Increasing Capacity for the Treatment of Common Musculoskeletal Problems: A Non-Inferiority RCT and Economic Analysis of Corticosteroid Injection for Shoulder Pain Comparing a Physiotherapist and Orthopaedic Surgeon

Darryn Marks[1,2]*, Leanne Bisset[2], Tracy Comans[2,3], Michael Thomas[1], Shu Kay Ng[2], Shaun O'Leary[4,5], Philip G. Conaghan[6], Paul A. Scuffham[2]

1 Gold Cost Hospital and Health Service, Gold Coast University Hospital, 1 Hospital Boulevard, Southport, 4215, Gold Coast, Australia, 2 Menzies Health Institute Queensland, Griffith University, Parklands Drive, Southport, QLD 4222, Gold Coast, Australia, 3 Metro North Hospital and Health Service, 112 Alfred Street, Fortitude Valley, QLD 4006, Brisbane, Australia, 4 School of Health and Rehabilitation Sciences, University of Queensland, Brisbane, St Lucia, QLD 4072, Australia, 5 Physiotherapy Department, Royal Brisbane and Women's Hospital, Butterfield Street, Herston, QLD 4006, Australia, 6 Leeds Institute of Rheumatic & Musculoskeletal Medicine, University of Leeds, & NIHR Leeds Musculoskeletal Biomedical Research Unit, Chapel Allerton Hospital, Leeds, LS7 4SA, United Kingdom

* darryn.marks@health.qld.gov.au

Abstract

Background

Role substitution is a strategy employed to assist health services manage the growing demand for musculoskeletal care. Corticosteroid injection is a common treatment in this population but the efficacy of its prescription and delivery by physiotherapists has not been established against orthopaedic standards. This paper investigates whether corticosteroid injection given by a physiotherapist for shoulder pain is as clinically and cost effective as that from an orthopaedic surgeon.

Methods

A double blind non-inferiority randomized controlled trial was conducted in an Australian public hospital orthopaedic outpatient service, from January 2013 to June 2014. Adults with a General Practitioner referral to Orthopaedics for shoulder pain received subacromial corticosteroid and local anaesthetic injection prescribed and delivered independently by a physiotherapist or a consultant orthopaedic surgeon. The main outcome measure was total Shoulder Pain and Disability Index (SPADI) score at baseline, six and 12 weeks, applying a non-inferiority margin of 15 points. Secondary outcomes tested for superiority included pain, shoulder movement, perceived improvement, adverse events, satisfaction, quality of life and costs.

Results

278 participants were independently assessed by the physiotherapist and the orthopaedic surgeon, with 64 randomised (physiotherapist 33, orthopaedic surgeon 31). There were no significant differences in baseline characteristics between groups. Non-inferiority of injection by the physiotherapist was declared from total SPADI scores at 6 and 12 weeks (upper limit of the 95% one-sided confidence interval 13.34 and 7.17 at 6 and 12 weeks, respectively). There were no statistically significant differences between groups on any outcome measures at 6 or 12 weeks. From the perspective of the health funder, the physiotherapist was less expensive.

Conclusions

Corticosteroid injection for shoulder pain, provided by a suitably qualified physiotherapist is at least as clinically effective, and less expensive, compared with similar care delivered by an orthopaedic surgeon. Policy makers and service providers should consider implementing this model of care.

Trial Registration

Australia and New Zealand Clinical Trials Registry 12612000532808

Introduction

Musculoskeletal disorders are the second largest cause of disability globally [1, 2]. In countries with publicly funded health systems, long waiting lists for specialist musculoskeletal care such as orthopaedics, attract much political attention [3] and service redesign effort [4]. In response, funding and service modernization in England has led to some improvement but up to 5% of patients still wait beyond recommended periods [5]. In many countries the response has been slower, for example patients seeking orthopaedic consultation in Australia's public hospitals often wait in excess of 12 months [6]. Internationally, access problems are expected to intensify as the rate of musculoskeletal disorders rise with population ageing [7], causing increased demand for care and mounting challenges for service providers [4, 8, 9].

A strategy aiming to improve access for patients [10], and to reduce cost and workforce shortages [11], is the substitution of doctors with other healthcare professionals. It has been proposed that lower costs, reduced waiting times and improved health outcomes may be achieved when extended-scope physiotherapists provide various aspects of musculoskeletal care in place of doctors [12–14]; however, the supporting evidence is generally low quality with conclusions drawn mostly from observational case reports rather than robust scientific investigation [12, 14]. With a lack of high quality evidence to inform service redesign, regulations, funding and delivery structures have evolved with substantial international variability, highlighted by the legalisation of independent prescribing by trained physiotherapists in the UK [15, 16], but not in other countries.

Shoulder pain is a common musculoskeletal disorder that frequently highlights a discrepancy between the evidence (which generally advocates non-surgical treatment) and health service delivery (which frequently directs patients to orthopaedic surgery waiting lists). It is the second to third most prevalent musculoskeletal condition [17–20], causes substantial physical, social and psychological deficits [21, 22], reduced ability to work and high levels of work

absence [23, 24]. The quality of primary care management of shoulder pain is variable, with a high reliance upon specialist referral [25], most commonly to orthopaedics [26, 27]. Yet there is evidence that involving a physiotherapist in the triage of orthopaedic referrals may be beneficial [13, 28], and shoulder pain is a frequent problem seen by physiotherapists providing early access orthopaedic services [29]. Subacromial impingement syndrome (referred to by various terms including rotator cuff disease) is the most common cause [30, 31], and should generally be managed non-surgically, unless symptoms persist despite best conservative efforts [32–34]. There are a variety of treatment options for subacromial impingement [32], and whilst not always indicated as the initial treatment, both subacromial corticosteroid injection [32, 35, 36] and exercises [32, 37] are frequently recommended and cost effective [38, 39]. Therefore, it is possible that care may be expedited and possibly enhanced, with a medical substitution model permitting patients to access trained physiotherapists capable of providing these injections. This model of care is now available in the UK but the efficacy remains unknown as no clinical trials have yet investigated health outcomes resulting from prescribing or shoulder injection provided by physiotherapists compared with consultant level doctors or general practitioners. Furthermore, the lack of evidence surrounding the safety, efficacy and cost of prescribing and injection by physiotherapists may also be preventing other countries from adopting this innovative care model with the potential to improve patient access to evidence based care.

Therefore, the purpose of this this study was to determine if corticosteroid injection for shoulder pain, prescribed and delivered by a physiotherapist, is at least as clinically effective as that by a consultant orthopaedic surgeon. To test this hypothesis we chose a non-inferiority design, as it is the most appropriate way to investigate a new treatment in comparison to an existing gold standard [40, 41]. Secondary aims were to compare the safety, satisfaction and cost of this care delivered by a physiotherapist compared with an orthopaedic surgeon.

Methods

Design

A double blind (patient and outcome assessor) non-inferiority randomized controlled trial was undertaken in the Gold Coast, Australia, as described in the published protocol [42]. Other elements within this protocol (investigation of the economic burden of shoulder pain and the level of decision-making agreement between a physiotherapist and orthopaedic surgeon) will be reported separately.

Approvals and governance

The trial was registered on the Australia and New Zealand Clinical Trials Registry 21 May 2012: 12612000532808. Ethical Approval was granted through the Gold Coast Hospital and Health Service Human Research Ethics Committee, NHMRC code EC00160 (HREC/12/QGC/30; SSA/12/QGC/97), and Griffith University Human Research Ethics Committee (MED/23/13/HREC). Legislative Approval was obtained under Queensland's Health (Drugs and Poison) Regulation 1996, to permit prescribing / injection by the research physiotherapist, as this practice is beyond the usual professional scope of physiotherapy in Australia. Adverse event reporting and management, and the function of the Data Safety Monitoring Committee, are detailed in the published protocol [42].

Patients

Adults aged 18 years or older were recruited between January 2013 and June 2014, providing they had a shoulder pain referral from their primary care doctor to the hospital orthopaedic

department, the ability to read trial literature and give consent. They were excluded if they had prior knowledge of the research physiotherapist or the orthopaedic surgeon (eg, from previous interactions or consultation), or no shoulder X-Ray in the previous 12 months (in keeping with hospital referral guidelines). Following an initial telephone call, potentially eligible patients were offered a clinic appointment at which eligibility was confirmed, and written informed consent obtained by the research assistant. Prior to randomization, participants were independently assessed by the orthopaedic surgeon and by the physiotherapist, on a 30-minute clinic schedule per clinician, in variable order (orthopaedic surgeon or physiotherapist first) according to clinician availability. Participants were ineligible for randomization if either clinician's assessment revealed that they were taking anticoagulant medication, required prophylactic antibiotics prior to injection, were pregnant, breastfeeding, or had previous surgery of the involved shoulder. Each clinician recorded their diagnosis, and a yes/no response to the question "would you provide subacromial injection today?" These were compared by the research assistant, and only if both clinicians recorded a "yes" response, was the participant eligible for randomization. Thus all randomized participants had (from both assessors) a diagnosis of subacromial impingement, and were deemed appropriate for immediate corticosteroid injection. Those not meeting this criteria, took no further part in the study. Providing the participant could complete the study questionnaires and follow post injection instructions, written informed consent to treatment in the study was obtained before they were randomized. In bilateral presentations, the painful shoulder identified in the referral was treated. In bilateral referrals both sides were assessed, the participant asked to nominate their most troublesome side and clinicians made their injection decisions for the most troublesome shoulder only. Patients were free to withdraw from the trial at any point, and receive usual orthopaedic care.

Blinding

The research physiotherapist (DM) and the orthopaedic surgeon (MT) each had their own room labelled "room A" or "room B", in which all assessments and injections were conducted independently. Both were blind to each other's clinical assessment findings and treatment decisions. Participants were blind to the profession of surgeon and the physiotherapist at all times throughout the entire trial. The outcome assessor was blind to the treating practitioner. Post injection, treatment physiotherapists were asked to not seek information regarding the profession of the injecting clinician, not discuss the identity or profession of injecting clinicians with participants and to report any breaches in blinding to the research assistant. The success of blinding was assessed immediately post injection, and at 6 and 12 weeks, when participants and the outcome assessor nominated whether they thought the injection was delivered by the physiotherapist or the surgeon. The research physiotherapist (DM) and orthopaedic surgeon (MT) took no part in the recruitment, consent, randomization, or data collection.

Randomisation

Using excel software, a computer generated randomization sequence was developed by one investigator (LB) and concealed from the research physiotherapist, orthopaedic surgeon and outcome assessor. Randomized participants were given a previously sealed opaque envelope by the research assistant, which contained a form directing them to either "room A" or "room B" for their injection.

Interventions

Injection. Subacromial corticosteroid and local anaesthetic (one ml of Betamethasone (Celestone Chronodose 5.7mg/mL) mixed with five ml of 1% lignocaine hydrochloride), was

delivered to the subacromial space using an aseptic injection technique by either the physio-therapist (intervention) or the orthopaedic surgeon (control) according to the randomization schedule. Subacromial corticosteroid injection is a common treatment for shoulder pain [43, 44], with evidence of clinical efficacy [35, 36] and cost effectiveness [38, 45]. Post injection, standard advice was provided verbally and participants were also given written information advising reduced activity for one week, attendance at physiotherapy and information pertain-ing to the recognition and reporting procedures for any adverse reactions.

Physiotherapy. All participants were referred for a course of physiotherapy within the hospital's outpatient physiotherapy department, beginning approximately one week post-injec-tion. The research (injecting) physiotherapist (DM) took no part in this course of post-injec-tion treatment. Consensus regarding best practice exercise and manual therapy interventions used for shoulder pain in the department was established pre-trial and treatment was delivered pragmatically, with specific interventions and the number of sessions at the discretion of the treating physiotherapist. All treating physiotherapists were directed to not deliver acupuncture to participants and adherence to this was monitored by the research assistant.

Clinicians providing injections. The research physiotherapist (DM) had 19 years post-graduation experience in a variety of musculoskeletal settings, a post-graduate Diploma in injection therapy and Non-Medical Prescribing registration obtained in the UK. The orthopae-dic surgeon (MT) was 20 years post-graduation, employed as a Staff Specialist Orthopaedic Consultant and was a Fellow of the UK Royal College of Surgeons (Trauma and Orthopaedics), and in 2005 was the recipient of an Australian Upper Limb Orthopaedic Fellowship.

Outcome measures. In addition to participant demographics, the usual waiting time for an initial appointment with an orthopaedic surgeon and for an appointment with an orthopae-dic screening service physiotherapist, were taken at baseline from hospital databases. The pri-mary outcome measure was the total Shoulder Pain and Disability Index (SPADI) score measured at baseline, 6 and 12 weeks post injection. This self-rating tool has demonstrated good responsiveness [46], reliability and validity in shoulder pain trials [47, 48], including the efficacy of corticosteroid injection [49, 50]. It uses a one week recall period and has 13 ques-tions with a scale of 0–10, divided into pain (five questions) and disability (eight questions). These are scored as two separate subscales and an overall score varying from 0 (best) to 100 (worst) is calculated [48]. A number of secondary outcomes were also measured at initial atten-dance, six and twelve weeks. Pain severity over the past three days was measured on a visual analogue scale (VAS). The pain VAS has demonstrated reliability, validity and responsiveness to change in relevant populations [51, 52]. Health related quality of life was measured using the European Quality of Life five dimensions, five levels (EQ-5D-5L). This is recommended as a generic patient reported outcome measure for use with musculoskeletal populations [53] and has demonstrated validity and responsiveness in chronic pain [54]. A five-point Global Rating of Change (GROC) scale varying from completely recovered (1) to much worse (5) was also used. GROC is a convenient clinical measurement tool with demonstrated validity and respon-siveness [55]. Within a period of 20 minutes before and 20 minutes after injection, the blinded outcome assessor also measured shoulder range of motion (ROM) three times in the scapular plane with a goniometer, by instructing the participant to "take your arm up as far as you feel able". Goniometry for shoulder ROM has good validity and reliability [56] and intra-rater change detection of six degrees [57]. Participants also rated the severity of their pain ('worst pain' and 'mean pain') during shoulder elevation on a 0–100 VAS anchored by "no pain" (0) and "worst pain imaginable" (100). Medicine use was recorded at baseline and twelve weeks. Participants were prompted to report any unwanted side-effects via written instructions on a standardised post injection information sheet and were also asked by the research assistant at six weeks whether they had suffered any adverse events. A serious adverse event was defined as

one that results in persistent incapacity, requires hospitalization (for example antibiotic treatment for infection related to the injection), or anything worse [58, 59]. Any adverse events reported over the twelve weeks post injection were recorded. At twelve weeks participants also rated their overall satisfaction with care on a 0–10 VAS anchored by "not satisfied at all" (0) to "completely satisfied" (10). The number of post injection physiotherapy sessions was obtained from hospital booking systems.

Sample size calculation

Assuming α = 0.05, β = 0.2, a non-inferiority margin of 15 points in total SPADI scores, we estimated a sample size of 64 participants (32 per group) to allow for dropouts, would be required to test for comparative efficacy between the intervention (injection by physiotherapist) and the control (injection by orthopaedic surgeon) groups. Detailed explanation of the sample size calculation, and non-inferioirty margin selection, are contained in the published protocol [42]. By using the generalised estimating equation (GEE) approach for repeated measures, this sample size provides the study with an increased power of above 90%. Fig 1 demonstrates the conceptual basis of non-inferiority design, and with reference to Fig 1, it means that the difference in mean SPADI scores between the two groups should be at most 5 points in order that the upper limit of the one-sided 95% confidence interval is smaller than the selected non-inferiority margin (Scenario C). We anticipated 256 participants would be assessed to achieve this, based on an estimate of 25% of participants being randomized.

Statistical Analysis

Data analysis was conducted using SPSS software version 22, with the analyst (DM) blinded to the identity of the treatment and control groups (labelled as group 0 and group 1). All tests were conducted with an alpha of 0.05, on an intention to treat (ITT) basis and non-inferiority tests were performed in both directions (group 0 relative to group 1, and vice-versa). The analyst was then unblinded to determine the per-protocol population and analysis. Per-protocol analysis was compared to ITT analysis for non-inferiority tests due to the increased risk of type 1 error with ITT analysis in non-inferiority design [41, 60, 61].

For the primary outcome (SPADI) the intervention (physiotherapist) was tested for non-inferiority compared to the control (orthopaedic surgeon) using the generalized estimating equation (GEE) with a first order autoregressive working structure (AR1) and robust estimator for covariance matrix. Time (within-group differences), practitioner (between-group differences), and practitioner by time interaction (between-group differences over time) were included in all models and assessed using the Wald chi-square test. The GEE is a widely used method for the analysis of longitudinal data [62]. It considers multiple time points simultaneously and allows for testing the overall significance of the effects. The GEE works well with missing data, assuming that they are missing completely at random (MCAR). Non-linear relationship between outcome and time was considered in the analysis. We included baseline demographic characteristics (age, duration of symptoms, number of prior injections) as covariates in the omnibus analysis and reported unadjusted results if they were found to not affect outcomes significantly. Non-inferiority of injection by the physiotherapist could be declared if the upper limit of the 95% one-sided confidence interval for the difference in mean change of SPADI in the physiotherapist group, relative to the surgeon group, was smaller than the non-inferiority margin of 15 points [40, 63]. Secondary outcome measures were compared for superiority; between group change scores for pain and EQ-5D-5L health utility scores with independent t-tests. GROC was compared on the day of injection, 6 and 12 weeks using Mann-Whitney U. Changes in shoulder medication use at 12 weeks were categorised (1 = stopped,
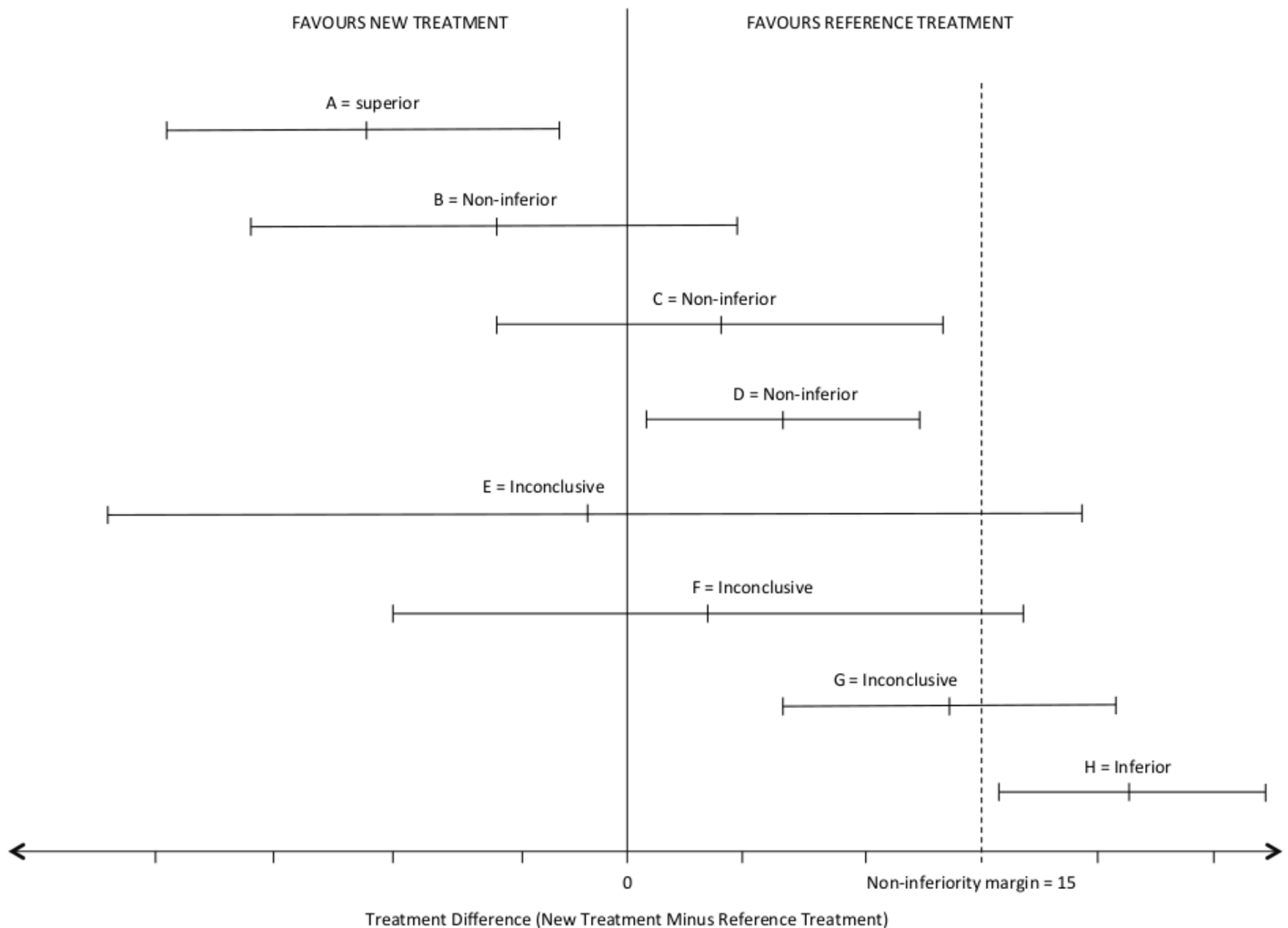
Fig 1. Possible scenarios of treatment differences and interpretation of non-inferiority results. Error bars indicate two sided (1–2 α) x 100% confidence intervals, where α is the Type I error rate. The zone of non-inferiority is to the left of the non-inferiority margin. Scenario A, new treatment is superior as the CI lie to the left of zero. Scenarios B and C, new treatment is non-inferior but not superior as the CI lie to the left of the non-inferiority margin and include zero. Scenario D, represents an unusual circumstance in which the new treatment is both non-inferior (as defined by the non-inferioirty margin), and inferior (as defined by exclusion of the null treatment difference). This can result from a very large sample size, or a non-inferiority margin that is too wide. Scenarios E and F, the difference is non-significant but non-inferiority is inconclusive. Scenario G, represents a significant result but non-inferioirty is inconclusive. Scenario H, inferior as the CI lie to the right of the non-inferiority margin. Adapted from Piaggio et al 2012 and 2006 [41, 60].

doi:10.1371/journal.pone.0162679.g001

2 = reduced, 3 = no change, 4 = increased) and analysed using Mann-Whitney U. Adverse events were presented descriptively, satisfaction with the treatment and the number of physiotherapy sessions were compared at 12 weeks using independent t-tests.

A within trial economic analysis with a 12 week time horizon, from the perspective of the health funder (Commonwealth and State governments), was undertaken and the incremental cost utility ratio estimated as: Cost-utility = (Cost_i—Cost_c) /(QALY_i—QALY_c), where: QALY = Quality adjusted life years calculated by mapping the EQ-5D-5L utility score across time and calculating the area under the curve, i = Intervention group for main effect analysis, and c = Control group. EQ-5D-5L scores were converted to Australian values using previously published Australian population data [64]. Inputs included direct staff costs derived from Queensland Government pay scales and total employment package costs to the employer [65,

66] for the injecting physiotherapist, orthopaedic surgeon and treating physiotherapists. A sample of 10,000 bootstraps was used to estimate the confidence interval around the incremental cost and effectiveness ratio. One-way sensitivity analyses were conducted to identify the key factors affecting the results, including physiotherapist pay rates and consultation time, support staff and a federal government reimbursement to the hospital, applicable only to consultation with a medical doctor [67].

Results

A total of 988 referrals on the orthopaedic waiting list were screened for eligibility by the research assistant. Of these, 305 attended a clinic appointment over the 17 month period between January 2013 and June 2014, of which 278 were assessed by the physiotherapist and surgeon before the target randomization sample size of 64 was achieved. This process and the reasons for exclusion are detailed in Fig 2.

Baseline characteristics were similar in both groups (Table 1) and did not significantly influence outcomes, thus unadjusted results have been reported. Although the orthopaedic surgeon group reported longer duration of symptoms, slightly higher SPADI scores and slightly more pain over the previous three days, there were no significant differences between the two groups in any baseline characteristics. The mean (and standard deviation) total SPADI score at baseline in the 64 randomized participants of 62.63 (19.07), was not significantly different to the 214 assessed but non-randomized patients at 56.97 (23.72), indicating that the inclusion criteria maintained external validity with respect to the severity of participant pain and disability. Compliance with the study protocol was high (Fig 2). One participant in the physiotherapist group reported difficult social circumstances, did not attend post injection physiotherapy or complete six or 12 week outcomes. One participant in the orthopaedic surgeon group withdraw from the trial and did not supply 12 week outcomes. Imputation of missing data was deemed unnecessary due to the low numbers with missing data and the use of the GEE, which accounts for missing observations [68]. Two participants (one from each group) were not included in the per-protocol analysis; one randomized to the physiotherapist group mistook the instruction within the sealed envelope, entered the wrong clinical room and received injection from the surgeon, instead of the physiotherapist. One other subject revealed they were un-blinded because they knew the surgeon from prior consultation with a family member. Both participants' results were included within their allocated group according to the randomization schedule for the intention to treat analysis. Post-injection physiotherapy was intended to be pragmatically delivered and consequently low attendance was not considered a protocol breach.

Participants in the physiotherapist group correctly guessed the profession of their injection provider 60% of the time at baseline, 68% at six weeks and 56% at 12 weeks. In the orthopaedic surgeon group, the profession of the injection provider was correctly guessed 68%, 71% and 60% at those time-points. This indicates participants were able to guess the clinician's profession slightly more than would be expected by chance. It also indicates there was no systematic unblinding that occurred over the 12 week trial. The blinded outcome assessor (responsible for measuring range of movement within 20 minutes pre and post injection) correctly guessed the profession of the clinician providing injection in 79% and 74% of cases for the physiotherapist and surgeon group respectively.

Primary outcome

Table 2 details the change in mean SPADI scores at 6 and 12 weeks compared to baseline. Mean total SPADI scores improved significantly in both groups at 6 and 12 weeks (p<0.001).
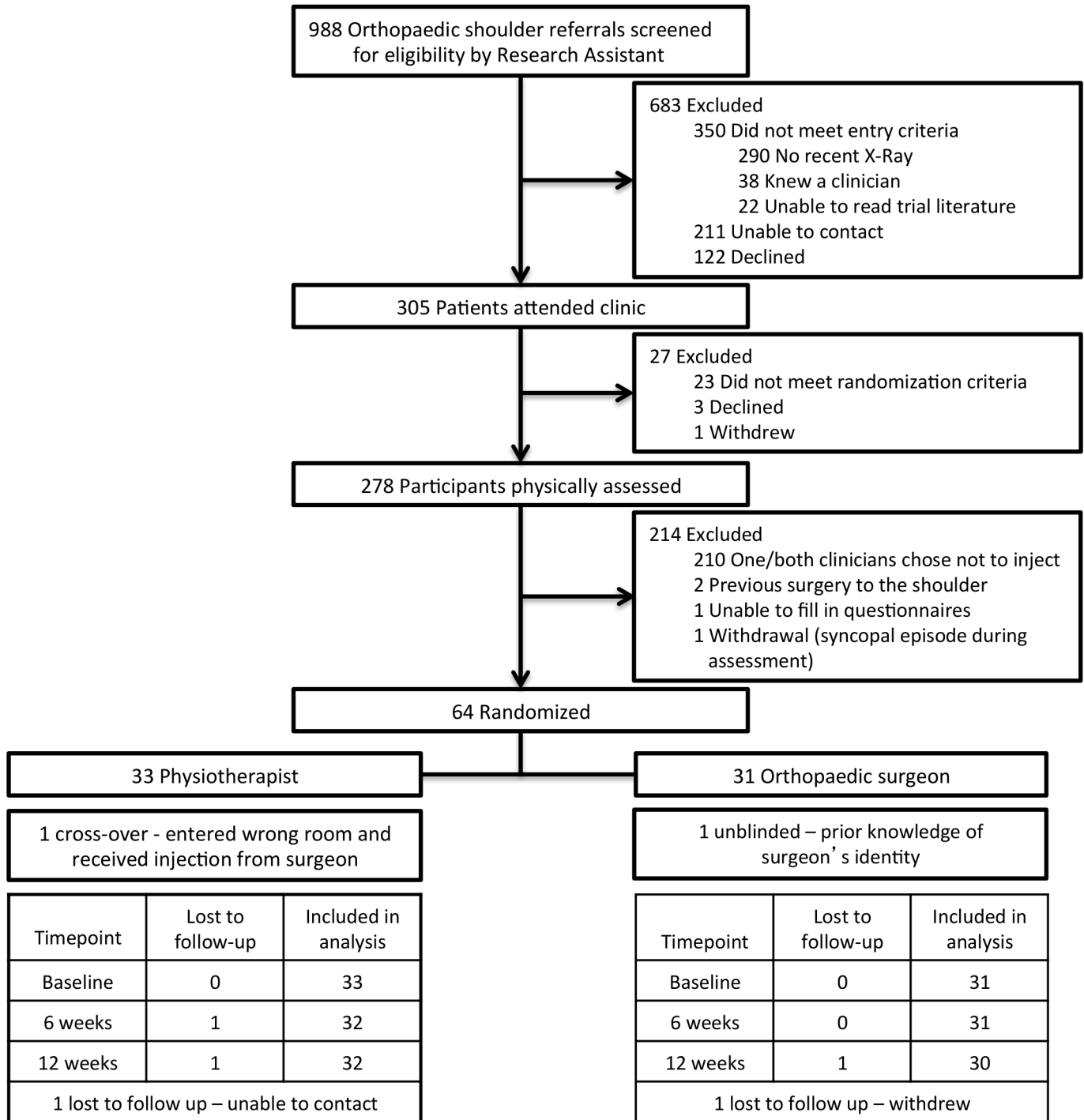
988 Orthopaedic shoulder referrals screened for eligibility by Research Assistant

683 Excluded
350 Did not meet entry criteria
290 No recent X-Ray
38 Knew a clinician
22 Unable to read trial literature
211 Unable to contact
122 Declined

305 Patients attended clinic

27 Excluded
23 Did not meet randomization criteria
3 Declined
1 Withdrew

278 Participants physically assessed

214 Excluded
210 One/both clinicians chose not to inject
2 Previous surgery to the shoulder
1 Unable to fill in questionnaires
1 Withdrawal (syncopal episode during assessment)

64 Randomized

33 Physiotherapist

1 cross-over - entered wrong room and received injection from surgeon

Timepoint	Lost to follow-up	Included in analysis
Baseline	0	33
6 weeks	1	32
12 weeks	1	32
1 lost to follow up – unable to contact		

31 Orthopaedic surgeon

1 unblinded – prior knowledge of surgeon's identity

Timepoint	Lost to follow-up	Included in analysis
Baseline	0	31
6 weeks	0	31
12 weeks	1	30
1 lost to follow up – withdrew		

Fig 2. CONSORT flow diagram.

doi:10.1371/journal.pone.0162679.g002

Improvement was greater in the surgeon group at 6 weeks and greater in the physiotherapist group at 12 weeks but between group differences did not reach significance. Non-inferiority of the physiotherapist compared to the orthopaedic surgeon was declared at both 6 (Fig 1 scenario C) and at 12 weeks (Fig 1 scenario B), as the upper limit of the one-sided confidence interval

Table 1. Baseline characteristics of randomised participants.

Baseline characteristics	Physio (n = 33)	Surgeon (n = 31)	p-value*
Age (years) mean (SD)	59.42 (10.49)	63.06 (10.07)	0.16
Gender female (%)	19/33 (57)	15/31 (48)	0.47
Duration of symptoms (months) median IQR	7 (4–18)	10 (4–24)	0.29^
Working (%)	17/33 (52)	15/31 (48)	0.81
Prior injections involved shoulder, mean (SD)	0.64 (0.70)	0.77 (0.85)	0.48
SPADI, mean (SD)	59.23 (19.90)	66.25 (17.74)	0.14
Worst pain last 3 days, VAS mean (SD)	60.00 (26.24)	69.26 (20.51)	0.12
Average pain last 3 days, VAS mean (SD)#	47.10 (26.05)	57.84 (21.35)	0.09
EQ-5D-5L health utility score, mean (SD)	0.54 (0.27)	0.45 (0.28)	0.23

*Independent sample t-test with 95% confidence intervals

^ Independent samples Mann-Whitney U

data missing for 5 subjects

IQR = interquartile range, VAS = visual analogue scale

doi:10.1371/journal.pone.0162679.t001

fell below the non-inferiority margin of 15 SPADI points (13.34 and 7.17 at 6 and 12 weeks respectively). This outcome was consistent across intention to treat and per-protocol analyses. SPADI pain and disability subscale and change scores, at both 6 and 12 weeks revealed no significant differences between groups (data not shown, available from corresponding author).

Secondary outcomes

Table 3 details the secondary outcome measures. Hospital data showed that in usual service delivery, patients would have waited significantly longer to see the orthopaedic surgeon (356 days), than to see the physiotherapist (119 days). With the exception of the GROC on the day of injection (significant result in favour of the physiotherapist), there were no statistically significant differences between intervention groups at any point in terms of safety, clinical efficacy, patient satisfaction or resource usage (post-injection physiotherapy treatment and

Table 2. Primary outcome: total Shoulder Pain and Disability Index.

	Physio	Surgeon	t-test		GEE
	Change from baseline. Mean (SD)	Change from baseline. Mean (SD)	Difference in change score. Mean (two-sided 90% CI)*	p-value	Difference Physio—surgeon (two-sided 90%CI)*
Intention to treat analysis					
6 weeks	N = 32	N = 31			
	-22.46 (23.43)	-25.87 (22.48)	3.41 (-6.25 to 13.08)	0.59	3.96 (-5.41 to 13.34)*
12 weeks	N = 32	N = 30			
	-29.40 (31.04)	-24.46 (26.47)	-4.93 (-17.21 to 7.34)	0.50	-4.65 (-16.46 to 7.17)*
Per-protocol analysis					
6 weeks	N = 31	N = 30			
	-22.93 (23.66)	-25.84 (22.87)	2.90 (-7.06 to 12.86)	0.63	3.49 (-6.17 to 13.14)*
12 weeks	N = 31	N = 29			
	-31.14 (29.92)	-24.67 (26.91)	-6.47 (-18.87 to5.84)	0.38	-6.14 (-18.02 to 5.73)*

* Non-inferiority of the physiotherapist compared to the surgeon declared as the upper limit of the two-sided confidence interval (which is equivalent to the one-sided 95% confidence interval) does not exceed 15. This equates to scenario C (Fig 1) at 6 weeks, and scenario B (Fig 1) at 12 weeks.

GEE = generalised estimating equation.

doi:10.1371/journal.pone.0162679.t002

Table 3. Secondary outcome measures.

	Week	Physio Mean (SD)	Surgeon Mean (SD)	Mean difference (95% CI)	p-value[+]
Worst pain—change from baseline (100mm VAS)	6	-10.58 (34.33)	-21.23 (26.71)	10.65 (-4.88 to 26.19)	0.18
	12	-25.97 (35.46)	-20.16 (37.73)	-5.8 (-24.41 to 12.78)	0.53
Av. pain—change from baseline (100mm VAS)	6	-14.87 (31.36)	-16.51 (25.61)	1.65 (-13.47 to 16.77)	0.82
	12	-22.55 (30.28)	-17.19 (30.90)	-5.36 (-21.62 to 10.89)	0.51
Health utility—change from baseline EQ-5D-5L	6	0.14 (0.24)	0.15 (0.20)	0.01 (-0.12 to 0.10)	0.86
	12	0.18 (0.25)	0.07 (0.24)	0.11 (-0.01 to 0.24)	0.07
GROC*^ (Mean rank)	0	23.65	37.04	N/A	0.001
	6	31.63	32.39	N/A	0.83
	12	30.02	34.05	N/A	0.31
Satisfaction (10cm VAS)	12	9.64 (0.73)	9.55 (0.76)	0.09 (-0.30 to 0.47)	0.65
Number of physiotherapy appointments	12	5.03 (1.60)	4.52 (2.20)	0.51 (-0.45 to 1.84)	0.29
Adverse events	12	1 non-serious	1 non-serious	N/A	N/A
Medication change $\$$*(Mean rank)	12	32.77	32.21	N/A	0.87
Post-injection ROM gain (degrees)	0	13.40 (11.55)	14.38 (16.02)	0.97 (-5.97 to 7.91)	0.78
Post-injection ROM gain at pain onset	0	31.05 (29.85)	38.51 (30.87)	7.47 (-7.70 to 22.64)	0.33
Post-injection worst pain reduction VAS	0	29.91 (26.93)	38.51 (29.70)	8.61 (-5.54 to 22.76)	0.23
Post-injection av. pain reduction VAS	0	23.36 (24.67)	28.82 (23.85)	5.44 (-6.70 to 17.58)	0.37
Usual days wait for appointment @	0	119.0 (28.59)	356.42 (113.08)	237 (261.96 to 212.79)	<0.001

* Mann-Whitney U test,

^ 5 point scale; 1 = completely recovered to 5 = much worse,

$\$$ categories of pain medicine use at 12 weeks; 1 = stopped, 2 = reduced, 3 = same, 4 = increased,

[+] p values form t-Tests, unless otherwise stated,

@ Usual waiting list duration (in days at the time of injection) for an appointment with physio and surgeon

doi:10.1371/journal.pone.0162679.t003

medication use). No serious adverse events were reported throughout the trial. One subject injected by the surgeon reported self-limiting symptoms of headache and mild confusion for approximately two weeks following injection. One subject injected by the physiotherapist reported symptoms of headache and a rash (torso). These symptoms resolved without treatment and as they had not appeared until two days after the injection, a causative relationship to the injection was not established.

Health economic evaluation

Labour costs per 30-minute consultation period were calculated to be $86.99 for the surgeon, $32.04 for the injecting physiotherapist and $29.21 for physiotherapists providing post injection treatment. As there was no appreciable difference between the groups in change of medicines usage (Table 3), this cost variable was omitted from the calculation. Results of the health economic analysis are contained in Table 4. The base case calculation (from the health funder perspective over a 12 week time horizon) reveals that the physiotherapist is the dominant option; the physiotherapist is both less expensive, and as or more effective than the orthopaedic surgeon. One-way sensitivity analyses (Table 4) reveal the stability of the dominant result for physiotherapist injection with doubling of the physiotherapist consultation time, increased physiotherapist remuneration and with incorporation of additional staff for the orthopaedic clinic. The first 1,000 bootstrapped estimates plotted in Fig 3, all fall within the dominant south east quadrant of the plot demonstrating that the effect was consistently better and at lower cost

Table 4. Health economic evaluation; base case and one-way sensitivity analyses.

Base case calculation	Physio	Surgeon	Increment	ICER*, Mean (95% CI)
Labour cost (30min)	$32.04	$86.99	N/A	
Base case effect—QALYs mean (SD)	0.16 (0.05)	0.13 (0.06)	0.03	Dominant
Base case total cost mean (SD)	$179 (46.62)	$214 (66.42)	-$35	
One-way sensitivity analyses				
Hospital perspective				
- include Medicare rebate^	$179	$150	$29	$989 ($365 to $1839)
Physiotherapist pay level				
- increase one grade	$182	$214	-$32	Dominant
Clinic support staff				
- orthopaedic clinic nurse	$179	$238	-$59	Dominant
Physiotherapist consultation time				
- Increase to 60 minutes	$211	$214	-$3	Dominant

*10,000 sample bootstrapping,

^ Federal Government Medicare rebate Item 104 ($64.20) only applicable to doctors, ICER: incremental cost effectiveness ratio. QALY: quality adjusted life year.

doi:10.1371/journal.pone.0162679.t004

compared with the orthopaedic surgeon. From the hospital perspective, the physiotherapist was slightly more expensive than the orthopaedic surgeon (incremental cost of $29) due to an Australian Government payment (Medicare) for services provided by doctors, which effectively subsidises the orthopaedic surgeon for the hospital. However, the physiotherapist also produced a slightly greater incremental QALYs score over the 12 week period (0.03), resulting in an ICER of $989. This indicates that for every additional QALY gained, the cost to the hospital is $989. This result is well below a conservative willingness to pay threshold (WTP) of AUD $50 000 per QALY [69], indicating that the physiotherapist is still cost effective.

Discussion

This is the first study to compare outcomes following the prescription and delivery of corticosteroid injection for the management of shoulder pain by a physiotherapist with the 'gold standard', the consultant orthopaedic surgeon. Results demonstrate similar [50] to more [49] improvement in total SPADI scores compared with previous studies of corticosteroid injection in a similar population, suggesting good effect size and that external validity was maintained with the inclusion criteria, which required participants to be selected for injection by two clinicians. There were no statistically significant or clinically important differences between the surgeon and the physiotherapist at six or 12 weeks, with mean differences below minimal clinically important difference (MCID) values for SPADI [47], pain VAS [52], and very small differences on other secondary outcomes (Table 2). The results also demonstrate that clinical outcomes measured by the SPADI were not inferior when the intervention was delivered by the physiotherapist compared with the orthopaedic surgeon at both the 6 and 12 week follow-up periods. Furthermore, the physiotherapist was less expensive than the surgeon. From a clinical and health services perspective, these findings indicate that for conditions such as shoulder pain that may not require surgery, care may be enhanced and expedited with physiotherapist prescription and delivery of injections if clinically indicated. This model creates potential for a seamless care pathway, as a physiotherapist also possesses skills in exercise prescription, which is also recommended within the management of these conditions [32, 37].
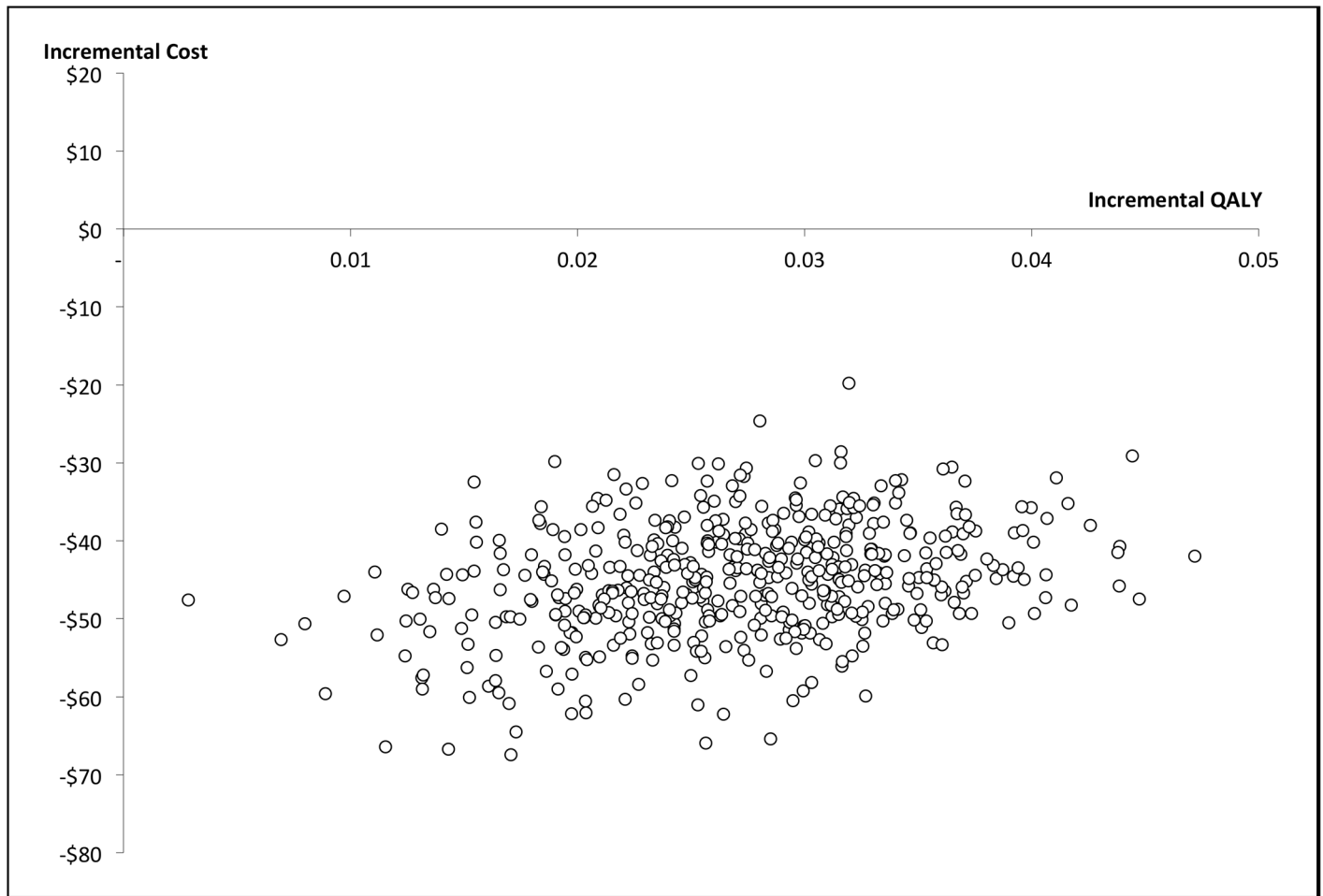
Fig 3. Plot of the first 1,000 bootstrapped estimates. Shows the incremental cost estimates per consultation and the incremental QALYs for the physiotherapist. All estimates place the physiotherapist as the dominant option with greater QALYs and cost saving.

doi:10.1371/journal.pone.0162679.g003

Shoulder pain poses a diagnostic and management conundrum for clinicians and researchers. Current evidence suggests that stating an exact pathoanatomical diagnosis may be misleading due to factors such as the inaccuracy of clinical assessment procedures [70] and a lack of correlation between radiological signs of rotator cuff deficiency and patient symptoms [71, 72]. In this trial we have attempted to take a balanced evidence-based perspective of shoulder pain, which includes the following considerations: that subacromial impingement comprises a variety of potential contributory factors [32] including such items as bone shape, rotator cuff pathology, acromio-clavicular joint changes, thickening or bursitis of the subacromial bursa and bio-mechanical factors such as scapula control [31, 73]; that subacromial impingement is likely to be the most common form of shoulder pain [31, 32]; that subacromial impingement is best diagnosed using clinical judgement and a variety of clinical tests combined with subjective history taking [30, 32, 74, 75]; that subacromial pain should generally be treated non-surgically [32], and that subacromial corticosteroid injection is an evidence-based recommended treatment option [32, 35, 36, 38, 39, 45]. Studies involving rat models have provided contradictory information about the impact of corticosteroid in the vicinity of the rotator cuff with one study reporting tendons to be weaker at 3 weeks post injection [76] and another reporting no lasting deficit [77]. Furthermore in humans one study simultaneously reported that 17% of subjects had

a full thickness cuff tear 12 weeks after injection and that injection significantly improved symptoms [78]. Such aspects of shoulder histopathology, diagnosis and management highlight important and ongoing research challenges that this study does not attempt to answer. Rather, the aim of this study was to take a common and evidence-based treatment option for subacromial impingement [32] and investigate whether a physiotherapist might provide a more efficient service delivery model. Although conducted in the Australian health system, the findings have relevance to musculoskeletal service delivery internationally. Whilst already available in the UK, a physiotherapy-led model of care has not previously been subjected to robust investigation or comparison with a consultant orthopaedic surgeon. Our results validate these models of care, as it appears that corticosteroid injection provided by a trained physiotherapist is safe and effective.

This study has addressed some inadequacies of previous research comparing corticosteroid injection delivered by physiotherapists to that delivered by medical practitioners. Previous studies have not been specific regarding the inclusion of shoulder conditions or injection site [79–81], or injection was only a small element within a multi-modal treatment arm [81], or the profession of the individual delivering the injections was unclear [82], or sub-consultant doctors provided the control group [81, 82]. One factor that is common between past studies [79–81, 83] and our current study, however, is the absence of any reported serious adverse events. Our study is therefore the first to investigate and demonstrate safety, clinical efficacy, cost benefit and patient satisfaction, with physiotherapist prescribing and injection compared to a surgeon, for the management of shoulder pain. Furthermore, in previous musculoskeletal professional substitution research, professional equivalence has been claimed on the basis of a non-significant result. This is not justified because it may result from a lack of power or include confidence margins that extend beyond a clinically acceptable limit [63]. Non-inferiority demonstrates equivalence in the relevant one sided-confidence interval (in this case the upper limit as higher scores on SPADI indicate a worse outcome) supporting our claim that care from the physiotherapist is "not worse" or "at least as good" [63] as that from the orthopaedic surgeon. This approach is common in the pharmaceutical literature but to our knowledge this is the first study to apply non-inferiority to a professional substitution hypothesis.

We did not record the exact time each clinician spent with patients, however both clinicians worked to the same clinic schedule of 30-minute consultation times. We consider our assumption of equal overall costs of a physiotherapist clinic compared to an orthopaedic surgeon clinic to be conservative because in practice consultant clinics tend to have greater support staff such as nurses. Our measure of the usual waiting time to see the orthopaedic surgeon is also conservative because hospital data is retrospectively calculated from the waiting time of patients seen each month. As lower priority patients remain on the waiting list without being seen, true prospective waiting times may be much longer. The physiotherapist in this trial acted independently regarding decisions and delivery of corticosteroid injection, yet outside the UK this level of autonomy is generally beyond the scope of physiotherapy practice. Therefore, the findings of this study have policy implications for medicines legislation and health funding. The potential for public healthcare benefit from innovative new models, can only be realised if the legal and funding barriers to its implementation are removed. Our expectation is that optimum service efficiency for this patient population will result from a multidisciplinary team, which includes general practitioners, physiotherapists, orthopaedic surgeons and rheumatologists working autonomously within an integrated outpatient musculoskeletal pathway. Details such as the optimal proportion of physiotherapists compared with doctors in such a pathway would depend upon local demand variables, and further research is needed to provide a wider societal perspective of the health economic impact of professional substitution within such a pathway.

This study has some limitations. Firstly, having only one clinician in each treatment arm potentially reduces the generalisability of results. This situation was a direct consequence of the

innovative nature of the research; prescribing and injecting by physiotherapists is beyond Australia's legislative framework, and the physiotherapist (DM) had to demonstrate competency and experience by drawing upon overseas (UK) experience. In the absence of domestic legislative, curriculum or education frameworks for prescribing and injection by physiotherapists, additional suitably qualified physiotherapists were not available. Secondly, while adequate, our sample size was not large which allowed us to balance the resource and time challenges associated with conducting pragmatic clinical research in a public outpatient setting. Our use of a repeated measures design and the GEE approach helped provide an increased and sufficient power to detect non-inferiority (such as the achieved scenarios B and C in Fig 1). Confidence in our results is further strengthened by the absence of very wide confidence intervals (scenarios E or F Fig 1) associated with an inadequate sample size. Furthermore, greater numbers of participants would only decrease the confidence intervals and strengthen our non-inferiority conclusion (such as Scenarios A or D in Fig 1). Thirdly, we chose a 12-week endpoint as prior research suggests the effect of corticosteroid is greatest in the short-term [35] and whilst we feel this time period was adequate to test our hypothesis, a longer-term follow up could be considered in future research. A fourth relates to post-injection physiotherapy. Whilst steps were taken to remove bias from this phase of treatment and the number of physiotherapy sessions were reported, we did not test the blinding of the treating physiotherapists, or monitor the exact home exercises given or participants' compliance with advice and exercises. More detailed monitoring of these factors, could provide more information about factors potentially impacting each participant's outcome. Finally, our findings apply to a shoulder pain population and extrapolation to other orthopaedic or musculoskeletal populations should not be assumed. Previous research has suggested physiotherapy care fares well in comparison to usual orthopaedic care in mixed, knee, hip and back pain populations [28, 81, 82, 84], however these studies have design limitations and therefore validation of our findings in other patient groups may help clarify optimal service delivery models.

Conclusions

A suitably qualified physiotherapist is able to prescribe and deliver corticosteroid injection for shoulder pain as least as effectively, and at less expense than a consultant orthopaedic surgeon. In the UK, where existing laws permit this practice, these findings support the employment of physiotherapists to provide these services. These findings also suggest that policy makers and service providers elsewhere should consider adopting this model of care.

Supporting Information

S1 File. Dataset.
(XLS)

S2 File. CONSORT checklist.
(DOC)

S3 File. Protocol.
(DOC)

Acknowledgments

possible. We thank the Allied Health Profession's Office of Queensland for support in obtaining recognition of competence and legislative approvals, M Gemmill and also the Queensland Orthopaedic Physiotherapy Screening Clinic and Multidisciplinary Service for organisational support and professional advice.

Author Contributions

References

1. Murray CJL, Lopez AD. Measuring the global burden of disease. New England Journal of Medicine. 2013; 369(5):448–57. doi: 10.1056/NEJMra1201534.

2. Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012; 380(9859):2163–96. doi: 10.1016/S0140-6736(12)61729-2 PMID: 23245607.

3. Curtis AJ, Russell COH, Stoelwinder JU, McNeil JJ. Waiting lists and elective surgery: ordering the queue. The Medical journal of Australia. 2010; 192(4):217. PMID: 20170460

4. Department of Health. The musculoskeletal services framework: a joint responsibility. London: 2006.

5. NHS. Referral to treatment (RTT) waiting times statistics for consultant-led elective care 2014 Annual Report. London: 2015.

6. Queensland Government QH. Hospital Performance [Webpage]. Queensland Government; 2015 [15 March 2015]. Available: http://www.health.qld.gov.au/performance/default.asp-7.

7. Murray CJL, Vos T, Lozano R, Naghavi M, Flaxman AD, Michaud C, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012; 380(9859):2197. doi: 10.1016/S0140-6736(12)61689-4 PMID: 23245608

8. Australian Government Productivity Commission. Caring for Older Australians, Report No. 53, Final Inquiry Report. Canberra 2011.

9. The Kings Fund. How much money does the NHS need?: The King's Fund; 2015 [updated 29 January 2015; cited 2015 1.4.2015]. Available: http://www.kingsfund.org.uk/projects/verdict/how-much-money-does-nhs-need.

10. Duckett SJ. Health workforce design for the 21st century. Australian Health Review. 2005; 29(2):201–10.

11. Laurant M, Reeves D, Hermens R, Braspenning J, Grol R, Sibbald B. Substitution of doctors by nurses in primary care. Cochrane Database of Systematic Reviews. 2004;(4:).

12. Desmeules F, Roy J-S, MacDermid JC, Champagne F, Hinse O, Woodhouse LJ. Advanced practice physiotherapy in patients with musculoskeletal disorders: a systematic review. BMC Musculoskeletal Disorders. 2012; 13:107-. doi: 10.1186/1471-2474-13-107 PMID: 22716771.

13. Joseph C, Morrissey D, Abdur-Rahman M, Hussenbux A, Barton C. Musculoskeletal triage: a mixed methods study, integrating systematic review with expert and patient perspectives. Physiotherapy. 2014; 100(4):277–89. doi: 10.1016/j.physio.2014.03.007 PMID: 25242531

14. Stanhope J, Grimmer-Somers K, Milanese S, Kumar S, Morris J. Extended scope physiotherapy roles for orthopedic outpatients: an update systematic review of the literature. Journal Of Multidisciplinary Healthcare. 2012; 5:37–45. doi: 10.2147/JMDH.S28891 PMID: 22359462.

15. Department of Health. Allied health professions prescribing and medicines supply mechanisms scoping project report London: 2009.

16. Millions of patients to benefit from easier access to medication and fewer trips to hospitals [Internet]. 2013; 20 August 2013 [cited 23 December 2014]. Available: https://www.gov.uk/government/news/

millions-of-patients-to-benefit-from-easier-access-to-medication-and-fewer-trips-to-hospitals
23888591

17. Parsons S, Breen A, Foster NE, Letley L, Pincus T, Vogel S, et al. Prevalence and comparative trouble-someness by age of musculoskeletal pain in different body locations. Family practice. 2007; 24(4):308–16. doi: 10.1093/fampra/cmm027 PMID: 17602173

18. Picavet HSJ, Schouten JSAG. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC3-study. Pain. 2003; 102(1–2):167–78. PMID: 12620608

19. Taylor W. Musculoskeletal pain in the adult New Zealand population: prevalence and impact. The New Zealand medical journal. 2005; 118(1221):U1629. PMID: 16138167

20. Urwin M, Symmons D, Allison T, Brammah T, Busby H, Roxby M, et al. Estimating the burden of muscu-loskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. Annals of the Rheumatic Diseases. 1998; 57(11):649–55. doi: 10.1136/ard.57.11.649 PMID: 9924205

21. Piitulainen K. The relationship between functional disability and health-related quality of life in patients with a rotator cuff tear. Disability and rehabilitation. 2012; 34(24):2071–5. doi: 10.3109/09638288.2012.670363 PMID: 22494417

22. Smith KL, Harryman DT, Antoniou J, Campbell B, Sidles JA, Matsen FA. A prospective, multipractice study of shoulder function and health status in patients with documented rotator cuff tears. Journal of Shoulder and Elbow Surgery. 2000; 9(5):395–402. doi: 10.1067/mse.2000.108962 PMID: 11075323

23. Kuijpers T, van Tulder MW, van der Heijden GJMG, Bouter LM, van der Windt DAWM. Costs of shoul-der pain in primary care consulters: a prospective cohort study in The Netherlands. BMC Musculoskele-tal Disorders. 2006; 7:83-. PMID: 17078883.

24. Virta L, Joranger P, Brox JI, Eriksson R. Costs of shoulder pain and resource use in primary health care: a cost-of-illness study in Sweden. BMC Musculoskeletal Disorders. 2012; 13:17-. doi: 10.1186/1471-2474-13-17 PMID: 22325050.

25. Buchbinder R, Staples MP, Shanahan EM, Roos JF. General practitioner management of shoulder pain in comparison with rheumatologist expectation of care and best evidence: an Australian national survey. Plos One. 2013; 8(4):e61243–e. doi: 10.1371/journal.pone.0061243 PMID: 23613818.

26. Dorrestijn O, Greving K, van der Veen WJ, van der Meer K, Diercks RL, Winters JC, et al. Patients with shoulder complaints in general practice: consumption of medical care. Rheumatology (Oxford, England). 2011; 50(2):389–95. doi: 10.1093/rheumatology/keq333

27. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheu-matology (Oxford, England). 2006; 45(2):215–21. PMID: 16263781.

28. Samsson K, Larsson MEH. Physiotherapy screening of patients referred for orthopaedic consultation in primary healthcare—a randomised controlled trial. Manual therapy. 2014; 19(5):386. doi: 10.1016/j.math.2013.10.004 PMID: 24246908

29. N/OPSC & MDS PSC3 database [Internet]. Queensland Health Electronic Publishing Service, Patient Safety Unit, Brisbane. 2013.

30. Carter T, Hall H, McIntosh G, Murphy J, MacDougall J, Boyle C. Intertester reliability of a classification system for shoulder pain. Physiotherapy. 2011; 98(1):40. doi: 10.1016/j.physio.2010.12.003 PMID: 22265384

31. Lewis JS, Green AS, Dekel S. The aetiology of subacromial impingement syndrome. Physiotherapy. 2001; 87(9):458–69.

32. Diercks R, Bron C, Dorrestijn O, Meskers C, Naber R, de Ruiter T, et al. Guideline for diagnosis and treatment of subacromial pain syndrome: a multidisciplinary review by the Dutch Orthopaedic Associa-tion. Acta orthopaedica. 2014; 85(3):314–22. doi: 10.3109/17453674.2014.920991 PMID: 24847788

33. Robb G, Arroll B, Reid D, Goodyear-Smith F. Summary of an evidence-based guideline on soft tissue shoulder injuries and related disorders—Part 2: Management. Journal of primary health care. 2009; 1 (1):42. PMID: 20690486

34. Scott A, Docking S, Vicenzino B, Alfredson H, Murphy RJ, Carr AJ, et al. Sports and exercise-related tendinopathies: a review of selected topical issues by participants of the second International Scientific Tendinopathy Symposium (ISTS) Vancouver 2012. British journal of sports medicine. 2013; 47(9):536. doi: 10.1136/bjsports-2013-092329 PMID: 23584762

35. Buchbinder R, Green S, Youd JM. Corticosteroid injections for shoulder pain. The Cochrane Database Of Systematic Reviews. 2003;(1:):CD004016. PMID: 12535501.

36. Hambly N, Fitzpatrick P, MacMahon P, Eustace S. Rotator Cuff Impingement: Correlation Between Findings on MRI and Outcome After Fluoroscopically Guided Subacromial Bursography and Steroid

Injection. American Journal of Roentgenology. 2007; 189(5):1179–84. doi: 10.2214/AJR.07.2421 PMID: 17954658

37. Green S, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. The Cochrane Database Of Systematic Reviews. 2003;(2:):CD004258. PMID: 12804509.

38. James M, Stokes EA, Thomas E, Dziedzic K, Hay EM. A cost consequences analysis of local corticosteroid injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care. Rheumatology (Oxford, England). 2005; 44(11):1447–51. PMID: 16091398.

39. Jowett S, Crawshaw DP, Helliwell PS, Hensor EMA, Hay EM, Conaghan PG. Cost-effectiveness of exercise therapy after corticosteroid injection for moderate to severe shoulder pain due to subacromial impingement syndrome: a trial-based analysis. Rheumatology (Oxford, England). 2013; 52(8):1485–91. doi: 10.1093/rheumatology/ket149 PMID: 23630367.

40. D'Agostino RB Sr., Massaro JM, Sullivan LM. Non-inferiority trials: design concepts and issues—the encounters of academic consultants in statistics. Statistics In Medicine. 2003; 22(2):169–86. PMID: 12520555.

41. Piaggio G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. JAMA: The Journal Of The American Medical Association. 2012; 308(24):2594–604. doi: 10.1001/jama.2012.87802 PMID: 23268518.

42. Marks D, Bisset L, Thomas M, S OL, Comans T, Ng SK, et al. An experienced physiotherapist prescribing and administering corticosteroid and local anaesthetic injections to the shoulder in an Australian orthopaedic service, a non-inferiority randomised controlled trial and economic analysis: study protocol for a randomised controlled trial. Trials. 2014; 15(1):503. Epub 2014/12/22. doi: 10.1186/1745-6215-15-503 PMID: 25527842.

43. Mitchell C, Adebajo A, Hay E, Carr A. Shoulder Pain: Diagnosis And Management In Primary Care. BMJ: British Medical Journal. 2005; 331(7525):1124–8. doi: 10.1136/bmj.331.7525.1124 PMID: 16282408

44. Murphy RJ, Carr AJ. Shoulder pain. Clinical evidence. 2010;2010.

45. Johansson K, Bergström A, Schröder K, Foldevi M, Institutionen för medicin och h, Linköpings u, et al. Subacromial corticosteroid injection or acupuncture with home exercises when treating patients with subacromial impingement in primary care-a randomized clinical trial. Family practice. 2011; 28(4):355–65. doi: 10.1093/fampra/cmq119 PMID: 21378086

46. Roy J-S, MacDermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. Arthritis and rheumatism. 2009; 61(5):623–32. doi: 10.1002/art.24396 PMID: 19405008

47. Angst F, Schwyzer H-K, Aeschlimann A, Simmen BR, Goldhahn J. Patient outcomes in rheumatology, 2011: a review of measures. Measures of adult shoulder function. Arthritis Care & Research (2151464X). 2011; 63(11):S174–88.

48. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. Arthritis Care And Research: The Official Journal Of The Arthritis Health Professions Association. 1991; 4(4):143–9. PMID: 11188601.

49. Crawshaw DP, Helliwell PS, Hensor EMA, Hay EM, Aldous SJ, Conaghan PG. Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised trial. BMJ (Clinical Research Ed). 2010; 340:c3037–c. doi: 10.1136/bmj.c3037 PMID: 20584793.

50. Ekeberg OM, Bautz-Holter E, Tveitå EK, Juel NG, Kvalheim S, Brox JI. Subacromial ultrasound guided or systemic steroid injection for rotator cuff disease: randomised double blind study. 2009; 338;a3112. doi: 10.1136/bmj.a3112 PMID: 19168537

51. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care & Research. 2011; 63 Suppl 11:S240–S52. doi: 10.1002/acr.20543 PMID: 22588748.

52. Tashjian RZ, Deloach J, Porucznik CA, Powell AP. Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease. Journal of Shoulder and Elbow Surgery. 2009; 18(6):927–32. doi: 10.1016/j.jse.2009.03.021 PMID: 19535272

53. Hill JC, Thomas E, Hill S, Foster NE, Windt Avd. Development and Validation of the Keele Musculoskeletal Patient Reported Outcome Measure (MSK-PROM). PLoS One 2015; 10(4):e0124557. doi: 10.1371/journal.pone.0124557 PMID: 25928807

54. Obradovic M, Lal A, Liedgens H. Validity and responsiveness of EuroQol-5 dimension (EQ-5D) versus Short Form-6 dimension (SF-6D) questionnaire in chronic pain. Health and quality of life outcomes. 2013; 11(1):110-. doi: 10.1186/1477-7525-11-110

55. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. The Journal of manual & manipulative therapy. 2009; 17(3):163–70. doi: 10.1179/jmt.2009.17.3.163

56. Kolber MJ, Hanney WJ. The reliability and concurrent validity of shoulder mobility measurements using a digital inclinometer and goniometer: a technical report. International journal of sports physical therapy 2012; 7(3):306–13. PMID: 22666645

57. Mullaney MM, Malachy P; Johnson Christopher P; Tyler Timothy F. Reliability of shoulder range of motion comparing a goniometer to a digital level. Physiotherapy Theory and Practice. 2010; 26(5):327–33. doi: 10.3109/09593980903094230 PMID: 20557263

58. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. The Lancet. 2000; 356(9237):1255–9. doi: 10.1016/S0140-6736(00)02799-9

59. Lazarou J, Pomeranz BH, Corey PN. Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. JAMA. 1998; 279(15):1200–5. doi: 10.1001/jama.279.15.1200 PMID: 9555760

60. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. JAMA: The Journal Of The American Medical Association. 2006; 295(10):1152–60. PMID: 16522836.

61. Brittain E, Lin D. A comparison of intent-to-treat and per-protocol results in antibiotic non-inferiority trials. Statistics In Medicine. 2005; 24(1):1–10. PMID: 15532089.

62. Liang K, Zeger S. Longitudinal data analysis using generalised linear models. Biometrika. 1986; 73:13–22.

63. Mascha EJ, Sessler DI. Equivalence and noninferiority testing in regression models and repeated-measures designs. Anesthesia and Analgesia. 2011; 112(3):678. PMID: 21304155

64. Norman R, Cronin P, Viney R. A Pilot Discrete Choice Experiment to Explore Preferences for EQ-5D-5L Health States. Applied Health Economics and Health Policy. 2013; 11(3):287–98. doi: 10.1007/s40258-013-0035-z PMID: 23649892

65. Government Queensland. Senior health employee contracts. Attachment 3—Total remuneration framework conditions for senior medical officers. In: Health Q, editor. Brisbane2014.

66. Government Queensland. Queensland Health Wage Rates 2014 [updated 06 January 20141 November 2014]. Available: http://www.health.qld.gov.au/hrpolicies/wage_rates/.

67. Australian Government Department of Health. MBS Online Medicare Benefits Schedule: Australian Government; 2015 [cited 2015]. Available: http://www9.health.gov.au/mbs/search.cfm?q=104&Submit=&sopt=I.

68. Twisk J, de Vente W. Attrition in longitudinal studies. How to deal with missing data. Journal of clinical epidemiology. 2002; 55(4):329. PMID: 11927199

69. Shiroiwa T, Sung Y-K, Fukuda T, Lang H-C, Bae S-C, Tsutani K. International survey on willingness-to-pay (WTP) for one additional QALY gained: what is the threshold of cost effectiveness? Health economics. 2010; 19(4):422–37. doi: 10.1002/hec.1481 PMID: 19382128

70. May S, Chance-Larsen K, Littlewood C, Lomas D, Saad M. Reliability of physical examination tests used in the assessment of patients with shoulder problems: a systematic review. Physiotherapy. 2010; 96(3):179–90. doi: 10.1016/j.physio.2009.12.002 PMID: 20674649

71. Moosmayer S, Tariq R, Stiris MG, Smith H-J. MRI of symptomatic and asymptomatic full-thickness rotator cuff tears. Acta Orthopaedica. 2010; 81(3):361–6. doi: 10.3109/17453674.2010.483993 PMID: 20450423

72. Yamamoto A, Takagishi K, Osawa T, Yanagawa T, Nakajima D, Shitara H, et al. Prevalence and risk factors of a rotator cuff tear in the general population. J Shoulder Elbow Surg. 2010; 19(1):116–20. Epub 2009/06/23. doi: 10.1016/j.jse.2009.04.006 PMID: 19540777.

73. Lewis JS. Rotator cuff tendinopathy/subacromial impingement syndrome: is it time for a new method of assessment? British Journal of Sports Medicine. 2009; 43(4):259–64. doi: 10.1136/bjsm.2008.052183.

74. Cadogan A, Laslett M, Hing W, McNair P, Taylor S. Clinical predictors of a positive response to guided diagnostic block into the subacromial bursa. Journal of Rehabilitation Medicine. 2012; 44(10):877. doi: 10.2340/16501977-1049 PMID: 23047472

75. Michener LA, Walsworth MK, Doukas WC, Murphy KP. Reliability and Diagnostic Accuracy of 5 Physical Examination Tests and Combination of Tests for Subacromial Impingement. Archives of Physical Medicine and Rehabilitation. 2009; 90(11):1898–903. doi: 10.1016/j.apmr.2009.05.015 PMID: 19887215

76. Maman E, Yehuda C, Pritsch T, Morag G, Brosh T, Sharfman Z, et al. Detrimental Effect of Repeated and Single Subacromial Corticosteroid Injections on the Intact and Injured Rotator Cuff: A

Biomechanical and Imaging Study in Rats. The American journal of sports medicine. 2016; 44(1):177. doi: 10.1177/0363546515591266 PMID: 26216105

77. Lee H-J, Kim Y-S, Ok J-H, Lee Y-K, Ha MY. Effect of a single subacromial prednisolone injection in acute rotator cuff tears in a rat model. Knee Surgery, Sports Traumatology, Arthroscopy. 2015; 23 (2):555–61. doi: 10.1007/s00167-013-2395-1 PMID: 23370982

78. Ramírez J, Pomés I, Cabrera S, Pomés J, Sanmartí R, Cañete JD. Incidence of full-thickness rotator cuff tear after subacromial corticosteroid injection: A 12-week prospective study. Modern Rheumatology. 2014; 24(4):667–70. doi: 10.3109/14397595.2013.857798 PMID: 24289196

79. Hattam P, Smeatham A. Evaluation of an orthopaedic screening service in primary care. Clinical Performance And Quality Health Care. 1999; 7(3):121–4. PMID: 10848384.

80. Hockin J, Bannister G. The extended role of a physiotherapist in an out-patient orthopaedic clinic. Physiotherapy. 1994; 80(5):281–4.

81. Weale AE, Bannister GC. Who should see orthopaedic outpatients—physiotherapists or surgeons? Annals Of The Royal College Of Surgeons Of England. 1995; 77(2 Suppl):71–3. PMID: 7574300.

82. Daker-White G, Carr AJ, Harvey I, Woolhead G, Bannister G, Nelson I, et al. A randomised controlled trial. Shifting boundaries of doctors and physiotherapists in orthopaedic outpatient departments. Journal Of Epidemiology And Community Health. 1999; 53(10):643–50. PMID: 10616677.

83. Resteghini P. Injection therapy within a physiotherapy department: a prospective audit. Journal of Orthopaedic Medicine. 2003; 25(2):58–62.

84. Overman SS, Larson JW, Dickstein DA, Rockey PH. Physical Therapy Care for Low Back Pain Monitored Program of First-Contact Nonphysician Care. Physical Therapy. 1988; 68(2):199. PMID: 2963349