

APPENDICES

UPDATE on the PREVALENCE of PERSISTENT POSTTRAUMATIC HEADACHE in ADULT CIVILIAN TRAUMATIC BRAIN INJURY: PROTOCOL for a SYSTEMATIC REVIEW and METE-ANALYSIS

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APPENDIX 1

PRISMA-P checklist [1]

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title: Identification	1a	UPDATE on the PREVALENCE of PERSISTENT POSTTRAUMATIC HEADACHE in ADULT CIVILIAN TRAUMATIC BRAIN INJURY: PROTOCOL for a SYSTEMATIC REVIEW and METE-ANALYSIS
Update	1b	Updating (with methodological modifications) Nampiaparampil, 2008. [2]
Registration	2	PROSPERO (CRD42018094138)
Authors: Contact	3a	Caroline Arbour PhD ^{1,2} (CA*), Yasmine Bouferguène BSc ^{1,3} , Roxanne Beaugard RN ^{1,2} , Gilles Lavigne PhD ^{1,3} , Alberto Herrero Babiloni MSc ^{1,3} * caroline.arbour@umontreal.ca 1) Hôpital du Sacré-Coeur de Montréal Research Center, Montreal, Canada; 2) Faculty of Nursing, Université de Montréal, Montréal, Canada; 3) Faculty of Dental Medicine, Université de Montréal, Montreal, Canada.
Contributions	3b	CA and GL conceived the study. YB and AHB performed the preliminary search. YB reviewed the search strategy. YB and RB will oversee data extraction and analysis. CA and AHB produced the first draft of the manuscript. The definitive protocol was reviewed and approved by all authors. [page 17 line 1]
Amendments	4	Significant changes to the protocol will be updated in PROSPERO and reported in the final paper.
Support: Sources	5a	This project is funded by a start up fund provided by the research center of the Hôpital du Sacré-Coeur de Montréal to CA. The Hôpital du Sacré-Coeur de Montréal had no role in the development of the protocol. GL holds a Canada Research Chair on Pain, Sleep, and Traumatic Injuries. [page 17 line 6]
Sponsor	5b	None declared. [page 17 line 12]
INTRODUCTION		
Rationale	6	Persistent posttraumatic headache (PTH) is a common consequence of traumatic brain injury. The only review providing information about headache prevalence after brain trauma was published in 2008 and was strictly derived from Medline database and combined data from civilian and military populations. Due to recent changes in brain trauma diagnosis and civil epidemiology, the aim of the current study is to carry out a systematic review and meta-analysis to derive updated prevalence estimates of persistent PTH in adult civilian traumatic brain injury. [page 5-6]
Objectives	7	To derive updated estimates on global and severity-specific prevalence of persistent PTH in adult civilian traumatic brain injury. [page 6 line 19]
METHODS		
Eligibility criteria	8	Study designs: Observational studies (case-control and Cohort studies) reporting prevalence of chronic headache (or from which prevalence can be derived); Published from March 2008 to this day. RCT, case control, case series, case report as well as duplicate reports will be excluded. Population: Representative sample of adult civilian traumatic brain injury patients (16 years and older); No geographic limitations; Patient identification by physician diagnosis, self-reported status, populational trauma registries, other

		<p>medical/administrative registers. Prevalence data reported based on brain trauma severity (mild, moderate/severe) will be treated separately.</p> <p>Outcomes: The primary outcome will be the global prevalence of persistent PTH following traumatic brain injury. The secondary outcome will be a better understanding of the associations between chronic headache and brain trauma severity.</p> <p>[page 9]</p>
Information sources	9	<p>Searching in the electronic databases (Medline, Embase, Cochrane, Google Scholar, and Directory of Open Access Journals), manual references' listing of included studies and authors' personal bibliography on Web of Science.</p> <p>[page 9 line 22]</p>
Search strategy	10	See Appendix 2
Study records:		
Data management	11a	<p>Studies retrieved will be grouped and duplicates removed with support of a reference management software package. Studies eligibility will be assessed independently by two authors. Discrepancies between authors will be resolved by discussion and consultation of a third author if needed. The study selection process will be reported in a PRISMA flow diagram. [page 10 line 17]</p>
Selection process	11b	<p>Studies will be selected independently by both authors based on pre-established eligibility criteria. Discrepancies between authors will be resolved by discussion and consultation of a third author if needed. Reasons for exclusion will be documented. [page 11 line 3]</p>
Data collection process	11c	<p>Data extraction will be performed independently by two authors using a pre-tested spreadsheet. Disagreements will be resolved by discussion between the two authors; if no agreement can be reached, consensus will be sought through discussions with a third author Up to three attempts by mail will be done if additional data or clarification will be required from the included studies. [page 11 line 15]</p>
Data items	12	<p>Data extraction will include: studies' title, journal, first author's name and affiliation(s), year and country of publication, design, response rate and sample size, sampling method, participants' sociodemographic and clinical characteristics, TBI severity, time elapsed since TBI, prevalence of chronic headache, characteristics of the headache, psychiatric comorbidities, risk factors, missing data, reasons for missing data. [page 12 line 4]</p>
Outcomes and prioritization	13	<p>Every headache lasting for more than 3 months after occurrence of brain trauma independent of its characteristics. [3] [page 9 line 7]</p>
Risk of bias in individual studies	14	<p>Risk of bias will be independently evaluated by two reviewers using the Risk of Bias Tool for Prevalence Studies developed by Hoy <i>et al.</i> Disagreements will be resolved by discussion between the two authors and a third author will be involved if needed. Hoy <i>et al.</i> checklist will be used as a reference when conducting sensitivity analysis restricted to high quality studies. [page 13 line 11]</p>
Data synthesis	15a	<p>We will estimate persistent PTH global prevalence in adult civilian traumatic injury. Whenever possible, persistent PTH prevalence estimates in mild cases and moderate/severe cases will be computed. The analysis will only include studies with sample sizes greater than 100 participants. [page 14]</p>
	15b	<p>Persistent PTH prevalence pooled estimates for all pre-specified outcomes will be computed applying random effect meta-analysis models. Heterogeneity within included studies will be assessed using the I² statistic and visual inspection of forest plots. [page 14]</p>
	15c	<p>Sub-group sensitivity analysis will be performed (if possible) and considering studies of highest methodological quality according to time elapsed since injury and head trauma severity (mild versus moderate/severe). [page 14]</p>
	15d	<p>Descriptive analysis and report the characteristics of included studies. [page 14]</p>

Meta-bias(es)	16	Considering confirmation of traumatic brain injury diagnosis can vary from one study to another, therefore introducing a selection bias, only studies using a clearly defined operational definition for the diagnosis of TBI will be considered for inclusion. <i>[page 7 line 19]</i>
Confidence in cumulative evidence	17	NA

APPENDIX 2

Medline search strategy (from 2008 to Present)

Traumatic brain injury (population)

1. Brain Injuries [MeSH]
2. Craniocerebral Trauma [tiab]
3. Head Injuries, Closed [tiab]
4. Skull Fractures [tiab]
5. mTBI* [tiab]
6. tbi* [tiab]
7. concuss* [tiab]
8. ((head* or cerebr* or crani* or skull* or intracran*) adj2 (injur* or trauma* or damag* or wound* or swell* or oedema* or edema* or fracture* or contusion* or pressur*)) [tiab]
9. ((brain* or cerebr* or intracerebr* or crani* or intracran* or head* or subdural* or epidural* or extradural*) adj (haematoma* or hematoma* or hemorrhag* or haemorrhag* or bleed*)) [tiab]
10. 1 OR/9

Chronic headache disorders (condition)

11. Headache [MeSH]
12. Head pain [tiab]
13. Hemicrania [tiab]
14. migraine* [tiab]
15. cephalia* [tiab]
16. cephalia* [tiab]
17. cephalgia* [tiab]
18. cephalgia* [tiab]
19. 11 OR/18
20. 10 AND 19

Prevalence

21. prevalen* [tiab]
22. Inciden* [tiab]
23. Percent* [tiab]
24. epidemiol* [tiab]
25. frequenc* [tiab]
26. occurrenc* [tiab]
27. morbidit* [tiab]
28. rate* [tiab]
29. Probabilit* [tiab]
30. Epidemiological studies [MeSH]
31. Population* [tiab]
32. Severit* [tiab]
33. Progress* [tiab]
34. Risk [tiab]
35. 21 OR/34

All combined

36. 20 AND 35

APPENDIX 3

Quality assessment checklist for prevalence studies adapted from Hoy et al. [4]

Risk of bias items	Risk of bias levels	Points scored
1. Was the study's target population a close representation of the national population in relation to relevant variables, e.g. age, sex, occupation?	Yes (LOW RISK): The study's target population was a close representation of the national population.	0
	No (HIGH RISK): The study's target population was clearly NOT representative of the national population.	1
2. Was the sampling frame a true or close representation of the target population?	Yes (LOW RISK): The sampling frame was a true or close representation of the target population.	0
	No (HIGH RISK): The sampling frame was NOT a true or close representation of the target population.	1
3. Was some form of random selection used to select the sample, OR, was a census undertaken?	Yes (LOW RISK): A census was undertaken, OR, some form of random selection was used to select the sample (e.g. simple random sampling, stratified random sampling, cluster sampling, systematic sampling).	0
	No (HIGH RISK): A census was NOT undertaken, AND some form of random selection was NOT used to select the sample.	1
4. Was the likelihood of non-response bias minimal?	Yes (LOW RISK): The response rate for the study was $\geq 75\%$, OR, an analysis was performed that showed no significant difference in relevant demographic characteristics between responders and non-responders.	0
	No (HIGH RISK): The response rate was $< 75\%$, and if any analysis comparing responders and non-responders was done, it showed a significant difference in relevant demographic characteristics between responders and non-responders.	1
5. Were data collected directly from the subjects (as opposed to a proxy)?	Yes (LOW RISK): All data were collected directly from the subjects.	0
	No (HIGH RISK): In some instances, data were collected from a proxy.	1
6. Was an acceptable case definition used in the study?	Yes (LOW RISK): An acceptable case definition was used.	0
	No (HIGH RISK): An acceptable case definition was NOT used.	1
7. Was the study instrument that measured the parameter of interest (e.g. prevalence of low back pain) shown to have reliability and validity (if necessary)?	Yes (LOW RISK): The study instrument had been shown to have reliability and validity (if this was necessary), e.g. test-re-test, piloting, validation in a previous study, etc.	0
	No (HIGH RISK): The study instrument had NOT been shown to have reliability or validity (if this was necessary).	1
8. Was the same mode of data collection used for all subjects?	Yes (LOW RISK): The same mode of data collection was used for all subjects.	0
	No (HIGH RISK): The same mode of data collection was NOT used for all subjects.	1
9. Were the numerator(s) and denominator(s) for the parameter of interest appropriate?	Yes (LOW RISK): The paper presented appropriate numerator(s) AND denominator(s) for the parameter of interest (e.g. the prevalence of low back pain).	0
	No (HIGH RISK): The paper did present numerator(s) AND denominator(s) for the parameter of interest but one or more of these were inappropriate.	1
10. Summary on the overall risk of study bias	LOW RISK	0-3
	MODERATE RISK	4-6
	HIGH RISK	7-9

REFERENCES

1. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst rev.* 2015; 4: 1.
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3. International Classification of Headache Disorders. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia.* 2018; 38: 1-211.
4. Hoy D, Brooks P, Woolf A, et al. Assessing risk of bias in prevalence studies: modification of an existing tool and evidence of interrater agreement. *J Clin Epidemiol.* 2012; 65: 934-9.