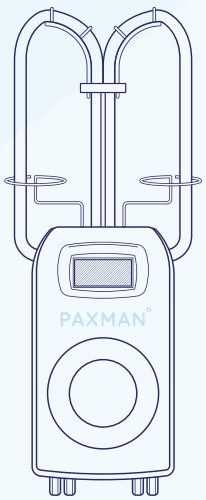
US

PAXMAN

STUDIES

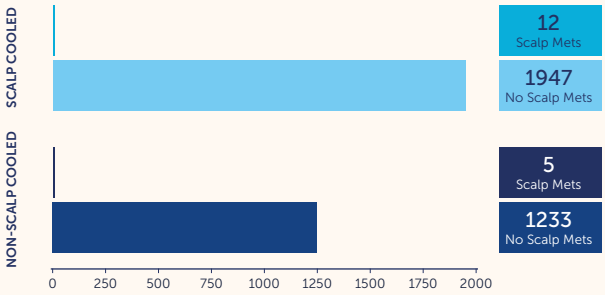
Paxman Scalp Cooling System



paxmangroup.com

Scalp cooling does not increase the risk of scalp metastases

American systematic review and meta-analysis shows no statistical difference in the incidence of scalp metastases in scalp cooled and non-cooled patients. This conclusion shows that previous concerns that have limited the use of scalp cooling were unfounded.[1]



0.61% of 1959 patient who scalp cooled showed incidence of scalp metastases over a mean time frame of 43.1 months.

0.41% of 1238 patients that didn't scalp cooled group showed signs of scalp metastases over a mean time frame of 84.7 months.[1]

Study	Lemieux[2]	Parker[3]	Protiere et al.[4]	Ridderheim[5]	Ron et al.[6]	Rugo[7]
Scalp Cooling						
Scalp Mets	6	0	0	0	0	0
Total Pts	553	6	77	3	19	101
No Scalp Cooling						
Scalp Mets	1		0		0	
Total Pts	87		109		16	
Length of follow-up (months) scalp cooling median	69	12	44	15	14	29.5
Weighted length of follow-up scalp cooling	19,478	0.037	1,729	0.023	0.136	1.521
Length of follow-up (months) no scalp cooling median	64				14	
Weighted length of follow-up no scalp cooling	4,498				0.181	
Characteristics	First time breast cancer patients. Study undertaken in Canada. Mainly T1 and T2 tumour size: stage 1&2, treated with mainly cyclophosphamides and doxorubicin.	Stage 4 recurrent disease. Treated with IV CMP (2 cycles).	First time breast cancer patients. 4 cycles of adjuvant IV chemotherapy with mitoxantrone + cyclophosphamide. Antiemetics also administered. Study undertaken in France.	Adjuvant treatment breast cancer.	Breast cancer patients treated with cyclophosphamide, methotrexate and 5-fluorouracil (CMF); unclear as to stage of breast cancer.	Early stage breast cancer patients.

Study	Spaeth et al.[8]	Tollenaar et al.[9]	Van de Sande[10]	Van den Hurk et al.[11]	Totals	Averages
Scalp Cooling						
Scalp Mets	3	0		3	**12**	
Total Pts	770	35		395	**1959**	
No Scalp Cooling						
Scalp Mets	0		4		**5**	
Total Pts	141		885		**1238**	
Length of follow-up (months) scalp cooling median	36	46		26		**32.39**
Weighted length of follow-up scalp cooling	14.150	0.822		5.242		**43.14**
Length of follow-up (months) no scalp cooling median	36		110			**56**
Weighted length of follow-up no scalp cooling	4.100		78.635			**87.41**
Characteristics	93% breast cancer patients. Treated with IV chemo mainly anthra-cyclines and/or taxotere. Unclear as to stage of breast cancer.	Patients treated with cyclo-phosphamide + 5-fluorouracil on a first operative day 9 one course of treatment. Unclear as to stage of cancer.	Stage 4 + lymph nodes.	Treated with CMF; unclear as to stage of breast cancer.		

Conclusion

Scalp metastases occur rarely in breast cancer (with metastases more commonly occurring in other areas of the skin including chest wall), and scalp metastases seem to accompany and usually occur following the diagnosis of widespread metastatic disease.[1]

Limitations

Retrospective studies use pre-recorded data, therefore, most studies used did not specifically assess scalp metastasis as a primary end point.

Studying of scalp metastases in scalp-cooled patients continues to assure data is relevant over a longer average time frame.[1]

Paper: Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer & the risk of scalp metastases

[1] Rugo HS, Melin SA, Voigt J. Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis. Breast Cancer Res Treat. 2017;163(2):199-205.

[2] Lemieux J, Provencher L, Perron L, Brisson J, Amireault C, Blanchette C, Maunsell E. No effect of scalp cooling on survival among women with breast cancer. Breast Cancer Res Treat. 2015 Jan;149(1):263-8. doi: 10.1007/s10549-014-3231-0. Epub 2014 Dec 16.

[3] Van den Hurk CJ, van den Akker-van Marle ME, Breed WP, van de Poll-Franse LV, Nortier JW, Coebergh JW. Impact of scalp cooling on chemotherapy-induced alopecia, wig use and hair growth of patients with cancer. Eur J Oncol Nurs. 2013;17(5):536-540.

[4] Udrea, A. Scalp cooling system in preventing chemotherapy-induced alopecia: a pilot study on 108 patients – a Romanian oncology – day hospital experience. Medisprof Oncology. Psycho-Oncology 23 (Suppl. 3):169-254 (2014), P1-0062.

[5] Van der Hurk CJ, Mols F. Impact of alopecia and scalp cooling on the well-being of breast cancer patients. Psycho-Oncology. 19(7):701-9 (2010).

[6] Dunnill CJ, Al-Tameemi W, Collett A, Haslam IS, Georgopoulos NT. A Clinical and Biological Guide for Understanding Chemotherapy-Induced Alopecia and Its Prevention. Oncologist. 23(1):84-96 (2018).

[7] Lemieux J, Amireault C, Provencher L, Maunsell E (2009) Incidence of scalp metastases in breast cancer: a retrospective cohort study in women who were offered scalp cooling. Breast Cancer Res Treat 118:547–552

[8] Parker R (1987) The effectiveness of scalp hypothermia in preventing cyclophosphamide-induced alopecia. Oncol Nurs Forum 14:49–53

[9] Protiere C, Evans K, Camerio J et al (2002) Efficacy and tolerance of a scalp-cooling system for prevention of hair loss and the experience of breast cancer patients treated by adjuvant chemotherapy. Support Care Cancer 10:529–537

[10] Ridderheim M, Bjurberg M, Gustavsson A (2003) Scalp hypothermia to prevent chemotherapy-induced alopecia is effective and safe: a pilot study of a new digitized scalp-cooling system used in 74 patients. Support Cancer Care 11(6):371–377

[11] Ron LG, Kalmus Y, Kalmus Z et al (1997) Scalp cooling in the prevention of alopecia in patients receiving depilating chemotherapy. Support Care Cancer 5:136–138

Survival Rates with Scalp Cooling

Scalp cooling has no impact on survival rates when used with chemotherapy in a non-metastatic setting.[2]

A Canadian, retrospective, multicentre cohort study based on 533 women who used scalp cooling and 817 women who did not.[2]

The following variables were considered – age at diagnosis, stage of cancer, presence of lymphovascular invasion grade, type of chemotherapy (taxane or anthracycline), oestrogen receptor status, timing of chemotherapy (adjuvant or neo adjuvant).[2]

Characteristics	No scalp cooling (n=817)	Scalp cooling (n=553)	*p* Value
Age at diagnosis (means in years +/-SD)	53.5 ± 10.9	51.8 ± 9.6	0.24
A60C600/D100[b] (ACD)			10/16 (63)
Stage*			**0.009**
I	206 (26.1%)	115 (20.8%)	
II	516 (65.4%)	367 (66.6%)	
III	67 (8.5%)	70 (12.1%)	
Unknown	28	1	
Grade			**0.11**
I	143 (18.4%)	85 (17.6%)	
II	325 (41.8%)	177 (36.7%)	
III	309 (39.8%)	220 (45.7%)	
Unknown	40	71	
Lymphovascular invasion			**0.0002**
Yes	295 (66.4%)	212 (38.5%)	
No	300 (50.4%)	338 (61.5%)	
Unknown	222	3	
Hormon receptors (oestrogens)			**0.0096**
Positive	525 (66.4%)	403 (73.0%)	
Negative	266 (33.6%)	149 (27.9%)	
Not done	26	1	
Type of chemotherapy			**<0.0001**
AC or CMF	339 (46.7%)	338 (61.1%)	
Anthracyclines**	300 (41.4%)	163 (29.5%)	
Taane-based	86 (11.9%)	52 (9.4%)	
Known	92	0	
Had neoadjuvant chemotherapy			**0.12**
Yes	75 (9.2%)	65 (11.8%)	
No	742 (39.7%)	488 (88.2%)	
Adjuvant hormone therapy			**<0.0001**
Yes	493 (60.3%)	392 (70.95%)	
No	324 (89.6%)	161 (29.1%)	
Participated in a clinical trial			**<0.0001**
Yes	85 (10.4%)	104 (18.8%)	
No	732 (89.6%)	161 (81.2%)	

Paper: No effect of sclap cooling on survival among women with breast cancer

SD standard deviation; AC doxorubicin, cyclophosphamide, methotrexate, 5-fluorouracil; CEF cyclophosphamide, epirubicin, 5-fluorouracil, CE cyclophosphamide, epirubicin; FED 5-fluorouracil, epricubicin, cyclophosphamide; FAC 5-fluorouracil, doxorubicin, cyclophosphamide.

*When neoadjuvant chemotherapy was given, the stage was clinical. Staging was based on the AJCC 5th edition.

**Anthracyclines chemtoehrapy corresponds here to the following regimens: CEF, CE, FEC or FAC.