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ORIGINAL RESEARCH

Use of informed consent for application of behavioral management techniques, procedure explanation, risks and complications during dental treatment

Utilización del consentimiento informado para la aplicación de técnicas de manejo conductual; explicación del procedimiento, riesgos y complicaciones durante el tratamiento dental

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ABSTRACT

Behavior management of pediatric patients requires training and knowledge of children's emotional and sociological development. When any type of behavior management is undertaken, it is important to bear in mind which are the patient's treatment objectives. It is equally important to determine the feasibility of reaching those objectives with non pharmacological techniques; if this is not possible, other alternatives such as sedation or general anesthesia should be taken into consideration. The objective of the present study was to assess knowledge of parents or tutors on the following: application of conduct management techniques as well as explanation of risks and complications through the use of informed consent. This was achieved with a questionnaire given to 50 parents in a three month time span, who attended for the first time the Pediatrics Service, to complete a clinical history for their offspring. The most used and accepted management technique was conduct management, which was preferred by females when compared to males. Sedation followed by general anesthesia was a technique more difficult to explain, and therefore, for the parents to understand. Nevertheless, most of the techniques used were explained to parents. Parents were aware of risks and complications inherent to each technique. Informed Consent was secured in verbal and written manner, and was obtained in 80% of cases.

RESUMEN

El manejo de la conducta del paciente pediátrico exige un entrenamiento y conocimiento del desarrollo emocional y sociológico del niño. Cuando se lleva a cabo cualquier manejo de la conducta es importante tener en cuenta cuáles son los objetivos de tratamiento del paciente y determinar la factibilidad de lograrlos con técnicas no farmacológicas. De lo contrario, deben considerarse otras alternativas tales como: la sedación o anestesia general. Por lo tanto el objetivo del presente estudio consiste en evaluar el conocimiento de los padres o tutores acerca de la aplicación de técnicas de manejo de conducta, explicación de riesgos y complicaciones mediante el uso del consentimiento informado a través de un cuestionario a 50 padres los cuales acudieron por primera vez al Servicio de Odontopediatría para realizar historia clínica en un periodo de 3 meses. La técnica de manejo más utilizada y aceptada fue el manejo conductual, presentándose ésta más en el sexo femenino que en el masculino, mientras que la sedación seguida de anestesia general son más complicadas de explicar y por lo tanto de comprender; pero aún así la mayoría de las técnicas utilizadas que se explicaron a los padres; conocieron los riesgos y complicaciones de cada una de ellas. Ya que el *consentimiento informado* se llevó a cabo tanto de forma verbal como escrita y fue obtenido en el 80% de los casos.

Key words: Parents, informed consent, behavioral management techniques, advantages, risks.
Palabras clave: Padres, consentimiento informado, técnicas de manejo conductual, ventajas, riesgos.

INTRODUCTION

BEHAVIOR MANAGEMENT TECHNIQUES

Behavior management of pediatric patients requires training and knowledge of the child's sociological and emotional development. Many restrictive techniques previously favored have been re-assessed after considering social trends, parents' attitudes, ethical factors as well as legal questions involved.

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Child behavior management is a critical aspect of dental procedures. Several techniques are presently used to handle patient behavior in the dental office. These techniques can be pharmacological or non-pharmacological.[1]

Within the scope of pediatric dentistry, there are several methods to control the behavior of pediatric patients. These can be divided into two large groups:

- Non pharmacological techniques.
- Pharmacological techniques.

Non pharmacological techniques are undertaken to control behavior without the help of any drug. They can be divided into three groups:

**Communication techniques:*
1. Show-tell-do
2. Voice control
3. Non verbal communication

* *Behavior modification*
4. Positive reinforcement
5. Negative reinforcement
6. Model presentation

* *Movement restriction*
7. Hand over mouth
8. Partial or total immobilization

Within the scope of **pharmacological techniques** we can find:

9. Conscious sedation
10. General anesthesia

Some of the methods mentioned here are used along with physical restrictions. These restrictions can vary from covering the patient 's mouth with the hand to restrain them with conventional techniques. Another would be achieving good behavior from the child on the strength of a future reward. When following this type of techniques for pediatric patient handling, dentists might encounter certain amount of problems that might be avoided if patient, parents or tutors (for under-age patients) are made aware of the fact that this type of techniques can be used within the scope of the treatment, as well as the reasons supporting this.

The number of lawsuits is in constant increase. CONAMED reports that, in 1999, the number of dentists being sued has increased. Dentists must therefore protect themselves by any possible means. One of these tools is obtaining informed consent for the use of behavior management techniques. This consent should be obtained in all cases, not just for some specialties. Thus, the dentist will possess a written document which will grant him protection in case of any legal problem.[2]

BEHAVIOR CLASSIFICATION

Behavior handling means assessing the patient and constantly adapting the patient through the application of several techniques, either isolated or simultaneously, according to each specific situation. Emotional state and social and family environment are important to be able to assess what type of treatment is required by every patient. Scientific literature reports global and restrictive scales which can be a guidance when assessing the child. At the Hospital Infantil de Mexico Federico Gomez (Federico Gomez Children's Hospital, Mexico) Frankl scale is widely used. This scale is presently described.

TYPE 1

DEFINITELY NEGATIVE

Patients refuse treatment as a whole, they scream loudly, are fearful, or show any other evidence of extreme negative attitude.

TYPE 2

NEGATIVE

Patients present difficulty in accepting treatment. The do not cooperate. They present some evidence of negative attitude, which is not very pronounced. They are surly or withdrawn.

TYPE 3

POSITIVE

Patients accept treatment. Often cautious, they show intention of following the dentist's orders, with certain reservations, but they follow indications. These patients suffer a high anxiety level which prevents them from cooperating.

TYPE 4

DEFINITELY POSITIVE

Children who present harmonious relationship with the dentists. They are interested in the dental proceedings, laugh, and enjoy the situation.

BEHAVIOR MANAGEMENT TECHNIQUES

NON PHARMACOLOGICAL TECHNIQUES

Communication

Tell-show-do

Description. It entails allowing the patient to be well acquainted with procedures to be performed. A sequence is followed whereby, first, in language appropriate to the patients development, explanations are proffered about what is going to be done (tell). Then a demonstration is shown (show), and lastly, the dental procedure is undertaken (do). This sequence is recommended all along the appointment. A face mirror is an advisable tool.

Objective: To decrease patient s anxiety through an explanation of a situation that is unknown for the patient.

Indications: Can be used in all patients.

Contraindications: It is indicated for all patients, nevertheless it is not very effective in very young patients who have not yet developed verbal communication skills.

Voice control

Description: The voice volume and tone is modified, as well as speed of speech. This cannot be mistaken with shouting at the patient, or becoming angry. It might imply increase or decrease of voice tone, and often is performed speaking with a very low tone at the child's ear.

Objective: To establish authority and communication with the patient.

Indications: Can be used in all patients. It is more useful in patients with developed verbal communication skills, especially in cases when the patient is rebellious and trying to be manipulative or question authority.

Contraindications: Very young patients who are as yet not able to assimilate the techniques' objective.

Non verbal communication

Description: It consists in using different attitudes such as facial expression, posture and physical contact changes, to direct and modify behavior.

Objective: To establish communication with the patient and control the manner in which he perceives his emotions.

Indications: Can be used in all patients. It is especially useful in very young patients who still lack verbal communication skills.

Contraindications: None.

Behavior modification techniques

Positive reinforcement

Description: This technique seeks the reinforcement of desirable behavior. In it, it is important to reinforce immediately, and repeat reinforcement several times, so as to positively condition behavior. It is generally used along with tell-show-do and negative reinforcement techniques. Prizes or presents at the end of the appointment are useful social reinforcements to establish good empathy with the patient. These measures, nevertheless, cannot be considered conditioning measures since they cannot be used immediately.

Objective: To act upon the patient's motor response so as to have him repeat a desirable behavior.

Indications: Can be used in all patients.

Contraindications: None.

Negative reinforcement

Description: Its aim is to modify an undesirable behavior though a rejection expression. As is the case with positive reinforcement, since this is a conditioning technique, it must be performed repeatedly and immediately. It is generally used along with voice control techniques to express disapproval. It can also be conducted conditioning some factor the patient desires (like having the parents into the office) to obtain better behavior. Negative reinforcement must not be confused with punishment. Punishment is contraindicated, since it bears negative impact on the child and predisposes towards a negative attitude with respect to treatment. Promises used to condition behavior must be feasible, immediate and must always be kept. If whatever was promised is not kept, or truth is not told, the patients lose confidence in the dentist.

Objective: To modify disruptive behavior with the help of patient's motor response conditioning.

Indications: Patients who have developed oral communications skills.

Contraindications: Must not be used in very young children who have not yet developed communication

and emotional skills to understand the conditioning technique.

Modelling

Description: This technique consists on allowing the patient to observe the desired appropriate behavior. This can be achieved with a model who is in a similar situation. It can be achieved live or with the help of videos.

Objective: To decrease patient's anxiety and reinforce positive behavior.

Indications: Patients possessing verbal communication and emotional development skills needed to understand the technique's objective.

Contraindications: Indicated for all patients. Nevertheless, this technique is not very useful in very young patients who do not yet possess emotional development skills needed to understand the technique.

Motion restrainers

Hand over mouth

Description: This controversial technique is fast coming into disuse. It entails placing the hand, softly but firmly, over the child's mouth so as to isolate sounds and achieve communication. It is used along with voice control technique; the removal of the hand is conditioned to the child's cooperation. When the child accepts, the hand is removed. This technique must not be used when simultaneously applying the hand over nose and mouth, interrupting respiration, as was at some point described in scientific literature. It is advisable to obtain parents' written and verbal consent before applying this technique.

Objective: Establish authority and communication with the patient.

Indications: The patient must be healthy, with well developed verbal communication skills and possessing cooperation potential but nevertheless showing challenging and rebellious behavior.

Contraindications: Patients unable to cooperate due to their young age, emotional immaturity or mental or physical disability.

Immobilization

Description: In certain situations, patient total or partial immobilization is needed so as to protect his physical integrity. Patient must be restricted, and no harmful, excessive force must be applied. The dentist, parents or auxiliary personnel can perform it. A restrictive device can also be used, (papoose board, Pedi-Wrap etc.). The mouth can also be immobilize using a bite block or different mouth openers. It is recommended to secure verbal and written consent from parents before undertaking this technique.

Objective: To protect the patient's physical integrity so as to safely conduct treatment under ideal quality clinical parameters. Physical integrity of dentist and auxiliary personnel is also sought with this technique.

Indications: Patients unable to cooperate due to their young age, emotional immaturity of mental or physical disability.

Contraindications: Cooperating patients or patients who cannot withstand safe immobilization due to their medical, sociological or physical development facts.[3]

INFORMED CONSENT

Informed consent is a legal, medical document whereby guarantee is provided that the subject has voluntarily expressed his intention to participate in the established treatment, after having understood information provided to him with respect to study objectives, benefits, discomforts, possible risks, any alternatives, his rights and responsibilities.

The participating subject will express his consent either in written form, or verbally, in front of an independent witness not related to the research team, who will then provide a written statement, and will be held responsible to it.

When patients are under age, or unable to give consent, consent will be granted by his legal representative, in all cases in writing, after having received and understood the appropriate information. Nevertheless, when the state of the patient so allows it, patients will also be able to give consent or refuse to participate in the study, after having received pertinent information adapted to his level of understanding.

Informed consent forms are signed by all persons involved in the research project; by one witness and by the researcher in charge of explaining the informed consent form. In this form, the participant expressly manifests the fact of having been informed on the objective sought by the research project, about requirements, procedures, risks, description of possible discomfort, sequels, foreseeable evolution, dangers and personal benefits which might derive from the research project. In the case of clinical essays, the researcher must explain the

possibility of other existing treatment alternatives, the patient must clearly express the fact that he is willing to be a subject of the research. When individuals are under-age or unable, consent must be granted by parents or legal representative. This status must be proved by either birth certificate or court order. The subject of research or his legal representative will receive a copy of the consent form, which must clearly state date and show all pertaining signatures.[4,5]

METHODS

Methods used in this research project were application of a direct questionnaire to 50 parents of pediatric patients who sought service at the pediatric stomatology department of the Federico Gomez Children's Hospital in Mexico City, in the period of April-June 2007. The survey encompassed 10 questions. The first 8 questions were solved over the phone. The 2 remaining questions were solved with the help of the clinical files. This was undertaken to assess whether the pediatric dentists used informed consent forms which explain the behavior management to be conducted on the patient (Annex 1). The study did not entail any risk for the patient, since it was just an observational type study.

RESULTS

The handling technique most used was behavior management. It was applied more to females than to males and counted with total parental approval. Sedation followed by general anesthesia is a more difficult technique, therefore more difficult to explain. Even though this was the case, in most used techniques, parents were aware of the risks and complications. Informed consent was gained in written and verbal manner, and was achieved in 80% of cases.

When studying behavior management techniques according to gender, females (75%) were more compliant than males (39.2%). Stabilizing protection was more frequently used for male patients (25%), whereas sedation was more used for female patients (66.6%). Conduct behavior management was the technique most used (50%), followed by sedation (27.5%) stabilizing protection (20.0%) and general anesthesia (2.5%) *(Table I)*.

Table II shows reactions of parents when asked whether they had fully understood handling techniques to be performed on their offspring. Parents chose conduct handling first (48.7%), parents grasped the concept of this technique better. After it came sedation (44.0%), stabilizing protection (20.5%) and general anesthesia (4.0%) *(Table II)*.

When dealing with detailed explanations about the technique to be used, it can be stated that female patients understood better conduct behavior technique (52.6%). Percentages were similar when explaining general anesthesia and sedation (23.3%), stabilizing protection rated 18.4%. When clearly explaining techniques to be used, in males, stabilizing protection technique presented the same percentage (50%) as sedation *(Table III)*.

Table IV shows concise explanation on risks and complications. Females rated a higher percentage (95%) than males (5%) *(Table IV)*.

With respect to parental complaints on child treatment, *Table V* shows that males rate 28.5% when compared to females, which rated 16.6% *(Table V)*.

In all patients, 72% signed the informed consent form without having true knowledge of what they were signing. 82.7% of all those claiming to understand what the forms were about, signed them. 17.1% of those not understanding what they were signing, nevertheless did so *(Table VI)*.

In most cases, consent was given verbally and in writing (84.8%). 66.6% gave written consent, and 50.0% granted verbal consent. This is reflected in *Table VII*.

Table VIII reflects information on complaints concerning behavior techniques used. Sedation techniques bear the highest percentage of parental complaints (60%) when compared to stabilizing protection techniques (10%).

Verbal and written informed consent (jointly) bear the 80% of complaints when compared to 10% of complaints on written informed consent *(Table IX)*.

Table X shows the relationship between elected technique and presence of parental signature. 63.3% of parents did not sign approval for behavior handling technique. 27.2 did not sign approval for stabilizing technique. 34.4% of parents granted signed approval for sedation technique. 3.4 % signed approval for general anesthesia.

DISCUSSION

Most pediatric dentists have not been sued for using behavior handling techniques. Nevertheless, parents have complained about those techniques having been used without their consent. This leads us to consider the fact that parents must be informed, to avoid any misunderstandings. To that effect a written informed consent sheet should be underwritten. CONAMED

(1999) informs about the increasing numbers of dentists being sued. Therefore, it is of utmost importance for all dentists to prevent legal actions with the help of a document.[6]

CONCLUSIONS

When a child's behavior is handled in the dental office, his collaboration in the treatment is achieved. This can be ascertained with teaching and learning processes, which will promote the child´s positive attitude towards the dental office. Selection of proper technique will bear influence on the child's emotional state.

Most parents are acquainted with the behavior management technique to be used on their offspring. They understand it as well as risks and complications which might arise during treatment.

Table I. Child handling technique related to gender.

		Gender		
		Female	Male	Total
Variable	Category	n (%)	n (%)	N (%)
Handling technique	Behavior management	9 (75.0)	11 (39.3)	20 (50.0)
	Stabilizing protection	1 (8.3)	7 (25)	8 (20.0)
	Sedation	2 (16.7)	9 (32.1)	11 (27.5)
	General anesthesia	0 (0.0)	1 (3.6)	1 (2.5)
Total		12 (100.0)	28 (100.0)	40 (100.0)

P = 0.061

Table II. Understanding of handling technique with respect to chosen technique.

		Understood handling technique		
		Yes	No	Total
Variable	Category	n (%)	n (%)	N (%)
Handling technique	Behavior management	19 (48.7)	1 (100)	20 (50.0)
	Stabilizing protection	8 (20.5)	0 (0)	8 (20.0)
	Sedation	11 (28.2)	0 (0)	11 (27.5)
	General anesthesia	1 (2.6)	0 (0)	1 (2.5)
Total		39 (100.0)	1 (100)	40 (100.0)

P = 0.061

Table III. Clear explanation of child's treatment with respect to chosen technique.

		Explains attention		
		Female	Male	Total
Variable	Category	n (%)	n (%)	N (%)
Handling technique	Behavior handling	20 (52.6)	0 (0.0)	20 (50.0)
	Stabilizing protection	7 (18.4)	1 (50.0)	8 (20.0)
	Sedation	10 (26.3)	1 (50.0)	11 (27.5)
	General anesthesia	1 (2.7)	0 (0.0)	1 (2.5)
Total		38 (100.0)	2 (100.0)	40 (100.0)

P = 0.061

Table IV. Clear explanation of child's treatment with respect to explanation of risks and complications.

Variable	Category	Explains treatment Female n (%)	Male n (%)	Total N (%)
Risks and complications	Sí	38 (95)	2 (5)	40 (100)

P = 0.061

Table V. Complaints about child's treatment with respect to gender.

Variable		Gender Female n (%)	Male n (%)	Total N (%)
Complaint	Yes	2 (16.7)	8 (28.6)	10 (25)
	No	10 (83.3)	20 (71.4)	30 (75)
Total		12 (100.0)	28 (100.0)	40 (100)

P = 0.061

Table VI. Knowledge of informed consent with respect to authorization (signature).

Variable	Category	Consent signature Yes n (%)	No n (%)	Total N (%)
Handling technique	Sí	24 (82.8)	8 (72.7)	32 (80)
	No	3 (10.3)	3 (27.3)	6 (15)
	Don't know	2 (6.9)	0	2 (5)
Total		29 (100.0)	11 (100.0)	40 (100)

P = 0.061

Table VII. Knowledge of informed consent with respect to type of consent.

Variable	Category	Type of consent Verbal n (%)	Written n (%)	Both n (%)	Total N (%)
Knows consent	Yes	2 (50)	2 (66.7)	28 (84.9)	32 (80)
	No	1 (25)	1 (33.3)	4 (12.1)	6 (15)
	Don't know	1 (25)	0 (0.0)	1 (3.0)	2 (5)
Total		4 (100)	3 (100.0)	33 (100.0)	40 (100)

P = 0.061

Table VIII. Complaints with respect to chosen handling technique.

Variable	Category	Complaint Yes n (%)	No n (%)	Total N (%)
Handling technique	Behavior handling	3 (30)	17 (56.7)	20 (50.0)
	Stabilizing protection	1 (10)	7 (23.3)	8 (20.0)
	Sedation	6 (60)	5 (16.7)	11 (27.5)
	General anesthesia	0 (0)	1 (3.3)	1 (2.5)
Total		10 (100)	30 (100.0)	40 (100.0)

P = 0.061

Table IX. Complaint with respect to type of informed consent.

Variable	Category	Complaint Yes n (%)	No n (%)	Total N (%)
Type of consent	Verbal	1 (10)	3 (10.0)	4 (10.0)
	Written	1 (10)	2 (6.7)	3 (7.5)
	Both	8 (80)	25 (83.3)	33 (82.5)
Total		10 (100)	30 (100.0)	40 (100.0)

P = 0.061

Table X. Presence of informed consent signature with respect to chosen technique.

Variable	Category	Consent signature Yes n (%)	No n (%)	Total N (%)
Handling technique	Behavior handling	13 (44.8)	7 (63.6)	20 (50.0)
	Stabilizing protection	5 (17.2)	3 (27.3)	8 (20.0)
	Sedation	10 (34.5)	1 (9.1)	11 (27.5)
	General anesthesia	1 (3.5)	0 (0.0)	1 (2.5)
Total		29 (100.0)	11 (100.0)	40 (100.0)

P = 0.061

This consent can be given verbally or in written form, and will enhance communication between parent and dentists in the better handling of the child in the dental office.

Pediatric patients must be assessed and adapted, with the help of several techniques, regardless of their age. Language and voice tone must be adapted to the patient's emotional state. Typical behavior patterns of all ages must be thoroughly studied, always bearing in mind that pediatric patients are at different stages of growth and development.

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ANNEX 1

Age _____ Gender F _____ M _____ Record _____

1. Do you know what informed consent is all about?

Yes _____ No _____ Don't know _____

2. Have you received a clear explanation of how your child is going to be treated?

Yes _____ No _____ Don't know _____

3. Have you any complaint of the treatment received by your child?

Yes _____ No _____ Don't know _____

4. Do you think informed consent is useful?

Yes _____ No _____ Don't know _____

5. Did you fully understand the handling technique applied to your child?

Yes _____ No _____ Don't know _____

6. Was the procedure clearly explained to you?

Yes _____ No _____

7. Were risks and complications clearly explained to you?

Yes _____ No _____

8. Was consent obtained in any of the following manners?

Verbal _____ Written _____ Both _____ None _____

In the clinical file

9. Which was the handling technique used?

Behavior handling _____ Stabilizing protection _____ Sedation _____ General anesthesia _____

10. Was informed consent underwritten?

Yes _____ No _____