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Self-reported bio-psycho-social factors partially distinguish rotator cuff tendinopathy from other shoulder problems and explain shoulder severity: A case-control study

Mehmet Delen¹ | Ateş Şendil² | Jean-François Kaux³ | Carles Pedret⁴ | Guillaume Le Sant⁵ | Jessica Pawson⁶ | Stuart Charles Miller¹ | Aleksandra Birn-Jeffery⁷ | Dylan Morrissey^{1,6}

¹Bart's and the London School of Medicine and Dentistry, Sports and Exercise Medicine, William Harvey Research Institute, Queen Mary University of London, Mile End Hospital, London, UK

²School of Physical Education and Sports, Cyprus Health and Social Sciences University, Güzelyurt, Cyprus

³Physical Medicine and Sport Traumatology Department, University and University Hospital of Liège, Liège, Belgium

⁴Sports Medicine and Clinical Ultrasound Department, Clínica Diagonal, Esplugues de Llobregat, Barcelona, Spain

⁵University of Nantes, Movement, Interactions, Performance, Nantes, France

⁶Barts Health NHS Trust, London, UK

⁷School of Engineering and Materials Science, Institute of Bioengineering, Queen Mary University London, London, UK

Correspondence

Dylan Morrissey, Bart's and the London School of Medicine and Dentistry, Sports and Exercise Medicine, William Harvey Research Institute, Queen Mary University of London, Mile End Hospital, Bancroft Road, London E1 4DG, UK.

Email: d.morrissey@qmul.ac.uk

Abstract

Objective: Examine how rotator cuff (RC) tendinopathy differed from other shoulder problems (OSP) by measuring a variety of self-reported bio-psycho-social factors, and establish which explain severity.

Methods: A validated online survey battery was used to collect self-reported biopsychosocial variables in an international population. Diagnostic group and severity were the dependent variables. Multiple logistic and linear regression analyses were utilised to generate explanatory models for group differences and severity after group comparison and univariate regression analysis.

Results: 82 people with RC tendinopathy (50 female, 42.8 ± 13.9 years) and 54 with OSP (33 female, 40.2 ± 14.1 years) were recruited. Both groups had comparable severity results (Shoulder Pain and Disability Index = 37.3 ± 24.5 vs. 33.7 ± 22.5). Seven factors individually differentiated RC tendinopathy from OSP. The multivariable model included 4 factors: activity effect on pain (OR(95%CI) = 2.24(1.02-4.90)), previous injury in the shoulder (OR(95% CI) = 0.30(0.13-0.69)), activity level (moderate OR(95% CI) = 3.97(1.29-12.18), high OR(95% CI) = 3.66(1.41-9.48)) and self-efficacy (OR(95%CI) = 1.12(1.02-1.22)) demonstrating acceptable accuracy. The second multivariable model for RC tendinopathy severity included one demographic, three psychological and two biomedical variables (β (range) = 0.19-0.38) and explained 68% of the variance.

Conclusion: Self-reported bio-psycho-social variables may be beneficial for further detailed clinical assessment as they partially distinguish RC tendinopathy from OSP, even when the groups have comparable overall pain and functional problems. Moreover, these variables were shown to be substantially associated with RC tendinopathy severity variance, implying that the clinical evaluation might be improved, perhaps by pre-consultation online data collection. The models should be

validated in the future and considered alongside data from physical and imaging examinations.

KEYWORDS

case-control, condition-specific, rotator cuff, severity, tendinopathy

1 | INTRODUCTION

Rotator cuff (RC) tendinopathy is the most frequent cause of shoulder pain (Littlewood et al., 2013; Luime et al., 2004; Ostor et al., 2005). Patients commonly report persistent or recurrent shoulder symptoms even 1 year after initial assessment (Chester et al., 2017; Van der Windt et al., 1996), from which researchers have reported a low (under 50%) recovery rate 6-12 months after initial examination (Bot et al., 2005; Ebenbichler et al., 1999; Pleiner et al., 2004). High-quality treatment needs to be condition-specific and individually tailored (Greenberg, 2014). Diagnostic approaches typically include a clinical examination and imaging, but currently a detailed assessment of a wide range of bio-psycho-social factors are rarely used (Hegedus et al., 2012; Iannotti & Williams, 2007; Michener et al., 2009). However, as is the case with all complex musculoskeletal conditions, the headline diagnostic label does not yield the detail of bio-psycho-social assessment. For example, RC tendinopathy diagnosis does not indicate whether a patient has severe symptom or fear avoidance. The bio-psycho-social details are required to guide management in the adequately individualised and holistic manner necessary to guide treatment and optimise outcomes. This study concerns detailed selfreported bio-psycho-social factors to complement clinical assessment.

The increasingly ubiquitous access to online assessment due to technological advances in Western societies, with the acceleration caused by the Sars Cov-2 pandemic, have yielded an opportunity and a necessity to increase and improve remote patient-level data collection in research and usual care (Nittas & von Wyl, 2020; Wosik et al., 2020). For example, Wosik et al. (2020) reported that before the pandemic, less than 1% of the total visits in many health services were made using remote examination methods. However, the visit percentage peaked to 70% during the pandemic restriction period. Therefore, detecting self-reported variables which help distinguish people with RC tendinopathy from other shoulder problems (OSP) could help augment diagnosis and, more importantly, provide some of the detail needed for holistic assessment while minimising the clinical time commitment and optimising safety.

As well as defining the detail of presenting conditions, self-report data could help explain RC tendinopathy severity. Associations between severity and psychological factors such as fear-avoidance beliefs and catastrophizing have been widely reported for various shoulder problems including RC tendinopathy, as have higher fearavoidance and catastrophisation scores (George & Hirsh, 2009; Kromer, Sieben, de Bie, & Bastiaenen, 2014; Martinez-Calderon et al., 2019; Mintken et al., 2010; Wong et al., 2020). However, the combinations of bio-psycho-social factors have been less well examined with multivariable models having the potential to inform our understanding of severity (Hosmer Jr, Lemeshow, & Sturdivant, 2013). For example, Kromer et al. (2014) examined whether a limited number of demographic, clinical and psychological factors could explain disability in people with subacromial shoulder pain. Although demographic factors alone could explain 15% of the variance in shoulder severity; demographic, clinical and psychological factors explained 37% of the variance in shoulder disability. Understanding severity is particularly important as it is typically the single most powerful predictor of outcome in the medium (Chester et al., 2019) and very long term (Jakobsen et al., 2018). Therefore, the associations between severity and a wide range of bio-psycho-social factors have been investigated to provide better understanding of shoulder severity in RC tendinopathy.

Our aims were to determine what self-reported assessment factors, alone and in combination, distinguish people with previously diagnosed RC tendinopathy from people diagnosed with other shoulder problems and to better explain severity. This should enable clinicians to better understand, and possibly manage, RC tendinopathy.

2 | METHOD

This study was approved by the United Kingdom Health Research Authority (264615), Queen Mary Ethics of Research Committee (QMERC2018/92) and University of Liège Hospital-Faculty Ethics Committee (2019/182). The STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guideline was followed (Cuschieri, 2019).

2.1 | Participants

Participants with shoulder problems were recruited through social media, private clinics, Barts Health NHS hospital trust and a network of collaborators (Supplement 1). After giving informed consent, participant eligibility was checked. The inclusion criteria were: (a) being aged 18 or over, and either (b) having a rotator cuff (RC) tendinopathy diagnosis from a medical professional or (c) having another musculoskeletal condition diagnosis in the shoulder (OSP) in the last 6 months. The exclusion criteria were having neurological diseases.

2.2 | Variable selection

Previous research revealed associations between shoulder severity in RC disorders and a single or limited number of bio-psycho-social

variables. Forty-two plausible self-reported bio-psycho-social variables were derived from previous studies as independent variables for regression analyses, and presented in Table 1 and Supplement 2 (references in Supplement 3).

2.3 | Online questionnaire battery

The online questionnaire battery consisted of 9 patient-reported outcome measures (PROMs) and a range of additional questions related to the selected demographic, biomedical, social and psychological factors which were administered using SmartTrial (version 4.0, MEDEI ApS, Aalborg, Denmark). For international recruitment, the online questionnaire battery was translated – and back translated as a check - to Turkish. French and Spanish to recruit a large number of people with shoulder problems. If a PROM had already been translated into one of the three languages, the translated version was used (Supplement 4). Ten French participants were recruited, representing 8% of the whole sample size (n = 136). These participants completed the Shoulder Pain and Disability Index (SPADI) but this has not been validated in French. However, in this study, the SPADI score of French participants strongly correlated (r = -0.87) with the French Western Ontario Rotator Cuff Index (WORCI) that has been previously validated for French speakers (St-Pierre et al., 2015). Pain details (such as pain locations, severity and pain types) were also collected separately using a body map on Navigate Pain (Version 1, Aglance Solutions, Denmark) (Supplement 5). If requested, the survey is available from the corresponding author. The validity, reliability and feasibility of the online survey had previously been established, showing that the selected bio-psycho-social factors could be collected remotely with good validity and good-excellent reliability). Participants' feedback and recruitment lessons were used to streamline the online survey.

SPADI was the primary measurement of shoulder severity. WORCI was also used to evaluate the severity. Moreover, for global shoulder assessment, Patient Acceptable Symptom State (PASS) was used to measure participant satisfaction about shoulder problems (Tashjian et al., 2009), and the Single Assessment Numeric Evaluation (SANE) used to evaluate to what extent a participant's shoulder condition was normal (Furtado & MacDermid, 2019). Five factors (activity level, catastrophizing, fear-avoidance, quality of life, and self-efficacy) have shown a univariate association with shoulder condition severity (Chester et al., 2019; Grobet et al., 2018; Imagama et al., 2019; Jain et al., 2018; Ranasinghe et al., 2011; Van Rijn et al., 2010; Wong et al., 2020), and were measured with The Global Physical Activity Questionnaire (GPAQ), The Pain Catastrophizing Scale (PCS), Fear Avoidance Belief Questionnaire (FABQ), EQ-5D-5L (five-level version of the five-dimensional EuroQol), and General Self-Efficacy Scale (GSES), respectively (Chester et al., 2019; Herrmann et al., 2013; Marti et al., 2016; Mintken et al., 2010; Osman et al., 1997). The Rheumatoid Arthritis Disease Activity Index-5 (RADAI5) was selected to measure disease activity (Leeb et al., 2008) as people with rheumatoid arthritis (RA) frequently have shoulder problems (Petersson, 1986; Walker-Bone et al., 2003). The eHealth Literacy Scale (eHEALS) was used to evaluate participants' confidence and ability to use electronic health resources for health problems (Norman & Skinner, 2006). Participants drew their pain on body diagram using Navigate Pain (Aalborg University, Denmark) (Supplement 5), previously shown to be valid and useful to improve clinicians' understanding as well as aiding diagnostic decisions (Bayam et al., 2017; Oliveira et al., 2020; Shaballout et al., 2019).

2.4 | Data analysis

Questionnaire scores were calculated using published formulae (Mintken et al., 2010; Osman et al., 1997; St-Pierre et al., 2016), yielding interval or categorical data. GPAQ was categorised into three groups: (1) Highly active (vigorous activity >1500 METs minutes per week, or sum of moderate and vigorous activities >3000 METs minutes per week); (2) Moderately active (total GPAQ >600 METs minutes per week); (3) Inactive (total GPAQ <600 METs minutes per week) (Ng et al., 2009). We visualised raw data to understand and check data spread and distribution. Participants' occupations were categorised into 3 categories (1- professionals, 2- white-collar and 3- blue-collar) according to the Job Australian Standard Classification of Occupations (ASCO) (1987) (Health & Welfare, 1994; Statistics, 1997).

Data were extracted from the pain map drawing for analysis: (1) pain location (generalised or focal (central, anterior, posterior, superior and lateral)) and (2) number of painful body regions (Ektor-Andersen et al., 1999; Itoi et al., 2006; Pribicevic, 2012; Ranasinghe et al., 2011).

2.5 | Statistical analysis

Statistical analysis was conducted using STATA (version 16.0, Stata-Corp LP, College Station, TX, USA). Data visualisation and calculation of descriptive statistics were used to profile the results for each participant group. Groups (RC tendinopathy and OSP) were then compared using t-tests, Mann-Witney U or chi-square in accordance with data type and normal distribution, and relevant effect sizes calculated (Cohen's D or Cramer's V) (Table 1). Univariate regression analyses were conducted to test the individual association of plausible independent variables, with the dependent variables being diagnostic group (logistic) and shoulder condition severity (linear). Each independent variable with a univariate analysis p-value under 0.10 was used in the model building process using multiple linear or logistic regression analysis with the manual forward approach (Chester et al., 2016). To avoid multicollinearity, correlations between independent variables were tested with Cramer's V or Pearson correlation coefficient based on data type in addition to the variance inflation factor (VIF) (Hosmer Jr et al., 2013; Kennedy et al., 2006). If correlation (Hosmer Jr et al., 2013) and individual VIF (O'brien, 2007) between any two independent variables was greater than 0.75 and 10, respectively, the two variables were not employed together in any model. The order of forward inclusion was from demographic to psychological categories (Table 1), with retention of independent variables which improved the model, tested using the likelihood-ratio procedure (Hélie, 2006) to detect

TABLE 1 Self-reported baseline participant characteristics

| Demographics ge (years) MI (kg/m2) | *p < 0.05 and +p < 0.10 compared to other shoulder problems 42.8 ± 13.9 26.3 ± 5.2 | | |
|---|--|----------------------------------|------------------|
| | | 10.0 + 11.1 | |
| MI (kg/m2) | $\textbf{26.3} \pm \textbf{5.2}$ | 40.2 ± 14.1 | <i>d</i> = -0.19 |
| | | 26.9 ± 5.7 | <i>d</i> = 0.06 |
| ex (female: Male) | 50: 32 | 33: 23 | V = -0.02 |
| anguage (English: Turkish: Spanish: French) | 58: 11: 5: 8 | 35: 15: 2: 2 | V = 0.20 |
| Biomedical | | | |
| houlder pain and disability index (0 ^a -100) | $\textbf{37.3} \pm \textbf{24.5}$ | 33.7 ± 22.5 | <i>d</i> = -0.15 |
| Vestern Ontario rotator cuff index (0-100ª) | 56.2 ± 22.0 | 60.3 ± 22.2 | <i>d</i> = 0.24 |
| ingle assessment numeric evaluation (0-100ª) | 56.6 ± 25.3 | 56.5 ± 28.7 | d = -0.004 |
| atient acceptable symptomatic state (No: Yes) | 51: 31 | 32:22 | V = -0.03 |
| heumatoid arthritis disease activity index (0^{a} -10) ($n = 21$) | 5.1 ± 3.1 | 5.9 ± 2.0 | d = 0.28 |
| revious injury presence (No: Yes) | +61: 21 | 30: 24 | V = -0.20 |
| urrent condition duration (<6 months: 6-12 months: >1 year |) 25: 16: 41 | 20: 14: 20 | V = 0.13 |
| amily tendon disorder history (No: Yes) | 61: 21 | 42: 12 | V = 0.04 |
| ain onset (sudden: Gradual: Others) | 33: 49: 0 | 23: 29: 2 | V = 0.16 |
| Iorning pain duration (hour) | 0.8 ± 2.1 | 1.1 ± 3.4 | <i>d</i> = 0.11 |
| lorning stiffness duration (hour) | 0.5 ± 1.7 | 1.2 ± 3.7 | d = 0.26 |
| ain at night (No: Yes) | 28: 54 | 24: 30 | V = 0.10 |
| ctivity effect on pain (get better: Get worse: No effect) | 18: 46: 18 | 24: 20: 10 | V = 0.27 |
| leck pain presence (No: Previous: Current) | 32: 14: 36 | 18: 8: 28 | V = 0.08 |
| lenopausal status (NA: Pre: Current or post) | 44: 20: 18 | 33: 11: 10 | V = 0.07 |
| lormonal contraception use (NA: No: Yes) | 26: 40: 16 | 21: 26: 9 | V = 0.07 |
| Social | | | |
| -health literacy score (8-40 ^a) | $\textbf{29.9} \pm \textbf{6.8}$ | 29.6 ± 5.5 | <i>d</i> = -0.04 |
| ducation level (high school or lower: Undergraduate: Postgraduate) | 22: 38: 22 | 21: 21: 12 | V = 0.13 |
| PAQ-activity level (inactive: Moderately active: Highly active |) 12: 22: 48 | 21: 10: 23 | V = 0.28 |
| xercises regularly (No: Yes) | ⁺ 34: ⁺ 48 | 35: 19 | V = 0.22 |
| Vork status (student or unemployed: Blue collar: White collar Professional: Athlete) | : 19: 5: 8: 48: 2 | 14: 4: 14: 22: 0 | V = 0.25 |
| hange in work participation due to shoulder problem (No: Yes |) 59: 23 | 40: 14 | V = -0.02 |
| PSYCHOLOGICAL | | | |
| Q-5D-5L index score (–1 to 1ª) | $\textbf{0.68} \pm \textbf{0.21}$ | 0.68 ± 0.22 | <i>d</i> = 0.01 |
| Q-5D-5L VAS score (0-100 ^a) | 69.4 ± 21.5 | 66.7 ± 24.2 | <i>d</i> = -0.12 |
| ain catastrophizing score (0 ^a -52) | 11.4 ± 10.4 | 11.1 ± 8.5 | <i>d</i> = -0.03 |
| eneral self-efficacy score (10-40 ^a) | *33.9 ± 4.2 | $\textbf{31.9} \pm \textbf{5.0}$ | <i>d</i> = -0.45 |
| ABQ (physical activity) (0 ^a -24) | 12.4 ± 6.8 | 12.0 ± 6.2 | <i>d</i> = -0.06 |
| ABQ (work) (0°-42) | 13.0 ± 12.5 | 10.9 ± 9.5 | d = -0.19 |
| leep difficulty (No: Yes) | 29: 53 | 21: 33 | V = 0.04 |
| eeling rested after sleep (fully: Partially: No) | 20: 40: 22 | 10: 29: 15 | V = 0.07 |

TABLE 1 (Continued)

3 |

RESULTS

| Variables | Rotator cuff tendinopathy ($n = 82$) | Other shoulder problems ($n = 54$) | Effect size |
|---|--|--------------------------------------|------------------|
| (E) Pain map drawing | Rotator cuff tendinopathy ($n = 57$) | Other shoulder problems $(n = 34)$ | Effect size |
| Number of painful body regions | 2.4 ± 2.2 | 3.0 ± 2.2 | <i>d</i> = 0.26 |
| Focal pain on anterior area of shoulder (No: Yes) | 40: 17 | 17: 17 | V = -0.20 |
| Focal pain on distal area of shoulder (No: Yes) | 37: 20 | 26: 8 | V = 0.12 |
| Current pain level (VAS) | 4.7 ± 2.1 | 4.6 ± 2.6 | <i>d</i> = -0.02 |

Note: Higher score is a worse outcome for SPADI, FABQ, RADAI-5 and PCS, but a better outcome for the rest of the PROMs. Mean \pm standard deviation for continuous data and the number of participants for categorical data. Independent *t*-test or Mann-Whitney *U* test was used based on the normal distribution for *p*-value with Cohen's d effect size. For categorical data, Chi-square with Cramer's V was used for group comparison and effect size, respectively.

Abbreviations: BMI, body mass index; cm, centimetre; DNK, do not know; EQ-5D-5L, Five-level version of the five-dimensional EuroQol; FABQ, Fear Avoidance Beliefs Questionnaire; GPAQ, Global Physical Activity Questionnaire; kg, kilogrammes; m, metre; MET, Metabolic equivalents; *n*, number of participants; NA, not applicable; PCS, Pain Catastrophizing score; PRMOs, patient-reported outcome measures; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5; SPADI, Shoulder Pain and Disability Index; VAS, visual analogue scale.

^aIndicates the best score in the patient reported outcome.

whether an observed model change was unlikely to be due to chance at the 5% significance level.

Model performance and accuracy for multiple logistic regression were tested using the Hosmer-Lemeshow test (goodness of fit, >0.05) and the area under the receiver operating characteristic curve (AUC, >0.7 acceptable, >0.8 excellent) used to estimate sensitivity and specificity (Hosmer & Lemeshow, 2010; Hosmer Jr et al., 2013). Model performance in the multiple linear regression was presented with R^2 , which showed to what extent the model explained the variance of shoulder severity. Odds ratios and beta coefficient (standardised coefficient) values were used to interpret the individual relationship of each independent variable in the logistic and linear regression analyses, respectively.

328 people with shoulder pain were reached 151 consented 151 consented 15 drop out 136 completed survey 82 Rotator cuff tendinopathy 57 recorded pain on the pain map 34 recorded pain on the pain map

FIGURE 1 Flow chart presenting how many participants were reached, recruited and completed each survey step

136 participants (82 people with RC tendinopathy and 54 people with OSP) completed the survey out of 151 who consented to the study between 5th April 2019 and 11th December 2020 (completion rate 91% with 15 excluded from analysis due to missing data). The survey took 32.4 ± 16.8 min 67% of the participants (n = 91) also recorded their pain on the pain map (Figure 1). Diagnoses of OSP and RC tendinopathy groups are presented in Supplement 6.

RC tendinopathy and other shoulder problem groups were similar in terms of all variables in the demographics, biomedical, social and pain map drawing categories (Table 1). For example, both groups had similar distributions in SPADI and age (Supplement 7 and 8). In the biomedical category, shoulder severity scores (SPADI, WORCI) in RC tendinopathy group were slightly worse compared to OSP (Table 1). The dominant arm involvement in both RC tendinopathy and OSP groups was more common compared to non-dominant arm, 73% and 72%, respectively. Moreover, in the psychological category, quality of life scores, pain catastrophising and physical activity subscale of the fear-avoidance questionnaire were very close (Table 1). Nevertheless, there was a significant difference (effect size d = -0.45) in this category as self-efficacy scores of people with RC tendinopathy (33.9 \pm 4.2) were significantly higher than participants in OSP group (31.9 \pm 5.0) (Table 1).

The most painful shoulder area in people with RC tendinopathy was the lateral area over the middle deltoid, being selected in 79% of participants (Table 1). According to univariate logistic regression analysis, pain distribution did not differ significantly between the two groups. However, the OSP group showed a greater tendency towards reporting shoulder pain in the anterior area than participants with RC tendinopathy (OR 0.43, 95% CI 0.18–1.02 p = 0.057) (Table 2 and Supplement 9). Moreover, the univariate linear regression analysis showed participants with distal shoulder pain (coefficient = 17.5, $R^2 = 0.12$, p = 0.01) and participants who reported pain in more sites around the shoulder had worse shoulder severity (coefficient = 6.6, $R^2 = 0.14$, p = 0.01).

3.1 | Model development

3.1.1 | Multi-variable model distinguishing between groups

Based on the univariate analysis, PROMs including the WORCI which has specifically been developed for RC disorders - did not distinguish people with RC tendinopathy from OSP, with the exception of GSES. After univariate logistic regression analysis of each plausible variable between the groups (Table 2 and Supplement 9), there were seven variables for the model construction as their p values in univariate analyses were less than 0.10. The final model was built with four variables ($\chi^2 = 28.08$, p < 0.0001). People with RC tendinopathy were prone to have no previous shoulder injury (OR = 0.30, p = 0.004), get worse pain with activity (OR = 2.24, p = 0.004)p = 0.044), have a higher self-efficacy score (OR = 1.12, p = 0.01) and be more active (moderately active OR = 3.97, p = 0.01 and highly active OR = 3.66, p = 0.01) compared to people with OSP. The model accuracy was acceptable (AUC = 0.77) with 76% specificity and 74% sensitivity, and the fit was good (Hosmer-Lemeshow test = 0.15). Pain localisation did not significantly improve any logistic regression model.

3.1.2 | Multi-variable model explaining severity in people with rotator cuff tendinopathy

In terms of univariate analysis, 34 variables were associated with the severity variance in the measures of people with RC tendinopathy (Table 2 and Supplement 9). However, PASS ($R^2 = 0.20$), SANE $(R^2 = 0.34)$ and WORCI $(R^2 = 0.65)$ were not used for model building as they could also be used to measure shoulder severity. Moreover, they were correlated with each other (Supplement 10), for example, the correlation between SPADI and WORCI was very strong (r = -0.80). Disease activity (RADAI-5) in RA explained well the severity variance ($R^2 = 0.64$). However, the disease activity score was not included in the model building process due to there being only 10 participants with RA in the RC group. The final linear regression model included six variables. Severity in people with RC tendinopathy was associated with: worse quality of life (β coefficient = -0.38, p < 0.001); having night pain ($\beta = 0.19$, p = 0.02); having unilateral morning stiffness symptoms ($\beta = 0.25$, p = 0.001); having higher body mass index (β = 0.29, p < 0.001); higher fear-avoidance in the work subscore ($\beta = 0.25$, p < 0.001); and higher pain catastrophizing $(\beta = 0.21, p = 0.02)$ (Table 3). Overall, the model explained 68% of the variance in RC tendinopathy severity ($R^2 = 0.68$, p < 0.0001) (Figure 2).

The secondary model including the pain map data to explain severity in rotator cuff tendinopathy.

To show the role of pain location on the explanation of shoulder severity, a mini model was built to include the pain drawings (n = 57) without current ($R^2 = 0.27$), and usual pain ($R^2 = 0.16$) levels as the SPADI included shoulder pain-related questions. The final multiple

linear regression model included four variables. Worse RC tendinopathy severity was associated with: having distal shoulder pain (β coefficient = 0.32, p = 0.002); having night pain (β = 0.34, p = 0.001); being less active (moderately active β = -0.42, p < 0.001 or being highly active β = -0.45, p < 0.001); and higher pain catastrophizing (β = 0.30, p = 0.001). Overall, the model explained 52% of the variance in people with RC tendinopathy severity (R^2 = 0.52, p < 0.0001) (Supplement 11).

4 | DISCUSSION

We found that seven self-reported bio-psycho-social factors partially distinguished RC tendinopathy from other shoulder disorders individually (univariate), with four being retained to construct the multivariable model including one social factor (activity level), one psychological factor (self-efficacy) and two biomedical factors (previous injury in the shoulder and activity effect on pain). Moreover, we found that RC tendinopathy severity was associated with many biopsycho-social factors, in particular, guality of life had a strong relationship ($R^2 = 0.42$). For example, the final model explaining severity in RC tendinopathy consisted of 6 self-reported factors, with 3 psychological (quality of life, fear avoidance and catastrophising), one demographic (body mass index) and two biomedical factors (night pain and morning stiffness) included. The models were associative and prospective validation is needed, so the identified relationships should not be considered as being causal. Also, we recruited only a few participants who were over 70 years old. However, we argue the addition of self-reported bio-psycho-social factors into clinical assessment could help clinicians better characterise and manage RC tendinopathy in digitally literate and white people younger than 70 years old - whether that is using remote data collection, such as that deployed in this study, or face to face data collection.

4.1 | Between group differences

Use of physical clinical tests and imaging in assessment has been extensively tested (Hopman et al., 2013; Michener et al., 2009; Ottenheijm et al., 2010) but self-reported bio-psycho-social data has not been examined, although the data may complement the usual history and physical examination. According to the guidelines for RC disorders assessment and management, it is recommended that clinical examination should consist of a combination of clinical tests and history, plus psycho-social characteristics (Hopman et al., 2013). Michener et al. (2009) carried out a study to test which combination of 5 clinical tests discriminate people with subacromial impingement syndrome (SIS) from those without. Acceptable performance (the area under the receiver operating characteristic (ROC) curve (AUC) = 0.79, specificity 74% and sensitivity 75%) for 3 positive results out of 5 clinical tests was found. If a person with RC disorders had persistent symptoms after 4-6 weeks of a treatment (e.g. exercise) period, it is recommended to use imaging such as ultrasound to

TABLE 2 (a) Univariate linear regression analysis for RC tendinopathy severity (dependent variable: SPADI), >0 in a coefficient of a variable in linear regression means that an increase in the variable is related to worse shoulder severity; (b) Univariate logistic (having rotator cuff (RC) Tendinopathy versus having other shoulder problem (OSP)), >1 in an odds ratio of a variable means that an increase in the variable is possibly related to having RC tendinopathy

| | (A) Univariate line: (Dependent variab | - | | (B) Univariate logistic regression (n = 136) (Dependent variable = RC tendinopathy vs. OSP) | | |
|--|---|----------------|---------|---|------------|---------|
| Variables | Coef | R ² | Prob> t | Odds ratio | 95% CI | Prob> z |
| (A) Demographics | $^{*}p$ < 0.05 and ^{+}p < | 0.10 | | | | |
| Age | 0.6 | 0.10 | 0.004* | 1.01 | 0.99-1.04 | 0.27 |
| Body Mass Index | 1.9 | 0.16 | <0.001* | 0.98 | 0.92-1.04 | 0.52 |
| Sex (ref: female) | -9.3 | 0.03 | 0.096+ | 0.93 | 0.46-1.88 | 0.84 |
| (B) Biomedical | | | | | | |
| Shoulder pain and disability index | NA as it is depende | ent variable | | 1.01 | 0.99-1.02 | 0.39 |
| Western Ontario rotator cuff index | -0.9 | 0.65 | <0.001* | 0.99 | 0.98-1.01 | 0.30 |
| Single assessment numeric evaluation | -0.6 | 0.34 | <0.001* | 1.0001 | 0.99-1.01 | 0.98 |
| Patient acceptable symptomatic state (ref: No) | -22.3 | 0.20 | <0.001* | 0.88 | 0.44-1.79 | 0.73 |
| RADAI-5 | 4.3 | 0.64 | 0.005* | 0.89 | 0.63-1.26 | 0.52 |
| Previous injury in shoulder (ref: No) | 4.9 | 0.01 | 0.43 | 0.43 | 0.21-0.90 | 0.02* |
| Family tendon disorder history (ref: No) | 11.4 | 0.04 | 0.07+ | 1.21 | 0.54-2.71 | 0.65 |
| Morning pain (ref: No) | 19.2 | 0.15 | <0.001* | 0.81 | 0.40-1.64 | 0.55 |
| Morning pain duration | 4.2 | 0.13 | 0.001* | 0.96 | 0.85-1.09 | 0.55 |
| Morning Stiffness (ref: No) | Unilateral: 19.6 | 0.18 | <0.001* | 0.62 | 0.29-1.30 | 0.21 |
| Morning stiffness duration (hour) | 4.48 | 0.10 | 0.004* | 0.90 | 0.76-1.06 | 0.19 |
| Pain at night (ref: No) | 26.4 | 0.27 | <0.001* | 1.54 | 0.76-3.12 | 0.23 |
| Activity effect on pain (ref: No effect) | Better -3.7 | 0.01 | 0.34 | 0.35 | 0.17-0.74 | 0.008* |
| | Worse 2.6 | | 0.49 | 2.17 | 1.08-4.39 | 0.03* |
| Neck pain presence (ref: No) | Current 17.1 | | 0.003* | 0.72 | 0.34-1.55 | 0.40 |
| Menopausal status (ref: Pre) | 23.0 | 0.15 | <0.001* | 1.23 | 0.52-2.93 | 0.63 |
| (C) Psychological | | | | | | |
| EQ-5D-5L index | -75.4 | 0.42 | <0.001* | 0.97 | 0.19-4.94 | 0.97 |
| EQ-5D-5L VAS | -0.3 | 0.07 | 0.02* | 1.005 | 0.99-1.02 | 0.50 |
| Pain Catastrophizing score | 0.6 | 0.07 | 0.02* | 1.003 | 0.97-1.04 | 0.86 |
| General Self-Efficacy score | -1.2 | 0.04 | 0.06+ | 1.10 | 1.02-1.19 | 0.01* |
| FABQ (Physical activity) | 1.0 | 0.08 | 0.01* | 1.01 | 0.96-1.06 | 0.38 |
| FABQ (Work) | 0.7 | 0.13 | 0.001* | 1.01 | 0.99-1.05 | 0.28 |
| Feeling rested (ref: Fully) | No 14.2 | 0.04 | 0.06+ | 0.73 | 0.27-2.003 | 0.55 |
| (D) Social | | | | | | |
| E-health literacy score | 0.4 | 0.01 | 0.34 | 1.01 | 0.95-1.06 | 0.80 |
| GPAQ-Activity level (ref: Inactive) | Moderately –29.5 | 0.17 | 0.001* | 3.85 | 1.37-10.79 | 0.01* |
| | Highly –27.3 | | <0.001* | 3.65 | 1.54-8.68 | 0.003* |
| Exercises regularly (ref: No) | -18.6 | 0.14 | <0.001* | 2.60 | 1.28-5.29 | 0.008* |
| Work status (ref: Student or unemployed) | Professional: 0.4 | 0.0001 | 0.95 | 2.05 | 1.02-4.13 | 0.04* |
| Change in work participation (ref: No) | 16.9 | 0.10 | 0.004* | 1.11 | 0.51-2.42 | 0.79 |
| | | | | | | |

(Continues)

TABLE 2 (Continued)

| | ••• | linear regressior riable = SPADI) | • • | ••• | e logistic regre ependent varia ⁄ vs. OSP) | |
|---|------|--------------------------------------|----------|------------|--|----------------------------------|
| Variables | Coef | R ² | Prob> t | Odds ratio | 95% CI | Prob> z |
| E) Pain map drawing | | inear regression riable = SPADI) | (n = 57) | | e logistic regres variable = RC te | sion (n = 91) endinopathy vs. |
| Number of painful body regions | 3.7 | 0.11 | 0.01* | 0.89 | 0.73-1.08 | 0.24 |
| Focal pain on anterior area of shoulder (ref: No) | 7.2 | 0.02 | 0.28 | 0.43 | 0.18-1.02 | 0.06+ |
| Focal pain on distal area of shoulder(ref: No) | 17.5 | 0.12 | 0.01* | 1.76 | 0.67-4.59 | 0.25 |
| Current pain level (VAS) | 6.32 | 0.27 | <0.001* | 1.01 | 0.83-1.22 | 0.94 |

Note: Bold values denote highlight significant values.

Abbreviations: CI, Confidence Interval; Coef, Coefficient; EPV, Event per variable; EQ-5D-5L, Five-level version of the five-dimensional EuroQol; FABQ, Fear Avoidance Beliefs Questionnaire; GPAQ, Global Physical Activity Questionnaire; NA, not applicable; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5; ref, Reference group; SPADI, Shoulder Pain and Disability Index; VAS, visual analogue scale.

measure tendon thickness and screen for pathology (Hopman et al., 2013). Ultrasound has good positive and negative likelihood ratios for diagnostic category in previously screened patients, but there is a mismatch between structure and function meaning imaging cannot lead to treatment prescription of RC disorders or stage its success (Hopman et al., 2013; Ottenheijm et al., 2010). We found that a range of self-reported factors do serve these purposes of deepening the assessment and better understanding severity and should therefore be considered in usual care. It is worthwhile noting that this is not being recommended as a diagnostic procedure but as part of a holistic assessment.

We found the groups with RC tendinopathy and OSP had similar pain and functional compromise while only seven bio-psycho-social factors could partially distinguish RC tendinopathy according to univariate logistic regression analysis (Table 1 and Table 3). This finding that the groups tended to be similar indicates that shoulder pain and function compromise is not specific to a given structural compromise (Salamh & Lewis, 2020; Van der Windt, Koes, de Jong, & Bouter, 1995). Despite the similarity of severity, as shown by SPADI and WORCI, demographic (language), biological (activity effect on pain and previous injury) and social (activity level, exercise regularly and work status) variables did partially distinguish the groups and these may indicate some presentation differences. Three out of the 7 distinguishing factors were related to activity (activity effect on pain, activity level and exercise regularly) and it has been reported that high activity level could cause alteration in RC tendons (Abraham et al., 2021; Girdwood et al., 2017). Similarly, clinical tests of RC tendinopathy include loading because of the presumed pathogenesis (Girdwood et al., 2017; Hegedus et al., 2012). Therefore, we recommend that variables related to activity should be examined in usual care as activity including high load may result in RC tendon alterations (Suzuki et al., 2021).

Researchers have developed many different PROMs to measure shoulder severity as unassisted PROMs are a cost-effective and easy way to collect data (Hopman et al., 2013; Streiner et al., 2015), and the choice of which to use is important in clinical or research settings. Kirkley et al. (2003) developed the WORCI, a disease-specific PROM for shoulder severity in RC disorders, without showing that it was superior to existing scales. Ekeberg et al. (2010) found that WORCI was not more responsive to severity change in RC disorders compared to SPADI and Oxford Shoulder Scale, nor could it distinguish people with impingement syndrome from a full-thickness cuff tear (de Witte, Henseler, Nagels, Vliet Vlieland, & Nelissen, 2012). SPADI has been most commonly selected, which is an additional reason for selection is it assists with comparison of populations and results (Mc Auliffe et al., 2021). We found a strong correlation (r = 0.80) between the SPADI and the WORCI in RC tendinopathy, with no between-group difference, but the WORCI is longer so we recommend using the SPADI due to the reduced questionnaire burden.

4.2 | Severity in people with rotator cuff tendinopathy

Study population characteristics are important to guide the reader whether and to whom they can generalise the findings, for example, in clinical populations (Gartlehner et al., 2006). For generalisability, the International Scientific Tendinopathy Symposium Consensus statement recently recommended Nine important domains which should be reported in clinical studies focussing on tendinopathy, of which we assessed seven (Vicenzino et al., 2020). According to a recent systematic review detailing how well tendinopathy studies report participants' characteristics, previous studies poorly reported participants' characteristics (Mc Auliffe et al., 2021). For example, only two out of 45 studies reported psychological factors (Mc Auliffe et al., 2021). Therefore, our study included a detailed characteristics table (Table 1) so that clinicians can easily decide whether the findings from our sampling are comparable to their clinical population.

Online surveys seem to be a suitable and cost-effective method to collect self-reported data in a research context (Hopman et al., 2013; Streiner et al., 2015), and may also be applicable in

Final multiple regression models

| with rotator cuff tend | inopathy ($n = 82$) | from othei | r shoulder problems ($n = 54$) |
|------------------------|--|--|--|
| Odds ratio | 95% CI | p> z | Interpretation: People with rotator cuff tendinopathy |
| 0.30 | 0.13-0.69 | 0.004 | were less likely to have had a previous shoulder injury, |
| | | | |
| 2.24 | 1.02-4.90 | 0.044 | tend to have worse pain with activity, |
| 1.12 | 1.02-1.22 | 0.01 | tend to have better self-efficacy, |
| | | | and tend to be more active |
| 3.97 | 1.29-12.18 | 0.01 | |
| 3.66 | 1.41-9.48 | 0.01 | |
| | Odds ratio 0.30 2.24 1.12 3.97 | Odds ratio 95% Cl 0.30 0.13-0.69 2.24 1.02-4.90 1.12 1.02-1.22 3.97 1.29-12.18 | 0.30 0.13-0.69 0.004 2.24 1.02-4.90 0.044 1.12 1.02-1.22 0.01 3.97 1.29-12.18 0.01 |

... in comparison to people with other shoulder problems

And reporting of higher pain catastrophising score

(B) The model explaining severity in people with rotator cuff tendinopathy (n = 82)

-22.2 (-33.9--10.4)

0.8 (0.3-1.3)

| Independent variable | Coefficient (95% CI) | Beta coefficient | p> t | Interpretation: Worse rotator cuff tendinopathy severity was associated with |
|---|---|---|-------------------------------|--|
| EQ-5D-5L index | -43.7 (-63.723.7) | -0.38 | <0.001 | Worse quality of life, |
| Night pain | 9.9 (2.0-17.9) | 0.19 | 0.02 | Having night pain, |
| Unilateral morning stiffness | 12.7 (5.1-20.2) | 0.25 | 0.001 | Having unilateral morning stiffness symptoms, |
| Body Mass index | 1.4 (0.8–1.9) | 0.29 | <0.001 | Having a higher BMI, |
| Fear avoidance belief | | | | |
| Questionnaire work score | 0.5 (0.2–0.7) | 0.25 | <0.001 | Reporting of higher fear avoidance |
| Pain catastrophising score | 0.5 (0.1-0.9) | 0.21 | 0.02 | And higher pain catastrophising. |
| 1 0 | | | | , the higher pair educer ophising. |
| (C) The mini model with the pain m | | everity in people v | | |
| (C) The mini model with the pain m Independent variable | | everity in people v Beta coefficient | | |
| Independent | ap drawing explaining s | | vith rotato | Interpretation: Worse rotator cuff tendinopathy severity was |
| Independent variable | ap drawing explaining s Coefficient (95% CI) | Beta coefficient | vith rotato p> t | Interpretation: Worse rotator cuff tendinopathy severity was associate with |
| Independent variable Distal shoulder pain | Coefficient (95% CI) 16.9 (6.3-27.5) 18.8 (8.1-29.6) | Beta coefficient | vith rotato p> t 0.002 | r cuff tendinopathy (n = 57) Interpretation: Worse rotator cuff tendinopathy severity was associate with Having pain in distal shoulder site |
| Independent variable Distal shoulder pain Night pain | Coefficient (95% CI) 16.9 (6.3-27.5) 18.8 (8.1-29.6) | Beta coefficient 0.32 0.34 | vith rotato p> t 0.002 | r cuff tendinopathy (n = 57) Interpretation: Worse rotator cuff tendinopathy severity was associate with Having pain in distal shoulder site |

Note: **A)** Multiple logistic regression analysis: the dependent variable is having rotator cuff tendinopathy compared to having other shoulder problems. **B&C)** Multiple linear regression analysis with the SPADI as the dependent variable.

0.001

0.001

-0.45

0.30

Abbreviations: BMI, body mass index; CI, Confidence Interval; EQ-5D-5L, Five-level version of the five-dimensional EuroQol; GPAQ, Global Physical Activity Questionnaire; SPADI, Shoulder Pain and Disability Index.

Equations of the models.

Highly active

Pain catastrophising score

A-Linear predictor = $-4.2 + (-1.2 \times \text{Having previous injury}) + (0.8 \times \text{Activity effect on pain}) + (0.1 \times \text{General self-efficacy score}) + (1.4 \times \text{Moderately Active}) + (1.3 \times \text{Highly active}).$

B- Severity in RC tendinopathy = $8.2 + (-43.7 \times EQ-5D-5L \text{ index}) + (9.9 \times \text{Night pain}) + (12.7 \times \text{Unilateral morning stiffness}) + (1.4 \times \text{Body mass index}) + (0.5 \times \text{Fear avoidance belief questionnaire work subscale score}) + (0.5 \times \text{Pain catastrophising score}).$

C- Severity in RC tendinopathy = $28.9 + (16.9 \times \text{Distal shoulder pain}) + (18.8 \times \text{Night pain}) + (-22.7 \times \text{Moderately Active}) + (-22.2 \times \text{Highly active}) + (0.8 \times \text{Pain catastrophising score}).$

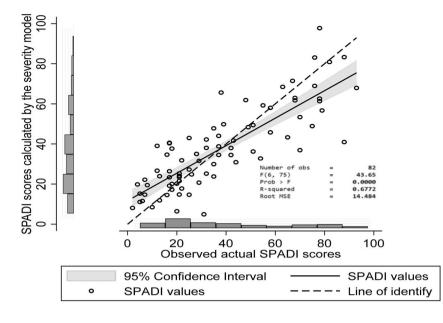


FIGURE 2 The final multiple linear regression model visualisation which explained 68% of the severity variance in rotator cuff tendinopathy. SPADI, Shoulder Pain and Disability Index

routine care. We were able to recruit an international sample and collect data related to many bio-psycho-social factors, finding that 34 self-reported factors were associated with severity. This meets the recommendations of both a large survey of 787 health professionals who agreed that 20 bio-psycho-social factors could be important factors preventing optimised function (Peters et al., 2020), and strong recommendations from systematic reviews concerning the importance of psycho-social factors in this population (Lin et al., 2020). Our final model included three psychological variables explaining severity (quality of life, fear avoidance and catastrophising). Similarly, George and Hirsh (2009) reported an association between higher catastrophising and worse shoulder severity for RC disorders. Kromer et al. (2014) found an association between fear-avoidance belief and shoulder severity for subacromial pain syndrome. Imagama et al. (2019) found higher shoulder severity was associated with poorer quality of life in people with shoulder problems. Moreover, Chester et al. (2019) reported that poor outcome was associated with worse severity with worse self-efficacy in people with shoulder pain. That could highlight that if shoulder severity was examined with psychological variables, clinicians could understand prognosis better as psychological variables explained severity variance strongly, in this study. Therefore, we recommend that clinicians should consider assessing psychological factors alongside the usual biomedical assessment in routine shoulder assessment.

4.3 | Pain mapping

Pain drawings complement clinical examination by improving clinicians' understanding (Shaballout et al., 2019). Itoi et al. (2006) found that more patients with RC tendinopathy had pain in the lateral shoulder compared to five other shoulder areas, which supports our findings. Ranasinghe et al. (2011) found that people who had pain in multiple body areas reported worse severity in the shoulder-neck region compared to people who had pain in a single body area. Similarly, we found that univariate linear regression analysis revealed that a higher number of painful body regions explained 11% of the variance of shoulder severity. Furthermore, night pain in the shoulder and distal shoulder pain were reported in a higher percentage of people with severe shoulder problems (Itoi et al., 2006). Likewise, our final model included both the biomedical and pain map drawing factors, so we recommend investigation of night pain and pain location to help understand severity, rather than solely as indicators of masquerading pathology or indicators of a likely culprit structure.

We did not find any significant differences in pain drawings between the RC tendinopathy and OSP groups, which may explain why the extracted variables did not make any significant change to the model distinguishing between groups. In contrast, Bayam et al. (2017) could differentiate 71.4% of people with RC tendinopathy according to non-assisted pain drawing data using a diagnostic guideline whose criteria were shoulder pain location, pain radiation, pain nature and age. This apparently conflicting result could be explained by the use of a differing guide, or previous results being over-optimistic (Bayam et al., 2017). The result could be related to low numbers of events as at least 10 events per variable are typically recommended for logistic regression analyses (Peduzzi et al., 1996). Therefore, pain drawing data validity and utility can be better established with higher numbers and completion.

4.4 | Limitations

In our study, participants self-reported the diagnosis based on previous consultation with a health professional instead of an in-person clinical examination, a deliberately chosen strategy to enable collection of a large international cohort. This may have caused a lack of homogeneity in the groups, despite numerous checks of the data, such as a set of confirmatory questions (which led to some exclusions) data visualisation and comparison of group characteristics. Furthermore, there might be an issue with overlap as eight people with RC tears was allocated in other shoulder problems due to reported tear size, perhaps reflecting the difficulty in making clinical diagnoses of shoulder pain. However, the overlap issue should not affect our results negatively as the distinguishing model's AUC score (0.77) was close to excellent threshold (0.8) (Hosmer and Lemeshow (2010). Hosmer Jr et al. 2013). Moreover, the pain drawing data could not be included in the main models as not all participants recorded their pain. The lack of completion could have been due to requiring participants to open a second survey link and learning some new software. Moreover, we found a strong association between disease activity and shoulder severity. This is expected as higher disease activity causes a decrease in all functions, including shoulder (Hochberg et al., 2015). Therefore, shoulder severity increases (Carroll, 2016). However, we could not develop a model specific to people with RA due to low number of event. The main limitation was that the analyses did not have factors related to imaging, clinical and biomechanical assessments. These examinations were commenced but had to be suspended because of the COVID-19 pandemic, and are therefore recommended in future research.

5 | CONCLUSION

Self-reported bio-psycho-social factors may help clinicians better understand the detail of how patients with RC tendinopathy and OSP present in digitally literate and white people younger than 70 years old, both in condition-specific terms and severity. Univariate analyses highlighted that shoulder severity in RC tendinopathy was associated with many bio-psycho-social factors. The combination of selfreported bio-psycho-social factors, including PROMs, explained shoulder severity to a moderate extent. Therefore, the results indicate self-reported factors could augment clinical assessment, either with online pre-consultation completion or face to face. Moreover, the study finding could be generalisable due to the recruitment of a unique international sample and the univariate and multivariable analyses of many factors. Future work is warranted to prospectively validate the models and consider the data alongside physical and imaging assessment, while we are undertaking a cohort study to determine which factors predict recovery.

AUTHOR CONTRIBUTIONS

Mehmet Delen and Dylan Morrissey made substantial contribution to study design; Mehmet Delen, Ateş Şendil, Jean-François Kaux, Carles Pedret, Guillaume Le Sant and Jessica Pawson collected data, Mehmet Delen analysed data; Dylan Morrissey, Stuart Charles Miller, AJM and Mehmet Delen interpreted analyses results; Mehmet Delen draughted the manuscript; Dylan Morrissey, Ateş Şendil, Jean-François Kaux, Carles Pedret, Guillaume Le Sant, Jessica Pawson, Stuart Charles Miller and Aleksandra Birn-Jeffery gave feedback to the draughted manuscript.

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CONFLICT OF INTEREST

The author declares that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This study was approved by the United Kingdom Health Research Authority (264615), Queen Mary Ethics of Research Committee (QMERC2018/92) and University of Liège Hospital-Faculty Ethics Committee (2019/182).

ORCID

Mehmet Delen b https://orcid.org/0000-0002-0693-8046 Guillaume Le Sant b https://orcid.org/0000-0001-7614-6389

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