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Tumor Ablation with Irreversible Electroporation

Bassim Al-Sakere[1,2], Franck André[1,2], Claire Bernat[1,2], Elisabeth Connault[1,2], Paule Opolon[1,2], Rafael V. Davalos[3], Boris Rubinsky[4,5,6], Lluis M. Mir[1,2]*

1 CNRS UMR 8121, Institut Gustave-Roussy, Villejuif, France, 2 University Paris-Sud, UMR 8121, Villejuif, France, 3 School of Biomedical Engineering and Sciences, Virginia Tech-Wake Forest University, Blacksburg, Virginia, United States of America, 4 Department of Bioengineering, University of California at Berkeley, Berkeley, California, United States of America, 5 Department of Mechanical Engineering and Graduate Program in Biophysics, University of California at Berkeley, Berkeley, California, United States of America, 6 Center for Bioengineering in the Service of Humanity and Society, School of Computer Science and Engineering, Hebrew University of Jerusalem, Givat Ram, Jerusalem, Israel

We report the first successful use of irreversible electroporation for the minimally invasive treatment of aggressive cutaneous tumors implanted in mice. Irreversible electroporation is a newly developed non-thermal tissue ablation technique in which certain short duration electrical fields are used to permanently permeabilize the cell membrane, presumably through the formation of nanoscale defects in the cell membrane. Mathematical models of the electrical and thermal fields that develop during the application of the pulses were used to design an efficient treatment protocol with minimal heating of the tissue. Tumor regression was confirmed by histological studies which also revealed that it occurred as a direct result of irreversible cell membrane permeabilization. Parametric studies show that the successful outcome of the procedure is related to the applied electric field strength, the total pulse duration as well as the temporal mode of delivery of the pulses. Our best results were obtained using plate electrodes to deliver across the tumor 80 pulses of 100 µs at 0.3 Hz with an electrical field magnitude of 2500 V/cm. These conditions induced complete regression in 12 out of 13 treated tumors, (92%), in the absence of tissue heating. Irreversible electroporation is thus a new effective modality for non-thermal tumor ablation.

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INTRODUCTION

Minimally invasive tissue ablation has become of central importance in the modern surgery armamentarium. In the treatment of benign or malignant tumors it is important to achieve ablation of the undesirable tissue in a well-controlled and precise way without affecting the surrounding healthy tissue. As an alternative to surgical resection, a number of minimally invasive methods have been developed to destroy specific areas of undesirable tissues. Most of these techniques are thermal using cold, e.g. cryosurgery [1–3] or heat, e.g. radiofrequency [4,5].

Electroporation, also known as electropermeabilization, is a term used to describe the permeabilization of the cell membrane as a consequence of the application of certain short and intense electric fields across the cell membrane, the cells or the tissues. The permeabilization can be temporary (reversible electroporation) or permanent (irreversible electroporation) as a function of the electrical field magnitude and duration, and the number of pulses [6]. Reversible electroporation is commonly used *in vivo* to facilitate the penetration of various otherwise non-permeable macromolecules across the cell membrane [7–9]. Irreversible electroporation, the ability of certain electrical pulses to permanently permeabilize the cell membrane, has been known for over three decades. For most of this period irreversible electroporation (IRE) was used primarily for ablation of microorganisms and cells *in vitro* and studied only as an upper limit of electrical parameters for reversible tissue electroporation applications. Our group has pursued the understanding of the electrical fields and processes that produce IRE with single cell micro-electroporation technology [10,11].

The study of Davalos, Mir and Rubinsky, which showed that IRE can ablate substantial volumes of tissue without inducing a thermal effect and therefore serve as an independent and new tissue ablation modality, opened the way to the use of IRE in surgery [12]. Subsequently, Edd *et al.* demonstrated tissue ablation with IRE *in vivo* in the normal liver of rats. [13]. Complete ablation of the targeted liver tissue was achieved by exposing the tissue to electrical parameters that do not induce thermal damage [13]. Massive blood vessel congestion was observed in the sinusoids of the treated volume, which should significantly enhance the treatment. The study concluded that IRE produces precisely delineated ablation zones with cell scale resolution between ablated and non-ablated areas and the ability of mathematical modelling to precisely predict the ablated area. A more recent study was performed to evaluate the long term effects of IRE in a large animal model [14]. The results demonstrated the ability of electroporation to ablate large volumes of tissue using electrical parameters that while substantially above those conventionally used in reversible electroporation do not induce substantial thermal effects. The histology has reconfirmed the results in Davalos *et al.* [12] and Edd *et al.* [13] showing that mathematical modeling of electrical and thermal fields are a powerful tool in designing IRE ablation protocols, that IRE can be used to ablate tissue with cell scale resolution and that indeed IRE affects only the cell membrane and therefore spares connective tissue. Another

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Competing Interests: R. Davalos and B. Rubinsky have potential interests in the revenues of pending patents held by Univ. of California at Berkeley (e.g. No 10/571,162, Tissue Ablation with Irreversible Electroporation). B. Rubinsky also has a financial interest in Excellin Life Sciences and in Oncobionic, companies in the field of electroporation. L. M. Mir was a consultant for Oncobionics.

* To whom correspondence should be addressed. E-mail: luismir@igr.fr

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Boris Rubinsky

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Doherty,2024-12-20 The evidence based point of care information you need to master the full scope of diseases and disorders most often treated by surgeons Organized by organ system Current Diagnosis and Treatment Surgery begins with the relationship between surgeons and their patients training and professionalism preoperative care postoperative care and surgical complications Subsequent chapters cover wound healing inflammation infection antibiotics fluid and electrolyte management and surgical metabolism and nutrition In addition to sections covering everything from head and neck tumors to hand surgery this comprehensive resource offers expert coverage of pediatric surgery oncology weight management organ transplantation and more Featuring 600 photographs and illustrations hundreds of chapter ending multiple choice review questions and the latest the latest research and discoveries Current Diagnosis and Treatment Surgery is designed to help you find all the answers you need quickly and easily **Enhanced Electric Pulse Technology for the Ablation of Pancreatic Cancer** Siqi Guo,2018 Electric pulse based technology has been developed and studied as a non thermal ablation method for local control of pancreatic cancer Irreversible electroporation IRE has shown a significant survival benefit for local advanced pancreatic cancer in clinical trials However incomplete ablation with local recurrence and major complications limit the potential of this new technology We have developed an integrated moderate heating electric pulse delivery system which consists of controllable tumor heating multi parameter monitoring and electric pulse delivery The impedance of tumor is greatly decreased after moderate heating at 42 C for 1 2 min which does not cause any cell death Moderate heating significantly enlarges the ablation zone of tumor treated with IRE In contrast to IRE alone moderate heating assisted IRE results in a high rate of complete tumor regression and a significant longer median survival Another electric pulse technology nanosecond electric pulses has been assessed for the treatment of pancreatic cancer as well Nanosecond electric pulse treatment achieves more survival benefit in animals with partial tumor ablation than those treated with IRE and leads to a vaccine like protective effect in animals with complete local ablation More studies are needed to demonstrate the advantages and translational feasibility of the enhanced electric pulse technologies Irreversible Electroporation in Clinical Practice Martijn R. Meijerink,Hester J. Scheffer,Govindarajan Narayanan,2018-01-24 This book provides a comprehensive overview of the clinical use of irreversible electroporation IRE better known by its commercial name NanoKnife which is one of the most exciting new needle guided cancer treatments The coverage includes the history of IRE general technique preclinical research applications in clinical practice and early clinical results and future perspectives Contraindications treatment planning potential complications follow up imaging and other practical aspects are fully discussed with highlighting of useful tips and tricks Through the delivery of short but highly intense electrical pulses IRE results in tumor cell membrane permeabilization causing cells to go into apoptosis The minimally invasive nature of IRE combined with the prospect of completely eradicating tumors while preserving delicate structures in the ablation zone makes IRE the object of worldwide clinical research This book will be of value for practitioners and trainees in interventional and diagnostic radiology surgery medical oncology HPB and gastroenterology urology and radiation oncology **Irreversible Electroporation in Hepatopancreaticobiliary Tumors** ,2021 Over the past years image guided tumor ablation especially thermal ablation techniques have gained ground clinically in the treatment arsenal for patients with surgically unresectable tumors Ablation of these tumors using radiofrequency ablation RFA or microwave ablation MWA is currently considered common practice and has led to improved survival 1 Unfortunately the suitability of RFA and MWA is limited when surgically unresectable tumors are located in proximity of heat susceptible structures such as large blood vessels bile ducts and intestines Thermal ablation of tumors adjacent to large blood vessels is associated with a higher incidence of incomplete eradication heat sink phenomenon 2 4 Because of the risk of biliary tract injury including severe quality of life diminishing consequences such as biliary duct occlusion haemobilia cholangitis leakage or the formation of fistulas or bilomas ablation of tumors within 1 cm of the major bile ducts is not recommended 5 8 Until recently these patients were designated to palliative chemotherapy Irreversible electroporation IRE is a relatively new image guided ablation technique based on electrical energy rather than thermal energy to eradicate the tumor High voltage electrical pulses are delivered through several needle electrodes placed in and around a tumor These electrical pulses distorts the cellular membrane potential leading to disruption of the membrane eventually causing the cell to lose its homeostatic properties and become apoptotic 9 The main advantage of IRE over thermal ablation techniques is that IRE mostly affects cells sparing the extracellular matrix thus preserving the consistency of the previously mentioned vulnerable structures bile ducts and large blood vessels 10 12 Furthermore since the working mechanism is based on electrical energy rather than thermal energy the technique efficacy is not impeded by heat sink

Clinical Aspects of Electroporation Stephen T. Kee,Julie Gehl,Edward W. Lee,2011-04-06 Electroporation is the forefront in tumor ablation This book presents the basic principles and clinical applications of electroporation including the latest research results and patient data A comprehensive approach to the basic science behind the development of this ground breaking technique and its introduction into clinical practice the book discusses the entire spectrum of currently available reversible treatments the emerging irreversible applications and their impact on patient care Clinical Aspects of Electroporation is the first book intended for clinicians on this extremely important and rapidly developing field

Irreversible Electroporation Boris Rubinsky,2010-04-30 Non thermal irreversible electroporation is a new minimally invasive surgical p cedure with unique molecular selectivity attributes in fact it may be considered the first clinical molecular surgery procedure Non thermal irreversible electro ration is a molecular selective mode of cell ablation that employs brief electrical fields to produce nanoscale defects in the cell membrane which can lead to cell death without an effect on any of the other tissue molecules The electrical fields can be produced through contact by insertion of electrode needles around the undesirable tissue and non invasively by electromagnetic induction This new dition to the medical armamentarium requires the active involvement and is of interest to clinical physicians medical researchers mechanical engineers che cal engineers electrical engineers instrumentation designers medical companies and many other fields and disciplines that were never exposed in their training to irreversible electroporation or to a similar concept This edited book is designed to be a comprehensive introduction to the field of irreversible electroporation to those that were not exposed or trained in the field before and can also serve as a reference manual Irreversible electroporation is broad and interdisciplinary Therefore we have made an attempt to cover every one of the various aspects of the field from an introductory basic level to state of the art

Irreversible Electroporation for Tumors of the Pancreas Or Liver ,2016 Due to the high toxicity and poor outcomes associated with chemotherapy options ablative therapies such as irreversible electroporation IRE are becoming more popular in palliative care for unresectable tumors however their effectiveness on cancer outcomes and adverse events are unclear Additionally it is unclear as to what role IRE may play in the treatment of resectable tumors IRE requires the purchase of a device and requires training thus the cost effectiveness is also a factor when considering whether or not to bring the technology into use The current review seeks to determine the clinical effectiveness safety and cost effectiveness of IRE for the treatment of patients with resectable and unresectable pancreatic or liver tumors The Molecular Selectivity of Non-Thermal Irreversible Electroporation and Tissue Regeneration In Vivo Mary Alice Phillips,2012 Non thermal irreversible electroporation NTIRE is new minimally invasive surgical technique for tissue ablation that utilizes molecular selectivity to ablate tissue tumors Short microsecond electrical pulses are applied to the tissue selectively targeting the cell membrane causing pores to form within the membrane and leading to cell death This tissue ablation technique has potential for a variety of medical applications and has shown great promise as a method for treating cancer tumors NTIRE has many promising attributes as a treatment modality such as the preservation of tissue scaffolding and the blood vessels Very little work however has been done in examining how the molecular selectivity of NTIRE affects tissue regeneration This work examines how tissues regenerate and recover after NTIRE with a focus on those critical tissues that are particularly susceptible to collateral damage from treating an adjacent tumor Two important tissues are examined the artery and the small intestine The artery may be embedded within a tumor Although complete tumor ablation is desired it is important that the artery can recover quickly in order to aid in overall tissue regeneration at the treated site It is also important to understand how the molecular selectivity of NTIRE affects the regeneration of the small intestine especially for the application of abdominal cancer treatment Damage to the small intestine is often the limiting factor in other types of cancer treatments such as localized radiation therapy causing pain and discomfort and even resulting in stopping the treatment early Understanding how the small intestine recovers after NTIRE is essential in developing this technology for treating abdominal cancers such as pancreatic cancer Finite element models were utilized to design electrical parameters for both the artery and the small intestine that would cause irreversible electroporation to occur within the tissue while avoiding thermal damage due to Joule heating effects These electrical parameters were then applied in vivo Electrical parameters chosen to apply to the artery were an electric field of 1750 V cm 90 pulses of a pulse length of 100 mu s and a frequency of either 1 or 4 Hz The chosen small intestine electroporation protocol consisted of 2000 V cm 50 pulses of 70 mu s each and a frequency of 4 Hz Additional finite element analysis was used to examine the effect of the heterogeneity of tissues such as the small intestine indicating that changes in electrical conductivity from layer to layer is an important factor that should be accounted for in clinical treatment planning and future work should include quantifying these electrical conductivity values By applying NTIRE to the rat carotid artery the recovery of the artery over the week following treatment was observed It was demonstrated that the electroporation protocol preserved the native tissue extracellular matrix Three days after NTIRE treatment the ablated cells had been naturally removed from the tissue leaving a decellularized construct By one week after electroporation new endothelial cells were seen lining the artery lumen This endothelial layer indicates that normal recellularization is taking place and that the artery is beginning to recover within 7 days of treatment In a similar fashion NTIRE was applied to the rat small intestine in vivo and the recovery of the small intestine was observed during one week post treatment The electrical parameters used were shown to be strong enough to initially cause complete cellular destruction The extracellular matrix however appeared undamaged and the structure of the small intestine remained intact The intestine showed signs of recovery developing an epithelial layer at 3 days post treatment and regenerating mucosa submucosa and muscular layers within a week These results suggest that the small intestine is only temporarily affected by NTIRE indicating that this procedure can be utilized for abdominal cancer treatment while minimizing collateral damage to adjacent tissues In addition to examining the recovery of the artery for cancer treatment applications the potential use of NTIRE to develop a decellularized arterial scaffold was also investigated The tissue scaffold is a key component for tissue engineering and the extracellular matrix is nature s ideal scaffold material Two different methods for applying NTIRE to the artery were compared the results obtained when plate electrodes were applied across the rat carotid artery were compared to the case when endovascular electrodes were applied to the rabbit iliac artery in a minimally invasive fashion Both methods were shown to preserve the native extracellular matrix and produce a scaffold that is functional and facilitates recellularization At 3 days post NTIRE the immune system had decellularized the electroporated tissue leaving behind a functional scaffold The endothelial regrowth at 7 days after treatment indicates that the extracellular matrix still maintained its important components to support cell growth In addition this endothelial layer shows promise for the tissue scaffold helping it to avoid issues such as thrombogenicity that many small diameter scaffolds face *Irreversible Electroporation* ,2024 Irreversible electroporation IRE employs high voltage electrical pulses for non thermal image guided tumor ablation in solid organs The pulses disrupt the membrane potential of all cells within the ablation zone causing loss of tumour cell homeostasis which results in death IRE has the advantage of sparing extracellular matrix structures and thereby preserves the anatomical integrity of blood vessels bile ducts and ureters Several prospective phase I and II studies demonstrated the safety and cytoreductive efficacy of IRE for the treatment of locally advanced pancreatic and local prostate tumours In addition IRE induces a systemic immune response When this immune effect can be amplified by combinatory treatment with immunotherapeutic drugs its synergy might form a bridge between local and systemic therapies with potential to develop into a fundamentally new approach to cancer treatment *Non-Thermal Irreversible Electroporation in Heterogeneous Tissues* Charlotte Sara Daniels,2011 Non thermal irreversible electroporation IRE is a new minimally invasive surgical technique that is part of the emerging field of molecular surgery which holds the potential to treat diseases with unprecedented accuracy IRE utilizes electrical pulses delivered to a targeted area producing irreversible damage to the cell membrane While electroporation is not fully understood to date evidence indicates that this damage is induced by the increased transmembrane potential due to high voltage pulses affecting the lipid bilayer Because IRE does not cause thermal damage the integrity of all other molecules and only effects cellular structures collagen and elastin in the targeted area is preserved Previous theoretical studies have only examined IRE in homogeneous tissues However tissues can be heterogeneous in two different capacities 1 they can be intrinsically heterogeneous due to anatomy and 2 they can be extrinsically heterogeneous due to external factors This investigation of heterogeneous tissues studies both cases in order to expand the depth and breadth of the field of electroporation Intrinsic Heterogeneous Tissues Because biological structures are complex collections of diverse tissues it becomes imperative to consider intrinsic heterogeneities In order to develop electroporation as a precise treatment in clinical applications realistic models for pre surgical planning are necessary In this way the study of heterogeneous tissues will enable refinement of electroporation as a treatment In this chapter three different intrinsic heterogeneous structures were taken into account nerves blood vessels and lactiferous ducts The subsequent results made it clear that heterogeneities significantly impact both the temperature and electrical field distribution in surrounding tissues indicating that heterogeneities should not be neglected While the surrounding tissue experienced a high electrical field the axon of the nerve the interior of the blood vessel and the ducts experienced no electrical field This indicates that blood vessels nerves and lactiferous ducts adjacent to a tumor treated with electroporation have the potential to survive while the cancerous lesion is ablated This clearly demonstrates the importance of considering heterogeneity in IRE applications Extrinsic Heterogeneous Tissues Extrinsic heterogeneous tissues can be induced by various external factors One such factor is an applied temperature gradient Two different temperature gradients were considered in this investigation 1 subzero temperatures induced by cryosurgery and 2 cooling temperatures Cryosurgery tissue ablation by freezing is a well established minimally invasive surgical technique The goal of this investigation was to study extrinsic heterogeneous tissues induced by externally applied subzero temperatures by combining cryosurgery and electroporation Analysis of the electric field and temperature distribution during simultaneous tissue treatment with cryosurgery and irreversible electroporation cryoIRE was used to study the effect of tissue freezing on electric fields The results indicate that this combination may resolve some of the major disadvantages that occur in each technology when used alone Because of decreased electrical conductivity in the frozen tissue this region experienced temperature induced magnified electric fields in comparison to IRE delivered to unfrozen tissue the control case This suggests that freezing confines and magnifies the electric fields to those regions a targeting capability unattainable in traditional electroporation This analysis also shows how temperature induced magnified and focused IRE can be used to ablate cells in the high subzero freezing region of a cryosurgical lesion in which cells can be resistant to freezing damage The next heterogeneous tissues that were studied were heterogeneities extrinsically produced by cooling This chapter explores the hypothesis that non subzero temperature dependent electrical parameters of tissue can also be used to modulate the outcome of IRE protocols providing a new means for controlling and optimizing this minimally invasive surgical procedure This chapter investigates two different applications of cooling temperatures applied during IRE The first case utilizes an electrode which simultaneously delivers electric fields and cooling temperatures The subsequent results demonstrate that changes in electrical properties due to temperature produced by this configuration can substantially magnify and confine the electric fields in the cooled regions while almost eliminating electric fields in surrounding regions This method can be used to increase precision in IRE procedures and eliminate muscle contractions and damage to adjacent tissues The second configuration considered introduces a third probe that is not electrically active and only applies cooling boundary conditions This second configuration demonstrates that with this probe geometry the temperature induced changes in electrical properties of tissue substantially reduce the electric fields in the cooled regions This novel treatment can potentially be used to protect sensitive tissues from the effect of IRE Perhaps the most important conclusion of this investigation is that temperature is a powerful and accessible mechanism to modulate and control electric fields in biological tissues and can therefore be used to optimize and control IRE treatments

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