

Persistent pain is common 1–2 years after shoulder replacement

A nationwide registry-based questionnaire study of 538 patients

Karen T BJØRNHOLDT¹, Birgitte BRANDSBORG², Kjeld SØBALLE³ and Lone NIKOLAJSEN^{2,4}

¹ Department of Orthopedic Surgery, Horsens Hospital; ² Department of Anesthesiology and ³ Department of Orthopedic Surgery, Aarhus University Hospital; ⁴ Danish Pain Research Center, Aarhus University Hospital, Aarhus, Denmark.

Correspondence: karenbjo@rm.dk

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Background and purpose — Persistent postsurgical pain is a well-recognized problem after various types of surgery such as amputation and thoracotomy. The prevalence of persistent pain, and the extent to which it involves neuropathic pain, is highly dependent on the type of surgery. We investigated the prevalence of, characteristics of, and risk factors for persistent pain 1–2 years after shoulder replacement.

Patients and methods — A questionnaire was sent to patients who underwent primary shoulder replacement between April 2011 and April 2012, and whose data were recorded in the Danish Shoulder Arthroplasty Register. Patients who had undergone reoperation or bilateral replacements were excluded. Persistent pain was defined as constant or daily pain within the last month, which interfered much or very much with daily activities. Multivariate logistic regression was used to assess risk factors.

Results — 538 patients were available for analysis. The prevalence of persistent pain was 22% (CI: 18–25), and the prevalence of presumed neuropathic pain was 13% (CI: 10–16). Persistent pain was more frequent in fracture patients (29%) than in osteoarthritis patients (16%), while the prevalence of neuropathic pain was similar. Severe pain during the first postoperative week increased the risk of persistent pain. Risk also increased with hemiprosthesis (as compared to total prosthesis) in osteoarthritis patients, and with previous osteosynthesis and pain elsewhere in fracture patients.

Interpretation — Persistent pain after shoulder replacement is a daily burden for many patients. Further studies should address patient and prosthesis selection, postoperative pain management, and follow-up of these patients.

There is a substantial amount of literature documenting that there is a possible risk of persistent pain after almost any surgical procedure (Macrae 2001, Johansen et al. 2012). The prevalence rates are highly dependent on the type of surgery, and vary from 5% to 85% (Kehlet et al. 2006, Macrae 2008). The consequences of chronic or persistent postsurgical pain are significant, not only in terms of suffering and reduced quality of life for the individual patient, but also with regard to the subsequent costs to healthcare services and social services. Many authors have reported putative risk factors for persistent pain, including genetic factors, age, psychosocial factors, type of anesthesia, pain elsewhere than the surgical site, other comorbidities, preoperative pain, and acute postoperative pain (Althaus et al. 2012, VanDenKerkhof et al. 2013). Intraoperative nerve damage and the extent of surgery are also important risk factors (Katz and Seltzer 2009). In fact, many patients with persistent postsurgical pain present with characteristic symptoms of neuropathic pain in the affected area (Kehlet et al. 2006).

There is a scarcity of data on persistent postsurgical pain after orthopedic surgery. To our knowledge, previous studies focusing on persistent postsurgical pain in orthopedic patients have concerned mainly amputation or hip or knee replacement (Nikolajsen et al. 2006, Lundblad et al. 2008, Beswick et al. 2012, Liu et al. 2012, Jansen et al. 2014). Trials of shoulder replacement surgery have more commonly reported pain relief, or a composite score including pain, rather than the prevalence of pain at follow-up. There has been very little research on predictive factors for persistent postsurgical pain following shoulder replacement, but the general outcome has been shown to be associated with diagnosis and prosthesis type (Radnay et al. 2007, Fevang et al. 2013) and with previous shoulder surgery, age, and preoperative Short Form-36 mental

score and DASH functional score (Simmen et al. 2008). Identification of subgroups at increased risk is important in order to establish interventions to prevent or minimize the impact of persistent postsurgical pain.

We investigated the prevalence of, the characteristics of, and risk factors for persistent pain 1–2 years after more than 500 shoulder replacements performed in Denmark.

Material and methods

This was a cohort study in which the baseline data were retrieved from the Danish Shoulder Arthroplasty Register (DSR) (Rasmussen et al. 2012) and the follow-up data were obtained using a patient questionnaire.

Patients

All patients were recruited from the DSR (see description below). For this study, the inclusion criteria were primary shoulder replacement between April 1, 2011 and April 1, 2012, and age above 18 years. Exclusion criteria were prosthesis in the contralateral shoulder and any type of reoperation. Patients who met these criteria were sent a questionnaire on May 30, 2013. A reminder was sent after 25 days to all patients who did not reply. Thus, the length of follow-up was 14–26 months. In order to reduce response bias, patients were strongly urged to respond regardless of whether they had experienced pain or not. The size of the study was determined indirectly by the number of patients in the registry who matched our criteria.

Questionnaire data

The questionnaire was in Danish and was developed especially for the study, as no suitable pre-existing questionnaire was found. Based on the literature and the experience of the authors, the questionnaire was drafted and assessed by research peers. After revision, the questionnaire was piloted in a group of 10 patients who had undergone shoulder replacement at the first author's institution. After evaluation of the responses, the final questionnaire was drawn (see the translated questionnaire in Supplementary data). The questionnaire included questions to assess (1) inclusion and exclusion criteria, (2) current pain characteristics and pain treatment, (3) neuropathic pain characteristics (DN4: Douleur Neuropathique, 4 questions) (Bouhassira et al. 2005), and (4) possible predictors of persistent pain (pain elsewhere, height and weight, preoperative and acute postoperative pain). The outcome of persistent pain was defined as pain experienced every day or constantly within the last month at a level that interfered much or very much with daily activities. Recall bias was expected for the questions concerning preoperative pain and acute postoperative pain. To minimize this bias, a verbal rating scale (none/mild/moderate/severe) was used instead of a numerical rating scale, and the period in question was limited to the week before/after surgery.

Registry data

The DSR was established in 2004. The DSR included 91% and 92% of all shoulder replacements performed in Denmark in 2011 and 2012, respectively (DSR annual report 2013). It collects reports by the surgeons at the time of the operation, and patients are routinely contacted by the registry after 1 year to complete the Western Ontario Osteoarthritis of the Shoulder Index (WOOS) (Lo et al. 2001, Rasmussen et al. 2013) with 2 supplementary questions. Data extracted from the registry included age, sex, diagnosis, prosthesis, previous shoulder surgery, supplementary surgery, and patient-reported data. Patient names, updated addresses, and status (e.g. death, emigration) were retrieved from the Danish Civil Registration System and matched to the registry data by means of the civil registration number.

Statistics

Data from the questionnaires were entered manually into Epidata version 3.1. They were then merged with registry data for analysis in Stata software version 12. Missing data were not constructed to expected values, and the analysis was based on the data available. Patients were not included in the final analysis if their dataset was incomplete for the grouping variables (questions 8 and 11) and the following predictive factors used in the regression: age, sex, diagnosis, prosthesis type, pain elsewhere, and severity of acute postoperative pain. For patients who had returned their questionnaires with these crucial data missing, and who had accepted to be contacted again, we obtained the missing data by telephone interview or e-mail. Descriptive statistics are presented as counts (with %), as mean (with SD) for normally distributed data, or as median (with interquartile range (IQR)) for data that were not normally distributed. Confidence intervals (CIs) for prevalence are calculated as exact binomial 95% CI (Clopper-Pearson). Analyses for association with persistent pain in Table 2 and for generalizability were performed by t-test, chi-squared test, or Wilcoxon rank-sum test as appropriate. Any p-value of less than 0.05 was considered statistically significant. A multivariate logistic regression model was used to assess whether selected factors predicted the outcome of pain at follow-up. Factors were considered suitable for inclusion in the risk factor analysis if they could correct for unknown confounders (age, sex, body mass index) or were clinically relevant and there were enough data to allow inclusion in analysis.

Ethics

The study was approved by the Danish Data Protection Agency and the committee of the DSR. Studies based on questionnaires or registers do not require approval from the regional or national Committee on Health Research Ethics in Denmark. The study was registered at <http://clinicaltrials.gov/> with identifier NCT01900223.

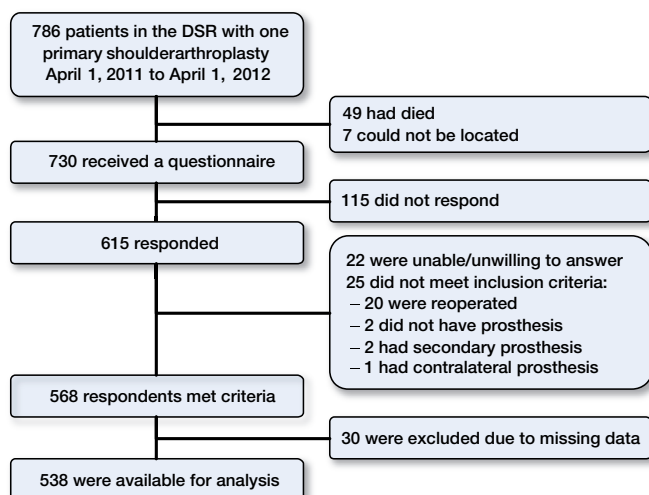


Figure 1. Flow chart of the patients. DSR: the Danish Shoulder Arthroplasty Register.

Results

The registry contained records of 786 patients with 1 primary shoulder replacement who were operated from April 2011 to April 2012. Replies were received from 615 patients (response rate 78%). Data from 538 patients were available for analysis (Figure 1). Mean follow-up time was 20 (14–26) months.

Pain status

Persistent pain, defined as pain experienced every day or constantly within the last month at a level that interfered much or very much with daily activities, was present in 117 of 538 patients (22%, CI: 18–25) (Table 1). The prevalence of persistent pain differed between the 2 predominant diagnoses, being present in 66 of 228 patients with fractures (29%, CI: 23–35) and 26 of 226 patients with osteoarthritis (16%, CI: 11–21). Neuropathic pain, assessed by the 7-item DN4 questionnaire, was present in 66 of 505 patients (13%, CI: 10–16). The prevalence of presumed neuropathic pain was similar between diagnoses: 32 of 212 fracture patients (15%, CI: 11–21) and 26 of 212 osteoarthritis patients (12%, CI: 8–17). There was no difference in the length of follow-up between those with persistent pain or presumed neuropathic pain and those without. Analgesics were used daily by 159 of 527 patients (30%) for pain limited to or including the operated shoulder, and a further 67 patients (13%) used analgesics less than once a day for pain limited to or including the operated shoulder. The drugs used were paracetamol ($n = 161$, 31%), non-steroid anti-inflammatory drugs ($n = 59$, 11%), opioids ($n = 98$, 19%), and other kinds ($n = 25$, 5%). Other analgesics included e.g. gabapentin, pregabalin, tricyclic antidepressants, and anti-epileptics. Non-pharmacological treatment of pain limited to or including the shoulder included physiotherapy ($n = 76$ of 490, 16%), use of a hot water pool ($n = 36$ of 490, 7%), acupuncture ($n = 20$ of 490, 4%) and chiropractic ($n = 14$ of 490, 3%).

Table 1. Prevalence and characteristics of pain in the shoulder 1–2 years after shoulder replacement. $n = 538$ unless otherwise stated

	n	%
Frequency of pain during the last month		
none	213	40
not every day	132	25
every day	115	21
constantly	78	14
Average pain intensity in the last month (NRS 0–10), $n = 527$		
none	199	38
1–3	126	24
4–7	149	28
8–10	53	10
Worst pain intensity in the last month (NRS 0–10), $n = 529$		
none	197	37
1–3	95	18
4–7	144	27
8–10	93	18
Interference with daily life		
none	210	39
a little	104	19
some	100	19
much	68	13
very much	56	10
Persistent pain ^a	117	22
DN4: Does the pain have one or more of the following characteristics? $n = 515$		
burning	77	15
painful cold	42	8
electric shocks	112	22
DN4: Is the pain associated with one or more of the following symptoms in the same area? $n = 517$		
tingling	82	16
pins and needles	92	18
numbness	46	9
itching	42	8
Neuropathic pain: 3/7 items of DN4 interview, $n = 505$	66	13
Pain present elsewhere		
none	185	34
mild	69	13
moderate	161	30
severe	123	23
Location of the other pain (may be several), $n = 532$		
head	9	2
back	147	28
upper extremity	110	21
lower extremity	167	31
stomach	7	1
other	27	5

^a Persistent pain defined as pain experienced every day or constantly within the last month at a level that interferes much or very much with daily activities.

NRS: numeric rating scale; DN4: Douleur Neuropathique, 4 questions.

For assessment of overall improvement in pain status, patients were asked to compare their current pain to their pain before the operation. However, this was problematic in patients with fractures less than 2 weeks old, who instead often compared their current pain to their pain before the fracture. In the

Table 2a. Persistent pain after shoulder replacement in relation to patient characteristics, surgical data, and complications. n = 538 unless otherwise stated

	All n = 538	Persistent pain at follow-up n = 117	p-value
Mean age at surgery (range)	69 (SD 10) (21–92)	67 (SD 11) (31–91)	0.02
BMI at follow-up, kg/m ² , mean (n=514) (range)	27 (SD 6) (17–63)	26 (SD 6) (17–47)	0.009

remainder of patients (n = 363), 80% reported being “better” or “much better”, 10% reported no change, and 11% reported being “worse” or “much worse”.

Persistent pain in relation to registry data and patient-reported complications

Factors associated with the occurrence of persistent pain were age, BMI, diagnosis, previous osteosynthesis, previous cuff reconstruction (marginally), duration of preoperative pain, prosthesis type, supplementary cuff reconstruction, infection, and frozen shoulder (Table 2). Other patient-reported complications included fever, kidney affection, pneumonia, hematoma, thrombosis in the arm, fistula, swelling, complex regional pain syndrome, 3–4 week paralysis of the arm, skin disorder, tight scar tissue, trapped nerve, irritated biceps, and other prosthesis-related complaints (“the prosthesis irritates me” and “it seems as if it is on its way out through the skin”). For patients with persistent pain compared to those without, all items of the WOOS (completed by 392 of the 538 patients) were highly significantly worse by 2-sample Wilcoxon rank-sum (Mann-Whitney) test ($p < 0.001$ for all items). Persistent pain was especially associated with the 3 emotional items (frustration/discouragement, worry, and feeling like a burden to others), pain with movement, and increased pain after activity.

As diagnosis interacted with other predictors, regression analysis was stratified for fractures and osteoarthritis (Table 3). The other diagnoses were too rare to allow separate regression models. The 2 patient-reported variables used in the regression were dichotomized from 4 categories (none/mild/moderate/severe) due to the number of patients available, so intensity of pain in the first week was dichotomized as “severe” or “other”, and pain elsewhere was dichotomized as “any pain” or “none”. Severe pain during the first postoperative week (experienced by 199 of 538 patients, 37%) was a risk factor regardless of diagnosis of fracture or osteoarthritis. For fractures, previous osteosynthesis and pain elsewhere were predictive of persistent pain. For osteoarthritis, operation with a hemiprosthesis (humeral head replacement) was associated with a higher risk of persistent pain compared to a total prosthesis. Effects of age, sex, and BMI were small or non-existent.

Table 2b. Persistent pain after shoulder replacement in relation to patient characteristics, surgical data, and complications. n = 538 unless otherwise stated

	All n = 538		Persistent pain at follow-up n = 117		p-value
	n	%	n	%	
Sex					0.4
male	165	31	32	19	
female	373	69	85	23	
Diagnosis (may be several)					
arthritis	19	4	1	5	0.08
osteoarthritis	231	43	37	16	0.005
fracture < 2 weeks	157	29	44	28	0.02
fracture > 2 weeks	81	15	26	32	0.01
cuff arthropathy	82	15	11	13	0.05
humeral head necrosis	26	5	10	38	0.03
other	11	2	2	18	0.8
Previous shoulder surgery					
osteosynthesis	25	5	13	52	< 0.001
cuff reconstruction	17	3	7	41	0.05
other	55	10	12	22	1.0
Hospital volume					1.0
1–25 primary SR per year	95	18	21	22	
26–50 primary SR per year	250	46	54	22	
> 50 primary SR per year	193	36	42	22	
Side operated, n = 534					0.9
right	298	56	64	21	
left	236	44	52	22	
Duration of preoperative pain n = 377 ^a					0.04
more than 6 months	318	84	55	17	
6 months or less	59	16	18	31	
Preoperative pain intensity n = 368 ^a					0.05
severe	233	63	52	22	
none/mild/moderate	135	37	19	14	
Prosthesis					
resurfacing	96	18	17	18	0.3
hemi	274	51	75	27	0.001
total	47	9	3	6	0.008
reverse	121	22	22	18	0.3
Supplementary surgery (may be several)					
cuff reconstruction	96	18	30	31	0.01
acromioplasty	7	1	2	29	0.7
acromioclavicular resection	11	2	2	18	0.8
biceps tenotomy	151	28	26	17	0.1
biceps tenodesis	212	39	44	21	0.7
Complications, patient-reported					
delayed wound healing	29	5	8	28	0.4
infection in the wound	19	4	10	53	0.001
frozen shoulder	36	7	19	53	< 0.001
other (various, less frequent)	34	6	6	18	0.5

^a This does not include patients with fractures less than 2 weeks old. SR: shoulder replacements.

Assessment of generalizability

To assess generalizability, we compared the patients who were analyzed to the 223 patients who were not available for analysis, but presumably meeting other criteria (they were excluded due to death, missing address, non-response, or missing data). There were no statistically significant differences with regard

Table 3. Risk factors for persistent pain 1–2 years after shoulder replacement. Values are odds ratio (CI)

Variable	All patients, univariate	All patients, multivariate	Fracture, multivariate n = 220	Osteoarthritis, multivariate n = 222
Age	0.98 (0.96–1.00)	0.97 (0.95–0.99)	0.98 (0.95–1.01)	0.94 (0.9–0.99)
Female sex	1.2 (0.8–1.9)	1.3 (0.8–2.2)	1.3 (0.6–2.8)	2.2 (0.9–5.5)
BMI, n = 514	0.95 (0.91–0.99)	0.94 (0.90–0.99)	0.94 (0.88–1.01)	0.94 (0.87–1.01)
Severe pain in first week	4.5 (2.9–6.9)	3.9 (2.4–6.2)	3.6 (1.9–7.0)	4.7 (2.1–10.8)
Pain elsewhere	1.9 (1.2–3.1)	2.0 (1.2–3.5)	2.9 (1.4–5.9)	1.2 (0.4–3.1)
Previous osteosynthesis	4.3 (1.9–9.6)	4.0 (1.7–11)	3.4 (1.3–8.9)	none, not included
Suppl. cuff reconstruction	1.9 (1.1–3.0)	1.6 (0.9–2.8)	1.2 (0.6–2.5)	2.3 (0.6–8.7)
Prosthesis type			too few, not included	
hemi	1 (reference)	1 (reference)		1 (reference)
total	0.18 (0.05–0.60)	0.19 (0.05–0.66)		0.11 (0.02–0.70)
resurfacing	0.57 (0.32–1.03)	0.60 (0.31–1.17)		0.52 (0.19–1.46)
reverse	0.59 (0.35–1.00)	0.83 (0.45–1.50)		1.55 (0.46–5.15)

to age, sex, side operated, previous surgery, hospital volume, or supplementary surgery. Patients who were not available for analysis were more often diagnosed with fracture < 2 weeks old (39%; $p = 0.01$), and less often osteoarthritis (28%; $p < 0.001$) and cuff arthropathy (9%; $p = 0.03$). The type of prosthesis was more often hemiprosthesis (62%; $p = 0.01$) and less often total prosthesis (4%; $p = 0.01$). WOOS and the 2 supplementary questions from the registry tended to be worse, but only 26% of the unavailable patients had completed WOOS.

Discussion

The prevalence of persistent pain 1–2 years after primary shoulder replacement was 22%, being higher in fracture patients (29%) than in osteoarthritis patients (16%). Comparisons with other studies are complex due to varying definitions and follow-up periods. For hip replacements due to degenerative hip arthritis, 12% of patients experienced pain with moderate, severe, or very severe impact on daily life after 12–18 months (Nikolajsen et al. 2006). For knee replacements mainly due to osteoarthritis, 20% experienced considerable problems with persistent pain (rated 4–5 out of 5) after 14–23 months (Baker et al. 2007). For shoulder replacements, in a review of 40 studies of Neer-II-type shoulder prostheses including 3,584 patients with osteoarthritis mainly, 85% of patients obtained good pain relief while 9% experienced severe pain after 2–12 years (van de Sande et al. 2006). This is comparable to our result of 80% of non-fracture patients reporting pain to be better or much better than before surgery and 10% reporting pain to be worse or much worse. Given the nature of our study, response bias may lead to overestimation of prevalence. However, our generalizability analysis suggested that those who were unavailable for analysis had comparable or worse WOOS, thus supporting the validity of our estimate.

The prevalence of neuropathic pain (as assessed by DN4) was 13%. In a recent article concerning evaluation of failed

shoulder replacement, nerve injury was estimated to occur in 0.6% to 4% of cases (Wiater et al. 2014). Our estimate of neuropathic pain is considerably higher, but it should be considered with caution. DN4 is a screening tool that has not been validated in the Danish language—or in a population of shoulder prosthesis patients.

Chronic or persistent postsurgical pain has been defined as pain that develops after surgery, persists for more than 2 months, and cannot be attributed to causes other than surgery (Macrae and Davies 1999). For certain types of surgery the healing period is longer, and the definition should be adjusted accordingly (Kehlet and Rathmell 2010, Wylde et al. 2013). In the present study, the definition was different, as identification of the underlying causes of persistent pain would require a thorough physical, radiological, neurophysiological, and biochemical examination of each patient. However, this would be necessary to more closely estimate the prevalence of persistent postsurgical pain as defined by Macrae and Davies (1999) and the prevalence of neuropathic pain as defined by the International Association for the Study of Pain (pain caused by a lesion or disease of the somatosensory nervous system). After our study, and in light of the high prevalence of pain found, it would be desirable in further studies to apply the definition of Macrae.

In the present study, complications that may reflect a neuropathic pain state were mentioned and could be investigated further, e.g. complex regional pain syndrome, paralysis of the arm, tight scar tissue, and trapped nerve. Some of the patients experiencing persistent pain would most likely benefit from such an evaluation, including assessment of the possibility of revision or alternative analgesic treatment. A surprisingly high number of the patients used opioids as analgesics (19%), and this also calls for a further assessment of the pain patients. In a review article focusing on complications after 4,010 shoulder replacements, 23% of the patients experienced 1 or more complications within a mean follow-up time of 6 (2–25) years. Many of the complications reported in the review were possibly avoidable or would lead to revision (Gonzalez et al. 2011).

Severe pain in the first postoperative week was associated with a markedly increased risk of persistent pain, although this result may have been influenced by recall bias. The association between acute and chronic postsurgical pain has also been found in other studies. The causal relationship has not been fully established, but the rather high prevalence of 37% of patients experiencing severe pain in the first week identifies a need to treat acute postsurgical pain more aggressively, regardless of the possibility of increased risk of persistent pain. Future intervention studies may determine whether better pain control is attainable, or whether preoperative assessment concerning the risk of severe acute and/or chronic pain could improve patient selection. In osteoarthritis patients, there was a higher risk with hemiprostheses than with total prostheses. This result is in accordance with other studies indicating a superior outcome with a total prosthesis compared to a hemiprosthesis (Bryant et al. 2005, Radnay et al. 2007, Singh et al. 2010, Fevang et al. 2013). As in all registry studies, a limitation exists in the completeness and reliability of registry data such as prosthesis type and supplementary surgery, and this problem is not easy to quantify. Also, the questionnaire developed did not undergo testing of reliability and validity beyond the method described.

In conclusion, persistent pain after shoulder replacement is a daily burden to many patients. Further prospective studies are required to confirm our results and to evaluate the causes of persistent pain and the treatments or preventive measures required. Studies should not only concentrate on prosthesis selection and surgical complications, but also involve (1) preoperative assessment to effectively improve patient selection, and (2) improvement of postoperative pain management and its effect on the development of persistent pain.

Supplementary data

The Questionnaire is available at www.actaorthop.org, identification number 7739.

LN came up with the idea. KTB collected the data and, assisted by BB, performed the analysis. All the authors contributed to study design, interpretation, and critical revision of the manuscript. The final manuscript was approved by all the authors.

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