



Three weeks of indomethacin is not superior to 1 week of meloxicam as prophylaxis for heterotopic ossifications after distal biceps tendon repair with a single-incision technique

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Background: The aim of this study was to assess the efficacy of 3 weeks of indomethacin, a nonselective nonsteroidal anti-inflammatory drug, in comparison to 1 week of meloxicam as prophylaxis for heterotopic ossifications (HOs) after distal biceps tendon repair.

Methods: A single-center retrospective study was performed on 78 patients undergoing distal biceps tendon repair between 2008 and 2019. From 2008 to 2016, patients received meloxicam 15 mg daily for the period of 1 week as usual care. From 2016 onward, the standard protocol was changed to indomethacin 25 mg 3 times daily for 3 weeks. All patients underwent a single-incision repair with a cortical button technique. The postoperative rehabilitation protocol was similar for all patients. The postoperative radiographs at 8-week follow-up were assessed blindly by 7 independent assessors. If HOs were present, it was classified according to the Ilahi-Gabel classification for size and according to the Gärtner-Heyer classification for density. Statistical analysis was performed to analyze the difference in HO between the patients who were treated with indomethacin and with meloxicam.

Results: Seventy-eight patients, with a mean age of 48.8 years (range 30–72) were included. The mean follow-up after surgery was 12 months (range 2–45). Indomethacin (21 days, 25 mg 3 times per day) was prescribed to 26 (33%) patients. The 52 other patients (67%) were prescribed meloxicam 15 mg daily for 7 days. HOs were seen in 19 patients 8 weeks postoperatively. Five of 26 patients treated with indomethacin developed HO, and 14 of 52 patients treated with meloxicam developed HO ($P = .5$). Two patients had symptomatic HO with minor restrictions in movement; neither patient was treated with indomethacin. Significantly more HOs were seen in patients with a longer time from injury to surgery ($P = .01$). The intraclass correlation score for reliability between assessors for HO scoring on postoperative radiographs was good to excellent for both classifications.

Conclusion: In this study, HOs were seen in 24% of postoperative radiographs. Three weeks of indomethacin was not superior to meloxicam for 1 week for the prevention of HO after single-incision distal biceps tendon repair.

Institutional review board approval was not required for this retrospective treatment study.

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Distal biceps tendon ruptures affect 0.9-2.55 per 100,000 patients per year.²² Surgical treatment is most often necessary to adequately restore the function and strength of the elbow.⁶ Nonoperative treatment leads to suboptimal outcomes for the patient, with reduction of flexion and supination strength and decrease of endurance.^{7,9} Various fixation techniques and different surgical approaches are described; all have generally good functional outcomes.^{1,28} However, complications such as heterotopic ossifications (HOs), reruptures, superficial wound infections, and nerve injuries can occur.² Several studies analyzed the complication rate and its possible risk factors. There is to date no consensus on the optimal surgical approach.^{1,2,5,10,14,23}

HO is the formation of extraskelatal bone in muscle and soft tissues. It is thought to be an issue of the tissue repair process and it is a common complication following trauma, surgery, or other local or systemic insults.²⁶ The incidence of HO after distal biceps tendon repair is 3.7%-11.5% and is next to reruptures the most common reason for reoperation.^{1,2,13,23} HO occurs in different sizes and densities, respectively, described in the Ilahi-Gabel classification (Fig. 2, A) and the Gärtner-Heyer classification (Fig. 2, B). As patients progress through the pathologic morphologies, symptoms progress from diffuse pain to focal impingement.^{16,29} The Hastings and Graham classification can be used for grading the location and functional impairment in patients with HO.¹⁹ Some HO lesions may be small and clinically irrelevant, whereas others may be symptomatic and can cause restrictions in mobility of the joint. Radioulnar synostosis, in particular, can be extremely disabling (Fig. 1).

Several studies showed that the incidence of HO was reduced with the use of indomethacin after distal biceps tendon surgery.^{3,4,8} Following these results, the postoperative protocol changed from prescribing 1 week of meloxicam (15 mg once daily) to 3 weeks of indomethacin (25 mg, 3 times daily) following a distal biceps tendon repair.

To date, there is no true comparative study that assessed the efficacy of indomethacin. In this study, we compared the effect of 3 weeks of indomethacin to 1 week of meloxicam on HO formation after distal biceps tendon repair with a single incision in 2 consecutive cohorts. Our hypothesis was that indomethacin reduces the formation of heterotopic ossifications.⁸

Methods

A single-center retrospective study was performed on patients who underwent primary distal biceps tendon repair using a

single-incision cortical button fixation technique between 2008 and 2019. The surgeries were performed by 2 surgeons (D.E., B.T.) with a similar volume of surgeries. In total 158 electronic patient files were assessed for the method of fixation, findings during the surgical procedure, the usage of a graft, medical comorbidities, postoperative radiographs, and documentation during the follow-up. Patients were included if they had a primary distal biceps tendon repair with a cortical button, documentation was available of postoperative prescription of meloxicam or indomethacin, and postoperative radiography was performed of the elbow 8 weeks after surgery. This is the first visit in the outpatient clinic following surgery. Patients were excluded if they had incomplete documentation regarding postoperative medication, a single-incision cortical button fixation was not used, or if postoperative radiographs were missing.

The postoperative rehabilitation protocol was similar for all patients, except for the prescription of meloxicam (15 mg once daily for 1 week as needed) or indomethacin (25 mg 3 times daily for 21 days). The elbow was immobilized in a splint at a 90° angle for 10-14 days. This was followed with a standardized physical therapy protocol. Follow-up in the outpatient clinic took place at approximately 8 weeks, 6 months, and 1 year postsurgery and consisted of physical examination and radiographs in the lateral and anterior-posterior direction. Radiographs were not performed by all surgeons in all patients.

The radiographs were anonymized and imported as an image in Castor Electronic Data Capturing system (Castor EDC). All radiographs were independently assessed and scored by 7 assessors. No patient characteristics were provided to isolate and solely assess the radiographs. Of these 7 assessors, 5 are board-certified orthopedic surgeons (A.S., I.K., N.C., B.T., D.E.), of which 3 are shoulder and elbow fellowship trained (B.T., D.E., I.K.) with >3 years' experience. The other 2 assessors are orthopedic residents (E.W., N.H.). All radiographs were assessed for the presence of HO. If HOs were present, they were scored with 2 classification scales: the Ilahi-Gabel classification (Fig. 2, A) for the size and the Gärtner-Heyer classification for the density of the ossification (Fig. 2, B).^{15,20} The Gärtner-Heyer classification is frequently used to assess calcific tendinitis of the supraspinatus tendon in the shoulder, but relatively recently in the elbow.¹⁵ All outcomes were gathered and compared in order to test the interrater reliability. Disagreements for the presence of HO were resolved by the final decision of the senior author (D.E.).

Statistical analysis

The indomethacin group was compared to the meloxicam group. Groups were compared with a *t* test when the data were normally distributed; otherwise, a Mann-Whitney test was used. A χ^2 test was used for the comparison of categorical variables. It was used to analyze the presence or absence of HO and calcification size and density. An unpaired *t* test was used to compare the time from

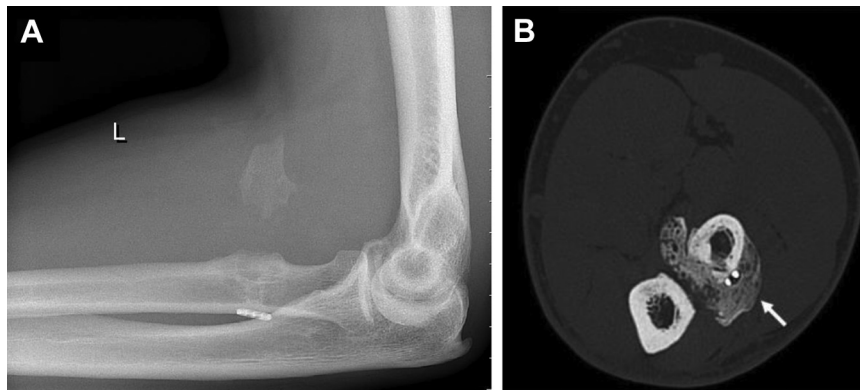


Figure 1 (A) Lateral view: postoperative radiograph following distal biceps tendon repair with presence of heterotopic ossifications (single-incision cortical button). (B) Axial-view computed tomographic scan: arrow pointing at radioulnar synostosis (different patient).

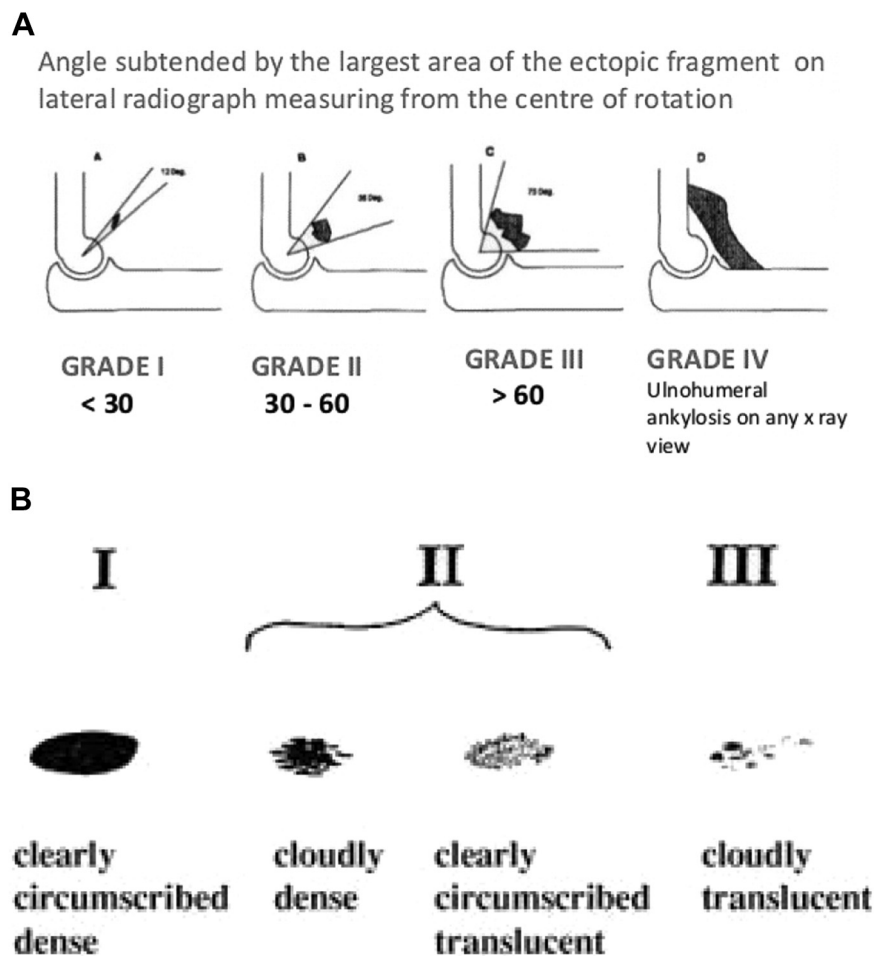


Figure 2 (A) Ilahi-Gabel classification. (B) Gärtner-Heyer classification.

injury to surgery to the presence of HO. The intraclass correlation (ICC) was determined in order to analyze the agreement between raters for the presence or absence of HO. If HOs were present, the same analysis was done for size measurements and density. The ICC and 95% confidence intervals (CIs) were calculated to study

the variation between all raters for each radiograph, based on mean rating ($\kappa = 7$), absolute agreement, and 2-way mixed effects model. ICC values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater

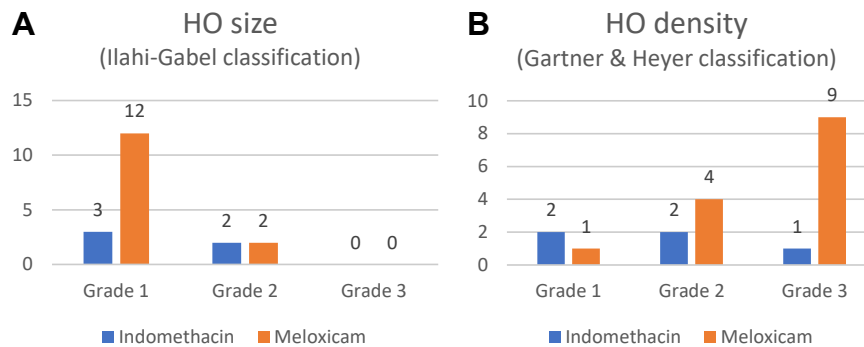


Figure 3 (A) Heterotopic ossification (HO) size per group. (B) HO density per group.

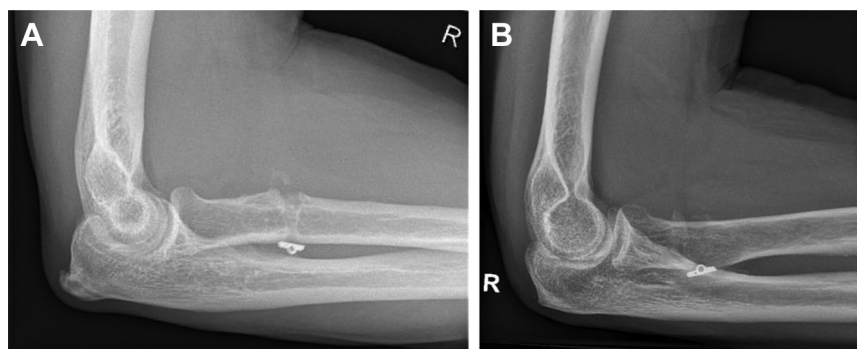


Figure 4 (A) Patient with crepitations and supination deficit without pain 8 weeks following surgery. (B) Patient with pronation deficit and pain 8 weeks following surgery.

than 0.90 indicate excellent reliability.²⁵ P values of $<.05$ were considered statistically significant.

Results

Of the 158 patients, 60 patients were excluded because there were no postoperative radiographs performed and 20 patients were excluded because another fixation technique was used. A total of 78 patients were included. Grafts were used in 14 patients; a fascia lata graft was used in 9 patients, and in 5 patients a palmaris graft was used. The mean age was 48.8 years (range 30-72); there were 6 women (7.7%) and 72 men (92.3%). The median follow-up time after surgery was 12 months (range 2-45).

None of the patients had a contraindication for nonsteroidal anti-inflammatory drugs, nor were complications observed relating to the use of nonsteroidal anti-inflammatory drugs. A total of 26 patients (33%) were treated with indomethacin, and 52 patients (67%) were treated with meloxicam. In 19 of 78 patients (24%), HOs were present on postoperative radiographs after 8 weeks. HOs were visible in 5 of 26 patients treated with indomethacin, and in 14 of 52 patients treated with meloxicam, no significant difference was found ($P = .5$). The size

(measured with the Ilahi-Gabel classification) of HO was grade 1 in 15 patients and grade 2 in 4 patients (no patients had a grade 3 size). No differences in size were found in the indomethacin group compared to the meloxicam group ($P = .23$) (Fig. 3, A). The density of the heterotopic ossification was grade 1 in 3 patients, grade 2 in 6 patients, and grade 3 in 10 patients (Fig. 3, B). A lower density was found in the group that was prescribed indomethacin, but it did not reach statistical significance ($P = .13$).

HOs were symptomatic in 2 patients; both patients were not treated with indomethacin ($P > .99$). One patient had a supination deficit of 20° compared with the other arm (Fig. 4, A) at follow-up 8 weeks after surgery. This resolved completely without intervention at longer-term follow-up. The other patient had pain and crepitations while pronating the forearm with a deficit of 20° compared with the other arm, at the 8-week follow-up (Fig. 4, B). This was treated with 2 corticosteroid injections around the distal biceps tendon insertion. The pain resolved, and the patient did not require a reoperation. None of the patients developed radioulnar synostosis.

The ICC for presence or absence of HO was 0.97 (95% CI 0.96-0.98), indicating an excellent interrater agreement. The ICC on size of HO was 0.93 (95% CI 0.88-0.96), and the ICC agreement on density was 0.88 (95% CI

Table I Patient demographics

Demographics	Indomethacin group (n = 26)	Meloxicam group (n = 52)	P value
Sex			
Female	1	5	n.s.
Male	25	47	n.s.
Age, yr, mean \pm SD	49.3 \pm 7.6	48.5 \pm 8.3	n.s.
Time injury to surgery, weeks, median (range)	32.5 (3-174)	18 (1-389)	n.s.
Tear characteristics			
Partial tear of the distal biceps tendon	13	24	n.s.
Complete tear of the distal biceps tendon	13	28	n.s.
Cause of rupture			
Traumatic onset	19	33	n.s.
Chronic onset	7	19	n.s.
Heterotopic ossifications after 8 weeks	5	14	n.s.
Ilahi-Gabel classification: size, n			
Grade 1	3	12	n.s.
Grade 2	2	2	n.s.
Grade 3	0	0	n.s.
Gartner-Heyer classification: density, n			
Grade 1	2	1	n.s.
Grade 2	2	4	n.s.
Grade 3	1	9	n.s.

SD, standard deviation; n.s., not significant.

Table II Characteristics heterotopic ossifications after 8 weeks

Characteristics	Heterotopic ossifications (n = 19)	No heterotopic ossifications (n = 59)	P value
Sex			
Female	4	3	—
Male	16	56	—
Time injury to surgery, weeks, median (range)	71.0 (1-389)	17.0 (1-203)	.01*
Tear characteristics			
Partial tear	13	28	—
Complete tear	6	31	—

* Significant $P < .05$.

0.81-0.93). This means that the classifications for size and density have a good to excellent agreement.

The median time from injury to surgery was 23 weeks (0.6-389) in all patients, not different between the groups (Table I). The mean time from injury to surgery in all patients who developed HO postoperatively was 85 (1-389) weeks, whereas the time to surgery in all patients who did not develop HO was 35 weeks (1-120; $P = .05$) (Table II). In the 2 patients who developed HO, surgery was performed 70 and 203 weeks following injury. There was no difference in grading when the time from injury to surgery was taken into account.

In 14 patients a graft was used; 4 of those patients developed HO postoperatively. No difference in occurrence

of HO was seen between patients whether the biceps was constructed with a graft ($P = .7$).

Complete distal biceps tendon ruptures were seen in 37 patients (47%), and 41 (53%) patients had a partial rupture. More HOs were seen in patients with a partial tear ($n = 13$) than in those with complete tears ($n = 6$), but it did not reach statistical difference ($P = .12$).

Discussion

To our knowledge, this is the first study to compare the effect of indomethacin to meloxicam on the formation of HO following distal biceps tendon repair with a

single-incision technique. The use of 3 weeks of indomethacin was not superior in reduction of postoperative HO in comparison to the prescription of 1 week of meloxicam. Our results do not support our hypothesis, or the common thought, that indomethacin is the most effective prophylaxis for the occurrence of HO following distal biceps tendon repair.

The overall incidence rate of HOs in this study is 24%, relatively high to what has been described prior on distal biceps repair with a cortical button, ranging from 3.7% to 11.5%.^{1,2,17,23,24,27} Factors that could have influenced the lower incidence of HOs are the differences in follow-up time between studies, underreporting of HO because postoperative radiography is not standard practice everywhere, or because a double-incision technique was used. In particular, in studies where indomethacin was prescribed per protocol, few HOs were observed (0.1%-2%).^{3,4,8,18} The use of indomethacin as a prophylaxis seemed to be beneficial for prevention of radioulnar synostosis as well. Costopoulos et al⁸ reported a significantly lower rate of radioulnar synostosis in the patients who received indomethacin ($n = 1$; 0.96%) compared with the untreated group ($n = 3$; 37%) ($P < .001$). There are, however, several differences between the study by Costopoulos et al⁸ and our study. Their study was mainly done on double-incision repairs ($n = 105$ of 112). A significantly higher rate of radioulnar synostosis was found in the single-incision group, but they confirm that the study was underpowered to draw any conclusions.⁸ Their study was also not a true comparative study, as only 8 of 112 patients were not treated with indomethacin postoperatively (because of contraindications). In our study, no patient developed radioulnar synostosis. Several previous studies compared the single-incision to the double-incision technique and found a lower incidence of HO in the single-incision technique, but modern techniques generate similar outcomes between techniques and approaches.^{10,12,13,21} Given the fact that in our study, only the single incision was performed, we were not able to compare the single- to the double-incision technique.

There were 2 patients who had symptomatic HO, and neither was treated with indomethacin. Probably because the incidence ($n = 2$) is low, it was statistically insignificant. Therefore, we can also not declare that the use of indomethacin would have prevented the symptoms related to HO. Indomethacin did not seem to influence the extensiveness regarding size and density of HO (Fig. 3). Two patients who had symptomatic HO were not treated with indomethacin, but no patient developed radioulnar synostosis and there was no need for a reoperation. This was the first study to examine the density and size of HO following distal biceps tendon repair; thus, there is a lack of comparison in the current literature. Further research with postoperative radiographs with at least 8 weeks of follow-up is necessary to study whether indomethacin has a prophylactic effect regarding size and density of HO.

Literature is not clear about the exact duration of the use of indomethacin, but it is most commonly prescribed as 75 mg daily (in 1 long-acting dose or 3 short-acting doses) for 21 days.^{11,18} Anakwenze et al⁴ analyzed 34 patients with a distal biceps tendon repair, all of whom were prescribed 75-mg oral sustained-release indomethacin once daily for 6 weeks postoperatively, and no cases of HO were observed. The patients in Costopoulos et al⁸ were treated with indomethacin (oral sustained-release 75 mg once daily) for 10-42 days, depending on each attending's protocol. The duration of indomethacin use was not related to the development of synostosis, and the authors recommended a minimum prescription of 10 days.

The time to surgery might be a factor for complications such as HO. In our study, the patients who postoperatively developed HO had a significantly longer time to surgery compared with patients who did not develop HO. However, the range in timing was rather wide, and it is difficult to draw conclusions relevant for clinical practice. In previous studies, the functional outcomes were similar after 1 year of surgery between acute (<4 weeks) and chronic repair.³

The strength of the current study is the comparison of 2 cohorts in a single-center setting with a relatively similar protocol, other than postoperative prescription medication, although the long time span. There are also some limitations to this study. Because it was a retrospective study, the compliance or self-medication of patients is not known. Not all patients had postoperative radiographs after 6 months and 1 year. In order not to introduce bias to our study, we were only able to compare the radiographs after 8 weeks. Even though it is possible that some patients developed HO after 8 weeks, patients were seen in the outpatient clinic at their 6-month and 1-year follow-ups and symptomatic complications would have been discovered. Another limitation is that postoperative functional outcome assessments and strength testing were not documented routinely.

In this study, postoperative prescription of indomethacin did not reduce HO in the single-incision technique. Based on our results, the prescription of indomethacin is not superior to meloxicam for HO prophylaxis in the anterior single-incision technique with a cortical button. Future research is important to study factors that may have an influence on the formation of HO.

Conclusion

The results of this study show no additional prophylactic effect of the use of 3 weeks' indomethacin following distal biceps tendon repairs with a single-incision technique to 1 week of meloxicam. Based on these results, we advise against the use of indomethacin. Further research is necessary to investigate other risk factors, such as incision technique, fixation technique, and

timing, for the formation of HO in order to prevent this phenomenon in the future.

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