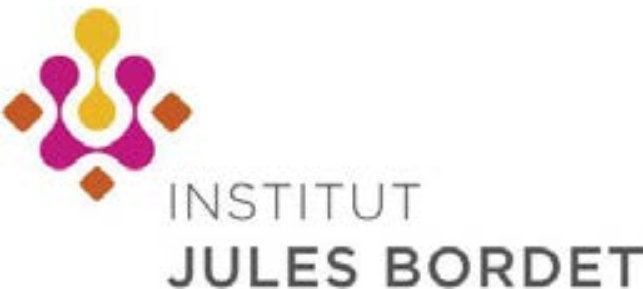


LOW LEVEL LASER THERAPY IN THE TREATMENT OF CHEMOTHERAPY AND TARGETED THERAPY INDUCED PALMAR-PLANTAR ERYTHRODYSESTHESIA (PPE)



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ANNUAL MEETING
SUPPORTIVE CARE IN CANCER



MAKES EXCELLENT
CANCER CARE POSSIBLE

Faculty Disclosure

<input checked="" type="checkbox"/>	No, nothing to disclose
<input type="checkbox"/>	Yes, please specify:



PPE : grades

Grade 1 : Minimal skin changes or dermatitis (e.g., erythema, edema or hyperkeratosis) without pain

Grade 2 : Skin changes (e.g., peeling, blisters, bleeding, edema or hyperkeratosis) with pain; slightly limiting instrumental activities of daily living (IADLs)

Grade 3 : Severe skin changes (e.g., peeling, blisters, bleeding, edema, or hyperkeratosis) with pain; limiting self-care ADL

CTCAE Version 4.0, June 2010, National Institutes of Health, National Cancer Institute



PPE: histology and pathogenesis

- First described in 1984 by Lokich and Moore during a 5FU infusion
- Pathogenesis – unclear
- Histology is not specific but shows:
 - interface dermatitis, keratinocyte necrosis, dilated blood vessels, edema, hyper or parakeratosis, perivascular lymphohistiocytic infiltration in the dermis, and possible eccrine squamous syringometaplasia
- **PPE etiology:** antimetabolites, anthracyclines , TKI, dermatologic diseases, infections, denutrition, GVH
- **Standard treatment:** dose reduction or discontinuation of anticancer treatment, symptom control and local treatment
- **Bio-photomodulation (LLLT):** active for mucositis and radiodermatitis



Methods

- N patients : 32 included and 31 evaluated
- Random allocation of treatment was done to determine the site to be treated with LLLT : left or right
- The other site had to be treated with sham laser

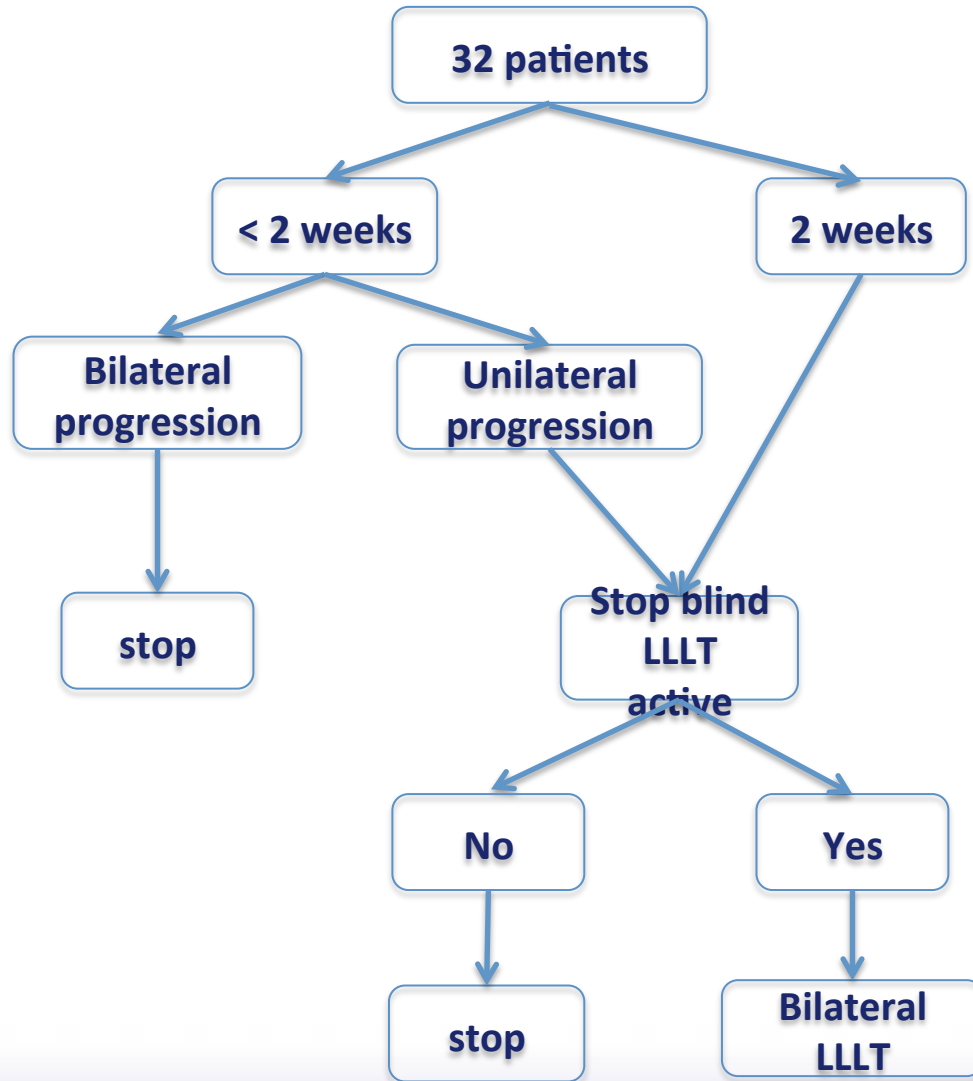
- The patient was his « own-control »

- Dose : 2 J/cm², 500 mW, 3 x week and with minimum 2 weeks blinded
- Total of 6 weeks

- Evaluation
 - blinded assessor 1 x week
 - treating nurse on every session
 - photos 1x week



Study design



Inclusions criteria

- Bilateral PPE grade 1, 2 et 3
- Patients on undergoing anti-cancer treatment: chemo and/or targeted treatment

Statistics

- Expectations: response in 57% for treated sites and 25% for sham treated sites; statistical power 90%

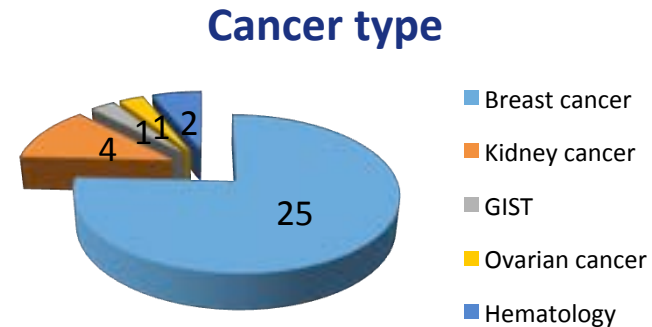


Results

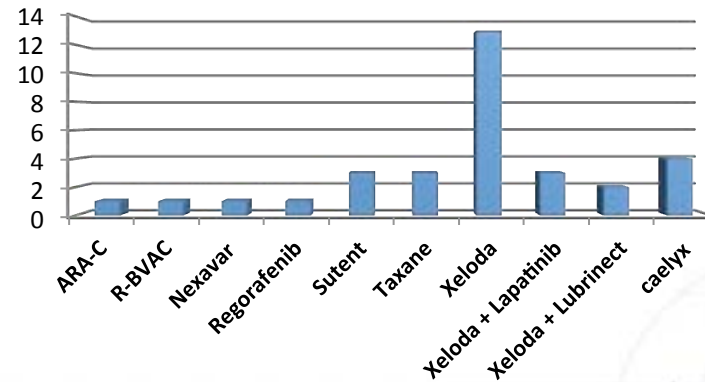


Patients characteristics	
N patients	32
- excluded	- 1
Sex	
- female	27
- male	5
Age	58 years (34-80)
Tumor	
- solid	30
- hematology	2
Treatment	
- chemotherapy	22
- TKI	5
- combination	5
Treatment body side	
- right	16
- Left	15

Frequency of PPE according to cancer type and treatment



Anticancer treatment

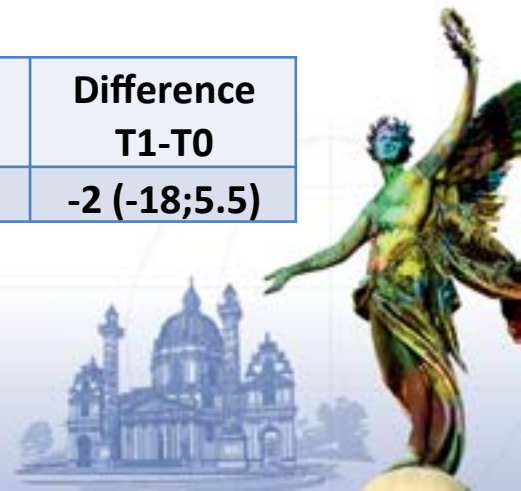


Results



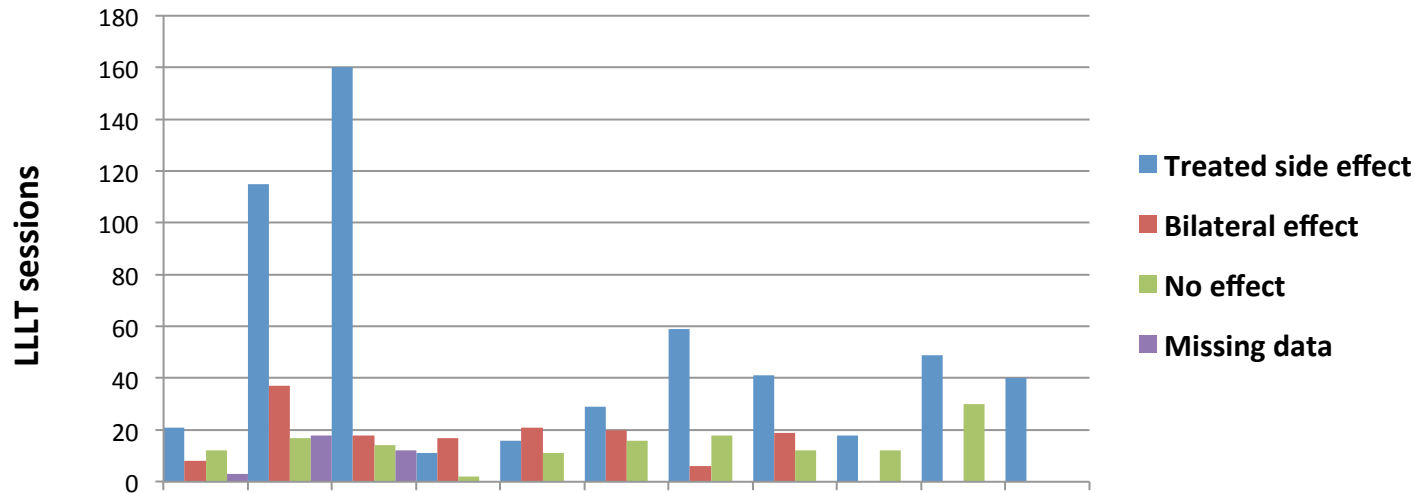
- There was no evidence that the severity of the lesions, at baseline, was different according to the body site :
Hand : $p=0.25$ Foot : $p=1$
- This first main assessment was done before unblinding (T1)
 - median 21 days (from 2 to 61 days)
 - median number of sessions 10 (from 2 to 18)
- At that point the results of the treatment for 27 patients with available data (median and range) show that the overall median difference is 0 (-5;5) and the p value is 0.42

ScoreT0LT	ScoreT1LT	Difference T1-T0	ScoreT0SL	ScoreT1SL	Difference T1-T0
11 (4;21)	8 (2;17)	-2 (-15;6)	10.5 (3;25)	8 (2;16)	-2 (-18;5.5)



Results

Individual data



- Mean number of 28.5 sessions (range: 3-160)
- 15 patients reported a decreased pain (40% of them with a grade benefit at T1)
- PPE grade decrease in 19 patients (11 of them at T1)
- 72% of the patients were satisfied with the LLLT treatment





Conclusions

- **Our study indicates that photo-biomodulation was not significantly beneficial for the control of treatment induced PPE**
- **Nevertheless pain was decreased or stabilized and patients satisfaction was greater with LLLT**
- **Caveats:**
 - small number of patients
 - investigator dependent subjectivity
- **Future :**
 - prospective data needed in larger cohorts
 - reevaluation of LLLT dosage, duration and frequency

