PROTOCOL

Official title: Randomized and Controlled Prospective Study on Use of the Adhesive Elastic Tape to Control Hand Edema in Patients With a Wrist Fracture Treated With Forearm Plaster

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INTRODUCTION

Wrist fractures are a very common event affecting patients of all ages (Crowe et al., 2020) and are estimated to represent approximately 10-25% of all fractures (Geraci et al., 2011; Smeraglia et al., 2016; Watson et al., 2018). These fractures are treated with closed reduction and forearm circular cast in 70-90% of cases (Letsch et al., 2003). There are several immobilization techniques, although there is no evidence identifying the best one in maintaining reduction. The forearm circular cast seems to be the best tolerated by patients (Okamura et al., 2018; Park et al., 2017; Peivandi et al., 2011).

Wrist fracture patients often develop oedema (Knygsand-Roenhoej & Maribo, 2011) and the presence of plaster increases the risk (Dresing et al., 2017). In 2019, 17.4% of patients with wrist fractures treated with circular plaster cast at one Orthopedic Emergency Room (OER) of Northern Italy, had a second visit in OER for oedema, pain or "intolerance to the plaster cast".

Kase has developed an adhesive elastic tape from 1973 to 1979 and marketed in 1982 with the name Kinesio tape (Wu et al., 2015). Since then, several authors have described this technique (Kase, 2005; Blow, 2015; Kumbrink et al., 2019) and several companies have started producing tapes with analogue characteristics. These devices are thin elastic stripes usually made of cotton, containing longitudinal interwoven elastic fibers and acrylic glue that is spread in a wavelike pattern. The material elasticity is approximately 130–140%, and the amount of traction used in its application to the skin influences the skin itself and various subcutaneous layers (Kase, 2005; Blow, 2015; Kumbrink et al., 2019). Taping technique is used to control the oedema, support of soft tissues, protect the joints and alleviate the heat produced by active inflammation.

There are many studies in the literature that demonstrate the efficacy of adhesive elastic tape in reducing lymphoedema in different pathologic conditions. Oedema secondary to breast cancer treatment is reduced by taping application compared to untreated controls (Lipinska et al., 2007; Pajero Otero et al., 2019; Tantawy et al., 2019). A recent meta-analysis showed a positive effect in reducing lymphoedema (perimeter or volume) before versus after taping treatment, although no significant differences were found comparing taping with control group or other treatments (Kasawara et al., 2018). A meta-analysis concerning limb lymphedema, not necessarily due to

breast cancer, did not detect differences in the volume drained by the tape compared to the control, but found a decrease in symptoms related to oedema (Gatt et al., 2017). A single study appears to support the no-effect thesis (Ergin et al., 2019).

Besides breast carcer, tape application has shown advantages after orthopedic surgery. The application of the tape seems to bring benefit in the post-operative period of knee arthroplasty, whether or not associated with manual lymphatic drainage (Donec & Kriščiūnas, 2014; Tornatore et al., 2020) and in the reduction of oedema in the knee after arthroscopy (Balki et al., 2016; Gülenç et al., 2019) however a trial does not recognize its effect in reducing oedema after shoulder arthroscopy (Gülenç et al., 2019). A systematic review supports the positive effects of the tape on post-operative oedema, although it recognizes some limitations including the small number of trials evaluated (Hörmann et al., 2020). One study reports good results in the control of oedema in patients treated with an Ilizarov type fixator (Białoszewski et al., 2009).

Given the importance of oedema control and the lack of definitive evidence in the literature regarding the effectiveness of the adhesive elastic tape, we decided to perform this study in order to evaluate tape effectiveness in counteracting the oedema formation in the hand of wrist fractured adult patients treated with forearm circular cast.

METHODS

Aim

The primary aim of our study is to evaluate whether the application of the tape with lymphatic technique to the fingers, both dorsal and volar, of wrist fractured patients treated with a forearm circular plaster cast is able to reduce the formation of hand oedema, compared to the untreated controls. Furthermore, we aim to assess the differences in pain and cast tolerability between the intervention group and the control group.

Primary endpoints

(*i*) difference in the circumference of the thumb between baseline (T0) and 7-days follow-up (T1), and (*ii*) difference in the circumference of the remaining 4 fingers merged together, between T0 and T1.

Secondary endpoints

(i) pain intensity at T0 and T1, (*ii*) analgesic use during the previous 4 hours at T0 and T1, and (*iii*) OER re-entry number for "intolerance to the plaster cast".

Design

Our study is a randomized controlled superiority trial, with parallel design and blinded data processing, developed at OER of Local Health Unit of Piacenza.

The ID NCT04683887 identify this study on clinicalrials.gov.

Participant characteristics

The patients' eligibility criteria to participate in our study are described in Table 1.

Sample size calculation

The sample size was calculated using the GPower 3.1 Software, setting the following parameters: effect size: 0.4, error α = 0.05, power = 0.80 and allocation ratio = 1.

The resulting sample size is 100 subjects per arm; the number of patients to be enrolled will be a total of 220 (110 per group), taking into account a 10% loss to follow up. The choice of medium effect size (0.4) was made based on feasibility and available literature (Gülenç et al., 2019; Pajero Otero et al., 2019; Tantawy et al., 2019) despite the absence of similar studies for pathology/type of intervention/primary endpoint.

Setting

Patient enrolment, execution of the fracture reduction maneuver, application of the plaster cast, application of the tape for the investigational treatment patient group, and endpoint T0 measurements will take place at the OER service of Local Health Unit of Piacenza. On day 7 the

tapes will be removed and endpoint T1 measurements will be assessed at the Orthopedics and Traumatology outpatient clinic.

Preliminary procedures and nurses' training

Before the enrolment of the first patient, all OER nurses will be trained for the tape application by a certified instructor.

All OER orthopedic doctors and nurses are trained and skilled in the closed reduction technique and forearm circular cast application. The closed reduction technique, done manually by three operators, and circular cast application are performed as described in Dresing et al. (2017).

Patients' enrolment

After having performed the necessary radiographic investigations and verified the presence of all inclusion criteria and the absence of exclusion criteria, complete oral and written information about the study will be given to each patient by OER nurses and physicians. A reflection period will be guaranteed to the patient during the waiting time before the control X-ray after reduction procedure.

Enrolment will be effective as soon as the patient has signed the consent form. We will then assign him/her to the intervention or control group after a telephone call to the Data Analysis Manager, as described in the following section.

Randomization, blind and control

We will generate the randomization list through the program called "Random Number Generator", available at https://stattrek.com/statistics/random-number-generator.aspx. The randomization will be simple with 1:1 allocation. The randomization list, known only to the Data Analysis Manager not involved in the clinical evaluation of patients, will be implemented and hidden inside a specific file protected by a password to prevent identification of the patient. We will assign the enrolled patients to group 0 or 1 according to the list by a telephone contact between Investigators and Data Analysis Manager.

The data-analyzing Researcher will not know which of the two groups will be the intervention nor the control one, to guarantee the blind. The Investigators are not allowed to collect data in a blind way due to the nature of study intervention.

We decided not to apply any type of alternative strip to the control group. Even if positioned without lymphatic technique, the tape would maintain its elastic properties and we cannot exclude that it may still have an effect. The application of a strip with properties different from the tape on one side would still have the adhesive effect induced by the glue-skin interaction, stimulating muscle function (Blow, 2015; Frignani, 2017; Zimaglia, 2014), but on the other hand, having a different elasticity from that of the tape, could reduce the range of motion (ROM) of the fingers (Frignani, 2017) and potentially could increase the risk of developing oedema in the control group.

Outcome evaluation details

OER nurses will evaluate the extent of oedema in the fracture-homolateral hand by measuring the circumference at the base of the 1st phalanx of the 1st finger and at the base of the 1st phalanx of the remaining 4 fingers merged together both at T0 and T1. The number of re-entries in OER between T0 and T1 will be registered. Furthermore, we will measure the intensity of pain with the Numerical Rating Scale (NRS) (Artioli et al., 2016; Peate et al., 2018) both at T0 and T1. At T0, the pain will be assessed before the possible administration of local anesthetic, while we do not expect differences between the intervention and the control group. Finally, the eventually analgesic use during the previous 4 hours will be recorded both at T0 and T1.

Procedure

An alphanumeric code will identify each patient in the case report form (CRF) and in the electronic database used for the analyzes, in order to guarantee pseudonymization.

We will report in the CRF the variables described in the Table 2.

Once the fracture reduction maneuver has been performed and the immobilization performed in a plaster cast, if the patient belongs to the intervention group, we will apply the tape only to the fingers of the hand with a lymphatic technique (Figure 2). We will not extend the application to the

metacarpals even if it would increase the surface of action, because portions of the tape will remain under the plaster, hiding possible skin reactions to the glue. Moreover, the tape application up to the metacarpals, inevitably performed before cast application, will increase the risk of detaching during the plaster wrap.

Blow (2015) suggests that the tape application needs to be proximal to the plaster cast. However, this indication is not supported by the literature. Other authors apply tape on the area that will probably form oedema (Donec, et al.,2014). Therefore, we believe that tape application on hand fingers is the most appropriate for achieving the objectives of this study.

The tape available at the Local Health Unit of Piacenza is the Leukotape K® by Essity, winner of the INTERCENTER AVEN tender for the supply of this type of medical device.

CRFs will be kept in OER until follow-up, so that any re-attendances can be noted.

Follow up

Even though tape results could be seen after 2-3 days, we choose to collect T1 variables (as previously described) at day 7 in order to avoid possible bias in the re-entry evaluation. The 7-day follow-up will be concomitant with the radiographic fracture control provided by organization procedure.

The completed CRFs will be delivered to the Researcher who will carry out the data analysis.

Statistical analysis

We will describe the general characteristics of the two groups. We will evaluate the effectiveness of randomization through the χ^2 test, for categorical variables, and the t-test, for continuous variables.

Intervention group versus control group analyses will be performed by comparing the respective mean of: the T0-T1 differences of circumference of both thumb (*i*) and the other 4 fingers (*ii*), the pain NRS score at T1(*iii*), and the number of OER re-entries (*v*), by t-test for independent groups (after verifying the normality of the distributions with the Shapiro Wilk test).

All analyses will be performed on an Intention-To-Treat principles: all randomized patients will be analyzed in the arm they were allocated by randomization. Only screening failures and patients

who refuse before the treatment start would be excluded. In the event of tape detachment in the first 48 hours after T0 and/or impossibility to evaluate study endpoints, missing data will be substituted by multiple imputation.

We will perform all analyzes using 2-tailed tests and consider significant a p value <0.05. We will report all analyzes according to the international guidelines for RCTs (Boutron et al., 2017).

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TABLES

Table 1: Inclusion and exclusion criteria of study population.

Inclusion criteria	**Exclusion criteria**
- Age ≥ 18 years.	- Bilateral wrist fracture (because these patients may have reduced motility increasing the risk of oedema formation and to avoid the risk of double counting bias).
- Growth plate closure at radiographic examination (in order to exclude any epiphyseal detachments).	- Multiple fractures.
- Unilateral distal radius fracture associated or not with ulnar styloid fracture (Colles or Goyrand types).	- Polytrauma.
- Need of closed reduction and immobilization with a forearm circular cast (Figure 1).	- Previous plegia/paralysis of the fractured limb.
- Signed informed consent.	- Previous lymphoedema of the fractured limb.
	- Access to OER during the night when the organization does not guarantee the presence of 2 nurses.
	- Wounds or abrasions in the area of application of the tape.*
	- Acute thrombosis (upper limb veins).*
	- Scars not perfectly healed in the area of application of the tape.*
	- Dermatitis, psoriatic manifestations or erythema in the area of application of the tape.*
	- Known allergy to acrylic (strip glue).*

	- Solid neoplasm.*

***** Further exclusion criteria introduced following advices of Blow and Kumbrink although to date there are no absolute contraindications to the application of elastic tapes (Blow, 2015; Kumbrink et al., 2019).

Table 2: Variables of study CRF and study timepoints.

Variable name	**Unit of measurement or possible categories**	**T0 (day1)**	**T1 (day7)**
Subject code	N/A	X	
Gender	Male/Female	X	
Age	Years	X	
Heart disease	Presence/Absence	X	
Kidney pathologies	Presence/Absence	X	
Respiratory diseases	Presence/Absence	X	
Diabetes	Presence/Absence	X	
Hypertension	Presence/Absence	X	
Assigned group	0/1	X	
Fractured limb	Right/Left	X	
1st finger circumference	Cm	X	X
Circumference of the remaining 4 fingers merged together	Cm	X	X
NRS	0-10	X	X
Analgesic use during the previous 4 hours	Yes/No	X	X
Accidental removal in the 48 hours after T0	Presence/Absence		X
Accidental removal	Presence/Absence		X
OER re-attendance between T0 and T1	Natural number		X

FIGURE LEGENDS

Figure 1. CONSORT flowchart modified for Randomized Trials of Nonpharmacologic Treatments (Boutron et al., 2017)

Figure 2. Tape application: a. lateral view, b. sight fly, c. dorsal view

FIGURES

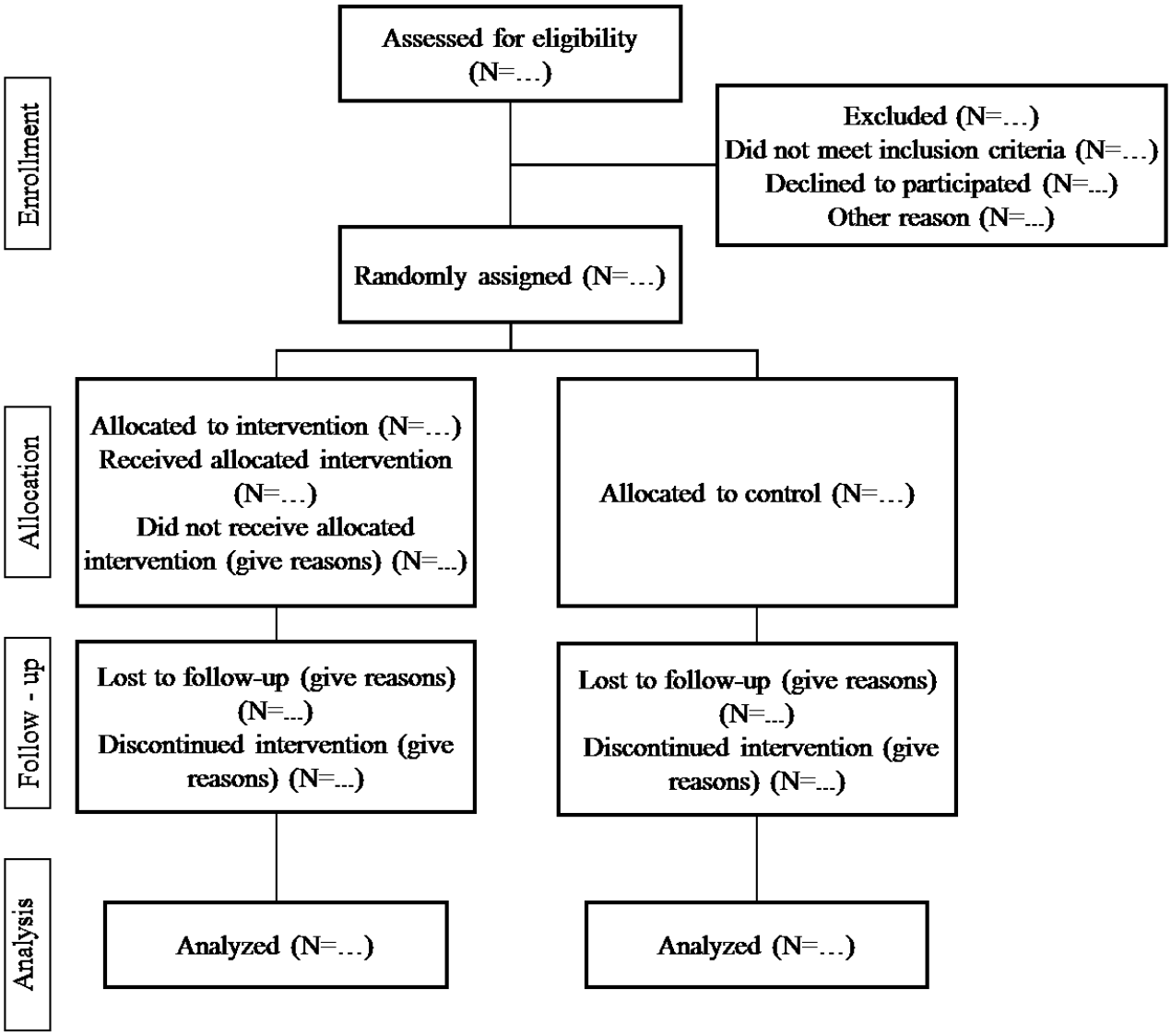

Figure 1

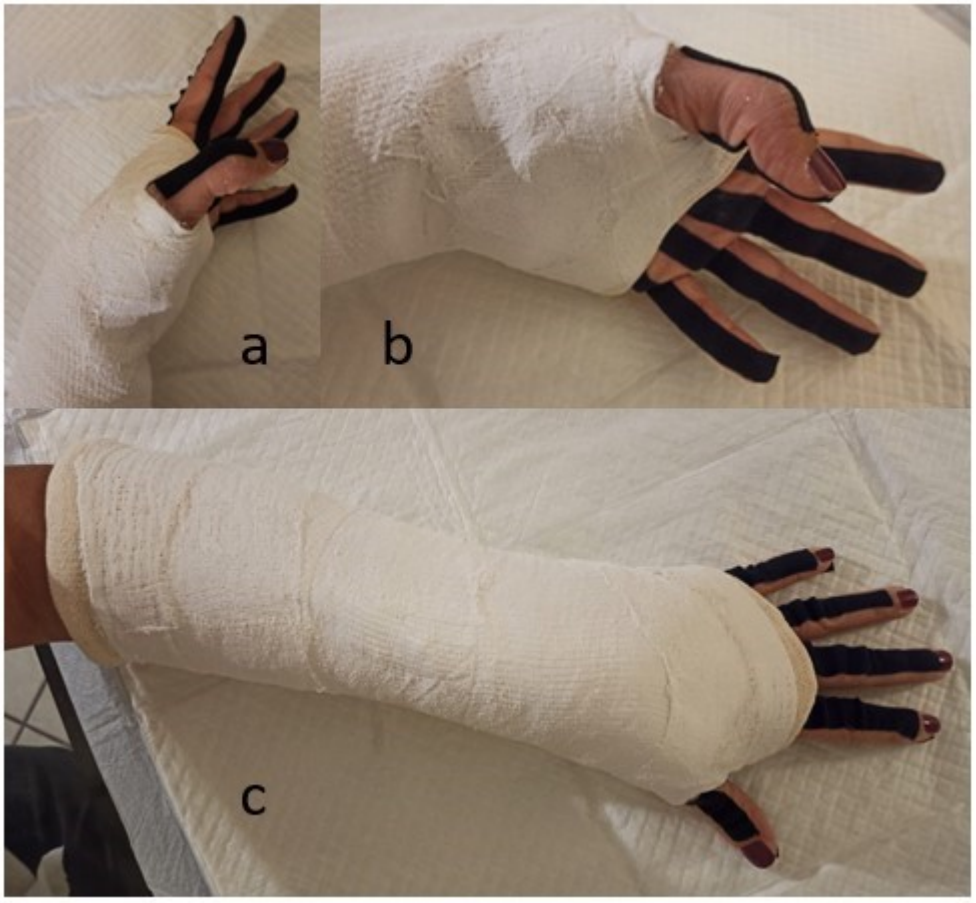

Figure 2.