Physiotherapy Protocol to Reduce the Evolution Time of Axillary Web Syndrome in Women Post-Breast Cancer Surgery: A Randomized Clinical Trial.

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Abstract

Objective: To reduce the evolution time of axillary web syndrome in women who have undergone breast cancer surgery.

Methods: A prospective, randomized, single-blind clinical trial was conducted on 46 post breast cancer surgery patients from October 2021 to September 2024, in a single university hospital with painful Axillary Web Syndrome that restricts arm mobility. The intervention consisted of stretching combined with manual therapy and scar massage to release adhesion and lymphatic cord during 15 physiotherapy sessions of 30 minutes duration each. The main outcome measures were: pain, evaluated with VAS and arm ROM, evaluated with goniometry.

Results: Significant differences were detected in pain and in range of motion. The effect of the intervention varied over time with 95% confidence interval (risk alpha 0.05) and a statistical power of 90% (risk beta 0.1). Comparisons between Control and Intervention Groups showed significant statistical and clinical differences in favour of Intervention Group after 30, 60 and 90 days of intervention at follow-ups for all measured parameters.

Conclusion: The results suggested that stretching combined with scar massage and manipulative tissue release techniques reduce the evolution time of axillary web syndrome. The physiotherapy technique described in this article could be the technique of choice for this surgical sequela.

*Trial Registration:*ClinicalTrials.gov Registry (NTC05115799) and the approval of the Andalucía Ethics Committee (PEIBA code 1909-N1-21, reg. number 171.21).

INTRODUCTION

Breast cancer is the most frequently diagnosed cancer in women worldwide with more than 2 million new cases in 2020 (1).

Axillary Web Syndrome (AWS) was described as a visible and palpable network of cords in the skin of the axillary cavity, tensed by shoulder abduction following surgery for breast cancer, significantly, limiting the function of the ipsilateral upper limb (UL) and causing pain (2–4). It is also known as “cording”, "axillary string”, “vascular string”, “lymphatic cord”, “fibrous banding,” or “Mondor’s disease” (2, 5).

The frequency of AWS is highly variable. Yeung's systematic review reports ranges from 0.6–85.4% after surgical intervention for breast cancer (6). AWS is an early complication of axillary surgery for breast cancer, which is more common than infection, seroma, or lymphedema (7).

AWS causes pain, reduces shoulder mobility and functionality, and involves a decrease in quality of life (3, 8). These may affect radiotherapy treatment, leading to delays or even loss of treatment (7, 9, 10). If sustained over time, it can lead to shoulder rotator cuff disease, adhesive capsulitis, and myofascial pain syndrome(11).

Axillary cords are always present in the axilla and may extend down into the medial ipsilateral arm. These cords frequently extend across the antecubital fossa and into the forearm. They occasionally may extend to the radial aspect of the wrist and into the base of the thumb (10).

AWS usually appears between weeks 8–12 after surgery. It usually resolves by itself within 3–4 months after surgery, but there is evidence of multiple cases persisting up to 24 months (12, 13). There are also cases of late recurrence after disappearance (7).

Diagnosis of AWS is based on palpation, visual inspection and reported symptoms. Sometimes it is not easy to palpate or see due to a large amount of adipose tissue (6). Baggi et al. suggested an accurate diagnostic method to improve the diagnosis of AWS (11). Nuclear magnetic resonance and ultrasound, as well as other methods that may be valid for diagnosis, can be considered (4). Some studies have used ultrasound to assess the thickness of AWS and its disorganization (14). Nevertheless, lymphoscintigraphy is currently considered the best method for lymphatic accurate diagnosis (5).

There is currently no treatment of choice for AWS. Physical therapy helps to improve symptoms and outcome, but there is no specific treatment (15). There is a wide heterogeneity of treatments within physiotherapy (3). Some studies use stretching together with snapping manual maneuver as a treatment strategy (13), other studies use strength and endurance exercises (16), while other studies use myofascial release (4, 14). Also, other publications describe exercises combined with manual lymphatic drainage (7, 8, 15). Systematic reviews and narrative reviews conclude that there is a need for more quality randomized clinical trials to define a treatment of choice for AWS (2, 13, 17).

In addition, physical therapy applied from the early postoperative period could prevent surgical sequelae. So far, no complications have been described (14, 18, 19).

The main objective is to reduce the evolution time of AWS in women who have undergone breast cancer surgery.

METODOLOGY

Study design and ethical considerations

This is a two-arm randomized clinical trial. This research uses the guidelines on Standards for Quality Improvement and Excellence in Reporting and Consolidated Standards of Reporting Trials (CONSORT) (20). Recommendations for Interventional Trials checklist is provided in the Fig. 1. The research procedure was approved by the Andalusian Ethics Committee on Human Research (PEIBA code 1909-N1-21, registration number 171.21) and with Clinical Trial Registration number: ClinicalTrials.gov Registry (NTC05115799).

Participants and settings

Inclusion Criteria were as follow: Women over 18 years of age, who underwent breast cancer surgery and AWS appeared within one year after such surgery. Patients who stated that AWS is palpable, caused pain greater than 6 VAS scale and limits ROM (at least with a limitation that does not allow them to raise over 120º of shoulder flexion or 120º of shoulder abduction). All users were patients within Campo de Gibraltar West Health Management Area. Exclusion criteria were as follow: (patients with one or more of the following criteria) Patients with psychological or neurological disorders, with active metastases without chemotherapy treatment, rheumatological or osteoarticular problems limiting joint mobility. Removal criteria were as follow: A mild adverse event; a serious, unexpected or clinically relevant adverse event or not achieving the suggested exercises at least six days a week.

Sample size

To determine the sample size for comparing two means, we aimed to detect a clinically meaningful difference in healing time for AWS, measured in days, between intervention and control groups. Both current literature and expert input agreed that a difference of at least 15 days would be clinically relevant. Given that healing time is a quantitative variable, we chose a comparison of means between the two groups as the basis for the sample size calculation.

For this study, we set a confidence level of 95% (alpha = 0.05) and a statistical power of 90% (beta = 0.1), while accounting for an anticipated loss to follow-up of 20%. Based on a standard deviation of 14 days in healing time for standard treatments, we used the pwr package in R to calculate the necessary sample size. To detect a difference of 15 days or more between groups with the specified confidence and power, 18 subjects per group were required. Adjusting for the potential 20% follow-up loss, the total sample size needed was determined to be 46 participants.

Randomization allocation: Before commencing the study, Excel program ‘randomization’ tool was used to provide an allocation sequence list for patients from 1 to 46. The position on the list would be assigned on the arrival order. As patients arrived at the clinic for the first evaluation, they were informed about the study. If they agreed to participate, and after giving written consent, their physiotherapist would enroll the patient to either control or intervention group, according to the previously mentioned Excel list.

Masking: Blinding could not be performed due to the nature of the intervention. Physiotherapy studies often face challenges in masking both the intervention and the therapist.

Interventions:

- **Control group**: Users are trained by the physiotherapist in the first consultation on Codman's pendulum exercises and on self-assisted stretching in seated and standing positions. The stretches are explained to the patient by the specialist physiotherapist and initially performed together to correct possible errors. Advice is given on possible postural compensations. The importance of performing these exercises daily

is explained. At least 15 repetitions of each exercise holding the stretch for 15–20 seconds. The exercises are described in Appendix 1.

After diagnosis, patients attend group therapy twice where exercises are repeated and corrected. The groups are limited to less than 6 people to ensure quality care. In addition, an informative talk about lymphoedema and AWS is delivered, in which preventive measures (usual care) are specified. Follow up is carried out monthly for the next 3 months. At each review, adherence to the program is assessed, confirming that the user performs the exercises at least 6 days a week.

-Intervention group: Users receive the same training as control group patients, but intervention group patients receive 15 physiotherapy sessions within three weeks, that is 5 sessions per week. Each session lasts 30 minutes. During the sessions, the patient is placed on the couch in the supine position. The physiotherapist applies stretches to the affected arm, considering patient's tolerance, the pain never beyond level 6 in the VAS. Initial warm-up is performed with self-assisted mobility of the upper limb and bringing the arm to the maximum flexion or abduction that the patient can tolerate without the appearance of elevated pain. The elbow is usually in almost full extension (if the cord allows such a position), supination, wrist extension and thumb opposition. For no more than 30 seconds in this position, the physiotherapist palpates the cord and works through it, with friction similar to the scar massage maneuver at the level of the axillary or mammary scar, where the AWS usually originates. This manipulative technique of friction is also applied to the cord in the area which the patient describes as discomforting. The friction is carried out perpendicular and longitudinally to the cord. The maneuver should be gentle to avoid the appearance of skin erythema (Appendix 2).

Outcomes

Firstly, the user's administrative data is collected: such as age, marital status, employment status, or educational level. Also, whether she has ever become a mother and if so, when. Regarding lifestyle, whether she practices sport and how often. whether she lives in an urban or rural area. It is also considered whether she smokes or not. Regarding medical records, body mass index (BMI), type of tumor, when the axillary web syndrome appeared, number of lymph nodes removed, whether her surgery was radical or conservative, whether she has received radiotherapy, and finally whether the patient received breast reconstruction or not.

Axillary cord syndrome: The presence of lymphatic cord was assessed by observation and palpation by the assessor. Physical exam performed as suggested in previous research: Patient laying in supine position with elbow extended and the shoulder in maximum abduction. The assessor observes and palpates the beads, including the armpit, down the upper arm from the armpit to the antecubital space and through the forearm to the base of the thumb (6).

Range of motion (ROM): For the assessment of the mobility goniometry has been used. Goniometer is the standard instrument for measuring the range of movement. The patients were asked to move their arms in flexion, extension, abduction and external and internal rotation of the shoulder. It was considered

that the maximum range of motion for the flexion and abduction was 180º, for extension it was 45º, 100º for internal rotation and 80º for external rotation. Finally, a single index was calculated as the percentage of global movement (21).

Visual Analog Pain Scale (VAS): According to the National Cancer Institute (NIH), it is a tool used to help the professional assess the intensity of certain sensations and feelings, such as pain. The Visual Analog Scale for pain is composed of a straight line on which an extreme means no pain and the other extreme means the worst pain imaginable. Extreme pain corresponds to 10 points. No pain corresponds to 0 points.

The patient marks a point on the line that matches the amount of pain they feel. Also known as VAS (22).

Statistical analysis

Descriptive statistics were computed as means and standard deviations for continuous variables, and medians with interquartile ranges for non-normally distributed data. Proportions and 95% confidence intervals were calculated for categorical variables. Cohort homogeneity at baseline was assessed by comparing all measured variables between patient groups using nonparametric Wilcoxon tests. P-values were adjusted using the FDR method to control for type I error (Table 1).

To evaluate the effect of physiotherapeutic treatment on the pain and range of movement of breast cancer surgery patients, mixed-effects regression models were employed. These models accounted for both fixed effects (e.g., intervention group, time, and covariates such as age, BMI, and tumor stage) and random effects (individual variability). This approach controlled for baseline differences and allowed for a more accurate estimation of treatment effects. Models were adjusted for several outcome measures, including the visual analog scale (VAS), and interactions between the intervention group and time were included. Model fitting followed Zuur & Ieno's protocol (23),with random effects for patient identity and fixed effects selected via backwards elimination. Model comparison was conducted using corrected Akaike Information Criterion (AICc), and the significance of categorical factors was assessed via ANOVA, with post-hoc comparisons using the emmeans package. Assumptions were verified through residual analysis and Shapiro-Wilk (normality) and Levene (homoscedasticity) tests.

Changes in goniometry were analyzed with two-way ANOVAs, assessing group (control/intervention) and time as fixed factors, including their interaction.

All analyses were performed using R v.4.4.2 (24). Statistical significance was set at $\alpha = 0.05$.

Assessment procedure (Adherence monitoring):

If during regular post-surgery checkups AWS was diagnosed, the patient was recruited for the study after signing informed consent. Patients were requested to answer a clinical interview in person on day one, day thirty, sixty and on day ninety. Performance and adherence were assessed.

In person appointment was reminded via telephone a few days beforehand. In case the patient could not attend, a three-day window was considered.

On appointment day, the specialist physiotherapist showed the patient how to perform the exercises and checked that the patient was able to perform them correctly.

Patients were required to perform those exercises at home at least six times per week. When a patient was unable to do so, she was excluded from the study.

A paper booklet and a YouTube video were provided to help them perform exercises accordingly. When needed, telephone and walk-in advice was offered.

RESULTS

Recruitment and characteristics of participants

Patients attending the Lymphoedema Unit with clinical manifestations of AWS (pain of more than 6 points on the VAS scale and reduced shoulder mobility of less than 120º of flexion and/or abduction). Enrollment began in October 2021 until September 2024. 46 patients participated, 24 in the intervention group and 22 in the control group.

The bio-demographic data of all participants at baseline showed homogeneity and non-significant differences between the two groups in terms of age, weight, height, body mass index, type of oncological treatment, type of surgical treatment, stage and type of cancer (Table 2).

Effectiveness of the intervention on the VAS outcome

There is a significant association between the total VAS score and the time of measurement of the test depending on the study group. On one hand, patients in the intervention group obtain a significant decrease in VAS score reaching pain levels very close to zero from the first month ($P < 0.001$), maintaining this improvement through the remaining visits (Fig. 2; Table 3). On the other hand, patients in the control group improve much gradually, never reaching the scores of the intervention group. In fact, in the control group, a significant improvement is only detected in the third month compared to the initial moment (Table 3).

Effectiveness of the intervention on the ROM outcome

In the case of the variables flexion ($p < 0.001$) (Fig. 3), abduction ($p < 0.001$) (Fig. 4), extension ($p < 0.001$), adduction ($p < 0.001$), external ($p < 0.001$) and internal rotation ($p < 0.001$) of the shoulder, the control patients gradually gained an increase in flexion over time, while the intervention patients reached a much greater increase from the first month and maintained this flexion through all visits. This is also

the case for the outcomes flexion ($p < 0.001$), supination ($p < 0.001$) and pronation ($p < 0.001$) of the elbow and for radial ($p < 0.001$) and ulnar deviation ($p < 0.01$) of the wrist (Table 4).

Complications during the treatment: Two of the patients in the intervention group developed a slight thickening around the forearm over the cord. This disappeared spontaneously after a few days.

Informed consent statement: An informed consent form was prepared, which had to be signed by all the subjects participating in the study who previously received sufficient information about the objectives and the procedure of the study. They were also informed of the possibility of revoking the consent given at any time without having to justify their decision without prejudice. All necessary permits were requested from the institutions for the development of the research.

DISCUSSION

The main finding of this study was that 22 out of the 24 patients in the intervention group did not suffer from AWS at the end of the treatment. The remaining 2 patients had no pain or limitation of mobility. All patients in the control group still suffered AWS on the 90th day of follow-up, with limited mobility and pain.

The correct performance of the exercises together with adherence are considered key factors in the reliability on this study results. Torres et al. (7) in their study also showed good and parallel adherence in both groups. Klein et al. (19) offered a paper booklet and phone call assessment one week and one month after the intervention. Cho et al. (15) focused on the support for the physical therapy and manual lymphatic drainage group during the first week. This posed a confusing factor in the perception of pain within such group. Their study neither detail the applied exercises nor the intervention group patients´ adherence. Moreover, the study by Cho et al. (15) considered unethical the presence of a control group, disregarding such group for the study. As a result, this study showed a big dropout rate, with a total loss of 29, out of the initial 70 patients within the intervention group.

As aforementioned, some studies had considerable patient drop-outs. The study by Meer et al. started with 36 patients in the intervention group and only 20 remained for the whole period (8), the study by Muñoz et al. where 31 patients in the intervention group initially started

only 20 finished (18) and the study by Ibrahim et al. where they initially had 59 patients and 33 patients finished at 18 months of follow-up (14). In contrast, other studies also followed up for more than one year without such a high percentage in drop-outs (16, 25).

Regarding the onset of postmastectomy lymphoedema, treatment of AWS does not appear to promote the development of such sequelae or other adverse effects (8, 13, 19). Some studies highlighted the benefits of starting physiotherapy early to reduce pain (19) and to improve mobility and strength (18). Some studies excluded patients with lymphoedema, and state that there is a need for further research to analyze the association between AWS and lymphoedema (7). The study by Klein et al. had no

conclusions regarding the relationship between AWS and lymphoedema, since surgery is currently usually conservative and without axillary emptying, in addition to the fact that postmastectomy lymphoedema usually develops 2 years after the operation. Therefore, studies should have longer follow-ups to draw conclusions in this regard. One study used moist heat as a treatment technique for AWS, but this may facilitate the development of lymphoedema, as it is known that thermal measures may provoke its development (4).

Many publications conclude that there is high heterogeneity of physiotherapy treatments. They indicate that more AWS related research is needed to have a physiotherapy treatment protocol of choice as there is currently none (2, 10, 17, 26). There are few randomized clinical trials and some of them had small sample sizes such as the study by Datar et al. with N = 10(4) or the study by Meer et al. with N = 36 (8). There is also no ideal timing within current treatment approaches(2) and AWS may possibly be under-diagnosed (10). All publications highlight the need for more research with better designs and larger sample sizes (18). Collaborative research in the multidisciplinary team with oncologists, surgeons, physiotherapists would be ideal (7, 26). Also, histological and pathophysiological studies of AWS are needed to better understand the mechanism of production and thus, facilitate a reference physiotherapy treatment (3). As some studies state, the lymphatic duct undergoing AWS could have future recanalizations or collateralizations and therefore disappear (26). This theory has been explored using lymphoscintigraphic imaging, although it was a retrospective study, its conclusions would be stronger if the study had been prospective (5). Current studies link AWS to lymphatic origin, excluding a venous process (3, 5, 9).

In our intervention group, within the 15 physiotherapy sessions, 21 of the 24 patients (87.5%) felt the unmooring effect. This effect can be described by the specialist physiotherapist as the sudden release of the AWS, comparing it to the release of the ropes when a vessel departs from the quay. An average of 3.62 clicks per patient, with 3 of the patients feeling more than 15 clicks. This effect was also cited in the study by Sandrin et al. and Josehans et al. and in the systematic review by Yeung et al. (6, 13, 27).

Strengths and Limitations:

- Our study registered good adherence to the scheduled activity in each group with almost no loss of recruited patients in either group. The physiotherapist ensured correct adherence to the exercises.
- Considering the good results in the intervention group in all outcomes from the first follow-up on day 30 after the first examination, this physiotherapy technique could become an effective and quick treatment for AWS.
- Our study was single center, so its external validity may be questioned. It would be highly advisable to perform this study as multi center to be able to reach a wider spectrum of target population.
- Blinding of the intervention could not be carried out due to the nature of the intervention. Physiotherapy studies often face this challenge as it is difficult for the patient to be unaware of the group they belong to.

*Future Directions

Ideally, future studies should include imaging tests, such as Indocyanine Green Lymphography (30) or Lymphoscintigraphic imaging (5), to better understand the process of making AWS disappear. Few studies use imaging techniques that visualize AWS, and out of the few that do, they seem to describe that the cord disappears and new recanalizations and collateralizations appear (5).

CONCLUSIONS

The results suggest that stretching combined with scar massage and manipulative tissue release techniques reduce the evolution time of axillary web syndrome. The physiotherapy technique described in this article could be the technique of choice for this surgical sequela.

Declarations

Conflict of interest: None declared.

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Ethical approval: Ethics approval was granted by the Andalusia Ethics Committee (PEIBA code 1909-N1-21, reg. number 171.21)

Trial registration number: ClinicalTrials.gov Registry (NTC05115799).

Protocol: The study protocol was approved by the Andalusia Ethics Committee.

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Author Contribution

All authors have made significant contributions to the article. JBGR, RMV and MJVG coordinated the project, contributed to the conception and design of this study, and composed this current article. RMV and MJVG were responsible for the methodological guidance. JBGR was responsible for developing the intervention and control protocols and patient acquisition. All authors have read and agreed to the published version of the manuscript.

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Tables

Tables 1 to 4 are available in the Supplementary Files section.

Figures

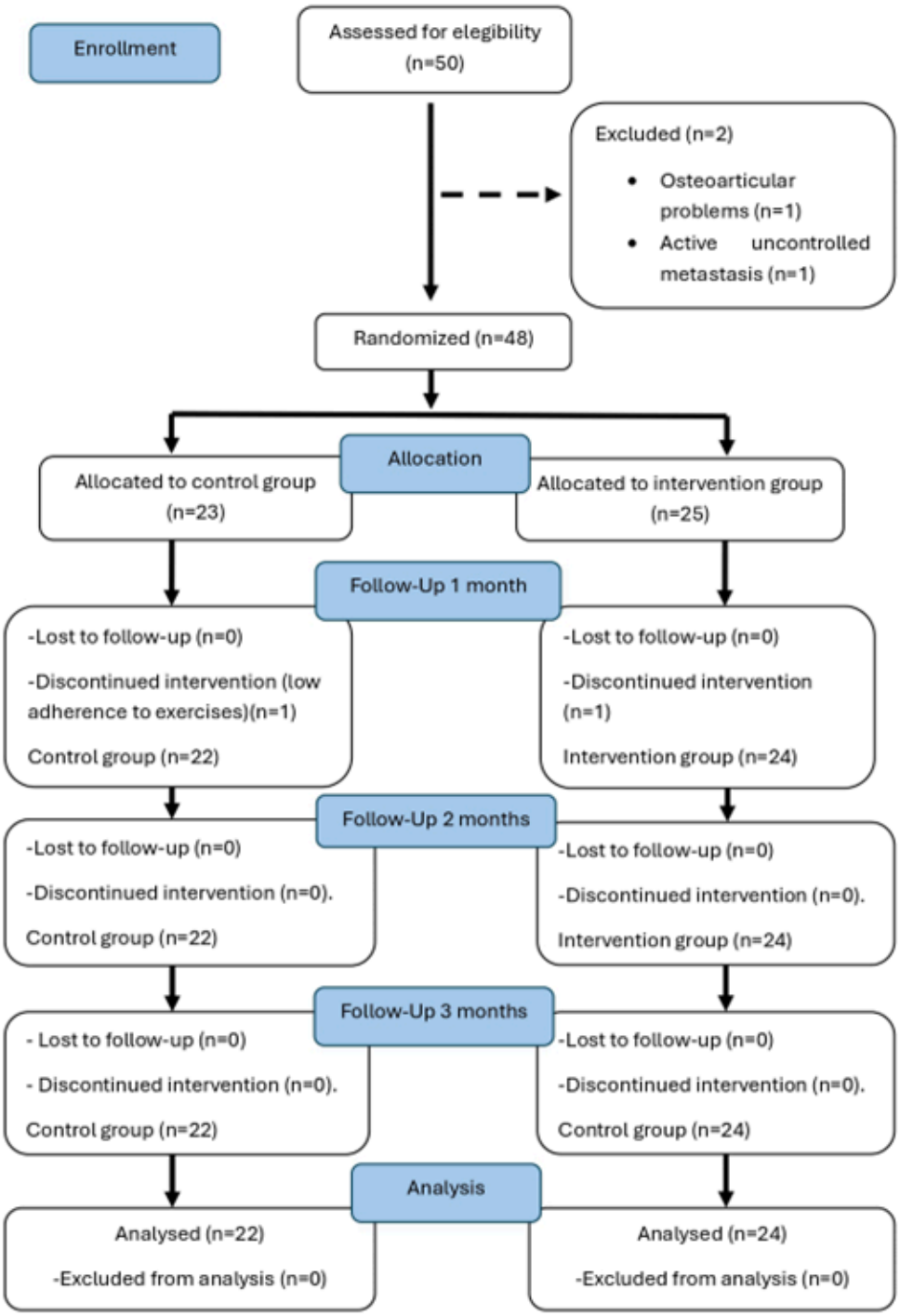

Figure 1

CONSORT flow chart.

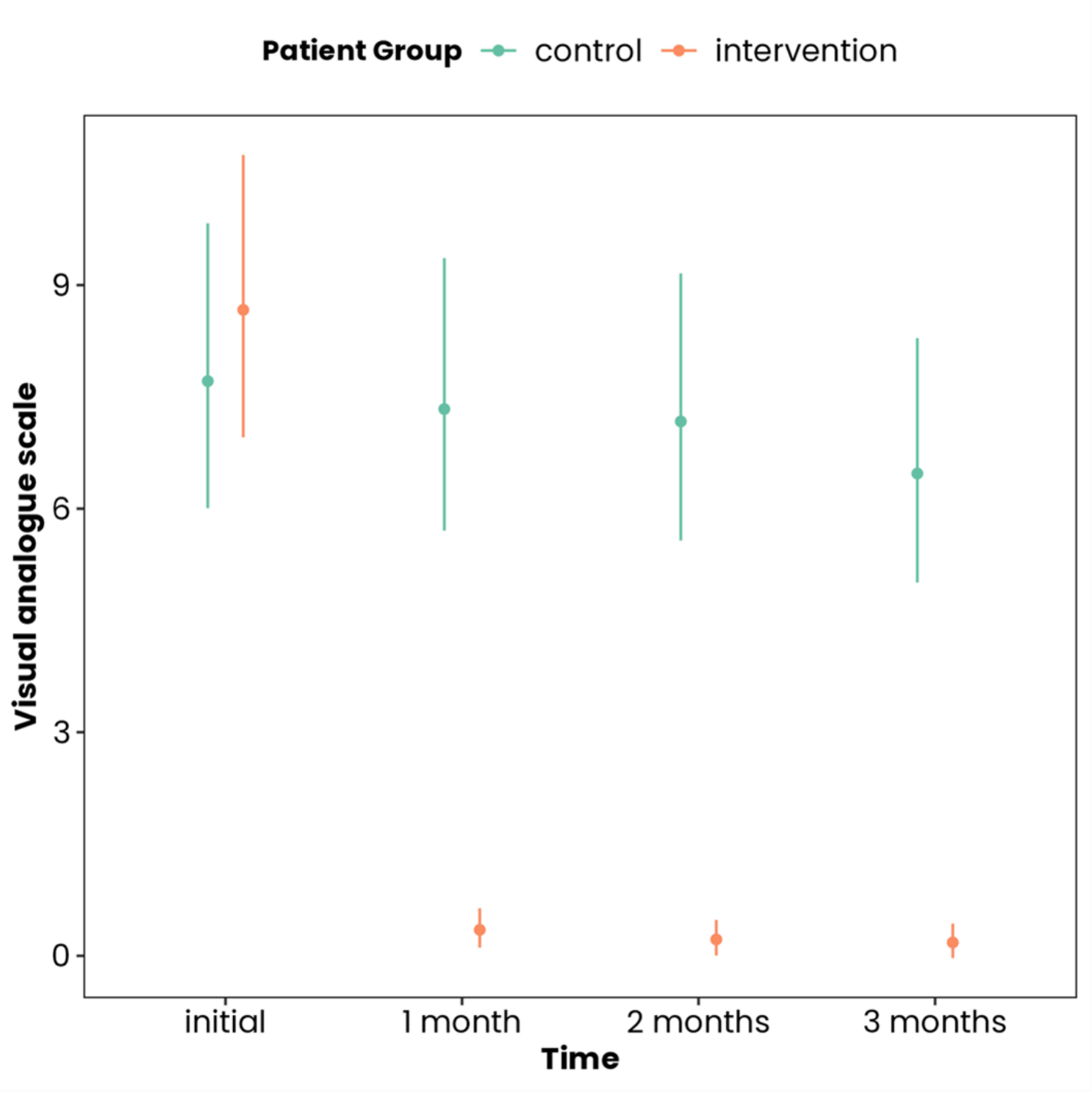

Figure 2

VAS score evolution for control group and intervention group and baseline, at 1 month, 2 months and 3 months.

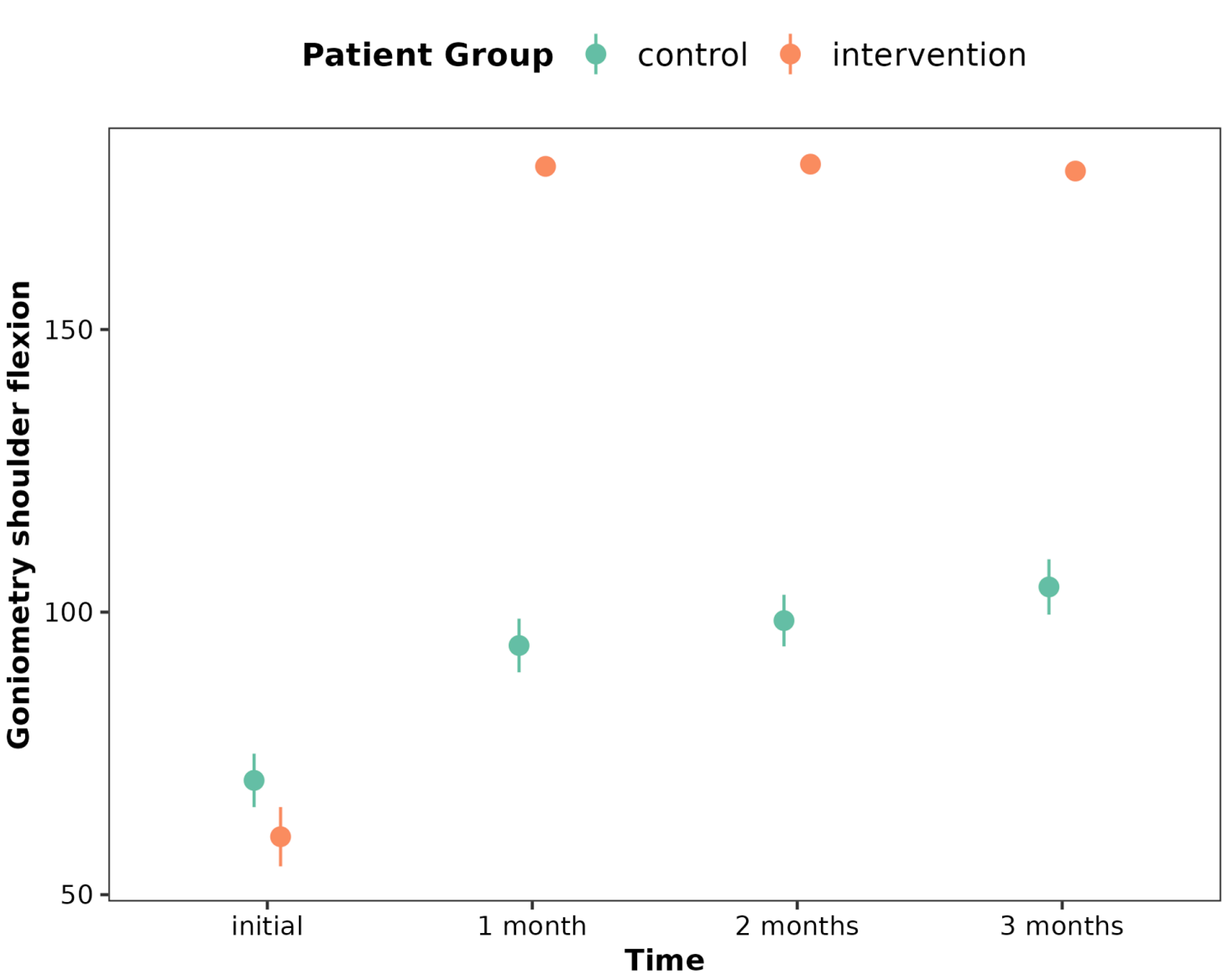

Figure 3

Evolution of shoulder flexion for control group and intervention group at baseline, first month, second month and third month.

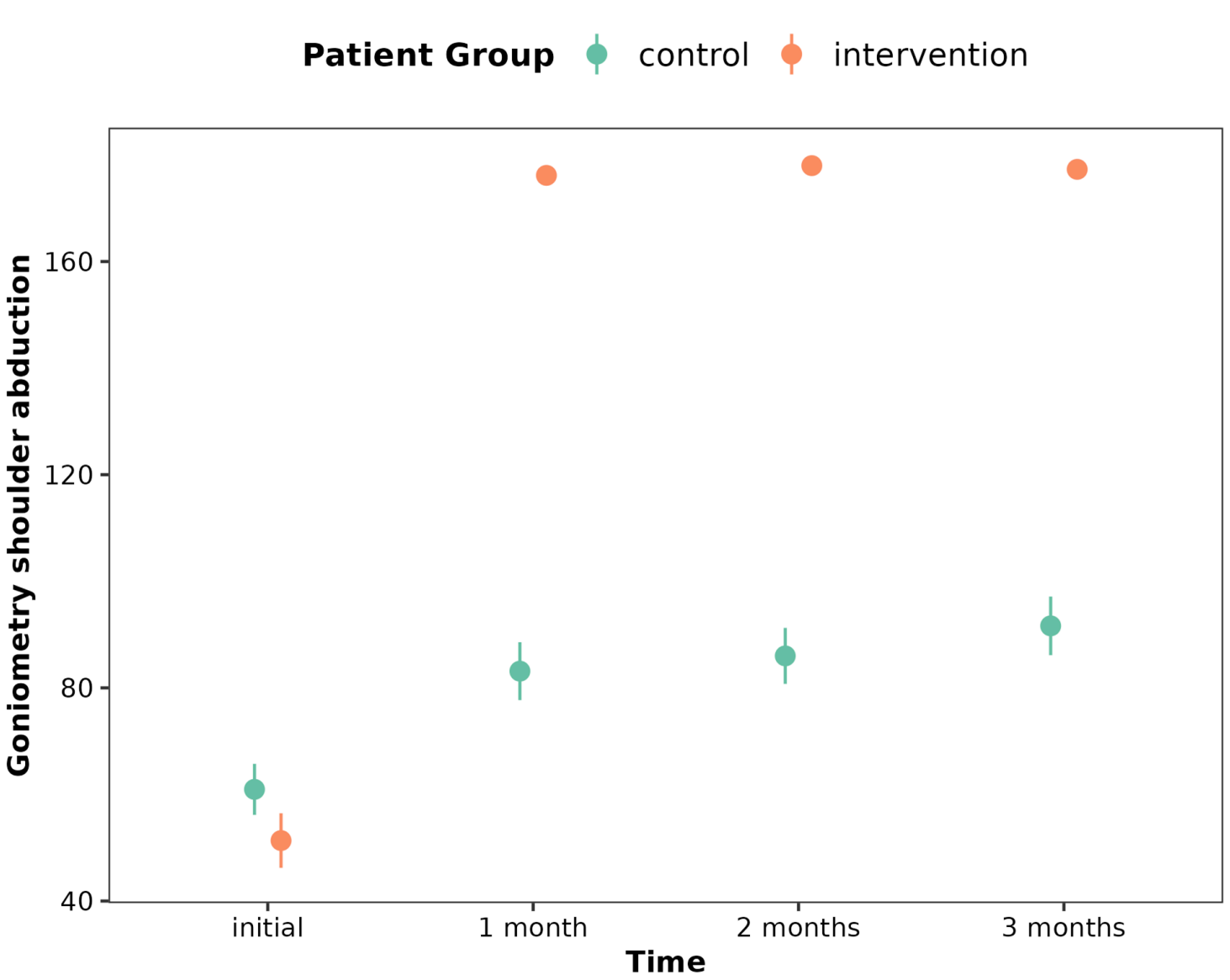

Figure 4

Evolution of shoulder abduction for control group and intervention group at baseline, first month, second month and third month.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Tables.docx
- APPENDIX1.docx