Efficacy and patient acceptability of the DigniCaP ScalpCooler to prevent hair loss in breast cancer patients receiving adjuvant chemotherapy

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Background and objective

Background: Alopecia is a common and distressing adverse effect in breast cancer (BC) patients (pts) receiving adjuvant chemotherapy. The aim of the study was to assess the effectiveness and safety of this device to prevent chemotherapy-induced alopecia in early breast cancer patients (EBCP) receiving adjuvant treatment. The quality of life of pts was also evaluated

Patients and methods

From January to December 2016, this device was proposed to a consecutive group of EBCP submitted to adjuvant chemotherapy at the Breast Unit of Spedali Civili Hospital of Brescia. Degree of hair loss was assessed by two nurse using Dean's alopecia scale by digital photographs at baseline and each chemotherapy cycle. EORTC QLQ-C30 questionnaire and self-reported visual analogical scale (VAS) of symptoms (anxiety, tone of mood, fatigue, nausea, well-being, activity) were collected at baseline and after the first two cycles of chemotherapy. Eighty-seven pts were enrolled and 64 completed the chemotherapy plan and were evaluable.

Acknowledgmen

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Results

Seventy % of pts completed treatment plan with DigniCap (table 1a, b)
In the ITT population 37/64 pts reported no hair loss or G1-hair loss (57%). Table 2
The pts receiving sequential chemotherapy with anthracycline and taxane were more likely to report hair loss, but the difference was not statistically significant (table 3)
The side effects presented with the use of DigniCap were the following: headache in 32% of pts and cold feeling in 57 % of pts.
There wasn't a significant difference between mean score value of QLQ-C30 at baseline and after 2-3 cycle of chemotherapy except for some symptoms related to chemotherapy (astenia, nausea and vomiting). Table 4.
VAS scale documented an increase of fatigue and decrease of anxiety from time 1 to time 2 (data not shown). 1

Table 1a-CHARACTERISTICS OF THE PATIENTS

Characteristics	N° of pts (%)
Median age (range)	51 (31-78)
Grading 2 Grading 3	4 (6) 60 (94)
Ductal Lobular	56 (87) 8 (13)
ER positive	51 (80)
PgR positive	47 (73)
Median Ki-67 (range)	41 (10-90)
Her 2 positive	31 (48)

Table 1b-CHARACTERISTICS OF THE PATIENTS

Treatment	N° of pts (%)
Anthracycline	9 (14)
Taxane	19 (30)
Anthracycline and Taxane	36 (56)

Table 2-% OF HAIR LOSS AND TREATMENT

% of hair loss	N° of pts (%)
No hair loss	17 (26)
G1 (< 25%)	20 (31)
G2 (25-50%)	7 (12)
G3 (50-75%)	18 (28)
G4 (> 75%)	2 (3)

Table 3- DEAN'S ALIPECIA SCALE SCORE AT THE END OF CHEMOTHERAPY

% of hair loss	Antra	Taxane	Antra+taxane
No hair loss	2 (22)	6 (31)	9 (25)
G1 (< 25%)	3 (34)	7 (37)	10 (27)
G2 (25-50%)	0	3 (16)	4 (12)
G3 (50-75%)	4 (44)	3 (16)	11 (30)
G4 (> 75%)	0	0	2(6)

DROUP OUT

Nineteen pts (30%) stopped the treatment because of loss of hair in 12 pts, headache in 4 pts and other problems in 3 pts).

Table 4- QUALITY OF LIFE BEFORE CHEMOTHERAPY (TIME 1) AND AFTER 2-3 CYCLES (TIME 2)

QLQ-C30	Time 1	Time 2	p
Global health status	68,12	59,79	0,07
Functional scale			
Physical functioning	90	85,3	0,02
Role functioning	85	87	0,44
Emotional functioning	68,75	73,12	0,11
Cognitive functioning	85,83	85	0,57
Social functioning	87,08	84,58	0,50
Symptom scales			
Fatigue	20,55	38,05	0,00008
Nausea and vomiting	4,58	11,25	0,006
Pain	9,58	10,00	0,77
Dyspnoea	7,5	11,66	0,26
Insomnia	29,16	28,33	0,85
Appetite loss	11,66	16,66	0,29
Costipation	11,66	10,83	0,89
Diarrhoea	2,50	2,50	1
Finantial difficulties	5,00	3,33	0,77

Conclusion

DigniCap appears to be an effective device in preventing alopecia induced by chemotherapy in a consistent proportion of patients undergoing chemotherapy and was well tolerated.