

ORIGINAL PAPERS

A Controlled Trial of Aromatherapy for Agitation in Nursing Home Patients with Dementia

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ABSTRACT

Objectives: Two controlled trials of aromatherapy to decrease agitation in persons with dementia have recently produced promising results. However, both studies combined the use of essential oils with massage. Thus, it is unclear if the effect of the aromatherapy intervention was the result of smelling or the cutaneous absorption of the oils. The purpose of this study was to determine whether smelling lavender oil decreases the frequency of agitated behaviors in patients with dementia.

Design: The study design was within-subjects ABCBA (A = lavender oil, B = thyme oil, C = unscented grapeseed oil): 4 weeks of baseline measurement, 2 weeks for each of the five treatment conditions (10-week total intervention time), and 2 weeks of postintervention measurement. Oil was placed every 3 hours on an absorbent fabric sachet pinned near the collarbone of each participant's shirt.

Setting: A long-term care facility specifically for persons with dementia.

Participants: Seven agitated nursing home residents with advanced dementia.

Measurements: Agitation was assessed every 2 days using a modified Cohen-Mansfield Agitation Inventory. Olfactory functioning was assessed with structured olfactory identification and discrimination tasks, and with qualitative behavioral observation during those tasks.

Results: Split-middle analyses conducted separately for each patient revealed no treatment effects specific to lavender, no treatment effects nonspecific to pleasant smelling substances, and no treatment effects dependent on order of treatment administration. There were no differences between participants with more and less intact olfactory abilities.

Conclusion: There is significant evidence in the neurologic and neuropsychologic literature that persons with dementia have impaired olfactory abilities. Concordant with this literature, this study found no support for the use of a purely olfactory form of aromatherapy to decrease agitation in severely demented patients. Cutaneous application of the essential oil may be necessary to achieve the effects reported in previous controlled studies.

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INTRODUCTION

Aromatherapy and other alternative therapies have received increased interest in medical research (Fontanarosa and Lundberg, 1998; Margolin, et al., 1998; Eisenberg, et al., 1998; Department of Health and Human Services, 1998; Cooke and Ernst, 2000). There has been growing interest in the use of aromatherapy for reducing agitation in demented patients because of the purported calming effects of some essential oils, and because the passive nature of the treatment makes it relatively easy to implement (Howdyshell, 1998; Kilstoff and Chenoweth, 1998; MacMahon and Kermode, 1998; O'Brien, 1997; Tobin, 1995; Vance, 1999; Wolfe and Herzberg, 1996).

Recently, two controlled trials of aromatherapy to decrease agitation in persons with dementia have produced promising results. One study randomly assigned residents with severe dementia and clinically significant agitation to aromatherapy with Melissa oil or to sunflower oil as a placebo. Both treatments were rubbed onto patients' faces and arms in a lotion base. A 35% decrease in agitation was found in the treatment group whereas the placebo group demonstrated only an 11% reduction (Ballard et al., 2002). However, this study did not include an aroma-only condition, and thus, it is unclear if the effect of the aromatherapy intervention was the result of smelling the essential oils or the cutaneous absorption of the oils.

Another study did include an aroma-only condition (Smallwood et al., 2001). Demented inpatients on a general hospital ward were divided into three groups and given one of three treatments: lavender aromatherapy administered by massaging the oil into the skin; lavender aromatherapy administered through a diffuser; or plain oil massage. Unfortunately, this study did not include agitation as an inclusion criterion. Furthermore, agitation was not measured specifically, although motor behavior was measured as a proxy. Although no overall group differences were observed, there was a trend toward more consistent reduction in motor behavior (approximately 11%) after the aromatherapy massage than either other condition.

It is important to determine if the aroma of a calming essential oil alone is sufficient to decrease agitation or if cutaneous absorption is required. Whereas massage might require a trained professional and requires one-on-one staff time, exposing patients to an aroma requires no significant training and could conceivably involve several patients simultaneously. There is some evidence to suggest that aroma alone might be beneficial. One uncontrolled study investigating the effects of lavender oil aroma, plain oil massage, and lavender oil massage on behavioral disturbance in four agitated nursing home residents with dementia reported lavender aroma alone was as effective as lavender oil massage (Brooker et al., 1997).

It is well established that olfactory functioning is impaired in Alzheimer's disease, as demonstrated by consistent find-

ings of impairments in olfactory discrimination, recognition, and identification (Doty et al., 1987; Murphy et al., 1990; Rezek 1987). However, there is widespread agreement that most patients with Alzheimer's disease are not totally anosmic (Nordin and Murphy, 1996; Thompson et al., 1998). Furthermore, there is little consensus on the precise nature of the olfactory deficits; some studies report elevated olfactory thresholds in patients with Alzheimer's disease (Rezek, 1987; Knupfer and Spiegel, 1986; Serby et al., 1991), whereas other studies find normal thresholds (Larsson et al., 1999). Precisely what olfactory processing capabilities might be necessary to derive a behavioral benefit from the lavender aroma is also unclear (Kilstoff and Chenoweth, 1998). It may be that even individuals displaying significant olfactory impairment are able to achieve treatment effects by smelling calming essential oils.

One possible mechanism for such an effect might be absorption into the bloodstream rather than by stimulation of the olfactory nerve (through binding to particular receptors in the nasal epithelium). A study of mice exposed to lavender aroma provides support for this mechanism because linalool, one of the key constituents of lavender, was found in the blood of the mice after exposure (Buchbauer et al., 1991). If this is so, then the ability to identify, recognize, discriminate, or even consciously perceive the odor may not be necessary for it to affect behavior.

This pilot study investigated whether exposure to lavender oil aroma decreased the frequency of agitated behaviors in patients with dementia and significant agitation. A secondary objective of this study was to assess the olfactory capabilities of aromatherapy responders and nonresponders. Finally, this study was designed to explore whether treatment benefits were the result of lavender's specific effects or the nonspecific effects of a pleasant odor.

Lavender, which has long been purported to have a calming effect in folk medicine and among those who practice aromatherapy (Worwood, 1996; Bartram, 1995), was chosen as the aromatherapy treatment for this investigation because its purported calming effects have been widely investigated (e.g., Zeilmann, et al., 2003; Kowalski, 2002; Gyllenhaal, et al., 2000), and it has a more favorable side-effect profile than many other essential oils (Tisserand, 1988). In addition, the sedative properties of lavender have been demonstrated in animal studies under laboratory conditions. After 30 minutes of lavender oil exposure, mice decreased motor activity by 78%, the most marked sedative effect of 42 essential oils and fragrance compounds tested (Buchbauer et al., 1993). It was hypothesized lavender oil would decrease the frequency of agitated behavior in nursing home residents with dementia, but a second odorant, thyme oil, would not. This hypothesis was based on the assumption that as the animal studies suggest, lavender has a pharmacologic effect as a result of bloodstream absorption, not an emotional effect dependent on pleasant smell. Thyme was chosen as the contrast treatment because it is also pleas-

ant-smelling, but is purported by aromatherapists to have a stimulating effect (Tisserand, 1988). This anecdotal claim is supported by evidence that thymol (the main constituent of thyme oil) increases motor activity in mice (Buchbauer et al., 1993).

MATERIALS AND METHODS

Participants

Seven residents of a nursing home specifically for persons with dementia participated in the study. Nursing staff were asked to nominate residents with probable Alzheimer's disease who displayed "marked agitation." To quantify agitation severity, staff completed a long-form Cohen-Mansfield Agitation Inventory (CMAI) for each nominated resident. The CMAI is an inventory of 29 observable agitated behaviors that are rated for frequency of occurrence over the past 2 weeks on a 7-point Likert scale (Cohen-Mansfield, 1991). A CMAI score of 24, indicating moderate agitation (i.e., 1 standard deviation [SD] above the mean CMAI score reported by day-shift nurses rating nursing home patients), was required for inclusion in the study (Cohen-Mansfield et al., 1989). Informed consent was obtained from relatives or proxies holding power of attorney for the dementia patients. The protocol was approved by the Institutional Review Boards of the nursing home and the university.

Procedure

A 2 × 2 inch absorbent fabric sachet was securely pinned to the front of each participant's shirt near the collarbone. Two drops of pure undiluted lavender oil (*Lavendula angustifolia*), pure undiluted thyme oil (*Thymus vulgaris*), or unscented grapeseed oil were placed on the sachet every 3 hours during the day shift, for a total of three applications per day. This dosing schedule is recommended by aromatherapists (Ergen, 1982; Price and Price, 1995), who claim it influences behavior without bringing about scent adaptation. All aspects of the aroma treatment procedure were developed for us by a certified aromatherapist (L. Kyle, R.N., M.S.N., C.S., C.M.T., 1999 President of the National Association of Holistic Aromatherapy, written communication, February, 1999).

Essential oils were obtained from a commercial supplier recommended by our aromatherapy expert for authenticity and purity of materials. Gas chromatography analysis of the terpene constituents established that the oils were acceptable samples of lavender and thyme (top two constituents: lavender = linalyl acetate (35%) and linalool (24%); thyme = thymol (43%) and para cymene (26%)).

The study design was within-subjects ABCBA (A = lavender oil, B = thyme oil, C = unscented grapeseed oil): 4 weeks of baseline measurement, 2 weeks for each of the five treatment conditions (10 week total intervention time), and 2 weeks of postintervention measurement. It was ex-

pected that agitation would significantly decrease only in the A condition. Significant decreases in A and B conditions would suggest a nonspecific effect of a pleasant-smelling substance, whereas significant decreases in A, B, and C conditions would suggest a placebo effect. The advantages of this design are that each subject served as their own control, and repetition of A and B conditions provided replication and tested for order effects (Hersen and Barlow, 1976). All participants received all aromas in the same order to avoid the cross-contamination of aromas that would have occurred in the shared nursing home environment if aroma orders had been randomized or counterbalanced.

Measures

The frequency and severity of agitated behaviors was assessed with a modified version of the CMAI short form (Cohen-Mansfield, 1991), completed by interviewing the day-shift nurse and day-shift nursing assistants every other day during the 16-week study.

Prior to the intervention, dementia severity and olfactory functioning were assessed. Dementia severity was assessed with the Severe Impairment Rating Scale (SIRS) (Rabins and Steele, 1996). The SIRS is an 11-item scale (range, 0–20) in which the patient is rated on a series of simple tasks during the course of a short interview, such as saying hello and goodbye appropriately and following simple commands. Ceiling effects are generally found with the SIRS when it is used with individuals with Mini Mental State Exam (MMSE) scores of greater than 5; thus in those individuals who do not receive a perfect score on the SIRS, corresponding MMSE range is from 4 to 0 (Rabins and Steele, 1996).

Olfactory functioning was tested through several approaches, in descending order of cognitive difficulty. Olfactory identification was assessed by giving the participant odorants to sniff and name. The participant was asked to choose the correct name of the stimulus from three possible choices. Olfactory discrimination was assessed by presenting participants with two stimulus odors successively, then asking them to determine if they were the same or different. In 50% of the trials (5 of 10 total trials), the second stimulus was identical to the first; in the other 50% the second stimulus was different (method developed by Corwin et al., [1985]). Finally, any participant reaction to the presentation of the odorants in the above two tasks was recorded verbatim. This allowed us to assess if the participant reacted to the odorant in a manner that might indicate the odorant was smelled, even if the participant was unable to complete the cognitive task. The odorants used for both tasks were common strong smelling substances with minimal trigeminal stimulation (e.g., coffee, peanut butter, soap).

Analyses

The split-middle data analytic approach for single case evaluation was used (Kazdin, 1984). This method involves

identifying the linear trend for each treatment phase, and comparing the slopes of these trend lines to each other to determine if the rate of behavior change over time is altered by the introduction of a new treatment condition. In terms of the split middle analytic approach, the hypothesized treatment effects for this ABCBA study were that: (1) compared to baseline, the rate of behavior change (slope) for lavender (A) would be significantly steeper and negative (indicating decreasing agitation); (2) compared to the slope for lavender the slope for thyme would indicate agitation decreasing at a slower rate or increasing, (3) the above hypothesized effects would be replicated at the second exposure to lavender and thyme.

This approach has several advantages over repeated measures analysis of variance for this sample. First, given the power limitations of this study and thus the limitations on our ability to detect smaller treatment effects if they do exist, it is better to treat the analyses as a series of single case evaluations rather than aggregating the subjects together. This approach allows us to the treatments closely examine each subject's responses, meaning that if a treatment effect was to exist for even just one subject, we would be more likely to detect it, whereas in using an analysis of variance (ANOVA) approach we might miss a treatment response in one or two subjects when looking at the sample response as a whole. Second, the split-middle approach analyzes trends in slope rather than mean differences, and thus is more likely to detect changes from phase to phase that might be obscured by averaging the observation values. Finally, the slopes that provide the basis of the analysis are based on median, not mean values, and thus are less influenced by outliers. This is important because our data was highly variable (Fig. 1).

RESULTS

The mean SIRS score was 13.29 (SD = 5.25, range, 8–18). A score of 13 means that of the 11 tasks, the individual was completely unable to complete 2 to 3 or could only partially complete 3 to 4. All tasks are very basic, representing those abilities preserved longest in the disease process including rote responses (saying "hello" in response to the same greeting from the examiner, saying one's name in response to that question), repetition (repeat after me; 1, 2, 3), and basic praxis (ability to walk, sit, hold a pencil, track examiner with one's eyes). Thus, these SIRS scores indicated all participants were severely to profoundly impaired.

Only two participants were able to respond meaningfully to the olfactory identification task, and neither performed better than chance (subject 2, 4/8 correctly identified; subject 6, 2/8 correctly identified). Three participants were able to respond meaningfully to the olfactory discrimination task,

and two performed slightly better than chance (subject 2, 5/8 correctly identified; subject 4, 3/8 correctly identified; subject 6, 5/8 correctly identified). Verbatim recordings of the responses of these three participants suggested these individuals did have some kind of olfactory experience. For example, when subject 4 was presented with ammonia the response was "my eyes water" whereas the response to cloves was "that's good." Of the other four participants, three sniffed the odorants when they placed in front of their noses, but did not make any meaningful verbal responses, and one did not respond at all when the odorants were presented.

In summary, two participants were able to perform slightly better than chance for a task of olfactory discrimination, suggesting that at least they were not anosmic, although the confounding of cognitive impairment with the olfactory testing precludes any specific conclusions about their olfactory capabilities. Similarly, qualitative data suggests that a third participant had at least rudimentary olfactory capability. The other four participants were completely untestable, and thus it is unclear if they were capable of any olfactory experience.

Figure 1 illustrates participant agitation scores across treatment phases; superimposed on this response profile for each phase is the slope of the agitation scores. No participant demonstrated the hypothesized treatment effect profile (which would have been that compared to preintervention and postintervention baselines, significant decreases would be present in both lavender conditions, and only the lavender conditions). Furthermore, no participant demonstrated the treatment effect profile that would suggest a nonspecific effect for pleasant smelling substances (which would have been that compared to baselines and the unscented phase, significant decreases would be present in both lavender conditions and both thyme conditions). There was also no indication of a global placebo effect (which would have been that compared to baselines, significant decreases would be present in all lavender, thyme, and unscented conditions). Finally, possible treatment effects dependent on the order of the administration of treatments were not supported; some participants did exhibit a decrease in one lavender condition that was not replicated in the other lavender condition, but there was no consistency across participants regarding which lavender phase (first or second) caused the effect.

DISCUSSION

This pilot study examined the effects of short-term lavender aromatherapy on agitation in severely demented individuals, as well as the nonspecific effects of pleasant smells on agitation. A secondary objective of this study was to assess the olfactory capabilities of aromatherapy responders and nonresponders. Neither lavender nor a second pleasant

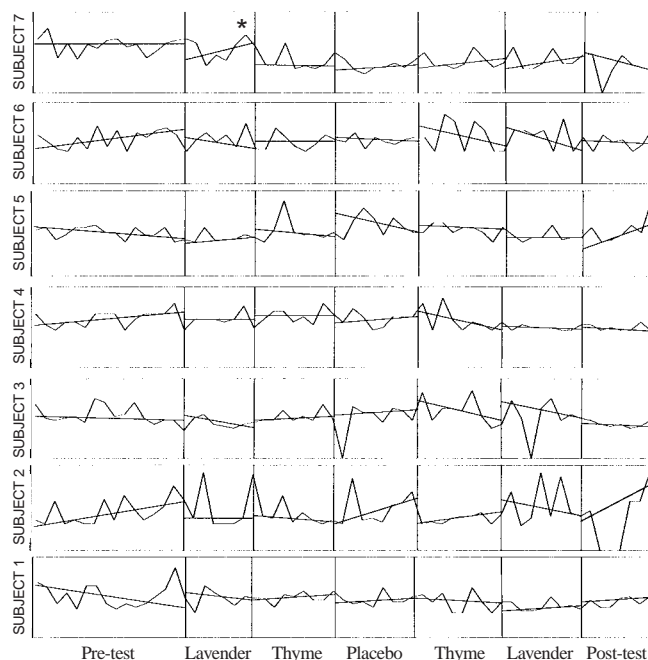


FIG. 1. *Significant difference in slope between indicated phase and the phase immediately following ($p < 0.05$). NOTE: X-axis represents time in days and treatment phase. Y-axis represents Cohen-Mansfield Agitation Inventory (CMAI) scores. For each subject, the Y-axis represents a continuum of CMAI scores from 0 (no agitation) to 40 (severe agitation).

smelling oil produced reductions in agitation. Furthermore, this absence of treatment effect was present across all participants, including those who evidenced some olfactory capability.

One striking difference between this study and previous controlled studies reporting positive treatment effects (Ballard, et al., 2002; Smallwood et al., 2001) was the mode of administration, suggesting cutaneous application of the essential oil may be necessary to achieve treatment effects. This conclusion contradicts a report that lavender aroma alone was as effective as lavender oil massage in decreasing agitation (Brooker et al., 1997). However, that study included only four participants, and they were not well characterized (dementia severity was not assessed, the “distress” inclusion criterion was not quantified using known standardized instruments, and individualized scales of problem behavior were developed for each resident with no psychometric evaluation). The present study represented a more stringent approach because treatments were replicated using the ABCBA design and agitation was assessed with a well-validated instrument.

Our findings also contradict the rodent study that reported sedative effects of lavender aroma (Buchbauer et al., 1991). Perhaps lavender aroma does have an effect, but it is too subtle and transient to be detected without the aid of the controlled environment possible in animal studies, or perhaps the doses used in our study were insufficient. If the actual effect of lavender is subtle or transient, we would not have been able to detect it, because the small sample size in

this pilot study meant that we would be able to detect only a medium or large effect. However, given the serious consequences of treating agitation with a weak treatment, and given that other efficacious treatments including pharmacotherapy and behavior therapy are available, it seems reasonable to assert that only a medium or large treatment effect would be of clinical interest.

We were unable to determine if there is a relationship between lavender aroma effectiveness and level of olfactory functioning. There is significant evidence in the neurologic and neuropsychologic literature that persons with dementia have impaired olfactory abilities, and thus it is reasonable to assume that all participants in our sample suffered from at least some olfactory impairment. Our results only tell us that persons with very rudimentary olfactory abilities are unable to receive benefit from lavender aroma. Further study is needed to examine the effects of aromatherapy on behavior across levels of olfactory ability. To sample a range of olfactory ability will require including less severely demented patients who are able to respond to the cognitive demands of olfactory neuropsychologic tests. However, dementia severity is positively correlated with agitation in Alzheimer’s disease (Lyketsos et al., 2000). One possibility might be to examine patients with fronto-temporal dementia, who typically have quite disturbed behavior with more modest cognitive impairment, and may also have less severe or consistent neuropathology in the hippocampus and amygdala (White and Cummings, 1997).

In summary, there is significant evidence in the neurologic and neuropsychologic literature that persons with dementia have impaired olfactory abilities. Concordant with this literature, this study found no support for the use of a purely olfactory form of aromatherapy to decrease agitation in severely demented patients. Cutaneous application of the essential oil may be necessary to achieve the effects reported in previous controlled studies.

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