HARD-TO-HEAL WOUNDS: RESULTS OF A TREATMENT BASED ON NEGATIVELY CHARGED POLYSTYRENE MICROSPHERES (NCM)

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INTRODUCTION:

Recently, a new therapy based on Negatively Charged Microspheres (NCM)*, has been proposed for the treatment of hard to heal and chronic wounds of different etiologies. The NCM suspension restarts the healing process and accelerates the production of healthy granulation tissue and epithelialization.

OBJECTIVE:

To describe the efficacy and safety of a new product based on Negatively Charged Polystyrene Microspheres (NCM) technology, in the treatment of hard-to-heal wounds, in order to create granulation tissue and accelerate the healing process.

METHODS:

Twenty four cases with hard to heal wounds attending a specialized unit of diabetic foot and chronic ulcers were selected for topical treatment with NCM.

The NCM suspension were applied once a day, for a maximum of 12 weeks of treatment, until the complete healing or preparation for grafting was achieved. The product was applied by the health care professional of the Unit and by the patient himself, following the Instructions of Use.

A weekly clinical evaluation of the wound area a photograph were done. Information of the following variables were collected:

- Grade of epithelialization (measurement of the wound area until complete healing or 8 weeks of treatment)
- Grade of granulation (appearance of red granulation tissue, score >6 of granulometer, in >75% of wound area)
- Presence of adverse events
- Treatment failures (treatment failure was considered and stopped when no improvement was reported within two weeks of starting treatment).

RESULTS:

24 cases were included. The cases were classified according to the wound etiology in neuropathic (25%), ischemic (25%), venous (25%) and other causes (25%).

At baseline, the mean patient age was 70 years old. All the wounds have a duration of more than three months (chronic ulcers), and at least one month were treated with specialized treatment in our Unit (Refractory).

The mean time of wound evolution prior to treatment was 16 weeks, the mean size was 13.2 cm² and 5 wounds had exposed bone and/or tendon (21%).

NCM treatment was applied once a day. The product was easy to apply.

NCM treatment was suspended after 2 weeks in 5 cases (21%): Absence of clear improvement in 4 cases and 1 case had an infection not associated with the product.

After a mean of 5 weeks of NCM treatment, an improvement in 79% of the cases was observed:

- Complete healing was achieved in 46% (11/24)
- In the others that did not reach complete healing:
  - ≥75% of granulation tissue coverage in 62% (8/13)
  - 37.5% wound area reduction (13.22 to 8.26 cm²)

In wounds with exposed bone and/or tendon, a clear improvement in granulation/epithelialization was obtained in 60% of the cases.

(Case Photographs in the next slide)

REFERENCES:

4. Instructions of Use PolyHeal Micro 2017
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RESULTS IN HARD TO HEAL WOUNDS:

After a mean of 5 weeks of NCM treatment, an improvement in 79% of the cases was observed:

<table>
<thead>
<tr>
<th>Ulcer Type</th>
<th>Healing Time with NCM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic ulcer in interdigital space</td>
<td>Complete healing after 8 weeks with NCM</td>
</tr>
<tr>
<td>Venous ulcer leg with edema</td>
<td>Complete healing after 4 weeks with NCM</td>
</tr>
</tbody>
</table>

RESULTS IN WOUNDS WITH EXPOSED BONE AND TENDON:

A clear improvement in granulation/epithelialization was obtained in 60% of the cases.

<table>
<thead>
<tr>
<th>Ulcer Type</th>
<th>Healing Time with NCM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure ulcer</td>
<td>5 weeks with NCM</td>
</tr>
<tr>
<td>Neuroischemic ulcer</td>
<td>6 weeks with NCM</td>
</tr>
<tr>
<td>Pressure ulcer with edema</td>
<td>8 weeks with NCM</td>
</tr>
<tr>
<td>Venous ulcer leg with edema</td>
<td>Complete healing after 4 weeks with NCM</td>
</tr>
</tbody>
</table>

CONCLUSIONS:

- Our case study provides clinical evidence to support the topical application of NCM in refractory chronic wounds.
- MCN acts on different cell lines and if used in hard to heal wounds, improves granulation tissue formation and reduces the wound size.
- A global trend towards the granulation of the wound bed and the epithelialization in ulcers of different etiologies is confirmed, obtaining an improvement in 80% of our cases.
- MCN could be a new treatment option, managing to "unstuck" healing process of chronic ulcers.