ISPOR Europe 2018 | 10-14 November 2018 | Barcelona - Spain

# PRESSURE INJURIES IN PATIENTS WITH URINARY INCONTINENCE: EFFICACY OF REGENERA, A NEW MEDICAL DEVICE TESTED AT THE OSPEDALE MAGGIORE IN NOVARA

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## Background

Urinary incontinence is a common and distressing problem, which affects around 4.5 million persons in Italy (Table 1) and may have a large impact on quality of life. It is often connected with superficial pressure injuries of stage I and II. The prevention and management of these superficial lesions is a big issue for healthcare organizations both in terms of resource consumption and available devices.
The development of new devices to prevent and treat the superficial injuries can represent an innovative strategy to tackle this problem.

*Table 1. Prevalence of Urinary Incontinence (UI) in Italy[1]*

| Age | UI Prevalence | Population with UI |
|---|---|---|
| 18 – 34 | 4,2% | 461.584 |
| 35 – 54 | 7,8% | 1.446.929 |
| 55 – 70 | 9,8% | 1.175.657 |
| Età >70 | 15,3% | 1.395.444 |
| **Total** | | **4.479.614** |

## Introduction

The aim of this study was to evaluate the efficacy of Regenera®, a medicated absorbent pad containing ozonised solution, in patients with urinary incontinence and pressure injuries (superficial lesions, stage 1 and 2).
Regenera® is a class A medical device with CE certification.

## Methods

A randomized, controlled, 1:1 parallel-arms clinical trial supported by Santex spa (Milan, Italy) was performed enrolling patients with urinary incontinence and superficial pressure injuries (PIs), hospitalized at the Internal Medicine Unit of Ospedale Maggiore in Novara, during the period December 2016-December 2017.
The primary endpoint was the recovery rate per treatment group within 10 days from the hospitalization date. A subanalysis for different ranges in the length of hospital stay was also performed.

## Results

124 patients were enrolled (Table 2). 63 randomly assigned to the Regenera® arm and 61 to the standard protocol arm (mean age 82,2).

*Table 2. Regenera® vs. standard protocol arm by duration of hospitalization.*

| HOSPITALIZATION STAY | REGENERA® | STANDARD PROTOCOL | TOTAL |
|---|---|---|---|
| Total Patients | 63 (100%) | 61 (100%) | 124 (100%) |
| 1-4 DAYS | 20 (32%) | 13 (21%) | 33 (27%) |
| 5-9 DAYS | 28 (44%) | 29 (48%) | 57 (46%) |
| >10 DAYS | 15 (24%) | 19 (31%) | 34 (27%) |

Patients treated with Regenera® showed a significantly higher recovery rate compared to the control arm: 56% vs 30% patients respectively (Table 3).

*Table 3. Regenera® vs. standard protocol arm by recovery rate.*

| | REGENERA® | STANDARD PROTOCOL | Delta |
|---|---|---|---|
| Recovered | 35 (56%) | 18 (30%) | +26% |
| Stable | 25 (40%) | 37 (61%) | -21% |
| Worsened | 3 (4%) | 6 (9%) | -5% |
| TOTAL | 63 (100%) | 61 (100%) | |

In the subanalysis by range (1-4 days, 5-9 days and > 10 days) of hospital stay, the recovery rate in the Regenera® group compared to control arm was 40% vs 0% in 1-4 days range, 57% vs 34% in 5-9 days range, 73% vs 42% in >10 days range (Table 4).
Regarding the overall duration of the hospitalizations, no significant differences between the two arms were observed.

*Table 4. Regenera® vs. standard protocol arm subanalysis by range of hospital stay.*

| HOSPITALIZATION STAY | REGENERA® (n=63) | STANDARD PROTOCOL (n=61) | Delta |
|---|---|---|---|
| 1-4 days (n) | 20 | 13 | 33 |
| *Recovered* | **8 (40%)** | **0 (0%)** | **+40%** |
| *Stable* | 11 (55%) | 11 (85%) | -30% |
| *Worsened* | 1 (5%) | 2 (15%) | -10%) |
| 5-9 days (n) | 28 | 29 | 57 |
| *Recovered* | **16 (57%)** | **10 (35%)** | **+22%** |
| *Stable* | 10 (36%) | 16 (55%) | -19% |
| *Worsened* | 2 (7%) | 3 (10%) | -3% |
| >10 days (n) | 15 | 19 | 34 |
| *Recovered* | **11 (73%)** | **8 (42%)** | **+31%** |
| *Stable* | 4 (27%) | 10 (53%) | -26% |
| *Worsened* | 0 (0%) | 1 (5%) | -5% |

## Conclusions

Despite the limit of this study, the analysis conducted has showed that innovative devices such as Regenera® may play an important role in the management of the fragile elderly population, often affected by superficial pressure injures in case of hospitalization. Further analysis is needed to assess implications for patient in terms of quality of life and potential economic impact from the NHS perspective.

**References**

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**POSTER CODE: PMD21**

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