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Effect of Ultrasound-Guided Ethanol Ablation in Management of Benign Cystic Thyroid Nodules

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Abstract

Background: Thyroid swellings are common in daily medical practice. Surgery was the standard curative treatment. However, the higher complications of surgery induced the search for alternative safe and effective options. Ethanol ablation under ultrasound guidance was introduced and considered a convenient alternative. However, no consensus yet was reached regarding the optimal treatment option.

The aim of the work: Evaluating the value of ultrasound guided ethanol ablation in the treatment of benign cystic thyroid nodules.

Patients and Methods: One hundred patients with cystic thyroid swelling were included. Patient evaluation was performed by careful history taking, clinical examination, laboratory investigations and ultrasound examination. Then drainage of the cyst followed by ethanol ablation was performed and outcome was assessed directly after the intervention, after 1 and 3 months. The reduction of cystic volume was recorded and any complications were documented.

Results: The majority of patients were females [78.0%] and compressive symptoms were the commonest presentation [95.0%]. The purely cystic nodules represented the highest nature [70.0%] followed by the septated cystic [20.0%] and predominantly cystic [10.0%]. The volume of injected ethanol ranged from 3 to 10 CC. By ultrasound, there was significant reduction of the nodule volume, and significant increase of VRR % after one month than the basal values and at three months than the first month in all patients. At the end of the third month, the volume reduction rate showed significant increase in the purely cystic than the predominantly cystic nodules [80.0- 97.2% vs 56.8 – 90.0%, respectively]. The complications during the procedure was reported in 4 cases in the form of acute severe cervical pain. After the intervention, 7 patients reported mild neck pain.

Conclusion: Ethanol ablation is an effective and safe procedures for cystic and predominantly cystic benign thyroid nodules on the short term follow up.

Keywords: Thyroid; Cystic nodule; Compression; Ultrasound; Ethanol Ablation.

INTRODUCTION

Thyroid nodules are common and detected accidentally recognized in up to 67.0% of populations by the ultrasound examination. About 15- 20% are cystic in nature [1-4].

The cystic nodules of thyroid gland are usually benign in nature and asymptomatic. However, some of these nodules are increased in size over time and usually presented by its compressive symptoms or the cosmetic problem may be the main complaint. The treatment is usually indicated for those patients [5, 6].

Surgery was the only available standard and curative option for malignant or benign thyroid nodules in the last decades, irrespective of the growing benign diagnosis by fine-needle aspiration cytology overtime [7-9]. However, surgery has many drawbacks, such as higher cost, need for the persistent long-life hormonal replacement therapy and permanent complications. However, permanent complications are infrequently reported [10, 11]. However, the last two decades witnessed higher acceptance of alternative minimally invasive, non-surgical approaches for treatment of benign nodules of the thyroid when there is a contraindication for surgery or the patient refused surgery [12-14].

Aiming to control symptoms of thyroid nodules, the simple aspiration was considered as the first line treatment option. However, it had a higher recurrence rate [up to 50-80%] [15, 16]. When aspiration failed as a treatment option, ethanol ablation guided by ultrasound can be a reasonable alternative treatment option for aspiration and surgery [17]. Sonography-guided percutaneous ethanol injection treatment [PEIT] was introduced in late 1990s. However, it did not gain wide acceptance until recently irrespective of the higher safety and efficacy [18, 19].

Ethanol ablation [EA] exerts its effects mainly by cell necrosis [coagulative and ischemic]. The coagulative necrosis is due to direct ethanol action which leading to dehydration of the cells and denaturation of proteins. However, the entrance of ethanol into the local circulation is associated with endothelial damage, thrombosis and ischemia. The coagulative necrosis is the predominant therapeutic mechanism for cystic lesions [20]. The treatment success is defined by a volume reduction rate [VVR] more than 50% of the original cystic volume [17]. However, the efficacy of ultrasound ethanol ablation therapy of cystic thyroid nodules remains controversial due to heterogeneous results.

THE AIM OF THE WORK

This work was designed to evaluate the effectiveness and safety of ultrasound guided ethanol ablation in the treatment of benign cystic thyroid nodules.

PATIENTS AND METHODS

This study included 100 patients who were presented by thyroid swelling or compression symptoms. Their clinical, ultrasound examinations and fine needle aspiration cytology confirmed the diagnosis of cystic thyroid benign nodules. They were selected from Al-Azhar university hospital [New Damietta].

We included patients over the 16 years old, from both genders, with benign cystic thyroid nodules [on the basis of ultrasound and fine needle aspiration cytology], provided that, they were presented by pressure manifestations or cosmetic compliant. However, **we excluded** patients with solid nodules, patient with previous ablation therapy [chemical or thermal] for the same lesion and those with coagulopathy or bleeding diseases.

All eligible patients signed an informed consent after full explanation of the study aim, producers and assurance of all patient rights. In addition, the study protocol was reviewed and approved by the institutional review board [IRB] of DFM, Al-Azhar University [Damietta, Egypt].

All included subjects were evaluated in a systematic manner by careful history taking, clinical examination and laboratory investigations [e.g., complete blood count, bleeding and coagulation profiles and thyroid function tests]. Finally, ultrasound examination was performed to confirm the diagnosis and detect any other abnormalities. Volsune E6 ultrasound machine was used to perform all examinations. During examination, the morphology of the gland was evaluated [e.g., echotexture, echogenicity and nodules]. Nodules were further assessed for their size, texture, echogenicity and vascularity. The Thyroid Imaging Reporting and Data System [TIRADS] classification system was used to define the grade for each nodule, as described previously [21].

As an initial procedure, all were submitted to drainage of the cyst by fine needle aspiration [FNA]. This was performed while patients were in the supine position with mild extension of the neck. Lidocaine 2% solution was injected at the site of the skin puncture and at the pericapsular space of the thyroid gland for pain control. Color Doppler was applied before needle insertion to guard against injury of vessels. A three-way connector was used to perform the procedure through a single puncture. The cystic content was drained as much as we can, using a 20 ml syringe of 21 G needle.

Ethanol ablation technique: A sterile ethanol solution [99.5%] was slowly instilled in the cyst. The injected volume was 30- 50% of the aspirated volume. The procedure was stopped once the patient complained of acute cervical pain [reported in 4 subjects].

Follow up was scheduled at 1 and 3 months after the procedure. It was carried out by ultrasound of the gland to detect the volume and VRR of the ablated cyst. Then the VRR index was calculated from the equation [VVR index = [[initial cyst volume – final cyst volume]/initial cyst volume] × 100.

Statistical analysis of data: Collected data were treated to assure anonymity of patients and then fed to the personal computer to calculate different statistics. Quantitative data were summarized by the measures of central tendency [mean or median] and dispersion [standard deviation or interquartile range]. The paired samples student test was used to compare values at the end of the third month to the corresponding values at the end of the first month. P value < 0.05 was considered significant.

RESULTS

This study included one hundred patients. Their age ranged from 16 to 60 year with female sex predominance [78.0% were females and 22 % were males]. The compressive manifestations were the commonest [95.0%] followed by cosmetic complaints [85.0%], then pain [40.0%] and the least symptom was the hoarseness of voice

[2.0%]. The majority of nodules were purely cystic [70.0%], septated cystic [20.0%] and predominantly cystic [10.0%]. The volume of the nodule ranged between 4.42 and 103 CC and the mean volume was 16.4 cm^3. In addition, the volume of injected ethanol ranged between 3 to 10 CC and the mean volume was 5.3 CC [Table 1].

During the first session of aspiration and ethanol ablation, 4 cases were lost due to severe cervical pain. However, at the end of the first follow up visit at the end of the first months, 3 cases were lost due to exposure of patients to surgical procedures and at the end of the second follow up visit at the end of the third months, 5 cases were lost due to exposure of patients to surgical procedures [Table 2].

The ultrasound assessment showed that, there was significant reduction of the nodule volume, and significant increase of VRR % after one month that the basal values and at three months than the first month in all patients [Table 3]. The same situation was recorded for the purely cystic nodules [Table 4].

At the end of the third month, the volume reduction rate was significant increase in the purely cystic than the predominantly cystic nodules [80.0- 97.2% vs 56.8 – 90.0%, respectively].

The complications during the procedure was reported in 4 cases in the form of acute severe cervical pain. After the intervention, 7 patients reported mild neck pain. Thus, no complications were recorded for 89% of studied patients reflecting the safety of the intervention [Table 5]. The first case presentation is of male patient, 28 years old, who was presented by neck swelling and disfigurement in the anteroinferior part of neck, associated with mild pain. His laboratory workup reflected normal levels of T3, T4 and TSH [i.e., euthyroid], with normal coagulation profile. The fine needle aspiration cytology showed a benign nature of the nodule [colloid nodule with cystic changes and no atypical cells were detected]. The ultrasound examination showed a single well-defined anechoic cystic lesion of the left lobe of the thyroid. It had fine internal echoes, no internal vascularity, with no solid component measuring about 2.5x1.7x2.1 cm giving a volume about 5.05 cc [TIRADS 1]. He submitted to EA and discharged on the same day with no complications. The volume of the nodule reduced from 5.05 CC at first assessment to 2.2 Cc and 0.22 CC after one and three months, respectively. The VRR after one month was 56.4% and increased to 95.6% at the third month [Figure 1, A to E].

The second presented cases of female patient, 17 years old presented by neck swelling and disfigurement, associated with mild pain. The laboratory work up showed euthyroid and normal coagulation profile. The FNAC showed a benign nodule [colloid cyst with secondary hemorrhage, no detected atypical or malignant cells were detected]. By ultrasound, the left lobe showing a single well-defined anechoic cystic lesion with fine internal echoes, no internal vascularity, with no solid component measuring about 3.2x2x1.7 cm giving a volume about 6.26 cc [TIRADS 1]. There was marked reduction of cystic volume from 6.26 to 2.39 and 1.78 cc, at first assessment, after one month and after three months respectively, with marked increase of VRR at the end of the third than the first month [71.5% vs 61.8%, respectively] [Figure 2; A to F] .

Table [1]: Patient gender, clinical manifestations and ultrasound data among study group.

Variables		Measures
Gender [n,%]	Male	22 [22.0%]
	Females	78 [78.0%]
Clinical Presentations [n,%]	Compressive symptoms	95 [95.0%]
	Cosmetic complains	85 [85.0%]
	Pain	40 [40.0%]
	Difficult swallowing	10 [10.0%]
	Hoarseness of voice.	2 [2.0%]
Cystic texture [n,%]	Purely cystic	70 [70.0%]
	Septated cystic	20 [20.0%]
	Predominantly cystic	10 [10.0%]
Ultrasound Characteristics	Volume [Mean, median [Min.-Max]]	16.4, 6.6 [4.42 – 103]
	Alcohol Volume [Mean, median [Min.-Max]]	5.3, 5.0, [3-10]

Table [2]: Study procedure stages limitations.

Procedure stage	Number of lost cases	Reasons
Aspiration & Ethanol ablation	4	Pain
First follow up after 1 month	3	Patients underwent surgical procedure Careless
Second follow up after 3 months	5	Patients underwent surgical procedure Careless

Table [3]: Follow up after 1 month for the whole study group.

		Mean	SD	Median	Range [Min. – Max.]
After one Month	Volume of the nodule	9.99	26.54	2	88.97 [1.03 – 90]
	VRR [%]	63.52	22.64	60.4	82.4 % [12.6% – 95%]
After three Months	Volume of the nodule	8.40*	24.41	1	81.78 [0.22-82]
	VRR [%]	77.2#	23.20	82.8	76.9 % [20.3% – 97.2%]

Significant increase in VRR percentage at the end of the third than the corresponding volume at the end of the first month after intervention; * Significant reduction at the third months compared to corresponding volume at the first month after intervention.

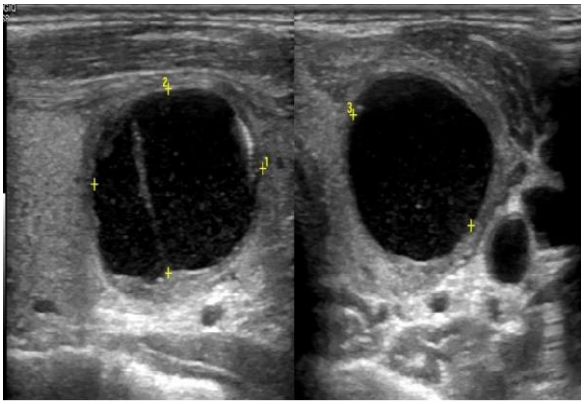
Table [4]: U/S assessment for cystic thyroid nodules across follow ups and the relation between baseline assessments.

		Baseline [n=96]	After 1 month [n=93]	After 3 months [n=88]
		Median [min.-Max]	**Median [min.-Max]**	**Median [min.-Max]**
Purely Cystic nodules	**Volume**	6.63 [4.42 – 103]	2 [1.03 – 90] *	1 [0.22 – 82] *
	VRR [%]	————	60.4 [12.6% – 95%]	82.8 [20.3% – 97.2%] #

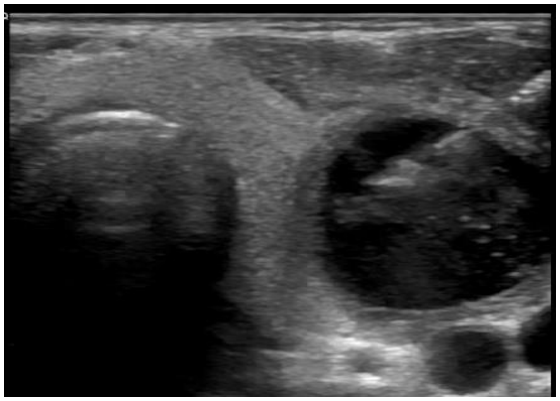
Significant increase in VRR percentage at the end of the third than the corresponding volume at the end of the first month after intervention; * Significant reduction at the third months compared to corresponding volume at the first month after intervention.

Table [5]: Recorded complications after intervention among study group.

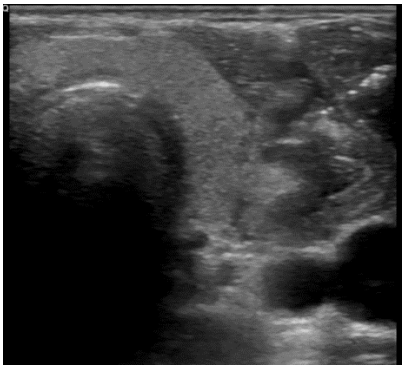
	Number of cases	Reasons
During the procedure	4	Acute sever cervical pain
After procedure	7	Mild neck pain
No complications	89	————



A [Initial Assessment]

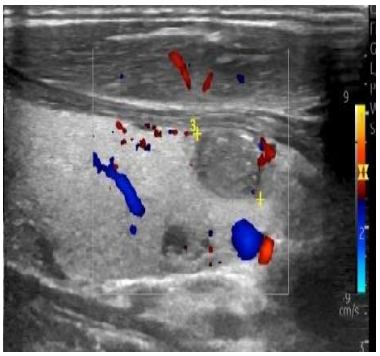


B [Fluid aspiration]



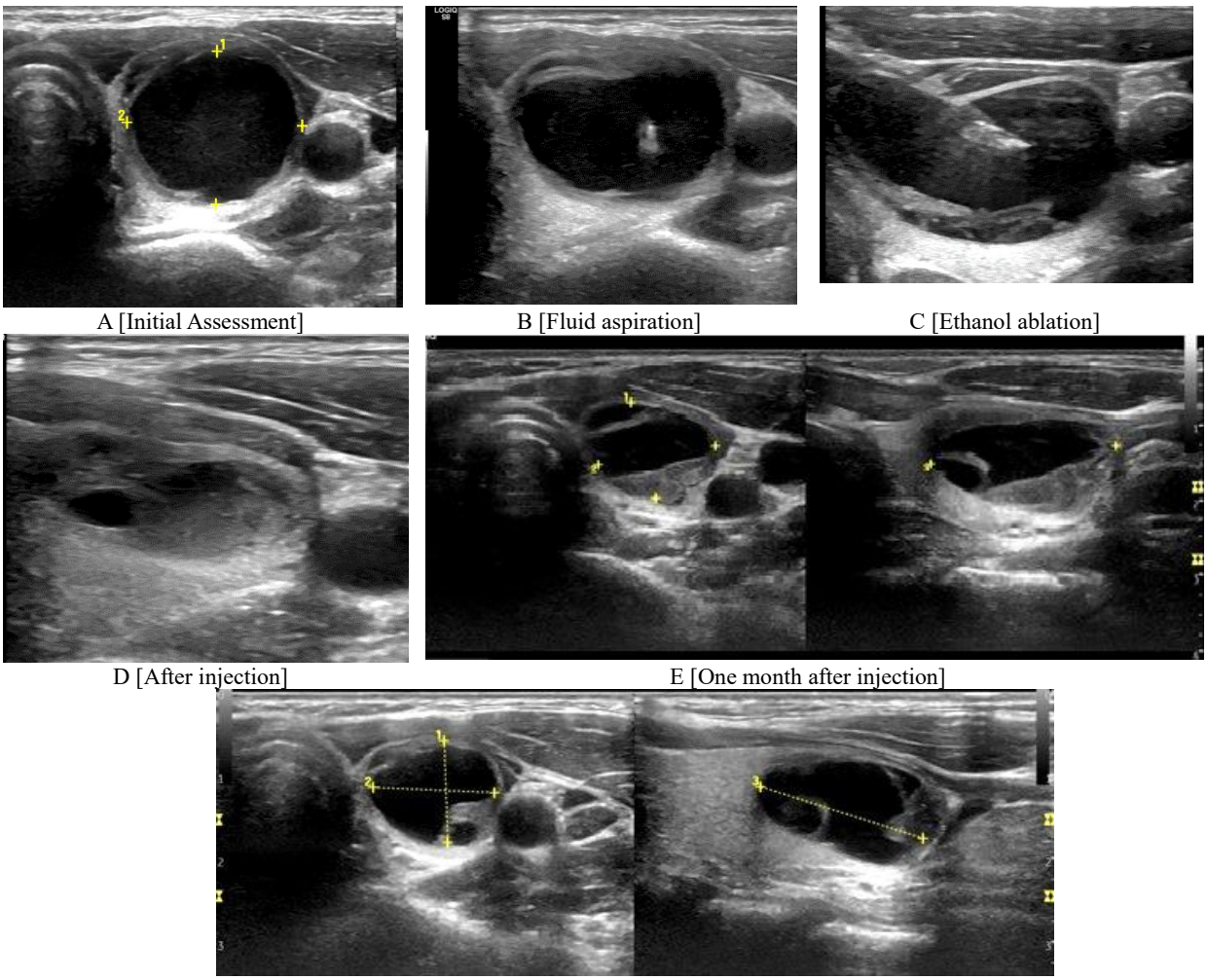
C [Ethanol ablation]

D [After one month]



E [after 3 months].

Figure [1]: Ultrasound results of the first presented patient



A [Initial Assessment] B [Fluid aspiration] C [Ethanol ablation]

D [After injection] E [One month after injection]

F [Three months after injection]

Figure [2]: Ultrasound results of the second presented patient

DISCUSSION

The current study was designed to evaluate the effect of ultrasound guided ethanol ablation in the management of benign cystic thyroid nodules. One hundred patients were included and majority of them were females in their fourth decade of life. Ethanol ablation was an effective and safe procedure for management of benign cystic thyroid nodules. Patients with purely cystic lesions achieved 80 % to 97.2 % reduction [>50%] of the nodule size at the end of the third month of follow up. The nodular size dropped from 16.4 at the start of the study to 9.99 and 8.4 at the end of the first and third months of follow up respectively. The Volume reduction rate [VRR] increased from 63.52% at the end of the first month to 77.2% at the end of the third month. In addition, the safety profile of the procedure is high [no complications were reported for 89%]. Thyroid nodules are very common as it is detectable in 65% of the general populations. Hence, the presence of effective and safe treatment options are of utmost importance [22]. In addition, the detection of possible preventable risk factors increase the opportunity of early detection and intervention. The risk factors for benign nodules include old age, female gender, and iodine deficiency [23].

Results of the current work reflected the female sex predominance and are in accordance with previous studies. For examples **Ozderya *et al.*** [24] reported the condition to affect 75.4% of their patients, while **Halenka *et al.*** [18] reported a much higher values [85.7%] and **Yang *et al.*** [20] reported that, 67.5% of their patients were females. Although these studies agree regarding the predominance of females, the values are different and this could be explained by the difference in mean age in each study [e.g., the mean age in the study of **Yang *et al.*** [20] was 56.02 years, but in the study **Halenka *et al.*** [18], the majority of patients were in their third decade of life].

In the current work, compressive symptoms were the commonest clinical presentations. This is in line with previous study reported that, benign thyroid nodules elicit compressive symptoms with or without cosmetic concerns. Interestingly, the symptomatic nodules are usually benign, but malignant nature is still a possibility. Thus, early treatment is advisable [25].

Several treatment options are available. All aiming to reduce the size of nodules to relieve compressive symptoms or cosmetic complaints. This varies between medical, surgical or minimally invasive approaches [ethanol ablation]. Medical treatment is less effective, while surgery is invasive, expensive with a considerable risk of complications [e.g., bleeding, recurrent laryngeal nerve injury, infection, permanent hypo- or hyper-thyroidism and scarring of open surgery] [26-29]. Alternatively ablation techniques were introduced for treatment of benign nodules. Of them the ethanol ablation is the most reasonable options. It is relatively cheap, needs no special equipment's and is usually performed as an outpatient procedure under local anesthesia. Its effect is limited to the thyroid nodule. Thus, it is more specific [superior to] thermal ablation techniques. In addition, it keeps the surrounding structures intact [24].

The mechanism of ethanol in ablation of thyroid nodules is thought to be due to a combination of coagulative necrosis [via dehydration] and ischemic necrosis [by means of endothelial injury and thrombosis] with subsequent reactive fibrosis [30].

The VRR reported in the current work is slightly lower than that reported in previous study, which showed that, ethanol ablation is able to produce VRRs as high as 90% in functional nodules and reached 100% in cystic nodules [31]. The same authors reported that, improvement occurred in a dramatic way in the first month after treatment, and showed more improvement at the 3-month, and remained stable at end of the sixth month after procedure.

Our results are comparable to those reported previous studies which have reported VRRs to be ranged between 70 to 95% after single or multiple ethanol ablation sessions and significant reductions in compressive symptoms [13, 32].

Furthermore, **Hahn *et al.*** [33] reported that ethanol ablation is 85%-98% effective in pure cystic nodules and 60%-90% effective in complex predominantly cystic nodules. **Patel and Sinclair** [34] concluded that, ethanol ablation, from their stand point of view, is still the reasonable first line treatment ablative option for cystic thyroid nodules. However they recommended the use of radiofrequency ablation instead or with ethanol ablation.

The lower VRR in the current work may be attributed to the shorter duration of follow up and inclusion of semi-cystic [septate] nodules in the current work. This was confirmed in previous work stated that cystic nature of nodules is the main predictor of success in ethanol ablation. It showed greater VRR in cysts than predominantly cystic nodules [89.7% *vs.* 78.2%, P<0.001] [35].

Papini *et al.* [36] reported that, ethanol ablation is highly effective in reducing the size of the cyst and resolve symptoms of cystic nodules. They carried a meta-analysis of randomized control trials and showed that, the pooled VRR at 1, 6, and 12 months after ablation were 70.01%, 90.75%, and 84.97%. Another study also reported that, ethanol ablation had a higher success rate [defined by more than 50% volume reduction as used in the current work] [20].

Interestingly one study with very long follow-up [10 years], median VRR after PEI continued to increase, indicating substantial treatment efficacy [5].

Wu *et al.* [37] evaluated the effect of combined ethanol with microwave in comparison to microwave alone and reported that the introduction of ethanol with microwave increased the success rate from 86 to 90% [$p < 0.05$]. In addition, the mean VRR after one year increased from 89.58% in the single group to 92.92% in the combined group. The volume is also reduced significantly when ethanol added to microwave ablation than microwave alone [i.e. adding ethanol to microwave increased the success rate with rapid reduction of volume]. However, it must be noted that, they treated mixed nodules, not only cystic nodules as in the current work

Regarding complications, our results are in line with **Yang *et al.*** [20] who reported that, mild pain is the commonest complaint after ethanol ablation. However, other major complications rarely reported [e.g., transient dysphonia in 0.53%]. This major complications did not reported in the current study. In addition, **Steinl *et al.* [31]** reported that there were no significant adverse effects and the ethanol ablation was well tolerated by all patients

In the same situation, the recurrent laryngeal nerve injury never reported with ethanol ablation. However, it is reported with other ablation methods [radiofrueqncy ablation; RFA] [38] and the incidence of transient dysphonia also increased in RFA than ethanol ablation [0.97% vs 0.53%] [39].

Irrespective of effectiveness and safety of ethanol ablation with many advantages over other ablation or minimally invasive procedures, it is not the magic option and it had its shortages. First, it is not suitable for nodules near the "danger triangle] regardless the nature of the nodule. Second, ethanol ablation prevents the determination of specimen pathology [22].

To summarize, the current work confirmed the efficacy and safety of ethanol ablation for cystic and predominantly cystic benign thyroid nodules on the short term follow up. The short term follow up and absence of comparative groups are the main limitations of the current work. Thus, it is recommended to perform future studies comparing different ablation techniques to have a consensus on the ideal and standard ablative methods for thyroid nodules.

Conflict of interest and financial disclosure: none

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