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Upper extremity motor quality evaluation in children with Cerebral Palsy

Avaliação da qualidade motora das extremidades superiores de crianças com Paralisia Cerebral

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Abstract

Introduction: Cerebral Palsy (CP) is a non-progressive disorder that may compromise functional abilities of the upper limbs due to motor and sensitive loss, that are still poorly evaluated and described by reliable tools. **Objective:** This study aimed to evaluate motor quality and skills of the upper extremity in children with CP in regions of Trairi and Seridó from Rio Grande do Norte state (Brazil). **Methods:** It is a cross-sectional exploratory study, with a qualitative approach, with 17 children with CP, aged between four and eight years. The following instruments were used for upper extremity evaluation: Manual Ability Classification System (MACS), Quality of Upper Extremity Skills Test (QUEST) and Gross Motor Function Classification System (GMFCS). **Results:** Mean and standard deviation (sd) of QUEST total score and the domains dissociated movement, grasp, weight bearing and extensive protection were, respectively, 41.06/37.08; 53.12/34.50; 15.51/62.98; 37.76/37.52; 42.48/47.26. MACS and GMFCS median scores were, respectively, 3 (three) and 5 (five); high positive correlation was observed between MACS and

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GMFCS (rs=0.83) and high negative correlation between GMFCS and total QUEST (rs=-0.83), as well as between MACS and QUEST (rs=-0.84); and MACS and all QUEST domains (rs=-0.73; rs=-0.82; rs=-0.76; rs=-0.79), p<0.001. **Conclusion:** Children with CP showed deficit in motor quality and skills of the upper limb, allowing to infer functional limitations regarding manipulation of objects and consequent dependence during life activities.

Keywords: Cerebral Palsy. Upper Extremity. Aptitude.

Resumo

Introdução: *A Paralisia Cerebral (PC) é uma desordem não progressiva que pode comprometer as habilidades funcionais dos membros superiores, frequentemente decorrentes das perdas motoras e sensitivas, que são ainda pouco avaliadas e descritas por meio de instrumentos confiáveis.* ***Objetivo:*** *Este estudo teve como objetivo avaliar a qualidade de habilidades motoras e da extremidade superior em crianças com paralisia cerebral em regiões de Trairi e Seridó do estado do Rio Grande do Norte (Brasil).* ***Métodos:*** *Estudo exploratório, com abordagem qualitativa e estrutura transversal, com 17 crianças com PC, com idades entre quatro e oito anos. Foram utilizados os seguintes instrumentos para avaliação da extremidade superior: Sistema de Classificação da Habilidade Manual (MACS), Teste de Qualidade de Habilidades da Extremidade Superior (QUEST) e Sistema de Classificação da Função Motora Grossa (GMFCS).* ***Resultados:*** *A média e o desvio padrão da pontuação total QUEST e domínios dissociação de movimento, preensão, descarga de peso e resposta extensiva protetora foram, respectivamente, 41,06/37,08; 53,12/34,50; 15,51/62,98; 37,76/37,52; 42.48/47.26. As pontuações medianas do MACS e GMFCS foram, respectivamente, de 3 (três) a 5 (cinco), sendo observados alta correlação positiva entre MACS e GMFCS (rs=0,83) e alta correlação negativa entre o GMFCS e QUEST totais (rs=-0,83), bem como entre MACS e QUEST (rs=-0,84); MACS e todos os domínios QUEST (rs=-0.73; rs=-0.82; rs=-0.76; rs=-0.79), p<0,001.* ***Conclusão:*** *As crianças com PC apresentaram déficit de qualidade motora e habilidades do membro superior, possibilitando inferir limitações funcionais quanto à manipulação de objetos e consequente dependência durante atividades de vida.*

Palavras-chave: *Paralisia Cerebral. Extremidade Superior. Aptidão.*

Introduction

Cerebral Palsy (CP) has a heterogeneous character and it is defined as a non-progressive neurological condition caused due to injury in the immature brain that affects movements and posture. There are multiple etiologies involved, which result in Central Nervous System (CNS) injury [1].

Upper extremities of children with CP are generally impaired in skills such as reaching, grasping, transport, release and manipulation of objects, that decisively cause low quality achievement and performance of daily living activities [2]. Thus, basic ability to interact with people and to adapt to different environments is another factor that limits activity and participation. Motor disability in children with CP causes limitation in physical activity and in general experience [3, 4].

The importance of Upper Limbs (UL) movements to perform Activities of Daily Living (ADLs) is acknowledged by therapists working in motor function rehabilitation. Without arm movement, for the hand to reach the object and/or target, hand motor skills are restricted, precluding many reaching and grasping motor functions [5-7]. For example, the act of pushing a wheelchair is only possible after a coordinated action of several hand, arm and torso muscles. Such motor actions, no matter how elementary they are, when not performed, they might generate serious barriers in personal activities and social interactions [8, 9].

Some clinical features such as spasticity, dystonia, choreoathetosis or ataxia, that often occur in combination [10], are associated with hand and arm movement disorders of children with CP. Thus, there are few clinical instruments for assessment of motor function of upper extremities dissociated movement

of children with CP. Other studies use complex tools, such as the kinematics to describe functional and motor impairment of the upper extremity of children with CP [8-11]. However, these instruments are not available for most therapists involved in upper extremity rehabilitation.

Studies show [12, 13] that children with CP have greater difficulty in releasing objects than reaching them, as well as to hold smaller objects, due to their limitation in fine movements [14, 15]. Upper-extremity disorders impair participation in daily life, therefore an adequate therapeutic planning is important to improve independence and integration on a day-to-day basis [16].

The evaluation process should be constant and make decisive contributions in planning therapeutic programs of widely different rehabilitation centers and in the use of valid, reliable and sensitive instruments, which generate useful information in determining care practices.

There are no studies that evaluate the upper extremity of children with CP in the northeastern region of Brazil. Thus, there is a need for information to identify which are the main motor changes and consequent functional limitations of children with CP in this region.

Therefore, identification of these quantitative characteristics may facilitate adoption of targets in order to provide purchasing of orthosis, wheelchairs and other relevant devices. It may also instigate inclusion of public policies that contribute to improve mobility, functionality and accessibility for this public.

In addition, a qualitative analysis is essential to determine a suitable physical therapy program, resulting in significant clinical improvement of these individuals. Thus, the aim of this study was to evaluate the motor quality and skills of the upper extremity in children with cerebral palsy attended in Trairi and Seridó regions in Rio Grande do Norte state (Brazil).

Methods

It is a cross-sectional exploratory study, with qualitative approach, developed at the school clinic of Physical Therapy of the College of Health Sciences of Trairi (Facisa/UFRN), at the Children's Rehabilitation Center (CRI) of Santa Cruz/RN and at the Rehabilitation Center Professor Crindélia Bezerra (Currais Novos/RN).

Sample was allocated by convenience, according to the following criteria: age between four and eight years (according to instruments adequacy), both genders, clinically diagnosed with Cerebral Palsy (CP), who agreed to participate voluntarily in the study by responsible adults' signature, at legal age, in the Informed Consent Form. Children who presented other diseases associated with CP (cardiorespiratory and rheumatic diseases), as well as joint and skeletal muscle changes that compromised the passive range of motion of the upper limb movement were excluded from the study.

Assessment Instruments

Three assessment instruments were used:

1) Manual Ability Classification System (MACS): it assesses manual skills in people aged from four to 18 years. MACS describes five levels (from level I, ability to manipulate objects easily and successfully; to level V, one does not manipulate objects and has severely limited ability to perform even simple actions), which are based on children's ability to start handling objects alone and the need for assistance or adaptation to perform manual activities in daily life. Information about relevant daily activities of objects manipulation was acquired by interviews with parents and/or guardians [17].
2) Quality of Upper Extremity Skills Test (QUEST) is a reliable and valid assessment tool that evaluates function quality of the upper limb in four areas: QUEST A — dissociated movement (shoulder, elbow, wrist, fingers — 32 items); QUEST B — grasp (cube of 2.5 cm, cereals, pencil or pen — 12 items); QUEST C — protective extension (anterior, lateral, posterior — 18 items) and QUEST D — weight bearing (in prone, quadruped — 25 items) [18]. QUEST evaluates head, trunk and shoulders position during grasp movement, classifying them under normal or atypical. Scores were calculated for each subject by adding items that corresponded to them, assigning one point for every "yes" answer. Thus, total and each

domain score may range from zero (worst performance) to 100 (best performance). Human hand grasping mechanisms depend on the object's characteristics, and a QUEST domain evaluates it through grasp tasks that replicate functional activities and verify hand motor skills [18]. Therefore, this domain demonstrates, by quantitative measures, great children inability to perform grasping of cubes, grains/beans and pencil/pen.

3) Gross Motor Function Classification System (GMFCS): it assesses abilities and limitations in child gross motor function and the need for manual devices for mobility on a five-level scale: Level I, the child walks without limitations; level II, the child walks with limitations; Level III, the child walks with a manual device mobility; Level IV, self-mobility with limitations, the child may use motorized mobility device; level V, the child needs a manual wheelchair to move [19, 20].

Instruments administration

This study was developed after approval by the Ethics Committee of the Federal University of Rio Grande do Norte, following guidelines and recommendations of Resolution 466/12 on research on humans (730.810/2014).

Instruments applications were performed by two previously trained investigators. Both used manuals of each instrument as an aid. The average total time for the instruments applications was 30 minutes.

The following material was used: one (1) wooden cube of an inch; one (1) ballpoint pen; one (1) chair and one (1) wooden table; and recreational toys.

QUEST and MACS are not translated into Portuguese language, therefore they were used in English and the illustrated manual accompanying, autodidactic QUEST and MACS was consulted in case of doubt. GMFCS was used in the Portuguese version [21].

Data analysis

Scores were tabulated in Microsoft Excel® for data analysis, domains were calculated according to their respective weights, whenever suitable, and then software BioEstat 5.3 was used. Data were subjected to descriptive analysis (mean, standard deviation, variance and median) and correlation (Spearman correlation coefficient).

Correlation coefficient was interpreted according to Munro [22]. From 0.00 to 0.25: little or no correlation; from 0.26 to 0.49: low correlation; from 0.50 to 0.69: moderate correlation; from 0.70 to 0.89: high correlation; 0.90-1.00: very high correlation. Thus, the higher the r value (Spearman), the stronger the correlation. If it is positive ($r>0$), as the variable x (abscissa) grows, so does y (ordinate). If the correlation is negative ($r<0$), as x grows, y decreases (on average).

Results

Seventeen children living in Trairi region (Santa Cruz) and Seridó (Currais Novos) of Rio Grande do Norte (Brazil) were evaluated. They were registered in rehabilitation centers of the two cities.

Age median was six years, and the levels five for GMFCS and three for MACS prevailed. Each QUEST domain was scored individually, with total QUEST (ranging from 0 to 100) expressed mostly by <50 values (Table 1).

The study showed high negative correlation between all instruments and their domains, except for MACS and GMFCS that presented high positive correlation, which ensures association between these research instruments (Table 2).

Table 1 - Sample characterization and assessment tools

Children	Genre	Age	GMFCS	MACS	QUEST A	QUEST B	QUEST C	QUEST D	QUEST total
1	F	5	1	2	96.87	96.29	100	100	98.29
2	M	6	2	3	98.43	92.59	96	100	96.75
3	M	6	1	3	96.87	66.66	98	100	90.38
4	F	5	1	2	81.25	55.55	66	100	75.70

(To be continued)

(Conclusion)

Table 1 - Sample characterization and assessment tools

Children	Genre	Age	GMFCS	MACS	QUEST A	QUEST B	QUEST C	QUEST D	QUEST total
5	M	6	1	2	93.75	55.55	68	83.33	75.15
6	M	4	4	3	76.56	51.85	68	83.33	69.93
7	F	6	5	3	64.05	81.48	50	50	61.38
8	M	8	2	3	54.68	14.81	24	100	48.37
9	M	6	5	3	31.25	11.11	12	0	18.12
10	F	5	5	5	68.75	-14.81	12	0	16.48
11	F	7	5	5	12.5	11.11	28	0	12.90
12	M	8	5	5	34.37	-7.40	12	5.55	11.13
13	F	7	5	5	43.75	-7.40	8	0	11.08
14	F	7	5	5	28.12	7.40	0	0	8.88
15	F	6	5	4	21.87	-11.11	0	0	3.587
16	M	8	5	5	0	-120	0	0	0
17	M	8	5	5	0	-120	0	0	0
Median	-	6	5	3	-	-	-	-	-
Min/Max	-	4/8	1/5	2/5	-	-	-	-	-
Average/dp	-	6.35/1.22	-	-	53.12/34.50	15.51/62.98	37.76/37.52	42.48/47.26	41.06/37.08

Note: F = female; M = male; Min = minimum; Max = maximum.

Table 2 - Spearman correlation between the scales used

TOOLS	GMFCS	QUEST (A)	QUEST (B)	QUEST (C)	QUEST (D)	QUEST (T)
MACS (rs)	0.83	-0.73	-0.82	-0.76	-0.79	-0.84
GMFCS (rs)	-	-	-	-		-0.83

Note: p-valor <0.001

According to the results reported on the tables previously mentioned, we observe disorders in the movement quality and upper limb activities limitation, emphasized by a bigger impairment in grasp domain (QUEST B = 15.51) and a lower impairment in dissociated movement domain (QUEST A = 53.12).

Discussion

Most children with CP evaluated in our study showed large function impairment of the arm and hand, confirming findings reported by Klingels et al. [23], that reaffirmed the development of such functions in children with CP are often impaired and they justify these shortcomings because of central nervous injury followed by motor and sensory changes.

According to Furuya [11], reaching trajectory shifts are well documented in subjects with moderate to severe cerebral stroke, when there is abnormal muscle coactivation in the paretic upper limb due to synergy impairment during abduction with external rotation of the shoulder, extension and elbow flexion, similar in cerebral palsy. In reaching and grasping activities, children with CP show more pronounced compensatory movements in proximal segments, with trunk movement to compensate the forearm pronation increase [16, 24, 25] and decreased shoulder range of motion, with lateral trunk compensation [12].

Considering that reaching when in sitting position is one of the main functional activities of children with CP and that inappropriate postural control [26, 27], normally seen in these children, may affect reaching and grasping movements, it seems essential that, in any instrument which aims to assess the upper limb, there must be an evaluation of head, trunk and its adjustment mechanisms.

However, QUEST does not standardize the way which the child should be positioned for the test. Thus, the following procedure was determined for evaluation in this study: a 45-cm chair with trunk support, no arms support and a table, allowing the child to perform the requested items according to his/her potential.

Still regarding postural control and reactive movements of the upper limb, our study assessed, through QUEST, the protective extension and weight bearing, and low scores in these two areas were found. It is explained by neuromotor deficits, present in this population, which results in inability to coordinate responses to the imbalance and the need to explore a wider support base [28].

In this study, MACS presented median III and only other three children showed MACS higher than median (level II). This MACS level is worrying, since according to Barroso et al. [29], children with CP who have the lowest MACS levels have significantly more deficiencies and limitations of unimanual and bimanual activities. Data above are different from those reported by Arner et al. [30], who conducted a study of 367 children with CP in Sweden, and only 36% of children were classified as level III or less in MACS, that is, they were not independent in manual tasks, even using two upper limbs.

Klingels et al. [23] conducted the first study that compared instruments that assess upper limb function: QUEST and the Melbourne Assessment, by statistical analysis of a homogeneous sample. In this study, Melbourne and QUEST showed high correlation between them, which explains the concurrent validity of scales. However, inspection of the instruments content indicates they measure different aspects of upper limb function. QUEST emphasizes each function level of the upper limb bilaterally including analysis of dissociated movement (domains). The Melbourne Assessment is a measurement tool based on activities according to the International Classification of Functioning, Disability and Health and it is more suitable to determine motor skills status (fine and functional) of a child unilaterally.

In this study, when comparing total QUEST score with each of its domains, it is observed that in the last domains, the value shown enables better understanding of the upper extremity in the population (Table 1), and it was also reported by Thorley et al. [31], in a previous study with 94 Australian children, that presented better details of the upper limb impairment in each evaluated domain than in the total QUEST score.

In arm and hand function assessment of children with CP, other methods are also used, such as hand dynamometer, used by Klingels et al. [23], to ascertain grasp strength. However, unilateral function analysis was not the aim of this study and possible cognitive deficits were observed in most affected children that would possibly hinder the implementation and use of dynamometer.

During QUEST application, a good convenience in handling the instrument has been disclosed, mainly due to manual graphics and the easily accessible materials (inch cube, pencil, A4 sheets, beans) and the rapid descriptive understanding regarding MACS and GMFCS levels. However, during the investigation, no studies that corroborate these findings were found. In addition, there was no pain and/or fatigue report during the time children were evaluated, that could affect the results, since, as described by Hirsh et al. [32], skeletal muscle changes may generate pain and fatigue in children with CP, compromising the evaluation process. Thus, the average time for evaluation was 30 minutes for the most compromised children and 20 minutes for the less compromised.

In addition, we suggest the importance of investigating the relationship among time, location and brain injury size with impaired function, ability and quality of the upper limb in children with CP, besides performing objective measurements generated by kinematic analysis of arm and hand [33].

Conclusion

Deficit in motor quality and skills of upper limb was observed through high scores in MACS and GMFCS and low scores on QUEST in children with CP from Rio Grande do Norte, allowing to infer functional limitations regarding objects manipulation and consequent dependence during life activities. Besides, such instruments were highly correlated, supporting their concomitant use.

Therefore, planning appropriate treatment in order to improve upper limb function (arm, wrist, hand and fingers) and independence in life is necessary, and it should be based on a comprehensive and detailed assessment of the upper limb.

Thus, we suggest further studies to be developed in this area, translation and validation of QUEST manual into Portuguese in order to make it more accessible for health professionals, mainly physical therapists and/or occupational therapists in northeastern region of Brazil, where there are no studies describing upper limb impairment profile by trusted and reliable clinical tools. Therefore, more research in this area with larger samples in order to trace the existing profile is necessary.

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TENS effects on dysesthesia and quality of life after breast cancer surgery with axilectomy: randomized controlled trial

Efeitos da TENS na disestesia e qualidade de vida após cirurgia de câncer de mama com finfadenectomia axilar: estudo controlado randomizado

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Abstract

Introduction: After breast cancer surgery, many women may present quality of life (QOL) impairment due to the presence of discomfort as dysesthesia in the anterolateral region of the chest, armpit and/or medial part of the arm caused by intercostobrachial nerve injury (ICBN). **Objective:** To investigate the effects of Transcutaneous Electrical Nerve Stimulation (TENS) on dysesthesia intensity at the intercostobrachial nerve (ICBN) dermatome and QOL in women after breast cancer surgery. **Methods:** A randomized, double-blinded, placebo controlled clinical trial was conducted. Women undergoing axillary lymphadenectomy (AL), with dysesthesia on ICBN dermatome were included. Patients were divided into active and placebo TENS groups. TENS was applied with a frequency of 100 Hz, pulse duration of 100 μs and amplitude at the highest sensory intensity tolerable for 20 minutes during 20 sessions, three times a week, on alternating days. In the placebo TENS group, electrical current was delivered only during the first 45 seconds of application. Skin sensitivity was assessed by

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esthesiometry. Dysesthesia intensity was assessed with a visual analogue scale (VAS) and QOL with the EORTC QLQ-C30 and the specific EORTC QLQ-BR23 which is the Breast Cancer Module. **Results:** VAS decreased significantly over the 20 sessions in the active TENS group ($p<0.006$) and no difference was found between groups. There weren't significant differences in EORTC QLQ-C30 and EORTC QLQ-BR23 after 20 sessions or between groups. **Conclusion:** TENS decreased dysesthesia intensity in the ICBN dermatome after breast cancer surgery, but did not improve quality of life.

Keywords: Breast Cancer. Transcutaneous Electrical Nerve Stimulation (TENS). Paresthesia. Quality of life (QOL). Pain.

Resumo

Introdução: *Após cirurgia para câncer de mama, muitas mulheres podem apresentar prejuízo na qualidade de vida (QV) pela presença do desconforto como disestesia na região anterolateral do tórax, axila e/ou parte medial do braço, causada pela lesão do nervo intercostobraquial (NICB).* ***Objetivo:*** *Investigar os efeitos da Estimulação Elétrica Nervosa Transcutânea (TENS) na intensidade da disestesia no dermátomo do NICB e na QV após cirurgia de câncer de mama.* ***Métodos:*** *Ensaio clínico, controlado, randomizado, duplo-cego. Mulheres submetidas à linfadenectomia axilar (LA), com disestesia no dermátomo do NICB foram distribuídas em: TENS placebo e TENS ativo (um par de eletrodos autoadesivos) no trajeto do NICB, frequência de 100 Hz, duração de pulso de 100 µs, e amplitude no limiar sensorial máximo tolerado pela paciente, por 20 minutos, durante 20 sessões, três vezes na semana. A sensibilidade da pele foi avaliada através da estesiometria e foi considerada disestesia a partir do terceiro monofilamento (2,48 g). A intensidade da disestesia foi avaliada através da Escala Visual Analógica (EVA) e a QV com o EORTC QLQ-C30 e o EORTC QLQ-BR23.* ***Resultados:*** *A intensidade da disestesia diminuiu significativamente ao longo das 20 sessões no grupo TENS ativa ($p<0,006$), mas não houve diferença entre os grupos. Não houve diferenças significativas na QV após as 20 sessões entre os grupos.* ***Conclusão:*** *A TENS foi capaz de diminuir a intensidade da disestesia no dermátomo do NICB, mas não melhorou a qualidade de vida.*

Palavras-chave: *Câncer de mama. Estimulação Elétrica Nervosa Transcutânea (TENS). Parestesia. Qualidade de Vida (QV). Dor.*

Introduction

Breast cancer is a highly prevalent disease among women and its treatment can have negative repercussions on physical, social, family, emotional and work-related aspects. The main complications are limitation of ipsilateral shoulder range of motion, scar adhesion, seroma, dehiscence, lymphedema, dysesthesia and/or pain in the shoulder, axillary and lateral chest wall [1-3]. Thus, survivors of this disease may experience impairments in quality of life (QOL), functionality and the ability to perform day-to-day tasks [1-6].

Chronic localized or regional discomfort, including dysesthesia, hypoesthesia, paresthesia and pain, after breast cancer surgery is a common and well-recognized problem with prevalence rates ranging from 20 to 65% [4]. This is a clinical situation that influences on their physical functioning, mood, work, relationships, sleep and QOL, but it has not been investigated. Post-mastectomy pain syndrome (PMPS) is defined as chronic pain for over a 3-month period [2-5, 7] PMPS is different from other painful syndromes because it is typically localized in axillary region and/or medial arm and anterior or lateral region of the chest, causing pressure sensation or numbness, burning and/or shooting pain [2-4, 7]. It is caused by either primary lesion or dysfunction in the nervous system and is considered a neuropathic condition that arises after surgical treatment for breast cancer. This can occur due to

intercostobrachial nerve (ICBN) lesion, neuroma and lesions of other nerves [3].

Taking into account complications after surgery, healthcare professionals must understand the impact of breast cancer treatment on the patient's QOL in order to promote a better health pattern. Health-related quality of life is a multidimensional concept that characterizes individual´s total well-being and includes psychological, social and physical dimensions. In this context, the rehabilitation can alleviate post-treatment side effects, maintain QOL and improve the survival [4, 5]. The Transcutaneous Electrical Nerve Stimulation (TENS) has been widely used to alleviate pain [8, 9]. In the case of neuropathic pain [10], its effect has been studied in trigeminal neuralgia [11], shingles [11], diabetic neuropathy [12], among others [13], but information about dysesthesia approach among patients after breast cancer surgery remains scarce.

TENS is an easy to apply, low cost, non-invasive therapy without side effects, which has already showed good results on reducing other types of neuropathic pain [9 – 12], because it promotes a sensory stimulus that activates Aβ afferent fibers and, consequently activates inhibitory descendent pathways, reducing central nociceptive cellular activity [9-14]. And peripherally, at the application place, opioid and α-2 noradrenergic receptors are involved in TENS induced analgesia [15, 16].

To date, no studies with TENS application for complaints of sensitivity-related discomfort have been found in the available literature, specifically on the path of ICBN after surgery for treatment of breast cancer. In addition, assessing health-related quality of life has been recommended in several clinical situations [17, 18] And in women undergoing surgical treatment for breast cancer, this evaluation may reflect how some functional limitations and the presence of symptoms in the homolateral limb may interfere with the daily life of these [3, 5].

Considering that ICBN dermatome dysesthesia causes a discomfort that compromises daily activities and consequently quality of life, it becomes relevant to investigate a new form of therapeutic intervention to minimize such discomfort. Thus, the objective of this study was to investigate the effect of TENS on dysesthesia intensity at the ICBN dermatome and quality of life of women after breast cancer surgery associated with AL.

Methods

Study design

Double-blind randomized placebo-controlled clinical trial.

Study Population

Women who underwent breast cancer surgery associated with AL of the three levels of lymph nodes, for more than 3 months and with a report of alteration of cutaneous sensibility at the ICBN dermatome, were included in the study. The exclusion criteria were: 1) Other underlying systemic diseases; 2) previous experience with TENS, 3) Contraindication for TENS use and 4) current use of antidepressants, psychoactive drugs and glucocorticosteroids.

Patients were randomly assigned at a 1:1 rate in two groups: Placebo TENS and Active TENS. The required sample for dependent groups was estimated at a significance level of 5% and power of 95%, Standard error of the mean corresponding to 1.2 and 1.5, and minimum difference between groups assumed as 2 of 10 points considering VAS scale. Thus, a sample of 12 subjects per group was estimated. After adding 20% considering loss of followup, the final estimation indicated around 15 participants per group. Calculation was performed by using WinPepi, version 11.65 (Portal JH Abramson, Aug 23, 2016).

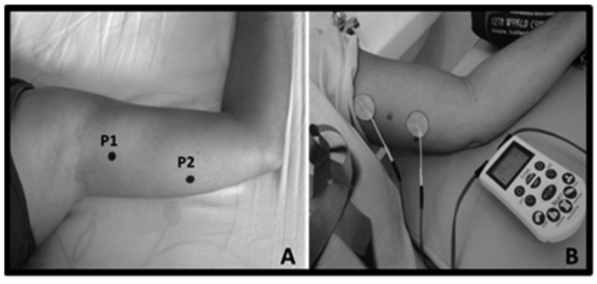

Figure 1 - A- Points of skin sensitivity assessment and TENS electrodes placement. B- TENS application at the ICBN dermatome.

The study was conducted in the Physical Therapy sector of OncoHematos at Hospital Cirurgia, city of Aracaju/SE, from the period of June 2011 to July 2012. It was approved by the Institutional Review Board of Federal University

of Sergipe with CAEE 0095.0.107.000-11 and adequately registered in the Brazilian Registry of Clinical Trial (RBR-3s39jp).

Sample selection is described in Figure 2. Sixteen patients were allocated in each group.

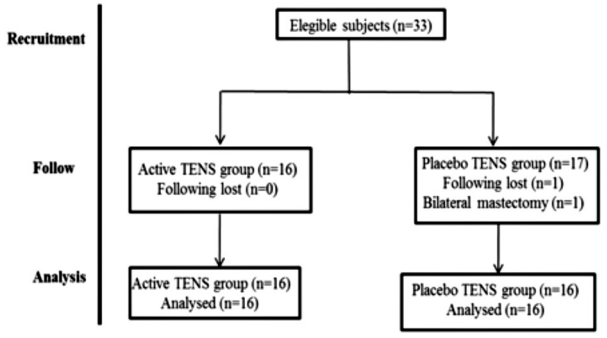

Figure 2 - Flowchart of recruitment, allocation and monitoring of patients in the different groups.

Protocol

For the stimulation, portable TENS units (Empi Select TENS, Empi Inc.®, St. Paul, MN, USA) were used, after calibration by using a digital osciloscopy (TBS2000, Tektronix™, Beaverton, Oregon, EUA), which outputs a biphasic and asymmetric waveform. Stimulation parameters were set at 100 Hz of frequency and pulse duration of 100 μs, which are reported by the patients as a more comfortable stimulation The current intensity was raised to the maximum sensory level tolerated by the patient, which was determined by raising the amplitude of current until obtaining a visible motor contraction and reducing it until the contraction dissipates. Two circular auto adhesive electrodes (3.2 cm2), were fixed at P1 and P2 points of the ICBN dermatome (Figure 1). However, in the placebo TENS group, the device's internal circuitry was modified by the manufacturer to interrupt electrical current transmission after 45 seconds of stimulation, characterizing the new method of placebo TENS [19]. Subjects were instructed that the current sensation could or not last through the whole session but that would not influence the analgesia. TENS was applied for 20 minutes, three times per week, on alternate days, during 20 sessions. Duration and place of stimulation were the same for both groups. All patients were under a conventional physical therapy program.

Investigator 1 was responsible for patient assessment of all variables, before and after TENS treatment. Investigator 2 performed TENS administration in all sessions. None of the researchers knew in which treatment group the patient was allocated. This procedure ensured that the study was double blind (neither the patient nor the researchers knew which treatment was being administered).

Measurements

Skin sensitivity

Skin sensitivity was assessed by using esthesiometry through the Semmer Weinstein esthesiometer (Sorri®, Bauru, SP, Brazil) at two points of ICBN dermatome (Figure 1). It was considered dysesthesia when the patient noticed stimulation only from the third monofilament (purple color — 2.48 g).

Dysesthesia Intensity

Visual analogue scale (VAS) was used to assess dysesthesia intensity on the intercostobrachial nerve-related dermatome. A horizontal line, 100 mm in length, with the left end (0 mm) representing "no discomfort" and the right end (100 mm) representing "worst discomfort". Patients were instructed to express their discomfort by marking the point in the line which represents their discomfort at the moment. The score was determined by measuring the distance in mm from the left end to patient mark. This test was performed from the first until the last session, before and after each TENS application.

Quality of life (QoL)

Translated version of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire- EORTC QLQ-C30 and breast cancer module — EORTC QLQ-BR23 questionnaires were employed before and after 20 sessions [20].

The EORTC QLQ-30 measures QOL and general status of health in a score called Global Health Status (GHS), allowing values in a range from 0 to 100. Therefore, high scores represent a high QOL and, oppositively, low scores a low one. Five functional scales measure body, role, and emotional, cognitive and social function of patients. Additionally, the questionnaire includes three symptom scores (fatigue, emesis and pain) and six further single-item symptom scores (dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties) which may occur in breast cancer patients.

The EORTC QLQ-BR23, the breast cancer module, incorporates four symptom scales (systemic therapy side effects, breast symptoms, arm symptoms, upset by hair loss) and four functional scales (body image, sexual functioning, sexual enjoyment, future prospects). All these scales have four scoring possibilities, ranging from1 (not at all) to 4 (very often). A high score presents a large amount of symptoms [20-22].

Statistical analysis

Collected data was transferred to a spreadsheet in Excel for Windows 2007 and, subsequently to the software Statistica, version 6.0. Absolute and relative frequencies, measures of central tendency (mean and median) and dispersion (standard diviation and minimum and maximum value) were used for descriptive analysis of the data. Shapiro Wilk normality test was applied, and since the data were not normally distributed, nonparametric tests were undertaken in all analyzes, with statistical significance set at $p<0.05$. To compare the intensity of dysesthesia over the 20 sessions, the Friedman test for repeated measures was applied adjusted by the Tukey test, and to comparisons between groups, Mann Whitney test was adopted. The value considered for VAS was the delta — the difference between the initial and final values. The variables of EORTC QLQ-30 and EORTC QLQ BR-23 were compared before treatment initiation and after the 20th session with the Wilcoxon Matched Pairs and between groups with the Mann Whitney test. For comparison of ratio, the chi-square or Fisher's exact test was used.

Results

Regarding personal, demographic and surgical characteristics, no significant differences were found between the groups (see Table 1).

Table 1 - Personal, clinical and surgical treatment-related characteristics of Active TENS (n = 16) e Placebo TENS (n = 16) groups

Personal, clinical and surgical characteristics	Active TENS / Placebo TENS				*p*
	Mean (±STDEV)		Median (min/max)		
Age (years)	50.37 (±8.11)	52.12 (±7.80)	54 (40/62)	54 (40/62)	0.45
Weight (kg)	68.00 (±10.43)	69.60 (±10.59)	69 (48/85)	69 (48/85)	0.47
Height (m)	1.54 (±0.04)	1.56 (±0.06)	1.56 (1.45/1.7)	1.56 (1.45/1.7)	0.37
BMI (kg/m²)	28.81 (±4.98)	28.04 (±4.77)	29.71 (19.33-34.9)	29.71 (19.33-34.9)	0.88
	n (%)	n (%)			
Educacional level					
High school and college	3 (18.75)	10 (62.5)	-	-	0.14
Elementary and illiterate	13 (81.25)	6 (37.5)	-	-	
Marital status					
Single/Widow	7 (43.75)	11 (68.75)	-	-	0.15
Married	9 (56.25	5 (31.25)	-	-	
Occupation					
Housewife, cooky, general servisse	10 (62.50)	12 (75.00)	-	-	0.35
Peasant	6 (37.50)	4 (25.00)	-	-	
Surgery type					
Mastectomy	11 (68.75)	13 (81.25)	-	-	0.41
Quadrantectomy	5 (31.25)	3 (18.75)	-	-	
Surgery Side					
Right	5 (31.25)	5 (31.25)	-	-	1.00
Left	11 (68.75)	11 (68.75)	-	-	

(To be continued)

(Conclusion)

Table 1 - Personal, clinical and surgical treatment-related characteristics of Active TENS (n = 16) e Placebo TENS (n = 16) groups

Personal, clinical and surgical characteristics	Active TENS / Placebo TENS				*p*
Radiotherapy					
No	5 (31.25)	9 (56.25)	-	-	0.15
Adjuvant/Neoadjuvant	11 (68.75)	7 (43.75)	-	-	
Chemotherapy					
No	1 (6.25)	3 (18.75)	-	-	0.59
Adjuvant/Neoadjuvant	15 (93.75)	13 (81.25)	-	-	
	Mean (±SD)				
Radiotherapy (number sessions)	32.00 (±9.36)	25.71(±6.77)	30 (25/60)	28 (25/60)	0.07
Chemoterapy (number sessions)	7.68 (±6.86)	5.68 (±4.49)	4.5 (0/28)	4 (0/16)	0.54
Lymph nodes removed	14.18 (±5.75)	13.87 (±7.70)	15.5 (5/24)	12 (7/35)	0.26
Lymph nodes committed	1.87 (±3.96)	3.62 (±4.14)	0.5 (0/16)	3 (0/12)	0.24
Time of surgery (months)	21.68 (±21.68)	22.31 (±53.99)	18 (3/36)	7.5 (2/23)	0.25

Note: Mann-Whitney and Chi-square test or Fisher´s exact for quantitative and categorical variables, respectively. There was no significant difference between groups for none of the variables. BMI: Body Mass Index (kg/m^2), kg = kilogram, m = meter.

Intensity of dysesthesia was assessed by using VAS and decreased significantly over 20 sessions in Active TENS group when compared to baseline (p<0.006). No significant decrease was observed in the placebo TENS group (p <0.403). However, there was no difference between placebo and active TENS (Figure 3).

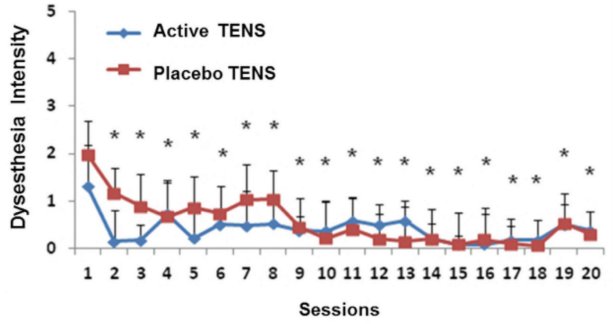

Figure 3 - Intensity of dysesthesia through the treatment sessions. *p<0.005 for active TENS group when compared to session 1.

No difference was observed between groups in relation to generic questions of QOL assessment. In the active TENS group, although significant difference wasn't found, an improvement was observed in the scores of overall health, physical, emotional and social functions after the 20th session, but the same was found in the placebo TENS group (insert Table 2). In the symptom scale, pain scores, dyspnea and insomnia decreased in the Active TENS group and in the Placebo TENS group. Scores of fatigue, nausea and vomiting, pain, constipation and financial difficulties decreased. No significant differences were observed after the 20th session and between the groups.

In specific questions there were no differences between groups or after the 20th session (insert Table 2). In the Active TENS group it was found a mild improvement of all scale scores, unlike the placebo TENS group, which showed worsening of the body image, sex and sexual enjoyment scores. In the scale of symptoms, systemic therapy side effects, breast and arm symptoms decreased the scores in both groups, while hair loss scores increased, but without significant difference.

Table 2 - Quality of life scores of EORTC QLQ-30 of Active TENS (n=16) e Placebo TENS (n=16) groups

EORTC QLQ-C30 Domains	Active TENS			Placebo TENS				
	Session1	Session 20	p	Session1	Session 20	p	p1	p2
Global Health Status	73.87±30.84	74.82±25.30	0.92	69.69±30.58	64.03±16.39	0.06	0.63	0.29
Functional Scales								
PhysicalFunctioning	74.58±14.41	76.25±23.47	0.38	70.83±20.34	84.03±23.47	0.50	0.63	0.41
Role Functioning	81.25±20.06	80.20±28.03	0.95	68.75±36.95	68.75±40.31	0.93	0.57	0.45
Cognitive Functioning	70.83±23.95	68.75±31.54	0.82	61.45±37.86	65.62±36.24	0.53	0.80	0.96
Emotional Functioning	25.43±29.94	34.42±34.42	0.46	33.07±33.07	31.76±31.76	0.11	0.86	0.85
Social Functioning	82.29±25.43	90.62±20.15	0.04	76.04±34.94	92.70±18.22	0.10	0.89	0.77
Symptom Scales								
Fatigue	22.88±25.45	24.65±25.19	0.80	31.11±28.44	29.76±34.26	0.62	0.39	0.72
Nausea and Vomiting	13.52±25.97	14.50±18.09	0.61	14.48±20.94	8.32±21.93	0.39	0.80	0.13
Pain	29.10±33.61	22.82±32.07	0.54	45.65±36.35	30.10±34.57	0.91	0.18	0.25
Dyspnea	12.49±29.49	10.37±26.40	0.89	10.37±29.02	10.41±29.09	1.00	0.77	0.76
Insomnia	39.53±36.95	35.34±39.34	0.68	33.28±43.85	43.71±43.42	0.12	0.48	0.51
AppetiteLoss	12.48±23.93	14.53±27.09	0.68	14.58±34.35	16.64±34.41	0.78	0.85	0.78
Constipation	22.88±33.79	37.45±43.67	0.20	22.80±31.45	14.57±32.11	0.34	0.96	0.16
Diarrhea	2.06±8.25	8.32±19.22	0.28	8.25±14.75	12.47±29.47	0.68	0.36	0.98
Financial Difficulties	31.15±35.36	31.20±42.97	0.86	54.11±45.35	39.53±38.91	0.10	0.13	0.30
EORTC QLQ- BR23 SCALE								
Functional Scales								
Body Image	79.68±22.35	84.89±23.80	0.41	38.87±31.76	32.00±32.18	1.00	0.59	0.32
Sexual Functioning	27.05±27.80	34.30±30.05	0.01	32.58±27.11	23.32±28.98	0.65	0.98	0.66
Sexual Enjoyment	33.30±33.32	42.31±39.65	0.91	28.36±40.81	24.91±35.82	0.79	0.56	0.62
Future Prospects	41.66±41.27	56.25±39.84	0.10	42.80±43.67	42.30±45.49	1.00	0.88	0.63
Symptom Scales								
Sistemic Therapy	33.10±16.11	26.03±18.12	0.14	38.87±29.96	32.00±22.12	0.19	0.98	0.41
Breast Symptoms	23.31±19.94	22.81±20.05	0.87	32.58±27.49	23.32±21.60	0.07	0.31	0.96
Arm Symtoms	32.55±24.49	28.36±23.27	0.47	28.36±18.13	24.91±19.17	0.48	0.65	0.93
Upset By Hair Loss	14.27±26.20	66.50±47.37	0.03	42.80±46.01	83.30±49.98	0.35	0.27	0.63

Note: Values in mean ± SD (standard deviation). There was no significant differences before and after the 20th session (Wilcoxon Matched Pairs Test) and between groups (Mann Whitney test) difference was found; p1: session 1 Active TENS x Placebo TENS; p2: session 20 Active TENS x Placebo TENS.

Discussion

The presence of dysesthesia and other postoperative complications of breast cancer could adversely affect QOL. Thus, the assessment of QOL has been recommended to assess perception patients have about their own disease. In our findings, baseline results from the scales of the quality of life, specific and generic, showed scores similar to baselines of other review studies involving women with breast [20-24].

In the active TENS group, there was a slight but not significant improvement in scores of overall health, physical, emotional and social functions. Regarding specific issues, there was an improvement in active TENS-treated patients and a worsening in placebo TENS group. It is believed that the decrease in dysesthesia intensity may have reflected the improvement in those women who received the active TENS. Since it decreases the discomfort, women might experience a better QOL. However, dysesthesia intensity was not different between groups.

Although the EORTC QLQ-C30 and QLQ-BR-23 are indicated to be used for oncological samples and has a specific module for patients with breast cancer, its domains may be targeted for different situations experienced by cancer patients and couldn't be sufficiently sensible to detect the negative role of dysesthesia on the quality of life of those patients. Thus, it is also possible that the questionnaire used in this study to measure QOL wasn't the most appropriate although it is a golden-standard tool for this proposal. A number of different questionnaires have been used to measure quality of life in breast cancer population, and maybe another questionnaire may better assess this outcome. Recently, Oliveira et al. [25] investigated the measurement properties of two generic (World Health Organization Quality of Life — bref, WHOQOL-bref, and the Medical Outcomes Study 36 — Item Short-Form Health Survey, SF-36) and one specific (Functional Assessment of Cancer Therapy - Breast plus Arm Morbidity, FACT-B+4) quality of life questionnaires for women with breast cancer. The WHOQOL-bref and FACT-B+4 showed adequacy to assess QOL in breast cancer patients in the majority of the properties examined.

Another possible reason for the lack of difference between groups in QOL scores is that the number of sessions may not have been enough to generate significant changes in the QOL [26], or some women were accustomed/adapted to the changes in sensitivity.

It is questioned whether the fact that the patients were subjected to the treatment with TENS in a later phase of NCIB injury and not in an acute phase of recovery would influence our findings. In the early phase after surgeries, there is the neuroplasticity phenomena and perhaps a better response to improve sensory perception can be targeted in this stage of recovery [27]. But active TENS was satisfactory to decrease dysesthesia intensity on the NICB dermatome. This type of sensitivity disturbance, besides being characterized as discomfort, can also be reported by some patients as a painful, burning and or tingling sensation. The use of TENS for dysesthesia management was not found in the available literature, but its analgesic effects on peripheral nerve injuries have been demonstrated in both experimental animal studies [14, 28, 29] and human studies, showing hypoalgesic effects on neuropathic-like pain such as trigeminal neuralgia, herpes zoster, diabetic neuropathy and neuropathic pain of spinal cord injured individuals [10-13].

In some studies, treatment protocols ranged from 10 to 20 applications of active TENS and sensitivity was enhanced, as TENS increased the cutaneous threshold in all of them [6, 9]. Maybe because TENS is an electroanalgesic resource of sensory modality that works directly in the central nervous system by activation of primary Aβ afferent fibers and promotes a reduction in the central nociceptive cell activity [8, 9]. In the clinical practice, the approach of sensory peripheral nerve injuries that have been proposed were dermal desensitization using apparatuses of different textures and temperature applied to ICBN dermatome, but only lymphatic drainage showed positive results to reduce dysesthesia [30, 31].

It was also found that the placebo TENS group decreased the intensity of dysesthesia but without significant difference. The literature suggests that there are positive effects of placebo TENS [32], as this is a part of the overall therapeutic action, beyond the expectation of response, which is the probability of a procedure or agent to promote pain relief. Thus, if the individual has an expectation of pain reduction after administration of placebo treatment, it is sufficient to generate pain relief [32].

Placebo response induced by analgesia expectations activates a number of central chemical mediators such as dopamine and endogenous opioids. The placebo effect is a psychobiological phenomenon characterized by the response of a subject to a substance or procedure known to have no therapeutic effect [12]. The placebo method may affect a wide variety of subjective, behavioral and physiological responses [13] and may be related to an expectation of clinical improvement [14, 16, 18].

There's a growing interest in the study of placebo effects. The study of this effect reflects current thinking in neuroscience, the idea that subjective constructions as expectations have identifiable physiological bases which are powerful modulators at motor, perceptual and homeostatic processes level [14].

Different expectations promote several analgesic effects, which can be used in clinical practice [20], such as the possibility of achieving

favorable pharmacological effects without the intake of drugs [21]. Pharmacological studies revealed that placebo analgesia was shown to be influenced by the type of expectation given for pain relief [20, 22, 23]. Motor responses seem to be mediated by verbally induced expectations. Furthermore, expectations that induce analgesia or hyperalgesia influence the relief or increase of pain, respectively [24]. It is believed that conscious physiological processes, such as pain and motor performance, are mediated by the expectation, however, unconscious physiological functions, such as hormone secretion is mediated by placebo [14].

Although no differences between the groups were observed, the effects of TENS on peripheral nerve injuries should be valued. Given that breast cancer is the most common in the female population, many women will undergo surgical procedures and may have alterations on sensitivity with the symptom of ICBN dermatome dysesthesia, the use of active TENS may represent a therapeutic option. This study is the first to suggest the use of TENS in this patient profile and this may represent a tool to relieve this discomfort [30].

Although the use of TENS did not bring additional effects on the QOL, it highlights the importance of evaluating it in clinical practice as it assists in the development of therapeutic strategies for the physical and functional complications.

Conclusion

Although not different from placebo, according to the methods used in the research, TENS could decrease dysesthesia intensity in the ICBN dermatome after breast cancer surgery, but did not improve the quality of life. Placebo effects might have been potentialized by the method use, which includes a brief active stimulation. These results may help clinicians and researchers in approaching oncology patients who have such altered cutaneous sensitivity. However, new protocols or different types of therapeutic electric currents can be employed in the search for positive repercussions on quality of life, since the physical and sensory functionality of the limb is important for women to perform their daily activities.

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