

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

Scale Name **“Sit-up testing” for the evaluation of cardiovascular autonomic function after spinal cord injury (SCI)**

Construct	
	<p>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.</p> <p>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). The orthostatic stress utilised may be head-upright tilting, standing, or sitting. “Sit up tests” are increasingly utilised to evaluate cardiovascular autonomic control e.g. as the placebo limb of research studies examining cardiovascular control during head-out water immersion, or seated cycling exercise. “Sit up testing” is also increasingly performed when evaluating patients for whom standing/tilting is difficult. “Sit up testing” does not require any specialised equipment, unlike tilt testing.</p> <p>Typical responses of HR and blood pressure to orthostatic stress require integrity of parasympathetic control of the heart, and sympathetic control of the heart and blood vessels. Impairment of autonomic function may present in various guises, but typically orthostatic hypotension (OH; evidenced by marked falls in blood pressure when upright) will develop in those with severe autonomic impairment. This may or may not be symptomatic.</p>
<p>Subscales / parameters measured</p>	<p>Typically HR and sometimes rhythm are recorded from a standard 3-lead ECG. Systolic (SAP), diastolic (DAP) and mean (MAP) arterial pressures are monitored either intermittently by sphygmomanometry, or continuously utilising the now widely available non-invasive beat-to-beat blood pressure monitoring techniques e.g. Finometer, Portapres, Finapres.</p> <p>The presence of symptoms (e.g. dizziness, nausea, or light-headedness) or signs (e.g. sweating or pallor) of OH are noted. OH is defined as a decrease in SAP of $\geq 20\text{mmHg}$ and/or in DAP of $\geq 10\text{mmHg}$¹⁷, according to the American Autonomic Society and American Academy of Neurology. The test is terminated and the subject returned to the supine position should marked or symptomatic OH occur.</p> <p>Some advanced protocols will include measurements of derived indices of stroke volume (SV), cardiac output (CO) and total peripheral resistance (TPR). Additional analyses of autonomic and baroreflex function may be performed on the beat-to-beat cardiovascular data e.g. spectral and cross-spectral analyses. In some instances catecholamine levels are determined, but this is not generally performed because invasive measurements themselves predispose to impaired orthostatic responses. These additional measures are usually confined to research protocols.</p>
<p>Statistics</p>	<p>Report relevant statistics reported, e.g. correlations among dimensions or other statistics you think are relevant or available formulas for conversion.</p> <p>Responses are determined for the time periods of interest. Usually averages of several readings are taken. Responses may be expressed as changes from a</p>

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	baseline control period, usually the end of a period of supine rest prior to testing.
Administration	
Type/mode/ equipment	<p>Describe type or mode of test, including equipment involved, nature of samples collected (if any), etc.</p> <p>Procedure While supine, the subject is instrumented with the appropriate monitoring devices (see below). A loose Velcro strap should be positioned around the subject’s waist to ensure they cannot slip during the “sit up” procedure. After a period of supine rest (typically 5-15min^{1-4,6-14,16,18}), during which time baseline recordings are made, the subject is then passively moved into an upright seated position by raising the head of the bed by 90°, and dropping the base of the bed by 90° from the knee. This position is essentially the same as when seated in a wheelchair, but with the feet unsupported and the legs dangling from the knee. This position is maintained for between 1 min⁸ to 2 hours⁶, but typically for 10-15 mins^{1-4,6-11,11-14,16,18}, unless the subject develops symptoms or signs of presyncope, at which point the test should be terminated and the subject returned to the supine position.</p> <p>Equipment/monitoring In its simplest form, the test simply entails the measurement and recording of SAP, DAP and MAP (sphygmomanometry) and HR (pulse). Recordings are typically performed every minute throughout testing. A procedure bed/examination table is recommended to facilitate the passive transition from a supine to a seated position, with appropriate safety straps as described above. However, testing can be performed at the bedside by sitting the subject up at the edge of the bed. This approach has generally only been employed in able-bodied individuals, however, and is not recommended for individuals with SCI who are likely to need considerable assistance in order for this manoeuvre to be performed both passively and safely.</p> <p>With the increasing availability of non-invasive beat-to-beat blood pressure monitoring equipment it is increasingly common to perform beat-to-beat measurements and analyses. The benefit of this technique is that sudden drops in blood pressure/pulse can be rapidly detected and intervention taken if necessary to prevent syncopal events elicited by the orthostatic stress. This is particularly useful in subjects who are largely asymptomatic, often despite marked OH, as has been reported in SCI^{1,5,9}.</p> <p>In research protocols SV, CO and TPR measurements are often performed, either from beat-to-beat blood pressure waveform analyses or impedance cardiography. Some groups monitor plasma catecholamine responses to the orthostatic stress, although these should be performed with caution, due to the potential effects of venepuncture upon orthostatic cardiovascular control. Additional frequency domain analyses may be performed upon the data. Again, this is typically a research procedure and is not common in clinical evaluations.</p> <p>In some instances cardiac rhythm is monitored in addition to rate. This is typically performed using a standard 3 lead ECG.</p>
Performance?	<p>Is substantial/maximal performance by the person required – or moderate involvement vs. passive acquiescence?</p> <p>Subjects are monitored in the supine and upright position. In SCI subjects, the transition from the supine to the upright posture is usually performed passively utilising adjustable examination tables. Passive acquiescence is typically all that</p>

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	is required, but minimal levels of subject cooperation may be necessary e.g. with transfers to the examination table.
Language/multi-cultural issues	<p>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.</p> <p>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.</p>
Burden / risk	<p>Inconvenience, discomfort, risks, # tests, expense, time to administer, special equipment, training required or available.</p> <p>Does not require specialized or costly equipment (standard examination table, sphygmomanometer and in some cases ECG are sufficient). Some training and experience is required.</p> <p>Administration time depends on the protocol employed, but would not usually be expected to exceed 1 hour.</p> <p>The procedure is not uncomfortable. If catecholamine assessments are performed, there is minimal discomfort associated with the venipuncture. Optional additional monitoring (see above) may increase the perceived level of discomfort.</p> <p>The test, by its nature, may provoke OH in susceptible individuals. Some subjects may experience symptoms of presyncope (near-fainting) e.g. dizziness associated with OH. In rare cases, loss of consciousness or syncope may occur. These events are transient, rapidly reversed upon the resumption of a supine position, and are not associated with any long-term adverse effects. Subjects who experience OH during “sit up testing” usually also experience OH during activities of daily living and do not typically find it overtly distressing.</p>
Population Applicability	
	<p>Describe problems/ groups and settings in which the scale has shown utility according to published sources.</p> <p>Has been used to assess cardiovascular autonomic control in able-bodied and SCI men and women.</p>
Extent of Use in SCI	<p>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.)</p> <p>A few (by several different research groups) in SCI individuals.</p>
Norms	<p>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?)</p> <p>Some normative data are available for acute^{9,12,14} and chronic¹ SCI, and the able-bodied population^{1,4,6,10,13,16,18}.</p> <p>In large studies of the able-bodied, gender differences in the cardiovascular responses to the “sit up test” have been noted^{4,6,16}, and the incidence of OH is reported to increase with increasing age^{2,8}. In able-bodied controls, the “sit up” manoeuvre typically increases SAP and DAP, and increases HR^{1,4,6,10,13,16,18}.</p> <p>Responses in SCI subjects may be variable, depending on the severity of injury to cardiovascular autonomic pathways¹. Certainly OH is common both in acute^{9,14} and chronic SCI¹, particularly in higher and autonomically more complete lesions^{1,9,14}. Failure to increase HR or maintain blood pressure is</p>

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	likely to signal cardiovascular autonomic dysfunction.
<i>Comment</i>	<p><i>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.</i></p> <p><i>This measure is promising in SCI and readily applicable to the SCI population as a whole. It does not require specialised or expensive equipment, is non-invasive, and can be readily applied at the bedside/clinic. 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.</i></p>
Reliability / Reproducibility and Bias	
Reliability, Reproducibility	<p>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.</p> <p>Formal measures of reproducibility and reliability have not been performed in SCI individuals to date. In able-bodied controls, preliminary studies suggest the reproducibility of blood pressure responses to a 5 min “sit up test” to be 95%¹⁰, and similar responses to “sit up testing” were obtained when assessments were performed 16 weeks apart¹⁸.</p>
Bias	<p>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</p> <p>As with all autonomic function assessments, controlled laboratory conditions are required in order to prevent bias. Evaluations should ideally be performed at the same time of day, under the same conditions. Medications that may affect autonomic control must be noted and, where appropriate, discontinued prior to testing. Experiments should be performed in a temperature controlled (thermoneutral) laboratory. It is usual to perform studies in the mornings, at the same time of day, following an overnight fast (except for water). Alcohol and caffeine must be avoided for at least 12 hours prior to study, and strenuous exercise avoided for 24 hours 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.</p>
Other reliability	<p>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.)</p> <p>If venepuncture is to be performed e.g. for catecholamine analyses, the incidence of OH and abnormal cardiovascular responses to orthostatic stress increases dramatically¹⁵. Blood sampling, if required, should be performed from a venous catheter that is inserted at least 1 hour prior to examination.</p>

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Sensitivity to Change	This test is able to discriminate between individuals with different SCI lesion levels and healthy control volunteers ^{1,9,14} . There are significant correlations between the cardiovascular responses to the “sit up test” and other measures of cardiovascular autonomic function ¹ . A case study in SCI has demonstrated the ability to detect differences in the response to “sit up testing” following treatment of severe OH with midodrine ¹² .
Sensitivity	Sensitivity and specificity are difficult to assess for this measure, because at present there is no “gold standard” of cardiovascular autonomic assessment for individuals SCI with which to compare data. Preliminary data utilising comparison with autonomic impairment as assessed from the palmar sympathetic skin response suggests strong agreement between the two measures ¹ . Ceiling and floor effects do not appear to be a problem. The range of values between subjects can be large depending on the severity of the autonomic impairment of the individual, but within appropriate groups e.g. able-bodied controls, cervical SCI, autonomically complete SCI, the SEM are small and sufficient to detect statistical significance.
Comment	<p><i>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?</i></p> <p><i>Cardiovascular responses to the “sit up test” are sufficient to determine differences in response patterns between individuals with various different levels and severities of SCI, and between individuals with SCI and the able-bodied. Gender differences are noted in the able-bodied, but have not yet been assessed in individuals with SCI. These changes are probably meaningful. A key point is the ability to detect differences in subjects with different severities of injury to autonomic pathways, and the correlation between cardiovascular variables obtained from this procedure and other clinical measures of autonomic function after SCI.</i></p>
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	<p>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 relationships need not be reported. Choose the most important one(s).</p> <p>The test is able to detect the presence or absence of OH, according to the diagnostic standard¹⁷. However, these diagnostic criteria are more usually applied to standing/tilting than seated orthostatic stress. The “sit up test”, therefore, imposes a milder orthostatic stress upon the individual, and thus may tend to underestimate the true incidence of OH. However, several studies report diagnoses of OH based on seated orthostatic stress^{1,2,8,9,12,14}. Since most individuals with SCI are typically exposed only to seated orthostatic stress, the “sit up test” may be more applicable to the reality of SCI, and more able to</p>

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	<p>diagnose meaningful OH in this population.</p> <p>Formal predictive/criterion-oriented validity assessments have not been performed, largely because of the lack a “gold standard” with which to compare responses. The presence of significant correlations between cardiovascular responses to the “sit up test” and other assessments of cardiovascular autonomic function e.g. plasma noradrenaline levels and sympathetic skin responses support, but do not define, the validity of this test.</p>
Clinical utility.	<p>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. <i>Comment if possible.</i></p> <p>The measurement of blood pressure in the seated position is the clinical standard. The use of this seated orthostatic stress test is not incorporated into the routine clinical assessment of cardiovascular autonomic control, although it has been utilised, particularly in elderly in-patients². It has also been used in the clinical setting to evaluate autonomic function and severity of OH in SCI individuals^{12,14}. This test has also been used to evaluate efficacy of treatment of OH in an individual with SCI in the clinical setting¹².</p>
Overall Ratings	Of validity, incorporating reliability.
Overall Validity in Similar Population	<p>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.</p> <p>*** = Content and metric reliability and validity shown. Formal reliability and substantial validity shown with substantial use in non-SCI groups.</p> <p>****= Very extensively validated and widely used. (e.g. SF36 or SIP for primary care, McGill Pain Questionnaire).</p> <p>*** = Content and metric reliability and validity shown. Formal reliability and substantial validity shown with substantial use in non-SCI groups.</p>
Overall Rating of quality in SCI	<p>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.</p> <ul style="list-style-type: none"> • = 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?) <p>** OR ***</p>

References:

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