**INTRODUCTION**

Treatment of chronic otitis externa can be very challenging and following failure of standard treatment, ablative surgery becomes the final option.

**Principles of KLOX Biophotonic System (KBS)**

KBS consists of a topical photoconverter gel which contains chromophores that, when illuminated by a multi-LED light (Bluephase® lamp), re-emit hyper-pulsed multi-wavelength fluorescent light which is capable of stimulating physiological responses that promote accelerated healing such as re-epithelialization and increased collagen production while controlling bacteria.

**METHODS**

**Inclusion criteria**

- Dogs with clinically apparent, spontaneous, chronic/relapsed otitis externa;
- integrity of the tympanic membrane;
- no concomitant antibiotic and anti-inflammatory therapy.

**Therapeutic Protocol (T₀ to T₄)**

Dogs were randomly divided in three groups:

- **Group QW** received KBS once a week for 6 times (duration of treatment: 6 weeks);
- **Group BW** received KBS twice a week for 6 times (duration of treatment: 3 weeks);
- **Group C** received standard of care (SOC) therapy (Baytril® Otis®) twice-a-day for 3 weeks.

**Evaluation Protocol (T₀ to T₄)**

T₀ = initial condition; T₁ = 7 days (QW), 3-4 days (BW and C); T₂ = 14 days (QW), 7-8 days (BW and C); T₃ = 21 days (QW), 10-12 days (BW and C); T₄ = 28 days (QW), 14-16 days (BW and C), T₅ = 35 days (QW), 18-21 days (BW and C).

- **Clinical assessment**
  - Otis3-Index-Scoring-System (0 to 12) (4 items: erythema, oedema/swelling, erosion/ulceration and exudate);
  - Pruritus-Score (VAS 0-10);
  - Pain-Score (VAS 0 to 10);
  - Aural temperature (°C);
  - Cytological scoring (0 to 15) (5 items: neutrophils, earwax/cerumen, rod shaped bacteria, coccioid bacteria and fungi/yeasts).
- **Bacteriologic assessment**
  - (pre/post treatment)
  - bacterial culture;
  - antibiotic susceptibility testing (Kirby Bauer method);
  - total bacterial count (CFU/mL).

**Statistical Analysis**

- Ordinal variables: Mann-Whitney rank sum test / Wilcoxon rank sum test;
- Categorical variables: Student t-test.
- Statistical significance: P-value ≤ 0.05.

**RESULTS**

Forty-three patients were included in the study. All groups (QW, n=15; BW, n=14; C, n=14) showed improvement for clinical, cytological and bacteriologic assessments [Table 1].

**Group BW** showed the highest clinical score reduction. No significant differences were found between groups QW and C [Fig. 1].

No significant differences among groups were found regarding pruritus, pain, aural temperature, cytologic score [Fig. 2-5].

**Group BW** showed a mean-%-reduction of CFU/mL (T₂-T₄) significantly higher than **Group C**. No significant differences were found between **group QW** with **C** and **BW** [Fig. 6].

| Table 1: Overall effect during treatment (T₀ vs T₄) in each group (mean ± sd) |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| **Group QW**                    | **Group BW**    | **Group C**     |
| Total otis                      | T₀   | T₁   | Stat  | T₀   | T₁   | Stat  | T₀   | T₁   | Stat  |
| Total otis                      | 5.93 | 2.50 | W=120 | 5.93 | 3.29 | W=91  |
| Pruritus                        | ±0.02 | ±1.60 | P=0.05 | ±0.92 | ±1.16 | P=0.05 |
| Pain                            | ±1.34 | ±1.92 | P=0.02 | ±1.18 | ±0.81 | P=0.05 |
| Pain                            | 5.27 | 2.86 | W=93  | 5.93 | 3.78 | W=68  |
| T °C                            | ±0.05 | ±1.51 | P=0.02 | ±0.44 | ±1.89 | P=0.02 |
| T °C                            | 37.66 | 36.86 | t=3.9  | 37.96 | 37.47 | t=3.3  |
| Total Cytol. (%)                | 5.93 | 1.20 | W=83  | 7.93 | 3.93 | W=105 |
| CFU (%)                         | 100.00 | 47.85 | t=2.0  | 100.00 | 11.43 | t=17.9 |

**DISCUSSION AND CONCLUSIONS**

- Therapeutic efficacy was found both for KBS and for SOC treatment.
- The most effective treatment was the KBS applied twice a week.
- KBS could be considered a new therapeutic strategy potentially able to delay or avoid ablative surgery in canine chronic otitis externa.
- The lower frequency of application of KBS compared to SOC could increase therapeutic compliance.
- Preliminary results encourage the fulfillment of the RCCT in order to clearly define the external validity and the potential generalizability of evidences.