Comparison of Programmable and Non-Programmable Ventriculoperitoneal Shunts as Initial Management of Hydrocephalus, and a cost-benefit analysis: A Meta-Analysis

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DOI: 10.29322/IJSRP.15.03.2025.p15911
https://dx.doi.org/10.29322/IJSRP.15.03.2025.p15911

Paper Received Date: 16th January 2025
Paper Acceptance Date: 25th February 2025
Paper Publication Date: 6th March 2025

Abstract

Background : Hydrocephalus is a pathological type that is often found in infancy and has a significant long-term impact. Currently, efforts are being made to perform optimal management to improve the patient's prognosis.

Aims: This research aims to assess the comparison between programmable and non-programmable VP shunt as an initial treatment for hydrocephalus, along with its costs and benefits.

Methods: This research is an analytical study using systematic review and meta-analysis methods at Department of Neurosurgery, Medical Faculty, University of North Sumatra, Medan from January to April 2023. A literature search was carried out by entering keywords in search column for online literature sites, namely PubMed, British Medical Journal, and ScienceDirect refers to PRISMA chart. The statistical measures used to analyze the combined variables are odds ratio (OR) and weighted mean differences (WMD). If the p value of heterogeneity test is greater than 0.05 or I^2 is small then the analytical model used is the fixed effect model (FEM). However, if the p-value of the heterogeneity test is less than 0.05 or I^2 is large, then the analysis model used is the random effects model (REM).

Results : Four literatures were found that met all inclusion criteria, namely study by Sæhle et al. (2014), Serarslan et al. (2017), Sundstrom et al. (2018), and Rinaldo et al. (2018). Total Odds Ratio (OR) 0.14 (95% CI: 0.03; 0.73) indicates that the control group (Non-Programmable VP Shunt) has a 0.14 times higher risk of experiencing shunt revision surgery. The value of $p<0.05$, i.e. $p=0.02$ indicates that the difference probability of shunt revision operative between experimental and control group is significant. None of the journals was considered significant because the horizontal line or confidence interval completely intersects the vertical line. The value of $p> 0.05$ ($p = 0.64$) indicates that the large difference in operational costs of experimental and control group is not significant.

Conclusion : Patients with non-programmable VP shunts are more likely to undergo revision surgery and programmable VP shunts is proven to reduce operational costs.

Keywords : Hydrocephalus, Programmable, Non-Programmable, Ventriculoperitoneal Shunt

I. INTRODUCTION

Hydrocephalus is defined as an increase in cerebrospinal fluid (CSF) volume. Hydrocephalus mostly occurs in the ventricles; however, in special cases such as external hydrocephalus, fluid accumulation is seen in the subarachnoid space.[1] When a patient presents with symptoms and signs of increased intracranial pressure (ICP) and the disease state is in an active stage it is

referred to as active hydrocephalus.[2] In contrast, occult hydrocephalus is defined as ventriculomegaly in the absence of increased ICP.[3]

Functional classification and CSF flow status divides hydrocephalus into two groups: communicating and non-communicating hydrocephalus. In communicating hydrocephalus, there is ongoing flow of CSF from the lateral ventricles to the cerebral subarachnoid space (SAS) and spinal cord. Interruption of outflow from ventricles resulted in non-communicating hydrocephalus.[2,3] Blockage of CSF flow in non-communicating hydrocephalus can occur both inside and outside the ventricles. The length of time hydrocephalus develops is the basis for other classifications into acute (within days), subacute (within weeks), and chronic (within months) hydrocephalus.[4]

Every year about 3.4 per 100,000 of the adult population undergo a surgical procedure for hydrocephalus. Epidemiological data on hydrocephalus show that the highest incidence occurs in infants, neonates and children (77%) compared to adults (10%) and the elderly (13%).[5] The hydrocephalus prevalence in the world reported to be 84.7 per 100,000 population. The incidence of congenital hydrocephalus reaches 3-4 per 1,000 live births. It is reported that around 100,000 shunt implantations are performed each year in developing countries.[6]

In Indonesia, epidemiological data regarding hydrocephalus are still scarce. Recent data states that hydrocephalus incidence in Indonesia reaches 10 per 1000 live births. Infants are the age group that has the most hydrocephalus (46.25%), while neonates only reach 5%. Male is more likely to experience hydrocephalus with a ratio of 2.1:1 which is reported to occur due to genetic factors, for example the X-linked recessive gene.[1,6]

The most common procedure for treating hydrocephalus is the ventriculoperitoneal shunt (VPS), which is an attempt to create an additional CSF shunt from the ventricular system into the peritoneum. VPS prolongs survival and provides better neurological outcomes, VPS has drawbacks that can compromise the patient's quality of life.[7] Clinical research on the effectiveness of programmable VP shunts (PV), where several studies have found no significant difference in shunt failure rates between PVs compared to non-programmable VP shunts (NPV) in children. Currently, there are no definite guidelines or provisions regarding the type of shunt and best outcome in patients with hydrocephalus.[8] The analysis shows that PV is superior to NPV. But this systematic review includes several clinical studies that had too small sample size.[9] The mortality rate in patients with perioperative shunts is only 0.5%. Research reports that it is estimated that the mortality rate within 30 years after a shunting procedure reaches 5-10%.[10]

II. MATERIAL AND METHODS

This research is an analytic study using systematic review and meta-analysis methods that assess comparisons between programmable and non-programmable VP shunts as an initial treatment for hydrocephalus. This research was conducted at the Department of Neurosurgery, Medical Faculty, University of North Sumatra, Medan from January to April 2023.

- **Research Criteria**

The research inclusion criteria were all retrospective, prospective and correlation studies that compared programable and non-programmable VP shunts in patients with hydrocephalus.

Table 1. PICO Table: Research Inclusion Criteria

Patients	Male and female patients, children to adults who underwent either programmable or non-programmable VP shunt procedures for hydrocephalus as interventional therapy.
Intervention	Patients undergoing treatment for hydrocephalus with a programmable VP shunt

Comparison	Patients undergoing treatment for hydrocephalus with a non-programmable VP shunt.
Outcome	Revision of shunts and operational costs.

Exclusion criteria in this research were studies with a Jadad score below 3, studies other than randomized controlled clinical trials (Randomized Controlled Trials), animal studies, studies comparing hydrocephalus with operative/non-operative techniques other than programmable or non-programmable VP Shunt , research that has different outcomes, does not use Indonesian or English, cannot be accessed, duplicated when searching for literature, case reports, review articles, and research that has poor quality after review journal quality.

- **Research Flowchart**

Literature searches were conducted online and sourced from Pubmed, British Medical Journal and Science Direct. The search includes a variety of terms and keywords related to programmable, non-programmable VP shunts and hydrocephalus. A search strategy design was carried out for MEDLINE. The search was also carried out by looking at the bibliography of several books. The research flow refers to the PRISMA chart.

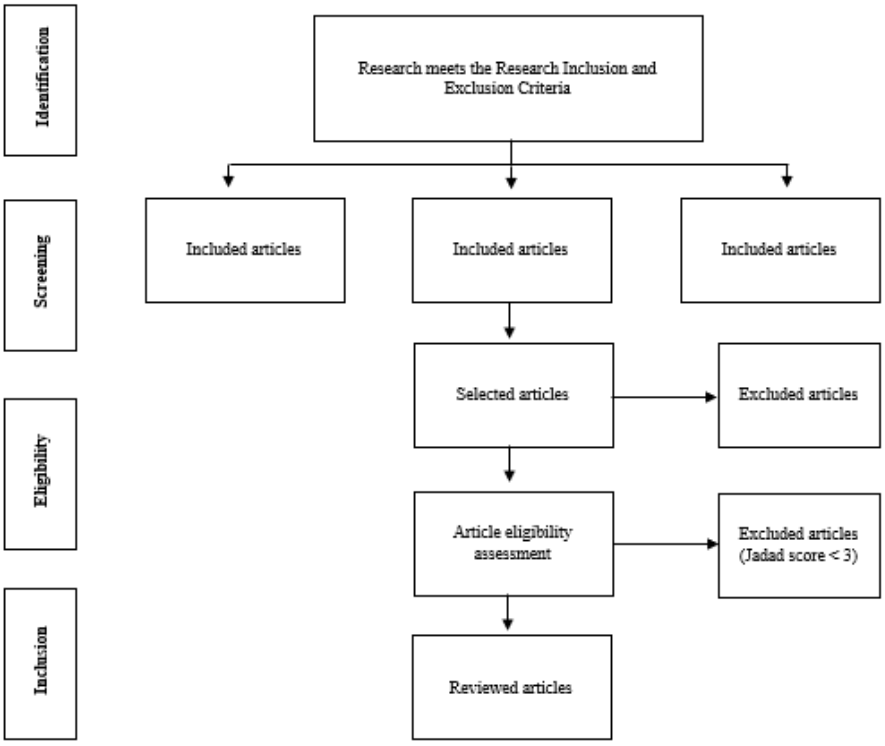

Figure 1. Research Flow according to PRISMA

- **Statistical Analysis**

The meta-analytic assessment was used with Review Manager software version 5.4 (Cochrane, Oxford, UK). The statistical measures used to analyze the combined variables are odds ratio (OR) and weighted mean differences (WMD). The confidence interval is set at 95%. Odds ratios were considered statistically significant if p value <0.05 and the confidence interval did not touch 1. The heterogeneity (I2) of the study was assessed by the Cochrane Q test.

The results of the research heterogeneity test will determine the analytical model to calculate the combined effect. If the p value of the heterogeneity test is greater than 0.05 or I^2 is small then the analytical model used is fixed effect model (FEM). However, if the p-value of the heterogeneity test is less than 0.05 or I^2 is large then the analysis model used is random effects model (REM). The overall research hypothesis was measured by the Z test and sensitivity analysis was used to test statistical heterogeneity.

III. Results

A literature search was carried out by entering keywords in the search field for online literature sites, namely PubMed, British Medical Journal, and ScienceDirect. When a search was carried out using the filtering feature for research article types with a range of years from 2013 to 2023. From the results of a literature search, there were 219 journals with details, eight journals were from PubMed, nine journals were from the British Medical Journal, and 202 journals were from ScienceDirect. Next, as many as 200 literatures were excluded because, 199 did not have appropriate titles and one literature experienced duplication. Of the 19 literatures assessed for abstract, 15 literatures were excluded, of which one literature could not be accessed, nine literatures did not have appropriate study criteria, and five literatures used inappropriate research designs. Furthermore, there are four literatures that are assessed in more detail. Of the four literatures, the four literatures fulfill high-quality research criteria. Finally there was a total of four literatures that met all inclusion criteria. The results of a more complete literature search can be seen in Figure 2.

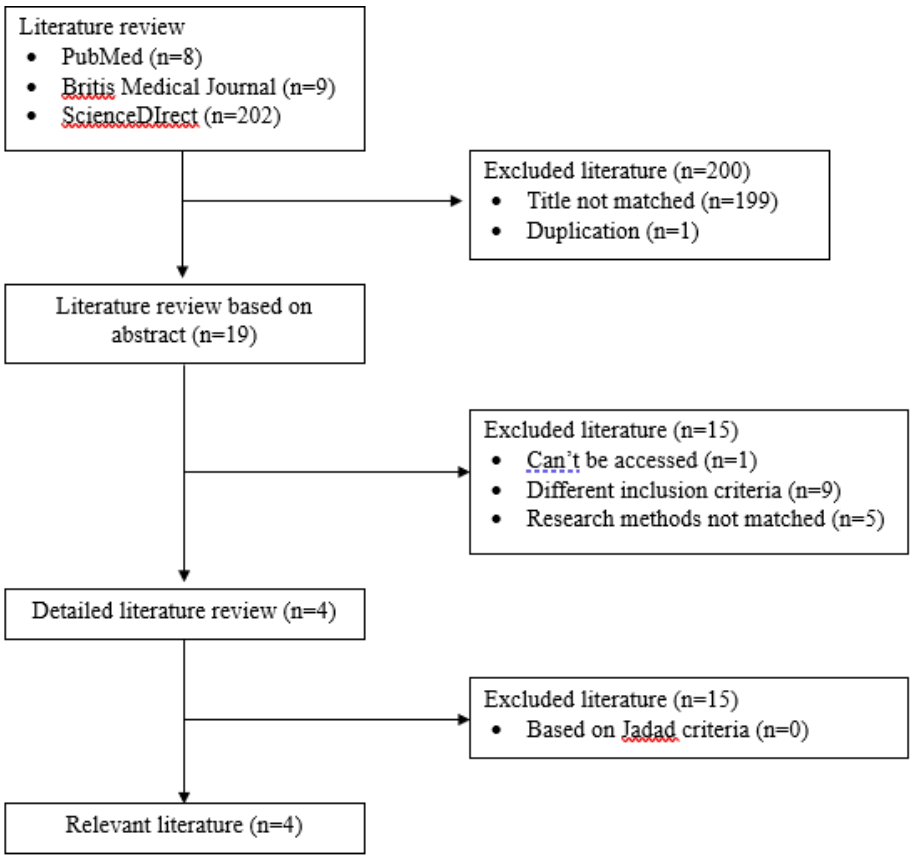

Figure 2. Literature Search

There are four literatures that report shunt revision as the variable studied. Based on research by Sæhle et al. (2014), Serarslan et al. (2017), Sundstrom et al. (2018), and Rinaldo et al. (2018), patients who use non-programmable VP shunts are more likely to get revision surgery as a revised shunt that has been used. This can be proven from the results of the forest plot which shows estimate point of confidence interval lines from four journals studied are in the experimental group. This result means that the experimental group is less likely to get revision surgery than the control group.

Research by Sæhle et al. (2014) showed that the control group had a tendency of 2.9% to experience a shunt revision compared to the control group which was 0%. One case in this study that required surgery was caused by obstruction of the proximal valve. In Serarslan et al. (2017) study showed that the control group had a 32.5% tendency to experience side effects compared to the control group which was 0%. Based on research by Serarslan et al. (2017), 29 of total patients using the non-programmable VP shunt had to undergo repeat surgery. As many as 18 patients who underwent repeat surgery also applied device replacement with a

programmable vp shunt due to various complications, such as effusion or subdural hematoma in these patients. In addition, 11 other patients who underwent repeat surgery did not applied device replacement due to infection and dysfunction of the shunt.

In direct comparison with two previous studies, Sundström et al. (2018) study showed that the control group had a tendency of 89.5% to experience repeat surgery, while the experimental group only had 29.7%. In this study, it was reported that the most frequent cause of repeat surgery was due to subdural bleeding and was generally performed in patients who had previously used a non-programmable VP shunt. Research conducted by Rinaldo et al. (2018) showed that the control group had a tendency of 24% to experience a shunt revision compared to the control group which was 13.2%. This causes diamond analysis (mean difference) results in the forest plot not to touch the vertical line indicating that the difference between the two groups is significant.

Table 2. Study Characteristics

Journal	Years	Location	Total Patient
Sæhle et al.[11]			
Experimental	2014	Oslo, Norwegia	34
Control			34
Serarslan et al.[12]			
Experimental	2017	Istanbul, Turki	30
Control			80
Sundström et al.[13]			
Experimental	2018	Umea, Swedia	165
Control			19
Rinaldo et al.[14]			
Experimental	2019	Minnesota, USA	98
Control			250

Table 3. Shunt Revision

Journal	Programmable		Non-Programmable	
	Incidence	Percentage	Incidence	Percentage
Sæhle et al.	0/34	0%	1/34	2,9%
Serarslan et al.	0/30	0%	29/80	36,2%
Sundström et al.	49/165	29,7%	17/19	89,5%
Rinaldo et al.	13/98	13,2%	60/250	24%

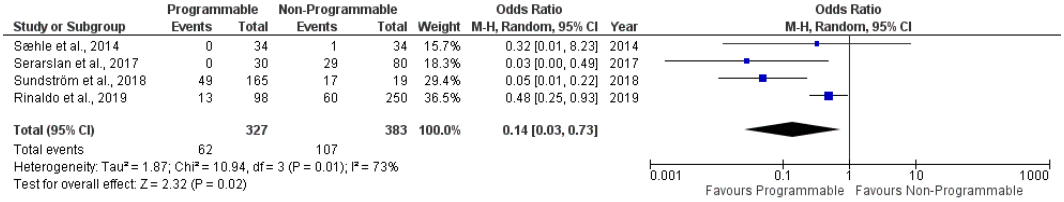

Figure 3. Forest Plot Shunt Revision

The shunt revision surgery was first outcome of this research using total four journals included in the meta-analysis. The forest plot analysis results show that I^2 value is more than 50% (I2=73%), which means that the data is heterogeneous, so a random effect model is used. It was found that three journals out of four journals were considered significant because the horizontal line or confidence interval did not cross the vertical line. Total Odds Ratio (OR) 0.14 (95% CI: 0.03; 0.73) indicates that the control group (Non-Programmable VP Shunt) has a 0.14 times higher risk of experiencing shunt revision surgery. The value of $p<0.05$, i.e. $p=0.02$ indicates that the possibility difference of shunt revision surgery between the experimental group and the control group is significant.

Table 4. Operational Costs

Journal	Programmable			Non-Programmable		
	Mean	SD	Patient	Mean	SD	Patient
Serarslan et al.	1,511	86.162.6	30	1,402.44	722.557	80
Rinaldo et al.	24,396.90	9,134.87	98	24,282.50	13,082.80	250

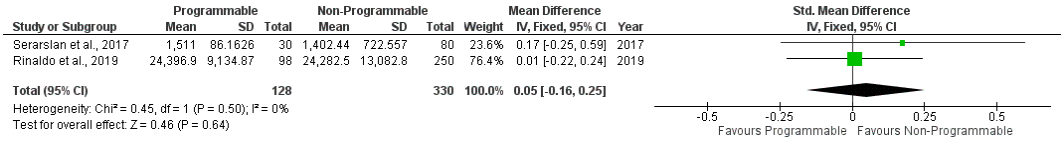

Figure 4. Forest Plot of Operational Costs

Total operational costs is the second outcome of this research using two of four journals included in the meta-analysis. The forest plot analysis results show that I^2 value is less than 50% (I2 = 0%), which means that data is homogeneous, so the fixed effect model is used. None of the journals are considered significant because the horizontal line or the confidence interval entirely intersects the vertical line. The value of p> 0.05 (p = 0.64) indicates that the large operational costs difference of experimental and control group is not significant.

There are two of four journals that report operational costs as the variable studied. Based on the discussion in the two journals, programmable VP shunts is proven to reduce operational costs compared to non-programmable VP shunts, which is supported by forest plot results which shows that the estimate point of confidence interval lines from journal under study is in the control group. This can be interpreted that the amount of surgery costs is smaller than in experimental group compared to control group.

According to research conducted by Serarslan et al. (2017) regarding operational costs, there is a greater amount of expenditure in control group than experimental group, although it is not statistically significant. In this research it was said that using a programmable VP shunt required an additional fee about 600 USD compared to a non-programmable VP shunt. However, the use of a non-programmable VP shunt has possibility additional expenses due to complications or after-effects from surgery compared to using programmable VP shunt. This causes the difference in magnitude of the operational costs between two categories is not too much different. Rinaldo et al. (2018) explained that there was no significant difference in the amount of operational expenses incurred between each group (p = 0.937). In this research, the average operating costs incurred for programmable VP shunt patients were around 24,396.90 USD, while for non-programmable VP shunt patients it was around 24,282.50 USD. This causes the results of diamond analysis (mean difference) in the forest plot touch the vertical line which indicates that the difference in operational costs between two groups is not significant.

IV. DISCUSSIONS

Research conducted on revision revised shunt variable found a significant relationship (p value = 0.02) between type of shunt used and risk of shunt revision surgery. Patients who have installed non-programmable VP shunt have a greater likelihood of having a revision o shunt in the future than patients who installed programmable VP shunt. The results of this variable research have the same results based on previous research conducted by Katiyar et al. (2021) used a meta-analysis method for two studies that were collected. Katiya et al. (2021) wrote that there was a significant difference between the experimental group and the control group from most of the journals included in the study in terms of repeat surgery possibility. According to Katiyar et al. (2021), using programmable VP shunt has been shown to reduce the possibility of repeat surgery or what is termed a shunt revision compared to using non-programmable VP shunt. In the research of Katiyar et al. (2021) also found that using programmable VP shunt can reduce the morbidity associated with additional surgical procedures such of shunt revision or evacuation of the subdural collection at the same time..[15]

The research successfully showed that group using Non-Programmable VP Shunt had a 0.14 times higher risk of experiencing shunt revision surgery. This is due to differences in shunt device specifications between programmable and non-programmable ventriculoperitoneal shunt. Based on existing theory, a programmable ventriculoperitoneal shunt is a type of shunt that has an externally adjustable magnetic valve that can change the opening pressure (valve setting) to regulate the outflow of cerebrospinal fluid. Maximum resistance adjustment in a programmable ventriculoperitoneal shunt can be used for chemotherapy

or radioimmunotherapy. The integrated reservoir also provides an easy source of diagnostic cerebrospinal fluid sampling, eliminating the need for invasive changes. This shows that using programmable VP shunts is better and easier to adjust externally without need for invasive measures to regulate the process.[16]

The theory of shunt revision surgery is usually triggered by several things that cause complications of damage VP shunt used, such as infection, obstruction, malfunction t, or other further complications (shunt fracture, meningeal fibrosis, to pneumocephalus). Shunt problems most often occurs due to shunt system contamination due to poor sterility, lack of operator skills, poor surgical materials, or too long operating periods. A rare type of shunt infection is meningitis. Meningitis can cause contamination of proximal catheter and peritonitis due to contamination of the distal catheter. Advanced stages shunt infection is rare and usually caused by distal catheter contamination of intestinal flora. Signs and symptoms of infection in this shunt include a local inflammatory reaction with signs of inflammation Classic symptoms include swelling, burning, redness and loss of shunt function. Patients who develop shunt infection also complain of lethargy, nausea, vomiting and fever.[17]

Shunt obstruction is one of common complications that causes need for shunt revision surgery. Obstruction can occur at several locations in the shunt. Regardless of obstruction location, obstruction usually presents with signs and symptoms related to increased intracranial pressure such as headache, vomiting, and fainting. The signs and symptoms that appear are one of indications for shunt revision. Complications of shunt malposition are rare with shunt insertion and usually occur with a proximal or distal catheter. Most cases involve a position change of shunt at several locations, such as scrotum, abdomen, chest wall, bladder, and colon. But this complication requires immediate shunt revision surgery to avoid further impact on patient due to shunt malposition.[17]

Research on operational cost variables showed that there was no significant relationship (p value = 0.64) between type of shunt and amount of operational costs incurred by patients. Although one of the journals studied has a large difference in operational expenses incurred amount between using programmable VP shunts and non-programmable VP shunts, this value is not strong enough to show a significant difference. In line with this research results, a meta-analytic study conducted by Katiyar et al. (2021) obtained similar results. Katiyar et al. (2021) didn't found significant difference in operational costs based on the journals included in this study.[15]

In addition, research conducted by Katiyar et al. (2021) state that even though associated with higher initial costs, programmable VP shunts do not increase long term health care costs, so they do not affect the total operational expenses. This is in accordance with amount of expenditure required during shunt maintenance and control period with non-programmable VP shunt type which causes the total operational costs incurred to be greater than programmable VP shunt. In addition, other factors such complications that can arise over time caused by ventriculoperitoneal shunt also affect the total costs that must be incurred. Although possibility of shunt revision is also smaller in patients using a programmable ventriculoperitoneal shunt compared non-programmable ventriculoperitoneal shunt, it does not result in a lower total cost. Although the results of this research are broadly in line with other studies results and existing theories, further research and trials with larger sample sizes are needed to confirm these findings because information currently obtained is still insufficient to reach decisions and firm conclusions.[15]

CONCLUSION

Patients with non-programmable VP shunts are more likely to undergo revision surgery to revised shunt that has been used. Programmable VP shunt is proven to reduce operational costs compared to non-programmable VP shunt.

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