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Does the addition of alcohol increase the efficacy of radiofrequency ablation of T2 and T3 sympathetic ganglia in hyperhidrosis?



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ABSTRACT

Background: We observe high rate of patient dissatisfaction after radiofrequency (RF) ablation of thoracic sympathetic ganglia in primary hyperhidrosis.

Objective: We did this study to test the hypothesis that addition of alcohol injection will cover the anatomical variations in position of sympathetic chain and increase the success rate.

Study design: Randomized controlled clinical trial.

Setting: Zagazig university hospitals.

Patients and Methods: Thirty patients were randomly allocated into two groups fifteen for each. Group (ARF) underwent radiofrequency ablation and alcohol injection. Group (RF) underwent radiofrequency ablation only. Patients of both groups were operated upon one side only; immediate dryness and hotness of the operated side were assessed and followed up by a visit to the pain clinic or telephone calls at one week, one month, three months and six months after intervention, also occurrence of complications was assessed and asked about.

Results: Immediate warmth and dryness occurred in 13 of 15 (86.7%) cases of group (ARF) and only 2 started sweating again at six months with 2 patients developed neuropathic pain in axilla for one month. In group (RF), immediate warmth and dryness of the hand occurred in 7 patients of 15 (46.7%) and only 6 patients completed until six months after intervention. Only one patient developed pain in the axilla for one month after the procedure.

Limitations: Short period of follow up and relatively small sample size.

Conclusion: Efficacy of T2 and T3 sympathetic ablation with radiofrequency and alcohol is significantly higher than their ablation with radiofrequency alone with possible higher incidence of axillary pain.

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1. Introduction

Primary hyperhidrosis is excess sweating in certain parts of the body due to sympathetic overactivity. It is more common in hands and feet. Severe hyperhidrosis results in significant functional and psychosocial problem to the patient. The gold standard in curative treatment of hyperhidrosis of hands and axilla is endoscopic thoracic sympathectomy which is a special surgery needs a special anesthetic considerations in the form of double lumen tube and one lung ventilation and the patient is sometimes left with bilateral intercostal tubes for a while. Many patients particularly young refuse to undergo this surgery. Percutaneous ablation of T2 and T3 sympathetic ganglia and sympathetic trunk using radiofrequency

is considered a convenient alternative to thoracoscopic sympathetic neurolysis in patients with severe hyperhidrosis in the hands and refuse surgery [1].

Despite radiofrequency ablation of thoracic sympathetic ganglia is considered an alternative to thoracoscopic sympathectomy; still its success rate is significantly lower than endoscopy [2].

McCormack et al. concluded that anatomical variations in the position of sympathetic trunk are present in most patients with different forms [3].

These anatomical variations are thought to be one of the main causes of failure and patient dissatisfaction after thoracic sympathetic neurolysis in hyperhidrosis. It was found that upper sympathetic trunks are mostly lying against the head of the ribs, but there is a variant of trunks running along the medial side of the ribs head, also there is another variant in which the sympathetic trunk is present in between the ribs neck and head [4].

In the current study we tried to increase the efficacy of percutaneous fluoroscopy guided radiofrequency ablation of T2,

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T3 sympathetic ganglia in hyperhidrosis after observation of moderately high rate of failure. We try to achieve that via adding alcohol injection to cover the anatomical variations in the position of sympathetic trunk.

2. Methods

We started the study in Zagazig university hospitals after approval of institute review board (IRB) of Zagazig faculty of medicine number (ZU- IRB # 2387/ 22-10-2015) and consolidated standards of reporting trials (CONSORT) guidelines were followed [5].

3. Patients

Enrollment included 36 patients of severe primary hyperhidrosis involving the hands. Feet and axillae may be also affected. Patients are beneficiaries of the pain clinic in Zagazig university hospitals.

We excluded from the study mild and moderate cases of primary hyperhidrosis also we excluded previously failed cases either after percutaneous or thoracoscopic sympathectomy.

4. Interventions

Only one hand was operated upon to avoid the possibility of occurrence of bilateral complications and also to avoid exhaustion of the operator that might affect his efficiency.

5. Procedure of radiofrequency ablation

Patients slept prone, sterilized and draped, sedation was given in the form of midazolam ketamine. C-arm was centralized in posteroanterior position, end plate of T2, T3 was aligned by cephalocaudal rotation then lateral tilt was obtained about 10–15

degrees angle to introduce the (NeuroTherm^R) radiofrequency cannula (10 cm length, 20 gauge size with 10 mm curved active tip) parallel to the direction of X rays targeting the lateral border of vertebral body then in the lateral view the needle tip was in the posterior part of the middle third of vertebral body *Figs. 1 and 2*. After negative sensory stimulation at 50 Hz and 0.4–0.7 V and negative motor stimulation at 2 Hz and 1.3–1.5 V. NeuroTherm^R NT1100 generator (MORGAN AUTOMATION Ltd. Liss, Hants, Gu33 7NT. UK) was used to deliver thermal radiofrequency lesion at 80 °C for 120 s then one lesion above and one below. After the lesions 3 ml methylprednisolone solution 4 mg/ ml were injected. The same steps were done at T2 and T3.

The first group was called (RF) group i.e. RF only group formed of 15 patients to whom radiofrequency ablation was done without injection of alcohol.

The second group was called (ARF) i.e. alcohol RF group formed of 15 patients to whom radiofrequency ablation was done at the same levels of T2, T3 sympathetic ganglia after which 0.5–1 ml of 100% alcohol solution was injected according to patient age after injection of the same volume of a nonionic contrast material Iohexol 300 mg I/ml (Omnipaque^R). After the lesion and alcohol injection the same volume of methyl prednisolone as in RF group was injected. Alcohol 100% was the only available adjuvant particularly when we didn't find phenol ampoules. After searching the literatures we found few studies that used alcohol for sympathetic neurolysis in hyperhidrosis with good safety profile [6–9]. Despite



Fig. 1. AP view of T3 needle position with contrast.



Fig. 2. Lateral view of T3 needle position.

the safety profile of alcohol shown in these studies we gave less volume of alcohol (0.5–1 ml) while Huang et al. [6] gave 2.5 ml of alcohol. We also injected that volume of alcohol after injecting the same volume of contrast and made sure that spread is away from somatic nerves.

6. Outcome measures

During the procedure we monitored the operated hand temperature and dryness and compared them with the other hand.

After the procedure the patient condition was followed up through a visit to our pain clinic or a telephone call if visit is not possible where he/she was assessed for hand dryness and any complications like pain, compensatory hyperhidrosis, over dryness and Horner syndrome.

During the procedures we monitored the occurrence of pneumothorax through abnormal spread of the contrast material and postoperatively via telephone call if the patient felt chest pain or dyspnea.

Dryness and complications were assessed after the first week via telephone calls, at one month, three months and six months.

7. Randomization

Patients were randomized in an allocation ratio of one to one between study groups. Randomization was electronically generated using random table from computer. 30 patients were selected after exclusion of 6 patients and were randomly allocated into two groups. Group (RF) underwent radiofrequency ablation only and consisted of 15 patients and group (ARF) underwent RF ablation plus alcohol 100% injection. Patients were blinded and the assessing physician was also blinded.

8. Statistical analysis

Sample size was calculated by using (Epi- Info) program. At 80% power and 95% C.I the estimated sample was 15 patients in each



Figure (2) CONSORT 2010 Flow Diagram

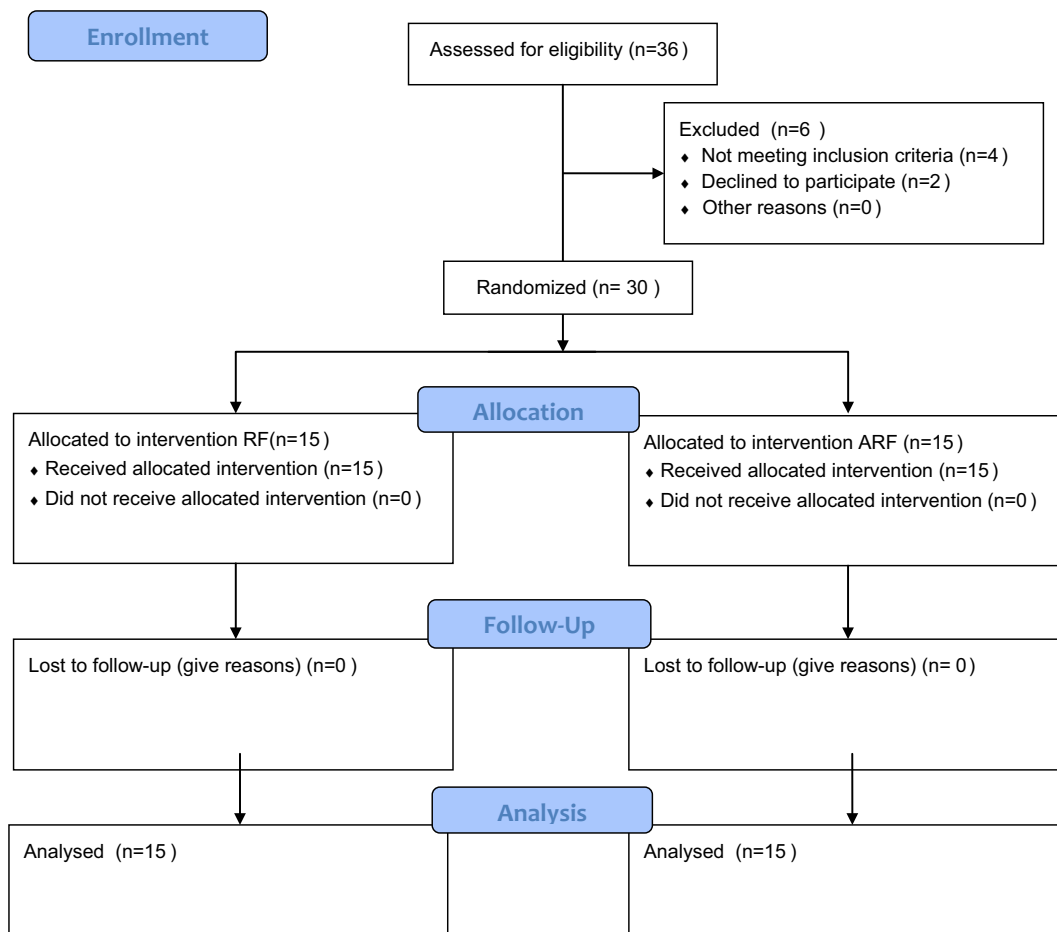


Fig. 3. Flow chart.

group. We enrolled 6 patients more in the study to compensate for drop out. We used the lowest permissible sample size in a randomized controlled study because previous studies were very few and case series.

Data were checked, entered and analyzed by using SPSS (version 20). Data were expressed as number and percentage or mean \pm SD. Chi-squared (X^2) and Fischer exact test or t test were used when appropriate. $P < 0.05$ was considered statistically significant.

9. Results

9.1. Participants flow

A total of 36 patients were enrolled in the study from October 2015 to January 2016. Of 36 patients assessed for eligibility, 6 were excluded due to 4 of them didn't meet the study selection criteria and 2 declined to participate in the study. Randomization allocation resulted in 15 patients receiving radiofrequency ablation only of T2 and T3 sympathetic ganglia and 15 patients receiving radiofrequency ablation and alcohol 100% (0.5–1 ml) injection. Enrollment chart is shown in Fig. 3.

As shown in Table 1 there is no significant difference in both groups as regard the age, sex and site of affection with hyperhidrosis.

Table 2 shows that in group RF there was immediate hotness and dryness after thermal radiofrequency of T2 and T3 in 7 of 15 patients (46.7%) while neither hotness nor dryness occurred in 8 of 15 patients (53.3). At one week, one month and three months after intervention the hand dryness continued in the same

patients. At six months after intervention hyperhidrosis recurred to one patient so the number of patients with hand dryness became 6 (40%) and those patients without hand dryness became 9 (60%).

In group ARF as shown in Table 2 there was immediate hotness and dryness of the hand in 13 of 15 patients (86.7%) and neither hotness nor dryness in 2 of 15 patients (13.3%). At one week, one month and three months after intervention the hand was still dry in the same number of patients. Hyperhidrosis started again in one case at six months after intervention so the number of patients with dry hand became 12 of 15 (80%) and those with wet hand became 3 of 15 (20%).

Only one type of complications occurred in the form of neuritis with pain in the axilla in one patient in group RF (6.7%) and 2 patients in group ARF (13.3%) as shown in Table 3. This pain started within 48 h after intervention and was controlled by gabapentin 200–400 mg/ day according to body weight and stopped within one month in all cases. We can notice from Table 2 that the number of patients with immediate dryness and hotness of the hand was significantly higher in group ARF than group RF. Also the difference was statistically significant at one week, one month, 3 months and at six months with the number of patients with dry hand being higher in group ARF than group RF.

10. Discussion

In the current study we tried to cover the failure rate after radiofrequency ablation of T2 and T3 sympathetic ganglia in hyperhidrosis by injecting alcohol 100% which is able to spread and

Table 1
Demographic and clinical data (original table).

	RF group N = 15		ARF group N = 15		t	P
<i>Age (years)</i>						
Mean \pm SD	21.7 \pm 3.9		20.1 \pm 4.1		1.09	0.28
Range	14–26		14–26			
<i>Gender</i>					X^2	P
Male	10	66.7	9	60	0.14	0.7
Female	5	33.3	6	40		
<i>Site of hyperhidrosis</i>					X^2	P
Hands only	10	66.7	9	60	0.14	0.7
Hands and feet	5	33.3	6	40		

Table 2
Dryness and hotness of hands after Intervention (original table).

	RF		ARF		X^2	P
	N	%	N	%		
<i>Immediate dryness and hotness</i>						
Yes	7	46.7	13	86.7	5.4	0.02
No	8	53.3	2	13.3		
<i>Dryness at one week</i>						
Yes	7	46.7	13	86.7	5.4	0.02
No	8	53.3	2	13.3		
<i>At one month</i>						
Yes	7	46.7	13	86.7	5.4	0.02
No	8	53.3	2	13.3		
<i>At 3 months</i>						
Yes	7	46.7	13	86.7	5.4	0.02
No	8	53.3	2	13.3		
<i>At 6 months</i>						
Yes	6	40	12	80	0.5	0.025
No	9	60	3	20		

Table 3
Complications (original table).

	RF		ARF		X ²	P
	N	%	N	%		
Yes	1	6.7	2	13.3	0.0	1.0
No	14	93.3	13	86.7		

cover larger area of damage of sympathetic trunk which may be probably missed by the precise lesion of radiofrequency.

There was non significant difference between group RF and ARF regarding the age, sex and distribution of hyperhidrosis.

The current results showed that the primary outcome (hand dryness) after alcohol and radiofrequency ablation is significantly higher than that of radiofrequency alone at all times of assessment starting from immediately after intervention until six months later. Thirteen out of 15 patients showed dryness in the (ARF) group (86.7%) for up to three months after intervention where one patient started to develop wet hand again i.e. 12 of 15 patients still have dry hands (80%). While, in group (RF) the dryness occurred in only 7 of 15 patients (46.7%) immediately after intervention and continued until three months and became 6 of 15 patients (40%) at six months as one patient regained wet hand.

These results agree with Garcia Franco et al. [1] who said that efficacy of radiofrequency was 41% in treatment of palmar hyperhidrosis where the patients were followed up for one year while patients of the current study were followed for six months only.

Regarding the use of alcohol, the results of the present study agree with Huang et al. [6] who found after first trial of alcohol neurolysis not combined with radiofrequency that 19 patients of 23 (82.6%) were cured and the other four patients also cured after a second trial. They also found that recurrence happened to two patients during 8–18 months follow up period.

The results of RF alone group disagreed with those of Purtuloglu et al. [2] who found that patients of hyperhidrosis who underwent radiofrequency ablation showed success rate of 76% while our results showed success rate of 46.7%. This may be due to their larger sample size retrospective study and also they operated on T4 sympathetic ganglion while we operated upon T2 and T3 ganglia.

We recommend further randomized controlled studies with larger sample size with changing doses of alcohol to get the highest results with least complications. Larger sample sizes will allow more accurate identification of incidence of complications.

11. Conclusion

Efficacy of T2 and T3 sympathetic ablation with radiofrequency and alcohol is significantly higher than their ablation with radiofrequency alone with possible higher incidence of axillary pain.

Disclosure

Author contribution: Dr. Osama Yehia A. Khalifa was responsible for review of literatures, interventions and publication. Dr. Ahmed Sobhi M.E. Hegab was responsible for interventions.

Conflict of interest

All authors have nothing to disclose.

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