Materials Design Analysis Reporting (MDAR) Checklist for Authors

The MDAR framework establishes a minimum set of requirements in transparent reporting applicable to studies in the life sciences (see Statement of Task: doi:10.31222/osf.io/9sm4x.). The MDAR checklist is a tool for authors, editors and others seeking to adopt the MDAR framework for transparent reporting in manuscripts and other outputs. Please refer to the MDAR Elaboration Document for additional context for the MDAR framework.

Materials

Antibodies	Yes (indicate where provided: section/paragraph)	n/a
For commercial reagents, provide supplier name, catalogue number and RRID, if available.		X

Cell materials	Yes (indicate where provided: section/paragraph)	n/a
Cell lines: Provide species information, strain. Provide accession number in repository **OR** supplier name, catalog number, clone number, **OR** RRID		X
Primary cultures: Provide species, strain, sex of origin, genetic modification status.		X

Experimental animals	Yes (indicate where provided: section/paragraph)	n/a
Laboratory animals: Provide species, strain, sex, age, genetic modification status. Provide accession number in repository **OR** supplier name, catalog number, clone number, **OR** RRID		X
Animal observed in or captured from the field: Provide species, sex and age where possible		X
Model organisms: Provide Accession number in repository (where relevant) **OR** RRID		X

Plants and microbes	Yes (indicate where provided: section/paragraph)	n/a
Plants: provide species and strain, unique accession number if available, and source (including location for collected wild specimens)		X
Microbes: provide species and strain, unique accession number if available, and source		X

Human research participants	Yes (indicate where provided: section/paragraph)	n/a
Identify authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	The study was approved by institutional ethics committee of the University Hospital Tübingen (Registration number 203/2021BO2) and individual consent for this retrospective analysis was waived.	
Provide statement confirming informed consent obtained from study participants.	Individual consent for this retrospective analysis was waived.	
Report on age and sex for all study participants.	Mean patient age at baseline was 65.9 years with a range of 46.9 – 83.7 years. 12 patients (38.7%) were female.	

Design

Study protocol	Yes (indicate where provided: section/paragraph)	n/a
For clinical trials, provide the trial registration number **OR** cite DOI in manuscript.		X

Laboratory protocol	Yes (indicate where provided: section/paragraph)	n/a
Provide DOI or other citation details if detailed step-by-step protocols are available.		X

Experimental study design (statistics details)	Yes (indicate where provided: section/paragraph)	n/a
State whether and how the following have been done**, or** if they were not carried out.		
Sample size determination		X
Randomisation		X
Blinding		X
Inclusion/exclusion criteria	Criteria for inclusion of patients were as follows: availability of 3 consecutive DECTs (one baseline CT before beginning of first line treatment and two follow-up CTs either during first line treatment or after termination of firstline treatment but before beginning of any secondline systemic treatment); histologically proven lung cancer; systemic lung cancer therapy; availability of hematological laboratory data including white blood cells (WBC), neutrophils, hemoglobin, red blood cells (RBC) and platelets at each of the three timepoints. Exclusion criteria were the following: known concurrent second malignant disease; previously received systemic anti-cancer treatment; any concurrent disease known to affect the bone or bone marrow; other conditions potentially affecting bone marrow composition (e.g. severe chronic anemia, chronic respiratory diseases, climbing, diving, obesity); known skeletal metastases.	

Sample definition and in-laboratory replication	Yes (indicate where provided: section/paragraph)	n/a
State number of times the experiment was replicated in laboratory		X
Define whether data describe technical or biological replicates		X

Ethics	Yes (indicate where provided: section/paragraph)	n/a
Studies involving human participants: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.	The study was approved by institutional ethics committee of the University Hospital Tübingen (Registration number 203/2021BO2) and individual	
Studies involving experimental animals: State details of authority granting ethics approval (IRB or equivalent committee(s), provide reference number for approval.		X
Studies involving specimen and field samples: State if relevant permits obtained, provide details of authority approving study; if none were required, explain why.		X

Dual Use Research of Concern (DURC)	Yes (indicate where provided: section/paragraph)	n/a
If study is subject to dual use research of concern, state the authority granting approval and reference number for the regulatory approval		X

Analysis

Attrition	Yes (indicate where provided: section/paragraph)	n/a
State if sample or data point from the analysis is excluded, and whether the criteria for exclusion were determined and specified in advance.		X

Statistics	Yes (indicate where provided: section/paragraph)	n/a
Describe statistical tests used and justify choice of tests.	To check for normal distribution of data the Shapiro–Wilk test was used. In case of multiple comparisons between subgroups we applied the Bonferroni method to adjust p-values. In descriptive statistics the mean and standard deviation (SD) are presented for normally distributed data and the median and interquartile range (IQR) for non-normally distributed data. We tested for interactions between the factors timepoint and therapy subgroup regarding VNCa attenuation and multiple hematological laboratory parameters (WBC, neutrophiles, RBC, hemoglobin, platelets). This was done via mixed ANOVA. The Huynh-Feldt adjustment was used to correct for violations of sphericity. To assess homogeneity of the error variances, we used Levene's test. To assess homogeneity of covariances Box's test was performed. In case of no statistically significant interaction additional one-way ANOVA to test for main effects of the intersubject factor (differences between therapy groups) and repeated measures ANOVA for main effects of the innersubject factor (differences between timepoints) were performed. Correlations between VNCa attenuation and hematological parameters were assessed via Pearson's correlation coefficient.	

Data Availability	Yes (indicate where provided: section/paragraph)	n/a
State whether newly created datasets are available, including protocols for access or restriction on access.		X
If data are publicly available, provide accession number in repository or DOI or URL.		X
If publicly available data are reused, provide accession number in repository or DOI or URL, where possible.		X

Code Availability	Yes (indicate where provided: section/paragraph)	n/a
For all newly generated code and software essential for replicating the main findings of the study:		
State whether the code or software is available.		X
If code is publicly available, provide accession number in repository, or DOI or URL.		X

Reporting

Adherence to community standards	Yes (indicate where provided: section/paragraph)	n/a
MDAR framework recommends adoption of discipline-specific guidelines, established and endorsed through community initiatives. Journals have their own policy about requiring specific guidelines and recommendations to complement MDAR.		
State if relevant guidelines (eg., ICMJE, MIBBI, ARRIVE) have been followed, and whether a checklist	ICMJE guidelines were followed, as the journal follows ICMJE recommendations for publication, and STARD	

(eg., CONSORT, PRISMA, ARRIVE) is provided with the manuscript.	guidelines were used, a checklist is provided.	

Article information: https://dx.doi.org/10.21037/qims-21-545

STARD 2015

Section & Topic	Item No	Item	Reported on Page Number/ Line Number	Reported on Section/ Paragraph
TITLE OR ABSTRACT				
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	n/a	n/a
ABSTRACT				
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Pages 2-3, line 21-51	Abstract
INTRODUCTION				
	3	Scientific and clinical background, including the intended use and clinical role of the index test	page 4, line 55-92	introduction, paragraph
	4	Study objectives and hypotheses	page 5, line 93-97	introduction, paragraph
METHODS				
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	page 6, line 103-105	methods and materials, paragraph 1
Participants	6	Eligibility criteria	page 6, line 105-114	methods and
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	page 6, line 103-105	methods and
	8	Where and when potentially eligible participants were identified (setting, location and dates)	page 6, line 103-105	methods and
	9	Whether participants formed a consecutive, random or convenience series	page 6, line 103-105	methods and
Test methods	10a	Index test, in sufficient detail to allow replication	page 7, line 136-158	methods and
	10b	Reference standard, in sufficient detail to allow replication	n/a	n/a
	11	Rationale for choosing the reference standard (if alternatives exist)	n/a	n/a
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	n/a	n/a
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	n/a	n/a
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	page 7, line 141-14	methods and
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	n/a	n/a

Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	n/a	n/a
	15	How indeterminate index test or reference standard results were handled	n/a	n/a
	16	How missing data on the index test and reference standard were handled	n/a	n/a
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	n/a	n/a
	18	Intended sample size and how it was determined	page 6, line 104-105	methods and
RESULTS				
Participants	19	Flow of participants, using a diagram	n/a	n/a
	20	Baseline demographic and clinical characteristics of participants	page 9, line 191-196.	results, paragraph 1
	21a	Distribution of severity of disease in those with the target condition	n/a	n/a
	21b	Distribution of alternative diagnoses in those without the target condition	n/a	n/a
	22	Time interval and any clinical interventions between index test and reference standard	n/a	n/a
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	n/a	n/a
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	n/a	n/a
	25	Any adverse events from performing the index test or the reference standard	n/a	n/a
DISCUSSION				
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	page 14, line 314-326	discussion, paragraph 4
	27	Implications for practice, including the intended use and clinical role of the index test	a) page 5, line 85-89	a) introduction,
OTHER INFORMATION				
	28	Registration number and name of registry	page 100, line 101-102	methods and
	29	Where the full study protocol can be accessed	n/a	n/a
	30	Sources of funding and other support; role of funders	n/a	n/a

AIM

STARD stands for “Standards for Reporting Diagnostic accuracy studies”. This list of items was developed to contribute to the completeness and transparency of reporting of diagnostic accuracy studies. Authors can use the list to write informative study reports. Editors and peer-reviewers can use it to evaluate whether the information has been included in manuscripts submitted for publication.

Explanation

A **diagnostic accuracy study** evaluates the ability of one or more medical tests to correctly classify study participants as having a **target condition**. This can be a disease, a disease stage, response or benefit from therapy, or an event or condition in the future. A medical test can be an imaging procedure, a laboratory test, elements from history and physical examination, a combination of these, or any other method for collecting information about the current health status of a patient.

The test whose accuracy is evaluated is called **index test**. A study can evaluate the accuracy of one or more index tests. Evaluating the ability of a medical test to correctly classify patients is typically done by comparing the distribution of the index test results with those of the **reference standard**. The reference standard is the best available method for establishing the presence or absence of the target condition. An accuracy study can rely on one or more reference standards.

If test results are categorized as either positive or negative, the cross tabulation of the index test results against those of the reference standard can be used to estimate the **sensitivity** of the index test (the proportion of participants with the target condition who have a positive index test), and its **specificity** (the proportion without the target condition who have a negative index test). From this cross tabulation (sometimes referred to as the contingency or “2x2” table), several other accuracy statistics can be estimated, such as the positive and negative **predictive values** of the test. Confidence intervals around estimates of accuracy can then be calculated to quantify the statistical **precision** of the measurements.

If the index test results can take more than two values, categorization of test results as positive or negative requires a **test positivity cut-off**. When multiple such cut-offs can be defined, authors can report a receiver operating characteristic (ROC) curve which graphically represents the combination of sensitivity and specificity for each possible test positivity cut-off. The **area under the ROC curve** informs in a single numerical value about the overall diagnostic accuracy of the index test.

The **intended use** of a medical test can be diagnosis, screening, staging, monitoring, surveillance, prediction or prognosis. The **clinical role** of a test explains its position relative to existing tests in the clinical pathway. A replacement test, for example, replaces an existing test. A triage test is used before an existing test; an add-on test is used after an existing test.

Besides diagnostic accuracy, several other outcomes and statistics may be relevant in the evaluation of medical tests. Medical tests can also be used to classify patients for purposes other than diagnosis, such as staging or prognosis. The STARD list was not explicitly developed for these other outcomes, statistics, and study types, although most STARD items would still apply.

DEVELOPMENT

This STARD list was released in 2015. The 30 items were identified by an international expert group of methodologists, researchers, and editors. The guiding principle in the development of STARD was to select items that, when reported, would help readers to judge the potential for bias in the study, to appraise the applicability of the study findings and the validity of conclusions and recommendations. The list represents an update of the first version, which was published in 2003. More information can be found on http://www.equator-network.org/reporting-guidelines/stard.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.