Original article

CLINICAL TRIAL OF VENTRICULOOPERITONEAL SHUNT MADE IN THAILAND

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Abstract

Objective To use ventriculoperitoneal shunt made in Thailand for treating patients with hydrocephalus.

Materials and methods Ten adult patients with symptoms and signs of increased intracranial pressure such as headache, dementia or ataxia, with radiographic imaging of the brain showing dilatation of the lateral and third ventricles, were treated by ventriculoperitoneal shunts made in Thailand, for drainage excessive cerebrospinal fluid to the peritoneal cavity. Radiographic examination of the brain was repeated in every patient after shunt insertion, with follow-up for at least six months.

Results There was no mortality or serious morbidity such as infection or intracranial hemorrhage. All patients had much improved clinical symptoms and signs, with a significant decrease in ventricular size ($p<0.01$). Two patients developed thin subdural hygroma without adverse effect and required no treatment.


Keywords: hydrocephalus, silicone tube, ventriculoperitoneal shunt

Hydrocephalus is always defined as an imbalance of cerebrospinal fluid (CSF) formation and absorption of sufficient magnitude to produce a net accumulation of fluid within the cerebral ventricles, and it usually leads to an elevation of intracranial...
pressure. The overall incidence of hydrocephalus in the general population is not known. Since the condition occurs in association with a large number of childhood and adult intracranial diseases, the incidence of hydrocephalus occurring as a single congenital disorder is given as 0.9 to 1.5 per 1,000 births, and that of hydrocephalus occurring with spina bifida and myelomeningocele varies from 1.3 to 2.9 per 1,000 births.\(^1,2\) In patients with acquired hydrocephalus, the most important etiologic factors include trauma, intracranial bleeding, meningitis, and tumors.\(^3\)

Hydrocephalus has many presentations. The disturbance of CSF dynamics may be mild or severe. The temporal course may be slowly progressive, sudden or even monophasic with symptoms and signs making a transient appearance after a brain injury, and then resolving completely. While there can be little disagreement about management of the patient with headaches, vomiting, lethargy, papilledema, and ventriculomegaly from an irreversible underlying disease process, many cases require more judgment. Generally, progressive hydrocephalus should be treated even if it is asymptomatic, and symptomatic hydrocephalus should be treated even if the symptoms are subtle or atypical. At first, hydrocephalus can be treated by getting rid of the offending pathology, such as removal of the tumor that caused obstructive hydrocephalus. Alternatively, many neurosurgeons prefer to treat hydrocephalus permanently by ventriculoperitoneal (VP) shunt insertion for diversion of the CSF pathway, from the lateral ventricle to the peritoneal cavity, where it can be absorbed at low pressure. At present the CSF shunt system is made from medical grade silicone rubber with a one-way valve that permits only unidirectional flow and the exact CSF pressure desired is controlled.\(^3\)

Maharaj Nakorn Chiang Mai Hospital has used about 140 sets of VP shunt per year (neurosurgical operative room record, 2005), with each set costing the patient about 10,000 baht. In 2007, Thailand spent about 20 billion (US) baht on medical products, materials and instruments (excepting drugs, which cost about another 30 billion (US) baht). One way to reduce imported medical products is by manufacturing these items in Thailand.

In 2002, our research group made a VP shunt at Maharaj Nakorn Chiang Mai Hospital.\(^4\) It was manufactured from 3 sizes of medical grade silicone tubing (Alliedsil, USA) and put together into a ventricular catheter, CSF reservoir and peritoneal catheter. Every part was connected to each other by medical grade silicone glue. This shunt had 2 sets of slit valves, 4 valves per set, situated at the distal end of the ventricular catheter and distal end of the peritoneal catheter (Figure 1). The results of laboratory characterization revealed that all slit valves could control closing pressure accurately at 4 to 7 mmHg, and the silicone glue averaged longitudinal pull strength at 1.44 kg (while

**Figure 1.** VP shunt system made in Thailand.
longitudinal pull strength of tying silk number 3-0 in knots was 0.84 kg). The slit valves could protect reverse fluid flow at a pressure of more than 400 mmHg. We tested these VP shunts for biocompatibility in 23 experimental dogs. All of the dogs were clinically normal and which have normal ventricular sizes. They were given hydrocephalus by injection of kaolin solution to the subarachnoid space of cisterna magna. Sixteen dogs survived the kaolin injection and these developed hydrocephalus. The hydrocephalic dogs were treated by VP shunts made in Thailand. Five dogs survived the operative VP shunt insertion, with all of them having clinical improvement to normal condition without complication for at least 6 months follow up. The repeated computerized tomographic brain scan of all these dogs showed smaller to near normal ventricles (Figure 2). After euthanasia for pathological examination, there were no abnormal foreign body reactions in the soft tissue around the VP shunts. These laboratory and animal tests verified that VP shunts made in Thailand have complete regulatory standards according to the American Society for Testing and Materials.

This research objective was to study clinical trial, from treating patients who had symptoms and/or signs of increased intracranial pressure, with findings of ventricular dilatation from radiographic imaging, by

![Figure 2](A). CT brain scan of animal trial. a) normal ventricle of a dog brain, b) ventricular dilatation after kaolin injection to the cisterna magna, c) ventricle returned to normal size after VP shunt insertion.
inserting VP shunts made in Thailand. This project was approved by the Animal Ethic Committee and Human Research Ethic Committee, Faculty of Medicine, Chiang Mai University.

Materials and methods

Research plan

1. **Population**: Ten patients from the neurosurgical unit, under supervision of our research group at Maharaj Nakorn Chiang Mai Hospital, Chiang Mai Neurological Hospital, and Khon Kaen Hospital.

2. **Inclusion criteria**: 1) Patients aged 18 to 60 years, any gender, 2) patients having symptoms and/or signs of elevated intracranial pressure, 3) patients having confirmed CSF ventricular dilation from computerized tomography (CT) and/or magnetic resonance imaging (MRI) of the brain, 4) patient who provided informed consent.

3. **Exclusion criteria**: 1) Patients failing to return for follow up for at least six months after treatment, 2) patients who denied entering the research plan.

Characteristic of the VP shunt

1. It is a unishunt.

2. It has 2 sets of slit valves, each set has 4 slit valves with an overall closing pressure of 5 mmHg.

3. The ventricular catheter is 11 cm long, with multiple open holes at the proximal closed end, and the distal closed end has slit valves at the side wall which are buried 2 cm into the reservoir.

4. The CSF reservoir is the largest sized silicone tube, at 3 cm long, for enclosing the slit valves from the ventricular catheter, and functionally checking the system.

5. The peritoneal catheter is 80 cm long, with single open hole enclosed in the reservoir and 4 slit valves at the side wall of the distal closed end.

6. The VP shunt is kept in a two-layered medical package and sterilized by ethylene oxide.

Details of the VP shunt operation

1. From the frontal horn of the lateral ventricle to the peritoneal cavity (Figure 3).

Every patient received preoperative preparation and an anesthetic schedule from our research group according to the standards of neurosurgical operative techniques. The patients lay in a supine position with their head turned to the left. Their hair was completely shaved off. Operative areas from the right coronal suture, right parietal boss, right retromastoid, right side of the neck, midsternal area and umbilicus were cleaned with soap solution and painted with povidine solution before being covered by sterile cloth. For antibiotic prophylaxis, cloxacillin at 1 gm was injected intravenously one hour before the operation and every 6 hr postoperation for 3 d. The operation was started by skin incision of the right precoronal suture, 3 cm lateral to the midline, and the pericranium to

Figure 3. VP shunt operation in clinical trial.
the skull was dissected. The skull was perforated by a 1.6 cm burr until approaching the dura mater, then the dura mater was incised to expose the cortex. A ventricular needle was stabbed past the right frontal brain tissue until it penetrated through the right frontal horn of the lateral ventricle, which was confirmed by CSF back flow. The ventricular catheter of the VP shunt was inserted along this tract at about 7 cm depth from the cerebral cortex. A hollow metal guide was used to create a subcutaneous space tract from the right coronal suture to the subxyphoid region. The shunt reservoir and peritoneal catheter passed along this tract, and the peritoneal catheter came out from 3 cm long subxyphoid skin incision. The linea alba was incised to 2 cm long to expose preperitoneal fat, which was dissected to the peritoneum. The peritoneum was opened and the peritoneal catheter inserted intraperitoneally by about 20 cm. The peritoneal incision was sutured around the catheter and all skin incisions were closed in layers. The anesthetic agents were reversed and the endotracheal tube was removed. The patients went back to the inpatient ward for 2 hr after postoperative observation. The patients could eat by mouth 24 hours postoperation, their stitches come out after 7 d postop, and then they went home.

2. From the occipital horn of the lateral ventricle to the peritoneal cavity

The preoperative, intraoperative and postoperative methods were the same as in 3.1, except that the ventricular catheter was inserted past the brain tissue at the lateral side of the right occipital area, with intention to pass the proximal end of the catheter to the right frontal horn by exceeding the foramen of Monro.

3. Our research group preferred to do VP shunt insertion on the patient’s right side of the brain, to obviate the dominant hemisphere, but there were some obstacles.

Postoperative plan

1. All patients received a repeated CT brain scan postinsertion.
2. All patients received follow up care for at least 6 months postinsertion.

Results

There were 10 patients in this study, 6 male and 4 female, aged 20 to 60 yr (Table 1). Their chief complaints were 6 with headache, 2 with ataxia, and 2 with dementia. Most patients had predisposing central neurological problems, including 3 with repeated cerebral ischemia (Figure 8,9,12), 2 with intracerebral hemorrhage (Figure 10,13) (both received craniotomy for hematoma removal at 6 mo and 1 yr, respectively), 2 with head injuries (Figure 5,7) (one patient had subdural hematoma and received craniectomy with clot removal for 3 mo, and the other had brain contusion and received craniotomy with contusion removal for 1 yr), and 1 with brain tumor (Figure 4) (receiving craniotomy for tumor removal for 2 yr), but 2 patients had no associated problems (Figure 6,11). The presenting times of symptoms and/or signs of increased intracranial pressure before an operation were about 1 to 3 months.

The first 4 patients received inserted ventricular catheters via the occipital region, and the last 6 had the same treatment via the frontal region. The ratios of the width at the same position of the frontal horn to the internal diameter of the skull inner table (FH/ID) before and after VP shunt insertion were recorded. All patients demonstrated smaller ventricles by decreasing the FH/ID ratios.
from 0.45±0.006 (0.37 to 0.57) to 0.36±0.04 (0.31 to 0.41) (except for the 5th patient, who had an increasing ratio from 0.39 to 0.40) (Figure 8). The time for repeated CT brain scan post VP shunt varied from 7 d to 3 mo, due to financial problems. Some findings from the repeated CT scan revealed that the 4th patient had proximal end of the ventricular catheter laid down in the temporal horn (Figure 7). The 6th and 8th patient (Figure 9,11) had subdural hygroma that was 8 and 10 mm thick, respectively, without signs of brain compression. (Table 1)

After VP shunt insertion, there was no mortality or morbidity. All patients had clinical improvement, especially those with headache symptoms, which were resolved clearly with no need for analgesic. Ataxia patients also improved, with one who was bed ridden being able to walk with help from assistants, and another with the use of a cane. Dementia patients partially improved according to relative observations. Every patient received follow up for at least 6 months, without showing complications.

**Discussion**

There were some CT brain scan findings that suggested hydrocephalus, such as:

1. both temporal ventricles being equal to or larger than 2 mm width (normally, temporal horns should not be seen,) with loss of

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**Figure 4.** CT brain scan of the 1st patient, A) cystic tumor at the left temporal lobe, B) hydrocephalus 2 yr after tumor removal, C) normal size ventricle 3 mo after VP shunt.
Figure 5. CT brain scan of the 2nd patient, A) posttraumatic subdural hematoma at the right cerebral hemisphere, B) hydrocephalus 3 mo postcraniectomy with brain tissue protrusion, C) normal size ventricle 2 mo after VP shunt.

Figure 6. CT brain scan of the 3rd patient, a) before VP shunt, b) 14 d after VP shunt, the ventricle is slightly decreased.
Figure 7. CT brain scan of the 4th patient, A) ventricular dilatation before VP shunt, B) at 2 mo post VP shunt, ventricular size has moderately decreased; note the ventricular catheter is in the temporal horn, C) at 12 mo post VP shunt, ventricular size has markedly decreased.

Figure 8. CT brain scan of the 5th patient, a) ventricular dilatation before VP shunt, b) same size ventricle at 1 mo postinsertion of the VP shunt.
### Table 1. Details of the clinical trial

<table>
<thead>
<tr>
<th>No.</th>
<th>Sex</th>
<th>Age (yr)</th>
<th>Chief complaint</th>
<th>Presenting time (mo)</th>
<th>Predisposing factors</th>
<th>Ventricular shunt</th>
<th>FH-ID ratio Before shunt</th>
<th>FH-ID ratio After shunt</th>
<th>Repeated CT post-shunt</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>60</td>
<td>Headache, drowsiness</td>
<td>3</td>
<td>2 yr postcraniotomy for cystic astrocytoma gr 2</td>
<td>Occipital</td>
<td>0.48</td>
<td>0.35</td>
<td>3 mo</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>20</td>
<td>Headache, brain</td>
<td>1</td>
<td>3 mo postcraniectomy for traumatic subdural hematoma</td>
<td>Occipital</td>
<td>0.57</td>
<td>0.31</td>
<td>1 mo</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>53</td>
<td>Ataxia, dementia</td>
<td>2</td>
<td>Not found</td>
<td>Occipital</td>
<td>0.42</td>
<td>0.38</td>
<td>14 d</td>
<td>Ventricular catheter in the temporal horn</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>29</td>
<td>Headache, vomiting, drowsiness</td>
<td>1</td>
<td>1 yr postcraniotomy for traumatic brain contusion</td>
<td>Occipital</td>
<td>0.47</td>
<td>0.41</td>
<td>2 mo</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>60</td>
<td>Dementia, ataxia</td>
<td>2</td>
<td>Repeated cerebral ischemia</td>
<td>Frontal</td>
<td>0.39</td>
<td>0.40</td>
<td>1 mo</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>59</td>
<td>Ataxia, dementia</td>
<td>3</td>
<td>Repeated cerebral ischemia</td>
<td>Frontal</td>
<td>0.45</td>
<td>0.33</td>
<td>2 mo</td>
<td>8 mm thick subdural hygroma at the rt frontal</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>58</td>
<td>Headache, vomiting</td>
<td>1</td>
<td>6 mo postcraniotomy of intracerebral hematoma</td>
<td>Frontal</td>
<td>0.45</td>
<td>0.39</td>
<td>9 d</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>53</td>
<td>Dementia, ataxia</td>
<td>2</td>
<td>Not found</td>
<td>Frontal</td>
<td>0.48</td>
<td>0.32</td>
<td>1 mo</td>
<td>10 mm thick Subdural hygroma at both frontal regions</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>31</td>
<td>Headache, ataxia</td>
<td>1</td>
<td>Repeated cerebral ischemia</td>
<td>Frontal</td>
<td>0.37</td>
<td>0.32</td>
<td>7 d</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>60</td>
<td>Headache, ataxia</td>
<td>1</td>
<td>1 yr postcraniotomy for intracerebral hematoma</td>
<td>Frontal</td>
<td>0.39</td>
<td>0.36</td>
<td>14 d</td>
<td></td>
</tr>
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sylvian and interhemispheric fissure and cerebral sulci. (2) FH/ID ratio of > 0.5, which is normally < 0.4, and should not be equal to 0.4 to 0.5. (3) Frontal horn dilatation (Mickey mouse sign) with third ventricular dilatation. (4) Low density area around ventricles seen from a CT scan or high intensity signal from T2W1. In MRI, signs of CSF diffusion from the ventricles to nearby cerebral tissue was seen, but these findings might be found in old patients with cerebral atrophy, leukoencephalopathies or hypertension. (5) Evan’s ratio (FH/maximal biparietal diameter) was more than 30%, and (6) MRI of the brain in the sagittal plain showed an upward curvature of corpus callosum. While Heinz advised that most reliable data were FH/ID ratios, with a normal ratio of 35%, the ventricular dilatation from cortical atrophy was between 45 to 50%. Hydrocephalus was always more than 45%, with some cases being over 55%, but this ratio must be used concurrently with

Figure 9. CT brain scan of the 6th patient, A) before VP shunt, B) 2 mo after VP shunt; note 8 mm thick subdural hygroma at the left frontal area.

Figure 10. CT brain scan of the 7th patient, A) before VP shunt, B) 9 d after VP shunt.
Figure 11. CT brain scan of the 8th patient, A) before VP shunt, B) and C) after VP shunt 2 mo and 12 mo, respectively; note 10 mm thick bifrontal subdural hygrama.

Figure 12. CT brain scan of the 9th patient, a) before VP shunt, b) 7 d after VP shunt.
other pathognomonic signs.\(^{(12)}\)

In this project, our research group paid most attention to the patients’s symptoms and signs which caused them poor quality of life until they or their relatives sought medical treatment. After VP shunt insertion, the symptoms and signs of the patients and the FH/ID ratio were used for quantitative assessment, which showed that all patients developed clinical improvement, and the FH/ID ratio significantly decreased \((p<0.01)\). Only the 5th patient had an increased FH/ID ratio from 0.39 to 0.40, but she showed improvement in her symptoms of dementia and ataxia. Since this patient had previous problems of repeated cerebral ischemia, her condition might have been caused by impairment in cerebral reexpansion ability. Therefore, even clinical symptoms could be improved from decreased pressure, when the FH/ID ratio is slightly increased.

In hydrocephalic treatment, most neurosurgeons traditionally prefer to insert a ventricular catheter through occipital, frontal, or posterior temporal positions, which are no different in producing good or poor results.\(^{(13)}\) Our research group ordinarily inserted via the occipital area, because it was easier to insert a peritoneal catheter from the occipital skull burr hole to the peritoneal cavity. For the first four patients in our project, we inserted a ventricular catheter via the occipital burr hole. From follow up with a CT scan, the ventricular catheters were in the frontal horn of the lateral ventricle in the first three patients, but the ventricular catheter of the 4th patient lay in the temporal horn of the lateral ventricles. Due to the silicone tube having more flexibility in the VP shunt made in Thailand, it has some tendency to curve down to the temporal horn during ventricular insertion, which increased the risk of catheter obstruction from the choroid plexus, or collapsed brain tissue. Nevertheless, after repeated CT scans 12 months postinsertion, the ventricle was reduced to normal size, thus revealing that the shunt system still functioned properly. To obviate this risk in the next 6 patients, we inserted a ventricular catheter via the frontal burr hole.

![Figure 13. CT brain scan of the 10th patient.](A) before VP shunt, (B) 14 d after VP shunt.)
After VP shunt insertion, CT scans showed subdural hygroma in 2 patients; the 6th patient developed an 8 mm thick subdural hygroma at the right frontal cortex, and the 8th patient developed approximately 10 mm thick subdural hygroma at both frontal regions. There were no signs of pressure effect, as seen from the CT brain scans finding in both patients, and their clinical symptoms and signs continuously improved. Subdural hygroma is normally defined as fluid collection of a clear, light yellow color, or slightly mixed with blood, in the subdural space following head injury. The mechanism for the formation of hygroma is probably a tear in the arachnoid membrane with resultant CSF leakage into the subdural compartment. Many patients present without focal findings, but some present more acutely and require more urgent treatment.\(^{(14,15)}\) Our 2 patients might develop subdural hygroma by operative injury from catheter insertion, in addition, they had some cerebral atrophy before shunt insertion, which might predispose to hygroma. Since they had no clinical problem, so there are no further treatment was necessary. All the other patients recovered well without complication after a follow up of at least 6 months.

**Conclusion**

Ventriculoperitoneal shunt made in Thailand was manufactured from low price materials, with technology up to the regulatory standards of the ASTM and Good Manufacturing Practice. It is biocompatible, functions well and has been approved by animal and clinical trials.

**Acknowledgment**

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**References**

การศึกษาทางคลินิกของท่อระบายน้ำหล่อเลี้ยงสมองผลิตในประเทศไทย

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บทคัดย่อ
วัตถุประสงค์ เพื่อทดสอบการใช้ท่อระบายน้ำหล่อเลี้ยงสมองผลิตในประเทศไทย ด้วยวิธีรักษาน้ำหล่อเลี้ยงสมองที่ผลิตในประเทศไทย ด้วยวิธีรักษาน้ำหล่อเลี้ยงสมองที่ผลิตในประเทศไทย

วิธีการศึกษา ผู้ป่วยที่มีโรคหัวใจจำนวน 10 ราย ที่มีอาการหรืออาการแสดงที่สำคัญของภาวะเด็กเกิดในประเทศไทย ได้มีอาการปวดศีรษะ หลงลืม และเดินทะเล หรือมีภาวะภาพอาการของทางวิทยาศาสตร์ที่มีการขยายใหญ่เกินขนาดปกติของห้องสมองข้างและห้องสมองท้าย สารจะได้รับการรักษาโดยใส่ท่อระบายน้ำหล่อเลี้ยงสมองผลิตในประเทศไทย เพื่อระบายน้ำหล่อเลี้ยงสมองไปสู่โพรงช่องท้าย ผู้ป่วยจะได้รับการออกภาพของอาการสำคัญologyหลักเป็นทางระบายน้ำหล่อเลี้ยงสมองผลิตในประเทศไทย

ผลการศึกษา ไม่มีการเกิดการติดเชื้อหรือโรคแทรกซ้อนจากการผ่าตัด เข้า การติดเชื้อ หรือการติดเชื้อที่ห้องสมอง ผู้ป่วยทุกคนมีการระลอกหลักชัดเจน  profundity ห้องสมองผลิตในประเทศไทย ผู้ป่วยทุกคนมีการระลอกหลักชัดเจน (p<0.01) มีผู้ป่วย 2 รายมี subdural hygroma ที่ไม่ได้เป็นเหตุให้การผ่าตัด


คำสำคัญ: hydrocephalus, silicone tube, ventriculoperitoneal shunt