Observational Studies

Kaia B. Engebretsen*, Hilde S. Robinson and Nina K. Vollestad Shoulder patients in primary and specialist health care. A cross-sectional study

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Abstract

Objectives: Shoulder pain is a prevalent problem and has a considerable impact on the use of primary and specialist health care in Norway. It is important to improve short-term recovery and reduce long-term consequences regarding pain and disability, the high costs of treatment and the amount of sick-leave. Treatment for non-specific shoulder pain is mainly non-operative. The aims of this study were to investigate if there are differences in main characteristics, pain and disability (SPADI-score) and psycho-social factors between patients in primary and specialist health care.

Methods: This cross-sectional study included patients consulting physiotherapy in primary health care and patients at an outpatient clinic in specialist health care. Well-known and tested questionnaires for these populations were used and variables were divided into clinical, sociodemographic, psycho-social, and shoulder pain and disability. Descriptive statistics were applied. Two-sample *t*-test and linear regression were used for continuous data whereas chi-square tests and logistic regression were applied to test differences in categorical data between the two study populations.

Results: Two hundred and 36 patients were recruited from primary health care (FYSIOPRIM, Physiotherapy In Primary Care) and 167 from specialist health care. Patients in primary health care reported less regular use of pain medication (30.7 vs. 61.3%) and fewer patients had symptom duration >12 months (41.9 vs. 51.0%). Furthermore, they reported lower pain intensity, less shoulder pain and disability (SPADI-score), lower scores on psycho-social factors, but higher on expectations of recovery.

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Conclusions: Patients with shoulder pain treated in primary health care and in specialist health care are different according to factors such as duration of symptoms, pain and disability, and some of the psycho-social variables. However, the differences are small and the variations within the two study samples is large. Patients treated in primary health care seemed to be less affected and to have higher expectations concerning their recovery. However, based on our results we may question why many patients are referred to specialist health care rather than continuing treatment in primary health care.

Keywords: clinical factors; pain and disability; primary health care; psycho-social factors; shoulder pain; specialist health care.

Introduction

Musculoskeletal disorders have considerable impact on the use of primary and specialist health services in Norway [1]. Shoulder complaints are among the three most frequent musculoskeletal health problems [2]. Approximately 50% of all new episodes of shoulder pain in primary health care show recovery within 6 months, but after 1 year this proportion increases to only 60% [3, 4]. Recurrence is common, but new episodes account for a majority of the consultations for shoulder pain [5, 6]. A goal for both primary and specialist health care is to improve the recovery and reduce the long-term consequences associated with pain and disability, the high costs of treatment (including surgery) and the amount of sick-leave [7, 8]. Virta et al. [7] found in a prospective costof-illness study, including 203 patients in primary care in Sweden, that one fifth of the patients were responsible for 91% of the total costs and for 44% of the health care cost. The costs of sick-leave contributed to 84% of the total costs, and physiotherapy treatments accounted for 60% of health care costs. Estimated costs for specialist health care increased the total costs by one third [7]. There is increasing evidence that patients with non-specific shoulder pain should be treated non-operatively; which

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is an argument for handling these patients in primary care at the lowest possible level of health care (the LEON principle) [9–11].

The most common shoulder diagnosis in both primary and specialist care is subacromial shoulder pain or rotator cuff disease [1, 4, 12, 13]. In primary care, Roddy et al. [14] found subacromial pain in 62% of the shoulder patients. Juel et al. [13] concluded that in a cohort of patients with shoulder pain in specialist health care, 36% of them had subacromial pain, 17% myalgia, 11% adhesive capsulitis, 8% a full thickness rotator cuff tear and 4% a gleno-humeral osteoarthritis. The differences between these studies can reflect variation in populations observed, but also reflect the lack of consensus on the diagnostic criteria. The use of different tests and inter-rater disagreement in the clinical tests applied may also have influenced the results [15-17]. Differences in the relative distribution of diagnosis do not necessarily imply differences in severity.

Patients with acute shoulder pain generally have a better prognosis compared to those with a more gradual onset [18, 19]. Previous studies found that psychological factors such as fear-avoidance beliefs and expectations contribute to outcomes in patients with more long-lasting pain [20–22]. Prognostic information can be useful to improve treatment efficiency and to decrease the costs of associated care [23].

General practitioners (GP) are usually the first point of contact for patients with shoulder pain. They refer some patients to physiotherapy in primary health care, some to specialist health care and some are not referred to further treatment. Although recommendations for referral of patients with shoulder pain from primary to specialist health care exist, some patients are referred directly to specialist health care mostly based on radiological findings and a medical history [12, 24]. The recommendations are mainly clinical criteria and are based on the evaluation of levels of pain and disability after at least 3 months of exercise treatment, a history of recurrent joint instability, full thickness cuff tear, or any red flag features [24-27]. We suggest that several patients are referred from primary to specialist care without meeting these criteria, whereas some are referred in order to get a second opinion. The patients in specialist health care should be more afflicted.

The main aim of this study is to get more knowledge of shoulder pain patients in primary and specialist health care by comparing these patients. We hypothesized that there should be differences between patients treated in primary and specialist health care especially when it comes to characteristics as pain and disability (SPADI-score) and psycho-social factors.

Materials and methods

Data collection

Patients with shoulder/arm- or upper limb pain were recruited from both primary and specialist health care in this cross-sectional study. Those who were between 18 and 74 years and willing and able to answer the questionnaires were included. The inclusion criteria were: shoulder pain (located to shoulder/arm- or upper limb pain towards the elbow) for at least 6 weeks (sub-acute and long-lasting pain). Patients with fractures, previous surgery and gleno-humeral joint dislocation during the last 6 months, cervical radiculopathy, inflammatory disease, cancer or hemiplegic arm and those with primary neurological- or psychological diagnosis were excluded [13, 28]. The data was collected during the first consultation with a physiotherapist in primary health care and in the specialist health care after referral to the Department of Physical Medicine and Rehabilitation at Oslo University Hospital (OUH).

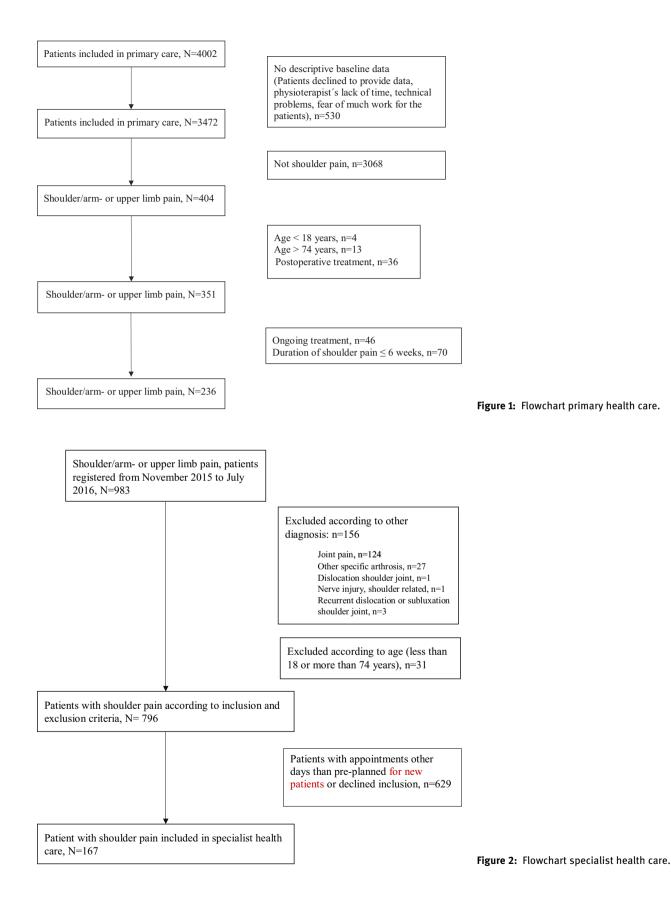
In primary care, participants were recruited from 12 different physiotherapy clinics in five regions and nine communities in Norway. All clinics participated in the FYSIOPRIM (Physiotherapy in Primary health Care) research program. The data was collected electronically (Infopad system) and stored in a database [29]. The present study used data collected during the period 2016–2018. The database contained data from 4,002 patients and baseline data was available for 3,472 (Figure 1). A total of 404 patients had shoulder/ arm- or upper limb pain as the main pain problem. From this, we excluded postoperative patients, those aged <18 or >74 years and those who were in an ongoing treatment period. Patients with a duration of shoulder pain ≤ 6 weeks (n=70) were excluded because we wanted to include predominantly patients that had passed the acute state.

In the specialist health care, participants were recruited from November 2015 to July 2016 at the outpatient Department of Physical Medicine and Rehabilitation, Ullevaal, OUH, Norway (Figure 2). Patients with appointments other days than pre-planned for new patients or declined inclusion (n=629), were not included (Figure 2). All patients at the department receive a standard questionnaire at home to answer before the initial consultation which is the routine clinical practice [30]. The questionnaire includes the variables previously described and are presented in the next section [30]. The patients in specialist health care recruited into the study also received an additional questionnaire which consisted of a screening tool (Örebro screening questionnaire, short form), the Tampa Scale of Kinesiophobia (TSK-13, 13 questions) and one question about their outcome expectation [31-33]. This additional questionnaire was included for the purpose of supplementing the study's baseline registration in specialist health care for comparison with primary health care. The diagnostic criteria for the various diagnosis (ICD-10 classification) in specialist health care is previously described and according to Juel et al. [13, 34]. A diagnosis was set at the first consultation. Additionally, previous treatments, and whether the patients were referred to physiotherapy in primary or in specialist health care were registered.

The patients in both primary and specialist health care received treatment as usual with no interference from the investigator.

Written informed consent was obtained from all patients. The study was approved by the Norwegian regional committees for medical and health research ethics, REC South East (2013/2030) and (2014/ 1968).

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Variables

Collected variables were divided into clinical, pain and disability, sociodemographic, and psycho-social factors [35, 36]. Clinical variables included duration of pain (6 weeks-3 months, 3–12 months and >12 months), pain intensity (Numeric Rating Scale, NRS, 0–10) and number of musculoskeletal pain areas (0–10) [29, 30, 37, 38]. Shoulder pain and disability were assessed by the SPADI Questionnaire (Shoulder Pain [5 questions] and Disability [8 questions]) [39].

Sociodemographic variables included age, gender, educational level ("what is your highest education level?" ≤12 years at school or University/college) and work status ("what is your current work status?" working ≥50% employment) [29, 38]. The status of "not working" included those on sick-leave, disability pension and vocational rehabilitation. Status of "retired" was in a separate category. Use of pain medication was registered in primary health care by the patients' response to; "have you used pain medication last week (yes/no)", and in specialist health care by response to; "how often have you used pain medication during the last 4 weeks (daily pain medication, each week, less than each week, not used last 4 weeks (1-4))" (Table 1). In both study populations, psycho-social factors included Hopkins Symptoms Checklist short form (HSCL-10). In primary care the patients reported according to the substitute question: "How much fear do you have that these complaints would be increased by physical activity?" (0-10) and in specialist health care, the Tampa Scale of Kinesiophobia (TSK-13) questionnaire was applied (Table 1) [32, 40, 41]. The screening schema Örebro short form to assess "yellow flags" (predicting long term disability) and healthrelated quality of life by EQ5D (Danish value set) were included in both populations with the 5L (5 levels of answers) in primary health care and the 3L version in specialist health care (Table 1) [31, 40, 42].We also asked about the patient's beliefs and expectation regarding future improvement. In primary care the question was; "I believe that physiotherapy will improve my function" (Response alternatives: Completely agree (1) to completely disagree (5) (1-5) (Table 1). In specialist care the patients were asked if they expected that their shoulder problem the next month would be much worse (1) to much better (6) (1-6) [33].

Data analysis

A formal a priori sample estimate was not performed for this crosssectional study. When the distribution of data was considered as normally distributed and the assumptions underlying the analyses were adequately met, we used mean and standard deviation (SD) to describe the study samples. Two-sample t-test and linear regression analyses were used to compare continuous data between the group of participants from primary and specialist health care. Chi-square tests and logistic regression were applied to test differences in categorical data between the two populations.

All analyses were performed using SPSS 24 (Statistical Package for Social Sciences, IBM, Armonk, NY). The level of significance was set to 0.05.

Results

A total of 236 patients were selected and recruited in primary care and 167 patients were recruited in specialist health care. The baseline characteristics are presented in Table 2.

Patients in primary health care reported less regular use of pain medication (30.7 vs. 61.3%), a smaller proportion had attended 12 years or less at school (39.2 vs. 46.7%), and fewer patients had symptom duration >12 months (41.9 vs. 51.0%) (Table 2).

Prior to study inclusion, 55 (23.3%) of the patients in primary health care reported that they had not received treatment for their shoulder problem during the last year whereas all the patients in specialist health care had received treatment during the last year. Of the 167 patients in specialist care, 140 (83.8%) of them had visited a physiotherapist. Treatment with exercises was most frequently registered (76 [45.6%]). More details are previously described [30].

Table 1: Variables registered different in the primary- and specialist health care.

	Primary health care	Specialist health care	
Pain medication	Have you used pain medication last week? yes/no	How often have you used pain medication during the last 4 weeks (daily, each week, not used last 4 weeks (1–4)	
Pain duration	Pain continuous	Continuous duration of pain: no pain, less	
	Pain duration: 0–1 w, 2–3 w, 4–5 w, 6–8 w, 9–11 w,	than 3 months, 3–12 months, >12 months	
	3–6 m, 6–9 m, 9–12 m, >12 m		
Tampa scale of	Substitute question: How much fear do you have that	Tampa scale of kinesiophobia (TSK-13, 13	
kinesiophobia (TSK)	these complaints would be increased by physical activity? (0–10)	questions)	
EQ5D	5L (5 levels of answers)	3L (3 levels of answers)	
Expectation	"I believe that physiotherapy will improve my func-	Do you expect that your shoulder problem	
	tion" (response alternatives: Completely agree (1) to	the next month will be much worse (1) to	
	completely disagree (5) (1–5)	much better (6) (1–6)	

w: weeks, m: months.

 Table 2: Baseline characteristics for the participants in the two study samples.

Characteristics	Primary health care N=236	Specialist health care N=167	p-Value
Age (years), mean (SD)	48 (13.8)	46 (12.3)	p=0.13
Female sex	139 (59.1)	92 (55.4)	p=0.47
Norwegian	224 (94.9)	140 (83.6)	p=0.002
Married/cohabitant	168 (71.5)	115 (69.7)	p=0.002
Current smokers	20 (8.5)	15 (9.0)	p=0.19
No pain medication last week/ no pain medication last 4 weeks	144 (61.3)	50 (30.7)	p<0.001
Employment status*			p=0.4
Sick-listed, disability pension, vocational rehab (50%<)	64 (30.3)	37 (32.2)	
Full- or part time work (≥50%)	125 (59.2)	72 (61.5)	
Retired	22 (10.4)	6 (5.2)	
Education			p=0.14
≤12 years at school	89 (39.2)	77 (46.7)	
University/college	138 (60.8)	88 (53.3)	
Duration of symptoms			p=0.003
6 weeks-3 months	45 (19.1)	8 (4.8)	
3-12 months	92 (39.0)	72 (43.1)	
>12 months	99 (41.9)	85 (51.0)	
Registrations of treatment for			
the shoulder problem last year			
(other than the by GP) before			
study inclusion. Categories			
not mutually exclusive			
No other treatment last year	55 (23.3)	0	
Specialist/clinician	38 (16.1)	-	-
Physiotherapist	49 (20.8)	140 (83.8)	
Manual therapist ^a	19 (8.1)	33 (19.7)	
Psychomotor physiotherapy ^b	11 (4.7)	6 (3.5)	
Chiropractor	17 (7.2)	26 (15.3)	
Alternative treatment	12 (5.1)	25 (14.7)	
Psychologist	9 (3.8)	0	
Other treatments (osteopath, naprapath, acupuncture)	18 (7.6)	33 (19.4)	

Values are numbers (percentages) unless stated otherwise. *(Primary care: n=211/Specialist care: n=115).^aPhysiotherapist specialist with post-graduate exam (Master) in manual therapy.^bPhysiotherapist specialist who focus on body awareness and change of tension.

Patients in primary health care reported lower pain intensity, less shoulder pain and disability (SPADI-score), but somehow higher mean number of pain sites compared to those in specialist health care (Table 3). They also reported lower scores on psycho-social variables (i.e. were less affected). Both groups scored below the mean values considered as clinical cut-off points for Örebro screening tool, short form according to "yellow flags" (Örebro short form, 50.0 points) and emotional distress (HSCL-10, 1.85 points). There was a similar fraction scoring above the cut-off point for emotional distress in the two samples. The results in Table 3 were consistent in linear regression analyses when adjusted for duration of pain. To check for selection bias for those not answering the SPADI questionnaire we compared the variable "pain last week" in both primary- and specialist health care (n=36 with mean value of 4.9 in primary care and n=12 with mean a value of 5.8 in specialist care). The mean difference was -0.9 in pain last week for those not answering the SPADI questionnaire compared to -1.0 for the study samples (Table 3) which are similar and do not indicate selection bias.

Two hundred and two (of 236) patients in primary care replied to the question whether they agreed that physiotherapy would improve their function, whereas 57.4% of them totally agreed, 36.6% agreed, 5.4% neither agreed nor disagreed, 0.5% disagreed, and 0% totally disagreed. In specialist health care 152 (of 167) replied and 10.5% expected that their shoulder problem/function would be much better in the next month, 50.0% expected better and 32.9% expected no change. Whether they expected that their shoulder problem/function would be little worse, worse or much worse the next month, were reported by 1.3, 3.3, and 2.0% of the patients, respectively.

We also registered that 137 (82.0%) of the patients in specialist health care were re-referred to physiotherapy, 74 (44.3%) to a physiotherapist in specialist health care and 63 (37.7%) to a physiotherapist in primary health care.

Discussion

The main finding in the present study is that patients with shoulder pain treated in primary health care and in specialist health care are different according to factors such as duration of symptoms, pain and disability (SPADI-score), and some of the psycho-social variables. However, the differences are small and the variations within the two samples are large. Only the difference in SPADI-score between the two samples was within the limit of the minimal clinically important difference (MCID) (reported between 8 and 13 points) [43]. Patients in specialist health care scored somewhat higher on psycho-social factors, but mean values were still below the cut-off values. A larger part of the patients in specialist health care scored above the cut-off value compared to primary health care on the Örebro screening tool, short form which may indicate a potential risk of delayed recovery or long term disability. Another finding is the differences in expectations whereas the patients in primary care were more optimistic.

There were no gender differences between the two populations and the frequency of women and men are in

	Primary health care N=236	Specialist health care N=167	Mean difference with 95% Cl	p-Value
Pain last week (mean and SD)	4.3 (2.0)	5.3 (2.6)	-1.05 (-1.50.6)	p<0.001
Pain drawing (mean and SD)	2.7 (1.8)	2.4 (1.5)	0.28 (-0.8-0.6)	p=0.13
(number of pain sites 0–10)*				
SPADI (mean and SD)**	39.2 (22.1)	47.9 (25.0)	-8.8 (-13.73.8)	p=0.001
Örebro screening tool short	42.1 (13.4)	49.3 (16.4)	-7.2 (-10.2-4.2)	p<0.001
form (mean and SD)***				
Örebro screening tool short	62 (27.1)	71 (45.8)		p<0.001
form score >50, ****				
Emotional distress, HSCL-10	1.6 (0.4)	1.7 (0.6)	-0.13 (-0.24-0.016)	p=0.025
(mean and SD) (short form 1-4)				
Emotional distress, HSCL-10,	55 (25.9)	40 (28.0)		p=0.7
short form (1–4) score				
>1.85*****				
Health-related quality of life	0.73 (0.1)	0.54 (0.3)	0.2 (0.15–0.24)	p<0.001
(EQ5D) (mean and SD) (P:5L,				
S:3L) (-0.24-1.0)******				

 Table 3: Differences in pain, disability, Örebro screening scheme short form, emotional distress (HSCL-10) and health-related quality of life

 (EQ-5D) between patients attending primary health care and specialist health care.

Baseline registrations (mean and SD) with mean differences, 95% CI interval, numbers and p-Value. P: Primary care, S: Specialist care. *(P:n=182/S:n=162), **(P:n=196/S:n=155), ***(P:n=229/S:n=155), ****(P:n=229/S:n=155), *****(P:n=212/S:n=143), ******(P:n=212/S:n=143), ******(P:n=231/S:n=155).

line with other studies on shoulder pain [2, 44, 45]. Some of the difference in use of pain medication is probably due to the difference in coding of the answers (no pain medication last week in primary care vs. no pain medication last 4 weeks in specialist health care).

More than 80% of the patients in specialist care had received physiotherapy in primary care before inclusion which is in line with Lentz et al. [46]. However, we know little about the treatment periods or how the psycho-social factors had been handled. We have not studied how the information according to these factors and "yellow flags" was integrated or taken into consideration. In a Swedish study Emilson et al. [47] found that the interpretation and integration of findings according to "red and yellow flags" in primary care were incomplete and indicate a need of further strategies.

We assume that some of the lower quality of life registered in specialist health care is due to using different versions of the EQ5D. The 5L version was applied in primary health care compared to the 3L version in specialist health care. A recent study showed that in seven different countries, the 3L version systematically overestimated health problems and consequently underestimated utilities compared to the 5L version [48]. Most probably, the same applies for the versions used in the present study.

Chester et al. [49] found that higher patient expectation of complete recovery compared to slight improvement because of physiotherapy and higher pain self-efficacy were associated with patient-rated outcomes. Therefore, we suppose that psycho-social factors play a role in patients with shoulder pain and increase the perpetuation of long-lasting pain and disability.

We found that a large number of the patients in our study had positive expectations. The lower expectations in specialist health care might, in addition to a longer duration of pain, also be explained by previous treatment without recovery [50]. Only 16% of the patients in primary health care had attended specialist health care last year. Some of the differences in expectations might also be explained by differences in the wording of the questions asked in the two study samples. The findings of expectations have to be validated in another study applying the same scale and question in both populations.

The group of patients treated in primary care differed from those in specialist health care regarding some variables, but there were large overlaps between the groups. The observed SDs for some of the variables within the groups was high, especially in specialist health care indicating heterogeneity of patients. The referral of patients to specialist health care cannot solely be explained by patients' diagnosis, pain, disability and registered psycho-social factors. Based on our findings and that most of the patients were re-referred to physiotherapy in primary care, we believe that many of them could have been handled in primary health care. This is also in accordance with the recommendation of non-operative treatment for these patients and to the "LEON principle" [11]. A new Norwegian guideline for treatment of patients with nonspecific shoulder pain in primary care, strongly recommends simple clinical examination and advice for exercises [51]. We may speculate whether many of our patients referred to specialist care had not received adequate treatment in primary care; or whether the referral was based on the need for a "second opinion" [52]? Future studies should explore these assumptions in both primary and specialist health care.

Although only a small fraction of eligible patients were recruited, the samples appear representative by many factors. The primary care sample has been compared with a national registry of all patients treated by physiotherapists in primary care in Norway and is comparable to this larger population which increases the generalizability [29].

The patients in specialist health care were included in the study during time-periods and days pre-planned for new patients. Although only 21% of all patients registered with shoulder pain at the Department of Physical Medicine and Rehabilitation were included during the inclusion period, the study sample is comparable according to the prevalence of diagnostic labels with the patients in the one vear cohort collected at the same place [13]. The baseline characteristics are also in line with previously randomised studies for patients with subacromial shoulder pain, with some exceptions [53-56]. Our patients reported lower quality of life compared to these studies (0.54 compared to 0.7) and a larger proportion attended college/university (53% compared to 51, 42 and 38%) [53, 56]. The psychological variables, Tampa Scale of Kinesiophobia (TSK-13), Örebro screening tool, short form and expectations were not included in these previously mentioned studies [53, 56]. The mean value regarding the expectations in the present study, was higher than recently reported (4.6 vs. 3.6) in a study by Skatteboe et al. [57]. This might be because they also included patients with neck- and low back pain, and that less than 40% of the patients in their study had shoulder pain. In general, patients with shoulder pain are regarded somehow more optimistic than patients with neck and low back pain [58].

The strengths of this study are that we compared patients with shoulder pain in two levels of the health system, recorded well-known variables of importance in both populations and that we included questions about patients' "expectations" [57, 59, 60]. We also checked for selection bias in our analysis by including those not answering the SPADI questionnaire and found that the mean differences for pain last week were similar between those answering and not answering this questionnaire. A limitation of the study is that we have no information about patients with appointments other days than preplanned for new patients or patients who declined to participate. This might limit the generalizability of the results. However, there is no reason to believe that the large overlap between the groups will disappear by including more patients.

It might be seen as a limitation that the sample from primary health care was included by physiotherapists only, and that other health providers were not involved. However, since patients with musculoskeletal complaints have direct access to physiotherapists, the sample is probably representing a majority of the shoulder patients seeking treatment in primary health care.

The differences in the coding of the variables regarding pain medication and the coding and wording of the question considering expectation might limit the comparability of the results.

The collection of data and inclusion of patients in primary health care was different and less standardized compared to specialist health care. Some participants declined to provide data for various reasons, and some questionnaires were optional. This may also have influenced our results. The physiotherapists in primary health care have presented certain reasons for not inviting patients to participate or not including questionnaires as; lack of time, time-consuming technical problems with the electronic system, fear of too much work for the patients, problems in interpreting some of the scores, or that psychosocial factors are not relevant in their daily practice ("*I just ask the patients*") [61, 62].

Finally, our data are based on two different patient populations and the data in primary care is collected over a longer time-period. We do not consider this as problematic because neither the evaluation of these patients nor the treatment process in general differed during the inclusion period.

Overall, based on our results we may question why many patients are referred to specialist health care instead of being followed-up in primary health care. A better understanding of factors involved may help to reduce the referral and treatment of patients in specialist health care.

Conclusions

In summary, small differences were found in pain, disability and psycho-social factors between shoulder patients in primary and specialist health care, and the group differences were small compared to the variation within the groups. Patients referred to specialist health care were on average more affected, but there are large overlaps between the two samples. Expectations about outcome showed that patients in primary health care were more optimistic. Factors such as previous physiotherapy and levels of pain in combination with some psycho-social factors should be considered in the referral of patients. Based on our results and the fact that several of the patients are referred back to treatment in primary health care, we assume that more patients could be treated and improve in primary care which will reduce the costs.

The study has some limitations, but generates hypotheses that should be tested in a longitudinal study.

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Competing interests: Authors state no conflict of interest. **Informed consent:** Written informed consent has been obtained from all individuals included in this study.

Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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