Status quo regarding compression therapy in Germany and current evidence

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The mediven® observational study

The scientific fundament of an individualized, patient-centred care
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Overview


• Study design:
  – prospective, non-interventional / non-invasive
  – multicentre: 47 participating practices

• Population for analysis:
  531 patients: indication for compression therapy of venous disease (CVI: C1s-C6 CEAP)

• Therapy: circular-knit medical compression stockings (MCS)

• Period of observation per patient: 18 months

The study was registered under DRKS00006124 and approved by Ethics Committees.
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Patient baseline characteristics

<table>
<thead>
<tr>
<th>BMI Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>37.5%</td>
</tr>
<tr>
<td>Normal weight</td>
<td>33.9%</td>
</tr>
<tr>
<td>Overweight</td>
<td>27.7%</td>
</tr>
</tbody>
</table>

BMI classification:
- Underweight: < 18.5
- Normal weight: 18.5 – 24.9
- Overweight: 25 – 29.9
- Obesity: ≥ 30

BMI values with corresponding percentage of patients in each category.
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Clinical classification according to CEAP

Distribution

- C3: 43.3%
- C2: 34.5%
- C1: 10.6%
- ≥ C4: 10.0%

missing value: n=8; 1.5%
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Comorbidities relevant for MCS therapy

38.0 % Spinal problems

19.2 % Osteoarthritis

27.7 % Obesity (BMI ≥ 30)
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Use of all circular-knit mediven® products

- All circular-knit mediven® products
  - mediven elegance®
  - mediven comfort®
  - mediven® for men
  - mediven plus®
  - mediven® forte
  - mediven ulcer kit®
- All sizes / lengths
- All CCL

Decisions regarding treatment and prescription: exclusively by the treating physician

Reality of outpatient care
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Use of all qualities

- The term 'quality' includes different textile MCS characteristics and is defined by strength, rigidity, and elasticity.
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Results: Product safety / tolerability and compliance

Physician-reported

- **High degree of product safety and tolerability:**
  Low rate of adverse events and no relevant skin findings over 18 months

Patient-reported

- **Very good subjective tolerability:**
  High acceptance of mediven MCS and subjective improvement of symptoms

- **Good patient compliance:**
  Compliance remained at a high level over 18 months
Outpatient medical care situation

Focus on

1. MCS qualities
2. Donning aids
3. Frequency of MCS prescription
Outpatient medical care situation

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Results

Qualities, CCL, lengths: at the beginning of the study

Uniform standard care rather than individualized, patient-centred care?
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Results

Quality: during the study period (CEAP)

Predominance of light quality during the study – irrespective of CEAP
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Quality: during the study period (BMI)

- **Under-/Normal-weight**
  - Predominance of light quality: 81.3%
  - Predominance of medium quality: 17.5%
- **Overweight**
  - Predominance of light quality: 73.5%
  - Predominance of medium quality: 24.5%
- **Obesity I-III**
  - Predominance of light quality: 64.4%
  - Predominance of medium quality: 31.4%

Predominance of light quality during the study – irrespective of BMI
Outpatient medical care situation

Focus on

1. MCS qualities
   What are the consequences of this uniform standard care?

2. Donning aids

3. Frequency of MCS prescription
mediven® observational study – Results

Changes in clinical findings according to CEAP

Total population

Duration 18 months

Subpopulation C3 patients (43.3 %)

Duration 18 months

Clinical findings (CEAP)

9.6 % Worsening

17.7 % Improvement

72.7 % Stabilization

3.5 % Worsening

22.4 % Improvement

73.7 % Stabilization

Correlation between clinical findings and uniform standard care? (light quality 74 %)
mediven® observational study – Results

Changes in clinical findings according to CEAP
● in C3 patients ● in relation to BMI and MCS quality

- Improvement of CEAP class in C3 patients (%)
  - BMI < 25: Under-/Normalweight
    - 13.3%
  - BMI ≥ 25: Overweight/Obesity
    - 22.4%
  - Patients benefited from medium and firm qualities – irrespective of BMI

- Patients benefited from medium and firm qualities – irrespective of BMI
Outpatient medical care situation

1. MCS qualities
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Reality of outpatient care

Comorbidities

27.7 % Obesity (BMI ≥ 30)

38.0 % Spinal problems

19.2 % Osteoarthritis

Frequency of donning aids (at the beginning of the study)

Total population: 8.1 %

Subpopulations:
- Obesity: 11.3 %
- Spinal problems: 9.9 %
- Osteoarthritis: 11.1 %

Rare consideration – despite BMI, and comorbidities
Obese patients: Regular users* in relation to donning aids

With donning aid
Without donning aid

Visit 2
28.0%

Visit 5
27.7%

* Regular use = daily or on more than 50 % of days per week
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Obese patients: Regular users* in relation to donning aids

- Visit 2: Without donning aid = 28.0% vs. With donning aid = 42.1%
- Visit 5: Without donning aid = 27.7% vs. With donning aid = 45.9%

* Regular use = daily or on more than 50% of days per week

Increased compliance due to the provision of donning aids
Outpatient medical care situation

Focus on

1. MCS qualities
2. Donning aids
3. Frequency of MCS prescription
Reality of outpatient care: Frequency of MCS prescription

No second pair of MCS at the start of treatment: 31.6%

No new MCS prescription after 6, 12, and 18 months: ≈ 33%

Possibilities of a 2nd pair of MCS and a new MCS prescription after 6 months were not utilised.

MCS therapy = maintenance therapy
- Natural wear and tear
- Daily administration → daily use
- Daily washing process
Reality of the outpatient medical care situation

1. MCS qualities
   - Light quality: 73.8%
   - CCL 2: 98%

2. Donning aids
   - Men: 8.1%

3. Frequency of MCS prescription
   - 1/3
     - no 2. MCS pair
     - no repeat prescription

Consideration of different qualities (and CCLs)
Consideration in patients with relevant comorbidities
Regular MCS provision

Individuated, patient-centred medical care
- Compliance
- Treatment success

Physicians` awareness
Medical retail store (Germany)
Patients` education
Thank you very much for your attention!

Dr. med. Christine Schwahn-Schreiber

CIRC Chiemsee
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Publications: mediven® observational study

First publication:
Journal „Phlebologie“ (Volume 2/2016)

Second publication:
Journal „Phlebologie“ (Volume 4/2016)