

Review Article

A Systematic Review of Topical Treatments to Control the Odor of Malignant Fungating Wounds

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Abstract

Context. Malignant fungating wounds (MFW) result from cutaneous infiltration by carcinogenic cells. Fetid odor, profuse exudate, pain, and infection are common symptoms that add to the physical and psychological suffering of patients with MFW. The topical treatment of MFW remains controversial.

Objectives. To collect evidence about topical treatments to control the odor of MFW.

Methods. Fourteen sources of data were used, without restriction in terms of language, period, or study design. The patient, intervention, comparison, and outcome strategy for the development of research questions yielded 334 descriptors related to oncology, MFW, topical treatments, medications, and symptoms of these lesions. Data from the abstracts of these articles were extracted by two independent researchers and decisions were reached by consensus among them. Through an analysis of these abstracts, studies that broached the topic of MFW odor were selected. These studies were analyzed in their entirety and were classified according to quality, levels of evidence, and grade of recommendation.

Results. Of 11,111 studies identified, 325 (2.93%) made reference to the control of some symptoms of MFW by means of topical interventions: 12.4% related to odor, 16.8% to exudate, 17.8% to bleeding, 31.0% to pain, and 22.0% to MFW-related infection. Within the 59 studies that analyzed odor control, seven were clinical trials (35%), five were case series (25%), and eight (40%) were case studies. Eleven topical treatments were identified. Topical metronidazole and Mesalt[®] dressing yielded 2b level of evidence or B grade of recommendation. Activated carbon dressing and curcumin ointment yielded 2c level of evidence or B grade of recommendation. C and D grades of recommendation were observed for seven topical treatments: topical arsenic trioxide, essential oils, green tea

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extract, hydropolymer dressings, antiseptic solutions, hydrogels, and debridement enzymes. The variety of interventions and of the methodological quality of the studies did not allow for meta-analysis.

Conclusion. Of the 59 studies of odor, 20 fulfilled all the criteria for inclusion. Few studies of high quality were found, and the principal methodological flaws were the design of the studies, the sample size, and the absence of scales to measure odor. Grade B evidence for the treatment of MFW was found with topical metronidazole, Mesalt[®] dressing, activated carbon dressing, and curcumin ointment. *J Pain Symptom Manage* 2010;39:1065–1076. © 2010 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Evidence-based medicine, wounds and injuries, palliative care, odor, neoplasms

Introduction

A malignant fungating wound (MFW) involves the infiltration of the epithelium by tumor cells. It can result from primary tumor growth of the skin, from metastasis, from the invasion of the skin by tumors from deeper levels, and from the accidental implantation of malignant cells into the epithelium during diagnostic or surgical procedures.¹ MFWs, in most instances, appear in patients during the terminal phase of an illness and develop from highly malignant tumors.

The prevalence of these wounds has not been well-established, but it is estimated to be between 0.6% and 9.0% for all types of cancer.^{2–8} MFWs are characterized by rapid proliferating growth, fetid odor, bleeding, localized pain, profuse exudate, local infection, and a vegetating appearance, that is to say, a fungal appearance reminiscent of cauliflower. When there are ulcerations, they are called malignant ulcerated and fungating wounds. The range of indicators and symptoms varies considerably and these may present themselves individually or collectively.^{4,7,9,10}

MFWs are associated with bleeding, edema, a great amount of exudate, and tissue necrosis. The bleeding results from an imbalance in the hemostatic process; edema, exudate, and necrosis arise from irregularity in cellular perfusion. Necrotic tissue is an ideal environment for bacterial growth (infection). The metabolic processes of the bacteria release volatile and fetid fatty acids, which give rise to a disagreeable odor. The bacteria that colonize the wound activate proteases that break down

the necrotic tissue, causing the dead tissue to liquefy and generate extensive exudate. The rapid growth of a tumor can lead to the compression of adjacent structures, such as soft tissues and nerves, leading to pain and diminished mobility.¹¹ The lesion will continue to develop, and local damage will get progressively worse until some sort of oncological treatment is employed successfully.¹² The diagnosis of MFW can be made after a biopsy or a histological evaluation of the wound.^{8,13} However, it is generally made based on clinical history and the characteristics of the wound.

Patients find MFWs to be extremely distressing and uncomfortable, and they often cause intense physical and psychological suffering because of their fetid odor, their vegetating appearance, the great quantity of exudate, the intense pain, and the constant risk of bleeding. They can lead to feelings of rejection, disgust, social isolation, anxiety, sadness, and loneliness. The patients' expectation that they will have to live with the wound until death gives substantial importance to the adequate treatment of these wounds.

The treatment of MFWs is a complex topic. It requires an evaluation of oncological etiology, of the characteristics of the wound, of the physical and emotional state of the patient, and of the stage of cancer. The aim should be to reduce fetid odor, pain, infection, and bleeding and to improve the absorption and control of excessive exudate but not to cure the lesion itself.^{7,14–18}

Recommendations for the treatment of MFWs are controversial, and conduct in clinical practice varies widely. Previous narrative

reviews^{14–18} indicate a considerable lack of publications about MFWs. In addition, these reviews are small in number, they fail to observe the methodology of systematic review, and it is questionable whether they were able to identify existing publications on the subject. There are difficulties worldwide with the prescription of local treatments for MFWs.

The aim of the present study was to obtain and organize high-quality information that could contribute to the improvement of topical treatments for the odor resulting from MFWs in cancer patients.

Methods

A systematic review of the literature was undertaken, based on the guidelines of the Centre for Reviews Dissemination¹⁹ and the Cochrane Collaboration;²⁰ this involved the formulation of a research question; the location, selection, and evaluation of the quality of articles; the collection of information; and the analysis, presentation, and interpretation of results.

The research question was structured according to the patient, intervention, comparison, and outcome (PICO) strategy, and the criteria for the inclusion of studies were defined as follows:^{21–23}

Patient: individuals with malignant neoplasms who developed MFWs, without reference to the clinical stage or severity of the MFW;

Intervention: different topical agents and/or dressings available in the global marketplace;

Comparison: not defined because of the lack of known treatment pattern for MFWs;

Outcome: the control or improvement of odor in MFWs.

The researchers proceeded by identifying the descriptors or key words to be used to search for articles in databases, analyzing for that purpose all the terminology of DeCS (Health Sciences Descriptors) and MeSH (Medical Subject Headings). They opted to use broader descriptions of the components of the question structuring the research to make the systematic review more encompassing and to reduce the possibility of selection bias.^{20,24}

The researchers also chose not to restrict the search by types of study, with the exception of narrative reviews, first to classify the level of evidence present in the studies found and then to quickly identify the gaps in knowledge and the subsequent steps for research to guide the topical treatment of MFWs.

The present review made use of 14 electronic databases: three primarily designed to identify dissertations and theses (Thesis Bank, Capes and Digital Library of Theses and Dissertations, University of São Paulo, for Brazilian publications; and Proquest Dissertation and Theses for international publications); one database of primary sources for the identification of reports of clinical trials (Current Controlled Trials); two databases of primary sources covering nursing (BDENF for Brazilian publications and CINAHL for international ones); one general database of primary sources for European material (Embase); five general databases of primary sources from North America (PubMed, Ovid, PsycInfo, Scopus, and Web of Science); one general Latin American database of primary sources (Lilacs); and one database of secondary sources (EBM Reviews). Different strategies were formulated to accommodate the specificities of the different databases.²²

The search was undertaken in August 2006 with 14 databases, without a lower limit for data, thus, making use of the total content of the databases. The results were exported using EndNote[®] (Thomson Reuters, New York, United States of America) and an archive for each database was created.

The selection of studies (articles, dissertations, and theses) followed different steps in the following order: the removal of duplicated studies, preclinical studies, studies not related to oncology, studies concerning benign neoplasms, studies not related to MFWs, and finally, studies that did not cover the five main symptoms (odor, pain, exudate, bleeding, and infection). Data from the studies were extracted by means of a form especially designed for this purpose and following the recommendations of Consolidated Standards of Reporting Trials (CONSORT) and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).^{25–27} Data from both experimental and observational studies were extracted. The same process was used for

studies that were identified by means of a manual search of the studies listed in the bibliographic references of the studies included.

Codes were developed for all of the selected studies based on an alphanumeric sequence derived from the alphabetical order of the authors' names. These studies were organized into a table of characteristics containing the authors' names, the year of publication, the country of publication, the study's title, the model of study used, and each study's clinical focus.

Qualitative studies and narrative reviews were excluded. The quantitative studies were classified according to the model of study proposed by Fletcher and Fletcher,²⁸ as follows: descriptive studies (case histories or case series); observational studies (transversal or prevalence studies, cohort studies, case-control studies, studies of therapeutic results); experimental studies (randomized clinical trials, controlled clinical trials, cross-sectional studies); and systematic reviews with or without meta-analysis.

The studies were organized hierarchically according to levels of evidence, grade of recommendation, and quality. The grade of recommendation²⁹ is a measure of quality attributable to a study's level of evidence; it aids in the interpretation of recommendations. For the analysis of the quality of clinical studies, the Jadad Scale was used.³⁰

The Oxford Centre for Evidence-Based Medicine classifies studies in five levels of evidence according to the study design (1, 2, 3, 4, and 5), grouping them in four grades of recommendation (A, B, C, and D).²⁹ Grade A comprises levels 1a, 1b, and 1c, and is used for systematic reviews of randomized clinical trials and for randomized clinical trials and represents the higher grade of evidence. Grade B (2a, 2b, 2c, 3a, and 3b) is for systematic reviews of cohort studies, cohort studies, outcomes research, systematic reviews of case-control studies, and case-control studies. Grade B represents moderate level of evidence. Grades C (4) and D (5) represent the lowest level of evidence. Grade C is used for case series studies, and Grade D is for expert opinion.

Results

The research question formulated through the PICO strategy was as follows: "What topical treatments and/or dressings are used for the

control of the symptoms of pain, odor, bleeding, exudate and infection arising from malignant fungating wounds in cancer patients?"

Three hundred thirty-four descriptors or key words were identified for the search strategy. A bibliographic search of 14 databases identified 11,111 studies. Of these, only 7,890 (71.0%) were unique, or in other words, 3,221 (29.0%) duplicate studies were removed. Among the 7,890 studies identified, most were clinical studies (82.9%). Most of the publications (56.8%) concerned malignant neoplasms. An analysis of the abstracts of studies of malignant neoplasms revealed 527 studies of MFWs, which represented 14.2% of all the wounds present in malignant neoplasms. The target symptoms of MFWs manifested themselves with the following frequency: pain (28.1%), infection (19.9%), bleeding (16.1%), exudate (15.2%), odor (11.2%), and other symptoms (38.3%) (Fig. 1).

Fifty-nine articles related to odor and that met the criteria for inclusion were identified, as set out in Fig. 2. An analysis of these articles as a unit was undertaken. Of these, nine did not refer to topical treatment for odor, two were repeats, and five could not be obtained (because of the lack of availability of the scientific journal, a lack of response from the author and/or the absence of cooperation from Bireme [Brazilian Library]). The 43 remaining articles were classified by focus. Five studies had a diagnostic focus, four studies had a prognostic focus, and 34 studies had a therapeutic focus. Articles with a therapeutic focus were retained for analysis, whereas the others were excluded.

The 34 articles were classified according to study design. Twenty narrative reviews and one prevalence study were excluded. Of the remaining 13 articles, five were clinical studies, five were case series, and three were case reports. The bibliographic references of the 13 selected articles were analyzed, and a further seven were thereafter obtained (two clinical studies and five case reports), making a total of 20 studies (Fig. 2).

The 20 studies were classified according to levels of evidence and grade of recommendation. The seven clinical studies also were classified according to their quality; scales for the evaluation of quality for the descriptive studies (series and case reports) could not be identified in the literature.

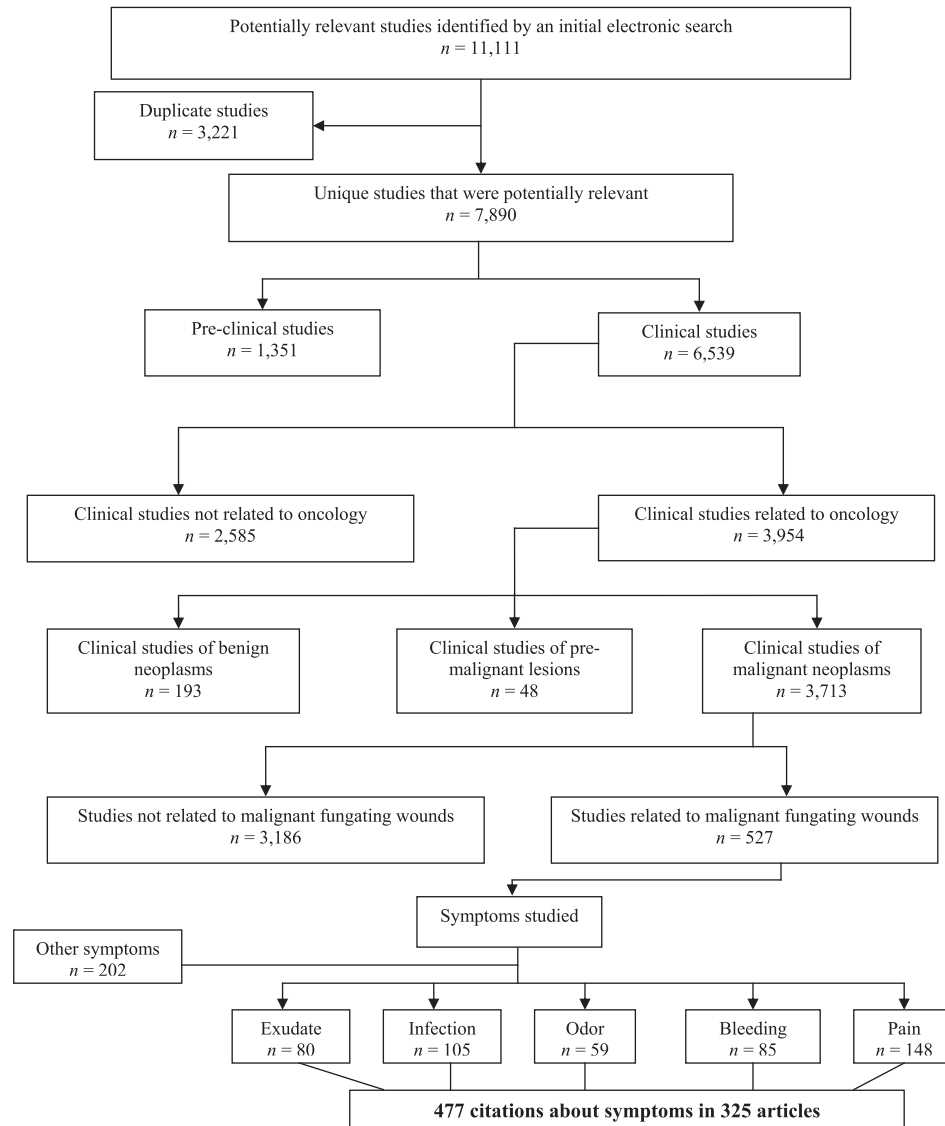


Fig. 1. The selection of studies about the topical treatment of odor, pain, exudate, bleeding, and infection in malignant fungating wounds.

Discussion

The small number of clinical trials ($n = 7$)^{3,31–36} did not make it possible to undertake a meta-analysis, because interventions, measurement scales, and sample sizes were not consistent. In addition, a number of these studies contained little description of their methods, of the interventions made, of the instruments used to measure odor and results, or of the strategies used to analyze the data (Table 1).

Eleven topical interventions were identified, which varied from traditional treatments (the

use of metronidazole or activated carbon) to innovative ones (the topical application of curcumin or green tea).

Among the instruments used to measure odor, a visual analog scale was cited in four studies. The other studies either reported that they used an instrument for the measurement of odor, without specifying what it was, or did not use an instrument to measure odor.

Metronidazole was cited in 10 studies.^{31–33,36–42} The interventions ranged from the topical application of a gel or solution of metronidazole in concentrations of 0.75%–0.8% to the

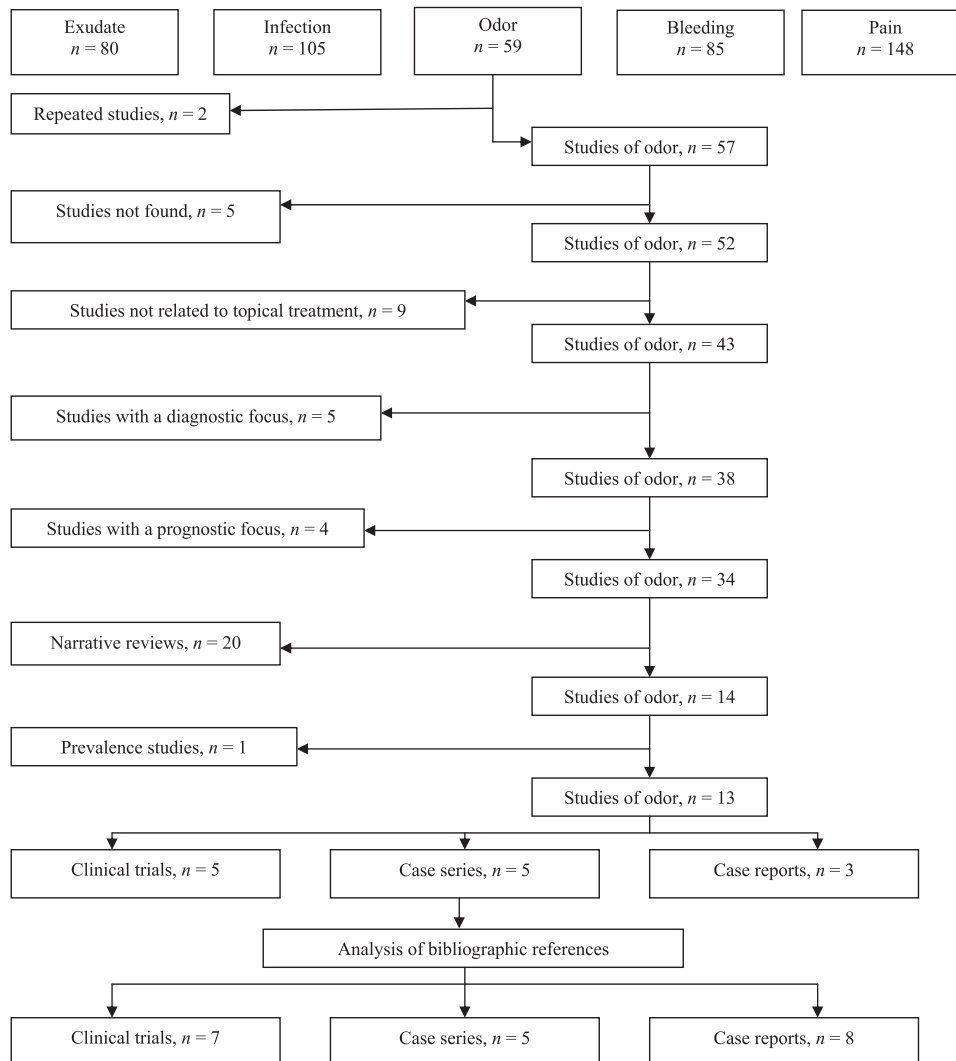


Fig. 2. The selection of clinical studies, case series, and case reports about the topical treatment of odor in malignant fungating wounds.

treatment of the MFWs with crushed metronidazole tablets; on average, application took place once a day, and treatment lasted for 14 consecutive days. Metronidazole is a synthetic antimicrobial drug, which is highly effective against anaerobic bacteria and protozoa.⁴³ The most frequent form of topical intervention presented a 2b level of evidence and a B grade of recommendation. Metronidazole gel was either used under medical prescription or was made available in accordance with institutional protocol, which, therefore, allowed for it to be prescribed in nursing environments. It seems that this is an intervention known in clinical practice to be effective for

the control of MFW odor, but this review has demonstrated that conducting more methodologically refined studies could raise the level of evidence and grade of recommendation for this practice.

Mesalt[®] dressing (Mölnlycke Health Care, Norcross, Georgia) is an absorbent nontissue material made up of viscose or polyester impregnated with sodium chloride and whose action stems from the hypertonic effect produced on the lesion.³ This intervention was cited in one study and showed a 2b level of evidence and B grade of recommendation. In addition, this was the only study that gave a measurement as to quality (Jadad Scale = 1).

Table 1
Classification of Controlled Clinical Trials (n = 2) and Uncontrolled Trials (n = 5) Using Topical Interventions for the Control of Odor in MFWs, by Level of Evidence, Grade of Recommendation, and Quality

Author, Year	Intervention	Sample/ Calculation of Sample	Control Group	Method of Randomization	Method of Double Blinding	Retained or Abandoned	ITT Analysis	Jadad Scale	Outcome	Evaluation of Odor With Instruments	LE	GR
Upright et al., 1994 ³	Mesalt [®] dressing + CWS treatments	11 patients/ not stated	Yes	1:1 Ratio	Not described	Not described	No	1	Alleviation of pain with statistical relevance	Not stated	2b	B
Bower et al., 1992 ³¹	Metronidazole gel at 0.8% + placebo	11 patients/ not stated	Yes	Not stated	Not described	2 patients	No	0	Reduction of odor	VAS used by the patient and by the investigator	2b	B
Finlay et al., 1996 ³²	Metronidazole gel at 0.75%	48 patients/ not stated	No	N/A	None, ongoing study	8 patients	No	0	64% reduction of odor on D0 and of 4% on D14	VAS (0–10), use by patient, nurse, and doctor	2c	B
Kalinski et al., 2005 ³³	Metronidazole gel at 0.75%	16 patients/ not stated	No	N/A	None, ongoing study	None	No	0	100% improvement in odor (partial or total)	VAS enumerated	2c	B
Kuttan et al., 1987 ³⁴	Curcumin ointment	111 patients/ not stated	No	N/A	None, ongoing study	59 patients	No	0	Reduction of odor in more than 90% of patients	Not stated	2c	B
Lund-Nielsen et al., 2005 ³⁵	SF 0.9% + primary treatment with activated carbon dressing and secondary treatment with an absorptive foam	12 patients/ not stated	No	N/A	None	Not described	No	0	Reduction of incidence of odor from 67% to 42%	Not stated	2c	B
Kuge et al., 1996 ³⁶	Metronidazole at 0.8% + placebo	5 patients/ not stated	No	N/A	None	Not described	No	0	Reduction of odor	Analysis performed by doctor in charge, nurse, and patient	2c	B

ITT = intention-to-treat; LE = level of evidence; GR = grade of recommendation; CWS = continuous wet saline; VAS = visual analog scale; N/A = not applicable.

This treatment was used as a primary covering; the dressing was changed once a day, and the treatment lasted for four consecutive weeks.

Treatment with activated carbon dressing^{35,37} was cited in two studies and showed a 2c level of evidence and B grade of recommendation. This treatment is produced through the carbonization of cellulose, rendering it able to promote the absorption of bacterial spores and molecules responsible for the fetid odor.³⁵ This treatment was used as a primary covering; the dressing was changed once a day, and the treatment lasted for four consecutive weeks. Traditionally, this intervention is known to be effective to control the odor of wounds; conducting more methodologically refined studies at the present time could raise the level of evidence and grade of recommendation for this practice.

Curcumin ointment was cited in one study³⁴ and showed a 2c level of evidence and B grade of recommendation for the control of the odor from MFW. Curcumin is the main biologically active phytochemical compound of turmeric (*Curcuma longa*); it is a compound that has various anti-inflammatory properties by virtue of its inhibition of cyclooxygenase and other enzymes that regulate the inflammatory process.³⁴ Its antineoplastic activity is currently being evaluated in Phase I, II, and III clinical trials.⁴⁴ This intervention was applied directly

to the wounds, three times per day, over a period of four consecutive weeks.

The interventions that obtained a B grade of recommendation are those currently recommended for the control of the odor of MFWs. However, it should be noted that the number of high-quality studies is small; there is a need for studies of a higher methodological quality to confirm the effectiveness of these interventions.

The remaining interventions received a classification of C grade of recommendation (topical arsenic trioxide,⁴⁵ essential oils,^{46–49} green tea extract,⁵⁰ and hydropolymer dressings⁵¹) and D grade of recommendation (antiseptic solutions,³⁷ hydrogels,³⁷ and debridement enzymes³⁷) (Tables 2 and 3). All these interventions were used infrequently, with the exception of essential oils, which were cited in four studies.^{46–49} Nevertheless, these treatments need to be tested by higher-quality studies, as the current evidence does not allow any recommendation to be made concerning the control of the odor from MFWs.

Conclusions and Future Trends

This review surveyed the literature about studies related to the control of the five principal symptoms of MFWs: odor, pain, exudate, bleeding, and infection. The factors that

Table 2
Classification of Case Series ($n = 5$) Using Topical Interventions to Control Odor in MFWs by Level of Evidence and Grade of Recommendation

Author, Year	Intervention	Sample	Outcome	Evaluation of Odor with Instruments		
				LE	GR	
Cheng et al., 2003 ⁴⁵	Topical arsenic trioxide	2 patients	Reduction of odor, of exudate, minimal absorption of arsenic into the bloodstream	Not stated	4	C
Mercier and Kneivitt, 2005 ⁴⁶	Topical aromatherapy (essential oils)	4 patients	Reduction of odor, on average, in 3 days.	Not stated	4	C
Schiech, 2002 ³⁷	Topical metronidazole at 0.75%; antiseptic solutions (Dakin [®] or CarraKlenz [®]); activated carbon dressing; hydrogels; debridement enzymes	2 patients	Resolution of odor within 5–7 days after the start of intervention; reduction of odor in all interventions tested	Not stated	5	D
Warnke et al., 2006 ⁴⁷	Essential antibacterial oils	30 patients, but discussion of only 3 patients	Improvement in odor	Not stated	4	C
Yian, 2005 ⁵⁰	Green tea extract	4 patients	Improvement in odor	VAS (1–5)	4	C

LE = level of evidence; GR = grade of recommendation; VAS = visual analog scale.

Table 3
Classification of Case Reports ($n = 8$) Using Topical Interventions to Control Odor in MFWs by Level of Evidence and Grade of Recommendation

Author/Year	Topical Treatment Used	Sample Size	Outcome	Evaluation of Odor With Instruments	LE	GR
Naylor, 2001 ⁵¹	Treatment with hydrophobic foam	1 patient	Complete resolution of fetid odor	Not stated	4	C
Warnke et al., 2005 ⁴⁸	Essential oils + systemic antibiotic + systemic chlorophyll	1 patient	Complete resolution of fetid odor	Not stated	5	D
Warnke et al., 2004 ⁴⁹	Essential oils + systemic antibiotic + systemic chlorophyll	1 patient	Complete resolution of fetid odor	Not stated	5	D
Bauer et al., 2000 ³⁸	Crushed metronidazole applied to wound + secondary dressing impregnated with petrolatum	1 patient	Improvement in fetid odor	Not stated	5	D
Jones, 1998 ³⁹	Metronidazole gel at 0.8%	1 patient	Reduction of odor	Not stated	5	D
Price, 1996 ⁴⁰	Topical metronidazole gel (concentration not indicated)	1 patient	Complete resolution of fetid odor	Not stated	5	D
Shulter et al., 1997 ⁴¹	Metronidazole gel at 0.9% + hydrogel treatment	1 patient	Improvement in fetid odor	Not stated	5	D
Dalton, 1990 ⁴²	Metronidazole treatment	1 patient	Complete resolution of fetid odor	Not stated	5	D

LE = level of evidence; GR = grade of recommendation.

enhanced the quality of this review include the number of descriptors and databases used, in addition to the fact that there were no restrictions as to the language in which the studies were written or their design.

Eleven interventions for the topical treatment of the odor from MFWs were identified. Metronidazole and Mesalt[®] dressing present a 2b level of evidence and B grade of recommendation. Activated carbon dressing and curcumin ointment yielded a 2c level of evidence and B grade of recommendation. C and D grades of recommendation were observed in seven other interventions: topical arsenic

trioxide, essential oils, green tea extract, hydrophobic dressings, antiseptic solutions, hydrogels, and debridement enzymes (Table 4).

The goal of identifying the evidence for odor control was achieved, and in addition, it was possible to point out the flaws to be avoided in the planning of future studies in this area. Few high-quality studies were found to guide the topical treatment of odor in the case of MFWs, and the principal limitations of existing studies were design (few controlled clinical and randomized trials), small sample sizes, and the absence of instruments or scales to measure odor.

Table 4
Synthesis of Evidence Regarding the Topical Treatment of the Fetid Odor of MFWs ($n = 11$)

Topical Intervention	Citations in Studies, n (%) ^a	Highest Level of Evidence Achieved	Highest Grade of Recommendation Achieved
Metronidazole	10 (50)	2b	B
Mesalt [®] dressing	1 (5)	2b	B
Curcumin ointment	1 (5)	2c	B
Activated carbon dressing	2 (10)	2c	B
Topical arsenic trioxide	1 (5)	4	C
Essential oils	4 (20)	4	C
Green tea extract	1 (5)	4	C
Hydrophobic dressings	1 (5)	4	C
Antiseptic solutions	1 (5)	5	D
Hydrogels	1 (5)	5	D
Debridement enzymes	1 (5)	5	D

^aThe total percentage exceeds 100%, because some studies involved more than one type of intervention.

Randomized clinical trials are the gold standard for treatment studies but are hard to conduct in many clinical conditions as, for example, wound care. The research challenges related to MFWs involve a number of methodological and ethical concerns, such as use of a placebo group, blinding researchers, blinding patients, assessing level of changes in odor, following patients for a long period, and others. To improve the level of evidence of future studies, we suggest an increase in the number of patients and the use of standardized scales for odor assessment. These strategies could bring important contribution and even support meta-analysis.

This study provides evidence to support the use of metronidazole, Mesalt[®] dressing, activated carbon dressing, and curcumin ointment in the treatment of patients with MFWs, but additional research in this area is still necessary. The use of metronidazole has spread around the world; it is inexpensive, easy to use, and easily available. Activated carbon dressing is easy to use, available in many countries, and well accepted by patients, but is still expensive for developing countries. Mesalt[®] dressing is not available in many countries, and there is very little experience with this dressing in MFWs. Curcumin ointment is a new practice not available commercially.

The palliative care target is holistic care that involves physical, social, emotional, and spiritual well-being. Odor causes social embarrassment and has a destructive psychological impact on the individual with this kind of wound, contributing even to isolation. The mainstays of the management of MFWs are anticancer treatments, symptom control (including pain management), and local wound care. The odor could be controlled by local care or systemic treatment, such as radiotherapy and chemotherapy.

MFWs require palliative care, and answers as to how this care should be administered cannot be found in studies in the area of wound care, a field which privileges research into healing rather than symptom control. The highest level of evidence currently available for the control of odor from MFWs indicates the use of metronidazole, Mesalt[®] dressing, activated carbon dressing, and curcumin ointment.

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