Long head biceps and rotator cuff surgery in the shoulder

van Deurzen, D.F.P.

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STRENGTH

CHAPTER 10

General discussion, clinical implications and future perspective

Surgery of long head biceps (LHB) pathology aims for improvement in anterior shoulder pain. A decrease in shoulder pain will likely lead to better function. To achieve this, several techniques have been proposed to perform either LHB tenotomy or tenodesis. When discussing treatment options, patients and doctors aim to reduce pain while also considering the risk of functional loss and muscular deformity. In the introduction of this thesis an overview of the relevant issues with regard to the LHB is provided. Diagnosis and interpretation of treatment effects of LHB pathology are hampered by the close proximity of the LHB to the insertion of the supraspinatus tendon. Results of LHB surgery may therefore be related to the location of the LHB tenodesis site or merely to the results of the concurrently performed rotator cuff repair. The objective of this thesis is to elucidate the role of LHB surgery when performed in conjunction with rotator cuff repair. The research presented in this thesis includes several methodological designs, such as systematic reviews and meta-analyses, information on cadaver studies, a randomized trial and a retrospective study. The results are discussed below and recommendations are made for future research. As well, recommendations are given for clinical relevance and for daily practice.

PART 2. TENOTOMY OR TENODESIS FOR LHB PATHOLOGY

In 2015 we systematically reviewed literature reporting on the results of studies comparing the outcome of LHB tenotomy and tenodesis. Nine studies were included in the meta-analysis reporting on the outcome of 650 patients. In Chapter 2 we reported the results of this meta-analysis which revealed no difference in clinical outcome parameters such as elbow flexion strength and forearm supination strength. The results in CMS seemed to favor LHB tenodesis. However, statistical analysis revealed no significant difference ($p=0.07$). In contrast, Popeye deformity and cramping pain were clearly more prevalent following LHB tenotomy. Generalizability of these results to all patients undergoing LHB surgery was limited due to several reasons. Information regarding recruitment procedure, surgical technique, timing of post-operative evaluation and post operative rehabilitation was not always reported, indicating varying quality of evidence displayed by widely ranging Coleman scores. Furthermore, patients in these studies were operated for different types of LHB pathology such as SLAP lesions or concomitant other pathology such as large size rotator cuff lesions as well. To increase the overall level of evidence and to compare LHB tenotomy with LHB tenodesis when performed in conjunction with rotator cuff repair we designed a multi center randomized trial, called the BITE trial (Chapter 3). As LHB tenotomy has the advantage of being a quicker procedure with fewer complications we selected a non-inferiority design. To decrease heterogeneity we included patients only after arthroscopically confirmed LHB pathology and small to medium sized lesions of the rotator cuff when measured with an arthroscopic ruler. Patients were randomized to undergo either treatment when an unstable, inflamed or partially ruptured LHB was encountered during arthroscopy. Although LHB tendinitis may be reversible it has been reported that severity

of degenerative changes in rotator cuff tendons is related to degenerative changes of the LHB (1). As the average period of symptoms before inclusion in the BITE trial was more than a year, patients were likely beyond the period of self-limiting LHB tendinitis. The diagnosis of a symptomatic SLAP lesion based on clinical history, physical examination and even MRI has proven to be difficult. (2-5) Therefore we excluded patients with suspected SLAP lesions from the BITE study. Performing LHB tenodesis with the anterior most anchor that was already used for repair of the rotator cuff lesion avoided costs of additional surgical material in the group of LHB tenodesis patients. Consistent with previous RCTs we selected CMS as primary outcome parameter for our study. (6-8) Next to the disadvantage of being an investigator dependent score, the CMS together with the DASH and OSS may be less appropriate to assess LHB treatment. The LHB scores presented by Scheibel et al and Euler et al are more focused on LHB pathology. (9, 10) Although both scores seem promising to evaluate LHB pathology, both were not validated when we developed our study protocol and therefore not used.

Results of the BITE trial (Chapter 4) showed that CMS in patients older than 50 year who are surgically treated for small to medium sized degenerative rotator cuff tears substantially improved after both LHB tenotomy and LHB tenodesis. However, the mean difference between groups of 4.8 points was less than half of the pre-stated margin of 10 points as a threshold for clinical relevance. As the upper bound of the confidence interval crossed this margin and resulted in a p-value of 0.06, this should be interpreted as statistically inconclusive. Furthermore, no clinically relevant difference was observed between groups with regard to other functional and cosmetic outcome parameters, including a Popeye deformity.

There may be several reasons to explain why we did not observe a clinically relevant difference in CMS between LHB tenotomy and tenodesis in this group of patients. Possibly, the suprapectoral location to perform LHB tenodesis does not effectively treat pathology arising from the bicipital groove. Several authors have raised concern about persistent pain in the bicipital groove and tendinopathy due to the remaining tendon within the bicipital groove.(11-13) Sanders and colleagues reported that a proximal tenodesis site may not solve the problem of persistent tenosynovitis of the LHBT resulting in higher revision rates. (12)

Although the CMS may be not specific enough to measure outcome of LHB surgery, it may be questioned whether repeating exactly this trial with more patients and using a LHB specific primary outcome would lead to different insights, as all other study outcomes (except surgical time) did not reveal significant differences either.

Before embarking on a subsequent trial to further elucidate the role of LHB surgery we recently updated our previous meta-analysis and added 7 RCTs that compared LHB tenotomy with LHB tenodesis.(14) Again the quality of included studies was highly variable, and the results were not essentially different than those of previous meta-analyses showing an increased incidence of a Popeye deformity or cramping bicipital pain after LHB tenotomy. (15)

Loss of strength may be an undesired result in case surgical treatment of the LHB is performed, but this was not confirmed in the BITE study. Hufeland and colleagues reported that LHB tenodesis results in 46% more elbow flexion strength compared to LHB tenotomy. (16) In a letter to the editor we have argued that fixation of the LHB tendon alone is not likely the only explanation for a better outcome with regard to elbow flexion strength. (15) Moreover, Morrey (17) and Nesterenko (18) have reported 30 % decreased flexion strength after conservative treatment of complete distal biceps tendon ruptures. Although the strength of the biceps muscle in their study was related to the elbow flexion angle, this implies that the biceps muscle as a whole contributes to as much as 30 % of the flexion strength in the elbow. We therefore postulated that the better strength after LHB tenodesis in Hufeland's study is likely related to a decrease in pain. Furthermore, it is known that the insertion of the distal biceps tendon is separate for the short head of biceps (SHB) and the LHB (19). The SHB inserts more distally on the radial tuberosity and the LHB more proximally. Elbow flexion strength is therefore more provided by SHB and the LHB provides greater supination strength. Although Lee and colleagues found more loss of supination strength following LHB tenotomy compared with tenodesis, the authors postulated that older patients would likely not be hindered by this. (8) Although not supported by level 1 evidence this likely holds for young patients as well.

Methodologically, the results of the BITE trial have to be interpreted in the light of the following limitations. Because we did not keep a screening log in the BITE trial we are unaware of the inclusion rate. The long recruitment phase of on average 50 months per including center threatens the external validity of our findings. Low inclusion rates can originate from both patients and physicians being hesitant to participate, which can lead to selection bias. The use of self-reported data in the BITE trial (chapter 4 and 5) and long term follow up study (chapter 9) may have been susceptible to socially desirable answers and recall bias. Although we believe the intervals were sufficient not to remember the answers from the previous measurement, this may have influenced the internal validity.

As a sham surgery group was not included in the study, it remains unknown to what extent a placebo effect affected the results of our trial. (20) Also, the natural course of tendinopathy may have played a role in not detecting a clinically relevant difference between groups. However, patients were included after an average minimum of duration of complaints of one year, signifying that only patients with long standing symptoms were operated. Lee and colleagues studied 162 MRIs one year after rotator cuff repair and found morphological changes in untreated LHBs, indicating that LHB pathology does not automatically reverse after rotator cuff repair. (21) Based on literature and expert opinion of an Italian group of shoulder surgeons, surgical treatment of tendinous pathology is suggested after three months of non-operative treatment. (22) Although LHB surgery has been reported to be beneficial for treatment of LHB pathology in patients undergoing rotator cuff repair, a study comparing LHB surgery with non-operative treatment has not been performed to date.

No significant difference with regard to CMS was found between groups, regardless whether the rotator cuff repair was fully healed, partially healed or showed a recurrent lesion. This observation is in accordance with previous publications (23, 24) and raises

questions with respect to the efficacy of rotator cuff repairs of degenerative rotator cuff tears in general.

Surgical time for LHB tenotomy was significantly shorter than for LHB tenodesis and the incidence of adverse events was similar between groups. Tenotomy is a simpler and quick procedure and all other outcome parameters were not significantly different. This questions the need for performing suprapectoral LHB tenodesis in our study population.

The Popeye phenomenon is a regular topic of debate in reports describing the results of treatment of LHB pathology and many studies reported considerably higher percentages of a Popeye sign and cramping pain after LHB tenotomy when compared to LHB tenodesis. (14) To maintain blinding of the patients in the BITE trial, both groups of patients received the same postoperative rehabilitation protocol in which active elbow flexion was prohibited during six weeks. Given the not significantly different percentages of Popeye signs between both groups in our study it may be hypothesized that this cautious rehabilitation protocol protected the LHB from contracting sufficiently to cause more Popeye signs and cramping pain after LHB tenotomy. Other factors such as muscle volume of the biceps, body fat percentage and sex may play a role in this respect as well. However, these factors were randomly divided over both groups in the BITE trial and therefore not of influence to a different percentage in Popeye signs.

The reported percentages of Popeye signs in literature are mostly originating from assessments by physicians. Only a few studies investigated patient's assessment of the upper arm following LHB surgery and reported that patients do not seem to be bothered by this cosmetic deformity, especially in the elderly population. (25) To our knowledge, no study has investigated the agreement between doctors before. In Chapter 4 we investigated the agreement between doctors and between patients and doctors with regard to the occurrence of a Popeye deformity. Consistent with literature we found that a Popeye sign was considerably more often identified by doctors than by patients. To investigate agreement between doctors we used digital photographs of the operated upper arms and asked a group of observers to assess these pictures for the presence of a Popeye sign. Negligible agreement was found in the group of doctors with regard to reporting a Popeye phenomenon. Detection of a Popeye sign was moderately related to male subjects, which may be related to a more positive muscle to fat ratio in the upper arm when compared with female subjects. Although a cosmetic deformity may be feared by patients undergoing LHB surgery, none of the patients with a Popeye phenomenon in our study population were unsatisfied. However, patients that are prospectively compared after tenotomy or tenodesis in a randomized fashion have to sign informed consent with regard to LHB treatment. It could be argued that patients who refused to participate in the BITE study dread a Popeye deformity and would cause a different outcome with regard to perception of a Popeye deformity in case these patients would have been included in the study. Adopting a rehabilitation regime with earlier elbow flexion range of motion than in the BITE study may lead to higher percentage of cramping pain and increased dissatisfaction with a Popeye sign.

Furthermore it may be questioned why doctors do not agree on the presence of a Popeye sign. Objective parameters to identify a Popeye sign following LHB surgery have not been clearly described in literature. Not only determining the presence but also grading the deformity is a subjective assessment and may explain the low agreement in our study. (26) Although photographs were taken with high resolution digital cameras in a standardized fashion, appraisal of a Popeye sign using photographs may be hampered due to factors such as lighting and exposure. The low agreement among observers in our study may either indicate that photographs are not suitable for identification of a Popeye sign (accuracy) or support that there is no consensus with regard to the assessment of a Popeye sign (reliability). If the latter is true, the reported incidences of a Popeye sign in previously reported meta-analyses have to be seen in a different perspective as well.

Clinical implications

- In patients older than 50 years LHB tenotomy seems not inferior to suprapectoral LHB tenodesis when performed in conjunction with arthroscopic rotator cuff repair in terms of both functional and cosmetic outcome.
- As operative time is shorter as well, these patients may be advised to undergo LHB tenotomy instead of suprapectoral LHB tenodesis.
- With regard to the occurrence of a Popeye sign, patients may be informed that opinions with regard to its presence vary, also among doctors, and female patients will less likely notice the deformity in their upper arm.

PART 3. SUPRA- OR SUBPECTORAL LHB TENODESIS

The results of the BITE study revealed no clinically relevant difference in outcome between a simple LHB tenotomy and suprapectoral LHB tenodesis. Several authors have suggested that suprapectoral tenodesis might give persistent pain at the bicipital groove if tenodesis is performed above or in the groove and may lead to performing revision surgery. (12, 27-29) In Chapter 6 we describe the surgically relevant anatomical factors in the bicipital groove that may play a role in the outcome of LHB surgery. A bottle neck narrowing in the bicipital groove and pain receptors in the transverse humeral ligament may be related to post-operative persisting pain and occurrence of a Popeye sign. Although releasing the THL has been suggested in the treatment of LHB pathology, this has not been routinely performed in studies reporting the results on supra- or subpectoral LHB tenodesis. In Chapter 7 we presented a systematic review and meta-analysis to provide an evidence based overview of the literature comparing the results of suprapectoral with subpectoral LHB tenodesis. No clinically relevant difference with regard to outcome scores, pain in the bicipital groove and avoiding a Popeye deformity was observed when subpectoral LHB tenodesis was compared with suprapectoral LHB tenodesis. Suprapectoral LHB tenodesis was performed proximally in the bicipital groove by fixation in the rotator cuff repair, in the bicipital groove or distal to the groove. The authors who performed LHB tenodesis proximally in the groove reported more pain (30, 31) in the bicipital groove than the two

studies (32, 33) that performed LHB tenodesis distal to the groove (yet still suprapectoral). The studies investigating tenodesis distal to the bicipital groove demonstrated similar pain scores compared to subpectoral tenodesis. Performing LHB tenodesis distal to the groove or in subpectoral region may therefore be favoured over a LHB tenodesis site located proximally in the bicipital groove. Although not reported in the analyzed studies, open subpectoral tenodesis may be accompanied with musculocutaneous nerve entrapment, fracture of the humerus and deep infection. (34-38) Although technically more demanding and accompanied with longer operating time, arthroscopic or open suprapectoral LHB tenodesis performed below the bicipital groove may therefore be preferred over an open subpectoral LHB tenodesis technique.

The conclusions of the meta-analysis in chapter 7 have to be seen in the light of similar limitations as the study presented in chapter 1, as patients were not only treated for LHB tendinopathy, but also for rotator cuff repair, lateral clavicle resection, subacromial decompression, labral and rotator cuff debridement, which may have influenced the outcome measures. Except for one RCT, all other studies displayed a retrospective design and Coleman scores indicated moderate quality of evidence. Given the heterogeneity in patients and performed procedures, further research may be needed to determine the optimal surgical protocol. A future trial would need a large sample size to be able to detect a clinically relevant difference between the groups, because outcome after any of the surgical techniques is likely to be good. It may be worthwhile to thoroughly evaluate cost-effectiveness and use specific LHB outcome score instead of CMS.

Clinical implications

- When performing either LHB tenotomy or tenodesis, routinely releasing the transverse ligament may decrease postoperative anterior shoulder pain.
- To avoid the bottle neck narrowing in the bicipital groove and prevent entrapment of the LHB, a location distal to the bicipital groove may be preferred for LHB tenodesis over a more proximal tenodesis site.
- To avoid reported postoperative infection, hematoma or neurovascular complications, arthroscopic LHB tenodesis below the bicipital groove may be preferred over an open subpectoral LHB tenodesis.

PART 4: RESULTS OF ROTATOR CUFF SURGERY

The results of the BITE trial revealed no clinically relevant difference with regard to several outcome scores between tenodesis and tenotomy for LHB pathology when performed in conjunction with repair of non-traumatic small to medium sized rotator cuff lesions. The primary outcome CMS showed an overall average improvement of 31 points (from 43 to 74) at one year follow up. VAS scores for pain improved 3.8 points (from 5.4 to 1.6) at one year follow up. In Chapter 8 a systematic review and meta-analysis of literature was presented to provide an overview of shoulder specific outcome scores with similar follow up of one year after repair of non-traumatic rotator cuff lesions. Sixteen randomized controlled trials

reporting the outcome of additional treatments that were performed in conjunction with rotator cuff repair were included. An average increase in CMS of 29.5 points was found. VAS scores showed an average decrease of 4.1 points. Other outcome scores such as ASES, SST en UCLA showed significant improvements as well, suggesting that rotator cuff repair may be an effective intervention for the treatment of degenerative lesions of the rotator cuff.

The rotator cuff repairs were performed in conjunction with other procedures causing heterogeneity that limits generalizability to the whole population.

Interestingly, we found similar results with regard to CMS and VAS scores when comparing the results of this meta-analysis with the outcome parameters of the BITE trial. Although the role of LHB surgery may not be readily interpreted from this analysis, it implies that the results of our trial are consistent with literature. The results of the meta-analysis that are presented in Chapter 1 show an overall median CMS of 85.5 points, which is 10 points more than the average results at one year follow up in the BITE trial. When compared with the results of Chapter 8, this implies that the final CMS in the BITE study may be more related to rotator cuff surgery than to the effect of LHB surgery. However, due to the heterogeneity of the patients in Chapter 1 and 7 it remains difficult to draw firm conclusions with regard to the exact role of long head biceps surgery, whether or not combined with rotator cuff surgery.

In Chapter 9 the long term functional outcome and structural integrity after repair of small- to medium sized rotator cuff lesions are described. With 11 years follow up this study revealed a median CMS of 82 points and comparable outcome with regard to OSS and EQ5D as in the BITE trial. Structural integrity at follow up was evaluated using ultrasound revealing an intact repair in 76% of patients who underwent primary rotator cuff repair. Patient satisfaction was high, especially with regard to pain reduction. Several authors showed that the rotator cuff degenerates with ageing and increasing percentages of recurrent rotator cuff lesions may therefore be expected in patients that are studied with longer term follow up. (39) However, the results of our study are in line with the study of Kluger and colleagues who found CMS of 86 points and re-rupture rate of 33% after 7 years and supports that rotator cuff repair yields favorable and sustainable results with regard to both function and integrity of the rotator cuff repair, even on long term. The favorable results of our study may be subject to selection bias, as 29% percent of patients were lost to follow up. Half of these patients could not be contacted and 4 percent could not participate due to medical reasons not related to the shoulder. On the other hand, issues with regard to lost to follow up may be expected in studies with long term follow up as was also encountered by Bell and colleagues who reported 36% lost to follow up 15 year after open repair of degenerative rotator cuff lesions. (40)

Clinical implications

- Patients may be informed that results of surgical treatment of degenerative rotator cuff lesions in terms of pain relief and improvement of function are durable.

- To evaluate patient's benefit of surgical repair of degenerative rotator cuff lesions and LHB surgery, a group of patients undergoing non-surgical treatment should be included as a study group in future randomized studies.

FUTURE RESEARCH

The different clinical implications presented in this thesis will contribute to the ongoing debate on how to treat patients with LHB pathology and degenerative rotator cuff lesions. Although pathology of LHB and rotator cuff has been known for more than a century, and countless papers have been published on this topic, important questions remain to be answered. For example, what is the pathogenesis and prognosis of LHB pathology? What is causing the pain in case of degenerative changes in LHB and rotator cuff?
Although many studies have been performed to elucidate the role of both LHB surgery and rotator cuff surgery some major concerns still exist. As most studies were performed with heterogeneous group of patients it remains difficult to determine the exact role of LHB surgery. Given the fact that isolated LHB pathology is relatively seldom and may present with resembling symptoms as rotator cuff pathology, it will be challenging to determine the exact of LHB pathology in the spectrum of diagnosis and treatment. Furthermore, at present it can not be determined whether surgical treatment is the actual factor of improvement in pain and shoulder function. Natural course may be less worrisome than we may consider at the present time. Trials comparing non-operative treatment with operative treatment of LHB pathology could help to determine which type of treatment is to be favored. Comparing non-operative treatment with surgical treatment inherently involves information bias of patients and doctors. Therefore a placebo trial may be considered, comparing operative treatment with sham surgery.
To further elucidate the implications of a Popeye sign with regard to its presence and patient satisfaction, it would be worthwhile to reach consensus with regard to its assessment. Currently there is no reference standard how to assess a Popeye phenomenon and Popeye signs have been reported in distal biceps ruptures as well. Next to reporting its presence it has been suggested to grade the deformity from less to severe. Agreement between doctors may be further investigated during outpatient follow up visits by using multiple assessors evaluating the operated arm for the presence of Popeye sign. Repeating this test and calculating kappa values and relating this to results of MRI or ultrasound could help to investigate accuracy and reliability.

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