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Prevalence of rotator cuff tendinopathy and the resulting impact on health services: the Chingford general population cohort

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Competing interests: No competing interests

Ethics approval: Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96.

Patient and public involvement

We would like to thank all the participants of the Chingford Women Study for their time.

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Thank you to Dr Gemma Wallis, Statistician, for reviewing statistical analysis processes used in this study.

Data sharing: For information about the Chingford 1000 Women Study, email chingford@ndorms.ox.ac.uk.

Dissemination to participants and related patient and public communities: We will disseminate our findings to patient organisations and media outlets.

Provenance and peer review: Not commissioned; peer reviewed at Orthopaedic meetings.

Structured Abstract

Objectives:
To define the population prevalence of rotator cuff tears and test their association with pain and function loss in a general population cohort. Secondly, to determine the impact of shoulder pain in association with rotator cuff tears on primary healthcare services.

Design:
Cross sectional observational study.

Participants:
Individuals were part of the Chingford 1000 women cohort, a 20-year-old longitudinal population study comprising 1003 women aged between 64 and 87, and representative of the population of the UK.

Main outcome measures:
To compare symptoms across stages of rotator cuff tendinopathy using the Oxford shoulder score, and to quantify resultant GP consultations.

Results:
The population prevalence of full-thickness tears was 22.2%, which increased with age ($p<0.001$), and in the dominant arm (RR 1.64, $p<0.001$).

Although 48.4% of full-thickness tears were asymptomatic there was an association between rotator cuff tears and patient reported symptoms. Individuals with at least one full-thickness tear were 1.97 times more likely, than those with bilateral normal tendons ($p<0.001$), to have symptoms. Severity of symptoms it not related to the severity of the pathology until tears are >2.5cm ($p=0.009$).

8.9% of the cohort had seen their GP with shoulder pain and a full-thickness rotator cuff tear, 18.8% with an abnormality and 29.3% overall.

Conclusion:
Rotator cuff tears are common, and primary care services are heavily impacted. As 50% of tears remain asymptomatic, future research may investigate the cause of pain and whether different treatment modalities, aside from addressing the pathology, need further investigation.

Trial Registration:
The local ethics committee approved the study (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Strengths and limitations of this study:

- Pain on the Oxford Shoulder Score is associated with the presence of rotator cuff tendinopathy, but not the extent of structural pathology identified on ultrasound imaging.
- Rotator cuff tendinopathy poses a large burden on the healthcare system with 28.8% of people seeking GP consultation for their shoulder pain.
- This epidemiological study demonstrates association but not causality and leaves unanswered questions as to what additional factors contribute to shoulder pain.

Introduction

Musculoskeletal pain is one of the most common sources of disability in the Western world[1]. The shoulder is the third most common site of musculoskeletal disease[2], with an estimated 20% of the population reporting pain at any given time[3]. Pain related to rotator cuff tears are estimated to account for 30-40% of these shoulder complaints[4], causing high levels of disability and associated healthcare costs [5-7]. High-definition ultrasound is the current gold standard for the detection of full-thickness tears, and is a valid tool to detect an abnormal tendon enthesis[8], but has poorer accuracy to detect partial-thickness tears[8-14]. Full thickness tears are recognised to be common and associated with increasing age[15-18], however, prevalence in symptomatic and asymptomatic shoulders varies widely across cadaveric[19], radiological[19] and retrospective cohort studies[16-18 20-28]. Furthermore, the presence of selection bias in studies undertaken in rotator cuff tendon tears [16-28], has meant population-based studies available, are not representative of Western demographics. Thus, research in this area may lead to a better understanding of the natural history of rotator cuff tears.

Clinical manifestations of rotator cuff tears are varied[15 17 22 26 28], and detection of pathology and its relationship to clinical symptoms is not well established. Many tears are asymptomatic but are thought to be at risk of developing symptoms with time[26]. Although larger tears are more likely to be painful, there is also no evidence to suggest that they have a greater severity of symptoms than smaller tears[29]. One population cohort from a mountainous region has suggested that only a third of full-thickness tears were painful, of which symptoms were more prevalent in the dominant arm[30]. Though, all studies investigating symptom association have looked at isolated shoulders, and have not considered that the individual, who has two shoulders, may have a significant influence on symptoms rather than solely the underlying pathology. To date, no study has explored the association between rotator cuff tears, pain and functional loss in a general population cohort, or how these impact on a health service.

This study aims to: (i) describe the population prevalence of different stages of rotator cuff tear in a general population cohort of women; (ii) determine what proportion of rotator cuff tears are symptomatic, and whether the severity of symptoms correlates with tear stage severity; (iii) identify individual influences on the likelihood of symptoms and (iv) quantify the impact of symptomatic rotator cuff tears on primary health care services.

Methods

Design

Study participants were identified from the Chingford Study, a well described prospective population-based longitudinal study of osteoarthritis and osteoporosis, comprising 1003 women, derived from the register of a large general practice in Chingford, North London[31-33]. The women aged 44-67 years at baseline are representative of women in the UK general population with respect to weight, height, and smoking characteristics. The study was established in 1989 and 516 women attended the year 20 follow-up visits. A musculoskeletal assessment, including the Oxford shoulder score, and bilateral shoulder ultrasound examination was performed in 463 women (of the original 1003, 158 women had died, 111 were unable to attend, 218 had moved away or been lost to follow up, 52 attended the year 20 visit but did not have a shoulder assessment due to lack of assessor, and 1 did not complete an Oxford shoulder score). The local ethics committee approved the study and consent was obtained from each woman (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Outcome measures:

Participant characteristics of age, height, weight, hand dominance, and a self-reported musculoskeletal questionnaire filled out a priori (including the Oxford Shoulder Score[34 35], body chart and questions regarding previous pain, treatments and whether medical advice has been sought), were all collected at baseline. A musculoskeletal ultrasound assessment on bilateral shoulders was then undertaken using a fixed SOPP (standard operating procedure protocol).

The ultrasound examination of the 464 women was completed by two orthopaedic assessors and performed using a GE voluson i-portable ultrasound machine with a 10-16MHz linear probe. Ultrasound training and appropriate validation studies[36] were completed as recommended by the BESS focus group - 343 individuals were scanned by assessor 1 and 121 individuals by assessor two. Appropriate inter and intra-rater reliability studies were performed and showed high reproducibility (weighted kappa 0.92 $p<0.001$) and no difference in reporting trends ($p=0.08$). The ultrasound protocol was derived according to the recommendations of the Nuffield Orthopaedic Centre Musculoskeletal radiology department. Tendons were classified into one of four working groups based upon ultrasound measurements as validated by Hinsley et al.[8]: (i) normal tendon; (ii) abnormal tendon and partial thickness tear; (iii) single tendon full-thickness tears (0-2.5cm) and (iv) multi-tendon full-thickness tears (>2.5cm) (Figure 1).

Figure 1: Ultrasound images

Data Analysis

All statistics were performed using IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA). Age, BMI, hand dominance, and symptom presence were compared across the four different tendinopathy groups. Wilcoxon rank sum test, one-way ANOVA, and chi-squared tests were used for non-normal, normal and categorical data respectively.

Population prevalence of full-thickness tears was defined as having at least one unilateral full-thickness tear. Population prevalence of tendon abnormalities was defined as having at least a unilateral tendon abnormality ranging from abnormal enthesis to a full thickness tear. This was calculated by summing the percentage with unilateral tears and the percentage with bilateral tears for each age group.

Binary symptoms were defined using a dichotomised Oxford shoulder score[34 35] where, any non-perfect score ($\leq 47/48$) was classified as symptomatic. Where questions are pain specific, the four pain specific questions of the OSS were used as a sub-scale. In symptomatic participants, the full OSS scale, scored on a 0-48 point scale, was used to define symptom severity. A Chi^2 test was used to determine any difference between tendinopathy groups. Multivariate binary logistic regression was used to adjust for the potential confounders age, BMI and hand dominance determined a priori. To account for a high positive skew of the OSS data, all asymptomatic shoulders were removed, and a logarithmic transformation of the inverse OSS was used to create a normal distribution. Symptom severity in symptomatic shoulders was compared across tendinopathy groups using a 1-way ANOVA. Multivariate linear regression was used to adjust for potential confounders age, and hand dominance determined a priori.

Results

464 individuals (928 shoulders) were included in the study (Table 1). The distribution of age across each tendinopathy group was significantly different (p<0.001), with age increasing in accordance with tear severity. There was a statistical difference in the proportion of dominant and non-dominant arms in each tendinopathy group (p=0.033), with there being significantly more non-dominant arms in the normal tendon group (p=0.010), and significantly more dominant arms in those with full-thickness tears (p=0.026). There were no between-group differences in BMI (p=0.080).

Table 1. Demographics of shoulders included in the study

	Frequency	%	Median age	Mean BMI	Dominant arm (%)
Normal	510	55.0%	70	27.5	46.1%
Abnormal/ Partial tear	294	31.7%	73	28.0	52.7%
Full-thickness tears (0-2.5cm)	85	9.2%	74	27.9	58.8%
Full-thickness tears (>2.5cm)	39	4.2%	74	29.6	61.5%
All	928	100%	71	27.8	50%

Prevalence of rotator cuff tendinopathy

The population prevalence of having at least one full-thickness tear was 22.2% (4.5% bilateral). For age groups 60-69, 70-79 and 80-89 these were 14.9%; 25.9% and 29% respectively, and bilateral tears 2.3%; 5.9% and 5.8% respectively. The difference in prevalence between age groups was statistically different (p<0.001).

The population prevalence of having at least a unilateral tendinopathy or tear was 59.5% (30.6% bilateral). For age groups 60-69, 70-79 and 80-89 these were 51.5%; 61.8% and 72.5% respectively, and bilateral tears 24.6%; 32.3% and 40.6% respectively. The difference in population prevalence between age groups was statistically significant (p<0.001).

Table 2 shows the prevalence of rotator cuff tendinopathy in the dominant and non-dominant arms in age deciles. The distribution of tendinopathy differed between age groups (Dominant arm p=0.002; non-dominant arm p=0.037) with more pathology found in older age groups, and in the dominant compared to non-dominant arms (p=0.004). There was no difference in prevalence according to BMI group. The relative risk of full-thickness tear was 1.64 (1.073-2.326, p=0.021) in the dominant compared to non-dominant arm. For those aged 70-79 it was 2.072 (1.286-3.190, p=0.002), and aged 80-89 was 2.293 (1.264-4.027, p=0.006), compared to those aged 60-69.

Table 2. Prevalence of rotator cuff tendinopathy according to age decile and arm dominance

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Non-dominant arm								
Normal tendon	115	65.7%	122	55.5%	38	55.1%	275	59.3%

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Abnormal tendon/Partial thickness tear	49	28.0%	70	31.8%	20	29.0%	139	30.0%
Full-thickness tear 0-2.5 cm	10	5.7%	18	8.2%	7	10.1%	35	7.5%
Full-thickness tear >2.5 cm	1	0.6%	10	4.5%	4	5.8%	15	3.2%

Association of symptoms (all shoulders)

An analysis of symptom association was completed in 926 shoulders (463/464 participants due to loss of one questionnaire). There were 289 (31.2%) symptomatic shoulders according to a dichotomised OSS. The presence of symptoms was statistically significant between tendon groups ($p<0.001$); 51.6% of all full-thickness tears were symptomatic. There was no difference in age, BMI or arm dominance between symptomatic or asymptomatic shoulders. The relative risks of having symptoms compared to those with a reported normal tendon were as follows: Abnormal/Partial tears 1.969; full-thickness tears 0-2.5cm 2.203; and full-thickness tears >2.5cm 4.718. All were significant ($p<0.001$) with the model correctly predicting 71% of symptom outcomes correctly.

Figure 2. Distribution of symptoms across each tendon group

Symptom severity

For the 289 symptomatic shoulders the full OSS was reported (Table 3). Median age was significantly different between groups ($p=0.047$), with age increasing with tear stage severity. No statistically significant between-group differences in BMI were identified, nor any within-group differences for arm dominance.

Table 3. Symptom severity demographics

	N	Median age	Mean BMI	Dominant arm (%)
Normal	116	70	28.3	46.6%
Abnormal/Partial tear	109	73	28.4	54.1%
Full-thickness tears 0-2.5cm	35	72	28.1	62.9%
Full-thickness tears >2.5cm	29	73	30.3	58.6%
All	289	71	28.5	50%

The mean OSS for symptomatic shoulders was 41.8. For normal tendons this was 42.5, abnormal tendons, 42.1; full-thickness tears (0-2.5cm), 40.2; and full-thickness tears (>2.5cm), 38.4. There was a statistical difference between the groups (1 way ANOVA $p=0.030$). Linear regression analysis after adjustment for age, BMI, and hand dominance (no interactions identified), showed that the only significant difference in OSS scores was between normal tendons (mean OSS 42.5) and large full-thickness tears (OSS 38.3), $p=0.009$, power 0.75 (overall model $p=0.007$, power 0.892).

Association of symptoms (individuals)

Table 4 shows the relationship between the individual, presence of full-thickness rotator cuff tear and the likelihood of symptoms. A clustering effect of bilateral symptoms or lack thereof is present, irrespective of the underlying pathology. After adjustment for age and BMI, compared to those with bilaterally normal shoulders the relative risk of having at least one symptomatic shoulder in the presence of a full thickness rotator cuff tear is 1.49, and 1.97 in the presence of at least a unilateral abnormality or cuff tear.

Table 4. Distribution of individual shoulder symptoms according to the presence of full-thickness tears

	No Symptoms	Unilateral Symptoms	Bilateral Symptoms	Total
Bilateral No FTT	226	71	63	360
Unilateral FTT	33	25	24	82
Bilateral FTT	10	3	8	21
Total	269	99	95	463

Shoulder pain and use of primary care health services

Table 5 shows the proportion of individuals with shoulder pain, past or present, seeking medical advice. The likelihood of seeking medical attention for shoulder pain was statistically different between each pathology group (Chi^2 test p=0.005) reflecting the increasing likelihood of pain. However, of those with pain the likelihood of seeking medical attention was not statistically different between groups (Chi^2 test p=0.179). Overall, 28.3% (131/463) of all individuals had at some stage seen their GP for shoulder pain. 8.9% (41/463) of this cohort had seen their GP with shoulder pain and a full-thickness tendon tear and 18.8% (87/463) had seen their GP with an abnormal tendon or full thickness tear.

A multivariable regression model using all individuals was used to predict the likelihood of attending a GP for shoulder pain. The presence of at least one full-thickness tear had a relative risk of 1.6 compared to those with normal tendons of attending the GP. There was no statistical difference in relative risk of those with any tendon abnormality compared to those with bilaterally normal shoulders.

Table 5. Proportion of individuals seeking medical advice

	Present symptoms (either shoulder)		Past or Present symptoms (either shoulder)		All individuals
	%	% seen GP	%	% seen GP	% seen GP
All individuals (n=463)	41.9 (n=194)	44.8 (n=87)	55.7 (n=258)	50.8 (n=131)	28.3 (n=131)
Bilaterally normal tendons (n=187)	29.9 (n=56)	41.1 (n=23)	48.1 (n=90)	48.9 (n=44)	23.5 (n=44)

At least one abnormality (no tear) (n=173)	45.1 (n=78)	41.0 (n=32)	57.2 (n=99)	46.5 (n=46)	26.6 (n=46)
At least one full-thickness tear (n=103)	58.3 (n=60)	53.3 (n=32)	67.0 (n=69)	59.4 (n=41)	39.8 (n=41)

Discussion

Statement of principle findings

Using a large general population cohort of women aged 65-84 years, this study has reported on the prevalence of rotator cuff pathology, the association of pathology to symptoms and uniquely the consequential impact on health services.

The prevalence of rotator cuff pathology has been well reported in the literature, and this general population study, supports previous findings. Prevalence was found to increase with every decile of age, and the relative risk of having a full thickness tear increased more than two-fold between the 65-69 and >80 age groups, suggesting a gradual decline of tendon tissue in response to aging. Overall, the prevalence of at least a unilateral full thickness tear was 22%. The dominant arm was 1.64 times likely to be affected, inferring that the presence of pathology may exist in shoulders with higher cumulative loading with functional tasks.

The relative risk of having symptomatic pathology (worsening OSS scores) increased with tear stage severity, though the severity of symptoms did not increase accordingly. Although larger tear size increased the likelihood of symptom presence, 48.4% of full-thickness rotator cuff tears remained asymptomatic.

The burden of musculoskeletal shoulder pain on health services is large, with 28.3% of individuals in this general population cohort having at some point sought medical advice for shoulder symptoms. This is the first study to look at the impact of rotator cuff tendinopathy and tears and the impact on the health services. Although on average only 50% of individuals with symptomatic rotator cuff tendinopathy will seek medical advice, the impact remains significant. Overall, almost 10% of individuals in the general population have sought medical advice for shoulder symptoms in the presence of a full-thickness tear, and almost 20% of the population for any tendon abnormality.

Strengths and weaknesses of this study

The major strength of this study is that it uses a large general population cohort, and therefore not subject to selection bias. The cohort was originally investigated with the primary focus of osteoporosis, and not shoulder symptoms, thus any continued participation is not driven by shoulder symptoms.

However, there are some potential limitations with the cohort used. Firstly, the cohort can only comment on associations in women aged between 65 and 84, but as previous studies have found no relationship between symptoms and age or sex [23 30], this will not bias the results. Potential survival bias is introduced by the cohort being in its 20th year, though, no known associations exist between shoulder pain and other medical co-morbidities. Furthermore, as the prime goal of the cohort was not

to investigate shoulder symptoms, this had no impact on continued study participation. Furthermore, only 463/516 individuals that attended the year-20 study underwent a shoulder examination.

However, individuals that did were selected at random, and the age and BMI of the groups was not statistically different to the full cohort. Bias arising from having two examiners was ameliorated by two inter-observer reproducibility studies that demonstrated minimal effect of intra-observer analytic bias. Furthermore, to demonstrate ultrasound-scanning accuracy a learning curve study was undertaken a priori by both examiners, which demonstrated scanning accuracies comparable to those quoted in the literature. Intra-observer studies also demonstrated good reproducibility. Reducing analytic bias. Potential risk of overreporting pathology in symptomatic presentations is acknowledged, though for pragmatic reasons, the physical assessment examiner was unblinded to the OSS results.

The effect of tear size on symptom severity may have been underestimated in this study. The inability to transform the complete data set, due to the skew of the OSS data, meant all asymptomatic shoulders had to be removed and that we were only able to compare pain severity in the presence of a tear compared to a painful normal shoulder. However, this may also reduce the background noise from other painful conditions of the shoulder.

The definition of symptoms in previous studies varies widely with no consensus. The decision to use the OSS was based upon its content, construct validity in relation to our research question, and validation of use against other pain scores. Furthermore, dichotomisation of the scale at perfect vs. non-perfect scores is not validated and may make results too sensitive. However, we ran a comparison with 3-point change, as validated as clinically significant by the makers of the OSS, and there was no statistical difference.

Relationship to other studies

This study has demonstrated similar prevalence figures to previous studies, but it is the first to use a general population cohort that has been extensively characterised as representative of the western world population.

Further studies have shown that the clinical presentation of rotator cuff tears varies and may or may not be associated with symptoms[17 22 23]. This general population cohort supports this with 48.4% of full-thickness rotator cuff tears being asymptomatic. Prior to this, the only other population-based study looking at symptom association with full-thickness tears was Yamamoto et al.[30] that investigated symptom association with full-thickness tears using a mountain cohort in Japan. They reported 34% of full-thickness tears to be symptomatic. However, unlike the current study, it was not a general population cohort representative of western society. Furthermore, it was subject to selection bias by removing any individuals with restricted shoulder movement or previous treatments.

Further studies have suggested that tear size affects the likelihood of symptoms. The current study supports this with larger tears having a greater than 2-fold increase in relative risk of symptoms than small tears[17 22 23]. A previous study in the Washington series investigated by Yamaguchi et al[26], reported development of symptoms in previously asymptomatic tendons in the context of a contralateral symptomatic tear. However, this study was subject to selection bias as recruitment occurred in a cohort actively being treated for contralateral symptomatic rotator cuff tears which may have strengthened associations.

This is the first study that has looked at individuals as entities, rather than shoulders, and has highlighted the effect the individual has on symptom presentation. It is also the first study to look at the impact on health services.

Meaning of the study and unanswered questions:

This study has shown that although patient reported pain on the Oxford Shoulder Score is associated with rotator cuff tendinopathy, it is not related to the extent of structural pathology identified on ultrasound imaging. The likelihood of pain also appears to be strongly dependent upon the individual rather than simply the pathology. Consequently, clinicians should rely less on imaging findings to explain the cause and severity of shoulder pain presentations. Furthermore, other drivers of shoulder pain should be considered (e.g. pain sensitisation), and treatment be targeted on symptom management rather than solely interventions to improve tendon pathology.

Investigation into the impact of musculoskeletal shoulder pain on the healthcare system revealed that 28.8% of people in this general population cohort sought consultation with their GP for shoulder pain, a third of whom had a full thickness tear, and a third with tendinopathy. This study highlights the huge burden of shoulder pain on the healthcare system. Though, it does not demonstrate causality of pain as is shown by the lack of symptoms in nearly half of cases and the lack of correlation with the severity of pain and pathology. Nor does it show how the individual affects pain presentation.

This epidemiological study clearly demonstrates association but not causality and leaves unanswered questions as to what additional factors contribute to pain. Particularly interesting is how individuals may or may not have painful shoulders irrespective of the pathology. Further research into this could provide alternative targets to treatment methods, and potentially reduce the cost of imaging modalities and surgical interventions.

Conclusion

In conclusion, this general population study has demonstrated that full-thickness rotator cuff tears are common affecting 22.1% of the over 60's and tendon abnormalities affecting 59.4%. Despite 41.7% of individuals with a full-thickness tear (48.4% of all full-thickness tears) being asymptomatic, tendon abnormalities and tears are associated with pain. The likelihood, but not severity of symptoms, increases with greater structural damage.

This high prevalence and association of symptoms results in a significant impact on primary care health services, with 28.3% of this population having presented to a GP with shoulder pain. Of these a third had a full-thickness tear and a third had an abnormal but not torn tendon. Overall 8.9% of this cohort had seen their general practitioner with shoulder pain and a full-thickness tear, and 18.8% had seen their general practitioner with an abnormal or torn tendon.

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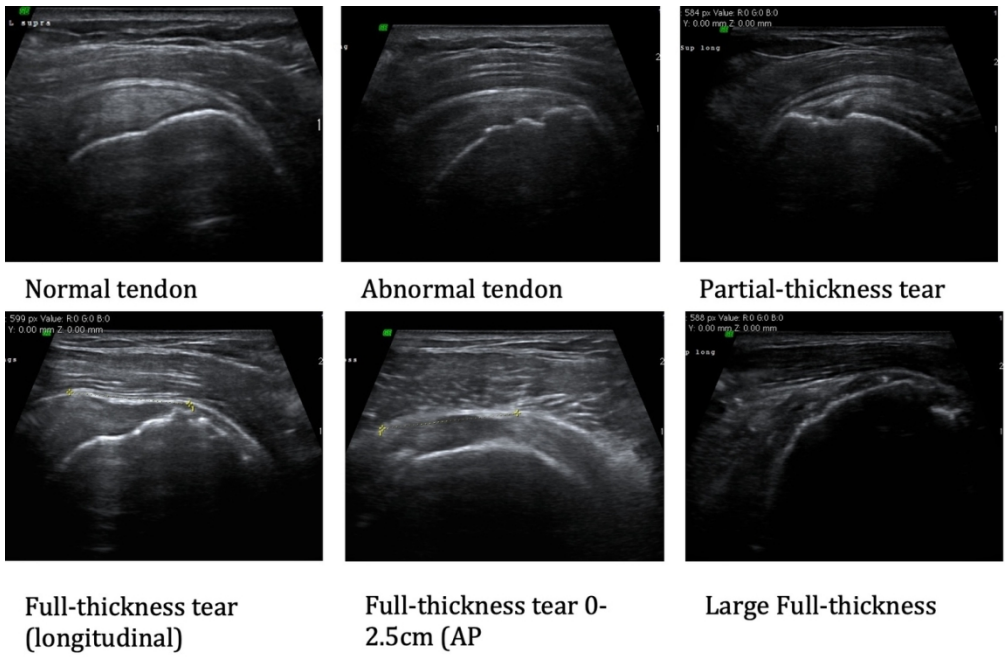

Figure 1: Ultrasound images

131x87mm (300 x 300 DPI)

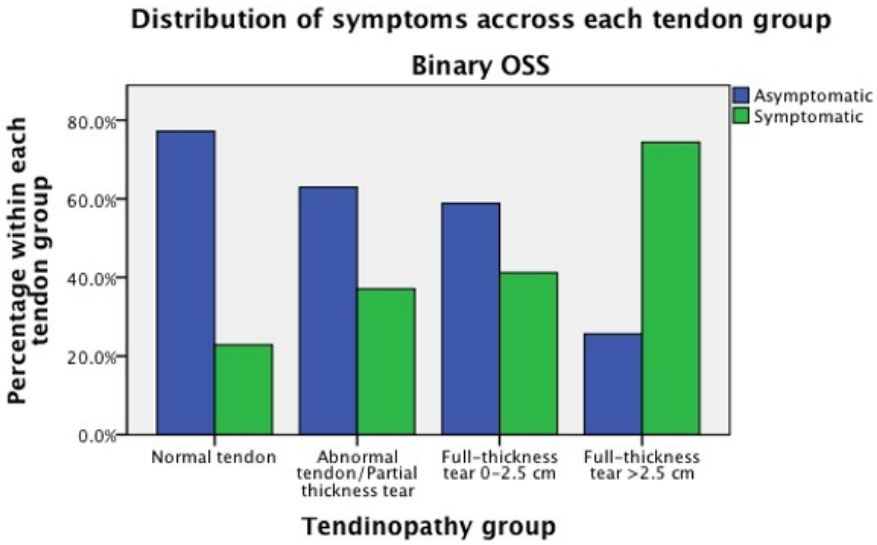

Figure 2. Distribution of symptoms across each tendon group

116x68mm (144 x 144 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 1	"large cross sectional observational study"
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4	
Objectives	3	State specific objectives, including any prespecified hypotheses	page 4 lines 150-154	
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4 - Design - from line 157	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	pages 4 and 5	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 - "Outcome measures"	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 5	
Bias	9	Describe any efforts to address potential sources of bias	Page 10 "Strengths and weaknesses of this study"	
Study size	10	Explain how the study size was arrived at	Page 4	

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5-6 "Data analysis"
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	SECTION 12 - See Page 5-6
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 6 "464 individuals (928 shoulders) were included in the study (Table 1)."
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	General cohort information described in the methods page 4
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Pages 6-9
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables 1-5, pages 6-9
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 10 "Strengths and limitations of the study"
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11 "Meaning of the study and unanswered questions"
Generalisability	21	Discuss the generalisability (external validity) of the study results	End of Page 11 - "This epidemiological study clearly demonstrates association but not causality..."
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 2 "role of the funding body"

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

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Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population cohort, and the resultant impact on United Kingdom health services: A cross-sectional observational study.

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Contributors: HH, NA, AC were responsible for planning, conducting, and reporting the work described in the article. HH and CG drafted the manuscript. All authors approved the final version of the article. HH, NA and AC had access to all the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. HH is guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. All authors fully acknowledge the contribution of the patients that participated in this study. No authors are employees of the National Institutes of Health.

Transparency Statement: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Competing interests: No competing interests

Ethics approval: Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96.

Patient and public involvement

We would like to thank all the participants of the Chingford Women Study for their time.

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Acknowledgement

Thank you to Dr Gemma Wallis, Statistician, for reviewing statistical analysis processes used in this study.

Data sharing: For information about the Chingford 1000 Women Study, email chingford@ndorms.ox.ac.uk.

Dissemination to participants and related patient and public communities: We will disseminate our findings to patient organisations and media outlets.

Provenance and peer review: Not commissioned; peer reviewed at Orthopaedic meetings.

Structured Abstract

Objectives:
To define the population prevalence of rotator cuff tears and test their association with pain and function loss; determine if severity symptom correlates with tear stage severity, and quantify the impact of symptomatic rotator cuff tears on primary health care services, in a general population cohort of women.

Design:
Cross sectional observational study.

Participants:
Individuals were part of the Chingford 1000 women cohort, a 20-year-old longitudinal population study comprising 1003 women aged between 64 and 87, and representative of the population of the UK.

Main outcome measures:
Rotator cuff pathology prevalence on ultrasound, shoulder symptoms using the Oxford shoulder score, and resultant number of GP consultations.

Results:
The population prevalence of full-thickness tears was 22.2%, which increased with age (p=0.004), and whether it was the dominant arm (RR 1.64, OR 1.58, 95% CI 1.07-2.33, p=0.021).

Although 48.4% of full-thickness tears were asymptomatic there was an association between rotator cuff tears and patient reported symptoms. Individuals with at least one full-thickness tear were 1.97 times more likely, than those with bilateral normal tendons (OR 3.53, 95%CI 2.00-5.61, p<0.001), to have symptoms. Severity of symptoms was not related to the severity of the pathology until tears are >2.5cm (p=0.009).

In the cohort 8.9% had seen their GP with shoulder pain and a full-thickness rotator cuff tear, 18.8% with an abnormality and 29.3% overall.

Conclusion:
Rotator cuff tears are common, and primary care services are heavily impacted. As 50% of tears remain asymptomatic, future research may investigate the cause of pain and whether different treatment modalities, aside from addressing the pathology, need further investigation.

Trial Registration:
The local ethics committee approved the study (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Strengths and limitations of this study:

- Pain on the Oxford Shoulder Score is associated with the presence of rotator cuff tendon pain, but not the extent of structural pathology identified on ultrasound imaging.
- Rotator cuff pathology and associated symptoms pose a large burden on the healthcare system with 28.8% of people seeking GP consultation for their shoulder pain.
- This epidemiological study demonstrates association but not causality and leaves unanswered questions as to what additional factors contribute to shoulder pain.

Introduction

Background

Musculoskeletal pain is one of the most common sources of disability in the Western world[1]. The shoulder is the third most common site of musculoskeletal disease[2], with an estimated 20% of the population reporting pain at any given time[3]. Pain related to rotator cuff tears are estimated to account for 30-40% of these shoulder complaints[4], causing high levels of disability and associated healthcare costs [5-7]. High-definition ultrasound is the current gold standard for the detection of full-thickness tears, and is a valid tool to detect an abnormal tendon enthesis[8], but has poorer accuracy to detect partial-thickness tears[8-14]. Full thickness tears are recognised to be common and associated with increasing age[15-18], however prevalence in symptomatic and asymptomatic shoulders varies widely across cadaveric[19], radiological[19] and retrospective cohort studies[16-18 20-28]. Furthermore, the presence of selection bias in studies undertaken in rotator cuff tendon tears [16-28], has meant population-based studies available, are not representative of Western demographics. Thus, research in this area may lead to a better understanding of the natural history of rotator cuff tears.

Clinical manifestations of rotator cuff tears are varied[15 17 22 26 28], and detection of pathology and its relationship to clinical symptoms is not well established. Many tears are asymptomatic but are thought to be a risk of developing symptoms with time[26]. Although larger tears are more likely to be painful, there is also no evidence to suggest that they have a greater severity of symptoms than smaller tears[29]. One population cohort from a mountainous region has suggested that only a third of full-thickness tears were painful, of which symptoms were more prevalent in the dominant arm[30]. However, all studies investigating symptom association have looked at isolated shoulders, and have not considered that the individual, has two shoulders. It is therefore plausible that there may be the presence of other physical or psychological factors unique to the individual, rather than the specific shoulder, that may have an influence on symptom presentation, rather than solely the underlying pathology. To date, no study has explored the association between rotator cuff tears, pain and functional loss in a general population cohort, or how these impact on a health service.

Objectives

This study aims to: (i) describe the population prevalence of different stages of rotator cuff tear in a general population cohort of women; (ii) determine what proportion of rotator cuff tears are symptomatic, and whether the severity of symptoms correlates with tear stage severity; (iii) identify individual influences on the likelihood of symptoms and (iv) quantify the impact of symptomatic rotator cuff tears on primary health care services.

Methods

Study Design, Setting and Participants (including study size)

Participants in this cross-sectional observational study were involved in the larger Chingford 1000 women study. This is an ethically approved well described prospective population-based longitudinal study of osteoarthritis and osteoporosis comprising 1003 white Caucasian women, derived from the register of a large general practice in Chingford, North London[31-33]. The cohort was recruited in 1989 where the women were aged 44-67. They have been characterised as representative of women in the UK general population with respect to weight, height, and smoking characteristics. The cohort has been subsequently listed by the National Institute for Health Research as an important epidemiological recourse. This study took place at the Chingford 20 year follow up visit where 516 of the original 1003 cohort attended (158 women had died, 111 were unable to attend, 218 had moved

away or been lost to follow up). A musculoskeletal assessment, including the Oxford shoulder score, and shoulder ultrasound examination was performed on both shoulders (left and right) in 463 women (Out of the 515, 52 attended but did not have a shoulder assessment due to lack of assessor, and 1 did not complete an Oxford shoulder score). The local ethics committee approved the study and consent was obtained from each woman (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Variables and data sources:

Participant characteristics of age, height, weight, hand dominance, and a self-reported musculoskeletal questionnaire filled out a priori (including the Oxford Shoulder Score[34 35], body chart and questions regarding previous pain, treatments and whether medical advice has been sought), were all collected at baseline. A musculoskeletal ultrasound assessment on bilateral shoulders was then undertaken using a fixed SOPP (standard operating procedure protocol).

The ultrasound examination of the 464 women was completed by two orthopaedic assessors and performed using a GE voluson i-portable ultrasound machine with a 10-16MHz linear probe. Ultrasound training and appropriate validation studies[36] were completed as recommended by the BESS focus group - 343 individuals were scanned by assessor 1 and 121 individuals by assessor two. Appropriate inter and intra-rater reliability studies were performed and showed high reproducibility (weighted kappa 0.92 $p<0.001$) and no difference in reporting trends ($p=0.08$). The ultrasound protocol was derived according to the recommendations of the Nuffield Orthopaedic Centre Musculoskeletal radiology department. Tendons were classified into one of four working groups based upon ultrasound measurements as validated by Hinsley et al.[8]: normal tendon; abnormal tendon and partial thickness tear; single tendon full-thickness tears (0-2.5cm) and multi-tendon full-thickness tears (>2.5cm) (Figure 1).

Figure 1: Tendon classification on ultrasound

Figure 1 legend: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

Quantitative variables and Statistical methods

All statistics were performed using IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA). Age, BMI, hand dominance, and symptom presence were compared across the four different tendon pathology groups. Wilcoxon rank sum test, one-way ANOVA, and chi-squared tests were used for non-normal, normal and categorical data respectively.

Population prevalence of full-thickness tears was defined as having at least one unilateral full-thickness tear. Population prevalence of tendon abnormalities was defined as having at least a unilateral tendon abnormality ranging from abnormal enthesis to a full thickness tear. This was calculated by summing the percentage with unilateral tears and the percentage with bilateral tears for each age group.

Symptoms were defined using the Oxford shoulder score[34 35]. This was chosen for what the authors believed represented the best content and construct validity as applicable to the study as it covers a range of symptoms (both relating to pain and function) over a 4-week time period, and also allows

discriminate ability. Binary symptoms were defined by dichotomising the Oxford shoulder score[34 35] where, any non-perfect score (≤ 47/48) was classified as symptomatic. The cut off at 47 was used to determine symptoms as we were not looking for significant changes, rather, the ability to detect any individual who was unable to perform an activity to the full, or who has pain at any given time. This showed good correlation with binary pain questions and the NRS and was not statistically different to the results using a 3-point gap. Where questions are pain specific, the four pain specific questions of the OSS were used as a sub-scale. In symptomatic participants, the full OSS scale, scored on a 0-48 point scale, was used to define symptom severity. A Chi^2 test was used to determine any difference between tendon pathology groups. Multivariate binary logistic regression was used to adjust for the potential confounders age, BMI and hand dominance determined a priori. To account for a high positive skew of the OSS data when determining symptom severity, all asymptomatic shoulders were removed, and a logarithmic transformation of the inverse OSS was used to create a normal distribution. Symptom severity in symptomatic shoulders was compared across tendon pathology groups using a 1-way ANOVA. Multivariate linear regression was used to adjust for potential confounders age, and hand dominance determined a priori.

Results

Participants and descriptive data

464 individuals (928 shoulders) were included in the study (Table 1). The distribution of age across each tendon pathology group was significantly different ($p<0.001$), with age increasing in accordance with tear severity. There was a statistical difference in the proportion of dominant and non-dominant arms in each tendon pathology group ($p=0.033$), with there being significantly more non-dominant arms in the normal tendon group ($p=0.010$), and significantly more dominant arms in those with full-thickness tears ($p=0.026$). There were no between-group differences in BMI ($p=0.080$).

Table 1. Demographics of shoulders included in the study

	Frequency	%	Median age	Mean BMI	Dominant arm (%)
Normal	510	55.0%	70	27.5	46.1%
Abnormal/ Partial tear	294	31.7%	73	28.0	52.7%
Full-thickness tears (0-2.5cm)	85	9.2%	74	27.9	58.8%
Full-thickness tears (>2.5cm)	39	4.2%	74	29.6	61.5%
All	928	100%	71	27.8	50%

Outcome data and main results

Prevalence of rotator cuff tendon pathology

The population prevalence of having at least one full-thickness tear was 22.2% (4.5% bilateral). For age groups 60-69, 70-79 and 80-89 these were 14.9%; 25.9% and 29% respectively, and bilateral tears 2.3%; 5.9% and 5.8% respectively. The difference in prevalence between age groups was statistically different ($p<0.001$).

The population prevalence of having at least a unilateral tendon pathology or tear was 59.5% (30.6% bilateral). For age groups 60-69, 70-79 and 80-89 these were 51.5%; 61.8% and 72.5% respectively, and bilateral tears 24.6%; 32.3% and 40.6% respectively. The difference in population prevalence between age groups was statistically significant ($p<0.001$).

Table 2 shows the prevalence of rotator cuff tendinopathy in the dominant and non-dominant arms in age deciles. The distribution of tendinopathy differed between age groups (Dominant arm p=0.002; non-dominant arm p=0.037) with more pathology found in older age groups, and in the dominant compared to non-dominant arms (p=0.004). There was no difference in prevalence according to BMI group. The relative risk of full-thickness tear was 1.64 (OR 1.580, 95%CI 1.073-2.326, p=0.021) in the dominant compared to non-dominant arm. For those aged 70-79 it was 2.072 (OR 2.026, 95%CI 1.286-3.190, p=0.002), and aged 80-89 was 2.293 (OR 2.256, 95%CI 1.264-4.027, p=0.006), compared to those aged 60-69.

Table 2. Prevalence of rotator cuff tendon pathology according to age decile and arm dominance

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Non-dominant arm								
Normal tendon	115	65.7%	122	55.5%	38	55.1%	275	59.3%
Abnormal tendon/Partial thickness tear	49	28.0%	70	31.8%	20	29.0%	139	30.0%
Full-thickness tear 0-2.5 cm	10	5.7%	18	8.2%	7	10.1%	35	7.5%
Full-thickness tear >2.5 cm	1	0.6%	10	4.5%	4	5.8%	15	3.2%

Association of symptoms (all shoulders)

An analysis of symptom association was completed in 926 shoulders (463/464 participants due to loss of one questionnaire). There were 289 (31.2%) symptomatic shoulders according to a dichotomised OSS. The presence of symptoms was statistically significant between tendon groups (p<0.001); 51.6% of all full-thickness tears were symptomatic. There was no difference in age, BMI or arm dominance between symptomatic or asymptomatic shoulders. The relative risks of having symptoms compared to those with a reported normal tendon were as follows: Abnormal/Partial tears 1.969 (OR 1.991, 95%CI 1.454-2.727); full-thickness tears 0-2.5cm 2.203 (OR 2.366, 95%CI 1.465-3.891); and full-thickness tears >2.5cm 4.718 (OR 9.800, 95%CI 4.638-20.705). All were significant (p<0.001) with the model correctly predicting 71% of symptom outcomes correctly. The distribution of symptoms across each tendon group is shown in Figure 2.

Figure 2. Distribution of symptoms across each tendon group

Symptom severity

For the 289 symptomatic shoulders the full OSS was reported (Table 3). Median age was significantly different between groups (p=0.047), with age increasing with tear stage severity. No statistically significant between-group differences in BMI were identified, nor any within-group differences for arm dominance.

Table 3. Symptom severity demographics

	N	Median age	Mean BMI	Dominant arm (%)
Normal	116	70	28.3	46.6%
Abnormal/Partial tear	109	73	28.4	54.1%
Full-thickness tears 0-2.5cm	35	72	28.1	62.9%
Full-thickness tears >2.5cm	29	73	30.3	58.6%
All	289	71	28.5	50%

The mean OSS for symptomatic shoulders was 41.8. For normal tendons this was 42.5, abnormal tendons, 42.1; full-thickness tears (0-2.5cm), 40.2; and full-thickness tears (>2.5cm), 38.4. There was a statistical difference between the groups (1 way ANOVA p=0.030). Linear regression analysis after adjustment for age, BMI, and hand dominance (no interactions identified), showed that the only significant difference in OSS scores was between normal tendons (mean OSS 42.5) and large full-thickness tears (OSS 38.3), p=0.009, power 0.75 (overall model p=0.007, power 0.892).

Association of symptoms (individuals)

Table 4 shows the relationship between the individual, presence of full-thickness rotator cuff tear and the likelihood of symptoms. A clustering effect of bilateral symptoms or lack thereof is present, irrespective of the underlying pathology. After adjustment for age and BMI, compared to those with bilaterally normal shoulders the relative risk of having at least one symptomatic shoulder in the presence of a full thickness rotator cuff tear is 1.49 (OR 1.867, 95%CI 1.200-2.904), and 1.97 (OR 3.352, 95%CI 2.003-5.609) in the presence of at least a unilateral abnormality or cuff tear.

Table 4. Distribution of individual shoulder symptoms according to the presence of full-thickness tears

	No Symptoms	Unilateral Symptoms	Bilateral Symptoms	Total
Bilateral No FTT	226	71	63	360
Unilateral FTT	33	25	24	82
Bilateral FTT	10	3	8	21
Total	269	99	95	463

Shoulder pain and use of primary care health services

Table 5 shows the proportion of individuals with shoulder pain, past or present, seeking medical advice. The likelihood of seeking medical attention for shoulder pain was statistically different between each pathology group (Chi^2 test p=0.005) reflecting the increasing likelihood of pain. However, of those with pain the likelihood of seeking medical attention was not statistically different between groups (Chi^2 test p=0.179). Overall, 28.3% (131/463) of all individuals had at some stage seen their GP for shoulder pain. In this cohort, 8.9% (41/463) had seen their GP with shoulder pain and a full-thickness tendon tear and 18.8% (87/463) had seen their GP with an abnormal tendon or full thickness tear.

A multivariable regression model using all individuals was used to predict the likelihood of attending a GP for shoulder pain. The presence of at least one full-thickness tear had a relative risk of 1.63 (OR 2.179, 95%CI 1.282-3.703) compared to those with normal tendons of attending the GP. There was

no statistical difference in relative risk of those with any tendon abnormality compared to those with bilaterally normal shoulders.

Table 5. Proportion of individuals seeking medical advice

	Present symptoms (either shoulder)		Past or Present symptoms (either shoulder)		All individuals
	%	% seen GP	%	% seen GP	% seen GP
All individuals (n=463)	41.9 (n=194)	44.8 (n=87)	55.7 (n=258)	50.8 (n=131)	28.3 (n=131)
Bilaterally normal tendons (n=187)	29.9 (n=56)	41.1 (n=23)	48.1 (n=90)	48.9 (n=44)	23.5 (n=44)
At least one abnormality (no tear) (n=173)	45.1 (n=78)	41.0 (n=32)	57.2 (n=99)	46.5 (n=46)	26.6 (n=46)
At least one full-thickness tear (n=103)	58.3 (n=60)	53.3 (n=32)	67.0 (n=69)	59.4 (n=41)	39.8 (n=41)

Discussion

Key results

Using a large general population cohort of women aged 65-84 years, this study has reported on the prevalence of rotator cuff pathology, the association of pathology to symptoms and uniquely the consequential impact on health services.

The prevalence of rotator cuff pathology has been well reported in the literature, and this general population study, supports previous findings. Prevalence was found to increase with every decile of age, and the relative risk of having a full thickness tear increased more than two-fold between the 65-69 and >80 age groups, suggesting age related change[18]. Overall, the prevalence of at least a unilateral full thickness tear was 22%. The dominant arm was 1.64 times likely to be affected, inferring that the presence of pathology may exist in shoulders with higher cumulative loading.

The relative risk of having symptomatic pathology (worsening OSS scores) increased with tear stage severity, though the severity of symptoms did not increase accordingly. Although larger tear size increased the likelihood of symptom presence, 48.4% of full-thickness rotator cuff tears remained asymptomatic.

The burden of musculoskeletal shoulder pain on health services is large, with 28.3% of individuals in this general population cohort having at some point sought medical advice for shoulder symptoms. This is the first study to look at the impact of rotator cuff pathology on the impact on the health services. Although on average only 50% of individuals with symptomatic rotator cuff tendon pathology (tendinopathy) will seek medical advice, the impact remains significant. Overall, almost 10% of individuals in the general population have sought medical advice for shoulder symptoms in the presence of a full-thickness tear, and almost 20% of the population for any tendon abnormality.

The major strength of this study is that it uses a large general population cohort, and therefore not subject to selection bias. The cohort was originally investigated with the primary focus of osteoporosis, and not shoulder symptoms, thus any continued participation is not driven by shoulder symptoms.

Limitations (including bias)

The cohort can only comment on associations in women aged between 65 and 84, but as previous studies have found no relationship between symptoms and age or sex [23 30], this will not bias the results. Potential survival bias is introduced by the cohort being in its 20th year. If a greater proportion of individuals with pathology were lost to follow up this may cause us to under-estimate any association, however, no known associations exist in the literature between rotator cuff tears and other medical co-morbidities. Furthermore, as the prime goal of the cohort was not to investigate shoulder symptoms, this had no impact on continued study participation. Furthermore, only 463/516 individuals that attended the year-20 study underwent a shoulder examination due to lack of an examiner being present at these follow up appointments. However, the age and BMI of the groups was not statistically different to the full cohort.

Bias arising from having two examiners was ameliorated by two inter-observer reproducibility studies that demonstrated minimal effect of inter-observer analytic bias. Furthermore, to demonstrate ultrasound-scanning accuracy a learning curve study was undertaken a priori by both examiners, which demonstrated scanning accuracies comparable to those quoted in the literature. Inter-observer studies also demonstrated good reproducibility reducing analytic bias. Potential risk of overreporting pathology in symptomatic presentations is acknowledged as the assessor (ultrasonographer) was unblinded to the OSS result, as for pragmatic reasons due to lack of assessors, both assessments were carried out by the same individual. To overcome this, a small intra-observer study was completed, and an additional ultrasound scan was performed on 18 willing participants. The examiner was blind to all pervious results and shoulder scores. Overall agreement gave a weighted kappa score of 0.915 ($p<0.001$).

The effect of tear size on symptom severity may have been underestimated in this study. The inability to transform the complete data set due to the skew of the OSS data, meant all asymptomatic shoulders had to be removed. Pain severity in the presence of a tear was then compared to a pain severity in a normal (no tendon pathology) shoulder. We recognise that there may be many causes of shoulder pain (e.g., rheumatological causes) and therefore referencing against all causes of painful shoulder may represent the contribution of rotator cuff tear to the symptoms.

The definition of symptoms in previous studies varies widely with no consensus. The decision to use the OSS was based upon its content, construct validity in relation to our research question, and validation of use against other pain scores. Furthermore, dichotomisation of the scale at perfect vs. non-perfect scores is not validated and may make results too sensitive. However, we ran a comparison with 3-point change, as validated as clinically significant by the makers of the OSS, and there was no statistical difference.

Relationship to other studies

This study has demonstrated similar prevalence figures to previous studies, but it is the first to use a general population cohort that has been extensively characterised as representative of the western world population.

Further studies have shown that the clinical presentation of rotator cuff tears varies and may or may not be associated with symptoms[17 22 23]. This general population cohort supports this with 48.4% of full-thickness rotator cuff tears being asymptomatic. Prior to this, the only other population-based study looking at symptom association with full-thickness tears was Yamamoto et al.[30] that investigated symptom association with full-thickness tears using a mountain cohort in Japan. They reported 34% of full-thickness tears to be symptomatic. However, unlike the current study, it was not a general population cohort representative of western society. Furthermore, it was subject to selection bias by removing any individuals with restricted shoulder movement or previous treatments.

Further studies have suggested that tear size affects the likelihood of symptoms. The current study supports this with larger tears having a greater than 2-fold increase in relative risk of symptoms than small tears[17 22 23]. A previous study in the Washington series investigated by Yamaguchi et al[26], reported development of symptoms in previously asymptomatic tendons in the context of a contralateral symptomatic tear. However, this study was subject to selection bias as recruitment occurred in a cohort actively being treated for contralateral symptomatic rotator cuff tears which may have strengthened associations.

This is the first study that has looked at individuals as entities, rather than shoulders, and has highlighted the effect the individual has on symptom presentation, which could include physical and psychological factors unique to that individual – not solely the presence of tendon pathology on imaging. It is also the first study to look at the impact on health services.

Interpretation

This study has shown that although patient reported pain on the Oxford Shoulder Score is associated with rotator cuff tendon pathology, it is not related to the severity of structural pathology identified on ultrasound imaging. The likelihood of pain also appears to be strongly dependent upon the individual rather than simply the pathology. Consequently, clinicians should rely less on imaging findings to explain the cause and severity of shoulder pain presentations. Furthermore, other drivers of shoulder pain should be considered (e.g. pain sensitisation), and treatment be targeted on symptom management rather than solely interventions to improve tendon pathology.

Investigation into the impact of musculoskeletal shoulder pain on the healthcare system revealed that 28.8% of people in this general population cohort sought consultation with their GP for shoulder pain, a third of whom had a full thickness tear, and a third with at least one abnormality (no tear). This study highlights the huge burden of shoulder pain on the healthcare system. Though, it does not demonstrate causality of pain as is shown by the lack of symptoms in nearly half of cases and the lack of correlation with the severity of pain and pathology. Nor does it show how the individual affects pain presentation.

Generalisability

This epidemiological study that is generalisable to the UK population, demonstrates association but not causality, and leaves unanswered questions as to what additional factors contribute to shoulder pain. Particularly interesting is how individuals may or may not have painful shoulders irrespective of the pathology. Further research into this could provide alternative targets to treatment methods, and potentially reduce the cost of imaging modalities and surgical interventions.

Conclusion

In conclusion, this general population study has demonstrated that full-thickness rotator cuff tears are common affecting 22.1% of women over the age of 60, and tendon abnormalities affecting 59.4%. Despite 41.7% of individuals with a full-thickness tear (48.4% of all full-thickness tears) being asymptomatic, tendon abnormalities and tears are associated with pain. The likelihood, but not severity of symptoms, increases with greater structural damage.

This high prevalence and association of symptoms results in a significant impact on primary care health services, with 28.3% of this population having presented to a GP with shoulder pain. Of these a third had a full-thickness tear and a third had an abnormal but non-torn tendon. Overall, 8.9% of this cohort had seen their general practitioner with shoulder pain and a full-thickness tear, and 18.8% had seen their general practitioner with an abnormal or torn tendon.

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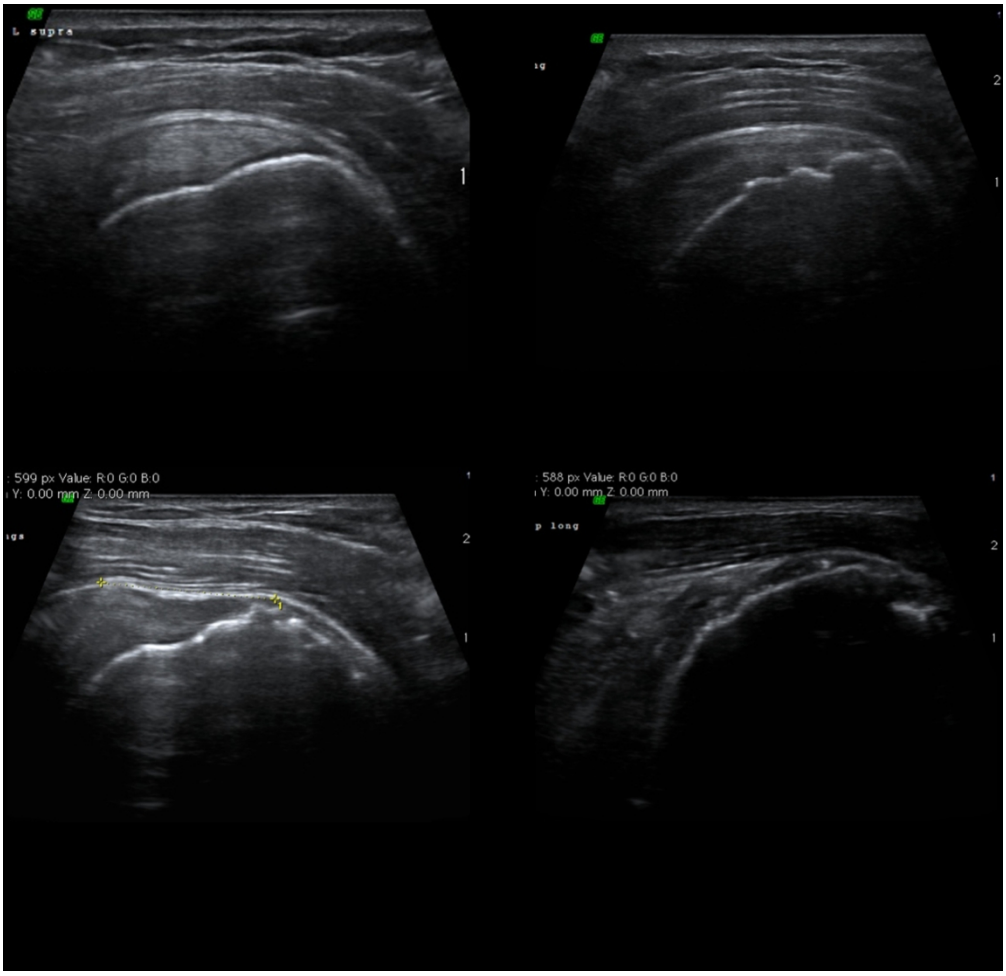

Tendon classification on ultrasound: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

106x102mm (300 x 300 DPI)

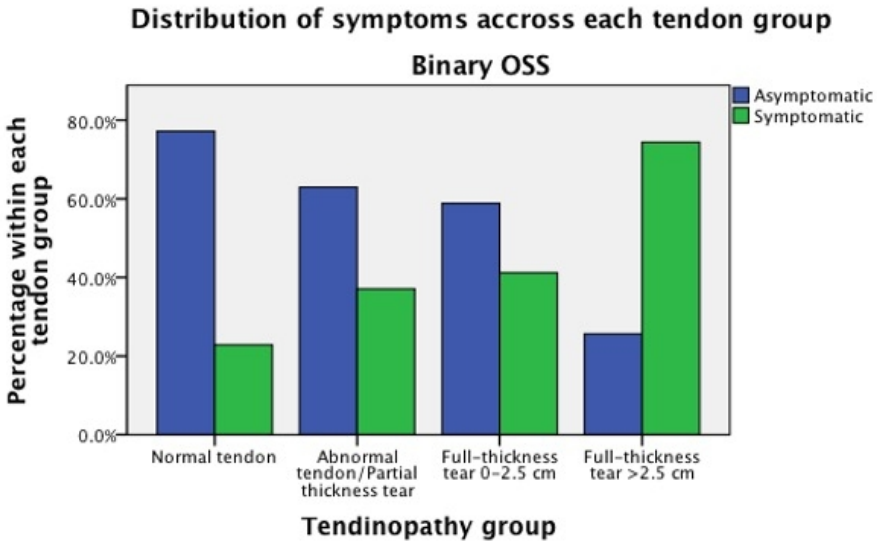

Figure 2. Distribution of symptoms across each tendon group

116x68mm (144 x 144 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 - title of the manuscript	
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4 - line 128-153	
Objectives	3	State specific objectives, including any prespecified hypotheses	page 4 lines 150-154	
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4 - lines 165-176	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4 - lines 165-176	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	ages - lines 165-176	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 - lines 182-198	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 5 - lines 181-198	
Bias	9	Describe any efforts to address potential sources of bias	Page 10 - lines 351-393	
Study size	10	Explain how the study size was arrived at	Page 4 - Lines 174-177	

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5-6 - lines 207-236
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	SECTION 12 - Page 5-6 - lines 207-236
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 6 - lines 239-246
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 6 - lines 239-246
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Pages 6-9
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Results tables, pages 6-9 - lines 248-325
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9- lines 328-351
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 10 - 356-392
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11 - lines 422-437
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 11- lines 440-445
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 2- lines 50-53

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population cohort, and the resultant impact on United Kingdom health services: A cross-sectional observational study.

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Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population cohort, and the resultant impact on United Kingdom health services: A cross-sectional observational study.

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Contributors: HH, NA, AC were responsible for planning, conducting, and reporting the work described in the article. HH and CG drafted the manuscript. All authors approved the final version of the article. HH, NA and AC had access to all the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. HH is guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. All authors fully acknowledge the contribution of the patients that participated in this study. No authors are employees of the National Institutes of Health.

Transparency Statement: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Competing interests: No competing interests

Ethics approval: Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96.

Acknowledgement
Thank you to Dr Gemma Wallis, Statistician, for reviewing statistical analysis processes used in this study.

Data sharing: For information about the Chingford 1000 Women Study, email chingford@ndorms.ox.ac.uk.

Dissemination to participants and related patient and public communities: We will disseminate our findings to patient organisations and media outlets.

Provenance and peer review: Not commissioned; peer reviewed at Orthopaedic meetings.

Structured Abstract

Objectives:
To define the population prevalence of rotator cuff tears and test their association with pain and function loss; determine if severity symptom correlates with tear stage severity, and quantify the impact of symptomatic rotator cuff tears on primary health care services, in a general population cohort of women.

Design:
Cross sectional observational study.

Participants:
Individuals were part of the Chingford 1000 women cohort, a 20-year-old longitudinal population study comprising 1003 women aged between 64 and 87, and representative of the population of the UK.

Main outcome measures:
Rotator cuff pathology prevalence on ultrasound, shoulder symptoms using the Oxford shoulder score, and resultant number of GP consultations.

Results:
The population prevalence of full-thickness tears was 22.2%, which increased with age (p=0.004), and whether it was the dominant arm (RR 1.64, OR 1.58, 95% CI 1.07-2.33, p=0.021).

Although 48.4% of full-thickness tears were asymptomatic there was an association between rotator cuff tears and patient reported symptoms. Individuals with at least one full-thickness tear were 1.97 times more likely, than those with bilateral normal tendons (OR 3.53, 95%CI 2.00-5.61, p<0.001), to have symptoms. Severity of symptoms was not related to the severity of the pathology until tears are >2.5cm (p=0.009).

In the cohort 8.9% had seen their GP with shoulder pain and a full-thickness rotator cuff tear, 18.8% with shoulder pain and an abnormality and 29.3% with shoulder pain.

Conclusion:
Rotator cuff tears are common, and primary care services are heavily impacted. As 50% of tears remain asymptomatic, future research may investigate the cause of pain and whether different treatment modalities, aside from addressing the pathology, need further investigation.

Trial Registration:
The local ethics committee approved the study (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Strengths and limitations of this study:

- Pain on the Oxford Shoulder Score is associated with the presence of rotator cuff tendon pain, but not the extent of structural pathology identified on ultrasound imaging.
- Rotator cuff pathology and associated symptoms pose a large burden on the healthcare system with 28.8% of people seeking GP consultation for their shoulder pain.
- This epidemiological study demonstrates association but not causality and leaves unanswered questions as to what additional factors contribute to shoulder pain.

Introduction

Background

Musculoskeletal pain is one of the most common sources of disability in the Western world[1]. The shoulder is the third most common site of musculoskeletal disease[2], with an estimated 20% of the population reporting pain at any given time[3]. Pain related to rotator cuff tears are estimated to account for 30-40% of these shoulder complaints[4], causing high levels of disability and associated healthcare costs [5-7]. High-definition ultrasound is the current gold standard for the detection of full-thickness tears, and is a valid tool to detect an abnormal tendon enthesis[8], but has poorer accuracy to detect partial-thickness tears[8-14]. Full thickness tears are recognised to be common and associated with increasing age[15-18], however prevalence in symptomatic and asymptomatic shoulders varies widely across cadaveric[19], radiological[19] and retrospective cohort studies[16-18 20-28]. Furthermore, the presence of selection bias in studies undertaken in rotator cuff tendon tears [16-28], has meant population-based studies available, are not representative of Western demographics. Thus, research in this area may lead to a better understanding of the natural history of rotator cuff tears.

Clinical manifestations of rotator cuff tears are varied[15 17 22 26 28], and detection of pathology and its relationship to clinical symptoms is not well established. Many tears are asymptomatic but are thought to be a risk of developing symptoms with time[26]. Although larger tears are more likely to be painful, there is also no evidence to suggest that they have a greater severity of symptoms than smaller tears[29]. One population cohort from a mountainous region has suggested that only a third of full-thickness tears were painful, of which symptoms were more prevalent in the dominant arm[30]. However, all studies investigating symptom association have looked at isolated shoulders, and have not considered that the individual, has two shoulders. It is therefore plausible that there may be the presence of other physical or psychological factors unique to the individual, rather than the specific shoulder, that may have an influence on symptom presentation, rather than solely the underlying pathology. To date, no study has explored the association between rotator cuff tears, pain and functional loss in a general population cohort, or how these impact on a health service.

Objectives

This study aims to: (i) describe the population prevalence of different stages of rotator cuff tear in a general population cohort of women; (ii) determine what proportion of rotator cuff tears are symptomatic, and whether the severity of symptoms correlates with tear stage severity; (iii) identify individual influences on the likelihood of symptoms and (iv) quantify the impact of symptomatic rotator cuff tears on primary health care services.

Methods

Study Design, Setting and Participants (including study size)

Participants in this cross-sectional observational study were involved in the larger Chingford 1000 women study. This is an ethically approved well described prospective population-based longitudinal study of osteoarthritis and osteoporosis comprising 1003 white Caucasian women, derived from the register of a large general practice in Chingford, North London[31-33]. The cohort was recruited in 1989 where the women were aged 44-67. They have been characterised as representative of women in the UK general population with respect to weight, height, and smoking characteristics. The cohort has been subsequently listed by the National Institute for Health Research as an important epidemiological recourse. This study took place at the Chingford 20 year follow up visit where 516 of the original 1003 cohort attended (158 women had died, 111 were unable to attend, 218 had moved away or been lost to follow up). A musculoskeletal assessment, including the Oxford shoulder score,

and shoulder ultrasound examination was performed on both shoulders (left and right) in 463 women (Out of the 515, 52 attended but did not have a shoulder assessment due to lack of assessor, and 1 did not complete an Oxford shoulder score). The local ethics committee approved the study and consent was obtained from each woman (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Variables and data sources:

Participant characteristics of age, height, weight, hand dominance, and a self-reported musculoskeletal questionnaire filled out a priori (including the Oxford Shoulder Score[34 35], body chart and questions regarding previous pain, treatments and whether medical advice has been sought), were all collected at baseline. A musculoskeletal ultrasound assessment on bilateral shoulders was then undertaken using a fixed SOPP (standard operating procedure protocol).

The ultrasound examination of the 464 women was completed by two orthopaedic assessors and performed using a GE voluson i-portable ultrasound machine with a 10-16MHz linear probe. Ultrasound training and appropriate validation studies[36] were completed as recommended by the BESS focus group - 343 individuals were scanned by assessor 1 and 121 individuals by assessor two. Appropriate inter and intra-rater reliability studies were performed and showed high reproducibility (weighted kappa 0.92 p<0.001) and no difference in reporting trends (p=0.08). The ultrasound protocol was derived according to the recommendations of the Nuffield Orthopaedic Centre Musculoskeletal radiology department. Tendons were classified into one of four working groups based upon ultrasound measurements as validated by Hinsley et al.[8]: normal tendon; abnormal tendon and partial thickness tear; single tendon full-thickness tears (0-2.5cm) and multi-tendon full-thickness tears (>2.5cm) (Figure 1).

[INSERT FIGURE 1]

Quantitative variables and Statistical methods

All statistics were performed using IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA). Age, BMI, hand dominance, and symptom presence were compared across the four different tendon pathology groups. Wilcoxon rank sum test, one-way ANOVA, and chi-squared tests were used for non-normal, normal and categorical data respectively.

Population prevalence of full-thickness tears was defined as having at least one unilateral full-thickness tear. Population prevalence of tendon abnormalities was defined as having at least a unilateral tendon abnormality ranging from abnormal enthesis to a full thickness tear. This was calculated by summing the percentage with unilateral tears and the percentage with bilateral tears for each age group.

Symptoms were defined using the Oxford shoulder score[34 35]. This was chosen for what the authors believed represented the best content and construct validity as applicable to the study as it covers a range of symptoms (both relating to pain and function) over a 4-week time period, and also allows discriminate ability. Binary symptoms were defined by dichotomising the Oxford shoulder score[34 35] where, any non-perfect score (≤ 47/48) was classified as symptomatic. The cut off at 47 was used to determine symptoms as we were not looking for significant changes, rather, the ability to detect any individual who was unable to perform an activity to the full, or who has pain at any given time. We validated this by running a Pearson correlation sub analysis between the OSS pain subset with the NRS (R=0.816, p<0.001, 95% CI 0.793-0.836) and a simple binary question (R=0.812, p<0.001, 95%

CI 0.789-0.833), and the full OSS with a binary pain question (R=0.759, p<0.001, 95% CI 0.730-0.785). Furthermore, we re-ran the analysis using a 3-point difference to reflect a clinically significant difference between groups and the results were not significantly different. Where questions are pain specific, the four pain specific questions of the OSS were used as a sub-scale. In symptomatic participants, the full OSS scale, scored on a 0-48 point scale, was used to define symptom severity. A Chi^2 test was used to determine any difference between tendon pathology groups. Multivariate binary logistic regression was used to adjust for the potential confounders age, BMI and hand dominance determined a priori. To account for a high positive skew of the OSS data when determining symptom severity, all asymptomatic shoulders were removed, and a logarithmic transformation of the inverse OSS was used to create a normal distribution. Symptom severity in symptomatic shoulders was compared across tendon pathology groups using a 1-way ANOVA. Multivariate linear regression was used to adjust for potential confounders age, and hand dominance determined a priori.

Patient and public involvement

We would like to thank all the participants of the Chingford Women Study for their time.
We would also like to thank Mrs Maxine Daniels and Dr Alan Hakim for their time and dedication, and both Mr Alex Nichols and Mr Michael Daines for their assistance with data collection and Dr Gemma Wallis for her assistance with data analysis.

Results

Participants and descriptive data

464 individuals (928 shoulders) were included in the study (Table 1). The distribution of age across each tendon pathology group was significantly different (p<0.001), with age increasing in accordance with tear severity. There was a statistical difference in the proportion of dominant and non-dominant arms in each tendon pathology group (p=0.033), with there being significantly more non-dominant arms in the normal tendon group (p=0.010), and significantly more dominant arms in those with full-thickness tears (p=0.026). There were no between-group differences in BMI (p=0.080).

Table 1. Demographics of all the shoulders included in the study

	Frequency	%	Median age	Mean BMI	Dominant arm (%)
Normal	510	55.0%	70	27.5	46.1%
Abnormal/ Partial tear	294	31.7%	73	28.0	52.7%
Full-thickness tears (0-2.5cm)	85	9.2%	74	27.9	58.8%
Full-thickness tears (>2.5cm)	39	4.2%	74	29.6	61.5%
All	928	100%	71	27.8	50%

Outcome data and main results

Prevalence of rotator cuff tendon pathology

The population prevalence of having at least one full-thickness tear was 22.2% (4.5% bilateral). For age groups 60-69, 70-79 and 80-89 these were 14.9%; 25.9% and 29% respectively, and bilateral tears 2.3%; 5.9% and 5.8% respectively. The difference in prevalence between age groups was statistically different (p<0.001).

The population prevalence of having at least a unilateral tendon pathology or tear was 59.5% (30.6% bilateral). For age groups 60-69, 70-79 and 80-89 these were 51.5%; 61.8% and 72.5% respectively,

and bilateral tears 24.6%; 32.3% and 40.6% respectively. The difference in population prevalence between age groups was statistically significant (p<0.001).

Table 2 shows the prevalence of rotator cuff tendinopathy in the dominant and non-dominant arms in age deciles. The distribution of tendinopathy differed between age groups (Dominant arm p=0.002; non-dominant arm p=0.037) with more pathology found in older age groups, and in the dominant compared to non-dominant arms (p=0.004). There was no difference in prevalence according to BMI group. The relative risk of full-thickness tear was 1.64 (OR 1.580, 95%CI 1.073-2.326, p=0.021) in the dominant compared to non-dominant arm. For those aged 70-79 it was 2.072 (OR 2.026, 95%CI 1.286-3.190, p=0.002), and aged 80-89 was 2.293 (OR 2.256, 95%CI 1.264-4.027, p=0.006), compared to those aged 60-69.

Table 2. Prevalence of rotator cuff tendon pathology according to age decile and arm dominance

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Non-dominant arm								
Normal tendon	115	65.7%	122	55.5%	38	55.1%	275	59.3%
Abnormal tendon/Partial thickness tear	49	28.0%	70	31.8%	20	29.0%	139	30.0%
Full-thickness tear 0-2.5 cm	10	5.7%	18	8.2%	7	10.1%	35	7.5%
Full-thickness tear >2.5 cm	1	0.6%	10	4.5%	4	5.8%	15	3.2%

Association of symptoms (all shoulders)

An analysis of symptom association was completed in 926 shoulders (463/464 participants due to loss of one questionnaire). There were 289 (31.2%) symptomatic shoulders according to a dichotomised OSS. The presence of symptoms was statistically significant between tendon groups (p<0.001); 51.6% of all full-thickness tears were symptomatic. There was no difference in age, BMI or arm dominance between symptomatic or asymptomatic shoulders. The relative risks of having symptoms compared to those with a reported normal tendon were as follows: Abnormal/Partial tears 1.969 (OR 1.991, 95%CI 1.454-2.727); full-thickness tears 0-2.5cm 2.203 (OR 2.366, 95%CI 1.465-3.891); and full-thickness tears >2.5cm 4.718 (OR 9.800, 95%CI 4.638-20.705). All were significant (p<0.001) with the model correctly predicting 71% of symptom outcomes correctly. The distribution of symptoms across each tendon group is shown in Figure 2.

When the same analysis was performed using a 3-point change in the OSS to define symptoms the results were not statistically different and compared to normal tendons were as follows: Abnormal/Partial tears 1.793 (OR 1.936, 95%CI 1.374-2.726); full-thickness tears 0-2.5cm 2.098 (OR 2.506, 95%CI 1.513-4.150); and full-thickness tears >2.5cm 3.924 (OR 9.678, 95%CI 4.784-19.580). All were significant (p<0.001).

[INSERT FIGURE 2]

Symptom severity

For the 289 symptomatic shoulders the full OSS was reported (Table 3). Median age was significantly different between groups (p=0.047), with age increasing with tear stage severity. No statistically significant between-group differences in BMI were identified, nor any within-group differences for arm dominance.

Table 3. Demographics of the 289 symptomatic shoulders

	N	Median age	Mean BMI	Dominant arm (%)
Normal	116	70	28.3	46.6%
Abnormal/Partial tear	109	73	28.4	54.1%
Full-thickness tears 0-2.5cm	35	72	28.1	62.9%
Full-thickness tears >2.5cm	29	73	30.3	58.6%
All	289	71	28.5	50%

The mean OSS for symptomatic shoulders was 41.8. For normal tendons this was 42.5, abnormal tendons, 42.1; full-thickness tears (0-2.5cm), 40.2; and full-thickness tears (>2.5cm), 38.4. There was a statistical difference between the groups (1 way ANOVA p=0.030). Linear regression analysis after adjustment for age, BMI, and hand dominance (no interactions identified), showed that the only significant difference in OSS scores was between normal tendons (mean OSS 42.5) and large full-thickness tears (OSS 38.3), p=0.009, power 0.75 (overall model p=0.007, power 0.892).

Association of symptoms (individuals)

Table 4 shows the relationship between the individual, presence of full-thickness rotator cuff tear and the likelihood of symptoms. A clustering effect of bilateral symptoms or lack thereof is present, irrespective of the underlying pathology. After adjustment for age and BMI, compared to those with bilaterally normal shoulders the relative risk of having at least one symptomatic shoulder in the presence of a full thickness rotator cuff tear is 1.49 (OR 1.867, 95%CI 1.200-2.904), and 1.97 (OR 3.352, 95%CI 2.003-5.609) in the presence of at least a unilateral abnormality or cuff tear.

Table 4. Distribution of individual shoulder symptoms according to the presence of full-thickness tears or tendon abnormalities

	No Symptoms	Unilateral Symptoms	Bilateral Symptoms	Total
Bilateral No FTT	226	71	63	360
Unilateral FTT	33	25	24	82
Bilateral FTT	10	3	8	21
Bilateral normal	131	28	28	187
Unilateral abnormality	72	34	28	134
Bilateral abnormality	66	37	39	142
Total	269	99	95	463

Shoulder pain and use of primary care health services

Table 5 shows the proportion of individuals with shoulder pain, past or present, seeking medical advice. The likelihood of seeking medical attention for shoulder pain was statistically different between each pathology group (Chi^2 test p=0.005) reflecting the increasing likelihood of pain. However, of those with pain the likelihood of seeking medical attention was not statistically different between groups (Chi^2 test p=0.179). Overall, 28.3% (131/463) of all individuals had at some stage seen their GP for shoulder pain. In this cohort, 8.9% (41/463) had seen their GP with shoulder pain and a full-thickness tendon tear and 18.8% (87/463) had seen their GP with an abnormal tendon or full thickness tear.

A multivariable regression model using all individuals was used to predict the likelihood of attending a GP for shoulder pain. The presence of at least one full-thickness tear had a relative risk of 1.63 (OR 2.179, 95%CI 1.282-3.703) compared to those with normal tendons of attending the GP. There was no statistical difference in relative risk of those with any tendon abnormality compared to those with bilaterally normal shoulders.

Table 5. Proportion of individuals seeking medical advice

	Present symptoms (either shoulder)		Past or Present symptoms (either shoulder)		All individuals
	%	% seen GP	%	% seen GP	% seen GP
All individuals (n=463)	41.9 (n=194)	44.8 (n=87)	55.7 (n=258)	50.8 (n=131)	28.3 (n=131)
Bilaterally normal tendons (n=187)	29.9 (n=56)	41.1 (n=23)	48.1 (n=90)	48.9 (n=44)	23.5 (n=44)
At least one abnormality (no tear) (n=173)	45.1 (n=78)	41.0 (n=32)	57.2 (n=99)	46.5 (n=46)	26.6 (n=46)
At least one full-thickness tear (n=103)	58.3 (n=60)	53.3 (n=32)	67.0 (n=69)	59.4 (n=41)	39.8 (n=41)

Discussion

Key results

Using a large general population cohort of women aged 65-84 years, this study has reported on the prevalence of rotator cuff pathology, the association of pathology to symptoms and uniquely the consequential impact on health services.

The prevalence of rotator cuff pathology has been well reported in the literature, and this general population study, supports previous findings. Prevalence was found to increase with every decile of age, and the relative risk of having a full thickness tear increased more than two-fold between the 65-69 and >80 age groups, suggesting age related change[18]. Overall, the prevalence of at least a unilateral full thickness tear was 22%. The dominant arm was 1.64 times likely to be affected, inferring that the presence of pathology may exist in shoulders with higher cumulative loading.

The relative risk of having symptomatic pathology (worsening OSS scores) increased with tear stage severity, though the severity of symptoms did not increase accordingly. Although larger tear size increased the likelihood of symptom presence, 48.4% of full-thickness rotator cuff tears remained asymptomatic.

The burden of musculoskeletal shoulder pain on health services is large, with 28.3% of individuals in this general population cohort having at some point sought medical advice for shoulder symptoms. This is the first study to look at the impact of rotator cuff pathology on the impact on the health services. Although on average only 50% of individuals with symptomatic rotator cuff tendon pathology (tendinopathy) will seek medical advice, the impact remains significant. Overall, almost 10% of individuals in the general population have sought medical advice for shoulder symptoms in the presence of a full-thickness tear, and almost 20% of the population for any tendon abnormality. The major strength of this study is that it uses a large population-based cohort, and therefore not subject to selection bias. The cohort was originally investigated with the primary focus of osteoporosis, and not shoulder symptoms, thus any continued participation is not driven by shoulder symptoms.

Limitations (including bias)

The cohort can only comment on associations in women aged between 65 and 84, but as previous studies have found no relationship between symptoms and age or sex [23 30], this will not bias the results. Potential survival bias is introduced by the cohort being in its 20th year. If a greater proportion of individuals with pathology were lost to follow up this may cause us to under-estimate any association, however, no known associations exist in the literature between rotator cuff tears and other medical co-morbidities. Furthermore, as the prime goal of the cohort was not to investigate shoulder symptoms, this had no impact on continued study participation. Furthermore, only 463/516 individuals that attended the year-20 study underwent a shoulder examination due to lack of an examiner being present at these follow up appointments. However, the age and BMI of the groups was not statistically different to the full cohort.

Bias arising from having two examiners was ameliorated by two inter-observer reproducibility studies that demonstrated minimal effect of inter-observer analytic bias. Furthermore, to demonstrate ultrasound-scanning accuracy a learning curve study was undertaken a priori by both examiners, which demonstrated scanning accuracies comparable to those quoted in the literature. Inter-observer studies also demonstrated good reproducibility reducing analytic bias. Potential risk of overreporting pathology in symptomatic presentations is acknowledged as the assessor (ultrasonographer) was unblinded to the OSS result, as for pragmatic reasons due to lack of assessors, both assessments were carried out by the same individual. To overcome this, a small intra-observer study was completed, and an additional ultrasound scan was performed on 18 willing participants. The examiner was blind to all pervious results and shoulder scores. Overall agreement gave a weighted kappa score of 0.915 ($p<0.001$).

The effect of tear size on symptom severity may have been underestimated in this study. The inability to transform the complete data set due to the skew of the OSS data, meant all asymptomatic shoulders had to be removed. Pain severity in the presence of a tear was then compared to a pain severity in a normal (no tendon pathology) shoulder. We recognise that there may be many causes of shoulder pain (e.g., rheumatological causes) and therefore referencing against all causes of painful shoulder may represent the contribution of rotator cuff tear to the symptoms.

The definition of symptoms in previous studies varies widely with no consensus. The decision to use the OSS was based upon its content, construct validity in relation to our research question, and validation of use against other pain scores. Furthermore, dichotomisation of the scale at perfect vs. non-perfect scores is not validated and may make results too sensitive. However, we ran a comparison with 3-point change, as validated as clinically significant by the makers of the OSS, and there was no statistical difference.

Relationship to other studies

This study has demonstrated similar prevalence figures to previous studies, but it is the first to use a general population cohort that has been extensively characterised as representative of the western world population.

Further studies have shown that the clinical presentation of rotator cuff tears varies and may or may not be associated with symptoms[17 22 23]. This general population cohort supports this with 48.4% of full-thickness rotator cuff tears being asymptomatic. Prior to this, the only other population-based study looking at symptom association with full-thickness tears was Yamamoto et al.[30] that investigated symptom association with full-thickness tears using a mountain cohort in Japan. They reported 34% of full-thickness tears to be symptomatic. However, unlike the current study, it was not a general population cohort representative of western society. Furthermore, it was subject to selection bias by removing any individuals with restricted shoulder movement or previous treatments.

Further studies have suggested that tear size affects the likelihood of symptoms. The current study supports this with larger tears having a greater than 2-fold increase in relative risk of symptoms than small tears[17 22 23]. A previous study in the Washington series investigated by Yamaguchi et al[26], reported development of symptoms in previously asymptomatic tendons in the context of a contralateral symptomatic tear. However, this study was subject to selection bias as recruitment occurred in a cohort actively being treated for contralateral symptomatic rotator cuff tears which may have strengthened associations.

This is the first study that has looked at individuals as entities, rather than shoulders, and has highlighted the effect the individual has on symptom presentation, which could include physical and psychological factors unique to that individual – not solely the presence of tendon pathology on imaging. It is also the first study to look at the impact on health services.

Interpretation

This study has shown that although patient reported pain on the Oxford Shoulder Score is associated with rotator cuff tendon pathology, it is not related to the severity of structural pathology identified on ultrasound imaging. The likelihood of pain also appears to be strongly dependent upon the individual rather than simply the pathology. Consequently, clinicians should rely less on imaging findings to explain the cause and severity of shoulder pain presentations. Furthermore, other drivers of shoulder pain should be considered (e.g. pain sensitisation), and treatment be targeted on symptom management rather than solely interventions to improve tendon pathology.

Investigation into the impact of musculoskeletal shoulder pain on the healthcare system revealed that 28.8% of people in this general population cohort sought consultation with their GP for shoulder pain, a third of whom had a full thickness tear, and a third with at least one abnormality (no tear). This

study highlights the huge burden of shoulder pain on the healthcare system. Though, it does not demonstrate causality of pain as is shown by the lack of symptoms in nearly half of cases and the lack of correlation with the severity of pain and pathology. Nor does it show how the individual affects pain presentation.

Generalisability

This epidemiological study that is generalisable to the UK population, demonstrates association but not causality, and leaves unanswered questions as to what additional factors contribute to shoulder pain. Particularly interesting is how individuals may or may not have painful shoulders irrespective of the pathology. Further research into this could provide alternative targets to treatment methods, and potentially reduce the cost of imaging modalities and surgical interventions.

Conclusion

In conclusion, this population-based study has demonstrated that full-thickness rotator cuff tears are common affecting 22.1% of women over the age of 60, and tendon abnormalities affecting 59.4%. Despite 41.7% of individuals with a full-thickness tear (48.4% of all full-thickness tears) being asymptomatic, tendon abnormalities and tears are associated with pain. The likelihood, but not severity of symptoms, increases with greater structural damage.

This high prevalence and association of symptoms results in a significant impact on primary care health services, with 28.3% of this population having presented to a GP with shoulder pain. Of these a third had a full-thickness tear and a third had an abnormal but non-torn tendon. Overall, 8.9% of this cohort had seen their general practitioner with shoulder pain and a full-thickness tear, and 18.8% had seen their general practitioner with an abnormal or torn tendon.

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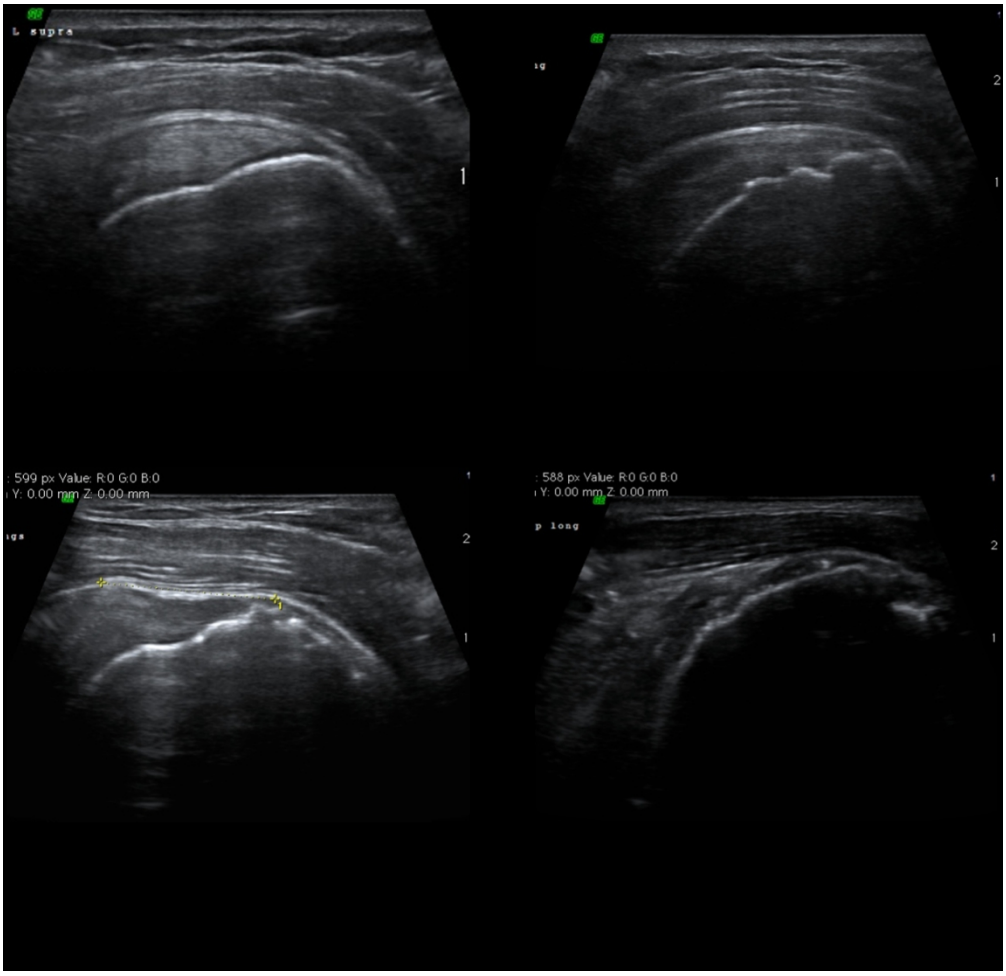
Figures

Figure 1: Tendon classification on ultrasound

Figure 1 caption: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

Figure 2: Distribution of symptoms across each tendon group



Tendon classification on ultrasound: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

106x102mm (330 x 330 DPI)

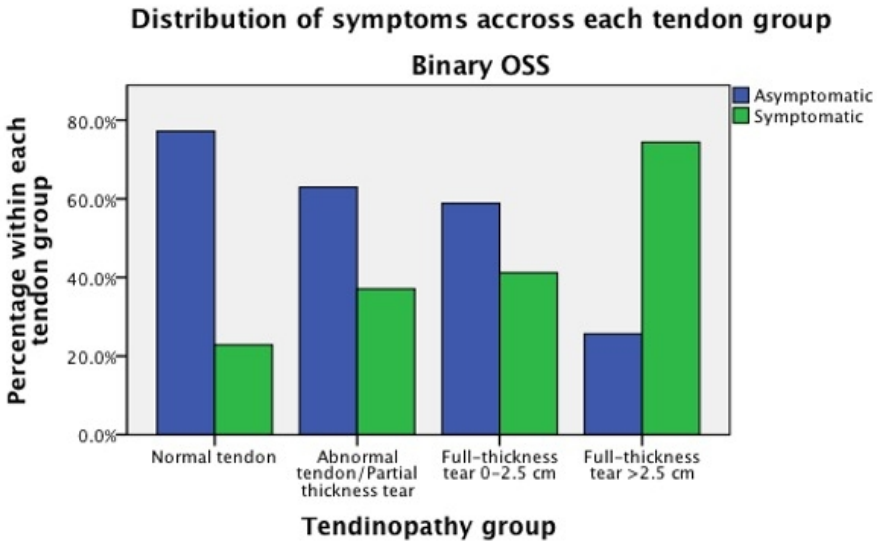


Figure 2. Distribution of symptoms across each tendon group

116x68mm (144 x 144 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 - title of the manuscript	
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4 - line 128-153	
Objectives	3	State specific objectives, including any prespecified hypotheses	page 4 lines 150-154	
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4 - lines 165-176	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4 - lines 165-176	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	ages - lines 165-176	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 - lines 182-198	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 5 - lines 181-198	
Bias	9	Describe any efforts to address potential sources of bias	Page 10 - lines 351-393	
Study size	10	Explain how the study size was arrived at	Page 4 - Lines 174-177	

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5-6 - lines 207-236
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	SECTION 12 - Page 5-6 - lines 207-236
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 6 - lines 239-246
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 6 - lines 239-246
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Pages 6-9
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Results tables, pages 6-9 - lines 248-325
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9- lines 328-351
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 10 - 356-392
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11 - lines 422-437
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 11- lines 440-445
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 2- lines 50-53

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.