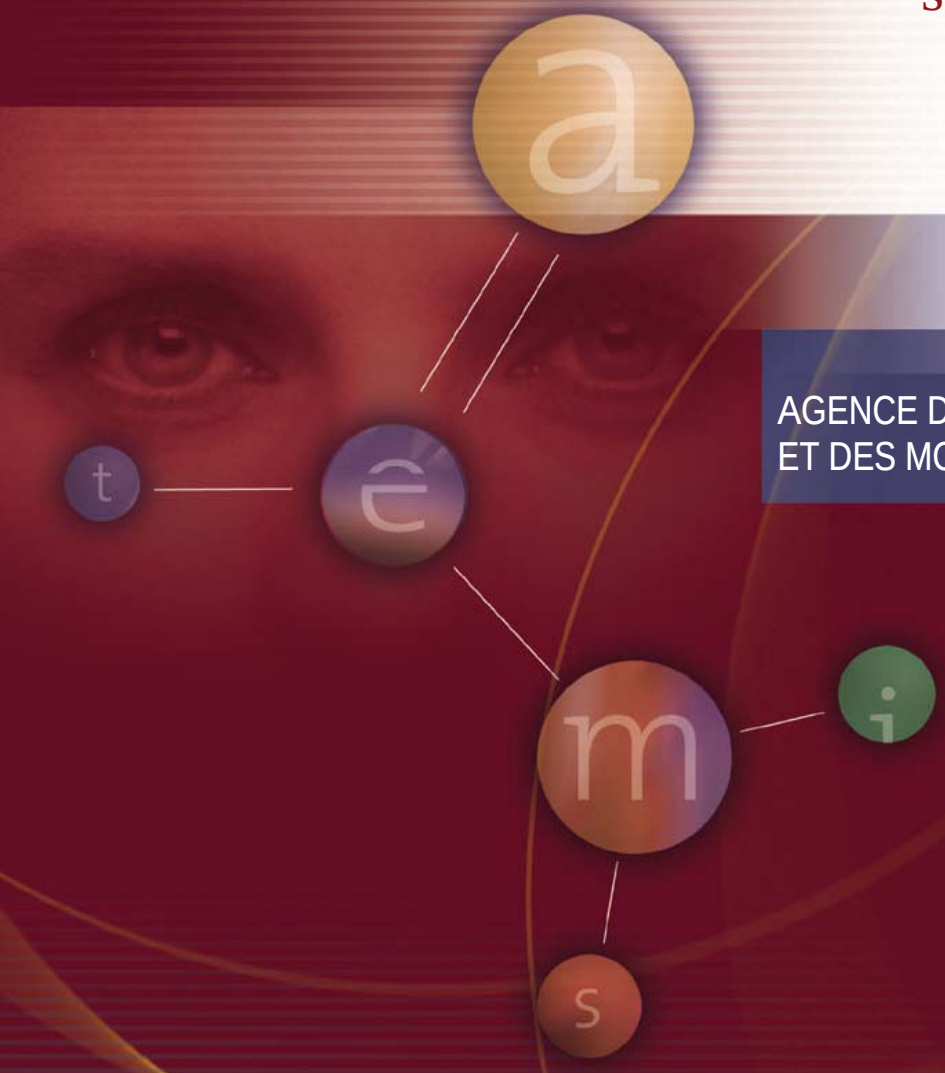
Acticoat™ for the Treatment of Severe Burns

Summary



AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Québec

Acticoat™ for the Treatment of Severe Burns

Summary

Technical note prepared for AETMIS by

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Mission

The mission of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is to help improve the Québec health-care system. To this end, it advises and supports the Minister of Health and Social Services and decision-makers in the health-care system with regard to the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for the disabled, as well as the methods of providing and organizing services. The assessments examine many different factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic issues.

Foreword

Acticoat™ for the Treatment of Severe Burns

Medical innovations for the treatment of severe burns are of interest to members of the *Programme québécois de traumatologie* (Quebec's trauma care program) and the *Comité aviseur du projet de gestion des fournitures spécialisées pour les personnes victimes de brûlures graves* (Quebec's advisory committee for the management of specialized medical products for victims of severe burns), which report to the *Ministère de la Santé et des Services sociaux* (Quebec's Ministry of health and social services). For this reason, these two groups asked AETMIS to assess the role of Acticoat™, a continuous-release silver dressing, in the treatment of severe burns.

The purpose of this assessment was to consider the medical context for the use of this product and to analyze published scientific studies on its effectiveness with respect to pain relief, reduction of infection, and healing. Studies which addressed cost outcomes were also considered, but an economic evaluation was not conducted.

This report concludes that Acticoat™ can reduce pain, especially during dressing removal, when compared to dressings with 1% silver sulphadiazine or 0.5% silver nitrate. This benefit can be made even more important by the possibility of less frequent dressing changes offered by this product. According to consulted clinicians, this feature could also contribute to a decrease in workload for nursing staff. Furthermore, according to the results of *in vitro* and *in vivo* analyses, Acticoat™ is effective in reducing colonization and preventing contamination by micro-organisms. However, the available clinical studies do not establish that Acticoat™'s ability to control infection and improve healing is superior, in statistically significant terms, to that of other topical silver agents, such as 0.5% silver nitrate solution and 1% silver sulphadiazine cream. Nevertheless, the observed effects are promising. Current published literature does not demonstrate Acticoat™'s potential for reducing hospital costs, but quicker discharge from hospital appears to be possible for children treated with Acticoat™ for medium-sized burns.

Given these results and the lack of good quality studies comparing Acticoat™ with similar silver-based dressings, AETMIS concludes that Acticoat™ is a therapeutic option for the treatment of severe burns. The rationale for its use is nonetheless based more on empirical results observed in the clinical setting than on published scientific evidence. Burn care is an emerging field of research, and its development paves the way for additional, better-designed clinical studies capable of demonstrating the potential benefits of this dressing.

With this technical report AETMIS wishes to address the relevance of adding Acticoat™ to the range of silver products used to treat severe burns in Quebec.

Dr. Juan Roberto Iglesias
President and Chief Executive Officer

Acknowledgments

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Lastly, AETMIS would like to thank **Janine Lepage,** Technical Director, Smith & Nephew Inc., Ville Saint-Laurent, Montréal (Québec), for providing information about Acticoat™, including an English translation of a recent publication.

DISCLOSURE OF CONFLICTS OF INTEREST

None declared.

Summary

Introduction

Silver occupies an important place in the medical arsenal for treating burns due to its ability to limit bacterial colonization. Its antimicrobial effect in burn patients is recognized and well-documented, especially since the use of 0.5% silver nitrate solution and 1% silver sulphadiazine cream as topical treatments. These products have limitations, however, including the rapid inactivation of silver, requiring frequent applications and leading to the development of dressings providing continuous release of ionized silver. Some of these dressings, including Acticoat™, are currently being used in Quebec and are covered under various insurance plans.

AETMIS was asked to evaluate the role of Acticoat™ in the topical treatment of severe burns by the *Programme québécois de traumatologie* (Quebec's trauma care program) and the *Comité aviseur du projet de gestion des fournitures spécialisées pour les personnes victimes de brûlures graves* (Quebec's advisory committee for the management of specialized medical products for victims of severe burns), which report to the *Ministère de la Santé et des Services sociaux* (Quebec's Ministry of health and social services).

Context of use

Approved for use in Canada in May 1999, Acticoat™ is currently utilized in health care facilities in Quebec, notably in the two units specializing in the care of major burn victims. This dressing releases a silver concentration of 70 to 100 mg/L, which exceeds the critical microbicidal threshold of 36 mg/L. Its release mechanism ensures a continuous distribution of silver and rapid start of action (within 30 minutes of application) in optimal moisture conditions. According to manufacturer recommendations, the Acticoat™ dressing can be kept in place for up to three days —unless daily assessment of the burn is required—which is a longer period than that possible for 1% silver sulphadiazine cream, for example. According to consulted clinicians, this feature may decrease the workload of nursing staff.

In vitro analyses

In vitro studies have examined the antimicrobial activity of silver products, but are difficult to compare because of differences in measurement methods, culture media, micro-organisms studied, and incubation times. Nevertheless, the *in vitro* antimicrobial activity of Acticoat™ has been demonstrated and appears to be comparable to, if not better than, that of other silver products such as Aquacel Ag™ and Silverlon™.

Pre-clinical studies

Pre-clinical studies (on animals) suggest that healing time for severe burns is shorter with Acticoat™ than with some other topical agents. Results for antimicrobial activity are variable (that is, sometimes superior with Acticoat™, sometimes not), depending on the products being compared and the micro-organisms under investigation. Overall, despite some positive findings favouring Acticoat™, results of these studies are insufficient to demonstrate superiority of Acticoat™ over the other topical products examined, such as 2% fusidic acid and 1% silver sulphadiazine, or to allow extrapolation to the human context.

Clinical studies

Three randomized controlled trials (of a limited number of patients, with two matched burns per patient in two of these studies) show a reduction of pain associated with Acticoat™, especially during dressing changes, compared with control dressings of 1% silver sulphadiazine or 0.5% silver nitrate.

The silver contained in Acticoat™ imparts a spectrum of antimicrobial action against the main strains of bacteria present in severe burns, but superiority over other silver agents, such as 0.5% silver nitrate solution, 1% silver sulphadiazine cream and Silvazine™ cream (not available in Canada), has not been demonstrated. Acticoat™ is part of the medical arsenal aimed at reducing microbial colonization and contamination of burns. In cases where silver sulphadiazine is contra-indicated (for patients allergic to sulpha products or when there is a risk of kernicterus), Acticoat™ is an alternative.

The clinical studies provide results that are variable and insufficient to affirm that Acticoat™ promotes better burn healing than the other topical products used in these studies, including 0.5% silver nitrate solution and 1% silver sulphadiazine cream. Unless daily assessment of a burn is required, Acticoat™ can be left in place for up to three days, according to manufacturer recommendations. This allows for longer intervals between dressing changes, which are a source of stress and pain for the patient.

The literature consulted on reduced average lengths of stay in hospital and other costs associated with the use of Acticoat™ is difficult to interpret, warranting further comparative studies, particularly economic analyses. Nevertheless, quicker discharge from hospital appears to be possible when Acticoat™ is used to treat medium-sized burns in children.

Conclusion

This technical note deals exclusively with the treatment of burns, although Acticoat™ is also used in the clinical context to treat wounds. The reviewed literature presents certain limitations, related to study methodology, small sample sizes, and heterogeneity of the products to which Acticoat™ is compared, among others. It is also important to note a lack of clinical studies that compare Acticoat™ with similar silver-based dressings.

Despite these limitations, studies show that Acticoat™ possesses effective antimicrobial activity *in vitro* and *in vivo* capable of reducing colonization and preventing contamination by micro-organisms. Its release mechanism ensures a continuous distribution of 70 to 100 mg/L of ionized silver over more than 48 hours and rapid start of action (within 30 minutes of application) in optimal moisture conditions. It also offers an alternative in the case of allergy to topical sulpha products.

According to the results of three randomized controlled trials, Acticoat™ reduces pain. This benefit can be intensified if dressings are changed only every three days, as recommended by the manufacturer. According to consulted clinicians, the lower frequency of dressing changes for Acticoat™, compared with 1% silver sulphadiazine cream for example, may reduce the workload of nursing staff, although this has not been formally evaluated.

The superiority of Acticoat™ for burn infection control and healing over other topical silver agents, such as 0.5% silver nitrate solution or 1% silver sulphadiazine cream, has not been demonstrated in a statistically significant manner, although the observed effects are promising.

The potential benefits of Acticoat™ for reducing hospital stays and other costs have not yet been put in evidence. To date one recent Canadian study suggests quicker hospital discharge for children with medium-sized burns.

Given these results and the lack of clinical studies comparing Acticoat™ with similar silver-based dressings, AETMIS concludes that:

1) Acticoat™ is a therapeutic option for the treatment of severe burns.

2) The rationale for its use is based more on empirical results observed in the clinical setting than on published scientific evidence.

3) Burn care is an emerging field of research, and its development paves the way for additional, better-designed clinical studies—and especially cost-benefit analyses—capable of demonstrating the potential benefits of Acticoat™ in the care of burns.

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