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Clinical Trials for Fu's Subcutaneous Needling used as a method for treatment

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Abstract

Fu's subcutaneous needling is a relatively new method that is derived from acupuncture and Traditional Chinese Medicine in general, and its main indication is treatment of pain on different localizations on patient's body. The origins of this methods are from 1996, and its developer is Dr. Zhonghua FU, a Doctor and practitioner of Traditional Chinese Medicine from a clinic in Nanjing which is affiliated to the Nanjing University of Chinese Medicine. While inventing this method of acupuncture, Dr. Fu's main idea was to accelerate the effect of the traditional acupuncture. While conducting his PhD Dr.Fu has conducted a lot of research to find out which method will be the best, and his major discovery was the usage of different type of acupuncture needles punctured differently compared to the normal acupuncture needles.

The needles used for this method are different than the normal acupuncture needles. They look more like a catheter needle with a core of 31mm in length and with diameter of 1mm. Each of the used needles are individually packed and all the different needles that are used for this method are made and patented in People's Republic of China.

Key Words: Subcutaneous Needling, Dr.Fu, Nanjing University for Chinese Medicine, New Treatment

Introduction

Fu's Subcutaneous needling is a new method with roots from Acupuncture and Traditional Chinese Medicine, or as some of the practitioners of it saying as a new modern acupuncture. The main developer and creator of it is Dr. Fu, a Medical Doctor and practitioner of acupuncture and Traditional Chinese Medicine, who have organized and conducted a high number of clinical trials on which the efficacy of this method have been tested. He has first started with different type of needles placement, and on some of this tests that he has conducted he find out the efficacy of this method. The method

first was tested on rats who have ongoing arthritis. Using traditional acupuncture Dr. Fu did not find any big improvement of the condition, so he has decided to try inserting the needles in a different way, parallel to the skin surface, and he has seen some notable changes in the condition of the rats.

Even though the root of this method is from the Acupuncture as a part of Traditional Chinese Medicine, the method does not follow strictly the Acupuncture rules, unlike acupuncture, the Fu's Subcutaneous needling, chose trigger points that are nearby tightened muscle, and the needle stimulate subcutaneous areas near these muscles.

The needles used for this method are different compared to the needles used for traditional acupuncture, called trocar needles. The needles are bigger and looks more like a needle for I.V catheter, there are 3 parts of the needle, a soft tube, protecting sheath of the needle and also a core of the needle. All of the needles are sterilized prior to usage and are kept in an individual package. Most of the needles are with dimensions 31 mm in length and with diameter of 1mm. The needles are with these dimensions so they can be easily inserted parallel to the skin surface and close to a tightened muscles and after inserting it the practitioner is swiping the needle near the muscle that needs to be treated. This movement of the needle near the tightened muscle led to relaxation of the muscle and after that less pain and effect of the method on the treated body localization. Regarding the needles, all of the needles used for Fu's subcutaneous needling technique are patented in People's Republic of China.

The differences between the traditional acupuncture and the Fu's subcutaneous needling method is that the acupuncture approach is holistic, and the acupuncture treatment is aiming to heal the cause of a disease, and the Fu's subcutaneous needling is healing the pain as a symptom of some disease. Therefore, the range of potential conditions treated with acupuncture is so much wider compared to the range of conditions that can be treated with Fu's subcutaneous needling.

The efficacy of this method is described as a mechanotransduction. The mechanotransduction can be described as an ability of the cells to convert the stimulus which in these cases are made by the needle inserted on the specific location with pain, to electrochemical activity. After this convert of the energy, the pain can disappear, or it can be felt less compared to the time prior to the treatment.

A drawing or magnetic effect on connective tissue has been observed upon needle manipulation as the contraction and shape changes of fibroblasts cause pulling of collagen fibers and secondary alignment of fibroblasts and collagen fibers [1].

FSN engages the immune system by merely stimulating the subcutaneous layer. The main functional basis of the hypothesized cobweb mechanism is the unique physiological and histological characteristics of the layer of loose connective tissue that all the connective tissue cells take place in tissue regeneration and immune activity. The cells likely contribute to the processes after activation by FSN acupuncture. [2]

So far there have been high number of organized clinical trials in which the efficacy of this method has been investigated. However, in this article we will take in consideration only the clinical trials reported on the biggest database for clinical trials.

Materials and methods

The number of all the organized clinical trials in which method of treatment is Fu's subcutaneous needling is collected and reviewed from https://clinicaltrials.gov/, that is one on the most used database for reporting clinical trials outside of People's Republic of

China. The reported clinical trials that can be found on this platform can be publicly or privately funded and organized and conducted again both publicly and privately.

Since the number of reported clinical trials in which Fu's subcutaneous needling is not that high on this platform only one filter was used for collecting the relevant data.

At the filter for intervention/treatment was added Fu's subcutaneous needling.

After getting the results the number of organized clinical trials from the first trial organized with treatment Fu's subcutaneous needling, there is also information regarding the indication treated with this method. There is information regarding the age and gender of the treated population with this method, information regarding the sponsor of the organized clinical trial, location where the clinical trial was taking place and also as expected information regarding the study type of the conducted clinical trial.

Since the number of the reported clinical trials on this platform is not that high the results will not be displayed in diagrams.

Result & discussion

From the available information it can be seen that that overall, there are only 9 clinical trials in which the treatment is with Fu's subcutaneous needling technique reported on the https://clinicaltrials.gov/ platform.

Indeed the number is really low, and indeed the organizers of clinical trials in which this is main treatment method are using platforms that are based in People's Republic of China, however the organizers and the researchers that are part of these types of clinical trials should start to report the clinical trials on platforms based outside of People's Republic of China so the number of new potential patients with this type of treatment can become higher, because people can learn a lot more if the information is spread more.

From the available information it can be seen that the first clinical trial reported on the platform that was under investigation was organized in June 2017. This date is more than 20 years since the method was firstly used 1996, and again from this it can be seen that the prior to this have beer organized clinical trials, but as expected the clinical trials are reported on different platforms, based in People's Republic of China. However, it is good that after the first one reported from 2017, reported are 8 more clinical trials, so it can be noted that the number is increasing slowly. And as the information for this type of treatment will spread across wider audience, more and more clinical trials with more indications can be organized.

From the available information for the clinical trials in which treatment is with Fu's Subcutaneous needling it can be seen that both genders are equally accepted in the clinical trials and in all of the 9 reported clinical trials only adult population is the target population. This information regarding gender and ages of the potential patients was expected, since the indications that are treated with this method are most commonly through the adult population compared to the young population.

Regarding the indication for treatment with this method, all of the indications on the 9 reported clinical trials are related to a pain on different part of the body. The indications are:

-Osteoarthritis of knee, two clinical trials

- Carpal Tunnel Syndrome,

- Post Operative treatment of pain on different location of the patient's body

- Shoulder pain at patients with hemiplegia,

-Tendinitis of musculus biceps brachii,

- Chronic pain of the muscles in the area of the neck,

-Lateral Epicondylitis,

- Chronic headache due to problems with the muscles in the area of the neck.

From the reported conditions treated with this method, it can be seen that all of the indications are related to pain on different localization on the patient's body, which is expected, since it is known that in most of the cases this method is treating symptoms, not like in the traditional acupuncture in which the main cause of the problem is treated.

As expected, all of the clinical trials in which treatment is with Fu's subcutaneous needling are from the interventional type. This was expected because new intervention is explored for efficacy of treatment of some pain on different location on patient's body.

Regarding the location of organization of this type of clinical trials, it can be seen that for 7 of the reported clinical trials, the location is in People's Republic of China, which was expected, however it will be good if this type of treatment can be used in different part of the world, so more and more patients can be treated with this type of method. For 2 of the reported clinical trials information regarding the localization was not available during our research. However, it is also expected to be in People's Republic of China as the rest of the 7 clinical trials. But it is not confirmed.

From the available information it can be seen that on 7 of the reported clinical trials sponsor is a China Medical University hospital, on one of the reported clinical trials sponsor is Guangdong Provincial Hospital of Traditional Chinese Medicine, and one of the clinical trials is sponsored by a private sponsor not directly affiliated to a university.

Conclusion

The study is based on a research of a data for clinical trials reported on one of the biggest platforms for reporting clinical trials https://clinicaltrials.gov/ . It is one of the biggest sources for this type of information, however it is mainly used in Europe, USA and some parts of Asia. From our research it can be seen that researchers from People's Republic of China are not reporting a lot of data on this platform.

That's why from the reported data the number of reported clinical trials in which treatment is with Fu's subcutaneous needling is low. The number of just 9 reported clinical trials is showing that the researchers are not using this platform a lot, however if their main goal is to spread the information about different type of treatments it will be better this platform to be used as well.

From the available data can be concluded that this technique is mostly used for treatment of relevant symptoms, in most of the cases pain, related to some other disease, not like in the treatment with traditional acupuncture in which the whole body is healed, however the reported method for treatment is good for some quick treatment which will have result in a short period of time, however there is possibility that the efficacy of this treatment at the beginning will last for short period of time.

From the available data can be noted that only adult patients were treated, this is due to the fact that most of the indications are more common in the adult population, new relevant clinical trials should be made for treatment of younger population with this method and it's safety and efficacy.

From the available data it can be seen that all the reported clinical trials are conducted in People's Republic of China, which was expected, since the method was invented in People's Republic of China and the roots of it are also from People's Republic of China. And 8 of the reported clinical trials are sponsored by hospitals in which Traditional Chinese Medicine is practiced, and one is sponsored by a private investigator who is not directly affiliated to some university or hospital.

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