Artificial Cervical Disc Replacement;"A Double Edged Sword" A Clinical Review

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ABSTRACT

Introduction: The era of ACDR began in Europe in the late 1990s. In recent years, artificial cervical disc replacement (ACDR) has been increasingly used by spine surgeons for degenerative cervical disc disease. There have been several reports of safety, efficacy and indications of ACDR. Cervical Disc arthroplasty offers several advantages over anterior cervical discectomy and fusion (ACDF) in the treatment of selected patients with medically refractory cervical radiculopathy. It preserves motion at the operated level, ACDR has the potential to decrease the occurrence of adjacent segment degeneration, reduced reoperation frequency, and it can enhance recovery rate. This study was intended to define the advantages and disadvantages of ACDR in comparison to ACDF

Material and Methods: This study reviews the current research regarding cervical arthroplasty, and emphasizes both benefits and potential complications of artificial cervical disc arthroplasty as compared with ACDF. Its an analysis of collected data from 150 journals (pubmed, conchrane library and springer) by searching key words ACDR, ASD, ACDF, heterotopic ossification, artificial disc.

Results: Early clinical outcomes show that cervical arthroplasty is more effective than the gold standard ACDF, because of its high clinical success rate. However, this new technology is also associated with an expanding list of novel complications,such as heterotopic ossification, adjacent vertebral body fracture, implant migration subsidence,metallosis,Implant failure,etc.

Conclusion: This clinical review shows that ACDR is having drawbacks of inevitable complication like heterotopic ossification,spinal trauma, hematoma during surgery, it does show other advantages; for example, faster return to work, and reduced need for postoperative bracing, reduced frequency of reoperation, reduced incidence of dysphagia, it can maintain the ROM of the treated level and prevent adjacent segment degeneration(ASD) as compared to ACDF.

Keywords: ACDR, ACDF, ROM, NDI Heterotopic Ossification (HO), Clinical Review

INTRODUCTION

Anterior cervical decompression and fusion (ACDF) with autologous bone graft is a well established and commonly performed procedure for symptomatic cervical disc disorder. Since its introduction in the 1950s by Robinson and Smith as well as Cloward, excellent clinical reports have been reported in the treatment of degenerative disorders of the spine.[1,2] Brilliant pain relief and excellent fusion rates in (73-90%) have been shown in the long-term results.[1,3,4] But, despite the high success of ACDF, there have been complications such as persistence of neurologic symptoms, donor site morbidity and pseudoarthrosis; hence the development of newer techniques and additional devices for fixation and improved stability.[1,3-5]

However, other complications of fusion such as the development of late symptomatic adjacent level disease still have to be addressed. These may include radiographic changes like anterior osteophyte formation or ossification of the anterior longitudinal ligament (ALL) and these have been reported following anterior cervical arthrodesis regardless of the use of plates or not.[6-8]

Degeneration of an intervertebral disc involves progressive dehydration and fibrosis of the nucleus pulposus. These modifications induce loss of elasticity, loss of intervertebral height, formation of osseous spurs, cracking and bulging of the annulus fibrosus, and eventually, extrusion of nucleus tissue.[9]

Based on this knowledge, Dr Vincent Bryan developed his total cervical disc arthroplasty device in the 1990s. Dr Goffin of Belgium implanted this prosthesis for the first time in January 2000. A variety of cervical disc prostheses are available in the market these days.[10-13]

This study was intended to define the advantages and disadvantages of ACDR in comparison to ACDF.

MATERIAL AND METHODS

Study Selection

All randomized controlled trials comparing Artificial cervical disc replacement with fusion for the treatment of cervical disk disease were identified. We searched electronic databases including PubMed (1966–2017), Cochrane Controlled Trials Register (CENTRAL; issue 1, 2017), and Embase (1984–2017). Springer.

The search strategy consisted of a combination of keywords concerning the technical procedure (*total disk replacement*, *prosthesis*, *implantation*, *discectomy*, and *arthroplasty*) and keywords regarding the anatomical features and pathology (*cervical vertebrae*). These keywords were used as MESH headings and free text words. In addition, a search was

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performed using the specific names of the prostheses.
We identified all relevant randomized controlled trials, searched reference lists of review articles, and included studies to identify other potentially eligible studies. The search was limited to studies published in English, and only trials with 24 or 36 months of follow-up results or long-term results reported were included in this clinical review.

Data Extraction

Independently extracted relevant data from the included studies regarding design, age, gender, type of disk prosthesis, type of control intervention, and follow-up period. The outcomes pooled in this analysis include overall success rate, reoperation rate for secondary surgery, reoperation rate for revision surgery, improvement of movement and functioning measured by a disability scale (Neck Disability Index [NDI]), improvement in pain measured by a validated pain scale (Visual Analog Score [VAS] for the arm, and VAS score for the neck), and SF-36 Mental and Physical Health Surveys.

RESULTS

The process of identifying relevant studies is summarized in Figures 1 and 2. From the selected databases, 350 references were obtained. By screening the titles and abstracts, 200 references were excluded due to the irrelevance to this topic. The remaining 150 reports underwent a detailed and comprehensive evaluation. Finally, 13 randomized controlled trials were included in this clinical review. 4 studies reported 2 year follow-up, 1 study reported 3 year follow up, 3studies reported 4year follow up, 1 study reported >2year follow up, 2 studies reported 7 years follow up, 1study reported 5year follow up, and remaining one study reported 4year follow-up. The main characteristics of included studies are summarized in tables
Heterotopic ossification is a well-known phenomenon after total hip arthroplasty. The rate of Heterotopic ossification following ACDR is unclear. In our clinical review we found different percentage of different grades of heterotopic ossification, occurrence of HO is mentioned in the following Table 1.

DISCUSSION

To be considered an overall success, patients had to achieve all of the following components: ≥15-point improvement in NDI score, maintenance or improvement in neurologic status, no serious adverse events related to the implant or surgical procedure, and no subsequent surgery or intervention. Several studies reported this outcome. Patients treated with total disk replacement showed a significant increase in overall success rate with a low degree of heterogeneity. Furthermore, overall reoperation rate was evaluated in the 14 trials; secondary surgical procedures were defined as any revision, removal, or reoperation of the implant or supplemental fixation. Patients in the total disk replacement group showed a significant decrease in the overall reoperation rate with a low degree of heterogeneity. In addition, patients in the total disk replacement group showed a significant decrease in the reoperation rate for revision surgery.
In 179 total no. of cases treated with ACDR the mean incidence percentage of grade I,II HO is 29.8% and grade III, IV 14.98%. But it does not affect clinical outcomes and this complication reaches upto grade III or IV in few cases. Which can restrict the ROM (Range of motion). Figure-4 shows ACDR has got a vast potential to start a new era of spinal surgery, which can maintain intervertebral movements to avoid rigid fusion in

Author	Cases	grade I-grade ii	grade iii- grade iv	Clinical outcome
Burna M[14]	39	12.5%	12.5%	No effect on clinical outcome
Mehren[15]	54	7.8%-39%	10.4%-12.96%	7 cases spontaneous fusion
TuTH[16]	36	0- 25%	3.8%- 1.9%	VAS improved in HO and non HO group
Chen J[51]	n/a	44.6%	16.7%-	Doesn't affect clinical outcome Clinical outcome Normal
Brenke[18]	22	NA	17.4%	VAS improved in HO and non HO group
Lee se[19]	28	21.4%-28.5%	10.7%-3.57%	No effect on NDI andVAS score

Table-1: Incidence of heterotopic ossification in ACDR

Author	No of patients	Follow-up	Clinical outcome
Ryu et al[20]	20	5 yrs	No significant kyphotic change No decrease in ROM Restore and maintain Pre-op kinematics
Park Sb et al[21]	58	NA	Preserve segmental ROM, Increases superior adjacent kinematics
Carstens c et al[22]	146	2.6 yrs	Over all mobility improved, explantation of prosthesis in 5 patients.
Sekhon lh et al[23]	15	12-43 months	No immediate device failure,Increase in VAS Subluxation of device 1 patient leads to hypermobility causes recurrent neck pain but clinically normal
Khadivi m et al[24]	153	2 yrs	Both neck and upper extremity pain improved Quaderiparesis in 1 patient due to iatrogenic spinal trauma
Yapu l et al[25]	39	23 months	Neck and pain score improved. JOA improved ASD occurrence-in 5 cases at last follow-up.
Guerin p et al[26]	90	24 months	Regression analysis shows that ACDR provides favorable outcome and maintains ROM of FSU, maintain overall cervical segmental alignment
Traynelis et al[57]	NA	NA	Patients treated with ACDR resumed work sooner than ACDF group though the rates are same in both groups

Table-2: Clinical outcomes of ACDR

order to avoid adjacent segment degeneration (ASD). Table 5 shows remarkable improvement in NDI, VAS, ROM. SF-36 Scores.it also depicts the less frequency of reoperation, and complication rate in patient treated with ACDR. In table-5 only 2 studies Coric et al and Skeppholm showed better results in case of ACDF, while Cheng et al's study showed both ACDR and ACDF group have similar results, rest of all studies proved superiority of ACDR over ACDF.

Cheng L et al 2009 reported a prospective study, A total of 65 patients with two-level cervical disc disease were randomly assigned to two groups, those operated on with Bryan Cervical Disc replacement and those operated on with anterior cervical fusion with an iliac crest autograft and plate. Substantial reduction in NDI scores occurred in both groups, with greater percent improvement in the Bryan group (P = 0.023). The arm pain VAS score improvement was substantial in both groups. Bryan artificial cervical disc replacement seems reliable and safe in the treatment of patients with two-level cervical disc disease.[9,39,49,50]

Clinical evaluation included NDI scores, SF-36 MCS and PCS scores, and VAS neck and arm pain scores. Regarding the NDI scores, the pooled results showed no difference between the 2 groups with a high degree of heterogeneity (I^2 =73%). Four trials were included. Of these, 3 trials included a small size of

Author	No of patients	Follow-up	Prosthesis	Outcome
JinY[28]	81	46 months 39 months 40 months	Bryan (35) PCM (30) Prestige (30)	HO occurrence 49% 80% 60%
YiS[29]	170	NA	Bryan (81) Mobi c (61) Prodisc (28)	21%. HO occurrence 52.5% 71.4%
Tu TH[16]	67	2 yrs	Prodisc c keel design	Vertical split fracture of C5 vertebral body. No device migration and neurological symptom.
Anderson[30]	242	NA	Bryan disc 242 Pts at 11 levels vs 221 Pts ACDF	Bryan disc more complaints of Dysphagia/dysphonic 26 vs 16
Goffin J[31]	146	NA	ACDR,103-1 level 43- 2 level	Evidence of device migration in 3 patients

Table-3: DRAWBACKS OF ACDR-

Author	Cases	NDI	VAS A/N*	RE-OP Fr*	SF-36	ROM	Complication Rate
Yoon[33]	46	24%	1.35	1	n/a	14.4±4.5	10.86%
Sasso[36]	56	11	16	2	51/54	n/a	n/a
Sekhon[23]	15	n/a	1.4±2.6	n/a	n/a	4.3°±2.6°	26.66%
Pickett[27]	74	7.1±9.6	1.7±2.2	6	46.5±9.1 50.3±9.9	n/a	35.1%
Yang[38]	15	8.9	2.4	0	n/a	10.9±2°	n/a
Chen J[51]	31	11	1.4/1.5	n/a	50/n/a	7.9°	3.22%
Heller[35]	242	16.2	19.1/23	6	47.9/51.7	8.1°±4.8°	1.7%
Garrido[39]	18	10	10.8/13.6	1	49.4/53.5	n/a	1%

*A/ N= arm pain,neck pain,RE-OP Fr= reoperation frequency, n/a=data not available

Table-4: Outcome of ACDR on the basis of different clinical assessment criterias

Author/year	Patient's no.		Operated levels(n)	Follow up time(Y)	Secondary surgical procedures		Clinical success (%)	
	ACDR	ACDF			ACDR	ACDF	ACDR(%)	ACDF(%)
Garrido et al. 2010[39]	21	26	1	4	1	6	95.2	76.92
Sasso et al. 2011[36]	242	221	1	4	20	24	91.7	89.14
Cheng et al. 2011[17]	41	42	1 or 2	3	0	0	100	100
Zhang et al, 2012[40]	60	60	1	2	1	4	98.33	93.33
Porchet et al, 2004[41]	27	28	1	2	1	3	96.29	89.33
Burkus et al, 2014[42]	276	265	1	7	22	53	92.02	80
Coric et al, 2011[43]	136	133	1	>2	15	14	88.97	89.47
Vaccaro et al, 2013[44]	151	140	1	2	4	14	97.35	90
Phillips et al, 2013[45]	211	184	1	7	18	24	91.46	86.95
Delamarter and zigler. 2013[46]	103	106	1	5	3	12	97.08	94
Davis et al. 2015[47]	225	105	2	4	9	16	96	84.7
Skeppholm, 2015[48]	81	70	1 or 2	2	9	2	88.88	97.14

Table-5: Shows-secondary surgical procedures in ACDR Vs ACDF and clinical success (%)

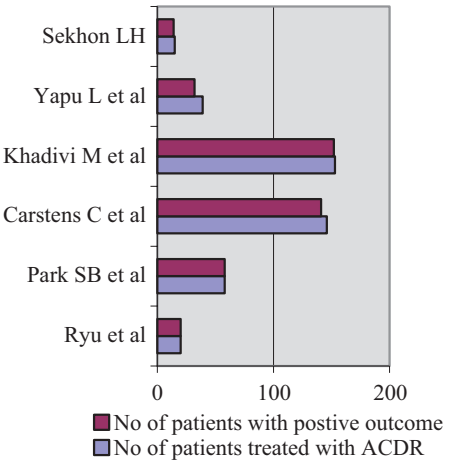
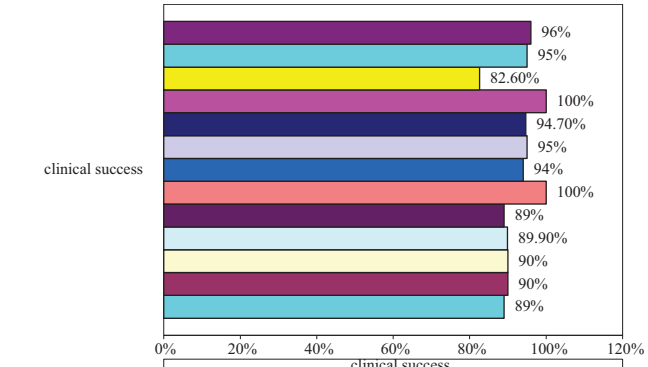


Figure-1: Showing positive outcome with ACDR[20-25]



	clinical success
Wenger et al n= 25	96%
Garrido et al n= 18	95%
Heller et al n=242	82.60%
Cheng et al n=15	100%
Riew et al n=47	94.70%
Sasso et al n=56	95%
Picket et al n=74	94%
Sekhon et al n=15	100%
Lafuente et al n=46	89%
Leung et al n=90	89.90%
Goffin et al n=103	90%
Goffin et al n= 60	90%
Bryan et al n=97	89%

Total no. of patients treated with ACDR n=731
Mean clinical success rate=93.29%

Figure-2: Showing clinical success of ACDR[12,23,31,32,36,37,39,50,59,60-63]

patients, with the number of patients <100. The pooled results for this small subgroup demonstrated a significant decrease in the NDI scores for patients in the total disk replacement group. However, the pooled results for another 6 trials with the number of patients >200 showed no difference in the NDI scores between the 2 groups. Thus, the heterogeneity may be mainly from the sample size.

ChengL 2011 reported Eighty-three patients with cervical myelopathy were randomized to undergo arthroplasty with implantation of a Bryan(®) cervical disc prosthesis (n = 41) or ACDF (n = 42). Patients were assessed preoperatively to 3 years postoperatively using difference to criteria. Patients who received the Bryan(®) prosthesis scored significantly better in three of the four functional assessment methods used (JOA scale, SF-36, and NDI score). ROM was retained by the patients in the Bryan(®) group but not in the patients in the ACDF group. Patients in the Bryan(®) group had fewer complications, primarily because dysphagia occurred in only one patient in the Bryan(®) group but in seven patients in the ACDF group. Other complications included pseudoarthrosis in three patients in the ACDF group and one patient had spontaneous fusion, one had deep vein thrombosis, and one had heterotopic ossification in the Bryan(®) group. Bryan(®) cervical disc arthroplasty appears reliable and effective in the treatment of cervical myelopathy.[52-54]

As to VAS neck pain scores, the pooled results from 2 trials demonstrated a significant decrease in patients in the total disk replacement group, whereas the pooled results from the same trials showed no difference in the VAS arm pain scores between the 2 groups. Regarding SF-36 PCS and MCS scores, a pooled analysis could not be performed due to a lack of appropriate information. Because of the limited number of trials, the sample size, and the methodological quality, we cannot conclude that the clinical status of patients in the Artificial cervical disk replacement group improved compared with patients in the anterior cervical discectomy and fusion group. In the context of anterior cervical discectomy and fusion being the standard surgery, Artificial cervical disk replacement can be at least an alternative for patients with single-level symptomatic cervical disk disease. A study conducted by Seok W K et al showed that in spite of the number of levels, clinical status of both the groups confirmed improvement. Compared to the clinical outcomes between the two groups that showed non-significant difference at final follow up, the radiographic parameters showed relatively well maintenance in our Bryan group compared to our ACDF group. The radiographic parameters include ROM and intervertebral heights at the operated site, some adjacent levels as well as FSU and overall sagittal alignment of the cervical spine. It was concluded that reduced development of adjacent level change can be contributed by the upholding of these parameters. It is of remarkable importance that for ACDF surgeries, radiographic change was observed 3.5 times more as compared to others.[20] Recently Sasso et al, 2017 reported that ACDR demonstrated an advantage in comparison to arthrodesis as measured by final 10 year NDI score (8 vs 16 p=0.0485). Patient requiring reoperation were higher in the arthrodesis cohort(32%) in comparison with arthroplasty.[36,55,56,58]

Our study has got some potential limitations, on one hand we included studies with the follow up period of 2 to 3 years or longer time period but time itself can be deciding factor for clinical outcomes.Secondary surgical procedures in case of ACDR and ACDF are usually needed after a long time period of follow up.

On the other hand we are considering less number of studies showing the comparison between ACDR and ACDF.

In some of studies datas are heterogenous so we are not able to compare all the selected studies thoroughly.

Last but not the least, studies published in other languages are missed because of restriction of language to English in our study.

Questions remained unanswered:

1. What is the relation between the clinical outcome of ACDR and no. of operated levels ?
2. Future of ACDR surgery for multiple level Disc Degenerative Disease ?
   So for finding a solution for these questions, further research is needed.

CONCLUSION

Finally, on the basis of outcome mentioned by different author we hypothesize that many complications can be avoided by meticulous planning before and during ACDR surgery.so for 1 or 2 levels ACDR may be a new gold standard. but a double edged intervention with several potential complications.

ABBREVIATION

VAS - visual analog scale, NDI - neck disability index, SF - 36 - short form 36, FDA - US food and drug administration, ACDR - artificial cervical disc replacement, ACDF - anterior cervical discectomy and fusion, TDA - total disc arthroplasty, MCS - mental component summary, PCS - physical component summary, SCDD - symptomatic cervical degenerative disc disease, IVDD - intervertebral disc degenerative disease, FSU - functional spinal unit, AIF - anterior interbody fusion, PIF - posterior interbody fusion, HO - heterotopic ossification, ASD - adjacent segment degeneration, ROM - range of motion. JOA score - Japanese Orthopedic Association score, COR - Center of Rotation, n/a, NA - data not available

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