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Exploring the experiences and challenges for patients undergoing cranioplasty: a mixed-methods study protocol

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ABSTRACT

Introduction Cranioplasty is a widely practised neurosurgical procedure aimed at reconstructing a skull defect, but its impact on a patient's rehabilitation following a traumatic brain injury (TBI) or stroke could be better understood. In addition, there are many issues that a TBI patient or the patient who had a stroke and their families may have to adapt to. Insight into some of the potential social barriers, including issues related to social engagement and cosmetic considerations, would be beneficial. Currently, little is known about how this procedure impacts a patient's recovery, the patient's perceptions of rehabilitation precranioplasty and postcranioplasty and the broader issues of cosmesis and social reintegration. This study hopes to understand some of these issues and therefore help inform clinicians of some of the difficulties and perceptions that patients and their relatives may have.

Methods and analysis A mixed-methods study. Data will be collected through focus groups with healthcare professionals (HCPs) and semi-structured interviews with patients and their relatives, field notes, a researcher diary and a patient questionnaire. Different perspectives will be brought together through method triangulation. Patient and relative data will be analysed using interpretive phenomenological analysis, and HCPs data will be analysed thematically using deductive and inductive coding.

Ethics and dissemination Ethical approval has been obtained from the Wales REC 7 ethics committee (Rec ref: 19/WA/0315). There is limited literature regarding a patient's perception of the cranioplasty process, the potential impact on rehabilitation and how this may impact their reintegration into the community. The results of this study will be presented at national brain injury conferences and published in peer-reviewed, national and international journals.

Strengths and limitations of this study

- ► First mixed-methods study exploring the views and experiences of patients and their relatives who have had or are awaiting cranioplasty.
- ► Interpretive phenomenological analysis studies are specific to the individuals' lived experiences and not necessarily a direct reflection in the broader cranioplasty cohort.
- ► In depth interviews allows for a detailed understanding of patients' lived experience.
- ► The focus of this study is around cranioplasty following a traumatic brain injury or stroke; other types of brain injury that can result in a cranioplasty have not been discussed and would warrant further investigation.
- ► Using a mixed-method approach which includes qualitative and quantitative data and multiple analysis approaches will enable a more comprehensive understanding of how people understand and experience cranioplasty.

INTRODUCTION

Following a severe traumatic brain injury (TBI) or stroke, life-threatening brain swelling may develop. In these instances, a decompressive craniectomy (DC)[1 2] can be performed, an operation where a large skull piece is removed, to control brain swelling and prevent death. The two most common indications for a DC are either a TBI or stroke. However, other indications include excision of tumours involving the skull, removal of bone flaps due to postoperative infection, and managing rarer causes of brain oedema and intracranial hypertension.[3]

Cranioplasty is a neurosurgical procedure aimed at repairing the cranial defect[4] to help restore an intact cranial vault for brain protection, to aid in the prevention of falls by improving vestibular system equilibrium and mitigate against the syndrome of trephined, and for cosmetic purposes. It is considered in those patients who have undergone a craniectomy and survived acute care and treatment. It is often planned for when the patient is medically and surgically stable. The timing of cranioplasty varies greatly, and in the UK, it tends to be 6–12 months following the original craniectomy. However, a growing

trend for an earlier cranioplasty results in timings within 3 months becoming increasingly common in some institutions. Apart from the apparent benefit of restoring a degree of mechanical protection to the brain, several studies suggest cranioplasty helps restore intracranial physiology, with a case study showing the integration of a wireless intracranial pressure monitor to aid in postoperative monitoring of these patients.[5] These known pathophysiological manifestations and developing technologies help us better understand why there is often an improved neurological function[6] following cranioplasty, with a growing body of evidence showing that an early cranioplasty can enhance this effect further.

However, there is very little evidence exploring how cranioplasty affects a patient's recovery, rehabilitation and social reintegration. A 'silent epidemic' is how Truelle *et al*[7] describe TBI's with the long-term cognitive, emotional and physical impairments that can affect a patient's quality of life through limitations of daily-life activities, self-image and coping strategies. These, often life-changing issues are also commonly seen in stroke survivors. Besides, for TBI patients and the patients who had a stroke, a significant skull defect with further neurosurgical intervention is required during their rehabilitation, likely putting further strain on their recovery. Therefore, it is vital to explore and understand this context in more depth, not only for direct patient benefit but also for future planning of cranioplasty practices and services.

AIM AND OBJECTIVES

Study aims

To explore the views and experiences of patients and their relatives who have had or are awaiting a cranioplasty and to understand the current clinical challenges within different cranioplasty services through the views of healthcare professionals (HCPs) and how this impacts the patient's recovery, rehabilitation and social reintegration.

Study objectives

- To explore how cranioplasty impacts a patient's recovery, rehabilitation and social reintegration, including the influence of the timing of the cranioplasty, engagement in rehabilitation and potential psychosocial implications.
- To explore the views of HCPs involved in the care of patients with craniectomy/cranioplasty and further understand current cranioplasty services and the challenges to patient engagement and recovery.
- To explore the approaches of rehabilitation that team members use with patients precranioplasty and postcranioplasty and how the timing of cranioplasty and patient's engagement with rehabilitation can influence outcomes.
- To explore patients' views regarding craniofacial cosmesis precranioplasty and postcranioplasty and how this may impact their engagement in the rehabilitation process and social reintegration and to understand patients' views of a novel external cosmetic cranioplasty currently under development.

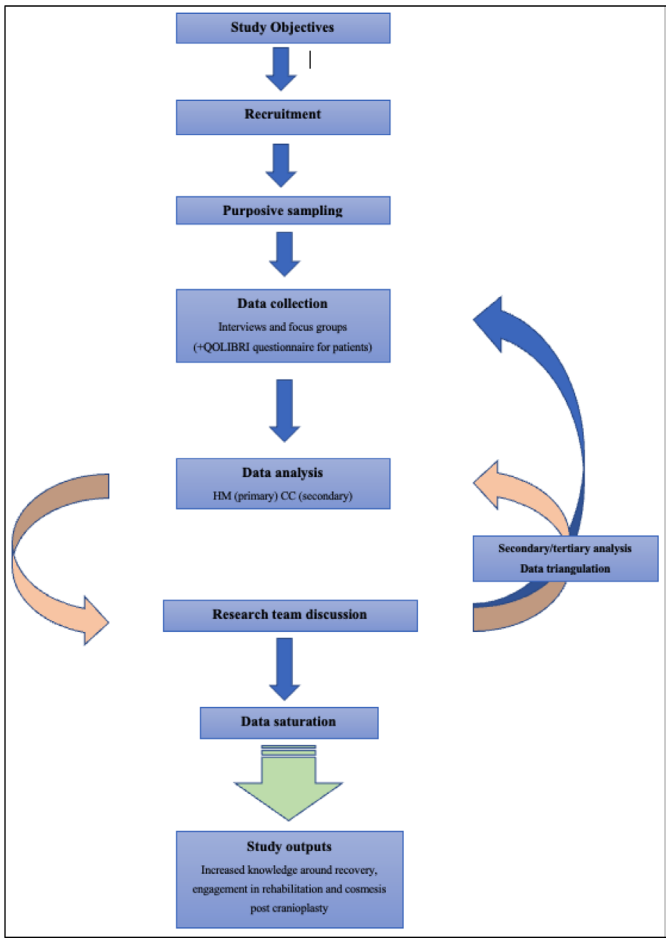

Figure 1 Study flow diagram. QOLIBRI, Quality of Life after Brain Injury.

METHODS AND ANALYSIS

Study design

This is a mixed-methods study. Data will be collected through focus groups or interviews with HCPs, semi-structured interviews with patients and their relatives, field notes, a researcher diary and a patient questionnaire (see figure 1 for study overview).

Methodological underpinning

The two qualitative analytical processes being used in this study are: interpretive phenomenological analysis (IPA)[8] and thematic analysis. IPA is informed by three key methodological approaches; phenomenology (study of structures of consciousness as experienced from the first person), hermeneutics (the theory of interpretation) and idiography (the study of individuals).[9] Phenomenology, was first introduced by Edmund Husserl, who argued we should interpret 'an experience' independent of our own beliefs, prior knowledge or the context and seting of that expeience. It was later developed by Martin Heidegger (a scholar in the 1960s) who argued that it is not possible to take the subject's perceptions and experiences out of context from the real world. Instead, the

interpretive approach helps examine contextual experiences in context with a particular environment and prior understandings. Therefore, IPA, using these methodological underpinnings allows for a commitment to explore, describe, interpret, and situate the participants' own experiences.[10]

Setting

The study will be conducted across different clinical environments, including acute hospital services, rehabilitation centres and the community, to capture a wide range of views and ensure the different stages of a patient's recovery and rehabilitation are explored.

Inclusion and exclusion criteria

Inclusion

- Patients over 16 years who have undergone a craniectomy and are either awaiting cranioplasty or have had cranioplasty for TBI or stroke.
- The patient must be able to consent themselves to participate in an interview.
- Relatives of patients who are awaiting or have undergone a cranioplasty.
- Multidisciplinary team (MDT) members in rehabilitation units, both acute and community-based, who specialise in rehabilitation patients who have had a craniectomy±cranioplasty.
- Clinicians who treat and care for patients who have had a craniectomy±cranioplasty.

Exclusion

- Patients aged 15 years or younger who have undergone a craniectomy and are awaiting or have had a cranioplasty.
- Patients who cannot consent themselves for participation in the study.
- Non-English-speaking patients, relatives and HCPs.

All patients who meet the inclusion criteria will be considered. Their disability and recovery levels will be considered when planning and conducting interviews, and adaptive interview techniques will be used where appropriate.[11]

Recruitment and sampling

Patients, relatives and HCPs will be sampled purposively to capture the maximum variation of views and experiences. They will be identified and recruited through hospital outpatient clinics, rehabilitation centres, brain injury charities and the UK cranial reconstruction registry, a prospective registry capturing implant data from the UK.[12] Approxomately 5–8 patients will be recruited, either awaiting a cranioplasty or following a cranioplasty, regardless of the type or degree of disability.

HCPs will be sampled according to their roles within the rehabilitation team and diverse experiences of caring and treating these patients across sites. The research questions will guide the number of participants, and sampling will stop when data saturation is reached[13 14] it is estimated that there will be between 20 and 30 participants giving an overall study number of between 28 and 38.

Data collection

Interviews will be conducted with patients and their relatives and will be conducted face-to-face. Focus groups or interviews if preferred by participants will be conducted with HCPs. Both interviews and focus groups will be guided by flexible topic guides developed based on the literature and study objectives. This will enable the researcher to focus on topics related to the research questions and allow participants to raise and discuss issues of importance to them. Box x outlines the topics for interviews with patients and their relatives. Focus groups and interviews will be audio-recorded, with written consent, and transcribed verbatim.

Patients who have sustained a TBI will also be asked to complete the Quality of Life after Brain Injury (QOLIBRI) questionnaire, a disease-specific measure of health-related quality of life after TBI,[7] and stroke sufferers will be asked to complete the abbreviated version. The QOLIBRI questionnaire is an instrument that has been developed to assess health-related quality of life after TBI.[15] There are 37 items covering six domains: 'Cognition', 'self', 'daily life and autonomy', 'social relationships', 'emotions' and 'physical problems'. In this study, the QOLIBRI is being used as an additional data collection method to increase the understanding of the patient's experience. Patients will complete the appropriate questionnaire before the face-to-face interview and responses will be used to guide interview discussion. For all interviews and focus groups if the participant/s are become increasingly distressed or upset, then the interview or focus group will be stopped and in these circumstances, the data excluded. This would be at the wishes of the participant.

Focus groups and interviews with HCPs will explore the current practice and how this can impact the patient across different rehabilitation settings. They will help develop a rich understanding of participant views and experiences. Topics for discussion will include timing of the cranioplasty, cosmesis, engagement in the rehabilitation pathway and social reintegration.

In addition, the field notes and researcher diary will enhance and complement the data gained through the focus groups and interviews.

Qualitative data analysis

The following data analysis techniques will be used.

Interpretive phenomenological analysis

The purpose of using IPA is to focus on understanding cranioplasty from the perspective of the individual experience. This can provide a richer account of how an individual perceives and copes with what can be a complex and difficult part of their recovery. Each participant's account is read and re-read with annotations and initial ideas recorded alongside the text, with thoughts, comments and observations forming the first part of

a narrative. As part of an IPA analysis, it is essential to describe and interpret the data to understand the lived experience. Resultant generated themes develop during this iterative process with patterns and themes from the individual being connected with master themes identified before moving onto the next account. The data will be primarily analysed by (HM) but a second researcher (CC), will analyse a subset of the transcripts to add to study transparency and rigour. On-going discussions will be had between the research team to ensure the traceability and development of themes remains clear. Themes from individual accounts are then 'bracketed'[8] and once all accounts are analysed, patterns across the accounts can be explored. Subordinate themes which captured the shared experiences of participants can then be generated.

Thematic analysis

Thematic analysis framework (17)

- Data familiraisation
- Generation of initial codes
- Generation of initial codes
- Searching for themes
- Reviewing themes
- Defining themes
- Write-up

HCP data will be analysed thematically.[16] Thematic analysis provides a way of looking for patterns in data and connecting them to conceptualise themes[17] with comparisons being made across and within groups. This will allow for the analysis of general topics of interest and generate new information as the study proceeds. Both deductive and inductive coding will be used. Coding is the process undertaken to label and organise a qualitative dataset. Deductive coding entails having a predefined set of codes. For example, when a researcher knows the topics of interest in the data to analyse, these are assigned appropriately to the data set. In contrast, inductive coding is a ground up approach where codes are derived starts from scratch, from the data and themes are then developed.

Field notes and diary

The study field notes and field diary will be both descriptive and reflective, and through a reflexive process will allow for a critical analysis of the influences posed by the researchers in the study.[18]

The analysis will commence shortly after data collection, and findings will be used to inform lines of enquiry in further data collection and analysis. Qualitative data analysis software (ATLAS.ti) will facilitate data management and analysis.

Quantitative data analysis

A standardised interpretation method will be adopted to analyse the QOLIBRI questionnaires, with the final scale between 0 and 100 (0 being the worst possible quality of life and 100 being the best). Total QOLIBRI score is used as health-related quality of life, but the subcategories can be analysed to provide greater detail in separate domains.

Triangulation

The different types of data will be analysed separately and then be brought together through meta-matrix triangulation.[19] This second-level analysis allows different data types to be linked together by creating a matrix into which the data is coded, allowing for themes to be generated. A triangulation strategy will allow the mixed data sources and findings to be brought together, allowing the formation of a more comprehensive and complete picture.[20]

DISCUSSION

There is limited literature regarding a patient's perception of the cranioplasty process, potential difficulties with rehabilitation before/after cranioplasty and how this may impact their reintegration into the community. A study by Gopaul *et al*[21] used the QOLIBRI questionnaire in 105 TBI patients who had undergone a DC and showed that anxiety and depression along with changes in cognition were the most significant challenges faced, but it was noted that further qualitative research was warranted here to understand these results better.

Any trauma or stroke can be a life-changing experience for the patient and their friends and family. Severe brain injury resulting from trauma often leads to prolonged intensive care admissions, neurosurgical interventions and long periods of rehabilitation and can lead to permanent disability and life-changing unexpected pressures. The risk of falls for patients following a brain injury is always a concern for an MDT which is often exacerbated following a craniectomy due to physical impairments, often observed impulsive behaviours, cognitive impairments and dysequilibrium. A recent survey[22] showed that the confidence of physiotherapists mobilising patients who had a stroke posthemicraniectomy was lower than those without a skull defect, demonstrating a coherent, more cautious approach with this cohort of patients. We hypothesise that patients postcraniectomy may be reluctant to engage in rehabilitation due to altered cosmetic appearance. This has the potential to impact their rehabilitation pathway, self-esteem and mental health. If potential factors such as these and the timing of cranioplasty, difficulties with engagement in rehabilitation and social implications can be better understood then a patient's engagement in rehabilitation has the potential to be maximised, and any potential barriers minimised, which would hopefully enable a more effective rehabilitation process for this cohort of patients.

Cosmetic appearance following DC can be challenging to overcome for some patients. A novel external prosthesis, which would fit within a series of head garments to aid with skull contouring is being developed and the opinion of patients is key to its success. A number of prototypes made from varying materials, with a range of head garments will be shown to patients for views and

feedback. This will be part of the interview around the broader subject of cosmesis and will be critical to the development and functionality of the external prosthesis.

Study strengths and limitations

This is the first mixed-methods study exploring the views and experiences of patients and their relatives who have had or are awaiting cranioplasty which will provide important insights into the current clinical challenges from the perspectives of patients, their relatives and HCPs. Relating this to the potential impact on the patient's recovery and rehabilitation, will allow for improved development of patient care and cranioplasty services.

Limitations include the small sample size for IPA analysis, limited inclusivity of patients and cross-sectional nature of data collection. The lived experience of a small number of individuals, analysed in-depth using IPA may not be generalisable across a wider cohort. However, findings may be transferrable to patients with similar experiences and circumstances. By the very nature of a detailed, often lengthy and sometimes challenging interview, it is only possible to enrol patients who can consent, who are cognitively able to engage in such discussions and who can write and who speak English. This may have excluded participants who may have different perspectives and experiences and limits inclusivity. In addition, it is common for patients to have other neurological disabilities, alongside their primary brain injury. These will be mitigated against as much as possible through purposive sampling and a range of time frames from cranioplasty. Longitudinal evaluation of patients is very important in being able to better understand the impact of cranioplasty. It is not possible to follow-up the same patient over a long period of time in this study, however, different patients will be interviewed regardless of time point from cranioplasty and so individual views will be captured at different time points. Wider education and training should be available for HCP's but is beyond the scope of this study. Hopefully the knowledge generated will help to bridge this gap.

Expected impact of the study and future directions

Findings from this study will provide an in-depth and comprehensive understanding of the impact a cranioplasty can have on patients and their families, including factors influencing recovery and engagement, the impact on rehabilitation pathways and cosmesis. Patients' views on the potential benefit of a novel external cranial plate to allow for improved cosmetic appearance can allow future development of the novel device. This will be the first study to explore the relationships, barriers and hurdles between these groups and further how patients view the cranioplasty and how this impacts their rehabilitation. Any new information generated from this study will help in developing a new series of cranioplasty, patient-focused resources, both in print and on a digital platform. This work would be part of a broader collaboration, and this study would help inform this work.

This study will help lay the foundations for a 5-year longitudinal study in cranioplasty follow-up in terms of Health Related Quality of Life (HRQoL), patient-reported complications, pain and cosmesis, which will be run in conjunction with the UK cranioplasty registry. In addition, the findings from this study will aid in the core areas of the cranioplasty health questionnaire, a patient-reported outcome measure specific to cranioplasty that is being developed for future clinical and academic work.

Data protection

All data will be stored securely on password-protected computers and locked filing cabinets and will only be accessible to members of the research team. During transcription, transcripts will be anonymised with all identifiable information removed before analysis. Anonymised study information will be kept for 15 years following the conclusion of the study. Questionnaire data will be stored in a local site file and analysed by a study team member.

Patient and public involvement

Development of the study and protocol has been guided by a local patient and public involvement (PPI) panel, who advised on the use of interviews and focus groups with the study population and technology. The format of the interview and focus groups was developed and changed due to the PPI group. On-going consultation on the best way to disseminate study results will be maintained.

Ethics and dissemination

Consent will be required from all study participants before being interviewed, participating in a focus group or completing questionnaires. Some HCP interviews and focus groups will be over the telephone; then, verbal consent will be obtained.

In-depth interviews and focus groups may bring up sensitive topics and expose vulnerabilities. The study team are aware of this, with support before and after interviews available if required. Similarly, confidentiality will be paramount within staff interviews and focus groups, and it will be emphasised that what is discussed will remain confidential. For all interviews and focus groups, if the participant is becoming increasingly distressed or upset, the interview or focus group will be stopped and the necessary support will be offered. If required, follow-up phone calls could be arranged individually with a member of the study team. Data already collected will be retained.

Only patients with the capacity to consent for participation in the study will be eligible. Ethical approval has been obtained from the Wales REC 7 ethics committee (Rec Ref: 19/WA/0315).

This study complies with the Declaration of Helsinki, adopted by the 18th World Medical Association (WMA) General Assembly, Helsinki, Finland, June 1964 and last revised by the 64th WMA General Assembly Fortaleza, Brazil, October 2013.

The results of this study will be presented at national brain injury conferences and published in peer-reviewed,

national and international journals. Along-side this, a new set of cranioplasty, patient-focused resources, will be developed.

Findings from this study will provide an in-depth and comprehensive understanding of the impact a cranioplasty can have on patients and their families. New information generated from this study can be used to produce a new series of cranioplasty, patient-focused resources, both in print and on a digital platform.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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