SENSOR-CONTROLLED SCALP COOLING TO PREVENT CHEMOTHERAPY-INDUCED ALOPECIA IN BREAST CANCER PATIENTS IN THE CLINICAL ROUTINE: SAFETY AND EFFECTIVENESS IN THE NEOADJUVANT, ADJUVANT, OR PALLIATIVE SETTING

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INTRODUCTION

Chemotherapy (Ctx)-induced alopecia (CIA) produces a deep psychological distress in many women involved. Sensor-controlled scalp cooling (SCSC) has been found to be both safe and effective to prevent CIA. However, it is still poorly understood which patient will benefit the most. This retrospective analysis sought to obtain detailed information which clinical parameter is able to predict the success of SCSC using the Paxman system (Paxman, Huddersfield, UK) in a routine population of in patients (pts) with primary (PBC) or recurrent/metastatic breast cancer (RMBC) exposed to CIA-inducing neoadjuvant (NACT), adjuvant (ACT), or palliative (PCT) using anthracyclines (A), taxanes (T), both of them given at different schedules (A+T/A→T; T→A), or none of them (non-A/non-T).

METHODS

109 pts who underwent SCSC from 2014-2017 were identified from our database: NACT, 47 (54.6%); ACT, 40 (45.4%); PCT 22; dose-dense (dd) Ctx, 38 (44.2%); non-dd Ctx 48 (55.8%); premenopausal, 48 (55.8%); postmenopausal, 38 (44.2%). The following Ctx regimens were used: A+T/A→T, 41 (37.6%), T→A, 23 (26.7%), T, 34 (31.2%), non-A/non-T, 11 (10.1%). Patients’ characteristics are summarized in Table 1. Pts were subjected to SCSC during each Ctx cycle (Figure 1). Adverse effects related to SCSC were classified in regard to the CTCAE Vs. 4.03 criteria. CIA was quantified according to the Dean score (DS) determined 3 wks after the last Ctx cycle. Typical examples are demonstrated in Figure 2. Data were analyzed regarding feasibility indicated by the SCSC completion rate, quality of hair preservation (success: DS 0-2, failure: DS 3-4), and reasons of SCSC discontinuation. Moreover, the following parameters were investigated in regard to the success of SCSC: menopausal status, pretreatment, setting of Ctx, Ctx schedule, Ctx regimen..

RESULTS

As can seen in Table 2, overall success rate was 67.9% with 47 pts (43.1%) experiencing complete hair preservation (DS 0), and another 27 (24.8%) showing partial response to SCSC (DS 1-2). 30 pts (27.5%) stopped SCSC prematurely with CIA being the reason in 26 pts (23.9%). In total, 79 patients completed SCSC (72.5%), whereas 30 (27.5%) discontinued the treatment (Table 3). Adverse effects were reported in 9 cases (8.3%) with local pain and discomfort being most frequently reported (Table 3). Side effects did not exceed CTCAE grade 2 and resolved quickly after cessation of SCSC. Effectiveness of SCSC did not differ for most analyzed subgroups. The outcome of SCSC by subgroup can be obtained from Table 4. The relative risk (RR) to experience CIA was 1.18 (CI: 0.91-1.53, p=NS) for post- vs premenopausal pts, 1.27 (CI: 0.99-1.64, p=NS) for Ctx-naïve vs pretreated pts, 1.18 (CI: 0.89-1.56, p=NS) for dd Ctx vs non-dd Ctx,, and 1.42 (1.11-1.85, 0.012) for A-based Ctx vs non A-based Ctx. Success rates for A+T/A→T, T→A, T, and non-A/non-T were 48.8%, 73.9%, 79.4%, and 90.9% (p=0.015). Moreover, success rates for NACT, ACT und PCT were 68.1, 60.0, and 81.8 percent, respectively (p=0.1054).

Table 1: Patients’ characteristics

Age (years)	
median	51
range	24-75
Menopausal status	n (%)
pre-/perimenopausal	53 (48.6)
postmenopausal	56 (51.4)
Prior chemotherapy	n (%)
No	87 (79.8)
Yes	22 (20.2)
Intention of chemotherapy	n (%)
neoadjuvant	47 (43.1)
adjuvant	40 (36.7)
palliative	22 (20.2)
Schedule of chemotherapy	n (%)
dose-dense	44 (40.4)
conventional (non dose-dense)	65 (59.6)
Type of chemotherapy	n (%)
anthracycline- and taxane-based	64 (58.7)
<i>anthracycline first</i>	41 (37.6)
<i>taxane first</i>	23 (21.1)
taxane-based (without anthracyclines)	34 (31.2)
non anthracycline/non taxane-based	11 (10.1)

Table 2: General outcome of sensor-controlled scalp cooling

Outcome	Percentage of hair loss	n (%)
Success		
Dean score 0	0%	47 (43.1)
Dean score 1-2	1-50%	27 (24.8)
Failure		
Dean score 3-4	51-100%	26 (23.9)
Discontinuation due to adverse effects	n. a.	9 (8.3)

Table 3: Safety

	n (%)
Scalp cooling completed	79 (72.5)
Scalp cooling discontinued	30 (27.5)
Reasons for discontinuation	
hair loss	26 (23.9)
adverse effects	9 (8.3)
<i>pain</i>	3 (2.8)
<i>discomfort (“feeling cold”)</i>	5 (4.6)
<i>nausea/vomiting</i>	1 (0.9)

Table 4: Outcome by subgroup

	Success rate n (%)	p
Menopausal status		
pre-/perimenopausal	39 (73.6)	0.2270
postmenopausal	35 (62.5)	
Prior chemotherapy		
no	56 (64.4)	0.1339
yes	18 (81.8)	
Intention of chemotherapy		
neoadjuvant	32 (68.1)	0.1054
adjuvant	24 (60.0)	
palliative	18 (81.8)	
Schedule of chemotherapy		
dose-dense	27 (61.4)	0.2963
non dose-dense	47 (72.3)	
Type of chemotherapy		
anthracycline- and taxane-based	37 (59.7)	0.0149
<i>anthracycline first</i>	20 (48.8)	
<i>taxane first</i>	17 (73.9)	
taxane-based	27 (79.4)	
non-anthracycline- and non-taxane-based	10 (90.9)	

CONCLUSIONS

- SCSC using the Paxman system is feasible, effective and safe in a real-world population of patients with breast cancer.
- More than two thirds of patients achieved a satisfying hair preservation and did not need to wear a wig.
- Adverse effects related to scalp cooling were all not severe and rarely the reason of discontinuation .
- Menopausal status, prior chemotherapy, treatment intention and chemotherapy intervals did not significantly affect the likelihood to benefit from sensor-controlled scalp cooling.
- The only parameter which significantly influenced the success rate of scalp cooling was the type of chemotherapy. Anthracycline-based chemotherapy was associated with a lower success rate which, however, was still around 60 percent.
- However, no difference was seen between anthracycline- and taxane-based and anthracycline-free was observed when the taxane preceded the anthracycline.

Figure 1: The Paxman cold cap correctly positioned in two patients with primary breast cancer during chemotherapy. **A**, half profile view; **B**, profile view.

Figure 2: Results of sensor-controlled scalp cooling three weeks after cessation of chemotherapy. **A**, Dean score 0: 42 year old premenopausal patient after neoadjuvant chemotherapy with 12 x paclitaxel/carboplatin weekly → 4 x dose-dense epirubicin/cyclophosphamide. **B**, Dean score 1: 59 year old postmenopausal after secondary adjuvant chemotherapy with 12 x paclitaxel/carboplatin weekly for local recurrence after exposure to prior epirubicin/cyclophosphamide and tamoxifen for primary breast cancer. **C**, Dean score 2: 48 year old patients after adjuvant chemotherapy with 4 x dose-dense epirubicin/cyclophosphamide → 12 x paclitaxel weekly, the patient was fully satisfied and abstained from wearing a wig during the whole duration of chemotherapy.