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Observational study

Assessment and treatment at a pain clinic: A one-year follow-up of patients with chronic pain

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HIGHLIGHTS

- This is a longitudinal observational study of patients at a pain clinic.
- Considerable pain and low health-related quality of life were reported at baseline.
- Patients treated at the pain clinic showed improvements at the one-year follow-up.
- Pain clinics need to collect comparable, valid data on a regular base to improve care.

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ABSTRACT

Background and aims: Pain is one of the most common reasons for patients to seek primary health care. Pain relief is likely to be achieved for patients suffering from acute pain, but for individuals with chronic pain it is more likely that the condition will persist. These patients have the option of being referred to specialised pain clinics. However, the complexity surrounding chronic pain patients is not well studied in these settings. This study aimed to describe patients with chronic pain referred to a pain clinic by using the information submitted during their first visit and one year later and also to identify associations between baseline characteristics and improvements in health-related quality of life in the follow-up.
Methods: This was a longitudinal observational study of a sample consisting of 318 patients referred to a pain clinic. One group of patients containing 271 individuals (median age 48, 64% females) was assessed and received conventional pain treatment (CPT group) and a second group of 47 patients (median age 53, 64% females) was assessed by a pain specialist and referred back to their physician with a treatment recommendation (assessment only, AO group). Patient-reported outcome measures in health-related quality of life (EQ-5D), pain intensity (VAS), mental health (HADS), insomnia (ISI), pain-related disability (PDI), kinesiophobia (TSK) and sense of coherence (SOC) were collected at the first visit and one year later.
Results: At baseline, the CPT group reported a low EQ-5D Index (median (md) 0.157) and EQ VAS (md 40) as well as considerable high, current pain intensity VAS (md 58), HADS anxiety (md 8), ISI (md 17), PDI (md 36) and TSK (md 39). The AO group showed similar problems (no significant differences compared to the CPT group), except for ISI, where the AO group reported less severe problems. At the one-year follow-up, the CPT group had a statistically significant improvement in EQ-5D, VAS, ISI, PDI and TSK. In the AO group no significant changes were observed. In the CPT group there was an association between a high ISI level at baseline and an improved EQ-5D Index in the follow-up.

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Conclusions: The study describes rarely explored groups of patients with chronic pain at a pain clinic. Severe pain problems were present in both groups at their first visit. A statistically significant improvement could be seen in the group that was conventionally treated while this was not the case among those subjects who were assessed and referred. The results imply, that relatively limited treatment strategies were helpful for the patients' health-related quality of life. Despite these improvements, the patients were not fully recovered, pointing to the chronicity of pain conditions and the need of support for many patients.

Implications: Increased knowledge about assessment, selection and treatment at pain clinics is important to improve the quality of the work performed at these clinics. Despite limited resources, further efforts should be made to collect comparable, valid data on a regular base from pain clinics in order to develop recommendation models.

1. Background

The conventional definition of chronic pain is a state lasting longer than three to six months (or the time needed for the injury to heal). This definition has been modified and now also includes the subject's experience in relation to dynamic interactions of physiological, psychological and social factors [1]. Neuroimaging studies support the view that chronic pain is a separate identifiable illness [2]. The development of chronic pain is due to several known and unknown factors. One contributing factor is sleep disturbance, which impairs endogenous pain inhibition [3]. Patients who suffer from chronic pain experience a life in a state with not only pain, but often also reduced quality of life and deteriorated mental health, sleep disorders and fatigue as well as sustained disability to perform daily tasks [4–9].

Pain relief has always been an important task for health care. Specialised pain clinics were developed after the Second World War based on the anesthesiological tradition of treating pain with nerve blocks and other pharmaceutical treatments. This was mostly successful regarding acute pain, but less apparent for chronic pain conditions [10]. To better cope with this, the bio-medical model was replaced by the bio-psychosocial model [1].

Systematic reviews showed evidence in favour of multidisciplinary/interdisciplinary treatment modalities compared to less comprehensive interventions for chronic musculoskeletal pain to improve quality of life and return to work despite difficulties to improve pain levels [11,12]. Recommendations for patients with other pain aetiologies often focus on pharmacological therapy, with little attention to the bio-psychosocial model or whether patients have their own ideas or desires for treatment [13,14].

In Sweden, primary care is the first line of treatment for patients with chronic pain, followed by the possibility to refer patients to pain clinics or pain rehabilitation units. Research on patients with chronic musculoskeletal pain and their treatment is frequent in the setting of rehabilitation clinics [15,16], but less common when it comes to pain clinics. The bio-psychosocial pain analysis is the first part of the work at the pain clinic and leads to a treatment plan. The pain analysis includes medical history and examination, supplementary investigations and assessment of psychosocial factors such as depression, anxiety or work-related issues [17,18]. Pharmacological therapy is often the basic approach in the treatment at pain clinics. At some clinics, the treatment can be extended to also include physiotherapeutic, educational and psychological treatment as well as invasive interventions.

Although treatment of patients with chronic pain at pain clinics is widespread, there are few studies reported from these settings [6,19–23]. To improve quality of care for patients at pain clinics, more knowledge is needed about the work, the referred patients and the treatment outcome [17,24]. Research in such a clinical context is challenging and needs to be pragmatic. However, it is almost impossible to perform randomised studies. Instead, selecting patients consecutively is a more realistic option.

This study aims to describe patients at a pain clinic, to follow them from their first visit to one year later and to identify associations between baseline characteristics and improved health-related quality of life (HRQoL) in the follow-up. The hypothesis is that there are significant improvements in HRQoL and reduction in pain intensity.

2. Material and methods

2.1. Study design

The study had a prospective and observational design. Patients treated with conventional pain treatment (the CPT group) at the pain clinic were followed from their first visit until one year later. In addition, patients who were referred back to the referring physician after assessment only (the AO group) were followed in the same way. Data were collected from patient questionnaires and medical records.

2.2. Setting

The pain clinic, at Södersjukhuset in Stockholm, Sweden, has broadened its treatment options in recent decades. Due to the complexity of treatment options, the team included members with different capabilities. The team consisted of physicians specialised in algology, anaesthesia, general medicine or rehabilitation medicine. In addition, there were nurses, a physiotherapist and a psychologist. To meet the patient's need, the team worked either as individuals, multidisciplinary (different professions loosely collaborating) or as an interdisciplinary team (regular team meetings leading to group decisions for planning, goal establishment and assessment of progress of the patient's situation).

Patients (≥18 years) were referred to the pain clinic for assessment or treatment from primary care and specialist units. A prerequisite for acceptance at the pain clinic was a complete medical examination and previous initial treatment of the underlying disease. Referrals were assessed by an interdisciplinary team and patients accepted for a visit were invited to a first appointment. This visit included a bio-psychosocial pain analysis and an individualised treatment plan. The treatment plan was then sent to the referring physician for information.

Patients referred for assessment only, identified at the first visit as being in need of minor or suitable interventions at other health care facilities, were referred back to their physician with a treatment plan, forming the AO group of this study. The majority of patients, assessed to benefit from CPT, continued their treatment at the clinic. The patients represented different categories of chronic pain conditions.

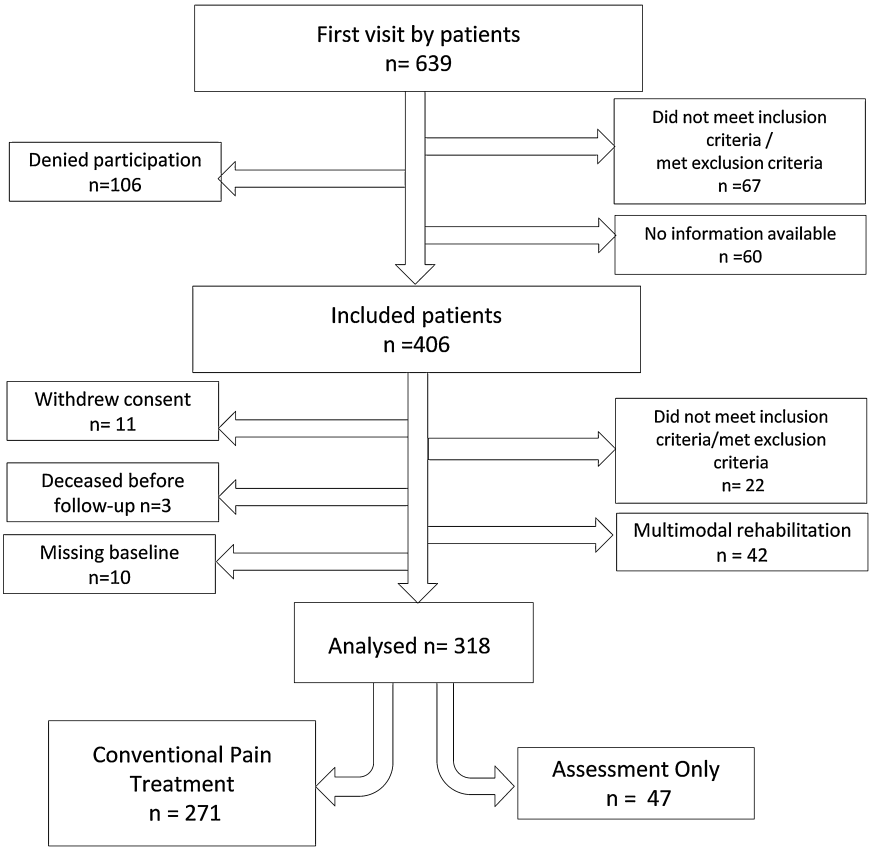

Fig. 1. Flow chart of all patients who came to the clinic during the study period and were screened for inclusion. Patients receiving treatment (CPT group) or where assessed and referred (AO group) are the sample in this study. The multimodal rehabilitation group was described elsewhere [29].

2.3. Conventional pain treatment

The CPT was mainly pharmacological, including different drugs appropriate for pain relief and pain-related symptoms such as oral analgesics and adjuvants. Strong opioids were avoided unless there were obvious indications for their use and any risk factors considered. Peripheral nerve or regional sympathetic blocks as well as topical use of lidocaine or capsaicine were also alternative treatments. If single-handed, pharmacological therapy was insufficient, the treatment was extended with interventions from the other team members. Transcutaneous electric nerve stimulation (TENS) [25,26] was used for a wide range of indications in patients who showed motivation for self-treatment. Psychological assessment and individual cognitive behavioural therapy were available for patients with mental distress. To increase understanding and better coping with pain, patients were invited to participate in a pain self-management course of eight sessions, which was based on behavioural medicine principles. Interested patients also had the possibility to participate in an eight-session mindfulness course [27]. The physiotherapist, who was trained in acceptance and commitment therapy (ACT), offered an ACT-inspired course of 6 sessions for women with endometriosis.

The treatment effect was followed up by the responsible health care professionals through patient visits or telephone calls. A major responsibility was also left to the patient, who had to make contact and report treatment results. The length of the treatment period depended on the need, usually ranging from some weeks to about six months. When the patient achieved satisfaction with the pain management, the treatment was continued by the regular physician in primary care. Some patients treated mainly pharmacologically had longer contact with the pain clinic.

2.4. Patients and procedure

The inclusion process is shown in Fig. 1. Participants were recruited from all patients ($n = 639$) entering the clinic at their first visit between April 2011 and March 2013. Inclusion criteria for the study were pain duration of >3 months, age of ≥18 years. Exclusion criteria were severe illness with expected survival <6 months and cognitive impairment assessed by the Short Portable Mental Status Questionnaire [28]. Of the 406 patients included, 14 individuals dropped out before the follow-up and 10 submitted empty baseline questionnaires. Three months after inclusion, the first author (A.H) reviewed the patients' records and differentiated the groups based on the actual treatment at that time point. Concurrently, 22 patients were identified as not meeting inclusion or meeting exclusion criteria. Patients included in a multimodal rehabilitation programme (MMR) ($n = 42$) were described elsewhere [29]. Patients conventionally treated (CPT group, $n = 271$) and patients assessed by the pain clinic team members, but referred back to the referring physician for further treatment or examination (AO group, $n = 47$) formed the sample in the current study.

A self-assessment questionnaire was handed out to the patients at their first visit to the pain clinic, when written consent was also obtained (baseline). The questionnaire included seven validated instruments (Table 1) [9,18,31–48] for patient-reported outcome measures (PROM), which were described in detail earlier [29]. In addition, questions about pain duration, localisation and education, country of origin and livelihood were identical to those in the questionnaire in the Swedish Quality Registry for Pain Rehabilitation (SQRP) [30]. Age and gender were obtained from medical records. After 12 months the follow-up questionnaires were sent by mail, followed by reminders as necessary.

Table 1
Instruments used for patient-reported measures.

Domain	Instrument	Abbreviation	Description	Total score min-max	Cut-off for severity levels	MCIC	References
Health-related quality of life Generic instrument	EuroQual Dimension index	EQ-5D Index	Dimensions: Mobility, self-care, usual activities, pain/discomfort, anxiety/depression Levels: no problems = 1, some problems = 2, extreme problems = 3	−0.594–1		0.1	[31–34]
	EuroQual Visual Analogue Scale	EQ VAS	20 cm vertical scale with endpoints "worst imaginable health state"0 respectively "best imaginable health state 100"	0–100			[33]
Current pain intensity	Visual Analogue Scale	VAS	100 mm horizontal visual analogue scale with the endpoints "no pain" to "worst imaginable pain"	0–100	Pain interference with function: ≤34 = mild 35–64 moderate ≥65 severe	18–19	[18,35,36,45]
Insomnia	Insomnia Severity Index	ISI	Dimensions: sleep onset, sleep maintenance, early morning awaking problems, sleep dissatisfaction, interference of sleep with daily activity, sleeping problems interfering with quality of life noticeable by others, distress due to sleep problems during the last two weeks Levels: 0= no problems, 4= severe problems	0–28	No insomnia ≤7 Sub-threshold 8–14 Moderate 15–21 Severe insomnia ≥22	6–8.4	[9,37,46,48]
Pain-related disability	Pain Disability Index	PDI	Domains: family/home responsibility, recreation, social activities, occupation, sexual behaviour, self-care, life-support activity Likert scales from no disability =0 to svere problems =10	0–70		8.5–9.5	[38,39]
Mental health screening questionnaire	Hospital Anxiety and Depression Scale	HADS-A	Anxiety subscale different statements regarding anxiety, four levels of severity	0–21	No cases of anxiety/depression 0–7 Doubtful cases 8–10 Definite cases 11–21		[40,41]
		HADS-D	Depression subscale different statements regarding depression, four sevrity levels	0–21			
Kinesiophobia	Tampa Scale of Kinesiophobia	TSK	17 items are assessed on 4-point Likertscales ranging from strongly disagree to strongly agree.	17–68	Low kinesiophobia 17–33, mild 34–41, high kinesiophobia 42–68		[43,44]
Pain localisation	Number of pain sites	NPS	Pain localisation in descriptions of 18areas represented at both right and left half of the body	1–36	Local pain: ≤4 Widespread pain ≥5		
Sense of Coherence	Sense of Coherence	SOC	Based on Antonovsky's Sense Of Coherence concept. 13 items to assess an individual's view of life as being comprehensible, manageable and meaningful. Likert scales from 1–7.	7–91	Weak SOC ≤ 57 Moderate 58–74 Strong SOC ≥ 75		[42,47]

MCIC, minimal clinically important change.

Table 2
Demographic data and pain characteristics at baseline in the conventional treatment group (CPT group) and the assessment group (AO group).

		CPT group		AO group		*P*-value
Gender	Female	173	(64)	30	(64)	1
	Male	98	(36)	17	(36)	
Age	Median (q1–q3)	48	(37–62)	53	(44–63)	0.156
Country of origin	Sweden	221	(83)	42	(91)	0.467
	Europe	20	(8)	2	(4)	
	Outside Europe	27	(10)	2	(4)	
	Missing	3		1		
Education	Elementary school	39	(15)	9	(21)	0.405
	Secondary school/vocational training	117	(44)	22	(50)	
	University	102	(38)	13	(30)	
	Other	8	(3)	0		
	Missing	5		3		
Family status	Living alone	80	(31)	16	(37)	0.690
	Living with family/children	73	(29)	13	(30)	
	Living with spouse/partner	87	(34)	13	(30)	
	Other	17	(6)	1	(3)	
	Missing	14		4		
Livelihood	Employment income only	80	(32)	14	(33)	0.11
	Employment income and sickness benefits	36	(14)	1	(2)	
	Sickness benefits only	70	(28)	16	(38)	
	Sickness benefits and/or other allowances[a]	68	(27)	11	(26)	
	Missing	17		5		
Pain duration	≤6 months	25	(10)	5	(18)	0.342
	7–24 months	59	(23)	7	(25)	
	≥25 months	168	(67)	16	(57)	
	Missing	19		19		
Number of pain sites	Median (q1–q3)	7	(4–12)	6	(4–12)	0.410
Localisation of worst pain	Head and face	8	(4)	4	(10)	
	Neck, shoulder, arm	41	(20)	3	(8)	
	Thorax	10	(5)	2	(5)	
	Abdomen	28	(13)	1	(3)	
	Sexual organs and groin	12	(6)	2	(5)	
	Back, upper and lower	41	(20)	12	(31)	
	Hip and buttock	10	(5)	2	(5)	
	Leg	39	(19)	9	(23)	
	Worst area varies	21	(10)	4	(10)	
	Missing	61		8		

Categorical variables presented with *n* (%) and tested with Fisher's exact test and continuous variables presented with median (q1–q3) and tested with Mann–Whitney *U* test.

[a] Other income such as pension, unemployment benefit, maternity/paternity benefit or patient's own savings.

2.5. Statistics

As all the questionnaires concern patient-reported measures, non-parametric statistics were used. Only instruments with full item responses were included in the analysis. Differences between the two groups were tested using Fisher's exact test for categorical data and the Mann–Whitney *U* test for continuous data. To analyse the change between baseline and follow-up, the Wilcoxon sign rank test was used.

To study the association between the independent variables (age, gender, country of origin, education and PROM) and EQ-5D Index increase, logistic regression analysis was performed in the CPT group. The AO group was too small to be analysed by logistic regression analysis. To dichotomize the EQ-5D Index, the minimal clinically important change (MCIC) of 0.1 described earlier was used to differentiate either increased or unchanged/decreased [34]. The independent variables HADS, ISI, and TSK were dichotomized in accordance with previously described cut-off points. EQ VAS, PDI and number of pain sites were categorised related to clinically important states represented in the data. The first and third quartiles were used to categorise SOC. The clinical state which represented best health was used as reference in all outcomes.

Firstly, the univariable association between increased EQ-5D Index and each of the independent variables was studied. Secondly, the statistically significant variables from the first analysis (ISI, PDI and SOC) were entered into a multivariable model together with age and gender. We report odds ratios (OR) and corresponding 95% confidence intervals. To measure the model fit, a Hosmer and Lemeshow test was performed.

In order to investigate possible bias due to missing data, we compared the baseline values of the questionnaires (EQ-5D, VAS, HADS, ISI, PDI, TSK and SOC) between the responders with valid values at baseline and follow-up and the dropouts with missing values at follow-up. We also compared the two groups (CPT and AO) concerning the demographic variables (age, gender, education and country of origin).

SPSS version 22 software was used for data analysis. *P*-values ≤ 0.05 (two-sided) were considered to be significant.

3. Results

3.1. Baseline assessments

The patients showed complex and heterogeneous pain categories. Mixed pain conditions were represented in 24% ($n = 73$). Solely neuropathic pain was found in 29% ($n = 88$), nociceptive pain in 16% ($n = 50$), visceral pain in 13% ($n = 40$) or other aetiology 18% ($n = 56$). In 11 patients no information about the pain condition was available. The demographics, pain duration and localisation are presented in Table 2. In both groups the majority

Table 3
Baseline values of PROM in the conventional treatment group (CPT group) and the assessment group (AO group).

	CPT group			AO group			*P*-value
	n	md	q1–q3	*n*	md	q1–q3	
EQ-5D Index	249	0.157	0.030–0.673	42	0.159	0.030–0.666	0.585
EQ VAS	225	40	30–61	40	50	23–74	0.489
VAS current pain	260	58	31–72	46	38	17–75	0.082
HADS anxiety	257	8	5–11	46	6	3–11	0.152
HADS depression	261	7	4– 11	44	6	2–10	0.207
ISI	255	17	12–21	47	13	9–19	0.020
PDI	239	36	26–47	41	35	23–42	0.319
TSK	241	39	33–46	42	37	31–43	0.209
SOC	237	59	49–69	40	60	52–72	0.709

Presented with median (q1–q3) and tested with Mann–Whitney *U* test. EQ-5D Index, EuroQol-5 Dimensions Index; EQ VAS, EuroQol Visual Analogue Scale; VAS, Visual Analogue Scale; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; PDI, Pain Disability Index; TSK, Tampa Scale of Kinesiophobia; SOC, Sense of Coherence scale.

of patients were female (64% in both groups). The majority were middle-aged (31–65 yrs) with 69% in the CPT group and 72% in the AO group, respectively. The young patients (18–30 yrs) were represented in 12% versus 9%, respectively while 19% were pensioner (≥66 yrs) in both groups. In general, the patients showed a long history of pain, with pain duration of >2 years found in 67% in the CPT group and 57% in the AO group, respectively. Employment income was reported by 46% of patients in the CPT group while the proportion was 35% in the AO group (Table 2).

Widespread pain was common, as pain localisation ≥6 areas (median) were found in both groups. Located pain on one site was only found in 8% in the CPT group and in 13% in the AO group. The most common pain localizations in the CPT group were shoulder/arm (20%), back (upper and lower, 20%) leg (19%) and abdomen (13%). In the AO group, upper and lower back pain (31%), pain in head and face (10%) and pain in leg (23%) were most frequent. The groups showed no statistically significant differences in baseline characteristics of demographics, pain duration or localisation.

In Table 3, the patient-reported outcome measures at baseline are presented. The CPT group showed higher insomnia than the AO group, otherwise there were no statistical significant differences in the patient-reported measures. No differences were found between genders at baseline apart from TSK, where males presented higher kinesiophobia.

The CPT group represented patients with complex pain problems since 37% reported severe current pain (VAS ≥65), which was associated with mild to severe anxiety (HADS-A ≥8) in 52%, mild to severe depression (HADS-D ≥8) in 47%, moderate insomnia (ISI 15–21) in 41% and severe insomnia (ISI ≥22) in 24%, as well as high disability (PDI ≥41) in 39% and high kinesiophobia (TSK ≥42) in 39%. The problems were similar in the AO group: 33% reported severe current pain, mild to severe anxiety in 46%, mild to severe depression in 39%, moderate insomnia in 28% severe insomnia in 17%, high disability in 32% and high kinesiophobia in 31%.

When reviewing the CPT group patients' records, three months after inclusion, the observed treatment was recorded. Medications started and prescribed at the pain clinic were described

Table 4
Changes in PROM from baseline to one year later.

	CPT group						
	Baseline			Follow up			
	n	md	q1–q3	md	q1–q3	*P*-value[a]	cs
EQ-5D Index	175	0.157	0.088–0.656	0.620	0.088–0.725	0.000	+
EQ VAS	140	40	30–60	49	30–70	0.024	
VAS current pain	185	57	30–73	48	21–69	0.002	
HADS anxiety	175	7	4–11	7	4–11	0.401	
HADS depression	184	7	4–10	7	3–11	0.814	
ISI summa	176	16	12–21	15	9–20	0.001	
PDI	158	36	25–46	32	18–43	0.000	
TSK	156	38	33–46	35	30–43	0.000	
SOC	163	59	50–69	60	50–70	0.951	

	AO group					
		Baseline		Follow up		
	n	md	q1–q3	md	q1–q3	*P*-value
EQ-5D Index	28	0.173	0.088–0.656	0.328	0.002–0.691	0.429
EQ VAS	25	60	27–71	50	29–72	0.940
VAS current pain	30	35	17–75	47	20–65	0.566
HADS anxiety	29	6	3–11	4	2 –10	0.415
HADS depression	26	5	2–8	6	3–11	0.357
ISI summa	30	14	8–20	13	9–19	0.591
PDI	23	35	21–42	32	22–44	0.721
TSK	24	39	31–48	35	29–54	1.000
SOC	25	61	50–74	63	52–72	0.843

Only patients with values at both baseline and the one-year follow-up are presented.

[a] Statistical significant improvement. cs Clinically significant improvement. Wilcoxon signed rank between baseline and follow-up assessments within the groups. EQ-5D Index, EuroQol-5 Dimensions Index; EQ VAS, EuroQol Visual Analogue Scale; VAS, Visual Analogue Scale; HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; PDI, Pain Disability Index; TSK, Tampa Scale of Kinesiophobia; SOC, Sense of Coherence scale.

Table 5
Associations between increment in EQ-5D Index and baseline variables in the CPT group.

		n, Total/(% with increment in EQ-5D Index*)	Univariable model			Multivariable model		
			OR	95% CI	*P*-value	OR	95% CI	*P*-value
Age	41–65 yrs vs ≤ 40 yrs	91 (40)/41 (44)	0.8	0.4–1.8	0.639	0.6	0.3–1.5	0.308
	≥66 yrs vs ≤40 yrs	43 (42)/41 (44)	0.9	0.39–2.2	0.850	1.3	0.6–2.6	0.675
Gender	Female vs male	110 (45)/65(35)	1.5	0.8–2.8	0.235			
Country of origin	Abroad vs Sweden	30 (50)/143 (39)	1.6	0.7–3.4	0.275			
Education	Primary/secondary school vs university	106 (41)/66 (42)	0.9	0.5–1.7	0.810			
EQ-5D Index	<0.3 (low) vs >0.31 (high)	113 (56)/62 (15)	7.4	3.3–16.5	<0.001			
EQ VAS	≤32 (low) vs ≥33 (high)	51 (35)/93 (43)	0.7	0.4–1.5	0.367			
VAS current pain	≥65 (severe) vs ≤64 (mild/moderate)	63 (41)/105 (40)	1.1	0.6–1.99	0.871			
ISI	≥22 (severe) vs ≤21 (No problems/sub-threshold/moderate)	39 (56)/127 (35)	2.4	1.1–4.9	0.021	3.5	1.3–9.2	0.013
PDI	≥41 (high) vs ≤40 (low)	59 (53)/97 (36)	1.96	1.01–3.8	0.045	1.7	0.8–3.96	0.198
HADS anxiety	≥11 (definite cases) vs ≤10 (no/doubtful cases)	43 (37)/123 (42)	0.8	0.4–1.7	0.561			
HADS depression	≥11 (definite cases) vs ≤10 (no/doubtful cases)	38 (37)/133 (41)	0.8	0.4–1.7	0.617			
TSK	≥42 (high) vs ≤41 (low/mild)	58 (43)/99 (37)	1.3	0.7–2.5	0.479			
NPS	General ≥5 pain sites vs local ≤4 pain sites	115 (40)/60 (43.3)	0.9	0.5–1.6	0.671			
SOC	≤49 (weak) vs ≥70 (high)	32 (19)/40 (14)	2.1	0.7–5.8	0.168	0.8	0.2–3.3	0.796
	50–69 (moderate) vs ≥70 (high)	84 (67)/40 (14)	3.6	1.5–8.5	0.003	2.2	0.8–5.8	0.115

Analysis performed with logistic regression analyses. * Increment in EQ-5D Index ≥0.1 difference between baseline and 1year follow-up. OR: odds ratio; CI: confidence interval; EQ-5D Index: EuroQol-5 Dimensions Index; EQ VAS: EuroQol Visual Analogue Scale; VAS: Visual Analogue Scale; ISI: Insomnia Severity Index; PDI: Pain Disability Index; HADS: Hospital Anxiety and Depression Scale; TSK: Tampa Scale of Kinesiophobia; NP: Number of Pain sites; SOC: Sense of Coherence scale.

for 169 patients. The drugs mainly prescribed at the pain clinic were: antidepressants (TCA/SNRI) ($n = 123$), antiepileptics ($n = 36$), strong opioids, including tapentadol ($n = 35$), tramadol ($n = 7$), paracetamol ($n = 8$), NSAID ($n = 4$) and topical administered pharmaceuticals ($n = 17$), and 5 patients were treated with regional blocks or local anaesthetics. The following interventions were also observed; 105 patients tested TENS and received instructions about self-care with the TENS equipment at home, 25 had individual psychological interventions, 20 participated in the pain management course, 8 in ACT-inspired groups, 5 in the mindfulness course and 6 were prescribed physical activity or recommended physiotherapy and 2 were referred for dorsal column stimulation.

3.2. Changes over time

Patient-reported outcome measures from patients answering both the baseline and the follow-up questionnaire are presented in Table 4. The CPT group showed statistically significant improvements in EQ-5D Index, EQ VAS, VAS, ISI, PDI and TSK. The AO group showed no significant changes. The response rate for the follow-up differed between the instruments. In the CPT group the response rate in all instruments was 62% (range from EQ VAS 52% to HADS 68%). In the AO-group the response rate for all instruments was 56% (range from PDI 49% to VAS current pain 63%). The dropout analysis of responders at baseline and follow-up compared to responders representing only baseline data (demographics and PROM) of the whole sample showed no significant differences except age. The dropouts were younger than the patients answering both questionnaires.

3.3. Associations for the improvement of patient-reported measures

Associations with an increased EQ-5D Index in the follow-up were found in the CPT group for patients with low EQ-5D Index, severe insomnia, high disability or moderate SOC at baseline in the crude model (Table 5). In the multivariable model, only ISI remained statistically significant. A Hosmer and Lemeshow test showed good adaption for the model (*P*-value 0.825).

4. Discussion

The main findings were that the CPT group showed substantial suffering from pain and related problems at baseline, but there was a statistically significant improvement in several outcome measures at the follow-up. Severe sleep disturbance was associated with a greater likelihood of showing improvement in health-related quality of life (HRQoL) at follow-up than if patients suffered from minor sleep disturbances. Patients in the AO group had similar characteristics at baseline, but did not show any significant changes at follow-up.

4.1. Baseline and follow-up PROM in CPT and AO group

Patients in both groups had low HRQoL (EQ-5D Index median 0.15) at their first visit, indicating deteriorated quality of life compared to subjects with other pain conditions. For comparison, patients in primary care with mixed chronic musculoskeletal pain reported an EQ-5D Index of 0.7 [49], patients with neuropathic pain an EQ-5D Index of 0.47 [50] and patients in a specialised rehabilitation programme 0.25 [7]. In a Swedish survey study, the EQ-5D Index in the normal population was found to range between 0.7 and 0.9, depending on age; individuals with different disease problems ranged between 0.66 and 0.79 [51]. In our follow-up, the CPT group improved in the EQ-5D Index (0.47 points) and reached the levels of the population with diseases [50]. By comparison, patients with chronic pain in our previous study who were treated with the more extensive MMR, improved in EQ-5D Index 0.5 points [29]. Similar findings from the SQRPR were reported from 152 patients from a rehabilitation unit in Stockholm [52], with improvement in EQ-5D Index of 0.47 points. These figures show that the acquired improvement is in line with other results and reflect possible outcomes by today's resources and available interventions.

In the CPT-group, 37% reported severe current pain (VAS ≥65) intensity at baseline. In the follow-up, the VAS median value had improved from VAS 57 to VAS 48 (Table 4a, $P < 0.002$). Other studies of patients with muskuloskeletal pain have shown varying results regarding improvements in pain intensity. In a one-year follow-up of a specialised rehabilitation programme, the improvement was 13 points on VAS [53], in a six-month follow-up at a multidisciplinary pain clinic VAS changed by 15 points [19]. These

examples of different follow-up periods and settings illustrate some difficulties in making conclusions.

Comorbidity of depression and anxiety are common in patients with chronic pain [7,53]. In our sample, an HADS-anxiety level indicating doubtful cases of anxiety (median 8), was found in the CPT-group at baseline. The subgroup of patients answering baseline and follow-up questionnaires scored below the level of probable anxiety at baseline. The HADS -depression median value was below the cut off for depression. These levels are surprisingly low, but might be related to the selection of patients for the treatment alternatives in the actual study. Patients with complex pain conditions with more severe comorbidity were selected for an MMR and thus not included in the study, but described earlier [29]. These findings support the fact that the clinical selection process is working well.

Moderate insomnia was found at baseline in the CPT-group, comparable to sleeping disorders reported in 50–65% of patients with chronic back pain [8] or in patients participating in chronic pain rehabilitation programmes [7,9]. In our follow up, statistically significant improvement in ISI was observed comparable to the study by Wilson et al. [9]. The disability rating in our sample at baseline (PDI median 36) was in accordance with PDI reported in patients with musculoskeletal pain and pain related to spinal disorders [54]. In the follow-up, PDI decreased significantly. Few studies use PDI as an outcome measure. However, in a study where a one year follow-up of patients participating in MMR was done, PDI improved after three months after which it returned to base line [55].

In spite of improvements, our patients still reported high levels of pain, insomnia and disability in the follow-up compared to the normal population. The remaining HRQoL level was still comparable to those of individuals with chronic diseases.

4.2. Analysis of associations

Insomnia was found to be the only factor which was associated with an improved EQ-5D Index at follow-up. There might be several explanations for this: sleeping disorders were assessed as one problem where the pharmacological treatment (high proportion of antidepressants and gabapentinoids) was appropriate to treat pain and insomnia. Furthermore, also psychological or educational interventions covered efforts to improve insomnia. Since previous studies have shown a clear relationship between insomnia and chronic pain [3,7,8], it seems obvious that improved insomnia may also affect the consequences of chronic pain as quality of life. In clinical practice, assessment and follow up of insomnia seems to be of importance when evaluating treatment results.

4.3. Strengths and limitations

This is a pragmatic study in a clinical context which is one of few attempts to describe patients and treatment outcome at a pain clinic [6,19–23]. Several difficulties have to be mentioned. Currently, few pain clinics report structured evaluation programmes in Sweden. The organisation of pain clinics differs greatly, and there is no agreement on which outcome instruments should be used. Furthermore, well-structured and valid studies are needed to explore, evaluate and compare. In the present clinical context, randomisation was not possible, since the treatment alternatives were decided individually and according to patient's need.

As we have sought to describe the complexity of chronic pain, a wide range of instruments was used. Our results are based on established statistical methods as significance. Another perspective is to value the results by using minimal clinical changes. However, this perspective has some problems. There are MCIC described for chronic pain in four out of the seven instruments used in the present study, and discussions about MCIC are ongoing in several [9,46,56].

The strengths of the study are its sample size, including all eligible patients during a two-year period and the use of a battery of PROM. The choice of instruments for assessing HRQoL and symptoms is crucial for clinical studies and an issue to be discussed continuously [50,57,58]. We used EQ-5D Index as our main outcome measure, meeting the needs for a validated, instrument used in research and in clinical settings, with the benefit of few items for the patient to respond to. Several other well validated instruments were chosen to monitor important outcome domains or factors which were assumed to be predictive.

The one-year follow-up response rate of all instruments was found in 62% (CPT group) and 56% (AO group), in line with or better than other findings in patients with chronic pain [21,23]. For ethical reasons and for a better response rate, as few items as possible are desirable. Efforts to find short versions of validated instruments are encouraged for future research, for instance to measure insomnia [59]. Another way to improve response rates and routines is to connect pain clinics to a national quality register.

The study does not allow conclusions about what kind of intervention is most successful, as the sample included different pain aetiologies, treatment alternatives and lengths of treatments. Patient's compliance with all kinds of initiated interventions is challenging and needs further research [19,21].

Bearing in mind the limited size of the AO group, the results must be interpreted with caution. It was not our objective to have them as a control, as done by Becker et al. [19]. Few studies have explored the significance of assessment by pain specialists [19,53,60]. More research is needed to study whether the recommended treatment was eligible and possible to implement by the referring physician.

5. Conclusions

The study describes rarely explored groups of patients with chronic pain at a pain clinic. Severe pain problems were present in both groups at their first visit. Statistically significant improvement could be seen in the group that was conventionally treated while this was not the case among those subjects who were assessed and referred. The results imply, that relatively limited treatment strategies were helpful for the patients' health-related quality of life. Despite these improvements, the patients were not fully recovered, pointing to the chronicity of pain conditions and the need of support for many patients.

Implications

Increased knowledge of patients referred to, assessed and treated at pain clinics is important in order to improve the quality of the work done at these clinics. Despite limited resources, further efforts should be made to systematically collect information from pain clinics in order to develop recommendation models.

Ethical considerations

The study was approved by the Regional Ethical Review Board, Stockholm (Dnr: 2010/1903-31/5) with a supplementary application (Dnr: 2012/75-32). Patients were given oral and written information about the study and written consent was obtained from the participants before inclusion.

Conflict of interest statement

The authors have no conflict of interest.

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