Is it necessary to be New to be Novel?

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Editorial

One area of my research, for the past five years, has been studying electrical stimulation and healing of chronic wounds. Mentioning electrical stimulation as a modality is not new, and for many, not novel. Electrical stimulation has been used as a modality to decrease pain for more than a century. It got approval from the Food and Drug Administration (FDA) of the United States in the 1970’s for increasing blood flow. Over the past five decades, numerous papers have been published on electrical stimulation stating its ability to decrease pain, facilitate strength, increase blood flow and heal wounds. This modality is not novel anymore, or is it? I believe taking into account three main aspects that can help us create a template to see if a modality can become novel.

1. Research: If we need an objective judge and jury for a modality, we must look at the research. In the case of electrical stimulation, transcutaneous electrical nerve stimulation (TENS) was prescribed to many people with pain, at one time. After 30 years of using TENS, health-care providers and insurance companies found the outcomes for long-term relief of pain to be controversial [1]. TENS decreased in popularity quickly. Electrical stimulation and its application to non-healing wounds has had varied outcomes for wound healing rates. The excitement about a novel modality – in this case, electrical stimulation – dwindled, as clinical outcomes could not justify the expense of a stimulator. But, was the research consulted? Were target populations, parameters and electrodes similar to the successful trials? Or, was the machine used “off label”.

2. Research that is “not significant”: In order to prevent a Type I error, we conveniently set the probability at 0.05. If a study using electrical stimulation to treat a wound compared its results of healing rates to standard care and had a result of p<0.05, does this immediately indicate that electrical stimulation is not a good modality for wounds? If we found out that P=0.08, would this be clinically meaningful? In the same scenario, researchers would want to prevent a type II error (also called power). Power is directly related to sample size and effect size. If the study indicated p=0.08, is that still clinically meaningful?

When looking at both Type I and II errors with electrical stimulation and healing rates for wounds our results may still be novel. We may need to increase the sample size (power) or analyze the methods before stating it is not significant.

3. Being novel with electrical stimulation: If a novel modality is still not achieving the desired outcomes, one may want to become novel with the parameters. In the case of electrical stimulation, we found significant increases in blood flow by adding heat plus electrical stimulation [2], biphasic vs monophasic waveforms, type of electrode [3] and a novel electrical stimulation device using a whirlpool type current [4].

Is it necessary to be new to be novel? In my opinion, the answer is no. Looking at three main areas of a modality can reveal its potential. Research, both significant and “not significant” is the first step toward optimizing the novel device. Finally, changing parameters of our device and observing outcomes can create something very novel that may not be new.

References


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