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7-10 novembre 2013

# Mini-invasive treatments for thyroid lesions RFA



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# Heating and tissue

Temperature (°C)	Cellular Effect
< 40	No significant cell damage
40-49	Reversible cell damage
49-70	Irreversible cell damage (denaturation)
70-100	Coagulation (collagens converted to glucose)
100-200	Desiccation (boiling of intra- and extra-cellular water)
>200	Carbonization



# RFA: previous applications



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**Heat induced radiofrequency ablation (RFA) is a consolidated, safe and minimally invasive approach for the treatment of neoplasms of different organs (liver, kidney, spleen, prostate, breast, lung and bone)**



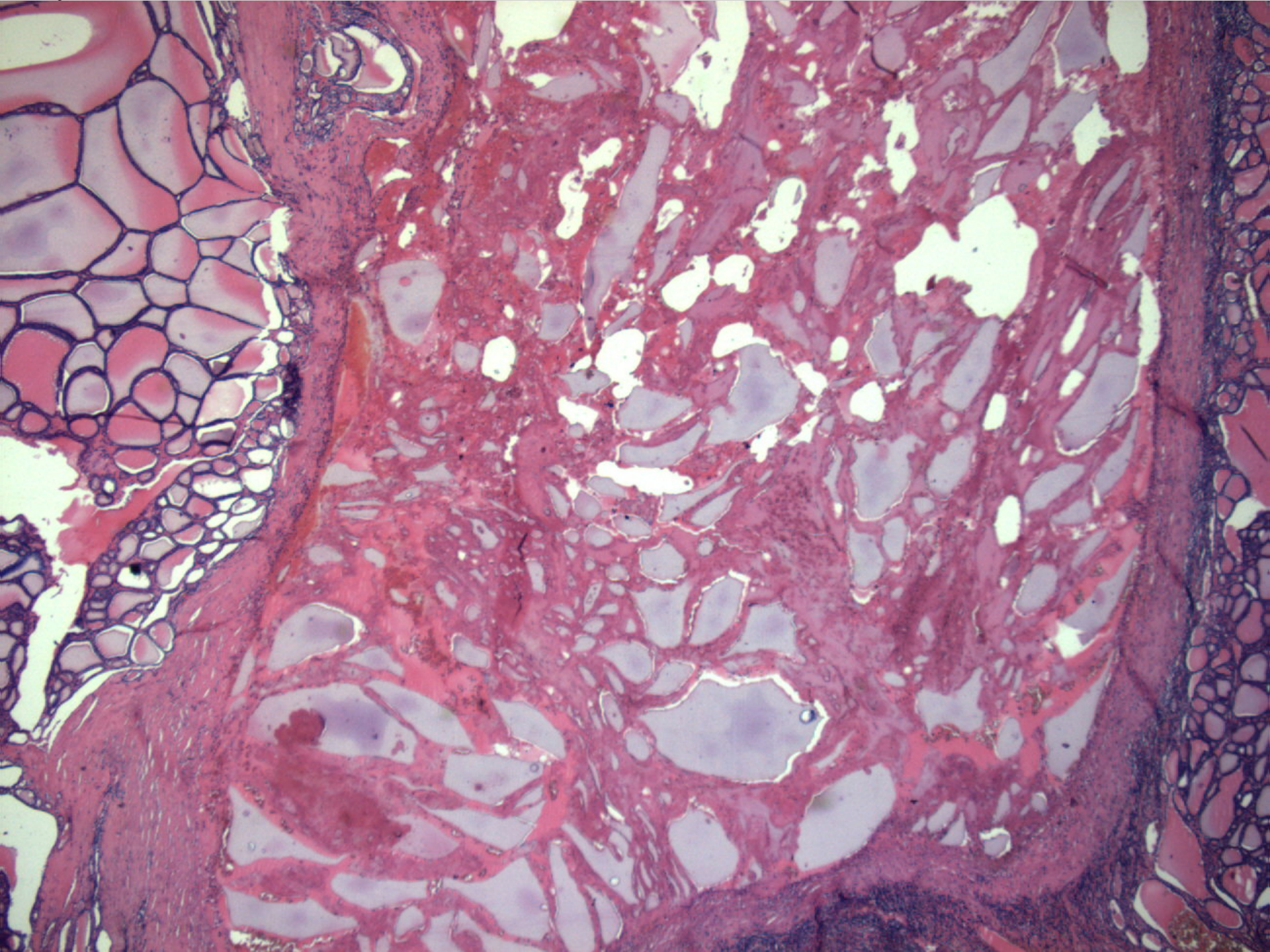


# RFA and the thyroid



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# RFA: 14 G hooked array



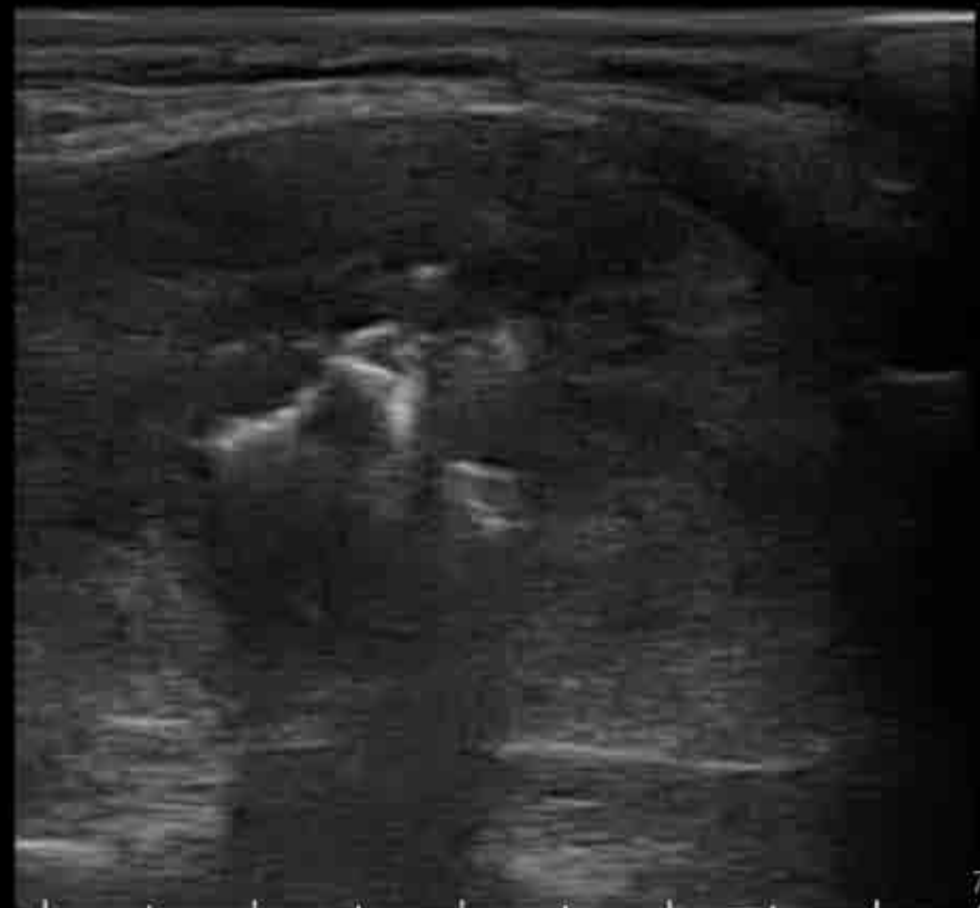
R-----



B	RIS-B	G	---
P	44mm	XV	6
PRC	11/1/1	PRS	10
PST	2	C	2

3  
GENERALE

9  
LA522

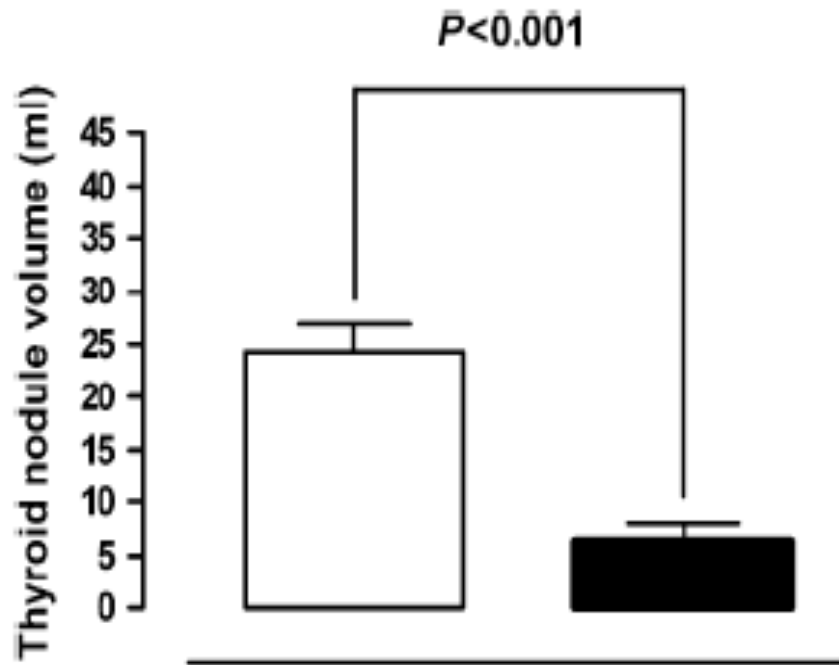


0  
1  
2  
3  
4

INIZIO

71Hz

# EFFICACY AND SAFETY OF RADIOFREQUENCY THERMAL ABLATION IN THE TREATMENT OF THYROID NODULES WITH PRESSURE SYMPTOMS IN ELDERLY PATIENTS



39 elderly patients with cytologically benign compressive TN underwent RTA (hook umbrella, Starburst, RITA Medical Systems, Mountain View, CA).

Pressure symptoms in the neck improved in all patients, with complete symptom disappearance in most.

No patient needed hospitalization after RTA, and no major complication was observed.

**TN volume decrease 6 months after RTA: 74%**



# US-GUIDED PERCUTANEOUS RADIOFREQUENCY THERMAL ABLATION FOR THE TREATMENT OF SOLID BENIGN HYPERFUNCTIONING OR COMPRESSIVE THYROID NODULES

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ANNAMARIA COLAO,<sup>§</sup> FILIPPO MOLINARI,<sup>¶</sup> and ROBERTO GARBEROGLIO<sup>¶</sup>

Ultrasound in Med. & Biol., Vol. 34, No. 3, pp. 784–791, 2008

## Patients

Number	57
Sex	16♂ / 41♀
Age range	28 - 88
Median age	63.8

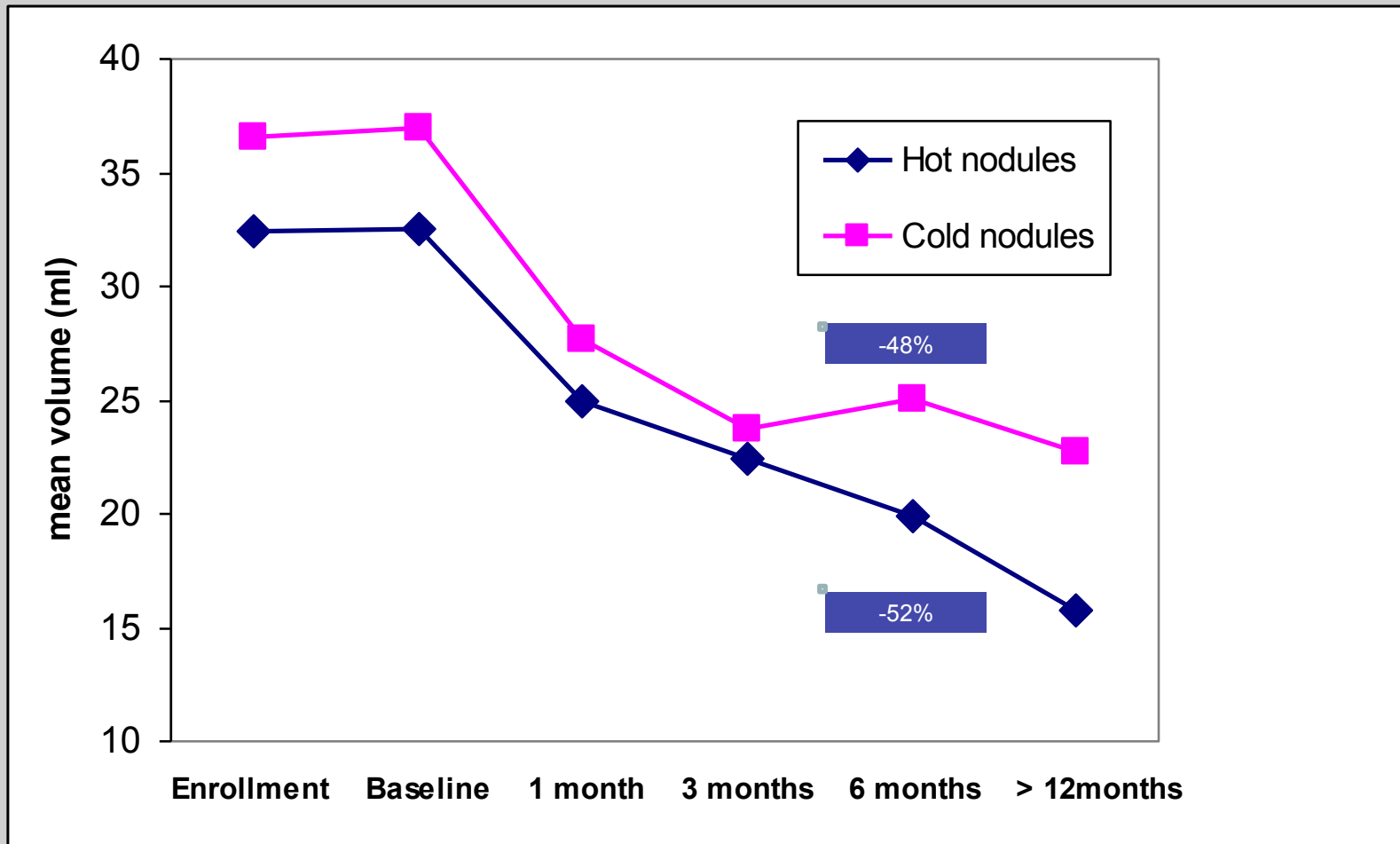
## Nodules

Number	59
Volume min-max (ml)	2.5 / 180.2
Volume medium $\pm 2$ SD (ml)	34.5 $\pm$ 31

## Function

Cold Nodules	26
Hot nodules	33

# Volume Shrinkage



## Thyroid Nodules and Related Symptoms Are Stably Controlled Two Years After Radiofrequency Thermal Ablation

Stefano Spiezia,<sup>1</sup> Roberto Garberoglio,<sup>2</sup> Francesco Milone,<sup>3</sup> Valeria Ramundo,<sup>3</sup> Corrado Calazzo,<sup>1</sup> Angelo Pio Assanti,<sup>1</sup> Maurilio Deandrea,<sup>2</sup> Paolo P. Limone,<sup>2</sup> Paolo E. Macchia,<sup>3</sup> Gaetano Lombardi,<sup>3</sup> Annamaria Colao,<sup>3</sup> and Antongiulio Faggiano<sup>3</sup>

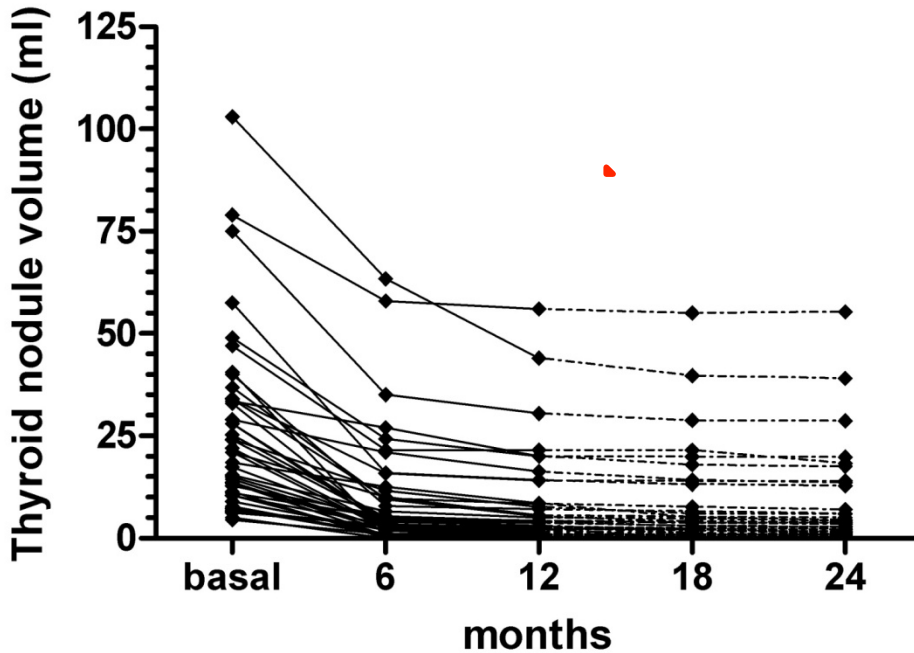


TABLE I. CHARACTERISTICS OF PATIENT POPULATION AND THYROID NODULES

No. of patients	94
Age (range, mean $\pm$ SEM)	66-89, 72.5 $\pm$ 0.5 years
Sex M/F	39/55
Thyroid nodule volume (nontoxic + toxic/pretoxic nodules)	
Mean $\pm$ SEM	24.5 $\pm$ 2.1 mL
Range	4.5-103 mL
Nontoxic thyroid nodule volume	
Mean $\pm$ SEM	21.1 $\pm$ 1.7 mL
Range	4.5-73.2 mL
Toxic and pretoxic thyroid nodule volume	
Mean $\pm$ SEM	32.7 $\pm$ 5.4 mL
Range	5.3-103 mL

*US response:*

- 2 year follow-up
- 1 to 3 (1.4) sessions
- 70.9% reduction





# RFA: saline infusion



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# Thyroid Nodules Treated with Percutaneous Radiofrequency Thermal Ablation: A Comparative Study

J Clin Endocrinol Metab, December 2012, 97(12):4439–4445

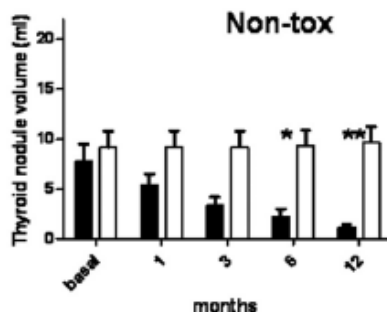
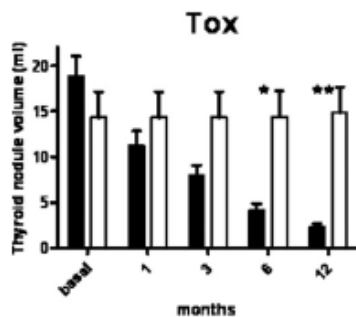
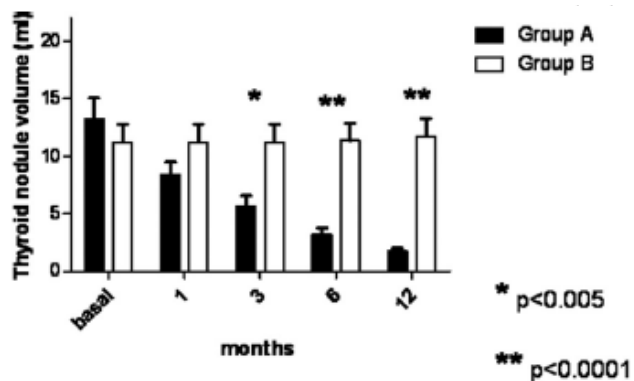
A. Faggiano, V. Ramundo, A. P. Assanti, F. Fonderico, P. E. Macchia, C. Misso, F. Marciello, V. Marotta, M. Del Prete, E. Papini, G. Lombardi, A. Colao, and S. Spiezia



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TABLE 1. Baseline characteristics of patients with TNs

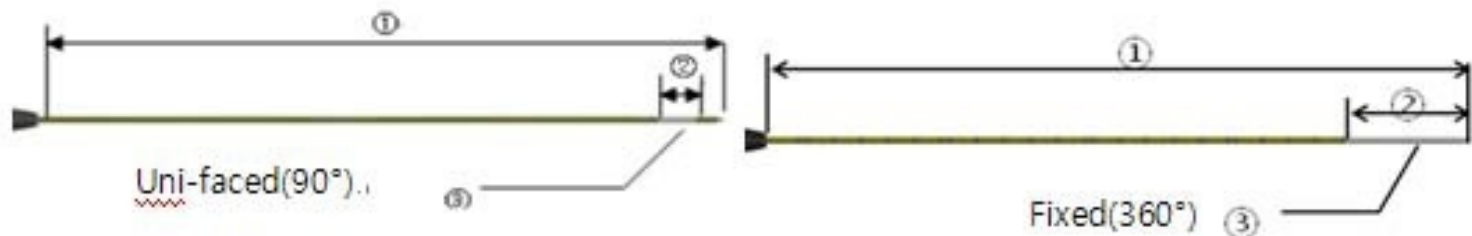
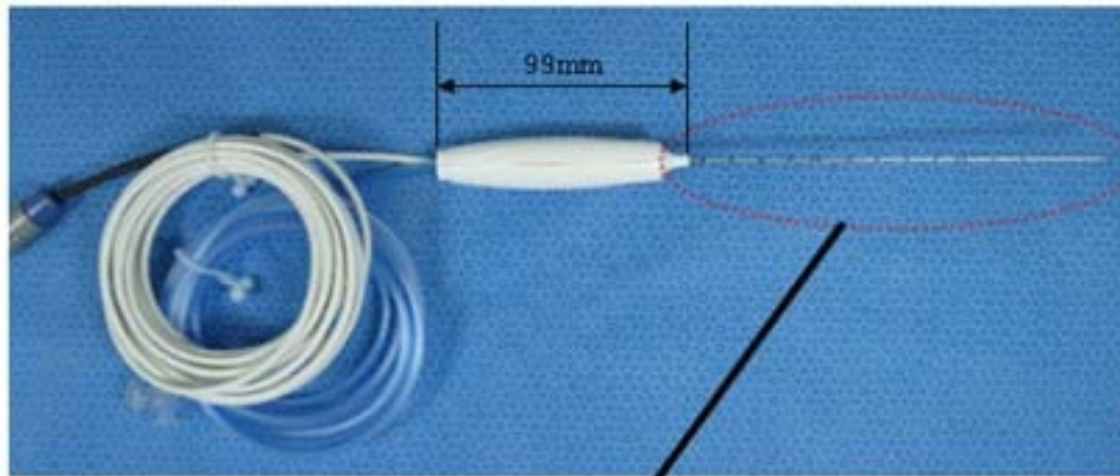
Parameter	Group A	Group B	P
n	20	20	NS
Sex (males/females)	4/16	5/15	NS
Age in years, mean ± SEM (range)	58.3 ± 4.3 (31–86)	62.1 ± 3.1 (36–85)	NS
TN volume (ml)			
Mean ± SEM	13.3 ± 1.8	11.2 ± 1.5	NS
Median	12.35	7.7	
Range	4–27.9	3.6–25.8	
Patients with nontoxic TNs (n)	10	12	NS
Patients with toxic TNs (n)	10	8	NS
SYS score (range)	3.4 ± 0.3 (1–5)	3.0 ± 0.3 (1–5)	NS



# Different Technology: cold needle, 18 G



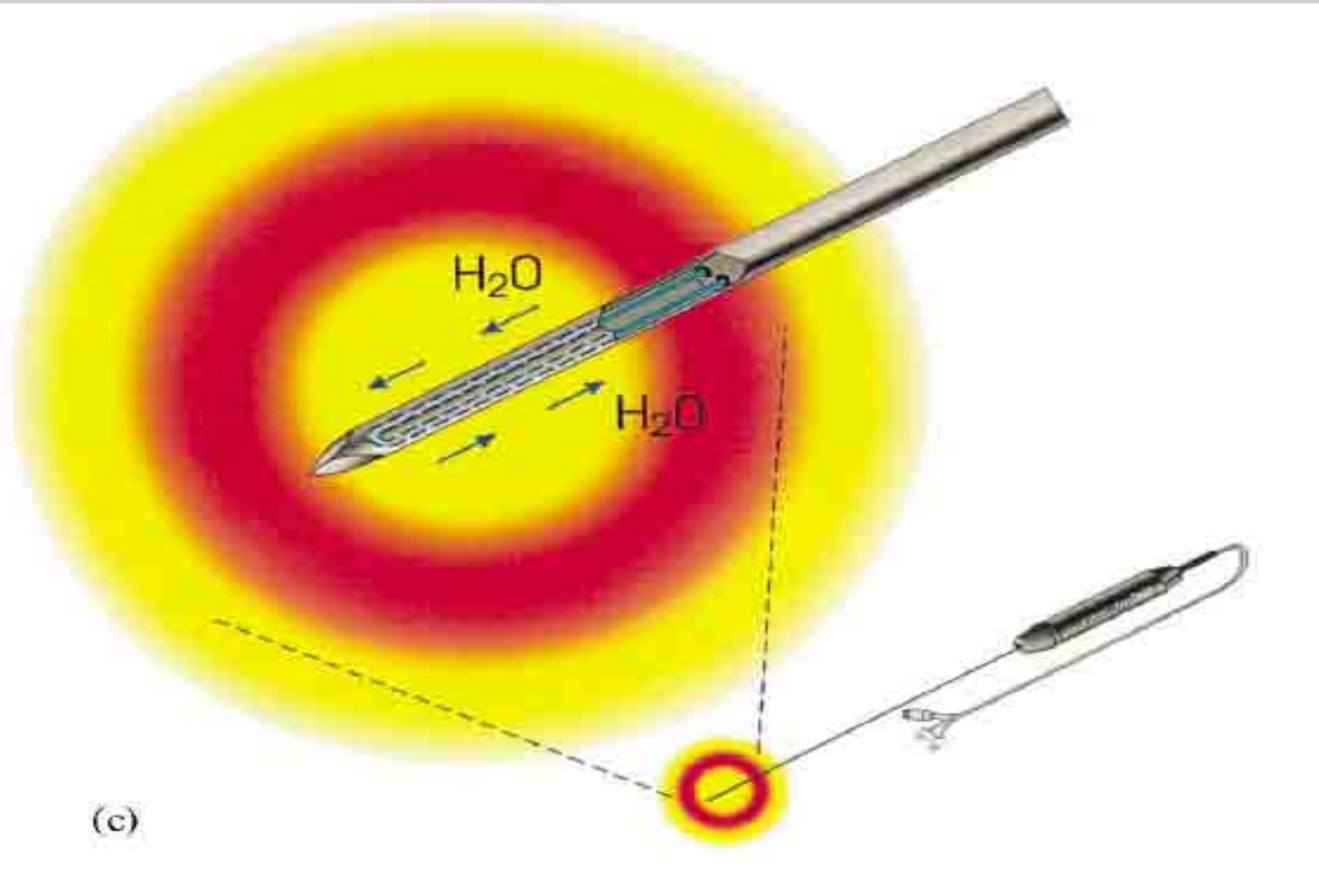
Fig. 1 Modified internally cooled electrode for thyroid lesion, which is shorter (7 cm shaft length) and thinner (18G) than conventional electrode



# Internally cooled needle



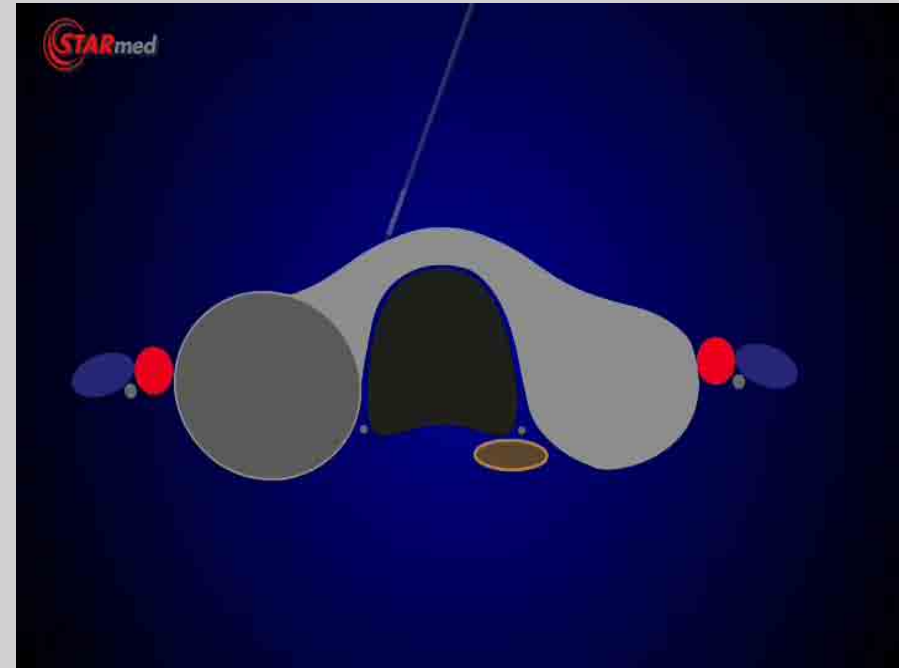
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# *The “moving – shot technique”*







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Jung Hwan Baik  
Hyunchul Rhim  
Yoon Suk Kim  
Min Sook Kwak  
Hyon Jo Jeong  
Ducky Lee

## Radiofrequency ablation of benign thyroid nodules: safety and imaging follow-up in 236 patients

**Table 1** The changes in volume before RFA and at each follow-up

	Initial	1 month later	3 months later	6 months later	Last follow-up
No. of nodules	302	247	155	140	302
Volume (ml) <sup>a</sup>	0.11–95.61 (6.13±9.59)	0.00–40.30 (2.53±4.40)	0.00–24.17 (2.00±3.24)	0.00–30.11 (1.54±4.38)	0.00–26.07 (1.12±2.92)
Largest diameter (cm) <sup>a</sup>	0.6–10.00 (2.44±1.36)	0.00–7.00 (1.73±1.03)	0.00–5.20 (1.60±0.97)	0.00–6.00 (1.26±1.07)	0.00–5.70 (1.01±1.00)
Volume reduction rate (%)		58.20	74.41	84.79	84.11

<sup>a</sup>Mean ±standard deviation in parentheses

**Table 2. Basic Characteristics and Treatment Results of Patients Undergoing Radiofrequency Ablation of Thyroid Nodules**

	Kim et al., 2006 (29)	Jeong et al., 2008 (2)	Deandrea et al., 2008 (26)	Spiezia et al., 2009 (28)	Baek et al., 2009 (25)	Baek et al., 2010 (24)	Lee et al., 2010 (15)
Number of patients	35	302	33	94	9	15	27
Number of nodules	30	236	31	94	9	15	27
Nodule type	Cold	Cold	Cold + AFTN	Cold + AFTN	AFTN	Cold	Cold
Solid component (%)	0-100	0-100	> 30	> 30	60-100	> 50	10-50
Follow-up period (months)	1-18	1-41	6	12-24	6-17	6-8	6-38
V initial (mL)	6.3	6.13	27.7	24.5	15.0	7.5	14.0
VR1 (%)	47	58	33	54	36	49	-
VR6 (%)	64	85	51	-	71	80	92
VRlast (%)	-	84	-	79	75	-	97
Session (mean)	1	1-6 (1.4)	1	1-3 (1.4)	1-4 (2.2)	1	1-4 (1.6)
Electrode type	Internally cooled	Internally cooled	Multitined expandable	Multitined expandable	Internally cooled	Internally cooled	Internally cooled

**Note.** — AFTN = autonomously functioning thyroid nodule, V = volume, VR = volume reduction



**Table 3. Complications Associated with Radiofrequency Ablation of Thyroid Nodules**

	Kim et al., 2006 (29)	Jeong et al., 2008 (2)	Deandrea et al., 2008 (26)	Spiezia et al., 2009 (28)	Baek et al., 2009 (25)	Baek et al., 2010 (24)	Lee et al., 2010 (15)	Total
Number of patients	30	236	31	94	9	15	27	442
Hematoma	1	5	-	-	-	-	1	7
Skin burn	1	-	-	-	-	-	-	1
Pain	1	13	Few	13	-	-	-	27
Elevation of fT4 level	3	-	-	-	-	-	-	3
Decreased TSH level	-	3	-	-	-	-	-	3
Hypothyroidism	-	-	-	-	1	-	-	1
Edema	-	-	3	-	-	-	-	3
Fever	-	-	-	5	-	-	-	5
Voice change	1	3	-	-	-	-	-	1

**Note.** — fT4 = free T4, TSH = thyrotrophin

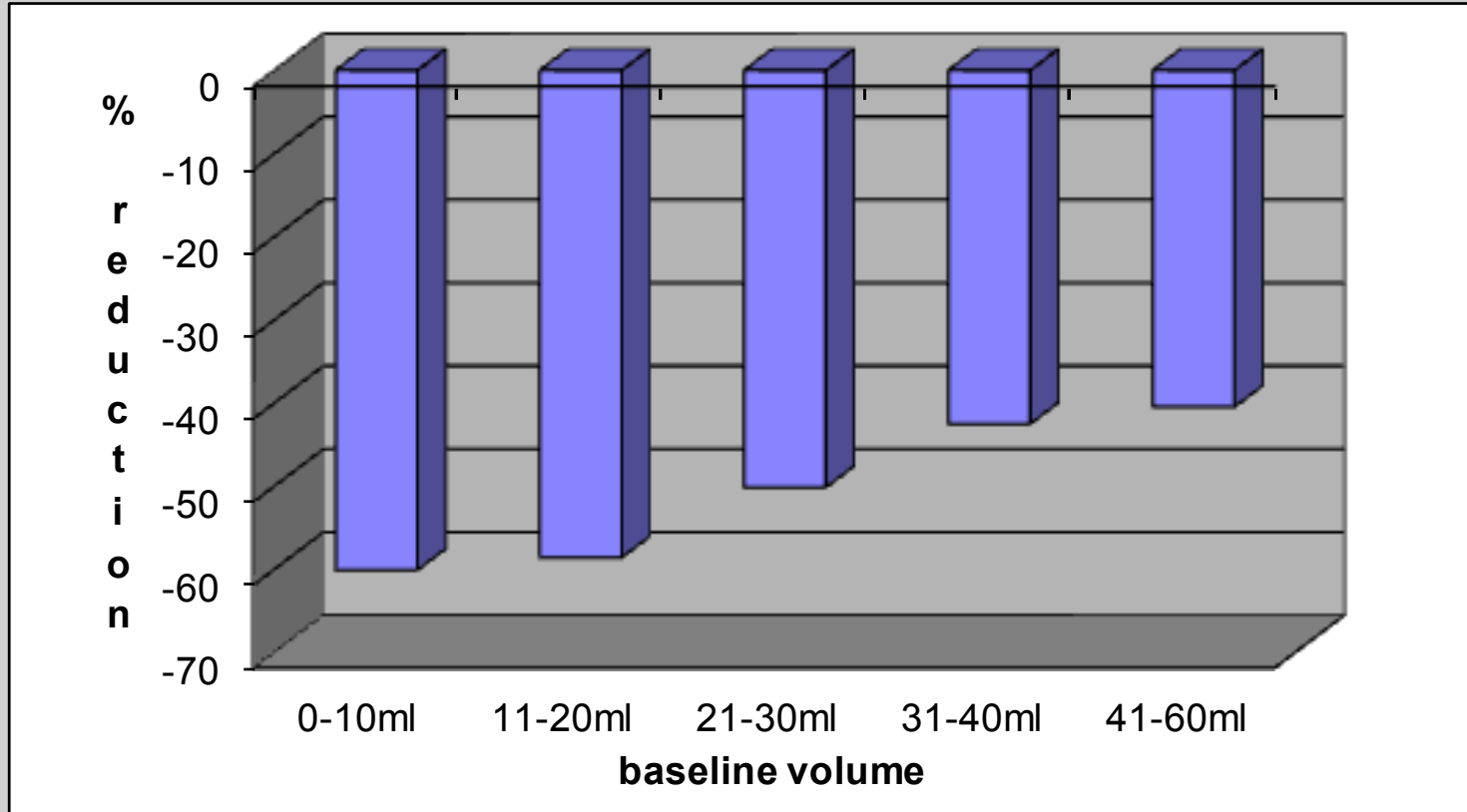




# (MOVING-SHOT - personal series - first 73 cases)



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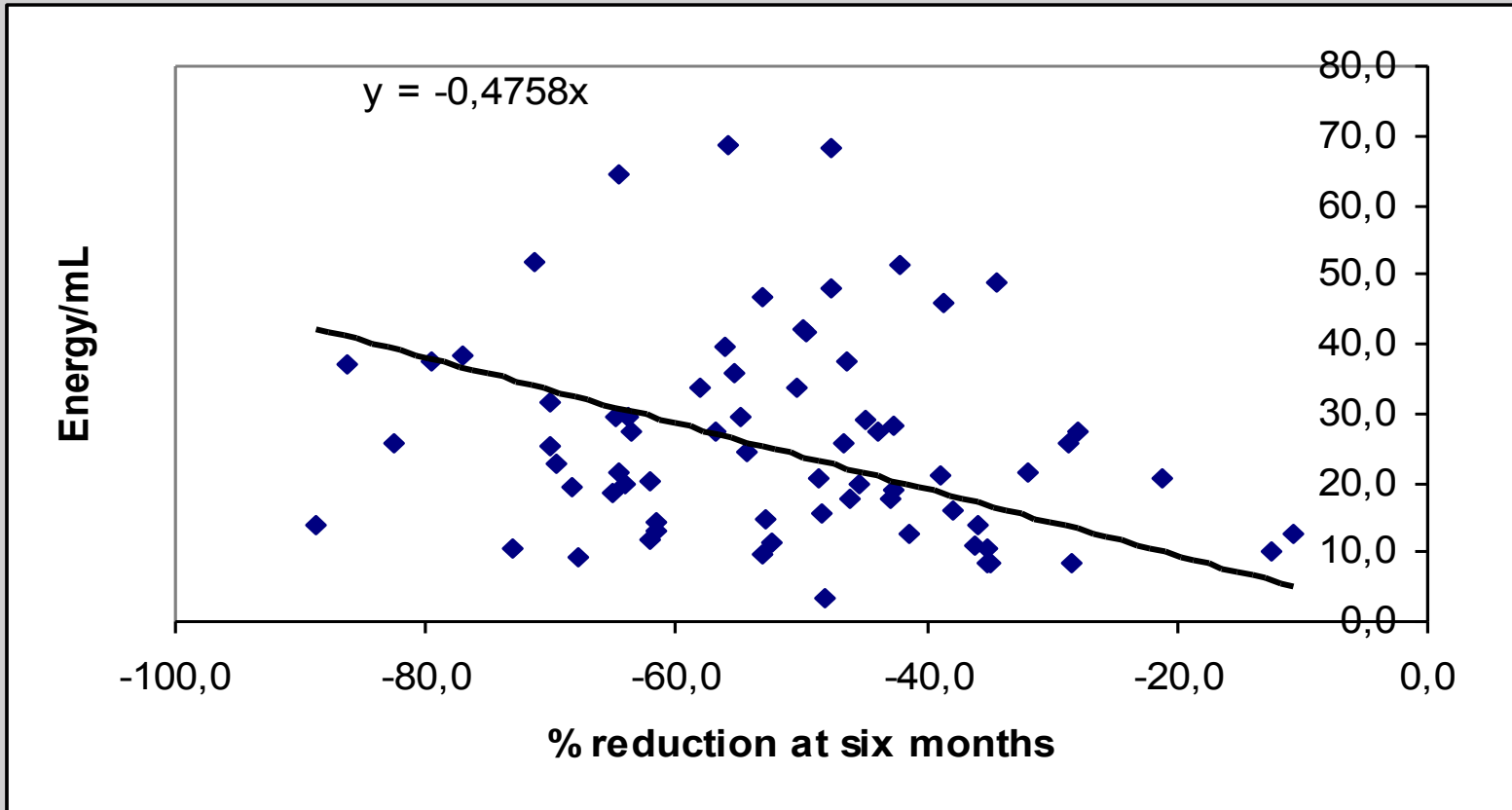




# Mean volume reduction according to the delivered energy/ml of the nodule volume



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# Open Issues



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- **Different nodule population**
- **Different needles**
- **Different methodology of treatment**
- **Only retrospective/perspective, not randomized studies available**



# Design of the study



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**Perspective randomized trial** to assess RF ablation efficacy in the treatment of compressive benign thyroid nodules

For this aim we selected a group of **benign nonfunctioning medium sized thyroid nodules** randomized to observation (40) or to a single session of RFA (40).

We applied the **moving-shot technique** in Italy and Korea centers to compare results in groups with large experience in radiofrequency thermal ablation.





# Treatment Methodology



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Moving shot technique (Baek protocol)♪

**Trans-isthmus approach in a single session treatment**♪

Internally-cooled electrode (1-cm active tip) StarMed 18G.♪

Power: 35-80 watts♪

Ablation time: less than 20 minutes (only ablation time)

## *Other methodological aspects*♪

Use only local anesthesia (mepivacaine)♪

No skin incision to prevent unnecessary scar♪

No aspiration of small fluid collection in the nodule when present.

**Neither analgesia nor sedation before or during the ablation.**♪

If the patient experienced intolerable pain during RF ablation, the power was reduced or turned off for several seconds, and when the pain or discomfort dissipated, the procedure was continued. ♪





# Results: pts and energy delivered



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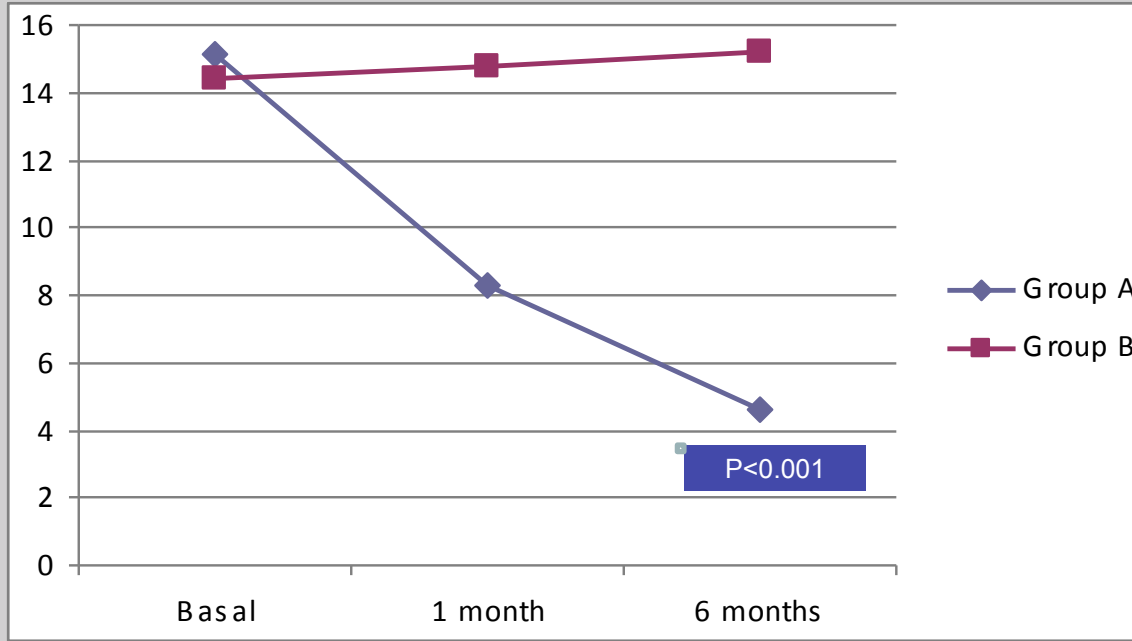
	Korea	Italy	P
<b>Females/Males</b>	36/4	34/6	NS
<b>Age</b>	39,5±9,5	56,5±14,2	0,06
<b>Ablation time</b>	7,2±2,3	14,2±3,5	0,03
<b>RF Power</b>	75,2±10,4	50,3±5,1	0,05
<b>Energy/ml</b>	40,6±15,2	43,6±12,7	NS
<b>Thyroid function</b>	normal	normal	
<b>Complications</b>	none	none	NS



# Results: volume reduction

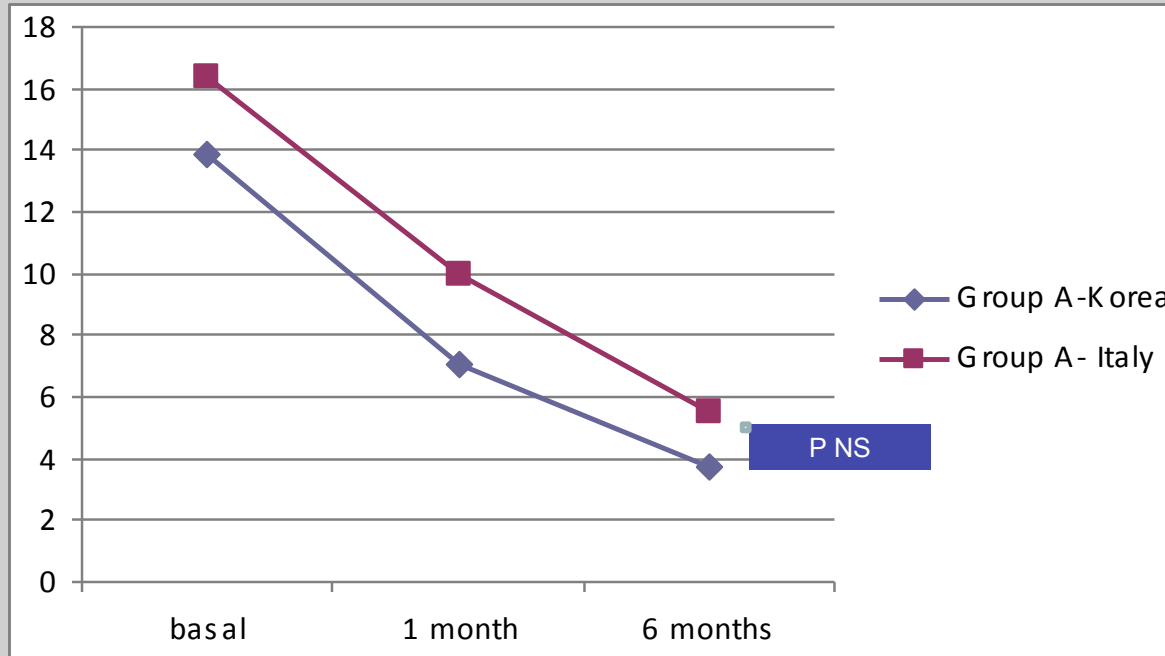


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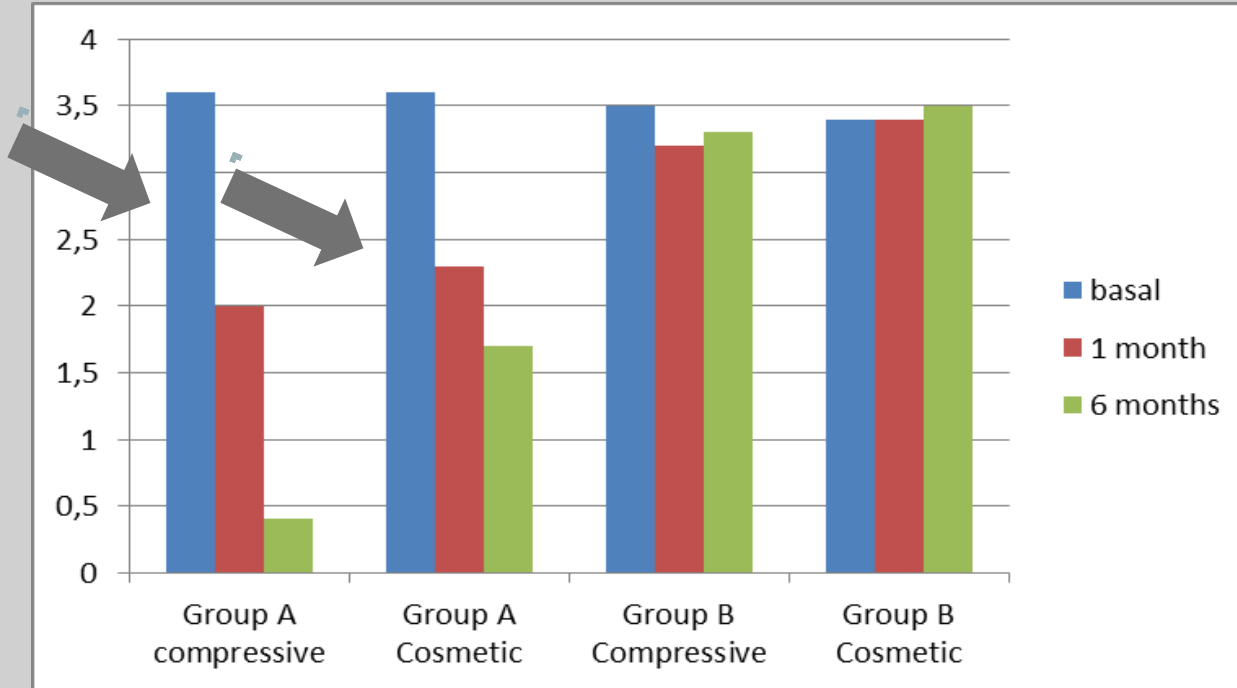
	Group A Volume (mean±SD)	% Volume	Group B Volume (mean±SD)	% Volume
<b>Basal</b>	15.1±3.1	-	14.4±3.3	-
<b>1 month</b>	8.3±2.9	- 40%	14.8±3.5	+2.7%
<b>6 months</b>	4.6±2.7	- 70%	15.2±3.5	+5.5%

# Volume reduction: different countries



	Group A- Korea Vol (mean±SD)	Volume reduction	Group A – Italy Vol (mean±SD)	Volume reduction
<b>Basal</b>	13.9±3.3	-	16.4±2.5	-
<b>1 month</b>	7.0±2.6	45%	9.9±2.7	35%
<b>6 months</b>	3.7±2.9	73%	5.5±2.2	66%

# Aesthetic/compressive symptoms



	Group A Compressive	Group A Cosmetic	Group B Compressive	Group B Cosmetic
<b>Basal</b>	3.6±1.9	3.6±0.5	3.5±1.7	3.4±0.7
<b>1 month</b>	2.0±1.7	2.3±0.7	3.2±1.9	3.4±0.9
<b>6 months</b>	0.4±0.7	1.7±0.8	3.3±1.7	3.5±0.7



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# Conclusions

- In our eight-year experience, RFA was very effective in obtaining a reduction of both volume and compressive symptoms of benign non-functioning solid thyroid nodules.
- The lack of a controlled randomized study including a large population, could have limited, until now, a wide acceptance of this technique.
- The results of the ongoing international study, if confirmed at a longer follow-up, could definitely establish the efficacy and the safety of RFA for the treatment of thyroid nodules.





# Further considerations



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- Our randomized study can provide useful information regarding technical procedure and clinical indications for selecting patients in order to obtain optimal nodule shrinkage, without serious side effects.
- Training in interventional ultrasound techniques is mandatory for a safe use of this therapeutic tool and for a good outcome.
- RFA could save money for the public health system.





# Acknowledgements



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# Acknowledgements



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**Thanks for your attention**

