ProGav

J.Sales-Llopis

Neurosurgery Department, University General Hospital of Alicante, Spain

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The ProGav Miethke shunt is a adjustable pressure valve composed of an adjustable balloon-spring valve unit and an integrated overdrainage compensating gravitational valve known as the ShuntAssistant®

Diagrams of the Miethke proGAV® shunt adapted from with the permission of authors. A: Adjustable unit in 'closed' state. The ball-in-cone valve is closed and drainage is blocked. B: Adjustable unit in 'open' state. Differential pressure overcomes the spring force. The ball moves out of the cone and the gap opens, allowing drainage. C: Gravitational unit in vertical position. When patient is upright unit closes, increasing effective opening pressure of the valve. Drainage occurs when the differential pressure exceeds the combined opening pressures of both unit. D: Gravitational unit in horizontal position. The unit is open and the opening pressure of the valve is determined only by the adjustable unit. E: Internal adjustment mechanism of the shunt with details of profiled rotor controlling pre-load of the spring supporting ball F: The magnetic tool is used to turn the rotor. In neutral position rotor cannot move even in a presence of very strong magnetic field (up to 3T) as the brake is engaged. G: The turning is only possible when the central part of valve's casing is depressed, releasing the brake.

Mentions: The adjustable unit uses a ball-in-cone valve system. The tension of the spring holding the

ball in place can be adjusted by turning the rotor (torsion bar) using the external magnetic adjustment tool, thus changing the operating pressure. The valve has a brake system that holds the rotor in place to prevent unwanted re-adjustment when the shunt is exposed to an external magnetic field. To release the brake, a downward force (800 to 1600 gram-force) is applied to the unit using the adjustment tool (Figure 1). The valve has a diameter of 18 mm. It has a relatively large internal volume compared to other models, which is intended to minimize the risk of obstruction [1)].

ProGAV combines the advantages of an adjustable valve with unsurpassed overdrainage protection of the ShuntAssistant® valve antisiphon device.

With this combination, physiological drainage can be maintained in any body position-from supine to upright.

The in-line combination of adjustable differential pressure valves with fixed gravitational units is increasingly recommended in the literature. The spatial positioning of the gravitational unit is thereby decisive for the valve opening pressure. Proven, integrated gravitational unit provides increased resistance as the patient moves to an upright position. 0-20 cm H2O pressure range in 1 cm increments.

Enables the surgeon to provide different opening pressures for the supine and standing positions, managing overdrainage complications and patient discomfort.

Titanium housing allows the proGAV valve to be made very small, but still have large flow paths to help reduce the risk of obstruction.

Portable, hand-held instruments for quick and easy adjustments of pressure. - See more at: http://www.aesculapusa.com/products/neurosurgery/hydrocephalus-shunts/progav#sthash.oGByTPFH.dpuf

MR-compatibility

The iPhone 12 model has elicited concerns over its interaction with medical devices such as pacemakers due to its integrated MagSafe technology. Historically, programmable ventriculoperitoneal (VP) shunts have been demonstrated to readjust when exposed to magnetic objects. Yet, the presence of interactions between the iPhone 12 and shunts is unknown. In this in-vitro study, we examined the effect on the programming of three VP shunts, Medtronic Strata II, Miethke ProGAV 2.0, and Codman Hakim, when exposed to the iPhone 12 model. We found that all three valves did not re-program when the iPhone was held near or moved in a swiping or rotational motion above the valves. Therefore, the risk of re-programming of these three shunts when exposed to iPhone 12 appears to be low. However, patients should take care until further work is undertaken to examine the complex interplay between programmable VP shunts with magnetic devices [2)].

Given the potential implications for patient safety, further research in real-world clinical settings with larger sample sizes and long-term follow-up is warranted. The study raises awareness of the need to understand the complex interplay between programmable VP shunts and magnetic devices and highlights the importance of continued vigilance regarding medical device interactions with evolving technology. Until further research is conducted, patients and healthcare providers should remain cautious and vigilant when using magnetic devices around programmable VP shunts.

Three proGAV 2.0 and 3 CODMAN CERTAS® Plus programmable VP-shunt valves were tested in three steps. 1) Deflection angle tests close to the bore opening at the location of a static magnetic field gradient of 3-5 T/m. 2) Valves were fixed on a spherical phantom in 3 positions (a. lateral, b. cranial, c. cranial with 22.5° tilt anteriorly) and assessed for keeping the programmed pressure setting and re-programmability. 3) Valves were fixed on the phantom and positioned laterally in a radiofrequency head coil. MRI scans were performed for both models, including MPRAGE, GRE, and SE sequences.

Results: Deflection angles were moderate (13°, 14°, 13°) for the proGAV valves and close to critical (43°, 43°, 41°) for the CODMAN valves at the test location. Taking a scaling factor of 2-3 for the maximum spatial magnetic field gradient accessible to a patient within the magnet bore into account renders both valves MR unsafe regarding ferromagnetic attraction. The proGAV valves kept the pressure settings in all positions and were reprogrammable in positions a. and b. In position c., reprogrammability was lost. The CODMAN valves changed their pressure setting and reprogrammability was lost in all positions. MR image signal homogeneity was unaltered in the phantom center, artifacts limit the assessability of structures in close vicinity to the valves.

Both tested programmable VP-shunt valves are MR unsafe for 7T systems. Novel programming mechanisms using permanent magnets with sufficient magnetic coercivity or magnet-free mechanisms may allow the development of programmable VP-shunt valves that are conditional for 7T MR systems [3)].

In adjustable or programmable valves, the settings may be changed by external magnetic fields of intensity above 40 mT (exceptions: ProGAV, Polaris, and Certas).

The MR-compatibility of medical implants and devices becomes more and more important with the increasing number of high-field MR-scanners employed. Until the end of 2004, about twenty 3T MR in Germany will be in clinical practice. Patients with hydrocephalus need frequent follow-up MR-examinations to assure correct functioning of a shunt.

There is strong evidence for maintenance of function of the valve after exposure to 3T. This also implies the programmable valve, as long as the brake mechanism is properly adjusted during MR-examination.

Unique “Active-Lock” MR Brake prevents inadvertent pressure changes by environmental or MR magnetic fields of 3 Tesla or less [4) 5) 6) 7)].

The iPad 3 can not change the pressure settings at a distance comparable to the thickness of certain regions of the scalp. Although the specific rotational motion described may be uncommon in real life, it is nevertheless recommended that children with hydrocephalus, caregivers, educators, and therapists are informed of the now-apparent risks of close contact with this increasingly popular technology [8)].

Protocols

The components of the Birmingham standardized IIH shunt protocol are evidence-based and address the technical challenges of CSF diversion in patients with IIH. This protocol is associated with a low

revision rate, and the authors recommend standardization for CSF shunting in IIH.

The protocol comprises the following: shunt surgery by neurosurgeons with expertise in CSF disorders; a frontal VPS usually right-sided but left-sided if the left ventricle is bigger; use of the proGAV 2.0 valve with gravitational unit, set at 10 and the M.scio telemetric sensor; cannulation of the ventricle with StealthStation EM navigation system; and laparoscopic insertion of the peritoneal catheter. The authors describe the protocol rationale and evidence behind each component and present the results of a prospective analysis of revision rates.

The protocol has been implemented since 1 July 2019, and by 28 February 2022, sixty-two patients with IIH had undergone primary VPS insertion. The 30-day revision rate was 6.5%, and overall 11.3% of patients underwent revision during the study period, which compares favorably with the literature. The etiology for early failures was related to the surgical technique [9].

Determination of Programmable Shunt Setting Using CT

Programmable shunts can be adjusted to optimize CSF diversion in patients with hydrocephalus without the need for re-operation. Currently, all shunts incorporate radiopaque markers so that their setting can be determined on skull X-ray images. The purpose of this study was to evaluate whether the shunt setting could also be determined ex vivo and in vivo using the data from a standard head CT scan since one is nearly always obtained when patients with VP shunts present with new symptoms that could be due to shunt malfunction. Materials and Methods: Four commonly used programmable shunts were attached to a dried skull and scanned using a variety of CT techniques. The shunts imaged were the CertasTM Plus (Codman, Raynham, Massachusetts), Polaris® (Sophysa, Orsay, France), proGAV 2.0® (Braun, Bethlehem, Pennsylvania), and Hakim® (Codman, Raynham, Massachusetts). Each shunt was scanned at two different valve settings using multiple CT techniques: CTDIvol 75, 140kVp, 330mAs, CTDIvol60, 120kVp 390mAs, CTDIvol40, 80kVp with 430mAs, 140kVp with 215mAs. Image reconstruction with and without CT metal suppression software was used for all scans, and the data was reconstructed into volume-rendered images. We enlisted ten observers to review the volume-rendered images only. After a short set of training slides viewed by all observers, they were asked to predict the shunt setting for each valve along with their level of confidence. One clinical case of a patient with a programmable valve was evaluated on a CT scan.

Results: Using the volume-rendered images only, the two shunt settings of the Polaris shunt were correctly predicted by all the observers and in nine of 10 settings for the CertasTM Plus valve. For the Hakim® shunt and the proGAV 2.0® shunt, setting prediction accuracy was 0% and 10%, respectively. In one clinical case, the programmable valve setting could be determined from the CT scan data.

Conclusion: The valve setting of at least two currently available programmable shunts can be determined using volume-rendered images generated from CT data. Reconstructions using metal suppression software were rated as superior and may be necessary for some valve designs [10].

The study's findings suggest that the setting of certain programmable shunts can be determined using volume-rendered images generated from CT data. This non-invasive approach has the potential to reduce the need for invasive procedures and additional radiation exposure, which is beneficial for patients with hydrocephalus. However, the study's limitations, including the small observer group and variability in accuracy among different shunt models, indicate that further research is needed to

validate the method's effectiveness. Additionally, a broader clinical evaluation involving more patient cases would enhance the practical application of this technique. The consideration of metal suppression software highlights the importance of optimizing image reconstruction for different valve designs. In conclusion, the study offers a promising avenue for non-invasive shunt setting assessment, but more research is needed to confirm its reliability and clinical utility.

Case series

ProGav case series.

Test

Multiple-Choice Test

1. What is the primary purpose of the ProGav Miethke shunt?
    1. [ ] a. To measure intracranial pressure
    2. [ ] b. To drain cerebrospinal fluid
    3. [X] c. To adjust shunt settings
    4. [ ] d. To detect magnetic fields

1. How can the setting of the ProGav Miethke shunt be adjusted?
    1. [ ] a. By changing the valve's diameter
    2. [X] b. By using external magnetic adjustment
    3. [ ] c. By applying pressure to the scalp
    4. [ ] d. By adjusting the gravitational unit

1. What is the role of the brake system in the ProGav Miethke shunt?
    1. [X] a. To hold the rotor in place during MRI scans
    2. [ ] b. To prevent the shunt from draining cerebrospinal fluid
    3. [ ] c. To adjust the shunt's opening pressure
    4. [ ] d. To measure the patient's intracranial pressure

1. What is the main concern regarding the interaction between the iPhone 12 and programmable ventriculoperitoneal (VP) shunts?
    1. [X] a. Re-programming of shunt settings
    2. [ ] b. Magnetic interference with shunt function
    3. [ ] c. Risk of overdrainage
    4. [ ] d. Pressure changes in the shunt

1. How did the study find the iPhone 12's interaction with programmable VP shunts, such as the ProGav Miethke?
    1. [ ] a. The iPhone 12 caused re-programming of shunt settings
    2. [X] b. The iPhone 12 had no effect on the shunt settings
    3. [ ] c. The iPhone 12 increased the risk of overdrainage
    4. [ ] d. The iPhone 12 was not tested with VP shunts

1. What is the significance of the MRI compatibility of medical implants and devices?
    1. [ ] a. It allows for shunt settings to be determined using MRI scans.
    2. [X] b. It enables patients to undergo MRI scans without shunt interference.

3. [ ] c. It reduces the risk of re-programming shunt settings during MRI.
4. [ ] d. It makes MRI scans safer for patients with VP shunts.

1. What did the study conclude regarding the MRI safety of programmable VP shunt valves for 7T MR systems?
    1. [ ] a. Programmable shunt valves are safe for all 7T MR systems.
    2. [X] b. All programmable shunt valves are MR-unsafe for 7T systems.
    3. [ ] c. Novel programming mechanisms can make shunt valves conditional for 7T MR systems.
    4. [ ] d. The safety of programmable shunt valves for 7T MR systems needs further evaluation.

1. What is the primary purpose of the Birmingham standardized IIH shunt protocol?
    1. [ ] a. To increase the diameter of the shunt valve
    2. [ ] b. To reduce the use of adjustable shunt valves
    3. [X] c. To standardize CSF shunting in IIH patients
    4. [ ] d. To eliminate the need for VPS insertion

1. What is the primary focus of the study related to the determination of programmable shunt settings using CT scans?
    1. [ ] a. To assess the compatibility of shunt settings with CT scans
    2. [ ] b. To validate the MRI safety of programmable shunt valves
    3. [X] c. To evaluate the feasibility of determining shunt settings using CT scans
    4. [ ] d. To determine the brake mechanism of programmable shunts

1. What is the key finding of the study on programmable shunt settings and CT scans?
    1. [ ] a. The shunt settings cannot be determined using CT scans.
    2. [X] b. The shunt settings can be determined accurately using CT scans.
    3. [ ] c. The brake mechanism in programmable shunts is ineffective during CT scans.
    4. [ ] d. The MRI compatibility of programmable shunt valves is not affected by CT scans.

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