Shoulder complaints

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Incidence, prevalence, interventions and outcome

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Chapter 1

General introduction

GENERAL INTRODUCTION

Shoulder complaints can be debilitating conditions and are encountered frequently in general practice. They constitute the second to third most common musculoskeletal condition presented to general practice[1,2] and have a reported incidence as high as 29.5 per 1000 person-years.[3] Little is known however about the consultation rates of this patient cohort. Many patients seen with shoulder complaints in general practice have recurrences, which contributes to a higher prevalence rate. The nature of shoulder complaints varies considerably over the course of time, leading to changes in diagnostic category.[4] Subacromial impingement syndrome (SIS) is, at 48%, the most frequently recorded shoulder disorder in general practice.[5]

Musculoskeletal disorders are the second most expensive disease group in the Netherlands, representing 6% of the total health care costs.[6] Information about direct health care costs as well as direct (e.g. travel expenses) and indirect non-health-related costs (e.g. productivity losses) associated with shoulder complaints is scarce though. Kuijpers et al. found relatively low mean total costs (€689) generated by patients in primary care for six months after a first consultation for shoulder pain.[7] Almost 50% of this total involved indirect costs, caused by sick leave from paid work. A small proportion (12%) of the population generated 74% of the total costs. For more chronic patients who participated in a randomized controlled trial and suffered from SIS 2.5 years on average, Ketola et al. calculated direct health care and non-health care costs (except for sick leave costs).[8] The mean health care costs during a 24-month follow-up for the combined treatment group (arthroscopic acromioplasty followed by a supervised exercise program) were €2961, and €1864 for the supervised exercise group. Next to these economic consequences there are losses incurred due to decreased fitness for work and activities of daily living as well as absence from work.[9]

To understand the etiology of SIS it is important to have a clear picture of the unique anatomical characteristics of the subacromial space. Within this space, a number of soft-tissue structures are situated between two rigid structures that move. The superior border (the roof) of the space is the coracoacromial arch, which consists of the acromion, the coracoacromial ligament and the coracoid process.[10] The inferior border (the floor) consists of the greater tuberosity of the humerus and the superior aspect of the humeral head. The height of the space between the acromion and the humeral head ranges from 1.0 and 1.5 centimeters as seen on radiographs.[11] Interposed between these two osseous structures are the rotator cuff tendons, the bursa and the coracoacromial ligament. Normally, the bursa facilitates the motion of the rotator cuff beneath the arch. Any abnormality that disturbs the relationship of these subacromial structures may lead to impingement.[12]

Many causes have been proposed for SIS. These factors can be broadly classified as intrinsic (intratendinous) or extrinsic (extratendinous), and can be further characterized as primary and secondary. A primary etiology, either intrinsic or extrinsic, causes the impingement process. A secondary etiology is the result of another process, such as shoulder instability. Possible intrinsic factors are muscle weakness, overuse of the shoulder and degenerative tendinopathy.[10] The following extrinsic factors are suggested:

acromial morphology (e.g. spurs protruding into the subacromial space), glenohumeral instability, degeneration of the acromioclavicular joint (which leads to osteophytes), impingement by the coracoacromial ligament, coracoid impingement, os acromiale and scapular dyskinesis.[10,13]

In the Netherlands, the choice of treatments for shoulder conditions is proposed by the National Guidelines for Shoulder Problems, published by the Dutch College of General Practitioners.[14] Primary treatment of SIS is conservative. A broad spectrum of conservative treatments for SIS is available in primary health care, including rest, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, physiotherapy and manual therapy. If patients do not respond sufficiently to these nonoperative measures, referral to an orthopedic surgeon for evaluation for (arthroscopic) subacromial decompression is recommended.[15] The best moment of referral is not well defined though, so a therapeutic dilemma for the general practitioner exists: how many different treatments from the spectrum of nonoperative interventions should be repeated or tried out before referring to surgery if previous ones have failed? And does surgery provide better results than conservative treatment? Such questions were the original guidance for the research described in this thesis.

Scope and outline

The aims of this thesis are threefold. The first is to gain insight into incidence, prevalence, patterns of consultation and medical consumption of patients with shoulder complaints in general practice during a ten year follow-up period. The second aim is to provide an overview of best evidence for surgical treatment of SIS compared with conservative treatment. The third aim and main focus of this thesis will be the presentation of the design of a new interdisciplinary treatment strategy for SIS and the results of the randomized controlled trial, comparing it to usual medical care.

Chapter 2 presents incidence and prevalence rates of shoulder complaints in general practice, calculated over a nine- and ten-year period respectively. A detailed report of primary physician consultations of a cohort of patients with shoulder complaints with a follow-up of ten years after initial presentation is also given. *Chapter 3* provides data on the consumption of medical care, including general practitioner consultation rates, medication consumption and referral to other care providers, of patients with shoulder complaints in general practice, also during a ten-year follow-up period. In a systematic review, which is presented in *Chapter 4*, randomized controlled trials comparing surgical and conservative treatment for SIS are summarized. No differences between these two treatment modalities were found. However, the idea existed that, if ineffective, a structured conservative route for treatment of SIS followed by a well-defined moment of referral for surgery would lead to a better surgical outcome. To this end, the design of a new interdisciplinary treatment strategy for SIS was developed. The design of the randomized controlled trial in which this strategy is compared with continuation of usual medical care is described in *Chapter 5*. The main results of this trial, including a cost-effectiveness analysis, are presented in *Chapter 6*. *Chapter 7* includes the general discussion of the studies presented in this thesis, outlining practical implications as well as recommendations for future research.

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Chapter 2

Incidence, prevalence and consultation rates of shoulder complaints in general practice

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Martin Stevens
Ron L. Diercks

Submitted

ABSTRACT

Objective
To study the incidence, prevalence and consultation rates of patients with shoulder complaints in Dutch general practice during ten years following initial presentation.

Methods
A primary care database with an average population of 30,000 patients per year aged 18 or older was used to select patients who consulted their general practitioner (GP) with shoulder complaints in the year 1998. Information about consultations for shoulder complaints was extracted. Incidence and prevalence for men, women and different age groups were calculated for nine and for ten years.

Results
A total of 526 patients consulted their GP with a new shoulder complaint. During an average follow-up of 7.6 years these patients consulted their GP 1331 times because of their shoulder complaints (average of 0.33 consultations per year). Almost half of the patients consulted their GP only once. Patients in the 45-64 age category had the highest probability of repeated GP consultations during follow-up. Average incidence was 29.3 per 1000 person-years. Women and patients in the 45-64 age category have the highest incidence. The annual prevalence of shoulder complaints ranged from 41.2 to 48.4 per 1000 person-years, calculated for the period 1998 to 2007, and was higher among women than among men.

Conclusion
Although the incidence of shoulder complaints in general practice is as high as 29.3 per 1000 person-years, GPs' workload is generally low, as nearly half of these patients consult their GP only once for their complaint.

INTRODUCTION

Musculoskeletal symptoms are common among the adult population, but only 33-42% of such patients consult their general practitioner (GP) for their complaints.[1] Shoulder complaints constitute the third most common musculoskeletal presentation.[2] Incidence and prevalence rates of shoulder problems in general practice are scarce and are mainly published for the Netherlands and the United Kingdom. Incidence rates range from 11.2 to 29.5 per 1000 person-years[3-6], and the reported prevalence rate is 23.6 per 1000 person-years.[5] As described in various studies, shoulder complaints often have a long course with recurrences, which contribute to the high prevalence.[7-9]

Most previous published studies that describe the clinical course of shoulder complaints have a prospective (observational) design.[8,9] In these studies, patients with a new shoulder complaint are periodically assessed for their level of pain and/or disability. Their medical consumption in terms of consultation rates is rarely investigated though. Only Linsell et al. report the period of consultation after initial presentation, but not the consultation rates during that period.[5] This study has the longest reported follow-up, which is limited to three years. Bot et al. present the number of consultations for new episodes of shoulder symptoms per 1000 registered persons in general practice.[3] So far it is unclear how consultations are distributed over the follow-up years after initial presentation.

The first aim of this study was to establish the rate of consultation of a GP in a cohort of patients with new shoulder complaints, grouped by gender and age categories over a ten-year period. The second aim was to estimate the incidence and prevalence of shoulder complaints.

MATERIAL AND METHODS

Design and setting

This is designed as a retrospective longitudinal cohort study. To select patients with shoulder complaints, data from the morbidity and medication Registration Network Groningen (RNG) were used.[10,11] The database of the RNG was established in 1989 and contains anonymised medical information from the patient population of about 20 GPs in the northern part of the Netherlands, divided over three group practices in three towns. Data such as gender, date of birth and consultation dates were extracted from this database. Data were used for the 10-year period 1998-2007, which will henceforth be referred to as follow-up period. The yearly average population was about 30,000 patients (all ages). GPs recorded all consultations in electronic medical records.

Symptoms, complaints and diagnoses were classified according to the International Classification of Primary Care (ICPC), developed by the World Organisation of Family Doctors.[12] The ICPC codes are based on a biaxial structure (a letter followed by a number). Letters stand for body systems (e.g. L is musculoskeletal system) and the two-digit numeric code represents symptoms, complaints or diagnoses. The codes L08 and L92 are used for shoulder symptoms and syndromes, respectively.

Patient selection
All patients classified by the codes L08 and L92 in the year 1998 were extracted from the RNG database and were included in this study. Patients under the age of 18 on 1 January 1998 and patients who had a history of shoulder complaints were excluded.

Consultations
In order to calculate the consultation rate during follow-up, the electronic medical records of selected patients were examined. Information like side of the affected shoulder was retrieved. Consultations were defined as every GP face-to-face contact.

Incidence
Incident cases were defined as patients with a new shoulder complaint who did not consult their GP for their shoulder in the preceding year. By using 1998 as control year, nine years were left for incidence rate calculation. A patient could be an incident case only once during those nine years of follow-up. Incidence was calculated per 1000 person-years for every year, grouped by age and gender, starting in the year 1999.

Prevalence
All new and current cases of patients with shoulder complaints were used to calculate the annual prevalence rate. Patients were only counted once as a prevalent case every year. Annual prevalence was calculated per 1000 person-years for every year, grouped by age and gender.

Procedures
The RNG database gives information about the date of entering and the date and reason for leaving a general practice (e.g. moving, death, etc.). The number of days patients were registered at the GP are called person-days and can be converted to person-years. Person-years were used to correct for an incomplete follow-up in further calculations. The following subgroups were defined for data presentation: men and women, and three age groups: 18-44, 45-64 and 65+. Age on 1 January 1998 was used to assign patients to their age category. Patients did not switch between subgroups during follow-up.

Statistics
Kaplan-Meier analyses were used to estimate the probability of patients consulting their GP for shoulder complaints during the ten years of follow-up. The RNG database did not provide information about recovery, therefore the assumption was made that a patient has recovered when he/she did not visit the GP within a year beyond the last consultation and thereafter. In the Netherlands, GPs act as gatekeepers who refer patients to other care providers within primary or secondary care. There is however a possibility that patients will still bypass the GP and refer themselves to alternative medicine, for instance. Those patients with no consultations within the year following the last GP visit (observation interval) in the 1998-2007 period leave the "survival" curve. Patients who left the GP practice within the year following the last consultation and

those who left the RNG database before the end of the observation period (due to e.g. moving, death) are defined as censored patients. Patients stayed in the analyses if they had a period of more than one year between two contacts. A Log-Rank test was used to compare differences in Kaplan-Meier curves for the gender and age categories.

An independent samples t-test was used to compare for differences in mean consultation rates per year between age and gender. The Pearson $\chi 2$ test was used ($P \leq 0.05$) for comparisons in incidence and prevalence. Analyses were performed with Microsoft Access 2003 and SPSS for Windows, version 16.0 (SPSS Inc., Chicago).

RESULTS

Patient selection

A total of 905 patients older than 18 were selected from the RNG database. After exploring the electronic medical records, six patients appeared not to have shoulder complaints and 373 patients had a history of shoulder complaints. Completing the search in the electronic medical records resulted in 526 patients with a new shoulder complaint. Their mean age at presentation was 47.2 (Standard Deviation (SD) 17.4) years, and 64.8% were women (Table 2.1). By the end of the ten years of follow-up, 199 patients had left the general practice (Figure 2.1). Their average follow-up was 4.3 (SD 2.6) years.

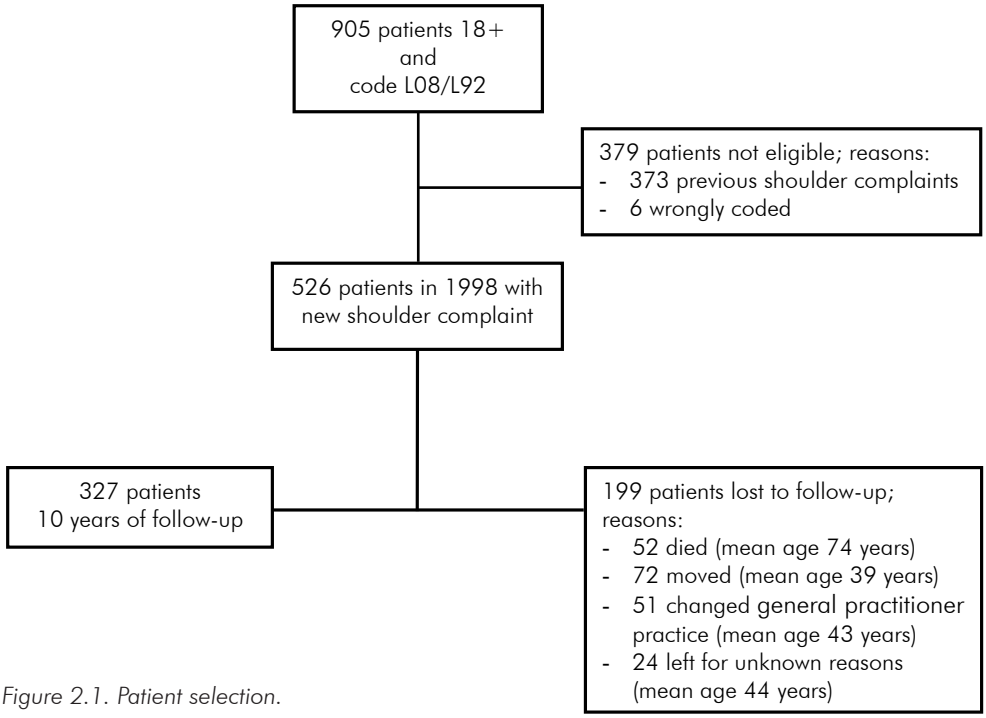

Figure 2.1. Patient selection.

Table 2.1. Demographic characteristics of the cohort.

	Gender			*Age category (yrs)*			
	Men	Women	Total	18-44	45-64	≥65	Total
n	185	341	526	250	184	92	526
%	35.2	64.8	100	47.5	35.0	17.5	100

Consultations

After ten years of follow-up the cohort had consulted their GP 1331 times for shoulder complaints. The average follow-up of the cohort was 7.6 (SD 3.0) years. Corrected for person-years, patients had an average of 0.33 consultations per year (men 0.36; women 0.32). The average number of consultations per year of patients aged 18-44 was 0.30, for the 45-64 and 65+ age groups 0.36. Almost half of the patients (251 out of 526) had consulted their GP only once because of shoulder complaints during ten years of follow-up, and 79.3% less than four times (Table 2.2). The maximum number of consultations by a patient in the first year was 14. Three-hundred and ninety one patients (74.3%) consulted the GP only during the first year following initial presentation (965 consultations). Four-hundred and fifteen patients had all their consultations within the first two years (1045 consultations) (Table 2.2 for the other follow-up years). Twenty-one patients consulted the GP more than seven times during the total follow-up, with a maximum of 25 consultations.

Table 2.2.Consultation rates concerning shoulder complaints during ten years of follow-up divided by gender and age category.

Year	*Gender*		*Age category (yrs)*			*Total consulations*
	Men	Women	18-44	45-64	≥65	
	n=185 (%)	n=341 (%)	n=250 (%)	n=184 (%)	n=92 (%)	n=526 (%)
1998	353 (26.5)	611 (45.0)	379 (28.5)	414 (31.3)	171 (12.8)	964 (72.4)
1999	41 (3.1)	40 (3.0)	32 (2.4)	39 (2.1)	10 (0.8)	81 (6.1)
2000	32 (2.4)	33 (2.4)	29 (2.2)	32 (2.4)	4 (0.3)	65 (4.9)
2001	22 (1.7)	43 (3.2)	45 (3.2)	11 (0.8)	9 (0.7)	65 (4.9)
2002	15 (1.1)	24 (1.8)	24 (1.8)	7 (0.5)	8 (0.6)	39 (2.9)
2003	16 (1.2)	28 (2.1)	28 (2.1)	16 (1.2)	0	44 (3.3)
2004	14 (1.1)	12 (0.9)	12 (0.9)	8 (0.6)	6 (0.5)	26 (2.0)
2005	7 (0.5)	14 (1.1)	6 (0.5)	11 (0.8)	4 (0.3)	21 (1.6)
2006	6 (0.5)	15 (1.1)	8 (0.6)	11 (0.8)	2 (0.2)	21 (1.6)
2007	2 (0.2)	3 (0.2)	2 (0.2)	2 (0.2)	1 (0.1)	5 (0.4)
Total	508 (38.2)	823 (61.8)	565 (42.4)	551 (41.4)	215 (16.2)	1331 (100)

Incidence

Figure 2.2A and 2.2B presents the incidence of patients with shoulder complaints, divided by gender and age category respectively. The average incidence was 29.3 (95% Confidence Interval (CI) = 28.48-30.04) per 1000 person-years over a period of nine years, with specific incidences of 32.2 (95% CI = 31.10-33.40) for women and 26.2 (95% CI = 25.11-27.21) for men (Figure 2.2A). Mean incidence of shoulder patients per 1000 person-years was 22.2 (95% CI = 21.32-23.10) in the 18-44 age category and 37.1 (95% CI = 34.67-39.47) in the 65+ age category, being the highest at 40.2 (95% CI = 38.50-41.95) patients for the 45-64-year-olds (Figure 2.2B).

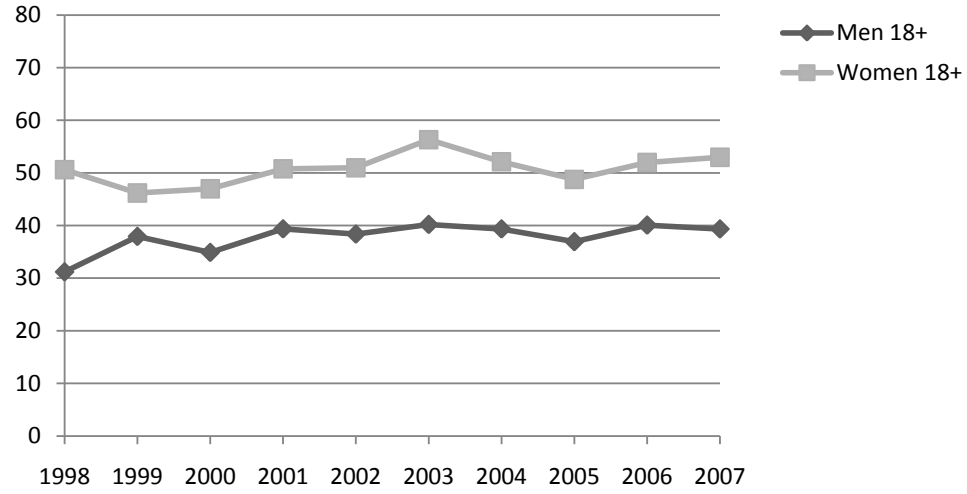

Figure 2.2A. Incidence per year divided by gender.

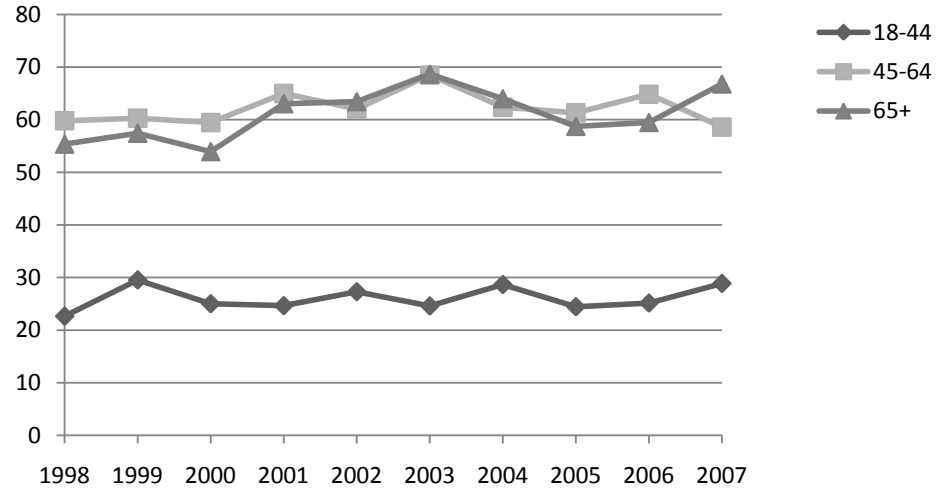

Figure 2.2B. Incidence per year divided by age category.

Prevalence

The annual prevalence of shoulder complaints ranged from 41.2 to 48.4 per 1000 person-years, calculated for the period 1998 to 2007, and was higher among women than among men, respectively 46.2 to 56.3 (range 95% CI = 42.3/50.0-52.1/60.5) and 31.2 to 40.2 (range 95% CI = 27.8/34.5-36.5/43.8) in the period 1998-2007 (Figure 2.3A).
In the 18-44 age category the annual prevalence ranged from 28.8 to 32.8 (range 95% CI = 25.9/31.7-29.7/35.9), in the 45-64 age category 58.6 to 68.5 (range 95% CI = 53.2/64.0-62.4/74.6), and in the 65+ age category it ranged from 53.9 to 68.7 (range 95% CI = 46.0/61.9-59.8/77.6) (Figure 2.3B).

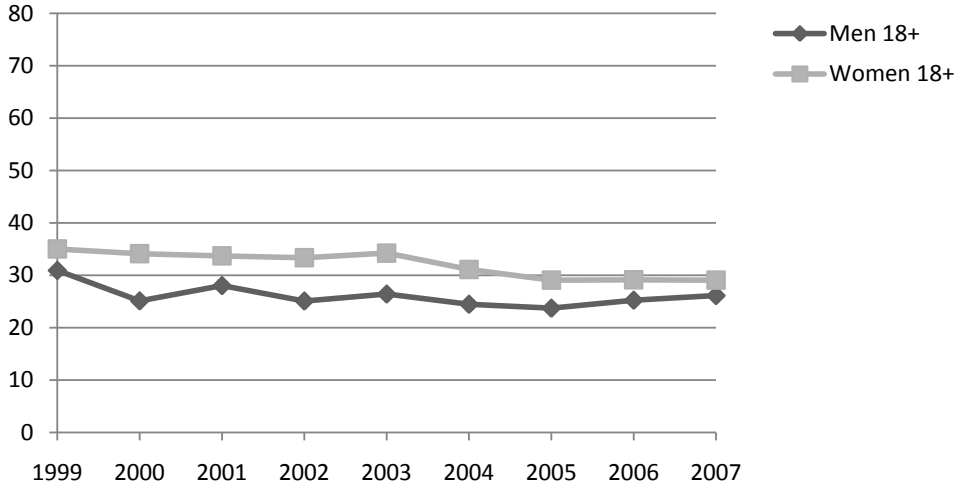

Figure 2.3A. Prevalence from 1998 to 2007 divided by gender.

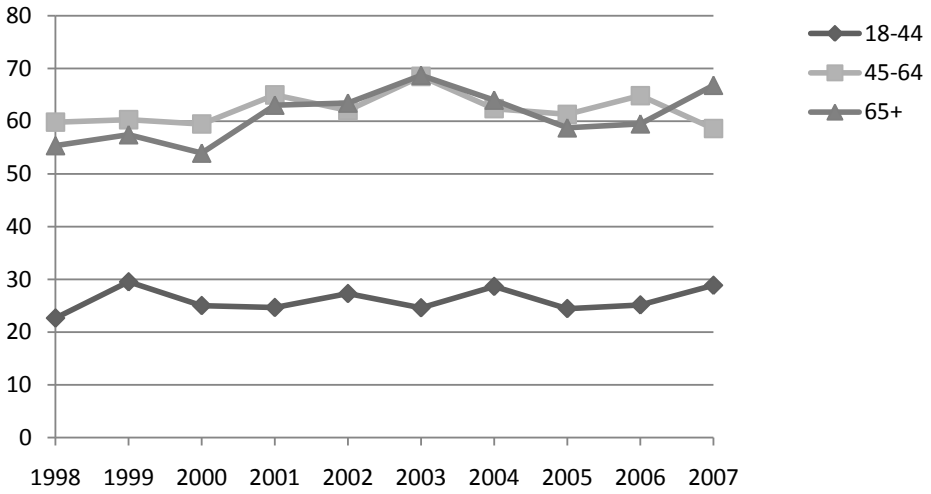

Figure 2.3B. Prevalence from 1998 to 2007 divided by age category.

Consultation rate probability

After 10 years of follow-up, 199 persons had left the RNG database. Figures 2.4A and 2.4B show the Kaplan Meier curves that estimate the probability of patients consulting their GP because of shoulder complaints during follow-up divided by gender and age category. The curve is horizontal in the first year, caused by the assumption that a patient had recovered when he/she did not visit the GP within a year beyond the last consultation. The logrank test was not significant for differences between men and women. There is a significant difference between the 45-64 and the 65+ age groups (P= 0.039). The elderly have a shorter survival, which means that, although they have higher incidence and prevalence figures than the youngest group, they have a lower probability for repeated consultation in the course of time.

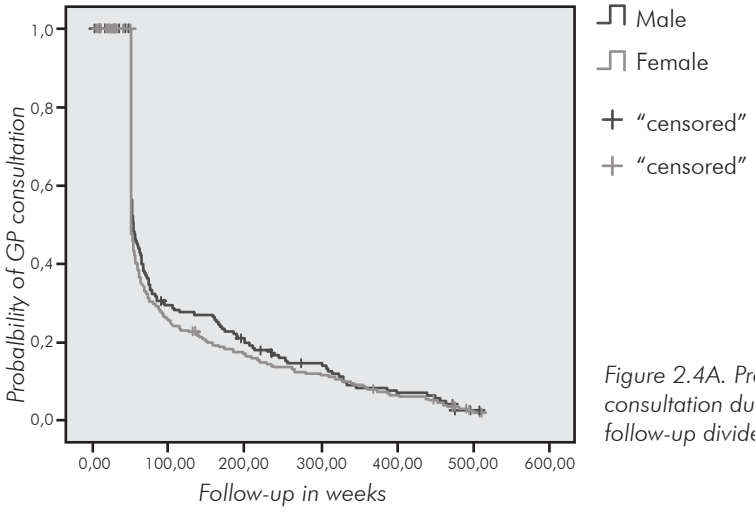

Figure 2.4A. Probability of GP consultation during 10 years of follow-up divided by gender.

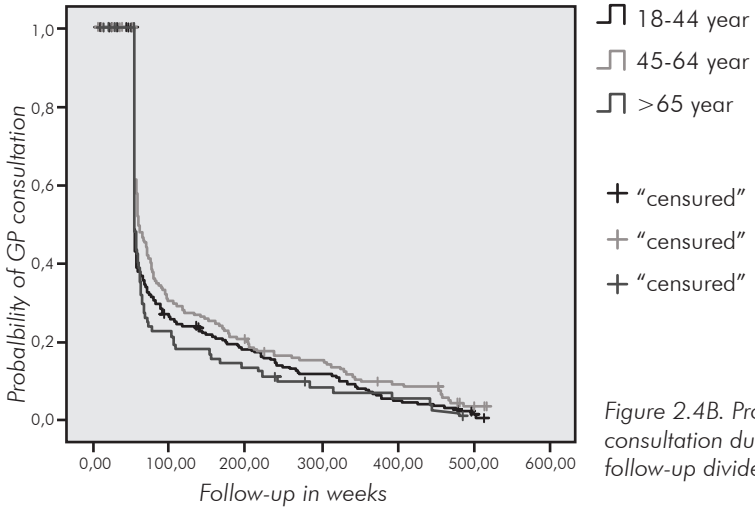

Figure 2.4B. Probability of GP consultation during 10 years of follow-up divided by age category.

DISCUSSION

Summary of main findings

This retrospective cohort study identified 526 incident cases with shoulder complaints. Their mean age at presentation was 47.2 years and 64.8% were women. During the ten years of follow-up they had an average GP consultation rate of 0.33 per year. Almost half of these patients consulted their GP only once.

The average incidence of shoulder complaints in general practice calculated over nine years was 29.3 per 1000 person-years and was higher among women than among men. Patients aged 18-44 had a significant lower incidence than the patients older than 45.

The annual prevalence of shoulder complaints in general practice ranged from 41.2 to 48.4 per 1000 person-years (period 1998-2007). Like the incidence, the prevalence was higher among women than among men and the 18-44 age category had a significantly lower prevalence than the two oldest categories.

The Kaplan-Meier curves did not show differences in probability for prolonged GP consultation between men and women, but there was a significant difference between the 45-64 age group and patients 65 aged and older. The elderly have a lower probability for repeated consultation in course of time.

Strengths and limitations of the study

A major strength of our study is that it not only provides information about consultation rates and distribution during follow-up, but also has a long average follow-up period of 7.6 years after initial presentation. Most previously published studies on incidence, prevalence and consultation rates of patients with shoulder complaints have a cross-sectional or longitudinal design with a limited follow-up period[3-5,13], and do not investigate the number of GP consultations during follow-up. By using data from the RNG database a reliable registration of actual consultation rates, incidence and prevalence could be made without influences of prospective study protocols. But this method has some limitations. First of all, the quality of registration by the GPs is very important for the reliability of the database. For the incident cases in 1998 and the consultation rates this was solved by checking data in electronic medical records. Six wrongly coded patients who did not suffer from shoulder complaints were excluded. On the other hand, patients may have remained undetected in our study when GPs did not use the right ICPC code for a shoulder patient. Chances of this happening were minimized through training sessions for GPs and their assistants, organized two to three times a year, during which patient cases were used to train encoding correctly.

The RNG is a dynamic database. Patients enter and leave at any time. Almost 40% of patients left the database before the end of follow-up, although the average follow-up was still a considerable 7.6 years. The RNG database gives no information about recovery. Therefore, in the Kaplan Meier curves patients could have wrongly been considered as recovered, while possibly taking some residual complaints for granted or referring themselves to alternative medicine for instance. There is no information either or whether, for example, a second consultation is because of a relapse after recovery or if this concerns a persisting shoulder complaint.

There are some differences when comparing demographic characteristics of the cohort of patients with a new shoulder complaint in 1998 with our reported incidence rates divided by gender and age. The proportion of women in the cohort is higher than the men/women ratio for incidence rates. Incidence decreased inversely to rising age categories in the cohort, except for the 45-64 age group compared to the 18-44 age group. This can be explained by the symptom-free period, which was one year for incidence calculations and the entire medical history for the cohort.

Comparison with existing literature

The incidence of shoulder complaints in general practice in our study is the same as that published by Feleus et al., who report an incidence of 29.5 per 1000 person-years.[4] However, they only included patients aged 18 to 64. Van der Windt et al., Linsell et al. and Bot et al. found lower incidence rates, respectively 11.2, 14.7 and 23.1 per 1000 patient-years.[3,5,6] The lower incidence reported by Bot et al. can be explained by the fact that they did not use age restrictions. Van der Windt et al. used a prospective study design, which might have influenced the incidence rate. The difference with Linsell et al. might be explained by the symptom-free period, which was three years for their study and one year in ours. Incident cases in the first years (e.g. 1999 and 2000) of our study can therefore include more recurrent cases. The highest incidence rate was also found for the year 1999. Differences in health care systems between the United Kingdom and the Netherlands might be another explanation, with GPs being more easily accessible for patients in the Netherlands.

In our study the incidence of shoulder complaints among women was higher than among men. This is in accordance with the studies of Bot et al., Feleus et al. and Van der Windt et al.[3,4,6] Linsell et al. did not find this difference.[5] Bot et al. identifies the highest incidence in the 40-60 age group, which is similar to our study.[3]

The annual prevalence of patients with shoulder complaints in general practice in our study ranged from 41.2 to 48.4 per 1000 person-years, higher than that reported by Linsell et al. at 23.6 per 1000 person-years.[5] The prevalence of shoulder complaints is higher among women than men, as described in the studies of Picavet et al. and Linsell et al. and the review by Luime et al.[1,5,13], which is in accordance with our study. Linsell et al. describe a prevalence rate that increases with age.[5] We only found a difference between the youngest and the two older categories.

In the study of Linsell et al., 52.1% of patients visited their GP only once for their shoulder complaint, which is similar to our study.[5] In contrast to our study, Linsell et al. describe that patients aged 60 or older consulted the GP for a longer period of time than younger patients. A good explanation for this difference is lacking.

Implications for clinical practice

Patients with shoulder complaints consulted their GP in a fast-decreasing rate during follow-up. Most of the consultations were during the first two years following initial presentation. An incidence rate of almost 30 per 1000 person-years seems high, but the workload for GPs proved to be small because nearly half of the patients consulted their GP only once for their complaint. Apparently, many shoulder complaints often have a favourable course.

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Chapter 3

Patients with shoulder complaints in general practice: consumption of medical care

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ABSTRACT

Objective
To describe the medical consumption (general practitioner consultation, referrals, medication consumption) of patients with shoulder complaints in general practice.

Methods
Data were obtained from a primary care medical registration network. All patients aged 18 years or older with new shoulder complaints who consulted their general practitioner in 1998 were included, and were followed 10 years beyond the initial consultation.

Results
526 incident cases were identified (average age 47 years, 65% women and average follow-up 7.6 years). Nearly half of the patients consulted their general practitioner only once. For 79% of those patients a wait-and-see policy or a prescription for NSAIDs sufficed. During follow-up 65% of all patients were prescribed medication. Medication consumption was significant higher among men than women, and higher for the 45-64 age group compared to the younger group. A total of 199 patients were referred, of which 84% to a physiotherapist and 16% to secondary care. Only two patients had surgery, done by an orthopaedic surgeon. In just 14% of the patients the general practitioner recorded a diagnosis; rotator cuff disorder was the most common one.

Conclusions
I. Nearly half of patients with a new shoulder complaint consult their general practitioner only once.
II. Medical consumption in general practice is highest for male shoulder patients and the 45-64 age group.
III. Shoulder problems are mainly an issue for primary care.

INTRODUCTION

Many studies have focussed on incidence and prevalence densities of shoulder complaints in general practice[1-4], yet little is known about the long-term course of shoulder complaints and its management in this setting. Different articles have described a follow-up ranging from six months[5-7] to 12 months[8], 18 months[9,10] and three years[1], but longer-term follow-up data are missing. Besides, information about prescribed treatments and patterns of referrals for shoulder conditions in primary care is still limited.

In the Netherlands nearly everybody is registered with a general practitioner. Dutch general practitioners have exclusive authority to refer patients to other practitioners in primary and secondary care. In addition, there is no private health care to which people can refer themselves. Therefore, general practitioner consultation and referral rates give a good reflection of the number of people seeking medical care. In the Netherlands, the choice of treatments for shoulder complaints in general practice is proposed by the National Guidelines for Shoulder Problems, published by the Dutch College of General Practitioners.[11,12] These guidelines recommend giving information on the prognosis of shoulder pain, advice provoking activities, and stepwise treatment consisting of acetaminophen, NSAIDs, corticosteroid injection or referral to physiotherapy. This stepwise approach is most cost-effective in terms of increase of costs by moving on to the next step.

Although these are guidelines, gaining insight into how patients and their general practitioners really deal with shoulder complaints in the long term is valuable for general practitioners as a reflection of their management and can guide decision-making for the future. Medical data registration networks in primary care are very useful in providing these data.

The aim of this study was to describe the consumption of medical care in Dutch general practice, including general practitioner consultation rates, medication consumption and referral to other care providers for patients with shoulder complaints in the age-group 18+ for a period of ten years after initial presentation.

METHODS

Design and setting

To select patients with shoulder complaints in Dutch general practice, this retrospective cohort study uses data from the morbidity and medication Registration Network Groningen (RNG), The Netherlands.[13,14] This database contains anonymised medical information like consultation date, date of birth, gender, prescribed medication, referrals and comorbidity, from 18 general practitioners in the northern Netherlands. Data were used for the 10-year period 1998-2007, which will henceforth be addressed as follow-up period. The average consulting patient population was approximately 30,000 persons per year (all ages). The registering general practitioners work in three group practices: one in the university city of Groningen and two in the smaller towns

Hoogezand-Sappemeer and Hoogeveen. All general practitioners use electronic medical records in their daily practice. During each consultation symptoms and/or diagnoses were registered according to the International Classification of Primary Care (ICPC).[15] This classification is designated by the World Organisation of Family Doctors as the ordering principle of the family practice domain. The ICPC codes are based on a simple biaxial structure consisting of a letter followed by a number. The letter represents a body system (e.g. L= musculoskeletal system), numbers 1-29 provide rubrics for symptoms and complaints, and numbers 70-99 represent a diagnosis/disease. Prescribed medication was coded according to the Anatomical Therapeutic Chemical Classification System developed by the World Health Organization.[16]

Medical Ethics Committee approval was waived because the study was a retrospective cohort study using anonymised data.

Patient selection and electronic medical records

Patients older than 18 years of age who consulted their general practitioner for shoulder problems in the year 1998 were selected from the RNG database by using ICPC codes L08 (shoulder symptom/complaint) and L92 (shoulder syndrome). Following this selection all general practitioners were visited to retrieve the same registered information in the electronic medical records as in the RNG database to check for correctness. Furthermore, the affected site is reported in the electronic medical records. Episodes concerning the contralateral site and those patients with documented previous shoulder complaints of the same shoulder were excluded. Additional information like diagnosis, if noted, was enlisted.

Medical Care Consumption

Every general practitioner visit and out-of-hours service was counted as a consultation. Telephone requests for prolonging prescriptions without general practitioner visit were excluded from this count. Per-case prescriptions and referrals were recorded and attached to the specific general practitioner visit; data on doses and number of tablets were not available. Data on treatments for the different subgroups will be described, as well as the treatment initiated at the first general practitioner consultation.

Procedures

The incident patients were followed-up for ten years beyond initial presentation. However, during follow-up several patients departed from general practitioner practices (moving, death, etc.), therefore the average follow-up is calculated for the study population, which is expressed in person-years. For data presentation the following subgroups were defined: men and women, and three age groups: 18-44 years (young working population), 45-64 (older working population) and 65+ (retired). Patients stayed within the same subgroup they were assigned to at initial presentation.

Statistical analysis

Microsoft Access 2003 was used to organise and select data from the RNG database. All calculations were made using the statistical package SPSS for Windows (SPSS Inc., version 16.0, 2007, Chicago). Statistical analyses were performed using a Pearson Chi-Square test for comparing proportions and a Mann-Whitney Test for comparing means ($P < 0.05$).

RESULTS

Patient selection

Nine hundred and five patients aged 18 years or older were selected from the RNG database (see figure 3.1). Information provided by the electronic medical records was used for patient exclusion. A total of 526 patients visited the general practitioner in 1998 because of a new shoulder complaint. Their mean (S.D.) age at presentation was 47 (17) years and 65% were women (n= 341). Of these patients, 199 were lost to follow-up for various reasons (see figure 3.1).

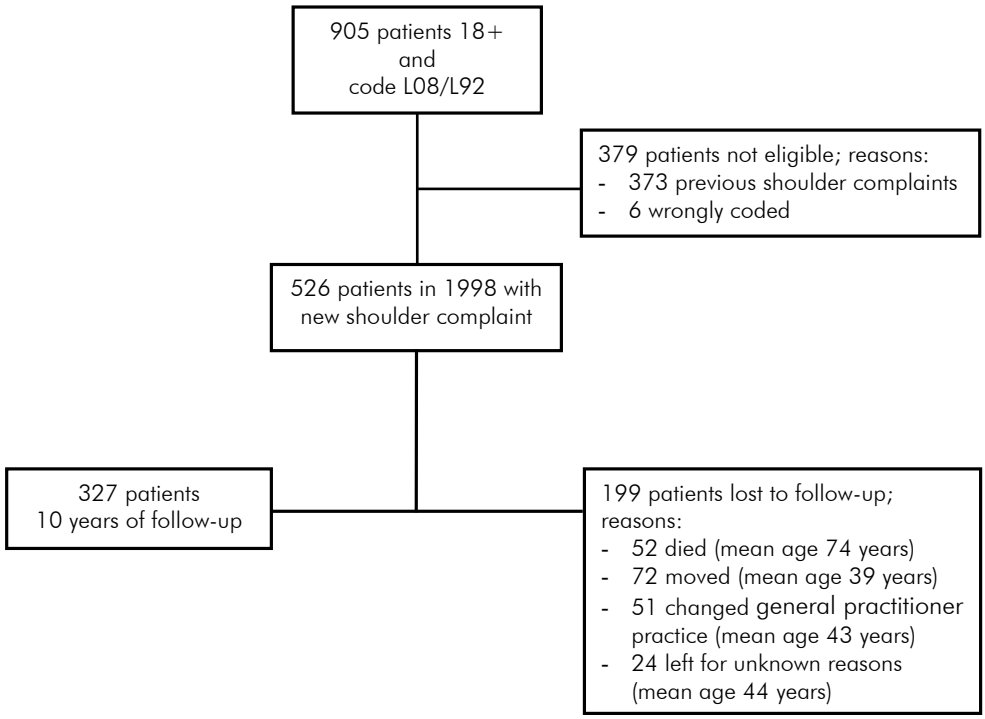

Figure 3.1. Patient selection.

Consultations

The patient cohort consulted the general practitioners 1331 times for shoulder complaints in ten years. Figure 3.2 shows the number of patients still consulting their general practitioner during follow-up. Their average follow-up was 7.6 (3.0) years. Corrected for person-years patients had 0.33 (0.22) consultations on average per year (men 0.36 (0.31); women 0.32 (0.28)). Corrected for person-years the 18-44 group had 0.30 (0.28) consultations per year on average and the 45-64 group as well as the 65+ group 0.36 (0.30) consultations per year. Three hundred and ninety-two patients (75%) consulted their general practitioner, once or repeatedly, only within the first year after initial presentation.

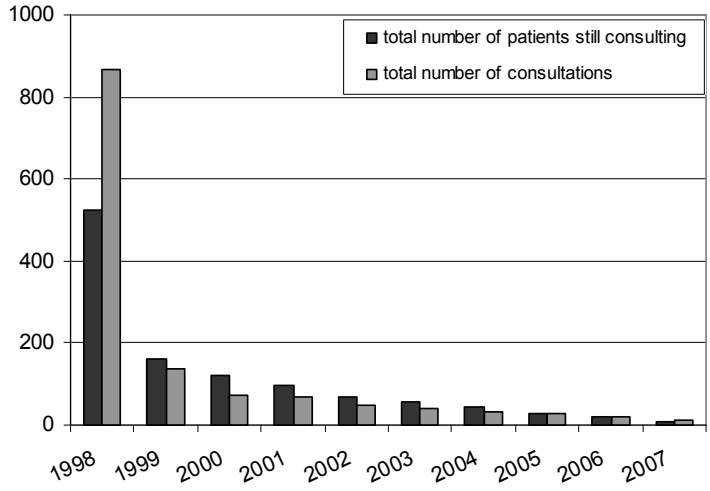

Figure 3.2. Number of patients consulting their general practitioner during follow-up.

Treatment - first consultation

Management at the first general practitioner consultation is presented in table 3.1. A wait-and-see policy was recommended for 32% of the patients, and 50% received a prescription for oral non-steroidal anti-inflammatory drugs (NSAIDs). In the oldest age group a wait-and-see policy was the most common practice. During the ten years of follow-up 253 patients (48%) consulted their general practitioner only once for shoulder problems; 40% of these patients had been recommended a wait-and-see policy, 39% received a prescription for oral NSAIDs and 16% was referred to a physiotherapist.

Table 3.1. Management for different subgroups at first consultation.

		total *n (%)*	men *n (%)*	women *n (%)*	18-44 *n (%)*	45-64 *n (%)*	>65 *n (%)*
Medication	Corticosteroid injection	14 (3)	4 (2)	10 (3)	5 (2)	4 (2)	5 (5)
	Oral NSAIDs	262 (**50**)	104 (**56**)	158 (**46**)	115 (**46**)	113 (**61**)	34 (37)
	Acetaminophen	13 (2)	3 (2)	10 (3)	6 (2)	4 (2)	3 (3)
	Remainder	10 (2)	1 (1)	9 (3)	5 (2)	2 (1)	3 (1)
Referrals	Physiotherapy	78 (15)	30 (16)	48 (14)	41 (16)	26 (14)	11 (12)
	Secondary care	4 (1)	2 (1)	2 (1)	2 (1)	1 (1)	1 (1)
Wait-and-see policy		168 (32)	49 (26)	119 (35)	86 (34)	42 (23)	40 (**43**)
*Total number of treatments**		*549*	*193*	*356*	*260*	*192*	*97*
Total number of patients		*526*	*185*	*341*	*250*	*184*	*92*

* More than one treatment modality may have been offered to a patient; therefore the total frequency may exceed 100%. The number of treatments is expressed as a percentage of the total patient group. Highest percentages are marked **bold**.

Table 3.2. Medication consumption for different subgroups during ten years of follow-up.

	total *n (%)*	men *n (%)*	women *n (%)*	18-44 *n (%)*	45-64 *n (%)*	>65 *n (%)*
Yes	343 (**65**)	131 (**71**)	212 (**62**)	146 (**58**)	136 (**74**)	61 (**66**)
No	183 (35)	54 (29)	129 (38)	104 (42)	48 (26)	31 (34)
Total	*526*	*185*	*341*	*250*	*184*	*92*

Highest percentages are marked **bold**.

Treatment - medication

During ten years of follow-up medication was prescribed in 53% of the general practitioner visits (701/1331) to a total of 343 patients (65%). Corrected for persons-years this is 1.7 prescriptions per person on average. In 74% of the cases the prescription was an oral NSAID, in 13% a corticosteroid injection, in 6% acetaminophen, in 5% a benzodiazepine, in 1% an opiate and in 1% of the cases different medication. The prescription consumption was significantly higher for men (71%) than for women (62%) (P= 0.047), and the highest for the age group 45-64 (see table 3.2) compared to the 18-44 group (P= 0.001) and the 65+ group.

Treatment - referrals

A total of 199 persons (38%) were referred during ten years of follow-up. They represent 274 referrals, which means that in 21% of all general practitioner consultations a patient was referred. The largest proportion of referrals was to a physiotherapist (84%), followed by referral to rehabilitation medicine (6%) and an orthopaedic surgeon (6%), and the remainder (4%) represented another type of secondary care. Only two patients had surgery, done by an orthopaedic surgeon. The distribution of referrals for men and women was about equal, in 21% and 20% of the general practitioner consultations respectively. The oldest age group (65+) had a significant lower rate of referral per consultation (15%) throughout the follow-up period compared to the 45-64 group (21%; P= 0.046) and the 18-44 group (22%; P= 0.024).

Diagnosis

In just 74 of the 526 shoulder patients (14%) a diagnosis was recorded in the electronic medical records. The most common diagnosis was rotator cuff disorder, representing 61 patients. The other diagnoses were acromioclavicular joint pathology (6 patients), frozen shoulder (5 patients) and glenohumeral instability (2 patients).

DISCUSSION

Main findings

This study is the first reporting on medical consumption of patients with a new shoulder complaint in primary care with a follow-up of 7.6 years. Nearly half of the patients consulted the general practitioner only once for shoulder problems during ten years of follow-up. For eight out of ten of those patients a wait-and-see policy or a prescription for NSAIDs sufficed.

At the end of the follow-up period 65% of all patients had medication prescribed, an oral NSAID in most cases. Medication consumption was significantly higher in men than women, and higher for the 45-64 age group compared to the younger group. Nearly 40% of the patients were referred, the largest proportion to a physiotherapist. Among just a minority of patients a diagnosis was recorded; rotator cuff disorder was the most common one.

Relationship to other research

The demographic characteristics of patients in this study are similar to those of other studies reporting on shoulder disorders in primary care, with a female predominance and a wide age range of patients.[6,10,17] In our study 50% of the initial treatments at first consultation were an oral NSAID prescription, 32% a wait-and-see policy, 15% a referral for physiotherapy and 3% a corticosteroid injection. These numbers are different from those presented by Van der Windt et al., who performed a prospective follow-up study in general practice; 48% of their reported initial treatments were a wait-and-see policy or medication only, 29% a referral to physiotherapy and 23% a local injection of anaesthetic or steroid.[8] This difference might be explained by the two different study

designs. In the prospective study general practitioners might have been more aware of the study setting and consequently have treated their patients more aggressively compared to the general practitioners participating in our study. Another explanation could be sought in the study population. Van der Windt et al. included patients who had a symptom-free interval of one year. In this study patients were included who had never had consulted for shoulder issues before. Patients who have a recurrence following (failed) previous treatments are likely to be treated more aggressively according to Feleus et al., who published an article on management decisions in amongst others nontraumatic complaints of the shoulder in general practice.[18] They found that long duration of complaints, high complaint severity, many functional limitation and recurrent complaints were negatively associated with watchful waiting.

Medication consumption was highest in men and the 45-64 age group. One other study presented data on NSAID consumption and found the highest consumption in a comparable age group.[1] A wait-and-see policy was recommended the least often to such groups – they generally have more physically demanding work, which might explain the higher medication consumption.

Just a few studies have reported on referrals for shoulder patients. In U.K. primary care 14% of patients were referred to a physiotherapist within three years after initial presentation and 6% to an orthopaedic or rheumatology clinic.[1] In a Dutch study 29% of patients were referred to a physiotherapist and 10% to a rheumatologist or orthopaedic surgeon during the first year following presentation.[8] In our study 32% of patients were referred during the ten years of follow-up to a physiotherapist and 5% to rehabilitation medicine or an orthopaedic surgeon. It thus appears that general practitioners in our study are quite selective when referring shoulder problems to a specialist. However, compared to U.K. primary care Dutch general practitioners are more likely to refer to a physiotherapist. In agreement with findings presented in a U.S. study, older patients are less likely to be referred to a physiotherapist or secondary care practitioner than younger patients.[17] Although in the Netherlands self-referral to a physiotherapist is possible since 2006, we did not see a decrease in our database of referrals by the GP, but an increase. Therefore we do not expect much influence on our study data caused by the possibility of self-referral.

In just a minority of cases the general practitioners recorded a specific diagnosis for the shoulder symptoms. This is in accordance with the findings of Linsell et al., who concluded that in U.K. primary care general practitioners may lack confidence in applying precise diagnoses to shoulder conditions.[1] Beside the complexity of the shoulder joint, the extensive differential diagnosis and the frequent coexistence of other disorders, the diagnosis is often complicated by symptoms that are not restricted to a single site.[3,19] Previous studies have shown that even more specialised practitioners than general practitioners, like rheumatologists and physiotherapists, have difficulty distinguishing different diagnoses in the shoulder region.[20,21] Furthermore, most Dutch general practitioners follow the clinical guidelines for treatment of shoulder complaints issued by the Dutch College of General Practitioners in 1990.[11] In these guidelines a classification of shoulder complaints was introduced, based largely on the concepts of Cyriax, describing four intrinsic shoulder syndromes: subacromial syndrome, capsular

syndrome, acute bursitis and acromioclavicular syndrome. However, research revealed that these concepts were not useful for daily practice.[12] In the present study it also became clear that general practitioners tend not to record a specific diagnosis. The research information and the restricted therapeutic options for the general practitioner resulted in a revised version of these guidelines in 1999, which stated that a specific diagnosis is not required to treat shoulder patients.[12]

When looking at the treatments initiated at first consultation in this study (table 3.1), for the majority of the patients the management decisions followed the Dutch Guidelines for Shoulder Problems. Management decisions advised in these guidelines should at least be based on available knowledge on preferable outcomes, or, when not available, on costs, as stated by Feleas et al.[18] There is, however, little evidence to support or refute the efficacy of common interventions for shoulder complaints. For corticosteroid injections for shoulder pain Buchbinder et al. performed a Cochrane review and found a small and not well-maintained effect of subacromial corticosteroid injections for rotator cuff disease and intra-articular injections for adhesive capsulitis.[22] No benefit of subacromial corticosteroid injections over NSAIDs was found. Another Cochrane review published on physiotherapy interventions for shoulder pain.[23] Exercise was demonstrated to be effective in terms of short term recovery in rotator cuff disease and longer term benefit with respect to function. Furthermore, there was some evidence that for rotator cuff disease, corticosteroid injections are superior to physiotherapy and no evidence that physiotherapy alone is of benefit for adhesive capsulitis. Although these Cochrane studies were published after the introduction of the Dutch Guidelines for Shoulder Problems, the Dutch guidelines are in accordance with this evidence. And, as there is little evidence for one treatment modality being superior to another (except for corticosteroid injections for rotator cuff disease compared to physiotherapy), treatment costs should be a determining factor in management decisions.

A good estimation of direct health care costs of this patient cohort is not possible due a lack of information about treatment details (e.g. numbers of physiotherapy treatments, kind of NSAIDs, etc.). However, to illustrate the costs involved in this cohort, a study published by Kuijpers et al. can be used, which gives a detailed overview on costs of shoulder pain in primary care consulters (n=587).[24] During six months after first consultation for shoulder pain, the mean total costs a patient generated were €689. A small part (12%) of the population accounted for 74% of the total costs. Almost 50% of these total costs concerned indirect costs, caused by sick leave from paid work. Treatment by a therapist accounted for 37% of the total direct costs of the 587 patients, although only few patients were referred. An explanation for the modest health care costs could be that many general practitioners stick to the interventions recommended in the Dutch guidelines for shoulder problems (wait-and-see policy with pain medication, followed by injections), which are relatively inexpensive.[11,12]

Strengths and limitations of this study

The primary care database RNG was very suitable for selecting shoulder patients by ICPC codes, but this method has some limitations. First of all, the reliability of the RNG database is determined by the accuracy of registration of the general practitioners. This objection was solved with the data check in the electronic medical records. Six of the initially selected 905 patients appeared to be wrongly coded and were removed from the database. A second limitation consists in the database being a representation of a dynamic population. Registered patients can die or move and can therefore leave the database at any time. A considerable number of patients were lost to follow-up (n= 199). Nevertheless, the cohort represented an average follow-up of 7.6 years. Furthermore, the database does not provide information about when a patient is cured. When there is a long period between two consecutive consultations a patient could have recovered in the meantime and have consulted the general practitioner the second time for a new shoulder symptom or a relapse. However, when looking at the consultation frequencies this seems very unlikely for most patients.

A major strength of this study is its design. Most other studies presenting information about prescribed treatments and patterns of referrals for shoulder conditions in primary care have prospective research settings in which general practitioners' management might have been influenced. This study is therefore more likely to give a true representation of the medical consumption of shoulder patients in primary care.

Rheumatology key messages

- Nearly half of patients with a new shoulder complaint consult their general practitioner only once.
- Medical consumption in general practice is highest for male shoulder patients and the 45-64 age group.
- Shoulder complaints are mainly an issue for primary care.

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Chapter 4

Conservative or surgical treatment for subacromial impingement syndrome? A systematic review

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ABSTRACT

Introduction

Patients suffering from subacromial impingement syndrome (SIS) are often operated on when conservative treatments fail. But does surgery really lead to better results than nonoperative measures? This systematic review was executed to compare effects of conservative and surgical treatment for SIS in terms of improvement of shoulder function and reduction of pain.

Materials and Methods

A literature search for randomized controlled trials (RCTs) in PubMed, Embase, PEDro and Cochrane register of RCTs was conducted. The methodological quality of the selected studies was assessed by two reviewers. A best-evidence synthesis was used to summarize the results.

Results

Four RCTs were included in this review. Two RCTs had a medium methodological quality and two a low quality. No differences in outcome between the treatment groups were reported for any of the studies, irrespective of quality.

Conclusion

No high-quality RCTs are available so far to provide possible evidence for differences in outcome, therefore no confident conclusion can be made. However, according to the best-evidence synthesis, there is no evidence from the available RCTs for differences in outcome in pain and shoulder function between conservatively- and surgically-treated patients with SIS.

INTRODUCTION

Shoulder disorders are encountered frequently in general practice. A recently published review has summarized eighteen studies on the prevalence of shoulder complaints in the general population (in the USA, UK, Scandinavia, Cuba, South Africa, Spain and Nigeria).[22] Prevalence figures ranged from 6.9 to 26% for point prevalence, 18.6 to 31% for 1-month prevalence, 4.7 to 46.7% for 1-year prevalence and 6.7 to 66.7% for lifetime prevalence. In a Dutch study, the cumulative incidence of shoulder problems was estimated at 19/1000 patients/year in Dutch general practice.[2] For the neck and upper extremity it was, after neck symptoms, the second most commonly presented musculoskeletal problem. A differentiation between several diagnoses of shoulder problems in general practice was presented in another Dutch study.[36] Subacromial impingement syndrome (SIS) was the most frequently recorded disorder (44%).

Treatment of SIS always starts conservatively. A broad spectrum of conservative treatments for SIS is available in primary health care: rest, non-steroidal anti-inflammatory drugs (NSAID), corticosteroid injections, physical therapy and manual therapy. Several RCTs have been developed to gather evidence on effectiveness of different treatments for SIS, and are summarized in systematic reviews, but until now these reviews have only focused on shoulder problems in general [1,6,11-14,35] and on nonoperative treatments for SIS.[8,23] These reviews show there is little evidence to support or refute the efficacy of common interventions (physical therapy, manual therapy, acupuncture, NSAID medication, corticosteroid injections) for shoulder pain. Subacromial corticosteroid injections for rotator cuff disease and intra-articular injections for adhesive capsulitis may be beneficial, although their effect may be small and not well maintained. Furthermore, there is limited evidence to support the efficacy of therapeutic exercise and manual therapy to treat SIS.

Although there is limited evidence for most conservative interventions, in a retrospective study among 616 participants approximately 60% had satisfactory results after nonoperative treatment (NSAIDs and/or physical therapy) at an average follow-up of 27 months.[24] A therapeutic dilemma arises when these nonoperative treatments fail. The literature recommends referral to an orthopedic surgeon, to be evaluated for (arthroscopic) subacromial decompression.[25] Several publications report good-to-excellent results for both open and arthroscopic subacromial decompression.[18,19,21,29,31,33,37] However, are the results of surgery really better than those of conservative treatments? In order to answer whether surgery produces better treatment results for SIS than conservative treatments, we performed a systematic review of randomized controlled trials (RCTs) to compare effects of conservative and surgical treatments for SIS in terms of improvement of shoulder function and reduction of pain.

MATERIALS AND METHODS

Literature search

A search of the literature in PubMed (from 1948 onward), Embase (from 1947 onward), PEDro (from 1929 onward) and the Cochrane Central Register of Controlled Trials was conducted to identify relevant publications until October 2007, without language restrictions. The literature search strategy for PubMed is presented in Table 4.I. Reference lists of retrieved articles and articles on surgical interventions for SIS were screened for additional publications. Names of first authors of selected articles were used for citation tracking.

Table 4.I. Literature Search Strategy for Medline.

Step	Search	Results
#1	Shoulder Impingement Syndrome"[Mesh] OR shoulder impingement [TW]	786
#2	Shoulder Joint"[Mesh] AND "Bursitis"[Mesh]	680
#3	Subacromial impingement [TW]	783
#4	Acromion [TW]	1071
#5	Rotator Cuff [TW]	4079
#6	#1 OR #2 OR #3 OR #4 OR #5	5591
#7	# 6 NOT (capsulitis [TW] OR frozen shoulder[TW])	5287
#8	# 7 AND ("surgery"[SH] OR "operative surgical procedures"[TW] OR "surgical procedures, operative"[Mesh] OR "Surgery"[Mesh] OR surgery[TW] OR "arthroscopy"[Mesh] OR arthroscopy[TW] AND ("therapeutics"[Mesh] OR therapeutics[TW] OR "therapy"[SH] OR therapy[TW]	2462
#9	"Randomized Controlled Trials"[Mesh] OR "Randomized Controlled Trial "[PT] OR "Clinical Trial "[PT] OR "Clinical Trials"[Mesh] OR "Controlled Clinical Trial "[PT]	625063
#10	#8 AND #9	162

MeSH indicates Medical Subject Headings; TW: Text Word; PT: Publication Type; SH: SubHeading.

Study selection

The publications had to meet the following selection criteria:

- Study design: RCT. Studies focusing on surgical repair of rotator cuff tears, adhesive capsulitis and shoulder instability were excluded.
- Participants: adult patients (over age 18) suffering from SIS, manifest as pain upon abduction of the shoulder. The diagnosis is confirmed with a positive impingement test. For this test the examiner injects lidocaine into the subacromial space and then repeats tests for the impingement sign (e.g. Neer and Hawkins sign). Elimination or a significant reduction of pain constitutes a positive impingement test. Furthermore, patients have been resistant to conservative treatments for at least three months.
- Interventions: all studies comparing (arthroscopic) subacromial decompression with conservative treatment.
- Outcome measures: all outcome measures for shoulder function or pain.

According to these criteria, two of the authors (MS and OD) independently selected the relevant articles for this review by reading all titles and abstracts retrieved by the search strategy. In case of disagreements a third reviewer (RLD) could be consulted.

Methodological quality assessment

All publications were assessed by two reviewers (MS and JCW) according to a methodological quality list for the assessment of RCTs (Table 4.2).[10] Questions regarding blinding patients or care providers to the intervention were excluded because this kind of blinding is not possible in this type of RCT. An item concerning blinding the outcome assessor was present. The questions on whether "outcome measures were suitable" and "the duration of follow-up was adequate to measure clinical differences between treatments" (items J and K) were added because they were considered relevant to measuring treatment effect.

Each criterion was graded as positive/yes (+), negative/no (-) or unclear (?). Disagreements were discussed in a consensus meeting. When no consensus could be reached, a third reviewer (RLD) was asked for a binding verdict. An intraclass correlation coefficient was used to calculate the overall agreement between the two reviewers.

A quality score was calculated for the selected studies by summing the positive answers. Items E and/or G were only answered if respectively D and/or F were scored negatively. The maximum attainable score was 9.

Table 4.2. Methodological quality list.

A	Was the treatment allocation randomized?	+ / - / ?
B	Was the treatment allocation concealed?	+ / - / ?
C	Was the outcome assessor blinded to the intervention?	+ / - / ?
D	Were the groups similar at baseline regarding the most important prognostic indicators?	+ / - / ?
E	If not, were adjustments made in the analysis for differences of prognostic indicators at baseline and/or for confounding variables?	+ / - / ? / n.a.
F	Was a sufficient proportion (≥ 80%) of included patients available for the full length of follow-up?	+ / - / ?
G	If not, was selective loss to follow-up excluded?	+ / - / ? / n.a.
H	Was an intention-to-treat analysis included?	+ / - / ?
I	Were co-interventions avoided or similar?	+ / - / ?
J	Were the outcome measures suitable to measure clinically relevant differences in treatment effects?	+ / - / ?
K	Was the duration of follow-up adequate to measure clinical differences between treatments (≥ 1 year)?	+ / - / ?

+ = positive/yes; - = negative/no; ? = unclear; n.a. = not applicable.

Data extraction

Using standardized forms, two reviewers (MS and JCW) independently extracted data from the selected studies on characteristics of the study population, description and standardization of interventions, outcome measures and results.

Data analysis

Extraction of results focused on obtaining risk ratios and their respective confidence intervals for dichotomous data or means (or median scores) with standard deviations, and differences in means (or median scores) and their confidence intervals for continuous outcomes. When not given, these descriptive data were calculated if sufficient data were available. The intention was to perform a quantitative analysis (meta-analysis). However, because of the diversity in outcome measures among the included studies and the different and sometimes incomplete presentation form (median scores, mean scores, relative risk ratios), meta-analysis was not possible. Efforts to retrieve raw data or means and their standard deviations in order to compute effect sizes by contacting the authors of the different articles were unsuccessful. We therefore chose to summarize the results by means of a qualitative analysis (best-evidence synthesis). Guidelines for systematic reviews from the Cochrane Collaboration Back Review Group were used.[38] The best-evidence synthesis was modified for purposes of this review, based on the method presented in another systematic review (Table 4.3).[32]

Studies were considered to be methodologically high-quality when at least seven items scored positively; the labels medium-quality and low-quality were assigned when respectively four-to-six or zero-to-three items scored positively.

Table 4.3. Best-evidence synthesis.

Strong evidence	Provided by consistent,† statistically significant findings in outcome measures in at least two high-quality RCTs*
Moderate evidence	Provided by statistically significant findings in outcome measures in at least one high-quality RCT* or Provided by consistent,† statistically significant findings in outcome measures in at least two medium-quality RCTs*
Limited evidence	Provided by statistically significant findings in at least one medium-quality RCT* or Provided by consistent,† statistically significant findings in at least two low-quality RCTs*
No or insufficient evidence	If results of eligible studies do not meet the criteria for one of the levels of evidence listed above, e.g. no statistically significant findings or In case of conflicting (statistically significant positive and statistically significant negative) results among RCTs or In case of no eligible studies

† Findings are considered consistent if they point in the same direction.
* If the number of studies showing evidence is lower than 50% of the total number of studies found within the same category of methodological quality, we state no evidence.

RESULTS

Study selection

The PubMed search resulted in a list of 162 citations (Table 4.1). One more citation was found in the Cochrane Register. No other studies were identified through the Embase or PEDro databases, by either hand-searching or citation tracking. One hundred and fifty-five articles were excluded on title and/or abstract (Figure 4.1). Eight articles were retrieved for a more detailed evaluation. Next, two RCTs were excluded, for reasons of poster presentation and commentary. Six articles describing four RCTs met our inclusion criteria.[4,5,15,16,27,28]

Two[4,5] articles were related to the same trial, one reporting on long-term outcomes (2.5 year follow-up). Only the short-term results were used for the best-evidence synthesis, given that the long-term outcomes were analyzed as a prognostic cohort study rather than an RCT, and contained changes in methodology and analysis that hampered use of these data for the present review.

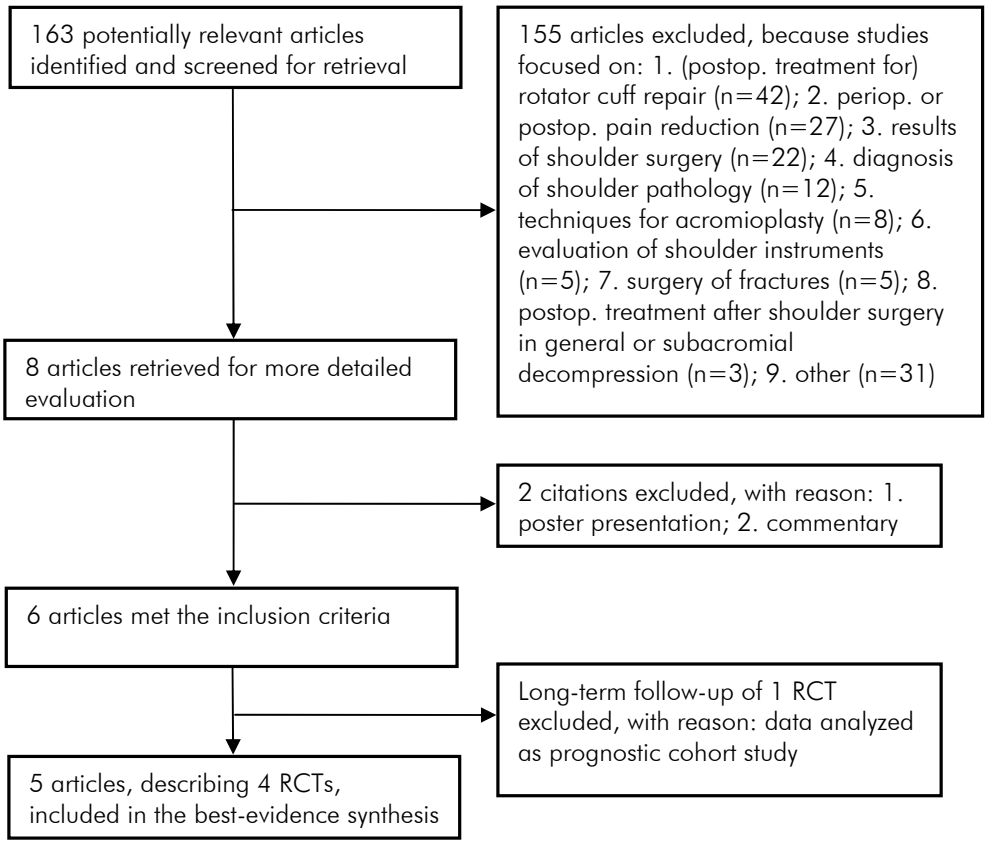

Figure 4.1. Flow diagram of included studies.

Methodological quality

The results of the quality assessment are presented in Table 4.4. The quality scores of the four trials ranged from 2 to 6. When using our cut-off points for quality, two trials were classified as medium-quality and two as low-quality (Table 4.5).

The overall agreement between the two reviewers for the 11 items applied to the four trials was quite good (Cohen's kappa coefficient 0.66 ± 0.09 (SE)). Disagreements between the two observers arose in one trial for item D[27], in one trial for item F[4,5], in three trials for item I[15,16,27,28] and in three trials for item J.[4,5,27,28] After the consensus meeting, in 56% of these items consensus between the two reviewers resulted in unclear.

Table 4.4. Results of the methodological assessment of all included randomized controlled trials, ranked by the number of validity criteria for which bias was considered unlikely.

Reference / *Item*	Haahr (2005/6)	Brox (1993)	Rahme (1998)	Peters (1997)
A (allocation randomized?)	+	+	+	?
B (allocation concealed?)	+	?	?	?
C (assessor blinded?)	-	+	?	?
D (groups similar?)	+	-	?	?
E (if not, adjustments analysis?)	n.a.	+	n.a.	n.a.
F (sufficient proportion of follow-up?)	+	+	+	-
G (selective loss to follow-up excluded?)	n.a.	n.a.	-	n.a.
H (intention-to-treat?)	+	+	-	+
I (co-interventions similar/avoided?)	?	+	?	?
J (outcome measures suitable?)	?	?	-	?
K (duration follow-up suitable?)	+	-	+	+
Quality score (sum "+" (%))	6 (67)	6 (67)	3 (33)	2 (22)

+ = positive/yes; - = negative/no; ? = unclear; n.a. = not applicable.

Data extraction and analysis

Table 4.5 presents the characteristics of the selected studies, including a description of interventions, population characteristics, treatment effect, follow-up period and study quality. All studies randomized participants between a physiotherapeutic regime and a subacromial decompression. A similarity of all the physiotherapeutic regimes applied was the focus on strengthening the rotator cuff (and the scapular stabilizing) muscles. In one trial[4,5], participants started with relaxed repetitive movements, in another[16] with application of heat, cold packs or soft-tissue treatments. In one study[28], strength training followed education about the shoulder problem and unloaded movements. In the last trial[27], participants in the conservative group were hospitalized for two weeks, in contrast to the other studies. During this period the participants received intensive physiotherapy training supported with NSAIDs and corticosteroid injections. One trial[4,5] had added a placebo group.

In the presented studies, the majority of the participants improved through either conservative treatment or surgery. In one study[16] the physiotherapy group improved 23.0 (16.9 to 29.1 (CI)) in mean Constant score (range 0-100) from 34.7 (2.2 SME) at baseline; the surgery group improved 18.8 (11.5 to 26.1) from 33.7 (2.3 SME). In another RCT[5] the median Neer score at entry was 67.5 for the physiotherapy group, 64.0 for the surgery group and 65.5 for the placebo group. After six months of follow-up the median scores had improved to 86.0, 87.0 and 66.0, respectively. The third RCT[28] did not report absolute scores, but presented proportions of "successes" versus "failures". Patients with a reduction greater than 50% in the initial pain score using the visual analogue scale technique were classified as a successful outcome. In the last RCT those patients who were operated on improved from 54 at baseline to 84 on the Subjective Shoulder Rating Scale, and the conservatively treated patients improved from 59 to 74. No additional statistical analyses were performed. The differences between conservative treatment and surgery were small for outcomes in both shoulder function and pain (Table 4.5). There were no statistically significant differences in treatment effect between the intervention groups for any of the studies.

Only one trial reported a significant improvement in Neer score for both surgery and exercise when compared to the placebo group.[5] In two trials, minimal scores were assigned to participants who left the exercise groups to be operated on.[4,28] Treatment effects were calculated by using these scores, incorrectly calling this an intention-to-treat analysis. By doing this, a significantly better outcome in VAS scores for surgery compared to physiotherapy was reported in one study.[28] Because of dubious data analysis, these specific results were excluded from the best-evidence synthesis. Four trials, two[5,15,16] with a medium and two[27,28] with a low quality, were left to be summarized with the synthesis. None of these studies resulted in significant differences in treatment effects between the treatment groups. Therefore, according to the best-evidence synthesis (as presented in Table 4.3) there is no evidence from the available RCTs for differences in outcome in pain and shoulder function between conservatively- and surgically-treated patients with SIS.

Table 4.5. Summary of characteristics of selected studies.

Study	Interventions (number of patients)	Population characteristics	Treatment effect[#] (95% CI)	Follow-up	Study quality
Haahr (2005/6) [20]	1. Arthroscopic subacromial decompression (41)	1. f/m: 29/12; mean age: 44.3 (SEM 1.3); DoC: < 6 months: 4; 6-12 months: 3; > 1 year: 34	Constant score$_{(12\ months)}$ (0-100), mean change (CI): 1. 18.8 (11.5 to 26.1); 2. 23.0 (16.9 to 29.1) SMD = -0.003 (-0.010 to 0.004) PRIM score$_{(4-8\ years)}$ (0-36), mean change (CI): 1. 9.1 (5.5 to 12.6); 2. 11.4 (8.7 to 14.11) SMD = 2.4 (-2 to 6.8) No differences between groups.	12 months / 4-8 year	Medium (67%)
	2. Supervised exercises (43)	2. f/m: 29/14; mean age: 44.5 (SEM 1.2); DoC: < 6 months: 3; 6-12 months: 10; >1 year: 29			
Brox (1993) [8]	1. Arthroscopic subacromial decompression (45)	1. f/m: 16/29; mean age: 48; DoC: < 6 months: 8; 6-12 months: 8; 1-3 years: 9; > 3 years: 20	Neer shoulder score (0-100), median change: 1. 23 †; 2. 18,5 †; 3. 0.5 † (p<0.001) Difference in median Neer score between active treatments: 4 (-2 to 11) Difference in median for pain between active treatments: - upon activity: 0 (-1 to 1) - at rest: 0 (-1 to 1) - at night: 0 (-1 to 2) Significant improvement in median Neer Score for groups 1 and 2 compared to placebo group. No differences between active groups.	6 months	Medium (67%)
	2. Supervised exercises and education (50)	2. f/m: 28/32; mean age: 47; DoC: DoC: < 6 months: 6; 6-12 months: 6; 1-3 years: 13; > 3 years: 25			
	3. Detuned soft laser treatment (30)	3. f/m: 15/15; mean age: 48; DoC: < 6 months: 5; 6-12 months: 5; 1-3 years: 5; > 3 years: 14			
Rahme (1998) [35]	1. Open subacromial decompression (21) ± rotator cuff repair (5)	1. & 2.: f/m 23/19; mean age: 42 (range 28-63); DoC: almost 4 years on average	Success for treatment received (reduction VAS >50%): group 1: 16/21 (76%; $RR_{1\rightarrow 2A}$= 1.1; $RR_{1\rightarrow 2B}$= 1,1) group 2A: 4/6 (67%) group 2B (operated on): 7/12 (58%) No differences between groups. When those who were operated on or were lost to follow-up in group 2 were considered as failed; success for group 2C: 4/21 ($RR_{1\rightarrow 2C}$=4; p<0.0005). These data were excluded from the synthesis.	12 months	Low (33%)
	2. Physiotherapy and education (18)				
Peters (1997) [34]	1. Open (n=17) or arthroscopic (n=15) subacromial decompression	1. f/m: 14/18; mean age: 56 (range 37-78); DoC: not given	Differences between groups not given. No statistical analysis for significance performed. Differences between median scores at baseline and at maximum follow-up for Subjective Shoulder Rating Scale: Group 1: 30 † Group 2: 15 †	48 months	Low (22%)
	2. Two-week hospital stay: physiotherapy supported with NSAIDs and corticosteroid injections (40)	2. f/m: 12/28; mean age: 59 (range 37-82); DoC: not given			

Abbreviations used: f/m: female-male-ratio; DoC: duration of complaints; SEM: standard error of the mean; SMD: standardized mean difference; PRIM: Project on Research and Intervention in Monotonous Work (pain and dysfunction); VAS: visual analogue scale; $RR_{1\rightarrow 2}$: relative risk for group 1 compared to group 2; # Treatment effects according to intention-to-treat analysis, unless stated otherwise; † Confidence interval could not be computed due to missing data.

DISCUSSION

Failed conservative treatment of SIS is often followed by surgery. This systematic review was designed to determine if the results of surgery for SIS are better than those of conservative treatment in terms of improvement of shoulder function and reduction of pain.

Validity of the trials

The results of this review should be interpreted with caution. No confident conclusion can be made based on the available results. However, according to the best-evidence synthesis it must be concluded that there is no evidence from RCTs for differences in outcome in pain and shoulder function between conservatively- and surgically-treated patients with SIS. This conclusion is based on a relatively small group of patients (N=323) in a small number of trials (N=4) with just low-to-medium quality.

The studies failed to reach a high-quality classification because most did not score positively on items B ("treatment allocation concealed?"), C ("outcome assessor blinded?"), D ("groups similar at baseline?"), I ("co-interventions similar?") and J ("outcome measures clinically relevant?").

In the quality assessment, most of the discussion concerned item J ("Were the outcome measures suitable to measure clinically relevant differences in treatment effects?"). As outlined in an extensive review on shoulder disorders, there is no gold standard that provides a valid and reliable estimate for clinically relevant changes in any subgroup of patients with shoulder disorders.[34] In the literature, few studies can be found describing validity, reproducibility, responsiveness or interpretability of the outcome measures used in the presented trials.

Item I ("Were co-interventions avoided or similar?") also led to discussion because it was not always described clearly in the articles. The same goes for item B ("Treatment allocation concealed?"). Several studies show empirical evidence that inadequate concealment of treatment allocation is associated with bias.[7,20,30] An inadequate description of randomization procedures does not automatically mean bias was present, but it cannot be excluded.

Another potential source of bias was caused by the way the data analysis was done. Two studies incorrectly transformed their data for an intention-to-treat analysis, which violates the principles of the method. The actual outcome scores should have been used for the patients in the conservative group who had been operated on, instead of assigning them the lowest available score as if they had failed. The intention-to-treat approach is often inadequately applied, which has also been noted in a survey of RCTs published in four major medical journals.[17] This inadequate use of the intention-to-treat approach is a potential source of bias.

Furthermore, bias could have been caused by the differences in treatments between the intervention and the control groups. Blinding the care provider and the participant to the intervention can prevent such bias, but this would not have been possible in the presented RCTs.

Another important aspect is the heterogenity of treatments of the different studies, which makes it difficult to compare them. Two trials performed subacromial decompressions using an arthroscopic technique[4,5,15,16], in one open surgery was used[28], and in another both were used.[27] Although both methods seem to result in adequate subacromial decompression[23,24,27], according to some studies the arthroscopic method seems to have an earlier restoration in active range of motion and a more quick return to work.[27,36] In one study co-existent rotator cuff ruptures were also sutured.[28] This of course makes it impossible to do a comparison with results of other studies. Furthermore, in one trial participants in the conservative group were hospitalized for two weeks.[34] This is not and will not become a common treatment method, due to its significant economic health implications.

Most participants in these RCTs had symptoms longer than a year and were resistant to previous conservative treatment, and therefore were probably in favour of being assigned to surgery because the previous conservative treatment was not effective on them. This might have led to a source of bias for the surgery groups. By contrast, high expectations of surgery can lead to disappointing results, even more when there are side effects (e.g. postoperative stiffness of the shoulder). Despite these possible biases this did not result in significant differences between the study groups.

All four trials together scored 17 times positively, 14 times unclear, seven times negatively and six times not applicable for the different items in the methodological assessment (a total of 44). Although for practical reasons certain methodological concessions can be made (e.g. not blinding an outcome assessor), a great gain in quality could be achieved by a clear and full presentation of the study design.

Effectiveness of treatment

No confident conclusion can be made based on the results available. The RCTs included in this review failed to provide evidence for differences in outcome between conservatively- and surgically-treated patients with SIS. Whether this failure is due to impairments in methodological quality or a lack of difference in treatment outcome remains unclear. For several decades, patients suffering from SIS were operated on when conservative treatments failed. In that respect, observational studies have reported satisfactory results in 67–90% of such patients.[18,29,31,37] However, the results of this review show that no conclusion can be made as to whether surgery is better than conservative treatment.

Limitations

A major limitation of this review is that there are only four RCTs concerning such a common shoulder disorder like SIS. A possible explanation for this could be that patients chronically suffering from SIS do not want to risk being randomized to a nonoperative treatment after extensive previous conservative treatments. Additionally, no data on cost effectiveness of treatments or sick leaves are available from the four RCTs. This information is indispensable for the decision-making process of care providers. For example, in the short term surgery is more expensive than conservative treatments, but it can be more cost-effective than conservative treatments with a shorter patient sick leave.

Recommendations

In order to answer the question of whether surgery for SIS is indeed more effective than conservative treatment, high-quality trials are needed. These trials should use outcome measures which measure improvement of shoulder function and reduction of pain that are valid, reliable and responsive in these study populations. Correct tests, like the impingement test, should be used to diagnose patients suffering from SIS, and strict inclusion and exclusion criteria should be observed to create homogenous study groups. Participants should suffer from a certain minimum severity of SIS to be potentially responsive to the study treatments. Proper power analysis is needed to determine sample size. Follow-up should be at least one year, and it would be important for studies to provide data on cost effectiveness. Furthermore, future trials should also take duration of symptoms into account. There is a trend for an earlier indication for surgery.[3] Several observational studies report a significantly better outcome in operated patients who had not responded to nonoperative measures and who had a short symptom duration compared to those who had prolonged symptoms before surgery[9,26], but so far there are no RCTs focusing on duration of symptoms. Future RCTs on patients suffering from SIS should therefore also investigate the influence of a shorter-than-usual preoperative duration of symptoms compared to usual medical care.

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Chapter 5

A new interdisciplinary treatment strategy versus usual medical care for the treatment of subacromial impingement syndrome: a randomized controlled trial

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ABSTRACT

Background

Subacromial impingement syndrome (SIS) is the most frequently recorded shoulder disorder. When conservative treatment of SIS fails, a subacromial decompression is warranted. However, the best moment of referral for surgery is not well defined. Both early and late referrals have disadvantages — unnecessary operations and smaller improvements in shoulder function, respectively. This paper describes the design of a new interdisciplinary treatment strategy for SIS (TRANSIT), which comprises rules to treat SIS in primary care and a well-defined moment of referral for surgery.

Methods/Design

The effectiveness of an arthroscopic subacromial decompression versus usual medical care will be evaluated in a randomized controlled trial (RCT). Patients are eligible for inclusion when experiencing a recurrence of SIS within one year after a first episode of SIS which was successfully treated with a subacromial corticosteroid injection. After inclusion they will receive injection treatment again by their general practitioner. When, after this treatment, there is a second recurrence within a year post-injection, the participants will be randomized to either an arthroscopic subacromial decompression (intervention group) or continuation of usual medical care (control group). The latter will be performed by a general practitioner according to the Dutch National Guidelines for Shoulder Problems. At inclusion, at randomization and three, six and 12 months post-randomization an outcome assessment will take place. The primary outcome measure is the patient-reported Shoulder Disability Questionnaire. The secondary outcome measures include both disease-specific and generic measures, and an economic evaluation. Treatment effects will be compared for all measurement points by using a GLM repeated measures analyses.

Discussion

The rationale and design of an RCT comparing arthroscopic subacromial decompression with usual medical care for subacromial impingement syndrome are presented. The results of this study will improve insight into the best moment of referral for surgery for SIS.

BACKGROUND

Shoulder disorders are encountered frequently in general practice. In a Dutch study the cumulative incidence of shoulder problems was estimated to be 23.1/1000 patients/year.[1] For the neck and upper extremity it was the most commonly presented musculoskeletal complaint. A differentiation between various diagnoses of shoulder problems in general practice was presented in another Dutch study.[2] Subacromial impingement syndrome (SIS) was the most frequently recorded disorder (44%).

The primary treatment of SIS is conservative. In primary health care a broad spectrum of conservative treatments for SIS is available: rest, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, physiotherapy and manual therapy. In the Netherlands, the choice of treatments for shoulder conditions is proposed by the National Guidelines for Shoulder Problems, published by the Dutch College of General Practitioners.[3] If patients do not respond sufficiently to these nonoperative measures, referral to an orthopedic surgeon for evaluation for (arthroscopic) subacromial decompression is recommended.[4] The best moment of referral is not well defined though, so a therapeutic dilemma for the general practitioner exists: how many different treatments from the spectrum of nonoperative interventions should be repeated or tried out if previous ones have failed? And how long should one wait for recovery before referring? The preoperative duration of symptoms reported in different articles published in the last two decades on surgery for SIS is quite long, ranging from an average of 18 to 40 months.[5-9] Expert opinions advocate orthopedic referral is warranted for patients who do not respond to nonoperative measures after (three to) six months.[10-13] Moreover, several observational studies report a significantly better outcome of surgery in patients who had a short symptom duration compared to those who had prolonged symptoms before surgery.[6,9] From these studies it seems that the moment of referral is crucial. However, approximately 60% of the patients recover within 27 months with nonoperative measures, which has to be taken into consideration.[14] Early surgery would therefore not always be appropriate because patients could recover nonoperatively. On the other hand, late surgery might lead to smaller improvements of shoulder function. To improve insight, we designed an interdisciplinary treatment strategy called TRANSIT (TRANSmural treatment strategy for Subacromial ImpingemenT), which contains rules to treat patients with SIS in primary care and a well-defined moment of referral to an orthopedic surgeon for arthroscopic acromioplasty. The TRANSIT outline for the treatment of SIS will be tested in a randomized controlled trial (RCT), comparing treatment results of participants allocated to arthroscopic subacromial decompression with continuation of usual medical care by the general practitioner. The present paper reports on the content of TRANSIT and the methodological design of this RCT.

METHODS/DESIGN

Study design

The study is designed as a randomized controlled trial to evaluate the effectiveness of a new interdisciplinary treatment strategy for SIS. Figure 5.1 presents the design. The Medical Ethics Committee of University Medical Center Groningen has approved the study design, the protocols and the informed consent procedure. Participants are assigned at random to the control or to the intervention group. The follow-up period after randomization is 12 months.

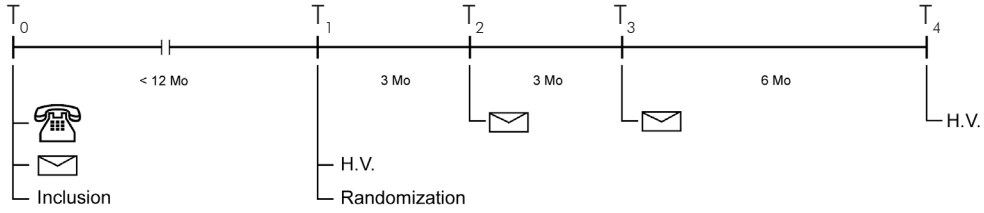

Figure 5.1. Study design and follow-up procedures.

Follow-up procedures. At T_0, potential participants are contacted by phone. After informed consent is received, patients are included. At T_0, T_2 and T_3 questionnaires will be returned by mail. At T_1 and T_4 participants visit the hospital (H.V.).

TRANSIT: an interdisciplinary strategy

Initially, TRANSIT follows the National Guidelines for Shoulder Problems to diagnose and treat patients with SIS.[3] For all new patients, treatment starts with NSAIDs. If results following a maximum of two weeks of treatment are insufficient, therapy is continued with a subacromial corticosteroid injection. When ineffective, this injection is repeated within one month. In case of recurrence within 12 months after the first successful subacromial injection, eligible patients (see "selection of participants") are asked to participate in the study. Recurrence means patients having pain again, having increased pain or no longer experiencing pain relief. Included patients will receive another subacromial injection from their general practitioner, which if necessary can be repeated within one month. In case of a second recurrence within 12 months after the last successful injection, participants will be randomized to either an arthroscopic subacromial decompression performed within four weeks or continuation of treatment by the general practitioner according to the National Guidelines for Shoulder Problems. Participants who have a recurrence more than 12 months after the last injection will not be randomized. Patients who do not respond to two injections within one month will not be included either. Their long preoperative duration does not fit within the concept of this study, in which participants have surgery after an on average shorter-than-usual duration of symptoms.

For both NSAIDs and subacromial corticosteroid injections there is evidence of their effectiveness for SIS, albeit for the short term (up to a nine-month period).[15,16]

The reason for repeating a subacromial injection within a month in case of ineffectiveness is to target inaccuracy of subacromial injections. Several studies have reported on accuracy rates, ranging from 60 to 80%.[17-20] In addition to being a treatment, the subacromial injection constitutes a diagnosis itself (Neer impingement test).[13] The injection fluid is a mixture of a corticosteroid and a local anesthetic (lidocaine). When a subacromial injection eliminates the pain immediately (as a result of the injected lidocaine), it confirms the diagnosis of SIS. If the injection does not eliminate the pain immediately, the diagnosis might be wrong or the injection could have been placed inaccurately. Furthermore, a positive reaction on a subacromial injection predicts better patient recovery following arthroscopic subacromial decompression compared to patients who have a negative reaction but a confirmed diagnosis through imaging.[21]

Setting

The trial is carried out in 50 general practices within an area of 20 kilometers from University Medical Center Groningen (UMCG) and at the Department of Orthopedic Surgery of UMCG. A total of 160 general practices in the surrounding area of Groningen were sent letters inviting them to participate in this study. Forty interested general practitioners attended an information meeting about the study protocol. Following a standard protocol, they were instructed in injecting into the subacromial space, which they subsequently practiced on phantoms and fresh-frozen cadaver shoulders. Another 10 general practitioners who could not attend the meeting were visited at their practice to be informed about the trial.

Study population

Sample size

The aim is to include 70 participants in the study. This number is based on the assumption that one year after randomization 50% of the participants will have recovered with conservative treatment[22,23] and 85% will successfully recover by means of arthroscopic subacromial decompression. The latter assumption is based on recovery rates presented in earlier studies in which successful results of arthroscopic subacromial decompression are reported in 86 to 95% of the cases.[24-26] A power analysis has been based on the effects of these treatments on shoulder function. In this study shoulder function will be measured with the Shoulder Disability Questionnaire, which is an outcome measure comparable to the instruments used in the referred articles. In order to detect a clinically relevant difference in shoulder function (35% differences in means) one year after randomization between the intervention and control group, 64 participants are needed — 32 in each group. These numbers are based on a power (1-B) of 0.80 and a significance level of 5% (two-sided). When a dropout rate of 10% is taken into account, 70 participants are to be included.

Selection of participants

Subjects participating in the study are recruited by the general practitioners involved. They introduce the study to patients who seem eligible and give interested patients a

brochure about the trial, to be read at home. After having received consent, the general practitioners fax the name and telephone numbers of the interested patients to the research team. Subsequently the researcher calls the interested patients within one week. During this conversation the aim and implications of the study are explained again and the eligibility criteria are checked. Patients are eligible for participation when they meet the inclusion and exclusion criteria presented in Table 5.1.

If patients meet these criteria and wish to join the study, an informed consent form is signed before participation begins. The new participants receive another subacromial corticosteroid injection from the general practitioner for treatment of their first recurrence. If ineffective, this injection will be repeated within one month. Participants who have a recurrence of problems within one year after the last injection will contact their general practitioner, who will inform the researcher by fax. Subsequently the participant will be invited to visit the researcher at UMCG for a physical outcome measurement and to be randomized to one of the two treatment groups. Participants who do not have a recurrence within one year will not be randomized.

Table 5.1. Patient eligibility criteria.

Inclusion criteria:
1. Pain upon abduction of the shoulder with painful arch;
2. Shoulder pain as a recurrence of an episode with a maximum duration of 12 months in which a partial or good response is achieved with subacromial corticosteroid injection(s);
3. A maximum duration of six months of shoulder problems prior to the first subacromial injection, possibly treated with non-steroidal anti-inflammatory drugs (NSAIDs) and/or physiotherapy;
4. No shoulder problems for at least two years prior to the current episode of shoulder pain;
5. Men and women, aged between 30 and 60 years;
6. Being able to give an informed consent.
Exclusion criteria:
1. Shoulder girdle pain;
2. Shoulder pain not based on pain upon abduction of the shoulder;
3. Signs of cervical root compression;
4. Bilateral shoulder pain;
5. Secondary subacromial impingement;
6. Presence of specific rheumatic diseases;
7. History of severe trauma of the shoulder within the previous two years (e.g. fracture, luxation);
8. History and/or clinical symptoms of a large rotator cuff tear;
9. Previous surgery of the affected shoulder;
10. Extrinsic causes of shoulder pain;
11. Presence of dementia or other psychiatric disorders;
12. Not being able to fill in questionnaires in Dutch.

Randomization

Participants will be block-randomized into two groups: surgery or usual medical care. Subsets of four participants are made per participating general practitioner. Two participants will be assigned to the treatment group and two to the control group. This process is repeated as the trial progresses. Block randomization is a method used to prevent unequal treatment-group sizes.[27] In this study, this method is used to ensure more or less equal treatment groups per general practitioner. It prevents participants referred by one single general practitioner from being all treated according to usual medical care or surgery.

Sealed, opaque envelopes in subsets of four per general practitioner are used for randomization. The envelopes look identical and have identification for the referring general practitioner as well as a sequential number for the subset. A random sequence of envelopes is generated by an independent person. The participants choose one envelope under supervision of the researcher.

Interventions

The treatments the two study groups are assigned to are not different from those in usual medical care. The only difference is that the surgery group, in most cases, will have an operation after a shorter preoperative duration of symptoms compared to patients who fail to respond to conservative measures in usual medical care.

The operative treatment is an arthroscopic subacromial decompression performed within four weeks after randomization. Preoperatively no imaging will be performed, except for a shoulder radiograph. This is because the positive reactions to the previous injections have confirmed the SIS diagnosis. The operation is carried out in day surgery under general anesthesia, possibly extended with a regional nerve block for postoperative pain reduction. During the operation the patient is in a beach-chair position. The arthroscopy starts with an inspection of the glenohumeral joint, the intra-articular surface of the rotator cuff and the biceps tendon. Then the endoscope is introduced in the subacromial bursa. Subsequently the treatment consists of a bursectomy with partial resection of the anteroinferior part of the acromion and the coracoacromial ligament. If seen, tears of the rotator cuff will be noted but not repaired – the reason being that there is little evidence to either support or refute the efficacy of common interventions for rotator cuff tears.[28] Therefore, an ongoing discussion exists as to whether to operate on tears of the rotator cuff. As most rotator cuff tears are caused by degeneration, which is confirmed by histochemical and morphometrical research[29], an operation consisting of suturing degenerated tissue is not expected to be effective in the long term because of the ongoing process of postoperative degeneration and the associated risk of retears.[30,31] In this study, all participants have a painful arc syndrome and a positive impingement test. These patients can have a partial thickness rotator cuff tear, or in the worst case a small full-thickness rotator cuff tear. Any patients with a history and clinical symptoms of a massive rotator cuff tear (i.e. an inability to reach overhead, lift with an outstretched arm, and an impairment of pushing and pulling) will be excluded. As the outcome measures of this study focus on pain and functioning of the shoulder and not on the integrity of the rotator cuff, the extent of the damage, on the

continuum from no tear to a small full-thickness tear, has no consequences for the study groups.
One senior surgeon (RLD) will undertake all procedures. Before discharge the participant receives a sling and instructions for daily pendulum exercises. Two weeks post- surgery the participant visits the clinic for wound inspection. New instructions will follow for home training exercises which focus on increasing the range of motion of the shoulder. Four weeks later the participant may start exercises for strengthening the rotator cuff muscles. If indicated, physiotherapy can be part of the rehabilitation process.

The group randomized to continuation of usual medical care will receive treatment prescribed by the general practitioner according to the Guidelines for Shoulder Problems of the Dutch College of General Practitioners.[3] In primary health care a broad spectrum of conservative treatments for subacromial impingement syndrome is available: rest, nonsteroidal anti-inflammatory drugs, corticosteroid injections, physiotherapy and manual therapy. If needed, the general practitioner can also refer the participant to a hospital of random choice for further assessment and/or to be evaluated for surgery.

Outcome assessment

At inclusion (T_0), at randomization (T_1) and at three (T_2), six (T_3) and 12 months (T_4) post-randomization, outcome assessment will take place in both study groups (Table 5.2). At all measurement points, outcome will be assessed by means of questionnaires which are sent to the participants by mail three days earlier. At T_1 and T_4 the participants are asked to visit the researcher at UMCG for an additional physical assessment. The questionnaires addressing those measurement moments can be filled in at home and be handed in at the patient's visit. The researcher checks all questionnaires for missing or incorrect data.

The outcome measures used focus on shoulder function, pain and health-related quality of life. They are disease-specific or generic, and from a patient- or physician-based perspective. The following applied measures are disease-specific and patient-based: the Shoulder Disability Questionnaire, the Shoulder Pain Score and the Shoulder Rating Questionnaire. The Individual Relative Constant Score is a disease-specific as well as a patient- and physician-based instrument. The Short-form 36 Health Survey and the Patient-perceived recovery are both generic and patient-based. For the cost effectiveness analysis a generic, patient-based questionnaire will be used. The specific characteristics of the outcome measures will be mentioned below.

Table 5.2. Follow-up measurements.

Outcome measures	T_0	T_1	T_2	T_3	T_4
SDQ	+	+	+	+	+
SPS	+	+	+	+	+
SRQ	+	+	+	+	+
PPR		+	+	+	+
SF-36		+			+
Cost effectiveness		+		+	+
IRCS		+			+

Abbreviations used: SDQ - Shoulder Disability Questionnaire; SPS - Shoulder Pain Score; SRQ - Shoulder Rating Questionnaire; PPR - Patient-perceived recovery; SF-36 - Short-form 36; IRCS - Individual Relative Constant Score.

Primary outcome measure

Shoulder Disability Questionnaire (SDQ)

The SDQ is a 16-item measure for functional status limitation in patients with shoulder disorders and assesses the past 24 hours.[32] The 16 questions can be answered with either yes, no or not applicable. The score is calculated by multiplying the yes/no ratio by 100.

Secondary outcome measures

The Individual Relative Constant Score

This shoulder assessment score is a modification of the Constant-Murley shoulder score, in which patient-reported subjective assessment and objective measurement of shoulder function takes place at a ratio of 35:65.[33] The system is divided into subjective measures for pain and daily activities and objective measures for range of motion (max. 75 points) and power (max. 25 points). The modified score contains the same items as the original score, but uses the functional performances of the uninjured collateral shoulder of the same individual as a reference.[34] It is expected to be more reliable for larger and incoherent patient populations because specific interindividual differences regarding the patient's age, gender and constitution as well as other individual physiological parameters are eliminated.

Shoulder strength measurement, which is a part of the Constant score, is performed according to a standard method, as proposed by Bankes et al.[35] A digital dynamometer, the Handyscale®, is used and validated for this application.[36] It measures a maximum of 15 kilograms with two decimals and an interval of 20 grams. The test position is the subject standing with the arm in 90° elevation in the scapular plane,

elbow extended and forearm pronated. An adjustable strap is placed around the forearm just proximal to the radiocarpal joint and attached to the Handyscale®. The dynamometer is firmly attached to a solid surface. The subjects are instructed to pull upward with maximum effort until requested to stop. The reading of the dynamometer is taken after five seconds of maximum effort. For both the uninjured and the affected arm, three successive maximum pulls will be obtained. The highest value out of these three provides the strength score for each arm. Patients unable to reach the test position will receive the value of zero. The scores for strength assessment in the Constant-Murley score range from zero to 25 pounds, hence to calculate the individual relative strength score the ratio of the maximum strength scores of the affected and the unaffected arm is multiplied by 25.

The scores for the other individual parameters range from zero to 75 points. To calculate the individual relative sum score for these items, the ratio of these scores for the affected and the unaffected arm will be multiplied by 75. The individual relative Constant score is calculated by adding the individual relative strength score and the individual relative sum score. The maximum attainable score is 100 points.

The Shoulder Pain Score (SPS)

The SPS is a questionnaire to assess pain experienced by patients with shoulder disorders and includes a 24-hour recall frame.[37] The score consists of six pain symptom questions and a 101-Numerical Rating Scale (NRS-101). The SPS has been proved to be a useful instrument for following the course of the disorder over time, and gives an indication when a patient feels cured. Each question receives a maximum of four points. The NRS-101 is also transposed to a four-point scale (0-9 = 1, 10-39 = 2, 40-69 = 3 and 70-100 = 4). The minimum SPS score is seven points, the maximum score 28.

Shoulder Rating Questionnaire (SRQ)

The SRQ is a self-administered patient-based instrument which assesses shoulder function in 19 multiple-choice questions covering seven domains.[38,39] Five subscales are graded separately by averaging the scores of the completed questions, multiplied by two and a weighting factor. The SRQ comprises two additional dimensions compared to the SDQ: recreational and athletic activities and work. The sum scores range from minimum 17 to maximum 100 points.

Short-form 36 Health Survey (SF-36)

The SF-36 is a generic health status measure. It is composed of 36 questions and standardized response choices, organized into eight multi-item scales: physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and general mental health.[40,41] For purposes of this study we used the standard version of the questionnaire, covering a four-week time frame. All raw scale scores are linearly converted to a zero-to-100 scale, with higher scores indicating higher levels of functioning or well-being.

Patient-perceived recovery (PPR)

In addition to the SF-36 there is the PPR, a one-item score concerning recovery following treatment, measured on a seven-point ordinal scale.[42]

Cost effectiveness

An economic evaluation will be performed using a questionnaire to assess direct health care costs as well as direct non-health related costs. The questionnaire is composed of 24 questions regarding costs of the last six months. The data will be used for a cost-effectiveness analysis, which will be done by the UMCG Medical Technology Assessment office.

Statistical Analyses

To estimate the effect of the interventions, analyses will be performed using SPSS 12.0 for the outcome measures. The baseline characteristics from both study groups will be compared for equality by means of an Independent Samples T-test ($P<0.05$) for continuous variables and a chi-square test for dichotomous variables. To compare treatment effects from measurement points T_0 to T_4, a GLM repeated measures analyses will be performed. Data will be analyzed according to the intention-to-treat principle and the per-protocol principle.

DISCUSSION

TRANSIT is designed to test if early referral for surgery leads to earlier and more complete improvement in shoulder pain and function than continuation of usual medical care for patients suffering from SIS. This has been advocated in expert opinions, but has never been proven in a randomized controlled trial.

The results of this study will improve insight into the best moment of referral for surgery for SIS. If, in the TRANSIT outline, participants who have had an arthroscopic subacromial decompression prove to have better results than those who continued with usual medical care, a future update of Dutch and/or international guidelines for shoulder conditions will be needed.

The rationale and design of an RCT comparing a new interdisciplinary treatment strategy with usual medical care for subacromial impingement syndrome have been presented.

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Chapter 6

Arthroscopic acromioplasty versus usual medical care for the treatment of subacromial impingement syndrome: a randomized controlled trial

A new interdisciplinary strategy

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Submitted

ABSTRACT

Background

The best moment of referral for surgery of patients with subacromial impingement syndrome (SIS) unresponsive to nonoperative measures is not well-defined. To improve insight, we designed an interdisciplinary treatment strategy (TRANSIT) which contains rules for treatment in primary care and a well-defined moment of referral for arthroscopic acromioplasty. TRANSIT was tested in a randomized controlled trial in which the control treatment consisted of continuation of usual medical care (UMC). (Cost)effectiveness was examined with a follow-up period of one year.

Methods

Primary outcome was functional status limitation (Shoulder Disability Questionnaire). Treatment effects were compared for all measurement points (at randomization and three, six and twelve months thereafter) by using a repeated-measures design. Data were analyzed according to the intention-to-treat principles.

Results

Twenty-six patients were randomized: 11 received UMC and 15 TRANSIT. Medium- and long-term adverse events were significantly more present in TRANSIT. Both groups had a clinically significant improvement in functional status limitation one year post-randomization. There were no statistically significant differences in means between the groups over time, except for functional status limitation six months post-randomization in favor of TRANSIT. In addition TRANSIT was significantly more costly than UMC.

Conclusions

These data do not justify the conclusion that early operation is beneficial over continuation of UMC. The small sample size and the significance of the adverse events in TRANSIT might have precluded statistical significance at one year follow-up. The great discrepancy of health care costs underscores the need to determine factors that predict which patients benefit most from surgery.

INTRODUCTION

Shoulder pain can be a debilitating condition and is commonly chronic and recurrent.[38,46] In general practice subacromial impingement syndrome (SIS) is the most frequently recorded disorder (44%) amongst various diagnoses of shoulder problems.[39] This syndrome can incur significant medical costs when surgery is needed.[7,21,23] Also, since the syndrome frequently occurs at ages below 65, it is associated with productivity loss.[11]

Primary treatment of SIS is conservative. In the Netherlands, the choice of treatments for shoulder conditions is proposed by the National Guidelines for Shoulder Problems, published by the Dutch College of General Practitioners.[44] The following conservative treatments are available: rest, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, physiotherapy and manual therapy. If patients do not respond sufficiently to these nonoperative measures, referral to an orthopedic surgeon to evaluate for (arthroscopic) subacromial decompression is recommended.[30] The best moment of referral is not well-defined though, so a therapeutic dilemma for the general practitioner (GP) exists: how many different treatments from the spectrum of nonoperative interventions should be repeated or tried out if previous ones have failed? And how long should one wait for recovery before referring?

The preoperative duration of symptoms reported in different articles on surgery for SIS published in the 20 years is quite long, ranging from an average of 18 to 40 months.[3,11,15,19,23,33] Expert opinions advocate orthopedic referral is warranted for patients who do not respond to nonoperative measures after three to six months.[1,5,6] Moreover, several observational studies report a significantly better outcome of surgery in patients who had a short symptom duration than those who had prolonged symptoms pre-surgery.[11,33] From these studies it seems that the moment of referral is crucial. Approximately 55% of patients fully recover within 24 months with nonoperative measures, which has to be taken into consideration.[10] Early surgery would therefore not always be appropriate because patients could recover nonoperatively. On the other hand, late surgery might lead to smaller improvements of shoulder function. To improve insight, we designed an interdisciplinary treatment strategy called TRANSIT (TRANSmural treatment strategy for Subacromial ImpingemenT) that contains rules to treat patients with SIS in primary care and a well-defined moment of referral to an orthopedic surgeon for arthroscopic acromioplasty.

The objective of this study was to compare the effectiveness of TRANSIT with that of continuation of usual medical care by the GP, testing this in a randomized controlled trial. Our main research questions were: 1. Is TRANSIT more effective than continuation of usual medical care for treatment of SIS in terms of reduction of functional status limitation? 2. Is the well-defined moment of arthroscopic acromioplasty beneficial in the treatment of SIS? 3. Is TRANSIT more cost-effective than continuation of usual medical care in terms of direct health care costs and direct/indirect non-health-care-related costs?

At the second injection episode patients were called to check the eligibility criteria. At T_0 and T_3 participants visited the hospital (H.V.), and at T_1 and T_2 questionnaires were returned by mail.

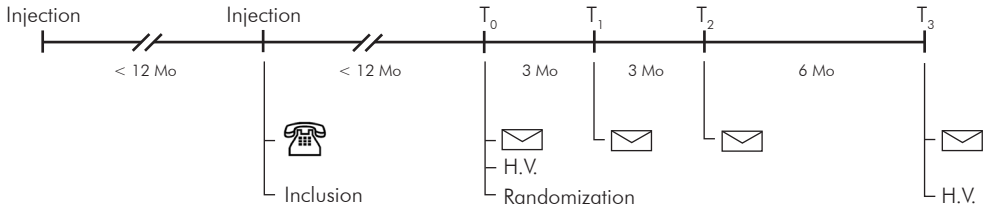

Figure 6.1. Study design and follow-up procedures.

Table 6.1. Patient eligibility criteria.

Inclusion criteria:
1. Pain upon abduction of the shoulder with painful arch;
2. Shoulder pain as a recurrence of an episode with a maximum duration of 12 months in which a partial or good response is achieved with subacromial corticosteroid injection(s);
3. A maximum duration of six months of shoulder problems prior to the first subacromial injection, possibly treated with non-steroidal anti-inflammatory drugs (NSAIDs) and/or physiotherapy;
4. No shoulder problems for at least two years prior to the current episode of shoulder pain;
5. Men and women, aged between 30 and 60 years;
6. Being able to give an informed consent.
Exclusion criteria:
1. Shoulder girdle pain;
2. Shoulder pain not based on pain upon abduction of the shoulder;
3. Signs of cervical root compression;
4. Bilateral shoulder pain;
5. Secondary subacromial impingement;
6. Presence of specific rheumatic diseases;
7. History of severe trauma of the shoulder within the previous two years (e.g. fracture, luxation);
8. History and/or clinical symptoms of a large rotator cuff tear;
9. Previous surgery of the affected shoulder;
10. Extrinsic causes of shoulder pain;
11. Presence of dementia or other psychiatric disorders;
12. Not being able to fill in questionnaires in Dutch.

MATERIALS AND METHODS

TRANSIT and study design

Initially, TRANSIT followed the Dutch Guidelines for Shoulder Problems for general practitioners to diagnose and treat patients with SIS.[44] When treatment with rest, acetaminophen or NSAIDs was insufficient, therapy was continued with a subacromial lidocaine-corticosteroid injection. When ineffective, this injection was repeated within one month because of possible target inaccuracy of the injection.[22,28,29,47] When a subacromial injection eliminated the pain immediately (as a result of the injected lidocaine), it confirmed the diagnosis of SIS 30. In case of recurrence within 12 months after the first successful subacromial injection, eligible patients (see "selection of participants" and Figure 6.1) were asked to participate in the study. Recurrence meant patients having pain again, having increased pain or no longer experiencing pain relief. Included patients received another subacromial injection from their GP, which if necessary could be repeated within one month. In case of a second recurrence within 12 months after the last successful injection, participants were randomized to either an arthroscopic subacromial decompression performed within six weeks (TRANSIT) or continuation of treatment by the GP (UMC). If needed, the GP could also refer the participant to a hospital of random choice for further assessment and/or to be evaluated for surgery.

The study design is extensively described elsewhere[13] and was approved by the Medical Ethics Committee of University Medical Center Groningen.

Setting

The trial was carried out at 75 general practices in or nearby Groningen, The Netherlands. The GPs attended an information meeting about the study protocol. Following a standard subacromial injection protocol they were instructed and subsequently practiced on phantoms and fresh-frozen cadaver shoulders. Because of small inclusion numbers after commencement, rehabilitation physicians in a nearby hospital were also asked to refer eligible patients. Participants were included from March 2006 to January 2009.

Sample size

A power analysis was performed using functional status limitation measured with the Shoulder Disability Questionnaire (SDQ) as primary outcome measure. A clinically relevant difference in shoulder function of 35% differences in means was expected between study groups.[12,20,26,36,45] The sample size was estimated to be 32 patients per group (power (1-B) of 0.80 and P=0.05 (two-sided)). 70 participants were to be included (dropout rate of 10%).

Selection of participants

GPs introduced the study to eligible patients. Subsequently the researcher called the interested patients. Eligibility criteria were checked (see Table 6.1) and implications of the study explained. Following written informed consent, participants received another

subacromial corticosteroid injection from the GP to treat their first recurrence. In case of recurring complaints within one year after the last injection the participant visited the researcher. Shoulders were inspected; active and passive range of motion was measured, as well as muscle strength. Impingement was tested with the combination of the Hawkins-Kennedy impingement sign, the painful arc sign, and the infraspinatus muscle test.[32] The drop arm test was used to ascertain presence of large supraspinatus tendon tears.

Randomization

Participants were block-randomized in subsets of four participants into two groups. Sealed, opaque envelopes in subsets of four per GP were used. A random sequence of envelopes was generated by an independent person. Participants chose one envelope under supervision of the researcher.

Interventions

The arthroscopic subacromial decompressions were performed within six weeks after randomization by one senior orthopedic surgeon (RLD). Patients underwent plain shoulder radiography preoperatively. The operations were done in day surgery under general anesthesia, extended with a regional nerve block. A bursectomy with partial resection of the anteroinferior part of the acromion was performed. If seen, tears of the rotator cuff were noted but not repaired. Before discharge the participant received a sling and instructions for daily pendulum exercises. Two weeks post-surgery the participant visited the clinic for wound inspection. New instructions followed for home training exercises which focus on increasing shoulder range of motion. If indicated, physiotherapy could be part of the rehabilitation process.

Outcome assessment

Outcome assessment took place at randomization (T_0) and at three (T_1), six (T_2) and 12 months (T_3) post-randomization. At all measurement points outcome was assessed by means of questionnaires which were sent to participants by mail. At T_0 and T_3 patients visited our hospital for a physical examination, which was performed by one independent researcher who was not blinded to the intervention (at T_3).

The difference in mean change in functional status limitation scored on the SDQ (0 (best) to 100 points) was used as primary outcome measure.[37] A clinically relevant improvement was determined as containing at least three items (18.75 points).[41]

The secondary outcome measures were:

- The Shoulder Rating Questionnaire (SRQ; 17 to 100 points (best)).[27,42]
- The Constant-Murley Score (0 to 100 points (best)).[9]
- The Short-form 36 Health Survey (0 to 100 points (best)).[2,43] The following domains were used: physical functioning, role-physical, bodily pain and general health perception.
- Patient-perceived recovery, a one-item score on recovery following treatment.[4]

At all outcome assessments participants were asked to fill in a form to report adverse events. In addition, a cost questionnaire assessed the healthcare costs in euros. Study participants were asked to fill out their health care utilization retrospectively for the past six months at the randomisation visit and at the six months and twelve months study visits. The questionnaire included medical costs within and outside the formal healthcare (in-patient and day patient care, outpatient and community care, physiotherapy, medication use) as well as indirect costs (productivity loss of paid and unpaid labour). Costs for the arthroscopic subacromial decompression were calculated according to the Dutch Manual for Costing in economic evaluations.[31] Where available, Dutch standard prices were used (inflated to the year 2008).[31] Costs for medication were derived from the Health Care Insurance Board (CVZ: www.medicijnkosten.nl). Productivity costs were calculated using the friction method.[24,25]

Statistical Analyses

All calculations were done using the statistical package SPSS for Windows (SPSS Inc., version 16.0, 2007, Chicago). Baseline characteristics from both study groups were compared for equality by means of a Mann-Whitney U-Test for continuous variables and a Fisher's exact test for comparing proportions ($P<0.05$). A repeated-measures design was used to compare changes in means between groups over time ($P<0.05$). The standardized mean differences with corresponding 95% confidence intervals (95%CI) were calculated for the primary outcome measure. The effect estimates were interpreted according to Cohen: a standardized mean difference of 0.2-0.4 was considered a small effect, 0.5-0.7 moderate and $\geq$0.8 large.[8] Data were analyzed according to the intention-to-treat principle and the per-protocol principle. Costs data of the two treatments groups were compared using the Mann-Whitney U-Test.

Protocol changes after commencement

The following protocol changes deviating from the original protocol, as published in a design paper[13], were made:

- After study commencement the upper age limit was raised from 60 years to 65. The reason was that we encountered physically fit patients without signs of massive rotator cuff tears aged over 60 who were also eligible for inclusion.
- The original design included the individual relative Constant Score, which uses the functional performances of the uninjured collateral shoulder of the same individual as a reference.[16] However, two patients developed bilateral shoulder problems at T_0 and four patients at T_3, which made the measuring method useless — therefore the absolute Constant-Murley Score was used.[9]
- The Shoulder Pain Score was excluded as secondary outcome measure because at data analysis one question appeared to be missing in the printed version.
- For logistic reasons, operations were performed within six weeks instead of the previously reported four weeks.

RESULTS

Study population

Thirty-five GPs and two rehabilitation physicians referred 83 patients for this study. A total of 26 patients were randomized (see Figure 6.2). One of two patients referred by the rehabilitation physicians was randomized. Characteristics of this patient were not different from the other included participants. One TRANSIT patient was not available for the T_3 measurement because of postnatal depression. As a consequence of the block randomization the treatment groups were unequal in size. Nevertheless, no statistical differences in baseline characteristics at randomization were found (see Table 6.2).

Treatments received and adverse events

Table 6.3 shows the treatments both study groups received the year following randomization. In the TRANSIT group operation of one patient was postponed for nine weeks due to ECG abnormalities, for which cardiac evaluation. The intraoperative findings in the TRANSIT group were: three full-thickness rotator cuff tears (one Ellman grade AI and two grade AII), one articular side partial thickness tear, one small SLAP lesion. No debridements or repairs were performed. Postoperatively, in the TRANSIT group two participants received intra-articular injections for a frozen shoulder (one and two injections, respectively), and one participant received one injection in the AC joint. The average number of physiotherapy sessions (19.3) was strongly influenced by one outlier in the TRANSIT group who had at total of 78 sessions during follow-up. Exclusion of this patient gives an average of 15.1 sessions.

Three participants in the UMC group consulted an orthopedic surgeon and one participant consulted a rehabilitation physician. One of them had an arthroscopic subacromial decompression and the other patient had an open acromioplasty combined with a rotator cuff repair for a small tear (Ellman grade AI).

Table 6.4 presents the adverse events for both study groups for the treatments received during follow-up. Medium- and long-term adverse events were significantly more present in the TRANSIT group ($P=0.036$). External rotation was not restricted at randomization for the two TRANSIT patients who developed a frozen shoulder postoperatively.

Treatment effectiveness

The results of the intention-to-treat analysis are presented in Table 6.5. Both treatment groups had significant improvements in functional status limitation, shoulder function and health-related quality of life (four selected domains) at T_3 compared to T_0 ($P \leq 0.011$). The difference in means between the groups over time showed better outcome for the TRANSIT group than for the UMC group for all outcome measures. These differences were not statistically significant, except for functional status limitation (SDQ) and shoulder function (SRQ) six months post-randomization (respectively $P=0.034$ and $P=0.019$). The standardized mean differences for functional status limitation for the different measurement points were: T_0 -0.01 (95%CI: -0.79 to 0.77); T_1 0.05 (95%CI: -0.74 to 0.84); T_2 -0.73 (moderate effect; 95%CI: -1.54 to 0.07);

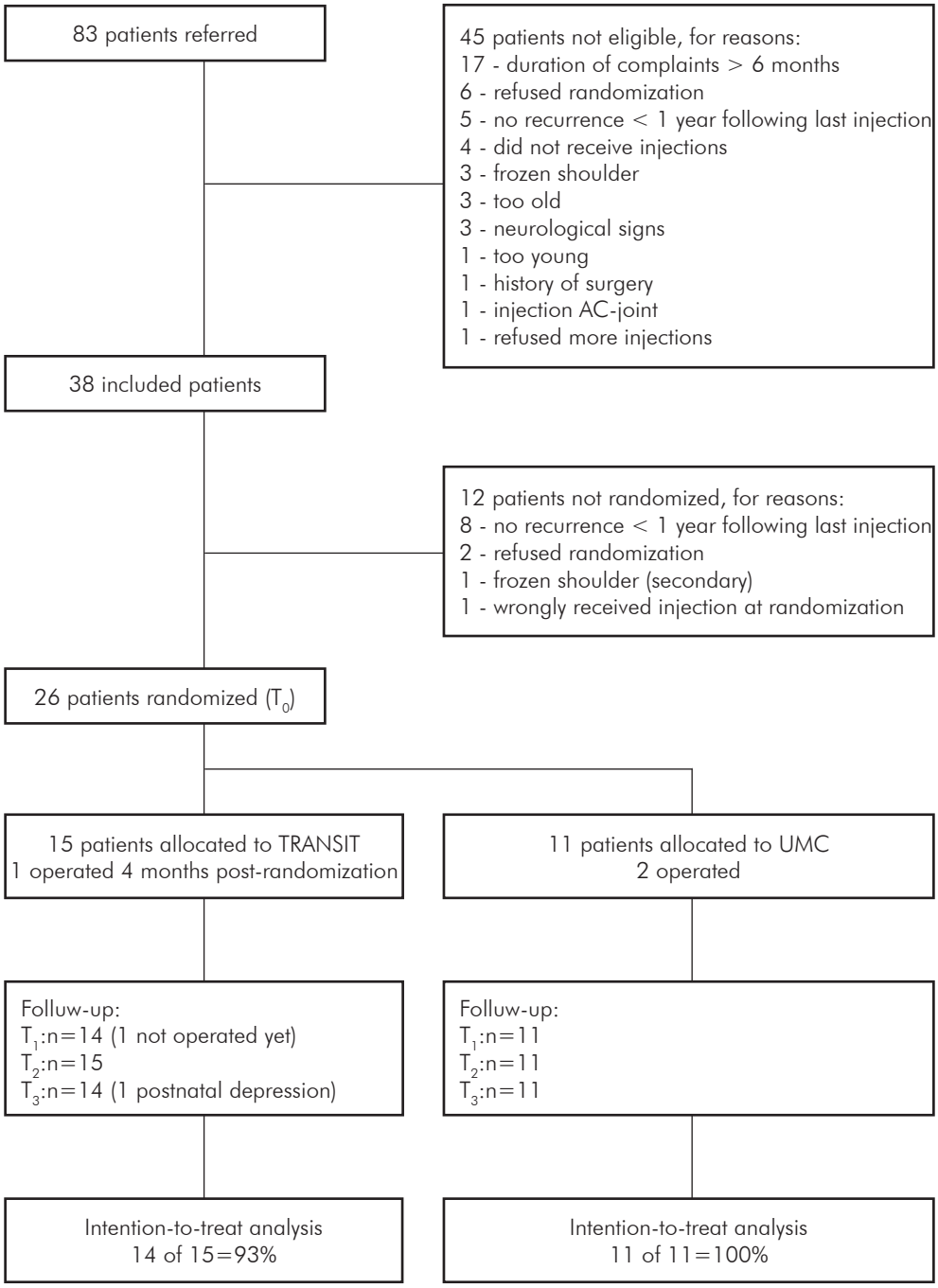

Figure 6.2. Consort flowchart.

Table 6.2. Patient characteristics at randomization (n=26).

	TRANSIT (n=15)	UMC (n=11)
Mean age in years (SD)	50.0 (11.8)	54.8 (6.6)
Male, n (%)	9 (60)	6 (54)
Mean body mass index in kg/m^2 (SD)	28.7 (3.1)	26.9 (4.2)
Living status (%)		
alone	1 (7)	1 (9)
cohabiting	4 (27)	6 (55)
cohabiting with children	10 (67)	4 (36)
Working status (%)		
paid work	10 (67)	8 (73)
retired	2 (13)	1 (9)
sick leave / workers' compensation	4 (27)	1 (9)
due to shoulder	2 (13)	0
Overhead activities (%)	9 (60)	8 (73)
Educational level[1] (%)		
lower	5 (33)	4 (36)
intermediate	7 (47)	5 (45)
higher	3 (20)	2 (18)
Dominant side affected (%)	10 (67)	5 (45)
Duration of symptoms in weeks (SD)	49 (16)	48 (21)
Gradual onset (versus acute) (%)	14 (93)	10 (91)
Same-shoulder problems in the past (%)	11 (73)	5 (45)
Concomitant neck problems (%)	7 (47)	6 (55)
Previous shoulder treatments (%)		
paracetamol/NSAIDs	11 (73)	5 (45)
subacromial corticosteroid injection	15 (100)	11 (100)
physiotherapy	5 (33)	2 (18)
manual therapy	1 (7)	0
Randomization preference operation (%)	14 (93)	10 (91)
Mean SDQ score (SD)	76.9 (15.7)	77.1 (12.0)
Mean SRQ score (SD)	49.2 (8.6)	47.3 (8.2)
Mean CM score (SD)	62.5 (16.8)	65.6 (7.3)
Mean SF-36 scores (SD)		
physical functioning	77.3 (15.8)	73.6 (16.3)
role-physical	40.0 (36.4)	43.2 (40.5)
bodily pain	50.5 (17.9)	46.4 (10.7)
general health perceptions	45.0 (21.5)	45.5 (15.1)

n Number of patients, SD Standard Deviation, SDQ Shoulder Disability Questionnaire, CM Constant-Murley, SRQ Shoulder Rating Questionnaire, SF-36 Short-Form 36 Health Survey
1 Educational level (Dutch system): lower: no education, primary school or lower vocational school; intermediate: lower or higher general secondary school level or middle vocational school; higher: higher vocational school or university.

Table 6.3. Treatments received by study groups.

Treatments (%)	TRANSIT (n=15)	UMC (n=11)
Arthroscopic decompression <6 wk p.r.	14 (93)	0
Arthroscopic decompression >6 wk p.r.	1 (7)	1 (9)
Open decompression + cuff repair >6 wk p.r.	0	1 (9)
Acetaminophen / NSAIDs ≤14 days	7 (47)	2 (18)
Acetaminophen / NSAIDs >14 days	6 (40)	5 (45)
Acetaminophen / NSAIDs total	13 (87)	7 (64)
Injection ≤2	3 (20)	3 (27)
Injection >2	0	3 (27)
Physiotherapy ≤10 sessions	4 (27)	2 (18)
Physiotherapy >10 sessions	9 (60)	3 (27)
Physiotherapy - average sessions	19.3	6.3
Manual therapy	0	0
Osteopathy	0	1 (9)
Other secondary care	0	2 (18)

p.r. post-randomization.
Data of one TRANSIT patient at T_1 and one TRANSIT patient at T_3 were missing.

Table 6.4. Adverse events per treatment group during follow-up.

Adverse events (%)	TRANSIT (n=15)	UMC (n=11)
Short term (<1 week)		
injection – flushes	0	2 (18)
physiotherapy – worsening pain	2 (13)	1 (9)
Medium term (1-8 weeks)		
physiotherapy – worsening pain	1 (7)	0
postoperative worsening pain	4 (27)	1 (9)
Long term (>8 weeks)		
frozen shoulder	2 (13)	0
keloid scar*	1 (7)	0
Total (%)	10 (67)	4 (36)

** Therapy: scar excision.*

Table 6.5. Results intention-to-treat analysis.

	TRANSIT (n=14)	UMC (n=11)	Significance ¥
Mean SDQ (SD) at:			
T_0	76.9 (15.7)*	77.1 (12.0)	-10.10 to 10.41
T_1	66.3 (21.6)	65.1 (23.9)	-18.52 to 16.13
T_2	47.9 (34.2)*	70.4 (21.9)	1.73 to 43.26
T_3	31.4 (29.4)	38.6 (31.0)	-15.73 to 30.11
Mean SRQ (SD) at:			
T_0	49.2 (8.6)*	47.3 (8.2)	-8.17 to 4.35
T_1	53.4 (13.1)	56.4 (10.5)	-5.85 to 11.90
T_2	68.1 (18.8)*	53.1 (15.1)	-27.48 to -2.41
T_3	82.6 (13.5)	74.1 (15.6)	-19.63 to 2.59
Difference in means CM Score T_0- T_3 (median)	19.3 (20)	11.0 (9)	P=0.062§
Difference in means SF-36 T_0- T_3 (median)			
- physical functioning	12.1 (15.0)	8.2 (10.0)	P=0.513§
- role-physical	32.1 (25.0)	25.0 (50.0)	P=0.846§
- bodily pain	26.6 (22.5)	23.7 (22.0)	P=0.659§
- general health perceptions	32.1 (25.0)	25.0 (25.0)	P=0.461§
Complete recovery (%)	5 (36)	1 (9)	P=0.180#
PPR at T_3 (%)			
- very much improved	2 (13)	1 (9)	
- much improved	3 (20)	3 (27)	
- improved	2 (13)	4 (36)	
- unchanged	1 (7)	1 (9)	
- got worse	1 (7)	1 (9)	
- got (very) much worse	0	0	
Working status at T_3 (%)			
- paid work	10 (71)	8 (73)	
- retired	3 (21)	1 (9)	
- (partial) sick leave / workers' compensation	3 (21)	0	
- due to shoulder	2 (14)	0	

n Number of patients, SD Standard Deviation, SDQ Shoulder Disability Questionnaire, CM Constant-Murley, SRQ Shoulder Rating Questionnaire, SF-36 Short-Form 36 Health Survey, PPR Patient-Perceived Recovery.
¥ Significance expressed in 95% confidence interval of the difference in means or P-value.
** n= 15.*
§ Mann-Whitney test.
 # Fisher's exact test.

Table 6.6. Total costs after one year follow-up.

cost component	unit prize (euro)	source	volume TRANSIT (n=14)	volume UMC (n=11)	total costs TRANSIT	total costs UMC	P-value
medical costs							
operation							
arthroscopic decompression	€ 1.412	calculation	14	1	€ 19.761	€ 1.412	
post-operative visits	€ 108,36	guideline price	43	5	€ 4.659	€ 542	
open decompression with cuff repair	€ 536,00	calculation	0	1	€ 0	€ 536	
hospital stay	€ 516,00	guideline price	0	6	€ 0	€ 3.096	
keloid scar correction	€ 248,15	guideline price	1	0	€ 248	€ 0	
visit physician							
general practitioner	€ 21,89	guideline price	23	24	€ 503	€ 525	
physical therapist	€ 24,65	guideline price	261	68	€ 6.434	€ 1.676	
other		guideline price	2	13	€ 85	€ 837	
medication							
over-the-counter		questionnaire	14	12	€ 162	€ 172	
prescription		CVZ	20	5	€ 423	€ 189	
total medical costs					€ 32.276	€ 8.984	
mean					€ 2.305	€ 817	0.002
non-medical costs							
informal care			14	9	€ 1.526	€ 5.695	
productivity loss							
unpaid work			0	0	€ 0	€ 0	
paid work			7	0	€ 38.856	€ 0	
total non-medical costs					€ 40.382	€ 5.695	
mean					€ 2.884	€ 518	
total costs					€ 72.657	€ 14.679	
mean					€ 5.190	€ 1.334	0.001
SD					3560	2945	

T_3 -0.23 (small effect; 95%CI: -1.02 to 0.56). The same trend applies to the per-protocol analysis.

Over time the TRANSIT group showed continuous improvement in functional status limitation (SDQ) and shoulder function (SRQ). On the other hand, the UMC group showed a relapse in both outcome measures at T_2, which at this point gave a significant difference between both groups.

Costs of treatment strategies

The mean total cost per patient for the complete follow-up period was significantly higher for the TRANSIT group than for the UMC group (€5.190 versus €1.334: P=0.001). Main drivers of the difference in costs are the arthroscopic subacromial decompression (€1412), the higher number of physiotherapy sessions and productivity losses in the TRANSIT group during the first six months after randomization. Table 6.6 gives an overview of the medical and non-medical costs during the first six months and the last six months of follow-up for the two treatment groups. Medical costs and total costs for the first six months were significantly higher for the TRANSIT group compared to the usual care group (P<0.001), while the non-medical costs were not significantly different. For the second half of the follow-up period, no significant differences were found.

DISCUSSION

Main findings

There were no statistically significant differences in means between the groups over time for all outcome measures, except for functional status limitation (SDQ) and shoulder function (SRQ) six months post-randomization in favor of the TRANSIT group (P=0.034). The medium- and long-term complication rate and the costs were significantly higher in the TRANSIT group than in the UMC group.

Links to other research

Up until now, randomized controlled trials were unable to provide evidence for possible differences in effectiveness between operative and conservative treatments.[14,23] In their randomized controlled trial Ketola et al. reported no clinically important effects from arthroscopic acromioplasty followed by a supervised exercise program (n=68) compared to a supervised exercise program (n=66) alone in terms of subjective outcome measured at 24 months.[23] However, the treatment groups could not be compared fairly due to significant differences in mean delay to the commencement of treatment in the exercise group (1.2 months (0.2 to 4.6)) and the arthroscopy group (8.3 months (1.4 to 11.8)). Twelve months post-intervention there was a significantly better improvement in self-reported pain (VAS, primary outcome measure) for the operated group compared to the exercise group. The authors therefore concluded that the operative group initially recovers faster when assessed from the start of the treatment.

Haahr et al. compared arthroscopic acromioplasty with physiotherapy for the treatment of SIS in a randomized controlled trial and also used the Constant-Murley score as outcome measure.[18] They found a trend for better outcome in the physiotherapy group. Although not statistically significant, in our study the TRANSIT group scored better than the UMC group for complete recovery and other outcome measures. A possible explanation for this difference in trends is the difference in treatments, which consisted of well-structured physiotherapy given by two experienced therapists in the study by Haahr et al. and mixed treatments of injections, NSAID's and/or physiotherapy in the UMC group of our study.

Adverse events were not reported in previous comparable randomized controlled trials.[6,18,23,34,35] Only Ketola et al. report that their operated participants (n=68) experienced no major surgical complications. A definition of a major surgical complication was not given though.

Strengths and limitations

The major limitation of this study is its small research population. The inclusion target of 70 patients seemed easily feasible with a reported incidence for SIS of 5/1000/year.[39] However, Lasagna's law applied for this study, which means that actual recruitment usually falls short of the expectations once the trial has started.[17] To increase patient recruitment many measures were undertaken, which were also advised in an article by Van der Windt et al.[40] To make as many GPs as possible interested in the study, they received post-graduate training credits for attending the information meeting. To encourage the GPs for inclusion three monthly newsletters were distributed, as well as posters and flyers to inform potential patients in the doctors' waiting rooms. Furthermore, the GPs were called regularly to keep them alert for new patients and to inform them if they experienced problems with patient inclusion. The recruitment period was extended from 1.8 to 2.8 years. When GPs were uncertain about the diagnosis patients could be referred to our outpatient clinic to be evaluated. As mentioned before, rehabilitation physicians in a nearby hospital were also asked to refer eligible patients. Although 83 patients were referred, due to subsequent strict inclusion and exclusion criteria only 26 patients could be randomized.

The use of more than one shoulder-specific outcome measure is a major strength of this study, which is different than previous comparable randomized controlled trials.[6,18,23,34,35] Six months post-randomization two of the three shoulder-specific outcome measures (SDQ and SRQ) showed a significant difference between treatment groups. This emphasizes that differences in domain of outcome measures and/or differences in clinimetric characteristics (responsiveness, validity, etc.) between outcome measures can lead to different results and conclusions when comparing treatment groups.

The utility of multiple assessments was shown by the course in SDQ and SRQ scores during follow-up. The UMC group showed a relapse six months post-randomization. This could be explained by the fact that many patients seen in general practice with shoulder complaints experience recurrence after six to 18 months, as reported in a previous study.[46] The strength of our study is that, by using multiple assessments, it provides more insight in fluctuations of outcome over time.

Lastly, this is the first randomized controlled trial of its kind which reports adverse events. These reports are indispensable, not only to make care providers and patients aware of potential treatment risks, but also for the interpretation of differences in treatment effects.

Conclusions

The results reported in our study do not justify the conclusion that early operation is beneficial over continuation of usual medical care. The small sample size and the significance of the adverse events in the TRANSIT group might have precluded statistical significance between groups at one year follow-up. For future randomized controlled trials we strongly advise to report adverse events of all treatments applied. The great discrepancy in health care costs, which were significantly higher for the TRANSIT group, underscores the need to determine factors that predict which patients benefit most from an operation.

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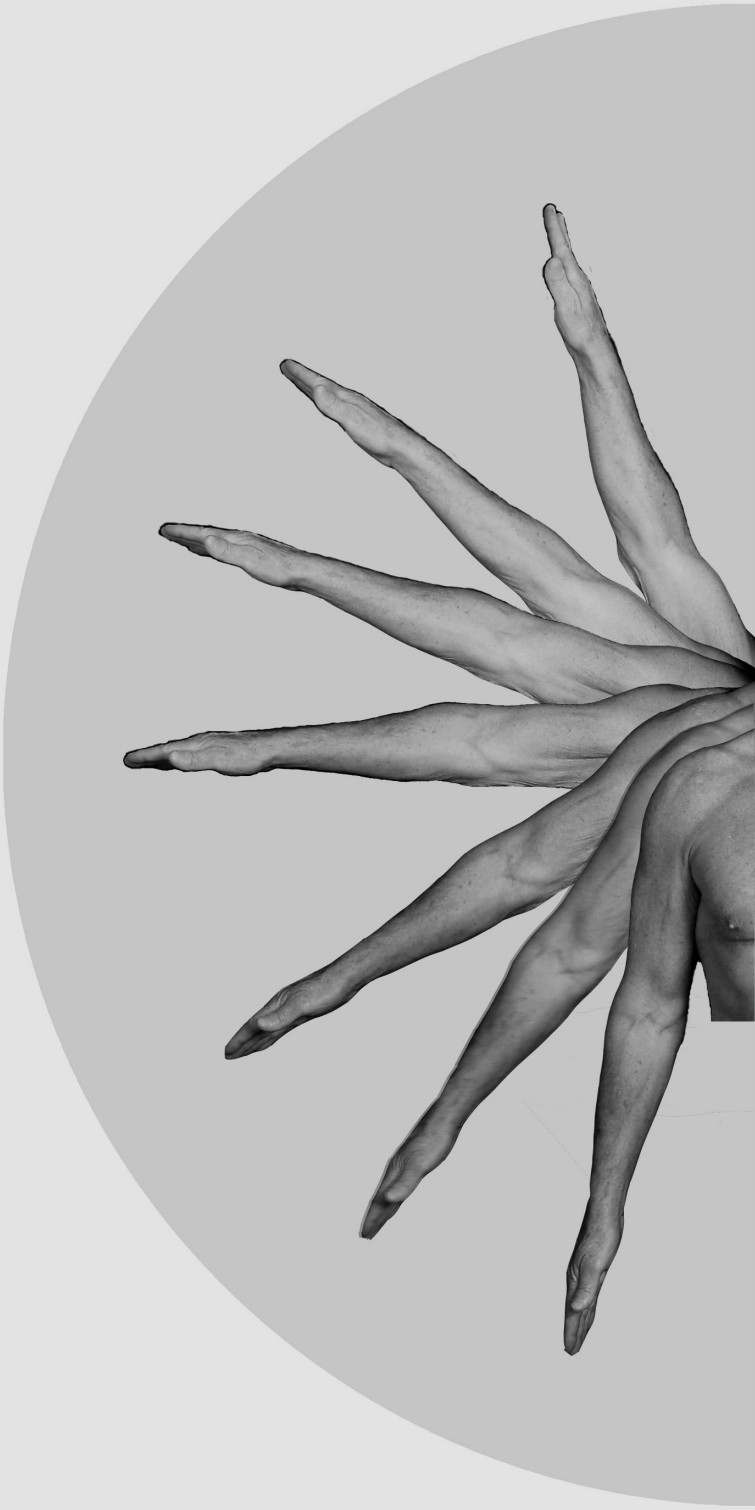

Chapter 7

General discussion

GENERAL DISCUSSION

In this final chapter, the general discussion, the results of the preceding chapters will be critically reviewed and integrated into the discussion of four mains topics. Recovery from shoulder complaints and its definition is the first one. So far there is no widely accepted definition of recovery from shoulder complaints, which is indispensable for shoulder research. Next, the role of general practitioners' treatment guidelines for shoulder complaints will be discussed, as well as prediction of recovery. Such guidelines are cost-effective and are applicable to most shoulder complaints; other complaints should be identified early to be treated differently. The section "Surgery for SIS" focuses on evidence for surgery for subacromial impingement syndrome (SIS) and possible causative relationships between acromion shape and SIS. The last main topic focuses on measuring clinical efficacy of shoulder treatments. Choosing the right instruments for measuring outcome is essential in shoulder research, and the interpretation outcome scores important for clinicians to value improvement in shoulder outcome scores. This chapter will end with the main findings of this thesis and recommendations for future research.

Recovery from shoulder complaints

From a socioeconomic viewpoint it is perhaps not that interesting to know the exact incidence of shoulder complaints in general practice. From earlier research we know that the majority of persons with musculoskeletal pain do not consult a health professional.[1] Incidence in general practice is therefore a poor representative of incidence in the general population. Far more interesting is the expected time of recovery and knowing which complaints become chronic. But how should we define recovery? Should someone be completely free of symptoms or should he/she be fit for work? A person can be restricted in activities of daily living or sports, yet be free of symptoms when not performing these activities. So can someone who is limited in his/her activities but free of symptoms be considered recovered? People who have returned to work and still experience complaints might have accepted their situation or have changed their activities at work.

The database research presented in Chapter 3 ("Patients with shoulder complaints in general practice: consumption of medical care") did not provide information about recovery. The assumption was made that patients were recovered when they ended consulting their general practitioner (GP) for their shoulder complaint, but in fact this is unknown. Patients who were referred to a physiotherapist at their last consultation could have been treated for a long time before (partial or complete) recovery. Others might have decided to live with their complaints or tried alternative medicine. A prospective study design would be more appropriate to estimate recovery with more confidence. Winters et al. prospectively studied the course of shoulder complaints in general practice, and found that 51% of patients experienced complaints after 26 weeks following first consultation and 41% after 12-18 months.[2] Van der Windt et al. found the same percentage of persistent complaints after 12 months.[3] Croft et al. reported 49% of patients experiencing complete recovery.[4] In our database study 75%

of patients consulted their GP only within the first year of initial presentation. This clearly would be an overestimation of patients who recovered.

Trial settings use objective or subjective outcome measures to compare treatment effects. At post-intervention follow-up, patients commonly have improved function and/or pain scores, but how many patients truly have recovered is mentioned less often. In our randomized controlled trial we asked the participants if they felt they recovered. Only a minority answered they experienced complete recovery. We did not, however, define recovery. From a systematic review of the literature of back pain research it is known that almost every study that measured recovery from low back pain did so differently.[5] A lack of consistency makes interpretation and comparison of research problematic. The same probably applies to research on shoulder complaints. It is likely that the failure to use a standardized measure of recovery is due to the absence of an established definition. This highlights the need for such a definition in shoulder research.

Treatment guidelines for shoulder complaints and prediction of recovery

In these times of inflating health care costs and cuts, information about consumption of medical care for common complaints is indispensable. Our article on consumption of medical care of shoulder patients has made a contribution, showing the function of the GP as gatekeeper of the health care system. Referrals to specialized, secondary care can in principle only be made by the GP. Most patients with shoulder complaints could be treated with relatively inexpensive modalities like a wait-and-see policy, NSAID prescriptions or corticosteroid injections. Just 6% of patients were referred to secondary care and only 0.3% (n=2) were operated on.

The Dutch College of General Practitioners provides guidelines for treatment of shoulder complaints in general practice. They constitute a stepwise approach that is effective in terms of cost increases by moving on to the next step. However, covering all the steps takes a considerable amount of time, which will automatically result in chronic complaints for those patients whose symptoms are still present at the end of the conservative treatment steps. Such symptoms can have substantial consequences in terms of being fit enough to work and receiving any workman's compensation. Recognition of those patients that risk developing chronic complaints is important. A different treatment approach consisting of a combination of treatments or skipping certain steps seems desirable toward the prevention of chronic symptoms. So far, the following predictors of poor outcome of shoulder symptoms are identified in the literature: middle age (45-54) in occupational population[6], longer duration of symptoms before presentation[7], gradual onset of symptoms[7], higher pain intensity[6-8], concomitant neck pain[3,7], psychological factors like distress, catastrophizing and somatization[7,8] and concomitant musculoskeletal complaints (high back pain, low back pain, upper and lower extremity complaints).[7] A validated model including patient characteristics and predictors of outcome in combination with a management framework would be desirable toward predicting and treating shoulder patients with an expected long course of complaints.

Surgery for SIS

Although in recent decades there has been an increase in randomized controlled trials that compare conservative treatments with surgery for shoulder pain, for SIS there is still no evidence for surgery being superior to nonoperative measures.[9,10] Our own randomized controlled trial did not contribute to this either. This notwithstanding, (arthroscopic) subacromial decompressions are probably the most common shoulder operations. Orthopedic surgeons who see SIS patients in outpatient clinics after extensive but failed conservative treatments have only one option left besides doing nothing or rehearsal of conservative treatments, and that is surgery. Although surgery is expensive and there are risks of complications, orthopedic surgeons may have many good experiences with previous (arthroscopic) subacromial decompressions. Whether this is a result of a placebo effect, the subacromial bursectomy itself[11], biomechanical advantages due to increased subacromial space, or other unknown factors also remains unclear.

The question is why conservative treatments and surgery are equally effective in trial settings, even among patients with a long history of failed nonoperative treatments.[12-14] Before participating in trials (nearly) all patients have unsuccessfully been treated with physiotherapy. During the trials patients were treated with supervised, well-structured exercise programs led by experienced physiotherapists. A possible explanation for the difference in efficacy could be that in daily practice many patients choose their own physiotherapist after referral. Their choice may not always be based on therapist qualifications or specializations but on convenient location or other considerations, therefore more heterogenic physiotherapy programs may produce less favorable results than those from trial settings. Furthermore, a placebo effect of physiotherapy in the trials can be expected.

The key in treating SIS must be sought in treating its cause. The medical literature describes different causes. In orthopedic practice, however, the diagnosis tends to be made based on history, physical examination and radiological findings without knowing the exact underlying pathology. In many cases of SIS it is even unclear or unproven that subacromial structures really impinge, therefore some practitioners, like Jeremy Lewis, propose substituting the term “subacromial impingement syndrome” with “subacromial pain syndrome”.[15]

Although subacromial decompressions seem effective for many patients, it is unclear whether this treatment is directed to its cause. In 1991 Bigliani et al. classified acromial morphology into type I (flat), type II (curved) and type III (hooked).[16] They reported that type III acromion was most often found in cases of rotator cuff tears and that type III tended to cause impingement, an important factor in the development of rotator cuff tears. This relationship is supported by other research.[17-19] However, Gohlke et al. found no hooked acromion in cadavers with rotator cuff tears.[20] Ozaki et al.[21] and Schippinger et al.[22] suggest that acromial morphology is acquired as a result of rotator cuff tears. More recent studies have not found a causative relationship between acromial shape and rotator cuff tears either.[23-25] Up until now, a possible causative relationship remains unclear.

Measuring clinical efficacy of shoulder treatment

An enormous number of questionnaires and instruments exist to measure shoulder function and pain. Some are disease-specific[26-30], others are generic.[31-36] Some have a patient-based perspective, others are physician-based. All sorts of modifications have been introduced for more commonly used shoulder questionnaires[37-40], and even more shoulder-specific or upper extremity assessment tools have been developed recently.[41,42] A few questionnaires are translated into different languages and validated. In this jungle of questionnaires it can be difficult for researchers to find the right instruments to measure clinical efficacy, the more so due to a lack of disease-specific instruments that are also translated and validated for the required language. It is not uncommon for shoulder assessment instruments to be used for measuring outcomes they are not designed for. An example is the use of the Constant-Murley score to measure outcome in patients treated for shoulder instability.[28,36,43] Using a variety of instruments and data presentation in different trials can make it difficult or even impossible to make a good comparison of study results. This is also what we experienced in our systematic review of randomized controlled trials for SIS, which hampered performance of meta-analysis.

In randomized controlled trials shoulder function and/or pain scores are measured pre- and post-intervention, and are compared between the study groups. Statistically significant improvements and differences between groups is a goal to be achieved. However, the question is whether statistically significant improvements are clinically relevant. Are patients free of pain during their sleep, are they able to return to their work or perform other activities of daily living? Such an interpretation of (improvement of) outcome scores is often lacking, which makes it difficult for clinicians to value the improvement in shoulder outcome scores.

Studies comparing the content and clinimetric quality of shoulder disability questionnaires are scarce. In the English literature only Bot et al. have published a systematic review evaluating evidence for the clinimetric quality of shoulder disability questionnaires.[44] Sixteen questionnaires were identified and evaluated by a checklist. None of the questionnaires demonstrated satisfactory results for all properties. Most questionnaires claimed to measure several domains, yet dimensionality was studied in only three instruments. Furthermore, nearly all publications on questionnaires lacked information on the interpretation of scores. It therefore seems more important to study the clinimetric quality of existing questionnaires and elaborate on their interpretation than to develop new questionnaires.

Main findings

This thesis has provided insight into the incidence, prevalence, patterns of consultation and medical consumption of patients with shoulder complaints in general practice. We found an average incidence as high as 29.3 per 1000 person-years. Because nearly half of these new patients consulted their general practitioner only once for this complaint, the work load for the GP is generally low. The second aim of this thesis was to provide an overview of best evidence for surgical treatment of subacromial impingement syndrome (SIS) compared with conservative treatment. No differences in outcome between the treatments groups were reported for any of the studies included in

the systematic review. The last aim was to present the results of a randomized controlled trial in which a new interdisciplinary treatment strategy for SIS was compared with usual medical care. No statistically significant differences in means between the groups were found at one year follow-up. The small sample size and the significance of the adverse events in the TRANSIT group might have precluded statistical significance between groups at one year of follow-up.

Recommendations for future research

As mentioned in the section "Recovery of shoulder complaints", there is a need for a definition of recovery following treatment of shoulder complaints. Such a definition would make it easier to interpret and compare effects of future research.

Several prognostic indicators for a favorable or a poor outcome of general shoulder complaints have been identified. Less is known however for a specific diagnosis like SIS. Sick-leave was reported as the best predictor of poor short-term outcome after corticosteroid injection for rotator cuff disease[45] and lower functional scores after acromioplasty.[46] Lopez et al., Mair et al. and Patel et al. found that the impingement test can be used as a predictor of outcome for patients with impingement syndrome treated by (arthroscopic) subacromial decompression.[46-48] Further research to identify other predictors of poor outcome would be desirable, as well as a comprehensive prognostic model with a framework for management.

Instead of developing new questionnaires, future research on shoulder-specific questionnaires should focus on their clinimetric quality and the interpretation of outcome scores.

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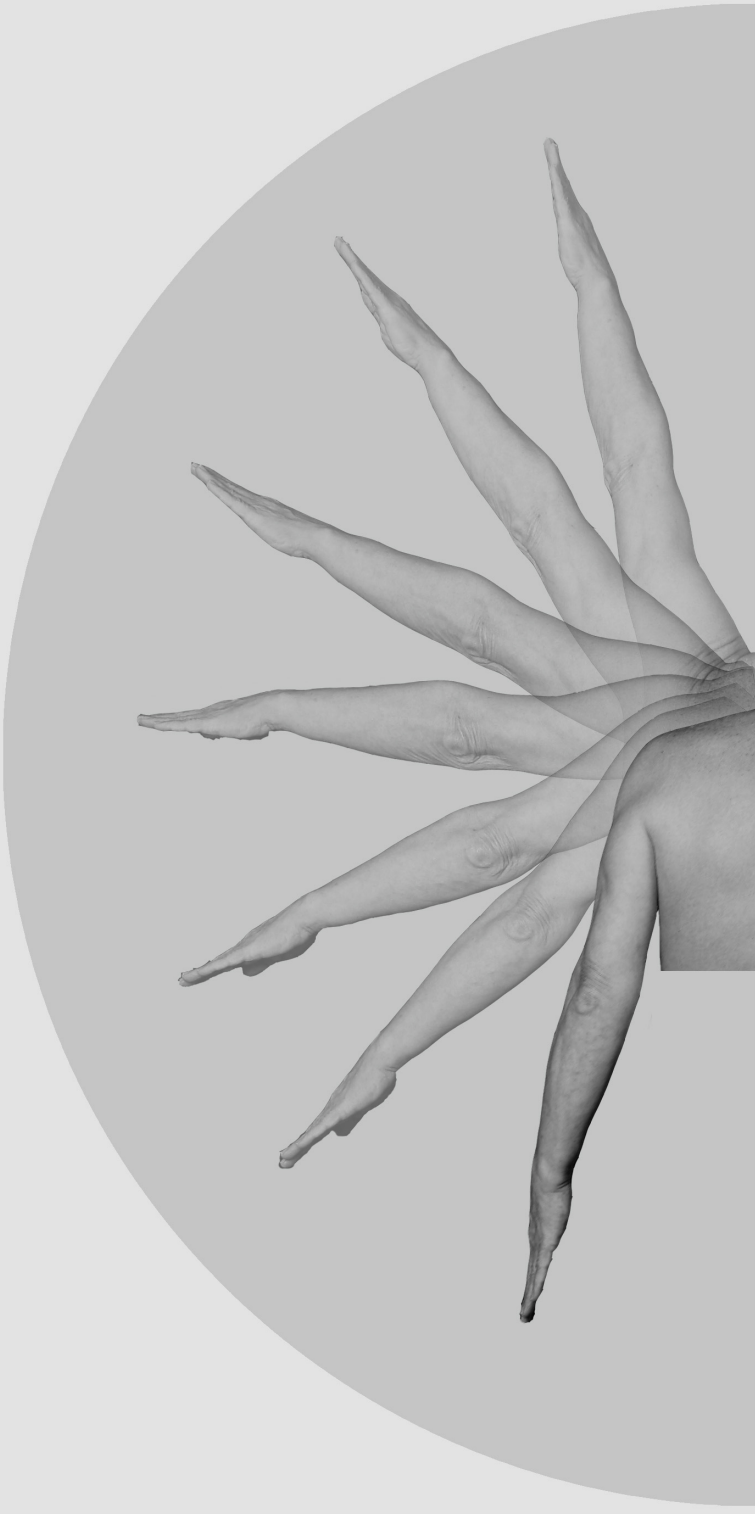


Appendix I

Summary

SUMMARY

Shoulder complaints constitute the second to third most common musculoskeletal presentation to general practice. Of all these shoulder complaints, SIS is the most frequently recorded. This thesis focuses on shoulder complaints in general practice as well as on treatments for SIS.

Chapter 1 is the general introduction of this thesis, describing its three aims. The first aim was to gain insight into incidence, prevalence, patterns of consultation and medical consumption of patients with shoulder complaints in general practice. The second aim was to summarize the available evidence for surgical treatment of SIS compared with conservative treatment. The last aim was the presentation of the design of a new interdisciplinary treatment strategy for SIS and the results of the randomized controlled trial in which it was compared with usual medical care.

Chapter 2 presents the incidence and prevalence of patients with shoulder complaints in Dutch general practice during a ten-year period. The data were generated from a primary care medical registration network with an average population of 30,000 persons per year aged 18 or older. Average incidence was 29.3 per 1000 person-years. Women and patients in the 45-64 age category have the highest incidence. The annual prevalence of shoulder complaints ranged from 41.2 to 48.4 per 1000 person-years, calculated for the period 1998 to 2007, and was higher among women than among men.

Chapter 3 focuses on the medical consumption (general practitioner consultation, referrals, medication consumption) of patients with shoulder complaints in general practice. The same registration network as mentioned in Chapter 2 was used. All patients aged 18 years or older with new shoulder complaints who consulted their general practitioner in 1998 were included, and were followed ten years beyond the initial consultation; 526 incident cases were identified (average age 47 years, 65% women and average follow-up 7.6 years). Nearly half of the patients consulted their general practitioner only once. For 79% of those patients a wait-and-see policy or a prescription for NSAIDs sufficed. During follow-up 65% of all patients were prescribed medication. Medication consumption was significantly higher among men than women, and higher for the 45-64 age group compared to the younger group. A total of 199 patients were referred, 84% of them to a physiotherapist and 16% to secondary care. Only two patients had surgery, done by an orthopedic surgeon. In just 14% of patients the general practitioner recorded a diagnosis, rotator cuff disorder being the most common one.

In *Chapter 4* the focus changes to SIS and reports on the results of a systematic review that was conducted to compare effects of conservative and surgical treatment for SIS in terms of shoulder function improvement and pain reduction. A literature search was conducted for randomized controlled trials in the PubMed, Embase, PEDro and Cochrane registers. The methodological quality of the selected studies was assessed by two reviewers. A best-evidence synthesis was used to summarize results. Four randomized controlled trials were included in this review. Two of the trials had a medium

methodological quality and two a low quality. No differences in outcome between the treatment groups were reported for any of the studies.
The best moment of referral for surgery of patients with SIS unresponsive to nonoperative measures is not well-defined. To improve insight, a transmural treatment strategy called TRANSIT (TRANSmural treatment strategy for Subacromial ImpingemenT) was designed which contains rules to treat patients with SIS in primary care and a well-defined moment of referral to an orthopedic surgeon for arthroscopic acromioplasty. This strategy was tested in a randomized controlled trial in which the control treatment consisted of continuation of usual medical care. *Chapter 5* describes the design of this randomized controlled trial. The primary outcome was functional status limitation measured with the Shoulder Disability Questionnaire. Secondary outcome measures included the Shoulder Rating Questionnaire, the Constant-Murley Score, the Short-form 36 Health Survey and a patient-perceived recovery score. Treatment effects were compared for all measurement points (at randomization and at three, six and twelve months thereafter) by using a repeated-measures design. Data were analyzed according to the intention-to-treat and the per-protocol principles. Health care utilization was assessed with a cost questionnaire.

Chapter 6 presents the results of the randomized controlled trial. Twenty-six patients were randomized: 11 received UMC and 15 followed the TRANSIT outline (arthroscopic acromioplasty). Medium- and long-term adverse events were significantly more present in the TRANSIT group (P=0.036). Both groups had a clinically significant improvement in functional status limitation one year post-randomization. There were no statistically significant differences in means between the groups over time for all outcome measures, except for functional status limitation and shoulder function (Shoulder Rating Questionnaire) six months post-randomization (respectively P=0.034 and P=0.019). The TRANSIT strategy was more costly than the UMC strategy. These data do not justify the conclusion that early operation is beneficial over continuation of usual medical care. The small sample size and the significance of the adverse events in the TRANSIT group might have precluded statistical significance between groups at one year follow-up. The great discrepancy of health care costs, which were significantly higher for the TRANSIT group, underscores the need to determine factors that predict which patients benefit most from surgery.

Finally, in the general discussion in *Chapter 7* the results of the preceding chapters are critically reviewed in the light of four main topics. The first topic is recovery of shoulder complaints and its definition. So far there is no widely accepted definition of recovery of shoulder complaints, which is indispensible for shoulder research. Next, the role of general practitioner treatment guidelines for shoulder complaints is discussed, as well as prediction of recovery. Such guidelines are cost-effective and are applicable for the gross of shoulder complaints. The third topic focuses on evidence for surgery for SIS and possible causative relationships between acromion shape and SIS. The last main topic focuses on measuring clinical efficacy of shoulder treatments. Choosing the right instruments for measuring outcome is essential in shoulder research, and the interpretation of outcome scores is important for clinicians to value changes in shoulder outcome scores. The chapter ends with recommendations for future research.

Appendix II

Nederlandse samenvatting

SAMENVATTING

Schouderklachten behoren tot de tweede tot derde meest voorkomende musculoskeletale aandoeningen in de huisartsenpraktijk. Van alle schouderklachten is subacromiaal impingement syndroom (SIS) de meest voorkomende in de huisartsenpraktijk. Dit proefschrift richt zich zowel op schouderklachten in de huisartsenpraktijk als op de behandeling van SIS.

Hoofdstuk 1 is de algemene introductie van dit proefschrift waarin de drie doelstellingen worden beschreven. Het eerste doel was om inzicht te krijgen in de incidentie, de prevalentie, de consultatie patronen en de medische consumptie van patiënten met schouderklachten in de huisartsenpraktijk. Het tweede doel was om al het beschikbare bewijs samen te vatten van onderzoeken die chirurgische behandeling van SIS vergelijken met conservatieve behandeling. En het laatste doel was de presentatie van het ontwerp van een nieuwe interdisciplinaire behandelingsstrategie voor SIS, en de resultaten van het gerandomiseerde onderzoek met controlegroep waarin dit vergeleken werd met de gebruikelijke medische behandeling.

Hoofdstuk 2 rapporteert over de incidentie en prevalentie van patiënten met schouderklachten in Nederlandse huisartsenpraktijken gedurende een periode van tien jaar. De data zijn gegenereerd uit een medisch registratie netwerk van huisartsen met een gemiddelde populatie van 30.000 personen per jaar met een leeftijd van 18 jaar en ouder. De gemiddelde incidentie was 29.3 per 1000 persoonsjaren. Vrouwen en patiënten in de leeftijdscategorie 45-64 jaar hebben de hoogste incidentie. De jaarprevalentie van schouderklachten varieerde van 41.2 tot 48.4 per 1000 persoonsjaren, berekend voor de periode 1998 tot 2007 en was hoger voor vrouwen dan voor mannen.

Hoofdstuk 3 richt zich op de medische consumptie (consultatie van de huisarts, verwijzingen, medicijngebruik) van patiënten met schouderklachten in de huisartsenpraktijk. Hetzelfde registratienetwerk als genoemd in Hoofdstuk 2 is gebruikt. Alle patiënten van 18 jaar en ouder met een nieuwe schouderklacht die de huisarts hiervoor in 1998 consulteerden werden geïncludeerd, en 10 jaar vervolgd na de initiële presentatie. Dit betrof 526 incidente patiënten (gemiddelde leeftijd 47 jaar, 65% vrouw en gemiddelde follow-up 7.6 jaren). Bijna de helft van de patiënten consulteerden hun huisarts slechts eenmalig. Voor 79% van deze patiënten volstond een afwachtend beleid of een recept voor NSAIDs. Gedurende de follow-up kregen 65% van alle patiënten een recept voorgeschreven. Het medicijngebruik was significant hoger onder mannen vergeleken met vrouwen, en hoger voor de leeftijdsgroep 45-64 jaar vergeleken met de jongere groep. In totaal werden 199 patiënten verwezen, waarvan 84% naar een fysiotherapeut en 16% naar de tweede lijn. Slechts twee patiënten zijn geopereerd door een orthopedisch chirurg. In slechts 14% van de patiënten had de huisarts een diagnose genoteerd. Rotator cuff aandoeningen kwamen hierbij het meeste voor.

Vanaf *Hoofdstuk 4* ligt de focus op SIS. Dit hoofdstuk doet verslag van de resultaten van een systematische review, welke is uitgevoerd om de effecten van conservatieve en operatieve behandelingen voor SIS te vergelijken in termen van

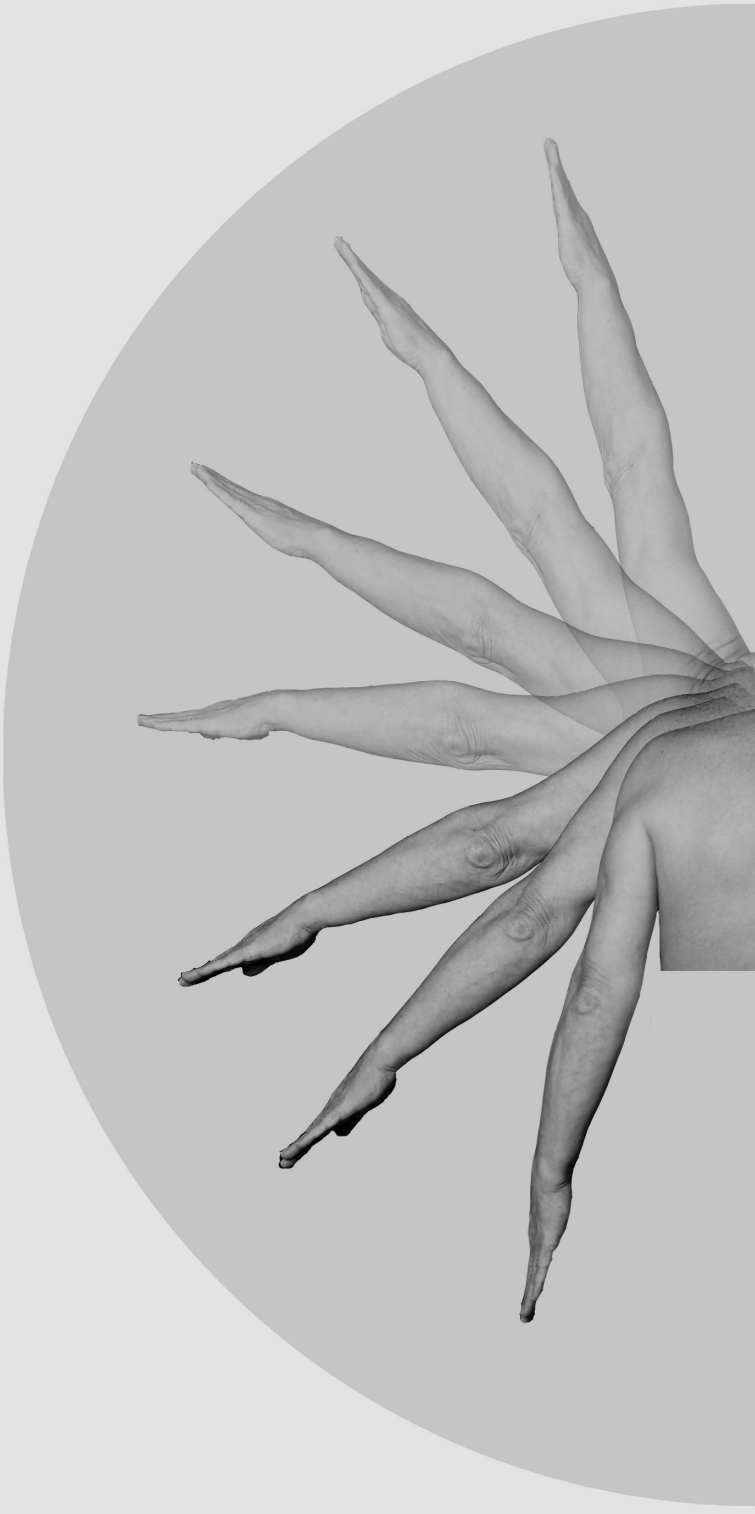
verbetering in schouderfunctie en vermindering van pijn. Een literatuurstudie naar gerandomiseerd gecontroleerde onderzoeken in PubMed, Embase, PEDro en het Cochrane register voor gerandomiseerd gecontroleerde onderzoeken is uitgevoerd. De methodologische kwaliteit van de geselecteerde studies is beoordeeld door twee personen. Een "best-evidence synthese" is gebruikt om de resultaten samen te vatten. Vier gerandomiseerd gecontroleerde onderzoeken zijn geïncludeerd. Twee hadden een medium methodologische kwaliteit en twee een lage kwaliteit. Geen verschil in uitkomsten tussen de groepen is gerapporteerd.

Het beste moment voor verwijzen van patiënten met SIS voor een operatie is niet goed gedefinieerd. Om hierin inzicht te krijgen is een transmurale behandeling strategie, TRANSIT (TRANSmurale behandeling strategie voor Subacromiale ImpingemenT) genaamd, ontwikkeld. Deze bevat regels voor behandeling van patiënten met SIS in de huisartsenpraktijk en een duidelijk gedefinieerd moment van verwijzing naar een orthopedisch chirurg voor een arthroscopische subacromiale decompressie. Deze strategie is getest in een gerandomiseerd gecontroleerd onderzoek waarin de controle groep bestaat uit het voortzetten van de gebruikelijke medische zorg (GMZ). *Hoofdstuk 5* beschrijft de opzet van dit onderzoek. De primaire uitkomstmaat bestond uit de functionele beperkingen gemeten met de Shoulder Disability Questionnaire (SDQ). De secundaire uitkomstmaten waren de Shoulder Rating Questionnaire (SRQ), de Constant-Murley Score, de Short-form 36 Health Survey en een score van het door de patiënt ervaren herstel. De behandeleffecten zijn vergeleken voor alle meetmomenten (bij randomisatie, en drie, zes en twaalf maanden daarna) met behulp van een "repeated-measures design". De data zijn geanalyseerd met behulp van een "intension-to-treat" analyse en het per-protocol principe. Het zorggebruik is beoordeeld met een kostenvragenlijst.

In *Hoofdstuk 6* worden de resultaten van het gerandomiseerd gecontroleerde onderzoek gepresenteerd. 26 patiënten zijn gerandomiseerd: 11 kregen GMZ en 15 ondergingen een arthroscopische subacromiale decompressie (TRANSIT). Middellange en langdurende complicaties kwamen significant meer voor in de TRANSIT groep (P=0.036). Beide groepen hadden een klinisch significante verbetering in hun functionele beperkingen één jaar na de randomisatie. Het verschil in gemiddelden over de follop-up duur tussen de groepen toonde een betere uitkomst voor de TRANSIT groep vergeleken met de GMZ groep voor alle uitkomstmaten. Deze verschillen waren echter niet significant, behalve voor de SDQ en de SRQ zes maanden na randomisatie (respectievelijk P=0.034 en P=0.019). De TRANSIT strategie was duurder dan de GMZ strategie. Deze resultaten ondersteunen de hypothese dat een vroegtijdige operatie tot betere resultaten leidt dan voortzetten van GMZ niet. De kleine onderzoeksgroep en de aanwezigheid van meer complicaties in de TRANSIT-groep hebben statistisch significante verschillen tussen de groepen één jaar na follow-up waarschijnlijk voorkomen. Het grote verschil in kosten tussen de twee strategieën, welke significant hoger is in de TRANSIT groep, benadrukt de noodzaak van het herkennen van prognostische factoren die voorspellen welke patiënten de meeste baat hebben bij een operatie.

Tot slot worden in de algemene discussie in *Hoofdstuk 7* de resultaten van de voorafgaande hoofdstukken kritisch bekeken in het licht van vier belangrijke

onderwerpen. Het eerste betreft het herstel van schouderklachten en de definitie hiervan. Tot op heden is er geen algemeen aanvaarde definitie van herstel van schouderklachten, welke onmisbaar is voor schouderonderzoek. Vervolgens wordt de rol van richtlijnen voor behandeling van schouderklachten voor huisartsen bediscussieerd, evenals het voorspellen van herstel. Dergelijke richtlijnen zijn kosteneffectief en zijn toepasbaar op het gros van de patiënten met schouderklachten. Het derde onderwerp richt zich op het bewijs voor opereren van SIS en mogelijke causale verbanden tussen de vorm van het acromion en SIS. Tot slot wordt ingegaan op het meten van de klinische effectiviteit van schouder behandelingen. Het juiste meetinstrument kiezen is essentieel binnen schouderonderzoek en de interpretatie van uitkomstmaten is voor de clinicus van belang voor het schatten van de waarde van veranderingen in schouder uitkomstmaten. Dit hoofdstuk eindigt met aanbevelingen voor verder onderzoek.



Appendix III

Dankwoord

DANKWOORD

Promoveren is net als roeien in een ploeg. Je kunt het niet alleen, en om zo snel mogelijk van A naar B te gaan moet ieder individu zorgen voor een perfecte timing om de boot zoveel mogelijk vaart te geven. In 2005 werd ik ingeselecteerd voor de ploeg genaamd "TRANSIT". Met mij erbij bestond de ploeg uit vijf teamleden. Het eindpunt was duidelijk, maar de vaarroute lag nog niet vast. Roeien doe je met je rug naar de vaarrichting, waardoor je niet ziet waar je heen vaart. Dit verschilt weinig met promoveren. Wegens ruig water is de route zelfs een stuk verlengd en er dreigde op een gegeven moment zelfs een vaarverbod. Uiteindelijk is mede door ieders enthousiaste inzet het eindpunt toch bereikt.

Naast de leden van de ploeg zijn de supporters langs de kant onmisbaar. Zij zorgen voor die extra motivatie waardoor je je voor meer dan 100% kunt inzetten. Al mijn teamleden, de praeses van de vereniging, de sparringpartners, de commissies, de reserve roeiers, de sponsor en natuurlijk de supporters onderweg, wil ik zeer hartelijk bedanken.

De teamleden

Ron Diercks en Jan Winters, jullie zijn eigenlijk de veteranen roeiers en het slagenpaar van de ploeg. Zonder jullie was de ploeg en ook de financiering voor de boot er niet gekomen. Na lang lobbyen en discussiëren hebben jullie de vereniging weten te overtuigen van het feit dat deze ploeg leven in geblazen moest worden. Jullie hebben je altijd vol enthousiasme ingezet en, zeker met jullie verschillende achtergrond, met een kritische blik gekeken of de boot wel de juiste koers hield. Jullie aanwezigheid en inbreng bij de veelvuldige team-overleggen heb ik enorm gewaardeerd.

Voordat we deze nieuwe ploeg vormden, hebben jij, Martin Stevens, en ik al een tijdje samen geroeid. Nu in deze nieuwe ploeg vormde jij in het middenschip de motor van de boot. Jij leverde de energie om de boot op gang te houden, de continue factor die het slagenpaar ondersteunde. Daarmee heb je zorg gedragen voor altijd weer een solide structuur, waar ik je zeer dankbaar voor ben.

De boegpositie in de boot werd ingenomen door Klaas van der Meer. In roeitermen gesproken: zonder boeg geen ploeg. Zo is het maar net. Van die positie kon jij de ploeg mooi overzien en bijsturen indien nodig. Ook wist je op de momenten dat we in zwaar water voeren, mij en de ploeg te overtuigen er een schepje bovenop te doen. Klaas, bedankt!

De praeses van de vereniging

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De sparringpartners
Zo nu en dan is sparren nodig om te beoordelen of alle inspanningen van de ploeg hebben geleidt tot een voldoende hoog niveau, of om het niveau nog verder te verhogen. Aan het eind van de trainingsperiode moesten de krachten gemeten worden met drie sparringspartners, te weten prof. dr. R.A. de Bie, prof. dr. R.G.H.H. Nelissen en prof. dr. K. Postema (leescommissie). Heren, mijn dank is groot voor jullie moeite en inspanningen.

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Zonder de inzet van de verwijzende huisartsen uit de regio en de verwijzende revalidatieartsen van het Martini Ziekenhuis zou dit project niet van de grond gekomen zijn. En zeker niet zonder de medewerking van de deelnemers. Dit heb ik zeer gewaardeerd.

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De supporters
Goede supporters weten door hun aanmoedigingen een ploeg maximaal te laten presteren. (ex)Collega-onderzoekers en/of kamergenoten Alette, Andrew, Barbara, Bas, Bertram, Henk, Ida, Inge (2x), Lauren, Mathijs, Natalie, Nienke, Paul, Sjouke bedankt voor alle hulp, motiverende woorden, gezelligheid tijdens lunches, dinertjes, barbecues en borrels, tennis en frisbee partijtjes.

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De sponsor
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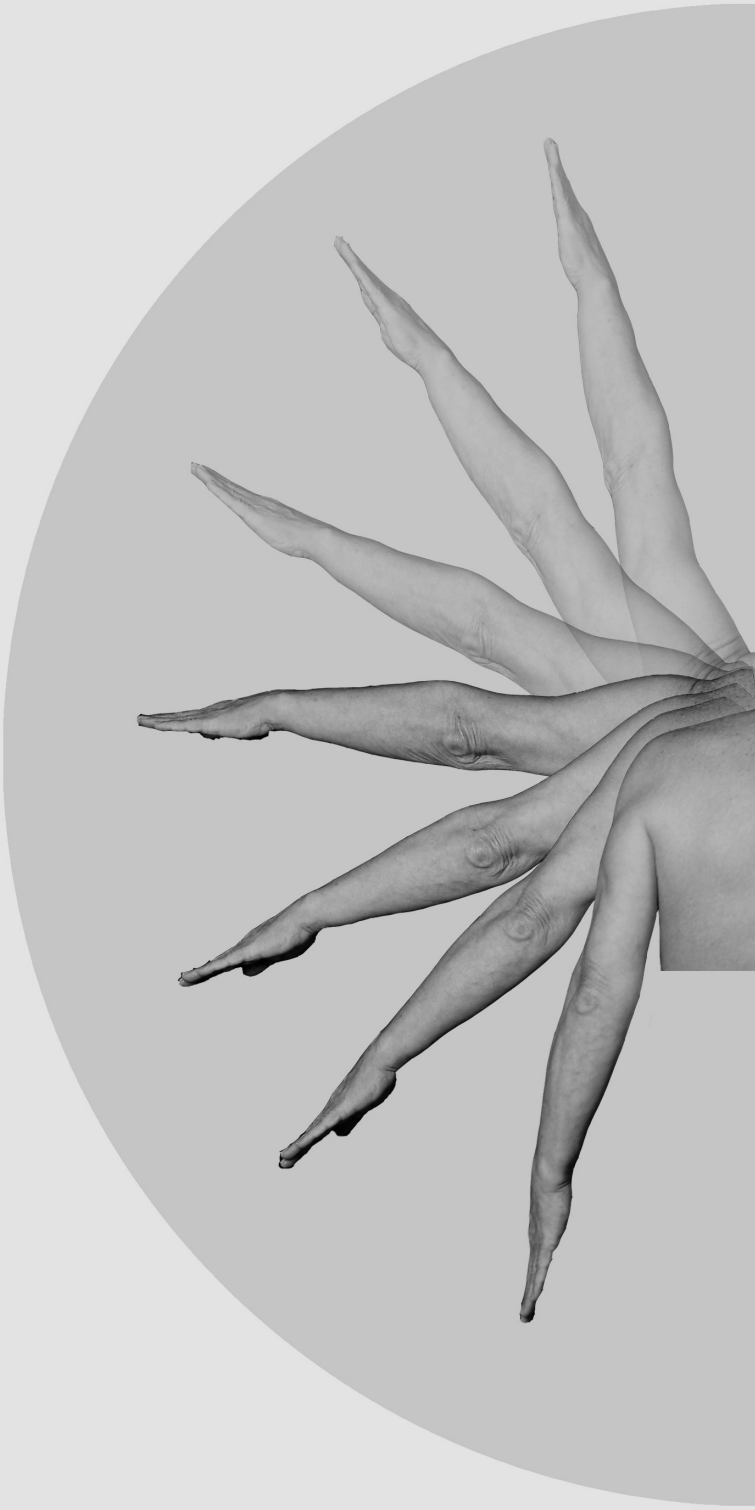
De hoofdsupporter
Tot slot nog een persoonlijk woord aan een bijzonder persoon voor mij, mijn hoofdsupporter en vriendin Liesbeth. Het was niet altijd makkelijk, naast je eigen baan, een kersverse lieve kleine meid en een promoverende kerel alles bol te werken. Vele avonden en weekenden moesten wijken voor het hogere doel. Jouw onvoorwaardelijke steun, je kritische blik, je organisatie van het feest en je inzet thuis hebben mijn leven een stuk aangenamer gemaakt en hebben er absoluut aan bijgedragen dat ik met de TRANSIT-ploeg de finish heb kunnen bereiken. Ik hou van jou!

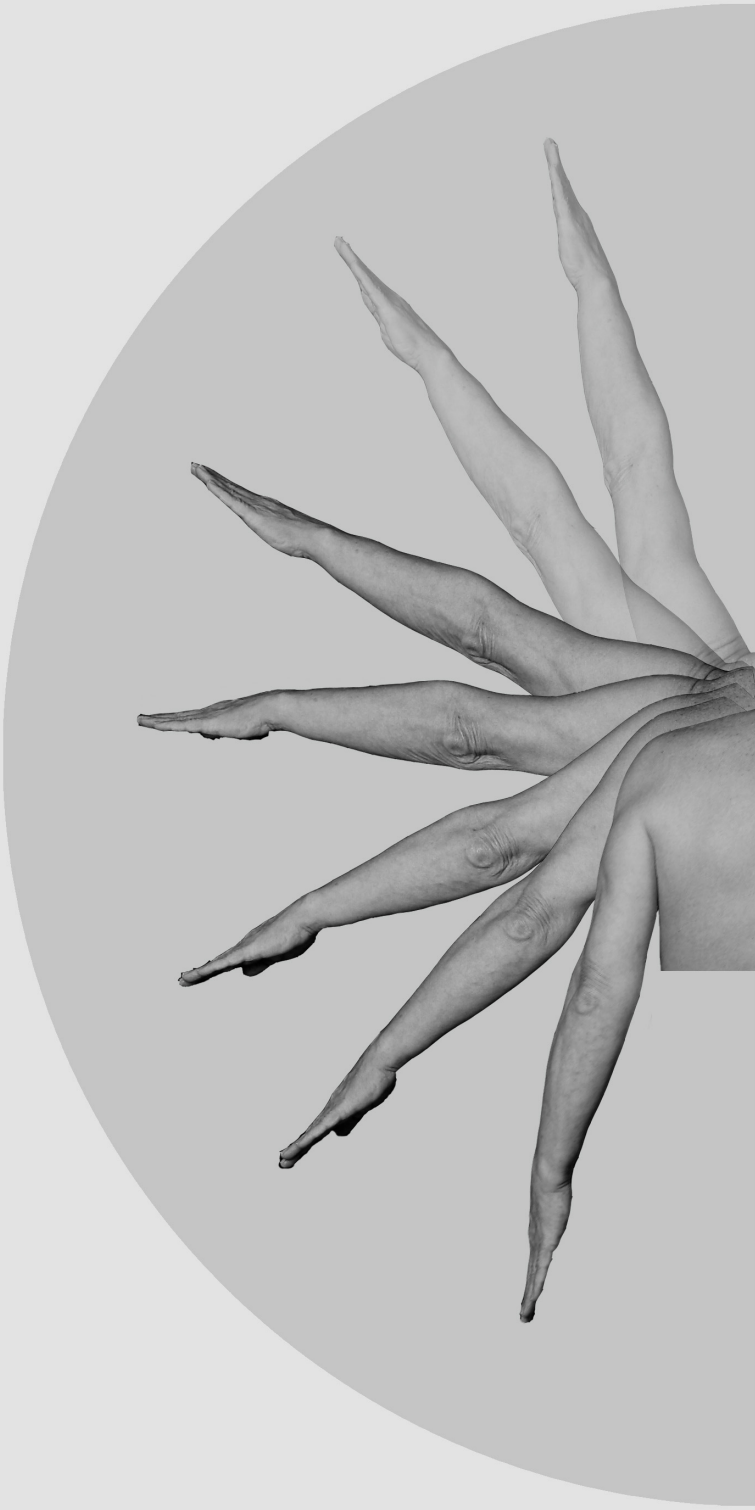


Appendix IV

About the author

ABOUT THE AUTHOR

Oscar Dorrestijn was born on February 16, 1974 in Delfzijl, the Netherlands. He studied Human Movement Science at the University of Groningen from 1992 to 1997. After graduating he was project officer for the Groningen Active Living Model Human Movement Science, University of Groningen (1997-2000). He also worked as team manager for the Groningen/ Dutch Bobsleigh Team (1997-1999). In 1999 he started Medical School at the University of Groningen. At the end of his clinical rotations he did a ten-week Orthopedic Surgery elective at Auckland City Hospital, New Zealand (head Dr. A. Hardy). Oscar graduated in January 2005 and started working for Sanquin Blood Bank for several months, followed by a position as resident in Orthopedic Surgery at Spaarne Hospital, Hoofddorp (head Dr. P.A. Nolte). In November 2005 he began his PhD studies at University Medical Center Groningen under the supervision of Prof. Dr. R.L. Diercks, Prof. Dr. K. van der Meer, Dr. M. Stevens and Dr. J.C. Winters. After ten months he started his surgical training at Medical Center Leeuwarden (head Dr. J.P.E.N. Pierie). He began his orthopedic training at Martini Hospital Groningen in December 2008 (head Dr. J.J.A.M. van Raay). In August 2012 he will return to University Medical Center Groningen for the last year of his residency period, under the supervision of Prof. Dr. S.K. Bulstra. Oscar lives in Groningen with Liesbeth Hoekstra and their daughter Elis Yke.



Appendix V

List of publications and presentations

LIST OF PUBLICATIONS AND PRESENTATIONS

Peer-reviewed articles

Patients with shoulder complaints in general practice: consumption of medical care
Dorrestijn O, Greving K, Stevens M, Winters JC, Van der Meer K, Diercks RL.
Rheumatology (oxford). 2011 Feb;50(2): 389-95.

A case of osteosarcoma in the distal femur two years after an ipsilateral femoral shaft fracture. Coincidence? A case report
Dorrestijn O, Jutte PC
Accepted – J Med Case Reports.

Arthroscopic acromioplasty versus usual medical care for the treatment of subacromial impingement syndrome: a randomized controlled trial. A new interdisciplinary strategy
Dorrestijn O, Diercks RL, Winters JC, Van der Meer K, Giepmans L, Stevens M
Submitted

Incidence, prevalence and consultation rates of shoulder complaints in general practice
Greving K, Dorrestijn O, Winters JC, Groenhof F, Van der Meer K, Stevens M, Diercks RL
Submitted

Bilateral Symptomatic Os Vesalianum Pedis: a Case Report
Dorrestijn O, Brouwer RW
Accepted - J Foot Ankle Surg.

Conservative or surgical treatment for subacromial impingement syndrome?
A systematic review
Dorrestijn O, Stevens M, Winters JC, Van der Meer K, Diercks RL
J Shoulder Elbow Surg. 2009 Jul-Aug;18(4):652-60

A new interdisciplinary treatment strategy versus usual medical care for the treatment of subacromial impingement syndrome: a randomized controlled trial
Dorrestijn O, Stevens M, Diercks RL, Van der Meer K and Winters JC
BMC Musculoskelet Disord. 2007 Feb 22; 8:15.

Book chapter

"Impingement Syndrome" in Evidence Based Orthopaedics (ed. M. Bhandari and S. Sprague)
Diercks RL, Dorrestijn O
Submitted

Oral and poster presentations

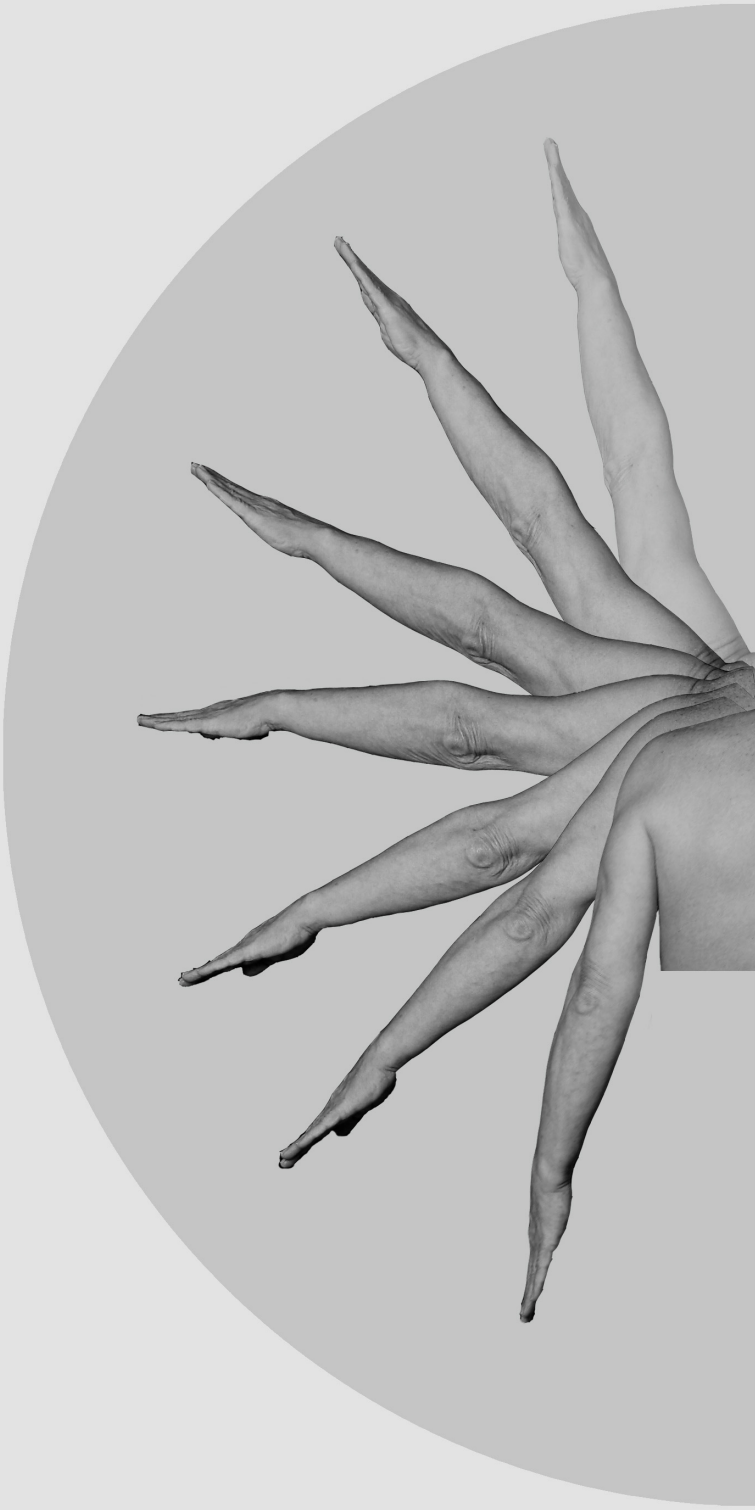
Patients with Shoulder Complaints in General Practice: Consumption of Medical Care
Dorrestijn O, Greving K, Stevens M, Winters JC, Van der Meer K, Diercks RL
ePoster, 11th International Congress of Shoulder and Elbow Surgery, Edinburgh, Scotland, 5-8 September 2010

Conservative or surgical treatment for subacromial impingement sydrome? A systematic review
Dorrestijn O, Stevens M, Winters JC, Van der Meer K, Diercks RL
ePoster, 21st congress European Society for Surgery of the Shoulder and the Elbow, Brugge, Belgium, 17-20 September 2008

Conservative or surgical treatment for subacromial impingement syndrome? A systematic review
Dorrestijn O, Stevens M, Winters JC, Van der Meer K, Diercks RL
Oral presentation, Dutch Orthopaedic Society Congres, WTC Rotterdam, The Netherlands, 2007

Transmural Project Subacromial Impingement. Study design TRANSIT
Dorrestijn O, Winters JC, Stevens M, Diercks RL, Van der Meer K
Poster presentation, Dutch College of General Practitioners Congress, Groningen, The Netherlands, 2006.

Implementation Groninger Fitness Test for Elderly
Dorrestijn O, De Greef M, De Jong J, Dirks C
Oral presentation, University of Sunderland, United Kingdom, 1999



Appendix VI

SHARE research and previous dissertations

RESEARCH INSTITUTE FOR HEALTH RESEARCH SHARE

This thesis is published within the Research Institute SHARE of the Graduate School of Medical Sciences (embedded in the University Medical Center Groningen / University of Groningen). More recent theses can be found in the list below.
Further information regarding the institute and its research can be obtained from our internetsite: www.rug.nl/share.

((co-)supervisors are between brackets)

2011

Mookhoek EJ. *Patterns of somatic disease in residential psychiatric patients; surveys of dyspepsia, diabetes and skin disease*
(prof AJM Loonen, prof JRBJ Brouwers, prof JEJM Hovens)

Netten JJ van. *Use of custom-made orthopaedic shoes*
(prof K Postema, prof JHB Geertzen, dr MJA Jannink)

Koopmans CM. *Gestational hypertension and mild pre-eclampsia at term*
(prof PP van den Berg, prof JG Aarnoudse, prof BWJ Mol, dr MG van Pampus, dr H Groen)

2010

Martirosyan, L. *Prescribing quality indicators for type 2 diabetes management: development, validation and selection*
(prof FM Haaijer-Ruskamp, dr P Denig, dr J Braspenning)

Zwerver J. *Patellar tendinopathy; prevalence, ESWT treatment and evaluation*
(prof RL Diercks, dr I van den Akker-Scheek, dr F Hartgens)

Heijne-Penninga M. *Open-book tests assessed: quality learning behaviour, test time and performance*
(prof JBM Kuks, prof J Cohen-Schotanus, prof WHA Hofman)

Veselská Z. *Intrapersonal factors, social context and health-related behavior in adolescence*
(prof SA Reijneveld, dr JP van Dijk, dr A Madarasova Geckova)

Dubayová T. *Parkinson's disease - psychological determinants of quality of life*
(prof JW Groothoff, dr JP van Dijk, dr I Nagyova, dr Z Gdovinona, dr LJ Middel)

Sarková M. *Psychological well-being and self esteem in Slovak adolescents*
(prof WJA van den Heuvel, dr JP van Dijk, dr Z Katreniakova, dr A Madarasova Geckova)

Oeseburg B. *Prevalence and impact of chronic disease in adolescents with intellectual disability*
(prof JW Groothoff, prof SA Reijneveld, dr DEMC Jansen)

Ittersum MW van. *Chronic musculoskeletal disorders assessment and intervention*
(prof JW Groothoff, prof CP van der Schans, dr CP van Wilgen, dr MF Reneman)

De Smedt RHE *Patients' perceptions of adverse drug events and their management in heart failure –towards a better understanding of the perspectives of the patients*
(prof FM Haaijer-Ruskamp, prof T Jaarmsa, prof K van der Meer, dr P. Denig)

Duyvendak M. *Pharmaceutical care by clinical pharmacists in patients with musculoskeletal disease*
(prof JRBJ Brouwers, dr M Naunton, dr EN van Roon)

Bakker MP. *Stressful life events and adolescents'mental health; The TRAILS study*
(prof AJ Oldehinkel, prof J Ormel)

Schokker MC. *Psychosocial outcomes in diabetes the interplay of intra-and interpersonal factors*
(prof M Hagedoorn, prof TP Links, prof R Sanderman, prof BHR Wolffenbuttel, dr JC Keers)

Hoedeman R. *Severe medically unexplained physical symptoms in a sick-listed occupational health population*
(prof JW Groothoff, dr B Krol, dr AH Blankenstein)

Voogd JN de. *Patients with chronic obstructive pulmonary disease in rehabilitation on psychological profiles, dyspnea and survival*
(prof R Sanderman, dr JB Wempe)

Vliet-Ostaptchouk JV van. *Revealing the genetic roots of obesity and type 2 diabetes*
(prof MH Hofker, prof C Wijmenga)

Bieleman A. *Work participation and work capacity in early osteoarthritis of the hip and the knee*
(prof JW Groothoff, dr FGJ Oosterveld, dr MF Reneman)

Voorham J. *Assessing cardiometabolic treatment quality in general practice*
(prof FM Haaijer-Ruskamp, prof BHR Wolffenbuttel, dr P Denig)

Meulenbelt HEJ. *Skin problems of the stump in lower limb amputees*
(prof JHB Geertzen, prof MF Jonkman, prof PU Dijkstra)

Connolly MP. *The economics of assisted reproduction; costs and consequences of fertility treatments*
(prof MJ Postma, prof W Ledger)

Spanjer J. *The Disability Assessment Structured Interview; its reliability and validity in work disability assessment*
(prof JW Groothoff, dr B Krol, dr S Brouwer)

Kooij L. *Diagnostic testing and screening in reproduction*
(prof PP van den Berg, prof MJ Heineman, dr Tj Tijmstra)

Tak LM. *Dysfunction of stress responsive systems in somatization*
(prof J Ormel, prof JPJ Slaets, dr JGM Rosmalen)

Vries R de. *Health-economics of interventions aimed at infectious diseases dynamic modeling inevitable for reliable medical decision making*
(prof MJ Postma, prof LTW de Jong-van den Berg)

Schorr SG. *Drug safety in patients with psychotic disorders*
(prof K Taxis, prof JRBJ Brouwers, dr R Bruggeman, dr CJ Slooff)

2009

Koopmans PC. *Recurrence of sickness absence; a longitudinal study*
(prof JW Groothoff, dr CAM Roelen)

Hell EA van. *The clinical learning environment; transition, clerkship activities and feedback*
(prof JBM Kuks, prof JCC Borleffs, prof J Cohen-Slaterus)

Bosmans JC. *Rehabilitation aspects of amputation*
(prof PU Dijkstra, prof JHB Geertzen)

Al Hadithy AFY. *Pharmacogenetics of antipsychotic-induced parkinsonism and tardive dyskinesia; a focus on African-Caribbeans and Slovanic Caucasians*
(prof JRBJ Brouwers, prof AJM Loonen, dr B Wilffert, dr R Bruggeman)

Hodselmans AP. *Psychophysical capacity in non-specific low back pain*
(prof JHB Geertzen, prof PU Dijkstra, dr CP van der Schans)

Andela RM. *Frailty in the clinical practice of nursing care*
(prof R sanderman, prof JPJ Slaets, dr A Dijkstra)

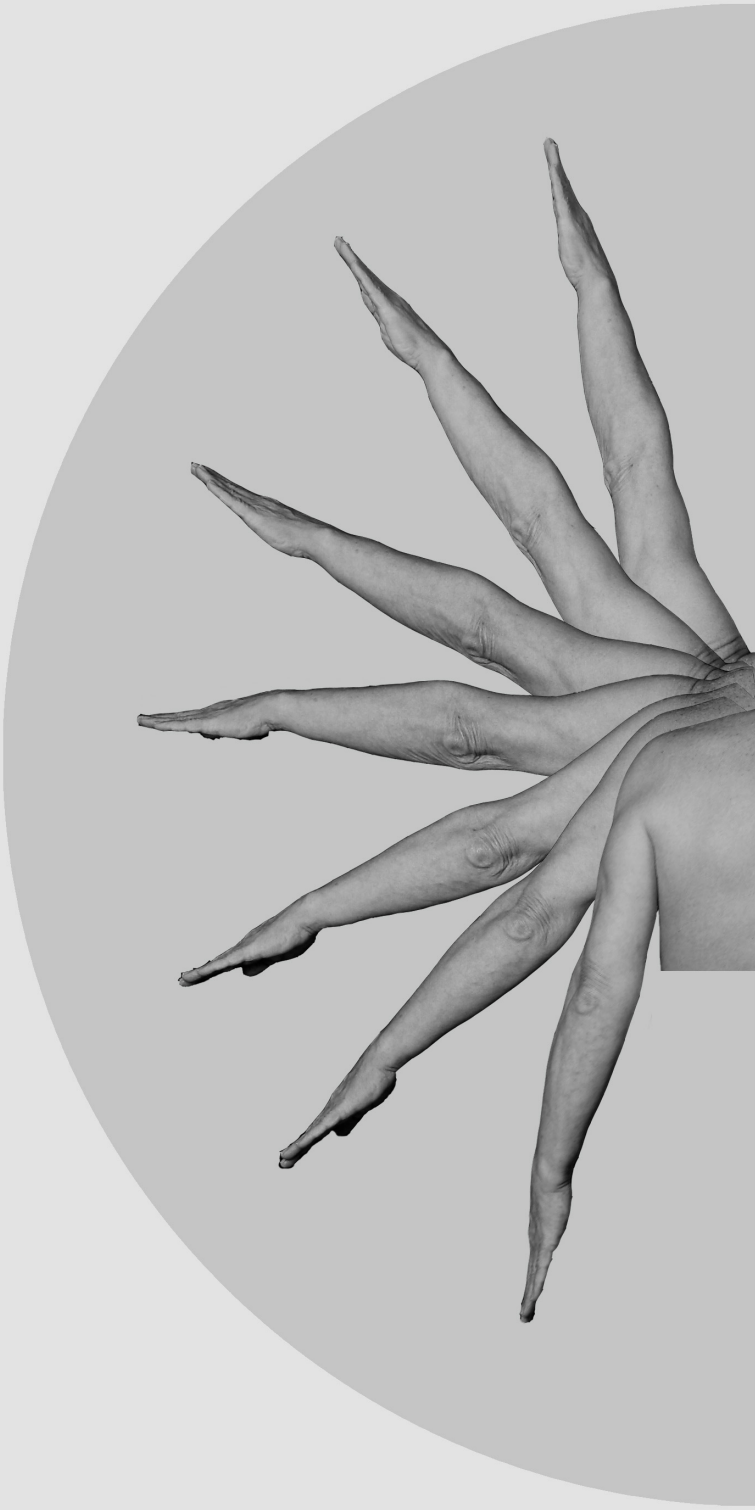
Henselmans I. *Psychological well-being and perceived control after a breast cancer diagnosis*
(prof AV Ranchor, prof R Sanderman, dr J de Vries)

Oud MJT. *Zorg voor mensen met ernstige psychische stoornissen*
(prof B Meyboom-de Jong, dr J Schuling, dr CJ Slooff)

Doormaal JE van. *Medication errors and adverse drug events in hospitalised patients; methodological issues and computerised intervention*
(prof FM Haaijer-Ruskamp, dr PGM Mol, dr JGW Kosterink, dr PLA van den Bemt)

Chang CMS. *Ageing with joy; the effect of a physical activity programme on the well-being of older people; a study conducted in five homes for the elderly in Paramaribo*
(prof JR van Horn, prof JW Groothoff, prof MA Vrede, dr M Stevens)

For more 2009 and earlier SHARE-theses see our website.



Appendix VII

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