EXECUTIVE SUMMARY

1. SCIRE Project overview

The Spinal Cord Injury Rehabilitation Evidence (SCIRE) is a synthesis of the research evidence underlying rehabilitation interventions to improve the health of people living with SCI. SCIRE covers a comprehensive set of topics relevant to SCI rehabilitation and community re-integration. This project is intended to translate existing knowledge to health professionals to inform them of best practice. This research synthesis will also enable relevant decision-making in public policy and practice settings applicable to SCI rehabilitation. In addition, transparent evidence-based reviews can guide the research community and funding organizations to strategically focus their time and resources on the gaps in knowledge and identify research priorities. People with SCI and their families may also find the information useful to understanding their health care.

The Spinal Cord Injury Rehabilitation Evidence developed from a research collaboration between Vancouver and London (Ontario) and involved their respective health centres (GF Strong Rehab Centre, St. Joseph's Health Care), research institutions (International Collaboration on Repair Discoveries, Lawson Health Research Institute) and universities (University of BC, University of Western Ontario).

2. Methods

Systematic Review

An exhaustive search (keyword literature search, previous practice guidelines and systematic reviews, review articles) was used to identify published literature evaluating the effectiveness of any treatment or therapy related to SCI rehabilitation. Topics relevant to rehabilitation were selected with input from scientists and clinicians in the field of SCI rehabilitation, in addition to the SCIRE Advisory Committee (which included consumers with SCI and policy-makers).

This search involved the review of over 17,000 titles and 8400 abstracts, and a final extraction and synthesis of almost 700 articles. A variety of study designs were included (from randomized controlled trials to case reports), however, controlled trials were given priority in generating conclusions. In order to provide transparent and unbiased evidence-based reviews, the rigor and quality of each study was scored on standardized scales by two independent reviewers (Physiotherapy Evidence Database Scale for randomized controlled trials and the Downs and Black Tool for all other studies). Following this individual study assessment, conclusions were drawn about the accumulated studies for each topic of interest (e.g., pressure ulcers) using a modified version of Sackett's description of levels of evidence. In this 5 point scale, the strongest evidence, level 1, was assigned if the intervention was supported by at least one randomized controlled trial, while a level 5 was assigned if no critical appraisal existed, but perhaps was supported by clinical consensus. Conclusions were based on the levels, quality and concurring evidence. When conflicting data was present, an explanation was provided as to how the conclusions were derived.

Outcome measure assessment

Outcome measures used in spinal cord injury evaluation were identified by keyword search of the major electronic databases and through hand searches of noted spinal cord journals. Only measures with published studies of the psychometric (reliability and validity) properties within the spinal cord population were identified for review. The measures were categorized into the

domains of the World Health Organization's International Classification of Functioning, Disability and Health (body function/structure, activity and participation). A fourth category was created for quality of life measures. Approximately 160 measures were identified of which 63 were selected for review based on clinician interest. The measures were evaluated using elements of the Health Technology Assessment to assess the psychometric properties, interpretability, acceptability, and feasibility. Summary tables identifying the rigor and quality of the psychometric properties were constructed. A clinical conclusion is offered based on the synthesis of the review.

3. Findings from the Systematic Review of SCI Rehabilitation

Given that the SCIRE consists of over 800 pages of evidence, we cannot represent all the findings here. What follows are selected findings which demonstrate the scope of the research and the value of the results.

Rehabilitation Practice
Earlier admission to specialized, interdisciplinary SCI care is associated with reduced length of total hospital stay and greater and faster rehabilitation gains with fewer medical secondary complications (especially pressure sores).

Community Re-integration
The average level of quality of life after SCI is slightly lower than in people without disability but a substantial number of people with SCI report good or excellent levels of quality of life. The severity of injury and other diagnostic factors do not significantly impact quality of life. Their influence may become significant through restrictions in community integration or social participation.

Upper Limb Rehabilitation
Upper limb muscle strength is identified as an important contributor to functional independence. Neuromuscular stimulation-assisted exercise (e.g., during arm ergometry) following a spinal cord injury is effective in improving muscle strength, preventing injury and increasing independence in all phases of rehabilitation. Practice of repetitive movements in conjunction with low intensity peripheral nerve stimulation may induce beneficial brain cortical changes, in addition to improved arm and hand function.

Lower Limb Rehabilitation
Body-weight supported treadmill exercise using a suspended harness is a relatively new treatment of interest. For patients less than 6 months post-SCI, body weight supported treadmill training has equivalent effects on gait outcomes to conventional rehabilitation consisting of overground mobility practice. Body weight-support gait training strategies can improve gait outcomes in chronic, incomplete SCI, but no single specific body weight-support strategy (overground, treadmill, with functional electrical stimulation) is more effective.

Cardiovascular Health and Exercise
There appears to be an earlier onset and increased prevalence of cardiovascular disease in individuals with SCI in comparison to the general population. Tetraplegics and paraplegics can improve their cardiovascular fitness and physical work capacity through aerobic exercise training (e.g., arm cycle or wheelchair ergometry), which are of moderate intensity, performed 20-60 min day, at least three times per week for a minimum of six to eight weeks.

Respiratory Management
Respiratory complications continue to be one of the leading causes of morbidity and mortality in people with spinal cord injury, especially among cervical and higher thoracic injuries. Unlike the cardiovascular system, the lungs and airways do not change appreciably in response to exercise training. For exercise training to improve respiratory function, the training intensity must be relatively high (70-80% of maximum heart rate) performed three times per week for six weeks.

Bone Health
There is a significant risk for lower extremity fragility fractures after SCI. Early assessment and ongoing monitoring of bone health is an essential element of SCI care. There is strong evidence from randomized controlled trials that support the use of medications for the prevention and treatment of bone loss following SCI. Non-pharmacological treatments have not been found to prevent bone loss in the first year, however, electrical stimulation can increase bone density over the area stimulated in people with SCI more than 1 year post-injury.

Depression
Depression is a common consequence of SCI. Cognitive behavioural interventions provided in a group setting appear helpful in reducing post-SCI depression. The benefits of drug treatment (including selective serotonin reuptake inhibitors and tricyclic antidepressants) in combination with psychotherapy may alleviate depression. However, pharmacological management for post-SCI depression is largely extrapolated from studies in non-SCI populations. Programs to encourage regular exercise, reduce stress, and improve or maintain health are beneficial in reducing reports of depressive symptoms in persons with SCI.

Sexual Health
In men with SCI, erections are often not reliable or adequate for sexual intercourse since there may be difficulties with maintenance of the erection. The pharmacological agent, Phosphodiesterase Type 5 Inhibitors (PDE5i, Viagra®) can be used safely and effectively for treatment of erectile dysfunction in men with SCI and are recommended as first line treatment for erectile dysfunction after SCI.

Bowel Management
Multifaceted programs incorporating intereventions such as, nutrition, fluid consumption, routine bowel evacuation, may improve movement of substances through the colon as well as decrease the incidences of difficult bowel evacuations. Pharmacological agents such as cisapride, prucalopride, and metoclopramide are effective for the treatment of chronic constipation in persons with SCI.

Bladder Management
Disruption of the signals from the brain resulting from a SCI prevents normal voluntary voiding without assistance. Intermittent catheterization and spontaneous triggered voiding are associated with the lower complications compared to indwelling catheters. Intermittent catheterization may be difficult to continue at home for those with tetraplegia and complete injuries. Assistive devices may enhance compliance with intermittent catheterization for those with impaired hand function.

Pain Management
Pain following a SCI is common, often severe and has a significant effect on quality of life. A shoulder exercise protocol (consisting of shoulder stretching and strengthening) reduces the intensity of shoulder pain post-SCI. Reduce pain may be achieved from massage, heat,

acupuncture or hypnosis. A number of pharmacological agents can provide pain relief, including the anticonvulsant Gabapentin, Intrathecal Baclofen, and Lidocaine through a subarachnoid lumbar catheter. Tricyclic antidepressants and Intrathecal Clonidine have not been shown to reduce post-SCI pain.

Venous Thromboembolism

Venous thromboembolism (blood clot) is very common in untreated spinal cord-injured patients. The pharmacological agent low molecular weight heparin is more effective than standard heparin in reducing the risk of venous thromboembolism post-SCI with less bleeding complications. Physical interventions such as pneumatic compression or pressure stockings may have some additional benefits when used in combination with pharmacological agents.

Orthostatic Hypotension

Orthostatic hypotension is an excessive reduction in blood pressure with changes in body position and can result in lightheadedness or dizziness. It is commonly experienced following SCI due to the loss of muscle activation. Although a wide array of physical and pharmacological measures are recommended for the general management of orthostatic hypotension, very few have been evaluated for use in SCI. Of the pharmacological interventions, only midodrine was found to be effective, while functional electrical stimulation is one of the only non-pharmacological interventions which demonstrates some evidence to support its use.

Autonomic Dysreflexia

Autonomic dysreflexia is a potentially life-threatening acute elevation of blood pressure commonly experienced post-SCI. The identification of the possible trigger and decrease of sensory stimulation to the spinal cord is the most effective prevention strategy. Urinary bladder irritation is one of the major triggers of autonomic dysreflexia following SCI. The pharmacological agents, nifedipine or captopril are commonly used and can prevent or control autonomic dysreflexia in SCI individuals.

Heterotopic Ossification

Heterotopic ossification, the formation of pathological bone in muscle or soft tissue, occurs frequently in the first two months following SCI. Anti-inflammatory medications or warfarin (anti-coagulant) can reduce the risk of heterotopic ossification post-SCI. Once ossification is identified, the pharmacological agent, etidronate or radiation therapy can reduce the progression of heterotopic ossification.

Nutrition

There is an increased risk for obesity, abnormal lipid metabolism, cardiovascular disease, impaired glucose regulation and diabetes mellitus post-SCI. Standard dietary counseling (daily total fat <30% of total daily calories, saturated fat <10% of total daily calories, cholesterol <300 mg, carbohydrates equal to 60% of total daily calories) can reduce total cholesterol. A holistic wellness program can help people adopt healthy nutritional behaviours following a SCI. Vitamin deficiency is common post-SCI, therefore individuals should be screened and if needed, replacement therapy should be initiated.

Pressure Ulcers

Pressure ulcers are a serious, lifelong secondary complication of SCI. A number of prevention strategies exist to reduce the risk of pressure ulcers and appropriate seating is one important consideration. No one cushion is suitable for all individuals with SCI. Cushion selection should be based on a combination of pressure mapping results, individual characteristics and preference. Adding lumbar support to the wheelchairs of individuals with chronic SCI is unlikely

to have a role in pressure ulcer prevention post-SCI. A forward leaning position or the wheelchair tilted back position (> 65º) are effective methods of pressure relief.

Spasticity

Spasticity is the excessive involuntary motor activity of a muscle or muscle group reacting to external stimuli. It is a major obstacle for community and workplace integration following SC. Oral baclofen or intrathecal baclofen reduces muscle spasticity following SCI. A number of non-pharmacological interventions (transcutanous electrical stimulation, massage, assisted standing, ice) have short term effects on spasticity lasting several minutes to hours.

Outcome measures

Numerous outcome measures are available for use in SCI practice and research. Many SCI specific measures are gaining acclaim such as the Spinal Cord Independence Measure which is slowly replacing the Functional Independence Measure as the outcome of choice for assessing personal activities of daily living. Several new generic measures of participation in higher order social activities and life habits are available. These tools are conceptually well developed and support for psychometric properties is accumulating.

4. Limitations in SCI Rehabilitation Literature

The task of compiling this vast amount of literature provided the SCIRE team a unique opportunity to appraise the body of SCI rehabilitation literature as a whole. There is a substantial amount of literature available in SCI rehabilitation as highlighted in the previous section. However, the SCIRE team noted several gaps and recurring methodological issues across different topics in SCI rehabilitation and highlight these limitations here.

Our topics were selected by clinicians, researchers and consumers with SCI and not necessarily by the abundance of research papers in a particular area. Little or no information was available in several areas. Despite the inherent value we place on integrating an individual in their community, we do not know the best methods to facilitate successful re-entry into community life and literature was either absent or based on observational studies for this topic. There was also a dearth of literature concerning sexual and reproductive health of women with SCI that would potentially guide selection of contraception, enhancement of sexual adjustment and response or access to routine gynecological procedures. Women make up a significant proportion of the SCI population (one-quarter to one-third) and were underrepresented across all areas of SCI rehabilitation literature.

For many areas, we rely on information based primarily on other medical conditions. Although guidelines exist for SCI related conditions such as depression, autonomic dysreflexia, and deep vein thrombosis, many of the recommendations are based on other patient populations (not SCI). SCI is a complex condition with effects and interactions on multiple systems and responses that are not always predictable. For example, a simple dietary intervention such as increased fibre, had a response in SCI (worsened constipation) which was opposite to what would be expected in able-bodied individuals (reduced constipation).

The SCI rehabilitation literature suffers from several methodological shortcomings, including small, heterogeneous samples, few controlled trials, and a lack of consensus as to common outcome measures. Study samples consisted of people who had sustained different injuries: paraplegia and tetraplegia, complete and incomplete injuries, and acute and chronic injuries. This was prevalent throughout the current literature, despite the knowledge that physiological responses from interventions are different in these subgroups. As a result, a heterogeneous

sample can also wash out what might have been important effects for a subsample of the population. For example, bone health interventions depend on the stage of injury; preventing bone loss during the rapid bone mineral loss in the first 4-6 months compared with maintaining or improving bone during the relative stabilization after 1-2 years after SCI. However, some of the bone health studies included participants within a few months to several years post-injury representing physiologically different phases.

Pharmacological interventions were supported by the largest proportion of randomized controlled trials (level 1 evidence) while other rehabilitation interventions were primarily supported by single group, pre-test/post-test studies (level 4 evidence). Without a comparable control group, one cannot determine if improvements are attributed to the intervention or other factors such as increased familiarity with the outcome measures, time post-injury or attention from the clinician. Furthermore, randomizing the subjects into the treatment and control group reduces the biases associated with patient selection. It was not surprising to see a number of interventions where the weaker evidence demonstrated positive effects, but the more rigorous controlled trials did not. For example, lower levels of study design (pre-test/post-test study or non-randomized trial) suggested that body-weight support treadmill training in sub-acute SCI resulted in better outcomes than conventional rehabilitation; however, stronger evidence from a single-blinded RCT suggested that no differences between body weight support treadmill training and conventional rehabilitation.

Rigorous randomized trials with homogeneous groups require a large available source of patients. The number of new spinal cord injuries is relatively small compared to conditions like arthritis or heart disease. There is no doubt that multi-site trials are required if we strive to increase the certainty as to whether a treatment is effective or not in SCI rehabilitation.

There is a lack of standardization when selecting the outcome measures for an intervention. For example, the chapter authors (Hsieh et al. 2006) noted that the spasticity interventions included 66 different outcome measures. No single outcome measure can capture the multi-dimensional nature of spasticity and its effects and studies should include effective outcome measures that meet minimum standards and that encompass the range of health outcomes relevant to the treatment and the patients. In addition, consensus on some common measures would assist the interpretation of results across studies.

5. Conclusions

The SCIRE combined the efforts of expert scientists, clinicians, consumers and stakeholders to increase the accessibility of quality information in SCI rehabilitation. A broad range of topics are evaluated, and future editions will continue to update, improve and add new topics for people seeking information relevant to SCI rehabilitation from bed side to community. The pre-appraised, synthesized research from SCIRE can translate into improved health for Canadians by keeping health care professionals, scientists, policy-makers and consumers with SCI informed of the latest evidence.