

# Intra-hospital physical therapy for patients with critical lower limb ischaemia: an expert consensus

Fisioterapia intra-hospitalar para pacientes com isquemia crítica de membro inferior: consenso de especialistas

Fisioterapia intrahospitalaria para pacientes con isquemia crítica de miembro inferior: consenso de especialistas

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ABSTRACT | Critical limb ischemia (CLI) is a disease with a great burden for the healthcare system, patient's functionality and quality of life. However, there is little evidence to guide intrahospital physical therapy programs for patients with CLI. Thus, this study aimed to provide an expert consensus on intrahospital physiotherapeutic care for CLI patients. An expert panel was made up with 18 experienced physical therapists, which represented 85.7% of physical therapists from a reference vascular surgery team in a university hospital. The Delphi method was used to produce a consensus, considering a minimum agreement of 70% and a mean or median score in the Likert scale ∝3.1. The questionnaires included items related to assessment, goals and physiotherapeutic interventions prior and after revascularization. A consensus was reached on assessing symptoms, cognitive, articular, musculoskeletal and cardiorespiratory functions. Pain control, edema drainage, range of motion gain, walking incentive and health education are goals in the pre-operatory and the muscular strengthening in postoperatory phase. In both phases there was a consensus on the use of passive, active-assisted and active exercises, including upper limb exercises. Walking and therapeutic education are essential during the hospitalization period with offloading practices in area of plantar ulcer.

Electroanalgesia should be used in preoperative phase and resisted exercises and lower limb elevation at postoperatory. **Keywords** | Peripheral Arterial Disease; Ischemia; Lower Extremity; Rehabilitation; Consensus.

RESUMO | A isquemia crítica de membro inferior (ICMI) impacta os sistemas de saúde e a qualidade de vida e funcionalidade dos indivíduos diagnosticados. Entretanto, há pouca evidência científica que fundamente a intervenção fisioterapêutica para pacientes internados ICMI. O objetivo desse estudo foi elaborar um consenso de especialistas sobre a fisioterapia intra-hospitalar para pacientes com ICMI. Para isso, foi utilizado o método Delphi. Um painel de especialistas foi formado por 18 fisioterapeutas que representavam 85,7% da equipe de um hospital de referência em cirurgia vascular. Foram consideradas, para o consenso, as respostas com valor mínimo de concordância de 70% e média ou mediana ∝3,1 na escala Likert. Os questionários abordaram itens de avaliação, objetivos e condutas fisioterapêuticas nas fases pré e pós-cirurgia de revascularização. Definiram-se como itens essenciais a avaliação de sintomas e as funções cognitiva, musculoesquelética e cardiorrespiratória. No pré-operatório, controle da dor, redução de edemas,

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ganho de amplitude de movimento, deambulação e educação em saúde são os objetivos; na fase pós-operatória, o ganho de força muscular. Exercícios passivo, assistido, ativo livre e circulatório, incluindo os membros superiores, são indicados antes e após as cirurgias. Educação em saúde e deambulação com redução de peso em área de lesão plantar são essenciais em todo o período de internação. A eletroanalgesia foi preconizada no pré-operatório; e, no pós-operatório, elevação do membro inferior e exercícios resistidos.

**Descritores** | Doença Arterial Periférica; Isquemia; Extremidade Inferior; Reabilitação; Consenso.

**RESUMEN |** La isquemia crítica de miembro inferior (ICMI) afecta a los sistemas de salud y la calidad de vida y funcionalidad de los individuos diagnosticados. Sin embargo, hay poca evidencia científica que fundamente la intervención fisioterapéutica para pacientes internados por ICMI. El objetivo de este estudio fue elaborar un consenso de especialistas sobre la fisioterapia intrahospitalaria para pacientes con ICMI. Para ello, se utilizó el método Delphi. Se formó

un panel de expertos con 18 fisioterapeutas que representaban el 85,7% del equipo de un hospital de referencia en cirugía vascular. Se consideraron, para el consenso, las respuestas con un valor mínimo de concordancia del 70% y media o mediana ∞3,1 en la escala Likert. Los cuestionarios abordaron ítems de evaluación, objetivos y conductas fisioterapéuticas en las fases pre y poscirugía de revascularización. Se definieron como elementos esenciales la evaluación de síntomas y las funciones cognitiva, musculoesquelética y cardiorrespiratoria. En el preoperatorio, control del dolor, reducción de edemas, ganancia de amplitud de movimiento, deambulación y educación en salud son los objetivos; en la fase posoperatoria, la ganancia de fuerza muscular. Los ejercicios pasivos, asistidos, activos libres y circulatorios, incluidos los miembros superiores, se indican antes y después de las cirugías. La educación en salud y la deambulación con reducción de peso en el área de lesión plantar son esenciales en todo el período de internación. La electroanalgesia fue preconizada en el preoperatorio; y, en el postoperatorio, elevación del miembro inferior y ejercicios resistidos. Palabras clave | Enfermedad Arterial Periférica; Isquemia; Extremidad Inferior: Rehabilitación: Consenso

### **INTRODUCTION**

Critical lower limb ischemia (CLI) is a manifestation of peripheral arterial disease (PAD) caused by a critical reduction of blood flow to the lower limb (LL) tissues, with a risk of amputation if LL is not revascularized<sup>1,2</sup>.

Hospitalizations related to vascular diseases generate significant expenditures for health systems<sup>3</sup>. In addition, the ischemic pain resulting from CLI causes important functional and psychic repercussions. Patients with CLI frequently present sleep and walking performance impairment, or even inability to walk<sup>1,4</sup>. The progressive ischemic process can also generate ischemic lesion and loss of muscle strength, which, if combined and untreated, can increase the impact on functionality<sup>1,5</sup>.

Approaches in CLI include conservative management, LL revascularization or amputation<sup>1</sup>. Considering the physical, psychic and functional repercussions of CLI, these patients should be approached by a multidisciplinary team during hospitalization periods<sup>4</sup>. However, there is no evidence of physical therapy intervention in this context. In such situations, the clinical practice of professionals can be guided by consensus built from the opinion of specialists<sup>6</sup>. Therefore, this study proposed to establish a consensus of specialists directed to in-hospital physical

therapy care for patients with CLI, pre- and post- LL revascularization.

### **METHODOLOGY**

To obtain the consensus, the Delphi method was used, a technique that applies questionnaires in rounds to organize, consensually, the opinion of a panel of specialists for clinical decision-making<sup>6</sup>. In the literature, the criteria of agreement considered to be satisfactory for obtaining the consensus vary between 50% and 80%7,8. As a criterion for the selection of panel members, a minimum of 15 specialists with qualification and experience in the field under consideration is required<sup>6,9</sup>. To form the expert panel of this study, we selected physical therapists with experience in approaching individuals with CLI, evidenced by monthly care of at least ten patients. The professionals were recruited at a vascular surgery unit of a teaching hospital in Belo Horizonte, Brazil. The study obtained ethical approval (CAAE 44000215.4.0000.5149) and followed the regulatory norms of research involving humans.

The results of each round indicated the agreed items and the level of agreement, which were formulated in guidelines for preoperative care and for patients successfully submitted to revascularization, considered as LL rescue and improvement of clinical symptoms and of local hemodynamics of  $\geq 0.10$  in the ankle-brachial index (ABI) or isolated improvement of  $\geq 0.15$  in ABI<sup>1</sup>.

According to the data and suggestions obtained in the first questionnaire, new questions were elaborated to refine the opinions in the subsequent round, exploring the concordant responses of the first round<sup>6</sup>.

After the second round, all participants were invited for a presentation and discussion of the results, and a third questionnaire was developed to establish the goals of the physical therapy treatment and relevant items of assessment.

The values of mean and standard deviation or median were calculated, providing the measure of dispersion and indication of the consensus degree. In the first and second rounds, a minimum of 70% agreement was determined on the participants' responses for reaching a consensus. Items

that reached between 50% and 70% were better explored in the subsequent round, and those with less than 50% were excluded<sup>7</sup>. In the third round, participants answered questions using the Likert scale with values between 1 and 5 to assess the level of agreement, 5 being the indicative of complete agreement, and 1 of complete discordance. To conclude the consensus, the results with mean or median  $\geq 3.1^9$  were considered.

## **RESULTS**

Of the 21 eligible experts, one did not respond to the invitation and two refused to participate, resulting in 18 participants for the three rounds of questionnaire. The final result, after three rounds of questionnaires, is presented in Table 1, in a mean or median score.

Table 1. Final result of the experts consensus

PREOPERATIVE PHASE	Mean/median*	Standard deviation
1. Evaluation Items		
(a) Symptoms	4.83	0.38
(b) Cognitive function	4.39	0.78
(c) Joint function	4.56	0.51
(d) Muscle function	4.56	0.51
(e) Cardiac function	4.94	0.23
(f) Respiratory function	4.78	0.55
(g) Functional mobility	4.89	0.32
2. Goals		
(a) Pain control	4.11	0.96
(b) Drainage of lower limb edema, if existing	3.50*	-
(c) Range of motion gain, if there is any restriction	3.50*	-
(d) Incentive to walking	3.50*	-
(e) Health education	4.83	0.38
(f) Muscle strengthening	2.50*	-
3. Conduct		
(a) Eletroanalgesia	4.00*	-
(b) Elevation of lower limb, if there is edema	1.00*	-
(c) Passive exercise	3.94	0.94
(d) Active-assisted exercise	3.72	1.13
(e) Active exercise	4.11	0.68
(f) Resisted exercise	2.17	1.04
(g) Exercises with the upper limbs	4.50	0.51
(h) Respiratory exercise	4.61	0.50
(i) Circulatory exercise	4.00	1.28
4. Incentive to walking in the patient with plantar trophic ulcer		
(a) Without walking-assist device	1.39	0.70
(b) With walking-assist device and pressure relief in the ulcer	4.00	1.19

(continues)

Table 1. Continuation

POSTOPERATIVE PHASE	Mean/median*	Standard deviation
1. Evaluation Items		
(a) Symptoms	5.00	0
(b) Cognitive function	4.67	0.49
(c) Joint function	4.94	0.24
(d) Muscle function	4.89	0.32
(e) Cardiac function	4.94	0.24
(f) Respiratory function	4.78	0.55
(g) Functional mobility	5.00	0
2. Goals		
(a) Pain control	4.11	0.76
(b) Drainage of lower limb edema, if existing	4.06	0.87
(c) Range of motion gain, if there is any restriction	4.50	0.51
(d) Incentive to walking	4.61	0.50
(e) Health education	4.83	0.38
(f) Muscle strengthening	4.39	0.78
3. Conduct		
(a) Eletroanalgesia	3.00*	-
(b) Elevation of lower limb, if there is edema	4.33	0.77
(c) Passive exercise	4.00	0.84
(d) Active-assisted exercise	4.28	0.57
(e) Active exercise	4.61	0.50
(f) Resisted exercise	4.39	0.50
(g) Exercise with the upper limbs	4.61	0.50
(h) Respiratory exercise	4.67	0.48
(i) Circulatory exercise	4.61	0.50
4. Incentive to walking in the patient with plantar trophic ulcer		
(a) Without walking-assist device	1.44	0.62
(b) With walking-assist device and pressure relief in the ulcer	3.38	1.33

Final result of the rounds of questionnaires with the values that obtained or not the consensus according to the panel of experts. The values presented correspond to the Likert scale, ranging from 1 to 5 Results were obtained with mean or median <a.1.\* Values shown in median.

There was consensus in evaluating symptoms, cognitive, articular, muscular, cardiorespiratory function and patient mobility. Regarding the goals, there was consensus for both phases in pain controlling, LL edema draining and ROM improving, besides stimulating walking and conducting therapeutic education. In the postoperative phase, the muscular strength gain was added.

There was consensus for the use of Transcutaneous Electrical Nerve Stimulation (TENS) and contraindication for the LL positioning in elevation pre-surgery. Passive, active-assisted, active and circulatory exercises, besides exercises with upper limbs, are indicated before the surgeries while resisted exercise is contraindicated. Health education and walking incentivation are essential throughout the hospital stay. The use of walking-assist device and offloading devices are recommended for individuals with plantar ulcer.

### **DISCUSSION**

After three rounds of questionnaires, a consensus was drawn up based on the opinion of an experts panel. This novel study should assist physical therapists in managing in-hospital rehabilitation for patients with CLI prior and after LL revascularization.

The panel indicated as relevant the evaluation of symptoms, cognitive, musculoskeletal, cardiorespiratory functions and trophic ulcers in the LL in all phases of the treatment. Assessing ischemic pain is important due to its relevance in the CLI and to consider the response to therapeutic approaches<sup>1</sup>. On the other hand, the evaluation of cognitive function allows us to track and identify some degree of dysfunction, frequently accentuated in the hospital picture. This is particularly important for health education actions<sup>10</sup>. In the musculoskeletal assessment, specialists pointed out the need to evaluate ROM, muscle strength and functional mobility. The CLI is followed by changes in morphology and muscle function<sup>5</sup>, leading to

important functional losses, especially in walking, and which tends to worsen during hospitalization, especially in older people, in which CLI prevalence is greater<sup>1,11</sup>. Regarding ambulation, it is important to point out that patients with CLI present a critical restriction of blood flow to the lower limbs and ischemic pain even at rest<sup>1</sup>, therefore, it is not appropriate to use the walking tests to assess functional capacity, especially in patients undergoing analgesia<sup>12</sup>. No parameters were found in the literature to assess functional capacity in these cases. After revascularization, walking tests can be performed as long as the tissue perfusion improvement in the LL is confirmed<sup>1</sup>.

A detailed assessment of possible cardiorespiratory diseases and risk stratification of patients should be performed for safe rehabilitation with exercises. In addition to the evaluation, the hemodynamic response to exercise should be monitored in the physical therapy sessions, especially in those with indication for using a WAD1. In fact, its prescription should be made considering the multimorbidities and the oxygen consumption by the myocardium. A study considering cardiovascular response, effort perception and oxygen consumption observed that disctint type of WAD affect the latter differently during walking<sup>13</sup>. Finally, regarding the items to be evaluated, if there are trophic ulcers, it is important to identify its location to guide the professional's decision on whether to allow weight bearing during walking so as not to impair the healing process<sup>14</sup>.

Treatment goals and behaviors were defined according to the treatment phase. The control of ischemic pain is important mainly before revascularization, when it is more limiting<sup>1</sup>. In the literature, studies using TENS for electroanalgesia have found results to reduce ischemic pain. However, only one of these studies used TENS in CLI, resulting in inconclusive efficacy of this resource<sup>15</sup>. Also due to ischemic pain, these patients often assume antalgic positions with the LLs pending, which can lead to edema formation. In the preoperative, specialists contraindicated LL elevation because it led to even greater reduction of blood flow and increased pain1. Kawasaki et al.<sup>16</sup> evaluated different placements and the degree of tissue perfusion of LL in patients with CLI, suggesting that alternate periods of sedestation and decubitus are within the rehabilitation program to aid in pain control and prevent edema in LLs<sup>16</sup>. Postoperatively, LL elevation may be performed if revascularization is successful<sup>1</sup>. In addition, maintenance of complete ankle

ROM is important for proper functioning of the leg muscles as efficient blood propulsor, preventing edema formation<sup>17</sup>.

Kinesiotherapy and walking in the preoperative phase aim to maintain the functional status of the patient with preservation of muscular strength, tissue elasticity and muscular trophism, until the surgical intervention occurs. According to the consensus, the passive, active-assisted, active and circulatory exercises can be performed, but the gain of muscle strength should not be among the goals of the rehabilitation in the preoperative phase. While there is no correction of the low blood supply by the LL revascularization, exercises that excessively increase the muscular demand for oxygen may aggravate the ischemic process<sup>1</sup>. In the postoperative phase, experts agreed that a muscle-strengthening program may bring benefits to patients with PAD. According to Pereira and collaborators<sup>18</sup>, there is a strong correlation between the muscular strength of the LL and the functional performance of patients with PAD. Still in relation to kinesiotherapy, Zwierska and collaborators19 found that the exercises with the upper limbs, through a cycloergometer, improved the walking performance of patients with PAD, being an alternative for patients who do not tolerate LL movement due to ischemic pain. The incentive to walking and educational actions should be among the rehabilitation goals in the preoperative phase, according to the consensus. It is important to preserve walking capacity in those patients who walk, using as a parameter the distance walked by the patient prior to hospitalization. The level of mobility of patients with CLI prior to LL revascularization surgery is a predictor of post-surgical hospital stay and mobility after 1 year of hospital discharge<sup>11</sup>. After revascularization, an increase in walking distance is expected1. Studies performed at this stage demonstrated the benefits of supervised training in increasing the maximum distance walked by patients.

Considering the presence of plantar ulcers, the use of orthoses and WAD, especially in patients with diabetic neuropathy, is recommended by an international guideline to assist in the healing process, however, its prescription should be made according to the characteristics of each patient<sup>14</sup>.

Health education for patients and their families should be part of the treatment plan to help change lifestyle and control modifiable risk factors, in order to postpone new hospitalizations and provide a better quality of life for the patient<sup>1,3</sup>.

Among the limitations of the expert consensus is the study design, which is at the base of the hierarchy of scientific evidence<sup>22</sup>. However, it is understood that this is the starting point for higher level scientific evidence to be carried out. It is desirable that protocols developed from this consensus are evaluated in randomized clinical trials, considering training parameters and their long-term effects<sup>23</sup>.

## **CONCLUSION**

The evaluation of symptoms, cognitive, musculoskeletal and cardiorespiratory function were defined as essential items. Pain control, edema reduction, range of motion gain, walking incentivation and health education are preoperative goals and muscle strengthening in the postoperative phase. Passive, active-assisted, active and circulatory exercises, besides exercises with upper limbs, are indicated before the revascularization, while resisted exercise is contraindicated. Walking and health education are essential throughout the hospitalization period, with reduction of weight bearing in the area of plantar ulcer. Electroanalgesia was recommended in the preoperative period, and elevation of the lower limb and resisted exercises in the postoperative period.

This consensus may assist physical therapists in the management of in-hospital rehabilitation protocols for patients with CLI pre- and post- LL revascularization.

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