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ABSTRACT

Introduction Currently, there are very few published studies on preinjury and postinjury assessments of quality of life (QoL) based on a prospective appraisal; specifically, knowledge of those who do not seek medical care following injury is lacking. To close these knowledge gaps, this study aims to identify the psychosocial consequences in terms of loss of QoL following injury in a Swedish population and to investigate the response shift in retrospective measures of self-reported QoL.

Methods and analysis We will analyse preinjury and postinjury (including both minor and severe unintentional injuries as well as different injury mechanisms) assessments of QoL, including the phenomenon of response shift, using register-based data from the nationwide collaboration project LifeGene, which includes over 52 000 individuals living in Sweden. In addition to LifeGene data, a short online survey including a 'ThenTest' questionnaire, that is, comparison of previous QoL to current using EuroQoL five-dimensional questionnaire, was sent out to the participants of LifeGene. This study will provide a unique opportunity to study the changes in QoL by comparing preinjury and postinjury assessments using a prospective appraisal, both for populations who have sought medical care as well as those who have not due to their injury. Similarly, the study will also assess the response shift in retrospective measures of QoL. This information can guide the next generation of QoL measures and interventions for those suffering injuries and have an impact on how to interpret evaluations of interventions.

Ethics and dissemination The study has been reviewed and approved by the Regional Ethical Review Board in Stockholm, Sweden (case number 2018/352-31), The results will be disseminated through peer-reviewed journals, conference presentations, print media and internet and via a report for the funding agency.

INTRODUCTION

The improvements in road safety during recent decades have led to higher survival rate following injury, with an increasing need for rehabilitation both for physical injuries and psychological consequences. The physical impact of an injury is well known, but its effects on the individual's perception of his

Strengths and limitations of this study

- ► This study offers the unique opportunity to study outcomes on an individual level as well as to provide access to assessments prior to specific events.
- Register-based data provide the opportunity to assess preinjury quality of life (QoL) with the absence of attribution and recall bias.
- The analysis of response shift will provide key information to help the understanding of measured QoL in persons with injuries, which can be used both in relation to self-reported QoL measures and interventions addressing QoL.
- As the LifeGene database is not dependent on hospital admission, it will become possible to study the impact of injury in the population that did not seek medical care for their injury but who might still have developed psychosocial reactions due to the trauma they have experienced not considering the physical
- Given the inclusion of participants to the LifeGene project, one of the limitations we need to consider is the risk of volunteer bias, which could affect the generalisability of the study results.

or her working life, social relationships and financial situation are not as well understood. By focusing on the individual's self-reported health, it is possible to get a broader picture of the sequel of the injury on people's lives. One way of doing this is by measuring self-reported quality of life (QoL) following an injury. QoL is a multidimensional construct that considers the 'individual's perception of their position in life in the context of the culture value system in which they live and in relation to their goals, expectations, standards and concerns'.

To assess the current knowledge on the relationship between QoL and road traffic injury and to appraise how QoL is affected by traffic injury, we conducted a systematic literature review including literature on road traffic injuries as the cause of trauma.³ We identified a total of 30 articles, which confirmed that irrespective of measure, the overall QoL was significantly reduced after a road traffic injury compared with the general population norms. This is congruent with literature from other causes of trauma, where there is growing evidence that injuries have a detrimental impact on QoL. ⁴⁻⁶

The difficulty in conducting research measuring QoL after injury is that it may be influenced by other factors than just the injury. Attribution bias, as this is called, may be overcome by measuring the change of QoL from the preinjury to postinjury; however, prospectively collected preinjury QoL data are difficult to obtain.³ To our knowledge, there are only two international publications on QoL following injury that have included a preinjury assessment of OoL, which has been based on a prospective appraisal.⁸⁹ Instead, studies, which have included preinjury assessments of QoL, have asked the patient to report QoL retrospectively after the injury, ^{4 5 10} for example, by using the 36-item Short Form (SF-36) instrument, which considers the previous 4weeks. With this method, there may be ambiguous and paradoxical findings. For example, two studies found that the retrospective preinjury QoL was higher than the general population norms. These findings might be due to participants remembering their preinjury QoL as better or worse than it actually was (recall bias) 13 or the person's perception of QoL might have been altered after the injury due to a change in the internal standards, that is, response shift. Response shift refers to the change in one's self-evaluation of QoL. 14 15 This is due to a change in the internal standards (recalibration), values (reprioritisation) or definition of QoL (reconceptualisation). The response shift theory has been used to explain why high QoL scores have been found in people with various conditions. 12 14 15 Although several studies have acknowledged the possibility of response shift in the interpretation of their results, more research is needed on the phenomenon.¹⁴ 15

Furthermore, little is known about the trauma population that does not seek medical care for their physical injuries. Majority of the studies on QoL after a trauma have been conducted among populations of patients admitted to the hospital^{5 16 17} or claimants of insurance schemes. ^{18 19} Even though it has been acknowledged that both minor and severe injuries contribute to the health burden,⁵ few studies have included different levels of injury severity and a mixed sample of trauma population. This paper presents the design of a register-based cohort study on the impact of injury that will aim to:

- ▶ Assess the QoL both preinjury and postinjury and compare it with both a population who has not reported an injury and to the Swedish general population norms.
- ► Investigate the response shift in retrospective measures of self-reported QoL.
- ► Identify predictors of QoL after injury among demographic data, injury characteristics and psychological and comorbidity variables.

Assess the psychological consequences of injury by the use of antidepressant medication preinjury and postinjury.

Study design and method

This is a register-based cohort study in which data retrieval started in 2018 and the study is estimated to end in 2019/2020. We will use register data from the LifeGene project. LifeGene is a nationwide collaborative project designed to develop a resource for research in all medical disciplines. Resources at LifeGene include information concerning health, lifestyle and exposures, and donation of biological samples.

The inclusion mode to LifeGene is threefold: invitation by random selection (approximately 44% of participants), volunteering (36%) and invitation by another participant (20%). The randomisation is based on the national population register in Sweden (ages 18–50 years). People also have the opportunity to register for participation in LifeGene via LifeGene's homepage (www.lifegene.se), and participants already registered in LifeGene have the opportunity to invite people to LifeGene, both adults and children. LifeGene has currently (2018) recruited more than 52100 participants (including children), of whom 34000 have fully completed the online questionnaire and more than 22000 participants have visited a test centre for donation of biological samples. LifeGene's baseline assessment involves an extensive range of questions and measures as well as the collection of biological samples that allow many different types of assessments and analysis. The majority of participants in the LifeGene project are aged between 25 years and 50 years and were women $(59.1\%)^{20}$

Inclusion criteria

Participants over the age of 18 years who have reported an injury in the LifeGene assessment and have at least one preinjury assessment of QoL registered.

A preliminary search of the LifeGene database indicated that approximately 3000 participants had suffered an injury (injury measure described more in detail below), hence expected to be included in the current study. The expected participation rate in the current study is 50% based on the voluntariness of the LifeGene project. Based on previous studies conducted in the research group on injuries impact on QoL, a medium effect size of QoL is expected (d=0.59). With an alpha set at 0.05 and a medium effect size of d=0.59, the estimated power in the study is 1, given that 50% of participants (n=1500) suffering an injury in LifeGene will participate in the current study.

Exclusion criteria

Participants under the age of 18 years and participants over the age of 18 years with a reported injury in their first LifeGene assessment, that is, participants with no QoL assessment before the injury, and participants who have not completed the QoL assessments during the

follow-up or have requested to exit the LifeGene project or deceased.

Control group

In addition to the participants who have reported an injury in the LifeGene project, a control group will be included in the study. This control group comprises all of the participants who have *not* reported an injury in the LifeGene project and who have answered the QoL assessment.

Patient and public involvement

Patients and the public were not involved in the design or planning of the study.

Measures

LifeGene data

Variables included from LifeGene consist of those from the general module (sex and age), sociodemographic (family, education, work history, unemployment and sick leave), lifestyle (general health and overall health state, including the EuroQoL five-dimensional questionnaire (EQ5D)), injury, mental health (depression, anxiety, Post-Traumatic Strss Disorder (PTSD) and traumatic life events) and medical history modules.

Quality of life

QoL will be assessed by the EQ5D, which is a validated standardised measure of self-rated health.²³ The EQ5D assesses QoL in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems and extreme problems. A single summary index can be retrieved by applying a weight to each of the levels in each dimension. EQ5D is one of the most commonly used instruments in studies assessing QoL for those who have suffered injuries.³

Injury

In the current study, we will include all type of unintentional injuries, for example, road traffic injuries and sports injuries, hence excluding injuries of self-harm and violence. Injury was defined by a self-reported question included in all of the LifeGene follow-ups. Participant were asked to indicate if they had suffered an injury during the past 12 months. Other injury-related variables included a statement (free text) of the cause of the injury and a dichotomised variable indicating if the participant has sought medical care for their injury.

Online questionnaire

A short questionnaire will be distributed as an online survey to all participants, including the 'ThenTest' questionnaire, that is, comparison of previous QoL to current using EQ5D.²³ The 'Then-Test' will incorporate two components in which the participant will first be asked to assess their QoL prior to the injury by a modified EQ5D and then to compare their preinjury QoL to their current QoL by stating if their QoL is better than before

the injury, the same or worse than before the injury. The EQ5D has been modified regarding the wording of the time frame in the introductory statement, that is, please indicate which statement best describe your own health state prior to the injury. The questionnaire will also include questions about the consequences of the injury, in terms of pain and the use of medication postinjury. These questions include assessment of experiencing pain following the injury in the back and neck, upper and lower extremities and headaches. Each assessment asks the participant to indicate pain for the location via a yes/no radio button option. Following each of the pain assessments, participants will be asked if they have used any pain relief medications for each specific pain reported. This assessment includes how often and what type of pain relief they have used. Moreover, insomnia and medication for insomnia will also be assessed in the same manner as pain and pain relief via the online questionnaire.

Register data

In addition to the previously mentioned variables from the LifeGene project, we will combine the data from LifeGene with data from the National Patient Register, the Swedish Prescribed Drug register and the Cause of Death register, held at the National Board of Health and Welfare. The National Patient Register contains information on patient data (Swedish identification number, gender, age and place of residence), geographical data, (county, hospital and department), administrative data (inpatient and outpatient data) and medical data (diagnosis, external cause of injury and procedures). Hence, it will become possible to identity medical data relating to injuries if the participant has sought care for their injury.

The Drug registry contains information on prescribed and dispensed medicines, including drug utilisation and expenditures for prescribed drugs in the entire Swedish population. The Cause of Death register contains information on underlying cause of death, coded according to the International Classification of Diseases (ICD-10) and for injuries; the external cause of injury is also recorded.

Data from each register will be retrieved by the register holders and merged by the National Board of Health and Welfare, who will deliver deidentified data to the researchers for analyses. According to Swedish regulations the key for reidentification is held 3 months by the register holder and then destroyed, and no future reidentification is possible.

Data analysis

All analysis will include a complete case analysis, meaning that only participants who have completed all QoL assessments (included in the current study) in LifeGene will be included. Hence, excluding deceased and those who have exited the LifeGene project during the follow-up period. To analyse the preinjury and postinjury QoL, we will include all participants who report an injury after their first QoL assessment in LifeGene. This will allow us to assess both the level of QoL preinjury and the absolute

loss of QoL in comparison with the preinjury levels. The analysis of the absolute levels of QoL loss will provide information regarding how much QoL a person may lose in absolute terms compared with their preinjury assessment; hence, we can assess how persons with high versus low preinjury QoL scores are affected by the injury. Is the loss of QoL the same, independent of preinjury score or are some groups affected more, for example, those with low/high preinjury scores? Moreover, the preinjury and postinjury QoL scores will be compared with the control group and with previously established general population norms in Sweden, which will give us a deeper understanding of the psychological consequences, in terms of QoL following injury.

Response shift will be investigated both by a new assessment of QoL measured by EQ5D and by structural equation modelling (SEM). By adding an additional measure of QoL, we will be able to compare their current QoL with participants preinjury QoL and to retrospectively rate their QoL prior to the injury. Moreover, assessing response shift with SEM²⁴ will allow us to understand the changes in internal standards, values and conceptualisation over time for different groups concerning injury variables.¹⁵

A stepwise regression analysis will be performed to determine how much of the variance in QoL can be explained by injury characteristics, socioeconomic variables and psychological and comorbidity variables. Variables included in the analysis are selected based on their predictive value as reported by previous studies.³

Lastly, the psychological consequences following injury will be investigated with the use of antidepressant medication (with Anatomic Therapeutic Chemical (ATC) codes starting with 'N06A'), both preinjury and postinjury. The use of antidepressant medication will serve as a proxy for the psychological consequences of the injury. By using the proxy of antidepressant usage, it will be possible to identify the psychological consequences for both those who have sought medical care when injured as well for those who did not seek medical care in proximity to their injury. We will identify the supply date for the first antidepressant for each individual who has reported an injury in LifeGene. This could range from 365 days before the injury to 365 days after the injury. To determine the overall usage of antidepressants within the sample, the usage will be expressed as the defined daily dose (DDD) per 1000 person-days. Tests for statistical differences in DDD (both preinjury and postinjury) will be conducted.

When appropriate, we will consider possible confounders in the analyses. These confounders include sex, age, relationship status and socioeconomic status (including highest education, employment status and category). For the fourth aim, we will also consider smoking status, as smoking has previously been shown to be associated with the use of antidepressant medication in other study populations. ^{25–27}

Ethics and dissemination

All participants included in the study have previously given their consent to the LifeGene project, and no new participants will be asked for participation in the current study. All participants who have reported an injury after their first assessment in LifeGene will be initially contacted via email by LifeGene, and a written consent for the current study will be requested. Thereafter, participants will be asked to fill out the questionnaire, distributed as an online survey. No written consent will be needed for the control group, that is, those who have not registered an injury in LifeGene, since we will only use register data already collected in the LifeGene project.

The results will be disseminated through peer-reviewed journals, conference presentations, print media and internet and via a report for the funding agency.

DISCUSSION

This project will provide a unique opportunity to study the absolute changes in QoL, both preinjury and postinjury and to assess the response shift in retrospective measures of QoL. These are areas of research that have been limited due to methodological constraints. To our knowledge, there are only two publications^{8 9} that have included a preinjury assessment of QoL, which has not been assessed by a retrospective appraisal. Since the retrospective preinjury assessments of QoL have been recognised as problematic due to the high risk of bias and response shift,²⁸ this project will provide an opportunity to assess the possible response shift in QoL following an injury by using a prospective preinjury assessment.

Strengths and limitations

The population-based registers in Sweden offer a unique opportunity to study outcomes on an individual level as well as to provide access to assessments prior to specific events. By using register-based data, it will be possible to identify individuals with a QoL assessment prior to their injury and hence get a 'true' preinjury assessment of QoL and assess the response shift regarding QoL. Hence, register-based data will also provide the opportunity to assess preinjury QoL with the absence of attribution and recall bias; such biases are difficult to control for in retrospective studies measuring QoL. Moreover, the approach is also beneficial in comparison with methods where normative values from the general population are used as a reference point for comparison of health status before injury. The application of population norms or matched non-injured comparison samples may introduce biases since populations with injuries may differ from general and non-injured populations. Previous research indicate that the preinjury health status of people with an injury is worse than for their counterparts, due to higher rate of comorbidities, hospitalisation and health service utilisation prior to their injury.^{29 30} However, people who suffer from injuries might be healthier and more active than the non-injured population, hence, exposing them to higher risk of injuries. One of the strengths of this study is that it will be possible to measure QoL in absolute terms and compare this with the general population norms.

In addition, as the LifeGene database is not dependent on hospital admission, a variation in injury severity and type of trauma, with or without hospital admission, is expected. Therefore, it will be possible to study the impact of injury in the population that did not seek medical care for their injury but who might still have developed psychosocial reactions due to the trauma they have experienced not considering the physical injury. However, there are limitations to this study, which need to be considered.

Given the inclusion of participants to the LifeGene project, one of the limitations we need to consider is the risk of volunteer bias, that is, that the volunteer in the study does not represent the general population. Although a part of the population in LifeGene have randomly been selected from the national population register in Sweden, participants have also had the opportunity to volunteer for the project by registering for participation via LifeGene's homepage; moreover, participants already registered in LifeGene have had the opportunity to invite people to LifeGene, both adults and children, hence the risk of volunteer bias. Although there is a risk for volunteer bias in the LifeGene project, the inclusion of randomly selected participants from the national registers is one counter measure by which this type of bias can be minimised. Another measure to minimise volunteer bias is by ensuring confidentiality for the people in the study, which the LifeGene project offers. Moreover, previous research on e-cohorts have shown that volunteers in these types of studies are more often female, have a higher educational level, are less likely to be current smokers and are more likely to be in excellent health compared with the general population. 31 32 Hence, it is important to consider the risk of the participants in the LifeGene project being systematically different from the target population when reporting the findings. However, this study offers a unique opportunity to study QoL prior to an injury. To our knowledge, there are only two international publications on QoL following injury that have included a preinjury assessment of QoL, which has been based on a prospective appraisal; thus, this study will provide new knowledge regarding preinjury QoL and the response shift in an injured population.

CONCLUSIONS

The purpose of this study is to assess the preinjury and postinjury QoL and to assess the response shift in retrospective QoL measures following injury; it also offers the unique opportunity to study outcomes on an individual level as well as to provide access to assessments prior to specific events. On a long-term scale, the knowledge gained from this project will provide new knowledge and broader understanding of the psychological consequences following an injury for various types of traumas. Furthermore, it will allow us to identify the need for, as

well as optimise, the psychosocial rehabilitation for those affected due to an injury. Analysis of the response shift will provide key information to help with the understanding of measured QoL in persons with injuries. This information can be used both in relation to self-reported QoL measures and interventions addressing QoL.

Contributors RR conceptualised the project and drafted the manuscript. MH reviewed and edited the manuscript. Both authors read and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

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