cervix)[1]

S.No.	Question	Range		Score
1.	What is your age? (in complete years)	30-39		0
		40-49		1
		50-59		2
2.	Do you smoke or consume smokeless products such as *gutkha* or *khaini*?	Never		0
		Used to consume in the past/ sometimes now		1
		Daily		2
3.	Do you consume alcohol daily?	No		0
		Yes		1
4.	Measurement of waist (in cm)	Male	Female	
		<80	< 90	0
		80-90	90-100	1
		>90	>100	2
5.	Do you undertake any physical activities for minimum of 150minutes in a week?	Less than 150 minutes in a week		1
		At least 150 minutes in a week		0
6.	Do you have a family history (any one of your parents or siblings) of diabetes?	No		0
		Yes		2

Table 2: Distribution of overall and subset score (mean±SD)among patients with diabetes (120) and non-diabetes (120), in a tertiary care settings of Himachal Pradesh, India, 2016.

Score	Diabetics (N=120)	Non-Diabetics (N=120)	p value	New Diabetics (N=21)	p value
Total	3.7 (1.4)	3.0 (1.4)	0.000	4.1 (1.3)	0.003
Age	1.7 (0.5)	1.2 (0.8)	0.000	1.6 (0.5)	0.105
Waist	0.8 (0.8)	0.7 (0.8)	0.190	0.7 (0.9)	0.957
Physical Activity	0.2 (0.4)	0.5 (0.5)	0.000	0.3 (0.4)	0.141
Smoking	0.2 (0.5)	0.2 (0.5)	0.634	0.5 (0.7)	0.054
Alcohol	0.1 (0.3)	0.0 (0.2)	0.412	0.2 (0.4)	0.132
Family History of Diabetes	0.5 (0.8)	0.2 (0.6)	0.003	0.7 (0.9)	0.002

87.2±13.1; Non-diabetics: 84.9±13.9). Assessment for mean blood sugar observed a significant difference (p=0.000) for its levels with 149.8±65.8 mg/dl in patients with diabetes compared to 100.5±15.3 mg/dl without diabetes.

CBAC checklist based scoring was done and it was found that patients with diabetes had a high average score of 3.7±1.4 as compare to without diabetes, which had a score of 3.0± 1.4 (p=0.000). Both patients with and without diabetes had high scores for age group which was 1.7±0.5 for diabetes and 1.3±0.8 for without diabetes (p=0.000). Except for physical activity which is significantly (p=0.000) more in patients without diabetes, patients with diabetes had higher scores as compared to patients without diabetes. Only 21 patients observed as a new case of diabetes and had high (p=0.003) average total score (4.1±1.3) in comparison to patients without diabetes. There was an insignificant difference across all the subset scores except for physical activity; new diabetes patients had high scores for the age group. (Table: 2)

CBAC based positive screening criteria (≥4) was present in 27.5% patients with diabetes and 12.5% without diabetes (p=0.004). Risk criteria observed with 80.5% diagnostic accuracy (Sensitivity: 42.9%; Specificity: 87.5%) with positive and negative predictive value of 37.5% and 89.7% respectively.(Table:3) Area under curve based on Receiver Operator Characteristic (AUC-ROC) curve was observed to be 0.62 (95% CI: 0.55-0.69) (p=0.001). Although there were only 21 new patients with diabetes, but considering only those with non-diabetics, CBAC score had AUC-ROC of 0.68 (95.0% CI: 0.56-0.80). AUC of >0.90 was observed at high cut-off score of 9, and CBAC has a maximum score of 10. Logistic regression analysis observed significant for age, physical activity, and family history of DM with 67.1% predictive capacity. Analysis limited for new cases with diabetes observed only age and family history of diabetes as a significant subset with 85.8% predictive capacity. (Table: 4)

Table 3: Internal validation of CBAC for patients with diabetes and non-diabetes, 2016 in a tertiary care settings of Himachal Pradesh, India.

Validation Criteria	Value (%)
Sensitivity	42.9
Specificity	87.5
Positive Predictive Value	37.5
Negative Predictive Value	89.7

Discussion:

Application of CBAC as a screening tool with an adopted cut-off score of ≥4 for DM observed with a very low sensitivity and high specificity. The predictive and discriminatory ability found to be sub-optimal. Screening tool for diseases needs to be validated in the target population before subjecting to its use as it has direct implications for program logistics.[7] In a resource limited settings, use of basic risk assessment tools and blood sugar assessment has a potential to improve the feasibility of DM screening Programs.[8] CBAC included age,

Table 4: Distribution of overall and subset score among patients with diabetes (120) and non-diabetes (120), in a tertiary care settings of Himachal Pradesh, India, 2016.

	All diabetics (120)			New diabetics (21)		
Variable	B	P value	OR (95% CI)	B	P value	OR (95% CI)
Constant	3.870	0.006	47.94	1.028	0.662	
Age	-0.060	0.000	0.94 (0.91-0.96)	-0.034	0.099	0.96 (0.92-1.00)
Waist	-0.013	0.251	0.98 (0.96-1.00)	0.006	0.777	1.00 (0.96-1.04)
Physical activity	-0.017	0.007	0.98 (0.97-0.99)	-0.007	0.474	0.99 (0.97-1.01)
Smoking	-0.742	0.083	0.47 (0.20-1.10)	0.415	0.488	1.51 (0.46-4.89)
Alcohol	0.480	0.403	1.61 (0.52-4.97)	0.602	0.458	1.82 (0.37-8.95)
Family history	1.267	0.001	3.55 (1.64-7.66)	1.72	0.003	5.59 (1.79-17.47)

-2 Log Likelihood: 286.57; Cox-Snell R^2: 0.17 -2 Log Likelihood: 104.73; Cox-Snell R^2: 0.09

smoking, daily consumption of alcohol, weekly physical activity, family history of DM, and waist circumference which are known risk factors for diabetes.[2] Obesity, sedentary lifestyle, age, ethnicity, weight, first degree relatives with type-2 DM and low birth weight are risk factors for type-2 DM and their inclusion has been recommended for development of risk assessment tool, once validated.[8] Validation exercise of a tool helps to standardize the set of questions and their scoring mechanism. Literature review did not suggest evidence for the development, administration and validation of CBAC tool, so present exercise is a maiden attempt to assess its validity. Review of program guidelines did not observe rationale for the number and scoring of CBAC subsets/questions.[3]

It is correct that the laboratory assessment for blood glucose and HbA1c is required for diagnosis of type-2 DM but evidence observed that even rate of annual testing in community is rarely attained and requires assistance.[10] It has become a justification for development of questionnaire based risk assessment tools, which are feasible and can be effectively implemented in community in order to improve laboratory testing for DM. Measure like a self report of risk factors like BMI and cardiovascular disease are observed to a quite useful in predicting the undiagnosed type-2 DM.[11] It has been suggested that screening tool should be simple and comprise of a limited set of variables without an invasive test.[12,13] CBAC has been developed as a simplified tool considering its implementation feasibility and effectiveness at village level in Indian contextual settings. Although present evidence does not support current form CBAC as a valid screening tool for detection of undiagnosed diabetes. Age, physical activity and family history of DM found as significant subsets for discrimination, though it observed to be poor. The current tool needs to be revisited for its scoring mechanism so that its discriminatory ability can be improved. Questions can be quantified like, number of cigarettes per day, current or former smoker, the presence of co-morbid conditions, number of family members with DM. It expects to improve the discriminatory ability of CBAC. Information about alcohol may not be required as evidence suggested that alcohol has no added discriminatory ability for risk prediction of DM.[14,15]

Preset study has a methodological limitation mainly selection bias, as it was a cross sectional study and all patients with diabetes were included irrespective to duration of disease, which could have underestimated parameter estimates. Also, inclusion of only newly detected patients with FBG $\geq$126 mg/dl could observe with correctly observed estimates as the AUC ROC curve observed an improvement once the analysis was done for newly detected diabetics and non-diabetics.

Current evidence does not support the use of CBAC to screen DM and requires inclusion of more sensitive and specific subsets to improve its accuracy. In its present form, age observed as only subset which scored high and the rest were comparatively low in both patients with and without diabetes. There was an insignificant difference between smoking and alcohol use in both the groups, though amount of daily exercise and mean age was high among diabetics. Despite regular exercise the waist circumference was observed to be more among diabetics as compared to non-diabetics. The FBG blood tests were collected after the CBAC assessment and categorization of diseased and non-diseased was done later that eliminated review bias. Present study also intends to avoid verification and selection bias as patients without diabetes were excluded based on FBG value using the same machine which was calibrated periodically. There is no probability of inter-observer bias as CBAC questions were easy and simple and all the data were collected by the same interviewer.

Conclusion:

Validity assessment of CBAC observed with a poor discriminatory capacity for DM. It can be recommended as a community based screening tool only after revision and repeat assessment for validity.

Conflict of Interest: None

Source of support::None

References:

1. National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) [Internet] Available from: http://nrhm.gov.in/images/pdf/NPCDCS.pdf (Accessed on 10.01.2017)
2. *Venkat Narayan KM, Zhang P, Kanaya AM, Williams DE, Engelgau MM, Imperatore G, Ramachandran A. Diabetes: The Pandemic and potential solutions. In: Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, Jha P, et al. Disease Control Priorities in Developing Countries. 2nd ed. New York. USA. Oxford University Press; 2006 pp:* 596-9.
3. Government of India. National Health Mission. Operational Guidelines. Prevention, Screening and Control of Common Non-Communicable Diseases: Hypertension, Diabetes and Common Cancers (Oral, Breast, Cervix). New Delhi; 2016
4. Zaidi M, Waseem HF, Ansari FM, Irfan M, Fahim S. Sample size estimation of diagnostic test in health sciences. Proceedings of 14th International conference on Statistical Sciences; 2016; Karachi, Pakistan.P. 239-46. [Available from: https://www.researchgate.net/publication/ 303897592_sample_size_estimation_of_diagnostic_test_studies_in_health_sciences (Accessed on 13.02.2017)]
5. Erba Mannheim. Transasia. Fully Automated Biochemistry Analyzer. Company Identification Number (CIN)U33110MH1985PLC036198. Mumbai. India
6. Hosmer DW, Lemeshow S. Assessing the fit of the model. In: Hosmer DW, Lemeshow S., *eds*. Applied logistic regression. 2nd edn New York: John Wiley & Sons, 2000:143–202.
7. *Buijsse B, Simmons RK, Griffin SJ, Schulze M.* Risk assessment tools for identifying individuals at risk of

developing type 2 diabetes. *Epidemiol Rev. 2011; 33: 46-62.*

8. West C, Ploth D, Fonner V, Mbwambo J, Fredrick F, Sweat M. Developing a Screening Algorithm for Type II Diabetes Mellitus in the Resource-Limited Setting of Rural Tanzania. Am J Med Sci 2016;351(4):408-15.
9. Savill P. Identifying patients at risk of type 2 diabetes. Practitioner 2012;256(1753):25-7.
10. Paul CL, Ishiguchi P, D'Este CA, Shaw JE, Sanson-Fisher RW, Forshaw K, et al. Testing for type 2 diabetes in Indigenous Australians: guideline recommendations and current practice. Med J Aust 2017;207(5):206-210.
11. Heltberg A, Andersen JS, Sandholdt H, Siersma V, Kragstrup J, Ellervik C. Predictors of undiagnosed prevalent type 2 diabetes - The Danish General Suburban Population Study. Prim Care Diabetes 2017 pii: S1751-9918(17)30140-7.
12. Noble D, Mathur R, Dent T, Meads C. Risk models and scores for type 2 diabetes: systematic review. BMJ 2011;343:1–31.
13. *Abbasi A, Peelen LM, Corpeleijn E, van der Schouw YT, Stolk RP, Spijkerman AM, van der A DL, Moons KG, Navis G, Bakker SJ, Beulens JW.* Prediction models for risk of developing type 2 diabetes: systematic literature search and independent external validation study. *BMJ. 201218; 345:e5900.*
14. *Mühlenbruch K, Joost HG, Boeing H, Schulze MB, Nuthetal. Risk prediction for type 2 diabetes in the German population with the updated German Diabetes Risk Score (GDRS). Ernaehrungs Umschau international 2014;6:90-3.*
15. Paprott R, Mühlenbruch K, Mensink GB, Thiele S, Schulze MB, Scheidt-Nave C, et al. Validation of the German Diabetes Risk Score among the general adult population: findings from the German Health Interview and Examination Surveys. BMJ Open Diabetes Res Care 2016; 4(1): e000280.

How to cite this article: Kumar D , Kalia R, Sharma SB, Raina SK. Validation of Community Based Assessment Checklist for Diabetes Mellitus in tertiary care setting, Himachal Pradesh, India. J Comprehensive Health.2019;7(1):14-18.