CLINICAL TRIAL

ALOVA MEMORY FOAM MATTRESS

METHOD

- An observational, longitudinal, prospective, multicentre study with descriptive analysis performed in 1998 in a healthcare centre; two follow-ups on D0 and D15
- 61 patients included: average age 60 years old; F/M sex ratio 0.64; initial average BMI 23.11; 26 patients with pain
- 23 different pathologies, such as neurology, orthopaedics, rheumatology, heart disease, PAD; 57.4% of the population have spinal cord injuries
- Bed-confined patients on average 15 hours/day; 18 are repositioned on average 6 times/day; 55 undergo physiotherapy; 21 have 1 special diet
- Initial average Waterlow score: 18.3
- Risk level of the entire population: 15 patients at risk, 24 at high risk, 22 at very high risk
- 43 patients with no pressure sores, 18 with pressure sores
- 18 pressure sores: 12 of stage 1-2, and 6 of stage 3-4; 9 of the sacrum and 4 of the heel
- Local treatment of the pressure sores: hydrocolloid (8), Sofra-Tulle (3), iodoform gauze (1), enzymatic debridement (3)
- Carer time in prevention and/or treatment: 31 patients ≤ 1 hour, 15 patients between 1 and 2 hours, 9 patients > 2 hours

PAD : Peripheral Arterial Disease

RESULTS

- PRIMARY ENDPOINT: Preservation or improvement of the skin condition
  - 1 favourable progress, 2 onsets of pressure sores, 1 study withdrawal
  - Efficacy % (favourable progress, stabilised lesions/population considered)
    - Total population: 93% (57/61)
    - Population at risk and without pressure sores: 98% (42/43)
    - Population with pressure sores: 83% (15/18)

- SECONDARY ENDPOINTS: Opinions of carers and patients
  - Ease of use carer 90,2%
  - Patients who wish to keep the support 88,5%
  - Patients who kept the support 93,5%
CLINICAL TRIAL

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METHOD

- An observational, longitudinal, prospective, multicentre study with descriptive analysis: clinical follow-up after marketing
- Study conducted in 2004 in a healthcare centre: 30% Medicine, 33% Spec. medicine, 20% Long-term stay, 12% Surgery, 5% ICU
- 40 patients included: average age 71.38 years old; M/F sex ratio 0.86; initial average BMI 16.25
- Bed-confined patients on average 18 hours per day with 3 daily turn-overs, raised at least once a day
- Two follow-ups conducted on D0 and DEND, average follow-up period of 25.27 days

- 20 patients with pressure sores (50%), 24 established pressure sores, of which 76% of stage 1-2 and 24% of stage 3-4

Mobility: 45% good to average, 50% no
Conscience: 87.50% good to average, 10% poor
Continence: 35.50% yes, 57.50% no
Nutrition: 20% good, 52.50% average, 25% poor
Pain: 37.50% yes, 50% no

RESULTS

- PRIMARY ENDPOINT: Onset of pressure sores of stage 1 to 4
  - No onset of pressure sores

- SECONDARY ENDPOINTS: Tolerance, results based on the actual responses (particularly the patients able to answer)

Level of satisfaction of the carers: 95%
Level of satisfaction of the patients: 76%
Level of tolerance of the patient: 87%

Efficacy 94%
Movement 95%
Safety 88%
Comfort 97%
Installation 95%
Bed remake 97%
Maintenace 97%
Is properly installed 93%
Sleeps better 60%
Does not slide 75%

Is not in pain 71%
Relaxed face 100%
Healthy skin 81%
Normal sweating 96%