ORIGINAL RESEARCH PAPER

Orthopaedics

A STUDY OF COMPARING EFFICACY OF TANTALUM CAGE IN CERVICAL INTERBODY FUSION WITH TITANIUM CAGE.

KEY WORDS: Tantalum, Titanium, Disectomy, Arthrodesis

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ABSTRACT

Anterior cervical discectomy and fusion (ACDF) can be done to effectively treat symptomatic cervical disc disease which has failed to respond to conservative treatment1,2,3. An ideal surgical outcome includes resolution of pain and neurological deficit including a solid arthrodesis. To help in arthrodesis and maintaining disc height stand alone cage is used. He on comparing clinical and radiological outcome of tantalum and titanium used as stand alone cage in ACDF. Based on our observation clinically patients who had tantalum cage had longer duration of neck pain than that of titanium group. Three patients for whom tantalum was used had longer duration of neck pain and and higher NDI compared to others, but it was not statistically significant. Based on Xray of cervical spine taken pre and post operative for both tantalum and titanium cage usage, the disc height was restored and cage was positioned well in all cases. The radiological fusion appears optimal at follow up without any cage subsidence or collapse of disc height. So based on our study we cannot recommend that tantalum cage is superior to titanium cage for better fusion in ACDF surgery. In-fact tantalum cage had caused longer duration of neck pain when compared to titanium cage, which cannot be proved statistically and a much larger sample size is required to prove it with statistical significance.

INTRODUCTION:

Anterior cervical discectomy and fusion (ACDF) can be done to effectively treat symptomatic cervical disc disease which has failed to respond to conservative treatment[1,2,3]. An ideal surgical outcome includes resolution of pain and neurological deficit including a solid arthrodesis. Fusion rates of more than 90% have been achieved in single-level ACDF using either bone autograft or allograft alone without the use of any implants[1,4,5].

The elastic modulus of Tantalum is similar to that of cancellous and cortical bone. It also has high porosity which allowing bone, vessels and other tissues ingrowth which provides secondary stability with biological fixation[6]. There are little data assessing the short term clinical outcome of tantalum cervical implants despite their increasing use[6].

Titanium is commonly used in orthopaedics in variety of implants. It is also a metal whose modulus of elasticity is closer to bone than other metals.

The aim of this prospective, randomized control study will be eliciting the effectiveness of tantalum cage in cervical interbody fusion by comparing with titanium cage.

AIM AND OBJECTIVES

AIM

To evaluate the efficacy of tantalum cage in cervical interbody fusion by comparing with titanium cage.

OBJECTIVES

1. Short term functional outcome using
a. Neck Disability Index
b. Visual Analogue Score for neck pain and radicular pain separately
2. Radiological assessment - Cage position and bone ingrowth
a. X ray AP , Lateral X ray

MATERIAL AND METHODS

1. Patient Selection:

Inclusion Criteria

1. All patients with single-level degenerative cervical disc disease who required ACDF (Anterior Cervical Discectomy and Fusion)
2. Age 18 to 80
3. Those who gave consent for this study

Exclusion Criteria

1. Patients with spinal infection, spinal tumors, spinal trauma.
2. Patients with neuromuscular disorders, traumatic brain injury, supra spinal lesions, demyelinating disorders, inflammatory arthritis, osteoporosis.
3. Conditions that require corpectomy, stabilization with plate or posterior stabilization
4. History of previous surgery at same level.
5. Age less than 18 and more than 80.
6. Those who did not give consent for surgery and study.

2. Study Design

Study Site : Orthopaedic department, Apollo hospitals, Greams lane, Chennai

Study Population : Consecutive cohort of 50 patients who had undergone vertebral interbody fusion in our institute, 25 patients with tantalum cage and 25 patients with titanium cage.

Study Design: prospective randomized control study in which alternative patients was taken for tantalum and titanium cage.

Study Period : April 2021 to March 2022

Outcome Measurement

Clinical outcomes

1. Visual Analog pain Scores (VAS) for neck pain pre operatively the day before surgery and postoperatively, 6 week, 3 month and 6 month follow up.
2. Visual Analog pain Scores (VAS) for radiating upper limb pain pre operatively the day before surgery and postoperatively, 6 week, 3 month and 6 month follow up.
3. Neck Disability Index (NDI) which was recorded pre operatively the day before surgery, 6 week, 3 month and 6 month follow up.

Radiological Outcome

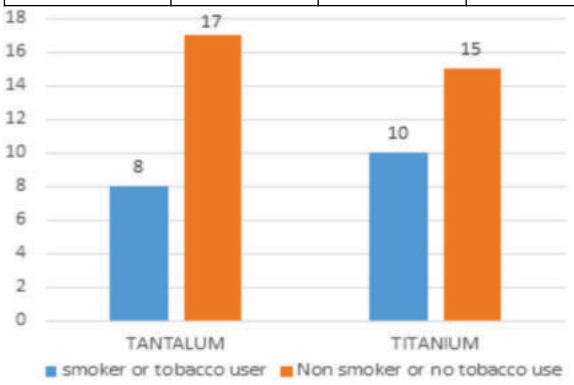
X ray of cervical spine AP and Lateral in second post operative day, 6 week, 3 month and 6 month. In X-ray segments was deemed fused when evidence was found of bony bridging through the intervertebral space with the absence of radiolucent lines in the interfaces. Cage subsidence was defined as the sinking of the cage into the upper or lower end plates, with a decrease of 2mm of disc heights compared with that observed on the immediate postoperative radiograph.

STATISTICAL METHOD

Normally distributed continuous variables was represented by mean ±SD. Comparison of independent variable between the groups was done by Mann Whitney U test. Data entry was done through Microsoft excel 2007. Data analysis was carried out by IBM SPSS statistics for windows version 25.0. All "P" values <0.05 was considered as statistically significant.

OBSERVATIONS & RESULTS

		Frequency	Percent
TANTALUM	C3-C4	4	16.0
	C4-C5	3	12.0
	C5-C6	11	44.0
	C6-C7	7	28.0
	Total	25	100.0
TITANIUM	C3-C4	4	16.0
	C4-C5	5	20.0
	C5-C6	13	52.0
	C6-C7	3	12.0
	Total	25	100.0



Complication - Immediate Post operative swallowing difficulty

Hypothesis Test Summary

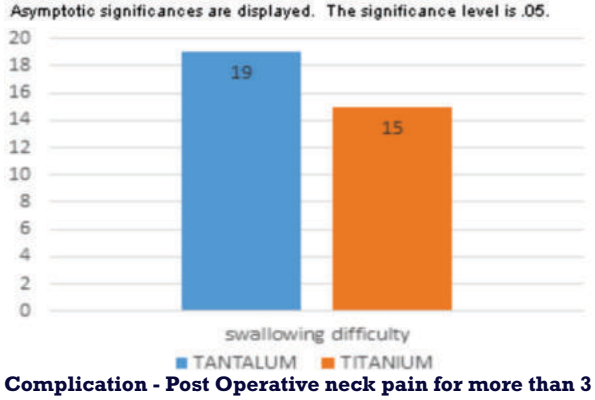
	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Pre op VAS Neck is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.721	Retain the null hypothesis.
2	The distribution of Pre op NDI is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.907	Retain the null hypothesis.
3	The distribution of Post op VAS neck is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.243	Retain the null hypothesis.
4	The distribution of Post of VAS upper limb is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.232	Retain the null hypothesis.
5	The distribution of Post op 6 weeks VAS neck is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.501	Retain the null hypothesis.
6	The distribution of Post of 6 weeks VAS upper limb is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.514	Retain the null hypothesis.
7	The distribution of Post op 6 weeks NDI is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.068	Retain the null hypothesis.
8	The distribution of Post op 3 months VAS neck is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.475	Retain the null hypothesis.
9	The distribution of Post of 3 months VAS upper limb is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.861	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
10	The distribution of Post op 3 months NDI is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.168	Retain the null hypothesis.
11	The distribution of Post op 6 months VAS neck is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.938	Retain the null hypothesis.
12	The distribution of Post of 6 months VAS upper limb is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.371	Retain the null hypothesis.
13	The distribution of Post op 6 months NDI is the same across categories of GROUP.	Independent-Samples Mann-Whitney U Test	.541	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.



Complication - Post Operative neck pain for more than 3 months

Hypothesis test summary

		Frequency	Percent
TANTALUM	YES	3	12.0
	NO	22	88.0
	Total	25	100.0
		Frequency	Percent
TITANIUM	YES	0	0
	NO	25	100.0
	Total	25	100.0

DISCUSSION

Anterior Cervical Disectomy and Fusion has become common surgery for patients suffering from neck or radiating upper limb or lower limb pain with or without neurological deficit. For ACDF surgery following disectomy, in order to maintain disc height and promote fusion of vertebra autologous bone graft from iliac crest had been used for several years which had given good results, in the cost of donor site morbidity. In order to over come the initially allograft were tried but it was not successful because of risk if infection transmission, pseudo arthrosis, delayed fusion, higher rate of subsidence.

Donor site Complications (especially pain) due to iliac crest autograft and dysphagia due to anterior plating led to use of cervical cages of various materials as stand alone in single level ACDF, which can as substitute to maintain disc height and promote fusion.

Various biological and clinical factors are responsible for success of most orthopaedic implants clinically, as well as on inherent properties of implant materials. Commercially pure titanium (cpTi) is one among the foremost commonly used orthopaedic implant materials thanks to its biocompatibility, attractive physiochemical and biomechanical properties. Successful use of Titanium fibermesh (TFM) which is porous, as various orthopaedic implant for over 20 years and as

demonstrated less than 1% failure rate due to mechanical or aseptic loosening at 8- to 11-year followup[7].

Alternative to titanium, recently there has been increasing interest in the use of tantalum for spinal fusion material considering its high compressive strength, a Young modulus similar to cancellous bone in biocompatibility and magnetic resonance compatibility [6,8]. There are reports of osteointegration of porous tantalum in human subjects that has been reported in acetabular shells, femoral stems, tibial trays and patella specimens, showing variable levels of bone ingrowth[9].

Titanium is also another metal which forms the prime in orthopaedics used as plate, screws and replacement implants, which is also used in spine surgery as cages, mesh and pedicle screws and rods. Nowadays Titanium cage is mainly used in ACDF surgery due to its inertness to body, MRI compatibility and acts as a scaffold for bone growth around the cage. But tantalum allows bone growth through the implants, which was confirmed histologically after implant removal due to the presence of radiolucency around the implant in the study done by Manish K. Kasliwal et al[9].

One drawback of tantalum is the high radio opacity, which makes it easily visible but interferes with the visualization of bridging trabecular bone at its margins[9]. We have also attempted CT imaging of cervical spine post operatively, from which it was found to to be highly radio opaque with flare even in bone window, so we cannot be able to comment on bone integration through the cage. So CT imaging was dropped our in view of unnecessary radiation exposure without any radiological measurements.

Also in the study done by Manish K. Kasliwal et al[9] concluded that the use of stand-alone tantalum cages without bone graft may not be an appropriate treatment strategy for cervical spine interbody fusion, as the fusion rate is subpar and there is risk of device fragmentation in patients who fail to fuse[9]. So as a precaution we used the tantalum cage with bone graft to address this problem.

In our study we selected a sample size of 50 members (100%) satisfying all inclusion and exclusion criteria of which 25 members (50%) had Tantalum cage for Anterior cervical interbody fusion and 25 members (50%) had Titanium cage for Anterior cervical interbody fusion.

Of all the patients who had undergone surgery on whom tantalum cage was used were 32% smokers and for tantalum group 40% were smokers. Of all 76% of tantalum cage used patients and 60% of titanium cage used patients developed immediate post operative swallowing difficulty (transient) which resolved within a week period, stating it was probably due to oesophagus edema during retraction. Of all the patients who had undergone surgery no one had any dural tear or CSF leak, vertebral artery or oesophageal inury, permanent voice change/ dysphagia, no cage subsidence, no recurrence, revision or mortality.

However for 12% (3 patients) for whom tantalum cage was used had longer duration of neck pain for more than 3 months which eventually recovered at the end of 6 months, but there is a delay in the improvement on NDI and VAS neck scores when compared to other patients, which was not a statistically significant difference.

Clinically patients who had tantalum cage had longer duration of neck pain than that of titanium group. Three patients for whom tantalum was used had longer duration of neck pain and and higher NDI compared to others, but it was not statistically significant.

But **Based on VAS for neck pain , VAS for radiating upper limb pain and NDI score, there is no significant statistical difference between pre-operative, post-operative, 6th week, 3rd month and 6th month follow up scores in use between tantalum and titanium cage.**

Based on Xray of cervical spine taken pre and post operative for both tantalum and titanium cage usage, the disc height was restored and cage was positioned well in all cases. The radiological fusion appears optimal at follow up without any cage subsidence or collapse of disc height.

So based on our study we cannot recommend that tantalum cage is superior to titanium cage for better fusion in ACDF surgery. In-fact tantalum cage had caused longer duration of neck pain when compared to titanium cage, which cannot be proved statistically and a much larger sample size is required to prove it with statistical significance.

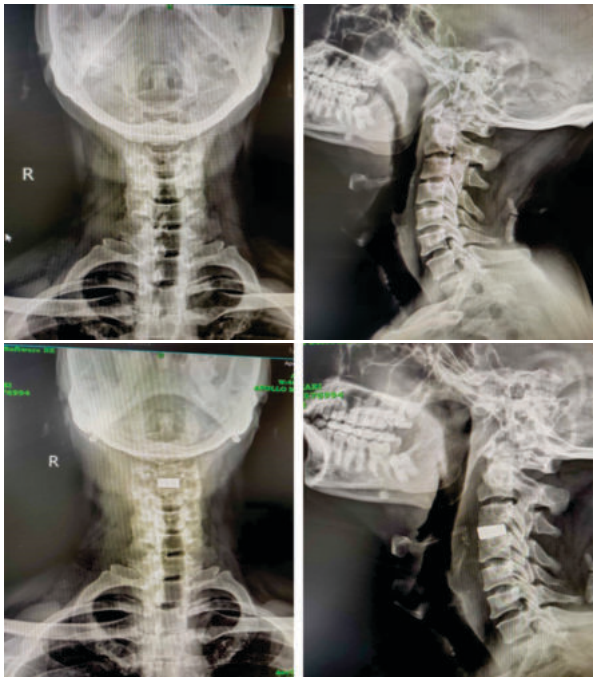


Figure -Pre and Post op Xray cervical spine AP and Lateral of Tantalum cage

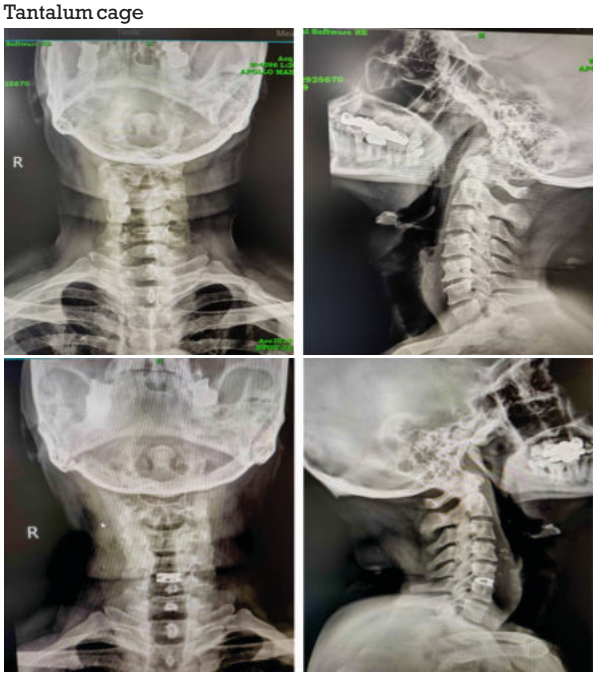


Figure -Pre and Post op Xray cervical spine AP and Lateral of Titanium cage

Limitations Of Study

1. Study was done within the inclusion criteria, to refine further we need to increase the inclusion criteria.
2. Only short-term outcome done. To know further long term survival we need long term study also mainly to assess radiologically significant difference.
3. CT was not done for these cases, as it showed significant flare around the cage so no bone growth is seen adjacent and through the cage even in bone window, so it was dropped due to unnecessary radiation with no radiological measurement.

CONCLUSION:

Based on our study there is no statistical significant difference stating one is better than the other from the clinical and radiological outcome between usage of tantalum and titanium for Anterior Cervical interbody fusion. However 3 patients for whom tantalum cage was used had longer duration of neck pain compared to titanium cage used patients.

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