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The general publication rules are summarized in the “Uniform Requirements” for Manuscripts Submitted to Biomedical Journals: “Writing and Editing for Biomedical Publication” (www.icmje.org/recommendations). Special suggestions are given to systematic bibliographic reviews and meta-analyses, retrospective and observational studies on epidemiology, clinical trials, diagnostic accuracy and prospective studies, case reports and case studies. We ask the authors to check the information below before submitting the manuscript to SALUS.

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The Salus – *Journal of Health Sciences* is the scientific magazine by EMESCAM – Escola Superior de Ciências da Santa Casa de Misericórdia de Vitória (School of Sciences of Santa Casa de Misericórdia in Vitória) and it is published every four months.

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The works submitted to publication in SALUS must concern themes related to health sciences and health policies.

The following article categories are published in the magazine: original article, editorial, review/update article, case report, brief communication and preliminary note, letter to the editor, experimental work, clinical-surgical correlation and multimedia. The acceptance will be based in originality, significance and scientific contribution. Articles with mere propagandistic or commercial aims will not be accepted. The authors are responsible for the content and information in their manuscripts. The magazine will be fully published in its website (www.salusjournal.org).

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All scientific contributions are reviewed by the Editor, Associate Editors, Members of the Editorial Council and/or Invited Reviewers. The reviewers answer a small questionnaire, in which they sort the manuscript and make a rigorous examination of all items that must compose the scientific work and assign a score to each item of the questionnaire. In the end, general comments about the work are done and it suggests if the work should be published, corrected – according to the recommendations – or definitely rejected. The editor will make the decision based in these data. In case of discrepancies among the evaluators, a new opinion may be requested in order to get a better judgment. When modifications are suggested, they will be forwarded to the main author and then to the reviewers, so they may check if the demands were attended. The authors have 10 days to

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Experimental works involving animals must be submitted to the Ethics Committee of Research with Animals, respecting Federal Law n. 11.794/2008, Decree n. 6.899/2009 and CONCEA (National Council for Control of Experimentation with Animals) Resolution n. 12/2013 – Brazilian Guideline of Practice for Care and Use of Animals for Scientific and Teaching Purposes (Diretriz Brasileira de Prática para o Cuidado e Utilização de Animais para fins Científicos e Didáticos – DBCA), available at: <http://concea.mct.gov.br>. The randomized studies must follow the guidelines of CONSORT (available at: www.consort-statement.org/consort-statement).

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The approval statement of the study by the Ethics Committee of Research must be forwarded along with the manuscript submission. Articles that do not demand such approval must be justified.

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2. To have written the work or revised the successive versions and taken part in the revision process;
3. To have approved the final version.

People who do not match the above requirements and who had merely technical or general support participation may be mentioned in the Acknowledgement section. The kind of contribution from each author to the study performance and to the manuscript preparation must be explained in the following areas, at the moment of submission:

1. Study design;
2. Data collection, analysis and interpretation;
3. Manuscript writing.

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The use of acronyms must be low. When long expressions need to be repeated, it is recommended that its capital initial letters substitute them after the first mention, which must be followed by the initials between parentheses.

All acronyms in tables and pictures must be defined in their respective legends.

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SALUS adopts the Universal Official Anatomical Terminology, approved by the International Federation of Associations of Anatomists (IFAA).

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Title and Authors: The work title, in Portuguese and English, must be concise and

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Descriptors: Three to five descriptors (keywords) must also be included. The descriptors may be consulted in the electronic address <http://decs.bvs.br/>, which contains words in Portuguese and English or www.nlm.nih.gov/mesh, for only English words, or in the respective links available at the submission system of the magazine.

Manuscript Body: The Original Articles and Experimental Works must be divided in the following sections: Introduction, Method, Results, Discussion, Conclusion and Acknowledgements (optional). The Case Reports must be structured with the sections: Introduction, Case Report and Discussion; and the Clinical-surgical Correlations must be divided in Clinical Data, Electrocardiogram, Radiogram, Echocardiogram, Diagnosis and Operation. The Multimedia section must present the following sections: Patient Featuring and Description of the Employed Technique. The Review Articles and Special Articles may be structured in sections according to the author's order.

The Letters to the Editor must, at first, comment, discuss or criticize articles published in SALUS, but they may also refer to other themes of general interest. It is recommended a 1.000 words maximum and it includes five references, maximum, with or without title. Whenever possible, an answer

from the authors of articles in discussion will be published along with the letter.

References

The references of printed and electronic documents must be standardized according to the Vancouver style, elaborated by the *International Committee of Medical Journal Editors* (ICMJE), available at: <http://www.icmje.org>.

The references must be identified with Arabic numerals in the text, superscript, obeying the citation order in the text. The accuracy of the references is an author's responsibility. If more than two references are cited in sequence, only the first and the last must be typed, separated by a dash (Example: ⁶⁻⁹). In cases of alternate citation, all the references must be typed separated by comma (Example: ^{6,7,9}).

All authors must be cited in publications with up to 6 authors; in publications with more than 6 authors, the first 6 are cited followed by the Latin expression "et al."

Titles of journals must be abbreviated according to the List of Journals Indexed for MEDLINE (available at: <http://www.nlm.gov/tsd/serials/lji.html>).

References Models

Magazine Article

Issa M, Avezum A, Dantas DC, Almeida AFS, Souza LCB, Sousa AGMR. Fatores de risco pré, intra e pós-operatórios para mortalidade hospitalar em pacientes submetidos à cirurgia de aorta. Rev Bras Cir Cardiovasc. 2013; 28(1):10-21.

Organization as Author

Diabetes Prevention Program Research Group. Hypertension, insulin, and proinsulin in participants with impaired glucose tolerance. Hypertension. 2002;40(5):679-86.

Without indication of authorship

21st century heart solution may have a sting in the tail. BMJ. 2002;325(7357):184.

Article published electronically before the print version ("ahead of print")

Atluri P, Goldstone AB, Fairman AS, Macarthur JW, Shudo Y, Cohen JE, et al. Predicting right ventricular failure in the modern, continuous flow left ventricular assist device era. *Ann Thorac Surg*. 2013 Jun 21. [Epub ahead of print]

Article of Internet Journal

Machado MN, Nakazone MA, Murad-Junior JA, Maia LN. Surgical treatment for infective endocarditis and hospital mortality in a Brazilian single-center. *Rev Bras Cir Cardiovasc* [online]. 2013[cited 2013 Jun 25];28(1):29-35. Available at: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-76382013000100006&lng=en&nrm=iso

Book Chapter

Chai PJ. Intraoperative myocardial protection. In: Mavroudis C, Backer C, eds. *Pediatric cardiac surgery*. 4th ed. Chichester: Wiley-Blackwell; 2013. p.214-24.

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Cohn LH. *Cardiac surgery in the adult*. 4th ed. New York: McGraw-Hill; 2012. p.1472.

Thesis

Dalva M. Estudo do remodelamento ventricular e dos anéis valvares na cardiomiopatia dilatada: avaliação anátomo-patológica [Tese de doutorado]. São Paulo: Universidade de São Paulo, 2011. 101p.

Legislation

Conselho Nacional de Saúde. Resolução n. 466, de 12 de dezembro de 2012. Dispõe sobre

diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. *Bioética*. 1996;4(2 Supl):15-25.

Conselho Nacional de Controle de Experimentação Animal. Resoluções n. 12 e 13, de 20 de setembro de 2013. Dispõem sobre as diretrizes brasileiras para o cuidado e a utilização de animais para fins científicos e didáticos (DBCA) e prática de eutanásia.

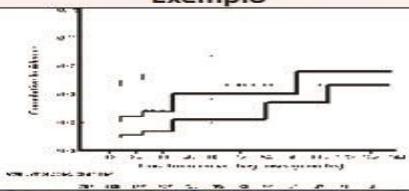
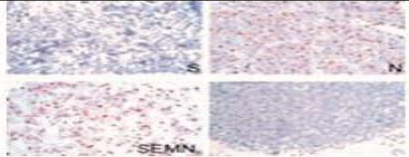
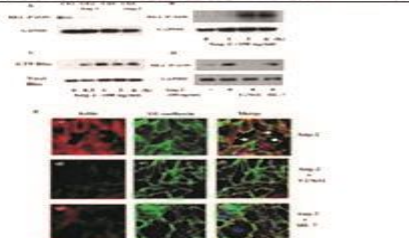
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http://www.nlm.nih.gov/bsd/uniform_requirements.html

Tables and Pictures

The Tables and Pictures must be numbered according to order appearance in the text, contain a title and be in separate files. The tables must not contain redundant data, previously mentioned in the text. They must be open in the sides and with a totally white background.

The acronyms used in the tables must be mentioned in alphabetical order, in the footnote, with their respective full forms. Similarly, the acronym used in pictures must be explained in the legends. The pictures will only be published in colors if the author agrees to afford the costs of impression of colorful pages. Only images in formats TIFF or JPEG will be accepted, with minimum resolution according to the kind of image, for both black and white and colorful images, according to the Table below:

Tipo	Exemplo	Formato	Resolução
LineArt (imagens com linhas lineares, normalmente gráficos com texto)		TIF ou JPG	900 a 1200dpi
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The following criteria sorted by type of publication must be observed, aiming to rationalize the space in the magazine and allow more articles per edition. The electronic word count must include the initial page, abstract, text, references and picture legends. The titles have 100 characters limit (counting the spaces) for Original Articles, Review and Updating Articles and Experimental Work; the other categories have 80 characters (counting the spaces) title limit.

	Original Article	Editorial	Review / Updating Article	Case Report	Case Report and Literature Review	Brief Communication and Preliminary Note	Letter to the Editor	Experimental Work	Clinical-Surgical Correlation	Multimedia
Maximum number of authors	10	4	5	4	6	4	2	10	4	4
Abstract – Maximum number of words	250	-	200	100	100	100	-	250	-	-
Maximum number of words	6,000	1,000	8,000	1,500	3,000	2,000	400	6,000	800	800
Maximum number of references	40	10	75	6	20	6	6	40	10	10
Number of tables and pictures	8	2	8	2	6	2	1	8	2	1
Abbreviated Title	—	—	—	—	—	40 Characters	—	—	—	—

Table Model:

Table 1 – Model table

AREAS	UNESP	UNICAMP	USP	TOTAL
Interdisciplinary	2	2	2	6
Biological and Health	2	2	2	6
Exact and Technological	2	2	2	6
Human and Arts	2	2	2	6
TOTAL	8	8	8	24

Picture Model:



Figura 3 – Exemplos de segmentações classificadas como parcialmente concordantes para o sistema Osiris (contorno amarelo) e o Sistema para a Detecção e a quantificação de Enfisema Pulmonar (SISDEP; contorno vermelho). Sobreposição dos contornos de segmentação em imagens de TCAR em nível de hilo (em a e b) e em nível de base (em c). Em a, a concordância é parcial por imprecisões geradas na segmentação dos dois sistemas; em b, por imprecisão realizada pela segmentação do SISDEP; e em c, por imprecisão ocasionada pela segmentação do sistema Osiris.

Check it before sending the work

- Submission letter indicating the manuscript category.
- Statement by authors and co-authors saying that they agree with the content of the manuscript.
- Approval Letter by the Ethics Committee of Research.
- Manuscript written in software Word 97 or above (formatted to A4); font size 12, space 1.5, font Times New Roman; paged; mathematical symbols and Greek characters using font Symbol.
- Manuscript in the limits adopted by SALUS for its category.

EDITORIAL

Pollinators and food security in the following decade

There are two divergent and worrying tendencies which are to become evident in the following decade: the decline of pollinators and the increasing demand for food.

The U.S. Agriculture Ministry has reported a decline in the number of domestic bee hives (*Apis mellifera*) over the last 50 years. Some specific events seem to have contributed to this decrease, such as the increasing use of pesticides and the alarming spread of plagues such as the varroa mite (*Varroa destructor*), pests and pathogens.

Despite the decline of pollinators, there has been growth in the agricultural production due to mechanization, expansion of productive areas, seed selection, precision agriculture, among other innovations in the countryside. Not all agriculture products depend on insects and other animals to pollinate. The most pollinator-dependent products are apple, cherry, citrus, diverse nuts and almost all vegetables. Besides these and many other products, pollinators have also an important role in the management of ecosystems. The actual pollinating task force are the bees (*Apis* or *Bombus*) for being tamable and for having a well-known life cycle.

In the following decade, the World will have to produce 60% more food to feed a population of nine billion people. Among the highest risks for food security are the climate change, which creates harvest losses due to extreme events, diseases, plague spread, and the decline of pollinators.

The events that will follow a world without enough pollinators to grant agricultural production are dreadful. In the first moment, apiculture will become economically inviable, despite the huge bee demand for pollination. Therefore, some farms which depend on this business will be shut down, in case the market does not agree to pay high prices for these products.

After that, the nutrition patterns of the population will be severely damaged and diseases related to malnutrition will grow disproportionally. Finally, the countries extremely dependent on agriculture will become a source of refugees.

The causes for the decline of pollinators are still not clearly known; it has been long since researches began. Journals such as *Salus* also contribute to this debate, particularly when it comes to the impact of change in nutritional quality in public health care. We look forward to seeing this journal as a medium for interdisciplinary information and update for healthcare professionals.

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Office of the Chief Executive Science Leader
Commonwealth Scientific and Industrial Research Organisation (CSIRO)
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REVISTA SALUS

JOURNAL OF HEALTH SCIENCES



ORIGINAL ARTICLE

Gastroschisis: incidence and associated factors

Rafaela Martins Togneri¹; Hector Yuri Conti Wanderley²; Andrea Lübe Antunes de S.Thiago Pereira³; Luiz Roberto da Silva Santos⁴; Vitor Ohnesorg Barbieri⁵; Maria do Carmo de Souza Rodrigues⁶; Larissa Souza Mario Bueno⁷; Vera Lucia Maia⁸; Geisa Hossokawa Eguchi Neves⁹; Sandra Willéia Martins¹⁰; Ingrid Hellen André Barreto¹¹; Renata Cristina Moreira Queiroz¹²; Marya Duarte Pagotti¹³; Aline Ximenes Fragoso¹⁴; Polyana Gonçalves Rocha¹⁵; José Carlos Frasson¹⁶; Regina Galvêas Oliveira Rebouças¹⁷; Maria Rita Passos Bueno¹⁸; Eliete Rabbi Bortolini¹⁹; Flávia Imbroisi Valle Errera^{20*}

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Gastroschisis;
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Abstract

Introduction: Gastroschisis is an abdominal wall defect closure with externalization of intra-abdominal structures, without fully established cause. Its prevalence has increased in various populations, making it a public health issue. The clinical description of new cases and the investigation of associated factors in each population is important for better understanding of disease etiology and adoption of preventive measures.

Objectives: To describe a series of cases of gastroschisis identifying the incidence and associated factors.

Methods: A total of eight cases of newborns (NB) with gastroschisis in a teaching hospital from April 2011 to April 2012. The variables analyzed were collected from the study database "Characterization and Clinical Epidemiology of Congenital Anomalies in the Maternity of two Hospitals School of Vitória - ES "and the medical records of mothers and newborns. The patients born during this period were investigated for the presence of congenital anomalies.

Results: There were eight cases of gastroschisis described, which was compared with 1139 RN without congenital anomaly. None of the cases mothers had higher education level five planned pregnancy, 87.5% of primiparous mothers, with a median maternal age of the cases (21 years old) reduced compared to the control group (26 years old) $p = 0.0089$). 12.5% was observed familial recurrence. Death occurred in three cases, one with karyotype 46, XX inv.9.

Conclusion: Mortality rates, prematurity and low birth weight were very high. The occurrence of gastroschisis was associated with low maternal age, socioeconomic and genetic factors.

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Introduction

Gastroschisis is a congenital malformation (OMIM 230750) characterized by a defect in the abdominal wall, with the externalization of abdominal viscera, especially the intestine. Usually there are no alterations in the umbilical cord due to the fact that the defect is located at the junction of the umbilicus and normal skin and usually to the right.¹

The most accepted hypothesis to explain the etiology of the defect is the occurrence of ischemia of the abdominal wall during its development. Between the 5th and 8th weeks of embryogenesis a nutritional transition occurs, with the involution of the right umbilical vein to the right omphalomesenteric artery. Embryo disruption of these vessels or the mismatch in the timing of this transition may cause vascular ischemia.² Although well accepted, this hypothesis does not explain the cases of gastroschisis to the left. Another hypothesis related to the etiology of gastroschisis is the hypothesis of the three parts. This consists of (1) an early estrogenic thrombophilia, which occurs mainly in the first trimester of pregnancy in young primigravida mothers; (2) different responses to thrombosis, according to ethnicity and (3) thrombotic byproducts which can interfere with early developmental signaling.³ Besides these, Jones et al (2013) recently suggested the hypothesis that a maternal inflammation during early pregnancy, possibly resulted of imbalance in fatty acid metabolism, can lead to vascular disruption.

The prevalence of gastroschisis is progressively increasing in all regions of the world. Next to the 60s when the monitoring programs and data collection on congenital malformations started, it was 1: 50,000 births and has increased about 10 to 20 times in various populations ever since. Currently, it presents reasons of 1-2 to 4-5 per 10,000 depending on the studied population. According to data of Latin

American Collaborative Studio of Congenital Malformations (ECLAMC), the prevalence in South America is 2.9: 10,000.⁴

Etiologies of gastroschisis are largely unknown, and even its pathogenesis is poorly understood. The non-genetic risk factors for gastroschisis includes sociodemographic, being education level the most important, maternal therapeutic medication, exposure to non-therapeutic drugs, being reduced maternal age (< 20 years old), smoking, illicit drug addiction the most replicated factors.⁵ On the other hand, there is no consensus on the contribution of genetic factors, being observed familial recurrence in 4.7% of cases. Recent studies have identified interaction between maternal smoking, genetic variants (single nucleotide polymorphism - SNP) in the enzyme gene nitric oxide synthase and the risk of gastroschisis.⁵

The objective of this study is to report the incidence of gastroschisis, with the description of eight cases and associated factors.

Method

This retrospective study is part of the project "Clinical and Epidemiological Characterization of Congenital Anomalies in the Maternity of two Teaching Hospitals of the Municipality of Vitória - ES" (approved in CEP EMESCAM under no. 148/2010), a cross-sectional study involving four higher education institutions, maternity units of two teaching hospitals and a children's hospital of reference in the state of Espírito Santo (ES), which was aimed at the clinical and epidemiological characterization of the CA in the ES, through the clinical evaluation of the newborn (NB) in maternity wards of teaching hospitals Hospital Santa Casa de Misericórdia de Vitoria (HSCMV) and Hospital Cassiano Antonio de Moraes of the

Federal University of Espírito Santo (HUCAM / UFES). The participation of the NB and his mother in the research was authorized by signing the Terms of Consent. Data from mothers who participated in the research were obtained through interviews and analysis of the records. For twelve months, the NB were evaluated 24 hours after birth by neonatologists and pediatricians for the presence of major and minor CA using, during the physical examination, the modified protocol of Merks et al (2003). Among the evaluated NB, those with at least one major anomaly and those with at least 3 or more minor anomalies were referred to genetic clinics at Hospital Infantil Nossa Senhora da Glória (HINSG), for specific clinical evaluation, monitoring of patients and families, diagnosis and genetic counseling. Peripheral blood was collected for cytogenetic and/or DNA study, which was isolated using commercial kits (Gentra and Puregene Blood Kit, Qiagen). Clinical data, karyotype, and additional tests were analyzed by staff and used to establish the etiology of the CA with regard to the type and frequency of genetic alterations. Clinical data of these mothers and their NB were placed in a database containing about 70 variables.

Variables of mothers, fathers and NB diagnosed with gastroschisis in HUCAM were obtained from the database and medical records of mothers and NB. Families were approached in hospitals, address and through phone. The following variables of NB were analyzed: sex, gestational age (GA), anthropometric parameters (weight, length, head circumference and appropriate weight for gestational age), prematurity, associated CA (major and minor), family history of CA and karyotype (when available), hospitalization time and outcome. In addition to these, were investigated age and occupation of both mother and father, maternal education, parity, abortion, stillbirth, pregnancy planning, use of folic acid, presence of chronic diseases,

TORCH's agents serology (when available), exposure to drugs, alcohol, tobacco and illicit drugs. Every NB with GA less than 37 weeks was considered premature⁶, and birth weight was considered low when less than 2500g and very low when less than 1500g.⁷

Patients who have been diagnosed with gastroschisis were considered cases and patients without AC were considered controls.

Statistical analysis was performed using the program GraphPad Prism and SPSS version 11.0. The Kolmogorow-Smirnov test was used to verify if the variables presented normal distribution. Variables where the probability distribution was not normal, the average was considered and the Mann Whitney test applied. Categorical variables were analyzed using Fisher's exact test. X^2 values less than 0.05 were considered significant.

Results

From April 2011 to May 2012 were attended 1242 NB in Hospital Santa Casa and 1057 in HUCAM totaling 2299 NB, being 1148 (49.94%) female and 1,145 (49.8%) male. Undefined sex was observed in three cases (0.13%): two with ambiguous genitalia and one without external genitals and anus. In other three it was not possible to obtain this information. Of 2299 NB studied eight were diagnosed with gastroschisis (cases), resulting in an incidence of approximately 1/287 births. All newborns with gastroschisis were born in HUCAM, hospital that attends high-risk pregnant women.

The control sample consisted of 1139 NB (49,54%), being 575 (50,48%) female and 564 (49,52%) male.

Of the eight cases, there were four males and four females. The median GA was 36 weeks (31-38 weeks) and six births were preterm. The median birth weight was

2.240g (1440g - 3756g), four infants with low birth weight, one of them being classified as very low. In the occurrence of associated abnormalities, it was found the presence of more than one CA in three cases. Of the three NB that died, two had associated CA. In three cases the family history of CA was positive, and in one of them, there are reports of gastroschisis in a cousin (Table 1).

Maternal age ranged from 13 to 25 years old, being the median 21 years old (13-26; IC95%: 17.16-23.84). In the control sample (N = 1133), the median was 26 years old (14-64, 95% CI 26.43 to 27.22; P = 0.0089). Two mothers had less than twenty years old, three twenty years old and three above this age. Seven mothers were primigravida, and only one multigravida (G3). No cases of stillbirth or miscarriage was found in the analyzed sample. Five mothers planned pregnancy, in two the pregnancy was

unplanned and in one case this information was not possible. All mothers had used folic acid only during pregnancy. It was observed that one mother had Familial Hypercholesterolemia and other Hypertensive Disease of Pregnancy. Serology for syphilis, hepatitis B and HIV were negative in three mothers, and in two of them found seronegative also for hepatitis C, toxoplasmosis and rubella. Two mothers denied the use of both alcohol as tobacco and illicit drug use during pregnancy and was not found data on these variables in the records. Analyzing the socioeconomic factors there is the education level, in which three had complete primary education, and five had finished high school, training at a higher level was not observed. Paternal age ranged from 18 to 26 years old (median 22.5 years old).

Table 1 – Clinical Description, associated anomalies, family history and hospitalization time of NB with gastroschisis

Case	Gender	GA (Weeks)	Weight (g)	Length (cm)	CP (cm)	Adequacy weight/GA	Other major CA	Minor CA	Family history of <u>Gastroschisis</u>	Karyotype	Hospitalization (days)
Case 1	F	36,3	2500	44	33,5	AGA	N	Low-set left ear	S – <u>Gastroschisis</u>	46, XX	13
Case 2	M	38	2795	46	33,5	AGA	N	Auricular Hypertrichosis. Stiff Limbs, Increased distance between 1 st and 2 nd toe	N	-	26
Case 3	F	38,3	1980	40	31,5	SGA	N	-	N	-	71
Case 4	M	31	1440	43	36,5	AGA	N	-	S – <u>Gastroschisis</u> (cousin)	-	83
Case 5	F	36	3756	51	34	AGA	N	-	Down's Syndrome (2 nd degree cousin)	-	2
Case 6	M	36,6	1700	41	30	SGA	N	<u>Macrostomia</u>	N	-	NO
Case 7	F	34	1614	42	30	SGA	N	-	Muteness (cousin)	-	42
Case 8	M	36	2540	-	-	-	N	Low-set ears	N	46, XX inv. (9)	2

Legend: F: Female; M: Male; GA: Gestational Age; CP: Cephalic Perimeter; AGA: Appropriate for Gestational Age; PIG: Small for Gestational Age; Y: Yes; N: No; CA: Congenital Anomaly. Source: author. Note: translated.

Discussion

The incidence of gastroschisis in the studied hospital was of 1: 287 births, which concurs with the data from different regions of

Brazil and the world, which show an increase in this incidence. In the 60s, after the implementation of monitoring programs and data collection related to congenital

malformations in many countries, the incidence was estimated at 1: 50,000 births. In the last two decades it was observed an increase in this rate, according to data from the Latin American Collaborative Study of Congenital Malformations (ECLAMC), the prevalence in South America is of 2.9: 10,000.⁴ Should be highlighted that the eight NB were born in the maternity ward of a hospital that serves high-risk pregnancies.

Hunter and Stevenson⁸ reported that there is a relation of prematurity and low birth weight with gastroschisis, this fact observed in our study, in which prematurity was seen in six NB with median GA of 36 weeks and weight of 2.240g, being the low birth weight in four of them and considered appropriate in only four cases. According to these authors, in the big series published in the last two decades, the average gestational age was 36.2 weeks and the average weight was 2400g.

The presence of severe CA, or genetic syndromes associated with gastroschisis is infrequent, occurring in 6.8% to 20% of cases, but there may be local malformations such as atresia or intestinal stenosis.⁹ However, Patroni et al¹⁰, analyzing 24 cases, found a high incidence, around 37.5%. The incidence found in this study was 50%, higher than those reported so far (Table 1), possibly by using the modified protocol Merks et al (2003), neonatologists and pediatricians team training, as well as triage held in the maternity.

It should be highlighted that the use of this protocol contributes to the identification of several minor CA, observed in four cases, being the ear abnormalities the most common. In both cases the karyotype was performed, one shown normal result and the other found a variant of normality (Table 1).

Poulain et al¹¹ also found high association rates with other CA (20% or more), such as congenital clubfoot, micrognathia, clinodactyly, holoprosencephaly, unilateral absence of the ulna and radius, and

aneuploidy, concluding that although gastroschisis is less often associated with other malformations and congenital anomalies, it is prudent to carry out a detailed ultrasound and karyotype analysis in all cases.

An interesting data was observed in relation to chromosomal alterations considered "normal variants", which are found in 3-4% of the general population, being more common in black individuals (3.57%) than in white people (0.73%), in women and in patients with Down Syndrome. In this work one NB presented the variant inv9 and died. There is controversy as to the pathogenicity of these variants, however, some authors show positive association with reduced fertility, leukemia, schizophrenia, abortions and unspecific CA¹². With use of the genomic methodologies this controversy can be clarified.

The main variables related to deaths in NB with gastroschisis are low birth weight, prematurity and presence of infections¹³, but none of these are specific factors of this CA. The complexity of gastroschisis is a specific factor for the increasing of morbidity and mortality. Such complexity is determined by large intestinal impairment, sepsis or complications of Short Bowel Syndrome⁹. In our study we observed that in one case the cause of death was pneumonia, possibly due to long periods of mechanical ventilation¹⁴. In another case observed as a cause of death, hypovolemic shock and renal failure; This patient required reoperation, and had severe edema handle, prognosis complicating factor.

Some studies discuss the influence of prenatal care on mortality rate for patients with gastroschisis. A retrospective study showed an association between non performing prenatal care and a higher mortality rate of patients with gastroschisis. According to these authors, when prenatal care is not performed properly, the diagnosis of gastroschisis is not made during this period and thus, there is no proper management of patients¹⁵. Also in

this study, Sbragia et al¹⁵ found that lacking the knowledge of having of this CA during pregnancy probably results in absence of additional care during childbirth, which aim to reduce the contamination of the abdominal cavity. In addition, they observed that prior knowledge of gastroschisis enables maternal transfer to a tertiary care center, providing most appropriate decision making regarding the child. In this study, only one of the mothers did not follow the prenatal and their NB did not come to death. In a national study, Vilela et al¹⁶ reported a mortality of 53% of cases of gastroschisis in a northeastern population of Brazil.

However, they studied a population where access to good care is precarious. In this series of cases a mortality rate of 37.5% was observed and even though high is still lower than in some Brazilian regions, such as Northeast that comes to be 52%.⁴ Unlikely, developed countries have low mortality, and survival is above 90% in these locations. The mortality rate of 25% (2/8) is smaller than those found in the Northeast and in Porto Alegre.

With regard to maternal age, a median of 20 years old (13-25 years old) was obtained, which corroborates data from other studies, such as Feldkamp et al⁵, in which the low maternal age (< 20 years old) is shown as a risk factor for the onset of gastroschisis.

Regarding socioeconomic factors, it was seen that none of the mothers had higher education, and that five of them had completed high school. Vu et al¹⁷, found that in California the prevalence of gastroschisis was higher in mothers with lower education levels, i.e., who did not have completed high school (46.27%). In a study conducted in Brazil between 2000 and 2004, Guerra et al¹⁸ observed a higher frequency of CA, including gastroschisis, in NB of mothers with fewer years of schooling; Furthermore, they found that The difference of prevalence among women with lower education levels and those with 12 years or more of schooling increased

throughout the study period, reaching a maximum in 2004: 106.5/10,000 (0-7 years of schooling) and 60.8/10,000 (12 and more years of schooling). More recently, in case-control studies, Nhoncanse et al¹⁹ found a greater number of mothers with education level of eight or less years of schooling in the group with CA (cases). These authors reported that there is probable evidence that low education level is responsible for the increased exposure to teratogens, due to the poor level of knowledge of the risks involved. However, the latter two studies have analyzed the relationship between education and gastroschisis directly, only evaluated the level of education regarding birth defects, even if gastroschisis was included among them. However, contrary results were obtained by Reis and Ferrari²⁰, which sought to identify the sociodemographic profile of mothers of NB with CA, and found a higher number of cases of CA in NB of mothers with secondary education (37.9%) when compared to mothers with primary education (5.2%) or no education (0.6%) in a total of 174 cases.

The use of illicit drugs has shown strong risk factor for the onset of gastroschisis, especially when using more than one drug in combination (cocaine, amphetamines and marijuana) or if compared to single use in which both parents make use of narcotics. This is shown by the study of population-based data from the California Birth Defects Monitoring Program - USA (CBDMP), directed by Torfs et al²¹. The increased risk by smoking is higher in older women (> 25 years old) and in higher socio-economic groups.^{22,21} None of pregnant women in this study reported use of alcohol, tobacco or illegal drugs.

Some patients make use of medications such as methyldopa, Bromopride, Clonazepam and Etilefrine Hydrochloride, however, there are currently no studies that prove the relationship of these medications with the onset of the disease. In one study, Aceves et al²³ demonstrated a relationship

between the onset of gastroschisis and the use of hormonal contraceptives during first trimester of pregnancy. In another study, by Mac T. Bird et al²⁴, the use of ibuprofen was revealed as a risk factor, however, in our study did not report the use of these medications for any of the mothers. Torfs et al²⁵ also mentioned the use of ibuprofen, aspirin and decongestants as strong risk factors and on the other hand has shown that antibiotics, antiemetics, sulfonamides and oral contraceptives do not offer risk.

Conclusion

Mortality rates, prematurity and low birth weight associated with gastroschisis were very high. The incidence of gastroschisis was associated with low maternal age, the presence of other minor congenital anomalies and socio-economic and genetic factors. The incidence of gastroschisis observed in this study was very high and the observed associations suggest the need for further investigation, proposal and adoption of preventive measures.

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REVISTA SALUS

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CASE REPORT

Acrodermatitis enteropathica like: case report

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Keywords

Acrodermatitis;
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Abstract.

The present study is a case report of Acrodermatitis Enteropathica-like syndrome of a patient who is female, white, and was detected at 5 months of age and treated with zinc supplementation. The etiology may be due to an inborn error of metabolism configured by autosomal recessive inheritance, or due to personal and/or environmental factors. The monitoring of the infant until total suspension of therapy is necessary to verify episode or non-recurrence of the condition.

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Introduction

Acrodermatitis enteropathica is a disease resulting from deficiency of zinc absorption from the gastrointestinal tract, causing low serum values of this element. Its etiology may be due to an inborn error of metabolism configured by autosomal recessive

inheritance, or due to personal and/or environmental factors such as prematurity, malabsorption syndrome, short bowel, low zinc intake, and other factors.

Zinc is an essential element in several metabolic functions and the lack of it triggers acral and periorificial skin lesions,

chronic diarrhea, weight loss, alopecia, growth retardation and immunodeficiency

This paper reports a case of Acrodermatitis Enteropathica at the Hospital of Pemphigus in the city of Uberaba, Minas Gerais, Brazil, in 2013. It is justified by the fact that this disease has a low incidence in the population, often observed in specific groups, such as premature babies hospitalized in intensive care units and the elderly.

The following databases have been used: Medline, SciELO, Lilacs-Bireme and Cochrane and the works have been selected according to their relevance from 1974 to 2015. The parents of the patient have also signed the informed consent form (ICS).

Case Report

AAC, female, caucasian, 5 months old, born in São José do Rio Preto, state of São Paulo (SP), originally Fernandópolis/SP. Born of caesarean section at 31 weeks due to maternal placental insufficiency, with birth weight of 1.300 kg, hospitalized in the intensive care unit for 55 days from birth. Exclusive breastfeeding.

In June 2013 the infant started to show reddish spots in the perilabial region with subsequent evolution to similar periungual stain on the hands and feet and finally reaching genital and lower limb regions. The stains gradually increased in size, as shown in Picture 1.



Picture 1: Initial stage of the lesion development in September 2013. Erythematous rash, bright and well defined edges, periorificial. Source: author.

The infant stool had a soft appearance and and difficulty to gain weight. She had no other systemic symptoms. The situation did not improve with topical or oral antibiotics and antifungals or with corticosteroids and topical immunomodulators.

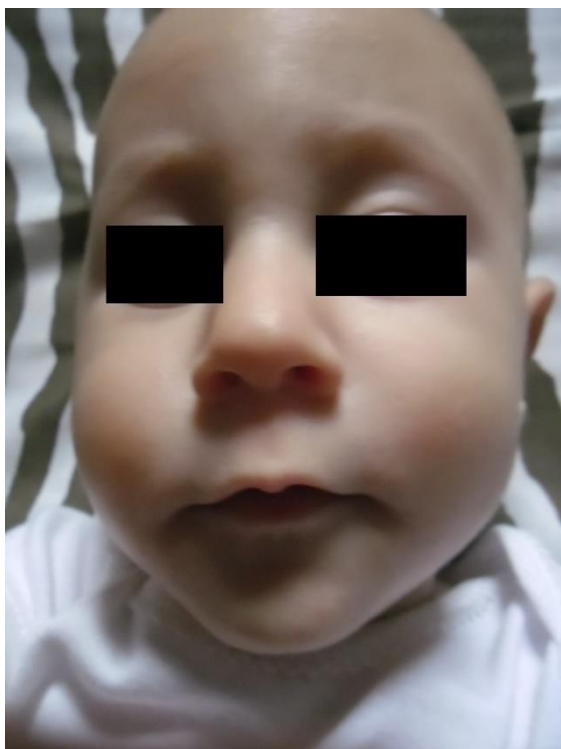
Physical examination was presented in good general condition, ruddy, hydrated, anicteric, acyanotic, emaciated. Distended abdomen, tympanic, normal bowel sounds, absence of visceromegaly. Cardiorespiratory system had no alterations. Reddish stains have been observed, of well-defined edges, bright, humid in perilabial regions, left ocular edge, periauricular, ears, buttocks, groin and labia majora, right and left thighs, phalanges, periungual regions of hands and feet, arms and legs and posterior occipital region. The infant had also a pressure ulcer in the lower back.

The laboratory test presented serum level of zinc of 63.4 (70 to 120 mg/dL) as of September 4 2013.

Zinc replacement started on September 7 2013, in the form of gluconate, at a dose of 100 mg per day orally. Eight days after the start of zinc replacement there had been significant lightening of stains and remission of some injuries, in addition to

improvement in the general state of the infant.

Lastly, twenty-two days after the start of the treatment, it was possible to observe almost 100% remission of the stains, as shown in Picture 2.



Picture 2: May 2014. Six months after the initial stage of zinc supplementation. Total lightening of injuries, without sequelae.
Source: author.

It must be emphasized that as the clinical aspect was improving, her serum levels of zinc were also increasing, reaching the end of treatment with physiological levels of serum zinc (serum zinc value (mg/dL), average: 70-120 mg/dL), according to zinc dosage method: Atomic Absorption Spectroscopy.

Serum zinc levels since start of medical treatment: September 4 2013 – 63.4 mg/dL, October 7 2013 – 121.3 mg/dL, November 7 2013 – 92.6 mg/dL, December 11 2013 – 128.4 mg/dL, January 13 2014 – 105.1 mg/dL, March 10 2014 – 156.0 mg/dL, April 22 2014 – 174.5 mg/dL, June 12 2014 – 213.0 mg/dL, August 10 2014 – 216.0

mg/dL, October 22 2014 – 122.1 mg/dL, December 10 2014 – 85.7 mg/dL.

On April 29 2014 the zinc gluconate dose had been reduced to 80 mg per day. In June 21 2014 the zinc gluconate dose had again been to 60 mg per day. On August 25 2014 the zinc gluconate dose had been reduced to 40 mg per day. On October 29 2014 the dose was further reduced to 30 mg per day and so it remained until January 2015.

The patient had no recurrence of the injuries and evolved with weight gain and significant improvement in general health and neuropsychomotor development.

Discussion

Zinc is one of the main chemical elements in humans that exert catalytic, structural and regulatory functions.¹ It is an essential cofactor for many enzymes throughout metabolism and plays an important role in growth and development, in cellular proliferation and tissue repair. It also has an important role in the immune system by depressing the cytotoxic activity of lymphocyte T killers and the phagocytic and bactericidal capacity of neutrophils.²⁻⁹

The term Acrodermatitis Enteropathica (AE) refers to a rare disease of autosomal recessive origin, where a disorder in zinc absorption occurs, typically observed after weaning, requiring zinc replacement throughout life.¹⁰⁻¹⁶ World distribution has an estimated incidence of 1 in 500,000 live births, and there is no predilection for gender nor race. Exclusive breastfeeding is a protective factor and an effective therapy due to the presence of a low molecular weight binding, which increases zinc absorption in the gastrointestinal tract of infants.^{2,10,11,16-18} At first, the mutation of a gene has been reported in mice and named "lethal milk" (lm).^{2,10,11,19,20} After that, the acrodermatitis enteropathica gene was isolated, named SLC39A4, located in 8q24-

3 chromosome region, which encodes the zinc transporter, Zip 4.^{5,12,13,16 19}

In contrast, the transient and symptomatic zinc deficiency (AE like), self-limited situation, usually occurs between the 8th and 24th week of life and can occur even in children on exclusive breastfeeding, premature or full term. In most cases, it is due to low amounts of zinc in breast milk, despite maternal serum levels being normal.^{1,10,11,14,15,18} Furthermore, after zinc supplementation, there had been an increase in serum level but not in breast milk. A defective secretion of zinc is observed by the mammary glands due to ineffective absorption of plasma zinc to the breast, then suggesting a deficiency or malfunction of the zinc binding.^{1,10,12,15,20} Studies indicate that the zinc transporter gene SLC30A2 (ZnT2) is responsible for this defective transfer.¹⁹

The zinc concentration in breast milk typically falls exponentially during the course of lactation. The concentration in the first week is 80 to 110 mmol/L and in the fourth, 30 to 80 mmol/L. The minimum acceptable level of the concentration in the 20th week is 11 to 12 mmol/L. The concentration of zinc in breast milk of mothers of premature or full term infants is not different.^{11,12}

There are cases described in the literature of premature in exclusive breastfeeding that develop zinc deficiency symptoms, and whose breast milk has normal levels of zinc.^{4,10,11} These cases are more complex due to numerous physiological and organic factors. The large zinc accumulation occurs in the 3rd trimester of pregnancy, therefore, the amount of body zinc is inversely proportional to the degree of prematurity. In addition, premature infants are prone to a negative zinc balance until 60 days of life, secondary to poor absorption of zinc, increased intestinal secretion of zinc, increased zinc demand due to the fast growth and development and high loss of this element in feces.^{1,2,4,10,12,18} This situation was more observed in premature

infants between 25 and 33 weeks of gestation.¹¹

The transient symptomatic zinc deficiency and Acrodermatitis Enteropathica share the same clinical characteristics, and include erythematous rash, vesiculobullous, or psoriasiform, symmetrical, in perioral and perineal regions, with acral distribution of lesions, paronychia, onychodystrophy, soft stools, alopecia, fever, growth disorders, conjunctivitis and behavioral changes such as irritability and prostration.^{2-4,6-11,13,15-17}

In transient symptomatic zinc deficiency, the effect of zinc supplementation is rapid, taking only 3 days to 2 weeks to show lightening of the skin injuries. Treatment in these cases is kept until weaning. In contrast, in congenital Acrodermatitis Enteropathica zinc supplementation is for life.^{2,11}

However, it is still important to report the differences between the variants of congenital acrodermatitis enteropathica and acquired acrodermatitis enteropathica, that until nowadays, are considered diseases of diagnostic importance. It is also important to recognize the etiology of zinc deficiency in infants.¹¹

Congenital: Acquired

1) Acrodermatitis Enteropathica: Inadequate supplementation of zinc:

- a) Low level of zinc in breast milk;
- b) Total parenteral nutrition with low level of zinc.

2) Prematurity:

- a) Low accumulated amount of zinc (obtained after 3rd trimester);
- b) Low absorption of zinc and high fecal loss.

3) Bad absorption:

- a) Cystic fibrosis;
- b) HIV infection.

Besides the differences presented, it is important to highlight other causes of zinc acquired deficiency which can result in skin injuries similar to those previously reported: Syndromes of intestinal malabsorption, extensive burns, Crohn's disease, sickle cell anemia, celiac disease, systemic malignancy, pancreatic insufficiency, renal tubular dysfunction, drugs, defects in the mammary secretion of zinc, short bowel syndrome, diets rich in phytates (leguminous) and calcium, total parenteral nutrition.³

The AE has as differential diagnosis: psoriasis, seborrheic dermatitis, atopic dermatitis, contact dermatitis, impetigo, mucocutaneous candidiasis, histiocytosis X, biotin deficiency and of multiple carboxylases.^{2,6,11}

The treatment of choice is zinc supplementation, which can be done through oral preparations based on acetate, gluconate, sulfate or amino acid chelate, in an average dose of 1 to 2 mg of elemental zinc/kg/day.^{2,12,17}

The case described in this paper is probably a transient and symptomatic zinc deficiency due to prematurity, although it is not possible to establish the precise cause due to unknown zinc dosage in breast milk. It was possible to reach this conclusion because of the following factors:

- Beginning of skin injuries with 3 months of life, when the infant was still in exclusive breastfeeding;
- Prematurity (31 weeks) and long period of stay in Intensive Care Unit;
- Quick improvement with zinc supplementation;

However, it is still necessary to monitor the infant until full suspension of therapy, to verify if there is recurrence of the situation, that if it occurs, speaks in favor of Acrodermatitis Enteropathica. Not less important is to track future pregnancies of the mother, due to a possible deficiency in

zinc binding in the mammary glands, which, if any, will cause the same clinical condition in subsequent pregnancies.

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ORIGINAL ARTICLE

Occurrence of enteroparasites in stallholders and their role as disseminators in Vitória, Espírito Santo, Brazil

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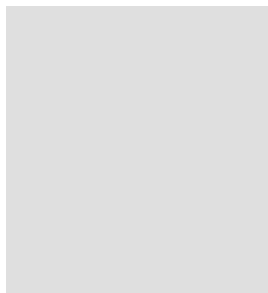
Keywords

Food
Parasitology;
Parasitic
Diseases; Market
Sanitation;
Helminths;
Protozoan
Infections; Health
Education

Abstract

Introduction: The enteroparasitosis are among the diseases transmitted by food due to its improper handling. Studies that evaluate the parasites in food handlers professionals may shed light on the matter, as well as aid in the control of their dissemination.

Objective: Assess the occurrence of enteroparasites in stallholders and characterize their importance in the dissemination of enteroparasitosis to customers. **Methods:** The samples were composed of biological material collected from stallholders in the municipality of Vitória, state of Espírito Santo, Brazil. The material from the stallholders' nail beds and hand palms were obtained through swab and analyzed by the modified Mello and collaborators method. Three stool samples were obtained and then analyzed by the Hoffmann, Pons and Janer method. **Results:** The helminths and protozoans with the highest prevalence in feces were: *Blastocystis* sp. (67.0%), *Ascaris lumbricoides* (40.0%), hookworms (40.0%), *Giardia lamblia* (20.0%), and *Schistosoma mansoni* (13.3%). Regarding the eggs and cysts found on the hands, they are: *A. lumbricoides* (33.3%), hookworms (16.7%), *Rodentolepis nana* (16.7%), and *G. lamblia* (16.7%). The results



indicate that food handlers still represent a risk factor in the transmission of enteroparasites to the population. **Conclusion:** The poor hygienic control, from food cultivation to commercialization, represents one of the main reasons for the dissemination of pathogens. Thus, in order to reduce the prevalence and transmission of these enteroparasites in markets, an intervention is fundamental through educative-sanitary measures.

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Introduction

Foodborne diseases (FDs) represent a major public health issue and negatively reflect on the health of populations and on the economic development of countries, leading to labor incapacity and costs with treatments and hospitalization.^{1,2} In Brazil, between 1999 and 2004, 3 million hospitalizations due to FDs were recorded, with an average of more than 500 thousand cases and 8 thousand deaths per year.³

According to the Atlanta Center for Disease Control and Prevention (CDC), most of the FDs are linked to the inadequate handling of food. Therefore, food handlers play an important role in the transmission, partly due to poor personal hygiene and domestic habits, besides a deficiency in hygiene and environmental control.^{4,5}

Some intestinal parasitosis can be found among FDs. In Brazil, despite of the decline of enteroparasites in the last decades, they still prevail in a high rate where the socioeconomic status of the population is low, being a cause of relevant health aggravation.⁵⁻⁷

Several scientists made evident the transmission of helminths and protozoans to humans through the ingestion of fruits and vegetables consumed raw, from cultivated areas contaminated by fecal matter.⁸⁻¹⁰ Even asymptomatic carriers may contaminate food while handling it.¹¹ However, despite being a relevant issue, there seems to be little research that characterizes the occurrence of enteroparasites in food

handlers and their importance in dissemination in a given environment.

Given the latter, this study aims at evaluating the occurrence of enteroparasite eggs and cysts in the hands and feces of stallholders in order to highlight the importance these professionals play in the transmission of enteroparasites to their clients. For this study, it was chosen as a model an open-air market, located in a wealthy district in the city of Vitória, state of Espírito Santo, Brazil.

Method

General considerations:

The samples of the present study are composed of socioeconomic data, habits, and biological material from *in natura* food handlers who work in an open-air market located in a wealthy district in the municipality of Vitória, state of Espírito Santo, Brazil. All market professionals have been informed of the project and invited to take part of it, being the following its required criteria to join it: be over 18 years old; work with *in natura* food handling; accept the research terms by signing the Informed Consent Form (ICF). The stallholders who accepted to take part of the study responded to a socioeconomic and habit questionnaire. Afterwards, nail beds and hand palm biological material were collected, besides stool samples.

Socioeconomic data and hygiene habits:

The stallholders responded to a socioeconomic questionnaire containing the following items: age, gender, marital status, ethnicity, hometown, municipality of residence, household type and characteristics, area where they live, occupation, workload, level of education, access to means of information, family income, type of agriculture, basic sanitation, and hygiene habits.

Collection of biological material:

Nail bed material was collected from all fingers of each stallholder, as well as the material from their hand palms. The method utilized was the swab technique rinsed in a fixative solution of acetic acid, sodium acetate, distilled water and formalin (SAF). During the collection, the material was promptly packaged in the same substance in a test tube. This solution also acts in the preservation of the parasites' infecting forms.

For the stool test, the stallholders were told to collect three samples, in consecutive weeks, in a dischargeable recipient, utilizing the built-in collection instrument, containing a 10% formalin solution for conservation. After each week of collection, the recipients were taken to laboratory for analysis.

Sample analysis:

The material collected from nail beds and hand palms was processed following the Mello, Souza-Jr¹² modified method, which consists in the vigorous agitation and later centrifugation of the sample for 10 minutes, under a speed of 3,000 rpm. After that, samples were analyzed in a microscope. It has been determined that the duration and speed of centrifugation be higher than the ones found in the literature (1,500 rpm for 2 min), since in the event of lower ones, litter was still present on the sides of the centrifuged tubes, which would affect the sediment quality analysis.

The stool samples were processed according to the Hoffman, Pons,¹³ method,

which consists in dissolving feces in water, filtering them through an appropriate gauze pad, and after allowing them to sediment in a conical graduate for 24 hours, and pipetting the accumulated deposit in the bottom. The use of the conical graduate provides a shorter fashion in sample sedimentation, increases parasite concentration for a microscopical analysis, minimizes risks of contamination, reduces odor and optimizes the workplace. In addition to the latter, this method can be easily carried out, provides a low-cost option, has a great sensibility in detecting helminths and protozoans, using conserved or fresh stool samples.¹⁴

At least 5 slides were produced and analyzed for each stool sample. In the negative cases of the first 5 slides, more 5 slides were produced afterward. The same criterion was adopted in the analyses of the nail bed. It was dedicated a minimum of 30 minutes of analysis per slide.

Statistical analyses:

The Fisher's exact test was utilized to verify the association between gender and parasitic disease. By applying the Logistic Regression Analysis, it has been verified the relationship between the occurrence of a determined parasite with the level of education, income and access to information. The statistical analyses were carried out with the aid of the Statistical Package for the Social Sciences (SPSS) software, version 20. Results were considered relevant when the value of *p* was lower than 0.05.

Ethics:

This project has been approved by the Ethics and Research Committee of the High School of Sciences of Santa Casa de Misericórdia in Vitória (Emescam) and has been registered under the protocol number 095/2010. The results were handed in individually and under absolute confidentiality to each subject, who have been referred when necessary to the Service

of Infectious Diseases of the Santa Casa de Misericórdia in Vitória, or directed to seek a physician of their trust. The biological material has been disposed of in accordance with the protocol of the Health Service Residue Management Program, following the Board of Trustee's Resolution no. 306/2004 by the Brazilian Health Surveillance Agency (ANVISA), implemented in Emescam's Parasitology laboratory.

Results

Out of the 15 participants, 11 were male and 4 female, ranging from 18 to 60 years of

age, residing in the municipalities of Iconha and Santa Maria de Jetibá, in the state of Espírito Santo. With regards to level of education, 46.7% partially attended the elementary school and 40.0% fully completed the latter. Concerning family revenue, there has been a prevalence of up to USD 591.00 (73.3%). The sewage system and water supply of more than 90% of the participants are made through a septic tank and without a piping arrangement, respectively (Table 1).

Table 1 - Results of the socioenomic questionnaire distributed to the stallholders

Epidemiologic Aspects	no.	%
Age		
18-30 years old	04	26.7%
30-45 years old	04	26.7%
45-60 years old	07	46.7%
Gender		
Male	11	73.3%
Female	04	46.7%
City of Residence		
Santa Maria de Jetibá, ES	11	73.3%
Iconha, ES	04	26.7%
Level of Education		
Unfinished primary school	07	46.7%
Complete primary school	06	40.0%
Unfinished high school	01	6.7%
Complete high school	01	6.7%
Family income (number of minimum wages)		
< 1	01	6.7%
1-2	05	33.3%
2-3	05	33.3%
3-5	02	13.3%
5-10	02	13.3%
Basic sanitation		
Sanitary sewage system		
General sewage system	01	6.7%
Septic tank	14	93.3%
Means of water supply		
General system with internal piping	01	6.7%
General system with internal piping, artesian well	02	13.3%
Well or river source without internal piping	12	80.0%

Source: author. Note: translated.

Based on the participants' habit questionnaire, more than 90% of the stallholders affirmed they wash their hands before and after meals, before handling food and after using the toilet. All stallholders affirmed handling both cash

and food while commercializing them, although only 13.3% claimed to wash their hands between these two processes — 53.4% of the stallholders wear jewelry or ornaments while working (Table 2).

Table 2 - Results on the hygiene habits distributed to the stallholders

Hygiene habits	no.	%
Do you wash your hands before meals?		
Yes	15	100.0%
No	--	--
Do you wash your hands after meals?		
Yes	14	93.3%
No	01	6.7%
Do you wash your hands after going to the toilet?		
Yes	14	93.3%
No	--	--
Sometimes	01	6.7%
Do you wash your hands before handling food?		
Yes	14	93.3%
No	01	6.7%
Do you wear hand jewelry or ornaments while working at the open-air market?		
Yes	08	53.4%
No	07	46.6%
Does the person who handle food also handle cash?		
Yes	15	100.0%
No	--	--
Do you wash your hands between these operations?		
Yes	02	13.3%
No	13	86.7%

Source: author. Note: translated.

Also out of the 15 participants, stool tests showed that 11 individuals were positive for at least one parasite (73.3%). In these samples, eight species (parasites and

commensals) were identified (Table 3 and Figures 1 and 2).

Table 3 - Prevalence of species present in the stallholders' stool tests

Species	Group	Pathogenic	Prevalence (%)
<i>Blastocystis</i> sp.	Protozoan	Variable	66.7
<i>Ascaris lumbricoides</i>	Helminth	Yes	40.0
<i>Ancilostomídeo</i>	Helminth	Yes	40.0
<i>Schistosoma mansoni</i>	Helminth	Yes	13.3
<i>Rodentolepis nana</i>	Helminth	Yes	13.3
<i>Giardia lamblia</i>	Protozoan	Yes	20.0
<i>Entamoeba histolytica</i>	Protozoan	Yes	6.7
<i>Balantidium coli</i>	Protozoan	Yes	6.7
<i>Endolimax nana</i>	Protozoan	No	13.3
<i>Iodameba bütschilii</i>	Protozoan	No	6.7
<i>Entamoeba poleck</i>	Protozoan	No	6.7

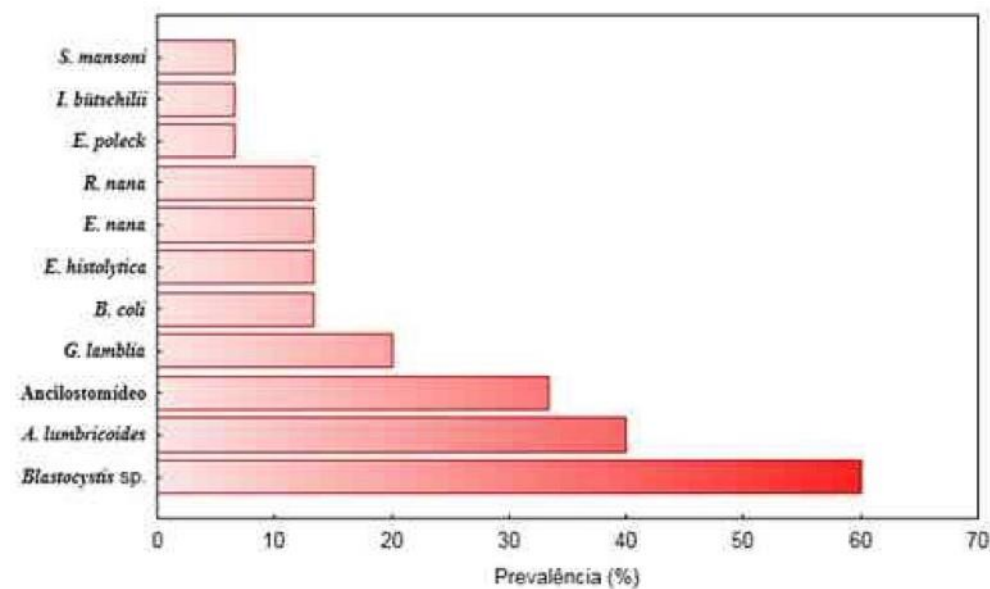
Source: author. Note: translated.

Figure 1: Eggs found in stool samples: (a) hookworm, (b) *Ascaris lumbricoides*, (c) *Rodentolepis nana*, (d) *Schistosoma mansoni*.



Source: author. Note: translated.

Figure 2: Prevalence of species found in the stallholders' stool tests



Source: author. Note: translated.

The species with the greatest prevalence were *Blastocystis sp.* Brumpt, 1912 (66.7%), *Ascaris lumbricoides* Linnaeus, 1758 (40%), hookworms (40.0%), *Giardia*

lamblia Kofoid and Christiansen, 1915 (20%), and *Schistosoma mansoni* Sambon, 1907 (13.3%). Other species recorded in a lower prevalence were *Rodentolepis nana* Siebold, 1852, *Entamoeba histolytica* Schaudinn, 1903, and *Balantidium coli* Stein, 1863. Multiple parasitosis was observed in nine stallholders (60%), ranging from individuals with two and up to five parasites. *A. lumbricoides* was present in all multiple-parasite affected individuals, and hookworms and *G. lamblia* in half of them.

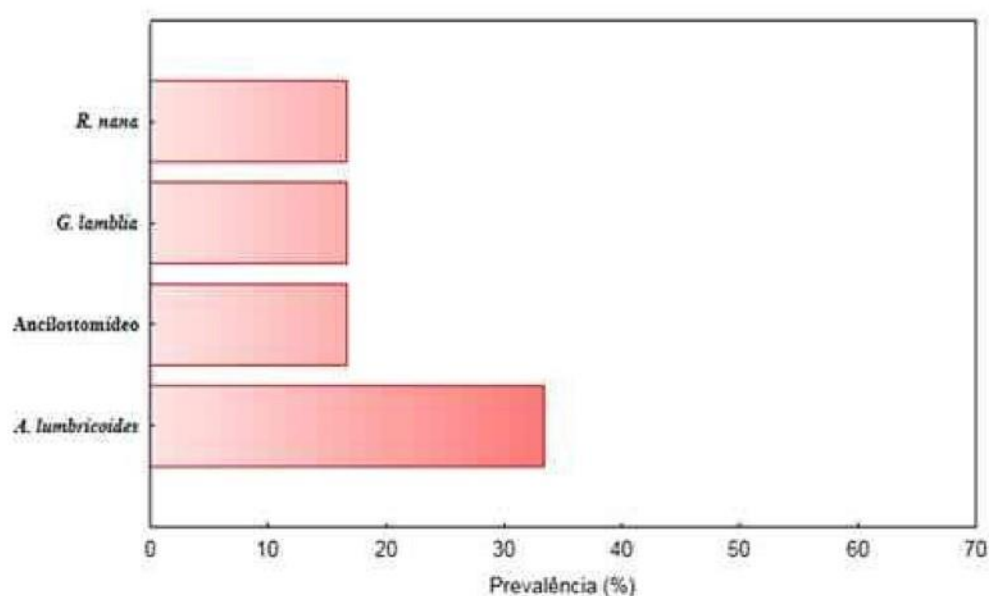
Biological material was analyzed from the hands of 6 stallholders, and 2 of them (33.3%) presented cysts/eggs of the following parasites: *Ascaris lumbricoides* (33.3%); hookworms (16.7%); *R. nana* (16.7%); and *G. lamblia* (16.6%). In one of them *A. lumbricoides* and *G. lamblia* was found in the hand, but not in the stool sample. In the other subject, *A. lumbricoides*, hookworm and *R. nana* was found both in the hands and in the stool sample, besides *Blastocystis sp.* and *G. lamblia* (Table 4 and Figure 3).

Table 4 - Prevalence of species present in the test of the stallholders' hand palms and nail beds

Species	Hand	Nail beds	Prevalence (%)
<i>Ascaris lumbricoides</i>	Yes	Yes	33.3
Hookworm	Yes	Yes	16.7
<i>Rodentolepis nana</i>	Yes	No	16.7
<i>Giardia lamblia</i>	No	Yes	16.7

Fonte:

Figure 3: Prevalence of the species found in the stallholders' hand tests



Source: author. Note: translated.

It has not been observed a significant statistical association ($p \geq 0.05$) between the stallholders' gender and any species, nor a relationship between the occurrence of a

determined species and level of education, income, and access to information.

Discussion

In Brazil, the intestinal enteroparasitosis are widely spread and present high rates of occurrence. In a multicentric study carried out in schools of several Brazilian states, 55% of students were diagnosed with some kind of parasitosis.^{15,16} Estimates show that Brazil is still among the countries with the highest rates of *A. lumbricoides*, being the infection detected in around 40% of the population.¹⁷ In a study administered with food handlers from the state of Paraná, Takizawa, Falamina⁹ have found an enteroparasite prevalence of 38.2%. The stallholder prevalence of the enteroparasites identified in this study was higher than 70%, value alarmingly higher than the ones found in human populations, especially in those populations whose prevalence usually tends to be higher, as in schoolchildren. Such prevalence of infection per species — whether they be parasitic or commensal — whose cycle contains the elimination of infecting forms in stool, makes room for one to argue about in which conditions the stallholders live.

The species found in the stool samples that presented the highest prevalence rate were *Blastocystis sp.* (66.7%), *A. lumbricoides* (40.0%) and hookworms (40.0%). Some authors argue over the pathogenicity of *Blastocystis sp.*, which varies according to some factors, such as its genotype and hosts. Furthermore, there is some evidence suggesting that some strains of *Blastocystis* may be part of the human intestine flora or even act in favor of the development of intestinal inflammatory diseases.¹⁸ The high frequency of *A. lumbricoides* is usually expected in groups exposed to inadequate conditions, due to its elevated biotic potential and great egg viability, factors which contribute to making this parasite the most common in the world, with an estimated prevalence of 25%.^{17,19} The ideal conditions for its existence can be observed in places where the sewage system infrastructure is of low quality. The presence of open-air sewage fluids and the

lack of sanitary facilities also facilitate the infection by other parasites, such as hookworms (7). Eggs of *S. mansoni* have also been found (13.3%), and according to the Ministry of Health, the state of Espírito Santo is among the seven Brazilian states with the highest prevalence rates of this parasite.²⁰

A poor sewage system, along with a bad sanitary education, are risk factors for the prevalence of the enteroparasitosis found in human populations.²¹ More than 90% of the interviewed professionals' households count with a sanitary sewage system connected to a septic tank, which facilitates the contamination of the water utilized for consumption and for the irrigation of the products commercialized in the markets. The water supply of these professionals is mostly performed through wells or river sources without an internal piping system, becoming a conducive environment for the infection of the own food handler while utilizing this water without proper treatment. Studies have shown that there is an inverse relationship between the prevalence and the quality of the sanitary conditions of the environment, as well as the adopted practices.²²

The low level of education found in the present study — approximately 90% of the subjects interviewed completed up to the primary school — represents an aggravating factor for the high prevalence of enteroparasitosis. Education, culture, and eating habits are factors that determinedly influence the exposure to infection.²³ Therefore, health education represents one of the most important interventions for improving the life quality of communities.^{24,25}

All stallholders have affirmed washing their hands before meals, and more than 90% have affirmed doing the same after meals, after using the toilet and before handling food. However, given the reported and observed characteristics during the study, with regards to the household water supply, the aspect of the hands and the conditions of

the market, we believe that the high rates of hand washing reported may have been biased data. Still in our study, all stallholders handled cash, and more than half of them wore ornaments and jewelry while working. Wearing ornaments and jewelry, as well as handling objects — such as coins and bills — are risk factors for the dissemination of infecting agents.²⁶

Conclusion

The results obtained show that *in natura* food handlers in open-air markets play an important role in the dissemination of enteroparasitosis to the population. As a general picture, the food handlers analyzed in the present study have contributed to several aspects in the dissemination and increase of the infection prevalence by enteroparasitosis. The recorded high prevalence of infection by enteroparasites, associated with several risk factors — low level of education, deficient basic sanitation, handling of bills and coins while selling vegetables, poor conditions of hand hygiene, and deficient control of hygiene from food cultivation to its commercialization — pose risks for consumers.

It is then important that interventions are made in order to reduce the prevalence of enteroparasites among stallholders, consequently reducing the risk of contamination of the food commercialized and infection of the consuming population. Among the forms of guaranteeing the hygiene and sanitary quality of foods are the promotion of continuous education programs for the food handlers and their communities, the conduction of parasitic tests on a regular basis and the treatment of these subjects and their family members, as well as making the sanitary surveillance system more solid for the fiscalization of foods offered to the population, including a proper legislation. In spite of that, the investment in basic sanitation, as well as the

improvement of the socioeconomic conditions and of the general infrastructure is of utmost importance for the success of the control programs.

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ORIGINAL ARTICLE

Microdiscectomy reduces low back pain in lumbar herniated disc patients

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Keywords

Low Back Pain;
Intervertebral
Disc
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Discectomy;
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Abstract

Objective: It is estimated that approximately 80% of the population will suffer from low back pain, which may be caused by lumbar disc herniation, impairing the quality of life of patients. Surgical intervention may be necessary in some cases when conventional treatment fails. Thus, we aim to assess quality of life and the low back pain score in patients who underwent surgical treatment for lumbar herniated disc through microdiscectomy.

Methods: Prospective and comparative study in which we compared the results of questionnaires for quality of life (SF-36) and low back pain (Roland Morris) in patients during pre- and postoperative microdiscectomy, through Student's t-test, $p < 0.05$.

Results: We evaluated 25 patients, 16 men and 9 women, with a mean age of 32.8 years old. There was an improvement in quality of life as indicated by the increase on the scores of all eight

components of the SF-36 questionnaire: 1) physical functioning: 15.4 to 82.1; 2) role-physical: 0 to 83.3; 3) bodily pain: 16.6 to 80.9; 4) general health: 56.2 to 80.3; 5) vitality: 50.6 to 78.8; 6) social functioning: 32.3 to 88.5; 7) role-emotional: 20.8 to 81.9; 8) mental health: 60.2 to 79.5. Furthermore, there was significant decrease in Roland Morris questionnaire scores (preoperative: 17.5 ± 5.1 vs. postoperative: 0.9 ± 2.2), reflecting a reduction of low back pain during the postoperative period. **Conclusion:** We conclude that low back pain is present and often disabling for herniated disc patients and that there is reduction or complete relief from back pain after lumbar microdiscectomy is performed.

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Introduction

Low back pain and lumbar sciatic pain are highly prevalent conditions among the world's population and often present lumbar disc herniation as their etiology, being one of the most common complaints of patients who seek for health care in emergency rooms and at doctors' offices. They are cause of significant disabling in everyday activities and growing labor absences due to the pain. Despite its high prevalence, there is still controversy among specialists and in medical literature regarding the proper way to manage the disease, leading to several different treatments and results.¹

The initial treatment for most of the disc herniations is usually conservative, through the association of rest, analgesics, anti-inflammatory drugs and physical therapy. However, if the conservative approach fails for at least twelve weeks, there is indication for surgical treatment. Among the diverse surgical interventions indicated for disc herniations, it is important to mention microdiscectomy, low back arthrodesis associated to discectomy and, more recently, the interspinous dynamic stabilization or still the disc prosthesis.

Microdiscectomy or simple discectomy still remain the gold standard treatments since both procedures present less comorbidity, in which only the herniated segment is

resected and there is neither overload of the levels adjacent to the discectomy, nor restriction to the lumbar arc of movement. The main advantage of the surgical procedure seems to be better seen in short term, showing relief of symptoms in 90% of cases when properly indicated.²

According to our group experience, we believe the low back pain is highly associated to lumbar disc herniation and, after microdiscectomy surgical intervention, there is significant relief of symptoms and an improvement in the quality of life for patients who suffer from the condition.

Thus, the aim here was to improve the understanding and management of the disease, with the objective of assessing the influence of microdiscectomy in quality of life and in low back pain for patients presenting lumbar disc herniation, quantifying these parameters via instruments validated by the medical literature: SF-36 and Roland Morris questionnaires, distributed in preoperative and late postoperative, for comparative analysis of the results.

Method

Comparative prospective study, conducted from the survey data collected via valid

questionnaires, between pre- and postoperative periods. The study was undertaken from July 2009 to January 2010 with an average follow-up of 6 (six) months.

This work was authorized by the Research Ethic Committee at EMESCAM, under the number 012/2010, complying with the requirements of Resolution no. 196/96 of the National Health Council / Ministry of Health.

Patients included in the study suffered from low back pain for over three months, showing no response to conservative treatment (rest, analgesics and anti-inflammatory drugs and at least 20 sessions of physical therapy). All of them had lumbar disc herniation diagnoses confirmed by Magnetic Resonance Imaging (MRI).

Patients who showed previous surgical interventions on the spinal cord, radiographic parameters of intervertebral instability, lumbar canal stenosis, previous spinal cord trauma records, osteometabolic diseases and equine tail syndrome have been excluded from this study.

Initially, patients' personal and anthropometric data were collected via a questionnaire to assess quality of life, being applied during the preoperative period, named SF-36, and another questionnaire used to assess low back pain, named Roland Morris. The fill out of these specific forms was repeated after 6 months of post-operative.

SF-36 is a questionnaire for general health care assessment, validated and adapted to the Portuguese language, composed of 36 items, organized in 8 domains or components, which were determined in order to represent the most commonly assessed concepts in health care questionings, such as physical functioning, physical aspects, bodily pain, general health, vitality, social functioning, emotional aspects and mental health.³⁻⁵

Roland Morris questionnaire, also validated and adapted to the Portuguese language, is composed of 24 items and is a specific instrument for assessing low back pain. It allows the analysis of functional disabling in patients with low back pain, showing 24 situations which represent the individual's difficulty in performing daily tasks due to their low back pain, referring to the current symptoms.⁶⁻⁸

After the distribution of the questionnaires at the preoperative period, the patients underwent microdiscectomy. All of them received antibiotic prophylaxis in anesthetic induction and underwent hemilaminectomy for resection of the herniated disc fragment. The amount of disc removed was decided by the surgeon during the operation and the performing of microdiscectomy was in accordance with literature description.⁹

After the surgical procedure, the patients stayed in hospital for about 72 hours. After hospital discharge, they were evaluated every two months or when necessary. Six months after the surgery, the patients were reassessed and replied to the SF-36 and Roland Morris questionnaires again.

Data analysis

Data regarding age, gender, weight, height and BMI were analyzed and described and, after that, the results of both forms, for assessing quality of life (SF-36) and for low back pain (Roland Morris) were analyzed individually at the preoperative period and also six months after the surgery, when a comparative analysis was performed.

For the evaluation of the results obtained from SF-36, the answers for each question were turned into a score which, afterwards, formed the final score calculus for the 8 components. Each component was scored separately, ranging from 0 (zero) to 100 (one hundred) in which zero is the worst result possible and one hundred represents the best result for each component. The way

of interpreting SF-36 may vary among different authors. In Figure 1, a summary of

how the final results for each SF-36's component can be interpreted is shown.⁴

SF-36 component	Lowest score interpretation	Highest score interpretation
Physical functioning	Severe restriction when performing everyday physical activities, such as showering or dressing.	Performs all kinds of everyday physical tasks, including vigorous ones, without any limitations caused by health condition.
Role-physical	Issues at work or other daily activities as a result of health condition.	No issues at work or any other daily activity.
Bodily pain	Severe or extremely disabling pain.	No pain or disability.
General health	Poor personal evaluation of health condition and belief it will get worse.	Excellent personal evaluation of health condition.
Vitality	Feeling of tiredness or fatigue all the time.	Feeling dynamic and full of energy all the time.
Social functioning	Physical and mental health condition interferes frequently and seriously with social activities.	Physical and mental health condition do not interfere with social activities.
Role-emotional	Issues at work or other daily activities as a result of mental health condition.	No issues at work or any other daily activity.
Mental health	Feeling nervous and depressed all the time.	Feeling calm and happy all the time.

Figure 1: Summary of the possible results interpretation of each SF-36's component. Adapted from Ware, 2004.

It is worth emphasizing that the SF-36 application result analysis of and its comparisons must be performed for each component at study and not in an overall form in which the result is the sum of all answers given by the patient when filling out the form.³

The Roland Morris questionnaire⁶⁻⁸ presents a single result that is represented by the amount of statements checked in by the patient, among the 24 situations exposed in the instrument. The absolute value does not imply absolute conclusions. It has to be compared with other situations for the same patient - in this case, the pre- with the postoperative period.

Results

25 patients were evaluated, 16 males (64%) and 9 females (36%), with a mean age of 32.8 ± 9.9 years old. The mean weight was $70.8 \text{ kg} \pm 10.5$ and the mean height was $1.69\text{m} \pm 0.1\text{m}$, being the mean BMI $24.7 \pm 1.7 \text{ kg.m}^{-2}$.

All the patients presented some reduction in quality of life, verified via the SF-36

questionnaire, mainly regarding the following components: physical functioning, role-physical and bodily pain. All the patients also presented low back pain, confirmed via Roland Morris questionnaire distributed at the postoperative period. The mean score was 17.5 ± 5.1 , which shows that among 24 situations described in the questionnaire, 72% caused low back pain in the patients assessed in this study.

There was improvement in quality of life verified by the increase of all 8 components in the SF-36: 1) physical functioning: 15.4 ± 11.8 to 82.1 ± 21.2 ; 2) role-physical: 0 to 83.3 ± 35.9 ; 3) bodily pain: 16.6 ± 6.4 to 80.9 ± 22.8 ; 4) general health: 56.2 ± 24.3 to 80.3 ± 21.2 ; 5) vitality: 50.6 ± 27.9 to 78.8 ± 21.1 ; 6) social functioning: 32.3 ± 25.8 to 88.5 ± 22.7 ; 7) role-emotional: 20.8 ± 37.8 to 81.9 ± 39.0 ; 8) mental health: 60.2 ± 22.9 to 79.5 ± 19.9 . The results in the first 4 components are grouped in Figure 2, as they represent physical health and the last 4 components are grouped in Figure 3, since they reflect mental health, as many authors have already suggested.¹⁰

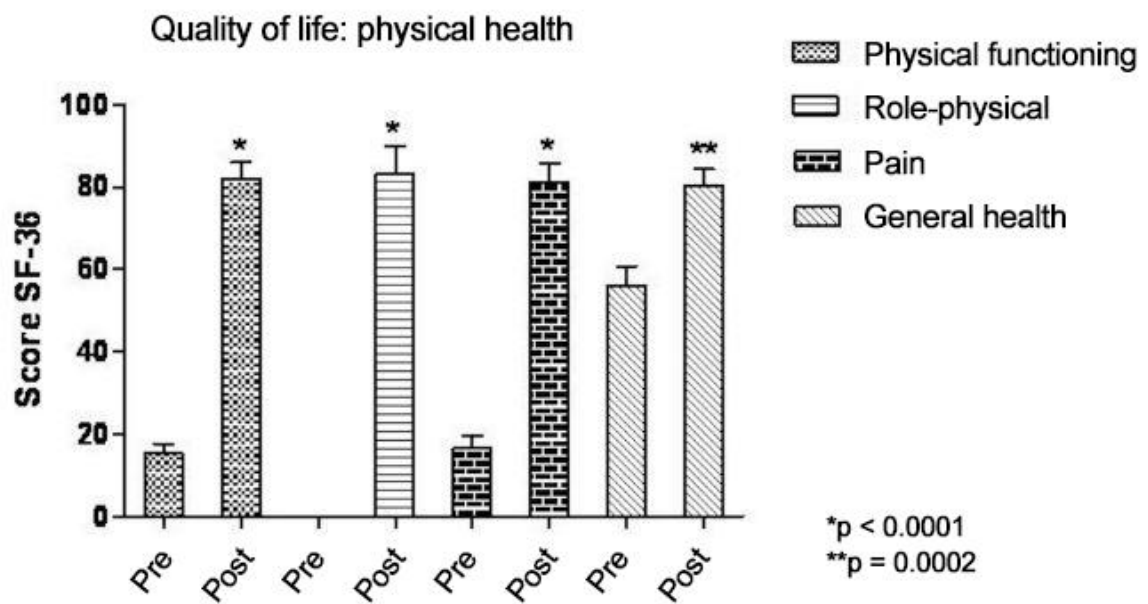


Figure 2: Quality of life (physical health) obtained via SF-36 questionnaire.
Source: author. Note: translated.

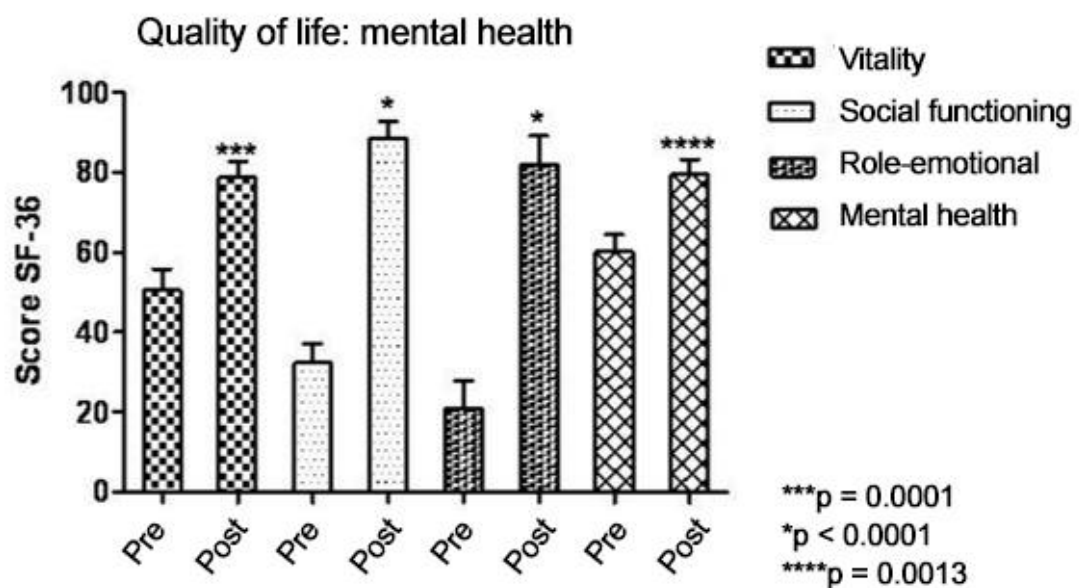


Figure 3: Quality of life (mental health) obtained via SF-36 questionnaire.
Source: author. Note: translated.

Besides that, there was a significant reduction in the Roland Morris

questionnaire's score (preoperative: 17.5 ± 5.1 vs. postoperative: 0.9 ± 2.2), which shows reduction in low back pain at the postoperative period (Figure 4).

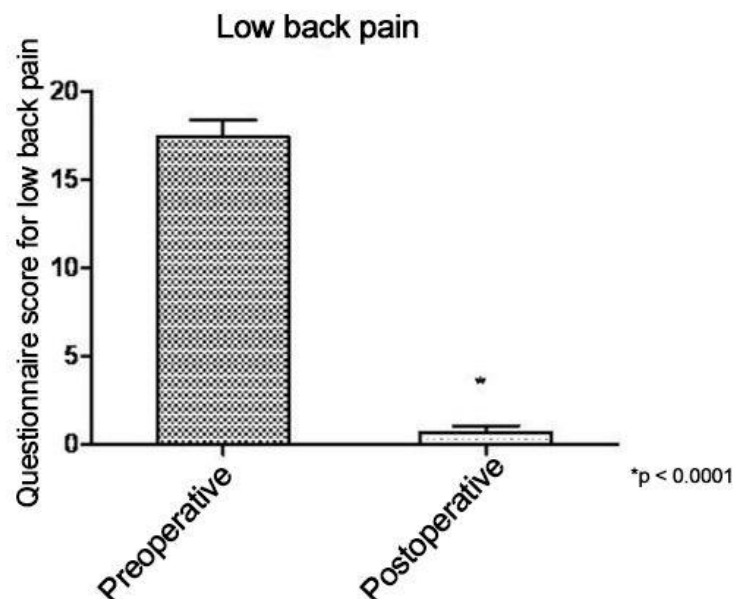


Figure 4: Low back pain represented through score of Roland Morris specific questionnaire
Source: author. Note: translated.

Discussion

Lumbar sciatic pain is a frequent complaint among patients evaluated in emergency rooms and ambulatory care facilities for spinal surgery. It is estimated an incidence of 1 to 2% in the North American population, with approximately 200,000 discectomies performed annually in that country.¹¹ Among the available treatments, literature shows that lumbar arthrodesis surgeries increased about 200% between 1979 and 1987, in contrast to an increase of 23% in laminectomy and 75% discectomy in the same period. In spite of its high prevalence, there is much controversy regarding the physiopathology and the treatment of lumbar discpathology.

The main risk factors for disc herniation are: sedentarism, prolonged driving habits, chronic cough, pregnancy, smoking habits and heavy objects lifting.¹²⁻¹⁴

The natural history of the disease shows a benign evolution in the long term for the most of the lumbar disc herniations. Several authors showed similar results between conservative and surgical treatments after a long postoperative observation, thus being the statistically relevant short term relief of

pain the main advantage of the surgical treatment.^{2,15,16}

The initial treatment of every lumbar discpathology is always conservative, except in cases when the patient shows progressive neurological deficit or equine tail syndrome, when it is indicated urgent surgical decompression, due to the risk of permanent sequel. The size of the herniation cannot be taken into consideration for surgery indication, since large herniations are the ones which present the highest reabsorbing rates, since they are mostly formed by water, different from the small ones, which are not so frequently reabsorbed.¹⁶⁻¹⁸

The surgical treatment is reserved for those patients who suffer from disabling and unbearable pain after 12 weeks of conservative treatment and, at least, 20 physical therapy sessions.

Early surgical interventions with discectomy present more than 90% of positive results. However, when evaluated in the long term, the scores are less positive, 40% to 79% in a minimum 7-year follow up. It shows there

is a deterioration of the results as the time passes after the surgery.^{19,20}

Many surgical techniques are indicated, such as laminotomy and discectomy, endoscopic discectomy and microdiscectomy, with similar postoperative results.²¹ Many factors influence the postoperative prognosis, such as the classification of the herniation, the level, the surgeon experience and the psychosocial aspects.

Complications related to the surgery include dura mater lesion, infection, nerve root lesion, recidivism, among others. Reherniation rates after discectomy vary from 3% to 18% in the literature.²²⁻²⁴ Among the related aspects are great defect in the fibrous annulus and a bigger residual volume in the disc after surgery. In other words, fewer parts of the disc were extracted during the surgical procedure.²⁵

In the last few years, the assessment questionnaires are becoming useful instruments either for evaluating postoperative results or to refer for treatments when there are several treatment options available for the same disease.^{5,10,26} The objective analysis performed via clinical, laboratorial and radiological exams are being complemented by the assessment of subjective aspects, such as quality of life regarding health, physical functioning, pain and satisfaction scores, once it provides scarce information regarding the functional, social and mental aspects of the patient.²⁶ It has been aiding doctors to manage patients who suffer from lumbar sciatic pain.^{27,28} For assessing quality of life, SF-36 was used, which evaluates the patient's health under their own perception. In this study, it was observed the significant improvement of subjective parameters related to the quality of life affected by the disease, namely physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health.

The SF-36 and Roland Morris questionnaires were selected due to their more responsive approach to the prospective evaluation of patients with lumbar sciatic pain. Besides that, they are widely known, studied and reproduced in the scientific community.^{8,29} Another well-known assessment method for low back pain is the *Oswestry Low Back Disability Questionnaire*³⁰, whose main disadvantage - in comparison with Roland Morris - is the difficulty and the longer time required to fill it out. This subjective analysis combined with the objective clinic evaluation allows the surgeon to have a more precise indication to the proper surgical procedure, improving the results and decreasing the number of postoperative complications, also allowing the quantification of subjective data at the postoperative period.

Another important aspect evaluated in our study was the association between lumbar disc herniation and low back pain. In developed countries, the "back pain" is quite prevalent and incident; approximately 70% of the people will suffer from it at some moment in life, being its incidence around 15% to 20% per year. It also represents the main cause of disability in adults under 40 years old and the second most frequent complaint in medical appointments. Approximately 1% of the North-American population presents low back pain constantly disabling associated to other 1% with temporarily disabling low back pain.³¹

We observed that microdiscectomy for the treatment of disc herniation reduces the low back pain condition in patients through the analysis of data obtained via Roland Morris and the bodily pain component in SF-36. Our results suggest that the unnecessary use of invasive surgeries in young patients can be avoided, since their high morbidity rates and complications.³²

Clinical studies show no significant difference between patients who have undergone discectomy only and those who have been subject to discectomy combined

with arthrodesis in the absence of instability¹⁹. The main advantage of arthrodesis compared with standard discectomy is the lower rate of disc disease recurrence³³, despite its higher morbidity.³²

The lateral flexion-extension radiograph of the spinal cord was used as a method to determine intervertebral instability, considering the following criteria to indicate instability: vertebral slippage higher than 3mm, posterior opening of the vertebral bodies higher than 5 degrees, stenosis in the lumbar canal or disc herniation that requires extended decompression and multiple discectomies.³⁴

For representing a non-consensual subject among experts, more studies are necessary to further evaluate the best way to understand and manage these patients. This study has showed that low back pain is present and, in most cases, disabling in patients with disc herniations and that, after undergoing lumbar microdiscectomy, there is a decrease or a complete relief from low back pain, followed by a significant improvement in quality of life, which strongly supports our idea that low back pain as a single criterion, without any instability sign to be seen in supplementary exams, must not be used for indicating lumbar spinal arthrodesis.

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REVISTA SALUS

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ORIGINAL ARTICLE

Evaluation of quality of life in patients who have undergone surgical treatment for idiopathic scoliosis

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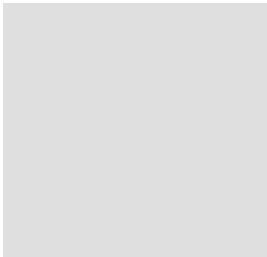
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Keywords

Scoliosis;
Quality of Life;
Treatment Results

Abstract

Objective: To evaluate quality of life via SF-36 questionnaire, in patients with Adolescent Idiopathic Scoliosis (AIS) who have undergone surgery for deformity correction, comparing the results at pre- and postoperative periods. **Methods:** We evaluated 29 patients, 24 females, with a mean age of 14.5 years old, all of them presenting measures of the Cobb angle greater than 50° and replied to the SF-36 questionnaire at the preoperative period and two years after surgery, on average. **Results:** We observed improvement in all eight components assessed by SF-36 after surgical treatment, with statistically significant improvement in the following components: physical functioning, role-physical, bodily pain and



general health. Vitality and mental health presented the lowest percentage of improvement postoperatively. **Conclusion:** Surgical treatment for deformity in AIS improved the functional aspects assessed by the SF-36, representing, in practice, an improvement in the quality of life of these patients. Evidence Level II, prospective study.

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Introduction

Idiopathic scoliosis is the lateral deviation of the spinal cord frontal plane larger than 10 degrees, without any described cause, which affects about 2-3% of the general population, being more prevalent in female teenagers. The most frequent complaint is due to aesthetical issues and, less frequently, pain, paresthesia, sphincter disorders or loss of body balance that may occur.^{1,2}

Although the etiology of idiopathic scoliosis remains unknown, there are several different multifactorial hypotheses, such as neuromuscular or connective tissue alterations, hereditary factors, alterations in the sagittal configuration of the spinal cord, asymmetric growth of limbs and torso, besides environmental factors, such as nourishment.³⁻⁶

Studies show non-treated scoliosis results in higher incidence of pain and disablement, which may lead to work-related and marital problems, besides causing respiratory dysfunction and even early death.⁷⁻⁹ For those severe cases, the orthopedist is responsible for referring patients to surgical treatment in order to prevent the progression of the condition, correct the curve and keep the spinal cord balance.¹⁰ However, even with proper treatment, it is known that there is a significant decrease in quality of life in patients who suffer from severe deformities, affecting daily activities

common to teenagers, as well as their psychosocial development.¹¹

The term 'quality of life' has been used in the healthcare milieu since 1970 and

comprehends a multidimensional concept, capturing the general health status impact, including disease and treatment in their physical, psychological and social aspects. Usually, the quality of life in a healthcare context is assessed through questionnaires due to the fact they allow higher reliability in treatment evaluation, being capable of revealing both positive and negative interferences in the patients' lives. When we analyzed quality of life in patients with Adolescent Idiopathic Scoliosis (AIS) at pre- and postoperative periods via SF-36 questionnaire, we judged to be possible to obtain important data on the disease and its interference in patients' lives. The goal was to make the treatment easier for both physicians and patients, therefore, increasing the patients' adherence to the treatment.^{12,13}

Method

This is a prospective study in which 29 patients were evaluated, 24 females, with a mean age of 14.53 years old. All of them have undergone surgical treatment performed by the Spinal Cord Surgery Group at *Hospital Santa Casa de Misericórdia de Vitória* (HSCMV). This research project was authorized by the

Committee of Ethics for Research in Human Beings of *Escola Superior de Ciências da Santa Casa de Misericórdia de Vitória* (EMESCAM), under the number 018/2012. The criteria for inclusion were all the AIS patients admitted at HSCMV who presented curves larger than 50 degrees and replied to the quality of life assessment questionnaire SF-36 at pre- and postoperative periods. The criteria for exclusion were some other cause for scoliosis, curves with indication for conservative treatment or patients who did not reply to the assessment questionnaires at the preoperative period.

Patients replied to the SF-36 questionnaire preoperatively and 24 months after the surgical treatment. The SF-36 questionnaire may be distributed via computer, telephone or by a trained interviewer and contains 36 items that assess mental and physical health aspects, through 8 components: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. For statistical analysis, we initially applied the Kolmogorov-Smirnov Test, used to assess whether data followed normal distribution, as shown in **Table I**.

TABLE I – Result of statistical significance (p) for each SF-36 component, according to Kolmogorov Smirnov test for verifying the data distribution pattern.

	Physical Functioning	Role-physical	Bodily Pain	General Health	Vitality	Social Functioning	Role-Emotional	Mental Health
Significance*	0.125	0.000	0.034	0.450	0.730	0.018	0.000	0.178

* $p \leq 0.05$: significant test – non-normal data.

Source: author. Note: translated.

The variables physical functioning, general health, vitality and mental health were normally distributed and correlated, and the Student-t Test was used for paired data. For the non-normal variables, we used the Wilcoxon Test, which is a non-parametric technique similar to the Student-t Test for paired data.¹⁴

Values of $p \leq 0.05$ were considered statistically irrelevant. The statistical data analysis was performed by using Microsoft Office/Excel 2010 and SPSS (Statistical Package for Social Sciences) version 8.0.

Results

The results showed an improvement in all eight components assessed by the SF-36 questionnaire, comparing the pre- with postoperative periods of patients who have undergone surgery for correcting vertebral scoliosis.

When we correlate data obtained from statistical analysis, we found that among the components assessed, physical functioning, role-physical, bodily pain and general health showed statistically relevant improvement at the studied periods, as seen in **Table II**.

TABLE II – Comparison between the overall mean scores for each functional component of SF-36 questionnaire at the pre- and postoperative periods, with their respective improvement rates after surgery.

	PRE (average) **	POST (average) **	Improvement	Significance (p)
Physical Functioning	75.00	87.24	16.32%	0.006*
Role-physical	59.65	82.75	38.72%	0.01*
Bodily Pain	64.37	81.68	26.89%	0.001*
General Health	72.27	80.17	10.93%	0.026*
Vitality	67.93	68.79	1.26%	0.819
Social Functioning	75.00	85.43	13.90%	0.055
Role-emocional	72.37	81.46	14.30%	0.268
Mental Health	71.03	76.44	7.61%	0.278

PRE: preoperative period; POST: postoperative period.

* $p \leq 0.05$.

** The values may vary from 0 to 100 points. 100 is the best possible score.

Source: author. Note: translated.

Among the 8 components studied, physical functioning, role-physical and bodily pain showed higher significance levels during the comparison, reflecting an improvement in the performance of daily activities, including vigorous ones, with decrease or complete relief from pain or pain-related limitations.

Despite not having statistical relevance for the social functioning component ($p=0.055$), the significance level was quite close to 0.05. Regarding the pain component, we observed that 21 patients – 72.74% of the sample – showed some improvement postoperatively, while in the vitality component, only 11 patients noticed improvement after surgery (37.93%).

Discussion

In this paper, we used the SF-36 questionnaire for assessing quality of life in AIS patients due to its easy distribution. This questionnaire can be used for more than 130 diseases, including spinal cord conditions, which may considerably affect the quality of life related to health.¹⁵⁻¹⁸

When we analyze the overall result of surgical treatment for AIS via SF-36

questionnaire, it is observed a significant improvement in quality of life even 2 years after the surgical correction. We have decided that this period of time was sufficient for evaluating how the surgical treatment can affect quality of life in these patients. Pellegrino and Avanzi¹⁹, in a similar study recently conducted, observed an aggravation in pain and physical functioning in patients at the early postoperative period (up to three months after the surgery), reporting significant improvement when the same patients were reassessed 12 months after the treatment.

A very important outcome of this study was the statistically significant improvement in physical functioning, bodily pain and role-physical, similarly to what Cabral et al. have found.¹⁷ The Literature reports the incidence of pain in scoliosis is equivalent to the incidence of pain in general population. In this study, we observed a betterment of spinal cord pain in 72.42% of the studied sample, which leads us to conclude that it is necessary to consider its prevalence in these patients. The improvement in the role-physical component assures that scoliosis is a physical problem and has little influence in vitality and mental health. It corroborates with the outcomes we have reached in this

study: in spite of showing some improvement, those two components have no statistical relevance.

The topic "quality of life" has become particularly important in the analysis of postoperative outcomes for AIS that less aggressive surgeries have been advocated for its treatment, such as selective arthrodesis, in which the goal is to perform the less amount possible of arthrodesis, once stiffness in the spinal cord segment is a constant cause of concern regarding these patients' quality of life.

Despite all the discussion on the topic, we still have not found any study in literature that directly highlights improvement in quality of life with fewer arthrodesis. What we have found indeed is that surgical treatment, when indicated, leads to an improvement in the quality of life of patients regardless the number of levels which have undergone arthrodesis.²⁰

Conclusion

Surgical treatment for AIS has improved all the functional aspects assessed by the SF-36 questionnaire, which actually shows an improvement in the quality of life for these patients.

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REVIEW ARTICLE / UPDATE

Biomechanics of absorbable implants

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Absorbable Implants;
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Intramedullary Fixation of Fractures

Abstract

The present paper addresses topics on the use of biodegradable implants in trauma orthopedic surgeries, from its development to clinical application. It also underlines the non-necessity of a new surgical procedure for its removal, since these implants are disintegrated and eliminated by the organism after the fracture consolidation, especially in the case of children.

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Over the last decades, the metallic devices for osteosynthesis, such as screws, plates and nails have made possible a technical improvement, as well as being efficient and safe in the surgical treatment of orthopedic trauma injuries.¹

However, metallic implants are still associated to some adverse effects, such as wire migration, growth abnormalities, difficulty in radiology visualization due to

implant white-out, infection, cellularity effects and rigid fixation that could cause bone atrophy. Sometimes, in areas with anatomic singularities where the subcutaneous tissue is scarce or due to the proximity to tendons, implants would need to be removed, being that case a must in children when considering their exponential bone growth.

Mittal et al², in a questionnaire distributed to 100 adult patients with fractures, asked subjects how they would like to have their fractures fixed: 95% responded it could be done with bioabsorbable material and 80% would be willing to take part of clinical studies comparing metallic with bioabsorbable materials.

The latter has been a reason for researchers to investigate bioabsorbable implants, not for them to be substituted, but to become an extra option in the instrumental apparatus for the surgical treatment of injuries in orthopedic traumatology.

Bioabsorbable implants should be sufficiently resistant to guarantee the maintenance of the fracture reduction and fixation (osteotomy) during the consolidation period, thus progressively degrading itself.

These materials should also be body-friendly, with no carcinogenic, teratogenic, toxic, inflammatory or allergic effects.

Review of the Literature

-Phases of development

The absorbable synthetic structures have been clinically used for more than 20 years.²

The first study with biodegradable implants was carried out in 1996 by Kulkarni et al³, analyzing the biocompatibility of the poly-L-lactic acid (PLLA) in animals, which showed to be non-toxic and that could gradually degrade itself. In 1971, the same author made evident the use of plates and screws made of PLLA in the fixation of canine jaws.

Since then, several studies have been conducted with biodegradable materials, being the 1990s a period when a great deal of publications emerged and when most of the investigations used the polyglycolic acid (PGA) and the polylactic acid (PLA) as instruments. Some innovations were

introduced to enhance material resistance and improve biodegradation.

However, despite arduous research effort, the development of an ideal bioabsorbable implant for the fixation of fractures or osteotomy is still a heated debate.

The basic elements for the production of bioabsorbable implants are the polyglycolic and polylactic acids, which after polymerization of the cyclic diesters, its outcome are polyglycolides and polylactides.

- Chemical properties

The polyglycolic acid (APG) and the polylactic acid (APL) are synthesized by the polymerization of the cyclical diesters from the glycolic and lactic acids.³

The polyglycolide (APG) is a crystalline polymer with a molecular weight ranging from 20,000 to 145,000.⁴ APG is hydrophilic and highly crystallized. Degradation and resistance loss occur prematurely, leading to post-surgical complications. In order to reach the point of deformability, its temperature must be over 36°C/96.8°F, and after decreased for application. This procedure is considered an issue, since surgical running time may take longer than planned. The suture threads made of polyglycolic acid have been commercially utilized since 1970.

The polylactide's (APL) molecular weight ranges from 180,000 to 530,000⁵ and has an extra methyl group in its monomer (lactic acid), which makes it more hydrophobic.

The copolymers commonly used from the glycolic, lactic, such as polyglactin 910, are substances prepared by the polymerization of 9 glycolic parts and 1 lactic part. The copolymer obtained displays good fibrous properties and has also been used as a suture material since 1975.³

The copolymer self-reinforcement technique has led to better mechanical properties and eliminated toxic adhesion issues. The high degree of molecular

orientation makes the implant rigid and strong in its longitudinal axis, allowing it to be compared with metallic implants. The microstructure of such materials is composed of a perpendicular bidirectional orientation, making the implant more resistant and deformable at the operating room's temperature, avoiding the surgical procedures of warming and cooling. They also withstand a higher bending load and a lower memory effect (material tendency to return to its original form after bending), being their sterilization possible through gamma irradiation, which is not allowed in non-reinforced materials, since it would alter their mechanical properties.⁴⁻⁶

-Biodegradation

The degradation of polyglycolide and polylactide takes place in vitro and in vivo through hydrolysis, leading to a reduction of its mechanical properties. Degradation is faster in vivo.⁶

Craig et al⁷ have verified that the sutures made of polyglactin 910 were absorbed within 90 days.

Vainionpää⁸ has shown that pre-molded-beam-shaped pins made of polyglycolide

are degraded in the cancellous bone within 12 weeks.

The outcome of the polyglycolide and polylactide degradation is used in the amino acid synthesis or in the tricarboxylic acid cycle.

The degradation final product is eliminated through urine, feces and exhaled as carbon dioxide, having the process complete, in rats, within 180 days.²

The factors that affect the implant biodegradation can be related to the implant itself – chemical composition, molecular weight, fiber orientation, monomer concentration, stereoisomerism, material phase, conformation, volume/surface rate, porosity, presence of impurities, sterilization methods and degradation mechanisms – or can be related to environmental factors – implantation place, type of tissue, implant stress and vascularization.

Table 1 shows the full time span of absorption and the loss of mechanical properties.

Table 1: Full absorption time and loss of mechanical properties

Material	FULL Absorption Time	Time Loss of Mechanical Property
PGA	4-7 weeks (17)	36 weeks (30)
SR-PGA	3 months (28)	1 month (28)
	6-12 months (31)	
PLLA	> 5 years (32,33,34)	
SR-PLLA	5-6 years (28)	Reduction to the level of a cortical bone in
	> 5 years (34)	36 weeks (35)
P(D/L)LA 70/30	2-3 years(28,36)	18-36 weeks (36)
PLA/PGA (PLGA)	1-2 years (36)	
80/20	1-1,5 years (24)	6-8 weeks (36)
P(D/L) LA 96/4	2 years (37)	

Source: Vainionpää S: Biodegradation of polyglycolic acid in bone tissue : an experimental study on rabbits. Arch Orthop Trauma; Surg. 104: 3338,1986.

- Tissue response

Hermann et al⁹ have compared the polyglycolide with other materials and

observed a discreet inflammatory response in the use of polyglycolide and a sharper one with the use of a catgut or nylon.

Vainionpää⁸, in an experimental study with rabbits, has not observed a reaction or a foreign-body reaction to the polyglycolide.

Craig et al⁷ have reported a subtle histological alteration, foreign-body reaction type, after the implantation of polylactide and polyglycolides sutures in the gluteal region of rats.

The discreet foreign-body reactions caused by bioabsorbable polymers have been considered, by several authors, as an initial biological response in the degradation evolution of bioabsorbable implants.¹⁰⁻¹²

- Internal fixation of the bone tissue with bioabsorbable implants

Mechanical properties

Törmälä et al¹³ have introduced the polyglactide pre-molded implants, which preliminarily were produced through mer copolymer modeling in metal, with a bending force of 45MPa and a tension force of 150MPa.

Based on these studies, the cylinder-shape bioabsorbable material nail was manufactured.

In the beginning, nails were made of polyglactine 910 with a resistance of 265 MPa.¹³ However, afterwards, due to better resistance value, nails made of polyglycolic acid were produced.

This type of nail was produced by using a reinforcement technique. Absorbable polymeric fibers were added in high temperature of the same polyglycolide material. By using this reinforcement with an initial resistance of 200-400 MPa, an inclination module of 220-400 MPa and a breaking resistance of 179-250 MPa have been obtained.¹³

In 1971, Frazza and Schmitt⁴ have shown that the initial tension force was reduced to half within a week, when sutures were implanted in the subcutaneous tissue of rats.

Nails made of polydioxanone present a low initial resistance, with a value of 92 MPa, which is reduced to around 50% within the first five weeks.¹⁴

- Experimental studies

The first experimental study on the use of bioabsorbable implants in the fixation of fractures was conducted by Cutright et al in 1971.¹⁵

In 1986, Vainionpää et al fixed osteotomy in the distal femur of rabbits with polyglycolic acid implants, associated to the trans bone suture of polyglycolide. Osteotomy was consolidated in all 19 rabbits. They have also observed bone formation within the canal, previously occupied by a pin, after the implant biodegradation. However, the device resistance was fairly weak for osteotomy fixation in the cortical bone.

In 1989¹⁶, Mäkelä et al studied the fixation properties on physal fractures of young rabbits and the effect of the bioabsorbable implant on the growth plate. It was concluded that a polydioxanone-2.0mm-diameter nail did not cause any growth disorder, although the 3.2mm-diameter nail caused a permanent damage to the rabbit's distal growth plate.

In 1989¹⁷, Vasenius et al investigated the resistance and properties of polyglycolic nails. It was shown that the nail resistance loss had lowered between 5 and 6 weeks in the rabbit's subcutaneous tissue. Besides that, the resistance loss of polyglycolic nails is lowered faster in vivo than in vitro.

Elias et al^{11,19} have carried out a comparative experimental study with rabbits in which polyglycolic nails were assessed, comparing it to Kirschner wires, both with a 2mm diameter, transfixing the distal growth plate of the femur. It was concluded the bioabsorbable implants only caused a temporary growth disorder, since the growth plate caused the implant to break off between the sixth and seventh week after

its implantation, which did not occur in the case of metallic pins.

-Clinical use of bioabsorbable implants

The first bioabsorbable implant for bone fixation, after experimental studies, was developed by Törmälä et al (1987). The experimental studies have also foregrounded that the fixation properties of these implants suffice the fixation of osteotomies in the cancellous bone.⁸

The clinical application of bioabsorbable implants in malleolar fractures was first employed in 1984 by Rokkanen et al¹², and then executed in various skeleton segments by other scholars.^{10, 11,15,19}

In 1985, Rokkanen et al¹² presented the result of a prospective randomized study on the fixation of ankle fractures utilizing bioabsorbable nails or metallic pins in 44 patients. No difference was found between the two groups.

In 1993, as a dissertation defended at the University of Helsinki, Partio et al¹⁴, in a clinical study with 318 patients (olecranon and ankle fractures, and ankle fusion) presented good results for the use of nails and screws made of polyglycolic acid. It was reported that the foreign-body reaction type did not compromise the bone consolidation, besides showcasing some advantages on the use of bioabsorbable material: satisfactory consolidation, less pain, no need for material removal, reduction of hospital costs since it would not be necessary a subsequent hospitalization and anesthesia procedure. Other authors also corroborate with the latter.^{10-12,14,19}

Elias et al^{11,18,19} have reported consolidation in all cases of elbow fractures in children and adolescents, fixed with bioabsorbable pins, and in ankle fractures of adults, fixed with bioabsorbable screws, with no loss of reduction or bone growth impairment. The occurrence of seroma was reported to be an issue in 8% of the cases, which besides sterile, has not interfered in the

consolidation, which evolved to a cure after puncture.

Final considerations

The use of bioabsorbable implants is an extra option in the surgical treatment of fractures, fusions and osteotomies. It offers a psychological and economic advantage since a subsequent surgical procedure for implant removal is not needed, especially in the case of children.

More study on this matter is necessary to assess its long-run safety with regards to tentative collateral effects, such as carcinogenic and teratogenic ones.

The resistance of a bioabsorbable implant is still low, its application working best in diaphyseal bones, since in this region the consolidation takes place before it loses resistance, eventually degrading itself.

There are several research centers around the globe investigating bioabsorbable implants, being the Swiss Association for the Study of Osteosynthesis (AO) and the Tampere University of Technology, based in Finland, the ones that have invested on this matter.

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REVISTA SALUS

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ORIGINAL ARTICLE

Chromosomal abnormalities in spontaneous miscarriages in a public maternity hospital in the city of Vitória, state of Espírito Santo, Brazil.

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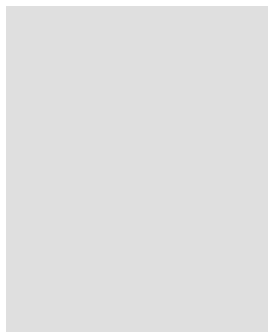
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Spontaneous
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Abstract

Objective: to verify the frequency of chromosomal abnormalities in miscarriage material from a public maternity hospital in the city of Vitória, state of Espírito Santo, Brazil. **Method:** A semi-direct culture of chorionic villi was performed. 70 samples were



collected; 24 showed no chorionic villi and 46 samples passed the cytogenetic examination. **Results:** 31 samples did not achieve the cell growth stage and 15 samples have succeeded. Five normal karyotype and ten abnormal have been found, including trisomies, tetraploidy, monosomy X, triploidy and autosomal monosomy. **Conclusion:** In this study the frequency of chromosomal abnormalities in spontaneous abortion material was high compared to similar studies in the literature.

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Introduction

Abortion is a hemorrhagic syndrome that leads to conceptus death and/or expelling before it reaches its viability¹. From the clinical standpoint, approximately 15% to 20% of pregnancies are spontaneously terminated.^{2,3} An abortion can be spontaneous, when there is no leading factor, or provoked, when there is a deliberate action for pregnancy termination. Considering the gestational age, it can also be classified into: early abortion, when it takes place up to the 12th week, and late, between the 12th and 22nd weeks, noting it usually happens within the first 12 weeks of pregnancy.⁴

Until the 1960s, the investigations carried out on fetus loss were limited to clinical and anatomic-pathological studies. The cytogenetics advent allowed the investigation of possible chromosomal anomalies in such cases⁴, which can be structural (isochromosome, translocation, inversion, deletion, insertion, duplication, ring chromosome) or numerical, and involve one or more autosomes, sexual chromosomes, or both.⁵ The numerical anomalies generally involve an extra chromosome, as in the Down Syndrome, for instance, in which occurs the trisomy of the chromosome 21 or the absence of a chromosome (monosomy), being the case of the Turner Syndrome, whose karyotype is 45,X.⁶ Besides the latter, there are other types of numerical alterations, such as

triploidy, tetraploidy, tetrasomy and pentasomy.⁵

The chromosomal anomalies are present in about 50% of the spontaneous abortions of the first trimester.¹⁻⁶ Due to the fact of many autosomal trisomies being incompatible with life, several embryos are spontaneously aborted. Many fetuses with autosomal trisomies may even survive, but their development is compromised. The Down Syndrome is the trisomy most compatible with life. Conversely, the monosomy of an autosome is always lethal, leading to a spontaneous abortion.⁶ Studies⁷⁻¹⁰ have spotted trisomies as the main causes for spontaneous abortions, followed by triploidies, monosomy X, tetraploidies, double trisomies and structural anomalies, not necessarily in this order.

The identification of a fetus loss cause helps to estimate the risks of recurrence in future generations, and by also promoting genetics counseling for the family. According to Horovitz et al,¹¹ (2005), once excluded and proportionally rearranged the badly defined causes for child mortality, the perinatal ones held the first position in 1980 in Brazil, accounting for 38% of the deaths of infants, and the congenital anomalies occupying the fifth position, with 5% of the total. In 1990, this profile started to change, being observed a proportional reduction in the infectious and nutritional causes, leading the congenital anomalies to 8% and to take over the fourth cause. In the last year of

evaluation (2000), the differences were substantially significant, with a great proportional reduction of deaths due to infectious and respiratory causes, now under 10%, and the congenital malformations holding the second position as a cause of the 13% of infant deaths. Such statistics on congenital defects and child mortality in Brazil can be seen as surprising, considering their magnitude and total lack of governmental policies with regards to their prevention and management.

In the face of a growing number of abortions of repetition and children born with congenital malformations, this study becomes relevant since it can contribute to the elaboration and/or improvement of public policies on this matter.

Objective

This paper's objective is to verify the frequency of chromosomal anomalies present in spontaneous abortions in a public maternity hospital in the city of Vitória, state of Espírito Santo, Brazil.

Method

This study is characterized as prospective and was conducted with patients submitted to post-abortion curettage, of unknown reason, at the Pro-Matre Maternity Hospital, located in the municipality of Vitória, state of Espírito Santo, between April and October of 2007. Patients claiming to have provoked abortion have been ruled out of the study. After being made aware of all the necessary research information, if agreed, the patients signed the Informed Consent Form (ICF).

During curettage, ovular leftovers were collected in flasks containing saline solution, under aseptic conditions, separating the most prominent portion of amnion and placenta. The surgical center

staff was also made aware of the necessary information for the most proper material collection. The labeled flasks were taken to the Cytogenetics Laboratory at the Federal University of Espírito Santo, by respecting the 48-hour deadline after sample collection.

The samples were submitted to a semi-direct culture of chorionic villus (24-48 hour culture). The villi present in the ovular leftovers were separated into sterile Petri plates. All procedures were conducted inside a biosafety cabinet (*Bio Protector VECO®*). *After separated, villi were kept in previously labeled and prepared culture flasks as a means of culture (Amniomax™ Gibco® INVITROGEN)* by utilizing 4.2ml of the solution. The culture flasks were sealed and put into warm water bath at 37°C/98.6°F, for 24 hours. After that, the cultures were removed and treated with Colchicine (SigmaALDRICH®) and once again submitted to the warm water bath. After 45 minutes, the sample supernatant was collected with the aid of a Pasteur pipette and 5ml of a hypotonic solution (sodium citrate 0.075M) were added to the cultures, which would then be returned to the warm water bath for more 30 minutes at 37°C/98.6°F. For fixation, three baths were performed with [Methanol (Merck®) and acetic acid (Merck®)] in the 3:1 proportion, respectively, in a 10-minute interval. The fixing solution of the last bath was not discharged. The flasks with cultures were kept in a fridge for the preparation of slides in the following day. The slides (Precisium®) were previously washed with mild soap and kept in alcohol 92.8%. After drying and labeling with the patients' data, they were put on a plate heated to 60°C/140°F. For each patient, an average of eight slides was prepared. The villi were then removed from the solution with a Pasteur pipette and put on a Petri plate in a scattered fashion and later addition of 2ml of a 60% acetic acid, allowing it to act for 2 minutes. After that, only the Petri plate material would be carefully dropped on each slide. The slides would only be

removed from the heated plate after the complete drying process was complete. They were also submitted to the GTG banding, which consisted in a submersion for 1s in a 1:250 Trypsin solution (Gibco® INVITROGEN), and then washed in a phosphate buffer solution. Staining was performed by utilizing a 30% Giemsa stain, in which slides would be immersed for 7 minutes and then washed with distilled water.¹²

Cellular growth was assessed with the aid of an optical microscope. An average of fifteen to twenty metaphases was analyzed per case, which were manually drawn, and after a thorough assessment, the diagnosis would be issued. The absence of cellular growth was informed in the research results. The reports were compiled and mailed to the patients. Subjects who claimed to need further information on their results showed up at the Laboratory for a more detailed explanation of the diagnosis.

Results

70 samples of ovular leftovers were collected, being 24 out of those did not display any chorionic villi. Out of the 46 semi-direct cultures performed with chorionic villi samples, in 31 (67%) of them cellular growth was not observed. Cellular growth and subsequent karyotype recognition were possible in 33% (15/46) of the samples submitted to cytogenetics test.

The cytogenetics study showed that 66% (10/15) of spontaneous abortion cases in the first trimester demonstrate chromosomal anomalies (Table 1). Three cases of chromosome 13 trisomy were found, compatible with the Patau Syndrome and one trisomy of a marker chromosome. Two cases of tetraploidy have also been found, besides two cases of monosomy X, compatible with the Turner Syndrome, and one case of triploidy. It was also found one case of monosomy of an autosomal chromosome of group D, karyotype 45,XX,-D. Out of the five cases found of normal karyotype, four were male (46,XY) and one female (46,XX).

Table 1 – Distribution of chromosomal anomalies into ten cases of spontaneous abortions with abnormal karyotypes in the cytogenetic study.

ANOMALY	N	(%)	KARYOTYPE	N
Trisomy	4	40	47,XX,+13	2
			47,XY,+13	1
			47,XX,+mar	1
Tetraploidy	2	20	92,XXXXY	1
			92,XXXX	1
Monosomy X	2	20	45,X	2
Triploidy	1	10	69,XXY	1
Autosomal monosomy	1	10	45,XX,-D	1
Total	10	100		

Source: author. Note: translated.

Discussion

Since the 1970s it is technically possible to investigate chromosomal anomalies in abortion material.⁴ However, despite genetics' great advancement, such analysis is performed in a few number of abortions in more developed centers.

In our study, 33% cellular growth success has been achieved. The literature suggests that up to 40% of cultures would not achieve cellular growth due to chorionic villi rapid degeneration.¹³ Nevertheless, taking into consideration that the present study was carried out with public hospital patients, it is possible that such percentage increase may have been caused by the long wait while the subjects had sought for medical assistance. Thus, the conception outcome was kept for a time longer than in the one where a sufficient amount of living cells could have been found, allowing us more cellular growth success and subsequent cytogenetics diagnosis.

Chromosomal anomalies are the most frequent known cause of a fetus death in our species. Its origin depends on several factors, including environmental and genetic reasons, besides an individual's innate factor. Chromosomal anomalies can be classified into aneuploidies and euploidies. The former occur when the extra number of chromosomes is not an exact number of the haploid number, as a result of a proper non-disjunction or non-separation of one or more chromosomes during meiosis – as in the case of trisomy, during mitosis, when a cell divides itself into two daughter-cells, with a haploid number of chromosomes. The process of meiosis is to produce haploid cells from diploid cells. In monosomy X (45,X), X is present in the maternal chromosome in 70% to 80% of the cases; that is, in these cases, paternal X or Y are the ones lost during meiosis or in the first stages of embryogenesis.¹⁵ Euploidies are alterations that comprise the entire genome, originating cells that contain an exact multiple of 23 chromosomes in its

nucleus, that is, an extra haploid group in a cell, besides the basic regular group of chromosomes. In turn, triploidies stem from maternal roots in approximately 80% of the cases, by the incorporation of a polar body into an oocyte. Less frequently, in about 20% of the cases, the origin is paternal, through dispermy, that is, the fertilization of an oocyte by two spermatozoa.¹⁵ Tetraploidies generally occur in the first mitotic division (cleavage) of the zygote, in which chromosomes are regularly divided, but cytokinesis does not occur, being the result just one cell with 92 chromosomes.¹⁴ Rare cases have been described on the fertilization of one normal oocyte by three spermatozoa.^{16,17}

In this study, the trisomies were the most common chromosomal anomalies and represented a 40% rate of the anomalies found, corroborating with several authors^{1-4,7-9,10,18}, who have come to a result ranging from 30% to 50% in their studies. Among them, we found a karyotype with one marker chromosome, 47,XX,+mar., which is a structurally abnormal chromosome that cannot be identified by conventional banding techniques, such as the G band. From an unknown origin, it is present as an additional chromosome in the karyotype, either present or not in all cells. After additional investigations with molecular cytogenetic, for instance, the *Fluorescent in situ hybridization* (FISH) and *array Comparative Genomic Hybridization* (aCGH), it is now possible to find out the additional material origin.^{19,20} The FISH technique is based on the formation of a hybrid between DNA sequences or specific regions in cells or in chromosomes of cytological preparations and marked DNA probes. The formed hybrid can be directly observed through a microscope, after a marking with specific fluorochromes.¹⁹ The aCGH technique allows the investigation of gains and losses of DNA sequences of the entire genome.²⁰

Other authors^{8,13} while studying cultures of chorionic villi have also found a rate

ranging from 4% (16 in 380) to 4.2% (12 in 287) of tetraploidy. In our study the cases of monosomy of the X account for 20% (2 in 10) of the chromosomal anomalies found, these being similar to some studies^{7,19,21}, whose rates are the ones of 21.4% (6 in 28); 23.7% (68 in 287) and 25% (75 in 305), respectively. Conversely, the study of Moraes et al. (2005) showed a significantly different rate, 4.2% (4 in 95). The studies' closest results to our triploidy rate (10%, 1 in 10) are the ones of Alberman and Creasy (1977), with a rate of 13.2% (38 in 287) and the one by Perrone, Silva and Cintra (2006), with a rate of 15.5% (11 in 71). Regarding the case of monosomy of one autosomal chromosome of group D, there is no similar case in the literature. The chromosome belonging to this group are the acrocentric pairs of 13, 14 and 15. The formed embryo could have been developed by a monosomic gamete due to a non-chromosomal disjunction-involving chromosome D during maternal or paternal gametogenesis.²² Considering the material quality, it was not possible to identify to which pair it belonged, even when evaluating more than ten metaphases.

Although the cytogenetic technique is applied as the main conduct to screen and identify chromosomal anomalies present in most of the spontaneous abortions in the first trimester, an ideal practice is the combination of more state-of-the-art technologies, such as FISH, *Multiplex Ligation-dependent Probe Amplification* (MLPA) or aCGH, for a better understanding and more accurate diagnosis in these cases.²³

Despite the sample analyzed being small, it was possible to observe that more than half of the cases of spontaneous abortions of the present study of cases have been caused by fetal chromosomal anomalies.

Several studies^{4,6,24,25} highlight the importance of the cytogenetic study of ovular leftovers and suggest that before gynecologists have couples undergo a series of additional and modern tests to investigate

tentative loss causes, it would be of utmost importance to analyze the karyotype of such abortions.

Conclusion

In our study ten abnormal karyotypes have been found and the frequency of such chromosomal abnormalities determined. It was found among them trisomies, tetraploidies, triploidies, monosomies of the X and autosomal monosomy. The chromosomal anomalies have been found responsible for a high number of spontaneous abortions when compared to the literature. In these cases, the cytogenetic diagnosis assists in the understanding of the fetus loss and helps couples and physicians in a more complete and clarifying genetic counseling.

There has not been any conflict of interests in the present study.

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ORIGINAL ARTICLE

Omalizumab efficacy in difficult asthma control therapy in pediatric patients: A literature review

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Pediatrics

Abstract

Objective: To review the literature on advances in the treatment of difficult-to-control severe asthma with the usage of omalizumab in pediatric patients. **Method:** review of recent literature (2010-2015), using the Pubmed database. **Result:** the drug reduced exacerbations in frequency and severity, and reduced the need for oral steroids therapy. However, the small population involved and the high cost of the drug makes it a dubious indication for that age range. **Conclusion:** It is an effective and safe drug in moderate/severe uncontrolled asthma; however, studies in the pediatric population remain incipient, suggesting that researches in this field should go on with the development of long-term studies.

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Introduction

Asthma has been increasing in incidence and in prevalence along the decades, reaching the top position among the chronic diseases that most assail the pediatric population. In the UK, 1.1 million children are affected, and among them, 307 suffer from the acute allergic and persistent stage of the illness, remaining uncontrolled despite the best treatment available, characterizing thus the difficult-to-control asthma.¹

There are no more reports about asthma as *causa mortis* in the majority of the countries, but it still increases the morbidity to an important degree.² Procedures due to asthma in emergency rooms in England reached 79,000 attendances over 2008 to 2009. Among them, 39,000 were children up to 14 years old; and 75% of the cases were avoidable, with a good therapeutic approach and adjoining follow-up.³ Thus, the improvement and the development of new therapies to optimize the treatment and avoid the hospital stays is a must needed effort.

The treatment is administered with inhalable corticoids and long lasting action bronchodilator drugs or leukotriene receptor antagonists in optimized dosages. If the patient remains uncontrolled, oral corticoids or other immunosuppression therapy can be used.³⁻⁵

However, oral corticoids present several collateral effects when used, fact that stimulates research and development of new alternative therapies.^{4,5} To face this demand and to offer support to those who do not respond to the oral corticoid therapy, new drugs are under studies, and one of them is omalizumab.

Omalizumab is an E (IgE) anti-immunoglobulin monoclonal antibody.⁴ This medicine is of subcutaneous administration. Its dosage is calculated upon the patient body mass index – BMI.⁴

The drug blocks the interaction between the IgE and its receptors, on the surface of the basophils and of the mast cells.^{4,6,7} This mechanism reduces the level of serum IgE and the level of its receptors (FcεRI) on the basophils, as well as its affinity for them.

This drug administration has been insufficiently studied in the pediatrics range of age, presenting many divergences about it in the literature.^{3,5,8} Nevertheless, there is a consensus that its usage reduces exacerbations and consequently corticoid therapy. The literature comprising the adult population is far larger, and some few differences regarding effectiveness, benefits over costs and the reduction of specific markers are registered.^{3-7,9,10} Thus, the objective of this study is to revise the literature about the treatment of difficult control severe asthma with omalizumab in pediatrics patients, knowing the risks and benefits already reported, emphasizing the quality of life of the patients by comparing the therapeutics between adults and the pediatrics population, and assessing the medicine cost-benefit.

Method

Data search was done by consulting the MEDLINE/PUBMED database about the terms “omalizumab” and “asthma” defined by the Medical Subject Headings (MESH Terms). The papers were filtered based on publications from the last five years and that reached the age from birth to 18 years old. 60 papers were found. Those with assessments from 12 years old on were excluded, for inadequacy with the objectives, and those classified as editorials were excluded too, leaving 25 to be reviewed. After a complete and thorough reading of all of them, 17 were selected. They were listed by type of study, highlighting the most relevant aspects in each one, comparing its effectiveness in the youth range of age; and, some difference in

specific studies about adults were also demonstrated.

Results

The distribution of paper types is on Table 1 and the synthesis of the results is on Table

2. The Table 3 shows evidences of the medicine effectiveness in the pediatrics range of age. Table 4 reports the differences found regarding the adult range of age presented in each study.

Table 1: Type of studies about Omalizumab usage in children over 2010 – 2015

Study	PUBMED
Cohort	01
Clinical	04
Review paper	07
Systematic review	01
Case report	04

Source: author. Note: translated.

Table 2: Main results from manuscripts about omalizumab usage in pediatric patients over 2010-2015 in the MEDLINE/PUBMED database.

Norman G, et al. ¹	Limited data amount on children. Beneficial effect: symptomatology, emergency care usage, quality of life and FEV ₁ (forced expiratory volume in one second). Low effectiveness over costs. The adverse effects of systemic corticoids may persist beyond treatment time.
Normansell R, et al. ²	Effective and safe in mild to severe uncontrolled asthma. It is not clear if it does justify the costs. The effects with extreme values for IgE were not assessed. There are no direct comparisons with other control drugs.
Neffen H, et al. ³	Decrease in the number of exacerbations, hospital stays, rescue medication and on the need for oral corticosteroids. Progressive reduction of the inhalant corticosteroid dosage.
Walker S, et al. ⁴	No benefit statistically important was registered using omalizumab for exacerbations requiring a hospital stay. Decrease in the exacerbations absolute numbers, mortality rate and improvement in the quality of life is low, while the additional cost of the treatment is high.
Brodie M, et al. ⁵	Improvement in the quality of life and decrease on the oral corticoid usage in all age ranges.
Hill DA, et al. ⁶	Reduction in the frequency and number of circulating basophils in asthmatic children, together with a better asthma control.
Baena-Cagnani CE, et al. ⁷	Beneficial in several conditions of IgE mediation (asthma, chronic rhinitis, anaphylaxis, food intolerance, atopic dermatitis and spontaneous chronic hives). Some studies have demonstrated an initial rise of IgE, and others, the opposite.
Fried AJ, et al. ⁸	Decreases exacerbations. The development of better affinity IgE agents might be necessary for another <u>allopathy</u> . Usage in food intolerance is being speculated.
Sorkness CA, et al. ⁹	Effective in mild and severe illness. Patients more susceptible of benefiting present high exhalation of nitrous oxide, <u>eosinophils in the blood stream</u> and high BMI.
Steil JO, et al. ¹⁰	Decrease in the level of serum IgE followed by clinical improvement. The patients remain for a long time without crisis after the treatment is over. It is not satisfactory in atopic dermatitis.
Robison PD, et al. ¹¹	Pediatrics age range: this intervention offers a unique potential to prevent and change the disease physiopathology.
Deschildre A, et al. ¹²	Effective for children suffering from severe allergic asthma.
Burch J, et al. ¹³	It shall not be dispensed routinely to children from 6-11 years of age, suffering from persistent allergic asthma, due to the high cost rate over the effectiveness. It can be an effective alternative to the oral corticosteroids.
Rizk C, et al. ¹⁴	Patients undergoing chronic corticoid therapy have developed collateral effects as renal failure and losses of bone tissue. Omalizumab offers progress.
Pite H, et al. ¹⁵	Improvement in the asthma and rhinitis biological and physical markers without alteration in the exanthema. Pain in the injection has been the only collateral effect observed.
Kao SL, et al. ¹⁶	Th1, Th2 and some pro-inflammatory cytokines do not show significant alterations. There was a clinical improvement and improvement in the respiratory parameters. The levels of serum IgE decreased but the levels for total IgE increased.
Busse WW, et al. ¹⁷	Clinical betterment, decrease in exacerbations and seasonal peaks.

Source: author. Note: translated.

Table 3: Omalizumab effectiveness in the pediatric age range

Identification	Effectiveness in the age range
Norman G, et. al. ¹	Yes
Normansell R, et.al. ²	Yes
Neffen H, et al. ³	Yes
Walker S, et al. ⁴	Low
Brodie M, et al. ⁵	Yes
Hill DA, et al. ⁶	Yes
Baena-Cagnani CE, et. al. ⁷	Yes
Fried AJ, et al. ⁸	Yes
Sorkness CA, et al. ⁹	Yes
Steiß JO, et al. ¹⁰	Yes
Robison PD, et. al. ¹¹	Yes
Deschildre A, et al. ¹²	Yes
Burch J, et al. ¹³	Yes
Rizk C, et al. ¹⁴	Yes
Pite H, et al. ¹⁵	Yes
Kao SL, et al. ¹⁶	Yes
Busse WW, et al. ¹⁷	Yes

Source: author. Note: translated.

Table 4: Omalizumab usage between the pediatrics and adults age range

Identification	Differences between the age range
Norman G, et al. ¹	Safety evidences very limited for the pediatrics age range.
Normansell R, et al. ²	The inhalant corticoid dosage decreased 100% in the patients under treatment, in comparison with the placebo. In the adult age range, the decrease was not so significant.
Neffen H, et al. ³	There are no differences pointed out in this study. However, it emphasizes the prescription only for children above 6 years of age.
Walker S, et al. ⁴	The study evidenced a mortality rate caused by severe exacerbations (requiring hospital stay) significantly lower in children below 12 years of age, with a more evident rate in adults above 45 years of age.
Brodie M, et al. ⁵	Regarding the improvement of the life quality and the decrease on corticoid usage, there were no differences found between the group below and above 12 years of age.
Hill DA, et al. ⁶	It has been not recognized in the age range the decrease in basophils, maybe due to the difference between the populations, or by the study design, or the new levels of color in the cytometry.
Baena-Cagnani CE, et al. ⁷	it might have an effect in the remodeling process found in asthma. Decrease in the clinical significant exacerbations has been low and the cost high. It should not be routinely dispensed to children 6-11 years of age undergoing treatment for severe persistent allergic asthma.
Fried AJ, et al. ⁸	The decrease of inhalant corticoids in children and adolescents, in need of a long time usage and above the desirable dosage, is one of the most relevant beneficial effects of omalizumab.
Sorkness CA, et al. ⁹	It is more effective for exacerbation decrease by age, in children 12 years old or older, but there are no corresponding differences observed in the effects from inhalant corticoid dosage, or symptoms referred in age.
Stein JO, et al. ¹⁰	It does not offer comparisons between age ranges.
Robison PD, et al. ¹¹	The intervention in this age range offers the unique potential to prevent and to modify the disease physiopathology.
Deschildre A, et al. ¹²	The only effect changer observed in response to omalizumab was the age (it is worth saying that the age below 12 years old has been associated to a better control).
Burch J, et al. ¹³	Even not being routinely indicated for the age range 6-11, the parents have the right to go on with the treatment.
Rizk C, et al. ¹⁴	It does not offer comparisons between age ranges.
Pile H, et al. ¹⁵	Decrease in pulmonary function is not a necessary criterion for decision making on omalizumab therapy in this age range.

Source: author. Note: translated.

Discussion

The initial treatment is based on inhalable corticoids and long lasting action bronchodilator drugs or leukotriene receptor antagonists in optimized dosages. When the disease remains difficult to control, oral corticoid therapy shall be

considered or other immunosuppressive therapies, despite its several collateral effects.³⁻⁵ Due to the discomfort with the usage of oral corticoids, other drugs are being studied.

Macrolide antibiotics presented a good safety margin for adults when used for

neutrophil asthma control. However, cyclosporine, methotrexate and intravenous immunoglobulin presented low effectiveness.⁵ Omalizumab usage presented some degree of effectiveness in all the papers herein reviewed. Other monoclonal antibodies, as anti-IL5, anti-IL9, and anti-TNF, presented a variable effectiveness in adults, and there are no studies on the age range of the pediatrics population.⁵

The action mechanism of these new drugs under studies regards the blocking of interleukins and IgE, related to the allergic asthma physiopathology. It is suggested that the basophils have influence in the start and progression of the allergic inflammation, and that it might be the actuating mechanism for the new therapeutics.⁶ Omalizumab is a monoclonal anti-IgE antibody approved by the Food and Drug Administration (FDA) for the allergic asthma treatment. It has been released in the United States in 2003 for patients above 12 years old, suffering from persistent severe asthma and without control gains with optimized dosages of inhalable corticoids. The DG Health and Food Safety of the European Commission released its usage for children above 6 years of age in 2005.⁴

The administration is subcutaneous. The dosage is calculated upon the patient body mass index.⁴ The actuating mechanism blocks interaction between IgE and its high affinity receptors on the surface of the basophils and of the mast cells.^{4,6,7} Thus, the therapeutics reduces the level of serum IgE and the level of its receptors (FcεRI) on the basophils, as well as its affinity for them.

Blocking the allergic cascade stops the liberation of cytokines, histamine, tryptase and arachidonic acid metabolites; holding back the allergic process that would be developed by a combination of genetic and environmental factors.⁷ In face of this fact, the other approach measures are preserved, even if undergoing medication.

Data on how the medicine acts on the circulating basophils are still inaccurate, and diverge somehow. Hill & partners for example, found in their study a reduction on the level of basophils, contributing to a better understanding about the physiopathology of asthma and its mechanisms.⁶ However, this reduction did not perform the same way in all the patients. Evidences of a possible population that will present a therapeutic lack of response in the future or just an inconsistency in the study? Our interpretation is limited due to the absence of a placebo group.

Even though the LgE level demonstrates to be a good predictor of clinical symptoms, there are evidences of normal level or low level of serum LgE patients with positive responses to omalizumab, which tells us that more studies are required to elucidate this molecule behavior in asthmatics.⁴

In the majority of the papers, omalizumab has demonstrated effectiveness in the treatment for difficult-to-control asthma. The research done by Walker *et al* is the exception, with results not demonstrating an important statistical effectiveness in cases of clinically significant exacerbations.¹ They concluded that there was a small reduction in the absolute numbers of exacerbations, as well as slight improvement in the quality of life (accordingly with a questionnaire proposed and validated), and in the mortality rate. The reduction of the daily symptoms was not evidenced as well as in the inhalant corticoid therapy. The high costs of the expenditures for the treatment are not justifiable.¹

The fact that long lasting collateral effects remain unknown has been mentioned.¹ However, Walker *et al* covered a small sample where most of the individuals were not given the prescribed optimum therapy. Even though, this study levels up with others when it acknowledges the benefits of the reduction of the corticoid therapy for those in constant usage, or say that the same was insufficient.

Several papers give evidence of the reduction on the number of exacerbations, hospital stays and unscheduled doctors' appointments for patients undergoing treatment with omalizumab. It is also observed the reduction on the use of relief medicines and on the need for oral corticoids.^{2,3,5,8,10,12,16,17}

The usage of inhalant corticoids was also progressively reduced to obtain the appropriate control of the disease.⁵ These data must be carefully assessed, once the population studied is small and some patients were not being monitored or were, but with insufficient follow up in determined groups. Just a few studies have had the care, when separating the samples, to make sure that the previously proposed therapy was well performed, for instance, they did not report on the wellness of the environmental measures and if the medication was properly administered.

Regarding the oral corticoid therapy, the reviewed studies share the same opinion: omalizumab not only reduces the dosages but also the frequency on its own necessity. Broadlie et al emphasizes a reduction of 15mg, in average, on the daily dosage of oral corticoid, or even its suppression in the difficult control asthma treatment.² Above all, patients using omalizumab have experienced long periods without crisis after the treatment is over, thus abolishing the relief medication.¹⁰

The reduction on oral corticoid therapeutics has valuable aspects eliminating its collateral effects. Among them are hypertension, leonine facies, suprarenal gland suppression, myopathy, growth restriction, obesity, osteopenia and cataract.²

It is worth highlighting that omalizumab addition is the only therapeutic intervention improving the severe allergic asthma control which does not respond to combined treatment with high doses of inhalant corticosteroids, before systemic corticosteroids usage, combined or not with

other controlling drugs.⁵ It corroborates the pediatrician must have theoretical knowledge and clinical practice when using this medication with youth in real need.

One important benefit more from omalizumab is the reduction of seasonal asthma exacerbations.¹⁷ The patients using the drug show a reduced number of exacerbations over the weather seasons favoring these events. In general, the peaks occur in spring and in the fall with lesser events in the summer.¹⁷

Another fact rising attention in favor of the omalizumab therapy, has been emphasized by Fried et al, observing that, in general, there is a significant statistical improvement in the patient's quality of life.⁸

Spirometry is commonly used to follow and diagnose the pathology under study. One of the main figures to be measured is the value of FEV₁, allowing measures of the pulmonary function in percentages. In case of flows under 60%, the asthma is considered severe, but values below 80% do demonstrate reduced pulmonary function.³ This parameter presents significant improvements in value for patients undergoing treatment with omalizumab.^{3,16} Such results were more commonly observed in adults than in young patients. It is an easy explainable fact, once there are limitations in the medical examination for the pediatrics age range: the patient must follow the commands of the professional in charge. That is why the reduction in the pulmonary function is not a parameter to apply in the pediatrics age range, to indicate which medicine shall be used, as it is done for the adult age range.¹⁵

In contrast, there are divergences regarding the improvements found with spirometry. Fried and Oettgen mention specifically that the FEV₁ results and the expiratory flow peak figures were not altered in patients using omalizumab, and consequently neither was the pulmonary function.⁸ The statement is confirmed by Busse et al in their report. They say that although clinical

improvements and diminishment of other drugs usage, the patients pulmonary function did not improve.¹⁷ Nevertheless, the study does not specify how the data was collected.

Omalizumab has also shown advantages in the treatment of other diseases, with high relevance for allergic rhinitis. However, there are evidences of effectiveness in therapies for nasal polyps, cystic fibrosis, atopic dermatitis, spontaneous chronic hives, food intolerance and anaphylaxis. It does demonstrate the increase in the quality of life, the decrease in the symptomatology and also the decrease in relief medication.^{7,8} It is worth remembering that prescription is based on the failure of other therapeutic measures already adopted. The studies are in the starting phase and in these circumstances, the data is scarce and insufficient for an exact prescription of omalizumab.

When comparing therapeutics between age ranges, it is observed a decrease in the inhalant corticoids dosage in 100% of the pediatrics range, meanwhile in the adult range the results were not quite relevant.⁴ The drug potential to perform in the pulmonary remodeling process done by asthma is being studied, eliciting a unique potential to prevent and modify the disease physiopathology.^{7,11} Another relevant information found is a better disease control and a reduced mortality rate among children below 12 years of age.^{1,12}

In spite of the innumerable benefits found, many papers point out at the advantages are not enough to justify the high cost of the omalizumab.^{1,3,4,10,13} The therapy brings benefits to a small population but in a very important way, and because of that its indication must be precise. The studies about the long time effects are still in development, and thus, these effects may influence the omalizumab indication criteria.

Conclusion

The drug is safe and effective for mild to severe uncontrolled asthma, but studies in the pediatric population remain incipient within the reviewed literature.

The good results already achieved, together with the significant benefits omalizumab may offer, strongly suggests that research must continue on the pediatric population, developing long range random and placebo studies, allowing thus the remaining doubts to be analyzed and the long lasting effects to be studied.

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CASE REPORT AND LITERATURE REVIEW

Muscle strength increase in osteogenesis imperfecta with the pilates method: A case study

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Abstract

Osteogenesis imperfecta is rare disorder of the connective tissue characterized by bone fragility and osteopenia, resulting in functional limitations and reduction in patient's quality of life. The physical therapy works in the treatment and prevention by methods such as Pilates. The goal of this study was to understand the benefits of the Pilates method in the treatment of patients with OI. The evolution of the patient was analyzed during eleven months, based on medical records. The Pilates exercises were performed three times a week, with one-hour long sessions. Muscle strength, better body awareness and self-esteem gains are some of the benefits observed in present study.

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Introduction

Osteogenesis imperfecta (OI), also known as *brittle bone disease* is a rare genetic

disorder of the connective tissue, characterized by bone fragility and osteopenia with several clinical signs due to a deficiency of Type 1 collagen.¹ Its

variable clinical records may be synonym of functional limitation and reduction in the quality of life.²

OI treatment consists in keeping patients' quality of life rather than reverse their health condition.³ Physical Therapy also works effectively on the treatment, mainly to prevent these patients fractures⁴ through kinesiotherapy, hydrotherapy and electrical stimulation as well as the Pilates method, the treatment proposed in this study.⁵

As in OI, patients suffering from osteoporosis develop bone brittleness and high chance of fractures. Therefore, such pathology must be considered, once its medication and physiotherapeutic treatments are similar to the OI one.

Osteoporosis is defined as an osteometabolic disorder reducing the bone mineral density, wearing out its structure and increasing fragility, rising the risks of fractures, which is the main clinical sign of the pathology. The practice of physical exercises is recommended for these patients' treatment so as to minimize bone tissue losses and avoid possible falls, consequently improving balance, walking pattern, defense reactions and individual proprioception. In this context, Pilates is suggested as a therapeutic approach, with available records of its effectiveness in the improvement in the quality of life of the patients suffering from osteoporosis.⁶

The method is recommended for gain of flexibility, body definition and health improvement.⁷ Besides that, it also works posture awareness, corrects muscular imbalance and strengthens the muscles. Currently it is also known as a rehabilitation resource for the treatment of elite athletes, neurological disorders, chronic pain, orthopedic problems and low back pain.⁸

There are no studies relating Pilates to OI treatment in the literature so far. However, the practice of physical exercises is a well-known ally in the osteoporosis treatment, since muscular contraction increases bone

density, strengthening this structure and decreasing the prevalence of fractures. Therefore, Pilates can be a therapeutic tool for OI treatment. It stimulates the production of calcium, strengthens tendons and joints, corrects posture alterations such as scoliosis, caused by bone deformities, develops the lung capacity and guides the patients on their daily activities.⁹

Case Report

Female patient, 34 years of age suffering from osteogenesis imperfecta type 4, showing a bluish sclerotic and a record of fractures as symptoms, aside from the short stature, 1.40m. Pilates practitioner from January to November 2014. Active, college student and part-time intern, she lives alone and is independent regarding her daily life activities.

She was born at 8 months of pregnancy, delivered in a normal childbirth with two bilateral femur fractures and bowing of the tibia and fibula. She would not crawl and started independent walking at 13 months of age. From that period on, a sequence of femur fractures started, fracturing the right femur, with an approximate frequency of one fracture per year.

Between 6 and 10 years of age, the number of fractures increased, raising to twice per year, allowing the installation of osteoporosis for lack of usage. In this time the patient used a HKAFO orthosis (with hips, knees and foot support) in order to help with her orthostasis.

After 10 years of age, she suffered 5 fractures, two in the same place of the tibia, one in the right fibula, and two in the femur, all due to the same trauma.

She underwent surgical procedures to fix a left femur fracture when she was 13 years old, having placed an intramedullary nail, being immobilized with plaster casting for 90 days.

According to her medical records, she suffered from ligamentous laxity, which

made room for 3 sprains in the right ankle, all of them after she was 20 years old.

She evolved with a left knee dislocation, several lower limbs deformities due to the fractures and bones bowing. She presented osteopenia and osteoporosis in the right hip and in the spinal cord.

She was following drug treatment (Protos 2g) and medical follow up with an orthopedist and a psychologist.

The first contact of the patient with the Pilates method was in 2011 by medical recommendation. She practiced it for about one year, after stopping and resuming activities on January 6 of 2014, in the studio where the research was conducted. After a Physiotherapeutic Assessment, it was noticed that the patient suffered from a light pain condition in the right hip and in the lower limbs, more intense in the mean line of the left knee due to previous dislocation. At the physical examination, she presented anterior deviation of the head, depressed left shoulder blade, convex scoliosis to the right, an elevated right hip, genu varum, pronated feet, thoracic rectification and lumbar hyperlordosis, balance decrease reported to have become significantly worse, after the knee dislocation and a thoracic hypomobility.

In an assessment, described in her medical records, the Medical Research Council (MRC) Scale for Testing Muscle Strength was applied, obtaining as a result, a grade 3 for abdominal muscular and limbs strength.

Pilates classes were attended along the entire period from January to November 2014, 3 times a week, 60-minute long sessions, comprising this research conduction time.

According to the patient's medical records, exercises were not performed on the Ladder Barrel, once the patient reported insecurity and fear of falling. The basic level exercises were preferably done on the ground level, always with a support base. They consisted of abdomen strengthening training, trunk

side stretching at the Reformer and the Step Chair (Mermaid), strengthening of the lower and upper limbs done not only at the Cadillac, but also at the Reformer and the Step Chair, by also executing series such as Foot Work and Arm Springs with low resistance.

In the bimonthly records found, it is observed that the evolution of the exercises in this patient's treatment followed the same parameters of any other training, gradually advancing as springs resistance was increased, with the association of other accessories to the exercises, along with an also gradual withdrawal of a supporting base.

In the bimonthly patient evolution recorded, the physiotherapist claims to have observed an improvement in the patient body awareness, a decrease in the left knee pain condition, and a slight gain of strength in the abdominal muscles.

In the 3rd month of treatment the main goal was to improve balance and prevent falls. First stage exercises were maintained, and accessories were introduced for exercise load increase, like balance disks, roller or Swiss ball as a feet support in the Bridge exercise; or with the Magic Circle between the knees. Besides that, exercises like Single Leg Kicks wearing 1kg leg-pads in lower limbs, Foot Work on the Reformer, Leg Circles Educational exercises on the ground and The Cat to Elephant by the end of the class. The balance training on the disk was intensified during this phase, with monopod support on the disk with the aid of upper limbs.

By the end of the second bimester it was reported that the patient had achieved a better abdominal contraction, better posture awareness, and would do exercises on the ball with more control, besides managing to reduce shaking on the balance disk.

By the 5th month of treatment, it was reported that the patient was able to perform intermediate level exercises by increasing

spring resistance, changing lower limbs position when doing exercises in dorsal decubitus, such as at The Hundred, with lower limbs at 90° and by removing the supporting base in the balance exercises.

At the third bimester, the exercises were: Leg Circles, Proprioception works at the Reformer, doing Foot Work with the feet supported on the Swiss ball while the therapist would hold the ball, scapulothoracic dissociation at the Step Chair and Ball Diving, aside from those already executed to perfection by the patient in the initial phases. Barrel exercises were introduced, like quadriceps stretching, Riding, lower limbs posterior stretching and spinal cord extension in ventral decubitus. Reports revealed important gains in physical conditioning and resistance, muscular strength and balance, and also revealed that the patient reported an improvement in her daily life activities, performed with more vitality and in absence of pain.

At the 5th month treatment reassessment, the MRC Scale for Muscle Strength Scale was applied again: the strength grade went up to 4 in abdominal muscles and in lower and upper limbs.

Up to the seventh month, the previous level of exercises executed was maintained, with a load increase by using 2kg leg pads and springs with a higher tension. It was reported that the patient presented a better thoracic spine mobility, performing exercises without so much dependence on external feedback.

By the ninth month, the exercises were of an advanced level, aiming at the improvement of movements fluidity and quality. Some exercises performed were the Leg Pull Up and Down, Jack Knife, The Hundred on the Reformer, the Board with the upper limbs supported on the ball, and Rolling Down and Up with the Swiss ball. Patient evolution was reported in this phase of training, with a reduction in her muscle

fatigue, observed when she would take on the advanced Teaser on the Cadillac.

Reports show that along the eleventh month, the sessions would flow better, allowing 20 exercises to be executed in a row without stopping. Sessions goals were to improve movement quality and fluidity, and add multitask capability with advanced level ground exercises, using a variety of accessories during the moves. Exercises such as The Teaser were performed, with resistance given accessories, glute kickbacks with Theraband resistance, Rows at the Cadillac on a dorsal decubitus position on the ball, quadriceps strengthening with associated upper limbs flexing movement with a Swiss ball in hand without any still point, and Jack Knife without the aid of the upper limbs. After the eleven-month training period the patient claimed: "Pilates has changed my life. I can't live without it anymore".

At the 11th month of treatment, the MRC Scale for Muscle Strength Scale was applied again: the strength grade went up to 5 in abdominal muscles and to 4 in lower and upper limbs.

In an unstructured interview about the changes occurred in the patient's life, registered in her medical records, the patient claimed: "(...) I've gained in a lot of strength and balance and my joints are more stable. My posture is much better and I do not feel pain anymore".

Discussion

Osteogenesis imperfecta (OI) is a rare genetic disorder of the connective tissue, characterized by bone fragility and osteopenia. It may be the synonym of functional limitation depending on its degree and clinical record in question.¹⁰

Concerning the Muscle Strength Grade, there was an increase in the upper and lower limbs strength between month 1 (one) and

month 5 (five), evolving from Grade 3, in which the muscle only beats gravity, to Grade 4, in which the muscle copes with gravity and is able to face small resistance, degree kept until the last reassessment in month 11 (eleven). Therefore, there has been a 20% total strength gain to the upper limbs (MMSS) and to the lower limbs (MMII). It has been observed a 40% increase in the abdominal muscle strength, between January and November 2014, with an alteration from Grade 3 in the first month, to Grade 4 in the fifth month, and to Grade 5 in the eleventh month, which represents a normal abdominal muscle strength to face great resistance, as shown in Table 1.

Table 1 – Degree of Muscle Force for the Medical Research Council

Variation	% Variation MMII & MMSS	% Variation Abdominal
Month 1 to Month 5	20.00%	20.00%
Month 5 to Month 11	0.00%	20.00%
Month 1 to Month 11	20.00%	40.00%

Source: Patient Medical Records. Note: translated.

The Pilates exercises are focused fundamentally on the core strength, aiming to align the trunk biomechanically, generating relief from the pain condition and health improvement, which contributes to this study since there was a reduction in the pain level in the lumbar spine region as reported by the patient.¹¹

Abdominal muscles comprehend the main muscle group for the Pilates method. In all of its exercises, abdominal contraction is always associated with the movements, hence the great importance abdominal muscles play, together with the paravertebral muscles and the pelvic floor, in giving support to the postural alignment

maintenance and to the action of defying gravity,¹² confirmed here in this study, once it has been observed a fast abdominal strength gain by the patient studied.

This patient's upper and lower limbs muscle strength increased and that may be related to the constant strengthening of upper limbs (MMSS) and lower limbs (MMII), gradually increasing spring resistance, as well as the usage of several accessories to enhance its activation, such as the Magic Circle and the Swiss Ball.¹³

The results found in this study corroborate with the findings from a 2012 research reporting on the importance of the centralization approach in the Pilates Method. There, the abdominal muscles are worked to stabilize the spinal cord, iliopsoas muscles, quadriceps, the lumbosacral region and the pelvic floor, in order to improve the muscle strength in the lower limbs, stabilize balance, and even improve the aerobic capacity, as a likely function of the increase in muscle tonus, thus reducing fatigue and improving muscle resistance to execute these tasks.¹⁴

Besides the quantitative gain previously mentioned, it was possible to observe a secondary qualitative gain, considering the patient's improvement in self-esteem and quality of life, with anxiety reduction and adequate physical fitness, described by the patient as seen in her everyday life. Pilates is said by her to be “indispensable” to her physical and mental well-being. This effect may be related to the level rise of serotonin, epinephrine and dopamine, natural antidepressants promoting the feeling of pleasure.¹⁵

Such benefits were also described by Joseph Pilates (1956), that affirmed: “Pilates develops the body uniformly (...) invigorates the mind and elevates the spirit”.

The pictures related to Pilates can be seen at the end of this paper.

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Figure 1

- a) Bipedal support on balance disk with the aid of MMSS (upper limbs)
- b) Monopod support on balance disk with the aid of one upper limb

Left: bipedal support on the balance disk with the aid of the upper limbs.

Right: monopodial support on the balance disk with the aid of an upper limb

Figure 2



Footwork on the Reformer with tensioned springs to strengthen the lower limbs

Figure 3



Riding the Barrel Exercise associated with weight ball to strengthen the upper limbs.

Figure 4



The Hundred



REVISTA SALUS

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LETTER TO THE EDITOR

Humanization in neonatal intensive care unit: a review

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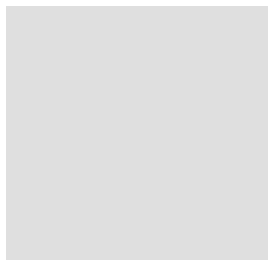
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Humanization of Assistance;
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Abstract

In Brazil there is a high rate of newborn preterm infants, a fact that places child mortality into the spotlight, thus becoming a major public health issue. However, hospitalization in the Neonatal Intensive Care Unit introduces the baby to an inhospitable environment. Given that, humanization claims for an association between the technical and scientific assistance with respect to individual-oriented actions, caring for the baby and his/her family, emphasizing care for a better development of the newborn, always attempting to improve their quality of life and survival. The aim of this study was to present a review of the literature regarding the importance of humanized care in Neonatal Intensive Care Units. Thus, search was conducted to review books, dissertations, journals and scientific articles, based on the following databases: LILACS, MEDLINE, PubMed and SciELO. After analyses of the most relevant articles, the results showed that humanization, that is, the caregiver and cared being relationship should have as a common thread sensitive listening skills to build a practice that is able to combine the best technology available with the promotion of acceptance and emotional attachment, providing the development, growth and recovery of the newborn in a satisfactory



way, minimizing the harmful effects caused by hospitalization. It is concluded that when assistance is to be based on comprehensiveness and respect for life, technological breakthroughs with the indissolubility of both mother and child, creating a bond of trust between family and staff, fundamental factors for the recovery of high-risk newborns.

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Introduction

Each year there are 20 million newborns (NBs) in the world with low weight, many as a result of a premature birth. This contributes substantially to the high neonatal mortality rate still present in various regions, especially in poor countries.¹

In Brazil, since the beginning of the 1990s, neonatal mortality has become the main cause of child mortality, mainly due to the proportional reduction of post-neonatal deaths.²

Nowadays the World Health Organization (WHO) adopts the classification related to gestational age of the newborn as follows: *preterm* is anyone born with less than 37 weeks of gestational age (or less than 259 days of gestation) *term* is anyone born between the 37th week and 41st week and six days of gestation and *post term* is anyone born at 42 weeks or later.^{1,3}

Newborns (NBs) preterm (also called premature) can be classified into three groups: late preterm is a gestation of 35 to 37 incomplete weeks, moderate preterm is a gestation of 31 to 34 full weeks and extreme preterm of less than 30 weeks of pregnancy.⁴

Premature infants often require hospitalization for several days or months in a Neonatal Intensive Care Unit (NICU) where they are kept in an incubator for special care, being exposed to hostile stimuli such as pain, stress, bright light,

loud noise, invasive, painful and unstable temperature.⁵

The preterm infants are forced to interact in a new environment to which they are not fully adapted and become more susceptible to several neonatal complications.⁶ Moreover, the lack of pleasurable stimuli in early life can lead to a difficulty of sensorial adaptation. The lower the weight and gestational age at birth, the greater the impairments of neurobehavioral development of the preterm infants. Their systems, especially the nervous one, are not yet mature at birth, and are not exposed to motor and sensorial experiences, making difficult the interaction of the NB with the environment.⁷

The child is a unique being, full of potential, living a number of changes that will be decisive in their healthy growth from womb life to birth.⁸

The Neonatal Intensive Care Unit of the Environment (NICU) provides the newborn an experience quite different from the uterine environment, since the latter is ideal for the fetus growth and development since it possess distinct characteristics, such as pleasant and constant temperature, softness, warmth and filtering and reduction of extra uterine sounds.⁹

Hospitalization in Neonatal Intensive Care Unit introduces the baby in a harsh environment, where intense exposure to hostile stimuli such as stress and pain is frequent. In the neonatal unit in question there is constant noise, intense and

continuous light and invasive clinical procedures.¹⁰

Despite the great importance of NICU for sick neonates, contradictorily, this unit, that should ensure children's well-being in all its aspects, stands out as an agitated, impersonal and even fearful environment for those who are not suited to their routines. Such an environment is full of strong and constant light, noise, temperature changes, disruption of the sleep cycle, as they are required repeated assessments and procedures, often leading to discomfort and pain.⁹

Baby care should be structured and organized in order to aid a population subject to risk. Therefore, there must be material resources and people that are skilled and able to ensure strict observation, besides suitable treatments to NBs that present pathologies capable of causing death or sequelae that interfere in their development.¹¹

about the concern with the humanization of care in a Neonatal Intensive Care Unit should not be restricted to the health act itself. To consider the improvement of care quality at hospitals means to change management practices, improve infrastructure and affirm the sense of commitment among staff members.¹²

A baby's survival depends on a highly specialized and that poses a number of challenges for the infants and their parents. Humanization represents a set of initiatives aimed at promoting health care, being able to combine the best technology available with promoting acceptance, ethical and cultural respect to the patient, as well as to create a conducive workplace that is favorable to the proper technical exercise that also aims to satisfy health professionals and users.¹³

The humanization of neonatal care advocates several actions proposed by the Ministry of Health, based on Brazilian adaptations of the Kangaroo Care Method

for low-weight newborns (LAMY; GOMES, 2003). These aim at the respect for individuals, the assurance to technology that provides security to the newborn and the sense of belonging of the baby and his/her family, with emphasis on care focused on the development and psyche, seeking to ease the mother-infant bond during their hospital stay and after discharge.¹⁴

The current hospital humanization policy, combined with technological advances and the development of policies aimed at better conditions of recovery of premature newborns, has made it possible for parents to be able to closely monitor their children. In this context, the family is essential for the premature infant's introduction in society and constitution as a being, having his/her participation improved, becoming an integral part of the group of people responsible for the recovery and healthy development of premature infants.¹⁵

To separate a mother from her baby before she is ready to share him/her with other people may jeopardize the mother's feeling of competence and importance towards the baby.¹⁶

In an attempt to reduce the effects of this separation, there have been programs and methods that seek to ensure the opportunity of mother and child to be together after childbirth or other hospitalization cases so that the development of their bond is not impaired. Among the programs, one that can be mentioned is rooming, which aims to ensure the mother the right to remain with the child during hospitalization; and the one of breastfeeding, that strengthens the bond between mother and NB and ensures better physical development for children, and lastly, the kangaroo care, defined by the Ministry of Health (1999) as a "type of neonatal care that involves an early face-to-face contact between the mother and the low-weight newborn, which happens gradually, and for as long as they both understand to be pleasant and fulfilling,

thereby allowing wider participation of parents in the care of their NBs".¹⁷

The NICU humanization must be based on individual care, comprehensiveness, and on respect for life. It depends on the relationship between the caregiver and the cared being. It is about paying attention, taking responsibility, nurturing, respecting the each and every one's singularities, and especially promoting a wholesome care of the baby and family.¹⁸

Despite the great effort that professionals might be investing to humanize care at the NICU, this is an arduous task since it demands sometimes individual attitudes against an entire dominant technological system. And many times the dynamics of working in a NICU does not allow moments of reflection on their work process.⁹

The effective presence of the staff with a sensitive listening is as important as the technical procedure, since not always the expertise works so well in the face of stress. Only by observing, listening and feeling the newborn and his/her family as a whole, we will be assisting and understanding the essence of human care.⁹

Facing this new reality, many professionals, including physiotherapists, consider important to highlight the benefits of humanized care for the development of newborns. Physiotherapy in Intensive Care Units can be considered a new therapeutic modality, which gives the NBs stability of respiratory and heart rate, blood pressure and oxygen saturation, besides deepening the interaction between children and the environment through visual, auditory and tactile stimuli, leading to obtain responses to near normal range and inhibiting learning abnormal movements and postures.¹⁹

The physiotherapist, as well as other neonatal professionals, should base their service on comprehensiveness and respect for life. The common thread that ties the relationship between the caregiver to the cared being should be bound by sensitive

listening skills, attempting to build of a care practice able to merge the best technology available with the promotion of receptiveness and bond, further benefiting high risk newborns.²⁰

This study aims to provide a review of the literature on the importance of humanized care in Neonatal Intensive Care Units.

Method

Since this paper is a bibliographic review, books, theses, dissertations and scientific papers were used for research, based on the following databases: LILACS, MEDLINE, PUBMED and SCIELO, with articles published both in Portuguese and in English. The most relevant published articles in the literature on humanization in NICUs were selected using the following keywords: prematurity, humanization and Neonatal Intensive Care Unit, being included in this research original studies published between 1996-2010.

Discussion

After an analysis of the subject, the most relevant articles were selected, as follows:

The Neonatal Intensive Care Unit is one of the most specialized sectors in health institutions and in this restricted space there is a wide range of professionals, technologies and body of knowledge concentrated in one place. The assistance offered to newborns is diagnosis and therapy oriented in the search for biological recovery of the premature ones or the cure of the disease.²¹

The study on the work in health services reveals that the word 'humanization' can be understood as the way to see and understand the human being from a global view, seeking to overcome the fragmentation of care. One of the aspects involved in the

practice of this nature is related to the way we deal with the others.²²

Humanizing essentially consists, in making a practice beautiful, as much as it deals with what there is of most degrading, painful and sad in the human nature: suffering, decline and death. According to these authors, the key point of the humanization practice is to enhance the management between an already structured and known technical-scientific care, with a care practice that incorporates the need and acceptance of the unpredictable.²³

The humanization practice in the health care sector goes beyond holding technical-scientific competence, but it also incorporates the development of interpersonal relationships that find its roots in the respect for life, solidarity and sensitivity of perception of the unique needs of the involved individuals.¹²

To Humanize is to embrace the need for rescue and articulate inseparable aspects: feeling and knowledge.²⁴

In the study on hospital care humanization of premature infants, the author reported that the quality of life maintenance of babies determined the search for personalized customer service driven to the full development of the newborn and his/her family. There, the father and the mother have been included in the work process, aiming to provide sensory stimulation to the neonate, besides establishing bond, attachment as well as previously introducing them to home care.²¹

The actions of humanization for baby care and family demonstrates the attempt to modify how care has been developed. However, it is the individual behavior that needs to be discussed by the communities of professionals, making room for projects that enable collective and far-reaching actions, but as respect for parental rights of each family that has a child in NICU.¹⁷

The humanization of a Neonatal Intensive Care Unit starts with the participation of a

multidisciplinary team of nurses, neonatologists, neurologists, psychologists, speech therapists, physiotherapists, occupational therapists, and not to forget the fundamental participation of the family.²⁵

In the neonatal environment, humanization stands for a set of initiatives aimed at a health care able to combine the best technology available with the promotion of acceptance, cultural and ethical respect toward the patient.²⁶

Humanization cannot be thought without simultaneously considering the issue of education as a priority in an agenda of change. That is, what we see today in the field of health care is that education is reduced to computer and instrumentalization knowledge.²⁷

It is necessary to invest in training and sensitivity of NICUs healthcare professionals, not only promoting technical training, but also increasing their sensitivity to plan an assistance based on the foundations of humanization and comprehensiveness of care so as to provide the baby and the family a peaceful and welcoming environment, despite being hospitalized.⁹

The humanization of the NICU care is to be based on individual care, integrity and respect for life. It is dependent on the caregiver and cared being relationship. This construction of the notion of comprehensiveness should not become a concept only, but indeed a care practice that deals with the value of life, respect for others and with the differences between human beings. Therefore, the profession exercise of NICU health care professionals (physiotherapists included) should target the family and child's needs, encouraging their affective attachment in caring for their offspring, an important element for their recovery.²⁸

Conclusion

The technology apparatus at a NICU loses its meaning if it is not integrated into the humanization process of care and if it is not linked to the ethical principles for life maintenance and value.

The NICUs cannot be only a physical and functional infrastructure environment. It should also be a place where the human feelings, the attention to family and solidarity are present. A team committed to humanized care for the baby is necessary, that is, looking, listening to and feeling him/her family as a whole. It is also important to provide humanized care for the family because only then we will be understanding the value of human care.

Humanized care is intended to bring comfort to the newborn, improving their quality of life and survival, since it can prevent the onset of multiple sequels common to prematurity, once technological resources can reduce mortality, but not always reduce the hospital neonatal stay time.

Humanization leads to a closer contact to a more human relationship between the baby, family and even to neonatal professionals themselves. The hospital is not an ideal environment for newborns, though many need this type of assistance, especially the premature ones. Nowadays professionals are increasingly technical wise, leaving a gap to create a more suitable space for humanization, not treating newborns as numbers. It is necessary to show that although they are fragile and small, first, these babies deserve respect as human beings.

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