

Compounding Topicals in Dermatology

Nadine Shabeeb, MD, MPH



RESIDENT PEARLS

- Compounding topical medications provides dermatologists with the ability to create custom formulations that cater to the individual needs of each patient.
- Dermatologists must keep in mind that data are limited regarding both safety and efficacy of compounded medications.

Compounding topical medications is a way for dermatologists to prescribe customized topical treatment options based on the individualized needs of patients. However, there are limited data on the safety of compounded medications and potential systemic absorption. Additionally, there also are limited data on the efficacy of compounded medications given their unique nature.

Cutis. 2020;105:E25-E26.

Compounding is a way of mixing or combining medications in formulations that are not widely available. Because dermatology is a field that includes a variety of topical treatments, compounding topicals is a way to create unique and customized treatment options for patients.

Advantages

Custom compounding topical medications has many benefits in comparison to traditional topical formulations. Compounding is a way of personalizing prescriptions to best suit the individual needs of each patient. Multiple ingredients with different mechanisms of action can be

combined in a single medication for patients to use, which ultimately can simplify their treatment regimen.¹ For rare conditions with uncommon treatments, compounding pharmacies can provide medications that are not widely available in retail pharmacies. Compounding topical medications also can be an efficient way of prescribing medications without dealing with the uncertainty of prior authorizations or how much the co-pay will be.

Disadvantages

One of the major disadvantages of compounding topical medications is the lack of safety data. Although most active drugs have been tested independently, there is little data on the safety of compounding 2 or more active drugs. Furthermore, the vehicle used may change the permeability of the topical formulation, and systemic absorption may be possible. Two deaths were reported with the application of compounded topical lidocaine and tetracaine gel due to systemic absorption. In these cases, the gel was used before laser hair removal, and it was applied under occlusion to greater than 50% of the body surface area, leading to fatal systemic absorption.^{1,2}

One of the hypothetical benefits of compounding topicals is being able to avoid side effects of systemic medications. However, depending on the skin intactness and the strength of the medication used, systemic adverse effects have been reported.¹ In a case series of 2 patients detailing the use of amitriptyline cream 5% and 10% for neuropathic pain, the patient using 10% cream experienced systemic effects of drowsiness and discontinued treatment.³

Another major disadvantage of compounding topicals is a lack of published data about the efficacy, especially

From the Department of Dermatology, University of Wisconsin Hospital and Clinics, Madison.

The author reports no conflict of interest.

Correspondence: Nadine Shabeeb, MD, MPH, One S Park, 7th Floor, Madison, WI 53715 (nshabeeb@uwhealth.org).

given the unique nature of what is being compounded. When combining multiple medications, there are little to no published data about the efficacy of these formulations and how they compare to monotherapy. Although there may be data about the efficacy of an oral agent, it does not translate to the topical form being safe and efficacious. Much of the published data of topical formulations is limited to case reports and case series.

Finally, many compounded medications are not covered by insurance, and the out-of-pocket cost may be prohibitive for some patients. Compounding pharmacies typically will give patients a price estimate before the prescription is filled. When compounding topicals for patient use, it is important to counsel patients about the following: the unknown safety profile; lack of data regarding efficacy; and cost, as the medication likely will not be covered by insurance.

Pharmaceutical Regulations

After a contaminated product at a compounding pharmacy in New England led to an outbreak of fungal meningitis, there has been increased regulation by the US Food and Drug Administration.⁴ To meet safety regulations, compounding pharmacies must adhere to the standards set by the US Pharmacopeia. The US Food and Drug Administration says that physicians are not to prescribe compounded medications that are “unapproved, adulterated, or misbranded drugs,” which has been interpreted to mean that compounded medications should not mimic a branded medication but should instead be a unique formulation or strength.^{4,5} Thus, while compounding topicals may provide an alternative when a specific medication is not covered by insurance, it cannot be the same as a branded medication.

Pharmaceutical Options

Most major cities have custom compounding pharmacies or apothecaries. One of the benefits of using a local compounding pharmacy is that you typically can speak directly with the pharmacist about your patient’s diagnosis and his/her specific needs. The pharmacist can guide you through which formulations to compound, which

strength to choose, and the best vehicle to use as a base. This expertise is invaluable in the compounding process. There also are online compounding pharmacies available.

Options for Bases

Dermatologists can request for their medications to be compounded in traditional over-the-counter emollients or petrolatum-based products, which work by passively diffusing through the stratum corneum into the superficial epidermis to treat skin conditions.¹ For a topical drug to be absorbed effectively through the skin and into the general circulation, the vehicle needs to have affinity for both lipid and aqueous environments. Lipophilic drugs will absorb better through the stratum corneum, while hydrophilic drugs will absorb better through the aqueous layer of the epidermis. For a topical formulation to be both hydrophobic and hydrophilic, components such as viscosity enhancers and permeation enhancers can be added.¹ Many compounding pharmacies also have proprietary bases that can be used.

Final Thoughts

Compounding topical medications in dermatology provides dermatologists with the ability to provide unique formulations to best suit their patients’ individual needs. However, dermatologists must keep in mind the limitations of compounding topicals, including a lack of data on efficacy and safety.

REFERENCES

1. Cline AE, Turrentine JE. Compounded topical analgesics for chronic pain. *Dermatitis*. 2016;27:263-271.
2. Ukens C. Coed death tied to compounded drug. *Drug Topics*. March 7, 2005. <https://www.drugtopics.com/community-pharmacy/coed-death-tied-compounded-drug>. Accessed May 31, 2020.
3. Kopsky DJ, Hesselink JM. High doses of topical amitriptyline in neuropathic pain: 2 cases and literature review. *Pain Pract*. 2012;12:148-153.
4. Campbell EH, Elston DM, Straughan CL, et al. Regulations, liability, safety, and economics related to compounding [published online December 9, 2019]. *J Am Acad Dermatol*. doi:10.1016/j.jaad.2019.11.061.
5. US Food and Drug Administration. Administrative Destruction of Certain Drugs Refused Admission to the United States; Final Rule: Docket No. FDA-2014-N-0504. <https://www.fda.gov/media/93525/download>. Accessed May 31, 2020.