

# Lower HAGOS subscale scores associated with a longer duration of groin problems in football players in the subsequent season

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**To cite:** Harøy J, Bache-Mathiesen LK, Andersen TE. Lower HAGOS subscale scores associated with a longer duration of groin problems in football players in the subsequent season. *BMJ Open Sport & Exercise Medicine* 2024;**10**:e001812. doi:10.1136/bmjsem-2023-001812

► Additional supplemental material is published online only. To view, please visit the journal online (<https://doi.org/10.1136/bmjsem-2023-001812>).

Accepted 10 April 2024

## ABSTRACT

**Introduction** Groin injuries represent a considerable problem in football. Although the Adductor Strengthening Programme reduced groin injury risk, players can still experience groin symptoms throughout the season. This study aimed to determine whether preseason Copenhagen Hip and Groin Outcome Score (HAGOS) and a history of previous injury can identify individuals at risk of having a longer duration of groin problems the subsequent season, using an ‘any physical complaint’ definition of injury.

**Methods** Preseason HAGOS score and weekly groin problems were registered with the Oslo Sports Trauma Research Center Overuse questionnaire during one full season in 632 male semiprofessional adult players.

**Results** The prognostic model showed a decreased number of weeks with groin problems for each increase in HAGOS score for ‘groin-related quality of life’ (QOL) (IRR=0.99, p=0.003). A 10-point higher ‘QOL’ score predicted 10% fewer weeks of groin problems. Additionally, previous hip/groin injury was associated with a 74% increase in the number of weeks with symptoms (p<0.001).

**Conclusion** The HAGOS questionnaire applied preseason can detect players at risk of getting more weeks with groin problems the following season. The ‘QOL’ subscale seems to be the superior subscale for estimating subsequent groin problem duration. While HAGOS appears promising in identifying players at risk, previous groin injury is the most robust indicator, showing a substantial 74% increase in weeks with symptoms.

## INTRODUCTION

Groin injuries represent a considerable problem in football.<sup>1,2</sup> Although introducing the Adductor Strengthening Programme (ASP) demonstrated a reduction in groin injury risk, it is expected that many players may still experience groin symptoms during a season.<sup>3</sup>

Moreover, injuries substantially impact individual players’ football performance, which may also significantly influence team performance and result in considerable rehabilitation costs for the players and teams.<sup>4–6</sup> Secondary preventative strategies have been

## WHAT IS ALREADY KNOWN ON THIS TOPIC?

⇒ Implementing the Adductor Strengthening Programme has demonstrated a reduction in groin injury risk in male football players. Many players, however, can expect experiencing groin symptoms during a season, particularly players having a history of previous injury.

## WHAT THIS STUDY ADDS?

⇒ This is the first study to report the prognostic value of all Copenhagen Hip and Groin Outcome Score (HAGOS) subscales using an ‘any physical complaint’ definition of injury.

⇒ A 10-point higher HAGOS ‘quality of life’ (QOL) subscale in preseason (a decrease in symptoms) was associated with 10% fewer weeks of groin problems in the subsequent season.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY?

⇒ Coaches and health practitioners are recommended to implement HAGOS as a tool for early detection and secondary prevention of groin problems in male football players.

suggested to identify early symptoms to reduce the groin injury burden.<sup>7,8</sup>

The Copenhagen Hip and Groin Outcome Score (HAGOS) questionnaire was developed to quantitatively measure hip and groin disability in young to middle-aged physically active individuals.<sup>9</sup> It consists of six separate subscales: ‘Pain’, ‘Symptoms’, ‘Physical function in daily living’ (ADL), ‘Physical function in Sport and Recreation’ (Sport/Rec), ‘Participation in Physical Activities’ (PA) and ‘hip and/or groin-related Quality of Life’ (QOL). It has been validated in physically active female and male patients (football players) and can differentiate between those with and without hip and groin injuries.<sup>9,10</sup> Since 2011, HAGOS has been translated into more than 15 languages and is frequently used in research and clinical settings assessing athletes with hip and groin injuries.<sup>8,11–17</sup>



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The prognostic value of the HAGOS score, however, is uncertain. Few prospective studies have examined the association between HAGOS score and subsequent hip and groin injury. Low HAGOS scores measured preseason showed an increased risk of injury the subsequent season in professional footballers<sup>11</sup> and Gaelic football players.<sup>12</sup> In contrast, Esteve *et al*<sup>14</sup> found no association between HAGOS score and groin problems in male amateur football players. However, no studies have examined the association between HAGOS score and the duration of symptoms so far.

It is well known that many players continue to participate with associated impairments or reduced performance despite having groin-related symptoms.<sup>1 16–18</sup> Thus, a time loss injury definition may be inappropriate for studying injuries with a large proportion of overuse injuries.<sup>19</sup> To address this, the Oslo Sports Trauma Research Center (OSTRC) has developed a new method to improve the recording of sports injuries using any physical complaint definition of injury to capture all cases leading to pain, decreased participation or decreased performance, not only those resulting in time loss.<sup>20 21</sup>

This study aimed to determine whether HAGOS and a history of previous injury can be used as a tool during preseason to identify players at risk of having groin problems and longer duration of symptoms in the subsequent season.

## MATERIALS AND METHODS

### Study design and participants

The study was based on data from a cluster-randomised controlled trial conducted from February to October 2016, examining the effect of the ASP on the risk of groin problems.<sup>3</sup> All 632 male football players from 34 semiprofessional adult teams (second and third level of play) in Norway were eligible for inclusion. At baseline (February 2016), we collected demographic data, such as playing position, dominant leg (eg, kicking leg) and years as an adult player. Players also registered current groin symptoms using the OSTRC-Overuse Questionnaire (OSTRC-O)<sup>18 20</sup> and the HAGOS.<sup>9</sup>

All players included registered symptoms weekly during the competitive season (28 weeks) and were followed until the end of the current competitive season (October 2016).

### Hip and Groin Outcome Score

In this project, we employed the Norwegian translation of HAGOS, which has not undergone validation or reliability testing. The original HAGOS questionnaire has demonstrated robust test–retest reliability, with intraclass correlation coefficients ranging from 0.82 to 0.91 across the six subscales.<sup>9</sup> At the individual level, the smallest detectable change varies from 17.7 to 33.8 points, while at the group level, it ranges from 2.7 to 5.2 points across different subscales. Additionally, construct validity and responsiveness have been established, showing high levels of correlation between HAGOS subscales and the

36-item short form (ranging from 0.37 to 0.73,  $p < 0.01$ ) for convergent construct validity and responsiveness (ranging from 0.56 to 0.69,  $p < 0.01$ ).<sup>9</sup>

The players received verbal and written information about HAGOS and completed the questionnaire at baseline in the preseason. Based on the individual responses, a summary score from 0 to 100 was calculated for each of the subscales; ‘Pain’, ‘Symptoms’, ‘ADL’, ‘Sport/Rec’, ‘PA’ and ‘QOL’, a score of 0 representing extreme hip and/or groin problems, and a score of 100 representing no hip and/or groin problems.<sup>22</sup>

### Recording and classification of groin problems

Groin symptoms were registered with the OSTRC-O questionnaire based on an ‘any physical complaint’ definition of injury.<sup>20 23 24</sup> OSTRC-O has been used in studies assessing injuries in different body parts and has shown to be a more accurate tool when recording overuse injuries, not necessarily leading to time loss.<sup>3 13 18 20 25–27</sup>

Weekly, the players reported groin problems they had experienced that week. They were categorised as having ‘a groin problem’ if they recorded any symptoms or reported reduced training participation, training volume or performance due to groin problems.<sup>3 18 20</sup> Players were categorised as having a ‘substantial groin problem’ if they reported moderate or severe reductions in training volume or football performance or a complete inability to participate in training or match play due to groin problems.<sup>3 18 20</sup>

### Data quality

Following HAGOS guidelines,<sup>22</sup> 51 (8%) non-responders and 9 (1%) partial responders were removed from the data set. The 4 098 (23%) missing OSTRC-O responses were deemed missing randomly.<sup>28</sup> Since these were the outcome variables, we did not impute.<sup>29 30</sup>

### Statistical analysis

Poisson regression was used to determine whether HAGOS-subscale can provide an estimate of the duration of a groin problem a player can expect in the subsequent season.<sup>31</sup> Each HAGOS subscale was an independent variable in the model, and the response was the number of weeks with a groin problem during the season, accounting for the possibility of multiple episodes. Missing data were treated as 0 (no groin problem) when summing the number of weeks per player. As a sensitivity analysis,<sup>32</sup> checked how model coefficients would change if the missing data were 1 (groin problem), representing the worst-case scenario.

Since we wished to infer whether HAGOS can be used as a prognostic tool, the variable selection was based on the information available to a clinician during a preseason consultation (ex-ante availability).<sup>33</sup> The model, therefore, included independent variables age (years), body mass index, and previous hip/groin injury (no/yes/unsure). By necessity, we also adjusted for intervention (yes/no), as the data were from an RCT.

A random intercept term accounted for within-team correlations.<sup>34 35</sup> The same analysis was performed for substantial groin problems. Significance was set at  $\alpha=0.05$ .

Incidence rate ratios (IRR) were calculated from model coefficients. Standardised IRRs were also calculated to improve the interpretation of continuous variables of varying scales. Correcting for overdispersion, 95% CIs and p values were based on robust SEs.<sup>36</sup> Overly influential outliers were checked with DFbeta,<sup>37</sup> and multicollinearity with variance inflation factor.<sup>38</sup> We performed a sensitivity analysis by bootstrapping the data 200 times with an equal sample size to the original data and running 200 models with the same specifications as the original model on these bootstrapped data.<sup>39 40</sup> This will inform how sensitive the model coefficients are to different combinations of players in the data.

Visualisations were made with the predicted number of weeks with groin problems per level of subscale score. To improve interpretation, we additionally visualised the model coefficients with the HAGOS subscales scores reversed, so that  $IRR>1$  would indicate an increased number of weeks with increased symptoms.

An analysis protocol was developed before conducting analyses. Analyses were performed in R V.4.1.1<sup>41</sup> with packages lme4,<sup>42</sup> MuMIn,<sup>43</sup> geffects,<sup>44</sup> rms<sup>45</sup> and jtools.<sup>46</sup>

### Patient and public involvement

Football players, coaches and sports medicine practitioners were involved in planning the intervention programme for the previously registered trial.<sup>3</sup> However, the present study did not involve patient and public involvement.

## RESULTS

### Descriptive statistics

Complete HAGOS scores were obtained from 572 football players from the intervention and control groups. All baseline characteristics are shown in [table 1](#). Of the players included in the analyses, 334 (58%) reported at least 1 week of groin symptoms, reduced training volume or reduced performance during the 28-week season. On average, players reported 3.8 (SD=6) weeks of symptoms and 1.5 (SD=4) weeks of time loss.

### Prognostic model

The prognostic regression model showed decreased weeks with groin problems for each increase in HAGOS scores for 'QOL' (IRR=0.99,  $p=0.003$ , [table 2](#), [figure 1](#)). As depicted in [figure 1](#), increasing the 'QOL' score from 50 to 51 predicts 0.1% fewer weeks with problems; from 50 to 60 predicts 10% fewer weeks with groin problems. In [figure 2](#), the scales are reversed, and  $IRR>1$  indicates an increased number of weeks with problems. A non-significant decrease in the number of weeks having groin problems was found for HAGOS subscales 'symptoms' (IRR=0.9,  $p=0.084$ ) and 'Sport/Rec' (IRR=0.98,  $p=0.070$ ).

**Table 1** Participant characteristics at baseline (preseason)

Parameter (categorical)	N (%)
Number of players	572
Randomisation group	
Intervention	288 (50)
No intervention	284 (50)
Previous groin/hip injury	
No	208 (36)
Yes	321 (56)
Unsure	43 (8)
Playing position*	
Goalkeeper	60 (11)
Defender	168 (30)
Midfielder	204 (36)
Attacker	139 (24)
Parameter (continuous)	Mean (SD)
Age (years)	22.7 (4.4)
Body mass index	23.1 (1.6)
Years as a senior player	5.7 (4.3)
HAGOS subscales†	Median (min, max)
Pain	95 (0, 100)
Symptoms	82 (21, 100)
Function in activities of daily living	100 (20, 100)
Function in sport and recreation	91 (0, 100)
Participation in physical activities	100 (0, 100)
Quality of life	90 (10, 100)

\*One player had missing data for playing position.  
 †HAGOS subscales had skewed distributions, and therefore, the median was calculated instead of the arithmetic mean.  
 HAGOS, Copenhagen Hip and Groin Outcome Score.

Regarding 'pain', the model demonstrated the opposite results (IRR=1.01,  $p=0.120$ ) and 'ADL' (IRR=1.01,  $p=0.232$ ), where higher HAGOS scores predicted a higher number of weeks with groin problems ([figure 1](#)), though not significant. The subscale 'PA' showed no association ([figure 1](#)).

The model predicted an increased number of weeks for each yearly increase in age (IRR=1.05,  $p=0.004$ ). Additionally, previous hip/groin injury was associated with a 74% increased number of weeks with injury ( $p<0.001$ ), as illustrated for each level of the HAGOS subscale in online supplemental figure S1. In the sensitivity analysis where missing data were assumed to represent the worst-case scenario, coefficients for HAGOS subscales became smaller but did not change direction (online supplemental table S1). In the bootstrap sensitivity analysis, subscales 'pain' and 'ADL' varied between increased numbers of weeks with increased groin symptoms to decreased number of weeks with increased symptoms,

**Table 2** Model coefficients from a multivariable mixed effects Poisson regression, where the number of weeks with groin problems was the outcome (n=572)

Term*	Standardised IRR†	IRR	CI (lower–upper)	Robust SE	P value
HAGOS subscales					
Pain	1.203	1.014	1.00–1.08	0.0091	0.120
Symptoms	0.858	0.991	0.98–1.00	0.0052	0.084
Function in activities of daily living	1.111	1.008	0.99–1.02	0.0068	0.232
Function in sport and recreation	0.809	0.989	0.98–1.00	0.0060	0.070
Participation in physical activities	0.974	0.999	0.98–1.00	0.0033	0.705
Quality of life	0.775	0.987	0.98–1.00	0.0045	0.003
Other continuous variables					
Age (years)	1.221	1.047	1.01–1.08	0.0159	0.004
Body mass index	1.955	0.971	0.89–1.06	0.0428	0.486
Categorical variables					
Randomisation group					
Intervention (reference)	–	–	–	–	–
No intervention	1.601	1.601	0.80–3.19	0.3515	0.181
Previous groin injury					
No (reference)	–	–	–	–	–
Yes	1.744	1.744	1.26–2.41	0.1658	< 0.001
Unsure	1.650	1.650	1.01–2.70	0.2514	0.046

\*Intercept IRR=2.67, CI 0.3 to 21.3; random intercept on football team SD=0.357.

†Standardised IRR refers to 1 SD increase in the corresponding continuous covariate.

IRR, incidence rate ratio; SE, standard error.

based on bootstrap samples (online supplemental figure S2).

## DISCUSSION

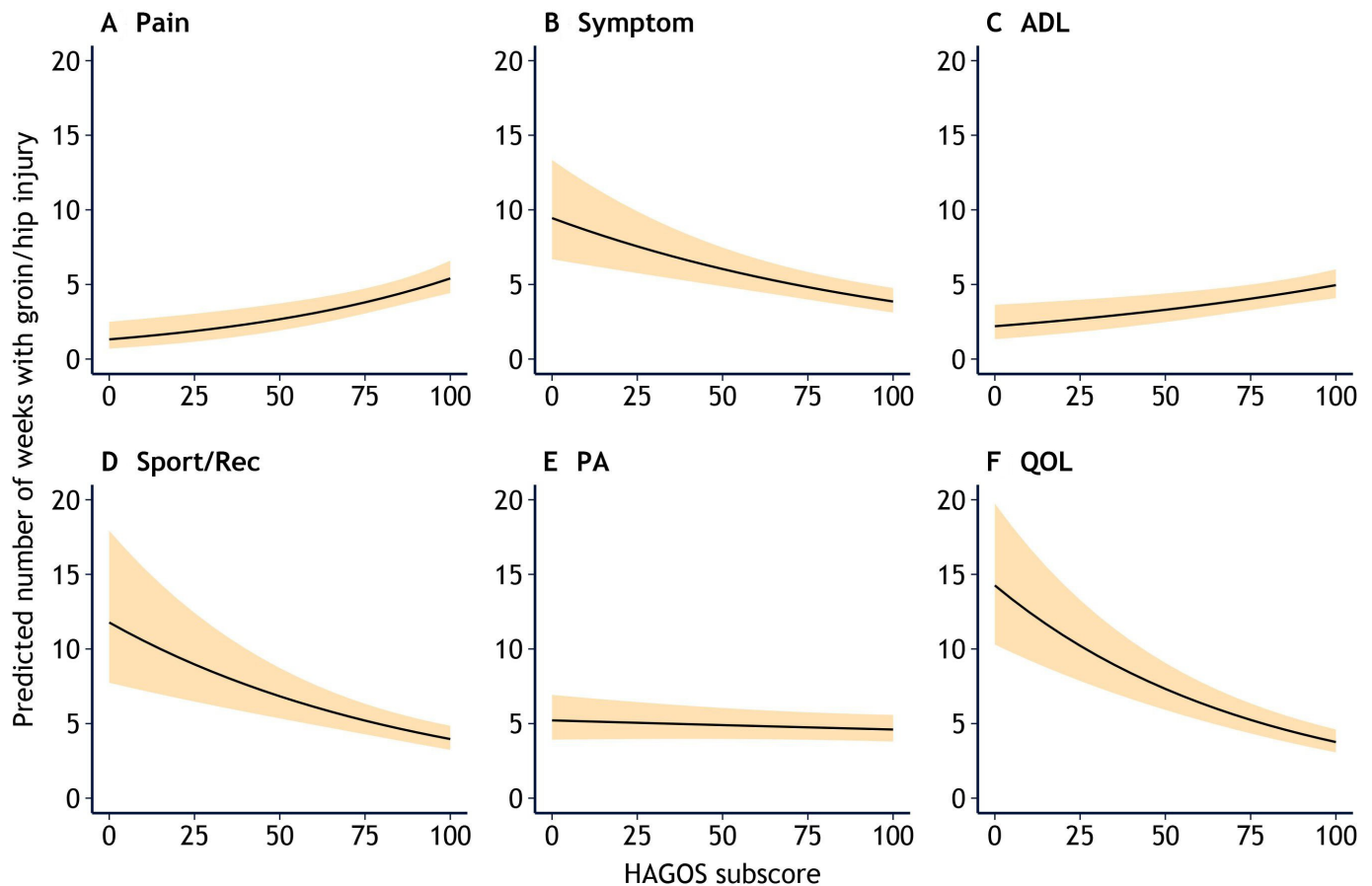
The present study is the first to report the prognostic value of all HAGOS subscales using an ‘any physical complaint’ definition of injury in semiprofessional adult male footballers. The main finding was that a 10-point higher HAGOS ‘QOL’ subscale in preseason (a decrease in symptoms) was associated with approximately 10% fewer weeks of groin problems in the subsequent season. Even if not significant, the HAGOS ‘Symptom’ and ‘Sport/Rec’ subscales showed similar tendencies. While HAGOS appears promising in identifying players at risk for an increase in the number of weeks with groin problems, it is noteworthy that a history of previous groin injury emerges as the most robust indicator, showing a substantial 74% increase in weeks with symptoms.

Previous studies examining the prognostic value using a time-loss injury definition have shown conflicting evidence. In professional footballers, an increased risk of groin injury for all subscales was demonstrated.<sup>11</sup> In Gaelic football, similar results were found for players who scored lower on the ‘Sport/Rec’ subscale.<sup>12</sup> In contrast, Esteve *et al*<sup>14</sup> found no association between HAGOS ‘Sport/Rec’ subscale and groin problems in male amateur footballers. It is well documented that a definition of an ‘any physical complaint’ injury is more

appropriate when measuring and reporting predominately overuse injuries.<sup>19</sup> Hence, our findings not only enhance the comprehension of the prognostic value of the HAGOS but also highlight that the ‘QOL’ subscale is important in identifying individuals at risk of longer duration having groin problems, surpassing the previous focus solely on injury risk as reported.

The “QOL” sub-scale contains five questions related to groin-specific QOL.<sup>9</sup> These selected questions are derived from the Hip disability and osteoarthritis outcome score,<sup>47</sup> which, in turn, is adapted from the Knee Injury and Osteoarthritis Outcome Score.<sup>48</sup> All three Patient-Reported Outcome Measures are widely adopted in research and clinical settings. While we acknowledge that HAGOS may not provide a comprehensive overview of a player’s overall QOL, it does offer a measurement of their QOL specifically related to their recent groin symptoms.

Currently, we are not aware of studies with the primary aim of evaluating how groin injuries affect QOL, and it is an area that requires further exploration. However, existing research indicates that sports injuries elicit cognitive, emotional and behavioural responses in injured athletes.<sup>49</sup> Moreover, studies demonstrate an increased likelihood of developing mental health disorders following injuries, underscoring the significant stress injuries impose on athletes.<sup>50</sup> Additionally, from the athletes’ perspective, perceived reduced performance and the inability to manage such situations have



**Figure 1** The estimated number of weeks with groin problems in the following season, for each level of Copenhagen Hip and Groin Outcome Score subscales (A) pain, (B) symptom, (C) activities of Daily Living (ADL), (D) function in sport and recreation (Sport/Rec), (E) participation in physical activities (PA) and (F) quality of life (QOL). The yellow band corresponds to 95% robust CIs. The results pertain to an individual with mean age (23 years), mean body mass index (23), previous injury in the groin/hip (yes) and intervention (no). Based on data from 572 semi-professional male football players.

been identified as key factors for athletes to perceive themselves as injured.<sup>51</sup>

While our data may not directly contribute to an increased understanding of why QOL explains an elevated risk of extended duration of groin problems, we can speculate that the QOL questions capture factors related to athletes' perceptions of their injury experience or their thoughts and emotions surrounding their situation when injured. In the future, gaining more insights into this aspect and considering alternative questionnaires, such as the widely adopted EQ-5D,<sup>52</sup> may offer a more comprehensive description and enhance our understanding of the impact on QOL for players experiencing groin injuries.

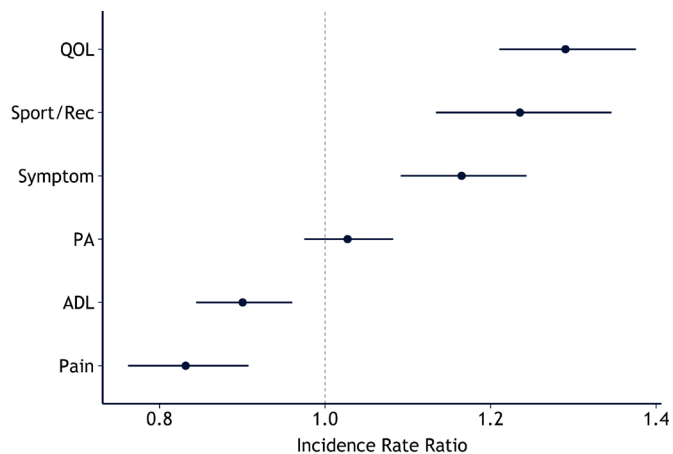
Consistent with the previous studies,<sup>8 11 12 14</sup> this study supports using HAGOS as a monitoring tool. Considering our findings, however, including all subscales may not be required. Hence, we argue that the 'QOL' represents the most relevant subscale for identifying players at risk of experiencing extended periods of groin problems, irrespective of their participation in football training or matches.

Although this study showed that preseason HAGOS subscales may be relevant for identifying players at

increased risk of having longer duration with groin problems, a previous groin injury had a much higher impact. Players reporting a previous groin injury had a 74% increased chance of more weeks with groin problems. These data align with previously published data identifying previous groin injury as the most consistent risk factor for a groin injury in football.<sup>53–59</sup> Consequently, the primary focus of secondary prevention strategies for medical staff or coaches should be identifying players with a history of groin problems. The FIFA 11+ and the ASP have been demonstrated to be effective in reducing the risk of groin problems in footballers and should be implemented early when symptoms occur.<sup>3 60 61</sup>

### Practical implications

Players' health, wellness and performance are closely monitored using various applications or digital tools designed to collect these data types. Especially at the professional and academy level, players often self-report health and wellness data daily or weekly.<sup>62–64</sup> At lower levels of play and in youth football, monitoring of hip and groin symptoms is equally important, as the groin injury rates and prevalence are expected to be high.<sup>13 17 18</sup> However, at lower levels of play, players and



**Figure 2** A ranking of the Copenhagen Hip and Groin Outcome Score (HAGOS) subscale coefficients, measured by standardised incidence rate ratios (IRR). The HAGOS subscales were reversed: 0 indicates no symptoms, and 100 indicates 100% symptoms. Therefore, the coefficients are opposite from table 2: an IRR>1 (right side of the vertical line) indicates an increased number of weeks with groin problems expected in the subsequent season for each SD increase in the HAGOS subscale. In other words, an increase in symptoms increases the number of weeks with groin problems. Vice versa, an IRR<1 (left side of the vertical line) indicates fewer expected weeks with groin problems in the following season for each SD increase in the HAGOS subscale. When symptoms increase, the expected number of weeks decreases. Coefficients are arranged by the largest increase in the expected number of weeks with groin/hip injury in the following season to the least increase in the predicted number of weeks. Error bars represent 95% CIs. ADL, activities of daily living; PA, participation in physical activities; QOL, quality of life; Sport/Rec, physical function in sport and recreation.

coaches are often part-time employees and weekly or monthly registration of HAGOS is perceived to be too time-consuming. Time constraints for players and healthcare practitioners around clubs are often cited as barriers to implementation.<sup>65 66</sup> The trade-off between benefit and time investment becomes crucial when introducing new measures. Based on our findings, the most impactful intervention for club healthcare practitioners aiming to reduce the prevalence of groin injuries is the early detection of players with a history of such injuries. These detected players will likely have the highest risk of groin problems in the subsequent season. Moreover, using HAGOS can identify players at risk of extended periods of groin problems. Administering the five questions in HAGOS ‘QOL’ is quick, making it time-efficient for identifying athletes at risk of prolonged problems. Therefore, based on our data, we recommend that healthcare practitioners maintain an overview of previous groin injuries among their players and use HAGOS ‘QOL’ as a supplement to identify players at an increased risk of extended periods of groin symptoms.

While more frequent use of HAGOS is likely preferred for identifying problems early, we face the same

challenge of balancing benefits versus time spent. Therefore, we suggest implementing preseason HAGOS as a minimum. Furthermore, according to a Spanish study, players with symptoms from the previous season may start the following season with strength deficits and be prone to increased groin injury risk.<sup>14</sup> Thus, by adding a postseason registration of HAGOS, we are likely to detect symptoms early and be able to intervene accordingly during the off-season period.

In addition, building on the approach used in a study among Australian adolescent football players, HAGOS was introduced monthly for early detection of hip and groin pain.<sup>8</sup> We suggest incorporating a change in HAGOS score as a trigger for medical attention and a thorough clinical examination. Players reporting a score <75/100 in any HAGOS subscale should trigger an alert notification, leading to a clinical examination. This recommendation is particularly relevant for clubs already conducting regular HAGOS assessments or considering its introduction as a valuable tool in their real-life setting.

### Methodological considerations

The main limitation of this study was that the footballers’ scores on all HAGOS subscales were heavily skewed, with most players having few symptoms at the time of inclusion (table 1). The explanation can be found in the study design: the RCT excluded players not expected to train or play during the first 6–8 weeks of the season due to injury or illness.<sup>9</sup> We argue that the excluded football players had such severe symptoms that they either would already be under rehabilitation or they would be detected and given treatment regardless of any prognostic model. This research aimed to distinguish those who could potentially benefit from rehabilitation and would not easily be picked up by traditional screening methods from players who do not need rehabilitation.

Nevertheless, the lack of players with more severe hip and groin symptoms may have affected the model coefficients. Indeed, the bootstrap sensitivity analysis showed some variability in the model from one bootstrap to another, emphasising the uncertainty that stems from the composition of players. The prognostic factors Pain and ADL varied the most; based on player composition, they often predicted not only an increased number of weeks with increased symptoms but also a *decreased* number of weeks with increased symptoms—the opposite conclusion. Most individuals had little pain and good ADL (skewed distributions). Therefore, the predictive ability of the subscales ‘Pain’ and ‘ADL’ in each bootstrap could be strongly influenced by the presence or absence of outliers with high pain or poor ADL. In future studies, we should aim to include players with a wider range of HAGOS scores to determine with certainty whether ‘Pain’ and ‘ADL’ subscales are valuable prognostic tools.

Another limitation was the amount of missing data in the OSTRC responses (23%). We assumed missing data to be weeks of no groin problems to avoid imputing discrete outcome data, which still has unclear recommendations

from statistical literature.<sup>29,30</sup> The missing data sensitivity analysis, which assumed that all missing data represented a week of groin problems, showed smaller predictive strength for each HAGOS subscale. This indicates that the strength of the true association between preseason HAGOS scores and the number of weeks with groin problems the following season is likely to be smaller than estimated in table 1, although larger than estimated in online supplemental table S1. For 'QOL', the true standardised IRR, estimated if we had no missing data, would be between 0.78 and 0.86.

## CONCLUSION

The HAGOS questionnaire, measured in the preseason, can detect players at risk of a longer duration of groin problems in the subsequent season. The 'QOL' subscale was strongly associated with a longer duration of groin problems. We recommend using HAGOS for early detection and secondary prevention of groin problems in male football players. While HAGOS appears promising in identifying players at risk, previous groin injury is the most robust indicator, showing a substantial 74% increase in weeks with symptoms.

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**Acknowledgements** The authors thank Alexander Brun, Even Eide Eriksen, Marianne Lislevand, Kevin Nordanger Martin, Kenneth Hammond Rosbach, Arve Kjøsnæs, Anders Megård and Inge Dehli Andersen for their assistance in data collection. We also thank all players and coaches who participated in the study, as well as the club's medical staff teams.

**Contributors** All authors were involved in the conception and design of the study. JH had the initial idea for the study and performed the literature search. LKB-M conducted the data analysis. JH drafted the manuscript. All authors critically reviewed and revised the manuscript. JH and TEA serve as the guarantors for the overall content of the manuscript, having full access to the data and making the final decision to submit for publication.

**Funding** Oslo Sports Trauma Research Center has been established at the Norwegian School of Sport Sciences through generous grants from the Royal Norwegian Ministry of Culture, the South-Eastern Norway Regional Health Authority, the International Olympic Committee, the Norwegian Olympic Committee and Confederation of Sport and Norsk Tipping AS.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Data used in this study is obtained from a previously published cluster-randomised controlled trial 5 registered with the International Standard Randomised Controlled Trial Number registry (ISRCTN98514933). The study was approved by the South-Eastern Norway Regional Committee for Medical Research Ethics (2015/1922/REK) and the Norwegian Data Inspectorate (45388/3/LT/LR). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer-reviewed.

**Data availability statement** No data are available.

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