First Aid Interventions for Presyncope

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Citation

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Methodological Preamble and Link to Published Systematic Review

The continuous evidence evaluation process for the production of the Consensus on Science and Treatment Recommendations (CoSTR) commenced with a systematic review of non-pharmacologic interventions for presyncope (Jensen 2018, PROSPERO CRD42018107726) conducted by Jan Jensen, Dalhousie University Halifax Canada, together with the involvement of the clinical content experts appointed by the First Aid and Pediatric ILCOR Task Forces. Evidence from adult and pediatric literature was sought and then considered in detail by the First Aid and Pediatric Task Forces. A second search of the scientific literature was performed following completion of the systematic review on November 23, 2018 and no additional studies were identified for inclusion.

Two randomized controlled trials and six observational studies were included in the systematic review. All of the included trials and studies examined the effect of the use of various physical counter-pressure maneuvers on outcomes related to presyncope of vasovagal (VVS) or orthostatic etiology. A physical counter-pressure maneuver (PCM) is a movement in which the individual contracts the muscles of the legs, arms, abdomen or neck, for example, leg tensing, crossing,

squatting, hand-gripping, or contracting abdominal muscles. PCMs are postulated to work through vascular compartment compression, causing an increase in systemic vascular resistance, resulting in a rise in blood pressure and subsequent abortion of or improvement in the acute symptoms of presyncope of vasovagal or orthostatic etiology.

The age range of the study participants was 15 -75 years. A sub-group analysis for children compared with adults was not possible. However, a sub-group analysis was performed for vasovagal compared with orthostatic etiology.

One included study (Brignole 2002, 2053) consisted of three unique phases that are identified separately throughout the Consensus on Science. This included a randomized control cross-over study conducted in the laboratory setting, in which two sub-studies were conducted. The first was in patients with vasovagal presyncope using a handgrip PCM compared with placebo. The second involved healthy volunteers using a handgrip PCM compared with an arm-tensing PCM. An observational follow-up study of vasovagal etiology presyncope patients made up the third phase. Each phase was treated as a separate study during this systematic review in terms of data extraction and in the assessment of certainty of evidence.

Systematic Review

Link to come

PICOST

The PICOST (Population, Intervention, Comparator, Outcome, Study Designs and Timeframe)

Population: Adults and children with signs and symptoms of faintness or presyncope of suspected vasovagal or orthostatic origin

Intervention: interventions such as physical counter-pressure maneuvers, body positioning, hydration or other

Comparison: no intervention or each other

Outcomes:

- Abortion of Syncope
    - (high number considered beneficial)
    - (critical)
- Injuries or adverse events
    - (low number considered beneficial)
    - (critical)
- Symptom improvement
    - (high number considered beneficial)
    - (important)
- Change in heart rate
    - (increase considered beneficial for VVS)
    - (important)
- Change in systolic blood pressure
    - (increase considered beneficial)

    - (important)
- Change in diastolic blood pressure
    - (increase considered beneficial)
    - (important)

Study Designs: Randomized controlled trials (RCTs) and non-randomized studies (non-randomized controlled trials, interrupted time series, controlled before-and-after studies, cohort studies) were eligible for inclusion. Case series and unpublished studies (for example, conference abstracts, trial protocols) were excluded.

Timeframe and Languages: All years and all languages were included provided an English abstract was available.

PROSPERO Registration CRD42018107726

Consensus on Science

Physical Counter-pressure Maneuver (PCM)

I. Any type of PCM compared with Control (No use of PCM/Standing)

Abortion of Syncope

For the critical outcome of abortion of syncope, we have identified one RCT (Brignole 2002 2053), which showed **a benefit** with the use of any PCM when compared with controls (RR, 1.80; 95%CI, 1.16 to 2.79; p = 0.01; Risk Difference (RD) with PCM of 421 more patients per 1,000 had abortion of syncope (from 137 more to 468 more). The overall quality of the evidence (certainty) was rated very low due risk of bias, inconsistency, and indirectness.

For the critical outcome of abortion of syncope, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency, and indirectness) from four observational studies (Clarke 2010 1019, Krediet 2002 1684, Krediet 2008 179, Kim 2005 1084) enrolling 92 adult participants with etiology of vasovagal and orthostatic presyncope, which showed **no benefit** with the use of any PCM when compared with controls (RR, 1.31; 95%CI, 0.98-1.75; p = 0.07);RD with PCM of 184 more patients/1000 had abortion of syncope (from 12 fewer to 454 more).

For the critical outcome of abortion of syncope, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency and indirectness) from a subgroup analysis of three observational studies (Krediet 2002 1684, Krediet 2008 179, Kim 2005 1084) enrolling 64 adult patients with etiology of vasovagal syncope, which showed **no benefit** with the use of any PCM, when compared with controls (RR, 2.20; 95%CI, 0.96-5.05; p = 0.06);RD with PCM of 333 more patients/1,000 had abortion of syncope (from 11 fewer to 1000 more).

For the critical outcome of abortion of syncope, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency and indirectness) from two observational follow-up studies (Brignole 2002 2053, Croci 2004 287) enrolling 37 patients with VVS, which showed **benefit** with the use of PCM in 99.4% of episodes (349/351) (RR not estimable).

Injuries or Adverse Events

For the critical outcome of injuries or adverse events related to the use of PCM, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency, and indirectness) from two observational follow-up studies (Brignole 2002 2053, Croci 2004 287) enrolling 37 adult

participants that reported **no adverse events** or injuries related to the use of PCM (0/37).

Symptom Improvement

For the important outcome of symptom improvement, we identified one RCT (Brignole 2002 2053), which showed **no benefit** with the use of PCM when compared with controls (RR, 1.57; 95%CI, 0.98 to 2.51; p=0.06); RD with PCM of 251 more patients/1,000 had symptom improvement with PCM (from 26 more to 409 more). The overall quality of evidence was rated as very low due to risk of bias, inconsistency, and indirectness.

For the important outcome of symptom improvement, we have identified one follow-up phase RCT (Alizadeh 2016 e5348) which showed **no benefit** with the use of PCM, when compared with controls (RR, 1.57; 95%CI, 0.98 to 2.51; p=0.06); RD with PCM of 251 more patients/1,000 had symptom improvement with PCM (from 26 more to 409 more). The overall quality of the evidence was rated as very low due to risk of bias, inconsistency, and indirectness.

For the important outcome of symptom Improvement, we identified one observational study (Krediet 2002 1684) enrolling 21 adult participants with vasovagal etiology presyncope, with results favoring the use of PCM. The overall quality of evidence was rated as very low due to a very serious risk of bias due to confounding.

Heart Rate

For the important outcome of change in heart rate (HR), we have identified very low certainty evidence (downgraded for risk of bias, indirectness, and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal etiology presyncope, which showed no benefit with the use of PCM, when compared with control (MD, HR 8 beats per minute higher; 95% CI: 6.4 lower to 22.4 BPM higher; p = 0.28).

Blood Pressure

For the important outcome of change in systolic blood pressure (SBP), we have identified very low certainty evidence (downgraded for risk of bias, indirectness, and imprecision; upgraded for large effect size) from two observational studies (Krediet 2002 1684, Krediet 2008 179) enrolling 39 adult participants with vasovagal etiology presyncope, which showed **benefit** with the use of PCM, when compared with control (MD, SBP 21 mmHg higher; 95%CI, 18.25-23.41 mmHg higher; p < 0.0001).

For the important outcome of change in systolic blood pressure (SBP), we identified one RCT (Brignole 2002 2053) enrolling 19 adults with vasovagal etiology presyncope, which showed **benefit** with the use of PCM, when compared with control (MD, SBP 32 mmHg higher; 95%CI, 12.48-51.52 BPM higher; p = 0.001). The overall quality of evidence was rated as very low due to risk of bias, inconsistency, and indirectness.

For the important outcome of change in diastolic blood pressure (DBP), we have identified very low certainty evidence (downgraded for risk of bias, indirectness, and imprecision; upgraded for large effect size) from two observational studies (Krediet 2002 1684, Krediet 2008 179) enrolling 39 adult participants with vasovagal etiology presyncope, which showed **benefit** with use of PCM, when compared with control (MD, DBP 11 mmHg higher; 95%CI, 9.39 to 13.10 mmHg higher; p < 0.001).

For the important outcome of change in diastolic blood pressure (DBP), we have identified very low certainty evidence (downgraded for risk of bias, indirectness and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal etiology presyncope, which showed **benefit** with the use of PCM compared with control (MD, DBP 20 mmHg higher; 95%CI, 5.95 to 34.05 mmHg higher; p = 0.005).

II. Lower body PCM compared with Control (No use of PCM/Standing)

Abortion of Syncope

For the critical outcome of abortion of syncope, we identified one observational study (Krediet 2002 1684) enrolling 18 adult participants with vasovagal etiology presyncope. The overall quality of evidence was rated as very low due to a very serious risk of bias due to confounding.

Symptom Improvement

For the important outcome of symptom improvement, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency, indirectness and imprecision) from one RCT (Alizadeh 2016 e5348) enrolling 96 adult participants with vasovagal presyncope, which showed **benefit** with the use of Lower Body PCM, when compared with control (RR, 1.66; 95%CI, 1.02 to 2.69; p = 0.04); RD with PCM of 290 more patients/1,000 had symptom improvement with lower body PCM (from 9 more to 744 more).

Blood Pressure

For the important outcomes of SBP and DBP, we identified one observational study (Krediet 2002 1684) enrolling 18 adult participants with vasovagal etiology presyncope with results favoring the use of Lower Body PCM. The overall quality of evidence was rated as very low due to a very serious risk of bias due to confounding.

III. Upper Body PCM (handgrip or arm tensing) compared with Control (No use of PCM/Standing)

Abortion of Syncope

For the critical outcome of abortion of syncope, we identified very low certainty evidence (downgraded for risk of bias, inconsistency, indirectness and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal etiology presyncope, which showed **benefit** with the use of Upper Body PCM when compared with control (RR, 1.80; 95%CI, 1.26-2.89; p=0.001); RD with upper body PCM of 421 more patients/1,000 had abortion of syncope with lower body PCM (from 84 more to 952 more).

For the critical outcome of abortion of syncope, we identified very low certainty evidence (downgraded for risk of bias, inconsistency and indirectness) from two observational follow-up studies (Brignole 2002 2053, Croci 2004 287) enrolling 37 patients with VVS, which showed **benefit** with the use of PCM in 99.4% of episodes (349/351) (RR not estimable, no comparison group).

Symptom Improvement

For the important outcome of symptom improvement, we identified evidence of very low certainty (downgraded for risk of bias, inconsistency, indirectness and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal presyncope, which showed **benefit** with

the use of Upper Body PCM when compared with control (RR, 6.00; 95%CI, 2.21-8.61; p=0.0096); RD for upper body PCM of 526 more patients/1,000 had symptom improvement (58 more to 1000 more).

Heart Rate

For the important outcome of change in heart rate (HR), we identified very low certainty evidence (downgraded for risk of bias, inconsistency, indirectness and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal etiology presyncope, which showed **no benefit** with the use of Upper Body PCM, when compared with control (MD HR 8 beats per minute higher; 95%CI, 6.4 lower to 22.4 BPM higher; p = 0.28).

Blood Pressure

For the important outcome of change in SBP, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency, indirectness and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal etiology presyncope, which showed **benefit** with the use of upper body PCM when compared with control (MD, SBP 32 mmHg higher; 95% CI, 12.48 to 51.52 mmHg higher; p=0.036).

For the important outcome of change in DBP, we have identified very low certainty evidence (downgraded for risk of bias, inconsistency, indirectness and imprecision) from one RCT (Brignole 2002 2053) enrolling 19 adult participants with vasovagal etiology presyncope, which showed **benefit** with the use of upper body PCM when compared with control (MD, DBP 20 mmHg higher; 95% CI, 5.57-34.43 mmHg higher; p < 0.001).

IV. Lower body PCM (Squat & leg crossing) compared with Upper limb PCM (Handgrip)

Abortion of Syncope

For the critical outcome of abortion of syncope, we identified one observational study (Kim 2005 1084) enrolling 27 adult participants with vasovagal etiology syncope, with results favoring the use of lower body PCM (Squat & leg crossing) when compared with upper limb PCM (Handgrip). The overall quality of evidence was rated as very low due to inconsistency, indirectness and imprecision.

Symptom Improvement

For the important outcome of symptom improvement, we identified very low certainty evidence (downgraded for inconsistency, indirectness and imprecision) from one RCT (Alizadeh 2016 e5348) enrolling 96 adult participants with vasovagal syncope, which showed **no benefit** with the use of lower body PCM (Squat), when compared with upper limb PCM (Handgrip) (RR 0.89; 95%CI, 0.65 to 1.22; p=0.46); RD for lower body PCM of 95 more patients/1,000 had symptom improvement (from 30 fewer to 130 more).

Heart Rate

For the important outcome of change in HR, we identified one observational study (Kim 2005 1084) enrolling 27 adult participants with vasovagal syncope, with results favoring the use of lower body PCM (Leg crossing) when compared with upper limb PCM (Handgrip). The overall quality of evidence was rated as very low due to inconsistency, indirectness and imprecision.

Blood Pressure

For the important outcomes of change in SBP and DBP, we identified one observational study (Kim 2005 1084) enrolling 27 adult participants with vasovagal syncope, with results favoring the use of lower body PCM (Leg crossing) when compared with upper limb PCM (Handgrip). The overall quality of evidence was rated as very low due to inconsistency, indirectness and imprecision.

V. Lower body PCM (Squatting) compared with Abdominal PCM (Abdominal Contraction/Compression)

Blood Pressure

For the important outcome of SBP, we identified one observational study (Bouvette 1996 847) enrolling 9 adult participants with neurogenic orthostatic hypotension, with results favoring the use of lower body PCM (Squatting), when compared with abdominal PCM. The overall quality of evidence was rated as very low due to indirectness and imprecision.

VI. Lower body PCM (Squatting) compared with Neck PCM (Neck Flexion)

Blood Pressure

For the important outcome of SBP, we identified one observational study (Bouvette 1996 847) enrolling 9 adult participants with neurogenic orthostatic hypotension, with results favoring the use of lower body PCM (Squatting) when compared with neck PCM. The overall quality of evidence was rated as very low due to indirectness and imprecision.

Body Positioning and Hydration

No evidence was identified for the interventions of body positioning or hydration using the inclusion and exclusion criteria.

Treatment Recommendations

We recommend the use of any type of physical counter-pressure maneuver by individuals with acute symptoms of presyncope due to vasovagal or orthostatic causes in the first aid setting (strong recommendation, low and very low-certainty evidence).

We suggest that lower body physical counter-pressure maneuvers are preferable to upper body and abdominal physical counter-pressure maneuvers (weak recommendation, very low-certainty evidence).

Justification and EtD Highlights

- PCM is a simple, feasible, no-cost intervention that has the potential to temporize symptoms and the task force believes this intervention will be acceptable to most stakeholders.
- In considering this recommendation, the First Aid Task Force places value on avoidance of progression of presyncope symptoms to full loss of consciousness. While several included observational studies failed to show a benefit in the critical outcome of aborting syncope, one RCT showed benefit for individuals with vasovagal etiology presyncope. The same RCT and another observational study identified improvement in symptoms. Only one observational study failed to demonstrate improvement of symptoms in a follow-up phase. Furthermore, the First Aid Task Force also placed value on the lack of harm associated with the use of PCM, and no adverse events or injuries were reported for this critical outcome.
- This review only identified the management of individuals with confirmed orthostatic or

vasovagal presyncope.

- No literature was identified for alternative interventions, such as hydration or body positioning, to manage the symptoms of presyncope once they had developed. However, the First Aid Task Force discussed the potential risk of loss of postural tone should individuals with presyncope remaining standing/upright while attempting PCM. It was the consensus of the task force that individuals should be positioned lying or sitting when possible before using PCM.
- The First Aid Task Force discussed that although First Aid providers could be trained to advise individuals with acute presyncope in the use of the major types of PCM, it may be challenging to train first aid providers to identify vasovagal and orthostatic causes of presyncope.
- Included studies comprised participants who had been trained in the use of PCM after the onset of symptoms (as compared with studies that provided interventions or instructions in the use of PCM prior to the onset of symptoms), which is similar to a first aid situation. We were unable to perform subgroup analysis for age, gender or etiology (vasovagal compared with orthostatic) of presyncopal symptoms.

Knowledge Gaps

- Considering the benefit and feasibility of PCM, additional research is needed to more fully evaluate the effect and clinical outcomes of PCM in groups based on age, gender, etiology of presyncope.
- Future research should focus on the ability of first aid providers to recognize or to be trained to recognize orthostatic or vasovagal presyncope/syncope.
- Research is required on the clinical outcomes of first aid providers instructing individuals with presyncope on how to use PCM.
- Research is required to determine the effect of various body positions such as lying supine, sitting or standing in combination with PCM.
- Research is required to compare various levels of hydration with PCM for the management of presyncope.

Attachments

EtD: Should physical counter-pressure maneuvers (PCM) of any type compared with no use of PCM be used for symptoms of PRESYNCOPE? (assets/images/photos/ETD-table-for-FA-798-PRESYNCOPE_final_CEE-approved_30-Jan-2019.pdf)

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