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Review Article

Measures to Use Electroceuticals and Secure Social Reliability in Korea: A Narrative Review

Sam-Hun Park [1], ****Jiwon Shim*** [2]

1. *Asia Contents Institute, Konkuk University, Seoul, Korea*
2. *Department of Philosophy, Dongguk University, Seoul, Korea*

***Corresponding Author:** Email: g1dmp@daum.net

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Abstract

Background: The purpose of this study was to present a plan for utilizing electroceuticals to secure social reliability in Korea by investigating and analyzing the trends of humanities and social science research in Korea regarding electroceuticals.

Methods: The present situation of academic papers in the fields of humanities and social sciences that had researched electroceuticals in Korea and the topics that were directly related to electroceuticals had been reviewed and analyzed.

Results: Regarding researches related to electroceuticals in the fields of humanities and social sciences in Korea, they were insufficient quantitatively. Qualitatively, they had leaned too much toward theoretical and abstract discourses regarding neuroethics and neurophilosophy.

Conclusion: If researches in the fields of humanities and social sciences known to play a role in preparing practical guidelines could be carried out sufficiently while preparing a base for solving actual problems raised by electroceuticals, they could actually help plan a specific electroceuticals policy and a law to secure social reliability. Among principles of general life medical ethics (principles of biomedical ethics), when considering the principle of justice, the investment by the Korean government regarding research and development of electroceuticals, the rationalization of electroceuticals regulations, the application of electroceuticals of public health insurance benefit, and voluntary efforts of electroceuticals corporations are important in order to have strong plans for securing the social reliability of electroceuticals.

Keywords: Electroceuticals; Bioelectronic medicine; Neuroethics; Neurophilosopy

Introduction

Electroceuticals derived from electronic and pharmaceutical are also called "bioelectronics medicine" as one of the many words that have appeared newly because of the 4th Industrial Revolution. This word appeared for the very first time in the year 2013. It means a medical treatment method that adjusts nerve stimulations that control the body by giving an electric stimulation to an individual nerve fiber or a specific brain circuit to recover a lost function or health (1). The dream of the humankind who intend to use electricity in the

illness medical treatment is old. Electric stimulation has already become essential in medical treatments of heart illness and neural illness. Electroceutical is a medical treatment method that could be imagined at last due to the 4th Industrial Revolution (2). Since the 20th century, science and technology have shown overall developments with absolute interest in human beings regarding life and health. Fusion technology, which is a technological paradigm that symbolizes the 4th Industrial Revolution, has been supporting electroceuticals, with epoch-making development of individual fields of life science and medical treatment technology playing a leading role. Fusion technology refers to the combination of nano technology, biotechnology, information technology, and cognitive science (known to develop rapidly) in order to produce a synergy effect. In the field of fusion science, life science, computer science, physics, engineering, chemistry, mathematics, and biology are included. Integrated synergy of the government, academic circle, and industrial circle is demanded. The intimate cooperation among academic organizations, mutual learning, new worldview, and the paradigm and interdisciplinary integration of the language and the knowledge will enable the handling of problems of the society and human health better in the future (3).

The purpose of research and development of electroceuticals is to minimize side effects caused by a drug therapy based on chemical ingredients. This is because the drug therapy accompanies a serious danger to the extent that the side effect occurring in the process of a drug is delivered to each part of the body through blood vessels, which has been reported to be one of the main causes of death (4). It has been forecasted that, regarding electroceuticals, not merely as a neural illness in the long term, they will include diverse domains, including immunity illnesses, cardiovascular illnesses, chronic illnesses, incurable illnesses, and so on which could not be medically treated satisfactorily through traditional methods (5). The shift of the medical treatment market paradigm from being centered on suppliers to being centered on consumers has been heightening the expectation regarding electroceuticals. Electroceuticals combined with high-tech hardware and software provided by information technology will heighten the possibility of precision medical treatment that makes 4Ps (predictive, preventive, personalized, and participatory) as ideals (6).

As an alternative regarding traditional drugs and medical treatment methods, the potential possessed by electroceuticals has been leading research and development investments of prominent pharmaceuticals companies in the whole world. Representatively, GlaxoSmithKline plc (GSK) introduced the concept of electroceuticals for the very first time in the year 2013 and announced a roadmap for the development of electroceuticals in the year 2014. In the year 2016, by establishing Verily (formerly Google Life Sciences) and Galvani Bioelectronics, an electroceuticals-specializing corporation, it invested 750 million dollars with the launch of an electronic medicine for medical treatment of rheumarthritis as a goal in the year 2023 (7). Elon Musk, the founder of Tesla, also jumped into the research and development of electroceuticals in the year 2017 and by creating a fund of 27 million dollars, Musk established Neuralink, a startup that had developed BCI (Brain-Computer Interface) technology and in the year 2019, by introducing a pig with a subminiature electrode connected to a computer transplanted into the brain through a live broadcast in YouTube, BCI had attracted the attention of the people in the whole world (7). BCI (Brain-Computer Interface) generally refers to an interface technology that controls a computer through brainwaves by directly connecting the brain of a human being and a computer. It has been utilized frequently in the electronic medicine technology development. Research papers on electroceuticals have shown an explosive increasing trend in the very recent five years as shown in Fig. 1. To investigate related theses over the whole time period through the title and abstract search in the database of the Web of Science, 55 cases of electroceuticals, 384 cases of bioelectronic medicines, and 9970 cases of BCI (Brain-Computer Interfaces) were searched.

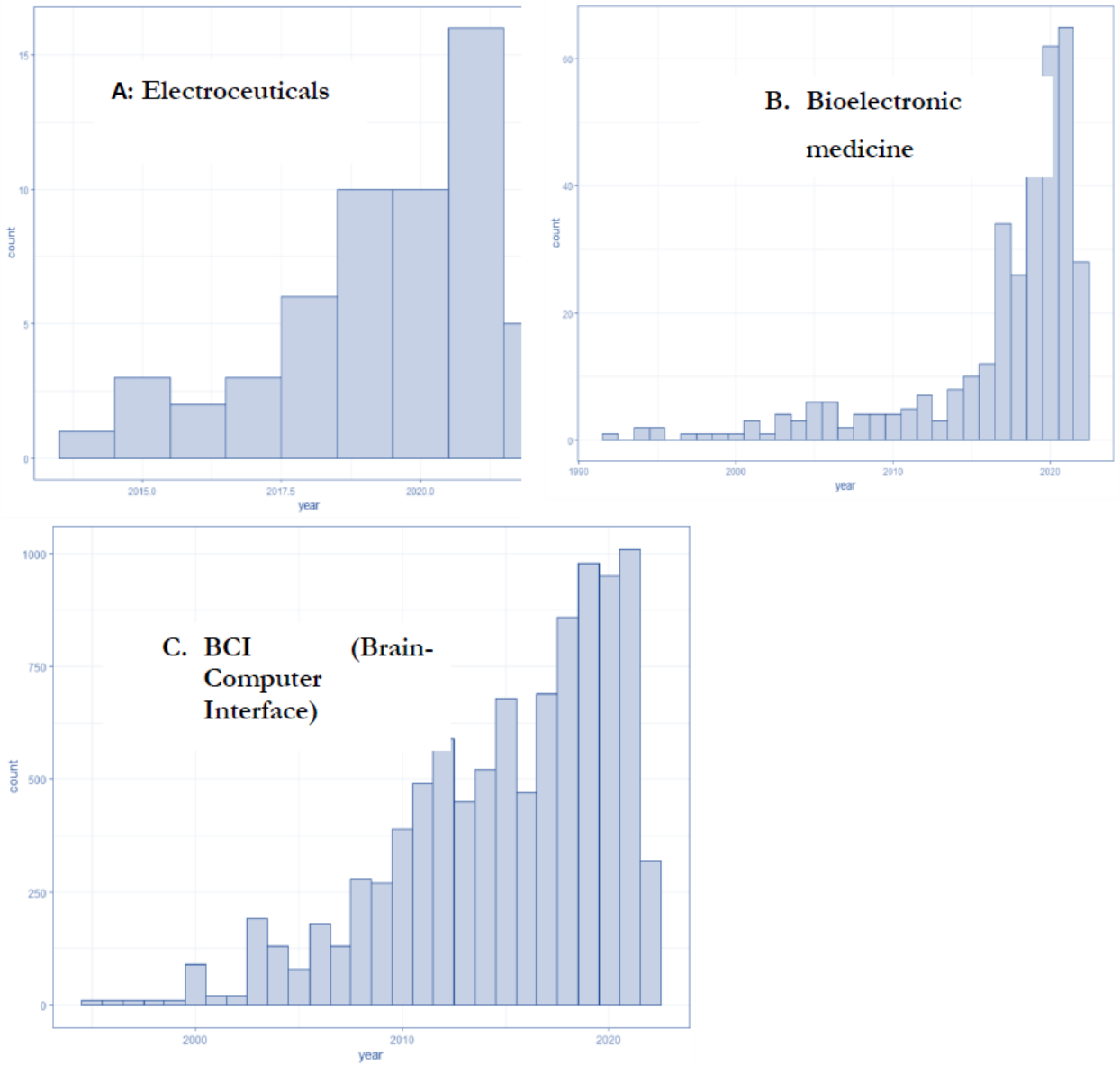

Fig. 1: The present situation of research papers related to electroceuticals in the whole world
Source: Web of Science. During the whole time period until March 31, 2022, in order to extract keywords that become topics in abstracts pertaining to each keyword collected in the Web of Science database, the LDA (Latent Dirichlet Allocation)-based topic modeling algorithm of MALLET was used (8)

An optimistic forecast regarding electroceuticals can be confirmed once again from the fact that electroceuticals were selected as one of the 10 major technologies of this year in the year 2018, which is announced every year by the WEF (World Economic Forum) (9). Results of market surveys announced by international market survey organizations have also been supporting such a forecast continuously. Regarding the size of electroceuticals market in the whole world, Market & Market forecasted that it would grow by 7.9% annually from 17.2 billion dollars in the year 2016 to 25.2 billion dollars in the year 2021 and Report &

Data forecasted that it would grow by 8.5% annually from 20 billion dollars in the year 2018 to 38 billion dollars in the year 2026 and Veried Market Research forecasted that it would grow by 8.9% annually from 24 billion dollars in the year 2020 to 47 billion dollars in the year 2026 and IDTechEx forecasted that it would grow by over 10% annually to be 60 billion dollars in the year 2029 (10). If electroceuticals that can medically treat illnesses are successfully developed, the market size will be expanded even more.

In Korea, keeping up with such an international flow centered on private corporations, the investment and the R&D regarding electroceuticals have been proceeded. Regarding some products, either they have already been launched in the market or they are in the preparation for a launch (Table 1) (11).

Table 1: Electronic medicine products in Korea

Type	*Illness*	*Corporation*	*Product*
Mental illness	Depression	Ybrain Inc.	MINDD
Mental illness	Depression	Remed Inc.	ALTMS
Incurable illness	Hemiplegia	Apsun Inc	Wireless Pro
Incurable illness	Hemiplegia	Cybermedic	Walking ManII
Incurable illness	The foot drop of a stroke patient	Daeyang Medical Co., Ltd.	WorkStimA
Incurable illness	Swallowing disorder	Stratek Inc.	STF-3300, STF-5500
Incurable illness	Swallowing disorder	Apsun Inc.	VitalStim Plus
Chronic illness	Migraine	Ybrain Inc.	DOOPANG
Chronic illness	Migraine	Nueyne Inc.	ELEXIR

Source: Websites of each corporation

Although it is difficult to accurately estimate the numerical value regarding the size of the electroceutical market in Korea in which imports of DBS's (Deep Brain Stimulations) from overseas global corporations account for a large portion, domestic production of non-invasive electroceuticals including tDCS's (Transcranial Direct Current Stimulation) and others has been in a trend of increasing definitely (11). As of 2019, at 6.5 billion dollars, compared to the size of the market of medical devices of Korea, which reaches the rank of the 10th in the world, it is still on a slight level. Regarding the Korean government, to the extent that, based on the superiority of the information communication technology, by developing the bio-health and the high-tech, precision medical treatment field, the health of the citizens is promoted, and it has been pursuing the leap toward a global, central country in this field as a continuing task, it can be said that the forecast for the electroceuticals industry of Korea is bright (12, 13). Especially, when Digital Therapeutics, which has been receiving the limelight in addition to electroceuticals, the Korean medical tourism industry, which reached 364189 people as of 2016, and the electroceuticals combine, the size of the market can grow rapidly (14). Meanwhile, separately from the positive forecast in the whole world and Korea regarding the technological potential of electroceuticals and the industrial effect, securing social reliability regarding electroceuticals is a task that must be decided beforehand for the commercialization and routinization of electroceuticals. Because the research and development of electroceuticals are still in the initial phase, concerns about side effects of electroceuticals, for which it is current unknown whether their side effects are different from those of traditional medicines, is unavoidable (10). Despite the totally global big conversion caused by the 4th Industrial Revolution will

bring fundamental changes to individuals and societies, the uncertainty regarding diverse influences of the act of stimulating the brain and nerves on the lives of human beings is the reason why securing social reliability is needed (15).

This research will investigate and analyze the present situation of academic theses in the fields of humanities and social sciences with electroceuticals presented in Korea in the context of securing social reliability of electroceuticals as the topic. By forming an opinion of the public having the mass media as the media, securing social reliability becomes possible at last. This is because one of the sources of information that can strongly decide the attitude and the content of the mass media is academic thesis (16). In addition, based on results of previous investigation and analysis, I will propose a few plans for sufficiently securing social reliability of electroceuticals. I have a high expectation that, regarding this research, scholars in the fields of humanities science and social sciences who research topics related to electroceuticals will proceed with the research and that the government and the industrial circle will provide suggestions for establishing the policy.

Methods

To investigate the present situation of academic theses in the fields of humanities and social sciences having electroceuticals presented in Korea as the topic, in the database of the KCI (Korea Citation Index) operated and managed by the government of Korea, those having titles as objects over the whole time period with words 'nerve' or 'brain' directly related to electroceuticals as the main keywords using 'philosophy', 'ethics', 'morality', 'law', and 'policy' as related keywords, a total of 8 pairs of related keyword combinations were searched. In the case of a thesis of which two or more related keywords overlap, by reviewing the contents through the abstracts, overlapped ones were removed.

Results

Because of the investigation, 79 theses were searched. The number of the theses was small. All 79 theses included 'nerve' or 'brain' as the main keyword. When considering the fact that, in contrast, there was no thesis that included 'electroceuticals' as a main keyword, it could be analyzed that interests in fields of humanities and social sciences regarding electroceuticals relatively could not attract the interest of the public.

Among a total of 79 theses, there were 20 cases on philosophy, in which 'nerve' and 'brain' were combined, 55 cases on 'ethics' or 'morality', three cases of 'law', and one case on 'policy'. It was analyzed that the fact that 'the ethics or the morality' captured an overwhelming relative importance and 'philosophy' in the background had continued to reflect the circumstance of the researches on 'neuroethics' and 'neurophilosophy', which have been settled down already as regular academic departments.

The list of top five ranked theses in terms of the number of times of being quoted is shown in Table 2.

Table 2: List of top 5 ranked papers in terms of the number of times of being quoted

Rank	*Title*	*Year of issue*
1	The Moral Educational Implication of Neuroscientific Approach in Morality	2013
2	Neuroscientific Challenges to deontological theory: Implications to Moral Education	2011
3	Moral Intuitions in Neuroscience and Moral Education	2012
4	New Paradigm of Moral Education in an Age of Neuroscience	2013
5	Neuroethics: Ethical, philosophical, legal, and social implications of neuroscience and its applications	2008

Source: Korea Citation Index

Among 5 cases, four were in the field of ethics education. Thus, it could be judged that the interest in the field of education was stronger than that in the other fields. From the list of the entire theses, the number of the cases of the theses that included the keyword of 'education' in the title was 28. This supports such an analysis.

Discussion

Direction for electroceuticals research in the fields of humanities and social sciences in Korea

Regarding neuroethics, while reflecting developments of brain science and nerve science with a broad interest that the development connotes, ever since these terms began to be widely used in the year 2002, they have been researched vigorously. 'Neuroethics' includes both 'ethics of neuroethics' and 'neuroethics of ethics'. Ethics of neuroethics deals with diverse ethical problems and research ethics that stem from neuroscience research (15, 17). Regarding neuroethics, in addition to freewill, determinism, moral responsibility, and so on, which are traditional topics of ethics, it approaches 'human enhancement', which is a modern topic that is newly raised by the development of bioengineering from neuroscience viewpoint (18). 'Human enhancement' includes cognitive enhancement, mood enhancement, and moral enhancement (19). Neurophilosophy that had fatally moved in the 1980's is involved throughout ontology, scientific philosophy, psychological philosophy, religious philosophy, and so on, which are traditional departments of philosophy (17).

As suggested by results of the investigation, researches in fields of humanities and the socials sciences in Korea regarding electroceuticals have been leaning too much on these two kinds of academic fields. Because neuroethics and neurophilosophy possess the personality of the fundamental discussion regarding human beings and the world, because abstraction and theorization levels are high, there is no choice but to have a certain restraint in referring to act guidelines regarding actual problems related to electroceuticals. For example, as shown by the report that all cases of approvals of electroceuticals by the FDA and the CE in the first half of the year 2019 are non-invasive, at present time, worries regarding the psychological feeling of denial and side effects of the public regarding invasive electroceuticals have been lures that make pharmaceutical companies concentrate on the R&D and investment regarding non-invasive electroceuticals to be applied to the peripheral nervous system, not the central nervous system (10). In addition to researches on neuroethics and neurophilosophy, through specifying, weighing, and balancing, if a practical, ethical research will play a role as the practical act guidelines carried out at the same time. When the relative importance increases and when preparing a basis for solving such an actual problem and securing social reliability, it can give an actual help in planning a specific electroceuticals policy and law (20).

A plan for securing social reliability of electroceuticals of the government and corporations

Among general principles of biomedical ethics (principles of biomedical ethics), regarding the principle of justice, it includes interest in freedom, interest in equality, and interest in efficiency. Securing social reliability is, also, possible for the cases with three kinds of interests materializing an appropriate harmony (21). To promote the health of citizens, the Korean government has been pursuing in the fields of bio-health and the high-tech. Precision medical treatment and a leap toward becoming a global and central country in these fields conform to the principle of justice.

With regard to improving the efficiency of the electroceutical industry in Korea, the roles that the government play can be largely divided into three kinds. Firstly, regarding the medical devices industry as a production industry with many kinds at small amounts, the low-price market is led by corporations whose sizes are small and medium. The high-price market that is centered on high-tech, high-value added products is led by a small number of large corporations. Regarding the medical

devices industry, as a capital and technology-depending type industry, because it takes around 3 to 5 years from the development to the production of the product, the period of the collection of the cost is long. This is because the life span cycle of the individual product is short (22). When considering the structure of the electroceuticals industry of Korea that is led by corporations whose sizes are small and medium, for the development of the electroceuticals industry, continuous investments by the government regarding research and development are unavoidable. There is a need to tow the electroceuticals industry aggressively by referring to the SPARC (Stimulating Peripheral Activity to Relive Conditions) program managed by the NIH (National Institute for Health) of the United States (23).

Secondly, in Korea, electroceuticals have been receiving regulations of the Medical Devices Act, although the establishment of the concept in terms of the law has not been taking place. Because the permission and evaluation procedures are the same as general ones, medical devices have been applied. Rationalization of electroceuticals regulations is needed. In the year 2020, fostering of medical devices industry, Innovative Medical Devices Supporting Act, and Outside the Body Diagnosing Medical Devices Act were enforced. Guidelines for evaluating permission of medical devices software and others of the like had been prepared. Despite the fact that the Korean government has been responding speedily to the appearance of high-tech medical devices, in the development of electroceuticals industry, it is the aspect of approaching passively (24). Regarding digital therapeutics, in order to strengthen the safety according to the special characteristic of the device, because the guidelines for the evaluation for the permission of the digital medical devices had been enforced, among the contents included in the technological document, regarding the items of the shape, the structure (the principle), the purpose of the use, the performance, the cautionary matters, and the test standard, according to a standard that is separate from the ordinary medical devices, the permission and evaluation procedure has been proceeded with (25).

Thirdly, for the creation of an industrial ecosystem that will become the foundation of the electroceuticals industry development, through the application of the public health insurance pay regarding electroceuticals, there is a need to alleviate the economic burden of the consumer. When the entry is done successively into the health insurance system of Korea, which has been receiving high evaluation to the extent of accomplishing universal application (universal coverage) at a time that is earlier than West European countries, the expansion, too, of the size of the stable market of electroceuticals is finally possible (26). The application of the public health insurance of electroceuticals will maximize the securing of social reliability of the electroceuticals by satisfying the yet different interest regarding freedom and equality possessed by the principle of justice.

Other than the government, electroceutical corporations also have sufficient reasons for exerting voluntary effort for securing social reliability. Based on the tDCS clinical data and results of the present research jointly with a related academic society by writing tDCS medical treatment guidelines, an electroceutical corporation in Korea is also disclosed to the public (27). Very recently, prominent corporations in the whole world have competed to autonomously present AI (Artificial intelligence) ethics guidelines. A strong plan that electroceutical corporations can refer to for securing social reliability is needed (28).

Conclusion

Studies on humanities and social sciences in Korea regarding electroceuticals have been quantitatively insufficient. They have been leaning too much toward neuroethics and neurophilosophy qualitatively. If researches in the fields of humanities and social sciences known to play a role in providing practical guidelines are carried out with such a flow at the same time with an increase quantitatively, they will actually help us plan a specific electroceuticals policy and law while preparing a base for solving actual problems raised by electroceuticals

to secure social reliability. Among general principles of biomedical ethics (principles of biomedical ethics), the principle of justice is considered. With investment by the Korea government in research and development of electroceuticals, the rationalization of electroceuticals regulations, the application of public health insurance to pay for the electroceuticals and voluntary endeavors of electroceutical corporations can lead to strong plans for securing the social reliability of electroceuticals.

Journalism Ethics considerations

Ethical issues (including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, and redundancy) have been completely observed by authors.

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Conflict of interest

The authors have no conflicts of interest relevant to this study to disclose.

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