

Original Research Article

A pilot study to assess the efficacy of VCare predict in early detection of pressure ulcer

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ABSTRACT

Background: The aim of the study to evaluate the efficiency of 'VCare' predict for early diagnosis of pressure ulcers/bedsores/pressure injury are a type of injury that breaks down the skin and underlying tissue leading to reddening of the skin to severe, deep craters with exposed muscle or bone necrosis. A pilot study was carried out to assess and compare efficacy of VCare predict and standard of care (SOC) in prediction of pressure ulcer among the high-risk patients being hospitalized.

Methods: The 30 female or male subjects aged >60 years were selected with inform consent and enrolled in the study. The efficiency of VCare predict was evaluated by comparison of arm A (VCare predict) and arm B SOC. The sensor patch is placed under sacrum for 30 seconds. It captures key parameters and transfer to the mobile app thru blue-tooth. Mobile app receives measured data, and it shows the risk level of the patient (Red, Yellow and Green) to recommend the frequency of flip to predict the early diagnosis of severity of pressure ulcer.

Results: The study results exemplified that efficiency of VCare predict which is more efficiently (with 31.4% lesser flips in Arm A) predict pressure injury leading to further complications.

Conclusions: This study was concluded that VCare predict can be a highly effective risk assessment and mitigation tool in pressure ulcer management. With VCare predict, there was no adverse event found or experienced, hence it is a safer tool to use.

Keywords: VCare predict, Pressure ulcer, Early detection of pressure ulcer

INTRODUCTION

Pressure ulcers, decubitus ulcers, bedsores, or pressure sores, range in severity from reddening of the skin to severe, deep craters with exposed muscle or bone. It significantly threatened the well-being of patients with reduced mobility. Though 70 percent of ulcers occur in persons older than 65 years, 1 younger patient with neurologic impairment or severe illness are also susceptible. Prevalence rates range from 4.7 to 32.1 percent in hospital settings and from 8.5 to 22 percent in nursing homes.¹ Pressure ulcer is a result of unrelieved pressure to the skin due to localized injury or underlying tissue usually over a bony prominence. The predisposing

factors are broadly classified into intrinsic (e.g., limited mobility, poor nutrition, comorbidities, aging skin) and extrinsic factors (e.g., pressure, friction, shear, moisture). The most common anatomical sites for pressure ulcers to occur are the sacrum and the heels, and the majority are grade 1 or grade 2 in severity.²

Patients admitted to hospital or those confined to bed, chair, or wheelchair are at risk for the development of pressure ulcers. Pressure ulcers pose a major burden for health care in western countries.³ Although many studies reported the prevalence to be higher in older patients, children are also at risk, and the prevalence of pressure ulcers in the paediatric population was also relatively

high (about 27%).⁴ The occurrence of pressure ulcers in hospitalized patients has clinical, emotional, and psychological implications. Studies have highlighted that patient with pressure ulcers have grieving issues, psycho spiritual concerns, relationship problems and social isolation.^{5,6} In addition, pressure ulcers may add to the total cost of patient management and be an important economic burden.⁷

Pressure ulcers are a significant financial burden to healthcare systems. According to a recent systematic review noted that the cost for prevention of pressure ulcers was lower than that for treatment, with the cost of pressure ulcer prevention per patient per day varying between 2.65€ to 87.57€ across all clinical settings.⁸ According to the WHO's annual world health statistic report 2010 Japan, Italy and Germany have the highest proportion (29%, 26% and 26%) of persons over 60 years of age in their populations, ranking slightly higher than Sweden, Bulgaria and Greece (all 24%) and far ahead of the U.S., China and India (18%, 12% and 7%,) respectively).⁹ In the Netherlands more than 1% of the total budget for health care is spent on prevention and treatment of pressure ulcers or prolonged hospital stay once a pressure ulcer develops.¹⁰ Pressure ulcers are often related to poor prevention or care and they significantly diminish the quality of life of persons affected, prolong the need for care and when hospitalized, prolong their duration of stay, incurring additional costs to the health care systems.¹¹

Each year, >2.5 million people in the United States and >3 million people in Europe develop pressure ulcers.¹² Pressure ulcers are associated with longer hospital stays and increased morbidity and mortality.¹³ They also remain a serious problem in nursing homes despite regulatory and market approaches to encourage prevention and treatment. Growing incidences of pressure ulcers, particularly among the rapidly growing, high-risk geriatric population, will significantly drive the global pressure relief device market.

In terms of mortality, 60,000 people in the US and 29,000 people in the UK die every year due to pressure ulcers. In 2012-2013, Australia spent an estimated A\$983 million in treatment costs representing approximately 1.9% of all public hospital expenditure or 0.6% of the public recurrent health expenditure. The opportunity cost was valued at an additional A\$ 820 million for the same period. These estimates were associated with a total number of 121,645 pressure ulcer cases in 2012-2013 and a total number of 524,661 bed days lost which expected to reach at least <250,000 cases by 2022. There are more than 650 million wheelchair bound people that are developing pressure ulcers in the spin and heel areas.^{14,15}

The cost burden of the treatment of pressure ulcers is also significantly high, which thereby leads to the demand for pressure ulcer management and prevention products such as pressure relief devices. Technological innovation

regarding the development of advanced products by companies such as Beta MedTech, have the potential to improve value-based healthcare by improving patient outcomes and dramatically reducing costs.

Agency for healthcare research and quality stated that every year the US is spending >US\$ 11 billion, the EU is spending >US\$ 10 billion, Australia is spending >US\$ 1.5 billion and the rest of world is spending >US\$ 10 billion on pressure ulcer related prevention, treatments, claims etc. However, the market of pressure relief devices is expected to grow to US\$ 11 billion by 2030. The growth in the market size allows more players to enter the market without impacting the bottom line of the current players. However, customers are looking for an effective, preventive tool to show the indications at earliest stage.

It has also been suggested that the length of hospital stay is significantly different between patients with and without pressure ulcers (median seven days (mean 11.1±15) compared to median three days (mean 4.6±6.8), respectively).¹⁶ The prevention of pressure ulcer which can reduce the incidence rate and will have a positive impact on patients. Early prediction/diagnosis and the severity determination will save the patients from further complications. Hence there is an immediate need of diagnostic tool for the same. The main objective of this study was to evaluate the accuracy and efficiency of VCare pressure ulcer diagnostic tool compare to the normal standard of care.

METHODS

Study design and patient selection

A pilot clinical trial was conducted on 30 patients, males or females aged >60 years which was screened from 35 subjects with Inform consent and enrolled in the study. Randomized clinical trial subjects were randomized in a 1:1 ratio to one of two arms. Randomization will be regulated by an envelope system.

These subjects who fulfil the inclusion/exclusion criteria This does-not have any impact on subjects' safety. The study was carried out in Medstar specialty hospital, Bangalore. The study was conducted on 10th December 2020 for 15 days.

The inclusion criteria were male and female patients aged >60 years at the time of consent, no existing wound(s)/ existing pressure ulcers at the time of consent, patients with a Braden scale score between <9 (severe risk) or 10-12 (high risk) or 13-14 (moderate risk) or 15-18 (mild risk) within 5 days of admission, patients who understand and are willing to participate in the clinical study and can comply with clinical trial protocol requirements.

The exclusion criteria were patients with presence of pressure ulcer(s)/ open or closed wounds at the time of consent, having skin erythema or any other skin

condition, any other co-morbidities /medical illness, unwilling to provide written informed consent on systemic steroids within 2 weeks prior to study and patients on statins, Presence of any condition(s) mental/physical) which seriously compromises the participant’s ability to take part this study and not willing to follow study procedures.

Pre-treatment evaluation

Volunteers were screened in order to provide 30 evaluable subjects, after taking written informed consent from volunteers, the following study screening procedures were done: Demographic data, including name, sex, date of birth, age, height, weight and BMI-medical / surgical history.

Assessment

After all baseline assessments, patients will be subjected to treatment arm A (VCare predict assessment) for pressure ulcer prediction once daily for 15 days consecutively or treatment arm B SOC repositioning as per clinical judgement for pressure ulcer management, as per randomization schedule.

Treatment arm A (VCare predict assessment) was evaluated with parameters of red, yellow and green.

Table 1: Gradation by risk level in patient.

Gradation by risk level in patient		
1	Red	Flip X hrs. once**
2	Yellow	Flip X +1 hrs once*
3	Green	Flip X +2 hrs once*

*Skip 1 mid night flip. **Skip 2 mid night flips

Study close-out

Post preliminary assessment 30 subjects were selected to take part in the study and their assessment outcomes were captured in the Patient data sheet for the treatment arm A (VCare predict assessment) and treatment arm B SOC.

Changes in the conduct of study or planned analyses

No changes were made in the conduct of the study or planned analyses.

Statistical analysis

The experimental subjects were compared by two-way analysis of variance (ANOVA) combined with Tukey's multiple comparison test $*\leq 0.05$ is compared to standard arm.

RESULTS

The present study was conducted on 15 patients with VCare predicts (Arm A) in comparison with 15 patients

of comparator SOC for pressure ulcers (Arm B). The results had shown the significant superiority in preventing the occurrence of pressure ulcer with zero subjects reported with pressure ulcer in arm A compare to arm B with 5 subjects developed pressure ulcer (33% of total population). VCare predict shows 33% better efficiency compare to standard of care with highly significant in reducing the number of flips by 31.4% lesser flips in arm A compare to arm B (Figure 1-3).

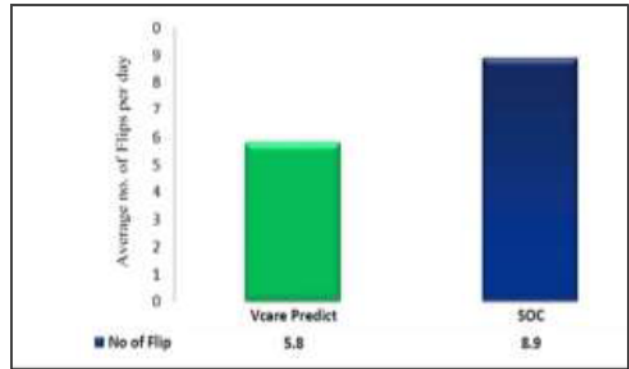


Figure 1: Flip count comparison arm a (VCare Predict) vs arm B (SOC).

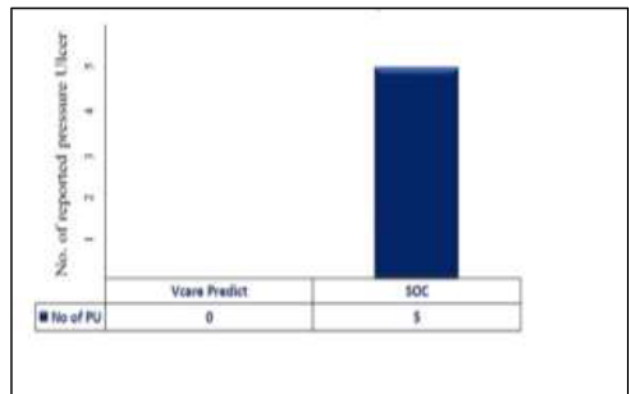


Figure 2: Pressure ulcer comparison arm A (VCare predict) vs arm B (SOC).

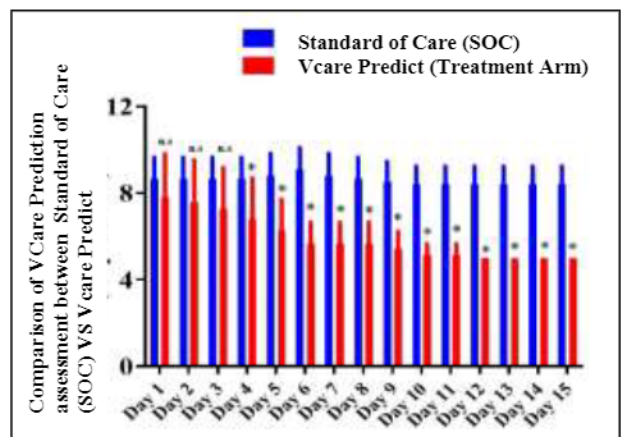


Figure 3: Comparison of Vcare prediction assessment arm A vs arm B (SOC).

DISCUSSION

Many preventive intervention opportunities exist, such as the use of prophylactic multi-layer dressing, using alternative pressure mattress and visco-elastic polymer pad (gel pad) on the operating table during surgery, patients' and caregivers' education on nutrition and skin care, frequent repositioning, and the use of positioning wedges.¹⁷

Although many of these interventions had clinically demonstrated benefits for preventing PUs or accelerating the healing of PUs, some are costly or burdensome. Therefore, to avoid excessive cost and burden, we need to be able to identify cases of high risk and apply appropriate levels of prevention according to need.

The study results indicated that VCare predict pressure evaluator provided the best balance between sensitivity and specificity.

This pressure evaluator may be better suited for assessing the risk of pressure ulcers in intensive care units and it was corroborated with Fazila et al. However, the efficacy was studied in large population. Since the pressure ulcers are also associated with comorbidities such as disrupt tissue perfusion, including diabetes, hypertension, and non-specific cardiac issues, will be included in the future studies. VCare predict will also be validated in other clinical settings and compare with the performance of other pressure ulcer prediction tool. Although the prediction accuracy of the present study (33%) was lesser than the Delmore and colleagues who were able to correctly identify 74% of their validation sample using their regression model, which included: vascular disease, diabetes, malnutrition, surgery, mechanical ventilation and perfusion issues, this VCare predict was found to be more efficient PU prediction using flip counts.¹⁸

Limitations

Our data from single site and studied less number of patients. More dataset/study population is required to get accurate prediction of VCare predict. Inclusion of more features may result in collinearity issues. To ignore the collinearity issues the variance inflation could be predicted.

CONCLUSION

Based on the outcome of the study it can be concluded that VCare predict can play a significant role in preventing occurrence of pressure ulcer in patients at high to mild risk of developing pressure ulcer. VCare predict can be an efficient tool (33% better than standard of care) in reducing the requirements of care taker's close motoring and related cost by accurately suggesting the frequency of flips needed. Hence, it can be concluded that VCare predict can be a highly effective risk assessment and mitigation tool in pressure ulcer management. With

VCare predict, there was no adverse event found or experienced, hence it is very safer tool to be used for pressure ulcer prediction.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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