NeuWave Microwave: Overview of thermal ablation

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DISCLAIMER

PLEASE NOTE: The Certus 140 2.45 GHz Ablation System is a tool, not a treatment for any disease or condition. It is cleared for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings in patients who present themselves to a treating physician with a wide variety of diseases or conditions. The Certus 140 2.45 GHz Ablation System is not indicated for use in cardiac procedures. The system is designed for facility use and should only be used under the orders of a physician.

The information in these cases is not meant to convey recommendations from NeuWave Medical, Inc. regarding appropriateness for a particular patient, power and time settings, final ablation zone size and shape or other procedure guidance. NeuWave Medical makes no representations and assumes no liability regarding the accuracy of the information provided herein or the effectiveness of any of the treatment or for any action or inaction you take based on or made in reliance on the information. These are individual cases and your results may vary. When planning a case, consider all unique aspects, including tissue type, lesion location, surrounding vasculature and proximity to critical structures when determining probe type and power/time settings. Consult the product Instructions For Use for information regarding expected ablation sizes

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Disclosure

- Co-founder of NeuWave Medical

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SYLLABUS

Objectives of Presentation

- Physics of microwave
- Benefits of synchronous in-phase technology
- Clinical differentiators
- Probe placement
- Advanced Education Programs
- Clinical cases for development of best practices

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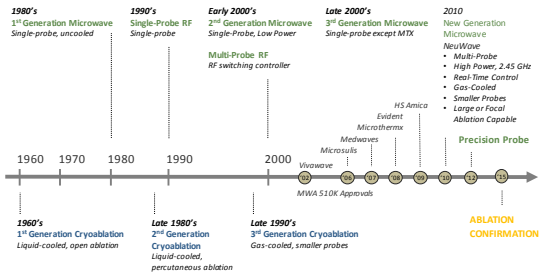
EVOLUTION OF ABLATION TECHNOLOGY



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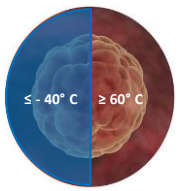
2 MODES OF THERMAL ABLATION

Freezing and Heating

Cryoablation

Cell death by freezing

When tissue is cooled to ≤ -40° C, intracellular ice formation ruptures cell membrane and kills cells via a freeze/thaw method



Radiofrequency ablation
Microwave ablation

Cell death by heating

When tissue is heated to ≥ 60° C, proteins denature, lipids in the cell membrane melt and cells are killed instantaneously

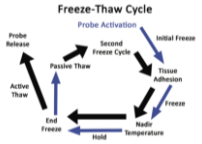
CRYOABLATION OVERVIEW

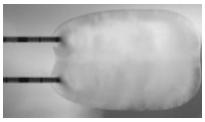
HOW CRYOABLATION WORKS:

- 1 probe per 1 cm ablation zone inserted into/near target[2]
- Cells are killed using a freeze/thaw method

FREEZE: Cell dehydration
Membrane & essential constituents are severely damaged and cells die slowly

THAW: Cell Re-hydration
Thaw phase causes the cells to burst from rapid rehydration. Ischemia is caused by damage to vascular system & membranes





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CRYOABLATION OVERVIEW

LOW PROCEDURAL PAIN[3]	REQUIRES MULTIPLE, OFTEN LARGE (13 GAUGE) PROBES[2]
PRESERVES ADJACENT NORMAL CRITICAL STRUCTURES & MINIMAL SCARRING[3]	VISIBLE ICE BALL IS NOT TREATMENT ZONE[4]
ICE BALL HIGHLY VISIBLE ON CT/MRI/US[3]	NO ACTIVE PROCESSES – COOLING IS PASSIVE BY CONDUCTION
	RISK OF SYSTEMIC EFFECTS (CRYOSHOCK, LIVER FRACTURE[5])
	LENGTHY PROCEDURE (APPROX. ≥ 30 MIN[6])
	POTENTIALLY HIGHER COST DUE TO MULTIPLE PROBES & EXPENSIVE GASES[6]

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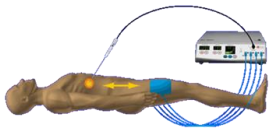
RADIOFREQUENCY OVERVIEW

HOW RADIOFREQUENCY ABLATION WORKS:

- Heating is produced when an electrical current agitates ions
- Grounding pads placed externally on patient to complete the electrical circuit



Tissue near electrode:
Active heating by ionic agitation

Tissue away from electrode:
Passive heating by thermal conduction. Once tissue becomes dehydrated/charred, the tissue acts as an electrical insulator preventing further current flow.

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RADIOFREQUENCY OVERVIEW

- PROVIDES CAUTERIZATION[5]
- MINIMAL # OF ELECTRODES AND GASES REQUIRED
- SUBSTANTIAL PEER-REVIEWED LITERATURE, (OLDER TECHNOLOGY)

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- DEHYDRATED/CHARRED TISSUE (>100 °C) → HIGH IMPEDANCE, LIMITED POWER[5]
- PULSING OR SLOW HEATING REQUIRED TO AVOID TISSUE DEHYDRATION/CHAR[5]
- HEAT SINK → LOBULATED ABLATIONS & HIGHER RECURRENCE RATES[7]
- GROUNDING PADS = RISK OF SKIN BURNS[8]

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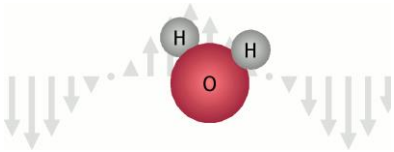
MW AND RF SIMILARITIES

- Mechanism of cell kill is identical (indistinguishable under the microscope)



- Microwave-penetrates all biologic tissues (including aerated lung, bone, char)[9]

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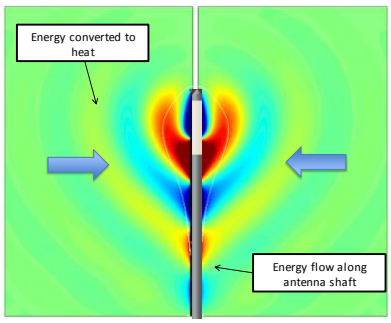
ANTENNA RADIATION



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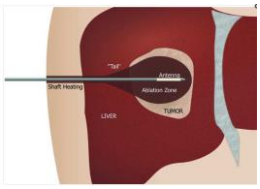
EARLY MICROWAVE SYSTEMS OVERVIEW

- EM field (915 MHz or 2.45 GHz)
- Rapidly oscillates water molecules to generate heat

- The EM field penetrates all biologic tissues including dehydrated/charred tissue created during ablation
  - No limit to temperature, power



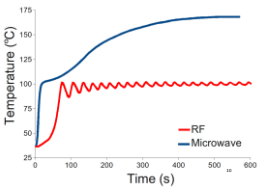


Exhibit 1: Because of the significant shaft heating that occurred with 1st gen microwave, a robust shaft cooling mechanism was required to minimize thermal damage to the subcutaneous tissues and the skin, especially with the development of higher power probes. 2015

EARLY MICROWAVE SYSTEMS OVERVIEW

ENERGY CAN BE APPLIED CONTINUOUSLY DESPITE CHANGES IN TISSUE	+	LARGE GAUGE ANTENNAS
IMPROVED PERIVASCULAR PERFORMANCE VS RF (LESS HEAT SINK EFFECT[7])	-	WAVE INTERFERENCE & INEFFECTIVE COOLING → UNPREDICTABLE "HOT DOG" SHAPED ABLATIONS[11]
SOME TISSUE CONTRACTION[11]		NO SYNCHRONY WITH MULTI-ANTENNA USE = INCONSISTENT ABLATION ZONES
EFFECTIVE IN ALL SOFT TISSUE TYPES[7]		UNDER POWERED

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Segment II
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Technical Differences

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NEUWAVE MICROWAVE SYSTEM OVERVIEW

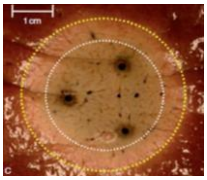
NEUWAVE IMPROVEMENTS[11]:

2.45 GHz frequency
- Less electromagnetic interference during multiple probe use for predictable, reproducible burns[12]

Triaxial antenna design
- High energy throughput
- Minimal backward heating

Multi-antenna wave synchrony
- Consistent, reproducible large burns

CO_2 cooling
- Eliminates heating along antenna shaft (no comet tail)
- Tissu-Loc™ for reducing antenna migration during scanning and additional antenna placement



Tissu-Loc iceball

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Power Distribution: 2.45GHz

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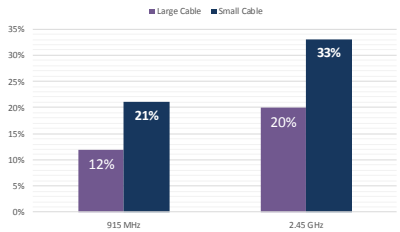
Power Distribution: Cable Loss

The inherent loss of generated microwave energy due to smaller diameter cables led to NeuWave creating the Power Distribution Module (PDM)



Delivered = Generated – Distribution Losses

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Antenna Design

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PR & LK ANTENNAS

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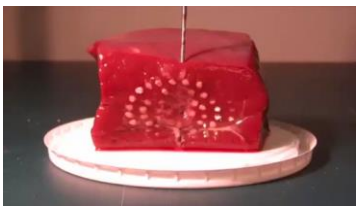
TISSUE SHRINKAGE CAUSED BY MW

Marked tissue shrinkage with high power MW devices

~30% liver/kidney

~50% lung[16]



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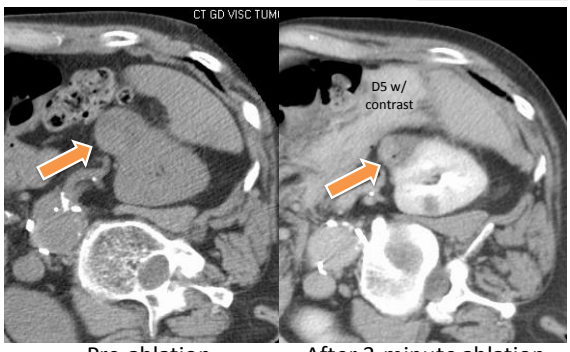

Pre-ablation

After 3-minute ablation

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ABLATION FOR RENAL SOFT TISSUE:

2014	A. Moreland, et al	UW paper	High-Powered Microwave Ablation of T1a Renal Cell Carcinoma: Safety and Initial Clinical Evaluation
2012	J. Yu, et al	Radiology	US-guided Percutaneous Microwave Ablation of Renal Cell Carcinoma: Intermediate-term Results
2014	Y. Lin, et al	Urology	Percutaneous Microwave Ablation of Renal Cell Carcinoma Is Safe in Patients With a Solitary Kidney
2013	M. Cristescu, et al	WCIO abstract	Percutaneous Microwave Ablation for the Treatment of Renal Angiomyolipoma (APL): Initial Experience
2014	J. Horn , et al	J Vasc Interv Radiol	Percutaneous Microwave Ablation of Renal Tumors Using a Gas-Cooled 2.4-GHz Probe: Technique and Initial Results

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REFERENCES

Disclosure: Dr. Christopher Brace is a shareholder and consultant for NeuWave Medical, Inc., and a co-inventor on patents related to thermal tumor ablation. Dr. Fred Lee is the founder and shareholder for NeuWave Medical, Inc., and a co-inventor on patents related to thermal tumor ablation. . Dr. Paul Laeseke is a shareholder and consultant for NeuWave Medical, Inc. and a co-inventor on patents related to thermal tumor ablation. Dr. J. Louis Hinshaw is a shareholder for NeuWave Medical Inc.

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Microwave ablation for T1a RCC

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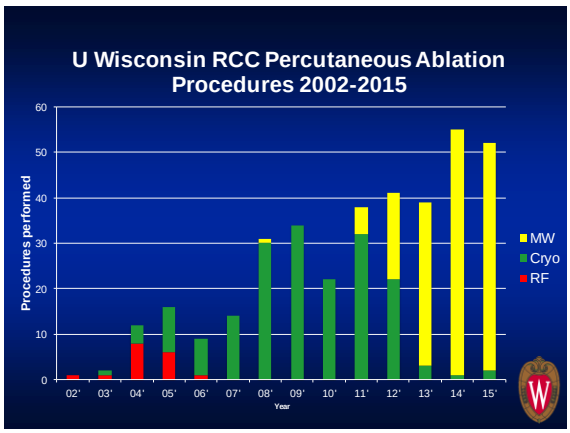
THE UNIVERSITY of WISCONSIN MADISON

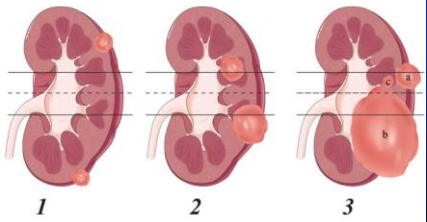
Disclosures

- Founder, NeuWave Medical Inc. (Microwave)
- Inventor, patents: Certus 140™
- Inventor, patents, royalties, Covidien Switching Controller™ (RF)
- NIH grants: R21RR018303
  R01CA108869
  R01CA118990
  R01CA112192

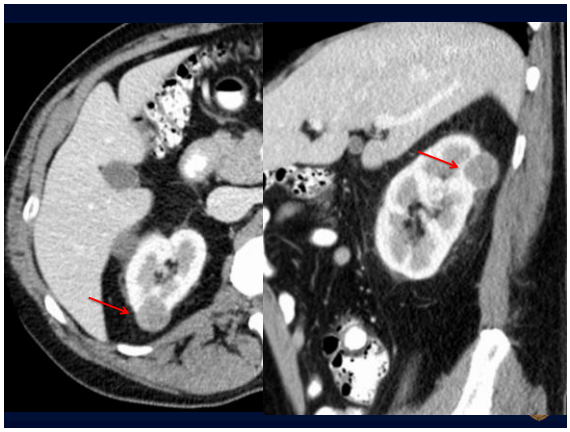


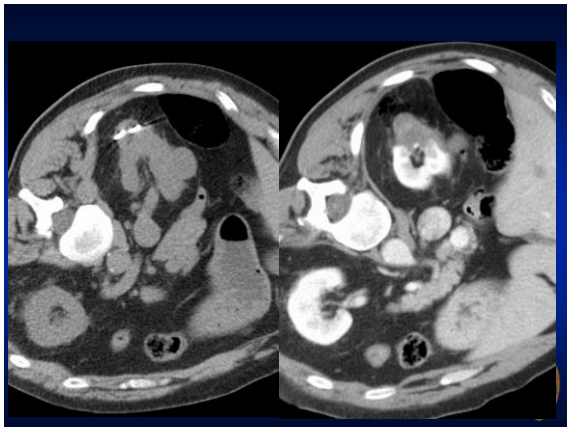
T1a RCC-anatomy is everything

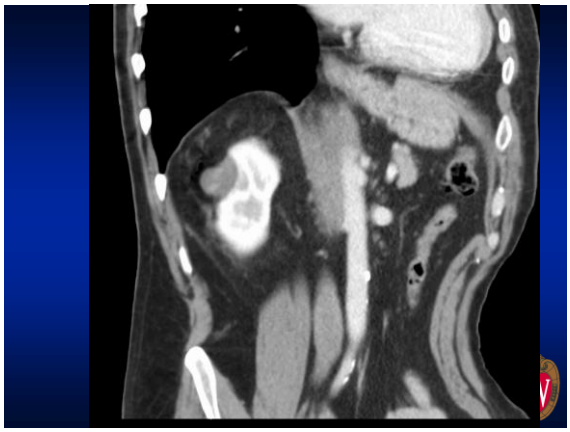
- Defined as < 4cm in size
- Not all are created equal
- Anatomic position is probably more important than size
- Nephrometry (RENAL) score predicts LTP and complications

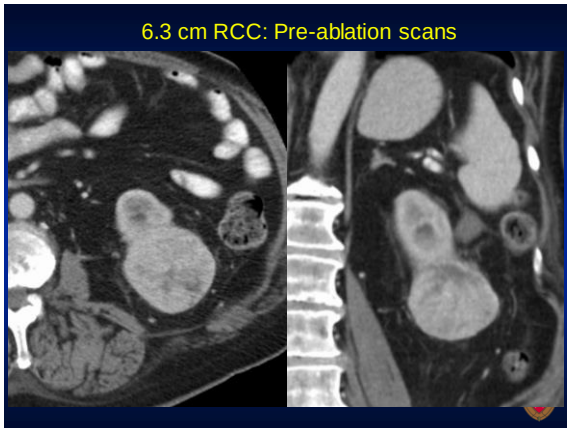


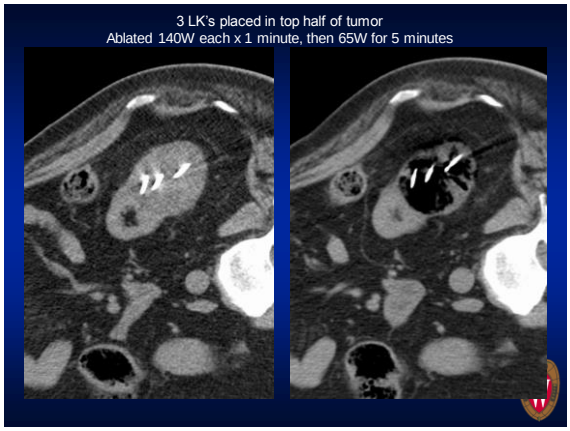
Reyes, et al. Urol Onc 2013;31
Schmidt, et al. J Urol 2013;189
www.nephrometry.com

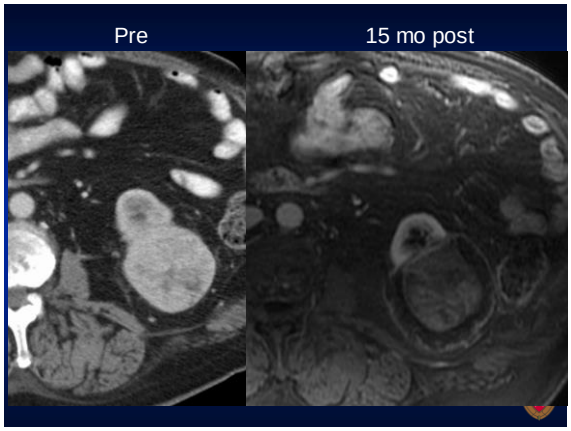


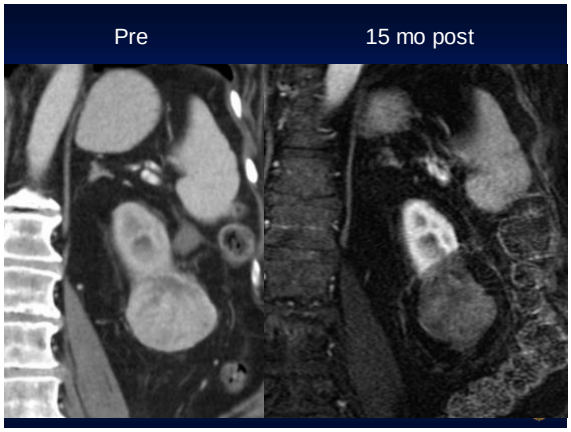


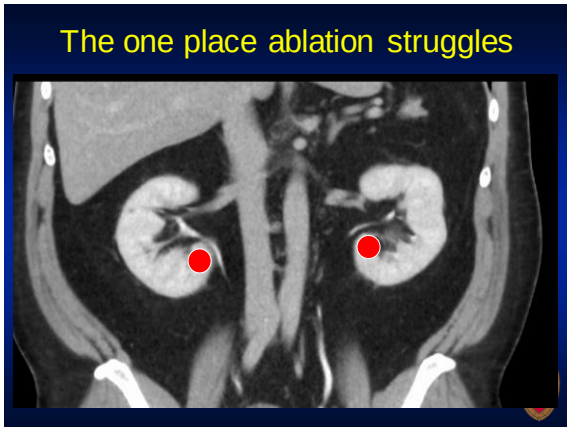



6.3 cm RCC: Pre-ablation scans


3 LK's placed in top half of tumor
Ablated 140W each x 1 minute, then 65W for 5 minutes


Pre
15 mo post


Pre
15 mo post


The one place ablation struggles

Ureteral injury after cryo

Why we use mostly MW

- Tumor control (I'll show you our data)
- Physics (esp tissue contraction)
- Speed
- Pain (?)
- Costs
- Hassle
- Visibility

MW and RF are closely related

- Mechanism of cell kill is identical (indistinguishable under the microscope)
- "Microwave" is actually in the RF spectrum
- AMA and SIR coding guidelines for MW: Use RF codes
- MW hotter (more likely to reach 60° C) , faster, no ground pads, fewer probes, better against vessels
- Microwave-penetrates all biologic tissues (including aerated lung, bone, char)
- Think of MW as an advanced RF system

Why do you need such high temps?

- *No resistant cells> 60 ° C*
- *Chemo, radiation, cryo all have resistant cells (Tatsutani)*
- Cancer stem cells are radio/chemo resistant, ?cold resistant
- Phospholipids in cell membranes melt between 45-55 ° C
  - Furuya, J Phys Soc Jn 1978

If you use heat: Hotter is better!

Costs

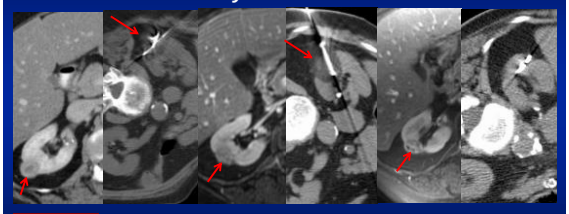
- UW experience:
  - Cryo 2.8 probes/procedure+gas ($113.65/tank)
  - MW: 1.8 probes/procedure+gas ($5.24/tank)
  - ~150 cases, assume $1500/probe
  - Cost savings= ~$271,270 + physician time + room time

Hassle factor:

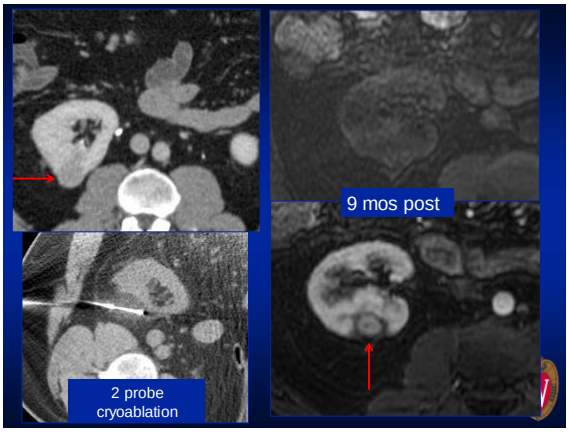
- No ground pads
- No heavy tanks
- No wrenches
- No heavy cables/lines
- No water lines
- Fast

Local tumor control: MW

Cryo Failures



2006 Preablation | 1st Cryo | 21 Months Post | 2nd Cryo | 4 Years Post | MW 8/2013



MW RCC-literature

- ~700 patients reported, pace increasing
- All studies positive w/one exception (Castle, Urology 2011). 10 patients, LTP 38%
  - Perc CT, 1st gen MW, cases done by urologists, no radiology
- Yu, et al (Radiology 2012): n=49, LTP 7.7%, 20.1 mo f/u, no severe complications
- Yu, et al (Radiology 2013): MW (n=65) vs. nephrectomy (n=98). 5-yr survival (cancer specific)=97.1 MW vs. 97.6% nephrectomy
- Martin, et al (Diagn Int Radiol 2013): Meta-analysis 1st gen MW vs. Cryo, conclusion: no difference (but more studies for cryo)

Abdominal Imaging
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Midterm results of percutaneous microwave ablation under ultrasound guidance versus retroperitoneal laparoscopic radial nephrectomy for small renal cell carcinoma

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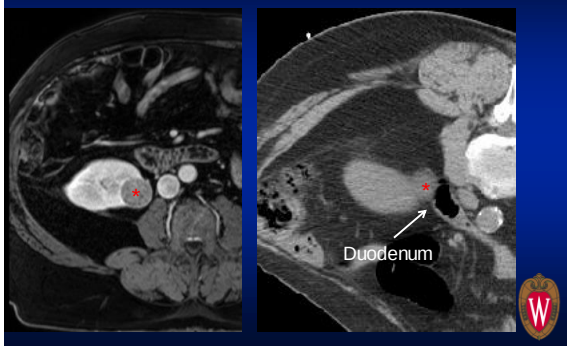
- MW=105 (2.7 cm) vs. Nephrectomy=328 (2.8 cm)
- MW patients older, sicker, worse renal fxn
- Complications NSD, renal function better w/ MW
- Overall survival better w/ nephrectomy (p=0.0004)
- Tumor specific survival same (p=0.38)

UW data-T1a RCC

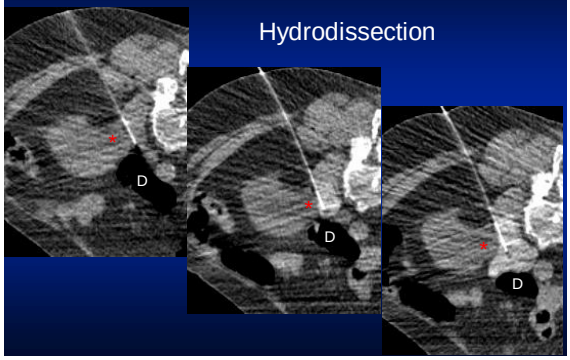
- N=100, dia=2.6 cm, f/u=17 mo (out to 48 mo)
- BMI 32.2, nephrometry score 7 (moderate complexity)
- eGFR pre 71.8, post 68.7
- Hydrodissection 34%
- 1.8 antennas, 65W, 5 min
- We've done 3 RCC in renal transplants

RCC in renal transplant



RCC in renal transplant

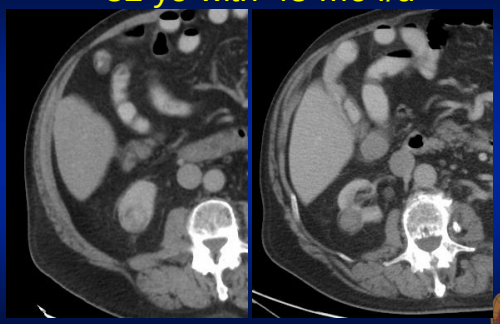
Hydrodissection



RCC in renal transplant

Ablation

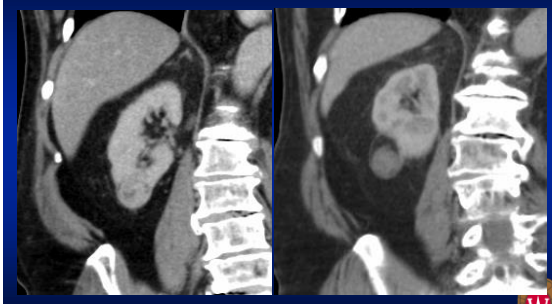
82 yo with 48 mo f/u



Pre MW

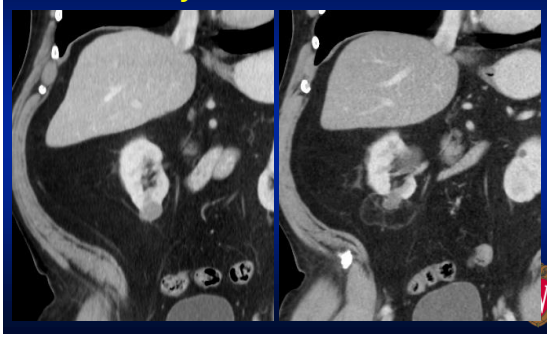
44 mo post MW

82 yo with 48 mo f/u



Pre MW 44 mo post MW

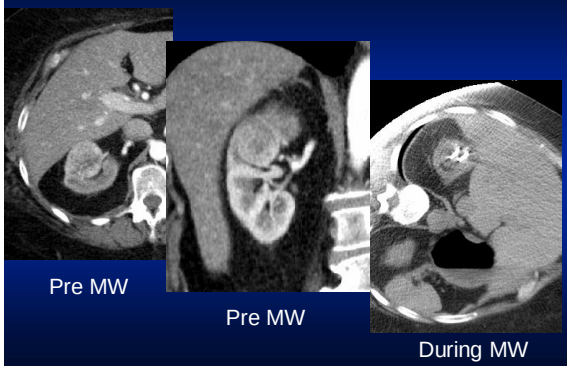
65 yo with 35 mo f/u



UW data-T1a RCC

- 1 LTP (1%), Furhman Gr 4, at 25 mo
- No RCC deaths, no mets
- 3 deaths: MI (5 mo), lymphoma (9 mo), GI bleed (39 mo)
- PFS=99%, CSS=100%, OS=97%
- Tumor complexity, BMI didn't effect results
- 11 complications, most minor, 3 related to procedure (RP bleed, hematuria x 2)
- 6 urinomas on delayed imaging

Retroperitoneal hematoma Day 10

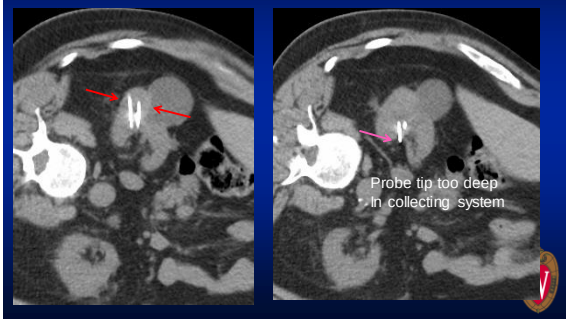


Retroperitoneal hematoma Day 10

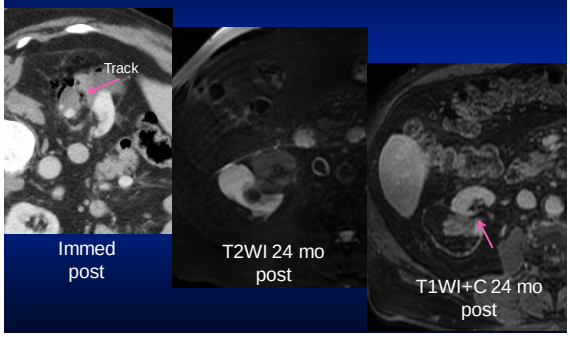
Retroperitoneal hematoma, POD#10
Coinciding w/ restarting heparin + warfarin

28 mo post

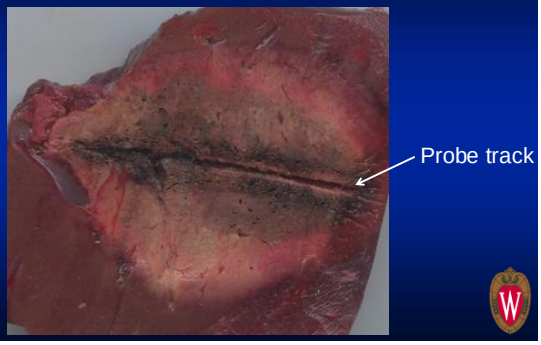
Urinomas, most detected late



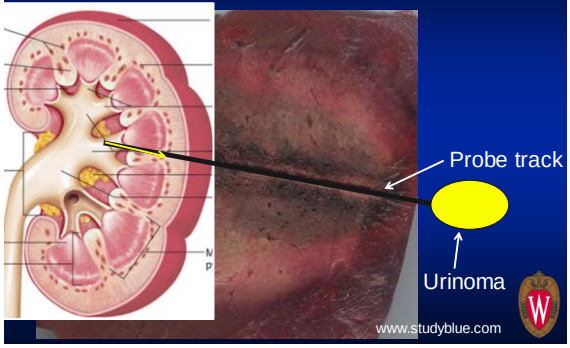
Urinomas, most detected late



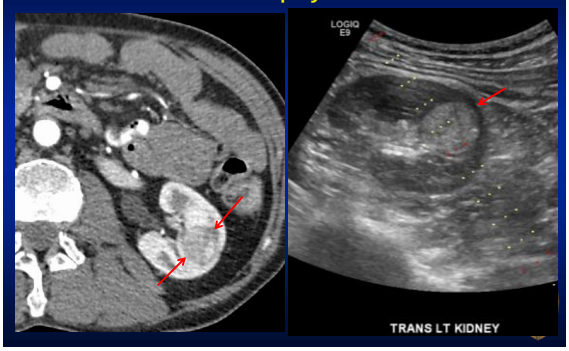
Urinomas, mechanism



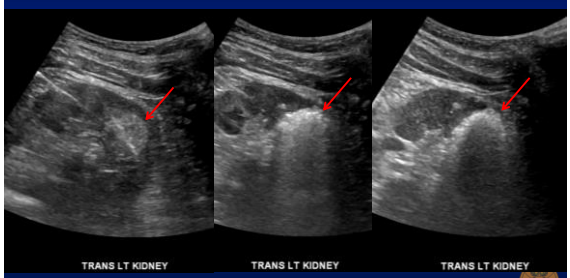
Urinomas, mechanism



How we place probes now
2.2 cm endophytic RCC

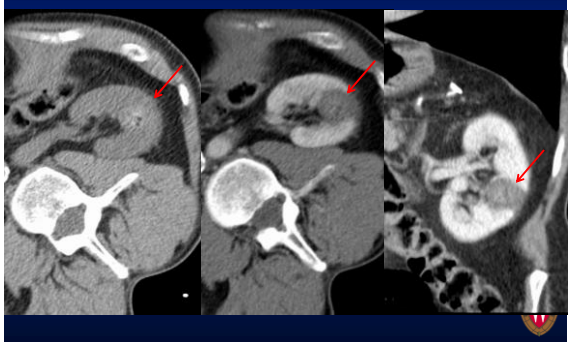


During ablation (bubbles highly visible)



2 PR's, 65W for 3 minutes, then 40W for 2 minutes

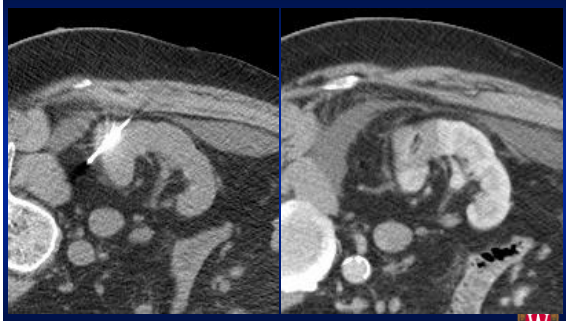
Post ablation CT



Tangential approach to avoid collecting system

Immediate Pre

Immediate Post ablation



7 months post ablation

Preventing urinomas: Don't puncture collecting system!

- Before tangential approach=29 endophytic RCC
- Median RENAL score of 8.5
- 6 urinomas
- With tangential approach=35 endophytic RCC
- Median RENAL score of 8.5
- 0 urinomas

Summary

- MW highly effective for local control T1a RCC
- Is MW "better" than other modalities? You be the judge
- We favor MW due to effectiveness, speed, costs, decreased hassle
- Watch out for inferior medial pole tumors with any modality
- Urinomas associated with puncture of collecting system, ergo, don't do it…

Thank you for your attention!

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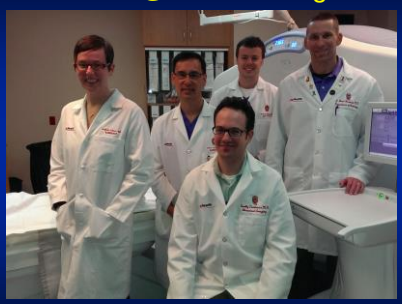

UW Tumor Ablation Team: Meg Lubner, Fred Lee, Tim Ziemlewicz, Shane Wells, Louis Hinshaw

Percutaneous Microwave Ablation

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Disclosures

Paid physician consultant by NeuWave for my time to present my experience in this presentation.

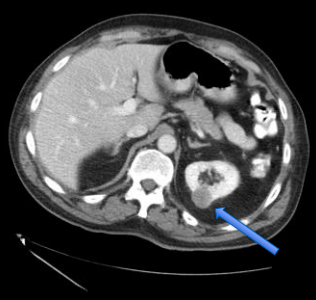
Virginia Approach: Small Renal Mass

- Multi-Disciplinary: Radiology and Urology Combined Decision-making
- Small Renal Mass Conference
- Active surveillance consideration
- Timing of biopsy
- US and CT
- Immediate imaging
- 6 month imaging
- Intraoperative uses?

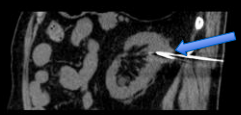
Case

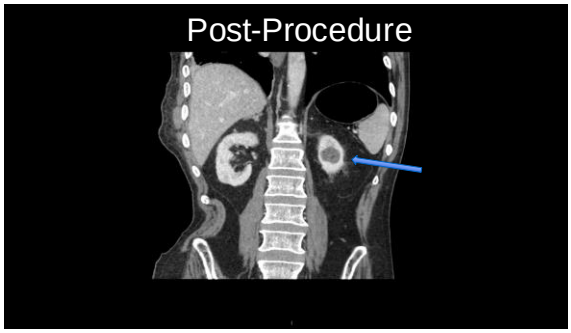
- 70 year old man incidentally found 1.5 cm renal mass
- Follow up CT 2 yrs later: 2.5 cm
- Biopsy: Papillary Renal Cell Carcinoma
- HTN, DM, paraplegia
- Serum Cr 0.9, eGFR= 97

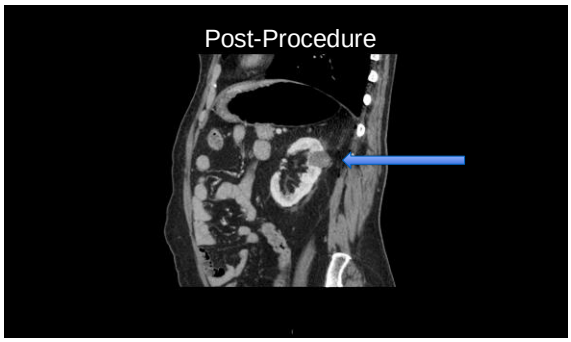
Preoperative CT



Needle Placement







	Cryoablation (n=21)	Microwave Ablation (n=38)	p-value
Gender			0.56
Male	13 (62%)	27 (71%)	
Female	8 (38%)	11 (29%)	
Age - years (range)	67.0 (44-88)	67.2 (40-87)	0.96
BMI - cm^2/kg (95%CI)	29.3 (27.1-31.5)	29.9 (28.0-31.8)	0.69
Charlson Comorbidity Score			
Nephrometry Score			
Numerical (95%CI)	6.6 (5.6-7.6)	6.7 (6.0-7.4)	0.93
Posterior location – N (%)	12 (57.1%)	26 (78.8%)	0.23
Volume – mm^3(95%CI)	12.5 (6.7-18.2)	15.3 (8.7-22.0)	0.50
Pathology			0.06
Clear Cell RCC	10 (47.6%)	17 (56.7%)	
Papillary RCC	4 (19.0%)	11 (36.7%)	
Chromophobe RCC	1 (4.8%)	1 (3.3%)	
NOS	6 (28.6)	1 (3.3%)	

	Cryoablation	Microwave Ablation	P-value
Recurrence	4 (19%)	1 (3.0%)	0.05
Average Cost (U.S. Dollars)	6354.1 (4777.1-7931.0)	4121.9 (3269.0-4974.8)	0.02

Complications

- Cryoablation
  - Non-ST Elevation Myocardial Infarction
  - Pulmonary Embolus
  - Hematoma Requiring Transfusion
- Microwave
  - Pneumonia
  - UTI

Building an Interventional Oncology

Renal Ablation Program

Dr Roger Williams
Interventional Oncology
Interventional Radiology
Quantum Radiology
Marietta, GA

Disclosure:

- Paid clinical education consultant for NeuWave Medical

Overview

The principle of moving to a new country.

- Securing Employment (Service line)
- Establish Housing (Clinic)
- Developing Friendships (Referrals)
- Understanding Landscape of Tumor Board (Bureaucracy)
- Partnering in Multidisciplinary Tumor Board (Currency)

Service Line

- Interventional oncologist = Clinician, administrator, scheduler, **advocate for patient, cache
- Become educated on the pertinent literature (SPO)
- Develop technical skills to become successful
  - Develop skill set through challenging cases

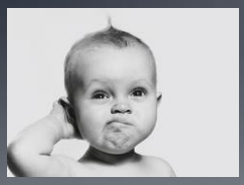
Clinic

- Establish a dedicated space, time and contact numbers
- Establish a streamline EASY means for referrals
- Lab and Imaging review
  - Lend Imaging expertise to patient

Referrals

- Simplify process for referrals
- Not all Urologist are the same (Prostate v. Kidney)
- Discuss criteria:
  - Operative/ Non Operative
    - Ablation under conscious sedation
  - Partial nephrectomy
  - TNM Staging

Bureaucracy



- Urologist thoughts on Ablation
  - Prior experience:
    - In training
    - At facility
- Cryo v. RFA v. Microwave
- Complications
  - Management

Currency

- Procedural control
  - Partial nephrectomy
  - Ablation
- Procedural control (Ablation)
  - Urology
  - Radiology
- Follow up
  - Urology
  - Radiology