CROWNING GLORY: IS THAT THE WHOLE STORY?
Implementing scalp cooling in an Australian setting

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Background: Hair loss from chemotherapy is one of the most feared and distressing consequences of treatment for breast cancer (1, 2), and may cause women to decline potentially life-saving treatment. Despite improvements in managing other side effects with newer anti-emetics and white cell growth factors, current anthracycline and taxane-based regimens almost universally cause chemotherapy-induced alopecia (CIA) severe enough to warrant the use of a wig or other head covering.

Severe hair loss usually starts at 2-3 weeks after the first dose of chemotherapy and often becomes clinically apparent after 1-2 months (2). Hair regrowth may take up to 12 months and hair quality is often altered during the recovery phase. On occasions hair does not regrow after Docetaxel and is thought to be related to follicle stem cell loss. This cannot only be expensive for the patient having to purchase wigs but it can also lead to a negative body image, stigmatizing patients with a disease (2) and attracting public comment. Scalp cooling has been shown to prevent around 50% - 60% of chemotherapy-induced alopecia in breast cancer patients and is widely used overseas. A growing number of centres in Australia now offer this preventative therapy.

Methods: Since 2010, the Patricia Ritchie Centre has been using scalp cooling technology; first using the Penguin Caps. These needed to be fitted and changed every half an hour which required extra staff resources. Patients' experience some discomfort because they are cold (minus 35 degrees) when placed on the patient's head, which limits acceptability. Since early 2013, the Dignitana system has been used which offers potential advantages as it is placed on the patients' head at room temperature and does not need to be changed.

This pilot study has investigated the effectiveness and feasibility of two different scalp cooling systems for women undergoing chemotherapy for early breast cancer in Australia. Variables recorded include patient demographics, chemotherapy regimens, grading of hair loss and side effects of cooling. These data form part of a larger international study which will establish a Scalp Cooling Registry of all patients with early breast cancer receiving chemotherapy with the protocols AC, TC and FEC-D.

Data sources/Collection: Patients were recruited from the practices of the Medical Oncology Consultants at the Patricia Ritchie Centre, The Mater Hospital, Sydney and were staged as early breast cancer (Stage 1 and II) patients receiving one of the following chemotherapy regimens: 1) AC or combination, 2) FEC or FEC-D, 3) TC or 4) Other chemotherapy combination.

Outcome measures

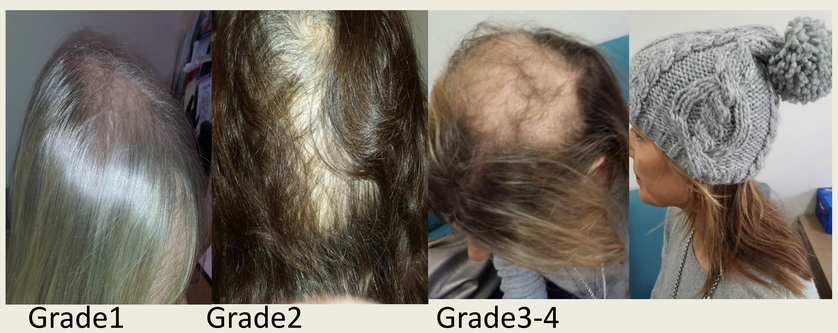
Completion rates

Hair loss - measured using Dean's Alopecia Grading (Consultant)

Grade: 1 Excellent, hair loss < 25 %.
Grade 2: Good, hair loss 25-50%
Grade 3: Moderate, hair loss 50-75%
Grade 4: Severe, hair loss 75-100%

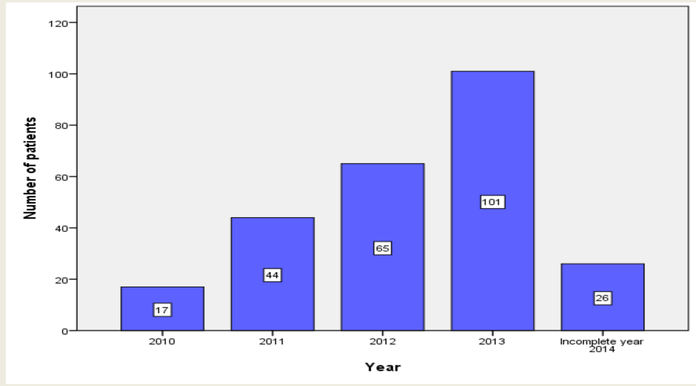
Other adverse events

Early discontinuation due to pain, vomiting
Scalp abnormalities e.g. "frost bite", ears, comfort

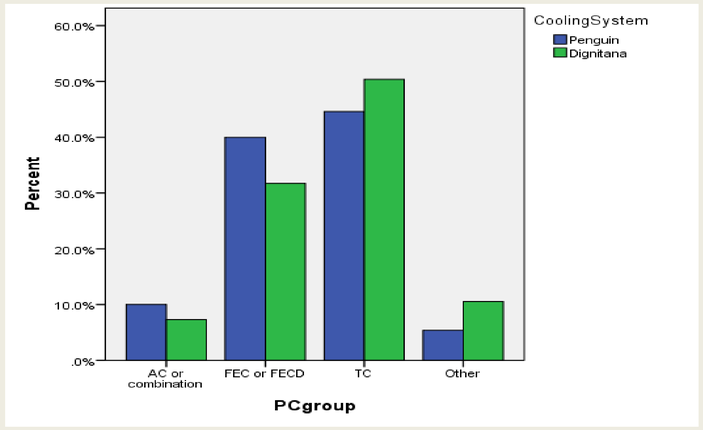


Grade1 Grade2 Grade3-4

Results: Since 2010, a dataset has been established which monitors the outcomes of scalp cooling for early breast cancer patients receiving chemotherapy at the Patricia Ritchie Centre (PRC), Sydney. Data from 253 patients have been analysed for patients who completed their planned chemotherapy treatment and were scalp cooled using i) Penguin Caps or ii) the DigniCap® system. During 2014, an additional option of a Paxman Orbis R machine has been introduced but sample size is insufficient at present for meaningful comparisons to be made.



- An increasing number of patients each year have opted for scalp cooling which is now offered as 'routine care' at the Patricia Ritchie Centre, The Mater Hospital
- 2014 data is not yet complete



- The proportions of patients in this sample were spread evenly across four treatment groups and between the two scalp cooling groups (Penguin and DigniCap®)
- Patients' mean age in the two scalp cooling groups was similar (Penguin group, 50 yrs; DigniCap® group 52 yrs)

Completion rates:

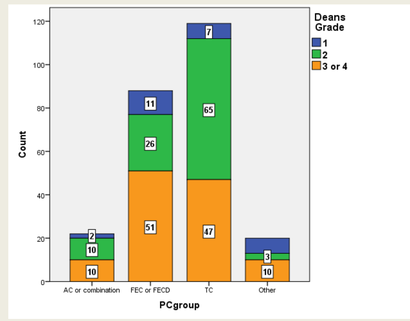
- 91 patients (70%) completed using the Penguin Caps
- 99 patients (80.5%) completed using DigniCap® System
- Although not statistically significant this represents a slightly higher completion rate for the DigniCap® group (Chi-square (continuity corrected) =3.18, df=1, p=0.075)

Patient feedback – completed scalp cooling:

- Very happy with result
- Regrowth seems to be happening quicker
- Not as painful as I thought
- Helped me take control and protect my privacy

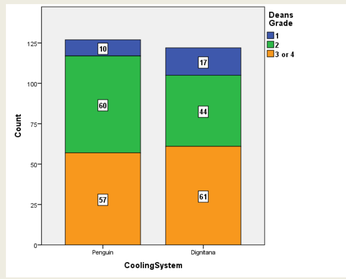
Patient comments – reasons for stopping

- 12 patients 'could not tolerate the cold' or 'pain'
- 12 felt it was not working (had lost all hair) so stopped mid-way through chemotherapy
- 7 patients had other issues (e.g. nausea, side effects of chemo, matting, ear infection)
- 32 patients discontinued – no specific reason



Hair Loss: Treatment groups

- 51 (58%) of patients in the FEC group recorded a Dean's Grade 3/4 (over 50% hair loss)
- 47 (40%) of patients in the TC group recorded a Dean's Grade 3/4
- Statistically more patients have a greater hair loss in the FEC group compared with patients in the other three treatment groups (Chi-square=28.8, df=6, p<0.0005)



Hair loss : Scalp cooling groups

- 57 (45%) of patients in the Penguin group recorded a Dean's Grade 3/4 (over 50% hair loss)
- 61 (50%) of patients in the DigniCap® group recorded a Dean's Grade 3/4
- No statistical difference in hair loss between the two groups of scalp cooling patients (Chi-square=4.31, df=2, p=0.12).

Noted Barriers to Change

- Oncologists and Nursing staff perceptions of efficacy and safety
- Fear of increased work loads
- Scheduling and chair time
- Patient comfort and support

SUMMARY

- **Scalp cooling is feasible and the opportunity to minimise hair loss is valued by patients**
- **Nursing staff input into changes in practice is integral to effective implementation**
- **Scalp cooling is now seen as standard of care at the Mater hospital cancer unit and is offered to all patients attending for treatment of early breast cancer, metastatic breast and prostate cancer patients**
- **Refrigerated systems are easier to use for staff and acceptable to patients**

REFERENCES:

1.Van den Hurk C, et al. Impact of alopecia and scalp cooling on the well-being of breast cancer patients. Psycho-Oncology 2010; 19: 701-09.
2. Breed W, et al. Presentation, impact and prevention of chemotherapy-induced hair loss: scalp cooling potentials and limitations. Expert Review of Dermatology 2011; 6: 109-25.
3. Van den Hurk et al, Impact of scalp cooling on chemotherapy induced alopecia, wig use, and hair growth of patients with cancer. European J Oncology Nursing, 2013.02.004 (in press).
4. Boyle et al, COSA 2014