Scalp Cooling
A literature review of efficacy, safety, and tolerability for chemotherapy-induced alopecia

Mikel Ross, BSN, RN, OCN®, CBCN®, and Erica Fischer-Cartlidge, MSN, CNS, CBCN®, AOCNS®

BACKGROUND: More than 75% of patients with cancer cite alopecia as the most feared side effect of treatment, with as many as 10% considering treatment refusal. Despite wide acceptance in other countries, scalp cooling to reduce chemotherapy-induced alopecia (CIA) has been uncommon in the United States because of long-standing concerns of scalp metastases and a lack of reliable efficacy data.

OBJECTIVES: This article reviews 40 years of efficacy, safety, and tolerability literature on scalp cooling to prevent CIA.

METHODS: A systematic review was performed in PubMed and CINAHL®. Forty articles were reviewed, with 12 articles demonstrating high levels of evidence and meeting inclusion criteria. Comparative trials, systematic reviews, and one large single-arm trial were included.

FINDINGS: Scalp cooling efficacy is dependent on many factors but demonstrates better hair preservation than no cooling. No increase in scalp metastases or statistically significant difference in overall survival was seen in retrospective safety data when cooling was used. Few patients discontinue cooling early because of adverse experiences.

KEYWORDS:
scalp cooling; chemotherapy-induced alopecia; efficacy; safety; literature review

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CANCER TREATMENT WITH CHEMOTHERAPY MAY RESULT in chemotherapy-induced alopecia (CIA), with rates from 10%–100%, depending on the drugs in the treatment regimen (Kadakia, Rozell, Butala, & Loprinzi, 2014; Roe, 2014) (see Table 1). Experienced oncology nurses know that, after the initial shock of diagnosis, treatment and side effect concerns are the second hurdle. Although management has improved for many other side effects (e.g., nausea and vomiting), alopecia still has no effective or widely accepted preventive intervention.

In one study, 77% of patients reported CIA as the most feared side effect of treatment (Kargar, Sarvestani, Khojasteh, & Heidari, 2011). It has been described as a greater threat to body image than mastectomy, leading to anxiety and isolation (Roe, 2011). As many as 10% of women consider refusing chemotherapy or choosing a less effective treatment to avoid CIA (Kadakia et al., 2014; Roe, 2014). Although most CIA is transient, persistent or chronic alopecia is possible. A study of women with breast cancer receiving docetaxel (Taxotere®) after doxorubicin (Doxil®) and cyclophosphamide (Cytoxan®) reported prevalence as high as 6.3% (Lemieux, Amireault, Provencher, & Maunsell, 2009). Although not common, it is impossible to know which patients will experience persistent CIA. Given the impact of CIA on patients, one might question why such a significant side effect remains without an effective management strategy.

History and Current State of Scalp Cooling
Scalp cooling is an intervention routinely used in the United Kingdom, France, Netherlands, and parts of Canada to limit CIA (Lemieux, 2012). A registry of more than 70 Dutch hospitals demonstrated usage rates as high as 80% for scalp cooling for patients with solid tumors (van den Hurk, van de Poll-Franse, Breed, Coeberg, & Nortier, 2013). This was consistent with a medical center in Canada, which estimated usage rates of 85% (Lemieux, 2012).

Scalp cooling data dates back more than 40 years and was first summarized in a systematic review in 2005. The mechanism of action is believed to be the result of two processes: (a) vasoconstriction, decreasing blood flow to hair follicles and limiting the uptake of cytotoxic agents, and (b) decreased follicle metabolism, making follicles less susceptible to chemotherapy damage (Grevelman & Breed, 2005; Kadakia et al., 2014; Shin, Jo, Kim, Kwon, & Myung, 2015).

Scalp cooling options available in other countries include cooling machines or cold caps (see Figure 1), both of which are initiated prior to
treatment, used throughout, and continued for a specified period of time postinfusion (Breastcancer.org, 2015). Despite the availability and acceptance of these options in Canada and Europe, scalp cooling has had little uptake in the United States, where there has been no clear consensus on efficacy and safety.

Clinical trials are underway for the U.S. Food and Drug Administration (FDA) marketing approval of the DigniCap® and the Paxman systems (National Institutes of Health, 2015a, 2015b). Although long-term safety data are still being collected, the DigniCap system was the first cooling cap to receive FDA marketing approval for reducing chemotherapy-related hair loss in 2015 (FDA, 2015). Experience from these trials, four decades of literature, and growing patient advocacy for effective CIA interventions are challenging the current oncology supportive care practice paradigm in the United States.

Within the literature, efficacy results for scalp cooling vary because of study design variables, such as population, chemotherapy regimen, outcome measure, type of cooling system/device, and cooling duration. This inconsistency and lack of control for confounding variables has been cited as a challenge in previous reviews of scalp cooling effectiveness (Grevelman & Breed, 2005; Rugo & Melisko, 2011).

Although efficacy is essential, perhaps more important is safety. In the case of CIA, where the toxicity is often viewed as transient, cosmetic, and without adverse physical outcomes, it can be difficult to demonstrate a safety profile satisfactory to clinicians and regulators in the United States. In 1990, the FDA prohibited the sale of scalp cooling devices because of a lack of data on efficacy and safety (Alley, Green, & Schuchter, 2002; Lemieux et al., 2009). Historically, arguments against scalp cooling have been two-fold. The first concern is the potential risk of scalp metastases. The second hypothesized concern has been the possibility of secondary seeding to other organs from dormant cancer cells in the scalp not killed by chemotherapy (Lemieux et al., 2009). Although unsupported, these concerns have remained powerful disincentives, particularly with treatment for curative intent (van den Hurk, van de Poll-Franse, et al., 2013).

TABLE 1. ALOPECIA RISK BY CHEMOTHERAPY CLASS

<table>
<thead>
<tr>
<th>CLASS OF CHEMOTHERAPY</th>
<th>RISK OF ALOPECIA</th>
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<tbody>
<tr>
<td>Antimetabolite (e.g., 5-fluorouracil, gemcitabine)</td>
<td>Low</td>
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<tr>
<td>Alkylating agent (e.g., cyclophosphamide)</td>
<td>High</td>
</tr>
<tr>
<td>Antimicrotubule (e.g., paclitaxel, eribulin)</td>
<td>High</td>
</tr>
<tr>
<td>Antitumor antibiotics (e.g., doxorubicin, epirubicin)</td>
<td>High</td>
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Note. Low risk indicates 50% or less; high risk indicates more than 50%.
Note. Based on information from Roe, 2014.

However, more than 40 years of literature exists on scalp cooling for preventing CIA. Careful analysis of the literature may provide a general sense of scalp cooling’s current role in care. To this aim, the authors of the current article set out to explore the following question: In patients receiving cytotoxic chemotherapy, is scalp cooling an effective, safe, and tolerable intervention for the prevention of CIA?

Methods
A systematic literature review was performed using PubMed and CINAHL® databases with the Boolean search terms cooling caps and alopecia, chemotherapy and cooling caps, and cryotherapy and alopecia. Additional publications were identified from the reference lists of articles. During the one-year period of investigation from January 2015 to January 2016, this search was performed on three unique occasions, most recently in January 2016. Inclusion criteria for full review included (a) comparative trials with intervention and control arms and (b) systematic reviews to control for variability in study design. Publication date was not limited during initial search; however, in final review, publications within the past five years were prioritized.

More than 40 articles were deemed relevant and reviewed for inclusion criteria; data saturation was achieved. Twelve articles...
were identified to have a high level of evidence (meta-analyses, systematic reviews, and controlled trials), meeting the criteria, and were included; four were systematic reviews. An exception for one single-arm trial was made because of a large sample size.

Comparing the trials analyzed to those reviewed in the two most recent systematic reviews (Kadakia et al., 2014; Shin et al., 2015), it was determined that (a) all of the individual studies in this review were also identified in those, (b) this review

### TABLE 2.
REVIEW OF STUDIES PUBLISHED ON SCALP COOLING EFFECTIVENESS

<table>
<thead>
<tr>
<th>STUDY</th>
<th>SAMPLE AND DESIGN</th>
<th>CHEMOTHERAPY USED</th>
<th>INTERVENTION RESULTS</th>
<th>CONTROL RESULTS</th>
</tr>
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<tbody>
<tr>
<td>Betticher et al., 2013</td>
<td>Prospective, nonrandomized, observational three-arm study of 238 patients with metastatic cancer (any solid tumor) on first-line therapy, with 128 using Paxman cooling system, 71 using cooling caps, and 39 controls</td>
<td>Docetaxel weekly or every three weeks with or without other chemotherapy</td>
<td>For Paxman weekly, 93% reported successful WHO score of 0–2 or no wig use; for Paxman every three weeks, 77% reported success. For cooling caps used weekly, 92% reported success; for cooling caps every three weeks, 73% reported success.</td>
<td>For chemotherapy every three weeks, 26% reported successful WHO score of 0–2 or no wig use; for chemotherapy weekly, 83% reported success*.</td>
</tr>
<tr>
<td>Kargar et al., 2011</td>
<td>Prospective, nonrandomized, observational two-arm study with 65 patients with multiple primary tumor types, with 51 using Penguin™ Cold Caps and 52 controls</td>
<td>Various agents used (paclitaxel, ABVD, BEP, CHOP, and other)</td>
<td>Successful results of less than severe or total hair loss were 77% at cycle 2 and 50% at cycle 6.</td>
<td>Results of less than severe or total hair loss were 59% at cycle 2 and 25% at cycle 6.</td>
</tr>
<tr>
<td>Lemieux et al., 2012</td>
<td>Prospective, nonrandomized, observational two-arm study with 266 patients with breast cancer on adjuvant treatment, with 98 using Paxman cooling system and 168 controls</td>
<td>Of 99 patients, 31 used TC, 50 used FEC-D, 22 used AC, and 16 used a different regimen.</td>
<td>49% of patients and 34% of hairdressers rated hair loss as none to moderate.</td>
<td>4% of patients and 9% of hairdressers rated hair loss as none to moderate.</td>
</tr>
<tr>
<td>Mols et al., 2009</td>
<td>Prospective, nonrandomized, observational two-arm study with 266 patients with breast cancer on adjuvant treatment, with 98 using Paxman cooling system and 168 controls</td>
<td>Various agents used (AC, FEC, FAC, and TAC)</td>
<td>Three weeks after completion of treatment, 52% did not use a head covering.</td>
<td>Three weeks after completion of treatment, 5% did not use a head covering; all four of those participants were bald.</td>
</tr>
<tr>
<td>Rugo et al., 2015</td>
<td>Prospective, nonrandomized, observational two-arm study of 117 participants with stages I and II breast cancer, with 101 using DigniCap® and 16 controls</td>
<td>Various agents used (paclitaxel, carboplatin, and docetaxel as a single agent; 29% used docetaxel in combination).</td>
<td>71% reported a successful Dean score of 0–2.</td>
<td>0% reported a successful Dean score of 0–2.</td>
</tr>
<tr>
<td>Van den Hurk, Breed, &amp; Nortier, 2012</td>
<td>Prospective, nonrandomized, observational study with 68 patients with breast (56%), prostate (22%), lung (16%), or other (7%) cancer who used Paxman cooling system. This table lists results only for phase I (no cooling) or versus 90-minute cooling time.</td>
<td>Various agents used (paclitaxel, carboplatin, and docetaxel as a single agent; 29% used docetaxel in combination).</td>
<td>71% used docetaxel as a single agent; 29% used docetaxel in combination.</td>
<td>81% reported no use of wig or head covering.</td>
</tr>
<tr>
<td>Van den Hurk, Peerbooms, et al., 2012</td>
<td>Multicenter observational study with 1,411 participants with multiple tumor types, primarily breast (86%), using Paxman cooling system. 71% were on adjuvant therapy, and 29% were palliative.</td>
<td>Various agents used (paclitaxel, carboplatin, and docetaxel as a single agent; 29% used docetaxel in combination).</td>
<td>19 different regimens were used (33% FEC).</td>
<td>50% reported no use of head covering.</td>
</tr>
<tr>
<td>Van den Hurk, van der Akker-van Marle, et al., 2013</td>
<td>Prospective, nonrandomized, observational two-arm study of 246 patients with multiple primary tumor types (93% with breast cancer), with 160 using Paxman cooling system and 86 controls</td>
<td>Various agents used (paclitaxel, carboplatin, and docetaxel as a single agent; 29% used docetaxel in combination).</td>
<td>Multiple regimens were used. FEC regimen was used in 66% of intervention participants and 45% control participants.</td>
<td>4% reported WHO score of 0, 16% reported score of 1, 50% reported score of 2, and 30% reported score of 3. 49% reported no use of wig or head covering.</td>
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</table>

*Only seven participants with a median of four cycles were included in the weekly chemotherapy control arm. Results have high potential to not be representative.

ABVD—doxorubicin, bleomycin, vinblastine, and dacarbazine; AC—doxorubicin and cyclophosphamide; BEP—bleomycin, etoposide, and cisplatin; CHOP—cyclophosphamide, doxorubicin, vincristine, and prednisone; DAC—docetaxel, doxorubicin, and cyclophosphamide; FAC—5-fluorouracil, doxorubicin, and cyclophosphamide; FEC—5-fluorouracil, epirubicin, and cyclophosphamide; FED—5-fluorouracil, epirubicin, and cyclophosphamide; then docetaxel; TAC—docetaxel, doxorubicin, and cyclophosphamide; TC—docetaxel and cyclophosphamide; WHO—World Health Organization

Note. All studies were comparative except van den Hurk, Peerbooms, et al. (2012), which was a single-arm study. Dean scores range from 0 (no hair loss) to 4 (greater than 75% hair loss). WHO scores range from 0 (none) to 4 (complete/noneversible).
includes more recent data from 2015, and (c) studies excluded in this analysis but included in other reviews either had no control arm or were older data from 1986–2003. Consequently, these results reflect the extensiveness of relevant data focused on the strongest-level evidence with the most recent data.

Results

Efficacy

COMPARATIVE TRIALS

Outcomes from studies reviewed demonstrated successful hair preservation in scalp cooling cohorts ranging from 34%–93% (see Table 2). Cohorts that did not use scalp cooling reported lower rates of successful hair preservation, ranging from 0%–26%. This excludes a small non–scalp cooling subset of seven patients treated with weekly paclitaxel (Taxol®) for a median of four cycles, with an 83% success rate. Those results, based on the small sample and limited drug exposure, can likely not be generalized to a larger population.

The majority of participants across the studies were women with breast cancer receiving adjuvant or neoadjuvant treatment. Numerous chemotherapy regimens were included; the majority included an anthracycline or a taxane. The most recent data were presented by Rugo et al. (2015) at the American Society of Clinical Oncology conference and perhaps represents the most rigorously designed trial of scalp cooling to date. Rugo et al.’s (2015) data comprised the basis for FDA (2015) clearance of the DigniCap cooling system.

SINGLE-ARM STUDY

Although single-arm studies do not have the same strength of evidence as comparative trials, data from one observational cohort were included because of its large sample size, which was the largest cohort reported in the literature. These data are useful not only for the size of the cohort, but also for the data on tumor types and chemotherapy regimens that do not exist outside this database. Among 1,411 patients who used scalp cooling, 50% did not use a head covering upon presentation for their last treatment (van den Hurk, van der Akker-van Marle, et al., 2013). The authors of that study continue to collect data and anticipate reporting more long-term data in the future.

SYSTEMATIC REVIEWS

Four systematic reviews were analyzed with data from 1973–2013 (see Table 3). The reviews reported outcomes based on percentage of successful hair preservation or relative risk of CIA. Rates of successful hair preservation ranged from 10%–100%, with most clustering around the 50% rate. When statistically evaluated, Shin et al. (2015) calculated a significantly lower relative risk (RR) of CIA with scalp cooling (RR = 0.38, 95% confidence interval [0.32, 0.45]). These reviews demonstrate that, although precise prediction of hair preservation is elusive, patients who use scalp cooling have better preservation than those who do not, despite variability in study design, populations, treatments, and outcome measure.

Safety

The safety data (see Table 4) include information relevant to scalp metastases and overall survival. Van den Hurk, Peerbooms, et al.’s (2012) large observational study lacked a control arm but had a large sample size and as many as five years of follow-up; however, individuals registered late were followed for only a few months until the data were reported. Taking into consideration that no comparative arm existed, the lack of any scalp metastases is an important safety finding for this cohort because of the sample size (van den Hurk, Peerbooms, et al., 2012).

“"The incidence of scalp metastases is low, and scalp cooling is unlikely to adversely affect their occurrence."
The consistency and low incidence of scalp metastases reported in the retrospective and systematic analyses are evidence of the safety of scalp cooling. Incidence of scalp metastases ranged from 0.4%–1.1% in patients who used scalp cooling versus 0.3%–3% in patients who did not use scalp cooling and who were followed from two to nine years (Lemieux et al., 2009; van den Hurk, van de Poll-France, et al., 2013). These data suggest that the incidence of scalp metastases is low and that scalp cooling is unlikely to adversely affect their occurrence.

Scalp metastases, while significant, are rarely a unique site of disease, generally do not prove to be lethal, and do not pose the same threat to survival as visceral or central nervous system involvement (van den Hurk, van de Poll-France, et al., 2013). For these reasons, the concern of secondary seeding may be more crucial to address. A retrospective study of 1,370 patients with breast cancer receiving adjuvant and neoadjuvant treatment were evaluated for overall survival with a minimum follow-up of six years (Lemieux et al., 2015). Results were based on a median of six to eight years of follow-up, adding to the validity of the analysis. Hazard ratio was adjusted for age, stage of disease, tumor grade, lymphovascular invasion, regimen, hormone receptor status, and clinical trial participation but demonstrated no difference in overall survival for scalp cooling versus non–scalp cooling patients. To the best of the current authors' knowledge, Lemieux et al. (2015) is the only published study evaluating survival associated with the use of scalp cooling.

Patients with locally advanced disease (i.e., stage III) have been of special concern because of higher rates of recurrence regardless of cooling. Although patients with stage III disease comprised only 12% (n = 7) of the cohort analyzed by Lemieux et al. (2009), four of seven experienced scalp metastases. All four patients used scalp cooling, but none received a taxane-based regimen. In addition, the scalp was never the sole site of metastatic disease. Study authors concluded that type of treatment was a more likely determinant of metastases than cooling. Overall survival analysis statistics found that those who cooled had no greater risk of death than those who did not. Neoadjuvant patients with stage III disease also demonstrated no difference in overall survival; however, the analysis approached the statistical cutoff (p = 0.07) for a difference, which indicates that more data are needed in this subpopulation to more definitively determine safety (Lemieux et al., 2015).

Contraindications to scalp cooling exist for certain populations. Those with known hematologic malignancies should avoid cooling because of case reports of scalp metastases in patients who use scalp cooling and a lack of safety data (Grevelman & Breed, 2005; Kadakia et al., 2014). In addition, five comorbidities have been identified as contraindications for scalp cooling: cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, and cryofibrinogenemia (Grevelman & Breed, 2005).

A complete medical history is necessary prior to recommending scalp cooling.

**T tolerability**

Similar to the data on efficacy, tolerability data are confounded by varying measures used to assess the patient experience.

<table>
<thead>
<tr>
<th>TABLE 4</th>
<th>PUBLISHED SCALP COOLING SAFETY DATA</th>
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<tbody>
<tr>
<td><strong>STUDY</strong></td>
<td><strong>DESIGN AND SAMPLE</strong></td>
</tr>
<tr>
<td>Lemieux et al., 2009</td>
<td>Retrospective study of 640 participants with breast cancer in neoadjuvant or adjuvant care (553 used scalp cooling; 87 were controls).</td>
</tr>
<tr>
<td>Lemieux et al., 2015</td>
<td>Retrospective study of 1,370 patients with breast cancer in neoadjuvant or adjuvant care (553 used scalp cooling; 817 were controls).</td>
</tr>
<tr>
<td>van den Hurk, Peerbooms, et al., 2012</td>
<td>Multicenter observational study with 1,411 participants with multiple tumor types (86% breast).</td>
</tr>
<tr>
<td>van den Hurk, van de Poll-Franse, et al., 2013</td>
<td>Systematic review of 12 studies and the Munich Cancer Registry. Of 48,711 participants with breast cancer, 6,035 used scalp cooling.</td>
</tr>
<tr>
<td><strong>FOLLOW-UP</strong></td>
<td><strong>INTERVENTION RESULTS</strong></td>
</tr>
<tr>
<td>Follow-up was 5.8 years for intervention and 5.4 years for control.</td>
<td>1.1% reported incidence of scalp metastases.</td>
</tr>
<tr>
<td>Follow-up was 6.3 years for intervention and 8 years for control.</td>
<td>Overall survival was measured, with 107 events and a hazard ratio of 0.89 (p = 0.4*).</td>
</tr>
<tr>
<td>Follow-up varied based on enrollment date.</td>
<td>No scalp metastases were reported as of last treatment through August 2011.</td>
</tr>
<tr>
<td>Follow-up was 2.2–9 years for intervention and 3–9.2 years for control.</td>
<td>0.04%–1% reported incidence of scalp metastases.</td>
</tr>
<tr>
<td><strong>CONTROL RESULTS</strong></td>
<td></td>
</tr>
<tr>
<td>1.2% reported incidence of scalp metastases.</td>
<td>Overall survival was measured with 199 events and a hazard ratio of 1.</td>
</tr>
</tbody>
</table>

*p = 0.4 is not considered statistically significant.
Depending on the cooling system used (cap versus machine), post-treatment cooling time ranges from 30–150 minutes (DigniCap, 2015; van den Hurk, Breed, & Nortier, 2012). Anecdotal reports from patients using the Penguin™ Cold Caps (2015) include post-treatment cooling of as many as eight hours in some cases. However, despite those limitations, the data are adequate to demonstrate good tolerability.

In one mixed cohort of patients who used machine and cap scalp cooling, more than 70% reported that they felt “very well” or “rather well” while cooling (Betticher et al., 2013). Other side effects, such as headache and a sensation of cold, were mild and resulted in low discontinuation rates (Mols, van den Hurk, Vingerhoets, & Breed, 2009). Mols et al. (2009) reported that, in a trial with 98 participants using the Paxman cooling system, 39% reported that it was cold, 33% reported that it was a burden, 29% reported that the cap was heavy, 27% reported that they felt bored during the cooling, and 20% reported that they got dizzy. Rugo et al. (2015) and van den Hurk, Peerbooms, et al. (2012) reported a 3% discontinuation rate among 1,528 participants, primarily participants receiving adjuvant treatment. Betticher et al. (2013) reported a higher rate of 12.6% in a metastatic cohort; this may be reflective of the long-term nature of metastatic treatment versus the defined period of adjuvant treatment, making it more challenging to persist. Looking at patient report and discontinuation rates, the literature supports scalp cooling as a well-tolerated intervention.

**Evidence Into Practice**

After the current nursing-led review of data, the breast medicine service at Memorial Sloan Kettering Cancer Center, a large National Cancer Institute–designated cancer center, revised its practice regarding scalp cooling. Traditionally, scalp cooling had

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**FIGURE 2.**
**EXAMPLES OF PATIENTS WHO USED SCALP COOLING**

**CASE A**
Patient underwent chemotherapy with doxorubicin and cyclophosphamide, followed by paclitaxel with scalp cooling.

**CASE B**
Patient is stage IV and underwent 14 doses of weekly paclitaxel with scalp cooling.

Note. Photos copyright 2016 by Memorial Sloan Kettering Cancer Center. Used with permission.
been discouraged because of the common concerns for efficacy and safety; however, after the comprehensive review of data, clinicians began to introduce the topic of scalp cooling to patients who would receive chemotherapy with a high incidence of alopecia. Two cases are presented to exemplify the impact of translating evidence into practice.

A 43-year-old woman was treated for breast cancer with adjuvant dose-dense doxorubicin and cyclophosphamide, followed by paclitaxel from November 2015 to February 2016. Scalp cooling was tolerated without incident, and hair preservation was successful post-treatment (see Figure 2). A 56-year-old woman received 14 doses of weekly paclitaxel for metastatic breast cancer with significant hair preservation. These cases are not intended to be representative, and they do not guarantee benefit. What they reflect is the experience of two patients who have successfully used scalp cooling to limit CIA when a literature review was translated into practice.

Discussion
Oncology supportive care is changing to incorporate scalp cooling. However, perceptions and clinical practice can be slow to change without a solid understanding of available data. Success rates vary depending on regimen and evaluation criteria, and it remains difficult to provide a concrete estimate of hair preservation for any single patient or treatment because of the small number of patients with the same cancer who have been treated with the same regimen within the literature. In addition, many studies include heterogeneous populations and demographics, which can affect outcomes (e.g., gender, age, baseline hair quality, comorbidities). Despite data limitations, an overall benefit is clear; those who use scalp cooling preserve more hair than those who do not. Measured another way, patients who use scalp cooling report lower rates of using head coverings.

Based on the evidence, scalp cooling has demonstrated sufficient efficacy to support the intervention. Similarly, data for safety is reassuring and growing. Reviews and retrospective analyses with large samples have demonstrated no difference in scalp metastases rates between cohorts who use scalp cooling versus those who do not. Of note, overall survival appears unaffected during six years of follow-up.

The vast majority of data on this subject exist in patients with breast cancer. Although more data will be reported from ongoing trials, the current evidence suggests the safety of scalp cooling and that the theoretical concerns of scalp metastases and sanctuary site seeding are unsupported. The known harm from patients choosing suboptimal chemotherapy or refusing treatment to avoid CIA must also be factored into the safety analysis.

The majority of patients reported that they feel well during the intervention, translating to favorable tolerability. In addition, some of the most common adverse events (e.g., cold sensation, headache) can be addressed with simple comfort measures (e.g., blankets, acetaminophen). Ultimately, patients will individually weigh tolerability with perceived benefits after being educated.

Newer clinical trial designs have more selective inclusion criteria and rigorous designs. The quality of data gathered from these trials should improve accordingly, allowing patients and providers to have more accurate expectations for efficacy, tolerability, and safety. The translation of evidence to practice will also require solutions to infrastructure and reimbursement barriers. Infusion centers will need to modify work flows and scheduling to accommodate cooling devices and extended cooling times. Currently, cooling is not covered by insurance and can result in thousands of dollars in out-of-pocket expense, depending on the treatment. Providers, patients, and advocates will need to work with third-party insurers to establish reimbursement mechanisms that achieve universal access at a reasonable cost. Although these issues may resolve over time, healthcare providers who wish to make this change must factor these issues into their implementation plan.

Implications for Nursing and Conclusion
Evidence-based practice calls for healthcare providers to move away from “how we have always done it” to a practice deeply rooted in evidence, which oncology nurses have done for years at the forefront of advances in supportive care. With scalp cooling becoming more available in the United States in clinical trials and in the free market, growing patient awareness related to traditional and social media visibility has occurred, leading to increased patient demand. Oncology nurses must understand available data on scalp cooling data related to safety, efficacy, and tolerability and its relevance to clinical practice. This knowledge can dispel longstanding myths, empower nurses, and provide them with a foundation to continue to be strong patient advocates. Nurses are positioned, once again, to lead the way in transforming practice, affecting the patient experience and improving quality of life.

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REFERENCES


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