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EXperienceS and aTtitudes towards Agitated behaviours in Traumatic brain injury in the Intensive Care unit patients (EXSTATIC): a protocol for an interprofessional mixed-method study

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ABSTRACT

Introduction Agitation and violent behaviours are common conditions developed by patients with acute traumatic brain injury (TBI) in intensive care units (ICUs). Healthcare professionals caring for these patients have various tools to manage these behaviours, but lack of a formal protocol to assess and manage them makes caring for these patients a challenge. Moreover, safety may often be compromised for both ICU professionals and patients encountering such situations. The EXperienceS and aTtitudes towards Agitated behaviours in Traumatic brain injury in the Intensive Care unit patients (EXSTATIC) study aims to explore the experiences and attitudes of ICU nurses and other ICU healthcare professionals on the management of agitated behaviours in patients with acute TBI.

Methods and analysis EXSTATIC is a multicenter mixed methods convergent study exploring experiences and attitudes of ICU healthcare professionals caring of agitated patients with TBI. The study includes three qualitative methods (observation, semistructured interviews and focus groups) and one quantitative method (retrospective cohort). The integration of the different methods will be done using sequential steps of the research and by the integration of results for each step. Qualitative data will be evaluated following a thematic analysis derived from a grounded theory approach. Quantitative data will be analysed using descriptive statistics. Qualitative and quantitative results will be combined in a convergent interactive interpretative design. Gender and race perspective will be integrated in collection, analysis and interpretation of data.

Ethics and dissemination This study has been approved by the Centre intégré universitaire de santé et de services sociaux du nord de l'île de Montréal (CIUSSS-NÎM) Research Ethics Board. The findings will be disseminated locally with ICU staff and health managers, international peer-reviewed journals, a PhD dissertation, and national and international conferences. The knowledge derived from this study is key in the development of clinical protocols to manage agitation and related behaviours in patients with TBI and designing further interventional studies targeting this specific problematic.

Trial registration number NCT04741399.

Strengths and limitations of this study

- EXperienceS and aTtitudes towards Agitated behaviours in Traumatic brain injury in the Intensive Care unit patients (EXSTATIC) is the first multisite study aming at exploring attitudes and experiences of healthcare professionals attending agitated traumatic brain injury patients in the intensive care units.
- This mixed-method study will allow to identify organisational and cultural factors and to better understand social interactions as well as healthcare delivery process.
- The interdisciplinary research team with content, methodological and clinical experts is a strength of EXSTATIC study.
- Gender and race perspective will be integrated all along the study in the collection, the analysis and the interpretation of data.
- The primary limitation of this study are the lack of persistent observation and long-term involvement on the field.

INTRODUCTION

Traumatic brain injury (TBI) occurs when an external force is applied to the head leading to alteration in brain function including decreased level of consciousness, loss of memory, and changes in cognition and/or changes in mental status at the time of the injury.[1] TBI is a leading cause of mortality and disability worldwide.[2 3] Each year, more than 50 millions TBIs occur internationally and it represents 30%–40% of all injury-related deaths. Neurological injury is projected to remain the most important cause of disability from neurological disease until 2030, ahead Alzheimer's disease or cerebrovascular disorders.[4] While TBI has a substantial impact on direct healthcare costs, indirect costs from

lost productivity also represent a significant economic burden.[5 6]

Among the complications of TBI, behavioural problems such as agitated behaviours are common and can be challenging. In the intensive care setting, physical agitation and aggression are frequently encountered behaviours. In our recent prospective pilot study, 57% of patients suffering from TBI developed significant agitation during their stay at the intensive care unit (ICU), reflecting the daily challenge that these behaviours represent for ICU healthcare profesionnals.[7] More specifically, psychomotor agitation and violent behaviour were reported by nurses in 42.9% and 12.9% of the 8-hour work periods, respectively.[7] These behaviours can be worrisome for patients, families and healthcare professionals as they compromise patient safety, delay weaning from mechanical ventilation, delay rehabilitation, interfere with usual care and can be intimidating or harming for caregivers.[8–10] The work of healthcare professionals in the ICU has been associated with an increased risk of physical and verbal violence.[11]

There is currently limited evidence to guide the management of agitated behaviours of critically ill patients suffering from TBI.[12] Different drugs (antipsychotics, sedatives, analgesics) and behavioural interventions (reorientation, physical restraints or presence of a supervisor) are commonly used to control agitated behaviours, with great variation between health institutions and healthcare professionals.[13] As the effectiveness and safety of these interventions remain unknown, there is a risk of an indiscriminate use of chemical or physical restraint practices in this vulnerable population.[14] Challenges to clinical assessment of agitated behaviours following TBI are that they may be the result of different processes (eg, pain, encephalopathy, delirium, iatrogenic opioid, alcohol, nicotine withdrawal) and there are no consensus definitions for use in the ICU setting. Some authors have defined agitation as a type of delirium that occurs during the stage of post-traumatic amnesia, whereby the patient exhibits extreme behaviour including aggression, akathisia, disinhibition and emotional lability.[15] As with delirium, agitated behaviours following TBI are probably the result of neuroinflammation, neurotransmitter dysregulation, network dysconnectivity and neuroendocrine abnormalities.[16] However, given the brain damages seen in TBI, agitated behaviours following TBI must be distinguished from other delirium states seen in non-TBI patients admitted to ICU without brain damages.[17]

Unexpected care practices and experiences with patients with TBI

A recent qualitative study using focus groups invited ICU nurses and physicians to identify various treatments to control delirium.[18] Given the absence of good scientific evidence, nurses often perceived physicians as prescribing drugs according to their experiences rather than efficacy and, doctors declared not having solutions to nurses' needs. In addition, verbal reorientation was not consistently applied and most professionals reported the indiscriminate use of physical restraints.[18] A recent study on nurses' perceptions and experiences in pain, agitation and delirium management found that the care of agitated patients' is more demanding than that of sedated ones and can impede on proper care of other health problems or even to other patients.[19] An interventional study found that pain, agitation and delirium management would be best managed through collaborative partnership between professionals and patients families.[20] In another qualitative study focusing on delirium, ICU nurses revealed mental and emotional exhaustion when caring for agitated or disoriented patients and also being afraid of patients' safety as well as their own safety.[21] Similarly, an emergency room study identified common themes relating to the management of agitation: nursing staff offer high quality services to this population which, despite everything, poses a risk to their safety; second, teamwork is essential to manage these situations, but working in shifts and professional hierarchy prevents coordinated care, and finally, organisational and environmental challenges exacerbate threats to the safety of patients and staff.[22] As patients with TBI frequently display a wider variety of agitated behaviours which can be more intense and threatening for patient and provider safety than other ICU patients, there is a need to specifically explore the experiences and attitudes of healthcare professionals towards them.

Objective(s)

The main objective of this study is to explore the experiences and attitudes of the healthcare professionals managing agitated behaviours of patients with TBI in two ICUs of level-1 Canadian trauma hospitals. The purpose of qualitative methods is to unveil the perceptions, the practices, the consequences and the risks of handling TBI agitated patients. Quantitative methods will complete the description of the reality through the interventions and the challenges noted by ICU professionals in patients' documentation.

METHODS AND ANALYSIS

Study design

A multicentric convergent design[23] will be performed using three qualitative research methods (structured observations, semistructured interviews and focus groups) and a quantitative research method (retrospective cohort study).

First, a researcher will observe the daily ICU routine, in two ICU units, when a patient with TBI is admitted. In this first step, the specific objective is to observe the care of patients with TBI during periods of agitated behaviours, to understand how it affects the actions of healthcare professionals and interactions between each other and families present in the unit. These observations will enable researchers to detect non-verbal expression of feelings, interactions and communication between patients, their family and health professionals as well as interactions

between health professionals at the bedside. The observations will also enable us to map bedside clinical activities made by health professionals and the time spent doing them. The goal is to develop a repertoire of situations combining the degree of agitation, the resources present, the experience and the effects on the staff, the patient and their relatives, the actions and medical decisions in response to agitated behaviours. The data gathered in this phase will inform the interview guide for the semi-structured interviews.[24]

In the second phase, we will conduct semistructured interviews with ICU nurses to explore their experiences and attitudes towards the care of patients with TBI with agitated behaviours. Nurses will be interviewed as they are the healthcare professionals most present at the bedside of patients with TBI and their families. Semistructured interviews will enable to explore nurse's perspectives and experiences. This will also allow us to investigate how these experiences can predict their reactions to agitated behaviours, and how these reactions are shared between different health professionals or also with hospital health personnel. This particular phase enables us to uncover unanticipated themes.

We will then undertake a retrospective cohort study aiming to describe the documentation of agitated behaviours in patients with TBI and interventions to manage them. By examinig documentation in the medical charts, we plan to explore the influence of agitated behaviours on the routines of the different healthcare professionals. Medical and nursing charts are also used as communication tools between professionals. Data collected in this step will also enhance the focus group interview guide. A convenience sample of consecutive admissions for severe, moderate and mild-complex TBI with an abnormal CT-scan will be reviewed.

Finally, interprofessional focus groups will be conducted in order to gain insights into ICU healthcare professionals experiences and explore organisational factors around TBI agitated patients. Group process can help people to explore and clarify their views and to share ideas and perceptions. All healthcare professional who participate in the care of patients with TBI in the ICU will be solicited for participation and distributed according to their discipline in different groups. Specifically, the aim is to discuss the various themes identified in the previous steps and understand their relational dimension among different healthcare professionals.[25]

The integration of the different methods will be done by the connection of the different steps and by the data integration of each step (figure 1). This multistep approach allows to identify organisational, cultural factors and to better understand social interactions as well as healthcare delivery process.[26]

Study setting

The study will be carried out in ICUs of two level-1 Canadian trauma hospitals of similar capacity (35–40 beds) in the region of Montreal, Quebec, Canada. There are approximately 220 healthcare professionals in each centre, of which 120 are nurses. Both ICU units have expertise and experience in the care of patients with TBI.

Sample size and recruitment

The EXperienceS and aTtitudes towards Agitated behaviours in Traumatic brain injury in the Intensive Care unit patients (EXSTATIC) project will initially be presented to unit coordinators and ICU heads of medical staff and, subsequently a minimum of one information meeting per hospital will be organised to present the project to the ICU care team. During these presentations,

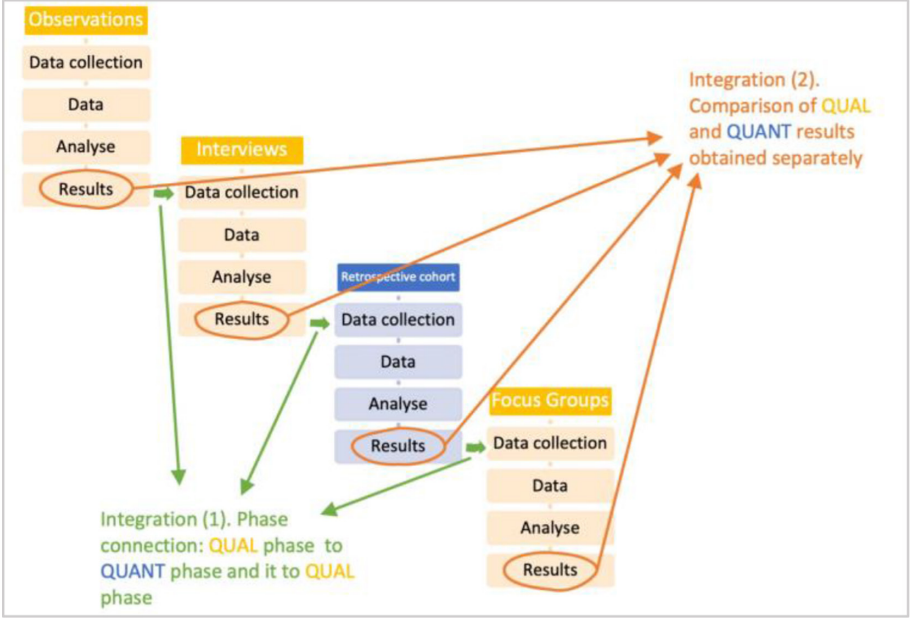

Figure 1 Integration strategy of the mixed-method study.

professionals will be invited to participate in the project and the emails of those participating will be collected.

As the study progresses, professionals will be contacted to participate in the semistructured interviews or in the focus groups, in order to create a purposive sample of the ICU professionals. Professional's involvement in the project will also be accepted in further steps of the study. All professionals belonging to the intensive care team (beneficiary attendants, ICU physicians, nurses, occupational therapists, pharmacists, physiotherapists, senior residents, respiratory therapists, unit coordinators), employed full time or part time in any shift with a minimum of 1 year of trauma intensive care experience will be eligible to participate. Temporary staff and students will be excluded.

During the observation period, the ICU research team will screen daily for patients with TBI admitted to the unit. All patients suffering from a TBI with an abnormal CT scan admitted to the ICU will be included for the structured observation. In the retrospective cohort study, a convenience sample of 50 patients per centre (100 patients in total) admitted 1 year before the observational period will be included for data collection.

Data collection

Structured observations

A researcher will observe the ICU routine when a patient with TBI is admitted to the unit. The observer will be integrated as an external and independent researcher. We expect to observe a minimum of 12 work shifts (six per site) with a TBI-agitated patient. One ICU site has two work shifts (day and night) while the other has work shifts of 8 hours (morning, evening, night). Observations will be carried out discontinuously on all shifts with the objective to observe the maximum number of TBI-agitated patients. Data collection will be supported by an observation guide developed by informal discussion within the research team and will be previously tested. Observation periods will be added as needed until no new information emerges from data analysis. Results from structured observation will be useful for adapting quantitative and qualitative data collection tools.

Semistructured interviews

Approximately 1-hour semistructured interviews will be conducted with ICU nurses in English or French (depending on nurses' preference) following a previously tested interview guide with open-ended, neutral, sensitive and clear questions. It will be constructed based on research team discussions and themes that will emerge from the field observation. The guide will include experiences, beliefs, feelings, knowledge and sensory questions. Researchers from the team without previous relationship with nurses will act as interviewers. Interviewers will be trained to conduct qualitative research interviews and will be familiar with the interview guide before the recruitment of participants. Interview guides will be refined until a final version is agreed. In addition, the guide can evolve during the analysis; thus, one question can be added as themes emerge from previous interviews or removed as saturation develops. By purposeful sample strategy, a minimum of 12 nurses (six per site) will be invited to participate until thematic data saturation. Samples will be contrasted regarding gender, race, work shifts and years of experience in TBI care. Demographic data will be collected. At the end of each interview, interviewers will fill a summary sheet to document the meeting and evoking themes emerged. Interviews will be audiorecorded and transcribed by professionals into anonymous verbatim.

Retrospective cohort

Data will be retrospectively collected from the medical records of 100 consecutive patients with TBI admitted (50 patients with TBI per site) who were admitted at least 12 months preceding the observation phase. As approximately 50%[7 27] of all patients with TBI develop agitated behaviours, this convenient sample is sufficient to appraise the interventions noted in medical records and get valid results. When an RASS (Richmond Agitation-Sedation Scale) score of 2 or more is noted in the medical records, the patient will be considered to have suffered an episode of agitation.[28] Severe, moderate and mild TBIs with an abnormal CT scan will be included. The severity of the TBI will be based on the Glasgow coma scale.[29] Data collected will cover from the ICU admission's day till a maximum of 21 days after ICU admission, discharge or death, whatever comes first. Physicians, pharmacists, nurses, respiratory therapists, physiotherapists and occupational therapists' notes will be reviewed using a pretested collection tool. Notes of agitation and aggression episodes, triggers of these episodes, pharmacological and non-pharmacological strategies used to control them and their justifications and communications between different healthcare professionals will be the focus of this step. A first data collection form will be generated by the research team following discussion and based on previous studies[7] and improved with the results of the two previous steps. Research data will be captured and managed using Research Electronic Data Capture a secure web-based application ideal for multi-site studies and licensed by the Centre de Recherche du Centre intégré universitaire de santé et de services sociaux du nord de l'île de Montréal (CIUSSS NÎM).[30]

Focus groups

Four 1-hour focus groups (two per site) will be carried out, in English or French. Two researchers without previous relationship with the group members will conduct the discussions, one as group facilitator and the other as an observer. Researchers will be trained to conduct focus groups and familiarised with the interview guide before the recruitment of participants. An interview guide based on results from the first three steps and pilot-tested among the research team will be built. Five to seven healthcare professionals will be sought by purposive

sample per focus group. Intensivists, occupational therapists, patient attendants, pharmacists, psychiatrists, physiotherapists respiratory therapists, senior residents and unit coordinators will be invited to participate, and groups will be formed balancing characteristic such age, gender, race, years' trauma ICU experience and role in the ICU to maximise the exploration of different perspectives. Demographic data will be collected. At the end of each focus group, researchers will fill a summary sheet resuming the meeting and evoking themes emerged. Focus group discussions will be audio-recorded and transcribed by professionals into anonymous verbatim.

Data analysis

Qualitative data analysis

The grounded theory using thematic analysis will be the approach used to analyse qualitative data. It provides a structured and systematic process of analysis that allows themes to emerge from data.[31] Data from the structured observations, from the integral and anonymous transcripts of both semistructured interviews and focus groups, will be imported to NVivo qualitative analysis software.[32] These will be analysed following the basics steps described by Guest and Namey: first, familiarisation and organisation of transcripts; second, identification of possible themes; third review and analysis of themes to identify structures; and finally, construction of theoretical model, constantly checking against new data.[33] Grounded theory data analysis is an iterative process where data collection and analysis occur concurrently. Two analytical team members will independently code the structured observation data, as well as transcription of interviews and focus group, in order to define the initial and subsequent code book. A reflexive journal will be completed justifying the code selection process as well as further steps of thematic analysis. Then, the combination of codes will generate themes. Discussion within the research team and validation with interviewees will be carried out to ensure themes are represented properly. Finally, a theoretical model will be inductively elaborated, using coded data and themes emerged from them. The use of triangulation in the analysis allows us to evaluate the theoretical model as a full and rigorous picture of the data.

Quantitative data analysis

Quantitative data will consist in describing the frequency with which agitated behaviours are documented in patients with TBI medical record by which professional from the interdisciplinary care team reports these behaviours. Quantitative variables will be described by mean and SD or median and IQR, depending on distribution. Qualitative variables will be described by frequencies as numbers and fractions. Statistical analysis will be performed using SPSS V.26.0 (IBM).[34]

Mixed-methods interpretation

Qualitative and quantitative methods of data collection will be analysed separately and later compared and contrasted in a convergent interactive interpretative design. This will allow us to see if a difference exists between what it is either done or said and what it is documented in the patients' medical record. This interpretation allows to compare and merge the results of the quantitative analysis with the themes that emerged from the qualitative data.

Gender, race and socioeconomic status

Gender is known to influence any human experience and attitudes; thus, it will be carefully taken in account in the collection (ie, respecting the gender distribution in the unit staff), analysis (ie, data will be analysed by different gender researchers) and interpretation of both qualitative and quantitative data (ie, in the context of gender power relationships).[35] The integration of gender (and sex) in research is part of the Institute of Gender and Health strategic plan. Gender refers to socially constructed roles, behaviours, expressions and identities, and is usually conceptualised as a binary diversity (woman or man) yet there is considerable diversity in how individuals understand, experience and express it.

Another aspect which will be carefully taken in account is the race, the social construction of ethnic origin. Specifically, the race of healthcare professionals and also their experiences and attitudes related to the race of patients with TBI on agitation episode. This will be accounted in data collection, analysis and interpretation of structured observations and semistructured interviews. Whenever is possible, socioeconomic status will be also documented and taken in account in analysis and interpretration of data.

Patient and public involvement

The development of the research question and outcomes measures were based on healthcare professionals' experiences in the intensive care settings. Patients were not involved in the design of, the recruitment to nor the conduct of the study.

ETHICS AND DISSEMINATION

Ethical considerations

This study has been approved by Research Ethics Boards (REB) of participating centres. All electronic data (audio files, verbatims, medical charts review) will be password protected and stored on Research Centre of CIUSSS NÎM security server. All paper documentation will be stored in the facilities of Research Centre of the CIUSSS NÎM. Data storage will last for maximum 10 years.

Structured observations

First, ICU patients or their surrogate will be approached for consent to participate, signing the consent form. If a patient or their surrogate accepts, bedside nurses will then be approached for consent. In addition, everyone present in the room (ICU staff, able to self-report patient and their relatives) will be orally informed of the research

project. Data collection will be done by writing notes, no recording technology (audio, video nor photo) will be used and the researcher–observer will remain objective and not intervene in discussions. During the observation periods, a poster will be hanged in the main entrance of the ICU as well as in the room entrance of the patient with TBI, recalling ICU staff that EXSTATIC observations are being carried out.

Semistructured interviews

Nurses who accept to participate will sign an informed consent form. Interviews will be held in each hospital facilities or online in convenience with the participants and hospital infection prevention measures in place at the moment because of the COVID-19 pandemic. Nurses will be contacted to share interpretations of their interviews.

Retrospective cohort

All medical records will be reviewed retrospectively after patient's discharge, therefore no written consent from patients or healthcare professionals will be necessary. For that and the low risk for patients, REB has waived the requirement to obtain an informed consent. Lists of medical charts of patients will be provided by the medical archivist and digitalised charts will be accessed by trained research staff (ie, two clinical research coordinators and a research trainee).

Focus groups

Given the infection prevention measures likely to be in place because of the COVID-19 pandemic, focus groups will be held online as we plan to meet more than six people par discussion. Consent form will be sent electronically, and a signed copy will be collected of each participant before online discussion starts. Participants will be contacted to share interpretations of discussions.

Validity and reliability/rigor

This mixed-method approach will allow triangulation of information and ensure the rigour of results. Specifically, in the qualitative methods, qualitative criteria will be assured by the triangulation of perspectives (participants, ICU sites, analysts), the return to the population of the results, the purposeful sampling of the healthcare professionals, the reflexive journal writing, the peer review and discussion. Nevertheless, weak points of the qualitative methods are the lack of persistent observation and long-term involvement. For the retrospective cohort, selection bias will be minimised by taking the medical records of patients admitted 12 months before the observational step. External validity will be assured taking medical records from two different hospitals. However, the internal validity can be compromised by the lack of data collection form validation.

An important strength of the study is the multidisciplinary research team. Clinically, the team includes nurses, pharmacists and physicians. For methodological expertise, the team includes sociology and qualitative methods experts, as well as quantitative methods experts. Regarding the sites, professionals from both ICUs complete the research team.

Impact and dissemination

The findings of EXSTATIC study will help to identify the experiences and attitudes of ICU healthcare professionals regarding TBI agitated patients and how these influence their practices. This research project will greatly help the development of a conceptual framework specific to agitation and related behaviours in patients with TBI in the ICUs. An in-depth knowledge of barriers, opinions, apprehensions, practices, motivations and even prejudices is essential for the development of future strategies for preventing and improving the treatment of agitated behaviours following TBI as well as the security of patients with TBI and ICU staff.

The results will be shared with healthcare professionals from both ICU in scientific presentations. In addition, the progress of the project and its results will be presented and discussed at national meetings of the Canadian Critical Care Trials Group. We also plan to present the results from the study at regional and international conferences and in peer-review journals.

Study status

We started data collection in April 2021 with the structured observation. By the end of this first step, we aim to begin with semistructured interviews during the summer of 2021. Between June and August 2021, we will pursue with the medical record review of the retrospective cohort of patients with TBI. Finally, focus group discussions will be carried out during fall 2021. Data will be concurrently analysed. As a result of the actual COVID-19 pandemic, the protocol can suffer from modification in order to adapt the research project to the health authorities directives.

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Contributors Conceiving, design and coordination of the study: MS-M, DW and P-MD. Writing the article: MS-M, DW and P-MD. Revising the article: A-JF, CA, FB, MP, VW and CA. All authors have read and approved the final manuscript.

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