Antimicrobial Properties of LidoDose® Research Report[1]

Assessment of LidoDose Antimicrobial Activity Against Common Skin Pathogens

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Background

LidoDose® gel, 3% Lidocaine HCl, combined with Gensco Pharma's patented transdermal delivery technology, is an amide type anesthetic that has demonstrated significantly faster onset of dermal anesthesia, 5-10 minutes after application, than other standard topical lidocaine formulations including patches. Enhanced absorption is the reason topical anesthesia is much more rapid than other topical preparations without the need for an occlusive dressing. This is a significant advantage as a pre-procedural anesthetic.

Prior to any procedure requiring penetration of the skin, such as Dialysis, Vaccinations, Venipuncture and other in-office procedures, the skin must be cleansed with an antiseptic to prevent contamination and potential infection. At particular risk is the Hemodialysis Vascular Access Device (HVAD) which is the most common cause of infection in the dialysis population. Complications of the vascular access are frequent and costly to the patient's health and to the healthcare system. Thrombosis and infection are the most frequent causes of vascular access failure.[2]

The availability of a combined effective and rapid dermal anesthesia with anti-microbial action can result in significant time and money savings. To demonstrate the anti-microbial activity of LidoDose® (3% lidocaine), it was tested against the common skin pathogens including Staphylococcus aureus and epidermis, Pseudomonas aeruginosa, Streptococcus pyogenes and Escherichia coli using a Time-Kill procedure.

Study Design

This study was designed to assess the Antimicrobial activity of LidoDose® using a Time-Kill procedure at 0, 1 and 3 minutes, and was conducted by a FDA registered, independent contract microbiology laboratory.

An inoculum suspension was well mixed prior to addition to test materials. At contact time samples were taken out and added to broth tubes. 10-fold serial dilutions were prepared and plated in duplicate and plates were incubated at 35± 20C for 48 hours aerobically. Colonies were counted, and the concentration of viable cells was calculated.

Results

LidoDose® Antimicrobial Activity

Pathogen	Activity	Exposure Time (Min)	
		1	3
S. Epidermis	% CFU Reduction	98.96%	>99.99%
	Log Reduction	1.9862	5.8435
S. Aureus	% CFU Reduction	0	99.98%
	Log Reduction		3.9776
E. Coli	% CFU Reduction	>99.99%	>99.98%
	Log Reduction	6.6879	6.6879
P. Aeruginosa	% CFU Reduction	>99.99%	>99.99%
	Log Reduction	6.5378	6.5378
S. Pyogenes	% CFU Reduction	>99.99%	>99.99%
	Log Reduction	5.9800	5.9800

FDA guidelines stipulate that in order for a product to claim anti-microbial activity, it must exhibit a 2 log10 reduction in colony forming units (CFUs) of the organism tested. LidoDose® surpassed the 2 log10 threshold in most organisms at 1 minute of application and far exceed it in all organisms tested by 3 minutes.

These results clearly demonstrate that LidoDose® exhibits clinically relevant antimicrobial activity after 3 minutes of application to the skin versus these clinically relevant organisms, and may be used as an effective antiseptic.

References

1 Accugen Laboratories, Inc., a FDA registered, independent contract microbiology laboratory. (Data on file at Gensco Pharma).
2 Berman, Steven, Infections in Patients Undergoing Chronic Dialysis, http://www.antimicrobe.org/e41.asp