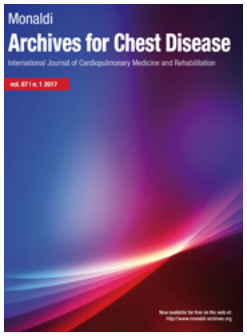

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Italian survey on the effectiveness of halotherapy administered *via* the Aerosal® system

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Abstract

Over the years, halotherapy (HT) has shown promise in the treatment of respiratory and dermatological diseases. However, its widespread acceptance remains limited due to the absence of official guidelines and awareness among doctors and patients. Among the patented systems of administration of HT, Aerosal® is the only one consisting of 3 certified elements, all classified as Medical Devices Class 2A: a dry saline dispenser called Aerosalmed®, a 30 g salt dose named AeroNaCL®, and a confined environment in marine multilayered construction with walls coated in salt called Aerosal®. We conducted an online survey of subjects undergoing Aerosal® HT across 80 Italian centers. Participants provided demographic data, reasons for choosing HT, and perceptions of its effectiveness. Following 10 treatment sessions, they rated improvements in various aspects, such as skin condition, sleep quality, relaxation, and respiratory benefits. Most participants learned about HT through word of mouth rather than medical advice, suggesting a discrepancy between patient satisfaction and medical endorsement. Over 92% reported resolution of their health issues post-treatment, with significant improvements in sleep quality and relaxation, particularly in adults. The therapy showed promise in various conditions, including respiratory and skin disorders, possibly attributed to stress reduction and intrinsic therapeutic effects. Despite skepticism, HT administered through the Aerosal® system has shown therapeutic potential. The psycho-physical benefits observed in patients advocate for greater consideration of this therapy by clinicians, emphasizing its safety, tolerability, and absence of notable side effects. In this context, standardized systems like Aerosal® are crucial for ensuring treatment safety and efficacy.

Key words: halotherapy, non-pharmacological approach, respiratory diseases.

Introduction

Halotherapy (HT) is a form of speleotherapy, a non-pharmacological approach consisting of inhalation of micronized medical sodium chloride into an indoor climate-controlled environment, that recreates the conditions occurring in the nature in salt mines and caves [1]. Due to its recognized beneficial effects on several respiratory system conditions (rhinosinusitis, allergic rhinitis, otitis, bronchitis and asthma), as well as on some dermatological pathologies

(atopic dermatitis and psoriasis), HT is nowadays considered an adjuvant therapy in the prevention of respiratory disease and their exacerbations, reducing the need for frequent pharmacological interventions [2-4]. Neverthless, there are no official guidelines on the use of HT in the form of salt rooms (halo chambers) or dry powder inhalers and both clinicians and patients are not yet fully aware of its potential benefits.

Among the patented systems of administration of HT, Aerosal® it is the only one to be certified as a medical device in all its components, represented by the salt chamber (Aerosal®), the salt dose (AeroNaCL®) and the dry saline dispenser (Aerosalmed®). This system consists in the delivery of a standard amount of micronized particles of NaCl by a dry salt aerosol generator that blows into the halo chambers. The Aerosal® salt rooms have standardized dimensions and are composed of walls and ceilings in marine plywood, completely covered with iodized rock salt of certified origin as ESCO (European Salt Company). The floors, also made of marine plywood, are covered with approximately 500 kg of rock salt of certified origin such as RESIMAX. The temperature and humidity are kept at constant values ranging between 20 °C and 24 °C and 44% and 60%, respectively. Moreover, as certified by SAS 90® measurements, the rooms environments are not contaminated by pathogenic microorganisms.

A double-blind placebo-controlled randomized clinical trial has already shown the effective of Aerosal® HT in otitis media with effution (OME) and in adenotonisllar hypertrophy [5]. However, although several studies and surveys have been conducted on HT beneficial effects, no studies have been conducted on the efficacy of patented Aerosal® HT in more complex conditions, including asthma, chronic pulmonary disease and dermatolical conditions [6,7].

Based on this background, we conducted an anonymous online survey involving subjects undergoing Aerosal® HT for different pathological conditions, with the aim of understanding the reasons that had driven patients to choose this treatment and their impression regarding its effectiveness.

Materials and Methods

An online survey was administered to patients undergoing Aerosal® HT, and their caregivers (if they also underwent Aerosal® HT) in 80 Italian Centres, in order to ensure a wide and complete national coverage.

The anonymous online survey concerned the demographic data of the subjects involved in the survey, their experience and their perception of halotherapy. Demographic included gender and age. Awareness/experience variables included “How did you find out about Aerosal®

haloterapy?" and "Would you recommend this treatment to friends and family?". The participants were also asked which pathologies they suffered from, why they had undergone halotherapy as well as the duration of the treatment.

After a complete cycle of ten sessions, participants were asked to evaluate their global assessment of the effectiveness of HT, as well as the improvement of several aspects, such as the skin characteristics, the quality of sleep, the degree of relaxation, the sporting benefit and the quality of breathing in smokers. Responses were scored from 0 (no effectiveness/no improvement) to 10 (maximum effectiveness/maximum improvement) (Figure 1).

The differences in the scores attributed to each item were evaluated using the Student's t test.

The ethical approval was waived by the ethics committee of Foggia since it was a real investigation conducted in Italian "Salt Clinics". This survey, conducted according to the Declaration of Helsinki, only provided for the collection of data, without in any way influencing the therapeutic choices of the participants. All participants provided informed consent prior to completing the survey.

Technical specification of salt room Aerosal®

The walls and ceiling of the salt room, measuring 2.30 meters by 2.90 meters by 2.20 meters, are entirely coated with certified-origin iodized rock salt from the European Salt Company (ESCO). Additionally, the floor, constructed with multilayer sea wood, is covered with about 500 kilograms of certified-origin rock salt of RESIMAX type. The room maintains a clean environment verified by SAS 90® measurements, free from pathogenic microorganisms, allowing patients to relax in comfortable chairs. Dry salt aerosol, circulated through a PVC pipe, is blown into the room from a generator located outside but adjacent to it.

To ensure air quality, a centrifugal extractor fan facilitates air changes meeting CO, ppm values (<750 ppm), while temperature (20°C to 24°C) and humidity (44% to 60%) remain constant (measured by TESTO 435-49 Digital Multimeter). The dry salt aerosol generator, housed in a cabinet adjacent to the salt room, disperses a standard quantity of NaCI in aerosol form through a PVC connector. The micronized NaCl particles, ranging from 0.23 to 20 micrometers, are monitored for consistent density (20 to 35 Mg/m) over time through an electronic system, ensuring stability.

Figure 2 summarizes the technical features of the dry sal aerosol generator (Aerosalmed®).

The salt sachet used in the generator (AeroNaCl®) contains 30 grams of NaCl, 20 grams of micronized RG salt (Reagent Grade), and 10 grams of non-micronized ESCO iodized feed salt. This composition aims to prevent clumping and maintain appropriate iodine exposure levels. Figure 3 provides a 3D graphical representation of a "Salt Clinic".

Results

Overall, 549 subjects participated in the survey. 61.9% (n=340) were caregiver and the remaining 38.1% (n=290) had undergone Aerosal® HT for the prevention or treatment of a specific disease. 52.5% (n=288) of patients were female, 47.5% were male (N=261). 61.9% (340) were aged between 0 and 17 years, 38.1% (n=209) were over 17 years old. One hundred and forty-eight/549 (26.9%) partecipants reported suffering from allergies, of which 50.6% (n=75) were seasonal allergies and 41.2% (n=61) were perennial. 86.3% (n=474) of the survey participants reported that it was the first time they had gone to a salt room: 74 for prevention, 45 for adenoid hypertrophy, 23 for asthma, 35 for bronchitis, 65 for allergies, 77 for sinusitis, 24 for skin diseases, 120 for recurrent respiratory infections, 154 for colds, 66 for ear infections and 38 for other pathologies (Figure 4). As shown from the latter data, some patients had undergone HT for multiple overlapping diseases. 45.7% (n=251) learned about HT from friends, 23.5% (n=129) via social media, 12.9% (n=71) from their doctor, the 9.8% (n=54) from the internet in general and the remaining 44 from other sources (Figure 5).

Over 92% (n=506) of them reported that the health problem that led them to undergo HT had resolved. 8.7% of all participants (n=48) reported an improvement in their skin, however this percentage rose among those (75%; 18/24) who had skin problems, giving an average score of 7.8±1.8 (range: 3-10).

67.6% (n=371) also reported an improvement in sleep (mean score: 8.0±1.7; range: 4-10) which continued at the time of the interview for 49.5% (n =272), lasted a few weeks for 46 respondents, a few days for 31 subjects and a few months for 4% (n=22). 75.9% (n=417) felt more relaxed after the sessions (average score 8.1±1.7; range: 3-10). Adults were more relaxed than minors ($p<0.05$).

33.3% (n=183) of the participants in the survey declared that they did sporting activity, of these 59.6% (109/183) had sporting benefits after HT(average score 7.8±1.6 ; range: 3-10) (Figure 6 a-b).

Almost all of the respondents (98%) would recommend the salt rooms to friends and family (average score 8.9±1.4; range: 5-10). 74.3% (n=408) have already planned another cycle soon.

99.6% (n=547) were satisfied with the information received, giving an average score of 9.2±1.2 (range: 4-10). 47.7% (n=262) were aware of the dedicated YouTube channel

Statistically significant differences in the average score attributed to the different degrees of improvement were found by age, since adults who benefited from the treatment attributed a higher average score of degree of relaxation than minors ($p<0,05$).

In line with expectations, those who went to the salt chambers to treat a pathology had ≥3 sessions/week compared to those who did not have any pathology. In particular, significant associations were detected for all the pathologies under study except for skin diseases and recurrent respiratory infections.

Discussion

The therapeutic role of the saline environment has been recognized since the 19th century, following some observation such as the absence of chronic bronchitis and asthma in the miners of the Wieliczka salt mines, as well as the rapid healing of these diseases in new employees [8]. The terms halotherapy (derived from Greek *halos*=salt) and speleotherapy (derived from the Greek *speleos*=cave), refer properly to the use of salt caves for healing [9]. In recent years, the possibility of using not only natural halochambers, such as rock salt mines, but also recreating artificial ones, has prompted research efforts to investigate the potential therapeutic effects of HT, as an adjuvant therapy for skin and respiratory disorders, capable of reducing the side effects of systemic treatments and improving clinical response.

In this context, with the view of standardize the treatment, studies have focused on the optimal microclimatic characteristics (temperature, humidity, lighting, pressure and concentration in CO2 and O2) as well of the size micronized particles of NaCl [10,11].

Aerosal® is the only HT administration system that is certified as a medical device in all its components, therefore capable of guaranteeing standardized and repeatable microclimatic conditions. Thus, we conducted an online survey to understand patients' level of knowledge of HT, as well as their impression regarding its effectiveness.

The results indicate that only a small percentage of patients (12.9%) opted for HT based on medical recommendations, with the majority learning about it through informal channels, particularly from friends. This highlights how even today, despite the growing data regarding the effectiveness of HT, doctors themselves are often skeptical, so much so that they do not suggest this non-pharmacological therapy as an adjunct to standard pharmacological treatments [2]. At the same time, the very fact that the subjects had undergone halotherapy

thanks to word of mouth demonstrates the high degree of satisfaction shown by the patients, who tend to recommend the treatment after having undergone it themselves. In line with these data, almost all of the participants of the survey (98%) would recommend HT to friends and family and over 92% of them reported that the health problem that led them to undergo HT had resolved. Moreover, it is worth mentioning that adults, more than minors, attributed a high average score for degree of relaxation. Therefore, the effects of HT should not only be considered in terms of reducing flare-ups of the pathologies from which patients suffer and/or reducing the pharmacological therapy, but also in terms of improving quality of life (QoL), which could be evaluated, as in this survey, precisely in relation to the quality of sleep or the feeling of relaxation. Indeed, it should be underlined that the salt rooms become real places that help support a correct lifestyle, in a time when stress is inseparable from everyday life, so that people do not have free time to rest and carry out outdoor activities [12].

Interestingly, our previous study showed no improvements in sleep quality, however the study population was exclusively pediatric [5]. Also in this survey, the improvement in sleep quality was found in the adult population, rather than in the pediatric population, highlighting how adults are more positively affected by the relaxing effects of HT than children [13].

Another important aspect is the heterogeneity of participants of the survey, as they suffered from several diseases, including adenoid hypertrophy, asthma, bronchitis, allergies, sinusitis, skin diseases, recurrent respiratory infections, and otitis. In accordance with the opinion expressed by patients, HT has proven useful in the treatment and prevention of each disease. The effectiveness of HT could be traced back to both stress reduction and the intrinsic effects of HT. As a matter of fact, several skin disorders, including psoriasis and atopic dermatitis, are closely related to stress since the skin has been shown to be not only a target of organismal distress but also an active participant of the stress response, through production of local hypothalamic–pituitary–adrenocortical (HPA) axis components [14]. Thus, bidirectional communication pathways between the brain and the skin may lead to sustained proinflammatory activity that self-amplifies and leads to cutaneous inflammatory states. In this context, behavioral and cognitive stress management therapies, relaxation techniques, hypnosis, and biofeedback have been proposed in people suffering from skin disorders [15]. HT could therefore fit into this context, so much so that previous studies have already shown its effectiveness in the treatment of psoriasis, highlighting the association with the improvement of the patient's quality of life [4]. Similarly, recent studies have identified chronic psychosocial stress as an additional environmental exposure to consider in relation to asthma and other

respiratory diseases [16]. The potential mechanisms underlying this association could by represented by changes in the methylation and expression of genes that regulate behavioral, autonomic, neuroendocrine, and immunologic responses to stress [17]. In addition to the stress effects mentioned above, the intrinsic effects of HT include antimicrobial activity, and promotion of mucociliary clearance, rehydration, and mucus clearance. Moreover, recent studies have demonstrated that HT improves lung function by inhibiting the NLRP3/ASC/Caspase-1 signaling pathway to reduce inflammation and pyroptosis [18]. All These antinflammatory and antiallergic properties determine considerable improvements in patients suffering from both respiratory and skin diseases [19,20].

Conclusions

Despite skepticism, HT is gaining more and more therapeutic dignity, given the increasing number of studies demonstrating its effectiveness as an adjuvant but not a replacement of traditional pharmacological therapies. The increased psycho-physical well-being of subjects undergoing HT should lead clinicians to give greater consideration to this therapy, which appears to be safe, well tolerated and free of noteworthy side effects. In this context, precisely to guarantee the safety of the treatment, the administration of HT using patented and standardized systems, possibly certified as medical devices such as Aerosal®, appears extremely important.

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	VAS SCORE (0= no effectiveness/no improvement; 10 =maximum effectiveness/maximum improvement)
How much has your skin improved?	0 1 2 3 4 5 6 7 8 9 10
How much has the quality of your sleep improved?	0 1 2 3 4 5 6 7 8 9 10
How much would you rate the level of relaxation?	0 1 2 3 4 5 6 7 8 9 10
Have you noticed a sporting benefit?	0 1 2 3 4 5 6 7 8 9 10
How much has the quality of breathing improved?	0 1 2 3 4 5 6 7 8 9 10
How much would you recommend therapy?	0 1 2 3 4 5 6 7 8 9 10

Figure 1. Online questionnaire.

AEROSALMED®

Technical features	
Power supply	100-240 VA – 50/60 Hz
Absorbed power	Max. 90 VA
Risk class	IIA
IP protection degree of the enclosures	21
Operating temperature	20 ÷ 25 °C
Operating humidity	30 ÷ 50 % RH
Atmospheric pressure	70 ÷ 106 kPa

Figure 2. Aerosalmed® technical features. Reproduced with permission from: AEROSAL DIVISIONE MEDICA SA.

Figure 3. 3D representation of a "Salt clinic: reception area (a); waiting room with a recreation area (b), Aerosal® HT room (c); Aerosalmed® Dry Salt Aerosol Generator(d). Modified from: Gelardi *et al*. (2103) [5].

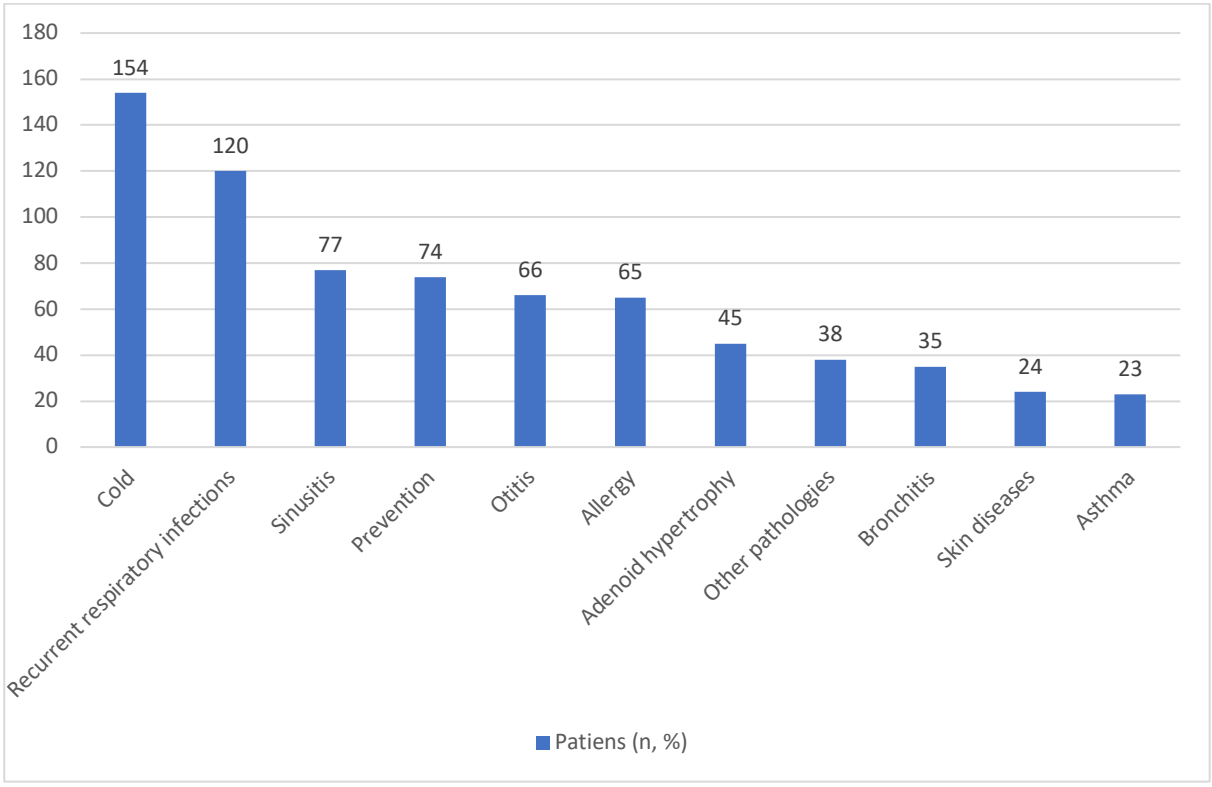

Figure 4. Reasons why participants underwent HT.

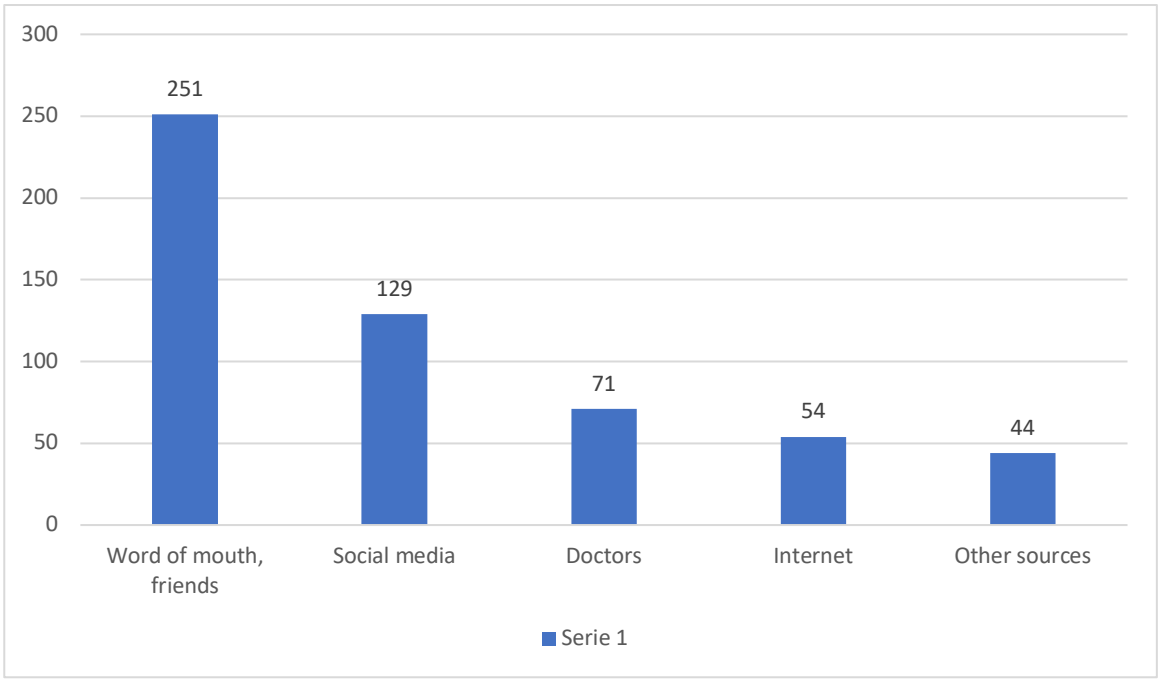

Figure 5. Means through which participants learned about HT.

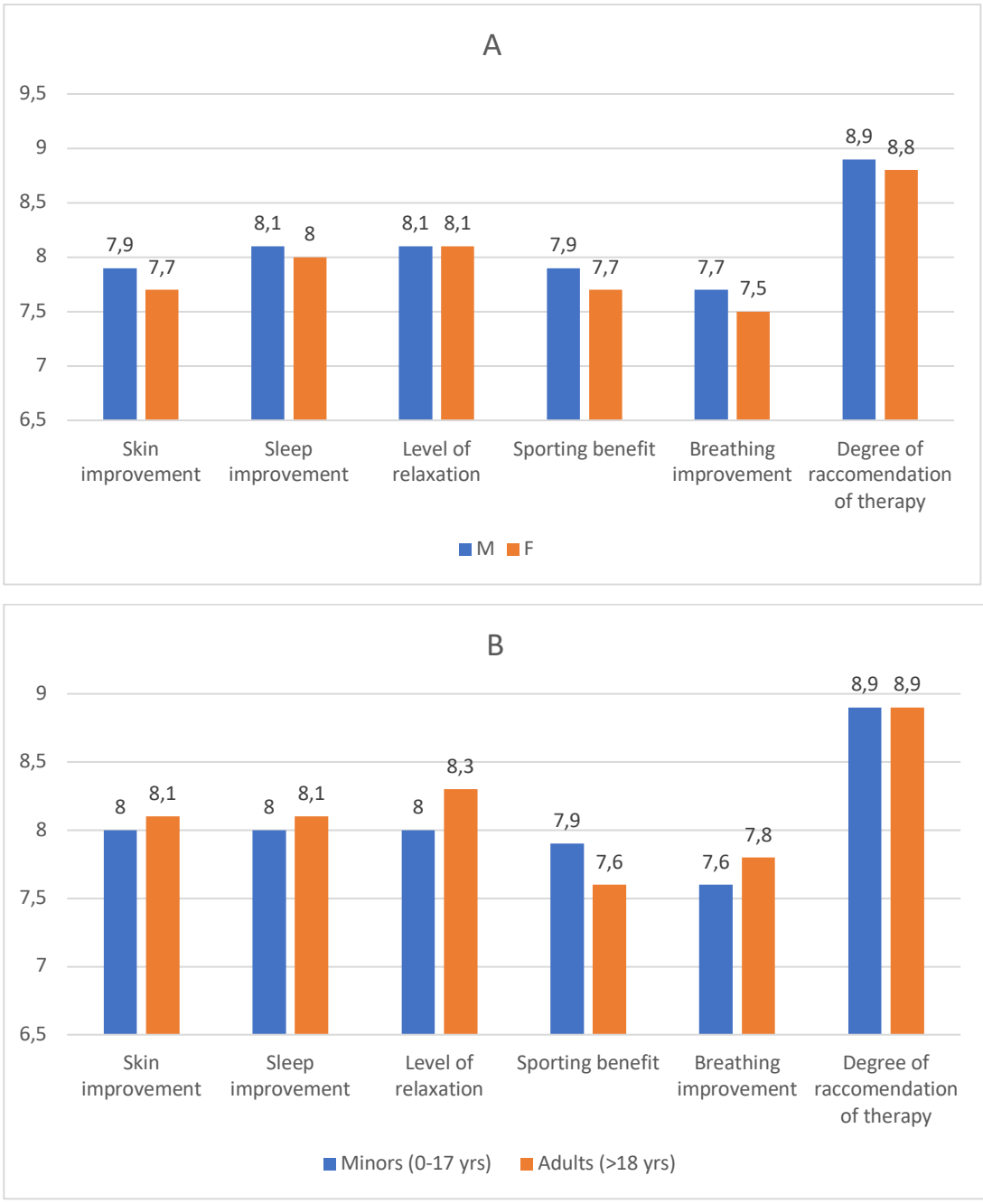

Figure 6. Scores attributed by patients to the improvement of the skin, the quality of sleep, the degree of relaxation, the sporting benefit and the quality of breathing in smokers, as well as the degree of satisfaction with HT. A) Comparison between male and female subjects. B) Comparison between minors and adults.