Accepted Manuscript

Pain Management in Photodynamic Therapy (PDT): A Retrospective Cohort Study

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PII: S0190-9622(19)32301-1

DOI: https://doi.org/10.1016/j.jaad.2019.06.1302

Reference: YMJD 13592

To appear in: Journal of the American Academy of Dermatology

Received Date: 31 October 2018
Revised Date: 19 June 2019
Accepted Date: 21 June 2019

Please cite this article as: Denny JWL, Barea A, Wertheim D, Valiallah N, Natkunarajah J, Pain Management in Photodynamic Therapy (PDT): A Retrospective Cohort Study, *Journal of the American Academy of Dermatology* (2019), doi: https://doi.org/10.1016/j.jaad.2019.06.1302.

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Article type: Research Letter

Title: Pain Management in Photodynamic Therapy (PDT): A Retrospective Cohort Study

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IRB Approval: Not applicable.

Funding sources: None.

Conflicts of Interest: Janakan Natkunarajah has been an honorary speaker for Leo, Galderma,

Crawford, La Roche Posay & Novartis.

Manuscript word count: 473 words [excluding references, figure legend]

References: 4 Figures: 1

Supplementary figures: 0

Tables: 0

Supplementary tables: 0

Attachments: Checklist, Transfer Form, Authorship Forms, COI Forms

Keywords: PDT, Photodynamic Therapy, Local Anaesthetic, Local Anesthetic, Pain

- 1 Conventional Photodynamic Therapy (PDT) is a well-established treatment for cutaneous cancers such as basal cell carcinoma (BCC), squamous cell carcinoma-in-situ (SCCis) and actinic keratosis 2 3 (AK). A high intensity light source is utilised with the main complaint from patients being burning pain 4 from the outset which often continues well after procedural completion.² Pain is a particularly 5 unpleasant experience and is widely associated with treatment abandonment and thus a significant therapy-limiting factor.^{3,4} 6 7 We assessed local anaesthetic (LA) versus no analgesia or cooling water spray/aerosol (NA/CWS) for 8 pain management in conventional PDT (MAL-PDT). A single-site, retrospective review was performed 9 over a three-year period for patients who received PDT to treat a solitary lesion. The Numeric Pain 10 Rating Scale from zero (no pain) to 10 (worst pain ever experienced) was employed; data from first 11 and second sessions of a PDT cycle were analysed with Minitab v18 (Minitab Inc., USA). 12 Included were male and female patients over 18-years-old who received PDT on at least one 13 occasion. If a patient underwent multiple sessions but on different body sites they were recorded 14 separately. Only treatments that involved NA/CWS or subcutaneous LA were included; combination 15 regimens were excluded. Patients were excluded if treatment was abandoned during the procedure 16 and if any patient requiring two sessions changed analgesic regimen between them, they had their 17 second session excluded. Finally, light source heights other than 5cm/8cm were excluded. Fifty-nine patients with 95 treatments for AK, Bowen's disease or nodular or superficial BCC were 18 19 eligible. The total number of treatments is greater for session 1 (n=56) than session 2 (n=39) due to 20 some patients requiring only one session, and others switching analgesic regimens. As shown in 21
 - eligible. The total number of treatments is greater for session 1 (n=56) than session 2 (n=39) due to some patients requiring only one session, and others switching analgesic regimens. As shown in Fig.1, NA/CWS produced a median (range) pain score of 5 (0 to 10) for the first session and 3 (0 to 9) for the second session. With LA the median was zero for both sessions (0 to 3; session 1 and 0 to 4; session 2). The pain scores of each group were similar between sessions with a median difference of 0 (-2 to 0.5; 95%CI) for NA/CWS and 0 (0 to 0.5; 95%CI) with LA (Wilcoxon paired test for both). The overall difference in pain scores between groups was significant (p<0.001, Mann-Whitney test) in session 1 and similarly for session 2 (p<0.001, Mann-Whitney test).

27 <FIGURE01>

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Limitations of this study include absence of randomisation, small cohort number and the potential for treatment channelling bias by the operator. The use of LA for actinic field damage was not assessed

in this study. This pilot study suggests subcutaneous LA to be an effective method of pain relief in conventional PDT for solitary lesions. Its use has considerable implications in patient experience and tolerance and may help reduce the rate of therapy abandonment. Our results suggest patients be offered LA at their first encounter and that this therapeutic option merits further investigation.

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- 45 Abbreviation & Acronym list
- 46 Photodynamic Therapy (PDT)
- 47 Basal cell carcinoma (BCC)
- 48 Squamous cell carcinoma-in-situ (SCCis)
- 49 Actinic keratosis (AK)
- 50 Local anaesthetic (LA)

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52 Figure Legend

- Figure 1: Difference in median and interquartile range between the analgesic regimens in session one
- and two. Each boxplot shows the median (line with filled circle) and the interquartile range (box and
- whiskers) excluding outliers (> 1.5 the interquartile range) shown with an asterisk (*).

