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Laser Ablation versus Radiofrequency Ablation for benign non-functioning thyroid nodules

Six-month results of a randomised, parallel, open-label, trial (LARA trial)

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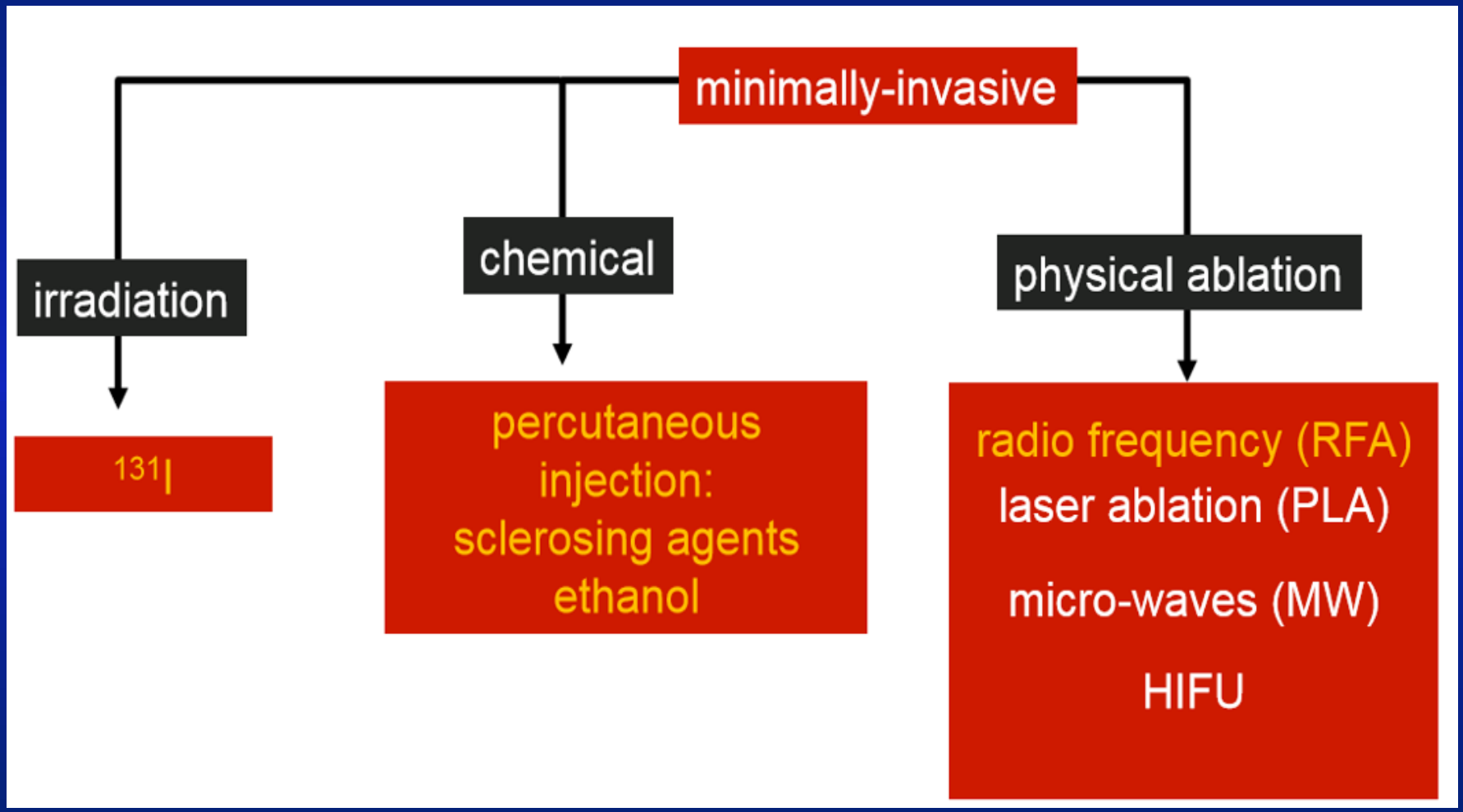
Conflict of interest

I DO NOT HAVE ANY CONFLICT OF INTEREST

NON SURGICAL TECHNIQUES FOR THYROID ABLATION



Minimally Invasive Ablation Techniques (AACE/AME GUIDELINES 2008)

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS, AMERICAN COLLEGE OF ENDOCRINOLOGY, AND ASSOCIAZIONE MEDICI ENDOCRINOLOGI MEDICAL GUIDELINES FOR CLINICAL PRACTICE FOR THE DIAGNOSIS AND MANAGEMENT OF THYROID NODULES – 2016 UPDATE

EXECUTIVE SUMMARY OF RECOMMENDATIONS

7.2.5. *Image-guided thermal ablation for benign nodules*

- Consider laser or radiofrequency ablation for the treatment of solid or complex thyroid nodules that progressively enlarge or are symptomatic or cause cosmetic concern [BEL 2, GRADE C].

ENDOCRINE PRACTICE 2016

2017 Thyroid Radiofrequency Ablation Guideline: Korean Society of Thyroid Radiology

Recommendation 1-1

Radiofrequency ablation is indicated for patients with benign thyroid nodules complaining of symptomatic or cosmetic problems.
(strong recommendation, moderate-quality evidence)

KJR 2017

Minimally-invasive treatments for benign thyroid nodules: a Delphi-based consensus statement from the Italian minimally-invasive treatments of the thyroid (MITT) group

Statement #5. Thermal ablation may be proposed as a first-line treatment for solid nonfunctioning thyroid nodules that are benign at cytology when they become symptomatic.

INT J HYPERT 2019

Efficacy of thermal ablation in benign non-functioning solid thyroid nodule: A systematic review and meta-analysis

Pierpaolo Trimboli[1] · Marco Castellana[2] · Luca Maria Sconfienza[3,4] · Camilla Virili[5] · Lorenzo Carlo Pescatori[6] · Roberto Cesareo[7] · Francesco Giorgino[2] · Roberto Negro[8] · Luca Giovanella[1,9] · Giovanni Mauri[10]

Table 3 Volume reduction rate of BNFSTN with all thermal treatments, RFA or laser ablation, according to follow-up and number of sessions

	6-month assessment			12-month assessment			24-month assessment			36-month assessment		
	Number of BNFSTN (number of studies)	VRR (%)	I^2	Number of BNFSTN (number of studies)	VRR (%)	I^2	Number of BNFSTN (number of studies)	VRR (%)	I^2	Number of BNFSTN (number of studies)	VRR (%)	I^2
Overall results of thermal ablation												
All studies	1479 (19)	60	97	2960 (17)	66	99	598 (7)	62	99	370 (5)	53	99
Single session treatment	1123 (16)	57	97	1034 (12)	59	99	323 (5)	51	98	289 (4)	44	94
Radiofrequency ablation												
All studies	1120 (11)	68‡	98	1023 (8)	75‡	98	315 (3)	87†‡	85	–	–	–
Single session treatment	779 (8)	67‡	97	631 (4)	71‡	98	–	–	–	–	–	–
Laser ablation												
All studies	359 (8)	48‡	11	1937 (9)	52‡	97	283 (4)	45‡	96	289 (4)	44	94
Single session treatment	344 (8)	47‡	0	403 (8)	49‡	86	283 (4)	45	96	289 (4)	44	94

†$p < 0.05$ versus previous assessment with the same technique

‡$p < 0.05$ for RFA versus laser ablation at the same follow-up

ENDOCRINE 2019

AIM OF THE STUDY

Laser **A**blation versus **Ra**diofrequency **A**blation for benign non-functioning thyroid nodules: Six-month results of a randomised, parallel, open-label, trial (**LARA trial**)

The primary endpoint was to evaluate the difference in nodule volume reduction between RF and LA group at six months.

The co-primary endpoint was the difference between groups in the rate of nodules (%) greater than the 50% baseline volume reduction, 6 months after the treatment (success rate)

As secondary endpoint we explored the hypothesis, never tested so far, that histopathological features of thyroid nodules could predict the volumetric response to treatment

METHODS 1

LARA is a six-month, single-use, randomized, superiority, open-label, parallel trial.

We enrolled subjects with a solitary BNTN or dominant nodule characterized by pressure symptoms/cosmetic problems.

Patients were randomly assigned (1:1) to receive treatment with either LA or RFA

Nodules underwent core needle biopsy (CNB) to evaluate the histological architecture.

Setting : *Unit of metabolic diseases, "S. M. Goretti" Hospital, Latina, Italy*

Trial registration: *Clinical trials: LA vs RFA for BTN; NCT02714946*;

METHODS 2

SAMPLE SIZE

Sample size of 30 partecipants per group was needed to have a power of about 90%, with a type error rate of 5%
With the same sample size, we could detect a medium-sized standardized difference in the successful rate (number of patients with volume reduction ≥50%) in the two groups

INCLUSION CRITERIA

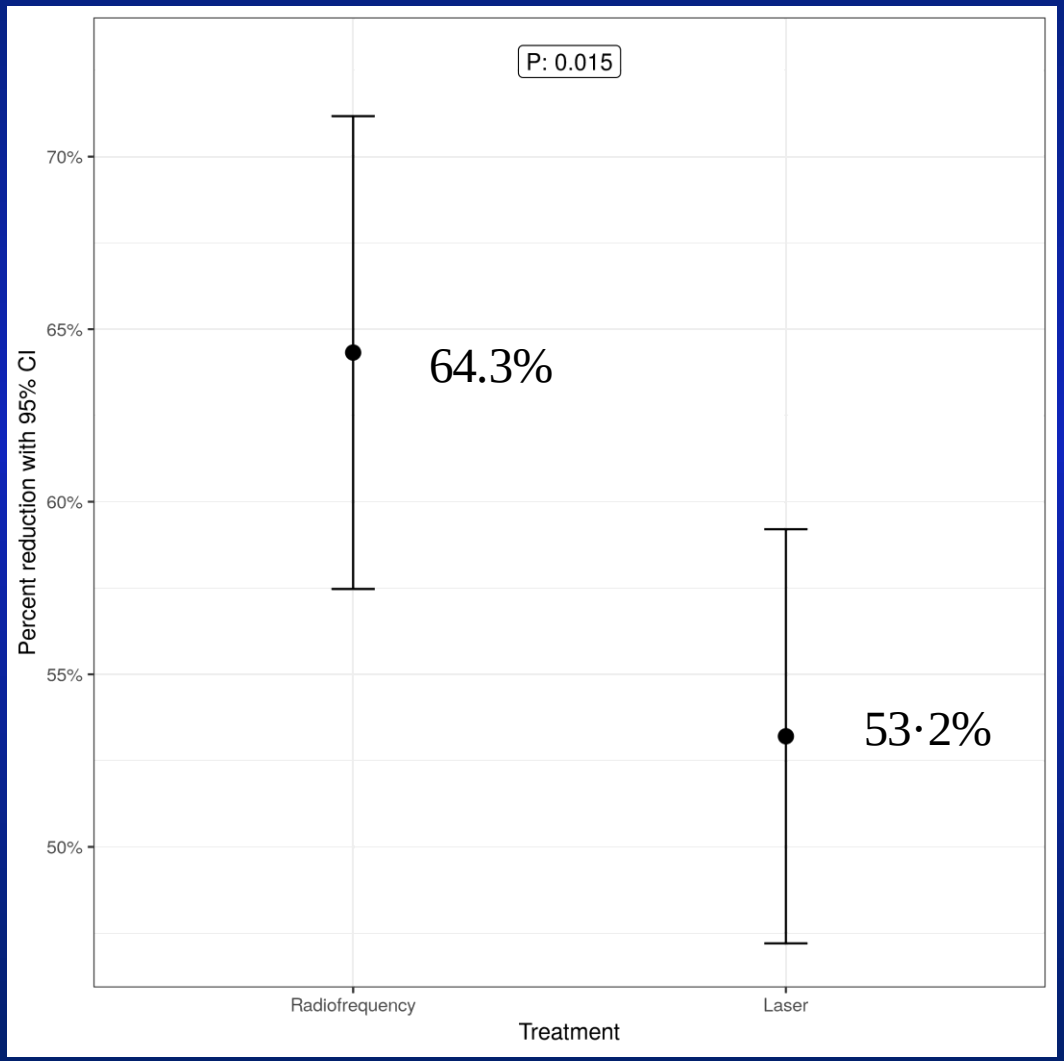
a) solitary thyroid nodule or dominating nodule in multinodular goitre;
(c) nodule volume ≥5 mL;
(d) presence of a solid thyroid nodule (solid portion >80%)
(e) occurrence of pressure symptoms or cosmetic problems or an increase in nodule volume >20% in one year regardless of symptoms
(f) confirmation of benign findings using one single fine-needle aspiration and thyroid core needle biopsy
(g) normal serum levels of thyroid hormones, thyrotropin (TSH) calcitonin, and absence of TgAb and TPOAb

BASELINE CHARACTERISTICS

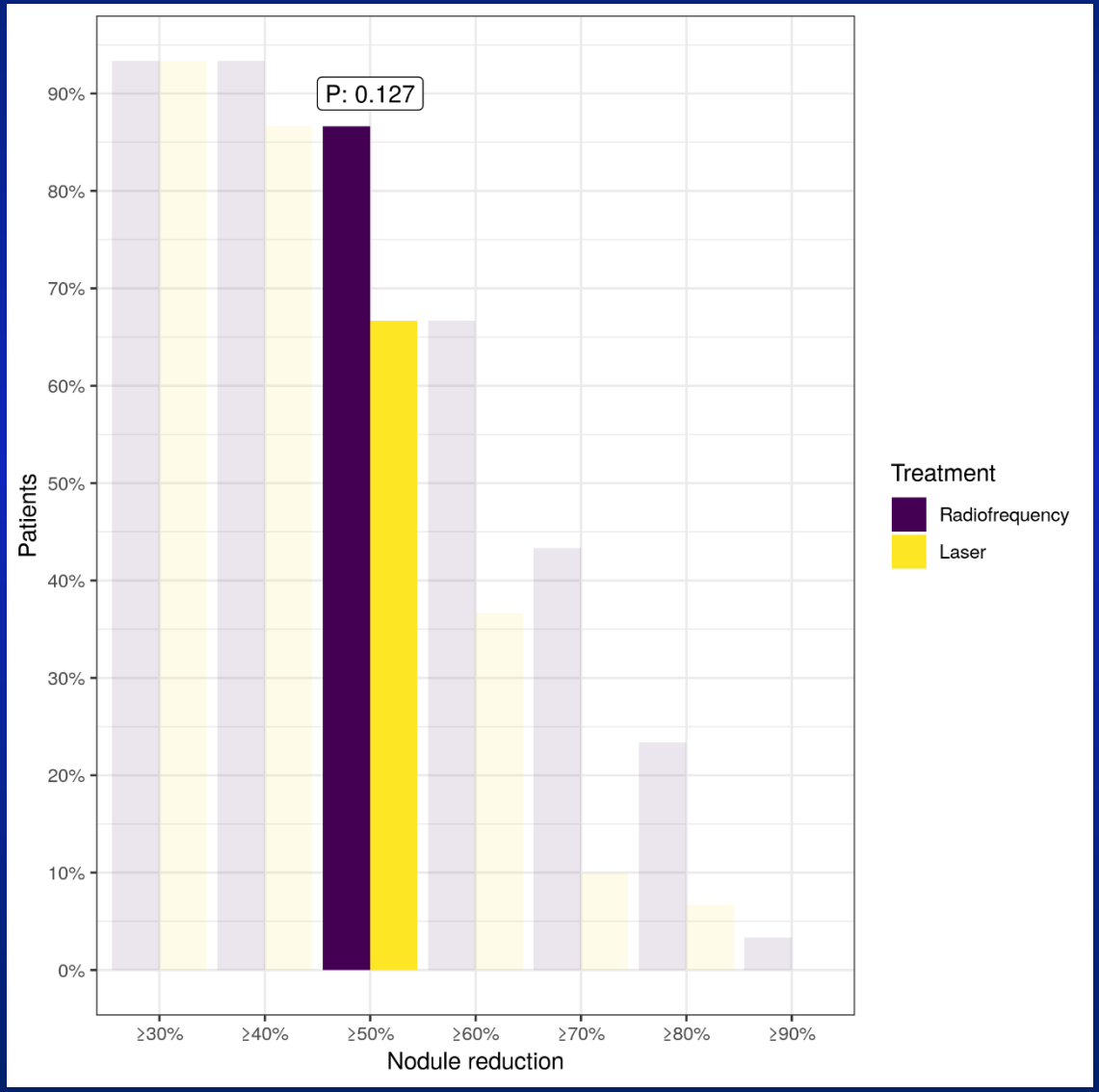
	Laser (SD)	RFA (SD)	P-value
Age (yrs)	59·3 (11·7)	53·3 (14·3)	0·08
Baseline volume (mL)	24·7 (24)	26 (20·9)	0·82
Cellular component (%)	49·2 (18)	50·1 (18)	0·85
Colloidal component (%)	31·7 (13·8)	31·3 (12·8)	0·92
Fibrotic component (%)	19·8 (18·8)	18·6 (18·7)	0·82
Symptoms score	4·5 (2·1)	4·5 (2·5)	1·00
Cosmetic score	3·4 (0·5)	3·4 (0·6)	0·82
TSH (μU/mL)	1·75 (0·6)	1·98 (0·8)	0·52
FT4 (ng/dL)	1·29 (0·22)	1·25 (0·279)	0·54
Necrosis volume (mL)	16·2 (10·4)	21·0 (14·5)	0·15
Total Energy (J)	9540 (3573)	53898 (47494)	<0·001
Energy delivered/volume (J/mL)	496 (209)	2011(95)	0·01
Time (minutes)	23 (8)	16 (13)	0·13

SD, standard deviation; RFA, radiofrequency ablation; TSH, thyrotropin; FT4, free thyroxine

VOLUME REDUCTION RATE AT SIX MONTHS



SUCCESS RATE AT SIX MONTH
(nodules with greater than 50% basal volume reduction)



Correlation between nodule characteristics and volume reduction at 6 months

	RFA *r* coefficient (P-value)	Laser *r* coefficient (P-value)
Baseline volume	0·177 (0·35)	0·296 (0·11)
Coagulative necrosis volume	0·069 (0·72)	0·145 (0·45)
Cellular component (%)	-0·41 (0·03)	-0·066 (0·76)
Fibrotic component (%)	0·366 (0·06)	0·192 (0·38)
Colloidal component (%)	0·042 (0·83)	-0·213 (0·32)

RFA, radiofrequency ablation

Complications and side effects no. (%) time of detection										
	Intra-procedural		Immediate post-procedural (within 24 h)		Peri-procedural (within 30 days)		Delayed (after 30 days)		Maximum Time to recovery (days)	
Type of complications (SIR Class) [a]	LA	RFA	LA	RFA	LA	RFA	LA	RFA	LA	RFA
Major										
Dysphonia	1 (3·3)	1 (3·3)							14	14
Hyperthyroidism					1 (3·3)		1 (3·3)	1 (3·3)	90	90
Minor										
Hematoma	2 (6.6)	3 (10)							10	10
Side effects										
Local pain	5 (17)	6 (20)							1	1
Headache				1(3·3)						1
Fever			3 (10)						60	

a. Society of Interventional Radiology (SIR) guidelines criteria;

The adverse event rates **(local pain, dysphonia, thyrotoxicosis, fever, haematoma)** were 37% (n=11) and 43% (n=13) for RFA and LA, respectively, with no requirement for hospitalization.

CONCLUSIONS

- LARA trial confirmed that both techniques are very effective in reducing thyroid nodules volume after a short period.
- RFA seems to be more effective in VRR than LA but both techniques did not show any difference in terms of success rate.
- RFA resulted in a lower VRR when there was a higher cellular component; instead the efficacy of LA seemed to be independent of the histological factors at baseline.
- The safety of the two procedures is very satisfactory in both techniques

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