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Guidelines for reporting diagnostic accuracy studies of Siddha anthropometric tool Manikkadai Nool

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Abstract---Background: Manikkadai-Nool (MK) is an ancient Siddha treatise of Anthropometric based predictions very much acclaimed for its diagnostic value in clinical practice. A well-set protocol is lacking for the methodology, limiting its expected outcome of predictive values. Moreover, the systematic approach of case reporting pertaining to its diagnostic accuracy studies (DAS) is showing many pitfalls. This purposes the induction of guidelines particular to MK that covers the entire aspects of case reporting. Materials and Methods: Available case reporting guidelines for Diagnostic studies (STARD guidelines) were overlooked to develop the core elements for DAS with 9 sections including 24 items. Discussion: The enlisted 24 items of Siddha Anthropometric Tool (SAT) guidelines have been depicted with examples that enable physicians and researchers to accomplish clinical reporting based on MK with much ease and accuracy. The guidelines may help peer reviewers for evaluating the concerning studies. Conclusion: SAT guidelines improve the quality of studies pertaining to MK that imprints the lead for further scientific acceptance. Further periodical up-gradation is warranted.

Keywords---diagnostic accuracy studies, Siddha anthropometric tool, SAT guidelines, prototype.

Introduction

Manikkadai-Nool (MK) is an exclusive Anthropometric method mentioned in Siddha literature that is purposed for disease or symptom prediction founded on readings based on Antebrachial circumference (ABC), and Finger Breadths (FB)(Kanthamsi mudaliyar, 1975; M.Shanmughavelu, 2006).The diagnostic accuracy of the method has been explored in many of the previous attempts with varying degrees of methodological deficits. Improper study design, data collection, and statistical interpretation resulted in indecisive assumptions.(Saravanan & Nair, 2018; Vinayak S et al., 2019; Yazhini & Sakthinathan, 2018). The validity of the method in terms of sensitivity and diagnostic accuracy has not been justified to date. The risk of bias generation is yet another setback that affects the overall outcome of the predictions. The existing conventional methodology is lacking a systematic approach as it misses important elements for reporting case studies pertaining to MK evaluation. Hence the Siddha Anthropometric Tool (SAT) guidelines were developed to improve the reporting of diagnostic accuracy studies pertaining to MK. The core elements of the theme were inspired from the updated STARD (guidelines 2015) for diagnostic studies.(Bossuyt et al., 2015; Cohen et al., 2016).

Materials and Methods

A total of 24 essential items under 8 main sections are included in SAT guidelines to mark the initial version. (Table.1) Each of the items was described with examples for easy understanding and thus may assist the researchers, and physicians to report diagnostic cases systematically for documentation and publications. The checklist of the guidelines further helps expert peer reviewers concerned with the subject of interest for scrutiny.

Table.1 SAT Guidelines (V1) – Protocol contents for Research and publication

S.no	Section	Subsection	NO	Prototype
1.	Title		1	Study of diagnostic accuracy of MK using the measure of accuracy (sensitivity, or diagnostic effectiveness) Diagnostic effectiveness / accuracy / sensitivity / clinical validation of Siddha Anthropometric method / Tool / approach – Manikkadai Nool for diagnosing [target disease (specific) or general conditions]
2.	Trial registry		2	Mandatory for a study involving >10 cases], excluded for case reports, and series Type: observational and diagnostic
3.	Abstract		3	The abstract should be well structured with contents like the

		background of the research question, study design, methodology, results, discussion, conclusion	
4.	Introduction	4	Introduction about the Target disease > how it is diagnosed> using diagnostic Tool of Siddha medicine>previous work done or not> Research question> Study hypothesis> study objectives> proposed study setting
	<i>Research question</i>	4a	Manikkadai measurements are effective for predicting Erigunmam cases (gastritis) in subjects established with OG endoscopy
	<i>Study hypothesis</i>	4b	Whether Manikkadai measurements are effective for predicting Erigunmam cases (gastritis) in subjects established with OG endoscopy
	<i>The expected outcome of the study</i>	4c	Evaluation of Diagnostic effectiveness (in %), and sensitivity of the diagnostic tool (in %)
	<i>Study objectives</i>	4d	To evaluate the Diagnostic effectiveness / accuracy / sensitivity / clinical validation of Siddha Anthropometric method / Tool / approach – Manikkadai Nool in patients/ study participants with suspected [target disease (specific) or general conditions]
5.	Methodology	5	
	<i>Study design</i>	5a	Diagnostic Accuracy study (observation field study)
	<i>Index Test</i>	5b	Tool of study – Manikkadai readings Interpretation of specific prediction readings of MK obtained from the study participants or random reading
	<i>Standard Operating Procedure of Index Test</i>	5c	SOP for uniform reading reduces the chances of bias
	<i>Standard reference test / Reference standards</i>	5d	Established reference test for comparison/ authentication of the study case
			Reference Gold standard tests /interpretation of scales and grades of specific diseases will be used for comparison/confirmation of data

		<i>Study participants & Sample size with the flow diagram</i>	5e	collected Inclusion criteria for study recruitment includes [adults/men or women] with age [18-60 yrs/>18yrs] with suspected target [disease/condition] whom are presenting /based on clinical presentations.
		<i>Study setting</i>	5f	Of [n] of study participants recruited in the study, the provisional diagnosis of the Target disease (suspected) was confirmed in [y] and excluded in [x] based on the Index test and reference standards. Location of the intended research/study, date range
		<i>Type of sampling</i>	5g	Monocentric/ multicentric studies were conducted in outpatient /inpatient facilities of [private clinic/primary health centers/institutes/ Govt dispensary/hospital] Random/ convenience sampling methods may be adopted for recruiting the study participants
		<i>Collection of data</i>	5h	How data is collected from the study participants Before or after MK reading
		<i>Statistical analysis used in the study</i>	5i	Diagnostic effectiveness (in %), sensitivity (in %), Pearson correlation, frequency of distribution with graphical representations, bar graph, or pie chart
		<i>Interpretation of the results</i>	6 6a	Distribution of MK readings, baseline demographic details, obtained results of diagnostic accuracy, sensitivity.
6.	Results			
7.	Discussion		7	A general outline of the study, Purpose of the study, the overall expected outcome achieved through the present studies. The index test [MK] showed [high/low/insignificant] diagnostic effectiveness and sensitivity for detecting/predicting the target disease [define]
		<i>Limitations of</i>	7a	Area of research uncovered/limited

	<i>the study</i>		and the study gap, limitations faced, and challenges of potential bias that impacted the study.
	<i>Future implications of the study</i>	7b	MK could be used as a reliable standalone tool for [diagnosing/detecting/predicting] the target disease [define] or along with the other reference gold standard tests
8.	Conclusion	8	MK could be subjected to further study for confirming its accuracy and diagnostic effectiveness.

SAT Guidelines – Explanation of sections and subthemes

Title

The title should include the key contents:

- Type of study: Field observational/exploratory
- Index test: Tool to be validated, here its MK readings
- Target disease: if a specific disease is out looked
- Outcome expected: Clinical validation, diagnostic accuracy, or sensitivity
- Reference tests: existing standard tests for the establishment of findings of the reading
- Study population: Study participants targeted in the study
- Study setting: the proposed place of study

Egs.

1. General: An exploratory study to evaluate the diagnostic effectiveness/ accuracy of Siddha diagnostic tool -Manikkadai Nool among the patients attending the outpatient facilities of _____
2. General: Clinical validation of Soodamani Kayaru Soothiram, an ancient Siddha diagnostic method for predicting clinical conditions among the patients attending General OP of _____
3. Case typical: Validating the diagnostic effectiveness/ accuracy of Siddha diagnostic tool -Manikkadai Nool in patients established with Erigunmam (gastritis)- a prospective exploratory trial /study.
4. Single Case/case series follow-up study: Evaluating the diagnostic accuracy/sensitivity of Soodamani Kayaru Soothiram, an ancient Siddha diagnostic method in patients under constant follow-up selected from General OP of _____

E.g., 1 & 2 from section 1 specify a general study that reports how MK helps in predicting clinical conditions in patients randomly assigned from a health facility. The results may help the practitioner to validate the tool in terms of accuracy and sensitivity. Eg.3 evaluates a typical case (target disease- Erigunmam (gastritis) with MK readings. Here a prospective study is conducted in clinically established

cases of gastritis recruited from a health facility further to determine whether MK readings correlate with the particular FB specified for Gunmam. Diagnostic accuracy and sensitivity of MK in predicting the particular disease are measured here. Eg.4 specifies the diagnostic accuracy/sensitivity of the MK tool in selected study participants under constant follow-up. The progress variation in the diagnostic pattern of each individual with time could be elucidated with this study.

Trial registry

Clinical Trial Registry of India (CTRI)

The prospective registration of diagnostic accuracy studies is mandatory before recruiting the study participants. CTRI is an online free public record system for registering clinical trials. The details of the study are added to the data set for future references in the public domain including the status of the trial conducted. (*Trial Registration in CTRI | NATIONAL INSTITUTE OF MEDICAL STATISTICS*, n.d.). The registration impacts the quality of the research done in Manikkadai Nool. The type of study pertaining to MK includes observational and diagnostic accuracy studies.

Abstract

The abstract should focus on the systematic data presentation about the summary of the study that includes study design, methodology, results, conclusion, and future implications of the work.

Introduction

This includes the background of the Index test to be evaluated i.e., MK diagnosis, the rationale of the research that highlights the pitfalls in existing research studies, expected outcome of the research, and the intended work. Whether the tool MK assists in diagnosis, predictions that open up a clinical space for further treatment selection are explained. If the MK tool is evaluated based on the findings of a modern test or an already existing established traditional method like Nadi is to be answered in detail. Adding up a standard test for the readings improves the authenticity of the findings. (Reitsma et al., 2009)

Research Question

A well-formulated Research question (RQ) is generated as it defines the objective of the study aimed either for finding its diagnostic accuracy or validating the tool. The components of the RQ include the detail of (1). Study participants/subjects. (2). Intervention (Manikkadai measurements). (3). Comparator /standard diagnostic reference (gold standard tests, imaging, serological investigations, clinical criteria) and (4). Outcome (Prediction accuracy, sensitivity). (Moons, 1996)

E.g., for the title “*Clinical validation of Manikkadai measurement for the prediction of Gunmam established with OG endoscopy, among the study participants enrolled from the OP Unit of Govt. Siddha Dispensary, Thiruvananthapuram, Kerala*”.

The RQ should be whether Manikkadai measurements are effective for predicting Gunmam cases in patients established with OG endoscopy.

- Here the standard test for gastritis is OG endoscopy which affirms the presence of the condition in study participants.
- The success of the reading is based on whether that particular Gunmam FB reading is shown by the study participant affirmed by the results from OG endoscopy or other reliable standards. In such cases, it may be considered that it could stand equal to the standard test for predicting the condition.
- It is wise if the RQ is generated to a specific condition from the reading has got the scope in modern diagnosis.
- As Gunmam is a general term that is inclusive to the 8 major classifications, the particular Gunmam analogous to Gastritis, i.e., Erigunmam could be specified in the studies. So, the RQ shall be *“whether Manikkadai measurements are effective for predicting Erigunmam cases (gastritis) in subjects established with OG endoscopy”*.

Hypothesis

A hypothesis is an important part of research that predicts the progression of an expected outcome of a particular RQ (Bossuyt et al., 2003). It clarifies RQ to a forecast of anticipated predictions. Generating a Hypothesis in Manikkadai nool is crucial before implementing any studies pertaining to its accuracy assessment, or sensitivity. From the above-mentioned RQ *“whether Manikkadai measurements are effective for predicting Erigunmam cases (gastritis) in subjects established with OG endoscopy”*, we could generate a hypothesis as *“Manikkadai measurements are effective for predicting Erigunmam cases (gastritis) in subjects established with OG endoscopy”*. Here the testing tool is Manikkadai measurements; the outcome of the tool is the prediction of Erigunmam cases (gastritis), with the reference standard used to establish the outcome being OG endoscopy.

Note: *Before taking an MK reading, it is wise to neglect any information obtained from the patient’s clinical history, physical examination, or other diagnostic tests. This will help to evaluate its standalone importance to predict a medical condition or its diagnostic value. Moreover, the observer won’t be influenced by it and reflects on his assumptions on the reading. Systematic observer Bias could be minimized to an extent. All the clinical data could be documented and interpreted after the reading is taken.*

Expected outcome of the study

Diagnostic accuracy: This is the ability of the diagnostic tool to find out or predict the particular health concern in support of the clinical history. (Šimundić, 2009)
Sensitivity (%): Outlines the percentage of true positive subjects with the disease in a total group of subjects with the disease (TP/TP+FN). (Šimundić, 2009)

Diagnostic accuracy of Manikkadai measurements is subjected to the following

- Whether the tool is capable of predicting the probability of a disease in an individual or not.
- Whether the obtained reading falls under any one of the following like True positive (TP), False-positive (FP), and false-negative (FN) cases to confirm its True relevance (Tr), and Zero relevance (Zr) to diagnosis
- How it starts, progress, and in its present condition what is the implication or associated symptoms
- How many symptoms mentioned in the textual descriptions under each FB unit are coinciding with the clinical presentation of the subject
- Whether the findings from the reading coincide with other traditional diagnostic methods like Nadi or Neerkuri/Neikuri.

Operational definitions

- True positive (TP): Subjects with the presenting symptom, disease pattern (mukutra nilai), or its progression stage coinciding with particular FB reading. This is the most considered aspect of reading interpreted from the direct perception of the clinical findings, or the leading questions put by the investigator.
- The sequence of True positive (SqTP): TP may be particular to a single FB unit pattern but in certain cases, a positive sequence of FB patterns (e.g., 8, $8^{1/2}$, and $8^{3/4}$) is also shown by the subject. All the features of multiple FB Unit patterns if appreciated by the subject and indicative of the progress of the symptoms or disease.
- False-positive (FP): Subjects not presenting, expressing, or having the symptoms even though the features are shown in the particular reading. The FB reading obtained fails to get a correlation with the actual symptoms, or disease pattern of the subject. This is common in practice and could be occurring due to the following: -
 - Either the symptom described in the reading is yet to manifest in them or is less appreciated by the subject.
 - The biased readings may be occurred due to misinterpreted or false assumptions (Diagnostic errors)
 - The subject is not willing to accept the symptoms (Subject errors)
- False-negative (FN): The subject is presenting the symptom or disease that has no description in the obtained reading. This is beyond the scope of MK as it is expressing only noted features of a patient based on the change in Ante brachial circumference or Finger breadths. Even though the presenting symptom is entirely different from the reading description, the physician should use logical reasoning to lead a connection.
- True relevance in MK reading (Tr): Both TP and SqTP are considered Tr as it helps the physician in reaching a fruitful diagnosis from the reading. Up to 60-70% of total cases may fall under Tr according to a recent study.
- Zero relevance in MK reading (Zr): Both FP and FN cases are considered as zero relevant as it doesn't help the physician in reaching a fruitful diagnosis from the reading. Up to 20 - 30% of the total case falls under this category according to a recent study.

Aim & Objectives of Diagnostic accuracy studies

We could set a Hypothetical deliberation, that the traditional diagnostic tool MK could be efficiently used for disease diagnosis and prognosis or prediction with limited error generation. The participants who report positive symptoms correlated with the findings of the MK measurement may be considered true positive (TP), and those with zero relevance with the findings of the MK measurement are considered to be False positive (FP) and negative (FN). (Šimundić, 2009) TP reflects the successful predictions that help in the part of diagnosis and vice versa. Accordingly, the study should be purposed to evaluate the prediction accuracy of the tool among the study participants. Here the prediction accuracy (Tool sensitivity /true positive rate) is dependent on the extent of unbiased measurement and the information collected by ensuing stringent SOP, and logical diagnostic reasoning. (Moons, 1996; Thammasitboon & Cutrer, 2013)

Disease	Manikkadai-reading describing the symptoms/signs	Clinical History / sign/symptom present
True positive (TP)	Yes	Yes
False positive (FP)	Yes	No
False positive (FN)	No	Yes

Methodology

Study design

Field observational/exploratory Diagnostic Accuracy study (observation field study)(Km et al., 2019; Mamede et al., 2008) Here MK Tool can determine, predict a particular health condition based on interpretations from reading and logical reasoning. The measures like sensitivity and diagnostic effectiveness (in %) are considered here.

Index Test

The approach of MK and its pattern of readings are put into the study of accuracy assessment and may consider as the Index test. (Šimundić, 2009)

Standard operating procedure for Manikkadai reading (MK)

Components of diagnostic study

1. A non-elastic thread of a standard length of 30 cm.
2. Clinical documentation form

Points to consider

1. Finger breadth (FB): One FB is the full perpendicular breadth of the finger
2. Finger Breadth units: Each FB is further divided into four namely, full FB, a quarter ($3/4^{\text{th}}$), half ($1/2$), and one fourth ($1/4^{\text{th}}$)

3. Ideal location for measuring the four FBS (ILM): The middle part of the four fingers when kept intact is the location taken for measuring by using the thread.
4. Circumference point (CP): The point where the 4FB length is reached when measured from the wrist crease
5. Antebrachial circumference (ABC): The circumference length obtained at CP

Procedure

1. Inform the study participant of the methodology of reading and how they should cooperate for the study
2. Keep the participant's right or left hand straight with all the fingers intact in the prone position (Fig 1a)
3. The middle part of the four fingers (ILM) was marked and the total perpendicular (mediolateral) length is measured by using the standard thread(Fig 1b)
4. The length obtained in the thread is measured back from the wrist crease to reach a point (CP) that is marked(Fig 1c)
5. The thread is encircled in the Antebrachial point and the circumference is measured (Fig 1d)
6. The Ante brachial circumference (ABC) length is converted into the total no of fingerbreadths(Fig 1e)
7. Interpret the reading with the descriptions and try to correlate with the clinical picture after interrogation
8. Repeat the measurement and reading thrice for confirming the finding and record it in the clinical documentation form.

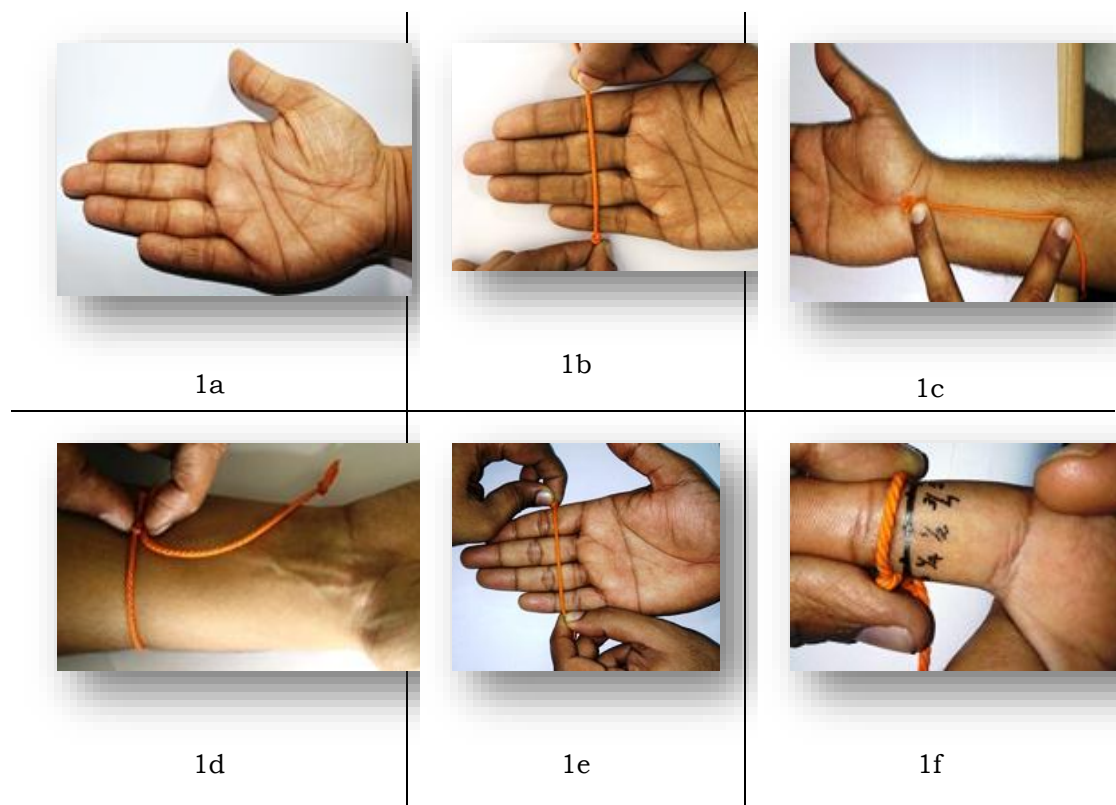


Fig.1 Standard operating procedure for Manikkadai reading

Standard Reference Test or Comparators

Standard Tests are mandatory for establishing the identity of the observed reading pattern and this could be one of the following.

1. Clinical criteria
2. Gold standard Tests: To evaluate the discriminative power of Manikkadai reading in identifying a common medical condition, the results should be compared with an established gold standard Test.
3. Special investigations

E.g., If the subject is showing symptoms of Venereal diseases (syphilis) with the particular reading pattern of 91/2 FB, then to establish the finding, the clinical criteria, examination including Vital signs (Body temp), serological markers (Rapid Plasma Reagin (RPR) and VDRL (Venereal Disease Research Laboratory) are used for initial screening. Specific treponemal tests (Gold standard) such as the Fluorescent Treponemal Antibody Absorption (FTA-ABS) are used to confirm the diagnosis. (Mabey et al., 2006)

Study participants & Sample size with the flow diagram

The study is presumed to be complete once a study participant completes the Index test (MK reading), case recording, and the concerned standard tests to avoid potential bias. (Fig 3) Inclusion criteria for study recruitment includes [adults/men or women] with age [18-60 yrs/>18yrs] with suspected target [disease /condition] whom are presenting /based on clinical presentations. Of [n] of study participants recruited in the study, the provisional diagnosis of the Target disease (suspected) was confirmed in [y] and excluded in [x] based on the Index test and reference standards.

E.g., the study was conducted during the period 1st of January 2022 to 3rd March 2022, in which a total sample size of 539 was randomly assessed with both MK readings, followed by case documentation and referral for standard investigations. Only 135 have completed the studies (25 %), remaining dropped out as they didn't finish the reference tests (75%).

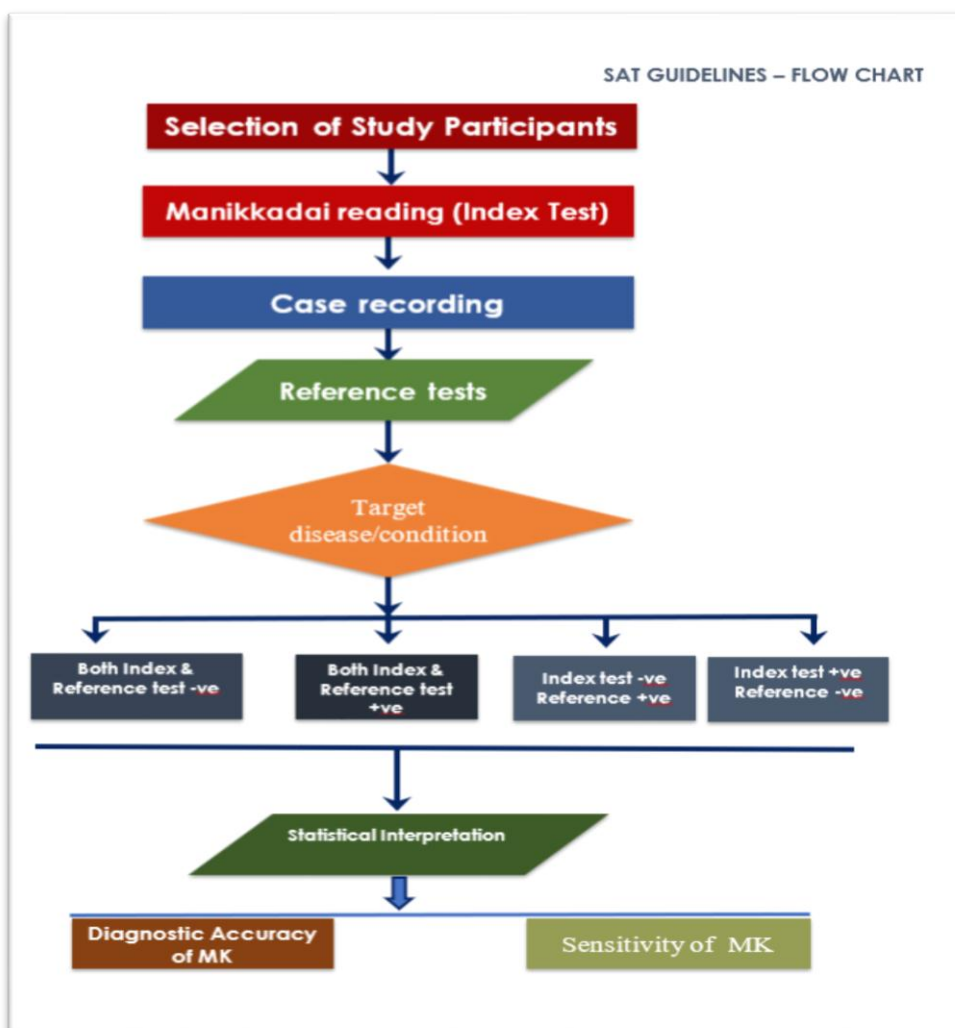


Figure 2. SAT Guidelines – Flow chart

Study setting

The location of the proposed/intended studies where participants are recruited for diagnostic accuracy studies

Type of sampling

Convenience sampling

The participants who meet the criteria of inclusion are selected for the studies. E.g., Subjects who are attending the medical camp/outpatient facilities of the corresponding clinic/Siddha dispensary/ public health center are included directly as per the inclusion criteria.(Acharya et al., 2013)

Data Collection

The raw data of the participants should be collected either through a developed Case Record Form (CRF), questionnaires, and case reports. CRF could be generated according to the specific expected outcome of the studies or in the general platform. But the information like demographic details and details of clinical history coinciding with MK measurements, and clinical reports to establish it is vital to the skeleton of all CRF. The model CRF for Diagnostic accuracy and validation studies of MK is depicted in the figures.

Statistical Interpretations

The entire outcome of the studies is expressed either in descriptive statistics to know the distribution/frequency of major variables of the study to perform the analysis of the correlation between the core variables and to determine the overall accuracy (%) and sensitivity of the Tool.(Belavendra Antonisamy et al., 2017) We may consider the following Dummy Table.2 for Statistical interpretations that are most commonly advocated in Diagnostic accuracy studies.

Table.2 MK reading from 110 cases (n=110)				
True positive (TP)	SqTP	FP	FN	
63	12	15	20	

Diagnostic effectiveness (accuracy) of MK: The proportion of Tr (TP + SqTP) subjects in a total group (sample size) of subjects recruited in the study (Tr + Zr) expressed in percentage (%).

$$\text{Diagnostic effectiveness (accuracy)(\%)} = \frac{\text{Tr (TP + SqTP)}}{\text{Tr (TP + SqTP) + Zr (FP + FN)}} \times 100\%$$

E.g., In an observational study, One hundred and ten (n+110) cases were examined with MK, 63 readings were found to be TP, 12 were SqTP, 15 were FP, and 20 were FN. The diagnostic effectiveness (accuracy) (%) of MK in that particular study will be 68%.

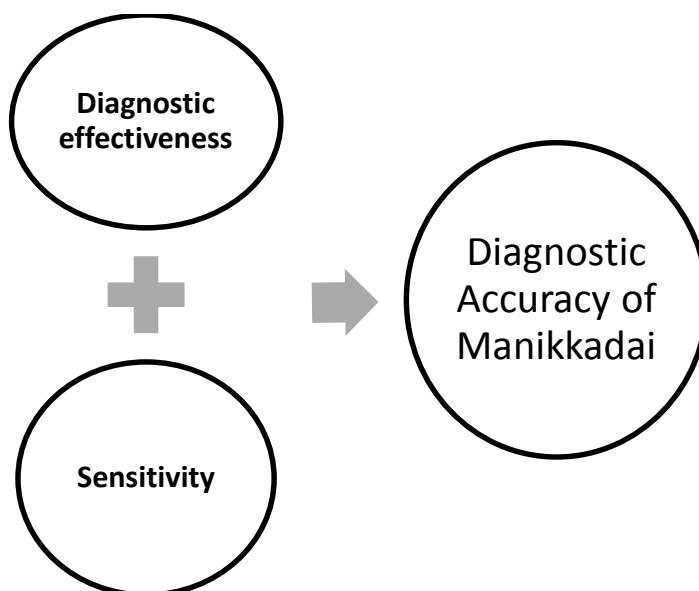
Sensitivity of MK reading: The proportion of TP subjects in a total group (sample size) of subjects with the particular disease (TP/TP+FN) expressed in percentage (%). This is the potential of MK that helps to recognize a particular diagnosis in the subject. it relates to the ability of a test to recognize the ill.(Šimundić, 2009)

$$\text{Sensitivity of Mk (\%)} = \frac{\text{TP}}{\text{TP + FN}} \times 100\%$$

E.g., According to table 3, twenty cases (n=20) were examined with MK for its correlation. The readings of 16 cases were obtained as 10, and 9^{3/4} which were TP to the particular diagnosis of Gunmam or its symptoms. Four cases had shown

readings other than 10 and $9^{3/4}$ which were FN to the diagnosis of Gunmam. So, the sensitivity of MK that identified a diagnosis in Gunmam will be 80%.

Table. 3. MK reading from 20 cases (n=20)	
TP for Gunmam	FN for Gunmam
16	4



- Note: Sensitivity of Mk is reliable if it recognizes the particular diagnostic feature from the reading before it is affirmed by interrogation or investigations.

Study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, or diagnostic effectiveness)

Results

The results should include the distribution of MK readings, demographic details of the study participants and the statistical data specific to sensitivity and diagnostic accuracy of the Index Test.

Discussion

This includes the general outline of the study, the purpose of the study, the overall expected outcome achieved through the present studies

Limitations of the study

This includes the clear-cut information about the study gap, limitations faced, and challenges of potential bias that impacted the study.

E.g. In our studies, many of the readings of MK obtained were beyond 10 FB has no description in the literature.

E.g., our study lacked the information on readings of study participants that is below 6FB.

E.g., In our study, we identified the source of ambiguity of readings as bias due to various factors that impacted the overall accuracy of the predictions.

E.g., our study was a single-time planning up of collecting readings from random study participants. As the consequent follow-up of the same participants is lacking, the variation of the readings within the subject (intra-subject variations) was not able to interpret.

Based on various studies, the following limitations of this tool are well recorded. The source of ambiguity of readings (biased readings) due to various factors impacts the overall accuracy of the predictions.

Manikkadai reading with false values: In cases (15-20%), the readings may not be fruitful enough to reach a diagnosis. This may happen due to the following

1. Tool errors: This occurs due to the usage of Inappropriate thread, elastic thread, etc., that generates faulty measurements.
2. Diagnostic errors: This part from the physician happens due to false assumptions, misinterpretations, or due to faulty reading (observer bias). This is the most common type of error in practice.(Thammasitboon & Cutrer, 2013)
3. Subject errors: This may occur on the part of patients who are unwilling to cooperate or are deceptive about the labelled symptoms.
4. Readings obtained beyond 10 FB (10 .25, 10.5, 10.75) have no descriptions in the literature. This is a major void in so many studies.
5. The readings may present the current clinical conditions but miss the important events.

Note: Systematic observer Bias usually happens when the observer is having well knowledge of the patient's condition, either obtained from a standard test before reading the MK. In such cases, there is a greater chance of shifting the observer's attention to the particular FB and assuming it as the true reading of MK.

Future implications of the study

E.g., the tool MK based on the accuracy studies could be used as a reliable predictor of diseases or could be used as an inexpensive supportive diagnostic tool with other traditional reference tests or standards. The studies had shown its accuracy rate to be more than 70 % with errors of more than 25 %. The area of pitfalls in research (mentioned under 8a. the limitations of the study) could be considered to improving the accuracy and generalisability of the Tool.

Future considerations for Manikkadai Diagnostic Research

1. Possibility of clubbing the findings of MK with modern interpretations, or reference standard tests to authenticate the accuracy of this traditional approach.

2. The variability between different observers or the same observer in reading and interpreting the readings from Manikkadai seldom happens. A reference SOP is followed stringently by the observers to reduce this, Bias.
3. Cases of severe debility, malnourishment, bedridden conditions, and critical care could be analyzed with MK readings, to obtain a picture of lower FB (<6FB).
4. Whether Higher FB readings obtained in the subject (>10) is a sign of good health or to define ideal health in MK readings.
5. Observation of MK readings in the paediatric population to evaluate its diagnostic importance.
6. To study the intra-subject variability of readings within the same subject under repeated follow-up. The readings were collected from the same participant at frequent time intervals (3 time zones in a single day, every day morning for 7 days, every week) and the presenting features could be monitored for a better understanding of the Tool.
7. Variation of MK reading before and after a medical intervention, medications, or therapies could be documented within the same subject who is presenting a group of symptoms or specific disease particular to the FB pattern.

Conclusion

SAT guidelines were set to ease the reporting of MK diagnostic accuracy studies. The various themes and prototype enlisted may assist researchers in documentation and publication of the concerned works. Moreover, the guidelines improve the quality of studies pertaining to MK that imprints the lead for further scientific acceptance. Further periodical up-gradation is warranted.

Conflict of Interest

None declared

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