

Aromatherapy: Ineffective Treatment or Effective Placebo?

The smell of apple pie may trigger a smile, and a whiff of formaldehyde may evoke memories of the anatomy lab, but can smell actually help patients? The often-overlooked second cranial nerve does have some interesting connections. When molecules arrive at the nose, the olfactory bulb is stimulated and it sends signals to the limbic system, including the amygdala, which governs emotional response.¹ Because certain smells elicit pleasant responses, it is not too great of a leap to imagine that they might also lead to decreased anxiety, pain, or nausea.

Aromatherapy refers to the practice of giving patients essential plant oils to smell. *Essential oils* are “steam distillates obtained from aromatic plants.”¹ Essential oils differ from other kinds of oils (e.g., cooking oils) because they have low boiling points and therefore evaporate quickly to produce an aroma. When used therapeutically, the oils may be placed on a cloth near a patient, put in a bowl of hot water to produce a steam, or administered by mist from a nebulizer or vaporizer. Aromatherapists often use massage in association with the odors. (As there are currently no licensing standards in the United States, anyone can call himself or herself an aromatherapist²).

Although aromatherapy has been used for centuries, there are few high-quality randomized, controlled trials examining the efficacy of this treatment. Most studies have used single-arm, before-and-after comparisons (e.g., “Patients were given a pleasant smell and reported feeling better afterwards”). These types of studies are not particularly helpful because almost any treatment without side effects is likely to produce a beneficial response, either due to a placebo effect or some aspect of the intervention. Although it could be argued that aromatherapy has no side effects and should therefore be given to all patients, any efforts to provide this therapy could detract from the use of other, potentially more beneficial treatments. Furthermore, aromatherapy can be expensive. Studies are clearly needed to determine if aromatherapy is beneficial and whether its effects are comparable to those of other conventional and complementary therapies.

In this issue of **ecp**, Wiebe reports the results of the first randomized, controlled trial to examine the effect of aromatherapy on preoperative anxiety.³ The trial is refreshingly simple and complete. Patients awaiting surgical abortion were randomly selected to sniff a blend of essential oils believed to reduce anxiety or to sniff a pleasant-smelling hair conditioner. Anxiety was assessed before and after the aromatherapy with a 10-point anxiety scale. Both groups of patients showed about a 1-point decrease in anxiety score, and there was no difference between groups. The essential oils were no more effective than the hair conditioner.

As with any negative study, it is reasonable to question whether this study had sufficient power to detect a difference, if one was present. In this case, the authors note that the study had an 80% power to detect a 1-point difference in anxiety scores between groups. A power of 80% is standard, and differences less than 1-point on this anxiety scale seem to be clinically unimportant.

But power calculations are more germane when planning studies; when a study is complete, the best way to scrutinize a negative study is to examine its confidence interval. The confidence interval provides a range of values over which the “true”

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TABLE 1

Possible Study Arms for Trials of Complementary and Alternative Therapies

STUDY ARM	DESCRIPTION	EXAMPLES	
		AROMATHERAPY	ACUPUNCTURE
Active treatment	The clinical treatment of interest (i.e., the strategy being evaluated in the trial)	Sniff the essential oil	Acupuncture with acupuncturist
Control groups			
Sham treatment	Intended to mimic the treatment of interest to facilitate blinding	Sniff hair conditioner	Sham needles with acupuncturist
Time	Equal time with a caring person, but no attempt to mimic treatment	Equal time with the study assistant	Equal time with an acupuncturist
No intervention	Gives insight into the natural history of the condition	Data collection only	Data collection only

value (in this case the difference in anxiety score between groups) is most likely to occur. If a confidence interval is very wide and includes clinically important values, then the negative study has not effectively ruled out important effects of the treatment. In this case, the confidence interval is very small: -0.75 to 0.55 ; thus, it is unlikely that the treatment has any substantial positive or negative effect.

Are pleasant aromas ineffective for reducing preoperative anxiety? Not necessarily. This study only tells us that essential oils are no more effective than hair conditioner. Both groups showed a 1-point reduction in anxiety scores, an amount that may be clinically important. Who would not want to have a little less anxiety before an operation? The observed reduction in anxiety could have been caused by the aromas or may have been due to some other aspect of the intervention or outcome assessment. Perhaps anxiety was reduced by the practice of sitting quietly for a brief period of time or by the short talk with the study assistant. Or maybe it truly was stimulation of the olfactory nerve by both pleasant odors that led to the small reduction in anxiety.

Determining whether either of the two treatments (essential oils and hair conditioner) were better than no treatment at all would require a third, no-intervention study arm. In this arm, patients could simply have their anxiety scores measured at the two time points before the procedure. If the anxiety scores improved by 1 point in this no-intervention group, then it would be possible to conclude that both the essential oils and the hair conditioner were completely ineffective. The 1-point improvement in each group might then simply reflect the natural history of the anxiety experienced in this setting (or some bias in the assessment of the outcome measure).

The Wiebe study³ raises a general question for trials of complementary and alternative medicine: What are the right “control” groups? Table 1 outlines several ways that a control group might be conceived. One approach is to sufficiently mimic active treatment so that blinding occurs (as was done in the Wiebe study). When the control groups become elaborate enough to blind patients, however, the control treatments may actually become effective. For example, acupuncture trials often involve the creation of a control “sham-acupuncture” intervention. In the sham-acupuncture group, patients relax on an acupuncture table and have an acupuncturist pretend to insert needles (or in some cases, insert needles into the wrong spots). Control groups in trials of massage or energy healing may also share some of the benefit of the active treatment. A third, no-intervention arm would allow investigators to determine whether any observed benefits in the control groups were better than doing nothing at all.

Another potential control group could be designed to control for practitioner time. Many complementary and alternative medicine treatments require the practitioner to spend a great deal of time with the patient. Some have speculated that it is not the therapy itself but merely the increased time with a caring person that leads to improved outcomes. In the current study, for example, the study assistant may have been a very caring person and may have eased the anxiety of all patients, regardless of whether they sniffed the pleasant odor. If this is a concern, a control group could be incorporated into a future study whereby the study assistant could spend an equal amount of time in comparison with the other groups but without offering any treatment.

Complementary and alternative medicine studies are more complicated than placebo-controlled, randomized trials of pharmaceutical agents. As the control groups

become more complex, it may be necessary to create several control groups in which different aspects of the intervention are examined. Given the complexity of complementary and alternative medicine studies, an extra helping hand (or arm) may allow investigators to determine which aspects (if any) of the treatments are truly effective.

References

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