ProGav case series

2023

Busse et al. from the Department of Neurosurgery, University Hospital Frankfurt, Rostock, and Jena compared two adjustable valves, proGAV and proGAV 2.0, for complications resulting in revision surgery.

Four hundred patients undergoing primary shunt implantation between 2014 and 2020 were analyzed for overall revision rate, 1-year revision rate, and revision-free survival observing patient age, sex, etiology of hydrocephalus, implantation site, prior diversion of cerebrospinal fluid, and cause of revision.

All data were available for all 400 patients (female/male 208/192). Overall, 99 patients underwent revision surgery after primary implantation. proGAV valve was implanted in 283 patients, and proGAV 2.0 valves were implanted in 117 patients. There was no significant difference between the two shunt valves concerning revision rate (p = 0.8069), 1-year revision rate (p = 0.9077), revision-free survival (p = 0.6921), and overall survival (p = 0.3232). Regarding the 1-year revision rate, we observed no significant difference between the two shunt valves in pediatric patients (40.7% vs 27.6%; p = 0.2247). Revision operation had to be performed more frequently in pediatric patients (46.6% vs 24.8%; p = 0.0093) with a significantly higher number of total revisions with proGAV than proGAV 2.0 (33 of 59 implanted shunts [55.9%] vs. 8 of 29 implanted shunts [27.6%]; p = 0.0110) most likely due to longer follow-up in the proGAV-group. For this reason, they clearly put emphasis on analyzing results regarding the 1-year revision rate.

According to the target variables analyzed, aside from lifetime revision rate in pediatric patients, there is no significant difference between the two shunt valves [1)].

Busse et al.'s study found that, apart from the lifetime revision rate in pediatric patients, there was no significant difference between the proGAV and proGAV 2.0 shunt valves. This suggests that both valves are generally comparable in terms of their performance and complication rates. However, given the limitations of the study, it is important to interpret the results with caution. Future research could benefit from longer-term follow-up and multicenter studies to confirm the findings and provide a more comprehensive understanding of the comparative effectiveness of these shunt valves. Additionally, considering the dynamic nature of medical device technology, ongoing evaluations of shunt valves are essential to ensure that patients receive the best available care.

Teping et al. from Departments of Neurosurgery and General Pediatrics and Neonatology, in Homburg, Germany. retrospectively analyzed all shunting procedures between January 2009 and January 2021 in children younger than 1 year of age. Postoperative complications and surgical revisions were set as outcome parameters. Shunt and valve survival rates were evaluated. Statistical analysis compared children who underwent implantation of the Miethke proGAV/proSA programmable serial valves with those who underwent implantation of the fixed-pressure Miethke paediGAV system.

Eighty-five procedures were evaluated. The paediGAV system was implanted in 39 cases and the

proGAV/proSA in 46 cases. The mean ± SD follow-up was 247.7 ± 140 weeks. In 2009 and 2010, paediGAV valves were used exclusively, but by 2019, the use of proGAV/proSA had evolved into the first-line therapy. The paediGAV system was significantly more often revised ($p < 0.05$). The main indication for revision was proximal occlusion, with or without impairment to the valve. The valve and shunt survival rates of proGAV/proSA were significantly prolonged ($p < 0.05$). The surgery-free valve survival of proGAV/proSA was 90% after 1 year and 63% after 6 years. There were no overdrainage-related revisions of proGAV/proSA valves.

Favorable shunt and valve survival validate the increasing use of programmable proGAV/proSA serial valves in this delicate population. Potential benefits in postoperative treatment should be addressed in prospective multicenter studies [2)].

Teping et al.'s study suggests that programmable proGAV/proSA serial valves exhibit favorable valve and shunt survival rates when used in infants with hydrocephalus. The observed reduction in revisions and extended survival rates for the proGAV/proSA system, when compared to the paediGAV system, may have significant clinical implications for the treatment of hydrocephalus in this delicate population. However, the study's retrospective nature and single-center design should be considered when interpreting the findings. To further validate the benefits of programmable serial valves, prospective multicenter studies with a larger and more diverse patient population may be warranted. Additionally, future research should explore the potential advantages of programmable valves in terms of postoperative treatment and long-term neurological outcomes for pediatric patients with hydrocephalus.

2022

The proGAV and proGAV2.0 valve systems are compared in this retrospective study for revision-free survival and isolated valve revision paradigms.

Methods: In the first part of the study, the shunt and valve revision-free survival rates were investigated in a retrospective historical comparison design for a period of 2 years in which each valve was used as a standard valve (proGAV: July 2012-June 2014; proGAV2.0: January 2015-December 2016) with subsequent 30-month follow-up period, respectively. In the second part of the study, the implant duration was calculated by detecting isolated valve (valve-only) revisions together with another valve explantation during the entire period of the first study and its follow-up period.

Results: Two hundred sixty-two patients (145 male and 117 female, mean age 6.2 ± 6.1 years) were included in the cohort of revision-free survival. During the 30-month follow-up period, 41 shunt revisions, including 27 valve revisions (shunt survival rate: 72.1%, valve survival rate: 81.6%) were performed in the proGAV cohort and 37 shunt revisions, including 21 valve revisions (shunt survival rate: 74.8% and valve survival rate: 85.0%) were performed in the proGAV2.0 cohort without showing statistically significant differences. In the second part of the study, 38 cases (mean age 4.0 ± 3.9 years) met the inclusion criteria of receiving a valve-only-revision. In those patients, a total of 44 proGAV and 42 proGAV2.0 were implanted and explanted during the entire study time. In those, a significantly longer implant duration was observed for proGAV (mean valve duration 961.9 ± 650.8 days) compared to proGAV2.0 (mean length of implantation period 601.4 ± 487.8 days; $p = 0.004$).

Conclusion: The shunt and valve revision-free survival rates were found to be similar among the groups during the 30-month follow-up. In patients who received “valve only” revisions and a

subsequent explanation, the implant duration was significantly longer in the proGAV. Although the amount of patients with valve-only-revisions is small compared to the entire cohort certain patients seem to be at higher risk for repeated valve revisions [3].

The study suggests that the shunt and valve revision-free survival rates are similar between the proGAV and proGAV2.0 valve systems during the 30-month follow-up. However, it highlights that certain patients, as indicated by the “valve-only” revision subgroup, may be at a higher risk for repeated valve revisions. Importantly, the study identifies a significantly longer implant duration for the proGAV compared to the proGAV2.0 in this specific patient subgroup. The results suggest that both valve systems are generally effective, but the choice between them may depend on individual patient characteristics and the risk of repeated valve revisions. Further research with larger patient populations and longer follow-up periods, particularly in the context of “valve-only” revisions, could provide a more comprehensive understanding of the factors influencing the performance of these shunt valves. Additionally, prospective studies could help mitigate some of the limitations associated with the retrospective design.

Auricchio et al. reviewed a series of 48 hospitalized patients with severe SVS whom we managed in a 10-year period. Thirty-seven patients harboring programmable valves (P-valves) first underwent attempts at valve reprogramming. This treatment produced no effect in 21 patients, who therefore required surgical treatment. Surgery was also required by 11 patients without P-valve. Accordingly, 32 patients had to be operatively treated by shunt externalization followed by valve replacement or endoscopic third ventriculostomy based on intracranial pressure and ventricular size. The new valve was either ProGav Mietke (Aesculap) or Medos Codman (Integra), each equipped with its own antisiphon system. In selected cases, a programmable antisiphon system (ProSa Mietke) was used.

Results: Surgical mortality was 3% and major morbidity accounted for 6%. Complete resolution was obtained in 55% of cases, improvement in 32%, and no effect or worsening in 13%. Only 1 patient became shunt free after endoscopic third ventriculostomy. Medos and ProGrav provided comparable outcomes, whereas ProSa was determinant in selected cases. Pediatric age, uncomplicated shunt courses, and short SVS histories were significantly favorable indicators.

Conclusions: SVS management remains problematic. However, this study individuated factors that may improve the outcome, such as wider use of P-valves to treat hydrocephalus, timely diagnosis of overdrainage, and earlier and more aggressive indications to manage SVS [4].

2021

Clinical records and imaging of all patients fitted with proGAV®2.0 valves and Miethke fixed-pressure valves between 2014 and 2019 at our tertiary centre were analysed. Patient demographics, indication for shunt and valve insertion/revision and time to shunt/valve revision were collected. Ventricular linear metrics (fronto-occipital horn ratio (FOHR) and fronto-occipital horn width ratio (FOHWR)) were collected pre- and post-valve insertion. Microsoft Excel and SPSS v24 were used for data collection and statistical analysis.

Results: Eighty-eight proGAV®2.0 valves were inserted in a population of 77 patients (n = 45 males (58%), mean age 5.1 years (IQR: 0.4-11.0 years)). A total of 102 Miethke fixed-pressure valves were

inserted over the same time period. Median follow-up was 17.5 months (1.0-47.3). One (1.1%) proGAV®2.0 was revised due to over-drainage, compared to 2 (1.9%) fixed-pressure valves ($p > 0.05$). ProGAV®2.0 insertion resulted in a significant decrease in the mean number of revisions per patient per year (1.77 vs 0.25; $p = 0.01$). Overall shunt system survival with the proGAV®2.0 was 80.4% at 12 months, and mean time to revision was 37.1 months, compared to 31.0 months (95%CI: 25.7-36.3) and 58.3% in fixed-pressure valves ($p < 0.01$). Significant decreases were seen following proGAV®2.0 insertion in both FOHR and FOHWR, by 0.014 (95%CI: 0.006-0.023, $p = 0.002$) and 0.037 (95%CI: 0.005-0.069, $p = 0.024$) respectively.

Conclusion: The proGAV®2.0 provides effective decompression of hydrocephalic patients, significantly reduces the number of valve revisions per patient and had a significantly greater mean time to revision than fixed-pressure valves [5].

2015

The proGAV was implanted in 29 infants (11 boys and18 girls, median age 9 months) with hydrocephalus of various origins between January 2010 and June 2014. The opening pressure was chosen based on the intraventricular pressure which was measured during operation, and a gravitational unit with a fixed opening pressure (15 cm H2O) was selected.

Regular clinical follow up ranged from 6 to 36 months, with a mean follow-up time of 15.7 ± 7.9 months. Five of these patients (17.2 %) underwent shunt revision because of malfunction, including two infections (6.9 %), two shunt exposed (6.9 %), and one proximal catheter occlusion (3.4 %). For readjustment in 10 infants, the opening pressure was changed at least once during the follow-up period.

The proGAV is efficacious in the treatment of hydrocephalus in infants. This individual selection of the opening pressures makes it probable that a better match of chosen opening pressure and actual hydraulic requirements of the patient might occur [6].

2014

At the Victor Horsley Department of Neurosurgery, National Hospital for Neurology and Neurosurgery , Queen Square, London , UK the Miethke proGAV is used and commonly lowered below 5 cmH2O to gain further clinical improvement.

To determine whether lowering the opening pressure to below 5cmH2O using the proGAV valve in iNPH patients results in a) improved clinical features; and b) no significant increase in complication rates.

A retrospective case series of iNPH patients was undertaken with 24 patients who had the proGAV shunt system inserted with an initial opening pressure of 5cmH2O. Exclusion criteria were secondary NPH, shunt system other than proGAV inserted, no valve adjustment to below 5cmH2O and inadequate follow-up. Outcome measures were clinical improvement (gait, cognition and urinary continence) and complications (subdural haematoma, low-pressure symptoms and valve damage). Results. Patients underwent a total of 29 adjustments to below 5cmH2O. The mean valve opening pressure after the first adjustment was 2.5cmH2O and the mean opening pressure after the second adjustment was 1cmH2O. Overall, outcome after adjustment included 26% no change, 48%

improvement and 26% deterioration clinically. One patient (4%) suffered traumatic subdural haematoma that resolved with increasing valve pressure to 20cmH2O. There was no valve damage or low-pressure symptoms after adjustment. Conclusion. This study found that lowering the opening pressure of the proGAV shunt system to below 5cmH2O results in clinical improvement and does not significantly increase the complication rate in iNPH patients [7)].

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376 consecutive patients who received a ventriculoperitoneal shunt with a proGAV valve. The incidence of both primary CSF overdrainage and underdrainage was correlated with the implantation angle of the gravitational unit in regard to the Frankfurt plane and the patients' general parameters.

Primary overdrainage was found in 41 (10.9 %) patients. Primary underdrainage was found in 113 (30.1 %) patients. A mean deviation of 10° (±7.8) for the gravitational unit in regard to the vertical line to the Frankfurt horizontal plane was found. In 95 % of the cases the deviation was less than 25°. No significant correlation between the implantation angle and the incidence of overdrainage or underdrainage of CSF was found. The patients' age and having single hydrocephalus entities were identified as factors significantly predisposing patients to overdrainage or underdrainage.

The implantation of the gravitational unit of the proGAV valve within a range of at least 10° in regard to the vertical line to the Frankfurt horizontal plane does not seem to predispose patients to primary overdrainage or underdrainage in ventriculoperitoneal shunting. The plane may serve as a useful reference for the surgeon's orientation [8)].

Four consecutive cases were evaluated in a retrospective review who had received a proGAV adjustable, gravitational assisted DP valve with secondary in-line implantation of an adjustable shunt assistant (proSA), together with a telemetric ICP sensor (Neurovent-P-tel) between December 2010 and June 2012 in our institution. The measured ICP values and the corresponding valve adjustments were analyzed in correlation with the clinical course and the cranial imaging of the patients.

No surgery-related complications were observed after implantation of the proSA and the telemetric ICP sensor additional to the proGAV. ICP values could actively be influenced by adjustments of the respective valve units. An increase of the position depending resistance of the proSA resulted in significant attenuated negative ICP values for the standing position, while adjustments of the proGAV could be detected not only in a supine position but also in a standing position. A clinical improvement could be achieved in all cases.

The combination of adjustability in the differential pressure valve and the gravitational unit reveals a complex combination which may be difficult to adapt only according to clinical information. Telemetric ICP-guided valve adjustments seem to be a promising tool as an objective measure according to different body positions. Further investigations are needed to select the patients for these costly implants [9)].

Fifty ambulatory patients with implanted proGAV valve were investigated consecutively. Patients were asked for any noise arising from the shunt. In all cases, the valve was auscultated in sitting and upright position. The position of the gravitational unit (GU) was determined in respect to the Frankfurt horizontal plane (FHP) and in head reclination. Ten valves were perfused in vitro at different settings. One valve was opened for video documentation, and a frequency analysis of the noise was performed

in nine valves.

Eight percent (4/50) of the patients reported a noise arising from the valve only in upright position in combination with maximum head reclination, and immediately stopped when performing Vasalva's maneuver. In three out of four of these patients, the noise was also audible for the investigator (FS) with a prepared stethoscope. Patients complaining about a noise had a larger GU deviation from vertical during head reclination (median: -80 vs -43°, p = 0.0007, t-test). A deviations threshold of less than -58.4° excluding audible noise by a negative predictive value of 1 (95 % confidence interval [CI] 0.9 to 1.0). In an experimental setting, the noise came from vibrations of the ball in the cone of the adjustable unit and was restricted to a flow of at least 220 ml/h. The noise frequencies tended to be higher at higher opening pressures.

Valve-related noise development may occur in patients with proGAV valves. This event could be prevented during shunt placement by avoiding posterior tilt of the gravitational unit, especially in patients with a good cervical mobility. The noise might indicate transient peak flows and was not associated with clinical or radiological signs of overdrainage [10].

2013

A total of 52 patients were provided with a Medos-Hakim valve(Codman®) with a Miethke shunt-assistant(Aesculap®) and 111 patients with a Miethke-proGAV(Aesculap®). 180 reductions of the valve-pressure took place (65% reactive, 35% planned). Most patients (89%) needed one or two adjustments of their valve-pressures for optimal results. In 41%, an improvement of the symptoms was observed. Gait disorder was improved most often after valve-pressure adjustments (32%). 18 times an elevation of valve-pressure was necessary because of headaches, vertigo, or the development of subdural hygroma. Optimal valve-pressure for most patients was around 50 mmH2O (36%).

The goal of shunt therapy in iNPH should usually be valve-pressure settings between 30 and 70 mmH2O. Reactive adjustments of the valve-pressure are useful for therapy of over- and underdrainage symptoms. Planned reductions of the valve opening pressure are effective even if postoperative results are already satisfactory [11].

The postoperative course of 55 proGAV® and 45 programmable Codman Hakim® patients was analyzed. The latest documented valve setting of the proGAV® group and Codman Hakim® group was median 50mm H2O and 120 mm H2O, respectively. Overdrainage occurred among both groups in 20% of the patients, while surgical intervention for overdrainage-related complications was seen to be necessary only in 7% of the cases in the Codman Hakim® group. Clinical outcome differed in an increasing manner over the observation period (median 4 points after 3, 12 months and at final presentation in the proGAV®; median 4 points after 3 and 12 months and 3 points at final presentation in Codman Hakim® group (p=0.001)).

Adjustable and gravity-assisted valves like the proGAV® improve overdrainage control and enable thus low-pressure settings for the horizontal body position. Freimann et al. observed an improved and more sustainable functional outcome for iNPH patients with an adjustable and gravity-assisted valve compared to iNPH patients without an integrated siphon regulatory device [12]

In a series of 132 consecutive patients (59 girls; 73boys, 0-29 years), families, caretakers, or the patients themselves were interviewed about their experiences after using the proGAV (Miethke-Aesculap, Germany) within a CSF-diverting shunt system. Thereby, the necessity and amounts of adjustments were evaluated. The subjective experiences of the adjustment process as well as the subsequent surgical interventions were documented with a follow-up period of 25.6 ± 9 months.

In 87.9 % of the cases, clinical symptoms improved subjectively after valve implantation. A total of 103 adjustments in 69 patients were performed. In 30 % of patients, more than one readjustment was done. As subjective experience, the adjustment process was described by 85 % of patients as painless or merely uncomfortable. Symptoms improved in 91 % in connection to a new pressure setting. During the entire follow-up period, 61 % of all patients remained free of surgery.

Although a mechanical manipulation of the skin is necessary, the mechanism of the integrated adjustment unit was mostly well tolerated and allows for a noninvasive and MRI stable treatment of over- and underdrainage [13)].

During the time period of July 2004 and December 2009, a total of 237 adjustable gravitational valves were used in 203 children (age, 6.5 ± 6.54; 0-27 years). In the follow-up period, valve and shunt failures as well as rate of infection were recorded.

Within the average follow-up time of 21.9 ± 10.3 months (range, 6-72 months), the valve survival rate was 83.8 %. The overall shunt survival rate including all necessary revisions was 64.3 %. Looking at the group of infants (<1 year of age) within the cohort, the valve survival rate was 77.3 % and the shunt survival rate was 60.9 %. The overall infection rate was 4.6 %.

In a concept of avoiding chronic overdrainage by using the proGAV in hydrocephalic children, Thomale et al. observed a good rate of valve and shunt survival. Compared to previous reported series, they experienced the proGAV as a reliable tool for pediatric hydrocephalus treatment. [14)].

2010

The MR images obtained in 8 patients with proGAV were assessed for artifact areas in different planes as well as the total volume for different pulse sequences.

Artifacts induced by the Strata II valve were significantly larger than those induced by proGAV valve in spin echo MR imaging pulse sequence (29,761 vs 2450 mm(3) on T2-weighted fast spin echo, p = 0.003) and DW images (100,138 vs 38,955 mm(3), p = 0.025). Artifacts were more marked on DW MR images than on spin echo pulse sequence for both valve types.

Adjustable valve-induced artifacts can conceal brain pathology on MR images. This should influence the choice of valve implantation site and the type of valve used. The effect of artifacts on DW images should be highlighted pending the development of less MR imaging artifact-inducing adjustable shunt valves [15)]

2009

The ProGAV was implanted in 53 children (29 boys and 24 girls, median age 7.3 years) with hydrocephalus of various origins.

The mean follow-up period was 15.2 months (range 6-44 months). The authors did not observe any valve-related complications. Four infections (7.5%) occurred, warranting the removal of the shunt. In 19 children, the opening pressure was changed at least once during the follow-up period, for underdrainage in 10, overdrainage in 8, and shunt weaning in 1, with substantial clinical improvement in 18 children. Overall, good clinical results were obtained in 47 (88.7%) of the 53 valve placements.

With an overall success rate of 88.7%, the first experiences with the ProGAV in childhood hydrocephalus are promising and justify its further use in the pediatric population [16].

2006

30 patients with idiopathic normal-pressure hydrocephalus were treated surgically between June 2004 and May 2005.

Clinical outcome correlates with opening pressure level of the valve. Controlled adjustment of the valve from 100 mmH2O to 70 mmH2O, and then to 50 mmH2O after 3 months, permits optimum adaptation of the brain to the implanted valve without overdrainage complications.

Advantages of this programmable gravity valve include: 1) the absence of unintentional readjustment through external magnets, and 2) the possibility of controlling the valve setting using an accessory instrument without the need for x-ray monitoring. A significant disadvantage is adjusting the valve after implantation. From the clinical point of view, this new “proGAV(Aesculap)” valve is a necessary development in the right direction, but at the moment it is still beset with technical problems [17]. Acta Neurochir Suppl. 2006;96:368-72. PubMed PMID: 16671487.)).

2005

Sprung et al. implanted in 16 patients with promising results [18].

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