Université de Montréal

Comparative Costs and Outcomes of Traumatic Brain Injury from Biking Accidents With or Without Helmet Use

par

Camille Costa

Département des Sciences Biomédicales

Faculté de Médecine

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présenté par
Camille Costa

a été évalué par un jury composé des personnes suivantes

Céline Lamarre, président-rapporteur

Jehane Dagher, directrice de recherche

Elaine de Guise, co-directrice

Geneviève Sirois, membre du jury

Résumé

Contexte: Évaluer les déterminants de maladies évitables et leurs coûts est nécessaire dans le contexte d'assurance maladie universelle. Le moment d'évaluer les impacts des traumatismes crâniocérébraux (TCC) survenus lors d'accidents de vélo est idéal vu la popularité récente du cyclisme au Québec.

Objectifs: Comparer les caractéristiques démographiques et médicales, ainsi que les coûts sociétaux qu'engendrent les TCC de cyclistes portant ou non un casque.

Méthodologie: Étude rétrospective de 128 cyclistes avec TCC admis à l'Hôpital Général de Montréal entre 2007 et 2011. Les variables indépendantes sont sociodémographiques, cliniques et le port du casque. Les variables dépendantes sont la durée de séjour, l'échelle GOS-E, l'échelle ISS, l'orientation au congé, les décès et les coûts à la société.

Résultats: Le groupe portant un casque était plus vieux, plus éduqué, retraité et marié; au niveau médical, ils avaient des TCCs moins sévères à l'imagerie, des hospitalisations aux soins intensifs plus courtes et moins de neurochirurgies. Les coûts médians à la société pour les TCC isolés de cyclistes avec casque étaient significativement moindres.

Conclusion: Dans cette étude, le port du casque semblait prévenir certaines complications des TCC et permettait de faire économiser de l'argent à l'état. Le port de casque est recommandé.

Mots-clés : Trauma Craniocérébral, Pronostic, Coûts, Casque, Vélo, Bicyclette

Abstract

Rationale: Establishing determinants of preventable disease and their societal costs are necessary in the context of publicly funded healthcare. With recent increases in Québec bicyclists, it is an opportune time to evaluate the impact of cycling traumatic brain injuries (TBI).

Objective: Compare demographic and medical characteristics and social costs of cycling TBIs according to helmet status.

Methods: Retrospective study of 128 cyclists with TBI, from a trauma database, admitted to the Montreal University Health Center - Montreal General Hospital (MUHC-MGH) between 2007 and 2011. The independent variables were sociodemographic and clinical characteristics, as well as helmet status. The dependant variables were LOS, GOS-E, ISS, discharge destination, deaths and societal costs, using a bottom up costing approach.

Results: The helmet group tended to be older, more educated, retired and married; from a medical perspective, they had reduced probabilities of severe TBIs on imaging, had shorter intensive care hospitalizations and less neurosurgeries. Median societal costs of TBI were significantly lower when a helmet was used.

Conclusion: In this study, helmets seemed to confer protective effects against certain TBI complications and decreased median overall costs to society. Helmet promotion is recommended.

Keywords: Traumatic Brain Injury, Costs, Outcome, Helmet, Bicycle, Cycling

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Article 1

To my supportive husband and my sweet daughter, you are my everything.

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List of Abbreviations

AIS	Abbreviated Injury Scale
CI	Confidence Interval
CLSC	Centre Local de Services Communautaires
CT	Computerized tomography
CTE	Chronic Traumatic Encephalopathy
ED	Emergency Department
EVD	External Ventricular Device
GCS	Glasgow Coma Scale
GOAT	Galvaston Orientation and Amnesia Test
ICU	Intensive Care Unit
IRGLM	Institut de Réadaptation Gingras Lindsay de Montréal
ISS	Injury Severity Score
LOC	Loss of Consciousness
LOS	Length of Stay
MSSS	Ministère de la santé et des services sociaux
MUHC-MGH	McGill University Health Center - Montreal General Hospital
MVA	Motor Vehicle Accident
OR	Operating Room, Odds Ratio
PTA	Post-traumatic Amnesia
RAMQ	Régie de l’assurance maladie du Québec
SAAQ	Société de l’assurance automobile du Québec
S.E.	Standard Error

TBI	Traumatic Brain Injury
TCC	Traumatisme craniocérébral
WHO	World Health Organization

Introduction

TBI is a major public health concern; nine percent of all traumas and one fifth of all injury related deaths are believed to be caused by TBIs in Canada [1]. The injuries most likely to cause severe injuries and death in cyclists are TBIs [2, 3]. Studies have shown that in the United-States an estimated 2% of all TBI deaths are caused by “pedal cycle” accidents [4]. The dynamics of recovery from TBIs are complex; largely dependant on severity, certain patients with TBIs require neurosurgical interventions, prolonged hospitalizations in acute care where they may develop a myriad of medical complications, followed by rehabilitation and possible long-term loss of productivity or even death [5, 6].

In the province of Quebec there has been a recent surge in cyclists, likely due to the multiple promotional programs related to active transportation, such as the expansion of cycling infrastructure, as well as the introduction of a bike-share program in Montreal [7, 8]. From 2005 to 2010, Quebec has seen its cycling population grow by approximately 500 000 people [9]. This increase may lead to more TBIs unless preventative measures are put in place [10].

Fortunately, bicycle helmets have been demonstrated to confer protection against TBIs [11, 12]. Despite the convincing evidence of their efficacy, many Quebecers persist in opting against wearing helmets, with certain reports estimating 43 to 54% cycle without protective headgear [8, 13]. With TBIs being such an important cause of morbidity and mortality, it is incumbent upon the public health sector to identify effective preventative actions.

The prolonged hospitalizations and long-term complications can be particularly costly to society, with certain estimates suggesting one patient may cost up to 8 million dollars over their lifetime [14]. Evaluating the economic burden of an illness is all the more relevant in Canada because of universally covered health care access.

The lack of Quebec legislation on bicycle helmets makes the city of Montreal a favourable setting to evaluate the effects of helmet wearing on TBIs. Identifying demographic differences between helmet groups allows for more focused public health interventions. Knowledge of the economic impact of TBIs in cyclists allows for more efficient cost-benefit analysis of these potential public health programs.

Literature Review

In the first section, terms commonly used in defining TBIs are explained and important distinctions between TBIs and head injuries are discussed. TBI general epidemiology is described to better define the repercussions and medical issues associated with TBIs, and the specific problem of TBIs as a result of cycling is outlined. The second section focuses on recent trends in cycling and explains the factors associated with recent increases in ridership. Cycling health benefits and injury risks are also described in order to achieve a more clear and balanced perspective of the issue of TBIs in cycling. The third section discusses current helmet use in Quebec, the literature on helmet effectiveness against TBIs as well as studies evaluating various helmet promotion measures. The effectiveness of helmet legislation at preventing TBIs is a hotly debated subject in the empirical literature, and will be discussed in this section, along with the relevant pros and cons of this approach. The fourth section describes costs associated with TBIs in general as a baseline with which to compare cycling TBIs. Afterwards, there is a brief overview of the Canadian health care system. Lastly, cost studies of TBIs in cyclists are reviewed to use as a comparison to our cost study.

Chapter 1. Traumatic Brain Injury

1.1 Definitions

In this section, TBI will be broadly defined and tools used to assess TBI severity and outcomes will be explained. Specific terms used within the TBI definition will also be explained in order to provide the reader with a more complete understanding of TBI nomenclature.

A recent position statement by The Demographics and Clinical Assessment Working Group of the International and Interagency Initiative toward Common Data Elements for Research on Traumatic Brain Injury and Psychological Health defines TBI broadly as "an alteration in brain function, or other evidence of brain pathology, caused by an external force" [15]. The authors go on to explain that an "alteration in brain function" is evidenced by at least one of the following clinical signs: a change in level of consciousness, anterograde or retrograde amnesia, neurological deficits and/or a modification in the person's mental state [15]. "Other evidence of brain pathology" may be an observable pathology, supported by neuroradiologic exams or laboratory tests [15]. Amongst other mechanisms, the "external force" can be caused by blunt objects, penetrating foreign bodies, explosions, accelerations or decelerations [15].

It is important to distinguish the term TBI from head injury. A head injury is broadly defined as an externally evident trauma to the head [16]. This trauma may or may not be associated with an actual brain injury. Failing to differentiate between both terms in a research setting can lead to skewed recovery outcomes of TBIs, and perhaps more importantly lead to misdiagnosis, excessive investigations, as well as inappropriate treatment and management.

Once a true diagnosis of TBI is emitted, its severity can further be defined into one of three subcategories: mild, moderate or severe. Grading TBI severity is important from an epidemiological standpoint and has been shown to be helpful in establishing an early prognosis [17]. TBIs are classically graded using the Glasgow Coma Scale (GCS), length of loss of consciousness (LOC) and post-traumatic amnesia (PTA) [18-21]. On imaging, TBIs can be graded using the Marshall Classification. Certain studies comparing TBIs with other bodily injuries favour the injury severity scale (ISS) that can be used to assess and compare severity of injuries of any body part. In the following paragraphs, terms used commonly for assessing TBI severity are explained.

Glasgow Coma Scale (GCS)

The GCS, created in 1974, was originally intended for research purposes, but quickly caught on as a clinically useful tool [18, 19]. It is meant to be a simple scale used to evaluate the initial severity and assist with prognostic determination of acute traumatic and non-traumatic brain injuries [19]. The scale comprises the assessment of three behavioral responses: eye opening, motor response and verbal response (see table 1 for detailed assessment grading) [18]. Many studies have evaluated the interrater reliability of the GCS, with results ranging from moderate to very good reliability, with inexperienced users and an emergency department (ED) setting tending to result in less reliable scores [18, 22-24]. According to a review by Gabbe et al., initial GCS scores have been found to be a good predictor of survival [24]. There is some evidence that, in trauma populations, the GCS is predictive of both short and long term functional status, though some authors question its prognostication value citing the effect of aggressive prehospitalization treatment, inconsistent time post trauma of GCS assessment and improved acute care treatments as causes for confounding the GCS's ability to predict outcomes [24, 25].

Eye Opening	***Verbal Response***	***Motor Response***
4. Spontaneous 3. To speech 2. To pain 1. None	5. Orientated 4. Confused 3. Inappropriate 2. Incomprehensible 1. None	6. Obeying 5. Localizing 4. Withdraws 3. Abnormal flexion 2. Extensor response 1. None

Table 1: Glasgow Coma Scale [18, 19]
Adapted from Teasdale et al. and Jennett et al.

Loss of Consciousness (LOC) and Post-traumatic Amnesia (PTA)

From a neurological standpoint, LOC is defined as an alteration in brain function that results in primitive or absent responses to external stimulation [26]. While no clear consensus definition is agreed upon in the literature for PTA, a recent review has defined it as anterograde amnesia that affects new memory storage and retrieval, as well as retrograde amnesia that incapacitates memory recollection immediately prior to the TBI [27]. PTA can also be defined as the persistence of imperfect Galveston Orientation and Amnesia Tests (GOAT) [28]. The GOAT evaluates orientation to person, place and time as well as memory of events prior to and following a trauma [28]. PTA length is important to assess because it is predictive of long-term prognosis following a TBI, as supported by a prospective study [29].

LOC and PTA are two variables that can easily be confused [15]. Since their respective time lengths in each TBI severity differs (see table 2), a misunderstanding of their definitions can lead to the misclassification of individuals' TBI severities. Considering that both LOC and PTA influence event recollection of the TBI, gathering collateral information is sometimes necessary. While often impractical, a bystander or an emergency medical service provider are best placed to most accurately assess LOC.

Marshall Classification

Another method to evaluate brain injury severity is the Marshall classification. It was developed by Marshall et al. to provide early prognostication of injuries according to imaging findings on computerized tomography (CT) scans [30]. It correlates with mortality and risk of increased intracranial pressure [30]. Four subgroups of diffuse head injury are defined as follows: Diffuse Injury I have no visible pathology; Diffuse Injury II have preservation of cisterns, a midline shift of 0-5mm and no high or mixed lesion densities >25cc; Diffuse Injury III differs from II by including compressed or absent cisterns; and Diffuse Injury IV differs from III by including midline shifts of more than 5mm [30]. The other two categories are the evacuated mass lesion that includes lesions that require surgical evacuation and the non-evacuated mass lesion are non surgical high or mixed density lesions of >25cc [30].

Injury Severity Scale (ISS)

The ISS allows for the comparison of severity between diverse trauma injuries in patients (e.g. comparing isolated injuries with polytraumas) [31-33]. The scale correlates with mortality, morbidity, and hospital stay amongst other outcomes [32, 33]. The ISS is calculated based on rating each injury according to the abbreviated injury scale (AIS). The AIS uses a gradation from 1 (minor) to 6 (maximal injury, nearly not survivable) for each of the following body regions: head & neck, face, thorax, abdomen, extremities (including pelvis) and external (i.e. skin and subcutaneous tissue) [32-36]. The ISS score is derived by squaring the three highest AIS ratings, and calculating their sum, resulting in ISS values between 0 and 75 [32-34]. A notable exception to the squaring rule is when an injury is attributed an AIS of 6, in which case the ISS is automatically assigned the maximal score of 75 [32, 33].

Now that the common terms used in TBI severity assessment have been delineated, the following section will focus on the various definitions for mild, moderate and severe TBIs.

TBI Severity

The definition of mild TBI in studies is the most contentious of the three TBI severities, as highlighted by a World Health Organization (WHO) neurotrauma taskforce in 2004 and was reiterated in a WHO update in 2014 [20, 37]. Beyond the broad definition of TBI mentioned above, a mild TBI must have a GCS (see tables 1 and 2) of 13-15, that should ideally be evaluated 30 minutes following the injury, or upon first presentation to a health care professional [20]. The individual's post-traumatic amnesia (PTA) must not exceed 24 hours, loss of consciousness (LOC) must be 30 minutes or less, and if an intracranial lesion is present, it must not require surgical intervention; if any of these parameters are not respected, the severity of the TBI may no longer be considered mild [20]. Given that the term concussion has multiple varying definitions in the literature, it is preferable to use the term mild TBI [38].

The notation of moderate TBI is generally agreed to be defined as a patient having had a TBI with a GCS score between 9-12 upon arrival at the hospital or 30 minutes after the accident [21]. Other definitions include a GCS score of 13 to 15 with an intracranial lesion necessitating a surgical intervention, LOC longer than 30 minutes but less than 24 hours and/or PTA between 24 hours and 1 week [21]. The designation of severe TBI is reserved for patients with a TBI and GCS score from 3 to 8, LOC longer than 24 hours and PTA longer than 1 week [21]. Of note, in the province of Quebec, moderate TBIs are considered to have PTA between 24 hours and 2 weeks and severe TBIs have PTA of longer than 2 weeks according to an expert consensus established by the minister of health [39].

	GCS	*PTA*	*LOC*
Mild	13-15	< 1 day	< 30 minutes
Moderate	9-12	1 day < to > 7 days	> 30 minutes to < 24 hours
Severe	3-8	> 7 days	> 24 hours

Table 2: Severity of traumatic brain injuries [21, 40]
Adapted from the Department of Defense/Veteran Affairs

1.2 Epidemiology

TBI represents a significant public health problem and is a leading cause of death and disability in North America. An estimated 1,7 million TBIs occur annually in the United-States according to a recent CDC report [41]. The incidence of patients with TBIs admitted to hospital in the United-States ranges from 180 to 250 per 100 000 population per year [16].

A 2006 report by the Canadian Institute for Health Information identified 16 811 TBI-related hospitalizations in Canada in 2003-2004, representing 9% of all traumas [1]. A review of emergency department visits and hospitalizations in Ontario, Canada found that the average rate of TBIs between 2006 and 2007 was 99,5 and 190,2 per 100 000 citizens for women and men respectively. These numbers are likely an underestimation since they do not include people who consult clinics with mild TBIs that do not require hospitalization or those that were deceased at the scene of the accident.

Sex

Men are 1,4 times more likely to have a TBI than women [41, 42]. This increased risk for men is likely a manifestation of their increased involvement in motor vehicle accidents (MVA); of those who succumb to unintentional injuries worldwide, an estimated 10,7% of men die due to road injuries compared to 0.5% of women [43]. Road injuries include pedal cycle vehicles (e.g. bicycles), motorized vehicles and pedestrian injuries caused by road vehicles [43]. Men are also more likely than women to have TBIs related to assaults [43]. However, elderly women are more likely to sustain a TBI following a fall than men [44]

Age

Incidence of TBI varies greatly by age group, following a bimodal distribution, with young children and the elderly having higher rates of TBIs [1, 41, 45]. In the United-States, very young children (0-4 years) have the highest rates of ED visits for TBI at 1256 per 100 000 population [41]. The elderly (>75 years) have the highest rate of hospitalization and deaths, 339 and 57 per 100 000 people respectively [41]. Canadian data find children (0-19 years) and the elderly (>60 years) nearly tied for the proportions of admissions due to TBI representing respectively 30% and 29% of all TBI admissions [1]. Of note, the number one cause of death for 15 to 34 year olds according to Statistics Canada is unintentional injury, many of which are from TBI caused by MVAs [46].

Other Variables

Other important factors increasing the risk of TBI include belonging to an ethnic minority, having a low socioeconomic status, consuming alcohol, and not wearing protective equipment with transportation related TBI [45]. Additional factors include having lower educational levels, having had previous TBIs and being single [45, 47, 48].

Etiology

The etiologies most commonly associated with TBI are falls, MVAs, and assaults [1, 41]. The proportion of TBIs caused by each etiology depends greatly on the age group. Overall, falls lead to the highest number of ED consultations and hospitalizations in both the United-States (60,7%) and Canada (45%), due mostly to very young (0-4 years) and the increasing contribution from the elderly population [1, 41]. The growing proportion of elderly patients with TBIs may be due to the increasing use of anticoagulation medication in that age group [49]. MVAs and traffic related TBIs account for 17,3% of all TBIs in the United-States, but are the most common cause of death [41]. Assaults represent 10% of all TBI causes [41]. Canadian data show similar percentages, with MVAs representing 23% of TBIs [1]. For those aged between 20 and 39 years, the leading cause of TBI are MVAs (51%), followed by assaults (20%) [1].

Mortality

TBIs account for a significant proportion of deaths from injuries. The percentage of deaths attributable to injuries was 9,6% globally according to the Global Burden of Disease review published in the Lancet in 2013 [43]. A 2010 official report by the Center for Disease Control in the United-States found that TBI made up 30,5% of all injury related deaths [41]. In Canada, an estimated 20% of all traumatic deaths are caused by TBIs [1].

In the United-States between 2002 and 2006, 52 000 patients died yearly of the 1,7 million patients with TBI-related injuries [41]. Canadian statistics for 2003-2004 found that 1368 individuals died following their TBI, representing 8% of TBI hospital admissions [1]. Of those 1368 deaths, 59% were in the elderly age bracket [1]. While specific numbers vary according to region and timeframe, it is clear that TBIs are the cause of many deaths.

Mortality is best predicted by initial severity of the TBI [50]. A review on mild TBI found a 0-0,9% mortality whereas an estimated 21% of severe TBIs are fatal within the first 30 days [45, 51]. Another factor influencing mortality rates is age. Patients over 65 years of age are more likely than younger patients to sustain fatal TBIs [50]. The combination of higher risk of incurring severe TBIs and pre-existing comorbidities that impede recovery is thought to explain the higher mortality in the elderly age bracket [50].

Morbidity

Though the majority of TBI patients survive their initial injuries, they may be left with short or long-term cognitive deficits and physical disabilities resulting in a loss of functionality. One source estimates that approximately 2% of the American population are living with disabilities related to a TBI [45].

Life expectancy following a TBI is debated. Certain groups have found that those who survive the initial six months have unaltered ten-year lifespans [45]. One review on the subject found that certain studies found that overall survival may be more than 20 years, but that other studies concluded life expectancy may be shortened by as many as 10-20 years [42]. Long-term survival information on this topic remains sparse.

Those who survive may have activity limiting impairments that impede return to work or lead them to require assistance with daily living tasks [45]. One method commonly used to measure outcomes is the GOS-E. The GOS-E is an extended version of the original Glasgow Outcome Scale. Both have been widely accepted as valid assessment tools for functional outcomes following TBI [52, 53]. The GOS-E is best determined following a structured interview [53]. According to the guidelines established by Wilson et al., the scoring is as follows: (1) death, (2) vegetative state, (3) lower severe disability. (4) upper severe disability, (5) lower moderate disability, (6) upper moderate disability, (7) lower good recovery and (8) upper good recovery [53].

As was the case with mortality, long-term functional outcomes often depend upon initial TBI severity [42]. As such, the following section has been separated into two distinct parts: the first part will cover mild TBI outcomes and the second part will discuss moderate and severe TBI outcomes.

Mild TBI

Comprehensive reviews by the WHO on the prognosis of mild TBI conducted in 2004 and updated in 2014 found that most patients had little to no disability [51, 54]. Despite early cognitive deficits and self-reported symptoms being described, such as headache, difficulty sleeping, decreased attention, impaired recall and processing speeds, they generally were completely resolved within three months [51], though some studies have found measurable cognitive deficits at six months [54]. Longer length of LOC and lower GCS scores are associated with increased frequency of cognitive deficits and slower recovery of symptoms [54]. The resolution rate of symptoms is estimated at 70% at 3 months and 90-95% at 12 months [51].

It is currently debated whether cognitive symptoms that persist beyond three months after a mild TBI are caused by the TBI itself or by associated injuries and/or medical comorbidities

[51]. Factors influencing persistence of symptomatology beyond three months are thought to possibly be litigation, compensation and, in certain instances, positive alcohol levels, positive imaging, advanced age, and polytrauma [51]. One study suggests that no association exists between persistence of cognitive deficits and pain or psychological distress, although it appears that negative expectations can lead to worse results on cognitive testing [54].

Mild TBIs are associated with several medical complications. The risk of seizure increases slightly after mild TBIs, however the cumulative prevalence over 5 years remains low (approximately 0,7%) [55]. After five years, it is generally considered to return to pre-TBI rates [55]. There does not appear to be an increase in brain tumors following a mild TBI [42, 51]. Dementia caused by mild TBI is debated, although a rigorous review by Godbolt found no evidence to support a causal relationship between mild TBI and dementia [56]. Current evidence suggests that repeated mild TBIs might lead to a condition called chronic traumatic encephalopathy (CTE) [57, 58]. CTE used to be called dementia pugilistica. It has best been described in athletes, such as football players or boxers [57, 58]. CTE is thought to be distinguished by its unique pattern of tau neurofibrillary tangles and paucity of beta-amyloid deposits [57]. Information regarding the number of TBIs and their severity, time lag following the TBI, clear diagnostic criteria, incidence and prevalence remain to be clarified [57].

Literature regarding return to work following a mild TBI is controversial [59]. Return to work percentages vary greatly, from only 30% return to modified work at 3-6 months (of which 12% returning to their regular employment) [60] to as high as 87,5% full employment at 6 weeks [61]. A recent prospective study evaluated the effectiveness of a vocational rehabilitation program after a mild TBI (requiring at least 48 hours of hospitalization) for patients who were previously employed or in school full time [62]. Return to work or school rates were around 7% at 4 weeks, 56% at 3 months, 68% at 6 months and 75% at 12 months without vocational rehabilitation [62]. With vocational rehabilitation, these return to work rates increased to 85-90% at 3-12 months [62]. The 2004 WHO taskforce on mild TBI that included a large group of mild TBI patients not necessitating hospitalization found that return to normal activities occurred for 70% of patients at 3 months [51]. The updated 2014 WHO report on mild TBI found that most studies were in agreement that return to full time work occurred 3 to 6 months post injury, although 5-20% of patients had longer term difficulties returning to work [63]. The differences in return to work following mild TBI emphasize the considerable variability within this group of patients.

The overall prognosis for patients with an isolated mild TBI is generally described as excellent, with the majority experiencing little to no symptoms three months following the event [51]. Most patients are able to return to their previous level of activities [51].

Moderate and Severe TBI

A review of the literature on productivity outcomes in patients with moderate and severe TBIs found that return to paid or unpaid work varied widely from 40% at 6 months to 83,5% at 11 years [42]. Certain studies evaluating strictly severe TBIs found the level of unemployment to be even higher [42]. A Finnish study reporting on outcomes ten years post event stated that the vocational status of 15 patients with severe TBIs remained stable as of 5 years post TBI, with 14 patients having retired and only one working at a less demanding job than pre-TBI [64]. A prospective study by Radford et al. found that, without vocational rehabilitation, less than 5% of patients with moderate and severe TBI were back at work 1 month following their injury, and by 3 months, employment remained stable at 40% until the end of follow-up at 12 months [62]. With vocational rehabilitation, return to work improved to

70% at 6 and 12 months [62]. Another prospective study by Grauwmeijer et al. on patients with moderate and severe TBIs without vocational rehabilitation found that return to work rates plateaued at 12 months around 50% [65]. While the studies on return to work are small and have at times conflicting results, returning to paid work for patients following a moderate or severe TBI appears to be possible; around 6 months with vocational rehabilitation following TBI, or at 12 months without intervention [42, 62, 65].

The Grauwmeijer et al. study found that risk factors for unemployment following moderate and severe TBIs were older age, increased length of hospital stay, discharge to a nursing home, psychiatric symptoms (specifically anxiety and depression), low Barthel Index (a measure for level of ADL independence), a GOS under 4 at hospital discharge (death, vegetative state or severe injury), as well as low functional independence and functional assessment measures [65]. Interestingly, employment prior to TBI was not an independent factor in predicting return to work [65].

One review concluded that most studies found a 100% rate of return to independent living for patients with moderate and severe TBI [42]. The studies in the previously mentioned review that identified long-term functional dependence had exclusively evaluated severe TBI [42]. A ten year follow-up of 15 patients with very severe TBIs (defined in the study as PTA >14 days and prolonged LOC), only 6 (40%) regained complete independence as measured by the Barthel Index [64]. Another study of 25 patients with memory impairments following severe TBIs, found that 64% were able to live independently [66]. Therefore, while independence is possible for many, a considerable number of patients with severe TBI require long-term assistance for daily living [42].

From a medical complication perspective, Annegers et al. found that the occurrence of seizures post TBI was strongly associated with the severity of the initial injury [55]. The five-year cumulative probability of seizure was 1,2% for moderate TBIs and 10% with severe TBIs, which are both much higher than for mild TBIs [55]. Posttraumatic epilepsy has been found to be an independent negative prognostic factor in cognitive functioning [67].

1.3 TBI due to Cycling

Ascertaining the scope of the problem relating to TBI caused by cycling is necessary before undertaking steps towards preventing it. The following section will attempt to define the issue of TBI and cycling.

Establishing precise estimates on the proportion of TBIs due to bicycle accidents is challenging given differences in study methodologies. In American emergency departments, the combined yearly incidence of pedestrian and cyclist TBIs was 25 per 100 000 population and accounted for 6,2% of all TBIs [68]. Another, older study, found that 6,4% of TBIs in the state of Minnesota were caused by bicycle accidents and the incidence of fatal TBIs associated with cycling was 1,7 per 100 000 of population [69]. A Center for Disease Control 2004 review found that 3,6% of hospitalizations for TBIs were caused by “pedal cycle” accidents and caused 2% of TBI-related deaths [4]. According to a statement by the American Association of Neurological Surgeons, cycling was the number one cause of sports related head injury in the United-States in 2009, with 85 389 cyclists being treated in emergency departments that year alone [70]. A Canadian review found that over a 10 year period, 2% of all hospitalized injuries were related to biking accidents, of those 24% were related to TBIs [1]. Though figures inevitably vary based on location, time period and study sample, it is evident that TBIs in cycling is a pervasive issue.

In the province of Quebec, accidents involving bicycles and road vehicles resulted in 16 deaths and 114 individuals being seriously injured in 2009 [71]. Many studies have found that collision with a motor vehicle is the most common cause of TBI in cyclists [72-74]. While most bicycle-related TBIs are mild, head injuries are among the most severe injuries a cyclist can have; they comprise one third of bicycle related ED visits and two thirds of bicycling deaths [2, 7, 75]. It is estimated that 60 to 80% of bicycle accident related deaths in Quebec are caused by head injuries [76]. Cars are thought to be involved in more than 80% of cyclist deaths in the province [77].

There exists a bimodal distribution of the age of cyclists incurring TBIs, with children under 15 and cyclists above 65 having respective rates of TBI 3,3 and 3,8 times higher than the middle aged group [78]. The younger age group fares better from a prognostic point of view, but it also means that surviving patients live longer with occasionally severe disabilities, causing longer-term morbidity [45]. Mortality from TBI is higher in the elderly, both for TBIs in general [1, 50, 79], and for TBIs resulting from cycling accidents [78].

The male predominance of TBIs is accentuated in cyclists, reaching a three to one ratio when compared with women [1]. This higher proportion may be explained by the fact that men make up two thirds to three quarters cyclists [8]. They are also less likely to follow traffic laws; in Quebec cyclists, it was found that 55% of men stop at a red light compared to 66% of women [8].

While severe cycling injuries (excluding head injuries) have remained stable, a decrease in TBI related to cycling by 46% occurred between 1994 and 2004 in Canada [1]. Comparatively, in Quebec cyclist injuries and deaths have remained relatively stable from 2000 to 2005, the total varying between 200 and 250 cyclists per year [80]. It is worthwhile noting that other provinces during that time adopted helmet legislation, whereas Quebec did not, perhaps accounting for some of the discrepancy in deaths.

In summary, TBIs are an important and pressing public health issue, being a leading cause of injury-related death and disability around the world. Cyclists are an interesting group to target for preventative measures since the majority of their severe injuries and deaths are caused by TBIs and, as will be described later, there exist effective ways of decreasing the risk of severe injury in cyclists, many of which are not currently being implemented to their realistic potential in Quebec. Furthermore, as will be detailed in the next section, cycling has increased significantly as a mode of transportation, particularly in the province of Quebec, making this population ideal for the implementation of such preventative measures.

Chapter 2. Cycling

2.1 Global Trends

According to an independent research group interested in global environmental concerns, bicycle production has been trending upwards for over a decade [81]. This trend is multifactorial, with most important increases likely due to a combination of globally increasing costs of oil and the comparatively inexpensiveness of cycling, public policy changes making cities more bicycle-friendly and the fact that most cities have not attained their maximal cycling potential [81]. More than 50% of all commutes occur with bikes in many Chinese cities, compared to 10-27% of all trips in the reputedly high cycling cities of the Netherlands and Denmark and only 1% of all transit trips in the United States and Australia [81]. Data from the 2000 census shows that Canadians use a bicycle for transit in 1,3% of trips, while Quebecers use it 1,2% of the time [82].

A decidedly global trend is the advent of bike-share programs. The first city to implement such a program was Amsterdam in 1965, where people were provided free bicycles to be returned at multiple locations, however many were stolen or abused making the program difficult to maintain [83]. In the 1990s, the programs evolved to include membership fees and coin operated docking systems [83]. However, it was not until the inclusion in the late 1990s of smartcard technology that the programs began spreading exponentially [83]. Over the past decade, public bicycle sharing has gone from the experimental phase to being fully integrated into many cities worldwide including Paris, Rio de Janeiro, New York City, Shanghai and Montreal [83]. As of 2011, an estimated 375 programs were implemented using approximately 236,000 bicycles [83]. Even children are becoming included in bicycle sharing: as of June 18th

2014, Paris' bike-share, Vélib', has launched a version for children called P'tit Vélib' [84]. The bicycles are available to rented in four sizes with helmets available for rent [84].

2.2 Quebec's Reality

Recent years have seen a surge in cycling-related initiatives from the provincial government as well as Vélo-Québec. Vélo-Québec is a not-for-profit group whose mandate is to promote cycling in the province in order to improve the well-being and health of Quebec citizens [85]. The "Route Verte", a project aiming to create a pan-Québec network of bicycle friendly routes to promote cycling tourism in the region, has been continuously expanding since 1995 and currently extends over 5,000 kilometers [7]. To address health issues such as the obesity epidemic and to help curb greenhouse gas emission, a bicycle policy was adopted in 1995 that encourages municipal development of bicycle paths and promotes cycling as a mode of active transportation for school-aged children [7].

Due to Quebec's harsh winters, the average cycling season lasts 5,6 months [8]. While most people cycle 3 seasons per year, tens of thousands of people cycle all year long in the cities. Certain bicycle paths benefit from snow removal services year-round, though most paths are accessible 7 ½ months per year [8]. A 2010 report by Vélo Québec found that 2 million adults biked at least once weekly, up from 1,8 million in 2005 and 1,6 million in the year 2000 [8]. The promotion of active transportation seems to have been effective in Quebec; while active leisurely activities in adults are generally losing popularity, cycling continues to increase in ridership [8].

An important factor contributing to the increase in cycling, particularly as a method of daily commuting, was the introduction of a bicycle-sharing program in Montreal. The BIXI bicycle, manufactured in Quebec, was first implemented in Montreal in May 2009 [86]. After

5 years of operation, the system includes around 5000 bicycles and 400 docking systems across the city [86]. Of note, a majority of the users are between the ages of 15 and 34 years and 85% of subscribers have a university education [8]. BIXI's important role in active transportation in Montreal is evident; only an estimated 3% of users would have cycled to work had they not had access to BIXI according to a Vélo Québec report [8]. Although possibly underpowered, an initial study evaluating the effects on collisions and near misses following BIXI implementation in Montreal found that with the increase in cycling, the rate of collisions and near misses remained the same [87].

Cities with helmet legislation that have attempted to introduce bicycle sharing programs have had limited success [88]. A study evaluating the barriers to the success of a bike-share program in Brisbane, Australia, where universal mandatory helmet laws are in place, found that access to a bicycle helmet was a great deterrent in convincing non-users to become bike-sharing adepts [88]. Vancouver plans to offer a helmet rental service alongside the BIXI bicycles to circumvent the problem [89], although some people question the hygiene of reusing bicycle helmets [88] . The presence of BIXI in Montreal may make implementation of helmet legislation difficult.

2.3 Benefits of Cycling

Maintaining an active lifestyle is beneficial in the context of the increasing obesity epidemic. An estimated 85% of adults in Canada do not achieve their recommended weekly physical activity targets [90]. The Quebec cycling network is estimated to provide the equivalent of $50 million yearly in health care cost benefits thanks to primary prevention of illness [8]. A 2012 review in the Lancet by Jarrett et al. evaluated the economic impact an increase in active transportation (walking and cycling) would have by decreasing chronic illnesses [91]. According to their calculations, while an increase of 21% in road traffic injuries could be expected, overall decreases in cardiovascular diseases, diabetes, dementia, breast and colorectal cancer, cerebrovascular disease and depression would by far outweigh the comparatively small increase in injuries [91]. A 2010 study reviewed the literature on the health benefits of cycling and found consistently an inverse linear relationship between rate of physical activity from cycling and all-cause mortality [92]. When compared with driving, the gain in life-expectancy from using cycling as a primary mode of transportation varied between 3 and 14 months, with the benefits of cycling outweighing the risks nine-to-one [92].

Active transportation also helps decrease traffic congestion and contributes to lowering greenhouse gas emissions [7, 8]. Despite global efforts to decrease greenhouse gas emissions from all causes, those due to ground transportation have continued to increase largely due to increasing motor vehicle use [93]. A European study has established that cycling is the most effective mode of transportation to decrease gas emissions [93].

Finally, cycling appears to improve the general quality of life of its users. While people generally dislike driving in traffic on their daily commute, 59% of commuter cyclists enjoy their travels to and from work [8].

2.4 Safety Concerns

Deaths from road injuries alone rank as the eighth cause of death worldwide and the number one cause of injury related deaths [43, 94]. In North America, traffic related accidents are the fifth cause of mortality [43]. While most of these accidents are MVAs, there is a non-negligible proportion of cyclists being injured as well; as previously discussed, an estimated 2% of TBI hospital admissions are due to cycling accidents [1]. Cycling is the primary cause of TBI in sports [70]. Yet, according to Vélo Québec, only 11 out of 1000 cyclists consult doctors for cycling related injuries, which is comparatively half of the consultations for skiing and one third of running consultations [8]. While cyclists may generally require less medical consultations than other sports per capita [8], they tend to have more severe injuries likely due to their higher speeds, risk of collision with motor vehicles and their exposed body parts [95]. Utilizing an algorithm that included both rural and urban environments, a team from the Netherlands estimated that overall 5,5 times more deaths occur while travelling by bicycle than by car for the same number of kilometers [92]. The risk of bodily injury increases when the mechanism of injury is a collision with a motor vehicle [96]. A study that surveyed Kansas cyclists in a metropolitan area found that 43% had had injuries while cycling, most commonly these were mild (self-treated) and involved the extremities [97]. The more severe injuries were more likely to involve MVAs [97]. Cycling accidents leading to injuries requiring hospital admissions appear to be somewhat more frequent in rural areas than urban ones [98]. While the majority of severe injuries involve brain traumatisms, other potentially severe injuries can occur due to intra-abdominal injury (often from handlebar trauma), hemothorax and pneumothorax [99, 100].

Bicycles sold in Quebec (or Canada) are not governed by federal standards, and safety equipment features such as lights and reflectors is the retailers' responsibility [7]. The Quebec Highway Safety code, however, clearly states that bicycle dealers must only sell bicycles that have: "one white reflector at the front, one red reflector at the rear, one amber reflector on each pedal, one reflector attached to the spokes of the front wheel and one reflector attached to the spokes of the back wheel" [101]. Due to variations in manufacturing requirements abroad, many bicycles sold in Quebec do not comply with these regulations; it ultimately becomes the individual's responsibility to know the rules and regulations of the road and to make sure their bicycles comply with them [7]. When reflectors are lacking, cyclists are less visible and therefore at higher risk of MVA [71], and fatalities [7].

2.5 Risk Reduction

There are many variables that impact the risk of injuries in bicyclists. A recent road and safety document for the province of Quebec denotes certain statistics surrounding bicycle accidents [71]. An estimated 85% of accidents occur in residential or commercial neighbourhoods, mainly in zones where the speed limit is 50 km/h or less. Negligence and inattention (on the part of both motorists and cyclists) are the principal causes of fatal accidents. Other notable factors that can result in accidents are: failure to stop at a stop sign, red light or failure to yield the right of way where required, failure to be clearly visible to other road users, and failure to ride in the direction of traffic [71]. Adverse environmental conditions also increase the risk of injuries in general, including TBI. For example, the Quebec ministry of Transportation estimates that accidents occurring at night lead to death in 7% of cases, whereas daytime accidents have a 0,7% death rate [7]. Other causal factors in bicycle accidents are road damage or obstacles and bicycle part failure [99]. A review of safe cycling structures recommended that pathways utilized at night be well lit, that bicycle paths be well maintained and that whenever possible the gradation remain minimal [96].

Safety equipment can be added to bicycles and cyclists in order to increase general safety. As described above, the Highway Safety Code of Quebec clearly states which reflectors are necessary at all times [101]. It also requires the use of a white head light and a red tail light at night [101]. Transport Quebec recommends the use of a horn or bell, a rearview mirror, a safety flag, a touring rack and using tires with reflective strips [7]. The reason for these recommendations is that an estimated 30% of fatalities involving cyclists and motor vehicles occur due to lack of visibility [7]. There is an absence of personal protective equipment (notably helmets) in 40 to 50% of transportation related TBIs [45].

As the number of cyclists increase, the rate of injuries related to cycling accidents decreases, this is known as the “safety in numbers” effect [87]. A study by Jacobsen suggests that as motorists become more accustomed to sharing the road, less cycling accidents occur [102]. This reality may be reflected in Quebec statistics: between 1987 and 2010, the amount of regular cyclists increased by 50%, yet the rate of accidental deaths, serious injuries and minor injuries fell by 58%, 72% and 52% respectively [8]. The increase in cycling following BIXI implementation in Montreal without increase in collisions also supports the safety in numbers theory [87]. Efforts should therefore be made to encourage good safety habits that do not hinder cycling uptake.

A key factor that increases the risk of severe injury and death in cyclists is their proximity to motor vehicles. One study evaluating the causes of death in children cyclists found that all deaths involved a motor vehicle [100]. In Quebec, more than 80% of cyclist deaths involved cars [77].

Considering that cycling-related TBIs are primarily caused by MVA, the issue of cycling specific infrastructure becomes salient in this discussion [72-74]. In a review of the literature on safety of cyclist specific infrastructure, it was found that the safest design was bicycle-specific laneways that physically separate cyclists from motor vehicles [96]. Indeed, a recent study found a steady decline in head injuries following the building of extensive cycling infrastructure in New South Wales, Australia [103]. Such an infrastructure may also explain why the Netherlands have low cyclist injury rates [92]. It is worthwhile to note that the built environment can also encourage more cyclists to use their bicycles to commute, while contributing to their safety [104, 105]. As suggested by De Jong, it may be more cost effective to invest the money required for helmet legislation into creating safer cycling environments [106].

In summary, while the health benefits of cycling certainly appear to outweigh the risks [92], the fact remains that a significant proportion of cyclists continue to suffer from the long-term consequences of TBIs that could potentially be either avoidable or minimized by employing preventative measures, such as helmet wearing [4, 70]. The next section focuses on the benefits of helmets and various implementation strategies for helmet promotion.

Chapter 3. Helmets

Up to half of TBI related to road accidents occur to people who were not wearing personal protective equipment [45]. It has been demonstrated repeatedly that helmet wearing while cycling is protective against TBI [11, 12, 48, 107, 108]. Yet, despite compelling evidence, helmet wearing among cyclists remains suboptimal, suggesting that many of the TBIs related to cycling might yet be preventable [13, 109].

3.1 Quebec Helmet Wearing Practices

There is currently no provincially mandated legislation with regards to helmet wearing at any age. Helmet wearing enforcement has been a subject of much debate over the years, with multiple bills introduced on the subject, that due to lack of consensus never passed into law [110]. The most recent bill suggested an amendment that would oblige children aged 12 and younger to wear helmets, however it also did not pass into law [110].

Although province-wide legislation does not exist, certain municipalities have implemented their own helmet policies, however few are enforced. Côte-St-Luc, a borough of the city of Montreal, has had a by-law regarding helmet wearing since 1992 [111]. There is also a by-law in the city of Westmount in effect since 1994 [112]. While some fines have been distributed, recently Westmount's director general has stated that they have no plans on enforcing the by-law [113]. In March 2011, the city of Sherbrooke became the first city in Quebec to legislate and enforce helmet wearing: children 18 years and younger must wear a bicycle helmet while cycling, those who do not are subject to a $30 fine [114]. In conjunction with legislation, the municipality of Sherbrooke implemented school based peer education and parent targeted education sessions, a social media campaign, and free helmet distribution [115].

Despite lack of legislation, the 2010 data on helmet wearing amongst Quebecers showed an increase from 36% in 1995 to 57% in 2010, with 65% of children under the age of 18 wearing their helmets [8]. A 2008 document on Bicycle Policy published by Transport Québec states: “if the next surveys were to reveal results nearing 40% [helmet usage], the Société [de l’assurance automobile du Québec] could consider proposing that the Minister of Transport establish legislation making the use of helmets mandatory” [7]. Vélo Québec also highlights that the percentage of cyclists who own helmets increased significantly in recent years, from 45% in 1995 to 67% in 2010 [8]. The discrepancy between helmet ownership and helmet wearing suggests that there is room for improvement in helmet wearing compliance.

A 2012 descriptive study on Montreal cyclists’ habits with regards to helmet wearing showed that 46% wear helmets, less than the rest of Quebecers [116]. This discrepancy may be explained by the different habits of BIXI bicycle users compared to other cyclists. Only 12% of people using BIXI bikes wore helmets, compared to 51% of other cyclists [116]. Similar observations of lower helmet use among bicycle sharing program users have been found in other cities [117, 118].

3.2 Evidence of Injury Prevention

A task force on mild TBI estimated that 80-90% of bicycle related TBIs were mild and found there was convincing evidence that helmets substantially reduce bicycle-related TBIs, decreasing the risk by up to 50% [48]. A Swedish group estimated that if all the injured cyclists in their study were considered, a helmet could have prevented deaths in two fifths of cases and decreased the severity of one in five brain injuries [107]. A German study of 4000 bicycle crashes found that 2/3 of the head injuries were in head regions that would have been protected by a helmet [119]. Rivara et al. found that helmet use decreases the risk of fatality by 93% [95]. Similarly, a Cochrane systematic review concluded that helmets reduce the risk of TBIs by 88% and more specifically severe TBIs by at least 75% for all age groups and were effective irrespective of the accident mechanism [11]. A meta-analysis by Attewell also concluded that helmets have a clearly protective effect [12]. A recent very large French case-control study found that helmets protected against head injury regardless of mechanism (MVA or not), having the most robust protective effect for severe injuries [120]. As evidenced by the previously described studies, helmet wearing is generally considered to confer a protection against TBIs.

Despite the ample evidence described above, certain authors put into question the protective effect of helmets and question the validity of the methodology of the studies that support it [121-123]. Curnow has written multiple articles putting into question the methodologies of the Attewell meta-analysis, primarily its lack of consideration for angular acceleration injuries as the primary mechanism of brain injury [121]. Curnow also later suggested that while some evidence supports the protective effects of older hard helmets, this cannot be generalized to the more modern helmets [124]. Elvik conducted a re-analysis of Attewell et al.'s meta-analysis [12] on the basis that it had publication and time-trend biases that were unaccounted for [123]. Following the reanalysis, the results still supported a protective effect of helmets against head injuries [123].

To address biomechanical efficacy of contemporary helmets at preventing head injury risk, Cripton et al. conducted paired impacts of a validated anthropomorphic head form with and without a helmet from drops at various heights [125]. The results unequivocally supported the idea that helmets provide protection against head injuries; at all heights the helmeted head form received less linear acceleration forces than the unhelmeted one [125]. According to a reconstructed bicycle accident model, the forces at play in a representative 20 km/h bicycle accident are similar to a free fall drop from 1.5 meters [126]. An analysis of over 4,000 bicycle crashes in Germany found that the average speed at the time of the crash was 21,3 km/h [119], supporting that a 20 km/h estimate is representative of typical bicycle crashes. The biomechanical study by Cripton et al. found that at the 1.5 meters level, unhelmeted forms had 99,9% probability of having a severe TBI (very likely), compared to 9,3% with a helmet (highly unlikely) [125]. Therefore, there exists biomechanical support to the epidemiological conclusions that helmets protect against brain injuries.

Helmet effectiveness is dependent on many factors. First and foremost, the helmet used should be held to a certain standard of safety. The American Association of Neurological Surgeons recommend helmets approved by the Snell Memorial Foundation, the American National Standards Institute or the American Society for Testing and Materials [70]. In Quebec, the SAAQ recommends wearing a helmet that is approved by the Canadian Standards Association, the Consumer Product Safety Commission or the American Society for Testing and Materials [127]. All of these groups submit the helmets to testing, each with their own drops heights (varying between 1,6 and 2,2 meters) and linear acceleration approval thresholds (250 to 300 g's or 2452 to 2943 m/s^2) [125]. Next, a helmet must be properly fitted and attached so as not to fall off in the event of a cycling accident. Finally, the helmet must be in good condition; helmets are meant to be effective for a one-time crash and should be replaced if there is any suspicion of compromised integrity [128]. Drops from as little as 0,5 meters can cause helmet deformation [125].

With biological plausibility [125] and rigorous case-control studies [11, 12] demonstrating their efficacy, helmets are generally believed to prevent head injuries. If an individual uses an approved helmet properly, it is nearly universally accepted that in the event of a crash, the helmet will confer a protection against TBI [106]. What is debated, as highlighted by De Jong, is whether societal measures (more specifically helmet legislation) aimed at imposing helmet wearing are beneficial to society's health as a whole [106].

3.3 Non-Legislative Helmet Implementation Strategies

The major non-legislative strategies to encourage helmet use amongst cyclists are educational programs, helmet subsidies, helmet legislation, or a combination of those three [129].

Educational campaigns can take various forms: community-based, school-based, physician-based or a combination [129]. Educational campaigns have varying effectiveness, with cyclist helmet use reaching between 15% to 51,8% post implementation [129]. According to the WHO task force on mild TBI, every study reviewed that evaluated educational interventions encouraging helmet use was effective to some extent, although somewhat less in lower socioeconomic groups [48]. The lesser effectiveness of helmet educational campaigns in populations with lower socio-economic status has been corroborated by others [129].

In a theoretical model, Thompson et al. found that subsidies between 5-10$ given to 5 to 9 year olds might realistically increase helmet use from below 10% to 40-50% and be cost-effective [130]. A Cochrane review found that providing free helmets was more effective than subsidizing helmets to increase helmet wearing in children [131]. No studies regarding helmet subsidies for adult populations were found in our literature search.

A community wide multi-promotional approach in Seattle including parental education, school based education and events, promotional television and radio advertisements, and helmet subsidies was found to increase helmet use in children from 5% pre-intervention to 40% over 5 years [132, 133]. In the province of Quebec, after an intensive four-year helmet promotion program amongst children that included subsidised helmets, the rates of helmet wearers went from 1,3% to 33% [76]. While the Quebec results were impressive, the absolute percentage of helmet wearers was significantly less than those found in Ontario and Nova Scotia children following their helmet legislation implementation for minors (65% and over 80% respectively) [75]. Although educational campaigns significantly increase the use of bicycle helmets, it has been observed that they plateau when helmet use reaches between 50-60%, suggesting that other approaches may be required to maximize results [134, 135].

Only one public health campaign targeting adults was identified: the French public health helmet campaign [136]. Its multiple campaigns advertised to a broad age range (youth to 50 year olds) with the message "Helmet use is not compulsory, it is essential" [136]. Helmet use increased from 7,2% to 22% over the 10 years it was in place [136].

A Cochrane review of the subject found that community based approaches that combined education with free helmets were the most effective at increasing helmet uptake among children [131]. Considering there is some evidence that helmet legislation targeted to children increases adult helmet wearing [137], it is possible that a similar adult helmet use increase might exist with non-legislative approaches as well.

3.4 The Legislation Debate

The effectiveness of helmet legislation is greatly debated. There appears to be sufficient evidence that legislation effectively increases the prevalence of helmet use among cyclists [70, 137, 138], however, what remains unclear is if the overall number of injuries are decreased following legislations [139].

Increasing Helmet Use

According to Dennis et al., Canadian youth and adults are significantly more likely to wear helmets as the comprehensiveness of helmet legislation increases [138]. Furthermore, even when legislation is specifically aimed at children, a notable increase in helmet uptake in adults is observed [137]. Similarly, the American Association of Neurological Surgeons state that the rate of helmet use in children 14 years and under more than doubled when comprehensive helmet legislation was implemented [70]. Three studies involving legislation of helmet wearing in child cyclists reviewed by the WHO task force on mild TBI found legislation to result in a modest increase in helmet use [48]. A systematic review of the effectiveness of helmet legislation found that all legislation created an increase in helmet uptake among cyclists, with the greatest differences observed in populations where the baseline helmet use was low, and with helmet uptake increasing the more age inclusive the legislation was [2]. A Cochrane review on the subject of helmet legislation also found evidence that legislation increases helmet use [140]. Helmet legislation appears much more effective than educational campaigns at increasing helmet use; over 8 years of educational campaigns, one program accounted for a 30% increase in helmet use, whereas after one year of legislation, helmet use rose from 36% to 73% [2]. Overall, it seems clear that helmet legislation increases helmet use.

Decreases in TBIs

In practice, many studies evaluating the aftereffects of helmet legislation on the prevalence of head injuries have not shown the decreases in injuries that may have been expected considering the increases in helmet use [139, 141]. Of those that have shown decreases, many are either not statistically significant [142], or have been criticized by other authors [141] for not considering other factors, such as baseline trends of decreasing TBIs due to infrastructure improvements [3, 140]. A notable pan-Canadian study lauded for its rigorous methodology that included baseline trends found substantial decreases in hospitalizations for head injuries in provinces with helmet legislation, however these decreases could not be independently attributed to the legislation [137]. In contrast, a few recent studies from New South Wales, Australia, that have accounted for background trends in head injuries have found decreases in head injuries post legislation when compared to limb injuries [103, 143]. These improved head injury outcomes were despite increases in cycling at a faster rate than population growth post legislation implementation [103, 143]. Thus, the efficacy of helmet legislation at preventing TBIs remains a controversial subject.

Theoretical effects of Helmet Legislation

Supporters of helmet legislation state that from a biomechanical standpoint, helmets must confer head protection from a direct blow [103].

Opponents of helmet legislation claim that case-control studies finding helmet wearing to be beneficial on an individual level assume incorrectly that helmet wearers are behaviourally similar to non-helmet wearers [141]. Many authors have proposed that people who spontaneously decide to wear helmets may be more precautious cyclists and therefore inherently less prone to injury [139, 141, 144]. There is some evidence to support that users of helmets have higher risk perceptions than non-helmet wearers [145]. Others argue that those with helmets tend to be more experienced, and tend to cycle faster and cover more distance, and therefore are a group generally at higher risk for injury [145]. A study on helmet wearing that included hospitalized cyclists and their police records found that non-helmeted cyclists had riskier behaviour but tended to cycle in safer areas [144]. Similarly, over 80% of cyclists in Montreal who travelled along very steep inclines wore helmets [13]. It is difficult to pigeonhole helmeted cyclists; perhaps in practice helmets affect various cyclists' behaviours differently.

The population shift hypothesis theorizes that many cyclists stop cycling following the implementation of legislation of helmets [145]. A decrease in ridership would put the remaining cyclists at higher risk of injuries according to the previously described "safety in numbers effect" [87, 102, 139, 146]. Furthermore, since cycling is a good cardiovascular exercise, the health benefits of potential head injury protection from helmet legislation may be outweighed by the loss of general population fitness if the population shift hypothesis is correct [91]. Negative health impacts (potential decrease in physical activity) are often not taken into account when evaluating health improvements (reduction in TBIs) following legislation [106]. While it is possible that those who stop cycling may take up another physical activity, it is deemed unlikely when cycling was used as a means of transportation [106]. Thus, helmet legislation may have two unintended negative health effects if it discourages cycling: decreasing populational physical activity and increasing injury risk to the remaining cyclists. As De Jong argues, these inadvertent negative health effects may effectively negate the positive effects of wearing a helmet [106]. However, evidence for general decrease in cyclists following legislation shows mixed results; certain studies have found a decrease in cycling (up to 40% in children) following legislation [122, 139], while others in Melbourne found that in the children group in their study cycling decreased by 36% following legislation, while adult use increased by 44% [147].

Some theorize that post legislation a population shift occurs, whereby the people who continue to cyclist are those with more equipment, for instance racers who might take more risks (like speeding) [145]. This increased proportion in risk taking cyclists may explain why many studies have not shown great improvements in injuries and fatalities following legislation [145]. Furthermore, people wearing a helmet due to legislation may be more likely to wear it incorrectly, only wanting to abide by the law [139, 141].

Risk compensation is another theory that may help to explain results demonstrating that helmet legislation is not more effective at preventing TBIs. The risk compensation hypothesis supposes that an individual will modify their caution according to the level of their perceived risk [148]. When applied to cycling, the theory supposes that either cyclists or people interacting with cyclists will be more reckless in the presence of a helmet, thereby making the cyclists more prone to an accident [139, 141, 149]. Risk compensation studies in other fields have yielded mixed results. A meta-analysis of the effects of helmets on head injuries in skiers and snowboarders found that helmet-wearing athletes did not exhibit higher risk behaviours [150]. A study by Ouellet comparing helmeted an non-helmeted motorcyclists found the opposite of risk compensation to be true; it was the motorcyclists who did not wear helmets that tended to exhibit more risky behaviour and there were more non-helmeted motorcyclists involved in accidents than helmet wearers [148].

The evidence for risk compensation in cyclists who wear helmets is sparse [149]. One study found that cars drove closer to cyclists who wore helmets [151]. Another study found that cyclists used to wearing helmets exhibited more precaution when asked to bike without helmets, but found no similar risk compensation of increased risk taking when habitual non-helmet wearers were asked to wear one [146]. In yet another study, lack of helmet wearing, and therefore greater risk of injury, was associated with more frequent traffic violations, thereby contradicting the risk compensation theory [152].

When evaluating the evidence for helmet legislation, it should be kept in mind that initially, seat-belt legislation was thought to lead to more reckless driving and that it did not reduce fatalities [153]. This belief was eventually refuted by a review of United-States MVA fatality data from 1985 to 2002 that showed seatbelt enforcement laws led to increased seatbelt use and a decrease in fatalities for both motor vehicle occupants and non-occupants (such as pedestrians or motorcyclists) [154]. While speculative, it is possible that the true effects of bicycle helmet legislation will require more hindsight to be properly appreciated. This hindsight may explain why the Australian study spanning 20 years showed a decrease in head injuries [103].

In conclusion, the current state of the evidence strongly supports the protective effects of helmets against TBIs [11, 12, 125]. Non-legislative efforts to increase helmet wearing appear to be successful at increasing helmet wearing to a total of 50-60% of cyclists, after which legislation appears necessary to achieve higher helmet wearing percentages. There is conflicting information on the effects of legislation on head injuries, with certain jurisdictions having little effects [137] and others seemingly having greatly reduced head injury prevalence [103]. Legislating helmet wearing may have unintended negative health effects (such as decreasing physical activity by discouraging cycling) that may outweigh, at least in the short or medium term from a societal perspective, its positive protective impact on head injuries [106, 139].

Chapter 4. Costs

TBIs place a substantial burden on society because of their primary costs (medical) and secondary costs (lost productivity). Average medical expenses per brain injury are more costly than all other bodily injury, with the exception of spinal cord injuries [45]. Patients who have TBIs comprise the injured group with the highest loss in productivity [94]. It has been shown that the estimated mean medical cost per head injury was $14 809, compared to lower limb injuries that cost on average $2085 [45].

The total economic impact of TBIs from all causes in the United States in the year 2000 were estimated to be $9,222 billion dollars in lifetime medical costs, and $51,212 billion dollars in productivity losses [94]. According figures from the S.A.A.Q., a patient who has a severe TBI resulting in long-term loss of productivity, with an average age of 25 and an assumed annual income of 30 000$ will have an estimated lifetime total cost of care and salary compensation of around 4 to 8 million dollars [14]. It is therefore evident that TBIs can be very costly, both acutely in hospitalization costs as well as in long-term loss of productivity costs.

4.1 Publicly Funded Health Care

Prior to 1947, while the Canadian government was responsible for managing and maintaining hospitals according to the Constitution Act, health care was privately funded [155]. The Régie de l'assurance maladie du Québec (RAMQ), the government health insurance plan in Quebec, was created in 1969 with full universal coverage coming into effect in 1970 [156]. In 1984, the *Canada Health Act* combined the previous acts into the one that continues to be enforced today, that ensures universal public health care [155].

Universal health care comes with a hefty price tag; the executive director of Montreal's Royal Victoria Hospital in 1958 warned in an opinion piece for the Canadian Medical Association Journal on public health care, that while the potential benefit was great, the risk of "costs […] [soaring] to astronomical proportions" could adversely affect the economy [157]. Indeed, costs have been rising. In 2012-2013, the Quebec government spent 42,3% of their total budget on Health Care and Social Services [158]. Comparatively, 31% of the provincial budget was used in 1980 for the same services [159]. According to a government budget report in 2011, if nothing is done to address these increasing health care costs, in 20 years, the budget for health care might encompass two thirds of total provincial spending [159]. In an attempt to decrease spending, the provincial government's cut $80 million from the Montreal public and social services agency budget for 2012-2013 and again for 2013-2014 [160]. Thus, with rising health care costs that need to be curtailed, identification of costly injuries that have already known effective preventative interventions can prove valuable.

4.2 Economic Burden of Disease

Cost-of-illness studies are commonly used in health economics to quantify disease burden [161]. For instance, a cost-of-illness approach was used to assess the economic burden of injury in Canada [162]. Cost in such studies refers to the "value of the consequences of using a particular good or service rather than its price" [163]. This specification essentially differentiates between the actual cost of using a good or service (what we are looking at), and what might be charged for them (that may not reflect the cost, but rather supply and demand). A nationally funded health care system requires an economic evaluation done from a societal perspective [164]. The societal perspective is also generally considered to be the most optimal because it is the most inclusive [165, 166].

Before detailing how the economic burden of disease may be calculated, acceptable practices for cost calculations will be presented. The use of proxy costs are considered acceptable when a study compares cost differences between two groups [165]. For instance, the use of charges to individuals for specific services or various accounting data may not be equivalent to the actual cost, but can be considered suitable proxy costs [165, 167]. The ideal costs to consider in hospitalizations are called marginal costs [166]. Marginal costs are defined as the "the extra cost of producing one extra unit", in this case, the extra cost of hospitalizing one more patient with TBI [166]. This is different from average costs because it does not take into account overhead costs, since whether one more patient is hospitalized or not, much of the overhead costs remain the same [166]. However, in the case of TBIs where the highest impact of costs reside in the indirect costs, and when information is lacking, average costs can be considered an acceptable compromise [166].

A complete overview of cost-of-illness studies was written by Segel, from which much of the following information was taken [167]. Various costs can be included in cost-of-illness studies depending on the point of view of the study, however these generally include direct costs (medical and non-medical), indirect costs and intangible costs [163, 167]. Conducting a study from the societal point of view necessitates the inclusion of all direct and indirect costs [167].

Direct costs theoretically involve some form of monetary exchange [163]. Direct medical costs encompass acute inpatient and rehabilitation hospital care and physician charges, allied health care (e.g. physiotherapy, occupational therapy), diagnostic testing, outpatient physician billing, long term care (hospice care), medications and medical supplies (e.g. orthoses) [163, 167]. Direct non-medical costs include transportation to health care appointments and the cost of relocation, however they are often excluded due to lack of good cost estimates [163, 167].

Indirect costs represent the "economic value of consequences for which there is no direct money transfer" [163]. These costs comprise mortality costs, morbidity costs (loss of productivity costs, homecare costs) and in certain rare cases, losses due to crime (e.g. legal costs, imprisonment) [163, 167]. The International Society for Pharmacoeconomics and Outcomes Research that establish research practices in pharmacoeconomics recommend that when assessing future costs, a discount rate should be applied [168]. A generally accepted discount rate is 3% [167].

There are three approaches that are accepted for calculating the indirect costs related to a disease: the human capital method, the friction cost method and the willingness to pay method [167]. The human capital method involves multiplying the earnings lost at each age by the probability of having lived to that age [167]. The friction cost method calculates only the labour lost during the time it takes the employer to hire a replacement employee [167]. The willingness to pay method attempts to estimate the amount an average individual would be willing to pay in order to decrease their probability of death or disability [167]. The most common method used is the human capital method because it is easier to attribute a cost to, though it places less value on disability or death in the elderly which has clear ethical issues (patients over the age of 65 are considered to be retired and therefore have a yearly salary of $0) [167]. The friction cost method tends to underestimate costs whereas the willingness to pay tends to overestimate costs compared to the other methods [167]. Though the three methods have their advantages, the human capital method was preferred in our study to calculate cost of indirect costs (death and loss of productivity), for its ease of calculation and also because we modeled our approach on other Canadian cost-of-illness studies [162].

Intangible costs, such as pain and suffering, are often mentioned in studies, however, due to difficulties associated with establishing appropriate cost estimates, they are usually omitted from the actual calculations [163, 167]. Also, costs related to disability payments, insurance payments, sick days and workers compensation should not be included because from a societal perspective they constitute transfers of funds and not actual loss of productivity [169].

Two approaches exist to evaluate cost-of-illness: prevalence based costs and incidence based costs [161, 167]. Prevalence based costs involve estimating annual costs for the prevalent population, whereas incidence costs require estimation of lifetime costs of all injuries of the incident population [161, 167]. Diseases that are more chronic in nature with long-term morbidities, such as TBIs, are best suited to be evaluated in an incidence based cost approach [167].

The actual cost calculations can be approached three ways: top-down, bottom-up or econometric [167]. A bottom-up costing approach “estimates costs by calculating the average cost of treatment of the illness and multiplying it by the prevalence of the illness” [167]. For instance, using the average hospitalization cost at the MUHC-MGH, then multiplying it by the number of days an individual patient was hospitalized to establish that person’s hospitalization cost. The approach favoured in our study was the bottom up approach, using hospital generated average costs and combining them with information from the trauma database and chart reviews. When information was missing, it was supplemented by information from relevant literature. Data that was considered to be of a lesser order of magnitude and therefore unlikely to influence the overall cost outcome was omitted when not readily made available to us through the trauma database (e.g. physician's consultations and medical devices such as orthotics). The omission of trivial costs are considered reasonable when all groups in a comparative study exclude them [166].

4.3 Cycling TBI Cost-of-Illness Studies

There are few studies evaluating the cost of illness associated with TBIs due to cycling. Many of them use pooled estimates, rather than bottom up cost methods to evaluate costs and often they do not include loss of productivity or long term care costs. Also, to our knowledge there are no cost-of-illness studies done in Canada, where health care costs may be different given the entirely government funded universal health care access when compared to for profit health care systems (such as in the United-States).

An American study by Schulman et al. estimated the economic burden of injury associated with lack of helmet use [170]. They used national data to estimate individual state bicycle related TBI injuries according to approximate state population [170]. Using bicycle helmet wearing rates from the literature and a relative risk of 3.32, they calculated approximate avoidable non-fatal and fatal TBI injuries [170]. Using those data, they estimated direct and indirect costs from a social perspective using state-to-national ratios, notably excluding long term care [170]. In one year in the United-States, they estimated that 327 fatalities, 6900 hospitalizations and 100 000 emergency department visits could have been prevented with a savings of 81 million dollars in direct and 2,3 billion dollars in indirect costs [170].

Helmkamp et al. evaluated costs of bicycle related deaths from all causes (including, but not exclusively TBI), and found that there was an increase in rates of death for children and adults from 2000 to 2005 in the United-States [171]. The costs associated with the child fatalities were 2,4 million dollars and 16,8 million dollars for adults in 2005 [171]. They believed helmet promotion would be helpful in decreasing bicycle related fatalities [171]. Unfortunately they did not mention whether the cyclists were wearing helmets at the time of their injury or not [171]. Another study examined hospitalization costs of cycling injuries amongst children [172]. While a third of injuries involved TBIs, again no mention of helmet wearing status was made [172].

A cost study on all pedal cyclists in the United-States found that TBIs in the over 15 year old group accounted for 4.6 billion dollars in medical, lost productivity and monetized quality of life lost for the year 2000, which averaged out to around 700 000 dollars per patient [173]. This figure is higher than the one found by Finkelstein et al. for the economic burden of disease for patients with TBIs from any cause (about 280 000 dollars). However, the latter study did not include cost estimates associated with quality of life lost. Once again, due to the use of pooled data from the health care system, no mention on helmet status was included in the study [173].

Thus, there are very few studies evaluating the cost of injury associated with TBIs in cyclists and to our knowledge there are none that have looked at a Canadian population. Only one study included helmet wearing as a variable, however they used approximations rather than actual patient data [170]. All of the studies mentioned that helmet wearing should be encouraged to help decrease injuries and their associated costs, regardless of whether they evaluated helmet wearing or not [170-173].

Summary Statement, Rationale and Thesis Goals

TBIs can have devastating consequences, from long-term dependent living [64] to death [1, 64]. An estimated 3,6 to 6,4% of all TBIs are caused by bicycle accidents [4, 69]. Cycling has been increasing in popularity worldwide [81] as well as locally [8]. Helmets have been demonstrated to protect against TBI, potentially preventing them [11, 12]. With the Canadian Health Care System being publicly funded, it makes sense to evaluate the economic burden of disease of preventable injuries [164], as well as identify populations at risk of more dangerous behaviour in order to provide targeted interventions.

Existing studies have described outcomes of cyclists who sustain TBIs with and without wearing helmets [11, 12]. However, to our knowledge, none have specifically evaluated the local population of Montreal. As for the cost-of-illness of sustaining a TBI while cycling, the majority use pooled cost estimates [170, 171], many only evaluated costs for children [171, 172] and only one study described helmet use as one of the variables [170].

What we are proposing is different in that we would be comparing two groups (helmet versus no helmet) using a bottom-up cost-of-illness approach, rather than extrapolating from risk calculated avoidable fractions. Furthermore, we include estimates of indirect costs (long-term care, loss of productivity and cost of death). To our knowledge, no other study directly compares outcomes in Montreal and cost of illness of TBI on the basis of helmet wearing status.

The methodologies of the following studies are meant to evaluate if at baseline, there is a difference of outcomes and societal costs between cyclists with TBIs who are helmeted and non-helmeted. In article number one, this approach allows us to determine if there is a difference in baseline characteristics among helmet wearers and non-helmet wearers in the Montreal area. We seek to identify demographic differences specific to our area in order to better guide future helmet promoting efforts to groups at highest risk of not wearing a helmet. Medical outcomes between the two groups are compared to determine if helmet wearing has a potential protective effect or not on TBIs in our patient population. Finally, we control for confounding factors, such as polytraumas, to better isolate the effects of medical outcomes between patients wearing and not wearing helmets.

Article number two focuses on the differences in costs both direct and indirect associated with TBIs in cyclists wearing and not wearing a helmet. The two groups are compared to identify if there are any cost differences when a helmet is worn. We seek to identify cost differences in order to establish a baseline to evaluate if future helmet-promoting efforts might be cost effective. Again, confounding variables, such as polytraumas, are accounted for.

A discussion elaborating on the main findings, strengths, limitations and overall recommendations is presented after the two articles.

ARTICLE 1

Comparative Outcomes of Traumatic Brain Injury from Biking Accidents With or Without Helmet Use

Jehane H. Dagher[1,2]

Camille K. Costa[2]

Julie Lamoureux[3]

Elaine de Guise[4,5]

Mitra Feyz[4]

[1]Département de médecine physique et réadaptation, Centre Universitaire de Santé McGill – Hôpital Général de Montréal.

[2]Département de médecine physique et réadaptation, Institut Réadaptation Gingras-Lindsay de Montréal, Université de Montréal.

[3] Département de médecine préventive et sociale, Université de Montréal.

[4]Programme de Traumatisme Crâniocérébral, Centre Universitaire de Santé McGill – Hôpital Général de Montréal

[5]Département de neurologie et neurochirurgie, Centre Universitaire de Santé McGill – Hôpital Général de Montréal

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Comparative outcomes of traumatic brain injury from biking accidents with or without helmet use

Jehane H. Dagher MD, FRCPC, FABPMR,[1,2] Camille Costa MD,[2] Julie Lamoureux DMD, M.Sc.,[3] Elaine de Guise PhD,[4,5] Mitra Feyz MSc Ps.[4]

[1]Physical Medicine and Rehabilitation Department, McGill University Health Centre-Montreal General Hospital
[2]Physical Medicine and Rehabilitation Department, Institut de Réadaptation Lindsay Gingras de Montreal, University of Montreal.
[3] Social and Preventive Medicine Department, University of Montreal.
[4]Traumatic Brain Injury Programme, McGill University Health Centre-Montreal General Hospital.
[5] Neurology and Neurosurgery Department, McGill University Health Centre-Montreal General Hospital

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Corresponding Author:

Jehane H. Dagher, MD, BSc PT, FRCPC, FABPMR
Physical Medicine and Rehabilitation
McGill University Health Centre
Montreal General Hospital site, Room D13-124
1650 Cedar Avenue
Montreal, Quebec
H3G 1A4, Canada
Phone: (514) 934-1934 ext. #42048

Abstract

Objective: To determine if demographics and health outcomes differ according to helmet status between persons with cycling-related traumatic brain injuries (TBI).

Methods: This is a retrospective study of 128 patients admitted to the Montreal General Hospital following a TBI that occurred while cycling from 2007-2011. Information was collected from the Quebec trauma registry. The independent variables collected were socio-demographic, helmet status, clinical and neurological patient information. The dependent variables evaluated were length of stay (LOS), extended Glasgow outcome scale (GOS-E), injury severity scale (ISS), discharge destination and death.

Results: 25% of cyclists wore a helmet. The helmet group was older, more likely to be university educated, married and retired. Unemployment, longer intensive care unit (ICU) stay, severe intracranial bleeding and neurosurgical interventions were more common in the no helmet group. There was no significant association between the severity of the TBI, ISS scores, GOS-E or death and helmet wearing. The median age of the subjects who died was higher than those who survived.

Conclusion: This study highlights the characteristics that differentiate helmeted cyclists from non-helmeted cyclists. These differences may be helpful in targeting helmet promotional measures to higher risk groups.

Introduction

Traumatic brain injury (TBI) is a major public health concern; one fifth of all injury related deaths are thought to be caused by TBIs in Canada [1]. The dynamics of recovery from TBIs are multiple and largely depend on the severity of the ensuing TBI [2]. Although likely less publicized than football or hockey, cycling constitutes the number one cause of TBI in sports due to its broad appeal [3]. TBIs cause at times severe long-term disability with repercussions not only on patients' their ability to be productive members of society [4] but also on their relatives' and their own quality of life [5].

According to a review by the Quebec public health authority, the increasing use and multiple promotional programmes related to active transportation in the province may lead to more TBIs unless preventative measures are put in place [6]. The lack of legislation on bicycle helmets makes the city of Montreal a favourable setting to evaluate the effects of helmet wearing on TBIs. With a recent bike sharing programme launch and a large increase in the number of cyclists in Quebec (500 000 more in 2010 than there were in 2005) [7], injury prevention efforts are greatly needed.

There exist many studies in the literature that compare medical outcomes of cyclists wearing helmets to those who do not, including prospective case-control studies [8-10]. These studies, discussed in a meta-analysis by Attewell and a Cochrane review by Thompson, have overwhelmingly concluded that helmets protect against serious head injuries and death [9, 10]. Furthermore, convincing biomechanical evidence exists supporting helmet efficacy against severe TBIs [11]. Our retrospective analysis contributes positively to the pre-existing literature in that it seeks to further describe new characteristics of high-risk individuals for TBI from cycling accidents. We sought to identify subgroups that would most benefit from health promotion interventions by evaluating their demographics.

Methodology

Study Design, Setting and Participants

This is a retrospective observational study of all patients admitted to McGill University Health Centre, the Montreal General Hospital (MGH), a tertiary trauma centre, following a TBI that occurred while cycling between April 1st 2007 and March 31st 2011. In that time frame, a total of 6197 trauma patients were admitted to the MGH. Of those 2297 patients suffered a TBI. Of the admitted patients with TBI, 143 patients were the result of bicycle accidents. Two patients were excluded for confounding comorbidities (brain metastasis and myocardial infarct at the time of the accident) and thirteen were excluded for lack of helmet wearing information. Thus, 128 patients were included in our study. The subjects were evaluated by the TBI team of the MGH that includes two physiatrists, two neurosurgeons, neuropsychologists, occupational therapists, physical therapists, social workers, speech language pathologists, clinical nutritionists and clinical researchers, who overviewed the information gathered for the trauma registry. The Montreal University Health Center's ethics committee and the director of professional services approved the research protocol.

Data Collection

Data was extracted from an existing Quebec trauma registry and the TBI programme database. Due to some missing data, a detailed manual review of every chart was performed to increase data completeness. The independent variables collected were socio-demographic, helmet status, clinical, and neurological patient information. The dependent variables are LOS in days (total and in ICU), GOS-E collected at discharge from hospital, ISS, discharge destination and mortality.

Description of Data

Sociodemographic information was collected on patients' age, gender, nationality, education, marital status and employment status.

Clinical Characteristics

Glasgow coma scale (GCS) score was collected on patient's arrival to the emergency department. Physiatrists assessed the severity of TBI separately in accordance with the most current guidelines. LOC was collected for the two fiscal years (2007-2008 & 2008-2009). We chose to conserve the binary (yes/no) annotation for LOC because length of time of LOC was unavailable in the registry and in the charts. Alcohol level and drug screen results for cocaine, cannabis and benzodiazepines were identified on admission. Helmet use was documented. Cycling accident mechanisms were categorized into the following categories: fall, bike vs bike, bike vs pedestrian, bike vs motor vehicle and bike vs stationary object. Imaging (computed tomography of the brain) was analysed using the Marshall Classification, a severity measure and good correlate for mortality [12]. Diffuse Injury I describes all injuries without visible pathology; Diffuse Injury II includes the presence of cisterns with a midline shift of 0-5mm without high or mixed lesion densities of more than 25cc; Diffuse Injury III designates injuries with swelling with compressed or absent cisterns and a midline shift of 0-5 mm, again without high or mixed lesion densities; and finally Diffuse Injury IV describes a midline shift of more than 5mm, the rest of the description being identical to Diffuse Injury III [12]. The other two categories are: the evacuated mass lesion that includes all lesions that must be surgically evacuated; and the non-evacuated mass lesion that describes high or mixed density lesions of more than 25cc that are not surgically evacuated [12].

Medical complications were identified (renal failure, cardiac complications, urinary tract infections, pneumonia, septicaemia, haemorrhage, deep vein thrombosis, diarrhea and delirium). Neurosurgical interventions including intracranial monitoring device installation, extraventricular drain, burr hole, craniotomy and craniectomy were identified. Patients were identified as having had a polytrauma when other injuries including one or more of the following: orthopaedic, spine, abdominal, thoracic and genitourinary. Patients without polytraumas were designated as having had isolated TBIs.

The ISS was also used to determine injury severity. It is an established medical score that equally assesses overall trauma severity in patients who have isolated injuries and those who have polytraumas [13-15]. It correlates with mortality, morbidity and hospital stay amongst other outcomes [14, 15]. The ISS is calculated based on rating each injury according to the abbreviated injury scale (AIS). The AIS uses a gradation from 1 (minor) to 6 (maximal injury, nearly not survivable) for each of the following body regions: head & neck, face, thorax, abdomen, extremities (including pelvis) and external [14-18]. The ISS score is derived from adding the squares of the three highest AIS ratings, resulting in ISS values between 0 and 75 [14-16]. A notable exception to the squaring is when an injury is attributed an AIS of 6, the ISS automatically is assigned the maximal score of 75 [14, 15].

Outcome Measures

The GOS-E, a validated functional outcomes measure [19, 20], was documented at patients' discharge from the acute care hospital upon consensus from the interdisciplinary team. The GOS-E is an extended version of the original Glasgow Outcome Scale, which have both been widely used and accepted as valid functional outcomes following TBI [19, 20]. The

GOS-E is best determined following a structured interview [20]. According to the guidelines established by Wilson et al., the scoring is as follows: (1) death, (2) vegetative state, (3) lower severe disability, (4) upper severe disability, (5) lower moderate disability, (6) upper moderate disability, (7) lower good recovery and (8) upper good recovery [20].

Total hospital and ICU LOS was calculated for all patients as a marker of disease severity. Finally, discharge destination from the acute hospital directly home to in or outpatient rehabilitation and death were collected for each patient.

Statistics

Descriptive statistics are presented using means, medians, standard deviations and ranges for numeric variables and proportions for categorical variables. Bivariate associations between helmet use and demographic or accident variables were done using t-tests for numeric variables with symmetric distributions, Wilcoxon rank tests for ordinal variables and numeric variables with asymmetric distributions and chi-square tests for categorical variables. Correlations were done using Spearman rank for ordinal variables and Pearson for numeric variables. We used simple and multiple logistic regressions for predicting helmet use and simple and multiple ordinal regressions to predict severity of trauma, GOS-E and length of stay. All analyses were done using Stata 12.0.1 (StataCorp, Texas) and the level of significance was set at 0.05.

Results

Demographic variables

The descriptive statistics for demographic variables can be found in table 1. Seventy-five percent of cyclists in our study did not wear helmets. The average age (±SD) of the total sample (n = 128) was 44.1±17.5 years old. The distribution of age of the sample was slightly skewed to the right. The helmet group was significantly older (t_{126df} = 2.1878, p = 0.030). Seventy-two percent of the subjects were men. The proportion of men and women was not significantly different between the helmet groups (χ^2_{1df} = 1.855,p = 0.173). The distribution of education was not statistically significantly different between the 2 groups (χ^2_{4df} = 9.382, p = 0.052) but there was a tendency for the group wearing helmets to be more schooled. The distribution of employment was significantly different between the helmet groups (χ^2_{4df} = 14.728, p = 0.005), with cyclists wearing helmets more likely to be retired and those without helmets more likely to be unemployed. Overall, 29.7% of the sample was married (the remainder single), this proportion was significantly higher in the helmet group (50.0%) compared to the no helmet group (22.9%) (χ^2_{1df} = 8.434, p = 0.004). The majority of the subjects were Canadian (77.3%).

A logistic regression was done to determine which of the demographic variables (age, gender, nationality, education, marital status and employment) were significantly associated with helmet wearing. The number of subjects considered in the regression was 103 because of missing values. The only two variables that had a significant predictive power (using backward deletion for p values > 0.05) were schooling and employment status (see table 2). Those with a university education had more than 5 times the odds of wearing a helmet compared to those with less education. Also, retired subjects were significantly more likely to wear a helmet compared to other employment groups.

	Helmet (25%)	No Helmet (75%)	Total
Sex (n=128)			
Female	12 (25%)	24(37.5%)	36 (28.1%)
Male	20 (75%)	72(62.5%)	92 (71.9%)
Age (mean)	49.86 ± 3.03	42.13 ± 1.77	44.07 ± 1.55
Nationality (n=123)			
Canadian	24 (77.4%)	75 (81.5%)	99 (80.5%)
Non-Canadian	7 (22.6%)	17 (18.5%)	24 (19.5%)
Education (n=114)			
No education	0 (0.0%)	4 (4.7%)	4 (3.5%)
Elementary	5 (17.9%)	21 (24.4%)	26 (22.8%)
High school	4 (14.3%)	21 (24.4%)	25 (21.9%)
College	3 (10.7%)	17 (19.8%)	20 (17.5%)
University	16 (57.1%)	23 (26.7%)	39 (34.2%)
Employment (n=121)			
Full time	16 (53.3%)	39 (42.9%)	55 (45.4%)
Part time	0 (0.0%)	6 (6.6%)	6 (5.0%)
Unemployed	1 (3.3%)	27 (29.7%)	28 (23.1%)
Retired	9 (30%)	10 (11.0%)	19 (15.7%)
Student	4 (13.3%)	9 (9.9%)	13 (10.7%)
Marital Status (n=128)			
Single	16 (50.0%)	74 (77.1%)	90 (70.3%)
Married	16 (50.0%)	22 (22.9%)	38 (29.7%)

Table 1: Demographic Characteristics of Cyclists with TBI, stratified according to helmet wearing status

	OR	S.E.	Prob. ($\chi 2$)	95% CI
Scholarity				
High School	0.824	0.745	0.831	0.140-4.848
College	0.781	0.769	0.802	0.114-5.371
University	5.692	5.010	0.048	1.014-31.955
Employment				
Unemployed	0.133	0.147	0.069	0.015-1.166
Retired	7.647	6.077	0.010	1.611-36.300
Student	1.059	0.785	0.938	0.247-4.529
Constant	0.993	0.392	0.985	0.458-2.153

Table 2: Results of logistic regression analysis for helmet wearing according to demographic factors

Accident variables

The average (±SD) GCS was 12.8±3.6 with a range of 3 to 15 and a median of 14. Overall, 74.2% of the sample had a mild TBI (n = 95), 11.7% a moderate TBI (n = 15) and 14.1% (n = 18) a severe TBI. There was no significant association between the severity of the TBI and either groups as seen in the table 3 ($\chi^2_{2df} = 2.349$, $p = 0.309$). The proportion of women in the mild severity category is higher (33.7%) compared to the other 2 severities (less than 15%). In fact, in a simple ordinal regression with severity as the dependent variable, men have three times the odds of having a more severe trauma compared to women (OR = 3.675, 95% CI [1.192; 11.323]). There was no significant association between nationality ($\chi^2_{4df} = 2.226$, $p = 0.694$), education ($\chi^2_{8df} = 7.978$, $p = 0.436$) or marital status ($\chi^2_{2df} = 0.709$, $p = 0.702$). There was a significant association between employment and the severity of the trauma. Simple ordered logistic regression found those with a full time job to have significantly milder traumas ($\chi^2_{8df} = 15.804$, $p = 0.045$) compared to those unemployed or retired.

Fifty percent of patients did not have alcohol levels tested. Half of those tested (n = 33) had positive alcohol tests, of which 94% were not wearing helmets. The great majority of patients (120) did not have drug testing. Of those tested (8), two tested positive for benzodiazepines, two tested positive for cannabis and none tested positive for cocaine.

Ninety-seven subjects (72.7%) had a positive scan. Eighty-five percent of the sample had either Diffuse I or Diffuse II Marshall classification. A simple ordinal regression revealed that the risk of having a higher Marshall Classification was significantly higher for those without helmets (OR = 2.833, p = 0.010). This is shown in the table 3, where the percentage of subjects in higher severity of Marshall categories is higher for the group without helmets. Almost 94% of all the subjects wearing helmets were in the first 2 categories of the Marshall Classification compared to 82.3% in the group without helmets.

Exactly 50% of the sample had an isolated TBI, the other half had a polytrauma. Bivariately, there was a significant association between wearing a helmet and polytrauma (χ^2_{1df} = 6.000, p = 0.014). The proportion of polytrauma was higher in the group wearing a helmet (68.8%) compared to the non-helmet group (43.8%). The odds of having a polytrauma for those wearing a helmet were 2.8 times higher in the group with a helmet (OR = 2.829, p = 0.016).

The average (±SD) ISS score was 23.2±10.7 with a median of 21.5. The distribution of the ISS scores is given in figure 1. Bivariately, there was no significant difference in the ISS scores between those with (22.6±11.7) and without (23.5±10.4) helmet (t_{124df} = 0.394, p = 0.694).

The most frequent mechanism of trauma is cyclist vs motor vehicle (47.7%) followed by cyclist's fall (35.9%). The age of the cyclist was not significantly different in the various mechanisms of accident groups ($F_{(3,124)} = 0.85$, $p = 0.469$). The mechanism of accident was not significantly associated with gender ($\chi^2_{3df} = 2.117$, $p = 0.548$), with nationality ($\chi^2_{4df} = 3.160$, $p = 0.368$), with education ($\chi^2_{12df} = 12.0529$, $p = 0.441$), with marital status ($\chi^2_{3df} = 2.1932$, $p = 0.533$) or employment ($\chi^2_{12df} = 15.343$, $p = 0.223$).

	Helmet	No Helmet	Total
TBI severity			
Mild	27 (84.4%)	68 (70.8%)	95 (74.2%)
Moderate	2 (6.25%)	13 (13.54%)	15 (11.7%)
Severe	3 (9.38%)	15 (15.68%)	18 (14.1%)
Scan			
Positive	19 (59.4%)	74 (77.1%)	93 (72.7%)
Negative	13 (40.6%)	22 (22.9%)	35 (27.3%)
Marshall Classification			
I	15 (46.9%)	23 (24.0%)	38 (29.7%)
II	15 (46.9%)	56 (58.3%)	71 (55.5%)
III	0 (0.0%)	9 (9.4%)	9 (7.0%)
IV	2 (6.3%)	7 (7.3%)	9 (7.0%)
Evacuated mass lesion	0 (0.0%)	1 (1.0%)	1 (0.8%)
Mechanism of Injury			
Cyclist vs MV	10 (32.3%)	51 (53.1%)	61 (47.7%)
Fall	15 (48.4%)	31 (32.3%)	46 (35.9%)
Cyclist vs fixed object	5 (16.1%)	14 (14.6%)	19 (14.8%)
Cyclist vs cyclist	1 (3.2%)	0 (0.0%)	2 (1.6%)
Unknown	1 (3.2%)	0 (0.0%)	1 (0.8%)
Polytrauma			
Polytrauma	22 (68.7%)	42 (43.8%)	64 (50%)
Isolated TBI	10 (31.3%)	54 (56.2%)	64 (50%)

Table 3: Accident variables stratified according to helmet status

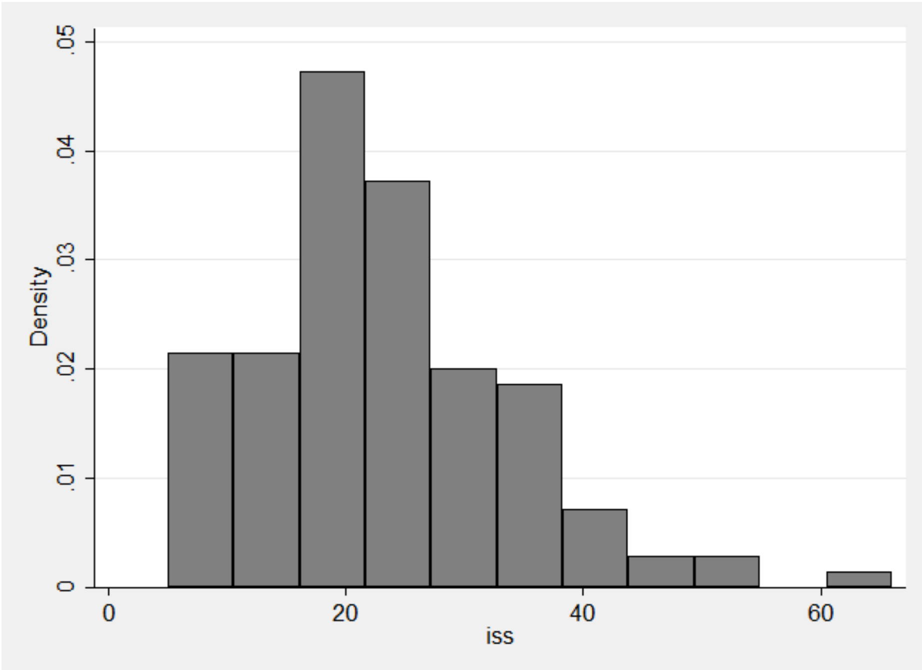

Figure 1: Distribution of ISS scores (n = 126)

Outcome variables

The LOS had an asymmetric distribution as shown in figure 2 with a mean (±SD) of 11.9±19.0 and a median of 5 days. Bivariately, a Wilcoxon rank sum test showed no significant difference in the hospital LOS between those with and without helmet ($z = 1.306$, $p = 0.191$). Table 4 shows the descriptive statistics for hospital LOS for each of the two helmet groups. Even after controlling for confounding variables (polytrauma, severity, employment status, age, gender, ISS, etc.), wearing helmets still was not a significant predictor of hospital LOS. LOS was significantly associated with increasing ISS scores (Spearman rank $r = 0.432$, $p < 0.001$).

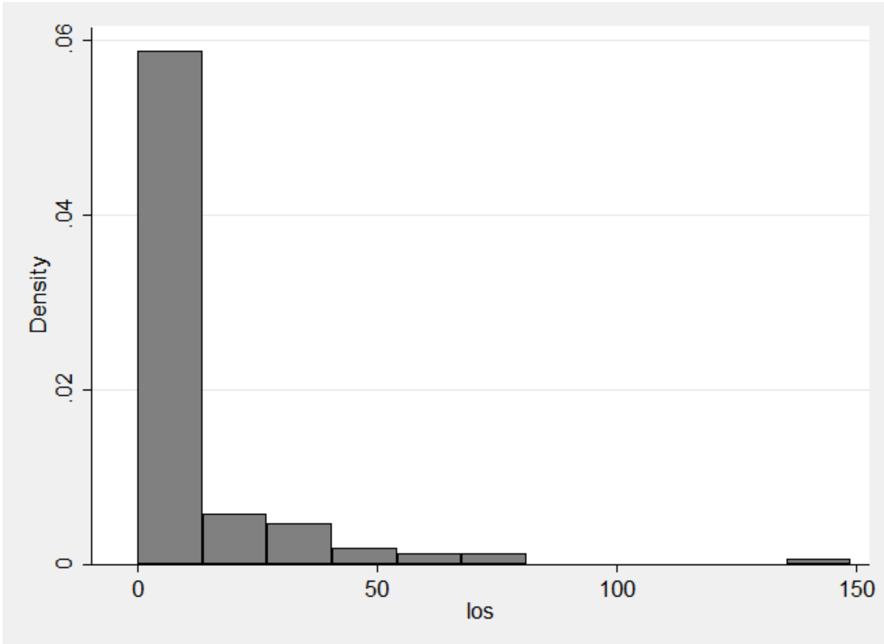

Figure 2: Distribution of LOS (n = 128)

	Helmet	No Helmet	Total
LOS (mean)			
Total	11.19	12.08	11.86
ICU	1.84	3.53	3.11
#Neurosurgical interventions			
0	30 (93.8%)	75 (78.1%)	105 (82.0%)
1	2 (6.3%)	12 (12.5%)	14 (10.9%)
2	0 (0.0%)	8 (8.3%)	8 (6.3%)
3	0 (0.0%)	1 (1.0%)	1 (0.8%)
Discharge Destination			
Home	21 (65.6%)	46 (47.9%)	67 (52.3%)
Outpatient Rehab	4 (12.5%)	19 (19.8%)	23 (18.0%)
Inpatient Rehab	6 (18.8%)	17 (17.7%)	23 (18.0%)
Long term Care	0 (0.0%)	1 (1.0%)	1 (0.8%)
Acute care transfer	0 (0.0%)	5 (5.2%)	5 (3.9%)
Death	1 (3.1%)	8 (8.3%)	9 (7.0%)

Table 4: Outcome variables stratified according to helmet status

The LOS in the ICU also followed an asymmetric distribution with a mean of 3.1±7.3 and a median of 0 days (since more than 50% of the subjects (n = 70) were not hospitalized in the ICU). Bivariately, a Wilcoxon rank sum test indicated a significant difference in the ICU LOS between those with and without helmet (z = 3.187, p = 0.001). Even after controlling for confounding variables (polytrauma, severity, employment, age, gender, ISS, etc.), helmets were still a significant predictor of ICU LOS. The results of this ordinal regression with significant predictive variables are given in table 5. The Lacy coefficient of determination (R2O) indicates this model explains 30% of the variability in ICU LOS. Without the helmet variable, this model explains 26% of the variation in ICU LOS. In this model, for everything else being equal, the risk of staying longer in the ICU is 6 times greater for those not wearing a helmet (OR 6.19, p = 0.001).

	OR	SE	Prob. >|z|	95% CI
No Helmet	6.185	3.465	0.001	2.063-18.546
Polytrauma	2.533	1.024	0.022	1.14705.596
Severity (compared to mild)				
Moderate	7.179	3.910	0.000	2.469-20.876
Severe	28.583	15.831	0.000	9.654-84.634

Table 5: ICU LOS ordinal regression

Medical complications were not observed frequently. One hundred and seven (83.6%) subjects had no medical complications. Overall, 11 subjects (8.6%) had one medical complication, 5 (3.9%) had two medical complications, 4 (3.1%) had 3 medical complications and 1 (0.8%) had six medical complications. There was no association with medical complications and the helmet groups (Wilcoxon rank sum test z = 1.230, p = 0.219). As for neurological complications, there were 4 occurrences of convulsions, 3 of them happened in subjects with no helmet. However, there was no statistical association between helmet wearing and convulsions ($\chi^2_{1df} = 0.000$, $p = 1.000$).

Neurosurgical interventions were not observed frequently. One hundred and five (82.0%) subjects had no neurosurgical interventions. Two subjects (1.6%) had intracranial monitoring (IC), but there was no statistical association between helmet wearing and IC monitoring ($\chi^2_{1df} = 0.677$, $p = 0.411$). Twelve subjects (9.4%) had an external ventricular device (EVD), none of which wore helmets. There was a statistical association between non-helmet wearing and EVD ($\chi^2_{1df} = 4.414$, $p = 0.036$). Two subjects (1.6%) had a burr hole, one in each helmet group ($\chi^2_{1df} = 0.677$, $p = 0.411$). Ten subjects had a craniotomy (2 of them twice) ($\chi^2_{1df} = 3.616$, $p = 0.057$). Seven subjects (4.7%) had a craniectomy (one of them twice) of which six of them were not wearing helmets ($\chi^2_{1df} = 0.453$, $p = 0.501$). Overall, patients who did not wear helmets were more likely to require neurosurgical interventions (Wilcoxon rank sum test $z = 2.051$, $p = 0.040$).

Just over half (52.3%) of the sample was discharged home and an equal proportion was discharged to either outpatient rehabilitation (18.0%) or inpatient rehabilitation (18.0%). Overall, there was no significant association between wearing a helmet and the discharge location, even after controlling for confounding factors ($\chi^2_{5df} = 5.088$, $p = 0.405$). There was a tendency for those wearing a helmet to be discharged home in a higher proportion (65.6%) compared to those not wearing a helmet (47.9%) but this tendency did not reach significance ($\chi^2_{1df} = 3.017$, $p = 0.082$).

Bivariately, there was no significant association between wearing a helmet and death (χ^2_{1df} = 0.996, p = 0.318). Overall, 7.0% of the sample died and this proportion was not significantly different between those wearing a helmet (3.1%) and those without a helmet (8.3%). The median age of the subjects who died after their accident was significantly higher (Wilcoxon rank z = 3.928, $p < 0.001$) than those who survived the accident (68 years of age for the group who died versus 44 years of age for the group who survived).

In a simple ordinal regression, there was no association between wearing a helmet and GOS-E (OR = 1.511, p = 0.315). Even when controlling for other confounding factors (age, gender, severity, polytrauma, ISS), the GOS-E outcome was not significantly different between those with and without helmet.

Discussion

Our study did not show a difference in TBI severity as measured by GCS between the group with helmets and the group without helmets. However, when compared to the general population at the time, helmeted cyclists were underrepresented in our study. Indeed, an observational study on helmet use while cycling in Montreal from 2011 found overall that 46% of cyclists wore helmets [21], nearly double the number of cyclists in our study who sustained a TBI (25%). The paucity of helmet wearers in our study contributes to the difficulty in attaining a power of significance. Also, while speculative, given that 46% of community cyclists were found to wear helmets [21], it may be reasonable to suspect that helmeted cyclists were better protected from sustaining TBIs in the first place and therefore did not need to be hospitalized for their bike injuries as has been demonstrated in multiple other case-control studies [9, 10]. For instance, a case-control study by Thompson found that 29.3% of cyclists with TBIs wore helmets compared to 56.8% of cyclist controls [22].

Although no differences were found for TBI severity (GCS) according to helmet wearing, non-helmet wearers were 2.8 times more likely to have worse Marshall Classifications on admission, were more likely to require neurosurgical interventions (more specifically EVDs) and had 6 fold increased risk of having prolonged ICU stays. While softer endpoints, they are still indicative of higher morbidity in the non-helmet group. We were unable to find other studies that evaluated neurosurgical interventions, Marshall Classification and ICU stay according to helmet status in cyclists. One study evaluated neurosurgical interventions, however it had an insufficient number of helmet wearing patients to be able to compare groups according to helmet status [23].

Our study may have been underpowered to distinguish differences in mortality between helmet and non-helmet wearers. Indeed, only nine patients deceased following their TBI in our sample. Seven of the 9 patients were not wearing a helmet at the time of their accident.

A Thompson case-control study found that helmets were effective at reducing brain injuries regardless of age [22]. It is well established that elderly patients sustaining TBIs are at increased risk for mortality than younger patients [24]. However, bicycling accidents are not the accidents one thinks of when considering potential risks for TBI in the elderly. Our results showing that elderly patients are more likely to die from TBIs while cycling than their younger counterparts is supported by previous studies [25]. This serves as a reminder that with the aging population, they represent a larger segment of the cycling population and perhaps there could be a benefit to preventative efforts targeted to them.

Our study corroborates others' findings that men cyclists are three times more likely to sustain severe TBIs than women [1]. This is indicative that our sample may be generalizable to other populations. The groups at highest risk of not wearing helmets in our study were the younger, unemployed, single and less educated cyclists. Other than the elderly patients, those at highest risk for adverse outcomes were the unemployed. Another Canadian study also found that helmet use was associated with higher income and higher education [26].

Finally, although there was an increased risk of polytrauma in the helmeted group, when comparing the severity as measured by ISS, there were no differences. Since ISS is a superior, objective and validated method to assess severity of injuries between groups, we believe that the increased risk for polytrauma should be downgraded in importance, as it is a soft measure of other bodily traumas. It may be hypothesized that the risk of having more bodily injuries in patients who wear helmets suggests that they are less cautious than certain authors have suggested [27].

We believe that helmet wearing is protective against certain complications related to TBIs in cyclists and should be promoted. Our recommendation is that promotion efforts target the young, single men, less educated, the unemployed, as well as include efforts to educate the elderly population due to their increased risk of death following TBIs.

Strengths and Limitations

In comparing TBIs sustained by helmeted cyclists compared to those non-helmeted assumes that the only difference between the two groups is the headgear. This assumption may not hold, perhaps cyclists who wear helmets are more likely to follow road regulations, speed less, be generally more precautious, as Goldacre postulated in their editorial [27]. They may be more conspicuous to drivers and therefore less likely to be hit in the first place, rather than protected by the headgear. Others have suggested that the most equipped cyclists usually are the most experienced and tend to cycle faster, therefore would be at risk for more severe injuries [28]. Yet others claim that wearing a helmet leads to risk compensation, whereby the wearer feels safer, thus engages in more risky behaviour to compensate [29]. Perhaps the truth is that helmet wearing is associated with different behaviours in different cyclists. Regardless, we were unable to assess it in our study and therefore it is possible that confounding variables exist to explain the worse outcomes in the helmet free cyclists.

From the data collected, it is impossible to evaluate if the cyclists wore their helmets correctly or if the helmet was in good working condition. A good example of this limitation is that one patient's helmet was found on the ground next to them; was this because it was broken off, improperly attached or simply hanging from the handlebars? It was decided to include them in the helmet-wearing group since they did indeed have a helmet with them when the accident occurred.

A strength of this study is the quality of all the information collected, particularly the GCS scores that were reviewed by one of two experienced Physical Medicine and Rehabilitation physicians subspecialized in TBI, thus qualifying them as experts rendering the reliability of their GCS score more valid. Furthermore, all GCS scores were collected upon hospital arrival. Also, unlike other studies that included head and facial injuries that were not traumatic brain injuries, our sample only includes strictly traumatic brain injuries as defined by international consensus including the WHO neurotrauma taskforce [30].

There was some missing demographic information: 3.9% (n = 5) nationality, 10.9% (n = 14) education and 5.5% (n = 7) employment. The majority of the sample (n = 78, 60.9%) did not have documentation about loss of consciousness at the time of the accident. Data was unavailable to quantify PTA and LOC was dichotomized, without any notion of length of

LOC. Half the subjects (n = 64) did not have their level of alcohol tested. A large majority of the subjects were not tested for drugs (n = 120, 93.8%).

Conclusion: Overall, not wearing a helmet was associated with having worse Marshall Classifications, longer LOS in ICU and more neurosurgical interventions, specifically EVDs. There were no negative medical outcomes associated with wearing a helmet. Helmet wearing cyclists were underrepresented in our patient population compared to the general population of Montreal (25% vs 46%) maybe indicative of the decrease need of hospitalization for helmeted cyclists. We believe that helmet wearing is protective against certain complications related to TBIs in cyclists and should be promoted. Ideally public health initiatives should be targeted to young, single men, the less educated, the unemployed, as well as include efforts to educate the elderly population due to their increased risk of death following TBIs.

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Declaration of interest

The authors report no declarations of interest.

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Article 2

Societal Cost of TBI: A Comparison of Cost-of-Injury Related to Biking With and Without Helmet Use.

Camille K. Costa[1]

Jehane H. Dagher[1,2]

Julie Lamoureux[3]

Mitra Feyz[4]

Elaine de Guise[4,5]

[1]Département de médecine physique et réadaptation, Institut Réadaptation Gingras-Lindsay de Montréal, Université de Montréal.

[2]Département de médecine physique et réadaptation, Centre Universitaire de Santé McGill – Hôpital Général de Montréal.

[3] Département de médecine préventive et sociale, Université de Montréal.

[4]Programme de Traumatisme Crâniocérébral, Centre Universitaire de Santé McGill – Hôpital Général de Montréal

[5]Département de neurologie et neurochirurgie, Centre Universitaire de Santé McGill – Hôpital Général de Montréal

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Societal cost of traumatic brain injury: a comparison of cost-of-injuries related to biking with and without helmet use.

Camille K. Costa MD,[1] Jehane H. Dagher MD, FRCPC, FABPMR,[1,2] Julie Lamoureux DMD, M.Sc.,[3] Mitra Feyz MSc Ps.[4] Elaine de Guise PhD[4,5]

[1]Physical Medicine and Rehabilitation Department, Institut de Readaptation Gingras Lindsay de Montreal, University of Montreal

[2]Physical Medicine and Rehabilitation Department, McGill University Health Center – Montreal General Hospital

[3] Social and Preventative Medicine Department, University of Montreal

[4]Traumatic Brain Injury Programme, McGill University Health Center – Montreal General Hospital

[5]Neurology and Neurosurgery Department, McGill University Health Centre-Montreal General Hospital

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Corresponding Author:

Jehane H. Dagher, MD, BSc PT, FRCPC, FABPMR

Physical Medicine and Rehabilitation

McGill University Health Centre

Montreal General Hospital site, Room D13-124

1650 Cedar Avenue

Montreal, Quebec

H3G 1A4, Canada

Phone: (514) 934-1934 ext. #42048

Abstract

Objective: The goal of this study is to determine if a difference in societal costs exists from traumatic brain injuries (TBI) in patients who wear helmets compared to non-wearers.

Methods: This is a retrospective cost-of-injury study of 128 patients admitted to the Montreal General Hospital (MGH) following a TBI that occurred while cycling between 2007 and 2011. Information was collected from Quebec Trauma Registry. The independent variables collected were socio-demographic, helmet status, clinical and neurological patient information. The dependent variables evaluated societal costs.

Results: The median costs of hospitalization were significantly higher (p=0.037) in the no helmet group ($7,246.67, vs. $4,328.17). No differences in costs were found for inpatient rehabilitation (p =0.525), outpatient rehabilitation (p = 0.192), loss of productivity (p = 0.108) or death (p = 1.000). Overall, the differences in total societal costs between the helmet and no helmet group were not significantly different (p=0.065). However, the median total costs for patients with isolated TBI in the non-helmet group ($22,232.82) was significantly higher (p = 0.045) compared to the helmet group ($13,920.15).

Conclusion: Cyclists sustaining TBIs who did not wear helmets in our study were found to cost society nearly double that of helmeted cyclists.

Introduction

Traumatic brain injuries (TBI) are a leading worldwide cause of injury-related death and disability. Recently the Global Burden of disease review estimated that 9.6% of deaths globally were attributable to TBIs [1]. Certain estimates suggest that 81-86% of cyclist deaths involve head injuries [2, 3]. A Cochrane review states that all cycling related TBIs could be decreased by 63 to 88% if everyone wore a helmet [4].

Quantifying the financial impact of preventable injuries is important in the context of publicly funded healthcare and recent austerity measures in health care budgets. The aim of this research is to identify whether there is a difference in societal costs associated with TBIs in cyclists wearing helmets, versus cyclists not wearing helmets at the time of their accidents. This research comes at an opportune time, due to the recent increase in cyclists in Quebec (500 000 more in 2010 than there were in 2005) and the 2009 launch of a bike share programme in Montreal [5].

To our knowledge, there is currently no study in the literature that directly compares costs of TBIs due to cycling accidents with and without helmets. One study estimated preventable head injuries by calculating the avoidable fraction using statistics on helmet effectiveness and the prevalence of its use [6]. A savings of 2.4 billion U.S. dollars was estimated if all US cyclists wore helmets in 1997 from extrapolation of data [6]. Their direct and indirect cost calculation included health services in acute and rehabilitative phases and potential income lost, but did not include long term care or home care [6]. What we are proposing is different in that we are comparing two groups of patients with TBI that wore or not a helmet rather than extrapolating from calculated avoidable fractions. Furthermore, we are including estimations of long-term care costs and cost of death.

Methodology

Study design, setting and participants

This is a retrospective cost-of-illness study of all patients admitted to the Montreal General Hospital (MGH), a designated tertiary trauma center, following a TBI that occurred while cycling between April 1st 2007 and March 31st 2011. In that time frame, 143 were coded to be the result of bicycle accidents. Two patients were excluded who had confounding acute illnesses (intracerebral neoplasm and acute myocardial infarct) and 13 patients were excluded due to missing information on helmet status. After exclusions, 128 patients remained. Each patient was evaluated by a multidisciplinary TBI team that oversaw the information gathered for the database used in this study. The Montreal University Health Center's ethics committee and the director of professional services approved the research protocol.

Data Collection

Data were extracted from an existing Information System database. Due to some missing data, a detailed manual review of every chart was performed to increase data completeness. The independent variables collected were socio-demographic, helmet status, medical and neurological patient information. The dependent variables are length of stay (LOS) in days (total and in the Intensive Care Unit), Extended Glasgow Outcome Scale collected at discharge from hospital, ISS, discharge destination, death, direct medical costs and societal costs.

Overview of Cost Calculation

A cost-of-illness approach was used; the incidence cost of disease was calculated using a bottom up method. Costs were calculated from a societal perspective, including direct medical costs and indirect costs (loss of productivity and death).

The existing Information System data were used to calculate the following direct medical costs: Emergency Department, LOS in ICU, LOS on the ward, neurosurgeries, orientation at discharge for inpatient rehabilitation, outpatient rehabilitation as well as long-term care. Information from the MGH's accounting department was utilized to make direct calculations related to hospital occupancy costs. These costs represent the average patient's cost of occupying a bed, including medications, allied health providers and diagnostic testing costs. Neurosurgery costs were acquired from the Quebec governing health insurance board (RAMQ). Inpatient and outpatient physician billings (other than for neurosurgeries), medical devices and medications taken by outpatients were not included in the calculations due to lack of data. However, these omissions are slight when compared to the costs of productivity losses or long-term care and therefore can be excluded, particularly given that both groups being compared lack these data [7].

Indirect costs were estimated using the human capital approach [8]. Loss of productivity was assumed when GOS-E was 4 or less (excluding death) or patients were transferred to long-term care. Intangible costs related to pain and suffering were not included in the calculations due to difficulties in establishing accurate estimates. Of note, all costs were converted to 2013 Canadian dollars.

ED visits, Acute Care and Rehabilitation

The ED, in-patient ward and ICU costs were determined according to the 2013-2014 daily charges to Quebec patients provided by the Montreal General Hospital accounting department. The costs retained were $215.17 for an ED visit, $1,371.00 per day hospitalized on the ward and $3,346.00 per day in the ICU. An overview of the ED lengths of stay found that the overwhelming majority of patients stayed less than 24h, therefore it was decided that to simplify cost calculations, each patient is considered to have one ED visit, totalling $215.17 each. Total ICU and ward cost were calculated using length of stay in each sector.

Only neurosurgeries were included in the cost calculation because these were the most common interventions in our patient population, and other surgeries are not specific to TBIs. See table 1 for the cost of each intervention which were determined by using information from the Medical Specialists' Manual that provides detailed physician billing information for various acts, including surgeries [9].

Intervention	*Cost(1) CAN$*	*Cost(2) CAN$*
Craniotomy	1120.00	896.20 (revision)
Craniectomy	447.50 (temporal)	540.60 (occipital)
External Ventricular Device	256.80 (includes burr hole)	
Intracranial Pressure Monitor	202.10	
Burr Hole	98.10	

Table 1: 2013 Costs of neurosurgical interventions according to the RAMQ [174]

These costs are strictly neurosurgical billing costs, which exclude OR usage cost, anesthesiologist costs, medications, hardware or surgical kits and therefore are underestimations of the actual cost. However, due to the lack of more specifications around the surgeries performed in the registry, this is the best estimate achievable. The cost of in-patient rehabilitation ($825/day) was determined according to daily in-patient Quebec charges obtained from the Institut de Réadaptation Gingras-Lindsey de Montréal (IRGLM), the intensive rehabilitation hospital where the majority (84% in our study) of the patients with TBI from the Montreal General Hospital are transferred. This cost is nearly all-inclusive, including physically occupying the bed, allied health professionals, medications and investigations. The only costs omitted are the physicians' costs. The average length of stay in rehabilitation at that site for a patient with mild, moderate and severe TBIs are 35 days, 30 days and 53 days respectively, during the 2012 calendar year.

The hourly cost for outpatient rehabilitation ($125) was provided by Quebec's provincial automobile insurance provider (SAAQ). While not all patients received outpatient rehabilitation after their inpatient stay, due to unavailability of data, we chose to attribute a conservative estimate of outpatient rehabilitation hours to all patients who required inpatient rehabilitation: two sessions per week in two disciplines for a total of 8 weeks. This approximation was also used for patients who were directly discharged home with outpatient rehabilitation. Thus, the total cost per patient in outpatient rehabilitation was fixed at $4,000.

Long-term Care Costs

According to a Sun Life Financial report, the most conservative 2012 cost coverage by the RAMQ for long-term care was on average $1,063.80 per month [10]. This cost converted to 2013 dollars comes up to $12,090.18 yearly [11]. There is no clear consensus regarding the life expectancy after a TBI [12]. As such, average life expectancy from Statistics Canada according to year of birth and sex was utilised [13], although this may be an overestimation of actual life expectancy post TBI. Costs for long-term care were then calculated according to life expectancy using a 3% discounting rate and 1% inflation rate.

Loss of Productivity

Loss of productivity costs were estimated in two ways: long-term loss of productivity for patients unable to return to work and the short-term loss of productivity due to hospitalization and recovery. We first determined the patients likely unable to return to work.

If patients were discharged to long-term care, they were assumed to no longer be productive. GOS at discharge from acute care has been found to be predictive of future unemployment independent of previous employment, thus patients in our cohort with a GOS-E at discharge of 2-4 were considered to have a long-term loss of productivity. Average yearly salaries for three age groups were determined according to 2013 Statistics Canada data; $24,096.80 for ages 15-24, $43,789.20 for ages 25-54, $42,970.20 for ages 55-64 and $0 for ages 65 and over (assumed retirement) [14]. With these salaries, we calculated the total yearly wages lost using a yearly 1% inflation rate and a 3% discounting rate [8].

For patients with short-term productivity losses, we considered total LOS and a period of convalescence depending on severity of TBI: three months for mild and six months for moderate and severe TBI [15-17]. These estimates are considered conservative, as our experience has found that the majority of patients with severe TBI never return to salaried work. Certain studies with limited patients have shown long-term return to productivity rates (paid or volunteer work) following severe TBI to be anywhere from 6 to 50% [15, 17, 18]. The same salaries as described above were used for short-term productivity losses.

Cost of Death

Cost of death was calculated using the human capital method. While somewhat controversial due to ageism, it remains the most widely used approach [8]. Much like loss of productivity, average yearly income was derived as above according to age group. Discounting and inflation were again applied to the age of 65.

Statistics

Descriptive statistics are presented using means, medians, standard deviations and ranges for numeric variables and proportions for categorical variables. Bivariate associations between helmet use and demographic or accident variables were done using t-tests for numeric variables with symmetric distributions, Wilcoxon rank tests for ordinal variables and numeric variables with asymmetric distributions and chi-square tests for categorical variables. Correlations were done using Spearman rank for ordinal variables and Pearson for numeric variables. We used simple and multiple logistic regressions for predicting helmet use and simple and multiple ordinal regressions to predict severity of trauma, GOS-E and length of stay. Due to the non normal distribution of costs, comparisons between groups were done based on the median costs, using Wilcoxon rank sum testing All analyses were done using Stata 12.0.1 (StataCorp, Texas) and the level of significance was set at 0.05.

Results

The characteristics of the subjects with TBI can be found in tables 2 and 3, stratified according to helmet wearing status. Overall, 75% of patients did not wear a helmet. Analysis of the demographic results can be found in another study currently submitted for publication (Brain Injury). In this previous study, our research group has shown that patients wearing helmets were significantly older (p=0.030), more educated (p=0.048), more likely to be retired (p=0.010) and be married (p=0.004) Moreover, the ICU LOS was significantly longer for the no helmet group (p=0.001), the risk of a prolonged ICU stay was six times greater for those not wearing a helmet (OR 6.19, p = 0.001). In addition, there was a significant association between wearing a helmet and polytrauma (p = 0.014). Overall, 50% of the sample had a polytrauma and the odds of having a polytrauma for those wearing a helmet were 2.8 times higher in the group with a helmet (OR = 2.829, p = 0.016,). In contrast, there was no statistical difference between groups for gender and nationality. Neither was there a difference in GCS, ISS, GOSE, total LOS scores and discharge destination (Dagher et al. submitted)[19].

Medical and societal costs of patients with TBI with and without helmets

Costs were broken down into six cost categories (hospital, inpatient rehabilitation, outpatient rehabilitation, long-term care, loss of productivity and cost of death), as illustrated in table 2. Of note, subcategories with median costs of zero had more than 50% of patient not incurring any costs in that category.

Costs (CAN$)	**Helmet**	**No Helmet**
Acute Care Hospital		
Median	5699.17	10 416.17
Mean	19 126.00	23 747.69
Inpatient Rehab		
Median	0	0
Mean	6213.28	7992.74
Outpatient Rehab		
Median	0	0
Mean	1827.21	1978.16
Long term Care	*	*
Loss of Productivity		
Median	12 265.62	10 613.33
Mean	42 110.70	47 645.89
Cost of Death		
Median	0	0
Mean	12 265.62	11 428.50
Total		
Median	17 007.37	24 115.54
Mean	80 840.61	92 093.19

*Insufficient data as only one patient required long term care

Table 2: Cost breakdown stratified according to helmet status in CAN$

The median costs of hospitalization were significantly higher (Wilcoxon rank sum test $z = 2.091$, $p=0.037$) in the no helmet group. When controlling for polytrauma, the median cost of hospitalization remained higher in the no helmet group compared to the helmet group

(Wilcoxon rank sum test z = 2.205, p = 0.027). The median costs for isolated TBI without helmets were $7,246.67, compared to $4,328.17 for the helmeted group.

Twenty-nine subjects (23.2%) went to inpatient rehab, 23 were in the non-helmet group. The costs varied between $24,750 and $43,725 and were not significantly different between the two groups (Wilcoxon rank sum test z = 0.636, p = 0.525). The proportion of subjects with costs associated with inpatient rehab was not significantly different (χ^2_{1df} = 0.478, p = 0.489) between the helmet (18.7%) and the non-helmet (24.7%) groups.

A total of 48 subjects (37.8%) were considered to have required outpatient rehab. The proportion of subjects in outpatient rehab was not significantly different (χ^2_{1df} = 1.702, p = 0.192) between the helmet (28.1%) and non-helmet (41.1%) groups. The costs were not significantly different between the two groups (Wilcoxon rank sum test z = 1.299, p = 0.194).

Costs associated with loss of productivity were not significantly different between the two groups (Wilcoxon rank sum test z = 1.610, p = 0.108). When controlling for polytrauma, the costs approached significance in the isolated TBI subgroup (isolated TBI cases Wilcoxon rank sum test z = 1.725, p = 0.085 versus polytrauma Wilcoxon rank sum test z = 1.111, p = 0.267).

Only one subject required long term care. He was a 60-year-old male, single and unemployed, without a helmet with a GCS of 10, a positive scan and a Diffuse IV Marshall Classification required long term care with a total cost of $68,957.76.

Nine of the patients in our study died. Due to the human capital method excluding patients over 65, only four subjects had death-associated costs. Three of the four patient deaths were in the non-helmet group. The costs varied between $166,717.50 and $495,390.10. The proportion of subjects with death-associated costs was not significantly different ($\chi^2_{1df} = 0.000$, p = 1.000) between the helmet (3.1%) and the no-helmet (3.1%) groups. The costs were not significantly different between the two groups (Wilcoxon rank sum test z = 0.009, p = 0.993).

Overall, the differences in total societal costs between the helmet and no helmet group are not significantly different (Wilcoxon rank sum test z = 1.838, p = 0.066). However, when controlling for polytrauma, the median total costs for patients with isolated TBI in the non-helmet group ($22,231.82) was significantly higher (Wilcoxon rank sum test z = 2.007, p = 0.045) compared to the helmet group ($13,920.15), as seen in table 3. The difference was not significant for the polytrauma cases (Wilcoxon rank sum test z = 1.421, p = 0.155) between the non-helmet group (Median = $33,419.07) and the helmet group (Median = $21,663.04).

	Helmet Status (n)	Mean	Median	SD	Range
Isolated TBI	No Helmet (54)	79 660.74	22 231.82	172 659.00	1 586.17-985 298.10
	Helmet (10)	17 269.78	13 920.15	13 244.06	7 610.37-53 655.17
Polytrauma	No Helmet (42)	108 077.80	33 419.07	198 910.5	7 610.37-944 595.80
	Helmet (22)	109 736.40	21 663.04	250 653.7	1 586.17- 1 129 978.00

Table 3: Total societal cost statistics subdivided into isolated TBI and polytrauma cases in CAD$

Discussion

The findings conclusively demonstrate that there is indeed a difference in cost between TBIs in cyclists who wore helmets and those that did not in our sampled population. We attribute this difference to a protective effect of the headgear. When patients with isolated TBIs are evaluated, a significant difference between helmets and no helmets is found. Indeed, the median costs associated with not wearing a helmet are nearly double those of wearing one.

Since helmets protect against head trauma, it is logical that helmets do not prevent costs in polytrauma cases.

The differences in costs appear to be during the acute hospitalization, more specifically due to six fold increased odds of staying longer in ICU and more neurosurgical interventions for the cyclists not wearing helmets. There was a trend towards lesser costs associated with loss of productivity in isolated head trauma cases who wore helmets compared to those who did not, however, significance was not achieved.

Interestingly, helmet wearers seemed to be somewhat underrepresented in our study. A 2011 descriptive study conducted in Montreal evaluating helmet wearing habits of cyclists had found that 46% of cyclists wore helmets [20]. Our study found that only 25% of cyclists admitted to hospital with a TBI were wearing helmets at the time of their accident. This large discrepancy supports the idea that helmet wearing is protective against TBIs while cycling.

Although there was an increased risk of polytrauma in the helmeted group, when comparing the ISS, there were no differences. Thus, both helmeted and not helmeted groups had overall similar injury severity, as well as similar TBI severity, even though the helmeted group was more likely to have bodily injuries as well. It is beyond the scope of this paper to identify the reason why patients wearing helmets were more susceptible to polytraumas. Regardless, patients with polytraumas were excluded in the final overall cost comparison to minimize confounding factors.

Strengths and Limitations

A strength of these studies are the quality of the information collected, particularly the GCS scores that were reviewed by one of two experienced Physical Medicine and Rehabilitation physicians subspecialized in TBI, thus qualifying them as experts rendering the reliability of their GCS score more valid. Furthermore, all GCS scores were collected upon hospital arrival. The bottom-up costing approach is also a strength in that it minimized the reliance on assumptions and extrapolated data, allowing for a more precise cost calculation than other methods. Including information on costs related to long term care and loss of long term productivity are also strengths of our study.

In comparing TBIs sustained by cyclists who wore helmets to those who did not assumes that the only difference between the two groups is the helmet wearing. This assumption may not hold, perhaps cyclists who wear helmets are more likely to follow road regulations, speed less, be generally more precautious, as Goldacre postulated in their editorial [21]. It is possible that a confounding variable exists to explain the differences in costs between the two groups.

Furthermore, our patient population is limited to the patients who required hospitalization for their injuries. Cyclists who died at the scene of the crash as well as those with seemingly minor injuries who chose not to present to the hospital are not included. While the hospital and rehabilitation cost calculations would not be affected by these omissions, certainly loss of productivity and cost of death would. It is uncertain how the differences in costs between helmeted and non-helmeted cyclists would be affected by the inclusion of these patients. Such an all-encompassing study would be difficult to perform, due to previously described inconsistencies in helmet wearing status in police reports for cyclist deaths [22] and obvious recruitment difficulties of minimally injured cyclists.

From the data collected, it is impossible to evaluate if the cyclists wore their helmets correctly or if the helmet was in good working condition. Others have found that drops from as little as 0.5 meters can cause helmet deformation [23], thereby compromising their protective effects.

An unforeseen limitation of this study is that the average age of patients who died is significantly higher than the whole sample. We incorrectly believed that cyclists would be younger, therefore would not be affected by the age bias associated with the human capital method. With the average being 66 years old, and the human capital method only including costs for patients under 65 years of age, that means that more than half of the patients who died were not considered in the cost calculation for death. Future studies might consider the willingness to pay method in studies concerning cost of death in cyclists.

Conclusion

In summary, cyclists sustaining TBIs who did not wear helmets in our study were found to cost society nearly double that of helmeted cyclists. Until better cycling infrastructure is built where cyclists and motor vehicles are physically separated, helmet wearing remains relevant when discussing cyclist safety and an important public health preventative measure.

Declaration of interest

The authors report no declarations of interest.

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Chapter 5: Discussion

5.1 Summary of Studies' Findings

The findings from both of the studies are discussed in greater detail below according to demographic differences, accident and injury variables, medical outcomes and societal costs.

Demographic differences

Only 25% of the cyclists in our studies wore helmets. This is in contrast with a contemporary observational study on helmet wearing habits in Montreal where 46% of cyclists wore helmets [13]. Similarly, a study evaluating cyclist injuries at an Urban Level 1 trauma center in Massachusetts found that 49% of all injured cyclists wore helmets, however, only 25% of cyclists with closed head injuries were wearing one [175]. Thompson et al. also found differences in helmet use between cases with TBI (29%) and controls (56%) [176], as did Bambach et al. (44,1-58,4% versus 77,2%) [144]. From the inferior proportion of cyclists wearing helmets in our studies compared to the general Montreal population, it can be hypothesized that helmets confer protective effects, though to confirm they did in our studies, a control group would be necessary. Indeed, there may be confounding biases whereby helmeted cyclists present other protective characteristics against TBIs. As discussed previously, if helmet wearing is more common in cautious cyclists [141], it is possible that prudent driving, rather than helmets, protected these cyclists against TBIs. Alternatively, cyclists wearing helmets may be more reckless, and the protective effect of helmet wearing is underestimated as a result.

Seventy-two percent of cyclists with TBIs were men in our studies. This finding is consistent with other TBI studies [41] and more specifically cycling injury studies [1, 95, 108, 137, 176]. As highlighted previously, the overrepresentation of men is likely because there are more male cyclists (in Quebec, 2/3 to ¾ of cyclists are men [8]). We found that an equal proportion of men and women wore helmets, which is similar to the distributions in some other studies [134], some studies described higher helmet use in women [76, 144, 177], whereas two French studies noted that women were less likely to wear helmets [120, 136].

It is difficult to compare the mean ages of the injured cyclists from our studies with those of other studies, as many other studies include children, thereby greatly reducing the average age of their cyclists. For instance, the mean age of all cyclists (including children) with head injuries from 2003-2004 across Canada was 24,6 years of age [1]. The average age of adult cyclists admitted to a level 1 trauma center in Boston from 1993 to 2000 was 37,6 years of age [175]. The mean age of our cohort was 42.1 years, slightly older than the Boston group.

Cyclists from our studies who wore helmets were five times more likely to have a university education than those not wearing helmets. An Ontario study evaluating factors associated with helmet wearing also found that higher levels of education correlated with helmet wearing, although to a lesser extent than in our studies (OR 1.68) [177]. This difference may be due to the fact that their study evaluated cyclists from all over Ontario, whereas ours was focused just on the city of Montreal, an urban environment, where there are four university institutions.

Older cyclists in our studies were more likely to wear helmets. This finding is corroborated by other studies [120, 134, 144, 178]. Retired cyclists were more likely to wear helmets than other employment groups in our studies. Similarly, another study found that nearly half (44%)

of retired cyclists in Arizona retirement complexes wore helmets while cycling outside the senior community complex [178].

Cyclists not wearing helmets were more likely to be unemployed in our studies. Other researchers have found similar tendencies [136, 177]. With cost being a known limiting factor to helmet use [76, 134], it is plausible that individuals with less disposable income are less likely to purchase, and therefore wear, helmets.

The proportion of married cyclists was higher in the group of helmet wearers versus non-helmet wearers (50% versus 22,9%). Although many studies evaluated determinants of helmet use, none of the ones we consulted evaluated marital status [136, 177]. Being single has previously been associated with higher risk of TBI [47], and generally negative health behaviours [179]. We believe that these differences in helmet use according to marital status may provide novel approaches for targeted helmet promotion. Additionally, we believe that this may be an important demographic variable for researchers to include in future studies.

Thirty-three patients in our studies tested positive for alcohol use (above the accepted motor vehicle driving limit of 0,08mg/mL). Of these patients, 94% were not wearing helmets. The finding that people under the influence of alcohol are less likely to wear helmet and is consistent with other studies [144, 175, 177, 180]. Only 8 cyclists were tested for drugs and 5 of them were positive, two for cannabis and two for benzodiazepines and one with both, none of which were wearing helmets. As was the case with alcohol, people who are under the influence of drugs are less likely to take safety precautions such as helmet wearing [177].

In sum, several variables correlating with helmet wearing tendencies were identified in our studies in groups of cyclists who sustained a TBI. Suboptimal helmet wearing habits in cyclists sustaining TBIs compared to the general population were consistent with the notion that helmets offer protection against TBIs. As others have found, the majority of cyclists in the current studies were men, and helmet wearers were more likely to be educated and retired. Also, they were less likely to be unemployed, or under the influence of drugs and/or alcohol. What sets the Montreal population apart from others is the elevated extent to which university educated individuals wear helmets. A determinant not previously described for helmet wearing is marital status, with single cyclists in our studies being less likely to wear helmets.

Accident and Injury Variables

The most frequent mechanism of trauma in our studies' sample was cyclist versus motor vehicle (47,7%) followed by cyclist fall (35,9%). This is in contrast to all the other studies consulted where the primary mechanism was from falling [95, 108, 120, 175, 176]. Again, the difference in mechanisms of injury is likely due to the population sampled. In our studies, the patient sample is comprised of hospitalized cyclists with confirmed TBIs, therefore the injuries tend to be more severe than those in studies of patients in the ED that include all head traumas. More severe injuries (particularly severe TBIs [72]) are also more likely a result of MVAs [95, 97]. Furthermore, the MGH's catchment area covers mainly the downtown core of Montreal, an area more dense in automotive traffic than some other studies may have been that included more suburbs and rural areas [120].

The GCS is an important component of severity determination for TBI, as discussed in chapter 1. Our studies found no differences in GCS or TBI severity as assessed by experienced Physiatrists between both helmet groups, even when controlling for confounding variables. The Physiatrists consulted the emergency department notes and evaluated if there were any inconsistencies (eg. patient described as disoriented, but attributed a GCS of 15). In cases of inconsistencies, they consulted with the team to establish the most accurate possible GCS at arrival to the hospital. Most of the other studies consulted relied strictly on the less TBI specific ISS to determine injury severity [95, 108, 120, 175]. Although Thompson et al. took into consideration GCS results, they did not perform any statistical tests on the GCS, instead choosing to transform them into AIS [176]. The advantage to using the GCS is that it is a validated and reliable assessment for TBI severity [18], is an excellent predictor of TBI outcomes when assessed by experienced clinicians [24], and is the tool used in clinical settings, therefore rendering our studies more accessible to clinicians. Given that our study considered only patients admitted to the hospital following a TBI, it is possible that the reason there were no statistical differences between GCS scores was that poor GCS is one of the reasons for admission to hospital. This fact would therefore introduce a selection bias. For future studies, having a control group of non-TBI related injured cyclists could assist in identifying whether helmets are protective against TBIs in our study population.

The ISS was not associated with helmet status in our studies and its overall mean was 23.2. This is considerably higher than the average ISS in all the other studies: 10,4 [175], 85% less than 9 [176], 90% less than 9 [108] and 93,2% less than 8 [95]. These lesser average ISS scores likely reflect differences in study methodologies: inclusion of non-TBI injuries [95, 175] and sampling from the ED rather than hospitalized patients [95, 108, 176]. Rivara et al. also found no association between helmet wearing and ISS, although they believed that was because only 6% of their sample had TBIs [95]. The more severe injuries of the cyclists in our studies may be due to the higher proportion of MVAs.

In our investigations, 72,7% had positive findings on CT scan and the risk of having a worse Marshall classification score was 2,8 times higher in the no helmet group. Many studies did not discuss brain imaging [95, 108, 120, 175]. While the Thompson study evaluated brain imaging, they did not discuss potential differences between helmet groups [176]. Thus, as far as we know, the finding that non-helmeted cyclists have a higher risk of worse brain injuries as assessed by imaging brings new evidence of the efficacy of helmet protection.

Exactly 50% of the sample had an isolated TBI, the other half had a polytrauma. Similarly, Rivara et al. found that 52% of cyclists had 2 injuries or less [95]. Other studies did not explicitly distinguish between isolated TBIs and polytraumas [108, 175, 176]. Unexpectedly, the odds of having a polytrauma for those wearing a helmet were 2,8 times higher in the group with a helmet. Contrary to our results, Bambach et al. found that non-helmeted cyclists were more likely to have severe bodily injuries [144], as did Spaite et al. [181]. McDermott et al. found, as we did, that helmeted cyclists were more likely to have other bodily injuries (e.g. pelvic and extremities) [182]. The increased risk of polytrauma must be evaluated in the context that there were no differences in ISS severities between groups. Thus, helmeted cyclists are not necessarily at higher risk for more severe polytraumas, rather, they may simply be less cautious than others have suggested [141], with their helmet providing the protection for their head, but not the rest of their bodies. Hospitalization was a requirement for inclusion in our studies; as such, it is possible that certain helmeted cyclists were admitted more so on the basis of their polytrauma, rather than their TBI.

Of note, on two separate occasions in our studies when patients without helmets died as a result of their injuries the coroner report stated that following their investigation they believed that the velocity of the impact was sufficiently low that the death would have been easily avoided with the use of a helmet. On one such occasion, security video footage from a nearby store showed the impact between the cyclist and motor vehicle was under 10 km/h.

In sum, our studies included a higher proportion of MVAs than other studies that had investigated medical outcomes in brain injured cyclists. There were no differences in classic severity markers of TBI (GCS and ISS). However, imaging severity was worse in the non-helmeted group. To our knowledge, this finding has not been investigated elsewhere in the literature. There also appeared to be an increased risk of polytrauma in helmeted cyclists, perhaps explained by a protective effect of the helmets against TBIs. Alternatively, unhelmeted cyclists with polytraumas and TBIs may have succumbed to their injuries at the scene of the crash, however we did not have access to this information.

Medical Outcomes

There were no associations between ward LOS and helmet wearing in our studies. There was however a six fold increased risk of ICU LOS in the helmet free group. The reason that non-helmeted cyclists were at increased risk of longer ICU LOS is likely because they required more neurosurgeries. Most studies did not discuss hospital or ICU LOS [95, 108, 120, 144, 176]. One study that did discuss length of stay both in the wards and ICU found no differences between helmet groups, however they included cyclists with all possible injury types, without assessing LOS of TBIs separately [175]. The concept of increased risk of longer LOS in ICU for unhelmeted cyclists seems to be a new addition to the current literature on outcomes of helmet use in cyclists.

Cyclists without helmets in our studies were two times more likely to require neurosurgery, in particular EVDs. No other study that was considered was found to discuss neurosurgical interventions [95, 108, 120, 144, 175, 176]. This finding brings forth new evidence of the protective effect of helmets.

Bivariately, there was no significant association between wearing a helmet and death in our studies. Though it must be considered that we did not have access to cyclist information in the catchment area of the MUHC-MGH for those who may have died before reaching the hospital. Other studies found that non-helmeted cyclists were up to 14.3 times more likely to die in a crash than those wearing helmets [95, 176]. There may have been too few deaths in our studies to identify differences. There were also an insufficient number of cases in other studies to be able to establish an association between helmet wearing and death [108, 175]. Future studies could include a longer time frame and information about cyclist deaths that never reached the hospital to clarify the role of helmets in those deaths.

The median age of subjects who died (68 years) was significantly higher than those who did not (44 years). This is in stark contrast with Rivara et al. where no deaths were noted in the group 40 years of age and older [95]. A study evaluating factors influencing fatalities in cyclists colliding with motor vehicles found that the 65 years and older group was more vulnerable to death and that this susceptibility increased with age [183]. Similarly, Ekman et al. found that nearly half (47%) of fatalities occurred in cyclists over the age of 65 [78]. Both of these studies concluded that the higher risk of fatality in the elderly cyclist subgroup was likely due to their greater bodily fragility [78, 183] as is the case with all-cause TBIs [1].

In short, the medical outcomes that were influenced by helmet wearing were LOS in ICU and number of neurosurgical interventions, which both increased in likelihood with the absence of helmet wearing. These are novel concepts in the literature. Also, as others have found [78, 183], elderly patients were more likely to die from their injuries.

Costs

Total median societal costs were 40% less in the helmeted groups ($13 920 compared to $22 231) when only isolated TBIs were considered. It is difficult to relate our results to other studies, as the only one that used helmet wearing as a variable used a top down cost calculation approach [170]. It seems that the differences in costs may be attributable to acute hospitalization, where non-helmeted cyclists were more likely to stay longer in the ICU and require neurosurgical interventions.

Cost of death was not significantly different between helmet groups in our studies, however there were only nine deaths in total. More than half the subjects who died were calculated to have no costs associated with their deaths due to the use of the human capital method. Although most commonly used in health economics [167], and used in another cycling TBI cost study [170], it may be advisable to use another cost method in future studies, such as the willingness to pay method, given the increasing proportion of elderly fatalities in cyclists [78].

5.2 Strengths and Limitations

One strength of these two studies is the quality of the information collected: the trauma database was compiled by health care professionals, and a detailed review of patient charts was performed. The use of the GCS for severity in addition to the ISS is novel in this field. It allows our studies to be more easily translatable to the clinical experience. The fact that the GCS scores were reviewed by experienced Physical Medicine and Rehabilitation physicians subspecialized in TBI also improves their reliability and validity. Furthermore, all GCS scores were collected upon hospital arrival, as per the recommendations of the WHO neurotrauma taskforce [20]. Including information on costs related to long term care and loss of long term productivity are also strengths of our studies and differentiate our research from others.

Likely the most important limitation of our studies is the lack of control groups (i.e. cyclists with injuries other than TBI). Our comparative observational design is sufficient to draw conclusions about demographic characteristics of non-helmet wearers in Montreal at highest risk of head injury (having all sustained a head injury). It is also a reasonable design to compare outcomes and costs. However, it is at risk of confounding biases. Comparing TBIs sustained by cyclists according to helmet use assumes that the only difference between the two groups is the helmet wearing. This assumption may not be accurate; perhaps cyclists who wear helmets are more likely to follow road regulations, speed less, be generally more precautious, as Goldacre postulated in their editorial [141]. Perhaps they are more likely to be experienced professional cyclists who tend to cycle faster as was proposed in two French studies [120, 136].

Our patient population is limited to those patients who required hospitalization for their injuries. Cyclists who died at the scene of the crash as well as those with seemingly minor injuries who chose not to present themselves to the hospital are not included. While the hospital and rehabilitation cost calculations would not be altered by these omissions, loss of productivity and cost of death would be affected from a societal perspective. It is uncertain how the differences in costs between helmeted and non-helmeted cyclists would be affected by the inclusion of these patients. Also, the low sample size of patients who died limited the ability to conclude much on the effects of helmet use in prevention of deaths.

From the data collected, it is impossible to evaluate if the cyclists wore their helmets properly, if the helmet was in good working condition or if it was a certified helmet. Also, as previously discussed, a fall from as little as 0,5 meters can compromise the protective effects of a helmet [125]. Thus, the effects of helmets may be underestimated in our studies.

Furthermore, we excluded 13 cyclists due to lack of information on helmet wearing. It is possible that this exclusion may have introduced a selection bias. Efforts were made to limit the effect of this potential bias by individually screening each chart. However, even after a thorough chart review, no information was found on helmet status. It is possible that these cyclists were less likely to wear a helmet, due to reporting biases, as helmet wearers may be more likely to bring up their good habit than non-helmet wearers. Also, it is possible that these patients had more severe injuries and therefore the emphasis was on their acute care, rather than details about their crash. For future avenues of research, a prospective study with telephone call follow-ups, as was done in the Thompson study [176], would address these issues.

A cost calculation limitation was the use of the RAMQ charges. It was not possible to confirm that the charges proposed by the RAMQ were representative of actual costs. The charges are different for Canadian citizens and non-Canadian citizens or patients not covered by provincial insurance, the latter two being exactly three times more than the former. Since most of the patients in the database were Canadian (77,3%), the costs chosen were those for Canadian citizens, regardless of the patient's actual origin. The reasoning for this decision is that we are assuming the non-Canadian costs are inflated by administrative costs, however, the accounting department was unable to specify whether this assumption was accurate or not.

Also, the true cost of care should not be influenced by someone's nationality. Charges to Canadians were also favoured to remain conservative in our cost estimates.

Due to the charge structure in Quebec hospitals being under multiple departments' responsibility, it was not possible to get comprehensive costs for hospitalizations. For instance, inpatient and outpatient physician billings (other than for neurosurgeries), medical devices and medications taken by outpatients were not included in the calculations due to lack of data. However, considering both groups had the same cost limitations and they are slight compared to the indirect costs, it is considered acceptable by some to omit them [166].

An unforeseen limitation of these studies is that the average age of patients who died is significantly higher than the mean age of the sample. We incorrectly believed that cyclists would be younger, therefore would be minimally affected by the ageism associated with the human capital method. The average age of death was 66 years and 55% (5/9) of patients who died in our studies were above the age of 65. Considering that the human capital method only includes costs for patients less than 65 years of age, more than half of the patients who died were not considered in the cost calculation. Future studies might consider the willingness to pay method in studies concerning cost of death in cyclists.

There was missing demographic information: 3,9% nationality, 10,9% education and 5,5% employment. The majority of the sample (60,9%) did not have documentation about loss of consciousness at the time of the accident. Half of the subjects did not have their level of alcohol tested. A large majority of the subjects were not tested for drugs (93,8%). This may have introduced biases due to missing data.

Our studies do not include a measurement for PTA, due to incomplete information in the trauma registry as well as our inability to extract enough information on it from our chart review; had the GOAT been available to us, we would have readily utilized the information. LOC data was dichotomized, without any notion of length. This is less than ideal, given that different lengths of LOC are associated with different TBI severities [20]. Considering that no other study consulted included PTA, LOC or GCS in their analyses, our omission of PTA and LOC, while not ideal, is acceptable.

Certain patients left against medical advice, meaning that they left the hospital before a physician authorized their discharge. The information on most of these patients was incomplete, most particularly their helmet status, therefore no statistical analyses were performed on their data. A recent study done at the MUHC-MGH found that although patients with TBI leaving against medical advice tended to have higher GCSs and better GOS-Es than their peers, many had functional limitations that could have benefited from further treatment [184]. Therefore, the long-term costs associated with these patients' TBIs were certainly underestimated in our studies, as the only costs documented in their cases were artificially truncated acute care costs. As several authors have noted, patients leaving against medical advice tend to raise costs of long-term treatments since an inadequately managed problem can put the patients at higher risk for complications, readmission and mortality [185-187].

5.3 Overall Recommendations

Due to the protective effect and cost saving potential of helmet wearing, we recommend that the information on efficacy of bicycle helmets be disseminated to the Montreal cyclist population. We recommend public health measures encouraging helmet use for men and women, with an emphasis directed at targeting men since more than three quarters of cyclists with TBIs in our studies were men. Other groups at higher risk of not wearing a helmet to be targeted are those with less education, the unemployed, and those who are single. A focus on elderly citizens should be considered, as they are far more likely to die as a result of a bicycle crash. Education on the dangers of cycling under the influence of alcohol or drugs should also be carried out in the Montreal area. A continued push for increased physical separation of cyclists and motor vehicles may prove particularly effective in Montreal as we found a comparatively high number of injuries were caused by MVAs. Finally, the idea of legislation must take into consideration the potential downsides (notably a potential decrease in overall cycling and therefore physical activity). Since children's helmet use uptake has been demonstrated to influence adults' helmet use [188], and even studies where no overall societal benefit was found for legislation postulated that subgroups of higher risk individuals (namely children) may benefit from helmet legislation [106], it may be reasonable to consider having helmet legislation strictly for children. Ideally, any measure used to increase the uptake of bicycle helmet use should undergo comprehensive cost effectiveness analysis prior or in conjunction with implementation.

Conclusion

This memoire and these studies illustrate that wearing helmets likely confers a protective effect against TBIs for Montreal cyclists. This protection is supported by the presence of fewer severity markers on brain imaging, the decreased likelihood of prolonged ICU hospitalization and fewer neurosurgical interventions. Helmets also contribute to a decrease in the median societal costs that result from TBIs in cyclists. It suggests that public health measures that successfully increase helmet wearing may have dual positive impacts: decreasing the morbidity associated with TBIs in cyclists and public health savings on associated direct and indirect costs. The positive cost-of-injury analysis lays the foundation for future program and legislation related cost-effectiveness studies. This research supports well-known demographic characteristics associated with the absence of helmet wearing and proposes novel ones based on the current findings. These characteristics may assist in developing interventions that better target the identified subgroups (men, young, single, less educated, unemployed, alcohol, and drug consumers). Also, older Montreal cyclists were found to be at highest risk of death following their TBI. As a result, they may be the adult age group with the most to gain from helmet wearing. By knowing that helmets protect against TBIs and allow for cost savings, and understanding the baseline differences between helmet wearing groups, a concerted public health approach may be undertaken. Helmet legislation targeted to subgroups of higher risk individuals may have an overall positive health effect on the population [106], and contribute to monetary savings [189]. In light of the recent cyclist deaths in Montreal, as well as the ongoing cyclist boom, now may be an auspicious time to start implementing new helmet promotion measures.

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