TRIPOD Checklist: Prediction Model Development and Validation

Section/Topic	Item		Checklist Item	Page
Title and abstract				
Title	1	D;V	Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted.	Title: target population and outcome Subtitle: developing and validation
Abstract	2	D;V	Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions.	All done
Introduction				
Background and objectives	3a	D;V	Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models.	Rationale: shared decision making for use of Sentinel Lymph Node Biopsy. References to existing models are given
	3b	D;V	Specify the objectives, including whether the study describes the development or validation of the model or both.	In the aim was included: target population, outcome, developing and validation of cohort
Methods				
Source of data	4a	D;V	Describe the study design or source of data (e.g., randomized trial, cohort, or registry data), separately for the development and validation data sets, if applicable.	For both cohort the source is described: registry of PALGA and NCR
	4b	D;V	Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up.	Incidence period described
Participants	5a	D;V	Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres.	Development cohort: population based NL Validation: pathology registries using protocol module for registration of biopsies
	5b	D;V	Describe eligibility criteria for participants.	In and exclusion criteria given
	5c	D;V	Give details of treatments received, if relevant.	Not relevant, surgery was inclusion criterium
Outcome	6a	D;V	Clearly define the outcome that is predicted by the prediction model, including how and when assessed.	Lymph node metastases found by primary of secondary axillary staging. Described was the check on metastases found afterwards.
	6b	D;V	Report any actions to blind assessment of the outcome to be predicted.	No actions. Study was retrospective and based on registry data.
Predictors	7a	D;V	Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured.	It was described whether the predictors were recorded in the registry or coded in the study based on free text fields
	7b	D;V	Report any actions to blind assessment of predictors for the outcome and other predictors.	No actions done
Sample size	8	D;V	Explain how the study size was arrived at.	In the analyses it was checked that the number of events was sufficient to develop a model given the number of predictors to test in the analyses
Missing data	9	D;V	Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method.	Described is that in the development cohort the missing data are handled with multiple imputation and in the validation cohort by complete case analysis
Statistical analysis methods	10a	D	Describe how predictors were handled in the analyses.	The several testing of the continuous variable is described
	10b	D	Specify type of model, all model-building procedures (including any predictor selection), and method for internal validation.	The pre-defined selection of predictors was described, as was bootstrapping for internal validation
	10c	V	For validation, describe how the predictions were calculated.	Applying the model on the validation cohort data
	10d	D;V	Specify all measures used to assess model performance and, if relevant, to compare multiple models.	Use of ROC curves and calibration plots was described
	10e	V	Describe any model updating (e.g., recalibration) arising from the validation, if done.	We did not update the model based on the validation
Risk groups	11	D;V	Provide details on how risk groups were created, if done.	Risk groups were created in given in a supplementary file
Development vs. validation	12	V	For validation, identify any differences from the development data in setting, eligibility criteria, outcome, and predictors.	The difference in the selection (population based versus laboratories using a registration model) was described. Differences in the outcome rate was given in the results
Results				
Participants	13a	D;V	Describe the flow of participants through the study, including the number of participants with and without the outcome and, if applicable, a summary of the follow-up time. A diagram may be helpful.	A figure of the axillary evaluation and the result of it (the outcome) is given in a supplementary file
	13b	D;V	Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome.	For the development cohort the characteristics including the missing data and the outcome is given in a table. For the validation cohort the characteristics

				are given in a supplement, missing data were an exclusion criterium.
	13c	V	For validation, show a comparison with the development data of the distribution of important variables (demographics, predictors and outcome).	The characteristics of both cohorts are described in the results or supplementary files
Model development	14a	D	Specify the number of participants and outcome events in each analysis.	The number of patients and number of events was given.
	14b	D	If done, report the unadjusted association between each candidate predictor and outcome.	The event rate for each value of the predictors in both cohorts are given
Model specification	15a	D	Present the full prediction model to allow predictions for individuals (i.e., all regression coefficients, and model intercept or baseline survival at a given time point).	The beta-coefficients and intercept are described
	15b	D	Explain how to the use the prediction model.	The range of prediction in which the model could be used (based on decision curve analysis) was described. A link to the Evidencio website was added, were individual risks can be calculated.
Model performance	16	D;V	Report performance measures (with CIs) for the prediction model.	In the development cohort the AUC was given, also the AUC after correction for bootstrapping. In the validation cohort the AUC including the CI was given.
Model-updating	17	V	If done, report the results from any model updating (i.e., model specification, model performance).	Not done
Discussion				
Limitations	18	D;V	Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data).	Missing data as limitation are described. Also to use the model on patients not on patients with characteristics of the exclusion criteria
Interpretation	19a	V	For validation, discuss the results with reference to performance in the development data, and any other validation data.	We discussed the AUC of the development data with the AUC of other studies. And discussed the overestimation of the risk in our validation cohort
	19b	D;V	Give an overall interpretation of the results, considering objectives, limitations, results from similar studies, and other relevant evidence.	We did, including the differences in event rate between the development cohort, the validation cohort and the rates in other studies
Implications	20	D;V	Discuss the potential clinical use of the model and implications for future research.	The results of the decision curve analysis and potential clinical use was discussed
Other information				
Supplementary information	21	D;V	Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets.	We included a link to Evidencio, for calculation of the individual risks.
Funding	22	D;V	Give the source of funding and the role of the funders for the present study.	The funders have been mentioned.

*Items relevant only to the development of a prediction model are denoted by D, items relating solely to a validation of a prediction model are denoted by V, and items relating to both are denoted D;V. We recommend using the TRIPOD Checklist in conjunction with the TRIPOD Explanation and Elaboration document.