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Complications of INA-Shunt® Insertion in Pediatric Patients with Hydrocephalus and its Variations

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ABSTRACT

Purpose: Hydrocephalus is characterized by an abnormal accumulation of cerebrospinal fluid (CSF), often necessitating treatment with a Ventriculoperitoneal Shunt (VP Shunt). Indonesia has introduced its own VP Shunt system, the INA-shunt. This study aims to assess complications associated with the INA Shunt system in paediatric hydrocephalus patients and identify influencing factors.

Materials and Methods: This multicentre retrospective study (January 2018 - December 2019) included 31 eligible subjects from Dr. Cipto Mangunkusumo General Hospital, Harapan Kita Hospital, and Sardjito Hospital. Complications were evaluated through clinical and radiological assessments within 1-year post-surgery.

Results: Among 31 subjects, 5 (16%) experienced complications: proximal shunt malfunction (10%, n=3), exposed shunt (3%, n=1), and infected shunt (3%, n=1). No subdural haemorrhages occurred. Most complications arose in patients ≤ 3 months old at VP shunt placement, with 80% within < 6 months post-surgery. No significant relationship emerged between subject characteristics and INA shunt pump-related complications.

Complications were observed in 5 out of 31 subjects (16%). These complications included proximal shunt malfunction (10%, n=3), exposed shunt (3%, n=1), and infected shunt (3%, n=1), with no incidents of subdural haemorrhage. All complications occurred in patients ≥ 3 months of age at the time of VP Shunt surgery, with 80% arising within 6 months post-surgery. No significant correlations were found between subject characteristics and postoperative VP shunt complications using the INA shunt pump.

Conclusion: The VP Shunt operation using the INA Shunt pump system exhibits a minimal and tolerable complication rate, supporting its use in paediatric hydrocephalus patients with various presentations.

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Introduction

Hydrocephalus is a condition of excessive accumulation of cerebrospinal fluid (CSF) caused by a process that causes an imbalance between the production and absorption of CSF. In 2017, at the Department of Neurosurgery, Faculty of Medicine Universitas Indonesia - Dr. Cipto Mangunkusumo National General Hospital, 29 VP Shunt procedures were performed, namely 27 procedures for patients with hydrocephalus and 2 procedures for patients with hydrancephaly. Management of hydrocephalus, one of which is done by transferring cerebrospinal fluid from the ventricular system to the blood circulation system or to other body cavities (pleural cavity, peritoneum) using a shunt system [1,2]. These design developments include anti-siphon equipment, on-off, gravity-related opening pressure changes, and even externally adjustable valves, some with electromagnetic programming [3,4].

Indonesia has been able to make its own pump system for VP Shunt operation under the name INA-shunt (Figure 1). INA-shunt is a pump with an antisiphon, semilunar valve system concept. This pump system with a semilunar valve has an operational hydrostatic pressure ranging from 19 – 23 mmH2O, at a flow rate of 20 cc/hour. The operating pressure of the semilunar valve pump system that has been connected to a distal catheter is between 123 – 130 mmH2O at a flow rate of 20 cc/hour (Figure 2) [5]. It is necessary to conduct further clinical trials to determine the effectiveness and complications of the production of INA-shunt devices in cases of hydrocephalus and its variants in paediatric patients.

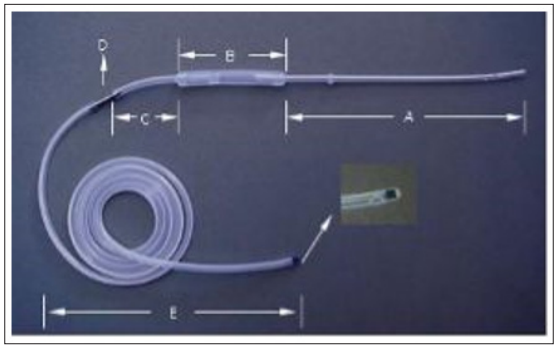

Figure 1: INA-Shunt Parts. A: Ventricle Catheter; B: Pump; C: Anti-Siphon; D: Connector; E: Peritoneal Catheter

Figure 2: INA-Shunt Product

Materials and Methods

This study is a retrospective descriptive study in patients with a diagnosis of hydrocephalus that was confirmed by history taking, physical examination, and head CT scan, which was then performed with a VP shunt operation using the INA-shunt device. This research was conducted by the Department of Neurosurgery Faculty of Medicine Universitas Indonesia - Dr. Cipto Mangunkusumo National General Hospital from January to December 2018 by taking secondary data from Dr. Cipto Mangunkusumo Hospital, Harapan Kita Hospital, and Sardjito Hospital. The affordable population in this study were all hydrocephalus sufferers under the age of 18 who underwent VP Shunt surgery by a neurosurgeon. Sampling was carried out consecutively, without randomization.

Data from patients who met the inclusion criteria were collected data through medical record searches in the form of demographic data; age, sex, head circumference, Evans ratio, aetiology of hydrocephalus, CSF protein, CSF glucose, CSF cell count and complications of VP shunt, decreased head circumference, and decreased Evan's Ratio that occurred in postoperative VP shunt patients in the first 3 months were reviewed from clinical and CT scans. Evan's ratio is the ratio of FH to the maximum biparietal diameter in the same section, a value > 0.3 indicates hydrocephalus [6].

Relative risk measurement, univariate and bivariate analysis were performed to determine the characteristics and description of the data. Bivariate analysis to determine the difference using the paired t-test and fisher test, with 95% confidence intervals and acceptable limits of significance if $p < 0.05$. Statistical test using SPSS series 21.

Results

In the period from January 2018 to December 2019, at the Dr. Cipto Mangunkusumo National General Hospital, Harapan Kita Hospital, and Sardjito Hospital, there were 31 patients that fit the inclusion and exclusion criteria. Data were collected from medical record. Of the 31 patients, patients with congenital hydrocephalus were the most common aetiology of hydrocephalus. Other causes of hydrocephalus are hydrocephalus in other congenital abnormalities of the central nervous system (meningoencephalocele posterior, meningoencephalocele anterior, spina bifida), hydrocephalus due to tumours, and hydrocephalus in history of trauma/head injury.

Demographic data and factors that influence the risk of complications after VP shunt are shown in Table 1.

Table 1: Demographic Data and Risk Factors of Complication after VP Shunt

Characteristics	N (%) Median (Min-max) Mean ± SD
Sex	
Man	20 (64.5)
Woman	11 (35.5)
Age (Months)	4 (0-186)
Pump Size	
C-medium	15 (48)
C-low	9 (30)
B-med	6 (19)
B-low	1 (3)
preOP head circumference	48 (32-95)
preOP head circumference (Category)	
>2SD	18(58.1)
0-2SD	13 (41.9)
PostOP head circumference 1 month	47 (31-92)
Decrease in LK Pre-Post OP 1 month	0.5 ((-2)-7)
Head Circumference of Post OP 3 months	46 (33-92)
Head Circumference Pre-Post OP 3 months	0 ((-6) - 8)
Evans Preoperative	0.6 (0.32-0.83)
Evans Ratio Post Operative	0.6 (0.22-0.75)
Decreasing Evans Index	-0.04 ((-0.35)-0.9)
CSF Formula	
Leukocytes	3 (0-620)
Leukocytes (Category)	
Tall	4 (12.9)
Low	27 (87.1)
CSF dominance	
PMN	4 (12.9)
MN	21 (67.7)
No Domination	6 (19.4)
Protein	32 (5-2190)
Tall	12 (38.7)
Normal	19 (61.3)
Glucose	45.71±15.42
Normal	100 (100)

Relationships between subject demographics and complications are shown in Table 2. In bivariate analysis using the chi square method, no significant difference was found between the aetiology of hydrocephalus and postoperative complications.

Table 2: Relationships between Subject Demographics and Complications

Etiology of hydrocephalus	Complications		P value
	Yes	No	
Aquaductal Stenosis	0 (0)	6 (100)	0.298
Craniosynostosis	1 (100)	0 (0)	0.258
Other Congenital Hydrocephalus	1 (11.1)	8 (88.9)	0.379
Hydrancephaly	1 (20)	4 (80)	0.583
Dandy Walker	1 (50)	1 (50)	0.456
MEP	0 (0)	1 (100)	1
ICH IVH Traumatic	0 (0)	2 (100)	1
Spina Bifida	1 (100)	0 (0)	0.258
MEA	0 (0)	1 (100)	1
Ependymoma	0 (0)	1 (100)	1

Relationship between head circumference, leukocytes, and protein with complications are shown in Table 3. In bivariate analysis using the chi square method, there was no significant difference between preoperative head circumference, leukocyte levels, and protein levels, on the incidence of postoperative complications.

Table 3: Relationship between Head Circumference, Leukocytes and Protein with Complications

		Complications		P value
		Yes	No	
Grade Head Circumference,	>2 SD	4 (22.2)	14 (77.8)	0.689
	0-2 SD	4 (30.8)	9 (69.2)	
Grade Leukocytes	High	2 (50)	2 (50)	0.268
	Normal	6 (22.2)	21 (77.8)	
Grade Protein	High	4 (33.3)	8 (66.7)	0.676
	Normal	4 (21.1)	15 (78.9)	

Head circumference analysis before and after surgery are shown in Table 4. Wilcoxon analysis was used to see if there was a significant difference in preoperative and postoperative head circumference at 1 month and 3 month. In the first month after surgery, there was a median change from 48 cm to 47 cm with a statistically significant value (0.02). in the third month after surgery, there was a median change from 48 cm to 46 cm with a statistically significant value (0.013).

Table 4: Relationship between Head Circumference, Leukocytes and Protein with Complications

	Pre Surgery (cm)	Post Surgery (cm)	P value
Head Circumference (1 Months)	48 (32-95)	47 (31-92)	0.02
Head Circumference (3 Months)	48 (32-95)	46 (33-92)	0.02

Evans Index analysis before and after surgery are shown in Table 5. Wilcoxon analysis was used to see whether there was a significant difference in the preoperative and postoperative Evan's index. There was no median change from preoperative to postoperative. However, the minimal-maximal data showed a significant change (p 0.001). This data analysis supports the pre-liminary research conducted in 2018 on the safety and effectiveness of the INA-shunt.

Table 5: Evans Index Analysis before and after Surgery

	Pre Surgery	Post Surgery	P value
Evans Index	0.6 (0.32-0.83)	0.6 (0.22-0.75)	0.001

Recapitulation of death subjects are shown in Table 6. Based on the investigation of the deceased subject, it can be concluded that in the first subject (By. RF), the subject experienced a shunt malfunction without other comorbidities, so it was thought that the subject had complications due to surgery. Meanwhile, in the second subject (By. S), it was concluded that the complications that occurred were due to the patient's poor pre-operative systemic condition, with a very large head circumference and immobilization condition,

so it was not included in the category of complications due to surgery. In the third subject (By. Ny. T), it was concluded that the death was not caused by surgery, but the presence of another congenital disease in the subject in the form of laryngomalacia which caused aspiration pneumonia. In the fourth subject (An. AJ), it was concluded that death was also not caused by surgery, but because the cerebellum tumour was getting bigger and pressing on the brain stem.

Table 6: Recapitulation of Death Subjects

No	Name	Age at surgery	Age at death	Cause of death	Complications	Remarks
1	By. RF	2 months	4 months	Aspiration pneumonia, sepsis	Proximal shunt malfunction	There are shunt complication
2	By. S	9 months	14 months	Pneumonia, pressure ulcers, sepsis	Shunt exposed	Complications occur due to the patient's poor systemic condition
3	By. Ny. T	4 months	6 months	Aspiration pneumonia, sepsis	N/A	Death unrelated to shunt
4	An. AJ	4 years 6 months	4 years 8 months	Compression brain stem ec cerebellum tumor	N/A	Death unrelated to shunt

Thus, complications that occurred in this study amounted to 5 of 31 subjects (16%). Complication-related mortality in this study was 1 of 31 subjects (3%).

Discussion

Complications of INA Shunt

The INA shunt system is an adaptation of the existing pump system. Complications of VP shunt surgery have an incidence of about 20-40% and can be broadly divided into mechanical, functional, and infective complications [7]. From the study of Merkler et al in 2018, the incidence of complications after VP Shunt was 23.8% [8]. Mechanical complications include obstruction, detachment or migration of components of the shunt system at the ventricular and peritoneal ends. Complications of infection include ventriculitis, swelling of the shunt channel, and necrosis of the skin adjacent to the shunt pathway. Other complications include subdural hematoma, ascites, pseudocyst formation, viscus perforation, or extrusion of the shunt system [9].

There are several theories regarding the occurrence of complications in the installation of a VP shunt. Obstruction in the VP shunt occurs due to the presence of high protein and cellular components in the cerebrospinal fluid so it can cause obstruction in the VP shunt. Mechanical obstruction in the proximal and distal parts can be caused by tissue accumulation in the valve so that the flow of cerebrospinal fluid is not smooth. Complications of infection occur due to many factors. However, the main factor most likely to be the cause is the contamination of the shunt system during operation. In addition, exposure to bacteria when changing bandages is also a risk factor. Disconnection of the shunt system generally occurs in sites of high mobility and is associated with patient growth. This is due to fibrosis and the strong adhesion of the catheter to the surrounding soft tissue, which prevents the displacement of the catheter which is necessary to adapt to the growing child. The incidence of subdural hematoma and craniosynostosis after VP shunt occurs due to craniocephalic disproportion. The skull is unable to reduce in size to match the size of the brain after the insertion of ventricular drains, thus forming an empty space between the skull and the brain. Craniosynostosis after VP shunt is the result of incorrect positioning of the cranial sutures and overlaps in infants after hydrocephalus treatment [9].

Research by Pan P showed the overall incidence of VP shunt complications was 35.76% [9]. Meanwhile, based on the patient data obtained, of the 31 patients who had a VP shunt with the INA shunt system, 5 patients (16%). In the study by Agarwal et al, the mortality associated with VP Shunt complications was 4.17% [10]. Meanwhile, in this study, the mortality associated with VP Shunt complications was 1 patient (35). From this, it can be seen that complications due to the use of the INA shunt system, both morbidity and mortality have a lower percentage compared to the VP shunt system and previous studies. There were 3 types of complications experienced by the patients in this study with the same percentage. These complications were proximal malfunction, exposed shunt, and infected shunt with percentages of 9%, 6%, and 3%, respectively. There were no complications such as subdural haemorrhage.

Factors Influencing Complications of using INA Shunt

Complications can occur as a result of problems with the device, in the patient, or in the surgical process [11]. The most important factor predicting the occurrence of patient-related complications was age at first VP shunt surgery (age < 2 years) and most complications occurred in the first 2 years postoperatively [10]. The predominant etiological factors responsible for early and late complications were infective and mechanical complications [9]. From the results of this study, all complications occurred in patients < 3 months of age, and 80% of complication onset occurred < 6 months postoperatively. From statistical analysis, there was no significant difference between subject demographics and complications related to INA shunt. Subject demographics included gender, age, preoperative head circumference, postoperative head circumference, preoperative Evan's ratio, and postoperative Evan's ratio. Differences in these results could be due to differences in the type of shunt system, differences in country demographics, and differences in the number of study participants.

Pal and Dubey found that the aetiology of hydrocephalus has a role in complications of VP shunt, in this case, it is emphasised that the aetiology of hydrocephalus due to infection and trauma are more likely to cause complications of VP shunt such as infection and obstruction occurred postoperatively and there was no significant difference between the two. There are several things that can explain the difference in the results obtained [12]. First, this study uses the INA shunt system which is a development of the VP shunt system so that there are possible differences in the final results. Second, there are differences in the number of samples obtained. Research conducted by Pal and Dubey, obtained 198 samples, while in this study there were 31 patients who were used as research samples. Third, the factors of demographic differences that can affect the results of the study. The research was carried out in India while this research was conducted in Indonesia. In the analysis related to preoperative head circumference, leukocyte level, and protein level, there was no significant difference in the incidence of postoperative complications [12].

Effectiveness of INA Shunt

From the results of the study, it was found that there was a change in the patient's head circumference from a median of 48 (32-95) cm preoperatively to a median of 47 (31-92) cm postoperatively 1 month. This indicates a significant reduction in head circumference (p-value = 0.02). Changes in the patient's head circumference were also seen in the preoperative and postoperative 3 months from 48(32-95) cm to 46(33-92) cm. It also showed a significant reduction in head circumference (p=0.013). Significant changes are also seen in Evan's index. However, the change in Evan's index was not seen in the median (0.6), but in the preoperative minimums (0.32-0.83) and postoperative (0.22-0.75) with a significant ratio (p=0.001). Statistical data related to the effectiveness of the INA Shunt system has never been published in national or international scientific publications before.

The advantages of this research are this study is the first study multicentre in Indonesia that examines complications of VP Shunt surgery using a pump system made in Indonesia, INA Shunt, which has been covered by the National Social Insurance System (JKN). The INA shunt pump system itself in terms of cost, is relatively cheaper than other pump systems. In this study, the research subjects were children with hydrocephalus and its variations. In addition to assessing the occurrence of complications, this study also measures the effectiveness of the INA Shunt pump system statistically.

The obstacles of this research are not all patients underwent complete data collection and examination during preoperative, during surgery, and during control, causing many samples to be excluded and not all control patients go to the postoperative hospital, this is thought to be due to poor patient compliance and constrained by the Covid-19 pandemic.

Conclusion

The INA Shunt pump system is useful for VP Shunt surgery in paediatric patients with hydrocephalus. The complication rate in paediatric patients with hydrocephalus who underwent VP Shunt surgery with an INA Shunt pump is minimal and tolerable. The complication rate related to surgery was 16%, and the complication-related mortality was 3%, which is lower than previous studies. All complications in paediatric patients with hydrocephalus who underwent VP Shunt surgery with an INA Shunt pump occurred in patients aged < 3 months and 80% of complication onset occurred < 6 months postoperatively.

Statement of Ethics

This study protocol was reviewed and approved by the Faculty of Medicine Universitas Indonesia and Dr. Cipto Mangunkusumo National General Hospital Research Ethical Committee, approval number KET-1384/UN2.F1/ETIK/PPM.00.002/2019. The Faculty of Medicine Universitas Indonesia and Dr. Cipto Mangunkusumo National General Hospital Research Ethical Committee waived the written informed consent since this study only used secondary data from medical health records.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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This research uses the authors' personal funds.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

References

1. Drake JM, Kestle J (1996) Rationale and methodology of the multicenter pediatric cerebrospinal sluid shunt design trial. The Pediatric Hydrocephalus Treatmen Evaluation Group. Child's Nervous System 12: 434-447.
2. Browd SR, Gottfried ON, Ragel BT, Kestle JRW (2006) Failure of Cerebrospinal Fluid Shunts: Part II: Overdrainage, Loculation, and Abdominal Complications. Pediatric Neurology 34: 171-176.
3. Kestle J, Drake J, Milner R, Sainte Rose C, Cinalli G, et al. (2000) Long-term follow-up data from the Shunt Design Trial. Pediatric neurosurgery 33: 230-236.
4. Limwattananon P, Kitkhuandee A (2021) Ventriculoperitoneal shunt failure in pediatric patients: an analysis of a national hospitalization database in Thailand. Journal of Neurosurgery Pediatrics 1-11.
5. Sudiharto P (2004) Surgical treatment in patient with hydrocephalus using semilunar VP shunt system.
6. Vinchon M, Rekate H, Kulkarni AV (2012) Pediatric hydrocephalus outcomes: a review. Fluids and Barriers of the CNS 9: 18.
7. Bober J, Rochlin J, Marneni S (2016) Ventriculoperitoneal Shunt Complications In Children: An Evidence-Based Approach To Emergency Department Management. Pediatric Emergency Medicine Practice 13: 1-23.
8. Merkler AE, Ch'ang J, Parker WE, Murthy SB, Kamel H (2017) The Rate of Complications after Ventriculoperitoneal Shunt Surgery. World Neurosurgery 98: 654-658.
9. Pan P (2018) Outcome Analysis of Ventriculoperitoneal Shunt Surgery in Pediatric Hydrocephalus. Journal of Pediatric Neurosciences 13: 176-181.
10. Agarwal N, Shukla RM, Agarwal D, Gupta K, Luthra R, et al. (2017) Pediatric Ventriculoperitoneal Shunts and their Complications: An Analysis. Journal of Indian Association of Pediatric Surgeons 22: 155-157.
11. Rocco CD, Turgut M, Jallo G, Martínez Lage JF (2015) Complications of CSF shunting in hydrocephalus. Prevention, identification, and management. https://link.springer.com/book/10.1007/978-3-319-09961-3.
12. Pal SS, Dubey S (2017) A study of VP shunt in management of hydrocephalus. International Surgery Journal 4: 1697-1701.