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A Model for Incorporating A Clinically-Feasible Exercise Test in Paraplegic Annual Reviews: A Tool for Stratified Cardiopulmonary Stress Performance Classification and Monitoring

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Abstract

Objectives: (i) To identify and characterize an exercise test for use in routine spinal cord injury clinical review, and (ii) to describe levels of, and factors affecting, cardiopulmonary stress performance during exercise in the chronic paraplegic population in Scotland, UK.

Design: Cross-sectional study.

Setting: Queen Elizabeth National Spinal Injuries Unit (Glasgow, Scotland).

Patients: 48 subjects with chronic paraplegia resulting from spinal cord injury at neurological levels T2-L2.

Methods: Peak oxygen uptake, peak power output, gas exchange threshold and peak heart rate were determined from an incremental arm-cranking exercise test. Using a general linear model, the effects of gender, high (injury level above T6) versus low paraplegia, time since injury, body mass and age on peak oxygen uptake and peak power output were investigated.

Results: All 48 subjects completed the arm-cranking exercise test, which was shown to be practical for fitness screening in paraplegia. Men (n=38) had a peak oxygen uptake of 1.302 ± 0.326 l.min-1 (mean ± SD) and peak power output of 81.6 ± 23.2W, which was significantly higher than for women (n=10), at 0.832 ± 0.277 l.min-1 and 50.1 ± 27.8 W, respectively. There was large intersubject variability in cardiopulmonary performance during arm-cranking exercise testing, but the overall mean for the Scottish population was lower than reference values from other countries.

Conclusions: Arm-cranking exercise tests are feasible in the clinical environment. The motivation for their implementation is threefold: (i) to determine cardiopulmonary stress performance of individual paraplegic patients, (ii) to stratify patients into cardiovascular risk categories, and (iii) to monitor the effects of targeted exercise prescription.

Keywords: Cardiopulmonary; Exercise testing; Fitness; Oxygen uptake; Paralysis; Paraplegia; Spinal cord injury

Abbreviations: GET: Gas Exchange Threshold; HR: Heart Rate; ICC: Intraclass Correlation Coefficient; PO: Power Output; RER: Respiratory Exchange Ratio; SCI: Spinal Cord Injury; V02; : Rate of Oxygen Uptake

Introduction

With an increase in life expectancy, patients with spinal cord injury (SCI) are exposed to a higher incidence of metabolic disorders (obesity, hypertension, diabetes and dyslipidaemias) [1] and a higher risk of developing cardiovascular disease than the general population [2]. These long-term health problems have been attributed to the resultant sedentary lifestyle and lack of cardiopulmonary stressors following SCI [3,4].

In the able-bodied population, there has been a considerable drive to increase participation in regular physical activity aimed at improving cardiopulmonary fitness. Regular physical activity using appropriate exercise modalities should also be encouraged in the SCI population [5]. In order to monitor the success or otherwise of exercise interventions, a practical tool for cardiopulmonary assessment is required.

The proactive approach of implementing annual reviews as part of long-term SCI management has already been shown to be beneficial [6]. Even so, such regular medical check-ups in chronic SCI patients have not been implemented internationally. In Scotland (U.K.), routine reviews of SCI patients currently consist of assessment mostly of bladder, bowel and sexual function, skin problems and spasticity. It is proposed that the annual reviews should also include some assessment of cardiopulmonary stress performance, as there are still too many deaths from cardiovascular disease in this population.

In this study we set out to determine the practicality of adding the incremental exercise test to routine SCI clinical review in paraplegia and to describe the typical level of cardiopulmonary stress performance in a cross-section of the national paraplegic population of Scotland. This would enable stratification of patients into cardiovascular risk categories, and provide reference data against which the effects of targeted community and outpatient interventions could later be measured. Previous studies of cardiopulmonary fitness in the SCI population were not available in the UK. In particular, such data were not available from Scotland, which continues to have the highest prevalence of ischemic heart disease in Western Europe [7-10]. The Scottish SCI population provides an ideal model to demonstrate the potential benefits of incorporating exercise tests in annual reviews.

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precisely because there is still such a high incidence of deaths from cardiovascular disease in this group.

Methods

Subjects

Paraplegics attending the national spinal injuries unit for Scotland in a university teaching hospital (Queen Elizabeth National Spinal Injuries Unit, Southern General Hospital, Glasgow) for annual review were invited to take part in the study. Inclusion criteria were: (i) SCI at neurological level T2 - L2, (ii) grade A - C on the American Spinal Injuries Association (ASIA) Impairment Scale [11], (iii) age 18-65 years. Candidates were excluded if they had diagnosed cardiovascular disease. A physician carried out medical screening of potential candidates for inclusion in the study, ensuring that individuals with history of blood pressure, angina, cardiac hypertrophy or any other cardiac conditions were not included in the study cohort. Each subject on the study was also asked to complete a Health Questionnaire, detailing any medical conditions, medication, and other relevant information. These data confirmed that participants on the study had no known cardiac conditions.

The 48 subjects’ details are summarized in Table 1. Ten women and 38 men took part. SCI level was categorized in relation to sympathetic innervations of the heart (T1-T5): SCI above T6 was classified as HIGH paraplegia (n=10, all male), and SCI at T6 and below as LOW paraplegia (n=38).

The study was approved by the South Glasgow Research Ethics Committee. Written informed consent was obtained from each subject prior to participation.

Protocol

Participants attended an exercise testing session (TEST 1) at the Queen Elizabeth National Spinal Injuries Unit. A subgroup of participants (n=11) repeated the test (TEST 2) on a different day, between 24 hours and two weeks later, to determine test-retest reliability.

Subjects were asked to refrain from eating, smoking, and drinking tea or cofee for at least two hours prior to the test, and from drinking alcohol for 24 hours prior to the test. They were required to empty their bladder (or urine bag) before starting the test. The subject’s body mass was measured to the nearest kilogram using wheelchair scales (DP 2400, Marsden).

An instrumented arm-crank ergometer (Viva, ReckMotomed, Germany) was used for the test, connected via RS232 cable to a PC (Viva, ReckMotomed). An instrumented arm-crank ergometer (Viva, ReckMotomed, Germany) was used for the test, connected via RS232 cable to a PC.

The subject was set-up at the arm-crank ergometer with the center of the cranks at shoulder-joint height and a distance between the wheelchair and the ergometer that ensured the elbow remained slightly flexed at the furthest position of the cranks. Detailed test instructions were given to the subject. A low-dead-space Hans-Rudolph face mask was placed over the nose and mouth and tightened to ensure a good seal. A volume turbine and sample line were attached to the mask and connected to a portable breath-by-breath cardiopulmonary measurement system (Metamax 3B, Cortex, Germany) to record volumes of air, and inspired and expired concentrations of oxygen and carbon dioxide for each breath. Prior to each test, the volume transducer was calibrated using a 3-litre syringe, and the gas analyzers were calibrated using two different reference gases of known concentration. A pulse oximeter (3800, DatexOhmeda) was connected to the subject via an earlobe sensor to monitor oxygen saturation of the arterial blood (SpO2) and heart rate (HR). HR was recorded once per minute.

Following a period of unrecorded rest to allow the subject to settle before formal testing, resting cardiopulmonary data were collected for at least two minutes (until consecutive values for oxygen uptake (VO2) over one minute remained within 5% of each other, and similarly for end-tidal CO2) before starting the exercise.

Visual feedback of actual and target work rate was provided in real time on the PC screen so that, as the target work rate changed, the subject was required to increase his/her power output (PO) accordingly, as in previous studies using a similar set-up [12,13]. Exercise began with three minutes of unloaded arm-cranking at a cadence of 50 rpm, after which the target work rate was increased every minute in equal steps. Step size was pre-programmed and varied between subjects from 4-10 W (taking into account self-reported physical activity levels, age and gender), with the aim of completing the incremental phase within the optimal 8-12 minutes [14]. The subjects were verbally encouraged to continue until volitional exhaustion. A 2-3 minute warm-down was included if tolerated by the subject. Cardiopulmonary monitoring continued for a further 4-5 minutes until heart rate stabilized.

Data analysis

Prior to analysis, the raw cardiopulmonary data were systematically edited to remove outliers, using a custom Graphical User Interface (Matlab v.7.3, Mathworks) [15-18]. Line-fitting and estimation of cardiopulmonary outcome parameters were carried out using the edited data.

The outcome measures from the exercise tests are given in Table 2.

Statistical analysis

Statistical analyses were carried out using SPSS software (v15.0). The significance level was set at 5%.

Relationships between absolute VO2 peak and other outcome measures (POpeak, HRpeak, and gas exchange threshold (GET)) were assessed using Pearson’s correlation coefficient.

A linear regression was fitted to absolute VO2 peak and POpeak data in a general linear model, to investigate the effects of gender, high versus low paraplegia, body mass, age, and time since injury.

| Lesion category | N | Age in years | Time since injury, in years | Body mass, in kg | N* |
|-----------------|---|--------------|----------------------------|------------------|----|
| **Women**       |   |              |                            |                  |    |
| LOW             | 10| 37.9 (12.4)  | 5.2 (5.1)                  | 61.9 (14.9)      | 9  |
| HIGH            | 0 |              |                            |                  | -  |
| **ALL**         | 10| 37.9 (12.4)  |                            | 61.9 (14.9)      | 9  |
| **Men**         |   |              |                            |                  |    |
| LOW             | 28| 39.3 (12.9)  | 7.9 (9.3)                  | 82.9 (18.3)      | 24 |
| HIGH            | 10| 43.1 (11.0)  | 12.2 (14.2)                | 78.2 (23.9)      | 9  |
| **ALL**         | 38| 40.3 (12.4)  | 9.0 (10.8)                 | 81.6 (19.7)      | 33 |
| **ALL**         | 48| 39.8 (12.3)  | 8.2 (9.0)                  | 77.4 (20.3)      | 42 |

Table 1: Subject details (LOW: lesion level at T6 or below, HIGH: lesion level above T6). There were no female subjects with high paraplegia. N*: number of subjects with body mass measurements in each lesion category. Data are presented as Mean (SD).
A two-tailed paired-sample t-test (n=11) was carried out to determine whether each outcome measure for TEST 1 was different to that in TEST 2. The intraclass correlation coefficient (ICC) was also calculated for each outcome measure [19] to determine test-retest reliability.

Results

All 48 subjects completed the exercise test and 11 of these subjects repeated the test on a different day. Body mass measurements were available for 41 patients. For TEST 1, the incremental phase of the tests was achieved within the target 8-12 minutes in 26/48 tests, in 6-7 minutes in 8/48 tests and 13-15 minutes in 14/48 tests. For TEST 2, the incremental phase was 8-12 minutes in all 11 tests.

59 tests were completed in 48 patients. In 2 sessions, there were technical problems with the cardiopulmonary measurements, but PO and HR were still monitored and recorded throughout. There were no adverse events during any of the exercise tests. Each testing session lasted approximately 30 minutes. Data analysis then required approximately 30 minutes per dataset.

The results for each outcome variable for the overall group, and for subgroups separately (female and male subjects, and subjects with low and high paraplegia), are summarized in figure 1.

Of all the variables investigated (HIGH versus LOW paraplegia p=0.983; time since injury, p=0.693, age, p=0.561; body mass, p=0.230), gender was the only factor in the model that explained some of the differences in PO_{peak} values (p=0.025).

Similarly, for absolute V̇O₂_{peak}, gender was the only variable found to explain some of the differences in V̇O₂_{peak} (p=0.041), compared to other parameters: HIGH versus LOW paraplegia (p=0.770), time since injury (p=0.432), age (p=0.901), and body mass (p=0.600). When oxygen uptake was normalized to body mass to give the relative V̇O₂_{peak}, the effect of gender was no longer significant (p=0.350). However, for 7 subjects, no body mass measurement was available, leaving a reduced sample size for relative V̇O₂_{peak} (n=41).

A plot of the relationship between absolute V̇O₂_{peak} and PO_{peak} is shown in Figure 2a, and between relative V̇O₂_{peak} and PO_{peak} in Figure 2b. Absolute V̇O₂_{peak} was strongly related to PO_{peak} (R²=0.863, p<0.001, n=46) and with GET (R²=0.676, p=0.001, n=36). For 12 out of 48 subjects, the GET could not be identified (Figure 2)

Table 2: Outcome variables from the arm-cranking exercise test and their method of calculation.

| Outcome variable | Abbreviation (Unit) | Calculation |
|------------------|---------------------|-------------|
| Peak power output | PO_{peak} (W) | Highest power output increment completed |
| Absolute peak oxygen uptake | Absolute V̇O₂_{peak} (l.min⁻¹) | Highest 30s-average oxygen uptake reached, following guidelines from Wasserman et al.[16]. |
| Relative peak oxygen uptake | Relative V̇O₂_{peak} (ml.min⁻¹.kg⁻¹) | Peak oxygen uptake normalized to body mass. |
| Gas exchange threshold | GET (l.min⁻¹) | V̇O₂ at the point of inflexion in the V̇CO₂,V̇O₂ relationship [15,17,18] |
| Peak heart rate | HR_{peak} (beats.min⁻¹) | Highest HR recorded during the incremental phase of the test |

Figure 1: Summary of outcome variables, shown as Mean ± SD. LP: low paraplegia; HP: high paraplegia. (a) PO_{peak} (b) absolute V̇O₂_{peak} (c) relative V̇O₂_{peak} (d) HR_{peak} (e) GET (f) RER at peak.
Test-retest reliability

For the subgroup of subjects who repeated the procedure on a different day (n=11), a 2-tailed paired-sample t-test revealed that only PO_{peak} for TEST 2 was significantly different (higher) to that in TEST 1. The paired t-test results and ICCs are shown in table 3. For 2 out of 11 subjects, a GET could not be identified in either TEST 1 or TEST 2. The highest ICC was 0.968, for PO_{peak}, and the lowest ICC was 0.626 for GET.

Discussion

We investigated whether it was feasible to add an exercise test to the standard set of health checks that are carried out in SCI annual reviews. An arm-crank ergometer was used, as it is a modality that is accessible in most spinal and other rehabilitation unit gyms. Other groups have suggested a range of tests and indicators that would need to be recorded to compile a complete assessment of physical capacity in SCI [20,21]. However, the use of a single test was evaluated here as it may be more easily adopted as a tool for fitness screening in a clinical setting.

Measurable and reliable indicators of cardiopulmonary stress performance are ultimately of benefit to the patient, clinician and trainer only if reference values are available for comparison and can be used to set achievable training targets. To attain this goal, the proposed test and its outcome measures should identify variation in cardiopulmonary stress performance between patients. This would enable the stratification of patients into cardiovascular disease risk categories, to highlight (or stress performance between patients. This would enable the stratification of patients into cardiovascular disease risk categories, to highlight (or “red-flag”) individuals in greatest need of exercise prescription. Based on this stratification, targeted exercise intervention aimed at the highest-risk individuals would be implemented; repeat exercise tests would then be appropriate for monitoring changes in cardiopulmonary stress performance over time to determine the effectiveness of the exercise intervention.

We assessed cardiopulmonary stress performance using breath-by-breath gas exchange measurements during an incremental arm-crank exercise test, and successfully incorporated this test into 48 routine reviews of paraplegic patients, adding 30 minutes to the average consultation. Both the \( \dot{V}_{\text{O}_2\text{peak}} \) reached during the exercise test and the GET are key measures of cardiopulmonary stress performance. We were able to determine the \( \dot{V}_{\text{O}_2\text{peak}} \) in all tests where cardiopulmonary data were collected, but unable to detect a GET for 12 out of 48 subjects.

The results from our study can be compared to cross-sectional data from untrained paraplegic populations investigated by other groups worldwide. In the US, arm-crank ergometry exercise tests were used to assess eight American paraplegics (men and women) [22]. The reported mean \( \dot{V}_{\text{O}_2\text{peak}} \) was 1.5 ± 0.6 l.min\(^{-1}\). Haisma et al. [20] carried out a review of the worldwide literature and pooled the results from 52 systematically-selected studies of physical capacity in SCI, suggesting a mean \( \dot{V}_{\text{O}_2\text{peak}} \) of 1.51 l.min\(^{-1}\) (range of 1.03 to 2.34 l.min\(^{-1}\)) and mean PO_{peak} of 85 W (range of 66 to 117 W) during arm-crank ergometry. The Scottish paraplegic overall means were 1.210 ± 0.367 l.min\(^{-1}\) for \( \dot{V}_{\text{O}_2\text{peak}} \) and 75.0 ± 27.2 W for PO_{peak}. Compared to published reference values for paraplegia, it appears that this study population is generally less fit, falling within the lower end of the range of the pooled international data. A program of exercise prescription monitored for its effectiveness through annual reviews may be warranted in Scotland.

![Figure 2](image)

**Figure 2:** (a) absolute \( \dot{V}_{\text{O}_2\text{peak}} \) and (b) relative \( \dot{V}_{\text{O}_2\text{peak}} \) against PO_{peak}. Each datapoint represents an individual subject (●: female subject; ○: male subject).

|               | TEST 1 (Familiarization) | TEST 2 (Formal Test) | P-value for paired-sample t-test | Intra-Class Correlation Coefficient |
|---------------|--------------------------|----------------------|----------------------------------|-------------------------------------|
| PO_{peak}(W)  | 67.8 (30.4)              | 76.8 (34.0)          | p=0.005 *                        | 0.968                               |
| Absolute \( \dot{V}_{\text{O}_2\text{peak}} \) (l.min\(^{-1}\)) | 1.083 (0.373)          | 1.134 (0.440)        | p=0.388                          | 0.897                               |
| HR_{max}(beats.min\(^{-1}\)) | 134.2 (18.6)          | 132.3 (25.1)         | p=0.705                          | 0.727                               |
| GET (l.min\(^{-1}\)) | 0.629 (0.122)          | 0.665 (0.222)        | p=0.538                          | 0.626                               |
| RER at \( \dot{V}_{\text{O}_2\text{peak}} \) | 1.136 (0.183)        | 1.167 (0.185)        | p=0.449                          | 0.755                               |

Table 3: Test-retest analysis results (RER: respiratory exchange ratio; *: value from TEST 2 statistically significantly different from value from TEST 1, at the 5% level; †: only 8 of 11 subjects’ datasets available for GET analysis.)
The long-term clinical implication is that routine cardiopulmonary stress performance assessment could become part of the development of a targeted health maintenance program in the SCI population. The linear spread of oxygen uptake data enables us to achieve fitness screening and patient stratification by identifying the most "at risk" individuals. $V_O2_{peak}$ values in the cross-section of the paraplegic population of Scotland studied here ranged from 0.437 to 1.996 L/min$^{-1}$. In much the same way as Janssen et al. [23] suggest, the categorization of normative values into five quintiles of physical capacity (Poor, Fair, Average, Good and Excellent), a similar definition could be used for fitness screening and patient stratification here. These "high risk" patients (in the "Poor" and "Fair" quintiles) could be primary targets for exercise prescription, and exercise regimes could be designed with the aim of gradually increasing cardiopulmonary stress performance and progressing into lower-risk categories. The success of the exercise interventions would be monitored through regular exercise testing during subsequent annual reviews.

Apart from identifying individual patients with low cardiopulmonary stress performance and potentially at high risk of developing cardiovascular diseases, it would also be useful to determine whether any subgroups of the population tend to have lower values and whether they should be targeted as a group for exercise prescription. Subgroup analyses of our data revealed that women tended to have lower cardiopulmonary stress performance levels than men. The effect of gender was significant for key outcome measures. Some women in our sample may not have given a maximal effort during the exercise tests. The finding that a GET could not be identified in 5 out of 10 female subjects lends some support to this speculation. Alternatively, women in the study may have had weaker upper limb muscles than the men, leading to peripheral rather than central limitation during arm cranking. However, it should be noted that the statistical significance of the gender effect on $V_O2_{peak}$ was lost when differences in body mass were taken into account to give relative $V_O2_{peak}$. The small number of female participants is a clear limitation of our study, and the proposed differences in performance between men and women with SCI in these exercise tests would need to be confirmed with larger numbers.

There are a number of additional limitations to our study. We developed a reference database for the Scottish paraplegic population which is currently relevant for SCI at T2-L2 only, but around half of SCIs occur at higher neurological levels and lead to tetraplegia. In the healthy neurologically-intact population, there is a linear relationship between heart rate and oxygen uptake during incremental exercise tests. However, a "blunted heart rate response" that results from differences in performance between men and women with SCI in these tests would need to be monitored through regular exercise testing during subsequent annual reviews.

As the method of cardiopulmonary stress performance assessment used here may not be applicable to tetraplegia, which includes paralysis of muscles of the upper limbs as well as the lower limbs, the test set-up and protocol would need to be modified to accommodate these factors. More specifically, due to the level of innervation of key muscles involved in arm-cranking exercise, we would not be able to implement arm-cranking for cardiopulmonary stress performance in patients with SCI above C5, without the addition of electrical stimulation to recruit key muscle groups [12,13]. In the absence of electrical stimulation of elbow flexors and extensors, alternative cardiopulmonary stressors would need to be investigated and evaluated in SCI at higher cervical levels.

In addition to feasibility, we investigated the repeatability of the proposed exercise tests. In our study, where subjects repeated the test on a different day (n=11), there was a higher $PO_{2peak}$ on the second test (p=0.005), but at a similar $V_O2_{peak}$. Possible explanations include that the power measurements are not very repeatable or that subjects had developed a more efficient technique for arm-cranking in the second test (a "practice effect"), coupled with reduced anxiety due to familiarity of the test when repeated. This test-retest analysis suggests that, if exercise testing were to be incorporated into annual reviews, a familiarization test may be warranted to determine a representative $PO_{2peak}$, but not necessary to determine $V_O2_{peak}$.

It may be argued that a different solution is to carry out the exercise tests using wheelchair ergometry (as described by Janssen et al. [23]). This exercise modality involves upper body movements that individuals with paraplegia (and low tetraplegia) use on a daily basis. The issue of technique and optimum positioning in terms of distances and angles between the wheelchair and the ergometer may not affect the wheelchair ergometry test to the same extent as the arm-crank ergometry test, which may negate the need for a familiarization test when using this alternative modality. However, as the set-up for wheelchair ergometry testing requires a considerable amount of space and specialized equipment, it may not be a practical alternative to arm-crank ergometry testing in many spinal and other rehabilitation units.

A possible implementation strategy of the tests described here might be that a full baseline cardiopulmonary stress performance assessment of arm-cranking exercise is made for each patient initially. Following this, an incremental power test without full breath-by-breath cardiopulmonary measurement could be sufficient for routine review because, as shown here and well known from the wider exercise physiology literature, $V_O2_{peak}$ and $PO_{2peak}$ are highly correlated. For patients with SCI at T2-L2, the best-fit regression of $V_O2_{peak}$ versus $PO_{2peak}$ data from the present study could then be used to interpolate $V_O2_{peak}$ from the $PO_{2peak}$ reached by the patient during the incremental power test. Peak power tests would be more manageable as a routine review assessment than the full cardiopulmonary assessment test, as the time (15-20mins) and expertise required by the clinician running the test would be reduced. These peak power tests could be performed by physiotherapists, instead of exercise or sports scientists, who are not typically part of the clinical rehabilitation team (in the UK at least).

The identification of a test (or choice of tests) that could be incorporated in routine clinical practice in a spinal injuries unit and accommodate different levels of injury may require a compromise between data quality and feasibility in a clinical setting. In terms of data quality, subjects would ideally have a sufficiently long resting period and a minimum of 4 hours without caffeine, food, or smoking prior to the test, and no distractions during the test. Achieving an ideal testing environment in a clinical setting may not always be possible due to

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mitigating circumstances, but this should not preclude the exercise test from being considered as a tool for health assessment as part of the SCI annual review.

In conclusion, the 30-minute arm-cranking exercise test proposed here proved feasible in a clinical setting. Implementing the exercise test enabled us to calculate VO2peak, PO2peak and HRpeak (and in 75% of cases, GET), and these outcome measures were used to describe cardiopulmonary stress performance levels for a cross-section of the untrained chronic paraplegic population. Compared with published reference values Scottish paraplegics, with a mean VO2peak of 1.21 L.min⁻¹, have lower cardiopulmonary stress performance levels than typically seen for this patient group. Furthermore, the clinical management of cardiovascular disease risk in this patient group could benefit from stratification of patients based on their cardiopulmonary stress performance, to inform targeted exercise prescription for those patients who would benefit the most from improvements in fitness.

Clinical Messages

- The incorporation of exercise tests in paraplegic annual reviews would enable the clinical team to (i) identify most unfit paraplegic patients, through stratification into “cardiovascular risk” categories, and (ii) monitor the effects of targeted exercise prescription.

- Systematic monitoring of cardiopulmonary stress performance can be achieved feasibly by adding a 30-minute arm-cranking exercise test to the annual reviews of paraplegic patients.

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