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# Expert assessment on the benefits of systematic application of Prontosan<sup>®</sup> solution in wound treatment with particular focus on cost-efficiency when compared to current standard treatment (saline / Ringer)

A retrospective analysis of existing data was performed on the (cost-)effectiveness of Prontosan<sup>®</sup> solution in supporting wound healing (duration of treatment / healing success) with systematic and controlled application in wound management in comparison to standard treatment (saline/Ringer).

Exclusively taken into account were chronic wounds of the type "Ulcus cruris venosum" with different chronicity. The analysed cases were selected from among patients of "GesundheitsManager", Wieseneckstraße 3, D - 90571 Schwaig / Nuremberg and from

own patients of the author.

# 1. Objectives

Based on a retrospective evaluation of the documentation of the patients' records the effect on wound healing with systematic application of  $Prontosan^{\$}$  solution in wound management was to be documented (n=59).

This group was compared to a second population of patients (n=53) who were treated with a conventional standard therapy (saline - / Ringer – solution).

The focus of the assessments was directed to the healing behaviour of the wounds. In particular it was examined whether a positive influence on the time to wound healing could be detectable. A comparison of both treatment groups was made as to the percentage of healed wounds related to time.

# 2. Investigation procedure and terms of the survey

### 2.1 Procedure

A key date data collection was performed. The following information was recorded on the patients:

- Sex
- Age
- Primary cause and diagnosis of the wound as Ulcus crusis venosum

### 2.2 Inclusion and exclusion criteria

Patients who were being treated and documented during the course of chosen time frame and who fulfilled the following criteria were selected and included in the analysis:

#### Inclusion Criteria

- Wound condition existed for at least three months ("wound duration")
- Known causal trigger of the wound condition
   Olcus cruris venosum
- Wound **treatment** was carried out based on the general criteria of "**moist wound treatment**"
- parallel observation of causal therapy aspects (compression therapy in venous ulcera by short stretch bandaging with a frequency of change from 1 to 5 days)
- clearly defined use of either Prontosan or Saline/Ringers during the duration of treatment
- **Treatment result** in terms of the therapeutic wound response
  - Healing with moist wound treatment under continuous use of

     a) Saline / -Ringer solution versus
     b) Prontocon<sup>®</sup> solution
    - b) Prontosan<sup>®</sup> solution

### within a maximum time period of six months

#### Exclusion Criteria

 persistent, severe, arterial circulatory disturbances (stage II and higher according to Fontaine), were not included

### 2.3 Term definitions

**Key date data collection:** Data was collected and analysed from the case records of patients who met the inclusion criteria set in paragraphs 2.1 and 2.2.

All cases that were analysed had complete follow-up documentation. Cases for which there was no follow-up documentation were not included.

Wound duration: Total time for which the actual wound condition consistently existed.

**Healing:** A wound was classified as **healed** once the original defect was stably and **completely closed** (epithelialised).

Healing time: describes the period from the beginning of the systematic observation until the occurrence of healing.

# 3. Results

### 3.1 Number of investigated cases:

# 3.1.1 Treatment group "conventional moist therapy" (physiological saline -, Ringer-solution) (treatment group 1)

### 53 cases, including

- 14 men
- 39 women

Age of patients was founded between 47 and 89 years with a mean of 75 years.

# 3.1.2 Treatment group "Prontosan<sup>®</sup> moist therapy" (treatment group 2)

59 cases, including

- 17 men
- 42 women

Age of patients in this group was founded between 55 and 93 years with a mean of 77 years.

### 3.2 Wound aetiology

Exclusively data of patients with "Ulcus cruris venosum" were evaluated in both groups ("conventional moist therapy" and "Prontosan moist therapy")

### 3.3 Time to healing

3.3.1 Healing time for treatment group 1 (Saline -, Ringer - solution)

During the observed period of 6 months 47 of 53 wounds healed completely (89 %). Performance of healing is as follows:

n=53			
Month of treatment	Performance of healing		
	patients per month	% per month	cumulated %
Month 1	1	2	2
Month 2	4	7	9
Month 3	10	19	28
Month 4	12	23	51
Month 5	9	17	68
Month 6	11	21	89
	total		%
<b>no</b> healing after 6 months	6		11



Figure 1: Performance of healing in treatment group 1 (X-axis healing time; Y-axis number of patients healed per month)

3.3.2 Healing time for treatment group 2 (Prontosan<sup>®</sup> solution)

During the observed period of 6 months 57 of 59 wounds healed completely (97 %). Performance of healing was as follows:

n=59			
Month of treatment	Performance of healing		
	patients per month	% per month	cumulated %
Month 1	4	7	7
Month 2	13	22	29
Month 3	18	31	60
Month 4	13	22	82
Month 5	7	12	94
Month 6	2	3	97
	total		%
<b>no</b> healing after 6 months	2		3



Figure 2: Performance of healing in treatment group 2 (X-axis healing time; Y-axis number of patients healed per month)

3.3.3 Direct comparison of healing performances

By superposition the data can be presented as follows:



Figure. 3: Comparison of healing performances between groups (number of patients saline/Ringer -orange- vs. Prontosan<sup>®</sup> -blue-)



The results by percentage – distribution are as follows:

Figure 4: Comparison of healing performances between the two groups (percentage distribution saline/Ringer -orange- vs. Prontosan<sup>®</sup> -blue-)

# 3.4 Typical complications - Development of infections

With regard to the frequency of **infections during the course of treatment** (regardless of the condition at the beginning of therapy; infection defined by typical clinical signs), the following frequencies resulted:

3.4.1 Treatment group "conventional moist therapy" (physiological saline -, Ringer-solution) (treatment group 1)

(n=53)

infection during the course of treatment:	<b>7 cases</b> (13 %)
no infection during the course of treatment:	<b>46 cases</b> (87 %)

3.4.2 Treatment group "Prontosan<sup>®</sup> moist therapy" (treatment group 2)

(n=59)

<ul> <li>infection during the course of treatment:</li> </ul>	2 cases (3 %)
<ul> <li>no infection during the course of treatment:</li> </ul>	57 cases (97 %)

# 4. Discussion, interpretation and consequences in practice

Treatment of the analysed patients was **performed exclusively in the outpatient area**, which often might present organisational and hygienic problems due to the home care of the patients.

### 4.1 Infection development during the course of treatment

Once more it should be mentioned that wound treatment takes place with above-average frequency in the home environment under difficult, sometimes alarming hygienic conditions.

**Infections** in the course of treatment of secondary healing wounds generally occur **not rare**. Data are scarcely available, especially regarding treatment that is carried out exclusively on an outpatient basis. Overall, infections in the treatment of secondary healing wounds in relation to place, type and duration of treatment as well as wound aetiology are given from just fewer than **2** to more than **7**, sometimes up to ca. **10** % (Duphar 1985, Gilchrist 1989, Debus 1998, Bowler 1999, Kramer 1999).

Considering the specifications of the problematical environment, an infection rate of ca. 2% has to be assessed as low overall. It appears that the principal reason fot that is to guarantee favourable healing and to create conditions of wound milieu that support the avoidance of an infection.

In the author's opinion, the good cleansing characteristics and the decontaminating effect are mainly responsible for this positive effect.

Therefore, the use of anti-infectious measures (local or systemic) is less frequently necessary.

Typical **infection complications** (systemic involvement with all ist consequences and impact on costs) occur **less frequently**.

# 4.2 Comparative healing performance upon between Prontosan<sup>®</sup> solution to conventional saline/ringer therapy

Wound healing is a highly complicated multifactorial process and it is by **no means** exclusively defined through the choice of wound dressing materials and the creation of local milieu conditions. The local management plays an important role.

**Moist wound treatment** is considered to be the **general standard** in the actual local wound therapy.

Typically, **neutral physiological solutions** are used for that purpose.

A new approach to local wound therapy must be at least comparable to this general standard in order to prove any advantage.

For the patient population treated with Prontosan<sup>®</sup> solution **a more frequent healing and** 

a significant reduced time to healing can be stated in comparison to the collective having been treated conventionally.

4.2.1 Statistical Analysis of Results

The wounds of the patients treated with Prontosan<sup>®</sup> solution healed

- with a higher number of cases in total over the observation period of 6 months (97% versus 89%).
- within a shorter time (e.g. 60 % versus 28% within the first 3 months of treatment).

In addition the healing time was compared between the two treatment groups via the log rank test. Patients not reporting a healing time had their data censored at six months. The Kaplan-Meier mean estimate (and associated standard error) were calculated for both treatment groups

There was a highly statistically significant difference between treatment groups(p<0.0001) in the time to healing. For the Prontosan group the Kaplan-Meier mean time to healing was 3.31 months (standard error 0.17) compared to 4.42 months(standard error 0.19) for subjects assigned Saline/Ringer solution.

Thus, it can be concluded that **Prontosan<sup>®</sup> solution** must have provided **a significant and quality-improving contribution** to the local milieu development as a base for the quick and efficient occurrence of reparative processes to the point of wound closure.

This positive milieu adaptation appears to be tendentially combined with an **improved wound cleansing** (minimisation of encrustations, fibrin layers, biofilm) and a **low infection rate** in the course of the treatment. This contributes to avoid complications, helps to reduce the treatment costs and shortens the total treatment duration (for example through lower risks of infection-provoking wound healing disturbances).

Consequently, the statement that the **additional use of Prontosan<sup>®</sup> solution** in the care of chronic wounds **lowers the frequency of typical problems, indisposed to wound healing** and subsequently increases the potential to achieve wound closure, is justified.

Although **quality of life** was not studied in detail as part of this retrospective analysis it would be reasonable to conclude that the quicker resolution of the wounds with the attendent reduction in pain and the reduction in odours due to less complications/infections improved the quality of life of the patients in the Prontosan group. In addition again it is reasonable to assume that if the leg ulcer resolves quicker than patients are likely to be ambulatory quicker and therefore be able to socialise quicker within their locality

### 4.3 Summary and conclusion

Thus, in summarising this assessment, it appears justified to recommend **Prontosan**<sup>®</sup> **solution** as a modern wound treatment agent with a number of remarkable, entirely positive properties for the **routine, situation-appropriate use**.

Additionally, an economic efficiency over the standard treatment can be stated from the observation of higher rates of healing, decreased total duration of therapy and reduced frequency of complications.

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