Algisite M and Aquacel Dressings in the Management of Various Types of Wounds

Kammerlander G* (DGKP, Certified Woundmanager §64 GuKG), Eberlein T (M.D. Dermatologist, Allergologist).

KAMMERLANDER-WFI *Wundmanagement Consulting , CH 8424 Embrach, Switzerland*

Corresponding author:

DGKP G. Kammerlander

Certified Woundmanager §64 GuKG

KAMMERLANDER-WFI *Wundmanagement Consulting Switzerland*

CH 8424 Embrach – Taleggstrasse 23

Switzerland

Email: kammerlander@wfi.ch

Tel: +41 79 246 7404

Abstract

Two parallel trials, with identical methodologies, were conducted in patients with granulating wounds, healing by secondary intention, requiring a moist environment and management of exudates. In the first trial (77 patients), wounds were treated with a calcium alginate dressing (Algisite M). In the second trial (77 patients), wounds were treated with a hydrofibre dressing (Aquacel).

In the Algisite M trial, complete closure of wounds was reported in 23/77 (30%) patients, a further 15/77 (19%) patients had wounds that had almost healed, and 23/77 (30%) patients had granulating wounds. Overall, improvement in wounds was observed for 82% of patients. A very positive, or positive clinician judgement on Algisite M was obtained for 74/77 (96%) patients. In the Aquacel trial, 14/77 (18%) patients had complete healing of wounds, 5/77 (6%) patients had wounds that had almost healed, and 9/77 (12%) patients had granulating wounds. Overall, improvement in wounds was noted for 80% of patients. A very positive or positive clinician judgement on Aquacel was recorded for 66/77 (86%) of patients.

In conclusion, Algisite M was effective in the management of wounds that produced moderate to high amounts of exudate in conjunction with the chosen secondary dressing, and was well accepted by clinicians. Aquacel was also effective in managing these types of wounds, although wound healing and stimulation of granulation was somewhat less than that observed in the Algisite M trial.

Introduction

Haemostasis and fibrin formation result in formation of a wound scab, and facilitate the repair process by providing a matrix for cell migration and angiogenesis[1, 2]. Macrophages are normally present in tissue but increase in number after injury, attracted by chemical messages released by the activation of inflammation. The long-lived cells release the protein chemical messages, growth factors, and growth stimulants that orchestrate healing in an organised fashion[3]. Macrophages have an essential role in the transition from wound inflammation and wound repair, the latter being characterised by granulation tissue formation[4]. A moist wound environment promotes faster healing, better quality of healing and less tissue necrosis than in dry wounds[5-7].

Some alginate-based dressings are reported to have haemostatic properties and are incorporated into wound dressings, where they act as calcium ion donors[8], which can be released from either a mannuronic (M) or glucuronic (G) group. Alginate dressings may also activate human macrophages, resulting in production of tumour necrosis factor-alpha, though this depends on the alginate used[9]. The use of moisture-retentive dressings leads to an environment that promotes earlier healing of wounds[5], and appears to be associated with fewer clinical infections, reduced scarring, and greater patient comfort[6]. Alginate dressings support moist wound healing and can absorb exudate[10]. Clinical studies have shown initiation or acceleration of healing of chronic wounds, providing that the underlying pathology has also been treated[9]. Alginate dressings have been proven to be effective in a wide variety of acute and chronic wounds[11].

Other dressings are used for the management of exuding wounds, such as hydrofibre dressings. Aquacel is a carboxymethyl-cellulose dressing intended for use in moderate to heavily exuding wounds. Exudate is directly absorbed into Aquacel's fibres[12], and it has been shown to be effective in the treatment of wounds such as pressure sores, leg ulcers and surgical wounds[13-15].

Two open studies were conducted in parallel to determine the performance of these dressings in two groups of patients with granulating wounds that required a moist wound healing environment and management of exudates. Although randomised controlled trials are considered a standard means of comparing wound dressings, the medical necessity of healing wounds, time constraints and numbers of patients who presented at clinic for treatment led to the decision to conduct non-comparative clinical evaluations of Algisite M and Aquacel. Patients were recruited from the same centres for both studies, and both trials used identical methodologies, inclusion and exclusion criteria, and efficacy endpoints.

Methodology

The selection of patients, wound assessments, efficacy and safety and analyses were identical for both trials, with patients receiving either Algisite M or Aquacel, depending on which trial they were enrolled into.

Patients

Patients were recruited from centres in Austria, Germany and Switzerland. They entered into one of two non-comparative studies run in parallel. Male and female patients, aged at least 18 years, were eligible to enter either study if the following requirements were met:

- they presented with granulating wounds, healing by secondary intention, which required a moist wound healing environment and management of exudates. Wounds that contained non-viable tissue (black necrotic, yellow slough, pus, debris) were included
- patients were willing and able to comply with the study requirements and gave their informed consent

Patient record forms were completed for one wound only. Where a patient presented with more than one wound, the largest wound was chosen for this study. Patients who were known to be poorly compliant with medical treatment were excluded from both trials.

Study Conduct

It was intended that patients continued in each study until they had received 6 weeks treatment or a total of 15 dressing changes had been performed, or the wound was closed, or they withdrew. However, if patients had extensive wounds, the condition of the wound was monitored until the wound had healed. If a patient's treatment was interrupted for more than 6 days, either consecutively or in total, the patient was withdrawn from the study.

Wound Dressing

Wounds were cleansed with normal saline solution before being photographed. Wounds were photographed at the initial assessment, every 2 weeks, and at the final assessment. The date of the photograph and a metric scale was included in the field of view. Wounds were then covered with the trial dressing (Algisite M or Aquacel, depending on which trial a

patient had entered) and the appropriate secondary dressing, which was wound-type specific such as Allevyn or Allevyn Adhesive, Hydrocolloids, Gauze or OpSite Flexigrid, and was chosen by the investigator[16, 17]. Frequency of dressing changes was at the discretion of the clinician, and depended on the quantity and nature of exudates from the wound. In the Algisite M study, it was recommended that the dressing be changes every 1–3 days. Depending on the condition of the wound, gels and antiseptics were used, e.g. Prontosan W gel, Prontosan W Solution, Octenisept or Lavasept.

Wound Area

The total area of the wound was measured at Week 0, at the time of withdrawal and at Weeks 2, 4 and 6, if the wound had not healed. The area was calculated from tracings of the ulcer margin and from digital photographs.

Wound Stage

Local wound stages were assessed using a modified (G. Kammerlander 1996/1999) DWCS classification model[18]. The modified model is based on the optical characteristics of wounds, which are classified on the basis of four colours and four mixed forms:

- black wounds - necrotic tissue (black to yellow, black - yellow - red)
- yellow wounds - sloughy tissue (yellow to red)
- red wounds - granulating tissue (red to pink)
- pink wounds - epithelium (wound healed)

This is shown diagrammatically in Table 1. The stage of wounds was monitored at Week 0, 2, 4 and 6.

Efficacy

The following were calculated to determine the effectiveness of each dressing:

- percentage of patients with wounds healed
- percentage reduction in wound area
- percentage improvement in wounds
- percentage change in the stage of the wound
- time between dressing changes

Safety

All adverse events were recorded, both spontaneously reported by the patient and those observed by the clinician.

Analysis

Data was entered and verified using database software. Statistical analysis was performed using the SPSS application. Demographic and other baseline variables were summarised by treatment, although formal statistical testing of baseline data was not performed. All patients admitted to either trial who received treatment, and had at least one usable assessment after treatment had started, were included in the analysis.

Results

Algisite M Trial

A total of 77 patients entered the Algisite M trial, of whom 47 (61%) were male and 30 (39%) female. The average age was 70.5 years (range: 30–94 years). The average age of males was 66.4 years (range: 30–89 years) and of females was 76.9 years (range: 45–94 years). The average baseline wound area was 5.1 cm^2 and the median baseline wound area was 3.0 cm^2 (range: 1.0 – 27.0 cm^2). The type of wounds at study entry are summarised in *Figure 1*.

The average duration of treatment per wound was 29.2 days, with an average of 13.7 dressing changes per wound. Dressings were left in place for an average of 2.3 days. Algisite M did not disintegrate in the wound, and had sufficient absorbent capacity to manage exudates. The cleansing and granulation effect was also observed to be very good.

The classification of wound stages at the start of treatment and at the end of treatment is shown in *Table 2*. Completely healing occurred in 23/77 (30%) of wounds, and 15/77 (19%) had almost healed, with a further 23/77 (30%) wounds showing granulation. The wound area at the start of treatment and at the end of treatment is shown in *Table 3*. The average percentage reduction in wound area was 54.9% and the median percentage reduction in wound area was 66.7%. Overall, improvement in the wound condition was observed for 82% of patients, the wound condition was unchanged in 13% of patients and had worsened in 5% of patients.

The clinician's subjective opinion on Algisite M was also recorded. The clinician's judgment was very positive for 47/77 (61%) patients, positive for 27/77 (35%) patients and acceptable for 3/77 (4%) patients.

Aquacel Trial

A total of 77 patients were recruited into the Aquacel trial, of whom 43 (56%) were male and 34 (44%) were female. The average age of patients was 68.5 years (range: 22–91 years). The average age of males was 65.9 years (range: 22–88 years) and of females was 71.8 years (range: 44–91 years). The average baseline wound area was 5.0cm^2 and the median baseline wound area was 2.0cm^2 (range: 0.2 – 45.0cm^2). The type of wounds at trial entry are summarised in *Figure 1*.

The average duration of treatment per wound was 37.9 days, with an average number of 16.3 dressing changes per wound. Dressings were left in place for an average of 2.5 days.

The classification of wound stages at the start of treatment and at the end treatment is shown in *Table 4*. Complete healing occurred in 14/77 (18%) of wounds, and 5/77 (6%) had almost healed, with a further 9/77 (12%) wounds showing granulation. The wound area at the start of treatment and at the end treatment is shown in *Table 5*. The average percentage reduction in wound area was 22% and the median percentage reduction in wound area was 50%. Overall, improvement in the wound occurred in 81% of patients, the wound condition was unchanged in 17% of patients, and had worsened in 3% of patients. The effect of protection against maceration in the wound area around was very good.

The clinician's subjective opinion on Aquacel was also recorded. The clinician's judgment was very positive for 30/77 (39%) patients, positive for 36/77 (47%) patients, acceptable for 10/77 (13%) patients, and poor for one patient.

Discussion

Two trials were conducted to assess the performance of Algisite M and Aquacel in the management of chronic wounds. The majority of wounds included in the studies were diabetic ulcers (micro- or macro-angiopathic) and venous ulcers. Although the performance of Algisite M with Aquacel was not directly compared, both studies included the same number of patients, identical inclusion and exclusion criteria, and the same study methodology.

The percentage of patients with completely healed wounds was 30% in the Algisite M trial, and 19% of patients had wounds that had nearly healed. In the Aquacel trial, 18% of patients had complete wound healing and 6% of patients had wounds that had nearly healed. Overall, improvement in the condition of wound was similar (80%) in both trials. A positive influence of a hydrofibre dressing has been reported for 92% of patients in an earlier trial involving chronic diabetic foot wounds[7]. The improvement noted in the current studies was somewhat lower (80%), but probably reflects the different types of chronic wounds treated. Higher rates of complete healing could be expected with acute and less serious wounds. A previous study of a calcium alginate dressing on split skin graft donor sites reported 67% of patients with completely healed wounds after 10 days treatment[19].

The mean dressing wear time was similar in both trials: 2.3 days for Algisite M and 2.5 days for Aquacel. Although longer wear times have been reported for hydrofibre dressings compared with alginate dressings[20], the time between dressing changes is influenced by a number of factors, including the amount of exudates produced by wounds and the secondary dressing used, making it difficult to compare results obtained from different trials. In the present trial, the methodology, number of patients and type of wound at entry were identical or very similar, facilitating an appraisal of results from these two studies.

In conclusion, Algisite M was effective in the management of wounds that produced moderate to high amounts of exudates in conjunction with the chosen secondary dressing, and was well accepted by clinicians. The protective effect against maceration in the surrounding wound area was notable in the Aquacel study. Aquacel was also effective in managing exuding wounds, although wound healing, stimulation of granulation and the cleansing effect of the woundbed was somewhat less with Aquacel than that observed in the Algisite M trial.

In the clinical setting, both Algisite M and Aquacel were effective in treating wounds at a variety of stages. Clinicians and patients found Algisite M to be more acceptable than Aquacel. Further clinical studies are needed to confirm these data.

Table 1: Wound Stage Classification Scheme[18]

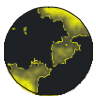
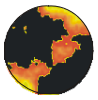
Criteria 1 (Interpretation of colours)	Criteria 2 (Interpretation of exudate production)
 **black** (necrosis)	- black (necrotic) - **slight** - black (necrotic) - **moderate - copious** - **necrosis adhered to wound edges** - **necrosis particularly non adhered**
 **black - yellow** (necrosis+ slough)	- **slight** - **moderate** - **copious**
 **black - yellow - red** (necrosis+ slough + granulation)	- **slight** - **moderate** - **copious**
 **yellow** (slough)	- **slight** - **moderate** - **copious**
 **red- yellow** (granulation+ slough)	- **slight** - **moderate** - **copious**
 **red** (granulation)	- **slight** - **moderate** - **copious**
 **red- pink** (granulation+ epithelium)	- **slight** - **moderate** - **copious**
 **pink (epithelium)**	- **unstable, athropic skin** - **partly eczema present in skin** - **dry skin** - **normal skin constitution**
Criteria - 3 **(Identification of local signs and symptoms of clinical infection)**	

Table 2: Wound Stage at Start of Treatment and End of Treatment for Algisite M Trial

Wound Stage	**Start of Treatment**	**End of Treatment**
Necrotic	5 (6%)	0
Slough	22 (29%)	4 (5%)
Granulation + slough	45 (58%)	12 (16%)
Granulation	4 (5%)	23 (30%)
Granulation + epithelium	1 (1%)	15 (19%)
Completely re-epithelialised	0	23 (30%)
TOTAL	77	77

Table 3: Wound Area (cm^2) at Start of Treatment and End of Treatment and Percentage Reduction in Wound Area for the Algisite M Trial

Statistic	**Start of Treatment**	**End of Treatment**	**% Reduction in wound area**
Mean	5.1	2.3	54.9
Median	3.0	1.0	66.7
Std	5.3	3.5	-
Minimum	1.0	0	-
Maximum	27.0	20.0	-
TOTAL	77	77	77

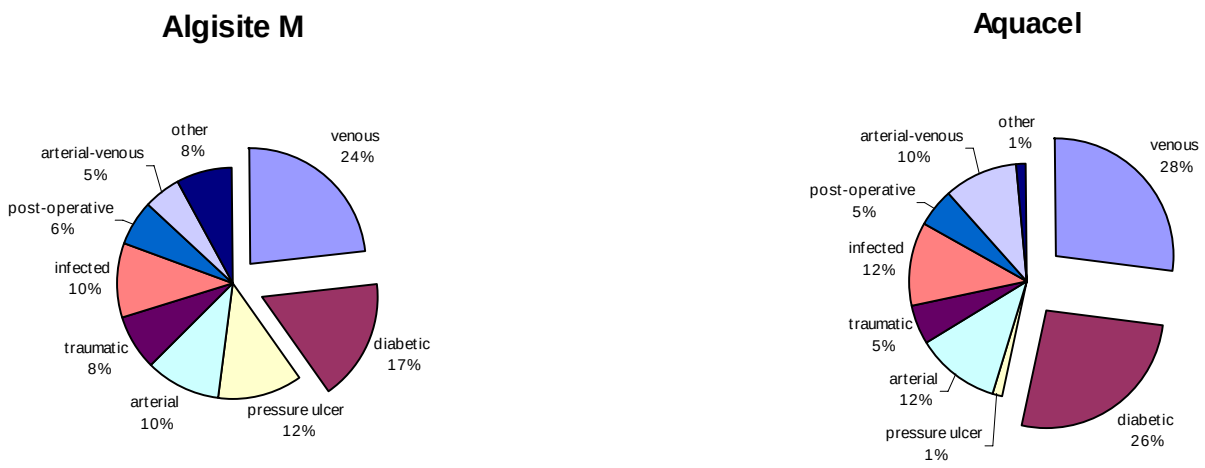
Table 4: Wound Stage at Start of Treatment and End of Treatment for the Aquacel Trial

Wound Stage	**Start of Treatment**	**End of Treatment**
Necrotic	2 (3%)	2 (3%)
Slough	11 (14%)	9 (12%)
Granulation + slough	48 (62%)	38 (49%)
Granulation	15 (19%)	9 (12%)
Granulation + epithelium	1 (1%)	5 (6%)
Completely re-epithelialised	0	14 (18%)
TOTAL	77	77

Table 5: Wound Area (cm^2) at Start of Treatment and End of Treatment and Percentage Reduction in Wound Area for the Aquacel Trial

Statistic	**Start of Treatment**	**End of Treatment**	**% Reduction in wound area**
Mean	5.0	3.9	22%
Median	2.0	1.0	50%
Std	7.9	7.8	-
Minimum	0.2	0	-
Maximum	45.0	45.0	-
TOTAL	77	77	77

Figure 1: Wound Types at Entry



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