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A Machine Learning Algorithm to Identify Patients at Risk for Recurrence Following an Arthroscopic Bankart Repair (CLEARER): a study protocol for a retrospective multicentre study

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Complete List of Authors:	Spanning, Sanne; OLVG, Orthopaedic Surgery; Clinique Générale Annecy, Orthopaedic Surgery Verweij, Lukas; Amsterdam UMC Locatie AMC, Orthopedic Surgery, Amsterdam Movement Sciences, ; Amsterdam UMC Locatie AMC, Academic Center for Evidence-based Sports Medicine (ACES) Allaart, Laurens; Vrije Universiteit Amsterdam, Department of Human Movement Sciences; Clinique Générale Annecy, Orthopaedic Surgery Hendrickx, Laurent; University of Amsterdam, Department of Orthopedic Surgery; Flinders University, Orthopaedic & Trauma Surgery Doornberg, Job; Flinders University, Orthopaedic Surgery Athwal, George; Schulich School of Medicine and Dentistry, Roth McFarlane Hand and Upper Limb Center Lafosse, Thibault; Clinique Générale Annecy, Orthopaedic Surgery Lafosse, Laurent; Clinique Générale Annecy, Orthopaedic Surgery van den Bekerom, M.P.J.; Vrije Universiteit Amsterdam, Department of Human Movement Sciences; OLVG, Orthopaedic Surgery Buijze, Geert Alexander; Clinique Générale Annecy, Orthopaedic Surgery; University of Montpellier, Montpellier University Medical Center, Department of Orthopedic Surgery

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Title: A Machine Learning Algorithm to Identify Patients at Risk for Recurrence Following an Arthroscopic Bankart Repair (CLEARER): a study protocol for a retrospective multicentre study

Corresponding author:

Full name: Sanne Hendrikje van Spanning

Postal address: Onze Lieve Vrouwe Gasthuis (OLVG) hospital, Oosterpark 9, 1091 AC Amsterdam, The Netherlands

Email: s.h.vanspanning@olvg.nl

Authors:

Sanne H. **van Spanning**[1,2,3]; Lukas P.E. **Verweij**[4,5,6]; Laurens J.H. **Allaart**[2,3]; Laurent A.M. **Hendrickx**[4,5,7]; Job N. **Doornberg**[7]; George S. **Athwal**[8]; Thibault **Lafosse**[2]; Laurent **Lafosse**[2]; Michel P.J **van den Bekerom**[1,3]; Geert Alexander **Buijze**[2,4,9] on behalf of the Machine Learning Consortium

Affiliations

1. Shoulder and Elbow Unit, Joint Research, Department of Orthopaedic Surgery, OLVG, Amsterdam, The Netherlands
2. Department of Orthopedic Surgery, Clinique Générale Annecy, Annecy, France
3. Department of Human Movement Sciences, Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam Movement Sciences, Amsterdam, the Netherlands
4. Department of Orthopedic Surgery, Amsterdam Movement Sciences, Amsterdam UMC, location AMC, University of Amsterdam, Amsterdam, The Netherlands.
5. Academic Center for Evidence-based Sports Medicine (ACES), Amsterdam UMC, Amsterdam, The Netherlands

6. Amsterdam Collaboration for Health and Safety in Sports (ACHSS), International Olympic Committee (IOC) Research Center, Amsterdam UMC, Amsterdam, The Netherlands
7. Department of Orthopaedic & Trauma Surgery, Flinders Medical Centre, Flinders University, Adelaide, SA, Australia
8. Roth McFarlane Hand and Upper Limb Center, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada
9. Department of Orthopedic Surgery, Montpellier University Medical Center, Lapeyronie Hospital, University of Montpellier, Montpellier, France

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ABSTRACT

Introduction: Shoulder instability is a common injury, with a reported incidence of 23.9 per 100,000 person-years. There is still an ongoing debate on the most effective treatment strategy. Non-operative treatment has recurrence rates of up to 60%, whereas operative treatments such as the Bankart repair and bone block procedures show lower recurrence rates (16% and 2%, respectively) but higher complication rates (<2% and up to 30%, respectively). Methods to determine risk of recurrence have been developed, however patient-specific decision-making tools are still lacking. Artificial Intelligence (AI) and machine learning algorithms use self-learning complex models that can be used to make patient-specific decision-making tools. The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice – as an online prediction tool – to estimate recurrence rates following a Bankart repair.

Methods and analysis: This is a multicentre retrospective cohort study. Patients with traumatic anterior shoulder dislocations that were treated with an arthroscopic Bankart repair without remplissage will be included. This study includes two parts. Part one, collecting all potential factors influencing the recurrence rate following an arthroscopic Bankart repair in patients using multicentre data. Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. Recurrence will be the primary outcome measure.

Ethics and dissemination: For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies.” No IRB is required for this study.

Trial registration: This study does not require a trial registration

ARTICLE SUMMARY

- This study aims to calculate a patient specific probability of recurrence following arthroscopic Bankart repair instead of the 'traditional' overall complication rate.
- Creating an online prediction tool for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting patients who benefit from this procedure.
- Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data from over 1000 patients.
- This study does have the limitation of being retrospective and therefore the study is dependent on the recordkeeping of each individual hospital.

INTRODUCTION

Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per 100,000 person-years.[1] Shoulder dislocations limit patients in their daily routine and participation in sports, cause irreversible damage to the shoulder joint and are associated with high costs.[2, 3] There is an ongoing debate on the most effective treatment strategy to prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone block procedures have lower recurrence rates (16% and 2%, respectively).[4, 5] However, the complication rates for bone block procedures compared to arthroscopic labrum repair (up to 30% and <2%, respectively) are higher and therefore pre-operative counselling with determination of the most suitable treatment is important in avoiding unnecessary risk of complications.[6, 7] Methods to determine risk of recurrence have been developed, including the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version, inclination), an off-track Hill-Sachs lesion and translation of the humeral head.[8-12] However, a patient-specific decision-making tool is still lacking.

The self-learning complex models used by Artificial Intelligence (AI) and Machine Learning algorithms express high levels of intelligence without human error and are therefore highly suitable to be used for interpretation of images, pathology slides and patient-specific decision-making tool.[13-17] Hendrickx and colleagues recently developed a prediction model based on machine learning algorithms to estimate acute and late complications after intramedullary nailing of a tibial shaft fracture.[16] In other words, the authors were able to use the computationally intensive methods of machine learning, to go from the 'traditionally' reported overall complication rate of a cohort to calculate the probability of a specific patient complication rate. This study resulted in an online prediction tool.

Aim and objectives

The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice – as an online prediction tool – to estimate

recurrence rates following a Bankart repair. No studies have yet been published applying machine learning algorithms to systematically reviewed/collected data in this field.

METHODS AND ANALYSIS

Study design

This multicentre retrospective cohort study includes two parts.

Part one – Collecting Data

Part one involves collecting all potential factors influencing the recurrence rate following an arthroscopic Bankart repair without remplissage in patients using multicentre data. Authors who will contribute to data contribution will be included in the Machine Learning Consortium, aiming to include data from over 1000 patients all over the world. To identify relevant studies, a systematic approach was used searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley, Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of Science/Clarivate according to the search terms used in Verweij *et al*. (see Supplemental appendix 1 for the search strategy).[18] The inclusion criteria are patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as either a complete dislocation or subluxation. [19] Exclusion criteria include patients who have undergone previous stabilization procedures or other surgical procedures to the ipsilateral shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or voluntary habitual instability.

Part two – Machine Learning

Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes.

Training Data & Test Data

Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium Database will be randomly allocated to the training dataset and 20% to the test dataset.

Output variables

Each Machine Learning Algorithms will be trained to recognize patterns related to recurrence rates.

Input Variables

For the primary outcome, a Random-Forest algorithm will be used to identify the variables with the highest predictive variables from all available data points in the Machine Learning Consortium Database. The data points available include demographics (age, sex), patient specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix 2 for the complete list of factors that will be collected from the electronic medical records).

Algorithms to be trained

It is not possible to know what Machine Learning algorithm will be most suitable to calculate recurrence following an arthroscopic Bankart repair.[20] However, based on previous studies, the following algorithms will be tested as prediction models for recurrence rates: Decision Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine.[16, 21-25]

Training and Testing of the algorithms

For each ML algorithm, ten-fold cross validation will be repeated three times on the training dataset (80%), to train the algorithms in recognizing patterns related to recurrence following an arthroscopic Bankart repair, and to subsequently assess their predictive performance based on the following performance characteristics: Area under the ROC-curve, calibration (calibration slope, calibration intercept) and Brier score will be calculated.[26] The model's predicted probability is plotted against the actual observed probability to calculate calibration of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.[27] The overall performance of the model will be assessed with the Brier-score. A perfect Brier score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of 1.[26] The remaining 20% of the data will be used as a test-set to assess the performance of the best performing machine learning algorithms based on “unseen” data. The technical appendix, statistical code, and dataset will be published.

External validation of the best performing algorithm

Before incorporation into an online open access decision-making tool, the best performing algorithm will be externally validated. The same performance metrics will be calculated as described above.

Open-access clinical prediction tool

An open-access clinical prediction tool will be developed using the best performing algorithm.

Patients and public involvement

Patients and the public were not involved in the making of this protocol.

ETHICS AND DISSEMINATION

For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies.” [28] No IRB is required for this study.

DISCUSSION

Operative treatment significantly reduces the risk of recurrent shoulder instability compared to non-operative treatment.[29] Patients with first-time dislocations who receive operative treatment are most often treated with labrum repair.[29] Risk factors associated with failure of an arthroscopic Bankart repair include young age (≤30 years), participation in competitive sports, multiple preoperative dislocations, > 6 months surgical delay from first-time dislocation to surgery, ISIS > 3 and associated lesions (Hill-Sachs, glenoid bone loss and ALPSA). [18] It is impossible to take all these risk factors into account and make an objective decision on what treatment is most suitable. Several prediction tools have been developed to help counselling patients, however these tools only provide an indicative overall score and are not patient specific.[8-12] Artificial Intelligence (AI) and machine learning algorithms have shown potential to make a patient-specific decision tool.[16] Creating an online prediction tool for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting patients who benefit from this procedure. Patients with a first-time anterior shoulder dislocations receive proper evidence-based information only in 29% of the cases.[30] An online prediction tool might elevate these numbers and makes it possible for shared decision making based on objective measures.

The strength of this study is the great amount of data that will be gathered. Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data of >1000 patients. This study does have the limitation of being retrospective and therefore the study is dependent on the recordkeeping of each individual hospital.

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AUTHORS CONTRIBUTION

Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E. Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception and design of the methods section, primarily focussing on the machine learning section and data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the design of the methods section and primarily focussed on how the data should he collected and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this version of the protocol and gave final approval for it to be published. All authors ensure that questions related to the accuracy or integrity of any part of this protocol are appropriately investigated and resolved.

CONFLICTS OF INTEREST

Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant for ConMed Linvatec. The remaining authors certify that neither he or she has funding or commercial associations that might pose a conflict of interest in connection with the submitted article.

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SUPPLEMENTARY 1 Search strategy

PubMed

#17	Search: **#14 AND #15 AND #16** Sort by: **Most Recent**	1,768
#16	Search: **((("Recurrence"[Mesh] OR recurr*[tiab] OR relaps*[tiab] OR recrudesc*[tiab] OR repeat*[tiab]) AND ("Joint Dislocations"[Mesh] OR dislocat*[tiab] OR luxat*[tiab] OR instabilit*[tiab])) OR risk*[tiab] OR lesion*[tiab] OR (hill[tiab] AND sachs[tiab]) OR injur*[tiab] OR Perthes[tiab] OR ALPSA[tiab] OR (anterior[tiab] AND (labro[tiab] OR labral[tiab]) AND periosteal[tiab] AND sleeve[tiab] AND avulsion*[tiab]) OR HAGL[tiab] OR (humeral[tiab] AND avulsion*[tiab] AND glenohumeral[tiab] AND ligament*[tiab]) OR (greater[tiab] AND tuberosity[tiab]) OR fracture*[tiab] OR "Fractures, Bone"[Mesh] OR "Rotator Cuff"[Mesh] OR (rotator[tiab] AND cuff[tiab]) OR tear*[tiab] OR age[tiab] OR sport*[tiab] OR laxity[tiab] OR (glenoid[tiab] AND bone[tiab] AND loss[tiab]))** Sort by: **Most Recent**	5,603,913
#15	Search: **(Bankart[tiab] OR "Bankart Lesions/surgery"[Mesh] OR arthroscopic stabilization[tiab] OR arthroscopic stabilisation[tiab] OR labral repair[tiab])** Sort by: **Most Recent**	2,300
#14	Search: **("Shoulder Dislocation"[Mesh] OR "Shoulder"[Mesh] OR "Shoulder Joint"[Mesh] OR shoulder*[tiab] OR glenohumeral[tiab])** Sort by: **Most Recent**	82,527

Embase/Ovid

1	exp shoulder dislocation/	6512
2	exp shoulder/	83055
3	(shoulder* or glenohumeral).ti,ab,kw.	101743
4	1 or 2 or 3	138684
5	(Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair).ti,ab,kw.	2813
6	Bankart lesion/su [Surgery]	198
7	5 or 6	2862
8	(recurr* or relaps* or recrudesc* or repeat*).ti,ab,kw.	1930525
9	exp joint dislocation/	4059

10	(dislocat*or luxat* or instabilit*).ti,ab,kw.	154727
11	9 or 10	158430
12	8 and 11	19548
13	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)).ti,ab,kw.	8234845
14	exp fracture/	336756
15	exp rotator cuff/	8999
16	12 or 13 or 14 or 15	8303779
17	4 and 7 and 16	2119

Cochrane Database of Systematic Reviews & Cochrane Central Register of Controlled Trials

#1	MeSH descriptor: [Shoulder Dislocation] explode all trees	143
#2	MeSH descriptor: [Shoulder] explode all trees	537
#3	MeSH descriptor: [Shoulder Joint] explode all trees	745
#4	(shoulder* or glenohumeral):ti,ab,kw	11763
#5	#1 OR #2 OR #3 OR #4	11763
#6	MeSH descriptor: [Bankart Lesions] explode all trees and with qualifier(s): [surgery - SU]	3
#7	(Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair):ti,ab,kw	238
#8	#6 OR #7	238
#9	MeSH descriptor: [Recurrence] explode all trees	12084
#10	(recurr* or relaps* or recrudesc* or repeat*):ti,ab,kw	159845
#11	#9 OR #10	159894
#12	MeSH descriptor: [Joint Dislocations] explode all trees	687
#13	(dislocat*or luxat* or instabilit*):ti,ab,kw	5839
#14	#12 OR #13	6413

#15	#11 AND #14	1018
#16	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)):ti,ab,kw	549185
#17	MeSH descriptor: [Fractures, Bone] explode all trees	6053
#18	MeSH descriptor: [Rotator Cuff] explode all trees	344
#19	#15 OR #16 OR #17 OR #18	549508
#20	#5 AND #8 AND #19	145

7

8 *CINAHL/Ebsco*

S18	S3 AND S6 AND S17	729
S17	S13 OR S14 OR S15 OR S16	1,482,038
S16	(MH "Rotator Cuff+")	3,063
S15	(MH "Fractures+")	58,529
S14	(TI (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss))) OR (AB (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss)))	1,469,860
S13	S9 AND S12	4,294
S12	S10 OR S11	33,871
S11	(TI (dislocat* OR luxat* OR instabilit*)) OR (AB (dislocat* OR luxat* OR instabilit*))	31,033
S10	(MH "Dislocations+")	8,266
S9	S7 OR S8	231,945

S8	(TI (recurr* OR relaps* OR recrudesc* OR repeat*)) OR (AB (recurr* OR relaps* OR recrudesc* OR repeat*))	212,296
S7	(MH "Recurrence")	48,901
S6	S4 OR S5	1,126
S5	(TI (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair)) OR (AB (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair))	1,123
S4	(MH "Bankart Lesions/SU")	58
S3	S1 OR S2	30,919
S2	(Ti (shoulder* OR glenohumeral)) OR (AB (shoulder* OR glenohumeral))	28,334
S1	(MH "Shoulder") OR (MH "Shoulder Dislocation") OR (MH "Shoulder Joint+")	12,823

Web of Science/Clarative

TOPIC: (shoulder* OR glenohumeral) AND (Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair) AND (((recurr* or relaps* or recrudesc* or repeat*) AND (dislocat*or luxat* or instabilit*)) OR risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss))

Database	Before deduplication	After deduplication
PubMed	1768	1762
Embase	2119	580
Cochrane Database of Systematic Reviews	1	0
Cochrane Central Register of Controlled Trials	143	51
CINAHL	729	55
Web of science	2578	1136

Total	7338	3584

SUPPLEMENTARY 2

We collect the following potential risk factors from the electronic medical records:

- Gender (male/female)
- Age at time of operation (years)
- Preoperative BMI
- ASA classification at time of operation (1-4)
- Epilepsy (yes/no)
- Hyperlaxity (Beighton score < 4 or ≥ 4)
- Affected side (right/left/bilateral)
- Side of operation (right/left/bilateral)
- Dominance (right/left/both)
- Daily smoking at time of operation (yes or no)
- Number of pre-operative dislocations
- Duration of follow-up (years)
- Bony lesions
    - Bony Bankart lesion (yes/no)
    - Hill-Sachs lesion
        - Yes/no
        - Off-track yes/no
    - Greater Tuberosity Fracture (yes/no)
    - Glenoid bone loss (<20%, ≥20%)
- Soft tissue lesions
    - Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
    - Superior labrum anterior and posterior (SLAP) lesion (yes/no)
    - inferior glenohumeral ligament (IGHL) (yes/no)
    - Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
    - Perthes lesion (yes/no)

    - Glenolabral articular disruption (GLAD) lesion (yes/no)
    - Full thickness Rotator Cuff Tear (yes/no)
    - Partial thickness Rotator Cuff Tear (yes/no)
- Nerve Palsy (yes/no)
- Surgical Characteristics:
    - Side (right/left/bilateral)
    - Time from injury to surgery (months)
    - Time to surgery from hospital admission (days)
    - Surgeon level (Surgeon/Resident/Fellow)

TRIPOD Checklist: Prediction Model Development

Section/Topic	Item	Checklist Item	Page
Title and abstract			
Title	1	Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted.	1
Abstract	2	Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions.	3
Introduction			
Background and objectives	3a	Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models.	5
	3b	Specify the objectives, including whether the study describes the development or validation of the model or both.	7,8
Methods			
Source of data	4a	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.	7,8,9
	4b	Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up.	7,8,9
Participants	5a	Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres.	7
	5b	Describe eligibility criteria for participants.	7
	5c	Give details of treatments received, if relevant.	7
Outcome	6a	Clearly define the outcome that is predicted by the prediction model, including how and when assessed.	7,8,9
	6b	Report any actions to blind assessment of the outcome to be predicted.	N/A
Predictors	7a	Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured.	8
	7b	Report any actions to blind assessment of predictors for the outcome and other predictors.	N/A
Sample size	8	Explain how the study size was arrived at.	N/A
Missing data	9	Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method.	N/A
Statistical analysis methods	10a	Describe how predictors were handled in the analyses.	7,8,9
	10b	Specify type of model, all model-building procedures (including any predictor selection), and method for internal validation.	7,8,9
	10d	Specify all measures used to assess model performance and, if relevant, to compare multiple models.	7,8,9
Risk groups	11	Provide details on how risk groups were created, if done.	N/A
Results			
Participants	13a	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.	7,8,9
	13b	Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome.	7
Model development	14a	Specify the number of participants and outcome events in each analysis.	N/A
	14b	If done, report the unadjusted association between each candidate predictor and outcome.	N/A
Model specification	15a	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).	7,8,9
	15b	Explain how to the use the prediction model.	9
Model performance	16	Report performance measures (with CIs) for the prediction model.	8,9
Discussion			
Limitations	18	Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data).	11
Interpretation	19b	Give an overall interpretation of the results, considering objectives, limitations, and results from similar studies, and other relevant evidence.	11
Implications	20	Discuss the potential clinical use of the model and implications for future research.	5, 11
Other information			
Supplementary information	21	Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets.	7,8,9
Funding	22	Give the source of funding and the role of the funders for the present study.	12

We recommend using the TRIPOD Checklist in conjunction with the TRIPOD Explanation and Elaboration document.

BMJ Open

Development and Training of a Machine Learning Algorithm to Identify Patients at Risk for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a Retrospective, Multicentre, Cohort Study

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Keywords:	Adult orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY, Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY

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Manuscripts

Title: Development and Training of a Machine Learning Algorithm to Identify Patients at Risk for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a Retrospective, Multicentre, Cohort Study

Corresponding author:

Full name: Sanne Hendrikje van Spanning

Postal address: Onze Lieve Vrouwe Gasthuis (OLVG) Hospital, Oosterpark 9, 1091 AC Amsterdam, The Netherlands

Email: s.h.vanspanning@olvg.nl

Authors:

Sanne H. **van Spanning**[1,2,3]; Lukas P.E. **Verweij**[4,5,6]; Laurens J.H. **Allaart**[2,3]; Laurent A.M. **Hendrickx**[4,5,7]; Job N. **Doornberg**[7]; George S. **Athwal**[8]; Thibault **Lafosse**[2]; Laurent **Lafosse**[2]; Michel P.J **van den Bekerom**[1,3]; Geert Alexander **Buijze**[2,4,9] on behalf of the Machine Learning Consortium

Affiliations

1. Shoulder and Elbow Unit, Joint Research, Department of Orthopaedic Surgery, OLVG, Amsterdam, The Netherlands
2. Department of Orthopedic Surgery, Clinique Générale Annecy, Annecy, France
3. Department of Human Movement Sciences, Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam Movement Sciences, Amsterdam, the Netherlands
4. Department of Orthopedic Surgery, Amsterdam Movement Sciences, Amsterdam UMC, location AMC, University of Amsterdam, Amsterdam, The Netherlands.
5. Academic Centre for Evidence-based Sports Medicine (ACES), Amsterdam UMC, Amsterdam, The Netherlands

6. Amsterdam Collaboration for Health and Safety in Sports (ACHSS), International Olympic Committee (IOC) Research Centre, Amsterdam UMC, Amsterdam, The Netherlands
7. Department of Orthopaedic & Trauma Surgery, Flinders Medical Centre, Flinders University, Adelaide, SA, Australia
8. Roth McFarlane Hand and Upper Limb Centre, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada
9. Department of Orthopedic Surgery, Montpellier University Medical Centre, Lapeyronie Hospital, University of Montpellier, Montpellier, France

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ABSTRACT

Introduction: Shoulder instability is a common injury, with a reported incidence of 23.9 per 100,000 person-years. There is still an ongoing debate on the most effective treatment strategy. Non-operative treatment has recurrence rates of up to 60%, whereas operative treatments such as the Bankart repair and bone block procedures show lower recurrence rates (16% and 2%, respectively) but higher complication rates (<2% and up to 30%, respectively). Methods to determine risk of recurrence have been developed, however patient-specific decision-making tools are still lacking. Artificial Intelligence (AI) and machine learning algorithms use self-learning complex models that can be used to make patient-specific decision-making tools. The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice –as an online prediction tool– to estimate recurrence rates following a Bankart repair.

Methods and analysis: This is a multicentre retrospective cohort study. Patients with traumatic anterior shoulder dislocations that were treated with an arthroscopic Bankart repair without remplissage will be included. This study includes two parts. Part one, collecting all potential factors influencing the recurrence rate following an arthroscopic Bankart repair in patients using multicentre data, aiming to include data from >1000 patients worldwide. Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. Recurrence will be the primary outcome measure.

Ethics and dissemination: For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation "Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies." The study results will be disseminated through publication in a peer-reviewed journal. No IRB is required for this study.

Trial registration: This study does not require a trial registration

STRENGTHS AND LIMITATIONS

- Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data from over 1000 patients.
- Retrospective studies are less suitable to train machine learning algorithms than prospective studies due to missing data through incomplete record keeping and possible confounding factors.
- Studies with different designs will be included. By combining data gathered by different studies to create one database, definitions may differ and therefore make it impossible to pool some of the data.

INTRODUCTION

Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per 100,000 person-years.[1] Shoulder dislocations limit patients in their daily routine and participation in sports, cause irreversible damage to the shoulder joint and are associated with high costs.[2, 3] There is an ongoing debate on the most effective treatment strategy to prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone block procedures have lower recurrence rates (16% and 2%, respectively).[4, 5] However, the complication rates for bone block procedures compared to arthroscopic labrum repair (up to 30% and <2%, respectively) are higher and therefore pre-operative counselling with determination of the most suitable treatment is important in avoiding unnecessary risk of complications.[6, 7] Methods to determine risk of recurrence have been developed, including the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version, inclination), an off-track Hill-Sachs lesion and translation of the humeral head.[8-12] However, a patient-specific decision-making tool is still lacking.

The self-learning complex models used by Artificial Intelligence (AI) and Machine Learning algorithms express high levels of intelligence without human error and are therefore highly suitable to be used for interpretation of images, pathology slides and patient-specific decision-making tool.[13-17] Hendrickx and colleagues recently developed a prediction model based on machine learning algorithms to estimate acute and late complications after intramedullary nailing of a tibial shaft fracture.[16] In other words, the authors were able to use the computationally intensive methods of machine learning, to go from the 'traditionally' reported overall complication rate of a cohort to calculate the probability of a specific patient complication rate. This study resulted in an online prediction tool.

Aim and objectives

The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice – as an online prediction tool – to estimate

recurrence rates following a Bankart repair. No studies have yet been published applying machine learning algorithms to systematically reviewed/collected data in this field.

METHODS AND ANALYSIS

Study design

This multicentre retrospective cohort study includes two parts.

Part one – Collecting Data

Part one involves collecting all potential factors influencing the recurrence rate following an arthroscopic Bankart repair without remplissage in patients using multicentre data. Authors who will contribute to data contribution will be included in the Machine Learning Consortium, aiming to include data from over 1000 patients all over the world. To make a reliable algorithm, it is estimated that the data should include 100 recurrences. With a recurrence rate of 12% following arthroscopic Bankart repairs, it was estimated that a minimum of 1000 patients would be sufficient.[18] To identify relevant studies, a systematic approach was used searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley, Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of Science/Clarivate according to the search terms used in Verweij *et al*. (see Supplemental appendix 1 for the search strategy) from inception up to July 2021. [19] The systematic review by Verweij *et al.* is completed and submitted for publication separately. All studies reporting on risk factors for recurrence following Bankart repairs were included. Studies published in languages other than English, Dutch and French were excluded. The inclusion criteria are patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as either a complete dislocation or subluxation.[20] Exclusion criteria include patients who have undergone previous stabilization procedures or other surgical procedures to the ipsilateral shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or voluntary habitual instability.

Part two – Machine Learning

Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. The statistician that performs the machine learning analysis will be blinded to the origin of the data.

Training Data & Test Data

Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium Database will be randomly allocated to the training dataset and 20% to the test dataset.

Output variables

Each Machine Learning Algorithm will be trained to recognize patterns related to recurrence rates.

Input Variables

For the primary outcome, a Random-Forest algorithm will be used to identify the variables with the highest predictive value from all available data points in the Machine Learning Consortium Database. The data points available include demographics (age, sex), patient specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix 2 for the complete list of factors that will be collected from the electronic medical records).

Algorithms to be trained

It is not possible to know what Machine Learning algorithm will be most suitable to calculate recurrence following an arthroscopic Bankart repair.[21] However, based on previous studies, the following algorithms will be tested as prediction models for recurrence rates: Decision Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine; Logistic Regression.[16, 22-27]

Training and Testing of the algorithms

For each ML algorithm, ten-fold cross validation will be repeated three times on the training dataset (80%), to train the algorithms in recognizing patterns related to recurrence following an arthroscopic Bankart repair, and to subsequently assess their predictive performance based on the following performance characteristics: Area under the ROC-curve, calibration (calibration slope, calibration intercept) and Brier score will be calculated.[28] The model's predicted probability is plotted against the actual observed probability to calculate calibration of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.[29] The overall performance of the model will be assessed with the Brier-score. A perfect Brier score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of 1.[28] The remaining 20% of the data will be used as a test-set to assess the performance of the best performing machine learning algorithms based on "unseen" data. The technical appendix, statistical code, and dataset will be published.

External validation of the best performing algorithm

Before incorporation into an online open access decision-making tool, the best performing algorithm will be externally validated in a prospective database. The same performance metrics will be calculated as described above.

Open-access clinical prediction tool

An open-access clinical prediction tool will be developed using the best performing algorithm.

Patients and public involvement

Patients and the public were not involved in the making of this protocol.

Current Status

Currently, the study is at the finishing stage of collection data from global databases. Re-evaluation of the data using machine learning algorithms to predict outcomes will start in March 2022. The expected time of completion is by the end of 2022.

ETHICS AND DISSEMINATION

For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation "Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies." [30] The study results will be disseminated through publication in a peer-reviewed journal. No IRB is required for this study.

DISCUSSION

Operative treatment significantly reduces the risk of recurrent shoulder instability compared to non-operative treatment.[31] Patients with first-time dislocations who receive operative treatment are most often treated with labrum repair.[31] Risk factors associated with failure of an arthroscopic Bankart repair include young age (≤30 years), participation in competitive sports, multiple preoperative dislocations, > 6 months surgical delay from first-time dislocation to surgery, ISIS > 3 and associated lesions (Hill-Sachs, glenoid bone loss and ALPSA). [32] It is impossible to take all these risk factors into account and make an objective decision on what treatment is most suitable. Several prediction tools have been developed to help counselling patients, however these tools only provide an indicative overall score and are not patient specific.[8-12] Artificial Intelligence (AI) and machine learning algorithms have shown potential to make a patient-specific decision tool.[16] Creating an online prediction tool for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting patients who benefit from this procedure. Patients with a first-time anterior shoulder dislocations receive proper evidence-based information only in 29% of the cases.[33] An online prediction tool might elevate these numbers and makes it possible for shared decision making based on objective measures.

The strength of this study is the great amount of data that will be gathered. Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data of >1000 patients. This study does have the limitation of being retrospective and therefore the study is dependent on the recordkeeping of each individual hospital. This may lead to a variance in listed variables per database, resulting in missing data. In addition, blinding of participants and personnel may have been addressed differently in every institute. Moreover, only risk factors that were identified in literature were included.

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AUTHORS CONTRIBUTION

Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E. Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception and design of the methods section, primarily focussing on the machine learning section and data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the design of the methods section and primarily focussed on how the data should be collected and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this version of the protocol and gave final approval for it to be published. All authors ensure that questions related to the accuracy or integrity of any part of this protocol are appropriately investigated and resolved.

CONFLICTS OF INTEREST

Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant for ConMed Linvatec. Dr. L. Lafosse is a consultant for Depuy Stryker, received royalties from Depuy. Dr. T. Lafosse is consultant for Depuy Mitek and Stryker. Dr. G.A. Buijze received consultancy fees from Depuy-Synthes and Research Funds from SECEC, Vivalto Santé. The remaining authors certify that neither he or she has funding or commercial associations that might pose a conflict of interest in connection with the submitted article.

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33. Hutyra CA, Streufert B, Politzer CS, et al. Assessing the Effectiveness of Evidence-Based Medicine in Practice: A Case Study of First-Time Anterior Shoulder Dislocations. *J Bone Joint Surg Am* 2019; 101: e6. 2019/01/18. DOI: 10.2106/JBJS.17.01588.

SUPPLEMENTARY 1 Search strategy

PubMed

#17	Search: **#14 AND #15 AND #16** Sort by: **Most Recent**	1,768
#16	Search: **((("Recurrence"[Mesh] OR recurr*[tiab] OR relaps*[tiab] OR recrudesc*[tiab] OR repeat*[tiab]) AND ("Joint Dislocations"[Mesh] OR dislocat*[tiab] OR luxat*[tiab] OR instabilit*[tiab])) OR risk*[tiab] OR lesion*[tiab] OR (hill[tiab] AND sachs[tiab]) OR injur*[tiab] OR Perthes[tiab] OR ALPSA[tiab] OR (anterior[tiab] AND (labro[tiab] OR labral[tiab]) AND periosteal[tiab] AND sleeve[tiab] AND avulsion*[tiab]) OR HAGL[tiab] OR (humeral[tiab] AND avulsion*[tiab] AND glenohumeral[tiab] AND ligament*[tiab]) OR (greater[tiab] AND tuberosity[tiab]) OR fracture*[tiab] OR "Fractures, Bone"[Mesh] OR "Rotator Cuff"[Mesh] OR (rotator[tiab] AND cuff[tiab]) OR tear*[tiab] OR age[tiab] OR sport*[tiab] OR laxity[tiab] OR (glenoid[tiab] AND bone[tiab] AND loss[tiab]))** Sort by: **Most Recent**	5,603,913
#15	Search: **(Bankart[tiab] OR "Bankart Lesions/surgery"[Mesh] OR arthroscopic stabilization[tiab] OR arthroscopic stabilisation[tiab] OR labral repair[tiab])** Sort by: **Most Recent**	2,300
#14	Search: **("Shoulder Dislocation"[Mesh] OR "Shoulder"[Mesh] OR "Shoulder Joint"[Mesh] OR shoulder*[tiab] OR glenohumeral[tiab])** Sort by: **Most Recent**	82,527

Embase/Ovid

1	exp shoulder dislocation/	6512
2	exp shoulder/	83055
3	(shoulder* or glenohumeral).ti,ab,kw.	101743
4	1 or 2 or 3	138684
5	(Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair).ti,ab,kw.	2813
6	Bankart lesion/su [Surgery]	198
7	5 or 6	2862
8	(recurr* or relaps* or recrudesc* or repeat*).ti,ab,kw.	1930525
9	exp joint dislocation/	4059

10	(dislocat*or luxat* or instabilit*).ti,ab,kw.	154727
11	9 or 10	158430
12	8 and 11	19548
13	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)).ti,ab,kw.	8234845
14	exp fracture/	336756
15	exp rotator cuff/	8999
16	12 or 13 or 14 or 15	8303779
17	4 and 7 and 16	2119

Cochrane Database of Systematic Reviews & Cochrane Central Register of Controlled Trials

#1	MeSH descriptor: [Shoulder Dislocation] explode all trees	143
#2	MeSH descriptor: [Shoulder] explode all trees	537
#3	MeSH descriptor: [Shoulder Joint] explode all trees	745
#4	(shoulder* or glenohumeral):ti,ab,kw	11763
#5	#1 OR #2 OR #3 OR #4	11763
#6	MeSH descriptor: [Bankart Lesions] explode all trees and with qualifier(s): [surgery - SU]	3
#7	(Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair):ti,ab,kw	238
#8	#6 OR #7	238
#9	MeSH descriptor: [Recurrence] explode all trees	12084
#10	(recurr* or relaps* or recrudesc* or repeat*):ti,ab,kw	159845
#11	#9 OR #10	159894
#12	MeSH descriptor: [Joint Dislocations] explode all trees	687
#13	(dislocat*or luxat* or instabilit*):ti,ab,kw	5839
#14	#12 OR #13	6413

#15	#11 AND #14	1018
#16	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)):ti,ab,kw	549185
#17	MeSH descriptor: [Fractures, Bone] explode all trees	6053
#18	MeSH descriptor: [Rotator Cuff] explode all trees	344
#19	#15 OR #16 OR #17 OR #18	549508
#20	#5 AND #8 AND #19	145

CINAHL/Ebsco

S18	S3 AND S6 AND S17	729
S17	S13 OR S14 OR S15 OR S16	1,482,038
S16	(MH "Rotator Cuff+")	3,063
S15	(MH "Fractures+")	58,529
S14	(TI (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss))) OR (AB (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss)))	1,469,860
S13	S9 AND S12	4,294
S12	S10 OR S11	33,871
S11	(TI (dislocat* OR luxat* OR instabilit*)) OR (AB (dislocat* OR luxat* OR instabilit*))	31,033
S10	(MH "Dislocations+")	8,266
S9	S7 OR S8	231,945

S8	(TI (recurr* OR relaps* OR recrudesc* OR repeat*)) OR (AB (recurr* OR relaps* OR recrudesc* OR repeat*))	212,296
S7	(MH "Recurrence")	48,901
S6	S4 OR S5	1,126
S5	(TI (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair)) OR (AB (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair))	1,123
S4	(MH "Bankart Lesions/SU")	58
S3	S1 OR S2	30,919
S2	(Ti (shoulder* OR glenohumeral)) OR (AB (shoulder* OR glenohumeral))	28,334
S1	(MH "Shoulder") OR (MH "Shoulder Dislocation") OR (MH "Shoulder Joint+")	12,823

Web of Science/Clarative

TOPIC: (shoulder* OR glenohumeral) AND (Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair) AND (((recurr* or relaps* or recrudesc* or repeat*) AND (dislocat*or luxat* or instabilit*)) OR risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss))

Database	Before deduplication	After deduplication
PubMed	1768	1762
Embase	2119	580
Cochrane Database of Systematic Reviews	1	0
Cochrane Central Register of Controlled Trials	143	51
CINAHL	729	55
Web of science	2578	1136

Total	7338	3584

SUPPLEMENTARY 2

We collect the following potential risk factors from the electronic medical records:

- Gender (male/female)
- Age at time of operation (years)
- Preoperative BMI
- ASA classification at time of operation (1-4)
- Epilepsy (yes/no)
- Hyperlaxity (Beighton score < 4 or ≥ 4)
- Affected side (right/left/bilateral)
- Side of operation (right/left/bilateral)
- Dominance (right/left/both)
- Daily smoking at time of operation (yes or no)
- Number of pre-operative dislocations
- Duration of follow-up (years)
- Bony lesions
  - Bony Bankart lesion (yes/no)
  - Hill-Sachs lesion
    - Yes/no
    - Off-track yes/no
  - Greater Tuberosity Fracture (yes/no)
  - Glenoid bone loss (<20%, ≥20%)
- Soft tissue lesions
  - Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
  - Superior labrum anterior and posterior (SLAP) lesion (yes/no)
  - inferior glenohumeral ligament (IGHL) (yes/no)
  - Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
  - Perthes lesion (yes/no)

- Glenolabral articular disruption (GLAD) lesion (yes/no)
- Full thickness Rotator Cuff Tear (yes/no)
- Partial thickness Rotator Cuff Tear (yes/no)

o Nerve Palsy (yes/no)

o Surgical Characteristics:

- o Side (right/left/bilateral)
- o Time from injury to surgery (months)
- o Time to surgery from hospital admission (days)
- o Surgeon level (Surgeon/Resident/Fellow)

TRIPOD Checklist: Prediction Model Development

Section/Topic	Item	Checklist Item	Page
Title and abstract			
Title	1	Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted.	1
Abstract	2	Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions.	3
Introduction			
Background and objectives	3a	Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models.	5
	3b	Specify the objectives, including whether the study describes the development or validation of the model or both.	7,8
Methods			
Source of data	4a	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.	7,8,9
	4b	Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up.	7,8,9
Participants	5a	Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres.	7
	5b	Describe eligibility criteria for participants.	7
	5c	Give details of treatments received, if relevant.	7
Outcome	6a	Clearly define the outcome that is predicted by the prediction model, including how and when assessed.	7,8,9
	6b	Report any actions to blind assessment of the outcome to be predicted.	N/A
Predictors	7a	Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured.	8
	7b	Report any actions to blind assessment of predictors for the outcome and other predictors.	N/A
Sample size	8	Explain how the study size was arrived at.	N/A
Missing data	9	Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method.	N/A
Statistical analysis methods	10a	Describe how predictors were handled in the analyses.	7,8,9
	10b	Specify type of model, all model-building procedures (including any predictor selection), and method for internal validation.	7,8,9
	10d	Specify all measures used to assess model performance and, if relevant, to compare multiple models.	7,8,9
Risk groups	11	Provide details on how risk groups were created, if done.	N/A
Results			
Participants	13a	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.	7,8,9
	13b	Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome.	7
Model development	14a	Specify the number of participants and outcome events in each analysis.	N/A
	14b	If done, report the unadjusted association between each candidate predictor and outcome.	N/A
Model specification	15a	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).	7,8,9
	15b	Explain how to the use the prediction model.	9
Model performance	16	Report performance measures (with CIs) for the prediction model.	8,9
Discussion			
Limitations	18	Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data).	11
Interpretation	19b	Give an overall interpretation of the results, considering objectives, limitations, and results from similar studies, and other relevant evidence.	11
Implications	20	Discuss the potential clinical use of the model and implications for future research.	5, 11
Other information			
Supplementary information	21	Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets.	7,8,9
Funding	22	Give the source of funding and the role of the funders for the present study.	12

We recommend using the TRIPOD Checklist in conjunction with the TRIPOD Explanation and Elaboration document.

BMJ Open

Development and Training of a Machine Learning Algorithm to Identify Patients at Risk for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a Retrospective, Multicentre, Cohort Study

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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Surgery
Keywords:	Adult orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY, Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY

Title: Development and Training of a Machine Learning Algorithm to Identify Patients at Risk for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a Retrospective, Multicentre, Cohort Study

Corresponding author:

Full name: Sanne Hendrikje van Spanning

Postal address: Onze Lieve Vrouwe Gasthuis (OLVG) Hospital, Oosterpark 9, 1091 AC Amsterdam, The Netherlands

Email: s.h.vanspanning@olvg.nl

Authors:

Sanne H. **van Spanning**[1,2,3]; Lukas P.E. **Verweij**[4,5,6]; Laurens J.H. **Allaart**[2,3]; Laurent A.M. **Hendrickx**[4,5,7]; Job N. **Doornberg**[7]; George S. **Athwal**[8]; Thibault **Lafosse**[2]; Laurent **Lafosse**[2]; Michel P.J **van den Bekerom**[1,3]; Geert Alexander **Buijze**[2,4,9] on behalf of the Machine Learning Consortium

Affiliations

1. Shoulder and Elbow Unit, Joint Research, Department of Orthopaedic Surgery, OLVG, Amsterdam, The Netherlands
2. Department of Orthopedic Surgery, Clinique Générale Annecy, Annecy, France
3. Department of Human Movement Sciences, Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam Movement Sciences, Amsterdam, the Netherlands
4. Department of Orthopedic Surgery, Amsterdam Movement Sciences, Amsterdam UMC, location AMC, University of Amsterdam, Amsterdam, The Netherlands.
5. Academic Centre for Evidence-based Sports Medicine (ACES), Amsterdam UMC, Amsterdam, The Netherlands

6. Amsterdam Collaboration for Health and Safety in Sports (ACHSS), International Olympic Committee (IOC) Research Centre, Amsterdam UMC, Amsterdam, The Netherlands
7. Department of Orthopaedic & Trauma Surgery, Flinders Medical Centre, Flinders University, Adelaide, SA, Australia
8. Roth McFarlane Hand and Upper Limb Centre, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada
9. Department of Orthopedic Surgery, Montpellier University Medical Centre, Lapeyronie Hospital, University of Montpellier, Montpellier, France

Word count: 1543**, Abstract:** 293

Keywords: Shoulder instability, dislocation, recurrence, Bankart, Machine Learning Algorithm, Artificial Intelligence

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ABSTRACT

Introduction: Shoulder instability is a common injury, with a reported incidence of 23.9 per 100,000 person-years. There is still an ongoing debate on the most effective treatment strategy. Non-operative treatment has recurrence rates of up to 60%, whereas operative treatments such as the Bankart repair and bone block procedures show lower recurrence rates (16% and 2%, respectively) but higher complication rates (<2% and up to 30%, respectively). Methods to determine risk of recurrence have been developed, however patient-specific decision-making tools are still lacking. Artificial Intelligence (AI) and machine learning algorithms use self-learning complex models that can be used to make patient-specific decision-making tools. The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice –as an online prediction tool– to estimate recurrence rates following a Bankart repair.

Methods and analysis: This is a multicentre retrospective cohort study. Patients with traumatic anterior shoulder dislocations that were treated with an arthroscopic Bankart repair without remplissage will be included. This study includes two parts. Part one, collecting all potential factors influencing the recurrence rate following an arthroscopic Bankart repair in patients using multicentre data, aiming to include data from >1000 patients worldwide. Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. Recurrence will be the primary outcome measure.

Ethics and dissemination: For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation "Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies." The study results will be disseminated through publication in a peer-reviewed journal. No IRB is required for this study.

Trial registration: This study does not require a trial registration

STRENGTHS AND LIMITATIONS

- Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data from over 1000 patients.
- Retrospective studies are less suitable to train machine learning algorithms than prospective studies due to missing data through incomplete record keeping and possible confounding factors.
- Studies with different designs will be included. By combining data gathered by different studies to create one database, definitions may differ and therefore make it impossible to pool some of the data.
- Due to the collection of individual patient data by previously published studies, variation in definitions may cause a significant source of bias.

INTRODUCTION

Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per 100,000 person-years.[1] Shoulder dislocations limit patients in their daily routine and participation in sports, cause irreversible damage to the shoulder joint and are associated with high costs.[2, 3] There is an ongoing debate on the most effective treatment strategy to prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone block procedures have lower recurrence rates (16% and 2%, respectively).[4, 5] However, the complication rates for bone block procedures compared to arthroscopic labrum repair (up to 30% and <2%, respectively) are higher and therefore pre-operative counselling with determination of the most suitable treatment is important in avoiding unnecessary risk of complications.[6, 7] Methods to determine risk of recurrence have been developed, including the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version, inclination), an off-track Hill-Sachs lesion and translation of the humeral head.[8-12] However, a patient-specific decision-making tool is still lacking.

The self-learning complex models used by Artificial Intelligence (AI) and Machine Learning algorithms express high levels of intelligence without human error and are therefore highly suitable to be used for interpretation of images, pathology slides and patient-specific decision-making tool.[13-17] Hendrickx and colleagues recently developed a prediction model based on machine learning algorithms to estimate acute and late complications after intramedullary nailing of a tibial shaft fracture.[16] In other words, the authors were able to use the computationally intensive methods of machine learning, to go from the 'traditionally' reported overall complication rate of a cohort to calculate the probability of a specific patient complication rate. This study resulted in an online prediction tool.

Aim and objectives

The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice – as an online prediction tool – to estimate

recurrence rates following a Bankart repair. No studies have yet been published applying machine learning algorithms to systematically reviewed/collected data in this field.

METHODS AND ANALYSIS

Study design

This multicentre retrospective cohort study includes two parts.

Part one – Collecting Data

Part one involves collecting individual patient data of published studies that evaluated potential factors predisposing recurrence following an arthroscopic Bankart repair without remplissage. The authors of these studies will be contacted by email and will be included in the Machine Learning Consortium when they provide the original patient data of their cohort. Through this process, we aim to combine the individual patient data from the published studies and create an international cohort of over 1000 patients. The current study will use the collected patient data to create a machine learning algorithm that can estimate the probability of recurrence for an individual patient. To make a reliable algorithm, it is estimated that the data should include at least 100 recurrences. With a recurrence rate of 12% following arthroscopic Bankart repairs, it was estimated that a minimum of 1000 patients would be sufficient.[18] To identify relevant studies, a systematic approach was used searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley, Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of Science/Clarivate according to the search terms used in Verweij *et al*. (see Supplemental appendix 1 for the search strategy) from inception up to July 2021. [19] The systematic review by Verweij *et al.* is completed and submitted for publication separately. All studies reporting on risk factors for recurrence following Bankart repairs were included. Studies published in languages other than English, Dutch and French were excluded. The inclusion criteria are patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as either a complete dislocation or subluxation.[20] Exclusion criteria include patients who have undergone previous stabilization procedures or other surgical procedures to the ipsilateral shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or voluntary habitual instability.

Part two – Machine Learning

Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. The statistician that performs the machine learning analysis will be blinded to the origin of the data.

Training Data & Test Data

Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium Database will be randomly allocated to the training dataset and 20% to the test dataset.

Output variables

Each Machine Learning Algorithm will be trained to recognize patterns related to recurrence rates.

Input Variables

For the primary outcome, a Random-Forest algorithm will be used to identify the variables with the highest predictive value from all available data points in the Machine Learning Consortium Database. The data points available include demographics (age, sex), patient specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix 2 for the complete list of factors that will be collected from the electronic medical records).

Algorithms to be trained

It is not possible to know what Machine Learning algorithm will be most suitable to calculate recurrence following an arthroscopic Bankart repair.[21] However, based on previous studies, the following algorithms will be tested as prediction models for recurrence rates: Decision Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine; Logistic Regression.[16, 22-27]

Training and Testing of the algorithms

For each ML algorithm, ten-fold cross validation will be repeated three times on the training dataset (80%), to train the algorithms in recognizing patterns related to recurrence following an arthroscopic Bankart repair, and to subsequently assess their predictive performance based on the following performance characteristics: Area under the ROC-curve, calibration (calibration slope, calibration intercept) and Brier score will be calculated.[28] The model's predicted probability is plotted against the actual observed probability to calculate calibration of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.[29] The overall performance of the model will be assessed with the Brier-score. A perfect Brier score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of 1.[28] The remaining 20% of the data will be used as a test-set to assess the performance of the best performing machine learning algorithms based on "unseen" data. The technical appendix, statistical code, and dataset will be published.

External validation of the best performing algorithm

Before incorporation into an online open access decision-making tool, the best performing algorithm will be externally validated in a prospective database. The same performance metrics will be calculated as described above.

Open-access clinical prediction tool

An open-access clinical prediction tool will be developed using the best performing algorithm.

Patients and public involvement

198 Patients and the public were not involved in the making of this protocol.

Current Status

Currently, the study is at the finishing stage of collection data from global databases. Re-evaluation of the data using machine learning algorithms to predict outcomes will start in March 2022. The expected time of completion is by the end of 2022.

205 **ETHICS AND DISSEMINATION**

206 For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation "Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies."[30] The study results will be disseminated through publication in a peer-reviewed journal. No IRB is required for this study.

DISCUSSION

Operative treatment significantly reduces the risk of recurrent shoulder instability compared to non-operative treatment.[31] Patients with first-time dislocations who receive operative treatment are most often treated with labrum repair.[31] Risk factors associated with failure of an arthroscopic Bankart repair include young age (≤30 years), participation in competitive sports, multiple preoperative dislocations, > 6 months surgical delay from first-time dislocation to surgery, ISIS > 3 and associated lesions (Hill-Sachs, glenoid bone loss and ALPSA). [32] It is impossible to take all these risk factors into account and make an objective decision on what treatment is most suitable. Several prediction tools have been developed to help counselling patients, however these tools only provide an indicative overall score and are not patient specific.[8-12] Artificial Intelligence (AI) and machine learning algorithms have shown potential to make a patient-specific decision tool.[16] Creating an online prediction tool for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting patients who benefit from this procedure. Patients with a first-time anterior shoulder dislocations receive proper evidence-based information only in 29% of the cases.[33] An online prediction tool might elevate these numbers and makes it possible for shared decision making based on objective measures.

The strength of this study is the great amount of data that will be gathered. Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data of >1000 patients. This study does have the limitation of being retrospective and therefore the study is dependent on the recordkeeping of each individual hospital. This may lead to a variance in listed variables per database, resulting in missing data. In addition, blinding of participants and personnel may have been addressed differently in every institute. Moreover, only risk factors that were identified in literature were included.

Funding

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AUTHORS CONTRIBUTION

Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E. Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception and design of the methods section, primarily focussing on the machine learning section and data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the design of the methods section and primarily focussed on how the data should be collected and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this version of the protocol and gave final approval for it to be published. All authors ensure that questions related to the accuracy or integrity of any part of this protocol are appropriately investigated and resolved.

CONFLICTS OF INTEREST

Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant for ConMed Linvatec. Dr. L. Lafosse is a consultant for Depuy Stryker, received royalties from Depuy. Dr. T. Lafosse is consultant for Depuy Mitek and Stryker. Dr. G.A. Buijze received consultancy fees from Depuy-Synthes and Research Funds from SECEC, Vivalto Santé. The remaining authors certify that neither he or she has funding or commercial associations that might pose a conflict of interest in connection with the submitted article.

References

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SUPPLEMENTARY 1 Search strategy

PubMed

#17	Search: **#14 AND #15 AND #16** Sort by: **Most Recent**	1,768
#16	Search: **((("Recurrence"[Mesh] OR recurr*[tiab] OR relaps*[tiab] OR recrudesc*[tiab] OR repeat*[tiab]) AND ("Joint Dislocations"[Mesh] OR dislocat*[tiab] OR luxat*[tiab] OR instabilit*[tiab])) OR risk*[tiab] OR lesion*[tiab] OR (hill[tiab] AND sachs[tiab]) OR injur*[tiab] OR Perthes[tiab] OR ALPSA[tiab] OR (anterior[tiab] AND (labro[tiab] OR labral[tiab]) AND periosteal[tiab] AND sleeve[tiab] AND avulsion*[tiab]) OR HAGL[tiab] OR (humeral[tiab] AND avulsion*[tiab] AND glenohumeral[tiab] AND ligament*[tiab]) OR (greater[tiab] AND tuberosity[tiab]) OR fracture*[tiab] OR "Fractures, Bone"[Mesh] OR "Rotator Cuff"[Mesh] OR (rotator[tiab] AND cuff[tiab]) OR tear*[tiab] OR age[tiab] OR sport*[tiab] OR laxity[tiab] OR (glenoid[tiab] AND bone[tiab] AND loss[tiab]))** Sort by: **Most Recent**	5,603,913
#15	Search: **(Bankart[tiab] OR "Bankart Lesions/surgery"[Mesh] OR arthroscopic stabilization[tiab] OR arthroscopic stabilisation[tiab] OR labral repair[tiab])** Sort by: **Most Recent**	2,300
#14	Search: **("Shoulder Dislocation"[Mesh] OR "Shoulder"[Mesh] OR "Shoulder Joint"[Mesh] OR shoulder*[tiab] OR glenohumeral[tiab])** Sort by: **Most Recent**	82,527

Embase/Ovid

1	exp shoulder dislocation/	6512
2	exp shoulder/	83055
3	(shoulder* or glenohumeral).ti,ab,kw.	101743
4	1 or 2 or 3	138684
5	(Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair).ti,ab,kw.	2813
6	Bankart lesion/su [Surgery]	198
7	5 or 6	2862
8	(recurr* or relaps* or recrudesc* or repeat*).ti,ab,kw.	1930525
9	exp joint dislocation/	4059

10	(dislocat*or luxat* or instabilit*).ti,ab,kw.	154727
11	9 or 10	158430
12	8 and 11	19548
13	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)).ti,ab,kw.	8234845
14	exp fracture/	336756
15	exp rotator cuff/	8999
16	12 or 13 or 14 or 15	8303779
17	4 and 7 and 16	2119

Cochrane Database of Systematic Reviews & Cochrane Central Register of Controlled Trials

#1	MeSH descriptor: [Shoulder Dislocation] explode all trees	143
#2	MeSH descriptor: [Shoulder] explode all trees	537
#3	MeSH descriptor: [Shoulder Joint] explode all trees	745
#4	(shoulder* or glenohumeral):ti,ab,kw	11763
#5	#1 OR #2 OR #3 OR #4	11763
#6	MeSH descriptor: [Bankart Lesions] explode all trees and with qualifier(s): [surgery - SU]	3
#7	(Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair):ti,ab,kw	238
#8	#6 OR #7	238
#9	MeSH descriptor: [Recurrence] explode all trees	12084
#10	(recurr* or relaps* or recrudesc* or repeat*):ti,ab,kw	159845
#11	#9 OR #10	159894
#12	MeSH descriptor: [Joint Dislocations] explode all trees	687
#13	(dislocat*or luxat* or instabilit*):ti,ab,kw	5839
#14	#12 OR #13	6413

#15	#11 AND #14	1018
#16	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)):ti,ab,kw	549185
#17	MeSH descriptor: [Fractures, Bone] explode all trees	6053
#18	MeSH descriptor: [Rotator Cuff] explode all trees	344
#19	#15 OR #16 OR #17 OR #18	549508
#20	#5 AND #8 AND #19	145

CINAHL/Ebsco

S18	S3 AND S6 AND S17	729
S17	S13 OR S14 OR S15 OR S16	1,482,038
S16	(MH "Rotator Cuff+")	3,063
S15	(MH "Fractures+")	58,529
S14	(TI (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss))) OR (AB (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss)))	1,469,860
S13	S9 AND S12	4,294
S12	S10 OR S11	33,871
S11	(TI (dislocat* OR luxat* OR instabilit*)) OR (AB (dislocat* OR luxat* OR instabilit*))	31,033
S10	(MH "Dislocations+")	8,266
S9	S7 OR S8	231,945

S8	(TI (recurr* OR relaps* OR recrudesc* OR repeat*)) OR (AB (recurr* OR relaps* OR recrudesc* OR repeat*))	212,296
S7	(MH "Recurrence")	48,901
S6	S4 OR S5	1,126
S5	(TI (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair)) OR (AB (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair))	1,123
S4	(MH "Bankart Lesions/SU")	58
S3	S1 OR S2	30,919
S2	(Ti (shoulder* OR glenohumeral)) OR (AB (shoulder* OR glenohumeral))	28,334
S1	(MH "Shoulder") OR (MH "Shoulder Dislocation") OR (MH "Shoulder Joint+")	12,823

Web of Science/Clarative

TOPIC: (shoulder* OR glenohumeral) AND (Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair) AND (((recurr* or relaps* or recrudesc* or repeat*) AND (dislocat*or luxat* or instabilit*)) OR risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss))

Database	Before deduplication	After deduplication
PubMed	1768	1762
Embase	2119	580
Cochrane Database of Systematic Reviews	1	0
Cochrane Central Register of Controlled Trials	143	51
CINAHL	729	55
Web of science	2578	1136

Total	7338	3584

SUPPLEMENTARY 2

The manuscript's authors will collect the following potential risk factors from the databases provided by authors of the Machine Learning Collaboration:

- Gender (male/female)
- Age at time of operation (years)
- Preoperative BMI
- ASA classification at time of operation (1-4)
- Epilepsy (yes/no)
- Hyperlaxity (Beighton score < 4 or ≥ 4)
- Affected side (right/left/bilateral)
- Side of operation (right/left/bilateral)
- Dominance (right/left/both)
- Daily smoking at time of operation (yes or no)
- Number of pre-operative dislocations
- Duration of follow-up (years)
- Bony lesions
  - Bony Bankart lesion (yes/no)
  - Hill-Sachs lesion
    - Yes/no
    - Off-track yes/no
  - Greater Tuberosity Fracture (yes/no)
  - Glenoid bone loss (<20%, ≥20%)
- Soft tissue lesions
  - Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
  - Superior labrum anterior and posterior (SLAP) lesion (yes/no)
  - inferior glenohumeral ligament (IGHL) (yes/no)
  - Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)

    - Perthes lesion (yes/no)
    - Glenolabral articular disruption (GLAD) lesion (yes/no)
    - Full thickness Rotator Cuff Tear (yes/no)
    - Partial thickness Rotator Cuff Tear (yes/no)
- Nerve Palsy (yes/no)
- Surgical Characteristics:
    - Side (right/left/bilateral)
    - Time from injury to surgery (months)
    - Time to surgery from hospital admission (days)
    - Surgeon level (Surgeon/Resident/Fellow)

BMJ Open

Development and Training of a Machine Learning Algorithm to Identify Patients at Risk for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a Retrospective, Multicentre, Cohort Study

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Complete List of Authors:	Spanning, Sanne; OLVG, Orthopaedic Surgery; Clinique Générale Annecy, Orthopaedic Surgery Verweij, Lukas; Amsterdam UMC Locatie AMC, Orthopedic Surgery, Amsterdam Movement Sciences, ; Amsterdam UMC Locatie AMC, Academic Center for Evidence-based Sports Medicine (ACES) Allaart, Laurens; Vrije Universiteit Amsterdam, Department of Human Movement Sciences; Clinique Générale Annecy, Orthopaedic Surgery Hendrickx, Laurent; University of Amsterdam, Department of Orthopedic Surgery; Flinders University, Orthopaedic & Trauma Surgery Doornberg, Job; Flinders University, Orthopaedic Surgery Athwal, George; Schulich School of Medicine and Dentistry, Roth McFarlane Hand and Upper Limb Center Lafosse, Thibault; Clinique Générale Annecy, Orthopaedic Surgery Lafosse, Laurent; Clinique Générale Annecy, Orthopaedic Surgery van den Bekerom, M.P.J.; Vrije Universiteit Amsterdam, Department of Human Movement Sciences; OLVG, Orthopaedic Surgery Buijze, Geert Alexander; Clinique Générale Annecy, Orthopaedic Surgery; University of Montpellier, Montpellier University Medical Center, Department of Orthopedic Surgery

Primary Subject Heading:	Surgery
Secondary Subject Heading:	Surgery
Keywords:	Adult orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY, Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY

Title: Development and Training of a Machine Learning Algorithm to Identify Patients at Risk for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a Retrospective, Multicentre, Cohort Study

Corresponding author:

Full name: Sanne Hendrikje van Spanning

Postal address: Onze Lieve Vrouwe Gasthuis (OLVG) Hospital, Oosterpark 9, 1091 AC Amsterdam, The Netherlands

Email: s.h.vanspanning@olvg.nl

Authors:

Sanne H. **van Spanning**[1,2,3]; Lukas P.E. **Verweij**[4,5,6]; Laurens J.H. **Allaart**[2,3]; Laurent A.M. **Hendrickx**[4,5,7]; Job N. **Doornberg**[7]; George S. **Athwal**[8]; Thibault **Lafosse**[2]; Laurent **Lafosse**[2]; Michel P.J **van den Bekerom**[1,3]; Geert Alexander **Buijze**[2,4,9] on behalf of the Machine Learning Consortium

Affiliations

1. Shoulder and Elbow Unit, Joint Research, Department of Orthopaedic Surgery, OLVG, Amsterdam, The Netherlands
2. Department of Orthopedic Surgery, Clinique Générale Annecy, Annecy, France
3. Department of Human Movement Sciences, Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam Movement Sciences, Amsterdam, the Netherlands
4. Department of Orthopedic Surgery, Amsterdam Movement Sciences, Amsterdam UMC, location AMC, University of Amsterdam, Amsterdam, The Netherlands.
5. Academic Centre for Evidence-based Sports Medicine (ACES), Amsterdam UMC, Amsterdam, The Netherlands

6. Amsterdam Collaboration for Health and Safety in Sports (ACHSS), International Olympic Committee (IOC) Research Centre, Amsterdam UMC, Amsterdam, The Netherlands
7. Department of Orthopaedic & Trauma Surgery, Flinders Medical Centre, Flinders University, Adelaide, SA, Australia
8. Roth McFarlane Hand and Upper Limb Centre, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada
9. Department of Orthopedic Surgery, Montpellier University Medical Centre, Lapeyronie Hospital, University of Montpellier, Montpellier, France

Word count: 1543**, Abstract:** 293

Keywords: Shoulder instability, dislocation, recurrence, Bankart, Machine Learning Algorithm, Artificial Intelligence

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ABSTRACT

Introduction: Shoulder instability is a common injury, with a reported incidence of 23.9 per 100,000 person-years. There is still an ongoing debate on the most effective treatment strategy. Non-operative treatment has recurrence rates of up to 60%, whereas operative treatments such as the Bankart repair and bone block procedures show lower recurrence rates (16% and 2%, respectively) but higher complication rates (<2% and up to 30%, respectively). Methods to determine risk of recurrence have been developed, however patient-specific decision-making tools are still lacking. Artificial Intelligence (AI) and machine learning algorithms use self-learning complex models that can be used to make patient-specific decision-making tools. The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice –as an online prediction tool– to estimate recurrence rates following a Bankart repair.

Methods and analysis: This is a multicentre retrospective cohort study. Patients with traumatic anterior shoulder dislocations that were treated with an arthroscopic Bankart repair without remplissage will be included. This study includes two parts. Part one, collecting all potential factors influencing the recurrence rate following an arthroscopic Bankart repair in patients using multicentre data, aiming to include data from >1000 patients worldwide. Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. Recurrence will be the primary outcome measure.

Ethics and dissemination: For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies.” The study results will be disseminated through publication in a peer-reviewed journal. No IRB is required for this study.

Trial registration: This study does not require a trial registration

STRENGTHS AND LIMITATIONS

- Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data from over 1000 patients.
- Retrospective studies are less suitable to train machine learning algorithms than prospective studies due to missing data through incomplete record keeping and possible confounding factors.
- Studies with different designs will be included. By combining data gathered by different studies to create one database, definitions may differ and therefore make it impossible to pool some of the data.
- Due to the collection of individual patient data by previously published studies, variation in definitions may cause a significant source of bias.

INTRODUCTION

Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per 100,000 person-years.[1] Shoulder dislocations limit patients in their daily routine and participation in sports, cause irreversible damage to the shoulder joint and are associated with high costs.[2, 3] There is an ongoing debate on the most effective treatment strategy to prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone block procedures have lower recurrence rates (16% and 2%, respectively).[4, 5] However, the complication rates for bone block procedures compared to arthroscopic labrum repair (up to 30% and <2%, respectively) are higher and therefore pre-operative counselling with determination of the most suitable treatment is important in avoiding unnecessary risk of complications.[6, 7] Methods to determine risk of recurrence have been developed, including the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version, inclination), an off-track Hill-Sachs lesion and translation of the humeral head.[8-12] However, a patient-specific decision-making tool is still lacking.

The self-learning complex models used by Artificial Intelligence (AI) and Machine Learning algorithms express high levels of intelligence without human error and are therefore highly suitable to be used for interpretation of images, pathology slides and patient-specific decision-making tool.[13-17] Hendrickx and colleagues recently developed a prediction model based on machine learning algorithms to estimate acute and late complications after intramedullary nailing of a tibial shaft fracture.[16] In other words, the authors were able to use the computationally intensive methods of machine learning, to go from the 'traditionally' reported overall complication rate of a cohort to calculate the probability of a specific patient complication rate. This study resulted in an online prediction tool.

Aim and objectives

The aim of the current study is to develop and train a machine learning algorithm to create a prediction model to be used in clinical practice – as an online prediction tool – to estimate

recurrence rates following a Bankart repair. No studies have yet been published applying machine learning algorithms to systematically reviewed/collected data in this field.

METHODS AND ANALYSIS

Study design

This multicentre retrospective cohort study includes two parts.

Part one – Collecting Data

Part one involves collecting individual patient data of published studies that evaluated potential factors predisposing recurrence following an arthroscopic Bankart repair without remplissage. The authors of these studies will be contacted by email and will be included in the Machine Learning Consortium when they provide the original patient data of their cohort. Through this process, we aim to combine the individual patient data from the published studies and create an international cohort of over 1000 patients. The current study will use the collected patient data to create a machine learning algorithm that can estimate the probability of recurrence for an individual patient. To make a reliable algorithm, it is estimated that the data should include at least 100 recurrences. With a recurrence rate of 12% following arthroscopic Bankart repairs, it was estimated that a minimum of 1000 patients would be sufficient.[18] To identify relevant studies, a systematic approach was used searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley, Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of Science/Clarivate according to the search terms used in Verweij *et al*. (see Supplemental appendix 1 for the search strategy) from inception up to July 2021. [19] The systematic review by Verweij *et al.* is completed and submitted for publication separately. All studies reporting on risk factors for recurrence following Bankart repairs were included. Studies published in languages other than English, Dutch and French were excluded. The inclusion criteria are patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as either a complete dislocation or subluxation.[20] Exclusion criteria include patients who have undergone previous stabilization procedures or other surgical procedures to the ipsilateral shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or voluntary habitual instability.

Part two – Machine Learning

Part two, the multicentre data will be re-evaluated (and where applicable complemented) using machine learning algorithms to predict outcomes. The statistician that performs the machine learning analysis will be blinded to the origin of the data.

Training Data & Test Data

Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium Database will be randomly allocated to the training dataset and 20% to the test dataset.

Output variables

Each Machine Learning Algorithm will be trained to recognize patterns related to recurrence rates.

Input Variables

For the primary outcome, a Random-Forest algorithm will be used to identify the variables with the highest predictive value from all available data points in the Machine Learning Consortium Database. The data points available include demographics (age, sex and ethnicity aiming to include >1000 patients with balanced demographics), patient specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix 2 for the complete list of factors that will be collected from the electronic medical records).

Algorithms to be trained

It is not possible to know what Machine Learning algorithm will be most suitable to calculate recurrence following an arthroscopic Bankart repair.[21] However, based on previous studies, the following algorithms will be tested as prediction models for recurrence rates: Decision Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine; Logistic Regression.[16, 22-27]

Training and Testing of the algorithms

For each ML algorithm, ten-fold cross validation will be repeated three times on the training dataset (80%), to train the algorithms in recognizing patterns related to recurrence following an arthroscopic Bankart repair, and to subsequently assess their predictive performance based on the following performance characteristics: Area under the ROC-curve, calibration (calibration slope, calibration intercept) and Brier score will be calculated.[28] The model's predicted probability is plotted against the actual observed probability to calculate calibration of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.[29] The overall performance of the model will be assessed with the Brier-score. A perfect Brier score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of 1.[28] The remaining 20% of the data will be used as a test-set to assess the performance of the best performing machine learning algorithms based on "unseen" data. The technical appendix, statistical code, and dataset will be published.

External validation of the best performing algorithm

Before incorporation into an online open access decision-making tool, the best performing algorithm will be externally validated in a prospective database. The same performance metrics will be calculated as described above.

Open-access clinical prediction tool

An open-access clinical prediction tool will be developed using the best performing algorithm.

Patients and public involvement

Patients and the public were not involved in the making of this protocol.

Current Status

Currently, the study is at the finishing stage of collection data from global databases. Re-evaluation of the data using machine learning algorithms to predict outcomes will start in March 2022. The expected time of completion is by the end of 2022.

ETHICS AND DISSEMINATION

For safe multicentre data exchange and analysis, our Machine Learning Consortium adhered to the World Health Organization (WHO) regulation "Policy on Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public Health Emergencies."[30] The study results will be disseminated through publication in a peer-reviewed journal. No IRB is required for this study.

DISCUSSION

Operative treatment significantly reduces the risk of recurrent shoulder instability compared to non-operative treatment.[31] Patients with first-time dislocations who receive operative treatment are most often treated with labrum repair.[31] Risk factors associated with failure of an arthroscopic Bankart repair include young age (≤30 years), participation in competitive sports, multiple preoperative dislocations, > 6 months surgical delay from first-time dislocation to surgery, ISIS > 3 and associated lesions (Hill-Sachs, glenoid bone loss and ALPSA). [32] It is impossible to take all these risk factors into account and make an objective decision on what treatment is most suitable. Several prediction tools have been developed to help counselling patients, however these tools only provide an indicative overall score and are not patient specific.[8-12] Artificial Intelligence (AI) and machine learning algorithms have shown potential to make a patient-specific decision tool.[16] Creating an online prediction tool for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting patients who benefit from this procedure. Patients with a first-time anterior shoulder dislocations receive proper evidence-based information only in 29% of the cases.[33] An online prediction tool might elevate these numbers and makes it possible for shared decision making based on objective measures.

The strength of this study is the great amount of data that will be gathered. Data will be obtained from global databases of all authors included in the Machine Learning Consortium, aiming to include data of >1000 patients. This study does have the limitation of being retrospective and therefore the study is dependent on the recordkeeping of each individual hospital. This may lead to a variance in listed variables per database, resulting in missing data. In addition, blinding of participants and personnel may have been addressed differently in every institute. Moreover, only risk factors that were identified in literature were included.

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AUTHORS CONTRIBUTION

Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E. Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception and design of the methods section, primarily focussing on the machine learning section and data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the design of the methods section and primarily focussed on how the data should be collected and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this version of the protocol and gave final approval for it to be published. All authors ensure that questions related to the accuracy or integrity of any part of this protocol are appropriately investigated and resolved.

CONFLICTS OF INTEREST

Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant for ConMed Linvatec. Dr. L. Lafosse is a consultant for Depuy Stryker, received royalties from Depuy. Dr. T. Lafosse is consultant for Depuy Mitek and Stryker. Dr. G.A. Buijze received consultancy fees from Depuy-Synthes and Research Funds from SECEC, Vivalto Santé. The remaining authors certify that neither he or she has funding or commercial associations that might pose a conflict of interest in connection with the submitted article.

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SUPPLEMENTARY 1 Search strategy

PubMed

#17	Search: **#14 AND #15 AND #16** Sort by: **Most Recent**	1,768
#16	Search: **((("Recurrence"[Mesh] OR recurr*[tiab] OR relaps*[tiab] OR recrudesc*[tiab] OR repeat*[tiab]) AND ("Joint Dislocations"[Mesh] OR dislocat*[tiab] OR luxat*[tiab] OR instabilit*[tiab])) OR risk*[tiab] OR lesion*[tiab] OR (hill[tiab] AND sachs[tiab]) OR injur*[tiab] OR Perthes[tiab] OR ALPSA[tiab] OR (anterior[tiab] AND (labro[tiab] OR labral[tiab]) AND periosteal[tiab] AND sleeve[tiab] AND avulsion*[tiab]) OR HAGL[tiab] OR (humeral[tiab] AND avulsion*[tiab] AND glenohumeral[tiab] AND ligament*[tiab]) OR (greater[tiab] AND tuberosity[tiab]) OR fracture*[tiab] OR "Fractures, Bone"[Mesh] OR "Rotator Cuff"[Mesh] OR (rotator[tiab] AND cuff[tiab]) OR tear*[tiab] OR age[tiab] OR sport*[tiab] OR laxity[tiab] OR (glenoid[tiab] AND bone[tiab] AND loss[tiab]))** Sort by: **Most Recent**	5,603,913
#15	Search: **(Bankart[tiab] OR "Bankart Lesions/surgery"[Mesh] OR arthroscopic stabilization[tiab] OR arthroscopic stabilisation[tiab] OR labral repair[tiab])** Sort by: **Most Recent**	2,300
#14	Search: **("Shoulder Dislocation"[Mesh] OR "Shoulder"[Mesh] OR "Shoulder Joint"[Mesh] OR shoulder*[tiab] OR glenohumeral[tiab])** Sort by: **Most Recent**	82,527

Embase/Ovid

1	exp shoulder dislocation/	6512
2	exp shoulder/	83055
3	(shoulder* or glenohumeral).ti,ab,kw.	101743
4	1 or 2 or 3	138684
5	(Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair).ti,ab,kw.	2813
6	Bankart lesion/su [Surgery]	198
7	5 or 6	2862
8	(recurr* or relaps* or recrudesc* or repeat*).ti,ab,kw.	1930525
9	exp joint dislocation/	4059

10	(dislocat*or luxat* or instabilit*).ti,ab,kw.	154727
11	9 or 10	158430
12	8 and 11	19548
13	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)).ti,ab,kw.	8234845
14	exp fracture/	336756
15	exp rotator cuff/	8999
16	12 or 13 or 14 or 15	8303779
17	4 and 7 and 16	2119

Cochrane Database of Systematic Reviews & Cochrane Central Register of Controlled Trials

#1	MeSH descriptor: [Shoulder Dislocation] explode all trees	143
#2	MeSH descriptor: [Shoulder] explode all trees	537
#3	MeSH descriptor: [Shoulder Joint] explode all trees	745
#4	(shoulder* or glenohumeral):ti,ab,kw	11763
#5	#1 OR #2 OR #3 OR #4	11763
#6	MeSH descriptor: [Bankart Lesions] explode all trees and with qualifier(s): [surgery - SU]	3
#7	(Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair):ti,ab,kw	238
#8	#6 OR #7	238
#9	MeSH descriptor: [Recurrence] explode all trees	12084
#10	(recurr* or relaps* or recrudesc* or repeat*):ti,ab,kw	159845
#11	#9 OR #10	159894
#12	MeSH descriptor: [Joint Dislocations] explode all trees	687
#13	(dislocat*or luxat* or instabilit*):ti,ab,kw	5839
#14	#12 OR #13	6413

#15	#11 AND #14	1018
#16	(risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss)):ti,ab,kw	549185
#17	MeSH descriptor: [Fractures, Bone] explode all trees	6053
#18	MeSH descriptor: [Rotator Cuff] explode all trees	344
#19	#15 OR #16 OR #17 OR #18	549508
#20	#5 AND #8 AND #19	145

CINAHL/Ebsco

S18	S3 AND S6 AND S17	729
S17	S13 OR S14 OR S15 OR S16	1,482,038
S16	(MH "Rotator Cuff+")	3,063
S15	(MH "Fractures+")	58,529
S14	(TI (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss))) OR (AB (risk* OR lesion* OR (hill AND sachs) OR injur* OR Perthes OR ALPSA OR (anterior AND (labro OR labral) AND periosteal AND sleeve AND avulsion*) OR HAGL OR (humeral AND avulsion* AND glenohumeral AND ligament*) OR (greater AND tuberosity) OR fracture* OR (rotator AND cuff) OR tear* OR age OR sport* OR laxity OR (glenoid AND bone AND loss)))	1,469,860
S13	S9 AND S12	4,294
S12	S10 OR S11	33,871
S11	(TI (dislocat* OR luxat* OR instabilit*)) OR (AB (dislocat* OR luxat* OR instabilit*))	31,033
S10	(MH "Dislocations+")	8,266
S9	S7 OR S8	231,945

S8	(TI (recurr* OR relaps* OR recrudesc* OR repeat*)) OR (AB (recurr* OR relaps* OR recrudesc* OR repeat*))	212,296
S7	(MH "Recurrence")	48,901
S6	S4 OR S5	1,126
S5	(TI (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair)) OR (AB (Bankart OR arthroscopic stabilization OR arthroscopic stabilisation OR labral repair))	1,123
S4	(MH "Bankart Lesions/SU")	58
S3	S1 OR S2	30,919
S2	(Ti (shoulder* OR glenohumeral)) OR (AB (shoulder* OR glenohumeral))	28,334
S1	(MH "Shoulder") OR (MH "Shoulder Dislocation") OR (MH "Shoulder Joint+")	12,823

Web of Science/Clarative

TOPIC: (shoulder* OR glenohumeral) AND (Bankart or arthroscopic stabilization or arthroscopic stabilisation or labral repair) AND (((recurr* or relaps* or recrudesc* or repeat*) AND (dislocat*or luxat* or instabilit*)) OR risk* or lesion* or (hill and sachs) or injur* or Perthes or ALPSA or (anterior and (labro or labral) and periosteal and sleeve and avulsion*) or HAGL or (humeral and avulsion* and glenohumeral and ligament*) or (greater and tuberosity) or fracture* or (rotator and cuff) or tear* or age or sport* or laxity or (glenoid and bone and loss))

Database	**Before deduplication**	**After deduplication**
PubMed	1768	1762
Embase	2119	580
Cochrane Database of Systematic Reviews	1	0
Cochrane Central Register of Controlled Trials	143	51
CINAHL	729	55
Web of science	2578	1136

Total	7338	3584

SUPPLEMENTARY 2

The manuscript's authors will collect the following potential risk factors from the databases provided by authors of the Machine Learning Collaboration:

- Gender (male/female)
- Age at time of operation (years)
- Ethnicity
- Preoperative BMI
- ASA classification at time of operation (1-4)
- Epilepsy (yes/no)
- Hyperlaxity (Beighton score < 4 or ≥ 4)
- Affected side (right/left/bilateral)
- Side of operation (right/left/bilateral)
- Dominance (right/left/both)
- Daily smoking at time of operation (yes or no)
- Number of pre-operative dislocations
- Duration of follow-up (years)
- Bony lesions
  - Bony Bankart lesion (yes/no)
  - Hill-Sachs lesion
    - Yes/no
    - Off-track yes/no
  - Greater Tuberosity Fracture (yes/no)
  - Glenoid bone loss (<20%, ≥20%)
- Soft tissue lesions
  - Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
  - Superior labrum anterior and posterior (SLAP) lesion (yes/no)
  - inferior glenohumeral ligament (IGHL) (yes/no)

  - Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
  - Perthes lesion (yes/no)
  - Glenolabral articular disruption (GLAD) lesion (yes/no)
  - Full thickness Rotator Cuff Tear (yes/no)
  - Partial thickness Rotator Cuff Tear (yes/no)
- Nerve Palsy (yes/no)
- Surgical Characteristics:
  - Side (right/left/bilateral)
  - Time from injury to surgery (months)
  - Time to surgery from hospital admission (days)
  - Surgeon level (Surgeon/Resident/Fellow)