Evaluation of the performance of the Blueback Physio® medical device in the management of patients suffering from chronic low back pain

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Abstract

Background: Chronic low back pain (CLBP) is one of the leading causes of disability in the world population. In 2017, in central Europe and North America, prevalence of CLBP was 12.51% and 9.80% respectively. The rehabilitation of the abdominal muscles, and notably the deep transversus abdominis, plays an important role in the management of CLBP in physiotherapy.
Objectives: The main objective of this study is to prove that a biofeedback device of the transversus abdominis, named Blueback Physio®, developed by the Blueback company, improves the management of patients suffering from this pain.
Design: The clinical trial is designed as a prospective, monocentric, comparative, open-label randomized and parallel group study.
Method: 41 subjects were included in this study and divided into two groups, one control group, in which the subjects used the device without visual biofeedback, and one intervention group, where the subjects used the complete biofeedback. The study included patients cared in day or full hospitalization in Clinique FSEF Rennes-Beaulieu as part of the PRESDO program ("programme de prévention secondaire des dorso-lombalgies").
Results: The probability of the intervention group achieving control of the voluntary contraction of the transversus abdominis earlier than the control group is 79% with a p-value of 0.004. Moreover, the use of Blueback Physio® allows a better control of the voluntary contraction of this muscle. Finally, the clinical protocol improves overall patient well-being.

Keywords— biomedical device, physiotherapy, chronic low back pain, biofeedback

1 Introduction

Chronic low back pain (CLBP) is defined as pain or disability that persists for at least three months without a clearly identified neurological cause. CLBP is one of the leading causes of disability in the world population. In 2017, the prevalence of CLBP, in central Europe and North America, was 12.51% and 9.80% respectively [1]. Dysfunction of the abdominal and back muscles that control the spine is correlated with this condition [2]. The transversus abdominis muscle (TrA) is an abdominal muscle, which is considered as a natural muscular belt. It is a paired muscle, *i.e.*, it is actually composed of two identical muscles on each side of the trunk. The most common theory of contraction of the TrA is the corset theory, *i.e.*, the TrA contracts simultaneously on both sides, which is called a bilateral contraction. This kind of contraction of the TrA increases thoracolumbar fascia tension [3], intra-abdominal pressure [4] and compression of the sacroiliac joint [5].This muscle has several functions including the control of intra-abdominal pressure for vocalisation, breathing, defecation, vomiting, etc [6]. In addition, its main mechanical role is to help maintain vertebral alignment either by regulating intra-abdominal pressure [7] or by transferring force to the spine via its attachments to the thoracolumbar fascia and the transverse processes of the vertebrae [8]. The TrA is partly responsible for maintaining neutral curvature and rigidity of the spine [9]. Furthermore, Thorstensson *et al.* have noted that the range of activation of the TrA appears to be affected by changes in postural demand [8]. At rest, posture has a significant effect on TrA thickness in healthy subjects [2]. However, this muscle does not act alone, as the process of stabilising the spine is complex and other muscles play a role, notably the multifidus (Mu), which is a deep back muscle, or the most superficial abdominal muscles such as the externus and internus obliquus. In particular, Kim *et al.* [9] have shown that the coactivation of lateral abdominal muscles such as the TrA and externus obliquus stabilises the spine against external disturbances. It has also been proposed that the deep trunk muscles (TrA and Mu) act as active stabilisers of the spine [10]. Futhermore, it has been shown that the TrA contracts in advance of other muscles, in order to stabilise the spine [10, 8, 2].

An altered pattern of abdominal muscle control has been observed in several studies in people suffering from low back pain. Some research teams have shown that the contraction of the TrA is delayed in these patients [11, 2] and that the amplitude of contraction of this muscle is reduced in these patients [12]. Miura *et al.* [2] have shown that there is a correlation between changes in the contraction patterns of the deep trunk muscles (Mu or TrA) and low back pain. Therefore, proper activation of the deep abdominal muscles is correlated with low back pain and it may play an important role in the recovery of patients suffering from such pain [12].

Nevertheless, the rehabilitation of the TrA can be complex because patients often have difficulty becoming aware of the contraction of this muscle. With this in mind, the Blueback company developed a medical device, that gives visual biofeedback of the TrA activation, named Blueback physio®. This device is intended to help raise awareness of the contraction of the transverse muscle.

One objective during the PRESDO program is to learn to the patients to control their deep abdominal muscles and to educate them how to activate and release it during the daily life. The Blueback Physio offers the possibility to see the activation of the TrA in real time and in motion, which can be of great help to reach this objective. Therefore, the main objective of this clinical investigation is to show the superiority of treatment including the Blueback Physio® compared to management without its use in terms of reducing the time needed to simultaneously learn how to control the voluntary

recruitment of the TrA and to get a full autonomy on this contraction, which is called further "the return to the patient's autonomy". The secondary objectives of this study concern the preservation of this control, the improvement of the patient's well-being and the reduction of the pain felt. This paper is structured as follows: The methodology is presented in Section 2, Section 3 illustrates the experimental results, leading to some discussions in Section 4. Finally, Section 5 concludes this work and opens on some perspectives.

2 Materials and Methods

2.1 Design

The clinical trial (NCT04592094) presented here is designed as a prospective, monocentric, comparative, open-label randomized and parallel group study. The inclusion time was 19 months and the mean duration of participation in the study was 23 ± 5.7 days. The clinical trial was conducted in accordance with the principles of the Declaration of Helsinki. It was approved by the committee for the protection of people of Ile de France (favorable opinion on April 28, 2020). For each patient, his/her consent was obtained in writing with regard to his/her participation in the protocol.

2.2 Participants

The study focused on patients undergoing day or full hospitalization at the Clinique FSEF Rennes-Beaulieu (CMPB), France, and was part of the PRESDO program ("programme de prévention secondaire des dorso-lombalgies"). Patients were accepted into the study when they met the following inclusion criteria: (1) male or female over 18 years old, (2) treated in and outpatient care by CMPB within the framework of the PRESDO program, (3) suffering from chronic low back pain (+2 months), (4) receiving social security benefits and (5) written consent. They were excluded from the study if they met any of the following non-inclusion criteria: (1) bedridden or in a wheelchair, (2) medical contraindication to muscular exercise, (3) other condition involving significant risk, (4) concurrently participating in another protocol or having recently participated in a protocol for which the exclusion period has not ended and (5) vulnerable person. A total of 42 subjects participated in the study. They were allocated to each group in a randomized procedure, 21 in the control group and 21 in the intervention group. One patient belonging to the intervention group left the study prior to the first physiotherapy session. Therefore, the intention-to-treat population contained 41 patients. In Table 1, we see that the gender distribution between the two groups is globally even. In both groups, there are slightly more females than males.

Table 1: Gender distribution by group

Group	**Intervention**	**Control**
Female	60%	66.7%
Male	40%	33.3%

Table 2 shows the mean and standard deviation of the age, the body mass index (BMI) and the history of CLBP. The age of the population is expressed in years, the BMI in kilograms per square metre, and the history of CLPB in months. Although age and BMI are similar in both groups, the CLBP history is much higher for patients of the intervention group.

Table 2: Resume of anthropomorphic criteria

Group	**Intervention**	**Control**
	$(mean \pm sd)$	
Age $(yr.)$	35.1 ± 9.4	33.4 ± 7.9
BMI (kg/m^2)	26.5 ± 5.5	26.1 ± 4.4
CLBP $(mo.)$	45.1 ± 44.0	26.1 ± 16.9

2.3 Intervention

The PRESDO program is a multidisciplinary program, including physiotherapy, postural gymnastics, occupationnal therapy, physical activity, bal-

neotherapy, psychological and socio-professionnal support. The physiotherapist intervention consists of 25 sessions of 30 minutes. The Blueback Physio® was used during the first sixteen sessions of this program. Physiotherapist were responsible for the physiotherapy sessions and tests. The patients in the intervention group used the Blueback Physio® with an active interface, *i.e.*, with visual biofeedback on the TrA contraction, where those of the control group used it in blind mode, *i.e.*, without visual biofeedback. At the beginning of each physiotherapy session, the Blueback physio was installed on the patients of each group. A calibration was made for each patient at each session, in order to normalize the electromyogram (EMG) curve obtained by the device. The amplitudes expressed hereafter will therefore be given as a percentage of the maximum value of the calibration. In order to quantify the main criteria of the clinical investigation, three tests were performed with the device. These tests allowed to assess two goals: the patient's capacity to voluntary contol the TRA muscle, and its ability to get a full autonomy on this activation. In these three tests, the patient had to perform the so-called Draw-in manoeuvre, known to be effective in strengthening of the deep abdominal muscle [13, 14]. During one minute, the maximum time during which the TRA contraction remained above a threshold of 30% of the amplitude was measured. The score for this test was between 0 and 60 points, 1 point being equivalent to 1 second. The second test was a rhythm test, during which the patient had to perform 5 draw-in manoeuvres of 5 seconds each in supine position, while resting 7 seconds between each. The goal was to assess the capacity of the patient to activate and to release correctly the TrA on a given rhythm. The score for this test was between 0 and 10 points. 1 point was attributed each time the activation was maintained on a contraction phase, or when the muscle stayed still during a resting phase. The last test corresponded to autonomous recruitment (AR). During this test, the patient had to perform a draw-in manoeuvre in 3 different positions, namely supine, sitting and standing, without visual biofeedback. For each position, a score between 0 and 2 (0 for no contraction, 1 for weak contraction (less than 50% of the EMG curve) and 2 for strong contraction (above 50% of the EMG curve) was calculated by the device , while the patient had to note his/her feeling on the same scale. The sum of the differences between both scores, noted AR, gave the final score for this test, which was between 0 and 6:

$$AR = \sum_{i=1}^{3}(2 - |score^i_{ph} - score^i_{pa}|) \qquad (1)$$

where i corresponds to the position, $score^i_{ph}$ and $score^i_{pa}$ are the score measured by the device and given by the patient, respectively, in the position i.

2.4 Outcomes measure

2.4.1 Primary outcome

The primary outcome is a composite criterion constituted of two parts. The first part of this criterion is to learn to control the voluntary recruitment of the TrA. In order to quantify it, the sum of the scores obtained in the first two tests (endurance and rhythm tests) were calculated. This first part of the criterion is validated if this sum was greater than 20 over one given session. The second part of this criterion is the return to autonomy. This part was validated if the score of the autonomous recruitment test was greater than 4 points over one session. In the following sections, this criterion will be referred as voluntary and autonomous control of TrA, and noted as VAC.

2.4.2 Secondary outcomes

The control of voluntary contraction of TrA and the sustainability of this control are assessed through the number of rehabilitation sessions and the maximum number of consecutive sessions,

where VAC is reached. The patient's well-being is measured by two types of criteria. The first one is a muscular assessment of the trunk muscles, and the second one is composed of the different scores obtained from the Nottingham Health Profile (NHP) questionnaires on Mobility, Social Isolation, Emotional Reactions, Energy, Sleep and Pain [15]. The muscle assessment was carried out using tests commonly used in physiotherapy. The first is the Sorensen test which evaluates the isometric endurance of the trunk extensors and the second is the Ito-Shirado test which evaluates the isometric endurance of the trunk flexors [16]. The result of the muscle assessment is the ratio between these two tests. For each item of the NHP questionnaire, a score between 0 and 100 is given. The higher the score the worse the patient's well-being in that item.

2.5 Statistical analysis

The time to occurrence of a binary event will be compared between 2 groups by the logrank test. The comparison of 2 independent means will be done by the Wilcoxon test. In case of non-independence, the Wilcoxon test for paired data will be used.

3 Results

Fig. 1 shows the Kaplan Meier curve for each group. The associated p-value is that of the logrank test ($p\text{-}value = 0.004$). Clearly, the probability of reaching the first event is higher in the intervention group than in the control group. In addition, the hazard ratio (HR) was estimated by a Cox model. The instantaneous probability of reaching the first event is higher in the intervention group than in the control group ($HR = 3.79$ $[1.44 - 9.99]$, $p\text{-}value = 0.0070$). In other words, the probability that patients in the intervention group achieve VAC earlier than patients in the control group is 79% ($P = \frac{HR}{(1+HR)}$).

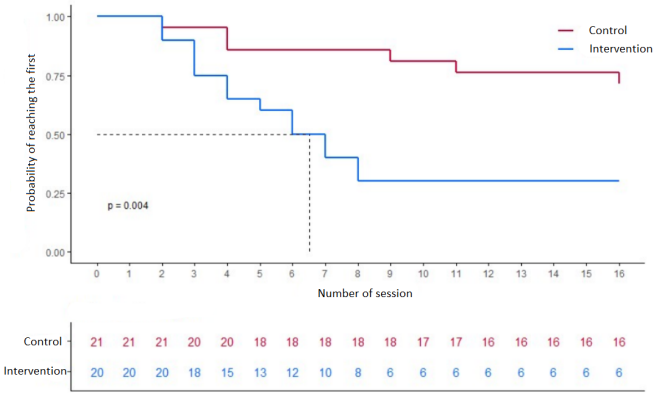

Figure 1: Kaplan Meier curve

Table 3 presents the results for the primary outcome. As a reminder, the criterion is the voluntary and autonomous control of TrA. We note a statistically significant difference between the two groups in terms of patients who met at least one time VAC (70% for the intervention group *vs* 28.6% for the control group). We can also observe a difference in terms of sessions required to achieve for the first time this criterion (for instance, the number of sessions needed for the intervention group to achieve VAC is around 4.9 whereas it is around 7.7 for the control group). There is a difference of 3 sessions between the groups in terms of the total number of sessions where VAC is achieved.

Table 3: Results of the primary outcome, (a) Percent of patients who met VAC, (b) Number of sessions required to achieve VAC at first, (c) Number of sessions where VAC is met and (d) Number of consecutive sessions where VAC is met.

	Intervention	**Control**	**p-value**
	$(mean \pm sd)$		
(a)	70%	28.6%	**0.0080**
(b)	4.9 ± 2.1	7.7 ± 5.3	0.2987
(c)	3.7 ± 3.3	0.7 ± 1.4	**0.0016**
(d)	2.0 ± 2.0	0.4 ± 0.8	**0.0028**

The remaining part of this section reports the results on the secondary outcomes. Table 4 sum-

Table 4: Results of Tests

	Session 1		Session 16	
	Intervention	**Control**	**Intervention**	**Control**
	$(mean \pm sd)$		$(mean \pm sd)$	
Sorensen (s)	46.7 ± 45.2	46.0 ± 44.2	95.6 ± 65.1	79.5 ± 46.9
Ito-Shirado (s)	57.6 ± 33.1	52.3 ± 43.4	95.7 ± 65.6	77.5 ± 28.7
Ratio	1.49 ± 1.04	3.78 ± 9.78	1.19 ± 0.70	1.19 ± 0.57
Mobility (pts)	29.1 ± 14.0	30.6 ± 16.4	22.5 ± 11.9	28.7 ± 17.8
Social Isolation (pts)	10.5 ± 13.4	22.8 ± 27.9	2.3 ± 10.1	14.4 ± 20.7
Emotional Reactions (pts)	22.7 ± 16.8	29.0 ± 24.8	14.1 ± 18.2	17.2 ± 23.2
Energy (pts)	64.3 ± 23.7	78.0 ± 35.5	31.9 ± 27.1	56.0 ± 33.2
Sleep (pts)	45.6 ± 28.1	43.7 ± 27.5	26.6 ± 26.1	33.9 ± 35.0
Pain (pts)	71.4 ± 21.1	64.8 ± 27.8	50.3 ± 26.1	59.8 ± 34.4

Table 5: P-value of Tests

	Session 1 *vs* Session 16		Intervention *vs* Control	
	Intervention	**Control**	**Session 1**	**Session 16**
Sorensen	$<$ **0.0001**	**0.0002**	1	0.5180
Ito-Shirado	**0.0003**	**0.0022**	0.3543	0.6429
Ratio	0.1514	0.4799	0.8197	1
Mobility	0.0752	0.1895	0.7690	0.2282
Social Isolation	**0.0156**	0.1914	0.2221	**0.0096**
Emotional Reactions	**0.0143**	**0.0183**	0.6643	0.7541
Energy	**0.0005**	**0.0039**	**0.0154**	**0.0234**
Sleep	**0.0208**	0.0898	0.8295	0.7091
Pain	**0.0031**	**0.0194**	0.4069	0.3520

marizes the results of the muscle assessment for both tests at session 1 and session 16, respectively. In Table 5, it can be seen that, for the Sorensen test and the Ito-Shirado test, the difference between session 1 and session 16 is statistically significant for each group. However, for a given session, there was no difference between the intervention and control groups for these two tests. Table 4 also reports the results for the items mobility, social isolation (SI), emotional reactions (ER), energy, sleep and pain of the NHP questionnaire at session 1 and session 16 respectively. In Table 5, concerning the intervention group, there is a significant difference between sessions 1 and 16, for all items except mobility. In contrast, for the control group, there is a statistically significant difference between the two sessions only for the items emotional reactions, energy and pain. Moreover, we observe a statistically significant difference between the two groups for the item social isolation in session 16, and for the energy item in sessions 1 and 16. For the items mobility, emotional reaction, sleep and pain, there was no significant difference between the groups.

4 Discussion

The time to learn the voluntary contraction of the TrA was shorter for the intervention group than for the control group with a differential of about three sessions. However, this difference is not statistically significant. On the other hand, the hazard

ratio allows us to estimate the probability of the intervention group achieving control of the voluntary contraction of the TrA earlier than the control group. This probability is equal to 79% with a p-value of 0.004. It can be concluded that the lack of significance of the Wilcoxon test is probably due to the small number of patients in each group. However, we have a significant difference between the groups for the percent of patients who met VAC, the number of sessions where VAC is met and the number of consecutive sessions where VAC is met. Obviously, more patients in the intervention group than in the control group manage to learn to voluntarily contract their TrA, and patients in the intervention group have better control of this voluntary contraction. It can also be seen that patients in the intervention group have more consecutive sessions where the VAC is met than those in the control group. However, in consideration of the low number of consecutive sessions, it cannot be concluded that the control of the voluntary contraction of the TrA is maintained regardless of the group. On the other hand, there was a clear improvement in the Sorensen and Ito-Shirado tests for both groups between session 1 and session 16. However, no statistically significant difference was observed between the groups whatever the session. It can be concluded that the use of Blueback Physio® does not influence these tests, but the clinical protocol significantly improves the endurance of the trunk flexors and extensors muscles. We observe no significant differences between groups and sessions in the ratio of the two muscular tests. It can be concluded that both tests improved proportionally between sessions. Finally, all items of the NHP questionnaire, except mobility, were improved between session 1 and session 16, for the intervention group. For the control group, the emotional reactions, energy and pain items improved between the two sessions, unlike the mobility, social isolation and sleep items. There was a statistically significant difference at session 16 between the intervention and control groups for the social isolation and energy items. It can therefore be concluded that the use of Blueback Physio® participates in the improvement of the social isolation and energy scores. We can also conclude that the clinical protocol improves all the items of the NHP questionnaire except mobility.

5 Conclusion

To conclude, a patient using the Blueback Physio® is more likely to learn to control his/her TrA than a patient without any access to a visual TrA biofeedback. In addition, a patient using visual biofeedback has a better control over the voluntary contraction of his/her TrA. The use of Blueback Physio® may participate to improve patients' social isolation and energy scores more effectively than in the control group. On the other hand, the clinical protocol, for patients of both groups, made it possible to improve the endurance of the flexor and extensor muscles of the trunk, as well as the scores of the emotional reactions, energy and pain headings.

Conflict of interest: The authors declare no conflict of interest.

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