A Decision Rule for Diagnostic Testing in Obstructive Sleep Apnea

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Obstructive sleep apnea (OSA) is traditionally diagnosed using overnight polysomnography. Decision rules may provide an alternative to polysomnography. A consecutive series of patients referred to a tertiary sleep center underwent prospective evaluation with the upper airway physical examination protocol, followed by determination of the respiratory disturbance index using a portable monitor. Seventy-five patients were evaluated with the upper airway physical examination protocol. Historic predictors included age, snoring, witnessed apneas, and hypertension. Physical examination–based predictors included body mass index, neck circumference, mandibular protrusion, thyro–rami distance, sterno–mental distance, sterno–mental displacement, thyro–mental displacement, cricomental space, pharyngeal grade, Sampsoon-Young classification, and overbite. A decision rule was developed using three predictors: a cricomental space of 1.5 cm or less, a pharyngeal grade of more than II, and the presence of overbite. In patients with all three predictors (17%), the decision rule had a positive predictive value of 95% (95% confidence interval [CI], 75–100%) and a negative predictive value of 49% (95% CI, 35–63%). A cricomental space of more than 1.5 cm (27% of patients) excluded OSA (negative predictive value of 100%, 95% CI, 75–100%). Comparable performance was obtained in a validation sample of 50 patients referred for diagnostic testing. This decision rule provides a simple, reliable, and accurate method of identifying a subset patients with, and perhaps more importantly, without OSA.

Keywords: obstructive sleep apnea; decision rule; diagnostic testing; physical examination

Obstructive sleep apnea (OSA) occurs in 2% and 4% of middle-aged women and men, respectively (1). Traditionally, OSA has been diagnosed using overnight polysomnography (PSG), which is costly in terms of personnel, time, and money. Decision rules are sets of prospectively validated criteria that predict a clinical outcome, thus facilitating clinical decision-making. They are appealing as diagnostic instruments because of their low cost.

Flemons and colleagues randomly selected a series of 180 patients referred to a tertiary sleep center (2). Increased neck circumference, hypertension, habitual snoring, and reports of nocturnal gasping/choking were predictive of OSA (PSG-apnea–hypopnea index of 10 hour^{-1} or more) using logistic regression modeling. Individuals with the highest clinical score (i.e., all four characteristics) had a likelihood ratio and post-test probability of OSA (apnea–hypopnea index of 10 hour^{-1} or more) of 5.17% and 81%, respectively. In contrast, patients with the lowest clinical score had a likelihood ratio of 0.25 and a post-test probability of OSA of 17%.

A morphometric model developed by Kushida and colleagues had an OSA diagnostic sensitivity and specificity of 98% and 100%, respectively; however, selection bias was a potential concern (3). Nevertheless, the model illustrated the potential value of physical examination–based decision rules in clinical decision-making.

Current decision rules have only intermediate diagnostic characteristics and are frequently too cumbersome, either arithmetically or logistically, for bedside implementation (2, 4–10). The objective of this study was to develop a standardized approach toward patient assessment in the OSA setting, with a specific emphasis on ease of use for the bedside clinician. Predictors of OSA were identified, and a decision rule was developed.

METHODS

Subjects were recruited from the Alberta Lung Association Sleep Centre (ALASC), which is the major sleep center in Southern Alberta. Referrals to the sleep center were assigned to one of four sleep physicians on a consecutive basis; that is, there was no systematic physician–patient allocation. The two physicians (W.H.T. and J.E.R.) participating in this study managed approximately 40% of patients seen at the center. All referrals not meeting exclusion criteria were eligible for study.

Exclusion criteria consisted of a refusal to undergo diagnostic testing, a previous assessment for a primary sleep disorder, insomnia, or a referral for a sleep disorder other than OSA. The diagnostic criteria for insomnia and other sleep disorders are standardized in the International Classification of Sleep Disorders (11).

The study was divided into three distinct phases: feasibility, model development, and validation. The Conjoint Ethics Committee of the University of Calgary approved the protocol, and all patients provided informed consent.

The selection of measurement variables was based on expert opinion (J.E.R., W.H.T., and J.M.D.) and upper airway scoring systems described in the anesthesia literature (12–15). Also included were known clinical predictors of OSA: hypertension, habitual snoring, nocturnal choking/gasping, witnessed apneas, age, alcohol use, and smoking history (2, 4–10). Clinical history was obtained by self-report or from the subject's bed partner.

During the feasibility phase, patients underwent routine clinical assessment plus the upper airway physical examination protocol (UAPP), performed by two investigators (W.H.T. and J.E.R.). Unreliable or time-consuming measurements were eliminated from the UAPP based on a consensus view (W.H.T., J.E.R., and J.M.D.).

During the subsequent model development phase, patients underwent a structured physical examination using the reduced UAPP, followed by assessment of the respiratory disturbance index (RDI) using a portable monitor. This portable monitor has been described previously and has excellent correlation and agreement with PSG (16). Data were collected prospectively, and a decision rule was developed using multiple logistic regression. The final predictive model was validated in a consecutive sample of all patients undergoing portable monitor-based testing at the ALASC.

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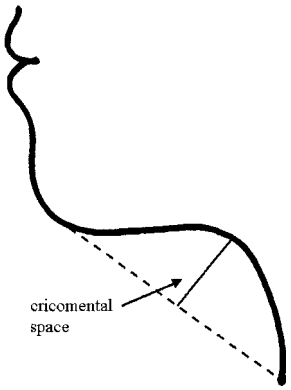

Figure 1. Assessment of the cricomental space. Use a thin ruler to connect the cricoid cartilage to the inner mentum. The cricomental line is bisected, and the perpendicular distance to the skin of the neck is measured.

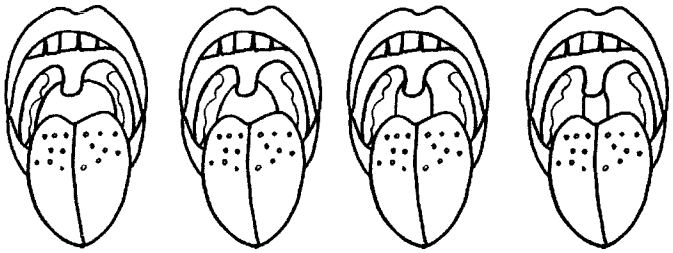

Figure 2. Pharyngeal grading system. Class I = palatopharyngeal arch intersects at the edge of the tongue. Class II = palatopharyngeal arch intersects at 25% or more of the tongue diameter. Class III = palatopharyngeal arch intersects at 50% or more of the tongue diameter. Class IV = palatopharyngeal arch intersects at 75% or more of the tongue diameter.

Portable Monitoring

OSA was defined by an RDI determined using a portable monitor. The monitor characteristics have been described in a previous article (16). Briefly, it samples nocturnal oxygen saturation, snoring, and body position. Using an automated algorithm that analyzes and scores the oximetry signal, an RDI is calculated. The monitor is used extensively at the ALASC as a screening tool for OSA.

This monitor has been validated in a previous study and demonstrates excellent agreement with PSG (ΔRDI [PSG − monitor] = 2.18 ± 12.34 [SE] hour^{-1}). The sensitivity and specificity for OSA were 98% and 88%, respectively.

UAPP

The UAPP is a structured physical examination protocol consisting of mandibular measurements, assessment of the facial profile, general profile (cricomental space, neck circumference), pharyngeal space (pharyngeal grade, tonsillar enlargement, palatal elevation), and head movement. "Mandibular" measurements consisted of maximum mandibular advancement, mandibular length, thyro–mental, sterno–mental, temporal mandibular joint–ramus, ramus–ramus, thyro–rami, and mastoid–medial clavicle distance. Distances were determined by taking the linear distance between two bony points using a measuring tape. Thyro measurements were taken from the thyroid notch. Mental measurements were taken from the posterior aspect of the inner mentum. Sternal measurements were taken from the sternal notch. Mandibular length refers to the distance between the posterior ramus and the inner mentum. Displacement was the difference between a measurement taken with the neck in the neutral position versus full extension.

The facial profile was categorized as retrognathic, neutral, or prognathic. To classify a profile, an imaginary line was created, joining the brow and maxilla. If the anterior chin was behind the line, retrognathia was said to exist. If the chin lay in front of the line, prognathia was present.

The cricomental space was determined using a thin ruler to connect the cricoid cartilage to the inner mentum, with the head in the neutral position. The cricomental line was bisected, and the perpendicular distance to the skin of the neck was measured (Figure 1). The use of a thin ruler (1 mm or less) was considered essential because thicker devices (e.g., tongue depressors) might influence measurement. The pharyngeal space (pharyngeal grade) was assessed using a four-point ordinal scale and is graphically presented in Figure 2.

Palatal position or tongue size was assessed using the Sampsoon-Young classification system (12): grade 1 = good visualization of the soft palate, fauces, uvula, and tonsillar pillars; grade 2 = pillars obscured by the base of the tongue, but posterior pharyngeal wall clearly visible below the soft palate; grade 3 = soft palate and base of uvula visible; and grade 4 = soft palate not visible.

Tonsillar enlargement (tonsillar grade) was assessed using a four-point ordinal scale: class I = tonsils absent; class II = tonsils do not extend beyond the palatopharyngeal arch; class III = tonsils at the palatopharyngeal arch; and class IV = tonsils extend beyond the palatopharyngeal arch.

Statistics

OSA predictors were identified by simple logistic regression, using a diagnosis of OSA (RDI of 10 hour^{-1} or more) as the dependent variable. The final predictive model was developed using a "significant p" approach, that is, automated stepwise reduction on a full model consisting of variables identified as predictive by simple logistic regression. A significance level of $p = 0.1$ was set for item elimination. Continuous variables identified as predictive in the parsimonious model were cross-tabulated against a diagnosis of OSA, and binary cut points were visually selected. All independent predictors were thus modeled as dichotomous variables.

A decision rule was created using the binary predictors derived from the reduced logistic regression model. Sensitivity, specificity, and positive and negative predictive values were then determined. Statistical analysis was performed using Stata 5.0 (Stata Corporation, College Station, TX).

Sample Size Determination

Sample size determination is difficult when using logistic regression models, and each technique has its own set of limitations. Sample size calculations were based on a minimum event per variable model. Freedman and Pee have demonstrated a significant increase in type I error when the event per variable is less than 4 (17). Based on the use of 15 variables and an event per variable of four or more, approximately 60 events were required (i.e., 60 patients diagnosed with OSA). Alternatively, Hsieh derived sample size tables based on the use of the Whittemore formula (18). Based on the results of Monte Carlo simulations, they determined that the tables do not explicitly require knowledge of the number of covariates in the regression model. Assuming the probability of OSA in the study population is 0.5, to detect an odds ratio of 3.0 for an individual 1 SD above the mean using a one-tailed test with a significance level of 5% and a power of 80%, we would require 62 patients.

RESULTS

Feasibility Phase

Twenty consecutive patients were assessed using the UAPP. Because the UAPP had to be acceptable to bedside clinicians, items were removed based on a consensus (W.H.T., J.E.R., and J.M.D.) impression of unreliability or excessive complexity.

The reduced UAPP was then used for decision rule development. Physical examination measurements included mandibular length, thyro–rami distance, mastoid–medial clavicle distance, temporal mandibular joint–rami distance, rami–rami distance, thyro–mental distance, thyro–mental displacement, sternal–mental distance, sterno–mental displacement, inter–incisor distance, cricomental space, mandibular advancement, facial profile, pharyngeal class, Sampsoon-Young classification, and the presence of overbite.

TABLE 1. SUMMARY OF PATIENT CHARACTERISTICS

Patient Characteristic	N (%)	Mean	SD	Range
Age		47.5	11.53	26–74
Sex, M/F				75%/25%
Body mass index		33.1	6.95	19–51
Neck circumference, cm		42.1	4.81	30–58
Epworth sleepiness scale		11.7	5.39	0–22
Respiratory disturbance index, hour^{-1}		29.96	34.28	0–138

Definition of abbreviations: F = female; M = male.
n = 75.

Model Development Phase

A total of 99 patients were evaluated, with 75 patients eligible for study. Of the 24 excluded patients, 14 met the International Classification of Sleep Disorders criteria for insomnia and did not undergo further diagnostic testing. Ten patients proceeded directly to PSG because of symptoms suggestive of a primary sleep disorder other than OSA: restless leg syndrome/periodic leg movement syndrome (n = 6), idiopathic hypersomnolence (n = 2), severe chronic obstructive pulmonary disease (n = 1), and narcolepsy (n = 1). None of the excluded patients who underwent PSG had a diagnosis of OSA.

The prevalence of OSA among the 99 patients was 61%, 48%, 43%, or 33%, depending on whether an RDI diagnostic criterion value of greater than 5, 10, 15, or 20 hour^{-1} was employed. Clinical characteristics are presented in Table 1. More detailed clinical characterization and physical examination findings are summarized in Tables E1 and E2 of the online supplement.

Univariate Predictors of OSA

Univariate predictors of OSA were identified by simple logistic regression using clinical and physical examination features as independent variables and OSA (RDI of 10 hour^{-1} or more) as the dependent variable. The univariate predictors of OSA were age, snoring history, witnessed apneas, and hypertension (Table 2). The physical examination measurements predictive of OSA were body mass index, neck circumference, mandibular length, thyro–ramus distance, thyro–mental displacement, sterno–mental displacement, cricomental space, pharyngeal grade, Sampsoon-Young class, and overbite.

No new predictive variables were identified when the data were independently analyzed using an RDI diagnostic criterion value of greater than 15 hour^{-1} to define OSA.

Model Development

A "significant p" model identified three predictive variables: cricomental space, pharyngeal grade, and overbite. No significant difference was observed between the reduced model and the model containing all "significant" univariate predictors ($p = 0.14$, LR test with degrees of freedom = 7). Identical results were obtained when an RDI of 15 hour^{-1} or more was used to define OSA.

Cricomental space and pharyngeal grade were continuous variables. To obtain binary cut points, these measurements were cross-tabulated against a diagnosis of OSA, and optimal cut points were visually selected. A cricomental space of more than 1.5 cm and a pharyngeal grade of more than II were chosen.

Diagnostic Performance of the Decision Rule

A cricomental space of 1.5 cm or less, a pharyngeal grade of more than II, and overbite was highly predictive of OSA: a positive predictive value of 95% (95% confidence interval [CI],

TABLE 2. UNIVARIATE OBSTRUCTIVE SLEEP APNEA PREDICTORS (USING AN RDI CUTOFF VALUE OF 10 HOUR^{-1})

Variable	Odds Ratio	p Value	95% Confidence Interval
Age, years	1.10	0.001	1.03, 1.16
Epworth sleepiness scale	1.03	0.558	0.93, 1.13
Snoring history	12.5	0.023	1.42, 110.6
Choking episodes	2.02	0.169	0.74, 5.49
Witnessed apneas	3.37	0.016	1.25, 9.06
Hypertension	10.3	0.029	1.27, 83.9
Alcohol use	1.20	0.658	0.53, 2.74
Smoker	1.28	0.482	0.64, 2.56
Body mass index, kg/m^2	1.13	0.009	1.03, 1.24
Neck circumference, cm	1.36	0.000	1.15, 1.61
Mandibular advancement, cm	0.69	0.107	0.43, 1.08
Mandibular length, cm	1.83	0.005	1.20, 2.79
Thyro–rami distance, cm	1.59	0.020	1.07, 2.35
Mastoid–medial clavicle, cm	1.25	0.129	0.94, 1.65
TMJ–ramus distance, cm	1.39	0.164	0.88, 2.19
Ramus–ramus distance, cm	0.97	0.891	0.67, 1.42
Thyro–mental, neutral, cm	1.23	0.359	0.79, 1.90
Thyro–mental displacement, cm	0.59	0.059	0.35, 1.02
Sterno–mental, neutral, cm	0.86	0.180	0.68, 1.07
Sterno–mental displacement, cm	0.75	0.041	0.57, 0.99
Retrognathia	0.89	0.706	0.48, 1.65
Cricomental space, cm	0.15	0.000	0.06, 0.38
Tonsillar grade, I–IV	0.85	0.415	0.57, 1.26
Pharyngeal grade, I–IV	1.52	0.046	1.01, 2.30
Sampsoon-Young class, I–IV	1.77	0.018	1.10, 2.86
Palatal elevation	1.41	0.303	0.73, 2.71
Inter–incisor distance, cm	0.86	0.673	0.44, 1.71
Overbite	2.19	0.044	1.02, 4.70

Definition of abbreviation: TMJ = temporal mandibular joint.

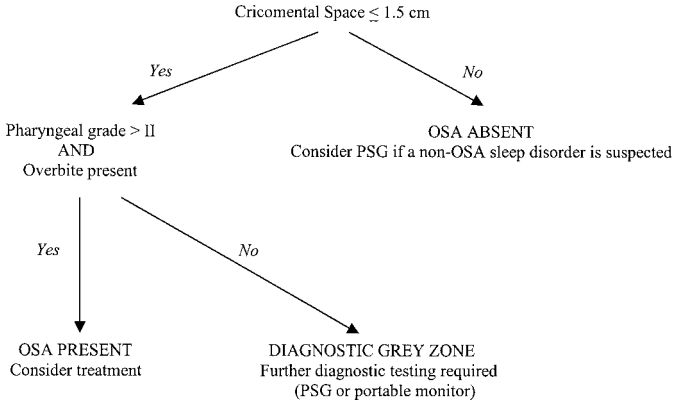

Figure 3. A decision rule for diagnostic testing in OSA.

75–100%) at an RDI cutoff value of 10 hour^{-1}. However, the absence of all three conditions did not exclude OSA: a negative predictive value of 49% (95% CI, 35–63%). In contrast, a cricomental space of more than 1.5 cm effectively excluded the possibility of OSA: a negative predictive value of 100% (95% CI, 75–100%). In total, 13 patients had a cricomental space of more than 1.5 cm, and 20 patients had all three conditions; therefore, 67% of patients could not be classified and fell into a diagnostic "gray" zone. The diagnostic performance of the decision rule (Figure 3) at a variety of RDI diagnostic criterion values is summarized in Table 3.

Reliability

Twenty patients underwent two independent assessments using the UAPP predictive variables, and agreement was determined: cricomental space of more than 1.5 cm ($\kappa = 1.0$), the presence of overbite ($\kappa = 0.61$), the presence of retrognathia ($\kappa = 0.22$), tonsil enlargement ($\kappa = 0.73$), pharyngeal narrowing (pharyngeal grade of more than II, $\kappa = 0.78$), and thyro–mental displacement ($\kappa = 0.58$). The inter-rater agreement was high for all variables (κ coefficient range: 0.58–1.00) except retrognathia ($\kappa = 0.22$).

Validation Sample

Fifty consecutive patients, referred to the ALA Sleep Centre for portable monitoring, were assessed using the UAPP predictive variables before diagnostic testing. The diagnostic performance of the three-variable model was similar to that observed in the model development cohort: a positive predictive value of 100% (95% CI, 63–100%) at an RDI cutoff value of 10 hour^{-1}. A cricomental space of more than 1.5 cm effectively eliminated the likelihood of OSA: negative predictive value of 100% (95% CI, 63–100%).

DISCUSSION

In a consecutive series of 75 patients referred to a tertiary sleep center, a number of predictors of OSA were identified. This study confirms the results of previous investigators by identifying age, snoring history, witnessed apneas, hypertension, body mass index, and neck circumference as predictive of OSA. A number of physical examination–based predictors were also identified, and a decision rule was subsequently developed: a cricomental space of 1.5 cm or less, a pharyngeal grade of more than 2, and the presence of overbite. In patients with all three predictors, the decision rule had a positive predictive value, 95% (95% CI, 75–100%); negative predictive value, 49% (95% CI, 35–63%); sensitivity, 40% (95% CI, 27–56%); and specificity, 96% (95% CI, 82–100%). A cricomental space or more than 1.5 cm excluded the possibility of OSA (negative predictive value of 100% [95% CI, 75–100%]). Comparable performance was obtained in a validation sample of 50 patients referred for diagnostic testing. The interrater reliability of UAPP measurement variables was high ($\kappa = 0.58$–1.00), other than for retrognathia.

It was not possible to identify any single combination of variables that simultaneously had a high sensitivity and specificity for OSA. However, the use of a three-variable model to rule in a diagnosis of OSA and a cricomental space or more than 1.5 cm to exclude OSA holds considerable promise. Patients with a cricomental space of more than 1.5 cm or those meeting all criteria of the three-variable model accounted for 17% and 27% of the study population, respectively. Clearly, most (approximately 60%) patients fell into a diagnostic gray zone. Although this might appear to be a seemingly high number of nondiagnostic assessments, because of the high cost of diagnostic testing, if even a subset of patients either avoid diagnostic testing or are referred directly for initiation of CPAP therapy, important economic gains may be realized.

A diagnostic instrument need not have a simultaneously high sensitivity and specificity to be of clinical value. For example,

TABLE 3. DIAGNOSTIC PERFORMANCE OF THE DECISION RULE AT A VARIETY OF RESPIRATORY DISTURBANCE INDEX DIAGNOSTIC CRITERION VALUES

OSA Diagnostic Criterion Value	n (%)	Cricomental Space of More Than 1.5 cm (*n = 13*)			
		Sensitivity	Specificity	PPV	NPV
RDI of 5 hour^{-1} or more	61 (81%)	90 (80–96)	50 (23–77)	89 (78–95)	54 (25–80)
RDI of 10 hour^{-1} or more	47 (63%)	100 (92–100)	46 (26–66)	76 (63–86)	100 (75–100)
RDI of 15 hour^{-1} or more	43 (57%)	100 (92–100)	41 (24–59)	69 (56–80)	100 (75–100)
RDI of 20 hour^{-1} or more	33 (44%)	100 (89–100)	31 (18–47)	53 (40–60)	100 (75–100)
		Three-Variable Model (*n = 20*)			
		Sensitivity	Specificity	PPV	NPV
RDI of 5 hour^{-1} or more	61 (81%)	33 (21–46)	100 (77–100)	100 (83–100)	25 (15–39)
RDI of 10 hour^{-1} or more	47 (63%)	40 (27–56)	96 (82–100)	95 (75–100)	49 (35–63)
RDI of 15 hour^{-1} or more	43 (57%)	37 (23–53)	88 (71–96)	80 (56–94)	51 (37–65)
RDI of 20 hour^{-1} or more	33 (44%)	42 (26–61)	86 (71–95)	80 (56–94)	65 (51–78)

Definition of abbreviations: NPV = the negative predictive value of OSA if all three variables are not present; PPV = positive predictive value of OSA with all three variables present (cricomental space of 1.5 cm or less and pharyngeal grade of III or more, and overbite).

for diagnosing clinically significant ankle fractures, the Ottawa Ankle Rule has a specificity of only 50% but a sensitivity of 100%. Not all patients will meet the decision rule criteria, but in those who do, the need for an ankle radiograph can be eliminated. The Ottawa Ankle Rule has a diagnostic gray zone of approximately 70%, but in field testing, it is estimated that the rule has reduced the need for ankle radiography by 30% (19). Similarly, a cricomental space of more than 1.5 cm has been demonstrated to have a very high negative predictive value with respect to excluding patients with OSA.

Several physical examination features that have been presumed predictive of OSA were subjected to formal evaluation. The predictive value of pharyngeal grade, Sampsoon-Young class, and overbite supports the suspicion that pharyngeal narrowing, a low-lying palate, and overbite are associated with OSA. In contrast, despite the commonly held belief, retrognathia, tonsil size, and change in palatal elevation with phonation (change in Sampsoon-Young classification with phonation) were not predictive of OSA. Moreover, measurements such as retrognathia could not be reliably determined between investigators. A recent study by Schellenberg and colleagues supports these findings. After controlling for body mass index and neck circumference, only lateral narrowing of the pharyngeal walls were predictive of OSA. Low-lying palate, retrognathia, and overjet were not found to be predictive (20).

Although both clinical and physical examination–based predictors were incorporated into the initial regression model, only physical examination–based predictors formed the final decision rule. This suggests that for patients referred to a tertiary sleep center, the inclusion of clinical features adds minimal predictive value for diagnosing OSA beyond that of physical examination alone.

In a consecutive sample of 300 patients referred to the Stanford University Sleep Centre, Kushida and colleagues developed a physical examination–based prediction index with a sensitivity and specificity of 98% and 100%, respectively (3). Body mass index, neck circumference, and intermolar distance were identified as predictive variables. However, the prevalence of OSA was 85%, which is considerably higher than the approximately 50% prevalence rate observed at most sleep centers. More significantly, BMI had a diagnostic sensitivity and specificity of 93% and 74%, respectively.

Criticism could be raised with respect to the subject selection process in this study, particularly as the study population consisted only of patients referred to the study investigators. However, no systematic triaging of referrals existed, and the study prevalence of OSA (63% at an RDI of 10 hour^{-1} or more) was similar to the institutional prevalence reported in a previous study (16). Referral bias may exist; however, the ALASC is the only major referral site for sleep disorders in Southern Alberta. Patients seen at the center range from highly specialized cases to uncomplicated snorers. Moreover, the diagnostic performance of the decision rule in the model development and validation samples was virtually identical.

As with most studies evaluating OSA, the choice of instrument and the criteria used to determine RDI could come under criticism. Redline and colleagues have clearly demonstrated that the choice of RDI definition can contribute to substantial variability in the identification of the disorder (21). Similarly, the choice of RDI diagnostic cutoff value may also influence the prevalence of disease. Until there is methodologic standardization of RDI determination and diagnostic cutoff values, this will be difficult to address. However, we attempted to deal with this issue by providing decision rule performance characteristics at a variety of cutoff values.

A key feature of this decision rule is its ease of implementation. From a practical standpoint, a decision rule is only of value if it is adopted into routine clinical practice. To achieve widespread acceptability, a decision rule must be easy to interpret and executable without extraneous equipment or complex mathematic algorithms. This decision rule makes use of only three clinical predictors, all of which can be assessed with no more than a ruler. Measurements are categorical so as to avoid the need for arithmetic calculations. Its simplicity may derive from the ability to combine several independently predictive variables into a single measurement. Specifically, the cricomental space is a novel multidimensional measurement that probably incorporates diverse characteristics such as neck circumference, body mass index, hyoid bone position, neck posture, mandibular positioning, and possibly pharyngeal length.

However, the decision rule requires prospective evaluation in different settings, specifically, at the primary care level. This decision rule is likely to have the largest clinical impact in settings where other sleep disorders are not under consideration (i.e., no further testing is necessary once OSA is excluded).

Conclusion

In a subset of patients, this decision rule provides a simple, reliable, and highly accurate method of identifying patients with and without OSA. Its validity in the primary care setting remains to be determined.

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