**Supplemental Table 35. Characteristics of Studies used to answer the following descriptive question: “For adult critically ill patients, is receiving rehabilitation/mobilization performed either in-bed or out-of-bed commonly associated with patient-related safety-events or harm?”**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Author, Yr | Study Type | Total n  (n/group if applicable) | No. of physical rehabilitation/mobilization Sessions | Potential Safety Events | | | | | No. of events  requiring management | Comments |
| **Respiratory** | **Cardiovascular System** | **Neuro** | **MSK** | **Lines** |
| Observational Studies | | | | | | | | | | |
| Stiller 2004 [1] | Prospective Observational | 31 | 69 sessions; functional activities | 17 : SpO2 fall <4%  7: SpO2 fall >4%  26: SpO2 increase | 13: HR drop  52: Increased HR  19: DBP decreased <20 mmHg  1: SBP decreased >20  39:SDBP increased  3: DBP decreased >10  10: DBP decreased <10  45: DBP increased | Not reported | Not reported | Not reported | 3: SpO2 dropped to <88% requiring increase in FiO2 | Increase in FiO2 resolved desaturation without stooping. Mobilization occurred a mean of 29 days after ICU admission (range 1-71 days) |
| Zanni 2010 [2] | Prospective Observational | 32 enrolled;  19 received PT/OT | 50 sessions; functional activities | Number not recorded for changes of -2% to +1%  0 SpO2 < 85% for > 3 min  0 unplanned extubations | Not recorded  Average HR changed 6 bpm, range 2-10  Average SBP change was 3mmHg, range -4 to +13 | 0 loss of consciousness | 0 falls | 0 devices (arterial, venous hemodialysis, urinary catheters, feeding tubes and chest tube or other/rectal tube) | 0 |  |
| Kho 2012 [3] | Case series | 22 | 42 video game treatments | 0 | 0 | 0 | 0 falls | 0 | 0 |  |
| Berney 2012 [4] | Cohort study | I =74  C= 72 (standard care) | I = 641 sessions  Not reported for standard care | 0 | 0 | 0 | 0 | 0 | 0 | “No adverse event occurred in the ICU”  First day of exercise was a mean of 7 days after ICU admission (range 5-11) |
| Titsworth 2012 [5] | Observational | 170  I=93 PUMP plus protocol  C=77  Usual care | Not reported | Not reported | Not reported | Not reported | Reported as incidence:  Falls: I=1.31  C= 1.39  per 1000 patient days | Reported as incidence of critical line pulls (arterial, endotracheal or extraventricular drains)  I=0.67  C=0.90  per 1,000 patient days | 0 | Serious adverse events reported as “none.”  Hospital acquired infections (UTI, VAP and CLABSI) decreased in the intervention group although only the decrease in VAP achieved significance |
| Damluji 2013 [6] | Prospective cohort | I = 101 patients received PT.  C = 138 patients | I= 253 sessions  of functional activities, A/P ROM, and supine cycle ergomety  C= 0 PT sessions | Not reported | Not reported | Not reported | Not reported | 0 events with femoral catheters | 0 | Only reported on adverse events related to femoral lines; None of the 6 potential femoral catheter-related adverse events occurred |
| Sricharoenchai 2014 [7] | Prospective Observational | 1110 patients received PT | 5267 sessions | 0: extubation (ETT or Trach)  4: Sp02<85 >3mins | 10: arrhythmias  8: MAP>140  5: MAP<55 | Not reported | 2: assisted Fall  1: injurious Fall | 4 devices including  1 radial arterial catheter; 2 OG feeding tube; 1 chest tube and 0 Venous/dialysis/pheresis catheters | 1 fall resulted in supraorbital laceration requiring debridement and suture. | (Most…) “events resolved quickly …and never required any additional therapy, cost, or LOS.” |
| Balas 2014 [8] | Prospective cohort (pre-post) | 296 received rehab;  Pre=146 (prior to ABCDE bundle)  Post=150 experienced ABCDE bundle | Pre 70/146 mobilized out of bed  Post  99/150 mobilized out of bed | Unplanned extubation  Pre= 7  Post = 7 | Not reported | Number of patients who underwent imaging due to change in mental status:  Pre 21;  Post 17 | Not reported | Not reported | 3 Number of unplanned extubations required re-intubation:  1-Pre;  2-Post. | The percent of ICU time in restraints: PRE 12.7%; POST 6.9% |
| Lee 2015 [9] | Prospective Observational | 99 received early rehabilitation include functional activities, A/P ROM and EMS | 520 | 6 desaturations  11 events with respiratory distress  1 tracheostomy removal | 4 events with bradycardia < 40bpm or tachypnea | Not reported | 0 Falls | 0 | Not determined | Trach removal did not require management  4 sessions occurred with “patient intolerance”(i.e., patient request to stop, legs trembling, or diaphoresis) |
| Skinner 2009 [10] | Observation | 12  Exercise training protocol | 50 | 0 Sp02 fall > 10% below resting level or SP02 <85%  0 tachypnea >35 breaths/min | 0; Sustained HR <50 or >140, or new arrhythmia; hypotension/HTN | Not reported | 0 falls | Not reported | 0 | 0 pale, sweaty or distressed appearance |
| Trials | | | | | | | | | | |
| Burtin 2009 [11] | RCT | 58  I=26  Passive or active bedside ergometer  C=32  Usual care including A/P ROM | 425 cycling | 16 desaturations to <90  0 Respiratory distress leading to intolerable dyspnea | 0 malignant arrhythmia  6 SBP>180  2 DBP reducing >20%  0 new chest pain onset | Not reported | 1 Achilles tendon rupture | Not reported | 1 Achilles tendon rupture | Outcomes of Achilles tendon not reported but assumed to need an intervention |
| Schweickert 2009 [12]  Pohlman 2010 [13] | RCT; Safety data were reported in Pohlman (Other data Schweickert) | 104  I=49  PT/OT beginning day 1 of ICU  C=55  Usual care | 498 sessions in the intervention group | 31 desaturation; 20 asynchrony/tachypnea  0 extubations | 21 HR increase > 20% | 10 Agitation /Discomfort | 0 falls | 4 devices inadvertently removed | 1 desaturation <80% | Adverse events occurred during 16% of all sessions (80/498) but unclear if or how many events required an intervention. 4% of sessions were stopped earlier as a result of patient instability (usually patient-ventilator asynchrony)  Time to PT/OT intervention:  I = 1.5 days  C = 7.4 days |
| Meesen  2010 [14] | Trial | 21  I =11  EMS of quadriceps  C=10  No EMS | Not reported | 0 changes in RR  0 changes in Sp02 | 0 events for HR 0 events for SBP or DBP changes | 0 | Not reported | Not reported | 0 | Adverse events reported as “Nil”.  All patients were sedated |
| Hanekom 2013 [15] | Pragmatic block controlled trial (quasi RCT) | 193 enrolled  I=96  Research PTs provided protocolized care  C=97  Usual PT care | 615 research sessions  193 “usual care” sessions | Not reported | 2 hemodynamic instability | Not reported | 1 fall | 2 devices: dislodged peripheral catheters | Not determined | 6/1000 =0.006 adverse events occurred across all sessions in the intervention group but it is not clear if any adverse events led to management. Most events occurred during a respiratory (e.g. manual hyperventilation, positioning for postural drainage or during percussion/vibration) not mobility session. |
| Brummel 2014 [16] | Trial | 65  I: protocolized physical therapy or physical and cognitive therapy. | 543 | Hypoxia reported, number of events not provided | 1: hypertensive urgency  Tachycardia reported, number of events not provided | Not reported | 1 back pain | 0 | 1 hypertensive urgency concurrent with back pain. (Intervention implied, not reported) | Serious event did not preclude participation in subsequent study interventions |
| Dong 2014 [17] | RCT | I = 30  Functional activities up to two times daily  C = 30  Information about control activities not reported. | Not reported |  | 1 orthostatic hypotensive event in intervention |  |  |  | 0 serious adverse events |  |
| Hodgson  2016 [18] | RCT | I=29  Early goal-directed PT  C=21  Usual care | Not reported | 0 ETT removal | 0 cardiac arrest  Hypotension;  I = 0  C= 2 | New agitation:  I =1  C =2 | 0 falls | Not reported | 0 |  |
| Moss 2016 [19] | RCT | 120 enrolled  I =59  Intensive therapy  C = 61  “usual care” | Calculated from mean number of sessions/patient while in ICU:  I = 378 sessions  C = 232 sessions | Not reported but see comments | Not reported but see comments | Not reported | Not reported | Not reported | 2:  1 syncopal episode during a PT session  1 readmit with polyarthralgia requiring pain management | Reported 13% had vital sign changes during interventions but unclear if changes in HR, SBP, RR, or SpO2 |
| Morris 2016 [20] | RCT | C=300  I=150  Rehab and A/PROM delivered three times daily and 7 days/week  C=150  “usual care” with delivery 5 days/week | I: sessions 3x/day for median of 8 days; calculated as 3600 sessions  C: not reported as average or total sessions | Not reported | Not reported | Not reported | 0 falls | 0 | 8 events were categorized as serious (7) or life-threatening (1)  I = 3 3vents per estimate 3600 sessions;  C = 5 events occurred but sessions not reported | An additional 16 mild-moderate events occurred; there were no statistical differences in the rate of adverse event occurrence.  I = 10  C = 6. |

**Yr:** Year; **NR**: Not Reported; **US:** United States; **n**: Number; **I:** Intervention; **C:** Control; **Neuro:** Neurological; **MSK:** Musculoskeletal; **RCT:** Randomized Controlled Trial; **SpO2**:Peripheral capillary oxygen saturation; HR: Heart Rate; **FiO2:** Fraction of Inspired Oxygen; **ETT:** Endotracheal Tube; **MAP:** Mean Arterial Pressure; **BP:** Blood Pressure; **HTN:** Hypertension; **SBP:** Systolic Blood Pressure; **DBP:** Diastolic Blood Pressure; **ICP:** Intracranial Pressure; **Cath:** Catheter; **OG:** Orogastric; **SAE**: Serious Adverse Event; **PT:** Physical therapy; **OT**: Occupational Therapy; **Functional Activities**: rolling, sitting at edge of bed, sit-to-stand, walking, grooming, and bathing; **UTI**: urinary tract infection; **VAP**: ventilator associated pneumonia; **CLABSI** central line associated blood stream infection; **A/P ROM:** Active/passive range of motion; **EMS**: neuromuscular electrical stimulation; **ABCDE** bundle; refers to a bundle of activities recommended by SCCM.

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