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Do nonsteroidal anti-inflammatory drugs affect the outcome of arthroscopic Bankart repair?

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To achieve pain control after arthroscopic shoulder surgery, nonsteroidal anti-inflammatory drugs (NSAIDs) are a complement to other analgesics. However, experimental studies have raised concerns that these drugs may have a detrimental effect on soft tissue-to-bone healing and, thus, have a negative effect on the outcome. We wanted to investigate if there are any differences in the clinical outcome after the arthroscopic Bankart procedure for patients who received NSAIDs prescription compared with those who did not. 477 patients with a primary arthroscopic Bankart procedure were identified in the Norwegian shoulder instability register and included in the study. 32.5% received prescription of NSAIDs post-operatively. 370 (78%) of the patients answered a follow-up questionnaire containing the Western Ontario Shoulder Instability index (WOSI). Mean follow-up was 21 months. WOSI at follow-up were 75% in the NSAID group and 74% in the control group. 12% of the patients in the NSAID group and 14% in the control group reported recurrence of instability. The reoperation rate was 5% in both groups. There were no statistically significant differences between the groups. Prescription of short-term post-operative NSAID treatment in the post-operative period did not influence on the functional outcome after arthroscopic Bankart procedures.

Shoulder instability is a common problem, with an overall incidence of acute glenohumeral dislocation in the general population reported from 11 to 56 per 100 000 person-years in different countries (Liavaag et al., 2011). The peak incidence occurs during the third decade of life, with a male dominance (Zacchilli & Owens, 2010) and anterior instability as the predominant direction (Owens et al., 2007). Young age predicts a high risk of recurrence and 67% of the patients below 35 years of age develop chronic instability, with new dislocations within 5 years of the primary dislocation (Robinson, 2006). With an annual incidence of shoulder stabilization procedures of 12 per 100 000 inhabitants in Norway (Blomquist et al., 2012) it is estimated that about one fourth of the patients in Norway with a traumatic dislocation end up with a surgical procedure to stabilize the shoulder joint, with a much higher proportion in the young patients.

The arthroscopic Bankart procedure is widely used in the treatment of recurrent anterior shoulder instability (Owens et al., 2011). Although a minimal invasive procedure, post-operative pain control after shoulder surgery can be difficult to achieve, even with the use of an interscalene nerve block (Fredrickson et al., 2010). Nonsteroidal anti-inflammatory drugs (NSAIDs) have been proven effective against post-orthopedic surgery pain (Heidrich et al., 1985; Alexander et al., 2002; Silvanto et al., 2002; Malan et al., 2003; Axelsson et al., 2008), but experimental studies in animal models have raised concerns that these drugs may have a negative effect on tendon and tendon-to-bone healing in the early proliferative phase (Dimmen et al., 2009a,b; Chen & Dragoo, 2012). NSAIDs have an inhibitory effect on fracture healing in animal studies (Bo et al., 1976) and have been shown to affect the clinical outcome of long bone fractures (Burd et al., 2003) and spinal fusion (Li et al., 2011). However, we have not found any studies that investigate the effects of NSAIDs on the clinical outcome after arthroscopic Bankart repair or other procedures that involve healing between soft tissue and bone in humans.

On this background, we wanted to investigate if there are any differences in the clinical outcome for patients that received NSAIDs in the post-operative phase compared with those who did not.

Materials and methods

The present study was based on the Norwegian shoulder instability register (Blomquist et al., 2012) that was established in 2008. The register includes 54% of the patients who had surgery for glenohumeral instability in Norway 1 year after start-up. The surgeon completed a form at the time of surgery specifying the type of surgical procedure, any previous surgery and shoulder history, including duration of symptoms, number of dislocations and the peroperative bone and soft tissue conditions. If NSAID was prescribed for post-operative administration, medicament name and duration of treatment was recorded. The patient completed a questionnaire with the Western Ontario Shoulder Instability Index (WOSI; Kirkley et al., 1998) pre-operatively. A questionnaire including the same items was answered by mail 1 and 2 years post-operatively. In addition, the patients were asked if they had experienced instability events or had been treated operatively for instability in the same shoulder after the primary operation. Revision surgery was linked to the original procedure in the register by the patient's social security number. The WOSI score is a disease-specific, quality of life measurement tool for patients with shoulder instability. It is built up of 21 visual analog scales in four domains, reflecting physical symptoms, disability in sport/recreation/work and impact on lifestyle and emotions. The score is presented either as an absolute number, ranging from 0 (best) to 2100 (worst), or as a percentage score were 100% represent the best possible result. The instrument is validated in several languages, including Norwegian, and is found to have a high validity, reliability, and responsiveness for shoulder instability patients. (Skare et al., 2013) A 10.4 percentage point difference in WOSI score is considered to reflect a clinically relevant difference in shoulder function, both for the individual patient over time and for comparison between groups. (Kirkley et al., 1998, 2005)

525 patients who underwent an arthroscopic Bankart procedure during the period from February 2008 to August 2011, without prior surgery in the same shoulder, were identified in the register and assessed for eligibility. Twenty-four patients that had no data on NSAID administration and 24 patients without both pre- and post-operative WOSI score were excluded from further analysis. Of the 477 included patients, 463 (97%) had completed the pre-operative questionnaire. 348 (73%) answered the 1-year follow-up questionnaire and 283 (59%) answered at 2 years post-operatively. 370 patients (78%) responded at either 1 or 2 years post-operatively and the last response was carried forward with a mean follow-up of 21.2 months. Dropout analysis were performed to evaluate if there were any systematic differences between the responders and the nonresponders.

322 (68%) of the patient did not receive NSAID in the post-operative period and was applied as control group. 78 (16%) had NSAID prescribed for 1–3 days, 63 (13%) for 4–7 days and 14 (3%) for more than 7 days. All patients treated with NSAIDs post-operatively were pooled in one group for the statistical analysis.

WOSI score and recurrence rate were both considered to be adequate as outcome variables that would reflect a true change in shoulder function. The statistical power to detect a 10.4 percentage point difference in WOSI score was calculated to be 99%, based on a significance level at 0.05 and a sample size of 200 and 100 in the respective groups. However, rate of recurrence was rejected as primary outcome variable, as the statistical power was low, estimated to 0.26, calculation based on sample size of 200 and 100, a 50% increase in recurrence rate from 10% to 15% and a significance level at 0.05.

The primary outcome variable was absolute WOSI score at follow-up. The null hypothesis was that there is no difference in outcome between the group treated with NSAIDs post-operatively and the control group. We also evaluated change in shoulder function compared with baseline, recurrence rate and reoperation rate for both groups. Possible confounders such as differences in baseline WOSI score, age at surgery, traumatic debut, duration of symptoms, number of dislocations, number of suture anchors used, post-operative immobilization, ambulatory or in-house surgery, duration of surgery and follow-up time were analyzed.

Statistics

Descriptive statistics were presented as mean values for normal distributed continuous variables, median for variables with a skewed distribution and ratios for categorical variables. *t*-tests were used to test differences in mean values and were presented with 95% confidence interval (CI), Kruskal–Wallis test for comparison of medians and chi-square test for categorical variables. Adjustments were done for possible confounding variables with uneven distribution in the two groups using univariate analysis of variance. SPSS Statistics 20 (IBM, New York, USA) software was used for the statistical evaluation.

Ethics

The study was evaluated by the local ethics committee and considered not to need an ethical approval. The data collection was authorized by the Norwegian Data Protection Authority.

Results

The mean age of the included patients was 28.8 years, ranging from 12 to 74 years. The patients in the NSAID group were significantly younger, had a shorter duration of symptoms and were more likely to be treated ambulatory (Table 1).

Table 1. Baseline characteristic of patients having a primary arthroscopic Bankart procedure divided by those receiving NSAIDs and the control group (not receiving NSAIDs)

Baseline characteristic	NSAID				Control group				*P*-value
	n	%	Mean (95% CI)	Median (range)	*n*	%	Mean (95% CI)	Median (range)	
WOSI%	125		51 (48–54)		231		52 (49–54)		0.63
Sex, male	127	66			243	68			0.79
Age at surgery	127			24 (58)	243			27 (62)	0.04
Trauma at first dislocation	125	92			236	90			0.50
Symptom duration (months)	116			28 (387)	218			37 (489)	0.02
Patients with > 5 dislocations	122	36			234	36			0.98
Number of suture anchors	118		2.6 (2.5–2.8)		228		2.6 (2.5–2.8)		0.90
Duration of surgery (minutes)	124		70 (64–75)		236		76 (72–79)		0.08
Ambulatory surgery	124	68			240	30			< 0.01
Weeks of immobilization	123		4.7 (4.4–5.0)		225		4.5 (4.3–4.7)		0.16

Patients treated with NSAIDs post-operatively had an unadjusted mean WOSI score at follow-up of 75%, compared with 74% for the control group. Recurrence rate was 12% in the NSAID and 14% in the control group, while reoperation rates were 5% in both groups. None of these differences were statistically significant. Age correlated with symptom duration with a *P*-value < 0.001 and the outcome score were therefore only adjusted for age and ambulatory surgery. The adjusted WOSI score at follow-up was 74% for the NSAID group and 71% for the control group, the difference between the groups were statistically nonsignificant (Table 2).

The increase in WOSI score from baseline to follow-up was 24 percentage points (95% CI 20.2–28.1, $P < 0.001$), from 51% to 75% for the NSAID group. The control group had an improvement of 22 percentage points (95% CI 18.9–24.7, $P < 0.001$), from 52% at baseline to 74% at follow-up. The difference between the groups was not statistically significant.

18% of the patients in the NSAID group and 25% of the patients in the control group did not answer the follow-up questionnaire. Males were overrepresented among the nonresponders, however evenly distributed between the two treatment groups. No other significant differences were found compared with the patients that answered the follow-up questionnaire (Table 3). None of the participating hospitals had an outcome that differed statistical significant from the mean.

Discussion

We found no effect of NSAIDs on the outcome after an arthroscopic Bankart procedure. This is in accordance with previously published articles where there is insufficient evidence of a detrimental effect on tissue healing, when using either NSAIDs or COX-2 inhibitors at standard doses for less than 2 weeks (Chen & Dragoo, 2012).

Anti-inflammatory drugs were prescribed to only one third of the patients included in the study despite documented effect on post-operative pain as part of a multimodal pain therapy (Marret et al., 2005). Although other side effects, mainly gastrointestinal (Thiéfin et al., 2010), may account for some restraint, the risk of affecting the long-term surgical result is probably the main reason for the limited use in this young patient population with supposedly few concomitant diseases. The use of NSAIDs for the treatment of post-operative pain is controversial for procedures involving healing between bone and tendon as it is shown that NSAIDs and COX2-inhibitors affect the tendon-to-bone healing in experimental animal models (Cohen et al., 2006; Dimmen et al., 2009b). Healing of labral lesions involve an inflammatory response (Abe et al., 2012) and could theoretically be inhibited by anti-inflammatory drugs, but there are no published data that support the theory that treatment with short-term NSAID in therapeutic doses has a negative effect on the outcome after

Table 2. Post-operative evaluation of patients having a primary arthroscopic Bankart procedure by those receiving NSAIDs and the control group (not receiving NSAIDs)

	NSAID			Control group			*P*-value
	n	%	Mean (95% CI)	*n*	%	Mean (95% CI)	
WOSI% at last follow-up	127		75 (72–78)	243		74 (71–77)	0.60
Adjusted* WOSI% at last follow-up	127		74 (70–78)	243		71 (68–75)	0.27
1-year WOSI%	119		76 (73–79)	229		74 (71–77)	0.42
2-year WOSI%	98		76 (72–79)	185		75 (72–78)	0.77
Recurrence rate at last follow-up	127	12		243	14		0.56
Reoperation rate at last follow-up	127	5		243	5		0.80

*Adjusted for age and ambulatory surgery.

Table 3. Nonresponder's analysis of baseline characteristics among patients that underwent a primary arthroscopic Bankart procedure

Baseline characteristic	Responders				Nonresponders				*P*-value
	n	%	Mean (95% CI)	Median (range)	*n*	%	Mean (95% CI)	Median (range)	
WOSI%	356		52 (50–53)		107		50 (46–53)		0.32
Sex, male	370	67			107	84			< 0.01
Age at surgery	370			27 (62)	107			25 (47)	0.13
Trauma at first dislocation	361	91			107	88			0.41
Symptom duration (months)	334			32 (489)	99			32 (322)	0.94
Patients with > 5 dislocations	356	36			104	43			0.18
Number of suture anchors	346		2.6 (2.5–2.7)		104		2.7 (2.5–2.9)		0.58
Duration of surgery (minutes)	360		74 (71–77)		106		74 (68–79)		0.97
Ambulatory surgery	364	43			106	47			0.46
Weeks of immobilization	348		4.6 (4.4–4.7)		103		4.5 (4.2–4.8)		0.71

arthroscopic shoulder surgery. It has been found in earlier clinical studies (Li et al., 2011) that any negative effect of NSAIDs on healing is dose-dependent. A majority of the patients in this study had NSAIDs prescribed for 7 days or less. A longer administration of anti-inflammatory drugs may have a clinical effect not investigated in the present study. Our data on NSAID use is obtained from the surgeons planned prescription at the time of surgery. We have no control on patient compliance and one must assume occurrence of crossover between the groups during the post-operative period, not accounted for in the study. This would dilute a potential effect of NSAID on the outcome. The study is well powered to detect changes in WOSI score and can tolerate a moderate amount of crossover, but the lack of compliance monitoring is a weakness.

The WOSI score is a well-established instrument to evaluate outcome after shoulder instability surgery. It is considered to reflect the change in the patients subjective shoulder function and quality of life and the groups have a very similar functional outcome. This was a prospective cohort study with participants from hospitals in all parts of Norway and we can anticipate that the sample population is representative for the general population who needs instability surgery and should therefore be valid for this group of patients. The groups differed in age, with a significantly lower age and a higher proportion of patients below 20 years in the NSAID group. Young age is found to be a risk factor for inferior outcome after arthroscopic stabilization (Boileau et al., 2006) and adjustment for age further strengthen the finding that NSAIDs have no negative influence on the outcome.

The study is underpowered to detect an increase in recurrence rate and one might therefore argue that a moderate increased recurrence rate cannot be ruled out, even though we found a slightly lower recurrence rate at 2 years in the NSAID group. Studies have shown a linear recurrence incidence over time after arthroscopic Bankart procedures (Castagna et al., 2010), and a weakened bone-labrum interface due to post-operative NSAID administration could theoretical affect the recurrence rate several years after the surgery. Long follow-up and a large patient population are needed to answer this question. An arthro-CT evaluation of the joint could assess attachment of labrum to bone after a certain post-operative time interval. It is however difficult to draw conclusions regarding risk of recurrence based on healing on MRI or CT, as studies have shown that Bankart lesion could be radiological well adapted, but without correlation with recurrence rate (Liavaag et al., 2009; Liavaag, 2011). Post-operative arthroCT also raise ethical questions and was not part of this register study.

The lack of randomization is a weakness to the study. The use of NSAIDs or not is usually consistent for each participating surgeon and there could be a performance bias between the groups that could mask an effect of NSAID administration. The finding that NSAIDs are more commonly used in ambulatory surgery might imply a higher experience level for the surgeons in this group. Based on knowledge of the participating hospitals and the national funding structure for health care, we see that the use of in-house or ambulatory surgery to a large extent is based on local routines and facilities and is more prone to follow hospital and region than the surgeon. We believe that the more extent use of NSAIDs for ambulatory patients reflects the need for proper pain control without the facilities for inter-scalene block or parenteral analgesics, but we have no information on this. The high number of participating hospitals would normally dilute a surgeon effect and none of the participating hospitals have a statistical significant below par outcome that would affect the result.

Perspectives

To achieve adequate and predictable pain control after shoulder surgery, a multimodal approach is normally used, where inter-scalene nerve block, opioid analgesics, and NSAIDs are the main components (Fredrickson et al., 2010). Single-injection inter-scalene block gives excellent immediate pain control, but because of its short and unpredictable duration, there is a high risk that the patient experience severe and uncontrollable pain the first night after surgery (Boezaart & Tighe, 2010). Continuous nerve block gives a better pain control but is more technically and logistically demanding (Boezaart, 2002). As the severity and duration of pain after shoulder surgery has a high inter-individual variation, it is challenging to safely administer an adequate dosage of opiate analgesics, especially after single-injection inter-scalene block and for ambulatory patients without professional post-operative monitoring. It is our experience that NSAIDs, in combination with other modalities, is a very valuable component to achieve post-operative pain control. In this registry study, we found that only one third of the patients received anti-inflammatory drugs in the post-operative phase and less than half were treated ambulatory. A randomized study would be the best tool to test if there is a difference in outcome between the group treated with NSAIDs post-operatively and the control group. So far, this cohort study support the view that short-term NSAIDs in moderate dosages can be safely administered after arthroscopic Bankart repair, without any affect on the outcome.

Key words: Shoulder surgery, shoulder instability, arthroscopic Bankart, nonsteroidal anti-inflammatory drugs, NSAID.

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