CERVICAL DISC PROSTHESIS: 2-YEAR FOLLOW-UP

PRÓTESE DE DISCO CERVICAL: 2 ANOS DE SEGUIMENTO

PRÓTESIS DE DISCO CERVICAL: 2 AÑOS DE SEGUIMIENTO

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ABSTRACT

Objective: To review the medical records of patients who underwent surgery for placement of cervical disc prosthesis after two years of postoperative follow-up, showing the basic epidemiological data, the technical aspects and the incidence of complications. Methods: Medical records of seven patients who underwent surgery for placement of cervical disc prosthesis were reviewed after two years of follow-up, at the Institute of Orthopedics and Traumatology, Faculty of Medicine, University of São Paulo. Results: The average age of patients participating in this study was 43.86 years. Six patients (85.7%) had one level approached while one patient (14.3%) had two levels addressed. The level C5-C6 has been approached in one patient (14.3%) while the C6-C7 level was addressed in five patients (71.4%). One patient (14.3%) had these two levels being addressed, C5-C6 and C6-C7. The mean operative time was 164.29±40 minutes. Three patients were hospitalized for 2 days and four for 3 days making an average of 2.57±0.535 days. Two patients (28.6%) underwent a new surgical intervention due to loosening of the prosthesis. The mean follow-up was 28.14±5.178 months (23-35 months). Conclusions: Although cervical arthroplasty appears to be a safe procedure and present promising results in our study as well as in many other studies, it requires long-term studies.

Keywords: Intervertebral disc degeneration; Arthroplasty; Joint prosthesis; Spine.

RESUMO

Objetivo: Revisar os prontuários de pacientes que foram submetidos à cirurgia para colocação de prótese de disco cervical, após dois anos de seguimento pós-operatório, evidenciando os dados epidemiológicos básicos, os aspectos da técnica e a incidência de complicações. Método: Foram revisados os prontuários de sete pacientes submetidos à cirurgia para colocação de prótese de disco cervical após dois anos de seguimento no Instituto de Ortopedia e Traumatologia da Faculdade de Medicina da Universidade de São Paulo. Resultado: A média de idade dos pacientes participantes no presente estudo foi 43,86 anos. Seis pacientes (85,7%) tiveram um nível abordado enquanto um paciente (14,3%) teve dois níveis abordados. O nível C5-C6 foi abordado isoladamente em um paciente (14,3%) enquanto o nível C6-C7 em cinco pacientes (71,4%). Um paciente (14,3%) teve dois níveis abordados sendo estes C5-C6 e C6-C7. A média de tempo cirúrgico foi de 164,29 ± 40 minutos. Três pacientes ficaram internados por 2 dias e quatro por 3 dias, perfazendo uma média de 2,57 ± 0,535 dias. Dois pacientes (28,6%) foram submetidos a reintervenção cirúrgica devido à soltura da prótese. O acompanhamento médio foi de 28,14 ± 5,178 meses (23-35 meses). Conclusões: A artroplastia cervical, apesar de parecer ser um procedimento seguro e apresentar resultados promissores em nosso estudo, bem como em diversos estudos da literatura, necessita de estudos a longo prazo.

Descritores: Degeneração de disco intervertebral; Artroplastia; Prótese articular; Coluna vertebral.

RESUMEN

Objetivo: Revisar las historias clínicas de los pacientes que se sometieron a cirugía para colocación de prótesis de disco cervical después de dos años de seguimiento postoperatorio, que muestran los datos epidemiológicos básicos, los aspectos técnicos y la incidencia de complicaciones. Métodos: Fueron revisados los registros médicos de siete pacientes que se sometieron a cirugía para colocación de prótesis de disco cervical después de dos años de seguimiento en el Instituto de Ortopedia y Traumatología de la Facultad de Medicina de la Universidad de São Paulo. Resultados: La edad media de los pacientes que participaron en este estudio fue de 43,86 años. Seis pacientes (85,7%) tuvieron un nivel a ser abordado mientras que un paciente (14,3%) tuvo dos niveles abordados. El nivel C5-C6 ha sido tratado por separado en un paciente (14,3%), mientras que el nivel de C6-C7 fue tratado en cinco pacientes (71,4%). Un paciente (14,3%) tuvo dos niveles abordados, C5-C6 y C6-C7. El tiempo quirúrgico promedio fue de 164,29 ± 40 minutos. Tres pacientes fueron hospitalizados por 2 días y cuatro por 3 días, lo que hace una media de 2,57 ± 0,535 días. Dos pacientes (28,6%) fueron sometidos a una nueva intervención quirúrgica debido al aflojamiento de la prótesis. El promedio de seguimiento fue de 28,14 ± 5,178 meses (23-35 meses). Conclusiones: Aunque la artroplastia cervical parezca un ser procedimiento seguro y que presente resultados prometedores en nuestro estudio, así como en muchos otros estudios, necesita estudios a largo plazo.

Descriptores: Degeneración del disco intervertebral; Artroplastia; Prótesis articulares; Columna vertebral.

INTRODUCTION

The primary cause of chronic neck pain is degeneration of cervical intervertebral discs due to aging.[1] Disc degeneration may result in rupture or herniation, spinal instability, facet joint syndrome, or radiculopathy affecting the upper ends, due to compression of spinal nerves.[2,3] The resulting pain can lead to significant disability.[1] Existing treatments for cervical disc degeneration include surgery or conservative methods such as rest, heat, electrotherapy, physiotherapy and analgesics.[3] Currently there are two main surgical techniques for the treatment of disc degeneration: the removal of the disc (discectomy or nucleotomy) i.e., removal of the nucleus, anterior and posterior components, and ring, followed by spinal fusion, which consists of grafting bone between the adjacent vertebrae to the degenerated disc to remove the damaged segment of the joint, which is typically performed for treating degeneration associated with instability and reduce inter-vertebral space.[2,4] Frontal cervical plate or rigid internal

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fixation may also be used to promote fusion.[4] However, there is significant evidence confirming that biomechanical stress increases between the discs above and below the fusion, resulting in symptomatic degenerative disc disease in the adjacent levels.[4-10]

Discectomy involves excision of part or the whole degenerated disc and it is typically performed in root syndrome treatment, in cases of disc herniation. Half of surgical discectomy procedures involve removal of disc material that is invading the spinal nerve.[1] Although discectomy often eases symptoms by removing the compression of spinal nerves, it does not treat degeneration of the nucleus pulposus, nor restores the integrity of the damaged disc. Therefore, although the discectomy alone can succeed in alleviating the symptoms of disc degeneration, natural mobility is reduced as a result thereof. Although complications are relatively rare, they include infection, dural injury, nerve injury, and segmental instability (which may require reoperation).[1]

Spinal fusion effectively eliminates motion segment between two vertebrae through bone graft or similar material, thereby providing improved stability, and pain reduction.[1,7] However, the spinal fusion success rate proved to be highly variable.[9] Therefore, in recent years, spinal fusion has been completed by various fixing methods to increase the fusion rate. Interbody fusion cages can yield high fusion rates, but internal fixation increases the rigidity of the welded area, resulting in additional strain on the adjacent non-welded segments.[9] Fixation methods have also included both dorsal and frontal plates, which are intended to increase the fusion rate and provide stability until the fusion occurs.[4,7-9] Although these devices may facilitate fusion, there is a growing concern about the disease of adjacent levels after the well succeeded fusion.[6-9] Moreover, complications with plate devices reported in the literature describe migrating or breaking pins or its housing into the esofagus.[9]

Patients whose charts were reviewed in this study were treated with a cervical disc prosthesis brand Porous Coated Motion (PCM-VTM) (Implamed, USA), designed to provide a new modality of treatment as an alternative to fusion with or without internal fixation. The device is a modular system designed to stabilize the spine after discectomy without fusion, thus preserving the flexibility of the operated level(s) of the cervical spine.[2,4] It is indicated for use in the treatment of disc degenerative disease in one or two levels of the cervical spine (C3-C4 to C6-C7), in patients with skeletal maturity with associated radicular pain aiming to provide an additional therapeutic option to maintain the position of the drive segment and the spacing while preserving the flexibility of the adjacent cervical vertebral levels.

The objective of this paper is to review the medical records of patients who underwent surgery for placement of cervical disc prosthesis, after two years of postoperative follow-up, showing the basic epidemiological data (gender and age), aspects of the surgical technique (surgical time, volume of intraoperative bleeding and length of hospital stay), as well as the incidence of complications or reoperation estimating, therefore, the safety of the procedure.

METHODS

This is a retrospective cross-sectional study in which records of seven patients undergoing surgery for placement of cervical disc prosthesis after two years of follow-up were reviewed. The study was conducted at the Institute of Orthopedics and Traumatology, *Faculdade de Medicina da Universidade de São Paulo*, an institution linked to the Unified Health System (SUS) which conducts medium and high complexity medical activities, becoming a reference in teaching, research and medical assistance. Data were statistically analyzed and as it is a descriptive work, the intention was to build tables and graphs on absolute and relative values (percentages) for comparison with the data from the literature.

This study was approved by the Research Ethics Committee of the Institution and follows specific resolution of the National Health Council (Nº 466/2012) under protocol Nº 030/06.

RESULTS

The mean age of patients participating in this study was 43.86 years old (minimum 32, maximum 55) with a standard deviation of 9.082 years old. Regarding the levels operated, six patients (85.7%) had one level operated while one patient (14.3%) had two levels operated. C5-C6 level has been operated in one patient alone (14.3%), while the C6-C7 level in five patients (71.4%). One patient (14.3%) had two levels operated, C5-C6 and C6-C7. (Figure 1) Regarding surgical time, the average value was 164.29 ± 40 minutes (minimum 75 and maximum 190 minutes). Regarding hospitalization days, three patients were hospitalized for two days and four for three days, 2.57 ± 0.535 days on average. Two patients (28.6%) underwent reoperation, one of them seven months after surgery for placement of the prosthesis and the other after nine months, resulting 8 ± 1.414 months on average, both due to loosening of the prosthesis. No heterotopic ossification was seen in the cases studied. The average follow-up tome was 28.14 ± 5.178 months (23-35 months) (Table 1).

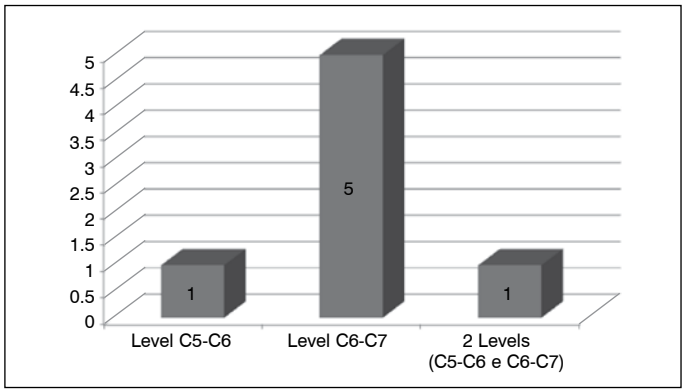

Figure 1. Number of patients distributed by neurological levels operated.

Table 1. Epidemiological and surgical data of cases.

P	A	G	Levels operated	Surgical time	Days in hospital	S	Reoperation
1	32	M	C6-C7	165	3	Loosening	9 months
2	47	M	C6-C7	180	3	-	-
3	38	F	C6-C7	180	3	-	-
4	46	F	C6-C7	75	2	-	-
5	55	M	C5-C6 C6-C7	180	2	-	-
6	35	F	C6-C7	190	2	Loosening	7 months
7	54	F	C5-C6	180	3	-	-

P= Patient; A=Age (years old); G=Gender; S= Surgical complications.

DISCUSSION

The current standard treatment for cervical myelopathy is anterior discectomy followed by arthrodesis. Since its introduction in the 50s, studies have shown excellent pain relief rates and a significant rate of fusion.[11-15] The advent of cervical plates further improved fusion rates, especially in cases of operation of multiple levels.[16-18] Although presenting good results in the short term, the literature has shown degeneration of adjacent levels due to segmental stiffness achieved with arthrodesis. Matsunaga *et al*.[19] analyzed the strength distribution on the intervertebral discs after cervical arthrodesis and confirmed an increase in immediately adjacent levels.

Data from long-term studies (5-10 years) suggest that in patients undergoing discectomy and anterior arthrodesis significant radiographic changes in adjacent levels such as joint narrowing or development of new osteophytes translated clinically as emergence of a new radiculopathy or myelopathy arising from this new impaired level.[20] A retrospective study showed that ossification of the

anterior longitudinal ligament occur in 59% of cephalic interdiscal space ad and 29% of caudal space ($p < 0.001$).[21] Goffin *et al*.[22] have shown in a follow-up of at least 60 months a ratio 6.11% of surgical re-intervention due to adjacent symptomatic degeneration. Seok *et al*.[23] demonstrated in a comparative study of patients undergoing cervical arthroplasty and decompression followed by arthrodesis a higher average motion and height of the intervertebral space in the group submitted to cervical disc prosthesis placement, while radiographic changes were 3.5 times more frequent in the discectomy and arthrodesis group. Also in this study, the authors reported a higher rate of degenerative alterations of neighboring levels (about twice) comparing two levels operated (both in arthrodesis surgery as in arthroplasty) in relation to only one level.[24]

In this context, the cervical disc prosthesis arises, where the preservation of some degree of motion in the affected joint has the advantage to lead to less stress on neighboring joints.[24-31] Recovery of cervical kinematic is partial, in relation to physiological, but this recovery seems to prove superiority over the discectomy and arthrodesis with regard to adjacent joint wear.[32] Nabhan *et al*.[33] used a radiostereometric analysis to quantify the intervertebral mobility and concluded that there is a significant difference between the group that underwent arthrodesis and the group submitted to arthroplasty after 3-24 weeks. In another study, the average mobility post- one level arthroplasty after 24 months was 7,95° (preoperative value was 6.43°) while the average mobility in arthrodesis is 1.11° and 0.87° in three and 24 months postoperative, respectively.[34] In the literature good results can be found, such as that reported by Goffin *et al*.[34] (90% good results with cervical disc prosthesis implants in one level and 88% and 86% of the cervical motion preservation in patients treated with one level and two levels arthroplasty, respectively, after one year).

Cheng *et al*.[25] reported few complications for this method over conventional discectomy followed by arthrodesis in a follow-up of 83 patients over three years, concluding that this method is safe and effective. Comparing these two methods, Zang *et al*.[35] described a surgery time in patients undergoing cervical arthroplasty, but their conclusion was that it is a feasible procedure as an alternative to conventional anterior decompression.

The mean age of 40.86 ± 9.082 years old presents similar data in the literature.[23,36]

CONCLUSION

Despite the good results, long-term studies are needed. Cervical arthroplasty appears to be a safe procedure and shows promising results in our study, as in many studies in the literature. However, this method is relatively new, and more studies, especially those with long term follow up are needed to confirm its effectiveness in preventing degenerative disease of the adjacent disc.

All authors declare no potential conflict of interest concerning this article.

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