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Functional and quality of life evaluation after single level cervical discectomy and fusion or cervical artificial disc replacement

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ABSTRACT. Purpose: to evaluate and compare clinical, functional and quality of life (QOL) outcomes after two types of surgical approach for single level cervical disc herniation: anterior cervical discectomy and fusion (ACDF) with cage and cervical artificial disc replacement (C-ADR).
Method: 119 patients with cervical disc herniation underwent surgery from January 2007 to December 2010; 55 patients were included in the study (27 ACDF, 28 C-ADR). We performed: a pre and postoperative clinical evaluation of cervicobrachial pain, motor and sensory deficit in the upper limbs; a functional and QOL evaluation with self assessment scales (VAS, NPNQ, SF-36); a postoperative instrumental evaluation of cervical ROM and pain. Mean follow-up period was 24 months.
Results: After surgery both groups showed clinical, functional and QOL improvement. No pre and postoperative differences were found between the groups. The postoperative instrumental evaluation showed a globally reduced cervical ROM and a decreased pain threshold in comparison with normal values in both groups.
Conclusion: Our results demonstrate the clinical equivalence of the two surgical techniques and the satisfaction of the two groups of patients two years after surgery. Although functional changes persist after surgery they do not affect quality of life.

Key words: ACDF, cervical artificial disc replacement, cervical prosthesis, QOL, cervical ROM, inclinometer, cervical pain, algometer, functional evaluation.

RIASSUNTO. L'incidenza annuale dell'ernia del disco cervicale è di 18.6/100.000. Se il trattamento conservativo non porta ad una risoluzione o se vi è un peggioramento della sintomatologia è indicato il trattamento chirurgico. Da anni viene impiegata la discectomia per via anteriore seguita da artrodesi intersomatica. Conseguenza dell'artrodesi è però un sovraccarico funzionale dei due dischi intervertebrali adiacenti. Allo scopo di limitare l'insorgenza di questa complicanza è stata introdotta l'artroplastica discale. Scopo del presente studio è un confronto clinico, funzionale con scale di autovalutazione e di QOL pre e post-operatorio in pazienti sottoposti ad intervento chirurgico di artrodesi (ACDF) e artroprotesi discale cervicale (C-ADR) ed una valutazione strumentale al follow-up. 119 pazienti sottoposti ad intervento chirurgico per ernia cervicale tra gennaio 2007 e dicembre 2010. 55 pazienti inclusi nello studio (27 ACDF, 28 C-ADR), sono stati sottoposti a valutazione clinica pre e post operatoria del dolore cervicobrachiale e del deficit motorio o sensitivo agli arti superiori; a valutazione funzionale e di qualità di vita (QOL) pre e post operatoria con scale di autovalutazione (VAS, NPNQ, SF-36); a valutazione strumentale post-operatoria (follow-up medio di 24 mesi) del ROM cervicale con inclinometro e del dolore cervicale con algometro.

Introduction

The annual incidence of disc prolapse resulting in cervical radiculopathy is 18.6 per 100000. C7 root is involved in 46% of cases followed by C6 (17%) and a combination of C5-C6 (10%) (1). Disc herniation can lead to radiculopathy with neck and arm pain and in severe cases to myelopathy with sensory and motor deficits. Surgery is indicated if conservative treatment does not solve the disease within two to three months (2, 3) or if there is a worsening in symptoms.

The standard approach is the Anterior Cervical Discectomy and Fusion (ACDF) (4, 5). A bone graft taken from the iliac wing of the same patient was historically used for fusion (6, 7). Autologous grafts were then followed by alloplastic grafts and cages in order to avoid problems associated with the iliac bone harvesting (8, 9).

However a functional overload of the two adjacent intervertebral discs seems to be consequence of ACDF ("adjacent segment degeneration and disease") (10, 11).

Cervical artificial disc replacement (C-ADR) has been introduced in order to avoid this complication. In vitro biomechanical studies (12) and in vivo clinical studies (13, 14) demonstrate the effectiveness of the prosthesis in preserving movement at the treated level.

Cervical prosthesis with two or three components are available (15). They can be classified (16) according to their degrees of freedom in:

- Constrained or Semiconstrained (eg. ProDisc-C): they include a mechanical stop respectively within the physiological range of motion and outside the normal range of motion. They generally exhibit greater stability, their fixed center of rotation minimize shear forces on the facet joints. The antero-posterior and lateral translatory movements are prevented, while rotational movements are permitted. These devices place greater stress on the implant-bone interfaces and are technically less forgiving, requiring more precise placement to effectively reproduce the natural axis of rotation of the cervical spine.
- Unconstrained (eg. Bryan, Prestige ST): they have no mechanical stop. Because of their variable center of rotation they allow some degree of translation. There is decreased stress concentration at specific points on the

Dopo intervento chirurgico entrambi i gruppi di studio mostrano un miglioramento clinico, funzionale e di QOL ($p < 0.05$) senza differenze significative pre o post operatorie per ogni parametro valutato. La valutazione strumentale post-operatoria mostra in entrambi i gruppi un ROM cervicale globalmente ridotto e una ridotta soglia di insorgenza di dolore rispetto a valori di normalità, senza differenze tra i gruppi. A due anni dall'intervento i risultati dimostrano l'equivalenza clinica delle due tecniche chirurgiche e la sostanziale soddisfazione dei due gruppi di pazienti. Anche se dopo l'intervento persistono alterazioni funzionali rispetto alla popolazione normale esse sono tali da non inficiare la qualità di vita dei pazienti.

Parole chiave: artrodesi cervicale, protesi discale cervicale, qualità di vita, artrodesi cervicale, inclinometro, dolore cervicale, algometro, valutazione funzionale.

articulating surface and they appear to be more forgiving in terms of their placement. However this lack of constraint provides less stability to the motion segment and exposes the adjacent facet joints to greater shear and torsional stress.

Preserving long-term mobility, cervical prosthesis should prevent (or slow down) the degeneration of adjacent segments.

Different opinions are reported regarding the vantage of C-ADR versus ACDF (17-20).

Furthermore, some authors suggest that adjacent segments degeneration is both due to spinal fusion and to the natural history of the degenerative disc disease (21-23).

The aim of the study was to perform a pre and post-operative clinical, functional and QOL comparison in patients undergoing ACDF or C-ADR. We also performed a post-operative instrumental evaluation of cervical ROM and pain in the two study groups. The mean follow-up time was 24 months.

Materials and methods

Between January 2007 and December 2010, 119 patients with single level cervical disc herniation underwent surgery at the Neurosurgery Unit of the San Matteo Research and Care Foundation, Pavia. They were treated with ACDF with PEEK cage and bone replacement or C-ADR with Prestige ST (Medtronic), Bryan (Medtronic) or Prodisc-C (Synthes) prosthesis. The following criteria were adopted:

- age between 18 and 60 years;
 - presence of an herniated cervical disc at a single level in C4-C5 or C5-C6 or C6-C7, surgically treated;
 - complete pre and post-operative evaluation at the Rehabilitation Unit of the San Matteo Research and Care Foundation, Pavia;
 - no previous surgery at the cervical spine.
- Thus were excluded from the study:
- 18 patients over the age of 60 years for the presence of multiple cervical disk disease;
 - 46 patients lost at follow up: patients came from different regions and some of them could not return to our center for follow up evaluation.

Therefore 55 subjects were included (16 M), mean age 41 years (27-54), 27 underwent ACDF and 28 underwent C-ADR.

We performed:

- pre and post operative clinical evaluation of symptoms: cervicobrachial pain and upper limbs motor and sensory deficit. Each symptom was categorized as: continuous, occasional, absent;
- pre and post operative functional evaluation with the following self-assessment scales:
 - Visual Analogue Scale (VAS) for cervicobrachial pain (24);
 - Northwick Park Neck Pain Questionnaire for neck pain (25);
- pre and post operative QOL evaluation with the Italian Version of the Short Form 36 Health Survey (SF-36) (26-28);
- post-operative instrumental evaluation with Tracker Freedom® Wireless (JTech Medical) and Tracker™ Software Version 5 of:
 - cervical ROM with Dual Inclinometer: it allows reliable range of motion testing of the spine. Dual inclinometry protocols outlined in all editions of the AMA Guides and the Tracker Multimedia Help system for testing protocols were followed. Each patient performed cervical movements of maximum flexion, extension, left and right lateral flexion and left and right rotation.
 - Pain Threshold with Algometer: it provides objective pain and pressure documentation. The unit of measure used was Kg/cm². Three specific bilateral trigger points were investigated: insertion of the suboccipital muscles, upper trapezius and levator scapulae. The examiner developed a growing pressure of 1 Kg/cm²/sec (29-31). The software provides a visual feedback to help the examiner to apply a correct rate of pressure. When the patient began to feel pain (pain threshold) the evaluation was interrupted.

Normal data for the instrumental evaluation came from our sample of 54 healthy subjects (22 M), mean age 32.3 years (22-46).

At follow-up physicians were not aware of the type of surgery performed, so evaluations were blinded to the surgery.

Patients underwent a non standardized post-operative rehabilitation protocol in different centers, so we did not report rehabilitative treatments because of their non-homogeneity.

All procedures conformed to the standards established by the Declaration of Helsinki and all patients gave their written informed consent to participate to the research study.

Statistical analysis

Quantitative data (VAS, NPNQ, ROM, pressure threshold, SF-36) are presented as median and interquartile range (IQR) if not normally distributed. Otherwise means and standard deviations were presented.

Analysis of the differences between the two study groups was performed with parametric (t-test for indepen-

dent or paired data in case of pre-post comparisons) or nonparametric tests (U test Man - Whitney or Wilcoxon test in case of pre-post comparisons).

Qualitative variables (cervicobrachial pain, motor deficit and sensory deficit in the upper limbs) were described as counts and percentages, differences between groups were assessed with the chi square test or Fisher's exact test in case of expected lower than 5. Cervical ROM and pain were compared with normal data from our sample of healthy subjects with Anova. All were two-tailed tests and the limit of significance chosen was the usual 5% ($p < 0.05$). Analyses were carried out with STATA software Stata 12.0 (StataCorp 2012, College Station, Texas).

Results

Population

28 patients underwent C-ADR: 7 males (25%), mean age 41 years (29-52). 27 patients underwent ACDF: 9 males (33.3%), mean age 41 years (27-54).

The two groups were homogeneous for gender ($p = 0.7015$) and mean age ($p = 0.7671$).

Clinical evaluation

Table I shows the comparison of pre-and post-operative symptoms and the comparison of symptoms between the two groups.

Before surgery no differences in symptomatology were found between the study groups, therefore the two groups were comparable.

After surgery symptoms improved in both groups with reduction of cervicobrachial pain, motor deficit and sensory deficit in the upper limbs. No significant differences were found between the groups.

Functional evaluation

Table II shows the comparison of pre-and post-operative VAS and NPNQ and the comparison of these values between the two groups. After surgery both groups of patients reported improvement for all self-assessments. However the two types of intervention showed no differences.

Table I. Symptomatology: number (and percentage) of patients. Horizontally: C-ADR vs ACDF comparison. Vertically: BEFORE vs AFTER surgery comparison

		CERVICOBRACHIAL PAIN			MOTOR DEFICIT			SENSORY DEFICIT		
		C-ADR	ACDF	CADR VS ACDF	C-ADR	ACDF	CADR VS ACDF	C-ADR	ACDF	CADR VS ACDF
BEFORE SURGERY	continuous	27 (96,4%)	26 (96,3%)	$p=0,97$	21 (75%)	22 (81,5%)	$p=0,561$	18 (64,4%)	16 (59,3%)	$p=0,801$
	occasional	1 (3,6%)	1 (3,7%)		0	0		5 (17,8%)	7 (25,9%)	
	absent	0	0		7 (25%)	5 (18,5%)		5 (17,8%)	4 (14,8%)	
AFTER SURGERY	continuous	4 (14,4%)	3 (11,2%)	$p=0,98$	9 (32,1%)	9 (33,3%)	$p=0,98$	5 (17,8%)	5 (18,5%)	$p=0,263$
	occasional	15 (53,5%)	14 (51,8%)		2 (7,1%)	1 (3,7%)		6 (21,4%)	11 (40,75%)	
	absent	9 (32,1%)	10 (37%)		17 (60,8%)	17 (63%)		17 (60,8%)	11 (40,75%)	
BEFORE VS AFTER		$p < 0,0001$	$p < 0,0001$		$p = 0,0042$	$p = 0,0015$		$p = 0,0009$	$p = 0,007$	

Table II. Functional evaluation: median values (and IQR). Horizontally: C-ADR vs ACDF comparison. Vertically: BEFORE vs AFTER surgery comparison.

		VAS (range 0 - 10) for cervicobrachial pain			NPNQ (range 0 - 100%) for neck pain		
		C-ADR	ACDF	C-ADR vs ACDF	C-ADR	ACDF	C-ADR vs ACDF
BEFORE SURGERY		10 (8 - 10)	10 (8 - 10)	$p = 0,8744$	65.2 (48.6 - 80.5)	66.6 (30.5 - 69.4)	$p = 0,1188$
AFTER SURGERY		2 (0,75 - 5,5)	3 (1 - 5)	$p = 0,9121$	23.6 (9.7 - 45.8)	11.1 (5.5 - 33.3)	$p = 0,3842$
BEFORE vs AFTER		$p < 0,00001$	$p < 0,00001$		$p < 0,00001$	$p = 0,002$	

Instrumental Evaluation

Table III shows the comparison of:

- cervical ROM measured with inclinometer, expressed in degrees: flexion, extension, rotation and inclination;
- pain threshold measured with algometer, expressed in Kg/cm²: corresponding to the minimum pressure which induces pain in trigger points in the occiput, trapezius muscle and elevator of the scapula.

After surgery, for each parameter there were no differences between C-ADR and ACDF patients.

Patients have globally reduced ROM and decreased pain threshold in comparison with normal values (normative data from our laboratory).

QOL Evaluation

After surgery the SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores improved significantly in both groups.

The median post-operative improvement in PCS was 9 (0.9 - 18.2) for C-ADR and 2.3 (0.9 - 15.7) for ACDF. The mean improvement in MCS was 9.1 ± 11.3 for C-ADR and 11.5 ± 13 for ACDF. There was no difference between the two groups in PCS ($p=0.178$) and MCS ($p=0.478$) improvement.

Discussion

The study showed a clinical, functional and QOL improvement in patients undergoing C-ADR and ACDF for cervical disc herniation with reduction of neck and cervicobrachial pain and neurological deficits. However there were no differences between the two groups.

The majority of the data in literature reports an overall improvement of symptoms and quality of life in patients undergoing surgery for herniated cervical disc (32-35).

In addition, our work reports clinical data of ROM and Pain Threshold of the cervical spine compared between the two surgical approaches and compared to healthy subjects.

At present there is no consensus on the vantage of ACDF vs C-ADR (17-20, 34, 35).

Rollinghof et al (34) reported a significant improvement of clinical symptoms and quality of life in 42 patients with radiculopathy treated with ACDF with cage (23 patients) or cervical arthroplasty (19 patients) with no differences between the two groups. Using dynamic lateral radiographs for the evaluation of segmental ROM these authors found that segmental ROM in the treated level is reduced in ACDF while it is preserved in C-ADR patients.

In a systematic review Zechmeister et al (35) confirmed a global clinical and quality of life improvement in all patients two years after surgery for herniated cervical disc with no difference between arthroplasty and arthrodesis.

Mummaneni et al (17) in a systematic review reported data from two studies of the Food and Drug Administration with long-term follow-up (> 48 months): patients undergoing C-ADR show a higher overall success rate, clinical improvement in cervicobrachial pain and quality of life than patients undergoing ACDF. In addition, the radiographic evaluation shows that the segmental ROM in the treated level is preserved in arthroplasty compared to arthrodesis.

Table III. Instrumental evaluation: mean values \pm SD. C-ADR vs ACDF comparison

ROM - degrees	C-ADR °	ACDF *	C-ADR vs ACDF	NORM	SURGERY vs NORM
Flexion	36.4 \pm 8.2	36.6 \pm 12.6	$p = 0.96$	66 \pm 12.6	** $p < 0.001$
Extension	34.3 \pm 12.9	34.6 \pm 14.9	$p = 0.98$	62 \pm 13	** $p < 0.001$
Right Rotation	63.5 \pm 18.5	64.4 \pm 21.2	$p = 0.98$	86.5 \pm 9.3	** $p < 0.001$
Left Rotation	64.6 \pm 15.1	61.6 \pm 20.3	$p = 0.97$	85.1 \pm 10.2	** $p < 0.001$
Right Lateral Flexion	26.5 \pm 10	25.3 \pm 10.3	$p = 0.95$	45.9 \pm 13.1	** $p < 0.001$
Left Lateral Flexion	33.8 \pm 10	32.1 \pm 12.2	$p = 0.99$	42.6 \pm 12.9	° $p = 0.007$ * $p = 0.001$
PAIN THRESHOLD - Kg/cm ²	C-ADR °	ACDF *	C-ADR vs ACDF	NORM	SURGERY vs NORM
Right Occiput	2.8 \pm 1.5	3.1 \pm 1.6	$p = 0.99$	6.3 \pm 2.2	** $p < 0.001$
Left Occiput	2.7 \pm 1.4	3.2 \pm 2	$p = 0.98$	6.6 \pm 2.3	** $p < 0.001$
Right Trapezius	3.3 \pm 2.1	3.8 \pm 2.9	$p = 0.99$	7 \pm 2.4	** $p < 0.001$
Left Trapezius	3.3 \pm 2.5	3.7 \pm 2.3	$p = 0.96$	7.2 \pm 2.7	** $p < 0.001$
Right Levator Scapulae	5.2 \pm 3.5	5.3 \pm 3.4	$p = 0.97$	9 \pm 3.8	** $p < 0.001$
Left Levator Scapulae	4.9 \pm 3.2	5.4 \pm 3.1	$p = 0.98$	9.2 \pm 3.8	** $p < 0.001$

° = C-ADR vs normal data (NORM) comparison;

* = ACDF vs normal data (NORM) comparison.

We do not present segmental radiographic data but overall ROM values of the cervical spine obtained with an electronic goniometer. This allows a standard assessment of ROM.

After surgery all patients have a reduction of cervical ROM compared to normal values, with no difference between arthroplasty and arthrodesis.

A two years follow-up is too short to highlight degeneration of adjacent segments (36) to the treated level. However this period is adequate to demonstrate that patients with joint arthroplasty do not obtain a greater articular recovery.

This reduction in cervical ROM in all patients can be due to residual pain. In fact after surgery about 50% of patients complain of occasional pain with a median VAS score of 2 for C-ADR and 3 for ACDF. Remarkably some patients reported a VAS >3. Besides local pain evaluation with algometry shows that pain threshold is significantly lower in all patients compared to normal values. This can be due to the relative atrophy of trapezius and paracervical muscles or to the presence of trigger points and muscular contracture. Again, however, there are no significant differences between the two types of surgery.

After surgery QOL evaluation showed an improvement both in the Physical and Mental Component Summary of the SF-36, with no differences between the two groups.

Our results demonstrate the clinical equivalence of the two surgical techniques and the substantial satisfaction of the two groups of patients. Although functional changes persist two years after surgery they do not affect quality of life. Residual pain can benefit of a specific rehabilitation program.

A limit of the study is the follow-up time of 24 months, this can be considered a short-term assessment. A longer follow up period is needed to assess long-term clinical and functional improvement and to evaluate any post-operative degenerative change at both the treated segment and the adjacent vertebral segments.

Furthermore, rehabilitative aspects were not evaluated for patients came from different regions and did not perform a standardized post-operative treatment at our institution.

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