Boston Scientific
Advancing science for life™

Radiofrequency Ablation

GREAT BODY OF LONG-TERM EVIDENCE TO SUPPORT CLINICAL UTILITY

SIMPLICITY AND PREDICTABILITY IN SOFT TISSUE ABLATION

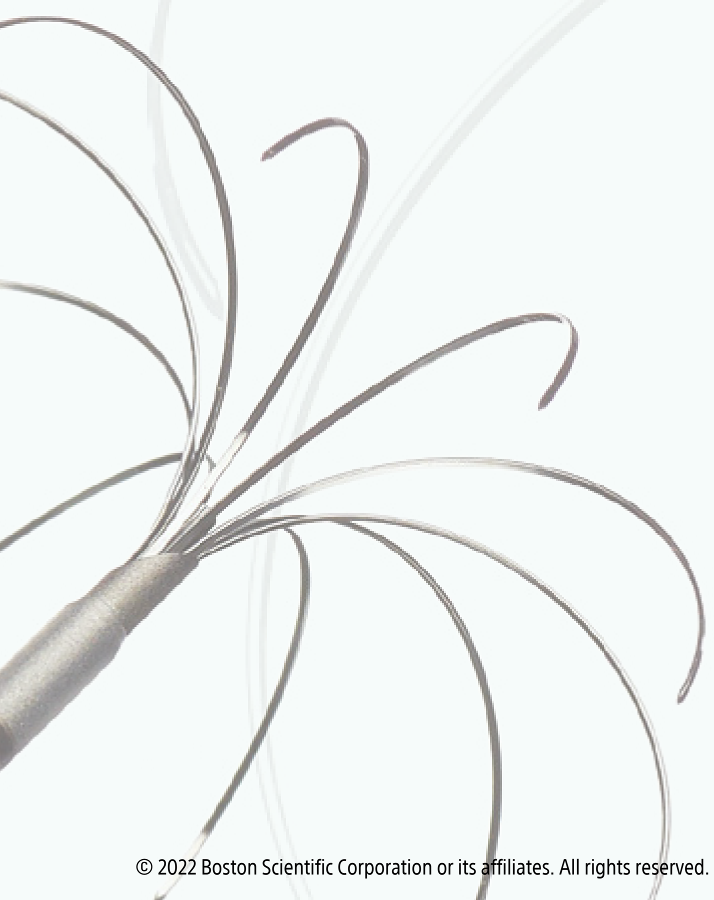
- *Introduction to our Radiofrequency System*
- *RF 3000™*
- *LeVeen™ Probes family*
- *Impedance principles*

CLINICAL OUTCOMES

- *Liver*
- *Lung*
- *Kidney*

Boston Scientific is the choice for Percutaneous and Open Radiofrequency Ablation

- Utilizes **impedance as a procedural endpoint.** As proteins denature and tissue desiccates, the resistance to the passage of electrical current (impedance) increases.
- Probes **do not require the use of saline or cooling** mechanisms.
- Umbrella shaped tine arrays are designed for **secure anchoring** and intended to provide **accurate and predictable ablation profiles.**



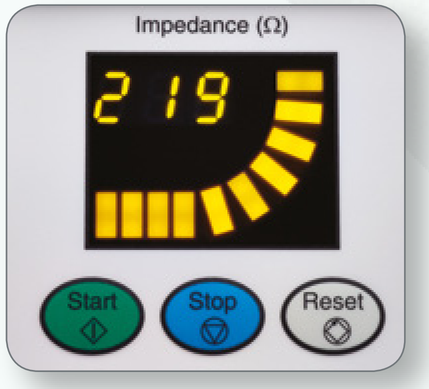
RF 3000™ Generator

Designed for complete predictable thermal ablation

- **200W capacity** promotes rapid, efficient ablation of large volumes of tissue.
- **Easy-to-read,** back lit displays and audible signal are designed to allow constant assessment of procedure progress.
- Because ablation algorithms and generator inputs are manual, there is **no need for generator software updates** if/when probe algorithms change.

The RF 3000 Generator uses a direct measurement of impedance feedback from the target tissue to monitor the course of tissue ablation

Initial tissue impedance is measured prior to application and is typically within the range of 40 to 80 ohms (Ω), illumination three bars on the front panel of the RF 3000 Generator.



Impedance rise is indicated by an increase in ohms (Ω) and a sequential illumination of the bars on the front panel, signaling cellular destruction and the completion of a thermal lesion.

Probe Family

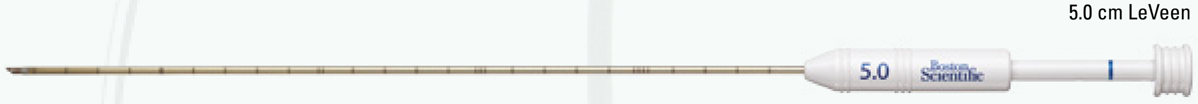
Probe Selection Guide

Procedural Need/Intent	LeVeen™ Needle Electrodes	LeVeen SuperSlim™ Electrodes	LeVeen CoAccess™ Electrodes	LeVeen Soloist™ Single Needle Electrodes
Stable probe array anchoring within tissue	✓	✓	✓	
Short, 12 cm cannula length for added CT Gantry Clearance	✓			
Less invasive, small diameter cannula		✓		
Coaxial access cannula for preprocedural planning and compound ablations			✓	
Ability to biopsy through the same introducer cannula			✓	
Single needle electrode for small diameter ablation zones				✓

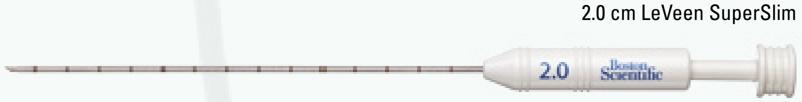
LeVeen Needle and LeVeen SuperSlim Needle Electrodes

- **Variety of array sizes** (3.0–5.0 cm) **and cannula lengths** (12,15, 25 cm) to provide more flexibility to treat a variety of lesion sizes and depths.
- **Small diameter cannula** intended to minimize invasiveness and bleeding risks (available on LeVeen SuperSlim Needle Electrode).

5.0 cm LeVeen



2.0 cm LeVeen SuperSlim



LeVeen CoAccess Needle Electrodes

- **Coaxial system with insulated introducer set** for pre-procedural lesion mapping and cannula placement prior to ablation(s). Excellent choice for compound ablations.
- **Introducer set and cannula** compatible with most soft-tissue biopsy devices.
- **Umbrella shaped array with sharpened tines** to promote lesion penetration and stable probe positioning.

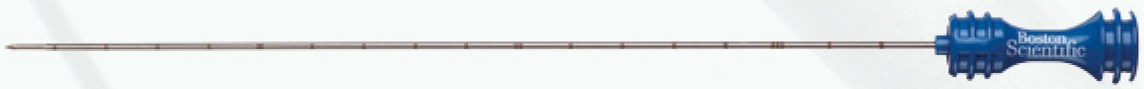
LeVeen CoAccess Introducer

3.0 cm LeVeen

LeVeen Soloist™ Single Needle Electrode

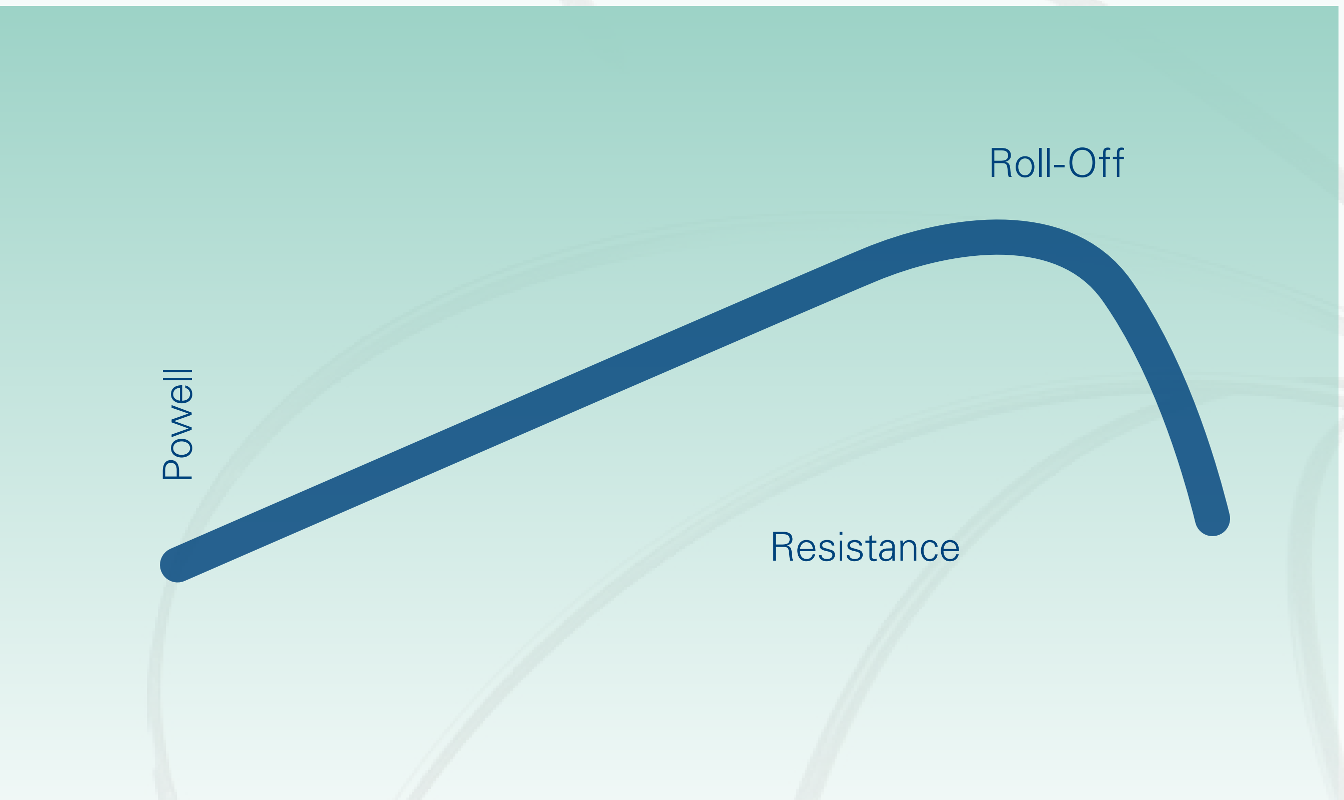
- **Single needle electrode** for small diameter ablations (approximately 1.5 x 1.0 cm).
- **Trocar tip** to access small and difficult-to-treat lesions.
- **1 cm shaft markings** intended to aid in accuracy of needle placement.

LeVeen Soloist



The Use of Impedance as a Procedural Endpoint

- **Impedance is a physical phenomenon** that is not dependent upon calculations or measurement systems.
- **Time and or temperature based ablation systems** may not fully account for variability in lesion composition.



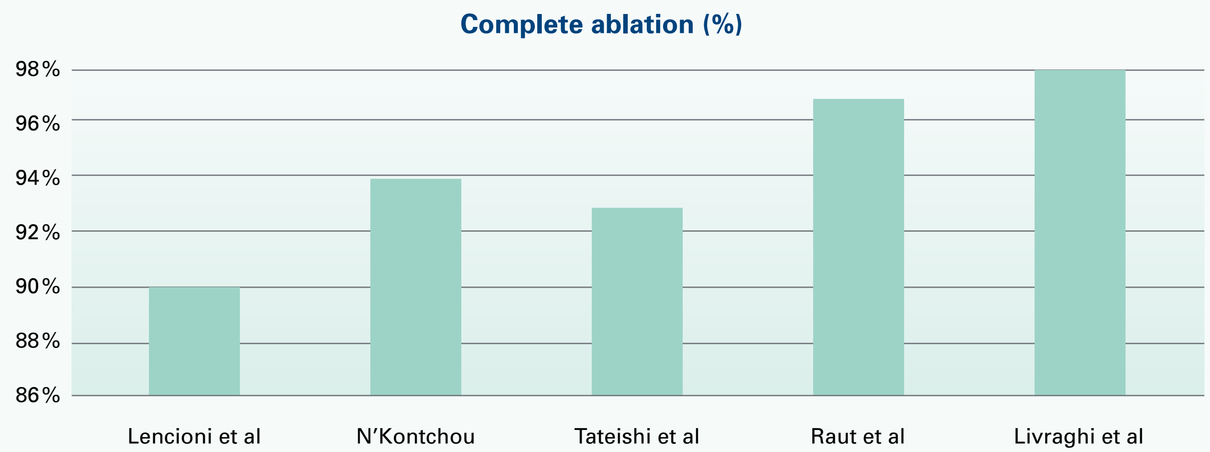
- Application of electrical current results in tissue heating above 50°C.
- Proteins denature and tissue desiccates, increasing tissue's impedance *(resistance to conduct electrical current)*.
- More power is applied to overcome the rise in electrical resistance.
- Once thermal coagulation and necrosis is achieved, the impedance will rise and a corresponding drop in delivered power results (Roll-Off Indication), indicating the completion of a thermal ablation.

CLINICAL OUTCOMES

LIVER

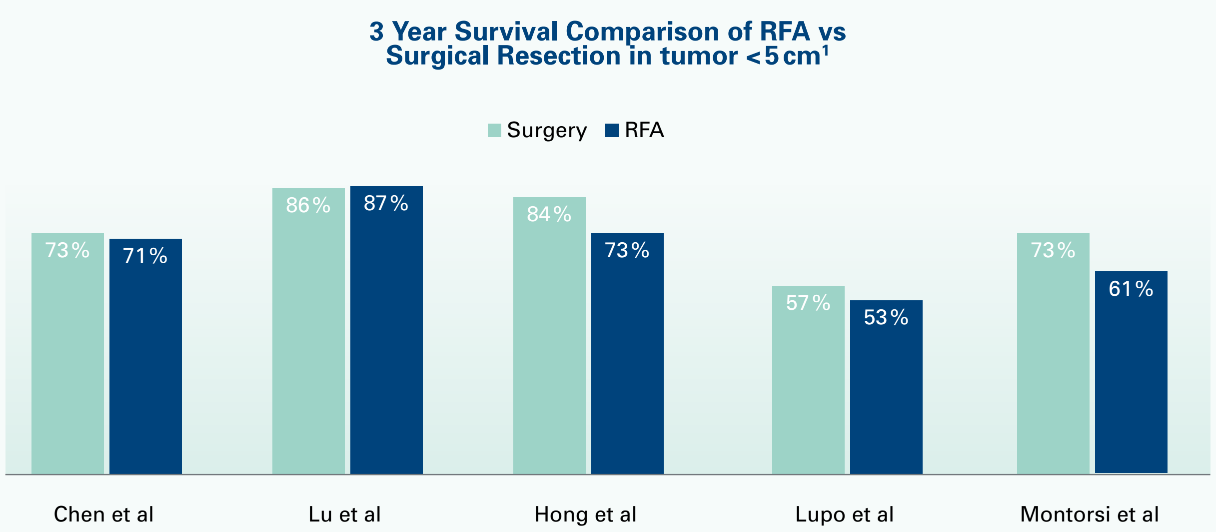
- *An effective treatment for the non Surgical patients*
- *Effective adjunction to sequential treatment*
- *A safe, robust and predictable Impedance Technology*

RFA is an alternative to resection for the 20% of HCC patient eligible for surgery[2]



- With up to 98 % complete ablation in early stage small carcinomas[1]

An alternative to Surgery in liver tumors[1]



- No difference in disease free and overall survival in <5 cm tumors and

- **Better quality of life[3]**
- **In HCC patients over 65 years old, RFA allows a significantly better quality of life than surgery[4]**
- **Better efficacy in ≤2 cm central HCC[5]**
- **Less major complication[5]**
- **Lower post-treatment morbidity[6]**
- **Decreased hospital stay[6] and at lower cost[6,7]**

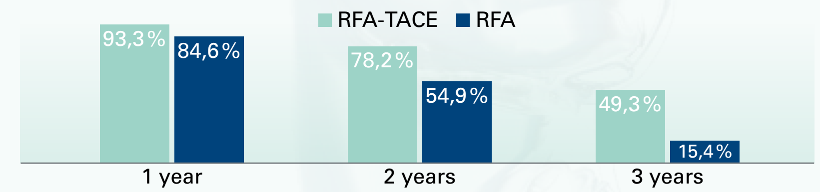
1. Percutaneous Ablation of Hepatocellular Carcinoma: Current Status, Justin P. McWilliams, MD et al. J Vasc Interv Radiol 2010; 21:S204–S213
2. Resection or ablation of small hepatocellular carcinoma : what is the better tratment? Petrowsky H et al. J Hepatology, 2008; 49:502-504
3. Quality of life after surgical resection compared with radiofrequency ablation for small hepatocellular carcinomas, Huang G et al Br J Surg. 2014
4. Radiofrequency ablation versus open hepatic resection for elderly patients (> 65 years) with very early or early hepatocellular carcinoma, Peng ZW et al. Cancer. 2013; 119 (21): 3812-20
5. Radiofrequency ablation versus hepatic resection for the treatment of hepatocellular carcinomas 2 cm or smaller: a retrospective comparative study. Peng ZW, Lin XJ, Zhang YJ, Liang HH, Guo RP, Shi M, Chen MS. Radiology. 2012; 262 (3): 1022-33
6. Cost-effectiveness of radiofrequency ablation and surgical therapy for small hepatocellular carcinoma of 3 cm or less in diameter. Kenji Ikeda et al. Hepatol Res 2005; 33:241–249.
7. Cost-effectiveness of hepatic resection versus percutaneous radiofrequency ablation for early hepatocellular carcinoma. Cucchetti A et al. J Hepatol. 2013; 59 (2): 300-7Ikeda K, Kobayashi M, Saitoh S, et al.

Effective adjunction to sequential treatment

For intermediate and large HCC in tandem treatment[8]

Improves overall survival rate, and provides better prognosis for patients when used in combination with TACE[8]

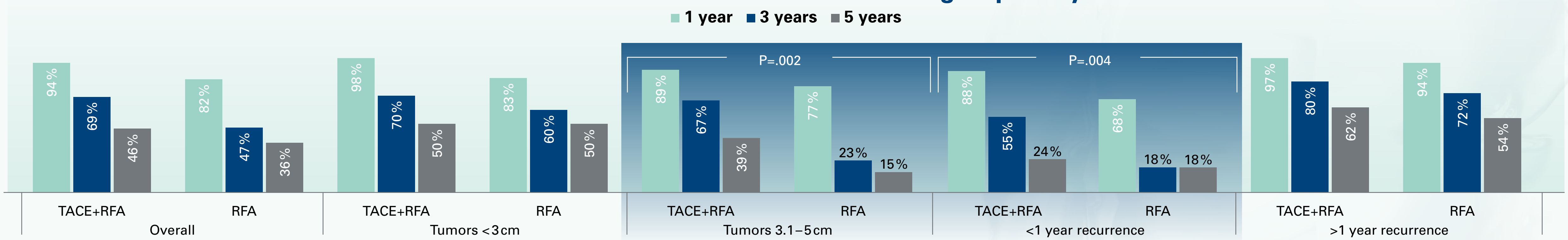
Survival after RFA-TACE vs RFA in intermediate 3–5 cm hepatocarcinoma



For early <1 year recurrent 3–5cm HCC[9]

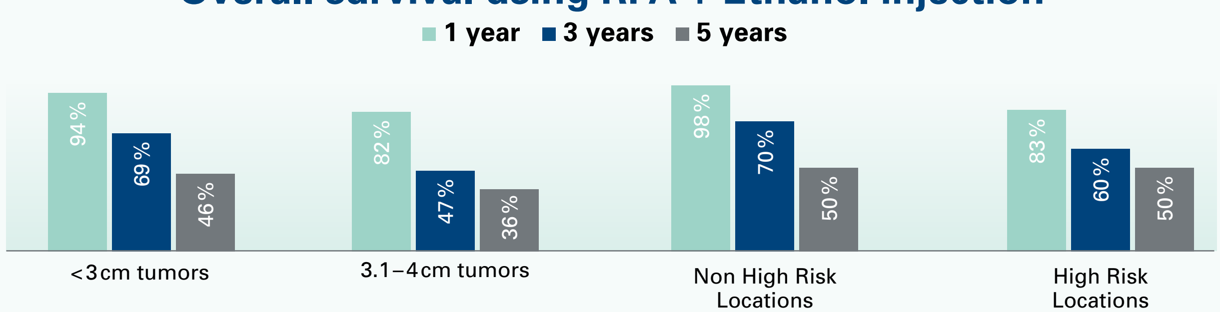
Improved Overall Survival when RFA used after TACE[9]

Recurrent HCC: Overall Survival ans subgroup analysis



Combined to ethanol injection for long-term outcomes in larger hepatocellular carcinoma (3.1–4 cm) and in high-risk locations[10]

Overall survival using RFA + Ethanol injection



For comparable long-term outcomes

8. Meta-analysis of radiofrequency ablation in combination with transarterial chemoembolization for hepatocellular carcinoma- Jia-Yan Ni et al -World J Gastroenterol 2013 June 28; 19(24): 3872-3882
9. Recurrent Hepatocellular Carcinoma Treated with Sequential Transcatheter Arterial Chemoembolization and RF Ablation versus RF Ablation Alone: A Prospective Randomized Trial 1 - Zhen-Wei Peng , MD Radiology: Volume 262: Number 2–February 2012 n radiology.rsna.org
10. Combining radiofrequency ablation and ethanol injection may achieve comparable long-term outcomes in larger hepatocellular carcinoma (3.1-4 cm) and in high-risk locations. Lin JW et al. 2014 Aug;30(8):396-401. doi: 10.1016/j.kjms.2014.04.006. Epub 2014 Jun 2

Using a safe, 18 years robust[11] and predictable impedance[12] technology

Umbrella Expandable design

Procedural Need/Intent	LeVeen™ Needle Electrodes	LeVeen SuperSlim™ Electrodes	LeVeen CoAccess™ Electrodes
No-Touch technique in single tumor	✓		✓
Bleeding Risk as the tumor is not perfored by the needle*	✓		✓
Security Margin ablation when nodule totally inside the umbrella	✓	✓	✓
Easy Placement & Ballistic	✓	✓	✓
Stable probe array enabling to slightly move the organ to be treated from sensitive structures	✓	✓	✓
17G low profile needle for more preservation of liver parenchyma		✓	
Anticipated precise targeting[13] when treating large tumors requiring multiple RF applications**			✓
Combined biopsies[13] through single tract			✓
Both protected biopsy[13,14] and RF ablation[13]			✓

* preventing intra-alveolar bleeding hiding the target and decreasing impedance
** 1st ablation compromizing potentially the imaging.

11. Radiofrequency Ablation of Unresectable Primary and Metastatic Hepatic Malignancies – Steven A Curley et al – Annals of Surgery – Vol 230 N°1 July 1999
12. Percutaneous Radiofrequency Ablation of Liver Tumors with the LeVeen Probe: Is Roll-off Predictive of Response? Michael A. Arata, MD, Harvey L. Nisenbaum, MD, Timothy W.I. Clark, MD, and Michael C. Soulen, MD1
13. Usefulness of Guiding Needles for Radiofrequency Ablative Treatment of Liver TumorsThierry de Baere, Cardiovasc Intervent Radiol (2005)
14. Seeding following percutaneous diagnostic and therapeutic approaches for hepatocellular carcinoma. What is the risk and the outcome? Seeding risk for percutaneous approach of HCC., 2007 Aug;33(5):437-47. Epub 2007 May 18. Stigliano R et al.

CLINICAL OUTCOMES

LUNG

- *Established treatment in Non-Small Cell Lung Cancer (NSCLC)*
- *A treatment option for small lung metastases*
- *Organ specificities favor RFA outcomes*

Introduced in 2000, RFA in Lung cancer is well documented and effective technique[15]

Established treatment in NSCLC non surgical patients[15]

95 % Technical success[16]

- Adequate margins of ablation are a key for success
- 4:1 ratio between RFA induced ground-glass opacity and tumor area before treatment.
- Primary tumor size + 8–10mm of ablation beyond the visible tumor margin[18]
- Oversizing and overlapping ablation prevents local failure and occurrence of complications in the treatment of primary stage I NSCLC, leading to improved survival in this fragile non-surgical population[17]

Median reported rate of 90 % of complete ablation, especially in small < 3cm tumors[17]

Improving Overall Survival over time[17]

	1 year	2 years
Stage 1 NSCLC Overall Survival	78–95 %[16]	57–84 %[16]

No statiscal difference in 3-y survival compared with sublobar resection[17]

	1 year	2 years	3 years	4 years	5 years
N0 NSCLC OS[4]	91,9 %	77,5 %	66,1 %	63,4 %	58,1 %

Baseline: 5-y OS in NSCLC non surgical patients without treatment is between 6 and 14 %[17]

Only 15 % of patients with Stage 1/2 meet physiological criteria for parenchymal resection[15]

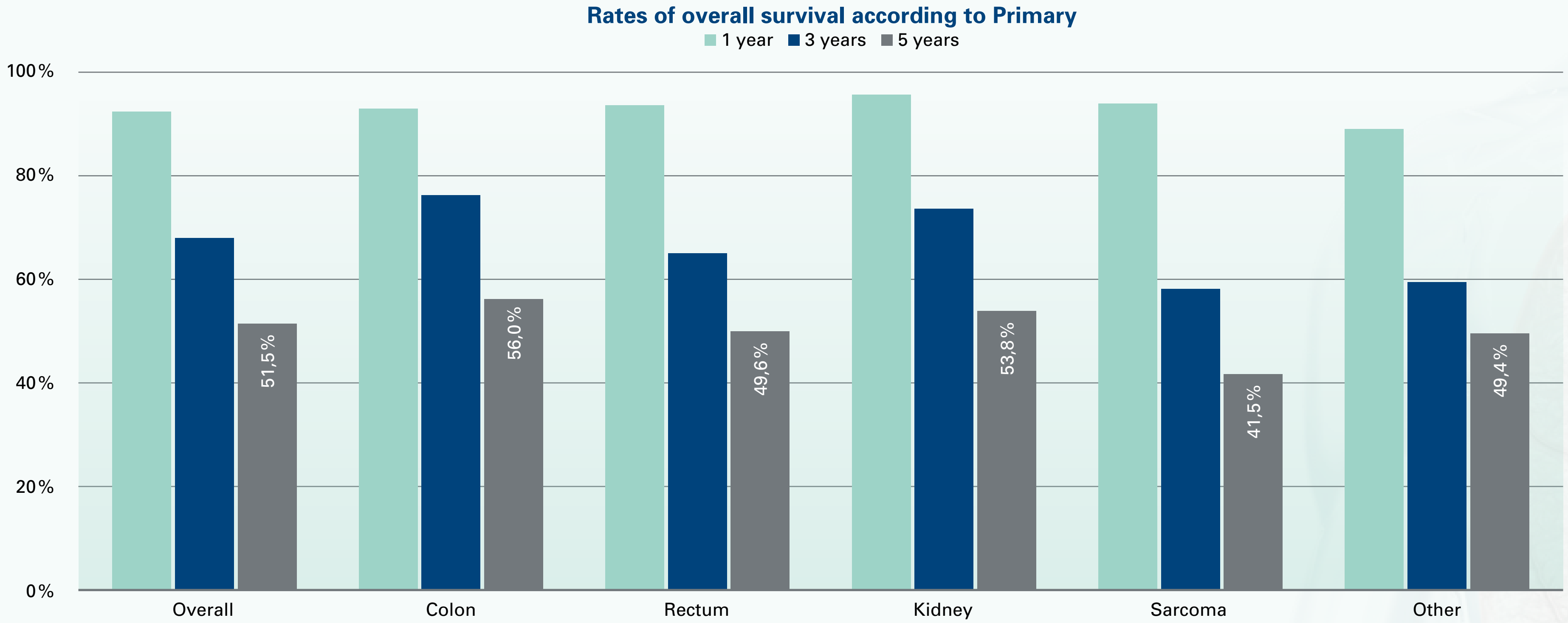
20 % of Stage 1 are ineligible to sublobar resection[18]

15. Thermal ablation in the treatment of lung cancer: present and future . Alessandro Baisia et al - European Journal of Cardio-Thoracic Surgery 43 (2013) 683–686 doi:10.1093/ejcts/ezs558 Advance Access publication 24 October 2012
16. Radiofrequency ablation of lung tumours . Irene Bargellini - Insights Imaging (2011) 2:567–576 DOI 10.1007/s13244-011-0110-7
17. Lung Cancer Ablation: What Is the Evidence?Thierry de Baere, MD1 Semin Intervent Radiol 2013;30:151–156
18. Percutaneous Lung Thermal Ablation of Non-surgical Clinical N0 Non-small Cell Lung Cancer: Results of Eight Years' Experience in 87 Patients from Two Centers. Jean Palussiere .Cardiovasc Intervent Radiol (2015) 38:160–166

A treatment option for small 2–3 cm lung metastases[19]

Comparable results to metastasectomy

- **100% tumor necrosis** at histopathology[20]
- **5-year 51% Overall survival** in the range of the best surgical results[19]



11,1% rate of local tumor progression per tumor at 4-y, similar to what reported for surgery.[19]

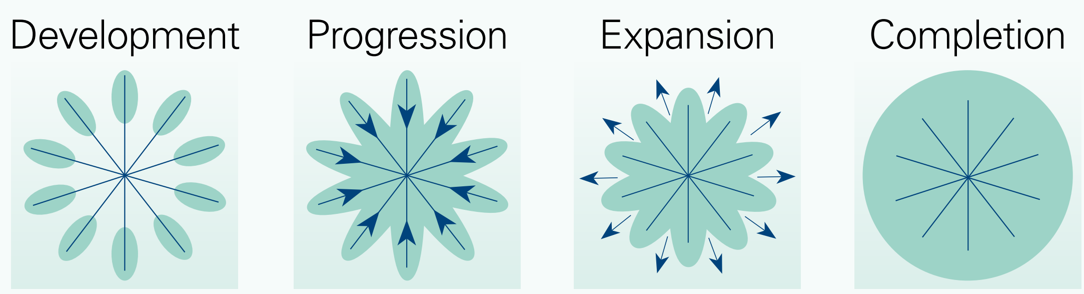
RFA provides also
- Superposable predictive factors as surgery[19]
- Minimally invasive technique for lung parenchyma sparing, especially in case of new metastases distant from the abation site[19]
- Good tolerance and no change in respiratory function[19]
- Possible repeated treatment[19]
- Use of biopsy at the same time to define which combined treatment[19]
- Cost effective compared to surgery[21]

19. Radiofrequency ablation is a valid treatment option for lung metastases: experience in 566 patients with 1037 metastases T. de Baère et al- Annals of Oncology 26: 987–991, 2015
20. Pathologic assessment of radiofrequency ablation of pulmonary metastases. Jaskolka JD et al. J Vasc Interv Radiol 2010; 21: 1689-1696.
21. Cost and effectiveness of radiofrequency ablation versus limited surgical resection for stage I non-small-cell lung cancer in elderly patients: is less more? J Vasc Interv Radiol. 2013; 24 (4): 476-82

Organ specificities favor RFA outcomes[5]

Parenchyma specificities in the Lung favor RFA outcomes. Same quantity of energy results in larger ablation volume in lung, due to heat insulation and low electric conductivity provided by the lung around the tumor[22]

Umbrella Expandable design



Expandable needled starts delivering on the periphery and will then concentrate on the center of the tumor with **predictable spherical ablation.**

Procedural Need/Intent	LeVeen™ Needle Electrodes	LeVeen SuperSlim™ Electrodes	LeVeen CoAccess™ Electrodes
No-Touch technique in single tumor	✓		✓
Bleeding Risk as the tumor is not perfored by the needle*	✓		✓
Security Margin ablation when nodule totally inside the umbrella	✓	✓	✓
Easy Placement & Ballistic	✓	✓	✓
Stable probe array*	✓	✓	✓
Anticipated precise targeting[13] when treating large tumors requiring multiple RF applications			✓
Combined biopsies[13] through single tract			✓
Ease of use under CT Gantry	✓**		✓

* Stability
- Under local anesthesia when uncontrolled breath or tough of the patient.
- During pneumothorax when lung is retracting to hilum location
- Expandable needles allow in poor tumor locations to slightly move the tumor from mediastin to enable same ablation condition as in the parenchyma

** short 12 cm length cannula

5. Radiofrequency ablation versus hepatic resection for the treatment of hepatocellular carcinomas 2 cm or smaller: a retrospective comparative study. Peng ZW, Lin XJ, Zhang YJ, Liang HH, Guo RP, Shi M, Chen MS. Radiology. 2012; 262 (3): 1022-33
13. Usefulness of Guiding Needles for Radiofrequency Ablative Treatment of Liver Tumors - Thierry de Bae` re, Cardiovasc Intervent Radiol (2005)
22. Radiofrequency ablation: effect of surrounding tissue composition on coagulation necrosis in a canine tumor model. Ahmed M, Liu Z, Afzal KS et al. Radiology 2004; 230: 761-767.

CLINICAL OUTCOMES

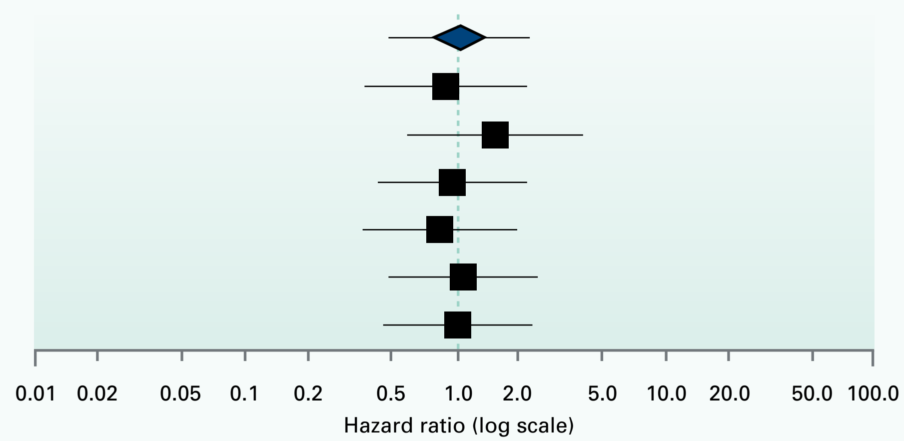
KIDNEY

- *Preserving renal function*
- *Effective treatment option in poor surgical candidates*
- *Minimally invasive Cost effective treatment option*

RFA is minimal invasive technique for preserving renal function[23]

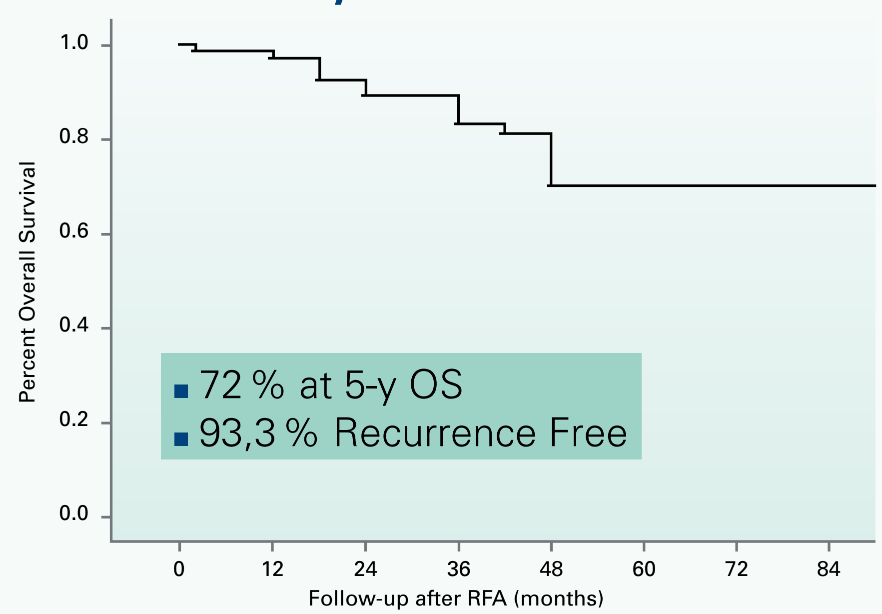
5-year oncologic outcomes comparable to resection in small 2–3 cm tumors[23,24]

Leave-One-Out Meta-analysis
Disease-free survival



Studies	Estimate (95 % C.I.)	
Overall	**1.040**	**(0.480, 2.250)**
Guan W et al.	0.908	(0.379, 2.179)
Olweny et al.	1.562	(0.604, 4.037)
Stem JM et al.	0.983	(0.435, 2.221)
Sung HH et al.	0.854	(0.369, 1.977)
Takaki et al.	1.099	(0.486, 2.483)
Bird VG et al.	1.043	(0.467, 2.330)

5-year Overall Survival[23]

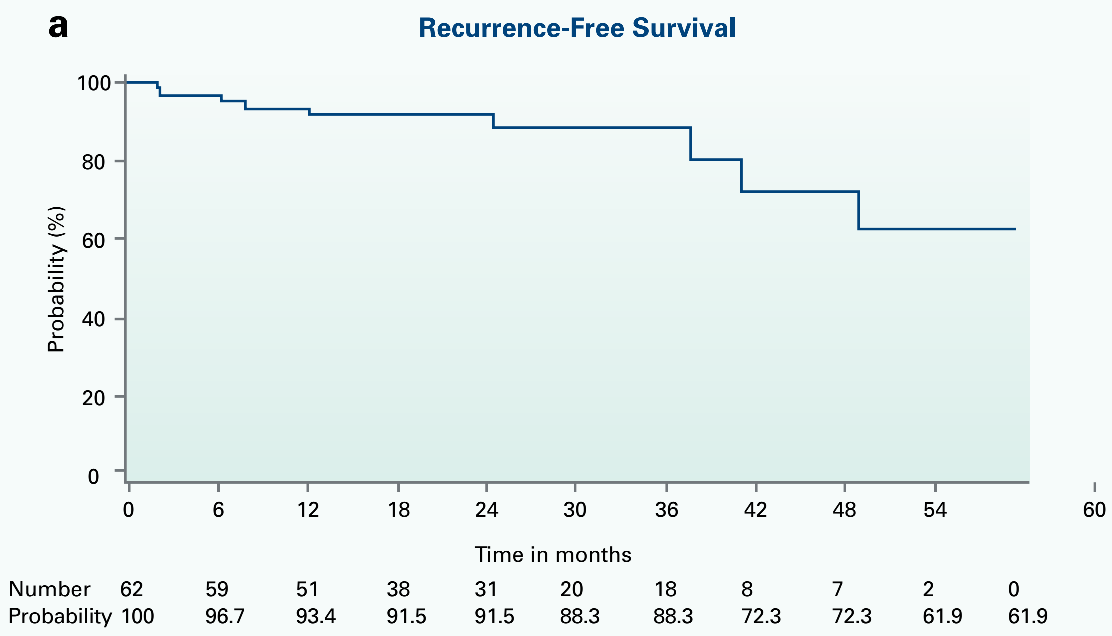


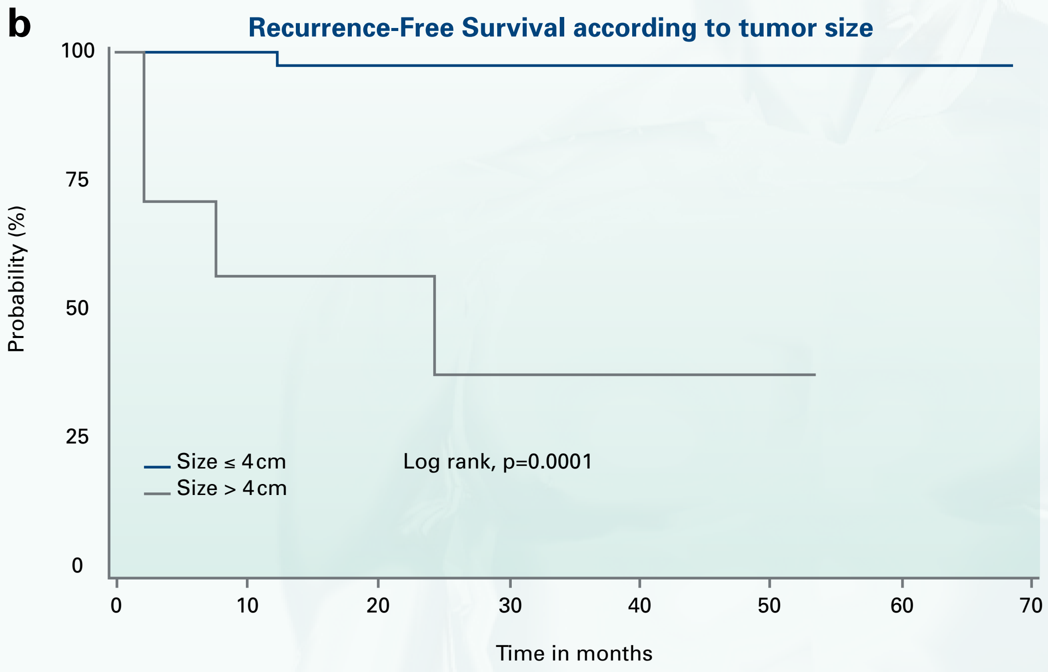
with
- Near 100 % of complete ablation[23]
- Low complication[23,24]
- Less morbidity than extirpation[23]
- Improved recuperation[23]
- Nephron sparing
- Laparoscopic approach to overcome poor locations such as close to ureter and bowel[23]
- Improved quality of life[25]

23. Laparoscopic radiofrequency ablation of small renal tumors: long-term oncologic outcomes. Ramirez D1 .et al. JOURNAL OF ENDOUROLOGY Volume 28, Number 3, March 2014 ª Mary Ann Liebert, Inc. Pp. 330–334
24. Systematic Review and Meta-Analysis of Thermal AblationVersus Surgical Nephrectomy for Small Renal Tumours.K. Katsanos et al - Cardiovasc Intervent Radiol (2014) 37:427–437 DOI: 10.1007/s00270-014-0846-9
25. Ten-year experience of percutaneous image-guided radiofrequency ablation of malignant renal tumours in high-risk patients- P. Balageas-Eur Radiol (2013) 23:1925–1932 DOI 10.1007/s00330-013-2784-3

Effective treatment option in poor surgical candidates, up to 4 cm exophytic and parenchymal tumors[25]

100 % primary technical success in < 4 cm tumors with complete ablation at 1st RFA.[26]





	≤ 3 cm	> 3 cm
Overall Survival	90,1 %	44 %
Median survival	68 Months	55 Months

Size of tumor is clearly predictive factor of residual tumor occurence[25]

Overcome adjacent structures poor locations using
- Physically separate and protect tissues adjacent to thermal ablations
  - **Contrast Media-Doped Hydrodissection for organ hydrodissection**[26]
  - Imaging-guided percutaneous CO_2 injection[27]
- Laparoscopic approach[23]

25. Ten-year experience of percutaneous image-guided radiofrequency ablation of malignant renal tumours in high-risk patients- P. Balageas-Eur Radiol (2013) 23:1925–1932 DOI 10.1007/s00330-013-2784-3
26. Contrast Media-Doped Hydrodissection During Thermal Ablation: Optimizing Contrast Media Concentration for Improved Visibility on CT Images- Calista Campbell et al. AJR:199, September 2012
27. Radiofrequency Ablation Combined with CO_2 Injection for Treatment of Retroperitoneal Tumor: Protecting Surrounding Organs Against Thermal Injury - Shuji Kariya et al. AJR:185, October 2005

Minimally invasive Cost effective treatment option[28]

Equivalent to Cryoablation but – Simple – Lower cost:
In average, cryoablation requires a greater number of probes than RFA.[28]

Local recurrence free survival rate[29]

	1 year	3 years	5 years
RFA	100%	98,1%	98,1%
Cryoblation	97,3%	90,6%	90,6%

Umbrella Expandable design

Procedural Need/Intent	LeVeen™ Needle Electrodes	LeVeen SuperSlim™ Electrodes	LeVeen CoAccess™ Electrodes
No-Touch technique in single tumor tumor as long as ablation zone is surrounding the tumor	✓		✓
Security Margin ablation when nodule totally inside the umbrella	✓	✓	✓
Easy Placement & Ballistic	✓	✓	✓
Stable probe array	✓	✓	✓
17G low profile needle for minimally invasive small tumors ablation		✓	
Combined biopsies[30] through single tract			✓
Both protected biopsy[30,31] **and RF ablation**[30]			✓

28. Comparison of procedure costs of various percutaneous tumor ablation modalities.Astani SA, Brown ML, Steusloff K. Radiol Manage. 2014 Jul-Aug;36(4):12-7; quiz 18-9.
29. Percutaneous ablation of renal masses measuring 3.0 cm and smaller: comparative local control and complications after radiofrequency ablation and cryoablation. AJR Am J Roentgenol. 2013; 200 (2): 461-6.
30. Usefulness of Guiding Needles for Radiofrequency Ablative Treatment of Liver TumorsThierry de Baere, Cardiovasc Intervent Radiol (2005)
31. Seeding following percutaneous diagnostic and therapeutic approaches for hepatocellular carcinoma. What is the risk and the outcome? Seeding risk for percutaneous approach of HCC., 2007 Aug;33(5):437-47. Epub 2007 May 18. Stigliano R et al.

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