

CO.ME.T.A (CopriMed Trial Analysis) STUDY Prevention of bed ulcers in patients with disabling neurological diseases. Principal Investigator: Dr. Andrea Zuccheri - Observational study conducted by: DR. CLAUDIO BARACCHINI - NEUROSURGEON, DEPARTMENT OF NEUROLOGICAL SCIENCES I - UNIVERSITY OF PADUA, VIA GIUSTINIANI, 5 - 35128 PADUA

“Since 1 January 2009, 10 patients with disabling pathology of the central nervous system have been enrolled in the study. A quilted mattress topper with original Tibetan goose down (CopriMed Aria) was given to these patients (Group 1) at the start of the study. The control group (Group 2) consisted of 10 other patients with similar demographic and clinical characteristics; these patients continued to use the mattress at home without a mattress topper. At the end of the observation period (31.12.2009), we collected the following data from the two groups:

1. Presence of bed ulcers: This was the primary end point, so it was important to evaluate not only the presence of these lesions, but also their location and evolution.
2. Pain evaluation: using the VAS (Analogue Visual Scale), i.e., a scale that quantifies what patients subjectively perceive as pain in all its physical, psychological and spiritual aspects without distinguishing which of these components has a major role. In the case of patients unable to communicate, the evaluation was made by the caregiver, based on objective data such as pain grimaces and defensive reactions to postural change.
3. Evaluation of the family member/caregiver: finally, an evaluation of the caregiver was conducted using the CBI (caregiver burden inventory), which evaluates the care load, and Hamilton's scale aimed at excluding the presence of pathological anxiety or depression that could interfere with proper patient management and communication of study data.

Results: During the study period, none of the patients or family members/caregivers developed a psychiatric condition that required pharmacological treatment or resulted in the interruption of the study. None of the patients in Group 1 showed signs or symptoms of allergy to mattress toppers. In Group 1, no bed ulcers were detected, while in the control group two (first-degree) pressure ulcers were observed, requiring pharmacological treatment, which was effective in resolving the condition of morbidity. With regard to breathability, in the study group patients or relatives/caregivers reported a significant reduction in perspiration and skin moisture compared to the period when the mattress topper was not used. Compared to the control group, the patients in the study complained of less pain in the morning, both in the back and lower limbs, also reporting a better quality of sleep.

Discussion: In this study we observed that proper information and education of patients, relatives and caregivers contributed to the overall reduction of bed

ulcers in both patient groups (0% in Group 1, 20% in Group 2) compared to the prevalence reported in the literature (30%). In particular, in the group of patients using the mattress topper, no pressure ulcer was observed; on the contrary, a significant reduction in pain and an improvement in sleep quality were observed. Finally, it is important to note that no patient showed any allergy to the device.

Conclusions: Bed ulcers are the indicator of a patient's poor clinical condition and often represent the failure of the rehabilitation programme. As part of a proper health education, devices such as the CopriMed mattress topper ensure safety and help in preventing bed ulcers by reducing pressure and friction and increasing breathability. Finally, pain reduction and improvement of sleep quality were significant, resulting in the overall improvement of the perceived quality of life of these severely disabled patients.”