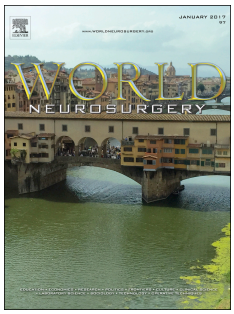

Mechanical complications of external ventricular and lumbar drains

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Mechanical complications of external ventricular and lumbar drains

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Contributions

A.K.T designed and conceived the study. J.P. performed data collection. A.S.P. quality checked the data and performed data analysis. A.S.P. and J.P. drafted the manuscript. A.K.T. and P.N. edited and revised the manuscript and supervised the study.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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Previous presentations

This work was presented, in part, as a platform presentation at the Hydrocephalus Society virtual meeting in October, 2021.

Mechanical complications of external ventricular and lumbar drains

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Abstract

Background

External ventricular drain (EVD) and lumbar drain insertion are two of the most commonly performed neurosurgical procedures worldwide for acute hydrocephalus. Mechanical complications, such as obstruction or CSF leakage are often seen and may contribute toward significant patient morbidity. Different CSF drainage methods are advocated to reduce the incidence of complications, but evidence regarding comparative effectiveness is limited.

Methods

In this single-centre prospective cohort study, the incidence of mechanical complications and associated interventional factors, including choice of drain, collecting system and location were studied in patients requiring CSF diversion for acute hydrocephalus. Univariate analyses were performed to explore trends within the data, followed by a repeated-measures, mixed-effects regression to determine the independent influence of drain device on mechanical failure.

Results

61 patients required CSF diversion between January 2020 to March 2021, via 3 different drain types (lumbar drain, tunnelled and bolted EVD) and 2 collection systems (LiquoGuard ® 7 and Becker®), performed in either theatre or intensive care. 21(39%) patients experienced a mechanical complication with blockage being the most common. Multivariate analyses demonstrated that bolted EVDs (Odds Ratio, 0.08; Confidence Interval,

0.01-0.58) and LiquoGuards (OR,0.23; CI,0.08-0.69) were significantly associated with a less mechanical complications as compared to tunnelled EVDs and Becker systems respectively ($p \leq 0.01$).

Discussion

Drain device has an influence on the occurrence of EVD-related complications. These preliminary findings suggest that choosing bolted EVDs and motor-assisted drainage can reduce drain-associated mechanical failure. A randomised controlled trial comparing drain devices is now required to confirm these findings.

Introduction

The insertion of an external ventricular drain (EVD) or ventriculostomy and lumbar drain (LD) represent two of the most commonly performed neurosurgical procedures worldwide [1]. Their use is especially important in the treatment of acute hydrocephalus, which often occurs in patients following a subarachnoid haemorrhage (SAH), traumatic brain injury or CNS infection.

Complications after drain placement are frequent and are associated with significant patient morbidity and healthcare costs. Commonly reported complications include drain-associated infection and intracranial haemorrhage after catheter placement or removal [2–4]. Mechanical complications such as catheter misplacement, obstruction and cerebrospinal fluid (CSF) leakage are no less dangerous. In the acute hydrocephalic patient, a non-patent drain can result in under-drainage, rapidly increasing intracranial pressure and, if no alternate CSF diversion is available, irreversible neurological injury. Manipulation of the drain system in order to restore patency may in itself contribute to intracranial haemorrhage, drain-associated infection [5], pneumocephalus and the need for revision with its attendant risks and costs. Finally, a non-functional catheter caused by malposition or blockage usually necessitates repeat CT imaging, exposing the patient to unnecessary ionising radiation.

Estimates regarding rates of mechanical complication and the factors which contribute toward them remain imprecise, at least partially because few studies have studied mechanical issues as primary endpoints [6–11]. Several surgical devices are currently available which divert and manage CSF flow in the acute setting. These include ventricular and lumbar drains inserted using tunnelled or bolted techniques [10,12], either in the intensive care unit or in the operating theatre and attached to either a conventional hydrostatic dripping chamber, such as the Becker® system or a motorised, automated CSF drainage system: such as LiquoGuard®7 (Möller Medical GmbH, Fulda, Germany).

Whereas bolt EVDs are associated with lower rates of CSF leakage, dislodgement and misplacement when compared to tunnelled EVDs [12–15], the effectiveness of other interventional parameters such as is unclear. To the best of our knowledge, no studies have been conducted to investigate the impact of lumbar drains, collecting system, or procedure location on the incidence of mechanical complications as a primary endpoint.

We suspect that three obstacles have previously limited this type of analysis. First, there is variation and inaccuracy in the documentation of mechanical faults, particularly on retrospective assessment [16]. Second, device-related factors are likely to be co-dependent, which necessitates more sophisticated modelling to confirm individual effects. Third, there are few centres in which there is sufficient volume and variety of available devices or practice to construct a comparative analysis.

To that end, the aim of this prospective observational study was to accurately assess the incidence of mechanical complications in a cohort of patients with acute hydrocephalus in a large-volume tertiary neurosciences centre. We investigate the relationship between drainage device, procedure location and the occurrence of mechanical complications using hierarchical modelling and collect sufficient data to formulate power calculations for future head-to-head clinical trials.

Methods

Reporting guidelines

This article adheres to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting cohort studies [17].

Ethics

The local institutional review board approved this study as a service evaluation. Informed consent for drain procedures was obtained for all patients in line with routine clinical practice.

Participants

This study was conducted in a large-volume tertiary neurosciences centre in London, United Kingdom. Included were all adult patients (> 18 years old) who were admitted between January 2020 to March 2021 and who required placement of a ventricular or lumbar drain to treat acute hydrocephalus. Selection of the drain device and CSF collecting system was at the discretion of the neurosurgical consultant caring for each patient and was not specified by a study protocol. Excluded were patients who had a proven infection prior to drain insertion, had chronic hydrocephalus, required a drain for treatment of CSF leakage secondary to operative complications, had prophylactic drain placement or who had more than one type of drain inserted.

Data collection

Patient data was collected daily and contemporaneously verified in person (J.P.). This data included drain parameters such as choice and timing of device, volume and pressure settings, placement issues and the

incidence of mechanical complications. Additional information was retrieved from the institution's electronic health record (Epic System Corporation, Madison Wisconsin, USA) and the electronic patient referral system (referapatient.org). This data encompassed clinical documentation from medical, nursing and auxiliary teams, laboratory investigations, radiological reports, and operation notes.

CSF drainage

Drains were placed by the resident neurosurgeon either in the operating theatre or in the neurosurgical intensive care unit (ITU). Tunnelled EVDs (Ares™, Medtronic), which incorporate an antibiotic-impregnated catheter were inserted in the operating theatre under general anaesthesia using a perforator to fashion the burrhole at Kocher's point before inserting the proximal catheter. The distal catheter portion was subcutaneously tunnelled away, exiting at least 7cm from the burr hole and anchored. Bolt EVDs (Spiegelberg Silverline®), which are silver impregnated, were inserted in either the operating theatre or ITU but here, a hand twist drill was used. A bolt was then placed over the catheter and secured at the burr hole site. Both ITU and theatre locations had access to neuronavigation assistance if required. Lumbar drains (Spiegelberg Silverline® lumbar drainage catheter), also silver impregnated, were inserted in theatre or at the ITU bedside under local anaesthesia with or without light sedation and the patient in a lateral decubitus position. The distal catheter was secured at the skin using stitches or adhesive film.

Two different types of CSF collection systems are used in our centre: a traditional gravity-based system (Becker®) and a motorised, electronic drainage system that allows automated pressure and volume-led CSF drainage as well as simultaneous intracranial pressure monitoring (LiquoGuard7®) [18]. These devices have been illustrated in Figure 1.

Figure 1. CSF drainage devices

Mechanical complications

Four drain associated mechanical complications were recorded in this study (Figure 1). *Retraction* and *dislodgement* describe the situation in which the catheter is pulled out partially or completely. This was evaluated by checking the measurement of the catheter at the skin or bolt exit point and on CT imaging. CT imaging was performed within 24 hours of drain insertion and was also used to confirm drain malposition if the drain was found to be non-patent. A *CSF leak* was diagnosed if there was evidence of fluid leakage from the site of the drain insertion, and required an immediate removal of the drain. A *blockage* was diagnosed if there was no drain output for at least 24 hours despite troubleshooting by the on-call resident including flushing of the catheter. The cause of the blockage e.g. catheter misplacement was documented if available. Patient outcomes regarding CNS infection, length of ITU and hospital stay as well as mortality were also recorded.

Data analysis

An exploratory data analysis was first performed with the aid of Sankey plots and Gantt charts permitting mechanical complications to be described at group-wise and patient-level (see Supplementary Material). All further statistical analyses were performed in Python (v=3.8.2) or R (v=1.2.1335).

Univariate testing examined relationships between modifiable interventional factors (choice of drain, drainage system and procedural location), occurrence of mechanical failure and potentially confounding variables (age, sex, diagnosis and number of procedures). Univariate testing was also performed to determine whether there was an association with patient outcomes. Group averages were compared using either a two-sided independent samples t-test or Mann-Whitney U (MWU) and Kruskal-Wallis (KW) test depending on whether the data was parametric. Normality of data was assessed by histogram visualisation and using the Kolmogorov-Smirnov test. Group frequencies were compared using the X^2 and Fisher-Exact (FE) tests. For contingency data larger than 2x2 tables, post-hoc pairwise comparisons were performed using the Z-test for

proportions. For the purposes of univariate analyses, in patients where more than one CSF collecting system was used, the variable was set as the device that was used on more than 80% of days.

A generalised mixed-effects logistic regression was fit with presence or absence of any mechanical complication as the target variable (Supplementary Methods), using repeated measures data, where each 'repeat' represented an admission day with the drain in situ. Using the repeated measures model, sample size estimation and power calculations were performed using Monte Carlo simulations (Supplementary Methods). 'Weak', 'medium' and 'strong' effect-sizes were assessed based on conversion between Cohen *d* values (0.3, 0.5, 0.8) to equivalent log-odds coefficients [19]. Study design was verified by an independent statistician within our institution.

Results

61 patients met our participant criteria in the study time frame, with a total of 69 drains inserted. (Table 1, Figure 2). The diagnosis for the majority of patients was hydrocephalus secondary to aneurysmal or non-aneurysmal SAH (89%).

Procedure location did not significantly differ by primary pathology (FE, p=0.73), age (MWU, statistic=572.0, p=0.11) or gender (χ^2, statistic=0.16, p=0.69). Similarly, the choice of drainage system did not significantly differ by primary pathology (FE, p=0.19), age (KW, statistic=1.88, p=0.39) or by gender (FE, p=0.42). Choice of drain type, did significantly differ by primary pathology (FE, p<0.01) but not by age (KW, statistic=0.52, p=0.77) or gender (FE, p=0.51).

5 patients had serial drainage (i.e. one drain was removed and another of identical type was inserted consecutively) while 3 patients had concurrent bilateral EVDs. Reasons for insertion of an additional serial drain included recurrent hydrocephalus and accidental removal. As might be expected, patients with multiple drains were significantly more likely to have had a mechanical complication (FE, statistic=24.0, p<0.001).

Table 1. Summary of patient demographics, device type and procedure location.

Figure 2. Sankey plot demonstrating patient flow and breakdown according to location of drain insertion, choice of drain and drainage system and mechanical complication

Figure 3. Onset and pattern of mechanical complications

21 patients (39.3%) in the cohort experienced at least one mechanical complication. 6.6% had a retracted drain (median onset, 1.5 days), 21.3% experienced a blocked drain (median onset, 4 days), 9.8% had a drain dislodged (median onset, 6.5 days) and 11.5% had a CSF leak (median onset, 8 days). Median days of onset were significantly different between groups (KW, statistic=7.9, $p<0.05$), with significant pairwise differences shown in Figure 3A. The pattern of mechanical complications for each individual patient is illustrated in Figure 3B. Of the patients who experienced one complication type, 8 experienced another of a different type. In addition, the chance of having another mechanical complication on a non-consecutive day given the first was 43%.

Univariate analysis

Choice of both drain type and drainage-system were significantly associated with a mechanical complication occurring (FE, $p\leq0.01$) (Table 2). Bolt-EVDs and LiquoGuard devices had the lowest mechanical failure rate within each category. Choice of procedure location did not significantly influence complication rate, although it did approach a trend for fewer mechanical complications when performed in ITU (X^2, statistic=2.59, p=0.11). Survival analysis curves to onset of the first mechanical complication complement these findings, in part (Supplementary Figure 1).

Table 2. Risk of mechanical complications by drain device or location.

The occurrence of each individual type of mechanical complication by drain device and location is described in detail in Supplementary Table 1. In brief, the risk of blockage was associated with choice of drain type (FE, p = 0.02) with tunnelled EVDs having the highest rate of blockages as compared to bolt EVDs (Z, statistic=2.47, p=0.01) and lumbar drains (Z, statistic=2.01, p=0.04). Both drain type (FE, p=0.05) and drainage system (FE, $p<0.01$) were significantly associated with a CSF leak occurring, with bolt EVDs and Becker systems linked to reduced leakage as compared to tunnelled devices (Z, statistic=2.02, p = 0.04) and mixed

system drainage (Z, statistic=3.80, p<0.001) respectively. Dislodgement or retraction were not significantly associated with any drain device, however, were significantly more likely to occur if the procedure took place in theatre rather than ITU (FE, statistic=8.64, p=0.03).

The presence of a mechanical complication was not associated with evidence of CNS infection or death but approached a trend for a longer length of stay (MWU, statistic=316.0, p=0.12) (Table 3).

Table 3. Patient outcome measures by device or location.

Multivariate analysis

The three modifiable factors (drain type, drainage system and procedure location) were selected as features for multivariate regression analysis in order to determine the degree to which they were independently associated with mechanical failure. Based on the findings from the univariate analysis, primary pathology and number of drain procedures were included as confounding variables. We performed a generalised mixed-effects logistic regression with each patient modelled as a random effect and other variables as fixed effects. Primary pathology was trialled as either a fixed or random effect. Utilising a stepwise grid-search approach, various permutations of model fitting were performed and compared (Supplementary Table 2). The model with the lowest AIC was found to retain drain type and drainage system, and patient as the random effects variable (Table 4).

Multivariate analysis demonstrated that when all other device variables were held constant, and factoring patient-related differences, choosing a bolted EVD resulted in approximately 12 times less odds of resulting in mechanical failure as compared to a tunnelled EVD. With regards to the drainage system, choosing a LiquoGuard had 4 times less odds of a mechanical failure as compared to a Becker set. Using a lumbar drain did not have a significant independent association with mechanical failure. Furthermore, these model findings remained significant after multiple comparison correction was applied and remained the same after exclusion of

lumbar drain patients from the model, with the model scores improving to 256 for the AIC. To prevent model overfitting which can result from smaller sample sizes and to improve generalisability of the results, we perform an additional repeated cross-validation analysis. Here, 20% of the dataset was removed at random and the model refitted 100 times. We find, after taking an average of the coefficient and respective p-values that the significance of the results was retained (Supplementary Table 3).

Finally, as an illustrative example, we take an 'average' patient from our cohort (PID=39), who has an age close to the mean (59.5 years), modal diagnosis (aneurysmal SAH) within a standard deviation of the mean drain duration (12.3±5.8 days). With a tunnelled-EVD, attached to a Becker system, their risk of any mechanical failure on each day of drainage was 11.4%. If a bolt-EVD was used, that risk would be 9.6%; with a LiquoGuard, 2.9%; and with both, 0.2%.

Table 4. Mixed-effects logistic regression, fixed-effect variables and corresponding odds ratios and significance levels.

Sample size estimation

Study power was assessed for a range of sample and effect sizes (Figure 4). Based on simulations using the fitted hierarchical model with drain type and drainage system as independent variables, for a power of 0.80 and alpha of 0.05, the sample size required for a large, anticipated effect size would be approximately 120 patients.

Figure 4. Sample size estimations and power levels for various effect sizes using the fitted hierarchical model.

Discussion

In this prospective study of acute hydrocephalus patients, we evaluated the occurrence of mechanical complications as primary endpoints, namely, catheter retraction, dislodgement, blockage, CSF leakage and modelled their association with drain device and location. Multivariate analysis demonstrated that using bolt external ventricular drains and LiquoGuard drainage systems were significantly associated with reduced odds of a mechanical complication occurring, whereas use of tunnelled EVDs or Becker-based drainage sets was linked to significantly greater odds of occurrence. These associations were independent and accounted for patient-related differences. Using simulation analysis based on the multivariate model, we derived sample size estimates and corresponding power calculations needed for a future randomised trial design.

Mechanical complications were common among our cohort. Consistent with previously reported data [20], nearly 40% of patients in this study experienced a mechanical failure. More than one-third of this group experienced at least two different types of complication on non-consecutive days, although this may not be surprising. For example, malposition of a drain can result in drain obstruction if the catheter tip does not terminate in the ventricle. If ICP remains high, CSF leakage may occur via the drain tract, resulting in overflow at the drain entry site [10]. A non-patent drain is especially dangerous in patients with poor intracranial compliance as a rapid increase in ICP may lead to secondary brain injury [21,22], yet the means to restore patency via irrigation or drain revision are not without risk. Drain replacement and revision raise the risk of haemorrhage, pneumocephalus, cerebral oedema [20,23] and revision-related infections [24–27]. Irrigation of the proximal catheter results in application of hydrostatic pressure directly on the brain parenchyma or within the ventricular space [20]. That 43% of the patients in our cohort had a repeat mechanical complication suggests that irrigation and bedside interventional methods only represent a temporary solution. These findings imply that for certain patients, a single mechanical issue can initiate a deleterious cascade of events that leads to additional complications which, once present, are difficult to manage definitively. Any attempt to revise the drain or correct the complication risks causing the patient further harm. Although a clear link between mechanical complications and worse

clinical outcomes was not found in this study, more detailed analyses are required to confirm if there is an impact on the long-term prognosis of these patients.

In this study, we evaluated four types of complications, their frequency and temporal pattern. Drain blockage was the most common type of mechanical complication in our cohort (21%), occurring at a median onset of 4-days after insertion and was significantly associated with choice of drain type on univariate analysis. CSF leakage was the second most common complication (12%), occurring at a comparatively later median onset of 8 days in our cohort and was associated with both drain type and drainage system. Previous research reports rates of catheter non-patency between 19 and 41% [20], while other data reveals a range of CSF leakage rates between 8 to 37% [9,11,28,29]. While this variability may be due to the interventional differences the present study seeks to investigate, it may also be related to the degree of accuracy in identifying specific complications, whether CT imaging was performed to confirm catheter location following mechanical failure, and if the analysis was retrospective [5,9,30,31].

After controlling for patient-related differences through multivariate analysis, we found that patients with a bolt EVD had a significantly reduced chance of a mechanical complication occurring whereas those with tunnelled EVDs had greater odds of mechanical complication. Bolt EVDs are screwed directly into the burrhole, theoretically ensuring a water-tight seal. Compared to tunnelled EVDs and lumbar drains, this mechanism has two advantages. Firstly, this type of fixation ensures that bolt EVDs are difficult to remove. Indeed, a recent meta-analysis found that bolted EVDs are significantly associated with less odds of accidental removal occurring [16]. Univariate analyses from this study found that using a bolt rather than tunnelled EVD was associated with a trend toward less dislodgement or retraction and was significantly less when compared to lumbar drains (Supplementary Results). By minimising the risk of retraction or dislodgement by securing the device, it is probable that the chance of a bolt EVD becoming blocked would also be reduced. Indeed, we note significantly reduced rates of blockage when compared to tunnelled drains (Supplementary Results), and that 63% of patients who had either retraction or dislodgement also experienced drain blockage (Figure 3).

Secondly, the chance of CSF leakage should also be less when using a bolt-secured drain. Jensen et al. found no cases of CSF leakage in bolt EVDs when comparing them to tunnelled EVDs [10] . Similarly, Aalborg et al. reported a lower incidence of CSF leakage in bolt EVDs, though this did not reach statistical significance [13]. Although we had two cases of CSF leakage in bolt EVD patients in our study, univariate analyses revealed that using a bolt rather than a tunnelled EVD or lumbar drain was significantly associated with a lower risk of CSF leakage (Supplementary Results).

The LiquoGuard draining system was originally designed for vascular surgery [32,33] but has more recently been applied as a device to assist with CSF diversion for patients with hydrocephalus [34,35]. It houses a motorised pump which can maintain or change flow rate and therefore enables automated pressure or volume-led drainage. In addition, it alerts users when the catheter is blocked, occluded or kinked, and if the intracranial pressure exceeds set thresholds. This array of functionality offers several advantages over conventional gravity-based dripping systems which require regular manual calibration to adjust for drainage and do not have the sophistry of automated warning systems to alert for common mechanical issues. Using conventional devices, an incorrect adjustment of the drop chamber and patient movements such as coughing, or leg elevation can cause incorrect CSF pressures to be displayed and affect flow resulting in over- or under-drainage. In our repeated measures multivariate analyses, the use of a LiquoGuard was independently associated with less odds of a mechanical complication occurring as compared to the Becker drainage system. Although, on univariate analysis, there was a trend for less incidence of dislodgement or retraction when using a LiquoGuard, we also found that Becker systems had a significantly reduced frequency of CSF leakage. It is possible that this result was confounded by the failure to account for frequency of use of drainage systems in univariate statistics and aggregation with a mixed drain variable.

There was a significant univariate association for less occurrence of dislodgement or retraction when the drain insertion procedure took place in ITU rather than theatre. However, this association was not borne out on multivariate analysis. Although it is possible that drain insertion in the intensive care environment may avoid

complications resulting from patient transfers to and from theatre, it may also be that the location is simply correlated with drain type e.g. that tunnelled EVDs can only be inserted in theatre.

In our multivariate analysis, using a lumbar drain was not significantly associated with mechanical complications, despite on univariate testing, their use appeared to be associated with a significantly lower incidence of blockage and a significantly higher chance of pull-out when compared to tunnelled EVDs and bolt EVDs. Complications associated with lumbar drains are scarcely described in the literature, but as a device, it is thought to be a less invasive and more effective method of CSF drainage [36,37]. The main reservations about lumbar drains are related to fears of brain herniation caused by excessive CSF drainage from the lumbar cistern [38]. Given the small sample size and representing the smallest group of patients, these results are likely to be inconclusive. The indications for CSF drainage via lumbar drain and external ventricular drain can differ in some neurosurgical centres. Acknowledging this as a potential cause of bias, the multivariate methods used were able to independently assess the impact of drain type. In addition, removal of patients who had a lumbar drain sited did not change the significance of the other obtained multivariate results.

Limitations and strengths

This work has a number of other limitations. This modestly-sized study only included participants from a single centre, and because it was an observational study, many factors remained uncontrolled. As a result, it was difficult to avoid the risk of selection bias in how patients were assigned to a treatment, especially since the choice of drain device is dependent on the attending neurosurgeon's preference. The allocation of the CSF drainage system, in particular, posed a significant challenge. Our institution, like many others, does not adhere to a strict drainage protocol, including how collection systems are assigned. For patients who used more than one drainage system, it is unclear whether the brief disruption to the integrity of a closed catheter system during this exchange is linked to other complications like CSF leakage or infection. To address this issue, we created a separate subgroup for these patients and evaluated their effects separately in our univariate analyses. Furthermore, we used extended statistical modelling with a mixed-effect logistic regression to better designate

the CSF drainage system on a day-by-day or repeated measures basis and demonstrated with cross-validation methods that our model was resistant to overfitting. We acknowledge that we did not specifically evaluate the experience of the neurosurgeon inserting the drain. Whereas some authors have suggested they may impact on drain accuracy [39], others have concluded that it does not impact upon complication rate [40]. This variance may be at least partly due to the training on insertion technique offered to neurosurgical trainees [41], and we highlight that in our centre guidance and a protocol is available to ensure conformity of technique.

In spite of these limitations we note the study's novelty. That our study was prospective, followed a rigorous protocol for acquisition of highly granular data and was validated with contemporaneous neuroimaging, represent significant strengths in addressing these many of the issues regarding data collection which have affected the quality of other studies [16]. This protocol enables complication frequencies to be estimated with greater precision. Analysing this data using the described multivariate model, permitted the independent influence of each device in the acute drain pathway to be ascertained, after accounting for patient-related factors. To the best of our knowledge this is the first time an analysis of this detail has been performed for this type of data. We will aim to address many of the design-related limitations mentioned above, by performing an adequately powered randomised control trial. To that end, we used the pilot results of this study in order to simulate a power analysis across a range of effect sizes and estimate the number of patients that would be required. Simulation methods are applicable across a wide range of statistical models and are often more accurate than approximate analytical methods [42].

Conclusion

In this prospective observational cohort study, we evaluated the incidence of drain-associated mechanical complications in patients with acute hydrocephalus. Our exploratory results cautiously suggest an advantage in using bolted external ventricular drains and automated, motorised drainage systems as devices which have a reduced rate of mechanical failure as compared to tunnelled external ventricular drains and gravity-

based collection systems. The results of controlled-design studies would help validate our findings, and we have accordingly taken steps to estimate the sample of patients needed to detect significant differences.

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Figure legends

Figure 1. CSF drainage devices. (A) Becker® collection system; (B) Spiegelberg Silverline® bolted external ventricular drain; (C) Spiegelberg Silverline® external lumbar drain; (D) Medtronic® ARES™ tunnelled external ventricular drain and (E) LiquoGuard7® motorised collection system. All patients in (B-D) provided their informed consent for the use of the photographs in this article.

Figure 2. Sankey plot demonstrating patient flow and breakdown according to location of drain insertion, choice of drain and drainage system and mechanical complication. (ITU = intensive treatment unit; LD = lumbar drain; LG = LiquoGuard; Dis / Retr = dislodgement or drain retraction)

Figure 3. Onset and pattern of mechanical complications. (A) Box plot of complication onset time. * = significant difference following Mann-Whitney U test at $p < 0.05$. (B) Gantt chart demonstrating pattern of complications for individual patients during admission up to drain removal.

Figure 4. Sample size estimations and power levels for various effect sizes using the fitted hierarchical model. A power level of 0.8 is shown as the blue horizontal line, with 95% confidence intervals shown in grey. Each curve represents a different effect size for fixed-effect variables (legend). All estimates assume an alpha of 0.05. Baseline represents the effect size observed in the present study. The model includes drain type and drainage system as fixed-effects and each patient as a random-effects variable.

Table legends

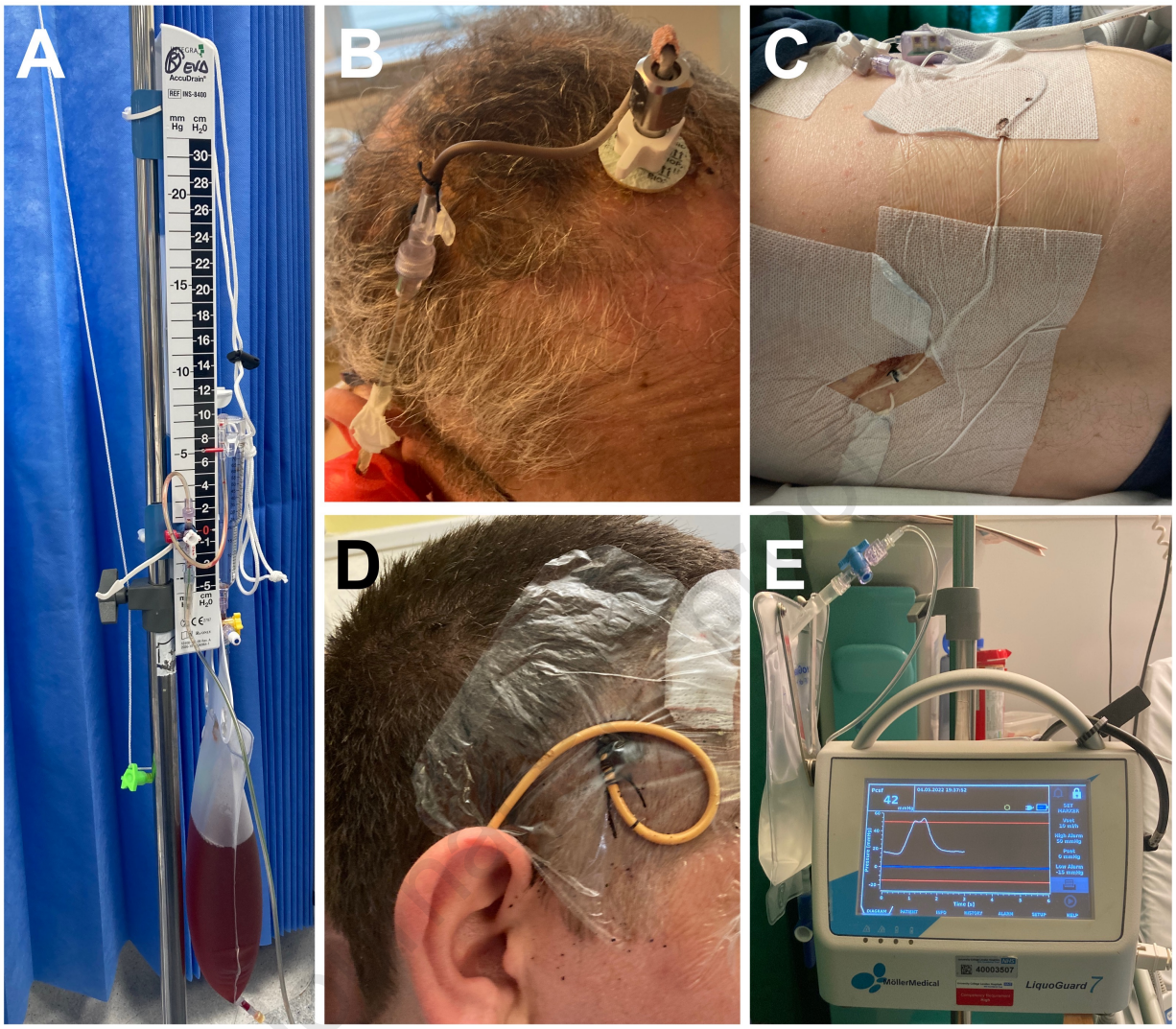
Table 1. Summary of patient demographics, device type and procedure location.

Table 2. Risk of mechanical complications by drain device or location. For pairwise comparisons - only trending ($p < 0.1$) or significant ($p < 0.05$) are presented. (EVD = external ventricular drain; ITU = intensive treatment unit; LG = LiquoGuard)

Table 3. Patient outcome measures by device or location.

(CNS = central nervous system)

Table 4. Mixed-effects logistic regression, fixed-effect variables and corresponding odds ratios and significance levels. (OR = odds ratio; CI = confidence interval; EVD = external ventricular drain)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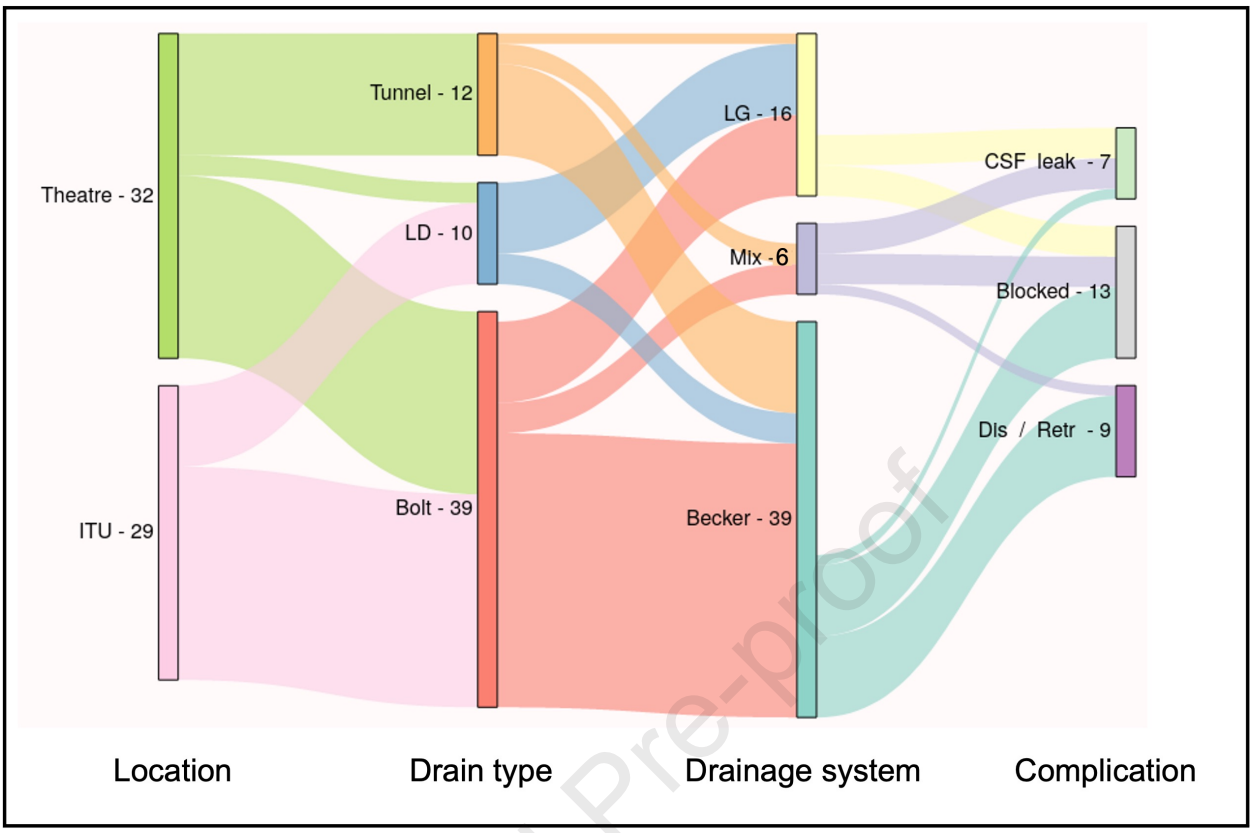

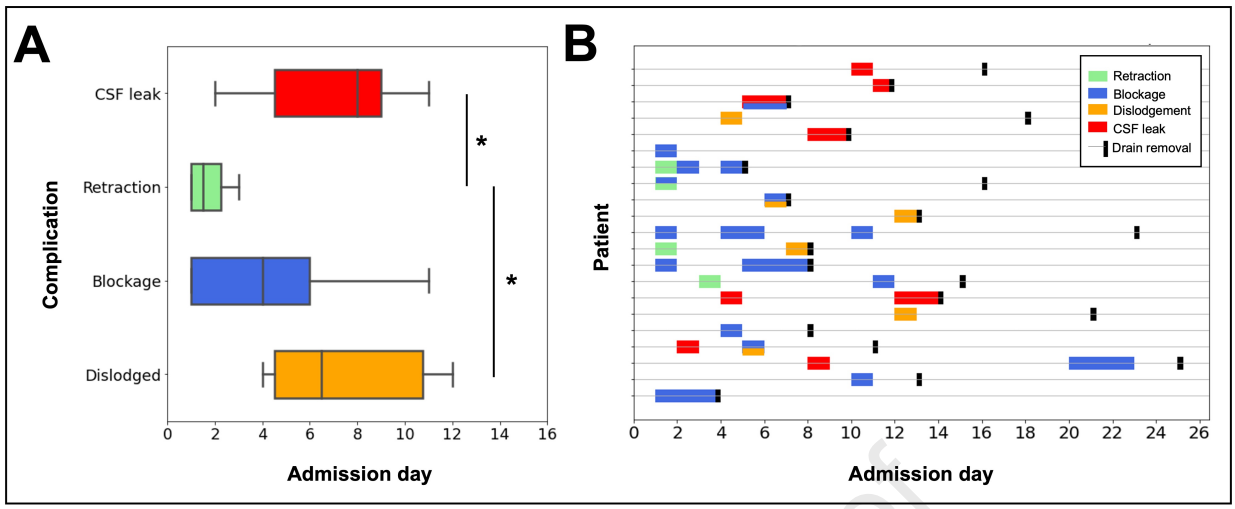

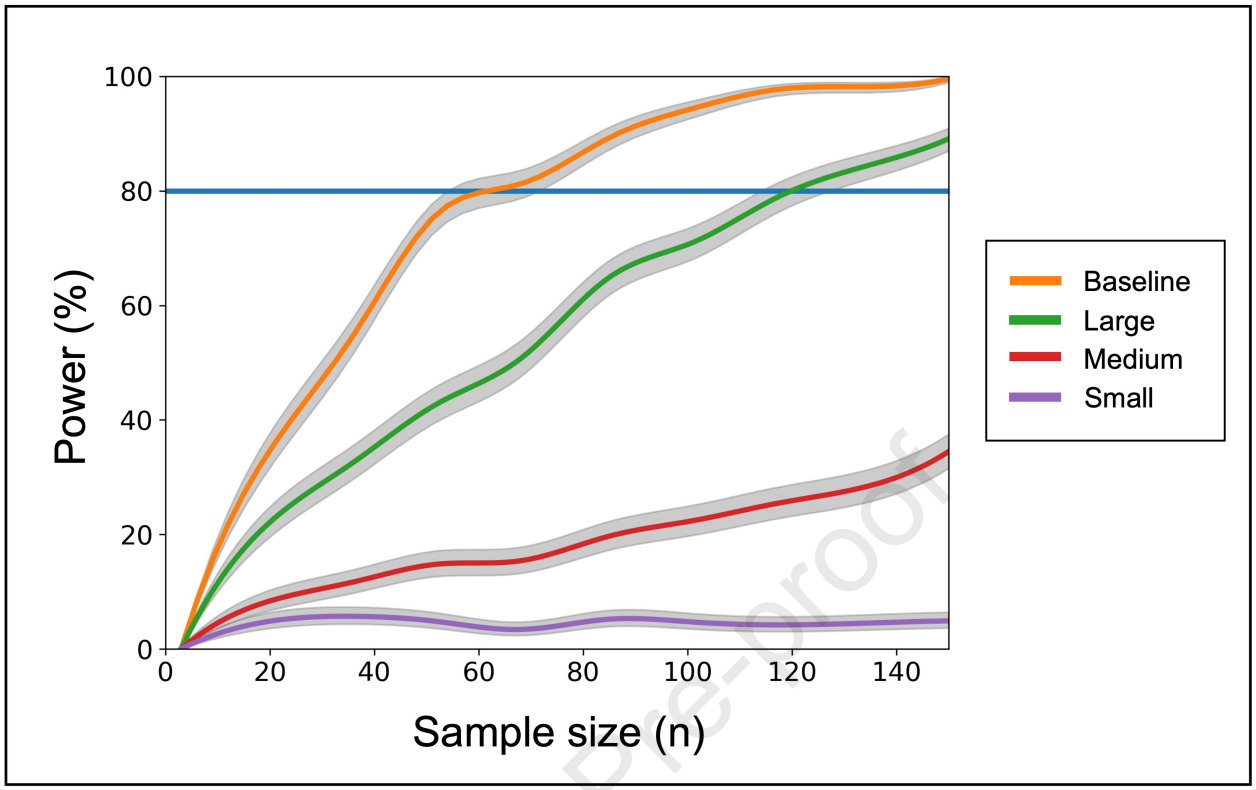

Abbreviations

AIC = Akaike Information Criterion
CSF = cerebro-spinal fluid
EVD = external ventricular drain
ICP = intracranial pressure
ITU = intensive care / treatment unit
MWU = Mann-Whitney U test
SAH = subarachnoid haemorrhage

We confirm that all authors have met ICMJE criteria for authorship and have no financial interests or conflicts of interest to disclose.