

The Efficacy in Shoulder Range of Motion of a Snapping Manual Maneuver Added to a Standardized Exercise Protocol in Axillary Web Syndrome: a Randomized Controlled Trial

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Abstract

BACKGROUND

Axillary Web Syndrome (AWS) is one of the most frequent conditions after surgical axillary lymph node dissection (ALND). The key symptom is the functional disability of the limb, which requires rehabilitation. Notwithstanding, a standardized rehabilitation protocol is currently lacking in clinical practice. Our primary objective therefore, was to evaluate the effectiveness of the use of a snapping manual maneuver (used in our clinical practice) in enhance range of motion (ROM) when compared with a standardized stretching exercise protocol. A three-year follow-up of the enrolled patients was also carried out to determine the incidence of Breast Cancer-Related Lymphedema (BCRL).

MATERIAL AND METHODS

Between July 2013 and January 2019 we conducted a single blinded randomized clinical trial. ALND patients with subsequent appearance of clinical symptoms of AWS were randomly assigned into two groups who underwent one treatment session per week for two weeks with a one month follow-up.

RESULTS

There were no statically significant differences in ROM at our one month follow-up and the incidence of BCRL was equally distributed after three years.

CONCLUSION

the addition of the manual snapping maneuver in a rehabilitation protocol was not better than a stretching exercise and does not appear to be a risk factor for lymphedema.

Trial Registration : NCTR 03284008 Retrospectively registered: September 15, 2017; Last Update Posted: July 17, 2019

Introduction

Axillary Web Syndrome (AWS) is one of the most frequent conditions to arise after surgical treatment for breast cancer, with a reported incidence ranging from 6–75% [1, 2]. This syndrome can affect shoulder mobility, thereby causing functional disability of the limb and may be defined as a thrombophlebitis of veno-lymphatic vessels caused by surgical trauma. In this context, lymph node removal procedures, such as sentinel lymph nodes biopsy (SLNB) and axillary lymph node dissection (ALND), are the most frequently reported causes for the onset of this syndrome [1, 3].

Notably, the clinical features of AWS partially overlap with those of Mondor's disease, which is reported in post-traumatic and surgical areas characterized by a large presence of veno-lymphatic capillaries (such as the inguinal region) [4, 5]. AWS symptoms typically manifest within the first month after surgery, and its complete resolution occurs in 3–24 months [1, 6]. The symptoms are frequently described as a sensation of pain and tension in the axillary region, at the elbow, forearm and wrist, following the lymphatic path [7]. Consequently, patients report a limited mobility of the arm and a reduction of their ability to perform activities that require a moderate amplitude of movement, often associated with the presence of a tendon-like cord [8, 9].

It is widely accepted among physiotherapists that AWS requires rehabilitation assistance to prevent possible further complications, such as frozen shoulder or impingement syndrome, which could lead to a reduction of the quality of life of patients as well as to a significant increase in time and cost of treatment [8, 10]. Notwithstanding, a standardized rehabilitation protocol is currently missing in clinical practice [11–20].

In our clinical experience, the use of a snapping manual maneuver aimed at breaking the cord is associated with immediate reduction of the symptoms of AWS in patients. Here we studied the effectiveness of this technique in enhancing range of motion (ROM) when compared with a standardized stretching exercise protocol as our primary end-point. We additionally assessed the treatment effect in reducing pain and disability and carried out a three-year follow-up of the enrolled patients in order to determine the incidence of breast cancer-related lymphedema (BCRL), a chronic disease which, if not properly treated, can lead to a dramatic reduction of the quality of life of patients.

Material And Methods

This single-blinded randomized experimental clinical trial was carried out between July 2013 and January 2019 at the European Institute of Oncology (IEO).

Inclusion criteria comprised axillary lymph nodes dissection for breast cancer with subsequent appearance of clinical symptoms of AWS, which was both self-diagnosed using the ST-AWS questionnaire and assessed by physical examination [21, 22] Exclusion criteria applied during the enrollment phase were: missing written informed consent, concomitant physical and psychological disorders having the potential to interfere with rehabilitation, previous axillary dissection or neck lymph node dissection, previous breast reconstruction with flaps or with an expander, and diagnosis of primary lymphedema with ongoing AWS treatment.

The enrolled patients were randomly assigned to two treatment groups. Patients of both groups underwent one treatment session per week for two weeks. At the end of the session, they were asked to continue the exercises autonomously on a daily basis, three times per day, for one month. A first follow-up examination was scheduled one month after the first session. A second re-evaluation was performed three years later.

Group of standardized stretching exercise (SSE)

Patients in this group followed a standardized stretching exercises protocol for the upper limb with the assistance of the therapist.[23]

Group of snapping manual maneuver (SMM)

Patients in this group were administered a manual therapy technique in addition to the standardized stretching exercises protocol already described for group one. The manual therapy technique consisted of a snapping maneuver of fibrotic adhesion. This technique is performed with the patient in the supine position with both legs extended; the patient is then asked to reach the maximum point of flexion she can achieve with the injured arm, so that the therapist can place his or her fingers at the extremity of the AWS cord while trying to apply a light pressure combined with a longitudinal traction. If the cord does not snap and break after the first try, the therapist repeats the maneuver for a maximum of six times in the shoulder flexion position, and six additional times in the abduction position.

Assessments

All treatments were performed by one therapist (SF). Measurements and data were collected by a second therapist who was not aware of the group to which the patient belonged (NTLF). ROM and pain with the numeric rating scale (NRS-11) was assessed before and after the treatments and during the first follow-up examination. The presence or absence of lymphedema was evaluated with the difference of circumferential measurement of the upper limbs and with the ratio of the Constant Dielectric Technique (TDC) in both arms by a third physiotherapist (GM).

Shoulder ROM

Flexion, extension, abduction, and medial and lateral rotation of the shoulder were evaluated by using a universal full-circle digital goniometer. No passive support was given to the arm [24].

NRS-11 scale

In this numerical unidimensional scale, patients were asked to describe the intensity of the pain by means of a number ranging from 0 to 10, with 0 corresponding to no pain and 10 to the maximum tolerable pain [25].

Lymphedema evaluation

Circumferential measurement was performed with the patient in the supine position with both arms relaxed and extended. The therapist measured the patient's arm every four centimeters starting from the ulnar styloid using a tape measure. The presence of lymphedema presence was confirmed if the difference between the two arms in at least one point was equal to or greater than two centimeters [26].

In addition to circumferential measurements, the therapist used a Moistmeter-D ® to evaluate the percentage of water under the skin. Five measurement points per arm were chosen: the anatomical snuffbox, two points on the medial part of forearm at 8 and 16 centimeters from the ulnar styloid, and two points on the medial part of the arm at 8 and 16cm from the medial epicondyle. Lymphedema presence was confirmed if the ratio difference between the two arms in at least one point was higher than 20% [27–29].

Randomization

Randomization was performed through the "web-based" TENALEA system (<https://it.tenalea.net/ieo/aleastudydef/>). We thus recorded: type of randomization; details of any restriction (such as blocking and block size); mechanisms used to implement the random allocation sequence (such as sequentially numbered containers). We described any steps taken to conceal the sequence until interventions were assigned.

Statistical Analysis

The statistical analysis was performed on an intention-to-treat basis. The statistician was given coded data and thus was blinded to the treatment groups. Categorical variables were reported as frequencies (percentages), whereas continuous variables were summarized with mean, median, and interquartile range (25th-75th percentiles). Differences between arms of categorical variables were evaluated with Chi-squared tests whereas Wilcoxon rank test was employed for continuous variables.

The trend over time of changes from baseline of continuous variables was investigated considering the random effects model for repeated measures. In order to take into account correlation within patients, we applied the repeated measurement analysis. Time effect was included in the model as fixed factor. Residuals from full models were checked to assess normal distribution.

The main endpoint is the change in abduction from baseline and first month after start of intervention. The sample size calculation was obtained to test the hypothesis that the SMM intervention can improve abduction compared to the ESS group. The expected difference in improvement in abduction between study arms ranged from 50 degrees, on average, to 70 degrees, with an estimated standard deviation of around 25 degrees. A sample size of 28 patients per arm reaching 80% of power, to test this hypothesis, considering a Student-T test and alfa equal to 0.05. The statistical analyses were performed using SAS software (SAS Institute Inc., Cary, NC; version 9.2).

Results

A total of 60 patients were enrolled between June 2013 and December 2015. The enrolled patients were subdivided into two groups, comparable in terms of demographic composition and clinical features (Table 1).

Table 1
General data

		Total	SMM	SSE
		60 (100)	30 (50.00)	30 (50.00)
Age, Median (Q1, Q3)		51 (44, 61)	57 (43, 63)	48 (44, 54)
BMI, Median (Q1, Q3)		23 (20.8, 26.3)	23.4 (20.8, 25.9)	22 (20.8, 26.4)
Smoking	Never	31 (51.67)	13 (43)	18 (60)
	Current	10 (16.67)	9 (30)	1 (3)
	Former	19 (31.67)	8 (27)	11 (37)
Education	Elementary	3 (5.08)	3 (10)	0 (0)
	Master's degree	21 (35.59)	8 (28)	13 (43)
	Middle school	6 (10.17)	4 (14)	2 (7)
	High school	29 (49.15)	14 (48)	15 (50)
Duration of surgery, Median (Q1, Q3)		124 (112, 155)	129 (111, 146)	123 (114, 185)
Surgery Side	Left	36 (60)	19 (63)	17 (57)
	Right	24 (40)	11 (37)	13 (43)
N. of Lymph-nodes removed, Median (Q1, Q3)		25 (19.5, 29.5)	23 (20, 33)	25 (19, 29)
TNM	Late Staging (I-IIA)	39 (65)	22 (73)	17 (57)
	Initial Staging (IIB-IIIC)	21 (35)	8 (27)	13 (43)
Breast Surgery Type	Mastectomy	20 (3.33)	8 (27)	12 (40)
	QUAD	40 (66.67)	22 (73)	18 (60)
Breast Reconstruction	Yes	18	7	11
	No	42	23	19
IORT*	Yes	5 (8.33)	2 (7)	3 (10)
	No	55 (91.67)	28 (93)	27 (90)
Chemotherapy	Yes	29 (74)	16 (89)	13 (62)
	No	10 (26)	2 (11)	8 (38)
Radiotherapy	Yes	27 (69)	13 (72)	14 (67)
	No	12 (31)	5 (28)	7 (33)
Hormone Therapy	Yes	36 (92)	16 (89)	20 (95)
	No	3 (8)	2 (11)	1 (5)
* Intraoperative radiation therapy				

Among the initial population of the study, unfortunately, nine patients of group one were lost at the three-year follow up. Conversely, as far as group two is concerned, six patients were lost to follow up after one month, and six additional patients were lost at the three-year follow up (Fig. 1).

Regarding our primary and secondary objective (ROM in abduction and pain), there were no significant differences between the groups in all time points assessed over time ($p = 0,82$) (Table 2) ($p = 0,67$) (Table 3). After the first treatment, patients who underwent the MMS manoeuvre showed a clinical improvement when compared with patients in the ESS group but without any statistical significance ($p = 0.21$) (Fig. 2, Table 4).

Table 2
Range of motion

	T0		T1		T2		T3		T4						
	Mean (sd)	Inter quartile range													
	25 th75 th		25 th75 th		25 th75 th		25 th75 th		25 th75 th						
Flexion (deg)															
SMM	138,5 (22,91)	126 156,75	153,8 (15,10)	148 165	151,3 (14,86)	142 162,75	161,9 (11,11)	154,25 170	164,6 (10,88)	157,75 173					
ESS	142 (26,6)	121,3 167,5	155,9 (20,5)	141,5 174,8	152 (20,7)	131,3 170	162,2 (15,8)	151 174	165 (12,5)	155,8 174					
Abduction (deg)															
SMM	117,9 (38,32)	92,25 144,5	150,6 (33,8)	134 180	141,7 (31,93)	114,75 176,75	161,4 (24,26)	147,75 180	169,6 (20,78)	169,75 180					
SSE	130,5 (37,28)	102 176	151,9 (33,01)	119,75 180	143,8 (34,72)	108,5 179,5	160 (26,29)	137 180	168,9 (20,35)	170 180					
Internal Rotation (deg)															
SMM	82,2 (6,48)	79,5 86,75	84 (6,61)	84 87	82,8 (8,41)	82,25 87	83,6 (6,7)	83 87	84,8 (4,01)	84,75 87					
SSE	80,1 (7,46)	77 85	83,3 (6,07)	82 86	83,9 (3,74)	82,25 87	84,6 (3,42)	83 87	84 (5,54)	83 87					
External Rotation (deg)															
SMM	72,9 (16,01)	60 85,75	78,8 (12,40)	73 87	75,2 (15,7)	71 86	80,4 (10,65)	79,25 86	80,3 (10,36)	76,75 87					
SSE	77,5 (9,88)	70 85,75	82,7 (6,34)	80 87,75	80,4 (10,86)	72 87,75	83,4 (7,07)	77,75 88	83,5 (6,67)	82,25 87,7					
T0- Baseline: First evaluation, T1: Evaluation after first treatment, T2: Evaluation before second treatment, T3: Evaluation after second treatment, T4: Evaluation follow up.															

Table 3
Pain

	T0	T1	T2	T3	T4	P-Value
Baseline						
Pain						
SMM	7.9	5.7	6.1	3.9	2.1	0.6778
ESS	7.3	5.3	6.2	3.9	2.1	
T0- Baseline: First evaluation, T1: Evaluation after first treatment, T2: Evaluation before second treatment,						
T3: Evaluation after second treatment, T4: Evaluation 1 month follow up.						
P-value for time from random effect models						

Table 4
Change Between T0 and T1

		Mean (sd)	P- value
Flexion			
	SMM	15,1 (15,2)	0,82
	ESS	13,9 (13,9)	
Abduction			
	SMM	31,8 (28,2)	0,21
	SSE	21,5 (23,6)	
Internal Rotation			
	SMM	1,8 (6,3)	0,63
	SSE	3,2 (6,3)	
Extremal Rotation			
	SMM	5,4 (7,8)	0,62
	SSE	5,2 (5,8)	

At three years of follow up, 13% of patients presented with full-blown BCRL and 21% with subclinical BCRL. Notably, the BCRL was equally distributed in both groups without significant differences (Table 5).

Table 5
Follow-up

		Total	SMM	SSE	P-value
	n.	60 (100)	30 (50)	30 (50.0)	
AWS Resolution (1 month)	No	27 (50)	10 (42)	17 (57)	0.27
	Yes	27 (50)	14 (58)	13 (43)	
	Missing	6			
AWS Resolution (3 Years)	No	0	0	0	
	Yes	39 (100)	18 (100)	21 (100)	
	Missing	15			
Lymphedema diagnosed with circumference	No	34 (87)	15 (83)	19 (90)	0.51
	Yes	5 (13)	3 (17)	2 (10)	
Lymphedema diagnosed with TDC	No	26 (67)	13 (72)	13 (62)	0.73
	Yes	13 (33)	5 (28)	8 (38)	
Sub-clinic lymphedema (TDC positive with negative circumference value)	No	31 (79)	16 (89)	15 (71)	0.25
	Yes	8 (21)	2 (11)	6 (29)	
Confirmed lymphedema (Both TDC and circumference positive results)	No	34 (87)	15 (83)	19 (90)	0.51
	Yes	5 (13)	3 (17)	2 (10)	
P-value from Chi-square test					

Discussion

Since the first description by Moskowitz and colleagues[1], numerous studies have been conducted to define the time of onset, the most appropriate diagnostic methods, and the pathophysiology of AWS.

Although many studies have contributed to underlining the importance of starting physiotherapy as early as possible once AWS has been diagnosed, there is still no unanimous consent regarding the most effective treatment, nor are there other studies that assess the efficacy of a rehabilitation protocol [6–8, 11–20]. Our study aim was to test the superiority of a manual treatment protocol compared with the established and standardized stretching exercises used for treatment of AWS.

As extensively described by many authors, one of the main symptoms of AWS is the reduction of shoulder ROM, especially during abduction [1, 8, 9]. Accordingly, patients enrolled in this study also presented with a reduction of shoulder ROM, as confirmed by the values measured at the beginning of the treatment (Table 2). After the treatment, SMM patients displayed a slightly higher abduction gain in comparison to ESS patients, with an average gain of 32.7° and 21.5° respectively. This therefore suggested that the additional manoeuvre might be associated with a higher efficiency; but these improvements were not statically significant. However, ROM values measured one month after the first treatment appeared to be very similar between the two groups, pointing to the possibility that the two management protocols might have the same efficiency over a longer time period. A reduction of ROM values was subsequently reported in both groups between the first and the second treatment sessions (8.9° for SMM group one and 8.1° for the ESS group). The possibility that the treatment undertaken at home was insufficient or not performed correctly, as well as the influence of still-ongoing AWS pathophysiological processes, might account for the reduced mobility observed in the patients between the two sessions. However, after the second session, all patients displayed a complete recovery of the shoulder ROM at the one-month follow-up.

Pain during shoulder movement appears to be another symptom caused by AWS [1, 30]. Indeed, pain reduction is intimately linked to the resolution of the syndrome. The SMM treatment did not lead to increased pain over the long term, despite being perceived as painful when performed (Table 3). Reduction of pain occurred in both groups with similar trends, allowing greater mobility to the affected upper limb (Table 2, Fig. 2). Importantly, after one month, a periodic follow-up aimed at assessing the AWS resolution in both groups was not performed in this study, but the three year follow-up did confirm that all patients had a complete regression of the syndrome.

Patients were subsequently re-examined three years after initial enrolment in order to evaluate the incidence of lymphedema in both groups, although previous studies had already ruled out that AWS and its management could be a risk factor for lymphedema [31]. Accordingly, the results obtained in our cohort appear to be in line with that published in the literature [17] and show an incidence of lymphedema in 13% of the patients (Table 4), with no clinically and statistically significant differences between the two treatment groups. We therefore concluded that the additional SMM treatment does not represent a risk factor for lymphedema. Notably, the incidence of lymphedema increases to 33% when taking into account the data obtained with the TDC method, a method that allows detection of subclinical lymphedema in the absence of clinical manifestations and could be an additional assessment tool in the surveillance of BCRL overtime.

As our study is the first randomized clinical trial to assess the efficacy of protocol in this syndrome, certain weaknesses were present. Unfortunately, our research suffered somewhat from loss of patients to the follow-up examinations. A total of 6 patients of the SSE group could not be evaluated at the one month follow-up, but the more substantial loss occurred at our three year follow-up in which a total of 19 patients were lost. As this last follow-up was necessary to assess the incidence of lymphedema, the patients needed to be evaluated in our hospital and as some of them lived outside the region in which our hospital is located (Lombardy), we were unable to perform this second end point evaluation in these patients. Nevertheless our data is consistent with the published literature regarding the incidence of lymphedema after AWS treatment.

Another weakness arises from the lack of verification that the exercises were correctly (indeed, if at all) performed at home by the patients. As there is no valid instrument to assess compliance with our protocol, the data presented here were collected in good faith, under the assumption that all the patients complied correctly with the proposed program. Nevertheless, our research and the results bear relevance, especially in terms of assisting other institutions and physiotherapists how to address treatment options in these populations. Moreover, our study could represent an initial step to incentivize others to replicate our protocol or to study the effects in other ALND populations such as those who undergo surgery for sarcoma or melanoma, or patients with AWS after SLNB.

In conclusion, the addition of the manual snapping manoeuvre to a rehabilitation protocol may bring about an immediate improvement of shoulder mobility. However, it was not found to be better than a stretching exercise protocol overall. Whether or not to employ this technique to speed up recovery will be for the therapist to decide, safe in the knowledge that this manoeuvre does not appear to be a risk factor for lymphedema. Further studies are still warranted to compare the effectiveness of our protocol with other treatment methods.

Declarations

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Author contribution

FS, LFNT, MCS and AL contributed to the study conception and design. Data collection were performed by LFNT, MG. Data analysis and interpretation were performed by SG. All the authors made the critical revision of the article and gave the final approval of the version to be published.

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Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the the European Institute of Oncology Ethics Committee approved this study (IE0712/412).

Consent To Participate

All participants gave written informed consent before data collection began

Consent For Publication

Written informed consent was obtained from all participants included in the study

Competing interests

The authors report no conflict of interest.

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Figures

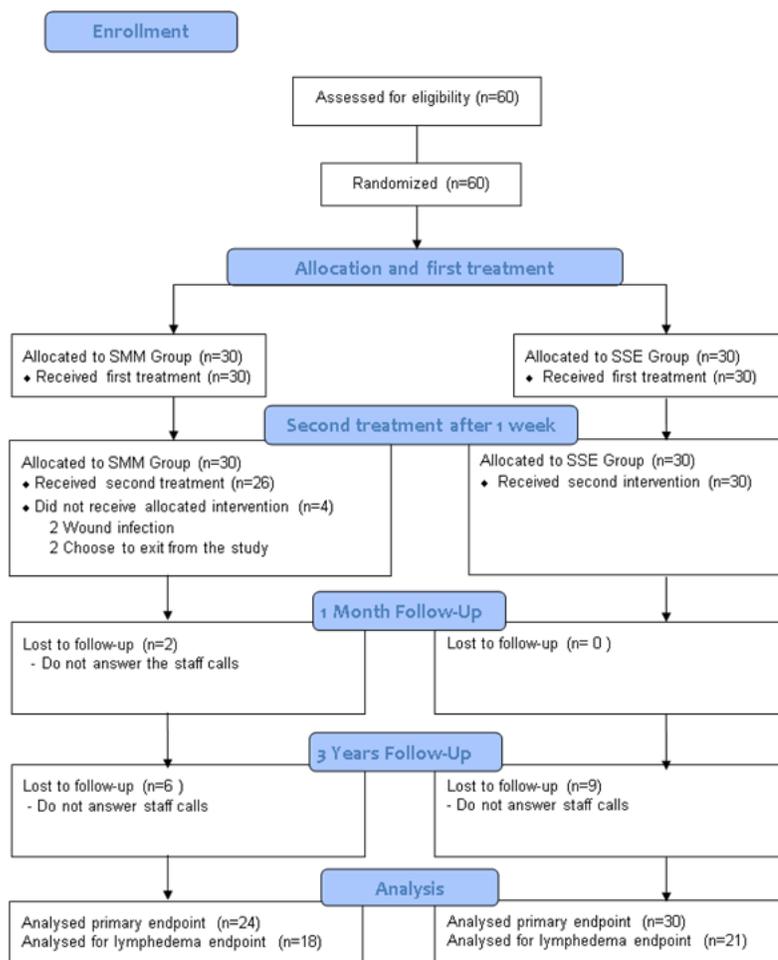


Figure 1

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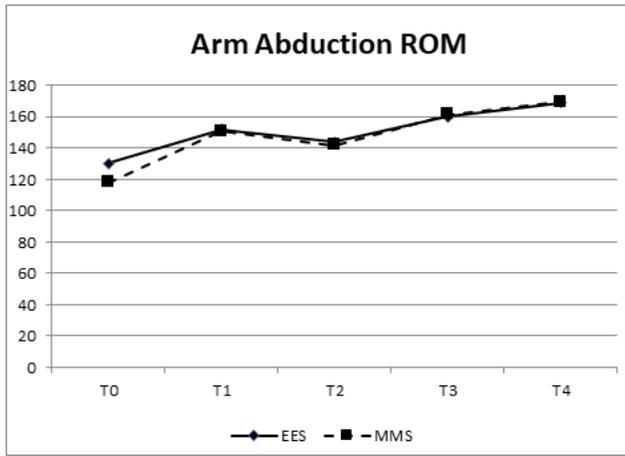


Figure 2

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