Evaluation of Lidocaine Absorption from a Lidocaine Hydrogel

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Background

Lidocaine is well known to be an excellent agent to help control pain during the wound healing process. However, topical lidocaine is contraindicated to be placed into non-intact skin such as wounds as there is a potential of systemic lidocaine toxicity occurring. Additionally, some prior evidence with agents similar to lidocaine have shown to inhibit wound healing.[1] This study looked to evaluate the safety of a 2% lidocaine collagen hydrogel containing hyaluronic acid, procollagen and aloe vera, intended for use in pressure ulcers, first- and second-degree burns, and superficial wounds.

Methods

Human skin surrogate was used for this study, with pieces of the skin surrogate being damaged through the application of a chemical irritant to produce non-intact skin surrogate. Duplicate sections of intact and non-intact human skin surrogate were then placed in a well that contained a solution that coated the underside of the skin surrogate. This solution was designed to mimic blood plasma, which would receive the transdermally absorbed lidocaine from the lidocaine hydrogel product. The lidocaine hydrogel was placed onto the surface of the human skin surrogate. The culture medium was then sampled every hour for 26 hours to analyze lidocaine absorption using a modified ELISA assay method in triplicate. The relative concentration of residual lidocaine was also evaluated. The skin surrogate pieces were also visually examined microscopically and validated for structure and function at the conclusion of the study. Descriptive statistics were performed to obtain the mean and standard deviation of the comparison groups and student T-tests were used to determine if a significant difference existed between groups.

Results

For both intact and non-intact skin surrogates, maximum lidocaine absorption occurred two hours after application. Lidocaine absorption then rapidly decreased the following four hours. Throughout the study, maximum lidocaine blood level was calculated to be 200ng/mL. The relative concentration of residual lidocaine at 25 hours as well as the lidocaine level that was absorbed between intact and non-intact skin was not significantly different. The microscopic evaluation of the skin surrogate tissue also revealed that there was not a significant difference in the epidermal layers between the intact skin and the control tissue. Non-intact skin saw some reduction of the epidermal layer, but it was not significant.

Conclusion

The lidocaine containing hydrogel did not significantly increase risk for lidocaine toxicity in non-intact skin, with the maximum blood level for an average person calculated to be 200ng/mL, well below the accepted threshold of 1-5µg/mL. However, this value would probably be much lower en vivo due to various factors including plasma protein binding. This study suggests that the 2% lidocaine collagen hydrogel is a preferable alternative to topical lidocaine to control pain and promote wound healing.

References

1. Drucker M, Cardenas E, Arizti P, Valenzuela A, Gamboa A. Experimental studies on the effect of lidocaine on wound healing. *World J Surg*. 1998;22(4):394-398. doi:10.1007/s002689900403

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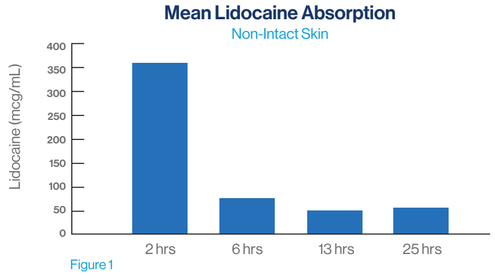

Figure 1

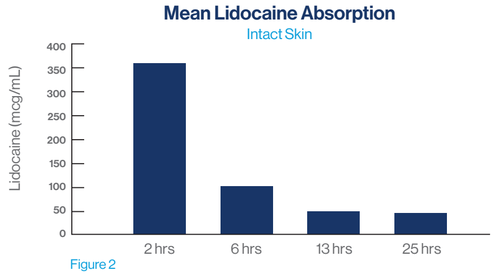

Figure 2

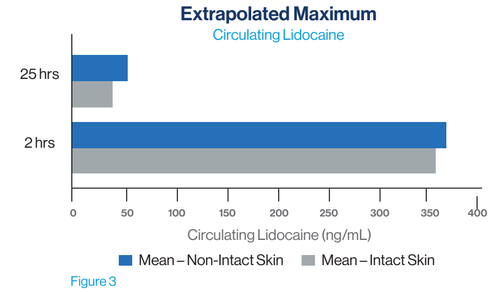

Figure 3