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PROGRAM



THE EUROPEAN SOCIETY
FOR PHOTODYNAMIC
THERAPY

9th Annual Congress
13th - 14th March 2009
Hotels Van Oranje, Noordwijk
The Netherlands

noordwijk
2009

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VISTA - EURO-PDT 2009
9 rue Henri Martin
92772 Boulogne Billancourt Cedex France
Tel. : +33 (0)1 46 43 33 42
Fax : +33 (0)1 46 24 88 38
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Noordwijk



Dr. Rianne M.J.P. Gerritsen
Congress President

It is a great pleasure and honour to welcome you to the 9th Euro-PDT Annual Congress in Noordwijk.

Photodynamic Therapy (PDT) is widely used as an effective and safe treatment for Actinic Keratosis, Bowen's Disease and Basal Cell Carcinoma in Europe.

The Congress will cover all aspects of PDT for skin diseases, from the latest research news and new developments to the practical use in private practice.

During the meeting, on the 12th of March, a training course will be organized at the University Medical Centre in Leiden, for those who wish to learn the technique.

Lectures will be given by experienced researchers and users of PDT. The participants also have the opportunity to present their research or experience orally or as a poster.

We will make every effort to ensure the success of the meeting, hoping many practitioners and researchers will participate in the scientific program.

This exchange of knowledge is the key factor for innovative development in PDT.

Welcome to Noordwijk!

Welcome *Lasse R. Braathen, Rianne M.J.P. Gerritsen*

- 9:00 Welcome address President EURO-PDT
Lasse R. Braathen, Bern, Switzerland
- 9:05 Welcome address Local Congress President
Rianne M.J.P. Gerritsen, Nijmegen, The Netherlands

New developments *Nicole Basset-Séguin, John Lear*

- 9:10 **C1** Sensitizers - latest developments
Rolf-Markus Szeimies, Regensburg, Germany
- 9:30 **C2** Different light sources in Photodynamic Therapy (PDT)
Harry Moseley, Dundee, United Kingdom
- 9:45 **C3** Optimizing PDT
Alison Curnow, Truro, United Kingdom
- 10:00 **C4** Fluorescence diagnosis in keratinocytic intra-epidermal neoplasias
Tim Smits, Nijmegen, The Netherlands
- 10:15 **C5** Enhancing practice with fluorescence
Steve Keohane, Portsmouth, United Kingdom
- 10:30 **Coffee Break and Poster Viewing**

PDT in NMSC *Alexis Sidoroff, Ann-Marie Wennberg*

- 11:00 **C6** Guidelines - what's new?
Colin A. Morton, Stirling, United Kingdom
- 11:15 **C7** PDT for Aktinic Keratosis (AK) - place in practice
Peter Foley, Melbourne, Australia
- 11:30 **C8** Squamous Cell Carcinoma (SCC) and SCC in-situ - what is the limit of PDT?
Piergiacomo Calzavara-Pinton, Brescia, Italy
- 11:45 **C9** PDT for Basal Cell Carcinoma (BCC): from studies to hospital practice
Nicole Basset-Séguin, Paris, France
- 12:00 **C10** PDT for BCC: clinical and pathologic factors influencing the therapeutic response
Fabrizio Fantini, Modena, Italy
- 12:15 **C11** PDT for Bowen's with monitoring using DNA image cytometry
Holger Petering, Hildesheim, Germany
- 12:30 **C12** Extra-mammary Paget's and PDT
Christophe Bédane, Limoges, France
- 12:45 **C13** PDT: Critical review of 5-year NMSC therapy in Portugal
Celeste Brito, Braga, Portugal
- 13:00 **Lunch Break and Poster Viewing**

Extending the scope of Cancer PDT *Colin A. Morton, Peter Foley*

- 14:00 **C14** Daylight PDT - Update
Hans-Christian Wulf, Copenhagen, Denmark
- 14:15 **C15** Long term data with Methyl Aminolevulinate (MAL)-PDT: Lessons for our routine practice
Lasse R. Braathen, Bern, Switzerland
- 14:30 **C16** PDT in field cancerization
Lasse R. Braathen, Bern, Switzerland
- 14:45 **C17** Cancer prevention using PDT
Stefano Piaserico, Padova, Italy
- 15:00 **C18** NMSC in Organ Transplant Recipients – the nephrologist's view
Trond Jessen, Oslo, Norway
- 15:15 **C19** PDT for Organ Transplant Recipients
Ann-Marie Wennberg, Gothenburg, Sweden
- 15:30 **C20** Experience of PDT in the renal transplant community
Günther Hofbauer, Zurich, Switzerland
- 15:45 **Coffee Break**

PDT beyond NMSC *Lasse R. Braathen, Rianne M.J.P. Gerritsen*

- 16:00 **C21** PDT for scarring
Sandra Campbell, Truro, United Kingdom
- 16:15 **C22** PDT: Acne update
Stine R. Wiegell, Copenhagen, Denmark
- 16:30 **C23** MAL-PDT for acne vulgaris
Laura Eibenschutz, Roma, Italy
- 16:45 **C24** PDT for connective tissue diseases
Carola Berking, Munich, Germany
- 17:00 **C25** Is PDT of use in viral infections?
Sigrid Karrer, Regensburg, Germany
- 17:15 **C26** PDT in actinic cheilitis
Carola Berking, Munich, Germany
- 17:30 **C27** PDT on the move - wearable light sources
Sally Ibbotson, Dundee, United Kingdom
- 17:45 **C28** Recently reported novel indications for PDT
Alexis Sidoroff, Innsbruck, Austria
- 18:00 **End of session**
- 19:00 **Congress Dinner in Amsterdam**



Photo-rejuvenation with PDT *Luis Torezan, Rolf-Markus Szeimies*

- 9:00 **C29** Photo-rejuvenation: UK experience
John Ashworth, Stockport, United Kingdom
- 9:15 **C30** Photo-rejuvenation: Italian experience
Christina Zane, Brescia, Italy
- 9:30 **C31** PDT for photo-rejuvenation - molecular basis
for mode of action
Luis Torezan, São Paulo, Brazil
- 9:45 **C32** Photo-rejuvenation: Nordic experience
Nils Bech Thomson, Naestved, Denmark

Cancer PDT in the Netherlands *Rianne M.J.P. Gerritsen*

- 10:00 **C33** Three non-invasive treatment options for superficial BCC
Aimee Arits, Maastricht, The Netherlands
- 10:10 **C34** PDT vs. surgery for Bowen's Disease
Annette Verzijl, Rotterdam, The Netherlands
- 10:20 **C35** The place of PDT for nodular BCC
Gertrud Krekels, Eindhoven, The Netherlands
- 10:30 **Coffee Break and Poster Viewing**

PDT Masterclass *Piergiacomo Calzavara-Pinton, Hans-Christian Wulf*

- 11:00 **C36** Pretreatment options in PDT
Rianne M.J.P. Gerritsen, Nijmegen, The Netherlands
- 11:15 **C37** Lights: making the best of what we have in the office
Rolf-Markus Szeimies, Regensburg, Germany
- 11:30 **C38** Minimizing pain during PDT
John Paoli, Gothenburg, Sweden
- 11:45 **C39** What we know about pain in PDT
Frank Hevert, Laupheim, Germany

- 12:00 **C40** PDT for difficult cases - Vulval Intraepithelial Neoplasia (VIN),
Gorlins and more
John Lear, Manchester, United Kingdom
- 12:15 **C41** PDT - practical pearls from treating challenging cases
Peter Foley, Melbourne, Australia
- 12:30 **C42** Converting lab observations into clinical practice
Lesley Rhodes, Manchester, United Kingdom
- 12:45 **C43** Coding and reimbursement status of PDT in Europe
Julien Lambert, Wilrijk, Belgium
- 13:00 **Poster & best presentation prizes**
- 13:15 **Closure of the meeting**

Glossary

AK:	Actinic Keratosis
BCC:	Basal Cell Carcinoma
BD:	Bowen's Disease
GS:	Gorlin's Syndrome
MAL:	Methyl Aminolevulinate
NMSC:	Non-Melanoma Skin Cancer
PDT:	Photodynamic Therapy
PWS:	Port Wine Stain
SCC:	Squamous Cell Carcinoma
VIN:	Vulval Intraepithelial Neoplasia





ABSTRACTS

Sensitizers – latest developments

Rolf-Markus Szeimies

Regensburg, Germany

C1

For photodynamic therapy in Dermatology the use of 5-aminolevulinic acid or its derivatives (methyl ester) is meanwhile a standard procedure. The advantage of the topical administration is the low level of invasiveness and the good penetration properties of this small molecules. However, there is still the possibility to optimize the therapeutic efficacy and handling of this procedure.

One option is to vary the galenic formulation of the photosensitizer. In the presentation several attempts to optimize this will be presented.

13

Key Words:

5-aminolevulinic acid, ALA-methyl ester, patch, nanoemulsion

Different light sources in PDT

Harry Moseley

Dundee, United Kingdom

C2

Many different light sources have been and continue to be used in PDT. The choice of light source is fundamental. Not only must the emission spectrum match the absorption characteristics of the drug but light penetration through tissue must also be considered. Over the years, lasers and incoherent light sources have been employed to perform PDT and the superiority of one over the other has not been demonstrated. More recently, low cost lamps and light emitting diodes (LEDs) have found increasing application in this area.

This presentation will show the characteristic features of light sources used for PDT. Ambulatory PDT is a novel approach to delivering treatment using a lightweight, portable, LED light source that is attached to the lesion following application of ALA or MAL. The emission characteristics of these exciting new devices, including organic LEDs (OLEDs) will be described.

14

Key Words:

ambulatory PDT, laser, LED, light, diode, OLED

Alison Curnow

Truro, Cornwall, United Kingdom

C3

Evidence indicates that good clinical outcomes (associated with excellent cosmesis) can be achieved when using porphyrin precursor-induced PDT to treat superficial dermatological lesions. Enhancement is required however, if thicker lesions are to be treated effectively with a single PDT treatment cycle.

Maximising the efficacy of topical PDT can be achieved in a number of ways and the most common technique currently being routinely employed clinically is the application of ALA esters. Additional enhancement is possible however through further manipulation of the haem biosynthesis pathway using iron chelating agents. Alternative non-pharmacological and experimental methods of PDT enhancement include different techniques used to improve cream application and penetration as well as fractionating the light dose or modifying the parameters employed during irradiation.

The importance of correct lesion preparation and cream application when employing dermatological PDT in clinical practice should not be underestimated however, if maximum clinical efficacy is desired.

Key Words:

ALA esters, enhancement, iron chelating agents, light dose fractionation, optimisation, penetration enhancement

Tim Smits, Rianne M.J.P. Gerritsen

Nijmegen, The Netherlands

C4

With Fluorescence Diagnosis with Aminolaevulinic acid (ALA)-induced Porphyrins (FDAP) porphyrin accumulation can be studied in vivo. Knowledge on porphyrin accumulation in different skin conditions may help to understand variable clinical results after PDT and to improve the clinical efficacy furthermore. In the current presentation several studies on FDAP conducted by our group are reviewed.

Protoporphyrin-IX (PpIX)-content and macroscopic fluorescence using FDAP were studied in lesional and non-lesional skin in psoriasis and actinic keratosis, showing macroscopic fluorescence and PpIX-content to be well correlated. Next, heterogeneous fluorescence, seen within most psoriatic plaques, was studied showing a negative correlation between the thickness of the stratum corneum and fluorescence intensity. Furthermore, the clinical applicability of FDAP was evaluated in actinic keratoses comparing macroscopic fluorescence with histopathology. To study the intrinsic capabilities of different tissues to accumulate PpIX, several ex vivo (skin explant culture) and in vitro (cell culture) studies were performed. The results of these studies will be discussed.

Key Words:

AK, ALA, fluorescence diagnosis, PDT, PpIX, psoriasis

Rupert Barry, Steve Keohane

Portsmouth, United Kingdom

C5

The fluorescence detection of BCC with resection margins left by Mohs micrographic surgery (MMS) was investigated after different applications of the methyl aminolevulinate (MAL).

This study was conducted in one centre as a three arms investigator blinded study ; 3 application times of Metvix cream were studied: 1 hour and 30 minutes, 2 hours and 2 hours 30 minutes.

At study baseline, 30 eligible patients with histological proven BCCs that required Mohs micrographic surgery were randomised to one of the application groups.

Fluorescence detection was performed using the Dyaderm System (Biocam). After 1 week , MMS (frozen sections) was performed.

There was no statistical significant correlation between extent of tumour by fluorescence detection and microscopic extent of tumour by MMS.

Application time and threshold may need to be adjusted according to tumour subtype and site to optimise predictive value of pre-operative fluorescence.

This study was sponsored by Galderma.

Key Words:

Mohs, dyaderm, BCC, fluorescence, threshold

Colin A. Morton

Stirling, United Kingdom

C6

Guidelines reflecting up-dated evidence for the use of topical PDT in non-melanoma skin cancer, inflammatory and infectious dermatoses have recently been published (Br J Dermatol 2008; 159; 1245-66).

Reflecting new data from long-term follow-up and transplant patient studies, good evidence for the use of PDT in routine clinical practice exists for AK, BD and superficial BCC, with fair evidence for nodular BCC. Sufficient evidence now exists for the use of PDT in epidermal dysplasias in transplant recipients, but evidence levels remain poor, despite encouraging case series and reports for PDT in vaginal intra-epithelial neoplasia, extra-mammary Paget's, and as a therapy for prevention of skin cancer.

Fair evidence exists also for the use of PDT in inflammatory acne, plantar and genital warts and potentially in cutaneous leishmaniasis and for photo-rejuvenation.

Updated guidelines reviewing all therapies for AK, BD and BCC, also confirm that PDT should now have a place in the routine treatment of these lesions.

Key Words:

guidelines, epidermal dysplasias, BCC, acne, warts, photo-rejuvenation

Peter Foley

Melbourne, Australia

C7

Actinic (or solar) keratoses (AK) are the 'pre-malignant' precursor of squamous cell carcinoma (SCC), often now referred to as incipient SCC or even SCC in situ (actinic keratosis type). As it is not possible to predict which actinic keratosis will progress to become invasive SCC, and there are now a number of non-scarring means of treating these lesions, it is considered good clinical practice to wherever possible treat all such lesions.

Cryotherapy has been available for decades but is really only a spot treatment for individual lesions. In comparison, photodynamic therapy (PDT) and the various topical applications available can treat entire zones of "field cancerisation" with a superior cosmetic outcome. While the topical applications are patient controlled, inflammation can be quite marked and prolonged. PDT, on the other hand, is clinician controlled, often only requires a single treatment session (>80% of lesions) and typically has settled within a week of treatment.

Key Words:

AK, PDT, solar keratosis, SCC in situ

Piergiacomo Calzavara-Pinton, M. Venturini, Christina Zane

Brescia, Italy

C8

It has been previously clearly demonstrated that photodynamic therapy (PDT) with methyl-aminolevulinic acid (MAL) is an effective and well-tolerated treatment for actinic keratosis (AK) and superficial in-situ squamous cell carcinoma (SCC) but its effects on poorly differentiated, invasive and nodular SCC are unclear.

In a prospective, non-randomized, single center study, 112 biopsy-proven SCC in 55 outpatients were treated with MAL-PDT. The overall complete response rate was 73.21% after 3 months and 53.57% after two years. The time to recurrence was 6.55±4.10 months.

Thin lesions were more responsive than nodular. The lesion diameter did not affect the outcome. Histological depth of dermal invasion (Clark level >3) and degree of cellular differentiation (Broders' score III and IV), influenced negatively the remission rate. Mild to moderate pain and erythema followed by erosion or ulceration was always reported. The cosmetic outcome was good or excellent for superficial lesions and frequently poor for nodular lesions.

Conclusion: MAL-PDT is an effective and well tolerated treatment option with a good cosmetic outcome for superficial and well-differentiated, in situ or microinvasive SCCs. In contrast, its use for nodular, invasive and poorly differentiated SCC should be discouraged.

Key Words:

Bowen's disease, clinical trial, cosmetic outcome, MAL, PDT, SCC

PDT for BCC: from studies to hospital practice

Nicole Basset-Seguin

Paris, France

C9

BCC are the most common non melanoma skin cancers (NMSC) and their incidence is increasing. While their mortality rate is very low, they have a high morbidity due to their frequency, their location in sun exposed sites and their multiplicity.

According to their good prognosis, alternative treatments to surgery can be proposed for non aggressive histological forms in order to avoid definitive dys-trophic scarring especially in young patients. A number of studies have looked at PDT using ALA or MAL for the treatment of BCC. Two major long term (60 months) clinical randomized studies using MAL-PDT have been performed. One compared the use of MAL-PDT with cryotherapy for the treatment of superficial basal cell carcinoma. It showed that both treatments had the same efficacy (97% vs 95%) at 3 months and comparable recurrence rate (22% vs 20%) at 5 years. The cosmetic outcome was however much superior with PDT (87%) compared to cryotherapy (47%). The other study compared MAL-PDT versus surgery for nodular basal cell carcinoma. The sustained lesion response rate was 76% vs 96 %, which is acceptable. Here again higher cosmetic evaluation of MAL-PDT was reported (87% vs 54%). This demonstrates that if surgery is still the gold standard treatment for nodular BCC, MAL-PDT is effective and has a more favourable cosmetic outcome. This suggests that PDT should be considered for certain patients especially those with multiple lesions such as patients with Gorlin's syndrome. Some studies have also looked at the use of fractionation of light to improve clinical efficacy of PDT in BCC.

The use of PDT has extended a great deal from hospital use to clinical practice. Its major inconvenient is the pain which still needs some effort to better control it. PDT offers an important non surgical alternative treatment for BCC which is of major interest for patients with multiple lesions.

Key Words:

BCC, PDT, NMSC

PDT for BCC: clinical and pathologic factors influencing the therapeutic response

**Fabrizio Fantini⁽¹⁾, Antonietta Greco⁽¹⁾,
Annamaria Cesinaro⁽¹⁾, Mariateresa Rossi⁽²⁾,
Piergiacomo Calzavara-Pinton⁽²⁾**

⁽¹⁾ University of Modena and Reggio Emilia, Italy

⁽²⁾ Azienda Ospedaliera Spedali Civili and University of Brescia, Italy

C10

Photodynamic therapy (PDT) is increasingly used in the treatment of basal cell carcinomas (BCC). Nevertheless, consistent evidences on which type of BCC is more responsive to PDT are still lacking, because most studies on this subject differ on key parameters, such as treatment modalities, patient selection, endpoint assessment.

We investigated which factors affect the response of BCC to PDT. 194 BCCs in 135 patients were treated with MAL-PDT. Clinical parameters (sex, age, site, clinical type, diameter) and pathologic parameters (histotype, depth of invasion, ulceration) were recorded.

Responses (Complete Response vs. partial/no response, considered as treatment failure) were evaluated with an extended follow up or by post-treatment biopsy. The overall CR rate was 62%, with superficial BCC responding better than nodular BCC (82% CR rate vs 33%). Univariate statistical analysis indicated nodular type, head/neck and limb location, tumor depth and ulceration as factors that negatively influenced prognosis. Multivariate analysis confirmed the limb vs. trunk location and the tumor depth (<0,5 mm vs >1 mm) as independent determinants of treatment failure.

Key Words:

BCC, histopathology, MAL, PDT, prognosis, thickness

PDT for Bowen's with monitoring using DNA image cytometry

Holger Petering, Markus Vogelbruch

Hildesheim, Germany

Background: Photodynamic therapy (PDT) using MAL has been proven effective for Bowen's disease, but its place as a first-line therapy remains to be established. DNA image cytometry (DNA-ICM) can be useful in distinguishing between effective and non-effective treated lesions.

Objectives: To provide additional evidence of MAL-PDT for Bowen's disease with DNA ICM.

Method: Twenty-six lesions of Bowen's disease were treated with MAL-PDT. MAL was applied topically for 3 1/2 h. Lesions were illuminated with light fractions of 37 J/cm and treatment was repeated 14 days later. Skin biopsies were taken before and 6 weeks after illumination and analyzed by DNA ICM. Stemline interpretation, 5[c]-exceeding events (5cEE) and the 2[c] deviation index (2cDI) were calculated in all cases.

Results: After a follow-up of 6 weeks an overall complete response of 96% was seen for all lesions as proven by DNA ICM. Cosmetic outcome was excellent in treated lesions. Therefore, DNA image cytometry is an effective diagnostic tool. MAL-PDT should be considered as a first-line non-invasive therapy for Bowen's disease.

Key Words:

Bowen's, DNA image cytometry, Metvix, NMSC, PDT

Extra-mammary Paget's and PDT

Christophe Bédane

Limoges, France

Extramammary Paget's disease is an uncommon cutaneous neoplasm presenting with erythematous plaques, most frequently located in the anogenital region. Management of patients needs to evaluate the occurrence of a visceral malignancy or a secondary carcinoma in the underlying dermis. Several modalities can be used to treat the cutaneous component of the disease: electrodesiccation and curettage, laser surgery, radiotherapy, topical chemotherapy or wide surgical excision. Among them topical ALA PDT offers a reliable treatment of extramammary Paget's disease.

To date only small series of ALA PDT treated patients have been published. Complete response needs at least three to four runs of treatment with an interval of one to two weeks due to local irritation. PDT in anogenital region is usually very painful and needs strong local or regional anesthesia before illumination which can limit the feasibility of the treatment. Small and circumscribed lesions offer a better control than larger and widespread Paget's disease.

Therefore ALA PDT remains a good therapeutic option in elderly patients with a good cosmetic outcome.

Key Words:

Paget's disease, PDT

PDT : critical review of 5-year NMSC therapy in Portugal

Daylight PDT - update

Celeste Brito

Braga, Portugal

Hans-Christian Wulf

Copenhagen, Denmark

C13

The São Marcos Hospital, at Braga in the Northern part of the country was the first institution to introduce in Portugal topical PDT for the treatment of melanoma skin cancer (NMSC) in 2003. Today 7 more institutions make use of PDT-MAL for treatment of NMSC. In 2006 the Dermatology Unit of the Hospital of São Marcos was recognized as a Centre of Excellence in PDT by the EURO-PDT.

The therapeutic technique consists of preliminary curettage or debulking of the lesion area, then photosensitising with MAL cream, and irradiation using visible red light.

The Caucasian population that was submitted to the therapy in the country amounted to nearly 600 individuals. The number of lesions was nearly three times higher and was mostly incident in the areas of sun-exposed skin . The resolution rate during this period was above 90%.

NC

C14

Key Words:

AK, BCC, MAL-PDT, NMSC

Long term data with MAL-PDT: lessons for our routine practice

PDT in field cancerisation

Trond Warloe

Oslo, Norway

Lasse R. Braathen

Bern, Switzerland

Introduction: PDT is not a new treatment modality for non-melanoma skin cancer (NMSC), but long time follow-up data have been missing.

Materials and Methods: From 1997 until 2002, the Norwegian Radium Hospital conducted a study with topical MAL-PDT. The database established has been updated and represents the basis of the actual study, with a minimum 5-year follow-up. A total of 424 patients with 1857 BCC and 601 AK were reviewed.

Results: The overall complete response rate for BCC was 79%, with decreasing cure rate, in the range of 84% to 52%, for increasing lesion thickness and infiltration grade. For AK, the overall complete response rate was 62%, varying in the range of 63% and 56%. The cosmetic outcome was considered most satisfactory.

Discussion: During the first 3 years, we observed a certain amount of recurrences. Thereafter, the recurrence rate appears to flatten out. The 5-year recurrence rate after MAL-PDT seems acceptable.

Key Words:

MAL-PDT, long term data, AK, BCC, recurrence rate

The term "field cancerisation" or "field cancerisation area" can be defined as an area of the skin, usually a sun-exposed area, with multiple and recurring precancerous and cancerous skin lesions. The skin of the bald scalp, face and dorsum of the hands are predilection areas.

Due to the widespread sun induced mutations in the epidermal cells facilitating cancer development, both subclinical and clinical precancerous and cancerous lesions may occur. It is therefore advantageous to treat the whole field cancerisation area.

PDT is especially suited for treatment of large areas demonstrating both excellent therapeutic effect as well as excellent cosmetic outcome.

Key Words:

field cancerisation

Cancer prevention using PDT

Stefano Piaserico, Mauro Alaibac

Padova, Italy

C17

The role of Photodynamic Therapy (PDT) in the prevention of skin cancer has been recently investigated both in animal models and humans.

Basically, the direct treatment of actinic keratosis (AK) might be considered per se a cancer prevention modality. However, the possibility to apply PDT to large areas theoretically allows not only the treatment of clinically apparent AK, but also the prevention of new AK and skin cancer development.

It has been demonstrated that weekly PDT with MAL or ALA is able to delay the appearance of UV-induced skin cancer in the hairless mouse. Most of the clinical studies on prevention of skin cancer by repeated PDT have reported a significant reduction of the occurrence of new AK. The mechanism by which PDT delays the onset of UV-induced skin cancer is unknown. PDT might induce a selective destruction of subclinical foci of atypical keratinocytes or modify the cytokines environment with the stimulation of tumor-specific immunity.

Key Words:

cancer prevention, MAL-PDT, ALA-PDT, mouse

NMSC in Organ Transplant Recipients – the nephrologists' view

Trond Jensen

Oslo, Norway

C18

The rate of renal transplantation is increasing in the Western World, ranging 20-50 transplantations per million people (p.m.p.) in Europe (2007). As for Norway, the number of organ transplantations increased from 22 to 77 p.p.m. in the period 1983-2007, out of which renal transplants accounted for 17-60 p.p.m.

The burden of immunosuppression have increased from duo therapy prednisolone/azathioprine in the 1970s to quadruple potent medication in the same period of time (IL-2 receptor antagonist, prednisolone, tacrolimus, mycophenolate). Accordingly, the rate of rejections has decreased, but on the expense of viral infections and cancers including NMSC. In general, the occurrence of NMSC in renal transplants is increasing because of:

- 1- more aggressive immunosuppression,
- 2- transplantation being available for even older persons,
- 3- longer life-time in the transplanted population due to more aggressive cardiovascular prophylaxis.

It should be called for a close collaboration between nephrologists and dermatologists both in the work-up and follow-up of the patients.

Key Words:

renal transplantation, immunosuppression, skin cancer

PDT for Organ Transplant Recipients

Ann-Marie Wennberg

Gothenburg, Sweden

C19 Patients who receive long-term immunosuppressive therapy after organ transplantation are at an increased risk of developing non-melanoma skin cancer as well as premalignant lesions. Patients on immunosuppressive therapy have a higher occurrence of actinic keratosis (AK) than an untreated population and the AKs are highly associated with development of squamous cell carcinomas (SCC). The risk increases with the duration of immunosuppressive therapy and is also associated with sunexposure before and after transplantation. Therefore there is a need for early treatment of pre-malignant lesions in this population. Photodynamic therapy (PDT) is a convenient and effective therapy for non-melanoma skin cancer as well as for premalignant lesions.

Animal studies indicate that UV-induced AK, SCC and basal cell carcinoma (BCC) formation may be delayed by using PDT. These findings suggest that PDT might have a potential for treatment of non-melanoma skin cancer in organ transplant patients.

Recent clinical studies indicate a role for PDT in immunocompromised organ transplant recipients.

Key Words:

AK, immunosuppressive therapy, organ transplant patients, NMSC

Experience of PDT in the renal transplant community

Günther Hofbauer

Zürich, Switzerland

C20 Renal transplantation – although a great success with ever increasing graft survival as well as expanding indications for transplantation and re-transplantation – shows on the downside a dramatic increase in skin cancer, in particular squamous cell carcinoma of the skin (SCC).

Sun damage is the major contributing factor next to the medically required immunosuppressive regimen. Over 20 years of transplantation duration, more than half of renal transplant recipients are repeatedly affected by SCC. Field cancerization of large areas of the face, ears, neck, hands and forearms, and, not infrequently, the trunk occurs. Early and superficial therapy seems most indicated in such a cancer-prone population. PDT is one of the well-suited modalities for such interventions.

Results which will be presented are encouraging, expanding the clinical potency of PDT observed in the general population to the high-risk group of renal transplant recipients.

Key Words:

renal transplant, organ transplantation, immunosuppression, UV damage, field cancerization, SCC, PDT

Effect of ALA/MAL-PDT on hypertrophic scarring

Sandra Campbell, Jessica Tyrrell, Alison Curnow
Truro, United Kingdom

C21 Patients with localised scleroderma receiving ALA/MAL-PDT have shown a reduction in skin tightness, suggesting that this therapy reduces skin sclerosis. In vitro studies have suggested that this is due to an induction of collagen degrading enzymes and a reduction of collagen production following PDT.

To further investigate the antisclerotic effects of PDT suggested above, the effects of this treatment were studied in patients with hypertrophic scarring.

Materials and Methods:

Patients with severe hypertrophic scars were treated with MAL-PDT (two treatments one week apart for three sessions, at 6 weekly intervals). PpIX estimations were taken before and after treatment to suggest PDT effect. Biopsies were also taken before treatment and after 6 weeks to compare the collagen to elastin ratio in the skin samples. PpIX estimations were also studied in patients during treatment for keloid scars.

Results:

Encouraging results were seen in this small observational study, suggesting that this is an application warranting further investigation.

Key Words:

collagen, keloid, PDT PpIX, scarring, scleroderma

PDT: acne update

Stine R. Wiegell
Copenhagen, Denmark

NC

Laura Eibenschutz

Rome, Italy

C23 Photodynamic therapy (PDT) is used for the prevention and treatment of non-melanoma skin cancer. The indications have been restricted to actinic keratoses, nodular and superficial basal cell carcinoma, and Bowen's disease. However, the range of indications has been expanding continuously. PDT is also used for the treatment of non-malignant conditions such as acne vulgaris.

The effect of ALA/ MAL-PDT on acne has been proven in a number of clinical studies and is practiced worldwide. Conventional treatments for acne are directed against the pathogenetic factors and include a variety of topical and oral medications. More recently, lasers and light-based therapies have been introduced as alternative treatments, including intense pulsed light, pulsed dye lasers and PDT with photoactivation of aminolevulinic acid or methyl-aminolevulinic acid by continuous wave light sources, lasers and IPL systems.

The supposed mechanisms of action for optical treatments are photothermal heating of sebaceous glands and photochemical inactivation of *P. acnes*, which produces coproporphyrins and protoporphyrins. We evaluated the efficacy and safety of MAL-PDT in patient with recalcitrant localized acne.

Key Words:

acne, MAL, ALA, NMSC, PDT

Carola Berking

Munich, Germany

C24 The spectrum of non-oncologic skin diseases treated with topical photodynamic therapy (PDT) has been increasing steadily. One subgroup comprises pathologic disorders of the connective tissue which have been reported to respond to PDT to a different extent. Localized scleroderma, lichen sclerosus and keloids have been shown to improve after PDT with respect to rigidity and pruritus. In vitro studies indicate that these findings could partially be due to an increase in MMP-1 and MMP-3 production and a decrease in collagen type I synthesis in dermal fibroblasts, possibly via paracrine effects by keratinocytes.

PDT has also been demonstrated to exert beneficial effects on granulomatous skin diseases. In anecdotal reports, granuloma annulare and necrobiosis lipoidica were cured by PDT, whereas case series showed response rates of only 57% and 39%, respectively, after repeated cycles of PDT.

Randomized and placebo-controlled studies are urgently needed to evaluate the future significance of PDT for connective tissue diseases.

Key Words:

connective tissue disease, granuloma annulare, lichen sclerosus, necrobiosis lipoidica, scleroderma

Sigrid Karrer

Regensburg, Germany

Carola Berking

Munich, Germany

PDT with ALA or MAL can be effective in treating certain viral infections, particularly those resulting in warts. Rapidly proliferating cells in viral acanthomas selectively accumulate ALA-induced PpIX as compared to surrounding non-infected cells. Thus, PDT can destroy virus-infected cells without harming adjacent normal tissue and can also target subclinically infected cells that are not clinically evident. In an animal model ALA-PDT showed also an antiherpes effect on HSV-I and HSV-II.

Several clinical studies have shown the efficacy of PDT for HPV-induced lesions. Placebo-controlled trials demonstrated the superiority of repeated PDT series in clearing recalcitrant hand and foot warts. Larger trials have shown that anogenital warts respond well to PDT and also for intraepithelial neoplasia promising results have been published. Only few case reports document the efficacy of PDT in epidermodysplasia verruciformis and plane warts. Single case reports also showed successful treatment of AIDS patients suffering from recalcitrant mollusca contagiosa, which are induced by a human pox virus.

Although several studies document promising results for PDT of viral infections, treatment modalities are not yet standardized.

Key Words:

condylomata acuminata, HPV, HSV, molluscum contagiosum, plane warts, vulgar warts

Actinic cheilitis is a common disease of the lower lip of patients with a history of chronic sun exposure. In accordance with actinic keratosis of the skin, actinic cheilitis should be treated to prevent the transformation into squamous cell carcinoma with increased potential for metastasis. Common therapeutic modalities include surgical excision, laser ablation, electrodesiccation, cryotherapy, 5-fluorouracil, and imiquimod. However, these procedures are either invasive or require a high grade of compliance and may be linked with disabling side effects.

PDT has been shown to be an effective alternative for the treatment of actinic cheilitis of the lower lip. Between 1996 and 2008 complete response rates between 47-100% have been published in case reports and case series of up to 19 patients. ALA (20%) or MAL were used in combination with red light (630 nm or 570-670 nm) or pulsed dye laser (595 nm or 630 nm) with and without local anesthesia and systemic analgesics.

Adverse effects included burning sensations, erythema, swelling, blistering, and scabbing. Tolerability was good and cosmetic outcome excellent.

In summary, PDT can be considered as a reasonable alternative to treat actinic cheilitis.

Key Words:

actinic cheilitis, lower lip, MAL, ALA, PDT

Sally Ibbotson

Dundee, United Kingdom

C27 Photodynamic therapy (PDT) is highly effective for superficial non-melanoma skin cancer. The inconvenience of time-consuming hospital visits and discomfort and pain during the irradiation process can be significant drawbacks for treatment of an elderly patient group. In an ideal world, pain-free home-based treatment would be a definite advantage.

We have developed the use of a low irradiance and potentially disposable lightweight organic light emitting diode (OLED) as an area emitting source with the potential for use in ambulatory PDT. We have treated 12 patients with Bowen's disease or superficial basal cell carcinoma with ALA PDT using this wearable OLED source for irradiation. We have shown encouraging preliminary efficacy data and, strikingly, that treatment was very well tolerated and virtually pain-free.

These preliminary home-based data suggest that OLED PDT could be a relatively painless alternative to conventional hospital-based treatment, and studies to explore this approach further are underway.

Key Words:

ambulatory, irradiance, LED, painless, PDT, wearable

Alexis Sidoroff

Innsbruck, Austria

C28 PDT in dermatology has - until now - mainly been used and gained approval in the therapy of NMSC. Over the last years this treatment modality has been investigated for efficacy and usability in many other cutaneous diseases.

The main groups are disorders of the pilosebaceous unit (acne, rosacea, sebaceous hyperplasia, hair removal, stimulation of hair), inflammatory skin diseases (psoriasis, scleroderma, sarcoidosis, granuloma anulare, necrobiosis lipoidica, pseudolymphoma, lichen planus), infectious diseases (warts, fungal infections, bacterial infections, leishmaniasis), hereditary disorders (Darier's disease), skin rejuvenation (photorejuvenation).

Among this plethora of diseases PDT has shown effects in a large number of them, but by far not in all the results suggest that use of this treatment modality makes sense at the time being. In some indications the results were disappointing, in some new approaches (like new sensitizers) will be necessary, and in some promising results just wait for some improvement of the treatment procedure and larger sized trials.

Key Words:

inflammatory skin diseases, novel indications, PDT, photorejuvenation, pilosebaceous disorders, skin infections

Photo-rejuvenation: UK experience

John Ashworth

Cheshire, United Kingdom

Photorejuvenation: UK experience Metvix®/Aktilite® Photorejuvenation therapy: practical perspectives

Photorejuvenation therapy (PRT) refers to skin treatment using identical or nearly identical exposures as used in conventional Photodynamic Therapy.

Instead of destructive benefits, PRT is concerned with tissue stimulation and improving the appearance of the skin.

The patient perspective is very different from the typical patient who attends for PDT for cancerous or pre-cancerous skin disease. PRT patients are entirely concerned with cosmetic benefits and are less willing to accept painful or embarrassing side effects even in the short term. PRT is typically delivered to a much greater area of skin (usually the whole face) than in conventional PDT. Side effects can therefore be much more troublesome to the patients.

The following points will be discussed:

- patient expectation and aims
- treatment levels compared with PDT needs to be carefully monitored
- the quantity of Metvix used for a full face treatment
- pre-treatment discussion and work up
- consent
- immediate post-treatment care in the clinic
- post-treatment care at home

Key Words:

Metvix®, Aktilite®, photorejuvenation therapy (PRT)

Photo-rejuvenation: Italian experience

Christina Zane, R. Capezzer, Piergiacomo Calzavara-Pinton

Brescia, Italy

Photodynamic therapy (PDT) with aminolevulinic acid has been, recently, employed in the treatment of photodamaged skin, so called photorejuvenation, even if results are hardly comparable because there are evaluated only on a clinical basis. Besides, the treatment protocols, e.g. formulation and concentration of the cream, application time, spectrum and dose of the activating light, number and frequency of treatments, vary widely.

We present Italian experience of photo-rejuvenation in 20 patients with pronounced photodamage of the face. They were treated with two monthly treatments with a proprietary preparation containing 160 mg/gr of MAL (Metvix®, Galderma) according to the standard treatment protocol that is approved by the European regulatory authorities for the treatment of AK. In brief, Metvix® was applied under occlusion for 3 hours before exposure to 37 J/cm² of red light that was delivered by a LED source (Aktilite® CL 128, Photocure).

Treatments were well tolerated and have given good results.

Key Words:

photoaging, PDT, MAL

PDT for photorejuvenation: molecular basis for mode of action

Cosmetic use of PDT

Luis Torezan

São Paulo, Brazil

Niels Bech-Thomsen

Naestved, Denmark

C31

PDT is an approved treatment option for superficial non-melanoma skin cancers. Photorejuvenation assisted PDT is currently being used for the improvement of signs of photoaging, but remains unsettled.

In this study, 26 patients with photodamaged skin and multiple actinic keratoses (AKs) were enrolled and submitted to 3 full-face MAL-PDT treatments (3h incubation time 37 J/cm² LED red light), one month apart. Skin biopsies were performed before and after 3 months of the last treatment, in a normal appearing skin free of AKs, and evaluated for histopathology and immunohistochemistry. Digital photographs were taken before and after treatment sessions. Global score of photodamage improved and was statistically significant ($p < 0,001$). AKs complete response (lesion base) was 89,5%. Individual parameters such as fine lines, mottled pigmentation, sallowness, roughness, facial erythema and telangiectasias also improved and statistically proved ($p < 0,001$ to $p = 0,003$). Histologic parameters showed a decrease in both grade and amount of keratinocyte atypia ($p < 0,001$) as well as an improvement of solar elastosis (smaller elastotic band) and an increased sub-epidermal collagen layer ($p = 0,002$ and $p = 0,001$). Quantitative analyses of MMPs and collagen I showed a trend toward new collagen deposition. Epidermal HP-53 expression was decreased in most of the patients after PDT. We hypothesize that besides the induction of necrosis and apoptosis in dysplastic keratinocytes leading to the destruction of AKs, acute photodynamic epidermal damage with a sublethal effect on unaltered keratinocytes triggers the inflammatory cascade and leads to over expression of metalloproteinases and collagen synthesis in the underlying dermis. These effects are then responsible for the excellent outcome with a significant improvement of the individual parameters.

Key Words:

AK, immunohistochemistry, MAL-PDT, photorejuvenation

43

C32

PDT can be used for cosmetic purposes to rejuvenate the skin. The temples, under the eyes, around the mouth and on the chest are areas of particular interest, because these areas are difficult to rejuvenate with botox and fillers.

The major end result is more volume of skin and less wrinkles. The side-effects are redness, oozing, pain and swelling of the treated area for up to a week.

We use standard concentration of Metvix® cream, 2 hours incubation under occlusion and normal standard dose of red light.

Key Words:

cosmetic, PDT

44

Three non-invasive treatment options for superficial BCC: PDT vs. imiquimod vs. 5-fluorouracil

Arits AHMM, Mosterd K, Steijlen PM, Sommer A, Kelleners-Smeets NJW, Hendriks MR, Essers BA
Maastricht University Medical Centre
De Rooij MJ, VieCuri Medical Centre, Venlo
Krekels GA, Catharina Hospital, Eindhoven
Quaedvlieg PJ, Atrium Medical Centre, Heerlen
Van Neer PAF, Laurentius Hospital, Roermond
Van Geest AJ, Jeroen Bosch Hospital, 's-Hertogenbosch
Rijzewijk JJ, Helmond, The Netherlands

Background: Worldwide surgical excision is the preference therapy for treatment of basal cell carcinoma (BCC). However, because of the increasing incidence of superficial BCC (sBCC), non-invasive techniques: PDT, imiquimod (Aldara®) and 5-fluorouracil (Efudix®), have gained weight. The effectiveness of these non-invasive treatment options has never been investigated in a comparative study.

Objective: In seven hospitals in The Netherlands a single blinded randomized controlled multicentre trial is performed comparing the efficacy (after 3 and 12 months), cosmetic result, compliance, side-effects, patient preference and cost-effectiveness of treating sBCC with PDT, imiquimod and 5-fluorouracil.

Methods: One histologically proven sBCC per patient was randomized to one of the treatment groups (PDT vs. imiquimod vs. 5-fluorouracil). Assuming a percentage of treatment failure of 20% in the PDT group, N = 197 patients per group enables us to detect a minimal clinical relevant difference of 10% between compared groups. An intention-to-treat analyses will be used.

Key Words:

5-fluorouracil, BCC, imiquimod, non-invasive therapy, PDT, superficial

PDT versus surgery for Bowen's disease

Annette Verzijl, Ellen Regina Margaretha de Haas, Gertruud Anna Maria Krekels
Rotterdam, The Netherlands

Morbus Bowen or Bowen's disease is also called squamous cell carcinoma in situ. Because of the risk of progressing to invasive squamous cell carcinoma and therefore the risk of metastasizing, an adequate, effective treatment is necessary.

Nowadays there are many different well-accepted treatment modalities used. Photodynamic therapy and surgery are two of the most widely applied forms of therapy. Several studies of PDT in Bowen's disease are performed, however difficult to compare because of different treatment settings. Overall initial clearance rates for ALA-PDT are likely around 90% with one or two treatments and recurrence rates of about 0-10% after one year. Although excision is one of the most applied therapies, good studies are not available. To give one's opinion on the best treatment option (PDT or excision) randomized controlled trials with a longer follow-up period are needed. Costs and cosmesis must also be taken into account.

Key Words:

morbus Bowen, PDT, excision

Gertruud Krekels

Eindhoven, The Netherlands

Rianne Gerritsen

Nijmegen, The Netherlands

In the past high cure rates for nBCC have been reported. In noncomparative studies with a follow-up of 1 year or less, cure rates of 95% after PDT were described.

However in a recent randomized controlled trial, with 3 year follow-up (BJD 2008, by Mosterd et al), it was shown that for nBCC, surgical excision proved to be significantly more effective than treatment with fractionated illumination ALA-PDT: approximately 30% failure with ALA-PDT versus 3% with surgical excision. The new multidisciplinary Dutch guideline for the treatment of BCC recommends surgical excision for nBCC.

From histopathological studies it is known that the depth of a tumour measured in a biopsy specimen is not representative for the entire lesion. In chronic skin cancer patients (eg nevoid BCC syndrome) mixed BCC are common and PDT combined with limited surgical excision or Mohs' micrographic surgery might reduce the number of large excisions or number of Mohs stages.

Treatment success of PDT varies widely. Limited uptake of topical 5-ALA or its methyl ester and suboptimal production of protoporphyrin-IX (PpIX) may account for these differences. Distribution of these drugs in the skin depends on drug permeability through the stratum corneum and diffusion through the epidermis and dermis. Factors like drug structure, formulation, the release from the vehicle, local drug clearance, de-esterification of ALA-esters, and the capability to convert ALA into PpIX eventually determine total PpIX content and are important for treatment success.

The present presentation will focus on pre-treatment of the skin, in order to improve the clinical outcome of ALA/MAL- PDT.

Recently we have demonstrated a negative correlation between thickness of the stratum corneum and fluorescence intensity in fluorescence diagnosis, indicating hyperkeratosis to be an important factor in intra- and interpatient differences in ALA uptake. Pre-treatment of hyperkeratosis is an important prerequisite in PDT for improving treatment results. This can be achieved with topical keratolytics, curettage/debulking, tape-stripping, microdermabrasion, or laser ablation. Penetration enhancers may alter the composition or organization of the intercellular lipids of the stratum corneum. Several studies have been reported on the use of dimethylsulfoxide, azone, glycolic acid, oleic acid or iontophoresis to increase the penetration of ALA. As PpIX production is also dominated by temperature-dependent processes, elevating skin temperature during ALA application and cooling down afterwards may also improve treatment results. Another approach to increase PpIX formation is the use of additives that interact with the heme-biosynthetic pathway, e.g. by removing ferrous iron with iron-chelating substances, e.g. ethylene diamine tetraacetic acid (EDTA), 3-hydroxypyridin-4-ones (HPOs) and desferrioxamine (DFO). It has been demonstrated that several iron-chelators are able to significantly increase PpIX formation in ALA treated skin.

In conclusion, pre-treatments or additions to the regular practice of PDT, aimed to optimize intralesional PpIX content, may improve the clinical outcome in PDT.

Key Words:

hyperkeratosis, PDT, penetration, PpIX formation, pre-treatment

Key Words:

nodular BCC, surgery, PDT, recurrence

Lights: making the best of what we have in the office

Rolf-Markus Szeimies

Regensburg, Germany

C37 A crucial part of the PDT procedure is the appropriate light source. Since porphyrin-based PDT for superficial tumors not necessarily requires coherent light, other systems are possible to use as well. Classical incoherent lamps equipped with filters matching the action spectrum of protoporphyrin IX (PpIX) are still in use, but the significant generation of heat and the energy consumption make those devices less desirable for routine office use.

In the moment the best option are devices with light emitting diodes (LED's) which perfectly match the last Q-band of the absorption spectrum of PpIX. Those devices are relatively cheap, reliable, small in size and easy to use.

Another alternative are pulsed light sources, which are widely used for other indications like hair removal, vascular and pigmentary changes. In case their emission spectrum matches the PpIX absorption as well, they are also useful tools for the illumination process.

Key Words:

lasers, incoherent light sources, LED, intense pulsed light

Minimizing pain during PDT

John Paoli, Christina Halldin, Marica B. Ericson, Ann-Marie Wennberg

Gothenburg, Sweden

C38 The main drawback of photodynamic therapy (PDT) when treating field cancerization of the forehead is the pain perceived during the irradiative phase.

Sixteen patients with field cancerization of the forehead received unilateral supraorbital nerve blocks with Carbocain® adrenalin 10 mg ml⁻¹ + 5 µg ml⁻¹ (AstraZeneca PLC, UK) 5-10 minutes before irradiation during PDT (Metvix® cream + Aktilite® CL128 LED lamp, PhotoCure ASA, Norway). The non-anaesthetised side of the forehead served as control. Pain was significantly reduced on the anaesthetised side (P<10⁻⁶, paired t-test). The mean visual analogue scale score (± standard error of the mean) on the blocked side was 1.2 (±0.3) compared to 7.5 (±0.6) on the non-anaesthetised side. The procedure was well tolerated and generally not experienced as painful. Excellent clinical results were observed in all patients.

Nerve blocks provide efficient pain relief during PDT when treating patients with field cancerization in the facial area.

Key Words:

AK, field cancerization, nerve block, pain, PDT

What we know about pain in PDT

PDT for difficult cases: VIN, Gorlin's and more

Frank Hevert

Laupheim, Germany

John Lear

Manchester, United Kingdom

C39

In order to find the best intervention to reduce pain during and after PDT, one should know the origin of this pain (pathophysiology). Two overlaying kinds (types) can be distinguished:

- Type I: pain with an onset shortly after commencing the illumination which is due to electrical depolarisations of polymodal receptors in C- and A-delta-nerve fibres within the epidermis.
- Type II: pain with an onset of some minutes to some hours afterwards which is caused by inflammatory- and pain-mediators such as prostaglandins and bradykinine.

For the type I, the photosensitizer must enter the epidermal nerve fibre which is easier for ALA than for MAL which is the reason why MAL-PDT is less painful than ALA-PDT. This type is “electrical” and is not mediated by any substances; this explains why it cannot be influenced by prostaglandin-antagonists or similar drugs but rather by nerve blocks or by changing the receptor threshold via cooling.

In contrast, the type II can be managed by cyclooxygenase antagonists or similar.

Key Words:

PDT pain, pain origin, epidermal C fibres, epidermal A-delta-fibres, polymodal receptors, MAL, ALA, cooling, nerve blocks

51

C40

PDT lends itself to treatment of wide areas, a major advantage over traditional surgical approaches to “field change” diseases.

Vulval intraepithelial neoplasia (VIN) and Gorlin's syndrome are 2 examples of field change problems which are very difficult to treat. They present major clinical challenges.

This presentation will focus on topical therapeutic approaches in these areas. In particular, data regarding sequential treatment with imiquimod and PDT in a cohort of VIN cases will be presented. Time permitting, data on topical and systemic PDT in Gorlin's syndrome will also be presented.

Key Words:

VIN, Gorlin's syndrome, PDT, imiquimod

52

PDT - practical pearls from treating challenging cases

Peter Foley

Melbourne, Australia

C41

PDT has over the last decade gained a place in the armamentarium of mainstream dermatologists routinely dealing with nonmelanoma skin cancer as part of their daily practice or those specialising in dermatological oncology.

While in many instances, the lesions indicated for PDT could have been treated with surgery or even other nonsurgical modalities, there are a number of situations in which PDT comes into its own as the treatment of choice. Such examples include extensive actinic keratoses/field cancerisation in solid organ transplant recipients ; digital, periungual and genital squamous cell carcinoma in situ ; nodular BCC on cosmetically sensitive but non "danger" sites ; and multiple superficial and/or nodular BCCs in particularly susceptible individuals such as those with basal cell naevus syndrome. Clinical examples of these challenging cases will be used to illustrate the versatility of this therapeutic modality.

53

Key Words:

PDT, AK, solar keratosis, SCC in situ, BCC

Converting laboratory observations into clinical practice

Ann Haylett, Lesley Rhodes

Manchester, United Kingdom

C42

Since the original demonstration that ALA generated PpIX led to cell destruction in a tissue culture model (Malik et al 1987) and induced fluorescence in tumour bearing mice (Peng et al 1987), topical PpIX based PDT has gained regulatory approval for clinical use in 18 countries world wide.

PDT requires a combination of photosensitizer, oxygen and light to effectively cause cell death or modify cell function. A wide range of variables may modify outcome including prodrug-light interval, depth of lesion and underlying mechanisms of action. Considerable research has been carried out to optimise treatment parameters and this review will consider current developments that may impact on clinical PDT practice.

54

Key Words:

MAL, outcome optimisation, treatment parameters

Current coding and reimbursement status of PDT in Europe

Julien Lambert

Wilrijk, Belgium

C43

Coding is a key element of the dermatologist daily practice. The current coding and reimbursement status of PDT in Europe shows variable situations including specific PDT codes, day care fees, analogue codes, or absence of coding. These can coexist in one single country according to treatment specificities and the health care setting.

While specific PDT codes and day care fees seem optimal, analogue codes or absence of coding raise several issues both for physicians and patients (e.g. ease of use, revenue, access to PDT, reimbursement).

The positive experiences of adequate coding and the involvement of Medical Associations may be very helpful to improve the coding system where needed.



POSTERS

MAL-PDT: efficacy and safety

**Corti-Rezzonico,
Michela Angela Maria Mainetti Carlo**
Bellinzona, Switzerland

P1

This study evaluates the efficacy and safety of methyl aminolevulinate (MAL) PDT in our ambulatory dermatologic center.

During a three months period, we enrolled 46 patients affected with 120 actinic skin precanceroses or nonmelanoma skin cancers treated with MAL PDT and checked 8 weeks thereafter.

The healing rate was 88.0% (73 of 83 lesions) for actinic keratoses, 100% (9 of 9 lesions) for Bowen diseases and 88.9% (16 of 18 lesions) for basocellular carcinomas. 65% of the treated lesions had no side effects and 90% of them healed. The most frequent cosmetic discomfort was skin discoloration.

MAL-PDT can be considered efficient and safe. According to our results, the profile of the patient with the highest relapse risk is: a man, treated on the scalp or on the back of the hands in a field cancerisation area.

Key Words:

efficacy, MAL-PDT, permanent side effects, relapse risk factor, safety

MAL PDT: pain, phototoxic reaction and patient satisfaction

**Corti-Rezzonico,
Michela Angela Maria Mainetti Carlo**
Bellinzona, Switzerland

P2

PDT can cause pain and a phototoxic reaction (PTR) resulting in erythema, edema and crusting. These conditions are considered transitory side effects and the resulting discomfort is often underestimated.

We describe our experiences with 46 patients affected with 120 lesions treated with MAL PDT. We interviewed each patient about pain, grade of PTR and personal satisfaction after 8 weeks of treatment.

Pain is higher during irradiation than during curettage or after irradiation. 27 lesions (22.5%) reported very high pain during irradiation and 54% reported pain after irradiation for an average time of 19h. Approximately 80% of the lesions reported light or no PTR. 90% of the patients showed a good or very good final satisfaction.

Overall, we found that pain generated by topical MAL-PDT causes a remarkable discomfort. Lesions on the head (scalp, forehead) or field cancerisation areas are risk factors for high pain or for a strong or medium PTR.

Key Words:

MAL-PDT, pain, phototoxic reaction, satisfaction

MAL-PDT for NMSC on the face: retrospective analysis of the data at 12 months

PDT for T cell lymphoma of the penis: a case report

Mateo Gonzalez-Carrascosa Ballesteros,
Miguel Aguilar Bernier, Francisco Javier del Boz
Gonzalez, Javier Romero Gomez,
Magdalena de Troya Martin, Francisco Rivas Ruiz
Marbella, Málaga, Spain

Nedzimidin Pelivani, Robert E. Hunger
Bern, Switzerland

P3

P4

Here we report the results in terms of efficacy and recurrence rates of photodynamic therapy in 35 non-melanoma skin cancer (23 superficial basal cell carcinoma and 12 in situ squamous cell carcinoma) localized on the face area at 12 months after the treatment.

Materials and methods: 35 non-melanoma skin cancer on the face treated with MAL-PDT are analyzed. We made a retrospective descriptive analysis of the data at 12 months, taking into account the age, sex, localization of the lesion, size of the lesion and the clearance or recurrence of the lesion 1 year after the treatment.

Conclusions: MAL-PDT is a good treatment option for superficial or in situ non-melanoma skin cancer on the face, with great results in terms of efficacy, aesthetic result and satisfaction of the patient.

Key Words:
face, in situ SCC, PDT, superficial BCC

Mycosis fungoides (MF), the most common form of primary cutaneous T-cell lymphoma (CTCL), is characterized by the expansion of monoclonal CD4+ T cells primary located in the skin. Clinically the disease is characterized by a chronic and lethal course.

Case report: We report on a 51-year-old who developed a histologically verified MF on the hands 4 years ago which was successfully treated with irradiation. 2 years later the patient developed a chronic inflammation of the glans penis which was first diagnosed as plasma cell balanitis of Zoon. 1.5 years ago, as the lesion recurred and started to ulcerate, a histological examination revealed the diagnosis: MF of the penis. These lesions were treated with photodynamic therapy (PDT) with methyl aminolevulinate. As the lesions recurred after an initial PDT, monthly PDT was started, resulting in an acceptable result.

This case report demonstrates that PDT may be used as a maintenance therapy to stabilize CTCL in difficult localizations.

Key Words:
CTCL, mycosis fungoides, penis, MAL

Topical PDT for the treatment of pseudoepitheliomatous hyperplasia

Filipa Ventura, Joana Gomes, Joana Rocha,
Celeste Brito

Braga, Portugal

P5

The pseudoepitheliomatous hyperplasia is a reactive epithelial proliferation commonly associated to a persistent inflammation of the subjacent dermis. It is usually caused by chronic wounds, infections, malignancy or inflammatory dermatitis.

PDT is considered as an efficient treatment of precancerous lesions and non-melanoma skin cancers.

A 78-year-old female patient presented an extensive hyperkeratotic plaque on the dorsal aspect of the right foot. This lesion resulted from a chronic inflammatory dermatitis that the biopsy confirmed as a pseudoepitheliomatous hyperplasia. The topical PDT technique was the choice for the treatment of this patient. It implied the use of methyl-aminolevulinic acid (MAL) as photosensitizing agent. After four cycles of MAL-PDT the wound was completely healed. The successful result of the therapy was confirmed by skin biopsy.

We believe this is one of the first cases of successful MAL-PDT application in the treatment of pseudoepitheliomatous hyperplasia.

Key Words:

MAL, PDT, pseudoepitheliomatous hyperplasia

63

Registration of PDT products in regulated and semi-regulated markets

Parminder Kaur

Noordwijkerhout, The Netherlands

P6

A very large number of novel therapy anti-cancer compounds have been and currently are under development worldwide. Only a minority have completed the clinical development and reached a marketing authorisation, due to insufficient evidence of efficacy or evidence of a detrimental safety profile.

In the European Union (EU), approval of new oncology drugs can be obtained for the entire EU via a centralised procedure on recommendations by the EMEA. In situations where it is impossible to produce comprehensive data at the time of submission, and there is an unmet medical need, products may receive approval "under exceptional circumstances".

In other semi-regulated markets, in case of unmet medical need, the product can get early licensing. However the evidence of preliminary benefit – risk assessment based on early data compatible with a favourable profile in the target population, must be provided.

This poster will highlight the complexities from a regulatory perspective in the regulated (EU) and semi-regulated (Russia, India, Latin America) markets.

Key Words:

data requirements, regulatory procedure, regulated & semi-regulated market, unmet medical need

64

Treatment of pigmented purpuric dermatosis with topical PDT

You Chan Kim, Sue Kyung Kim,
Eun Hyung Kim

Suwon, South Korea

P7

Pigmented purpuric dermatosis (PPD) is an all-encompassing term to describe a group of cutaneous lesions that have in common petechiae and bronze discoloration of the skin. Treatment with topical or systemic steroids has been unsatisfactory with limited benefit. Griseofulvin, psoralen plus ultraviolet A (PUVA), and pentoxifylline have all been tried.

A 40-year-old woman presented with 3x4 cm brownish patch that was first noted three years previously. The histopathological examination was consistent with the diagnosis of PPD. We attempted to treat the lesion with PDT and topical MAL (Metvix®, Galderma). The lesion was illuminated with red light from a Waldman PDT 1200 lamp, at a light dose of 15 J/cm² and a fluence rate of 50 mW/cm². After seven treatment sessions, the lesion showed clinical and histopathological improvement.

The successful treatment of PPD suggests that PDT might be considered for the treatment of other vascular skin diseases.

Key Words:

PDT, pigmented purpuric dermatosis

65

Pharmacokinetic study of m-THPBC in blood and tumor of mice

Boris Kogan, Alexander Butenin,
Larisa Ostrovskaya, Natalia Bluhterova,
Margarita Fomina, Valentina Rykova,
Georgy Vorozhtsov

Moscow, Russia

P8

5,10,15,20-tetrakis (m-hydroxyphenyl) bacteriochlorin (m-THPBC) is one of few photosensitizers that is suitable for PDT using total bleaching technique⁽¹⁾, because of high quantum yield of photobleaching. This technique can be used when the photosensitizer is not yet in the blood but still in the tumor.

Colon adenocarcinoma (BALB/c mice) was used as experimental tumor model. m-THPBC was injected intravenously in dose of 0.5 mg/kg 3 days after tumor transplantation. Mice were decapitated through various time intervals after injection, and samples of blood plasma and tumor have been taken. m-THPBC luminescence intensity was used for determination of relative concentration of photosensitizer in samples.

m-THPBC concentration in tumor was at a maximum at 4 days but very low 7 days after injection when it was still high enough in blood plasma. Thus other tumor models must be investigated in order to estimate their suitability for technique of total bleaching.

⁽¹⁾B.Y. Kogan, *Photochem. Photobiol. Sci.*, 2003, 2, 673-676.

Key Words:

PDT, m-THPBC, total bleaching, pharmacokinetic

66

Tissue oxygenation measurement possibility during PDT using photosensitizer fluorescence

PpIX-induced fluorescence in normal skin

Boris Kogan

Moscow, Russia

P9

Quenching of dyes triplet states by oxygen is most suitable tool for noninvasive optical measurement of tissue oxygenation. Special phosphorescent dyes are needed here usually. Photosensitizers (PS) used for clinical PDT have not phosphorescence therefore technique using their fluorescence can be very useful.

Here we present theoretical analysis of technique with laser radiating a series of pulses with duration about 1 microsecond every one. Intervals between pulses are comparable with PS triplet life time in tissue (10 – 100 microseconds). Method is based on distinction of the first fluorescence pulse from subsequent pulses which begin when part of PS molecules do not have the time to return to a ground state from triplet.

This technique can be applied in clinics. It can inform about oxygen concentration in places where there is PS in contrast to measurement haemoglobin/oxyhaemoglobin ratio that informs about blood vessels oxygenation only. Endogenous fluorescence in tissue can be used as well.

Key Words:

PDT, tissue oxygenation, photosensitizer, fluorescence

67

Harry Moseley, Andrea Lesar, James Ferguson

Dundee, United Kingdom

P10

The purpose of this study was to investigate the characteristics of PpIX-induced fluorescence in normal skin following the application of ALA and MAL.

Three aspects were studied: namely dosage, site of application, and duration of application. Fluorescence was not dose-dependent, within the range investigated. Four different body sites were investigated (inner forearm, outer forearm, lower leg and lower back). Inner forearm consistently showed the highest fluorescence. Application times from 1 to 6 h were studied and fluorescence monitored for periods up to 28 h. Maximum ALA-induced fluorescence for shorter application times (1–3 h) was noted at 7 h, compared to 24 h for longer application times (4–6 h). Peak MAL-induced fluorescence for all application times was noted at 7 h.

These results help to define the kinetics of PpIX production in normal cells exposed to ALA/MAL PDT.

Key Words:

fluorescence, MAL, ALA, PDT, PpIX, skin

68

Experimental evaluation of Radachlorin® sensitizer for PDT

Samuel Douillard, David Olivier,
Thierry Patrice

Nantes, France

A new photosensitizer, Radachlorin®, was evaluated in comparison with Chlorin e6.

The photodynamic properties, cell uptake and localisation were compared. *In vitro* studies involved human adenocarcinoma (HT-29) and lung carcinoma (A549). Fluorescence was recorded through an optical fibre spectrofluorimeter using the 666nm peak for detection. For *in vivo* studies, Swiss athymic mice were grafted with human lung carcinoma (line A549).

Both dyes showed absorption maximums between 640 and 650nm, with a shift in serum to 661nm. Radachlorin® intracellular fluorescence decreased after 4h, whereas we did not observe that for Chlorin e6 for up to 24h.

In vitro, phototoxicity of Radachlorin® and Chlorin e6 were nearly identical for HT29 and A549 cells. However, Radachlorin® reached its optimal LD50 sooner (0.59µg/ml for 3h incubation followed by 20J/cm² of 664nm light (0.02W/cm²)) than Chlorin e6 (0.60µg/ml for 4h incubation).

In vivo, maximum Radachlorin® fluorescence in tumor was observed 2h after injection. Maximum ratios (1.45±0.14 for tumor-to-skin and 1.95±0.29 tumor-to-muscle) were observed 7h after injection. Maximal Chlorin e6 fluorescence was observed in 1h and highest tumor-to-muscle ratio (2.56±0.97) in 8 hours. Chlorin e6 fluorescence in skin was always at least equivalent to tumor fluorescence.

In the PDT experiments, CR (no recurrence in 15 days) was achieved after 20mg/kg and 200J/cm² (0.3W/cm²) with both dyes. Optimal delays between injection and light delivery was between 1 and 7h with Radachlorin® and 3h for Chlorin e6 but severe adverse effects were noted for both drugs when drug-light intervals were shorter than 3h.

This suggests that clinical use would be more efficient and easier with Radachlorin® than Chlorin e6.

Key Words:

carcinoma, chlorin, laser, lung, photosensitizer, radachlorin

MAL-PDT in the treatment of "difficult to treat" BCC: a case report

Pavone Paolo Sergio, Lovati Silvia

Menaggio, Italia

Basal cell carcinoma (BCC) is the most common malignant neoplasia in the Caucasian population.

Simple surgical excision is currently regarded as the treatment of choice; however, patients may not be appropriate for surgery in certain situation (large, extensive and multiple lesions, unsuitability for invasive therapy, poor ability for wound care, high risk of disfigurement, poor vasculature, concomitant use of anticoagulants, immunosuppression, diabetes, or inadequate prior response to standard therapies).

Photodynamic therapy (PDT) offers an advantage in the treatment of large, extensive and multiple lesions and in "difficult-to-treat" patients.

We present a case of a large, extensive and multiple BCC of the trunk in an 85 years old woman, unsuitable for surgical therapy, successfully treated with MAL-PDT.

Three treatment cycles (7 and 28 days apart) of MAL-PDT were performed. The clinical response was evaluated 3, 6 and 12 months after the 3rd MAL-PDT treatment session.

Key Words:

BCC, "difficult-to-treat" BCC, MAL, PDT

MAL-PDT in the treatment of nodular BCC of the face: three case reports

Pavone Paolo Sergio, Lovati Silvia

Menaggio, Italia

Basal cell carcinoma (BCC) is the most common malignant neoplasia in the Caucasian population. Cosmetic outcome of surgical excision is often less than optimal, particularly for BCC of the face. PDT provides a good cosmetic outcome, due to selective uptake of a photosensitising agent by malignant cells.

We present three cases of nodular BCC of the face, treated with MAL-PDT, with an excellent cosmetic outcome.

Lesions were prepared by debulking curettage and three treatment cycles (7 and 28 days apart) of MAL-PDT were performed. The clinical response was evaluated 3, 6 and 12 months after the third MAL-PDT treatment.

The aim of NMSC treatment is efficacy with a good cosmetic outcome.

The three cases we present show that MAL-PDT is not only an effective and reliable treatment option for nBCC of the face, but really the first line therapy for thin nBCC of the face.

Key Words:
nodular BCC, MAL, PDT

Chlorin e6 based photosensitizer Radachlorin® for PDT of skin cancer

Valery A. Privalov¹, Viktor V. Sokolov²,
Elena G. Vakulovskaya², Alexander V. Geinits²,
Andrei V. Reshetnickov³

¹ Chelyabinsk, Russia

² Moscow, Russia

³ Noordwijkerhout, The Netherlands

Chlorin e6 from chlorophyll converted to a water-soluble amphiphilic photosensitizer Radachlorin®, in the form of a solution for intravenous infusions 0.35% (RCS) and a gel for external use 0.1% (RCG), as well as laser LAHTA-MILON® 662nm, underwent phase I and randomized phase II studies according to skin BCC treatment protocols.

PDT efficacy	RCS		RCG	
	patients	%	patients	%
CR	71	84.5	28	82.4
PR	12	14.3	4	11.8
S	1	1.20	2	5.80
P	–	–	–	–
Totally	84	100	34	100

Safety study showed no side effects and a good tolerability by patients. A low dark toxicity, 48h clearance of RCS from the human's body and a low affinity to the skin help to avoid the skin phototoxicity to daylight.

Having successfully passed the trials, RCS got approved in Russia and South Korea. It is a candidate for phase III clinical trials and can be commercialized as a prospective second generation photosensitizer.

Key Words:
carcinoma, chlorophyll, laser, photosensitizer, Radachlorin®, skin

Immunoadjuvant PDT mode

**Olga N.Sergeeva, Andrei V.Kukushkin,
Vadim O.Panov**

Moscow, Russia

P15 A hypothesis about a systemic antitumoral immune response following a local PDT action has found additional proofs in our clinical practice.

A 47-year-old patient got three palliative intraductal PDT (IPDT) treatments for hilar cholangiocarcinoma with the primary sclerosing cholangitis as the background. We used sensitizer Radachlorin®, 1.2-2.0mg/kg, and 662nm laser LAHTA-MILON, 80-120J/cm². Postprocedural MRI revealed partial regression of an intraductal tumor component and an enlargement of the regional lymph nodes in 3-5 months.

We hypothesize that PDT along with tumor destruction cause some local maturation of tumor-infiltrating myeloid-derived cells, their move to the draining lymph nodes and initiation of the specific T-lymphocyte proliferation, resulting in the lymph node reactive hyperplasia and size increase.

Clinically, the patient demonstrated a better performance status and lab tests after the IPDT.

Additional immunoadjuvants like retinoids, flavonoids, melatonin, glycyrrizic acid, pseudopeptides and bone marrow peptides may contribute in further regress of the tumor.

Key Words:

anticancer immunity, cholangiocarcinoma, immunoadjuvant, PDT, Radachlorin®

Successful treatment of disseminated superficial actinic porokeratosis with 5-ALA-PDT

Denny Siem, Gertruud Krekels

Eindhoven, The Netherland

P16 Disseminated superficial actinic porokeratosis (DSAP) responds differently to conventional treatments. There is no ideal treatment available for DSAP. A number of benign skin conditions, premalignant skin diseases and nonmelanoma skin cancers have been reported to be successfully treated with topical photodynamic therapy (PDT).

We treated a group of 5 patients with classical disseminated superficial actinic porokeratosis with ALA-PDT. In all of the patients, we used 5-aminolaevulinic acid (5-ALA) occluded 3-4 hours, following irradiation with red light 630 nm (Omnilux®) always with the same parameters (60 J/cm², 13 min). We repeated the session every 4 weeks. The maximum treated area per session was one limb (or two lower or upper limbs). After 3 or 4 sessions (per limb) the lesions responded well and improved or completely disappeared. Patients reported a "softening" of the skin.

Our results in this small case series suggest that ALA-PDT is a promising treatment for DSAP.

Key Words:

ALA-PDT, DSAP, treatment

Treatment of AK with PDT using a novel 5-ALA patch is superior to cryosurgery with respect to efficacy and cosmetic outcome

Rolf-Markus Szeimies¹, Georg Popp², Frank Borrosch³, Harald Brüning⁴, Rolf Dominicus⁵, Anne. C. E. Moor⁶, Christoph Ortland⁶, Marcus Brunnert⁷, Eggert Stockfleth⁸

¹ Regensburg, Germany, ² Augsburg, Germany, ³ Vechta, Germany, ⁴ Kiel, Germany, ⁵ Dülmen, Germany, ⁶ Wedel, Germany, ⁷ Düsseldorf, Germany, ⁸ Berlin, Germany

A new 5-ALA formulation, a patch containing 8 mg 5-ALA (AlaCare®), has been developed for PDT.

In a phase III clinical trial, 5-ALA patch was tested against cryosurgery on 346 patients with up to 8 mild to moderate AK lesions on the head or face. Patients were treated with 5-ALA patch or placebo patch for 4 hours, both with subsequent illumination with red light or with cryosurgery.

After 12 weeks, complete clearance on lesion basis was 89% for 5-ALA patch, 77% for cryosurgery and 29% for placebo. 5-ALA patch was significantly superior to cryosurgery ($p=0.007$) and placebo ($p<0.001$). 95% of patients were very satisfied or satisfied with the overall cosmetic outcome of 5-ALA patch as opposed to 82% after cryosurgery and 44 % after placebo. Pigmentation status was found to be statistically significantly different between 5-ALA patch PDT and cryosurgery ($p<0.001$).

In conclusion, PDT using a novel 5-ALA patch offers a one-step application procedure, which shows excellent results superior to cryosurgery with respect to efficacy and cosmetic outcome.

Key Words:

AlaCare®, clinical trial, cosmetic outcome, cryosurgery, 5-ALA patch, PDT

5-ALA PDT for decreasing the size of excisional defects in NMSC designated as safety margin PDT : part II

Tanner Mark M.D.⁽¹⁾, Paredes Bruno M.D.⁽¹⁾, Field Lawrence M.D. (FIACS)⁽³⁾

⁽¹⁾ Noerdlingen, Germany

⁽²⁾ Friedrichshafen, Germany

⁽³⁾ Foster City, CA, U.S.A.

We discontinued further surgery after a facial NMSC R 1 excision and implemented three photodynamic applications at two week intervals in a first case presented at the 8th Euro PDT (Barcelona 2008). We designated this new concept as "Safety Margin PDT".

Now we present a small case series (n=6) of squamous cell carcinoma (SCC) and basocellular carcinoma (BCC) removed with a clinically sufficient safety margin, while the intraepidermally located neoplastic cells continued to be detectable. The final R 1-excisions measured up to 3.7 x 4.2 cm.

The premalignant in situ component bordering the excision margins was marked by positive PpIX-fluorescence. PDT's efficacy was successfully confirmed by complete bleach-out of PpIX-fluorescence and disparition of premalignant changes as atypia of keratinocytes, uneven epidermal thickness or parakeratosis. We did not observe any clinical relapse.

We conclude that safety margin PDT can be a useful tool to decrease the size of excisional defects and to lower recidive rates in NMSC.

Key Words:

bilevel anaesthesia, excision margins, NMSC, non-invasive surgery, safety margin PDT

PDT for hyperkeratotic psoriasis of both hands

Van Haselen, Christian Willem

Doetinchem, The Netherlands

P19 Efficacy of topical photodynamic therapy (PDT) has been demonstrated in the treatment of non-melanoma skin cancer and its precursors. PDT for inflammatory disorders including psoriasis has also been described although the effectiveness is a matter of debate.

In this case report a 49-year-old patient is described with therapy-resistant, histology-proven psoriasis of the hands. Topical methyl aminolevulinate (Metvix®) PDT resulted in a complete remission.

PDT may therefore be an alternative therapy in the treatment of selected cases of psoriasis.

Key Words:

alternative, case report, PDT, psoriasis, therapy

www.euro-pdt.org

Website of the European Society for Photodynamic Therapy in Dermatology

Zange C, Szeimies RM, Morton C, Sidoroff A, Braathen LR

Regensburg, Germany

P20 The aim of the European Society for Photodynamic Therapy in Dermatology is to offer a communication platform for those who either actively do research in the field of photodynamic therapy and fluorescence diagnosis or use PDT clinically or want to catch up on it. Thus, Euro-PDT started to collect contact details of departments of dermatology and private offices in which PDT is a standard procedure, and posted these addresses on the EURO-PDT website. By January 2009, we have already listed 316 departments and offices in 16 European countries.

The website was launched only six months after the foundation of the Society in 2000. In 2008 alone euro-pdt.org got about 30.000 visits from all over the world.

If you offer PDT in your department or your office and if you are interested in getting listed on the EURO-PDT website, please log on to the website, download and answer the short questionnaire and send it via e-mail to: info@euro-pdt.org

Key Words:

EURO-PDT, website, questionnaire, database

