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CAN CONTINUOUS KNEE PAIN OUTCOME MEASURES BE HARMONISED?

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Abstract:

Purpose: Several numerical patient-reported outcome measures (PROMs) have been used for measuring knee pain. Each aims to measure the participant's experience of pain, but may address different pain characteristics. There is increasing need for pooling pain data from studies using different PROMs and implementing such techniques as Individual Patient Data (IPD) analyses. Harmonised data should give the same numerical value for pain severity, irrespective of the host PROM. Our recent meta-analysis of data taken from different patient groups (Georgopoulos et al., OARSI 2021, DOI: <https://doi.org/10.1016/j.joca.2021.02.076>) indicated that if knee pain PROMs are harmonised by linear transformation to a 0 to 100 scale (100 = worst pain), a score of 30/100 may correspond to the Patient Acceptable Symptom State (PASS). In the current study, we aimed to further explore the validity of a harmonised continuous pain PROM at the individual patient level.

Methods: Using data from 4 studies of knee OA and knee injury, we conducted an IPD analysis of 3 commonly used knee pain PROMs (Western Ontario and McMaster Universities Osteoarthritis Index-WOMAC Pain Subscale, Knee injury and Osteoarthritis Outcome Score-KOOS Pain Subscale, Numerical Rating Scales-NRS) in which each participant completed at least 2 of the 3 PROMs permitting paired

analysis. Data were from WebEx: a randomised trial exploring the effectiveness of Internet-Based Exercises in individuals with knee OA, KICK and MenTOR: longitudinal studies exploring associations of biomarkers with clinical outcomes in individuals with an acute knee injury and in individuals with a symptomatic degenerative meniscal tear respectively, and NEKO: a cross-sectional study exploring neuromuscular control in individuals with knee OA. PROMs data were standardised to a 0 to 100 scale before analysis (100 = worst pain). WOMAC Pain subscale scores, if not otherwise available, were derived from corresponding items within KOOS. Strength of association (Spearman's rank-order correlation) and agreement between paired PROMs (Concordance correlation co-efficient) were determined. Variance estimates were calculated by linear regression using the whole study population. Bland-Altman plots were developed to visually assess whether there was evidence of heteroscedasticity and establish the limits of agreement (LoA) between pairs of standardised PROM scores.

Results: The 4 cohorts comprised diverse participant populations (**Table 1**). PROMs were strongly and significantly correlated with each other within each cohort (**Table 2**), and across the whole study population; NRS and KOOS; $n=325$ $\beta=0.76$ (95%CI: 0.65 to 0.88), $SE=0.06$, $p<0.0001$, $R^2=0.35$ (<0.0001), Intercept: 12.10 (95%CI: 7.01 to 17.19); NRS and WOMAC; $n=430$, $\beta=0.65$ (95%CI: 0.56 to 0.74), $SE=0.05$, $p<0.0001$, $R^2=0.31$ (<0.0001), Intercept: 21.77 (95%CI: 18.20 to 25.33); KOOS and WOMAC; $n=325$, $\beta=0.86$ (95%CI: 0.82 to 0.90), $SE=0.02$, $p<0.0001$, $R^2=0.85$ (<0.0001), Intercept: 13.44 (95%CI: 11.98 to 14.90). Mean differences between standardised PROMs were low, but limits of agreement were wide; NRS:KOOS: Mean difference: 2.49 (95%CI: 0.22 to 4.76), +LoA: 43.26, -LoA: -38.29; NRS:WOMAC: Mean difference: 10.25 (95%CI: 8.24 to 12.26), +LoA: 51.81, -LoA: -31.32 KOOS:WOMAC: Mean difference: 9.03 (95%CI: 8.15 to 9.90), +LoA: 24.78 -LoA: -6.73.

Conclusions: Different PROMs provide related data on knee pain. Although standardised scores from different PROMs give similar mean data (i.e. mean differences that may not be clinically important), we identified substantial heterogeneity within individuals' data. PROMs should ideally be selected according to clinical population and research question being studied, and interpreted carefully with respect to what aspects of their knee pain are important to the patient. Our results further suggest exercising caution in attempting to harmonise differing longitudinal pain PROM data within or between participants and studies. It may be that a dichotomisation at harmonised PASS threshold on a PROM, as proposed in our systematic literature review, may have greater tolerance to allow comparisons between different pain PROMs datasets, which will be tested in corresponding research.

Table 1. Participant demographics, descriptives, differences between PROMs pairs within all cohorts

Variables (Value, Range, %)	Descriptives			
	WebEx	KICK	MenTOR	NEKO
	Median (IQ Range)	Median (IQ Range)	Median (IQ Range)	Median (IQ Range)
No. participants	105	139	113	73
Female (n (%))	71 (68%)	25 (18%)	38 (34%)	44 (60%)
Age (y)	68 (60 to 73)	25 (21 to 33)	48 (40 to 53)	63 (55 to 69)
BMI (kg/m²)	31 (28 to 34)	25 (23 to 28)	29 (23 to 35)	39 (26 to 34)
NRS (0-100)	50 (30 to 60)	30 (20 to 50)	50 (30 to 70)	46 (25 to 69)
KOOS-Pain Subscale (0-100) [†]	-	36 (25 to 47)	42 (25 to 56)	42 (31 to 56)
WOMAC-Pain Subscale (0-100)	40 (25 to 50)	20 (10 to 35) ^{\$}	35 (20 to 50) ^{\$}	35 (25 to 50) ^{\$}
BMI: Body Mass Index, NRS: Numerical Rating Scale, KOOS: Knee Injury and Osteoarthritis Score (pain subscale), WOMAC: Western Ontario and McMaster Universities Arthritis Index (pain subscale).				
Data are n (%) or median (interquartile range)				
[†] KOOS was lineary transformed to a 0 to 100 scale where 100 represents worst pain.				
^{\$} WOMAC: Scores here were a pseudoWOMAC pain scale, claculated, when otherwise available, from the Questions 5 to 9 in the KOOS pain subscale.				

Table 2. Associations between PROMs within all cohorts

Variables (PROMs combinations and test types)	Associations			
	WebEx	KICK	MenTOR	NEKO
NRS ~ KOOS (Pain subscale) association				
Spearman's coefficient (p)	-	0.54 (<0.0001) [‡]	0.65 (<0.0001) [‡]	0.64 (<0.001) [‡]
CCC (p)	-	0.80 (<0.001) [‡]	0.81 (<0.0001) [‡]	0.80 (<0.001) [‡]
NRS ~ WOMAC (Pain subscale) association				
Spearman's coefficient (p)	0.41 (<0.0001)	0.55 (<0.0001) ^{\$}	0.60 (<0.0001) ^{\$}	0.65 (<0.001) ^{\$}
CCC (p)	0.74 (<0.001)	0.76 (<0.001) ^{\$}	0.77 (<0.0001) ^{\$}	0.79 (<0.001) ^{\$}
KOOS (Pain subscale) ~ WOMAC (Pain subscale) association				
Spearman's coefficient (p)	-	0.89 (<0.0001) ^{‡,\$}	0.95 (<0.0001) ^{‡,\$}	0.92 (<0.001) ^{‡,\$}
CCC (p)	-	0.80 (<0.001) ^{‡,\$}	0.90 (<0.0001) ^{‡,\$}	0.88 (<0.001) ^{‡,\$}
CCC: Concordance Correlation Coefficient, NRS: Numerical Rating Scale, KOOS: Knee Injury and Osteoarthritis Score (pain subscale), PROMs: Patient Reported Outcome Measures, WOMAC: Western Ontario and McMaster Universities Arthritis Index (pain subscale).				
[‡] KOOS was lineary transformed to a 0 to 100 scale where 100 represents worst pain.				
^{\$} WOMAC: Scores here were a pseudoWOMAC pain scale, claculated, when otherwise available, from the Questions 5 to 9 in the KOOS pain subscale.				

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