ORIGINAL STUDY

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Prevalence and clinical implications of heterotopic ossification after distal biceps tendon repair

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Complete distal biceps tendon ruptures are relatively uncommon. Conservative treatment may result in persistent pain and weakness. Therefore, surgical repair is usually indicated in order to restore strength. Different surgical techniques and fixation methods have been described. The most reported complications after surgery are iatrogenic nerve damage, heterotopic ossification (HO) and re-rupture. Heterotopic ossification can be variable in size. Significant HO can limit range of motion while minor HO often remains asymptomatic. The overall presence of HO is likely underreported in literature, as imaging is reserved for symptomatic patients. The purpose of this study is to report the prevalence and clinical implications of heterotopic ossification after surgical repair of the distal biceps tendon. This retrospective study assessed the prevalence and clinical relevance of postoperative HO after distal biceps tendon repair. CT-scans were used to evaluate size and location of the HO. VAS scores, DASH scores, MEPI, and range of motion (ROM) were assessed to evaluate pain, patient satisfaction and elbow function. HO was observed on CT images of 19 out of 35 patients (54%). The use of interference screws, timing of surgery after rupture and timing of radiographic assessment postoperatively did not influence the prevalence of HO. The presence of HO had no statistically significant impact on the VAS scores, ROM measurements and MEPI and DASH scores. According to our findings, the overall incidence of HO is higher than previously reported but there are no differences in clinical outcomes when compared to patients without HO.

Keywords: elbow, biceps, complication, imaging, sports.

INTRODUCTION

Distal biceps tendon ruptures have an incidence rate of 2.5 per 100,000 patients per year[1]. The vast majority of complete distal biceps tendon ruptures occur in men between 40 and 60 years of age, but a bimodal incidence distribution, which includes elite athletes, has also been described[2-3]. The typical mechanism of injury is an isometric contraction with the elbow in extension and the forearm in supination[4-5]. Conservative treatment may result in decreased resistance to fatigue and loss of supination and flexion strength[6-7]. Surgical management has been shown to lead to better outcomes over the nonoperative approach regarding the functional outcomes, with better flexion and supination strength[8].

Various surgical approaches and fixation methods have been described, all with similar outcomes[9-10]. The most frequently used fixation techniques are buttons, suture anchors, bone tunnels, with or without the use of an interference-screw and are performed through either a single- or double-incision approach[11-12-13].

Complications following distal biceps tendon repair are common. Amarasooriya et al. included 3091 primary distal biceps tendon repairs in a systematic review and described an overall complication rate of 25%, including 4.6% major and 20.4% minor complications.[14] The most common complications were re-rupture, nerve injuries, radio-ulnar (RU) synostosis, and heterotopic ossifications (HO).

Heterotopic ossification occurred in 3.9% of cases and was more frequently observed with the double incision approach (5.8%)[14]. Ford et al. reported a prevalence of 1.3% of patients with symptomatic postoperative HO in a cohort of 970 patients[15]. Although the patient sample was large, HO was evaluated in symptomatic patients only. The reported clinical findings were mostly of mild or moderate severity. Routine HO screening is rarely performed. Huynh et al. and Caekebeke et al. reported on routine postoperative radiographs[16-17]. Postoperative heterotopic ossification was found in 56.7% and 28.6% respectively. In all cases, it was minor HO that did not require further treatment. It is highly likely that routine

screening for postoperative HO in a larger cohort is likely to reveal a higher prevalence of HO.

The purpose of this study is to evaluate the prevalence of HO after distal biceps tendon repair and evaluate its clinical significance in a long-term follow-up.

MATERIALS & METHODS

After obtaining internal review board approval, a two-center retrospective study of patients that underwent an acute repair of a distal biceps tendon rupture, using a single incision, bicortical metallic button repair with or without the use of an interference screw, was conducted. The use of an interference screw depended on the institution where the patient was treated. The creation of the bone tunnel is relevant to this study[17].

A single incision approach was used in this case series[18].

The radial tuberosity is visualized, and a guide pin is drilled bicortically through the center of the radial tuberosity with the forearm in full supination. An 8mm cannulated drill bit is used to prepare the first cortex and the canal. Care is taken not to violate and the second cortex. In this way, the guide pin remains stable in the second cortex. The second cortex is then drilled with 4.5mm cannulated drill bit. Excess bone is then removed with the use of a rongeur, after which the wound is irrigated with saline solution. Postoperatively, both active and passive ROM exercises were permitted and a maximal lifting of 20 kilograms was allowed if tolerated.

Class I: radiographic heterotopic ossification without functional limitation.

Class II: radiographic heterotopic ossification with subtotal functional limitations.

- IIA: limited flexion - extension.
- IIB: limited pronation - supination.
- IIC: limited in both planes.

Class III: radiographic and functional ankylosis.

- IIIA: ankylosis in flexion - extension.
- IIIB: ankylosis in pronation - supination.
- IIIC: ankylosis in both planes.

Fig. 1. — Overview of the Hastings and Graham classification[19].

All patients underwent CT imaging of the proximal radius at the study-related follow-up to evaluate the presence and size of heterotopic ossification. The clinical relevance of HO was assessed based on ROM through the Hastings and Graham classification (Figure 1)[19]. Visual analog scale (VAS), Mayo Elbow Performance Index[20], and Disabilities of Arm, Shoulder and Hand (DASH) scores were used to assess for pain and patient satisfaction. Functional outcome measurements included range of motion (extension, flexion, pro- and supination).

Data were checked for normality using the Shapiro-Wilk test. Comparisons of pain and function outcomes between groups (HO and non-HO) were based on the Mann-Whitney U test for independent samples due to the non-normal data distribution. Outcomes were considered significantly different if the calculated p-value was < 0.05.

RESULTS

In this retrospective study, a total of 35 patients who underwent distal biceps tendon repair were included. All 35 patients were male with the dominant side affected in 19 cases. Heterotopic ossification of the distal biceps tendon was identified in 19 patients on postoperative CT imaging (incidence of 54.29%) with an average size of 60.37 mm^2 (Range 11-364) The duration of clinical and radiographic follow-up were not significantly different between patients with or without HO ($p = 0.92$), with a mean follow-up period of 33 months (Range 3 to 70) for the HO group and 32 months (Range 16 to 55) for the non-HO group. The mean age at time of surgery of the affected group was 48 years (Range 29 to 60) versus 46 years (Range 25 to 56) of the non-affected group.

Out of the 19 patients with radiographic HO, 1 patient experienced a clinically relevant decrease in ROM due to limited pronation (10°) and was consequently classified as Class IIB. All other patients with positive CT-scan findings did not experience any functional limitation (Class I).

The mean VAS score for pain of the cohort was 0.4 (Range 0 to 3) and did not statistically differ between

Table I. — Patient characteristics

	Age at surgery (years)		Trauma-surgery interval (days)		Follow-up (months)	
	HO group	non-HO group	HO group	non-HO group	HO group	non-HO group
Mean	47.737	46.375	6.474	10.000	33.526	32.375
Std. Deviation	7.271	8.237	4.019	12.182	17.602	12.176
Shapiro-Wilk	0.948	0.915	0.943	0.721	0.988	0.937
P-value of Shapiro-Wilk	0.364	0.139	0.302	< .001	0.995	0.312
Minimum	29.000	25.000	0.000	0.000	3.000	16.000
Maximum	60.000	56.000	13.000	49.000	70.000	55.000

Table II. — ROM outcomes

	Flexion (°)		Extension (°)		Pronation (°)		Supination (°)	
	HO group	non-HO group	HO group	non-HO group	HO group	non-HO group	HO group	non-HO group
Mean	135.000	131.875	−0.263	−0.313	71.053	75.000	82.500	76.250
Std. Deviation	4.714	6.292	1.147	1.250	17.367	8.367	9.825	10.567
Shapiro-Wilk	0.850	0.859	0.244	0.273	0.725	0.870	0.920	0.926
P-value of Shapiro-Wilk	0.007	0.019	< .001	< .001	< .001	0.027	0.112	0.212
Minimum	130.000	115.000	−5.000	−5.000	10.000	60.000	60.000	55.000
Maximum	145.000	140.000	0.000	0.000	90.000	90.000	100.000	90.000

Table III. — Pain and function outcomes

	VAS score		DASH score		MEPI score	
	HO group	non-HO group	HO group	non-HO group	HO group	non-HO group
Mean	0.263	0.563	3.991	3.281	98.421	95.938
Std. Deviation	0.653	0.964	4.751	4.188	4.730	9.699
Shapiro-Wilk	0.452	0.653	0.800	0.779	0.362	0.494
P-value of Shapiro-Wilk	< .001	< .001	0.001	0.001	< .001	< .001
Minimum	0.000	0.000	0.000	0.000	85.000	65.000
Maximum	2.000	3.000	15.000	11.667	100.000	100.000

Table IV. — Statistical analysis

	W	df	p
Age at surgery (years)	166.000		0.654
Trauma-surgery interval (days)	144.500		0.816
Follow-up (months)	155.500		0.921
Extension (°)	153.500		0.934
Flexion (°)	193.000		0.158
Pronation (°)	138.500		0.651
Supination (°)	203.000		0.089
VAS score	128.000		0.289
DASH score	169.000		0.578
MEPI score	165.500		0.479

Note. Mann-Whitney U test.

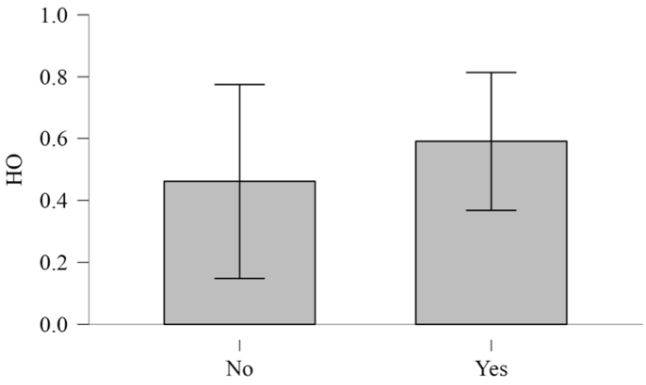

Fig. 2. — Interference screw usage.

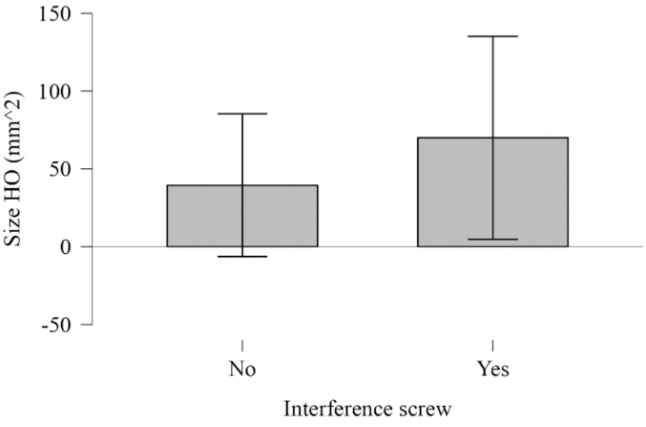

Fig. 3. — Size of HO.

the two groups (non-HO 0.3 versus HO 0.6, p = 0.3).

Patient satisfaction was assessed using the MEPI score and DASH score (Table III). There was no significant difference in outcomes between the two groups with p-values of 0.5 and 0.6 respectively.

There was no significant difference in postoperative range of motion between the two groups (Table II). The mean range of motion for the HO group was 135° of flexion (Range 130 to 145), -0.3° of extension (Range -5 to 0), 71° of pronation (Range 10 to 90) and 83° of supination (Range 60 to 100) compared to 132° of flexion (Range 115 to 140), -0.31° of extension (Range -5 to 0), 75° of pronation (Range 60 to 90) and 76° of supination (Range 55 to 90) for the non-HO group.

In 22 of the 35 patients, an interference screw was used as an additional fixation. Patients in whom an interference screw was used had a higher incidence (%) and mean size (mm^2) of postoperative HO compared to those in who no interference screw was used (59% versus 46.2% and 70 mm^2 versus 39 mm^2) (Figure 2 and 3). However, the differences were not statistically significant (p = 0.5 and p = 0.8).

Timing of surgery after trauma varied substantially, from 0 to 49 days. The mean time of surgery after trauma in the HO group was 6 days versus 10 days in the non-HO group, with a p-value of 0.8, which was not statistically significant.

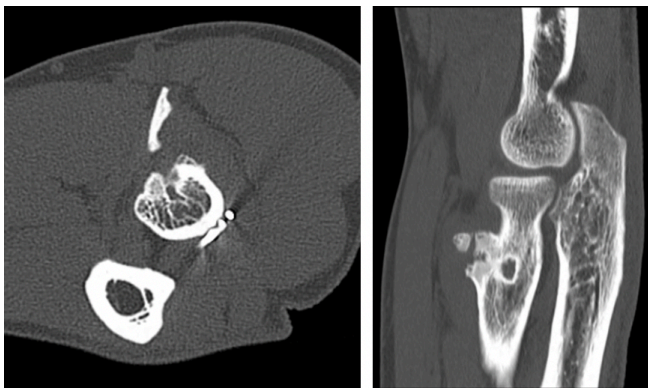

Fig. 4. — Example of heterotopic ossification on CT-scan (axial and sagittal plane).

DISCUSSION

Heterotopic ossification of the biceps tendon is a well-recognized complication following distal biceps tendon repair. The prevalence described in current literature is generally an underestimation, as diagnostic imaging is almost always obtained only in cases of symptomatic HO and most patients are asymptomatic or experience only mild or moderate discomfort.

In this case series, HO could be visualized on post-operative CT-scans in more than half of the patients, with a prevalence of 54.29%. These findings support our presumption of a higher prevalence of postoperative HO than is commonly reported. One patient experienced limited pronation (10°), but no further treatment was needed since it did not compromise his daily activities. None of the other patients with HO exhibited any symptoms and would probably not have been diagnosed if no imaging had been done. Larger cohort studies described rates of postoperative HO of 1.3% up to 3.9%[14-15]. However, no asymptomatic patients were included, and criteria used for patient screening were not clear. Smaller studies that included routine postoperative imaging showed a higher prevalence[16-17]. In addition to the inclusion of asymptomatic patients, the longer follow-up period and the use of CT-scans might contribute to the higher prevalence of postoperative HO in our study. We performed control CT-scans, on average almost 3 years postoperatively whereas most studies used a minimum follow-up period of only 8 weeks[14-15]. Although there is no consensus on the timing of screening, some studies describe that HO can manifest up to 12 weeks after trauma or surgery, with maturation occurring 3 to 6 months after the onset of HO[21-22].

The clinical implications of major HO have been well described. The most prevalent clinical implications of this ectopic lamellar bone formation in soft tissues are restricted joint range of motion, chronic pain, and soft-tissue breakdown[23]. These complications can result in substantial morbidity. As a result, clinically relevant heterotopic ossification often requires surgical intervention to restore joint motion and function[24]. This study evaluated the clinical implications of minor postoperative HO. Despite its high incidence, we were not able to detect any significant difference in pain, function and patient satisfaction between the HO group and the non-HO group. No patients with HO in our case series required additional treatment for their HO.

Some prophylactic measures in the prevention of postoperative HO have been described. Indomethacin prophylaxis after distal biceps tendon repair has been shown to reduce RU synostosis and HO rates[25-26]. However, a recent paper has reported no benefit of 3 weeks of Indomethacin over 1 week of Meloxicam alone in the prevention of HO formation after distal biceps tendon repair[27]. Due to the potential negative effects on capsule healing, we do not integrate standard NSAIDs or indomethacin prophylaxis in our postoperative protocol[28]. This may have contributed to the relatively high incidence of HO in our study cohort. We do use extensive wound lavage when drilling our tunnels. Although literature on the protective effect of intraoperative lavage in the formation of postoperative HO in the elbow is lacking, it has been proven to reduce the incidence as well as the severity of heterotopic ossification after total hip arthroplasty[29]. Future research should investigate whether the prophylactic effect of extensive lavage can be extrapolated to this type of surgery.

According to Wörner et al., one of the factors influencing the occurrence of HO is timing of surgery after trauma, prolonged trauma to surgery intervals were associated with a higher prevalence of HO[27]. Contrary to the findings of Wörner et al., we could not show a significant difference between the HO group and the non-HO group regarding the timing of surgery after trauma[27]. In our case series, the HO group underwent surgical repair even slightly earlier after trauma compared to the non-HO group.

Limitations of this study are the following. First, the relatively small sample size of the cohort, which increases the likelihood of type II error. Therefore, possible differences might have been detected with a greater number of patients. Nevertheless, our results do not show any difference between the two groups. Second, the fact that only one surgical approach was evaluated. Recent literature shows a lower incidence of HO after a single-incision compared to a two-incision approach[14-15]. In our study a single-incision approach

was used in all patients, implying that the overall incidence of HO might be even higher than the incidence we described. Finally, the influence of tourniquet use, lavage and NSAID use could not be assessed separately in this study, as the same prophylactic measures were applied in all patients.

CONCLUSION

We reported a higher prevalence of HO than previously described, possibly because most studies do not perform routine screening for HO in asymptomatic patients. No patient received additional treatment and we were unable to detect any difference between the two groups regarding patient satisfaction and ROM. Since minor postoperative HO does not require additional treatment, routine screening of asymptomatic patients is therefore not recommended.

Future research should investigate the effect of prophylactic measures on symptomatic, major HO formation after distal biceps repair as this may lead to significant functional impairment.

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