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RESEARCH

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A comparison of survival rate and overdrainage rate between pressure-regulated and flow-regulated ventriculoperitoneal shunt valves for the management of hydrocephalus in the first year of life

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Abstract

Introduction Ventriculoperitoneal shunts are a common treatment of hydrocephalus in the first year of life; shunts can be fitted with pressure- regulated valves or flow-regulated valves. Currently, there is limited evidence suggesting which valve system is more appropriate in this population. Literature suggests that shunt survival and failure rates across both shunt systems is largely equal; however, a previous study in 2020 at Sheffield Children's Hospital suggested that flow-regulated OSV II valves were less likely than pressure-regulated ProGAV 2.0 valves to cause overdrainage in neonates. We sought to test the hypotheses that for shunts inserted in the first year of life there is no difference in survival rate between pressure-regulated and flow-regulated valves, and that flow-regulated valves are less likely to cause overdrainage.

Methods A retrospective case series of primary ventriculoperitoneal shunt insertions in the first year of life at Sheffield Children's Hospital was carried out. The total sample size was 61. 20 patients were fitted with Miethke ProGAV 2.0 programmable pressure-regulated valves, and 41 patients were fitted with Orbis-Sigma OSV II flow-regulated valves. Of the 61 patients, 34 had the same shunt system throughout their first year, and were assessed for overdrainage through head circumference measurements.

Results The mean 6 month shunt survival was 45% for the Miethke ProGAV 2.0 valves and 71% for the OSV II valves ($p=0.089$). Mean shunt survival at 1 year was 30% and 54% for ProGAV 2.0 and OSV II valves, respectively ($p=0.134$). The overall overdrainage rate at 1 year was 35%, with no significant difference between the ProGAV 2.0 valves and OSV II valves.

Conclusion Our findings corroborate previous research demonstrating the lack of a significant difference in shunt survival between the pressure-regulated and flow-regulated valve systems in this age group. However, we were unable to demonstrate any significant difference in overdrainage rates between the valve systems in the first year of life.

Keywords Ventriculoperitoneal shunt, Hydrocephalus, Overdrainage, OSV II, ProGAV 2.0

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Background

Hydrocephalus is a well-established pathology observed in the early paediatric population, characterised by increased intraventricular pressure and subsequent dilatation of the cerebral ventricles [1]. The current gold standard of management involves the insertion of a ventriculoperitoneal (VP) shunt. VP shunts are designed to drain CSF to the peritoneum in order to restore normal intracranial pressure.

Shunt valves can be flow regulated or pressure regulated. Pressure-regulated valves are dependent on the pressure differential across the valve; when the pressure differential between the ventricles and the peritoneum exceeds a threshold defined by the mechanical resistance of the valve, the valve opens (shown in Fig. 1). Programmable valves, such as the Miethke ProGAV series, allow the mechanical resistance to be changed. Flow-regulated valves maintain CSF drainage at a fixed flow rate, and are not adjustable (shown in Fig. 2).

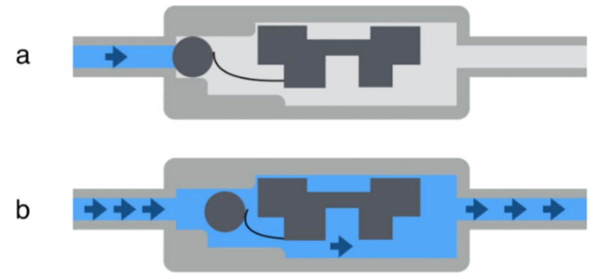

Fig. 1 Simplified sketch of a pressure-regulated valve a Low cranial pressure, valve is closed as ball blocks flow through the valve b Cranial pressure exceeds threshold maintained by spring attached to ball, causing ball to be pushed into the valve, opening the valve and allowing CSF to flow through [2]

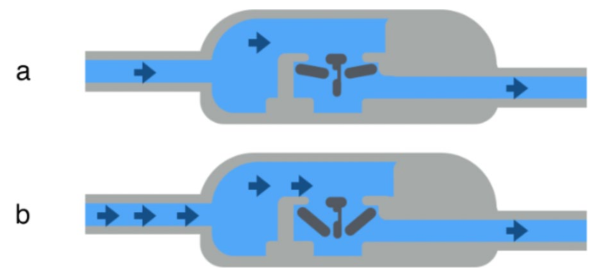

Fig. 2 Simplified sketch of a flow-regulated valve **a**, **b** As cranial pressure increases, the valve diaphragm is pushed further open, which diverts CSF flow through a path of increased resistance. This maintains a steady output flow rate [3]

Ventriculoperitoneal shunt insertion is associated with a variety of risks; shunt obstruction followed by infection are the most common cause of shunt malfunction, and are indications for urgent revision [4–6].

Overdrainage occurs when too much CSF drains into the peritoneum, leading to lower intraventricular pressure, and is associated with an increased risk of subdural haematoma, craniosynostosis, and slit ventricle syndrome [7]. Overdrainage can be identified clinically by the presence of low-pressure symptoms such as postural headache, nausea and irritability; or through decreasing head circumference trajectory, or radiographically.

Henderson et al. [8] failed to demonstrate a significant difference in survival rate between ProGAV 2.0 and OSV II valves in early infancy, however suggested that OSV valves were less likely to cause overdrainage symptoms. Following this, Sheffield Children's Hospital adopted a policy to insert OSV II valves in patients in the first year of life. A recent review of 19 studies by Hall et al. [9] also showed no significant difference in failure rate between shunt valve types.

We planned to ascertain whether contemporary data at Sheffield Children's Hospital continues to support the hypotheses that there is no difference in survival rate between flow-regulated and pressure-regulated valves, and that flow-regulated valves are associated with lower rates of overdrainage.

Methods

A retrospective case series was carried out on patients who had primary shunt insertions in the first year of age at Sheffield Children's Hospital between January 2014 and October 2021. Sixty-one patients were included, 41 of which had OSV II flow-regulated valves inserted and 20 of which had ProGAV 2.0 pressure-regulated valves. Valves were identified through the shunt insertion operation notes.

Shunt lifetime was defined as the duration between insertion and removal or revision of the shunt. This was then used to calculate shunt survival, as the proportion of inserted shunts that were still in situ 6 months, and 1 year later. In addition to shunt survival, valve survival was also calculated. Valve lifetime was defined as the time between insertion and removal of the valve, as mentioned explicitly in the operation notes; we did not count shunt revisions where the valve was not changed or removed as valve revisions, and thus these revisions did not affect the valve lifetime.

Indications for shunt insertion and removal or revision were recorded. The most common indications for shunt insertion included intraventricular haemorrhage, and myelomeningocele; the most common indication for shunt revision was shunt blockage, followed by infection.

Overdrainage rate was measured by head circumference trends in cases where the same shunt system was used throughout the first year. Head circumference centiles immediately before shunt insertion, 1 month, 3 months, 6 months and 12 months after shunt insertion were procured from electronic growth charts (shown in Fig. 3). Cases with values below the 25th centile or trends crossing two centile lines within the 12 months were attributed to overdrainage. Additionally, change in centile values were calculated at each of the head circumference measurement points, as the relative change in centile with respect to the previous measurement point.

Results

Shunt survival

Sixty-one shunt insertions were included, 20 of which were ProGAV 2.0 and 41 of which were OSV II valves. Of the 20 ProGAV 2.0 shunt insertions, 9 were still present at 6 months, and 6 were still present at 1 year; of the 41 OSV II shunt insertions, 29 were still present at 6 months, and 22 were still present at 1 year. The mean 6 month survival was therefore 45% for the ProGAV 2.0 valves and 71% for OSV II valves ($p=0.089$), and the mean 1 year survival was 30% for ProGAV 2.0 and 54% for OSV II ($p=0.134$). Indications for shunt revision included distal blockage, proximal blockage and shunt infection.

Valve survival, which excluded shunt revisions where the valve was not removed or replaced, was also calculated. The mean 6 month valve survival was 55% for the ProGAV 2.0 valves, and 73% for OSV II valves ($p=0.177$), and the mean 1 year survival was 50% for ProGAV 2.0 and 59% for OSV II ($p=0.512$) (shown in Table 1, Fig. 4).

Mean time to shunt revision was calculated from the 34 shunt insertions that led to a revision. The mean time to revision was 166.8 days for ProGAV 2.0 valves, and 287.2 for OSV II valves ($p=0.323$) (shown in Fig. 5).

No significant differences between ProGAV 2.0 or OSV II valves were found in this data set.

Overdrainage

The mean 1 year overdrainage rate was 33% and 36% for patients treated with the ProGAV 2.0 valves and OSV II valves, respectively (shown in Table 2). Change-in-centile data for both OSV II and ProGAV 2.0 valves demonstrated that centile lines were crossed most frequently in the first month after the shunts were inserted, and less frequently throughout the first year (shown in Fig. 6). No statistically significant differences between the valve types were identified.

Discussion

Overall shunt survival

Shunt survival is lower in the paediatric population when compared to adults. Limwattananon and Kitkhuandee [10] found a higher proportion of shunt failure in patients aged below 1 when compared to patients aged 1–17. Markov modelling carried out by Stein and Guo [11] using data present in the literature at the time demonstrated that the shunt failure rate in children is markedly higher than in adults, and that failure rate is highest in the first year after insertion.

Henderson et al. [8] reported an overall 1 year shunt survival of 34%. Our findings at the same site including more contemporary data demonstrate an overall 1 year shunt survival of 46%. However, the 2020 study was limited to patients who had shunt insertions in or shortly after the neonatal period, with 82% of patients in the study having primary insertions in the first 42 weeks of life. In contrast, we included patients with shunt insertions at any point in the first year of life, as our primary objective was to compare shunt survival between shunt valve types.

Gebert et al. [12] reported a 1 year survival rate of 69% in patients with a mean age of 4 months at the time of insertion, and Thomale et al. [13] found an overall shunt survival of 61% in patients aged below 1 year. A 2016 study of proximal shunt malfunctions by Buster et al. [14] reported a 1 year shunt failure rate of 51.3%. Limwattananon and Kitkhuandee [10] demonstrated an overall shunt failure of 33.7% with a median age at insertion of 8.8 months, and a median follow up of 29.9 months.

Interestingly, in data from a single centre in Nepal, Paudel et al. [15] reported 16% overall shunt complications in infants compared with 31.3% overall shunt complications in children aged over 1 year, with a mean follow up of 16 months.

Despite some recent reports of exceptionally low infant shunt failure rates in the literature, our data are largely consistent with published evidence on shunt survival rates in the early paediatric population.

Shunt survival between valve types

Deciding between shunt valve systems remains controversial. A 2020 study on fixed pressure valves inserted in in patients aged 0–18.6 years by Sokratous et al. [16] at The Alder Hey Children's Hospital in Liverpool reported a 1 year shunt survival of 62.6%, and concluded that Miethke fixed pressure valves were superior to other valves. Hall et al. [17] found that in patients with a mean age of 5.1 years, programmable differential pressure valves were linked with a 1 year shunt survival of 80.2%,

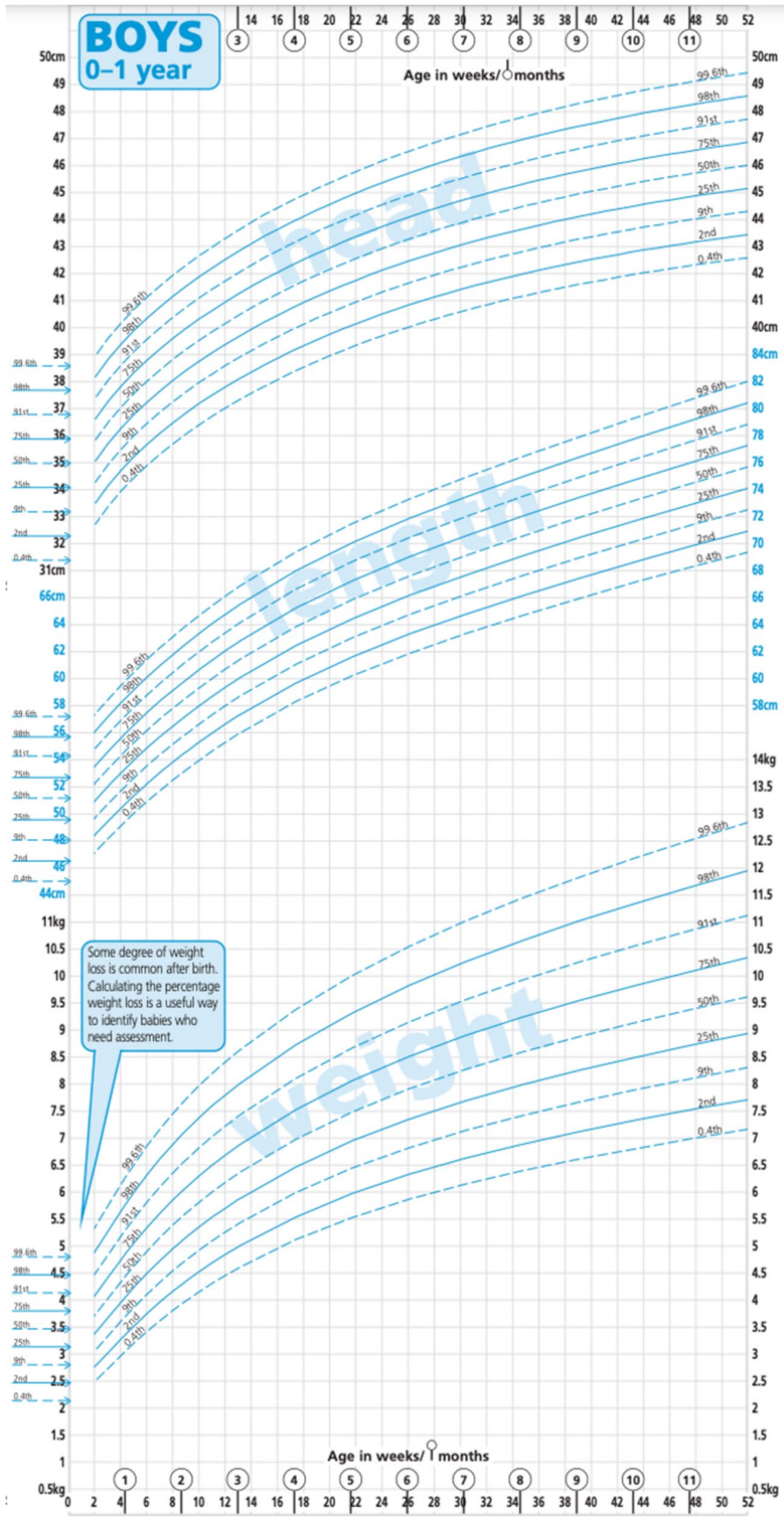

Fig. 3 Electronic growth chart used to record head circumference

Table 1 Six month and 1 year survival for ProGAV 2.0 and OSV II shunts

	n	6 month shunt survival (95% CI)	1 year shunt survival (95% CI)	6 month valve survival (95% CI)	1 year valve survival (95% CI)
ProGAV 2.0	20	0.45 ± 0.22	0.30 ± 0.20	0.55 ± 0.22	0.50 ± 0.22
OSV II	41	0.71 ± 0.14	0.54 ± 0.15	0.72 ± 0.13	0.59 ± 0.15

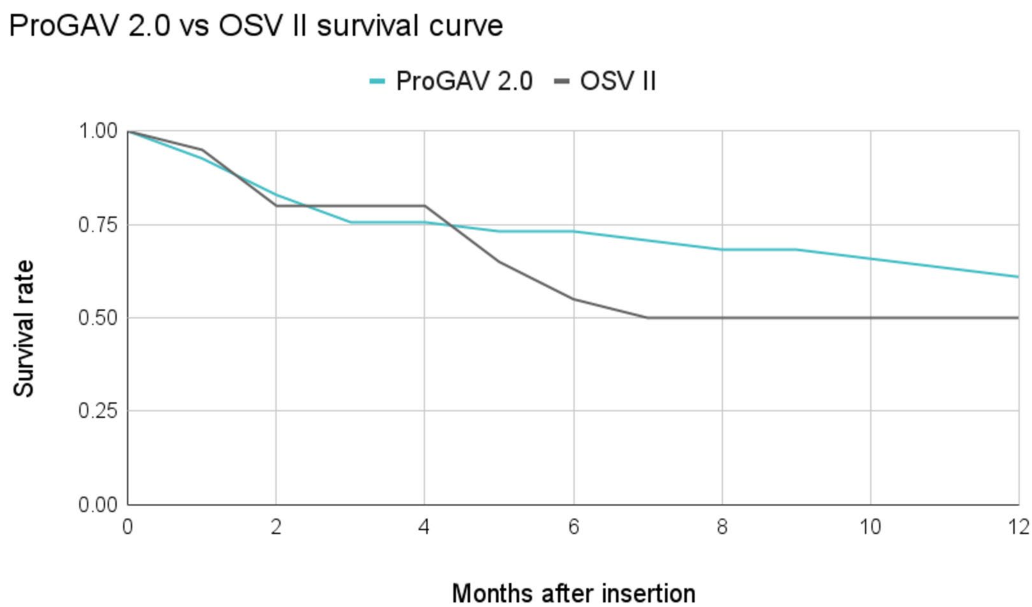

Fig. 4 No significant difference in survival between OSV II and ProGAV 2.0 valves in the first year post-insertion

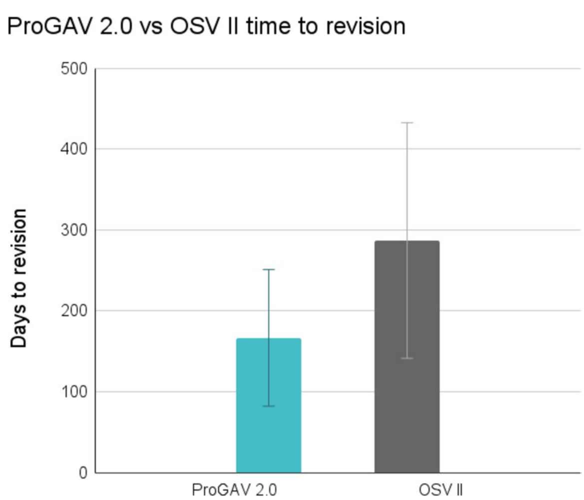

Fig. 5 No significant difference in time to revision between ProGAV 2.0 and OSV II valves inserted in the first year of life

Table 2 Overdrainage rate for ProGAV 2.0 and OSV II shunts

	n	Overdrainage cases	Overdrainage rate (95% CI)
ProGAV 2.0	12	4	0.33 ± 0.27
OSV II	22	8	0.36 ± 0.20

while fixed pressure valves carried a 1 year shunt survival of 58.3%.

Studies comparing pressure-regulated valves to flow-regulated valves are scarcer. Beuriat et al. [18] reported a 1 year shunt survival of 60% and 70% with differential pressure valves and flow-regulated valves, respectively, in children with a mean age of 3.2 years at insertion. However, Jain et al. [19] demonstrated no significant difference in shunt survival between pressure-regulated and flow-regulated valves, in children with a mean age of 26.4 months at insertion.

Research in patients in the early paediatric population is even further limited. The Henderson et al. [8] study published with data from Sheffield Children's Hospital looks specifically at the neonatal period, and the authors were unable to demonstrate a significant difference in shunt survival between pressure-regulated and flow-regulated valves. Our findings on shunts inserted at any

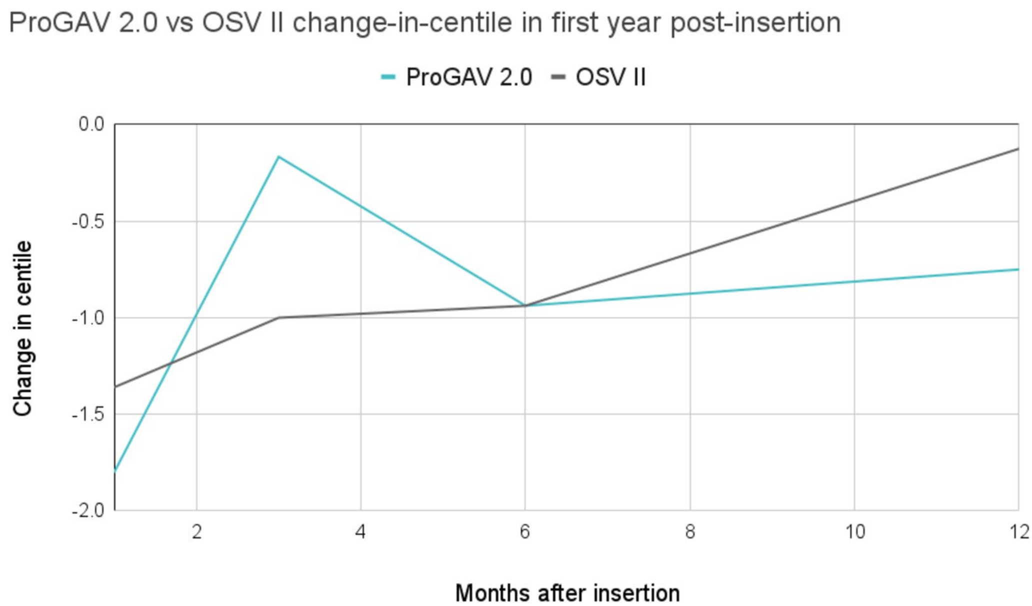

Fig. 6 No significant difference in change-in-centile trends in first year post-insertion. Change-in-centile becomes less negative with time, with most centiles crossed in first month post-insertion

point within the first year further corroborate this data, with no significant difference in shunt survival between the valve types at 6 months and 1 year post-insertion.

Shunt survival versus valve survival

Shunt survival is the predominant measure of valve efficacy in the literature. However, shunts can fail for reasons un-attributable to the valve itself, such as infections or distal blockages. We therefore hypothesised that valve survival, which excluded shunt revisions where the valve remained in situ, may be a more accurate measure of shunt efficacy.

However, we found that valve survival data had a number of confounding factors. Firstly, deciding if a shunt revision event affected the valve lifetime was dependent on operation notes, which were occasionally unclear about whether a new system was inserted. Additionally, different surgeons had differing practices with respect to managing shunt blockages—some replaced the entire valve system even if the valve was demonstrated to be working, while others only changed the valve if there was no flow.

In addition, the rate of failure from non-valve causes is likely to be similar for each valve- and therefore any significant difference between the valves in shunt survival can be presumed to be from the valves themselves.

Like our shunt survival data, our valve survival data failed to show any significant difference between the valve types at both 6 months and 1 year after insertion.

Overdrainage

Overdrainage is an important and well documented complication of ventriculoperitoneal shunting [20].

Comparisons of overdrainage rates between shunt types is limited in the literature, particularly in the paediatric population. Additionally, the methodology for measuring overdrainage varies. Studies in adults often use incidence of complications associated with overdrainage, such as slit ventricle syndrome and subdural collections, to assess overdrainage rates.

In a study of 289 adults, Decq et al. [21] found that flow-regulated valves were associated with fewer overdrainage-related complications as compared to pressure- regulated valves. Overdrainage-related complications were defined as subdural collections, slit ventricle syndrome, or low ICP syndrome; however, 94% of the complications reported were subdural collections. Corroborating findings were reported by Hanlo et al. [22], and a study by Drake et al. [23] reported no overdrainage complications, defined as SDH or slit ventricle syndrome, with OSV flow-regulated valves.

However, Desai et al. [24] used incidence of subdural haematoma (SDH) in shunted adult patients as a measure of overdrainage and found no difference in SDH incidence between flow-regulated and pressure-regulated valves.

Henderson et al. [8] measured overdrainage in children through presence of clinical signs, which included a sunken fontanelle, overriding sutures, and decreasing head circumference, and found that clinical signs were found in 59% of patients with ProGAV 2.0 valves and 24% of patients with OSV II valves. However, the authors did not specify which clinical signs were used to determine overdrainage in each case.

We solely used head circumference trends to determine overdrainage rate. We believed this was appropriate as head circumference is serially measured in all individuals in this population; this approach is less reliant on clinical notes, which may be more prone to subjectivity, and could therefore lead to inconsistency across the cohort. Our findings failed to demonstrate any difference in overdrainage rates between the valve types, with patients in both groups crossing centile lines in a similar pattern throughout the first year.

Conclusion

Shunt survival in the first year of life is poor, and there is limited evidence in the literature that suggests that pressure-regulated or flow-regulated valves are more prone to failure in this population. While some reports suggest that flow-regulated valves are associated with fewer overdrainage complications in the neonatal period, we were unable to find any significant difference in rates of decreasing head circumference between the valve types within the first year.

Author contributions

BK, MY, SS, MM, HZ, JM, SU, PDL and VB made substantial contributions to the conception and design of the work. BK wrote the work, with critical reviews by MY, SS, MM and VB.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The required Ethical Approval has been confirmed by the Sheffield Children's Hospital Quality and Standards Department, and the Registration Code is SE1324."

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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