



Effect of Giving Brochures to Ventriculoperitoneal Shunted Children's Mothers About Preventing Shunt Infections

Ventriküloperitoneal Şanlı Çocukların Annelerini Şant Enfeksiyonlarını Önleme Konusunda Bilgilendirmenin Etkisi

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Abstract

Objective: The aim of this study was to evaluate and compare the effectiveness of giving oral information and printed informative brochures on information and application levels of mothers with VP shunted children to prevent infections.

Material and Methods: A prospective, randomized controlled trial design was conducted. Nine mothers in the study group were given printed informative brochures after a 15-minute oral informative session, whereas nine mothers in the control group were given only oral information. The effectiveness of these interventions was assessed at 15th and 90th days.

Results: Mothers in both groups achieved significantly higher information and application level scores at 15th and 90th days when compared to their initial evaluation ($p < 0.05$). In the study group, 90 days after the informative session, the mothers achieved statistically higher information level scores than the mothers in the control group ($U = 8.000$, $p = 0.019$).

Conclusion: Giving printed informative brochures is more effective than giving only oral information on mothers' knowledge about preventing VP shunt infections. Printed informative brochures about preventing VP shunt infections could improve mothers' level of knowledge in the long term and avoid shunt infections.

Keywords: Hydrocephalus, infection, information, nurse, ventriculoperitoneal shunt

Öz

Giriş: Ventriküloperitoneal şantlar (VP) hidrosefalinin tedavisinde yaygın olarak kullanılmaktadır. VP şantlarının en sık görülen komplikasyonu enfeksiyon olup, cerrahi süreçteki koruyucu önlemlere rağmen ortaya çıkabilmektedir. Bu çalışmanın amacı, şant takılan çocukların annelerine şant enfeksiyonlarını önlemeye yönelik yapılan bilgilendirmenin annele- rin bilgi ve uygulama düzeylerine etkisini belirlemektir.

Gereç ve Yöntemler: Prospektif, randomize kontrollü çalışma tasarımı kullanıldı. Çalışma grubundaki dokuz anneye 15 dakikalık sözel bilgilendirme oturumundan sonra bilgilendirme broşürü verildi, kontrol grubundaki dokuz anneye ise sadece sözel bilgilendirme yapıldı. Girişimle- rin etkinliği 15. ve 90. günlerde değerlendirildi.

Bulgular: Her iki gruptaki annelerin bilgilendirme öncesindeki bilgi ve uygulama düzeylerinin 15. ve 90. günlerde istatistiksel olarak anlamlı derecede yükseldiği belirlendi ($p < 0.05$). Çalışma grubunun bilgilendirmeden 3 ay sonraki bilgi puan ortalamasının kontrol grubundan istatistiksel olarak anlamlı derecede yüksek olduğu belirlendi ($U = 8.000$, $p = 0.019$).

Sonuç: Annelerin VP şant enfeksiyonlarını önleme konusundaki bilgilerin artırılması konusunda basılı bilgilendirme broşürlerinin verilmesi, sadece sözel bilgi vermekten daha etkilidir. VP şant enfeksiyonlarının önlenmesine yönelik bilgilendirme broşürleri, annelerin uzun vadede bilgi düzeylerini artırabilir ve şant enfeksiyonlarını önleyebilir.

Anahtar Kelimeler: Hidrosefali, enfeksiyon, bilgilendirme, hemşire, ventriküloperitoneal şant

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Introduction

Hydrocephalus (HCP) occurs when there is imbalance between the production and absorption of the cerebrospinal fluid (CSF) so that excess CSF accumulates in the cerebral ventricles (1). According to the Hydrocephalus Association, the prevalence of hydrocephalus is 1/1000 live births in the USA (2), and 0.3-2.5/1000 live births in Turkey (3,4). Ventriculoperitoneal (VP) shunts are widely used in the treatment of HCP (5). VP shunts are composed of 3 parts: the ventricular catheter, pressure or flow controlled oneway valve, and peritoneal catheter. Thus, excess CSF is diverted from cerebral ventricles to the peritoneal cavity in a controlled unidirectional way; decreasing excess intracranial pressure (6,7). HCP is mostly diagnosed in the pediatric group of patients. 1660 of 3000 VP shunt surgeries yearly performed to treat HCP in England are reported to be on pediatric patients (8). In Turkey, VP shunt surgery is performed on 88% of neonatal infants diagnosed with clinical HCP (9).

Infection is the most common complication of VP shunt surgery especially in the pediatric group of patients (10,11). It results in prolonged periods of antibiotherapy and revision surgeries increasing hospital stay, infection related morbidities, and health expenditures (12,13). VP shunt infections are reported to be seen in 10.5% of the infants and children (14). In a recent study by Tervonen et al. VP shunt related infection rate has been reported to be 12.5% (15). Telhan et al. have reported that 42.5% of pediatric patients with VP shunt infections are infants (< 1 year), and the rest are between the ages of 1-7 years (16).

Delay in recognition of VP shunt infections results in worse clinical outcome, prolonged hospital stay and increased health costs. Furthermore, long-term quality of life is affected in these patients due to permanent infection-related sequelae (5,17,18). According to the Hydrocephalus Association, 2 million dollars are spent to treat HCP every year (2). Reinforcing aseptic/hygienic preventive measures during peri-operative, early post-operative, and long-term daily care are important in preventing VP shunt related infections (19). However, infections are common regardless of strict peri-operative preventive measures (20). Thus, post surgery in-hospital and long-term care are important in preventing shunt related surgery as well.

Hand hygiene, using aseptic techniques in surgical wound care, antibiotic prophylaxis, nursing, and education about taking care of children with VP shunts are reported to be paramount in preventing infections in literature (21). According to the 2017 evidence-based recommendations by the World Health Organization (22), maintaining hand hygiene is strongly suggested to prevent infections. Educating parents and caretakers, preparing informative brochures and posters are recommended to prevent VP shunt infections (23). In a study involving parents of children with VP shunts, the percentage of VP shunt revision surgery is reported to be statistically less in children with parents educated about care of VP shunt related

symptoms and complications (13). Nevertheless, in a study on the parents of children with VP shunts experience, it is reported that 80% of the parents are not informed about potential VP shunt complications and 50.7% of parents lack information about appropriate shunt care (24).

Nurses play an important role in the early postoperative care of VP shunt patients (25). They share significant responsibility for surgical wound care and recognizing VP shunt related complications. In addition, they are responsible for maintaining effective health-care environment and inform and educate the parents of these patients about appropriate daily care (26). Regarding the long-term care of children with VP shunts, nurses play important roles in educating the parents and increasing the quality of life (27). In Turkey, the caregivers of children are almost always mothers, especially when the child bears a health problem. Mothers recognizing the early symptoms of infections and VP shunt related complications are of paramount importance in pediatric VP shunt patients as it affects the long-term well being of the child as well as avoidable revision surgeries, long hospital stays, and increased health costs (6).

Providing written and oral information for patients and caregivers is a standardized procedure in developed countries and it is recommended to establish healthcare educations to families of children to maintain development on their needs (28). However, in underdeveloped or developing countries, educating the caregiver of a chronic patient is either totally overlooked or substandard in most institutions. As authors, we would like to emphasize that families of the children with VP shunts should be educated on surgical wound care, skin care, and signs and symptoms of infection. Furthermore, we aimed to compare the effectiveness of supplying mothers with written education material versus only oral education on recognizing and avoiding VP shunt infections.

Purpose and Hypotheses

The purpose of this study was to evaluate and compare the effectiveness of giving oral information and printed informative brochures on information and application level of mothers to prevent VP shunt infections.

Hypothesis 1: Information level of the mothers in the study group will be higher than the control group at 90 days after giving oral information and informative brochure.

Hypothesis 2: Application of the learned information will be higher in the study group than the control group at 90 days after giving oral information and informative brochure.

Materials and Methods

Study Design and Sample

This study is a prospective, randomized controlled trial, conducted between 5th May 2016-3rd March 2018 by voluntary participation of mothers of children treated in neurosurgery department of a university hospital.

We determined the number of the study and control groups according to the number of patients hospitalized in the neurosurgery department in the previous year. Between 1st January 2015 and 31st December 2015, 1015 patients, six of which were pediatric VP shunt patients (between 0-15 years of age), were hospitalized by neurosurgery department. The percentage of pediatric HCP patients undergoing VP shunt surgery were 0.6%. Using power analysis yielding 95% confidence interval, 5% margin of error and 85% statistical power, we included nine mothers for the study group, and nine mothers for the control group, totaling 18 mothers.

The study was conducted in a reference hospital, where referred patients from whole Thrace region of Turkey are hospitalized and treated. In the neurosurgical department, both pediatric and adult patients are hospitalized. Pediatric patients are hospitalized in single rooms.

We included voluntary mothers who are the sole caregiver of the pediatric patients (0-15 years of age) undergoing first time or revision VP shunt surgeries, and who speak Turkish as their native language, and who are literate in Turkish. The mothers satisfying the inclusion criteria were randomized to study and control groups.

Randomization was performed by researcher (ZKÖ) as follows: In-patient protocol numbers of the patients were written down and a consecutive number starting with one (1) was assigned for each protocole number. The odd protocole numbers assigned were included in the study group, and the even protocole numbers assigned were included in the control group.

Blindedness of the Study

The study is not a blinded study.

Study Protocol and Data Collection

In the study, "identification form", "questionnaire on information about preventive measures regarding VP shunt infections", and "questionnaire on application of preventive measures regarding VP shunt infections" were used to collect research data. These questionnaires were prepared by the authors according to the literature review, and the content validation of them was accomplished by consulting three neurosurgery specialists and two specialist nurses.

"Identification form" is composed of 10 questions about descriptive information on the mother and the patient such as ages of the mother and the patient, sex of the patient, previous education on VP shunt related infections, and the number of VP shunt surgeries the patient underwent.

"Questionnaire on information about preventive measures regarding VP shunt infections" aimed to determine the information level of preventive measures by the mothers before and after they were informed about VP shunt related infection

prevention measures. The questionnaire consists of a total of 25 phrases. Sixteen of the 25 phrases are affirmative sentences such as "The cleanliness of the child's clothes prevents the development of infections", "Healthy and balanced nutrition of the child helps to prevent infections", and nine of them are negative sentences, such as "Being in a crowded, polluted environment does not pose a risk of infection for child", "Tooth decays do not cause infections". The mothers are asked to check the phrases as "correct" or "false". Every correct answer was scored as "1" point so that the highest score obtainable was "25" and the lowest score was "0". The higher the scores the better informed the mothers were about VP shunt related problems (Figure 2).

"Questionnaire on application of preventive measures regarding VP shunt infections" aimed to determine the application level of preventive measures by the mothers before and after they were informed about VP shunt related infection prevention measures. The questionnaire consists of 20 affirmative phrases on application of shunt infection prevention measures such as "I keep away my child from people who have influenza and flu", "I consult a physician immediately in case of any infection with fever (throat infection, urinary tract infection, etc.)" etc. The phrases were selected from the informative questionnaire and included accurate information about what the mothers should do to prevent infection. The mothers were asked to check the phrases as "correct" or "false". The correct answers were scored as "1" point and the wrong answers were scored as "0" so that the highest possible score was "20" and the lowest was "0". The higher the scores the more accurate the mothers applied the preventive measures (Figure 2).

An "informative brochure" on preventing VP shunt infections was prepared by the authors in the light of the literature and specialist opinions. The brochure included information about diagnosis and the clinical signs of HCP, the description of the VP shunt system, signs and symptoms of shunt infection and infection prevention measures such as hand and body hygiene, clean clothes, oral hygiene, tooth-care, measuring body temperature, seeking early medical care for common infections such as upper respiratory tract infections or urinary tract infections.

Both oral and written consents were obtained from all the mothers. The mothers were initially interviewed by the researcher (ZKÖ) while their children were hospitalized, and the "identification form", the "questionnaire on information about preventive measures regarding VP shunt infections" and the "questionnaire on application of preventive measures regarding VP shunt infections" were completed to get baseline information and assess the mothers' baseline information, and application level. As the follow up interviews were planned to be conducted on the phone, the forms and the questionnaires

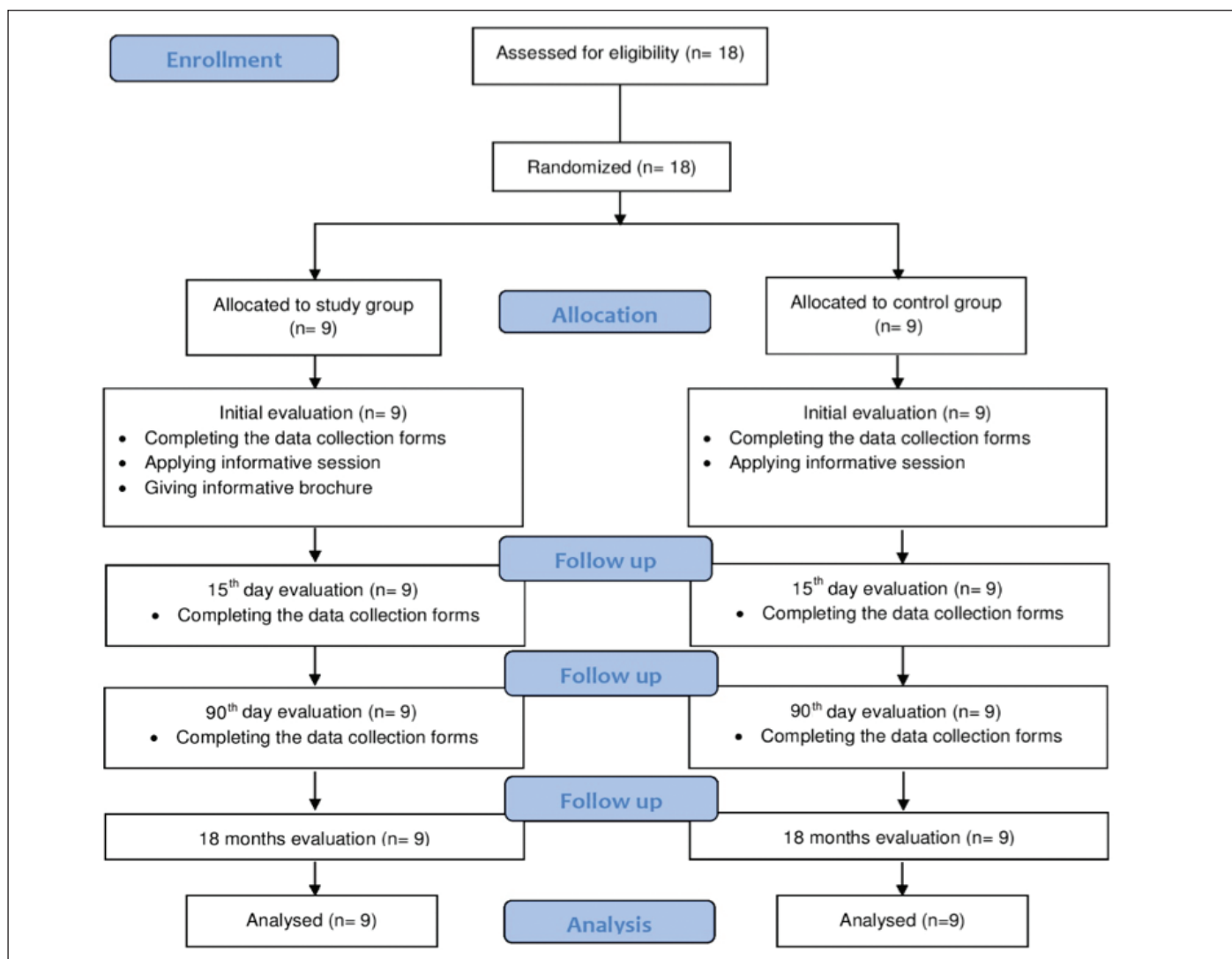


Figure 1. The CONSORT flow diagram.

were read aloud to the mother, and the answers were filled in by the researchers to ensure that the mothers understand the phrases. During their hospital stay, a 15-minute informative session about VP shunt infections and preventive measures was carried out with mothers by the researcher (SÜ). The mothers were allowed to ask questions, and their questions were answered. After the session, the “informative brochure” prepared by the authors were given to mothers in the study group as printed education material. No “informative brochure” was given to the control group.

Fifteen days and 90 days after the 15-minute informative session, mothers both in the study and control group were interviewed on the phone by researcher (SÜ) to assess the effectiveness of the informative session and the brochure. Mothers completed the “questionnaire on information about preventive measures regarding VP shunt infections” and the

“questionnaire on application of preventive measures regarding VP shunt infections” on the phone during both of the follow up interviews. The CONSORT flow diagram of this study is presented on Figure 1.

Ethical Considerations

The study was approved by the university research ethics committee (approval number: 06/02 on 30.03.2016), and the hospital directory (approval number: 79056779-600 on 05.04.2016). The volunteering participants gave oral and written consent. The participants were informed that the information they revealed would only be used for research purposes, and that their privacy would be maintained. The study was carried out in accord with Helsinki Declaration, National Good Clinical Practices Guideline and Research Ethics Committee Regulations.

Questionnaire on information of preventive measures regarding VP shunt infections	
1	Child should be bathed at least twice a week and body hygiene should be maintained.
2	Redness, swelling, and tenderness on the shunt trajectory indicates infection
3	There is no need to check for redness, and swelling on the shunt trajectory daily.
4	Child can have a bath after the sutures are removed.
5	Child should be consulted a physician immediately when the infection signs and symptoms are observed.
6	Cotton can be used while cleaning the surface of sutures.
7	Oily creams or powder can be applied on the surface of the sutures.
8	Hands should be washed after changing the diaper of the child or after helping the child with cleaning up after using the wc.
9	There is no need to measure the body temperature of the child when suspected of fever.
10	Abdomen should be observed daily for any tension or bloating.
11	Child can sleep on the shunt valve area for more than 2 hours.
12	Hands should be washed before dressing surgical wound
13	Being in a crowded, polluted environment does not pose a risk of infection for child.
14	The cleanliness of the child's clothes prevents the development of infections.
15	There is no need to observe surgical wounds daily
16	Child should be allowed to sleep in the same position every day.
17	Child's clothes such as beret, hat and underwear should be ironed.
18	Child should be kept away from people who have influenza and flu.
19	Child's head circumference should be measured once a week./ If the child complains about frequent and persistent headache, doctor should be consulted
20	Contaminating abdominal sutures should be avoided while changing the diaper or while helping cleaning up after the child uses wc
21	Healthy and balanced nutrition of the child helps to prevent infections.
22	Tooth decays do not cause infections.
23	Child should be consulted a physician immediately in case of any infection with fever (throat infection, urinary tract infection, etc.).
24	The surface of the gauze placed on the sutured area should not be touched if the dressing is changed at home.
25	Weight loss of the child increases the risk of shunt infection development.
Questionnaire on application of preventive measures regarding VP shunt infections	
1	I bathe my child at least twice a week to maintain body hygiene.
2	I daily control and check for infection signs on the shunt area.
3	I do not use cotton while dressing surgical wounds.
4	I do not apply oily creams or powder on the surface of the sutures.
5	I wash my hands with soap after changing the diaper of the child or helping cleaning up after my child uses wc.
6	I daily measure the body temperature of my child.
7	I observe the abdominal area daily if there is any tension or bloating.
8	I do not let child to sleep on the shunt valve area for more than 2 hours.
9	I wash my hands before touching surgical wound.
10	I prevent my child from getting in a crowded, and polluted environment.
11	I keep my child's clothes clean.
12	I daily control and check for the infection signs on the catheter insertion site on the abdominal area.
13	I iron my child's clothes such as beret, hat and underwear.
14	I keep away my child from people who have influenza and flu.
15	I measure my child's head circumference once a week.
16	I avoid contacting on the abdominal sutures while changing the diaper or help my child clean up after wc.
17	I ensure healthy and balanced nutrition of my child to prevent infections.
18	I check my child's teeth for any decays.
19	I consult a physician immediately in case of any infection with fever (throat infection, urinary tract infection, etc.).
20	I do not touch on the surface of the gauze placed on the sutured area while changing the dressing at home.

Figure 2. Questionnaires on information and application of preventive measures regarding VP shunt infections. Note: The grey lines show the negative sentences.

Data Analysis

Data were analyzed in terms of percentage, arithmetical mean, and standard deviation. Kolmogorov-Smirnov normality test is applied to confirm normal distribution of patient data. Data were statistically analyzed using chi-square, paired samples t-test, and Mann Whitney-U test on SPSS (Statistical Package for Social Sciences for Windows, Version 20.0). Statistical significance was set at $p < 0.05$.

To analyze the content validity of the questionnaires, the Content Validation Index (CVI) was calculated based on the

relevance score of the expert responses using a four-likert rating scale (not relevant= 1, somewhat relevant= 2, quite relevant= 3, very relevant= 4). The CVI for each item was found as +1.00 as having acceptable relevancy (for five experts expected CVI > 0.99).

The G-Power (G Power 3.1 9.2, Kiel, Germany) program was used for post-hoc power analysis to determine if the sample size is enough to detect significant effects. The statistical power was calculated as 0.47 (effect size $d = 0.8$, α err prob= 0.05, sample size= 18).

Table 1. Descriptive information on VP shunted children and their mother (n= 18)

Descriptive Features	Study group (mean ± SD)	Control group (mean ± SD)	Statistical values
Age of the mother (years)	31.33 ± 7.33	32.88 ± 6.62	t= -0.472
Age of the child (months)	52.22 ± 47.36	63.55 ± 73.89	p= 0.643* t= -0.387 p= 0.704*
Number of shunt surgeries	1.55 ± 0.72	2.00 ± 0.86	t= -1.180 p= 0.255*
	n (%)	n (%)	
Education of the mother Elementary school	9 (100)	9 (100)	-
Previous education of the mother on VP shunt related infections			
Yes	0 (0)	0 (0)	-
No	9 (100)	9 (100)	
Sex of the child			
Female	2 (22.2)	3 (33.3)	p= 0.500**
Male	7 (77.8)	6 (66.7)	
Time of birth			
Term	8 (88.9)	7 (77.8)	p= 0.500**
Preterm	1 (11.1)	2 (22.2)	

* Paired samples t test, ** Fisher's exact test.

Results

Mean age of the mothers participated in the study group was 31.33 ± 7.33 years, and mean age of the children with VP shunts were 57.88 ± 60.49 months. All mothers had graduated from elementary school. None of them had been previously educated about VP shunt related complications. There were no significant differences in VP shunted children's and their mother's demographic features between the study and the control group. Detailed information about the demographic features of mothers and children is presented in Table 1.

Information level of the mothers was evaluated based on the scores the mothers achieved on the "questionnaire on information about preventive measures regarding VP shunt infections".

There was no statistical difference in the initial scores the mothers achieved in the study group and the control group (U= 27.500, p= 0.246). Mothers both in the study and control group achieved significantly higher scores 15 and 90 days after informative session when compared to their initial evaluation. When we compared the difference between the study and the control group 15 days after the informative session, there was no statistical significance (U= 20.500, p= 0.063). However, 90 days after the informative session the mothers in the study group performed statistically higher scores than the mothers in the control group (U= 8.000, p= 0.019) (Table 2). Hypothesis 1 was supported.

The mothers' application levels of preventive measures on VP shunt infections was evaluated based on the scores on the "questionnaire on application of preventive measures regarding VP shunt infections".

Fifteen days and 90 days after the informative session both the control and the study group achieved higher scores than the initial evaluation (p< 0.05) (Table 2). There was no statistical difference in the initial scores the mothers achieved in the study group and the control group (U= 35.000, p= 0.622). Furthermore, there was no statistical difference between the groups both 15 days and 90 days after the informative session (U= 37.000, p= 0.750; U= 30.000, p= 0.320, respectively) (Table 2). Hypothesis 2 was not supported.

Discussion

HCP in pediatric patients is a relatively common entity in pediatric neurosurgery practice. The treatment and long-term management of HCP patients are economically exhaustive and clinically labor-demanding because of the high frequency of complications both in short and long term. Although endoscopic techniques are becoming increasingly popular, it has not completely replaced the use of VP shunt placement. VP shunt insertion surgery is still widely used in HCP treatment. In spite of the progress in the VP shunt system technology (antibiotic coated shunts, etc), VP shunt related infections remain to be the most frequent complication in pediatric patients.

Table 2. Distribution of the scores mothers achieved on information and application questionnaires (n= 18)

	Groups	Initial evaluation	15 th day evaluation	90 th day evaluation	Statistical values*
Information score	Study	19.77 ± 3.38	24.33 ± 1.11	24.44 ± 1.01	p0-1= 0.006 t= -3.682 p0-2= 0.006 t= -3.677 p1-2= 0.347 t= -1.000
	Control	18.22 ± 2.63	23.00 ± 1.73	23.00 ± 1.50	p0-1= 0.001 t= -4.793 p0-2= 0.001 t= -4.932 p1-2= 1.000 t= 0.000
Statistical values**		p= 0.246 U= 27.500	p= 0.063 U= 20.500	p= 0.019 U= 8.000	
Application score	Study	14.44 ± 3.50	18.55 ± 1.01	17.66 ± 2.69	p0-1= 0.003 t= -4.203 p0-2= 0.002 t= -4.566 p1-2= 0.500 t= -0.707
	Control	13.11 ± 3.14	17.66 ± 2.69	17.66 ± 2.69	p0-1= 0.002 t= -4.428 p0-2= 0.002 t= -4.428
Statistical values**		p= 0.622 U= 35.000	p= 0.750 U= 37.000	p= 0.320 U= 30.000	
* Eşleştirilmiş gruplar t testi. ** Mann-Whitney U testi.					

In this study, although a small sample of mothers was included, we uncovered the fact that revision surgery patient or not, none of the mothers was previously informed about VP shunt infections. This is a valuable observation for professionals dealing with pediatric VP shunt surgery in developing countries. We believe that this calls attention to improve parent education in healthcare institutes at least, but not the least in Thrace region of Turkey.

Mothers were willing to get information about their children's health problem. Hence, both the study and the control group achieved significantly higher scores after a 15-minute informative session. Furthermore, giving the mothers informative brochures significantly increased the level of information in the study group at 90th day evaluation. We were happy to observe the instances that mothers kept the brochures we gave in their purses, at their child's bedside, etc., and that mothers acknowledged referring to the brochure frequently to give their child best care. We believe that giving mothers printed education materials keep the mothers' interest of getting further information about their children's health conditions, and serve as a brief guidance reference (7,13,29). Therefore, it is a cheap and effective means of preventing

avoidable causes of VP shunt infections, and early recognition of infections by parents (29).

In our study, 15-minute oral informative session alone significantly increased the evaluation scores of the mothers' application skills of preventive measures regarding VP shunt infections both in the study and the control group. There was no statistical difference in applying the given information levels of mothers between the study and the control group on 15th and 90th days of evaluation. The mothers included in the study had elementary formal education and no previous guidance about VP shunt complications and their preventive measures. We assumed that although single brief informative session was effective in increasing their awareness of infection prevention measures, it takes time and repeated education to transform given information to practice. There are reports supporting the view that printed education materials boost the caregivers' awareness of infection prevention measures (30,31). They also support the coping mechanism of families having children with chronic care needs (26). In a review on day care of VP shunted children, informative internet sites recommended by physicians were also reported to be effective in educating parents about recognizing and avoiding VP shunt related problems (32).

In our study, we observed that none of the 18 mothers included in the study were previously informed about infection recognition and prevention measures. Oral informative sessions significantly increased the level of information about preventing VP shunt infections and their behavior patterns in the short (15 days) and the long term (90 days) both in the study and the control group of mothers. Giving the mothers informative brochure handouts significantly increased the mothers' level of information in the long term. We concluded that giving mothers printed informative brochures keeps their interest and their motivation of learning about their children's health conditions alive.

In conclusion, oral information and/or printed informative brochures on preventing VP shunts are effective in educating mothers of VP shunted children, and printed informative brochures may be more effective in changing mothers' child care practices on avoiding infections.

Study Limitations

There are some limitations in the study. First of all, the number of the study and the control group samples are low. Secondly, although the study is randomized and controlled, it is not blinded. Thirdly, all the caregivers of the VP shunted children were their mothers, so the results of this study cannot be generalized to children with fathers or state employed caregivers as their primary caregiver.

Conclusion

We strongly suggest surgical nurses and other healthcare professionals at neurosurgery departments give the mothers of VP shunted children printed informative brochures on their discharge from the hospital, and organize informative sessions at regular intervals to improve the mothers' level of information, and their ability to apply them in daily practice to prevent avoidable causes of VP shunt infections.

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Ethics Committee Approval: The ethical approval for this study was obtained from the Ethics Committee of Trakya University Medical Faculty (Decision number: 06/02, Date: 30.03.2016)

Informed Consent: The verbal and written informed consent was taken from the children's mothers.

Peer-review: Externally peer-reviewed.

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