

Black salve: risky escharotic

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Abstract

Introduction: Black salve ointments are variable in their composition with no standard formula. Patient's may turn to unregulated products to self-treat their conditions. Products that are accessible without a prescription are not necessarily safe and may pose risk to those who use them, as in this case with the use of black salve ointment.

Methods: This case report discusses the use of black salve ointment on a nodular neck cyst in a 55-year-old Hispanic male patient. The patient applied the black salve ointment (Two Feathers Healing Ointment®) to the cyst, where the ointment remained in contact with his skin for seven days. He required oral antibiotics and was referred to wound care for follow up.

Discussion: After close follow up and treatment with antibiotics, the eschar healed and left a concave scar on his neck with no other observed complications.

Conclusion: Healthcare providers are encouraged to discuss complementary and alternative medicine options with patients as some may lead to dangerous effects.

Keywords

Black salve, bloodroot, topical escharotic, eschar, nodular cyst

Lay Summary

This is a case report about a 55 year old male patient who used an over the counter product called Black Salve to treat a cyst on his neck. He came to his primary care doctor's office for a usual checkup. Just before leaving his appointment, he mentioned a dark discolored area on his neck appeared after applying the black salve ointment. The black salve caused his skin to break down, get infected, and turn black. He was treated with antibiotics and close follow up care. After the wound healed, he was left with a scar on his neck from where the ointment broke down the skin. Since this product is available without a prescription, it is important that consumers know that it is not safe for use and may cause complications. If in doubt, ask a healthcare provider about a products risks before use.

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Introduction

Black salve is an unregulated topical preparation that is comprised of bloodroot extract and minerals such as zinc, chloride, calcium, and magnesium. Bloodroot (*Sanguinaria canadensis*) is derived from a flowering plant that can be found in eastern North America. The liquid sap turns to a paste that has been used by Native American tribes as a dye, body paint, and medicine.¹ The ingredients of most black salve preparations include bloodroot and zinc chloride; however, there is no standard formula with much variability in the composition of black salve products.² This poses a risk for patients to utilize these escharotic topical agents.

While not fully elucidated in the literature, black salve causes tissue necrosis and the formation of an eschar. Many black salve preparations include zinc chloride, a synthetic corrosive agent that also leads to tissue destruction.³ Due to these destructive effects, the sale of black salve was banned in Australia in 2012 after causing harm to Australian consumers who utilized black salve for skin conditions including cancer.^{4–7} Additionally, there have been many case reports in the United States (US) documenting the adverse outcomes of using the black salve for topical ailments.^{8–11} Patients have used black salve to remove and self-treat conditions such as basal cell carcinoma, malignant melanoma, and metastatic colon cancer. However, in many reported cases, black salve has harmed patients.

The salve causes necrosis of tissue where it is applied. Days later, this leads to the formation of an eschar with surrounding tissue erythema and pain.³ At times patients can develop cellulitis of the surrounding skin or tissue. Those with chronic conditions such as poor blood circulation or uncontrolled diabetes may be at risk for complications related to wound healing due to decreased oxygenation of tissues and elevated blood sugars damaging blood vessels respectively.¹² Patient education is critical to prevent this dangerous and potentially disfiguring agent from being utilized.

The eschar can cause cosmetic and functional abnormalities after the necrotic area heals.³ Cosmetic and functional consequences to the site of application include indented scars when applied to areas of soft skin, loss of nasal nares when applied to lesions around the nose, and stool leaking from the wound site when applied to anterior abdominal wall.^{5–11} These complications have been documented in the literature along with more severe outcomes including death from delays in initiating conventional treatment.

The US Food and Drug Administration (FDA) issued a warning letter in April 2017 to the company Healing Within Products and Services who made claims that black salve “will work on malignancies and viruses as well as other skin problems such as warts.” Healing Within Products also claimed, “if you are removing a hard tumor or wart, we suggest that you prick the wart or tumor to help penetration of Black Salve.” The FDA letter stated that Healing Within Products are “not generally recognized as safe and effective for the above references uses... your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners... Thus, the products are misbranded.”¹³ The scientific consensus is to discourage the use of these unregulated products that do not have evidence for use to treat conditions, especially when there is evidence of harm.

Many clinicians are not trained in alternative medicine. Continuing education courses are offered on alternative medicine, but often these courses focus on the potential positive effects and not on the adverse effects. This case demonstrates a serious side effect of black salve for a nodule that the patient wanted removed for cosmetic reasons. Clinicians who review this article will be more prepared to educate and discourage patients from using black salve products.

Case report

A 55-year-old Hispanic male presented to the primary care clinic for a checkup following an emergency room visit due to a work-related concussion. His past medical history was significant for type 2 diabetes mellitus, hyperlipidemia, and lower extremity neuropathy. His A1c on file was elevated at 9.4% (reference range < 6.4%). All other laboratory tests were unremarkable.

Two months prior to this visit, the patient was referred to a dermatologist to have a 1.3 cm diameter-nodule on his right neck removed (Figure 1A) due to cosmetic concerns. He was evaluated by the dermatologist and scheduled for excision of the nodule in one month.

During the primary care visit, the physician inspected the right side of the patient’s neck at the location of the nodule. However, a week before this visit, the patient applied black salve ointment (Two Feathers Healing Ointment®) to the nodule and let it remain on his skin for seven days under the impression that this compound would remove the cyst or any tumor he

might have. The patient reported the scab had grown in size over the last few days and was becoming painful.

At this initial presentation, the plaque had an oval shape and measured approximately 4.5 cm by 3.5 cm. It appeared as a well-demarcated



Figure 1. (A) Appearance of nodular cyst prior to patient applying black salve ointment. (B) Macerated skin 9 days after the application of black salve ointment. (C) Healing of site 22 days after applying black salve ointment. (D) Healed ulcerated area 26 days after applying black salve.

ulceration with indurated borders and a depth of about 0.5 cm. Except for the perimeter of the ulcer, the plaque was covered with a thick and dark eschar. The surrounding tissue was

edematous, erythematous, and tender to palpation. The plaque was rinsed with sterile saline, and a sterile wet to dry dressing was applied for debridement of the wound as a cost effective

Table 1. Black salve utilization and respective adverse effects and outcomes⁵⁻¹¹

Black salve product	Age / Sex	Condition	Adverse effect & outcome	Country of occurrence
Unspecified "black salve"	50 y/o female	Keratoacanthoma lesion	Hyperkeratotic nodule with a necrotic edge and surrounding erythema.	Australia
Unspecified "black salve"	50 y/o female	Ovarian cancer	Skin necrosis from pubic bone to ribcage, ultimately death.	Australia
Unspecified "black salve"	78 y/o female	Melanoma	Eschar, inflammation, ulceration of the tumor. Delayed conventional treatment led to the metastases of the melanoma to the lungs, liver, right groin, subcutaneous tissues, and musculature.	Australia
Unspecified "bloodroot black salve"	53 y/o male	Skin lesion, unspecified	A 0.5 cm papule became blackened and returned 6 months later increasing in size. On medical evaluation, the patient had malignant melanoma.	US
Unspecified "black and yellow bloodroot salve"	42 y/o male	Subcutaneous nodules on the anterior abdominal wall (history of metastatic colon cancer)	Ulcer developed at site of salve application, patient admitted to hospital until the enterocutaneous fistula healed.	US
Unspecified "black salve (300mg) with galangal, red clover, sheep sorrel"	63 y/o male	Unknown neoplasm of nares	Extensive tissue necrosis leading to loss of left nostril. Approximately 11 years later, he returns with basal cell carcinoma under right eye – patient had Mohs surgery. A few months later, he was diagnosed with colon cancer and self-treated with black salve. He ultimately died.	US
Unspecified, "black salve"	47 y/o female	Melanoma of foot	Tissue necrosis, ulceration. Delayed conventional care led to metastases to liver, kidneys, and subcutaneous tissues. Ultimately death 32 days after presentation to hospital.	US
Alpha Omega Labs Cansema® black salve	~ 70 y/o male	Basal cell carcinoma	Eschars with peripheral erythema and necrotic ulcerations.	US

option since the patient was uninsured. The patient was prescribed amoxicillin-clavulanate 875–125mg 1 tablet by mouth twice daily for 10 days.

Two days after the initial primary care visit, the pain and tenderness had improved and the erythema surrounding the eschar was decreased. The ulcer maintained its size in diameter, but the eschar was darker and concave (Figure 1B) with the depth increased by 0.5 cm. The ulcer was prepped and draped with sterile irrigation. The patient was counseled on changing gauze dressings twice daily. A prescription was sent to the pharmacy for collagenase 250 unit/gram topical ointment to apply to the affected area daily for enzymatic debridement in addition to the oral antibiotic. However, the patient did not fill the collagenase prescription. The primary care physician was concerned for potential ulceration of the jugular and carotid vessels due to the proximity of the eschar to the vasculature. Thus, the patient was referred to wound care for further evaluation; however, the patient did not attend the wound care appointment.

Six days after the initial visit, the patient reported the pain and tenderness had improved further. The ulcer appeared circular, measuring 3.5 cm in diameter, with one-third of the anterior portion of the ulcer dislodged. The eschar continued to thicken and covered the ulcer with the borders and underlying tissue, having less erythema and healthy granulation growth.

On the seventh day after the initial visit, the patient stated the eschar was mobilized and close to sloughing off. Twelve days after the initial visit, the eschar was dislodged from the ulcer except for a thin string of eschar.

Fifteen days after the initial visit, the ulcer measured 2.4 cm by 1.2 cm and with no eschar. The ulcer was clean, with well-demarcated borders and no signs of infection (Figure 1C). Nineteen days after the initial evaluation, the ulcer had healed, and there were no more signs of infection (Figure 1D). At this time, it was too early to tell if the original nodular cyst was eliminated from the use of the black salve ointment.

Discussion

The use of bloodroot dates before the 1500s. Bloodroot has been used for many indications, including an emetic, expectorant, and escharotic.¹ However, the medical community does not recommend the use of black salve, as there are many risks. This is evident through black salve being banned in Australia since 2012 after case reports

demonstrated its harmful effects. Additionally, the FDA issued statements about misbranding and condemns the use of black salve ointments for conditions such as skin cancers.

Common adverse effects of bloodroot include vasodilatory effects, dizziness, vertigo, nausea, vomiting, and respiratory failure when consumed orally.^{1,2,14} When applied topically, adverse reactions range from mild local irritation to tissue necrosis. Additionally, case reports document the delay in conventional medicine as a contributing factor to patient deaths after the use of black salve ointments (Table 1).^{6,9,10} Despite these well-documented risks, bloodroot salves are still available for purchase from some online naturopathic stores.

Although the outcome for this patient was not catastrophic or overly disfiguring compared to those listed in Table 1, this patient took a risk due to:

- Having uncontrolled diabetes and the potential for delayed healing
- Potential for worsening infection
- The ulcer proximity to the main jugular and carotid vessels
- Potential for remaining malignant tissue under the scar if not fully removed

Due to the availability of this product from online sources, healthcare providers must be aware of this agent, its adverse effects, claimed uses, and the FDA position on its use. With this heightened awareness, providers can open the lines of communication with patients related to the use of topical black salve for various ailments. Additionally, providers who notice eschars on patients during a physical exam should inquire further about natural topical products the patient may be using.

Conclusions

The US FDA has prohibited black salve from being marketed as a topical cancer agent due to potentially serious side effects, including necrosis and formation of an eschar. Patients should be counseled extensively against using black salve products due to evidence of harm, especially among patients with conditions that may lead to impaired wound healing. The use of black salve can delay patients in receiving conventional medical care for serious medical conditions that have evidence-based and effective treatment options. Healthcare providers should discuss complementary and alternative medicine therapies with patients as it may lead to risky adverse effects.

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