

BMJ Open The impact of road traffic injury in North India: a mixed-methods study protocol

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ABSTRACT

Background: Road traffic injuries are a large and growing public health burden, especially in low and middle income countries where 90% of the world's deaths due to road traffic injuries are estimated to occur. India is one of the fastest growing economies, with rapid motorisation and increasing road traffic burden. However, there are limited data addressing the problem of non-fatal road traffic injuries, with existing data being of poor quality, non-representative and difficult to access, and encompassing a limited number of relevant variables. This study aims to determine the outcomes of road traffic injuries on function and health-related quality of life, to assess their social impact and to weigh the economic cost of road traffic crashes in an urban setting in India.

Methods and analysis: This prospective observational study will recruit approximately 1500 participants injured in road traffic crashes, who are admitted to hospital for >24 h at any of three participating hospitals in Chandigarh, India. Face-to-face baseline interviews will be conducted by telephone at 1, 2, 4 and 12 months postinjury. Standardised tools will be used to collect data on health and social outcomes, and on the economic impact of road traffic crashes. Descriptive analysis and multivariate models will be used to report outcome data and associations. The qualitative in-depth interviews will be analysed thematically using content analysis. This study will provide the first comprehensive estimates on outcomes of serious road traffic injury in India, including economic and social costs, and the impact on individuals and families.

Ethics and dissemination: Primary ethics approval was received from the Postgraduate Institute for Medical Education and Research, institute's ethics committee, Chandigarh, India. Results will be disseminated via the usual scientific forums including peer-reviewed publications and presentations at international conferences.

BACKGROUND

The WHO estimates that over 1.2 million people die each year on the world's roads, and between 20 and 50 million fall victim to

Strengths and limitations of this study

- This study provides the first estimates of outcomes of serious road traffic injury in India, including economic and social costs, and the impact on individuals and families.
- It uses validated tools at regular intervals for comprehensive estimates.
- Systems cost will not be generated through this research work.
- Quality of life of carers will not be comprehensively captured using the protocol.

non-fatal injuries.¹ The WHO projects that, unless immediate action is taken, traffic crashes will increase from the ninth to the fifth leading cause of death by 2030, and will then cause around 2.4 million deaths per year.¹ Road traffic injuries (RTI) are also projected to rise to the third leading cause of disability-adjusted life years (DALYs) lost worldwide by 2020.² The burden of traffic crashes, in terms of mortality and morbidity, is increasing fastest in developing countries, due to rapid motorisation associated with economic growth.^{3 4}

The situation is particularly acute in India, a nation of more than 1 billion people, with one of the fastest growing economies in the world. This economic growth has also meant a rapidly increasing number of vehicles sold every year (around 6 million) and one of the highest reported mortality rates from RTI in the world.⁵ Road traffic fatalities in India increased by about 5% per year from 1980 to 2000 and then by about 8% per year to reach 105 725 in 2006 with the mortality rate increasing from 36/million persons in 1980 to 95/million persons in 2006.⁶ Non-fatal injury is a more common consequence of road crashes than death, and injuries sustained are often severe. The incidence of RTI remains poorly measured in India, though the number of people injured in

road traffic crashes in 2006 was estimated to exceed 450 000. Cautious interpretation is necessary, as previous studies have found traffic crashes to be under-reported in India by 5% for deaths and more than 50% for serious injuries.⁷

Weak or no estimates of morbidity due to road traffic crashes is a common problem in low and middle income countries (LMICs), where data sources are often of poor quality, non-representative, difficult to access and contain a limited number of relevant variables.⁸

A review of four studies in India estimated the cost of traffic crashes in the country to be between 0.29% and 0.69% of the gross domestic product (GDP), and identified a number of limitations related to the methods used.⁹ At least two studies used rudimentary methods of cost analysis that omitted many components of the cost of traffic crashes. The studies were each for a single locality, had small sample sizes, focused mainly on direct costs, and did not take into account the impact on families or estimate the injury burden. A study by Reddy *et al*¹⁰ examined direct and indirect costs related to traffic crashes based on interviews with victims and their families instead of relying on secondary data. However, that study shared limitations of the previous studies on cost of traffic crashes in India including small sample size (148 crashes), the localised nature and the lack of estimates related to disability mainly due to the cross-sectional nature of the study. More importantly, each of these previous studies adopted a patient perspective in estimating the economic cost. None of them estimated the health system cost of delivering treatment to patients with RTI. Since the curative care for patients with injury at public sector hospitals is highly subsidised by the Government, patients' costs do not include the true costs of the gamut of resources that are spent on patient care.

As reviewed above, the gaps in knowledge result both in underestimation and limited understanding of the burden of injury, limiting the capacity to inform policy development and capacity building for medical management, rehabilitation and support services. Given the potentially catastrophic effects of injuries on families and communities in such settings, particularly among those of low socioeconomic status, there is a need to study non-fatal outcomes in LMICs settings in order to inform the public health response to RTI.¹¹

AIMS

The aims of this study are to describe:

1. The impact of RTI on function and health-related quality of life (HRQoL) in urban settings in India;
2. The social impact of RTI on victims and their families, including their participation and utilisation of health and social services;
3. The economic cost of RTI using the human capital approach, including the direct and the indirect costs to individuals and their families.

METHODS/DESIGN

This is a prospective observational study.

Study settings

Participants will be recruited from patients with RTI admitted to a hospital in Chandigarh (Advanced Trauma Centre, Postgraduate Institute of Medical Education and Research) and two secondary care public sector hospitals, one each in Chandigarh and Panchkula, during a 4-month period beginning in April 2014.

The study involves recruitment of patients of all ages admitted to hospital for at least 24 h due to a RTI. All types of road users injured as a result of a traffic crash will be eligible for participation. Eligible participants will be identified by trained research staff located in emergency departments; the staff will also review admissions registers daily. The research staff will explain the study and the consent process to prospective participants, and invite them to participate. For participants who are unable to give informed consent due to injury, consent will be sought from a proxy (relative or carer) and consent will be sought from the patient when he or she is able to give or withdraw it. For children aged less than 18 years, consent will be sought from the carer/guardian, and from the child to the extent of the child's capabilities from the age of 7 years up to the age of 18 years, as per Indian Council of Medical Research ethical guidelines.¹²

Approximately 1500 patients from the three hospital sites will be approached to join the study over the 4-month period. Stratification for follow-up will be determined by the prevalence of key variables of interest in baseline data (road user group, severity of injury, age, gender and socioeconomic status) to ensure the study has sufficient power to describe, with precision, measures of function, HRQoL and cost in the longitudinal sample across these factors. The sample size calculations are for 90% power, to detect independent effects of about 5% of the size of the variable in multiple linear regression analysis. These calculations are based on experience from a pilot study.

Recruitment procedures and follow-up

All baseline, interviews will be administered face-to-face at the hospital and subsequent interviews will be conducted by telephone. Trained staff will conduct the telephone interviews to collect data from the injured (or from a proxy where appropriate) at standardised time points over the first 12 months (at 1, 2, 4 and 12 months), selected based on the recommendations of a previous injury outcomes study consensus paper.¹³ If the participant dies during follow-up, his or her family will be asked to complete the final interview at 12 months to ascertain impact of RTI-related mortality. Patient recruitment and follow-up will be conducted by appropriately qualified and trained research assistants.

Where possible, the following information will be collected for patients who do not consent to the follow-up

study: sex, age, place of injury and type of injury, to establish any biases in the participating sample.

Measures

All measures recorded are reported in [table 1](#).

Baseline interview

The interview administered in hospital will collect participants' demographic information as well as information related to the circumstances of the traffic crashes. Data will (where possible) be collected directly from participants or their carers. Items will include age, gender, education, occupation, household income and consumption expenditure, road user type and vehicle counterpart, use of alcohol and other drugs in the hours prior to the injury, use of safety devices at the time of the crash, setting of accident, road type and time of day. Preinjury HRQoL, the use of health and social services in the 4 weeks prior to the injury, and contact information for follow-up interviews, will also be obtained. The trained research assistants at each site will extract data from the medical records on date and time of injury, type of injury, anatomical site of the body, comorbidities, length of the hospital admission as well as diagnosis and treatment procedures, and will score injury severity according to the Abbreviated Injury Scale (AIS 2005-Update 2008).

Follow-up interviews

Subsequent follow-up interviews posthospital discharge will include measures of quality of life, functioning and disability, economic costs and social impact. Interviews will be conducted by trained research staff.

Quality of life, functioning and disability

To measure HRQoL, we will use the EuroQOL five dimensions questionnaire (EQ-5D), the Pediatric Quality of Life Inventory (PedsQL) and the WHO Disability Assessment Schedule 2.0 (WHODAS II), which have been translated into Hindi. Functioning will be measured according to the Glasgow Outcome Scale—Extended (GOSE), and its paediatric version (King's Outcome Scale for Childhood Head Injury, KOSCHI). These instruments were selected because they cover most of the important dimensions of quality of life, function and disability, as defined by the International Classification of Functioning, Disability and Health (ICF), they are applicable to a broad range of injuries and age groups, and they have been recommended as being valid and appropriate measures of the impact of injury.^{13–16} The EQ-5D will be used to produce a single utility score between <0 and 1 based on individuals' responses to questions regarding the impact of RTI on their lives. The paediatric measures will be completed by the parents, as well as by any children aged 5 years and

Table 1 Data collected at baseline and follow-up

Baseline (face-to-face)	
Sociodemographic	Age, sex, place of birth, primary language, education, marital status
Employment	Employment status, occupation, household income
Health	BMI (height and weight), history of chronic illness
Lifestyle habits	Smoking status and alcohol consumption
Circumstances of crash	Road user type, role of the injured and use of any preventive measure such as helmet or seatbelt, road type, time of the day
Quality of life, disability and functioning	Likert scale for overall health, PedsQL, EQ-5D-3L, 4 weeks prior to crash and at baseline. History of any disability, WHODAS II (12-item version). GOSE and KOSCHI
Injury	Type of injury and associated hospitalisation, AIS score
Work	Return to work, modified duties, hours
Cost	Direct and indirect costs such as medical costs, drugs, diagnostics, transportation, legal costs, property damage and compensation. Separate assessment of health system costs will be undertaken
1, 2, 4 and 12 months follow-up (telephone interviews)	
Health-related quality of life	Likert scale for overall health, EQ-5D-3L and SF-12.
Healthcare utilisation	Days of hospitalisation, rehabilitation and home care
Quality of life, disability and functioning	Likert scale for overall health, PedsQL, EQ-5D-3L, 4 weeks prior to crash and at baseline. History of any disability, WHODAS II (12-item version). GOSE and KOSCHI.
Disability and functioning	History of any disability, WHODAS II
Cost	Direct and indirect costs such as medical costs, drugs, diagnostics, transportation, legal costs, property damage and compensation
Social impact at 12 months follow-up (10% of the sample)	
In-depth interview	Exploring issues related to access to healthcare, impact on carer, insurance, advice seeking (health and compensation), social life, impact on work, perception of recovery, impact of injury general view

AIS, Abbreviated Injury Scale; BMI, body mass index; EQ-5D-3L, EuroQol five-dimension three-level version; GOSE, Glasgow Outcome Scale—Extended; KOSCHI, King's Outcome Scale for Childhood Head Injury; PedsQL, Pediatric Quality of Life Inventory; SF-12, Short Form-12; WHODAS II, WHO Disability Assessment Schedule 2.0.

above, as there are differences in HRQoL reported by parents and children after injury.¹⁷

Economic costs

The economic impact of RTI will be measured by the human capital approach. The study will seek to quantify the direct costs of RTI (out-of-pocket (OOP) costs) as well as the indirect costs. A review of cost of illness studies identified six most common categories of direct medical costs, including emergency department/hospital services, outpatient physician services, drugs, diagnostic procedures/laboratory tests, other healthcare services and ancillary personnel.¹⁸ In addition to these elements, cost of injury studies also included, as part of direct costs, ambulance/transport costs, home care, nursing home and other long-term care as well as vocational rehabilitation and insurance administration costs.^{19 20} Direct non-healthcare costs including those associated with police attendance and investigation of crashes, other legal and coroners costs, vehicle and other property damage costs as well as other general costs associated with travel delays and fire, and other emergency services costs, will also be included.²¹

Taking into consideration the common cost items included in previous studies as well the context of traffic crashes in India, we will collect data from participants and their families using standardised questionnaires on OOP direct costs associated with a RTI during prehospital care: transportation to the hospital; hospital facility and services, diagnostic procedure/laboratory tests, surgery, inpatient physician visits, medication, in-hospital rehabilitation, equipment; posthospital costs: rehabilitation, medication, home care and other related costs. In addition to direct costs incurred by victims, we will also collect information on costs incurred by victim's relatives/caretakers. These include accommodation during victim's hospitalisation, transportation as well as other costs specified by respondents. Costs of legal fees relating to the crash and of vehicle replacement or repair will also be included. Information on compensation (insurance or legal) paid to the participant or to his/her family because of the RTI will also be collected. This will include information on whether claims were accepted and on timeliness of payment or reimbursement.

This study will rely on interviews with injured people and their family to obtain detailed direct medical costs. Recent work has highlighted the important need to validate OOP expenditure and the lack of a gold standard for measures of these costs,²² and the difficulties in validating such costs.²³ To ensure maximum accuracy, we will utilise a short recall period (time since previous interview), standardised questionnaires will be developed to collect information during interviews. Receipts, hospital and insurance cost records will also be sourced, where available, from participants to validate reported costs.

Finally, the health system costs of providing treatment and care will be collected. An economic costing will be undertaken using bottom-up costing methods.

Cost centres, namely, service and support centres, will be identified. All resources spent on provision of care over a period of 1 year will be enlisted. Information on price of these resources will be obtained from suitable sources. In case the same is not available, a market survey to assess the price will be undertaken.

Indirect costs

To estimate indirect costs for RTI for participants, the human capital approach will be applied, using lost working days and occupation rates.²⁴ To calculate the indirect costs attributable to morbidity, income loss and the working day loss of the victims and of their relatives/carers during the hospitalisation and follow-up period will be collected.

Social impact

Impact of RTI on families and their changed circumstances, including work and caring roles, will be assessed at each follow-up. Additionally, we will conduct 15 semi-structured face-to-face interviews from each site and, based on saturation of themes, 5 additional interviews might be considered.²⁵ These interviews will explore issues related to patients' experiences postcrash including impact of the traffic crash on their life and the lives of their family members, access to healthcare, health insurance and other services, as well as other factors that impact on recovery, such as return to work and carer responsibilities. This is chiefly a qualitative aspect of the project. Families of participants who have died during the study period due to their injuries will be invited to participate, to ensure the wider impact of fatal injuries is included. For fatal and for non-fatal injuries, the interviews will also cover any long delays or other negative aspects of compensation processes and their implications for families and individuals.

Data management and analysis

Data will be entered into an electronic database by study staff in Chandigarh. Logic and range checks will be used in the data entry process to minimise data entry errors and identify missing data or problems with completed data. The electronic database will be stored on a "firewall-protected" local network server.

Data will be analysed in order to describe the burden, the associated disability and length of time for recovery, as well as the economic cost of injurious road traffic crashes. Descriptive analyses will be performed to estimate the outcomes of traffic crashes in terms of health, social and economic consequences, including catastrophic health expenditure.

Multivariate modelling will also be undertaken to explore the role of demographic-related, injury-related and healthcare-related factors in predicting the health and socioeconomic impact of hospitalised RTI, as well as mixed-effects regression models to examine recovery, predictors of recovery, predictors of catastrophic health expenditure and other outcomes. Estimates of duration

of disability and disability weights for each injury health state will be calculated from the EQ-5D. The potential will be assessed for extrapolating from findings at the study sites to generate population-based estimates of years lived with disability (YLD) and years of life lost (YLL) due to RTI, and overall DALYs.

Cost data will be analysed using standard methods. Capital costs will be annualised after discounting the life of the capital item. Joint costs will be apportioned for injury care by using appropriate statistics. OOP expenditure will be analysed to assess its mean value and dispersion. Financial hardship will be assessed by analysing the extent of catastrophic health expenditures, at 40% threshold of non-food household expenditure. Poverty impact of RTI will be estimated by computing the poverty headcount increase and poverty gap as a result of OOP expenditure. Finally, the private OOP expenditure will be analysed using an equity lens, by computing concentration curves and concentration index. This will provide a snapshot of vertical equity in financing care for RTI cases.

Qualitative interviews on social impact will be transcribed and analysed thematically using content analysis. Frameworks will be identified and coding plan will be developed to explore interactions. A deductive approach will be used to explore similarities or differences in the context of people and their interactions with health, compensation and related systems, such as occupational rehabilitation. Detailed information on the victim's personal experience and factors influencing injury outcomes will be explored.²⁵

OUTCOMES AND SIGNIFICANCE

The proposed study will provide the first comprehensive estimates of outcomes of serious RTI in India, including economic and social costs, and the impact on individuals and families. The study will contribute considerable information to enable debate about societal context, culture and injury impact of traffic crashes. The result will contribute to the required evidence for generating future investments in RTI prevention and document non-fatal outcomes in LMICs settings in order to inform investment prioritisation.²⁶

Contributors JJ and RQI conceived the study concept. BG contributed to the preparation of the protocol and study tools. SP is the principal investigator for funding. SP, SA and PVML contributed to the development of research methods on site and are responsible for the management of the project. All the coauthors contributed to the writing of the manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The study has been approved by the Postgraduate Institute of Medical Education and Research, institute's ethics committee, along with administrative approvals from hospital sites.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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