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Treatment of major depressive disorder (MDD) or dysthymic disorder (DD) in spinal cord injury (SCI) patients: a protocol for a systematic review and network meta-analysis

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ABSTRACT

Introduction Although various treatments exist for depression in patients with spinal cord injury (SCI), the comparative effects and relationships between these treatments have not been clearly presented. This study aims to present comprehensive evidence for the treatment of major depressive disorder or dysthymic disorder in patients with SCI by comparing the therapeutic and adverse effects of pharmacological and non-pharmacological treatments through a systematic review and network meta-analysis.

Methods and analysis We will search for studies in five databases (Medline, Central, Embase, PsycINFO and CHINAL) as well as clinical trial registries (US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov), WHO International Clinical Trials Registry Platform (www.who.int/trialsearch)) and grey literature (Google Scholar). The references of the included studies, previous systematic reviews and meta-analyses will be reviewed. Study selection, data extraction and quality and risk of bias assessments will be independently performed by two authors (JMH and WSC), and disagreements will be resolved by discussion with JHK. Moreover, a Bayesian network meta-analysis will be performed using R software.

Ethics and dissemination Our systematic review and network meta-analysis will be performed based on existing studies; thus, we did not seek ethical approval. Our results will be published in a peer-reviewed journal and presented at both domestic and international conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a systematic review protocol for depression treatment in patients with spinal cord injury.
⇒ This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocols guidelines and the PRISMA extension statement for reporting systematic reviews incorporating network meta-analyses of healthcare interventions.
⇒ A network meta-analysis will be performed to compare the therapeutic and adverse effects of various treatments.
⇒ The heterogeneity and level of evidence of the various studies may affect the implications of our study.
⇒ It may not be possible to combine both randomised controlled trials and non-randomised controlled trials in a single network meta-analysis.

INTRODUCTION

In the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V), depression is classified as a depressive disorder[1] that requires treatment as persistent feelings of depression and hopelessness are difficult to overcome without assistance.[2] To be diagnosed with depression, either depressed mood or loss of interest or pleasure must be present for at least 2 weeks.[3] Dysthymic (persistent depressive) disorder (DD), a chronic form of depression, is a depressed mood that persists for at least 1 year in children and at least 2 years in adults.[4] Two or more of the following symptoms are presented: poor appetite or overeating, insomnia or hypersomnia, low energy or fatigue, low self-esteem, poor concentration or difficulty making decisions and feelings of hopelessness.[5]

Depression is a common illness that affects about 3.8% of the world's population.[6 7] Depression can become a serious health condition when it recurs with moderate or severe intensity, and in the worst case, depression can lead to suicide.[7] More than 700 000 people were reported by WHO to die of suicide every year.[7] Recently, the incidence of depression has been increasing worldwide[8 9]; the comparison of depression

incident cases in 1990 and 2017 showed 172 million in 1990 and 25.8 million in 2017; thus, an increased rate of 49.86% was confirmed.[10] WHO has predicted that the burden caused by depression will reach its peak in 2030.[8 9]

Depression is more likely to occur in people who have experienced adverse events such as accidents, bereavements or unemployment; various factors such as social, psychological and biological can influence the development of depression.[7] In addition, psychosocial function is reduced in individuals with severe depression,[9 11] and the likelihood of suicide ideation has been reported to be 7.8 times higher in individuals with depressive symptoms than in those without.[9 12] The severity of depression depends on many factors, such as age, sex, social status, income level, marital status and health condition. In a study analysing data of 749 491 adults with physical/sensory disabilities in Taiwan, the incidence of depression in adults with physical/sensory disabilities was 6.29 per 1000 person-years, which is 3.7 times higher than that of the general population.[13]

Spinal cord injury (SCI) is caused by a disease or a sudden accident, and physical function deteriorates according to the degree of SCI level. Most patients with SCI experience a major change in their life after the injury.[14] Depression is one of the most common mental health problems in patients with SCI, with one in five people experiencing depression a year after the onset of SCI and 40% of patients with depression during rehabilitation.[15] In addition to the temporary shock at the beginning of the disability, patients with SCI experience low self-esteem, depression, feelings of alienation and anxiety[16 17] because of impaired activities of daily living and the resultant interruption in social and economic activities.[16 18] Major depressive disorder (MDD) has been observed in more than 25% of the patients with SCI living in the community.[19 20] Depression in patients with SCI is also associated with prolonged hospitalisation and high medical costs. It has a negative impact on short and long-term rehabilitation because of high suicide risk and low motivation to return to daily life.[21–27]

For patients diagnosed with depression, pharmacological treatment should be considered the first line of treatment.[28–32] Antidepressant selection should consider the specific symptoms of individual patients and various clinical criteria.[2 33] Major considerations include target symptoms, adverse effects, efficacy and the patient's reaction to past medications.[2] Previous studies have shown that combined medication and talk therapy, cognitive–behavioural therapy and exercise programmes effectively treat depression in patients with SCI. However, further studies are needed to determine the most effective intervention for treating depression in patients with SCI.[15] Nevertheless, there has been no reliable evidence published for the therapeutic and adverse effects of medications for depression in patients with SCI. Furthermore, effective priorities of interventions for the treatment of depression in patients with SCI have not been identified to date because the effects of pharmacological treatments have not been directly compared with non-pharmacological treatments, such as exercise and psychotherapy, which have recently been in increasing demand.[2] Therefore, to provide the highest level of evidence on the treatment of depression in patients with SCI, this study aims to compare the therapeutic and adverse effects of pharmacological treatment and non-pharmacological treatment for MDD or DD in patients with SCI through a systematic review and network meta-analysis.

Review question

Which treatment is most effective for the treatment of MDD or DD in patients with SCI?

Objective

This study aims to compare the therapeutic and adverse effects of pharmacological and non-pharmacological treatments for MDD or DD in patients with SCI through a systematic review and network meta-analysis and to provide the highest level of evidence on the treatment of depression in patients with SCI.

METHODS AND ANALYSIS

We report this protocol according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocols guidelines[34] and the PRISMA extension statement for reporting of systematic reviews incorporating network meta-analyses of healthcare interventions.[35]

Study eligibility criteria

Inclusion criteria

Types of participants

We will include studies with adult patients (≥18 years old) with SCI and MDD or DD regardless of SCI aetiology. In addition, we will include studies with patients who have been diagnosed with MDD or DD based on the DSM-III[36] or more recent criteria (including cases diagnosed using evaluation tools other than the DSM developed after 1980). The period after diagnosis of SCI in patients in previous studies will not serve as a limitation.

Types of study designs

We will include randomised controlled trials as well as non-randomised controlled trials. Before-and-after studies, quasi-randomised trials and case reports will be excluded.

Types of interventions

Antidepressants (selective serotonin reuptake inhibitors (SSRI), serotonin-norepinephrine reuptake inhibitors (SNRI), tricyclic antidepressants (TCA), mirtazapine, agomelatine, bupropion, vortioxetine, moclobemide, tianeptine, trazodone), atypical antipsychotics (quetiapine, aripiprazole), lithium, thyroid hormones (cinacalcet, lecithin iodide, levothyroxine, liothyronine, potassium iodide) and psychostimulants (methylphenidate, modafinil) have been selected as intervention drugs

according to the guidelines for the treatment of depression from the Korean Academy of Medical Sciences.[37]

Comparisons

The comparator for this study intervention is placebo or any other intervention, including non-pharmacological treatment, such as exercise and psychotherapy.

Outcomes

Primary outcome

- Severity of depressive symptoms.

Secondary outcome

- Anxiety.
- Pain.
- Sleep disorder.
- SCI-related disability.
- Social participation.
- Quality of life.
- Adverse effects.
- Adherence and tolerability.

Exclusion criteria

- Studies that did not report separate outcomes for patients with SCI and MDD or DD.
- Studies that applied the DSM-II[38] or earlier diagnostic criteria.
- Studies containing data that cannot be extracted, and the correct data cannot be obtained by contacting the authors.

Information sources

We will search for studies in five databases (Medline, Central, Embase, PsycINFO and CHINAL) as well as clinical trial registries (US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov), WHO International Clinical Trials Registry Platform (www.who.int/trialsearch)) and grey literature (Google Scholar). The references of the included studies, previous systematic reviews and meta-analyses will be reviewed. Studies conducted since the development of the DSM-III in 1980 will be included.[36]

Search strategy

The search strategy was established by author JMH using keywords related to SCI, depression, antidepressants, atypical antipsychotics, lithium, thyroid hormones, psychostimulants, exercise, psychotherapy, etc. The full search strategy is presented in online supplemental appendix 1. Author JMH will collect studies using these search strategies and will remove duplicate studies.

Data management

ENDNOTE V.X9 will be used for the study selection and reference management. In addition, studies retrieved through database search will be managed with ENDNOTE V.X9. Duplicate studies exclusion will be carried out in two steps: (1) using the automatic deduplication function of ENDNOTE V.X9 and (2) comparing authors, year, data, etc.

Selection process

The study selection process will consist of two steps (step 1: reviewing titles and abstracts; step 2: full-text review). First, two review authors (JMH and WSC) will independently screen the study titles and abstracts. Two authors (JMH and WSC) will independently review the full texts of the selected studies based on the title and abstract, and the results will be reviewed and reported by JMH. Disagreements in the study selection process between the two authors will be resolved by discussion with author JHK. Our study selection process will be reported using a PRISMA flow diagram.

Data collection process

Data collection will be independently performed by two authors (JMH and WSC). Disagreements in the data extracted by the two authors will be resolved by discussion with JHK.

Data items

The following types of data will be collected: methodology (eg, date of the study, study design, study setting, total study duration, details on the duration of the intervention, research centre, location and withdrawals); participants (eg, the total number and number of each group, inclusion and exclusion criteria, mean age, age range, severity and duration of the condition, diagnostic criteria, physical or mental comorbidity, duration of SCI); intervention (eg, number of intervention groups, types of interventions and comparisons, critical details about the intervention (eg, dosage, compliance, delivery quality, concomitant drugs and prohibited drugs); results (eg, details of outcome measurement, outcomes, timing of outcome measurement and reporting, and adverse events); analysis (eg, statistical techniques, unit of analysis for each result); and other (eg, type of publication and year of publication, authors and journal, funding for the trial and notable conflicts of interest of trial authors).

Outcomes and prioritisation

We will include studies evaluating intervention outcomes using well-established and validated questionnaires. The primary outcome is the severity of depressive symptoms (eg, it could be the Patient Health Questionnaire-9 Item, Hamilton Depression Rating Scale or Maier-Philipp Severity subscale). Secondary outcomes are anxiety (eg, it could be the Generalised Anxiety Disorder-7 Scale), pain (eg, it could be the Visual Analogue Scale), sleep disorder (eg, it could be the General Sleep Disturbance Scale), SCI-related disability (eg, it could be the Sheehan Disability Scale), social participation (eg, it could be the Craig Handicap Assessment and Reporting Technique), quality of life (eg, it could be the EuroQol-5Dimention or WHO Quality of Life assessment instrument), adverse effects, adherence and tolerability. If at least one of the outcome lists presented by us is also presented in the

primary literature, we plan to analyse and include it in the study.

Geometry of the network

A network plot, which is mainly composed of nodes and lines, where the size of the node represents the number of subjects, and the thickness of the line represents the number of studies,[39] will be drawn using R V.4.1.1. software.

Risk of bias within individual studies

Two authors (JMH and WSC) will independently assess the risk of bias in randomised controlled trials. This will be accomplished using the Cochrane risk of bias tool for randomised trials (RoB) version 1.[40] This consists of seven evaluation domains (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other bias). The risk of bias in non-randomised controlled trials will be assessed by two authors (JMH and WSC) using the Risk of Bias Assessment tool for Non-randomised Studies,[41] which consists of six domains (selection of participants, confounding variables, measurement of intervention, blinding for outcome assessment, incomplete outcome data and selective outcome reporting). The results of assessment will be reviewed and reported by author JMH, and disagreements between the two authors will be resolved on discussion with JHK.

Summary measures

We will use OR and 95% CIs for dichotomous outcomes. For continuous outcomes, we will use standardised mean differences with 95% CIs (if studies measure the same outcome using different tools) or use mean differences with 95% CIs when all studies used the same measurement tool. To rank the treatments for each outcome by probability of best treatment, we will use the surface under the cumulative ranking curve and the mean ranks.

Planned methods of analysis

Pairwise analysis

For pair-wise analysis, we will use RevMan V.5.4. We will choose a random-effect model or a fixed-effect model, according to the degree of heterogeneity. In cases where significant heterogeneity exists, a random-effect model will be used. In cases where there is no substantial heterogeneity, a fixed-effect model will be used. If pairwise analysis is not possible, we will report a narrative review of the findings according to the synthesis without meta-analysis guideline.[42]

Network meta-analysis

A Bayesian network meta-analysis will be performed using the package 'gemtc' of R V.4.1.1. software. We will conduct a Markov chain Monte Carlo simulation,[43] and run both random-effects and fixed-effect models, according to guidance from the National Institute for Health and Care Excellence decision support unit documents.[44] In order to improve the completeness of our research, we will report the results of both models. The model convergence will be assessed using the Gelman-Rubin plots method.[45–47]

Assessment of heterogeneity

According to the Cochrane handbook, we will perform a heterogeneity assessment using the τ^2 statistic in network meta-analyses and the χ^2 test and the I^2 statistic in pairwise analysis. Further, the I^2 statistic will be interpreted as follows.[48]

- 0%–40%: might not be important.
- 30%–50%: may represent moderate heterogeneity.
- 50%–90%: may represent substantial heterogeneity.
- 75%–100%: considerable heterogeneity.

Assessment of inconsistency

Consistency is a special type of heterogeneity to converge direct and indirect comparisons.[49 50] Consistency testing is an important tool for identifying the applicability of network meta-analysis results.[43] Therefore, we will perform a consistency test using the method presented by Bucher to statistically test the differences between direct and indirect comparisons (in pairs by each treatment) to demonstrate the significance of the network meta-analysis results.[50]

Risk of bias across studies

The possibility of publication bias will be evaluated by visual inspection of funnel plot.[50] In addition, the risk of bias assessment tools will identify whether studies indicate selective reporting of outcomes.

Additional analyses

- Sensitivity analysis: We will perform sensitivity analyses to test the robustness of our review findings.
  - The analysis excluding non-peer reviewed studies.
  - The analysis excluding studies high risk of bias in almost domains.
  - The analysis to compare the results of the random-effects model and the fixed-effect model.
  - The analysis excluding missing data.
- Subgroup analysis: We will conduct the following subgroup analyses for primary outcomes.
  - Sex (male, female).
  - Level of injury (cervical, thoracic, lumbar).
  - Marital status (married, single).
  - Employment status (employed, unemployed).
  - Class of antidepressant (SSRI, SNRI, TCA, Monoamine oxidase inhibitor (MAOI), etc).

Confidence in cumulative evidence

We will evaluate the level of evidence (or quality) using the Grading of Recommendations Assessment, Development and Evaluation approach. The level of evidence will be rated as high, moderate, low or very low.[51] Factors that reduce the quality of evidence include risk of bias, indirectness, inconsistency, imprecision and publication bias. In addition, three factors promote the level of evidence: large effect size, dose–effect relationship and related confounding.[52]

DISCUSSION

Evidence synthesised through systematic review and network meta-analysis at the level of scientific persuasion is evidence with the highest level of confidence.[53 54] The results derived through network meta-analysis play an important role in evidence-based decision making.[53 55 56] Therefore, our results obtained through the systematic review and network meta-analysis will be helpful in making important decisions in the treatment of depression in patients with SCI. Furthermore, our results may provide vital evidence that can be used to assist policy makers and clinical specialists in decision-making for managing patients with SCI and MDD or DD.

Ethics and dissemination

Our findings will be submitted for peer-reviewed publication. Deviations from the study protocol will be noted in the manuscript. Findings will be disseminated through conference presentations. Ethical approval and patient consent are not required since this is a systematic review and network meta-analysis based on published studies.

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Contributors JHK and HC planned the study. JMH and JHK conceptualised the systematic review and network meta-analysis. JMH wrote the protocol, with critical inputs from JHK. B-HJ contributed to performing the expert review for this protocol. JHK, JMH, CHS, WSC, H-JK, JYP, YSK and HJJ reviewed the final protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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