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# **ORIGINALES**

# Influence of continuous subcutaneous insulin infusion in the control of type 1 diabetes in children

Influencia de la infusión contínua de insulina subcutánea en el control de la diabetes tipo 1 en niños

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#### ABSTRACT:

Diabetes mellitus type 1 is the most frequent endocrinological chronic disease during childhood. Self-care and the knowledge about this disease are the facts that are directly related to the reduction of health costs as well as the improvement of the life quality. The continuous subcutaneous insulin infusion pump (CSII) emulates the normal physiology and eliminates the need of continuous injections, remaining to determinate if this treatment contributes positively to the self-control of the diabetes.

**Didactic Materials and Methods:** Retrospective cohort study. The data collection is made by a survey based on the NOC's "Conocimiento: control de la diabetes" (Knowledge: diabetes control) and "Autocontrol diabetes" (Diabetes self-care) of all the children with continuous subcutaneous insulin infusion pump (CSII) at the health area number 2 from the Region of Murcia, as well as to their homologous with multiple injection. To draw the results, the statistic program SPSS v21, was the one used.

**Results:** The study subjects have an average age of 11 years, being the 60% male and 40% female. Statistical significance was not obtained concerning to the level of knowledge, self-control and HbA1c values between the exposed group (CSII) and nonexposed group (multiple injection), except for the diet monitoring, where there was obtained a connection with the CSII treatment (p=0.037). The age was also related to a knowledge increasement (p=0.001).

**Conclusion:** Households units with children under 7 years with multiple injections should have a more intense training in order to reduce the anxiety and doubts of the parents.

Keywords: insulin pump, paediatrics, self-care, knowledge, diabetes mellitus type 1

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#### **RESUMEN:**

La diabetes mellitus tipo 1 es la enfermedad crónica endocrinológica más frecuente en la edad pediátrica. El autocuidado y el conocimiento sobre la enfermedad están relacionados con la reducción en costes en salud y con una mejora en la calidad de vida. La bomba de infusión s continua de insulina subcutánea (ICIS) imita la fisiología normal y elimina la necesidad de inyecciones repetidas, quedando por determinar si este tratamiento favorece el autocontrol de la diabetes.

**Material y Métodos:** Estudio de Cohortes retrospectivo.La recogida de datos se realiza a través de un cuestionario basado en los NOC "Conocimiento: control de la diabetes" y "Autocontrol diabetes" a todos los niños con ICIS del área II de salud de la Región de Murcia, así como a sus homólogos de inyecciones múltiples. Para la determinación de resultados se utilizó el programa estadístico SPSS v.21.

**Resultados:** Los sujetos del estudio tienen una edad media de 11 años, siendo 60% hombres y el 40% mujeres. No se obtuvieron diferencias estadísticamente significativas con respecto al nivel de conocimientos, autocontrol y valores de HbA1c entre el grupo de expuestos (ICIS) y no expuestos (inyecciones múltiples), excepto en el siguimiento de la dieta, donde si se obtuvo relación con el tratamiento con ICIS (p=0.037) . La edad también se relacionó con un aumento en los conocimientos (p=0.001).

**Conclusión:** Las unidades familiares con menores de 7 años con inyecciones múltiples, deberán tener una formación más intensa sobre todo dirigida a disminuir la ansiedad y dudas de los padres.

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Palabras clave: bomba de insulina; pediatría; autocuidado; conocimientos; diabetes mellitus tipo 1

#### INTRODUCTION

The diabetes mellitus (DM) has turned into one of the main health problems of our society due to it's high prevalence and costs <sup>(1)</sup>. At a clinic level, the DM is a group of diverse processes whose common characteristic is the hyperglycemia, due to a deficiency in the insulin secretion. This imperfection is the result of the destruction of the pancreatic beta cells due to an autoimmune origin in the DM type 1 (DM1), or a gradual resistance to the adjacent action of the insulin, with or without deficit of the secretion, in the DM type 2 (DM2) <sup>(2)</sup>.

It's estimated that in 2012, 1.5 million people died as a direct consequence of this disease <sup>(3)</sup>. Because of that, World Health Organization's (WHO) perspectives point that the diabetes will be the seventh mortality cause in 2030, year in which the number of people with diabetes will be 366 millions. This is the reason why some authors start to consider this disease epidemic <sup>(4)</sup>.

Concerning to childhood and adolescence, the diabetes mellitus type 1 (DM1) constitutes over more of the 90% of the cases diagnosed during these phases. This circumstance has supposed the development of 2 projects by part of the OMS: el DIAbetes MONDiale (DiaMond), and the study EURODIAB, whose goal is the development of health records based in population studies in order to monitor the trends of the disease in children and teenagers under 15 years old. At the moment these projects have confirmed through their epidemiological studies the increase of the DM1 incidence in this age group, and predict that between 2005 and 2020 the new cases of diabetes type 1 in European children under 5 years will be double, and that the prevalence of the cases in children under 15 years old will increase up to the 70% (5,6).

Taking into consideration all these records and knowing that there aren't any known interventions to prevent the start of the DM1, it's fundamental the availability of

effective treatment regimes. So, in order to maintain the glycemic control it's used the insulin replacement, which can be through multiples injections or continuous infusion. The continuous subcutaneous insulin infusion includes the union of the patient to an insulin pump, through an external catheter. The pump it's set in a customized way, by this mean the insulin is administrated in function of the needs of the patient, thus this one activates the dose to provide to the meals and correct the glycemic variation <sup>(6)</sup>. Nowadays the continuous subcutaneous insulin infusion pump (CSII) it's considered as the optimum method of insulin administration, because emulates the activity of the pancreas, ensures a precise dosage and also, offers a high level of comfort <sup>(7)</sup>. As a result, this is the most physiological insulin administration method available, being able to face the change of the insulin needs during the childhood and adolescence <sup>(8)</sup>. In addition, the consensus statement between pediatricians and diabetologists of 2007, recommended the pump therapy with childs and adolescents that may have a non optimum control of the diabetes, a insulin regime that may commit the life style and wide fluctuations in blood of the HbA1c <sup>(9)</sup>levels.

According to the American Diabetes Association and the International Society of Pediatric and Adolescence Diabetes (ISPAD) is recommendable an objective glycosylated hemoglobin (A1c) of 6,5%-7,5% (48-59 mmol/mol) for the most of the people with DM1. Nevertheless, data published recently, shows that only the 30% of male and 29% of females of age <15 years old reach this aim (10). Considering these values, aleatory controlled studies, systematic revisions and cohort studies have revealed that the pediatric patients with insulin pumps have a inferior HbA1c compared to the patients that use the daily multiple injections, also they have more probabilities to achieve the HbA1c goals than the ones using injections, as well as less hypoglycemia and hyperglycemia less severe<sup>(10)</sup>. The severe hypoglycemia is defined in the studies as the one where emerges the need of assistance of other person for it's recovery or that induces coma or an epileptic seizure. Well then, the data indicates that the CSII can be better than the multiple injections (IM) to reduce the incidence of severe hypoglycemic episodes. Regardless the CSII and the IM have been successful methods of the treatment with insulin, the CSII can be a superior option because permits emulate, in a more elaborately way, the normal physiology and eliminates the need of repeatedly injections. The CSII provides a more effective way to dispense insulin into the blood, decreases the threat of hypoglycemic events and may be advantageous for the patients that have difficulties to accomplish the regime of multiple injections (6).

Despite all the advances achieved with the development of these new therapies, the diabetes type 1 still has a huge impact over the lifestyle of the patient and it's family. The economic burden is high for the family, the healthcare area and the society in general, because the healthcare assistance costs do not only take place in the moment of the diagnosis, but also with the future hospitalisations <sup>(6)</sup>. In addition the management of the diabetes is complex, specially during the childhood and adolescence. The families must deal with healthcare tasks, cognitives demands and also face the logistic burdens. This reality turns self-care in a effective method to decrease the health costs, as well as a reduction of the number of hospitalisations and the emergency consultations. This in turn, provides a judicious medication use and a better relation between the healthcare professional and the patient <sup>(11)</sup>.

Inside the healthcare area, the nursing professionals have large competences in the promotion of the user's self-care. The self-care is an activity of the individual learned by this one and goal-oriented. This is a behaviour that appears under specific life

situations, and that the individual directs towards it's self or the environment to regulate the factors that affect its own development and activity in benefit of life, health and wellness. We are talking about a complex activity that requires traineeship, and that turns into an essential behaviour to cronic diseases as the Diabetes Mellitus type 1 (12). The traineeship process that the household unit develops, in front of the diabetes debut in some of their children, it's framed in a concept named by some authors as "Literacy in health", and this one defines itself as: "Grade in which the individuals have the capacity to obtain, process and understand the health basic information and the necessary services to take the appropriate health decisions" (13). Any of these three components of the literacy in health presents a modifiable barrier to attend the diabetes patients in an ideal way: 1. Reading skills (Comprehension of written texts, such as health management plans), 2. Arithmetic (The accomplishment of easy mathematical calculations, such as the insulin dosage according to the glucose in blood, diet and activity), 3. Navigation skills (in order to access resources, such as clinics, doctors and other services). Through one study, it was demonstrated that arithmetic skills in the parents, but not reading skills, where positevely related in the results of the children with the disease (14).

Despite of the importance of self-care and development of these traineeship skills, few studies relate them with the different types of treatments of the diabetes, making difficult to known how they affect the new therapies to the knowledge about the disease and the self-management of this one. By other hand, nevertheless, they have found studies that relate the CSII with the reduction in the frequency and intensity of the parents tension, the decrease of the fear of a hypoglycemia, the increase of the flexibility in the meals and sleeping schedules, a better mental health perception, general health and quality of life<sup>(6, 10)</sup>. All these findings makes us suppose that the treatment with CSII improves the level of knowledge and control over the diabetes, because of that, the aim of this work is to relate the insulin dispense type (intermitent subcutaneous injection or continous infusion) with the level of knowledge and control over the diabetes.

#### **METHODOLOGY**

Retrospective Cohort study or historic.

Target population: Paediatric diabetic type 1 population.

Study population: Paediatric diabetic type 1 patients belonging to the Health Service of Murcia,II Health Área, up to 17 years old. Nowadays this population is composed by 62 individuals.

Sample chracteristics: the cohort design requires the division of the sample in two groups, exposed groups and nonexposed groups. The exposed group will be composed by those paediatric type 1 patients with CSII, and the nonexposed group that will be composed by those paediatric type 1 patients that control their diabetes through multiple insulin injections.

Exposed group. Criterion for inclusion: paediatric type 1 patients that started the CSII treatment, at least 1 year before the beginning of the study. Criterion for exclusion: paediatric type 1 patients, with CSII, whose parents hadn't signed the informed consent.

Non exposed group. Criterion of inclusion: paediatric type 1 patients with multiple insulin injections. Criterion of exclusion: paediatric type 1 patients, with multiple insulin injections, whose parents hadn't signed the informed consent.

Sample size and sample assignment in the exposed and nonexposed groups. The sample size is limited by the number of children with CSII that accomplishes the selection criterion, the exposed group is composed by a total of 10 children (population total). The nonexposed group is composed by 10 selected paedriatic patients with multiple injections. In order to control some confusion values, the members of the sample have been paired (paring 1:1), creating a nonexposed paired group with the following criterion: same gender (except one of the pairs), age (up to a 26 month gap period), debut diabetic date: (up to a 46 month gap period).

**Board 1**: paring group board.

Nonexi injectio	oosed group: ı ons	multiple	Expos	ed group: CS	<u>II</u>
Code	Age	Debut	Code	Age	Debut
14	4 years old	January/2015	6	4 years old	January/2014
12	5 years old	August/2013	8	5 years old	June/2014
19	8 years old	August/2012	9	8 years old	April/2012
20	9 years old	July/2011	1	8 years old	November/2011
18	9 years old	June/2014	7	10 years old	April/2014
15	12 years old	March/2011	3	12 years old	March/2008
17	14 years old	March/2014	2	14 years old	February/2015
11	15 years old October/2011		4 14 years old No		November/2010
16	16 years old	April /2011	10	14 years old	June/2007
13	16 years old	February/2014	5	17 years old	November/2014

The pairing purpose is to increase the comparisons precision and improve the validity of the interferences result of the control of the possible confusion factors.

In patients under 7 years old, due to the relative difficulty that may appear in the comprehension of some of the indicators of the NOC selected in children, the unit sample will be the household unit (parents and child).

To establish the level of diabetes control in the subjects of the investigations, the NOC used were:

Result 1820: "Knowledge: Diabetes control"

Result 1619: "Self-control: Diabetes"

The result 1820 "Knowledge: Diabetes control" has a total of 25 indicators, and the result 1619: "Self-control: Diabetes", has a total of 42.

After a previous filter process in which took part 3 nurses with more of 10 years of experience and professional experts in diverse areas: diagnostic taxonomies,

paediatric nursery and diabetology, the result 1820 was condensed in 16 indicators and the 1619 in 17 indicators.

A heteroadministered survey was chosen, in other words, the one in charge of doing the questions to the sample subjects was a trained interviewer. The survey preparation and the training of the interviewer was done with the help of an expert nurse in diabetes. In addition, for one of the used NOC "Knowledge: Diabetes control" some questiones were operationalized to facilitate the comprehension of the interviewed children. It was decided that the NOC "Self-control:diabetes" wouldn't be operationalized because the answer options didn't induce to doubt.

All the variables were obtained through a heteroadministered survey, it only was necessary to consult the clinic record to determine some of the variables, such as the value of the HbA1c, or the date of the pump setting, when it wasn't remembered during the interviews.

The data compilation process took place between april and june of 2016.

All the interviews were done in person taking advantage of the healthcare education activities developed in the general university hospital "Santa Lucía" of Cartagena or external consults in the pediatric service, except for 4 of them, which were taken over the phone, because the hospital visit didn't match with the period of data compilation.

Dependent variables (NOC indicator selected:1820 "Knowlegde: Diabetes control" and "Self-control: diabetes"):

- Diet's role in the glycaemia control
- Exercise's role in the glycaemia control
- Hyperglycemia and related symptoms
- Hyperglycemia prevention
- Procedures to follow to treat the hyperglycemia
- Treat of the hyperglycemia symptoms
- Hypoglycemia and related symptoms
- Procedures to follow to treat hypoglycemia
- Treat of the Hypoglycemia symptoms
- Importance of keeping the glycaemia level inside the objective range
- Impact of a an acute disease over the glycaemia
- How does the patient uses a monitoring device
- Correct use of insulin
- Proper technique to prepare and dispense insulin
- Proper elimination of siringes and needles
- When to contact a healthcare professional
- Correct procedure for the ketonuria analysis (for nonexposed groups)
- Correct procedure for the ketonuria analysis (for exposed groups)
- Accepts the diagnose
- Participates in the decisions of the health cares
- Participates in the educational program prescribed
- Does the regime of treatment prescribed
- Does the correct procedure in order to control the glycemia
- Controls the glycemia
- Controls the frequency of the hypoglycemia episodes
- Informs of complication symptons

- Uses a diary to control the glycemia during time
- Obtains health assistance if the glycemia fluctuates over the recommendations
- Follows the recommended diet
- Does the usual life routine
- Uses the correct procedure to dispense the insulin
- Storages the insulin correctly
- o Controls the therapeutic effects of the medication
- Rotates the injection places

## Independent variables

- Age
- Gender
- Pediatrician
- Debut date
- Pump settlement date
- 2 last HbA1c2 samples

The data analysis was made with the statistic program SPSS v.21.

Descriptive and tendency statistical (dispersion and centralisation) were used to describe the sample.

The relation between the qualitative variables was done with the statistical Chi square and the Fisher's Exact Test. To determine the relation between the dependent variables (self-control and diabetes knowledge) and the exposition factor ( CSII treatment), the Relative Risk (RR) was calculated.

An evaluation of the project was demanded to the Santa Lucia's University General Hospital Clinic Investigation Ethical Committee of the II health area of Murcia, which gave the approval to the project implementation.

Because it was an investigation with subjects under legal age, the parents or legal tutor are the ones in charge of the signment of the informed consent in order to be able to be part of the study. Nevertheless, a child at the age of 7 already understands the effect that may have in the participation of an investigation and would have the authority to decide it's own inclusion<sup>(15)</sup>. When older is the individual, their maturity and capacity to participate in the consentment process increases. Despite, and because all the children were minors, the consent of all the children parents who participated in the sample, was requested and also the consent of all the children over 7 years.

#### **RESULTS**

The quantitative variables of the analysis examined shows that they follow a normal distribution in each of the groups, just as in the exposed group as the nonexposed.

Concerning to the samples subjects characteristics, the average age in both groups is of 11 years, matching also the percentage of male (60%) and female (40%). While in the group of exposed, the average number of months since the debut of using the pump is of 53 and in the nonexposed group is of 42, remaining less than a year gap between them. By other hand, the average months with the pump settled is of 16. In the exposed group, the 50% of the patients are treated by the pediatrician 1 and the

other 50% by the pediatrician 2, while in the group of nonexposed an 80% belong to the pediatrician 2 and only the 20% to the pediatrician 1.

In relation to the HbA1c, in the exposed group the average is on the 6.77%, while in the nonexposed group is on the 7.46%, remaining a 0.69% difference in favour of the exposed group. The same happens with the NOC scoring results, in the NOC Knowledge: diabetes control, the exposed group obtains a 3.99 while the nonexposed group obtains a 3.75, raiming a difference of 0.24 points. In the NOC Self-control: diabetes, the score obtained in the exposed group was of 4.12 against the 3.99 of the nonexposed, being the difference of 0.13 points, also in favour of the group with insulin pumps. See board 2.

**Board 2:** Sample subjects characteristics

SAMPLE (	CHARA	CTERISTI	CS BY	<b>GROUPS</b>
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		Gr <u>o</u>	<u>oup</u>
			Nonexposed group
		Exposed group	(with multiple
		(with insulin pump)	injections)
Age		11	11
Gender	<u>male</u>	6	6
	<u>female</u>	4	4
Months since the debut		53	42
Months with the pump		16	
P <u>a</u> ediatrician	Paediatrician 1	5	2
	Paediatrician 2	5	8
HbA1c (ratio of the 2		6,77	7,46
last samples)			
Average score		3,99	3,75
NOC Knowedge			
Average score		4,12	3,99
NOC Self_control			

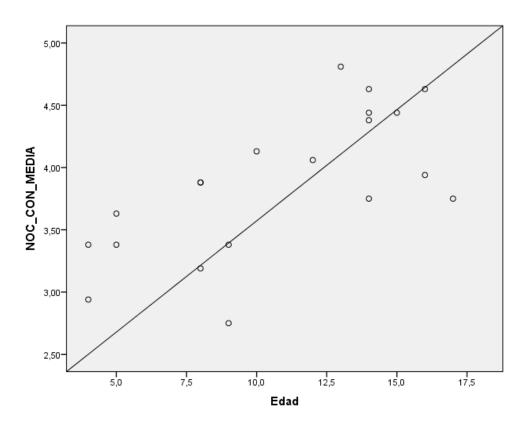
Both groups were compared using the T of Student for independent samples\_and besides obtaining a higher score the exposed group with the NOC Knowledge; diabetes control and self-control: diabetes, meaningful statistical differences weren't found between the exposed group and the nonexposed and the average score of the NOC (s=0.971 and s= 0.740 respectively).

Either were found meaningful statistical differences between the exposed and nonexposed groups according to the HbA1c average in the two last analitical determinations (s=0.09), however in a descriptive level may be observed a lower value in the group with CSII (exposed patients).

According to gender and the NOC scores and HbA1c results, meaningful statiscal ratios weren't found, neither with the NOC Knowledge: diabetes control ( P=0.161), the self-control NOC: diabetes ( p=0,373) or the HbA1c values ( p=0,062)

By other hand, it does appear a meaningful statistical ratio between the age and the NOC knowledge: diabetes control (p=0.001), increasing the score as the age

increases, but not with the NOC selfcontrol: diabetes (p=0.195) neither with the HbA1c average (p=0.859).



Graphic 1: Age-NOC knowledge: diabetes control ratio.

Between the debut lapse and the NOC: "Diabetes control" (p=0.074) and "Self-control: diabetes (p=0.224), as also with the HbA1c (p=0.514), there weren't found meaningful statistical ratios.

In order to know the magnitude between the cause and the effect, in the Cohortes studies does exist the relative risk ratio (RR) or Risk reasons. If the incedence is higher in the exposed group than in the nonexposed group, association will exist.

Relative risk= Incidents in the exposed group / Incidents in the non exposed group.

Through the average we know that the treatment with the insulin pump is not related to higher scores (equal scores or higher than 4) in the NOC Knowledge: diabetes control (p= 0,714) and self-control: diabetes (P=1.000).

Board 3: RR NOC Self-control: diabetes

#### **Risk estimation**

		Confidence interval o 95%					
	Value	Lower	Higher				
Reason of the	1,000	,167	5,985				
advantages for the							
group (Exposed group							
/non exposed)							
For the cohort	1,000	,342	2,926				
$MEDIA\_AU = lower$							
than 4							
Fort he cohort	1,000	,489	2,046				
MEDIA_AU = higher							
or equal to 4							
Number of successful	20						
cases							

Board 4: RR NOC Knowledge: diabetes control

# **Risk estimation**

		Confidence 95			
	Value	Lower	Higher		
Reason of the	,429	,068	2,684		
advantages for the					
group (Exposed group					
/non exposed)					
For the cohort	,714	,341	1,498		
MEDIA_CON= lower					
than 4					
Fort he cohort	1,667	,538	5,168		
MEDIA_CON= higher					
or equal to 4					
Number of successful	20				
cases					

Board 5: Knowledge relative risk

	HIGH KNOWLEDGE	LOW KNOWLEDGE				
EXPOSED	A 5	B 5				
NONEXPOSED	C 7	D 3				

RR = (a/a+b)/(c/c+d) = 0.5/0.7 = 0.71

By other hand, having in mind all the indicators of both NOC, meaningful differences aren't found, except for the NOC self-control: diabetes, the indicator 13 "Follows the

recommended diet", obtains a meaningful difference in the exposed group and in the group control (p=0.037), in the way that the patients with CSII, obtain higher scores in the self-control of the diet.

**Board 6**: Ratio between the groups and NOC Self-control: diabetes indicators.

Estad	iction	ah s	cont	racte

	NA1	NA2	NA3	NA4	NA5	NA6	NA7	NA8	NA9	NA10	NA11	NA12	NA13	NA14	NA15	NA16	NA17	NA18
U de Mann-Whitney	46,500	50,000	35,500	38,000	38,500	45,500	46,000	48,000	30,000	46,000	42,500	38,000	24,000	41,000	48,500	43,500	40,000	45,500
W de Wilcoxon	101,500	105,000	90,500	93,000	93,500	100,500	101,000	103,000	85,000	101,000	97,500	93,000	79,000	96,000	103,500	98,500	95,000	100,500
I	-,276	,000	-1,175	-,959	-,919	-,376	-,323	-,161	-1,584	-,344	-,629	-1,011	-2,090	-,765	-,119	-,650	-,951	-,358
Sig. asintót. (bilateral)	,782	1,000	,240	,338	,358	,707	,747	,872	,113	,731	,529	,312	,037	,445	,905	,516	,342	,721
Sig. exacta [2*(Sig. unilateral)]	,796ª	1,000ª	,280ª	,393ª	,393ª	,739ª	,796ª	,912ª	,143ª	,796ª	,579ª	,393ª	,052ª	,529ª	,912ª	,631ª	,481ª	,739ª

a. No corregidos para los empates. b. Variable de agrupación: Grupo

#### DISCUSSION

The patients with the pump obtain better levels of HbA1c than those who follow the treatment with multiple injections, nevertheless the estatistical difference found isn't statistically meaningful. In the following study, the 83,3% of male and the 37,5% of females have an HbA1c <7, value that reaches the one recommended by the American Diabetes Association and the International Society for Paediatric and Adolescent Diabetes (ISPAD), and which is higher than other values established in other studies ( HbA1c <7 in the 30% of male and 29% of female) <sup>(10)</sup> Taking as sample the percentage of patients well controlled (HbA1c <7), the 50% of both genders follow the treatment with CSII.

After taking place the measurement of the values, it was verified that the age is a relating factor according to the knowledge of the individual (NOC Knowledge: diabetes control), even though it doesn't affect the self-control (NOC self-control: diabetes). The diabetic debut lapse didn't affect any of these NOC, so the increase of the knowledge wasn't due to the time that the indivual lived with the disease, it was just due to the age. These results have a complex interpretation, because we should remember that in case of minors under 7 years old the questions were answered by the household unit ( single parents or parents with children) . By other hand, the low scores between the minors can indicate a lack of real knowledge (limited knowledge comprehension due to their age), as the lack of confidence that the parents have about the diabetes knowledge of the younger childs ( point that will be reflecting the insecurities and fears of the household unit facing the diabetes with such little children).

By other hand, the following study, the results show that there is any relation between the gender and the increase of the knowledge or the self-control, in the same way, either exists a relation between the gender ante the values of HbA1c. Gender is not a variable that is considered that has influence in the metabolic control, besides there are authors that have found HbA1c higher levels on female than in male, without pointing the causes of it <sup>(16)</sup>

In relation to the influence of the CSII treatment about the knowledge and self-control, the patients with the pump obtained a higher scores than those who used multiple

inyections, nevertheless meaningful differences weren't obtain between the two groups. Also the cut-off score at 4, determines that there is a good level of knowledge and self-control in both groups. Meaningful statistical differences between the both groups were just found inmthe indicator "Follows the recommended diet" of the NOC: "Self-control", in the way that individual with CSII obtained higher scores. In this way it is confirmed the relation of the individual with the insulin pump and a higher control of the diet that other studies have found (10,17), and that explains the capacity of the pump to simulate the pancreas physiology and adapt the insulin secretion in a more physiological way during the schedules and carbohydrates quantitymon the diet of the diabetic child.

## **Study limitations**

Even though the selected sample includes all the type 1 pediatric diabetic population of the 2 area with CSII, this sample is small, because of that the development of this kind of studies should have a multicenter nature.

Potential acquiescense bias or tendency to give positive or afirmative answers, in an accentual way with the subjects interviewed by phone.

#### **CONCLUSIONS**

The patients with CSII treatment do not have better HbA1c values according to the ones with multiple injection treatments. However the sample is very small to be able to obtain meaningful values in this aspect, because the results show better valeus in individuals with the pump, and because of that it would be important to wide the study by using a larger sample.

Gender wasn't related with better HbA1c values, or either with the level of knowledge and self-control of the diabetes.

The age in contrast with the diabetic debut lapse it was related to higher knowledge of the disease but not to a higher self-control. This data is important inside the health education environment, in the way that the household units where the patient is under 7 years, they should have a more intense and specific training that may content information focused in the disease and management, as parent psychosocial support to decrease anxiety and fears due to the debut young age of the childs.

The patients with insulin pump do not obtain better results that the ones with multiple injections in the knowledge and self-control area, except for the diet management, result that shows a higher flexibility that the insulin pump permits in the meals and shows a better monitoring of the diet of this group.

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