SENSOR-CONTROLLED SCALP COOLING TO PREVENT CHEMOTHERAPY-INDUCED ALOPECIA IN WOMEN TREATED FOR EITHER BREAST OR FEMALE GENITAL TRACT CANCER: A GERMAN EXPERIENCE USING THE PAXMAN SYSTEM

Abstract #10118

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INTRODUCTION

Chemotherapy-induced alopecia (CIA) is among the most common side effects of systemic anti-cancer treatment. Although not life-threatening and mostly reversible, CIA produces a deep emotional impact in many patients (pts) exposed to antineoplastic chemotherapy (Ctx), particularly in women. A recent German survey showed that CIA is even the most distressing Ctx-related side-effect among 1509 female cancer pts [Schilling, 2016] Sensor-controlled scalp cooling (SCSC) is effective in preventing CIA [Friedrichs, 2014; Van den Hurk, 2014; Cigler, 2015; Shin, 2015]. Nevertheless, SCSC is infrequently used in many countries including Germany due physicians´ concerns regarding both safety and feasibility. However, recent reviews showed that SCSC does not increase the risk of developing scalp metastasis nor is it associated with a negative impact on patients´ survival [Rugo, 2013; Lemieux, 2015]. This prospective non-interventional study was initiated to achieve detailed information about the effectiveness and safety of SCSC using the Paxman cooling system (Paxman Inc., Huddersfield, UK) in a real-world population of German female outpatients exposed to CIA-inducing Ctx due to either breast (BC) or gynecologic cancer.

METHODS

A total 87 pts were included of whom the majority (n=68, 78.2%) suffered from BC. 19 pts had various female genital tract cancers (epithelial ovarian carcinoma, n=14; 16.1%). 42 pts were pre- or perimenopausal, 45 pts were postmenopausal. In 63 individuals (72.4%) received Ctx in a curative intent. In 24 cases (27.6%), Ctx was given In a palliative setting. 57 pts (65.5%) were Ctx-naïve. The majority of pts were exposed to anthracyclines (A), taxanes (T) or both (AT). 14 pts (16.1%) had non-anthracycline/non-taxane-based Ctx (non-AT). Detailed patients´ characteristics are summarized in Table 1. Pts were exposed to SCSC during every Ctx course with a 60 min pre-Ctx cooling period and a 90 min post-Ctx rewarming time (Figure 1). All pts were advised to take 600 mg ibuprofen orally prior to SCSC. CIA was quantified according to the Dean score (DS) determined 3 weeks after completion of Ctx (Table 2). SCSC related adverse effects were recorded according to the Common Terminology Criteria of Adverse Effects (CTCAE) scale, version 4.03. The primary endpoint was feasibility indicated by the SCSC completion rate. Secondary endpoints were quality of hair preservation with DS 0-2 qualified as success and DS 3-4 qualified as failure, reasons for discontinuation of SCSC, and safety. Moreover, the following subgroup analyses in regard to SCSC were performed: tumor type (BC vs others), menopausal status, prior systemic cancer treatments, type of Ctx (A /T, AT, non-AT). Subgroups were compared by Fisher´s exact tests and Chi square tests, respectively. For all statistical analyses, $p<0.05$ indicated significance.

RESULTS

57 pts (64.5%) completed SCSC whereas 30 pts (35.5%) prematurely stopped CTCS. Three weeks after completion of Ctx, hair preservation was qualified as complete (DS 0) in 47 pts (53.0%), partial (DS 1-2) in 10 pts (11.5%), or insufficient (DS 3-4) in 30 pts (34.5%). Therefore, satisfying hair preservation was achieved in 57 pts (64.5%) who did not need to wear a wig during the whole course of Ctx (Table 2, Figure 2). Results of the aforementioned subgroup analyses are presented in Table 3. In general, no significant differences in hair preservation could be observed in regard to tumor type, menopausal status, or history of prior systemic anticancer treatment. Considering the individual Ctx protocol administered, a non-significant advantage was observed favoring non-AT regimens over AT, and A/T (p=0.1696), The main reason of SCSC discontinuation was CIA that occurred in 21 pts (24.1%). Headache was reported in 4 (5.0%) and discomfort (“feeling cold”, earache) in 3 pts (3.4%). In 2 pts (2.3%), the reason of SCSC discontinuation remained unclear. Side effects were did not exceed CTCAE grade 2 and resolved quickly after cessation of SCSC Table 4).

Table 1: Patients´ characteristics

Age (years)	
median	50.0
range	31-79
Tumor type	**n (%)**
breast	68 (78.2)
ovarian	14 (16.1)
miscellaneous	5 (5.7)
Menopausal status	**n (%)**
pre-/perimenopausal	42 (48.3)
postmenopausal	45 (51.7)
Intention of chemotherapy	**n (%)**
curative	63 (72.4)
palliative	24 (27.6)
Prior systemic treatments	**n (%)**
No	57 (65.5)
Yes	30 (34.5)
Type of chemotherapy	**n (%)**
anthracycline-based (A)	4 (5.0)
taxane-based (T)	21 (24.1)
anthracycline- and taxane-based (AT)	48 (55.2)
non-anthracycline/non-taxane-based (non-AT)	14 (16.1)

Table 2: General outcome of sensor-controlled scalp cooling

Outcome	Percentage of hair loss	n (%)
Success		
Dean score 0	0%	47 (53.0)
Dean score 1-2	1-50%	10 (11.5)
Failure		
Dean score 3-4	51-100%	21 (24.1)
Discontinuation due to adverse effects	n. a.	7 (8.4)

Table 3: Outcome by subgroup

	Success rate n (%)	p
Tumor type		
breast cancer	45/68 (66.2)	
other	12/19 (63.2)	0.792
Menopausal status		
pre-/perimenopausal	28/42 (66.7)	
postmenopausal	29/45 (64.4)	1.000
Prior systemic treatment		
no	36/57 (63.2)	
yes	21/30 (70.0)	0.637
Type of chemotherapy		
anthracycline- or taxane-based	14/25 (56.0)	
anthracycline- and taxane-based	31/48 (64.6)	
non-anthracycline- and non-taxane-based	12/14 (85.7)	0.170

Table 4: Safety

	Proportion (%)
Scalp cooling completed	57/87 (64.5)
Scalp cooling discontinued	30/87 (35.5)
Reasons for discontinuation	
hair loss	21/87 (24.1)
adverse effects	7/87 (8.4)
headache	*4 (5.0)*
discomfort (“feeling cold”)	*3 (3.4)*
unknown	2 (2.3)

CONCLUSIONS

- SCSC using the Paxman system is feasible, effective and safe in a real-world population of patients with breast or female genital tract carcinoma.
- Nearly 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 infrequently the reason of discontinuation .
- Our results are in good agreement with previous reports although this study included more patients in the palliative setting or with a history of prior antineoplastic chemotherapy.
- Tumor type, menopausal status, preceding antineoplastic treatments or type of chemotherapy did not significantly affect the likelihood to benefit from sensor-controlled scalp cooling.

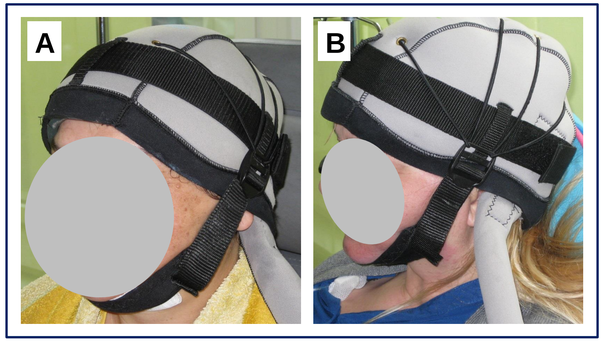

Figure 1: The Paxman cold cap correctly positioned in two patients with primary breast cancer during chemotherapy. **A**, half profile view; **B**, profile view

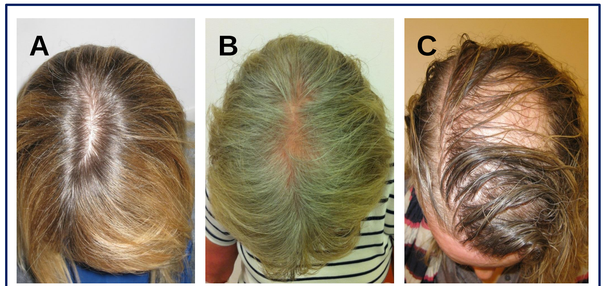

Figure 2: Results of sensor-controlled scalp cooling using the Paxman system in three breast cancer patients three weeks after cessation of chemotherapy. **A**, Dean score 0: 42 year old premenopausal patient after neoadjuvant chemotherapy with 12 x paclitaxel/carboplatin weekly → 4 x dose-dense epirubicin/cyclophosphamide. **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.

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