Wei YY, Xi Q, Guo Y. Review on the development and application of electroacupuncture apparatus in the past 5 years in China. J Acupunct Tuina Sci, 2019, 17(4): 284-288
DOI: https://doi.org/10.1007/s11726-019-1120-0

Literature Study

Review on the development and application of electroacupuncture apparatus in the past 5 years in China

近5年中国电针仪研制及应用述评

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Abstract

Objective: To review the problems existing in the development and application of current electroacupuncture (EA) apparatuses, and provide reference for the development of EA apparatuses.

Methods: Related literatures about EA apparatus were derived from China National Knowledge Infrastructure (CNKI), Wanfang Academic Journal Full-text Database (Wanfang) and Chongqing VIP Database (CQVIP) between 2013 and 2017. Literatures about the development of EA apparatuses and the application for experimental research and clinical treatment published in Chinese journals were retrieved, and the development and application of EA apparatuses were summarized.

Results: Among the 107 selected literatures, 48 types of EA apparatuses were used, of which only 11 models could be found in the registration list and within the validity period. There was no registration information for the EA apparatus newly developed in the past 5 years. The EA parameters used in experimental research and clinical treatment in Chinese medicine were different, and the combination of stimulation parameters was diverse.

Conclusion: At present, most of the new EA products are still in the experimental or research stage, and the transformation of results has not yet been achieved. Moreover, there is no unified standard for the use of EA apparatus and its stimulation parameters in experimental research and clinical treatment, which is not conducive to the standardization process of EA stimulation.

Keywords: Acupuncture Therapy; Electroacupuncture; Electroacupuncture Apparatus; Electric Stimulation; Parameter; Review; Literature

【摘要】目的：评述目前电针仪研制及应用中存在的问题，为电针仪发展提供参考。**方法：**在中国知网(CNKI)、万方全文数据库(Wanfang)和重庆维普数据库(CQVIP)中检索2013年-2017年电针仪相关文献，筛选出中国期刊上发表的电针仪研制及应用电针仪进行实验研究和临床治疗的文献，归纳总结电针仪的研制及应用情况。**结果：**在107篇入选文献中，共使用了48种型号的电针仪，其中只有11种型号能查到注册信息并在有效期之内，近5年新研制的电针仪尚无注册信息。中医实验研究和临床治疗中使用的电针仪刺激参数不一，刺激参数组合多样。**结论：**目前多数新型电针治疗产品仍停留在试验或研究阶段，尚未实现成果转化，并且实验研究和临床治疗中电针仪及其刺激参数的使用缺乏统一规范，不利于电针刺激的标准化进程。

【关键词】针刺疗法；电针；电针仪；电刺激；参数；综述；文献
【中图分类号】R245-33　　**【文献标志码】**A

The electroacupuncture (EA) apparatus refers to an electronic apparatus capable of outputting pulse current and meeting the requirements of EA therapy, including a host, electrode wires and a power adapter[1]. The birth of EA was inseparable from EA therapy. EA therapy connects a suitable current to a needle that penetrates acupoint on the basis of obtaining qi, so as to stimulate the points and prevent diseases[2]. Since the French physician Louls Berloiz proposed to add electric stimulation onto the needles to replace the hand manipulation at the beginning of the 19th century, EA began to develop abroad and was gradually applied to clinic. The earliest EA therapy in China was recorded in the *Study of Electroacupuncture* published by Tang Shi-zhen, *et al* in 1934[3]. EA has the dual characteristics of electrical stimulation and acupoint stimulation, and overcomes the shortcomings of time and labor of manual acupuncture that unable to last for a long time of manipulation. With the development of science and technology, domestic physicians and engineers began to develop a variety of EA therapeutic devices, and performed a large number of experimental and clinical studies. We reviewed and analyzed the literatures on the development or design and application of EA

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apparatus published in China in the past five years, so as to provide references for the development of EA therapeutic equipment.

1 Materials and Methods

1.1 Literature resources

China National Knowledge Infrastructure (CNKI), Wanfang Academic Journal Full-text Database (Wanfang), and Chongqing VIP Database (CQVIP) were searched. Key words were 'Electroacupuncture Apparatus', 'Electroacupuncture', 'Development', 'Design', 'Frequency', 'Waveform, 'Voltage' and 'Current Intensity'. Subject, title or keyword retrieval was used, and 'AND' or 'OR' connectives were used to construct the logical retrieval form. The search period was 2013-2017.

1.2 Inclusion criteria of literature

Literatures based on the development or design of EA apparatuses, no limit of literature type; Chinese medical literatures on the application of EA, no limit of literature types; EA parameters were clearly described in the literatures, such as frequency, waveform, voltage and current intensity, one or more.

1.3 Exclusion criteria of literature

Duplicate publications, or published in different languages, such as in Chinese and English; multiple similar literatures published by the same research group for the same subject; with EA parameters that referenced other literatures; and literatures with significant errors in data.

2 Results

2.1 Overview of the included literature

A total of 7 papers on the development of EA apparatuses and 320 papers on researches of Chinese medicine using EA were retrieved. According to the inclusion criteria and exclusion criteria, a total of 107 articles were selected for analysis.

2.2 Development of EA apparatus

Compared with previous EA apparatuses, in the development of EA apparatuses in the past five years, more attention has been paid to the tolerance and safety of patients during the treatment, and more modern technologies and software have been used, such as electronics, display, control and computer. To a certain extent, the function of the EA apparatus has increased, the integration and intelligence has improved, and the volume has greatly reduced. Scholars combined single-chip microcomputer control technology with other technologies and programming software in the development of EA apparatus, to achieve and change the function of the EA apparatus by programming and modification, which solved the problems such as tolerance, safety and inconvenience to carry, and improved the intelligence of EA apparatus[3-7]. Wu ZX, *et al*[8] combined the virtual apparatus developed by Labview program with EA apparatus, and used Labview software as a platform to complete the programming of various complex waveforms, which solved the problem that the slope of triangular pulse generator was not adjustable in traditional EA apparatus, and broke through the limitation of fixed waveform of traditional EA apparatus. Yang Y, *et al*[9] introduced the cloud technology into EA apparatus, used intelligent terminal application program to generate stimulus signals, and realized the upload, storage, and transfer of diagnosis and treatment information of patients, as well as the doctor-patient remote communication and guidance, which was conducive to the standardization of EA parameters and the optimal parameters for diseases.

2.3 Problems in the development of EA apparatus

According to the development of the EA apparatuses mentioned above, it can be found that current researches on EA were mainly to solve the problems of clinical tolerance, inaccurate parameter adjustment, unreasonable stimulation intensity setting and safety of EA apparatus. There is still no great improvement in the function of the EA apparatus. Although there are many types and functions of existing EA apparatuses, they are relatively limited. The functions of a single EA apparatus are not integrated. In practice, different EA apparatuses need to be replaced in order to achieve therapeutic purposes, which limit the promotion of EA apparatus to a certain extent. Secondly, EA apparatus is a product of medicine and industry integration. It needs to be jointly developed by engineering researchers and medical researchers. However, engineering researchers may not have a comprehensive and systematic understanding of traditional Chinese medicine theory, while medical researchers may have shortcomings in understanding the theory of engineering. It was unable to integrate the theory of traditional Chinese medicine with engineering theory perfectly during the development. There is still a certain gap between the EA apparatus developed and the actual clinical needs. Finally, although the newly developed EA apparatuses had certain advantages compared with the traditional ones, some higher integration chips and more advanced technologies had been adopted in the process of development, which may lead to an unsatisfactory performance-price ratio.

2.4 Application of EA apparatus

2.4.1 Selection of EA apparatus

Among the included literatures, G6805 series EA apparatus had the highest frequency of use, accounting for 26%; followed by HANS series EA apparatus, accounting for 17%; Hwato series EA apparatus accounted for 11%; and other various apparatuses accounted for 35%; the remaining 11% were not labeled with specific brands or models in the literatures.

G6805 series EA apparatus included apparatuses with or without labeled manufacturer. Those with labeled

manufacturer mostly were Huayi G6805 EA apparatus, including 5 types in all: Shanghai G6805, Huayi G6805, Huayi G6805-C, Huayi G6805-1A and Huayi G6805-2B. Those without labeled manufacturer in 26 literatures included 4 types: G6805, G6805-1, G6805-1A and G6805-2. HANS series EA apparatus had 7 types: HANS-100A, HANS-200, HANS-202, HANS-200A, HANS-200E, HANS-LH202H and HANS-202. Hwato series EA apparatus had 6 types: Hwato SD-1, Hwato SDZ-2, Hwato SDZ-Ⅴ, Hwato SDZ-H, Hwato SDZ-O and Hwato SDZ-17. There were 22 literatures about EA apparatuses of other types; 9 were only labeled types but not manufacturer and 4 were only labeled manufacturer but not types. Other types were 16 in all, including Great Wall KWD-808 series, Yingdi KWD-808 series, WQ-6F and Hengming series.

According to the literature statistics, there were two problems in the selection of EA apparatus. First, the description was not standardized. The type of the EA apparatus should be marked together with the manufacturer and the medical device number, to provide reference for later research. Second, there were various EA products and types, but the G6805 series EA apparatus was preferred, and the new EA products were rarely used.

We inquired about the registration information of the equipment in the database of China Food and Drug Administration, and searched for the 'needle therapy apparatus', 'acupuncture therapy apparatus' and 'EA apparatus' as keywords. A total of 80 relevant items were retrieved. After rejecting the expired and repeated information, we found that there were 29 series (76 types) of registered active EA therapeutic apparatuses (which relied on electric energy or other non-human or gravity-generated energy), but only 11 types used in those included literatures were registered and valid for the period of registration between April 28, 2013 and February 24, 2018, which were 6805-A, 6805-D, 6805-AⅡ, BT701-1B, G91-D, NT6021, SDZ-Ⅱ, SDZ-V, XS-998-B, WQ-6F and Yingdi KWD-808-I. It was found that some of the EA apparatuses used in clinic or laboratory were no longer in the valid period of medical device registration or there was even no medical device registration certificate at all. Most of the new EA products were still in the experimental or research stage and the results had not yet been transformed.

2.4.2 Selection of EA stimulation parameters

EA stimulation parameters include pulse waveform, pulse frequency, waveform width, stimulation time, etc.[10] Studies had confirmed that different EA stimulation parameters could have different effects on the body[11]. About the description of the EA parameters in the included literatures, 78 articles mentioned waveform, 97 articles mentioned frequency, 9 articles mentioned pulse width, 89 articles mentioned stimulation time and 73 mentioned stimulation intensity. Whether in experimental research or clinical treatment, frequency, stimulation time and waveform had been valued by most researchers, which were related to the quantitative labeling of the EA apparatuses currently used.

Further analysis of the included literature found the following six characteristics. First, the plan of EA parameter selection was to select 3-5 items from waveform, frequency, wave width, stimulation time and stimulation intensity[12-14], and mostly was the selection of waveform + frequency + stimulation time + stimulation intensity combination. Second, the commonly used waveforms included dense wave, continuous wave and intermittent wave[14-16]. The dense wave was the most widely used and intermittent wave was the least used. Third, most of the frequencies used were below 100 Hz. Only one literature had a higher frequency, 120 Hz, which was related to the selected EA apparatus and the subject studied[17]. The frequencies commonly used in clinic were 2 Hz and 2 Hz/100 Hz. Fourth, the selection of pulse width was rarely described in the literatures, which might be due to the lack of corresponding quantitative labeling on the EA apparatus, the influence of the pulse width on the EA apparatus was not clear at present, and the related research was rare. Furthermore, the range of pulse width used was small, usually between 0.2 ms and 0.6 ms[18-20], and 0.2 ms was often used. Fifth, there were 7 kinds of schemes describing the intensity of stimulation[16,21-26]: ① only described by 'slight tremble in a certain part', 'slightly vibrate in a certain part without squeaking', 'slight shaking in shaft of the needle', 'animal could tolerate' and 'patient could tolerate'; ② added current intensity on the basis of ①; ③ applied both ① and ② plus voltage intensity; ④ only expressed by current intensity; ⑤ only expressed by voltage intensity; ⑥ applied both ④ and ⑤; ⑦ no expressions. This was related to the fact that there was no unified standard on the stimulation intensity of EA, no clear quantitative stimulation intensity on EA apparatus, and that the researchers were not clearly aware of the three concepts of stimulation intensity, current intensity and voltage intensity. Sixth, the voltage intensity used in the literatures varied from 0.2 V to 30 V[27-29]. The voltage used in experimental study was less than 10 V, and mostly 2-4 V. In clinical treatment, the voltage intensity was rarely used to describe the stimulation intensity, and the range was 0.2-30 V. This may be related to the national standard 'safety voltage' (GB3805-83), which was that 'in order to prevent electric shock accidents, under normal and fault conditions, the upper limit of voltage between any two conductors or between conductors and ground shall not exceed 50 V of AC voltages'. Seventh, the current intensity ranged from 0.1 mA to 50 mA[12,18,30], of which the current intensity

used in the experimental study was lower, ranging from 0.1 mA to 10 mA, while the current intensity used in clinical treatment was wider, ranging from 0.1 mA to 50 mA. This was because that the industry stipulates the maximum current that people can get rid of after electric shock was 10 mA in AC, and 50 mA in DC. Therefore, considering the safety factors, most of the current intensity used in clinical EA apparatuses did not exceed 50 mA. It can also be found that most of the literatures had the problem that the current intensity was not marked as AC or DC. Eighth, the time of needle retention varied from 9 min, 10 min, 15 min, 20 min, 25 min, 30 min to 60 min[21,24,31-35]. In the experimental study, 20 min was most frequently used, while in the clinical treatment, 30 min was most frequently used.

Stimulation parameters are one of the key factors affecting the efficacy of EA therapy and important in determining the stimulation intensity. Only by using uniform standards and specifications can the results of research be comparable. Promoting the quantification of stimulation can promote development of EA therapy.

3 Problems and Prospects

The results of this study suggested that there are some shortcomings in the development and application of EA apparatus, such as incomplete parameter annotations, inaccurate parameter adjustment, low safety, less function, low efficiency, tolerance, few output channels, inability to store and recall patient information, lack of optimal parameter schemes for specific diseases, large size and inability to carry with.

With continuous advance in science and technology, the related problems in the development and application of EA apparatus at present are expected to be solved. The development of EA apparatus can be in the following directions. First, intellectualization. Future EA apparatuses will have higher processing capacity, faster processing speed, larger storage space and more powerful functions, which can not only realize the functions of precise adjustable parameters, cloud storage and transfer, and acupuncture simulation, but also determine the effective treatment plans for patients according to the patient information, summarize the using regulation of parameters in continuous treatment process for patients, evaluate and timely feedback the disease status of the patients, so as to predict the development trend of the disease. Second, self-adaptive. Future EA apparatuses will be able to give a timely feedback on patient responses and adjust the stimulation parameters themselves. Third, the current EA apparatus has been able to output a 'gastrointestinal bioelectricity-like' pulse plexus and treat gastrointestinal-related diseases with 'physiologic-like waves' close to the bioelectricity of the human gastrointestinal tract[36]. Therefore, the stimulation parameters of future EA apparatus, especially the stimulation waveforms, will be able to output waveforms similar to those of various parts of healthy human body, and treat the diseases of the corresponding parts of patients with bioelectricity-like waveforms of specific parts of healthy human body, overcome tolerance in using square waves and triangular waves of traditional EA apparatuses, and improve the clinical efficacy to a certain extent.

In summary, EA apparatuses in the future will gradually meet the various needs of people, improve clinical efficacy, and achieve intelligent prescription, diagnosis and treatment, bring greater application value and social benefits, and promote the development of traditional Chinese medicine.

Conflict of Interest

There was no conflict of interest in this article.

Acknowledgments

This work was supported by Tianjin City High School Science & Technology Fund Planning Project (天津市高等学校科技发展基金计划项目, No. ZD200707).

Received: 25 September 2018/Accepted: 4 November 2018

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