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The effect of paper patching on aural fullness of unknown aetiology

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Abstract. *The effect of paper patching on aural fullness of unknown aetiology. Objective*: To assess the effect of paper patching on aural fullness.
Methodology: We conducted a prospective, single-blind, placebo-controlled study using urn randomization. Twenty-two patients presenting with the complaint of aural fullness, without middle-ear pathology, were recruited from a secondary referral centre. The tested intervention was the application of paper patches on specified areas of the tympanic membrane. The main outcome measure was the change in subjective symptoms of average aural fullness and peak aural fullness, based on differences between pre- and post-intervention measurements on a scale from 0 to 10.
Results: Paper patching led to significant improvement in subjective symptom scores. In the treatment group, the change in average aural fullness was –2.00 (SD 2.00, p = 0.006), and the change in peak fullness was –1.77 (SD 2.49, p = 0.01). In the placebo group, these values were –0.13 (SD 1.55, p = 0.72) and +0.33 (SD 1.10, p = 0.37), respectively. No major adverse effects were reported.
Conclusion: After one week of treatment, paper patching showed a beneficial effect on aural fullness of vague or unknown aetiology.

Introduction

A feeling of fullness in the ear (often referred to as aural fullness) is frequently experienced in a variety of ailments, including otitis media with effusion, barotrauma, tubal dysfunction, patulous eustachian tube (PET), tensor tympani syndrome (TTS), acoustic shock, Ménière's disease, third window syndromes, and sudden deafness. It can also occur in relation to head and neck malignancies, dental problems, temporomandibular joint dysfunction (TMD), cervical muscle tensions, and other conditions. In many cases, no clear diagnosis can be reached, making therapy particularly difficult.

Among patients suffering from PET syndrome, the application of paper patches, Steri-Strips™ , or clay on certain locations of the tympanic membrane (TM) can reportedly eliminate autophony and aural fullness.[1-3] This treatment is also effective against other PET-related complaints, including slight vertigo and subjective hearing loss. Similarly, our patients with these complaints, but without autophony, have often shown favourable responses following paper patch application.

The combination of varied complaints in these patients corresponds to the clinical picture presented in TTS[4]. It is however difficult to study such a broad array of complaints that present in variable combinations in a prospective way. Therefore, here we studied the effect of paper patches on the symptom that is, in our experience, cardinal and most commonly encountered: aural fullness.

Materials and methods

For this prospective, single-blind, placebo-controlled study, between October 2011 and August 2012, we recruited consecutive patients with the complaint of aural fullness independent of suspected or proven aetiology. Patients were included if they complained of aural fullness or pressure, a dull feeling or unexplained pain in the ear, or a feeling like they were underwater or in a plane, and if they fully agreed when asked whether their complaint could be accurately described as a "feeling of fullness in the ear". Exclusion criteria were as follows: (1) middle-ear diseases, including otitis media with effusion, tubal dysfunction associated with low pressure in the middle ear, acute otitis media, cholesteatoma, cerumen, TM perforation, or atelectasis of the TM (patients with otosclerosis were not excluded); (2) serious causes of aural fullness requiring urgent action, such as temporal bone infection or tumours in the head and neck

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region; (3) pregnancy; (4) severe psychological disorders; (5) unclear response reliability (for example, from mentally handicapped individuals); and (6) age of <18 years.

Patients were screened for inclusion based on patient history; microscopic examination of the TM; examination of the throat, nasopharynx, hypopharynx, and larynx; neck palpation; and tympanometry. Hearing loss revealed by audiometry was not considered relevant. Computed tomography or magnetic resonance imaging was only performed when appropriate, for the same indications as in routine clinical practice. All included patients provided written informed consent, and this study was approved by the ethical committee of our institution.

The study included 22 patients (9 men and 13 women). From these patients, a total of 28 ears were allocated to groups using urn randomization: 13 ears (11 patients) received treatment, and 15 ears (11 patients) underwent a placebo procedure. Of the six patients with bilateral complaints, one received treatment in both ears, three received the placebo intervention in both ears, and two received treatment in one ear and the placebo intervention in the other. Three patients with unilateral complaints (two in the treatment group and one in the placebo group) had previously received paper patch treatment.

The treatment involved application on the TM of 1 to 3 small, slightly wet paper patches of 2–4 mm in size (cigarette paper RIZLA + blue, 14.5 g/m^2; L. Lacroix, Wilrijk, Belgium). Two smaller patches were placed on the upper half of the TM, one anterior and one posterior to the malleus (Figure 1A), and/or one larger patch was positioned to cover the inferior half of the TM (Figure 1B). Patches covering the lower half of the TM were placed close to the annulus, covering the outer edge of the TM, where the curve is most prominent. The paper patch location for each individual patient was determined as follows. If an area was visibly thin, that area was chosen. Otherwise, the examiner gently touched the TM with an instrument. If the TM appeared very sensitive to touching, the upper quadrants were chosen. Otherwise, the lower half or the whole TM was covered. Local anaesthesia of the TM was not required. Patches were applied on the upper quadrants in six ears, on the lower half in three ears, and covering the whole TM in four ears.

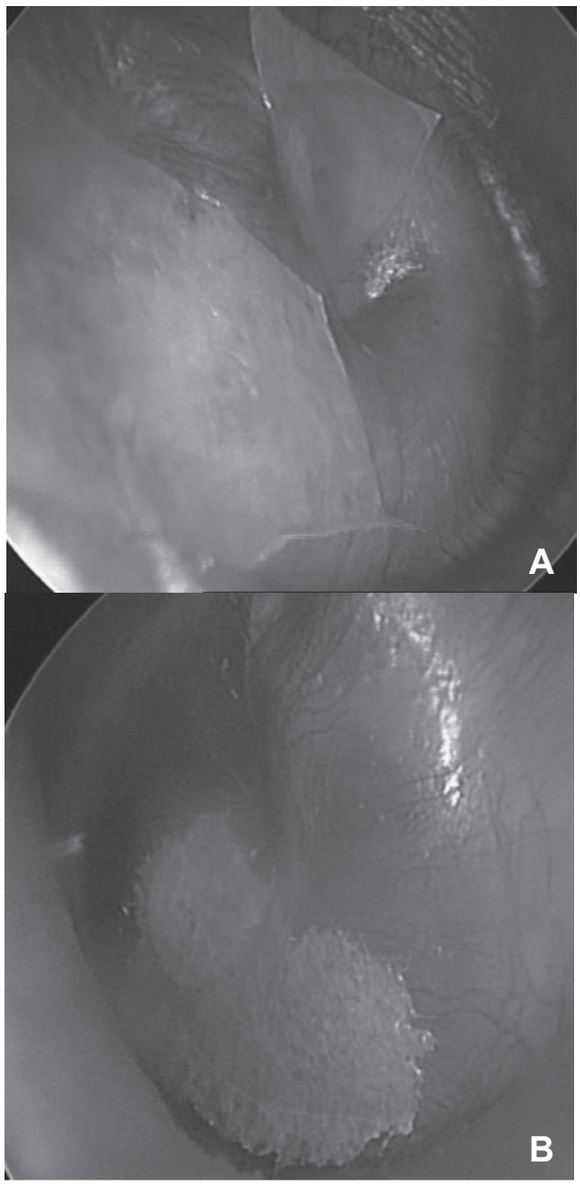

Figure 1

Paper patches covering the upper quadrants (A) and the lower half (B) of the TM.

The placebo intervention involved touching the skin of the external ear canal in the same manner as in the treatment group, followed by application of patches lateral to the annulus.

At one week post-intervention, the ears were examined to determine the patch condition—i.e. whether they were in place or dislodged, and dry or wet.

For each included ear, the patient's perception of aural fullness was scored on a scale of 0 to 10, with

0 representing "no complaints" and 10 representing an "unbearable feeling of fullness". Patients completed this scoring three times: at enrolment, immediately after the intervention, and at one week post-intervention. At enrolment and at one week post-intervention, patients provided separate scores to reflect the average and peak aural fullness experienced during the preceding week. If the patients had not experienced aural fullness on every day of the week, they considered only the days on which the symptoms had been present. Prior to the intervention and immediately after the intervention, patients scored the severity of aural fullness felt at that moment.

Patients were also asked to score the severity of other complaints in their head and neck region, any changes in hearing associated with aural fullness, and any adverse effects of the intervention. Patients were encouraged to note any other complaints in their head and neck area, even if these were not clearly related to aural fullness. These complaints were scored separately, in the same manner as described above for aural fullness—i.e. average and peak scores for the week before and the week following the intervention, and the present score for immediately before and after the intervention. Any subjective change in hearing that may have accompanied the feeling of aural fullness was scored at enrolment, immediately after the intervention, and at one week post-intervention. Subjective hearing loss was ranked as considerable, moderate, slight, or very slight, and was classified as unchanged or as showing very slight, slight, moderate, or considerable hearing improvement. Adverse effects due to the intervention were scored immediately after the intervention and again one week later.

The Mann-Whitney U test and Fisher's exact test were used to compare the distributions of patients' characteristics and between-group differences in baseline symptom perception scores. The Wilcoxon signed ranked test was used to evaluate changes in complaint scores at the different assessment time-points. We used multivariate linear models (adjusted for baseline scores, age, and gender) to compare between-group differences in the post-intervention scores. Regression coefficients associated with an explanatory variable were calculated to estimate the impact on the post-intervention scores, independently of the other variables in the model. By including appropriate multiplicative terms in these models, we evaluated the statistical interactions with treatment. Model assumptions were validated by graphical inspection of the Pearson residuals. All analyses were performed using SAS software (version 9.3; SAS Institute Inc., Cary, NC, USA). An alpha level of 0.05 was considered to indicate statistical significance.

Results

Mean patient age was 48.4 years in the overall group (range, 29–74 years), 47.0 years in the treatment group, and 49.6 years in the placebo group ($p = 0.89$). The treatment group included a greater percentage of men compared to the placebo group (46.2% vs. 26.7%, $p = 0.43$).

Baseline aural fullness perception scores were equal in the two groups. The average feeling of fullness during the week preceding the intervention was 5.62 (SD 1.26) in the treatment group, and 5.20 (SD 1.86) in the placebo group ($p = 0.59$). The peak feeling of fullness during the week before the intervention was 7.23 (SD 1.74) for the treatment group, and 6.13 (SD 2.00) for the placebo group ($p = 0.13$). The average aural fullness score immediately prior to the intervention was 5.00 (SD 2.55) in the treatment group, and 3.53 (SD 2.59) in the placebo group ($p = 0.14$).

Immediately after the intervention, aural fullness was not significantly reduced in the treatment group (Table 1), with a mean reduction in complaint score of –0.77 (SD 2.01, $p = 0.20$). On the other hand, the placebo group showed a significant immediate effect, with an average reduction in complaint score of –1.00 (SD 1.89, $p = 0.02$). At one week following treatment, the treatment group showed a significant effect with regards to both the average and peak aural fullness scores. In the treatment group, the mean score reduction was –2.00 (SD 2.00, $p = 0.006$) for average aural fullness, and –1.77 (SD 2.49, $p = 0.01$) for peak fullness. In the placebo group, the average aural fullness score showed a mean reduction of –0.13 (SD 1.55, $p = 0.72$), while the peak fullness score showed a mean increase of +0.33 (SD 1.10, $p = 0.37$) (Figure 2 A,B).

Multivariate analysis revealed a significant treatment effect in both the average and the peak aural fullness scores, independent of age, gender, and baseline complaint scores (Table 2). The model showed estimated net between-group differences in perception scores of –1.66 for average fullness ($p =$

Table 1

Changes in symptom perception scores following intervention

Group	Mean (SD) score		Change		
	Before	After	Mean (SD)	95% CI for mean	*p**
Placebo (N = 15)					
On average	5.20 (1.86)	5.07 (1.83)	-0.13 (1.55)	-0.99 to +0.73	0.72
Peak	6.13 (2.00)	6.47 (2.13)	+0.33 (1.10)	-0.44 to +1.11	0.37
At visit	3.53 (2.59)	2.53 (2.64)	-1.00 (1.89)	-2.05 to +0.05	0.02
Treatment (N = 13)					
On average	5.62 (1.26)	3.62 (2.26)	-2.00 (2.00)	-3.21 to -0.79	0.006
Peak	7.23 (1.74)	5.46 (2.60)	-1.77 (2.49)	-3.27 to -0.26	0.01
At visit	5.00 (2.55)	4.23 (1.48)	-0.77 (2.01)	-1.98 to +0.44	0.20

Average and peak aural fullness were scored for the week preceding the intervention and at one week after the intervention (for the preceding week); aural fullness at the visit was scored immediately before and immediately after the intervention. *According to the Wilcoxon signed rank test

Table 2

Multivariate analysis of the change in symptom perception scores

	Outcome: Symptom perception score following intervention					
	On average		**Peak**		**Time of intervention**	
	β (SE)*	*p*	β (SE)	*p*	β (SE)	*p*
Intercept	1.62 (1.76)	0.37	3.19 (2.12)	0.15	1.94 (1.34)	0.16
Age (per 10 years)	-0.07 (0.28)	0.81	-0.31 (0.30)	0.32	-0.32 (0.27)	0.25
Gender (male vs. female)	-0.63 (0.76)	0.42	-0.72 (0.89)	0.43	-0.24 (0.67)	0.72
Score prior to intervention	+0.76 (0.23)	0.003	+0.81 (0.23)	0.002	+0.63 (0.13)	<0.001
Treatment vs. placebo	-1.66 (0.70)	0.02	-1.84 (0.78)	0.03	+0.74 (0.68)	0.29

*β (SE) = estimated regression coefficient (standard error)

0.02) and −1.84 for peak fullness ($p = 0.03$). There was no significant immediate effect in the treatment group compared to the placebo group. Multivariate modelling analysis confirmed an immediate placebo effect, as the reduction in complaint score immediately following intervention was significantly larger in the placebo group (interaction $p = 0.02$).

Many patients reported complaints in their head and neck region accompanying their aural fullness during the week before the intervention (Table 3). Eleven patients (11 ears) had one additional complaint, 6 patients (6 ears) had two, 1 had four, and 1 had five additional complaints, and six patients (9 ears) reported no additional complaints. Eight patients reported tinnitus. During the week prior to intervention, the average tinnitus score was 5.11 and the peak score was 6. Just prior to intervention, the average tinnitus score was 4. Immediately following the intervention, the mean tinnitus score was slightly increased (+0.33 treatment vs. +0.67 placebo). A slight decrease was reported at one week post-intervention (−1.33 treatment vs. −1.33 placebo for average tinnitus, and −1.17 vs. −1.33 for peak tinnitus). None of these differences in tinnitus score were significant. With regards to other accompanying symptoms, none were reported to increase following the intervention, and some patients reported post-intervention improvements in the average and peak perception of some complaints.

Aural fullness was accompanied by some subjective hearing in 19 of the 28 ears. This hearing loss was categorized as moderate or considerable in five ears (two in the treatment group, three in the placebo group). Among these five ears, improvement (N = 1) or considerable improvement (N = 1) was reported for the two ears in the treatment group at one week post-intervention, while a very slight improvement was noted for one of the three ears in the placebo group. At one week post-intervention, no patient reported increased hearing loss.

Adverse effects reported immediately after patching included slight itching (N = 1), duller

sound (N = 1), and slight ear pain caused by the patch (N = 2) or by manipulation (N = 2). These complaints resolved quickly. At one week post-treatment, one patient reported a salty taste in the mouth, and another reported that some aural fullness and vibration had endured for the first few days following patch application.

Examination at one week post-intervention showed that none of the patches were dry or dislodged from the TM.

Discussion

Our present results indicate that paper patching is an efficient symptomatic treatment for aural fullness of unproven or vague aetiology, with benefits experienced during the first week following the intervention. We also detected immediate benefits that resulted from a placebo effect and were not predictive of the results after one week.

We previously found that the choice of patch location on the TM was important,[1] with improper patch application being less effective, not effective at all, or even leading to exacerbation of complaints. Some rules of thumb for choosing the most appropriate location have emerged in a rather heuristic way (as described in "materials and methods". If patching shows no benefit after one week, we patch other locations with one-week intervals. Incorrect patching location typically leads to increased complaints or the emergence of resonance after around 3 days, and these complaints will generally disappear around 3 days after patch removal. However, in anxious patients, this temporary symptom exacerbation may greatly enhance anxiety, with a subsequent risk of a potentially lasting increase in certain complaints, such as tinnitus. Therefore, patients are warned of the possibility of a temporary worsening of symptoms, and are asked to return immediately for patch removal or repositioning if this happens.

Drying out of the patches should be suspected when the original symptoms recur after a symptom-free period, accompanied by cracking noises or slight pain upon swallowing. In such cases, these complaints immediately disappear upon addition of a drop of water on the patches. As a preventive measure, patients are advised to apply a drop of ordinary tap water deep in the ear with a syringe, twice weekly. In most patients, the patches remain in place for about a month. As in PET, some patients remain symptom-free long after patch dislodgement, while others regularly return for repeated patching.

The effect of patching on autophony in PET is explained based on how patching influences the TM resonance frequency (RF).[1] The RF of a vibrating membrane is dependent on mass and stiffness, with

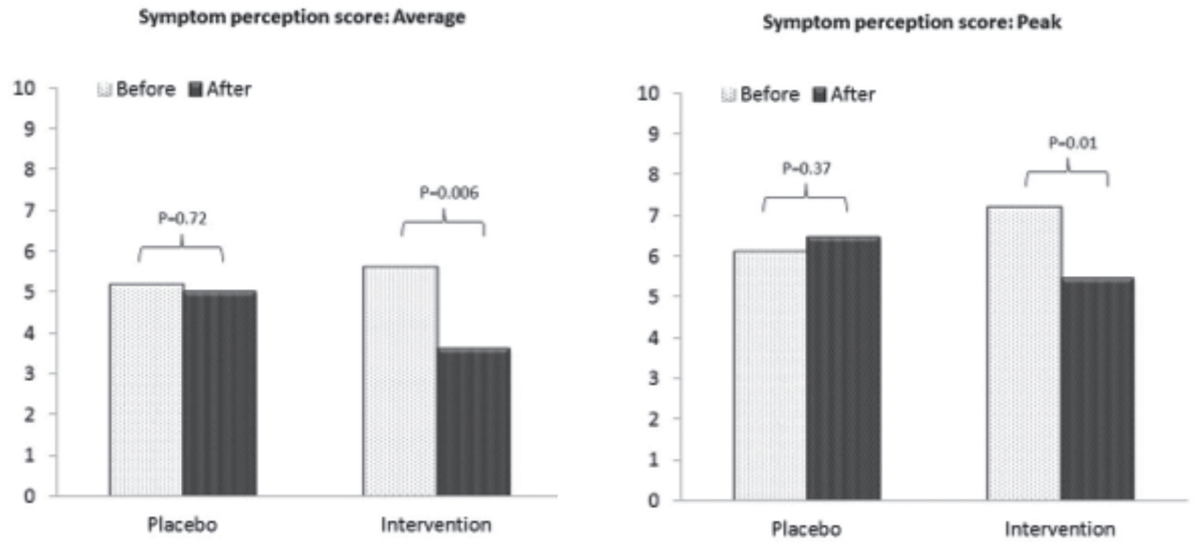

Figure 2
Symptom perception scores for average and peak aural fullness.

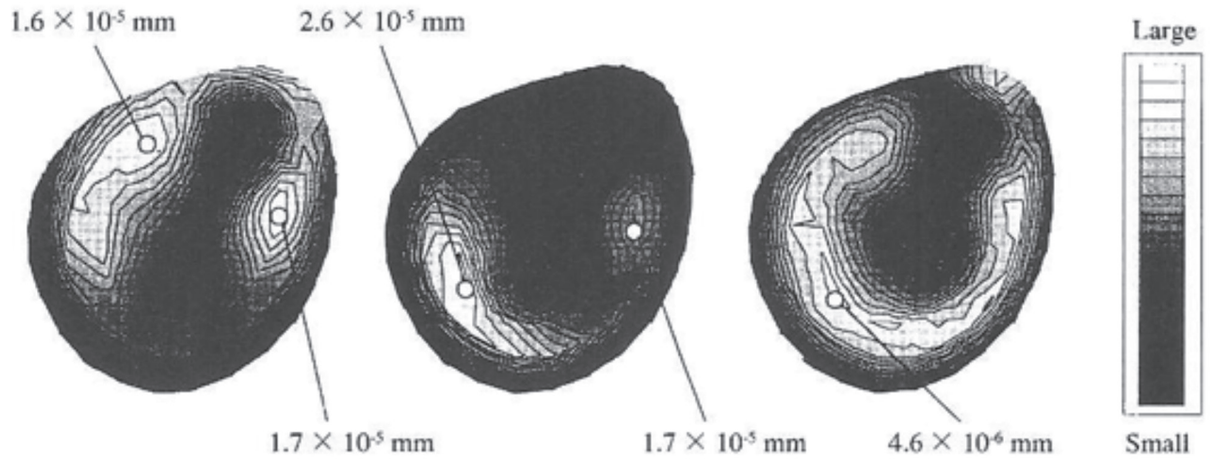

Figure 3

Finite element model analysis, showing vibration patterns of the human TM with stimulus of 80 dB SPL for 850 Hz (left), 2000 Hz (middle), and 4000 Hz (right). Maximal vibration patterns for the lower frequencies are situated in the upper quadrants, while those for the middle frequencies are mainly situated on the lower half of the TM. Reproduced with permission.[5]

Table 3

Complaints accompanying aural fullness*

Complaint	Examples
Tinnitus	–
Pain in head & neck region	Frontal headache or pressure feeling, toothache & temporo-mandibular joint pain, pain over neck extending to shoulder, pain in neck, pain in ear when exposed to loud noise, inflated feeling in head, warm glow in ear
Hypersensitivity to sounds, or unwanted sounds in ear	Tinnitus becoming louder when exposed to loud noises/radio, noises too loud, background noises too loud, vibration feeling in ear, heartbeat in ear
Imbalance	Balance problems, nausea, carsickness
Throat symptoms	Mucus, deglutition problems, throat pain

*Presented in order of frequency

increased membrane stiffness inducing an upward shift in RF. The TM RF can shift downward, for example, in TMs with thinner areas, in cases of ossicular discontinuity, or when the middle-ear air cushion is lost in the presence of a wide open ET.[5–10] In PET patients, this downward shift (or increase in admittance for the lower frequencies), is likely to be at least partly responsible for the autophony.[1] Paper patching artificially increases TM stiffness, resulting in an upward shift of TM RF that eliminates autophony.

The TM possesses many RFs that correspond to maximum vibration patterns, located on specific areas of the TM.[5,6,11-13] The RFs for lower frequencies are located on the upper half of the TM, while those for mid-range frequencies exist on the lower half of the TM (Figure 3). Patch application on a specific area of the TM increases the stiffness for that particular TM region, inducing an upward shift of the RFs for the frequencies associated with that location. Patching, however, also eliminates the aural fullness that often accompanies autophony in PET. We hypothesize that this effect may be linked to termination of the contraction of the tensor tympani muscle (TT).

The effects of TT contraction on TM RF have been well studied. Moderate TT contraction increases the stiffness of the tympano-ossicular system and shifts the overall RF of the TM upward, damping lower frequencies (grossly 500–1000 Hz) and promoting mid-range frequencies (grossly 1000–4000 Hz).[14–18] This upward shift can presumably counteract the downward shift observed in PET, thus effectively eliminating unwanted resonances for the lower

and mid-frequencies, including autophony. The artificially produced upward shift brought about by patching may result in termination of this sustained contraction.

Aural fullness is suggested to be the main symptom caused by sustained TT contraction in TTS and in masticatory muscle pathology (labelled as Costen's syndrome, otognatic syndrome, or otomandibular syndrome).[4,19-23] This mechanism also appears to be involved in the aural fullness experienced in Ménière's disease.[24,25] No available data explain the aetiology of aural fullness accompanying sudden deafness. However, this symptom appears to be associated with the lower frequencies, and may originate from a functional factor rather than from an organic lesion of the cochlea.[26]

Our present study results suggest that the above-mentioned acoustic mechanism may also be involved in patients suffering from aural fullness without autophony. Additional research in larger patient groups with more specific inclusion criteria is needed to investigate this intriguing possibility.

Our present study has several limitations, including a high likelihood of selection bias. In the vast majority of patients presenting with aural fullness, it is not possible to make an exact diagnosis sufficient for scientific reporting. Thus, we chose to study the feeling of aural fullness, irrespective of its putative aetiology. Our inclusion criteria were broadly defined, and most (if not all) included patients had a vague diagnosis, such as TTS or atypical "possible Ménière's disease", or only a suspected link with TMD, bruxism, or neck muscle tensions. None of the included patients were diagnosed with sudden deafness, definite Ménière's disease, or oncological disease. Notably, our extended list of accompanying symptoms closely matched the symptoms associated with myofascial pain syndrome and TTS.[4,23] We therefore consider this first-in-man study to be a pilot study. Pending the attainment of more precise data from further studies in larger patient cohorts divided into clinically defined groups, our present findings cannot be extended to these specific diseases, but must rather be limited to patients presenting with aural fullness of unknown or vague aetiology. Another shortcoming of our present study was the lack of follow-up to document how long the perceived effect lasted after patch dislodgement.

Pending the availability of additional data from further studies, paper patching should be regarded as only a symptomatic treatment, and not as an established diagnostic tool. It remains unknown whether and how patching may affect aural fullness secondary to petrous apex infections, or head and neck tumours. Importantly, a positive response to patching should not influence regular diagnostic investigations focused on these possible aetiologies.

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