"Randomised controlled trial of Scalp Cooling (SC) for the prevention of Chemotherapy Induced Alopecia (CIA)"

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Background:
- Chemotherapy Induced Alopecia (CIA) is the most visibly distressing chemo Side effect
- The only randomized trial of SC to prevent CIA did not evaluate its effect on CIA and HR
- We conducted a randomized trial of SC in a setting of anthracycline (A) and taxane chemotherapy and assessed its effect on CIA and HR

Methods:
- Eligibility Criteria:
  - Non-metastatic breast cancer women undergoing neo/adjuvant chemotherapy
- Primary Endpoint:
  - To compare success in hair preservation, between the Paxman Scalp Cooling System versus control
- Secondary endpoints:
  - Cooling System and control (no cooling) after 4 cycles of anthracyline chemotherapy and assessed its effect on CIA and HR

Results:
- Hair preservation (HP) rate was significantly higher in SC arm (18/32, 56.3%) compared to control arm (0/17, 0%; difference 56.3%, 95% CI 31%-73%, P = 0.00004).
- Hair Regrowth (HR) was higher in SC arm compared to control at 6 weeks (89% vs 12%; difference 77%, 95% CI 49%-83%; p = 0.001) and 12 weeks (100% vs 50%; difference 45%, 95% CI 7%-88%, p = 0.003).
- Hair preservation after 4 cycles was higher in patients receiving T versus those receiving A (77% vs 33%, p = 0.030).

Quality of life and Adverse Events
- Majority reported hair loss at primary endpoint evaluation landmark was significantly lower in SC versus control arm (45% vs 82%, p = 0.016) with comparable head cover use of 47% in SC vs 100% in controls (p = 0.001).
- Of 33 patients who started on SC, 23 (69%) patients experienced grade 1-2 cold related adverse effects in SC arm with no grade 3-4 events.

Conclusions:
- Women with breast cancer receiving A or T chemotherapy were significantly more likely to have <50% hair loss after chemotherapy, had superior hair regrowth and improved patient reported outcomes, if scalp cooling was used.

References:

Limitations
- The most rate limiting step in the use of SC in patients in high turn over centers especially in most LMICs would be the lack of space and time.
- The treatment time would also be considerably longer consisting of precooling for 30 minutes, followed by administration of chemo and 90 minutes post chemotherapy cooling period (around 3-4 hours in total).
- Reimbursement of scalp cooling is not so far offered by insurance companies (Cost USD 50 to 75 per cycle in India).

Aims:
- To test if, the Paxman Scalp Cooling System is safe and effective in reducing chemotherapy-induced alopecia in women with non-metastatic breast cancer undergoing neo/adjuvant and adjuvant anthracycline and/or taxane chemotherapy

Method:
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  - To test if the Paxman Scalp Cooling System is safe and effective in reducing chemotherapy-induced alopecia in women with non-metastatic breast cancer undergoing neo/adjuvant and adjuvant anthracycline and/or taxane chemotherapy
  - Hair Regrowth at 6 and 12 weeks after completion of chemotherapy
  - Secondary endpoints:
    - Cooling System and control (no cooling) after 4 cycles of anthracyline chemotherapy
    - Adverse events and comparative quality of life scores
    - To compare success in hair preservation, between the Paxman Scalp Cooling System versus control
  - Aims:
    - Scalp Cooling Device on Alopecia in Women Undergoing Chemotherapy for Breast Cancer: The SCALP Randomized Clinical Trial.

Quality of Life

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