Melaleuca armillaris essential oil as an odor reducer in intestinal ostomy bags: a semi-experimental study*

Óleo essencial de Melaleuca armillaris redutor de odor em bolsas de estomia intestinal: estudo quase experimental

Aceite esencial de Melaleuca armillaris reductor de olores en bolsas de ostomía intestinal: estudio cuasi-experimental

ABSTRACT

Objective: Evaluate the effect of essential oil in odor reduction for intestinal ostomy bags. Method: Primary study, semi-experimental, prospective clinical trial with quantitative approach. A product prepared with Melaleuca armillaris leaves was tested in ostomy pouches, with and without effluents, for adhesion and odor control. Instrument: Labeled Magnitude Scale. Results: Colostomized participants, with a mean age of 73 ± 14.94, predominantly males; and informal caregivers, with a mean age of 44 ± 8.98, predominantly females. In the visual evaluation of the oil, 100% of the participants perceived its adherence. Regarding the evaluation of effluent odor by the colostomized, five reported “strong odor” before oil use and, six reported “weak” odor after use (p = 0.005). Five informal caregivers reported “very strong” effluent odor before oil use; and one reported “weak” and nine reported “moderate” after use (p = 0.0025). Conclusion: There was a reduction in the odor of effluents in the ostomy pouches with the essential oil of Melaleuca armillaris at 10%. Application for patent registration in the Brazilian National Institute of Industrial Property (INPI) under no. BR 10 2020 026987 9.

DESCRIPTORS

Enterostomal Therapy; Ostomy; Oils, Volatile; Melaleuca; Odor Neutralizers.
INTRODUCTION

Ostomy is the exteriorization of a loop of intestine from the anterior abdominal wall, performed during a surgical procedure, to divert or decompress the remaining intestine. Most stomas are continent, which means that there is no voluntary control over the passage of flatus and feces from the stoma\(^1\). The indications are: intestinal obstruction due to benign or malignant tumors, peritonitis due to perforation, inflammatory bowel disease, colorectal malignancies and anorectal malformations\(^2\).

The colon harbors trillions of bacteria that protect the intestine and produce substantial amounts of vitamins by fermentation\(^3\). More than 90% of the entire human gut microbiota population is represented by two phyla, Firmicutes (mainly includes Clostridium, Enterococcus, Lactobacillus and Faecalibacterium) and Bacteroidetes (notably includes Bacteroides and Prevotella genera)\(^4,5\).

A healthy person excretes an average of 700 milliliters of gas a day, and in general there are approximately 200 milliliters of gas in the gastrointestinal (GI) tract. The gases in the upper part of the GI tract arise from reactions that occur during the digestion process or from swallowing air (aerophagia). Only a small portion of these gases from the upper GIT (stomach) reach the lower part (gut), which can cause discomfort, distention and abdominal pain in the small intestine, unlike what occurs in the colon, as the latter has a greater tolerance in relation to its presence\(^6\).

Most of the gases eliminated (99%) are odorless, they are: composed of carbon dioxide, hydrogen, nitrogen and oxygen. However, what causes the unpleasant odor (1%) of the gases produced is due to the elimination of sulfur, methane and hydrogen gas, among others. Sample analysis is an alternative to assess the origin of gases and see their composition. Flatus composed predominantly of hydrogen come from swallowing, that is, swallowed air. Compounds predominantly of methane, carbon dioxide and hydrogen are of intraluminal origin, produced by the intestine\(^7\). The odors from the released gases can be correlated with the concentrations of hydrogen sulfide and sulfur\(^8\).

Stoma surgeries change patients’ functioning, restrict their daily activities, and significantly influence their quality of life\(^9\). A colostomy is a type of ostomy in which the colon (ascending-transverse-descending-sigmoid) is exteriorized to treat diseases, the output of feces from the stoma with a drainable pouch and can be left attached to the skin during removal of the ostomy contents\(^10\).

One study reports difficulties in ability to travel and recreation, due to concerns about gases, odors, sounds and leakage, and also difficulty sleeping and resting. It is noteworthy that impaired social relationships and isolation can occur due to physical and psychological changes resulting from the making of the ostomy, demonstrating a relationship between physical complications and social disorders\(^11\). A population-based survey of patient concerns (n = 332 with 109 permanent colostomies) concluded that painful or irritated peristomal skin, pouch odor and noise were the most commonly reported ostomy-related difficulties\(^12\).

In another study, among the various physical, social, cognitive and emotional problems caused by an ostomy, the loss of bowel control, flatulence, odor, loneliness, reduced self-esteem, rejection from friends and family stand out. The authors emphasize that odor was the biggest concern of colostomates followed by the production of gases. Faced with this problem, they used lavender essential oil to control odor and obtained favorable results\(^13\). It is estimated that the population uses the knowledge of phytotherapy to solve health-related problems\(^14\). Among the phytherapics studied, the tea tree (Melaleuca alternifolia) is one of the most important. The major biological application of essential oils is their action as an antimicrobial agent, representing an extension of the role they play in plants, protecting them from the action of bacteria. Its most important genera are: Eucalyptus, Melaleuca, Eugenia and Psidium\(^15\). Plants and their essential oils have properties that act against different types of microorganisms\(^16\). However, it was only from the 1990s onwards that studies emerged that proved the antimicrobial action of these compounds\(^17\).

Melaleuca is a botanical genus belonging to the Myrtaceae family, with more than 3,500 species spread around the world. Australia was the pioneer country to work with oil of this genus and each one has a specific action property (antimicrobial, anti-fungal, antiseptic and disinfectant). The Melaleuca armillaris species is one of the most cultivated and, when squeezing its leaves in the hands, exudes a scent of eucalyptol\(^18\).

The oil extracted from Melaleuca armillaris is rich in eucalytol (1.8 cineole), but only in recent years has research shown antimicrobial action attributed to this molecule, which acts as a facilitator of membrane permeability in microorganisms such as Staphylococcus aureus\(^19\). Gas control in colostomized collection bags demonstrated odor reduction\(^14\). Melaleuca armillaris oil, in addition to its antimicrobial action, has characteristics such as: accessible raw material, liquid consistency, easy handling and pleasant fragrance (eucalyptol).

The idea of this product arose due to the need to develop a natural product, with a pleasant smell, accessible to most colostomy patients, to reduce the odor of fecal effluents collected by these devices. Odors make patients uncomfortable, afraid to leave the house and carry out their daily, occupational and social activities, causing them embarrassment.

The hypothesis of the study is that the 10% Melaleuca armillaris oil, associated with the surfactant and emulsifier for
homogenization, alleviates the odor coming from the effluents in the intestinal ostomy bags. Given this context, the objectives of the study are to evaluate the use of this oil in spray formulation and its effectiveness in reducing odor in intestinal ostomy bags.

**METHOD**

**DESIGN OF STUDY**

This is a primary study, a quasi-experimental, prospective clinical trial with a quantitative approach.

**POPULATION**

The study was carried out at the homes of colostomized patients undergoing surgery on the left descending colon, together with their informal caregivers, linked to the Family Health Strategy in the municipality of Santa Rita do Sapucaí-MG. Of the 11 colostomized patients registered in the city (100%), ten (90%) agreed to participate and one (10%) withdrew after signing the Free and Informed Consent Form (ICF). All informal caregivers of these 10 colostomized patients participated in the evaluation. Inclusion Criteria: patients with intestinal ostomy, colostomies in the left colon (descending); informal caregiver, for being present in the direct care of patients, of both sexes and aged over 18 years, a parameter extended to patients. Non-inclusion criteria: patients with ileostomy, users of intestinal control methods, because liquid and semi-pasty feces have less odor. Exclusion criteria: Patients and informal caregivers who withdrew from continuing the study after signing the informed consent; patients who underwent stoma reversal surgery and those who died before the assessments.

**DATA COLLECTION**

Data collection was performed during home visits to each participant. At first, the participants were invited and instructed about the study, their information and possible eligibility were obtained. After the participants' voluntary agreement, the TCLE was signed in two copies, one being kept by the researcher and the other in the possession of the researcher.

**MATERIALS**

The extraction of the essential oil of Melaleuca armillaris was carried out at the Botany Laboratory of the Universidade do Vale do Sapucaí (UNIVAS) and the leaves were collected from trees located in the following geographic data of the university itself: latitude 22° 13' 11.548” S longitude 45° 54' 53.051” W and altitude 816, 9863. The oil from the leaves of the Melaleuca armillaris plant was extracted by means of hydrodistillation, using a Clevenger type equipment (Hermex Glasware – Brazil). 400 grams of leaves were placed in a flask with 300 ml of water, covered over a heating blanket until boiling, releasing the steam that drags the oil with it. The vapor passed through the condenser was cooled and returned to the liquid phase. In the collection flask, liquids that are not soluble in each other have separated. After removal, the plant oil was placed in a dark bottle and kept in a refrigerator at a temperature of 5°C until the moment of its use in the formulation of the product. Essential oil chromatography was performed and was Australian compliant. The product was prepared using concentrations of 5% and 10% of the essential oil of the Melaleuca armillaris plant, which was previously studied in the botany laboratory and verified that the concentration at 10% showed better adhesion and homogeneous distribution inside the collection bags without effluents.

Four drainable collection bags were tested, within the validity period, new, intact and without activated carbon filter, two of "one piece" and two of "two pieces", obtained from the Municipal Health Department of the city of Santa Rita do Sapucaí-MG. For seven days, 2.5 ml of each concentration of the product was sprayed into the bags once a day and evaluated by the researcher daily through the visual, olfactory and mechanical strength senses, paying attention to possible physical changes in the constituent material (such as tear and dry), the permanence of the fragrance of the product inside these bags was also evaluated. It was then confirmed that there was no negative damage to the product. The application in the bags was also tested in two ways: one in the vertical position (using two bags fixed to a tiled wall – simulating the patient in the orthostatic position) and two in the horizontal position (using a glass plate, representing the patient in the supine position). The supine position favored distribution and adherence on the surfaces of the inner walls of the bag, while in the orthostatic position, the jet had less adherence on the sides. At the end of this period, all bags were preserved, intact and with the permanence of the product's fragrance.

The essential oil of Melaleuca armillaris at 10% was mixed with a product based on surfactant and emulsifier for homogenization without influencing the odor of the product. The product had a milky white color and a characteristic odor, bottled in a spray bottle for use by the participant.

Colostomized patients were instructed to use 2.5 ml of the Melaleuca armillaris-based product, which is equivalent to ten controlled sprays (for better product adherence) by the bottle dispenser inside the bag after each cleaning, according to the prescribed method. This amount of product was sufficient to homogeneously adhere to the interior of the walls of the effluent collection bags.

**OLFACTORY SENSORY ANALYSIS**

The intensity of the odor of the effluents in the collection bag was evaluated by the patients and their informal caregivers using the Labeled Magnitude Scale (LMS) two hours after application of the product. The LMS is a semantic perceptual intensity scale, characterized by intensity labels: – Hardly Perceived; – Weak; – Moderate; – Strong; – Very Strong and – The Strongest Possible. In order to carry out this study, this scale was adapted to the odor of the effluents in the bags of colostomized patients. The LMS can measure perceptions and judgments, reflecting a person's perception of an evaluated characteristic. In practice, a perimeter of one meter was delimited, the colostomized patient was inserted in the center and the caregiver was positioned in front of him, towards the exit of gases from the collection bag. This distance was marked with adhesive tape, whose delimitation of the area served as a template for all evaluations carried out in this study. The evaluation of the effluent odor was perceived from a distance of half a meter between the patient with the bag open and pointed at the caregiver. The colostomy patient also
evaluated and signaled their perception of effluent odor on the LMS scale, assessments were performed before using the product and eight days after the patient started using it. A copy of the linear LMS scale was given to each participant (patient and informal caregiver) with phrases “Hardly Perceptible” – “Weak” – “Moderate” – “Strong” – “Very Strong” – “The Strongest Possible” and asked to tick the option that they perceive the intensity of the odor of the effluents released before and after the use of the product.

**DATA ANALYSIS AND TREATMENT**

Data were tabulated in Microsoft Excel 2016 and subjected to statistical analysis, measures of central tendency were used for quantitative variables and absolute and relative frequency for categorical variables. Minitab version 18.1 and Statistical Package for the Social Sciences, inc. (SPSS) Chicago, USA, version 22.0 were used. The significance level used as an acceptance or rejection criterion in the statistical tests was 5% (p < 0.05). To analyze the results, the T Test (used when there are two groups with data that adhere to a normal distribution, but they are independent) was applied to study the mean between the groups with continuous levels and the Wilcoxon Test (used when there are two groups related) for the classification of: patients before and after use of the product; informal caregivers before and after using the product; patients and informal caregivers before using the product; and patients and informal caregivers after using the product.

**ETHICAL ASPECTS**

The present study follows the precepts established by Resolution 466/12 of the Code of Ethics in Research of the Ministry of Health, which deals with research involving human beings. The autonomy, privacy and anonymity of study participants were respected due to their free decision to participate in the research. The project was submitted to the Ethics and Research Committee of the Universidade do Vale do Sapucaí – UNIVAS with opinion No. 3,345,531 in 2019. Participants with intestinal ostomy and informal caregivers who agreed to participate in the research were advised and signed the informed consent.

**RESULTS**

Regarding the adherence of the product in a homogeneous way inside the collection bags, 100% of the colostomized participants and informal caregivers, when asked about the greasiness and the adherence of the product in the collection equipment, answered that it was oily, which contributed to the non-fixation and drying of fecal effluents. For the analysis of the participants’ results regarding the perception of effluent odor, measures of central tendency were used for quantitative variables and absolute and relative frequency for categorical variables.

The mean age of patients with intestinal ostomy was 73 years, ± 14.94 with a male predominance.

The collection of results applying the LMS Scale showed that the perception of the patient with an intestinal stoma before the application of the product presented a judgment between “strong” and “stronger possible”. Five people (50%) reported a “strong” odor, three (30%) “very strong” and two (20%) “strongest possible”. After using the product, the results showed that six patients (60%) attributed a “weak” characteristic to the effluent odor and four (40%) attributed a “moderate” odor.

Regarding the age of informal caregivers, the median was 44.0 years, ± 8.98 and the female gender prevailed.

The estimation of the odor perceived by the informal caregiver who lives with the intestinal ostomy patient was similar to that of the patient (Table 1). The product showed a reduction in the odor noticed by the patient and his caregiver.

In Tables 1 and 2, the odor level after using the product is statistically lower.

Table 2 shows that the odor level before is statistically equal for patients and informal caregivers, p value = 0.414.

Table 3 shows that the level of odor perceived after using the product is lower for patients and informal caregivers, p = 0.0025 and there is a statistically significant difference between the perceptions of odor intensity by the caregiver and the patient after using the product.

<p>| Table 1 – Perception of the odor of intestinal stoma effluents by informal caregivers using the Labeled Magnitude Scale, before and after the use of the spray containing 10% Melaleuca armillaris essential oil – Santa Rita do Sapucaí, MG, Brazil, 2020. |</p>
<table>
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<tr>
<th>Evaluator</th>
<th>Before the product</th>
<th>After using the product</th>
<th>Wilcoxon test</th>
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<tbody>
<tr>
<td>1</td>
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</table>

Source: The authors.

2* Weak
3** Moderate
4*** Strong
5**** Very strong
6***** As Strong As Possible

<p>| Table 2 – Perception of the odor of intestinal stoma effluents by patients and informal caregivers using the labeled magnitude scale, before and after using the spray containing 10% Melaleuca armillaris essential oil – Santa Rita do Sapucaí, MG, Brazil, 2020. |</p>
<table>
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<tr>
<th>Before the product (patient)</th>
<th>Before the product (reviewer)</th>
<th>Wilcoxon test</th>
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Source: The authors.

4* Strong
5** Very strong
6*** As strong as possible
The effects observed with the product developed based on 10% Melaleuca armillaris essential oil showed favorable results on the LMS Scale for colostomized patients and their informal caregivers. Similar results were seen when researchers used lavender essential oil in colorectal cancer patients with a permanent colostomy to eliminate odor and improve their quality of life. In this study, the authors found that those who received lavender essential oil in the bags for a while stated that the odor problem was eliminated, and 93.3% of the patients in the control group, who did not receive the oil to put in the bags, declared that they had problems due to odor.

The present study did not aim to adapt the patients’ diet and, therefore, they were not instructed on food restriction. However, during the home visits to the colostomy patients, the diversity of the eating habits of all of the research was known, with six patients having an adequate diet for the colostomy and four patients following an inappropriate diet for colostomy patients. The product, which was called “ODOR FREE”, reduced the perceived odor in all patients, regardless of the type of food. Several authors have described that eating habits affect the formation of odor in individuals with colostomy.

In a recent study in Poland with the objective of evaluating the acceptance of the disease and the quality of life in colostomy patients, 101 patients participated who responded to the Health-Related Quality of Life (HRQoL) questionnaire and the Health-Related Quality of Life (HRQoL) scale, acceptance of the disease (Acceptance of Illness Scale – AIS). Researchers concluded that sex and education have an impact on the level of acceptance of the disease, but do not influence the quality of life. However, acceptance of the disease is linked to quality of life in patients with ostomy – the higher the level of acceptance of the disease, the better the quality of life. Research indicates the need to deepen the education of patients regarding their role in society.

A systematic review of problems related to intestinal stomas and their impact on people’s quality of life showed that the problems mentioned by the study participants were related, mainly, to the concern with noise resulting from the involuntary elimination of gases in public, constipation, and even, dissatisfaction with appearance, travel difficulties, sexual problems and depression.

Such problems can thus impact on deprivation of leisure activities as they are often associated with embarrassment or the apparent presence of gas in the bag. These changes related to sounds and odors are often perceived by the colostomized person, mainly as a sign of pollution and dirt, since the loss of sphincter control leads to the breaking of body limits and the understanding of the intestinal stoma as a physical invasion.

By verifying the reduction of odor control in intestinal stoma pouches with Melaleuca armillaris at 10%, the study contributed to scientific knowledge with an innovative approach. This product presented satisfactory results for patients and informal caregivers in relation to the perceived odor and adherence to the bag, facilitating the dispensing of effluents.

There is a possibility that the product will be commercialized and enter the market with an innovative approach.

### DISCUSSION

No study was found using the essential oil of Melaleuca armillaris at 10% to obtain the reduction of effluent odors in intestinal ostomy collection bags, with few comparative results in the literature, which makes the study innovative. The essential oil of Melaleuca armillaris was tested at concentrations of antimicrobial inhibition, evaluating the inhibitory effect on the growth of Staphylococcus aureus from antibiotic-resistant lower limb wounds.

The 10% concentration established in the product was the one that presented the best result in relation to the 5% concentration when evaluated in the pre-test. The results showed that the product in the concentration of 10% of essential oil was more efficient than in the concentration of 5%, when tested in relation to the adherence and intensity of the fragrance, adhering homogeneously inside the collection bags. It is worth noting that the Minimum Inhibitory Concentration (MIC), that is, the lowest concentration of the antimicrobial agent capable of inhibiting the development of the microorganism tested in Melaleuca oil against the most common pathogens is between 0.5 and 1%. However, they emphasize that the concentration can vary between 0.5 and 5% in cosmetics and between 5 and 10% in pharmaceutical formulations.

There were no reports from patients and caregivers about damage to the material constituting the intestinal ostomy bags, prevailing their initial characteristics regarding the color of the plastic and adherence – perceived oily impregnation of the product inside the bags and regarding the resistance to tears – proven by force exercised with the compatibility of the use of the product in the collection bags.

The application of the product in the orthostatic position requires jets directed to the sides of the collection bags for better lubrication and homogeneous distribution, so the supine position was chosen, which favored the distribution and adherence to the inner walls of the bags.

<table>
<thead>
<tr>
<th>After the product (patient)</th>
<th>After the product (informal caregiver)</th>
<th>Wilcoxon test</th>
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</table>

*p = 0.0025

Source: The authors.

Note: The numbers described in “After the product (patient)” and “After the product (informal caregiver)” represent the judgment of the evaluators.

2* Weak
3** Moderate

**Table 3 – Perception of the odor of intestinal stoma effluents by patients and informal caregivers using the labeled magnitude scale, after using the spray containing 10% Melaleuca armillaris essential oil – Santa Rita do Sapucai, MG, Brazil, 2020.**

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contributing to colostomized patients, making them comfortable and confident, especially regarding the judgment of odor.

Therefore, the product based on Melaleuca armillaris represents a natural option in odor control for the colostomized person and with good acceptance.

The patent application at the INPI was registered under no. BR 10 2020 026987 9 and, for the product developed, the trade name “FREE OF ODOR” was created and a label containing information and guidelines was created.

CONCLUSION

The product based on the essential oil of Melaleuca armillaris developed at 10% reduced the odor of the effluents of the intestinal ostomy bags, noticeable for the patient and for his informal caregiver.

RESUMO


DESCRITORES

Estomaterapia; Estomia; Óleos Voláteis; Melaleuca; Neutralizadores de Odores.

RESUMEN

Objetivo: Evaluar el efecto del aceite esencial en la reducción del olor en bolsas de ostomía intestinal. Método: Estudio primario, ensayo clínico cuasiexperimental, prospectivo de tipo cuantitativo. Se evaluó un preparado con hojas de Melaleuca armillaris, probado en bolsas de recogida con y sin efluentes, en cuanto a adherencia y olor. Se aplicó como instrumento la Escala de Magnitud Etiquetada. Resultados: Los participantes colostomizados tenían edad media de 73 años ± 14,94, con predominio del sexo masculino, y los cuidadores informales, edad media de 44 años ± 8,98 y prevalencia mayor para el sexo femenino. En la evaluación visual del aceite, el 100% de los participantes notaron la adherencia. Respecto a la evaluación del olor del efluente por los pacientes colostomizados, cinco reportaron sentir un “olor fuerte” antes de usar el aceite y, después del uso, seis reportaron sentir un olor “débil” (p = 0,005). Cinco cuidadores informales detectaron un olor “muy fuerte” de los efluentes antes de usar el aceite y, después de usarlo, uno sintió un olor “débil” y nueve “moderado” (p = 0,0025). Conclusión: El olor de los efluentes en las bolsas de recolección con el aceite esencial de Melaleuca armillaris se redujo en un 10%. Solicitud de registro de patente ante el INPI bajo el n. BR 10 2020 026987 9.

DESCRITORES

Estomaterapia; Estomía; Aceites Volátiles; Melaleuca; Neutralizadores de Olores.

REFERENCES


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