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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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3 1 **Title:** A Machine Learning Algorithm to Identify Patients at Risk for Recurrence Following an
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5 2 Arthroscopic Bankart Repair (CLEARER): a study protocol for a retrospective multicentre
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3 45 **ABSTRACT**
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5 46 **Introduction:** Shoulder instability is a common injury, with a reported incidence of 23.9 per
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7 47 100,000 person-years. There is still an ongoing debate on the most effective treatment
8
9 48 strategy. Non-operative treatment has recurrence rates of up to 60%, whereas operative
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11 49 treatments such as the Bankart repair and bone block procedures show lower recurrence
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13 50 rates (16% and 2%, respectively) but higher complication rates (<2% and up to 30%,
14
15 51 respectively). Methods to determine risk of recurrence have been developed, however
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17 52 patient-specific decision-making tools are still lacking. Artificial Intelligence (AI) and machine
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19 53 learning algorithms use self-learning complex models that can be used to make patient-
20
21 54 specific decision-making tools. The aim of the current study is to develop and train a
22
23 55 machine learning algorithm to create a prediction model to be used in clinical practice – as
24
25 56 an online prediction tool – to estimate recurrence rates following a Bankart repair.
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27

28 57 **Methods and analysis:** This is a multicentre retrospective cohort study. Patients with
29
30 58 traumatic anterior shoulder dislocations that were treated with an arthroscopic Bankart repair
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32 59 without remplissage will be included. This study includes two parts. Part one, collecting all
33
34 60 potential factors influencing the recurrence rate following an arthroscopic Bankart repair in
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36 61 patients using multicentre data. Part two, the multicentre data will be re-evaluated (and
37
38 62 where applicable complemented) using machine learning algorithms to predict outcomes.
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40 63 Recurrence will be the primary outcome measure.
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43 64 **Ethics and dissemination:** For safe multicentre data exchange and analysis, our Machine
44
45 65 Learning Consortium adhered to the World Health Organization (WHO) regulation “Policy on
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47 66 Use and Sharing of Data Collected by WHO in Member States Outside the Context of Public
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49 67 Health Emergencies.” No IRB is required for this study.
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51 68 **Trial registration:** This study does not require a trial registration
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3 70 **ARTICLE SUMMARY**
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- 5 71 • This study aims to calculate a patient specific probability of recurrence following
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7 72 arthroscopic Bankart repair instead of the 'traditional' overall complication rate.
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9 73 • Creating an online prediction tool for recurrence following an arthroscopic Bankart
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11 74 repair can help guide surgeons in selecting patients who benefit from this procedure.
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13 75 • Data will be obtained from global databases of all authors included in the Machine
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15 76 Learning Consortium, aiming to include data from over 1000 patients.
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17 77 • This study does have the limitation of being retrospective and therefore the study is
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19 78 dependent on the recordkeeping of each individual hospital.
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81 INTRODUCTION

82 Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per
83 100,000 person-years.¹ Shoulder dislocations limit patients in their daily routine and
84 participation in sports, cause irreversible damage to the shoulder joint and are associated
85 with high costs.^{2,3} There is an ongoing debate on the most effective treatment strategy to
86 prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates
87 of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone
88 block procedures have lower recurrence rates (16% and 2%, respectively).^{4,5} However, the
89 complication rates for bone block procedures compared to arthroscopic labrum repair (up to
90 30% and <2%, respectively) are higher and therefore pre-operative counselling with
91 determination of the most suitable treatment is important in avoiding unnecessary risk of
92 complications.^{6,7} Methods to determine risk of recurrence have been developed, including
93 the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version,
94 inclination), an off-track Hill-Sachs lesion and translation of the humeral head.⁸⁻¹² However, a
95 patient-specific decision-making tool is still lacking.

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

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106 Aim and objectives

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

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3 109 recurrence rates following a Bankart repair. No studies have yet been published applying
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5 110 machine learning algorithms to systematically reviewed/collected data in this field.
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113 **METHODS AND ANALYSIS**

114 **Study design**

115 This multicentre retrospective cohort study includes two parts.

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117 **Part one – Collecting Data**

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

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133 **Part two – Machine Learning**

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

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137 *Training Data & Test Data*

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

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3 141 *Output variables*
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5 142 Each Machine Learning Algorithms will be trained to recognize patterns related to
6
7 143 recurrence rates.
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11 145 *Input Variables*
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13 146 For the primary outcome, a Random-Forest algorithm will be used to identify the variables
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15 147 with the highest predictive variables from all available data points in the Machine Learning
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17 148 Consortium Database. The data points available include demographics (age, sex), patient
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19 149 specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors
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21 150 (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical
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23 151 characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix
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25 152 2 for the complete list of factors that will be collected from the electronic medical records).
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31 154 *Algorithms to be trained*
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33 155 It is not possible to know what Machine Learning algorithm will be most suitable to calculate
34
35 156 recurrence following an arthroscopic Bankart repair.²⁰ However, based on previous studies,
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37 157 the following algorithms will be tested as prediction models for recurrence rates: Decision
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39 158 Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine.^{16, 21-25}
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43 160 *Training and Testing of the algorithms*
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45 161 For each ML algorithm, ten-fold cross validation will be repeated three times on the training
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47 162 dataset (80%), to train the algorithms in recognizing patterns related to recurrence following
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49 163 an arthroscopic Bankart repair, and to subsequently assess their predictive performance
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51 164 based on the following performance characteristics: Area under the ROC-curve, calibration
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53 165 (calibration slope, calibration intercept) and Brier score will be calculated.²⁶ The model's
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55 166 predicted probability is plotted against the actual observed probability to calculate calibration
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57 167 of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.²⁷
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59 168 The overall performance of the model will be assessed with the Brier-score. A perfect Brier
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3 169 score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of
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5 170 1.²⁶ The remaining 20% of the data will be used as a test-set to assess the performance of
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7 171 the best performing machine learning algorithms based on “unseen” data. The technical
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9 172 appendix, statistical code, and dataset will be published.
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13 14 174 *External validation of the best performing algorithm*

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16 175 Before incorporation into an online open access decision-making tool, the best performing
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18 176 algorithm will be externally validated. The same performance metrics will be calculated as
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20 177 described above.
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23 24 179 *Open-access clinical prediction tool*

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26 180 An open-access clinical prediction tool will be developed using the best performing
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28 181 algorithm.
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31 32 183 *Patients and public involvement*

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34 184 Patients and the public were not involved in the making of this protocol.
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3 186 **ETHICS AND DISSEMINATION**
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5 187 For safe multicentre data exchange and analysis, our Machine Learning Consortium
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7 188 adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of
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9 189 Data Collected by WHO in Member States Outside the Context of Public Health
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11 190 Emergencies.”²⁸ No IRB is required for this study.
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3 193 **DISCUSSION**
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5 194 Operative treatment significantly reduces the risk of recurrent shoulder instability compared
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7 195 to non-operative treatment.²⁹ Patients with first-time dislocations who receive operative
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9 196 treatment are most often treated with labrum repair.²⁹ Risk factors associated with failure of
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11 197 an arthroscopic Bankart repair include young age (≤ 30 years), participation in competitive
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13 198 sports, multiple preoperative dislocations, > 6 months surgical delay from first-time
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15 199 dislocation to surgery, ISIS > 3 and associated lesions (Hill-Sachs, glenoid bone loss and
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17 200 ALPSA).¹⁸ It is impossible to take all these risk factors into account and make an objective
18
19 201 decision on what treatment is most suitable. Several prediction tools have been developed
20
21 202 to help counselling patients, however these tools only provide an indicative overall score and
22
23 203 are not patient specific.⁸⁻¹² Artificial Intelligence (AI) and machine learning algorithms have
24
25 204 shown potential to make a patient-specific decision tool.¹⁶ Creating an online prediction tool
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27 205 for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting
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29 206 patients who benefit from this procedure. Patients with a first-time anterior shoulder
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31 207 dislocations receive proper evidence-based information only in 29% of the cases.³⁰ An
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33 208 online prediction tool might elevate these numbers and makes it possible for shared decision
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35 209 making based on objective measures.
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39 210 The strength of this study is the great amount of data that will be gathered. Data will be
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41 211 obtained from global databases of all authors included in the Machine Learning Consortium,
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43 212 aiming to include data of >1000 patients. This study does have the limitation of being
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45 213 retrospective and therefore the study is dependent on the recordkeeping of each individual
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47 214 hospital.
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3 216 **Funding**
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3 220 **AUTHORS CONTRIBUTION**
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5 221 Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E.

6
7 222 Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning

8
9 223 of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception

10
11 224 and design of the methods section, primarily focussing on the machine learning section and

12
13 225 data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the

14
15 226 design of the methods section and primarily focussed on how the data should be collected

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17 227 and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den

18
19 228 Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this

20
21 229 version of the protocol and gave final approval for it to be published. All authors ensure that

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23 230 questions related to the accuracy or integrity of any part of this protocol are appropriately

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25 231 investigated and resolved.
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3 232 **CONFLICTS OF INTEREST**
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5 233 Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant
6
7 234 for ConMed Linvatec. The remaining authors certify that neither he or she has funding or
8
9 235 commercial associations that might pose a conflict of interest in connection with the
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11 236 submitted article.
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1 **SUPPLEMENTARY 1** Search strategy2 *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

3

4 *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

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6 *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

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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

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10 *Web of Science/Clarative*

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

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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

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Total	7338	3584
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3 22 **SUPPLEMENTARY 2**
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5 23 We collect the following potential risk factors from the electronic medical records:
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- 7 24 o Gender (male/female)
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9 25 o Age at time of operation (years)
10
11 26 o Preoperative BMI
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13 27 o ASA classification at time of operation (1-4)
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15 28 o Epilepsy (yes/no)
16
17 29 o Hyperlaxity (Beighton score < 4 or ≥ 4)
18
19 30 o Affected side (right/left/bilateral)
20
21 31 o Side of operation (right/left/bilateral)
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23 32 o Dominance (right/left/both)
24
25 33 o Daily smoking at time of operation (yes or no)
26
27 34 o Number of pre-operative dislocations
28
29 35 o Duration of follow-up (years)
30
31 36 o Bony lesions
32
33 Bony Bankart lesion (yes/no)
34
35 37 Hill-Sachs lesion
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37 38 Hill-Sachs lesion
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39 39
 - Yes/no
40 40
 - Off-track yes/no
41 41 Greater Tuberosity Fracture (yes/no)
42 42 Glenoid bone loss ($<20\%$, $\geq 20\%$)
43 43 o Soft tissue lesions
44 44 Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
45 45 Superior labrum anterior and posterior (SLAP) lesion (yes/no)
46 46 inferior glenohumeral ligament (IGHL) (yes/no)
47 47 Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
48 48 Perthes lesion (yes/no)
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- 49 Glenolabral articular disruption (GLAD) lesion (yes/no)
- 50 Full thickness Rotator Cuff Tear (yes/no)
- 51 Partial thickness Rotator Cuff Tear (yes/no)
- 52 o Nerve Palsy (yes/no)
- 53 o Surgical Characteristics:
 - 54 o Side (right/left/bilateral)
 - 55 o Time from injury to surgery (months)
 - 56 o Time to surgery from hospital admission (days)
 - 57 o Surgeon level (Surgeon/Resident/Fellow)
- 58
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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 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-055346.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Feb-2022
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

SCHOLARONE™
Manuscripts

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3 1 **Title:** Development and Training of a Machine Learning Algorithm to Identify Patients at Risk
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5 2 for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a
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7 3 Retrospective, Multicentre, Cohort Study
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28 13 **Hendrickx**^{4,5,7}; Job N. **Doornberg**⁷; George S. **Athwal**⁸; Thibault **Lafosse**²; Laurent

29 14 **Lafosse**²; Michel P.J **van den Bekerom**^{1,3}; Geert Alexander **Buijze**^{2,4,9} on behalf of the

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24 38 **Word count:** 1543, **Abstract:** 293

25
26 39 **Keywords:** Shoulder instability, dislocation, recurrence, Bankart, Machine Learning
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28 40 Algorithm, Artificial Intelligence
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32 42 **Date:** 03-02-2022

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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

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3 72 **STRENGTHS AND LIMITATIONS**
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- 5 73 • Data will be obtained from global databases of all authors included in the Machine
6
7 74 Learning Consortium, aiming to include data from over 1000 patients.
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9 75 • Retrospective studies are less suitable to train machine learning algorithms than
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11 76 prospective studies due to missing data through incomplete record keeping and
12
13 77 possible confounding factors.
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15 78 • Studies with different designs will be included. By combining data gathered by
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17 79 different studies to create one database, definitions may differ and therefore make it
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19 80 impossible to pool some of the data.
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82 INTRODUCTION

83 Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per
84 100,000 person-years.¹ Shoulder dislocations limit patients in their daily routine and
85 participation in sports, cause irreversible damage to the shoulder joint and are associated
86 with high costs.^{2,3} There is an ongoing debate on the most effective treatment strategy to
87 prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates
88 of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone
89 block procedures have lower recurrence rates (16% and 2%, respectively).^{4,5} However, the
90 complication rates for bone block procedures compared to arthroscopic labrum repair (up to
91 30% and <2%, respectively) are higher and therefore pre-operative counselling with
92 determination of the most suitable treatment is important in avoiding unnecessary risk of
93 complications.^{6,7} Methods to determine risk of recurrence have been developed, including
94 the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version,
95 inclination), an off-track Hill-Sachs lesion and translation of the humeral head.⁸⁻¹² However, a
96 patient-specific decision-making tool is still lacking.

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

106

107 Aim and objectives

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

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3 110 recurrence rates following a Bankart repair. No studies have yet been published applying
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5 111 machine learning algorithms to systematically reviewed/collected data in this field.
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114 **METHODS AND ANALYSIS**

115 **Study design**

116 This multicentre retrospective cohort study includes two parts.

117

118 **Part one – Collecting Data**

119 Part one involves collecting all potential factors influencing the recurrence rate following an
120 arthroscopic Bankart repair without remplissage in patients using multicentre data. Authors
121 who will contribute to data contribution will be included in the Machine Learning Consortium,
122 aiming to include data from over 1000 patients all over the world. To make a reliable
123 algorithm, it is estimated that the data should include 100 recurrences. With a recurrence
124 rate of 12% following arthroscopic Bankart repairs, it was estimated that a minimum of 1000
125 patients would be sufficient.¹⁸ To identify relevant studies, a systematic approach was used
126 searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley,
127 Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of
128 Science/Clarivate according to the search terms used in Verweij *et al.* (see Supplemental
129 appendix 1 for the search strategy) from inception up to July 2021.¹⁹ The systematic review
130 by Verweij *et al.* is completed and submitted for publication separately. All studies reporting
131 on risk factors for recurrence following Bankart repairs were included. Studies published in
132 languages other than English, Dutch and French were excluded. The inclusion criteria are
133 patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior
134 shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as
135 either a complete dislocation or subluxation.²⁰ Exclusion criteria include patients who have
136 undergone previous stabilization procedures or other surgical procedures to the ipsilateral
137 shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or
138 voluntary habitual instability.

139

140 **Part two – Machine Learning**

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3 141 Part two, the multicentre data will be re-evaluated (and where applicable complemented)
4
5 142 using machine learning algorithms to predict outcomes. The statistician that performs the
6
7 143 machine learning analysis will be blinded to the origin of the data.
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10 144

11 145 *Training Data & Test Data*

12
13 146 Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium
14
15 147 Database will be randomly allocated to the training dataset and 20% to the test dataset.
16
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18 148

19 149 *Output variables*

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21
22 150 Each Machine Learning Algorithm will be trained to recognize patterns related to recurrence
23
24 151 rates.
25
26 152

27 153 *Input Variables*

28
29
30 154 For the primary outcome, a Random-Forest algorithm will be used to identify the variables
31
32 155 with the highest predictive value from all available data points in the Machine Learning
33
34 156 Consortium Database. The data points available include demographics (age, sex), patient
35
36 157 specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors
37
38 158 (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical
39
40 159 characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix
41
42 160 2 for the complete list of factors that will be collected from the electronic medical records).
43
44
45 161

46 162 *Algorithms to be trained*

47
48
49 163 It is not possible to know what Machine Learning algorithm will be most suitable to calculate
50
51 164 recurrence following an arthroscopic Bankart repair.²¹ However, based on previous studies,
52
53 165 the following algorithms will be tested as prediction models for recurrence rates: Decision
54
55 166 Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine; Logistic
56
57 167 Regression.^{16, 22-27}
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60 168

169 *Training and Testing of the algorithms*

170 For each ML algorithm, ten-fold cross validation will be repeated three times on the training
171 dataset (80%), to train the algorithms in recognizing patterns related to recurrence following
172 an arthroscopic Bankart repair, and to subsequently assess their predictive performance
173 based on the following performance characteristics: Area under the ROC-curve, calibration
174 (calibration slope, calibration intercept) and Brier score will be calculated.²⁸ The model's
175 predicted probability is plotted against the actual observed probability to calculate calibration
176 of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.²⁹
177 The overall performance of the model will be assessed with the Brier-score. A perfect Brier
178 score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of
179 1.²⁸ The remaining 20% of the data will be used as a test-set to assess the performance of
180 the best performing machine learning algorithms based on "unseen" data. The technical
181 appendix, statistical code, and dataset will be published.

182

183 *External validation of the best performing algorithm*

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

187

188 *Open-access clinical prediction tool*

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

191

192 *Patients and public involvement*

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

194

195 **Current Status**

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3 196 Currently, the study is at the finishing stage of collection data from global databases. Re-
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5 197 evaluation of the data using machine learning algorithms to predict outcomes will start in
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7 198 March 2022. The expected time of completion is by the end of 2022.
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3 200 **ETHICS AND DISSEMINATION**
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5 201 For safe multicentre data exchange and analysis, our Machine Learning Consortium
6
7 202 adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of
8
9 203 Data Collected by WHO in Member States Outside the Context of Public Health
10
11 204 Emergencies.”³⁰ The study results will be disseminated through publication in a peer-
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14 205 reviewed journal. No IRB is required for this study.
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3 206 **DISCUSSION**
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5 207 Operative treatment significantly reduces the risk of recurrent shoulder instability compared
6
7 208 to non-operative treatment.³¹ Patients with first-time dislocations who receive operative
8
9 209 treatment are most often treated with labrum repair.³¹ Risk factors associated with failure of
10
11 210 an arthroscopic Bankart repair include young age (≤ 30 years), participation in competitive
12
13 211 sports, multiple preoperative dislocations, > 6 months surgical delay from first-time
14
15 212 dislocation to surgery, ISIS > 3 and associated lesions (Hill-Sachs, glenoid bone loss and
16
17 213 ALPSA).³² It is impossible to take all these risk factors into account and make an objective
18
19 214 decision on what treatment is most suitable. Several prediction tools have been developed
20
21 215 to help counselling patients, however these tools only provide an indicative overall score and
22
23 216 are not patient specific.⁸⁻¹² Artificial Intelligence (AI) and machine learning algorithms have
24
25 217 shown potential to make a patient-specific decision tool.¹⁶ Creating an online prediction tool
26
27 218 for recurrence following an arthroscopic Bankart repair can help guide surgeons in selecting
28
29 219 patients who benefit from this procedure. Patients with a first-time anterior shoulder
30
31 220 dislocations receive proper evidence-based information only in 29% of the cases.³³ An
32
33 221 online prediction tool might elevate these numbers and makes it possible for shared decision
34
35 222 making based on objective measures.
36
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38

39 223 The strength of this study is the great amount of data that will be gathered. Data will be
40
41 224 obtained from global databases of all authors included in the Machine Learning Consortium,
42
43 225 aiming to include data of >1000 patients. This study does have the limitation of being
44
45 226 retrospective and therefore the study is dependent on the recordkeeping of each individual
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47 227 hospital. This may lead to a variance in listed variables per database, resulting in missing
48
49 228 data. In addition, blinding of participants and personnel may have been addressed differently
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51 229 in every institute. Moreover, only risk factors that were identified in literature were included.
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3 235 **AUTHORS CONTRIBUTION**
4

5 236 Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E.
6
7 237 Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning
8
9 238 of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception
10
11 239 and design of the methods section, primarily focussing on the machine learning section and
12
13 240 data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the
14
15 241 design of the methods section and primarily focussed on how the data should be collected
16
17 242 and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den
18
19 243 Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this
20
21 244 version of the protocol and gave final approval for it to be published. All authors ensure that
22
23 245 questions related to the accuracy or integrity of any part of this protocol are appropriately
24
25 246 investigated and resolved.
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3 247 **CONFLICTS OF INTEREST**
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5 248 Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant
6
7 249 for ConMed Linvatec. Dr. L. Lafosse is a consultant for Depuy Stryker, received royalties
8
9 250 from Depuy. Dr. T. Lafosse is consultant for Depuy Mitek and Stryker. Dr. G.A. Buijze
10
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12
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14
15 253 associations that might pose a conflict of interest in connection with the submitted article.
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1 **SUPPLEMENTARY 1** Search strategy2 *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 recrudes*[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

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4 *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 recrudes* 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

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6 *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

9

10 *Web of Science/Clarative*

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

18

19

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

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Total	7338	3584
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3 22 **SUPPLEMENTARY 2**
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5 23 We collect the following potential risk factors from the electronic medical records:
6

- 7 24 o Gender (male/female)
8
9 25 o Age at time of operation (years)
10
11 26 o Preoperative BMI
12
13 27 o ASA classification at time of operation (1-4)
14
15 28 o Epilepsy (yes/no)
16
17 29 o Hyperlaxity (Beighton score < 4 or ≥ 4)
18
19 30 o Affected side (right/left/bilateral)
20
21 31 o Side of operation (right/left/bilateral)
22
23 32 o Dominance (right/left/both)
24
25 33 o Daily smoking at time of operation (yes or no)
26
27 34 o Number of pre-operative dislocations
28
29 35 o Duration of follow-up (years)
30
31 36 o Bony lesions
32
33 Bony Bankart lesion (yes/no)
34
35 37 Hill-Sachs lesion
36
37 38 Hill-Sachs lesion
38
39 39
 - Yes/no
40
41 40
 - Off-track yes/no
42
43 41 Greater Tuberosity Fracture (yes/no)
44
45 42 Glenoid bone loss ($<20\%$, $\geq 20\%$)
46
47 43 o Soft tissue lesions
48
49 44 Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
50
51 45 Superior labrum anterior and posterior (SLAP) lesion (yes/no)
52
53 46 inferior glenohumeral ligament (IGHL) (yes/no)
54
55 47 Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
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57 48 Perthes lesion (yes/no)
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- 49 Glenolabral articular disruption (GLAD) lesion (yes/no)
- 50 Full thickness Rotator Cuff Tear (yes/no)
- 51 Partial thickness Rotator Cuff Tear (yes/no)
- 52 o Nerve Palsy (yes/no)
- 53 o Surgical Characteristics:
 - 54 o Side (right/left/bilateral)
 - 55 o Time from injury to surgery (months)
 - 56 o Time to surgery from hospital admission (days)
 - 57 o Surgeon level (Surgeon/Resident/Fellow)
- 58
- 59



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 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-055346.R2
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Date Submitted by the Author:	05-Apr-2022
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

SCHOLARONE™
Manuscripts

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2
3 1 **Title:** Development and Training of a Machine Learning Algorithm to Identify Patients at Risk
4
5 2 for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a
6
7 3 Retrospective, Multicentre, Cohort Study
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27
28 13 **Hendrickx**^{4,5,7}; Job N. **Doornberg**⁷; George S. **Athwal**⁸; Thibault **Lafosse**²; Laurent

29
30 14 **Lafosse**²; Michel P.J **van den Bekerom**^{1,3}; Geert Alexander **Buijze**^{2,4,9} on behalf of the

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32 15 Machine Learning Consortium
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24 38 **Word count:** 1543, **Abstract:** 293

26 39 **Keywords:** Shoulder instability, dislocation, recurrence, Bankart, Machine Learning
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28 40 Algorithm, Artificial Intelligence
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32 42 **Date:** 29-03-2022

34 43 **Version:** 2.1
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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

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3 72 **STRENGTHS AND LIMITATIONS**
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- 5 73 • Data will be obtained from global databases of all authors included in the Machine
6
7 74 Learning Consortium, aiming to include data from over 1000 patients.
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9 75 • Retrospective studies are less suitable to train machine learning algorithms than
10
11 76 prospective studies due to missing data through incomplete record keeping and
12
13 77 possible confounding factors.
14
15 78 • Studies with different designs will be included. By combining data gathered by
16
17 79 different studies to create one database, definitions may differ and therefore make it
18
19 80 impossible to pool some of the data.
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21 81 • Due to the collection of individual patient data by previously published studies,
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23 82 variation in definitions may cause a significant source of bias.
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83 INTRODUCTION

84 Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per
85 100,000 person-years.¹ Shoulder dislocations limit patients in their daily routine and
86 participation in sports, cause irreversible damage to the shoulder joint and are associated
87 with high costs.^{2,3} There is an ongoing debate on the most effective treatment strategy to
88 prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates
89 of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone
90 block procedures have lower recurrence rates (16% and 2%, respectively).^{4,5} However, the
91 complication rates for bone block procedures compared to arthroscopic labrum repair (up to
92 30% and <2%, respectively) are higher and therefore pre-operative counselling with
93 determination of the most suitable treatment is important in avoiding unnecessary risk of
94 complications.^{6,7} Methods to determine risk of recurrence have been developed, including
95 the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version,
96 inclination), an off-track Hill-Sachs lesion and translation of the humeral head.⁸⁻¹² However, a
97 patient-specific decision-making tool is still lacking.

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

107

108 Aim and objectives

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

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3 111 recurrence rates following a Bankart repair. No studies have yet been published applying
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5 112 machine learning algorithms to systematically reviewed/collected data in this field.
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115 **METHODS AND ANALYSIS**

116 **Study design**

117 This multicentre retrospective cohort study includes two parts.

118

119 **Part one – Collecting Data**

120 Part one involves collecting individual patient data of published studies that evaluated
121 potential factors predisposing recurrence following an arthroscopic Bankart repair without
122 remplissage. The authors of these studies will be contacted by email and will be included in
123 the Machine Learning Consortium when they provide the original patient data of their cohort.
124 Through this process, we aim to combine the individual patient data from the published
125 studies and create an international cohort of over 1000 patients. The current study will use
126 the collected patient data to create a machine learning algorithm that can estimate the
127 probability of recurrence for an individual patient. To make a reliable algorithm, it is
128 estimated that the data should include at least 100 recurrences. With a recurrence rate of
129 12% following arthroscopic Bankart repairs, it was estimated that a minimum of 1000
130 patients would be sufficient.¹⁸ To identify relevant studies, a systematic approach was used
131 searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley,
132 Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of
133 Science/Clarivate according to the search terms used in Verweij *et al.* (see Supplemental
134 appendix 1 for the search strategy) from inception up to July 2021.¹⁹ The systematic review
135 by Verweij *et al.* is completed and submitted for publication separately. All studies reporting
136 on risk factors for recurrence following Bankart repairs were included. Studies published in
137 languages other than English, Dutch and French were excluded. The inclusion criteria are
138 patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior
139 shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as
140 either a complete dislocation or subluxation.²⁰ Exclusion criteria include patients who have
141 undergone previous stabilization procedures or other surgical procedures to the ipsilateral

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3 142 shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or
4
5 143 voluntary habitual instability.
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9 145 **Part two – Machine Learning**

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11 146 Part two, the multicentre data will be re-evaluated (and where applicable complemented)
12
13 147 using machine learning algorithms to predict outcomes. The statistician that performs the
14
15 148 machine learning analysis will be blinded to the origin of the data.
16

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20 150 *Training Data & Test Data*

21
22 151 Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium
23
24 152 Database will be randomly allocated to the training dataset and 20% to the test dataset.
25

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28 154 *Output variables*

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30 155 Each Machine Learning Algorithm will be trained to recognize patterns related to recurrence
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32 156 rates.
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36 158 *Input Variables*

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39 159 For the primary outcome, a Random-Forest algorithm will be used to identify the variables
40
41 160 with the highest predictive value from all available data points in the Machine Learning
42
43 161 Consortium Database. The data points available include demographics (age, sex), patient
44
45 162 specific factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors
46
47 163 (e.g. affected side, number of pre-operative dislocations, associated lesions) and surgical
48
49 164 characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix
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51 165 2 for the complete list of factors that will be collected from the electronic medical records).
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55 167 *Algorithms to be trained*

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57
58 168 It is not possible to know what Machine Learning algorithm will be most suitable to calculate
59
60 169 recurrence following an arthroscopic Bankart repair.²¹ However, based on previous studies,

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3 170 the following algorithms will be tested as prediction models for recurrence rates: Decision
4
5 171 Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine; Logistic
6
7 172 Regression.^{16, 22-27}
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11 174 *Training and Testing of the algorithms*

13 175 For each ML algorithm, ten-fold cross validation will be repeated three times on the training
14
15 176 dataset (80%), to train the algorithms in recognizing patterns related to recurrence following
16
17 177 an arthroscopic Bankart repair, and to subsequently assess their predictive performance
18
19 178 based on the following performance characteristics: Area under the ROC-curve, calibration
20
21 179 (calibration slope, calibration intercept) and Brier score will be calculated.²⁸ The model's
22
23 180 predicted probability is plotted against the actual observed probability to calculate calibration
24
25 181 of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.²⁹
26
27 182 The overall performance of the model will be assessed with the Brier-score. A perfect Brier
28
29 183 score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of
30
31 184 1.²⁸ The remaining 20% of the data will be used as a test-set to assess the performance of
32
33 185 the best performing machine learning algorithms based on "unseen" data. The technical
34
35 186 appendix, statistical code, and dataset will be published.
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41 188 *External validation of the best performing algorithm*

42
43 189 Before incorporation into an online open access decision-making tool, the best performing
44
45 190 algorithm will be externally validated in a prospective database. The same performance
46
47 191 metrics will be calculated as described above.
48

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51 193 *Open-access clinical prediction tool*

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53 194 An open-access clinical prediction tool will be developed using the best performing
54
55 195 algorithm.
56

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58 197 *Patients and public involvement*

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2
3 198 Patients and the public were not involved in the making of this protocol.
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6 199

7 200 **Current Status**

8
9 201 Currently, the study is at the finishing stage of collection data from global databases. Re-

10
11 202 evaluation of the data using machine learning algorithms to predict outcomes will start in

12
13 203 March 2022. The expected time of completion is by the end of 2022.

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3 205 **ETHICS AND DISSEMINATION**
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5 206 For safe multicentre data exchange and analysis, our Machine Learning Consortium
6
7 207 adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of
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9 208 Data Collected by WHO in Member States Outside the Context of Public Health
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11 209 Emergencies.”³⁰ The study results will be disseminated through publication in a peer-
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14 210 reviewed journal. No IRB is required for this study.
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211 DISCUSSION

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

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

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238 or not-for-profit sectors.

239

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3 240 **AUTHORS CONTRIBUTION**
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5 241 Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E.
6
7 242 Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning
8
9 243 of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception
10
11 244 and design of the methods section, primarily focussing on the machine learning section and
12
13 245 data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the
14
15 246 design of the methods section and primarily focussed on how the data should be collected
16
17 247 and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den
18
19 248 Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this
20
21 249 version of the protocol and gave final approval for it to be published. All authors ensure that
22
23 250 questions related to the accuracy or integrity of any part of this protocol are appropriately
24
25 251 investigated and resolved.
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3 252 **CONFLICTS OF INTEREST**
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5 253 Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant
6
7 254 for ConMed Linvatec. Dr. L. Lafosse is a consultant for Depuy Stryker, received royalties
8
9 255 from Depuy. Dr. T. Lafosse is consultant for Depuy Mitek and Stryker. Dr. G.A. Buijze
10
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12
13 257 Santé. The remaining authors certify that neither he or she has funding or commercial
14
15 258 associations that might pose a conflict of interest in connection with the submitted article.
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1 **SUPPLEMENTARY 1** Search strategy2 *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 recrudes*[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

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4 *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 recrudes* 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

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6 *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 sach's) 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

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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 sach's) 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 sach's) 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

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10 *Web of Science/Clarative*

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

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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

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Total	7338	3584
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3 22 **SUPPLEMENTARY 2**
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5 23 The manuscript's authors will collect the following potential risk factors from the databases
6
7 24 provided by authors of the Machine Learning Collaboration:

- 9 25 o Gender (male/female)
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11 26 o Age at time of operation (years)
12
13 27 o Preoperative BMI
14
15 28 o ASA classification at time of operation (1-4)
16
17 29 o Epilepsy (yes/no)
18
19 30 o Hyperlaxity (Beighton score < 4 or ≥ 4)
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21 31 o Affected side (right/left/bilateral)
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23 32 o Side of operation (right/left/bilateral)
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25 33 o Dominance (right/left/both)
26
27 34 o Daily smoking at time of operation (yes or no)
28
29 35 o Number of pre-operative dislocations
30
31 36 o Duration of follow-up (years)
32
33 37 o Bony lesions
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35 38 Bony Bankart lesion (yes/no)
36
37 39 Hill-Sachs lesion
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39 40
 - 41 • Yes/no
 - 42 • Off-track yes/no
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44 41 Greater Tuberosity Fracture (yes/no)
45
46 42 Glenoid bone loss ($<20\%$, $\geq 20\%$)
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48 43
49 44 o Soft tissue lesions
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51 45 Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
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53 46 Superior labrum anterior and posterior (SLAP) lesion (yes/no)
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55 47 inferior glenohumeral ligament (IGHL) (yes/no)
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57 48 Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
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- 49 Perthes lesion (yes/no)
- 50 Glenolabral articular disruption (GLAD) lesion (yes/no)
- 51 Full thickness Rotator Cuff Tear (yes/no)
- 52 Partial thickness Rotator Cuff Tear (yes/no)
- 53 Nerve Palsy (yes/no)
- 54 Surgical Characteristics:
 - 55 Side (right/left/bilateral)
 - 56 Time from injury to surgery (months)
 - 57 Time to surgery from hospital admission (days)
 - 58 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-055346.R3
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Date Submitted by the Author:	23-Apr-2022
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3 1 **Title:** Development and Training of a Machine Learning Algorithm to Identify Patients at Risk
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5 2 for Recurrence following an Arthroscopic Bankart Repair (CLEARER): Protocol for a
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7 3 Retrospective, Multicentre, Cohort Study
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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

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3 72 **STRENGTHS AND LIMITATIONS**
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- 5 73 • Data will be obtained from global databases of all authors included in the Machine
6
7 74 Learning Consortium, aiming to include data from over 1000 patients.
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9 75 • Retrospective studies are less suitable to train machine learning algorithms than
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11 76 prospective studies due to missing data through incomplete record keeping and
12
13 77 possible confounding factors.
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15 78 • Studies with different designs will be included. By combining data gathered by
16
17 79 different studies to create one database, definitions may differ and therefore make it
18
19 80 impossible to pool some of the data.
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21 81 • Due to the collection of individual patient data by previously published studies,
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23 82 variation in definitions may cause a significant source of bias.
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83 INTRODUCTION

84 Anterior shoulder dislocation is a common injury, with a reported incidence of 23.9 per
85 100,000 person-years.¹ Shoulder dislocations limit patients in their daily routine and
86 participation in sports, cause irreversible damage to the shoulder joint and are associated
87 with high costs.^{2,3} There is an ongoing debate on the most effective treatment strategy to
88 prevent recurrence. Non-operative treatment of first-time dislocations has recurrence rates
89 of up to 60%, whereas operative treatment such as the arthroscopic labrum repair and bone
90 block procedures have lower recurrence rates (16% and 2%, respectively).^{4,5} However, the
91 complication rates for bone block procedures compared to arthroscopic labrum repair (up to
92 30% and <2%, respectively) are higher and therefore pre-operative counselling with
93 determination of the most suitable treatment is important in avoiding unnecessary risk of
94 complications.^{6,7} Methods to determine risk of recurrence have been developed, including
95 the instability severity index score (ISIS), glenoid morphology (i.e. concavity, version,
96 inclination), an off-track Hill-Sachs lesion and translation of the humeral head.⁸⁻¹² However, a
97 patient-specific decision-making tool is still lacking.

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

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108 Aim and objectives

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

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3 111 recurrence rates following a Bankart repair. No studies have yet been published applying
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5 112 machine learning algorithms to systematically reviewed/collected data in this field.
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115 **METHODS AND ANALYSIS**

116 **Study design**

117 This multicentre retrospective cohort study includes two parts.

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119 **Part one – Collecting Data**

120 Part one involves collecting individual patient data of published studies that evaluated
121 potential factors predisposing recurrence following an arthroscopic Bankart repair without
122 remplissage. The authors of these studies will be contacted by email and will be included in
123 the Machine Learning Consortium when they provide the original patient data of their cohort.
124 Through this process, we aim to combine the individual patient data from the published
125 studies and create an international cohort of over 1000 patients. The current study will use
126 the collected patient data to create a machine learning algorithm that can estimate the
127 probability of recurrence for an individual patient. To make a reliable algorithm, it is
128 estimated that the data should include at least 100 recurrences. With a recurrence rate of
129 12% following arthroscopic Bankart repairs, it was estimated that a minimum of 1000
130 patients would be sufficient.¹⁸ To identify relevant studies, a systematic approach was used
131 searching PubMed, Embase/Ovid, Cochrane Database of Systematic Reviews/Wiley,
132 Cochrane Central Register of Controlled Trials/Wiley, CINAHL/Ebsco, and Web of
133 Science/Clarivate according to the search terms used in Verweij *et al.* (see Supplemental
134 appendix 1 for the search strategy) from inception up to July 2021.¹⁹ The systematic review
135 by Verweij *et al.* is completed and submitted for publication separately. All studies reporting
136 on risk factors for recurrence following Bankart repairs were included. Studies published in
137 languages other than English, Dutch and French were excluded. The inclusion criteria are
138 patients treated with arthroscopic Bankart repair without remplissage for traumatic anterior
139 shoulder instability with a minimum of 2 years follow up. Shoulder instability is defined as
140 either a complete dislocation or subluxation.²⁰ Exclusion criteria include patients who have
141 undergone previous stabilization procedures or other surgical procedures to the ipsilateral

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3 142 shoulder than arthroscopic Bankart repair and patients with posterior, multidirectional or
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5 143 voluntary habitual instability.
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9 **145 Part two – Machine Learning**

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11 146 Part two, the multicentre data will be re-evaluated (and where applicable complemented)
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13 147 using machine learning algorithms to predict outcomes. The statistician that performs the
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15 148 machine learning analysis will be blinded to the origin of the data.
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20 150 *Training Data & Test Data*

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22 151 Eighty percent (80%) of all (>1000) patients included in the Machine Learning Consortium
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24 152 Database will be randomly allocated to the training dataset and 20% to the test dataset.
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28 154 *Output variables*

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30 155 Each Machine Learning Algorithm will be trained to recognize patterns related to recurrence
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32 156 rates.
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36 158 *Input Variables*

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39 159 For the primary outcome, a Random-Forest algorithm will be used to identify the variables
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41 160 with the highest predictive value from all available data points in the Machine Learning
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43 161 Consortium Database. The data points available include demographics (age, sex and
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45 162 ethnicity aiming to include >1000 patients with balanced demographics), patient specific
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47 163 factors (e.g. preoperative BMI, comorbidity, dominance), disease specific factors (e.g.
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49 164 affected side, number of pre-operative dislocations, associated lesions) and surgical
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51 165 characteristics (e.g. time from injury to surgery, surgeon level) (see Supplemental appendix
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53 166 2 for the complete list of factors that will be collected from the electronic medical records).
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58 168 *Algorithms to be trained*
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3 169 It is not possible to know what Machine Learning algorithm will be most suitable to calculate
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5 170 recurrence following an arthroscopic Bankart repair.²¹ However, based on previous studies,
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7 171 the following algorithms will be tested as prediction models for recurrence rates: Decision
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9 172 Tree Models; Support Vector Machine; Neural Network; Bayes Point Machine; Logistic
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11 173 Regression.^{16, 22-27}
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15 175 *Training and Testing of the algorithms*

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18 176 For each ML algorithm, ten-fold cross validation will be repeated three times on the training
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20 177 dataset (80%), to train the algorithms in recognizing patterns related to recurrence following
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22 178 an arthroscopic Bankart repair, and to subsequently assess their predictive performance
23
24 179 based on the following performance characteristics: Area under the ROC-curve, calibration
25
26 180 (calibration slope, calibration intercept) and Brier score will be calculated.²⁸ The model's
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28 181 predicted probability is plotted against the actual observed probability to calculate calibration
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30 182 of a model. Perfect models will have calibration intercepts of 0, and calibration slopes of 1.²⁹
31
32 183 The overall performance of the model will be assessed with the Brier-score. A perfect Brier
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34 184 score, indicating total accuracy, is a score of 0. The lowest possible score is a Brier score of
35
36 185 1.²⁸ The remaining 20% of the data will be used as a test-set to assess the performance of
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38 186 the best performing machine learning algorithms based on "unseen" data. The technical
39
40 187 appendix, statistical code, and dataset will be published.
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44 189 *External validation of the best performing algorithm*

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47 190 Before incorporation into an online open access decision-making tool, the best performing
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49 191 algorithm will be externally validated in a prospective database. The same performance
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51 192 metrics will be calculated as described above.
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54 194 *Open-access clinical prediction tool*

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57 195 An open-access clinical prediction tool will be developed using the best performing
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59 196 algorithm.
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5 198 *Patients and public involvement*
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7 199 Patients and the public were not involved in the making of this protocol.
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11 201 **Current Status**
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13 202 Currently, the study is at the finishing stage of collection data from global databases. Re-
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15 203 evaluation of the data using machine learning algorithms to predict outcomes will start in
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17 204 March 2022. The expected time of completion is by the end of 2022.
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3 206 **ETHICS AND DISSEMINATION**
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5 207 For safe multicentre data exchange and analysis, our Machine Learning Consortium
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7 208 adhered to the World Health Organization (WHO) regulation “Policy on Use and Sharing of
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9 209 Data Collected by WHO in Member States Outside the Context of Public Health
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11 210 Emergencies.”³⁰ The study results will be disseminated through publication in a peer-
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14 211 reviewed journal. No IRB is required for this study.
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212 DISCUSSION

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

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

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5 242 Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den Bekerom, Lukas P.E.
6
7 243 Verweij and Laurens J.H. Allaart contributed to the conception, overall design and planning
8
9 244 of the study. Laurent A.M. Hendrickx and Job N. Doornberg contributed to the conception
10
11 245 and design of the methods section, primarily focussing on the machine learning section and
12
13 246 data analysis. George S. Athwal, Thibault Lafosse and Laurent Lafosse contributed to the
14
15 247 design of the methods section and primarily focussed on how the data should be collected
16
17 248 and interpreted. Sanne H. van Spanning, Geert Alexander Buijze, Michel P.J van den
18
19 249 Bekerom and Lukas P.E. Verweij contributed to writing the protocol. All authors revised this
20
21 250 version of the protocol and gave final approval for it to be published. All authors ensure that
22
23 251 questions related to the accuracy or integrity of any part of this protocol are appropriately
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25 252 investigated and resolved.
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3 253 **CONFLICTS OF INTEREST**
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5 254 Dr. G.S. Athwal reports as 'financial activities outside the submitted work' to be a consultant
6
7 255 for ConMed Linvatec. Dr. L. Lafosse is a consultant for Depuy Stryker, received royalties
8
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15 259 associations that might pose a conflict of interest in connection with the submitted article.
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1 **SUPPLEMENTARY 1** Search strategy2 *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 recrudes*[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

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4 *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 recrudes* 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

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6 *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

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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

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10 *Web of Science/Clarative*

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

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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

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Total	7338	3584
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3 22 **SUPPLEMENTARY 2**
4

5 23 The manuscript's authors will collect the following potential risk factors from the databases
6
7 24 provided by authors of the Machine Learning Collaboration:

- 9 25 o Gender (male/female)
10
11 26 o Age at time of operation (years)
12
13 27 o Ethnicity
14
15 28 o Preoperative BMI
16
17 29 o ASA classification at time of operation (1-4)
18
19 30 o Epilepsy (yes/no)
20
21 31 o Hyperlaxity (Beighton score < 4 or ≥ 4)
22
23 32 o Affected side (right/left/bilateral)
24
25 33 o Side of operation (right/left/bilateral)
26
27 34 o Dominance (right/left/both)
28
29 35 o Daily smoking at time of operation (yes or no)
30
31 36 o Number of pre-operative dislocations
32
33 37 o Duration of follow-up (years)
34
35 38 o Bony lesions
36
37 39 Bony Bankart lesion (yes/no)
38
39 40 Hill-Sachs lesion
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41 41
 - 42 • Yes/no
 - 43 • Off-track yes/no
44 42 Greater Tuberosity Fracture (yes/no)
45
46 43 Glenoid bone loss ($<20\%$, $\geq 20\%$)
47
48 44 o Soft tissue lesions
49
50 45 Anterior labrum periosteal sleeve avulsion (ALPSA) lesion (yes/no)
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52 46 Superior labrum anterior and posterior (SLAP) lesion (yes/no)
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54 47 inferior glenohumeral ligament (IGHL) (yes/no)
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3 49 Humeral avulsion of the glenohumeral ligament (HAGL) lesion (yes/no)
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5 50 Perthes lesion (yes/no)
6
7 51 Glenolabral articular disruption (GLAD) lesion (yes/no)
8
9 52 Full thickness Rotator Cuff Tear (yes/no)
10
11 53 Partial thickness Rotator Cuff Tear (yes/no)
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13 54 o Nerve Palsy (yes/no)
14
15 55 o Surgical Characteristics:
16
17 o Side (right/left/bilateral)
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19 o Time from injury to surgery (months)
20
21 o Time to surgery from hospital admission (days)
22
23 o Surgeon level (Surgeon/Resident/Fellow)
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