



Prospective Study to Evaluate Rate and Frequency of Perturbations of Implanted Programmable Hakim Codman Valve After 1.5-Tesla Magnetic Resonance Imaging

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■ **BACKGROUND:** Exposure to magnetic fields may alter the settings of programmable ventriculoperitoneal shunt valves or even cause permanent damages to these devices. There is little information about this topic, none on live patients.

■ **OBJECTIVE:** To investigate the effects of 1.5-tesla magnetic resonance imaging (MRI) on Hakim-Codman (HC) pressure programmable valves implanted in our hospital.

■ **METHODS:** A single-center prospective study to assess the rate of perturbations of HC programmable valve implanted. One hundred consecutive patients implanted for different clinical reasons between 2008 and 2012 were examined. A conventional skull x-ray before and after a standard MRI on 1.5 tesla. We evaluated before and after results, analyzed modification rate, and verified eventual damages to the implanted devices.

■ **RESULTS:** Implanted HC valves are extremely handy and durable, even if they are likely to change often due to the exposure to magnetic fields. None of the patients complained of heating effects. Oscillations range from 10–30 mm H₂O with a patient who reached 50 mm H₂O and 1 who reached 60 mm H₂O. Global alteration rate was 40%: 10 patients (10%) experienced a 10 mm H₂O change; 14 patients (14%) had a 20 mm H₂O change; 6 patients (6%) had a 30 mm H₂O change; 8 patients (8%) had a 40 mm H₂O change; 1 patient had a 50 mm H₂O change; and 1 patient had a 60 mm H₂O change.

■ **CONCLUSIONS:** HC valves presented a variable perturbation rate, with an alteration rate of 40% with 1.5-tesla

MRI. We have not observed malfunctioning hardware as a result of magnetic influence. We claim a cranial x-ray immediately after the MRI because of a high risk (40%) of decalibration, especially in patients with low ventricles compliance.

INTRODUCTION

Hydrocephalus is one of the most common neurosurgical problems in children and adults. Survival and intellectual outcome of these patients were dramatically improved with the introduction of shunt systems.¹⁻⁴

Next was the introduction of pressure-regulated valves paired within the cerebrospinal fluid (CSF) shunt systems.^{5,6} At present valve-regulated CSF shunt systems are used in the treatment of many conditions such as virtually all hydrocephalus, symptomatic intracranial cysts, pseudotumor cerebri, and hygromas.^{4,7-9}

In the past 40 years, various types of valve designs were developed and produced.

In 1973 Hakim designed a new shunt system with an adjustable valve to regulate opening pressure, suggesting that the most important factor in CSF drainage was the valve's opening pressure.⁶ This was such an innovation. Surgeons could adjust the opening pressure noninvasively according to the clinical and radiologic findings in the postoperative period, managing overdrainage and underdrainage, thus avoiding a surgical revision, decreasing the duration of the hospital stays, and improving the quality of the patient's life. As a result every patient receives a personalized treatment regimen.¹⁰⁻¹³

Key words

- Hakim-Codman programmable valve
- Hydrocephalus
- Implantable valves
- Magnetic field exposure
- Shunt susceptibility

Abbreviations and Acronyms

- CSF:** Cerebrospinal fluid
HKV: Hakim Codman valve
MRI: Magnetic resonance imaging
T: Tesla
TMS: Transcranial magnetic stimulation

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The Codman Hakim programmable valve is a double-ball valve.¹² The opening pressure is adjustable between 30 and 200 mm H₂O by raising the spring on a spiral polyethersulfone staircase with a “stepper motor” containing a magnet turned by an external electromagnetic field provided by an external programmer. A radiopaque marker reveals the opening pressure setting after implantation. If needed, the opening pressure of the valve could be adjusted by using an external programmer tool to magnetically match the shunt’s setting to the CSF flow. It is not unusual that patients might encounter magnetic fields in their daily life—magnetic resonance imaging (MRI), transcranial magnetic stimulation (TMS), or be in contact with extremely common magnetic devices and newly designed hardwares.^{14–16} Exposure to powerful magnetic fields may move the valve, alter the programmed settings, or even permanently damage the device.^{16–23}

METHODS

The Codman Hakim programmable valve has been used in our department since 2004. In this article we present data obtained from a prospective study, which considers 100 consecutive patients operated on from June 2010 to November 2012, in which we investigate the effect of 1.5 tesla (T) magnetic field exposure on implanted Codman Hakim programmable valves. None of the recent studies, however, placed special emphasis on this problem. This study estimates the changes of pressure setting in shunt-dependent patients bearer of the Hakim Codman programmable valve and undergo a 1.5-T MRI. All investigations were performed using a Philips Achieva 1.5 T MRI (Philips Medical Systems, Best, Holland) and a neurovascular 16-channel head coil. The tests were performed at room temperature (between 20° and 23°C). The effect of exposure to the magnetic field was tested, checking the pressure setting before and after MRI by a lateral skull x-ray. The imaging protocol consisted of the following sequences with specific parameters: T₁-weighted sequences, TR 596 mseconds, TE 15 mseconds, and FOV 23 mm (288 matrix); T₂-weighted Turbo spin Echo sequence, TR 4454 mseconds, TE 100 mseconds, FOV 230 mm (480 matrix); and diffusion-weighted single shot sequences with enhanced gradient mode and sense, TR 2929 mseconds, TE 62 mseconds, FOV 240 mm (288 matrix).

RESULTS

Statistical analysis

The number and rate of changes in valve before and after MRI exposure were as follows: we observed an overall rate of deregulation of 40% (40 of 100 patients); rate of deregulation was as follows: 10 patients (10%), 10 mm H₂O; 14 patients (14%), 20 mm H₂O; 6 patients (6%), 30 mm H₂O; 8 patients (8%), 40 mm H₂O. In 1 patient we observed both deregulation of 50 and 60 mm H₂O. Our results primarily demonstrated that the settings of the Hakim Codman valves were variably perturbed with a rate of deregulation of 40% by 1.5-T MRI. In 60% of the cases, valves were unperturbed. No patients complained of heating consequence and

we have not observed hardware malfunctioning after magnetic influence.

DISCUSSION

CSF shunts are widely positioned to drain CSF away from the cerebral ventricles to treat hydrocephalus (e.g., the peritoneal cavity, the right atrium of the heart or pleural space) through an elastic catheter. A valve is inserted into the catheter pathway to ensure that the CSF flows away from the brain and to control the pressure and the flow. The use of a programmable device enables noninvasive modulation of the opening pressure level and avoids the need for surgical fine-tuning. In addition, the patient can receive a personalized treatment. Most programmable valves incorporate a magnetically activated component regulated by an external programmer device to match the shunt’s setting to the CSF flow. Thus, exposure of these shunts to magnetic fields may cause inadvertent changes in valve settings.^{18,19} This can be problematic for patients subjected to a high magnetic field by a vagal nerve stimulator magnet,¹⁷ a toy magnet,^{14,20–23} or more commonly, MRI.^{16,18,19} Exposure to powerful magnetic fields may move the valve, alter the programmed settings, or even permanently damage the device.^{14,17–23} TMS (now used routinely to evaluate motor cortex excitability and motor corticospinal pathways in clinical neurophysiology laboratories) is another powerful magnetic source that can potentially interact with programmable valves. Like MRI, TMS may expose valves to an intense, focal magnetic field of up to 2 T¹⁷ by generating a powerful, focal magnetic field over cortex areas. Because patients will be exposed to them during their lifespan, we question the absolute necessity of this procedure. The risk and urgency of the procedure must be calculated. We established that is an extremely common condition that always needs an urgent confirmation. Because ventriculoperitoneal shunt hardware might be damaged under magnetic influence we tested it with a 1.5-T MRI—a far more common and diffused MRI than the 3 T. We believe that data resulting from a 1.5-T study would be more beneficial. Although in November 2011, Codman made available CERTAS PLUS, a programmable valve designed to withstand unintended pressure setting changes due to external magnetic influences, including MRI up to 3 T we support the usage of HAKIM programmable valve because of their manageability (18 options that range from 30–200 mm H₂O) and because CERTAS PLUS are contraindicated for atrium drainage and have “only 8” discrete settings including a “virtual-off.”

CONCLUSIONS

In conclusion, the 1.5-T MRI was responsible for perceptible changes in opening pressure settings and/or movement in Hakim Codman programmable hydrocephalus valves in our experiment. These results prompt us to give the following general advice: given that MRI did not damage valves, the technique is not strictly contraindicated in patients with hydrocephalus. However, caution should be applied. To ensure safety, valve settings should be checked immediately after all MRI sessions in shunted patients with hydrocephalus.²⁴

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