The Results Of Maggot Debridement Therapy In The Ischemic Leg: A Study On 89 Patients With 89 Wounds On The Lower Leg Treated With Maggots

P Steenvoorde, C Jacobi, J Oskam

Abstract
Maggot Debridement Therapy (MDT) is an effective debridement method, however results in ischemic patients are worse; in some clinics this even means ischemic ulcers are not treated with MDT. However the only alternative sometimes seems to be amputation. In the present study it was shown that vascular patients had statistically significant more often a bad outcome after MDT compared to non-vascular patients (Odds ratio (OR): 12.2; 95% Confidence Interval: 3.3-45.2; P-value<0.001) However still 52% of vascular patients had a good outcome, with a 68% good outcome in the succesfully revascularized patients and 41% in the non-revascularized patients (p=0.12) We believe MDT results in patients with ischemic ulcers are worse compared to patients without ischemia, but these worse results do not justify to withhold MDT in these subgroup of patients.

INTRODUCTION
Maggot Debridement Therapy (MDT) is a debridement method with great advantages over sharp debridement. It's highly selective, without inflicting to much damage to the healty tissue, moreover it has other beneficial effects wich promote woundhealing. Another advantage is that for MDT, no aneshtesia is needed and the patient does not need to be admitted, wich is of great importance in a time of an ever growing elderly population with co-morbidity. Some authors do not treat patients with inadequate vascular supply with MDT, unless healing is not the goal. Hofman points out that in deep ischemic wounds maggots will die for they need oxygen to survive. Sherman states that arterial insufficiency is a relative contra-indication for MDT, Wound healing seems almost impossible if the absolute systolic ankle pressure is below 50 mmHg, it is difficult between 50-80 mm Hg, and good if above 80 mm Hg,. If a patient has an ischemic ulcer, and there are no possibilities to improve revascuralzation, prognosis for the patient is poor. The patient is likely to end up with a major amputation. In our clinic MDT was started in august 2002. Contra-indications for the therapy were patient-preference, septicaemie and patients from whom informed consent could not be obtained. Vascular insufficiency was not a contra-indication, although we believed results in these patients would be worse. In this analysis we studied the results of MDT in patients with and without vascular problems in order to answer the question if MDT could be worthwhile in the ischemic leg.

METHODS
Patients with chronic wounds on the leg were found eligible for MDT treatment. Of each patient it was recorded whether arterial insufficiency was present. The diagnosis of arterial insufficiency was made if both pedal pulses of the involved foot were absent and/or the ankle-brachial pressure index was less than 0.6 and/or the absolute ankle pressure was below 50 mm Hg. Conservative wound healing usually takes place above the threshold of chronic critical limb ischemia. If the absolute systolic ankle pressure and/or the ankle-brachial index are below this threshold, foot pulses tend to be absent, the extremities are cold and wound pain is common. The Second European Consensus, has outlined the following criteria for a diagnosis of chronic limb ischemia: recalcitrant rest pain or distal necrosis of more than 2 weeks' duration in the presence of (1) a systolic ankle pressure of 50 mm Hg or less, or (2) systolic toe pressure of 30 mm Hg or less, or (3) a transcutaneous oxygen pressure of 10 mm Hg or less.

In this study a patient was recorded as a vascular patient if the patient met the criteria for chronic critical limb ischemia,
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or if the patient had a history of a peripheral bypass or radiological intervention of the ipsilateral leg. The patient was recorded as a successfully re-vascularized patient if the patient had an ankle-brachial index of more or equal to 0.6 and/or the absolute ankle pressure was above 50 mm Hg and had a previous history of interventional vascular procedures of the involved leg, including both surgical and radiological procedures.

In the period August 2002 and the first of January 2006, all patients who presented at the surgical department of the Rijnland Hospital, Leiderdorp, The Netherlands, with infected wounds with signs of gangrenous or necrotic tissue who seemed suitable for maggot debridement therapy (MDT), were asked whether they would enrol in a prospective case series study regarding MDT. All types of patients were included: patients from the dermatology department sent directly for this therapy, patients with infected diabetic feet, with arterial leg ulcers, with traumatic infected ulcers and with chronic wounds that would not heal despite treatment by the primary physician. Patients were excluded from the study if the treating surgeon believed an urgent amputation could not be postponed (for example in case of severe sepsis) or if life expectancy was shorter than a few weeks (ASA V). For this current study, patients were also excluded if the wound was not located below the knee or if they died before the MDT results could be registered. Of all wounds of patients, only the first wound with which they presented at the clinic was included. For analysis we grouped the patients according to their vascular status. As 3 groups of patients could be distinguished, 4 comparisons could be made. These encompassed: 1) Non-vascular patients vs. vascular patients; 2) Non-vascular patients vs. successful revascularized patients; 3) Non-vascular patients vs. vascular (non-revascularized) patients; and 4) Successful revascularized patients vs. vascular (non-revascularized) patients.

RESULTS

In the period between the first of August 2002 and the first of January 2006 101 patients with 117 wounds were treated with MDT. Excluded from this current study were patients with wounds localized above the knee (11 patients with 16 wounds) and if patients had more than one wound, all second wounds were excluded (11 wounds). One patient was excluded, for unfortunately the patient died before the result of the MDT could be checked. The number of patients included in the present study 89 patients, with 89 wounds.

There were 50 male patients (56%) and 39 females patients treated (see Table 1 for patient-characteristics). The average age was 70.9 years (range: 25-93 years, SD: 14.7). The wounds existed on average 7.0 months before starting with MDT (range 1 week-11 years). Based on our definitions (see section methods), 43 patients (48.3%) had no vascular problems, 19 patients (21.3%) had had vascular problems but underwent successful revascularization treatment, and 27 patients (30.3%) were (untreated) vascular patients.

Figure 1

Table 1: Patient- wound- and Interventioncharacteristics of the studies group.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Male</th>
<th>Female</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70.9</td>
<td>72.3</td>
<td>0.41</td>
</tr>
<tr>
<td>Wound Duration</td>
<td>2.8</td>
<td>2.8</td>
<td>0.97</td>
</tr>
<tr>
<td>Wound Depth</td>
<td>1.1</td>
<td>1.1</td>
<td>0.99</td>
</tr>
<tr>
<td>Wound Size</td>
<td>1.1</td>
<td>1.1</td>
<td>0.99</td>
</tr>
<tr>
<td>Result</td>
<td>Good (100)</td>
<td>Poor (0)</td>
<td>0.001</td>
</tr>
<tr>
<td>Interventions</td>
<td>None</td>
<td>Minor amputation</td>
<td>0.001</td>
</tr>
</tbody>
</table>

* Deep visible bone, joint or tendons.

**Effect of MDT observed (beneficial outcome)

1. Wound fully closed by second intervention (for example split skin graft);
2. Wound spontaneous fully closed;
3. Wound free from infection and <1/3 of original wound size;
4. Clean wound (free from infection/necrosis/slough), but same as initial size;

No effect of MDT observed (unsuccessful outcome)

1. No difference observed between the pre- and post-MDT-treated wound;
2. The wound is worse;
3. Minor amputation (for example partial too amputation);
4. Major amputation (for example below knee amputation).

In the vascular group of patients (n=46) significantly more
often diabetes occurred (63% versus 35%; p=0.015), the wounds existed for a longer period, the wounds were more often deep and more often had a worse result, compared to the non-vascular-group. If we look at the successfully revascularized patients, we found that there were no statistically significant differences between patient- and wound characteristics compared to the vascular patients. Good outcome was reached in 52% of all vascular patients, with 68% good outcome in the successfully revascularized patients and 41% in the non-revascularized patients. This difference in outcome, however, was not statistically significant (p=0.12).

The univariate logistic regression analyses showed that sex and wound size had no impact at all on MDT results, i.e. good vs. bad outcome. These two characteristics were, therefore, not selected for the multivariate analysis. All other characteristics, i.e. age (split by age of 60 years), the presence of diabetes, wound duration, and wound depth had a statistically significant impact or showed a trend on the outcome of MDT. So, these characteristics were selected for the multivariate analysis.

Regarding vascular problems, four univariate analyses were performed, as described in the methods section. These analysis, looking at the impact of vascular problems on MDT results, showed that vascular patients had statistically significant more often a bad outcome after MDT compared to non-vascular patients (Odds ratio (OR): 12.2; 95% Confidence Interval: 3.3-45.2; P-value<0.001). Successful revascularized patients had statistically significant more often a bad outcome after MDT compared to non-vascular patients (OR: 6.2; 95% CI: 1.3-28.2; P=0.019). Similarly, vascular patients (non-revascularized) had statistically significant more often a bad outcome after MDT compared to non-vascular patients (OR: 19.4; 95% CI: 4.8-78.8; P<0.001). With these univariate analysis, we could not show a statistically significant difference in MDT outcome between successful revascularized patients and vascular (non-revascularized) patients (OR: 3.2; 95% CI: 0.9-10.8; P=0.068). Although this difference in MDT outcome was not statistically significant, but on a trend level, it might be clinically relevant, as we are dealing with small groups of patients. We also have to keep in mind that these results are unadjusted for differences in patient and clinical characteristics.

If we adjust for differences between groups, i.e. age, presence of diabetes, wound duration, and wound depth, the statistic significant difference in outcome between non-vascular patients and vascular patients (revascularized and non-revascularized) is no longer present (Table 2). Only the trend regarding the difference in MDT outcome between successful revascularized patients and vascular patients holds (P=0.051).

**Figure 2**

**Table 2: Results of multivariate results of logistic regression analyses: impact on MDT outcome.**

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-vascular patients vs. vascular patients;</td>
<td>Non-vascular patients vs. successful revascularized patients;</td>
<td>Non-vascular patients vs. vascular (non-revascularized) patients;</td>
<td>Successful revascularized patients vs. vascular (non-revascularized) patients.</td>
</tr>
<tr>
<td>Multivariate results</td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Vascular problems</td>
<td>2.27 (0.94-6.12)</td>
<td>1.08 (0.78-1.47)</td>
<td>3.39 (0.39-21.19)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.229</td>
<td>0.65</td>
<td>0.159</td>
</tr>
</tbody>
</table>

* Adjusted for age, diabetes, wound duration, and wound depth.

In conclusion, these results indicate that, although it seems that vascular problems have a negative influence on wound healing, it might be the case that other patient characteristics have larger impact on MDT outcome than the vascular problems itself. The results, however, give the impression that a revascularization intervention does have some beneficial effect, as we found even in the multivariate analysis that (on a trend level) revascularized patients have more often good results after MDT compared to vascular, non-revascularized, patients. Good outcome was reached in 52% of all vascular patients, with 68% good outcome in the succesfully revascularized patients and 41% in the non-revascularized patients. We therefore believe MDT could be used in the ischemic leg, especailly for the lack of other treatment modalities besides amputation.

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