THE SAHLGRENSKA ACADEMY

Do new routines decrease complications after treatment of hydrocephalus in children?

Degree Project in Medicine

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Table of contents

Abstract

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BACKGROUND: A study from 2010 showed that hydrocephalic children undergoing shunt surgery or endoscopic third ventriculostomy (ETV) in 2001-2005 at Sahlgrenska University Hospital suffered a high rate of failure of treatment, especially due to infection. Other studies have reported a significant decrease in infection after implementing a shunt protocol, therefore we introduced specific routines in 2012 for ETV/shunt surgery. AIM: This study aimed to evaluate the effect of the new protocol on shunt and ETV failure rate. Another aim was to identify risk factors for failure of treatment and failure of treatment due to infection. METHODS: A search in patient charts was done to include 59 children subject to their first shunt/ETV surgery in 2012-2016. Patients were followed until reaching failure of the hydrocephalus treatment or until 1st Jan 2017. Statistical analysis was used to compare failure rate of the patient population of this study to the population of 2001-2005. Risk factor analysis was carried out through Cox regression. RESULTS: Total failure in shunts decreased from 58% to 36% (p=0.019). Failure due to infection in shunts decreased from 17% to 9% (p=0.180). In shunts, Cox regression did not prove any factors to increase risk of failure of treatment, or risk of failure due to infection. CONCLUSIONS: This study suggest that implementation of a shunt protocol is an effective way to reduce failure of treatment.

KEYWORDS: children, failure, hydrocephalus, infection, protocol

Background

Hydrocephalus is a condition where cerebrospinal fluid (CSF) excessively accumulates in the ventricles of the brain. This leads to a buildup in pressure and an expansion of the ventricles, potentially harming the brain tissue and causing impairments of function. Both children and adults are subject to getting the disorder, though more common in the former, where it is estimated to occur in 0.8 per 1000 live births [1]. Pediatric hydrocephalus can be either congenital or acquired and has several different causes, all of them leading to an imbalance between the production of CSF and the absorption into the blood stream. Common etiologies are tumor, intraventricular hemorrhage (IVH), aqueductal stenosis (AS), CNS infection, myelomeningocele and cysts. The treatment of hydrocephalus consists of one of the two possible surgical procedures, either the insertion of a shunt or the performance of an endoscopic third ventriculostomy (ETV) [2]. Shunt insertion means diverting CSF from the brain's ventricles to some other part of the body, either to the peritoneal cavity with a ventriculoperitoneal shunt (VPS) or to the atrium of the heart with a ventriculoatrial shunt (VAS). ETV means creating an opening in the floor of the third ventricle, between the ventricle and the subarachnoid cisterns, often to bypass an obstruction of some sort. These two ways to manage hydrocephalus are both associated with a high rate of complication resulting in the patient requiring new surgery and thereby the failure of the primary treatment [3]. The complications leading up to failure of the treatment are slightly different for shunts and ETVs, however both can suffer from infections involving the operation wound or the CNS. In shunts, complication of mechanical dysfunction can occur, caused by an obstruction or overdrainage/underdrainage. In ETVs, complication of insufficient function can occur, due to closure of the stoma or insufficient absorption of CSF [4].

In 2010, our team published a study regarding children undergoing surgical treatment for hydrocephalus in our facilities between 2001-2005. Those patients suffered a relatively high

rate of failure, especially due to infection [5]. Other studies had reported a significant decrease in infection after implementing a shunt protocol [6, 7]. Therefore in 2012 a protocol with specific routines was introduced for shunt and ETV surgery in our facilities, intending to decrease infections, thereby decreasing total failure of treatment.

This study looked at a population of hydrocephalic children in south-western Sweden in 2012-2016 to investigate the rate of failure of treatment for shunts and ETVs. Results were compared to our team's study of 2010, i.e. prior to protocol introduction.

Aim

The aim of this study was to evaluate the effect of the new protocol on shunt and ETV failure rate. Failure of treatment due to infection was hypothesized to decrease after protocol implementation while the failures due to mechanical dysfunction or insufficient function were expected to remain unaltered. Another aim was to identify risk factors for failure of treatment and failure of treatment due to infection.

Material and Methods

This retrospective study was conducted in Sahlgrenska University Hospital, Gothenburg, using the hospital's electronic patient charts for surgeries where all operations are logged. This hospital takes care of all shunt insertions and ETVs in south-western Sweden, a general population of about 2 million people. A broad search was done for surgeries performed between 2012 and 2016 using the procedure codes for VPS insertion (AAF05), VAS insertion (AAF15) and ETV performance (AAF00). The found patients were investigated to exclude the ones having received any of the aforementioned procedures before 2012, i.e. before the implementation of the protocol. Thereby the only patients included were the ones who underwent their first shunt or ETV surgery in 2012 to 2016. Only children aged 0-18 years at the time of first procedure were included. The implemented surgery protocol included rules

concerning personnel passing in/out of the operation room, more strict use of prophylactic antibiotics, surgery staff wearing head cap, surgeon using double gloves, etc. (fully specified in appendix 1.). The included patients were investigated for data collection regarding gender, age, etiology of hydrocephalus (tumor, malformation, IVH, aqueductal stenosis, CNS infection, myelomeningocele, cyst, other), total time of follow up until 1st Jan 2017 and if death occurred during study. Surgical data for the primary surgery was collected for type of procedure (shunt or ETV), if shunt was antibiotic-impregnated, time of day of surgery (morning = 8 am-12 noon, afternoon = 12 noon-6 pm, evening = 6 pm-10 pm, night = 10 pm-8 am), duration of surgery, emergency procedure (surgery within 24 h of presentation of clinical symptoms), department where surgery was performed (department of pediatric surgery or department of neurosurgery), any concomitant procedure performed during surgery and type of shunt valve used; Codman (Johnson and Johnson, New Brunswick, New Jersey, USA), Delta (Medtronic, Fridley, Minnesota, USA) or Strata (also Medtronic). CSF leakage occurring after surgery was noted. If the primary surgery was performed within a year from the patient's birth date it was also noted if the patient was born preterm (<35 6/7 weeks of gestation).

Patients were followed until reaching the defined endpoint of this study, being the failure of the hydrocephalus treatment. This meaning that the primary surgery of shunt insertion or ETV surgery required reoperation because of mechanical dysfunction, insufficient function or infection of either CNS or operation wound. The reoperation either consisted of shunt revision, removal of the shunt, shunt insertion or ETV. Patients experiencing failure were collected for data including time until failure from primary surgery, reason of failure (mechanical dysfunction, insufficient function or infection of operation wound/CNS), location of obstruction causing mechanical dysfunction of a shunt (ventricle catheter, shunt valve, distal catheter, unknown). The treatment failures were evaluated and graded based on their

severity; minor (residual symptoms resolving in less than a week), medium (residual symptoms resolving in less than three months), serious (residual symptoms for more than 3 months, with mild sequelae), catastrophic (persistent residual symptoms and serious sequelae or death).

Patients that did not experience a failure of treatment were followed until 1st January 2017, allowing a follow up period of at least 1 year after the primary surgical procedure.

Statistical methods

Descriptive statistics were computed using either Microsoft Excel 2013 or SPSS version 24 (IBM, Armonk, New York, USA). To compare data regarding failure, patient data and data concerning surgery, statistical tests were executed in SPSS version 24. The used methods were Student's t-test, Welch's t-test, Mann-Whitney U test, Pearson's chi-squared test and Fisher's exact test, where the choice of test depended on the type of analyzed data, distribution of the data and the sample size. Comparisons were made to our team's previous study covering surgeries in 2001-2005. Kaplan-Meier survival analysis of different treatments was carried out in SPSS. Risk factors for failure of treatment were investigated in SPSS by constructing several univariate Cox regression models. A separate univariate Cox regression model for failure due to infection was also fitted. 95% CI and p-value<0.05 was considered statistically significant.

Ethics

Since patient data, although coded, was used and analyzed without seeking patient consent, an ethical permit was obtained from the regional ethical board of Gothenburg (appendix 2.).

Results

Fifty-nine patients were included in this study, 12 with an ETV and 47 with a shunt. The group of 47 shunts included 44 VPSs and 4 VASs. Of the 59 patients, 24 (41%) were female and 35 (59%) were men. The median age at surgery was 0.4 and 6.9 years for the population of shunt and of ETVs respectively (table 1.). The shunt and ETV population both had a 2.3 year mean of follow up time (table 1.).

Table 1. Descriptive statistics for patient age at primary surgery and follow up time of included patients. Patients either treated with ventriculoperitoneal shunt (VPS), ventriculoatrial shunt (VAS) or endoscopic third ventriculostomy (ETV).

	Patient age at primary surgery (years)		**Follow up time (years)**	
	Shunts (VPS+VAS)	ETVs	Shunts (VPS+VAS)	ETVs
Minimum	0	0.1	1.1	1.1
1st quartile	0.3	1	1.5	1.7
Mean	1.7	7.1	2.3	2.3
Median	0.4	6.9	2.3	2.2
3rd quartile	1.6	13.2	3.3	3.0
Maximum	11.1	16.2	3.9	3.8

The most common etiology of hydrocephalus was IVH for shunts (30%) and Tumor for ETVs (67%). The category “Other” included perinatal infection with fever (n=2), pseudotumor cerebri (n=1), myotonic dystrophy (n=1), septo-optic dysplasia (n=1), trisomy 9 (n=1), congenital (n=1), membrane formation in the posterior cranial fossa (n=1), unknown (n=1). The full distribution of hydrocephalus etiologies is shown in figure 1, together with shunt/ETV frequency.

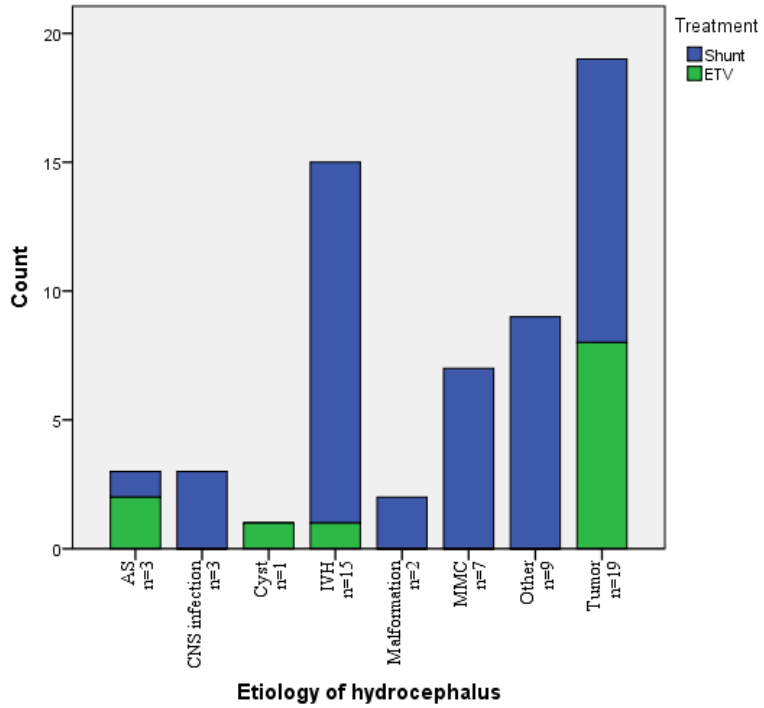

Figure 1. Bar graph showing frequency of hydrocephalus etiologies and treatments. Treatments including shunts and endoscopic third ventriculostomy (ETV). Hydrocephalus etiologies including aqueductal stenosis (AS), CNS infection, cyst, intraventricular hemorrhage (IVH), malformation, myelomeningocele (MMC), other, tumor.

7 deaths occurred during the study where 5 of the deceased patients had hydrocephalus caused by tumor. Of the 59 primary surgeries, 9 (15%) had a concomitant procedure, including biopsy, ventriculoscopy, fenestration of cyst, neuroendoscopic septostomy, coagulation of choroid plexus, patching of CSF leakage from previous operation wound, or a combination of the above. Of the 47 shunt valves, Strata accounted for 96%, i.e. 45 in absolute numbers, whereas 2 Delta and no Codman were used. 2 (4%) shunts were antibiotic-impregnated. Seventy-five percent of the ETV procedures took place in the department of neurosurgery and 25% in the department of pediatric surgery. Of the shunt surgeries 15% were performed in the neurosurgery dept. and 85% in the dept. of pediatric surgery.

The distribution of failure of treatment for shunts and ETVs is shown in figure 2.

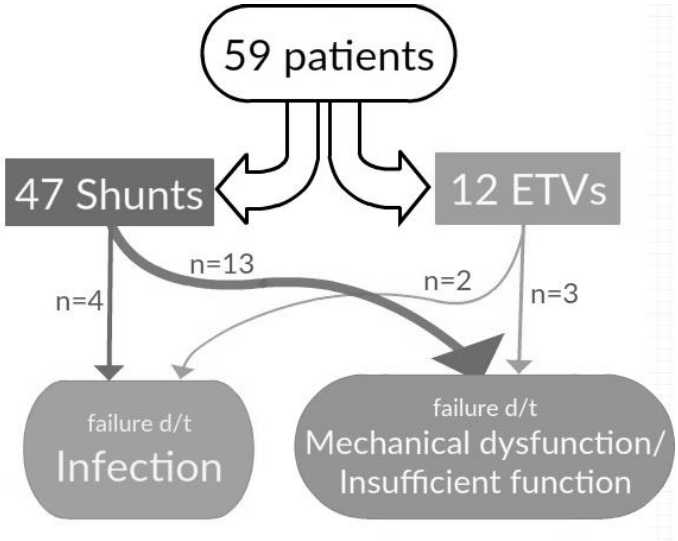

Figure 2. Distribution of treatments and subsequent types of failure with frequency shown in absolute numbers. Hydrocephalic patients treated with either shunt or endoscopic third ventriculostomy (ETV).

Of the 47 shunts, 15 (32%) were affected of complications graded as minor and 2 (4%) as medium. In the 12 ETVs, 4 (33%) complications were minor and 1 (8%) was serious. The location of the obstruction of shunts, causing failure due to mechanical dysfunction was distributed as follows: ventricle catheter (n=8), shunt valve (n=1), distal catheter (n=1), unknown (n=3).

The survival of shunts and ETVs is visualized in the Kaplan-Meier analysis, in figure 3. The corresponding analysis from our previous study of 2010 is found in figure 4.

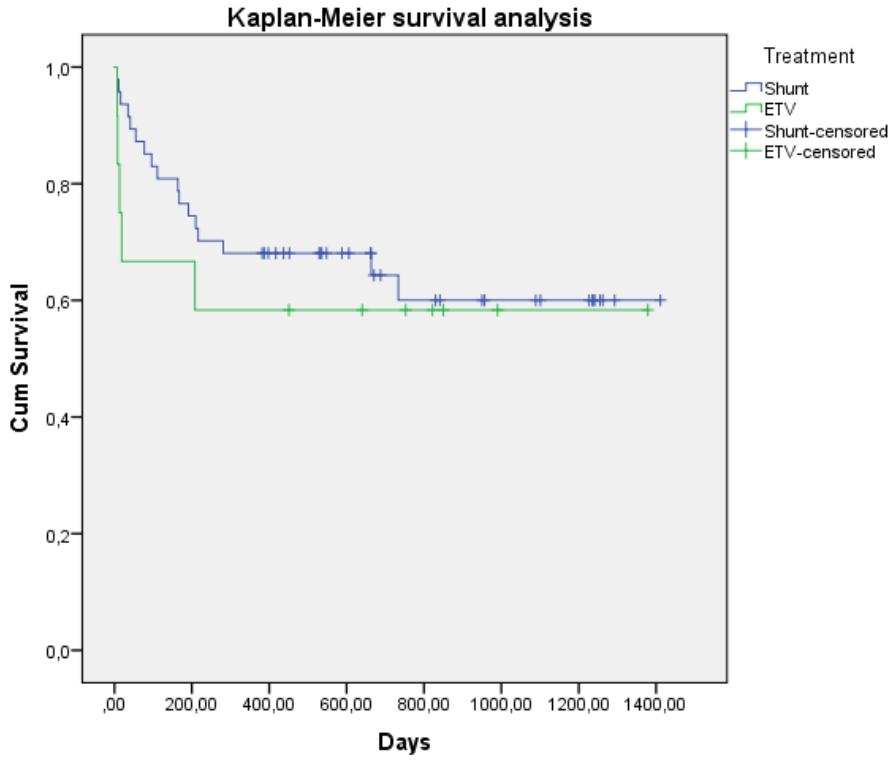

Figure 3. Kaplan-Meier survival analysis of treatments, including shunt and endoscopic third ventriculostomy (ETV).

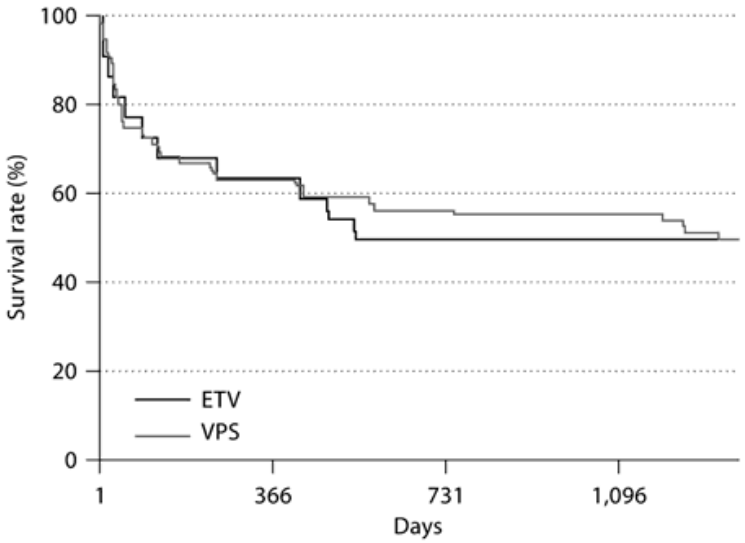

Figure 4. Kaplan-Meier survival analysis of treatments, including ventriculoperitoneal shunt (VPS) and endoscopic third ventriculostomy (ETV). Data from our previous study of 2010 [5]. Figure reprinted with permission from S. Karger AG, Basel.

Comparison to pre-protocol study of 2010

Comparisons were made to our team's previous study covering surgeries in 2001-2005. The rates of total failure of treatment, failure due to infection and failure due to mechanical dysfunction/insufficient function are visualized in figure 5, 6, 7.

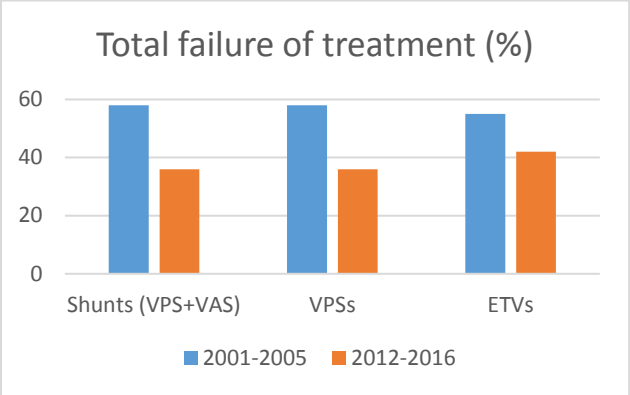

Figure 5. Rate of total failure of treatment. Treatments including ventriculoperitoneal shunt (VPS), ventriculoatrial shunt (VAS) and endoscopic third ventriculostomy (ETV).

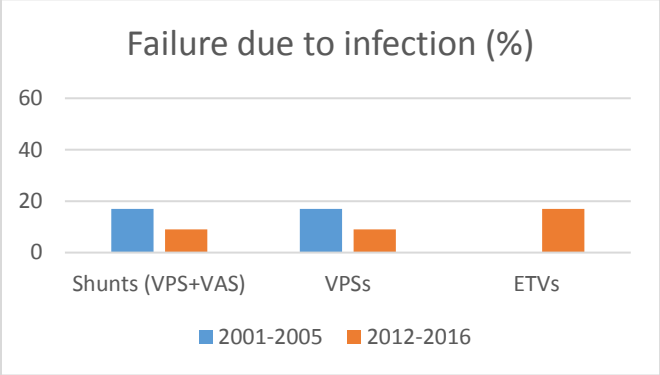

Figure 6. Rate of failure due to infection. Treatments including ventriculoperitoneal shunt (VPS), ventriculoatrial shunt (VAS) and endoscopic third ventriculostomy (ETV).

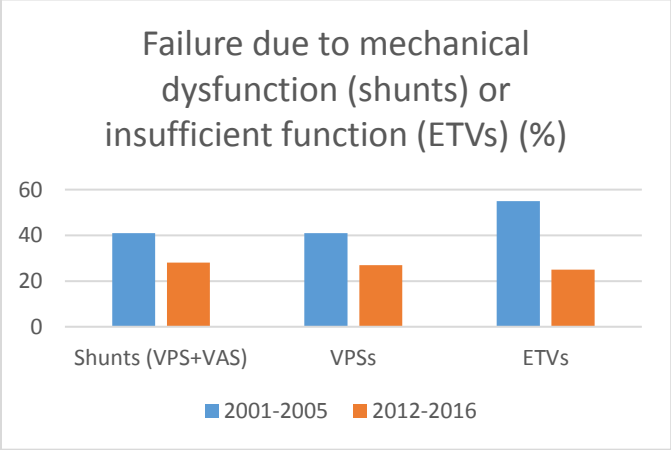

Figure 7. Rate of failure due to mechanical dysfunction (shunts) or insufficient function (ETVs). Treatments including ventriculoperitoneal shunt (VPS), ventriculoatrial shunt (VAS) and endoscopic third ventriculostomy (ETV).

Shunts 2001-2005 vs. shunts 2012-2016

Total failure decreased significantly from 58% to 36% (p=0.019). Both failure due to infection and failure due to mechanical dysfunction decreased, although not significantly, (p=0.180 and p=0.140 respectively). Several data variables were significantly different between the groups. The patients of the 2010 study were of lower age at primary surgery (p=0.000), had longer follow up time (p=0.000) and were different in shunt valves used (p=0.000). Comparisons are shown in table 2.

Table 2. – Comparisons of failure rate and other data variables for patients treated with shunts. Shunted patients of this study were compared to the shunted patients of our previous study [5]. Abbreviations; IVH: intraventricular hemorrhage, MMC: myelomeningocele, VAS: ventriculoatrial shunt, VPS: ventriculoperitoneal shunt.

	Study 2001-2005	Study 2012-2016	P-value
Failure	58%	36%	**0.019**
Patient age at primary surgery (years)	Mean 0.9 Median 0.1	Mean 1.7 Median 0.4	**0.000**
Follow up time (years)	Mean 4.9 Median 4.8	Mean 2.3 Median 2.3	**0.000**
Type of shunt valve (Codman, Delta, Strata)	3% Codman 42% Delta 55% Strata	0% Codman 4% Delta 96% Strata	**0.000**
Failure due to infection	17%	9%	0.180
Failure due to mechanical dysfunction	41%	28%	0.140
Treatment distribution (VPS:VAS)	76:0	44:3	0.054
Gender (female:male)	32:44	18:29	0.676
Etiology hydrocephalus (3 most prevalent)	26% IVH 25% MMC 13% Malformation 13% Other	30% IVH 23% Tumor 18% Other	0.090
Duration of primary surgery (hours)	Mean 1.0 Median 0.7	Mean 0.9 Median 0.7	0.651
Premature	43%	38%	0.575
Concomitant procedure	18%	9%	0.131
Emergency procedure	16%	11%	0.447
Time of day of surgery (morning, afternoon, evening, night)	25% morning 64% afternoon 8% evening	19% morning 60% afternoon 17% evening	0.412
CSF leakage	11%	6%	0.529
Infection following CSF leakage	38%	33%	1.000

Shunt failure due to mechanical dysfunction per mean time of follow up equaled 11.9% compared to 8.4% of the 2010 study.

To further enhance comparability between the studies, VASs were excluded from this study's population of shunts to only include VPSs. This since the study of 2010 did not contain any VASs. Comparison of VPSs proved the same statistically significant differences as for the total shunts, although the p-values were slightly different.

ETVs 2001-2005 vs. ETVs 2012-2016

In ETVs there was no significant difference in total failure (p=0.473), failure due to insufficient function (p=0.097) or failure due to infection (p=0.118). There was a significant difference in the two following factors: Follow up time (p=0.000) where the earlier study had a longer follow up time, and in the rate of patients with CSF leakage (p=0.013), where this study had a higher rate. Comparisons are shown in table 3.

Table 3. – Comparisons of failure rate and other data variables for patients treated with endoscopic third ventriculostomy (ETV). ETV treated patients of this study were compared to the ETV treated patients of our previous study [5]. Abbreviations; AS: aqueductal stenosis, IVH: intraventricular hemorrhage.

	Study 2001–2005	Study 2012-2016	P-value
Follow up time (years)	Mean 5.2 Median 5.2	Mean 2.3 Median 2.2	**0.000**
CSF leakage	9%	50%	**0.013**
Failure	55%	42%	0.473
Failure due to infection	0%	17%	0.118
Failure due to insufficient function	55%	25%	0.097
Gender (female:male)	12:10	6:6	0.064
Patient age at primary surgery (years)	Mean 4.5 Median 2.3	Mean 7.1 Median 6.9	0.149
Etiology hydrocephalus (3 most prevalent)	50% Tumor 18% AS 14% Malformation	67% Tumor 17% AS 8% IVH 8% Cyst	0.867
Duration of primary surgery (hours)	Mean 1.4 Median 0.7	Mean 1.3 Median 0.9	0.279
Premature	9%	8%	1.000
Concomitant procedure	27%	42%	0.459
Emergency procedure	14%	8%	1.000
Time of day of surgery (morning, afternoon, evening, night)	27% morning 55% afternoon 14% evening	25% morning 67% afternoon 0% evening	0.714
Infection following CSF leakage	0%	33%	1.000

ETV failure due to insufficient function per mean time of follow up equaled 11.1% compared to 10.5% of the 2010 study.

Risk factor analysis - failure of treatment - shunts

Several univariate Cox regression models for failure of treatment (either due to infection or mechanical dysfunction) assessed the hazard ratio (HR) of possible risk factors. For the 47 patients with shunts, none of the tried variables proved significant risk factors (table 4.).

Table 4. Univariate Cox regression analyses of failure of treatment in shunts. I.e. different data variables were separately investigated to assess their correlation to failure of treatment in shunted patients.

	Hazard Ratio (95% CI)	P-value
CSF leakage (0=no, 1=yes)	0.95 (0.13-7.25)	0.962
Gender (0=men, 1=female)	0.46 (0.15-1.43)	0.181
Premature (0=no, 1=yes)	1.00 (0.39-2.72)	0.950
Emergency procedure (0=no, 1=yes)	0.56 (0.07-4.16)	0.562
Duration of primary surgery (hours)	0.48 (0.14-1.63)	0.240
Time of day of surgery (0=morning, 1=not morning)	1.27 (0.36-4.42)	0.709
Concomitant procedure (0=no, 1=yes)	0.62 (0.08-4.64)	0.673
Location of primary surgery (0=dept. of neurosurgery, 1=dept. of pediatric surgery)	1.53 (0.35-6.71)	0.571
Type of shunt valve (0=Strata, 1=Delta)	1.40 (0.18-10.66)	0.746

Risk factor analysis - failure of treatment due to infection - shunts

Of the 47 patients with shunts, 3 experienced leakage of CSF following the primary surgery. Out of those 3 patients, 1 later experienced failure due to infection. Using a univariate Cox regression model for failure due to infection, the hazard ratio (HR) of CSF leakage was assessed for patients with shunts. HR amounted to 6.25 (p-value 0.114 and 95% CI=0.65-60.40).

Discussion

In this study, we looked at the effects of implementing a protocol for shunt and ETV surgery. It was expected to show a decrease in failure of treatment due to infection, which we observed in shunts from 17% to 9%, however the difference was not significant. The shunt population was also analyzed to identify risk factors for failure of treatment and failure of treatment due to infection. Results proved no significant risk factors for neither.

Shunts

Studies have shown that 42-54% of children with VPSs require new surgery due to failure of treatment [8-10]. There are, to our knowledge, no studies reporting the corresponding figure for VASs in children. When failure rates in children were researched in our facilities for the years 2001 to 2005, total VPS failure was found to be 58% [5]. By using Chi square test the total failure rate of this study, 36%, was compared to that of the previous one and proved a statistically significant decrease. Although when separately considering the causes of failure, i.e. infection and mechanical dysfunction, both decreased but not significantly.

Failure due to infection in shunts was reported to be 17% in our team's study from 2010, which is in the high range of the 4-17% stated by the literature [11]. Several studies have shown significant decrease of infection rates after implementing a shunt protocol. Sarmey et al. evaluated eight studies implementing shunt protocols, reporting a range of 2-12% in absolute risk reduction [12]. The protocol we introduced in 2012 has applied for both ETV and shunt surgery and was created by combining what was outlined in the studies that reported a successful infection decrease. Our evaluation shows that failure rate due to infection decreased from 17% to 9% after implementing the protocol, although the difference was not significant. The two compared populations of shunt patients were fairly similar in terms of patient and surgical data. However, the following factors were significantly different: follow up time, patient age at surgery and type of shunt valve. The mean follow up time was

2.3 years compared to 4.9 years of the previous study. Instinctively one might think a shorter follow up time automatically would decrease failure rate since late failure of treatment might not be recorded. However, there is a consensus that the great majority of shunt infections occur in the first few months after primary surgery, which Lee et al. recently confirmed [13]. Therefore, we believe our minimum follow up time of 1 year per patient (2.3 years in previous study) was sufficient to record infection failures, and suitable for comparison. Regarding patient age at time of surgery, the previous study included younger patients with a median of 0.1 years compared to this study's median of 0.4. This may be due to a change in routines after the previous study, where hydrocephalic neonates used to undergo early shunt surgery but new routines recommend the use of a Rickham reservoir for CSF drainage, thereby delaying the shunt surgery. The difference in patient age might have affected the comparison of failure between the populations, since studies have reported low patient age to increase shunt failure [9, 10]. The type of shunt valve used in this study was predominantly Strata whereas the previous study included more Delta and some Codman. This difference in shunt valve distribution is most probably due to a shift and development in routines, where the Strata valve was introduced and properly researched about halfway through the time period of the study of 2010, increasing its frequency [14]. In addition, some patients previously eligible for a Delta valve now use a Rickham reservoir and later a Strata valve. To our knowledge there are no studies suggesting an inherent difference in risk of failure in different types of shunt valves.

Although a decrease in infection was observed after protocol implementation, the lack of a *significant* decrease might attribute to many things. A bigger patient population might be needed, where only 47 shunts were included in this study compared to 76 in the previous. Using the observed decrease and a desired level of statistical power of 80%, concludes that each compared population would need 236 patients included to prove a statistically significant

difference. Also, one can argue whether the specified routines of this protocol have been the same as the protocols of other centers reporting a significant decrease. There might be differences that are not stated and expressed in the protocols of previous studies, e.g. local differences in surgical technique and surgery routines in general. The compliance of health care personnel when using the introduced protocol is also of great importance.

Failure due to mechanical dysfunction decreased from 41% to 28% after protocol implementation. We believe that the shorter time of follow up might have affected the observed difference. While shunt infections mainly happen within a few months of surgery, mechanical dysfunction in shunts occurs within a much wider range, up to several years after primary surgery [15]. To enhance comparability between the populations we calculated the failure rate due to mechanical dysfunction per mean time of follow up, resulting in 8.4% prior to protocol implementation compared to 11.9% for this study. Therefore, we don't believe that there was a *real* decrease in mechanical dysfunction pre-protocol to post-protocol.

ETVs

Studies have shown that 26-48% of ETVs require new surgery due to failure of treatment [8, 16, 17]. Fifty-five percent of ETVs failed in our team's study from 2010, while 42% failed in this study, a non-significant decrease. Failure due to insufficient function also decreased, from 55% to 25%. However, there was a significant difference in follow up time between the two studies, the previous having a mean of 5.2 years compared to 2.3 years of this study. Similar to what discussed concerning shunt mechanical dysfunction, we believe this might have affected the validity of the comparison of failure rate. This due to the wide time range of when complications of insufficient function occur in ETVs, up to several years following primary surgery [18]. Failure due to insufficient function per mean time of follow up equaled 10.5% for the previous study compared to 11.1% for this study, thereby making it less likely that a *real* decrease did occur.

Failure of treatment due to infection increased in this study compared to 2001-2005, from 0% to 17%, a non-significant difference. In absolute numbers the increase was 2 infections, from a previous 0 to 2 in this study. If not merely attributable to chance, it is possible that the significant increase of CSF leakage in this study can explain the increase of infection. This since studies, although in adults, have reported CSF leakage as a significant risk factor for shunt infection, which possibly also might apply to ETVs [19, 20]. In line with this, both ETV patients suffering infection had experienced previous CSF leakage.

Risk factors

The assessment of risk factors for failure of treatment in shunts did not prove any significant factors. When assessing failure of treatment due to infection, CSF leakage was not found a significant risk factor. These results of the risk factor analysis differ from our previous study of 2010 where CSF leakage, duration of surgery, prematurity and concomitant procedure all proved to significantly increase risk for failure in shunts. We believe this is due to a small population, where Long suggests a minimum sample size of 100 as a rule of thumb [21]. Risk factor analysis of ETVs was not carried out due to the limited number of patients.

Strengths and Weaknesses

This study included a relatively small number of patients and we believe further studies would benefit of a larger sample size, to allow for a more diverse use of statistical analysis, multiple regression analysis for example. In turn, this would enable for adjustment of possible confounders and stronger conclusions to be made.

Unfortunately, the raw data of the 2010 study lacked information of the department where surgery was carried out, therefore no comparison of the populations was possible in this field. In addition, the data lacked information of time until occurrence of failure after primary surgery, preventing comparisons.

The decade passed between patients of this study and patients in 2001-2005 might have brought changes affecting failure rates, changes that don't show in our chosen parameters of patient and surgery data. The routines in health care concerning hygiene might have changed, so might have surgical procedures and techniques. The current consensus of which patient characteristics that make a shunt or ETV suitable could also differ from a decade ago.

Our facilities take care of all shunt and ETV surgeries in a large region of South Western Sweden. This gives strength to the data of failure rates since there is no possibility of patients undergoing failure of treatment in other centers in the region without our knowledge.

Conclusions and Implications

Implementation of a new protocol decreased failure due to infection from 17% to 9% in shunts, however the difference was not significant. Total failure in shunts decreased significantly from 57% to 37%.

This study suggest that implementation of a shunt protocol is an effective way to reduce failure of treatment.

Populärvetenskaplig sammanfattning - Ger nya rutiner färre komplikationer efter kirurgisk behandling av hydrocefalus hos barn?

Hydrocefalus, även kallat vattenskalle, är ett sjukdomstillstånd som innebär förhöjt tryck inuti skallen. Normalt finns en viss mängd vätska, kallad likvor, som flödar kring hjärnan och där mängden balanseras av en jämn ström av nyproduktion och avflöde. Av olika orsaker kan denna balans rubbas och leda till en för stor mängd likvor i systemet, det kan bero på tumör, blödning, infektion, cysta, etc. Den förhöjda mängden vätska orsakar ett tryck på själva hjärnan samt på skallbenet vilket kan orsaka kognitiva funktionshinder och ett expanderat skallben. Hydrocefalus kan drabba såväl barn som vuxna, men barn är vanligast. Av nyfödda drabbas ungefär 0,8/1000 födslar [1]. Behandling av hydrocefalus finns i två former, där båda

syftar till att sänka trycket i skallen. Den ena kallas shunt och innebär att ett rör inopereras för att avleda vätskan till annan plats, ofta in i bukhålan eller till hjärtats förmak. Den andra sortens behandling kallas ventrikulocisternostomi (VCS) och innebär att man under operation skapar en extra öppning i vätskesystemet, ofta för att förbipassera ett hinder av något slag. Vilken behandling som används beror mestadels på orsaken till sjukdomen.

Till båda behandlingarna finns en relativt stor risk för att komplikationer sker och att då ytterligare operation måste göras. Dessa komplikationer kan antingen bestå av infektion i vätskan eller operationssåret, alternativt i att behandlingen slutar hjälpa vätskans avflöde.

År 2010 publicerades en studie från Sahlgrenska sjukhuset inriktad på komplikationer för de barn med hydrocefalus som behandlats mellan år 2001 och 2005. Jämfört med andra studier så visade denna studien på en hög andel komplikationer, speciellt i shuntar på grund av infektion. Andra studier har i sin tur rapporterat om en tydlig minskning av infektionskomplikationer i shuntar efter att dom infört särskilda rutiner kring den behandlande kirurgin. Därför infördes liknande rutiner på Sahlgrenska år 2012, bland annat ska operationspersonalen bära hjälmmössa, förebyggande antibiotika användas mer strikt och kirurgen använda dubbla handskar.

Denna studie har syftat till att utvärdera nyttan av dessa rutiner, genom att mäta antalet komplikationer på patienter som behandlats 2012–2016 och sedan jämföra med patienterna från 2001–2005 i den tidigare studien. Ett annat syfte med studien var att avgöra vilka riskfaktorer som finns för komplikationer totalt sett, samt specifikt för infektion som komplikation.

Resultatet blev att antalet infektioner hos shuntar minskade efter införandet av de nya rutinerna, från tidigare 17% till 9%. Denna minskning var dock inte statistiskt signifikant, med andra ord kan det inte uteslutas att den beror på slumpen. Riskfaktoranalysen kunde inte

visa på några faktorer som ökar komplikationsrisken. För att kunna dra tydligare slutsatser behöver fler patienter ingå i en framtida studie.

Sammanfattningsvis antyder studien att ett införande av specifika rutiner skulle kunna vara ett effektivt sätt att minska komplikationer av hydrocefalusbehandling.

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Appendices

1. Shunt/ETV protocol 2012

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Barn
Operation/Anestesi

Plockkort

AAF Ventrikulo-Peritoneal Shunt

Framtagen av: Martina Gustavsson
Publicerat:
Reviderad av/datum: Ing-Marie Söderberg/ 2012-10-16

DIAGNOS

Hydrocefalus, intracraniella cystor

INGREPP:

Inläggning av ventrikulo-peritonial eller cysto-peritoneal shunt

FRAMPLOCKNING:

Shuntgaller
Koppset
Universalset eller delbar hålduk+ medium eller slits-lakan
Rockar
Knivblad
Gröna dukar
Diatermihållare
Kona/kona slang + smalt hjärtsugsmunstycke
Sug/diapåse
Mepiform
Märkpenna
Spruta + kanyler till lokalbedövning

X-INSTRUMENT:

Shunt-troakar tredelad
Till större barn: Power-Pro Driver med batteri tillsammans med Hudson trepan chuck
Till mindre barn: Handborr

SUTURER:

4/0 Vikryl Rb-1 nål till subcutis
4/0 Ethilon till huden
Ev. 0 eller 2/0 Nurolon till att knyta fast slangen runt en konnektor

APPARATUR:

Bipolär diatermi
Sug

Plockkort

AAF Ventrikulo-Peritoneal Shunt

LÄKEMEDEL UNDER OP:

Marcain-Adrenalin 2,5 mg/ml eller 5 mg/ml
Ringeracetat som sköljvätska
Klorhexidinsprit att tvätta med vid hel hud
Vid reop med öppet sår tvätta med 70 % finsprit

UPPLÄGG:

OBS! ALLTID LATEXFRITT
Ryggläge på tempurmadrass. Huvudet i gelring. Ha med kirurgen vid upplägg.

DESINFEKTION och DRAPERING:

Operatören markerar var shunten skall ligga på skalpen. Han tunnelerar därifrån bakom öra och ner till buken och ut strax under navelhöjd. Klä in örat så man kan se konturerna av detta. Förtvätta med descutan och steriltvätta med Klorhexidinsprit (eller 70% finsprit vid öppet sår).

ÖVRIGT:

Läs ”protokoll för shuntoperationi ” som är bifogat detta plockkort.

FÖRBAND:

Huvud: Steristrips , tegaderm samt kompresser som tryckförband under el binda och nätmössa.
Mage: steristrips och Mepilex border.

Plockkort

AAF Ventrikulo-Peritoneal Shunt

Protokoll för shuntoperation/endoskopisk ventrikulostomi

Enligt gällande rutin	• Hibiscrub – tvätt kvällen före operation av hela kroppen, huvud, hår. Vid akut operation kan detta steg hoppas över, men då skall extra Hibiscrub-tvätt göras på operationssal. Huden kan vid behov smörjas med Sterisol hudlotion. Undvik andra hudkrämer, de kan inaktivera desinfektionsmedlet. • Typen av preoperativ desinfektion skall dokumenteras.	

PEROPERATIVA ÅTGÄRDER

Åtgärd/syfte	Specifikation	
Reducera spridning av mikrober.	• Bara nödvändigt, minimalt, antal personer på operationssal. • Bara nödvändig trafik ut och in - undvik byte av personal vid korta operationer! • Märk operationssalen med skylt "implantatkirurgi"	
Operation	• Operationsteamet skall ha hjälm-mössa. Allt hår/skägg skall täckas, inga smycken synliga • Munskydd skall täcka näsan.	
Normoterm patient	• Begränsa tiden mellan desinfektion och klädning till ett minimum. • Använd kroppstempererade sköljvätskor – även vid endoskopi! • Slå på operationslampan under desinfektion	
Antibiotika	• Ges enligt särskilt PM, minst 15 min innan hudincision.	
Hårklippning	• Hårklippning, ej rakning.	
Preoperativ desinfektion	• Använd klorhexidin 5 mg/ml med sprit. Vid reoperation med öppet sår/suturer ej tagna 70 % -ig sprit.	
Steril dukning	• Markera incisionsstället med penna, ej med ristning i huden (undvik skada i hudbarriär innan steriltvätt) • Endoskopi + instrument skall göras helt klara innan operationsstart (vitbalanserat, kopplat dropp, bipolär kopplad/testad) • Täck över instrumenten mellan uppackning och operationsstart.	

Plockkort

AAF Ventrikulo-Peritoneal Shunt

Dubbla handskar/handskbyte	• Använd dubbla handskar. Operationssjuksköterska byter ytterhandskar efter dukning och kirurgen byter ytterhandskar innan beröring och internalisering av shunten	
Typ av shunt	• Kirurgen väljer shunt och ventrikelkateter och ställer in shunt i förväg	
Implantatet	• Öppna inte implantat innan det skall användas!	
No touch	• Använd no-touch-metod! • Operationssjuksköterska undviker att ta i shunten, använder anatomisk pincett. • Lägg lösa shuntslingor i en steril diatermipåse eller under grön duk.	
Använd nya sterila instrument på shunten	• Använd inte instrument som använts tidigare under ingreppet som kan vara kontaminerade med hudbakterier	
Operationsteknik	• Förbered ingreppet så långt det går (shuntdelar på sal, ev koppla ihop delar i förväg) • Öppna nödvändiga incisioner. • Före internalisering/ manipulering av shunten byter kirurgen ytterhandskar • Hudsuturering skall vara perfekt, i huden i första hand monofilament icke-resorberbar (t ex Ethilon).	
Provtagning	• Prov från CSF (glukos, proteiner, och cellräkning samt odling) görs enligt särskild ordination från kirurg. 2 st gula rör samt remiss för likvordiagnostik samt odlingsremiss tas fram av undersköterska.	
Kort operationstid	• Erfaren kirurg och operationssjuksköterska att föredra • God planering	
Hårtvätt	• Skölj blod från håret med steril NaCl 9mg/ml, torka med steril handduk.	

Peroperativa åtgärder dokumenteras (förutom i Operätt) på särskild blankett som sparas i därför avsedd pärm!

Plockkort

AAF Ventrikulo-Peritoneal Shunt

POSTOPERATIVT

Åtgärd	Specifikation	
Bandage/Läge	• Valfritt sterilt bandage (T ex Tegaderm). Kompresser och nätmössa på huvudet. • Undvik tryck mot såret/shuntdelar, avlasta ev med skumgummi. Hos barn < 6 mån skall huvudet byta sida minst var tredje timme för att undvika trycksår. • Vid lättare genomblödning lämnas bandagen kvar, förstärks eventuellt. Om bandaget lossnar tvätta med steril NaCl och torka, sätt på nytt bandage.	
Hårtvätt	• Håret kan tvättas (försiktigt) efter 3 dagar, suturer tas normalt efter 10 dagar.	

2. Ethical permit

EPN *Regionala etikprövningsnämnden i Göteborg*

Projektansvarig:
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Ledamöter som företräder allmänna intressen
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Projekttitel: Behandling av hydrocefalus hos barn - minskad komplikationsfrekvens och effekter på huvudomlängstillväxt

Beslutsprotokoll från sammanträde med Regionala etikprövningsnämnden i Göteborg, Medicinska avdelningen (M 1), den 9 januari 2012

Föredragande: Gunnar Göthberg

Godkännes

Nämnden beslöt godkänna studien.

Att denna avskrift i transumt överensstämmer med originalet intygar:

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