Dana-Farber Cancer Institute

Scalp cooling & breast cancer treatment: What providers need to know

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Objectives

- ❑ Providers who participate in the program will understand:

- The goals of scalp cooling and its relevance to breast cancer patients
- How scalp cooling works and who is eligible to receive it
- The impact of scalp cooling on hair preservation and quality of life
- The patient and provider experience
- Costs and resources associated with scalp cooling
- Best practices for health systems

Background

- Approximately 252,710 people are diagnosed annually with breast cancer
  - 50% of pts consider hair loss the most traumatic aspect of treatment (tx),
  - 8% would decline chemo treatment for this reason (Nangia et al. 2017)

- Chemotherapy induced alopecia (CIA) is defined in Common Terminology Criteria for Adverse Events as an adverse event
- The FDA approved two scalp cooling systems intended to prevent alopecia during cancer treatment:

  Dignicap® approved 12/2015

  Paxman® approved 4/2017

- NCCN added: Preoperative/Adjuvant Therapy Regimens(BINV-L) (early-stage breast cancer)
  - Footnote f: Consider scalp cooling to reduce the incidence of chemotherapy-induced alopecia for patients receiving chemotherapy. Results may be less effective with anthracycline-containing regimens.
  - Also added as a 2A category of treatment option to patients with invasive breast cancer, ovarian cancer, fallopian tube cancer, and primary peritoneal cancer to reduced incidence of CIA in those receiving chemotherapy

Scalp Cooling

- A scalp cooling device works by introducing cold temperatures to induce vasoconstriction, to reduce the metabolic activity resulting less effect of cytostatic agents on follicular cells
- To be effective, the device must be applied 30 minutes before the chemo treatment, continued during the treatment, and remain in place up to 90 minutes after the treatment.
- Other factors: correct size of the cap, texture, race, and cancer biology.
- Not always standardly offered to patients with metastatic disease, yet hair loss remains a concern for these patients
- Data about efficacy of scalp cooling is not well known for many agents used to treat metastatic breast cancer, particularly with newer antibody drug conjugates

Scalp Cooling System

Scalp Cooling: Outcomes

- Rugo Study

- Original abstract presented at ASCO 2015 and led to Dignicap® FDA approval
- Most common chemotherapy was docetaxel and cyclophosphamide (75%); paclitaxel (12%); docetaxel, carboplatin, and trastuzumab (12%).
- **66.3% (95% CI 56.2-75.4) of scalp cooling group compared to 0% in control group had a Dean score of 0-2 (p=<.001); no differences based on patient characteristics**
- 27.3% of patient in scalp cooling group felt less physically attractive compared to 56.3% of control (p=.02)
  - 3 QOL measures were better 1 month after end of chemotherapy in the scalp cooling group

Rugo et al, JAMA 2017

Scalp Cooling: Outcomes

- Nangia Study: SCALP TRIAL
- Led to Paxman FDA approval in 2017
- 142 evaluable pts randomized to scalp cooling or control for adjuvant anthracycline or taxane-based therapy
- **Successful hair preservation in 50.5% compared to 0% in control**

  demonstrated Alopecia grade 0-1 (49.5% grade 1) (p=<.001)
- 16% with anthracycline c/w 59% with Taxanes
- No difference seen in QOL

Nangia J et al, JAMA 2017

Efficacy data from the Dutch scalp cooling registry

Chemotherapy	Number of Patients	% No Wig/Head Cover
A60C600	1422	44
D75	710	94
D100	241	72
D75A50C500	159	12
F500A50C500	59	53
F500E90C500	628	51
F500E100C500	607	33
F500E100C500-D100*	808	44
Irino 350	196	27
T80	415	86
T90	87	79
T175Car**	178	39

A: doxorubicine, C: cyclofosfamide, Car: carboplatin, D: docetaxel,
E: epirubicine, F: 5-fluorouracil, Irino: irinotecan, T: paclitaxel
* 3xFEC followed by 3xD ** AUC6

Corina van den Hurk et. Acta Oncol 2012

Safety and Tolerability

- Published data report the incidence of scalp metastasis following scalp cooling is consistently low and exceedingly rare; comparative to that typically seen in breast cancer and associated with treatment
- **Contraindicated in hematological malignancies**, cold sensitivity (patient or drug related), cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia
- Overall, scalp cooling is well tolerated.
  - Cold sensation
  - Headache/Migraine
  - Nausea
- The use of PRNs in improve tolerability.
  - Ativan, Ibuprofen, Tylenol

What is the Cost and Who Will Pay?

- ❑Cost varies depending on the duration of the chemotherapy
- ❑Average total cost is estimated between $ 1500 to 2200 per patient depending on the number of treatment cycles. Maximum $2200.
- ❑Currently not generally reimbursed. Recent quality randomized trials and FDA approval of devices will influence insurance coverage
- ❑Submit medical necessity form
- ❑ Effective 01/01/2022 US centers of Medicare and Medicaid Services (CMS) has reassigned the repayment for SC for Medicare claims filed with 0662T CPT code. National average payment of $1850.50
- ❑Some financial aid is available for eligible patients: meet federal poverty guidelines
  - Application at time of referral

DFCI Yawkey 9 Scalp Cooling Program

- Opened scalp cooling program with Paxman vendor in November 2017
- Approximately 85 patients enrolled per year
- Patient and provider driven
- Success varies with regimen and patient characteristics
- 80 % success with Taxol/Herceptin (TH)

Improve the Efficacy of Scalp Cooling by Re-designing the Best Practice Process

- ❑ Method

- Site: Dana Farber Cancer Institute (DFCI), Boston, MA, outpatient breast oncology clinic located on Yawkey 9th floor involving infusion nurses.
- A qualitative approach using traditional open-ended questions, guided the interview process using a focus group format
- SWOT analysis (strength, weaknesses, opportunities, and threats).
- The focus group interview guide contained 10 questions. 3 sessions of 30-60 minutes each were conducted by the project leader.
- Discussions were recorded, transcribed, and evaluated using content analysis.
- Comments from sessions and specific responses to questions were reviewed for themes using NVivo software

Result

- Four main themes emerged from the data:
  - (1) work flow-working,
  - (2) work flow-needs improvement,
  - (3) patient experience and
  - (4) nursing satisfaction.

- Patient/provider education and patients' expectations were the primary factors that had the most influence for improving efficacy and decreasing anxiety.

OUTCOME

- Create standardized educational module for patients and nursing
- Schedule time to review the information with patients and family members.
- Plan nursing, and other provider in-service
- Ongoing discussion groups
- Obtaining data for BOC efficacy
- Additional space for cooling time
- Build program for scalp cooling for all solid tumors.
- Build “oncology therapy plan” in Epic

Knowledge Gap

- Studies to date has focused on efficacy of scalp cooling in CIA and less so assessing QOL/body image
- Limited information about the efficacy of scalp cooling in preventing alopecia or improving QOL in metastatic breast cancer patients undergoing treatment with chemotherapy or antibody-drug conjugates
- Limited data for success of scalp cooling with antibody drug conjugates (ADCs)

Background: expected rates of alopecia

- Sacituzumab govitecan (IMMU-132 or Trodelvy™)
  - FDA approved monoclonal antibody linked to a topoisomerase inhibitor for treatment of metastatic TNBC
  - Randomized phase 3 ASCENT trial showing both progression-free survival advantage and overall survival benefit in the third line and beyond setting.
  - Alopecia rate was 46%

- Trastuzumab deruxtecan (DS-8201a or Enhertu®)
  - FDA approved for unresectable or metastatic HER2-positive breast cancer who have received ≥2 prior anti—HER2-based regimens in the metastatic setting
  - Antibody-drug conjugate composed of an anti-HER2 antibody
  - DESTINY trial showing ORR 61.4% and median DRR 20.8
  - Alopecia rate was 48.4%

- Eribulin (Halaven®)
  - FDA-approved chemotherapy for metastatic breast cancer that is associated with an overall survival benefit.
  - Alopecia is a common adverse effect associated with Eribulin therapy. In the EMBRACE study and Study 301, 45% and 35% of patients experienced alopecia. The EMBRACE data likely underestimate rates of alopecia as some patients began treatment with alopecia and as such estimate that 60% of patients with Eribulin will have hair loss with Eribulin.

Hypothesis

- We believe that patients treated with sacituzumab govitecan (IMMU-132), trastuzumab deruxtecan (TDxd, DS8201), or eribulin will experience lower rate of alopecia and will report an improvement of QOL with scalp cooling compare to those who do not undergo scalp cooling.

Objectives/Endpoints

- **Primary Objective:**

To compare hair preservation, in the scalp cooling group after use of the Orbis Paxman Hair Loss Prevention System and no scalp cooling group during treatment with sacituzumab govitecan (IMMU-132), trastuzumab deruxtecan (DS8201), or eribulin.

- **Secondary Objective:**

To assess the impact of scalp cooling on QOL in these participants. The Chemotherapy-Induced Alopecia Distress Scale (CADS) and body image scale (BIS) will be used to measure participant's QOL at baseline, C3D1 and C5D1, and after completing therapy or at the time of disease progression whichever occurs first.

Trial Design

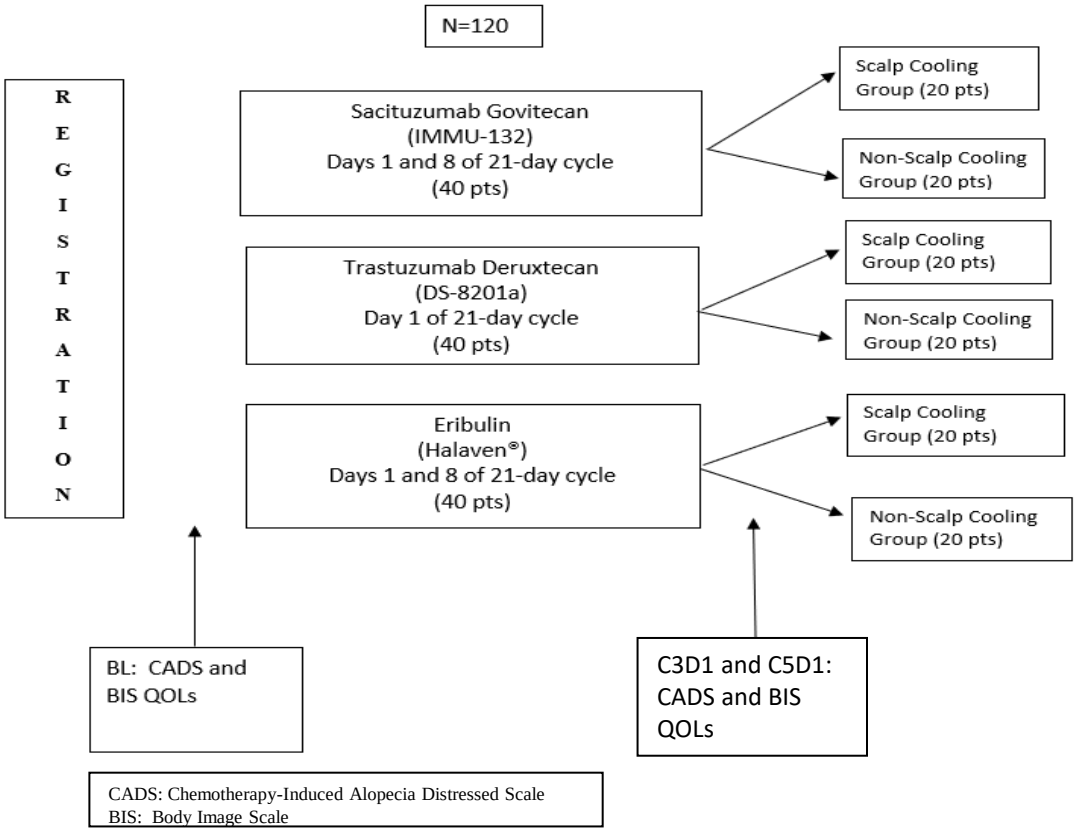
- This is a prospective clinical investigation to assess the efficacy of the Orbis Paxman Scalp Cooling System at preventing hair loss in undergoing treatment for metastatic breast cancer
  Sacituzumab govitecan (IMMU-132 or Trodelvy™)
  Trastuzumab deruxtecan (DS-8201a or Enhertu®), or
  Eribulin (Halaven®).

- 40 patients will be recruited into each treatment arm. In each treatment arm, 20 patients will receive scalp cooling and 20 patients will receive no scalp cooling, for a total of 120 participants.
  - Patients electing to undergo scalp cooling will enroll into the scalp cooling group and patients electing to not receiving scalp cooling will enroll into the non -scalp cooling (control) group.

- Hair loss will be measured in participants at baseline, C3D1 and C5D1, and after completing therapy or at the time of disease progression whichever occurs first by CTCAE criteria.

- We will also assess the impact of scalp cooling on quality of life (QOL) in these participants. The Chemotherapy-Induced Alopecia Distress Scale (CADS) and body image scale (BIS) will be used to measure participants' QOL at baseline, C3D1 and C5D1, and after completing therapy or at the time of disease progression whichever occurs first.

Schema



Note: Not randomized– patients choose if they want scalp cooling or not

Conclusion

- ❑ Scalp cooling has shown to be effective in most regimens, specially Taxane.
- ❑ Well tolerated by patients. Consider the use of PRN medications
- ❑ Improves QOL and Body Image
- ❑ Education and expectations are key component of effectiveness and awareness of outcome among patients.
- ❑ Finance continues to be an issue. Not covered by insurance. New Medicare guidelines.
- ❑ Very limited data in AA and Hispanic population.
- ❑ Data needed in novel agents

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Questions?