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Effectiveness and adverse events of the DigniCap® Scalp Cooling System

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BACKGROUND

- Chemotherapy-induced alopecia (CIA) is able to affect a patient's self-image and confidence negatively.
- The DigniCap® scalp cooling system consists of a silicon cap that includes two sensor controlled cooling cycles (Fig.1). These cycles regulate the scalp temperature to lead to a continuous vasoconstriction in the scalp. Thus, it is indicated to reduce the likelihood of CIA.
- No evidence of an increased risk of scalp metastases [1].

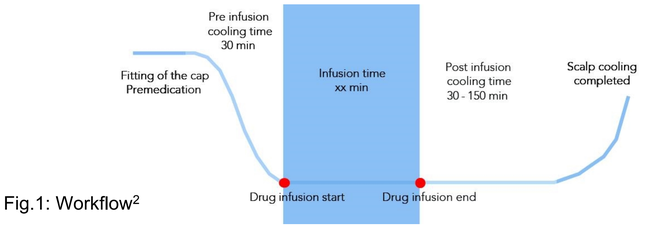

Fig.1: Workflow[2]

OBJECTIVES

- The endpoint of this study was to to quantify the grade of alopecia, satisfaction and side effects of the scalp cooling system.
- Alopecia quantification was done by a standardized questionnaire and photo documentation. Success was defined as patient self-assessed maximum Dean grade of ≤ 1 (Table 1).

Table 1: Dean Scale [3]

Dean Grade	Percentage of hair loss	Success/ Failure
0	No hair loss	Treatment Success
1	>0 up to 25% hair loss	
2	>25% up to 50% hair loss	Treatment Failure
3	>50 up to 75% hair loss	
4	>75% hair loss	

PATIENTS and METHODS

Study Design: prospective, non-randomized, unicentric cohort study

•Since October 2015, 58 of 60 planned breast cancer patients undergoing (neo-) adjuvant or palliative chemotherapy in the certified breast cancer center at AGAPLESION Markus Hospital, Frankfurt am Main, Germany (Table 2).

•The average age was 52.9 years (range 33 – 76).
•100% caucasian phenotype (N = 58)

Table 2: Chemotherapy regimen

Chemotherapy Regimen	N (%)
4x EC q3w → 12x paclitaxel q1w	35 (60.34)
4x TC q3w	5 (8.62)
6x carboplatin + paclitaxel q3w	5 (8.62)
6x docetaxel, carboplatin, trastuzumab (TCbH) q3w + pertuzumab	2 (3.47)
eribulin d1, 8 q3	2 (3.47)
4x *nab*-paclitaxel m 3 q4	1 (1.72)
4x *nab*-paclitaxel m 3 q4 + bevacizumab	1 (1.72)
4x *nab*-paclitaxel m 3 q4 → 4x EC q3w	1 (1.72)
4x paclitaxel q2w → 4x EC q2w	1 (1.72)
18x paclitaxel q1w	1 (1.72)
18x paclitaxel q1w + myocet q1w	1 (1.72)
6x paclitaxel + carboplatin q3w + bevacizumab	1 (1.72)
4x EC q3w → 12x paclitaxel q1w + trastuzumab + pertuzumab	1 (1.72)
4x EC q3w → 12x paclitaxel + carboplatin q1w	1 (1.72)
Total	**58 (100 %)**

RESULTS

- The interim analysis showed a success rate of 63% (hair loss <25%).

Table 3: Effectivenes of DigniCap® Scalp Cooling System

Dean Grade	N (%)	Success/ Failure % (N)
0	4 (7.4)	**Success: 63%** (34)
1	30 (55.6)	
3	7 (12.9)	**Failure: 37%** (20)
3	9 (16.7)	
4	4 (7.4)	

Total: 54 (100%) 4 patients were not evaluable.
Discontinuing treatment because of cooling side effects e.g. headache.

- In 27/ 58 patients (46.5%) adverse reactions caused by the DigniCap®, like headache (10.3%) or CIA (27.6%) or headache and CIA (8.6%) were reported.
- In 22.4% discontinuing treatment because of cooling side effects or CIA.

CONCLUSIONS

DigniCap® Scalp Cooling System has a minimal rate of adverse events (46.5%) and reduces the likelihood of CIA (<25% hair loss) effectively by 63%, even in anthracycline-based regimen.

REFERENCES

[1] Rugo et al. Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis. Breast Cancer Research and Treatment. June 2017, Volume 163
[2] Copyright bei Sysmex Europe GmbH, Bornbarch 1, D-22848 Norderstedt
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