News in erosive lichen planus of the vulva

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- a great challenge

**WHY?**

- No evidence based treatment
- A lack of research
- 1 randomized controlled study (RCT)
  
  “Vulvovaginal photodynamic therapy vs. topical corticosteroids in genital erosive lichen planus: a randomized controlled trial”
  
  [A.L.O. Helgesen et al. BJDerm 2015](#)

- No standardized measurement of treatment effect
- A chronic and systemic disease
Lichen planus (LP)

- Autoimmune inflammatory disease
- Pathogenesis unknown, T-cell mediated
- Prevalence 1%
- Mucocutaneous location:
  - **Skin** – many different subtypes
  - **Genital** - erosive, papulosquamous, hypertrophic
  - **Oral, oesophageal, conjunctival, anal**
  - **Nail**
- Menopausal
- Not in children
Genital erosive lichen planus - GELP - symptoms

• Pain
• Burning
• Bleeding
• Discharge
• Dyspareunia
Genital erosive lichen planus (GELP) - findings

- Labia minora - introitus
- Erythema /erosions/absorbtion
- Vagina - 70%
- Stenosis, obliteration
- White stripes on the border (biopsy!)
Histopathological findings

- Inflammatory band
- Lymphocytes
- Basal layer degeneration
Treatment of GELP

- **Topical treatment**
  
  *Ultra-potent steroids*, daily for 4-8 months, then x 1-2 pr week.
  *(Dermovate*, Colifoam*)
  *Tacrolimus* (*Protopic*) or *pimecrolimus* (*Elidel*) daily

- **Systemical treatment**
  
  *Prednisolon, Ciclosporin, Methotrexate, Neotigason, Azathioprin, biologics*

- **Surgery/laser**
  
  splitting adhesions, dilatator
- lack of evidence based treatment

"..there is a **frustrating lack of clinical trials** or evidence base for different treatments." Niell et al. Arch Dermatol, 2008.


« ..**evidence-based** management **guidelines are lacking** » Caoimhe et al. JAAD, Des 2017.
What’s new??

Other studies –
Different case reports
Immuno-pathological
Quality of life

Photodynamic treatment - RCT
Oral treatment with Apremilast (Otezla*) - RCT (in process)
What IS new?

- Topical steroids useful after splitting synechies. *J Obst&Gyn*, 2018
  
  Dermovate and colifoam daily for 2 weeks, every second day for 2 weeks, and twice weekly for 4 more weeks. Then dilatators were used daily.

- Esophagus involvement in LP *Eur J Gastroent Hepat*, 2016

- Increased P16 in oral and genital LP *Med Oral Patol*, 2018

- Quality of life and sexual distress *J Low Genit Treact Dis*, 2017

- Pimecrolimus vs topical steroids in oral LP *Clin Oral Invest*, 2018
Photodynamic treatment (PDT)

- **Oral** lichen planus:
  Excellent long term effect:
  
  *Kvaal & Warloe,*
  *Oral Surg Med Pathol Radiol,* 2013
- Premalignant skin lesions and skin cancer
- Anesthetics?
- Pain?
What is photodynamic therapy?

Three key components:

**Photosensitizer + light source + tissue oxygen**
The PDT GELP study - a randomized controlled trial

- 40 women with GELP
- Vulva and/or vagina

Randomized to:
- one PDT session (using HAL (Hexvix*) and red light)
- Dermovate*/Colifoam* daily for 6 weeks

- Clinical examination with GELP score
- Pain VAS score (by patient and doctor)
## GELP score

<table>
<thead>
<tr>
<th>Clinical findings (by blinded doctor)</th>
<th>Number (0-3)</th>
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<tbody>
<tr>
<td>Area of Involvement</td>
<td></td>
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<tr>
<td>(0 = no, 1 = 1-3 cm, 2 = 3-6 cm, 3 = &gt;6 cm)</td>
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<tr>
<td>Intensity of Erythema</td>
<td></td>
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<tr>
<td>(0 = no, 1 = mild, 2 = moderate, 3 = strong)</td>
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<tr>
<td>Number of Erosions</td>
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<tr>
<td>(0 = no, 1 = one erosion, 2 = 2-3 erosions, 3 = &gt;four erosions)</td>
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<tr>
<td>Degree of Striae</td>
<td></td>
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<td>(0 = no, 1 = few, 2 = moderate, 3 = many)</td>
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<tr>
<td>VAS (pressure induced pain)</td>
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<tr>
<td>(0 = no, 1 = mild (1-3), 2 = moderate (4-6), 3 = strong (7-10))</td>
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</tbody>
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Max score: 15
Number of patients using Dermovate – before and 24 weeks after study start

![Bar chart showing the number of patients using Dermovate in PDT and steroidgruppen groups.](chart.png)
Patient reported **weekly use of Dermovate** for 24 weeks (days per week)
Conclusions:

Photodynamic treatment (PDT):

- a treatment option for GELP
- one treatment session
- reduce adverse effects from topical steroids
- better patient’s compliance
Conclusions:

- no significant difference in the effect of PDT and the use of topical steroids in women with GELP

- after PDT, the use of topical steroids was significantly reduced at 6 months follow-up
So what?

• PDT is implanted in regularly treatment
• PDT every 6-18 months.
• PDT is easy!
• Collaboration
• *Treatment is painful, but so is the disease!*
Oral Apremilast treatment of GELP - the AP-GELP study

Apremilast – «Otezla»
PDE4 (phosphodiesterase)- inhibitor
Broad anti-inflammatory effect
T- cell inhibitor
Oral LP and Behcet
Few side effects
Systemic effect
AP-GELP Study:
A randomized, placebo-controlled clinical trial on the effects of phosphodiesterase 4-inhibitor apremilast in female genital erosive lichen planus

- 40 patients with GELP
- Double blinded
- 5-6 follow-ups
- 1 years treatment with Otezla
- Inclusion from Jan-19
AP-GELP Study:
A randomized, placebo-controlled clinical trial on the effects of phosphodiesterase 4-inhibitor apremilast in female genital erosive lichen planus

- assess the effect of apremilast on GELP
- assess quality of life and sexual function
- describe immuno-histochemical changes in biopsies
The future...