Occurrence of aspiration pneumonia in dysphagic children post video fluoroscopy

Ocorrência de pneumonia aspirativa em crianças disfágicas pós videofluoroscopia

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RESUMO

Introdução: A literatura relata que quando se trata de avaliação instrumental da deglutição em crianças, sem dúvida, a videofluoroscopia da deglutição oferece grandes vantagens sobre o estudo endoscópico (6).

Objetivo: Verificar o risco de pneumonia aspirativa após a realização do estudo da deglutição por vídeofluoroscopia, em crianças com disfagia.

Método: Em estudo de corte prospectivo, participaram 16 crianças com idade entre 6 meses e 10 anos, com média de 5,2 anos, encaminhadas para estudo da deglutição por videofluoroscopia. Foram testadas 4 consistências, pudim, néctar, mel e líquido. A presença de sinais e/ou sintomas respiratórios foram avaliados pré e pós estudo da deglutição por videofluoroscopia, por meio de histórico e exame clínico. Quando necessário solicitado radiografia de tórax.

Resultados: Das 16 crianças, 5 não apresentaram disfagia. Em 11 crianças o exame demonstrou 4 com disfagia leve, 2 moderada e 5 grave, conforme Classificação de OTT (1996) - Classificação da gravidade da disfagia à videofluoroscopia9. Das 7 crianças que aspiraram durante a realização do exame, apenas 1 apresentou sintomas respiratórios após o estudo da deglutição, porém sem sinais de pneumonia ao exame físico. Conclusão: Na população estudada, não houve ocorrência de pneumonia aspirativa após a realização do estudo da deglutição por vídeofluoroscopia, apesar da ocorrência de aspiração durante o exame em cerca de 50% dos casos.

Palavras-chaves: transtorno de deglutição, fluoroscopia, pneumonia aspirativa.

SUMMARY

Introduction: The literature reports that when it comes of instrumental assessment of swallowing in children, undoubtedly, video fluoroscopy of swallow offers great advantages over the endoscopic study.

Objective: Check the risk of aspiration pneumonia after the study of swallowing by video fluoroscopy, in children with dysphagia.

Method: In a study of prospective cutting, participated 16 children aged between 6 months and 10 years, with an average of 5,2 years, referred for study of swallowing by video fluoroscopy. Were tested 4 consistencies, pudding, nectar, honey and liquid. The presences of signs and/or respiratory symptoms were evaluated pre and post study of deglutition by video fluoroscopy, through history and clinical exam. When necessary was asked chest x-ray.

Results: Of 16 children, 5 didn't presented dysphagia. In 11 children the exam showed 4 with mild dysphagia, 2 moderate and 5 severe, as classification of OTT (1996) - Classification of severity of dysphagia to the video fluoroscopy. Of the 7 children who aspirated during the exam, only 1 presented respiratory symptoms after the deglutition study, but without signal of pneumonia to the physical examination.

Conclusion: In the studied population there were no occurrences of aspiration pneumonia after the study of deglutition was performed by video fluoroscopy, despite the occurrence of aspiration during the exam in about 50% of cases.

Keywords: deglutition disorders, aspiration pneumonia, fluoroscopy.

INTRODUCTION

In oropharingeal dysphagia, the complications of lung diseases caused by aspiration are the most difficult clinical management. Therefore, the detect ability and the characterization of this aspiration, which occurs in the pharyngeal phase, are primary for prognosis and rehabilitation. The aspiration can be inferred through clinical evaluation, but its objective confirmation should be done by video fluoroscopy (1).

The videofluoroscopy of deglutition is considered the best instrumental method to evaluate deglutition in children, as it evaluates from the beginning of the oral preparatory stage to conclusion of esophageal stage (2). However, studies indicate that children with severe dysphagia possess high risk in having complications during the examination (3).

The instrumental exam such as video fluoroscopy is a great ally to evaluate babies and children with deglutition disorders. Through this exam we have been observed high incidence of silent aspiration in radiographics studies involving children with multiple disabilities (1).

Dysphagia patients have the risk of aspiration raised, i.e., the passage of food and/or fluids enter below the vocal cords through the airways, raising the risk of pneumonia and problems associated (4). Yet according to these authors, most studies about silent aspiration in dysphagic patient, supports the use of video fluoroscopy of deglutition for its detection, considering the most sensitive exam in detection of aspiration during deglutition (2).

To Langmore (1999) there are three prerequisites to evolve pneumonia aspiration: a) pathogenic germ present in the aspirated material; b) the material must be aspirated and c) the lungs should be unable to resist to the pathogenic germs (5,6).

In child, without any doubt, the video fluoroscopy of deglutition offers great advantages over the endoscopic study, as well as being technically feasible, it practically reproduces the real situation of deglutition (7).

Despite of advantages, as the analysis accurate and immediate of deglutition and the non-invasive procedure, there is for the pediatric population a greater risk than the adults, as the radiosentivity of the thyroid is known to be particularly elevated (8).

During the exam, the examiner must observe if there is or not perception signs of laryngotracheal aspiration, such as cough, choke, clean the throat and weep. If the patient does not show any of those signs, he will be considered as a silent aspirator with risk to evolve pneumonia by aspiration (9). Some of the authors refer to close the examination if it will be any significant aspiration of the bolus without any cleaning reflex or voluntary cleanup of the airways, for although barium is considered inert, the entry of large amount into the respiratory tree is not recommended, once it could cause problems to the persons with systemic diseases or respiratory.

This study aims to verify in children with high risk by accompanying speech therapist and physician the occurrence of aspiration pneumonia right after the video fluoroscopy exam.

METHOD

This was a prospective cohort study in 16 children aged between 06 months and 10 years-old, with an average of 5,2 years-old, being 50% male and 50% female, with average weight 14kg with complaints of dysphagia, they had been referred by the pediatric department for deglutition study through video fluoroscopy to research dysphagia.

In the description of underlying disease, 13 children presented Cerebral Paralysis, 01 child with Microcephaly and 02 children with Encephalopathy.

All of the children who presented the dysphagia symptoms were referred to study of deglutition by video fluoroscopy.

The criteria to include the children in this research were: clinical condition to take examination is awake, active and with medical permission. It was excluded all of children who presented pneumonia before taking examination.

The study was approved by the Ethics in Research Committee, under no. 000025/2009, (Annex I).

To collect data about the underlying disease, dysphagia, signs and pneumonia symptoms cause, it was used patients' records and initial interview with children's responsible who signed a term authorizing the use of the data in the research.

It was used the Functional Oral Intake Scale - FOIS, which follows an scale from Level 1 to Level 7, of which, less the value is less is the via oral food ingestion (10), in order to classify the children oral intake.

Before video fluoroscopy examination children were underwent chest radiography in order to exclude any

possibility of prior pneumonia. The x-ray equipment used was Siemens - model Axiom R100, monitor Siemens and model M44-2, which was also used to the video fluoroscopy of deglutition examination.

In order to perform examination children were placed sit alone in 90° or, when necessary, on the mother's or responsible lap, vision with lateral radiograph.

The consistencies presented were: Pudding, Honey, Nectar and Liquid, composed of water, Barium Sulfate (100% Bariogel brand), as radiological contrast which contains 1g barium sulfate and vehicle g.s.p. 1ml, for pediatric and adult use, and as thickener we used the instant modified cornstarch from the brand THICK UP®, which is composed by modified cornstarch (E1442), malt dextrin, Tara gum, xanthan gum and guar gum.

To obtain the consistencies, we used the nomenclature of National Dysphagia Diet: Standardization for Optimal Care (11) and the thickner THICK UP®, which it was used for the nectar (from 51 to 350cP), -200 ml of water, 2 sachets (10 gr) of THICK UP®, Honey (from 351 to 1750cP) - 200ml of water, 2½ sachets (12,5 gr) of THICK UP® and for Pudding (> than 1750cP), - 200ml of water, 3 sachets (15 gr) of THICK UP®. instant food thickener from brand Thick&Easy® (HORMEL HEATH LABS. SWISS) composed of starch, nutritional composition presented as 100g: 375kcal, 100g of carbohydrates and e 125mg of sodium.

The utensils used to offer those consistencies were spoon, glass and bottle in case of the babies.

In order to record the examination were used computer from brand HP Pavilion tx2075BR Notebook PC and for image collector we used Sapphire - Wonder TV-USB.

To classify the dysphagia, we used the Severity of Dysphagia to Fluoroscopy - OTT (1996), which classifies as Normal Deglutition, Light Dysphagia, Moderate Dysphagia and Severe Dysphagia (12).

After examination patients returned within a week for medical evaluation in order to check if there are signs or respiratory symptoms and for clinical speech evaluation for the signs or symptoms of dysphagia, history of aspiration and clinical conditions by means of a protocol. This period of 07 days to return was set according to the availability of the targeted group, using the limited days for that evaluation. It was conducted new chest radiography, when the signs and respiratory symptoms suggested pneumonia.

RFSULTS

From the referrals of deglutition study by video fluoroscopy of deglutition, 06 children were referred by Gastroenterologist, 03 by pediatrician, 04 by Speech Therapist, 02 by Pulmonologist and 01 by Immunologist.

Within the 16 children only 02used metal type tracheotomy and only 01 had been hospitalized.

Before the examination, 04 children presented respiratory symptoms, cough with phlegm, respiratory difficulty, fever and dry cough, although without pneumonia diagnosis.

From those patients with respiratory symptoms before examination, for 02 children the symptoms persisted after taking the exam and the other 02 children the symptoms disappeared.

Related to the via oral by Functional Oral Intake Scale - FOIS (9), 5 (31,25%) were on N1 (Level 1), 1 (6,25%) on N2, 1 (6,25%) on N3, 6 (37,50%) on N5 e 2 (12,50%) on N7. But the occurrence of aspiration during the videofluoroscopy it was 7 (43,75%) children, as shown on Table 1.

By the classification OTT (11) of the Severity of Dysphagia to Fluoroscopy, 5 (31,25%) children presented normal deglutition, 4 (25%) light dysphagia, 2 (12.50%) moderate dysphagia and 5 (31,25%) severe dysphagia (Table 1).

Table 1. Relation of oral intake -FOIS, tracheal aspiration during video fluoroscopy and dysphagia classification level by OTT scale.

	Oral intake - FOIS				Trachealas in examina		Dysphagia classification by OTT					
ΝΙ	N2	N3	N4	N5	N6	N7	Р	Α	Normal	Light	Moderate	Severe
5	- 1	- 1	0	6	0	2	7 (43,7)	9 (56,2)	5 (31,2)	4 (25,0)	2(12,5)	5(31,2)

Source: Author

Note: FOIS® functional scale for nutrition; A=Absent; P=Present; Patients numbers (%).

From 7 (43,75%) children whose examination showed aspiration, 2 (28,5%) simultaneously aspirated consistencies of pudding, honey, nectar and liquid, other 3 (42,8%) children aspirated honey, nectar and liquid and finally, 2 (28,5%) aspirated only the consistency of liquid, as shown on Table 2.

Among 7 (43,75%) children, whose presented tracheal aspiration during examination, only 2 (28,5%) presented respiratory symptoms after deglutition study, however without pneumonia signs on physical examination (Table 3).

DISCUSSION

In this oropharingeal dysphagia, the complications of lung diseases caused by aspiration are the most difficult clinical management. Therefore, the detect ability and the characterization of this aspiration, which occurs in the pharyngeal phase, are primary for prognosis and rehabilitation. The aspiraton can be inferred through clinical evaluation, but its objective confirmation should be done by video fluoroscopy (1).

The video fluoroscopy of deglutition is considered the best instrumental method for evaluation of deglutition

Table 2. Aspiration Occurrence in each consistency tested.

Aspirated consistencies during examination					
Pudding/Honey/	Honey/Nectar/	Liquid			
Nectar/Liquid	Liquid				
simultaneous	simultaneous				
2 (28,5)	3 (42,8)	2 (28,5)			

Source: Author

Note: Patients numbers (%).

in children, therefore it evaluates since the beginning of the oral phase to the esophageal conclusion phase (2).

Table 1 shows that amongst those 16 children evaluated, 7 (43,75%) presented tracheal aspiration, which according to the literature it would be a potentiating to aspiration pneumonia occurrence, as AHCPR, U.S. Government Agency, dysphagia patients who aspire has 50% chance higher to evolve aspiration pneumonia, compared to the patients who don't aspire (5).

Among the survey population, 5 (31,25%) children were classified with severe dysphagia and some studies indicate that children with dysphagia have high risk to develop complications during the examination (3).

Observing Table 02 in this research, we realized that in the examination liquid consistency was the most aspired, and the minor occurrence was the pudding consistency, indicating that the liquid consistency has a higher incidence of aspiration which, according to the literature, it would be another complicating, as the risk on patients who present aspiration pneumonia rises when the liquid consistency is aspirated. In a study, in which there was a retrospective examination of deglutition video fluoroscopy conducted in 150 children with deglutition dysfunction, there were more cases of children with pneumonia who had aspired liquid consistency, which indicated different results from those who had aspired thick liquids and purée consistency, in which pneumonia cases were much lower (13).

In 7 (43,75%) children who aspired during the deglutition examination, after a week only 2 (12.50%) children presented some respiratory symptom, therefore a child presented the same symptom before the

Table 3. Occurrence of respiratory symptoms after deglutition study in patients with light, moderate and severe dysphagia.

Signs and	Level of dysphagia by OTT (1996) classification							
Symptoms	Light			erate	Severe			
afterexamination	Α	Р	Α	Р	Α	Р		
Cough with phlegm	4 (100%)			I (50%)		I (20%)		
Fever	4 (100%)		I (50%)		4 (80%)			
Respiratory difficulty	4 (100%)		I (50%)		4 (80%)			
Nutrition intake								
diminishing	4 (100%)			I (50%)		I (20%)		

Source: Author

Note: A=Absent; P=Present; Patients Numbers (%).

evaluation, and the other child despite having aspirated all of the consistencies and being classified with severe dysphagia, didn't have positive for pneumonia in physical examination, contradicting what literatures had quoted before.

These results also shows the opposite from what the other authors states (14), which say that one of the complications in doing studies of deglutition through video fluoroscopy is that the patient with that disorder can be exposed to the risk of aspirating the contrast, and in this present research is possible to observe a few number of pulmonary complication after examination (Table 3), and without diagnosis for pneumonia.

With this we can answer to two great questions which motivated this research:

- a) The video fluoroscopy of deglutition examination increased the risk of pneumonia?
- b) The risk benefit justifies the procedure?

It is worthy to clarify here that, during the video fluoroscopy evaluation, we could only observe a fractional part of deglutition, and therefore we could not interfere effectively in the occurrence or not of aspiration during deglutition, we could only infer if patient had aspired or not at that fraction of time. Thus, it keep on being the best method to evaluate deglutition on children, as this present research showed evidences and safety on the procedure, even in children with severe dysphagia, and further more, also it is important to underline that video fluoroscopy may have on clinical evaluation not only a complementary nature , but also it helps to determine the therapeutic approaches in a more objective way (1).

CONCLUSION

Video fluoroscopy of deglutition has been the most instrumental method used simultaneously to the deglutition clinical evaluation. But, it is worth to say that is very important having a specialized multidisciplinary examination team.

At the present study there are evidences of safety on this procedure, but in order to affirm this question with more accuracy, it's necessary a greater amount of population researched, leaving it amongst another as a suggestion for continuing researches in this field, as well as correlate the examination data with the underlying disease.

In the studied population, there was not occurrence of aspiration pneumonia after study of video fluoroscopy of deglutition, despite of occurrence of aspiration during examination in about 50% of cases (7/16).

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BIBLIOGRAPHY REFERENCES

- 1. Furkim AM, Behlau MS, Weckx LLM. Avaliação clínica e videofluoroscópica da deglutição em crianças com paralisia cerebral tetraparética espástica. Arq Neuropsiquiatr. 2003, 61:611-616.
- 2. Singh V, et al. Investigation of aspiration: milk nasendoscopy versus videofuoroscopy. Eur Arch Otorhinolaryngol. 2009, 266:543-545.
- 3. Levy DS, Cristovão PW, Gabbi S. Protocolo do estudo da deglutição por videofluoroscopia. In: Jacobi SJ, Levy DS, Silva LMC. Disfagia: Avaliação e tratamento. RJ: Editora Revinter, 2004. p137.
- 4. Ramsey D, Smithard D, Kalra L. Silent Aspiration: What Do We Know? Dysphagia. 2005, 20:218-225.
- 5. Gomes GF. Identificação de fatores preditivos de pneumonia aspirativa em pacientes hospitalizados com doença cerebrovascular complicada por disfagia orofaríngea, Curitiba. 2001 (Tese de Doutorado Universidade Federal do Paraná).
- 6. Marik PE. Aspiration pneumonitis and aspiration pneumonia. New England J Med. 2001, 344(9):665-671.
- 7. Mello-Filho M, Silva DD, Issa RE. Videofluoroscopia da deglutição em crianças. In: Jotz GP, Angelis EC, Barros APB. Tratado de deglutição e disfagia No adulto e na criança. RJ: Editora Revinter, 2009. p.94-96.
- 8. Maempel IZ, Chapple CL, Leslie P. Radiation Dose in Videofluoroscopic Swallow Studies. Dysphagia. 2007, 22:13-15.
- 9. Corbin-Lewis K. Liss JM. Sciortino KL. Bases fisiológicas da disfagia neurogênica e estratégias de tratamento. In:
 ______. Anatomia clínica e fisiologia do mecanismo da deglutição. SP: Cengage Learning, 2009. p.161.
- 10. Crary MA. A direct intervention program for chronic neurogenic dysphagia secondary to brainstem stroke. Dysphagia, New York, 1995: 6-18.
- 11. ADA. National Dysphagia Diet: Standardization for

Optimal Care. American Dietetic Association. 2002; V-1.

- 12. Ott DJ, Hodge RG, Pikna LA, Chen MYM and Gelfand DW. Modified barium swallow: clínical and radiographic correlation and relation to feeding recommendations. Dysphagia. 1996, 11:187-190.
- 13. WEIR K. et al. Oropharyngeal Aspiration and Pneumonia in Children. Pediatric Pulmonology. 2007, 42:1024-1031.
- 14. Eckley CA, Fernandes AM. Método de avaliação Otorrinolaringológica da deglutição. ACTA ORL/Técnicas em Otorrinolaringologia. 2005, 23:12-16.

Annex I

Occurrence of aspiration pneumonia after the performance of the swallow study by videofluoroscopy in infants of high risk

Ocorrência de pneumonia aspirativa após realização do estudo da deglutição por videofluoroscopia em crianças de alto risco

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Original Article

Introduction: The literature report that when it comes of instrumental evaluation of swallowing in infants, without a doubt, the video fluoroscopy of swallow offers a great advantage over the endoscopic study, besides being more feasible, reproduces practically the real situation of a swallow, but there are not reports from the literature about the risks of a aspiration during the exam potentiate the occurrence of a aspiration pneumonia (MELLO-FILHO, et al, 2009). Objective: Verify the occurrence of aspiration pneumonia after the performance of the video fluoroscopy exam, in infants of high risk. Method: Participated of the study 16 children, with age from 6 months to 10 years old, sent with complaints of dysphagia for the area of pediatrics, for the performance of the swallowing video fluoroscopy exam. Before the exam the children were submitted to a x-ray of chest to exclude the possibility of a preview pneumonia. Was performed a comeback after a week for the clinic evaluation and phonological and in the suspicious of a pneumonia were sent to a chest x-ray. This study was approved by the Research Ethics Committee, under the number: 000025/2009, from University Tuiuti do Paraná. For the classification of the dyphagia, was used the Classification of Severity of Dysphagia on Video Fluoroscopy from OTT et al. (1996), in which is classified from Normal, Light dysphagia, moderate and severe. Results: of respiratory symptoms before the exam, 2 children presented cough with mucus and respiratory difficulty, 1 presented fever and dry cough and 1 presented only cough with mucus. As the patients that presented respiratory symptoms only after the exam, only one patient had aspirated the material of the exam, although he did not have a positive diagnosis of pneumonia. In regard of the degree of dysphagia, there were 5 normal children, 4 presented light dysphagia, 2 presented moderate and 5 had severe dysphagia. During the performance of the exam, 7 patients presented aspiration in the liquid consistency, and 2 of them aspirated also in the solid consistency, 4 also aspirated in the pasty consistency and thin paste and the rest did not aspirated. Conclusion: in the present work we can conclude that, among the researched population there were no occurrence of aspiration pneumonia after the exam.

Descriptors: swallow disorder; fluoroscopy; aspiration pneumonia.

Anexo II.

TERM OF CONSENT FREE AND INFORMED

You are being invited to participate of a research. The existent information in this document is for you to understand perfectly the objectives of the research, and knows that is a spontaneous participation. If during the reading of this document you have any doubt you must ask questions for you to perfectly understand of what is about. After being informed about the following information, in the case of acceptance to be part of this study, sign in the end of this document, that contend two ways, being one yours and the other from the responsible researcher.

Information about the research:

Title of the Research Project: "Occurrence of Aspiration Pneumonia after the performance of the swallow study by video fluoroscopy in infants of high risk".

Responsible researcher: Rosane Sampaio Santos Contact telephone: (41) 3331 – 7807

INTRODUCTION:

The aspiration functional dysphagia is the most feared disorder, provoked by aspiration, that is the passage of material under the vocal folds (BOTELHO, M.I.M.R. SILVA, A.A.,2003), and when it happens can occur beyond of other problems the aspiration pneumonia.

The aspiration pneumonia develops after the inhalation of oropharyngeal contaminated material. Even though of this mechanism is common to most of pneumonias the expression of aspiration pneumonia refers to the development of pulmonary infiltrates radiographically evident in patients with increased risk of oropharyngeal aspiration (MARIK, P.E.).

The most used procedure for the investigation of dysphagia is the dynamic study of swallow (LEVY, D.S. CRISTOVÃO, P.W. GABBI, S. 2004).

GOAL OF THE RESEARCH

This work has as goal verify the occurrence of aspiration pneumonia after the performance of the video fluoroscopy exam, in children by means of accompaniment after the realization of the same.

PROCEDURE

The patient is sent for the sector of endoscopy Peroral from Hospital das Clínicas – UFPR, for the realization of the swallowing exam by video fluoroscopy, before the performance of the exam data of the patient will be collected, through interviews from parents or responsible ones, and by collected information from the medical records.

The patient will do the exam, and the data will be collected by means of protocol.

In one week the patient must return to the same sector for the accompaniment of a speech therapist and pediatric, and will be evaluated in regard of the signs of dysphagia, history of aspiration and clinical conditions, and when necessary will be sent to a chest x-ray, to confirm the pneumonia by aspiration.

RISKS AND BENEFITS

The exam is quick and painless. The findings of this research can elucidate questions about the risks of pneumonia after the realization of the exam, being that this exam has great diagnostic importance for the evaluation of dysphagia.

DISCOMFORT

The exam of swallow by video fluoroscopy has as inconvenient the flavor of the consistencies that will be presented, composed by water and barium sulfate.

COSTS

You will not have any spent with the research, because it will be funded by the researcher itself.

PARTICIPATION

In case you want to quit from the participation of the research, you can do it at any time and moment you want to. All the participants of the research will be evaluated by the researcher: Hellen Nataly Correia Lagos graduate from the course of phonoaudiology in which will be under orientation from the speech therapist Rosane Sampaio Santos.

During the ongoing of the research, in case you have any doubt or need a extra orientation use the telephone above.

PRIVACY AND CONFIDENTIALITY

You have the commitment of the researcher that your image and identity will be preserved in absolute secret.

RESPONSIBILITY

In case of any damage during the research, the researchers Rosane Sampaio Santos and Hellen Nataly Correia Lagos are responsible by the eventual reimbursements.

In case of new information during the research, they will be submitted to the evaluation from the Ethics Committee for a new insight.

DECLARATION OF CONSENT

<u>I</u> ,,
carrier of the RG:, signed below,
agree that my child
participate of the study above described as a subject.
I was properly informed and enlightened by the researches
Hellen Nataly Correia Lagos and Rosane Sampaio Santos about the
research and the contained procedures in it.
I was assured that, I can retrieve my consent at any moment,
without this leading for some kind of penalty.
Curitiba,/
Signature of the responsible

Signature of the responsible researcher