

TurnCare

Guardian

Optimizing Protection and Management of Critically Ill, Mechanically Ventilated COVID-19 Patients Using the TurnCare Guardian System



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Introduction

The outbreak of the COVID-19 pandemic and the resulting stress imposed on Hospitals has forced clinicians to rethink the way they care for patients. Several key priorities have emerged:

1. Stretch the scope and capacity of interdisciplinary care teams to optimize the number of patients the staff can care for at any point in time with the limited resources available
2. Maximize patient safety and positive outcomes by identifying the highest impact measures that minimize patient harm and adverse events with less manual intervention
3. Optimize isolation procedures and protocols by evaluating best practices to handle high volumes of contagious frequently unstable patients while minimizing the risk of transmission to both caregivers and other patients.

Given the scale and resource demands of the pandemic, these objectives have proved difficult to execute. In particular, as described in a recent position paper from the National Pressure Injury Advisory Panel (NPIAP) entitled Unavoidable Pressure Injury during COVID-19 Pandemic:

“In the context of the critically ill COVID-19 patient, there is a greater potential of being unable to safely turn the patient due to the profound hypoxia and/or hemodynamic instability. Turning critically ill patients from side-to-side is within the standard of care when it can be done without causing harm to the patient. For example, in certain situations it is not only challenging but sometimes not possible to reach an angle allowing adequate reperfusion of skin and soft tissue while maintaining adequate oxygenation, hemodynamic status and a safe airway for patients. For the COVID-19 patient with acute respiratory distress syndrome, prone positioning is often used for many hours and/or days and “turning” is limited to micro-shifts and changing the position of the head, arms and upper body according to “swimmer position” protocols.”

The paper goes on to state: “despite reasonable attempts made to incorporate prevention strategies into the critically ill COVID-19 patient’s care, the COVID-19 crisis rendered some of them impossible to achieve and pressure injury formation was unavoidable.”

Described herein is a single center’s experience with the TurnCare Guardian System as an intervention for optimizing the protection and management of critically ill, primarily mechanically ventilated, COVID-19 patients to prevent the formation of hospital acquired pressure injuries (HAPIs) in the sacral region.

The Guardian System: Therapy and Application

The TurnCare Guardian System is a portable, reusable patient support system that utilizes unique Vasotactic technology to prevent vascular compromise in the Sacral Region. The system consists of

- a) anatomically specific inflatable support surfaces (called “Enhancers”) that are designed to provide support specific to the geometry and location of the patient’s bony prominences and
- b) a high-precision computerized air pump (the “Controller”) that delivers an adaptive, proprietary, non-repeating, multi-step pressurized air support algorithm.

The unique capability of the Guardian System is its ability to support mobility compromised patients for long periods of time on existing hospital beds, recliners, wheelchairs, and procedure tables, in prone, supine, seated and upright positions, all while mitigating impeded blood flow. The challenge with ventilated COVID-19 patients is that they can go for extended periods of time without turning yet need to be weaned as quickly as is feasible. Clinicians need a support system that is both effective and flexible, delivering effective protection for these patients in whatever position and on whatever surface is required to optimize the patient’s care. The Guardian System’s capabilities with regard to the surfaces and patient positions it supports enables it to help staff facilitate the transitioning and mobilization of patients, allowing clinicians the flexibility to choose the positions and durations that are most beneficial for the patient’s care protocol.



The Guardian System for Ventilated, Critically Ill COVID-19 Patients

To meet the rising clinical demand during the COVID-19 pandemic, the Guardian system was utilized as a widespread intervention throughout multiple existing and newly constructed COVID-19 Intensive Care Units (ICUs) on increased numbers of highly contagious critically ill ventilated patients. Guardian Systems were both pre-deployed on ICU beds and placed on patients as soon as possible in COVID-19 units; allowing for immediate pressure injury prevention therapy upon admission, reducing clinical effort, risk, and care team exposure.

Protecting Unstable Patients Who are Difficult to Turn or Unable to be Turned

Often, the COVID-19 patient is difficult to turn or unable to be turned, as turning would lead to severe hypoxia, hemodynamic instability, and risk of further desaturation or cardiac arrest evolving into multi-system organ failure. Additionally, in severe cases, as a result of a profound systemic inflammatory response, COVID-19 patients often require hemodialysis (HD) or continuous veno-veno hemofiltration (CVVH). Routine repositioning of critically ill patients on renal replacement therapy is often contraindicated due to fear of large bore cannula dislodgement and bleeding. These patients are at high risk for PI formation due to hemodynamic instability requiring vasopressors, combined with pharmacologic paralytics, sedative and pain management therapy, and sub-optimal repositioning.

Further, CVVH therapy is typically much longer than standard three to four-hour HD runs, resulting in an even higher risk of PIs. This particular patient cohort is reminiscent of the “no turn” extracorporeal membrane oxygenation therapy (ECMO) patient population, wherein turning is not possible due to risk of large bore arterial and venous cannula dislodgement. With these patient conditions, PI formation is likely and often expected to occur.

The Guardian System was utilized as a PI mitigation strategy for these COVID-19 patients who were either unable to be turned or difficult to turn due to risk of life-threatening desaturation or during hemodialysis. In previous use, there have been multiple anecdotal reports of success of the Guardian System in preventing PIs in individual patients who were difficult or unable to be turned. During the first few months of the COVID-19 pandemic, a group of several hundred similar, critically ill, mechanically ventilated, minimally and “no turn” patients have been supported on the Guardian System. To date, in this patient population, there has been no significant rise in sacral region hospital-acquired PI rates (HAPI). These HAPI rates had already been declining with use of the Guardian System.

Protecting Patients During Periods of Prolonged Prone Positioning

Many COVID-19 patients with severe Acute Respiratory Distress Syndrome (ARDS) require prone positioning to improve oxygenation, reduce ventilator-associated lung injury, and to improve mortality. To prone and then supinate the mechanically ventilated patient allows for recruitment of less compromised, non-dependent portions of the lung fields, improving oxygen delivery and pulmonary secretion drainage. As an intervention for COVID-19, prone positioning is recommended for 12-hour periods of time. While in the prone position, the anterior superior iliac spines (ASIS) are the most

prominent bony structure to be at risk for PIs. For example, PIs of the ASIS are frequently seen in long duration spine surgeries performed with the patient in the prone position. During the COVID-19 pandemic, the Guardian System has been used with an unprecedented number of patients in prone positions up to 12, sometimes 24 hours at a time, without any reported PIs to the ASIS.

Protecting Patients During Extended Turning Intervals

The opening of new ICUs and expansion of ICU beds occurred as large numbers of critically ill patients were admitted. Tiered staffing models, repurposing of staff and space, and utilization of time and resources through prioritization demanded reassessment. Clinicians from the interdisciplinary team truly were in the middle of unprecedented times, facing challenges never seen. Due to the criticality of patients, assessing risk versus benefit, and being resource challenged, clinicians had to prioritize, focusing on lifesaving procedures and medication administration. Typically, turning schedules occur on an every 2 hour basis; however, with conditions in the COVID-19 crisis, maintaining this standard has proven difficult to achieve. In the case of this single center example, the Guardian System was provided to all ventilated ICU patients, including those with COVID-19 as well as other critical conditions, as a preventative therapy. Despite the unavoidable reduction in turning frequency, an increase in PI incidence has not been observed in this high-risk patient population.



Conclusion

Even though standard turning schedules were challenged secondary to patient acuity, high ICU census, as well as staffing resource challenges, the Guardian System showed benefits in preventing skin breakdown in complex, critically ill COVID-19 isolation patients. The additional time not required, or prevented due to instability, for patient turning was allocated towards prioritizing more critical lifesaving tasks. Most notable was time focused on management of the most critical cases requiring triage for invasive procedures or intubations, ultimately freeing up clinicians to practice to the full extent of their licensure. It was remarked that despite not being able to perform routine turning, knowing their patients' skin was protected and seen to remain healthy and intact while on the Guardian System was encouraging to staff.

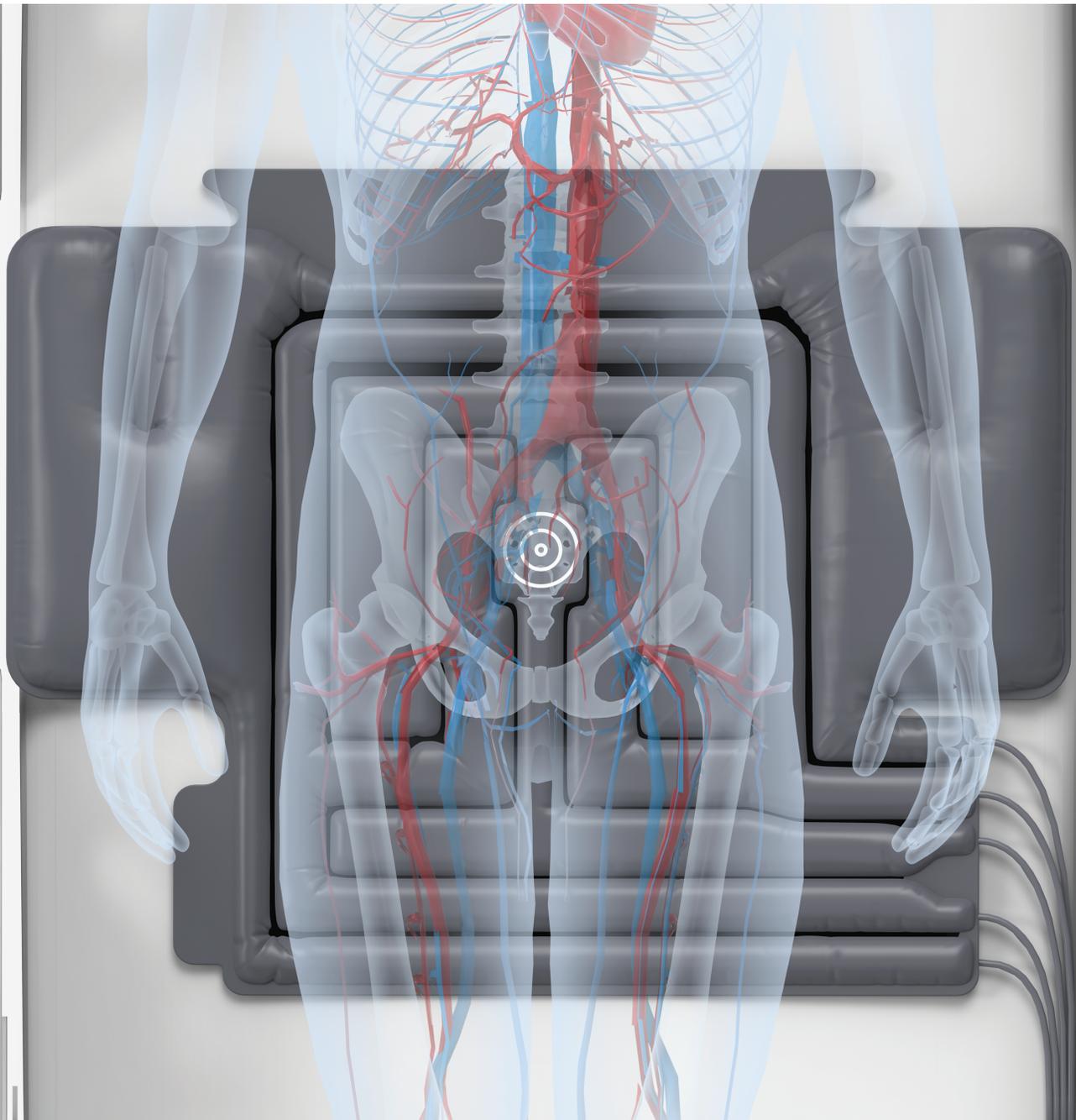
Additionally, it has been widely reported that personal protective equipment (PPE), primarily N95 masks as well as gloves and eye protection, were in short supply. The Guardian System could be used to conserve supplies and protect the staff by minimizing the number of times required to enter the COVID-19 patient treatment isolation rooms. Depending on the BMI and clinical condition of each COVID-19 patient, typical turning teams can involve as many as two to three additional staff with the primary caregiver. Deployment of the Guardian System would likely reduce the amount of PPE required by minimizing the frequency and number of staff members required to enter negative pressure isolation rooms. Conjointly, this approach could reduce the risk of staff exposure to the virus.

The COVID-19 pandemic is the first time a large group of similar critically ill, mechanically ventilated, "no turn" and difficult to turn patients were supported on the Guardian System, paving the way for future randomized control trials. By maintaining consistent protection and management throughout the era of COVID-19, the Guardian System has effective potential in supporting the repurposing of staff for critical care, maximizing patient and staff safety, and minimizing transmission risk to caregivers and other patients.

About Turncare

TurnCare is a medical systems company that works to improve outcomes for high risk patients and increase patient care flexibility for clinicians. Founded by Dr. Rafael Squitieri, a Cardiothoracic surgeon and Kim Orumchian, a technology entrepreneur, TurnCare's unique Vasotactic support technology is designed to prevent sacral-region vascular compromise and mitigate the harmful effects of I/R injury while offering clinicians more options to support clinical workflows.

To learn more please visit the TurnCare website at [TurnCare.com](https://turncare.com) or contact TurnCare by phone or email at (203) 437-6768 or info@turncare.com.



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