The Hakim programmable valve: reasons for reprogramming failures

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Object. In patients with hydrocephalus, the pressure settings of a Medos Hakim programmable valve may require adjustments even months after implantation. In some cases, however, adjustment proves to be impossible. The object of this study was to illuminate the reasons for reprogramming failures.

Methods. Data pertaining to the authors’ experience with programmable valves at their clinic were obtained through retrospective review of patient records from 1992 to 1998 and prospectively collected from 1998 to 2006. Between 1992 and 2006, 585 Medos Hakim programmable valves were implanted at the authors’ center, and reprogramming failure was observed in 12 of these 585 cases. The authors investigated and recorded the reasons for reprogramming failure. In cases in which the valves had to be explanted, the valves were returned to the manufacturer for further investigation and the results were recorded.

Results. In three of the 12 cases of reprogramming failure, the pressure settings could eventually be adjusted by placing the transmitter upside down against the flow direction. In the remaining nine cases, the valve had to be removed, yielding a rate of valve explantation of approximately 1.5% in this series. In two of these nine cases, the valve was found to be rotated longitudinally along its axis. In two cases the ratchet wheel had become loose and in one the radiopaque marker had become dislodged from the baseplate. Extensive deposits were identified macroscopically and microscopically within four explanted valves.

Conclusions. The reasons for failed reprogramming of Codman Medos Hakim valves as described in this article have not been mentioned in the literature so far. Failure of adjusting the pressure setting is a very rare event in a Medos Hakim programmable valve. The programming and adjustment mechanism appears to be very reliable. Valve replacement was required due to failed reprogramming in only a few cases. (DOI: 10.3171/JNS-07/10/0788)

Key Words • biological debris • failed programming • hydrocephalus • programmable valve

The use of a programmable valve for the treatment of hydrocephalus in children and adults is very well established.34 For more than 15 years, we have used the Medos Hakim programmable valve (Codman). In our clinical experience, the programmable Medos Hakim valves allow successful treatment of symptoms related to CSF over- and underdrainage by noninvasive adjustment of the pressure settings. This is consistent with the published literature.12 In up to 50% of cases, the opening pressure of the implanted valves has to be changed.13 Programmable valves are more expensive than nonadjustable valves. Nevertheless, Arnell et al.2 calculated a lower total cost because of a reduced revision rate, reduced hospitalization time, and improved quality of life. Zemack and Romner14 reported similar findings.

Sometimes, the settings of a Medos Hakim programmable valve may have to be adjusted even months after implantation.13 This need for adjustment may be caused by changed catheter mobility or a different pressure situation in the peritoneal cavity. The setting has also been changed by MR imaging. The rate of accidental resetting of opening pressure has been reported as 26.8% in a series of 583 patients.13 Yet in isolated cases the adjustment of pressure level has proved to be impossible.

Clinical Material and Methods

From 1992 to 2006, 585 Medos Hakim programmable valves were implanted at our hospital. During this period, reprogramming failure occurred in 12 cases according to our standardized documentation of complications within the Department of Neurosurgery. In all 12 cases, changing the pressure of the valve was required because of clinical symptoms of over- or underdrainage. In nine of these 12 cases, the reprogramming failure necessitated valve explantation. The reasons for reprogramming failure were investigated in these nine cases.

Until the end of 2005 the Codman-Medos valve programmer was used; from 2000 to 2005 we used a version with a more powerful magnet than the one we had used earlier. In the beginning of 2006, the Codman VPV system was introduced, and we have used that system consistently ever since. The VPV system does not require radiographic follow-up after successful programming.

Abbreviations used in this paper: CSF = cerebrospinal fluid; MR = magnetic resonance; VPV = valve programming verification.
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Results

Three of 12 valves could be adjusted by placing the programmer (transmitter) upside down against the flow direction. Under normal circumstances, at the beginning of the programming cycle the wheel of the valve is turned counterclockwise back to the lowest position (30 mm H2O) and then gradually turned clockwise to the desired setting. If it is not possible to reset the valve to the lowest position using this method, it may be possible to position the programmer against the flow direction—that is, rotated 180˚ from the normal position. In this position, it may be possible to turn the wheel clockwise in one motion and then gradually, stepwise, adjust it counterclockwise in the direction of the lower settings. We were able to reprogram the valve normally after applying this maneuver in three cases.

The remaining nine valves could not be adjusted by any method, not even with an MR imaging sequence (a typical T2-weighted sequence). In these cases, the reprogramming failure led to the replacement of the valves.

In two patients radiographs revealed that the valve was rotated along its longitudinal axis (Fig. 1). Attempts to reprogram the valve according to the manufacturer’s instructions failed.

In two other patients in whom efforts at reprogramming using the VPV system had repeatedly failed, loosening of the ratchet wheel was seen in standard radiographs (Fig. 2). In one additional case a radiopaque marker was found to have become dislodged from the baseplate (Fig. 3). All three valves where sent to the manufacturer for confirmation of our findings. Two of these valves had been implanted in 1997, and one in 1992. The three reprogramming failures occurred in the first half of 2006, after introduction of the VPV system. According to the manufacturer, the strength of the magnetic field of the VPV system is the same as that of the preceding programmer (Codman 82-3190). This assertion appears plausible and is supported by the finding of a broken valve housing in these three cases (Fig. 4). The most probable cause of the cam’s becoming dislodged is some form of mechanical shock. It is possible that the patients involved fell or suffered an impact, yet none of the three could remember any traumatic incidents. On the other hand, all three patients were children between the ages of 8 and 13, and a minor head trauma might have been perceived as unimportant.

In four other cases the results of radiographic evaluation of the valve performed before explantation were normal. Upon explantation, extensive deposits were visible in the valves upon macroscopic examination. The valves were subsequently checked in the manufacturer’s laboratory.

All four patients from whom these valves were removed had reasons for increased CSF protein levels. Two were infants who were born extremely prematurely and had intraventricular hematomas; the third was an elderly man who was being treated with dialysis and consequently suffered from amyloidosis; and the fourth was a young woman who had had a subarachnoid hemorrhage. The valves had been in place in these patients for 4 and 6 months, 5 years, and 4 years, respectively.

The valves were tested in the manufacturer’s laboratory for pressure performance before being disassembled for scanning with the microscope (Fig. 5). One valve failed in the pressure test. However, the reflux test gave a satisfacto-

Discussion

Some of the reasons for reprogramming failure of Codman Medos Hakim valves as described in this article have not been mentioned in the literature. Even studies of large series, including more than 500 valves each, do not refer to any technical complaints involving the valve mechanism or the valve housing. Reinprecht et al.11 mentioned an 8-year-old girl with overdrainage and blockage of the valve readjustment mechanism in the analysis of their experience using the Medos Hakim valves in 78 children. They reported removing the valve but did not report on examining it after explantation. Kurosaki et al.3 described one valve blocked for reprogramming by “fibrinoid-like tissues,” and Okazaki et al.9 mentioned a broken valve in a patient who had sustained a blow to the head.

In the case series that have been reported in the literature, the proportion of revisions that are required because of valve problems appears not to be a particular problem. There are no other reports of the rate of such complications in a large series. It is possible, however, that reprogramming failures have occurred and have remained undetected.

In all our cases of reprogramming failure, a mechanical
cause was found. There was not any hint that an MR imaging investigation or use of a magnetic tool like the programmer or the VPV system caused the damage, but such problems sometimes become obvious after exposure to a magnetic field.

Akbar and colleagues\textsuperscript{1} claimed that exposing a valve to high-field MR imaging could cause mechanical dysfunction, but all the valves described by these authors were valves that had been explanted (that is, valves that had been used and removed). The authors did not provide reasons for the explantation and did not mention anything about conditions of the patients from whom they had been removed (for example, CSF protein levels). Similarly, no reasons for reprogramming failure were given by Ortler et al.\textsuperscript{10} who reported on a valve that had been exposed to a 1.5-tesla MR imaging unit four times. It is unclear whether the valves were further examined after failure.

In a report of a small case series, Katano et al.\textsuperscript{6} claimed that the rate of revision and complication is less in Codman Hakim than in Sophy (Sophysa) programmable valves.

**Conclusions**

In our experience failure of the programming mechanism leads to explantation of the valve infrequently. In some cases of reprogramming failure the valve could be repaired using an alternative approach. Patients with explanted valves may have an increased level of protein in their CSF or may have sustained trauma to the head. The risk of reflux or pressure failure even in valves with programming problems is very low.

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