## Use of photobiomodulation for the treatment of lymphedema after mastectomy: a randomized controlled clinical trial protocol.

**Luir Ruaro Filho1, Beatriz Nascimento Motta2, Adriana Lino dos Santos Franco3, Maria Fernanda Setúbal Destro Rodrigues3 and Rebeca Boltes Cecatto4.**

1. Postgraduate Program in Biophotonics Applied to Health Sciences, Universidade Nove de Julho/UNINOVE, 249 Vergueiro Street, Liberdade, São Paulo, SP, 01504-001, Brazil;
2. Medical Student, School of Medicine of Universidade Nove de Julho UNINOVE, 249 Vergueiro Street, Liberdade, São Paulo, SP, 01504-001, Brazil;
3. Ph.D. Postgraduate Program in Biophotonics Applied to Health Sciences, Universidade Nove de Julho/UNINOVE, 249 Vergueiro Street, Liberdade, São Paulo, SP, 01504-001, Brazil;
4. Ph.D. Postgraduate Program in Biophotonics Applied to Health Sciences, Universidade Nove de Julho/UNINOVE, 249 Vergueiro Street, Liberdade, São Paulo, SP, 01504-001, Brazil and Rehabilitation Service of the Instituto do Câncer do Estado de Sao Paulo School of Medicine of the University of Sao Paulo, Sao Paulo, 01246-903, Brazil;

Lymphedema is a complication of breast cancer treatment characterized by swelling of the upper limb. Photobiomodulation (PBM) may be an option in the treatment of lymphedema after mastectomy for breast cancer. However, the level of evidence is uncertain due to the scarcity of studies designed with equivalent parameters. The objective of this study will be to evaluate whether PBM is able to reduce lymphedema, improve manual function and improve the quality of life of patients with lymphedema after mastectomy for breast cancer. This study will be double blind, randomized and controlled. Participants with lymphedema after mastectomy for breast cancer will be randomized at two groups. The treatment group will use the Institution's standard protocol for lymphedema (complete decongestive therapy) plus laser treatment at wavelength 850 nm, power 5 mW and radiant exposure 1.5 J/cm2. The control group will receive the Institution's standard protocol for lymphedema plus placebo laser treatment, all of both groups with 20 minutes sessions twice a week and duration of 12 sessions. It was estimated that 57 patients should be included per group in a total of 114 participants. Demographic data, quality of life, analogue pain scale, limb perimetry and manual function will be analyzed. Follow-up sessions will be performed at four and twelve weeks after first therapeutic session. Descriptive analyzes will consider all variables: quantitative (mean and standard deviation) and qualitative (frequencies and percentages). All statistical tests will adopt the 5% significance level. The SAS for Windows program, version 9.1 will be used. The data will be statistically analyzed and the results reported and discussed.

Keywords: photobiomodulation, breast cancer and lymphedema.

Biography:

Graduated in Medicine from the State University of West Paraná (2003). He participated for four years in the scientific initiation. He completed his medical residency in gynecology and obstetrics in São Paulo (SP) at Ipiranga Hospital in 2010. In the same year, he began his master's degree in obstetrics at Hospital das Clínicas, Faculty of Medicine, University of São Paulo. Completion of the master's degree in 2013. He works as preceptor in the medical residency of Gynecology and Obstetrics at Ipiranga Hospital since 2012. Professor at Nove de Julho University in the Medicine course and doctoral student of the postgraduate degree in biophotonics applied to health sciences at the same University.

References

|  |  |
| --- | --- |
| 1 | Almeida LAA e col. Terapia Física complexa no Câncer de Mama. Procedimentos Instituto do Câncer do Estado de São Paulo. FMUSP. Setor de Reabilitação – Fisioterapia. Set 2020.. |
| 2 | Almeida LLA e col. Perimetria de membros. Procedimentos Instituo do Câncer do Estado de São Paulo. FMUSP. Setor de Reabilitação - Fisioterapia. Abril 2020. |
| 3 | Baxter GD, Liu L, Petrich S, et al. Low level laser therapy (photobiomodulation therapy) for breast cancer-related lymphedema: A systematic review. BMC Cancer 2017;17(1): 833. |
| 4 | Baxter GD, Liu L, Tumilty S, Petrich S, Chapple C, Anders JJ. Low Level Laser Therapy for the Management of Breast Cancer-Related Lymphedema: A Randomized Controlled Feasibility Study. Lasers in Surgery and Medicine. 2018; 50:924–932. |
| 5 | Bjordal JM, Johnson MI, Iversen V, et al. Low-level laser therapy in acute pain: a systematic review of possible mechanisms of action and clinical effects in randomized placebo-controlled trials. Photomed Laser Surg. 2006;24(2):158–168.. |
| 6 | Camargo MC, Marx AG. Reabilitação Física no Câncer de Mama. 1a ed. São Paulo: Roca; 2000. |
| 7 | Carati, Colin J et al. “Treatment of postmastectomy lymphedema with low-level laser therapy: a double blind, placebo-controlled trial.” Cancer vol. 98,6 (2003): 1114-22. doi:10.1002/cncr.11641. |
| 8 | Ciconelli RM. Tradução para o português e validação do questionário genérico de avaliação de qualidade de vida “Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)”. São Paulo, 1997. |
| 9 | Dirican A. et al. The short-term effects of low-level laser therapy in the management of breast-cancer-related lymphedema. Support Care Cancer (2011) 19:685–690. |
| 10 | DiSipio T, Rye S, Newman B, et al. Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. Lancet Oncol. 2013;14(6):500–515.. |
| 11 | DiSipio T, Rye S, Newman B, Hayes S (2013) Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. Lancet Oncol 14:500–515.. |
| 12 | E Lima JGM, de Andrade MFC, Bergmann A. Low-level laser therapy in secondary lymphedema after breast cancer: systematic review. Lasers Med Sci. 2014;29(3):1289–1295.. |
| 13 | Geigle R, Jones JB. Outcomes measurement. A report from the front. Inquiry, 27: 7-13, 1990. |
| 14 | H.-Y. Chen, et al. Effects of photobiomodualtion therapy on breast cancer-related lymphoedema: A systematic review and meta-analysis of randomized controlled trials. Complementary Therapies in Medicine 47. 2019; 102200. |
| 15 | https://www.inca.gov.br/tipos-de-cancer/cancer-de-mama (2021 - INCA). |
| 16 | Hwang JM, Hwang JH, Kim TW, Lee SY, Chang HJ, Chu IH (2013) Long-term effects of complex decongestive therapy in breast cancer patients with arm lymphedema after axillary dissection. Ann Rehabil Med 37:690–697.. |
| 17 | Instituto Nacional de Câncer (INCA). Normas e recomendações do Ministério da Saúde: controle do câncer de mama – documento de consenso. Rev Bras Cancerol. 2004;50(2):77–90. |
| 18 | International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology. Lymphology. 2003;36(2):84–91.. |
| 19 | Kärki A, Simonen R, Mälkiä E, et al. Impairments, activity limitations and participation restrictions 6 and 12 months after breast cancer operation. J Rehabil Med. 2005;37(3):180–188. |
| 20 | Kaviani A, Fateh M, Yousefi Nooraie R, Alinagi-zadeh MR, Ataie-Fashtami L. Low-level laser therapy in management of postmastectomy lymphedema. Lasers Med Sci. 2006;21(2):90-94. doi:10.1007/s10103-006-0380-3. |
| 21 | Kilmartin L et al. Complementary low-level laser therapy for breast cancer-related lymphedema: a pilot, double-blind, randomized, placebo-controlled study. Lasers Med Sci (2020) 35:95–105. |
| 22 | Klausner, Guillaume et al. Clinical use of photobiomodulation as a supportive care during radiation therapy. Supportive Care in Cancer. Springer-Verlag GmbH Germany, part of Springer Nature; 2021.. |
| 23 | Kozanoglu E. et al. Efficacy of pneumatic compression and low-level laser therapy in the treatment of postmastectomy lymphoedema: a randomized controlled trial. Clinical Rehabilitation 2009; 23: 117–124. |
| 24 | Kuhnke E. Volumenbestimmung aus Umfangsmessungen. Folia Angiologica 1976;24:228–232. |
| 25 | Lau RWL. et al. Managing Postmastectomy Lymphedema with Low-Level Laser Therapy. Photomedicine and Laser Surgery Volume 27, Number 5, 2009. |
| 26 | Leal NFBS, Carrara HHA, Vieira KF, Ferreira CHJ. Tratamentos fisioterapêuticos para o linfedema pós-câncer de mama: uma revisão de literatura. Rev Lat Am Enfermagem. 2009;17(5):730–6. |
| 27 | Li K et al. Far infrared ray (FIR) therapy: An effective and oncological safe treatment modality for breast cancer related lymphedema. Journal of Photochemistry & Photobiology, B: Biology 172 (2017) 95–101. |
| 28 | Li L, Yuan L, Chen X, et al. Current treatments for breast cancer-related lymphoedema: a systematic review. Asian Pac J Cancer Prev. 2016;17(11):4875–4883.. |
| 29 | Liao SF. Lymphedema Characteristics and the Efficacy of complex Decongestive Phisiotherapy in Malignant ymphedema. Am J Hosp Palliat Care 2016 Aug;33(7):633-7.. |
| 30 | LL Campanholi, JMT Baiocchi, FP Mansani – Mastology. Use of compression garment in the treatment of malignant lymphedema in a patient with recurrent breast cancer: case report. Mastology, 2019;29(1):47-51. |
| 31 | Maiya AG, Olivia ED, Dibya A. Effect of low energy laser therapy in the management of post-mastectomy lymphoedema. Physiotherapy Singapore. 2008 Mar 1;11(1):2-5. |
| 32 | Martinez JR. Análise da aplicabilidade de três instrumentos de avaliação de dor em distintas unidades de atendimento: ambulatório, enfermaria e urgência. Rev Bras Reumatol. 2011;51(4):299-308. |
| 33 | McHorney, C.A e col. The MOS 36-Item Short-Form Health Survey (SF-36): III. Tests of Data Quality, Scaling Assumptions and Reliability Across diverse patient groups. Med Care, 32; 40-60,1994. |
| 34 | Moseley AL, Carati CJ, Piller NB. A systematic review of common conservative therapies for arm lymphoedema secondary to breast cancer treatment. Ann Oncol. 2006;18(4):639–646. |
| 35 | Omar MTA. Treatment of Post-Mastectomy Lymphedema with Laser Therapy: Double Blind Placebo Control Randomized Study. Journal of Surgical Research 165, 82–90 (2011) doi:10.1016/j.jss.2010.03.050. |
| 36 | Panobianco MS, Mamede MV. Complicações e intercorrências associadas ao edema de braço nos três primeiros meses pós mastectomia. Rev Lat Am Enfermagem. 2002;10(4):544–51.. |
| 37 | Piller NB, Thelander A. Treating Chronic Post-Mastectomy Lymphoedema With Low Level Laser Therapy: A Cost Effective Strategy To Reduce Severity and Improve the Quality of Survival. LASER THERAPY. 1995;7(4):163-168.. |
| 38 | Piller, N B, and A Thelander. “Treatment of chronic postmastectomy lymphedema with low level laser therapy: a 2.5 year follow-up.” Lymphology vol. 31,2 (1998): 74-86.. |
| 39 | Posten W, Wrone DA, Dover JS, et al. Low‐level laser therapy for wound healing:mechanism and efficacy. Dermatol Surg. 2005;31(3):334–340.. |
| 40 | Rezende LF, Rocha AVR, Gomes CS. Avaliação dos fatores de risco no linfedema pós-tratamento de câncer de mama. J Vasc Bras. 2010;9(4):233–8.. |
| 41 | Rinder SH, Poage-Hooper E, Kanar C, et al. A pilot randomized trial evaluating lowlevel laser therapy as an alternative treatment to manual lymphatic drainage for breast cancer-related lymphedema. Oncol Nurs Forum. 2013;40(4):383–393.. |
| 42 | Siegel, R.L.; Miller, K.D.; Jemal, A. Cancer statistics, 2020. CA Cancer J. Clin. 2020, 70, 7–30. |
| 43 | Smoot B, Chiavola-Larson L, Lee J, Manibusan H, Allen DD (2015) Effect of low-level laser therapy on pain and swelling in women with breast cancer-related lymphedema: a systematic review and meta-analysis. J Cancer Surviv 9:287–304.. |
| 44 | Stanton AW, Badger C, Sitzia J. Noninvasive assessment of the lymphedematous limb. Lymphology 2000; 33: 122–135. |
| 45 | Stanton AW, Modi S, Mellor RH, et al. Recent advances in breast cancer-related lymphedema of the arm: lymphatic pump failure and predisposing factors. Lymphat Res Biol. 2009;7(1):29–45.. |
| 46 | Storz MA, Gronwald B, Gottschling S, et al. Photobiomodulation therapy in breast cancer‐related lymphedema: a randomized placebo‐controlled trial. Photodermatol Photoimmunol Photomed. 2017;33(1):32–40.. |
| 47 | Warren AG, Brorson H, Borud LJ, et al. Lymphedema: a comprehensive review. Ann Plast Surg. 2007;59(4):464–472.. |