

Health Education Intervention for Patients Undergoing Placement of Percutaneous Nephrostomy Tube: A Randomized Controlled Trial

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Abstract

Purpose: The purpose of this study was to evaluate the economic impact (cost) on patients with a percutaneous nephrostomy (PCN) tube.

Design: Randomized controlled trial.

Subjects and setting: The sample comprised 178 patients recruited between May 2017 and April 2019. The study setting was the Marqués de Valdecilla University Hospital located in Cantabria on the northern coast of Spain. Data were collected in the hospital's Radiology Department.

Methods: Participants were randomly allocated to two groups; an intervention group received an educational intervention that specifically addressed living with a percutaneous nephrostomy tube, and a control group that received standard instruction. The intervention group received the educational intervention twice, before placement of the nephrostomy and at first tube change (6 weeks later). The main outcome variables were economic impact of the PCN, defined as unscheduled or urgent visits and health care costs related to PCN tube placement.

Results: When compared to control group subjects, participants who received the educational intervention had fewer urgent (unscheduled) visits (1.9 vs. 4.0; $p=0.004$) and lower direct and indirect health care costs (reflecting a savings of €5.277 euros, approximately \$6.257 US dollars).

Conclusions: The health education intervention reduced costs associated with these additional visits when compared to patients receiving standard postprocedural education.

Key Words: Percutaneous Nephrostomy; Health Education; nursing education, Cost Analysis; Anxiety; Quality of Life.

Introduction

Placement of a percutaneous nephrostomy tube diverts urine from the renal pelvis into a collection bag placed on the patient's abdomen. The first case was described by Goodwin in 1955.(Goodwin, Casey, & Woolf, 1955; Ogg, Saxton, & Cameron, 1969). A patient is placed in a prone position and local anesthesia is administered at the puncture site.(Garry & Bivens, 1988; Segura, 2002) A needle is inserted into the flank via ultrasound guidance and subsequent radioscopic imaging. A small incision is made in the flank and a trocar is placed into the renal pelvis, followed by insertion of guide wire through the trocar. A nephrostomy tube (pig tail type catheter) is then inserted over the guide wire and advanced into the renal pelvis, enabling drainage of urine. Urine is collected in a drainage bag worn on the flank.

Self-care associated with a nephrostomy tube includes regularly emptying the drainage bag, routine site care (cleansing the insertion site weekly), bathing with a nephrostomy tube in place, and undergoing regular nephrostomy tube replacement, we advocate changes every six weeks, to prevent blockage and reduce the risk of infection.(Cofield, 1995) Clinical experience indicates that many patients experience blockage or leakage around the nephrostomy tube requiring urgent replacement. We previously evaluated health related quality of life, anxiety and pain in a group of 150 patients managed by PCN.(Fernandez-Cacho & Ayesa-Arriola, 2019) We found that presence of a PCN significantly reduced quality of life, created mild levels of anxiety upon initial tube placement that was alleviated with subsequent tube placement, and reduction in tube related pain when the tube remained in place for 6 weeks or longer.

Given inevitable limitations in health care resources, cost analysis has risen as a means to determine direct and indirect costs of procedures.(Alvarez, 2019) Findings from these analyses are used to optimize use of health care resource and reduce costs whenever possible while maintaining quality of care. (Florido Alba, Garcia-Agua Soler, Martin Reyes, & Garcia Ruiz, 2019; Lopez-Casasnovas, 2014; Raymond, Darsaut, & Roy, 2019)

Patient education is a potentially powerful method of reducing the cost of health care while maintaining quality.(Ackermann, 2019) The World Health Organization describes health education as a fundamental element for managing multiple health challenges including acute exacerbations of chronic conditions. Education assists patients to understand the causes and course of a chronic condition,

and to develop coping strategies or lifestyle changes to prevent complications related to the chronic condition.(Alleyne & Jumaa, 2007; Hallock, 2019)

The Vascular Radiology Service at the Marqués de Valdecilla University Hospital in northern Spain has performed approximately 2,231 nephrostomies since 1995, and we perform approximately 150 PCN tube placements annually. The purpose of this study was to evaluate the effects of a health education intervention for patients undergoing placement of a percutaneous nephrostomy (PCN) tube. This study expands on our previous research into patients living with a PCN. Specifically we hypothesized that subjects receiving a health education intervention will be less likely to require urgent PCN tube changed and associated costs when compared to subjects receiving standard post-procedure education.

Methods

We completed a parallel group, non-blinded randomized controlled trial. Data were collected at the Department of Radiology of the University Hospital Marqués de Valdecilla (UHMV) in Santander, located in northern Spain. Data were collected between 2017 and 2019. Inclusion criteria were: ≥ 18 years of age, undergoing placement of a PCN tube (Spanish Society of Medical Radiology, SERAM code 72200), and attended at least one planned PCN tube change (SERAM code 72251). Exclusion criteria were prior history of PCN tube placement, removal of the PCN tube before first scheduled change, living with an ostomy, and deemed unable to participate in the study due to cognitive impairment. Patients provided verbal and written informed consent. Study procedures were reviewed and approved by the Ethics and Clinical Research Committee of Cantabria (Approval number 2015.099). Patients were selected by convenience sampling. The assignment to the intervention group or control group was carried out through a random number table created with the statistical program EPIDAT 3.1 (Epidata Software, Odense, Denmark).

Outcome Variables

The main outcome variables were economic impact of PCN tube use; defined as unplanned (urgent) visits for PCN tube changes and direct health care costs related to management of the nephrostomy tube. In our radiology service PCN tube changes are scheduled every 6 weeks. For purposes of this study, any patient visit requiring a PCN tube change because of a complication (accidental extrusion of the PCN tube,

obstruction of the tube with flank pain, or signs of urinary tract infection) was deemed urgent.

Data Collection

Direct healthcare costs related to PCN tube care are based on review of costs identified in previous studies. (Gonzalez Lopez et al., 2014; Mayoral-van Son et al., 2018) These were nurse time required to deliver the educational intervention, travel from the participant's home to hospital for care (based on distance in kilometers), admission to the emergency service, replacement of the nephrostomy tube, time of room and materials used, days of hospital stay in those patients who have required admission, as well as the different tests that may have been performed during their admission (analytical, image tests as well as percutaneous nephrostomy). We excluded indirect costs such as loss of income or people taking sick leave. The rates we applied are published in the last Public Price Order of the SCS Health Services (BOCN° 248 of December 29, 2017) by Order SAN / 35/2017. The fees we calculated were taken from the fees charged by the Cantabrian Health Service (CHS) centers.

Health Education.

The health educational intervention/health (HE) lasted approximately 30 minutes; instruction was provided to the study participant and family or caregivers. The intervention occurred during a pre-procedural nurse consultation. Participants were given verbal instruction regarding care of the PCN and drainage system, and the care of their probes, including dietary and fluid intake avoiding tight clothing, sudden movements, sleeping on the side of the probe. They were taught signs and symptoms of tube blockage such as flank pain, fever, and reduced urine output from the nephrostomy tube, along with signs of symptoms of urinary tract infection such as fever. Participants were counseled about physical activities such as participation in various sporting activities including swimming, and sexual intimacy. In addition, they were shown a nephrostomy tube and its different parts and the importance of each of them was explained. Finally, participants were given an educational brochure, links to pertinent websites, and videos for understanding and care and they provided along with an email address for follow up questions.

The control group received information related to the catheter implantation process and basic care. They did not receive additional written information.

Study Procedures

Data were collected prior to PCN tube placement and during the first planned tube change (approximately six weeks after implantation). During baseline data collection, sociodemographic and pertinent clinical data were collected, and the participant was randomized to intervention or control group. Information from the health educational intervention was reviewed upon the first scheduled PCN tube change.

The economic impact of PCN tube placement was calculated based on planned versus urgent visits over 12 months for each group. Direct costs included the price of the health intervention was quantified, along with admission to the emergency department, tube changes, admission to hospital if necessary, and tests (analytical, ultrasound or new nephrostomy) via a review of the participant's medical records.

Sample Size Calculation

The sample size was calculated taking into account the average annual incidence of nephrostomies in Cantabria in the last 10 years. For the sample size calculation GRANMO program version 7.12. April 2012 was used. For assessment of differences between two means of independent samples with an $\alpha=0.05$, power of 0.20 (80%), a common standard deviation of 1 and a minimum detectable difference of 0.5 and a intervention group / control group ratio of 1, 57 patients in each of the two groups were needed.

Data Analysis.

The data were analyzed with the Statistical Package for Social Science, version 19.0 (SPSS Inc., Chicago, IL, USA). Kolmogorov-Smirnov was used to verify whether the variables had a normal distribution. In cases of non-normality, non-parametric tests were used, such as U-Mann Whitney for categorical variables and chi-square for dichotomous variables. Cohen's d test (r) was carried out with the values indicated above. The results were considered significant for p values <0.05 .

Results.

The group of patients who had NOT received health education had to attend unscheduled 32 times a year. Analyzing economically the consumption of health care resources and taking into account direct health costs (26.425 euros) and indirect costs (274 euros), the total cost of the group that did not receive health education was 26.699 euros / year. In the group that received EpS, the direct healthcare costs (19.680 euros) and the indirect costs (92 euros) have meant a total of 21,422 euros / year, taking into account the 24 times they have had to come urgently. The cost of health education was also taken into account

in the 66 patients who had not come urgently. In summary, the patients who did not receive the educational intervention had a ratio of 1.24 times / more consumption of economic resources (human and material) than the group that received education. The results are shown in TABLE 3.

Direct healthcare costs:

Healthcare costs come from the collection of all costs related to a Functional Unit X applied to the activity of any kind that they carry out.

In the case of the Emergency and the Imagin test, the rates are published in the last Public Price Order of the Health Services of the SCS (BOC No. 248 of December 29, 2017) by Order SAN / 35/2017. These rates come from the application of the cost system of the analytical accounting of the SCS centers. *Emergencies.* In the case of emergencies, all the cost of personnel, warehouse consumption, pharmacy consumption, depreciation of its equipment and costs of the hospital structure, are taken at the cost of its activity. In the case of urgency, the information system does not discriminate by type of urgency, so the entire cost is divided by the total number of emergencies performed. Emergencies NOT admitted (cost of the emergency itself) and RECEIVED (whose cost is added to the cost of the hospitalization process). *Cost of the Imaging test.* Here the cost is quantified according to the SERAM; (Spanish Society of Medical Radiology) that has published a catalog of all its tests, and applies a different weighting or complexity index, according to the theoretical cost of each one. This index of complexity multiplied by the average occupation time of the room will result in the price of each procedure. *Hospitalization.* In this study, it has been taken into account that five patients who have come urgently due to an accidental exit of the catheter, have had to be admitted to services such as Urology, High resolution hospital unit or monitored emergency room due to the need to schedule a new nephrostomy due to the inability to reposition the catheter. In these cases, the usual tests to which they are subjected, such as an analysis (hemogram and biochemistry), as well as an ultrasound of the renal system, have also been taken into account. *Unassisted medical transport.* Finally, it has been taken into account that five patients have required non-urgent medical transport with a cost per service of € 112.45.

Non-health direct costs:

As direct non-healthcare costs, the distance in kilometers (2.033 km) from the patient's home to the HUMV emergency service has been taken into account. This value has been multiplied by a factor of € 0,18 / kilometer to obtain the final result.

Table 4 shows the description of both direct healthcare and non-healthcare costs:

Discussion. Receiving health education is a saving in economic terms for the Health System. Those patients who received an EpS about their process attended less frequently on an unscheduled basis (that is, urgently) due to problems related to the nephrostomy tube, which translates into less consumption of healthcare resources. This result coincides with other studies of a similar nature in which health education improved skills and catheter management (Mackay et al., 2018). Other studies consulted (Abad-Corpa et al., 2013; Acharya, Bedanta Mishra, Ipsita, & Azim, 2019) also confirm that a health education by nursing helps improve perception in the quality of life at the same time as saving in health resources.

Strength and limitations. The main strength of this work lies in the randomization and the size of the sample, as well as in the absence of studies after the extensive bibliographic review carried out on the economic impact of patients with nephrostomies. The main limitation lies in the fact that no distinction has been made between patients with a single tube or patients with bilateral nephrostomy, since the latter may present a greater number of complications with the tubes. Another of the main limitations is that we have followed the guidelines of the Spanish Society of Vascular and Interventional Radiology (SERVEI) which determine that catheters must be changed every six weeks. Other authors such as Young and Leslie recommend that except during pregnancy where catheters should be changed every 4 to 6 weeks for most other patients, routine changes every 3 months are generally suggested.

Conclusions

A structured health education intervention reduced cost associated with PCN tube by reducing the number of times urgent tube changes. Based on these findings we recommend incorporate economic analysis as mandatory in all health interventions carried out with the purpose of incorporating procedures that are not only based on the best possible scientific evidence but are also cost-effective.

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TABLE 1. Comparison of Baseline Sociodemographic and Pertinent Clinical Characteristics of Participants Based on Group

	CG*		IG*		Total				
	N=88		N=90		N=178				
	Mean	SD	Mean	SD	Mean	SD	Statistic	Value	p
Age (years)	62.0	15.8	67.2	14.3	64.6	15.3	t	-2.280	0.024
	N	(%)	N	(%)	N	%	Statistic	Value	p
Age							Fisher	7.376	0.060
18 to 35	4	4.5	2	2.2	6	3.4			
36 to 45	6	6.8	4	4.4	10	5.6			
46 to 65	41	46.6	28	31.1	69	38.8			
>65	37	42.0	56	62.2	93	52.2			
Sex (Males)	49	55.7	63	70.0	112	62.9	χ^2	3.910	0.048^
Employment status							Fisher	8.784	0.025^
Working	2	2.3	3	3.3	5	2.8			
Leave due to Illness	39	44.3	21	23.3	60	33.7			
Unemployed	6	6.8	8	8.9	14	7.9			
Retired	41	46.6	58	64.4	99	55.6			
Civil status							Fisher	3.205	0.375
Single	7	8.0	11	12.2	18	10.1			
Married	65	73.9	61	67.8	126	70.8			
Separated	5	5.7	2	2.2	7	3.9			
Widowed	11	12.5	16	17.8	27	15.2			
Living arrangement (Living alone)	7	8.0	11	12.2	18	10.1	χ^2	0.892	0.345
Education							χ^2	4.605	0.203
No formal education	8	9.1	13	14.4	21	11.8			
Primary school	32	36.4	33	36.7	65	36.5			
Secondary school	25	28.4	31	34.4	56	31.5			
University	23	26.1	13	14.4	36	20.2			
Engage in Recreational Activities Outside Home							χ^2	0.973	0.808
None	18	20.5	20	22.2	38	21.3			
<2 times/week	23	26.1	20	22.2	43	24.2			
2 to 5 times per week	29	33.0	27	30.0	56	31.5			
> 5 times / week	18	20.5	23	25.6	41	23.0			
Psychotropic medication							χ^2	5.105	0.164
Anxiolytics	24	27.3	21	23.3	45	25.3			
Antidepressants	7	8.0	4	4.4	11	6.2			
Other medications	39	44.3	54	60.0	93	52.2			
Do not take medication	18	20.5	11	12.2	29	16.3			
Taking any Psychotropic medication (Yes)	31	35.2	25	27.8	56	31.5	χ^2	1.145	0.285

* Abbreviations: CG = control group (received standard teaching), IG = intervention group (received health education intervention)

^ = p value <0.05

TABLE 2. Between Group Cost Comparisons

	Control Group N=88		Intervention Group N=90		Total N=178		Statistic	Value	p
	N	(%)	N	%	N	%			
Urgent (unscheduled) PCN tube changes							χ^2	1.940	0.1
Yes (At least 1 time)	32	(36.4)	24	(26.7)	56	(31.5)			
No	56	(63.6)	66	(73.3)	122	(68.5)			
Outcome of unscheduled visit							FE	1.646	0.2
Probe is changed	29	(90.6)	18	(78.3)	47	(85.5)			
Probe is unblocked or repositioned	3	(9.4)	5	(21.7)	8	(14.5)			
Transport to hospital							FE	1.171	0.3
Drove their own vehicle	28	(87.5)	23	(95.8)	51	(91.1)			
Transported by ambulance	4	(12.5)	1	(4.2)	5	(8.9)			
Required Hospital Admission							FE	1.882	0.2
No	27	(84.4)	23	(95.8)	50	(89.3)			
Yes	5	(15.6)	1	(4.2)	6	(10.7)			

Abbreviations: FE = Fisher's Exact test

TABLE 3. Cost-effectiveness analysis of receiving a Health Education

Options	Cost (€)			Cost / benefit ratio
	YES. They come urgently		NO. They do not come urgently	
	Direct healthcare costs (€)	Direct non-health costs (€)	Direct healthcare costs (€)	Ratio
Not receive Health Education	26425	274	0	1.24
		Total cost: 26.699		
Yes. Receive Health Education	19680	92	1650	Total saving 5.277 €
		Total cost: 21.422		

TABLE 4. Description of the sanitary and non-sanitary COSTS applied.

Expense Vectors	Description	Cost measure	Economic amount (€)
Emergencies	Out-of-hospital emergencies	average unit cost	165
SERAM code 72251	Replacement drainage catheter	average unit cost	520,80
SERAM code 609883	Long-term nephrostomy drainage catheter with thread	average unit cost	75,13
SERAM code 72200	Percutaneous nephrostomy	Rx room occupancy time (30 minutes)	664,15
Laboratory	Hemogram and biochemistry	average unit cost	29
Nurse	Health Education	average unit cost (€/hour)	25,35
Hospitalization	Urology	average unit cost	292,59
Hospitalization	High Resolution Hospital Unit	average unit cost	217,61
Hospitalization	Emergencies	average unit cost	231,66
Unassisted medical transport (medicalized)		unit cost	112,45
SERAM code 71346	Urological ultrasound	average unit cost	39,30

