



Newsletter No. 46

Applications and Development of Irreversible Electroporation Technology in China

Newsletter by: John G.J. Zhao, Asia-Pacific Institute of Biomedical Research, HK
johnzhao@hotmail.com

Cancer is the leading cause of death in China with 3.8 million new incidents and 2.3 million deaths annually. Tissue ablation is an important means for treatment of cancer. All known modalities of tissue ablation are used in China. However, the most popular are radiofrequency ablation (RFA), microwave ablation (MW), and cryosurgical ablation (CA). Recently, a new tissue ablation technology has captured the interest of physicians, engineers and medical device manufacturers in China – Irreversible Electroporation (IRE).

Dr Simon Yu of the Chinese University of Hong Kong has performed the first percutaneous IRE treatment on liver cancer in Asia, as reported by South China Morning Post on December 31, 2013. Dr. Yu noted that the cost of one IRE treatment is HK\$50,000, while microwave and radio frequency ablation treatments cost HK\$10,000 and HK\$6,000, respectively.

NanoKnife from Angiodynamics, Inc. is the first IRE device approved by China Food and Drug Administration (CFDA). It was cleared for ablation of liver and pancreatic tumors in 2015. There are now over twenty hospitals using the NanoKnife for tissue ablation in China. The IRE technology is mainly used to treat liver cancer and pancreatic cancer in China, especially for tumors near the hilar area, gallbladder, bile duct, pancreas, and ureter.

Fuda Cancer Hospital of Guangzhou initiated a study on the safety and efficacy of IRE combined with chemotherapy for unresectable pancreatic carcinoma (stage III/IV). A total of 54 patients (30 men; median age 61.0 years; range 41–73 years) were treated by IRE with or without chemotherapy for pancreatic cancer between July 2015 and August 2016. The study concluded that patients with pancreatic carcinoma could benefit from the IRE treatment. IRE improved the overall survival, especially in those patients who had also undergone chemotherapy.

Doctors at the First Affiliated Hospital of Sun Yat-sen University evaluated the safety and effectiveness of IRE on 15 patients with unresectable locally advanced pancreatic cancer (LAPC). All patients underwent ultrasound-guided laparotomy IRE. The median survival was 10 months. Five patients survived more than one year. They concluded that ultrasound-guided IRE is a safe and effective treatment for unresectable LAPC, with shorter procedure time, fewer postoperative complications, and faster recovery.

Fuda Cancer Hospital also performed a study of 14 unresectable large liver tumors patients (8 with tumor diameter of 5.1-11.5 cm and 6 with tumor diameter of 3.0-4.1 cm) treated with percutaneous IRE. The extent of ablation for tumors of large and medium diameter was 25.0 % and 66.6 %, respectively.



Newsletter Editor
Damijan Miklavčič
University of Ljubljana, Slovenia
damijan.miklavcic@fe.uni-lj.si

**Newsletter Technical Editor and
Website Administrator**
Samo Mahnič-Kalamiza
University of Ljubljana, Slovenia
samo.mahnic-kalamiza@fe.uni-lj.si

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They concluded that IRE is safe for unresectable large hepatocellular carcinoma, with no major complications. Short-term efficacy is relatively good; however, long-term efficacy remains to be explored.

The potential of the IRE market has attracted much interest on research and development of innovative IRE products in China. Shanghai Remedicine Co., Ltd. has developed a composite steep pulse treatment system with the help of researchers at Chongqing University and Shanghai Changhai Hospital. The apparatus generates high-frequency bipolar pulses. The burst of HF bipolar pulses, consisting of 20 pulses each of 5 μ s, had a total energized time of 100 μ s, with a 10 ms delay time between the positive and the negative pulses. By May 2019, a multi-center clinical study of prostate cancer jointly conducted by five leading Hospitals in China successfully enrolled 110 cases. The tumor control is effective for the first 54 cases who have completed the 6-month follow-up.

Dr. Xinhua Chen from the First Hospital of Zhejiang University, Hangzhou, China wrote a Chinese book Medical Applications of Nanosecond Pulse Technology in 2019. She also developed a nanosecond pulse tumor ablation device. The device is used in clinical trials in four hospitals in China.

An IRE device developed by Tianjin Intelligent Health Medical Technology Ltd. jointly with Tianjin Medical University, is used in clinical trials in China since late 2018. Dozens of cases using IRE ablation show that the performance of the Chinese-made IRE device is good, and the ablation effect is clear.

IRE is a new type of ablation technology, which appears to have the advantages of being safe, effective, and with fewer complications. There is great interest in this technology, from among physicians, scientists, engineers, and manufacturers. This suggests that, in the near future, all pulsed electric field ablation technologies will achieve prominence in China.

Forthcoming events

5th Veterinary Workshop on Electroporation-Based Treatments

Ljubljana, May 5 – 6, 2020

https://www.kmz.si/dl/5th_Veterinary_workshop_flyer.pdf

7th School on Pulsed Electric Field Applications in Food and Biotechnology

Zaragoza, May 25 – 29, 2020

<http://pefschool2020.electroporation.net/>

8th European Medical and Biological Engineering Conference – EMBEC 2020

Portorož, June 14 – 18, 2020

<http://embec2020.org/>

Electroporation-Based Technologies and Treatments

Ljubljana, November 15 – 21, 2020

<http://2020.ebtt.org>

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The First Nano Knife (irreversible electroporation) Treatment for Cancer in Mainland of China Completed in Guangzhou.
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