CODMAN CERTAS® Plus Programmable Valve

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- A Rare Case of Shunt Malfunction Due to the Needle Guard Coming Off During Ventriculoperitoneal Shunt Surgery
- Smartphone Magnetometers for Assessing Programmable Shunt Valve Settings: A Proof-of-Concept Study
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- Advanced Imaging of Shunt Valves in Cranial CT Scans with Photon-Counting Scanner
- Spinal magnetic resonance imaging artifacts in lumboperitoneal shunt surgery using adjustable valve implantation on the paravertebral spinal muscles
- Safety and function of programmable ventriculo-peritoneal shunt valves: An in vitro 7 Tesla magnetic resonance imaging study

Web Site

Codman Site

The Codman CertasTM is a adjustable differential pressure valve for hydrocephalus treatment

introduced into clinical practice in January 2011.

Settings

It has 8 different settings with an opening pressure varying from 36 to over 400 mm H2O at a flow rate of 20 mL/h. The 8th setting is designed to provide a “virtual off” function.

Czosnyka et al. described the initial clinical experience with the CertasTM valve and evaluate clinical usage with the main focus on the portable adjustment device - Therapeutic Management System (TMS), the “virtual off” setting and compatibility with magnetic resonance imaging (MRI).

In the laboratory the Certas valve appears to be a reliable differential-pressure programmable valve. Laboratory evaluation should be supplemented by results of a clinical audit in the future [1].

Configuration

With SiphonGuard® Anti-Siphon Device

Without SiphonGuard® Anti-Siphon Device

Interactions

The Codman CERTAS Plus electronic programmer detects the magnetic field emitted from an Apple Watch and mistakes it for the valve, rendering programming difficult. These smartwatches and similar electronic devices should be kept away from the programmer and not worn by Healthcare providers to avoid inappropriate readings and setting changes [2]

Smartphones exert reversible effects on Strata programmable valves without producing remarkable radiologic findings and irreversible effects on Codman Certas valves [3]

Tests

Chen et al. tested Three proGAV 2.0 and 3 CODMAN CERTAS® Plus programmable VP-shunt 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 reprogrammability. 3) Valves were fixed on the phantom and positioned lateral in a radiofrequency head coil. MRI scans were performed for both models, including MPRAGE, GRE and SE sequences.

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 7 Tesla magnetic resonance imaging 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 [4)]

He et al. tested: Strata NSC Adjustable Pressure Valve, Strata NSC Burr Hole Valve, Strata II small valve, Sophysa Polaris model SPV, Aesculap valve proGAV, and Codman Certas Programmable Valve. The left front edge of the iPad 3 with Smart Cover was found to have the strongest magnetic flux, measuring approximately 1,200 G and was moved linearly directly over the tested valve and then parallel to the first path at approximately 30 cm/s. Also, this area was rotated once at varying distances above the valve at approximately 1 rad/s.

Almost all shunt valves were immune to reprogramming by the iPad 3 at varying distances (including direct contact) except for the Strata II small valve, where rotating the peak flux location 4 mm above the valve changed the valve pressure settings every time.

The iPad 3 can change pressure settings of the Strata II small valve at a distance comparable to the thickness of certain regions of the scalp. Although the specific rotational motion described here 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 [5)].

Case series

Post-shunt MRI is usually performed at 1.5T under the general assumption that shunt-related susceptibility artifacts would be greater at higher field strengths.

Purpose: The purpose is to show that imaging post-shunt idiopathic normal pressure hydrocephalus (iNPH) patients at 3T is feasible and with reduced artifacts as compared to 1.5T.

Camerucci et al. manually measured transverse dimensions of artifact at the levels of lateral ventricles, cerebral aqueduct, and cerebellar hemisphere. Areas/volumes of artifacts were calculated assuming an elliptic/ellipsoid shape. Relative extent of shunt-related artifact between field strengths was rated by 3 readers on a 5-point Likert scale. A Wilcoxon Signed Rank Test was used to compare artifact at 1.5T vs 3T for each sequence, with a significance level set at $p < 0.05$.

Artifact areas were calculated in 22 iNPH patients; artifacts were on average smaller at 3T vs 1.5T on MPRAGE, DWI, and GRE sequences. On T2 FLAIR and T2 FSE, artifacts at 3T were larger than 1.5T. On the qualitative analysis, artifact effects were less at 3T vs 1.5T on DWI, greater at 3T on T2 FSE, and had mixed results on GRE.

The results indicate feasibility of post-shunt imaging with the CERTAS Plus valve at 3T based on shunt-related artifact that is less than or equal in extent to that on 1.5T on most standard clinical imaging sequences. Findings, corroborated by the qualitative image review, suggest that dedicated clinical imaging sequences for devices may allow for reduction in artifact extent at both 1.5T and 3T [6].

Patients were randomized to a Codman Certas Plus valve (Integra LifeSciences) set at 4 (open shunt group) or 8 (“virtual off”; placebo group). Patients and assessors were blinded to treatment group. The primary outcome measure was 10-m gait velocity. Secondary outcome measures included functional scales for bladder control, activities of daily living, depression, and quality of life. Immediately after 4-month evaluation, all shunts were adjusted in a blinded fashion to an active setting and followed to 12 months after shunting.

Results: A total of 18 patients were randomized. At the 4-month evaluation, gait velocity increased by 0.28 ± 0.28 m/s in the open shunt group vs 0.04 ± 0.17 m/s in the placebo group. The estimated treatment difference was 0.22 m/s ([P = .071], 95% CI -0.02 to 0.46). Overactive Bladder Short Form symptom bother questionnaire significantly improved in open shunt vs placebo (P = .007). The 4-month treatment delay did not reduce the subsequent response to active shunting, nor did it increase the adverse advents rate at 12 months.

This multicenter, randomized pilot study demonstrates the effectiveness, safety, and feasibility of a placebo-controlled trial in iNPH, and found a trend suggesting gait velocity improves more in the open shunt group than in the placebo group [7]

The valve setting of two different programmable shunts (Codman Certas Plus® and Sophysa Polaris®) were assessed by two blinded observers in 24 patients using 65 head CT scans (slice thickness ≤2 mm). Using multi-planar reconstruction (MPR) tools, images were resliced according to the direction of the valve, allowing a direct readout of the valve settings. We validated our CT based method against 32 available skull X-rays.

Results: For all CT scans it was possible to assess the valve setting. No interobserver variability was found and there was a 100 % concordance between the CT based method and skull X-rays.

Discussion: CT based assessment of programmable shunt valve settings is feasible and reliable. It may obviate the need for additional skull x-rays when a head CT scan is available.

Conclusions: This technique can reduce radiation exposure and can be applied to historical CT imaging with unknown valve settings [8].

Forty-two patients with hydrocephalus from different etiologies were treated with the CertasTM adjustable shunt system. Data regarding implantation procedures, the use of the TMS system, x-ray imaging, and MRI procedures were recorded prospectively. All patients had clinical follow-up at four weeks after implantation and every three months until a stable clinical condition was obtained.The mean time for follow-up was 8.6 months (1-16.6). Seventy-one adjustments were performed with the

TMS, 12 were problematic. Twenty-nine MRI procedures were performed and did not cause accidental resetting. Five patients were treated with the “virtual off” function for a period.

Watt et al. found the CertasTM valve valuable in the treatment of hydrocephalus, usability of the TMS was high because it is small and portable, but in some cases we experienced adjustment problems with the first procedures performed by a surgeon, indicating that there is a learning curve. The “virtual off” function provided a possibility of treating over-drainage without the need for shunt ligation or other invasive procedures [9)].

Case reports

A 50-year-old man presented with daily headaches, visual loss (right > left), and increased lumbar opening pressure consistent with IIH. A VPS was inserted using a Strata II valve with a pressure setting of 1.5, lowering ICP into the normal range. The patient initially had a normal postoperative course, but then became comatose and developed imaging signs consistent with intracranial hypotension. A Codman Certas valve was placed at a setting of 7 and a distal slit-cut peritoneal catheter was used (as opposed to standard open output). This custom system drained at pressure >26 mm Hg based on intraoperative manometry. The patient tolerated this well and is currently planned for a gradual reduction in ICP with valve setting adjustments as an outpatient.

In patients with chronic IIH, reduction to normal ICP may unexpectedly lead to encephalopathic changes. Personalized shunts may facilitate reduction of ICP to still elevated but tolerable levels in these patients [10)]

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