Scale Name	**"Tilt-Table Testing" for the Evaluation of Cardiovascular Autonomic Function after Spinal Cord Injury (SCI)**

Construct	
	Explain the general construct being measured, emphasizing content in plain English. Provide the author's labels and describe the nature of items if not clear from the labels. Orthostatic stress is commonly utilised to evaluate cardiovascular autonomic function. This typically involves the passive movement from a supine to an upright position, while cardiovascular parameters are measured (e.g blood pressure and heart rate (HR). One of the most commonly used techniques for assumption of orthostatic stress is head-upright tilt table testing (TTT). This testing requires specialised equipment, (i.e., a tilt table) and trained technician/physical therapists for proper administration; however, most rehabilitation facilities are adequately equipped. The most common TTT protocol is one that incorporates an angle of upright tilt of 60-80º which is generally sustained for 30-60 minutes or until signs and/or symptoms of orthostatic intolerance ensue. Depending on the population tested, the TTT can be either a rapid transition (within seconds) or a progressive manoeuvre (5-10 minutes) from the supine to upright position. The immediate cardiovascular responses to TTT in the non-SCI population is an increase in heart rate (HR), slight fall in systolic blood pressure (BP), slight increase in diastolic BP and maintained mean arterial blood pressure (MAP). These cardiovascular responses are attained through adequate and appropriate autonomic response to the orthostatic challenge. Alterations in the response of one or both branches of the autonomic nervous system may compromise the cardiovascular response to TTT which can be defined by measuring the HR and BP response during an orthostatic challenge.
Subscales / parameters measured	The duration of the TTT is a standard criterion to define an (in)appropriate cardiovascular autonomic orthostatic responses. The development of syncope or presyncope (e.g. dizziness, nausea, light-headedness, blurry vision) or signs (e.g. yawning, sweating or pallor) is noted. A standard 3-lead ECG is typically used to assess the beat-to-beat HR response to TTT while BP is typically monitored on a beat-to-beat basis at the radial artery (Collin tonometer) or at the finger arterioles (photoplethysmography: Finometer, Portapres, Finapres). BP is also closely monitored (1-5 minute intervals) manually using sphygmomanometry at the brachial artery. Orthostatic hypotension as defined according to the American Autonomic Society and American Academy of Neurology as a decrease in SAP of ≥20mmHg and/or in DAP of ≥10mmHg, with or without symptoms, signals test termination and the subject should be returned to the supine position. Measurements of stroke volume, cardiac output and total peripheral resistance as well as measures of cerebral blood flow are often made during TTT. Non-invasive assessments of cardiovascular autonomic integrity using HR and BP variability techniques may be utilized as well as the documentation of plasma concentrations of catecholamine.

Statistics	Report relevant statistics reported, e.g. correlations among dimensions or other statistics you think are relevant or available formulas for conversion. Cardiovascular autonomic responses during TTT may be expressed as absolute values, but most often are reported as a change from the baseline and/or supine position, either expressed in absolute values (i.e., beats/minute for HR) or as a percentage change. The change from baseline is then reported compared to an expected response and in relation to the degree of the tilt and the length of time a given angle.
Administration	
Type/mode/ equipment	Describe type or mode of test, including equipment involved, nature of samples collected (if any), etc. **Procedure** *Prior to TTT in the SCI population, bladder emptying should be encouraged.* In the supine position on the tilt table the subject is instrumented with the appropriate monitoring devices. Then, several (usually 3) wide (3-5 inch) Velcro straps are secured around the individual prior to TTT. These straps should be positioned about the lower chest (just below the nipple line), across the hips and across the knees; these are general recommendations, strap placement should be modified according to the specific needs and requirements of each patient. Tightening of the straps should be just enough to secure the patient in the upright position without applying too much pressure which might stimulate other autonomic perturbations (autonomic dysreflexia). After a period of supine rest (typically 5-15min), baseline recordings are made and the subject is passively moved into an upright position usually within 3-5 seconds, although a progressive manoeuvre may be used (several minutes to attain desired angle). The degree of tilt varies depending, in part, on the population to be tested and the anticipated degree of autonomic impairment. For persons with SCI angles of tilt between 20º-80º have been reported for durations of between 5-60 minutes or until symptoms and/or signs of presyncope are evident. **Equipment/monitoring** Electronic tilt tables are most commonly used and there are many manufacturers. The surface of the tilt table is a consideration in persons with SCI; use of lambs wool or foam padding can be applied to a hard tilt table surface to reduce subject discomfort. HR, BP and autonomic measurements are typically recorded every minute throughout testing, although data may be continuously collected. In research designed protocols, cardiovascular autonomic measures are collected and viewed in real-time on a beat-to-beat basis allowing for visual assessment of the objective criteria. Real-time viewing allows for the installation of rapid counter-manoeuvres (return to the supine position within 3-5 seconds) should signs of orthostatic compromise precede symptoms, which is often the case. In addition, during TTT other cardiovascular parameters such as SV, CO and TPR can be estimated (via the beat-to-beat blood pressure waveform) or measured using several well known and established techniques (impedance cardiography, acetylene uptake, CO_2 re-breathe, venous occlusion plethysmography). The systemic sympathetic response to TTT is often characterized by measurement of the plasma catecholamine responses, although these should be performed with caution, due to the potential effects of venepuncture upon orthostatic cardiovascular control. These last techniques are most often used in research and may play a smaller part in clinical assessments of autonomic cardiovascular integrity during TTT.

	In some instances cardiac rhythm is monitored in addition to rate. This is typically performed using a standard 3 lead ECG.
Performance?	Is substantial/maximal performance by the person required – or moderate involvement vs. passive acquiescence? Subjects are monitored supine and then in the upright position. In SCI subjects, the transition from the supine to the upright posture is usually performed passively utilising an adjustable tilt table. Passive acquiescence is typically all that is required, but minimal levels of subject cooperation may be necessary e.g. with transfers to the examination table.
Language/multi-cultural issues	Record any information relevant to special language/multicultural or gender issues. This is particularly relevant if the test requires involvement or performance by the person, especially if accurate comprehension of the task is a concern. There are no specific language gender or cultural issues relating to this test, although some individuals may be less comfortable with this type of laboratory-based procedure.
Burden / risk	Inconvenience, discomfort, risks, # tests, expense, time to administer, special equipment, training required or available. The TTT required transfer from either bed or wheelchair to the tilt table which may be perceived as an inconvenience to some subjects and may require staff assistance and/or a lift system. As with any transfer there is some risk of a fall/drop of the individual, care and supervision can not be minimized. During testing there may be some discomfort associated with breathing difficulties from one or more of the following: the tilt table surface (hard surfaces are often poorly tolerated); the placement of the straps (diaphragm & rib restriction) and the angle of tilt (gravitational changes). There is the risk of syncope and presyncope with upright positioning in persons with SCI, monitoring of cardiovascular autonomic parameters should be with an eye towards the development of signs/symptoms. If blood is to be drawn during the TTT, there is minimal discomfort associated with the venapuncture. The typical TTT will take no less then 32 minutes in a persons with SCI (i.e., 10-20 minutes pre-baseline transfer and instrumentation; 5-15 minutes pre-baseline acclimation; 2-5 minutes baseline data collection; 5-60 minutes of upright tilt; 10-15 minutes recovery, removal of instrumentation and transfer.

Population Applicability	
	Describe problems/ groups and settings in which the scale has shown utility according to published sources. Has been used to assess cardiovascular autonomic control in able-bodied and SCI men and women.
Extent of Use in SCI	Extent of use in SCI: None/virtually none, A Few (e.g. 2-4), Many (e.g. 5-10), Extensive use (10 or more).. Judgmental rating for 5 year period 2000-2004. Judgmental rating. Studies not used at least 2 times should not be reviewed (unless there is no good alternative or other justification provided by the author.) TTT has been extensively reported in the SCI population (23 peer reviewed manuscripts 1981-date) for the assessment of autonomic & cardiovascular function. See attached bibliography (2, 5, 9, 10, 15, 17, 27-32, 42, 44, 51, 54, 57, 61, 63-67).
Norms	Report whether norms are available and exist for SCI, the general population, or other relevant population, and other relevant details (e.g. age/gender adjusted? With regard to level/completeness of injury?)

	The response to TTT has been reported in the healthy 'normal' population as well as in disorders of the autonomic nervous system (4, 7, 8, 11, 16, 20, 34-36, 38, 39, 43, 49, 52, 55, 59, 60). The expected 'normal' response to TTT is a slight fall in systolic blood pressure (5-10 mmHg) an increase in diastolic pressure (5-10 mmHg) maintenance or slight elevation of mean arterial pressure (MAP) and an increase in HR of 10-25 bpm. In the healthy 'normal' population sustained passive tilt for 30-60 minutes at angles of 60-80º results in the maintenance of MAP and increased HR without symptoms of cerebral hypoperfusion. The degree of autonomic impairment can be objectively quantified during TTT by measuring BP, HR and the duration of the test and subjectively by symptoms surveys and comparing these values to the expected 'normal' responses. Responses in SCI subjects may be variable, depending on the severity of injury to cardiovascular autonomic pathways (13). Certainly OH is common both in acute (3, 6, 10, 12, 14, 18, 23, 33, 40, 41, 46, 47, 58, 62, 67) and chronic SCI (3, 10, 12-14, 26, 37, 40, 56, 68), particularly in higher and autonomically more complete lesions (22, 45). Failure to increase HR or maintain blood pressure is likely to signal cardiovascular autonomic dysfunction.
Comment	*Comment on comparative use in SCI and other populations. If the measure was developed primarily in another group, comment here. If this measure was developed outside of SCI, is it promising in SCI? Comment on applicability to SCI or to subgroups in SCI.* *TTT has promise for assessment of cardiovascular autonomic integrity following SCI. It requires a tilt table and trained technician/staff; clinical parameters are obtained non-invasively, which may provide valuable information to guide clinical intervention for the improvement of cardiovascular stability in persons with SCI. Furthermore, corresponding assessments can be performed in the basic science laboratory facilitating the transmission of research and clinical findings from the bench to the bedside and vice-versa.*
Reliability / Reproducibility and Bias	
Reliability, Reproducibility	Reliability and reproducibility deal with random or erratic variation in resulting numbers. Usually we are interested in obtaining a stable number that characterizes the person. Values may vary as a function of environmental factors, instrumentation, and moment-to-moment changes in the person being assessed. Report standard error of measurement (SEM), signal to noise ratio, or other reliability statistic. Formal measures of reproducibility and reliability have not been performed in SCI individuals to date. In the non-SCI population, the reproducibility of TTT is between 35-85%, most studies report between 65-85% reproducible (35, 38).
Bias	Bias means some factor produces a systematically high or low value that is not accurate. Note reports of biasing factors (e.g. higher scores in morning, sensitive to temperature, or other factors that could bias results). Personal characteristics, environmental changes, or other factor can also influence results systematically Controlled laboratory conditions are required in order to prevent testing bias. Testing should be performed at the same time of day, in a temperature controlled environment and food is generally withheld for a period of 4-12 hours prior. Prior to testing, alcohol and caffeine should be avoided for at least 12 hours, and strenuous exercise for 24 hours. Medications that may affect autonomic control must be noted and, where appropriate, discontinued prior to

	testing. For women, repeat evaluations should be performed at the same phase of the menstrual cycle, and testing should be avoided during menstruation when menstrual cramps may give rise to autonomic dysreflexia, and thus influence cardiovascular control. In addition, it is important to avoid reflex sympathetic activation due to bladder or bowel distension, and associated autonomic dysreflexia (AD). Care should be taken to ensure the subject is comfortable and relaxed. Given that AD can be triggered by any sensory stimulus, and may even be produced by relatively mild stimuli investigators must always be vigilant for the potential influence of AD upon cardiovascular control in SCI individuals with high level lesions.
Other reliability	Use this for other reliability and bias information. (For instance, on a probabilistic rating such as ASIA Motor Scores, classical (Cronbach alpha), Rasch (item separation) or marginal reliability (2 p IRT) could be reported.) The presence or absence of muscle spasm below the level of lesion may affect cardiovascular control during upright positioning with TTT. This will relate to the level and/or completeness of injury. Also, blood draws via venapuncture increases the risk of an abnormal cardiovascular response to TTT; if necessary, blood sampling should be performed from a venous catheter inserted at least 1 hour prior.
Sensitivity to Change	TTT is frequently used to assess the degree of autonomic impairment in a growing number of clinical disorders/diseases (8, 11, 16, 19-21, 35, 39, 48-50, 53, 60, 69) including SCI (2, 3, 5, 6, 10, 12-14, 23, 28, 30, 31, 40, 47, 51, 63-67). The cardiovascular autonomic responses to the TTT can distinguish level and completeness of lesion in persons with SCI (24, 25) and dependence on other systems for blood pressure maintenance have been investigated in persons with SCI during TTT (63, 64, 66, 67).
Sensitivity	In general, higher and more complete lesions tend to score uniformly low on all tests of autonomic integrity, including TTT. That said there is no gold standard with which to compare scores on the TTT and this is a commonly used test of autonomic function in other populations.
Comment	*Is the scale insensitive to clinically significant changes? Or does it detect changes that are meaningless to most people with SCI/the problem at issue?* *TTT can distinguish between the level and completeness of SCI, its utility in determining efficacy of an intervention in this population has not been reported to date. Also, TTT has not been used to determine improvements/changes in autonomic pathways from the acute to sub-acute to chronic period of SCI.*
Validity	
Analysis Framework(s)	Physical quantity, diagnostic/screening validity (per AAN/Cochrane), conceptual development, (alternatives include Rasch, IRT, and classical frameworks but are infrequently relevant for biological/physical measures, unless they involve subjective estimation of a physical property, e.g., strength.).
Criterion-oriented validity: technical	Most measures of biological or physical constructs require validation at a technical medical/biological level; significance in terms of the person's life goes below. Report prediction with a "gold standard" or the most important technical predictive/criterion validity figure(s). AAN and Cochrane employ this if there is a gold standard; describe nature of criterion. Relevant statistics to look for include: accuracy, sensitivity, specificity, and positive (or negative) predictive value, or ROC (receiver operating characteristic). If the study involves diagnostic or predictive accuracy, please comment on whether the study employed a wide or narrow band of patients/participants and whether the population is similar to that seen in clinical practice or similar to the general population of persons with SCI. (Some authors simplify the predictive problems by excluding hard-to-diagnose patients. "Pre"-diction here should usually be of a future event, preferably a "gold standard" or other important criterion. Discriminant validity could also be reported. Does the scale distinguish between two outcomes that need to be distinguished (e.g. differential diagnosis)? All predictive coefficients and

Rating Form for Physical and Biological Constructs (Pathologies and Impairments) and their Implications for Diagnosis, Health, Function, and QOL

	relationships need not be reported. Choose the most important one(s). TTT is able to define the degree of autonomic impairment and orthostatic hypotension in multiple populations, according to the diagnostic standard (1). The validity of this test has not been defined in the SCI population per se'. Formal predictive/criterion-oriented validity assessments have not been performed, largely because of the lack a "gold standard" with which to compare responses. The relation between cardiovascular responses to TTT with other measures of cardiovascular autonomic function (i.e., plasma catecholamine) provides evidence of a correlation, but does not define the validity of this test in the SCI population.
Clinical utility.	Also called prescriptive validity and consequential validity. Do decisions in clinical practice hinge on the test or measure? This is a concrete way of asking whether the measure is clinically significant. Note or rate extent of use in clinical practice per expert knowledge: not used, rarely, occasionally, frequently, very frequently/routinely. *Comment if possible.* Attempting to define the degree of autonomic impairment in a patient with SCI and the cardiovascular consequences of such impairment would be facilitated by the use of TTT. Relevance to every day life is good, and laboratory responses to orthostatic challenge in this population would be expected to guide clinical treatment in the hopes of improving quality of life and independence in the SCI population.
Overall Ratings	Of validity, incorporating reliability.
Overall Validity in Similar Population	Rate quantity and quality of study results supportive of the construct when applied in similar target groups, e.g. other patients with pain or with paralysis. This is an experimental overall rating of validity. See scale below. Do NOT review non-SCI scales unless they have been well validated in the other target groups and they are potentially valuable in SCI: that is, skip ** and below. *** = Content and metric reliability and validity shown. Formal reliability and substantial validity shown with substantial use in non-SCI groups. ****= Very extensively validated and widely used. (e.g. SF36 or SIP for primary care, McGill Pain Questionnaire). *** = Content and metric reliability and validity shown. Formal reliability and substantial validity shown with substantial use in non-SCI groups.
Overall Rating of quality in SCI	Experimental overall rating of evidence demonstrating appropriateness for use in SCI studies/clinical trials, including reliability and validity and other relevant characteristics. Rate quantity and quality of study results supportive of application in SCI. • = No formal validity/reliability published, content inappropriate – do not review). * = Questionable or insufficient. Little or no formal validity or reliability support, or questionable content for SCI. Development is required for application to SCI. ** = Minimal validity. Apparently applicable content with good validity/reliability in SCI, but little use in SCI. Or used in SCI, but some limitations shown. Further development is desirable. *** = Content and metric reliability and validity shown. (Widely use outside of SCI, with formal studies/use in SCI.). OK to use in studies, although checking of assumptions or small improvements may be desirable to further improve the measure (e.g. classical measures would benefit from IRT or Rasch analysis). ****= Extensively validated and widely used. (e.g. SF36 for primary care)., Few scales, if any, in SCI would be rated at this level. (CHART?) *** Content and metric reliability and validity shown.

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