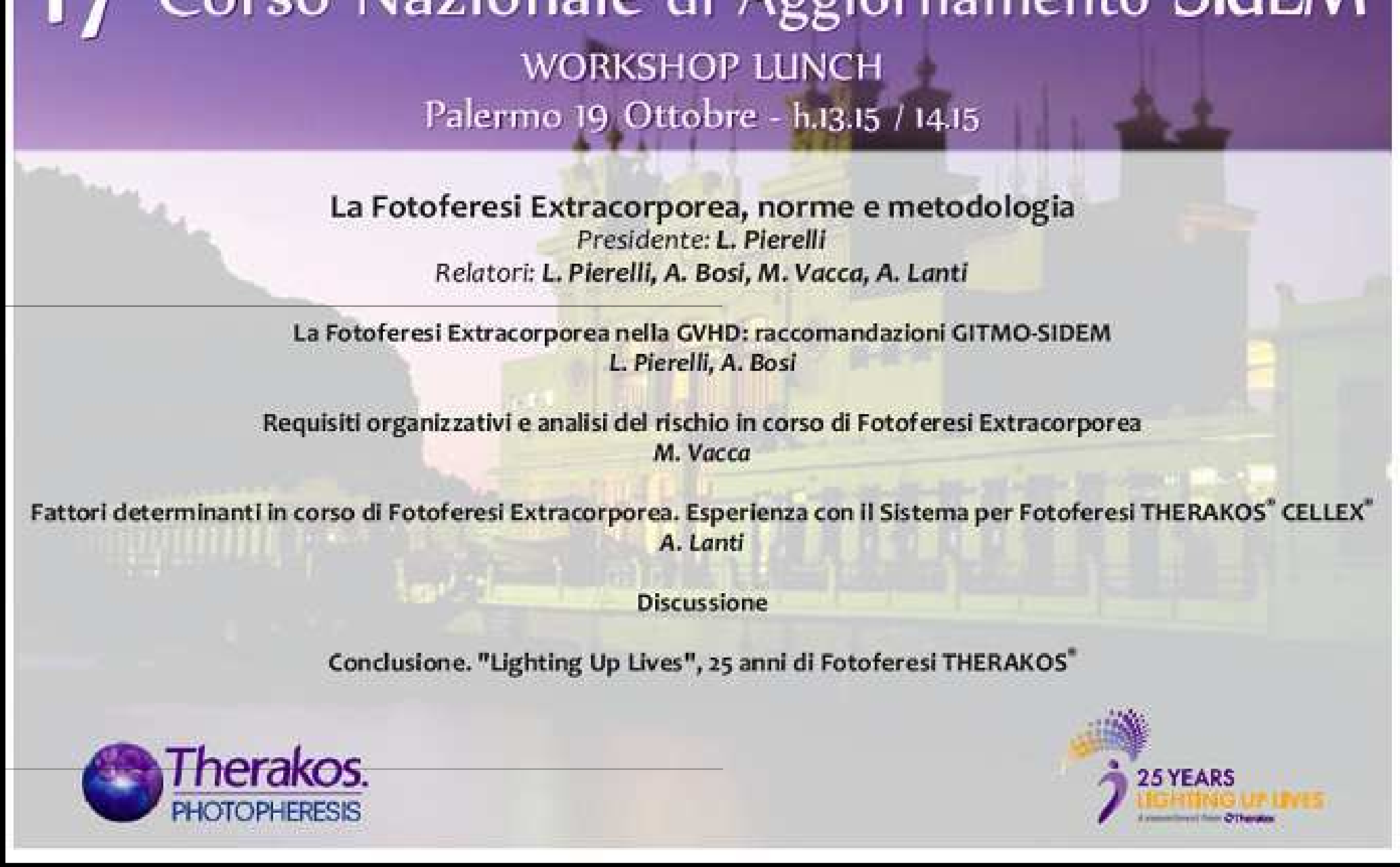

Prof. Alberto Bosi
Past President-GIMTO

Prof. Luca Pierelli
Presidente SIdEM

Quale la necessità di raccomandazioni?

Migliaia di procedure di fotoferesi sul territorio nazionale: l'Ita
uno dei paesi piu' attivi in tale attività terapeutica

Principali applicazioni cliniche:

- malattia da trapianto contro l'ospite (GvHD) acuta e cro
- linfomi cutanei
- malattie autoaggressive
- rigetto di trapianto d'organo solido (prevenzione
  trattamento)

Anche a causa di un così grande volume di attività nel no

niche, tecniche e metodologiche o entamenti nella specifica materia

Redazione di Linee Guida sulla base del principio della evidence-based medicine (forza tratta principalmente dalla disponibilita' di studi di fase III di opportune dimensioni)

Metanalisi (super-analisi di studi pubblicati in merito)

Conferenze di consenso per la identificazione di "best practices" su argomenti eventualmente scoperti in termini di studi organizzati (aspetti metodologici, affinamento di strategie, indicazioni cliniche consolidate ma non formalmente comprovate, etc, etc)

Tavolo tecnico SIdEM-GITMO

10 esperti: 5 di provenienza SIdEM, 4 GITMO, 1 metodologo

Metodologia adottata per la definizione della best practice: “The Expert Panel agreed on clinical key areas and key questions, within each clinical area, using the criterion of clinical relevance through a Delphi process. William PL, Webb C. The Delphi technique: a methodological discussion. J Adv Nur 10 1994,19:180–6

EXTRACORPOREAL PHOTOPHERESIS FOR THE TREATMENT OF ACUTE AND CHRONIC GvHD IN ADULTS AND CHILDREN – BEST PRACTICE RECOMMENDATIONS FROM A SIdEM (SOCIETÀ ITALIANA DI EMAFERESI E MANIPOLAZIONE CELLULARE) AND GITMO (GRUPPO ITALIANO TRAPIANTO MIDOLLO OSSEO) CONSENSUS PROCESS

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Key words:	pheresis, Transplantation – Stem Cell

EBMT-GRMC best practice recommendations

cations of ECP in acute GvHD

estion 1 – Is ECP recommended in aGvHD?

commendations:

ilable evidence indicate that ECP is an option in aGvHD

P may be applied in patients, either adults or children, v
vHD not responding to steroids and calcineurin inhibitors.

l candidates are patients with isolate skin involvement, w
effciacy of the procedure in visceral aGvHD is less well defin
vever, ECP superiority over the other therapies used in
ng cannot be stated yet due to the lack of controlled clin

EMN-GRMG best practice recommendations

cations of ECP in chronic GvHD

estion 3 – Is ECP recommended in cGvHD?

commendations:

P is recommended in both adults and pediatric patients w
HD, either steroid resistant or steroid dependant, irrespectiv
sease extent and severity

P is an effective method with the potential to allow for ste
ring in responding patients

P is a safe therapy

EMN-GRMC best practice recommendati

estion 5 – Is ECP recommended for overlap syndrome

commendations:

same statements as for cGvHD hold also for patients w
rlap syndrome although based on scant evidence

EM-GHMO best practice recommendati

estion 6 – Is ECP recommended for prophylaxis of HD?

commendations:

definitive evidence supports the use of ECP for preven
ID occurrence

EBMT-GRMC best practice recommendations

estion 8 – Which are the hematologic contraindication ECP?

commendations:

ents with severe anemia or thrombocytopenia should no luded from ECP

should be delayed until anemia and thrombocytopenia have been corr oglobin >8g/dl, platelets >20.000 mm^3) by an adequate transfusion su liated apheresis or irradiated/leukoreduced pool buffy coat platelets ar reduced and irradiated red blood cells as required)

procedure should be deferred in case of leukocyte c 00mm^3

re is no evidence for a minimum mononuclear cell (MNC) c

estion 9 – Which are the non-hematologic traindications to ECP?

commendations:

ere cardiovascular or renal impairment are absolute exclu ria to ECP

er itself should not be considered an absolute contraindica CP

procedure should be deferred in the presence of se n/without fever)

ne presence of a severe infection a careful assessmen benefit of ECP should be done

estion 14 – Which is the appropriate schedule for ECP

commendations:

either acute or chronic GvHD in the absence of contro
s the most frequently applied schedule is two ECP sessions
k until maximum response followed by tapering tailored to
vidual patient, i.e. according to the clinical response

schedule is recommended according to the panel ex
sonal experience

ical response should be assessed by 8-12 weeks and
uld be discontinued in the case of no-response

...EMA/CHMP best practice recommendations

...estion 16 – How should ECP quality be monitored

...ommendations:

...ne procedure should be performed in a class A laminar air f...
...net in a class D laboratory - European Guidelines for mini...
...manipulation (Directive 2007/86/EC Regulation N° 1394/2007/EC)

...ne procedures: culture of the product for aerobic, anaero...
...eria and fungi should be done immediately before ...
...duction of 8-MOP and before reinfusion into the patient

...ne procedures: cultures should be done when a change...
...osable ECP set lot occurs or to verify the first 6 procedu...
...lucted by a recently habilitated operator

...EM-GMMG best practice recommendations

...estion 16 – How should ECP quality be monitored

...ommendations:

...nctional test should be performed in order to validate ...edure (in-line and off-line)

...suggest to perform a functional test in each enrolled pat...ng the first two sessions except when a change in disposa...or drug lot occurs or in the presence of a major change in E...edure (change in cell separator, UVA illuminator and drug during each ...peutic cycle)

... procedure evaluation should be performed evaluating ...ber of non-viable linfocytes as 7-AAD CD3+ cells by us...cytometry within 72/96 hours from the completion of

MO and SIdEM faced the challenge of setting up and sharin
mon approach to ECP use in GvHD. Evidence was operati
ched for each specific issue, after adequate framing of
e itself.

sensus among experts belonging to two scientific socie
ved to select and critically review literature, to consider diffe
oints (i.e. safety, efficacy, quality of life) and to translate s
ence into valid recommendations.

articular the panel aimed at recommending safe, effective
ent procedures that would minimize both heterogen
veen centers and associated costs.

ever, evidence is still lacking, even in good retrospec
yses, for peculiar clinical aspects to GvHD treatment by E

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