

Acquisition of new medical devices among the persistently critically ill

A retrospective cohort study in the Veterans Affairs

Elizabeth M. Viglianti, MD, MPH, MSc^{a,b,*} , Erin F. Carlton, MD, MSc^{c,d}, Joanne McPeake, PhD^{e,f}, Xiao Qing Wang MPH^a, Sarah Seelye, PhD^b, Theodore J. Iwashyna, MD, PhD^{a,b,g}

Abstract

Patients who develop persistent critical illness remain in the ICU predominately because they develop new late-onset organ failure(s), which may render them at risk of acquiring a new medical device. The epidemiology and short-term outcomes of patients with persistent critical illness who acquire a new medical device are unknown.

We retrospectively studied a cohort admitted to the Veterans Affairs (VA) ICUs from 2014 to 2019. Persistent critical illness was defined as an ICU length of stay of at least 14 days. Receipt of new devices was defined as acquisition of a new tracheostomy, feeding tube (including gastrostomy and jejunostomy tubes), implantable cardiac device, or ostomy. Logistic regression models were fit to identify patient factors associated with the acquisition of each new medical device. Among hospitalized survivors, 90-day posthospitalization discharge location and mortality were identified.

From 2014 to 2019, there were 13,184 ICU hospitalizations in the VA which developed persistent critical illness. In total, 30.4% of patients (N = 3998/13,184) acquired at least 1 medical device during their persistent critical illness period. Patients with an initial higher severity of illness and prolonged hospital stay preICU admission had higher odds of acquiring each medical device. Among patients who survived their hospitalization, discharge location and mortality did not significantly differ among those who acquired a new medical device as compared to those who did not.

Less than one-third of patients with persistent critical illness acquire a new medical device and no significant difference in short-term outcomes was identified. Future work is needed to understand if the acquisition of new medical devices is contributing to the development of persistent critical illness.

Abbreviations: aOR = Adjusted odds ratio, CI = Confidence interval, CPT = Current procedural terminology, ICD 9/10 = International classification of diseases ninth and tenth revisions, ICU = Intensive care unit, IQR = Interquartile range, LOS = Length of stay, SD = Standard deviation, VA = Veteran Affairs

Keywords: gastrointestinal tubes, implantable cardiac devices, medical devices, outcomes, ostomy, persistent critical illness, prolonged ICU stay, tracheostomy

1. Introduction

The study of patients with prolonged intensive care unit (ICU) stays has often been narrowed to focus on patients receiving prolonged mechanical ventilation, operationalized by receipt of tracheostomies and feeding tubes.^[1,2] More recent work has suggested that the persistently critically ill remain in the ICU for a

range of reasons other than persistent hypercarbia, placing them at increased risk of developing late organ failures and consequently acquiring other new medical devices.^[3–6]

Recent work has shown that gastrostomy tube placements have more than doubled over the past 20 years in the critically ill and the incidence of tracheostomy placement has also increased in patients.^[7,8] However, the extent to which other new

Funding: This work was supported by the following National Institute of Health grants NHLBI K12HL138039 (TJJ), K23HL157364 (EMV), NCATS KL2TR002241 (EFC), and VA IIR 17-045 (TJJ).

The authors of this work have no conflict of interest to disclose.

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

Disclaimer: This work does not necessarily represent the views of the U.S. Government or Department of Veterans Affairs. No authors have no competing interests to disclose.

Supplemental Digital Content is available for this article.

^a Department of Internal Medicine Division of Pulmonary and Critical Care, University of Michigan, Ann Arbor, MI, USA, ^b Veterans Affairs Center for Clinical Management Research, HSR&D Center for Innovation, Ann Arbor, MI, USA, ^c Department of Pediatrics Division of Pediatric Critical Care, University of Michigan, Ann Arbor, MI, USA, ^d Susan B. Meister Child Health Evaluation and Research Center, Department of Pediatrics, University of Michigan, Ann Arbor, MI, USA, ^e University of Glasgow, School of Medicine, Dentistry and Nursing, Scotland, UK,

^f NHS Greater Glasgow and Clyde, Glasgow Royal Infirmary, Intensive Care Unit, Scotland, UK, ^g Institute for Social Research, Ann Arbor, MI, USA.

*Correspondence: Elizabeth M. Viglianti, University of Michigan, 2800 Plymouth Road NCRC building 16 016-370, Ann Arbor, MI 48109, USA (e-mail: eviglian@med.umich.edu).

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How to cite this article: Viglianti EM, Carlton EF, McPeake J, Wang XQ, Seelye S, Iwashyna TJ. Acquisition of new medical devices among the persistently critically ill: A retrospective cohort study in the Veterans Affairs. *Medicine* 2022;101:27(e29821).

Received: 20 December 2021 / Received in final form: 20 May 2022 / Accepted: 31 May 2022

<http://dx.doi.org/10.1097/MD.00000000000029821>

medical devices are acquired among the persistently critically ill remains unknown. Outcomes of such device-acquisition are also not known. Data have suggested dismal postdevice mortality in some populations, including ICU patients,^[9] leading to questions about the appropriateness of device placements in some populations.^[10-12]

In light of this gap, we sought to understand among the persistently critically ill, how many acquire new medical devices beyond tracheostomies and feeding tubes, are there patient characteristics associated with receipt of new medical devices, and are there differences in 90-day mortality and healthcare facility use among those who acquire a new medical device as compared to those who do not.

2. Methods

2.1. Study population

We studied all patients admitted to the ICU from the Veterans Affairs Patient Database (VAPD) 2014-2019, prior to the COVID-19 pandemic.^[13,14] Analyses were approved by the IRB of the VA Ann Arbor Health System (IRB-2016-357). STROBE guidelines were followed.

We abstracted data from the VAPD for all patients admitted to the ICU from 2014 to 2019 and used 2013 as a look-back year to identify patients with preexisting neuromuscular

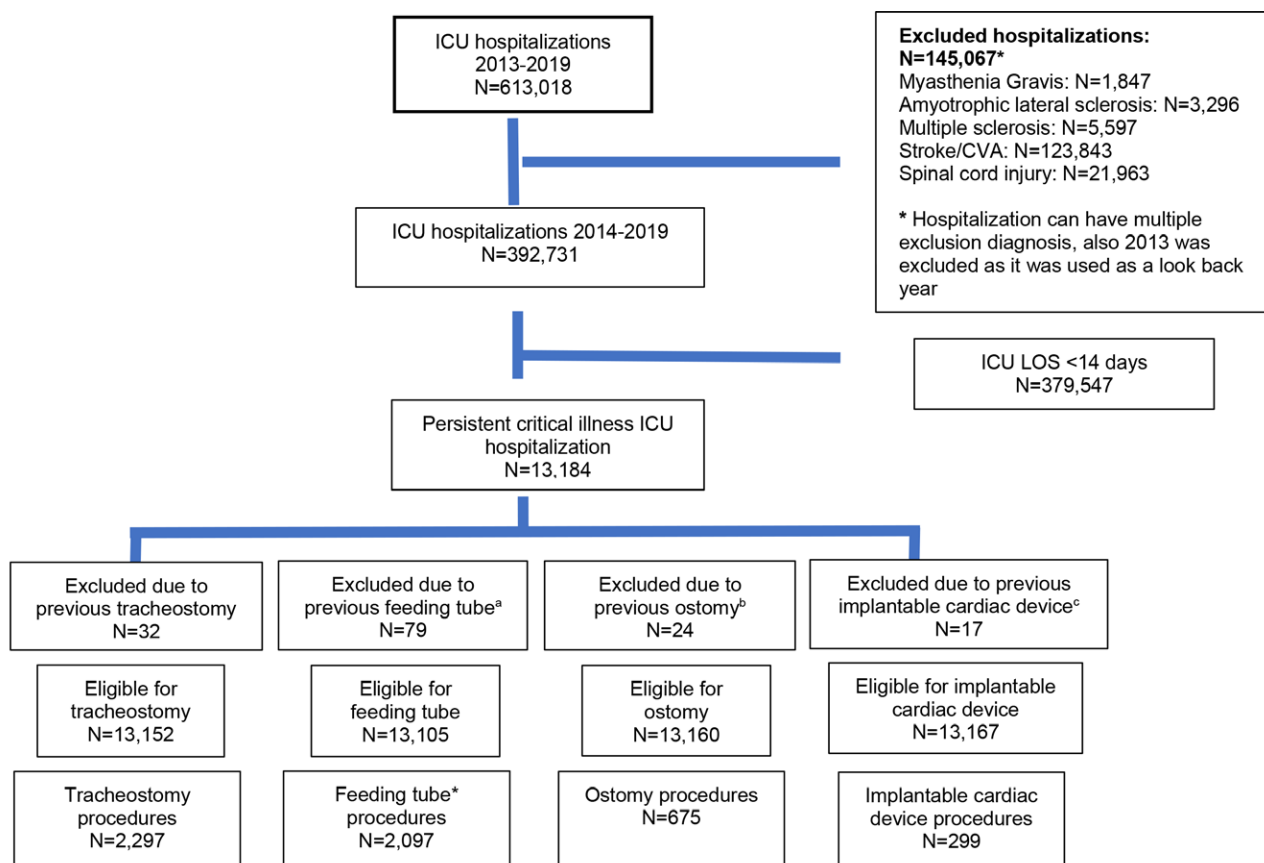
diseases. We excluded patients with preexisting neuromuscular diseases which inherently would contribute to prolonged recoveries, and patients with preexisting device placements.

2.2. Identification of persistent critical illness

We defined persistent critical illness as a minimum of 14 consecutive ICU days as previously done based on data specific to this institutional setting and population.^[4,15,16]

2.3. Identification of medical device acquisition

We used international classification of diseases ninth (ICD-9) and international classification of diseases tenth revisions (ICD-10) procedure codes, and current procedural terminology (CPT) codes to identify medical device acquisition. Specifically, we measured new tracheostomy, gastrostomy/jejunostomy tube, implantable cardiac devices (pacemakers and implantable cardioverter-defibrillators), and ostomy acquisition. (See Table, Supplemental digital content, <http://links.lww.com/MD/G856>) Patients with preexisting medical devices were also excluded. For example, patients with a prior ICD-9, ICD-10, or CPT codes of tracheostomy placement were excluded from the assessment of a new tracheostomy placement but could acquire new gastrostomy tube placement resulting in different denominators for each medical device.



^a Includes percutaneous and surgical gastrostomy/jejunostomy feeding devices

^b Includes ileostomy, cecostomy, colostomy

^c Implantable cardiac device includes cardiac pacemakers and defibrillators

Figure 1. Flow chart.

Table 1
Demographics of the ICU hospitalizations in the VA from 2014 to 2019.

Variable	Persistent critical illness	Any new medical device
Variable	N = 13,184	N = 3998
Age (yr) median (IQR)	68 (62, 73)	68 (62, 73)
Race		
White: N (%)	9159 (69.5)	2857 (71.5)
African American: N (%)	3115 (23.6)	843 (21.1)
Other: N (%)	910 (6.90)	298 (7.5)
Male: N (%)	12,748 (96.7)	3859 (96.5)
Elixhauser: median (IQR)	14 (7, 21)	14 (7, 22)
VA ICU severity score: median (IQR)	0.07 (0.03, 0.17)	0.08 (0.03, 0.18)
ICU length of stay (d): median (IQR)	19 (15, 26)	25 (18, 37)
Hospital length of stay: (d) median (IQR)	28 (20, 41)	38 (26, 57)
In-hospital mortality: N (%)	3171 (24.05)	833 (20.8)

ICU = intensive care unit, IQR = interquartile range, VA = Veterans Administration.

2.4. Healthcare facility use

Among hospital survivors, we used the VAPD to identify discharge location and duration.^[14] Patients who were alive and not known to be admitted to a healthcare facility were assumed to be at home.^[17]

2.5. VA severity score

For internal risk adjustment, the VAPD uses an illness severity score which predicts 30-day mortality based on several variables (age, admission diagnosis category, 30 comorbid conditions, and 11 laboratory values) which we calculated on ICU day of admission.^[18]

2.6. Analysis

We present patient characteristics as counts (percentages), means ± standard deviations, or medians (interquartile ranges [IQRs]) as appropriate. Elixhauser comorbidities were combined using the method described by van Walraven.^[19] We used 2-sided significance testing and considered *P* < 0.05 to be significant.

We fit logistic regression models to identify patient characteristics (age, gender, race, comorbidities) associated with acquisition of each new medical device, adjusting for severity of illness, type of ICU, and hospital length of stay (LOS) preICU admission.

Among hospital survivors, we measured 90-day postdischarge mortality and healthcare facility utilization. All code is available at GitHub. (https://github.com/CCMRcodes/PERCI_MedicalDevices-.git)

3. Results

From 2014-2019, there were 13,184 ICU hospitalizations in the VA which developed persistent critical illness (Fig. 1). The median age of patients was 68 (IQR: 62,73), and patients were predominately white men with median ICU LOS of 19 days (IQR 15, 26) and an in-hospital mortality of 24% (Table 1).

In total, 30.4% of patients (N=3998/13,184) acquired at least 1 medical device during their persistent critical illness period. The most frequently acquired devices were tracheostomies (17.5%; N = 2297/13,152) and feeding tubes (16.0%; N = 2097/13,105) with 8.5% (N = 1015/13,079) receiving both. Other acquired medical devices included ostomies (5.1%; N = 675/13,160) and implantable cardiac devices (2.3%; N = 299/13,167).

Patients with a higher severity of illness and prolonged hospital stay preICU admission had higher odds of acquiring each medical device. (Table 2) Older patients were more likely to acquire feeding tubes and implantable cardiac devices (Adjusted odds ratio [aOR]: 1.01, 95% CI: 1.00–1.01 and 1.02, 95% CI: 1.01–1.03 respectively), but patients with more comorbidities were more likely to acquire implantable cardiac devices (aOR: 1.02, 95% CI: 1.01–1.03). (Table 2)

Among patients who survived their hospitalization, discharge location and mortality did not differ among those who acquired a new medical device as compared to those who did not. (Fig. 2) For example, the majority of patients who acquired a new tracheostomy were discharged home and remained home—similar to patients who did not acquire a new tracheostomy.

4. Discussion

In this national cohort of persistently critically ill patients, nearly 1 in 3 acquired a new medical device during their ICU hospitalization with only 17% acquiring a tracheostomy, and 16% a feeding tube. Patients with a higher severity of illness and prolonged preICU admission hospital stay had higher odds of acquiring each medical device. However, older patients and patients with more comorbidities were less likely to acquire a tracheostomy. Acquisition of a new medical device was not

Table 2
Association of patient-level characteristics comparing patients who received each medical device as compared to those who did not.

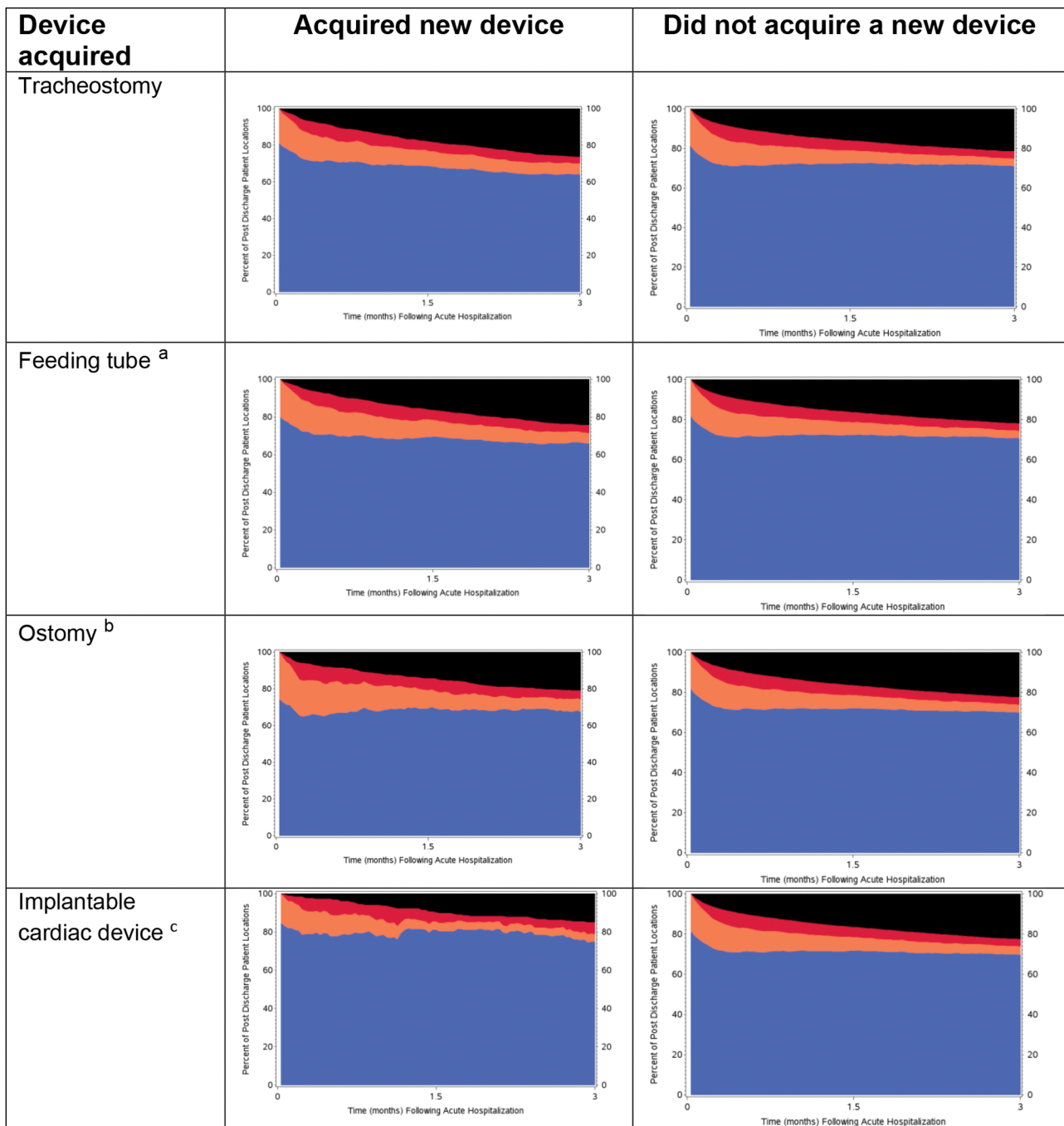
Variable	Medical devices acquired											
	Tracheostomy			Feeding tube*			Implantable cardiac device†			Ostomy‡		
	aOR	95% CI	P value	aOR	95%CI	P value	aOR	95%CI	P value	aOR	95%CI	P value
Age (yr)	0.99	0.99–1.00	<0.01	1.01	1.00–1.01	0.04	1.02	1.01–1.03	<0.01	1.01	1.00–1.02	0.08
Female (vs Male)	1.06	0.82–1.35	0.67	0.98	0.75–1.29	0.89	0.61	0.25–1.50	0.29	1.62	1.07–2.47	0.03
Race (vs White)												
Black	0.89	0.79–0.99	0.03	0.83	0.74–0.94	<0.01	0.91	0.68–1.20	0.49	0.88	0.72–1.09	0.24
Unknown	1.10	0.89–1.37	0.36	1.01	0.80–1.26	0.96	1.10	0.61–2.00	0.75	1.05	0.72–1.54	0.80
Other	1.06	0.80–1.41	0.68	1.11	0.83–1.49	0.48	1.55	0.85–2.84	0.15	1.02	0.59–1.76	0.95
Elixhauser (per Walraven point)	1.00	1.00–1.01	0.19	1.00	1.00–1.01	0.08	1.05	1.03–1.06	<0.01	0.98	0.97–0.99	<0.01
VA risk score (per percent)	1.52	1.11–2.09	0.01	1.87	1.35–2.60	<0.01	0.01	0.00–0.05	<0.01	3.76	2.03–6.97	<0.01
Hospital LOS prior to ICU admission (per day)	1.01	1.01–1.02	<0.01	1.01	1.01–1.02	<0.01	1.01	1.00–1.01	0.04	1.01	1.00–1.01	<0.01
ICU type (vs medical)												
Surgical	1.01	0.91–1.11	0.93	1.42	1.28–1.57	<0.01	2.03	1.57–2.63	<0.01	11.97	9.60–14.92	<0.01
Cardiac	0.09	0.05–0.18	<0.01	0.11	0.06–0.22	<0.01	5.64	3.92–8.11	<0.01	0.19	0.03–1.40	0.10

aOR = Adjusted odd ratio, CI = Confidence interval, VA = Veterans Administration, LOS = Length of stay, ICU = Intensive care unit.

*Includes gastrostomy/jejunostomy feeding devices.

†Includes ileostomy, cecostomy, colostomy.

‡Includes implantable cardiac pacemakers and cardiac defibrillators.



^a Includes percutaneous and surgical gastrostomy/jejunostomy feeding devices;

^b Includes ileostomy, cecostomy, colostomy

^c Includes cardiac pacemakers and defibrillators

Figure 2. Healthcare facility use and mortality 90-days after discharge among survivors by subgroups. Patients are depicted as being at home (blue), admitted to a non-acute facility (orange), admitted to a hospital (red), or dead (black).

associated with higher 90-day postdischarge healthcare facility use or mortality.

4.1. Relationship to previous studies

Historically, prolonged ICU stays were thought to be synonymous with prolonged mechanical ventilation, which was operationalized by the need for tracheostomy.^[1,20] Recent work has challenged this definition and has found that the persistently critically ill often acquire other new late onset organ failures beyond respiratory failure.^[2-4,6,21] Our work validates and

expands our knowledge by evaluating the epidemiology of the persistently critically ill beyond tracheostomies and feeding tubes. Our work also infers that defining the persistently critically ill by any medical device is likely to miss a significant proportion of patients.

Multiple single center studies have demonstrated that patient characteristics on ICU admission cannot reliably identify who will develop persistent critical illness.^[3,5,6,22] However recent work has found that frailty is associated with the development of persistent critical illness and subsequent mortality.^[23] Additionally frailty has been associated with increased ICU

organ support.^[24] Our work found that patients with higher severity of illness on ICU admission and prolonged hospitalization prior to ICU admission had a higher odds of acquiring each medical device which may add support that frailty is contributing to device acquisition.

Significant morbidity, mortality, and hospital utilization has been reported for patients with prolonged ICU stays.^[1,25,26] Interestingly, our work found that new medical device acquisition was not associated with higher 90-day postdischarge healthcare facility use or mortality as compared to patients with similarly long initial stays but who did not acquire a new medical device. In this way, our results appear quite different from those reported by Law et al who found that among a fee-for-service Medicare ICU cohort who acquired a new tracheostomy, gastrostomy or both, over half the cohort died within 180 days of the procedure.^[9] Notably, the patient populations are not identical even in the different systems, as Law et al presents work on all ICU patients, not just those with persistent critical illness.^[9] Yet, these differences between VA and Medicare data raise an urgent question about the extent to which the short-term outcomes for the persistently critically ill who acquire new medical devices may not have worse outcomes, or the extent to which such worse outcomes are driven by differences in patient-selection, postdischarge quality of care, or other modifiable factors.

There are several limitations to our study. First, we used a cohort of Veterans who are disproportionately white men and may not be representative of other cohorts in other health systems. Second, we could not account for patient's code status or limitations of care which may impact the acquisition of medical devices. Third, we do not know timing of device acquisition within the ICU hospitalization. Fourth, we cannot account for treatment costs.

5. Conclusions

Less than one-third of patients with persistent critical illness acquire a new medical device and no significant difference in short-term outcomes was identified. Future work is needed to understand if the acquisition of new medical devices is contributing to the development of persistent critical illness.

Author contributions

E.M.V designed the study, performed the statistical analyses, interpreted the results, compiled the manuscript. E.F.C. provided critical revisions for the manuscript. J.M.P provided critical revisions of the manuscript. X.Q.W. performed the statistical analyses and provided critical revisions. S.S. provided critical revisions. T.J.I. refined the statistical analysis and provided critical revisions of the manuscript.

References

- [1] Nelson JE, Cox CE, Hope AA, et al. Chronic critical illness. *Am J Respir Crit Care Med.* 2010;182:446–54.
- [2] Viglianti EM, Kruser JM, Iwashyna T. The heterogeneity of prolonged ICU hospitalisations. *Thorax.* 2019;74:1015–7.
- [3] Viglianti EM, Kramer R, Admon AJ, et al. Late organ failures in patients with prolonged intensive care unit stays. *J Crit Care.* 2018;46:55–7.
- [4] Viglianti EM, Bagshaw SM, Bellomo R, et al. Late vasopressor administration in ICU patients: A retrospective cohort study. *Chest.* 2020;158:571–578.
- [5] Darvall JN, Boonstra T, Norman J, et al. Persistent critical illness: baseline characteristics, intensive care course, and cause of death. *Crit Care Resusc.* 2019;21:110–8.
- [6] Jeffcote T, Foong M, Gold G, et al. Patient characteristics, ICU-specific supports, complications, and outcomes of persistent critical illness. *J Crit Care.* 2019;54:250–5.
- [7] Law AC, Stevens JP, Walkey AJ. Gastrostomy tube use in the critically ill, 1994–2014. *Ann Am Thorac Soc.* 2019;16:724–30.
- [8] Cox CE, Carson SS, Holmes GM, et al. Increase in tracheostomy for prolonged mechanical ventilation in North Carolina, 1993–2002. *Crit Care Med.* 2004;32:2219–26.
- [9] Law AC, Stevens JP, Choi E, et al. Days out of institution after tracheostomy and gastrostomy placement in critically ill older adults. *Ann Am Thorac Soc.* 2022;19:424–32.
- [10] Choosing wisely campaign. Feeding tubes for people with Alzheimer's. *Choosing Wisely.* Accessed: 5/2022. Available at: [https://www.choosing-wisely.org/patient-resources/feeding-tubes-for-people-with-alzheimers/]
- [11] Finucane TE, Christmas C, Travis K. Tube feeding in patients with advanced dementia: a review of the evidence. *JAMA.* 1999;282:1365–70.
- [12] Clinical P; American Geriatrics Society Ethics C, Models of Care C. American Geriatrics Society feeding tubes in advanced dementia position statement. *J Am Geriatr Soc.* 2014;62:1590–3.
- [13] Fihn SD, Francis J, Clancy C, et al. Insights from advanced analytics at the Veterans Health Administration. *Health Aff (Millwood).* 2014;33:1203–11.
- [14] Wang XQ, Vincent BM, Wiitala WL, et al. Veterans Affairs patient database (VAPD 2014–2017): building nationwide granular data for clinical discovery. *BMC Med Res Methodol.* 2019;19:94.
- [15] Iwashyna TJ, Hodgson CL, Pilcher D, et al. Timing of onset and burden of persistent critical illness in Australia and New Zealand: a retrospective, population-based, observational study. *Lancet Respir Med.* 2016;4:566–73.
- [16] Bagshaw SM, Stelfox HT, Iwashyna TJ, et al. Timing of onset of persistent critical illness: a multi-centre retrospective cohort study. *Intensive Care Med.* 2018;44:2134–44.
- [17] DeMerle KM, Vincent BM, Iwashyna TJ, et al. Increased healthcare facility use in veterans surviving sepsis hospitalization. *J Crit Care.* 2017;42:59–64.
- [18] Render ML, Deddens J, Freyberg R, et al. Veterans Affairs intensive care unit risk adjustment model: validation, updating, recalibration. *Crit Care Med.* 2008;36:1031–42.
- [19] van Walraven C, Austin PC, Jennings A, et al. A modification of the Elixhauser comorbidity measures into a point system for hospital death using administrative data. *Med Care.* 2009;47:626–33.
- [20] Carson SS, Bach PB. The epidemiology and costs of chronic critical illness. *Crit Care Clin.* 2002;18:461–76.
- [21] Iwashyna TJ, Hodgson CL, Pilcher D, et al. Towards defining persistent critical illness and other varieties of chronic critical illness. *Crit Care Resusc.* 2015;17:215–8.
- [22] Viglianti EM, Zajic P, Iwashyna TJ, et al. Neither vitamin D levels nor supplementation are associated with the development of persistent critical illness: a retrospective cohort analysis. *Crit Care Resusc.* 2019;21:39–44.
- [23] Darvall JN, Bellomo R, Bailey M, et al. Impact of frailty on persistent critical illness: a population-based cohort study. *Intensive Care Med.* 2022;48:343–51.
- [24] Zampieri FG, Iwashyna TJ, Viglianti EM, et al. Association of frailty with short-term outcomes, organ support and resource use in critically ill patients. *Intensive Care Med.* 2018;44:1512–20.
- [25] Nelson JE, Meier DE, Litke A, et al. The symptom burden of chronic critical illness. *Crit Care Med.* 2004;32:1527–34.
- [26] Iwashyna TJ, Viglianti EM. Patient and population-level approaches to persistent critical illness and prolonged intensive care unit stays. *Crit Care Clin.* 2018;34:493–500.