Evidence-based Study to evaluate Effects of Conservative and Operative treatment for Carpal Tunnel Syndrome by MRI and evolve a Management Protocol

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Abstract

Introduction CTS is the most common nerve entrapment syndrome of upper limb. Treatment protocol, whether conservative or surgical has always been an area of debate. Conservative treatment includes physical therapy, drugs and Corticosteroid injection. Open or endoscopic Carpal tunnel release has been the surgical modality of treatment as of now.

Objective Device a management protocol for CTS based on MRFindings.

Study design Non randomized comparative assessment based on MR Findings was undertaken over 30 patients between May2016 to Jan2017.Based on DASH, CTSAQ ,SF 30 and SCL-90 and MR findings patients were divided into two groups for Conservative and Surgical treatment. A treatment protocol has been evolved based on MRfindings. Follow up was done for 6 months.

Results Out of total 35 patients, 5 were excluded, remaining 30 patients revealed significant MN alteration on MRI. MN CSA at wrist of an average Indian measures 8mm² to 11mm². In our study patients who had an average median nerve CSA of 18mm² at proximal border of carpal ligament had significant symptoms without any motor changes. Patients with average median nerve cross section area of 22mm² and above suffered with variable motor deficiencies along with entrapment symptoms and signs.

Conclusion MRI assisted radiological findings can help in early surgical intervention, when MN CSA is between 18mm²-22mm², leading to considerable decrease in morbidity and motor loss. MRI findings help to decide whether a patient has to undergo conservative management for CTS or surgical management. Also ,the protocol evolved from the study can help decrease significant morbidities in patients suffering from CTS.

Keywords

1. CTS-Carpal Tunnel Syndrome
2. CSA-Cross-sectional-Area
3. MN-Median-nerve

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Carpal tunnel syndrome (CTS) is one of the commonest neuropathies caused by the compression of median nerve at the level of wrist. Its prevalence is reported to be nearly 4% of the general population with a female predominance. It is the most common entrapment neuropathy of the upper extremity and is often a debilitating disorder that is commonly encountered in primary care. The classic symptoms include nocturnal pain associated with tingling and numbness in the distribution of the median nerve in the hand.. These symptoms may or may not be accompanied by objective changes in sensation and strength of median-innervated structures in the hand, Treatment strategies for CTS include physical therapy such as therapeutic ultrasound[iii,iv] occupational therapy[v,vi,vii], steroid injection[viii, ix], non-steroidal anti-inflammatory drugs, diuretics, vitamin B-6 or B-12. MRI has been shown to have a high diagnostic accuracy in the detection of probable causative lesions which might help in staging the disease and hence might help in decision-making to choose between non-surgical and surgical modalities,. MRI of the carpal tunnel provides a clear delineation of its soft tissue contents and bony boundaries.

Imaging Studies

Radiology

Plain radiography may be useful if structural abnormalities, such as bone or joint disease, are suspected .

Ultrasonography

The cross-sectional area of the median nerve is closely correlated with CTS symptoms and severity. A meta-analysis found that a cross-sectional area of 9 mm^2 or more is 87.3% sensitive and 83.3% specific for CTS. Advantages of ultrasonography include lower cost; noninvasiveness; patient comfort; and evaluation of etiologies such as tenosynovitis, mass lesions, and tendinopathies. However, ultrasonography relies on local expertise and cannot rule out etiologies such as polyneuropathies or gauge the severity of CTS.

Magnetic Resonance Imaging

The recent years, among different radiologic imaging methods, magnetic resonance imaging (MRI) has consistently shown the greatest sensitivity and specificity in the diagnosis and evaluation of carpal tunnel syndrome. MRI is useful for the evaluation of all of the intrinsic structures of the wrist (including the carpal bones) however, it is often limited by difficult accessibility, especially in resource-limited settings like India. It visualizes the morphological changes following chronic nerve compression. It is particularly useful in cases of suspected lesions within the carpal tunnel as a cause of CTS. It has been found to have >90% accuracy in diagnosing the median nerve compression correctly ,. It helps in the diagnosis of special conditions, viz. in patients with idiopathic carpal tunnel syndrome, median nerve area measured by wrist magnetic resonance at the hamate level may be considered as a valuable indicator to grading the severity of disease[xvi]. It has also shown a useful role in the postoperative evaluation of the carpal tunnel[xvii] Severe denervation changes which are only recognized using electromyography can be diagnosed as increased thenar muscles on MRI[xviii] . MRI diagnosis helps to diagnose additional pathologies that may not only change the applicable type of surgery but also decrease the number of postoperative failures. Wrist MRI is recommended, especially for young cases with unilateral CTS history accompanied by dubious clinical symptoms and lacking any pronounced predisposing factors[19]

Classification	Duration	Two-point Discrimination test	Weakness	Atrophy	Electromyography	Nerve conduction test
Mild	Shorter than one year	Normal	Absent	Absent	No denervation	No to mild velocity decrease
Moderate	Shorter or longer than one year	Possible abnormality	Minimal presence	Minimal presence	No to mild denervation	No to mild velocity decrease
Severe	Longer than one year	Marked abnormality	Marked presence	Marked presence	Marked denervation	Marked velocity decrease

Treatment

Chammas et al. in a recent systematic review described the various treatment modalities for CTS. A brief account of these is as follows:

Conservative treatment

In relation to corticoid injection, immobilization by means of orthotic braces, and oral corticoid therapy, the level of evidence is sufficient to confirm their effectiveness.

Local injection of corticoid

The action implemented through local corticoid injection comprises a reduction of the tenosynovial volume, with a direct effect on the median nerve. The main risk is injury to the median nerve, which is very painful, with the sensation of an electric shock, and the risk of developing a neurological deficit and persistent pain. Another complication is the risk of tearing the tendon.

Generally, an injection point is located from 4 cm proximally to the wrist flexion crease to halfway between the tendon of the long palmar muscle and the ulnar flexor of the carpus, which is an extension of the axis of the fourth finger. After performing local antisepsis, the needle is slowly inserted obliquely, at 45° to the carpal tunnel.

Surgical treatment

The principle of surgical treatment is to achieve a reduction in intratunnel pressure through increasing the volume of the carpal tunnel, by sectioning the flexor retinaculum. The procedure is done under locoregional or local anesthesia, ideally as an outpatient procedure, and frequently using a tourniquet. The procedure is generally unilateral. Three techniques are currently used:

1. Open procedures;

2. Techniques known as “mini-open”;

3. Endoscopic techniques.

Open technique

The open technique is the oldest form of treatment. An incision of 3–4 cm is made, extending from the wrist flexion crease along the prolongation of the radial edge of the fourth finger to Kaplan's cardinal line.

Associated procedures

1. Synovectomy of the flexors

2. Epineurotomy of the median nerve
3. Release of Guyon's canal in cases of acroparesthesia of the fifth finger
4. Reconstruction of the flexor retinaculum
5. Transfer of thumb opposition (Camitz technique)[xix]:

Lacunae in Study: The review of literature showed that there is lack of consensus regarding the relative efficacy of surgical and local corticosteroid injections. One of the reasons for this lack of consistency could be consideration of equal suitability of both the treatment modalities irrespective of the stage of disease and use of a decision making criteria to decide the prospective suitability of one of the two treatment modalities.

MATERIAL AND METHODS

Department of Plastic & Reconstructive Surgery, Vivekananda Polyclinic & Institute of Medical Sciences (VPIMS), Lucknow. Sample size was 53 for each group, after adding for contingency of 10% and rounding to nearest ten we get a sample size of 60. Non-randomized comparative assessment based on MRI characteristics as the criteria for group allocation.

Inclusion Criteria

1) Patients of either sex aged between 20 yrs to 60 years of age.
2) Patients having symptoms suggestive of CTS of at least 3 months' duration consecutively referred by their primary care physicians
3) Patients having a confirmed diagnosis of CTS based on clinical, electrophysioogical and/or MRI findings and who had been unresponsive to a course of at least 2 weeks of nonsteroidal anti inflammatory drugs (NSAIDs) .
4) Those completing a minimum follow up of 3 months.

Exclusion Criteria

1) Previous steroid injection or previous surgical intervention and polyneuropathy.
2) Patients suffering from Diabetes Mellitus, Thyroid disorders, Pregnancy, thenar atrophy.

On the basis of this criteria the patients were allocated to any of the two study groups:

Study Group A (Local Corticosteroid group): Patients in this group had MRI guided cross-sectional area of median nerve <18 mm2. In this group patients underwent treatment with local intralesional corticosteroid injection alongwith night splintage.

Study Group B (Surgical intervention group): Patients in this group had MRI guided cross-sectional area of median nerve >18 mm2. In this group patients will undergo treatment with surgical decompression.

Study Duration and Follow up: The study was spanned over a period of 3½ years. However, the recruitment to the study was stopped 12 months prior to entire duration of study. All the patients will undergo clinical, functional and radiographic evaluation at the follow-up intervals:

a) Baseline
b) 1 month after intervention
c) 3 months after intervention

Method of Measurement of Outcome of Interest:

a) Clinical improvement in terms of signs and symptoms using Carpal Tunnel syndrome Assessment Questionnaire (CTSAQ) – pain was also be assessed using visual analog scale.

b) Functional improvement using DASH scale

c) Disability (in terms of activity and work days lost)

d) Psychological improvement (using SCL-90 somatization and depression scale)

e) Electrophysiological evaluation, and

f) Magnetic resonance findings

Results

The aim of the proposed study is to compare the efficacy of surgical decompression and local corticosteroid injection in management of patients of carpal tunnel syndrome unresponsive to conservative treatment using a MRI guided decision making criteria for selection of patients. For thispurpose, a total of 60 patients falling in sampling frame were enrolled from amongst two of the following groups:

In Group A, there were 30 cases of carpal tunnel syndrome (CTS) who were found to have median nerve cross sectional area <18 mm2 on MRI evaluation. These patients underwent conservative management using local intralesional corticosteroid injection alongwith night splintage.

In Group B, there were 30 cases of carpal tunnel syndrome (CTS) who were found to have median nerve cross sectional area >18 mm2 on MRI evaluation. These patients underwent surgical decompression using open surgical procedure.

In Group A, median nerve cross sectional area ranged from 13 to 17 mm2 with a mean of 16.07 and a standard deviation of 1.02 mm2. Median area was 16 mm2.

In Group B, median nerve cross sectional area ranged from 18 to 24 mm2 with a mean of 20.00 and a standard deviation of 2.03 mm2. Median area was 19 mm2.

Overall, median nerve cross sectional area ranged from 13 to 24 mm2 with a mean of 18.03 and a standard deviation of 2.54 mm2. Median area was 17.50 mm2. On comparing the data statistically, mean median nerve cross sectional was found to be significantly higher in Group B as compared to that in Group A ($p<0.001$).

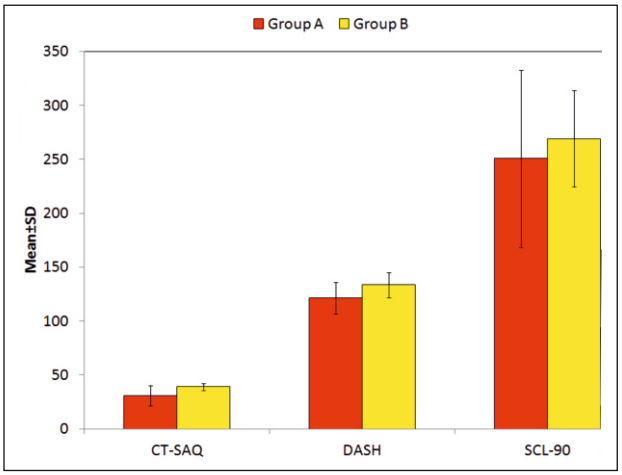
SN	Group	Description	No. & Percentage
1.	A	Patients who had median nerve cross sectional area <18 mm^2 as measured by MRI and who underwent conservative management	30
2.	B	Patients who had median nerve cross sectional area ≥18 mm^2 as measured by MRI and who underwent surgical management	30

Comparison of two study groups according to MRI Measurement of Median Nerve Cross sectional area (mm2)

SN	Variable	Group A (n=30)	Group B (n=30)	Total (n=60)
1.	Minimum	13	18	13
2.	Maximum	17	24	24
3.	Mean	16.07	20.00	18.03
4.	Standard deviation	1.02	2.03	2.54
5.	Median	16	19	17.50

Baseline evaluation of Functional and QOL Parameters

SN	Parameter	Group A (n=30)		Group B (n=30)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	CT-SAQ	30.57	9.31	38.93	3.30	4.640	<0.001
2.	DASH	121.50	14.72	133.40	11.57	3.482	0.001
3.	SCL-90	250.63	82.06	269.27	44.89	1.091	0.280



Evaluation of change in cross-sectional area of median nerve from enrolment to last follow-up

SN	Variable	At enrolment (Mean± SD)	At last follow up (Mean± SD)	Significance of change
1.	Group A	16.07±1.02	17.10±1.42	't'=3.474 ; p=0.002
2.	Group B	20.00±2.03	12.20±1.81	't'=19.53 ; p<0.001

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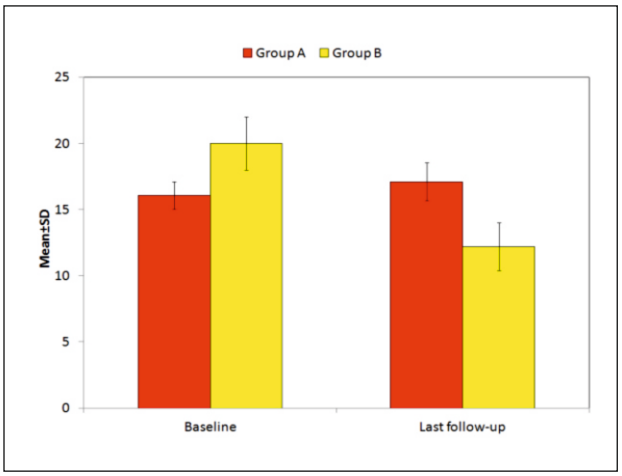

In Group A, at enrolment mean cross-sectional area of median nerve was 16.07+1.02 mm2 which was found to be 17.10+1.42 mm2 at six months' follow-up thus showing an increase of 1.03±1.63 mm^2 (6.4% increase). On evaluating the data statistically, this change was found to be significant (p=0.002).

In Group B, at enrolment mean cross-sectional area of median nerve was 20.00+2.03 mm2 which was found to be 12.20+1.81 mm2 at six months' follow-up thus showing a decrease of 7.80±2.19 mm2 (% decrease). On evaluating the data statistically, this change was found to be significant (p<0.001).

Discussion

Carpal tunnel syndrome (CTS) is the most common compressive neuropathy of upper extremity. Decompressive surgery and steroid injection are widely used forms of treatment for carpal tunnel syndrome (CTS) but there is no consensus on their effectiveness in comparison to each other. One of the reasons for the indecisive state regarding efficacy of surgical as compared to non-surgical treatment is absence of any robust criteria while deciding the treatment modality. The mode of treatment has in general remained the choice of the treating surgeon depending upon his subjective perceptions and skills. In order to provide a robust criteria for such decision making and to provide an objective basis for this, the present study was planned with an aim to compare the efficacy of surgical decompression and local corticosteroid injection in management of patients of carpal tunnel syndrome unresponsive to conservative treatment using a MRI guided decision making criteria for selection of patients.

The first part of this work was directed towards evolution of a criteria for suitability of surgical intervention in cases of carpal tunnel syndrome based on Magnetic Resonance Imaging characteristics. This purpose was tackled by a consensus development among an expert panel comprising of senior consultants in our facility. Various abnormal MRI findings include presence of pathological conditions like ganglion cysts, tenosynovitis, avascular necrosis, degenerative bone cysts, space occupying lesions, fibrosis and position of pisiform and hamate bones apart from median nerve enlargement,,,. However, considering the fact that management strategies of carpal tunnel syndrome are primarily targeted at decompression of median nerve enlargement, the expert panel reached to the consensus that cross-sectional area of median nerve could be considered as a criteria for deciding the management protocol. Median nerve width has been reported to be one of the determinants in recurrence of carpal tunnel syndrome. It has also been considered as an outcome measure among patients with carpal tunnel syndrome,. Increase in cross-sectional area of median nerve have also been suggested to correlate with the increasing severity of carpal tunnel syndrome,. The expert panel was of the opinion that surgical decompression of the median nerve should be done only in those cases where cross-sectional area of median nerve indicates extreme severity where chances of success of conservative management are uncertain as also observed by Marschall et al. in their study.

Evaluation of another by Pimentel et al. revealed that post-operative changes in median nerve cross-sectional area were much more pronounced among patients with cross-sectional area of 20 mm2 or above as compared to those having lower cross-sectional areas, thus showing that surgical intervention could be more useful in patients having a larger cross-sectional area of median nerve.

As such, as yet, there is no cut-off value for cross-sectional area of median nerve, that can be considered as the basis for deciding the course of management of carpal tunnel syndrome. However, in literature, mean values in range of 0.15 to 0.20 have been reported to be indicators of most severe form of carpal tunnel syndrome in different studies , , . Consecutively, the criteria chosen by expert panel in present study was cross-sectional area >18 mm2 as the parameter for deciding surgical decompression. Incidentally, this cut-off point was also successful in dividing the non-randomized study population into two equal groups of 30 patients each.

In present study age of patients ranged from 29 to 60 years. Mean age of patients was 43.28+7.75 years. Majority of patients were females (88.3%), from urban areas (83.3%) and were housewives (70%). Statistically, there was no significant difference between two groups with respect to age, sex, place of residence and occupation. The larger proportion of female population in present study is in accordance with the epidemiological studies that report a female predominance , , , . In different intervention studies reviewed by us too, female predominance is a general finding. Ismatullah too had 72.5% females in their study. In another study Awan et al. had 86.3% females. As far as age is concerned, though epidemiological studies report the peak age range as 45-60 years , however, they do not deny its occurrence at any age. However, most of the intervention studies report age profile of patients similar to ours. Ismatullah reported the mean age of patients as 45.35+11.65 years while Jafari et al. reported the mean age of patients as 45.8+8.1 years, these figures are close to the mean age of patients in present study. Awan et al. in their study reported even a younger age profile of patients with mean age 32.8+5.1 years. The reason for relatively younger age of patients reporting for intervention in different studies despite peak incidence being in much older age group could be owing to the occupational needs of the patients where disabilities posed by carpal tunnel syndrome cannot be ruled out as an age-related degenerative change.

As far as dominance of patients from urban areas is concerned it could be attributable to the generalized urban profile of patients visiting our facility, moreover, lack of awareness and financial barriers could also be added as the reasons for lower representation of rural patients. The dominance of housewives in present study could also be explained owing to a female predominance and also shows that despite concerted efforts of policy makers in India to increase the participation of women in economic activities by easing the employment opportunities for women, they are still destined to play a major role as housewife.

In present study, pain (30%), burning sensation (28.3%), weakness (23.3%) and difficulty in holding (23.3%) were the major presenting complaints. All these are classic symptoms of carpal tunnel syndrome[2,4,5,41]

In present study, duration of complaints ranged from 3 to 48 months. Mean duration of complaints was significantly higher in surgical intervention group (24.27+13.67 months) as compared to that in conservative management group (6.74+5.51 months). As surgical intervention group was selected on the basis of cross-sectional area of median nerve, which has shown to be related with the severity of carpal tunnel syndrome in previous studies , , hence the findings of duration of

symptoms could be related with prolongation of unattended problem of carpal tunnel syndrome which eventually enhanced the severity of disease and resulted in larger cross-sectional area of median nerve. Similar to findings of present study, Chen et al. also found a significant association between cross-sectional area of median nerve and duration and severity of symptoms, thus reinforcing our hypothesis that longer duration of symptoms in surgical intervention group was an indicator of increased severity of disease as reflected by larger cross-sectional area of median nerve in this group. As such, in present study mean median nerve cross-sectional area in surgical intervention group was also 25% larger as compared to that in conservatively managed group (20.00+2.03 mm2 vs 16.07+1.02 mm2).

In present study, pre-intervention cross-sectional areas of median nerve ranged from 13 to 24 mm2. In a previous study, Hammer et al. reported median nerve cross-sectional areas <10 mm2 in healthy controls as compared to 10.0-13.0 mm2 in patients with mild symptoms of CTS, 13.0-15.0 mm2 in patients with moderate CTS and >15 mm2 in patients with severe CTS. In present study, we had included symptomatic patients of CTS only and measurements were done through MRI instead of USG used by the authors. The systematic progression of cross-sectional area values in present study also indicated an incremental trend in severity of disease. The absence of cross-sectional area values below 13 mm2 in turn indicated that cross-sectional area of median nerve can play a good discriminatory role in diagnosing and differentiating the carpal tunnel syndrome patients from healthy controls. These findings in turn also justify the focus of our expert panel for deciding the management protocol based on median nerve cross-sectional area.

In present study, clinical signs and symptom scores (CT-SAQ) and functional score (DASH) were significantly lower in conservatively managed group as compared to that in surgically managed group which can be related with association of median nerve cross-sectional area and severity of CTS as described above. Although psychological health scores were also higher in surgically managed as compared to conservatively managed group yet this difference was not significant statistically. The findings in turn suggested that cross-sectional area of median nerve, which is an objective parameter for discrimination of severity of CTS, does not correlate well with the psychological health. This finding is in agreement with the observations of Khan et al. who in their study concluded that psychological factors correlate more with subjective symptoms rather than objective severity as measured by electrophysiological assessment in their study. In another study, Bademci et al. used SCL-90 psychological assessment for outcome measurement instead of correlating it with disease severity. In present study too, although we used it for dual purpose of measurement of disease severity as well as outcome measurement, we found that its use as status of disease severity was not in agreement with the functional and objective assessments of median nerve cross-sectional area. The psychological impact of a disease, no doubt is dependent on the severity of the disease, but is also guided by a host of other factors including patient characteristics, lifestage, occupation, social and financial support and might not be related with the disease severity alone as observed in present study.

In present study, for clinical symptom scores (CT-SAQ), between baseline and 3 months follow-up, mean scores declined from 30.57±9.31 to 19.57±5.52 in conservatively managed group (36% decline) whereas in surgically managed group, these scores declined from 38.93±3.30 to 5.57+3.58 (% decline), thus showing that the rate of decline was significantly higher in surgically managed group as compared to conservatively managed group.

Conclusion

The present study was carried out with an aim to evaluate effects of conservative and operative treatment for carpal tunnel syndrome following magnetic resonance screening for evolving a management protocol. For this purpose, a total of 60 patients aged 20 to 60 years with symptoms suggestive of carpal tunnel syndrome for >3 months' duration were enrolled and underwent Magnetic Resonance imaging evaluation. On the basis of MRI findings, the expert panel recommended surgical intervention in cases having median nerve cross-sectional area >18 mm2 while all those having median nerve cross-sectional area <18 mm2 were recommended conservative management using corticosteroid injections and splintage. Patients were followed upto six months. Following were the key findings of the study:

A total of 30 (50%) patients had median nerve cross sectional area <18 mm2 while remaining 30 (50%) had median nerve cross sectional area >18 mm2 and were thus subjected to conservative and surgical interventions respectively.Age of patients ranged from 29 to 60 years. Mean age of patients was 43.28+7.75 years. Majority of patients were females (88.3%), from urban areas (83.3%) and were housewives (70%). Statistically, there was no significant difference between two groups with respect to age, sex, place of residence and occupation.Pain (30%), burning sensation (28.3%), weakness (23.3%) and difficulty in holding (23.3%) were major presenting complaints. Statistically, there was no significant difference between two groups with respect to presenting symptoms.Duration of complaints ranged from 3 to 48 months. Mean duration of complaints was significantly higher in surgical intervention group (24.27+13.67 months) as compared to that in conservative management group (6.74+5.51 months). At enrolment, MRI evaluated cross-sectional area of median nerve ranged from 13 to 24 mm2. Mean cross-sectional area of surgical intervention group was 20+2.03 mm2 as compared to 16.07+1.02 mm2 for those managed conservatively.At enrolment, clinical signs and symptom scores (CT-SAQ), functional score (DASH) and psychological health scores (SCL-90) were 30.57±9.31, 121.50±14.72 and 250.63±82.06 respectively in conservatively managed group as compared to 38.93+3.30, 133.40+11.57 and 269.27+44.89 respectively in surgically managed group. The difference between two groups was significant statistically for CT-SAQ and DASH scores.Mean CT-SAQ scores at enrolment, 1 month and 3 months follow up were 30.57+9.31, 20.30+6.39 and 19.57±5.52 respectively in conservatively managed group as compared to 38.93±3.30, 11.50±4.48 and 5.57±3.58 respectively in surgically managed group. Statistically, the difference between two groups was significant at all the three time intervals.Mean DASH scores at enrolment, 1 month and 3 months follow up were 121.50+14.72, 90.40+18.98 and 85.07±18.10 respectively in conservatively managed group as compared to 133.40±11.57, 51.43±10.21 and 35.93±6.91 respectively in surgically managed group. Statistically, the difference between two groups was significant at all the three time intervals.Mean SCL-90 scores at enrolment, 1 month and 3 months follow up were 250.60+82.06, 110.27+36.88 and 90.60±42.19 respectively in conservatively managed group as compared to 269.27±44.89, 28.53±9.33 and 7.63±3.18 respectively in surgically managed group. Statistically, the difference between two groups was significant for 1 month and 3 month follow-up intervals.Mean time taken for return to work was 1.97+0.93 days in conservatively managed group as compared to 10.83+1.88 days in surgically managed group. Statistically, this difference was significant.At final follow-up mean median nerve cross-sectional area was 17.10+1.42 mm2 in conservatively managed group as

compared to 12.20+1.81 mm2 in surgically managed group. Statistically, this difference was significant.During the study period, mean cross-sectional area showed an increase of 6.4% in conservatively managed group as compared to 39% decrease in surgically managed group.

The findings of the study thus showed that magnetic resonance imaging could be a useful criteria for planning the management of carpal tunnel syndrome. In both the groups, a substantial improvement in clinical, functional and psychological scores was observed following respective interventions. However, surgical intervention showed a better outcome as compared to conservative management. As such, conservatively managed groups showed a mild increase in median nerve cross-sectional area at last follow-up thus showing that the criteria for deciding surgical intervention could be improvised. Further studies in order to select a more suitable criteria are reccommended.

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