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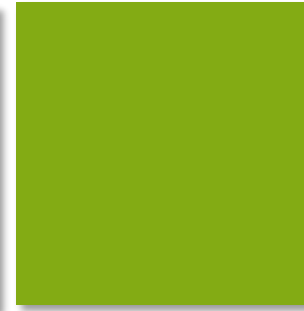
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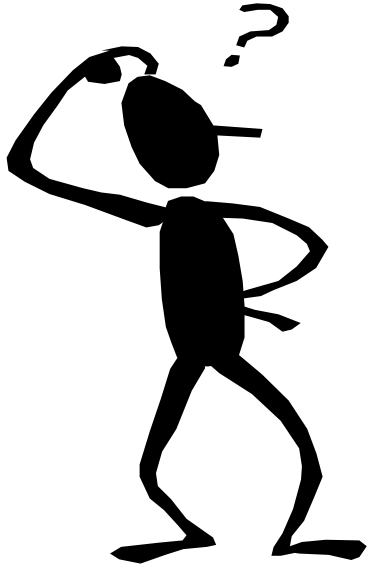
EvaSCALP: Scalp cooling experience at LMU Munich

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**Brustzentrum der
Universität
München**
Leitung:
Prof. Nadia Harbeck





Scalp Cooling

- Scalp cooling
- Set-up LMU outpatient clinic
- EvaSCALP
- First experiences
- Conclusions
- Your Questions

Scalp cooling: Efficacy

- “Our analyses of CCTs and RCTs to date show that scalp hypothermia is effective in **reducing** the **occurrence rate of CIA**, by **2.7-fold in the CCTs** and **3.9-fold in the RCTs**”.

Shah et al, J Eur Acad Dermatol Venereol. 2017

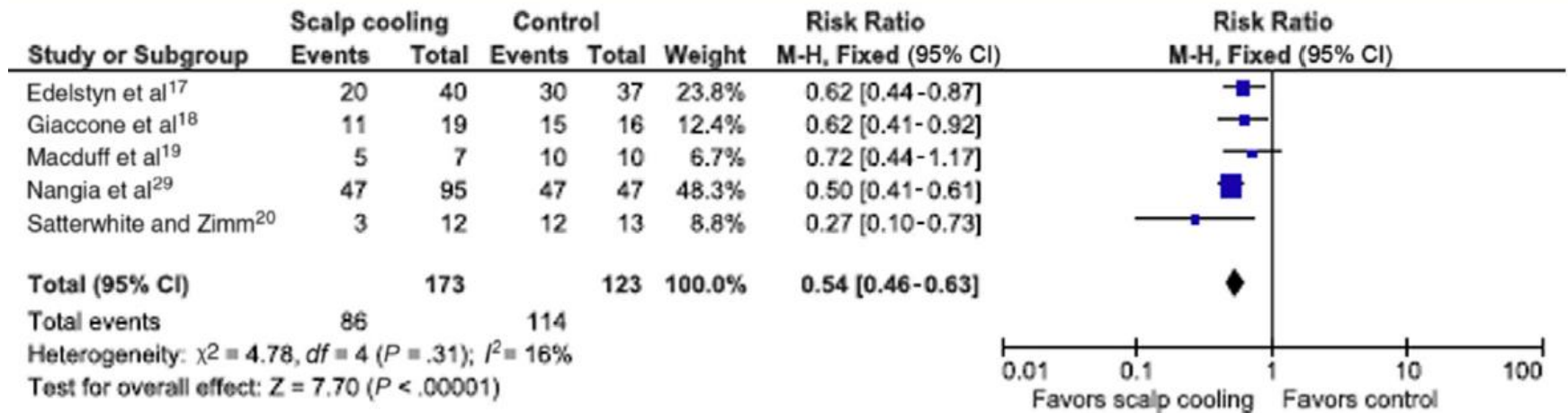
Scalp cooling: Efficacy

- Systematic review, 10 studies (n=654) included
- Majority breast cancer patients (n=432, 66%), mostly receiving anthracyclines
- Binary outcome (<50% vs. >50% alopecia):
RR 0.57; 95% CI, 0.45-0.72; $I^2 = 11\%$; $P < .00001$
- Ordinal outcomes (alopecia scale of 0-3): MD -0.80; 95% CI, -1.19 to -0.41; $I^2 = 0\%$; $P < .0001$
- The quality of the evidence was graded as moderate

Scalp cooling: Efficacy

Study	Number of Patients	Scalp Cooling Method Used	Treatment (Cancer Therapies)	Number of Treatments	Cancer Type
Dougherty ²⁷	48	Gel cap	Doxorubicin and/or epirubicin	Unclear	Mainly breast cancer (statistics not available)
Dougherty ²³	170	Chemocap and Gel cap	Epirubicin or doxorubicin, fluorouracil, cyclophosphamide	Unclear	Breast cancer
Edelstyn et al ¹⁷	87	Cryogel bag	Doxorubicin, vincristine, 5-fluorouracil, chlorambucil, methotrexate	1	Breast cancer
Giaccone et al ¹⁸	35	Spenco Hypothermia Cap	Cyclophosphamide, 5-fluorouracil, vincristine, cisplatin, carboplatin, mitomycin	2	Advanced or metastatic cancer: breast, 91%; ovary 9%
Kennedy et al ²¹	19	Chemocap	Cyclophosphamide, doxorubicin	6	Metastatic cancer: breast 53%; gastric 15%; lymphoma 11%; sarcoma 11%; pancreatic 5%; mesothelioma 5%
Macduff et al ¹⁹	17	Gel cooling cap	Epirubicin with docetaxel	6	Breast cancer
Nangia et al ²⁹	142	Paxman scalp cooling system	51 With doxorubicin and cyclophosphamide; 43 with docetaxel and cyclophosphamide; 32 with docetaxel with carboplatin and trastuzumab; 10 with paclitaxel; 3 with docetaxel; 2 with docetaxel with pertuzumab and trastuzumab; 1 with paclitaxel with carboplatin	4	Stage I and II breast cancer
Parker ²²	14	Spenco Hypothermia Cap	Cyclophosphamide with methotrexate and 5-fluorouracil	Minimum of 7 treatments	Stage IV breast cancer
Satterwhite and Zimm ²⁰	25	Chemocap	All with doxorubicin with combinations of 16 and Cytoxan (cyclophosphamide); Cytoxan, vincristine, cisplatin, 5-fluorouracil/mitomycin C; dacarbazine, Velban (vinblastine)/thiotepa/fluoxymesterone	Average of 2 treatments	Breast 36%; stomach 16%; lung 12%; all others 40%
van den Hurk et al ²⁸	97	Paxman scalp cooling system	Docetaxel	Unclear	Unclear

Scalp cooling: Efficacy



BREAST CENTER, UNIVERSITY OF MUNICH (LMU)

- Certified interdisciplinary breast center (DKG, DGS)
- Part of Comprehensive Cancer Center Munich
- Two hospital sites (Grosshadern, Maistrasse-Innenstadt)
- Two outpatient clinics (each: 14 chairs and ~ 20 therapies/day)
 - Breast cancer, gynecological malignancies
 - EC-paclitaxel q7w, TCHP, TC, paclitaxel q7w (+ mAB)
- Extensive clinical trials program, affiliation with WSG



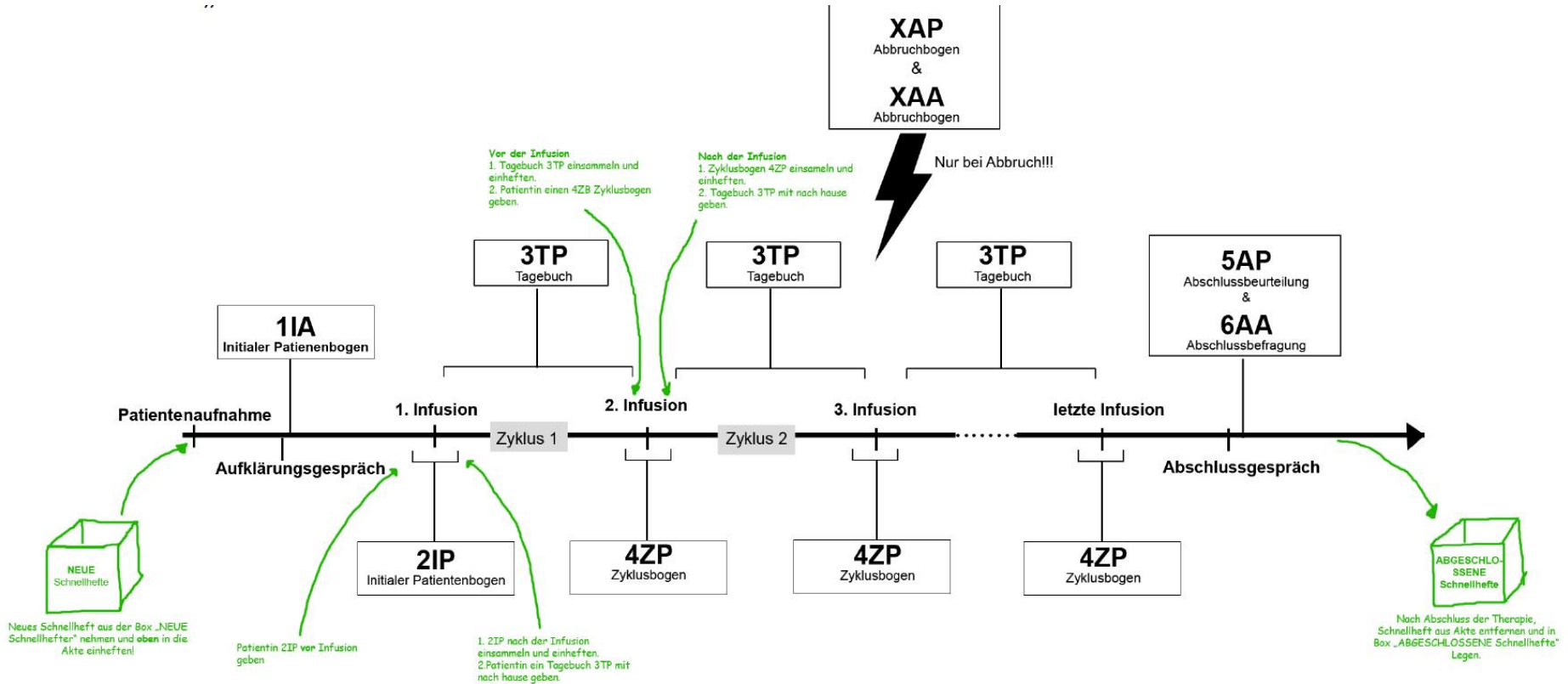
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EvaSCALP

- Evaluation of user satisfaction with the scalp cooling system Orbis II for reduction of chemotherapy-associated hairloss



EvaSCALP Clinical Trial



EvaSCALP: Initial physician assessment

Alter (Jahre):

Geschlecht:
 Weiblich
 Männlich

Karzinom:
 Mammakarzinom
 sonstiges:

Chemotherapie:
 adjuvant
 neoadjuvant
 metastasiert

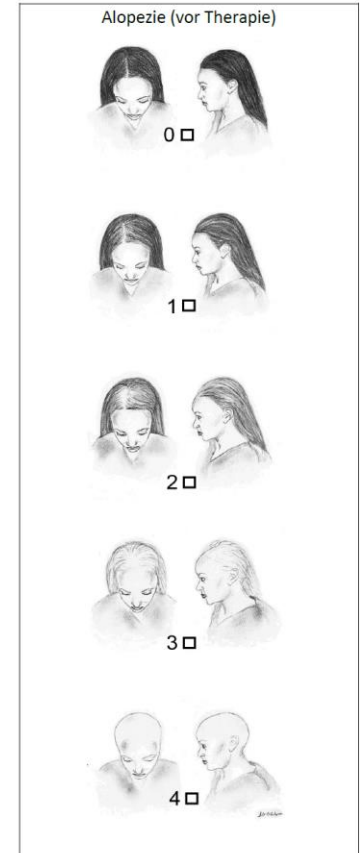
Therapieregime:
(Medikament / Zyklen / geplanter Zeitintervall)
Beispiel: AC-Paclitaxel 60mg, 4 Zyklen à 21 Tage

Chemotherapie:

- Anti HER2-Substanz:

- Knochensubstanz:

- Sonstige Substanzen:



Datum: _____.2013

Patient **21P**
Initialer Patientenbogen (SC)

EvaSCALP: Initial patient questionnaire

- Additional questions regarding QoL and side effects
- EOT questionnaire

Waren Sie früher schon ein mal an Krebs erkrankt?

Ja
 Nein

Glauben Sie, dass die Kühlkappe Sie vor Haarverlust bewahren kann?

Ja
 Nein

Haben Sie schon ein mal eine Chemotherapie bekommen?

Ja, wann zuletzt? _____
 Nein

Wenn Ja, haben Sie dabei die Haare ganz oder teilweise verloren?

Gar nicht
 Teilweise
 Ganz

Bitte beurteilen Sie nach dem abgebildeten Schema den Grad Ihrer aktuellen Haarsituation.



Leiden Sie unter einer der folgenden Stoffwechselstörungen?

- Diabetis Mellitus Ja Nein
- M. Crohn Ja Nein
- Schilddrüsenunterfunktion Ja Nein
- Essstörung Ja Nein
- Sonstige: _____

Nehmen Sie eines der folgenden Medikamente regelmäßig ein?

- β -Blocker Ja Nein
- Gerinnungshemmer Ja Nein
- Retinoide Ja Nein
- Gestagene Ja Nein
- Thyreostatika Ja Nein
- Jod Ja Nein
- Statine (Cholesterinsenker) Ja Nein
- Steroidhormone/Androgen Ja Nein

Haben Sie Angst bei dieser Chemotherapie ihre Haare zu verlieren?

Ja
 Nein

Evaluation zum Thema **Chemotherapie-induzierte Alopezie**
Verantwortlich: Daniel Schiltz; Prof. Dr. Nadia Harbeck; Prof. Timo Schinköthe; Dr. Rachel Würstlein
Ansprechpartner: Daniel Schiltz, daniel.schiltz@tum.de; Dr. Rachel Würstlein, Tel. 089 5100 4779

Scalp cooling: LMU experience



Scalp cooling: LMU experience



Patients with Scalp Cooling

- Interim analysis (presented 05/2017):
- 41 patients stopped or finished scalp cooling within EvaScalp
- Good acceptance
- Few complications

EvaSCALP: Summary of patients*

Outcome	Number of patients	Percentage
Finished cooling (and chemo)	20	48.78%
Stopped cooling because of hair loss	18	43.90%
Stopped cooling because of side effects	3	7.32%

* interim analysis

EvaSCALP: Patients who stopped cooling because of side effects (all during EC)*

Side effect	Patients	Percentage
Migraine	2	4.88%
Paranasal sinusitis	1	2.44%
Total	3	7.32%

* interim analysis

EvaSCALP: Patients who completed scalp cooling / who quit because of hair loss, stratified by chemotherapy*

Drugs	Total	Finished cooling (total)	Finished cooling (percent)	Stopped because of hairloss (total)	Stopped because of hairloss (percent)	Stopped because of side effects (total)
EC	13	1	7.69%	9	69.23%	3
Abraxane	2	1	50%	1	50%	-
Carboplatin/ Nab-paclitaxel	1	0	0%	1	100%	-
Docetaxel	1	0	0%	1	100%	-
TCbH (+P)	5	3	60%	2	40%	-
Paclitaxel (+H +P)	19	15	78.95%	4	21.05%	-
Total	41	20	48.78%	18	43.90%	3

EvaSCALP: Current numbers 11/2017 (n=75)

Outcome	Number of patients	Percentage
Finished cooling (and chemo)	35	46.7%
Stopped cooling because of hair loss	32	42.7%
Scalp cooling ongoing	8	10.6%

EvaSCALP: Patient case

- Inflammatory TNBC, cM0, cN1
- After Paclitaxel 12 x weekly with Carboplatin AUC2
- Hair loss after EC 4x q3w



EvaSCALP: Patient case

- mTNBC (LYM, OSS, PUL, HEP)
- End of treatment with nab-Paclitaxel



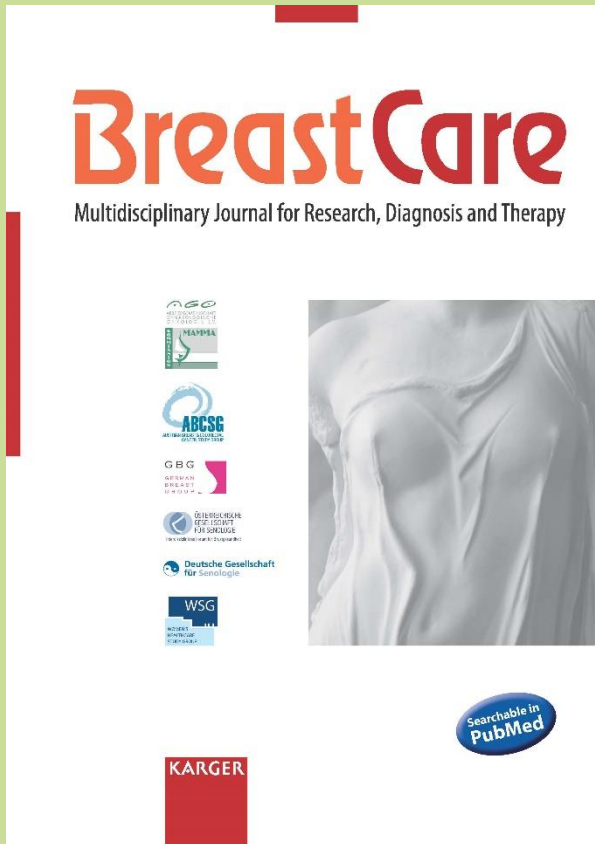


So, Where are we exactly?

LMU scalp cooling experience

- ✓ Few complications and good acceptance
- ✓ Good implementation in daily routine
- ✓ Best results with paclitaxel weekly (with or without antibodies) and TCbH (+P)
- ✓ Results with anthracyclines (mostly EC q21) not satisfactory
- ✓ Motivation of oncology nurses and detailed patient information is key to success !

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