

Silver Spike Point Therapy in smoking cessation

What is it and does it work?

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ABSTRACT

يُعد التدخين تحدياً صحياً عالمياً، ويسبب عدداً لا يُحصى من الأمراض. تُعد خدمات الإقلاع عن التدخين جزءاً من أسلحة مكافحة تفشي التدخين. بالإضافة إلى العلاجات المعتمدة، تم اقتراح علاجات بديلة بما في ذلك التحفيز الكهربائي. الهدف من مقالة المراجعة هذه هو مراجعة وتلخيص الأدلة حول فعالية التحفيز الكهربائي بما في ذلك العلاج بالملامس الفضي في الإقلاع عن التدخين. تقدم المقالة خلفية تاريخية وملخصاً وصفيًا للطرق المختلفة للعلاج بالوخز بالإبر الصينية والعلاجات ذات الصلة. تمت مراجعة المراجعات المنهجية والدراسات الأصلية، وتم تلخيص نتائجها. في الختام، فإن أفضل الأدلة المتاحة الحالية لا تدعم استخدام التحفيز الكهربائي بما في ذلك الملامس الفضي في الإقلاع عن التدخين. يجب أن يهدف صانعو السياسات ومقدمو الرعاية الصحية إلى الاستخدام الأفضل للموارد المتاحة لتوفير خيارات العلاج المسندة بالبراهين للإقلاع عن تعاطي التبغ.

Smoking is a global health challenge that causes a myriad of diseases. Smoking cessation services are part of the armamentarium to combat smoking epidemic. In addition to the approved treatments, alternative therapies, including electrical stimulation, have been proposed. The aim of this study is to review and summarize the evidence for the efficacy of electrical stimulation, including Silver Spike Point therapy, in smoking cessation. A historical background and descriptive summary of various acupuncture and related therapies is provided. Systematic reviews and original studies were reviewed, and their results were summarized. In conclusion, the current best available evidence does not support the use of electrical stimulation, including Silver Spike Point therapy, in smoking cessation. Policy makers and healthcare providers should aim to utilize the available resources to provide evidence-based treatment options for patients seeking to quit tobacco use.

Keywords: acupuncture therapy, auriculotherapy, complementary therapies, electroacupuncture, smoking, smoking cessation, tobacco use

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I. Introduction. Smoking is a significant global health challenge. Tobacco is responsible for more than 8 million deaths in the world each year, with a cost of US\$1.4 trillion to the global economy.^{1,2} Smoking can cause a wide range of diseases, including coronary heart disease, cancers, respiratory disease, cataracts, infertility, and hip fractures.³ Although manufactured cigarette smoking is the most common form of tobacco use, other non-cigarette forms of tobacco are gaining popularity, including shisha (waterpipe), smokeless tobacco, and heated tobacco products. Therefore, tobacco control continues to be a target for national and coordinated international initiatives and legislations. Target 3.a of the United Nations Sustainable Development Goals seeks to enhance the enforcement of the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC) across all nations. The WHO-FCTC is an international treaty adopted by WHO member states in 2003 that provides a framework to combat the tobacco pandemic.

Among the population aged 15 years or older in Saudi Arabia, 30% of men and 4.2% of women are tobacco users.⁴ Although the prevalence of tobacco use is relatively low among women in Saudi Arabia, it is expected to rise due to several factors.⁵ Tobacco smoking was estimated to contribute 16.3% of cancer cases in the Arabian Gulf countries, 14.6% of adult cancer cases in the Eastern Mediterranean region, and more

than 6% of colorectal cancer cases in Saudi Arabia.⁶⁻⁸ In 2002, a national program was initiated to combat the smoking problem in the country; since then, efforts have continued to combat the smoking epidemic including providing smoking cessation treatment, capacity building of tobacco treatment workforce, and plain packaging implementation.^{9,10}

II. Smoking cessation. Smoking cessation efforts are based on the evidence that the health risks of smoking among smokers can be reversed if they quit.¹¹ Moreover, smokers usually want to quit but are unable due to nicotine addiction.¹² A variety of interventions have been investigated, including pharmacological therapies, such as nicotine replacement therapy (NRT), nicotine receptor partial agonists, and antidepressants, and non-pharmacological therapies, such as clinicians' advice and physical exercise. All forms of NRT, including gum, transdermal patch, nasal spray, inhaler, and sublingual tablets/lozenges, are effective and enhances the success rate of smoking cessation.¹³ Varenicline (nicotine receptor partial agonist) and cytisine were found to be effective in aiding smoking cessation and were likely more effective than NRT.¹⁴ The antidepressants bupropion and nortriptyline were found to be effective in long-term smoking cessation; however, there is insufficient evidence to determine the effectiveness of selective serotonin reuptake inhibitors.¹⁵ The effect sizes of various therapies compared to placebo, as reported in the Cochrane systematic reviews, are summarized in (Table 1). Brief advice from either a physician or a nurse has a small effect on cessation rate, while more intensive interventions are more effective.^{16,17} The available evidence on the effectiveness of physical exercise for smoking cessation is of low certainty, and higher quality studies are required.¹⁸ Likewise, the existing evidence does not support mindfulness-based interventions.¹⁹

III. Acupuncture and related therapies. Acupuncture therapy has been utilized as treatment for thousands of years, originally in China and then in other parts of the world. In China, acupuncture was excluded from medical practice in the 19th century by a decree from the emperor and was finally prohibited in 1929; however, it was reintroduced in 1950s.²⁰ In Chinese

medicine theory, acupuncture is based on the yin-yang concept. Yin represents cold, darkness, passiveness, and being stationary, while yang represents heat, light, stimulation, dominance, and movement. The human body is believed to be in a balanced state between Yin and Yang. Any imbalance in yin and yang can lead to a state of disharmony. In addition, the theory describes "qi" as the vital energy that flows through the body and influences health. Qi flows in the body along pathways called meridians. Disturbance of the yin-yang balance disrupts the flow of qi, leading to disease; the target of acupuncture is to restore this balance.²⁰ Fine needles are inserted into specific points on the body (known as acupoints) to correct the disharmony. The classical theory identifies 365 points distributed over the body along 14 main meridians.²¹ In Chinese medicine theory, these acupoints are where qi enters, exits, and accumulates. Needle insertion can be augmented by a variety of stimulation methods. Mechanical stimulation includes lifting-thrusting, twisting the needle, pressing, and squeezing. Acupressure (simple hand pressure) and cupping (vacuum suction over acupuncture points) are other forms of mechanical stimulation.²¹ Moxibustion is thermal stimulation that involves burning herbs near the acupoints. Electrical, infrared, laser, and magnetic field have been used in stimulation, with electrical stimulation being the most popular form.²¹ (Table 2) summarizes the various modalities of acupuncture treatment.

In recent decades, several studies have been carried out to explore 2 aspects related to acupuncture: i) to empirically evaluate the effectiveness of acupuncture in various conditions to determine whether it has a real or placebo effect, and ii) to seek an understanding of the biological basis and mechanism of effect of acupuncture.²²⁻²⁵

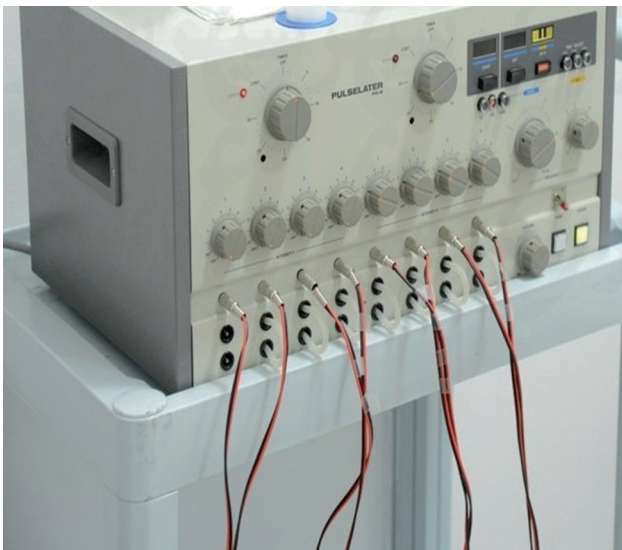
A. Acupuncture with electrical stimulation. Electrical stimulation can take one of 2 forms: i) electroacupuncture (EA) where an electrical current is connected to the inserted needles, or ii) transcutaneous electrical nerve stimulation (TENS), where no needles are inserted and electrodes are instead placed on the surface of the points.²⁶ The major advantage of electrical over mechanical stimulation is its reproducibility, and a major advantage of TENS over EA is that it is non-invasive. TENS initiated a new wave of acupuncture-related therapies described collectively as "needle-less acupuncture," avoiding the potential biological hazards of acupuncture needles.^{27,28} Two commonly used TENS varieties are SSP and microcurrent electrical nerve stimulation (MENS), both of which are described in the following sections. Application of other sources

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Table 1 - Summary of the effect of various pharmacotherapies on smoking cessation.

Interventions	Effect size and confidence interval from meta-analyses	Number of primary studies
<i>Nicotine replacement therapy (NRT)</i>		
Any form of NRT ¹³	RR 1.55, 95% CI 1.49 to 1.61	133
Nicotine gum ¹³	RR 1.49, 95% CI 1.40 to 1.60	56
Nicotine patch ¹³	RR 1.64, 95% CI 1.53 to 1.75	51
Nicotine inhaler ¹³	RR 1.90, 95% CI 1.36 to 2.67	4
Nicotine nasal spray ¹³	RR 2.02, 95% CI 1.49 to 2.73	4
Oral tablets/lozenges ¹³	RR 1.52, 95% CI 1.32 to 1.74	8
<i>Nicotine receptor partial agonists</i>		
Varenicline versus (vs.) placebo ¹⁴	RR 2.24, 95% CI 2.06 to 2.43	27
Varenicline vs. bupropion ¹⁴	RR 1.39, 95% CI 1.25 to 1.54	5
Varenicline vs. NRT ¹⁴	RR 1.25, 95% CI 1.14 to 1.37	8
Cytisine vs. placebo ¹⁴	RR 3.98, 95% CI 2.01 to 7.87	2
<i>Antidepressants</i>		
Bupropion ¹⁵	RR 1.64, 95% CI 1.52 to 1.77	45
Bupropion and NRT vs. NRT alone ¹⁵	RR 1.19, 95% CI 0.94 to 1.51	12
Nortriptyline ¹⁵	RR 2.03, 95% CI 1.48 to 2.78	6

RR: relative risk, CI: confidence interval

**Figure 1** - Silver Spike Point device.

for stimulation has also been proposed for smoking cessation (for example, laser light and magnetic stimulation); however, these will not be covered in this review.²⁹⁻³²

B. Silver Spike Point (SSP) therapy. Silver Spike Point Therapy is a form of needle-less electrical acupuncture therapy that uses low-frequency electrical stimulation applied to the acupuncture points using special electrodes (Figure 1). It was developed in the seventies in Japan through joint collaboration between Osaka Medical College and a private company.³³ In Saudi Arabia, SSP is commonly known as “Almolamis

Alfidhi” (“the silver toucher” in Arabic) and had been used for years in smoking cessation facilities, especially by tobacco control charities.

Silver Spike Point is like TENS in that it does not involve needle insertion. Unlike TENS, which uses flat-surface electrodes, it uses “pointed” cone-shaped electrodes, which are believed to focus the electrical stimulation on a precise point. The electrodes are made from silver-plated brass, which is believed to enhance the transfer of electrical stimulation.³⁴ The electrodes are housed within a rubber cup to sustain contact with the skin via a vacuum mechanism. In addition, SSP uses a low-frequency, spike-wave, fluctuated electrical stimulation system named “1/f Yurag.” Silver Spike Point has the advantage of being needle-less and is thus painless, has a lower risk of infection, produces no hazardous wastes, and there is no risk of complications associated with needle use.

C. Microcurrent electrical nerve stimulation. Like SSP, MENS is a needle-less acupuncture therapy that delivers weak electrical currents lower than 1000 μ A (hence the name “microcurrent”) using pen-like probes.³⁵ It is thought to have a similar mechanism of action to TENS and has been tested in several conditions, such as temporomandibular disorders, rotator cuff tear, and myofascial pain.³⁵⁻³⁷

D. Auriculotherapy. Several studies investigating the use of acupuncture or electrical stimulation have focused on acupoints in the ears, especially in addiction treatment.³⁸ Applying mechanical, electrical, or other sources of stimulation to the ears is known as auriculotherapy. Auriculotherapy literature states that acupoints in the ears are the optimal target for treating

Table 2 - Acupuncture and related therapies.

Type of acupuncture therapy and description
<p>Acupuncture</p> <p>An ancient healing practice with roots in Chinese medicine It involves inserting special needles into specific points (called acupoints) in the skin to relieve pain and other symptoms. Therapeutic effects of acupuncture are thought to be due to the activation of neural pathways and the release of neurotransmitters.</p>
<p>Electroacupuncture</p> <p>A variation of acupuncture that involves applying a small electrical current to the inserted needles.</p>
<p>Transcutaneous electrical nerve stimulation (TENS)</p> <p>A non-invasive technique that involves applying electrical stimulation to the skin through electrodes placed on the skin. Flat-surface electrodes are used. No needles are inserted.</p>
<p>Microcurrent electrical nerve stimulation</p> <p>A similar technique to TENS but uses a much lower level of electrical stimulation. Uses weak electrical currents (<1,000 μA).</p>
<p>Silver Spike Point therapy</p> <p>A more recent form of needle-less acupuncture. Uses low-frequency electrical stimulation applied to the acupuncture points using special electrodes. It uses "pointed" cone-shaped electrodes made of silver. The treatment typically lasts between 15 and 30 minutes, and multiple sessions are usually required.</p>

addiction.³⁹ Studies have shown that combining body acupuncture with auricular acupuncture does not increase the effectiveness compared to auricular acupuncture alone.⁴⁰

E. Therapeutic uses. TENS and similar techniques have been investigated in the treatment of various conditions, including acute and chronic pain in adults, cancer-related peripheral neuropathy, knee osteoarthritis, dry mouth following radiotherapy, lower urinary tract dysfunction in children, enuresis in children, chronic obstructive pulmonary disease, labor pain relief, and rehabilitation after stroke.⁴¹⁻⁴⁹

F. Acupuncture and related therapies in scientific research. Acupuncture therapy has been the focus of interest for several decades in a variety of diseases, especially diseases with no effective treatment in Western medicine. Complementary and alternative medicine (CAM) was the term coined to describe therapeutic practices not belonging to Western medicine, including acupuncture. These methods have been received with skepticism among physicians and healthcare workers. Early studies on acupuncture had varying levels of quality, both in design and reporting. To evaluate the efficacy of CAM, many CAM techniques have been assessed using randomized-controlled trials, which is the gold standard for the demonstration of efficacy.

There are certain methodological issues surrounding acupuncture.^{50,51} First, there is no standard for selecting the acupuncture points in terms of which points are most effective for a certain disease and whether to use single or multiple points. Point selection depends on the personal experience of the practitioner. Second, there is no standard for the type of manipulation and

stimulation (manual, electric, magnetic, or other forms) or the frequency and intensity of the specific stimulation. Third, the basic theory behind acupuncture is primitive; some aspects do not agree with modern anatomy, and the mechanism of action is not well understood.

Therefore, there have been efforts to improve research practices in acupuncture and related therapies. These efforts involve developing standards of practice, providing recommendations on the design of valid randomized-controlled trials to investigate acupuncture and related treatments, and developing standards for reporting acupuncture-related clinical trials and clinical practice guidelines.⁵²⁻⁵⁸

IV. Acupuncture, electroacupuncture, and SSP in smoking cessation.

Acupuncture, auricular acupuncture, EA, and SSP were proposed as standalone treatments in smoking cessation and in combination with approved therapies.⁵⁹⁻⁶⁴ The interest in the use of EA in smoking cessation started in the 1970s when Wen et al⁶⁵ used auricular acupoints to treat opiate addiction. It was suggested that the effect of EA on smoking cessation is mediated through increased serotonin levels in the brain and consequent activation of the reward circuit.

Table 3 summarizes the results of 2 systematic reviews and meta-analyses on the efficacy of acupuncture and related therapies in smoking cessation. A Cochrane systematic review found no evidence supporting sustained smoking cessation for acupuncture compared to a waiting list or sham acupuncture (**Table 3**).⁴⁰ Authors note that the studies were heterogeneous and showed evidence of methodological and publication

Table 3 - Summary of the results of systematic reviews on the efficacy of acupuncture and related therapies in smoking cessation.

Author, year	Comparison	Short-term (<6 months)	Number of participants (n of studies)	Long-term (≥6 months)	Number of participants (n of studies)
White, ⁴⁰ 2014 (Cochrane review)	Acupuncture vs. waiting list	2 trials with high heterogeneity (I ² =84%)	-	1.79 (0.98 to 3.28); I ² =57%	393 (3)
	Acupuncture vs. sham	1.22 (1.08 to 1.38); I ² = 46%	2588 (16)	1.10 (0.86 to 1.40); I ² =23%	1892 (9)
	Acupuncture vs. nicotine replacement therapy	0.76 (0.59 to 0.98); I ² =0%	814 (2)	0.64 (0.42 to 0.98); I ² =0%	814 (2)
	Acupuncture vs. counselling and psychological approaches	0.95 (0.72 to 1.26); I ² =43%	396 (3)	1.34 (0.80 to 2.24); I ² =64%	396 (3)
	Acupressure vs. sham	2.54 (1.27 to 5.08); I ² =0%	253 (3)	No studies	-
	Electrostimulation vs. sham	1.13 (0.87 to 1.46); I ² =0%	634 (6)	0.87 (0.61 to 1.23); I ² =46%	405 (2)
	Continuous auricular stimulation vs. sham	1.69 (1.32 to 2.16); I ² =16%	1155 (13)	1.47 (0.79 to 2.74); I ² =22%	570 (5)
Zhang, ⁶⁶ 2021	Acupressure vs. sham or conventional therapy	Short term (1–3 months): 1.41 (1.04 to 1.91); I ² =31%	637 (8)	1.85 (0.59 to 5.82); I ² =14%	74 (2)
		Mid-term (3–6 months): 1.63 (1.27 to 2.09); I ² =10%	749 (8)		
	Intradermal needle vs. sham	1.62 (0.85 to 3.08); I ² = 64%	346 (5)	No studies	-
	Transcutaneous electrical stimulation vs. sham or counseling	1.27 (0.96 to 1.67); I ² = 64%	485 (5)	0.50 (0.05 to 5.28)	76 (1)
	Laser acupuncture vs. sham	2.98 (0.24 to 37.81); I ² = 96%	427 (2)	2.25 (1.23 to 4.11)	160 (2)
Acupoint catgut embedding	0.99 (0.7 to 1.40)	177 (2)	No studies	-	

n: number

bias. Furthermore, they reported limited evidence for the short-term effects of acupressure and continuous auricular stimulation compared to sham procedures. Furthermore, there was no evidence supporting the long-term effects of either therapy (no trials for acupressure and null findings for continuous auricular stimulation). Importantly, they pooled the results of 6 trials on the short-term and 2 trials on the long-term effects of electrostimulation and found no evidence of superiority compared to sham electrostimulation (Table 3). A more recent systematic review and meta-analysis reported that there was no evidence that transcutaneous electrical stimulation has short-term (5 trials [n=485] odd ratio [OR]=1.27; 95% confidence interval [CI] 0.96–1.67; I²=64%) or long-term benefits in smoking cessation (1 trial [n=76] OR=0.50; 95% CI 0.05–5.28).⁶⁶

In conclusion, the current best available evidence does not support the use of electrical stimulation, including SSP therapy, in smoking cessation. Healthcare providers should advise tobacco users to opt for evidence-based options to quit tobacco use. Resources should be used wisely to support the provision of evidence-based therapy in governmental and non-governmental institutions providing smoking cessation treatment.

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