DEFORMITIES

CLINICAL OUTCOMES OF PATIENTS UNDERGOING CORRECTION OF NEUROMUSCULAR SCOLIOSIS WITH A CONTROLLED HOSPITAL PROTOCOL – PRELIMINAR OUTCOMES

DESFECHOS HOSPITALARES DE PACIENTES SUBMETIDOS À CORREÇÃO CIRÚRGICA DE ESCOLIOSE NEUROMUSCULAR COM UM PROTOCOLO HOSPITALAR GERENCIADO – RESULTADOS PRELIMINARES

RESULTADOS HOSPITALARIOS EN PACIENTES SOMETIDOS A CORRECCIÓN QUIRÚRGICA DE ESCOLIOSIS NEUROMUSCULAR CON UN PROTOCOLO HOSPITALARIO GESTIONADO -RESULTADOS PRELIMINARES



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ABSTRACT

Objectives: To identify the main hospital outcomes of patients undergoing surgical correction of neuromuscular scoliosis and to assess complication rates and achievement of mobility goals after the use of a managed protocol. Methods: This is a longitudinal, retrospective study, with data obtained six months after the application of a protocol in 103 patients of both sexes submitted to surgical correction of neuromuscular scoliosis, at a tertiary level hospital in São Paulo, between June and December 2018 (pre-protocol) and between May and September 2019 (post-protocol). Data from patients who had previously undergone other orthopedic spine surgeries were excluded. In addition to the data for epidemiological characterization of the underlying diseases, the clinical characteristics and complications were analyzed. Results: Of the 103 patients evaluated, there was a predominance of females (53.4%) and a mean age of 14.9 years. The most frequent diagnosis was cerebral palsy, the mean angle of curvature was 75°, and the most frequently observed comorbidities were lung diseases (25%). The protocol was partially adhered to by professionals and after its implementation, there was a significant decrease in pain and the systemic inflammatory response syndrome (SIRS), prevention of immobility and a low rate of infection. Conclusions: The use of a protocol focused on patients undergoing correction of neuromuscular scoliosis led to reduced complications of SIRS and reduced pain; kept the surgical site infection rate low, and prevented short-term immobility. **Level of evidence III; Retrospective study.**

Keywords: Scoliosis; Postoperative Care; Treatment Protocols.

RESUMO

Objetivos: Identificar os principais desfechos hospitalares dos pacientes submetidos à correção cirúrgica de escoliose neuromuscular, avaliar as taxas de complicação e o cumprimento de metas de mobilidade depois do uso de um protocolo gerenciado. Métodos: Trata-se de um estudo longitudinal e retrospectivo, com dados obtidos seis meses depois da aplicação do protocolo em 103 pacientes de ambos os sexos submetidos à correção cirúrgica de escoliose neuromuscular, em um hospital de nível terciário em São Paulo, nos períodos de junho a dezembro de 2018 (pré-protocolo) e entre maio e setembro de 2019 (pós-protocolo). Foram excluídos os dados dos pacientes submetidos a outras cirurgias ortopédicas de coluna previamente. Além dos dados para caracterização epidemiológica das doenças de base, foram analisadas as características clínicas e complicações. Resultados: Dos 103 pacientes avaliados, 53,4% eram do sexo feminino, média de idade de 14,9 anos, o diagnóstico mais frequente paralisia cerebral, ângulo médio da curvatura de 75º e as comorbidades mais observadas foram doenças pulmonares (25%). O protocolo atingiu adesão parcial dos profissionais, e depois da implementação, observou-se diminuição significativa da dor e da síndrome da resposta inflamatória sistêmica (SIRS), prevenção da imobilidade e baixa taxa de infecção. Conclusões: O uso de um protocolo com foco em pacientes submetidos à correção de escoliose neuromuscular, reduziu as complicações por SIRS e dor, manteve a taxa de infecção de sítio cirúrgico baixa e preveniu a imobilidade a curto prazo. **Nível de evidência III; Estudo Retrospectivo.**

Descritores: Escoliose; Cuidados pós-operatórios; Protocolos de tratamento.

RESUMEN

Objetivos: Identificar a los principales resultados hospitalarios de los pacientes sometidos a corrección quirúrgico de escoliosis neuromuscular, evaluar las tasas de complicación y el cumplimiento de metas de movilidad tras la implementación de un protocolo gestionado. Métodos: Se trata de un estudio longitudinal y retrospectivo, con dados obtenidos después de 6 meses de la aplicación de un protocolo en 103 pacientes de ambos sexos, sometidos a corrección quirúrgica de escoliosis neuromuscular, en un hospital de nivel terciario en São

Study conducted at the Hospital AACD – São Paulo, SP, Brazil.

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Paulo, en los periodos de junio a diciembre de 2018 (pre-protocolo) y mayo a septiembre de 2019 (postprotocolo). Se excluyeron los datos de los pacientes que se habían sometido previamente a otras cirugías ortopédicas de la columna vertebral Además de los dados para la caracterización epidemiológica de las enfermedades de base, se analizaron las características clínicas y las complicaciones. Resultados: De los 103 pacientes evaluados, el 53,4% eran mujeres, con una media de edad de 14,9 años, el diagnóstico más frecuente fue parálisis cerebral, el ángulo de curvatura promedio de 75° y las comorbilidades más observadas fueron las enfermedades pulmonares (25%). El protocolo logró una adhesión parcial de los profesionales, y tras su implementación, se observó una disminución significativa del dolor y del síndrome de respuesta inflamatoria sistémica (SRIS), prevención de la inmovilidad y una baja tasa de infección. Conclusiones: El uso de un protocolo centrado en pacientes sometidos a corrección de escoliosis neuromuscular redujo las complicaciones por SIRS y dolor, mantuvo baja la tasa de infección del sitio quirúrgico y previno la inmovilidad a corto plazo. **Nivel de evidencia III; Estudio Retrospectivo.**

Descriptores: Escoliosis; Cuidados posoperatorios; Protocolos clínicos.

INTRODUCTION

Neuromuscular scoliosis occurs in patients with muscle disorders and develops secondarily to imbalance between axial muscle forces resulting from the underlying disease. The pace of its progression is contingent on the child's growth and can advance even after bone maturity.¹

Surgical intervention^{2,3} is usually indicated for curves greater than 40°, aimed at preventing progression of the curvature, improving sitting posture, facilitating hygiene and improving the patient's quality of life.³⁻⁶

The approach to postoperative patient management requires caution, as this patient profile has a high potential for complications, with risk rates ranging from 18% to 75%. A recent study showed that 94% of patients with neuromuscular scoliosis had some type of mild complication, such as constipation, in the immediate postoperative period, while a small proportion had more severe complications, with the development of systemic inflammatory response syndrome in 16% of patients, and surgical site infection in 12%.⁷

The postsurgical complications most frequently reported in the literature are acute respiratory distress syndrome, pneumonia, venous disorders such as thrombosis, gastrointestinal complications, surgical wound infection and dehiscence, pseudarthrosis and exacerbation of convulsive syndromes. Secondary complications are mostly related to reduced mobility in the postoperative period, and range from soft tissue injuries and decreased levels of physical fitness and bone/muscle mass, to impaired ventilatory function due to the high degree of curvature of the previous spinal deformity.⁸⁻¹⁰

Although complication rates have decreased in recent years, prevention strategies for complications are important in all phases of treatment, as they are related to the general preoperative and intraoperative status and to the care received in the postoperative period.^{1,4,5}

Health services are increasingly focused on patient-centered care, accreditations and safety standards. As a result, institutional safety protocols have been created that include mobility goals and standardization of services, aimed at reducing the incidence of complications. ¹¹

Protocols can improve the quality and safety of care, while providing safer environments for patients, family members, caregivers and professionals, seeking to reduce the number of adverse events and as a consequence, the hospital costs generated. These protocols seek to minimize the inherent risks of surgery, determine the patient profile, and predict adherence to a set of preventive measures that involve the multidisciplinary team, including preoperative assessments and advance tests.¹²

Improving the quality and safety of patient care, implementing and managing protocols and promoting discussions still present operational and scientific challenges. It is necessary to plan, organize, direct and evaluate the actions carried out, in order to measure the outcomes and processes and determine the influences and repercussions of those actions. ¹³ But for this specific patient profile, there have been few published studies on patient care and hospital outcomes.

OBJECTIVES

The objectives of this study were to identify the main hospital outcomes of patients undergoing surgical correction of neuromuscular scoliosis and to assess the rate of complications and achievement of mobility goals after the implementation of a managed protocol.

METHODS

This is a retrospective longitudinal study approved by the institutional review board of the AACD, under opinion 3,353,032. Preliminary data were obtained six months after the implementation of a managed protocol for the surgical correction of neuromuscular scoliosis, by performing searches in the electronic medical records of Hospital AACD - Tasy® system and the Channel® institutional protocol management program. Data from 103 patients of both sexes, age indifferent, undergoing elective surgical correction of neuromuscular scoliosis, were included in the study. Data from patients who had already undergone other corrective spinal surgeries were excluded.

The data were separated into two groups: Group of patients operated on between June and December 2018 before the implementation of the managed protocol for this surgery and Group that underwent surgery between May and September 2019, when the protocol was already in place.

The following personal details were collected: age, sex, diagnosis, Cobb angle and comorbidities. The following variables were analyzed: duration of surgery, length of hospital stay in days, history of pain and complications; surgical site, respiratory infection, constipation, postoperative pain (moderate/intense), immobility and systemic inflammatory response syndrome (SIRS), according to the criteria of the Latin American Sepsis Institute - LASI. 14,15

The following personal details collected: age, sex, diagnosis, Cobb angle and comorbidities. The following variables were analyzed: duration of surgery, length of hospital stay in days, history of pain, complications and early mobility.

Important items covered in the institutional protocol were the multidisciplinary preoperative assessment, preemptive antibiotic therapy and vacuum-assisted wound closing in the postoperative period, in addition to monitoring with the rehabilitation team for postural adjustment, achievement of mobility goals and guidance at hospital discharge.

The mobility goals were defined as follows:

- Immediate postoperative period: bed mobility
- 1st postoperative day: Head of bed elevated to 60°
- 2nd postoperative day: Sitting in a chair or walking (for those able to walk)
- 3rd postoperative day: Assisted transfers or gait training and guidance at hospital discharge.

Statistical Analysis

Frequency (percentage), mean and standard deviation of the continuous variables were calculated for dichotomous and categorical data (95% confidence interval). A p-value \leq 0.05 was considered for statistical significance.

RESULTS

Of the 103 patients analyzed, 53.4% were female and 46.6% male, with a mean age of 14.9 years. The most frequent baseline diagnosis was cerebral palsy, followed by neuromuscular dystrophies. The most common prior comorbidities were pulmonary diseases (25%). The analyzed groups exhibited homogeneity in their characteristics as a sample, including variables related to duration

of surgery and length of hospital stay. The mean degree of scoliosis curvature was 75°, ranging from 50° to 122°, (Table 1)

Regarding adherence to the measures proposed by the protocol, we observed greater adherence to the performance of preoperative chest x-rays (98%) and control (92.4%), and less adherence to the use of the Prevena® dressing (30.1%) and pulmonary assessment by a pneumologist (20.7%). (Table 2)

Regarding complications, there was a statistically significant difference for SIRS with a reduction from 16.0% to 1.9% (p-value = 0.011), and for moderate/intense postoperative pain, there was a reduction from 42.0% to 22.6% (p-value = 0.035). (Table 3)

Regarding the prevention of immobility, daily mobility goals were adopted, which included early mobilization starting in the immediate PO period, with elevation of the head of the bed, sitting off the bed, and transfers/walking until the date of discharge, with training of caregivers and patients for transfers and guidance on home care. The graph below shows the mobility goals achieved in the pre- and post-protocol groups. It can be noted that all the mobility goals proposed by the team had greater adherence after the protocol, with a statistically significant difference in the iPO period (p=0.001), 1st PO day (p<0.001) and 3rd PO day (p<0.001). (Figure 1)

DISCUSSION

The clinical conditions of the profile of patients studied are factors that can influence surgical treatment outcomes⁴ due to the clinical complexity of these patients. Therefore, the pre- to postoperative role of the multidisciplinary team is a trend in health services, as the implementation of managed protocols, with a systemic view of various specialties, can result in fewer complications and better clinical and functional outcomes.¹¹

We observed a similarity in the characteristics of the pre- and post-protocol samples in terms of sex, age, Cobb angle and the most prevalent underlying pathology. This similarity may minimize the influence of variations in postoperative outcomes with respect to sample characteristics.

The similarity of the Cobb Angle in the pre- and post-protocol groups (74° and 75°) corroborates published findings on the need for surgical intervention in cases where there is a high degree of curvature. ^{16,17} Miladi et al., ¹⁸ report, in their study, that surgically treated neuromuscular scoliosis patients had a mean Cobb angle of 89°.

Table 2. Adherence to the main measures of the Protocol.

Managed protocol	No.	%
Chest x-ray on admission	52	98
Chest x-ray for control after 3 hours of surgery	49	92.4
Preoperative tests	44	83
Preoperative assessment: Physiotherapy	40	75.4
Preoperative assessment: pediatric/clinical	34	64.1
Prevena® dressing (Vacuum-assisted)	16	30.1
Preoperative assessment: Pulmonologist	11	20.7
Preoperative assessment: Speech therapy	20	37.7
Preoperative assessment: Nutrition	25	47.1

Table 3. Comparison of pre- and post-protocol outcomes.

	Pre		Post		P-value
	N (50)	%	N (53)	%	P-value
Surgical site infection	6	12.0%	2	3.8%	0.119
Respiratory infection	5	10.0%	4	7.5%	0.660
Constipation	26	52.0%	34	64.2%	0.211
SIRS	8	16.0%	1	1.9%	0.011
Moderate/severe postoperative pain	21	42.0%	12	22.6%	0.035
Patients with 1 or more complications	31	62.0%	37	69.8%	0.403
Immobility	1	2.0%	0	0.0%	0.301
Continue CIDS - Sustamia inflammatory response a undrama					

Caption: SIRS - Systemic inflammatory response syndrome

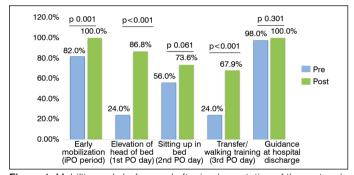


Figure 1. Mobility goals before and after implementation of the protocol.

Table 1. Characteristics of the sample.

		Distribution (%)		Mean and standard deviation (sd)	
		Pre- protocol	Post-protocol	Pre-protocol	Post-protocol
Sex	Female	22 (44%)	33 (62.2%)	-	-
	male	28 (56%)	20 (37.7%)	-	-
Age		-	-	13.9 (5.6)	16 (4.1)
Diagnosis	Cerebral Palsy	42	62.2	-	-
	NMD*	18	15	-	-
	MFC**	8	-	-	-
	Myelomeningocele	20	7.7	-	-
	other	12	15	-	-
Surgical variables	Duration of surgery (min)	-	-	240 (131)	300 (107)
	Length of hospital stay ICU (days)	-	-	2.6 (2.7)	2 (5.8)
	Total length of hospital stay (days)	=	-	10.8 (7.2)	8 (7.4)
Characteristics	Cobb Angle (degrees).			74(19.1)	75(21.8)
Comorbidities					
	pulmonary Disease	14	26.4%	-	-
	OSAS	6	11.3%	-	-
	Cardiac dysfunction	5	9.4%	-	-
	Malnutrition	3	5.6%	-	-
	Dysphagia	2	3.7%	-	=

Regarding the baseline diagnosis, cerebral palsy followed by myelomeningocele continued to be the most prevalent pathologies in the samples, as well as in the studies by Brooks et al., ¹¹ and Obid et al., ¹⁹ who confirm the fact that patients with cerebral palsy (Gross Motor Function Classification System levels IV and V) have a high risk of developing scoliosis, with a 95% chance of curve progression.

Due to the severity of these underlying diseases, and considering their comorbidities, the risks of surgery for the treatment of neuromuscular scoliosis are a reality, despite technological advances and the development of surgical techniques.²⁰ In the early postoperative period, the complications most frequently described in the literature are surgical site infections, complications in the cardiorespiratory and neurological systems, nutritional problems, constipation, excess fluid, skin lesions, bleeding, and death.^{21,22}

In this study, immobility, respiratory and surgical site infection, constipation, SIRS and moderate to severe pain were regarded as complications, despite having variable rates; the total rate of complications was 64.1%. In the study by Turturro et al., 4 complications were present in between 18% and 75% of cases, with respiratory complications representing 23.5% to 57% of cases.

The literature presents very heterogeneous findings when it comes to the criteria used to define complications inherent to surgery and the classification of these complications in terms of severity. This makes it difficult to compare data between studies. 4,20,21

In a systematic review carried out in 2017, including 51 studies that evaluated the main PO outcomes of scoliosis correction, 45 of the studies investigated reported postoperative complications, and despite the shortage of data and the inconsistency in its presentation, the main complications were related to the neurological and respiratory systems.²²

The implementation of a managed protocol for the sample profile proved to be effective in minimizing risks, as there was a statistically significant decrease in the rate of systemic inflammatory response syndrome - SIRS cases (p=0.011) and pain (p=0.035).

A recent study evaluated the outcomes of 29,000 patients between 2004 and 2015 who presented with complications in 6.3% of cases in the immediate postoperative period (with special emphasis on superficial/deep infection and infection related to the implant), and although surgical site infection did not show a statistically significant reduction in this study, the decrease in more than 50% of cases of infection, with a rate of 3.8%, appears to be a clinically relevant finding, considering that the data are preliminary, and based on the findings in the literature, in which surgical site infection can vary between 5% to 20% of patients. It is also known that infections increase the risk of morbidity and mortality, with a consequent increase in medical and hospital expenses. As a consequence, reductions in infection rates reflect not only the patient's survival, but also the financial aspect of the institution.

As regards pain control, it is known that optimizing analgesia in combination with the use of opioids can result in constipation, and that this is the side effect most commonly associated with chronic opioid use. Meanwhile, studies report that constipation can occur in between 40% and 90% of patients treated after just a single dose of opioid. 26 Although expected, a significant increase in the rate of constipation (p = 0.211) was not observed after adjusting the post-protocol pain management.

Adequate pain management is always a challenge for the health professional teams, and the reduction of pain following neuromuscular scoliosis surgery, after implementing the protocol (p=0.035) was an important outcome for the service, as it is rather challenging to adequately assess and manage pain, especially in patients with communication difficulties, and as is often the case with patients with cerebral palsy.²¹

In addition to the reduction of postoperative complications after the protocol, there was an average 2-day decrease in the length of hospital stay, which is reflected in decreased hospital costs and patient exposure to infections. According to a study conducted by Samdani et al.,²⁷ a postoperative complication rate of 39% was observed in a sample group of 127 patients with cerebral palsy, and the presence of complications was directly proportional to the increase in the length of hospital stay.

Another fact that impacts the length of hospital stay, and consequently, hospital outcomes is immobility. Therefore, defining and managing mobility goals is essential for monitoring results and their impacts on hospital outcomes. In this study, greater achievement of postoperative mobility goals was observed after the protocol, with an emphasis on early mobilization (p=0.001), elevation of the head of the bed to 60° on the 1^{st} PO day (p<0.005), and transfer/walking training on the 3^{rd} PO day (p<0.001).

Protocols in general are designed to standardize the multidisciplinary care provided to patients in certain areas of healthcare. In this specific case, consisting of patients undergoing surgical correction of neuromuscular scoliosis, the managed protocol aims to recognize and minimize postsurgical risks and complications, ²⁰ as well as enabling the mapping of weak points of the process, constant adjustments and corrections of the adverse effects of any actions implemented.

We noted that even without full adherence to the main measures of the managed protocol for correction of neuromuscular scoliosis six months after implementation, the reduction in the number of complications and improvement in patient mobility were impacted by the use of the protocol in the short term. This suggests that managed data should be continuously tracked, and may present even better rates in the long run.

The studies in the literature are heterogenous in regard to the profiles studied, risks, types of complication, and severity classification of complications. The topic needs to be studied in more depth, with managed outcomes for subsequent comparison of data and groups stratified by underlying pathology.

CONCLUSION

The implementation of a multidisciplinary managed protocol focused on postoperative care for patients undergoing neuromuscular scoliosis correction was able to reduce SIRS complications and pain, keeping the rate of surgical site infections low and preventing short-term immobility.

All authors declare no potential conflict of interest related to this article.

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