

CLINICAL PRACTICE

Incidence of pressure ulcer in patients using an alternating pressure mattress overlay: the ACTIVE study

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ACTIVE : Axtair Clinical Trial InVestigating Efficacy.

Method

- Observational, non-interventional, prospective, multicenter, single-arm study.
- Study conducted from June 2019 to December 2019 in 8 French establishments (5 rehabilitation centers, 3 geriatric centers).
- 89 patients inclus >18 ans, sans escarre, alités 15 à 20 h/j, poids 30 à 165 kg, risque moyen à élevé de survenue d'escarre (jugement clinique et Braden 10 à 14).

Objective

To determine the clinical benefit of using a specific alternating-pressure mattress overlay (APMO) in the prevention of pressure ulcer (PU) in patients at medium to high risk.

- **Primary endpoint:** the percentage of patients who developed a sacral, spine, heel or trochanteric PU (supine support areas) of at least category II, at day 35. All patients were included in the analysis..
- **Statistical hypothesis :** demonstrate that 7% of patients develop a pressure sore (stage II) in the predominant areas between D0 and D35.

Results

- **ACTIVE** shows **no appearance of stage 2 or more pressure ulcers** in the sacral, heel, trochanter or dorsal area between D0 and D35, **i.e. an incidence of 0%** with a confidence interval of 95% according to the method exact Clopper-Pearson [0% ; 4,1%].
- In combination with the usual measures to prevent PU, the results of our study showed a **low incidence of PU in high-risk patients lying** for between 15 and 20 hours a day on an APMO, use of which is therefore recommended in these patients.
- AXTAIR AUTOMORPHO PLUS has **an interest in the therapeutic strategy** related to the management of patients with a medium to high risk of developing a pressure ulcer. Because of its action, this device has **an interest for public health** given the disability and the deterioration of life caused by the appearance of pressure ulcers.

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Population

■ DEMOGRAPHIC CHARACTERISTICS

- Gender **57,3%** of male
- **Middle Age** : **73,1** +/- 20,5 years old
- **Average BMI** : **25,3** +/- 6,2 kg/m²

■ COMORBIDITIES

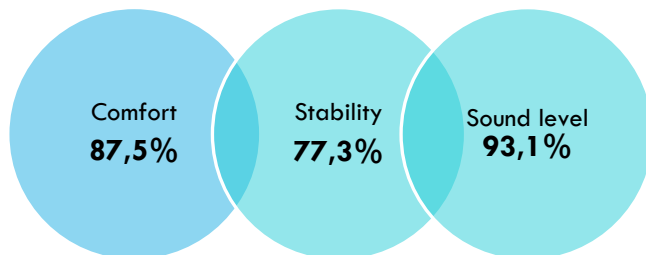
- Urinary **Incontinence** **85,4%** and/or anal **68,5%**
- Artériel Hypertension **53,9%**
- Diabetes **19,1%**
- Arteriopathy of the lower limbs **5,6%**
- Others **38%** (at least 1 other co-morbid condition)

Satisfaction

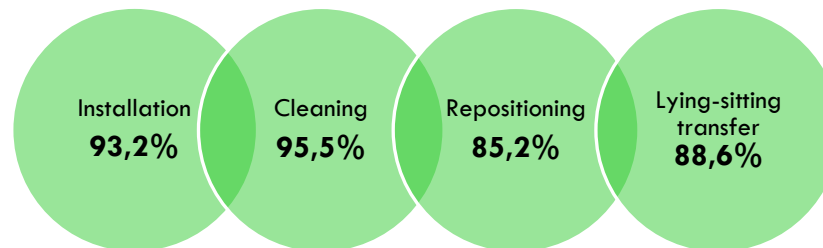
■ CRITERES SECONDAIRES

A stage I sacral ulcer occurring 9 days after installation in an 85-year-old woman with dementia, urinary and anal incontinence, Braden score of 10, bedridden 15 hours per day. Worsening of his general condition reported. The stage I pressure ulcer still present at D32.

Satisfaction of patient



Satisfaction of caregivers



■ CHARACTERISTICS RISK OF PUs

Neurological pathology responsible for the pressure ulcer risk situation in **49.4%** of cases

- Average **bed rest** **16,6** +/- 1,8 hour per day
- **Braden score** **12,8** +/- 1,6
- Mobility criterion : Immobile **38,2%** to very limited **50,6%**
- Activity criterion : Bed rest **12,3%** to Confinement to the (wheel)chair **70,8%**
- Sensory perception : Completely limited **16,9%** to very limited **37,1%**

■ PATHOLOGIES RESPONSIBLE FOR THE SITUATION AT RISK OF PUs

- Neurological : **49,4%**
- Accidental : **28,1%**
- Plurifactorial : **28,1%**
- Others : **22,5%**

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Care

■ POSITIONS USED IN BED

- Lying down **34,8%**
- Bust raised **53,9%**
- Right lateral decubitus **43,8%**
- Left lateral decubitus **44,9%**
- Number of repositioning **5,2** (+/- 1,4) par 24 h
- Maximum time between 2 changes **4,0** (+/- 1,2)
- Number of sheets changes **1,0** per 24 h

■ ARM(WHEEL)CHAIR POSITIONS

- Patients equipped with a PU prevention cushion : 77,5%
- Catégorie 1 (gel/foam) **14,9%**
 - Catégorie 2 (viscoelastic) **49,3%**
 - Catégorie 3 (air cells) **32,6%**

■ PHYSIOTHERAPY

- Active physiotherapy **41,6%** (end of study **45,5%**)
- Active physiotherapy **1 heure** per day (1,4)
- Passive physiotherapy **49,4%** (end of study **45,9%**)
- Passive physiotherapy **1 heure** per day (1,4)

■ HUMIDITE

- Constantly wet **20,2%** (end of study **21,4%**)
- Wet **46,1,2%** (end of study **41,4%**)