PAXMAN
PIONEERS IN SCALP COOLING

USO DA TOUCA INGLESA PAXMAN FAZ PARTE DO GUIDELINE MÉDICO PARA TRATAMENTO DE CÂNCER DE MAMA

A **Touca Inglesa**, sistema pioneiro em crioterapia capilar e líder global no segmento, faz parte das Diretrizes de Prática Clínica em Oncologia da **NATIONAL COMPREHENSIVE CANCER NETWORK – NCCN** para pacientes que vão iniciar o tratamento para câncer de mama. A inclusão foi publicada na atualização 2019.1 da NCCN, após a Paxman submeter o estudo que deu origem à certificação da FDA realizada no MD Anderson, Baylor College, Cleveland Clinic and Memorial Sloan Kettering, entre outros.

National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2019
Invasive Breast Cancer
NCCN Evidence Blocks™

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Discussion

PREOPERATIVE/ADJUVANT THERAPY REGIMENS[a,b,c,d,e,f]

HER2-Positive[j]

Preferred regimens:

- **AC followed by T + trastuzumab[k] (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab, various schedules)**
- **AC followed by T + trastuzumab + pertuzumab[k] (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab plus pertuzumab)**
- **Paclitaxel + trastuzumab[l]**
- **TCH (docetaxel/carboplatin/trastuzumab)**
- **TCH (docetaxel/carboplatin/trastuzumab) + pertuzumab**
- **If no residual disease after preoperative therapy or no preoperative therapy: Complete up to one year of HER2-targeted therapy with trastuzumab (category 1) ± pertuzumab.[m]**
- **If residual disease after preoperative therapy: Ado-trastuzumab emtansine (category 1) alone[n] If ado-trastuzumab emtansine discontinued for toxicity, then trastuzumab (category 1) ± pertuzumab to complete one year of therapy.[m]**

Useful in certain circumstances:

- **Docetaxel + cyclophosphamide + trastuzumab**

Other recommended regimens:

- **AC followed by docetaxel + trastuzumab[k] (doxorubicin/cyclophosphamide followed by docetaxel plus trastuzumab)**
- **AC followed by docetaxel + trastuzumab + pertuzumab[k] (doxorubicin/cyclophosphamide followed by docetaxel plus trastuzumab plus pertuzumab)**

See Evidence Blocks on BINV-L (EB-2)

[a] Retrospective evidence suggests that anthracycline-based chemotherapy regimens may be superior to non–anthracycline-based regimens in patients with HER2-positive tumors.
[b] Randomized clinical trials demonstrate that the addition of a taxane to anthracycline-based chemotherapy provides an improved outcome.
[c] CMF and radiation therapy may be given concurrently, or the CMF may be given first. All other chemotherapy regimens should be given prior to radiotherapy.
[d] Chemotherapy and endocrine therapy used as adjuvant therapy should be given sequentially with endocrine therapy following chemotherapy.
[e] Albumin-bound paclitaxel may be substituted for paclitaxel or docetaxel due to medical necessity (ie, hypersensitivity reaction). If substituted for weekly paclitaxel or docetaxel, then the weekly dose of nab-paclitaxel should not exceed 125 mg/m^2.
[f] Consider scalp cooling to reduce incidence of chemotherapy-induced alopecia for patients receiving chemotherapy. Results may be less effective with anthracycline-containing regimens.
[j] Trastuzumab and hyaluronidase-oysk injection for subcutaneous use may be substituted for trastuzumab. It has different dosage and administration instructions compared to intravenous trastuzumab. Do not substitute trastuzumab and hyaluronidase-oysk for or with ado-trastuzumab emtansine.
[k] Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided.
[l] Paclitaxel + trastuzumab may be considered for patients with low-risk T1,N0,M0, HER2-positive disease, particularly those not eligible for other standard adjuvant regimens due to comorbidities.
[m] Consider extended adjuvant neratinib following adjuvant trastuzumab-containing therapy for patients with HR-positive, HER2-positive disease with a perceived high risk of recurrence. The benefit or toxicities associated with extended neratinib in patients who have received pertuzumab or ado-trastuzumab emtansine is unknown.
[n] Ado-trastuzumab emtansine 3.6 mg/kg cycled every 21 days for 14 cycles. von Minckwitz G, Huang C, Mano M, et al. Trastuzumab emtansine for residual invasive HER2-positive breast cancer. N Engl J Med 2019;380:617-628.

Note: For more information regarding the categories and definitions used for the NCCN Evidence Blocks™, see page EB-1.
All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

Continued

[f] Consider scalp cooling to reduce incidence of chemotherapy-induced alopecia for patients receiving chemotherapy. Results may be less effective with anthracycline-containing regimens.

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FDA APROVADO

ESTUDO REALIZADO NOS ESTADOS UNIDOS QUE FOI PUBLICADO NA REVISTA JAMA E LEVOU À CERTIFICAÇÃO DA FDA E INCLUSÃO NOS GUIDELINES DO NCCN

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Effect of a Scalp Cooling Device on Alopecia in Women Undergoing Chemotherapy for Breast Cancer

The SCALP Randomized Clinical Trial

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IMPORTANCE Chemotherapy may induce alopecia. Although scalp cooling devices have been used to prevent this alopecia, efficacy has not been assessed in a randomized clinical trial.

OBJECTIVES To assess whether a scalp cooling device is effective at reducing chemotherapy-induced alopecia and to assess adverse treatment effects.

DESIGN, SETTING, AND PARTICIPANTS Multicenter randomized clinical trial of women with breast cancer undergoing chemotherapy. Patients were enrolled from December 9, 2013, to September 30, 2016. One interim analysis was planned to allow the study to stop early for efficacy. Data reported are from the interim analysis. This study was conducted at 7 sites in the United States, and 182 women with breast cancer requiring chemotherapy were enrolled and randomized.

INTERVENTIONS Participants were randomized to scalp cooling (n = 119) or control (n = 63). Scalp cooling was done using a scalp cooling device.

MAIN OUTCOMES AND MEASURES The primary efficacy end points were successful hair preservation assessed using the Common Terminology Criteria for Adverse Events version 4.0 scale (grade 0 [no hair loss] or grade 1 [<50% hair loss not requiring a wig] were considered to have hair preservation) at the end of 4 cycles of chemotherapy by a clinician unaware of treatment assignment, and device safety. Secondary end points included wig use and scores on the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30, Hospital Anxiety and Depression Scale, and a summary scale of the Body Image Scale.

RESULTS At the time of the interim analysis, 142 participants were evaluable. The mean (SD) age of the patients was 52.6 (10.1) years; 36% (n = 51) received anthracycline-based chemotherapy and 64% (n = 91) received taxane-based chemotherapy. Successful hair preservation was found in 48 of 95 women with cooling (50.5%; 95% CI, 40.7%-60.4%) compared with 0 of 47 women in the control group (0%; 95% CI, 0%-7.6%) (success rate difference, 50.5%; 95% CI, 40.5%-60.6%). Because the 1-tailed *P* value from the Fisher exact test was <.001, which crossed the superiority boundary (*P* = .0061), the data and safety monitoring board recommended study termination on September 26, 2016. There were no statistically significant differences in changes in any of the scales of quality of life from baseline to chemotherapy cycle 4 among the scalp cooling and control groups. Only adverse events related to device use were collected; 54 adverse events were reported in the cooling group, all grades 1 and 2. There were no serious adverse device events.

CONCLUSIONS AND RELEVANCE Among women with stage I to II breast cancer receiving chemotherapy with a taxane, anthracycline, or both, those who underwent scalp cooling were significantly more likely to have less than 50% hair loss after the fourth chemotherapy cycle compared with those who received no scalp cooling. Further research is needed to assess longer-term efficacy and adverse effects.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01986140

JAMA. 2017;317(6):596-605. doi:10.1001/jama.2016.20939

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Related article at jamaoncology.com

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